Anexa 9

SPECIFICATIE TEHNICA

Model: EPK-i7010 / Optivista; Producător: PENTAX Medical/HOYA Corporation; Țara: Japonia.

Specificarea tehnică deplină solicitată de către autoritatea contractantă	Specificarea tehnică deplină propusă de către autoritatea ofertantă
Sistem videoendoscopic pentru videogastroscopie	Sistem videoendoscopic pentru videogastroscopie
Descriere Sistem video pentru investigarea și tratamentului căilor gastrice	Descriere Sistem video pentru investigarea și tratamentului căilor gastrice **DA**
Parametrul Specificația	Parametrul Specificația
Videoprocesor Intrări cameră ≥1	Videoprocesor Intrări cameră - 1 **DA**
Caracteristici Ajustare nuanță da	Caracteristici
Iluminare auto	Ajustare nuanță **DA**
Balans de alb auto	Iluminare auto **DA**
Videocompensare da	Balans de alb auto **DA**
Ajustarea culorilor da	Videocompensare **DA**
Zoom Electronic da	Ajustarea culorilor **DA**
Suporta tehnologie cromoscopie digitală sau analogica in 3 nivele da	Zoom Electronic **DA**
Protocol de amplificarea adaugator pentru fiecare regim de cromoscopie digitala sau analogica. Da	Suporta tehnologie cromoscopie digitală sau analogica in 3 nivele **DA Tehnologie i-Scan 1,2,3 si disponibil filter optice care tip OE, OPTIVISTAplus Brochure pag. 3**
Inclus posibilitatea de transfer a imaginilor direct pe USB sau HDD Extern da	Protocol de amplificarea adaugator pentru fiecare regim de cromoscopie digitala sau analogica. **DA este disponibil, Operation manual EPK-i7010 pag. 29-38**
Inclus posibilitatea de inregistrare video direct pe USB sau HDD Extern da	Inclus posibilitatea de transfer a imaginilor direct pe USB sau HDD Extern **DA Operation manual EPK-i7010 pag. 91**
Programa/soft de achizitie si transmitere a imaginilor pe calculator da	Inclus posibilitatea de inregistrare video direct pe USB sau HDD Extern **DA Operation manual EPK-i7010 pag. 71, 73, 91.**
Inscrierea pacientilor in baza interna da	Programa/soft de achizitie si transmitere a imaginilor pe calculator **DA este inclus in completatia de livrare.**
Programarea protocolului pentru fiecare utilizator da	Inscrierea pacientilor in baza interna **DA Operation manual EPK-i7010 pag. 75-76**
Afisarae datelor video endoscopului atasate la procesor la necesitatea utilizatorului. Da	Programarea protocolului pentru fiecare utilizator **DA Operation manual EPK-i7010 pag. 77-79**
Control Tastatura Alfa numerica da	Afisarae datelor video endoscopului atasate la procesor la necesitatea utilizatorului. **DA odata ce se apasa tasta space bar de pe tastiera alfnumerica pe monitor apare SN si Modelul Video endoscopului folosit**
Ecran tactil cu meniu minim in limba rusa da	Control Tastatura Alfa numerica **DA Operation manual EPK-i7010 pag. 72-74**
Dimensiunile pentru ecran tactil ≥ 5 inch	Ecran tactil cu meniu minim in limba rusa **DA Operation Manual EPK-i7010 pagina 5**
Ieșiri Video semnal live/real SXGA	Dimensiunile pentru ecran tactil ≥ 5 inch **DA**
Digital (DVI, HD-SDI,) ≥ 1	Ieșiri Video semnal live/real SXGA **DA analogic VGA Operation manual EPK-i7010 pag. 91**
Rezolutia de iesire ≥ 1080i	Digital (DVI, HD-SDI,) ≥ 1 **DA DVI , HD-SDI-2 Operation manual EPK-i7010 pag. 91**
Iesire date si control	Rezolutia de iesire - 1080i **DA Optivista EPK-7010 Spec Sheet**
RJ45 ≥1	Iesire date si control
RS-232C sau analogic ≥1	RJ45 - 1 **DA Operation manual EPK-i7010 pag. 91**
Compatibil cu video endoscoape	RS-232C sau analogi -1 **Operation manual EPK-i7010 pag. 91**

Digitally signed by Ceaicovschi Tudor
Date: 2022.07.19 19:34:37 EEST
Reason: MoldSign Signature
Location: Moldova

Anexa 9

Video gastroscop da Video Colonoscop da Video Duodenoscop da Video Bronhoscop da de clasa joasa si inalta da prezentarea listei cu care video endoscoape este compatibil – obligatoriu	Compatibil cu video endoscoape - **Operation manual EPK-i7010 pag. 91** Video gastroscop **DA** Video Colonoscop **DA** Video Duodenoscop **DA** Video Bronhoscop **DA** de clasa joasa si inalta da prezentarea listei cu care video endoscoape este compatibil – **DA Operation manual EPK-i7010 pag. 91**
Sistema de irigare integrata in procesor Control Direct de pe procesor	Sistema de irigare integrata in procesor Control Direct de pe processor **DA Operation manual EPK-i7010 / Air Supply pag. 26-27, 91**
Nivele de irigare minim 5 nivele cu valorile curpinse intre 0,2-0,7 L/min	Nivele de irigare minim 5 nivele cu valorile curpinse intre 0,2-0,7 L/min **DA pompa de irigare si aier find o pompa comuna are umataore nivele de lucru pentru aier** **Level 1: 2.0 - 2.8 L/min** **Level 2: 2.9 - 3.4 L/min** **Level 3: 3.5 - 4.0 L/min** **Level 4: 4.1 - 4.5 L/min** **Level 5: 4.6 - 7.2 L/min** **Operation manual EPK-i7010 / Air Supply pag. 91** **Pentru apa este rata aierului raporta aproximativ la 10 astfel int cumprinde valorile de 0,2-0,7L/min.** **Devierele de 2.0-2.8 L/min este raportate in dependeta de tipul video endoscopoul si diametrul capului distal.**
Sursa de lumină Tip integrată in procesor Tip lampă Xenon/Led Timp de viață lampă ≥500 h Putere lampă ≥ 300 W Contor lampă in nivele/ intensitate da Mod standby da Lampă de rezervă da Lampa de rezervă integrata in video procesor tip LED	Sursa de lumină Tip integrată in procesor Tip lampă **Xenon de baza DA Operation manual EPK-i7010 pag. 91** Timp de viață lampă ≥500 h **DA** Putere lampă - **300 W DA Operation manual EPK-i7010 pag. 91** Contor lampă in nivele/ intensitate **DA Operation manual EPK-i7010 pag. 6, 26 prin intermediul butonului BRIGHNESS este posbil motificari intensitati** Mod standby **DA se deconecteaza, sursa de lumina, se poate deconecta video endoscopul de la Video processor fara deconectarea video procesorului (Operation manual EPK-i7010 pag. 6 butonul scope eject) astfel inct video procesorul ramine in stare de asteptare pentru conectarea urmatorului endoscop.** Lampă de rezervă **nu necesita are solutie LED** Lampa de rezervă integrata in video procesor **tip LED DA Operation manual EPK-i7010 pag. 91**
"Periferice disponibile" Display medical Nu mai mica de 24 inch Nu mai mare de 26 inch Rezolutia minima ≥ 1080i	"Periferice disponibile" Display medical 24 Inch **DA** Rezolutia minima 1080i **DA**
Sistem de furnizare a aerului/apei minim 5 nivele	Sistem de furnizare a aerului/apei **DA Operation manual EPK-i7010 pag. 91** minim 5 nivele **Level 1: 2.0 - 2.8 L/min** **Level 2: 2.9 - 3.4 L/min**

	Level 3: 3.5 - 4.0 L/min **Level 4: 4.1 - 4.5 L/min** **Level 5: 4.6 - 7.2 L/min**
volumul vasului pentru apă minim 200 ml	volumul vasului pentru apă **200 ml Operation manual EPK-i7010 pag. 91**
Sistem de aspirație endoscopic Tip Separat de processor	Sistem de aspirație endoscopic Tip Separat de processor **DA va Fazzini F60-F cu pedala. Broshura atasata**
Volumul rezervorului ≥ 2 litri	Volumul rezervorului - 2 litri **DA**
Vid da	Vid **DA**
Dirijarea nivelului de aspirare în trepte	Dirijarea nivelului de aspirare în trepte **DA**
Puterea de aspiratie minim 60 L/min	Puterea de aspiratie minim 60 L/min **DA**
Control Prin buton	Control Prin buton **DA**
Prin pedala	Prin pedala **DA**
Troleu	Troleu – **ITD Troleu reprading PENTAX MEDICAL (endo-cart)**
Polițe reglabile la înălțime minim 4 unit	Polițe reglabile la înălțime 4 unit **DA**
Transformator electric integrat da	Transformator electric integrat **DA operation manual ITD English, pag38**
Numarul de prizi integrate in troleu minim 5	Numarul de prizi integrate in troleu **≥ 7 DA este inclus**
Suport pentru 2 video endoscope da	Suport pentru 2 video endoscope **DA este inclus**
reglabil pe inaltime	reglabil pe inaltime **DA cu posibilitate de schimbarea a positie minerului la necsitate**
Sertar pliant pentru tastiera da	Sertar pliant pentru tastiera **DA este inlus**
Miner pentru controlul in timpul deplasarii da	Miner pentru controlul in timpul deplasarii **DA este posibil de pus in partea dreapta sau stinga a troleui si un miner indegrat in partea din fata**
Roti Pentru pozitionarea si deplsarea troleului minim 4 buc	Roti Pentru pozitionarea si deplsarea troleului 4 buc **DA**
Frine minim 2	Frine 2 **DA**
Accesorii	Accesorii
Piesă bucală minm 2 unit.	Piesă bucală 2 unit. **DA OF-Z5 Accessories Pentax**
Tester automat (sa se indice modelul oferit) 1 unit.	Tester automat **(SHA-P6)** 1 unit. **DA Factsheet SHA-P6**
Vas de reverv̆ă pentru aspirator ≥ 2l minim 1 unit	Vas de reverv̆ă pentru aspirator - 2l minim 1 unit **DA**
Filtre pentru aspirator 5 unit.	Filtre pentru aspirator 5 unit. **DA**
Monitor medical (sa se indice modelul oferit) 1 unit.	Monitor medical **(EndoVue Monitor, 24")** 1 unit. **DA**
Videogastroscop cu marire tip optic	Videogastroscop cu marire tip optic **DA model EG-2990Zi**
Cantiatea 1 unit	Cantiatea 1 unit **DA**
Compatibil cu video procesorul de mai sus da	Compatibil cu video procesorul de mai sus **DA**
Compatibil cu tehnologia de cromoscopie digitala sau anologica in minim 3 nivele da	Compatibil cu tehnologia de cromoscopie digitala sau anologica in minim 3 nivele **DA si compatibil cu tehnologia de cromoscopie optica**
Tip Rezolutie inalta min. HD	Tip Rezolutie inalta **HD+ DA**
Tehnologie de marire tip optic "zoom optic"/ "Magnification optic" ≥ 100x	Tehnologie de marire tip optic "zoom optic"/ "Magnification optic" **DA** 136x **DA Broshura MagniView 136**
Tubul de inserție Lungime totală ≥ 1300 mm	Tubul de inserție Lungime totală - **1376 mm DA Operation Manual EG-2990Zi pag. 80**
Lungime de lucru ≥ 1000 mm	Lungime de lucru **1050 mm DA 2021 Product Overview brochure pag. 8**

Anexa 9

Diametrul exterior ≤ 10 mm Marcaj de lungime da Canal de lucru Numărul de canale ≥1 Diametrul nu mai mic de 2,8 mm Canal adaugator pentru jetul de apa da Optica Unghiul cîmpului vizual ≥ 140 grade Înclinația cîmpului vizual 0 grade Adîncimea cîmpului vizual in regim normal 5-100 mm Tipul și unghiurile de deflecție Sus/jos ≥210/90 grade Stînga/dreapta ≥100/100 grade Spălarea obiectivului da Videogastroscop cu marire tip optic Metode de sterilizare Chimic Etilen oxid optional Posibilitatea de a se efectua multiple proceduri de sterilizare **DA** Compatibil cu masina automata de dezinfectare Programarea butoanelor da Accesori Pensa pu biopsie de mutipla folosinta compatibil cu canalul de de lucru a videogastroscopului cu lungimea maxima de 1600 mm Minim 4 unitati Ace pentru injectare endoscopica de unica folosinta Set minim 10 bucati Prezent certificatul CE sau declaratie de conformitate da Garantia minim 24 luni	Diametrul exterior **- 9,8 mm DA 2021 Product Overview brochure pag. 8** Marcaj de lungime **DA** Canal de lucru Numărul de canale **- 1 DA** Diametrul - **2,8 mm DA 2021 Product Overview brochure pag. 8** Canal adaugator pentru jetul de apa **DA Water Jet system – 2021 Producat Overview brochure pag 8** Optica Unghiul cîmpului vizual - **140 grade DA 2021 Producat Overview brochure pag 8** Înclinația cîmpului vizual **0 grade DA** Adîncimea cîmpului vizual in regim normal **5-100 mm DA Operation manual EG-2990Zi pagina 80** Tipul și unghiurile de deflecție Sus/jos - 210/120 grade **DA Operation manual EG-2990Zi pagina 80** Stînga/dreapta - **120/120 grade Operation manual EG-2990Zi pagina 80** Spălarea obiectivului **DA** Videogastroscop cu marire tip optic **DA** Metode de sterilizare Chimic **DA** Etilen oxid optional **DA** Posibilitatea de a se efectua multiple proceduri de sterilizare **DA** Compatibil cu masina automata de dezinfectare **DA** Programarea butoanelor **DA Operation manual EPK-i7010 (Customize > Assign scope button) pag. 44-45** Accesori Pensa pu biopsie de mutipla folosinta compatibil cu canalul de de lucru a videogastroscopului cu lungimea maxima de 1600 4 unitati – **PN KH2415S – Single and Reusable Accessory Pentax Medical** Ace pentru injectare endoscopica de unica folosinta **1 set de 10 bucati** – **PN VDK-IN-23-180-2204-A - Stella Line Broshure pag. 3** Prezent certificatul CE sau declaratie de conformitate **DA** Garantia **24 luni DA**

AGENȚIA MEDICAMENTULUI ȘI DISPOZITIVELOR MEDICALE

REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

Tip	Denumire
I.2. Declarația de conformitate CE	Declaratie de conformitate CE
I.3. Certificatul CE	Certificat CE

Введите текст для поиска...

Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data	Cod vamal
			EPK							
DM000031516	VIDEOGASTROSCOP	PENTAX MEDICAL	EPK-I7010	A010107	Japonia	HOYA CORPORATION	GBG-MLD S.R.L.	A07.PS-01.Rg04-247	01-12-2017	
DM000031515	VIDEOGASTROSCOP	PENTAX MEDICAL	EPK-I7000(A)	C010490	Japonia	HOYA CORPORATION	GBG-MLD S.R.L.	A07.PS-01.Rg04-247	01-12-2017	
DM000031514	VIDEOGASTROSCOP	PENTAX MEDICAL	EPK-I7000	C010936	Japonia	HOYA CORPORATION	GBG-MLD S.R.L.	A07.PS-01.Rg04-247	01-12-2017	
DM000031517	VIDEOGASTROSCOP	PENTAX MEDICAL	EPK-P(C)	B011594	Japonia	HOYA CORPORATION	GBG-MLD S.R.L.	A07.PS-01.Rg04-247	01-12-2017	
DM000031512	VIDEOGASTROSCOP	PENTAX MEDICAL	EPK-3000	A020033	Japonia	HOYA CORPORATION	GBG-MLD S.R.L.	A07.PS-01.Rg04-247	01-12-2017	
DM000031513	VIDEOGASTROSCOP	PENTAX MEDICAL	EPK-I5000	E013560	Japonia	HOYA CORPORATION	GBG-MLD S.R.L.	A07.PS-01.Rg04-247	01-12-2017	
DM000031511	VIDEOGASTROSCOP	PENTAX MEDICAL	EPK-100P	F013808	Japonia	HOYA CORPORATION	GBG-MLD S.R.L.	A07.PS-01.Rg04-247	01-12-2017	
DM000031510	VIDEOGASTROSCOP	PENTAX MEDICAL	EPK-1000	H016084	Japonia	HOYA CORPORATION	GBG-MLD S.R.L.	A07.PS-01.Rg04-247	01-12-2017	

Содержит([Model], 'EPK')

Очистить

PENTAX
MEDICAL

EU DECLARATION OF CONFORMITY

We ; HOYA Corporation
6-10-1 Nishi-shinjuku, Shinjuku-ku, Tokyo
160-0023, Japan

declare under our sole responsibility that PENTAX or PENTAX Medical brand product:

Product Category : Endoscopes, video processors and accessories
Model Name : See attached

Meets;

1) the conformity assessment procedure in Annex II in accordance with the provisions of Medical Devices Directive 93/42/EEC. The classification and rules applied to each model are described in the attachment.
This declaration is based on EC quality system approved by
TÜV SÜD Product Service GmbH (No.0123), Ridlerstraße 65, 80339 München, Germany

2) the provisions of RoHS Directive 2011/65/EU.

Tokyo, May 25, 2021

Kazunori Shimada
Manager
Regulatory Affairs Department
PENTAX Lifecare Division
HOYA Corporation

Authorized Representative in the European Union :
PENTAX Europe GmbH, Julius Vosseler Straße 104, 22527 Hamburg, Germany

PENTAX MEDICAL

ER-QL-193
Date : 2021/5/25

List of products labeled with CE marking

Category : Endoscopes, video processors and accessories
MDD Class Ⅱa&Ⅱb / RoHS

Model Name	General Name	MDD Class	Rule	Initial date of declaration of conformity	Remarks
DN-D2718B	Electro-Surgical Knife	Ⅱb	9	2016.06.01	
DN-D2722B	Electro-Surgical Knife	Ⅱb	9	2016.06.01	
DO-D2618	Snare	Ⅱb	9	2016.08.29	
DO-D2622	Snare	Ⅱb	9	2016.08.29	
DP-D2518	Electro-Surgical Knife	Ⅱb	9	2016.08.29	
DP-D2622	Electro-Surgical Knife	Ⅱb	9	2016.08.29	
EB-1170K	Video Bronchoscope	Ⅱa	5	2017.12.25	
EB15-J10	Video Bronchoscope	Ⅱa	5	2016.06.01	
EB-1970TK	Video Bronchoscope	Ⅱa	5	2017.12.25	
EB-1990i	Video Bronchoscope	Ⅱa	5	2017.12.25	
EB19-J10	Video Bronchoscope	Ⅱa	5	2016.06.01	
EB11-J10	Video Bronchoscope	Ⅱa	5	2019.04.05	
EB11-S01	Video Bronchoscope	Ⅱa	5	2021.05.25	20210525 added
EB15-S01	Video Bronchoscope	Ⅱa	5	2021.05.25	20210525 added
EC-2990Li	Video Colonoscope	Ⅱa	5	2017.12.25	
EC-3490FK	Video Colonoscope	Ⅱa	5	2017.12.25	
EC-3490LK	Video Colonoscope	Ⅱa	5	2017.12.25	
EC-3490MK	Video Colonoscope	Ⅱa	5	2017.12.25	
EC-3490TFi	Video Colonoscope	Ⅱa	5	2017.12.25	
EC-3490TLi	Video Colonoscope	Ⅱa	5	2017.12.25	
EC-3490TMi	Video Colonoscope	Ⅱa	5	2017.12.25	
EC34-i10F	Video Colonoscope	Ⅱa	5	2017.12.25	
EC34-i10L	Video Colonoscope	Ⅱa	5	2017.12.25	
EC34-i10M	Video Colonoscope	Ⅱa	5	2017.12.25	
EC34-i10NL	Video Colonoscope	Ⅱa	5	2019.07.05	
EC34-i10NF	Video Colonoscope	Ⅱa	5	2019.07.05	
EC34-i10TF	Video Colonoscope	Ⅱa	5	2017.09.15	
EC34-i10TL	Video Colonoscope	Ⅱa	5	2017.09.15	
EC34-i10TM	Video Colonoscope	Ⅱa	5	2017.09.15	
EC38-i10cL	Video Colonoscope	Ⅱa	5	2018.07.19	
EC38-i10cF	Video Colonoscope	Ⅱa	5	2018.07.19	
EC38-i10cF2	Video Colonoscope	Ⅱa	5	2018.10.25	
EC38-i10cM	Video Colonoscope	Ⅱa	5	2018.07.19	
EC34-i10cL	Video Colonoscope	Ⅱa	5	2018.07.19	
EC34-i10cF	Video Colonoscope	Ⅱa	5	2018.07.19	
EC34-i10cM	Video Colonoscope	Ⅱa	5	2018.07.19	
EC-3890Fi	Video Colonoscope	Ⅱa	5	2017.12.25	
EC-3890Fi2	Video Colonoscope	Ⅱa	5	2017.12.25	
EC-3890FK	Video Colonoscope	Ⅱa	5	2017.12.25	
EC-3890FK2	Video Colonoscope	Ⅱa	5	2017.12.25	
EC-3890FZi	Video Colonoscope	Ⅱa	5	2017.12.25	
EC-3890Li	Video Colonoscope	Ⅱa	5	2017.12.25	
EC-3890LK	Video Colonoscope	Ⅱa	5	2017.12.25	
EC-3890LZi	Video Colonoscope	Ⅱa	5	2017.12.25	
EC-3890MK	Video Colonoscope	Ⅱa	5	2017.12.25	
EC-3890MZi	Video Colonoscope	Ⅱa	5	2017.12.25	
EC-3890TLK	Video Colonoscope	Ⅱa	5	2017.12.25	
EC38-i10F	Video Colonoscope	Ⅱa	5	2017.12.25	
EC38-i10F2	Video Colonoscope	Ⅱa	5	2017.12.25	
	Video Colonoscope	Ⅱa	5	2019.07.02	
EC38-i10L	Video Colonoscope	Ⅱa	5	2017.12.25	
EC38-i10M	Video Colonoscope	Ⅱa	5	2017.12.25	
EC38-i10M2	Video Colonoscope	Ⅱa	5	2017.12.25	
EC38-i10NF	Video Colonoscope	Ⅱa	5	2016.06.01	
EC38-i10NL	Video Colonoscope	Ⅱa	5	2016.06.01	
ECY-1575K	Video Cystoscope	Ⅱa	5	2017.12.25	
ED-3490TK	Video Duodenoscope	Ⅱa	5	2017.12.25	
ED34-i10T	Video Duodenoscope	Ⅱa	5	2017.12.25	
ED34-i10T2	Video Duodenoscope	Ⅱa	5	2017.06.23	
OE-A63	Single Use Sterile Distal End Cap with Elevator	Ⅱa	5	2020.03.24	
ED32-i10	Video Duodenoscope	Ⅱa	5	2019.08.23	
OE-A65	Single Use Sterile Distal End Cap with Elevator	Ⅱa	5	2020.03.24	
EE17-J10	Video Esophagoscope	Ⅱa	5	2019.06.12	
EG16-K10	Video Upper GI Scope	Ⅱa	5	2017.12.25	
EG17-J10	Video Upper GI Scope	Ⅱa	5	2019.06.12	
EG-1690K	Video Upper GI Scope	Ⅱa	5	2018.02.16	
EG-2490K	Video Upper GI Scope	Ⅱa	5	2017.12.25	
EG-2790K	Video Upper GI Scope	Ⅱa	5	2017.12.25	
EG27-i10	Video Upper GI Scope	Ⅱa	5	2017.12.25	

PENTAX MEDICAL

ER-QL-193
Date : 2021/5/25

List of products labeled with CE marking

Category : Endoscopes, video processors and accessories
MDD Class Ⅱa&Ⅱb / RoHS

Model Name	General Name	MDD Class	Rule	Initial date of declaration of conformity	Remarks
EG-2990i	Video Upper GI Scope	Ⅱa	5	2017.12.25	
EG-2990K	Video Upper GI Scope	Ⅱa	5	2017.12.25	
EG-2990Zi	Video Upper GI Scope	Ⅱa	5	2017.12.25	
EG29-i10	Video Upper GI Scope	Ⅱa	5	2017.12.25	
EG29-i10N	Video Upper GI Scope	Ⅱa	5	2018.02.16	
EG29-i10c	Video Upper GI Scope	Ⅱa	5	2018.07.19	
EG-3490K	Video Upper GI Scope	Ⅱa	5	2017.12.25	
EG34-i10	Video Upper GI Scope	Ⅱa	5	2017.09.08	
EG-3890TK	Video Upper GI Scope	Ⅱa	5	2017.12.25	
EPK-3000	Video Processor	Ⅱa	2	2016.06.01	
EPK-i5000	Video Processor	Ⅱa	2	2017.12.25	
EPK-i5500c	Video Processor	Ⅱa	2	2018.07.19	
EPK-i7010	Video Processor	Ⅱa	2	2016.06.01	
FB-10V	Broncho Fiberscope	Ⅱa	5	2017.12.25	
FB-15RBS	Broncho Fiberscope	Ⅱa	5	2017.12.25	
FB-15V	Broncho Fiberscope	Ⅱa	5	2017.12.25	
FB-18RBS	Broncho Fiberscope	Ⅱa	5	2017.12.25	
FB-18V	Broncho Fiberscope	Ⅱa	5	2017.12.25	
FB-19TV	Broncho Fiberscope	Ⅱa	5	2017.12.25	
FB-8V	Broncho Fiberscope	Ⅱa	5	2017.12.25	
FC-38FV	GI Fiberscope	Ⅱa	5	2017.12.25	
FC-38LV	GI Fiberscope	Ⅱa	5	2017.12.25	
FCN-15X	Choledocho-Nephro Fiberscope	Ⅱa	5	2017.12.25	
FCP-9P	Peroral Choledocho Fiberscope	Ⅱa	5	2017.12.25	
FCY-15RBS	Portable Cystoscope	Ⅱa	5	2017.12.25	
FD-34V2	GI Fiberscope	Ⅱa	5	2017.12.25	
FG-16V	GI Fiberscope	Ⅱa	5	2017.12.25	
FG-24V	GI Fiberscope	Ⅱa	5	2017.12.25	
FG-29V	GI Fiberscope	Ⅱa	5	2017.12.25	
FHY-10RBS	Portable Hysteroscope	Ⅱa	5	2017.12.25	
FHY-15RBS	Portable Hysteroscope	Ⅱa	5	2017.12.25	
FI-10RBS	Portable Intubation Scope	Ⅱa	5	2017.12.25	
FI-13RBS	Portable Intubation Scope	Ⅱa	5	2017.12.25	
FI-16RBS	Portable Intubation Scope	Ⅱa	5	2017.12.25	
FI-7RBS	Portable Intubation Scope	Ⅱa	5	2017.12.25	
FI-9RBS	Portable Intubation Scope	Ⅱa	5	2017.12.25	
FNL-10RBS	Naso-Pharyngo-Laryngoscope	Ⅱa	5	2017.12.25	
FNL-10RP3	Naso-Pharyngo-Laryngoscope	Ⅱa	5	2017.12.25	
FNL-15RP3	Naso-Pharyngo-Laryngoscope	Ⅱa	5	2017.12.25	
FNL-7RP3	Naso-Pharyngo-Laryngoscope	Ⅱa	5	2017.12.25	
FS-34V	GI Fiberscope	Ⅱa	5	2017.12.25	
FUR-9RBS	Portable Ureterorenoscope	Ⅱa	5	2017.12.25	
HS-D2618	Hot Hemostasis Forceps	Ⅱb	9	2016.06.01	
HS-D2622	Hot Hemostasis Forceps	Ⅱb	9	2016.06.01	
LH-150PC	Halogen Light Source	Ⅱa	2	2017.12.25	
OF-B130	Single Use Suction Control Valve	Ⅱa	5	2020.04.06	
OF-B194	Single Use Suction Control Valve	Ⅱa	5	2020.04.06	
OF-B205	Single Use Suction Control Valve	Ⅱa	5	2016.06.01	
OF-G11	Single Use Suction Control Valve	Ⅱa	5	2020.04.06	
OS-H4	Water Bottle Assembly	Ⅱa	2	2016.06.01	
OS-H5	Water Bottle Assembly	Ⅱa	2	2016.06.01	
VNL-1190STK	Video Naso-Pharyngo-Laryngoscope	Ⅱa	5	2017.12.25	
VNL-1070STK	Video Naso-Pharyngo-Laryngoscope	Ⅱa	5	2018.02.15	
VNL-1570STK	Video Naso-Pharyngo-Laryngoscope	Ⅱa	5	2018.02.15	
VNL11-J10	Video Naso-Pharyngo-Laryngoscope	Ⅱa	5	2016.06.01	
VNL-1590STi	Video Naso-Pharyngo-Laryngoscope	Ⅱa	5	2017.12.25	
VNL15-J10	Video Naso-Pharyngo-Laryngoscope	Ⅱa	5	2016.06.01	
VNL8-J10	Video Naso-Pharyngo-Laryngoscope	Ⅱa	5	2016.06.01	
VSB-2990i	Video Small Bowel Enteroscope	Ⅱa	5	2017.12.25	

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT
TÜV SÜD

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

TÜV SÜD Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 068357 0028 Rev. 00

Facility(ies):

HOYA Corporation PENTAX Miyagi Factory
30-2 Okada, Aza-Shimomiyano, Tsukidate,
Kurihara-shi, Miyagi, 987-2203 JAPAN

HOYA Corporation PENTAX Yamagata Factory
4-1 Hinode-cho, Nagai-shi, Yamagata, 993-0012
JAPAN

HOYA Corporation
6-10-1 Nishi-shinjuku, Shinjuku-ku, Tokyo,
160-0023 JAPAN

HOYA Corporation PENTAX Lifecare Division
Showanomori Technology Center
1-1-110 Tsutsujigaoka, Akishima-shi, Tokyo,
196-0012 JAPAN

HOYA Corporation PENTAX Lifecare Division
Production Technology Center / Ogawa Factory
395 Oaza-kakuyama, Ogawa-machi, Hiki-gun,
Saitama, 355-0316 JAPAN

-/-

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 068357 0028 Rev. 00

Manufacturer:
HOYA Corporation
6-10-1 Nishi-shinjuku
Shinjuku-ku
Tokyo
160-0023 JAPAN

EC-Representative:
PENTAX Europe GmbH
Julius-Vosseler-Str. 104,
22527 Hamburg,
GERMANY

Product Category(ies): **Endoscopes, Ultrasound Endoscopes, their Related Equipment and Accessories (IIa, IIb)**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: **JAQ235034630**

Valid from: **2019-02-01**
Valid until: **2024-01-31**

Date, **2018-12-12**

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT
TÜV SÜD

A4 / 07.17

令和元 年登簿第 175 号

認　　証

嘱託人 長谷川 勇人 が提出した別紙編綴の書類の謄本は、その原本と対照し、符合することを認めた。

よって、これを認証する。

令和元年 8 月 21 日、本公証人役場において

東京都立川市柴崎町3丁目9番21号

東京法務局所属

公証人
Notary 佐藤道明

Michiaki Sato

証　　明

上記署名は、東京法務局所属公証人の署名に相違ないものであり、かつ、その押印は、真実のものであることを証明する。

令和元 年 8 月 21 日

東京法務局長 岩山伸二

APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. Country: JAPAN
   This public document
2. has been signed by Michiaki Sato
3. acting in the capacity of Notary of the Tokyo Legal Affairs Bureau
4. bears the seal/stamp of Michiaki Sato Notary
   Certified
5. at Tokyo
6. AUG. 2 1. 2019
7. by the Ministry of Foreign Affairs
8. 19- No 065483
9. Seal/stamp:
10. Signature

MINISTRY OF FOREIGN AFFAIRS JAPAN 外務省 日本国

T. TANAKA

Toshie TANAKA

For the Minister for Foreign Affairs

NOTARIAL CERTIFICATE

This is to certify that the attached copy of the document exactly corresponds with the seen original.

Dated this 21st day of August, 2019.

Michiaki Sato

TOKYO LEGAL AFFAIRS BUREAU
NOTARY
NO.9-21, 3-CHOME, SIBAZAKICHO,
TACHIKAWA, TOKYO, JAPAN

Michiaki Sato

NOTARY

9 - 21, 3 - CHOME, SHIBAZAKICHO

TACHIKAWA, TOKYO, JAPAN

TOKYO LEGAL AFFAIRS BUREAU

Логотип: [ZLG] Уполномочено
Центральным ведомством земель по охране здоровья в области лекарственных средств и медицинской продукции
ZLG-BS-244.10.08
www.zlg.de

Логотип:
[TÜV
SÜD
Product Service]

СЕРТИФИКАТ ЕС

Комплексная система менеджмента качества продукции
Директива 93/42/EEC о медицинских изделиях (MDD), Приложение II, исключая (4)
(Изделия Класса IIa, IIb или III)
№: G1 068357 0028 Верс. 00

Производственный(е) объект(ы)

ХОЯ Корпорейшн Фабрика ПЕНТАКС Мияги
30-2 Окада, Аза-Шимомияно, Цукидате, Курихара-Ши, Мияги, 987-2203, ЯПОНИЯ

ХОЯ Корпорейшн Фабрика ПЕНТАКС Ямагата
4 – 1 Хиноде-чо, Нагаи-ши, Ямагата, 993-0012 ЯПОНИЯ

ХОЯ Корпорейшн
6-10-1 Ниси-синдзюку, Синдзюку-ку, Токио, 160-0023, Япония

ХОЯ Корпорейшн Подразделение ПЕНТАКС Лайф Кеар Технологический центр Шованомори
1-1-110 Цуцуджигаока, Акишима-ши, Токио, 196-0012 ЯПОНИЯ

ХОЯ Корпорейшн Подразделение ПЕНТАКС Лайф Кеар Производственно-технологический центр/Фабрика Огава
395 Оаза-Какуяма, Огава-мачи, Хики-гун, Сайтама 355-0316 ЯПОНИЯ

TÜV SÜD Product Service GmbH является уполномоченным органом, имеющим идентификационный номер 0123.

Логотип: [**ZLG**] Уполномочено
Центральным ведомством земель по охране здоровья в области лекарственных средств и медицинской продукции
ZLG-BS-244.10.08
www.zlg.de

[штрих-код]

Логотип:
[**TÜV**
SÜD
Product Service]

СЕРТИФИКАТ ЕС

Комплексная система менеджмента качества продукции
Директива 93/42/EEC о медицинских изделиях (MDD), Приложение II, исключая (4)
(Изделия Класса IIa, IIb или III)

№: G1 068357 0028 Верс. 00

Производитель: **ХОЯ Корпорейшн**
(HOYA Corporation)
6-10-1 Ниси-синдзюку
Синдзюку-ку
Токио
160-0023 ЯПОНИЯ

Представитель в ЕС: **ПЕНТАКС Европа ГмбХ**
(PENTAX Europe GmbH)
Юлиус-Фосселер-Штрассе 104,
22527 г. Гамбург
ГЕРМАНИЯ

Категория изделия(й): **Эндоскопы, ультразвуковые эндоскопы, их сопутствующее оборудование и принадлежности к ним (IIa, IIb)**

Орган сертификации TÜV SÜD Product Service GmbH заявляет, что вышеуказанный производитель внедрил систему менеджмента качества в отношении проектирования, производства и контроля соответствующих изделий/категорий изделий согласно Приложению II к MDD. Данная система менеджмента качества соответствует положениям указанной Директивы и подлежит периодической проверке. Для реализации на рынке продукции класса III обязателен дополнительный сертификат – по Приложению II (4). См. также примечания на обороте.

Номер отчета: **JAQ235034630**

Действителен с: **01.02.2019**
Действителен до: **31.01.2024**

Дата, 12.12.2018

[Подпись]
Штефан Прайс

TÜV SÜD Product Service GmbH является уполномоченным органом, имеющим идентификационный номер 0123.

Печать: Нотариус Митиаки Сато.

Документ зарегистрирован за номером: № «**175**» за «**2019**» год

Подтверждение

Настоящим подтверждаю тот факт, что прилагаемая копия документа в точности соответствует представленному оригиналу. На основании чего я подтверждаю изложенные факты.

21 августа 2019 года
Документ составлен в офисе нотариуса,
г. Токио, Татикава, Сибасаки-тё, 3-тёме, 9-21
Нотариус, подведомственный Токийскому бюро по юридическим вопросам
Печать: Нотариус Митиаки Сато.
Нотариус Митиаки Сато

Свидетельство

Вышеприведенная подпись является подлинной подписью нотариуса, подведомственного Токийскому бюро по юридическим вопросам, кроме того, я подтверждаю подлинность приложенной личной печати упомянутого лица.
21 августа 2019 года
Директор Токийского бюро по юридическим вопросам ИВАЯМА СИНДЗИ

Печать: Директор Токийского бюро по юридическим вопросам.

АПОСТИЛЬ

(Гаагская конвенция от 5 октября 1961 года)

1. Страна: ЯПОНИЯ
   Данный официальный документ
2. подписан **Митиаки Сато**
3. выступающим в качестве **нотариуса Токийского бюро по юридическим вопросам**
4. заверен печатью/штампом **Митиаки Сато, нотариуса**

Удостоверено
5. в г. Токио 6. 21 АВГУСТА 2019 Г.
7. Министерством иностранных дел
8. 19-**№ 065483**
9. Печать/штамп

Гербовая печать: ЯПОНИЯ. МИНИСТЕРСТВО ИНОСТРАННЫХ ДЕЛ.

10. Подпись *[Подпись]*
Тоси ТАНАКА
От имени Министра иностранных дел

НОТАРИАЛЬНОЕ СВИДЕТЕЛЬСТВО

Настоящим свидетельствуется, что прилагаемая копия документа в точности соответствует представленному оригиналу.

Датировано 21 августа 2019 года.

[Подпись]

Митиаки Сато
НОТАРИУС
9-21, 3-ТЁМЕ, СИБАЗАКИТЁ
ТАТИКАВА, ТОКИО, ЯПОНИЯ
ТОКИЙСКОЕ БЮРО ПО ЮРИДИЧЕСКИМ ВОПРОСАМ

Печать: ТОКИЙСКОЕ БЮРО ПО ЮРИДИЧЕСКИМ ВОПРОСАМ. **НОТАРИУС**.
9-21, 3-ТЁМЕ, СИБАЗАКИТЁ
ТАТИКАВА, ТОКИО, ЯПОНИЯ.

Перевод данного текста сделан мной, переводчиком Алексеевым Алексеем Александровичем.

_____

Российская Федерация

Город Москва
Двадцать восьмого августа две тысячи девятнадцатого года
Я, Ребрина Елена Дмитриевна, временно исполняющая обязанности нотариуса города Москвы Акимова Глеба Борисовича, свидетельствую подлинность подписи переводчика Алексеева Алексея Александровича.

Подпись сделана в моем присутствии.
Личность подписавшего документ установлена.

Зарегистрировано в реестре: № 77/09-н/77-2019- 73-1426
Взыскано государственной пошлины(по тарифу): 100 руб.
Уплачено за оказание услуг правового и технического характера: 200 руб.

_____ *Е.Д. Ребрина*

Всего прошнуровано, пронумеровано и скреплено печатью 7 лист(а)(ов)

ВРИО нотариуса

PENTAX
MEDICAL

令和４年３月２日

関係各位

宣 言 書

私どもＨＯＹＡ株式会社、東京都新宿区西新宿６－１０－１は、添付の下記文書が書類原本の写しであることを証明致します。

「Certificate No. Q5 068357 0027 Rev. 01」

HOYA 株式会社
PENTAX ライフケア事業部
開発統括部長代理
兼 カスタマーソリューション開発部　部長
坂井 康弘

March 2, 2022

To whom it may concern,

STATEMENT

We, HOYA Corporation (6-10-1 Nishi-shinjuku Shinjuku-ku, Tokyo 160-0023 Japan), hereby certify that attached document listed in above is the copy of the original document.

SAKAI Yasuhiro
Senior General Manager
Customer Solution Development
Japan Research & Development Department
PENTAX Lifecare Division
HOYA Corporation

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 068357 0027 Rev. 01

Holder of Certificate: PENTAX MEDICAL

HOYA Corporation
6-10-1 Nishi-shinjuku
Shinjuku-ku
Tokyo
160-0023 JAPAN

Certification Mark:

TÜV SÜD
EN ISO 13485
tuvsud.com/ps-cert

Scope of Certificate: **Design and Development, Production, Distribution and Servicing of Medical Endoscopes and Related Products**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 068357 0027 Rev. 01

Report No.: **JA1768298**

Valid from: **2022-02-27**
Valid until: **2025-02-26**

Date, 2022-02-24

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 068357 0027 Rev. 01

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

HOYA Corporation PENTAX Miyagi Factory
30-2 Okada, Aza-Shimomiyano, Tsukidate, Kurihara-shi, Miyagi, 987-2203 JAPAN

Production and Distribution of Medical Endoscopes and Related Products

HOYA Corporation PENTAX Yamagata Factory
4-1 Hinode-cho, Nagai-shi, Yamagata, 993-0012 JAPAN

Production of Medical Endoscopes and Related Products

HOYA Corporation
6-10-1 Nishi-shinjuku, Shinjuku-ku, Tokyo, 160-0023 JAPAN

Regulatory Affairs

HOYA Corporation PENTAX Lifecare Division Medical Instrument SBU Japan Sales Headquarters
3-35-1 Shimo-renjaku, Mitaka-shi, Tokyo, 181-0013 JAPAN

Distribution of Medical Endoscopes and Related Products

HOYA Corporation PENTAX Lifecare Division Showanomori Technology Center
1-1-110 Tsutsujigaoka, Akishima-shi, Tokyo, 196-0012 JAPAN

Design and Development and Distribution of Medical Endoscopes and Related Products

HOYA Corporation PENTAX Lifecare Division Production Technology Center / Ogawa Factory
395 Oaza-kakuyama, Ogawa-machi, Hiki-gun, Saitama, 355-0316 JAPAN

Production, Distribution and Servicing of Medical Endoscopes and Related Products

-/-

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

令和４年登簿第　56　号

認　　証

嘱託人 HOYA 株式会社 PENTAX ライフケア事業部 開発統括部 開発統括部長代理 兼 カスタマーソリューション開発部 部長 坂井康弘 の代理人 長谷川 勇人 は、本公証人に対し坂井康弘が別紙証書の署名につき、自らしたものであることを承認している旨陳述した。

よって、これを認証する。

令和４年　３月　10 日、本公証人役場において

東京都立川市柴崎町３丁目９番21号

東京法務局所属

公証人

Notary

綿引 裕

WATAHIKI Yutaka

証　　明

上記署名は、東京法務局所属公証人の署名に相違ないものであり、かつ、その押印は、真実のものであることを証明する。

令和４年　３月　10 日

東京法務局長　坂本佳胤

APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. Country: JAPAN
   This public document
2. has been signed by WATAHIKI Yutaka
3. acting in the capacity of Notary of the Tokyo Legal Affairs Bureau
4. bears the seal/stamp of WATAHIKI Yutaka ,Notary

Certified

5. at Tokyo
6. MAR. 10. 2022
7. by the Ministry of Foreign Affairs
8. 22- No 042117
9. Seal/stamp:
10. Signature

HAMAMOTO Hiroki

For the Minister for Foreign Affairs

令和４年登簿第　56　号

認　　証

嘱託人 HOYA 株式会社 PENTAX ライフケア事業部 開発統括部 開発統括部長代理 兼 カスタマーソリューション開発部 部長 坂井康弘 の代理人 長谷川 勇人 は、本公証人に対し坂井康弘が別紙証書の署名につき、自らしたものであることを承認している旨陳述した。

よって、これを認証する。

令和４年　３月　10 日、本公証人役場において

東京都立川市柴崎町３丁目９番21号

東京法務局所属

公証人

Notary

綿引 裕

WATAHIKI Yutaka

証　　明

上記署名は、東京法務局所属公証人の署名に相違ないものであり、かつ、その押印は、真実のものであることを証明する。

令和４年　３月　10 日

東京法務局長　坂本佳胤

APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. Country: JAPAN
   This public document
2. has been signed by WATAHIKI Yutaka
3. acting in the capacity of Notary of the Tokyo Legal Affairs Bureau
4. bears the seal/stamp of WATAHIKI Yutaka ,Notary

Certified

5. at Tokyo
6. MAR. 10. 2022
7. by the Ministry of Foreign Affairs
8. 22- No 042117
9. Seal/stamp:
10. Signature

MINISTRY OF FOREIGN AFFAIRS JAPAN 日本国 外務省

HAMAMOTO Hiroki

For the Minister for Foreign Affairs

NOTARIAL CERTIFICATE

This is to certify that HASEGAWA Hayato, an agent of SAKAI Yasuhiro, Senior General Manager of HOYA Corporation PENTAX Lifecare Division Japan Research & Development Department Customer Solution Development has stated in my very presence that said SAKAI Yasuhiro acknowledged himself to have signed to the attached document.

Dated this 10th day of March, 2022.

Watahiki · Yutaka

TOKYO LEGAL AFFAIRS BUREAU
NOTARY
NO.9 21,3 CHOME, SHIBAZAKICHO
TACHIKAWA, TOKYO, JAPAN

WATAHIKI Yutaka

NOTARY
9 - 21, 3 - CHOME, SHIBAZAKICHO
TACHIKAWA, TOKYO, JAPAN
TOKYO LEGAL AFFAIRS BUREAU

Перевод с японского и английского языков на русский

PENTAX
MEDICAL

[Сертификат № Q5 068357 0027 Верс. 01]

ХОЯ
ПЕНТАКС

2 марта 2022 года

По месту требования

ПОДТВЕРЖДЕНИЕ

Мы, «ХОЯ Корпорейшн», (6-10-1, Ниси-Синдзюку, Синдзюку-ку, Токио, 160-0023, Япония), настоящим свидетельствуем, что прилагаемый документ, указанный выше, является копией оригинального документа.

[Подпись]
САКАИ Ясухиро
Старший Генеральный менеджер
Отдел разработки клиентских решений
Отдел исследования и развития Японии
Подразделение ПЕНТАКС Лайф Кеар
ХОЯ Корпорейшн

Печать: Нотариус Ютака Ватахики.

Логотип: **[DAkkS]**
Немецкий орган аккредитации
D-ZM-11321-01-00

[QR код]

Логотип: **[TÜV SÜD** Product Service]

СЕРТИФИКАТ
№: Q5 068357 0027 Верс. 01

Держатель сертификата: **PENTAX MEDICAL**	**ХОЯ Корпорейшн (HOYA Corporation)** **6-10-1 Ниси-синдзюку** **Синдзюку-ку** **Токио** **160-0023 ЯПОНИЯ**
Сертификационный знак:	**TÜV SÜD** EN ISO 13485 tuv-sud.com/ps-cert
Область применения Сертификата:	**Проектирование и разработка, производство, реализация и обслуживание медицинских эндоскопов и сопутствующих изделий**

Орган сертификации TÜV SÜD Product Service GmbH свидетельствует, что вышеуказанная компания внедрила и поддерживает систему менеджмента качества, которая соответствует требованиям указанных стандартов. Все применимые требования регламента испытаний и сертификации организации TÜV SÜD Product Service GmbH выполняются. Подробные сведения и информацию о действительности данного сертификата см. по ссылке: www.tuvsud.com/ps-cert?q=cert:Q5_068357_0027_Rev._01

Номер отчета:	**JA1768298**
Действителен с:	**27.02.2022**
Действителен до:	**26.02.2025**

Дата, 24.02.2022

[Подпись]
Кристоф Дикс
Руководитель сертификационного/Нотифицированного органа

Логотип: [DAkkS]
Немецкий орган аккредитации
D-ZM-11321-01-00

Логотип: [TÜV SÜD Product Service]

СЕРТИФИКАТ
№: Q5 068357 0027 Верс. 01

Применяемый(ые) стандарт(ы):

EN ISO 13485:2016
Медицинские изделия – Системы менеджмента качества – Требования в нормативных целях
(ISO 13485:2016)
DIN EN ISO 13485:2016

Производственное(ые) предприятие(ия):

ХОЯ Корпорейшн Фабрика ПЕНТАКС Мияги
30-2 Окада, Аза-Шимомияно, Цукидате, Курихара-ши, Мияги, 987-2203, ЯПОНИЯ

Производство и реализация медицинских эндоскопов и сопутствующих изделий

ХОЯ Корпорейшн Фабрика ПЕНТАКС Ямагата
4 – 1 Хиноде-чо, Нагаи-ши, Ямагата, 993-0012 ЯПОНИЯ

Производство медицинских эндоскопов и сопутствующих изделий

ХОЯ Корпорейшн
6-10-1 Ниси-синдзюку, Синдзюку-ку, Токио, 160-0023, ЯПОНИЯ

Нормативно-правовое регулирование

ХОЯ Корпорейшн Подразделение ПЕНТАКС Лайф Кеар СБУ Медицинских инструментов Штаб-квартира продаж в Японии
3-35-1 Шимо-ренджаку, Митака-ши, Токио, 181-0023 ЯПОНИЯ

Реализация медицинских эндоскопов и сопутствующих изделий

ХОЯ Корпорейшн Подразделение ПЕНТАКС Лайф Кеар Технологический центр Шованомори
1-1-110 Цуцуджигаока, Акишима-ши, Токио, 196-0012 ЯПОНИЯ

Проектирование и разработка, а также реализация медицинских эндоскопов и сопутствующих изделий

ХОЯ Корпорейшн Подразделение ПЕНТАКС Лайф Кеар Производственно-технологический центр/Фабрика Огава
395 Оаза-Какуяма, Огава-мачи, Хики-гун, Сайтама 355-0316 ЯПОНИЯ

Производство, реализация и обслуживание медицинских эндоскопов и сопутствующих изделий

Печать: Нотариус Ютака Ватахики.

Документ зарегистрирован за номером: № «**56**» за «**2022**» год

Подтверждение

Настоящим подтверждаю тот факт, что Хасегава Хаято, представитель Сакаи Ясухиро, Старшего Генерального менеджера, компания «Хоя Корпорейшн», Подразделение ПЕНТАКС Лайф Кеар, отдел исследования и развития Японии, разработки клиентских решений, заявил в моем присутствии о том, что упомянутый Сакаи Ясухиро подтвердил, что он подписал прилагаемый документ. На основании чего я подтверждаю изложенные факты.
10 марта 2022 года
Документ составлен в офисе нотариуса,
г. Токио, Татикава, Сибазаки-тё, 3-тёме, 9-21
Нотариус, подведомственный Токийскому бюро по юридическим вопросам
Печать: Нотариус ВАТАХИКИ Ютака.
Нотариус *[Подпись]* ВАТАХИКИ Ютака

Свидетельство

Вышеприведенная подпись является подлинной подписью нотариуса, подведомственного Токийскому бюро по юридическим вопросам, кроме того, я подтверждаю подлинность приложенной личной печати упомянутого лица.
10 марта 2022 года
Директор Токийского бюро по юридическим вопросам САКАМОТО ЁСИТАНЭ

Печать: Директор Токийского бюро по юридическим вопросам.

АПОСТИЛЬ

(Гаагская конвенция от 5 октября 1961 года)

1. Страна: ЯПОНИЯ
   Данный официальный документ
2. подписан **ВАТАХИКИ Ютака**
3. выступающим в качестве **нотариуса Токийского бюро по юридическим вопросам**
4. заверен печатью/штампом **ВАТАХИКИ Ютака, нотариуса**

Удостоверено

5. в г. Токио 6. 10 МАРТА 2022 Г.
7. Министерством иностранных дел
8. 22-**№ 042117**
9. Печать/штамп

Гербовая печать: ЯПОНИЯ. МИНИСТЕРСТВО ИНОСТРАННЫХ ДЕЛ.

10. Подпись *[Подпись]*
    ХАМАМОТО Хироки
    От имени Министра иностранных дел

НОТАРИАЛЬНОЕ СВИДЕТЕЛЬСТВО

Настоящим свидетельствуется, что ХАСЕГАВА Хаято, представитель САКАИ Ясухиро, Старшего Генерального менеджера, компания «Хоя Корпорейшн», Подразделение ПЕНТАКС Лайф Кеар, отдел исследования и развития Японии, разработки клиентских решений, заявил в моем присутствии о том, что упомянутый Сакаи Ясухиро подтвердил, что он подписал прилагаемый документ.

Датировано сегодня, 10 марта 2022 года.

[Подпись]

ВАТАХИКИ Ютака
НОТАРИУС
9-21, 3-ТЁМЕ, СИБАЗАКИТЁ
ТАТИКАВА, ТОКИО, ЯПОНИЯ

Печать: ТОКИЙСКОЕ БЮРО ПО ЮРИДИЧЕСКИМ ВОПРОСАМ. **НОТАРИУС**.
9-21, 3-ТЁМЕ, СИБАЗАКИТЁ
ТАТИКАВА, ТОКИО, ЯПОНИЯ.

Перевод данного текста выполнен переводчиком Котляровым Антоном Игоревичем.

_____

Российская Федерация

Город Москва
Одиннадцатого марта две тысячи двадцать второго года
Я, Родина Ульяна Алексеевна, временно исполняющая обязанности нотариуса города Москвы Корсика Владимира Константиновича, свидетельствую подлинность подписи переводчика Котлярова Антона Игоревича.
Подпись сделана в моем присутствии.
Личность подписавшего документ установлена.

Зарегистрировано в реестре: № 77/2138-н/77-2022- 13-2753
Уплачено за совершение нотариального действия: 400 руб. 00 коп.

У.А. Родина

Всего прошнуровано, пронумеровано
и скреплено печатью 10 лист(а)(ов)

ВРИО нотариуса

PENTAX
MEDICAL

INSTRUCTIONS FOR USE

EPK-i7010

PENTAX Medical VIDEO PROCESSOR

INDICATION FOR USE:

The PENTAX Medical EPK-i7010 Video Processor is intended to be used with the PENTAX camera heads, endoscopes, light sources, monitors and other ancillary equipments for endoscopic diagnosis, treatment and video observation.
The PENTAX Medical EPK-i7010 includes a digital post-processing imaging enhancement technology (PENTAX i-Scan™) and a optical imaging enhancement technology (OE). These imaging enhancement technologies are intended to be used as an optional adjunct following traditional white light endoscopy and is not intended to replace histopathological sampling. i-Scan and OE are compatible with PENTAX video endoscopes.

DEVICE DESCRIPTION:

The PENTAX Medical EPK-i7010 video processor consists of a video system, integrated light source, monitor, and ancillary equipment. This processor is intended for endoscopic diagnostic, treatment and video observation.

The PENTAX Medical EPK-i7010 video processor contains two types of contrast enhancement techniques: PENTAX i-Scan technology, and optical enhancement (OE) technology. PENTAX i-Scan technology is a digital filter-based contrast enhancement technique, while OE technology combines the band limited light and the digital processing.

PENTAX i-Scan technology has three modes, i-Scan 1, 2 and 3. i-Scan 1 enhances image topography and edges and i-Scan 2 and 3 enhances the color tone of the image by dissecting and recombining the individual red, green and blue (RGB) components of a white light image.
PENTAX i-Scan modes 1, 2, and 3, are intended to give the user an enhanced view of the texture of the mucosal surface and blood vessels. i-Scan 1 provides the user with a view that sharpens surface vessels and enhances surface texture of the mucosa. i-Scan 2 provides the user with increased visibility of blood vessels while also providing the same enhancements to the mucosa achieved in i-Scan 1. i-Scan 3 provides the user with increased visibility of blood vessels including dimly illuminated far-field regions while also providing the same enhancement to the mucosa achieved in i-Scan 1. The user can select either white light image or i-Scan modes by pressing a pre-programmed button on the scope, by using a pre-programmed foot pedal or by pressing a keyboard button. i-Scan is intended to be used as an optional adjunct following traditional white light endoscopy and is not intended to replace histopathological sampling.

The PENTAX Medical EPK-i7010 video processor is equipped with two optical filters placed inside Xenon lamp light path to provide optical enhancement (OE), which combines the band limited light and the digital processing. PENTAX OE technology has two modes, OE Mode1, 2.
In addition to i-Scan, OE Mode1 and 2 are intended to provide alternative methods to improve blood vessel visibility (emphasizes mucosal microvasculature and fine mucosal structures) on the mucosal surface by combination of band limited light illumination source. OE Mode1 uses a spectral filter that transmits band limited green and blue light and is intended to provide the user with enhanced image of blood vessels and fine structure of mucosa. OE Mode2 uses a different spectral filter that transmits band limited red, green and blue light and is intended to provide the user with enhanced image of blood vessels and fine structure of mucosa in an image closer to white light image.
The user can select either white light image or OE modes by pressing a pre-programmed button on the scope, by using a pre-programmed foot pedal or by pressing a keyboard button. OE is intended to be used as an optional adjunct following traditional white light endoscopy and is not intended to replace histopathological sampling.

White light is captured from a 300 Watt xenon lamp housed in the PENTAX Medical EPK-i7010 video processor. All visualization is done with the white light mode first. White light (BGR) illuminates the tissue and transfers the captured light through the video scope or a charged coupled device (CCD). Note that the white light visualization mode is always used first by the physician. For i-Scan image enhancement, the modification of the combination of RGB components for each pixel occurs when the i-Scan function is turned on in the PENTAX Medical EPK-i7010 video processor. The resulting i-Scan image is then displayed on the observation monitor. For OE image enhancement, one of the two optical filters corresponding to Mode1 and Mode2 are inserted into illumination light path when the OE function is turned on in the PENTAX Medical EPK-i7010 video processor. The resulting OE image is then displayed on the observation monitor.

FUNCTIONS USED FREQUENTLY:

The functions used frequently on this equipment are the still image display function, image capture function, white balance adjustment function, and patient information registration/display function.

APPLICATION:

① Intended medical use:	Observation of body cavities (Lighting and air/water supply through a connected endoscope and monitor output of observed images from the endoscope itself)
② Patient populations:	Patients ranging from pediatric to adult (Patients who are considered suitable for the application of equipment by the physician)
③ Intended anatomical area (tissues/organs):	Pharynx; Larynx; Esophagus; Stomach; Duodenum; Small Intestine; Large Intestine; Pancreatic and Biliary Duct; Trachea; Bronchial Tree; Ear; Nasal Passage; Kidney; Renal Cavity; Renal Calyces; Urethra; Endometrial Canal (all require endoscope connection)
④ User:	An operator with experience, or an operator working under the supervision of someone with experience
⑤ Usage environment:	Hospitals, Ambulatory Surgery Centers, and Medical Clinics

IMPORTANT:

This Instructions for Use (IFU) describes the recommended procedures for inspecting and preparing this video processor prior to its use and the care and maintenance after its use. It does not describe how an actual procedure is to be performed, nor does it attempt to teach the beginner the proper technique or any medical aspects regarding the use of the equipment.
Failure to follow the instructions in this IFU may result in damage to and/or malfunction of the equipment.
If you have any questions regarding any of the information in this IFU or concerns pertaining to the safety and/or use of this equipment, please contact your local PENTAX Medical service facility.

⚠CAUTION

After the product has been delivered, promptly install, set up, and start using the equipment. Avoid storing the equipment over an extended period of time without using.

TRADEMARKS:

- PENTAX is either registered trademark or trademark of HOYA Corporation.
- PENTAX Medical is the trademark of HOYA Corporation.
- Windows 7, Windows 7 Ultimate, Windows Media Player are either registered trademarks or trademarks of Microsoft Corporation in the United States and/or other countries.
- All other product names mentioned in this IFU provided with this processor are registered trademarks or trademarks of their respective manufacturers.

Contents

1 Safety Precautions - Important 1

2 Nomenclature, Controls, and Functions 5

Main Unit 5
Touch Panel 6
Rear Panel 7
PENTAX Medical Water Bottle Assembly (OS-H5) 8

3 Preparation 9

System Configuration 9
Installation 10
Connecting a Video Endoscope 17

4 Pre-use Inspections 19

Power-On and Lamp Inspection 19
On-screen Image Check 20
Automatic Brightness Control Inspection 20
Endoscope Control Button 20
Exposure and Measurement Inspection 21
Color Adjustment 21
Suction Inspection 21
Air/Water Supply Inspection 22

5 Operating Procedure 23

Turning On/Off the Processor 23
Monitor Screens 23
Touch Panel Operation 25
i-scan 30
Optical Enhancement (OE) 32
Image Processing Settings 33
Setup Menu Operations 35
[i-scan] Tab 35
[Image] Tab 39
[Customize] Tab 44
[System] Tab 58
[Peripheral] Tab 71
Keyboard Operations 72
Operations in the Keyboard Menu Screen 75
Operations in the [Patient list preset] Tab 75
Operations in the [User list preset] Tab 77
Settings in the [Setup] Tab 78

6 Maintenance 80

After Use 80
Cleaning and Storage of the Water Bottle Assembly 81
Storage 81
Replacing the Lamp 82
Replacing the Fuses 84
Repair 85

7 Troubleshooting 86

8 Specifications 91

9 Electromagnetic Compatibility 92

1 Safety Precautions - Important ⚠

The following precautions should always be exercised with the use of all electro-medical equipment to ensure safety to all involved parties - user(s), patient(s), etc.

Please carefully read and follow this IFU.

1-1. TRAINING

1. This equipment should only be used under the supervision of a trained physician in a medical facility. Do not use in other locations or for any other purposes than the intended application. Failure to observe this precaution may result in personal injury.

1-2. INSTALLATION

1. This equipment should NEVER be installed or used in areas where the unit could get wet or be exposed to any environmental conditions such as high temperature, humidity, direct sunlight, dust, salt, etc., which could adversely affect the equipment.
2. This equipment should NEVER be installed or used in the presence of flammable or explosive gases or chemicals.
3. This equipment should NEVER be installed, used or transported in an inclined position nor should it be subjected to impact or vibration.
4. For safety reasons, this equipment must be properly grounded.
5. Ensure that all power requirements are met and conform to those specified on the rating plate located on the rear panel.
6. Do not block the air intake vent grid of this equipment.
7. Do not allow the power cord to become twisted, crushed or pulled taut.
8. When using an isolation transformer for any ancillary equipment, ensure the power requirements of the devices do not exceed the capacity of the isolation transformer. For further information, contact your local PENTAX Medical service facility.

1-3. PRIOR TO USE

1. Confirm that this equipment functions properly and check the operation of all switches, indicators, etc.
2. To prevent electrical shock when used with endoscopes, this equipment is insulated (type BF electro-medical equipment). Do not allow it to be grounded to other electrical devices being used on the patient. Rubber gloves should always be worn to prevent grounding through user(s).
3. Confirm that other devices used in conjunction with this equipment function properly and that these other devices will not adversely affect the operation or safety of this equipment. If any component of the endoscopic system is not properly functioning, the procedure should not be performed.
4. Check and confirm that all cords or cables are connected correctly and securely.
5. The lamp life when used in this equipment is 500 hours. Prior to use, check the lamp life indicator on the operation panel to ensure the indicator is lit green. After 500 hours of use, the indicator turns red and the image quality will deteriorate. The lamp life could be affected by frequency of use. In which case, the lamp life might become shorter than 500 hours.
6. Right after turning on the power of the processor, wait till the backlight of the touch panel comes on. Using the operation panel or the keyboard before the backlight comes on would result in system malfunction.

1-4. DURING USE

1. To prevent electric shock, the endoscope and/or any other ancillary device should NEVER be applied directly to the heart.
2. Make sure that no contact is made between the patient and this equipment.

3. To avoid damage to the luminous display and flat membrane switches, do not press any keys with any sharp or pointed objects.
4. The light emitted by the Xenon lamp is extremely intense. Avoid looking directly at the light exiting the endoscope and/or this equipment.
5. To protect the users eyes and avoid risk of thermal injury during an endoscopic examination, use only the minimum amount of brightness required.
6. During clinical procedures, avoid unnecessary prolonged use which could compromise patient/user safety.
7. Continually monitor this equipment and the patient for any signs of irregularities.
8. In the event that some type of irregularity is noted to the patient or this equipment, take the appropriate action to ensure patient safety.
9. If the operation of any of the components of the endoscopic system fails during the procedure and the visualization of the procedure is lost or compromised, place the endoscope in the neutral position and slowly withdraw the endoscope.
10. This equipment should only be used according to the instruction and operating conditions described in this IFU. Failure to do so could result in compromised safety, equipment malfunction or instrument damage.
11. The equipment may become hot during use. Take special care when touching the equipment.
12. If an error message is displayed on the monitor, follow the message instruction. Failure to do so could result in compromised safety for patient and/or user or equipment malfunction.
13. When the observation object moves quickly, the after image might appear on the monitor.
14. The processor's performance could be negatively affected by electromagnetic waves emitted from cellular phones or other portable wireless equipments. Recommended separation distance between the processor and the portable/mobile equipment is shown on a table near the end of this IFU. Follow these recommendation to avoid electromagnetic interference by the portable/mobile equipments.

1-5. AFTER USE

1. The equipment may become hot immediately after use. Take special care when touching the equipment.
2. Refer to the operating instructions provided with all the components of the endoscopic system to establish the right order in which components should be turned off. Some peripheral devices may have to be turned off first to avoid compromising their operation.
3. Wipe all surfaces clean with gauze slightly dampened with alcohol.
4. Be sure connector interfaces and air intake vents are not allowed to become wet or splashed with liquids.
5. Clean this equipment regularly. Remove substances on movable units as well as dirt on the surface. Substances on endoscope locking lever and/or endoscope electrical connector may cause malfunction.

1-6. STORAGE

1. This equipment should NEVER be stored in areas where the unit could get wet or be exposed to any environmental conditions such as high temperature, humidity, direct sunlight, dust, salt, etc., which could adversely affect the equipment.
2. This equipment should NEVER be stored in the presence of flammable or explosive gases or chemicals.
3. This equipment should NEVER be stored or transported in an inclined position, nor should it be subjected to impact or vibration.
4. Cords, accessories, etc., should be cleaned by wiping the surface with alcohol-dampened gauze and neatly stored.
5. This equipment should be maintained in a clean condition during storage and be ready for subsequent use.

1-7. SERVICE

1. Alterations/modifications to the equipment should NEVER be made. Repairs should only be performed by an authorized PENTAX Medical service facility.
2. When replacing the lamp, use only the lamp recommended by PENTAX Medical and follow all PENTAX Medical instructions provided.

1-8. MAINTENANCE

1. Periodically this equipment and any applicable accessories should be inspected for operation and safety.

1-9. DISPOSAL

1. The equipment should be returned for disposal to PENTAX Medical.
   Contact your local PENTAX Medical representative or service facility.

An information on Disposal for users in the European Union

This product is a medical device. In accordance with European Directive 2002/96/EC on Waste Electrical and Electronic Equipment, this symbol indicates that the product must not be disposed of as unsorted waste, but should be collected separately. Contact your local PENTAX Medical service facility for correct disposal and recycling.

By disposing of this product correctly you will help ensure that the waste undergoes the necessary treatment, recovery and recycling and thus prevent potential negative effects on the environment and human health which could otherwise arise due to inappropriate waste handling.

POWER REQUIREMENTS

Check the standard power plug configurations that are used in your country. If the appropriate power cord is not included in your product, notify your local PENTAX Medical service facility.

SOFTWARE VERSION

The software version of the products corresponding to this IFU is described on its back cover.

SYMBOLS ON MARKING

Manufacturer

Date of manufacture

 Alternating current

Type BF applied part (Safety degree specified by IEC 60601-1)

Switches the power on and off.

Warning

Warning, electricity

Caution

Warning; Hot surface

Protective earth (ground)

Equipotentiality

Instructions for Use

Follow the Instructions for Use

Endoscope

Illumination lamp model

Authorized representative in the European Community

CONVENTIONS

The following conventions have been established in the text of this IFU to aid in the identification of potential hazards of operation:

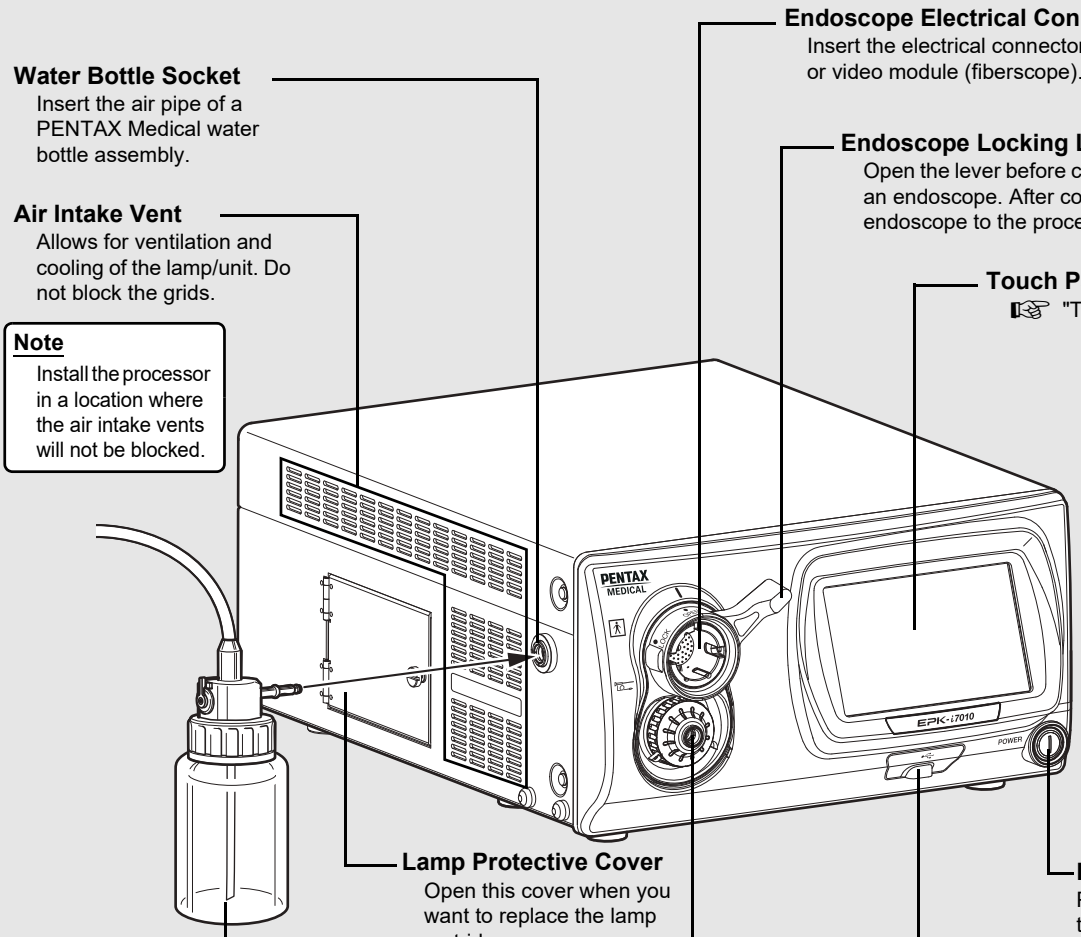
: Could result in death or serious injury.

: May result in minor or moderate injury or property-damage.

: May result in property-damage. Also, advises owner/operator about important information on the use of this equipment.

2 Nomenclature, Controls, and Functions

Main Unit



Water Bottle Socket
Insert the air pipe of a PENTAX Medical water bottle assembly.

Air Intake Vent
Allows for ventilation and cooling of the lamp/unit. Do not block the grids.

Note
Install the processor in a location where the air intake vents will not be blocked.

Endoscope Electrical Connector
Insert the electrical connector of a video endoscope or video module (fiberscope).

Endoscope Locking Lever
Open the lever before connecting or removing an endoscope. After connecting an endoscope to the processor, close the lever.

Touch Panel
☞ "Touch Panel"(P.6)

Lamp Protective Cover
Open this cover when you want to replace the lamp cartridge.

Power Switch ⏻
Press this switch to turn the processor on or off.

Water Bottle Assembly
☞ "PENTAX Medical Water Bottle Assembly (OS-H5)"(P.8)

Light Guide Receptacle (AE-P2)
Insert the light guide of a video endoscope or fiberscope. Use in combination with a video module of a fiberscope is possible.
When using an adapter other than AE-P2, contact a PENTAX Medical service facility.

USB Port
Connect "Image Recording Media"(P.91) or USB printer.

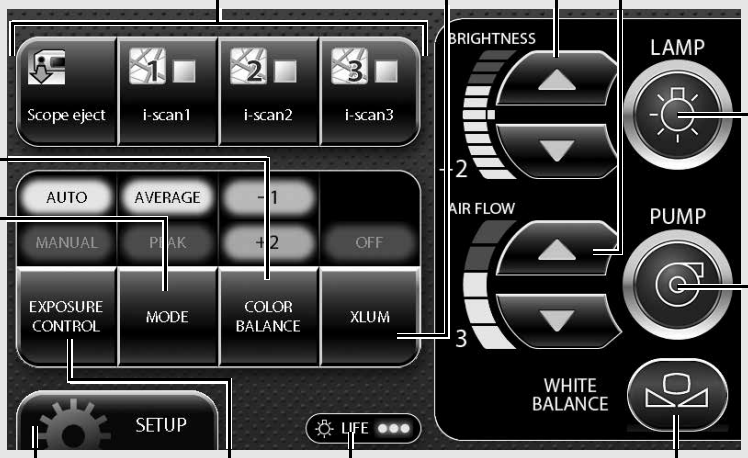
NOTE

- Always insert an endoscope prior to turning on the processor. Also, always turn off the processor before removing an endoscope.
- Before turning on the processor, make sure the air intake vents are not blocked.
- The lamp of the processor should be turned off except during pre-use inspections and clinical use.
- After connecting an endoscope to the processor, check that the endoscope is firmly secured and that the endoscope locking lever is in the LOCK position.

⚠CAUTION

- Immediately after use, the metal light guide prong and the electrical contacts/pins of the endoscope may be hot. To avoid burns, do not touch these parts immediately after use. For safe handling after a procedure, grasp the PVE connector housing of the endoscope.
- The light emitted by the Xenon lamp is extremely intense. Avoid looking directly at the light exiting this equipment without Light Guide Receptacle being attached.

Touch Panel



COLOR BALANCE Button COLOR BALANCE

Use this button to display the color balance adjustment screen.

☞ "Color Balance Button"(P.28)

Brightness Setting Buttons

Use ▲▼ to adjust the brightness level.

☞ "Brightness Setting Buttons"(P.26)

Customize Buttons

Each press of a button changes the setting of the indicated function. You can set the functions you use very frequently for these four buttons. Depending on the function, the setting may be displayed on the top right of a button.

☞ "Customize Buttons"(P.29)

XLUM ON/OFF Button XLUM

Use this button to maximize the light intensity of the endoscope.

☞ "XLUM ON/OFF Button"(P.29)

Pump Level Setting Buttons

Use ▲▼ to adjust the strength of the pump.

☞ "Pump Level Setting Buttons"(P.27)

LAMP Button

Use this button to turn the lamp on or off.

☞ "Lamp Button"(P.26)

PUMP Button

Use this button to operate or stop the air/water pump.

☞ "Pump Button"(P.26)

MODE Button MODE

Use this button to select the light measuring method.

AVERAGE: Adjust the [BRIGHTNESS] level in relation to the average value of the brightness of the video signal.

PEAK: Adjust the [BRIGHTNESS] level in relation to the maximum value of the brightness of the screen.

☞ "Mode Button"(P.28)

EXPOSURE CONTROL Button EXPOSURE CONTROL

Use this button to change the method of adjusting the screen brightness.

AUTO: Adjust the screen brightness automatically.

MANUAL: Adjust the screen brightness manually.

☞ "Exposure Control Button"(P.28)

WHITE BALANCE Button

Use this button to adjust the white balance.

☞ "White Balance Button"(P.27)

SETUP Button SETUP

Use this button to display the setting menus.

☞ "Setup Button"(P.29)

Lamp Life Indicator [LIFE]

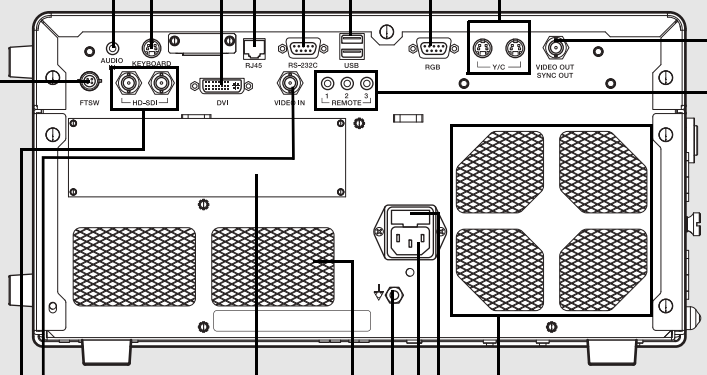
The lamp usage time is indicated by this indicator.
3 green circles: Less than 400 hours
2 green circles: 400 hours to 449 hours
1 yellow circle: 450 hours to 499 hours
1 red circle: 500 hours or more (the lamp needs to be replaced)

☞ "Replacing the Lamp"(P.82)

NOTE

- The lamp life is 500 hours. Check the LIFE indicator (lamp life indicator) on the touch panel before using the processor. Replace the lamp cartridge if a red circle is displayed on the LIFE indicator. The lamp life may not be as long as 500 hours depending on the method of use and operating environment.
  ☞ "Replacing the Lamp"(P.82)
- When pressing a button on the touch panel, make sure to press the center of the button. If the edge of the button is pressed, the system might activate the button that is next to the button you intended to press.
- When pressing a button on the touch panel, make sure that the setting/configuration change that was intended to be made in the previous press has been correctly applied. Pressing a button in succession may cause a system error. If a system error occurs, turn the power off and then on again.

Rear Panel



RS-232C
This connector (D-sub 9-pin connector) is for connecting an external output device. It is an RS-232C compliant interface.

RJ45
This connector is exclusively for RJ45 communication.

USB
These connectors are for connecting "Image Recording Media"(P.91) or a USB printer.

DVI
This connector is for outputting video signals (DVI signals [digital] and VGA signals [analog]) to send to a monitor or image processor.

RGB
This connector is for outputting video signals (RGB color signals and synchronous signals) to send to a monitor or image processor.

KEYBOARD
This connector is for connecting a keyboard. Connect the supplied keyboard (OS-A83) designed specifically for use with this processor.

Y/C
These connectors (separated video outputs) are for outputting separate video signals (video signals separated into luminance signals and color signals) to send to a monitor, printer, or image processor.

AUDIO IN
This connector is for inputting audio signals when recording video images to "Image Recording Media"(P.91).

VIDEO OUT/ SYNC OUT
This connector (BNC) is for outputting composite video signals and strobe synchronous signals to send to a monitor or image processor.

FTSW
This connector is for connecting foot switches (OS-A61) for operating peripheral devices.

REMOTE
These connectors are for outputting operation trigger signals to remotely operate peripheral devices.

HD-SDI
These connectors (BNC) are for outputting digital video signals (HD-SDI signals) to send to a monitor or image processor.

Air Intake Vent

Note
Install the processor in a location where the air intake vents will not be blocked.

Rating Plate
This plate shows the processor rating specifications, acquired standards, etc.

VIDEO IN
This input connector (BNC) is for P-in-P (Picture in Picture). It inputs composite video signals to send to a monitor when P-in-P mode is set.

Fuse Box
This fuse box contains two fuses.

Power Input Socket
Connect the AC power cord.

Air Intake Vent

Note
Install the processor in a location where the air intake vents will not be blocked.

Potential Equalization Terminal
This terminal is used with a potential equalization busbar to equalize the potential of other equipment connected to the processor.

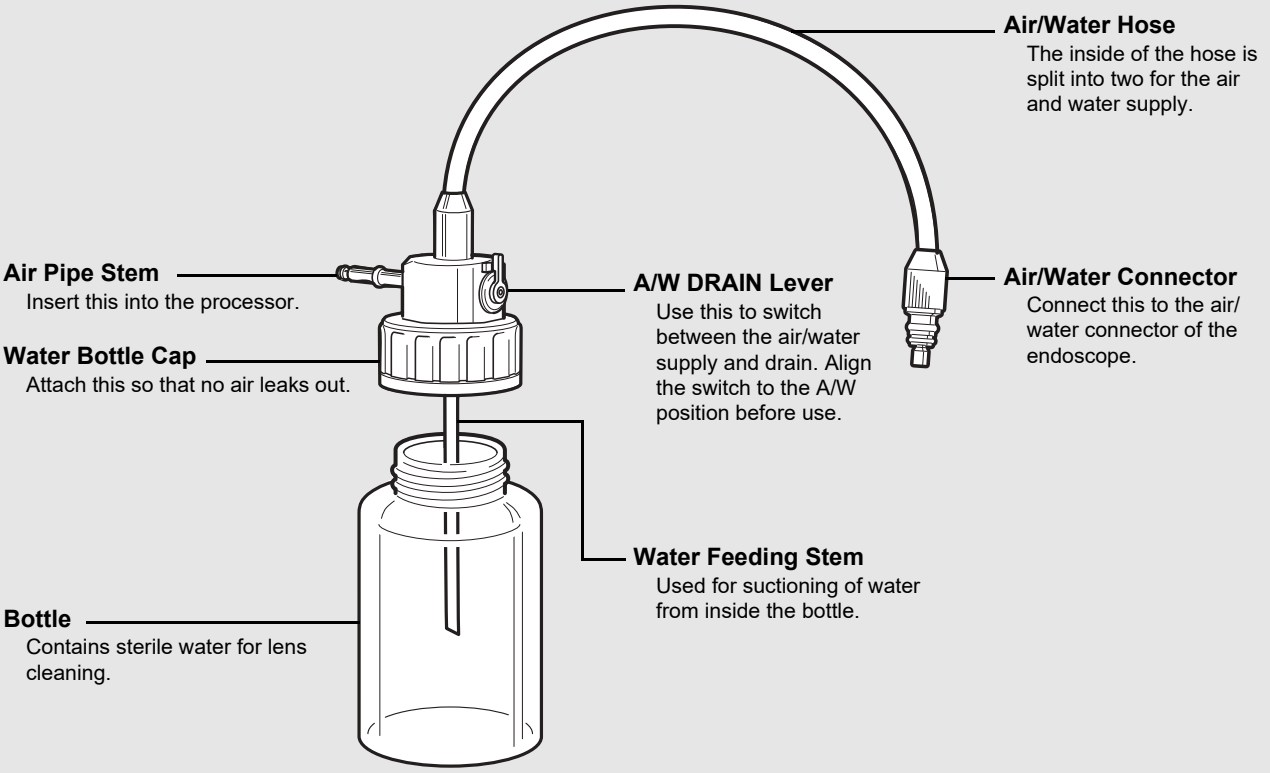
WARNING

- To avoid the risk of electric shock, this equipment must only be connected to a power supply with protective earth.
- This equipment must be connected to an appropriate power supply.

CAUTION

Make sure to firmly connect each connector to the specified position. Failing to do so could cause certain function to be unavailable.

PENTAX Medical Water Bottle Assembly (OS-H5)



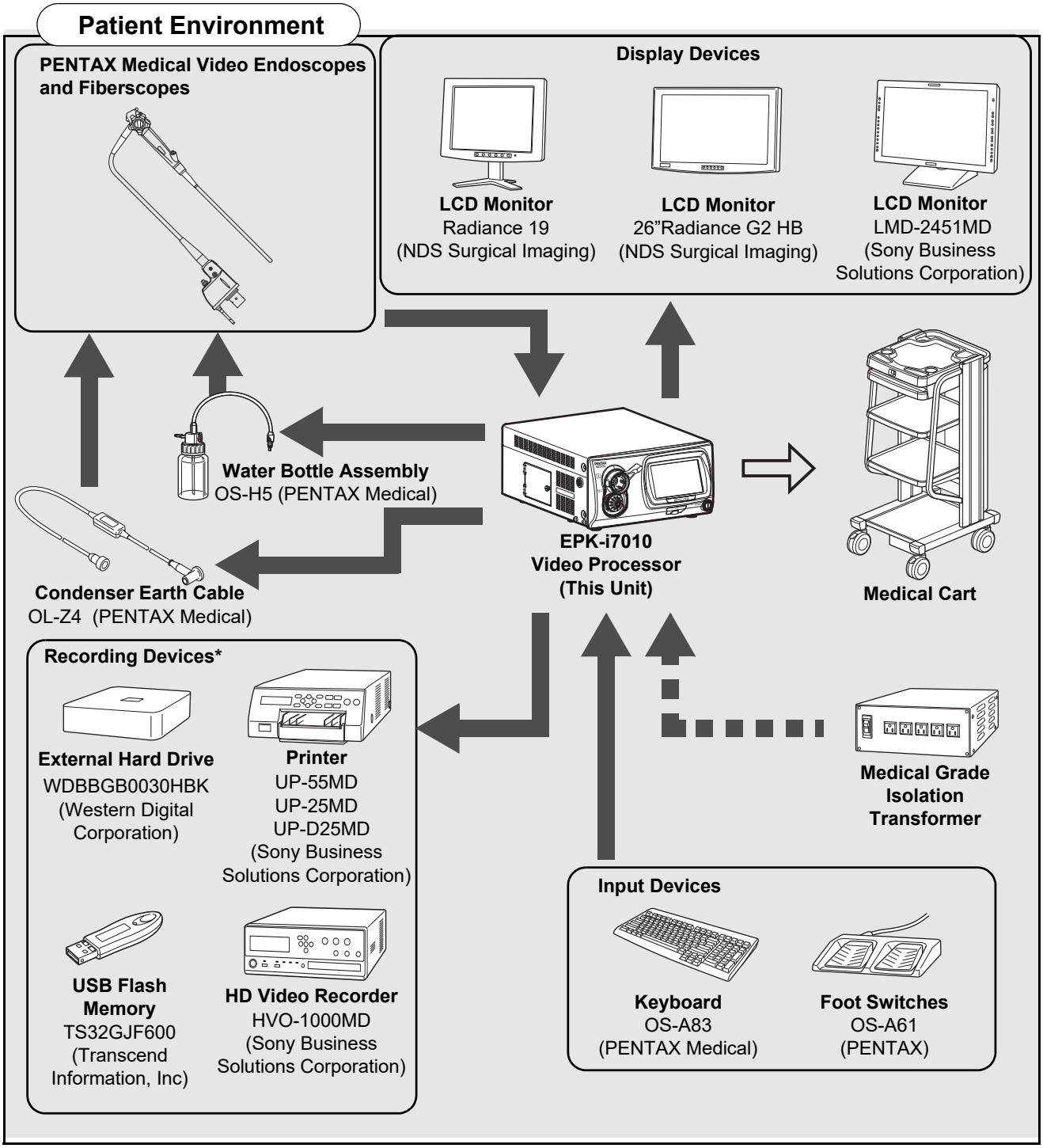
NOTE

When cleaning and sterilizing the water bottle assembly (OS-H5), follow the instruction given in the Instructions for Use for OS-H5.

3 Preparation

System Configuration

The following shows examples of system configurations for using the processor.



*: **NOTE**

Recording devices specified in the diagram have been tested for compatibility with the EPK-i7010. Equivalent devices can be used but may not be compatible with the EPK-i7010.

NOTE

- For peripheral devices, use the recommended devices shown above or equivalent products.
- PENTAX Medical recommends the devices shown above based on the independent test results.
- The processor or the peripheral devices may not operate normally by the combination of their connections including the recommended devices.
- When any connected peripheral devices are added, use the processor and the peripheral devices after confirming their normal operations by checking their connected combinations.
- The data may not be recorded properly if non-compatible external hard drive or non-compatible USB flash memory is used, or if the USB flash memory is connected to the USB port of this product using USB extension cable.

Installation

g Installing the Processor in a Cart

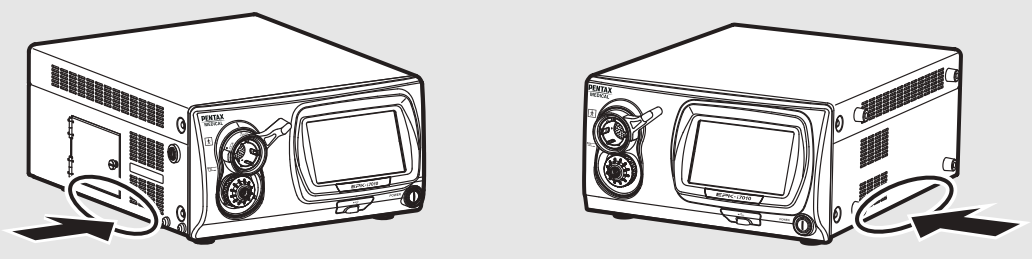
Install the processor and peripheral devices in a cart while referring to the installation examples in "System Configuration" (P.9). Place the cart on a stable and level surface.

⚠ WARNING

- The processor is an electro-medical device incorporating precision components and sophisticated circuitry so do not install it in a location where it will be subject to harsh conditions, including excessive vibrations and/or severe impact. Never drop the processor or subject it to a severe impact as doing so could compromise the functionality and/or safety of the unit. Should this equipment be mishandled or dropped, do not use it. Return it to an authorized PENTAX Medical service facility for inspection and repair.
- Because of the adverse effect that one equipment could cause to another equipment, it is possible that the correct operation of this processor could be compromised if another equipment is placed right nearby or stacked on top of the processor. If such situations cannot be avoided for extenuating reasons, be sure to check the correct operation of each equipment before using them in clinical use.
- Do NOT block the ventilation grids on the sides and at the back of the processor. In particular make sure to separate the ventilation grids on the processor's left side at least 15 cm (6 inches) from the wall. Blocking ventilation may cause equipment temperature to rise.

⚠ CAUTION

- When you raise this processor, hold the portion from the both sides shown in the figure.
- Make sure to firmly connect each connector to the specified position. Failing to do so could cause certain function to be unavailable.
- Install the processor on a stable and level surface (cart, counter, stand, etc.).
  - Avoid places where the processor may be splashed with liquid.
  - Never use the processor where explosive or flammable gases are present.
  - Do not install the processor where it will be exposed to high temperature and humidity or direct sunlight.
  - Do NOT use this equipment by installing it to stand vertically. Doing so will hinder the air to vent through the ventilation grid, and eventually it will become the cause of product damage.
- Never install, operate, or store electro-medical equipment in a dusty place. The accumulation of dust within the equipment may cause a malfunction, smoke, or ignition.
- Do not block the air intake vents on the back and the sides of the processor.
- When moving the processor, do not hold the endoscope locking lever.
- Connect a water bottle assembly (OS-H5) before using the processor.
- When loading the processor on a shelf of the cart, provide sufficient space for attaching or detaching the water bottle assembly (OS-H5) easily.



g Connecting a Power Supply

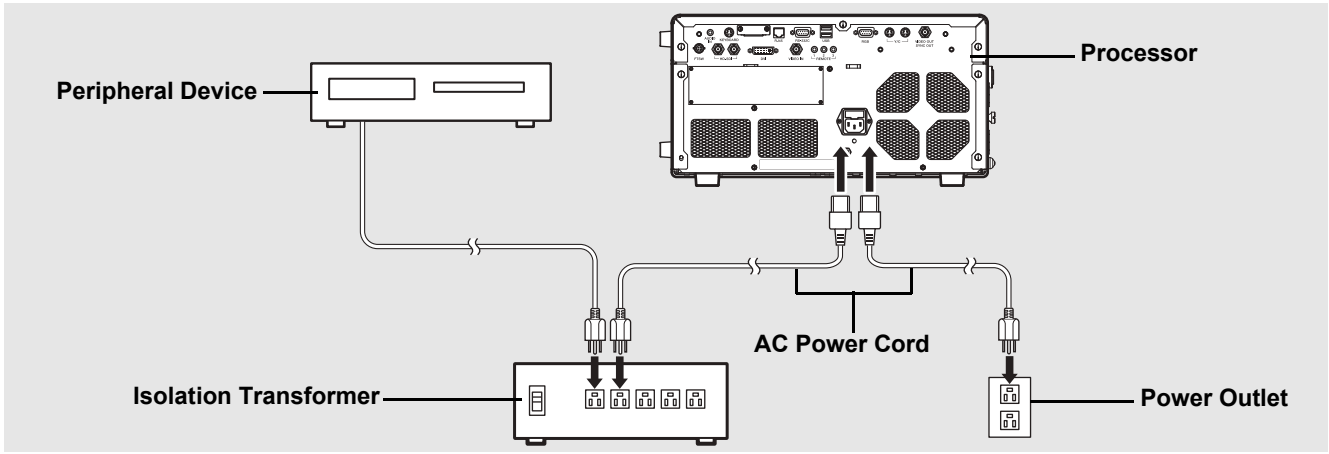
Connect the power cord to a suitable power outlet with a protective earth terminal that meets the power rating indicated on the rating plate or a medical grade isolation transformer. When peripheral devices are used, connect the devices to the medical grade isolation transformer of the appropriate power rating in order to reduce the risk of electric shock.

WARNING

- To reduce the risk of electric shock, connect the power cord of the equipment into a power outlet with protective earth.
- When peripheral devices such as a monitor are used, connect the devices to the medical grade isolation transformer of the appropriate power rating. Do not connect the devices which are not used to the isolation transformer.

CAUTION

- Check that the total power consumption of all connected devices does not exceed the isolation transformer's power rating.
- Make sure that output is in compliance with IEC 60601-1.
- Make sure that the power cord is connected to a suitable power outlet with a protective earth terminal.



1 Connect the AC power cord to the power input socket of the processor.

2 Connect the power cord to a suitable power outlet with a protective earth terminal that meets the power rating indicated on the rating plate or a medical grade isolation transformer.

- Make sure the processor is turned off beforehand. If the switch has "looseness", the processor is turned on. If the switch has "looseness", push the switch again and confirm there is no "looseness".
- When connecting peripheral devices to an isolation transformer, make sure the peripheral devices are turned off beforehand. For details, refer to the IFU for the peripheral devices.

g Connecting Peripheral Devices

Connect the peripheral devices to the processor. Make sure the processor and peripheral devices are turned off beforehand.

⚠ WARNING

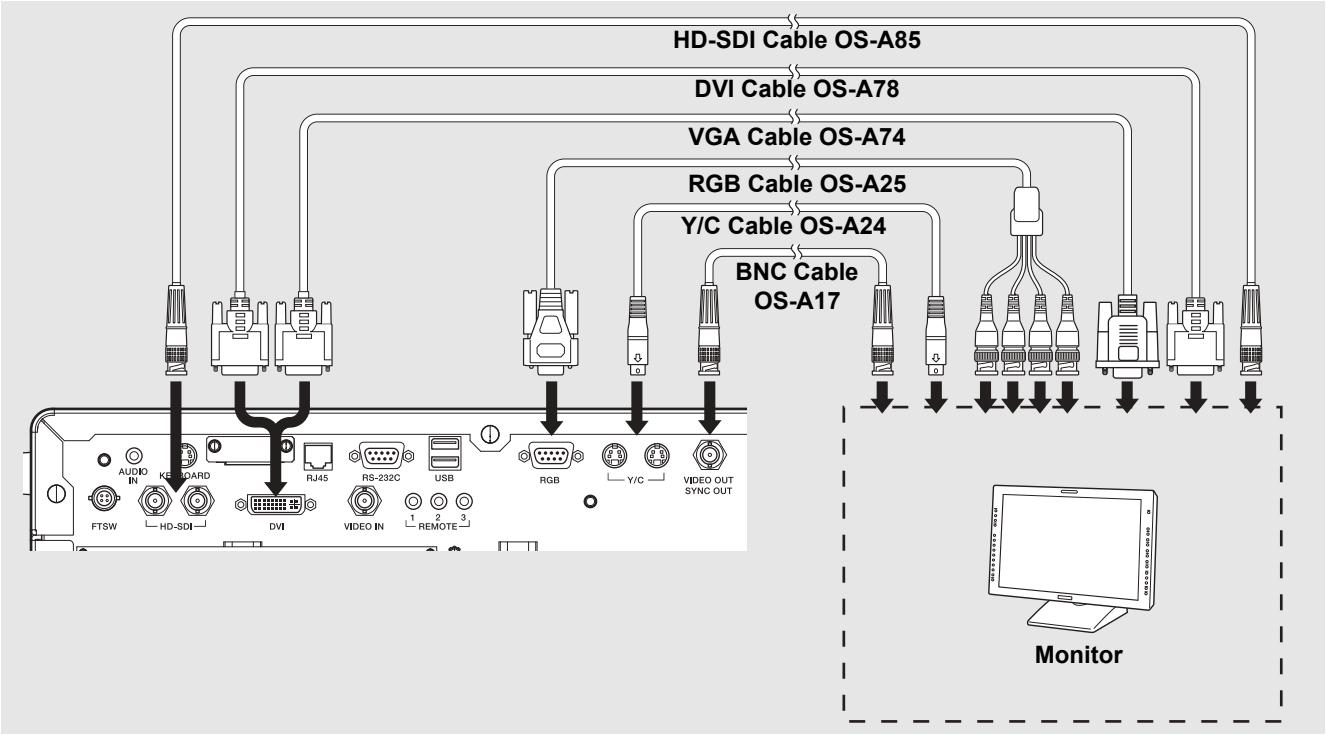
When connecting peripheral equipments to the processor, use only the cables specified in this IFU. If different cables are used, the equipments' resistance to the electromagnetic waves will change, and the equipments could cause adverse effect to each other. If you use different cables, please contact your local PENTAX Medical service facility.

⚠ CAUTION

- Before connecting peripheral devices, check that the devices operate correctly.
- Before connecting or removing peripheral devices, make sure the processor and peripheral devices are turned off.
- To avoid malfunction caused by changing the connecting configuration, use after confirming the normal operation of the processor and the peripheral devices by checking adequately.
- Since the processor may not operate normally if the peripheral devices are removed while in use, be sure to remove them after turning off the power.
- To avoid malfunction caused by updating or upgrading of the peripheral devices, use after confirming the normal operation of the processor and the peripheral devices by checking adequately.
- When used near a radio or TV receiver in clinical or residential areas, the processor may be subjected to radio interference.
- To reduce electromagnetic interference, do not keep turning on the main power switch of the processor while an endoscope is connected but not ready for use.
- To avoid and resolve adverse electromagnetic effects, do not operate the processor near RF (Radio Frequency) generating equipment.

n Connecting a Monitor or Recorder

Connect a monitor or recorder to the processor. For details, refer to the IFU for the monitor and recorder.



⚠ CAUTION

- The range of display may not match with the following connection methods because the image output specifications differ.

Connecting a monitor or recorder with an HD-SDI input connector (BNC) (recommended)

Use the PENTAX Medical HD-SDI cable (OS-A85) to connect an HD-SDI connector to an HD-SDI input connector on the monitor(26”Radiance G2 HB).

Connecting a monitor or recorder with a DVI or VGA input connector
Use the PENTAX Medical DVI cable (OS-A78) to connect the DVI connector to a DVI input connector of the recorder(HVO-1000MD), or use the PENTAX VGA cable (OS-A74) to connect the DVI connector to a VGA input connector on the monitor(Radiance19).

Connecting a monitor or recorder with a composite video input connector
Use the PENTAX Medical BNC video cable (OS-A17) to connect the VIDEO OUT/SYNC OUT connector to a video input connector on the monitor or recorder.

Connecting a monitor or recorder with an RGB input connector (BNC)
Use the PENTAX Medical RGB cable (OS-A25) to connect the RGB connector to the RGB input connector on the monitor.

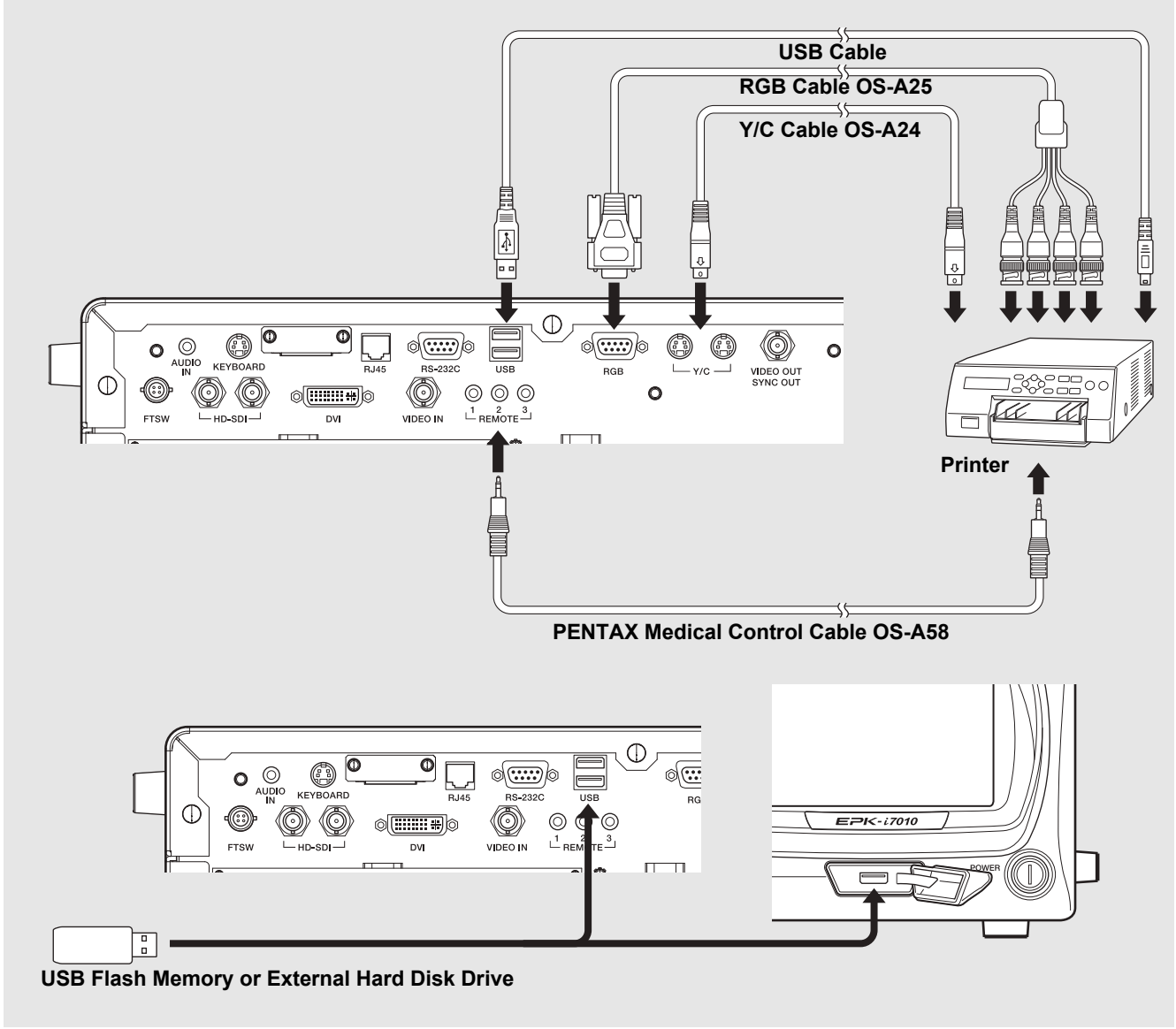
Connecting a monitor or recorder with a 4-pin female mini-DIN connector
Use the PENTAX Medical Y/C cable (OS-A24) to connect a Y/C connector to the 4-pin female mini-DIN connector on the monitor or recorder.

NOTE

Depending on the setting of the monitor screen, endoscopic image or text information might spill out of the screen. Adjust the display position by performing overscan/underscan adjustment or vertical/horizontal adjustment and make sure that the image as well as text is correctly displayed on the screen.

n Connecting a Printer, USB Flash Memory or External Hard Disk Drive

Connect a printer or "Image Recording Media" (P.91) to the processor.
For details on a printer, refer to the IFU for the printer.



Using RGB output method
Use an RGB cable (OS-A25) to connect the RGB connector to the connector on the printer.

Using Y/C output method
Use a Y/C cable (OS-A24) to connect the Y/C connector to the connector on the printer(UP-55MD).

Connecting a printer with an video input connector
Connect the VIDEO OUT/SYNC OUT terminal of the processor with video input terminal of the printer (UP-25MD) using a BNC cable (OS-A17).

Connecting a USB printer
Use a USB cable(2.0m) to connect a USB port on the front or rear of the processor to the port on the USB printer(UP-D25MD).

⚠CAUTION

- When using a printer, be sure to adjust the settings of the printer so that the colors in images appear the same on the monitor and in printouts.
- Compatible USB printer with the processor is UP-D25MD (Sony Business Solutions Corporation).

Connecting USB flash memory
Connect the USB flash memory(TS32GJF600) to a USB port on the front or rear of the processor.

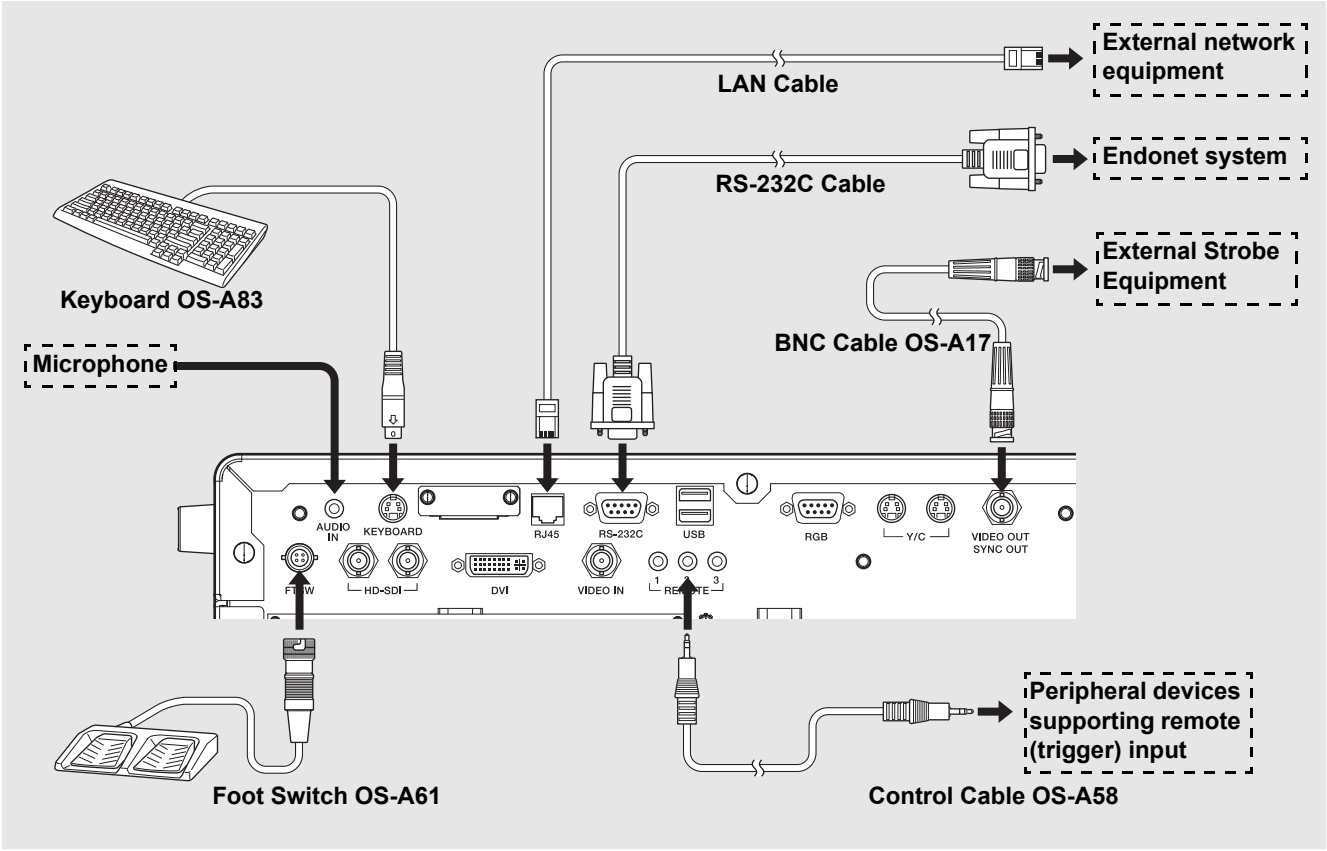
Connecting an external hard disk drive
Connect the external hard disk drive (WDBBGB0030HBK) to a USB port on the front or rear of the processor.

NOTE

- Some Image Recording Media may not be recognized by the processor.
- It is possible that the correct data recording could be compromised because of using the USB3.0 compatible cable.

n Connecting Other Peripheral Devices

For details, refer to the corresponding IFU.



Connecting a keyboard
Connect the PENTAX Medical keyboard (OS-A83) to the KEYBOARD connector.

Connecting foot switches
Connect the PENTAX foot switches (OS-A61) to the FTSW connector.

Connecting a peripheral devices supporting remote (trigger) input
When you want to use a peripheral device that includes support for remote (trigger) input, use a control cable (OS-A58) to connect the REMOTE connector to the remote connector on the peripheral device. For details on a peripheral device, refer to the IFU for the peripheral device.

Connecting an external strobe device
Connect the VIDEO OUT/SYNC OUT connector to the signal connector on an external strobe device recommended by PENTAX Medical. For details on connecting a compatible device, refer to the IFU for the compatible device.

Connecting a microphone
If you want to record video images with audio, connect a microphone to the AUDIO IN connector. Use a microphone (with the following specifications) recommended by PENTAX Medical.

Type: Stereo mini-plug (three pins)
Support for plug-in-power
Microphone characteristics: Sensitivity of -40 to -50 dB(0dB = 1V/1Pa, 1kHz)

Connecting a computer with an RS-232C connector
Use an RS-232C cable (2.0m) to connect the RS-232C connector to the connector on the computer with Endonet installed. For details on connecting an Endonet equipment, refer to the Instructions for Use for the equipment.

Connecting a computer with Endoimage2 installed
Connect one end of a LAN cable (5.0m) to the RJ45 port of a computer with Endoimage2 installed and connect the other end to the processor. For details on connecting compatible devices, refer to IFU for each compatible device.

Connecting a compatible device recommended by PENTAX Medical
Connect the RJ45 connector and a compatible device recommended by PENTAX Medical. For details on connecting a compatible device, refer to the IFU for the compatible device.

⚠CAUTION

- When the processor is connected to an existing network environment through the RJ45 connector, it is necessary to use a router equipped with security functions between the RJ45 connector of the processor and network.
- Do not use a router to connect to other than the processor and the existing network.
- For details on the specification of the router, contact your PENTAX Medical service facility.
- This equipment is a Class B Medical Equipment (specified CISPR 11) and is intended for hospitals, ambulatory surgery centers, and medical clinics.
- Use the connection cable of length specified below:
  HD-SDI cable (2.0 m), DVI-A cable (2.0 m), Composite video cable (1.5 m), Y/C video cable (1.5 m), Control Cable (1.5 m), RS-232C cable (2.0 m), Audio cable (1.5 m), and Keyboard cable (1.65 m)
- Refer to [Peripheral] Tab(P.71) for a connection setup of the peripheral devices. Also refer to [Network setup](P.78) for a setup of the network connected with RJ45 terminal.
- This processor transmits an observation image, patient information, etc. to Endoimage2, and receives a still image capture command. To endoPRO, it transmits an observation image and receives patient information, a still picture capture command, etc..

PENTAX Medical Policy on Antivirus Software

Connecting the processor to a network may result in the processor being exposed to computer viruses and security vulnerabilities. If the processor is connected to a security-compromised network or virus-infected computers and USB flash drives, this could cause the processor to be vulnerable to computer virus infection. For these reasons, you should consult with the IT coordinators in your hospital or clinic before connecting the processor to a network or USB flash drives via the LAN port or USB port. It is the responsibility of the customer to establish a secure network connection and ensure appropriate virus protection software is regularly updated and the network is configured with security. Due to the increasing major antivirus solutions and licensing issues, it is not possible for PENTAX Medical to predict and prepare appropriate antivirus solutions for each customer. Therefore, PENTAX Medical customers typically have to install virus protection software at each medical facility according to the policies of the facility.

Connecting a Video Endoscope

Connect an endoscope to the processor. Connect the water bottle assembly and suction unit to the endoscope before use. For details on an endoscope, refer to the IFU for the endoscope.

1 Check to ensure the endoscope locking lever is open.

2 Insert the endoscope firmly into connector ① of the processor. Close the endoscope locking lever in the direction of ② until it clicks into position. (Refer to Figure 3.1.)

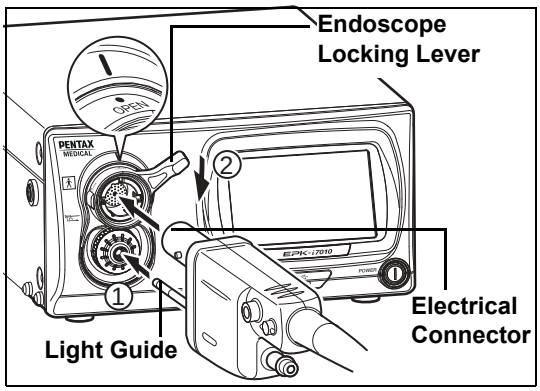


Figure 3.1

NOTE

- After connecting the endoscope to the processor, make sure that the endoscope is firmly secured and that the endoscope locking lever is in the LOCK position.
- On rare occasions, noise may be temporarily displayed on endoscopic images immediately after the start-up video processor or endoscope connection.

3 Fill the bottle approximately 2/3 full (to the "200" marking on the bottle scale) with sterile water, and then screw the cap onto the bottle and securely tighten it.

⚠ WARNING

Check whether there are any defects such as cracks on the water bottle assembly exterior. If there is a defect on the water bottle assembly, do not use it.

NOTE

Do not overtighten the water bottle cap.

4 Align the A/W DRAIN lever with the A/W (air/water supply) position. (Refer to Figure 3.2.)

5 Insert the air pipe of the water bottle assembly into the water bottle socket of the processor until it clicks into position.

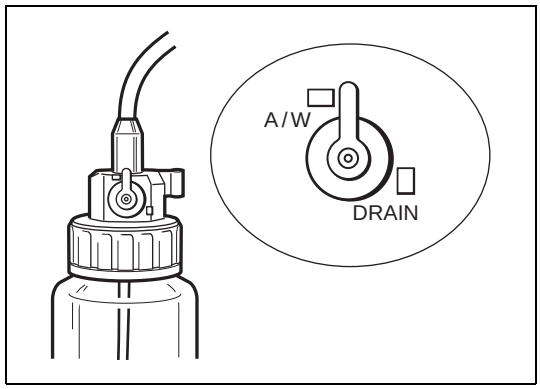


Figure 3.2

NOTE

Do not use excessive force when pushing the water bottle towards the processor. Rough handling may cause water to leak from the bottle onto/into the video processor.

- Insert the air/water connector into the holder on the water bottle cap until the endoscope is connected. (Refer to Figure 3.3.)

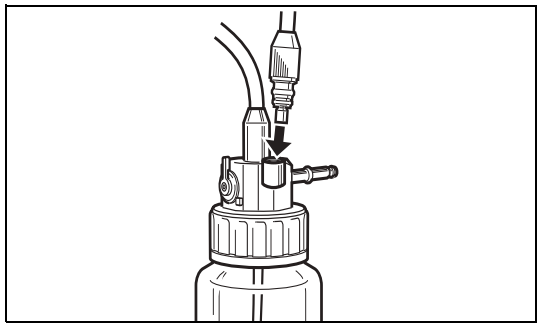


Figure 3.3

NOTE

- Remove the water bottle assembly before moving the processor to a place other than the usual place of use.
- Remove the water bottle assembly before packing the processor for transportation.

6 Connect the air/water connector to the air/water socket on the PVE connector of the endoscope. (Refer to Figure 3.4.)

7 Connect the suction tube of the suction unit to the suction nipple on the PVE connector of the endoscope.

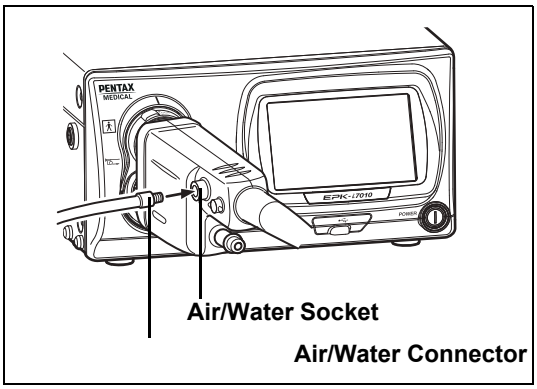


Figure 3.4

g When Using an Endoscopic Electrosurgery Device

WARNING

When performing endoscopic electrosurgery, use the PENTAX Medical condenser earth cable OL-Z4 as shown below to reduce noise appearing on the screen.

1 Connect the condenser earth cable OL-Z4 to the potential equalization terminal on the processor. (Refer to Figure 3.5.)

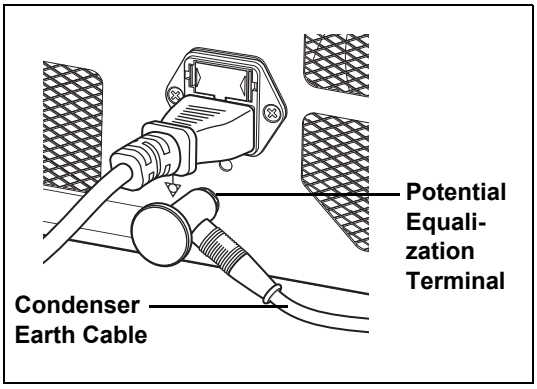


Figure 3.5

2 Connect the other end of condenser earth cable to the feedback terminal on the PVE connector of the endoscope. (Refer to Figure 3.6.)

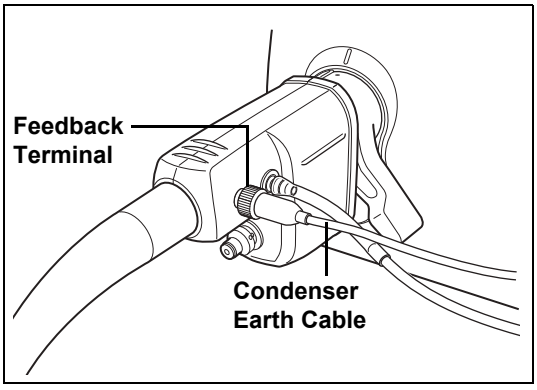


Figure 3.6

NOTE

- Some of the 90i series endoscopes are be necessary to update the scope's software. If a 90i series endoscope with outdated software is connected to this video processor, the error message is displayed on the monitor. In this case, contact your local PENTAX Medical service facility to have them inspect the endoscope and ask them to update the endoscope's software.
- Depending on the endoscope model that is being used, there is a possibility that slight oscillating noise may be visible in the top and bottom sides of the endoscopic image.

4 Pre-use Inspections

To ensure the equipment is in good working condition for use with patients, check that the endoscope, processor, and accessories are clean and operate properly before use. Also, provide spare equipment in case use of the equipment must be stopped as result of a malfunction or other unforeseen problem.

Be sure to perform the following inspection steps before using the processor. If you discover any abnormality, stop using the processor immediately and contact a PENTAX Medical service facility.

Check the following before you begin the inspection.

- The processor is turned off.
- The processor is installed on a stable and level surface.
- The water bottle assembly is prepared properly and connected correctly.
- The power cord is connected properly.
- The endoscope is connected properly.
- The keyboard is connected properly.
- The USB flash memory or other storage media is connected properly.

Before saving any images, check that

(a) the format for the data to be saved to the USB flash memory is the desired format, and

(b) the USB flash memory or similar is selected as the storage location.

☞ "Select drive (Still image)" (P.60), "Select drive (Video image)" (P.63)

⚠ WARNING

Be sure to perform the following inspections before you use the processor. In the event that any function or device in the video endoscope system does not work properly, do not perform the endoscopic examination. Contact a PENTAX Medical service facility before using the equipment.

Power-On and Lamp Inspection

1 Turn on the monitor and peripheral devices.

2 Press the ⏻ power switch to turn on the processor, and check that the ⏻ LED illuminates.

- The touch panel turns on.
- Check that the LIFE indicator (lamp life indicator) on the touch panel is lit green.
- If pressing ⏻ does not turn on the processor, check the fuses.
  ☞ "Replacing the Fuses" (P.84)

⚠ CAUTION

- The lamp life is 500 hours. Check the LIFE indicator (lamp life indicator) on the touch panel before using the processor. Replace the lamp cartridge if one red circle on the LIFE indicator is lit red and a message prompting you to replace the lamp is displayed on the monitor. The lamp life may not be as long as 500 hours depending on the method of use and operating environment.
  ☞ "Replacing the Lamp" (P.82)
- If the touch panel does not lit up after more than one and a half minutes from the system startup, restart the system.

3 Press ☼ on the touch panel.

- ☼ illuminates green.

4 Check that the main lamp of the processor illuminates, and the distal end of the endoscope emits light.

⚠ WARNING

- Do not look directly at the light emitted from the distal end of the endoscope. Doing so can cause eye injury.
- Do not open the lamp housing cover to avoid electric shock.

NOTE

- If the lamp fails to illuminate, stop the inspection and contact a PENTAX Medical service facility.
- If a PENTAX Medical video endoscope or video module that is not compatible with the processor is connected, endoscopic images will not be displayed.
- The auxiliary lamp is for the purpose of ensuring that you can see what you are doing while removing the endoscope in the event of the main lamp fails during a procedure. If this occurs, release the angulation of the endoscope, remove the endoscope from the patient's body cavity, and stop the examination. Do not perform a procedure using the auxiliary lamp.

On-screen Image Check

1 Check the image displayed on the monitor.

⚠ WARNING

Check the live image is properly output on the monitor in the right direction.

Automatic Brightness Control Inspection

Check the video images from the endoscope on the monitor while the lamp is lit.

1 Exercise the endoscope's automatic iris. Bring the tip of the endoscope within 1 cm of the palm of your hand and move it to about 5 cm away from your palm. Watch the image displayed on the monitor to ensure the brightness at both distances is similar. Lift the distal end of the endoscope close to the room lights, and check that the light being emitted from the distal end of the endoscope lowers significantly (dependent on the ambient light levels in the room). Return the distal end of the endoscope to a point on your palm and ensure that the light is being emitted from the distal end of the endoscope. (Refer to Figure 4.1.)

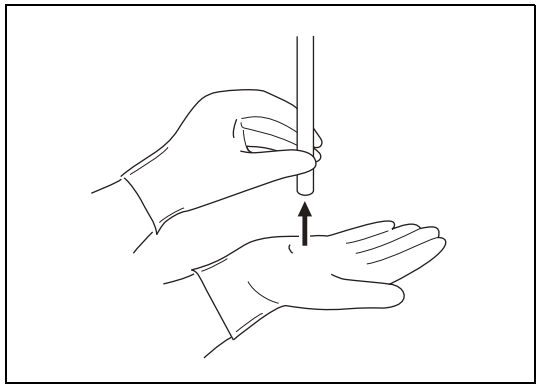


Figure 4.1

⚠ CAUTION

- Wear rubber gloves when performing the inspection.
- If items are brought up close to the distal end of the endoscope and left there for a long time, it could cause heat to be generated by the light being emitted from the distal end of the endoscope.
- If dark-colored gloves are brought close to the distal end of the endoscope, it may cause heat to be generated, which may result in a burn injury.

NOTE

- It may take more than 10 seconds for the endoscopic image to appear on the monitor.
- If the endoscopic image does not appear on the monitor, turn the power off and then on again.

Endoscope Control Button

1 Press each button on the control body of the endoscope and check that a confirmation tone sounds. (Refer to Figure 4.2.)

- For details on each of the buttons on the control body of the endoscope, refer to the IFU for the endoscope.

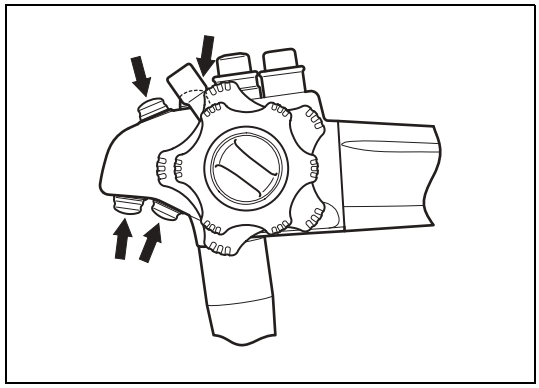
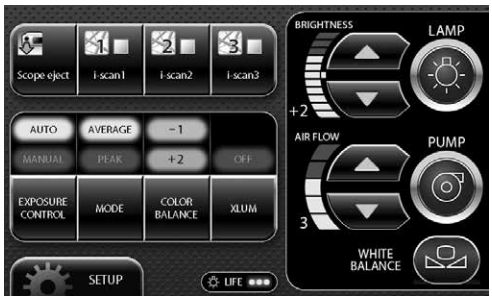


Figure 4.2

Exposure and Measurement Inspection

1 Press EXPOSURE CONTROL on the touch panel, and select [MANUAL].

- The selected item illuminates green. Each press switches the item between [AUTO] and [MANUAL].



2 Press ▲▼ of [BRIGHTNESS] and check that the level of the indicator changes.

3 Press EXPOSURE CONTROL, and select [AUTO].

- The selected item illuminates green. Each press switches the item between [AUTO] and [MANUAL].
- Selection is not possible when an endoscope is not connected.

4 Press MODE, and select [AVERAGE] or [PEAK].

- The selected item illuminates green. Each press switches the item between [AVERAGE] and [PEAK].
- Selection is not possible when an endoscope is not connected.

Color Adjustment

1 Adjust the white balance before adjusting the color balance.

☞ "White Balance Button" (P.27)

2 Press COLOR BALANCE on the touch panel.

- The color balance adjustment screen appears.

3 Press ▲▼ of [BLUE] or [RED] and check the level value. Gently place your hand around the distal end of the endoscope, and check the changes in the image of your hand on the monitor.

Suction Inspection

1 Place the distal end of the endoscope in a basin of sterile water, and press the suction control valve. (Refer to Figure 4.3.)

- The sterile water should be rapidly aspirated into the suction system.

NOTE

Be sure to use freshly distilled or sterilized water.

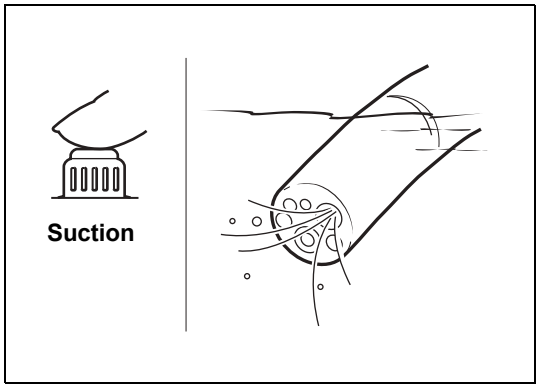


Figure 4.3

Air/Water Supply Inspection

1 **Set the A/W DRAIN lever to A/W position. (Refer to Figure 4.4)**
Insert the air pipe of the water bottle assembly into the water bottle socket of the video processor and press until the water bottle assembly 'clicks' into position.

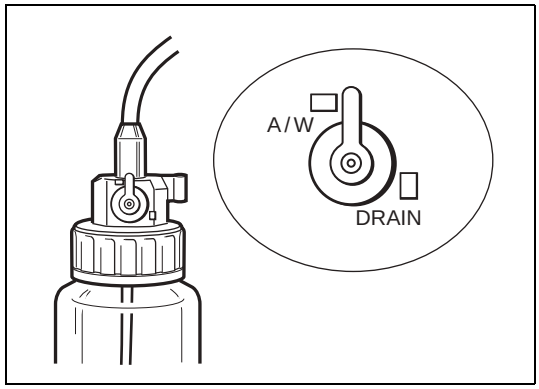
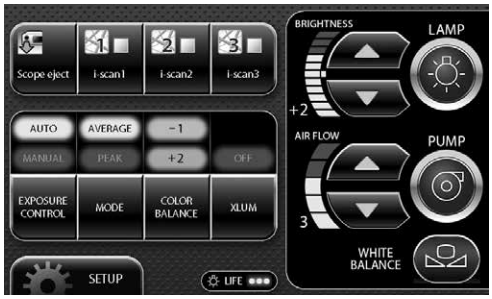


Figure 4.4

2 **Press (ON/OFF) on the touch panel so that illuminates green and the operating sound of the air pump can be heard.**

3 **Press of [AIR FLOW] to select the strength level.**



4 **Air/water is supplied through the endoscope. If you insert the distal end of the endoscope into water and gently cover the air hole on the air/water feeding valve, air will come out of the distal end of the endoscope. You can confirm the air supply by checking whether air bubbles are generated. (Refer to Figure 4.5.)**

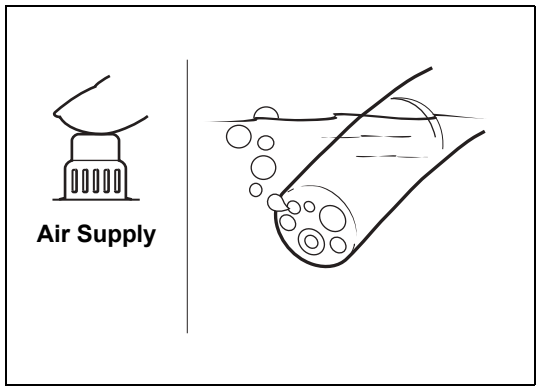


Figure 4.5

NOTE

Be sure to use freshly distilled or sterilized water.

5 **Fully press the air/water feeding valve and check that water comes out of the distal end of the endoscope. (Refer to Figure 4.6.)**

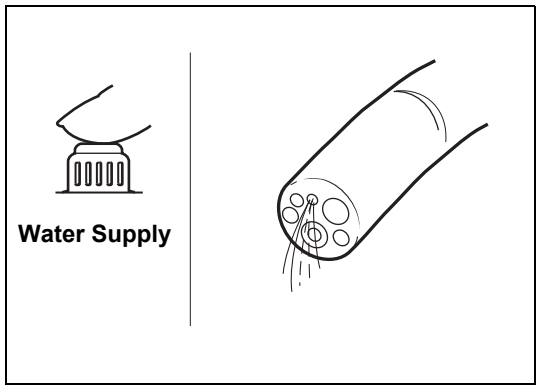


Figure 4.6

NOTE

For details about air and water delivery, refer to the Instructions for Use for the endoscope.

⚠CAUTION

If all of the inspection items are working properly, then the endoscopic examination can be performed. If there is a problem with any of the functions, do not perform the endoscopic examination. Contact a PENTAX Medical service facility.

5 Operating Procedure

Turning On/Off the Processor

1 Press ⏻ on the front of the processor. (Refer to Figure 5.1.)

- The processor turns on, the touch panel illuminates, and the screen for normal mode appears on the monitor.
  ☞ "Normal Screen" (P.23)
- The patient information and user information displayed immediately prior to turning off the processor last time appear on the monitor.

2 Press ⏻ again to turn off the processor.

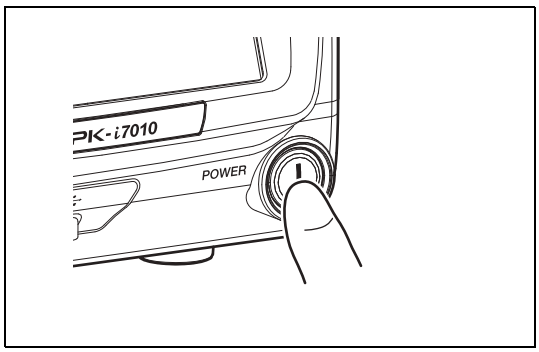


Figure 5.1

⚠CAUTION

- The processor can be shut down the power supply by turning off a power switch.
- After the processor has been turned off, wait at least 30 seconds before turning it back on again. A fuse may be blown if you turn the power on and off repeatedly within a short period of time. ☞ "Replacing the Fuses" (P.84)
- Do not use a sharp object such as the tip of a pen to press buttons on the touch panel.
- On rare occasions, the processor may not start up when it is turned on. If this happens, turn the processor off and then on again.
- Do not use the end of the light guide of the endoscope to operate buttons or switches.
- Data may not be saved correctly to an external device if power is turned off to the processor while the data is being transferred.

NOTE

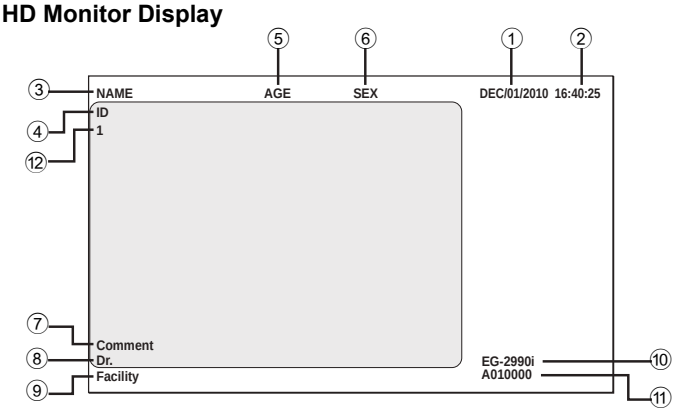
On rare occasions, noise may be temporarily displayed on endoscopic images immediately after the start-up video processor or endoscope connection.

Monitor Screens

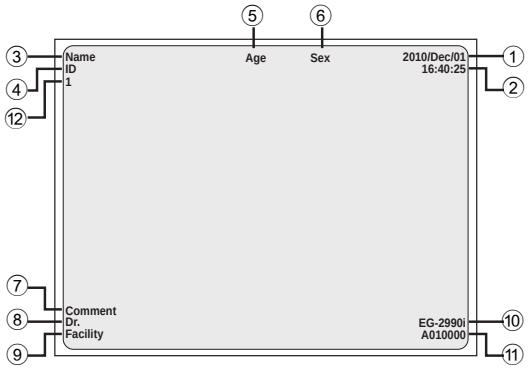
g Normal Screen

The normal screen shown below appears on the monitor when you turn on the processor.

HD Monitor Display



SD Monitor Display



① Date
② Time (Hours/Minutes/Seconds)
③ Patient's Name (Up to 24 Characters)
④ ID (Up to 12 Characters)
⑤ Age (Up to 3 Characters)
⑥ Sex (1 Character)
⑦ Comment (Up to 40 Characters)
⑧ Doctor's Name (Up to 24 Characters)
⑨ Facility (Up to 16 Characters)
⑩ Endoscope Name
⑪ Endoscope Serial No.
⑫ Film counter

NOTE

- You can change the display for the HD monitor and the SD monitor in [Display setting]. ☞"Display setting" (P.66)
- Depending on the setting of the monitor screen, endoscopic image or text information might spill out of the screen. Adjust the display position by performing overscan/underscan adjustment or vertical/horizontal adjustment and make sure that the image as well as text is correctly displayed on the screen.
- Displayed/undisplayed of each item can be set up by [Character display]. ☞"Settings in the [User data edit No.*] Screen" (P.78)

g Freeze Screen P-in-P Mode Screen

When the freeze function is executed, the monitor display is split into a main screen and sub screen, and still images are displayed in the main screen and endoscope video images are displayed in the sub screen.
When images are input from an external device, you can continue to display the endoscope video images in the main screen and display the images input from the external device in the sub screen. (P-in-P mode)

HD Monitor Display

SD Monitor Display

⚠CAUTION

Be sure to check that the endoscopic images on the monitor are not static and that the images are displayed with the correct orientation each time before attempting to use the equipment or after changing the image mode from freeze screen to normal screen or twin mode screen.

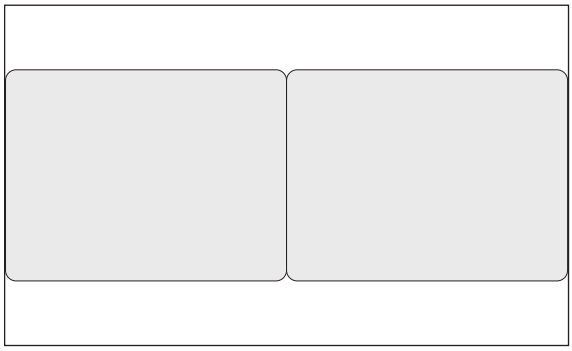
NOTE

If you set the [Sub screen position] to [Upper Right] on an SD monitor, [Date] and [Time] will be hidden.

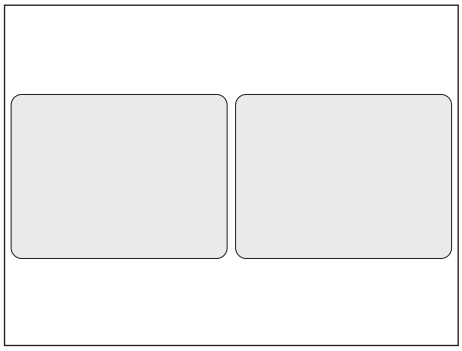
g Twin Mode Screen

This screen displays two endoscope video images together. It enables you to confirm an image for which image processing has been performed and an unprocessed image at the same time.

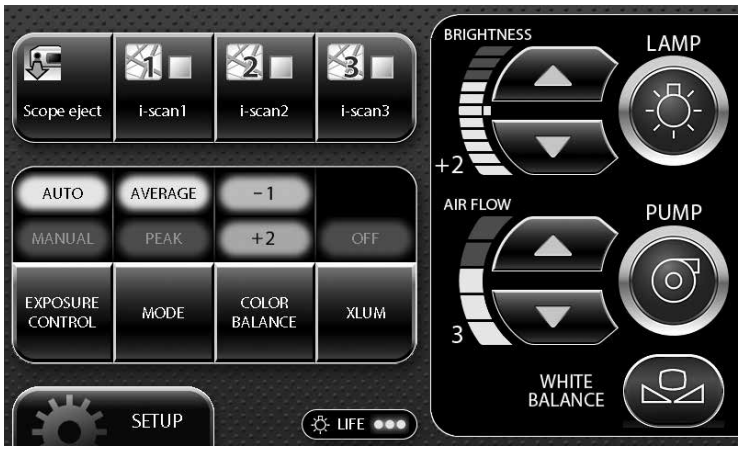
HD Monitor Display



SD Monitor Display



Touch Panel Operation



⚠CAUTION

- Do not use a sharp object such as the tip of a pen to press the buttons on the touch panel.
- Do not use the end of the light guide of the endoscope to operate the touch panel.

Lamp Button

1 Press ☼ on the touch panel.

- ☼ illuminates green. The processor's main lamp illuminates, and the distal end of the endoscope connected to the processor emits light.
- If the lamp does not illuminate, the auxiliary lamp illuminates and ☼ flashes green.

⚠CAUTION

- To protect your eyes, avoid looking directly at the light emitted from the endoscope and/or processor.
- The lamp life used by the processor is 500 hours. Prior to use, check the lamp life indicator on the touch panel and confirm that it is lit green or yellow. After 500 hours of use, the indicator will turn red and image quality will deteriorate. Excessive use of the lamp beyond its rated 500 hours (approaching a thousand hours of use or more) could cause the lamp to explode resulting in damage to the video processor. The lamp life may not be as long as 500 hours depending on the method of use and operating environment.
  ☞ "Replacing the Lamp" (P.82)

NOTE

- If the main lamp does not illuminate even if you press ☼, check the lamp life indicator on the touch panel. Replace the lamp if the indicator is red (☞ "Replacing the Lamp" (P.82)). If the indicator is green or yellow, the lamp system or lamp cartridge is broken.
  ☞ "Troubleshooting" (P.86)
- The lamp of the processor should be turned off except during pre-use inspection and clinical use.
- The auxiliary lamp is for the purpose of ensuring that you can see what you are doing while removing the endoscope in the event of the main lamp failing during a procedure. Release the angulation of the endoscope, remove the endoscope from the patient's body cavity, and stop the examination. Do not perform a procedure using the auxiliary lamp.
- If the auxiliary lamp is lit, all image processing is disabled.

Brightness Setting Buttons

You can manually adjust the brightness of images appearing on the monitor.

1 Press ▲ or ▼ of [BRIGHTNESS].

- Each press of ▲ increases the brightness by one step and each press of ▼ decreases the brightness by one step.
- When you adjust the brightness, the level is indicated by the indicator and the value is displayed on the monitor. Note that the standard value is [0] when you make adjustments.

NOTE

The brightness setting is stored in memory even after you turn off the processor.

Pump Button

1 Press ◎ on the touch panel.

- ◎ illuminates green, and the air/water pump operates. Press the button again to stop operation.
- Press ▲▼ of [AIR FLOW] to set the strength of the pump air flow.
  ☞ "Pump Level Setting Buttons" (P.27)

NOTE

When pump button becomes inoperable, stop the procedure. Release the finger tip from the air/water feeding valve of the endoscope to stop feeding of the air and water into the patient's body. Then, carefully withdraw the endoscope from the patient.

Pump Level Setting Buttons

Set the strength of the air and water supply of the pump.

1 Press ▲ or ▼ of [AIR FLOW].

- When you set the pump level, the level is indicated by the indicator and the value is displayed on the monitor.

⚠CAUTION

- Regardless of pump level setting selected, avoid delivering too much air to minimize the potential for perforation or other medical complications.
- Monitor the patient continuously, and ensure that an air embolism does not occur due to excessive air supply.

NOTE

- If the objective lens is difficult to clean, the level of the pump setting on the processor can be temporarily raised but simultaneously press the air/water feeding valve and suction control valve on the endoscope while the level is raised to minimize the potential of perforation. After removing the dirt from the lens, return the pump setting to a normal level.
- When the pump level setting is [1] to [3], the setting is stored in memory even after you turn off the processor. When the setting is [4] or [5], the setting is automatically changed to [3] when you turn off the processor.

White Balance Button

Adjust the white balance. If the message “Check white balance.” appears when the processor is turned on or an endoscope is connected to the processor, adjust the white balance. You can also adjust it whenever you want.

1 Connect the endoscope to the processor, and turn on the processor.

2 Set the exposure control mode to [AUTO].

3 Press ☼ on the touch panel to emit light from the distal end of the endoscope.

4 Insert the distal end of the endoscope into the supplied white balance adjuster. Move the adjuster so that the circle at the bottom can be viewed completely on the monitor screen, and verify that the inside of the adjuster can be seen clearly.(Refer to Figure 5.2.)

⚠CAUTION

- Be careful not to hit the distal end of the endoscope against the bottom of the white balance adjuster.
- Be sure to use the PENTAX Medical white balance adjuster OS-A43H when adjusting the white balance. Do not attempt to adjust the white balance under any other condition.

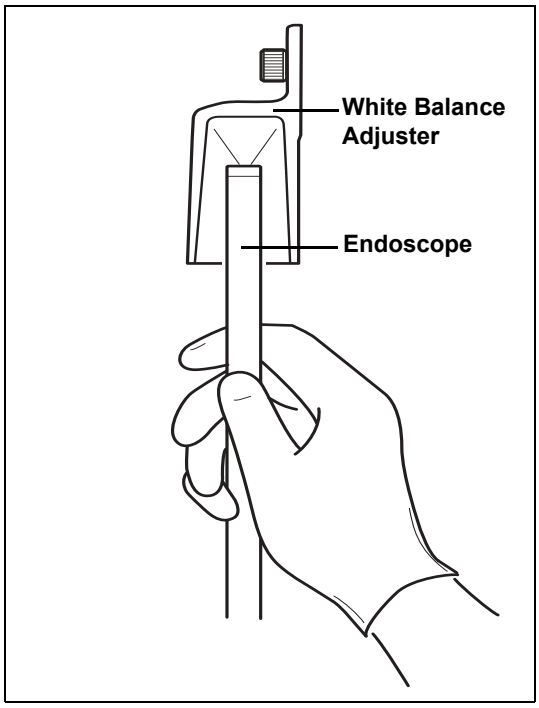
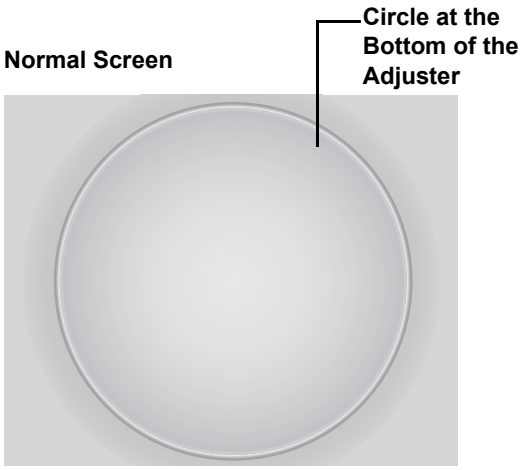


Figure 5.2

5 Hold the distal end of the endoscope in place and press on the touch panel for at least 2 seconds.

- The white balance is adjusted. After the white balance is set, the message “White balance OK!” appears on the monitor for about 5 seconds.
- If adjustment of the white balance fails, the message “White balance failed! Please retry.” appears on the monitor. Adjust the white balance again.



CAUTION

Be sure to press and adjust white balance before the procedure.

EXPOSURE CONTROL Exposure Control Button

You can select from two exposure control modes for adjusting the brightness of images appearing on the monitor.

[AUTO]: The brightness set with the brightness setting buttons is automatically adjusted so that it is uniform. Selection is possible when an endoscope is connected.

[MANUAL]: The brightness set with the brightness setting buttons is applied without any automatic adjustments.

1 Press EXPOSURE CONTROL on the touch panel and select a setting.

- Each press switches the item between [AUTO] and [MANUAL].
- The selected item illuminates green.
- When changing the brightness, press ▲ or ▼ of [BRIGHTNESS] to set the level.

MODE Mode Button

1 When the exposure control method is set [AUTO], select the light measuring method from [AVERAGE] and [PEAK]. The indicator of the selected method illuminates.

[AVERAGE]: Adjust the [BRIGHTNESS] level in relation to the average value of the brightness of the video signal.

[PEAK]: Adjust the [BRIGHTNESS] level in relation to the maximum value of the brightness of the screen.

NOTE

The light measuring method setting is stored in memory even after you turn off the processor.

COLOR BALANCE Color Balance Button

You can manually adjust the color tones of images appearing on the monitor.

1 Press COLOR BALANCE on the touch panel.

- The color balance adjustment screen appears.

2 Press ▲▼ of [BLUE] or [RED].

- Each press of ▲ or ▼ changes the color tone.
- When you adjust a color tone, the level is indicated by the indicator and the value is displayed on the monitor. Note that the standard value is [0] when you make adjustments.

NOTE

The color balance setting is stored in memory even after you turn off the processor.

XLUM ON/OFF Button

Use this button when you want to know the position of the distal end of the endoscope from outside the body. When this is set to on, the light intensity of the endoscope is set to maximum and you can confirm the position of the distal end of the endoscope from outside the body.

1 Press [XLUM] on the touch panel.

- When this is turned on, [ON] of the button illuminates green and the [BRIGHTNESS] indicator indicates the Maximum value.
- Press the button again to turn it off.

⚠CAUTION

- Do not use the XLUM ON function during routine use.
- When XLUM is used, Brightness cannot be adjusted.
- XLUM is the function that enables the physician to locate the distal end of the endoscope within the patient's body by intensifying the light emitted by the endoscope to its maximum level. However, the effectiveness of XLUM function can be limited by such factors as patient's body size and so on.

Customize Buttons

Pressing a customize button activates the function assigned to it. Depending on the registered function, you may be able to change, for example, the setting value by just pressing the button repeatedly or you may be able to display the setting screen for that function by just pressing the button once.
You can change the functions set for the customize buttons in [Customize button settings] on the [Customize] tab of the Setup menu.
☞ "Customize button settings" (P.44)

1 Press the desired customize button.

- The setting value changes or the screen for setting the function appears.

Setup Button

Pressing the Setup button displays the menu for configuring the settings of each of [i-scan], [Image], [Customize], [System], and [Peripheral].

1 Press [SETUP] on the touch panel.

- The Setup menu appears.
  ☞"Setup Menu Operations" (P.35)

i-scan

This video processor includes three, optional preprogrammed modes of i-scan.

i-scan is an optional digital, post-processing imaging enhancement technology, which is intended to be used as an adjunct to traditional white light endoscopy.

i-scan 1, 2, and 3 are preprogrammed default settings. Only one default setting can be activated at a time. The user is able to either choose the default settings or change the volumetric options of the settings for customizability.

The i-scan modes 1, 2 and 3 can be accessed by using a pre-programmed button on the endoscope, by using a pre-programmed foot switch or by pressing a keyboard button.

Surface Enhancement (SE), Contrast Enhancement (CE) and Tone Enhancement (TE) are software based image enhancement functions that work in combination to produce the enhancements of i-scan 1, 2 and 3.

g Surface Enhancement (SE)

The software based SE mode allows for enhancement of detailed patterns and micro-unevenness (texture) of the surface structures of the image.

g Contrast Enhancement (CE)

The software based CE mode allows for enhancement of micro-unevenness (texture) by identifying locally dark areas in the images and further enhancing them with a slight blue tone.

NOTE

- If [Enhancement], [SE], or [CE] is used, noise may become visible in images on the monitor screen.
- [Enhancement], [CE], [SE] settings are stored in memory even if the processor is turned off.

g Tone Enhancement (TE)

The software based TE mode allows for the adjustment of color contrast in the image to enhance contrast between mucosa and blood vessels. Each TE setting displays a unique combination of red, green and blue contrast.

⚠ WARNING

- If any newly identified irregularities in the endoscopic image are observed during any of the image enhancement observational modes, immediately return to the normal white light observation mode.
- Do not rely on the image enhancement observational modes alone for primary detection of lesions or for decisions regarding any potential diagnostic or therapeutic intervention.

⚠ CAUTION

The tone and the brightness of the endoscopic image of the i-scan observation are different from the white light observation. Please use the i-scan observation after a thorough white light examination and reviewing the property of each mode. i-scan observation is an adjunct to white light endoscopy, and is not a substitute for either a thorough traditional examination or for histopathological results.

i-scan Setting

No.	Setting Item	Setting Value	Explanation
1	Enhancement (Enh)	Off, +1, +2, +3, +4, +5, +6, +1/a1, +2/a2, +3/a3, +4/a4, +5/a5, +6/a6	Enhances the sharpness of edges and emphasizes the mucosal structures (the enhancement level is increased with the setting value).
2	Surface Enhancement (SE)	Off, +1, +2, +3, +4, +5, +6	Enhances detailed patterns and micro-unevenness (texture) of the surface structures of the image.
3	Contrast Enhancement (CE)	Off, +1, +2, +3, +4, +5, +6	Enhances micro-unevenness (texture) by identifying locally dark areas in the images and further enhancing them with a slight blue tone.
4	Brightness (B)	-5, -4, -3, -2, -1, 0, +1, +2, +3, +4, +5	Allows for adjustment of brightness of image (a larger value increases brightness).
5	Color Balance	-5, -4, -3, -2, -1, 0, +1, +2, +3, +4, +5	Allows for adjustment of red and blue tone (a larger value increases red or blue color intensity).
6	Tone Enhancement (TE)	Off, p, v, b, e, g, c	Allows for adjustment of color contrast in image to enhance contrast between mucosa and blood vessels. Each TE setting displays a unique combination of red, green and blue contrast.
7	Light Measuring Method (LMM)	Ave, Peak	Allows for adjustment of brightness level with respect to an averaging of the brightness of the video signal or with respect to the peak brightness of the screen.
8	Noise Reduction (NR)	Off, Low, Medium, High	Allows for correction of noise appearing by image processing.

Optical Enhancement (OE)

This video processor is equipped with two optical filters placed inside Xenon lamp light path to provide optical enhancement (OE), which combines the band limited light and the digital processing.

PENTAX OE technology has two modes, OE Mode1, 2.
OE Mode1 uses a spectral filter that transmits band limited green and blue light and is intended to provide the user with enhanced image of blood vessels and fine structure of mucosa.
OE Mode2 uses a different spectral filter that transmits band limited red, green and blue light and is intended to provide the user with enhanced image of blood vessels and fine structure of mucosa in an image closer to white light image.

NOTE

OE mode cannot be processed simultaneously with [SE], [CE], [TE].

WARNING

- If any newly identified irregularities in the endoscopic image are observed during any of the image enhancement observational modes, immediately return to the normal white light observation mode.
- Do not rely on the image enhancement observational modes alone for primary detection of lesions or for decisions regarding any potential diagnostic or therapeutic intervention.

Optical Enhancement (OE) setting

Setting Item	Setting Value	Explanation
OE (Optical Enhancement)	Off, Mode1, Mode2	Inserts one of two optical filters corresponding to Mode1 and Mode2 into the illumination light path to provide a band-limited spectrum. The band-limited spectrum enhances blood vessels and fine structure of mucosa.
Enhancement (Enh)	Off, +1, +2, +3, +4, +5, +6, +1/a1, +2/a2, +3/a3, +4/a4, +5/a5, +6/a6	Enhances the sharpness of edges and emphasizes the mucosal structures (the enhancement level is increased with the setting value).
Brightness (B)	-5, -4, -3, -2, -1, 0, +1, +2, +3, +4, +5	Allows for adjustment of brightness of image (a larger value increases brightness).
Ave / Peak (Light Measuring Method)	Average, Peak	Allows for adjustment of brightness level with respect to an averaging of the brightness of the video signal or with respect to the peak brightness of the screen.
Red / Blue (Color Balance)	-5, -4, -3, -2, -1, 0, +1, +2, +3, +4, +5	Allows for adjustment of red and blue tone (a larger value increases red or blue color intensity).
Noise Reduction (NR)	Off, Low, Medium, High	Allows for correction of noise appearing by image processing.

Image Processing Settings

⚠CAUTION

Be sure to check that the endoscopic images on the monitor are not static and that the images are displayed with the correct orientation each time after changes have been made to image processing settings.

g Using SE

1 Press the [SE] key on the keyboard / customize button on the touch panel or configure setting on [i-scan] Tab.

- Each press changes the level of SE.
  ☞ "Function Keys" (P.73), "Customize button settings" (P.44), "[i-scan] Tab" (P.35)

⚠CAUTION

SE is an observation mode that employs software image enhancement of regional concavity and convexity after the image has been collected by the endoscope.
All mucosal areas are to be viewed using traditional white light. SE should not be used as a substitute for a thorough traditional white light examination of the mucosa.

g Using CE

1 Press the [CE] key on the keyboard / customize button on the touch panel or configure setting on [i-scan] Tab.

- Each press changes the level of CE.
  ☞ "Function Keys" (P.73), "Customize button settings" (P.44), "[i-scan] Tab" (P.35)

NOTE

- If [Enhance level], [SE], or [CE] is set to high level, noise may become visible in images on the monitor screen.
- [Enhance level], [CE], [SE] settings are stored in memory even if the processor is turned off.
- K series with CE: Equivalent effectiveness to i series with CE mode.

g Using TE

1 Press the [TE] key on the keyboard / customize button on the touch panel or configure setting on [i-scan] Tab.

- Each press changes the mode of TE.
- Select from [p], [v], [b], [e], [g], [c], and [off].
  ☞ "Function Keys" (P.73), "Customize button settings" (P.44), "[i-scan] Tab" (P.35)

NOTE

K series with TE [e], [g], [c]: Equivalent effectiveness to i series with TE [e], [g], [c] mode.

g Using OE

OE modes can be activated during i-scan or white light observations.

Switching from White light image to OE image:

1 If i-scan functions are activated: Press [i-scan1], [i-scan2], [i-scan3] key on the keyboard, or customize button on the touch panel, or configure setting on [i-scan] Tab.

- Select OFF of i-scan1, 2 or 3.
  ☞ "Function Keys" (P.73), "Customize button settings" (P.44), "[i-scan] Tab" (P.35)

2 Press the [OE] key on the keyboard / customize button on the touch panel or configure setting on [i-scan] Tab.

- Each press changes the mode of OE.
- Select from [Mode1], [Mode2] and [off].
  ☞ "Function Keys" (P.73), "Customize button settings" (P.44), "[i-scan] Tab" (P.35)

Switching from i-scan1, i-scan2, or i-scan3 image to OE image:

1 Press the [OE] key on the keyboard / customize button on the touch panel or configure setting on [i-scan] Tab with i-scan1, 2 or 3 function are been activating.

- Each press changes the mode of OE.
- Select from [Mode1], [Mode2] and [off].
  ☞ "Function Keys" (P.73), "Customize button settings" (P.44), "[i-scan] Tab" (P.35)

NOTE

- 70K and 80K series endoscopes are not compatible with OE, therefore OE function cannot be used.
- 90K, K10 and J10 series endoscopes are not compatible with Twin mode viewing in OE mode image observation.
- Some of 90K series endoscope require software update to be used with OE. Please contact your local PENTAX Medical service facility.

g Using Enhancement

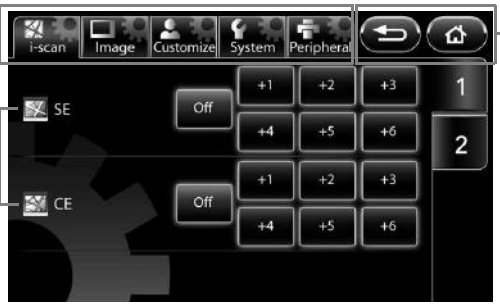
Configure the edge enhancement setting.

1 Press the [Enhance level] key on the keyboard / customize button on the touch panel.

- Each press changes the intensity of enhancement.
  ☞ "Function Keys" (P.73), "Customize button settings" (P.44)

Setup Menu Operations

Pressing [SETUP] on the touch panel displays the Setup menu.



Return to the main screen.

Press a tab to display the setting items for the corresponding category.

The Setup menu contains the following categories.

i-scan Configure settings for image processing related to i-scan mode.
☞ "[i-scan] Tab" (P.35)

Image Configure settings for image processing performed on endoscopic images, and settings related to twin mode.
☞ "[Image] Tab" (P.39)

Customize Configure settings for functions assigned to customize buttons, endoscope buttons, and foot switches, settings related to monitor display, and other settings.
☞ "[Customize] Tab" (P.44)

System Configure settings related to saving endoscopic images, and settings related to the processor unit. Be sure to check the setting options before using the processor for the first time.
☞ "[System] Tab" (P.58)

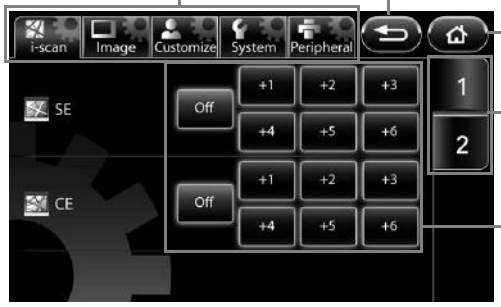
Peripheral Configure settings related to the peripheral device.
☞ "[Peripheral] Tab" (P.71)

5

[i-scan] Tab

Pressing the [i-scan] tab displays the following screen. The screen has two pages.

Display the setup menu for each of the categories.

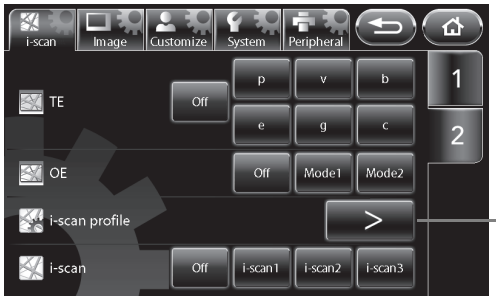


Return to the previous screen.

Return to the main screen.

Change the page.

Press any of the buttons to configure the setting.



Display the advanced settings screen.

g SE

Set the level for SE (surface enhancement).

1 Press [Off] or one of the six levels.

- A higher numerical value sets a higher level.

g CE

Set the level for CE (contrast enhancement).

1 Press [Off] or one of the six levels.

- A higher numerical value sets a higher level.

NOTE

- If [SE] or [CE] is used, noise may become visible in images on the monitor screen.
- The [SE] and [CE] settings are stored in memory even after you turn off the processor.

g TE

Set the mode for TE (tone enhancement).

1 Select [Off], [p], [v], [b], [e], [g], or [c].

⚠CAUTION

Be sure to check that the endoscopic images on the monitor are not static and that the images are displayed with the correct orientation each time after changes have been made to [SE], [CE], and [TE].

g OE

Set the mode for OE (optical enhancement).

1 Select [Off], [Mode1], or [Mode2].

- It cannot be processed simultaneously with [SE] [CE] [TE].
- If an endoscope is not connected to the processor, the message “Connect endoscope.” appears.

NOTE

- [OE] setting remains even when an endoscope is taken out and inserted by [Scope eject] with a processor's main body turned on.
- When changing the mode of OE, an image may be disturbed until its completion.

g i-scan profile

Set the functions of [i-scan1], [i-scan2], and [i-scan3].

1 Press [>].

- The [i-scan profile] screen appears.
- The setting value in the main screen and other screens is displayed for each item.

2 Select [i-scan1], [i-scan2], or [i-scan3].

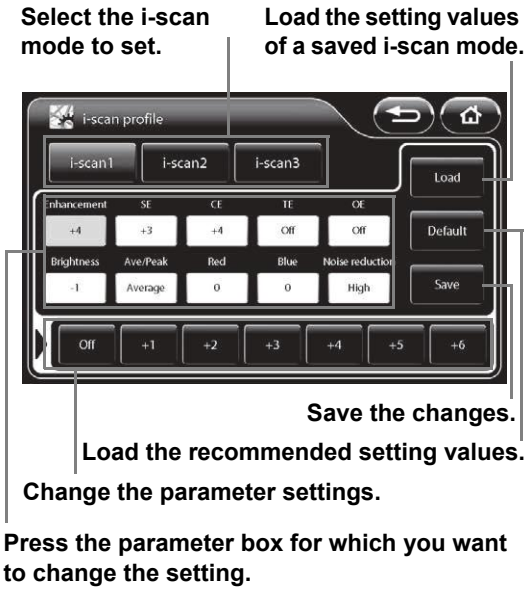
- If one of the i-scan modes is already selected, the currently enabled button will be lit.

3 Press the parameter box for which you want to change the setting.

- When a parameter box is selected, it turns blue and the buttons for changing the selected parameter appear at the bottom of the screen.

4 Change the setting with the buttons at the bottom of the screen.

- [SE] [CE] [TE] and [OE] cannot be processed simultaneously.



5 Press [Save].

- The changes are saved.
- If [Load] was pressed when the setting values were changed, the saved setting values are loaded.

5

List for assignable i-scan setting

Setting Item	Setting Value
Enhancement (Enh)	Off, +1, +2, +3, +4, +5, +6, +1/a1, +2/a2, +3/a3, +4/a4, +5/a5, +6/a6
SE (Surface Enhancement)	Off, +1, +2, +3, +4, +5, +6
CE (Contrast Enhancement)	Off, +1, +2, +3, +4, +5, +6
TE (Tone Enhancement)	Off, p, v, b, e, g, c
OE (Optical Enhancement)	Off, Mode1, Mode2
Brightness (B)	-5, -4, -3, -2, -1, 0, +1, +2, +3, +4, +5
Ave / Peak (Light Measuring Method)	Average, Peak
Red / Blue (Color Balance)	-5, -4, -3, -2, -1, 0, +1, +2, +3, +4, +5
Noise Reduction (NR)	Off, Low, Medium, High

NOTE

- With [Brightness] and [Ave/Peak], [No change] can be selected in addition to the normal levels. [No change] enables the level for when the [i-scan] setting is [Off] to be used.
- If you attempt to perform a keyboard operation other than pressing the [Lamp] or [Pump] key, endoscope button operation, or foot switch operation in the [i-scan profile] screen, the message “Close profile menu.” appears on the monitor and the operation cannot be performed.

g i-scan1-3

Select the i-scan mode.

1 Select [Off], [i-scan1], [i-scan2], or [i-scan3].

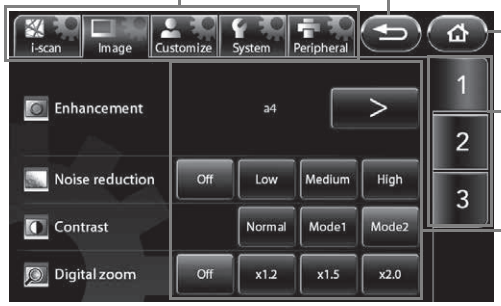
- The selected button illuminates, and the settings registered in [i-scan profile] are loaded.
- If one of the i-scan modes is already selected, the currently enabled button will be lit.
- If an endoscope is not connected to the processor, the message “Connect endoscope.” appears.

NOTE

- Configure each setting of [i-scan1], [i-scan2], and [i-scan3] in [i-scan profile].
- The [i-scan1-3] settings are retained even if the endoscope is removed and inserted using [Scope eject] while the processor is on.

[Image] Tab

Pressing the [Image] tab displays the following screen. The screen has three pages.



Display the setup menu for each of the categories.

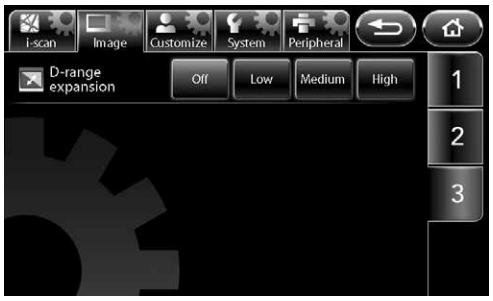
Return to the previous screen.

Return to the main screen.

Change the page.

Press any of the buttons to configure the setting.

Display the advanced settings screen.



g Enhancement

Set the level for edge enhancement/structure enhancement display.

1 Press [>].

- The [Enhancement] screen appears.

When [Scope enhancement] on the [Customize] tab is set to [Enable] (Only 70K series)

2 Select [Off], [Low], [Medium], or [High].

When [Scope enhancement] on the [Customize] tab is set to [Disable]

3 Press [Off] or one of two types × six levels.

- A higher numerical value sets a higher level for edge enhancement / structure enhancement display.
  [+1 to +6] Edge enhancement mode
  [+1/a1 to +6/a6] Edge enhancement / Structure enhancement mode : allows for enhancing the mucous membrane structure and contour.
  When connecting the 70K, 80K, 90K, K10 and J10 series endoscope, the edge enhancement mode [+1 to +6] is effective, and when the i series endoscope is connected, the structure enhancement mode [a1 to a6] becomes effective.
  Structure enhancement mode and [SE] cannot be processed simultaneously.

⚠CAUTION

Be sure to check that the endoscopic images on the monitor are not static and that the images are displayed with the correct orientation each time after changes have been made to [Enhancement].

g Noise reduction

Set the level for noise reduction.

1 Select [Off], [Low], [Medium], or [High].

⚠CAUTION

Be sure to check that the endoscopic images on the monitor are not static and that the images are displayed with the correct orientation each time after changes have been made to [Noise reduction].

NOTE

If [SE], [CE], or [Enhancement] is used, noise may become visible in the image on the monitor screen.

g Contrast

Select the mode for contrast processing.

1 Select [Normal], [Mode1], or [Mode2].

⚠CAUTION

Be sure to check that the endoscopic images on the monitor are not static and that the images are displayed with the correct orientation each time after changes have been made to [Contrast].

NOTE

The [Enhancement], [Noise reduction], and [Contrast] settings are stored in memory even after you turn off the processor.

g Digital zoom

Set the magnification ratio of endoscopic images.

1 Select [Off], [x1.2], [x1.5], or [x2.0].

NOTE

As the optical or electronic expanded observation display has a narrow view, please secure a view enough when performing an operation.

g Image rotate

Set the display orientation of the endoscopic image.

1 Press [Normal] or [Rotate].

[Normal]

[Rotate]

g Twin mode

Set or cancel twin mode.

☞ "Twin Mode Screen" (P.24)

1 Press [Off] or [On].

- If an endoscope is not connected to the processor, the message “Connect endoscope.” appears.

NOTE

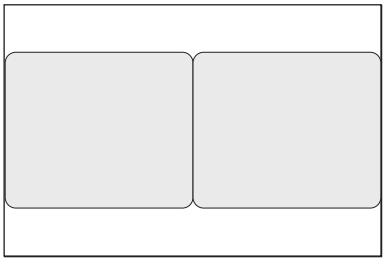
- If [SE] or other image processing is performed in twin mode, the processing is only reflected on the image on the right side of the screen. The image processing parameters are inherited by the normal screen when twin mode is cancelled.
- When the Twin mode setup is made after freezing, an image processing is not reflected in the left side screen. In the case where the USB capture is performed as is, an image-processing parametric information is added to the still picture even if not checking [Add image processing parameter information.]of [Option (Still image)]. And the image-processing parametric information of the left side screen displays "-". Image processing of the left side screen will become effective after freezing release.
- 90K, K10 and J10 series endoscopes do not correspond to the Twin mode of white light and OE.
- (When executed an image-processing)In case that the display is too dark to obtain a proper observation result, we recommend you to return to a normal observation display or change one display into white light.

g Twin mode display

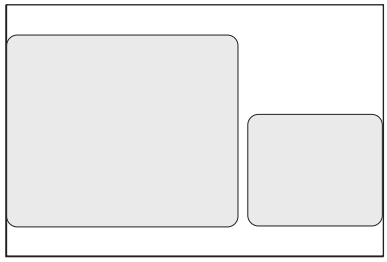
Set the sizes of the image on the left side of the screen and on the right side of the screen in twin mode.

1 Select [1:1], [3:2], or [2:3].

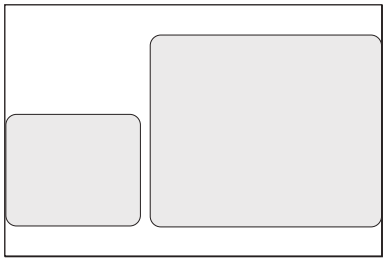
[1:1]



[3:2]



[2:3]

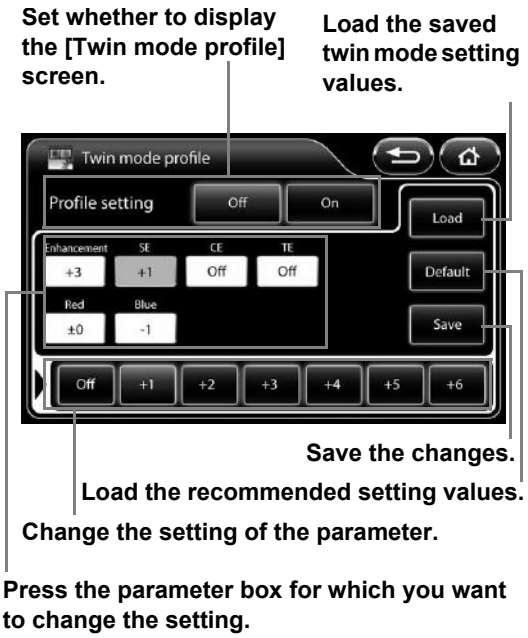


NOTE

The [Twin mode display] setting is stored in memory even after you turn off the processor.

g Twin mode profile

Set the image processing for twin mode.



1 Press [>].

- The [Twin mode profile] screen appears.
- The setting value in the main screen and the other screens is displayed for each item.

2 Select [Off] or [On] for [Profile setting].

[Off]: The [Twin mode profile] screen is not displayed in twin mode. Image processing parameters other than [Enhancement] are not reflected on the left side of the screen.

[On]: The [Twin mode profile] screen is always displayed on the left side of screen in twin mode. “TM profile” is displayed in the upper left of the left side of the screen.

3 Press the parameter box for which you want to change the setting.

- When a parameter box is selected, it turns blue and buttons for changing the selected parameter appear at the bottom of the screen.

4 Change the setting with the buttons at the bottom of the screen.

- If the parameter box does not turn blue, the buttons will not function properly.

5 Press [Save].

- The changes are saved.
- If [Load] was pressed when the setting values were changed, the saved setting values are loaded.

NOTE

- If you attempt to perform a keyboard operation other than pressing the [Lamp] or [Pump] key, endoscope button operation, or foot switch operation in the [Twin mode profile] screen, the message “Close profile menu.” appears on the monitor and the operation cannot be performed.
- When the Twin mode setup is made after freezing, an image processing is not reflected in the left side screen. In the case where the USB capture is performed as is, an image-processing parametric information is added to the still picture even if not checking [Add image processing parameter information.]of [Option (Still image)]. And the image-processing parametric information of the left side screen displays "-". Image processing of the left side screen will become effective after freezing release.

g ND mode

Set the level for ND mode.

1 Select [Off], [Low], [Medium], or [High].

⚠CAUTION

- If an option other than [Off] is set, a normal screen will not be displayed on the monitor when a PDT or other strong light is not utilized.
- When [Low], [Medium], or [High] is set, the current user cannot be changed. ☞ "Operations in the [User list preset] Tab" (P.77)
- When the setting screen is displayed by pressing the [Menu] key, [ND mode] operation is not possible.
- If [ND mode] is set to an option other than [Off], [i-scan1], [i-scan2], and [i-scan3] cannot be used.
- When the [ND mode] is set to anything other than [Off], the settings for [Shutter mode], [OE] will be canceled.
- Depending on the endoscope model being used, the time it takes to resume from the ND mode varies. It takes maximum of 10 seconds.
- There are certain models among 90K series endoscopes that cannot utilize ND mode. In order to use the ND mode, it is necessary to update the integrated software of the endoscope. Contact your local PENTAX Medical service facility to arrange the software update and inspection of the endoscope.

g D-range expansion

Select the mode for D-range expansion processing.

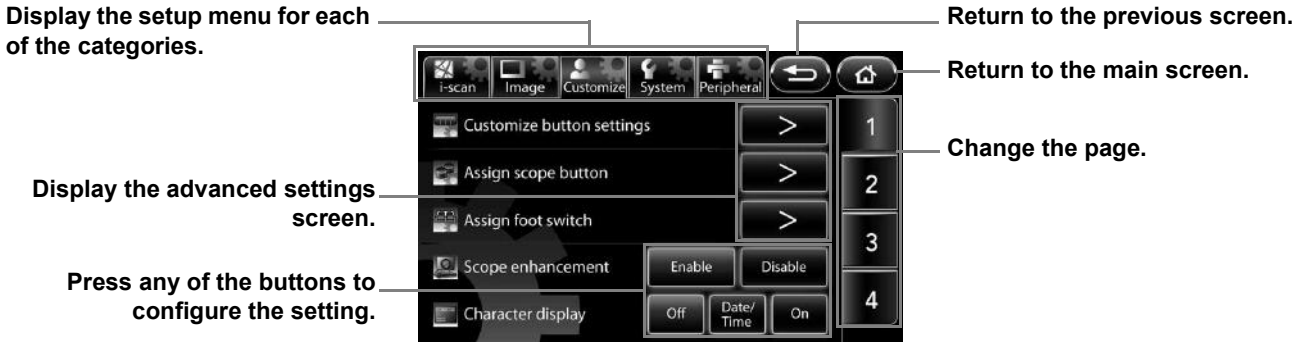
1 Select [Off], [Low], [Medium], or [High].

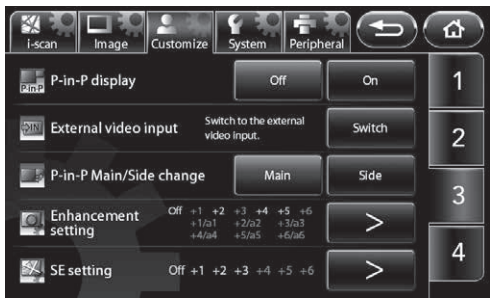
NOTE

The [D-range expansion] settings are stored in memory even after you turn off the processor.

[Customize] Tab

Pressing the [Customize] tab displays the following screen. The screen has four pages.





g Customize button settings

Set the functions for the customize buttons (four buttons at the top of the main screen).

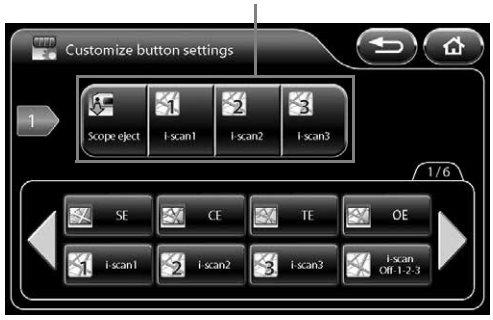
1 Press [>].

- The [Customize button settings] screen appears.

2 Press the customize button for which you want to set the function.

- The selected customize button illuminates blue.

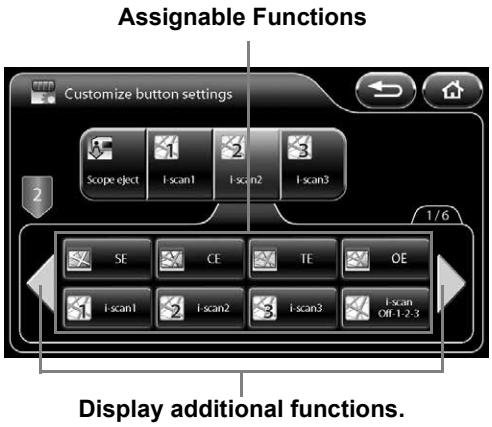
The function assigned to each customize button is displayed.



5

3 Press the button of the function to set.

- You can press ◀▶ to display additional functions.
- The name of the assigned function is displayed below the customize button.



The following functions can be assigned.

Function Name	Function Description	Reference Page
SE	Switch the SE level to a level available in [SE setting]. It cannot be processed simultaneously with [OE] or the structure enhancement mode [a1 to a6].	P.55
CE	Switch the CE level to a level available in [CE setting]. It cannot be processed simultaneously with [OE].	P.56
TE	Switch the TE mode to a mode available in [TE setting]. It cannot be processed simultaneously with [OE].	P.56
OE*	Switch the OE mode to a mode available in [OE setting]. It cannot be processed simultaneously with [SE] [CE] [TE].	P.56
i-scan1*	Use the settings of [i-scan1]. When the function is configured, a check mark is displayed in the check box of the corresponding button.	P.37
i-scan2*	Use the settings of [i-scan2]. When the function is configured, a check mark is displayed in the check box of the corresponding button.	P.37
i-scan3*	Use the settings of [i-scan3]. When the function is configured, a check mark is displayed in the check box of the corresponding button.	P.37
i-scan Off-1-2-3*	Switch the i-scan mode between [Off], [i-scan1], [i-scan2], and [i-scan3].	P.38
i-scan profile	Open the i-scan profile menu.	P.37
Remote1*	Output a signal from the REMOTE1 connector on the back of the processor.	—
Remote2*	Output a signal from the REMOTE2 connector on the back of the processor.	—
Remote3*	Output a signal from the REMOTE3 connector on the back of the processor.	—
Freeze*	Switch between video mode and freeze mode.	—

Function Name	Function Description	Reference Page
USB capture*	Save a still image to Image Recording Media in accordance with the setting of [File storage setting (Still image)].	P.60
USB printer*	Send a still image to the connected USB printer.	P.71
Video Rec/Stop*	Start and stop recording video. The video files are saved to Image Recording Media in accordance with the setting of [File storage setting (Video image)].	P.62
Enhancement*	Switch the edge enhancement/structure enhancement level available in [Enhancement setting].	P.39
Noise reduction	Switch the level for noise reduction between [Off], [Low], [Medium], and [High].	P.40
Contrast	Switch the mode for contrast processing between [Normal], [Mode1], and [Mode2].	P.40
Twin mode*	Set or cancel twin mode.	P.41
Twin mode display	Switch the size of the images on the left and right sides of the screen in twin mode between [1:1], [3:2], and [2:3].	P.41
Digital zoom*	Switch the magnification ratio for the endoscopic image in accordance with the setting of [Digital zoom setting].	P.54
Image rotate	Switch the display orientation for the endoscopic image between [Normal] and [Rotate].	P.41
ND mode*	Switch the level for ND mode between [Off], [Low], [Medium], and [High].	P.43
Film counter reset	Reset the film counter to 1.	P.68
Optical zoom speed	Switch the zoom speed for an optical zoom endoscope between [Low], [Medium], and [High].	P.54
P-in-P display	Switch P-in-P mode display between [Off] and [On].	P.54
External video input	Display images input from an external device on the touch panel.	P.54
P-in-P Main/Side change	Switch between the endoscopic image and external input video screens in P-in-P mode.	P.55
Scope eject*	Press and hold the button to remove the endoscope while the processor is on.	P.66
Image size	Switch the display size of the endoscopic image between [Full] and [Medium].	P.66

Function Name	Function Description	Reference Page
Stopwatch	Start or stop the stopwatch. Press and hold the button to reset the stopwatch.	P.66
System information	Display the [System information] screen.	P.68
Shutter mode*	Switch the shutter mode for the endoscope between [Off] and [On] (K series endoscope) or between [Off], [Low], [Medium], and [High] (i series endoscope).	P.52
Copy*	Capture a still image and output it to the Endonet system or endoPRO.	—
Video*	Start/stop recording video to the Endonet system or endoPRO.	—
PC capture*	Output the image to PC via Endoimage2.	—
D-range expansion	Switch the level for D-range expansion between [Off], [Low], [Medium], and [High].	P.43
Manual brightness level	Set the brightness adjustment level by endoscope type while [MANUAL] is set for [EXPOSURE CONTROL].	P.67
iDoc button	Send the current settings for i-Doc management to endoPRO.	—
Cecum marker	Send a command for the Cecum marker to endoPRO.	—

*: The button does not function when an endoscope is not connected to the processor.

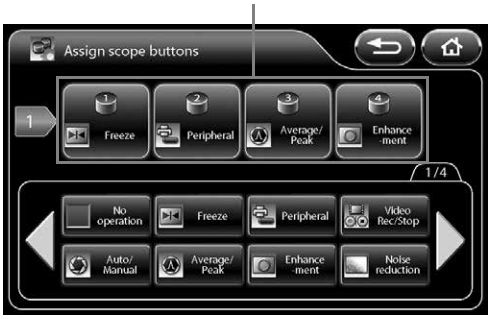
g Assign scope buttons

Set the functions for the endoscope buttons.

1 Press [>].

- The [Assign scope buttons] screen appears.

The function assigned to each endoscope button is displayed.



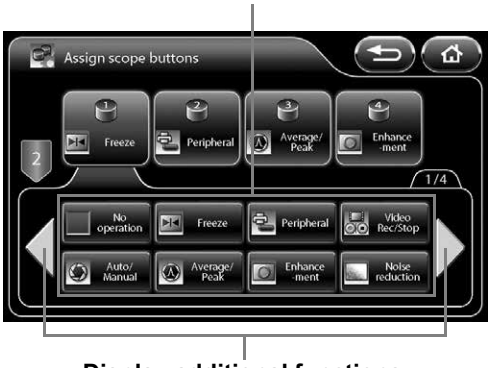
2 Select the endoscope buttons ([1], [2], [3], or [4]) for which you want to assign a function.

- The selected endoscope button illuminates blue.

3 Press the button of the function you wish to configure.

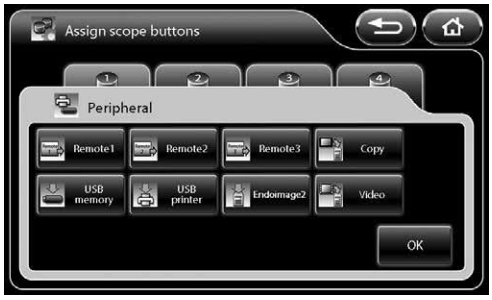
- You can press ◀▶ to display additional functions.
- The name of the assigned function is displayed below the endoscope button.

Assignable Functions



Display additional functions.

- Pressing [Peripheral] displays the [Peripheral] screen. On this screen, each external output can be switched on or off. Press the button of the function to output so that the button illuminates blue. Simultaneous output of multiple functions is possible.
- Pressing the button again switches off the output.



The following functions can be assigned.

Function Name	Function Description	Reference Page
No operation	A function is not assigned to the button.	—
Freeze	Switch between video mode and freeze mode.	—

Function Name		Function Description	Reference Page
Peripheral	Remote1	Output a signal from the REMOTE1 connector on the back of the processor.	—
	Remote2	Output a signal from the REMOTE2 connector on the back of the processor.	—
	Remote3	Output a signal from the REMOTE3 connector on the back of the processor.	—
	Copy	Capture a still image and output it to the Endonet system, or endoPRO. This cannot be configured simultaneously with [USB memory], [USB printer], [Endoimage2], and [Video].	—
	USB memory	Save a still image to Image Recording Media in accordance with the setting of [File storage setting (Still image)]. This cannot be configured simultaneously with [Copy], [USB printer], [Endoimage2], and [Video].	P.60
	USB printer	Send a still image to the connected USB printer. This cannot be configured simultaneously with [Copy], [USB memory], [Endoimage2], and [Video].	P.71
	Endoimage2	Output the image to a PC via Endoimage2. This cannot be configured simultaneously with [Copy], [USB memory], [USB printer], and [Video].	—
	Video	Start/stop recording video to the Endonet system or endoPRO. This cannot be configured simultaneously with [Copy], [USB memory], [USB printer], and [Endoimage2].	—
Video Rec/Stop		Start and stop recording video. The video files are saved to Image Recording Media in accordance with the setting of [File storage setting (Video image)].	P.62
Auto/Manual		Switch between [AUTO] and [MANUAL] for exposure control.	P.28
Average/Peak		Switch between [AVERAGE] and [PEAK] for the light measuring mode.	P.28
Enhancement		Switch the edge enhancement/structure enhancement level to a level available in [Enhancement setting].	P.39
Noise reduction		Switch the level for noise reduction between [Off], [Low], [Medium], and [High].	P.40
SE		Switch the SE level to a level available in [SE setting]. It cannot be processed simultaneously with [OE] or the structure enhancement mode [a1 to a6].	P.55
CE		Switch the CE level to a level available in [CE setting]. It cannot be processed simultaneously with [OE].	P.56

Function Name	Function Description	Reference Page
TE	Switch the TE mode to a mode available in [TE setting]. It cannot be processed simultaneously with [OE].	P.56
OE	Switch the OE mode to a mode available in [OE setting]. It cannot be processed simultaneously with [SE] [CE] [TE].	P.56
i-scan1	Use the settings of [i-scan1].	P.37
i-scan2	Use the settings of [i-scan2].	P.37
i-scan3	Use the settings of [i-scan3].	P.37
i-scan Off-1-2-3	Switch the i-scan mode between [Off], [i-scan1], [i-scan2], and [i-scan3].	P.38
Digital zoom	Switch the magnification ratio for the endoscopic image in accordance with the setting of [Digital zoom setting].	P.54
Stopwatch	Start or stop the stopwatch.	P.66
Stopwatch reset	Reset the stopwatch.	P.66
ND mode	Switch the level for ND mode between [Off], [Low], [Medium], and [High].	P.43
P-in-P Main/Side change	Switch between the endoscopic image and external input video screens in P-in-P mode.	P.55
Optical zoom (T)	Enlarge the display of the endoscopic image for an optical zoom endoscope.	—
Optical zoom (W)	Reduce the display of the endoscopic image for an optical zoom endoscope.	—
Twin mode	Set or cancel twin mode.	P.41
Twin mode display	Switch the size of the images on the left and right sides of the screen in twin mode between [1:1], [3:2], and [2:3].	P.41
Shutter mode	Switch the shutter mode for the endoscope between [Off] and [On] (K series endoscope) or between [Off], [Low], [Medium], and [High] (i series endoscope).	P.52
D-range expansion	Switch the level for D-range expansion between [Off], [Low], [Medium], and [High].	P.43
iDoc button	Send the current settings for i-Doc management to endoPRO.	—
Cecum marker	Send a command for the Cecum marker to endoPRO.	—

g Assign foot switch

Set the functions for the foot switches.

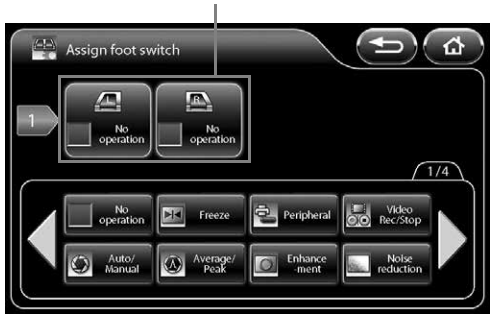
1 Press [>].

- The [Assign foot switch] screen appears.

2 Select the foot switch for which you want to set a function from [L] and [R].

- The selected foot switch button illuminates blue.

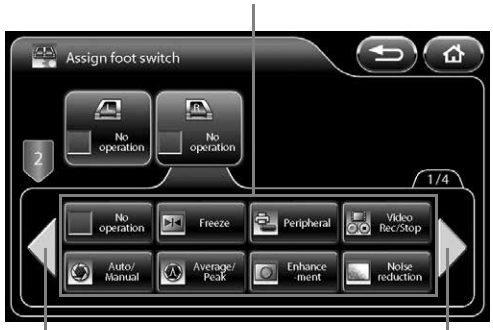
The function assigned to each foot switch is displayed.



3 Press the button of the function you wish to configure.

- You can press ◀▶ to display additional functions.
- The name of the assigned function is displayed below the foot switch.
- The functions that can be assigned are the same as "Assign scope buttons" (P.48).

Assignable Functions



Display additional functions.

g Scope enhancement

Set whether or not to enable enhancement processing in the endoscope.

[Enable] Enable endoscope enhancement processing in the endoscope. Enhancement processing in the processor is disabled.

[Disable] Disable endoscope enhancement processing in the endoscope. Enhancement processing in the processor is enabled.

1 Press [Enable] or [Disable].

⚠CAUTION

When a 90i/i10/90K/K10/J10 series endoscope is connected, only enhancement processing in the processor is used, regardless of the setting of [Scope enhancement].

NOTE

For use in combination with a different model color video processor, we recommend setting [Enable]. When an endoscope that was used with this set to [Disable] is connected to a different model color video processor, the [Enhancement] setting will be set to [Off].

g Character display

Set character display for the monitor.

[Off] All characters are not displayed.

[Date/Time] Only the date and time are displayed.

[On] The information set to [ON] in [Character display] of the keyboard menu is displayed.

1 Select [Off], [Date/Time], or [On].

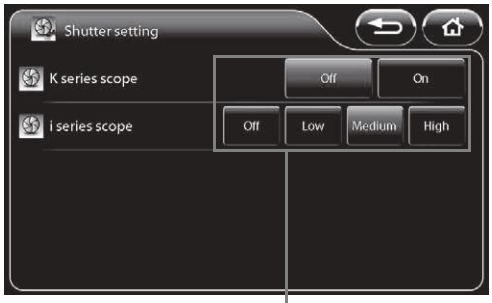
g Shutter setting

Configure the shutter speed settings of the endoscope.

1 Press [>].

- The [Shutter setting] screen appears.

2 Configure the settings of [K series scope] or [i series scope].



Press any of the buttons to configure the setting.

n K series scope

Set whether or not to automatically change the shutter speed of a K series endoscope when capturing normal images and close-up images. “K series” consists of 70K, 80K, 90K, K10 and J10 series.

[Off] The shutter speed is not changed. Select [Off] when using an external light source.

[On] The shutter speed is changed. When capturing close-up images, this enables clear images to be obtained if sufficient amount of light is emitted from the lamp.

1 Press [Off] or [On].

n i series scope

Set whether or not to automatically change the shutter speed of an i series endoscope when capturing normal images and close-up images.

[Off] The shutter speed is not changed. Select [Off] when using an external light source.

[Low] The shutter speed is changed in low speed mode. Select [Low] if limited amount of light is emitted from the lamp when capturing close-up images.

[Medium] The shutter speed is changed in medium speed mode. When capturing close-up images, this enables clear images to be obtained if sufficient amount of light is emitted from the lamp.

[High] The shutter speed is changed in high speed mode. When capturing close-up images, this enables the clearest images to be obtained if sufficient amount of light is emitted from the lamp.

1 Select [Off], [Low], [Medium], or [High].

NOTE

When turned off the lamp, the shutter speed is not changed.

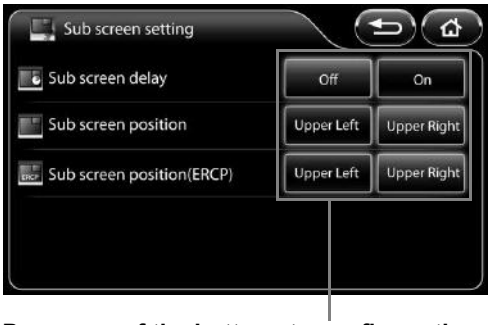
g Sub screen setting

Configure the settings for the sub screen displayed when, for example, the freeze function is executed.

1 Press [>].

- The [Sub screen setting] screen appears.

2 Configure the [Sub screen delay], [Sub screen position], and [Sub screen position (ERCP)] settings.



Press any of the buttons to configure the setting.

n Sub screen delay

Set the display of the sub screen to be delayed.

[Off] The sub screen is displayed immediately after the freeze function is executed.

[On] The sub screen is displayed shortly after the freeze function is executed.

1 Press [Off] or [On].

n Sub screen position

Set the position to display the sub screen.

[Upper Left] Display the sub screen on the upper left of the monitor.

[Upper Right] Display the sub screen on the upper right of the monitor.

1 Press [Upper left] or [Upper right].

n Sub screen position (ERCP)

When using a side viewing endoscope (ED series), set the position to display the sub screen.

[Upper Left] Display the sub screen on the upper left of the monitor.

[Upper Right] Display the sub screen on the upper right of the monitor.

1 Press [Upper left] or [Upper right].

NOTE

The [Sub screen position] and [Sub screen position (ERCP)] settings are enabled only on SD monitor displays.

g Digital zoom setting

Configure the zoom settings for when [Digital zoom] is assigned to a customize button on the touch panel, endoscope button, or foot switch, and when zoom operations are performed with the keyboard.

1 Press [>].

- The [Digital zoom setting] screen appears.

2 Select [Off - x1.2], [Off - x1.5], [Off - x2.0], [Off - x1.2 - x1.5], [Off - x1.5 - x2.0], [Off - x1.2 - x2.0], or [Off - x1.2 - x1.5 - x2.0] to set the zoom ratio.

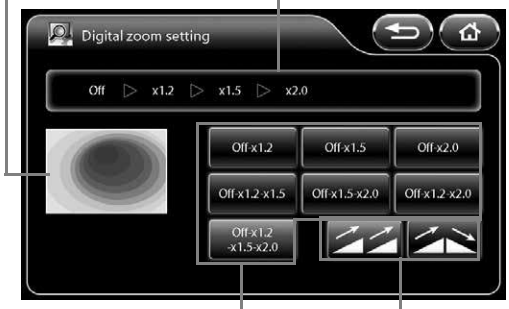
3 Select [ ] or [ ] to set the up/down order of the zoom.

[ ] When the zoom ratio has reached the maximum, pressing the customize button will return the zoom ratio to actual size.

[ ] When the zoom ratio has reached the maximum, pressing the customize button will incrementally reduce the zoom ratio until it returns to the actual size.

An animation is played at the set zoom ratio and up/down order.

Indicates the set zoom ratio and up/down order.



Set the up/down order of the zoom.

Set the zoom ratio.

g Optical zoom speed

You can adjust the zoom speed of an optical zoom endoscope.

1 Select [Low], [Medium], or [High].

NOTE

As the optical or electronic expanded observation display has a narrow view, please secure a view enough when performing an operation.

g Film counter type

Set the display format of the film counter.

1 Select [1-99], [1/2], [1/4], [1/8], or [1/16].

- If [1/2], [1/4], [1/8], or [1/16] is selected, the counter is reset to 1 when the number in the numerator becomes equal to the number in the denominator.

g P-in-P Display

Configure the display settings for P-in-P mode.

[Off] The images input from an external device are not displayed on the monitor.

[On] The images input from an external device are displayed on the monitor.

1 Press [Off] or [On].

g External video input

Display images input from an external device on the touch panel. Only images that are input from an external device to the VIDEO IN connector can be displayed.

1 Press [Switch].

- The images input from an external device are displayed on the touch panel. Touching the touch panel displays the previous screen.

g P-in-P Main/Side change

Switch between the endoscopic image and external input video screens in P-in-P mode.

[Main] The images input from an external device are displayed on the main screen of the monitor. The endoscopic images from the endoscope are displayed in the sub screen.

[Side] The endoscopic images from the endoscope are displayed on the main screen of the monitor. The images input from an external device are displayed in the sub screen.

1 Press [Main] or [Side].

⚠CAUTION

Confirm that the message “Main:External video” is displayed on the monitor while [Side] is selected.

NOTE

During the twin mode, the setting for [P-in-P Main/Side change] is fixed to [Main].

g Enhancement setting

Specify the edge enhancement/structure enhancement display levels that can be switched using a customize button on the touch panel, endoscope button, foot switch, or keyboard.

1 Press [>].

- The [Enhancement setting] screen appears.
- The level that is currently specified is indicated by green characters at the top of the screen.

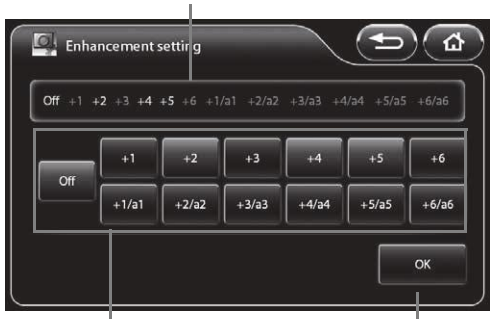
2 Press the buttons of the levels you want to use.

- The selected level buttons illuminate blue.
- Pressing a button again cancels the selection.

3 Press [OK].

- If you switch to another screen without pressing the [OK] button, the settings will not be applied.

The level that is currently specified is indicated by green characters.



Select the levels you want to use.

Confirm the selection.

g SE setting

Specify the SE display levels that can be switched using a customize button on the touch panel, endoscope button, foot switch, or keyboard.

1 Press [>].

- The [SE setting] screen appears.
- The level that is currently specified is indicated by green characters at the top of the screen.

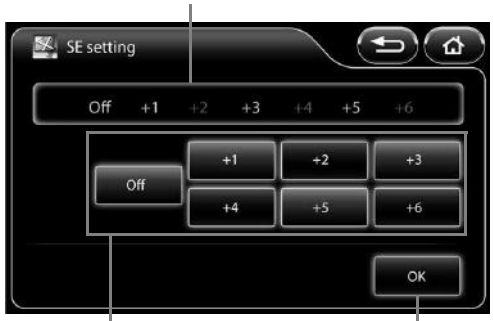
2 Press the buttons of the levels you want to use.

- The selected level buttons illuminate blue.
- Pressing a button again cancels the selection.

3 Press [OK].

- If you switch to another screen without pressing the [OK] button, the settings will not be applied.

The level that is currently specified is indicated by green characters.



Select the levels you want to use.

Confirm the selection.

g CE setting

Specify the CE display levels that can be switched using a customize button on the touch panel, endoscope button, foot switch, or keyboard.

1 Press [>].

- The [CE setting] screen appears.
- The level that is currently specified is indicated by green characters at the top of the screen.

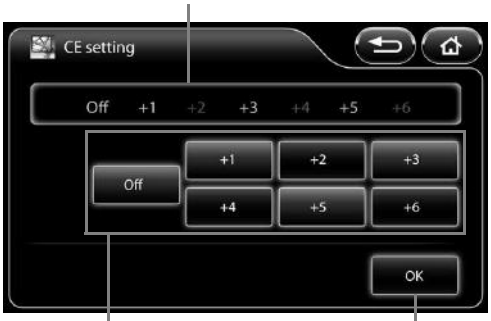
2 Press the buttons of the levels you want to use.

- The selected level buttons illuminate blue.
- Pressing a button again cancels the selection.

3 Press [OK].

- If you switch to another screen without pressing the [OK] button, the settings will not be applied.

The level that is currently specified is indicated by green characters.



Select the levels you want to use.

Confirm the selection.

g TE setting

Specify the TE display modes that can be switched using a customize button on the touch panel, endoscope button, foot switch, or keyboard.

1 Press [>].

- The [TE setting] screen appears.
- The mode that is currently specified is indicated by green characters at the top of the screen.

2 Press the buttons of the modes you want to use.

- The selected mode buttons illuminate blue.
- Pressing a button again cancels the selection.

3 Press [OK].

- If you switch to another screen without pressing the [OK] button, the settings will not be applied.

The mode that is currently specified is indicated by green characters.

Select the modes you want to use.

Confirm the selection.

g OE setting

Specify the OE modes that can be switched using a customize button on the touch panel, endoscope button, foot switch, or keyboard.

1 Press [>]

- The [OE setting] screen appears.
- The mode that is currently specified is indicated by green characters at the top of the screen.

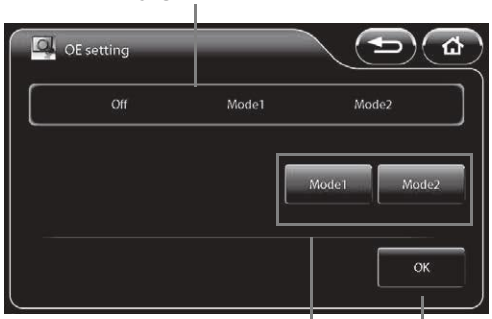
2 Press the buttons of the modes you want to use.

- The selected mode buttons illuminate blue.
- Pressing a button again cancels the selection.

3 Press [OK].

- If you switch to another screen without pressing the [OK] button, the settings will not be applied.

The mode that is currently specified is indicated by green characters.



Select the modes you want to use.

Confirm the selection.

g i-scan setting

Specify the i-scan modes that can be switched using a customize button on the touch panel, endoscope button, foot switch, or keyboard.

1 Press [>].

- The [i-scan setting] screen appears.
- The mode that is currently specified is indicated by green characters at the top of the screen.

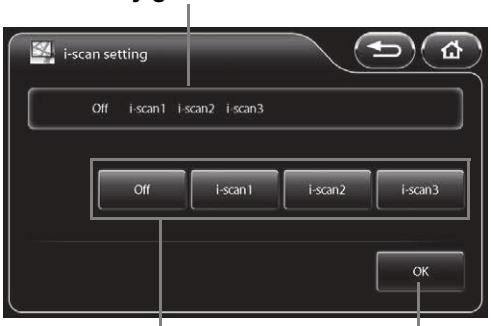
2 Press the buttons of the modes you want to use.

- The selected mode buttons illuminate blue.
- Pressing a button again cancels the selection.

3 Press [OK].

- If you switch to another screen without pressing [OK], the settings will not be applied.

The mode that is currently specified is indicated by green characters.



Select the modes you want to use.

Confirm the selection.

g Freeze scan

Set whether or not to use the freeze scan function.
[Off]: The image is displayed as is when the freeze function is executed.
[Short][Middle][Long]:
The image with the least blur is selected automatically from the images up to a few seconds before the freeze function was executed.
The amount of time for image selection increases in the following order:[Short],[Middle], and [Long].

1 Press [Off],[Short],[Middle] or [Long].

NOTE

When you use the freeze scan function, wait for the endoscopic image on the LCD monitor to show the effect of desired image processing before capturing the image.

[System] Tab

Pressing the [System] tab displays the following screen. The screen has four pages.

Display the setup menu for each of the categories.

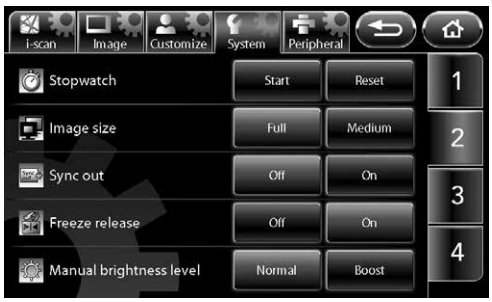
Return to the previous screen.

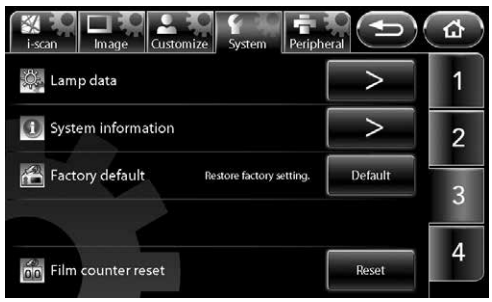
Return to the main screen.

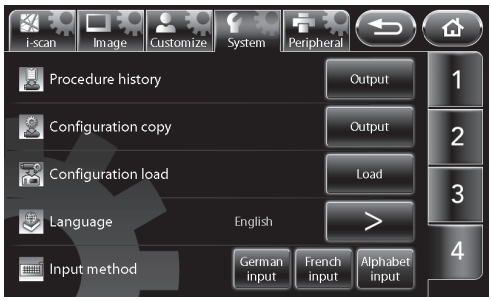
Change the page.

Display the advanced settings screen.

Press any of the buttons to configure the setting.







g Date & Time

Set the date and time to be displayed on the monitor.

1 Press [>]

- The [Date & Time] screen appears.

2 Set the time zone setting.

- When pressing [>] in the [Time zone setting], the [Time zone setting] will be displayed. ☞ "Time zone setting" (P.59)

3 Press the box of the item for which you want to change the setting from the year, month, day, hour, minute, and second items.

- The selected box turns blue, and ▲▼ appear above and below the box.

4 Press ▲▼ to change the setting.

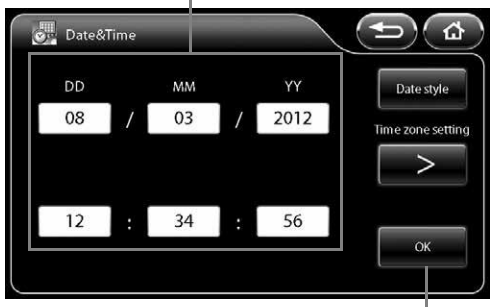
5 Repeat steps 3 and 4 to set all of the items you want to change.

- If you press [Date style], you can change the display format of the date. Each press of the button switches the order between “year/month/day,” “month/day/year,” and “day/month/year”.

6 Press [OK].

- If you switch to another screen without pressing the [OK] button, the settings will not be applied.

Press the box of the item for which you want to change the setting.



Confirm the settings.

n Time zone setting

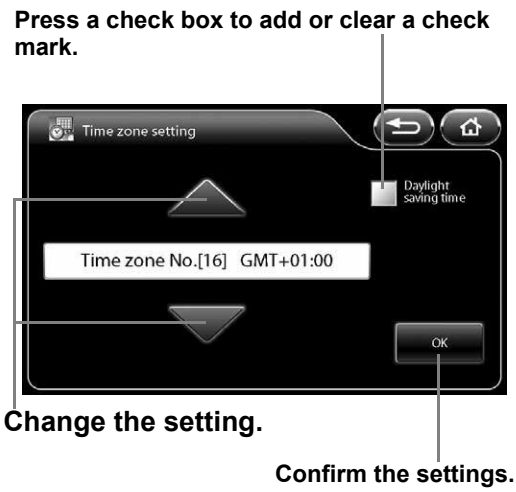
Set the time zone setting.

1 Press [>] of [Time zone setting] in the [Date & Time] screen.

- The [Time zone setting] screen appears.

2 ▲▼ to change the setting.

- Adding a check mark in the [Daylight saving time] check box adds 1 hour to the current time. Please add a check mark into the [Daylight saving time] check box manually during Daylight saving time period.



The time zone can be selected from the followings.

Time zone No.[01]	(GMT -12:00)	IDL (west side)
Time zone No.[02]	(GMT -11:00)	UTC-11
Time zone No.[03]	(GMT -10:00)	Hawaii
Time zone No.[04]	(GMT -09:00)	Alaska
Time zone No.[05]	(GMT -08:00)	PST (in the United States and Canada)
Time zone No.[06]	(GMT -07:00)	Arizona, Chihuahua, MST (in the United States and Canada)
Time zone No.[07]	(GMT -06:00)	Guadalajara, Mexico City, Monterrey, Saskatchewan, Central America, CST (in the United States and Canada)
Time zone No.[08]	(GMT -05:00)	Eastern Indiana, Bogota, Lima, Quito, EST(in the United States and Canada)
Time zone No.[09]	(GMT -04:30)	Caracas
Time zone No.[10]	(GMT -04:00)	Asuncion, Cuiaba, Santiago, AST (in Canada)
Time zone No.[11]	(GMT -03:30)	Newfoundland
Time zone No.[12]	(GMT -03:00)	Greenland, Salvador, Buenos Aires, Brasilia, Montevideo
Time zone No.[13]	(GMT -02:00)	UTC-2, Central Atlantic Ocean
Time zone No.[14]	(GMT -01:00)	Azores, Cape Verde
Time zone No.[15]	(GMT)	UTC, GMT, Dublin, Edinburgh, Lisbon, London, Monrovia, Reykjavik
Time zone No.[16]	(GMT +01:00)	Amsterdam, Berlin, Bern, Rome, Stockholm, Sarajevo, Windhoek, Warsaw, Zagreb, Brussels, Paris, Copenhagen, Madrid, Belgrade, Budapest, Ljubljana, West and Central Africa
Time zone No.[17]	(GMT +02:00)	Athens, Bucharest, Amman, Istanbul, Jerusalem, Cairo, Helsinki, Kiev, Sofia, Riga, Tallin
Time zone No.[18]	(GMT +03:00)	Kuwait, Riyadh, Nairobi, Baghdad, Kaliningrad, Minsk
Time zone No.[19]	(GMT +03:30)	Tehran
Time zone No.[20]	(GMT +04:00)	Abu Dhabi, Muscat, Yerevan, Caucasus Standard Time, Moscow, Baku, Saint Petersburg
Time zone No.[21]	(GMT +04:30)	Kabul
Time zone No.[22]	(GMT +05:00)	Islamabad, Karachi, Tashkent
Time zone No.[23]	(GMT +05:30)	Sri Jayewardenepura Kotte
Time zone No.[24]	(GMT +05:45)	Kathmandu
Time zone No.[25]	(GMT +06:00)	Astana, Ekaterinburg, Dhaka
Time zone No.[26]	(GMT +06:30)	Yangon
Time zone No.[27]	(GMT +07:00)	Novosibirsk, Bangkok, Hanoi, Jakarta
Time zone No.[28]	(GMT +08:00)	Ulan Bator, Kuala Lumpur, Singapore, Krasnoyarsk, Perth, Taipei, Beijing, Chongqing, Hong Kong, Urumqi
Time zone No.[29]	(GMT +09:00)	Irkutsk, Seoul, Osaka, Sapporo, Tokyo
Time zone No.[30]	(GMT +09:30)	Darwin
Time zone No.[31]	(GMT +10:00)	Canberra, Melbourne, Sydney, Guam, Port Moresby

Time zone No.[32]	(GMT +11:00)	Vladivostok, Solomon Islands, New Caledonia
Time zone No.[33]	(GMT +12:00)	Auckland, Wellington, Fiji, UTC+12
Time zone No.[34]	(GMT +13:00)	Samoa, Nuku'alofa

3 Press [OK].

- If you switch to another screen without pressing the [OK] button, the settings will not be applied.
- Make sure to set the date correctly.

g File storage settings (Still image)

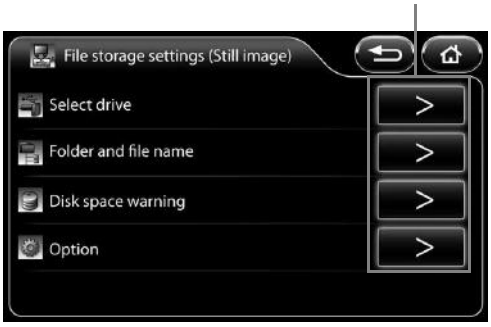
Set the method to save still images.

1 Press [>].

- The [File storage settings (Still image)] screen appears.

2 Configure the settings of [Select drive], [Folder and file name], [Disk space warning], and [Option].

Display the advanced settings screen.



n Select drive (Still image)

Set the "Image Recording Media" (P.91) as the destination for saving still images.

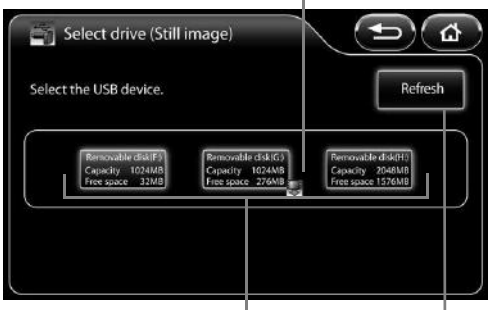
1 Press [>] of [Select drive] in the [File storage settings (Still image)] screen.

- The [Select drive (Still image)] screen appears. The Image Recording Media currently connected and the total size and free space of each Image Recording Media is indicated on the screen.
- If you connect Image Recording Media after displaying the [Select drive (Still image)] screen, press [Refresh] to perform recognition of the Image Recording Media.

2 Press the button of the Image Recording Media to use as the save destination.

- The selected Image Recording Media button illuminates blue.

Icon indicating that the Image Recording Media is selected as the save destination for video images.



Indicates the Image Recording Media currently connected and the total size and free space of each Image Recording Media.

Perform Image Recording Media recognition again.

NOTE

- Only one Image Recording Media can be set to save images at one time.
- Up to three Image Recording Media can be connected at one time. However, do not connect Image Recording Media via a USB hub.
- After replacing Image Recording Media, make sure you recheck that the [Select drive] setting is configured properly.
- High capacity Image Recording Media tends to take longer to be recognized by the system. Wait till the system recognizes the external module before start operating.

n Folder and file name (Still image)

Set the names of the folders and files generated in the PENTAX folder of the "Image Recording Media" (P.91) when still images are saved.

1 Press [>] of [Folder and file name] in the [File storage settings (Still image)] screen.

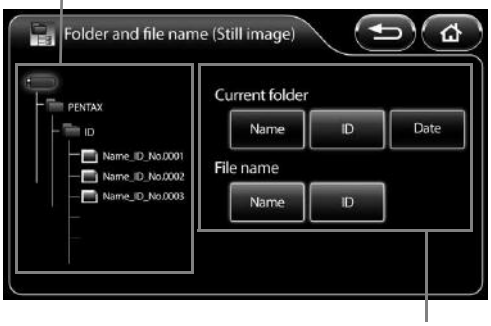
- The [Folder and file name (Still image)] screen appears.

2 Select [Name], [ID], or [Date] of [Current folder] to set the name.

3 Press [Name] or [ID] of [File name] to switch it on or off.

- Each press of a button switches the name on or off.
- In addition to [Name] or [ID], a consecutive number is automatically added to a file name. A four-digit number is added when either [Name] or [ID] is on, and an eight-digit number when both of them are off.

The current folder and file name settings are displayed in a folder tree.



Set the folder and file names.

n Disk space warning (Still image)

Set the threshold for displaying the "Image Recording Media" (P.91) free space warning message.

1 Press [>] of [Disk space warning] in the [File storage settings (Still image)] screen.

- The [Disk space warning (Still image)] screen appears.

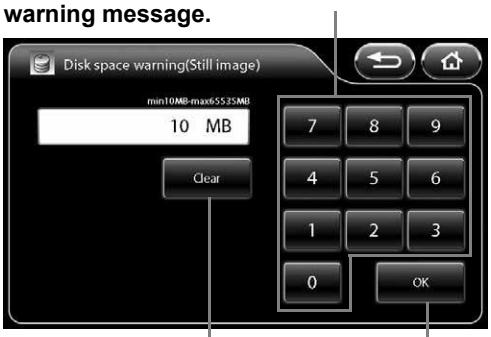
2 Set the threshold value for displaying a warning message by pressing the number buttons.

- You can set a value within the range of 10 to 65,535.
- Pressing [Clear] resets the value to 0.

3 Press [OK].

- If you switch to another screen without pressing the [OK] button, the settings will not be applied.
- If the free space of the Image Recording Media reaches the set value, the message “Check memory space (Still image).” appears on the monitor.

Set the value for which to display a warning message.



Reset the setting value.

Confirm the setting.

n Option (Still image)

Set options related to saving still images.

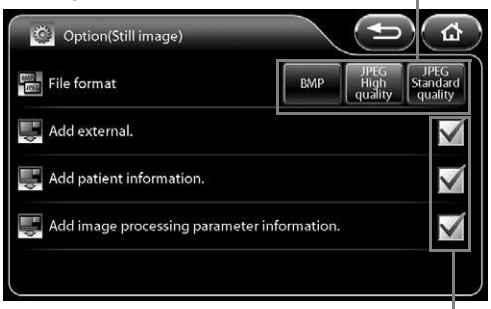
1 Press [>] of [Option] in the [File storage settings (Still image)] screen.

- The [Option (Still image)] screen appears.

2 Set each of the items.

- [File format]
  Select the setting for the format and compression rate for saving files from [BMP], [JPEG High quality], and [JPEG Standard quality].
- [Add external.] check box
  Add a check mark to save endoscopic images and external input images as one file while external input images are displayed in P-in-P mode.
- [Add patient information.] check box
  Add a check mark to save the patient's name, ID, and other patient information together with still images.
- [Add image processing parameter information.] check box
  Add a check mark to save the SE, CE, and other image processing parameter information together with still images.

Press any of the buttons to configure the setting.



Press a check box to add or clear a check mark.

NOTE

- Since lossy compression is used for JPEG images, it may result in the loss of details in images.
- Please make sure to check the JPEG image quality prior to use if it is stored in JPEG format.
- When the setting allows for simultaneous saving of endoscopic image and the external input image in a single file, the file containing both image (endoscopic image and external input image) will be saved in peripheral device also. (The peripheral device must be specified under "Add external." menu)
- While still image data remains in the processor during the process of capturing to a USB printer or saving to Image Recording Media, a white "○" is displayed on the bottom right of the monitor. Do not disconnect the USB printer or Image Recording Media or turn off the processor until the "○" disappears.
- Please try not to execute the next capture until the "○" disappears.
- When trying to capture an image while system is processing the image at the same time, wait for the endoscopic image on the LCD monitor to be switched before proceeding to capture the next image.
- When the Twin mode setup is made after freezing, an image processing is not reflected in the left side screen. In the case where the USB capture is performed as is, an image-processing parametric information is added to the still picture even if not checking [Add image processing parameter information.]of [Option (Still image)]. And the image-processing parametric information of the left side screen displays "-". Image processing of the left side screen will become effective after freezing release.

g File storage settings (Video image)

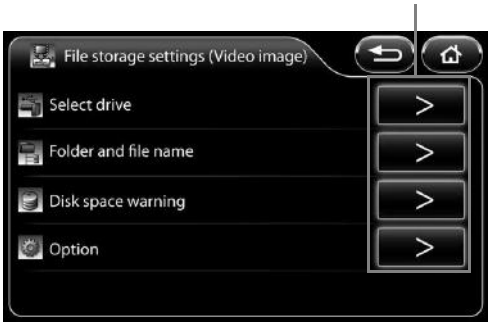
Set the method to save video images.

1 Press [>].

- The [File storage setting (Video image)] screen appears.

2 Configure the settings of [Select drive], [Folder and file name], [Disk space warning], and [Option].

Display the advanced settings screen.



n Select drive (Video image)

Set the "Image Recording Media" (P.91) as the destination to save video images.

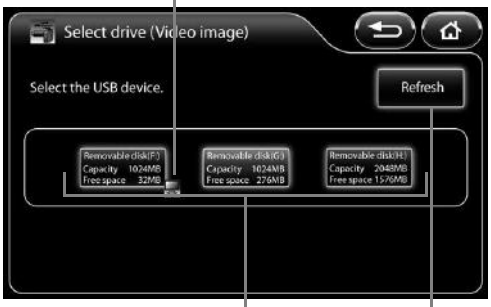
1 Press [>] of [Select drive] in the [File storage settings (Video image)] screen.

- The [Select drive (Video image)] screen appears. The Image Recording Media currently connected and the total size and free space of each Image Recording Media is indicated on the screen.
- If you connect Image Recording Media after displaying the [Select drive (Video image)] screen, press [Refresh] to perform recognition of the Image Recording Media.

2 Press the button of the Image Recording Media to use as the save destination.

- The selected Image Recording Media button illuminates blue.

Icon indicating that the Image Recording Media is selected as the save destination for still images.



Indicates the Image Recording Media currently connected and the total size and free space of each Image Recording Media.

Perform Image Recording Media recognition again.

NOTE

- Only one Image Recording Media can be set to save images at one time.
- Up to three Image Recording Media can be connected at one time. However, do not connect Image Recording Media via a USB hub.
- After replacing Image Recording Media, make sure you recheck that the [Select drive] setting is configured properly.
- High capacity Image Recording Media tends to take longer to be recognized by the system. Wait till the system recognizes the external module before start operating.

n Folder and file name (Video image)

Set the names of the folders and files generated in the PENTAX folder of the "Image Recording Media" (P.91) when video images are saved.

1 Press [>] of [Folder and file name] in the [File storage settings (Video image)] screen.

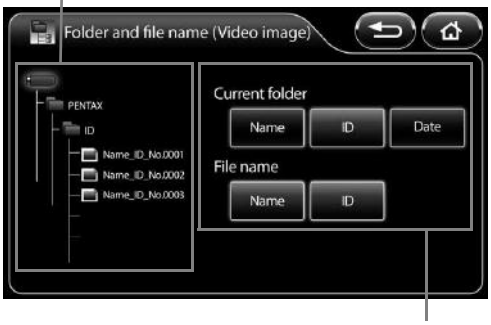
- The [Folder and file name (Video image)] screen appears.

2 Select [Name], [ID], or [Date] of [Current folder] to set the name.

3 Press [Name] or [ID] of [File name] to switch it on or off.

- Each press of a button switches the name on or off.
- In addition to [Name] or [ID], a consecutive number is automatically added to a file name. A four-digit number is added when either [Name] or [ID] is on, and an eight-digit number when both of them are off.

The current folder and file name settings are displayed in a folder tree.



Set the folder and file names.

n Disk space warning (Video image)

Set the threshold for displaying the "Image Recording Media" (P.91) free space warning message.

1 Press [>] of [Disk space warning] in the [File storage setting (Video image)] screen.

- The [Disk space warning (Video image)] screen appears.

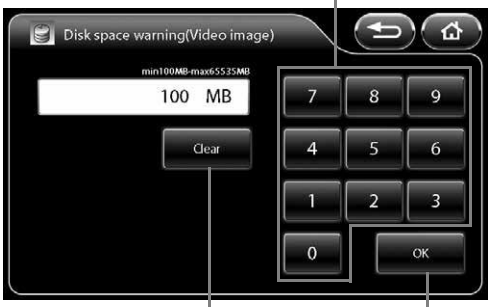
2 Set the threshold value for displaying a warning message by pressing number buttons.

- You can set a value within the range of 100 to 65,535.
- Pressing [Clear] resets the value to 0.

3 Press [OK].

- If you switch to another screen without pressing the [OK] button, the settings will not be applied.
- If the free space of the Image Recording Media reaches the set value, the message “Check memory space (Video image).” appears on the monitor.

Set the value for which to display a warning message.



Reset the setting value.

Confirm the setting.

n Option (Video image)

Set options related to saving video images.

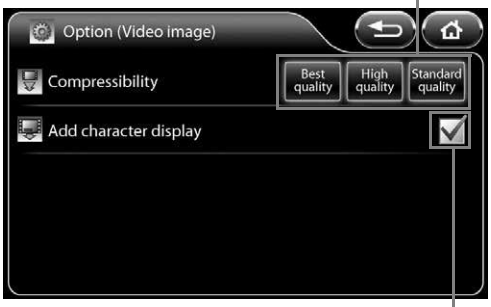
1 Press [>] of [Option] in the [File storage settings (Video image)] screen.

- The [Option (Video image)] screen appears.

2 Set each of the items.

- [Compressibility]
  Select the setting for the compression rate for saving files from [Best quality], [High quality], and [Standard quality].
- [Add character display.] check box
  Add a check mark to save the character information together with the video images.

Press any of the buttons to configure the setting.



Press a check box to add or clear a check mark.

NOTE

- “○ Rec” or the recording time is displayed on the monitor during the recording of video images. If the Image Recording Media is removed and inserted or the processor is turned off while “○ Rec” is displayed, the video images may not be played normally or other problems may occur.
- The maximum recording time varies depending on the setting of [Compressibility]. The maximum recording time is displayed in parenthesis on the monitor during recording.
  The maximum recording times for each [Compressibility] setting are as follows:
  [Best quality]: 15 minutes / [High quality]: 30 minutes / [Standard quality]: 50 minutes
- Minimum of 2 GB or more of availability is required in a Image Recording Media to record videos in each compression rate for maximum time period.
- The video images are automatically saved to Image Recording Media at the point in time that the maximum recording time is reached.
- Do not remove the Image Recording Media or turn off the processor during the message “Now saving.” when displayed on the monitor after stopping the video image recording.
- Once the recording is started, do not stop recording at least for 10 seconds, If the recording is terminated without recording certain amount of time, abnormal values may be displayed on the computer monitor. When the video recording time is short, the length of video recording time indicated in Windows 7 might differ from the actual recorded time.

n Operation checked Software

1 The video images (MPEG-2 TS format) generated by this video processor are checked their operation with the following software in "Operation check list". But this check only guarantees against its performance in our testing environment (PC) but not for your usage environment.

Test environment	
Item	**Contents**
CPU	Core2 Quad @2.66GHz
Memory	4GB
OS	Windows 7 Ultimate 32bit
Monitor	1920 x 1200 resolution

2 For some software, the operation check is done after installing Service Pack.

3 As for the device drivers like Graphics Card, etc., replay and edit in the latest condition.

4 As to the each operation method of software, contact to the customer service of each software manufacturer.

5 In following "Operation check list", "○" means that check has been done, and "-" means inoperative.

6 "○" of "Sound replay" means the sound replayable case during the movie replay.

7 "○" is marked in case that all processes like loading, trimming, saving and format conversion are possible against the movie files (MPEG-2 TS type) generated by this product or in the case replayable the edited movie/audio file by each software.

Operation check list					
Name of software	**Version Edition**	**Manufacturer**	**Operation check**		
			Movie replay	**Sound replay**	**Edit**
Windows Media Player	11	Microsoft Corp.	○	-	-
PowerDVD	Ver.11, 12 Ultra	CyberLink Corp.	○	○	-
Adobe Premiere	Ver.10 Elements	Adobe System Inc.	○	○	○

⚠CAUTION

Don't make a diagnosis based on the digital file of still image or video image generated by this video processor.

NOTE

- The usage of the monitor of this video processor's system configuration example is recommendable when replaying the still images and video images generated by this video processor by PC. If not, please be in mind that its reproduction characteristic may be inadequate and its color reproducibility and gradation may be variable.
- Use DVI-D output for outputting from PC when replaying the still images and video images. Or its color reproducibility and gradation may become inadequate.
- On rare occasions, the seek bar or the seek time does not be displayed appropriately.

g Display setting

Set the display format of the monitor.

[16:9 mode1] Setting for HD monitor display (The character information is displayed on the right side of the endoscopic image.)(The DVI-D signal is output from the DVI connector.)

[16:9 mode2] Setting for HD monitor display (The character information is displayed at the top and bottom of the endoscopic image.)(The DVI-D signal is output from the DVI connector.)

[4:3] Setting for SD monitor display(The VGA signal is output from the DVI connector.)

1 Select [16:9 mode1], [16:9 mode2], or [4:3].

NOTE

If [4:3] is selected, images cannot be output from the HD-SDI connector.

g Scope eject

Use this button when you want to remove and insert an endoscope while the processor is on.

1 Press and hold [Eject] for 2 seconds or longer.

- The message “OK to eject.” appears on the touch panel and the monitor.
- If an endoscope is not connected, the button will not function.

2 Remove the endoscope from the processor.

NOTE

- Reconnect the endoscope when you want to use it again.
- If the “Eject” button does not change from blue to black even when the endoscope is reconnected, please try reconnecting the endoscope.

g Stopwatch

Use the stopwatch function.

1 Press [Start].

- The stopwatch “S 00:00:00” indication is displayed below the time indication on the monitor.
- To pause the stopwatch, press [Stop]. To cancel the pause, press [Restart].
- Pressing [Reset] resets the counter to “00:00:00.” Pressing [Reset] when the counter is “00:00:00” ends the stopwatch function.

g Image size

Change the display size of endoscopic images.

[Full] Set the display size of the endoscopic image to normal size.

[Medium] Set the display size of the endoscopic image to smaller than normal size.

1 Press [Full] or [Medium].

NOTE

- In twin mode, the display size does not change even if you change the [Image size] setting. The [Image size] setting will be applied when you set [Twin mode] to [Off].
- During analog output(exclude VGA output) of the endoscopic image, the image is always displayed in [Full] size even if the [Image size] setting is changed.

g Sync out

Set the output from the VIDEO OUT/SYNC OUT connector to a synchronous signal for an external strobe device.

[Off] Video signals are output.

[On] Synchronous signals for a strobe device are output.

1 Press [Off] or [On].

g Freeze release

Set the method for freeze release.

[Off] The frozen image is maintained even after the still image is saved. Release the frozen image manually.

[On] Freeze is released automatically when the still image is saved.

1 Press [Off] or [On].

g Manual brightness level

Set the brightness adjustment level by endoscope type for when the exposure control method is set to [MANUAL].

[Normal] Use this mode for the observation with normal brightness adjustment level.

[Boost] Use this mode for the observation with higher brightness adjustment level. This mode is intended for the use with an otolaryngology endoscope with small diameter.

1 Press [Normal] or [Boost].

⚠CAUTION

- Use [Normal] mode at first for any observation.
- If the [Boost] mode is used when a gastrointestinal endoscope with large diameter is connected, do not perform observation for a long time with brightness level +4 or higher. Failure to do so could result in a burn injury.

NOTE

If an electronic endoscope is connected, [Boost] cannot be selected.

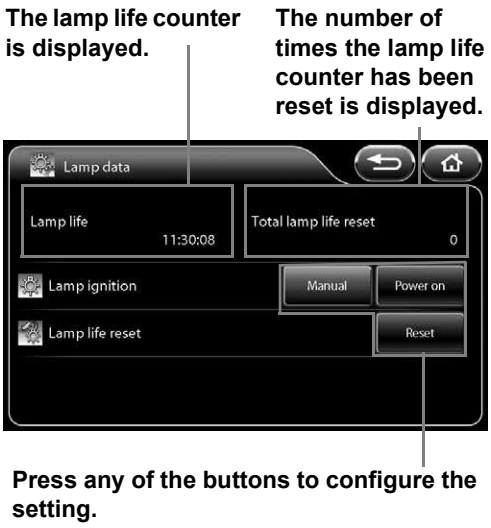
g Lamp data

Confirm the lamp usage time, configure the lamp ignition method setting, etc.

1 Press [>].

- The [Lamp data] screen appears.

2 Configure the [Lamp ignition] setting or reset the lamp life counter with [Lamp life reset].



n Lamp ignition

Set the lamp ignition method.

[Manual] The lamp can be turned on manually from the touch panel or keyboard.

[Power on] The lamp turns on automatically when the processor is turned on.

1 Press [Manual] or [Power on].

n Lamp life reset

Reset the lamp life counter.

1 Press [Reset].

- The confirmation screen appears.

2 Press [Yes].

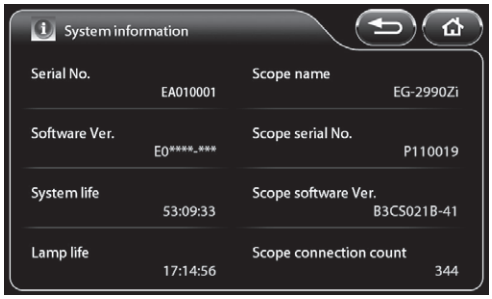
- The lamp life counter is reset to “00:00:00.”
- Pressing [No] returns to the previous screen without resetting the lamp life counter.

g System information

Displays the system information of the processor.

1 Press [>].

- The [System information] screen appears.
- The “Serial No.” “Software Ver.” “System life” “Lamp life” “Scope name” “Scope serial No.” “Scope software Ver.” and “Scope connection count” information appear on the screen.



g Factory default

Reset all settings to their default values.

1 Press [Default].

- The confirmation screen appears.

2 Press [Yes].

- Pressing [No] returns to the previous screen without resetting the settings.

g Film counter reset

Reset the film counter.

1 Press [Reset].

- The film counter indication on the monitor is reset to “1.”

g Procedure history

Save the patient’s name, recording date and time, and other procedure history to "Image Recording Media" (P.91).

1 Press [Output].

- The [Procedure history] screen appears. The Image Recording Media currently connected and the total size and free space of each Image Recording Media is indicated on the screen.
- If you connect Image Recording Media after displaying the screen, press [Refresh] to perform recognition of the Image Recording Media.

2 Press the button of the Image Recording Media to be used as the save to destination.

3 Press [Output].

- The procedure history is saved to Image Recording Media.

Indicates the Image Recording Media currently connected and the total size and free space of each Image Recording Media.

Perform Image Recording Media recognition again.

Output the procedure history.

NOTE

- The procedure history for up to 1,000 procedures is saved to a file in CSV format.
- If the procedure history is saved properly, the message “Procedure history saved.” appears on the monitor. If it is not saved properly, the message “Copy failed.” appears on the monitor.

g Configuration copy

Copy the system configuration data of the processor to "Image Recording Media" (P.91).

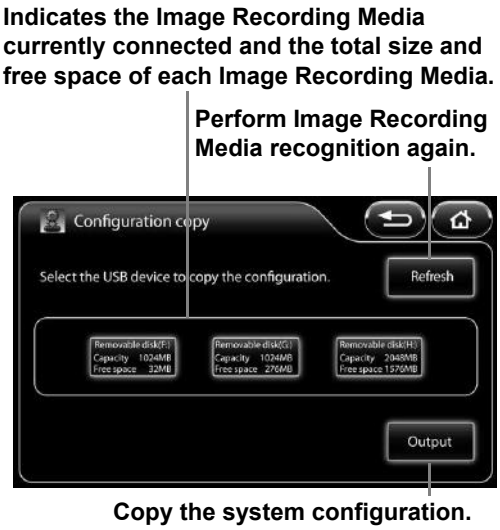
1 Press [Output].

- The [Configuration copy] screen appears. The Image Recording Media currently connected and the total size and free space of each Image Recording Media is indicated on the screen.
- If you connect Image Recording Media after displaying the screen, press [Refresh] to perform recognition of the Image Recording Media.

2 Press the button of the Image Recording Media to be used as the copy to destination.

3 Press [Output].

- The system configuration data is copied to Image Recording Media.



NOTE

If the configuration data is copied properly, the message “Configuration saved.” appears on the monitor. If it is not copied properly, the message “Copy failed.” appears on the monitor.

5

g Configuration load

Load the system configuration data saved in "Image Recording Media" (P.91) to the processor.

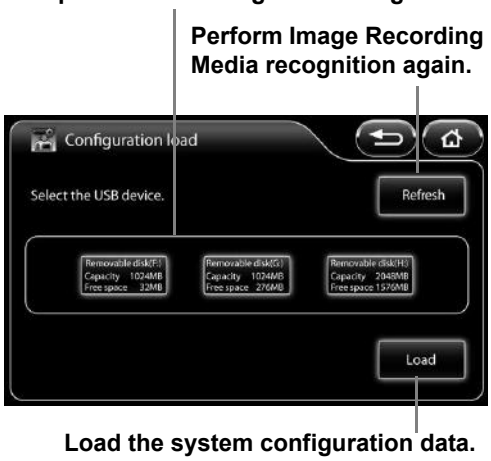
1 Press [Load].

- [Configuration load] screen appears. The Image Recording Media currently connected and the total size and free space of each Image Recording Media is indicated on the screen.
- If you connect Image Recording Media after displaying the screen, press [Refresh] to perform recognition of the Image Recording Media.

2 Press the buttons of the Image Recording Media with the system configuration data to load.

3 Press [Load].

- The system configuration data is loaded to the processor.



NOTE

- The system configuration data is loaded from the file “EPK-i7010ConfigurationDataEx.dat” in Image Recording Media.
  The following files cannot be read.
  "EPK-i7000ConfigurationData.dat", "EPK-i7010ConfigurationData.dat"
- The files saved other model's system settings cannot be read.
- If there is no data to load in Image Recording Media, the message “No data.” appears.
- Configuration load is not available while the endoscope is being connected.

g Language

Change the display language of the touch panel menus.

1 Press [>].

- The [Language] screen appears.

2 Select [English], [Français], [Deutsch], [Español], [Italiano], [Magyar], [Polski], [Русский], or [中文].

- [English] The menus are displayed in English.
- [Français] The menus are displayed in French.
- [Deutsch] The menus are displayed in German.
- [Español] The menus are displayed in Spanish.
- [Italiano] The menus are displayed in Italian.
- [Magyar] The menus are displayed in Hungarian.
- [Polski] The menus are displayed in Polish.
- [Русский] The menus are displayed in Russian.
- [中文] The menus are displayed in Chinese. (Only products for China display Chinese.)

The language that is currently specified is indicated by green characters.

NOTE

In case that any incomprehensible language is displayed, user(s) should refer to the English IFU to manipulate.

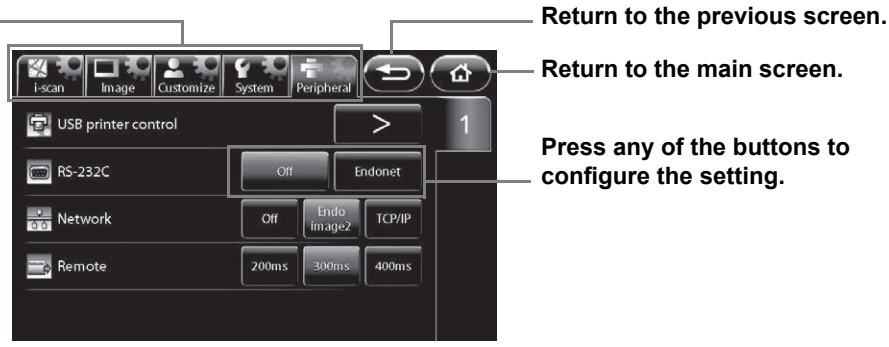
g Input method

Set the input method of the keyboard.
[Alphabet input] Input English alphabet letters.
[French input] Input French alphabet letters.
[German input] Input German alphabet letters.

1 Select [Alphabet input], [French input], or [German input].

[Peripheral] Tab

Pressing the [Peripheral] tab displays the following screen. The screen has one page.



g USB printer control

Capture and output endoscopic images to the USB printer or print captured images.

1 Press [>].

- The [USB printer control] screen appears.

2 Select [1-up], [2-up], or [4-up] to set [Multi picture mode].

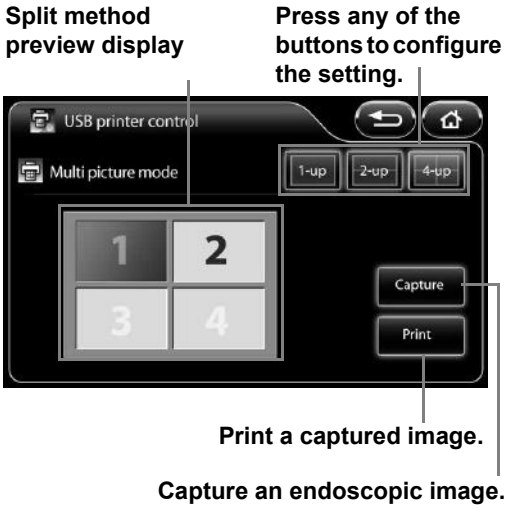
- The set split method is displayed in a preview.

3 Press [Capture].

- The endoscopic images are captured and output to the USB printer. "○" is displayed on the monitor during the capture.
- The boxes in the preview display illuminate blue. When [2-up] or [4-up] is set for [Multi picture mode], the boxes for the number of captured images illuminate blue in numerical order, and the box number in which the next image will be captured flashes.

4 Press [Print].

- The captured endoscopic images are printed.
- An animation indicates the print progress.



CAUTION

- Do not connect more than one USB printer or connect a printer via a USB hub.
- A white "○" is displayed on the monitor until printing has finished. Do not turn the processor off while "○" is displayed.

NOTE

If a USB printer is not connected, [USB printer control] is not available.

g RS-232C

Set the device connected to the RS-232C connector.

1 Press [Off] or [Endonet].

g Network

Set the network connected to via the RJ45 connector.

1 Press [Off] or [Endoimage2].

g Remote

Set the active period for output from the REMOTE connector.

1 Select [200ms], [300ms], or [400ms].

Keyboard Operations

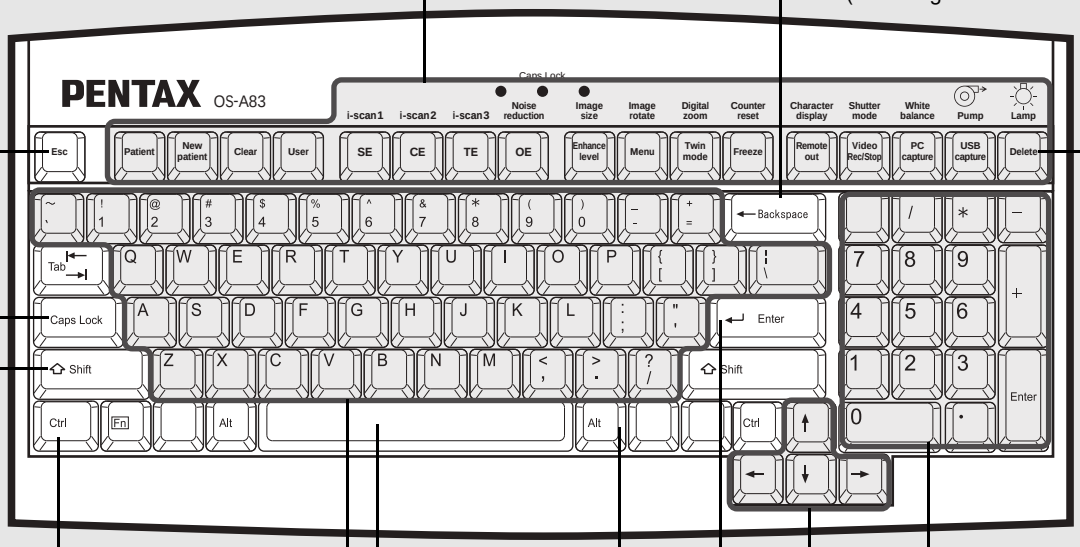
WARNING

Do not use the keyboard as well as the keyboard menu while the message “Network/File system loading” is being displayed on the bottom right corner of the monitor screen.

CAUTION

For the EPK-i7010 processor, use the following PENTAX Medical keyboard OS-A83.

g Key Assignment



Backspace Key
Used to delete entered characters (on the left of the cursor).

Esc (Escape) Key
Used to cancel input and close submenus.

Function Keys
Refer to the next page.

Delete Key
Used to delete entered characters (on the right of the cursor).

Ctrl (Control) Keys
Refer to the next page.

Spacebar
Used to enter a space.

Numeric Keypad
Used to enter numbers and arithmetic symbols, and confirm entered numbers.

Shift Keys
Used when entering uppercase letters with the letter keys while the caps lock is disabled and to enter special characters. Hold down a Shift key while pressing the alphanumeric keys.

Alphanumeric Keys
Used to enter alphanumeric characters and special characters.

Caps Lock Key
Used when entering uppercase letters.

Alt Key
Used when increasing or decreasing a numerical value by a large amount in the white balance adjustment screen.

Cursor Keys
Used to move the cursor in the directions indicated by the arrows.

Enter Key
Used to confirm entered information or a selected item.

CAUTION

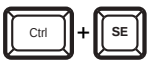
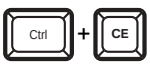
The cursor does not appear when typing the text. In case you need to correct the text, delete the text and re-type it again.

NOTE

- Do not use a sharp object such as the tip of a pen to press the keys on the keyboard.
- Do not use the end of the light guide of the endoscope to press keys.
- Only the keyboard designed specifically for use with the processor can be used (OS-A83).
- The above illustration may not be true to the real keyboard.

g Function Keys

The following list shows the functions assigned to the function keys of the keyboard designed specifically for use with the processor.

Function Keys Keyboard OS-A83	Key Name	Function Outline
	[Patient]	Display the patient list.
	[New patient]	Register new patient data.
	[Clear]	Clear patient data or user data.
	[User]	Display the user list.
	[SE]	Switch the SE level to a level available in [SE setting]. (It cannot be processed simultaneously with [OE] or the structure enhancement mode [a1 to a6].)
	[CE]	Switch the CE level to a level available in [CE setting]. (It cannot be processed simultaneously with [OE].)
	[TE]	Switch the TE mode to a mode available in [TE setting]. (It cannot be processed simultaneously with [OE].)
	[OE]	Switch the OE mode to a mode available in [OE setting]. (It cannot be processed simultaneously with [SE] [CE] [TE].)
	[Enhance level]	Switch the edge enhancement/structure enhancement level to a level available in [Enhancement setting].
	[Menu]	Display the Setup screen.
	[Twin mode]	Switch twin mode on or off.
	[Freeze]	Switch between still image mode and video mode.
	[Remote out]	Output a signal from the REMOTE connector.
	[Video Rec/Stop]	Start/stop recording video.
	[PC capture]	Output the image to a PC via Endoimage2.
	[USB capture]	Output images to Image Recording Media.
	[i-scan1]	Switch the [i-scan1] i-scan mode on or off.
	[i-scan2]	Switch the [i-scan2] i-scan mode on or off.

Function Keys Keyboard OS-A83	Key Name	Function Outline
Ctrl + TE	[i-scan3]	Switch the [i-scan3] i-scan mode on or off.
Ctrl + OE	[Noise reduction]	Change the noise reduction level.
Ctrl + Enhance level	[Image size]	Change the endoscopic image display size.
Ctrl + Menu	[Image rotate]	Change the endoscopic image display orientation.
Ctrl + Twin mode	[Digital zoom]	Change the endoscopic image display magnification.
Ctrl + Freeze	[Counter reset]	Reset the film counter.
Ctrl + Remote out	[Character display]	Change the character display on the monitor.
Ctrl + Video Rec/Stop	[Shutter mode]	Change the shutter mode.
Ctrl + PC capture	[White balance]	Display the [White balance] screen.
Ctrl + USB capture	[Pump]	Display the [Pump] screen.
Ctrl + Delete	[Lamp]	Display the [Lamp] screen.

⚠CAUTION

Do not press multiple keys in combinations not described above.

Operations in the Keyboard Menu Screen

Pressing the [Patient], [User], [Menu], [White balance], [Pump], or [Lamp] key displays the keyboard menu screen on the monitor.
The keyboard menu screen consists of the [Patient list preset], [User list preset], and [Setup] tabs.

1 Press the [←] or [→] key to select a tab.

2 Press the [↑] or [↓] key to select an item and press the [→] key.

- Some settings require pressing the [←] or [→] key repeatedly to change the value and some settings require advanced settings to be configured in a sub screen.

3 Press the [Enter] or [Esc] key.

- Pressing the [Enter] key returns to the normal screen where any changes to the settings are reflected.
- Pressing the [Esc] key returns to the normal screen where any changes to the settings are not reflected.

5

Operations in the [Patient list preset] Tab

g Registering New and Editing Existing Patient Data

Display the patient list. Then, register new patient data or edit registered patient data. You can register the following patient data items: [Name], [ID], [Age], [Sex], and [Comment].

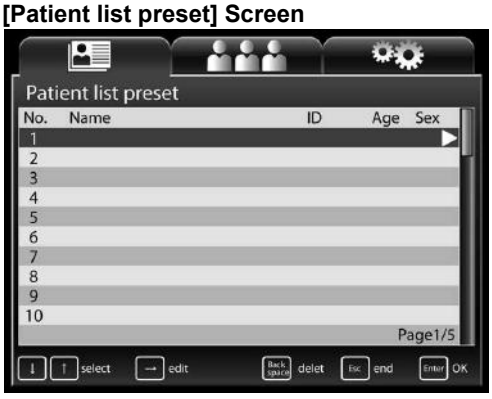
1 Press the [←] or [→] key in the keyboard menu screen to select the [Patient list preset] tab.

- The [Patient list preset] screen (registration numbers 1 to 10) appears.

2 Press the [↑] or [↓] key to select a patient. To register a new patient, select a number with no patient registered. To edit existing patient data, select the corresponding patient.

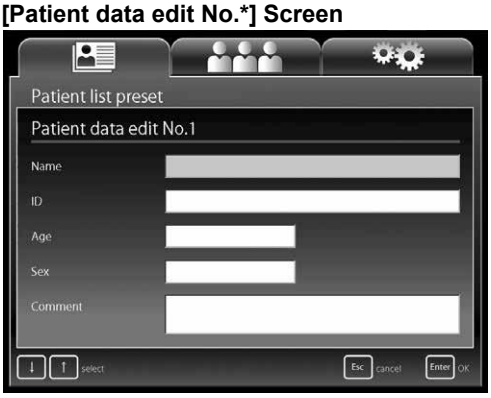
- To change the page of the patient list, press the [↑] or [↓] key to align the cursor with [Page */*] and then press [←] or [→].
- To delete the selected patient data, press the [Backspace] or [Delete] key. Also, to delete all patient data, press the [Clear] key. Pressing each key displays the deletion confirmation message. Select [Yes] or [No] and press the [Enter] key. If you select [Yes], the patient data is deleted from the patient list.

[Patient list preset] Screen



3 Press the [→] key.

[Patient data edit No.*] Screen



- The [Patient data edit No.*] screen for a new patient or the selected patient appears.
- Follow the procedure below to enter or change data in the [Patient data edit No.*] screen. Be sure to enter a name in the [Name] field.

  ① Press the [↑] or [↓] key to select an item.

  ② Press the alphanumeric keys to enter or change data.
  Press the [Backspace] key in the [Patient data edit No.*] screen to delete one character on the left of the cursor. Press the [Delete] key to delete one character on the right of the cursor.

  ③ Press the [Enter] or [Esc] key to return to the [Patient list preset] screen.
  Pressing the [Enter] key reflects any data entered and changes made and pressing the [Esc] key discards any data entered and changes made.
  Pressing the [Esc] key after changing data displays the change cancellation confirmation message. Select [Yes] to return to the [Patient list preset] screen. Select [No] to return to the [Patient data edit No.*] screen.

4 To enter or change data for another patient, press the [↑] or [↓] key to select a patient and repeat Step 3.

5 Press the [Enter] or [Esc] key.

- Press the [Enter] key to return to the normal screen where the information of the patient selected in the [Patient list preset] screen is displayed.
- Press the [Esc] key to return to the normal screen displayed prior to the [Patient list preset] screen.

⚠CAUTION

- If the capture function is enabled, do not use any special symbols such as the ones below.
  Examples of symbols not to use: / . * ? " < > : \ |

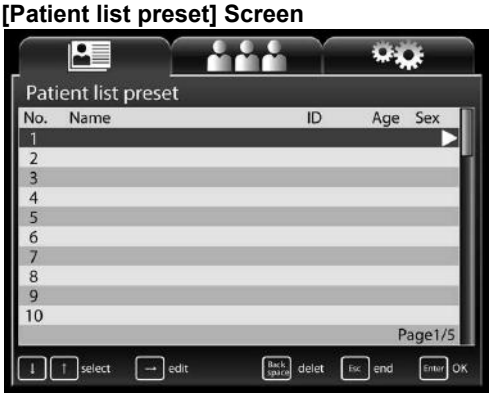
5

g Deleting Patient Data

Press the [Backspace] or [Delete] key while the [Patient list preset] is displayed to delete the data for that patient.

1 Press the [Backspace] or [Delete] key.

[Patient list preset] Screen



- A confirmation message for deleting the data appears.
- Select [Yes] to delete the displayed patient data. Select [No] to keep the registered data.

2 Press the [←] or [→] key to select [Yes] or [No] and press the [Enter] key.

- The [Patient list preset] screen reappears.
- Press the [Esc] key to return to the [Patient list preset] screen without deleting patient data.

g Registering New and Editing Existing User Data

Display the user preset list. Then, register new user data or edit registered user data. You can register the following user data items: [User name], [Character display], [Assign scope buttons & foot SW], [Picture data], and [Picture data initialize].

1 Press the [←] or [→] key in the keyboard menu screen to select the [User list preset] tab.

- The [User list preset] screen (registration numbers 1 to 10) appears.

[User list preset] Screen

2 Press the [↑] or [↓] key to select a user. To register a new user, select [New] or a number with no user registered. To edit existing user data, select the corresponding user.

- To change the page of the user list, press the [↑] or [↓] key to align the cursor with [Page */*] and then press [←] or [→].
- To delete the selected user data, Press the [Backspace] or [Delete] key. Pressing each key display the deletion confirmation message. Select [Yes] or [No] and press the [Enter] key. If you select [Yes], the selected user data is deleted from the user list.
- To delete all user data, press the [Clear] key. Pressing the key displays the deletion confirmation message. Select [Yes] or [No] and press the [Enter] key. The deletion confirmation message appears again. If you select [Yes] again, all user data is deleted from the user list.

3 Press the [→] key.

- The [User data edit No.*] screen appears.
- Follow the procedure below to enter or change data in the [User data edit No.*] screen.

  ① Press the [↑] or [↓] key to select an item.

  ② Press the [→] key. The corresponding setup screen appears.

  ③ Press the alphanumeric keys to enter or change data. Press the [↑], [↓], [←], and [→] keys to select items and configure the settings.

  ④ Press the [Enter] or [Esc] key. The [User list preset] screen reappears.
  Pressing the [Enter] key reflects any data entered and changes made and pressing the [Esc] key discards any data entered and changes made.

[User data edit No.*] Screen

4 To enter or change other data, press the [↑] or [↓] key to select a user and repeat Step 3.

5 Press the [Enter] or [Esc] key.

- The normal screen reappears.
- Press the [Enter] key to return to the normal screen where the information of the user selected in the [User list preset] screen is displayed.
- Press the [Esc] key to return to the normal screen displayed prior to the [User list preset] screen.

g Settings in the [User data edit No.*] Screen

You can configure the following settings for the user selected in the [User list preset] screen.

[User name]

Enter the name of the user.

During user input, press the [Backspace] key to delete one character on the left of the cursor. Press the [Delete] key to delete one character on the right of the cursor.

[Character display]

Set the items to display on the monitor. Select [On] for each of the [Patient name], [ID], [Age], [Sex], [User name], [Facility name], [Comment], [Date], and [Film counter] items you want to display, and [Off] for each of the items you do not want to display.

[Assign scope buttons & foot SW]

Assign a function to each endoscope buttons 1, 2, 3 and 4 and foot switches L and R.

☞ "Assign scope buttons" (P.48)
☞ "Assign foot switch" (P.51)

[Picture data]

Configure the image processing settings for endoscopic images.

- [SE] Select [Off] or one of six levels for the SE (surface enhancement) display setting.
- [CE] Select [Off] or one of six levels for the CE (contrast enhancement) display setting.
- [Enhancement] Select [Off] or one of two types × six levels for the edge enhancement/structure enhancement display setting.
- [Average/Peak] Select [Average] or [Peak] for the light measuring method.
- [Noise reduction] Select [Off], [Low], [Medium], or [High] for the noise reduction level.
- [Sub screen setting]
  - [Sub screen delay] Set the display of the sub screen to be delayed when the freeze function is executed.
    - [Off] The sub screen is displayed immediately after the freeze function is executed.
    - [On] The sub screen is displayed shortly after the freeze function is executed.
  - [Sub screen position] Select [Upper Right] or [Upper Left] for the position of the sub screen displayed on the monitor when using an endoscope (except when using a side viewing endoscope).
  - [Sub screen position (ERCP)] Select [Upper Right] or [Upper Left] for the position of the sub screen displayed on the monitor when using a side viewing endoscope (ED series).
- [Manual brightness level] Select one of 11 levels for the brightness setting when exposure control is set to [MANUAL].
- [Auto brightness level] Select one of 11 levels for the brightness setting when exposure control is set to [AUTO].

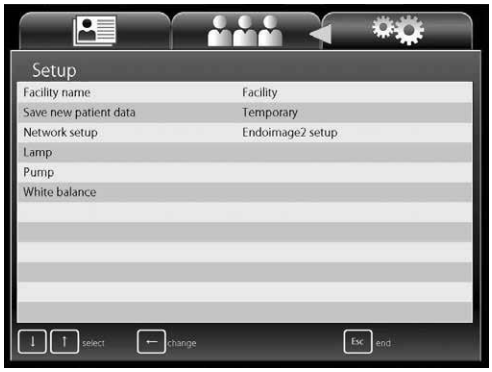
[Picture data initialize]

Restore the endoscopic image settings to their initial values. Select [Yes] and then press the [Enter] key in the confirmation screen that appears. Select [No] or press the [Esc] key to return to the [User data edit No.*] screen without initializing the settings.

Settings in the [Setup] Tab

Configure the settings related to the processor unit and peripheral devices.

[Setup] Screen



[Facility name]

Enter the hospital name.

[Save new patient data]

Set the registration method for registering patient information with the [New patient] key.

- [List+Temporary] The information is saved to the patient list.
- [Temporary] The registered information is only reflected in the monitor screen as temporary data.

[Network setup]

Configure the settings for the network to connect to via the RJ45 connector. The items that can be set in [Network setup] vary depending on the setting of [Network] in the [Peripheral] tab on the touch panel.

- [Endoimage2 setup] (when [Network] is set to [Endoimage2])
  - [Processor setup]
    - [DHCP mode]

Select [Enable] or [Disable]. If you select [Enable], the settings for [IP address], [Subnet mask], and [Default gateway] become invalid.

[IP address] / [Subnet mask] / [Default gateway]

Follow the procedure below to enter or change settings.

① Press the [←] or [→] key to select an item when entering the four items separated by "."

② Press the alphanumeric keys or the keys on the numeric keypad to enter or change the numbers. Each press of the [Backspace] key deletes one character on the left of the cursor. Each press of the [Delete] key deletes one character on the right of the cursor.

[Password]

Press the alphanumeric keys to enter a password. Only alphanumeric characters can be used (a to z, A to Z, and 0 to 9) and up to 12 characters can be entered. The password is case sensitive. Leave the field blank if you do not wish to set a password.

[Authorization]

Configure the network settings for the connection destination. Use the numeric keypad to configure of the [Connect ID] settings. Use alphanumerical keys to enter the Connect ID. The number of characters that can be used for the connect ID is between 6 and 12. Alphabet use in the connect ID is case sensitive.

- [iPro setup] (when [Network] is set to [TCP/IP])

[Processor setup]

[DHCP mode]

Select [Enable] or [Disable]. If you select [Enable], the settings for [IP address], [Subnet mask], and [Default gateway] become invalid.

[IP address] / [Subnet mask] / [Default gateway]

Follow the procedure below to enter or change settings.

① Press the [←] or [→] key to select an item when entering the four items separated by "."

② Press the alphanumeric keys or the keys on the numeric keypad to enter or change the numbers. Each press of the [Backspace] key deletes one character on the left of the cursor. Each press of the [Delete] key deletes one character on the right of the cursor.

[Password]

Press the alphanumeric keys to enter a password. Only alphanumeric characters can be used (a to z, A to Z, and 0 to 9) and up to 12 characters can be entered. The password is case sensitive. Leave the field blank if you do not wish to set a password.

[iGate setup]

[iGate address] / [Gateway port] / [Active port] / [Maintenance port]

Follow the procedure below to enter or change settings.

① Press the [←] or [→] key to select an item when entering the four items separated by "."

② Press the alphanumeric keys or the keys on the numeric keypad to enter or change the numbers. Each press of the [Backspace] key deletes one character on the left of the cursor. Each press of the [Delete] key deletes one character on the right of the cursor.

⚠CAUTION

- Do not operate the processor when there is an IP address conflict.
- Once an IP address conflict occurs, set the correct IP address, and turn the processor off and then on again.

[Lamp]

Turn the lamp on or off.

- [On] Turn on the lamp.
- [Off] Turn off the lamp.

[Pump]

Set the pump level or operate/stop the pump.

- [Pump level] Press [←] or [→] key to set the pump to one of five levels.
- [On] Operate the pump.
- [Off] Turn off the pump.

[White balance]

Set the white balance of the endoscope.

- [White balance] Adjust the white balance of the connected endoscope.
- [R gain] Display the red gain value of the endoscope (K series only). Press the [←] or [→] key to adjust the value. Pressing the [Alt] key and [←] or [→] key simultaneously increases or decreases the value in increments of 10.
- [B gain] Display the blue gain value of the endoscope (K series only). Press the [←] or [→] key to adjust the value. Pressing the [Alt] key and [←] or [→] key simultaneously increases or decreases the value in increments of 10.
- [Reload] Restore the state before the white balance was adjusted.(K series only)

6 Maintenance

After Use

Follow the procedure below after use.

⚠CAUTION

Make sure no water spills on the processor when you are performing the after care procedure. In particular, getting the connector parts and ventilation grids wet may cause a malfunction.

1 Turn off the peripheral devices.

⚠CAUTION

Turning off the processor prior to turning off any connected peripheral devices may cause the peripheral devices to malfunction.

NOTE

When turning off the peripherals of the processor, follow the instructions in the IFU for each peripheral device.

2 Press ⏻ to turn off the processor.

3 Disconnect the power plug, endoscope, and water bottle assembly. (Refer to Figure 6.1.)

NOTE

Always turn OFF the processor BEFORE disconnecting an endoscope.

⚠WARNING

Recommend irrigation devices that are reprocessed after every patient use or recommend disposable irrigation devices.

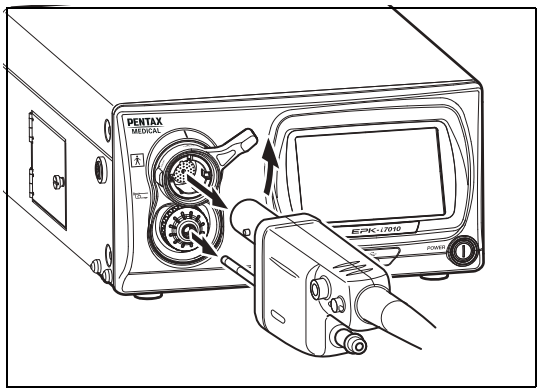


Figure 6.1

4 Wipe the surfaces of the processor with a gauze dampened with 70-90% ethyl or isopropyl alcohol.

- The procedure below should be followed to decontaminate the surface of this video processor that is suspected of being contaminated.

① Wipe the surface with gauze lightly dampened with a detergent (neutral pH, low foaming, with or without enzymes, mild/compatible with PENTAX Medical product, etc.)

② Wipe the same areas with gauze lightly dampened with clean water (to remove residual detergent).

③ Wipe the processor with dry gauze or lint-free cloth to remove remaining water/fluids.

④ Wipe all of the surfaces with gauze dampened with 70-90% ethyl or isopropyl alcohol.

NOTE

- Do not allow liquid to splash onto/into the processor. In particular, make absolutely sure that the connector interfaces and air intake vents do not get wet. Do not use harsh chemicals, cleaning agents, or the like when wiping the front panel of the processor because doing so may result in a malfunction of the processor. Be sure to use ethanol for disinfection when wiping the surfaces.
- Do not use spray-type medical agents such as rubbing alcohol directly to the video processor. Medical agents might enter the video processor through the air intake vents, etc. and may result in property-damage.

⚠CAUTION

- If the processor is turned off prior to turning off any connected peripheral devices, it may result in malfunction of the peripheral devices.
- Make sure that no water spills on the processor when you perform the aftercare procedure. In particular, getting water into the connector parts and air intake vents may result in malfunction in the processor.

Observe the following points when storing the processor.

- Be sure to turn off the processor and disconnect the power plug prior to storage.
- Do not store the processor in a location with high temperature and humidity or a location where the processor could get wet or be exposed to direct sunlight.
- Store the processor in a location where dust does not enter inside the processor. Wipe off any dust on the processor. Excessive amount of dust accumulation inside the processor may result in malfunction in the processor, smoke or fire from the processor.
- Be careful not to drop the processor or subject it to an excessive mechanical shock. The processor may become unsafe to use or damaged. If the processor is subjected to an excessive mechanical shock, stop using it and contact your PENTAX Medical service facility.

Cleaning and Storage of the Water Bottle Assembly

When washing, disinfecting, and sterilizing the water bottle assembly, be sure to follow the instructions in the IFU for OS-H5.

Storage

Observe the following points on storage

- Be sure to turn off the processor and disconnect the power plug prior to storage.
- Do not store the processor in a very hot and humid location, or where it is likely to be exposed to water or direct sunlight.

⚠WARNING

- Store the processor in a location where dust will not enter inside the unit. Wipe off any dust on the processor. Furthermore, when storing the processor for a long term, take precautions to reduce dust build up within the processor. Excessive amount of dust accumulation inside the unit may cause the processor to malfunction, emit smoke, or catch fire.
- Do NOT store the unit in direct sunlight or where temperature and humidity are high or where it can be exposed to liquids.

⚠CAUTION

Be careful not to drop the processor or subject it to an excessive mechanical shock. The processor may become unsafe to use or damaged. If the processor is subjected to an excessive mechanical shock, stop using it and contact our service personnel.

Replacing the Lamp

Check the LIFE indicator (lamp life indicator) on the touch panel before using the processor. Follow the procedure below to replace the lamp cartridge (OL-X29) if one circle on the LIFE indicator illuminates red and a message prompting you to replace the lamp appears on the monitor.

⚠CAUTION

- The lamp life is 500 hours.
- When the total usage time of the lamp becomes 500 hours or longer, one of the circles on the LIFE indicator illuminates red and the message “Please replace the lamp.” appears on the monitor.
- The lamp life may not be as long as 500 hours depending on the frequency of use.
- Please confirm lighting when you replace the lamp cartridge. ☞"Power-On and Lamp Inspection" (P.19)
- Replacement lamp should not be stored over an extended period of time.

g Removing the Lamp Cartridge

1 Press ⏻ to turn off the processor and disconnect the plug from the power outlet.

2 Turn the screw on the lamp protective cover counterclockwise, open the cover, and check the lamp cartridge. (Refer to Figure 6.2.)

⚠CAUTION

Immediately after use, the metal lamp protective cover and the lamp bulb may be hot. To avoid burns, do not touch these parts immediately after use.

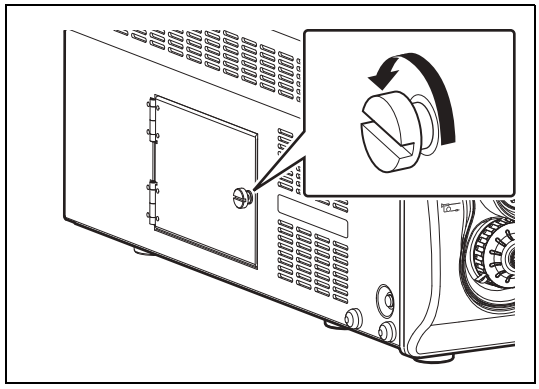


Figure 6.2

3 Turn the two screws at the top of the lamp cartridge counterclockwise until the fixed lamp cartridge loosens. (Refer to Figure 6.3.)

4 Pull the lamp cartridge out towards you while making sure it does not bang against the lamp cartridge housing.

5 Follow local regulations for discarding the old lamp. If unsure of appropriate procedures for lamp disposal, return the lamp cartridge/module to PENTAX Medical after packing it appropriately to avoid any damage during shipping.

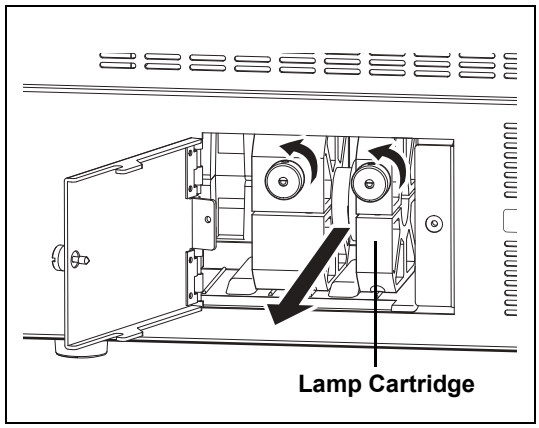


Figure 6.3

⚠WARNING

When the lamp needs to be replaced, we strongly recommends replacing both the lamp and lamp cartridge as a set. Use the PENTAX replacement lamp cartridge OL-X29, which has been developed to ensure optimal brightness and safety. Using a lamp not authorized by PENTAX Medical may result in excessive brightness and/or heat, and it is not known what kind of adverse effect that may have on the patients.

⚠CAUTION

- To avoid electric shock, do not touch both parts on the processor and the patient at the same time when performing this operation.
- During these procedures, always wear rubber gloves.

g Installing a Lamp Cartridge

⚠CAUTION

When performing the following procedure, always wear rubber gloves to prevent oil from your hands from getting on the glass surfaces. Do not directly touch the glass surfaces of the new lamp with your fingers.

1 Hold the lamp cartridge so that the two screws on the lamp cartridge are at the front and fully insert it into the housing while keeping it straight. (Refer to Figure 6.4.)

2 Turn the screws of the lamp cartridge clockwise to secure the lamp cartridge into place.

3 Close the lamp protective cover and turn the screw on the right side of the cover clockwise.

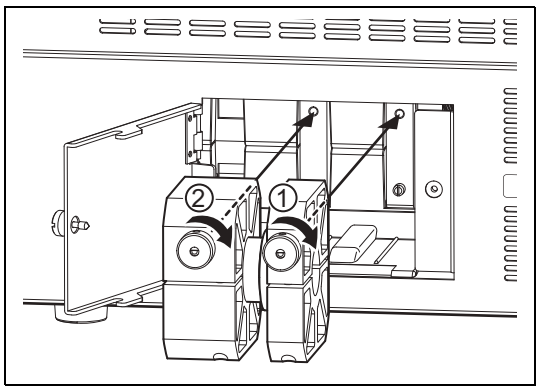


Figure 6.4

⚠CAUTION

Be sure to turn screw ① on the lamp cartridge first to secure the lamp cartridge in place.

g Resetting the Lamp Life Indicator

After replacing the lamp cartridge, reset the lamp life indicator on the front panel of the processor.

1 Plug the power cord into the power outlet and turn on the processor.

2 Press SETUP on the touch panel.

- The setup screen appears.

3 Press the [System] tab at the top of the screen.

- The system setup screen appears.

4 Press the page [3] tab on the right side of the screen.

5 Press [>] of [Lamp data].

- The [Lamp data] screen appears.

6 Press [Reset] of [Lamp life reset].

- The [Lamp life reset] confirmation screen appears.

7 Press [Yes].

8 Press the ⏻ power switch to turn off the processor and then press ⏻ again to turn the processor back on. Confirm that the lamp life indicator illuminates green.

Replacing the Fuses

If the power does not come on when you press the power switch, turn off the power switch and then check the following.

- The power cord is securely plugged in.
- The power breaker is activated. When activated, turn on the power switch.

If the power still fails to come on, follow the procedure below to replace the fuses.

NOTE

A flat blade screwdriver is required to replace the fuses.

1 Unplug the power cord.

2 Insert a screwdriver into the notch on either or both sides of the fuse box immediately above the power inlet socket. (Refer to Figure 6.5.)

3 Move the inserted screwdriver slightly in the inward direction.

4 When the fuse box pops out a little, pull it out by hand.

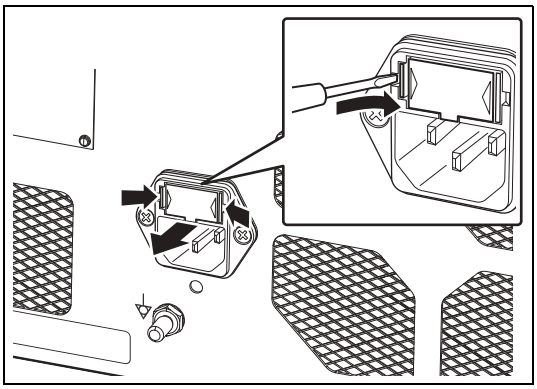


Figure 6.5

5 Inspect the fuses, and remove and replace any fuse that has blown with a supplied spare fuse. (Refer to Figure 6.6.)

WARNING

- Always replace a fuse with a supplied spare fuse (Ø5 x 20, T3.15AH, 250V).
- Never bypass a fuse.
- If the supplied spare fuse specified on the rating plate on the rear panel is not available, contact your local PENTAX Medical service facility.
- To avoid electric shock, do not touch both parts on the processor and the patient at the same time when performing this operation.

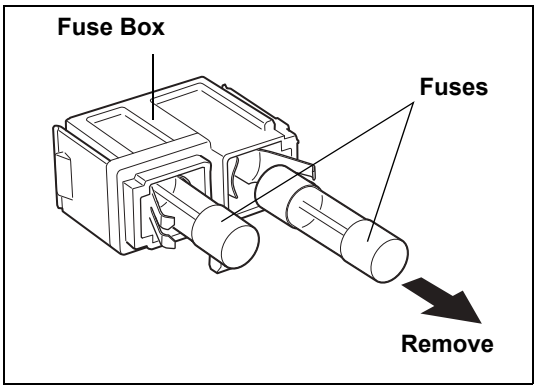


Figure 6.6

6 Reinsert the fuse box, and push it with a finger until it clicks into place.

7 Connect the power cord, press the ⏻ power switch on the processor to turn on the power, and check that the LED of ⏻ illuminates.

NOTE

If the processor cannot be turned on even after the fuses have been replaced with new ones, immediately turn off the power, disconnect the power cord, and contact a PENTAX Medical service facility.

The service life of this product is six years.
Follow the instruction given in the IFU on care after use, maintenance, and usage of this product. If the processor is maintained and used improperly, it could shorten the service life of a product. Some consumable components of this product have the service life of less than six years. Contact your nearest PENTAX Medical service facility every three years for inspection and maintenance of all consumable components except lamp and fuse. Replacement of consumable components may be necessary. If the product is kept being used without periodic maintenance, it might cause a problem in switching between modes from Exposure control mode to Observation mode.

Repair

⚠CAUTION

When the abnormalities of the processor are not improved after it is performed the maintenance according to the Instructions for Use or exchanged a lamp or a fuse, please be sure to request repair to your local PENTAX Medical service facility.

When returning any instrument for repair to PENTAX Medical, please be aware of the following points. Check with your local PENTAX Medical distributor for more details.

(1) All equipment requiring repair should be shipped in a carrying box with appropriate packing together with details on the instrument damage or problem.

(2) Write down the repair order number and your contact name, phone number, and shipping address on a piece of paper and include it in the package.

⚠WARNING

- Be sure to submit the instrument to a PENTAX Medical service facility for repairs. Note that PENTAX Medical is in no way liable for any injuries to patients or users, damage or malfunction of the processor, and inadequate disinfection or sterilization as a result of repairs being undertaken by an unauthorized personnel or agency.
  It must be recognized that PENTAX Medical does not evaluate non-PENTAX Medical parts, components, materials and/or servicing methods. Therefore, questions regarding material compatibility and/or functionality of PENTAX Medical instruments built with the unauthorized, untested and unapproved items, materials, repair/assembly methods must be referred to the third party service organization and/or device remanufacturer. It is unknown to PENTAX Medical if serviced or remanufactured instruments (performed by unauthorized PENTAX Medical entities) which still bear a PENTAX Medical label are within PENTAX Medical device specifications and/or if unauthorized activities have significantly changed the instrument's performance, intended use, safety and/or effectiveness.
  Ultimately, owners of these medical devices are responsible for selecting an appropriate service facility or vendor whose activities render an instrument to the same expectations and quality of a finished device supplied by the endoscope OEM.
- Be sure to delete any user and patient data from the processor before shipping in order to prevent the disclosure of personal information.
- Technical information related to repairs is listed in the service manual.
- For details about repairs, contact your local PENTAX Medical service facility.

7 Troubleshooting

Symptom	Possible Cause	Possible Solution	Reference Page
Cannot turn on the processor.	The power cord is not connected properly.	Securely connect the power cord to the power input socket and isolation transformer.	P.11
	A fuse has blown.	Replace the fuse.	P.84
	Lamp protective cover is not closed.	Close the lamp protective cover and turn the screw knob on the cover clockwise	—
The lamp does not illuminate.	The lamp life is over the limit.	Replace the lamp cartridge if the lamp life indicator on the touch panel is lit red and a message prompting you to replace the lamp is displayed on the monitor.	P.82
No image appears on the monitor.	The monitor settings are not configured properly.	Turn on the monitor.	P.23
		Set the proper video input signal.	P.12
		Reset the adjustment values for the monitor.	*1
	A cable is not connected properly.	Connect all cables properly.	P.12
	The endoscope is not connected properly.	Align the endoscope locking lever to the LOCK position.	P.17
	The lamp is not lit.	Press ☼ on the touch panel to turn on the lamp.	P.26
	The endoscope is not compatible with the processor.	Contact a PENTAX Medical service facility.	—
	Abnormality in the connectors.	Contact a PENTAX Medical service facility.	—
	The monitor is connected to VIDEO OUT/SYNC OUT connector, and [Sync out] is set to [On].	Set [Sync out] to [Off].	P.66
Images are dark.	The lamp is not lit.	Press ☼ on the touch panel to turn on the lamp.	P.26
Text cannot be typed to screen.	The keyboard is not connected properly.	Connect the keyboard to the processor properly.	P.15
The peripheral devices cannot be operated.	The peripheral devices are not connected properly.	Connect the peripheral devices to the processor properly.	P.12 -16
A long beep tone sounds and the [Copy] and [Video] functions do not work.	The settings of the customize buttons, endoscope buttons, or foot switches are not configured properly, or the peripheral devices are not connected properly.	① Change the settings of the [Copy] and [Video] functions in the [Customize button settings], [Assign scope buttons], and [Assign foot switch] screens. If the device that is the output destination is not connected or turned off, cancel the settings. ② Connect the cables of the peripheral devices properly and then turn on the peripheral devices.	P.44 P.48 P.51 P.15
The endoscopic image stopped being displayed on the LCD monitor. Or observation is difficult due to insufficient illumination.	Power outage or there may be a damage in equipment such as lamp, processor, or LCD monitor.	Release the endoscope locking lever and the endoscope's distal tip should be straightened to its neutral position. Then, carefully withdraw the endoscope from the patient.	*2
Software version cannot be displayed correctly.	Attempting to display software version or failed to display software version.	Exit the software version display menu, and enter another menu. Then, reenter the software version display menu. Or, restart the processor.	P.68

Symptom	Possible Cause	Possible Solution	Reference Page
The endoscope buttons do not work.	Cannot communicate properly with the endoscope.	Press [Scope eject] button and remove the endoscope from the processor by aligning the endoscope locking lever to the OPEN position, and then connect the endoscope again. If the function is still not available, release the endoscope locking lever and the endoscope's distal tip should be straightened to its neutral position. Then, carefully withdraw the endoscope from the patient.	P.66
Cannot release freeze.	System malfunction caused by static generation.	Release the endoscope locking lever and the endoscope's distal tip should be straightened to its neutral position. Then, carefully withdraw the endoscope from the patient.	—
The time stamp of the saved still image file/video image file does not match the time when the image was captured.	This processor's "Time zone setting (P.59)" or "Date & Time (P.58)" differs from PC settings.	Set up this processor's "Time zone setting (P.59)" and "Date & Time (P.58)" to become the same as PC settings.	P.58 P.59
		When replayed the still image file/the video image file captured by PC having been set a different ""Date & Time" or "Time zone setting", the time stamp on the still image file/video image file may be different from the date and time captured. Therefore, confirm the date and time displayed on the PC monitor.	—
Seek bar or seek time of video image file is not displayed appropriately by reproduction software.	As time property of video image file can't be read out appropriately by reproduction software.	Use other reproduction software to replay.	P.65
Image processing is not reflected in the left side screen after the Twin mode setup.	Setup of Twin mode was made after freezing.	Release freezing and check Twin mode being set, then execute freezing again.	P.41
It cannot be copied from Endonet during a "VCU ready." display.	RS-232C cable is not connected.	Connect RS-232C cable correctly and try to copy again.	—
Image is deteriorated when the saved recording file is played with PC.	This is generated originating in a compression codec processing while setting up the compression ratio Best quality.	Use setting it up with the compression rate for High quality or Standard quality.	P.64
"No Signal" is displayed in a still image.	Checked [Add external.] box of [Option (Still image)] while a still image was captured in a state of no inputting an external input image in P-in-P mode.	Capture a still image again after check that an external input image is inputted correctly. Or when an external input is not used, cancel P-in-P mode and capture a still image again.	—

*1: For details, refer to the Instructions for Use for the monitor.
*2: For details, refer to the Instructions for Use for the endoscope.

NOTE

- If there is no response even if you press any key on the keyboard, turn off the processor and contact a PENTAX Medical service facility.
- If the problem persists even after taking the measures described in the corresponding solutions above, contact a PENTAX Medical service facility.

g Error Messages

When an error message is displayed on the monitor, try the following solutions. If there is a problem that cannot be resolved with the following solutions, contact your PENTAX Medical service facility.

Message Displayed on Monitor	Meaning	Solution	Reference Page
Please be prepared to replace the lamp soon.	It is almost time to replace the lamp.	Prepare to replace the lamp.	P.82
Please replace the lamp.	It is time to replace the lamp cartridge.	Replace the lamp.	P.82
Scope is not connected.	An endoscope is not connected.	Connect an endoscope.	P.17
The scope is not supported.	The endoscope is not compatible to this processor.	Connect a compatible endoscope.	P.91
Please contact your PENTAX service facility.	90i series endoscope with outdated software is connected to this video processor.	Contact a PENTAX Medical service facility.	—
Check scope connection(No**).	There is a problem communicating with the endoscope.	Reconnect the endoscope.	P.17
White balance failed! Please retry.	The white balance is abnormal.	Set the white balance again.	P.27
Change exposure control to Auto.	Set the Exposure control to [MANUAL] and adjusted the white balance of the i series endoscope.	Change the method of Exposure control to Auto.	—
Change OE mode to Off.	OE is set up except "Off" and the white balance was performed.	Set up OE "Off" and perform white balance.	—
Check USB memory.	Image Recording Media is not connected or there is insufficient space.	Connect Image Recording Media with sufficient space to the processor.	P.14
Capture failed.	Saving of the still image failed.	Try saving the still image again. If problem is not resolved after the above procedure, contact a PENTAX Medical service facility.	—
Check memory space(Still image).	Available space in the Image Recording Media for saving still images has become as low as the value set for the disk space warning.	Connect Image Recording Media with sufficient space to the processor.	P.14
Check memory space(Video image).	Available space in the Image Recording Media for saving video images has become as low as the value set for the disk space warning.	Connect Image Recording Media with sufficient space to the processor.	P.14
Check video printer.	USB printer is not connected.	Connect USB printer to the processor.	P.14
No response from VCU.	Communication with Endonet is abnormal.	Connect Endonet properly.	—
No VCU connection.	No Endonet is connected.	Connect Endonet properly.	—
AUX lamp ON. Check main lamp.	The auxiliary lamp is lit.	Check main lamp.	P.26
Lamp cooler fan stopped. Please contact your PENTAX service facility.	There is a problem with lamp cooler fan rotation.	Contact a PENTAX Medical service facility.	—
Close profile menu.	The [i-scan profile] or [Twin mode profile] screen is open.	Close the [i-scan profile] or [Twin mode profile] screen.	P.37, P.42
Retry - C function. Freeze release - F function or Frz-key on KBD.	Capturing an endoscope still image failed.	• To try capturing again: Press the Copy button. • To cancel capturing: Press the Freeze button. • When the error message does not disappear even if the copy button and the freeze button are pressed, please try reconnecting the endoscope.	—

Message Displayed on Monitor	Meaning	Solution	Reference Page
System error. Please restart the processor(No**-**).	There was a problem with the system startup.	Restart the processor. When the same message is displayed repeatedly, contact a PENTAX Medical service facility.	P.23
System error. Please contact your PENTAX service facility(No**-**).	There was a problem with the system startup.	Contact a PENTAX Medical service facility.	—
AUX lamp ON. Please contact your PENTAX service facility.	Either the lamp was turned on when an illumination function error occurred, or an illumination function error occurred when turning on the lamp.	Contact a PENTAX Medical service facility.	—
Copy failed.	Copying the procedure history or system configuration to Image Recording Media failed.	Try copying the data again.	—
Data transfer failed.	Failed to transfer data to peripheral devices.	Retry to transfer data after confirming network connection.	—
PC:Not ready.	Capture is done while unconnected to Endoimage2.	Confirm the connection with a PC activating Endoimage2.	—
PC:HDD alert.	There is no sufficient space at PC in which installed Endoimage2.	Connect the processor to a PC with sufficient memory.	—
PC:HDD warning.	The amount of memory in PC installed Endoimage2 decreased to the alert level of insufficient space.	Connect the processor to a PC with sufficient memory.	—
PC:Transfer error.	Failed to transfer data to Endoimage2.	Contact a PENTAX Medical service facility.	—
IP CONFLICT	Setting value of IP address conflicts.	Set the IP address not to conflict and reboot the processor.	—
Video rec error.	Failed to save a movie.	Confirm the correct connection with an image record media or reboot the processor. If problem is not resolved after the above procedure, contact a PENTAX Medical service facility.	—
		When image processing level is set up highly, an error may occur to the compression codec technology. In that case, use setting it up with the compression ratio for High quality or Standard quality.	P.64
No data.	There is no data file to load in an image record media in spite of [Configuration load].	Confirm the existing file to load in an image record media.	—
Changing OE mode failed! Please retry.	When OE was changed into Mode1 or Mode2, the mode change failed.	Perform the mode change again.	—
Changing OE mode Off failed! Check scope connection.(No.**)	Because of the abnormalities occurred in communication with an endoscope when changed OE into Off, the mode change of OE failed.	Reconnect the endoscope.	—
Out of internal memory space.	It has reached the continuous-capture ceiling of the memory capacity.	Try capture again after a while.	—

g Other Messages

Message Displayed on Monitor	Meaning	Reference Page
Now printing.	USB printer is printing now.	—
Now saving.	Saving to Image Recording Media.	—
Connect to VCU.	Connected to Endonet.	—
VCU ready.	Ready to communicate with Endonet.	—
Connected to Net	Connected to the network.	—
Capture OK.	Successfully captured the endoscope still image.	—
Check white balance.	Adjust the white balance.	P.27
White balance OK!	Successfully adjusted the white balance.	P.27
Not available.	The auxiliary lamp is lit. (Some functions such as image processing cannot be used.)	—
Procedure history saved.	Saving of the procedure history is complete.	P.68
Configuration saved.	Saving of system configuration is complete.	P.69
Network/File system loading...	Loading the network and file systems required to save the endoscopic still images. ⚠ WARNING Do not use the keyboard as well as the keyboard menu while this message is being displayed on the monitor screen.	—
Data transfer OK.	Successfully data transferred to peripheral devices.	—
Waiting for the mode change.	Light control function is switching.	—
PC:Ready.	Ready to start transporting to Endoimage2.	—
PC:Capture OK.	Successfully captured endoscope static image to Endoimage2.	—
PC:Buffer full.	File is being saved to Endoimage2.	—
PC:Command from PC.	Capture required from Endoimage2.	—
OK to eject.	Possible to eject the endoscope.	—
This scope is not supported OE.	The connected K series endoscope is non-OE-compliant.	—
Main:External video	The images input from an external device are displayed on the main screen of the monitor.	P.54

8 Specifications

Model Name			EPK-i7010
Power Requirements	Voltage		230 VAC
	Frequency		50 - 60 Hz
	Input current		2.4 A
	Voltage fluctuation		±10%
Mode of Operation			Continuous Operation
Operating Environment	Ambient temperature		10 - 40°C
	Relative humidity		30 - 85%
	Air pressure		700 - 1060 hPa
Storage and Transport Environment	Ambient temperature		-20 - 60°C
	Relative humidity		0 - 85%
	Air pressure		700 - 1060 hPa
Illumination	Lamp		Xenon lamp (300 W) Model: OL-X29
	Color temperature		6,000 K
	Brightness control		Selection: Automatic/Manual
	Auxiliary lamp		3W White LED
Endoscope Compatibility	Colonoscope Family Gastroscope Family Duodenoscope Family Bronchoscope Family Naso-Pharyngo-Laryngoscope Family		K series video endoscopes, i series video endoscopes, PENTAX Fiberscopes (via video module) (“K series” consists of 70K, 80K, 90K, K10 and J10 series. “i series” consists of 90i and i10 series.)
Video Module Compatibility			PENTAX video module PVK-1070, PVK-1070Z
Air Supply Function	Air pump system		DC diaphragm
	Air supply pressure (at flow rate of 0)		45 - 70 kPa (6.5 - 10.2 PSI)
	Air supply rate (at inlet of water bottle assembly)		Level 1: 2.0 - 2.8 L/min Level 2: 2.9 - 3.4 L/min Level 3: 3.5 - 4.0 L/min Level 4: 4.1 - 4.5 L/min Level 5: 4.6 - 7.2 L/min
Water Supply Function	Water bottle assembly		Capacity = 200 ml
Brightness Control System	Auto		Selection: Average/Peak ±5 step adjustment
	Manual		±5 step adjustment
Color System	Color correction		Red/Blue ±5 step adjustment
Freeze Function			Live video images displayed while freeze mode activated.
Cooling			Forced air cooling
Video Signals	Digital output	HD-SDI	2 sets
		DVI	1 set (combined with VGA)
	Analog output	RGB	1 set
		Y/C	2 sets
		VIDEO OUT	1 set (combined with SYNC OUT)
		VGA	1 set (combined with DVI)
	Analog input	VIDEO IN	1 set
Synchronous Signal	SYNC OUT		1 set (combined with VIDEO OUT)
Voice Signal	Microphone		1 set
Control Signals	RS-232C		1 set
	RJ45		1 set
	Remote		3 sets
	Keyboard		1 set
	Foot switches		1 set
Image Recording Media	USB flash memory, external hard disk drive		
Classification as Electro Medical Equipment	Type of protection against electric shock		Class I equipment, 3 prong plug
	Degree of protection against electric shock		Type BF (Body Floating), using insulated endoscope. Use on a heart is prohibited.
	Degree of explosion proofing		Do not use in potentially flammable surroundings.* * The processor is not suitable for use in a mixture of air and flammable anesthetic gas or a mixture of oxygen/nitrous oxide and flammable anesthetic gas.
Compliance	Designed in accordance with		IEC 60601-1:2005+A1:2012 IEC 60601-2-18:2009
Size (Excluding Protrusions)			400 mm (W) 205 mm (H) 520 mm (D)
Weight			21.5 kg
Electro Magnetic Compatibility			IEC 60601-1-2:2007
IP Classification			IPX0

9 Electromagnetic Compatibility

This product conforms to IEC60601-1-2: 2007: Medical electrical equipment, EMC standard.

Guidance and manufacturer's declaration-electromagnetic emissions

This product is intended for use in the electromagnetic environment specified below. The customer or the user of this product should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment-guidance
RF emissions CISPR 11	Group 1	This product uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	This product is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer’s declaration-electromagnetic immunity

This product is intended for use in the electromagnetic environment specified below. The customer or the user of this product should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of this product requires continued operation during power mains interruptions, it is recommended that this product be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	It is recommended that this product be used apart from other devices operated with large current.
Note: U_T is the a.c. mains voltage prior to application of the test level.			
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	The recommended separation distance: d = 1.2 √P
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	The recommended separation distance: d = 1.2 √P 80 MHz to 800 MHz d = 2.3 √P 800 MHz to 2.5 GHz
● *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. *d* is the recommended separation distance in metres (m).			

Note:

- At 80 MHz and 800 MHz, the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
- Interference may occur in the vicinity of equipment marked with the following symbol:

- Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a)] should be less than the compliance level in each frequency range.[b)]
  a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which this product is used exceeds the applicable RF compliance level above, this product should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating this product.
  b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and this product

This product is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of this product can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and this product as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz **$d = 1.2\sqrt{P}$**	80 MHz to 800 MHz **$d = 1.2\sqrt{P}$**	800 MHz to 2.5 GHz **$d = 2.3\sqrt{P}$**
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note:

- At 80 MHz and 800 MHz, the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people

Software Version: E0C100

Contacts

Manufacturer

HOYA Corporation
6-10-1 Nishi-shinjuku,
Shinjuku-ku, Tokyo
160-0023 Japan

Distributors

PENTAX Europe GmbH EC REP
Julius-Vosseler-Straße 104
22527 Hamburg, Germany
Tel: +49 40 561 92-0
Fax: +49 40 560 42 13

PENTAX Medical
A Division of PENTAX of America, Inc.
3 Paragon Drive
Montvale, NJ 07645-1782
USA
Tel: +1 201 571 2300
Toll Free: +1 800 431 5880
Fax: +1 201 391 4189

PENTAX Medical Shanghai Co., Ltd.
Room 701, 291 Fumin Road, Shanghai
200031 P. R. China
Tel: +86 21 6170 1555
Fax: +86 21 6170 1655

PENTAX Medical Singapore Pte. Ltd.
438A Alexandra Road, #08-06
Alexandra Technopark, 119967 Singapore
Tel: +65 6507 9266
Fax: +65 6271 1691
Customer Service Toll Free:
400 619 6570 (within China)
1800 2005 968 (within India)
1300 PENTAX (within Australia)

81240 CE 0123

2018. 07 6217001 P227 R03

LCPM 02/2018/09/35011802

Specifications are subject to change without notice and without any obligation on the part of the manufacturer.

PENTAX MEDICAL
Excellence in Focus

OPTIVISTA™ EPK-i7010

Product Specifications

PENTAX MEDICAL

Power Supply

Voltage	120V AC (NTSC) / 230 V AC (PAL); within ± 10 %
Frequency	50-60 Hz

Size and Weight

Dimensions (W x H x D)	400 x 205 x 520 mm
Weight	21.5 kg

Classification (Medical Electrical Equipment)

Type of protection against electric shock	Class I equipment, 3 prong plug
Degree of protection against electric shock	Type BF (Body Floating), using insulated endoscope. Use on a heart is prohibited.
Degree of explosion proofing	Do not use in potentially flammable surroundings.

Illumination

Lamp	300W Xenon (Life: 500 hrs, depending on usage)
Brightness	Brightness adjustment is possible in ±11 steps using the button on the touchscreen.
Light exposure control	The auto light exposure control can be selected using EXPOSURE CONTROL and MODE on the touch screen. - EXPOSURE CONTROL AUTO: The light exposure is automatically adjusted. MANUAL: The light exposure is fixed in the certain level which is set on the brightness. - MODE (in AUTO mode) AVE: The light exposure is controlled based on the average level of brightness in the endoscopic image. PEAK: The light exposure is controlled to reduce halation area in the endoscopic image.

Air flow function

Pump	Diaphragm type pump / Air flow can be selected from 5 different levels.
Air pressure	45-70 kPa (6.5-10.2 PSI)

Observation

HD signal output	Digital: 1080i (1920 x 1080) thru DVI and HD-SDI / Analog: SXGA (1280 x 1024) thru DVI
Analog SD signal output	RGB, S-Video, Composite Video
White balance adjustment	White balance adjustment is possible using the white balance button on the touchscreen.
Color balance adjustment	The following color balance adjustments are possible using the touch screen interface: Red adjustment: ±11 steps, Blue adjustment: ±11 steps.
Contrast	Image contrast can be adjusted in 3 settings (illumination, Mode 1 and Mode 2).

Observation

D-Range Expansion	D-Range Expansion can improve far field illumination.
Image enhancement setting	Post-processing image enhancement / i-SCAN (Mode 1, Mode 2, and Mode 3) OE Optical image Enhancement (Mode 1, Mode 2)
TwinMode	TwinMode shows white light image and images with image enhancement side by side on the monitor.
Digital zoom	Digital zoom is available. Magnification ratio: OFF, 1.2, 1.5, 2.0.
Image size selection	The size of the endoscopic image can be changed in 2 modes (Full, Med).
Freeze	The still image can be shown when activating Freeze mode.
Freeze Scan	Freeze Scan is a software function that selects the sharpest image from a series of images temporarily stored in the video processor.

System settings

Customizable buttons	There are 4 customizable buttons in the touchscreen and functions on the video processor can be assigned to these buttons.
PinP	External composite video signal can be the input into the video processor and shown on the monitor.
Endoscope's remote button function	The video processor's functions can be set on the remote buttons of the endoscope by using the touchscreen.
Remote control	The following peripheral devices can be controlled by the remote control. (LAN, RS-232C, USB, Remote terminal) / Video Printer, Video recorder, Filing system.

Documentation

Patient data	The following data can be displayed on the monitor: Patient ID, Patient name, Sex, Age, Facility, Comments.
Displaying the recorded state	The recording state of the following peripheral devices can be displayed on the monitor. External storage media, Filing system, Video printer.
Displaying the image information	The following data is displayed on the monitor. Enhancement level, image enhancement (i-SCAN modes and OE modes), Zoom Level, Color balance, Brightness.
Advance registration of patient data	Up to 50 patients' data can be registered.
HD video recording	Integrated HD video recorder (20 mins with high quality to 40 mins with standard quality) the video file is stored into the external storage media.

External storage

Media	USB port is equipped on the front panel and the rear panel. USB memory stick, USB HDD drive.
Recording format	Still image: JPEG, BMP / Video: TS format.

Memory Backup

User settings	Up to 20 user settings can be registered.
Memorization of selected settings	Following settings can be individually set for users: - SE, CE - Enhancement - Ave / Peak - Noise reduction - Sub screen position - Manual brightness level - Auto brightness level
Lithium battery	Lithium battery is equipped in the processor for a real time clock.

Americas Head Office
3 Paragon Drive
Montvale, NJ 07645
Phone +1 800 431 5880
Fax +1 201 391 4189
pentaxmedical.com`

Canadian Head Office
6715 Millcreek Drive, Unit 1
Mississauga, ON L5N 5V2
Phone +1 800 750 5558
Fax +1 905 286 5571
pentaxmedical.ca

Legal Manufacturer
HOYA Corporation
6-10-1 Nishi-shinjuku
Shinjuku-ku, Tokyo
160-0023 Japan

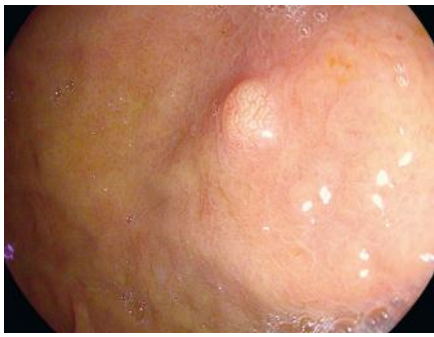
PENTAX MEDICAL

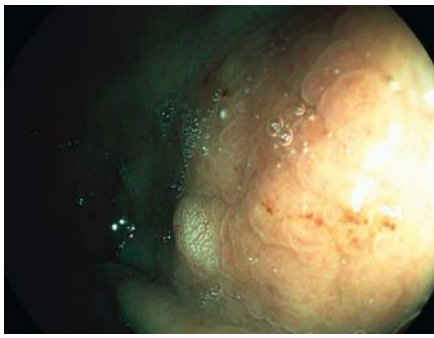
Copyright 2016. All Rights Reserved. All company and product names and marks contained within are federally registered trademarks, trademarks or service marks of PENTAX of America, Inc. Product specifications are subject to change without notice, and without any obligation on the part of the manufacturer.

OPTIVISTA plus

A unique combination of optical and digital enhancements, for improved in vivo *diagnosis*

PENTAX MEDICAL





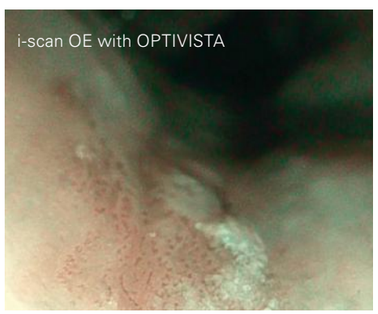
Courtesy of Dr. Federico Buffoli, Cremona Hospital, Italy

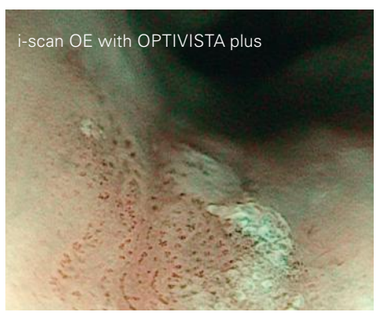
Made for you: the OPTIVISTA plus

Further improved *in vivo* diagnosis for therapeutic guidance

PENTAX Medical is proud to introduce the new OPTIVISTA plus, the next generation processor that enhances the OPTIVISTA's already superb image quality and other capabilities.

- OPTIVISTA plus supports the best clinical outcome by providing sharper, brighter image quality thanks to i-scan and i-scan OE.
- It supports diagnosis and case documentation, and guides treatment and therapeutic decisions through easier image capture and sharper than ever frozen images.
- It is is an effective cross-segment investment due to its proven clinical characterization capabilities being expanded into pulmonology and ENT.





Courtesy of Dr. Fujishiro, The University of Tokyo Hospital, Japan

A leap forward for *in vivo* histology with i-scan and i-scan OE, a unique combination of digital and optical enhancements

1 Enhanced detection

i-scan

Sharp High-Definition image, combined with **i-scan imaging** and **excellent illumination** for a more detailed view of the mucosa and enhanced detection.

2 Improved *in vivo* diagnosis

i-scan OE

A unique combination of **digital enhancement** (i-scan) and **optical enhancement** (i-scan OE) provides extra information for a more accurate *in vivo* diagnosis through improved vessel and mucosal pattern characterization.

3 Powerful educational platform

Twin Mode

The **TwinMode** is perfectly designed to demonstrate the appropriate interpretation of image enhancement endoscopy by providing simultaneous comparison of side by side endoscopic images.

HD+ Video Recording

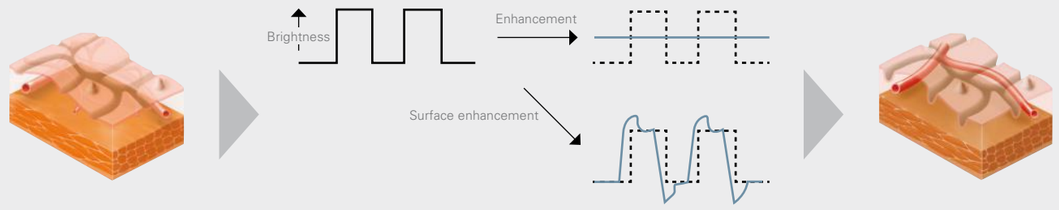
The **integrated audio and HD+ video recorder** enables to collect and share the latest scientific findings from the endoscopy room with fellows and peers.

i-scan for enhanced detection and characterization

i-scan technology is a digital, image enhanced endoscopy (IEE) technology by PENTAX Medical. As a virtual chromo-endoscopy tool, i-scan provides an enhanced view of the mucosal structures and vascular patterns, supporting early detection, demarcation and characterization.

i-scan 1 (SE) for detection

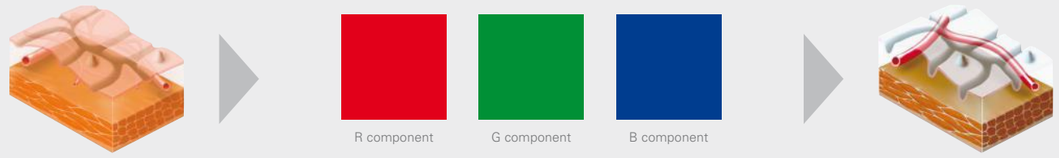
By enhancing the mucosal structure in a natural color tone, SE (Surface Enhancement) supports detection, especially of flat lesions by highlighting abnormalities.



With SE, the difference in luminance intensity between the pixels concerned and the surrounding pixels is analyzed and the edge components are enhanced. SE adjustment of the noise erasure function allows more evident enhancement of the edges, which corresponds to minor changes in structure.[1]

i-scan 2 (TE) for pattern characterization

TE (Tone Enhancement) enhances the changes of vascular and mucosal structure with a color tone change, supporting pattern characterization.

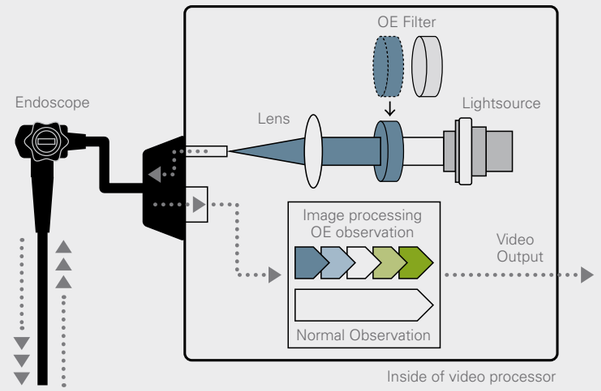


The RGB components of an ordinary endoscope image are disintegrated into each component (R, G and B), and each component thus isolated is converted independently along the tone curve, followed by a reconstruction of the three components in one single image.[1]

i-scan OE for vessel characterization

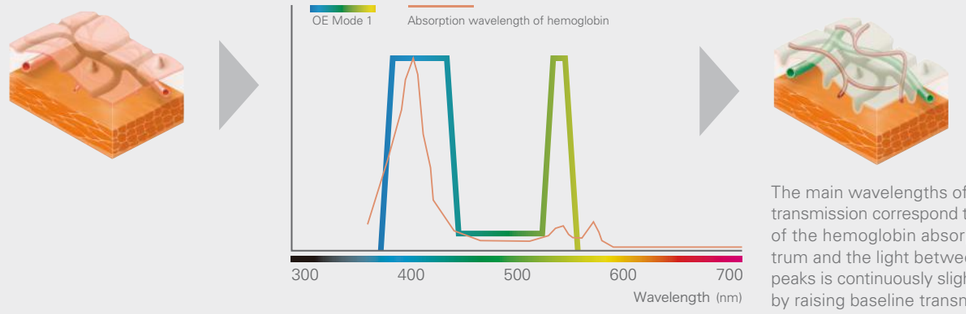
PENTAX Medical has recently developed the i-scan OE (Optical Enhancement), an optical filter that produces bandwidth-limiting light. When combined with image enhancement processing technology it clearly displays the surface structures of blood vessels, glandular ducts and mucosal membranes in higher contrasts than white light.

i-scan OE technology



i-scan 3 (OE) for vessel characterization

i-scan OE displays the surface structures of the blood vessels, glandular ducts and mucosal membranes in a color tone **and supporting vessel's characterization.**



The main wavelengths of spectral transmission correspond to the peaks of the hemoglobin absorption spectrum and the light between these peaks is continuously slightly emitted by raising baseline transmittance.[2]

[1] Kodashima et al: Novel image-enhanced endoscopy with i-scan technology. World J Gastroenterol 2010

[2] K Mönkemüller et al.: Present and future perspectives of virtual chromoendoscopy with i-scan and optical enhancement technology. Digestive Endoscopy 2013; 26.

Improved *in vivo* diagnosis

A unique combination of digital and optical enhancements

OPTIVISTA, a powerful educational platform

The OPTIVISTA EPK-i7010 video processor is a state-of-the-art educational tool with customizable functions operated easily by the touch screen, or via the endoscope buttons.

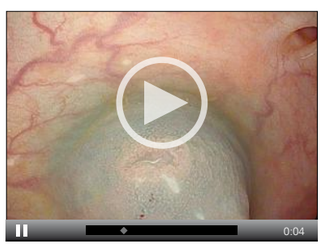
Teach and assess with the unique TwinMode

- TwinMode is useful in teaching the appropriate interpretation of image enhanced endoscopy, providing simultaneous comparison of side by side endoscopic images.
- Among experts, TwinMode is appreciated as an educational tool for non-experts in "building the bridge" between HD+ white light images and the different i-scan modes and findings.
- The simultaneous comparison of enhanced clinical images is useful in teaching the appropriate characterization of lesions.

Colon adenoma

Collect and share with the unique integrated video and audio recording

- The video recording function enables capture of HD+ video files through a USB storage device, for fast and easy sharing of findings with peers. Audio recording for video is captured through external microphone.
- Contributes to cost savings in the endo-scopy room by avoiding unnecessary external HD recording devices.
- For best image collection, the OPTIVISTA also incorporates freeze scan technology which automatically selects the sharpest picture.



Exchange and expand your knowledge of i-scan by visiting the i-scan website

www.i-scanimaging.com

OPTIVISTA plus
A multifunctional platform across segments

1. VNL-J10

The new VNL-J10 series will provide support to both diagnostic as well as therapeutic procedures. The VNL product range can be used in a wide variety of applications in ENT such as FEES examinations and functional video stroboscopy examinations.

2. J10 - Pulmonology

The Video Bronchoscope EB-J10 product range offers sharp and clear High-Definition image quality, with unmatched ergonomic design and flexibility to ease operation in daily use.

3. GI i10

Slim caliber, bigger working channel and Close Focus, all combined in an i10 HD+ endoscope, the high performance endoscopes series, for the day-to-day advanced endoscopy practice.

4. 90i

With the 90i endoscope series, you can experience HD+ images combined with exceptional illumination, during routine examinations.

EC REP **EMEA Headquarter Germany**
PENTAX Europe GmbH
Julius-Vosseler-Straße 104
22527 Hamburg
Tel.: +49 40 / 5 61 92 - 0
Fax: +49 40 / 5 60 42 13
E-mail: info.emea@pentaxmedical.com

United Kingdom
PENTAX U.K. Limited
PENTAX House
Heron Drive, Langley
Slough SL3 8PN
Tel.: +44 17 53 / 79 27 33
Fax: +44 17 53 / 79 27 94
E-mail: medical.uk@pentaxmedical.com

France
PENTAX France Life Care S.A.S.
116 quai de Bezons
B.P. 204
95106 Argenteuil Cedex
Tel: +33 1 / 3025 7575
Fax: +33 1 / 3025 7445
E-mail: clients.fr@pentaxmedical.com

Netherlands
PENTAX Nederland B.V.
Edisonring 4
6669NB Dodewaard
Tel.: +31 88 / 5 30 30 30
Fax: +31 84 / 885 30 30 40
E-mail: info.nl@pentaxmedical.com

Italy
PENTAX Italia S.r.l.
Via Dione Cassio, 15
20138 Milano
Tel.: +39 / 02 50 99 58 1
Fax: +39 / 02 50 99 58 60
E-mail: marketing.it@pentaxmedical.com

Spain
SIMMEDICA – Sistemas Integrales
de Medicina, S.A.
Avenida del Sistema Solar 25
28830 San Fernando de Henares, Madrid
Tel.: +34 91 / 301 62 40
Fax: +34 91 / 751 31 15
E-mail: sim@simmedica.com

Russia
Moscow Representative office
of PENTAX Europe GmbH (Germany)
13, 4-y Lesnoy pereulok
125047 Moscow
Tel.: +7 495 114 52 31
Fax: +7 495 114 52 31

Turkey
PENTAX Turkey
Veko Giz Plaza, Meydan Sokak No:3/43
343396 Maslak Istanbul
Tel.: +90 212 / 705 05 26
Fax: +90 212 / 705 05 00

Japan
HOYA Corporation
6-10-1 Nishi-shinjuku
Shinjuku-ku
Tokyo 160-00231

TÜV Süd CE0123 • Medical device class: IIa • This product must be used only by Healthcare professionals. Before usage and for detailed product specifications, please refer to the instructions for use. In the interest of technical process, specifications may change without notice.

PENTAX MEDICAL
Excellence in Focus

LCM/03/05/16/320143/02

PENTAX MEDICAL

NEW

The MagniView endoscopes.

A step forward in characterisation.

The PENTAX Medical MagniView endoscopes join the outstanding HD+ image series with an optical zoom function. In combination with i-scan, the MagniView endoscopes provides a new standard for daily practice, supporting enhanced characterisation in a wide range of procedures, with its 136 times magnified image.

Advanced ergonomics and graduated flexibility of the insertion tube, increases both patient and physician comfort.

MagniView: HD+ and Optical Zoom technology combined.

HD+, Optical Zoom technology and i-scan - the perfect combination for improved characterisation.

Powerful magnification

- The optical zoom technology magnifies the image 136 times, allowing for detailed surface structure observation and supporting enhanced characterisation.

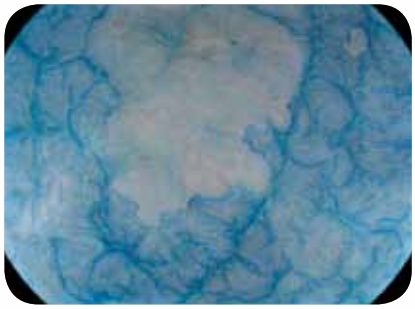
Excellent imaging capabilities

- The combination of i-scan, HD+ and magnification in a standard endoscope provides state-of-the-art technology in detection and characterisation in daily clinical routine.

Fully functional endoscope

- Designed to have the same working channel and equivalent outer diameter as a standard diagnostic endoscope, with optical magnification capabilities. Easy to position, easy control of magnification and advanced ergonomic design.

Magnified endoscopic image



Magnified endoscopic image

MagniView VIDEO ENDOSCOPES

	Product	Insertion tube [ø mm]	Distal end [ø mm]	Instrument channel [ø mm]	Working length [mm]	Field of view [mm]	Tip deflection up/down [°]	Tip deflection right/left [°]	Remarks
Gastroscope	EG-2990Zi	9.8	10.6	2.8	1,050	140	210/120	120/120	HD+, MagniView, Water Jet System
Colonoscopes	EC-3890LZi	13.2	13.0	3.8	1,700	140	180/180	160/160	HD+, MagniView, GDF, Water Jet System
	EC-3890FZi	13.2	13.0	3.8	1,500	140	180/180	160/160	HD+, MagniView, GDF, Water Jet System
	EC-3890MZi	13.2	13.0	3.8	1,300	140	180/180	160/160	HD+, MagniView, GDF, Water Jet System

*Distal Rubber Hood: OE-A58 compatible with EG-2990Zi, OE-A59 compatible with EC-3890Zi series

PENTAX doesn´t take any liability for the accuracy of the content as laid out in this brochure. In the interest of technical progress specifications are subject to change without notice. Details concerning the compatibility with other medical devices are to be found within the corresponding Instructions for Use.

PENTAX Europe GmbH
Julius-Vosseler-Straße 104 · 22527 Hamburg · Tel.: +49 40 / 5 61 92 - 0
Fax: +49 40 / 5 60 42 13 · www.pentaxmedical.com

PENTAX MEDICAL

LCM/01/06/13/320168/02

Gastroenterology
Endoscopic Ultrasound
Pulmonology
ENT & Speech
Urology
Advanced Imaging
Video Equipment
Accessories & Peripherals
Accessories

Accessories List

Sl No	Accessory Image	Accessory Title	Linked Products
1		OE-C12 WATER JET CHECK VALVE ADAPTER	**Colonoscopes** • i10 Series Video Colonoscopes • UltraSlim EC-2990i Video Colonoscope **Gastroscopes** • MagniView EG-2990Zi Video Gastroscope • i10 Series Video Gastroscopes More...
2		OF-B118 WATER JET CONNECTOR CAP	**Colonoscopes** • i10 Series Video Colonoscopes • UltraSlim EC-2990i Video Colonoscope **Gastroscopes** • MagniView EG-2990Zi Video Gastroscope • i10 Series Video Gastroscopes More...
3		OS-A43H WHITE BALANCE ADJUSTER	**Video Processors** • EPK-i5000 High-Definition Video Processor
4		OS-I3 IMAGE CAPTURE SOFTWARE ENDOIMAGE2	**Video Processors** • EPK-i5000 High-Definition Video Processor
5		OF-Z11 SILICONE OIL	**Duodenoscopes** • 90K Series Video Duodenoscopes **Portable Fiber Ureteroscope** • FUR-9RBS Portable Fiber Ureteroscope More...
6		OF-Z5 BITE BLOCK	**Duodenoscopes** • 90K Series Video Duodenoscopes **Gastroscopes** • MagniView EG-2990Zi Video Gastroscope • Transnasal EG16-K10 Video Gastroscope More...
7		OF-D6 EYEPIECE CAP	**Portable Fiber Ureteroscope** • FUR-9RBS Portable Fiber Ureteroscope **Portable Fiber Bronchoscopes** • RBS Series Portable Fiber Bronchoscopes More...
8		OF-D1 EYEPIECE CAP	**Fiber Bronchoscopes** • V Series Fiber Bronchoscopes
9		OF-D3 EYESHIELD	**Fiber Bronchoscopes** • V Series Fiber Bronchoscopes
10		OS-H4 WATER BOTTLE ASSEMBLY	**Video Processors** • EPK-i5000 High-Definition Video Processor

Prev 1 2 3 4 5 6 7 8 9 Next 10

© Copyright PENTAX Medical
All Rights Reserved.

PENTAX MEDICAL

Auto Leakage Tester SHA-P6

Better care for your scopes

By alerting you to existing leaks in your flexible endoscopes, the SHA-P6 Automatic Leakage Tester helps to avoid costly repairs.

Intuitively Simple

The SHA-P6 Auto Leakage Tester is specifically designed for use with PENTAX Medical flexible endoscopes to avoid costly service interventions.

Improved operational efficiency
Default pressure setting, automated pressurization cycle, and air release reduce the risk for human error and potential risky variability within the reprocessing process.

Space saving and mobile
No need to have large space available in the reprocessing room, due to the handy format of SHA-P6. With the re-chargeable battery, the automatic leakage tester is usable in several stations without power connection need.

Optimized economic outcomes
Lowers overall repair costs, improves scope utilization and prevents downtime as a result of the optimized, automated process capability.

PENTAX Medical Auto Leakage Tester SHA-P6 Specifications

AC adapter	DC output voltage / current	7.5V, 1.6A
	AC input frequency	50 to 60Hz
	AC input voltage	AC100 - 240V
Built - in packaged lithium battery	Battery capacity	2,600 mAh
Mode of Operation		Continuous Operation
Operating Environment	Ambient temperature	10 to 40 °C (50 to 104°F)
	Relative humidity	30 to 85% RH
	Air pressure	700 to 1,060 hPa (10.2 to 15.4 psl)
Storage Environment	Ambient temperature	-20 to 60 °C (-4 to 140°F)
	Relative humidity	10 to 85% RH
	Air pressure	700 to 1,060 hPa (10.2 to 15.4 psl)
Pressurization		Automatic (air pump)
Air release		Automatic rapid air release valve
Displayed pressure range		0 to 40 kPa (0 to 5.80 psl)
Pressurization setting range		20 to 30 kPa (in increments of 1kPa) (2.90 to 4.35 psl)
Size		154mm (W) x 63.2mm (H) x 95.6mm (D) (6.06in (W) x 2.49in (H) x 3.76in (D))
Weight		380g (0.84lb) (main unit only)
Electric shock protection Degree of Electric schock protection		Internal power supply equipment and Class II Equipment Type BF (Body Floating)
Electro Magnetic Compatibility		IEC60601 - 1 - 2 : 2007
Electrical Safety		IEC60601 - 1 : 2005 + A1 : 2012
IP Classification		IP22

EC REP **EMEA Headquarter**
Germany
PENTAX Europe GmbH
Julius-Vosseler-Straße 104 . 22527 Hamburg
Tel.: +49 40 / 5 61 92 - 0 . Fax: +49 40 / 5 60 42 13
E-mail: info.emea@pentaxmedical.com . www.pentaxmedical.com

Medical device class: I • This product must be used only by healthcare professionals.
Before use and for detailed product specifications, please refer to the instructions
for use. In the interest of technical process, specifications may change without notice.

PENTAX MEDICAL
Excellence in Focus

LCM/01/07/18/320461/02

PENTAX MEDICAL

Instructions for Use

PENTAX Video Upper G.I. Scope
PENTAX Video Colonoscope

Operation

EG-2990Zi
EC-3890LZi/FZi/MZi

For cleaning, high-level disinfection, and sterilization of the product after use, refer to the separate Instructions for Use (Reprocessing) with the model name of the endoscope.

Instructions for Use

This Instructions for Use (hereinafter referred to as "IFU") contains essential information, such as operating procedures and handling precautions, on using this endoscope safely and effectively. Before use, fully understand the contents of, and properly follow, this IFU and the instruction manuals of all equipment that are going to be used in combination. Do not use this endoscope for any purpose other than its intended use.

In addition, review and fully understand the contents of the separate IFU for reprocessing (hereinafter referred to as "IFU (Reprocessing)"). Inappropriate use of the product may result in damage to the equipment or injuries, including, but not limited to, burns, electric shock, perforation, infection, and bleeding.

This IFU does not describe specific endoscopic procedures. The specific procedures should be determined according to the discretion of a medical professional.

If you have any questions or concerns about any information in this IFU, contact your local PENTAX Medical service facility.

The content of the IFU may be changed without prior notice.

Unauthorized reproduction of any part of this IFU is prohibited.

Keep this IFU and all related instruction manuals in a safe, accessible location.

Signal words and symbols

Signal words

The following signal words are used throughout this IFU.

Warning	Indicates a situation that could result in death or serious injury if not avoided.
Caution	Indicates a potentially hazardous situation that could result in minor or moderate injury or damage to equipment if not avoided.
Note	Indicates supplementary or useful information regarding use.

Symbols

The meaning(s) of the symbol(s) on the endoscope, accessories, and/or on their packaging are as follows:

Symbol	Description
	Caution
	Date of Manufacture
	Type BF applied part
	Follow the Instructions for Use
	Manufacturer
EC REP	Authorized representative in the European Community
CE	This product complies with the applicable standards harmonised under the Directive 93/42/EEC and Directive 2011/65EU.

Contents

Instructions for Use **3**

Signal words and symbols **3**

Important information: Please read before use **6**

Product summary 6
Intended use 6
Application 6
Classification 6
Specifications 7
Compatible products 7
Reprocessing before the initial use, reprocessing, and storage after use 8
General warnings and cautions 9
Maintenance management 10

1 Package contents **12**

1-1. Package contents 12

2 Nomenclature and functions **14**

2-1. Control body, insertion portion 14
2-2. Connector 16

3 Preparation and inspection **17**

3-1. Preparation of the equipment 18
3-2. Inspection of the endoscope 20
3-3. Inspection of accessories and attachment to the endoscope 28
3-4. Inspection and connection of ancillary equipment to the endoscope 42
3-5. Inspection of the endoscopic system 45

4 Directions for use **56**

4-1. Preparation immediately before insertion of the endoscope 58
4-2. Insertion and observation 59
4-3. Using an endoscopic device 65
4-4. Using a non-flammable gas 68
4-5. Laser cauterization 70
4-6. Electrosurgery 71
4-7. Withdrawal of the endoscope 72
4-8. Care after use .....

5 Troubleshooting ····· 74

5-1. Withdrawal of an endoscope with an abnormality ····· 74

5-2. Returning the endoscope for repair ····· 75

Disposal ····· 76

Electromagnetic compatibility (EMC) ····· 77

Endoscope specifications ····· 80

System chart ····· 81

Important information: Please read before use

Product summary

This endoscope visualizes subjects under illumination transmitted from a dedicated video processor with a solid-state image sensor located at the distal end of the endoscope and provides images for observation of the target anatomy through the images reproduced on the video monitor via the video processor.
It can be used with endoscopic devices which are introduced from the instrument channel inlet of the control body.
The endoscope also allows for angulation operation of the bending sections via operation of the angulation control knob; air/water feeding from the distal end of the endoscope via operation of the air/water feeding valve; and suction through the channel at the end of the endoscope via operation of the suction control valve.

Intended use

■ EG-2990Zi:

This PENTAX Video Upper G.I. scope is intended to provide optical visualization of (via a video monitor), and therapeutic access to, the upper gastrointestinal tract. This anatomy includes, but is not restricted to, the organs; tissues; and subsystems: esophagus, stomach, and duodenum.
This endoscope is introduced via the mouth or the nose, as decided by the physician, when indications consistent with the need for the procedure are observed in adult and pediatric patient populations.

■ EC-3890Zi series:

These PENTAX Video Colonoscopes are intended to provide optical visualization of (via a video monitor), and therapeutic access to, the lower gastrointestinal tract. This anatomy includes, but is not restricted to, the organs, tissues, and subsystems: large bowel to the cecum.
These endoscopes are introduced via the rectum when indications consistent with the need for the procedure are observed in adult and pediatric patient populations.

Application

Medical purposes	Provide images for observation, diagnosis, visualization, and treatment.
Patient population	Patients who are considered suitable for the application of this endoscope by the physicians (pediatric to adult patients).
Intended anatomical area	EG-2990Zi; Upper gastrointestinal tract (esophagus, stomach) duodenum EC-3890Zi series; Large intestine and terminal ileum
User qualifications	Physicians (Experts who have been approved by the endoscopic medical safety administrator at each medical facility. If the eligibility requirements are defined by an official body, such as a government entity and/or an academic society, follow such requirements). Specific training to use this endoscope is not required.
Location of use	A medical facility

Classification

Degree of protection against electric shock for the applied parts	TYPE BF applied part (when connected to a compatible PENTAX Medical video processor)
Degree of protection against water	IPX7 (with the soaking cap attached)
Mode of operation	Continuous operation

Specifications

■ Environment

Operating environment	Ambient temperature	10 to 40 °C
	Relative humidity	30 to 85 % RH
	Air pressure	700 to 1,060 hPa

Storage/transportation environment	Ambient temperature	–20 to 60 °C
	Relative humidity	0 to 85 % RH
	Air pressure	700 to 1,060 hPa

■ Software version

For the software version for each model, refer to the back cover.

■ Endoscope specifications

For details, refer to "Endoscope specifications" (p. 80).

Compatible products

This section describes the equipment that can be used in combination with this endoscope. For more details, refer to "System chart" (p. 81).
For the equipment used in combination during cleaning/high-level disinfection/sterilization, refer to the separate IFU (Reprocessing) of this endoscope.
The combinations of equipment and accessories that can be used with this product are listed below.
Prior to use, the product must be prepared and inspected according to its IFU.

Warning

PENTAX Medical does NOT warrant compatibility with unlisted products.
If products are NOT listed, contact the manufacturer of the equipment or accessory to confirm the compatibility and instructions for use with PENTAX Medical products.

Note

When this endoscope is used in combination with other equipment, depending on how it is connected, it may result in malfunction and/or unforeseen events to patients and/or medical professionals. Pre-use operation checks and risk management associated with such changes are recommended, particularly when the equipment used in combination is changed, added, or upgraded.

■ Video processor

Video processor models that can be connected with these endoscopes are shown below. For instructions on video processor operation, refer to the IFU of the respective video processor.

Model Name	Brand Name
EPK-i7000 series	PENTAX Medical
EPK-i5000 series	
EPK-i	

Reprocessing before the initial use, reprocessing, and storage after use

■ Reprocessing before the initial use

The endoscope identified in this IFU is a reusable semi-critical device. Since it is packaged non-sterile, it must be cleaned and high level disinfected, or cleaned and sterilized, or cleaned and disinfected and additionally can be sterilized (if applicable) according to the separate IFU (Reprocessing) of this product before initial use. Insufficient reprocessing may increase the risk of cross contamination.

Note

The wording "high-level disinfection" in this IFU defines the disinfection of the endoscope and the accessories with a completely virucidal disinfectant.

■ Reprocessing

After use, the endoscope must be appropriately cleaned, high-level disinfected and/or sterilized, and stored. Insufficient and/or incomplete cleaning, high-level disinfection, and/or sterilization of this endoscope may result in its non-optimal function of and/or damage to the endoscope and may pose a risk of infection to the patient and/or users.

Warning

When using an endoscope and its accessories on patients with Creutzfeldt-Jakob disease (CJD) or variant Creutzfeldt-Jakob disease (vCJD), use only dedicated instruments and equipment. The instruments and equipment used on these patients must be discarded so that they cannot be used again on another patient. The pathogenic agents that cause this disease, which are called “prions”, cannot be destroyed or inactivated using the cleaning, disinfection, and sterilization methods presented in this IFU. Please consult the guidelines that apply to your country or region for more detailed information regarding the handling of prion-contaminated instruments.

■ Storage after use

Warning

Observe the following guidelines. Failure to do so may result in contamination of the endoscope with bacteria or pose a risk of infection to patients and/or users.

- Ensure that all removable accessories, such as air/water feeding valve, suction control valve, inlet seal, cleaning adapter, and soaking caps are removed from the endoscope when storing.
- Do NOT store the endoscope in areas of high humidity or high temperature.
- Do NOT store the endoscope, its components, and accessories in the carrying case.
- Ensure that the endoscope, its components, and accessories are completely moisture-free before storage.
- Before the next use, the endoscope, its components, and accessories that have been stored inappropriately or for a prolonged period of time must be subjected to appropriate cleaning, high-level disinfection, and/or sterilization processes according to the separate IFU (Reprocessing).

Caution

Observe the following precautions when storing the endoscopes, its accessories, or device. Failure to do so may result in damage to property.

- Endoscope insertion portion, umbilical cord, and endoscopic devices should be kept as straight as possible during storage.
- Keep away from chemicals, direct sunlight, or ultraviolet rays.
- Maintain adequate distances between the endoscope, its accessories, and devices, so that they do NOT hit against each other.

Note

It is recommended to store the endoscope hanging down straight in a well-ventilated room or cabinet dedicated for endoscope storage.

For storage after use, also refer to the separate IFU (Reprocessing) of this endoscope.

General warnings and cautions

Warning

- The medical facility should determine restrictions or non-use of the endoscope in patients suspected of having lowered immunity.
- Users as well as the assisting personnel should always wear protective equipment (e.g., gloves, goggles, masks, medical gowns, etc.) to minimize the risk of cross contamination, as patient's body fluids may be dispersed from instrument components such as the instrument channel inlet and the suction control valve.
- Do NOT use this endoscope for any purpose other than its intended use. Doing so may result in patient injury.
- Do NOT use this endoscope with equipment other than those that have been specified for combined use. Endoscope operation in the freeze or magnification mode may result in damage to the endoscope and patient injury.
- Do NOT drop this endoscope or apply a strong shock to it. Doing so may result in damage to the endoscope. In particular, do NOT apply a strong shock to the lens surface at the distal end. Visual abnormalities may occur, which may result in unforeseen events.
- Ensure to attach/connect an appropriate device to the connectors of the PVE connector such suction nipple, air/water port, venting connector, or feedback terminal according to the IFU.
- Always check the endoscopic image during endoscope angulation, air/water feeding, and suctioning, use of endoscopic devices, and endoscope insertion and withdrawal. Ensure that these operations are performed in the normal (non-frozen, non-magnified) mode. Endoscope operation in the freeze or magnification mode may result in damage to the endoscope and/or patient injury.
- Do NOT forcefully insert and withdraw the endoscope. Doing so may result in patient injuries, including bleeding and perforation.
- Do NOT perform reverse observations inside a narrow lumen. Doing so may cause patient injury or make it impossible to withdraw the endoscope.

Warning

After using operational/cleaning accessories (e.g., forceps, needles, snares, brushes etc.) with the endoscope, carefully check that all accessories are intact and that no parts have fallen off and become lodged within the endoscope's instrument/suction channel. Furthermore, ensure that any therapeutic devices (e.g., clips, stents, etc.) passed through the channel are accounted for after use. If the instrument/suction channel becomes blocked or clogged due to the accumulation of debris, an accessory that cannot be removed, or other cause, do NOT attempt to correct the blockage or continue to use the endoscope. In such a case, contact your local PENTAX Medical service facility to have the endoscope repaired. The use of an endoscope with a blocked internal channel may result in ineffective reprocessing and/or the introduction of debris and/or device components into a patient during a subsequent procedure, posing a risk of cross contamination.

Caution

- Do NOT excessively twist, rotate, or bend any of the insertion portions, strain relief boots, or umbilical cord. Doing so may damage the endoscope.
- Do NOT hit the remote buttons with hard objects or pull or twist them. Doing so may cause internal damage to the endoscope that may lead to water leaks.
- Do NOT attach or remove the PVE connector of the endoscope while the power of the video processor is turned on. Doing so may damage the endoscope.
- Electromagnetic interference may occur with equipment labeled with the following symbol or near mobile RF communication equipment such as mobile phones. If electromagnetic interference occurs, reorient or relocate the endoscope or shield the location of use.

Maintenance management

The service life of this endoscope is 6 years after date of shipment with the following conditions.

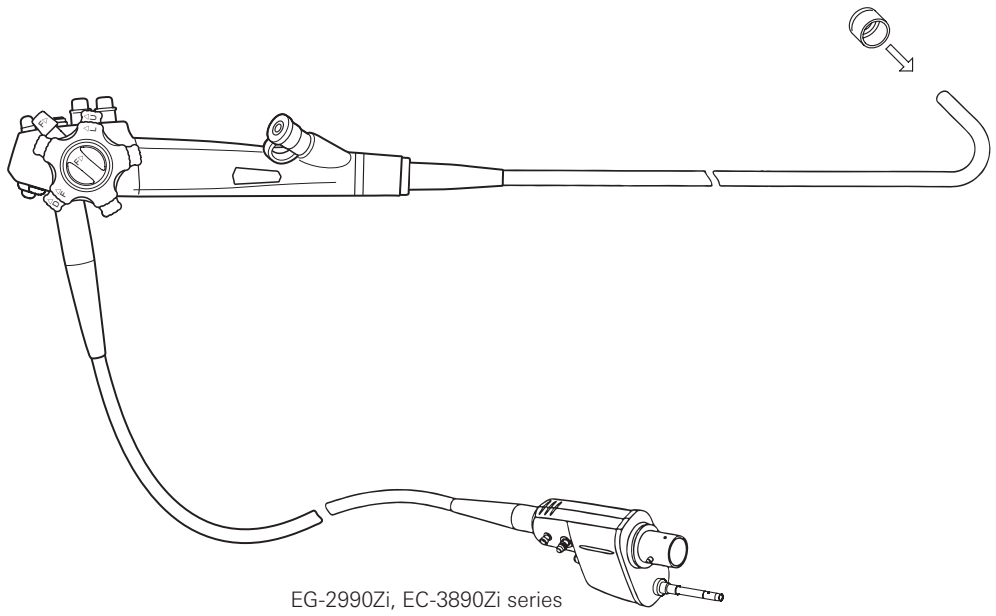
- Perform inspection before use, care after use, storage, and replacement of consumables according to this IFU.
- Have a specialist specified by PENTAX Medical perform repairs and at least annual periodic inspections.

1 Package contents

1-1. Package contents

Check the package contents according to the separate Standard Accessories List provided with this product. For detail picture of the contents/accessories, refer to Figure 1.1 and 1.2 in the IFU.
If there are any damaged or missing components, do not use the endoscope; immediately contact your local PENTAX Medical service facility. (Optional depending on the model.).

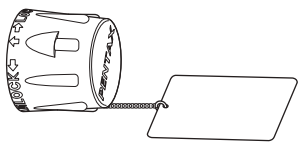
■ Endoscope



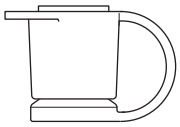
EG-2990Zi, EC-3890Zi series

Figure 1.1

■ Accessories

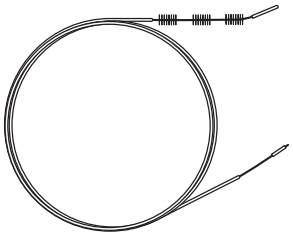


PVE Soaking Cap (OE-C9)

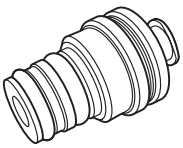


Inlet Seal (OF-B190)
(Installed)

Cleaning Brush (CS-C9S)



Cleaning Brush (CS6021T)

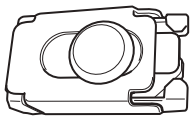


Cleaning Adapter
(OF-G17)

Silicone Oil Lubricant (OF-Z11)

Figure 1.2

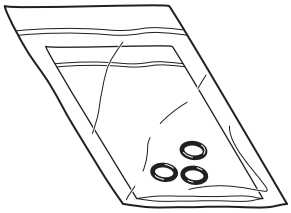
■ Accessories



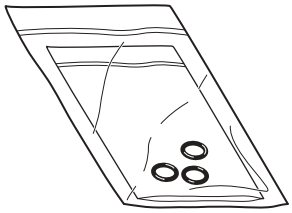
Cleaning Adapter
(OF-B153)

Irrigation Tube (OF-B113)

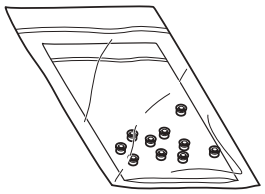
Ventilation Cap (OF-C5)



O Ring Set (OF-B192*)
* For Air/Water Feeding Valve (OF-B188)

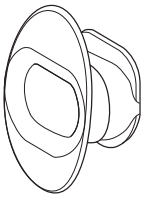


O Ring Set (OF-B127**)
** For Suction Control Valve (OF-B120)

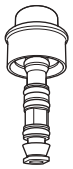


Check Valve Sets (OE-C15)

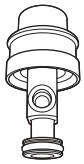
Distal Hood
(For EG-2990Zi, OE-A58)
(For EC-3890Zi series, OE-A59)



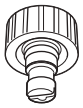
Bite Block (OF-Z5)
(For EG-2990Zi)



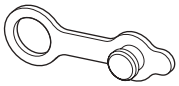
Air/Water Feeding Valve (OF-B188)
(Installed)



Suction Control Valve (OF-B120)
(Installed)



Water Jet Check Valve Adapter (OE-C12)
(Installed)



Water Jet Connector Cap (OF-B118)
(Installed)

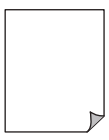
■ Endoscopic device***
*** This is an optional device depending on the sales region.

Biopsy Forceps
(EC-3890LZi/3890FZi: KW2422R), (EC-3890MZi: KW2418R), (EG-2990Zi: KW2415R)

■ Others

IFU (Operation; this document)

IFU (Reprocessing)



Standard Accessories List

Figure 1.2

2 Nomenclature and functions

2-1. Control body, insertion portion

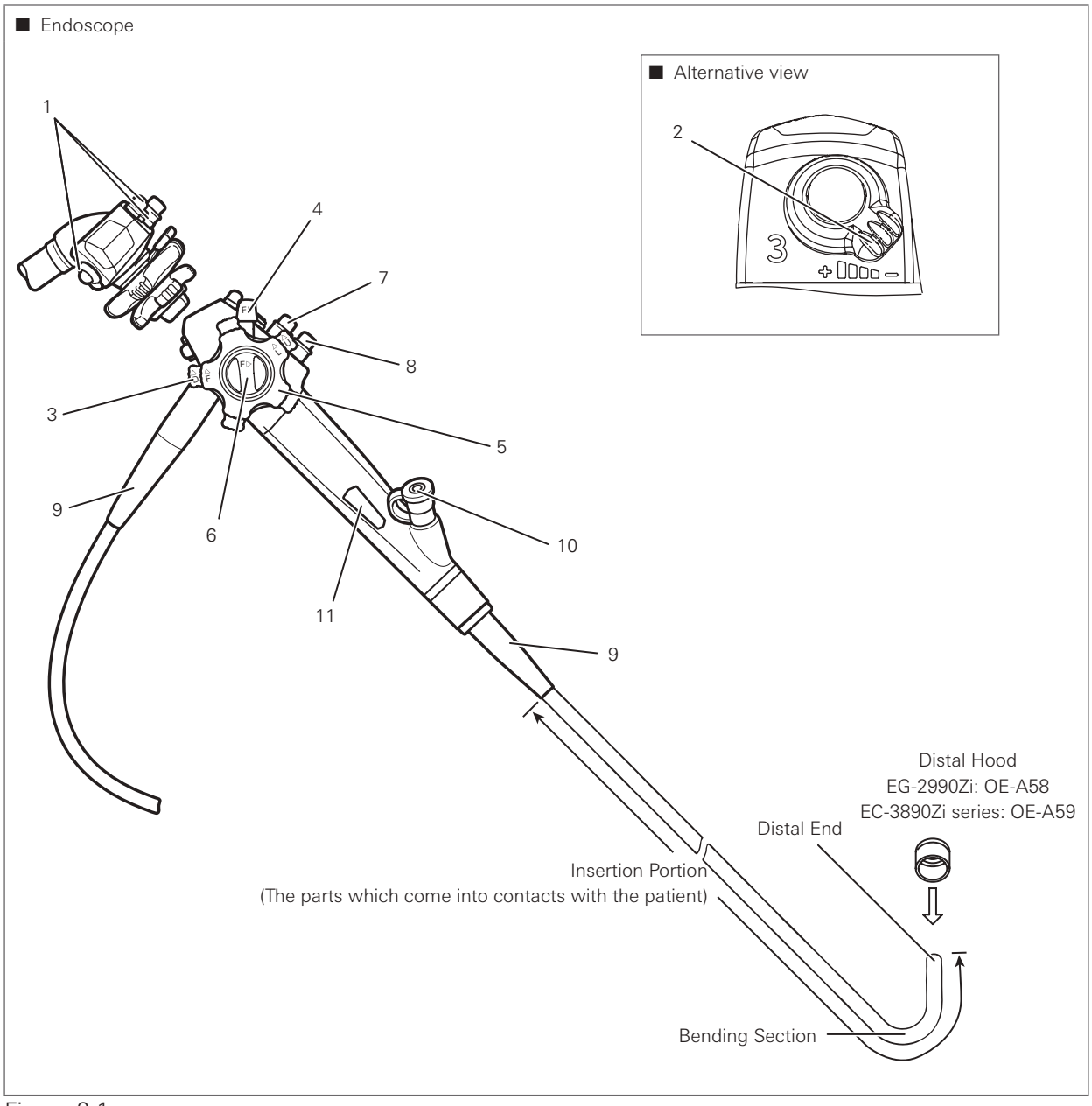


Figure 2.1

1. Remote Buttons 1-3
   Functions assigned to each button can be remotely controlled by pressing each of the remote buttons.
   Functions of the remote buttons 1-3 are assigned from the video processor.
   Refer to the IFU of the respective video processor for assignment of functions to each remote button.
2. Magnification control lever
   The optical zooming function is available through the magnification control lever operation.
3. Up/Down Angulation Control Knob
   By turning in the "▲ U" direction, the bending section moves upwards.
   By turning in the "▲ D" direction, the bending section moves downwards.
4. Up/Down Angulation Lock Lever
   By turning counterclockwise, upward/downward bending of the bending section is locked.
   By turning in the "F ► " direction, the bending lock is released.
5. Right/Left Angulation Control Knob
   By turning in the "▲ R" direction, the bending section moves to the right.
   By turning in the "▲ L" direction, the bending section moves to the left.
6. Right/Left Angulation Lock Knob
   By turning counterclockwise, right/left bending of the bending section is locked.
   By turning in the "F ► " direction, the bending lock is released.
7. Suction Control Valve (OF-B120)
   Attach to the suction cylinder. Depress it to suction fluids or air through the instrument channel of the endoscope.
8. Air/Water Feeding Valve (OF-B188)
   Attach to the air/water feeding cylinder. Covering the hole on the top of the valve feeds air from the air nozzle at the distal end of the endoscope. Depressing the valve feeds water from the water nozzle.
9. Strain Relief Boot
   The strain relief boot protects the connecting parts.
10. Inlet Seal (OF-B190)
    The inlet seal is attached to the instrument channel inlet to avoid fluid/air leakage.
11. Model Name Label
    The model name label shows the model name, minimum instrument channel width, and other related information. (Figure 2.2)

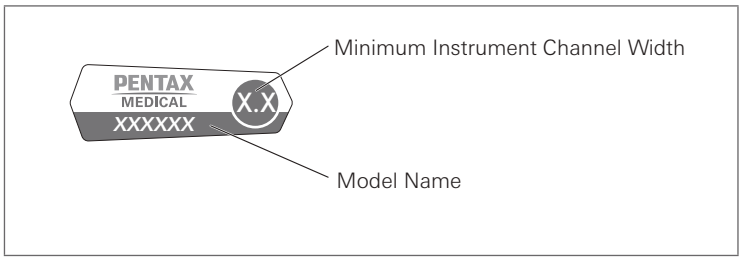


Figure 2.2

2-2. Connector

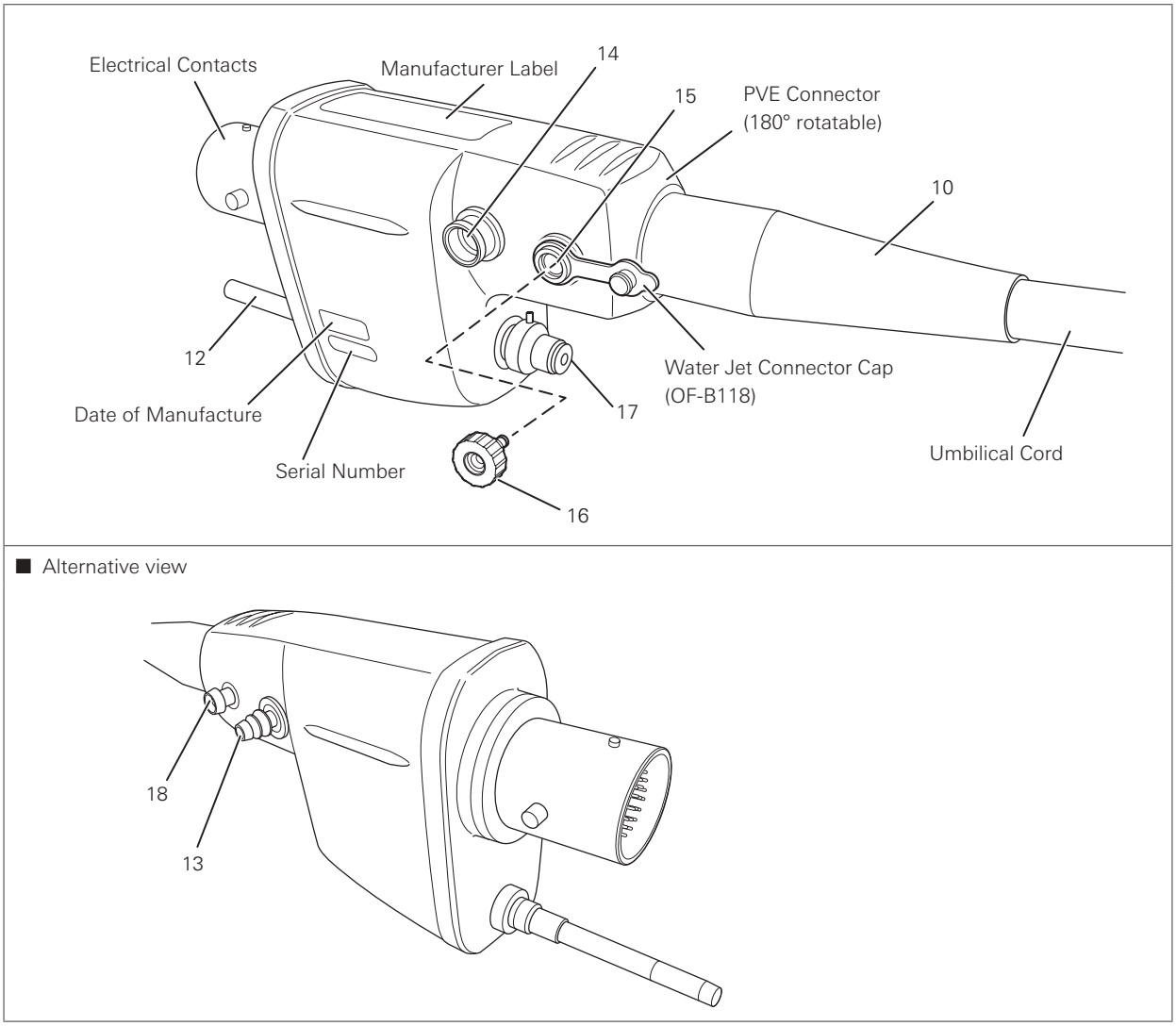


Figure 2.3

12. Light Guide Plug
    The light guide plug transmits the light received from the light source to the distal end of the endoscope..
13. Suction Nipple
    Connect the suction tube on the suction source to the suction nipple.
14. Air/Water Port
    Connect the air/water feeding hose on the water bottle assembly to the air/water port.
15. Water Jet Port
    Attach a water jet check valve adapter (OE-C12).
16. Water Jet Check Valve Adapter (OE-C12)
    Use it by attaching to the water jet port.
    Connect the irrigation tube (OF-B113) to send sterile water from a syringe or irrigation pump to the water jet nozzle at the distal end of the endoscope.
    When an irrigation tube is not connected, close it with the water jet connector cap (OF-B118).
17. Venting Connector
    Attach the ventilation cap (OF-C5) or the endoscope connector of the leakage tester here.
18. Feedback Terminal
    When using an electrosurgical device, connect the electrosurgical unit's endoscope feedback cord (S-cord) or the condenser earth cable (OL-Z4/OL-Z3: check the package contents according to the separate standard accessories list provided with this product.).

3 Preparation and inspection

Before use, the endoscope, accessories, video processor, and other components must be prepared and carefully inspected according to the IFU. Any equipment used in combination with the endoscope must also be prepared and inspected according to the respective instruction manuals.
Always perform pre-use inspection before each use.

If any abnormality is suspected during inspection, do not use the endoscope; send it for repair according to “5-2. Returning the endoscope for repair” (p. 75).

Warning

Always perform pre-use inspection before each use. NEVER use an endoscope with a suspected abnormality. Doing so may result in malfunction, endoscope damage, and/or injury to the patient and/or user.

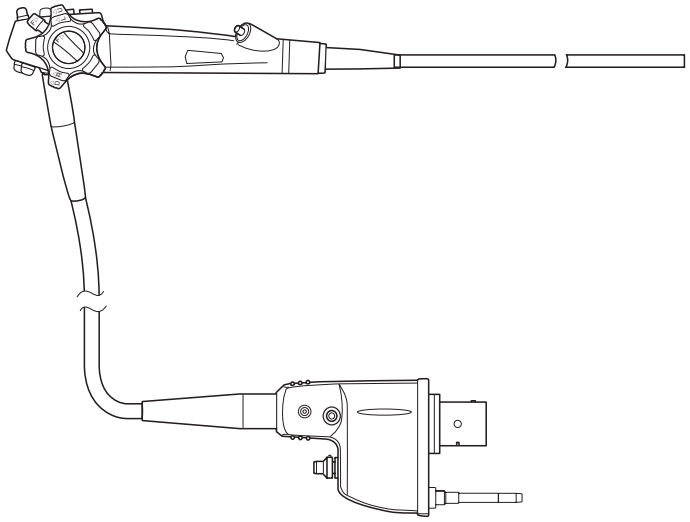
Caution

Ensure that another endoscope is also prepared to avoid interruption of the procedure due to endoscope failure or unforeseen events.

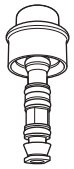
3-1. Preparation of the equipment

Prepare the endoscope, accessories, ancillary equipment, and protective equipment. Refer to the "Compatible products" to prepare the ancillary equipment as necessary and to the IFU provided with the video processor for its inspection.

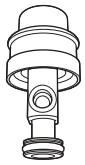
■ Endoscope



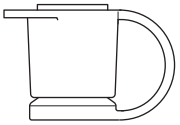
■ Accessories



Air/Water Feeding Valve (OF-B188)



Suction Control Valve (OF-B120)

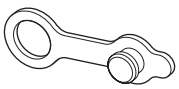


Inlet Seal (OF-B190)

Silicone Oil Lubricant (OF-Z11)

Water Jet Check Valve Adapter (OE-C12)

Irrigation Tube (OF-B113)

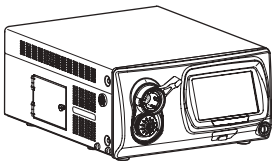


Water Jet Connector Cap
(OF-B118)

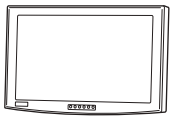
Bite Block (OF-Z5)
(For EG-2990Zi)

Distal Hood
(For EG-2990Zi, OE-A58)
(For EC-3890Zi series, OE-A59)

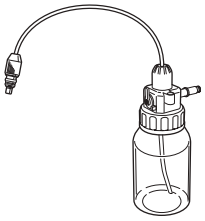
■ Ancillary Equipment



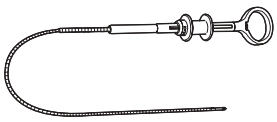
Video Processor



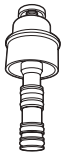
Monitor



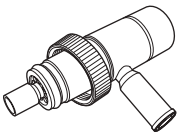
Water Bottle Assembly



Endoscopic Device

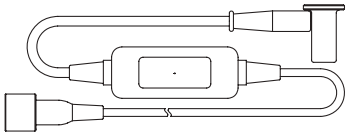


Gas/Water Feeding Valve (OF-B194*)
* Optional item



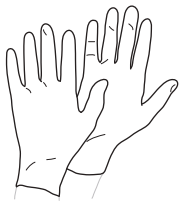
Gas Adapter (OF-G11*)
* Optional item

Suction Source



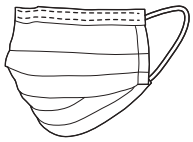
Condenser Earth Cable
(OL-Z4/OL-Z3)

■ Protective Equipment (example)



Gloves

Goggles



Mask

Medical Gown

■ Others

Gauze, sterile water, container for sterile water, etc.

Figure 3.1

3-2. Inspection of the endoscope

Prepare an endoscope that has been reprocessed according to the procedure specified in the separate IFU (Reprocessing) of this endoscope.

Warning

- NEVER disassemble or modify the endoscope. Doing so may impair its original functionality and possibly result in serious injury to the patient and/or user.
- NEVER use an endoscope with any abnormality. Doing so may result in endoscope damage, detachment of parts into the patient's body cavity, malfunction during use, and/or injury to the patient and/or user.
- Use only sterile water for inspection. Failure to do so may result in contamination of the endoscope with waterborne bacteria and other microorganisms. Do NOT use water that has been left uncovered for a prolonged period of time.

Caution

- Do NOT excessively twist, bend, or rotate any of the strain relief boots on the instrument (See Figure 3.2 (1) and 3.2 (2) to identify the strain relief boots). Doing so may result in instrument damage. Pay special attention to the careful handling of the strain relief boot of the insertion portion (See Figure 3.2 (1)) of the endoscope, because it has a small diameter and is more likely to suffer damage due to mishandling.
- When carrying the endoscope, do NOT grasp or carry it only by its umbilical cord or insertion portion. Moreover, do NOT squeeze or forcefully bend the bending section. (Figure 3.3) Doing so may result in equipment damage.

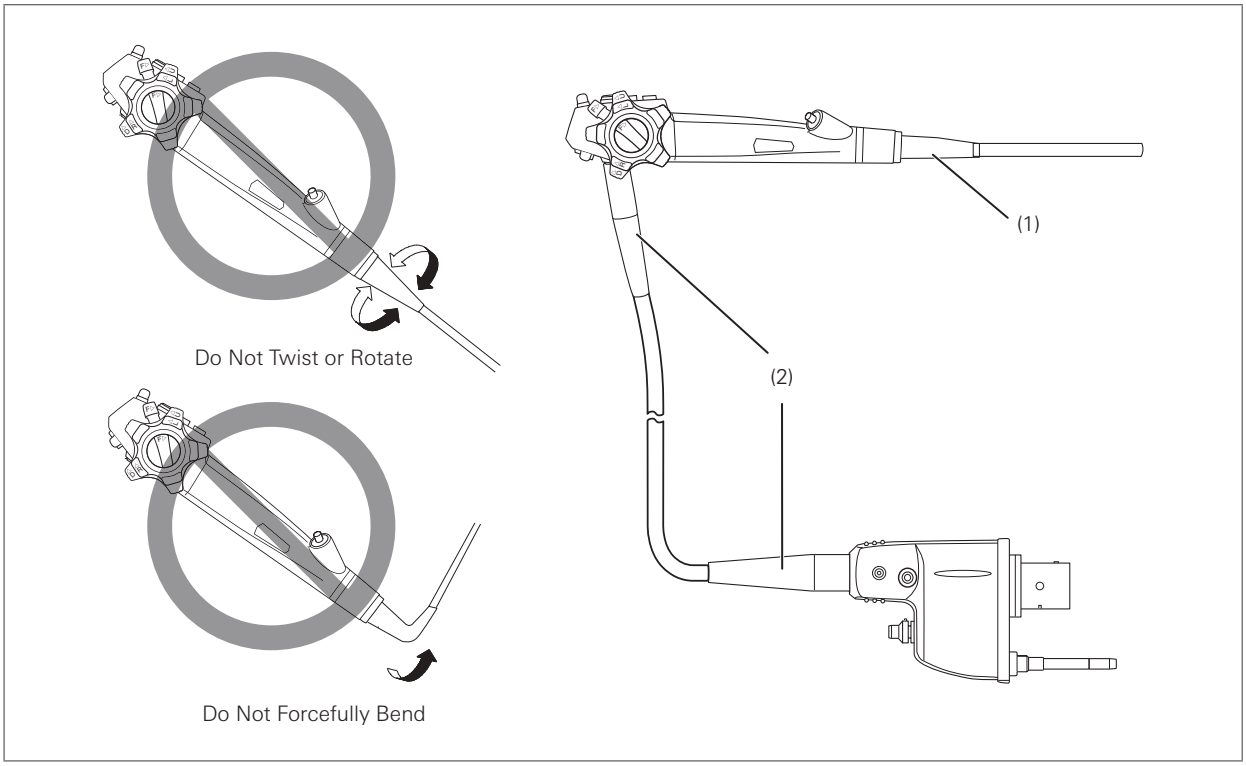


Figure 3.2

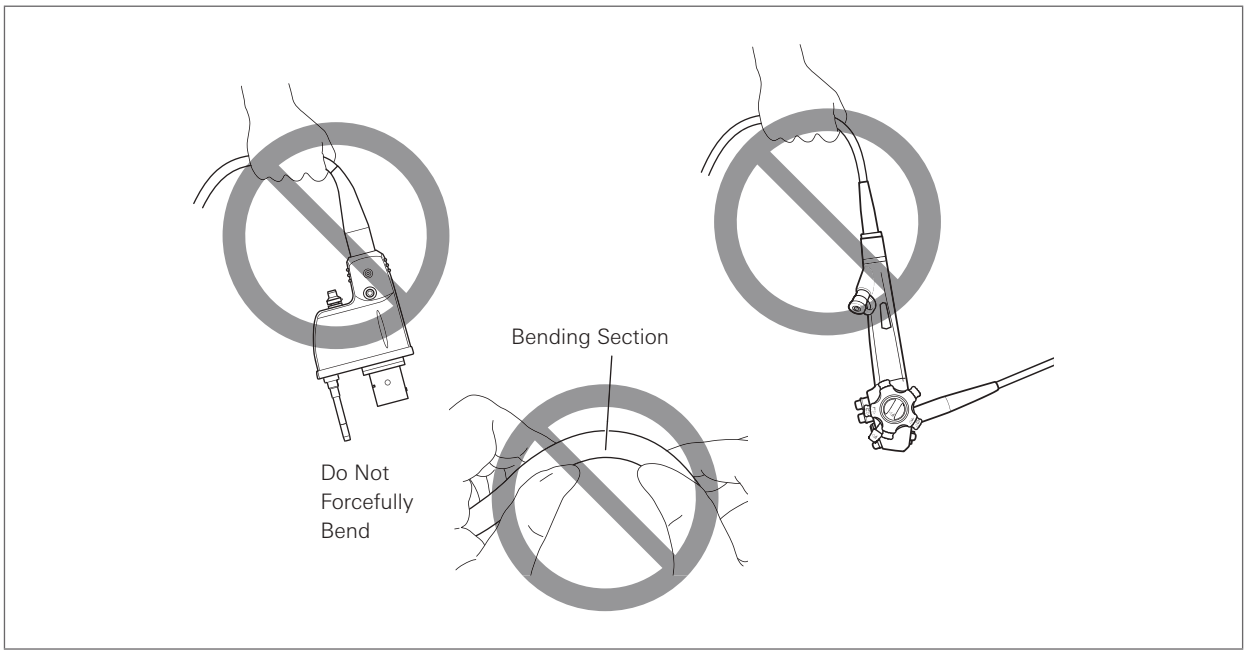


Figure 3.3

Note

In case the endoscope is hot/cold immediately after cleaning, high-level disinfection, and/or sterilization, wait until it returns to room temperature before using it. Observation may be hindered by fogging of lens and other effects because of the difference in the temperature of the endoscope and the room.

■ Carrying the endoscope by hand

When carrying the endoscope by hand, loosely loop the umbilical cord and insertion portion, hold the control body and insertion portion (near the bending section) in one hand, and hold the PVE connector in the other hand as shown in Figure 3.4.

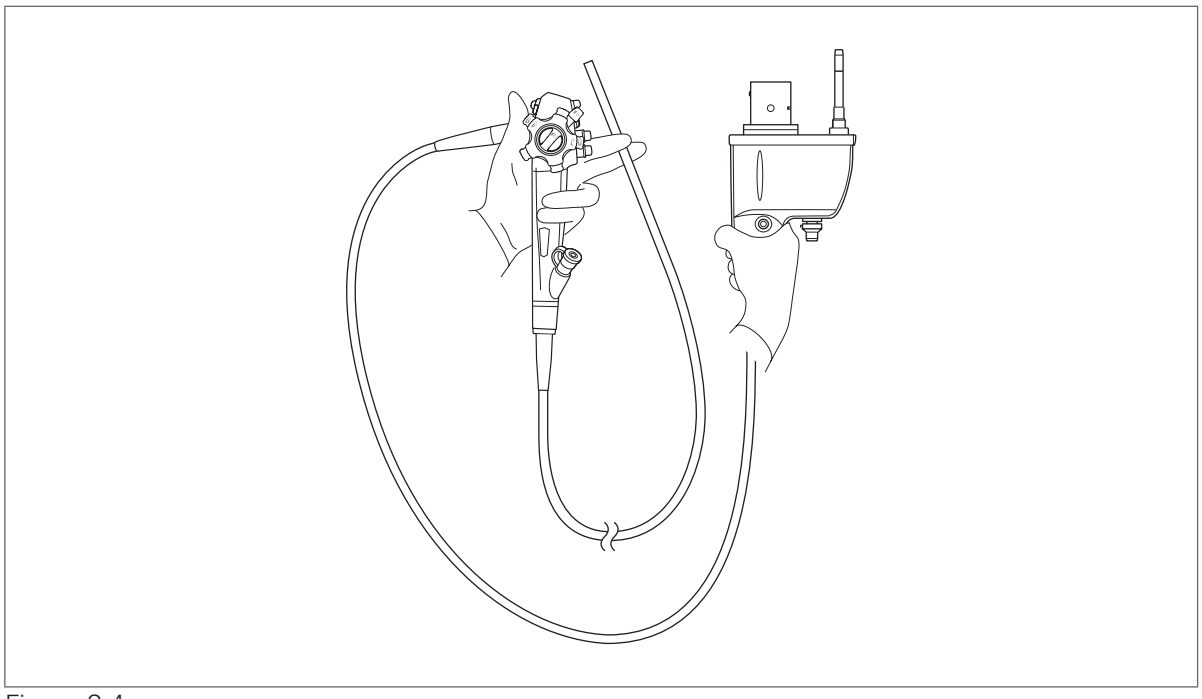


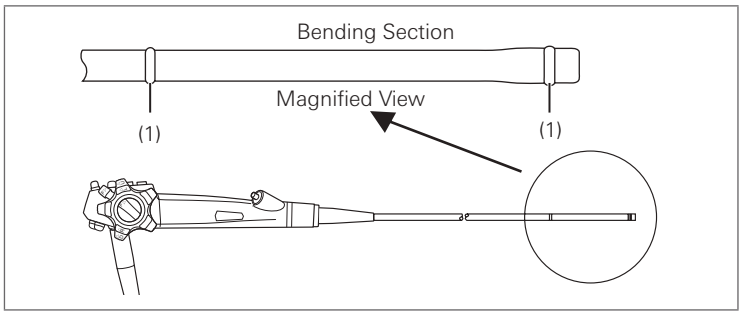
Figure 3.4

Inspection of the entire endoscope

Warning

NEVER use the endoscope with any abnormality in function. Doing so may result in endoscope damage, detachment of parts into the patient's body cavity, endoscope malfunction during use, and/or injury to the patient and/or user.

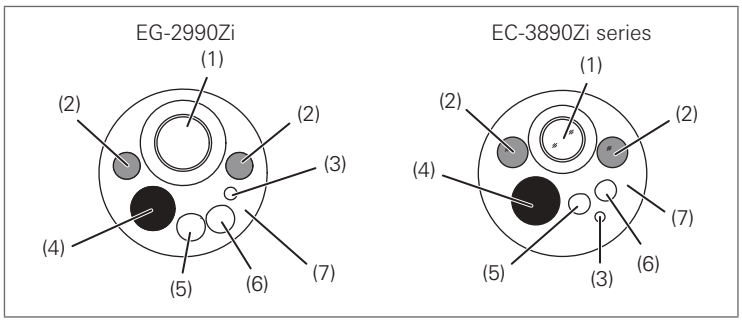
1. Check the entire surface of the endoscope for any visible adhered material.
2. Check the entire surface of the insertion portion for abnormalities such as wrinkles, scars, sharp edges, clouding of the surface, dents, catching, protrusions, attachment of foreign materials, detachment of parts, etc.
3. Check the surface of the adhesive bands on both ends of the bending section for abnormalities such as scratches, clouding, and peeling. With clean gauze, lightly wipe the surface of the adhesive bands to ensure that there is no catching and/or attachment of the adhesive on the gauze.



(1) Adhesive Bands

Figure 3.5

4. Check the case of the distal end of the endoscope (especially around the periphery of the instrument channel) for any abnormalities such as deformation or chipping.



(1) Objective Lens
(2) Light Guide
(3) Water Jet Nozzle
(4) Instrument Channel
(5) Air Nozzle
(6) Water Nozzle
(7) Case

Figure 3.6

5. Check the objective lens at the distal end of the endoscope and the light guides for any abnormalities such as attachment of foreign material, scratches, or chipping, and ensure that there is no gap on the periphery of the lens.
6. Ensure that there are no scratches, clouding, or peeling on the surface of the adhesive glue around the objective lens at the distal end of the endoscope and it looks glossy.
7. Gently clean the objective lens and light guides with clean gauze or a cotton-tip applicator moistened with 70%–90% medical grade ethyl or isopropyl alcohol. Check that there is no attachment of the adhesive on the gauze.

Note

Clear images cannot be obtained when there are any attachment of foreign material or residuals on the objective lens or light guides. When an endoscope with any attachment of foreign material or residuals on the objective lens or light guides is used, vapor may be generated from the water contents of the attachment of foreign material or residuals being heated by the light.

8. Check the air nozzle and water nozzle at the distal end of the endoscope for any abnormalities such as clogging, dents, deformations, chipping, etc.
9. Form an arch with the insertion tube as shown in Figure 3.7 using both hands. By sliding the insertion tube in the direction of the arrow in Figure 3.7, check that the entire insertion tube can be bent smoothly and easily to form an arch.

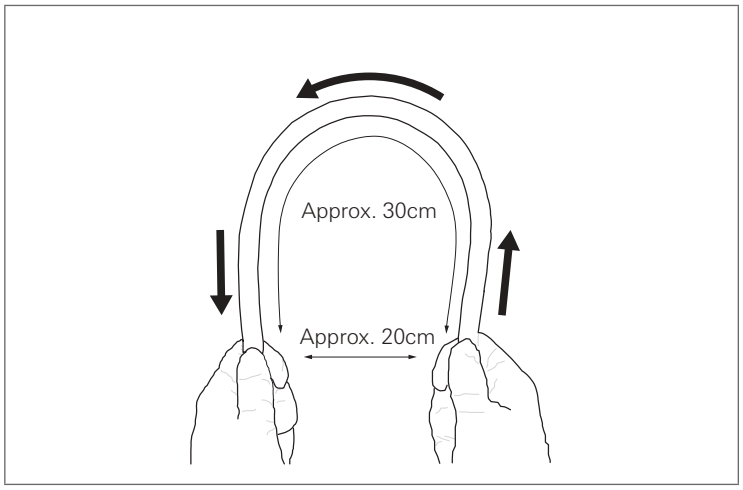
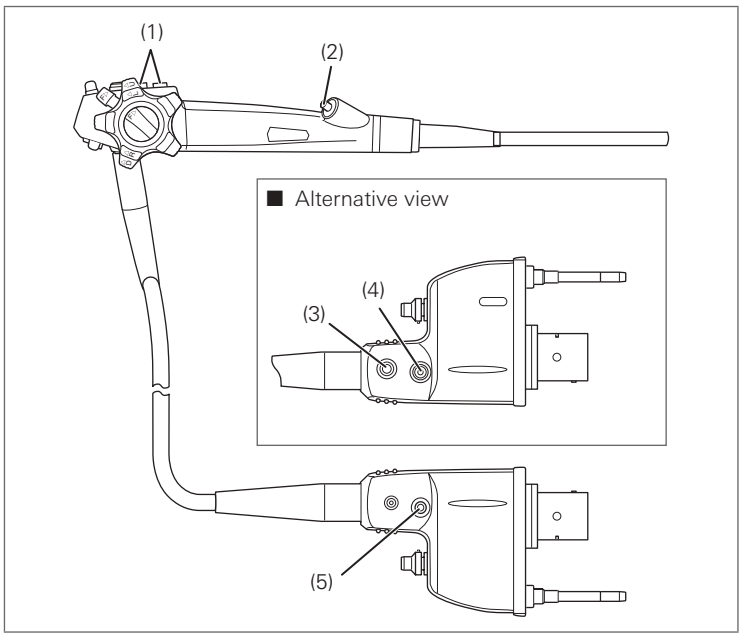


Figure 3.7

10. Check the entire surface of the umbilical cord for abnormalities such as wrinkles, scars, sharp edges, clouding of the surface, catching, protrusions, attachment of foreign materials, detachment of parts, etc.

11. Check the control body, PVE connector, and electrical contacts for abnormalities such as scratches, deformities, loose parts, etc. Pay special attention when checking the parts shown in the Figure 3.8. Take clean, lint-free gauze to gently hold these parts, and move them in various directions to ensure that there are no abnormalities such as looseness.



(1) Suction Cylinder & Air/Water Feeding Cylinder
(2) Instrument Channel Inlet
(3) Water Jet Port
(4) Air/Water Port
(5) Suction Nipple

Figure 3.8

Inspection of the angulation mechanism

Ensure that there is nothing near the bending section that would hinder its operation, and inspect the angulation mechanism while the insertion portion is kept straight.

■ Inspection of bending function

> ⚠ Warning
>
> Do NOT use the endoscope with angulation abnormalities such as non-smooth operation, excessive play in the angulation control lever, or excessive angulation attenuation, as the inside of the endoscope may be damaged. Using the endoscope in this state may result in worsening of endoscope damage, malfunction during use, and patient injury.

1. Turn the up/down angulation lock lever and right/left angulation lock knob in the "F ▶ " direction until they stop to release the lock of the angulation control knobs.

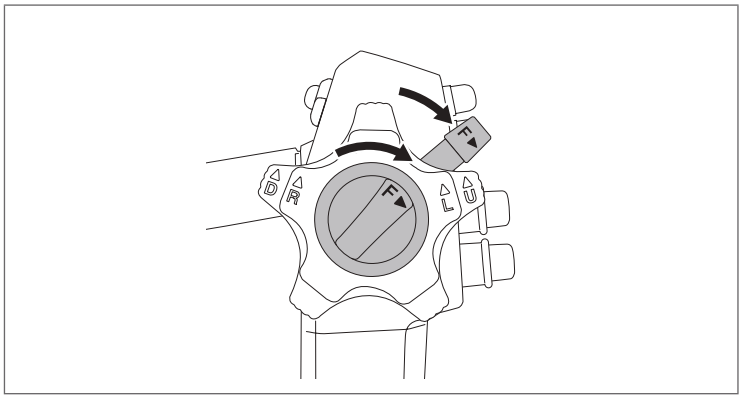


Figure 3.9

2. Turn the up/down and right/left angulation control knobs slowly in each direction until they stop, and return them to their original position. Check that the angulation control knobs operate smoothly with no roughness or catching.

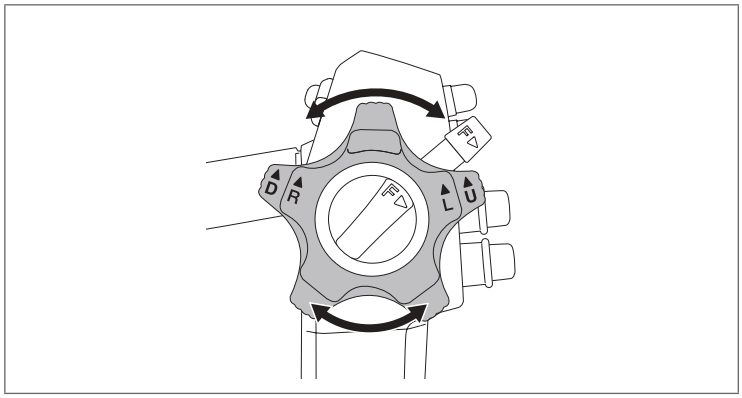


Figure 3.10

3. Check that the bending section angulates in the direction in which the angulation control knobs are turned and that the maximum angulation can be achieved.

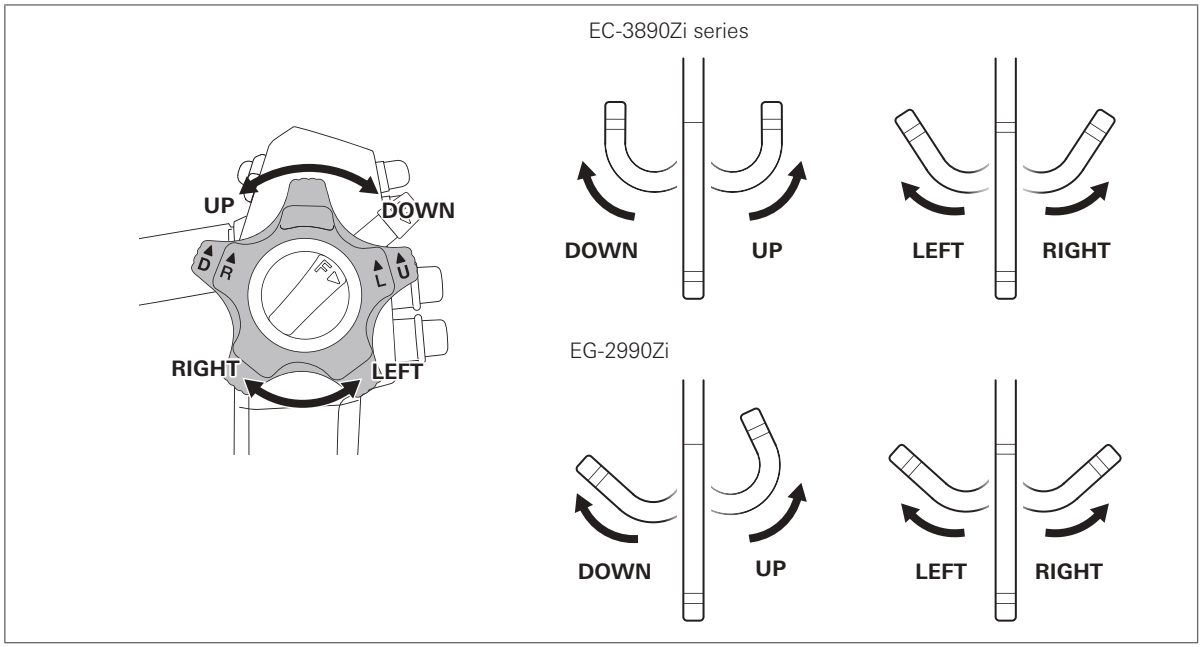


Figure 3.11

4. Turn the angulation control knobs back to the neutral position. Check that the bending section returns to an approximately straight condition.

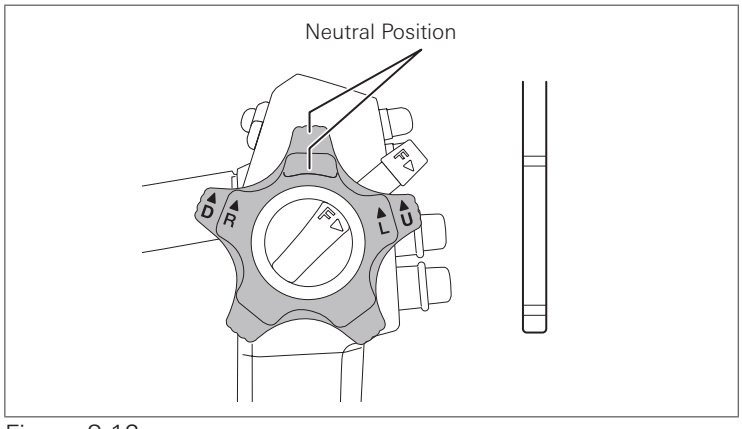


Figure 3.12

■ Inspection of the up/down bending lock mechanism

1. Turn the up/down angulation lock lever counterclockwise until it stops.

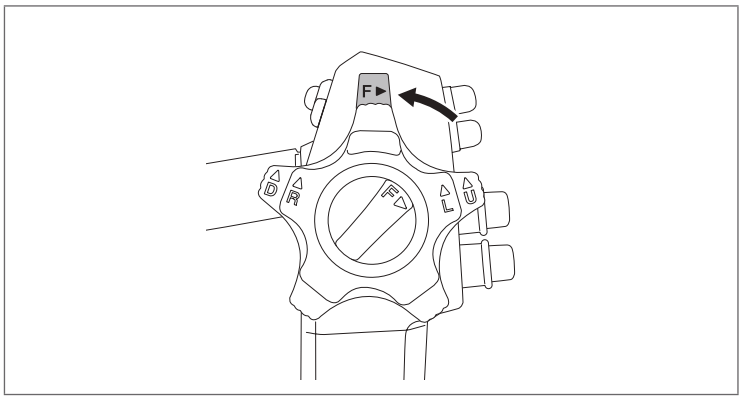


Figure 3.13

2. Turn the up/down angulation control knob slowly in the "▲U" or "▲D" direction until it stops.

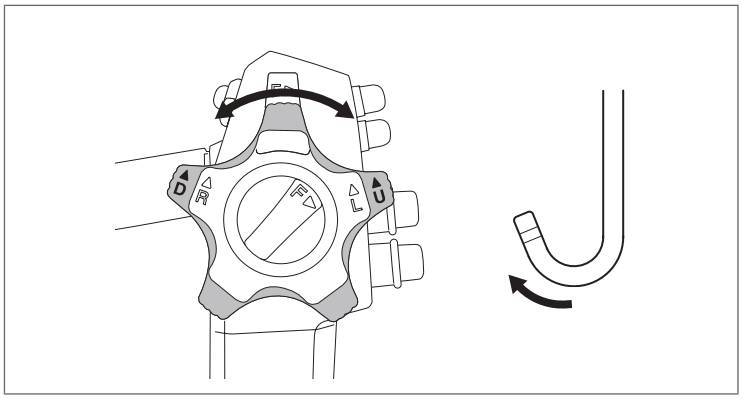


Figure 3.14

3. Check that the curved form of the bending section is fixed when releasing the angulation control knob.
4. Turn the up/down angulation lock lever in the "F►" direction until it stops to release the lock. Check that the bending section returns to an approximately straight condition.

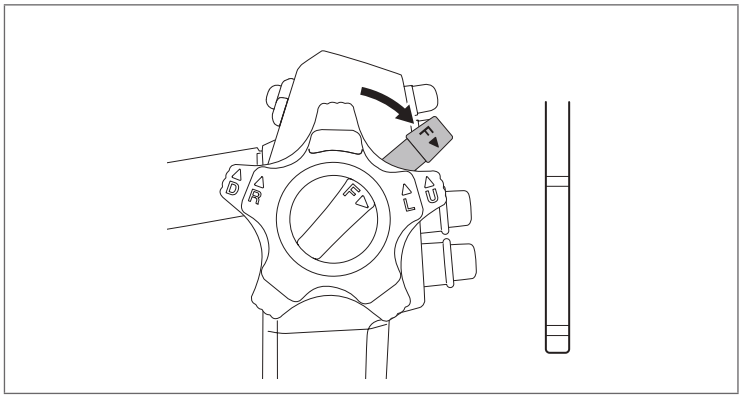


Figure 3.15

■ Inspection of the right/left bending lock mechanism

1. Turn the right/left angulation lock knob counterclockwise until it stops.

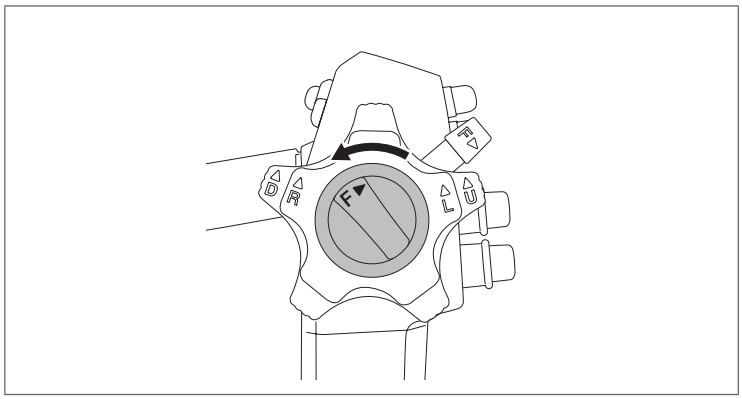


Figure 3.16

2. Turn the right/left angulation control knob slowly in the "▲ R" or "▲ L" direction until it stops.

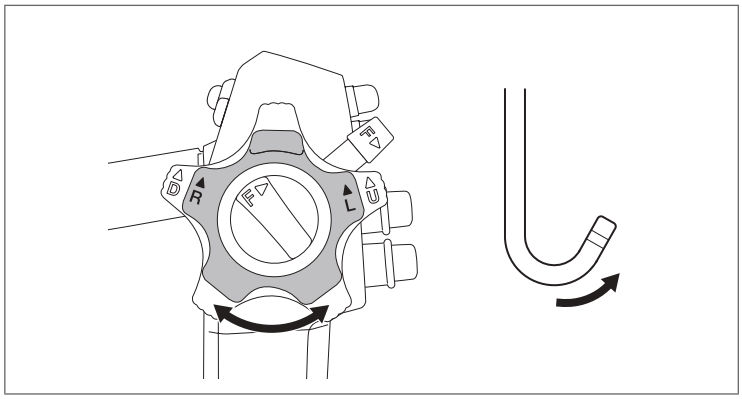


Figure 3.17

3. Check that the curved form of the bending section is fixed when releasing the angulation control knob.
4. Turn the right/left angulation lock knob in the "F ► " direction until it stops to release the lock. Check that the bending section returns to an approximately straight condition.

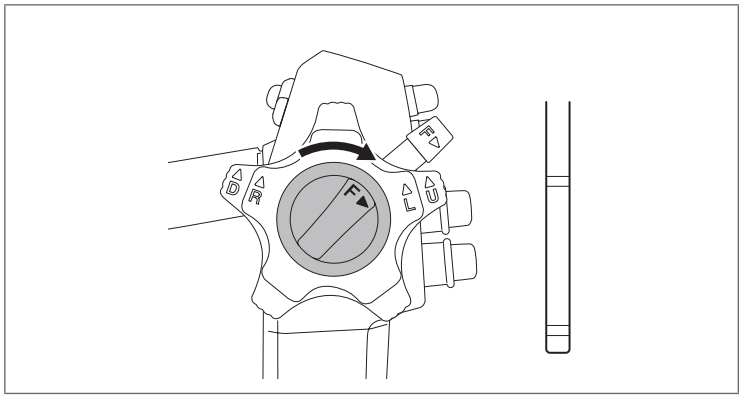


Figure 3.18

3-3. Inspection of accessories and attachment to the endoscope

When using reusable accessories, ensure that they have been cleaned, high-level disinfected, and/or sterilized according to the separate IFU (Reprocessing) of this endoscope.

Warning

NEVER disassemble or modify the accessories and endoscopic devices. Doing so may impair their original functionality and possibly result in serious injury to the patient and/or user.

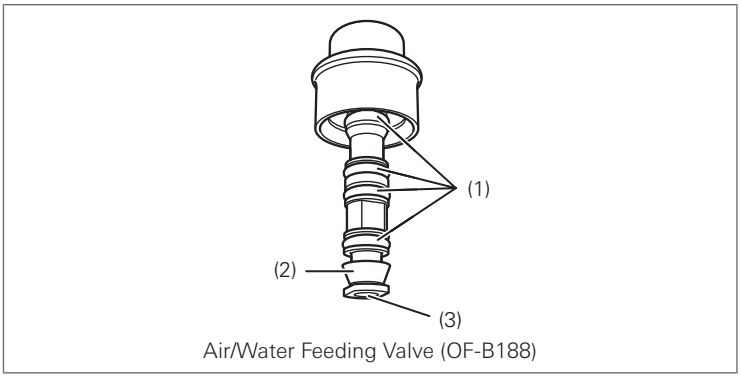
Inspection of the air/water feeding valve (OF-B188)

Warning

- If any abnormality is suspected with the check-valve, replace the air/water feeding valve with a new one. Continue use of the air/water feeding valve with abnormalities could cause unintended continuous air feeding and pose a risk of pain or perforation to the patient. It could also pose a risk of infection to the user as result of reflux or dispersal of patient's body fluids from the air/water feeding valve.
- The O-ring of the air/water feeding valve is a consumable. If any abnormality is suspected with the O-ring, stop use immediately and replace it with a new one. Use the compatible O-ring set for replacement. Using an O-ring with abnormalities or non-compatible O-ring could lower the function of air/water feeding, cause unintended continuous air feeding, and pose a risk of pain or perforation to the patient. It could also pose a risk of infection to the user as result of reflux or dispersal of patient's body fluids from the air/water feeding valve.
- The replacement O-ring is NOT sterilized or disinfected before shipment. Perform cleaning and high-level disinfection, and/or sterilization of the air/water feeding valve after O-ring replacement.

Note

Use the O ring set (OF-B192) for air/water feeding valve (OF-B188) for replacement.
For details on the O-ring replacement method, refer to the IFU provided with the O ring set (OF-B192).



Air/Water Feeding Valve (OF-B188)

(1) O-ring
(2) Check Valve
(3) Hole

Figure 3.19

1. Check the air/water feeding valve (OF-B188) for any abnormalities such as attachment of foreign materials, deformation, cracks, or hole blockage.

2. Check that the O-ring is properly attached and that there is no chipping, breaks, or peeling in the O-ring or check-valve.

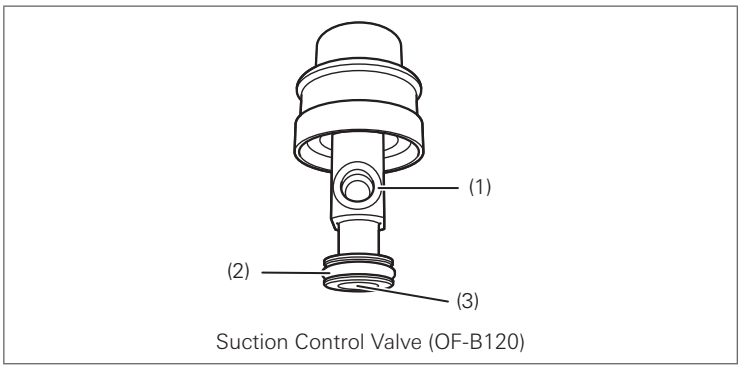
Inspection of the suction control valve (OF-B120)

Warning

- If any abnormalities are suspected in the rubber seal, replace the suction control valve with a new one. Using a suction control valve with any abnormality could result in continuous weak aspiration, which may hinder the procedure. It could also result in potential reflux or dispersal of patient's body fluids, posing a risk of infection.
- The O-ring of the suction control valve is a consumable. If any abnormality is suspected with the O-ring, stop use immediately and replace it with a new one. Use the compatible O-ring set for replacement. Using an O-ring with abnormalities or non-compatible O-ring could result in unintended continuous suction and may hinder the examination. It could also pose a risk of infection to the user as a result of reflux or dispersal of patient's body fluids from the suction control valve.
- The replacement O-ring is NOT sterilized or disinfected before shipment. Perform cleaning and high-level disinfection, or sterilization of the suction control valve after O-ring replacement.

Note

Use the O ring set (OF-B127) for the suction control valve (OF-B120) for replacement.



Suction Control Valve (OF-B120)

(1) Rubber Seal
(2) O-ring
(3) Hole

Figure 3.20

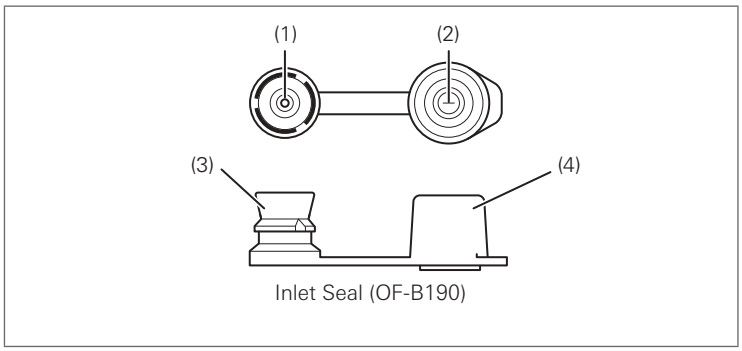
1. Check the suction control valve (OF-B120) for any abnormalities such as attachment of foreign materials, deformation, cracks, or hole blockage.
2. Check that the O-ring is properly attached and that there is no chipping, breaks, or peeling in the O-ring or sealing rubber part.

Inspection of the inlet seal (OF-B190)

Warning

NEVER use an inlet seal (OF-B190) that has any abnormality. Replace it with a new one. Inlet seals are consumables. Using a damaged and/or worn inlet seal may result in lowered suction function and potential reflux or dispersal of patient's body fluids, posing a risk of infection.

1. Check the slit in the cap of the inlet seal (OF-B190) and the hole of the body of the inlet seal for any abnormalities such as cracks, wear, chipping, and attachment or presence of foreign materials. Check that the light does not shine through the slit of the cap.



(1) Hole
(2) Slit
(3) Body
(4) Cap

Figure 3.21

2. Put the cap to the body of the inlet seal and check that the cap is correctly attached.

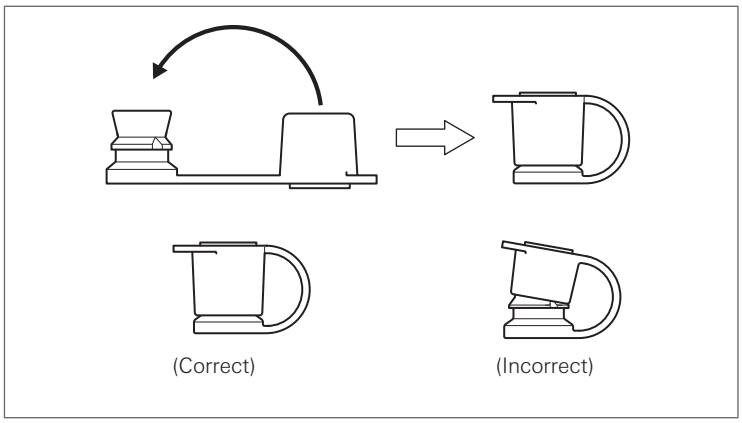


Figure 3.22

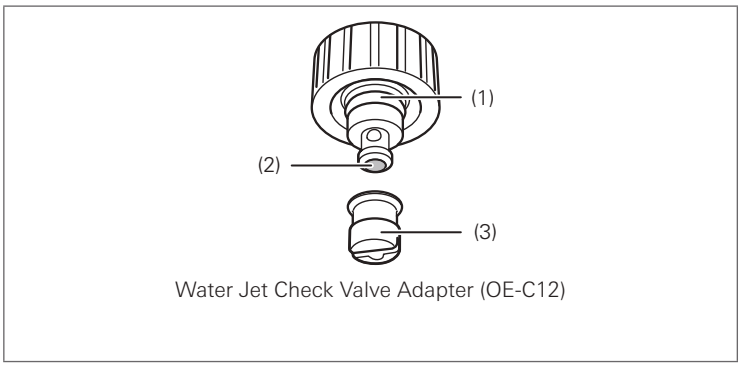
Inspection of the water jet check valve adapter (OE-C12)

Warning

- NEVER use a water jet check valve adapter (OE-C12) that has any abnormality. Replace it with a new one. Check valve adapters are consumables. Using a damaged check valve adapter may result in potential reflux or dispersal of patient's body fluids, posing a risk of infection.
- Replacement check valve sets (OE-C15) are NOT sterilized or disinfected before shipment. Perform cleaning and high-level disinfection or sterilization of the water jet check valve adapter after check valve replacement.

Note

Use the check valve set (OE-C15) for replacement.



Water Jet Check Valve Adapter (OE-C12)

(1) O-ring
(2) Hole
(3) Check Valve (OE-C14)

Figure 3.23

1. Check the water jet check valve adapter for any abnormalities such as attachment of foreign materials, deformation or cracks, or hole blockage.
2. Ensure that the check valve is attached correctly to the water jet check valve adapter without any gaps or pinching.

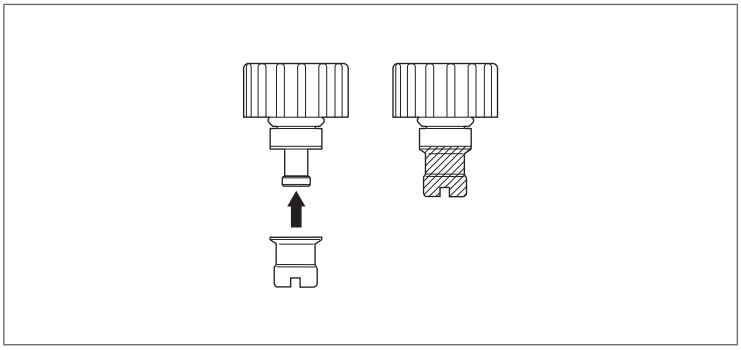


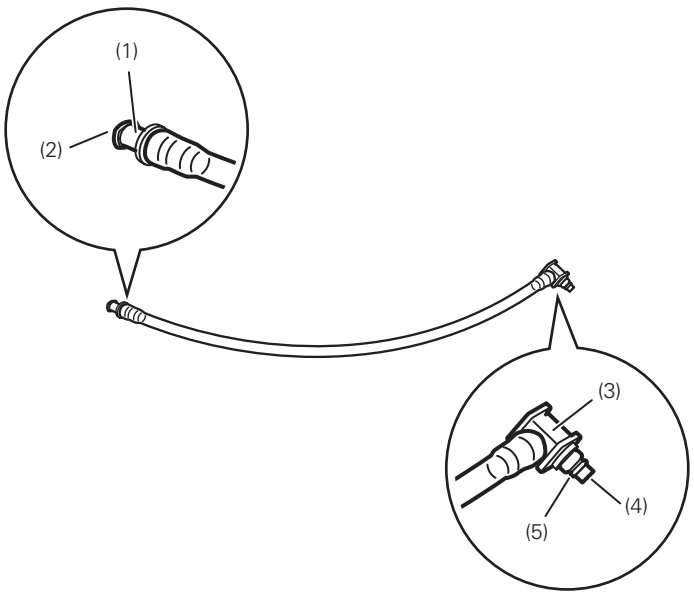
Figure 3.24

3. Check the O-ring and check valve for any abnormalities such as cracks, breaks, and peeling.

Inspection of the irrigation tube (OF-B113)

Warning

NEVER use the irrigation tube (OF-B113) when abnormality is suspected in inspection. Replace it with a new one. Using the OF-B113 with abnormality in the process of cleaning, high level disinfection, or sterilization may cause leaking of detergent from the connection part and detachment of the OF-B113. The cleaning, high-level disinfection or sterilization may NOT be effective due to the insufficient processing.



Irrigation Tube (OF-B113)

(1) Luer Connector
(2) Hole
(3) Connector
(4) Hole
(5) O-ring

Figure 3.25

1. Check the entire surface of the irrigation tube (OF-B113) for abnormalities such as bending/breakage/looseness of the connector, cut/chip of the O-ring, buckling/deterioration/hardening of the tube, and/or broken luer.
2. Attach the syringe filled with the sterile water to the luer connector of the irrigation tube (OF-B113) and flush sterile water.
3. Check that sterile water flows in a steady stream from the connector of the irrigation tube (OF-B113).

Inspection of the distal hood (OE-A58/OE-A59)

Warning

- The distal hoods (OE-A58 / OE-A59) are provided non-sterile and non-disinfected. Prior to the initial use, it must be subjected to appropriate cleaning and high-level disinfection, or sterilization according to the respective IFU for the distal hood (OE-A58 / OE-A59). Insufficient processing prior to use may increase the risk of cross contamination.
- NEVER use a distal hood that has any abnormality. Replace it with a new one. Using a distal hood with an abnormality may result in endoscope damage and patient injury.

Note

Distal hoods are consumables. Even while it is still within its service life, avoid reuse whenever possible, instead replace it with a new one on every use.

Check the distal hood for any abnormalities such as attachment of foreign materials, cracks, deformity, chipping, and discoloration.

Distal Hood
(OE-A58 for EG-2990Zi, OE-A59 for EC-3890Zi series)

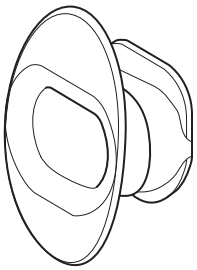
Figure 3.26

Inspection of the bite block (OF-Z5) (EG-2990Zi only)

Caution

NEVER use a bite block with any abnormality. Replace it with a new one.
Using a bite block with an abnormality may result in endoscope damage and injury to the oral cavity of patients.

Check the bite block for any abnormalities such as attachment of foreign materials, cracks, deformity, chipping, and discoloration.



Bite Block (OF-Z5)

Figure 3.27

Inspection of the endoscopic devices

For details on the inspection of each endoscopic device, refer to the instruction manual provided with the specific endoscopic device. For reusable endoscopic devices, prepare ones that have been cleaned and sterilized by following the instruction manual for the respective endoscopic device.

Warning

- NEVER use an endoscopic device with signs of damage and/or operational abnormality. Doing so may result in malfunction during use, endoscope damage, and/or patient injury.
- All reusable endoscopic devices must be cleaned and sterilized before initial use as well as before every subsequent use.
- Use endoscopic devices specified by PENTAX Medical whose compatibility has been confirmed. Using endoscopic devices whose compatibility has NOT been confirmed may result in endoscope damage and/or patient injury caused by failure during use.

This section describes the use of a biopsy forceps.

1. Check the entire surface of the forceps for any visible adhered material.
2. Check the insertion portion and control body of the biopsy forceps for abnormalities such as wrinkles, scars, sharp edges, clouding of the surface, dents, catching, protrusions, attachment of foreign materials, falling of parts, etc.

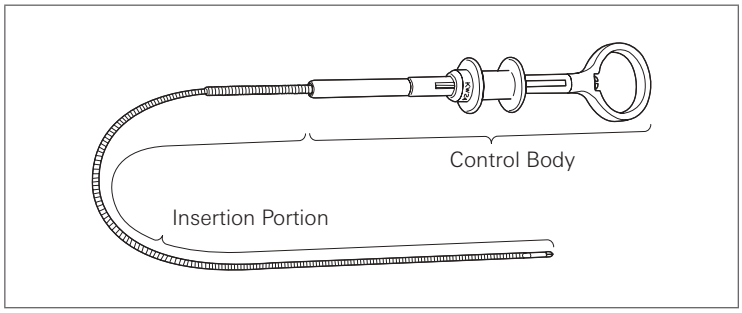


Figure 3.28

3. Check that the cups of the biopsy forceps open/close smoothly by operating its handle.

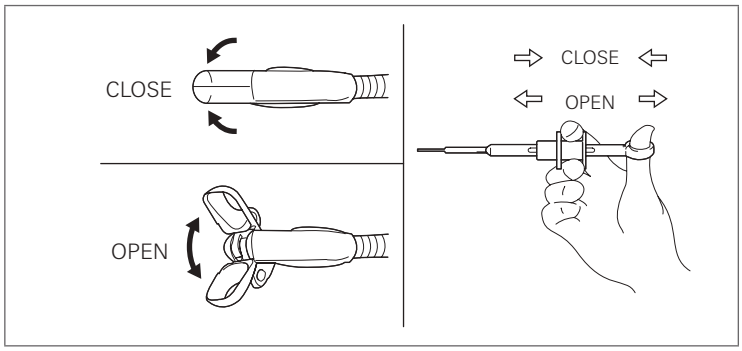


Figure 3.29

4. Form a loop with a diameter of 20 - 30 cm with the flexible shaft at approximately 20 - 30 cm from the tip of the insertion portion of the biopsy forceps. Check that the cups of the biopsy forceps open/close smoothly by operating its handle.

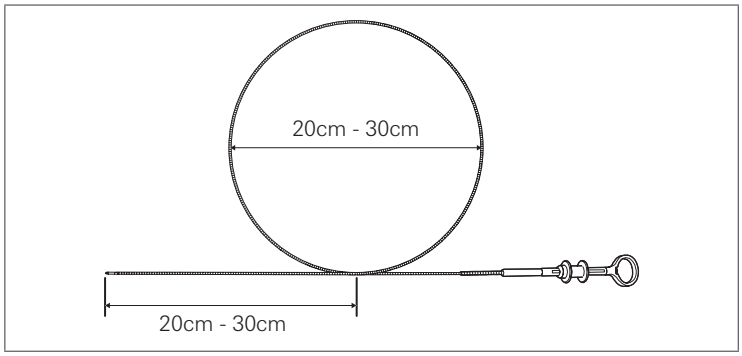


Figure 3.30

5. Check that the cups align with each other when closed.

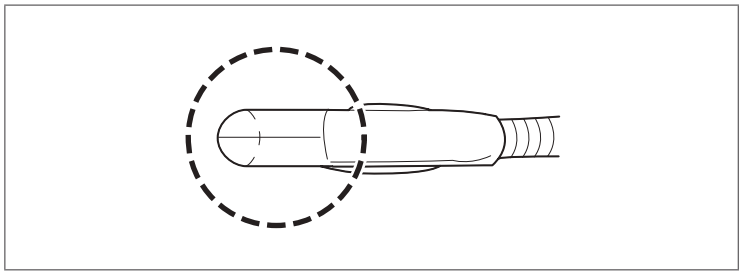


Figure 3.31

Attachment of accessories

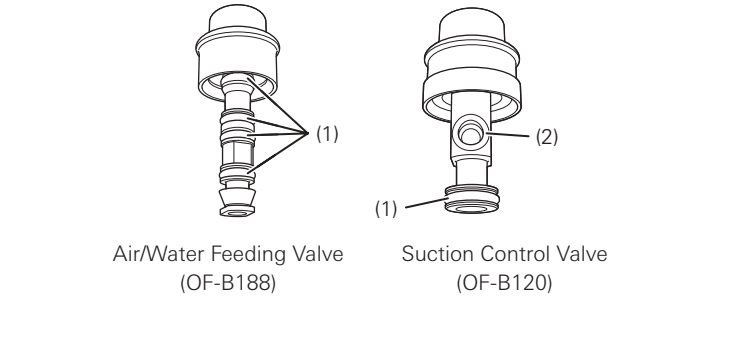
Warning

- Attach the accessories properly to the endoscope. Failure to do so may result in lowered function and potential reflux or dispersal of patient's body fluids, posing a risk of infection.

■ Attachment of the air/water feeding valve (OF-B188) and suction control valve (OF-B120)

Caution

- Ensure to apply silicone oil lubricant (OF-Z11) onto the O-ring of each valve and the rubber seal of the suction control valve (OF-B120). Using the valves without applying the oil or applying a silicone oil other than the specified one could deteriorate the functions and may result in damage to the endoscope and/or patient injury.
- Attach the air/water feeding valve (OF-B188) and suction control valve straight to the cylinder of the endoscope. Pressing them at an angle may result in damage to the O-ring and check valve.



(1) O-ring
(2) Rubber Seal

Figure 3.32

1. Apply a small amount of silicone oil lubricant (OF-Z11) onto the O-rings of the air/water feeding valve (OF-B188) and suction control valve (OF-B120), and the rubber seal. Place a small droplet of oil onto a sterile gloved forefinger, gently swirl the oil between the thumb and the forefinger, and apply it onto the necessary parts. Wipe off the excess lubricant with soft gauze.
2. Attach the air/water feeding valve to the air/water feeding cylinder of the endoscope.

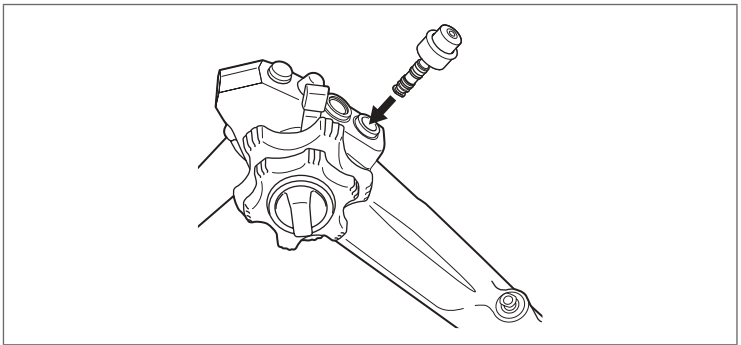


Figure 3.33

3. Ensure that the air/water feeding valve (OF-B188) is firmly attached. Press down the air/water feeding valve a few times to ensure that it moves smoothly.

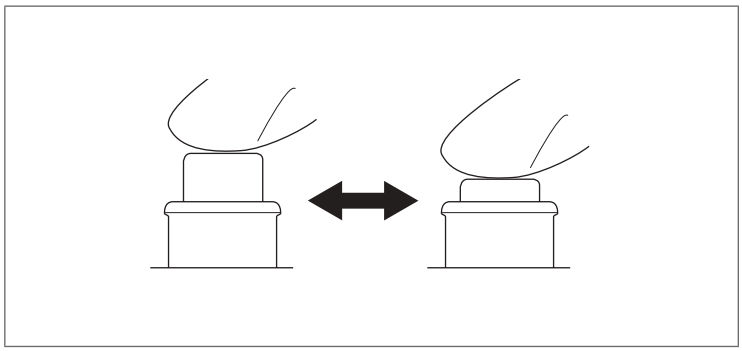
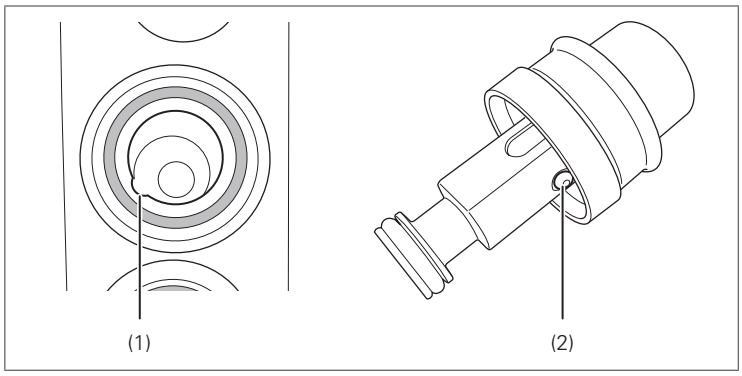


Figure 3.34

4. Align the metal tab on the shaft of the suction control valve (OE-B120) with the notch on the suction cylinder of the endoscope.



(1) Notch
(2) Metal Tab

Figure 3.35

5. Attach the suction control valve to the suction cylinder of the endoscope.

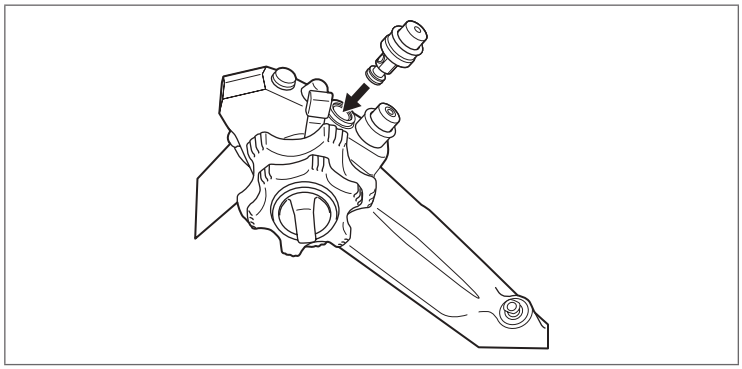


Figure 3.36

6. Check that the suction control valve is firmly attached. Press down the suction control valve a few times to ensure that it moves smoothly.

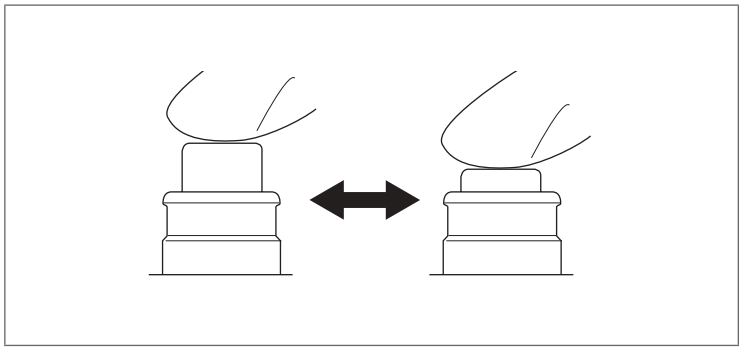


Figure 3.37

■ Attachment of the inlet seal (OF-B190)

1. Attach the inlet seal (OF-B190) to the instrument channel inlet.

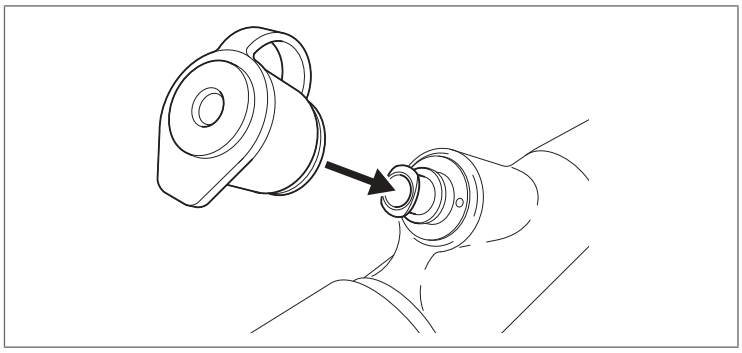


Figure 3.38

2. Ensure that the inlet seal is tightly attached to the instrument channel inlet without gaps.

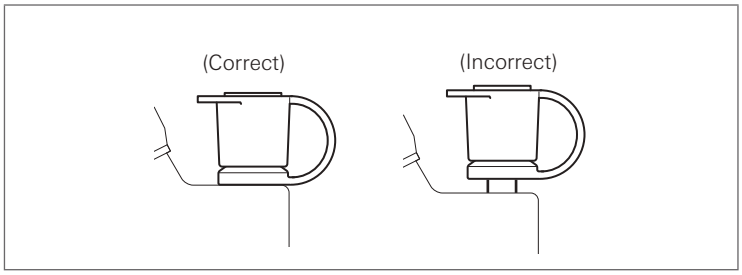


Figure 3.39

■ Attachment of the water jet check valve adapter (OE-C12) and water jet connector cap (OF-B118)

1. Attach the water jet connector cap (OF-B118) and water jet check valve adapter (OE-C12) to the water jet port of the endoscope.

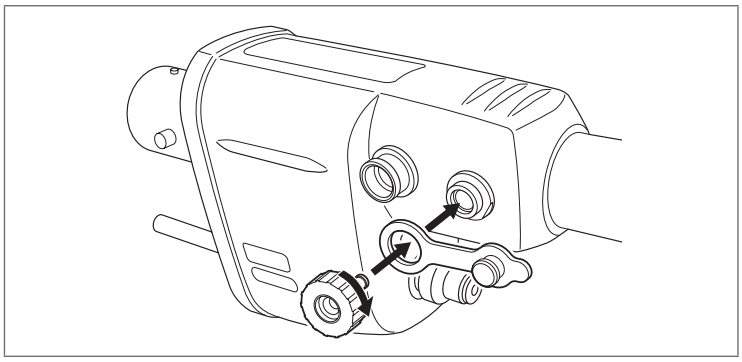


Figure 3.40

2. Ensure that the water jet check valve adapter is firmly attached to the water jet port without gaps. (Close the lid of the water jet connector cap.)

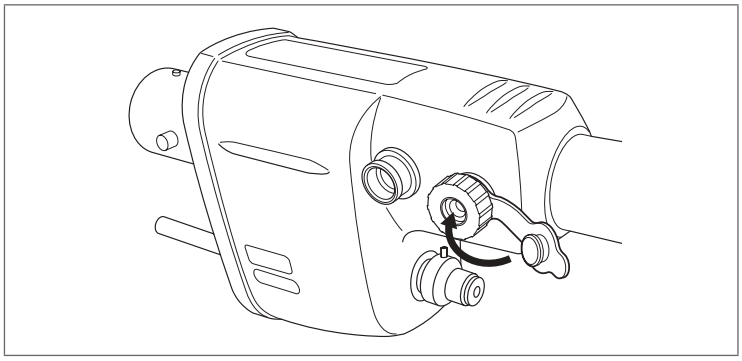


Figure 3.41

■ Attachment of the distal hood (OE-A58/OE-A59)

Warning

The distal hood (OE-A58/OE-A59) is provided non-sterile and non-disinfected. Prior to use, it must be subjected to appropriate cleaning, high-level disinfection, and/or sterilization processes according to the respective IFUs.

Caution

Lightly hold the distal end of the endoscope when attaching/removing the distal hood (OE-A58/OE-A59).
Do NOT apply excessive force to hold the distal end of the endoscope as it may deform the bending section and damage the endoscope.

Note

- The distal hood OE-A58 can be attached to EG-2990Zi, and the distal hood OE-A59 can be attached to EC-3890Zi series. By attaching the distal hood, the distance with the observed section is kept constant, making it easier for magnified observation.
- The distal hood may appear in the monitor in the non-magnified state.

1. Check the distal end of the endoscope for presence of lubricant or water.
2. Hold the distal end gently and push the distal hood into the flange portion inside.

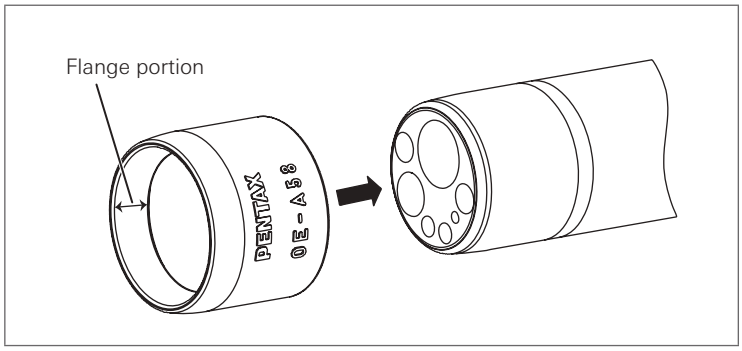


Figure 3.42

3. Ensure that there is no gap between the flange portion of the distal hood and the distal end of the endoscope.

3-4. Inspection and connection of ancillary equipment to the endoscope

Inspect the ancillary equipment prepared in "3-1. Preparation of the equipment", such as the video processor, monitor, and suction source, according to their respective manuals.

Video processor
Monitor
Water bottle assembly
Endoscopic device
Suction source, etc.

Inspection of the video processor

Only use compatible PENTAX Medical video processors.
For compatible video processors, refer to "Compatible products" (p. 7) or "System chart" (p. 81).

For details on the preparation and inspection of the video processor, refer to the IFU of the respective video processor.

Connection of the endoscope and ancillary equipment

■ Connection to the video processor

1. Ensure that all ancillary equipments are turned off.
2. Ensure that the endoscope locking lever is placed in the "OPEN" position. Securely insert the endoscope electrical contacts and light guide plug into the processor connector and receptacle.

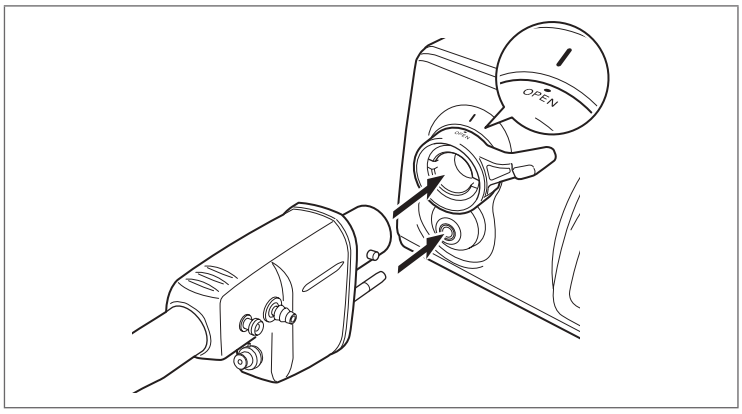


Figure 3.43

3. Turn the endoscope locking lever to the "LOCK" position.

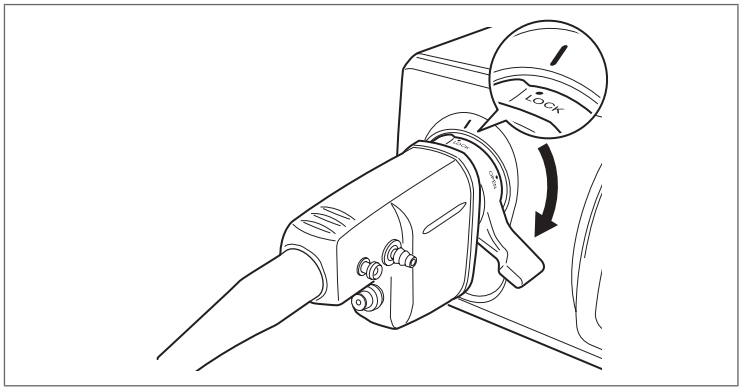


Figure 3.44

4. Lightly pull the PVE connector to ensure that it is connected securely.

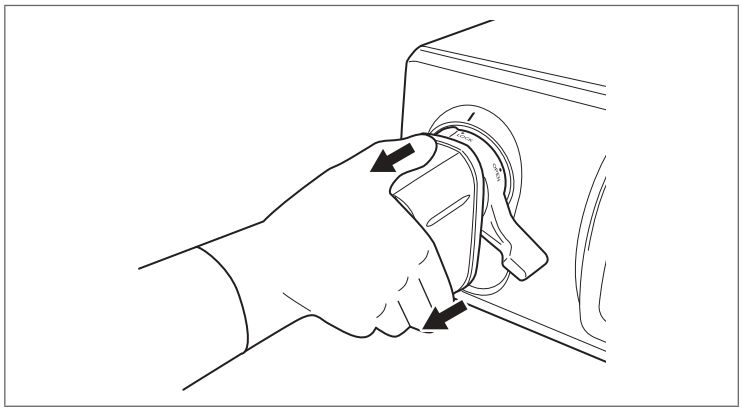


Figure 3.45

■ Connection of the water bottle assembly, suction tube, and irrigation tube (OF-B113)

Warning

- Use only sterile water in the water bottle assembly. Failure to do so may pose a risk of infection.
- Connect the suction tube of the suction source firmly to the suction nipple. Failure to do so may result in disconnection of the suction tube during use and pose a risk of cross contamination to the user as a result of reflux or dispersal of patient's body fluids.

Caution

Do NOT use defoaming agents in the water bottle assembly. Such agents cling to the inside channel of the endoscope. A blocked channel can lower the air/water feeding function and cause damage to the endoscope.

Note

Turn off the air/water feeding pump of the video processor beforehand.

1. Attach the water bottle assembly correctly according to the IFU of the video processor.
2. Insert the air/water connector of the water bottle assembly into the air/water port of the endoscope until it clicks.

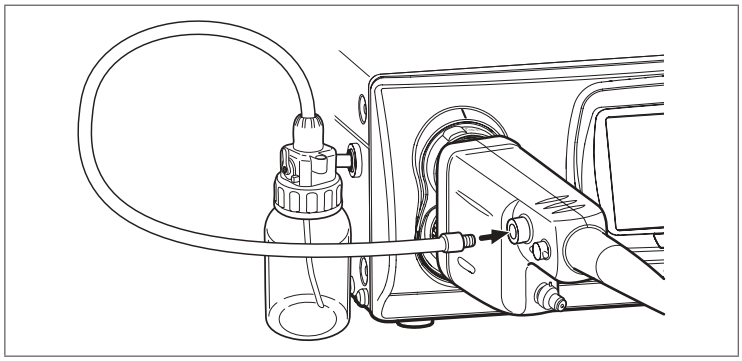


Figure 3.46

Note

Failure to connect the water bottle assembly correctly not only lowers the air/water feeding function, but may also cause insufficient cleaning of the objective lens.

3. Connect the suction tube of the suction source to the suction nipple of the endoscope.

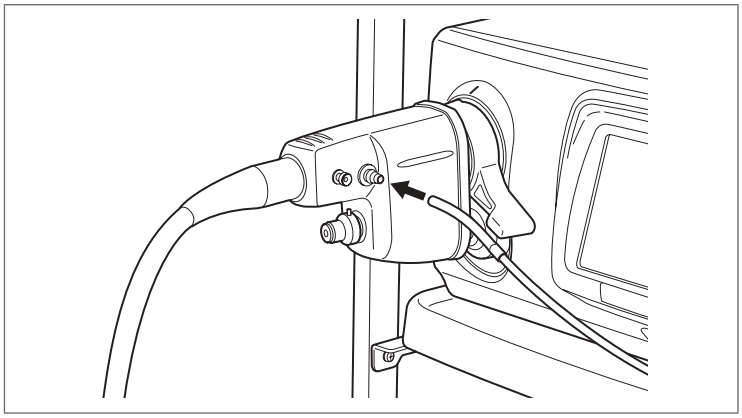


Figure 3.47

4. Remove the lid of the water jet connector cap (OF-B118) and push the irrigation tube (OF-B113) into the water jet check valve adapter (OE-C12) until it clicks.

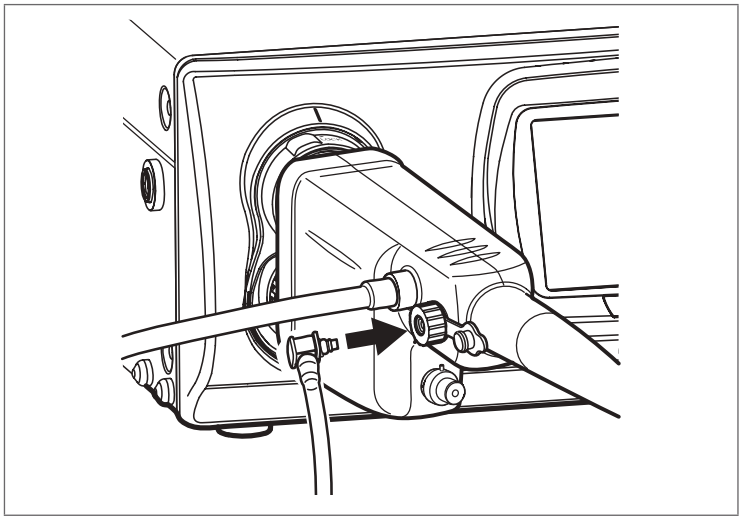


Figure 3.48

Caution

Have the irrigation tube (OF-B113) exactly parallel to the water jet check valve adapter (OE-C12) when attaching or removing it. Attaching or removing it diagonally may break the irrigation tube.

Note

Do not use the irrigation tube (OF-B113) if you have any difficulty in attaching or you could not feel a click feeling when attaching it to the endoscope. The use of damaged luer connector may result in water leakage from the connected part or tube disconnection.

3-5. Inspection of the endoscopic system

Inspection of the endoscopic image

Caution

- Do NOT look directly at the light emitted from the distal end of the endoscope or the video processor unit. The intense light may cause eye injuries. Turn off the lamp when looking directly at the distal end of the endoscope.
- Do NOT attach or remove the PVE connector while the video processor power is turned on. Doing so may damage the endoscope.

Note

- If the video processor connected has scope eject function, the PVE connector can be removed when the power of the video processor is turned on by using the scope eject function of the video processor. For details, refer to the IFU of the respective video processor.
- The video processor shown in the Figure is just an example. For details on the operation of each video processor, refer to the IFU of the respective video processor.

1. Turn on the video processor by pushing the Power Switch.

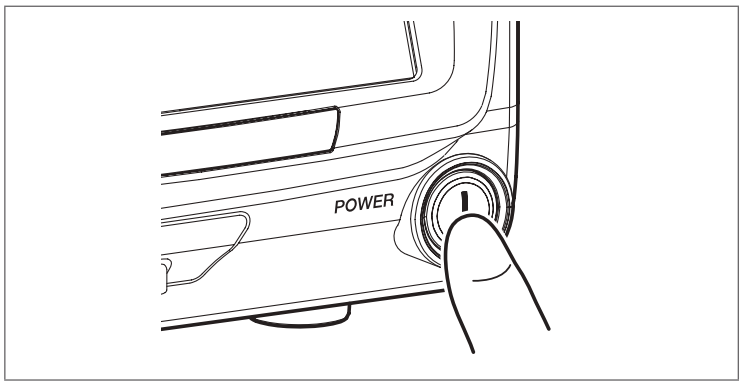


Figure 3.49

2. Turn on the lamp button of the video processor control panel.
3. Ensure that the lamp is lit and light is being emitted from the distal end of the connected endoscope. After pushing the lamp button, it takes several seconds for the lamp to light up.

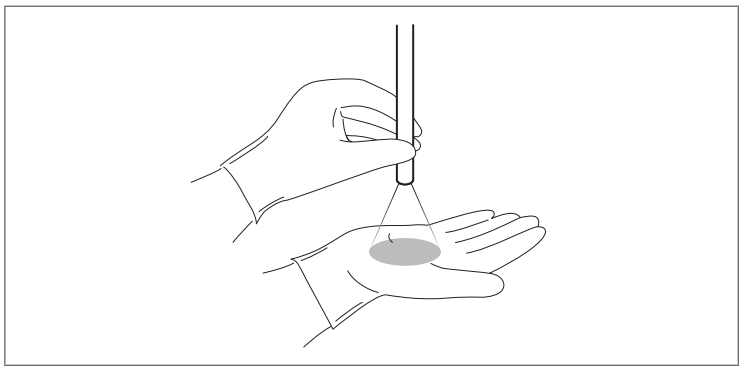


Figure 3.50

4. Check that the endoscopic image is clear and is displayed normally.

Note

In case the image is not clear, gently clean the endoscope objective lens with clean gauze moistened with 70%–90% medical grade ethyl or isopropyl alcohol.

5. On the control panel of the video processor, check that the exposure control is set to [AUTO].
6. While checking the image displayed on the monitor and following the IFU of the respective video processor, adjust the brightness level as appropriate.
7. Adjust the white balance by following the IFU of the respective video processor.
8. While observing the palm of your hand, check that the brightness adjustment is made normally by moving your palm closer to and away from the distal end of the endoscope.

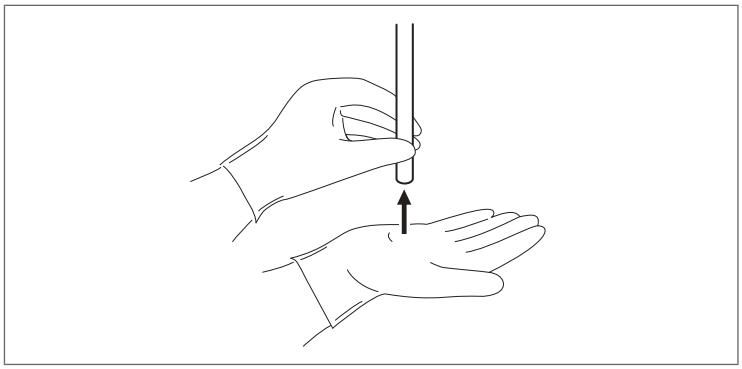


Figure 3.51

Caution

Do NOT directly touch the distal end of the endoscope (particularly the light guide) for a prolonged period of time when the light is being emitted. Doing so may result in burn injury.

9. Operate the angulation control knobs of the endoscope to move the bending section, and check if the image of the intended direction is displayed by corresponding to the angulation of the bending section. Also check for abnormalities such as appearance of noise in the endoscopic image or disappearance of the image.

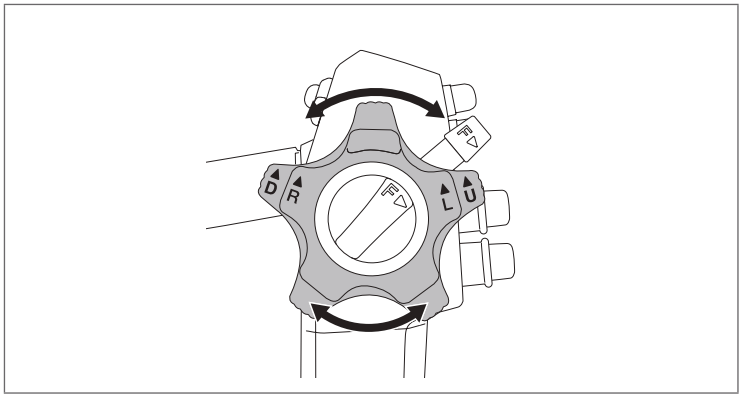


Figure 3.52

Inspection of the remote buttons

Warning

Always inspect the remote buttons even if they are NOT expected to be used. During a procedure, the endoscopic image may freeze or other abnormalities may occur, which may result in patient injury.

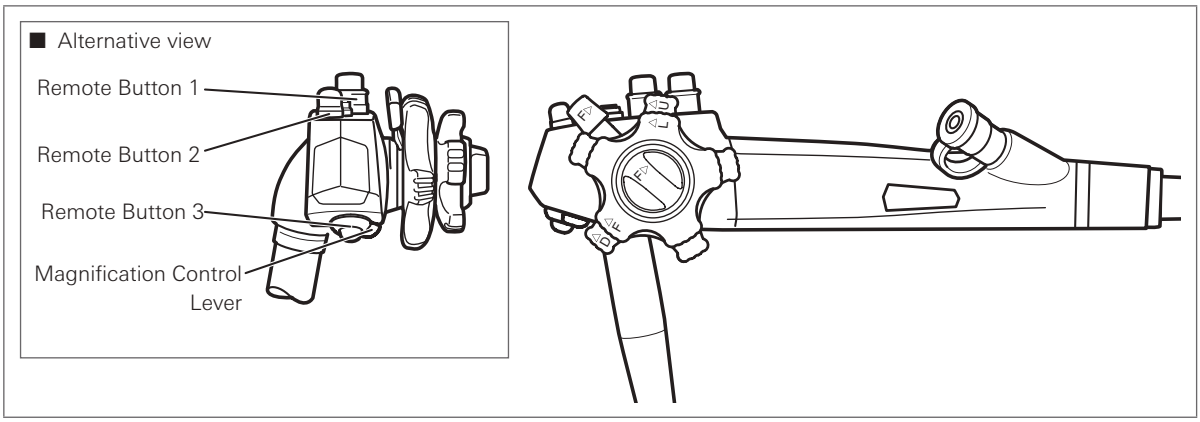
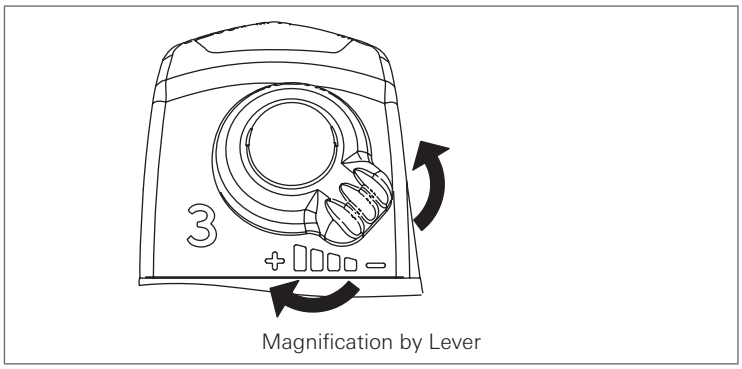


Figure 3.53

1. Press each remote button.
2. Check that the function assigned to each remote button is operating normally.

Inspection of the optical magnification function



Magnification by Lever

Figure 3.54

1. When the endoscope is connected to the processor, the lens position initialization starts automatically. When the initialization is finished, the standard (non magnified) image will appear on the monitor.
2. Check that turning the magnification control lever on the control body clockwise zooms the image, and turning it counter-clockwise returns the display to the standard image size.
3. Check that the magnification changes one by one with each operation of the magnification control lever, and that the image keeps the same state when the finger is removed from the lever.

Caution

When the monitor image stays zoomed after connecting with the video processor, remove the endoscope from the processor once, make sure that the bending section and insertion section are in the straight state, and then connect it again. The initialization may NOT have finished correctly. If the image remains zoomed, stop using this product and contact your local PENTAX Medical service facility.

Note

The optical magnification function and electrical magnification function can be used together in this product, however, the magnification control lever of the 90Zi series can be used only for the optical magnification function. The magnification control lever cannot be used for the electrical magnification function.

Inspection of the air/water feeding function

Warning

Use sterile water for inspection of the air/water feeding function. Failure to do so may pose a risk of infection.

Note

Refer to the separate IFU of water bottle assembly for details of the operating procedure.

1. Set the A/W-drain lever of the water bottle assembly at the “A/W” position.

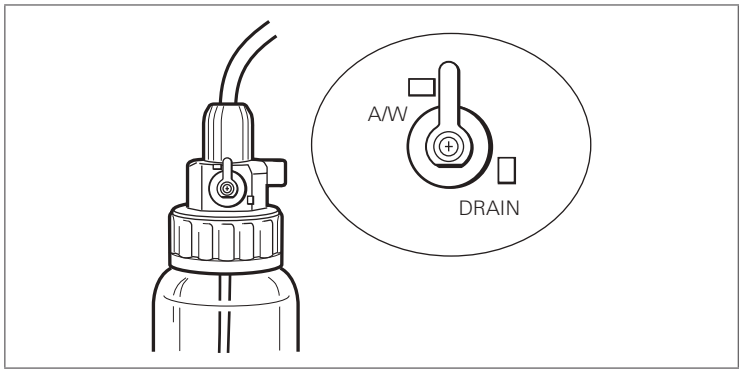


Figure 3.55

2. Press the pump button on the control panel of the video processor.
3. Set the pump level to “5” using the pump level setting button on the control panel of the video processor.
4. Insert the distal end of the endoscope into a container filled with sterile water, and check that air bubbles are not continuously discharged from the air nozzle at the distal end of the endoscope. (The example shown in the figure is of the EC-3890Zi series)

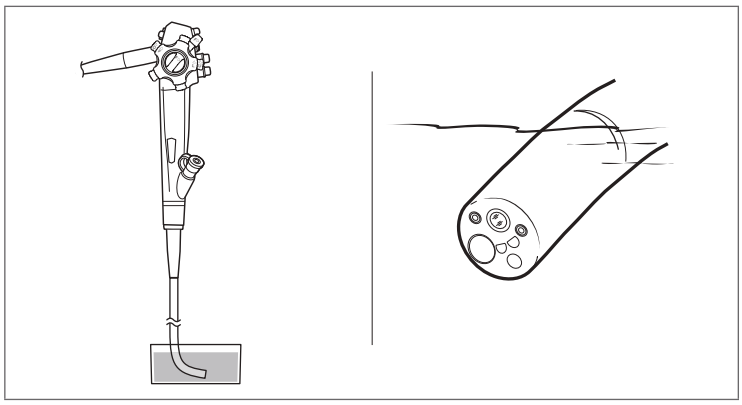


Figure 3.56

Warning

If air bubbles are continuously discharged from the air/water nozzle at the distal end of the endoscope when the hole on the top of the air/water feeding valve is NOT closed, stop use immediately and replace the air/water feeding valve with a new one. Continuous use of an air/water feeding valve with abnormalities could cause unintended continuous air feeding and pose a risk of pain or perforation to the patient.

5. Block the hole in the top of the air/water feeding valve. Check whether air bubbles come out vigorously from the air/water nozzle of the distal end of the endoscope.

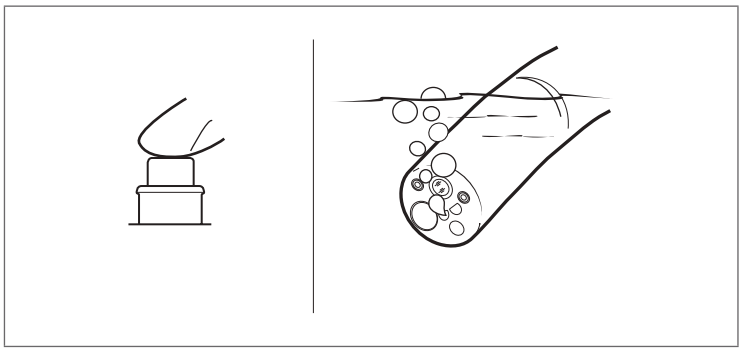


Figure 3.57

6. Check that the discharge of air bubbles stops when releasing the finger from the air/water feeding valve.

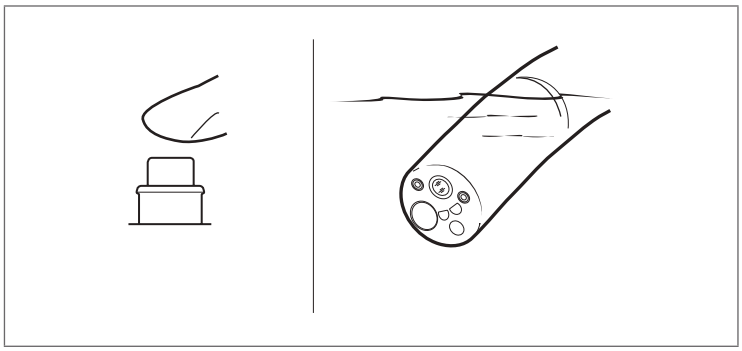


Figure 3.58

7. Pull the endoscope out of the container, and depress the air/water feeding valve. Check that a certain amount of water flows out from the air/water nozzle. (It takes a few seconds until water comes out the first time.)

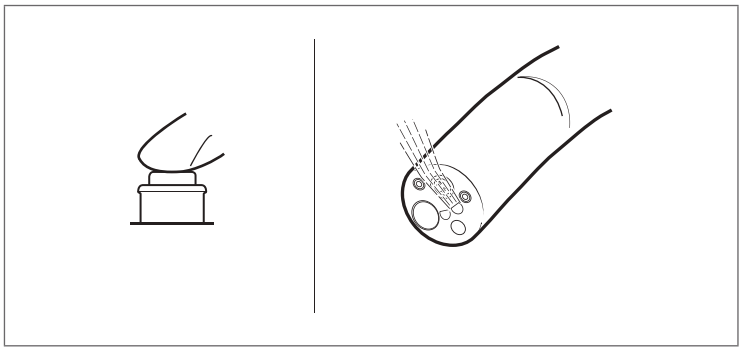


Figure 3.59

8. Remove the finger from the air/water feeding valve. Check that the air/water feeding valve returns to the original position smoothly and that the water stops at the same time as the finger is removed from the valve.

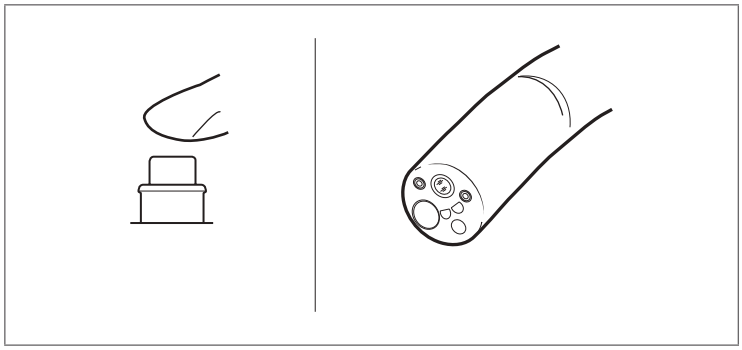


Figure 3.60

Caution

Do NOT attempt to clear the air or water nozzles with a needle or any other sharp object if nozzle blockage is suspected. It may result in lowered performance as well as damage to the endoscope.

Note

Do not attempt to correct the blockage or continue to use the endoscope, if air/water cannot be fed smoothly and blockage in the nozzle or channel of the endoscope is suspected. In such a case, contact your local PENTAX Medical service facility to have the endoscope repaired.

Inspection of the irrigation function

Warning

Use sterile water for inspection of the irrigation function. Failure to do so may pose a risk of infection.

1. Fill a syringe with sterile water.
2. Put the distal end of the endoscope to the clean container, attach the syringe filled with sterile water, and insert it into the inlet seal (OF-B190).

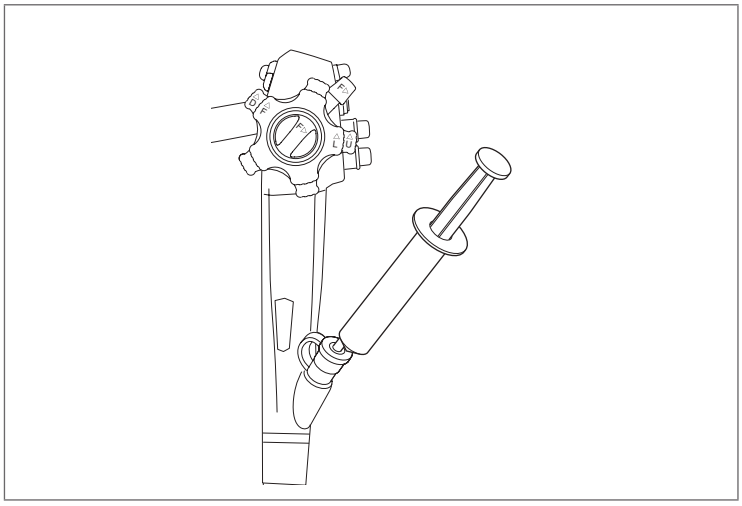


Figure 3.61

3. Check that sterile water comes out of the opening of the instrument channel when the syringe is pressed to flush the channel. Moreover, check that no foreign materials come out.
4. Remove the syringe from the inlet seal (OF-B190).
5. Fill the syringe with air and insert it into the inlet seal.
6. Flush the sterile water remaining inside the channel by pressing the syringe.
7. Remove the syringe from the inlet seal.

Inspection of the suction function

Warning

Use sterile water for inspection of the suction function. Failure to do so may pose a risk of infection.

Note

Before inspecting the suction function, attach the cap to the inlet seal. Failure to do so may cause lowered suction function.

1. Turn on the suction source and adjust to an appropriate pressure setting.
2. Insert the distal end of the endoscope into a container filled with sterile water and press the suction control valve (OF-B120). Check that water is being suctioned up. (The example shown in the figure is of the EC-3890Zi series)

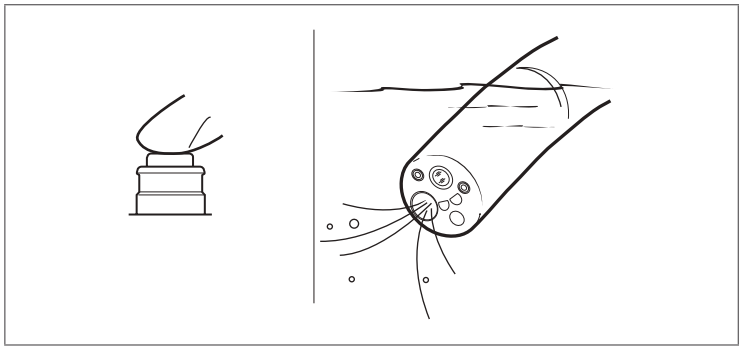


Figure 3.62

3. Check that when the suction control valve is released, it smoothly returns to the initial position and the suctioning stops.

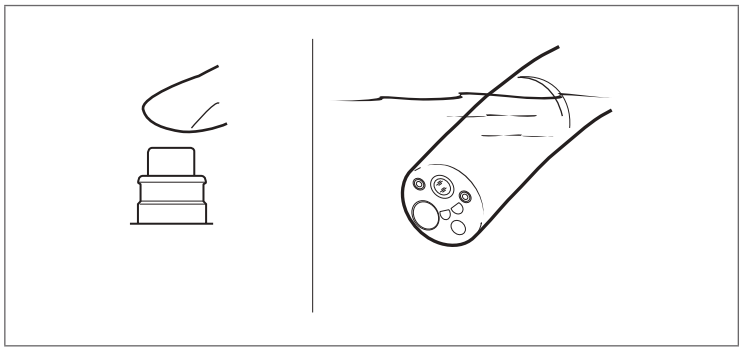


Figure 3.63

4. Repeat steps 2 and 3 several times to check that there is no water leakage from the suction control valve or the inlet seal.
5. Pull the distal end of the endoscope out of the container. Press the suction control valve, and suction air in order to remove the water remaining inside the instrument channel.

Inspection of the instrument channel

Use a biopsy forceps for inspection of the instrument channel.
Prepare a biopsy forceps which has been cleaned and sterilized according to the manual provided with that product and ensure to perform a pre-use inspection.

Warning

Do NOT use the endoscope if you feel a significant resistance when inserting a biopsy forceps. The inside of the channel may be damaged and it may result in unforeseen events to patients and/or medical professionals.

Caution

- Slowly and gently insert and withdraw the forceps from the inlet seal (OF-B190). Applying strong force may cause endoscope damage.
- Keep the endoscope bending section as straight as possible when inserting the forceps. When the endoscope bending section is greatly angulated, it may NOT be possible to insert the forceps.

1. Close the biopsy forceps cups by operating its handle.

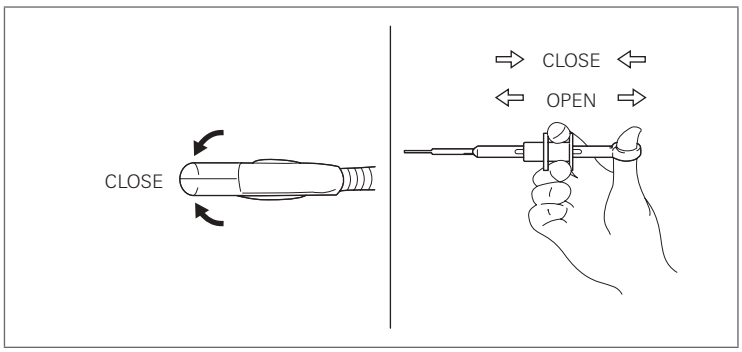


Figure 3.64

Note

Do not close the biopsy forceps cups tightly. Doing so may make its insertion into the instrument channel difficult.

2. Insert the biopsy forceps into the inlet seal (OF-B190). When the cups are first passed through the inlet seal, temporary resistance will be encountered. Hold the shaft at approximately 5cm from the cups and push the biopsy forceps through.

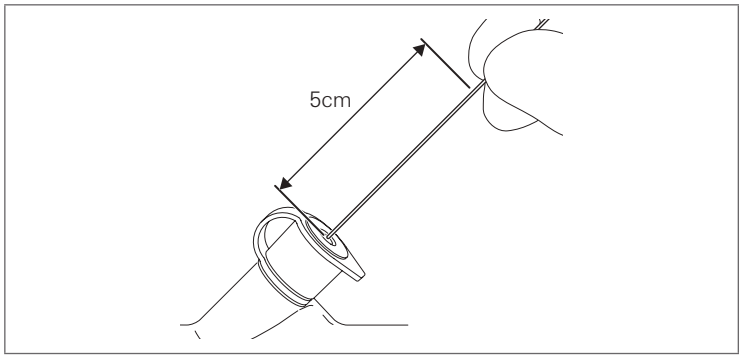


Figure 3.65

3. Slowly advance the biopsy forceps and check that its tip appears from the distal end of the endoscope. Moreover, check that no foreign materials come out.
4. Check that the biopsy forceps can be smoothly withdrawn from the inlet seal.

Inspection of the water jet feeding function

Warning

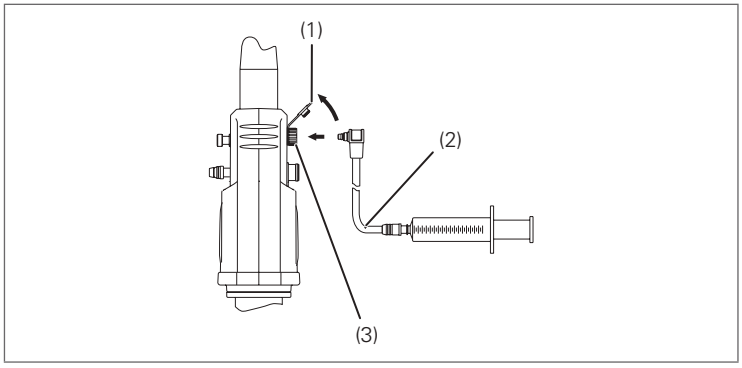
Use sterile water for inspection of the water jet feeding function. Failure to do so may pose a risk of infection.

1. To use the irrigation pump, prepare to feed sterile water by following the instructions for use for the irrigation pump.
2. Check the entire surface of the irrigation tube (OF-B113) for abnormalities such as bending/breakage/looseness of the connector, cut/chip of the O-ring, buckling/deterioration/hardening of the tube, and/or broken luer.
3. Open the water jet connector cap (OF-B118) and push tube for water pump irrigation or the irrigation tube (OF-B113) in until the water jet check valve adapter (OE-C12) clicks.

Note

Do not use the irrigation tube (OF-B113) if you have any difficulty in attaching or you could not feel a click feeling when attaching it to the endoscope. The use of damaged luer connector may result in water leakage from the connected part or tube disconnection.

4. Feed sterile water using the irrigation pump or syringe filled with sterile water attached to the luer connector of the irrigation tube (OF-B113).



(1) Water Jet Connector Cap (OF-B118)
(2) Irrigation Tube (OF-B113)
(3) Water Jet Check Valve Adapter (OE-C12)

Figure 3.66

Note

When the irrigation tube (OF-B113) is connected with locking type of luer connector, ensure that the luer connectors are properly locked. Do not use the irrigation tube (OF-B113) if there is damage on the luer connector of the irrigation tube (OF-B113) and/or luer connection is not properly locked.

5. Check that a certain amount of water flows out forward from the water jet nozzle at the distal end of the endoscope. (It takes a few seconds until water comes out the first time.) (The example shown in the figure is of the EC-3890Zi series)

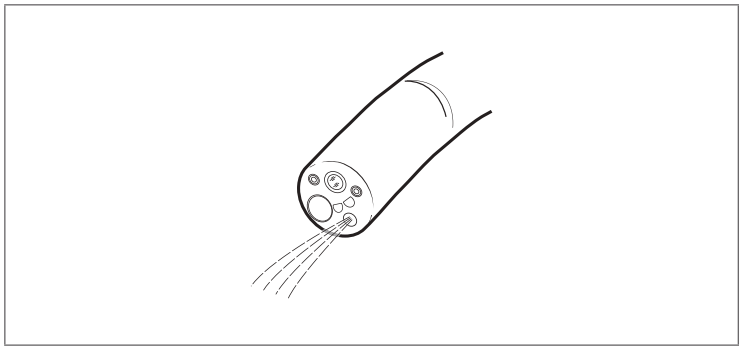


Figure 3.67

6. Check that there is no water leakage from the connection between the water jet port of the endoscope and the water jet check valve adapter (OE-C12), or from the connection between the water jet check valve adapter and the irrigation tube (OF-B113).

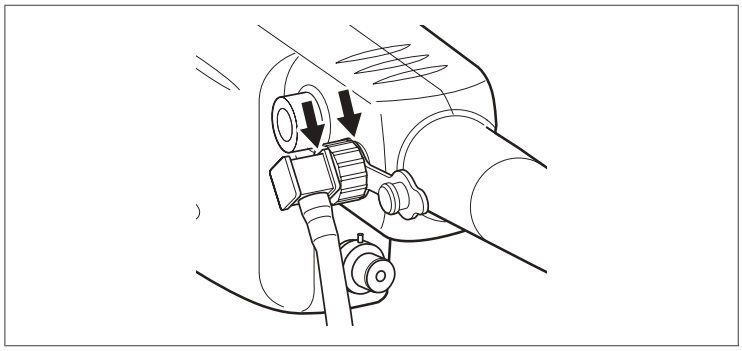


Figure 3.68

4 Directions for use

This endoscope should only be used by a physician authorized by the medical safety administrator at each medical facility to perform endoscopy.
The device should never be used by individuals who are not licensed medical professionals or used at facilities other than medical facilities.
This section describes the essential information, such as operating procedures and handling precautions, on using this endoscope safely and effectively. This IFU does not describe specific endoscopic procedures. The specific procedures should be determined according to the discretion of a medical professional.

Warning

- Users as well as the assisting personnel should always wear protective equipment (e.g., gloves, goggles, masks, medical gowns, etc.) to minimize the risk of infection, as the patient's body fluids may be dispersed from endoscope components such as the instrument channel inlet and the suction control valve.
- Immediately stop the endoscopic procedure and slowly and cautiously withdraw the endoscope when any abnormality, such as roughness, is felt during angulation. NEVER forcefully turn the angulation control lever. Continuing to use the endoscope with any abnormality may result in endoscope damage and/or patient injuries, including bleeding and perforation.
- NEVER withdraw the endoscope while the bending section is angulated. Doing so may result in patient injury.
- Always check the endoscopic image during endoscope angulation, air/water feeding, and suctioning, use of endoscopic devices, and endoscope insertion and withdrawal. Ensure that these operations are performed in the normal (non-frozen, non-magnified) mode. Endoscope operation in the freeze or magnification mode may result in damage to the endoscope and patient injury.
- Do NOT forcefully insert and withdraw the endoscope. Doing so may result in patient injury.
- When inserting the endoscope into narrow lumina, Do NOT rotate the endoscopic image using the video processor. Doing so may result in patient injury or make the withdrawal of the endoscope impossible.
- Immediately stop the endoscopic procedure if the endoscopic image disappears unexpectedly because of blackout and/or damage to the lamp, video processor, and/or endoscope. Slowly withdraw the endoscope following the instructions in "5-1. Withdrawal of an endoscope with an abnormality" (p. 74). Continuing to use the endoscope may result in patient injury.
- Set the brightness to the minimum necessary. Maintain an appropriate distance between the distal end of the endoscope and the mucosa in order to avoid prolonged illumination of the mucosa. The temperature at the distal end of the endoscope may exceed 41°C and even reach 50°C due to the light emitted from it. This may result in mucosal injury to the patient.

Caution

- Do NOT look directly at the light emitted from the endoscope or direct it at the eyes of other individuals as the intense light may cause eye injuries.
- Do NOT use the endoscope with suspected adherence of patient's body fluid, blood, etc., on the light guide, as this causes the observation image to become dark. The temperature at the distal end of the endoscope may increase and result in mucosal injury to the patients.
- Use the minimum pressure necessary for suctioning. Do NOT suction from the mucosa for a prolonged period of time. Doing so may result in patient injury.
- Do NOT use a water supply device that can exert 30kPa or greater of water pressure to the suction channel (suction valve) during endoscopic examination.

Note

- Prior to a procedure, remove any debris or secretions from the observation area as much as possible to obtain a clear image.
- The objective lens may be cleaned during a procedure by performing air/water feeding and suctioning simultaneously or alternately.

4-1. Preparation immediately before insertion of the endoscope

Perform appropriate patient preparation for endoscopy as necessary.

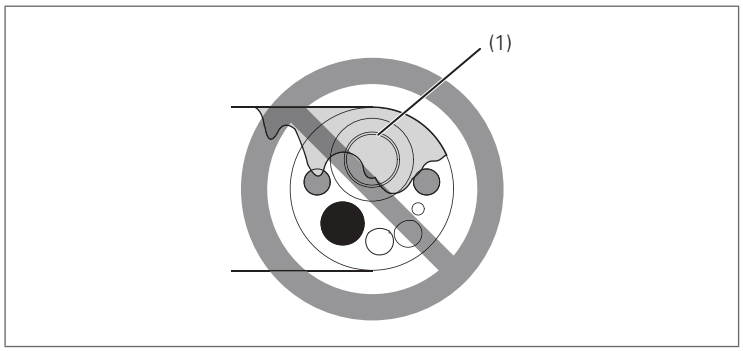
Caution

Do NOT spray or wipe the surface of the endoscope insertion portion with an anesthetic (particularly anesthetic spray containing alcohol) or non-medical lubricant (such as petroleum jelly). Doing so could cause cracking or peeling of the external surface of the insertion portion and may result in endoscope damage.

1. Apply a medical grade lubricant to the insertion portion, as necessary.
2. Place a bite block (OF-Z5) into the patient's mouth (only for EG-2990Zi).

Note

- Do not apply lubricants to the objective lens for getting clear observation images.
- When using lens cleaner, ensure to follow the instructions of that product.



(1) Lubricant

Figure 4.1

4-2. Insertion and observation

Insertion of the endoscope

Caution

Do NOT forcefully bend the strain relief boot as shown (Figure 4.2). Doing so may result in endoscope damage.

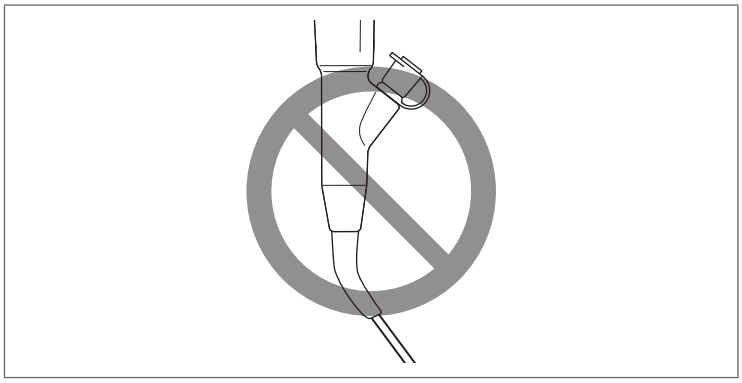


Figure 4.2

Slowly and cautiously insert the endoscope.
Adjust the brightness as appropriate for observation with the video processor.

Note

Clear images cannot be obtained if any foreign material is attached to the objective lens or the light guide. Continued use of the light guide with any foreign material attached to it might cause visible steam-like vaporization associated with water vaporization of the organic material heated by the light.
If this vapor is observed, stop the procedure immediately and withdraw the endoscope from the patient. Using clean gauze, clean off any foreign material that has attached and then resume endoscopy.

Angulation operation

Warning

Immediately stop the endoscopic procedure and slowly and cautiously withdraw the endoscope when an abnormality, such as roughness, is felt during angulation. NEVER forcefully turn the angulation control knob as it may result in endoscope damage and/or patient injuries, including bleeding and perforation.

1. Slowly and cautiously operate the angulation control knobs according to the position of the endoscope.
2. Turn the up/down angulation lock lever and right/left angulation lock knob to hold the bending angle of the distal end of the endoscope, as necessary.

Air/Water feeding

Warning

Be careful NOT to feed too much air and to properly control air insufflation into the body cavity. Excessive air insufflation into the patient's body cavity may pose a risk of pain, embolism, and perforation to the patient.

1. Set the appropriate pump level using the pump level setting button on the control panel of the video processor.
2. Cover the hole on top of the air/water feeding valve with a finger to feed air through the air/water nozzle at the distal end of the endoscope.
3. Press in the air/water feeding valve to feed water from the air/water nozzle onto the objective lens.

Suction

Warning

- Do NOT aspirate solid materials as it may cause a clogging in the suction control valve and/or the suction channel.
- If the instrument/suction channel becomes blocked or clogged due to the accumulation of debris, an accessory that cannot be removed, or other cause, do NOT attempt to correct the blockage or continue to use the endoscope. In such a case, contact your local PENTAX Medical service facility to have the endoscope repaired. The use of an endoscope with a blocked internal channel may result in ineffective reprocessing and/or the introduction of debris and/or device components into a patient during a subsequent procedure, causing patient injury and/or posing a risk of cross contamination.
- The use of an endoscope with a blocked internal channel may result in ineffective reprocessing and/or the introduction of debris and/or device components into a patient during a subsequent procedure, causing patient injury and/or posing a risk of cross-contamination.
- Securely attach the cap to the inlet seal. Failure to do so may result in lowered suction function as well as potential reflux or dispersal of patient's body fluids, posing a risk of infection.

Caution

- Do NOT use a cleaning brush or biopsy forceps to remove a foreign object that has occluded the suction channel. This may result in damage to the channel.
- Observe these precautions when suctioning. Failure to do so may result in mucosal injury to the patient.
  - Do NOT apply excessive suction pressure.
  - Maintain distance between the distal end of the endoscope and the mucosa to ensure that the instrument channel opening of the distal end of the endoscope does NOT suction the mucosa.
  - Immediately stop suctioning if the mucosa is suctioned. Do NOT suction mucosa for a prolonged period of time.
  - Stop use immediately when any abnormality is suspected of the suction control.

Suction fluid from inside the body cavity through the instrument channel by pressing the suction control valve.

Water jet feeding

Warning

Use sterile water for water jet feeding. Failure to do so may pose a risk of infection.

Caution

Use minimum pressure for water feeding while observing the condition of the patient's mucosa. Water feeding with the excessive pressure may result in mucosal injury to the patient.

Use the irrigation pump by following its operation manual for the irrigation pump or by attaching a syringe to the luer connector of the irrigation tube (OF-B113) and delivering water into it.

Note

When the irrigation tube (OF-B113) is connected with locking type of luer connector, ensure that the luer connectors are properly locked. Do not use the irrigation tube (OF-B113) if there is damage of the luer connector of the irrigation tube (OF-B113) and/or luer connection is not properly locked.

Remote control

Caution

Do NOT apply strong force to the remote button from its side or in an oblique direction, as the button may get stuck and become inoperable.

Operate the remote button for image capture, hardcopy, VCR recording, etc., as necessary.

Note

Leaving a finger on the remote button may result in unintentional pressing of the remote button, causing it to operate.

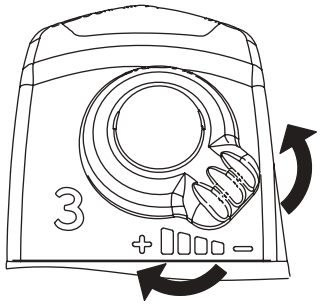
Optical Magnifying System

Warning

Ensure to insert the endoscope after turning the magnification control lever counterclockwise to return the standard size image. Under the magnified vision the field of view is limited, which worsens insertion operability and could result in a health hazard to the patient.

Note

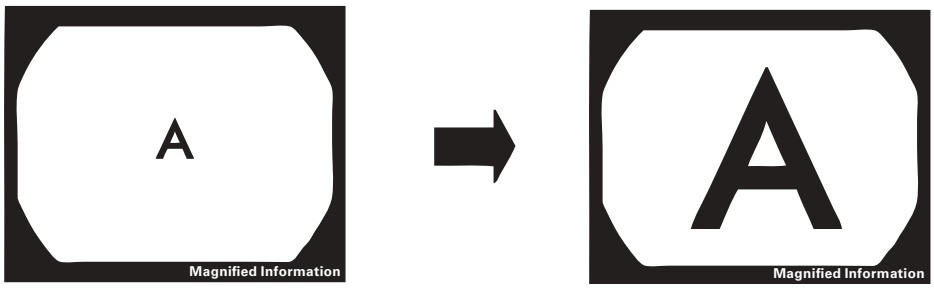
The optical magnification system gives change in the focal distance and the depth of field. Adjust the distance between the distal end of the endoscope and the observation area to obtain the optimum image. With the maximum magnification rate, the optimum image can be obtained with an observation distance of 2 to 3 mm from the observation area.



Magnification by Lever

Figure 4.3

1. Control the optical magnification system by the magnification control lever on the control body. Turning it clockwise magnifies the image, and turning it counterclockwise returns the image to the normal rate.
2. The operation speed of the magnification system can be adjusted in three stages: Low, Medium, and High. For how to change the operation speed, refer to the IFU of the respective video processor.
3. The figure below shows the monitor screen when the optical magnification system is in use. The information for the magnification is displayed in the lower right of the monitor screen. The "+" position in the magnification information shows the approximate magnification rate. On the normal rate of the image the mark "+" is positioned in the left end, and moves to the right with the magnified operation. With the maximum magnification rate, the mark "+" is displayed in the right end. When using EPK-i7000, the mark "▼" moves from left to right.



Normal

Optical Magnification

Figure 4.4

Note

The optical magnification system is also available using the foot switch. Each pressing of the foot switch can switch the magnification rate in four steps, from the normal rate (or the largest magnification rate) to the largest magnification rate (or the normal rate). For how to allocate the magnification system to the foot switch, refer to the IFU of the respective video processor.
The magnification system allocable to the foot switch can be allocated to the remote buttons 1 to 3 of the endoscope. For how to allocate the magnification system to the remote button of the endoscope, refer to the IFU of the respective video processor.

Electrical magnifying system

The electrical magnification system is available when this magnification system is allocated to the control panel, keyboard, or foot switch of the video processor, as well as to the remote buttons of the endoscope. For how to allocate the magnification system to the remote buttons of the endoscope, refer to the IFU of the respective video processor.

4-3. Using an endoscopic device

Warning

- NEVER use an endoscopic device showing signs of damage and/or operational abnormality. Doing so may result in endoscope malfunction or damage and/or patient injury.
- All reusable endoscopic devices must be cleaned and sterilized before initial use as well as before every subsequent use.
- Before using the endoscopic device, check its compatibility with the endoscope and read and understand the respective IFU of the endoscopic device. Incorrect use of the endoscopic device may result in damage to the endoscopic device and patient injury.
- When inserting or withdrawing the endoscopic device, ensure that its distal tip is closed or retracted within the sheath. Straighten the endoscopic device and slowly withdraw it. Failure to do so may result in inlet seal damage and/or falling of the broken inlet seal particle(s) into the patient's body cavity.
- Ensure that the distal tip of the endoscopic device is adequately projecting from the distal end of the endoscope before operating it. Failure to do so may result in damage to the instrument channel and/or falling of the broken instrument channel particle(s) inside the patient's body cavity.
- After the endoscopic device is inserted into the inlet seal, NEVER let it hang down. Ensure that the endoscopic device is supported with a hand and no load is applied to the inlet seal. Failure to do so may result in lowered suction function as well as potential reflux or dispersal of patient's body fluids, posing a risk of infection.
- Use only compatible endoscopic devices specified by PENTAX Medical. Using non-compatible endoscopic devices NOT specified by PENTAX Medical may result in clogging and/or damage to the instrument channel and/or endoscopic device. If a liquid such as sterile water or physiological saline is injected with a syringe from the instrument channel inlet while the instrument channel is clogged, the suction control valve may detach and result in potential reflux or dispersal of patient fluids, posing a risk of infection.
- Immediately stop the endoscopic procedure if the endoscopic device cannot be withdrawn from the endoscope. Do NOT attempt to forcefully withdraw the endoscopic device. Slowly and cautiously withdraw the endoscope in which the endoscopic device is inserted. Failure to do so may result in damage to the endoscopic device and/or instrument channel as well as potential reflux or dispersal of patient's body fluids, posing a risk of infection.

Caution

- Do NOT forcefully insert the endoscopic device when the instrument channel is clogged, as this may result in damage to the endoscope.
- Constantly check the endoscopic image while cautiously inserting and withdrawing the endoscopic device.
- Keep the endoscope bending section as straight as possible when inserting and withdrawing the endoscopic device. Forcefully inserting and withdrawing the endoscopic device may result in damage to the instrument channel and endoscopic device and/or patient injury.

Note

The minimum instrument channel width is found on the model name label.

Insertion and operation of the endoscopic device

1. Ensure that the distal tip of the endoscopic device is closed or retracted into the sheath. In case of biopsy forceps, operate the forceps to fully close the cups at the tip. There is a certain amount of resistance when inserting for the first time. Hold the shaft at approximately 5 cm away from its end, and press it in.

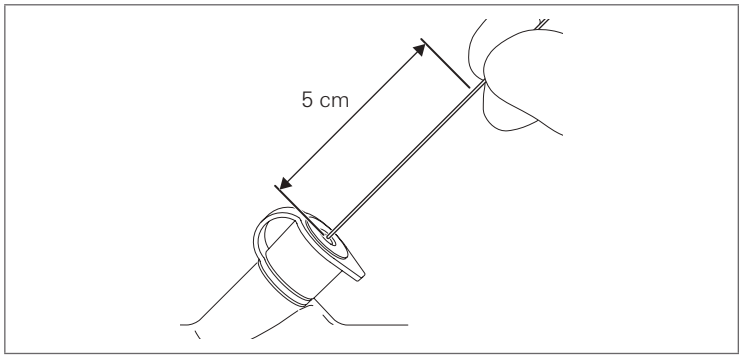


Figure 4.5

2. Slowly insert the endoscopic device, and check that the distal tip of the endoscopic device is within the field of view.

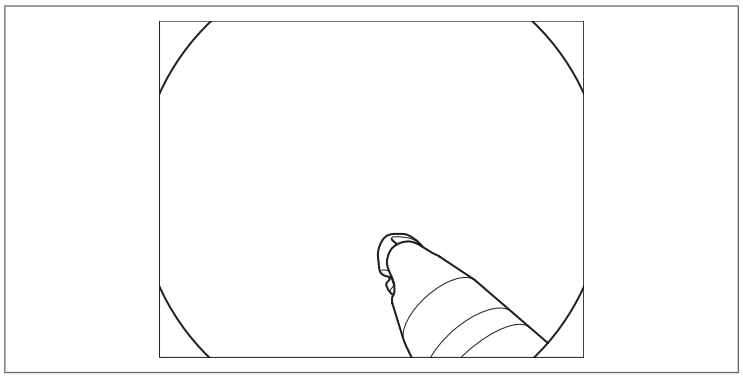


Figure 4.6

3. Operate the endoscopic device according to the IFU provided with it.

Withdrawal of the endoscopic device

Warning

- Do NOT forcefully withdraw the endoscopic device or in an oblique direction. Doing so may result in lowered suction function caused by inlet seal damage, falling of the broken inlet seal particle(s) into the patient's body cavity, and potential reflux or dispersal of patient's body fluids, posing a risk of infection. When withdrawing the endoscopic device, prevent the dispersal of patient's body fluids by covering the inlet seal with clean gauze, and withdraw the device slowly in a straight direction against the inlet seal.
- Immediately stop the therapeutic procedure if significant resistance is encountered when withdrawing the endoscopic device or if the endoscopic device cannot be withdrawn from the endoscope. Do NOT attempt to forcefully withdraw the endoscopic device. Failure to do so may result in equipment damage. Close or retract the distal tip of the endoscopic device and slowly withdraw the endoscope into which the endoscopic device is inserted.

1. Ensure that the distal tip of the endoscopic device is closed or retracted into the sheath.
2. Slowly withdraw the endoscopic device in a straight direction against the inlet seal.

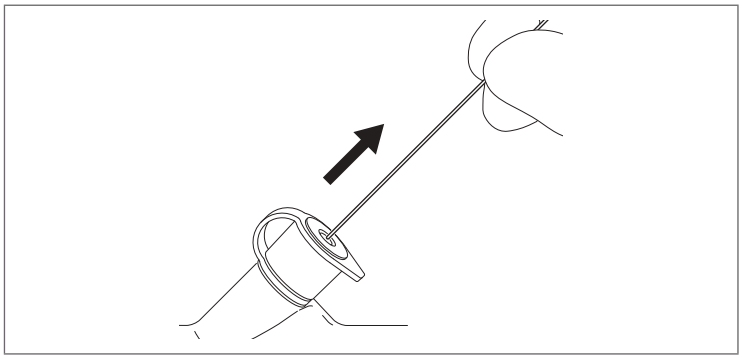


Figure 4.7

4-4. Using a non-flammable gas

If there is a possibility of an inflammable gas being present within a body cavity, convert the gas to a non-flammable gas using carbon dioxide prior to laser cautery or electrosurgery.

Warning

- Do NOT use non-flammable gas cylinders whose pressure and flow settings cannot be controlled. Set the gas pressure to 49 kPa or less, and the flow to 4 L/min or less. Using a gas cylinder whose settings cannot be controlled or whose settings are uncertain may result in damage to the endoscope and excessive insufflation of gas into the patient's body cavity.
- Be careful NOT to deliver too much gas and to properly control gas delivery into the channel. Excessive insufflation of gas into the patient's body cavity may pose a risk of a pain, embolism, and perforation to the patient.

Caution

- Perform adequate ventilation when using a non-flammable gas in a small room prolong period of time. An elevated CO_2 concentration in the room may pose a risk of negative effects to the physical condition of the patient and/or user.
- Turn off the air/water feeding pump of the video processor before opening/closing the gas cylinder. If the gas cylinder is opened without turning it off, excessive load is applied to the air/water feeding pump of the video processer, which may result in damage to the air/water feeding pump.

Note

Use of the optionally available gas/water feeding valve (OF-B194) is recommended instead of the air/water feeding valve to prevent gas leakage into the room. Use the gas/water feeding valve according to the IFU provided with it.

1. Prepare a gas cylinder and the optionally available gas adapter (OF-G11). Ensure that the gas cylinder valve is closed. Turn off the air/water feeding pump of the video processor.
2. Remove the air/water connector of the water bottle assembly from the air/water port of the endoscope, and connect the gas adapter instead.

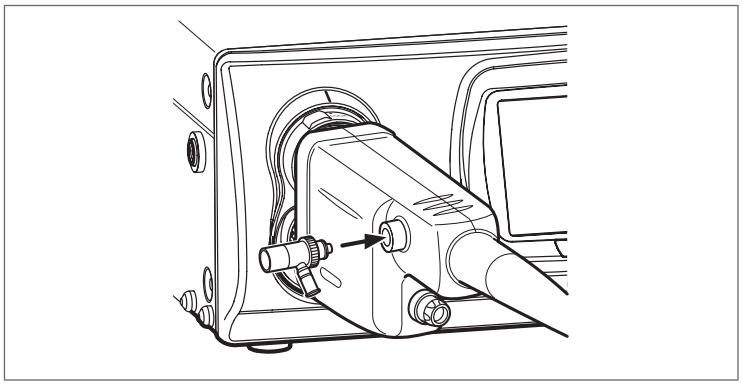


Figure 4.8

3. Connect the gas cylinder to the gas adapter (OF-G11).

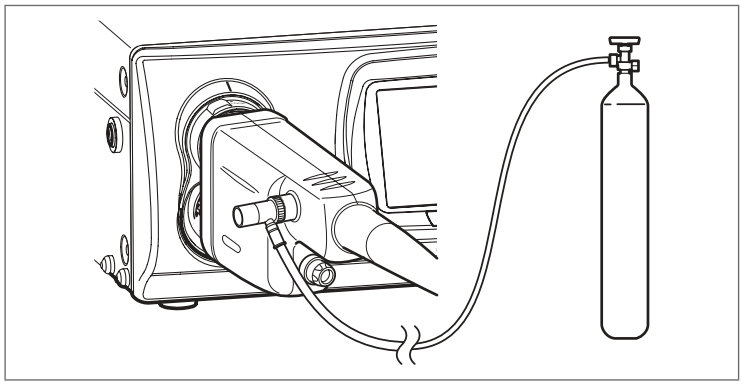


Figure 4.9

4. Connect the air/water connector of the water bottle assembly to the gas adapter.

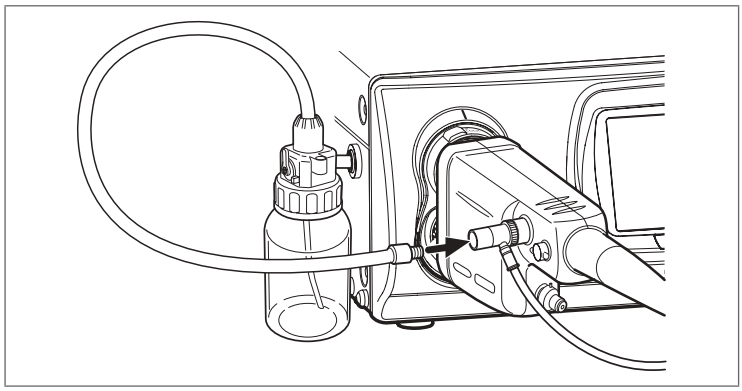


Figure 4.10

5. Ensure that all the devices are securely connected before opening the gas cylinder valve.

4-5. Laser cauterization

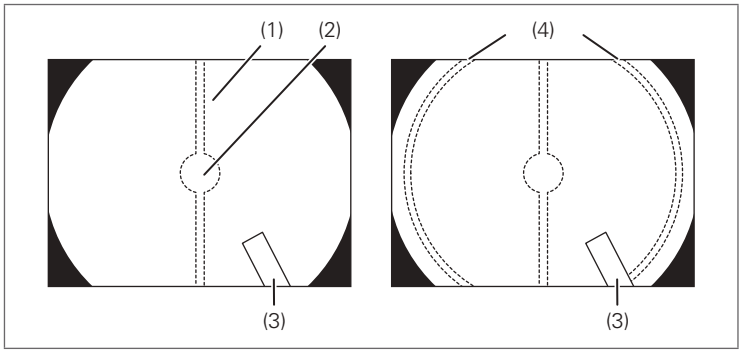
Warning

- Laser equipment should be used only by experts who have thorough knowledge of the laser equipment and endoscopic laser treatment.
- Before using the laser equipment, thoroughly read the manual supplied with it, and always perform pre-use inspection. Ensure that the laser equipment is ready for use by performing the safety checks specified in the manual.
- Use Nd:YAG laser (wavelength 1064 nm) or a laser with a wavelength of 800–1000 nm only.
- When using laser equipment, both users and the assisting personnel should wear goggles. Failure to do so may result in eye injuries.
- Do NOT use the laser equipment in flammable surroundings, such as an oxygen-rich environment. If there is a possibility of a flammable gas being present within a body cavity, convert the gas to a non-flammable gas prior to laser cauterization. Using the laser equipment in flammable surroundings may result in combustion or an explosion.
- Set the laser output to the minimum level necessary.
  - If the laser is continuously emitted at a high level, the endoscopic image may become white (whiteout). Do NOT perform laser cautery during whiteout, as it may result in patient injury.
  - Continuously emitting the laser at a high level may damage the instrument.
- Maintain an adequate distance between the distal end of the endoscope and the patient's body cavity wall. Before activation of the laser, ensure that the distal tip of the laser probe emerges from the distal end of the endoscope. Failure to do so may result in instrument damage and patient injury.

1. Insert the laser probe into the inlet seal (OF-B190) as described in "4-3. Using an endoscopic device".
2. Operate the laser probe according to the manual provided with it.
3. When the procedure is complete, withdraw the laser probe via the inlet seal as described in "4-3. Using an endoscopic device".

Note

- It is normal for the guide beam to appear white in the video endoscopic image.
- If the distal end of the endoscope is within 20 mm of the irradiated target surface, the guide beam may create a smear in the image. If such a smear affects visibility of the target, decrease the intensity of the light.
- When operating the laser at a high power and/or if the distal end of the endoscope is moved within 10 mm of the irradiated target, a flare may appear at the corners of the image.



(1) Smear
(2) Irradiated target
(3) Probe
(4) Flare

Figure 4.11

4-6. Electrosurgery

Warning

- Thoroughly read the manual provided with the high frequency generator and device before using them, and always perform a pre-use inspection. Ensure that the high frequency generator and device are ready for use by performing the safety checks specified in the manual. Use in combination with the electrosurgical device could result in increased leakage of current to the patient.
- Ensure that the released energy from the high-frequency does not affect the peripheral device such as pacemaker and to use the minimum necessary output level of high-frequency when using it near the heart. It may stimulate the heart.
- Do NOT use the high frequency generator in flammable surroundings, such as an oxygen-rich environment. If there is a possibility of a flammable gas being present within a body cavity, convert the gas to a non-flammable gas prior to electrosurgery. Using the high frequency generator in flammable surroundings may result in combustion or an explosion.
- Ensure that the active portion of the endoscopic device does NOT come in contact with the peripheral tissues, as it may result in patient injuries.
- Set the high-frequency output level and waveform mode appropriately according to usage. Minimize the energization time, as it can result in patient injury.
- Before using an electrosurgical device, check the entire surface of the endoscope for any abnormalities such as cracks and exposure of internal metals. Failure to do so may result in burns from high-frequency current.

Caution

- Users as well as the assisting personnel should always wear insulated gloves. Failure to do so may result in burns from high-frequency current.
- High frequency generators may be of the floating (Type BF or Type CF) or non-floating (Type B) types. Only use floating-type high frequency generators to avoid patient and user burns.
- There are two types of floating-type high frequency generators: those with an endoscope feedback cord (S-cord) and those without.
  1) High frequency generator with an S-cord: Connect the S-cord to the feedback terminal located on the PVE connector of the endoscope.
  2) High frequency generator without an S-cord: Connect the condenser earth cable (OL-Z4/OL-Z3) between the endoscope feedback terminal and the video processor potential equalization terminal.

  Follow the directions for each type described above, as failure to do so may result in burns from high-frequency current.
- Only use insulated devices. Failure to do so may result in burns from high-frequency current.
- Ensure that the distal tip of the electrosurgical device is adequately projecting from the distal end of the endoscope before operating it. Failure to do so may result in endoscope damage.
- During use, follow the precautions below, as failure to do so may result in endoscope damage, burns, and/or mucosal injury.
  - Maintain an adequate distance between the distal end of the endoscope and the insulated tip and active portion of the endoscopic device. Ensure that the distal tip of the endoscopic device is adequately projecting from the distal end of the endoscope before operating it.
  - Users and the assisting personnel should NOT touch the patient during device use.
  - Turn on the high frequency generator just before the procedure and turn it off immediately after the procedure.

1. Insert the electrosurgical device into the inlet seal as described in “4-3. Using an endoscopic device”.
2. Operate the electrosurgical device according to the IFU provided with it.
3. When the procedure is complete, withdraw the electrosurgical device via the inlet seal as described in “4-3. Using an endoscopic device”.

4-7. Withdrawal of the endoscope

Warning

- When withdrawing the endoscope, prevent dispersal of patient’s body fluids by holding clean gauze along the insertion portion. Failure to do so may pose a risk of infection.
- Before withdrawing the endoscope, do NOT remove the water bottle assembly from the video processor while the water bottle assembly is connected to the endoscope. Doing so may result in reflux of patient’s body fluids into the water bottle assembly.
- Do NOT withdraw the endoscope while the bending section is angulated. Doing so may result in patient injury.

1. Operate the suction control valve to suction any fluid remaining inside the patient’s body cavity.
2. If the electrical magnifying function used, set it back to standard image size.
3. Turn the up/down angulation lock lever and right/left angulation lock knob in the “F► ” direction until they stop to release the lock of the angulation control knobs.
4. While checking the endoscopic image, slowly and cautiously withdraw the endoscope.
5. Remove the bite block from the patient’s mouth. (Only for EG-2990Zi)
6. Turn the video processor lamp off.

4-8. Care after use

Caution

Do NOT touch the light guide plug and electrical contacts after use. It could result in burns.

■ Endoscope:

Perform cleaning, high-level disinfection, and/or sterilization according to the procedure specified in the separate IFU (Reprocessing) of this endoscope.

■ Accessories:

Air/water feeding valve (OF-B188), suction control valve (OF-B120), inlet seal (OF-B190), bite block (OF-Z5) (Only for EG-2990Zi), water jet check valve adapter (OE-C12), water jet connector cap (OF-B118), irrigation tube (OF-B113), distal hoods (OE-A58/OE-A59), and other optional equipment:
Perform cleaning, high-level disinfection, and/or sterilization according to the procedure specified in the respective IFU provided with them.

■ Endoscopic devices:

Reusable endoscopic devices:
All reusable devices must be cleaned and sterilized according to the respective IFUs provided with them.
Single use endoscopic devices:
Follow the national or local laws/guidelines to appropriately dispose of single use endoscopic devices.

■ Video Processors/irrigation pump:

Follow the IFU provided with it for its care after use.

■ Water bottle assembly:

For cleaning and disinfection and/or sterilization of the water bottle assembly, refer to IFU provided with the water bottle assembly.

Disconnecting the endoscope from the video processor

Caution

Do NOT attach or remove the PVE connector while the video processor power is powered on. Doing so may damage the endoscope.

1. Immediately after use, perform pre-cleaning according to the separate IFU (Reprocessing) of this endoscope.
2. After completion of cleaning in the examination room, turn off power of the video processor.

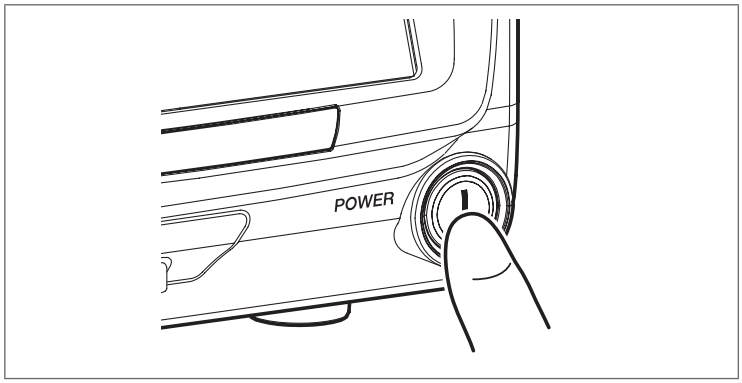


Figure 4.12

3. Turn the endoscope locking lever to the “OPEN” position; then, hold the endoscope PVE connector and remove the endoscope electrical contacts and light guide plug from the processor connector and receptacle.

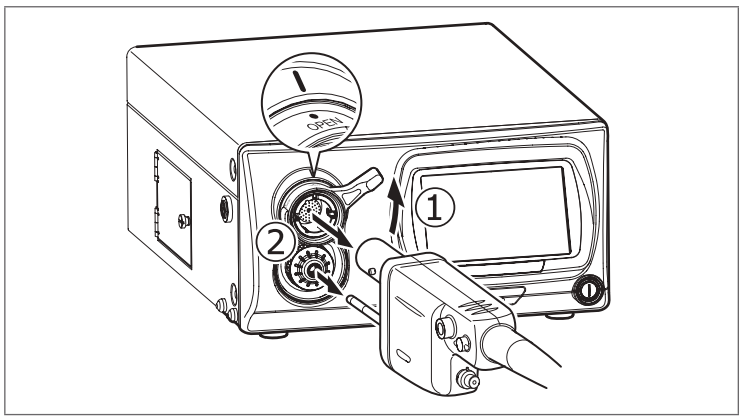


Figure 4.13

Note

- If the video processor connected has a scope eject function, the PVE connector can be removed when the power of the video processor is turned on by using the scope eject function of the video processor. For details, refer to the IFU of the respective video processor.

5 Troubleshooting

After inspecting the endoscope according to “Chapter 3 Preparation and inspection”, if any abnormality is suspected, do not use the endoscope; send the endoscope for repair according to “5-2. Returning the endoscope for repair” (p. 75).

Warning

Do NOT use an endoscope with any apparent abnormality. Continuing to use an endoscope with an abnormality may result in endoscope damage, malfunction, and/or injury to the patient and/or user.

5-1. Withdrawal of an endoscope with an abnormality

Immediately stop the endoscopic procedure and slowly and cautiously withdraw the endoscope when any abnormality occurs.

When the endoscopic image is displayed

1. When using the endoscopic device, close the distal tip or retract it within the sheath. Then, slowly withdraw the endoscopic device from the endoscope.
2. Operate the suction control valve to suction any fluid remaining inside the patient’s body cavity.
3. If the electrical magnifying function used, set it back to standard image size.
4. Turn the up/down angulation lock lever and right/left angulation lock knob in the “F►” direction until they stop to release the lock of the angulation control knobs.
5. While checking the endoscopic image, slowly and cautiously withdraw the endoscope.

When the endoscopic image is not displayed

1. When using the endoscopic device, close the distal tip or retract it within the sheath. Then, slowly withdraw the endoscopic device from the endoscope.
2. Turn the up/down angulation lock lever and right/left angulation lock knob in the “F►” direction until they stop to release the lock of the angulation control knobs.
3. Remove your hand from the up/down and right/left angulation control knobs.
4. Slowly and cautiously withdraw the endoscope.

5-2. Returning the endoscope for repair

When returning the endoscope for repair, follow the instructions below. For more details, contact your local PENTAX Medical service facility. Always subject the endoscope to cleaning and high-level disinfection before returning it for repair.

Warning

Only qualified personnel from PENTAX Medical are authorized to repair this endoscope. PENTAX Medical is NOT liable for any damage or injury that occurs as a result of repairs attempted by non-PENTAX Medical personnel. It must be recognized that PENTAX Medical does NOT evaluate non-PENTAX Medical parts, components, materials and/or servicing methods and therefore questions regarding material compatibility and/or functionality of PENTAX Medical endoscopes built with these unauthorized, untested and unapproved items, materials, repair/assembly methods must be referred to the third party service organization and/or device remanufacturer.

1. Place this endoscope in the dedicated carrying case. Ensure that the PVE soaking cap is included for water leakage test.
2. When transporting by air, ensure that the ventilation cap is attached to prevent damage to the endoscope.
3. Include any PENTAX Medical accessory that is suspected to be associated with the damage.
4. Contact your local PENTAX Medical service facility for shipping address and inform us the description of failures that need repair, model name, serial number, and name/phone number/address of the contact person.

Disposal

Warning

Follow the national or local laws/guidelines to appropriately dispose of the consumables. Failure to do so may create a risk of cross contamination or infection.

Contact your local PENTAX Medical service facility when disposing the endoscope(s).

Electromagnetic compatibility (EMC)

This product conforms to IEC60601-1-2: 2007: Medical electrical equipment, EMC standard.

Guidance and manufacturer's declaration – electromagnetic emissions

This product is intended for use in the electromagnetic environment specified below. The customer or the user of this product should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	This product uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	This product is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacturer's declaration – electromagnetic immunity

This product is intended for use in the electromagnetic environment specified below. The customer or the user of this product should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/ burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycle 70 % U_T (30 % dip in U_T) for 25 cycle <5 % U_T (>95 % dip in U_T) for 5 s	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycle 70 % U_T (30 % dip in U_T) for 25 cycle <5 % U_T (>95 % dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of this product requires continued operation during power mains interruptions, it is recommended that this product be powered from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	It is recommended that this product be used apart from other devices operated with large current.
Note: U_T is the a.c. mains voltage prior to application of the test level.			
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	The recommended separation distance: $d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	The recommended separation distance: $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz
• P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. d is the recommended separation distance in metres (m).			

Note

- At 80 MHz and 800 MHz, the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
- Interference may occur in the vicinity of equipment marked with the following symbol:

- Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b]
  a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which this product is used exceeds the applicable RF compliance level above, this product should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating this product.
  b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and this product

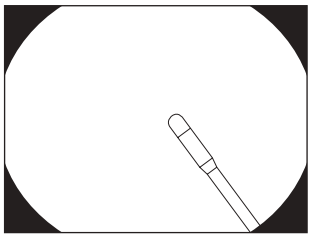
This product is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of this product can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and this product as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Recommended distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			

Note

- At 80 MHz and 800 MHz, the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Endoscope specifications

Model Name		EG-2990Zi	EC-3890FZi	EC-3890MZi	EC-3890LZi
Direction of view		Forward (0°)			
Field of view		Normal observation (WIDE): 140°, Observation with the maximum zooming (TELE): 49°			
Depth of field		Normal (WIDE): 5-100mm	Normal (WIDE): 4-100mm		
Magnification method		Optical/electrical			
Tip angulation	Up–Down	210°-120°	180°-180°		
	Right–Left	120°-120°	160°-160°		
Rigid distal width		Ø10.6mm [Ø12.6mm]	Ø13.0mm [Ø15.0mm]		
Distal end width		Ø10.2mm [Ø12.0mm]	Ø12.0mm [Ø14.4mm]		
Insertion tube width		Ø9.8mm	Ø13.2mm		
Maximum insertion portion width *1		Ø11.6mm [Ø12.9mm]	Ø14.65mm [Ø15.3mm]		
Minimum instrument channel width *2		Ø2.8mm	Ø3.8mm		
Endoscopic device view on the endoscopic image					
Insertion Tube Working Length *1		1,050mm [1,053mm]	1,500mm [1,503mm]	1,300mm [1,303mm]	1,700 mm [1,703mm]
Total Length		1,376mm [1,379mm]	1,825mm [1,828mm]	1,625mm [1,628mm]	2,025 mm [2,028mm]
Laser cauterization		Available			
Electrosurgery treatment		Available			
Water jet feeding function		Available			

[ ]: Values when a distal hood is attached

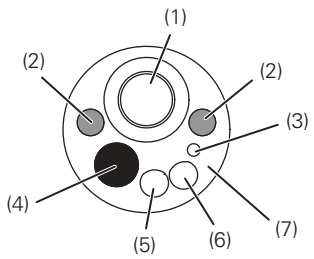
Specifications are subject to change without prior notice and without any obligation on the part of the manufacturer.

*1 There is no guarantee that equipment selected solely using the maximum insertion portion width and insertion portion working length will be compatible when used in combination.

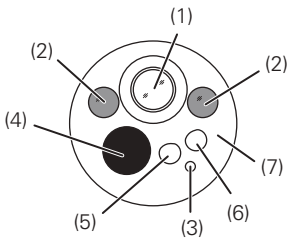
*2 There is no guarantee that equipment selected solely using this minimum instrument channel width will be compatible when used in combination.

Distal End

EG-2990Zi



EC-3890Zi series



(1) Objective Lens
(2) Light Guide
(3) Water Jet Nozzle
(4) Instrument Channel
(5) Air Nozzle
(6) Water Nozzle
(7) Case

System chart

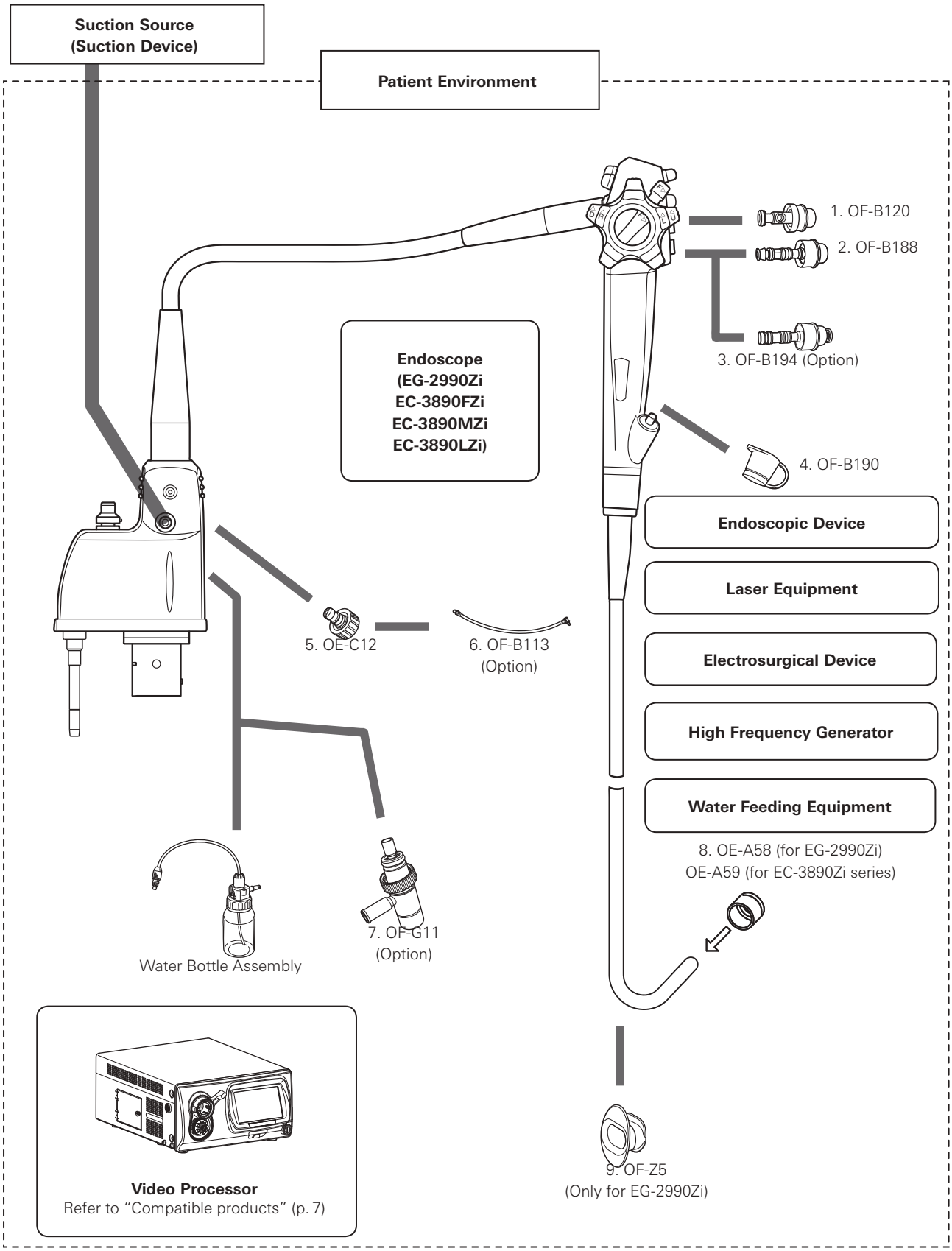
This section shows the system chart (configuration) for this endoscope and the ancillary equipment.

Warning

Use this product in combination only with compatible products shown in “Compatible products” (p. 7) and the “System chart”. Failure to do so may result in lowered function and patient/user injury or damage to the equipment.

Note

When this endoscope is used in combination with other equipment, depending on how it is connected, it may result in malfunction and/or unforeseen events to patients and/or medical professionals.
Pre-use operation check and risk management associated with changes are recommended, particularly when the equipment(s) used in combination is changed, added, or upgraded.



1. Suction Control Valve (OF-B120)
2. Air/Water Feeding Valve (OF-B188)
3. Gas/Water Feeding Valve (OF-B194*) *Optional Equipment
4. Inlet Seal (OF-B190)
5. Water Jet Check Valve Adapter (OE-C12)
6. Irrigation Tube (OF-B113)
7. Gas Adapter (OF-G11*) *Optional Equipment
8. Distal Hood OE-A58 (for EG-2990Zi) OE-A59 (for EC-3890Zi series)
9. Bite Block (OF-Z5) (Only for EG-2990Zi)

Software Version

EG-2990Zi	00B3C-4
EC-3890Zi series	

Contacts

Manufacturer

HOYA Corporation
6-10-1 Nishi-shinjuku,
Shinjuku-ku, Tokyo
160-0023 Japan

Distributors

PENTAX Europe GmbH EC REP
Julius-Vosseler-Straße 104
22527 Hamburg, Germany
Tel: +49 40 561 92-0
Fax: +49 40 560 42 13

PENTAX Medical
A Division of PENTAX of America, Inc.
3 Paragon Drive
Montvale, NJ 07645-1782
USA
Tel: +1 201 571 2300
Toll Free: +1 800 431 5880
Fax: +1 201 391 4189

PENTAX Medical Shanghai Co., Ltd.
Room 701, 291 Fumin Road, Shanghai
200031 P. R. China
Tel: +86 21 6170 1555
Fax: +86 21 6170 1655

PENTAX Medical Singapore Pte. Ltd.
438A Alexandra Road, #08-06
Alexandra Technopark, 119967 Singapore
Tel: +65 6507 9266
Fax: +65 6271 1691
Customer Service Toll Free:
400 619 6570 (within China)
1800 2005 968 (within India)
1300 PENTAX (within Australia)

80566

CE 0123

LCPM: 04/2018/06/35010302 2018. 03 6217001 S069 R01

In the interest of technical progress, specifications may change without notice.

PENTAX MEDICAL
Excellence in Focus

GEBRAUCHSANWEISUNG
OPERATING MANUAL
MODE D´EMPLOI
INSTRUCCIONES PARA EL USO
MANUALE D´USO
操作手冊

GEBRAUCHSANWEISUNG
für mobile Geräteträger uni-cart, vexio-cart, pro-cart, duo-cart, compact-cart, classic-cart und endo-cart mit und ohne Trenntransformator

Deutsch Seite 2

OPERATING MANUAL
for mobile equipment carts uni-cart, vexio-cart, pro-cart, duo-cart, compact-cart, classic-cart and endo-cart with and without isolating transformer

English Page 26

MODE D´EMPLOI
pour les supports d´appareils mobiles uni-cart, vexio-cart, pro-cart, duo-cart, compact-cart, classic-cart et endo-cart avec et sans transformateur de séparation

Français Page 50

INSTRUCCIONES PARA EL USO
para carros porta aparatos uni-cart, vexio-cart, pro-cart, duo-cart, compact-cart, classic-cart y endo-cart con y sin transformador de separación

Español Página 74

MANUALE D'USO
per carrelli porta-attrezzi uni-cart, vexio-cart, pro-cart, duo-cart, compact-cart, classic-cart e endo-cart con e senza trasformatore di separazione

Italiano Pagina 98

操作手冊
裝有和不裝有隔離變壓器的 uni-cart, vexio-cart, pro-cart, duo-cart, compact-cart, classic-cart 及 endo-cart 隔離變壓器

繁体中文 第 122 頁

Dies ist ein Medizinprodukt der Klasse I im Sinne der Europäischen Medical Device Directive (MDD) 93/42/EWG, Anhang IX.
Der Hersteller erklärt die Konformität dieses Produktes mit den grundlegenden Anforderungen gemäß MDD 93/42/EWG, Anhang VII, und dokumentiert dies durch die CE-Kennzeichnung.

Hersteller:

ITD GmbH
Sportplatzstr. 3
84381 Johanniskirchen
Tel: + 49 89 61 44 25- 0
Fax: +49 89 61 44 25- 200
Email: sales@itd-cart.com

Vertrieb und Service:

Nordamerika
ITD Corporation
50 RADO DR UNIT A
Naugatuck, CT 06770-2211, USA
Tel: +1 203 714 67-00
Email: sales.usa@itd-cart.com

Europa
ITD GmbH - Geschäftsstelle Unterhaching
Gruenwalder Weg 13a
82008 Unterhaching, Germany
Tel: +49 89 61 44 25 0
Email: sales@itd-cart.com

China
ITD Medical Technology Products (Shanghai) Co., Ltd.
Section A, Room 101, 1st Floor
11 South RiYing Road
Pilot Free Trade Zoon
Shanghai 200131, China
Tel: +86 21 6442 5704
Email: s.pan@itd-cart.com

Australien
ITD Australia Pty Ltd
Aviation Place 3
3043 Tullamarine, Victoria, Australia
Tel: +61 3 9330 50 50
Email: s.oconnor@itd-cart.com

Wir arbeiten ständig an der Weiterentwicklung unserer Produkte. Bitte haben Sie Verständnis dafür, dass wir uns jederzeit Änderungen des Lieferumfangs in Form, Ausstattung und Technik vorbehalten müssen.

Nachdruck, Vervielfältigung oder Übersetzung, auch auszugsweise, ist ohne schriftlicher Genehmigung der ITD GmbH nicht gestattet! Alle Rechte nach dem Gesetz über das Urheberrecht bleiben der ITD GmbH ausdrücklich vorbehalten.

Stand © 11/2018 Druckdatum 12/2018

Diese Gebrauchsanweisung hat Gültigkeit für folgende Produkte:

Typenbezeichnung	Beschreibung
CC.02xx.xxx / 03xx.xxx	Systemkomponenten und Zubehör compact-cart
CC.45xx.xxx / 50xx.xxx / 65xx.xxx	Gerätewagen compact-cart, 30 E – 40 E
CC.45xx.xxx / 50xx.xxx / 65xx.xxx	Systemkomponenten und Zubehör compact-cart
DC.42xx.xxx / 53xx.xxx / 64xx.xxx	Gerätewagen duo-cart, 21 E – 30 E
DC.40xx.xxx / 50xx.xxx / 60xx.xxx	Systemkomponenten und Zubehör duo-cart
EB.45xx.xxx / 50xx.xxx / 65xx.xxx	Gerätewagen compact-cart Economy
EC.04xx.xxx	Gerätewagen endo-cart, 30 E
GW.52xx.xxx / 53xx.xxx / 54xx.xxx	Gerätewagen classic-cart, 21 E – 40 E
GW.62xx.xxx / 63xx.xxx / 64xx.xxx	
GW.01xx.xxx / 02xx.xxx / 03xx.xxx	Systemkomponenten und Zubehör classic-cart
GW.04xx.xxx / 05xx.xxx / 06xx.xxx	
GW.07xx.xxx / 08xx.xxx	
GW.40xx.xxx / 41xx.xxx / 45xx.xxx	
GW.50xx.xxx / 51xx.xxx / 55xx.xxx	
GW.60xx.xxx / 61xx.xxx / 65xx.xxx	
GW.80xx.xxx / 98xx.xxx / 99xx.xxx	
HA.1xxx.xxx / 2xxx.xx	Systemkomponenten und Zubehör flexion-port
HA.45xx.xxx / 5xxx.xxx	
HA.60xx.xxx / 65xx.xxx	
NT.20xx.xxx / 40xx.xxx / 41xx.xxx	Systemkomponenten und Zubehör vexio-cart
NT.50xx.xxx	Gerätewagen vexio-cart, 21 E – 50 E
PT.20xx.xxx / 40xx.xxx / 41xx.xxx	Systemkomponenten und Zubehör pro-cart
PT.50xx.xxx / PT.90xx.xxx	Gerätewagen pro-cart, 21 E – 50 E
RS.41xx.xxx/ 48xx.xxx / 49xx.xxx	Gerätewagen uni-cart, 21 E – 50 E
RS.00xx.xxx / 01xx.xxx / 02xx.xxx	Systemkomponenten und Zubehör uni-cart
RS.4xxx.xxx / 5xxx.xxx	
TS.03xx.xxx / 05xx.xxx	Systemkomponenten und Zubehör flexion-port

Diese Gebrauchsanweisung hat Gültigkeit für folgende Produkte:

Typenbezeichnung	Beschreibung
VS.53xx.xxx / 54xx.xxx / 63xx.xxx	Videoschrankwagen classic-cart, 30 E – 40 E
VS.63xx.xxx	
VT.43xx.xxx	Videowagen mit Trenntransformator pro-cart, 30 E
VT.45xx.xxx	Videowagen mit Trenntransformator compact-cart, 40 E
VT.54xx.xxx / 64xx.xxx	Videowagen mit Trenntransformator classic-cart, 40 E
VW.54xx.xxx / 64xx.xxx	Videowagen classic-cart, 40 E
ZV.94xx.xxx / 96xx.xxx / 97xx.xxx	Systemkomponenten und Zubehör allgemein
ZV.98xx.xxx / 99xx.xxx	

KD.7xxx.xxx / 8xxx.xxx / 9xxx.xxx	Kundenspezifische, mobile Geräteträger der Baureihen uni-cart, pro-cart, duo-cart, classic-cart, compact-cart und endo-cart
KU.0xxx.xxx – KU.9xxx.xxx	Kundenspezifische, mobile Geräteträger der Baureihen uni-cart, vexio-cart, pro-cart, duo-cart, classic-cart, compact-cart und endo-cart
OC.0xxx.xxx – OC.9xxx.xxx OC.1 – OC.999	
OM.0xxx.xxx-OM.9xxx.xxx	

Inhalte

1 Wichtige Informationen

1.1 Bestimmungsgemäße Verwendung 6
1.2 Allgemeine Symbolerklärung 7
1.3 Sicherheitshinweise 9

2 Montage

2.1 Vollzähligkeit 10
2.2 Beladung 10
2.3 Beladungsreihenfolge 10
2.4 Gefährdung durch mechanische Instabilität 11
2.5 Rollen 11
2.6 Belastung 11
2.7 Montage / Bedienung 11
2.8 Nachträglicher Anbau von Systemkomponenten 12

3 Elektrische Sicherheit

3.1 Platzierung von elektrischen Geräten ... 12
3.2 Energiesäule (classic-cart, compact-cart, endo-cart) und Vertikalsäule (uni-cart, vexio-cart und pro-cart) ... 12
3.3 Gase ... 13
3.4 Potentialausgleich ... 13
3.5 Trenntransformator – Ableitstrom ... 13
3.6 Isolationswächter ... 13
3.7 Kabelsteckverbindung ... 15
3.8 Kombination von Geräten ... 15
3.9 EMV ... 16
3.10 Von der elektrischen Ausgangsprüfung ausgeschlossene Systemkomponenten / Zubehörteile ... 16
3.11 Mindestsicherheit ... 17

4 Transport

4.1 Sicherer Transport auf Rollen ... 17
4.2 Sicherer Transport durch Tragen ... 17

5 Mechanische und elektrische Höhenverstellung ... 18

6 Tragarme

6.1 Verkabelung ... 19
6.2 Horizontales Schwenken ... 19
6.3 Neigen / Rotieren der Geräte ... 19
6.4 Höhenverstellbare Tragarmsysteme (flexion-port) ... 20
6.5 Abbau und Umbau von Systemkomponenten und Zubehör ... 20
6.6 Bestimmungsgemäße Verwendung beim Manövrieren der mobilen Geräteträger ... 20
6.7 Bedienung der höhenverstellbaren Tragarmsysteme (flexion-port) auf dem Monitorboden (2-fach) ... 21

7 Sonstiges

7.1 Reinigung und Desinfizierung ... 21
7.2 Instandsetzung / Service ... 22
7.3 Umweltbedingungen ... 22
7.4 Entsorgung ... 22
7.5 Ersatzteile ... 22

8 Zubehör ... 23

9 Wartung ... 23

10 Technische Daten

10.1 Tragfähigkeit uni-cart ... 24
10.2 Tragfähigkeit vexio-cart ... 24
10.3 Tragfähigkeit pro-cart ... 24
10.4 Tragfähigkeit duo-cart ... 24
10.5 Tragfähigkeit compact-cart ... 24
10.6 Tragfähigkeit classic-cart / endo-cart ... 25
10.7 Tragfähigkeit modul-port ... 25
10.8 Tragfähigkeit flexion-port ... 25

1 Wichtige Informationen

Alle Produkte der ITD GmbH werden für eine lange und störungsfreie Lebensdauer gefertigt.

Entwicklung, Konstruktion, Vertrieb und Produktion sind bei der ITD GmbH nach DIN 13485 zertifiziert.

Das ist Grundlage für:
- höchste Qualität und eine lange Lebensdauer
- einfache, sichere und ergonomische Bedienung
- funktionales Design
- Optimierung für den Einsatzzwecke

Die Produkte entsprechen den Forderungen der European Medical Device Directive (EMDD) und tragen die CE-Kennzeichnung.

- Lesen Sie diese Gebrauchsanweisung sorgfältig von Anfang an, um sich mit den Funktionen schrittweise vertraut zu machen.
- Bei Rückfragen oder bei Zweifeln wenden Sie sich unbedingt an den Hersteller.
- Die mobilen Geräteträger sind nur für die beschriebene, bestimmungsgemäße Verwendung bestimmt.
- Diese Anleitung ist für die Lebensdauer des Produktes aufzubewahren.

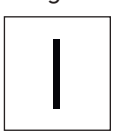
Die Gebrauchsanweisung für die Gesamtkonfiguration hat der Systemkonfigurierer dem Endkunden bereitzustellen.
Es wird ausdrücklich darauf hingewiesen, dass der Systemkonfigurierer für die Einhaltung der Anforderung der IEC 60601-1 und der EMV-Norm IEC 60601-1-2 in der gültigen Fassung verantwortlich ist!

1.1 Bestimmungsgemäße Verwendung

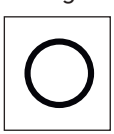
Die mobilen Geräteträger der ITD GmbH dienen:
- zur Aufnahme von medizinischen und IEC geprüften Geräten gemäß der zulässigen Belastungangaben unter Einhaltung der Forderungen der IEC 60601-1 in der aktuell gültigen Fassung.
- zu Anschluss und Verteilung von Netzspannungen ab der örtlichen Stromentnahmestelle sowie von Datenleitungen.
- zur Befestigung von originalen ITD Systemkomponenten und Zubehör.

Mit Hilfe des mobilen Geräteträgers können medizinische Geräte vor und nach der Anwendung innerhalb des Gebäudes bewegt bzw. im Raum positioniert werden. Somit ist eine flexible, wirtschaftliche Auslastung aller Geräte möglich. Zudem wird die Reinigung der Bodenfläche erleichtert.

1.2 Allgemeine Symbolerklärung



„EIN“ (Spannung) leuchtet grün



„AUS“ (Spannung)

„EIN“ leuchtet grün / „AUS“ (druckbetätigt)

Potentialausgleich: markiert u. a. durch POAG-Zapfen am Trenntransformator-gehäuse; der Potentialausgleich stellt sicher, dass der Widerstand zwischen allen leitfähigen Materialien genügend klein ist.

Schutzleiteranschluss:
Leiter, der Körper von Betriebsmitteln, leitfähige Teile, Haupterdungsklemme und Erde verbindet.

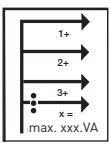
Leitfähige Rollen:
Leitfähige Rollen werden durch einen Blitz oder einen gelben Punkt gekennzeichnet.

Nur mit eingeklapptem Arm bewegen

Griff zum Schieben verwenden

Gebrauchsanweisung befolgen

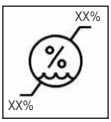
Wechselstrom



Gesamtleistung:
Die Summe der Leistungen, die an den einzelnen Steckplätzen abgegeben werden, darf die Gesamtleistung nicht übersteigen.

Gesamtzuladung Basisgestell:
Maximale Gesamtzuladung (= Summe der Belastungsangaben aller einzelnen Systemkomponenten). Bitte beachten Sie für die zulässige Belastung den entsprechenden Aufkleber.

Belastungsangabe (Systemkomponenten):
Bitte beachten Sie für die zulässige Belastung den entsprechenden Aufkleber.



Feuchtigkeitsgrenze

Allgemeiner Warnhinweis:
Dieser ist an der Steckdosenleiste angebracht. Die am Typenschild angegebene Gesamtleistung darf nicht überschritten werden.

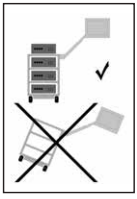
Nur für Innenräume geeignet.

Schwerer Gegenstand:
Es ist sicherzustellen, dass mind. zwei Personen die mobilen Geräteträger uni-cart, vexio-cart, pro-cart, duo-cart, classic-cart, compact-cart und endo-cart anheben müssen, um Verletzungen zu vermeiden.

Vertrieben durch

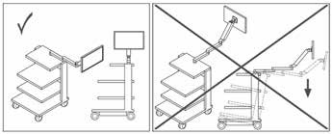
Einstellung der Klemmkraft (Dreh- und Schwenkeinheit).

Lasteinstellung:
Beschreibt den Lastbereich sowie die Drehrichtung für die Lasteinstellung .

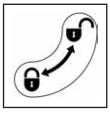


Kippgefahr:
Beim mobilen Geräteträger ist unbedingt auf die Reihenfolge der Be- und Entladung zu achten.

Bremsfunktion:
Diese informiert über die Positionierung des Tragarms im Falle der Geräteabnahme und gibt die Richtung für die Freigabe bzw. Sperrung der Feststellfunktion an.



Arbeitsposition:
Dieses Symbol beschreibt die erlaubten Arbeitspositionen (rechts / links) und weist auf eine bestehende Kippgefahr beim Seitenwechsel hin.



Verriegelungsfunktion:
Diese beschreibt die Richtung des Verriegelns bzw. Öffnens von Komponenten.

Kein Schieben:
Ein Schieben des Gerätewagens oberhalb des Griffes ist wegen Kippgefahr nicht zulässig.

1.3 Sicherheitshinweise

Allgemeines:

- Es dürfen nur mobile Geräteträger in Betrieb genommen werden, deren Netzspannungseinrichtungen von qualifiziertem Fachpersonal geprüft und freigegeben sind!
- Stellen Sie sicher, dass der Trenntransformator nur an ein Stromversorgungsnetz mit funktionsfähigem Schutzleiteranschluss angeschlossen wird, das den Bestimmungen der IEC 60364-7-710 2012-10 „Elektrische Installation in Gebäuden Teil 7-710 Anforderungen für spezielle Instalationen oder Räume- Medizinisch genutzte Räume" genügt. Wenden Sie sich im Zweifelsfall an einen Fachbetrieb des Elektrohandwerks oder einen autorisierten Mitarbeiter der Krankenhaustechnik.
- Personal (Krankenhaus- und Service-Personal), das mittelbar oder unmittelbar mit einem mobilen Geräteträger arbeitet, muss eingewiesen sein!
- Einstellungsarbeiten dürfen nur von Fachpersonal durchgeführt werden.
- Reparaturen und Wartungsarbeiten dürfen nur durch die Fa. ITD GmbH durchgeführt werden.

Sicheres Arbeiten am Gerätewagen:

- Trennung vom Versorgungsnetz ist nur gewährleistet wenn der Netzstecker aus der Steckdose gezogen ist.

Bedienung:

- Bei jeder Ortsveränderung ist darauf zu achten, dass keine Menschen verletzt oder Gegenstände beschädigt werden!

Anschlüsse:

- Beim Anschluss von Trenntransformatoren im 115 V Betrieb ist in den Ländern USA und Kanada ein Hospital Grade-Anschlusskabel und in Japan das optional erhältliche japanische Anschlusskabel zu verwenden.
- Beim Anschluss an die Mehrfachsteckdosenleiste sind die Stecker durch optional verfügbare Steckerauszugssperren zu sichern.
- An die Steckdosen / Anschlussleitungen dürfen nur Geräte angeschlossen werden, die den Anforderungen der IEC 60601-1 entsprechen oder IEC geprüft sind.
- Zusätzliche Medizingeräte mit Anschlussbolzen für Potentialausgleich sind mittels grüngelber Leitung am optional erhältlichen Potentialausgleichs-Anschlussbolzen anzuschließen!

Achtung: Die am Typenschild angebrachte Gesamtleistung darf nicht überschritten werden. Bitte beachten Sie, dass an die vorhandene Mehrfachsteckdose keine weitere Mehrfachsteckdose angeschlossen werden darf.

Belastung:

- Das Gesamtgewicht der Geräte und des Zubehörs auf dem mobilen Geräteträger darf die zulässige Gesamtzuladung nicht überschreiten (siehe Belastungsaufkleber auf dem Basisgestell).
- Die auf den Systemkomponenten aufgedruckte Flächenbelastung darf nicht überschritten werden!
- Die auf den Anbauten (z. B. Infusionsstativ, Gelenkarme) angegebene Last darf nicht über schritten werden!

Infektionsschutz:

- Bei Reinigungsarbeiten sind die Hygiene-Vorschriften zu beachten!
- Übergeben Sie nur gereinigte und desinfizierte Geräte sowie Ausrüstung einem

Servicetechniker für Wartungs- und Reparaturarbeiten!

Umweltschutz:

- Entsorgen Sie alle Reinigungs- und Desinfektionsmittelreste oder Rückstände schadlos sowie umweltverträglich!

2 Montage

2.1 Vollständigkeit

Packen Sie den Gerätewagen uni-cart, vexio-cart, pro-cart, duo-cart, classic-cart, compact-cart oder endo-cart zunächst aus und kontrollieren Sie anhand des beiliegenden Lieferscheins, ob alle bestellten Teile vorhanden sind.

2.2 Beladung

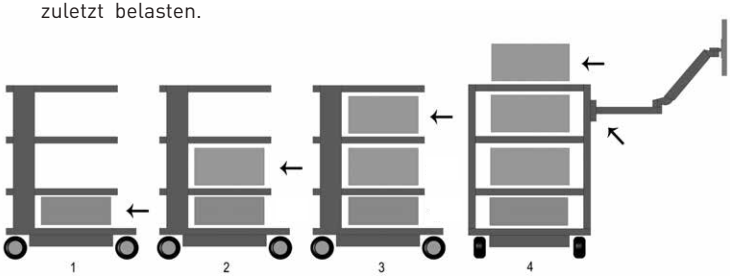
Stellen Sie den Gerätewagen uni-cart, vexio-cart, pro-cart, duo-cart, classic-cart, compact-cart oder endo-cart auf eine ebene, waagrechte Fläche. Stellen Sie die Geräte unter Berücksichtigung der Beladungsreihenfolge in den Wagen. Die Beladung und Montage darf nur netzgetrennt erfolgen. Zur Sicherung der einzelnen Geräte empfehlen wir das optionale Zubehör (z. B. Spanngurt) zu verwenden. Die maximale Beladung je Produktlinie ist in Kapitel 10 aufgeführt. Sollte die Standsicherheit nicht ausreichen, muss der Wagen gemäß der 5°-Kennzeichnungspflicht erkennbar gekennzeichnet sein.

2.3 Beladungsreihenfolge

Versichern Sie sich, dass alle auf dem Gerätewagen uni-cart, vexio-cart, pro-cart, duo-cart, classic-cart, compact-cart oder endo-cart abgestellten Geräte sicher gegen Verrutschen, Kippen, Herunterfallen oder Ähnliches durch geeignete Maßnahmen gelagert sind (auch während der Fahrt). Es ist ratsam, die Platzierung aller schweren Teile auf dem Gerätewagen uni-cart, vexio-cart, pro-cart, duo-cart, classic-cart, compact-cart oder endo-cart mit zwei Personen vorzunehmen. Beachten Sie, dass sich der Schwerpunkt mit der Beladung ändert.

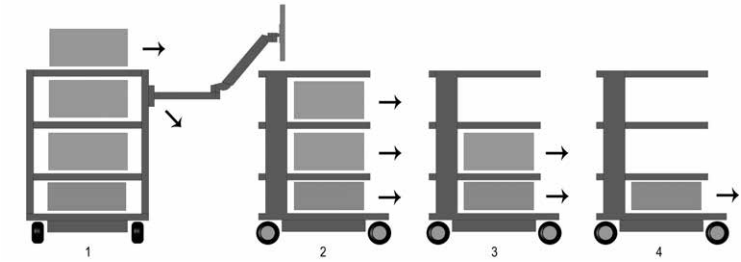
Der Wagen ist in folgender Reihenfolge zu beladen:

- Ablageböden und Schubfächer von unten nach oben.
- Tragarmsysteme (starr, schwenkbar, neigbar, höhenverstellbar, einfach oder mehrfach) zuletzt belasten.



Der Wagen ist in folgender Reihenfolge zu entladen:

- Tragarmsysteme (starr, schwenkbar, neigbar, höhenverstellbar, einfach oder mehrfach) zuerst entlasten
- Ablageböden und Schubfächer von oben nach unten entlasten.

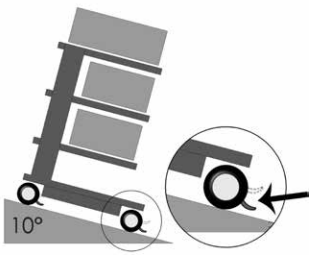


Bitte berücksichtigen Sie zudem beim Einsatz eines Gerätewagens (Transport) die Hinweise in Kapitel 4.

2.4 Gefährdung durch mechanische Instabilität

Das Gesamtsystem muss den Anforderungen gemäß IEC 60601-1 entsprechen.

2.5 Rollen



An den Gerätewagen uni-cart, vexio-cart, pro-cart, duo-cart, classic-cart, compact-cart oder endo-cart befinden sich Doppellenkrollen mit Bremsen. Versichern Sie sich vor Inbetriebnahme der Gerätewagen uni-cart, vexio-cart, pro-cart, duo-cart, classic-cart, compact-cart oder endo-cart, dass die Feststeller funktionieren.
Nach Erreichen der Parkposition sowie dem Halten während des Transportes sind am Gerätewagen alle Rollenbremsen (Sperrvorrichtung der Rolle) zu betätigen.
Entsprechend sind vor dem Bewegen bzw. dem Transport alle Rollenbremsen zu lösen.

Die Laufrollen müssen alle 12 Monate auf ihre Sicherheit sowie den spaltfreien, festen Sitz des Rollenbefestigungsbolzen geprüft werden. Sollten sich diese lösen, setzen Sie sich bitte sofort mit Ihrem Lieferanten in Verbindung.

2.6 Belastung

Es ist unzulässig, die Tragkraft der Gerätewagen uni-cart, vexio-cart, pro-cart, duo-cart, classic-cart, compact-cart oder endo-cart zu überschreiten.
Bitte beachten Sie die Höchstbelastbarkeit der Gerätewagen uni-cart, vexio-cart, pro-cart, duo-cart, classic-cart, compact-cart oder endo-cart (siehe Abschnitt 10).

2.7 Montage / Bedienung

2.7.1 Ablageböden

Ablageböden können entfernt oder an einer anderen Stelle eingebaut werden. Lösen Sie dabei die Schrauben, positionieren Sie den Boden neu und verschrauben Sie den Boden anschließend wieder. Überprüfen Sie danach den Schutzleiterwiderstand.

2.7.2 Schubfächer

Schubfachblöcke (pro-cart) sind mit einer Verriegelung versehen.

Bei pro-cart muss der Bediengriff an der Frontblende nach oben gezogen werden, um die Verriegelung zu lösen.

Die Schubfächer sind im ausgezogenem Zustand aushängbar.
An der Frontblende kann ein Beschriftungsstreifen angebracht werden (ausgenommen pro-cart). Das Schubfach ist beim Transport einzuschieben.

2.7.3 Trenntransformator

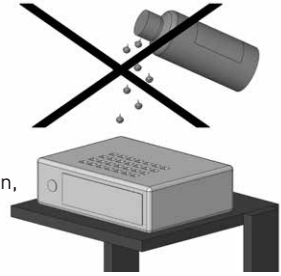
Gebrauchsanweisung des Trenntransformators befolgen. Der Trenntransformator ist in einem Gehäuse unter der Basis des Grundgestells montiert. Diese Montage erfolgt werkseitig.

2.8 Nachträglicher Anbau von Systemkomponenten

Ein nachträglicher Anbau von ITD Systemkomponenten darf nur von Fachpersonal nach den Vorgaben der mitgelieferten Montage-Anleitungen durchgeführt werden. Das veränderte Gesamtsystem ist erneut entsprechend der IEC 60601-1 zu prüfen.

3 Elektrische Sicherheit

3.1 Platzierung von elektrischen Geräten



Bitte beachten Sie, dass elektrische Geräte auf den Gerätewagen uni-cart, vexio-cart, pro-cart, duo-cart, classic-cart, compact-cart oder endo-cart nicht nass werden dürfen.
Platzieren Sie keinesfalls Produkte, die Flüssigkeit verlieren können, über elektrischen Geräte bzw. Steckdosenleisten, in welche Flüssigkeiten eindringen können.

3.2 Energiesäule (classic-cart, compact-cart, endo-cart) und Vertikalsäule (uni-cart, vexio-cart, pro-cart)

Steckdosenleiste oder das Verkabelungssystem befinden sich bei classic-cart, compact-cart und endo-cart in der linken oder rechten Energiesäule, bei uni-cart und pro-cart in der Vertikalsäule und bei vexio-cart unterhalb der Basis (die Kabelführung erfolgt hier in optional erhältlichen Kabelkanälen, die seitlich an der Vertikalsäule angebracht werden).

Energiesäulen befinden sich links und rechts hinter dem Vertikalprofil und ermöglichen eine optimale Unterbringung der vorhandenen Gerätekabel. Bohren Sie die Energiesäulen / Vertikalsäule keinesfalls an, da sich innerhalb stromführende Kabel befinden können.

3.3 Gase

Wenn elektrische Geräte betrieben werden, darf dies nicht in der Nähe von Gasen, z. B. entzündbarem Narkosegas oder ähnlichem stattfinden. Dafür zeichnet sich der Anwender verantwortlich, ebenso für die Einhaltung der IEC 60601-1-2.

3.4 Potentialausgleich (POAG)

Bei den Gerätewagen uni-cart, pro-cart, classic-cart, compact-cart oder endo-cart mit Trenntransformator ist ein Potentialausgleich notwendig. Bei vexio-cart ist optional ein POAG-Set ohne Trenntransformator erhältlich. Hierzu verbinden Sie zunächst die POAG-Leitung mit der Basis der Gerätewagen uni-cart, vexio-cart, pro-cart, classic-cart, compact-cart oder endo-cart und anschließend mit dem POAG-Stecker des Raumes. Als nächstes verbinden Sie die POAG-Leitungen mit dem POAG-Stift der Mehrfachsteckdose und der Geräte.

3.5 Trenntransformator – Ableitstrom

Der Zweck der Gerätewagen uni-cart, vexio-cart, pro-cart, duo-cart, classic-cart, compact-cart oder endo-cart ist es, eine praktische und mobile Arbeitsstation für elektromedizinische Anlagen zu schaffen. Damit das gesamte elektrische Medizinsystem der IEC 60601-1 entspricht, darf die Summe der Erdableitströme den maximalen Grenzwert von 0,5 mA nicht überschreiten. Falls die Summe der Erdableitströme diese Toleranzgrenze überschreiten würde, muss die Anlage über einen Sicherheitstrenntransformator gespeist werden.

Falls kein Trenntransformator montiert ist, darf die Mehrfachsteckdose / Hilfssteckdosen-system der Gerätewagen uni-cart, pro-cart, duo-cart, classic-cart, compact-cart oder endo-cart nicht für Anschlüsse von Geräten benutzt werden, die den Anforderungen der Ableitströme gemäß IEC 60601-1 nicht entsprechen.

Ist ein Trenntransformator montiert, muss die gesamte Leistungsaufnahme aller angeschlossenen Geräte innerhalb des Nennwertes des Transformators liegen.

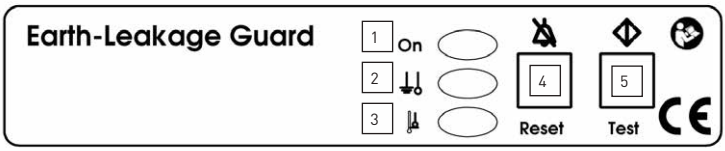
3.6 Isolationswächter

Die nachfolgenden Beschreibungen gelten nur bei den in den Geräteträgern verbauten Artikeln “Trenntransformator mit Isolationswächter”.

3.6.1 Bedienfeld des Isolationswächters (ELG)

Bei den Geräten mit integriertem Isolationswächter ist die Auswerte-Elektronik im Transformatorengehäuse eingebaut, das Bedien- und Anzeigefeld befindet sich in einem der Ablageböden. Beide Komponenten sind über ein im Vertikalprofil verlegtes Schnittstellenkabel miteinander verbunden.

Bedienfeld des Isolationswächters ELG (optional):



1 Netzkontroll-Leuchte (grün)
2 Isolationswiderstand (gelb)
3 Temperaturüberschreitung (gelb)
4 Fehlerquittiertaste
5 Test-Button

3.6.2 Bestimmungsgemäßer Gebrauch

Der Isolationswächter ELG dient zur Überwachung des Isolationswiderstandes von Geräten oder Gerätegruppen, die an Trenntransformatoren zur Schutztrennung angeschlossen sind. Gleichzeitig wird der Transformator hinsichtlich seines Temperaturverhaltens überwacht. Die Auswertung erfolgt prozessorgesteuert.

3.6.3 Bedienungsanleitung

Schalten Sie den Hauptschalter des Trenntransformators auf „EIN“, läuft innerhalb von 5 s der Selbsttest des Isolationswächters ELG automatisch im Hintergrund ab.
Nach Abschluss des Selbsttestes ist der Isolationswächter ELG betriebsbereit. Die Netzkontroll-Leuchte (grüne LED) leuchtet permanent. Der Test wird im Betrieb zyklisch alle 8 Stunden selbständig durchgeführt und kann zusätzlich manuell über den Test-Button ausgelöst werden.

Bei einem manuellen Test wird folgende Prüfroutine ausgeführt:

- Ein Isolationsfehler wird simuliert, die gelbe LED des Isolationswiderstandes leuchtet dauerhaft, ein Warnton mit 2,4 kHz erklingt auf Dauer, beides erlischt nach ca. 5 s.
- Anschließend wird ein Temperaturfehler simuliert, die gelbe LED als Zeichen der Temperaturüberschreitung leuchtet auf Dauer, ein Warnton mit 2,4 kHz erklingt pulsierend, beides erlischt nach ca. 5 s.

Ein Fehlerfall ist wie folgt zu erkennen:

- Tritt ein Isolationsfehler auf, leuchtet die gelbe LED des Isolationswiderstand dauerhaft, ein Warnton mit 2,4 kHz erklingt permanent. Der Warnton kann mit der Fehlerquittierungstaste zurückgesetzt werden. Die LED leuchtet, bis der Fehler behoben wurde.
- Wird der Isolationswächter ausgeschaltet und der Fehler zwischenzeitlich nicht behoben, beginnt der obige Ablauf von vorne.
  Beim Auftreten eines Isolationsfehler bleibt nach dessen Weggehen der akustische und optische Alarm bis zur Quittierung an:
  Erste Quittierung: akustischer Alarm aus
  Zweite Quittierung: optischer Alarm aus

- Tritt ein Temperaturfehler auf, leuchtet die gelbe LED als Zeichen der Temperaturüberschreitung auf Dauer, ein Warnton mit 2,4kHz erklingt pulsierend. Der Warnton kann mit der Fehlerquittierungstaste zurückgesetzt werden, die LED leuchtet weiterhin bis der Fehler behoben wurde. Wird der Isolationswächter ausgeschaltet und der Fehler zwischenzeitlich nicht behoben, beginnt der obige Ablauf von vorne.
- Bei einem gleichzeitigen Auftreten von Isolationsfehler und Übertemperaturfehler hat der Isolationsfehler beim akustischen Alarm immer Priorität.

Selbsttest des Isolationswächters
Der Isolationswächter führt zusätzlich zu dem über den Test-Button auslösbaren Selbsttest einen zyklischen Selbsttest im Zeitraum von ca. 8 Stunden durch. Der Test wird auch nach jedem Einschalten durchgeführt.
Der Selbsttest dauert cirka 5 Sekunden und ist nach außen nicht erkennbar. Im Fehlerfall blinkt die Netzkontroll-Leuchte (grüne LED) mit einer Frequenz von 0,5 Hz. Mit gleicher Frequenz ertönt der akustische Alarm. Die Fehlermeldungen sind nicht mit der Fehlerquittiertaste rücksetzbar.

3.6.4 Beseitigung von Störungen

Versuchen Sie nicht, das Gerät eigenmächtig zu reparieren. Wird ein unsachgemäßer Versuch der Reparatur festgestellt, so verfällt der Garantieanspruch. Reparaturen und Wartungsarbeiten werden aus Sicherheitsgründen ausschließlich vom Hersteller durchgeführt.

Hinweis:
Weitergehende technische Daten und Informationen entnehmen Sie bitte der dem Produkt beiliegenden separaten und ausführlichen Gebrauchsanweisung für Trenntransformatoren und Isolationswächter.

3.7 Kabelsteckverbindung

Der Betreiber der Gerätewagen uni-cart, vexio-cart, pro-cart, duo-cart, classic-cart, compact-cart oder endo-cart ohne eingesetzten Trenntransformator hat darauf zu achten, dass es sich bei der Kabelsteckverbindung zwischen der Mehrfach-Steckdosenleiste des Wagens und den Geräten um eine nur mit Werkzeug lösbare Verbindung handelt. Eine Auswahl an Abdeckungen für Mehrfach-Steckdosenleisten finden Sie in unserem Zubehörprogramm.

3.8 Kombination von Geräten

Für die Kombination von Geräten auf dem Gerätewagen ist folgendes zu beachten:

- Zusatzausrüstungen, die an die analogen und digitalen Schnittstellen des Gerätes angeschlossen werden, müssen nachweisbar den entsprechenden Spezifikationen (z. B. IEC 60950 für datenverarbeitende Geräte und IEC 60601-1 für elektromedizinische Geräte) genügen.
- Weiterhin müssen alle Konfigurationen der gültige Version der Norm IEC 60601-1 genügen. Wer zusätzliche Geräte an den Signaleingangs- oder Ausgangsteil anschließt, ist Systemkonfigurierer und ist damit verantwortlich, dass die gültige Version der Norm IEC 60601-1 eingehalten wird.

Bei Rückfragen kontaktieren Sie bitte Ihren lokalen Fachhändler oder den technischen Dienst.
Hinweis:
Gilt auch für die Adaption von Geräten in den Versorgungsstromkreis (z. B. Vielfachsteckdose)!

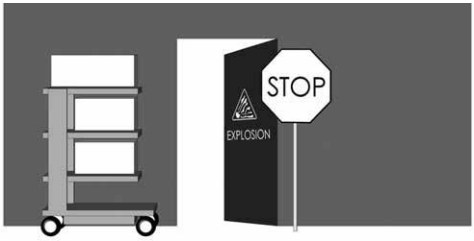
3.9 EMV

Die elektromagnetische Verträglichkeit der auf dem Wagen befindlichen elektromedizinischen Geräte untereinander ist vom Gesamtsystemkonfigurierer zu prüfen. Vor dem medizinischen Einsatz einer anderen Gerätekombination überprüfen Sie die elektromagnetische Verträglichkeit der einzelnen Geräte untereinander.

Kundenspezifische Gerätewagen, die innerhalb der Kernspinumgebung verwendet werden, müssen wegen anteiliger ferromagnetischer Stoffe durch den Kunden auf Gebrauchstauglichkeit geprüft werden.

Die ITD GmbH schließt jegliche Haftung diesbezüglich aus!

Eine Verwendung des Gerätewagens mit Trenntransformator innerhalb einer explosionsgefährdeten Umgebung ist nicht zulässig.



3.10 Von der elektrischen Ausgangsprüfung ausgeschlossene Systemkomponenten und Zubehörteile

Die ITD GmbH führt bei folgenden Systemkomponenten und Zubehörteilen keine elektrische Ausgangsprüfung durch:

- Mehrfachsteckdosen ohne zusätzlichen Schutzleiter, die nicht in der Montage verdrahtet werden
- beigelegte ME-Leitungen und Geräteleitungen
- beigelegte POAG-Platten bzw. -Leitungen

- Gerätewagen und Trägersysteme ohne Elektrifizierung
- Höhenverstellungen und Anbauteile an Höhenverstellungen
- Griffe, Mousepads, Schubfächer, Schubfachkorpusse und Anbauten (Flaschenhalterungen, Körbe, Kamerahalterungen, Infusionsstative, ...)
- Tastaturauszüge und ausziehbare Ablageböden
- Trenntransformatoren, die nicht montiert sind, sondern als Einzelnteil die ITD verlassen
- Rechnerhalterungen oben und unten
- Leitfähige Rollen
- Montierte Tragarme und Monitorhalterungen
- Sekundärstromkreise mit Isolationswächter sind nur von der Spannungsfestigkeitsprüfung ausgeschlossen!

3.11 Mindestsicherheit

Der ITD GmbH ist kein Gerät bzw. Zubehör bekannt, das die Mindestsicherheit des Systems verringert. Es dürfen nur Geräte verwendet werden, die keine Gefährdung darstellen. Gegebenenfalls ist dies durch eine Risikoanalyse (ISO 14971) abzuklären.

4. Transport

4.1 Sicherer Transport auf Rollen

Stellen Sie sicher, dass vor dem mobilen Einsatz des Gerätewagens:

- Alle darauf befindlichen Geräte / Produkte gegen Herunterfallen gesichert sind.
- Alle Gelenkarme eingeschwenkt und gesichert sind.
- Die Netzzuleitung von der örtlichen Stromentnahmestelle ausgesteckt ist.
- Die Bremsen der Rollen gelöst sind.

Der Gerätewagen darf nur mit einer maximalen Schrittgeschwindigkeit von 6 km/h bewegt werden. Beim Überfahren von Schwellen, Kabeln sowie Schläuchen ist die Geschwindigkeit deutlich zu reduzieren.

Beim Befahren von Rampen mit einer max. Steigung von 10° ist sicherzustellen, dass der Gerätewagen jederzeit zum Stillstand gebracht werden kann.

Obwohl alle Vorsichtsmaßnahmen beachtet wurden, um die maximale Stabilität dieses Produktes zu gewährleisten, sollte auf Unebenheiten des Fußbodens, Fahrstuhl-Türrahmen, Kabel etc. geachtet werden, um Unfälle zu verhindern.

Grundsätzlich gelten die Anforderungen der IEC 60601-1.

4.2 Sicherer Transport durch Tragen

Griffe dienen nicht zum Anheben des mobilen Geräteträgers, sondern besitzen lediglich eine reine Schiebefunktion. Das Anheben und Tragen der mobilen Geräteträger darf nur durch zwei Personen an den Auslegern der Basis erfolgen.

Grundsätzlich gelten die Anforderungen der IEC 60601-1.

5 Mechanische und elektrische Höhenverstellung

Sowohl für die „mechanische Höhenverstellung über „Gasdruck“ als auch für die elektro-mechanische Höhenverstellung mittels „Linearantrieb“ sind besondere Sicherheitsvorschriften gemäß IEC 60601-1 „Mechanische Gefährdung in Verbindung mit bewegten Teilen“ zu beachten. Dabei gilt:

- Die zulässigen Abstände zwischen bewegten Teilen gemäß IEC 60601-1 in Tabelle 20 (ISO 13857:2008) sind zu berücksichtigen und einzuhalten.
- Produkte mit Höhenverstellung werden ab Werk, normkonform unter Einhaltung der zulässigen Sicherheitsabstände gefertigt und geliefert. Durch die Bestückung bzw. den Tausch von ME-Geräten und / oder Komponenten verändern sich diese Abstände. Dies kann dann zu einer mechanischen Gefährdung führen. Verantwortlich für die Einhaltung der geforderten Mindestabstände ist der jeweilige Systemkonfigurierer.
- Das Gesamtgewicht der montierten Geräte und Zubehörteile darf die vorgeschriebene maximale Gesamtzuladung der Höhenverstellung nicht überschreiten. Überladungen führen zu Beschädigungen an der Höhenverstellung und zum Verlust der Gewährleistung.

- Bei der mechanischen Höhenverstellung über Gasdruck wird gespeicherte Energie freigesetzt. Bei unbeladenen Systemen kann eine schlagartige, ungebremste Betätigung der Höhenverstellung zu Verletzungen und Beschädigungen führen.
  - Zur Vermeidung von Verletzungen und Beschädigungen ist vor der Montage und Demontage von Geräten die Höhenverstellung in die oberste („energiefreie“) Position zu bringen.
  - Das höhenvariable Tragarmsystem „flexion-port“ muss in oberster („energiefreier“) Position zusätzlich mit Hilfe des Klemmhebels fixiert und gesichert werden (siehe separate Gebrauchsanweisung für „flexion-port“ sowie Gefahrhinweise am Tragarmsystem).

- Eine ungewollte Betätigung der elektro-mechanischen Höhenverstellung mittels Handtaster kann ebenfalls zu Verletzungen und Beschädigungen führen.
  - Zur Vermeidung von Verletzungen und Beschädigungen ist vor der Montage und Demontage von Geräten die Höhenverstellung von der Stromversorgung zu trennen.
  - Service- und Wartungsarbeiten im „Innenbereich“ der Höhenverstellung, d. h. im abgedeckten, von außen nicht zugängigen Bereich innerhalb der Trägersäule, darf nur durch geschultes Fachpersonal durchgeführt werden.
  - Achtung: Bei der Bedienung der Höhenverstellung mit Hilfe des Ferntasters ist darauf zu achten, dass sich keine Personen im Gefahrenbereich befinden.

6 Tragarme

6.1 Verkabelung

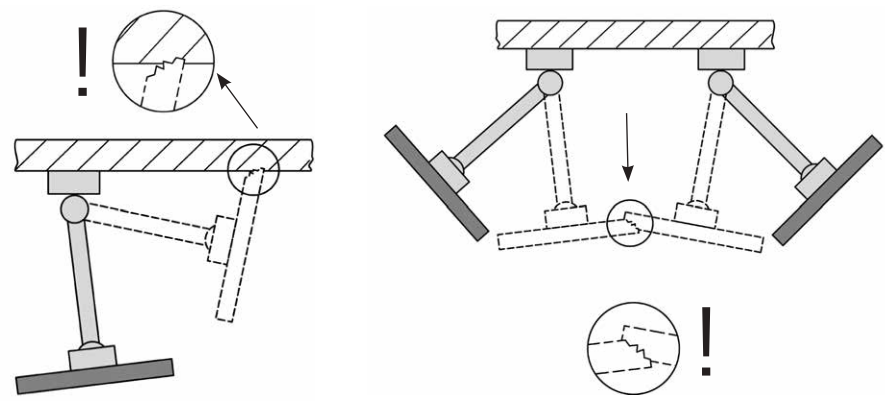
Beachten Sie bitte folgende Hinweise:

- Damit es beim Schwenken nicht zu einer Beschädigung des Kabels oder zum Ausfall der Geräte kommt, müssen die Kabel ausreichend bemessen sein.
- Möglicherweise herunterhängende Kabel dürfen keinesfalls als Griff benutzt werden.
- Bitte achten Sie darauf, dass das beigelegte Montagematerial ordnungsgemäß laut der Montageanleitung verwendet wird.
- Beim Schwenken der Arme ist auf eventuell vorhandene Kabelschlaufen zu achten.

6.2 Horizontales Schwenken

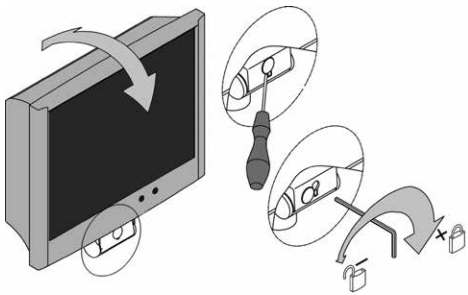
Stellen Sie sicher, dass der Schwenkbereich von Systemkomponenten sowohl auf die Gerätegröße als auch auf die Raumbedingungen abgestimmt ist.

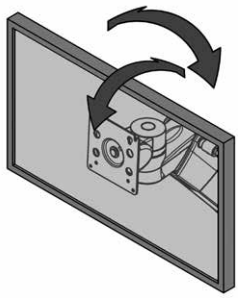
Bei horizontalem Schwenken der Systemkomponenten mit darauf befestigten Geräten dürfen diese weder mit anderen Geräten noch mit anderen Systemkomponenten oder mit der Wand kollidieren. Eine Kollision kann zur Beschädigung von Geräten führen und Verletzungen von Personen zu Folge haben.



6.3 Neigen / Rotieren der Geräte

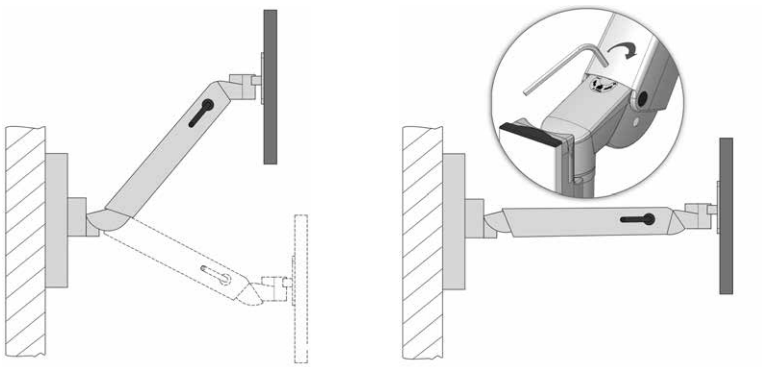
Bei neigbaren bzw. rotierbaren Systemkomponenten muss überprüft werden, ob die Klemmkraft auf das zu befestigende Gerät abgestimmt ist. Bei falscher Einstellung droht ein Abkippen des Gerätes. Daher muss diese so vorgenommen werden, dass zwar ein Neigen bzw. Rotieren des Gerätes leicht möglich ist, es jedoch in jeder gewünschten Position stabil bleibt.





6.4 Höhenverstellbare Tragarmsysteme (flexion-port)

Beim Beladen der höhenverstellbaren Systemkomponenten muss unbedingt auf das minimal bzw. maximal zulässige Gesamtgewicht geachtet werden. Bitte stellen Sie zudem sicher, dass der Platz unter dem höhenvariablen Tragarmsystem (flexion-port) aus Sicherheitsgründen frei bleibt. Um den Tragarm auf Last einstellen zu können, muss dieser in eine waagerechte Position gebracht werden.



6.5 Abbau und Umbau von Systemkomponenten und Zubehör

Sobald Systemkomponenten und Zubehör abgebaut oder in der Position verändert werden, muss vorher unbedingt das darauf aufgenommene Gerät entfernt werden. Handelt es sich hierbei um die (De-)Montage der höhenvariablen Tragarme flexion-port, müssen diese erst in die oberste Position gebracht und die Klemmung (Bremse) festgestellt werden (siehe Aufkleber).

6.6 Bestimmungsgemäße Verwendung beim Manövrieren der mobilen Geräteträger

Beim Manövrieren der mobilen Geräteträger ist unbedingt darauf zu achten, dass die angebrachten Tragarme (schwenkbar, höhenverstellbar) möglichst über dem Ablageboden zusammengefaltet und gegebenenfalls fixiert werden. Ansonsten kann die Standsicherheit (siehe Punkt 2.4) nicht garantiert werden.

6.7 Bedienung der höhenverstellbaren Tragarmsysteme (flexion-port) auf dem Monitorboden (2-fach)

Bei der Bedienung der höhenverstellbaren Tragarmsysteme (flexion-port) auf dem Monitorboden, 2-fach, ist stets darauf zu achten, dass der Schwenkarm, der für den Seitenwechsel verantwortlich ist, immer parallel zur Vorderseite des Wagens platziert ist (eingerastete Position). Bitte beachten Sie, dass dabei nur zwei Stellungen des Tragarms (rechts / links) als Arbeitsposition erlaubt sind (siehe unter "Arbeitsposition" im Kapitel "1.2 Allgemeine Symbolerklärung", Seite 9). Bei einem Seitenwechsel von der linken in die rechte Arbeitsposition oder umgekehrt müssen die Verriegelungselemente nach unten gedrückt und der höhenvariable Tragarm auf die andere Seite geschwenkt werden. Hierbei ist zu beachten, dass flexion-port mit Schwenkarm beim Seitenwechsel zusammengeklappt ist. Ansonsten kann die Standsicherheit (siehe Punkt 2.4) nicht garantiert werden.

7 Sonstiges

7.1 Reinigung und Desinfizierung

Achtung: Nehmen Sie das Gesamtsystem vom Netz bevor Sie eine Reinigung bzw. Desinfizierung vornehmen.

Die Gerätewagen uni-cart, vexio-cart, pro-cart, duo-cart, classic-cart, compact-cart oder endo-cart dürfen mit handelsüblichen Allzweckreinigern (Neutralreiniger) gereinigt werden.

Zur Desinfizierung können handelsübliche Desinfektionsmittel verwendet werden, die für Flächendesinfektion bzw. Wischdesinfektion zugelassen sind. Die Desinfektionsmittel sind nach den Vorgaben der Hersteller als reine Wischdesinfektion anzuwenden und einzusetzen.

Mit folgende Desinfektionsmittel wurden von ITD beispielhaft Tests durchgeführt:

Produkt	**Hersteller**
Bacillol plus	Bode
Cleanisept Wipes	Dr. Schumacher
Mikrobac Tissues	Bode
Mikrozid Sensitive Wipes	Schülke
Terralin Protect	Schülke
Incidin PLUS	Ecolab
Incidin Foam	Ecolab

Bei komplett notwendiger Desinfektion können Baugruppen durch einen Fachmann demontiert und im demontierten Zustand durch Wischen desinfiziert werden.

7.2 Instandsetzung / Service

Der Gerätewagen ist vor jeder Instandsetzungsmaßnahme, auch bei Rücksendung zu Reparaturzwecken, mit geeignetem Reinigungsmittel zu reinigen und desinfizieren!
Instandsetzungen am Gerätewagen dürfen nur durch Fachpersonal vorgenommen werden.
Für alle Serviceleistungen empfehlen wir, sich an die ITD GmbH zu wenden.

7.3 Umweltbedingungen

Die Gerätewagen uni-cart, vexio-cart, pro-cart, duo-cart, classic-cart, compact-cart oder endo-cart sind für den üblichen Krankenhaus- und Praxisbetrieb konzipiert worden.

Betrieb:

Umgebungstemperatur:	10° C bis 40° C
Luftfeuchtigkeit:	30 % bis 75 %
Luftdruck:	700 hPa bis 1060 hPa
Schutzart:	IP20

Transport / Lagerung:

Umgebungstemperatur:	-25° C bis 70° C
Luftfeuchtigkeit:	10 % bis 95 %
Luftdruck:	500 hPa bis 1200 hPa

7.4 Entsorgung

Getrennte Sammlung von Elektro- und Elektronikgeräten in Übereinstimmung mit der WEEE-Richtlinie (Reg.-Nr. DE35464575 für Deutschland).
Elektro- und Elektronikschrott, der nach dem 13. August 2005 in Verkehr gebracht wurde, ist mit dem dargestellten Symbol für getrennte Entsorgung von Elektro-und Elektronikschrott markiert. Dies besagt, dass der Schrott in Ländern, in denen die EU-Richtlinie 2002/96/EC gültig ist, einer getrennten Müllentsorgung zugeführt werden muss.

7.5 Ersatzteile

Es dürfen nur von der ITD GmbH zugelassene Ersatzteile verwendet werden!
Auf der Basis Ihres Gerätewagen befindet sich ein Aufkleber mit einer Auftragsnummer. Alle Auftragsnummern und die dazu gehörenden Einzelteile sind bei der ITD GmbH archiviert. Anhand dieser können Sie die benötigten Ersatzteile bei der ITD GmbH beziehen.

8 Zubehör

Ein umfangreiches Angebot an Zubehör finden Sie in unseren Katalogen oder unter www.itd-cart.com (Information für Händler).

9 Wartung

Die Gerätewagen uni-cart, vexio-cart, pro-cart, duo-cart, classic-cart, compact-cart oder endo-cart wurden für viele problemlose Nutzungsjahre entwickelt und gebaut. Überprüfen Sie alle 12 Monate die Funktionsfähigkeit der folgenden Teile, um die Sicherheit zu gewährleisten:

Monitor-Ablageboden:
- Das Drehen und Kippen funktioniert reibungslos, ohne zuviel Spiel.

Ablageböden:
- Prüfen Sie, ob die Befestigungsschrauben festgezogen sind und somit der Ablageboden stabil und gerade ist.

Rollen:
- Prüfen Sie, ob die Rollen frei laufen und ob alle Bremsen funktionieren.
- Prüfen Sie, dass die 4 Bolzen, die die Rollen an der Unterseite der Basis halten, sowie die Rollen selbst fest in ihren Halterungen sitzen.
- Bei leitfähigen Rollen müssen die Laufflächen frei von Verunreinigungen sein, damit ihre Funktion gewährleistet ist.

Steckdosenleisten:
- Prüfen Sie Hauptkabel auf Beschädigung und festen Sitz.

Hilfssteckdosen:
- Prüfen Sie Kabel auf Beschädigung und festen Sitz.

Höhenvariable Tragarme flexion-port:
- Die Höhenverstellung funktioniert leichtgängig, die Hubkraft ist auf das Gerätegewicht abgestimmt.

Tragarme:
- Das Drehen und Kippen funktioniert reibungslos, ohne zuviel Spiel.

Trenntransformator:
- Sicherheitstechnische Kontrolle von Trenntransformatoren.

Seriennummern:
- Vergleichen Sie die Seriennummer des Wagens mit den Daten des Gerätebuchs.

Sicherungen:
- Prüfen Sie, ob die korrekten Sicherungen eingebaut sind.

Sollten Sie bei dieser Überprüfung ein Problem entdecken, melden Sie sich bitte umgehend bei Ihrem Lieferanten.

10 Technische Daten

10.1 Tragfähigkeit uni-cart

- Basisgestell, gesamte Zuladung ab 50 kg / 110 lbs
- Ablageboden 10 kg / 22 lbs
- Rackboden 20 kg / 44 lbs
- Schubfach 3 kg / 6.6 lbs (absperrbar: 10 kg / 22 lbs)
- Monitorhalterung 14 kg / 30.8 lbs
- Mousepad 3 kg / 6.6 lbs

10.2 Tragfähigkeit vexio-cart

- Basisgestell, gesamte Zuladung 65 kg / 143 lbs
- Ablageboden 15 kg / 33 lbs
- Schubfach 3 kg / 6.6 lbs
- Monitorhalterung 14 kg / 30.8 lbs
- Mousepad 3 kg / 6.6 lbs

10.3 Tragfähigkeit pro-cart

- Basisgestell, gesamte Zuladung 80 kg / 176 lbs
- Ablageboden 20 kg / 44 lbs
- Schubfachblock 15 kg + 3 kg / 33 lbs + 6.6 lbs
- Monitorhalterung 14 kg / 30.8 lbs
- Mousepad 3 kg / 6.6 lbs

10.4 Tragfähigkeit duo-cart

- Basisgestell, gesamte Zuladung 80 kg / 176 lbs
- Ablageboden 50 kg / 110 lbs (ausziehbar: 20 kg / 44 lbs)
- Schubfach 3 kg / 6.6 lbs (absperrbar: 20 kg / 44 lbs)
- Mousepad 3 kg / 6.6 lbs

10.5 Tragfähigkeit compact-cart

- Basisgestell „Profi“, gesamte Zuladung 180 kg / 396 lbs
- Basisgestell „Economy“, gesamte Zuladung 150 kg / 330 lbs
- Ablageboden 50 kg / 110 lbs
- Schubfach 3 kg / 6.6 lbs
- Monitor-Ablageboden max. 35 kg / 77 lbs (je nach Typ)
- Mousepad 3 kg / 6.6 lbs

10.6 Tragfähigkeit classic-cart / endo-cart

- Basisgestell, gesamte Zuladung 150 kg / 330 lbs
- Ablageboden 50 kg / 110 lbs (ausziehbar: 20 kg / 44 lbs)
- Schubfach 3 kg / 6.6 lbs
- Monitor-Ablageboden max. 35 kg / 77 lbs (je nach Typ)
- Mousepad 3 kg / 6.6 lbs

10.7 Tragfähigkeit modul-port (Stationäre Trägersysteme)

• Trägerprofil, gesamte Zuladung je nach Länge	25-150 kg / 55-330 lbs
• Tragarm	bis 23 kg / 50.6 lbs
• Schwenkarm, 1-fach	bis 23 kg / 50.6 lbs
• Schwenkarm, 2-fach	bis 18 kg / 39.6 lbs
• Monitoraufnahme mit VESA 75/100 Adaption	bis 18 kg / 39.6 lbs
• Monitoraufnahme mit Universaladapter	bis 14 kg / 30.8 lbs
• Monitoraufnahme mit Table Top Mount Adapter	bis 14 kg / 30.8 lbs
• Ablageboden	10 kg / 22 lbs
• Schubfach	3 kg / 6.6 lbs
• Tastaturhalterung	5 kg / 11 lbs
• Mousepad	3 kg / 6.6 lbs

10.8 Tragfähigkeit flexion-port (Höhenverstellbare Tragarmsysteme)

• flexion-port (je nach Modell)	3-10 kg / 6.6-22 lbs 8-14 kg / 17.6-30.8 lbs 11-20 kg / 24.2-44 lbs
• Dreh- und Schwenkeinheit	bis 14 kg / 30.8 lbs
• Pfosten (“Down-Post”)	10 kg / 22 lbs
• Mousepad	3 kg / 6.6 lbs

Kontaktadressen:

Nordamerika	Europa
ITD Corporation	ITD GmbH - Geschäftsstelle Unterhaching
50 RADO DR UNIT A	Gruenwalder Weg 13a
Naugatuck, CT 06770-2211, USA	82008 Unterhaching, Germany
Tel: +1 203 714 67-00	Tel: +49 89 61 44 25 0
Email: sales.usa@itd-cart.com	Email: sales@itd-cart.com

China	Australien
ITD Medical Technology Products (Shanghai) Co., Ltd.	ITD Australia Pty Ltd Aviation Place 3
Section A, Room 101, 1st Floor	3043 Tullamarine, Victoria, Australia
11 South RiYing Road Pilot Free Trade Zoon	
Shanghai 200131, China	
Tel: +86 21 6442 5704	Tel: +61 3 9330 50 50
Email: s.pan@itd-cart.com	Email: s.oconnor@itd-cart.com

Für die Richtigkeit des Inhaltes zeichnet sich die ITD GmbH verantwortlich.

This is a Class I medical product in accordance with the European Medical Device Directive (MDD) 93/42/EEC, Appendix IX.
The manufacturer declares the conformity of this product with the basic requirements according to MDD 93/42/EEC, Appendix VII, and documents this with the CE designation.

Legal manufacturer :

ITD GmbH
Sportplatzstr. 3
84381 Johanniskirchen, Germany
Tel: + 49 89 61 44 25- 0
Fax: +49 89 61 44 25- 200
Email: sales@itd-cart.com

Sales and service:

North America

ITD Corporation
50 RADO DR UNIT A
Naugatuck, CT 06770-2211, USA
Tel: +1 203 714 67-00
Email: sales.usa@itd-cart.com

Europe

ITD GmbH - Office Unterhaching
Gruenwalder Weg 13a
82008 Unterhaching, Germany
Tel: +49 89 61 44 25 0
Email: sales@itd-cart.com

China

ITD Medical Technology Products (Shanghai) Co., Ltd.
Section A, Room 101, 1st Floor
11 South RiYing Road
Pilot Free Trade Zoon
Shanghai 200131, China
Tel: +86 21 6442 5704
Email: s.pan@itd-cart.com

Australia

ITD Australia Pty Ltd
Aviation Place 3
3043 Tullamarine, Victoria, Australia
Tel: +61 3 9330 50 50
Email: s.oconnor@itd-cart.com

We work constantly to further develop our products. Please understand that we must reserve the right to make changes to the delivery package in terms of form, equipment and technology at any time.

Reproduction, multiplication or translation, in part or in entirely, is not permitted without the written permission of ITD GmbH!

All rights according to copyright law are expressly reserved for ITD GmbH.

Version © 11/2018 Print date 12/2018

These instructions for usage are valid for the following products:

Part number	Description
CC.02xx.xxx / 03xx.xxx	System components and accessories compact-cart
CC.45xx.xxx / 50xx.xxx / 65xx.xxx	Equipment cart compact-cart, 30 U – 40 U
CC.45xx.xxx / 50xx.xxx / 65xx.xxx	System components and accessories compact-cart
DC.42xx.xxx / 53xx.xxx / 64xx.xxx	Equipment cart duo-cart, 21 U – 30 U
DC.40xx.xxx / 50xx.xxx / 60xx.xxx	System components and accessories duo-cart
EB.45xx.xxx / 50xx.xxx / 65xx.xxx	Equipment cart compact-cart Economy
EC.04xx.xxx	Equipment cart endo-cart, 30 U
GW.52xx.xxx / 53xx.xxx / 54xx.xxx	Equipment cart classic-cart, 21 U – 40 U
GW.62xx.xxx / 63xx.xxx / 64xx.xxx	
GW.01xx.xxx / 02xx.xxx / 03xx.xxx	System components and accessories classic-cart
GW.04xx.xxx / 05xx.xxx / 06xx.xxx	
GW.07xx.xxx / 08xx.xxx	
GW.40xx.xxx / 41xx.xxx / 45xx.xxx	
GW.50xx.xxx / 51xx.xxx / 55xx.xxx	
GW.60xx.xxx / 61xx.xxx / 65xx.xxx	
GW.80xx.xxx / 98xx.xxx / 99xx.xxx	
HA.1xxx.xxx / 2xxx.xxx	System components and accessories flexion-port
HA.45xx.xxx / 5xxx.xxx	
HA.60xx.xxx / 65xx.xxx	
NT.20xx.xxx / 40xx.xxx / 41xx.xxx	System components and accessories vexio-cart
NT.50xx.xxx	Equipment cart vexio-cart, 21 U – 50 U
PT.20xx.xxx / 40xx.xxx / 41xx.xxx	System components and accessories pro-cart
PT.50xx.xxx / PT.90xx.xxx	Equipment cart pro-cart, 21 U – 50 U
RS.41xx.xxx/ 48xx.xxx / 49xx.xxx	Equipment cart uni-cart, 21 U – 50 U
RS.00xx.xxx / 01xx.xxx / 02xx.xxx	System components and accessories uni-cart
RS.4xxx.xxx / 5xxx.xxx	
TS.03xx.xxx / 05xx.xxx	System components and accessories flexion-port

English

These instructions for usage are valid for the following products:

Part number	Description
VS.53xx.xxx / 54xx.xxx / 63xx.xxx	Video rack cart classic-cart, 30 U – 40 U
VS.63xx.xxx	
VT.43xx.xxx	Video cart with isolating transformer pro-cart, 30 U
VT.45xx.xxx	Video rack cart with isolating transformer compact-cart, 40 U
VT.54xx.xxx / 64xx.xxx	Video rack cart with isolating transformer classic-cart, 40 U
VW.54xx.xxx / 64xx.xxx	Video cart classic-cart, 40 U
ZV.94xx.xxx / 96xx.xxx / 97xx.xxx	System components and accessories universal
ZV.98xx.xxx / 99xx.xxx	

KD.7xxx.xxx / 8xxx.xxx / 9xxx.xxx	Customer-specific, mobile equipment carrier, series uni-cart, pro-cart, duo-cart, classic-cart, compact-cart and endo-cart
KU.0xxx.xxx – KU.9xxx.xxx	Customer-specific, mobile equipment carrier, series uni-cart, vexio-cart, pro-cart, duo-cart, classic-cart, compact-cart and endo-cart
OC.0xxx.xxx – OC.9xxx.xxx OC.1 – OC.999	
OM.0xxx.xxx – OM.9xxx.xxx	

Content

1 Important information

1.1 Correct usage 30
1.2 General explanation of the symbols 31
1.3 Safety instructions 33

2 Assembly

2.1 Completeness 34
2.2 Loading 34
2.3 Loading sequence 34
2.4 Risk through mechanical instability 35
2.5 Castors 35
2.6 Load capacity 35
2.7 Assembly / handling 35
2.8 Additional mounting of system components 36

3 Electrical safety

3.1 Positioning of the electrical equipment ... 36
3.2 Power columns (compact-cart, classic-cart, endo-cart) and vertical columns (uni-cart, vexio-cart and pro-cart) ... 36
3.3 Gases ... 37
3.4 Equipotential bonding (POAG) ... 37
3.5 Isolating transformer - leakage current ... 37
3.6 Earth-Leackage-Guard (ELG) ... 37
3.7 Cable connection ... 39
3.8 Combination of equipment ... 39
3.9 EMC ... 40
3.10 Excluded from the final electrical inspection of system components and accessories ... 40
3.11 Minimum safety ... 41

4 Transportation

4.1 Safe transportation on castors ... 41
4.2 Safe transprotation by carrying ... 41

5 Mechanical and electrical height adjustment ... 42

6 Support arms

6.1 Wiring ... 43
6.2 Horizontal swivel ... 43
6.3 Tilting / rotating equipment ... 43
6.4 Variable height support arms (flexion-port) ... 44
6.5 Dismantling and repositioning system components and accessories ... 44
6.6 Intended use when manoeuvring the mobile equipment carts ... 44
6.7 Operation of the height adjustable support arms (flexion-port) on the monitor shelf, 2-fold ... 45

7 Miscellaneous

7.1 Cleaning and disinfection ... 45
7.2 Service / Repair ... 46
7.3 Environmental conditions ... 46
7.4 Disposal ... 46
7.5 Spare parts ... 46

8 Accessories ... 46

9 Maintenance ... 47

10 Technical data

10.1 Load capacity uni-cart ... 48
10.2 Load capacity vexio-cart ... 48
10.3 Load capacity pro-cart ... 48
10.4 Load capacity duo-cart ... 48
10.5 Load capacity compact-cart ... 48
10.6 Load capacity classic-cart / endo-cart ... 48
10.7 Load capacity modul-port ... 49
10.8 Load capacity flexion-port ... 49

English

1 Important information

All products from ITD GmbH are manufactured for a long and trouble-free service life. Development, construction, sales and production are certified at ITD GmbH according to ISO 13485.

This is a basis for:

- highest quality and a long service life
- easy, safe and ergonomic operation
- functional design
- optimisation for the planned usage

The products satisfy the requirements of the European Medical Device Directive (EMDD) and bear the CE designation.

- Carefully read these instructions for usage from the beginning in order to become familiar with the functions step-by-step.
- Please be sure to address all questions or concerns to the manufacturer.
- The mobile equipment carriers are only intended for the use as described.
- These instructions are to be kept for the service life of the product.

The system configurator is to make the instructions for usage of the overall configuration available to the final customer.
We expressly note here that the system configurator is responsible for the observance of IEC 60601-1 and the EMC norm IEC 60601-1-2 in the valid version!

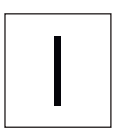
1.1 Correct usage

The functions of the mobile equipment carriers of ITD GmbH are:

- mounting medical and IEC-tested devices according to the permitted load information in compliance with the requirements of IEC 60601-1 in the currently valid edition.
- Connection and distribution of mains voltage from the local electricity outlet as well as from data lines.
- Consolidation of original ITD system components and accessories.

Using the mobile equipment carrier, the medical equipment can be transported inside the building or arbitrarily positioned in the area before and after the application. Therefore, a flexible, economical efficiency of all equipment is possible. In addition, it is easier to clean the floor area.

1.2 General explanation of the symbols



"ON" (voltage) lights up green

"OFF" (voltage)

"ON" lights up green/"OFF" (pressure actuated)

Equipotential bonding: Identifies equipotential bonding terminals on the housing of the isolating transformer; equipotential bonding ensures that resistance between all conductive materials is sufficiently low.

Connection to protective conductor:
Connects conductors, equipment units, conducting parts, main earth terminals and earth

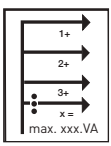
Conductive castors:
Conductive castors are indicated by a flash or a yellow point

Move only with arm folded up

Use the handle to push

Follow the instruction manual

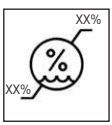
Alternating current



Total output:
Total power that can be supplied by the individual plug in locations must not exceed the total power.

Total load rating (basic frame)
max. total load rating (= total of all load ratings of mounted system components)
Please refer to the label for appropriate load.

Load rating (system components)
Please refer to the label for appropriate load.



Humidity limit

General warning sign:
This symbol is used at the socket strips. The overall rating given on the name plate must not be exceeded.

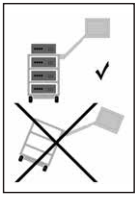
Only suitable for the interior

Heavy object:
It is recommended that two people lift the uni-cart, pro-cart, duo-cart, compact-cart, classic-cart or endo-cart to prevent injury.

Distributed by

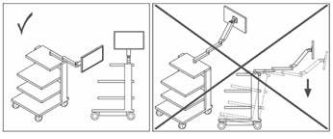
Adjustment of the clamping force (tilt and swivel unit)

Set load:
Describes the load range and also the direction of rotation for setting them.

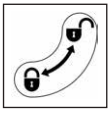


Risk of tilting:
It is imperative to observe the sequence of loading and unloading mobile equipment carts.

Brake:
Information about positioning of the support arm in the event of device acceptance and indicates the direction for release and blocking the locking function.



Operating position:
This symbol describes the permitted operating positions (right/left) and indicates a prevailing danger of tilting when changing over.



Locking function:
This describes the closing / opening direction for components.

Do not push:
It is forbidden to push the equipment cart above the handle because of a risk of tipping over.

1.3 Safety instructions

General:

- Only those mobile equipment carriers may be operated whose main voltage equipment has been tested and approved by appropriate, qualified personnel!
- Ensure the isolating transformer is only connected to a power supply with a functioning protective earth connection that complies with the provisions of the IEC 60364-7-710 2012-10 "Electrical installations in buildings, part 7-710: Requirements for special installations or locations – Medical locations". If in doubt, contact a specialist in the electrical trade or an authorised employee of the hospital's engineering team.
- Personnel (hospital and service personnel) working directly or indirectly with a mobile equipment carrier must be instructed!
- Setting adjustments may only be carried out by qualified personnel.
- Repairs may only be carried out by ITD GmbH.

Safe working with the equipment cart:

- The device is only disconnected from the mains supply when the power plug is removed from the socket.

Operation:

- With every change of location it must be ensured that no one is injured or objects damaged!

Connections:

- In the USA and Canada, use a hospital-grade connection cable when connecting isolating transformers in the 115 V mode and in Japan use the optional Japanese connection cable.
- When connecting to the multiple-socket strip, secure the plug using an optional available plug pull-out lock.
- Only devices that fulfil the requirements of IEC 60601-1 or are IEC-tested may be connected to the sockets/connecting lines.
- Additional medical equipment with connecting bolts for equipotential bonding are to be connected with the green-yellow cable to the optional equipotential bonding connecting bolts!

  - Caution: The overall rating given on the nameplate must not be exceeded. Please observe that no further multiple sockets must be connected to an existing multiple socket.

Load capacity:

- The total weight of the equipment and the accessories on the mobile equipment carrier may not exceed the permitted payload weight (see load capacity sticker on the base frame).
- The surface load imprinted on the system components may not be exceeded!
- The load shown on the fittings (e.g. infusion stand, jointed arms) may not be exceeded!

Infection protection:

- Hygiene regulations are to be observed when cleaning!
- Give only cleaned and disinfected equipment and fittings to a service technician for maintenance and repair work!

Environmental protection:

- Dispose of all cleaning and disinfection agent residue in a manner not harmful to the environment!

English

2 Assembly

2.1 Completeness

Unpack the uni-cart, vexio-cart, pro-cart, duo-cart, compact-cart, classic-cart or endo-cart carrier system and check wether all the parts you have ordered have been included in the consignment.

2.2 Loading

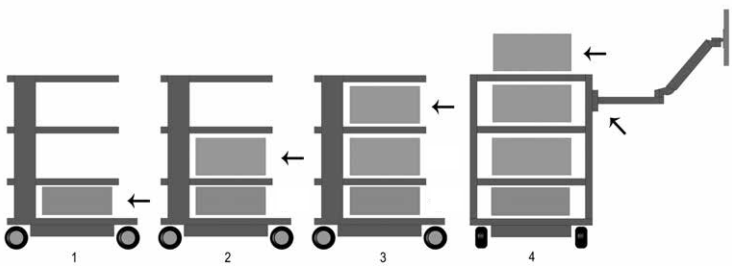
Place the uni-cart, vexio-cart, pro-cart, duo-cart, compact-cart, classic-cart or endo-cart carrier system on a level, horizontal surface. Place the appliances in the cart taking into consideration the loading sequences. Loading and assembly may only be effected if the cart is separated from current. We recommend the optional accessory (e. g. tension belt) to be applied for the safety of each appliance.
The maximum loading is specified in section 10. If the tilt stability is not adequate, the cart must be clearly labelled in conformity with the 5° labelling specification.

2.3 Loading sequence

Make sure that all the equipment placed on the uni-cart, pro-cart, duo-cart, compact-cart, classic-cart or endo-cart carrier system is stowed securely to prevent slipping, tipping, falling down, etc. by taking appropriate measures (especially also during transport). It is advisable to position all heavy components on the uni-cart, pro-cart, duo-cart, compact-cart, classic-cart or endo-cart carrier system using two people. You should take into account the fact that the centre of gravity changes with the loading.

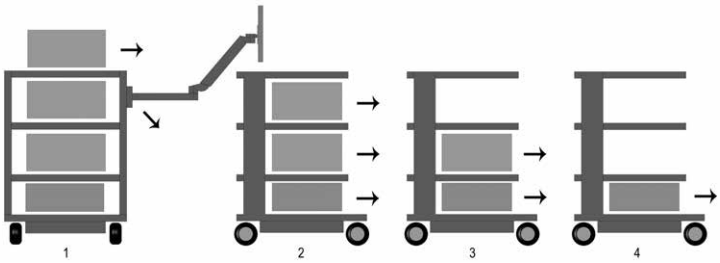
The cart should be loaded in the following sequence:

- shelves and drawers from the bottom to top
- support arm system (rigid, traversable, tiltable, height adjustable, single or multiple) should be burdened last.



The cart should be unloaded in the following sequence:

- support arm system (rigid, traversable, tiltable, height adjustable, single or multiple) should be relieved first.
- shelves and drawers should be unloaded from top to bottom.



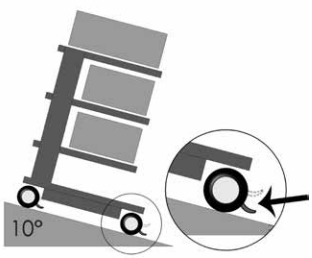
For transportation please refer to section 4 of this manual.

2.4 Risk of mechanical instability

The overall system must be in accordance with IEC 60601-1.

2.5 Castors

The uni-cart, vexio-cart, pro-cart, duo-cart, compact-cart, classic-cart or endo-cart carrier system has twin swivel castors with brakes. You should check to see that the wheel locks are working properly before using the uni-cart, vexio-ca pro-cart, duo-cart, compact-cart, classic-cart or endo-cart carrier system. When parking the cart or stopping during transport, all roller brakes on the equipment cart must be pressed (roller locking device). Accordingly, all roller brakes must be released before moving and transport.



The castor must be tested every 12 months for safety as well as the undamaged, full length of the castor attachment pin. If these should be lost, please contact your supplier immediatly.

2.6 Load capacity

It is not permitted to exceed the load rating of the uni-cart, vexio-cart, pro-cart, duo-cart, compact-cart, classic-cart or endo-cart carrier system.
You should observe the maximum load capacity of the uni-cart, vexio-cart, pro-cart, duo-cart, compact-cart, classic-cart or endo-cart carrier system (see section 10 of these operating instructions).

2.7 Assembly / Handling

2.7.1 Shelves

Shelves can be removed or installed in another position. Loosen the screws, re-position the shelf and then screw the shelf tightly in position again. Check the safety-earth resistance.

2.7.2 Drawers

Drawer unit blocks (pro-cart) are provided with a latch mechanism.

To release the lock on the pro-cart, the operating handle on the front cover must be pulled upwards.

The drawers can be lifted out in the extended position.
A label strip can be affixed to the front trim (except pro-cart).
Insert drawer during transport.

2.7.3 The isolating transformer

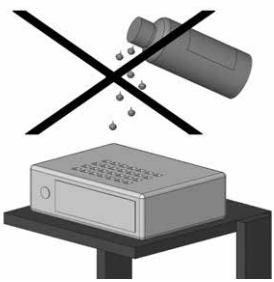
Follow the instruction manual for the isolating transformer. The isolating transformer is mounted in a housing under the base of the basic frame. This is assembled at the factory.

2.8 Additional mounting of system components

Retrospective installation of ITD system components must only be carried out by specialists in accordance with the specifications of the installation instructions supplied. The modified overall system must be rechecked in accordance with the IEC 60601-1.

3 Electrical safety

3.1 Positioning of the electrical equipment



Make sure that electrical equipment on the uni-cart, vexio-cart, pro-cart, duo-cart, compact-cart, classic-cart or endo-cart carrier system does not get wet.
Under no condition should you position the products, which may lead to loss of their fluidness, over the electrical equipment or extension lead in which fluidity may be permeate.

3.2 Energy column (compact-cart, classic-cart, endo-cart) and vertical column (uni-cart, vexio-cart, pro-cart)

The socket strips or the cabling system are located in the left or right power columns of classic-cart, compact-cart or endo-cart, with uni-cart and pro-cart it is in the vertical column. The vexio-cart´s socket strips and cabling system are located beneath the base (cabling can be routed through optional cable ducts, which are attached laterally to the vertical column).

Power columns are located on the left and right behind the vertical extrusion and permit optimum accommodation of the power equipment cables available. Do not drill holes in the power columns / vertical columns because power cables may be located inside the columns.

3.3 Gases

Electrical equipment should not be operated in the vicinity of gases, e.g. flammable gas used in anaesthesia or similar gases. The user is responsible for maintaining this requirement and for compliance with IEC 60601-1-2 standard.

3.4 Equipotential bonding (POAG)

Equipotential bonding should be carried out for the uni-cart, pro-cart, classic-cart, compact-cart or endo-cart carrier system with an isolating transformer. vexio-cart offers an optional POAG set without isolating transformer. The equipotential bonding cable should be first connected to the base of the uni-cart, vexio-cart, pro-cart, classic-cart, compact-cart or endo-cart carrier system and then be connected to the equipotential bonding plug in the room. Next, connect the POAG supply cables to the POAG pins of the multiple sockets and the appliance.

3.5 Isolating transformer – leakage current

The uni-cart, vexio-cart, pro-cart, duo-cart, compact-cart, classic-cart or endo-cart carrier system is intended to provide a practical and mobile workstation for medical electrical equipment. Total earth leakage currents must not exceed a maximum value of 0.5 mA so that the entire medical electrical system can be compliant with IEC 60601-1. If the sum of the ground leakage currents would exceed the tolerance range, the system must be supplied through a safety transformer.

If an isolating transformer is not mounted, the multiple socket strip / auxiliary socket strip system of the uni-cart, pro-cart, duo-cart, compact-cart, classic-cart or endo-cart carrier system must not be used to connect up equipment that is not in conformity with requirements for earth leakage currents under IEC 60601-1.

If an isolating transformer is mounted, the total power uptake of all the connected units must remain within the rated value for the isolating transformer.

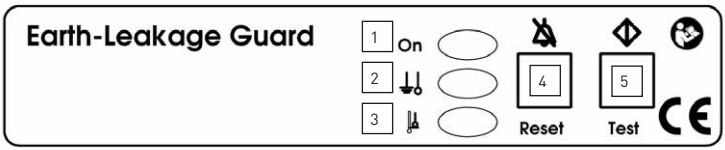
3.6 Earth-leakage-guard (ELG)

The following descriptions are only applicable for the carrier systems in which the item "isolating transformer with insulating monitor" is installed.

3.6.1 Control panel of the earth-leckage-guard (ELG)

At the devices with integrated-earth-leakage guard the evaluation unit is in the transformer case, the separate control panel is placed in one of the shelves. Both components are connected with an interface cord, which lays in one of the profiles.

Control panel of the earth-leakage-guard (optional):



1 Power on control (green)
2 Signals exceeding dielectric resistance (yellow)
3 Signals exceeding temperature (yellow)
4 Reset-button for fault release
5 Test-button starting self-test function manually

3.6.2 Application requirements

The earth-leakage-guard monitors the dielectric resistance for equipment (where safety isolation is necessary) which are connected to the isolation transformers. Simultaneously, the temperature of the transformer is evaluated by a built-in thermal switch which responds when triggered. The evaluation procedure is processor controlled.

3.6.3 Application requirements

Turn the main power switch of the isolating transformer to "ON". Within 5 s the self-test of the ELG is automatically activated. After the self-test of the ELG is concluded, the green LED (Power on control) glows permanently. During operation this test is repeated (automatically) in a time cycle of 8 hours. This self-test may also be activated manually through the test-button.

The control procedure for the manual self-test is as follows:

- An insulation error is simulated, the yellow LED (signals exceeding dielectric resistance) glows, a warn signal (2.4 kHz) is activated. Both signals stop after approx. 5 s.
- Following this, a temperature error is simulated. The yellow LED (signals exceeding temperature) glows, a warn signal (2.4 kHz pulse tone) is activated. Both signals stop after approx. 5 s.

An error situation is recognized as follows:

- In case of an insulation error, the yellow LED (signals exceeding dielectric resistance) glows permanently, the warn signal with 2.4 kHz is activated permanently. The warn signal can be deactivated through the reset-button for fault release. The LED glows until the error is eliminated.
- If the earth-leakage-guard is turned "OFF" in the meantime and the error is not eliminated, when turning the ELG back "ON" the above described procedure begins anew.
  With the occurrence of an isolation error the acoustic and optical alarm stays activated (even if the isolation error is corrected on its own) until deactivated through the fault release:

  First activation of the fault release: acoustic alarm is deactivated
  Second activation of the fault release: optical alarm is deactivated

- In case of a temperature error, the yellow LED (signals exceeding temperature) glows permanently and the warn signal with 2.4 kHz is activated intermittent. The warn signal can be deactivated through the reset-button for fault release. The LED glows until the error is eliminated. If the earth-leakage-guard is turned "OFF" in the meantime and the error is not eliminated, when turning the earth-leakage guard back ON the above described procedure begins anew.
- Should an insulation error and a temperature error occur simultaneously, the dielectric resistance fault has priority (acoustic).

Self test for the Earth-Leakage Guard
In addition to the manual self-test, during operation the earth-leakage-guard repeats the self-test in a time cycle of 8 hours and each time the unit is turned "ON".
From outside, you will not notice the self-test, the time period for this process is approx. 5 seconds. In case of fault, the green LED (power on control) blinks in a frequency of 0.5 Hz and with the same frequency an acoustic alarm is activated. The fault signal can not be deactivated through the reset-button.

3.6.4 Trouble shooting

Do not attempt to repair on your own. Warranty will be invalid if unauthorized repair has been carried out. Due to safety reasons repair and maintenance may only be done by the manufacturer.

Please note:
For further technical data and information, please refer to the separate and comprehensive instructions for use, enclosed with the product, isolating transformer and insulating monitor.

3.7 Cable connection

Users of the uni-cart, vexio-cart, pro-cart, duo-cart, compact-cart, classic-cart or endo-cart carrier system without an isolating transformer must ensure that the detachment of the cable plug connection between the cart's multiple power outlet strip and devices can only occur using tools. Our line of accessories includes a selection of covers for multiple power outlet strips.

3.8 Combination of equipment

The following should be observed for combination of equipment on the carrier system:

- Auxiliary equipment connected to analogue and digital interfaces of the equipment must be certified in compliance with the relevant EN specifications (e. g. IEC 60950 for data-processing equipment and IEC 60601-1 for medical electrical equipment).
- Furthermore, all configurations must comply with the valid version of the standard IEC 60601-1. Anyone connecting additional equipment to the signal input or signal output is a system configurer and is therefore responsible for ensuring compliance with the valid version of the standard IEC 60601-1.

If you have any questions, you should contact your local dealer or technical services.

Please note:
Make sure that this is also the case for adaptation of equipment in the power supply circuit (e. g. multiple socket strip).

3.9 EMC

Electromagnetic compatibility of the medical electrical equipment positioned on the cart has to be checked by the overall system configurer. If you use a different equipment combination, you should check electromagnetic compatibility between individual items of equipment before using in a medical setting.

Customer-specific equipment trollies used within the nuclear spin environment must be tested by the customer for suitability for use due to the ferromagnetic materials they contain.

ITD GmbH excludes any liability in this respect.

Using the carrier system with an isolating transformer within an environment subject to explosive hazard is not permissible.

3.10 Excluded from the final electrical inspection of system components and accessories

ITD GmbH exclude the following system components and accessories from the final electrical inspection:

- Multiple socket strips without additional protective conductors that are not wired in the mounting
- ME cables and appliance cables included
- POAG plates and cables included

- Non-electrified equipment carts and support systems
- Height adjustments and attachment parts to height adjustments
- Handles, mouse pads, drawers, drawer bodies and attachments (bottle mounting brackets, baskets, camera mounting brackets, infusion tripods, ...)
- Isolation transformers, which are not mounted but instead leave the ITD as a single part.
- Keyboard extensions and extendable shelves
- Computer mounts at the top and bottom
- Conductive castors
- Support arms installed and monitor mounting brackets
- Secondary power circuit with insulation monitors are only excluded from the dielectric strength inspection!

3.11 Minimum safety

ITD GmbH is not aware of any item of equipment or accessory that reduces the minimum safety of the system. Only equipment not presenting a hazard may be used.
If necessary, this should be clarified by means of a risk analysis (ISO 14971).

4 Transportation

4.1 Safe transportation on castors

Please ensure that before the mobile use of the equipment cart:

- All equipment / products in transit are secured against detachment.
- All swivel arms must be swivelled in and secured.
- The feeder from the local outlet must be disconnected.
- The brakes of the castors are released.

The equipment cart should only be moved at a maximum walking pace of 6 km/h. The velocity is significantly reduced when knocked down by bedplates, cables as well as hoses. It is safer to deliver by driving on ramps having a max. gradient of 10° so that the equipment cart can be brought to a standstill at any time.

Although all precautionary measures have been observed to guarantee maximum stability for this product, it is important to pay attention to unevenness in floors, lift door frames, cables, etc. in order to prevent accidents.

Fundamentally, the requirements of the IEC 60601-1 apply.

4.2 Safe transportation by carrying

Handles are not provided for lifting the mobile equipment carts, but exclusively have a function for pushing. Lifting and carrying the mobile device carrier must only be carried out by two persons using the extensions of the base.

Fundamentally, the requirements of the IEC 60601-1 apply.

5 Mechanical and electrical height adjustement

Specific safety regulations must be observed for the „mechanical height adjustment“ using the „gas pressure“, as well as for the electro-mechanical height adjustment using „Linear drive“, in accordance with IEC 60601-1 „Mechanical Risk in Conjunction with Moving Parts“. Hereby:

- Take into consideration and adhere to the permitted distance between moving parts, in accordance with IEC 60601-1 in Table 20 (ISO 13857:2008).
- Products with height adjustment are manufactured and supplied ex works conforming to the standard, under consideration of the permitted safety distances. Due to the equipping of or replacement with ME devices and / or component, these distances change. This can result in a mechanical risk. The respective person who configures the system is responsible for adhering to the minimum distances required.
- The overall weight of the devices and accessories installed must not exceed the specified maximum overall payload of the height adjustment. Overloading results in damage to the height adjustment and loss of the warranty.

- Stored energy is released with the mechanical height adjustment using gas pressure. Thereby, for unloaded systems sudden, unbraked activation of the height adjustment can result in injuries and damage.
  - o In order to prevent injuries and damage, before installation and removal of the devices, place the height adjustment at the uppermost position („energy-free“).
  - o The height adjustable supporting arm system „flexion-port“ must also be fixed and secured at the uppermost position („energy-free“) with the aid of the clamping lever (refer to the separate user instructions for the „flexion-port“, as well as the risk notes on the supporting arm system).

- Unintended activation of the electro-mechanical height adjustment using the manual button can also result in injuries and damage.
  - o In order to prevent injuries and damage, before installation and removal of the devices, disconnect the height adjustment from the power supply.
  - o Servicing and maintenance tasks in the „interior area“ of the height adjustment, i.e. in the covered area within the supporting column not accessible from outside, must only be carried out by specialists.
  - o Caution: If operating the height adjustment using a remote control, make sure that no persons are in the hazard area.

6 Support arms

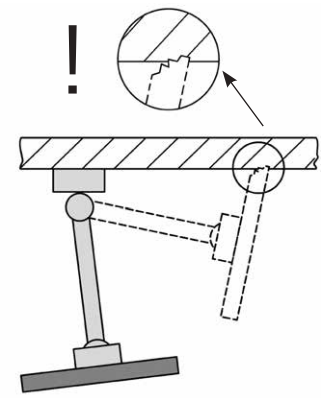
6.1 Wiring

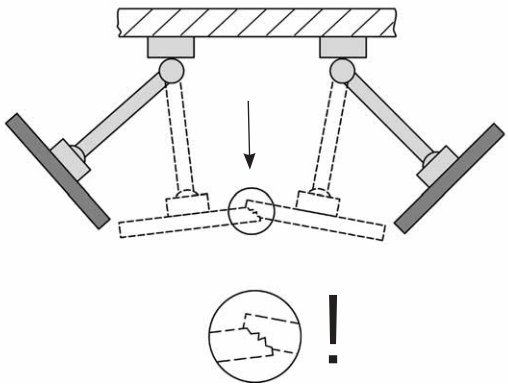
Please observe the following instructions:

- So that there is no damage to the cable or failure of the device when swivelling, the cable must be sufficiently dimensioned.
- Possible sagging cables must under no circumstances be used as a handle.
- Please make sure that the enclosed assembly material is correctly applied, in accordance with the assembly instructions.
- When swivelling the arms, pay attention to possible cable loops present.

6.2 Horizontal swivel

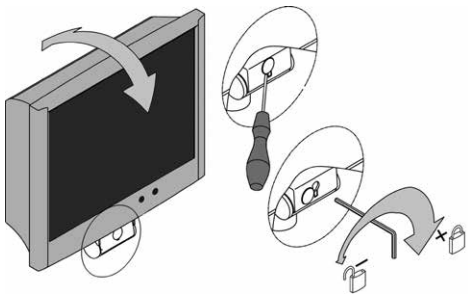
Make sure that the swivel range of the system components matches the dimensions of the equipment and the ambient conditions in the working environment.
When system components and attached equipment are swivelled horizontally, they must not collide with other equipment, with other system components or with the wall. Any collision may result in damage to equipment and injuries to persons.

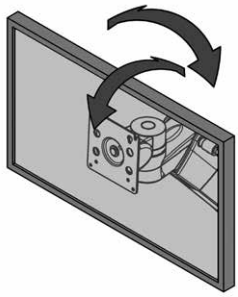




6.3 Tilting / rotating equipment

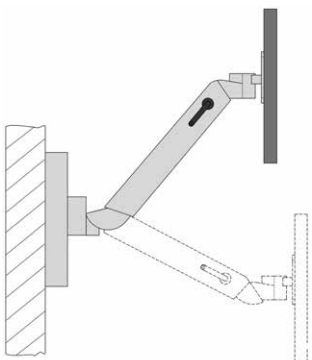
If system components are tiltable or rotatable, it is important to ascertain whether the clamping force is appropriate for the unit being fixed in place. If the force applied is incorrectly adjusted, the equipment is at risk of tilting over. Adjustment must therefore be carried out to ensure that the unit can be slightly tilted or rotated, while the unit remains stable in any desired position.

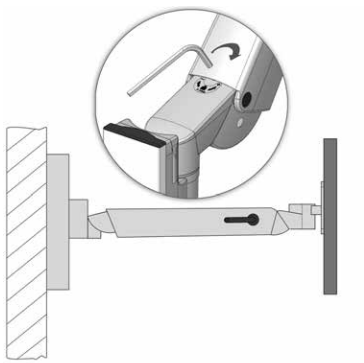




6.4 Variable height support arms (flexion-port)

When loading the system components that can be height adjusted, unconditionally observe the minimum and maximum permitted total weight. Also, due to safety reasons, please make sure that the space below the height-adjustable support arm (flexion-port) remains clear. In order to be able to set the support arm to the load, it must be placed into the horizontal position.





6.5 Dismantling and repositioning system components and accessories

When system components and accessories are dismantled or repositioned, it is important to remove any units mounted on these elements before any changes are made. If this concerns the disassembly / assembly of the height-adjustable support arms flexion-port, these must first be placed in the uppermost position and the clamping (brake) must be determined (refer to decal).

6.6 Intended use when manoeuvring the mobile equipment carts

When manoeuvring the mobile equipment carts it is imperative to make sure that the support arms attached (swivelling, height adjustable) are placed into the respective park position and, as necessary, locked. Otherwise, the stability cannot be guaranteed (refer to Point 2.4).

6.7 Operation of the height adjustable, support arm system (flexion-port) on the monitor shelf, 2-fold

When operating the height adjustable support arm system (flexion-port) on the monitor shelf, 2-fold, always make sure that the swivelling arm that provides the changeover, is always placed parallel to the front side of the cart (engaged position). Thereby, please observe that only two operating positions of the support arm (right / left) are permitted (refer to „Operating position“ in Chapter „1.2 General symbol explanation“, Page 31).

By a changeover of the operating position from left to right, or vice versa, the locking elements must be pushed downwards and the height adjustable support arm swivelled to the other side. Hereby, for flexion-port with swivelling arm make sure that it is folded when changing over. Otherwise, the tilting stability cannot be guaranteed (refer to Point 2.4).

7 Miscellaneous

7.1 Cleaning and disinfection

Caution: Disconnect from power before cleaning and disinfection!

The equipment cart uni-cart, vexio-cart, pro-cart, duo-cart, compact-cart, classic-cart or endo-cart must be cleaned using commercial all-purpose cleaning agents (neutral cleaning agents).

For disinfecting, commercial disinfectants approved for disinfecting surfaces or wipe disinfection can be used. The disinfection agents must be used solely as disinfection for wiping, in accordance with the manufacturer's specification.

For example, ITD have carried out tests using the following disinfectants:

Product	**Manufacturer**
Bacillol plus	Bode
Cleanisept Wipes	Dr. Schumacher
Mikrobac Tissues	Bode
Mikrozid Sensitive Wipes	Schülke
Terralin Protect	Schülke
Incidin PLUS	Ecolab
Incidin Foam	Ecolab

If complete disinfection is required, assemblies can be disassembled by a specialist and wipe disinfected when disassembled.

7.2 Service / Repair

The cart should be always be cleaned and disinfected with a suitable cleaning agent before any service operations are undertaken, and before the cart is returned for purposes of repair. Repairs to the cart should only be effected by professional personnel. We recommend consulting ITD GmbH on all matters relating to service activities.

7.3 Environmental conditions

The uni-cart, vexio-cart, pro-cart, duo-cart, compact-cart, classic-cart or endo-cart carrier systems are designed for standard operation in hospitals and medical practices.

Operation:

Ambient temperature:	10° C to 40° C
Air humidity:	30 % to 75 %
Air pressure:	700 hPa to 1060 hPa
Protection class:	IP20

Transport/storage:

Ambient temperature:	-25°C to 70°C
Air humidity:	10% to 95%
Air pressure:	500 hPa to 1200 hPa

7.4 Disposal

Separate Collection for Electrical and Electronic Equipment in compliance with Waste Electrical and Electronic Equipment Directive WEEE (registration number for Germany: DE35464575). All electrical and electronic equipment provided with systems released after 13 August 2005 is marked with a Separate Collection for Electrical and Electronic Equipment symbol, indicating that this equipment must undergo separate collection for disposal, in countries where EU directive 2002/96/EC is in effect.

7.5 Spare parts

Only spare parts authorized by ITD may be used. A sticker with an order number is attached to the base of your cart. All order numbers and the associated spare parts are archived at ITD GmbH. Spare parts may be obtained from ITD GmbH.

8 Accessories

A comprehensive range of accessories is provided in our catalogues or under www.itd-cart.com (information for dealers).

9 Maintenance

The uni-cart, vexio-cart, pro-cart, duo-cart, compact-cart, classic-cart or endo-cart has been developed and constructed for many years of trouble-free use.
Check the functional capability of the following parts every 12 months in order to guarantee safety.

Monitor shelf:
- Swivels and tilts easily without too much play.

Shelves:
- Check whether the mounting screws have been tightened and whether the shelf is stable and flat.

Castors:
- Check that the castors run freely and the brakes operate correctly.
- Check that the 4 bolts holding the castors to the bottom side of the base and the castors themselves are seated firmly in their holders.
- The running surfaces of castors must be free from contamination, so that they can function correctly.

Socket strips:
- Check the main cable for damage and firm seating.

Auxiliary sockets:
- Check the cable for damage and firm seating.

Variable height support arms (flexion-port):
- The height adjustment functions freely, the raising force is adjusted to the weight of the device.

Support arms:
- Rotating and tilting functions smoothly, without excess play.

Isolating transformers:
- Safety-relevant checks of isolating transformers.

Serial number:
- Compare the serial number of the cart with the data of the equipment log book.

Fuses:
- Check whether the correct fuses have been installed.

If you encounter any problems during these checks you should contact your supplier immediately.

English

10 Technical data

10.1 Load capacity uni-cart

• Basic frame, total payload	from 50 kg / 110 lbs	
• Shelf	10 kg / 22 lbs	
• Rack shelf	20 kg / 44 lbs	
• Drawer	3 kg / 6.6 lbs	(lockable: 10 kg / 22 lbs)
• Monitor holder	14 kg / 30.8 lbs	
• Mouse pad	3 kg / 6.6 lbs	

10.2 Load capacity vexio-cart

• Basic frame, total payload	65 kg / 143 lbs
• Shelf	15 kg / 33 lbs
• Drawer unit	3 kg / 6.6 lbs
• Monitor holder	14 kg / 30.8 lbs
• Mouse pad	3 kg / 6.6 lbs

10.3 Load capacity pro-cart

• Basic frame, total payload	80 kg / 176 lbs
• Shelf	20 kg / 44 lbs
• Drawer unit	15 kg + 3 kg / 33 lbs + 6.6 lbs
• Monitor holder	14 kg / 30.8 lbs
• Mouse pad	3 kg / 6.6 lbs

10.4 Load capacity duo-cart

• Basic frame, total payload	80 kg / 176 lbs	
• Shelf	50 kg / 110 lbs	(pull-out: 20 kg / 44 lbs)
• Drawer unit	3 kg / 6.6 lbs	(lockable: 20 kg / 44 lbs)
• Mouse pad	3 kg / 6.6 lbs	

10.5 Load capacity compact-cart

• Basic frame „Profi“, total payload	180 kg / 396 lbs	
• Basic frame „Economy“, total payload	150 kg / 330 lbs	
• Shelf	50 kg / 110 lbs	
• Drawer unit	3 kg / 6.6 lbs	
• Monitor shelf	max. 35 kg / 77 lbs	(depends on type)
• Mouse pad	3 kg / 6.6 lbs	

10.6 Load capacity classic-cart / endo-cart

• Basic frame, total payload	150 kg / 330 lbs	
• Shelf	50 kg / 110 lbs	(pull-out: 20 kg / 44 lbs)
• Drawer unit	3 kg / 6.6 lbs	
• Monitor shelf	max. 35 kg / 77 lbs	(depends on type)
• Mouse pad	3 kg / 6.6 lbs	

10.7 Load capacity modul-port (stationary carrier systems)

- Support profile, total added load depends on length — 25-150 kg / 55-330 lbs
- Support arm — up to 23 kg / 50.6 lbs
- Swivel arm, 1-fold — up to 23 kg / 50.6 lbs
- Swivel arm, 2-fold — up to 18 kg / 39.6 lbs
- Monitor mount with VESA 75/100 adapter — up to 18 kg / 39.6 lbs
- Monitor mount with universal adapter — up to 14 kg / 30.8 lbs
- Monitor mount with Table Top Mount Adapter — up to 14 kg / 30.8 lbs
- Shelf — 10 kg / 22 lbs
- Drawer unit — 3 kg / 6.6 lbs
- Keyboard holder — 5 kg / 11 lbs
- Mouse pad — 3 kg / 6.6 lbs

10.8 Load capacity flexion-port (variable height support arms)

- flexion-port (depends on modell) — 3-10 kg / 6.6-22 lbs or 8-14 kg / 17.6-30.8 lbs 11-20 kg / 22.4-44 lbs
- Tilt and swivel unit — bis 14 kg / up to 30.8 lbs
- Post ("Down-Post") — 10 kg / 22 lbs
- Mouse pad — 3 kg / 6.6 lbs

Contacts for queries:

North America	Europe
ITD Corporation	ITD GmbH - Geschäftsstelle Unterhaching
50 RADO DR UNIT A	Gruenwalder Weg 13a
Naugatuck, CT 06770-2211, USA	82008 Unterhaching, Germany
Tel: +1 203 714 67-00	Tel: +49 89 61 44 25 0
Email: sales.usa@itd-cart.com	Email: sales@itd-cart.com

China	Australia
ITD Medical Technology Products (Shanghai) Co., Ltd.	ITD Australia Pty Ltd Aviation Place 3
Section A, Room 101, 1st Floor	3043 Tullamarine, Victoria, Australia
11 South RiYing Road Pilot Free Trade Zoon	
Shanghai 200131, China	
Tel: +86 21 6442 5704	Tel: +61 3 9330 50 50
Email: s.pan@itd-cart.com	Email: s.oconnor@itd-cart.com

Responsible for content: ITD GmbH.

Il s'agit ici d'un dispositif médical de la classe 1 au sens de la directive européenne 93/42/CEE relative aux dispositifs médicaux (DDM), Annexe IX.
Le fabricant déclare que ce dispositif est conforme aux exigences fondamentales visées à la DDM 93/42/CEE, Annexe VII, ce qu'il documente par le marquage CE.

Fabricant:

ITD GmbH
Sportplatzstr. 3
84381 Johanniskirchen, Allemagne
Tel: + 49 89 61 44 25- 0
Fax: +49 89 61 44 25- 200
Email: sales@itd-cart.com

Distribution et Service:

Amérique du Nord	Europe
ITD Corporation 50 RADO DR UNIT A Naugatuck, CT 06770-2211, USA Tel: +1 203 714 67-00 Email: sales.usa@itd-cart.com	ITD GmbH - Agence d'Unterhaching Gruenwalder Weg 13a 82008 Unterhaching, Allemagne Tel: +49 89 61 44 25 0 Email: sales@itd-cart.com
Chine	**Australie**
ITD Medical Technology Products (Shanghai) Co., Ltd. Section A, Room 101, 1st Floor 11 South RiYing Road Pilot Free Trade Zoon Shanghai 200131, China Tel: +86 21 6442 5704 Email: s.pan@itd-cart.com	ITD Australia Pty Ltd Aviation Place 3 3043 Tullamarine, Victoria, Australia Tel: +61 3 9330 50 50 Email: s.oconnor@itd-cart.com

Nous travaillons en permanence au perfectionnement de nos produits.Veuillez faire preuve de compréhension pour le fait que nous devons nous réserver à tout moment le droit de procéder à des modifications de l'ampleur de la livraison sur le plan de la forme, de l'équipement et de la technique. Toute reproduction, duplication ou traduction, même sous forme d'extrait, est interdite sans autorisation écrite d'ITD GmbH !

Tous les droits aux termes de la loi sur le droit d'auteur sont réservés expressément à ITD GmbH.
Version © 11/2018 Date d'impression 12/2018

Le présent mode d´emploi est valide pour les produits suivants :

Désignation de type	Description
CC.02xx.xxx / 03xx.xxx	Composants de système et accessoires compact-cart
CC.45xx.xxx / 50xx.xxx / 65xx.xxx	Chariots à appareils compact-cart, 30 U – 40 U
CC.45xx.xxx / 50xx.xxx / 65xx.xxx	Composants de système et accessoires compact-cart
DC.42xx.xxx / 53xx.xxx / 64xx.xxx	Chariots à appareils duo-cart, 21 U – 30 U
DC.40xx.xxx / 50xx.xxx / 60xx.xxx	Composants de système et accessoires duo-cart
EB.45xx.xxx / 50xx.xxx / 65xx.xxx	Chariots à appareils compact-cart Economy
EC.04xx.xxx	Chariots à appareils endo-cart, 30 U
GW.52xx.xxx / 53xx.xxx / 54xx.xxx	Chariots à appareils classic-cart, 21 U – 40 U
GW.62xx.xxx / 63xx.xxx / 64xx.xxx	
GW.01xx.xxx / 02xx.xxx / 03xx.xxx	Composants de système et accessoires classic-cart
GW.04xx.xxx / 05xx.xxx / 06xx.xxx	
GW.07xx.xxx / 08xx.xx	
GW.40xx.xxx / 41xx.xxx / 45xx.xxx	
GW.50xx.xxx / 51xx.xxx / 55xx.xxx	
GW.60xx.xxx / 61xx.xxx / 65xx.xxx	
GW.80xx.xxx / 98xx.xxx / 99xx.xxx	
HA.1xxx.xxx / 2xxx.xxx	Composants de système et accessoires flexion-port
HA.45xx.xxx / 5xxx.xxx	
HA.60xx.xxx / 65xx.xxx	
NT.20xx.xxx / 40xx.xxx / 41xx.xxx	Composants de système et accessoires vexio-cart
NT.50xx.xxx	Chariots à appareils vexio-cart, 21 U – 50 U
PT.20xx.xxx / 40xx.xxx / 41xx.xxx	Composants de système et accessoires pro-cart
PT.50xx.xxx / PT.90xx.xxx	Chariots à appareils pro-cart, 21 U – 50 U
RS.41xx.xxx/ 48xx.xxx / 49xx.xxx	Chariots à appareils uni-cart, 21 U – 50 U
RS.00xx.xxx / 01xx.xxx / 02xx.xxx	Composants de système et accessoires uni-cart
RS.4xxx.xxx / 5xxx.xxx	
TS.03xx.xxx / 05xx.xxx	Composants de système et accessoires flexion-port

Le présent mode d'emploi est valide pour les produits suivants :

Désignation de type	Description
VS.53xx.xxx / 54xx.xxx / 63xx.xxx	Chariot-armoire vidéo classic-cart, 30 E – 40 U
VS.63xx.xxx	
VT.43xx.xxx	Chariot-armoire vidéo avec trans. de séparation pro-cart, 30 U
VT.45xx.xxx	Chariot-armoire vidéo avec trans. de séparation compact-cart, 40 U
VT.54xx.xxx / 64xx.xxx	Chariot-armoire vidéo avec trans. de séparation classic-cart, 40 U
VW.54xx.xxx / 64xx.xxx	Chariot de vidéo classic-cart, 40 U
ZV.94xx.xxx / 96xx.xxx / 97xx.xxx	Composants de système et accessoires généraux
ZV.98xx.xxx / 99xx.xxx	
KD.7xxx.xxx / 8xxx.xxx / 9xxx.xxx	Chariot d'équipement mobile de la gamme uni-cart, pro-cart, duo-cart, classic-cart, compact-cart et endo-cart
KU.0xxx.xxx – KU.9xxx.xxx	Chariot d'équipement mobile de la gamme uni-cart, vexio-cart, pro-cart, duo-cart, classic-cart, compact-cart et endo-cart
OC.0xxx.xxx – OC.9xxx.xxx OC.1 – OC.999	
OM.0xxx.xxx – OM.9xxx.xxx	

Français

Sommaire

1 Informations importantes

1.1 Utilisation conforme à la destination 54
1.2 Explication des symboles 55
1.3 Consignes de sécurité 57

2 Montage

2.1 Intégralité 58
2.2 Chargement 58
2.3 Chronologie de chargement 58
2.4 Risques dus à l'instabilité mécanique 59
2.5 Roulettes 59
2.6 Sollicitations 59
2.7 Montage / commande 59
2.8 Addition suplémentaire des élements du systéme 60

3 Sécurité électrique

3.1 Emplacement des appareils électriques ... 60
3.2 Colonnes énergétiques (classic-cart, compact-cart, endo-cart) et colonnes verticales (uni-cart, vexio-cart et pro-cart) ... 60
3.3 Gaz ... 61
3.4 Compensation de potentiel (POAG) ... 61
3.5 Transformateur de séparation - courant de décharge ... 61
3.6 Contrôleur d´isolement ... 61
3.7 Fiche de raccordement pour les câbles ... 63
3.8 Combinaison d'appareils ... 63
3.9 CEM ... 64
3.10 Composants système et accessoires exclus du contrôle électrique en sortie ... 64
3.11 Sécurité minimum ... 65

4 Transport

4.1 Transport en sécurité sur roulettes ... 65
4.2 Transport en sécurité en le portant ... 65

5 Système de réglage mécanique et électrique de la hauteur ... 65

6 Accolades

6.1 Treillage métallique ... 67
6.2 Rotation horizontale ... 67
6.3 Inclinaison / rotation équipement ... 67
6.4 Réglable de montage des systèmes de bras (flexion-port) ... 68
6.5 Démantèlement et la reconstruction du système de composants et accessoires ... 68
6.6 But d'utilisation lorsque le transporteur mobile de manoeuvre ... 68
6.7 Utiliser les systèmes de bras de montage réglable en hauteur (flexion-port) au bas de l'écran (2) ... 69

7 Divers

7.1 Nettoyage et Désinfection ... 70
7.2 Réparation / Service ... 70
7.3 Conditions d'environnement ... 70
7.4 Mise au rebut ... 70
7.5 Pièces de rechange ... 70

8 Accessoires ... 70

9 Maintenance ... 71

10 Données techniques

10.1 Force portante uni-cart ... 72
10.2 Force portante vexio-cart ... 72
10.3 Force portante pro-cart ... 72
10.4 Force portante duo-cart ... 72
10.5 Force portante compact-cart ... 72
10.6 Force portante classic-cart / endo-cart ... 72
10.7 Force portante modul-port ... 72
10.8 Force portante flexion-port ... 73

Français

1 Informations importantes

Tous les produits fabriqués chez ITD GmbH sont conçus pour une grande durée de service sans pannes. Le développement, la construction, la vente et la production sont certifiés selon la norme ISO 13485.

Pour vous, c'est un gage :

- une qualité supérieure et une longe longue vie utile
- un functionnement simple, sûr et ergonomique
- un design fonctionnel
- une optimisation de l´usage prévu

Les produits satisfont aux exigences de la directive européenne applicable aux dispositifs médicaux (EMDD) et portent le marquage CE.

- Lisez minutieusement le présent mode d'emploi dans son intégralité afin de vous familiariser avec les fonctions.
- En cas de demande de renseignement ou de doutes, adressez-vous impérativement au fabricant.
- Les supports d'appareils mobiles sont destinés uniquement à l'utilisation conventionnelle décrite.
- La présente instruction doit être conservée pendant toute la durée de service du produit.

Le configurateur de système est tenu de mettre à la disposition du client final le mode d'emploi pour la configuration complète.
Nous attirons expressément votre attention sur le fait que le configurateur de système est responsable du respect des exigences visées dans les normes IEC 60601-1 et dans la norme de CEM IEC 60601-1-2 dans la version respectivement en vigueur!

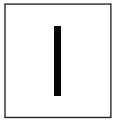
1.1 Utilisation conforme à la destination

Les portes-appareils mobiles de ITD servent aux butes suivants :

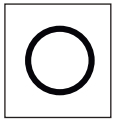
- l'installation d'appareils médicaux et d'appareils CEI testés conformément aux spécifications de charge admissibles en respectant les exigences de la norme CEI 60601-1 dans sa version en vigueur.
- au raccordement et à la distribution des tensions d'alimentation provenant de la prise de courant proche, ainsi que des lignes de donnés
- pour la fixation des élements du systéme de ITD et du accessoires

À l'aide des porte-appareils mobiles vous pouvez faire movements de votre choix avec les appareils médicaux avant et aprés d'application ou les placer de votre choix dans la piéce.
De telle façon vous pouvez utiliser tous vos appareils élastiquement et rationellement. En plus, le nettoyage des planchers devient plus facile.

1.2 Explication des symboles



«MARCHE» s'allume en vert (tension)



«ARRÊT» (tension)

«MARCHE s'allume en vert ARRÊT» (à commande hydraulique)

Compensation de potentiel : marque, notamment, les tétons de compensation de potentiel sur le carter du transformateur de séparation et la compensation de potentiel et garantit que la résistance entre tous les matériaux conductibles soit suffisamment petite.

Raccordement de conducteur de protection :
Conducteur qui relie les corps de moyens d'exploitation, de pièces conductibles, de bornes de mise à la terre principale et la terre.

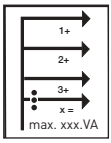
Roulettes conductrices :
Les roulettes conductrices sont marquées par un éclair ou un point jaune.

Déplacez uniquement avec le bras replié

Utilisez la poignée pour pousser

Respectez le mode d'emploi

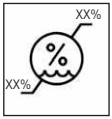
Courant alternatif



Puissance totale :
La somme des puissances obtenues à chaque poste d'enfichage individuel ne peut excéder la puissance totale.

Indications de sollicitation totale (châssis) :
Max. charge totale (= indications de sollicitation de tous les composants du système installés). Veuillez consulter l'autocollant correspondant pour connaître les charges permises.

Indications de sollicitation (composants du système)
Veuillez consulter l'autocollant correspondant pour connaître les charges permises.



Limit de la humidité

Français

Avertissement général :
Celui-ci se trouve sur le bloc multiprise. La puissance totale indiquée sur la plaque signalétique ne peut pas être excédée.

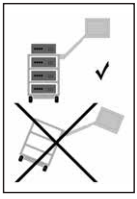
Ne convient qu'aux environnements intérieurs.

Objet lourd :
S'assurer qu'il y ait au moins deux personnes pour soulever les chariots mobiles uni-cart, vexio-cart, pro-cart, duo-cart, classic-cart, compact-cart ou endo-cart afin d'éviter toute blessure.

Commercialisé par

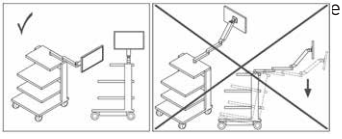
Ajustement de la force de serrage (unité de rotation et de bâche, l'inclinaison)

Charger le dernier montage:
Décrit la charge et le sens de rotation pour la mise au point, le réglage de la charge

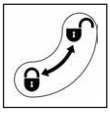


Risque de se retourner :
Le mécanisme mobile de support est absolument nécessaire d'assurer l'ordre de chargement et de déchargement.

Fonction de frein :
Fournit le renseignement sur le positionnement du bras de support en cas de l'acceptation du dispositif la perte d'équipement et spécifie la [illegible] décharger ou bloquer la fonction de stationnement.



Situation de travail :
Ce symbole décrit les positions de manoeuvres (droite / gauche) et pointe vers un danger de basculement existant lors de la modification des côtès.



Fonctionnalité de fermeture :
Elle décrit le sens de fermeture ou d'ouverture des composants.

Ne pas pousser :
Il est interdit de pousser le chariot au-dessus de la poignée, en raison des risques de basculement.

1.3 Consignes de sécurité

Généralités:

- Seuls les chariots mobiles dont les dispositifs de raccordement à la tension de secteur ont été testés et approuvés par un personnel technique qualifié peuvent être mis en service!
- Veuillez vous assurer que le transformateur d'isolement soit raccordé à un réseau électrique équipé d'une prise de mise à la terre en bon état de fonctionnement, qui satisfait aux dispositions de la directive IEC 60364-7-710 2012-10 « Installation électrique des bâtiments Partie 7-710 Règles pour les installations ou emplacements spéciaux - locaux à usage médical ». En cas de coute, veuillez contacter une entreprise professionnelle du secteur électrique ou un artisan qualifié dans la technologie utilisée en milieu hospitalier.
- Tout personnel (hospitalier ou le personnel de service) qui travaille indirectement ou directement avec un support d'appareils mobile doit avoir été initié de façon correspondante!
- Seul un personnel spécialisé est autorisé à procéder aux travaux de réglage.
- Les réparations et travaux de maintenance ne doivent être exécutés que par la société ITD GmbH.

Travail en toute sécurité sur les supports d'appareils mobiles :

- Le débranchement de l'alimentation secteur n'est garanti que si la fiche secteur est débranchée de la prise de courant.

Commande:

- Lors de chaque changement de lieu, veiller à ce que personne ne soit blessé et à ce qu'aucun objet ne soit endommagé!

Raccordements:

- Il faut utiliser un câble de qualité hospitalière aux USA et au Canada lors du raccordement des transformateurs de séparation en mode 115 V et au Japon il faut utiliser le câble optionnel japonais.
- Lors du raccordement à la prise de courant multiple, les prises de courant doivent être assurées par des dispositifs de blocage de prise optionnellement disponibles.
- Seuls des dispositifs respectant les exigences de la norme CEI 60601-1 ou IEC peuvent être raccordés sur les prises / les lignes de raccordement.
- Les appareils médicaux supplémentaires avec goupilles de raccordement pour la compensation de potentiel doivent être raccordés à l'aide d'un conducteur jaune-vert sur les goupilles de raccordement de compensation de potentiel disponibles en option!

- Attention: La puissance totale indiquée sur la plaque signalétique ne peut pas être excédée. Veillez à ce qu'aucune autre multiprise ne puisse être raccordée à la multiprise disponible.

Sollicitations:

- Le poids total des appareils et des accessoires placés sur le support d'appareils mobile ne doit pas dépasser le poids de chargement autorisé (cf. autocollant de sollicitation sur le châssis).
- La sollicitation de surface imprimée sur des composants de système ne doit pas être dépassée!
- La charge indiquée sur les périphériques (par ex. pied d'infusion, bras articulés) ne doit pas être dépassée!

Protection contre les infections:

- Lors des travaux de nettoyage, respecter les prescriptions d'hygiène!
- Ne remettez que des appareils ou équipements nettoyés et désinfectés à un technicien de service en vue des travaux de maintenance et de réparation!

Protection de l'environnement:

- Mettre au rebut tous les restes de détergents et de désinfectants ou les résidus de façon non polluante et respectueuse de l'environnement!

2 Montage

2.1 Intégralité

Déballer tout d'abord les chariots à appareils uni-cart, vexio-cart, pro-cart, duo-cart, classic-cart, compact-cart ou endo-cart et, à l'aide du bordereau de livraison joint à la commande, contrôler si toutes les pièces commandées ont bien été livrées.

2.2 Chargement

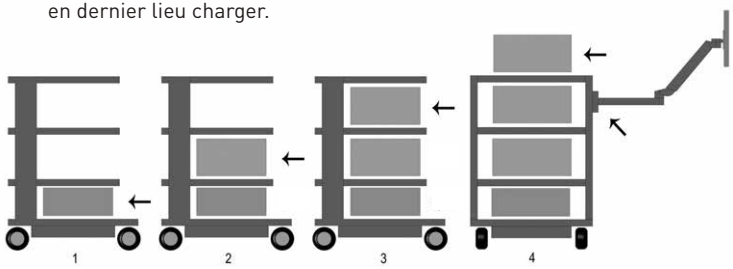
Placer le chariot à appareils uni-cart, vexio-cart, pro-cart, duo-cart, classic-cart, compact-cart, ou endo-cart sur une sur-face horizontale plane. Choisissez l'emplacement du chariot en fonction de la séquence de chargement de celui-ci. Le chargement et le montage ne doivent s'effectuer que lorsque le chariot n'est pas raccordé au réseau. Nous vous recommandons l'utilisation des accessories propices (par example ceintures de sécurité) pour assurer les appareils particuliéres.
La charge maximum pour chaque ligne de produits est indiquée au chapitre 10. Au cas où la stabilité statique ne suffirait pas, le chariot doit être pourvu d'une marque reconnaissable, conformément à l'obligation de marquage de 5°.

2.3 Chronologie de chargement

S'assurer, en prenant des mesures appropriées (également durant les déplacements), que tous les appareils installés sur le chariot uni-cart, vexio-cart, pro-cart, duo-cart, classic-cart, compact-cart ou endo-cart ne peuvent pas glisser, basculer, tomber par terre ou autre.
Il est recommandé de procéder à la mise en place de toutes les pièces lourdes sur le chariot à appareils uni-cart, vexio-cart, pro-cart, duo-cart, classic-cart, compact-cart ou endo-cart en faisant appel à deux personnes. Tenir compte de ce que le centre de gravité varie en fonction du chargement.

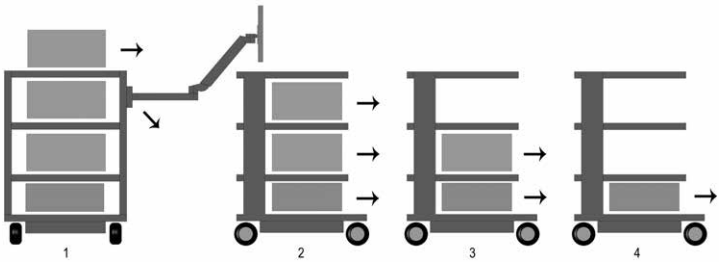
Le chariot doit être chargé en observant la chronologie suivante :

- étagères et tiroirs, de bas en haut.
- bras porteurs (rigides, pivotants, inclinables, réglables en hauteur, simples ou multiples) en dernier lieu charger.



Le chariot doit être déchargé en observant la chronologie suivante :

- bras porteurs (rigides, pivotants, inclinables, réglables en hauteur, simples ou multiples) en premier lieu décharger.
- décharger les étagères et tiroirs de haut en bas.

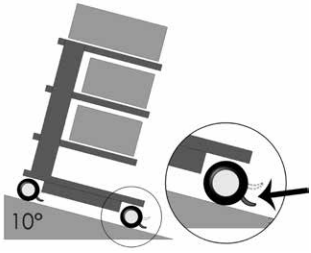


Veuillez également consulter les instructions données au chapitre 4 pour l'utilisation d'un chariot mobile (transport).

2.4 Risques dus à l'instabilité mécanique

Le système complet doit respecter les exigences du règlement IEC 60601-1.

2.5 Roulettes



Sur les chariots à appareils uni-cart, vexio-cart, pro-cart, duo-cart, classic-cart, compact-cart ou endo-cart se trouvent roulettes doubles avec un frein. Avant la mise en service des chariots à appareils uni-cart, vexio-cart, pro-cart, duo-cart, classic-cart, compact-cart ou endo-cart,s'assurer que les freins de blocage fonctionnent bien. En position d'arrêt et pour le maintien en cours de transport, tous les freins à rouleaux (dispositif de verrouillage des rouleaux) du chariot sont à serrer. De la même manière, il faut desserrer tous les freins à rouleaux en vue d'un déplacement ou du transport.
Il faut vérifier les roulettes du chariot pour sécurité et pour fixation sans fissure sur tourillons de roulette. Si les tourillons sont libre, joignes vous avec le fournisseur.

2.6 Sollicitations

Il est interdit de dépasser la force portante de chariots à appareils uni-cart, vexio-cart, pro-cart, duo-cart, classic-cart, compact-cart ou endo-cart.
Prière de tenir compte de la charge admissible maximale des chariots à appareils uni-cart, vexio-cart, pro-cart, duo-cart, classic-cart, compact-cart ou endo-cart (cf. section 10).

2.7 Montage / commande

2.7.1 Les étagères

Peuvent être enlevées ou placées à un autre endroit. Pour cela, desserrer les vis, placer l'étagère au nouvel endroit et la revisser ensuite. Vérifier ensuite la résistance du conducteur de protection.

2.7.2 Tiroirs

Les blocs de tiroirs (pro-cart) scomportent un verrouillage. Pour le chariot pro-cart, tirez la poignée de commande située sur le panneau avant vers le haut pour déclencher le dispositif de verrouillage.

Une fois ouverts, il est possible de décrocher les tiroirs. Une languette d'inscription peut être placée sur la façade avant (sauf pro-cart). Refermer le tiroir lors du transport.

2.7.3 Transformateur de séparation

Respecter les instructions mentionnées dans le mode d'emploi du transformateur d'isolement. Il est monté dans un carter sous la base du châssis. Ce montage est effectué à l'usine même.

2.8 Addition suplémentaire des élements du systéme

Le montage subséquent des composants du système ITD ne peut être réalisé que par le personnel technique, conformément aux prescriptions fournies avec les instructions de montage. Suite à toute modification, le système complet doit de nouveau être testé conformément au règlement IEC 60601-1.

3 Sécurité électrique

3.1 Placement des appareils électriques

Prière de tenir compte de ce que les appareils électriques se trouvant dans le chariot à appareils uni-cart, vexio-cart, pro-cart, duo-cart, classic-cart, compact-cart ou endo-cart ne doivent pas être mouillés. En aucun cas ne placez pas les produits, qui peuvent perdre le liquide, au-dessus les appareils électiques ou au-dessus des prises de courant électrique dans laquelles le liquid peut pénetrer.

3.2 Les collones énergétiques (classic-cart, compact-cart, endo-cart) et verticales (uni-cart, vexio-cart, pro-cart)

Le bloc multiprises ou le système de câblages se trouve dans la colonne énergétique de gauche ou de droite de chariot à appareils classic-cart, compact-cart ou endo-cart, chez uni-cart / pro-cart en les colonnes verticales. Des prises multiples et un système de câblage se trouvent sous la base du vexio-cart (les câbles passent dans des conduits de câbles disponibles en option, et qui sont installés latéralement sur la colonne verticale).

Les colonnes énergétiques se trouvent à gauche et à droite derrière le profilé vertical et permettent un déroulement optimal des câbles d'appareils existants. Ne perforer en aucun cas les colonnes énergétiques / verticales, car des câbles conducteurs de courant peuvent se trouver à l'intérieur de celles-ci.

3.3 Gaz

Les appareils électriques ne peuvent pas s'utiliser à proximité d'une source de gaz, p.ex. de gaz anesthésique inflammable ou de tout gaz semblable. L'utilisateur a la responsabilité de s'en assurer ainsi que de respecter le règlement IEC 60601-1-2.

3.4 Compensation de potentiel (POAG)

Avec les chariots à appareils uni-cart, pro-cart, classic-cart, compact-cart ou endo-cart avec transformateur de séparation, une compensation de potentiel est nécessaire. Pour le vexio-cart, un dispositif de compensation du potentiel sans transformateur de séparation est disponible. Pour cela, relier tout d'abord le câble de POAG à la base des chariots à appareils uni-cart, vexio-cart, pro-cart, classic-cart, compact-cart ou endo-cart et, ensuite, à la prise de POAG de la pièce. Connectez ensuite les prises pour compensation de potentiel aux goupilles des multiprises et des appareils.

3.5 Transformateur de séparation – courant de décharge

Le but des chariots à appareils uni-cart, vexio-cart, pro-cart, duo-cart, classic-cart, compact-cart ou endo-cart est de procurer une station de travail pratique et mobile pour les installations électromédicales. Pour que la totalité du système médical électrique respecte la norme IEC 60601-1, la somme des courants de décharge à la terre ne doit pas dépasser la valeur plafond maximale de 0,5 mA. Si la somme des courants de décharge à la terre devait dépasser cette limite de tolérance, l'installation devrait être alimentée par le biais d'un transformateur de séparation de sécurité.

Si aucun transformateur de séparation n'est monté, la prise multiple / le système de prises auxiliaires des chariots à appareils uni-cart, pro-cart, duo-cart, classic-cart, compact-cart ou endo-cart nine doivent pas être utilisés pour les raccordements d'appareils qui ne respectent pas les exigences de courant de décharge conformément à la norme IEC 60601-1.

Si un transformateur de séparation est monté, la totalité de la puissance consommée de tous les appareils raccordés doit respecter la valeur nominale du transformateur

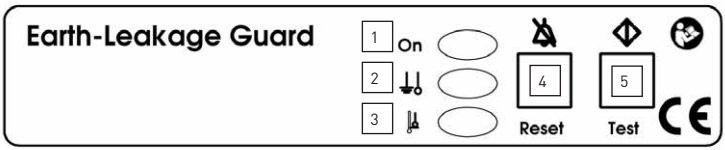
3.6 Contrôleur d'isolement

Les descriptions suivantes sont uniquement applicables aux articles installés dans les appareils „Transformateur de coupure avec contrôleur d'isolement"

3.6.1 Panneau de commande du contrôleur d'isolement (ELG)

Sur les appareils avec un contrôleur d'isolement intégré, l'électronique d'évaluation est intégrée dans le boîtier des transformateurs, le champ de commande et d'affichage se trouve dans un des plateaux de réception. Les deux composants sont reliés par le biais d'un câble d'interface acheminé dans le profil vertical.

Panneau de commande du contrôleur d'isolement ELG (en option) :



1 Témoin de contrôle de réseau (vert)
2 Résistance d'isolement (jaune)
3 Dépassement de température (jaune)
4 Touche d'acquittement de panne
5 Bouton test

3.6.2 Utilisation conforme

Le contrôleur d'isolement ELG sert à la surveillance de la résistance d'isolation d'appareils et de groupes d'appareils qui sont raccordés à des transformateurs de coupure pour la coupure de protection. Le transformateur est de plus simultanément surveillé du point de vue de son comportement de température. L'évaluation est réalisée par commande de processeur.

3.6.3 Mode d'emploi

Lorsque vous commutez l'interrupteur principal du transformateur de coupure sur "ON" („MARCHE"), l'autotest du contrôleur d'isolement ELG est automatiquement réalisé en arrière-plan. Suite à la clôture de l'autotest, le contrôleur d'isolement ELG est prêt à l'emploi. Le - témoin de contrôle de réseau (LED verte) est allumé en permanence. En cours de fonctionnement, le test est réalisé automatiquement de manière cyclique toutes les 8 heures et peut être en complément manuellement déclenché par le biais d'un bouton test.

Lors d'un test manuel, la routine de contrôle suivante est réalisée :

- Une erreur d'isolement est simulée, le témoin LED jaune de la résistance d'isolement est allumée en permanence, un signal sonore avec 2,4 kHZ retentit durablement, les deux s'éteignent au bout de 5 s environ.
- Une erreur de température est ensuite simulée, le témoin LED jaune du dépassement d'isolement est allumée en permanence, un signal sonore avec 2,4 kHZ retentit par pulsation, les deux s'éteignent au bout de 5 s environ.

Un cas de panne est détecté comme suit :

- Lorsqu'une panne d'isolement se produit, le témoin LED jaune de la résistance d'isolement s'allume durablement, un signal sonore de 2,4 kHZ retentit en permanence. Le signal sonore peut être remis à zéro avec la touche d'acquittement de panne. Le témoin LED s'allume jusqu'à ce que la panne soit éliminée.
- Lorsque le contrôleur d'isolement est éteint et que la panne n'est entre temps pas éliminée, la procédure ci-dessus décrite recommence depuis le début. Lors de l'apparition d'une panne d'isolation, l'alarme acoustique et optique reste allumée jusqu'à ce qu'elle soit acquittée :

  Premier acquittement: alarme acoustique éteinte
  Deuxième acquittement: alarme optique éteinte

- Lorsqu'une panne de température se produit, le témoin LED jaune s'allume pour indique un dépassement de température durable, un signal sonore de 2,4 kHZ retentit par pulsation. Le signal sonore peut être remis à zéro avec la touche d'acquittement de panne, le témoin LED continue à être allumé jusqu'à ce que la panne soit éliminée. Lorsque le contrôleur d'isolement est éteint et que la panne n'est entre temps pas éliminée, la procédure ci-dessus décrite recommence depuis le début.
- Lors de l'apparition simultanée d'une panne d'isolement et de température trop élevée, la panne d'isolement est toujours prioritaire lors d'une alarme acoustique.

Autotest du contrôleur d'isolement
En complément de l'autotest déclenchable par le biais du bouton Test, le contrôleur d'isolement réalise un autotest cyclique sur une période de 8 heures environ. Le test est également réalisé après chaque mise en marche.
L'autotest dure environ 5 secondes et n'est pas détectable de l'extérieur. En cas de panne, le témoin de contrôle de réseau (LED verte) clignote avec une fréquence de 0,5 Hz. L'alarme acoustique retentit avec la même fréquence. Les messages d'erreurs ne peuvent pas être remis à zéro avec la touche d'acquittement de panne.

3.6.4 Elimination de pannes

N'essayez pas de réparer l'appareil de votre propre chef. Si une tentative de réparation non conforme est constatée, le droit à la garantie n'est alors pas applicable. Pour des raisons de sécurité, les travaux de réparation et de maintenance sont exclusivement réalisés par le fabricant.

Remarque: Pour obtenir des informations et des caractéristiques techniques complémen - taires, veuillez consulter le mode d'emploi séparé et plus détaillé joint au produit pour les transformateurs de coupure et les contrôleurs d'isolement.

3.7 Fiche de raccordement pour les câbles

L'exploitant des chariots à appareils uni-cart, vexio-cart, pro-cart, duo-cart, classic-cart, compact-cart ou endo-cart sans transformateur de séparation utilisé devra s'assurer, pour la connexion des câbles entre les prises multiples du chariot et l'appareil, qu'il s'agisse d'un connecteur détachable exclusivement avec des outils. Vous trouverez un large choix de couvercles de protection pour prises multiples dans notre gamme d'accessoires.

3.8 Combinaison d'appareils

Pour la combinaison d'appareils sur le chariot à appareils, respecter ce qui suit :

- les équipements supplémentaires qui sont raccordés aux interfaces analogues ou numériques de l'appareil doivent de façon avérée respecter leurs spécifications correspon-dantes (par ex. IEC 60950 pour les appareils de traitement de données et EN 60601-1 pour les appareils électro-médicaux).
- En outre, toutes les configurations doivent respecter la version valide de la norme de système IEC 60601-1. Quiconque raccorde des appareils supplémentaires à la partie d'entrée ou de sortie de signaux est configurateur de système et est donc responsable de ce que la version valide de la norme de système IEC 60601-1 soit respectée.

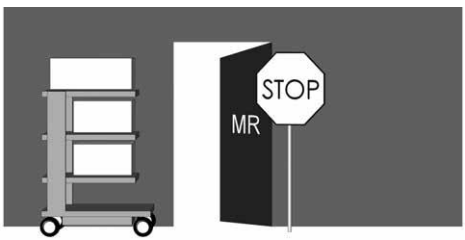
En cas de demandes de renseignements, prière de contacter le distributeur spécialisé local ou le service technique.
Remarque :
Cela vaut aussi pour l'adaptation des instruments au circuit d'alimentation (p.ex.: multiprise).

3.9 CEM

La compatibilité électromagnétique entre les divers appareils électro-médicaux se trouvant sur le chariot doit être testée par la personne ayant configuré le système complet. Avant toute utilisation médicale d'une autre combinaison d'appareils, vérifier la compatibilité électromagnétique réciproque des différents appareils.

Les chariots d'instrumentation spécifiques au client, qui sont utilisés dans l'environnement de spin nucléaire, doivent être testés par le client afin de vérifier leur aptitude à fonctionner en raison de la proportion de substances ferromagnétiques.

ITD GmbH exclut toute responsabilité à ce point de vue !



Toute utilisation du chariot à appareils avec transformateur de séparation à l'intérieur d'un environnement explosif est interdite.

3.10 Composants système et accessoires exclus du contrôle électrique en sortie

ITD GmbH exclut les composants système et les accessoires suivants du contrôle électrique en sortie :

- Blocs multiprises sans conducteur de protection supplémentaire, non raccordés au montage
- Les câbles d'appareils et liaisons ME fournis
- Les plaques ou liaisons POAG fournis

- Chariots et supports d'appareil non électrifiés
- Les réglages en hauteur et les pièces de fixation des réglages en hauteur
- Les poignées, tapis souris, bloc tiroirs, corps et fixations de bloc tiroirs (porte-bouteilles, corbeilles, supports de caméras, pieds à sérum...)
- Des transformateurs d'isolement non montés mais quittant ITD en pièces détachées
- Supports pour claviers et tablettes télescopiques
- Supports pour unité centrale en bas et en haut
- Roulettes conductibles
- Bras porteurs montés et supports d'écrans
- Les „circuits secondaires avec contrôleurs d'isolement" ne sont exclus que du contrôle de résistance électrique !

3.11 Sécurité minimum

ITD GmbH ne connaît aucun appareil, ni aucun accessoire, qui diminue la sécurité minimum du système. Il n'est permis d'utiliser que des appareils qui ne représentent aucun danger. Le cas échéant, ceci doit être éclairci à la lumière d'une analyse de risques (ISO 14971).

4. Transport

4.1 Transport en sécurité sur roulettes

Assurez vous, que avant usage mobile des chariots portes-appareils :

- tous les appareils, qui sont placés sur le chariot, sont fixés contre chute
- tous les branches articulés sont basculés et fixés
- il faut que les conducteurs d'alimentation sont tirés de prises
- les freins sont desserées

Le mouvement avec le chariot porte-appareil est possible avec la vitesse maximale de 6 km/heure. Il faut considérablement reduir la vitesse du chariot en passant des seuils, câbles et tuyaux.

En marchant sur les rampes inclinéés 10° il faut s'assurer, que le chariot porte-appareil piusse s'arréter à tout moment.

Bien que toutes les mesures de précaution aient été respectées pour garantir la stabilité maximum de ce produit, il s'agit de faire attention aux inégalités du sol, aux encadrements de porte des ascenseurs, aux câbles etc., afin d'éviter tout accident.

Les exigences du règlement IEC 60601-1 sont à appliquer en principe.

4.2 Transport en sécurité en le portant

Les poignées ne sont pas conçues pour soulever le chariot mobile, mais elles servent seulement à le pousser. Les chariots mobiles ne peuvent être soulevés ou portés que lorsqu'il y a deux personnes disponibles pour saisir les leviers se trouvant à la base.

Les exigences du règlement IEC 60601-1 sont à appliquer en principe.

5 Système de réglage mécanique et électrique de la hauteur

Qu'il s'agisse du système de réglage mécanique de la hauteur par « pression à gaz » ou de réglage électro-mécanique de la hauteur utilisant un « dispositif d'actionnement linéaire », des consignes de sécurité particulières doivent être respectées selon la norme IEC 60601-1 « risques mécaniques en rapport avec les parties mobiles ». Les directives suivantes s'appliquent :

- Les espacements autorisés entre les parties mobiles doivent être pris en compte et être respectés selon la norme IEC 60601-1 dans le tableau 20 (ISO 13857:2008).
- Les finitions et la livraison départ usine des produits comportant une possibilité de réglage de la hauteur sont effectuées conformément aux normes en respectant les espacements de sécurité autorisés. Les espacements subissent des modifications du fait du montage ou du remplacement des appareils médicaux et/ou des composants. Cela peut conduire à des dommages mécaniques. Le configurateur de système correspondant est responsable du respect des espacements minimum exigés.
- Le poids total des appareils et des accessoires montés ne doivent pas dépasser la charge totale maximale autorisée par le système de réglage de la hauteur. Les surcharges causent des dommages empêchant le réglage de la hauteur et l'application de la garantie.

- Le système de réglage mécanique de la hauteur par « pression à gaz », fonctionne grâce à la libération de l'énergie accumulée. En cas de système non rechargé, un actionnent soudain ou illimité du système de réglage de la hauteur peut conduire à des dommages corporels ou envers les appareils.
  - Avant le montage ou le démontage des appareils, le système de réglage de la hauteur doit être positionné au niveau le plus haut (« sans alimentation en énergie ») afin d'éviter les dommages corporels ou envers les appareils.
  - Le système de bras porteur « flexion-port » doit en plus être fixé et sécurisé au niveau le plus haut (« sans alimentation en énergie ») à l'aide du levier de serrage (consultez le mode d'emploi annexe pour « flexion-port» ainsi que les indications de dangers sur le système de bras porteur).

- L'actionnement non sollicité du système de réglage de la hauteur électro-mécanique à l'aide des boutons peut également conduire à des dommages corporels ou envers les appareils.
  - Avant le montage ou le démontage des appareils, le système de réglage de la hauteur doit être débranché de l'alimentation afin d'éviter les dommages corporels ou envers les appareils.
  - Seules les personnes spécialisées et qualifiées peuvent exécuter des travaux de réparation et d'entretien au niveau de la « partie interne » du système de réglage de la hauteur, à savoir la partie couverte et non accessible de l'extérieur, au niveau de la colonnette porteuse.
  - Attention : lors de l'utilisation du système de réglage de la hauteur à l'aide de la télécommande, veillez à ce que personne ne se trouve autour de l'appareil.

6 Accolades

6.1 Treillage métallique

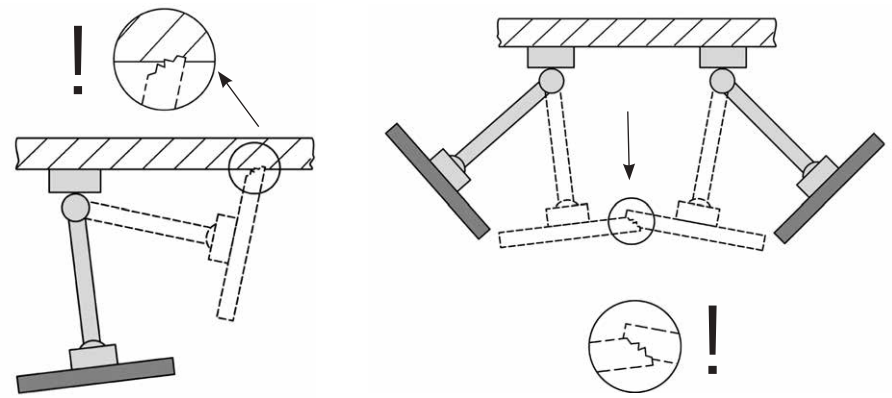
S'il vous plait noter le suivant :

- C'est la bassine qui ne fait aucun dommage au câble ou de perte d'équipement, le câble doit être suffisamment grand.
- En fait les câbles suspendus ne doivent être jamais utilisés comme un manche.
- Veuillez-vous noter que le matériel de montage inclus est utilisé comme il faut selon les instructions d'installation.
- Quand oscillant les bras, prendre soin des boucles de tout câble.

6.2 Rotation horizontale

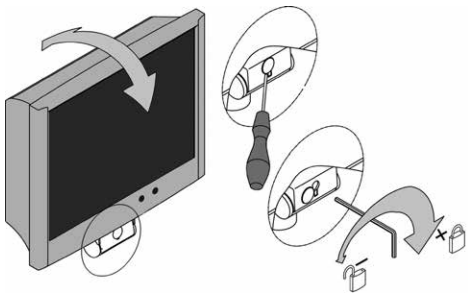
Assurer qu'elle est pareil au pivot de composants système fois la taille de l'appareil et conditions de chambre est mis en correspondance.

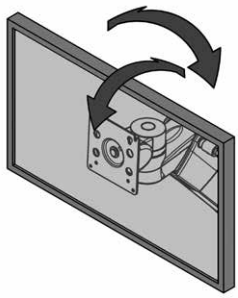
Pour un panoramique horizontal des composants du système avec les périphériques attachés à eux pourrait entrer en collision avec d'autres dispositifs ou avec les autres composantes du système ou de la paroi. Une collision peut causer des dommages matériels et l'effet de la blessure.



6.3 Inclinaison / rotation équipement

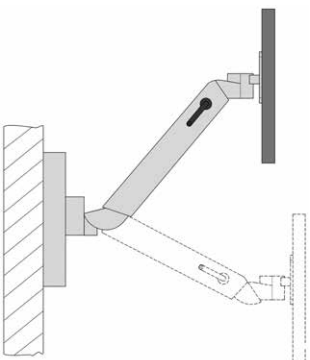
En inclinaison ou doivent examiner les composants de système de rotation, la force de serrage pour le dispositif de verrouillage est mis en correspondance. Si mal ajusté menace un abaissement de l'appareil. Alors ajustement doit donc être faites afin qu'une inclinaison ou la rotation de l'appareil est facile, mais dans toute position souhaitée reste stable.

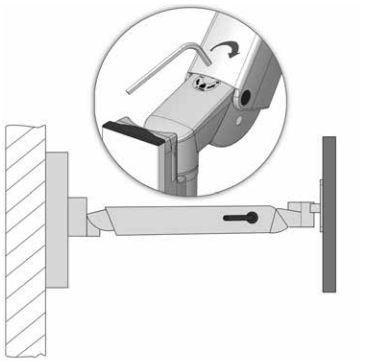




6.4 Réglable de montage des systèmes de bras (flexion-port)

Lorsque les composants du système ascenseur de chargement doit être prise strictement pour le poids total autorisé minimal ou maximal. Assurez-vous également que l'espace ci-dessous est la variable de hauteur de montage du système des bras (flexion-port) reste libre. Pour définir le poids de bras de montage, elle doit être présentée en position horizontale.





6.5 Démantèlement et la reconstruction du système de composants et accessoires

Une fois démonté ou modifiés aux composants de système de position et accessoires, l'appareil qui enregistre doit être enlevé nécessairement avant. C'est l'installation d'hauteur suspension variable armes flexion-port, ils doivent seulement placer en haut et établir de la pince (frein) (voir l'étiquette).

6.6 But d'utilisation lorsque le transporteur mobile de manoeuvre

Lorsque le transporteur mobile de manoeuvres, il est obligatoire que les bras attachés de montage pivotent (réglable en hauteur) dans la position respectif de stationnement et fixe si nécessaire. Autrement il n'est pas la garantie de stabilité (voir la section 2.4).

6.7 Utiliser les systèmes de bras de montage réglable en hauteur (flexion-port) au bas de l'écran (2)

Quand en utilisant les systèmes de bras de montage réglable (flexion-port) au bas de l'écran (2) est toujours important de s'assurer que le bras pivotant est responsable d'un saut de page toujours parallèle (poste pressé) est situé vers l'avant de la voiture. Veuillez noter que seulement deux positions du bras de montage (gauche / droite) comme un élément de travail sont autorisées (voir „Situation de travail" dans le chapitre „1.2 déclaration de symbole générale", page 55).

Quand une page brise de la gauche vers la droite, poste de travail ou vice versa doit être les éléments verrouillage poussé vers le bas et descendu à la variable de hauteur de montage des bras de l'autre côté. Il est à noter que le port de flexion-port avec bras pivotant pour la pause est plié. Par ailleurs, la stabilité d'un tonneau (voir point 2.4) ne peut être garantie.

7 Divers

7.1 Nettoyage et Désinfection

Attention: Déconnectez le système entier avant de procéder à son nettoyage ou à sa désinfection.

Les chariots mobiles uni-cart, vexio-cart, pro-cart, duo-cart, classic-cart, compact-cart ou endo-cart ne peuvent être nettoyés qu'avec les produits de nettoyage usuels (produits neutres). Pour la désinfection il est possible d'utiliser des produits du commerce destinés à la désinfection des surfaces ou au dépoussiérage. Les produits de désinfection sont à utiliser selon les instructions données par le fabricant pour une désinfection simple.

Des tests ont par exemple été menés par ITD avec les produits désinfectants suivants :

Produits	**Fabricant**
Bacillol	Bode
Lingettes Cleanisept	Dr. Schumacher
Lingettes Bacillol	Bode
Lingettes mikrozid AF	Schülke
Terralin Protect	Schülke
Incidin PLUS	Ecolab
Incidin Foam	Ecolab

Pour une désinfection complète, les éléments peuvent être démontés par un professionnel et être désinfectés par essuyage, une fois démontés.

7.2 Réparation / Service

Avant toute mesure d'entretien, également cas de renvoi à des fins de réparation, le port appareil doit être nettoyé avec un détergent approprié et désinfecté!
Pour toutes les prestations de services, nous vous recommandons de vous adresser à ITD GmbH.

7.3 Conditions d'environnement

Les chariots à appareils uni-cart, vexio-cart, pro-cart, duo-cart, classic-cart, compact-cart ou endo-cart ont été conçus pour le service usuel en hôpital et cabinet médical.

Opération:

Température ambiante:	10° C jusqu'à 40° C
Humidité relative de l'air :	30 % jusqu'à 75 %
Pression atmosphérique :	700 hPa jusqu'à 1060 hPa
Indice de protection:	IP20

Transport/stockage

Température ambiante :	De -25°C à 70°C
Humidité relative de l'air :	10% à 95%
Pression atmosphérique :	500hPa à 1200hPa

7.4 Mise au rebut

Collecte séparée d'appareils électriques et électroniques en conformité avec la directive DEEE. (Numéro d'enregistrement pour l'Allemagne: DE35464575).
Les déchets électriques et électroniques mis en circulation après le 13 août 2005 portent le symbole représenté indiquant l'élimination séparée des déchets électriques et électroniques. Cela signifie que dans les pays où la directive EU 2002/96/EC est en vigueur, les déchets doivent être gérés dans un site de traitement séparé.

7.5 Pièces de rechange

Il est permis d'utiliser uniquement des pièces de rechange agréées par ITD GmbH ! Sur le socle de votre chariot à appareils se trouve un autocollant avec un numéro d'ordre. Tous les numéros d'ordre et les pièces de rechange qui y correspondent sont détenus en archive chez ITD GmbH. A l'aide de ceux-ci, vous pouvez vous procurer les pièces de rechange nécessaires à ITD GmbH.

8 Accessoires

Dans nos catalogues et à l'adresse www.itd-cart.com (Information pour les distributeurs), vous trouverez une offre très complète d'accessoires.

9 Maintenance

Les chariots à appareils uni-cart, vexio-cart, pro-cart, duo-cart, classic-cart, compact-cart ou endo-cart ont été développés et construits pour de nombreuses années d'utilisation sans problèmes. Vérifier tous les 12 mois le bon fonctionnement des pièces suivantes afin de garantir la sécurité.

Étagère à écran :
- La rotation et le basculement fonctionnent sans difficultés et sans jeu excessif.

Étagères :
- Vérifier si les vis de fixation sont bien insérées et, par conséquent, si l'étagère est stable et bien droite.

Roulettes :
- Veillez à ce que les roulettes tournent sans entrave et à ce que les freins fonctionnent bien.
- Vérifier que les quatre boulons qui maintiennent les roulettes sur la face intérieure du socle ainsi que les roulettes elles-mêmes sont positionnées solidement dans leurs supports.
- Pour garantir la fonction des roulettes conductrices, les surfaces de roulement doivent être sans impuretés.

Bloc multiprises :
- Contrôler que le câble principal n'est pas endommagé et est bien positionné.

Prise de courant auxiliaire :
- Vérifier que le câble n'est pas endommagé et est bien positionné.

Réglable de montage des systèmes de bras flexion-port:
- Réglage en hauteur fonctionne sans heurt, la capacité de levage est adaptée pour le poids.

Accolades :
- La rotation et le retournement travaille en douceur sans trop de jeu.

Transformateurs de séparation :
- Contrôle en matière de sécurité des transformateurs de séparation.

Numéro de série :
- Comparer le numéro de série du chariot et les données du carnet d´appareils.

Fusibles :
- Vérifier que des fusibles corrects sont bien montés.

Si vous deviez découvrir un problème lors de cette vérification, veuillez vous adresser directementà votre fournisseur.

10 Données techniques

10.1 Force portante uni-cart

• Châssis, charge totale	à partir de 50 kg / 110 lbs	
• Etagère	10 kg / 22 lbs	
• Etagère de rack	20 kg / 44 lbs	
• Tiroir	3 kg / 6.6 lbs	(autobloquant: 10 kg / 22 lbs)
• Support d'écran	14 kg / 30.8 lbs	
• Tapis de souris	3 kg / 6.6 lbs	

10.2 Force portante vexio-cart

• Châssis, charge totale	65 kg / 143 lbs	
• Etagère	15 kg / 33 lbs	
• Tiroir	3 kg / 6.6 lbs	
• Support d'écran	14 kg / 30.8 lbs	
• Tapis de souris	3 kg / 6.6 lbs	

10.3 Force portante pro-cart

• Châssis, charge totale	80 kg / 176 lbs	
• Etagère	20 kg / 44 lbs	
• Tiroir	15 kg + 3 kg / 33 lbs + 6.6 lbs	
• Support d'écran	14 kg / 30.8 lbs	
• Tapis de souris	3 kg / 6.6 lbs	

10.4 Force portante duo-cart

• Châssis, charge totale	80 kg / 176 lbs	
• Etagère	50 kg / 110 lbs	(télescopic: 20 kg / 44 lbs)
• Tiroir	3 kg / 6.6 lbs	(autobloquant: 20 kg / 44 lbs)
• Tapis de souris	3 kg / 6.6 lbs	

10.5 Force portante compact-cart

• Châssis „Profi“, charge totale	180 kg / 396 lbs	
• Châssis „Economy“, charge totale	150 kg / 330 lbs	
• Etagère	50 kg / 110 lbs	
• Tiroir	3 kg / 6.6 lbs	
• Etagère à écran	max. 35 kg / 77 lbs	(selon le type)
• Tapis de souris	3 kg / 6.6 lbs	

10.6 Force portante classic-cart / endo-cart

• Châssis, charge totale	150 kg / 330 lbs	
• Etagère	50 kg / 110 lbs	(télescopic: 20 kg / 44 lbs)
• Tiroir	3 kg / 6.6 lbs	
• Etagère à écran	max. 35 kg / 77 lbs	(selon le type)
• Tapis de souris	3 kg / 6.6 lbs	

10.7 Force portante modul-port

- Profil porteur, charge totale selon la longueur 25-150 kg / 55-330 lbs
- Bras porteur max. 23 kg / 50.6 lbs
- Bras pivotant, simple max. 23 kg / 50.6 lbs
- Bras pivotant, double max. 18 kg / 39.6 lbs
- Support d'écran avec adaptateur VESA 75/100 max. 18 kg / 39.6 lbs
- Support d'écran avec adaptateur universel max. 14 kg / 30.8 lbs
- Support d'écran avec adaptateur Table Top Mount max. 14 kg / 30.8 lbs
- Etagère 10 kg / 22 lbs
- Tiroir 3 kg / 6.6 lbs
- Support pour clavier 5 kg / 11 lbs
- Tapis de souris 3 kg / 6.6 lbs

10.7 Force portante flexion-port (Réglable de montage des systèmes de bras)

- flexion-port (selon de modèle) 3-10 kg / 6.6-22 lbs ou 8-14 kg / 17.6-30.8 lbs 11-20 kg / 22.4-44 lbs
- La rotation et l'inclinaison / unité de rotation 14 kg / 30.8 lbs
- Poste ("Down-Post") 10 kg / 22 lbs
- Tapis de souris 3 kg / 6.6 lbs

Adresse de contact :

Amérique du Nord	Europe
ITD Corporation	ITD GmbH - Agence d'Unterhaching
50 RADO DR UNIT A	Gruenwalder Weg 13a
Naugatuck, CT 06770-2211, USA	82008 Unterhaching, Allemagne
Tel: +1 203 714 67-00	Tel: +49 89 61 44 25 0
Email: sales.usa@itd-cart.com	Email: sales@itd-cart.com

Chine	Australie
ITD Medical Technology Products (Shanghai) Co., Ltd.	ITD Australia Pty Ltd Aviation Place 3
Section A, Room 101, 1st Floor	3043 Tullamarine, Victoria, Australia
11 South RiYing Road Pilot Free Trade Zoon	
Shanghai 200131, China	
Tel: +86 21 6442 5704	Tel: +61 3 9330 50 50
Email: s.pan@itd-cart.com	Email: s.oconnor@itd-cart.com

La société ITD GmbH est responsable de la véracité du contenu.

Es un producto médico de la clase I en el sentido de la Directiva Productos Sanitarios 93/42/CEE (Medical Devices Directory), Anexo IX.

El fabricante declara que el producto cumple los requisitos fundamentales según MDD 93/42/CEE, Anexo VII, y por esto lleva el símbolo de la CE.

Fabricante:

ITD GmbH
Sportplatzstr. 3
84381 Johanniskirchen, Alemania
Tel: + 49 89 61 44 25- 0
Fax: +49 89 61 44 25- 200
Email: sales@itd-cart.com

Venta y Servicio:

América del Norte

ITD Corporation
50 RADO DR UNIT A
Naugatuck, CT 06770-2211, USA
Tel: +1 203 714 67-00
Email: sales.usa@itd-cart.com

Europa

ITD GmbH - Office Unterhaching
Gruenwalder Weg 13a
82008 Unterhaching, Alemania
Tel: +49 89 61 44 25 0
Email: sales@itd-cart.com

China

ITD Medical Technology Products (Shanghai) Co., Ltd.
Section A, Room 101, 1st Floor
11 South RiYing Road
Pilot Free Trade Zoon
Shanghai 200131, China
Tel: +86 21 6442 5704
Email: s.pan@itd-cart.com

Australia

ITD Australia Pty Ltd
Aviation Place 3
3043 Tullamarine, Victoria, Australia
Tel: +61 3 9330 50 50
Email: s.oconnor@itd-cart.com

Estamos trabajando constantemente para desarrollar nuestros productos. Por esto nos reservamos en todo momento el derecho de modificar el volumen de suministro en su forma, equipamiento y técnica.¡Está prohibido reimprimir, copiar o traducir la totalidad o cualquier parte del presente sin el consentimiento específico y escrito de ITD GmbH!

Propiedad intelectual de ITD GmbH; todos los derechos reservados.

Version © 11/2018 Fecha de impresión 12/2018

Las presentes instrucciones para el uso tienen validez para los siguientes productos:

Denominación del tipo	Descripción
CC.02xx.xxx / 03xx.xxx	Componentes del sistema y accesorios compact-cart
CC.45xx.xxx / 50xx.xxx / 65xx.xxx	Carro porta aparatos compact-cart, 30 U – 40 U
CC.45xx.xxx / 50xx.xxx / 65xx.xxx	Componentes del sistema y accesorios compact-cart
DC.42xx.xxx / 53xx.xxx / 64xx.xx	Carro porta aparatos duo-cart, 21 U – 30 U
DC.40xx.xxx / 50xx.xxx / 60xx.xxx	Componentes del sistema y accesorios duo-cart
EB.45xx.xxx / 50xx.xxx / 65xx.xxx	Carro porta aparatos compact-cart Economy
EC.04xx.xxx	Carro porta aparatos endo-cart, 30 U
GW.52xx.xxx / 53xx.xxx / 54xx.xxx	Carro porta aparatos classic-cart, 21 U – 40 U
GW.62xx.xxx / 63xx.xxx / 64xx.xxx	
GW.01xx.xxx / 02xx.xxx / 03xx.xxx	Componentes del sistema y accesorios classic-cart
GW.04xx.xxx / 05xx.xxx / 06xx.xxx	
GW.07xx.xxx / 08xx.xxx	
GW.40xx.xxx / 41xx.xxx / 45xx.xxx	
GW.50xx.xxx / 51xx.xxx / 55xx.xxx	
GW.60xx.xxx / 61xx.xxx / 65xx.xxx	
GW.80xx.xxx / 98xx.xxx / 99xx.xxx	
HA.1xxx.xxx / 2xxx.xxx	Componentes del sistema y accesorios flexion-port
HA.45xx.xxx / 5xxx.xxx	
HA.60xx.xxx / 65xx.xxx	
NT.20xx.xxx / 40xx.xxx / 41xx.xxx	Componentes del sistema y accesorios vexio-cart
NT.50xx.xxx	Carro porta aparatos vexio-cart, 21 U – 50 U
PT.20xx.xxx / 40xx.xxx / 41xx.xxx	Componentes del sistema y accesorios pro-cart
PT.50xx.xxx / PT.90xx.xxx	Carro porta aparatos pro-cart, 21 U – 50 U
RS.41xx.xxx/ 48xx.xxx / 49xx.xxx	Carro porta aparatos uni-cart, 21 U – 50 U
RS.00xx.xxx / 01xx.xxx / 02xx.xxx	Componentes del sistema y accesorios uni-cart
RS.4xxx.xxx / 5xxx.xxx	
TS.03xx.xxx / 05xx.xxx	Componentes del sistema y accesorios flexion-port

Las presentes instrucciones para el uso tienen validez para los siguientes productos:

Denominación del tipo	Descripción
VS.53xx.xxx / 54xx.xxx / 63xx.xxx	Carro porta armario de Video classic-cart, 30 U – 40 U
VS.63xx.xxx	
VT.43xx.xxx	Carro porta armario para Video con transformador de separación pro-cart, 30 U
VT.45xx.xxx	Carro porta armario para Video con transformador de separación compact-cart, 40 U
VT.54xx.xxx / 64xx.xxx	Carro porta armario para Video con transformador de separación classic-cart, 40 U
VW.54xx.xxx / 64xx.xxx	Carro porta Video classic-cart, 40 U
ZV.94xx.xxx / 96xx.xxx / 97xx.xxx	Componentes del sistema y accesorios en general
ZV.98xx.xxx / 99xx.xxx	
KD.7xxx.xxx / 8xxx.xxx / 9xxx.xxx	Carros portaaparatos móviles específicos de clientes de las series uni-cart, pro-cart, duo-cart, classic-cart, compact-cart y endo-cart
KU.0xxx.xxx – KU.9xxx.xxx	Carros portaaparatos móviles específicos de clientes de las series uni-cart, vexio-cart, pro-cart, duo-cart, classic-cart, compact-cart y endo-cart
OC.0xxx.xxx – OC.9xxx.xxx OC.1 – OC.999	
OM.0xxx.xxx – OM.9xxx.xxx	

Contenido

1 Informaciones importantes

1.1 Uso reglamentario ... 78
1.2 General pictogramas ... 79
1.3 Avisos de seguridad ... 81

2 Montaje

2.1 Integridad ... 82
2.2 Modo de carga ... 82
2.3 Orden de la carga ... 82
2.4 Peligro por inestabilidad mecánica ... 83
2.5 Ruedas ... 83
2.6 Capacidad de carga ... 83
2.7 Montaje / manejo ... 83
2.8 Montaje posterior de componentes del sistema ... 84

3 Seguridad eléctrica

3.1 Colocación de los aparatos eléctricos ... 84
3.2 Columna de energía (classic-cart, compact-cart, endo-cart) y columnia vertical (uni-cart, vexio-cart y pro-cart) ... 84
3.3 Gases ... 85
3.4 Equipotencialidad (POAG) ... 85
3.5 Transformador de separación - corriente de puesta a tierra ... 85
3.6 Controlador de aislamiento ... 85
3.7 Dispositivo de enchufe de cables ... 87
3.8 Combinación de aparatos ... 87
3.9 CEM ... 88
3.10 Desde los componentes del sistema / accesorios excluidos de la verificación de la salida eléctrica ... 88
3.11 Seguridad mínima ... 89

4 Transporte

4.1 Transporte seguro sobre rodillos ... 89
4.2 Transporte seguro por cargar ... 89

5 Ajuste de altura mecánico y eléctrico ... 90

6 Brazos portantes

6.1 Cableado ... 91
6.2 Giro horizontal ... 91
6.3 Inclinación / giro de los aparatos ... 91
6.4 Sistemas de brazo portante con altura ajustable (flexion-port) ... 92
6.5 Desmontaje y cambio de componentes de sistema y accesorios ... 92
6.6 Uso conforme a lo previsto al maniobrar con los soportes de aparatos móviles ... 92
6.7 Manipulación de los sistemas de brazo de portante con altura ajustable (flexion-port) sobre la base de supervisión (doble) ... 93

7 Otros

7.1 Limpieza y desinfección ... 93
7.2 Reparaciones / Servicio ... 94
7.3 Condiciones del medio ambiente ... 94
7.4 Eliminación ... 94
7.5 Piezas de recambio ... 94

8 Accesorios ... 94

9 Mantenimiento ... 95

10 Datos técnicos

10.1 Capacidad de carga uni-cart ... 96
10.2 Capacidad de carga vexio-cart ... 96
10.3 Capacidad de carga pro-cart ... 96
10.4 Capacidad de carga duo-cart ... 96
10.5 Capacidad de carga compact-cart ... 96
10.6 Capacidad de carga classic-cart / endo-cart ... 97
10.7 Capacidad de carga modul-port ... 97
10.8 Capacidad de carga flexion-port ... 97

1 Informaciones importantes

Todos los productos de ITD GmbH se fabrican para una vida útil, prolongada y sin averías.
El diseño desarrollo, construcción, distribución y producción de ITD GmbH están certificados de acuerdo con la norma ISO 13485.

Esto es fundamental para:
- mayor calidad y una vida larga
- control fácil, seguro y ergonómico
- diseño funcional
- optimización para el objetivo de aplicación

Los productos cumplen los requisitos de la Ley para productos médicos y llevan el símbolo de la CE.
- Léa estas instrucciones para el uso, concienzudamente desde el principio, para poder familiarizarse con las funciones paso por paso.
- En caso de preguntas o dudas, póngase en contacto con el fabricante.
- Los portaaparatos móviles están solamente previstos para el uso descrito y conforme a su destino.
- Estas instrucciones deben guardarse durante la vida útil del producto.

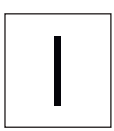
El configurador del sistema debe poner estas instrucciones para el uso a disposición del cliente final.
¡Se advierte expresamente que el configurador del sistema es responsable del cumplimiento del requisito de IEC 60601-1 y de la CEM IEC 60601-1-2 en la versión vigente respectivamente!

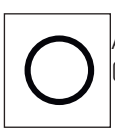
1.1 Uso reglamentario

Los carros porta aparatos móviles de ITD GmbH sirven:
- para el alojamiento de aparatos médicos y equipos ensayados según las normas IEC de acuerdo con las indicaciones de carga permitida bajo el cumplimiento de los requisitos de IEC 60601-1 en su versión vigente actual.
- para la conexión y distribución de tensiones de red desde el punto de toma local, así como los cables de datos.
- fijación de componentes del sistema originales de ITD y accesorio.

Con la ayuda del portaaparatos móvil es posible mover los aparatos médicos dentro del edificio y/o colocarlos libremente en la sala antes y después de la aplicación. Esto permite un mayor grado de utilización flexible y económica de todos los aparatos. Además, facilita la limpieza de la superficie.

1.2 General pictogramas


ENCENDIDO (Tensión)


APAGADO (Tensión)

ENCENDIDO se ilumina de color verde/ APAGADO (accionar presionando)

Equipotencialidad: Marca equipotencialidad, entre otros, el conductor de equipotencialidad en la caja del transformador de separación y asegura que la resistencia entre todos los materiales conductivos sea lo suficientemente pequeña

Conexión a conductor de protección:
Conductor que conecta a tierra los cuerpos de utilajes, componentes conductivos y borne de puesta a tierra

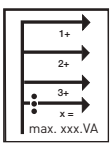
Ruedas conductivas:
Las ruedas conductivas son marcadas con un rayo o un punto amarillo.

Muévase solo con el brazo plegado

Utilice el asa para empujar

Siga las instrucciones de uso

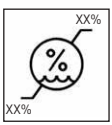
Corriente alterna



Potencia total:
La suma de las potencias, las cuales son dadas en cada uno de los enchufes no debe sobrepasar la potencia total.

Carga total (soporte de base):
max. carga total (= el total de las indicacjones de carga de todes les componentes del sistema). Por favor considere las etiquetas adhesivas correspondientes para las cargas permitidas.

Indicaciones de carga (componentes del sistema):
Por favor considere las etiquetas adhesivas correspondientes para las cargas permitidas.



Límite de la humedad

Indicaciones generales de advertencia:
El se encuentra en el zócalo de la toma corriente. La potencia total dada en la placa de características no se debe sobrepasar.

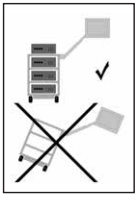
Solamente adecuado para las áreas internas.

Objeto pesado:
Se debe asegurar, que los portaaparatos móviles uni-cart, vexio-cart, pro-cart, duo-cart, classic-cart, compact-cart o endo-cart se deben levantar mínimo por dos personas para evitar lesiones.

Comercializados por

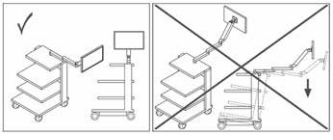
Ajuste de la fuerza de apriete (unidad de giro y basculación).

Ajuste de carga:
Describe el margen de carga así como el sentido de giro para el ajuste de carga.

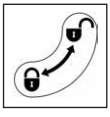


Riesgo de vuelco:
En soportes de aparatos móviles ha de controlarse necesariamente el orden de carga y descarga.

Función de frenado:
Informa sobre la colocación del brazo portante en caso de recepción del aparato e indica el sentido para la habilitación o bloqueo de la función de retención.



Posición de trabajo:
Este símbolo describe las posiciones de trabajo permitidas (de recha / izquierda) y advierte sobre un riesgo de vuelco existente al cambiar de lado.



Función de bloqueo:
Describe el sentido de bloqueo o la apertura de componentes.

Ningún empuje:
No esta permitido empujar el carro de aparatos sobre el mango por peligro de volteo.

1.3 Avisos de seguridad

Generalidades:

- ¡Solamente se deben poner en marcha los portaaparatos móviles, los cuales sus instalaciones de tensión de red fueron verificados y liberados por el personal experto clasificado!
- Asegúrese de que el transformador de aislamiento esté conectado solamente a una red de alimentación de corriente que tenga una conexión de protección del conductor que funcione adecuadamente, y que cumpla con los requisitos establecidos en las disposiciones según IEC 60364-7-710 2012-10 «Instalaciones eléctricas en edificios Apartado 7-710: Requisitos para instalaciones especiales o para salas destinadas a uso médico». En caso de duda, diríjase a una empresa eléctrica especializada o a un trabajador autorizado en sistemas hospi talarios.
- El personal (personal de servicio, o del hospital) que trabaje directa o indirectamente con un portaaparatos móvil, debe haber sido instruído!
- Los trabajos de ajuste deben efectuarse únicamente por personal especializado.
- Las reparaciones deben efectuarse únicamente por la empressa ITD GmbH.

Trabajo seguro con los carros para equipos:

- Solamente se podrá garantizar una desconexión segura de la red de alimentación cuando se haya extraído el enchufe de red de la toma.

Mando:

- En el caso de cualquier desplazamiento, deberá prestarse atención para no causar daños a personas u objetos!

Conexiones:

- Al conectar transformadores de separación en servicio de 115 V, en EE.UU. y Canadá ha de utilizarse un cable de conexión "Hospital Grade" y en Japón ha de utilizarse un cable de conexión opcional japonés.
- En la conexión a la regleta de toma de corriente múltiple, los conectores han de protegerse con mecanismos de bloqueo de extracción de conectores disponibles opcionalmente.
- A las tomas de corriente/líneas de alimentación solo se deben conectar dispositivos que cumplan los requisitos de IEC 60601-1 o que hayan sido ensayados según las normas IEC.
- ¡Los aparatos médicos adicionales con conector de equipotencialidad, deberán conectarse mediante la línea verde-amarrillo existente en el conector de equipotencialidad opcionalmente disponible!

- Atención: La potencia total dada en la placa de características no se debe sobrepasar. Por favor considere, que en la toma corriente múltiple existente no se deben conectar más tomas corrientes múltiples.

Carga:

- El peso total de los aparatos y accesorios en el portaaparatos móvil, no deberá exceder el peso de la carga admisible. (Véase la pegatina con las indicaciones de carga en soporte de base).
- ¡No se debe exceder la carga de superficie impresa en los componentes del sistema!
- ¡No se debe exceder la carga indicada en los elementos de montaje posterior (p.e. soporte para infusiones, brazos articulados)!

Protección contra infecciones:

- ¡Observar las prescripciones de higiene al efectuar trabajos de limpieza!
- ¡Por favor, entregue únicamente aparatos y equipamiento limpios y desinfectados a un técnico de servicio para trabajos de mantenimiento y reparaciones!

Protección del medio ambiente:

- ¡Elimine todos los restos o residuos de detergentes y desinfectantes sin causar perjuicios, de forma compatible con el medio ambiente!

2 Montaje

2.1 Integridad

Primero desempaquete el carro porta aparatos uni-cart, vexio-cart, pro-cart, duo-cart, classic-cart, compact-cart o endo-cart y verifique mediante el recibo de entrega la integridad del suministro.

2.2 Modo de carga

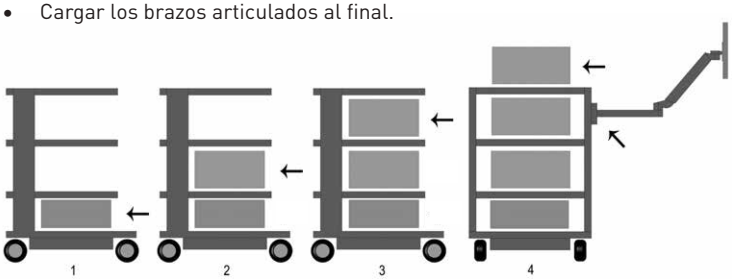
Coloque el carro porta aparatos uni-cart, vexio-cart, pro-cart, duo-cart, classic-cart, compact-cart o endo-cart a un nivel, superficie vertical. Coloque los equipos considerando la orden de carga en el carro. Su carga y montaje deben efectuarse únicamente cuando esté separado de la red. Para la sujeción de los aparatos individuales recomendamos el uso del accesorio ópcional (p.e. correa tensora).
La carga máxima de cada línea de producto está listada en el capítulo 10. Si la estabilidad no es suficiente, hay que caracterizar visible el carro según la 5° obligación de caracterización.

2.3 Orden de la carga

Asegúrese de que todos los aparatos depositados en el carro porta aparatos uni-cart, vexio-cart, pro-cart, duo-cart, classic-cart, compact-cart o endo-cart aqueden apoyados de forma segura mediante medidas apropiadas contra su deslizamiento, vuelco, caída, etc. (también durante el desplazamiento).
Es recomendable que se depositen todos los componentes pesados en el carro porta aparatos uni-cart, vexio-cart, pro-cart, duo-cart, classic-cart, compact-cart o endo-cart entre dos personas.
Observe que el punto de gravedad cambia en función de la carga.

Cargar el carro en el siguiente orden:

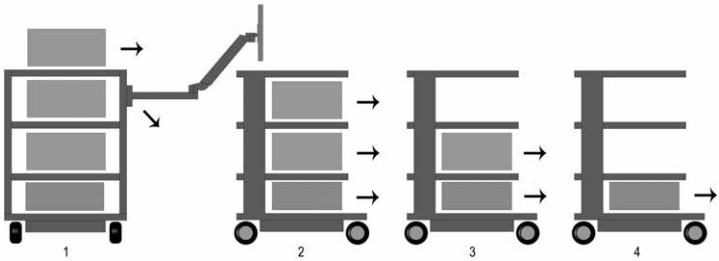
- Cargue al final los sistemas de brazo portante (rígidos, orientables, inclinables, con altura regulable, simples o múltiples).
- Cargar los brazos articulados al final.



Descargar el carro en el siguiente orden:

- Descargue primero los sistemas de brazo portante (rígidos, orientables, inclinables, con altura regulable, simples o múltiples).

- Descargar las bandejas y cajones desde arriba hacia abajo.



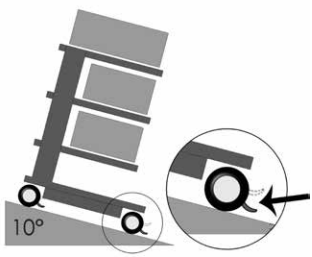
Además considere en el uso de un carro de aparatos (transporte) las indicaciones en el capítulo 4.

2.4 Peligro por inestabilidad mecánica

El sistema completo tiene que corresponder a los requerimientos según IEC 60601-1.

2.5 Ruedas

Los carros porta aparatos uni-cart, vexio-cart, pro-cart, duo-cart, classic-cart, compact-cart o endo-cart están dotados con ruedas guía gemelas con frenos. Antes de poner en servicio los carros porta aparatos uni-cart, vexio-cart, pro-cart, duo-cart, classic-cart, compact-cart o endo-cart, asegúrese de que los antichoques funcionen. Una vez alcanzada la posición de aparcado, así como en el caso de parada durante el transporte, es necesario accionar todos los frenos de rodillos (dispositivo de bloqueo de los rodillos) en los carros de equipo. En consecuencia es necesario liberar todos los frenos de rodillos antes de la puesta en movimiento o transporte.



Las ruedas deben verificarse cada 12 meses acerca de su seguridad así como el ajuste fijo y sin ranura del perno de fijación de las ruedas. Si se soltaran, contacte inmediatamente a su distribuidor.

2.6 Capacidad de carga

Es inadmisible exceder la capacidad de carga de los carros porta aparatos uni-cart, vexio-cart, pro-cart, duo-cart, classic-cart, compact-cart o endo-cart.
Por favor, observe la capacidad de carga máxima de los carros porta aparatos uni-cart, vexio-cart, pro-cart, duo-cart, classic-cart, compact-cart o endo-cart (véase párrafo 10).

2.7 Montaje / manejo

2.7.1 Bandejas

Las bandejas se pueden quitar y colocar en otra posición. Para hacer esto, saque los tornillos, coloque la bandeja en su nueva posición y vuelva a atornillarla. A continuación, controle la resistencia del conductor de toma de tierra.

2.7.2 Módulos de cajones

Los módulos de cajones (pro-cart) constan de un dispositivo de cierre.

En el pro-cart hay que tirar hacia arriba el mango de control en el panel frontal para aflojar el bloqueo.
Es posible separar los cajones cuando están extraídos.
La parte frontal consta de un spacio para el etiquetado (excepto pro-cart).
Cerrar el cajón para el transporte.

2.7.3 Transformador de separación

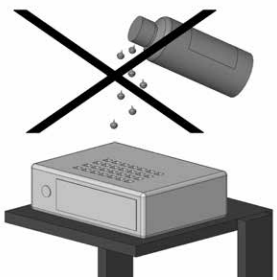
A continuación encontrará las instrucciones de uso del transformador de aislamiento. Está montado dentro de una caja por debajo del soporte de base. Su montaje se ha efectuado en la fábrica.

2.8 Montaje posterior de componentes del sistema

Una instalación posterior de los componentes del sistema ITD se debe realizar solamente por el personal expertosegún las pautas de las instrucciones de montaje suministradas. El sistema completo cambiado se debe verificar nuevamente según IEC 60601-1.

3 Seguridad eléctrica

3.1 Colocación de aparatos eléctricos



Por favor, tenga en cuenta que los aparatos eléctricos en los carros porta aparatos uni-cart, vexio-cart, pro-cart, duo-cart, classic-cart, compact-cart o endo-cart no deben mojarse en modo alguno.
En ningún caso, coloque productos que puedan perder líquidos por encima de aparatos eléctricos y/o regletas de enchufes en las que puede entrar líquido

3.2 Columna de energía (classic-cart, compact-cart, endo-cart) y columna vertical (uni-cart, vexio-cart, pro-cart)

Las regletas de enchufes o el sistema de cableado se encuentra en la columna de energía izquierda o derecha de classic-cart, compact-cart o endo-cart. En el caso de uni-cart y pro-cart en perfil vertical. Las regletas de tomas de corriente y el sistema de cableado se encuentran por debajo de la base en el caso del vexio-cart (el paso del cable se realiza aquí en conductos de cables disponibles opcionalmente, que podrán colocarse lateralmente en las columnas verticales).
Las columnas de energía se encuentran al lado izquierdo y derecho por detrás del riel vertical y facilitan la ubicación óptima de los cables de aparatos existentes. En ningún caso deberá taladrar las columnas de energía / vertical porque puede haber cables eléctricos en su interior.

3.3 Gases

No deben manejarse aparatos eléctricos cerca de gases, p.e. gas anestésico inflamable o similares. Para eso es responsable el usuario, también para el cumplimiento del IEC 60601-1-2.

3.4 Equipotencialidad (POAG)

Los carros porta aparatos uni-cart, pro-cart, classic-cart, compact-cart o endo-cart con transformador de separación requieren equipotencialidad. En el vexio-cart hay disponible opcionalmente un juego de enchufes de conexión equipotencial (POAG) sin transformador de separación. Para esto, conecte primero la línea equipotencial con el soporte de base de los carros porta aparatos uni-cart, vexio-cart, pro-cart, classic-cart, compact-cart o endo-cart y a continuación con el conector de equipotencialidad de la sala. Luego conecte los cables POAG con los pernos POAG de la toma corriente múltiple y los equipos.

3.5 Transformador de separación – corriente de puesta a tierra

El objetivo de los carros porta aparatos uni-cart, vexio-cart, pro-cart, duo-cart, classic-cart, compact-cart o endo-cart consiste en proporcionar una estación de trabajo práctica y móvil para instalaciones de electro-medicina. Para que el sistema médico eléctrico corresponda en su totalidad a la norma IEC 60601-1, la suma de las corrientes para la conexión a tierra no debe exceder el valor límite máximo de 0,5 mA. En el caso de que la suma de las corrientes para la conexión a tierra excediera dicho límite de tolerancia, deberá alimentarse el equipo através de un transformador de seguridad.

Si no hay ningún transformador de separación montado, no se deberá utilizar la caja de enchufe múltiple/sistema de enchufes auxiliar de los carros porta aparatos uni-cart, pro-cart, duo-cart, classic-cart, compact-cart o endo-cart para la conexión de aparatos que no cumplan los requisitos de las corrientes para la conexión de puesta a tierra según la norma IEC 60601-1.

Si consta de un transformador de separación, la toma entera de todos los aparatos conectados deberá hallarse dentro del valor nominal del transformador.

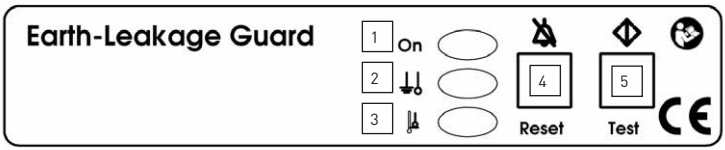
3.6 Controlador de aislamiento

Las descripciones siguientes sólo se aplican a los artículos montados en los soportes de aparatos "transformador de separación con controlador de aislamiento".

3.6.1 Panel de mando del controlador de aislamiento (ELG)

En los aparatos con controlador de aislamiento integrado, la electrónica de evaluación se halla incorporada en la carcasa de los transformadores, y el panel de mando e indicación se encuentra en una de las bases de colocación. Los dos componentes están conectados entre sí por medio de un cable de interfaz tendido en el perfil vertical.

Panel de mando del controlador de aislamiento ELG (opcional):



1 Piloto de control de red (verde)
2 Resistencia de aislamiento (amarillo)
3 Superación de temperatura (amarillo)
4 Tecla de confirmación de errores
5 Botón de test

3.6.2 Uso conforme a lo previsto

El controlador de aislamiento ELG sirve para vigilar la resistencia del aislamiento de aparatos o grupos de aparatos que se encuentran conectados a transformadores de separación a efectos de aislamiento de protección. Al mismo tiempo se vigila la temperatura del transformador. La evaluación es controlada por procesador.

3.6.3 Instrucciones de uso

Ponga el interruptor principal del transformador de separación en "ON" (conectado); al cabo de 5 s, el autotest del controlador ELG funciona automáticamente en el trasfondo.
Una vez finalizado el autotest, el controlador de aislamiento ELG está preparado para funcionamiento. El piloto de control de red (LED verde) luce permanentemente. Durante el funcionamiento, el test se ejecuta cada 8 horas de forma automática y cíclica, y también puede activarse manualmente con el botón de test.

En un test manual se ejecuta la siguiente rutina de prueba:

- Se simula un error de aislamiento, el LED amarillo de la resistencia de aislamiento luce permanentemente, un sonido de advertencia se emite permanentemente a 2,4 kHz, y el LED y el sonido se apagan al cabo de aprox. 5 s.
- A continuación se simula un error de temperatura, el LED amarillo luce permanentemente como señal de superación de temperatura, un sonido de advertencia se emite intermitentemente a 2,4 kHz, y el LED y el sonido se apagan al cabo de aprox. 5 s.

Un caso de error se detecta de la siguiente forma:

- Si se produce un error de aislamiento, el LED amarillo de la resistencia de aislamiento luce permanentemente, y un sonido de advertencia se emite permanentemente a 2,4 kHz. El sonido de advertencia puede resetearse con la tecla de confirmación de errores. El LED luce hasta que se subsana el error.
- Si el controlador de aislamiento se desconecta y el error no se subsana entretanto, la secuencia de arriba comienza desde el principio. Al producirse un error de aislamiento, cuando desaparece el mismo, la alarma acústica y visual permanece hasta que se confirma:
  Primera confirmación: se desconecta la alarma acústica
  Segunda confirmación: se desconecta la alarma visual

- Si se produce un error de temperatura, el LED amarillo luce permanentemente como señal de superación de temperatura, y un sonido de advertencia se emite intermitentemente a 2,4 kHz. El sonido de advertencia puede resetearse con la tecla de confirmación de errores, y el LED sigue encendido hasta que se subsana el error. Si se desconecta el controlador de aislamiento y el error no se subsana entretanto, la secuencia de arriba comienza desde el principio.
- Si aparecen simultáneamente el error de aislamiento y sobretemperatura, el error de aislamiento tiene siempre prioridad en la alarma acústica.

Autotest del controlador de aislamiento
Junto al autotest que se activa con el botón de test, el controlador de aislamiento ejecuta un autotest cíclico en un intervalo de aprox. 8 horas. El test también se ejecuta después de cada conexión. El autotest dura aproximadamente 5 segundos y no es detectable hacia el exterior. En caso de error, el piloto de control de red (LED verde) parpadea con una frecuencia de 0,5 Hz. La alarma acústica se emite con la misma frecuencia. Los mensajes de error no pueden resetearse con la tecla de confirmación de errores.

3.6.4 Instrucciones de uso

No intente reparar el aparato por sí mismo. Si se descubre un intento inadecuado de reparación, se extingue el derecho de garantía. Por motivos de seguridad, las reparaciones y trabajos de mantenimiento sólo se realizan por el fabricante.

Indicación:
En las instrucciones de uso de transformadores de separación y controladores de aislamiento, las cuales se adjuntan al producto por separado y son detalladas, encontrará datos técnicos e información adicional.

3.7 Dispositivo de enchufe de cables

El operario del carro porta aparatos uni-cart, vexio-cart, pro-cart, duo-cart, classic-cart, compact-cart o endo-cart sin transformador de separación montado deberá prestar atención a que la conexión por enchufe entre la regleta de toma de corriente múltiple del carro y los dispositi vos se trata de una unión solamente separable mediante el uso de herramientas. En nuestro programa de accesorios podrá acceder a una selección de cubiertas para las regletas de tomas de corriente múltiples.

3.8 Combinación de aparatos

Para la combinación de aparatos en el carro porta aparatos deberá observarse lo siguiente:

- Los equipos adicionales que se conecten a los interfaces análogos y digitales del aparato, deberán satisfacer de forma justificada sus respectivas especificaciones de la norma (p.e. IEC 60950 para aparatos de elaboración de datos y IEC 60601-1 para aparatos electro-médicos).
- Además, todas las configuraciones deberán satisfacer la versión vigente de la Norma IEC 60601-1. El que conecte aparatos adicionales en el componente de entrada o salida de señales, será un configurador de sistema y, por lo tanto, responsable para el cumplimento de la versión vigente de la Norma IEC 60601-1.

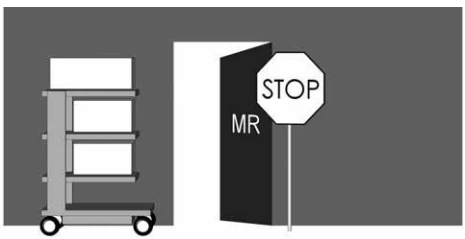
En el caso de preguntas consulte a su suministrador especializado local o al servicio técnico.

Nota:
También es valido para la adaptación de equipos en el circuito de suministro de corriente (por ejemplo: toma corriente múltiple).

3.9 CEM

La compatibilidad electromagnética de los aparatos electromédicos entre ellos que se encuentren situados sobre el carro, por el configurador del sistema completo. Antes de emplear otra combinación de aparatos, controle la compatibilidad electromagnética de los aparatos individuales entre sí.

La idoneidad de los carros para equipos específicos del cliente que se utilizan dentro de la zona de espín nuclear será comprobada por el cliente debido a la presencia de material ferromagnético.
¡Queda excluída cualquier responsabilidad de la ITD GmbH al respecto!



No se admite el empleo del carro porta aparatos con transformador de separación en un entorno con riesgo de explosión.

3.10 Desde los componentes del sistema y los accesorios excluidos de la verificación de la salida eléctrica

La empresa ITD GmbH excluye los siguientes componentes del sistema y accesorios de la verificación de la salida eléctrica

- regleta de enchufes múltiples sin conductor de protección adicional que no se conecta durante el montaje
- cables ME y cables de equipos añadidos
- chapas y/o cables POAG añadidos

- carros de aparatos y sistemas de soporte sin electrificación
- ajustes de altura y piezas añadidas en los ajustes de altura
- mangos, alfombrillas, cajones, módulos de cajones e instalaciones (soportes de botellas, cestas, soportes de cámaras, trípode de infusión, ...)
- transformadores de aislamiento sin necesidad de montaje, puesto que salen de ITD como piezas individuales
- fundas de teclado y pisos de colocación desplegables
- soportes para ordenador superiores e inferiores
- rodillos conducibles
- brazos portantes y soportes de monitores instalados
- Los circuitos eléctricos secundarios con supervisor de aislamiento están excluidos solamente de la verificación de la rigidez dieléctrica.

3.11 Seguridad mínima

La ITD GmbH no tiene conocimiento de ningún aparato y/o accesorios, que reduzca la seguridad mínima del sistema. Se deben emplear únicamente aparatos que no representen ningún peligro.
Si es preciso, compruébelo mediante una valoración de riesgos (ISO 14971).

4. Transporte

4.1 Transporte seguro sobre rodillos

Antes del uso móvil del carro porta aparatos, asegúrese de que:

- Todos los aparatos/productos colocados encima, estén bien sujetos y no puedan caerse.
- Todos los brazos articulados deben estar girados hacia dentro y asegurados.
- La línea de alimentación debe estar desconectada del punto de toma de corriente local.
- Se hayan soltado los frenos de las ruedas.

El carro porta aparatos debe moverse con una velocidad de peatón máxima de 6 km/h.
Al pasar por umbrales, cables y mangueras deberá reducirse la velocidad considerablemente.

Al pasar por rampas con una pendiente máxima de 10° deberá asegurarse de que pueda pararse el carro en cualquier momento.

Aunque se consideraron todas las medidas de cuidado para garantizar la estabilidad máxima de este producto, se deben considerar las desigualdades del suelo, los marcos de puerta del ascensor, los cables, etc., para evitar accidentes.
En general son validos los requerimientos del IEC 60601-1.

4.2 Transporte seguro por cargar

Los mangos no son para elevar el portaaparato móvil, sino son solamente para la función de deslizamiento. La elevación y carga de los portaaparatos móviles se deben realizar solamente por dos personas en los brazos de la base.

En general son validos los requerimientos del IEC 60601-1.

5 Ajuste de altura mecánico y eléctrico

Tanto para el ajuste de altura mecánico, mediante "presión de gas", como para el ajuste de altura electromecánico, mediante actuador lineal, deberá cumplirse la normativa de seguridad especial de conformidad con la directiva IEC 60601-1 "Riesgos mecánicos asociados a piezas móviles". Para lo cual se aplican las siguientes normas:

- Deberán tenerse en cuenta y cumplirse las distancias permitidas entre piezas móviles de conformidad con la directiva IEC 60601-1, tabla 20 (ISO 13857:2008).
- Los productos equipados con ajuste de altura se fabrican y entregan de fábrica conforme a las normas y respetando las distancias de seguridad permitidas. Dichas distancias varían en función del equipamiento o del intercambio de aparatos y / o componentes electro-mecánicos, lo cual puede conllevar un riesgo mecánico. La responsabilidad del cumplimiento de las distancias mínimas exigidas será del configurador del sistema en cuestión.
- El peso total de loa aparatos y accesorios montados no podrá exceder la carga del ajuste de altura máxima autorizada. Los excesos de peso conllevarán daños en el ajuste de altura y la pérdida de la garantía.

- El ajuste de altura mecánico, mediante presión de gas se libera energía almacenada. En sistemas no cargados, un accionamiento brusco e incontrolado del ajuste de altura puede producir lesiones y daños:
  - Para evitar las lesiones y daños, el ajuste de altura deberá colocarse en la posición más elevada antes del montaje y del desmontaje de los aparatos ("sin energía").
  - El sistema de brazo portante de altura variable "flexion-port" deberá fijarse y bloquearse en la posición más elevada ("sin energía") con la ayuda de la palanca de bloqueo (consulte las instrucciones de uso separadas para el "flexion-port" y las advertencias de peligro en el sistema del brazo portante).

- El accionamiento involuntario del ajuste de altura electromecánico mediante el botón manual podrá igualmente causar lesiones y daños:
  - Para evitar las lesiones y daños, el ajuste de altura deberá desconectarse de la corriente antes del montaje y del desmontaje de los aparatos.
  - Las tareas de servicio y mantenimiento en el área interna del ajuste de altura, es decir, en el área cubierta no accesible desde el exterior, situada dentro de la columna portante, sólo podrán ser realizadas por personal especializado e instruido en la materia.
  - Atención: antes de usar el ajuste de altura con la ayuda del botón remoto, deberá asegurarse de que no haya ninguna persona en el área de peligro.

6 Brazos portantes

6.1 Cableado

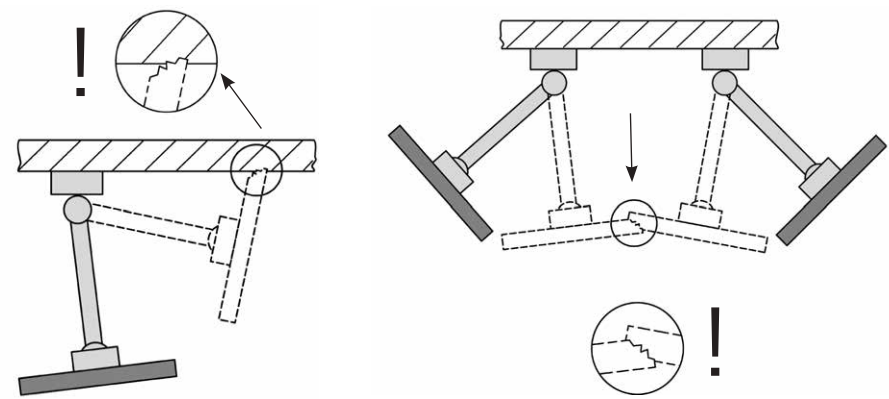
Tenga en cuenta las siguientes indicaciones:

- Al girar, para que no se produzcan daños en el cable o fallos en los aparatos, los cables han de tener unas dimensiones adecuadas.
- Los cables que cuelgan hacia abajo no deben utilizarse como asa en ningún caso.
- Controle que el material de montaje incluido se utilice adecuadamente según las instrucciones de montaje.
- Al girar los brazos han de comprobarse bucles de cables eventualmente existentes.

6.2 Giro horizontal

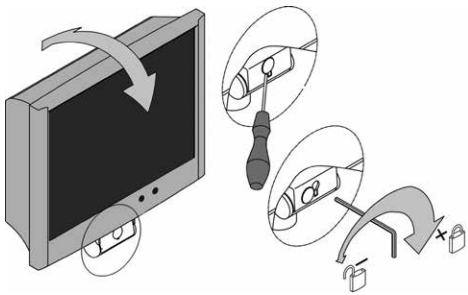
Asegúrese de que el margen de giro de componentes del sistema se adapte al tamaño de los aparatos y a las condiciones ambientales.

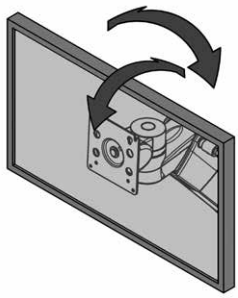
En el giro horizontal de los componentes del sistema con aparatos fijados encima, los mismos no deben colisionar con otros aparatos ni con otros componentes del sistema, ni tampoco con la pared. Las colisiones pueden provocar daños en los aparatos y lesiones en personas.



6.3 Inclinación / giro de los aparatos

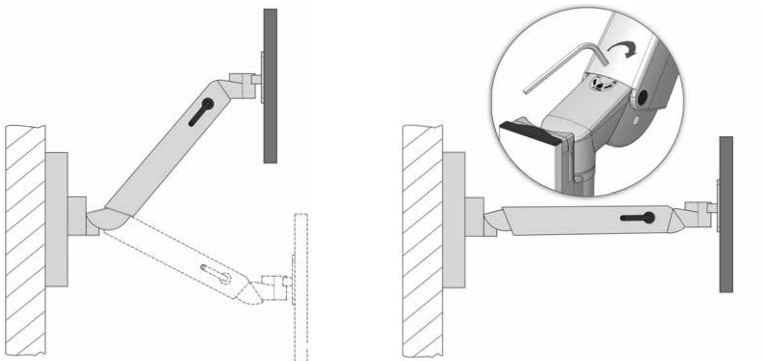
En componentes de sistema inclinables o giratorios tiene que comprobarse si la fuerza de apriete se adapta al aparato de fijación. Si el ajuste es erróneo, existe riesgo de vuelco del aparato. Por esa razón, el ajuste ha de realizarse de forma que la inclinación o el giro se realicen fácilmente, pero que la estabilidad se mantenga en cualquier posición deseada.





6.4 Sistemas de brazo portante con altura ajustable (flexion-port)

Al cargar los componentes de sistema con altura ajustable, se tiene que controlar necesariamente el peso total mínimo o máximo permitido. Asegúrese además de que el lugar situado debajo del sistema de brazo portante con altura variable (flexion-port) permanece libre por motivos de seguridad. Para poder ajustar el brazo portante a la carga, el mismo tiene que colocarse en posición horizontal.



6.5 Desmontaje y cambio de componentes de sistema y accesorios

Tan pronto como los componentes del sistema y los accesorios se desmonten o cambien de posición, antes tienen que retirarse los aparatos superpuestos. En este caso, si se trata del (des)montaje de los brazos de soporte con altura variable flexion-port, primero tienen que situarse en la posición superior y fijarse la sujeción (freno) (véase las pegatinas).

6.6 Uso conforme a lo previsto al maniobrar con los soportes de aparatos móviles

Al maniobrar con los soportes de aparatos móviles ha de procurarse que los brazos portantes existentes (giratorios, con altura ajustable) se desplacen hasta la posición de estacionamiento respectiva y se fijen eventualmente. En otro caso no puede garantizarse la estabilidad (véase el punto 2.4).

6.7 Manipulación de los sistemas de brazo de portante con altura ajustable (flexion-port) sobre la base de supervisión (doble)

En la manipulación de los sistemas de brazo de portante con altura ajustable (flexion-port) sobre la base de supervisión doble ha de procurarse siempre que el brazo giratorio encargado del cambio de lado esté siempre en paralelo con el lado frontal del carro (posición encajada). En ese caso, tenga en cuenta que sólo se permiten dos posiciones del brazo portante para el trabajo (derecha / izquierda) (véase "Posición trabajo" en el capítulo de "1.2 Explicación general de símbolos", página 79).

Si se cambia de lado, de la posición de trabajo izquierda a la derecha o viceversa, los elementos de bloqueo tienen que presionarse hacia abajo, y el brazo portante con altura variable tiene que girarse en el otro lado. En este caso ha de tenerse en cuenta que el flexion-port con el brazo giratorio está cerrado al cambiar de lado. En otro caso no puede garantizarse la estabilidad de vuelco (véase el punto 2.4).

7 Otros

7.1 Limpieza y Desinfección

Atención: Desconecte el sistema completo de la red antes de realizar una limpieza y/o desinfección.

Los carros de aparatos uni-cart, vexio-cart, pro-cart, duo-cart, classic-cart, compact-cart o endo-cart se deben limpiar con limpiadores universales comerciales (limpiadores neutrales).

Para la desinfección se pueden utilizar medios de desinfección comerciales, los cuales están permitidos para la desinfección de áreas y/o limpieza. Los medios de desinfección se deben utilizar y aplicar según las pautas del fabricante como puros desinfectantes.
Con los siguientes medios de desinfección por ejemplo realizó ITD pruebas:

Productos	**Fabricante**
Bacillol plus	Bode
Cleanisept Wipes	Dr. Schumacher
Mikrobac Tissues	Bode
Mikrozid Sensitive Wipes	Schülke
Terralin Protect	Schülke
Incidin PLUS	Ecolab
Incidin Foam	Ecolab

Cuando es necesaria una completa desinfección, se pueden desmontar los grupos constructivos por un experto, y en el estado desmontado se pueden desinfectar.

7.2 Reparaciones / Servicio

Se deberá limpiar y desinfectar el carto porta aparatos con un detergente apropiado antes de adoptar cualquier medida para su puesta en servicio, incluso en el caso de su reenvío para reparaciones! Recomendamos que se ponga en contacto con la ITD GmbH para cuestiones de servicio.

7.3 Condiciones del medio ambiente

Los carros porta aparatos uni-cart, vexio-cart, pro-cart, duo-cart, classic-cart, compact-cart o endo-cart han sido diseñados para el servicio habitual de hospitales y consultas médicas.

En uso

Temperatura ambient:	10° C hasta 40° C
Humedad del aire:	30 % hasta 75 %
Presión del aire:	700 hPa hasta 1060 hPa
Protección:	IP20

Transporte / Almacenamiento

Temperatura ambiente:	Entre -25 °C y 70 °C
Humedad del aire:	del 10 % al 95 %
Presión atmosférica:	Entre 500 hPa y 1200 hPa

7.4 Eliminación

Reciclaje separado de equipos eléctricos y electrónicos en conformidad con la directiva WEEE. (número de registro para Alemania: DE35464575).
La chatarra electrónica y eléctrica, la cual se vendió después del 13 de agosto de 2005, está marcada con el símbolo para el reciclaje separado de chatarra electrónica y eléctrica. Esto significa, que la chatarra en los países, en los cuales es valida la Directiva UE 2002/96/CE, hay que llevarla a la eliminación separada de residuos.

7.5 Piezas de recambio

Se deberán utilizar únicamente piezas de recambio admitidas por la ITD GmbH! En el soporte de base de su carro porta aparatos hay una pegatina con un número de pedido. Todos los números de pedido con las correspondientes piezas de recambio están archivados en ITD GmbH. Con esto podrá adquirir las piezas de recambio necesarias en ITD GmbH.

8 Accesorios

Vd. puede encontrar una amplia oferta de accesorios en nuestros catálogos o en la página web www.itd-cart.com (Información para comerciantes).

9 Mantenimiento

Los carros porta aparatos uni-cart, vexio-cart, pro-cart, duo-cart, classic-cart, compact-cart o endo-cart han sido diseñados y construídos para muchos años de utilización sin problemas. Controle la funcionabilidad de los siguientes componentes cada 12 meses para garantizar la seguridad.

Bandeja Monitor:

- Se gira y se inclina sin rozamientos y sin demasiado juego.

Bandejas:

- Verificar que el tornillo de sujeción esté apretado y que la bandeja esté puesta de forma recta y estable.

Ruedas:

- Verifique si los rodillos se pueden desplazar libremente, y si los frenos funcionan.
- Controlar si los 4 pivotes, que las soportan en la parte inferior de la base, así como las ruedas mismas, están asentadas en sus soportes de forma fija.
- En las ruedas conductivas, las superficies de rodadura tienen que estar exentas de suciedad a fin de garantizar su funcionamiento.

Regleta de enchufes:

- Verifique que el cable principal esté libre de daños y fijado correctamente.

Cajas de enchufe auxiliares:

- Verifique que el cable esté libre de daños y fijado correctamente.

Sistemas de brazo portante con altura ajustable flexion-port:

- El ajuste de la altura funciona suavemente, y la fuerza de elevación se adapta al peso del aparato.

Brazos portantes:

- El giro y la basculación funcionan perfectamente, sin demasiado juego.

Transformadores de separación:

- Control técnico de seguridad de transformadores de separación.

Número de serie:

- Comparar el número de serie del carro con los datos del manual del aparato.

Fusibles:

- Controlar si está dotado con los fusibles correctos.

Si durante este control surgiera algún problema, consúlte a su suministrador ITD GmbH inmediatamente.

10 Datos técnicos

10.1 Capacidad de carga uni-cart

- Soporte de base, carga total desde 50 kg / 110 lbs
- Bandeja 10 kg / 22 lbs
- Rack 20 kg / 44 lbs
- Cajón 3 kg / 6.6 lbs (interceptable: 10 kg / 22 lbs)
- Soporte para monitor 14 kg / 30.8 lbs
- Alfombrilla 3 kg / 6.6 lbs

10.2 Capacidad de carga vexio-cart

- Soporte de base, carga total 65 kg / 143 lbs
- Bandeja 15 kg / 33 lbs
- Cajón 3 kg / 6.6 lbs
- Soporte para monitor 14 kg / 30.8 lbs
- Alfombrilla 3 kg / 6.6 lbs

10.3 Capacidad de carga pro-cart

- Soporte de base, carga total 80 kg / 176 lbs
- Bandeja 20 kg / 44 lbs
- Cajón 15 kg + 3 kg / 33 lbs + 6.6 lbs
- Soporte para monitor 14 kg / 30.8 lbs
- Alfombrilla 3 kg / 6.6 lbs

10.4 Capacidad de carga duo-cart

- Soporte de base, carga total 80 kg / 176 lbs
- Bandeja 50 kg / 110 lbs (extraíble: 20 kg / 44 lbs)
- Cajón 3 kg / 6.6 lbs (interceptable: 20 kg / 44 lbs)
- Alfombrilla 3 kg / 6.6 lbs

10.5 Capacidad de carga compact-cart

- Soporte de base „Profi“, carga total 180 kg / 396 lbs
- Soporte de base „Economy“, carga total 150 kg / 330 lbs
- Bandeja 50 kg / 110 lbs
- Cajón 3 kg / 6.6 lbs
- Bandeja Monitor max. 35 kg / 77 lbs (según el tipo)
- Alfombrilla 3 kg / 6.6 lbs

10.6 Capacidad de carga classic-cart / endo-cart

- Soporte de base, carga total 150 kg / 330 lbs
- Bandeja 50 kg / 110 lbs (extraíble: 20 kg / 44 lbs)
- Cajón 3 kg / 6.6 lbs
- Bandeja Monitor max. 35 kg / 77 lbs (según el tipo)
- Alfombrilla 3 kg / 6.6 lbs

10.7 Capacidad de carga modul-port (portaaparatos fijo):

- Perfil portante, carga total según longitud 25-150 kg / 55-330 lbs
- Brazo portante (según modelo) max. 23 kg / 50.6 lbs

- Brazo orientable, simple max. 23 kg / 50.6 lbs
- Brazo orientable, doble max. 18 kg / 39.6 lbs
- Alojamiento de monitor con VESA 75/adaptación 100 max. 18 kg / 39.6 lbs
- Alojamiento de monitor con adaptador universal max. 14 kg / 30.8 lbs
- Alojamiento de monitor con adaptador de montaje superior en mesa max. 14 kg / 30.8 lbs
- Bandeja 10 kg / 22 lbs
- Cajón 3 kg / 6.6 lbs
- Soporte para teclado 5 kg / 11 lbs
- Alfombrilla 3 kg / 6.6 lbs

10.8 Capacidad de carga flexion-port (Sistemas de brazo portante con altura ajustable)

- flexion-port (selon de modèle) 3-10 kg / 6.6-22 lbs ou 8-14 kg / 17.6-30.8 lbs 11-20 kg / 22,4-44 lbs
- Unidad de giro y basculación / rotación 14 kg / 30.8 lbs
- Poste ("Down-Post") 10 kg / 22 lbs
- Alfombrilla 3 kg / 6.6 lbs

Dirección de contacto:

América del Norte	Europa
ITD Corporation	ITD GmbH - Office Unterhaching
50 RADO DR UNIT A	Gruenwalder Weg 13a
Naugatuck, CT 06770-2211, USA	82008 Unterhaching, Alemania
Tel: +1 203 714 67-00	Tel: +49 89 61 44 25 0
Email: sales.usa@itd-cart.com	Email: sales@itd-cart.com

China	Australia
ITD Medical Technology Products (Shanghai) Co., Ltd.	ITD Australia Pty Ltd Aviation Place 3
Section A, Room 101, 1st Floor	3043 Tullamarine, Victoria, Australia
11 South RiYing Road Pilot Free Trade Zoon	
Shanghai 200131, China	
Tel: +86 21 6442 5704	Tel: +61 3 9330 50 50
Email: s.pan@itd-cart.com	Email: s.oconnor@itd-cart.com

ITD GmbH es responsable de la veracidad del contenido.

Si tratta di un dispositivo medico di classe I ai sensi della direttiva europea 93/42/CEE relativa ai dispositivi medici (DDM), Allegato IX.

Il produttore dichiara che questo dispositivo è conforme alle esigenze fondamentali riguardanti l'Allegato VII DDM 93/42/CEE e documentato dalla marcatura CE.

Fabbricante:

ITD GmbH
Sportplatzstr. 3
84381 Johanniskirchen, Germania
Tel: + 49 89 61 44 25- 0
Fax: +49 89 61 44 25- 200
Email: sales@itd-cart.com

Vendita et Servizio:

America del Nord
ITD Corporation
50 RADO DR UNIT A
Naugatuck, CT 06770-2211, USA
Tel: +1 203 714 67-00
Email: sales.usa@itd-cart.com

Europa
ITD GmbH - Office Unterhaching
Gruenwalder Weg 13a
82008 Unterhaching, Germania
Tel: +49 89 61 44 25 0
Email: sales@itd-cart.com

Cina
ITD Medical Technology Products (Shanghai) Co., Ltd.
Section A, Room 101, 1st Floor
11 South RiYing Road
Pilot Free Trade Zoon
Shanghai 200131, Cina
Tel: +86 21 6442 5704
Email: s.pan@itd-cart.com

Australia
ITD Australia Pty Ltd
Aviation Place 3
3043 Tullamarine, Victoria, Australia
Tel: +61 3 9330 50 50
Email: s.oconnor@itd-cart.com

Lavoriamo costantemente per il perfezionamento dei nostri prodotti. In qualsiasi momento ci riserviamo il diritto di effettuare modifiche dell'ampiezza della consegna sul piano della forma, dell'attrezzatura e della tecnica.Sono vietati riproduzioni, duplicati o traduzioni, anche sotto forma di estratto, senza previa autorizzazione della ITD GmbH!

Tutti i diritti secondo la legge sul diritto d'autore sono riservati espressamente alla ITD GmbH.

Versione © 11/2018 Data di stampa 12/2018

Il presente manuale d'uso è valido per i prodotti:

Modello	Descrizione
CC.02xx.xxx / 03xx.xxx	Componenti di sistema e accessori compact-cart
CC.45xx.xxx / 50xx.xxx / 65xx.xxx	Carrelli porta-attrezzi compact-cart, 30 U – 40 U
CC.45xx.xxx / 50xx.xxx / 65xx.xxx	Componenti di sistema e accessori compact-cart
DC.42xx.xxx / 53xx.xxx / 64xx.xxx	Carrelli porta-attrezzi duo-cart, 21 U – 30 U
DC.40xx.xxx / 50xx.xxx / 60xx.xxx	Componenti di sistema e accessori duo-cart
EB.45xx.xxx / 50xx.xxx / 65xx.xxx	Carrelli porta-attrezzi compact-cart Economy
EC.04xx.xxx	Carrelli porta-attrezzi endo-cart, 30 U
GW.52xx.xxx / 53xx.xxx / 54xx.xxx	Carrelli porta-attrezzi classic-cart, 21 U – 40 U
GW.62xx.xxx / 63xx.xxx / 64xx.xxx	
GW.01xx.xxx / 02xx.xxx / 03xx.xxx	Componenti di sistema e accessori classic-cart
GW.04xx.xxx / 05xx.xxx / 06xx.xxx	
GW.07xx.xxx / 08xx.xxx	
GW.40xx.xxx / 41xx.xxx / 45xx.xxx	
GW.50xx.xxx / 51xx.xxx / 55xx.xxx	
GW.60xx.xxx / 61xx.xxx / 65xx.xxx	
GW.80xx.xxx / 98xx.xxx / 99xx.xxx	
HA.1xxx.xxx / 2xxx.xxx	Componenti di sistema e accessori flexion-port
HA.45xx.xxx / 5xxx.xxx	
HA.60xx.xxx / 65xx.xxx	
NT.20xx.xxx / 40xx.xxx / 41xx.xxx	Componenti di sistema e accessori vexio-cart
NT.50xx.xxx	Carrelli porta-attrezzi vexio-cart, 21 U – 50 U
PT.20xx.xxx / 40xx.xxx / 41xx.xxx	Componenti di sistema e accessori pro-cart
PT.50xx.xxx / PT.90xx.xxx	Carrelli porta-attrezzi pro-cart, 21 U – 50 U
RS.41xx.xxx/ 48xx.xxx / 49xx.xxx	Carrelli porta-attrezzi uni-cart, 21 U – 50 U
RS.00xx.xxx / 01xx.xxx / 02xx.xxx	Componenti di sistema e accessori uni-cart
RS.4xxx.xxx / 5xxx.xxx	
TS.03xx.xxx / 05xx.xxx	Componenti di sistema e accessori flexion-port

Il presente manuale d'uso è valido per i prodotti:

Modello	Descrizione
VS.53xx.xxx / 54xx.xxx / 63xx.xxx	Carrello armadio video classic-cart, 30 U – 40 U
VS.63xx.xxx	
VT.43xx.xxx	Carrello video con trasformatore di separazione pro-cart, 30 U
VT.45xx.xxx	Carrello video con trasformatore di separazione compact-cart, 40 U
VT.54xx.xxx / 64xx.xxx	Carrello video con trasformatore di separazione classic-cart, 40 U
VW.54xx.xxx / 64xx.xxx	Carrello video classic-cart, 40 U
ZV.94xx.xxx / 96xx.xxx / 97xx.xxx	Componenti di sistema e accessori generali
ZV.98xx.xxx / 99xx.xxx	

KD.7xxx.xxx / 8xxx.xxx / 9xxx.xxx	Carrelli porta-apparecchiature mobili personalizzati delle serie uni-cart, pro-cart, duo-cart, classic-cart, compact-cart e endo-cart
KU.0xxx.xxx – KU.9xxx.xxx	Carrelli porta-apparecchiature mobili personalizzati delle serie uni-cart, vexio-cart, pro-cart, duo-cart, classic-cart, compact-cart e endo-cart
OC.0xxx.xxx – OC.9xxx.xxx OC.1 – OC.999	
OM.0xxx.xxx – OM.9xxx.xxx	

Indice

1 Informazioni importanti

1.1 Impiego conforme alla destinazione ... 102
1.2 Spiegazione dei simboli ... 103
1.3 Avvertenze di sicurezza ... 105

2 Montaggio

2.1 Integrità ... 106
2.2 Carico ... 106
2.3 Ordine di carico ... 106
2.4 Pericolo dovuto a instabilità meccanica ... 107
2.5 Ruote ... 107
2.6 Sollecitazioni ... 107
2.7 Montaggio / comando ... 107
2.8 Aggiunta supplementare di componenti di sistema ... 108

3 Sicurezza elettrica
3.1 Ubicazione degli apparecchi elettrici ... 108
3.2 Colonna energetica (classic-cart, compact-cart, endo-cart) e colonna verticale (uni-cart, vexio-cart, pro-cart) ... 108
3.3 Gas ... 109
3.4 Compensazione di potenziale (POAG) ... 109
3.5 Transformatore di separazione – corrente di scarico ... 109
3.6 Controllore d'isolamento ... 109
3.7 Spina di collegamento per cavi ... 111
3.8 Combinazione di apparecchi ... 111
3.9 CEM ... 112
3.10 Esclusione dei componenti di sistema e degli accessori dal controllo elettrico di uscita ... 112
3.11 Sicurezza minima ... 113
4 Trasporto
4.1 Trasporto sicuro su rotelle ... 113
4.2 Trasporto sicuro durante il sollevamento ... 113
5 Spostamento verticale meccanico ed elettrico ... 113
6 Bracci portanti
6.1 Cavi ... 115
6.2 Rotazione orizzontale ... 115
6.3 Inclinazione / rotazione degli strumenti ... 115
6.4 Sistemi a bracci portanti con altezza regolabile (flexion-port) ... 116
6.5 Smontaggio e utilizzo diverso dei componenti del sistema e degli accessori ... 116
6.6 Utilizzo dei porta strumenti mobili conformemente alla loro destinazione d'uso durante le manovre 116
6.7 Utilizzo dei sistemi a bracci portanti ad altezza regolabile (flexion-port) sui supporti (doppi) del monitor ... 117
7 Varie
7.1 Pulizia e Disinfezione ... 117
7.2 Manutenzione / Prestazioni di assistenza ... 118
7.3 Condizioni ambientali ... 118
7.4 Entsorgung ... 118
7.5 Pezzi di ricambio ... 118
8 Accessori ... 118
9 Manutenzione ... 119
10 Dati tecnici
10.1 Portata uni-cart ... 120
10.2 Portata vexio-cart ... 120
10.3 Portata pro-cart ... 120
10.4 Portata duo-cart ... 120
10.5 Portata compact-cart ... 120
10.6 Portata classic-cart / endo-cart ... 121
10.7 Portata modul-port ... 121
10.8 Portata flexion-port ... 121

1 Informazioni importanti

Tutti i prodotti fabbricati dalla ITD GmbH sono concepiti per una lunga durata di servizio senza guasti. Lo sviluppo, la costruzione e il prodotto sono certificati secondo la norma ISO 13485.

Questa è la premessa per:
- alta qualità per una lunga durata di esercizio
- comando semplice, sicuro e ergonomico
- design funzionale
- ottimizzazione in vista dell'applicazione

I prodotti corrispondono alle esigenze previste nelle legge sui dispositivi medici e portano il marchio CE.

- Leggere attentamente il presente manuale d'uso in modo da familiarizzare gradulalmente con le varie funzioni.
- In caso di informazioni o dubbi, contattare il produttore.
- I porta-strumenti mobili sono previsti solo per un utilizzo idoneo.
- Conservare le istruzioni per tutta la durata di utilizzo del prodotto.

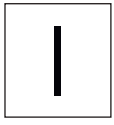
Il configuratore di sistema è tenuto a mettere a disposizione del cliente finale il manuale d'uso per la completa configurazione.
Far attenzione che il configuratore di sistema è responsabile del rispetto delle esigenze previste dalle norme CEI 60601-1 e dalla norma CEM CEI 60601-1-2 nella versione rispettivamente in vigore!

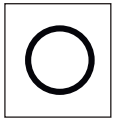
1.1 Impiego conforme alla destinazione

I carrelli porta-attrezzi della ITD GmbH servono:
- per l'alloggiamento di dispositivi medicali e dispositivi controllati secondo IEC ai sensi dei dati di carico ammessi e in conformità ai requisiti della versione della IEC 60601-1 attualmente valida.
- per l'allacciamento e la distribuzione di tensioni di rete dalle prese di corrente locali e di collegamenti per dati.
- al fissaggio degli accessori.

I carrelli porta-attrezzi possono essere posizionati in qualsiasi luogo del locale, prima e dopo l'applicazione, per permettere all'utente di lavorare in modo comodo e professionale.

1.2 Generale spiegazione dei simboli


"ON" (tensione) si illumina in verde


"OFF" (tensione)

"ON" si illumina in verde/"OFF" (azionamento a pressione)

Compensazione del potenziale: indica, in particolare, le prese di compensazione di potenziale sul carter del trasformatore di separazione e garantisce che la resistenza tra tutti i materiali conduttori sia sufficientemente bassa.

Collegamento del conduttore di protezione:
conduttore che collega i corpi dei mezzi di utilizzo, dei pezzi conduttori, dei morsetti di messa a terra principale e la terra.

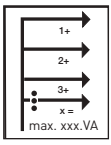
Ruote conduttricio:
Le rotelle conduttrici sono contrassegnate con il simbolo del lampo o da un punto giallo.

Spostare solo con braccio ripiegato

Utilizzare la maniglia per spingere

Attenersi al manuale d'uso

Corrente alternativa



Potenza totale:
La somma delle potenze trasmesse ai singoli ingressi non può superare la potenza totale.

Portata totale del sostegno di base:
Portata totale massima (= somma dei valori di carico di tutti i singoli componenti di sistema). Per i carichi ammissibili è necessario osservare la corrispondente etichetta.

Indicazioni di sollecitazione (Componenti di sistema):
Per i carichi ammissibili è necessario osservare la corrispondente etichetta.

Limite di umiditá

Avvertenze generali:
Applicabile alla multipresa. La potenza totale indicata sulla targhetta dati non può essere superata.

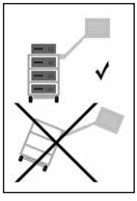
Adatto solo per spazi interni.

Oggetti pesanti:
Per evitare infortuni, devono essere almeno due le persone addette al sollevamento dei porta-strumenti mobili uni-cart, vexio-cart, pro-cart, duo-cart, classic-cart, compact-cart o endo-cart.

Distribuito da

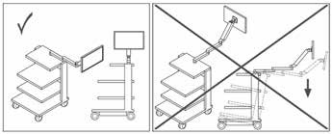
Regolazione della forza di bloccaggio (dispositivo girevole orientabile.

Regolazione del carico:
Descrive l'area di carico e il senso di rotazione per la regolazione del carico.

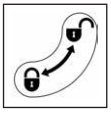


Pericolo di ribaltamento:
Quando si utilizza il porta strumenti mobile, è necessario prestare attenzione alla sequenza delle operazioni di carico e scarico.

Funzione frenante:
Fornisce informazioni sul posizionamento del braccio portante in caso di rimozione degli strumenti e indica la direzione per il rilascio o il blocco della funzione di arresto.



Posizione di lavoro:
Questo simbolo descrive le posizioni di lavoro consentite (lato destro / lato sinistro) e segnala il pericolo di ribaltamento quando si cambia lato.



Funzione di blocco:
Indica il senso di chiusura o apertura dei componenti.

Non trascinare:
Il trascinamento del carrello medicale mediante la maniglia non è indicato, a causa del rischio di ribaltamento.

1.3 Avvertenze di sicurezza

Generale

- È indispensabile che entrino in funzione solo porta-strumenti mobili con dispositivi per la tensione di rete testati e rilasciati da personale qualificato.
- Assicurarsi che il trasformatore di separazione sia collegato soltanto a una rete elettrica dotata di un conduttore di protezione funzionante conforme alle disposizioni previste dalla norma IEC 60364-7-710 2012-10 "Impianti elettrici per edifici Parte 7-710 Requisiti per impianti o locali particolari - Locali adibiti a uso medico". Per qualsiasi dubbio si prega di rivolgersi a un'azienda specializzata in artigianato elettronico oppure a un operatore autorizzato dell'ospedale.
- Tutto il personale (ospedaliero e di servizio) che lavora direttamente o indirettamente con i carrelli porta-attrezzi deve essere istruito!
- Gli interventi di regolazione devono essere eseguiti unicamente de personale specializzto. Le riparazioni devono essere effettuati dalla società ITD GmbH.

Lavorare in sicurezza con i carrelli medicali:

- La separazione dalla rete di alimentazione è garantita solo se la spina è stata tolta dalla presa.

Comando

- Ad ogni spostamento, far attenzione che nessuno venga ferito e nessun oggetto danneggiato!

Collegamenti

- Per il collegamento di trasformatori di separazione con tensione d'esercizio di 115V, nei paesi come gli USA e il Canada, si deve utilizzare un cavo di collegamento di tipo ospedaliero. In Giappone si deve utilizzare il cavo di collegamento in vendita opzionale.
- In caso di collegamento ad una presa multipla, le spine devono essere fissate per mezzo di dispositivi antiestrazione disponibili su richiesta.
- Alle prese/ai cavi di allacciamento possono essere collegati solo dispositivi conformi ai requisiti della IEC 60601-1 o controllati secondo IEC.
- Gli apparecchi medici supplementari con spine di collegamento per la compensazione del potenziale devono essere collegati tramite un conduttore giallo-verde sulle prese di collegamento di compensazione del potenziale disponibili a scelta!

- Attenzione: non superare la potenza totale riportata sulla targhetta dati. Verificare che alla multipresa in dotazione non sia allacciata nessun'altra presa.

Sollecitazioni

- Il peso totale degli apparecchi e degli accessori posizionati sui carrelli porta-attrezzi non deve superare il peso del carico autorizzato (cf. autoadesivo di sollecitazione sul telaio).
- La sollecitazione di superficie stampata sui componenti di sistema non deve essere superata!
- Il carico indicato sulle periferiche (ad es. stativo per infusione, braccio articolato) non deve essere superato!

Protezione contro infezioni

- Durante i lavori di pulizia rispettare le norme relative all'igiene!
- Fornire ai tecnici solo apparecchi o attrezzature pulite e disinfettate al momento dei lavori di manutenzione e riparazione!

Protezione dell'ambiente

- Smaltire tutti i resti di detergenti e di disinfettanti o i residui non inquinanti rispettando l'ambiente!

2 Montaggio

2.1 Integrità

Disimballare i carrelli porta-attrezzi uni-cart, vexio-cart, pro-cart, duo-cart, classic-cart, compact-cart o endo-cart e, tramite la bolla di consegna allegata all'ordine, controllare se tutte le parti ordinate sono a posto.

2.2 Carico

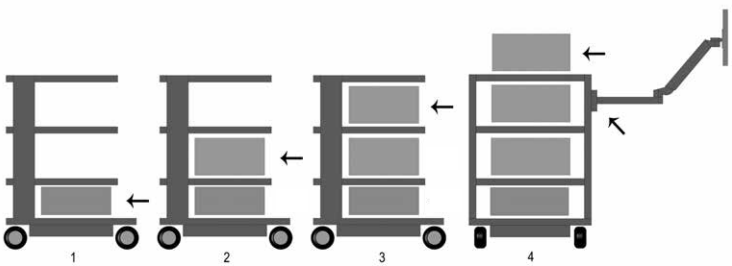
Posizionare il carrello porta-attrezzi uni-cart, vexio-cart, pro-cart, duo-cart, classic-cart, compact-cart o endo-cart su una superficie piana e orizzontale. Disporre gli apparecchi nel carrello rispettando l'ordine di carico. Il carico e il montaggio devono avvenire solo se il carrello è scollegato dalla rete elettrica. Per la sicurezza dei singoli apparecchi si consiglia di utilizzare gli accessori optional (ad esempio cinghia di tensionamento).
Il carico massimo per ogni linea di prodotti è riportato nel capitolo 10. Se la stabilità non doves se essere sufficiente, il carrello dovrà essere contrassegnato in modo riconoscibile con l'obbligo di etichettatura 5°.

2.3 Ordine di carico

Assicurarsi, prendendo misure adeguate (anche durante lo spostamento), che tutti gli attrezzi installati sul carrello uni-cart, vexio-cart, pro-cart, duo-cart, classic-cart, compact-cart o endo-cart non siano in condizione di scivolare, oscillare, cadere per terra o altro.
Si consiglia di procedere alla sistemazione di tutti i pezzi pesanti sul carrello porta-attrezzi uni-cart, vexio-cart, pro-cart, duo-cart, classic-cart, compact-cart o endo-cart con l'aiuto di due persone. Tener conto del centro di gravità che varia a seconda del carico.

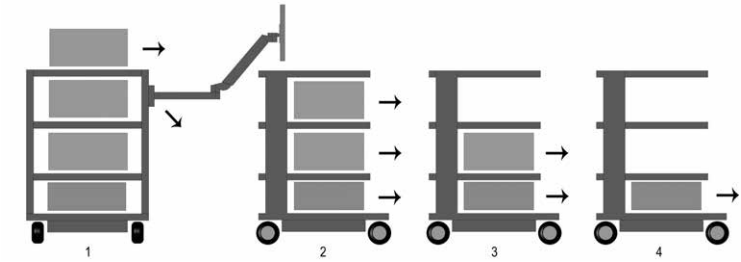
Il carrello deve essere caricato osservando l'ordine seguente:

- Caricare i sistemi a braccio portante (fisso, orientabile, inclinabile, regolabile in altezza, semplice o multiplo).
- Caricare per ultimo il braccio telescopico.



Il carrello deve essere scaricato osservando l'ordine seguente:

- Prima, scaricare i sistemi a braccio portante (fisso, oscilla bile, inclinabile, regolabile in altezza, semplice o multiplo).
- Scaricare i ripiani e i cassetti dall'alto verso il basso.

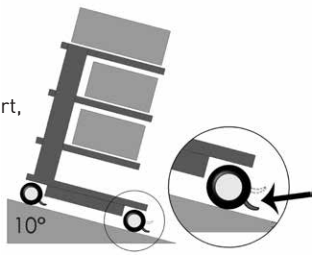


In caso di impiego di un carrello medicale (con trasporto), considerare inoltre le avvertenze contenute nel capitolo 4.

2.4 Pericolo dovuto a instabilità meccanica

L'intero sistema deve essere conforme ai requisiti di CEI 60601-1.

2.5 Route



Sui carrelli porta-attrezzi uni-cart, vexio-cart, pro-cart, duo-cart, classic-cart, compact-cart o endo-cart si trovano ruote doppie con un freno. Prima della messa in funzione dei carrelli portaattrezzi uni-cart, vexio-cart, pro-cart, duo-cart, classic-cart, compact-cart o endo-cart, assicurarsi che i freni di bloccaggio funzionino bene. Una volta raggiunta la posizione di stazionamento e per mantenerla dopo il trasporto, è necessario azionare tutti i freni delle ruote del carrello medicale (arpionismo rotella). Analogamente, prima di effettuare il movimento o il trasporto è necessario rilasciare tutti i freni.

Controllare ogni 12 mesi la sicurezza delle ruote di spostamento. Se rischiano di aprirsi, contattare immediatamente il fornitore.

2.6 Sollecitazioni

È vietato superare la portata dei carrelli porta-attrezzi uni-cart, vexio-cart, pro-cart, duo-cart, classic-cart, compact-cart o endo-cart.
È vietato superare la portata dei carrelli porta-attrezzi uni-cart, vexio-cart, pro-cart, duo-cart, classic-cart, compact-cart o endo-cart (cf. sezione 10).

2.7 Montaggio / comando

2.7.1 I ripiani

I ripiani possono essere sollevati o posizionati in un altro luogo. Per effettuare ciò allentare le viti, posizionare il ripiano nella nuova posizione e avvitare nuovamente le viti. Verificare la resistenza del conduttore di protezione.

2.7.2 Cassetti

I blocchi dei cassetti (pro-cart) sono provvisti di un dispositivo di bloccaggio.

In pro-cart la manopola di comando sul pannello anteriore deve essere tirata verso l'alto, per sbloccare il meccanismo di bloccaggio.

Una volta aperto, è possibile sganciare i cassetti.
Una linguetta d'iscrizione può essere fissata sul lato anteriore (eccetto pro-cart).
Richiudere il cassetto durante il trasporto.

2.7.3 Trasformatore di separazione

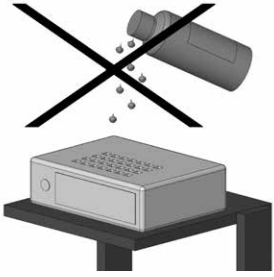
Seguire le istruzioni per l'uso del trasformatore di separazione. È montato su un carter sotto la base del telaio. Questo montaggio è effettuato dalla fabbrica.

2.8 Aggiunta supplementare di componenti di sistema

Una successiva applicazione di componenti di sistema ITD può essere eseguita solo da personale qualificato in base alle disposizioni delle istruzioni di montaggio in dotazione. Tutto il sistema modificato deve essere nuovamente verificato in conformità con CEI EN 60601-1.

3 Sicurezza elettrica

3.1 Ubicazione degli apparecchi elettrici



Tener conto del fatto che gli apparecchi elettrici che si trovano nel carrello porta-attrezzi uni-cart, vexio-cart, pro-cart, duo-cart, classic-cart, compact-cart o endo-cart non devono essere bagnati. Non poggiare in nessun caso apparecchi che potrebbero perdere liquidi sopra gli apparecchi elettrici aperti verso l'alto.

3.2 Colonna energetica (classic-cart, compact-cart, endo-cart) e colonna vertical (uni-cart, vexio-cart, pro-cart)

Il blocco multiprese o il sistema di cablaggio si trova nella colonna energetica di sinistra o di destra dei carrelli porta-attrezzi classic-cart, compact-cart o endo-cart, per i carrelli uni-cart e pro-cart isi trovano nella colonna verticale. In vexio-cart, le multiprese e i sistemi di cablaggio si trovano sotto la base (i cavi passano qui attraverso appositi condotti optional, applicati lateralmente sul montante verticale).

Le colonne energetiche si trovano a sinistra e a destra dietro il profilo verticale e permettono uno srotolamento ottimale dei cavi degli apparecchi esistenti. Non perforare in nessun caso le colonne energetiche, in quanto dei cavi conduttori di corrente possono trovarsi all'interno.

3.3 Gas

Se vengono azionati apparecchi elettrici, tale operazione non deve avvenire in prossimità di gas, ad esempio gas anestetici infiammabili o simili. Di questo è ritenuto responsabile l'utente, così come per l'osservanza di CEI 60601-1-2.

3.4 Compensazione di potenziale (POAG)

Con i carrelli porta-attrezzi uni-cart, pro-cart, classic-cart, compact-cart o endo-cart con trasformatore di separazione, è necessaria una compensazione di potenziale. Con vexio-cart è possibile avere come optional un set di compensazione del potenziale senza trasformatore di isolamento. Per effettuare ciò, collegare il cavo di POAG alla base dei carrelli porta-at trezz uni-cart, vexio-cart, pro-cart, classic-cart, compact-cart o endo-cart e, poi, alla presa di POAG della stanza. Collegare, inoltre, i cavi d'alimen-tazione di POAG al perno di POAG dell'apparecchio.

3.5 Trasformatore di separazione – corrente di scarico

Lo scopo dei carrelli porta-attrezzi uni-cart, vexio-cart, pro-cart, duo-cart, classic-cart, compact-cart o endo-cart è fornire una stazione di lavoro pratica e mobile per le installazioni elettro-mediche. Per far sì che la totalità del sistema medico elettrico rispetti la norma CEI 60601-1-1, la sommadelle correnti di scarico a terra non deve superare il valore massimo di 0,5 mA. Se la somma delle correnti di scarico a terra dovesse superare questo limite di tolleranza, l'installazione dovrebbe essere alimentata da un trasformatore di separazione di sicurezza.

Se non è montato alcun trasformatore di separazione, la presa multipla / il sistema di prese ausiliari dei carrelli porta-attrezzi uni-cart, pro-cart, duo-cart, classic-cart, compact-cart o endo-cart non devono essere utilizzati per i collegamenti di apparecchi che non rispettano le esigenze di corrente di scarico conformemente alla norma IEC 60601-1.

Se un trasformatore di separazione è montato, la totalità della potenza consumata di tutti gli apparecchi collegati deve rispettare il valore nominale del trasformatore.

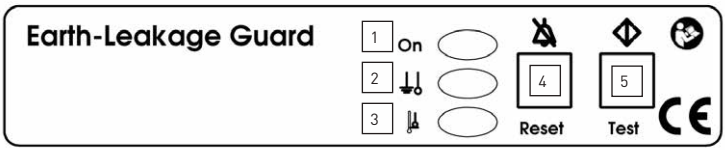
3.6 Controllore d'isolamento

Quanto illustrato di seguito vale solamente per l'articolo "Trasformatore d'isolamento" inglobato nell'alloggiamento.

3.6.1 Pannello operatore del controllore di isolamento (ELG)

I dispositivi con trasformatore di isolamento hanno il sistema elettronico di elaborazione integrato nella carcassa del trasformatore, il pannello operatore e il display si trovano in uno dei ripiani. I due componenti sono collegati tra loro tramite un cavo interfaccia posato in un profilo verticale.

Pannello operatore del controllore d'isolamento (facoltativo):



1 Spia di rete (verde)
2 Resistenza d'isolamento (gialla)
3 Superamento della temperatura (giallo)
4 Pulsante di conferma errori
5 Pulsante di test

3.6.2 Utilizzo conforme

Il controllore d'isolamento ELG consente di monitorare la resistenza d'isolamento di macchinari o gruppi di macchinari collegati a trasformatori d'isolamento per garantire una protezione differenziale. Parallelamente viene monitorato l'andamento della temperatura del trasformatore. L'analisi è controllata dal processore.

3.6.3 Istruzioni per l'uso

Se l'interruttore principale del trasformatore d'isolamento viene impostato su "ON", entro 5 secondi viene automaticamente eseguito l'auto-test in background del controllore d'isolamento.
Al termine dell'auto-test, il controllore d'isolamento ELG è pronto all'uso.
La spia di rete (LED verde) sarà fissa. Il test viene eseguito autonomamente ogni 8 ore di funzionamento e può essere, inoltre, avviato manualmente con l'apposito pulsante test.

Il test manuale implica l'esecuzione della seguente routine di controllo:

- Viene simulato un errore di isolamento, il LED giallo della resistenza d'isolamento si accende e resta acceso, parte un segnale di avvertimento costante a 2,4 kHz.; il tutto cessa dopo circa 5 s.
- Viene quindi simulato un errore di temperatura, il LED giallo del segnale di superamento della temperatura si accende e resta acceso, parte un segnale acustico pulsante di avvertimento a 2,4 kHz.; il tutto cessa dopo circa 5 s.

L'occorrenza di un errore si riconosce per le seguenti ragioni:

- Se si verifica un errore di isolamento, si accende e resta acceso il LED giallo della resistenza d'isolamento e viene emesso un segnale acustico costante di avvertimento a 2,4 kHz. Il segnale acustico di avvertimento può essere resettato con il pulsante di conferma errori. Il LED resta acceso sin tanto che l'errore non viene corretto.
- Se il controllore d'isolamento viene spento senza aver prima rimosso l'errore, la suddetta routine viene ripetuta dall'inizio. Al verificarsi di un errore di isolamento, l'allarme acustico e visivo persistono fino alla conferma:

  Prima conferma: si spegne l'allarme acustico
  Seconda conferma: si spegne l'allarme visivo

- Se si verifica un errore di temperatura, si accende e resta acceso il LED giallo per notificare il superamento della temperatura e viene emesso un segnale acustico pulsante di avvertimento a 2,4 kHz. Il segnale acustico di avvertimento può essere resettato con il pulsante di conferma errori, mentre il LED resta acceso sino alla eliminazione dell'errore. Se il controllore d'isolamento viene spento senza aver prima rimosso l'errore, la predetta routine viene ripetuta dall'inizio.
- Se l'errore d'isolamento si verifica contemporaneamente all'errore di temperatura, il segnale acustico darà priorità all'errore d'isolamento.

Auto-test del controllore d'isolamento

Il controllore d'isolamento oltre all'auto-test lanciato tramite il pulsante test, esegue un auto-test ogni 8 ore circa. Il test viene eseguito subito dopo l'accensione.
L'auto-test dura circa 5 secondi e non si nota. In caso d'errore, la spia di rete (LED verde) lampeggia con una frequenza di 0,5 Hz. Contemporaneamente risuona anche l'allarme acustico. I messaggi d'errore non possono essere resettati con il pulsante di conferma errori.

3.6.4 Eliminazione dei disturbi

Non tentare mai di riparare l'apparecchio da soli. Tutti gli interventi non qualificati di riparazione comportano la decadenza della garanzia. Le riparazioni e i lavori di manutenzione devono essere eseguiti esclusivamente dal produttore per ragioni di sicurezza.

Nota:
Per gli altri dati tecnici e maggiori informazioni si rimanda al manuale di istruzioni per l'uso dei trasformatori d'isolamento e controlli d'isolamento fornito con il prodotto.

3.7 Spina di collegamento per cavi

L'utente dei carrelli porta-attrezzi uni-cart, vexio-cart, pro-cart, duo-cart, classic-cart, compact-cart o endo-cart senza trasformatore di separazione utilizzato deve verificare che la spina di collegamento dei cavi tra la ciabatta multipresa del carrello e gli apparecchi sia scollegabile solo con gli appositi utensili. Nel nostro programma d'accessori è presente una selezione di coperchi per ciabatte multipresa.

3.8 Combinazione di apparecchi

Per la combinazione di apparecchi sul carrello porta-attrezzi, rispettare quanto segue:

- Gli attrezzi supplementari che sono collegati alle interfacce analogiche o numeriche dell'apparecchio devono rispettare le specifiche EN corrispondenti (ad es. CEI 60950 per gli apparecchi di trattamento dei dati e CEI 60601-1 per gli apparecchi elettro-medici).
- Inoltre, tutte le configurazioni devono rispettare la versione valida della norma CEI 60601-1. Chiunque collega degli apparecchi supplementari all'estremità d'entrata o di uscita di segnali è configuratore di sistema ed è quindi responsabile che la versione valida della norma CEI 60601-1 sia rispettata.

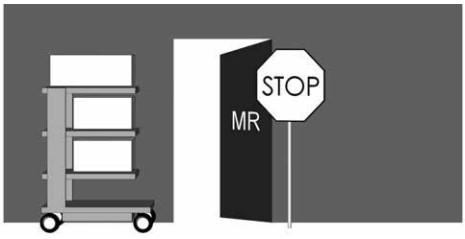
In caso di richiesta di informazioni, contattare il distributore locale o l'assistenza tecnica.
Nota:
Valido anche per l'adattamento di apparecchi nel circuito di corrente di alimentazione (ad esempio: presa multipla).

3.9 CEM

La compatibilità elettromagnetica reciproca degli apparecchi elettro-magnetici che si trovano uno sotto l'altro sul carrello deve essere verificata dal configuratore dell'intero sistema. Prima dell'utilizzo medico di un'altra combinazione di apparecchi, verificare la compatibilità elettromagnetica reciproca dei diversi apparecchi.

I carrelli medicali personalizzati, che vengono utilizzati all'interno di ambienti in cui si effettuano risonanze magnetiche, a causa della presenza di materiali ferromagnetici, devono essere controllati dal cliente per quanto riguarda l'idoneità all'uso.

ITD GmbH esclude tutta la responsabilità da questo punto di vista!



L'utilizzo del carrello porta-attrezzi con trasformatore di separazione all'interno di un ambiente esplosivo è vietato.

3.10 Esclusione dei componenti di sistema e degli accessori dal controllo elettrico di uscita

ITD GmbH effettua l'esclusione dei seguenti componenti di sistema e accessori dal controllo elettrico di uscita:

- prese multiple senza conduttore di protezione supplementare, che non vengono cablate durante il montaggio
- collegamenti ME e linee di apparecchiature presenti
- piastre o cavi per la compensazione del potenziale presenti

- carrelli medicali e sistemi di supporto senza elettrificazione
- spostamenti verticali e parti meccaniche necessarie a tali regolazioni
- maniglie, mousepad, cassetti, scomparti estraibili ed applicazioni (porta-flaconi, cestini, supporti telecamera, piantane per fleboclisi, ecc.)
- trasformatori di isolamento non montanti ma che escono da ITD come pezzo singolo
- porta-tastiere e ripiani di supporto estraibili
- supporti calcolatori sopra e sotto
- rotelle conduttive
- montaggio bracci portanti e agganci per monitor
- I circuiti secondari con controllore d'isolamento sono esclusi solo dal controllo della rigidità dielettrica.

3.11 Sicurezza minima

ITD GmbH non conosce alcun apparecchio, alcun accessorio, che diminuisce la sicurezza minima del sistema. Utilizzare solo apparecchi che non rappresentano alcun pericolo. All'occorrenza, deve essere chiarito alla luce di un'analisi dei rischi (ISO 14971).

4. Trasporto

4.1 Trasporto sicuro su rotelle

Durante lo spostamento del carrello assicurarsi che:

- tutti gli attrezzi / prodotti siano protetti per evitare cadute.
- tutti i bracci articolati siano ripiegati e fissati.
- la spina sia tirata dalla presa.
- i freni delle ruote sia liberi.

Il carrello porta-attrezzi può essere spostato solo con una velocità massima di 6 km/h. Se si trasportano traverse, cavi o tubi, è necessario diminuire la velocità.

In caso di rampe con una pendenza massima di 10° assicurarsi che il carrello porta-attrezzi possa essere sempre fermato in qualsiasi momento.

Benché siano state rispettate tutte le misure precauzionali per garantire la massima stabilità di questo prodotto, per evitare incidenti è necessario prestare attenzione a eventuali difetti di planarità del pavimento, ai telai delle porte degli ascensori, ai cavi, ecc.

Sostanzialmente valgono i requisiti di CEI 60601-1.

4.2 Trasporto sicuro durante il sollevamento

Le maniglie non servono a sollevare il porta-strumenti mobile, ma hanno una semplice funzione di scorrimento. Il sollevamento e il trasporto dei porta-strumenti mobili può avvenire solo tramite due persone che afferrano le barre.

Sostanzialmente valgono i requisiti di CEI 60601-1.

5 Regolazione in altezza

Sia per lo spostamento verticale meccanico tramite „pressione del gas“, sia per quello elettromeccanico tramite „motore lineare“, è necessario osservare particolari norme sulla sicurezza secondo IEC 60601-1, che riguarda il pericolo meccanico connesso a parti in movimento.
Nello specifico:

- È indispensabile considerare e rispettare le distanze ammissibili tra le parti in movimento secondo IEC 60601-1 indicate nella tabella 20 (ISO 13857:2008).
- I prodotti con spostamento verticale vengono prodotti e forniti franco fabbrica e rispondenti alle norme, dietro osservanza delle distanze di sicurezza ammissibili. Tali distanze cambiano con il montaggio o la sostituzione di apparecchi elettromedicali e / o componenti, ma si possono verificare pericoli di tipo meccanico. Responsabile del rispetto delle distanze minime richieste è il configuratore di sistema.
- Il peso complessivo degli apparecchi e dei componenti montati non deve superare il carico massimo previsto per lo spostamento verticale. I sovraccarichi possono provocare danni al sistema di spostamento verticale e la perdita della garanzia.

- Con spostamento verticale meccanico mediante pressione del gas si libera energia immagazzinata. In caso di sistemi senza carico, l'attivamento improvviso e incontrollato dello spostamento verticale può provocare ferimenti e danneggiamenti.
  - Per evitare tali situazioni, prima di montare e smontare gli apparecchi è necessario portare lo spostamento verticale nella posizione più alta („senza energia“).
  - Il sistema a braccio „flexion-port“ variabile in altezza deve inoltre essere fissato e assicurato nella posizione più alta („senza energia“) mediante la leva di fissaggio (vedere le istruzioni per l'uso a parte per „flexion-port“ e le avvertenze di pericolo sul sistema a braccio).

- Anche il comando involontario dello spostamento verticale elettromeccanico mediante pulsante manuale può provocare ferimenti e danneggiamenti.
  - Per evitare tali situazioni, prima di montare e smontare gli apparecchi è necessario staccare dall'alimentazione il sistema di spostamento verticale.
  - I lavori di assistenza e manutenzione nella „zona interna“ dello spostamento verticale, ovvero nella zona coperta non accessibile all'interno della colonna di supporto, possono essere eseguiti solamente da personale qualificato.
  - Attenzione: azionando lo spostamento verticale mediante telecomando è necessario far sì che nessuno si trovi nell'area a rischio.

6 Bracci portanti

6.1 Cavi

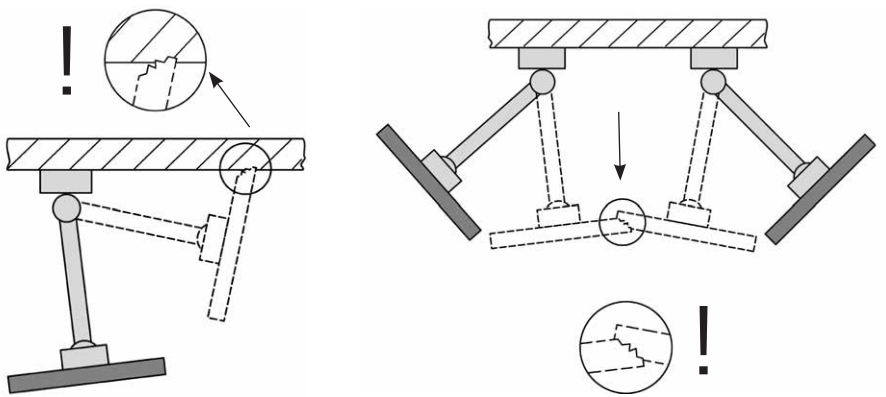
Prestare attenzione alle indicazioni che seguono:

- Per evitare di danneggiare il cavo o provocare guasti agli strumenti durante la rotazione, i cavi devono essere di dimensioni sufficienti.
- Eventuali cavi sospesi non devono mai essere utilizzati come maniglie.
- Utilizzare correttamente il materiale di montaggio fornito secondo quanto indicato nelle istruzioni di montaggio.
- Quando si fanno ruotare i bracci, fare attenzione ai fermacavi eventualmente presenti.

6.2 Rotazione orizzontale

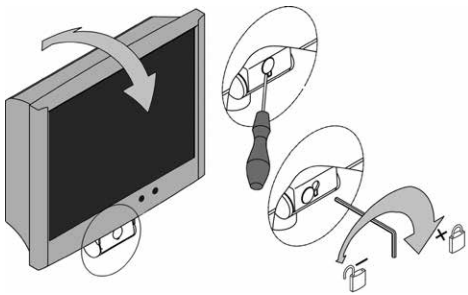
Accertarsi che l'area di rotazione dei componenti del sistema sia adeguata sia per le dimensioni degli strumenti sia per le condizioni ambientali.

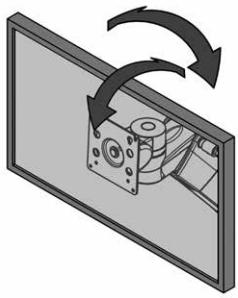
Quando i componenti del sistema su cui sono fissati gli strumenti vengono orientati orizzontalmente, non devono urtare né altri strumenti, né altri componenti, né le pareti. L'urto può provocare danni agli strumenti e, di conseguenza, lesioni alle persone.



6.3 Inclinazione / rotazione degli strumenti

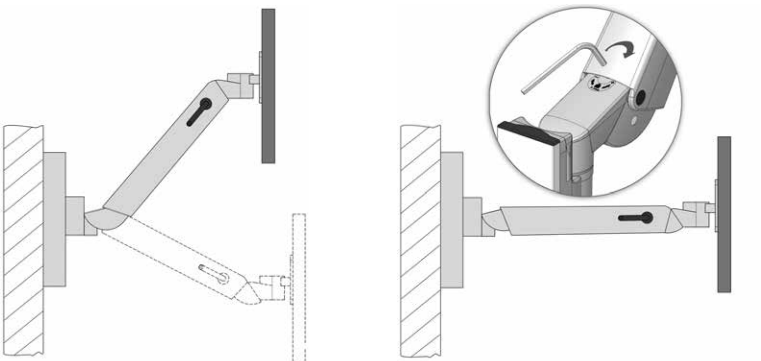
In caso di componenti inclinabili o rotanti controllare che la forza di serraggio sia appropriata per l'apparecchio da fissare. Se l'impostazione è errata, c'è il rischio che lo strumento si ribalti. La regolazione deve essere eseguita, quindi, in modo tale che sia possibile inclinare o ruotare lo strumento senza alcuna difficoltà, ma anche garantirne la stabilità in qualsiasi posizione richiesta.





6.4 Sistemi a bracci portanti con altezza regolabile (flexion-port)

Quando si caricano i componenti del sistema con altezza regolabile, occorre prestare attenzione al peso totale minimo e massimo consentito. Assicurarsi inoltre che, per motivi di sicurezza, lo spazio sottostante al sistema a bracci portanti con altezza regolabile (flexion-port) resti libero. Per poter eseguire la regolazione del braccio portante in base al carico, è necessario posizionare il braccio orizzontalmente.



6.5 Smontaggio e utilizzo diverso dei componenti del sistema e degli accessori

Quando si devono smontare i componenti e gli accessori o si deve cambiare la loro posizione, è assolutamente necessario rimuovere dapprima lo strumento montato su di essi. Se tale operazione implica il montaggio o lo smontaggio dei bracci portanti ad altezza regolabile flexion-port, dapprima portare i bracci nella posizione più alta e bloccare il fermo (freno) in posizione (vedi adesivo).

6.6 Utilizzo dei porta strumenti mobili conformemente alla loro destinazione d'uso durante le manovre

Nel manovrare i porta strumenti mobili, prestare attenzione che i bracci portanti applicati (orientabili e ad altezza regolabile) si trovino nella rispettiva posizione di stazionamento e, all'occorrenza, siano bloccati, altrimenti non è possibile garantirne la stabilità (vedi punto 2.4).

6.7 Utilizzo dei sistemi a bracci portanti ad altezza regolabile (flexion-port) sui supporti (doppi) del monitor

Quando si utilizzano i sistemi a bracci portanti ad altezza regolabile (flexion-port) sui supporti (doppi) del monitor, accertarsi che il braccio orientabile che comanda il cambio lato sia posizionato sempre parallelamente al lato anteriore del carrello (posizione bloccata). Tenere presente che sono ammesse soltanto due posizioni del braccio portante (lato destro / lato sinistro) come posizioni di lavoro (vedi sotto „Posizione di lavoro“ nel capitolo „1.2 Spiegazione generale dei simboli“, pag. 103). Cambiando lato, passando dalla posizione di lavoro a sinistra a quella a destra o viceversa, premere verso il basso gli elementi di bloccaggio e orientare il braccio portante ad altezza regolabile sull'altro lato. Fare attenzione che, durante il cambio lato, flexion-port con il braccio orientabile sia ripiegato, altrimenti non è possibile garantirne la stabilità al ribaltamento (vedi il punto 2.4).

7 Varie

7.1 Pulizia e Disinfezione

Attenzione: staccare l'intero sistema dalla rete, prima di intraprendere operazioni di pulizia o disinfezione.

I carrelli medicali uni-cart, vexio-cart, pro-cart, duo-cart, classic-cart, compact-cart o endo-cart devono essere puliti con detergenti multiuso comunemente reperibili in commercio (detergenti neutri).

Per la disinfezione, è possibile utilizzare disinfettanti comunemente reperibili in commercio, ammessi per la disinfezione di superfici e la pulizia per strofinamento. I disinfettanti devono essere applicati e impiegati in base alle disposizioni dei fabbricanti disinfettando per strofinamento.
A titolo di esempio, con i seguenti disinfettanti sono stati effettuati da ITD dei test:

Prodotti	**Fabbricanti**
Bacillol plus	Bode
Cleanisept Wipes	Dr. Schumacher
Mikrobac Tissues	Bode
Mikrozid Sensitive Wipes	Schülke
Terralin Protect	Schülke
Incidin PLUS	Ecolab
Incidin Foam	Ecolab

Nel caso risulti necessaria una disinfezione completa, è possibile fare smontare i gruppi di componenti da personale qualificato, che provvederà a pulire e disinfettare prima di eseguire di nuovo il montaggio.

7.2 Manutenzione / Prestazioni di assistenza

Prima di qualsiasi lavoro di manutenzione, e nel caso di riparazioni, l'apparecchio deve essere pulito con un detergente appropriato e disinfettato!
Solo personale specializzato può effettuare lavori di manutenzione alla macchina.
Per tutte le prestazioni di assistenza, contattare la ITD GmbH.

7.3 Condizioni ambientali

I carrelli porta-attrezzi uni-cart, vexio-cart, pro-cart, duo-cart, classic-cart, compact-cart o endo-cart sono sono concepiti per il servizio usuale in ospedale e studio medico.

Usato

Temperatura ambientale:	tra 10° C e 40° C
Umidità atmosferica:	tra 30 % e 75 %
Pressione atmosferica:	tra 700 hPa e 1060 hPa
Grado di protezione:	IP20

Trasporto/Stoccaggio

Temperatura ambiente:	compresa tra -25 °C e 70 °C
Umidità atmosferica:	10% - 95%
Pressione dell'aria:	compresa tra 500 hPa e 1200 hPa

7.4 Smaltimento

Raccolta differenziata di apparecchiature elettriche ed elettroniche in accordo con la direttiva RAEE. (Numero di registrazione per la Germania: DE3546457).
I rifiuti da apparecchiatura elettriche ed elettroniche messi in circolazione dopo il 13 agosto 2005 sono contrassegnati con il simbolo rappresentato per lo smaltimento differenziato di rifiuti da apparecchiature elettriche ed elettroniche.
Secondo tale direttiva, i rottami nei paesi in cui è valida la direttiva UE 2002/96/CE devono essere portati allo smaltimento differenziato dei rifiuti.

7.5 Pezzi di ricambio

Utilizzare unicamente pezzi di ricambio forniti dalla ITD GmbH! Sulla base del carrello porta-attrezzi si trova un autoadesivo con un numero d'ordine. Tutti i numeri d'ordine e i pezzi di ricambio corrispondenti sono tenuti in archivio dalla ITD GmbH. Tramite questi numeri, sarà possibile procurare i pezzi di ricambio necessari dalla ITD GmbH.

8 Accessori

Nei nostri cataloghi e sull'indirizzo www.itd-cart.com (Informazione per i distributori), troverete un'offerta completa di accessori.

9 Manutenzione

I carrelli porta-attrezzi uni-cart, vexio-cart, pro-cart, duo-cart, classic-cart, compact-cart o endo-cart sono stati sviluppati e costruiti per numerosi anni di utilizzo senza problemi. Controllare ogni 12 mesi il corretto funzionamento dei seguenti componenti al fine di garantirne la sicurezza.

Mensola a schermo:
- La rotazione e l'oscillazione funzionano senza difficoltà e senza eccessivo gioco.

Mensole:
- Verificare che le viti di fissaggio siano ben avvitate e di, conseguenza, se la mensola è stabile e diritta.

Ruote:
- Verificare che le route girino bene e i freni siano funzionanti.
- Controllare che i quattro bulloni che mantengono le ruote sulla superficie interna della base,e le ruote stesse, siano posizionate solidamente nei supporti.
- Per quanto riguarda le rotelle conduttrici, le superfici di rotolamento devono essere prive di impurità, in modo da assicurarne il corretto funzionamento.

Blocco multipresa:
- Controllare che il cavo principale non sia danneggiato e che sia posizionato correttamente.

Presa di corrente ausiliare:
- Verificare che il cavo non sia danneggiato e che sia posizionato correttamente.

Sistemi a bracci portanti con altezza regolabile flexion-port:
- La regolazione dell'altezza è estremamente facile, la forza di spinta è adeguata al peso degli strumenti.

Bracci portante:
- La rotazione e il ribaltamento vengono eseguiti senza problemi, senza troppo gioco.

Trasformatori di separazione:
- Controllo tecnico di sicurezza dei trasformatori di separazione.

Numero di serie:
- Confrontare il numero di serie del carrello con i dati del manuale degli attrezzi.

Fusibili:
- Verificare che i fusibili corretti siano ben montati.

Se doveste scoprire qualche problema durante questa verifica, siete pregati di contattare direttamente il fornitore.

10 Dati tecnici

10.1 Portata uni-cart

• Telaio, carico totale:	min. 50 kg / 110 lbs	
• Mensola	10 kg / 22 lbs	
• Mensola rack	20 kg / 44 lbs	
• Cassetto	3 kg / 6.6 lbs	(autobloccante: 10 kg / 22 lbs)
• Supporto dello schermo	14 kg / 30.8 lbs	
• Mousepad	3 kg / 6.6 lbs	

10.2 Portata vexio-cart

• Telaio, carico totale:	65 kg / 143 lbs	
• Mensola	15 kg / 33 lbs	
• Cassetto	3 kg / 6.6 lbs	
• Supporto dello schermo	14 kg / 30.8 lbs	
• Mousepad	3 kg / 6.6 lbs	

10.3 Portata pro-cart

• Telaio, carico totale:	80 kg / 176 lbs	
• Mensola	20 kg / 44 lbs	
• Blocco cassetto	15 kg + 3 kg / 33 lbs + 6.6 lbs	
• Supporto dello schermo	14 kg / 30.8 lbs	
• Mousepad	3 kg / 6.6 lbs	

10.4 Portata duo-cart

• Telaio, carico totale:	80 kg / 176 lbs	
• Mensola	50 kg / 110 lbs	(estraibile: 20 kg / 44 lbs)
• Cassetto	3 kg / 6.6 lbs	(autobloccante: 20 kg / 44 lbs)
• Mousepad	3 kg / 6.6 lbs	

10.5 Portata compact-cart

• Telaio „Profi“, carico totale:	180 kg / 396 lbs	
• Telaio „Economy“, carico totale:	150 kg / 330 lbs	
• Mensola	50 kg / 110 lbs	
• Cassetto	3 kg / 6.6 lbs	
• Mensola a schermo	max. 35 kg / 77 lbs	(a seconda del modello)
• Mousepad	3 kg / 6.6 lbs	

10.6 Portata classic-cart / endo-cart

• Telaio, carico totale:	150 kg / 330 lbs	
• Mensola	50 kg / 110 lbs	(estraibile: 20 kg / 44 lbs)
• Cassetto	3 kg / 6.6 lbs	
• Mensola a schermo	max. 35 kg / 77 lbs	(a seconda del modello)
• Mousepad	3 kg / 6.6 lbs	

10.7 Portata modul-port (supporto attrezzature fisso):

- Profilo portante, carico totale in funzione della lunghezza 25-150 kg / 55-330 lbs
- Braccio portante max. 23 kg / 50.6 lbs
- Braccio oscillante, semplice max. 23 kg / 50.6 lbs
- Braccio oscillante, doppio max. 18 kg / 39.6 lbs
- Alloggiamento monitor con adattatore VESA 75/100 max. 18 kg / 39.6 lbs
- Alloggiamento monitor con adattatore universal max. 14 kg / 30.8 lbs
- Alloggiamento monitor con Table Top Mount Adapter max. 14 kg / 30.8 lbs
- Mensola 10 kg / 22 lbs
- Cassetto 3 kg / 6.6 lbs
- Supporto tastiera 5 kg / 11 lbs
- Mousepad 3 kg / 6.6 lbs

10.8 Portata flexion-port (Sistemi a bracci portanti con altezza regolabile)

- flexion-port (in funzione del modello) 3-10 kg / 6.6-22 lbs o 8-14 kg / 17.6-30.8 lbs 11-20 kg / 22.4-44 lbs
- Dispositivo girevole e orientabile / dispositivo rotante 14 kg / 30.8 lbs
- Montante ("Down-Post") 10 kg / 22 lbs
- Mousepad 3 kg / 6.6 lbs

Indirizzo di contatto:

America del Nord	Europa
ITD Corporation	ITD GmbH - Office Unterhaching
50 RADO DR UNIT A	Gruenwalder Weg 13a
Naugatuck, CT 06770-2211, USA	82008 Unterhaching, Germania
Tel: +1 203 714 67-00	Tel: +49 89 61 44 25 0
Email: sales.usa@itd-cart.com	Email: sales@itd-cart.com
Cina	**Australia**
ITD Medical Technology Products (Shanghai) Co., Ltd.	ITD Australia Pty Ltd Aviation Place 3
Section A, Room 101, 1st Floor	3043 Tullamarine, Victoria, Australia
11 South RiYing Road Pilot Free Trade Zoon	
Shanghai 200131, Cina	
Tel: +86 21 6442 5704	Tel: +61 3 9330 50 50
Email: s.pan@itd-cart.com	Email: s.oconnor@itd-cart.com

ITD GmbH si dichiara responsabile della correttezza del contenuto.

根據歐洲醫療器械指令 EEC（M5）附錄九，此
製造商聲明，此產品符合 MDD 93/42/EWG 附錄七中規定的基本要求，並加註了 CE 標誌。

生產廠家:

ITD GmbH
Sportplatzstr. 3
84381 Johanniskirchen
電話號碼: + 49 89 61 44 25- 0
傳真號碼: +49 89 61 44 25- 200
Email: sales@itd-cart.com

銷售和服務:

北美

ITD Corporation
50 RADO DR UNIT A
Naugatuck, CT 06770-2211, USA
電話號碼: +1 203 714 67-00
Email: sales.usa@itd-cart.com

歐洲

ITD GmbH - Unterhaching 辦公室
Gruenwalder Weg 13a
82008 Unterhaching, Germany
電話號碼: +49 89 61 44 25 0
Email: sales@itd-cart.com

中國

ITD Medical Technology Products (Shanghai) Co., Ltd.
Section A, Room 101, 1st Floor
11 South RiYing Road
Pilot Free Trade Zoon
Shanghai 200131, China
電話號碼: +86 21 6442 5704
Email: s.pan@itd-cart.com

澳大利亞

ITD Australia Pty Ltd
Aviation Place 3
3043 Tullamarine, Victoria, Australia
電話號碼: +61 3 9330 50 50
Email: s.oconnor@itd-cart.com

我們致力於不斷改進我們的產品。因此我們的供貨範圍在形式、裝備和技術方面隨時可能會有所變化，請予以諒解。
未經 ITD GmbH 書面許可，不得全部或部分翻印、複製或翻譯本操作手冊。
ITD GmbH 明確保留依照版權法的所有權利。

申明 © 11/2018　　打印日期 12/2018

本操作手冊適用於以下產品：

型號名稱	描述
CC.02xx.xxx / 03xx.xxx	compact-cart 系統部件和附件
CC.45xx.xxx / 50xx.xxx / 65xx.xxx	compact-cart 醫療設備推車，30 E - 40 E
CC.45xx.xxx / 50xx.xxx / 65xx.xxx	compact-cart 系統部件和附件
DC.42xx.xxx / 53xx.xxx / 64xx.xxx	duo-cart 醫療設備推車，21 E - 30 E
DC.40xx.xxx / 50xx.xxx / 60xx.xxx	duo-cart 系統部件和附件
EB.45xx.xxx / 50xx.xxx / 65xx.xxx	compact-cart 醫療設備推車，經濟型
EC.04xx.xxx	endo-cart 醫療設備推車， 30 E
GW.52xx.xxx / 53xx.xxx / 54xx.xxx	classic-cart 醫療設備推車， 21 E - 40 E
GW.62xx.xxx / 63xx.xxx / 64xx.xxx	
GW.01xx.xxx / 02xx.xxx / 03xx.xxx	classic-cart 系統部件和附件
GW.04xx.xxx / 05xx.xxx / 06xx.xxx	
GW.07xx.xxx / 08xx.xxx	
GW.40xx.xxx / 41xx.xxx / 45xx.xxx	
GW.50xx.xxx / 51xx.xxx / 55xx.xxx	
GW.60xx.xxx / 61xx.xxx / 65xx.xxx	
GW.80xx.xxx / 98xx.xxx / 99xx.xxx	
HA.1xxx.xxx / 2xxx.xxx	flexion-port 系統部件和附件
HA.45xx.xxx / 5xxx.xxx	
HA.60xx.xxx / 65xx.xxx	
NT.20xx.xxx / 40xx.xxx / 41xx.xxx	vexio-cart 系統部件和附件
NT.50xx.xxx	vexio-cart 醫療設備推車， 21 E - 50 E
PT.20xx.xxx / 40xx.xxx / 41xx.xxx	pro-cart 系統部件和附件
PT.50xx.xxx / PT.90xx.xxx	pro-cart 醫療設備推車，21 E - 50 E
RS.41xx.xxx/ 48xx.xxx / 49xx.xxx	uni-cart 醫療設備推車，21 E - 50 E
RS.00xx.xxx / 01xx.xxx / 02xx.xxx	uni-cart 系統部件和附件
RS.4xxx.xxx / 5xxx.xxx	
TS.03xx.xxx / 05xx.xxx	flexion-port 系統部件和附件

本操作手冊適用於以下產品：

型號名稱	描述
VS.53xx.xxx / 54xx.xxx / 63xx.xxx	classic-cart 視頻設備推車， 30 E – 40 E
VS.63xx.xxx	
VT.43xx.xxx	配有隔離變壓器的 pro-cart 視頻設備推車，30 E
VT.45xx.xxx	配有隔離變壓器的 compact-cart 視頻設備推車， 40 E
VT.54xx.xxx / 64xx.xxx	配有隔離變壓器的 classic-cart 視頻設備推車， 40 E
VW.54xx.xxx / 64xx.xxx	classic-cart 視頻設備推車， 40 E
ZV.94xx.xxx / 96xx.xxx / 97xx.xxx	一般系統部件和附件
ZV.98xx.xxx / 99xx.xxx	

KD.7xxx.xxx / 8xxx.xxx / 9xxx.xxx	適用於 uni-cart, pro-cart, duo-cart, classic-cart, compact-cart 及 endo-cart 系列的定制移動醫療設備機架
KU.0xxx.xxx – KU.9xxx.xxx	適用於 uni-cart, vexio-cart, pro-cart, duo-cart, classic-cart, compact-cart 及 endo-cart 系列的定制移動醫療設備機架
OC.0xxx.xxx – OC.9xxx.xxx OC.1 – OC.999	
OM.0xxx.xxx – OM.9xxx.xxx	

內容

1 重要信息

1.1 預期用途 126
1.2 通用符號 127
1.3 安全信息 129

2 裝配

2.1 完整性 130
2.2 裝載 130
2.3 裝載順序 130
2.4 機械不穩定性所引起的危險 131
2.5 腳輪 131
2.6 負載 131
2.7 裝配/操作 131
2.8 系統組件的後續安裝 132

3 電氣安全
3.1 電氣設備的安置 132
3.2 能量柱(classic-cart, compact-cart, endo-cart) 及立柱 (uni-cart, vexio-cart, pro-cart) 132
3.3 氣體 133
3.4 電位均衡 133
3.5 隔離變壓器 – 漏電流 133
3.6 絕緣檢測儀 133
3.7 電纜接頭 135
3.8 設備組合 135
3.9 EMV 136
3.10 不需執行電輸出測試的系統組件及附件 136
3.11 最低安全標準 137
4 運輸
4.1 腳輪的安全運輸 137
4.2 推車的安全運輸 137
5 機電高度調節 138
6 支撐臂
6.1 電纜 139
6.2 橫向移動 139
6.3 設備的擺動/轉動 139
6.4 可調高度支撐臂 (flexion-port) 140
6.5 系統組件和附件的拆解和改裝 140
6.6 操縱移動設備推車時的預期用途 140
6.7 顯示器支架（兩折）上高度可調支撐臂（flexion-port）的操作 141
7 其他
7.1 清潔和消毒 141
7.2 維修/服務 142
7.3 環境規範 142
7.4 處置 142
7.5 零件 142
8 配件 142
9 保養 143
10 產品規格
10.1 uni-cart 負載能力 144
10.2 vexio-cart 負載能力 144
10.3 pro-cart 負載能力 144
10.4 duo-cart 負載能力 144
10.5 compact-cart 負載能力 144
10.6 classic-cart / endo-cart 負載能力 145
10.7 modul-port 負載能力 145
10.8 flexion-port 負載能力 145

1 重要信息

ITD GmbH 所有產品的製造均能為客戶提供無故障且壽命長的性能，其開發、設計、銷售和生產都通過 DIN 13485 的認證。

這是保證以下幾點的前提：

- 最高的質量和超長的壽命
- 簡單、安全和人性化的操作
- 功能性設計
- 為操作目的進行優化

產品均達到歐盟醫療器械指令（MDD）的要求，並帶有 CE 標誌。

- 請從頭開始仔細閱讀本操作手冊，以慢慢熟悉產品的功能。
- 若您存有任何疑問或質疑，請聯繫製造商。
- 移動設備推車僅用於本操作手冊中所描述的用途。
- 在產品的壽命週期內，請妥善保存本操作手冊。

整體配置的使用說明為終端用戶提供了系統配置。
本操作手冊明確指出了，系統配置符合 IEC60601-1 和最新有 效版本的 IEC 60601-1-2 中指定的要求!

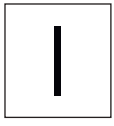
1.1 預期用途

ITD 的移動設備推車：

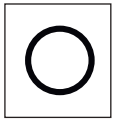
- 根据当前有效IEC 60601-1版本中的允许负载规定，容纳医疗和IEC测试设备。
- 從本地電力提取點以及數據線連接和分配電源電壓。
- 用於連接原有 ITD 系統組件及附件。

有了移動設備推車的協助，醫療器材在使用前後可被輕鬆移動或置於建築物的任何一個空間內。因此，這將能讓工作人員靈活且經濟地利用所有設備。此外，地面的清潔工作也會輕鬆得多。

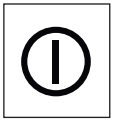
1.2 通用符號



「開」绿灯亮起
（電壓）



「關」
（電壓）



「開」 绿灯亮起/
「關」
（壓力致動）

電位均衡：其標誌是隔離變壓器外殼上的 POAG 針。
電位均衡可確保所有導電材料之間的電阻足夠小。

接地端子：
導體、設備、導電部件、主接地端子和地面。

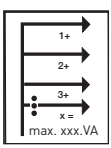
導電腳輪：
導電腳輪的特徵為閃電或黃點符號。

只可用折臂移動

使用手柄推動

遵循操作說明

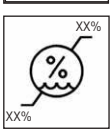
交流電



總功率：
被排出到各個插槽的功率總和，不得超出總功率。

底架總負載:
最大總負載（= 所有系統組件的負載值總和）。請注意容許負載的相應標籤。

載重指數（系統組件）：
請注意容許負載的相應標籤。



濕度限制

一般警告：
這被安裝於插座上。標識牌上指明的總功率不得被超過。

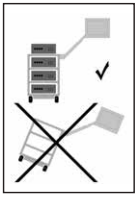
只適於室內。

重物：
必須確保至少有兩個人移動 uni-cart, vexio-cart, pro-cart, duo-cart, classic-cart, compact-cart 及 endo-cart 移動設備推車，以避免受傷。

負責分發的單位

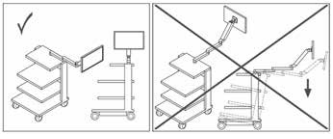
調整夾緊力（傾斜和旋轉單元）

裝載設置：
描述了負載範圍以及用於負載調整的旋轉方向。

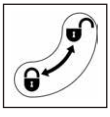


傾翻風險：
必須觀察移動設備推車的加載和卸載順序，這一點非常重要。

剎車功能：
這提供了有關支撐臂定位的信息，並指示了啟用或禁用鎖定功能的方向。



操作位置：
此符號表示了容許的工作位置（左/右）以及改變支撐臂方向時的傾斜風險。



鎖定功能：
此符號描述了鎖定或打開組件的方向。

禁止推動：
基於傾翻風險，在把手上方推動推車是不被允許的。

1.3 安全信息

一般

- 只有在合資格的人員對移動設備推車的電源電壓進行檢查和批准後，移動設備推車才能被投入使用！
- 隔離變壓器所連接的電源供應器務須依照 IEC 60364-7-710 2012-10「建築物電氣安裝第 7-710 篇：特殊安裝或場所要求 – 醫療場所」的規定，接上有效的接地線。若有疑慮，請聯絡電氣業專家或是醫院工程團隊中有權處理的員工。
- 直接或間接操作移動設備推車的工作人員（護理人員或服務人員）必須經過培訓！
- 調整工作只能由合資格的人員進行
- 維修和保養工作只能由 ITD GmbH 進行。

安全操作设备推车：

- 只有从插座上拔下电源插头，才能确保完全断开电源。

操作

- 當移動已加載的推車時，請格外小心，以避免造成人身傷害和設備損壞！

連接

- 當在美國和加拿大等國家連接 115 V 隔離變壓器時，請使用醫院等級的連接電纜，當在日本使用時，日本的連接電纜則可作為一種選擇。
- 當連接到複式插座時，插頭必須用可選的插頭拆卸屏障固定。
- 只有符合IEC 60601-1要求或经过IEC测试的设备才能连接到插座/连接电缆。
- 有連接螺栓的額外醫療設備必須透過綠黃線被連接到可選的電位均衡連接螺栓！

警告： 標識牌上指明的總功率不得被超過。請注意，不可在現有的電源板上連接更多的電源板。

負載

- 移動設備推車上的設備和附件總重量不得超過容許的總負載（參閱底架上的負載貼紙）。
- 印在系統部件上的表面負載不得被超過！
- 附件（如輸液架、鉸接臂）的負載能力不得被超過！

感染控制

- 當清洗推車時，必須遵守衛生規則！
- 只有在清潔和消毒設備後，才可轉交給技術服務人員進行維護和維修工作！

環境保護

- 以無害的和環境友好的方式丟棄洗滌劑和消毒劑殘留物！

2 裝配

2.1 完整性

首先打開 uni-cart, vexio-cart, pro-cart, duo-cart, classic-cart, compact-cart 或 endo-cart 的包裝，然後檢查所附的送貨單，確保所有物品都齊全。

2.2 裝載

將 uni-cart, vexio-cart, pro-cart, duo-cart, classic-cart, compact-cart 或 endo-cart 推車放置於平整及水平的表面。在考慮到裝載順序的同時，將您的設備放入推車內。裝載和裝配工作必須分別進行。為了固定各個設備，我們建議使用可選附件（如：捆綁帶）。

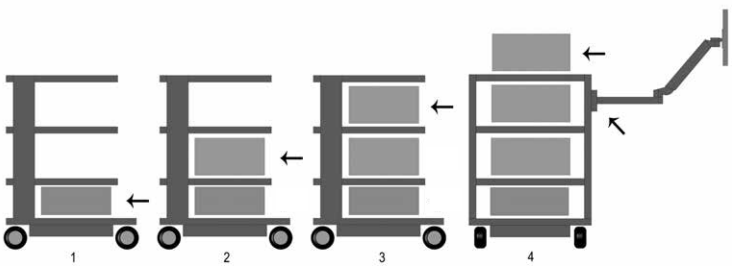
第 10 節列明了每個產品系列的最大負載。如果推車的結構穩定性不足，則必須按照標籤規定清楚標明。

2.3 裝載順序

確保 uni-cart, vexio-cart, pro-cart, duo-cart, classic-cart, compact-cart 或 endo-cart 推車上的所有物品被安全置放，並採取相應的措施，以避免物件在存放期間（即使在移動時）打滑、傾覆、墜落或發生其他類似的事情。 當搬動重物到 uni-cart, vexio-cart, pro-cart, duo-cart, classic-cart, compact-cart 或 endo-cart 推車時，我們建議您安排兩個人進行此操作。請注意，推車的重心位置會隨著負載而有所改變。

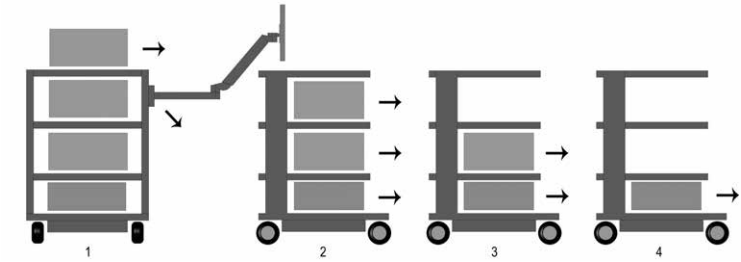
推車的裝載順序應按下述進行：

- 從下往上裝載架子和抽屜。
- 最後才裝載支撐臂（固定、傾斜、旋轉、高度可調、單個或多個）。



推車的卸載順序應按下述進行：

- 先卸載支撐臂（固定、傾斜、旋轉、高度可調、單個或多個）
- 從上往下卸載收納架和抽屜。



當使用移動工作站（運輸）是，請考慮第 4 節中的說明。

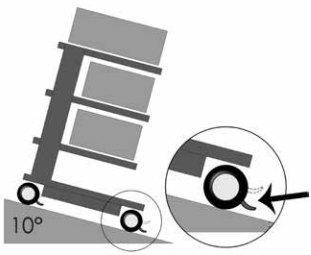
2.4 機械不穩定性所引起的危險

整個系統應符合 IEC 60601-1 的要求。

2.5 腳輪

uni-cart, vexio-cart, pro-cart, duo-cart, classic-cart, compact-cart 或 endo-cart 推車設有二個帶有剎車功能的旋轉式腳輪。在操作 uni-cart, vexio-cart, pro-cart, duo-cart, classic-cart, compact-cart 或 endo-cart 推車前，請確保剎車功能正常運作。

到達停放位置後或在移動時需要停止推車，必須致動所有腳輪制動器（腳輪的鎖定裝置）。同樣的，在移動或運輸之前，必須放開所有腳輪制動器。每 12 個月必須進行一次檢查，以確保腳輪無間隙現象發生，且安裝螺栓被鎖緊。如果出現鬆脫現象，請立即與您的供應商聯繫。



2.6 負載

不得超過 uni-cart, vexio-cart, pro-cart, duo-cart, classic-cart, compact-cart 或 endo-cart 推車的負載能力。

請了解 uni-cart, vexio-cart, pro-cart, duo-cart, classic-cart, compact-cart 或 endo-cart 推車的最大負載能力（參閱第 10 節）。

2.7 裝配/操作

2.7.1收納架

收納架可被移除或安裝至其他位置。鬆開固定螺釘，重新定位底部，然後再次上鎖。然後檢查保護導體電阻

2.7.2抽屜

抽屜（pro-cart）設有一個鎖。

欲解開 pro-cart 的鎖，只需將操作手柄向上拉至前擋板即可解鎖。

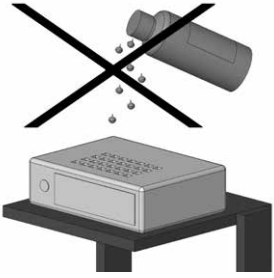
抽屜在伸出狀態下是可拆卸的。前面板上提供了一個標籤條（除了pro-cart）。 在運輸過程中，抽屜必須被關上。

2.7.3 隔離變壓器

請遵守隔離變壓器的指導手冊。隔離變壓器被安裝於底架下方的殼體內。組件在工廠內已完成裝配。

2.8 系統組件的後續安裝

ITD 統組件的改造必須由合資格的人員負責，並根據附帶的安裝說明書的技術要求進行。修改後的整體系統應按照 IEC 60601-1 進行复核。



3 電氣安全

3.1 電氣設備的安置

請注意，uni-cart, vexio-cart, pro-cart, duo-cart, classic-cart, compact-cart 或 endo-cart 推車上的電氣設備不可被弄濕。千萬別將產品置於電氣設備，它們可能會滲漏出一些液體，然後滲入電子設備和電源板內。

3.2 能量柱（classic-cart, compact-cart, endo-cart）及立柱（uni-cart, vexio-cart 或 pro-cart）

classic-cart, compact-cart 及 endo-cart 的電源板或電纜系統均位於能量柱的左側或右側，uni-cart 及 pro-cart 的電源板或電纜系統則位於立柱，至於 vexio-cart，電源板或電纜系統則位於底架下方（電纜置於可選的電纜管道內，並被安裝在能量柱旁）。

能量柱位於垂直單元後方的左側和右側，並允許現有設備電纜的優化佈置。千萬不要在能量柱/立柱位置鑽洞，因為裡面可能含有載流電纜。

3.3 氣體

若裝載了電器，推車絕不能靠近可燃性麻醉劑或類似的氣體的。
因此，用戶必須承擔任何後果，並得遵守 IEC60601-1-2 的規定。

3.4 等電位連接（POAG）

當 uni-cart, pro-cart, classic-cart, compact-cart 或 endo-cart 設有隔離變壓器時，等電位連接將會是必須的。對於未設有隔離變壓器的 vexio-cart，POAG 可作為選裝配置。若要執行此操作，首先將 POAG 線連接至 uni-cart, vexio-cart, pro-cart, classic-cart, compact-cart 或 endo-cart 推車的底部，然後連接至室內的 POAG 插頭。接著，將POAG 線連接至複式插座和設備的 POAG 引腳。

3.5 隔離變壓器 – 漏電流

uni-cart, vexio-cart, pro-cart, duo-cart, classic-cart, compact-cart 及 endo-cart 推車的目的是為電子醫療設備提供實用的移動工作站。因此，根據 IEC 60601-1 標準，整個醫學電氣系統的漏電流總和不得超過 0.5 mA 的最大極限。
如果漏電流的總和超過容許限度，系統必須透過一個安全隔離變壓器供電。

如果沒有安裝隔離變壓器，這將不符合 IEC 60601-1 有關漏電流的要求，uni-cart, pro-cart, duo-cart, classic-cart, compact-cart 及 endo-cart 推車的複式插座/輔助插槽系統將不可被用於連接設備。

如果隔離變壓器已被安裝，所有已連接設備的總功率消耗應介於變壓器的標稱值範圍內。

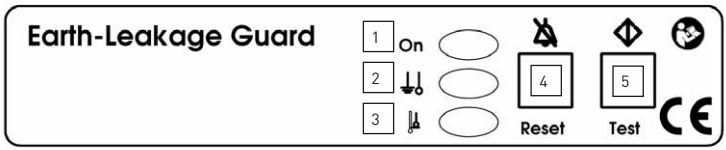
3.6 絕緣檢測儀

以下說明僅適用於安裝了“配有絕緣檢測儀的隔離變壓器”的設備推車。

3.6.1 絕緣檢測儀面板 (ELG)

對於設有集成式絕緣檢測儀的設備，其傳送器安裝於變壓器殼體內，控制和顯示面板則位於其中一個收納架內。兩個部件經由垂直單元內的螺紋接口電纜互連。

絕緣檢測儀面板 (ELG) （可選）：



1 電源指示燈（綠色）
2 絕緣電阻（黃色）
3 溫度過高（黃色）
4 確認故障
5 測試按鈕

3.6.2 預期用途

絕緣檢測儀 ELG 是用於監視連接到隔離變壓器的設備或設備組的絕緣電阻。
變壓器的溫度性能也會同時被監測。
評估是在處理器控制下進行的。

3.6.3 操作手冊

將隔離變壓器的主開關調為“ON”，絕緣檢測儀 ELG 的自檢功能在 5 秒內將在後台自動運行。
絕緣檢測儀 ELG 在自檢後將準備好運行。
電源指示燈（綠色 LED 燈）將持續發亮。在操作過程中，絕緣檢測儀將會每 8 小時進行週期性的檢測，同時也可以通過測試按鈕進行手動觸發。

對於手動檢測，以下程序將被執行：

- 模擬絕緣故障，絕緣電阻（黃色 LED 燈）持續發亮，並發出 2.4 kHz 的聲音警報，大約 5 秒鐘後消失。
- 然後，模擬溫度故障，作為溫度過高徵兆的黃色 LED 燈持續發亮，並發出 2.4 kHz 的聲音警報，大約 5 秒鐘後消失。

出現錯誤時，可看到以下情況：

- 如果發生絕緣錯誤，絕緣電阻（黃色 LED 燈）持續發亮，並發出 2.4 kHz 的聲音警報。該聲音警報可以透過確認故障按鈕被重置。LED 燈將保持發亮，直到錯誤得到糾正。
- 如果絕緣檢測儀已被關閉，且錯誤沒有得到糾正，請重複上述的程序。

如果聲音警報和燈光警報消失後，絕緣錯誤仍然存在：

首先確認：聲音警報
第二個確認：燈光警報

- 如果開啟了溫度感應器，作為溫度過高徵兆的黃色 LED 燈將持續發亮，並發出 2.4kHz 的聲音警報。聲音警報可以透過確認故障按鈕被重置，LED 燈將保持發亮，直到錯誤得到糾正。如果絕緣檢測儀已被關閉，且錯誤沒有得到糾正，請重新開始進行上述程序。
- 如果絕緣故障和過熱故障同時出現，絕緣故障的聲音警報將始終優先。

絕緣檢測儀的自檢

除了每 8 小時一次的週期性自檢外，絕緣檢測儀可經由觸發測試按鈕進行自檢。每次開啟後，絕緣檢測儀也將進行一次自檢。
自檢大約需時 5 秒鐘，這從外部是無法區分的。如果發生故障，電源指示燈（綠色 LED 燈）將以 0.5 Hz 的頻率閃爍。這與聲音警報的頻率相同。故障信息不可以透過確認故障按鈕被重置。

3.6.4 故障處理

切勿嘗試自行維修本設備。若發現不當的維修嘗試，保固期即時失效。出於安全原因，維修和保養工作只能由製造商進行。

注意：
欲了解更多技術數據和資料，請參閱產品隨附的隔離變壓器及絕緣檢測儀詳細使用說明。

3.7 電纜接頭

對於未設有隔離變壓器的 uni-cart, vexio-cart, pro-cart, duo-cart, classic-cart, compact-cart 或endo-cart 推車，操作人員應確保推車及設備之間的電纜接頭是可拆卸連接的。我們的附件系列中可找到複式插座板的蓋子。

3.8 設備組合

對於推車的設備組合，請注意以下幾點：

- 與模擬和數位接口相連的輔助設備必須經相關標準（例如數據處理設備 IEC 60950 標準和醫療設備 IEC 60601-1 標準）認證。

- 此外，所有配置都應符合系統標準 IEC 60601-1-1。任何人若將其他設備與信號輸入部分或信號輸出部分相連，他/她即已配置了一套醫療系統，並因此應負責確保該系統遵守系統標準 IEC 60601-1-1 的要求。

如有疑問，請聯繫您當地的代表或技術服務。

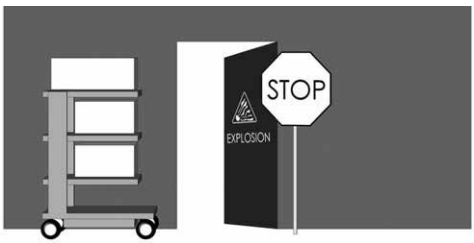
注意：
同時也適用於供電電路中的設備適配（即：複式插座）！

3.9 EMV

系統配置人員應檢查推車上電子醫療器械的電磁兼容性。在使用設備組合作醫療用途之前，請檢查各個設備之間的電磁兼容性。

在核磁共振环境中使用的定制设备推车由于含有一定比例的铁磁材料必须由客户测试其适用性。ITD GmbH 將不負責這方面的任何法律責任！

在易燃易爆的環境中使用帶隔離變壓器的推車是不被允許的。



3.10 不需執行電輸出測試的系統組件及附件

ITD GmbH 沒有對以下系統組件及附件執行電輸出測試：

- 未接線的複式插座（無附加保護導體）
- 所附的 ME 線和設備線
- 所附的 POAG 板或軟管

- 不帶點的推車和支撐系統
- 高度調節和高度調節的安裝零部件
- 手柄、鼠標墊、抽屜、抽屜櫃和附件（氧氣筒支架、籃子、攝像頭支架、輸液架...）
- 鍵盤托架和拉出式擱板
- 未安裝的隔離變壓器
- 頂部和底部的安裝支架
- 導電腳輪：
- 已安裝的支撐臂和顯示器支架
- 配有絕緣檢測儀的二次迴路可排除接受電氣強度測試！

3.11 最低安全標準

ITD GmbH 不知道哪些設備或配件能降低系統的安全操作。您只能使用不構成危險的設備。如有必要，請按照 ISO 14971 標準進行風險分析。

4. 運輸

4.1 腳輪的安全運輸

使用移動設備推車前，請確保：

- 所有設備/產品被固定好，以防止墜落。
- 所有铰接臂被迴轉及固定好。
- 本地电源提取点的电源线被拔掉。
- 釋放腳輪的制動器。

只能以每小時 6 公里的最高步速移動推車。當經過顛簸區域、電纜和軟管時，必須放慢速度。

當經過最大爬坡度為 10° 的斜坡時，請確保能隨時停止推車。

尽管已採取所有预防措施以确保该产品的最大稳定性，但仍應注意地板、電梯的門框、電纜等不均匀的情況，以防止意外發生。

原則上應符合 IEC 60601-1 標準的要求。

4.2 推車的安全運輸

手柄並非用於抬升移動設備推車，其功能只是用於移動推車。移動設備推車的抬升及搬運必須由兩個人透過抬起底架的臂架來執行。

原則上應符合 IEC 60601-1 標準的要求。

5 機電高度調節

對於有關“氣壓”的“機械式高度調節”及“線性致動器”的“機電式高度調節”，請遵守 IEC 60601-1 有關“與運動部件相關的機械危險”的特別安全措施。其中：

- 應考慮和遵循 IEC 60601-1 表 20（ISO 13857:2008）的防止上下肢觸及危險區域的安全距離。
- 可調高度產品的製造應符合標準，並按照允許的安全距離從工廠發貨。组装或替换 MED 设备和/或部件後，這些安全距離可能會有所改變。這可能會導致机械危险。系統配置人員應自行負責遵守所需的最小距离间隔。
- 所安裝的設備及配件的總重量不得超過高度調節所規定的最大負載。過載將會導致高度調節損壞，並導致保修失效。
- 通過氣壓控制的機械式高度調節，其存儲的能量在調節時會被釋放。對於空載系統，突然的高度調節將可造成傷害和損壞。
    - o 組裝和拆卸設備之前，將高度調節至最上端（“無能量”）位置，以避免造成傷害和損壞。
    - o 必須使用固定桿，將“flexion-port”的可調高度支撐臂固定至最上端（“無能量”）位置（請參閱“flexion-port”支撐臂的單獨使用說明書和危險警告）。
- 意外透過手動按鈕執行的機電高度調節也可能會引起傷害和損壞。
    - o 組裝和拆卸設備之前必須從電源插座上斷開連接，以避免造成傷害和損壞。
    - o 高度調節的“內部”（即支撐柱內從外部無法接觸的區域）的維修和維護工作必須由專業人員執行。
    - o 警告：當通過遙控鑰匙來操作高度調節時，請確保危險區域內無人站立。

6 支撐臂

6.1 電纜

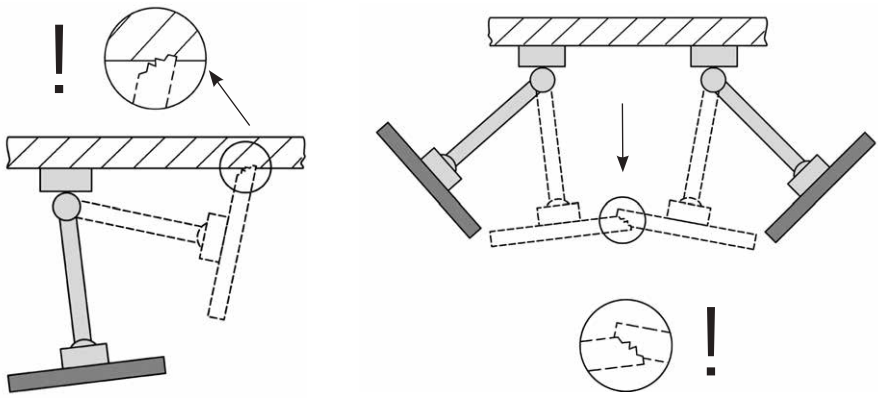
請注意以下信息：

- 為了避免支撐臂在擺動時導致電纜損壞或設備故障，電纜必須足夠長。
- 請勿抓握懸掛的電纜。
- 請確保按照安裝說明正確地使用所附的安裝部件。
- 當擺動支撐臂時，請注意任何現有的電纜迴路。

6.2 橫向移動

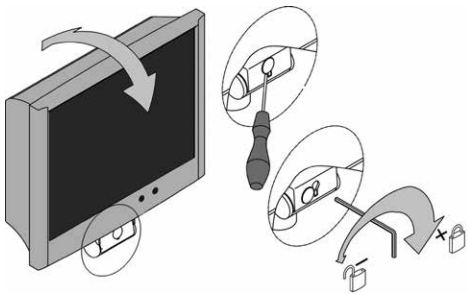
確保系統組件的旋轉範圍隨著設備尺寸以及室內條件進行調整。

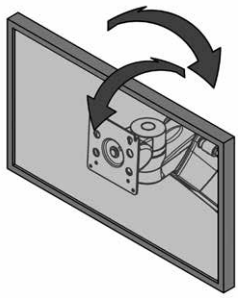
對於橫向移動的系統組件，請確保它們不會跟其他設備、其他系統組件或牆壁發生碰撞。碰撞可能會導致設備損壞，進而導致人身傷害。



6.3 設備的擺動/轉動

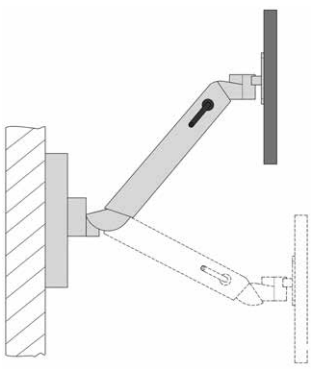
當檢測可擺動或可轉動的系統組件時，請確保夾緊力被調節至能將設備固定住。不正確的設置會導致設備傾覆。因此，除了確保容易擺動及轉動設備外，也必須確保支撐臂在任何位置上都能保持穩定。

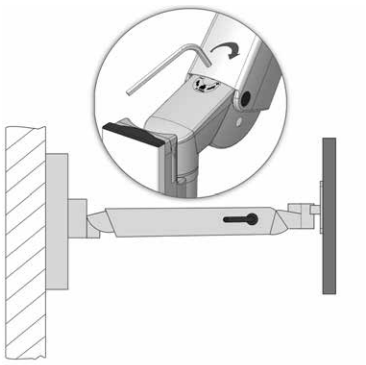




6.4 可調高度支撐臂（flexion-port）

當裝載可調高度的系統組件時，請務必留意最小和最大的總重量。出於安全原因，請確保可調高度支撐臂（flexion-port）的下方留有空間。當要調整已加載的支撐臂時，該支撐臂必須被置於水平位置。





6.5 系統組件和附件的拆解和改裝

當拆解或改裝系統組件和附件時，相關儀器必須先被拆除。當拆解 flexion-port 的可變高度支撐臂時，它們必須先被置於最上端位置，並確定已被夾緊（制動器）（見標籤）。

6.6 操縱移動設備推車時的預期用途

當操作移動設備推車時，請務必確保支撐臂（可旋轉，高度可調節）被折疊在架子上，在適當情況下，將支撐臂固定起來。否則將無法保證其穩定性（參見第 2.4 節）。

6.7 顯示器架（兩折）上可調高度支撐臂（flexion-port）的操作

當在顯示器架（兩折）上操作可調高度支撐臂（flexion-port）時，請注意旋臂平行擺放在推車前方（嚙合位置）。
請注意，支撐臂只能以兩種位置（左/右）進行操作（參見第 9 頁“1.2 通用符號”的“操作位置”）。
當操作位置從左側轉到右側或從右側轉到左側時，必須將鎖定元件往下推，以便可將可調高度支撐臂轉動到另一側。請注意，當轉換方向時，旋臂是折疊起來的。否則將無法保證其穩定性（參見第 2.4 節）。

7 其他

7.1 清潔和消毒

警告：在清潔或消毒之前，請從主電源上斷開

整個系統。

應使用商業用途的清潔劑（中性清潔劑）清晰 uni-cart, vexio-cart, pro-cart, duo-cart, classic-cart, compact-cart 或 endo-cart 推車。

至於消毒方面，可使用經批准用於表面消毒的商用消毒劑或消毒濕巾。必須按照製造商規定的方法使用消毒劑以進行擦拭消毒。

以下是 ITD 進行過測試的消毒劑例子：

產品	生產廠
Bacillol plus	Bode
Cleanisept Wipes	Dr. Schumacher
Mikrobac Tissues	Bode
Mikrozid Sensitive Wipes	Schülke
Terralin Protect	Schülke
Incidin PLUS	Ecolab
Incidin Foam	Ecolab

如果需要拆卸組件以進行完全的消毒處理，可請專家進行拆卸和組裝。

7.2 維修/服務

在送往維修之前，請先用合適的清潔劑和消毒劑清洗推車！應只有具備資格的維修人員修理推車。對於所有服務，我們建議您聯繫 ITD GmbH。

7.3 環境規範

uni-cart, vexio-cart, pro-cart, duo-cart, classic-cart, compact-cart 及 endo-cart 推車的設計適用於一般的醫院和實踐操作。

環境溫度:	10° C 至 40° C
濕度:	30 % 至 75 %
氣壓:	700 hPa 至 1060 hPa
防護等級:	IP 20

運送/存放

環境溫度:	-25° C 至 70° C
濕度:	10% 至 95%
氣壓:	500 hPa 至 1200 hPa

7.4 處置

根據廢電機電子設備指令（WEEE），對電氣和電子設備進行分類收集（德國註冊號為 DE35464575）對於在 2005 年 8 月 13 日以後被投放市場的電氣和電子設備，它們將被貼上廢電機電子設備分類收集的標籤。這表明了在歐盟 2002/96/EC 指令有效的國家，所有廢物必須以分類的方式進行處置。

7.5 零件

只能使用 ITD GmbH 核准的零件！推車的底部附有印了訂單編號的標籤。所有訂單編號和相關項目已被 ITD GmbH 記錄存檔。您可以聯繫以下地址，以獲得所需的更換ITD GmbH 記錄存檔.

8 配件

您可在我們的產品目錄或 www.itd-cart.com（經銷商信息）中找到各種各樣的配件。

9 保養

uni-cart, vexio-cart, pro-cart, duo-cart, classic-cart, compact-cart 及 endo-cart 推車的設計和構造旨在為用戶提供多年的無故障使用。每 12 個月進行一次檢查，以確保以下部件的功能安全性：

顯示器收納架：
- 旋轉和傾斜功能順暢運作，不會有太多的間隙。

收納架：
- 檢查所有固定螺栓是否擰緊，收納架是否穩固和平衡。

腳輪：
- 檢查腳輪是否自由轉動，所有剎車是否正常運行。
- 檢查固定住底架腳輪的 4 個螺栓以及腳輪本身是否緊固。
- 若使用的是導電腳輪，腳輪表面應無異物，以確保正常操作。

插座板：
- 檢查主電纜是否有損壞，以及連接是否緊固。

輔助插座：
- 檢查插座是否有損壞，以及連接是否緊固。

flexion-port 的可變高度支撐臂：
- 高度調節能正常運作，提升力與設備的重量相匹配。

支撐臂：
- 旋轉和傾斜功能順暢運作，不會有太多的間隙。

隔離變壓器
- 隔離變壓器的安全檢查。

序列號：
- 比較推車的序列號及設備插座的數據。

保險絲：
- 檢查是否安裝了正確的保險絲。

如果您在檢查時發現了問題，請立即聯繫您的供應商。

10 產品規格

10.1 uni-cart 負載能力

- 底架，總負載能力 50 公斤/110 磅
- 收納架 10 公斤/22 磅
- 機架 20 公斤/44 磅
- 抽屜 3 公斤/6.6 磅 （可鎖定：10 公斤/22 磅）
- 顯示器支架 14 公斤/30.8 磅
- 鼠標墊 3 公斤/6.6 磅

10.2 vexio-cart 負載能力

- 底架，總負載能力 65 公斤/143 磅
- 收納架 15 公斤/33 磅
- 抽屜 3 公斤/6.6 磅
- 顯示器支架 14 公斤/30.8 磅
- 鼠標墊 3 公斤/6.6 磅

10.3 pro-cart 負載能力

- 底架，總負載能力 80 公斤/176 磅
- 收納架 20 公斤/44 磅
- 抽屜櫃 15 公斤 + 3 公斤 / 33 磅 + 6.6 磅
- 顯示器支架 14 公斤/30.8 磅
- 鼠標墊 3 公斤/6.6 磅

10.4 duo-cart 負載能力

- 底架，總負載能力 80 公斤/176 磅
- 收納架 50 公斤/110 磅 （可擴展：20 公斤/44 磅）
- 抽屜 3 公斤/6.6 磅 （可鎖定：20 公斤/44 磅）
- 鼠標墊 3 公斤/6.6 磅

10.5 compact-cart 負載能力

- 底架 "Profi“，總負載能力 180 公斤/396 磅
- 底架 "Economy“，總負載能力 150 公斤/330 磅
- 收納架 50 公斤/110 磅
- 抽屜 3 公斤/6.6 磅
- 顯示器收納架 最多 35 公斤/77 磅 （取決於類型）
- 鼠標墊 3 公斤/6.6 磅

10.6 classic-cart / endo-cart 負載能力

- 底架，總負載能力 150 公斤/330 磅
- 收納架 50 公斤/110 磅 （可擴展：20 公斤/44 磅）
- 抽屜 3 公斤/6.6 磅
- 顯示器收納架 最多 35 公斤/77 磅 （取決於類型）
- 鼠標墊 3 公斤/6.6 磅

10.7 modul-port 負載能力（固定承載系統）

• 承載配置，總負載能力具體取決於長度	25–150 公斤/55–330 磅
• 支撐臂	最多 23 公斤/最多 50.6 磅
• 旋臂，單向	最多 23 公斤/最多 50.6 磅
• 旋臂，雙向	最多 18 公斤/最多 39.6 磅
• 採用 VESA 75/100 安裝標準的顯示器	最多 18 公斤/最多 39.6 磅
• 採用通用適配器的顯示器	最多 14 公斤/最多 30.8 磅
• 採用檯面安裝適配器的顯示器	14 公斤/最多 30.8 磅
• 收納架	10 公斤/22 磅
• 抽屜	3 公斤/6.6 磅
• 鍵盤架	5 公斤/11 磅
• 鼠標墊	3 公斤/6.6 磅

10.8 flexion-port 負載能力（可調高度支撐臂系統）

• flexion-port（取決於型號）	3–10 公斤/6.6–22 磅 8–14 公斤/17.6–30.8 磅 11–20 公斤/24.2–44 磅
• 傾斜和旋轉單元	最多 14 公斤/30.8 磅
• 柱（“Down-Post”）	10 公斤/22 磅
• 鼠標墊	3 公斤/6.6 磅

聯繫地址：

北美

ITD Corporation
50 RADO DR UNIT A
Naugatuck, CT 06770-2211, USA
電話號碼: +1 203 714 67-00
Email: sales.usa@itd-cart.com

歐洲

ITD GmbH - Unterhaching 辦公室
Gruenwalder Weg 13a
82008 Unterhaching, Germany
電話號碼: +49 89 61 44 25 0
Email: sales@itd-cart.com

中國

ITD Medical Technology Products (Shanghai) Co., Ltd.
Section A, Room 101, 1st Floor
11 South RiYing Road
Pilot Free Trade Zoon
Shanghai 200131, China
電話號碼: +86 21 6442 5704
Email: s.pan@itd-cart.com

澳大利亞

ITD Australia Pty Ltd
Aviation Place 3
3043 Tullamarine, Victoria, Australia
電話號碼: +61 3 9330 50 50
Email: s.oconnor@itd-cart.com

ITD GMBH對內容之正確性負責。

ITD GmbH
Sportplatzstraße 3
84381 Johanniskirchen
Germany
sales@itd-cart.com
www.itd-cart.com

DS.0043.999-3.0 - Rothe Druck 12/2018. Printed in Germany. Änderungen vorbehalten

PENTAX MEDICAL

PRODUCT OVERVIEW

Discover the fascinating world of
PENTAX Medical endoscopy

PENTAX Medical innovation and responsibility

With a combination of technological innovations and medical responsibility, PENTAX Medical sets new standards for endoscopic diagnosis and therapy.

State-of-the-art medical and technological equipment of the highest quality that come with intelligent system compatibility as well as a comprehensive system program. Furthermore, an efficient endoscope drying and storage system, in addition to an efficient service program provides the highest level of investment security for endoscopists of all relevant disciplines.

Index

Solutions for every discipline and market 4

Upper GI and Lower GI solution: 8
- Advanced diagnosis and treatment 8
- Diagnostic and standard therapeutics 16
- Basic diagnosis and treatment 22
- Peripherals and Accessories 26

Biliopancreatic solution: 28
- Advanced diagnosis and treatment 28
- Diagnostic and standard therapeutics 30
- Basic diagnosis and treatment 32
- Peripherals and Accessories 34

Pulmonology solution: 36
- Advanced diagnosis and treatment 36
- Diagnostic and standard therapeutics 38
- Basic diagnosis and treatment 40
- Peripherals and Accessories 42

Intubation solution: 44
- Advanced diagnosis and treatment 44
- Basic diagnosis and treatment 46
- Peripherals and Accessories 48

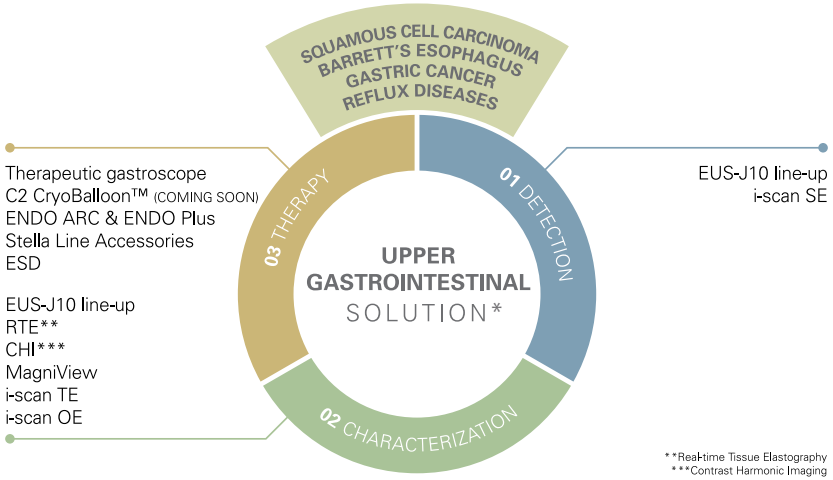
ENT solution: 50
- Advanced diagnosis and treatment 50
- Diagnostic and standard therapeutics 52
- Basic diagnosis and treatment 54
- Peripherals and Accessories 56

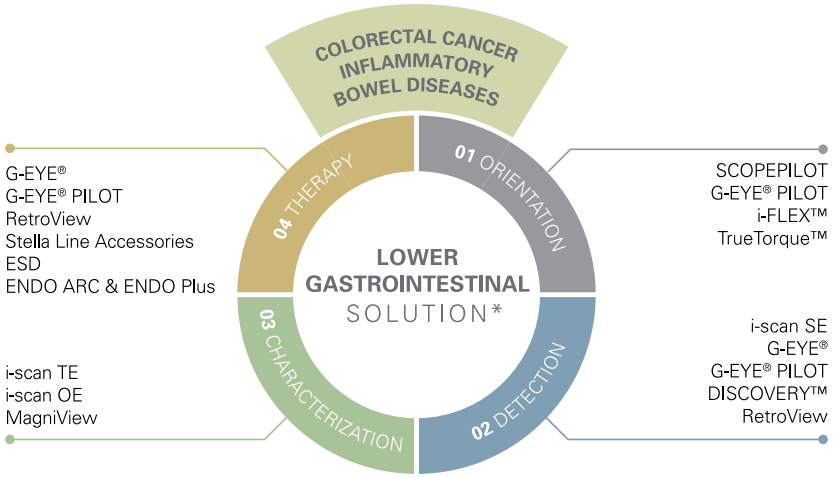
Urology solution: 58
- Diagnostic and standard therapeutics 58
- Basic diagnosis and treatment 60
- Peripherals and Accessories 62

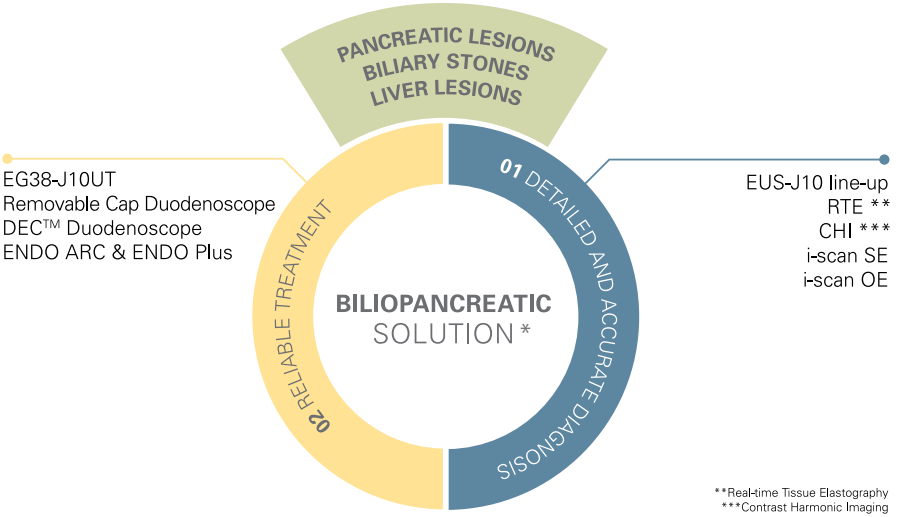
Endoscope Drying and Storage:
- Endoscope drying and storage 64

Product Compatibility Chart 66

Solutions for every discipline and market

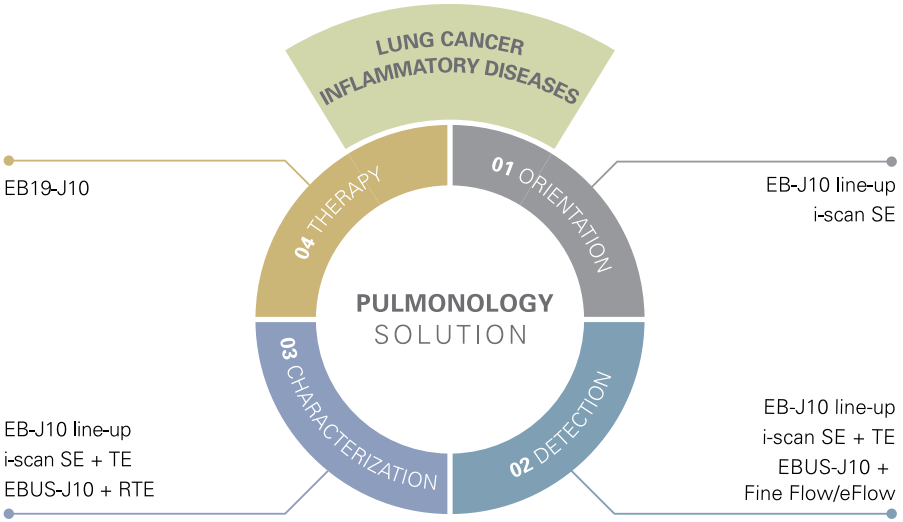


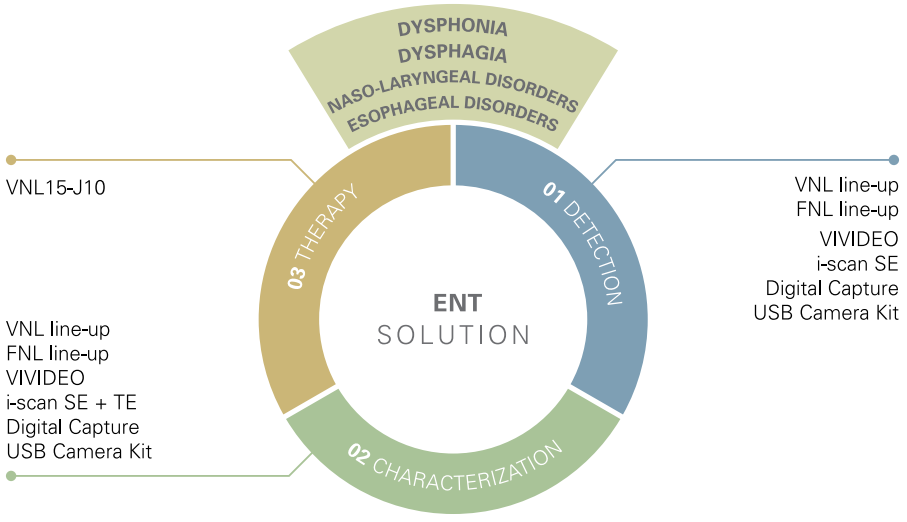




* All PENTAX Medical solutions can be combined with PlasmaTYPHOON and PlasmaBAG system for a complete endoscope drying and controlled storage solution. Please refer to page 64 for solution details.

Solutions for every discipline and market





Upper GI and Lower GI

Advanced diagnosis and treatment

Upper GI Endoscopes

Product	Insertion Tube ø (mm)	Min. Instrument Channel ø (mm)	Working Length (mm)	Tip angulation up/down (°)	Tip angulation right/left (°)	Field of view (°)	Remarks
EG17-J10 Video Gastroscope	5.7	2.0	1100	210/120	120/120	140	HD, Transnasal, wide angle
EG27-i10 Video Gastroscope	9	2.8	1050	210/120	120/120	140	HD+, Close Focus, Optimal ratio outer diameter/working channel
MagniView EG-2990Zi Video Gastroscope	9.8	2.8	1050	210/120	120/120	140	HD+, Optical Zoom, MagniView, Water Jet System, Compatible with Distal Rubber Hood: OE-A58
EG29-i10 Video Gastroscope	9.8	3.2	1050	210/120	120/120	140	HD+, Close Focus, Wide Therapeutic Option, Optimal ratio outer diameter/working channel, Water Jet System
EG34-i10 Video Gastroscope	11.6	3.8	1050	210/120	120/120	140	HD+, Close Focus, Wide Therapeutic Option, Water Jet System
EG-3890TK Video Gastroscope	12.8	3.8/2.8	1050	180/120	120/120	140	HD, Twin Channel, Water Jet System

Lower GI Endoscopes

Product	Insertion Tube ø (mm)	Min. Instrument Channel ø (mm)	Working Length (mm)	Tip angulation up/down (°)	Tip angulation right/left (°)	Field of view (°)	Remarks
RetroView EC34-i10TM Video Colonoscope EC34-i10TF Video Colonoscope EC34-i10TL Video Colonoscope	11.6	3.2	1300 1500 1700	210/180	160/160	140	HD+, Close Focus, Wide Therapeutic Option, i-FLEX and TrueTorque, Water Jet System, RetroView radius
EC34-i10M Video Colonoscope EC34-i10F Video Colonoscope EC34-i10L Video Colonoscope	11.6	3.8	1300 1500 1700	180/180	160/160	140	HD+, Close Focus, Wide Therapeutic Option, Optimal ratio outer diameter/working channel, i-FLEX and TrueTorque, Water Jet System
MagniView EC-3890MZi Video Colonoscope EC-3890FZi Video Colonoscope EC-3890LZi Video Colonoscope	13.2	3.8	1300 1500 1700	180/180	160/160	140	HD, MagniView, i-FLEX and True-Torque, Water Jet System, Distal Rubber Hood (OE-A59)
EC-3890TLK Video Colonoscope	13.2	3.8/2.8	1700	180/180	160/160	140	HD, i-FLEX and TrueTorque, Water Jet System, Twin Channel
EC38-i10M Video Colonoscope EC38-i10F Video Colonoscope EC38-i10L Video Colonoscope	13.2	3.8	1300 1500 1700	180/180	160/160	140	HD+, i-FLEX and TrueTorque, Water Jet System
EC38-i10M2 Video Colonoscope EC38-i10F2 Video Colonoscope	13.2	3.8	1300 1500	180/180	160/160	140	HD+, i-FLEX and TrueTorque, increased rigidity, Water Jet System

Upper GI and Lower GI

Advanced diagnosis and treatment | G-EYE® System

G-EYE® Endoscopes

Product	Insertion Tube ø (mm)	Min. Instrument Channel ø (mm)	Working Length (mm)	Tip angulation up/down (°)	Tip angulation right/left (°)	Field of view (°)	Remarks
G-EYE34-i10F Video Colonoscope G-EYE34-i10L Video Colonoscope	11.6	3.8	1500 1700	180/180	160/160	140	HD+, Close Focus, Wide Therapeutic Option, Optimal ratio outer diameter/working channel, i-FLEX and TrueTorque, Water Jet System, permanently integrated reusable balloon
G-EYE38-i10F Video Colonoscope G-EYE38-i10L Video Colonoscope	13.2	3.8	1500 1700	180/180	160/160	140	HD+, Close Focus, i-Flex and TrueTorque, Water Jet System, permanently integrated reusable balloon
G-EYE38-i10F2 Video Colonoscope	13.2	3.8	1500	180/180	160/160	140	HD+, i-Flex and TrueTorque, Water Jet System, permanently integrated reusable balloon, increased rigidity
G-EYE38-i10NF G-EYE PILOT Video Colonoscope G-EYE38-i10NL G-EYE PILOT Video Colonoscope	13.2	3.8	1500 1700	180/180	160/160	140	HD+, Water Jet System, Permanently integrated G-EYE® reusable balloon for increased mucosa visualization, Laser treatment, electrosurgery treatment, 3D navigation support

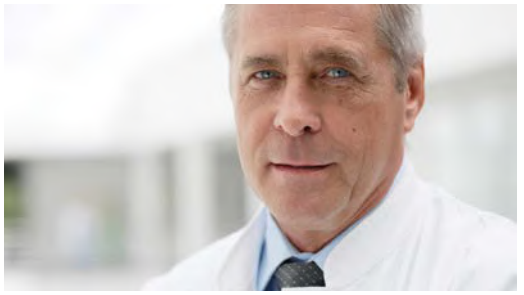
Inflation System

Electrical input voltage [VAC]	Electrical input frequency [Hz]	Dimensions [mm]	Set Pressure Tolerance [mbar]	Inflated Balloon Set Pressure [mbar]
NaviAid™ SPARK²C (Compatible with G-EYE® endoscopes and NaviAid™ AB-F)				
100 - 240	50-60	280 x 195 x 90	±10	Anchoring pressure 70. Unique Controlled Withdrawal™ pressure- 3 intermediate levels

NaviAid™ AB-F (Advancing Balloon)

Catheter Length [mm]	Compatible Working Channel [mm[	Balloon Diameter [mm]	Inflated Balloon Set Pressure [mBar]	Set Pressure Tolerance [mBar]	Balloon Inflation System - Power Supply
3,500	≥ 3.7	40	60	± 10	100-240 VAC; 50-60 Hz

Upper GI and Lower GI



Advanced diagnosis and treatment | SCOPEPILOT System

SCOPEPILOT Video Colonoscope

Product	Insertion Tube ø (mm)	Min. Instrument Channel ø (mm)	Working Length (mm)	Direction of view (°)	Tip angulation up/down (°)	Tip angulation right/left (°)	Field of view (°)	Remarks
EC38-i10NF SCOPEPILOT Video Colonoscope EC38-i10NL SCOPEPILOT Video Colonoscope EC34-i10NF SCOPEPILOT EC34-i10NL SCOPEPILOT	13.2 13.2 11.6 11.6	3.8 3.8 3.2 3.2	1500 1700 1500 1700	Forward	180/180	160/160	140	HD+, Water Jet System, i-FLEX and TrueTorque, 3D navigation support

PENTAX Medical Navigation Control Unit NCU-7000

	Item	Specifications
Power	Voltage	100 - 230VAC
	Voltage fluctuation	±10%
	Frequency	50 - 60Hz
	Rated input	150VA
Operating Environment	Ambient temperature	10°C - 30°C
	Relative humidity	30% - 75%
	Air pressure	700 - 1,060hPa
Storage and Transportation Environment	Ambient temperature	-20°C - 60°C
	Relative humidity	10% - 85%
	Air pressure	700 - 1,060hPa
Video Signal	Digital output: DVI	Resolution of the entire monitor screen: 1920 x 1080p (1 set)
Control Signal	RCU	1 set
	Keyboard	1 set
	USB	1 set (USB 2.0 compliant) USB flash memory
Image Recording Functions	Recording media	USB flash memory *USB hard drive is not available
	Recording format	JPEG
Dimensions (NCU)	Excluding protrusions	400mm (W) x 100mm (H) x 400mm (D)
	Maximum dimensions	400mm (W) x 115mm (H) x 400mm (D)
Weight		7.4kg

Processor

EPK-i7010 OPTIVISTA plus Video Processor with i-scan and i-scan OE	
Light source	300W Xenon
Advanced modalities	Digital image enhancement (i-scan SE, CE, TE) Optical image enhancement (i-scan OE)
Digital output	HD-SDI, DVI
Analog output	RGB, VGA, Y/C, VIDEO OUT
User Interface	Touch screen
Digital Zoom	yes
Dimensions (W x H x D) / Weight	400 x 205 x 520 mm, 21,5 kg

Upper GI and Lower GI

Advanced diagnosis | Artificial Intelligence

PENTAX Medical DISCOVERY™ PENTAX Medical Smart Assistant System SAS-M10
PENTAX Medical DISCOVERY™ assists endoscopists in finding potential polyps during a colonoscopy examination

Type	SAS-M10
Display	32″ LCD capacitive touch-screen
Max. resolution	3,840 × 2,160
Max. colors	10 bits (8 bits + FRC) / 1.07B colors
Pixel Pitch (mm)	0.1845 x 0.1845
Luminance (cd/m2)	350 (TYP)
Mounting/Holder	VESA 100/200 mm
Size and weight	778 × 478 × 102 mm (W × H × D); 20.6 kg
Power supply	100 – 240 V AC, 50 – 60 Hz
Degree of protection against electric shock / ingress of water	Class I / IPX0
Compatible Video Processors	EPK-i7010, EPK-i7000, EPK-i7000(A), EPK-i5500c, EPK-i5000

Upper GI and Lower GI

Diagnostic and standard therapeutics

Upper GI Endoscopes

Product	Insertion Tube ø (mm)	Min. Instrument Channel ø (mm)	Working Length (mm)	Tip angulation up/down (°)	Tip angulation right/left (°)	Field of view (°)	Remarks
EG-2490K Video Gastroscope	8	2.4	1050	210/120	120/120	140	HD
EG-2790K Video Gastroscope	9	2.8	1050	210/120	120/120	140	HD
EG-2990i Video Gastroscope	9.8	2.8	1050	210/120	120/120	140	HD+, Water Jet System

Lower GI Endoscopes

Product	Insertion Tube ø (mm)	Min. Instrument Channel ø (mm)	Working Length (mm)	Tip angulation up/down (°)	Tip angulation right/left (°)	Field of view (°)	Remarks
RetroView EC-3490TMi Video Colonoscope	11.6	3.2	1300	210/180	160/160	140	HD+, RetroView radius, i-FLEX and TrueTorque, Water Jet System
EC-3890Fi2 Video Colonoscope	13.2	3.8	1500	180/180	160/160	140	HD+, i-FLEX and TrueTorque, Water Jet System
EC-3890Fi Video Colonoscope EC-3890Li Video Colonoscope	13.2	3.8	1500 1700	180/180	160/160	140	HD+, i-FLEX and TrueTorque, Water Jet System
EC-3890TLK Video Colonoscope	13.2	3.8/2.8	1700	180/180	160/160	140	HD, i-FLEX and TrueTorque, Twin Channel, Water Jet System

Upper GI and Lower GI

Diagnostic and standard therapeutics

Processors

EPK-3000 DEFINA Video Processor with i-scan

Light source	150W Xenon
Advanced imaging modalities	Digital image enhancement (i-scan SE, CE, TE)
Digital output	DVI-D
Analog output	RGB, Y/C, composite
User Interface	Control panel, keyboard
Digital Zoom	yes
Dimensions (W x H x D)	350 x 180 x 485 mm

EPK-i5000 Video Processor with i-scan

Digital output	SXGA (native resolution) via DVI-D
Analogue output	RGB, Y/C, composite, VGA
i-scan virtual chromoendoscopy	Quick access via i-scan keys 1, 2, 3
Light source	300W Xenon
Dimensions (W x H x D / weight)	400 x 205 x 485 mm / 22.0 kg

Upper GI and Lower GI

Diagnostic and standard therapeutics | IMAGINA System

Upper GI Endoscope IMAGINA

Product	Insertion Tube ø (mm)	Min. Instrument Channel ø (mm)	Working Length (mm)	Tip angulation up/down (°)	Tip angulation right/left (°)	Field of view (°)	Remarks
EG29-i10c IMAGINA Video Gastroscope	9.8	3.2	1050	210/120	120/120	140	HD+ image, LED, Water Jet System

Lower GI Endoscopes IMAGINA

Product	Insertion Tube ø (mm)	Min. Instrument Channel ø (mm)	Working Length (mm)	Tip angulation up/down (°)	Tip angulation right/left (°)	Field of view (°)	Remarks
EC34-i10cM IMAGINA Video Colonoscope EC34-i10cF IMAGINA Video Colonoscope EC34-i10cL IMAGINA Video Colonoscope	11.6	3.8	1300 1500 1700	180/180	160/160	140	HD+ image, i-FLEX and TrueTorque, Water Jet System, LED
EC38-i10cF2 IMAGINA Video Colonoscope	13.2	3.8	1500	180/180	160/160	140	HD+ image, i-FLEX and TrueTorque, Water Jet System, LED, increased rigidity
EC38-i10cM IMAGINA Video Colonoscope EC38-i10cF IMAGINA Video Colonoscope EC38-i10cL IMAGINA Video Colonoscope	13.2	3.8	1300 1500 1700	180/180	160/160	140	HD+ image, i-FLEX and TrueTorque, Water Jet System, LED

IMAGINA G-EYE® Endoscopes

Product	Insertion Tube ø (mm)	Min. Instrument Channel ø (mm)	Working Length (mm)	Tip angulation up/down (°)	Tip angulation right/left (°)	Field of view (°)	Remarks
G-EYE34-i10cF Video Endoscope G-EYE34-i10cL Video Endoscope	11.6	3.8	1500 1700	180/180	160/160	140	HD+ image, i-FLEX and TrueTorque, Water Jet System, LED, permanently integrated reusable balloon
G-EYE38-i10cF2 Video Endoscope	13.2	3.8	1500	180/180	160/160	140	HD+ image, i-FLEX and TrueTorque, Water Jet System, LED, permanently integrated reusable balloon
G-EYE38-i10cM Video Endoscope G-EYE38-i10cF Video Endoscope G-EYE38-i10cL Video Endoscope	13.2	3.8	1300 1500 1700	180/180	160/160	140	HD+ image, i-FLEX and TrueTorque, Water Jet System, LED, permanently integrated reusable balloon

Processor IMAGINA

Product	Light Source	Advanced imaging modalities	Video Output	Digital Input	Printer-specific output	User Interface	Digital Zoom	Dimensions (W x H x D / weight)
EPK-i5500c IMAGINA Video Processor with i-scan and LED Technology	LED (build into the endoscope, not into the processor)	Digital image enhancement (SE, CE, TE)	DVI, VGA	DVI	Y/C	7 inch customizable, smartphone-like touchscreen	Up to x 2.0	400 x 172.6 x 471mm / 13kg

Upper GI and Lower GI

Basic diagnosis and treatment

Upper GI Endoscopes

Product	Insertion Tube ø (mm)	Min. Instrument Channel ø (mm)	Working Length (mm)	Tip angulation up/down (°)	Tip angulation right/left (°)	Field of view (°)	Remarks
EG-2490K Gastroscope 90K	8.0	2.4	1050	210/120	120/120	140	
EG-2790K Gastroscope 90K	9.0	2.8	1050	210/120	120/120	140	
EG-2990K Gastroscope 90K	9.8	2.8	1050	210/120	120/120	140	
EG-3890TK Gastroscope 90K	12.8	3.8/2.8	1050	180/120	120/120	140	

Lower GI Endoscopes

Product	Insertion Tube ø (mm)	Min. Instrument Channel ø (mm)	Working Length (mm)	Tip angulation up/down (°)	Tip angulation right/left (°)	Field of view (°)	Remarks
EC-3490FK Colonoscope 90K	11.6	3.8	1500	180/180	160/160	140	
EC-3490LK Colonoscope 90K	11.6	3.8	1700	180/180	160/160	140	
EC-3890FK2 Colonoscope 90K	13.2	4.2	1500	180/180	160/160	140	Insertion tube with increased rigidity in comparison with standard equipment
EC-3890FK Colonoscope 90K	13.2	4.2	1500	180/180	160/160	140	
EC-3890LK Colonoscope 90K	13.2	4.2	1700	180/180	160/160	140	
EC-3890TLK Colonoscope 90K	13.2	3.8/2.8	1700	180/180	160/160	140	

Upper GI and Lower GI

Basic diagnosis and treatment | Versa System*

Upper GI Endoscopes

Product	Insertion Tube ø (mm)	Min. Instrument Channel ø (mm)	Working Length (mm)	Tip angulation up/down (°)	Tip angulation right/left (°)	Field of view (°)	Remarks
EG27-V10c VERSA Video Gastroscope EG29-V10c VERSA Video Gastroscope	9 9.6	2.8	1050	210/90	100/100	140	HD, LED

Lower GI Endoscopes

Product	Insertion Tube ø (mm)	Min. Instrument Channel ø (mm)	Working Length (mm)	Tip angulation up/down (°)	Tip angulation right/left (°)	Field of view (°)	Remarks
EC38-V10cL VERSA Video Colonoscope EC38-V10cM VERSA Video Colonoscope	12.8	3.7	1650 1300	180/180	160/160	140	HD, LED

Processor

EPK-V1500c VERSA Video Processor with HD and LED Technology	
Video output	Y/C, DVI, RGB, SYNC, AV
Imaging enhancement	E-stressed mucosal morphology or profile for increasing the sharpness of endoscopic images. Profile enhance level has four gears to choose from.
Light source	LED
Dimensions (W x H x D / weight)	452 x 167 x 456 mm / 11.5 kg
Color tone adjustment	"R", "B" adjustment: ±25 steps
Brightness adjustment	"Y" adjustment: ±25 steps
Freeze, save, review	Endoscopic images can be frozen and saved, so that images can be reviewed
Gain control	(OFF, 1, 2 and 3)
Metering mode	Average; Peak
White balance adjustment	Press the white balance switch to perform the white balance adjustment.
Voltage	100 - 240VAC
Power frequency	50Hz/60Hz
Air flow	2 steps (H/L)

* available in selected countries only

Upper GI and Lower GI

Peripherals and Accessories

Recommended Leak Testers

Product	Remarks
SHA-P6 Automatic Leakage Tester	
Manual Leakage Tester for VERSA*	only for VERSA system

Recommended Trolleys

Product	Remarks
Classic Cart with Insulation Transformer	
PT-V10c - Endoscopic Trolley	
Uni-Cart	
Uni Cart DISCOVERY	

Recommended Monitors

Product	Remarks
21" EndoVue Monitor	
24" EndoVue Monitor	
27" Radiance Ultra Monitor	
32" EndoVue Monitor	
PENTAX ZeroWire G2 Pair, for 32" Monitor	
PENTAX ZeroWire G2 Pair, for 27" Monitor	

Pumps

Product	Remarks
EGA-500 - irrigation pump	
EGA-501 - CO_2 insufflator	
Senator30 - suction pump	

*available only in selected countries

Electrosurgery

Main Units

Product	Remarks
ARC 400 Electrosurgical Unit	
ARC PLUS Unit for ARC 400	
ENDO ARC Electrosurgical Unit	
ENDO PLUS Unit for ENDO ARC	
Fuego Basic Trolley II	

Basic Accessories for ENDO ARC

Product	Remarks
Monopolar Cable Endoscopy 2,8 mm Socket 4 mm	
Single Use Cable Return Plate 4,5 m	
Split Neutral Electrode, 90 cm^2, EASY (100 pieces)	

Basic Accessories for ARC 400

Product	Remarks
Monopolar Cable Endoscopy 2,8 mm Socket Comfort	
Single Use Cable Return Plate 4,5 m	
Split Neutral Electrode, 110 cm^2, EASY (100 pieces)	

Consumables for ENDO PLUS and ARC PLUS

Product	Remarks
Disposable Filters (50 pieces)	
Reusable Cable for Flexible Argon Probe Comfort 2,5 m	
Disposable Flexible Argon Probe, Ø 2,3 mm, 2.2 m (10 pieces)	
Disposable Flexible Argon Probe, Ø 3,2 mm, 2.2 m (10 pieces)	
Disposable Flexible Argon Probe, Ø 1,5 mm, 3 m (10 pieces)	
Disposable Flexible Argon Probe, Ø 2,3 mm, 3 m (10 pieces)	
Disposable Flexible Argon Probe, 90°, Ø 2,3 mm, 2.2 m (10 pieces)	

Biliopancreatic

Advanced diagnosis and treatment

ERCP Endoscopes

Product	Insertion Tube ø (mm)	Min. Instrument Channel ø (mm)	Working Length (mm)	Tip angulation up/down (°)	Tip angulation right/left (°)	Field of view (°)	Remarks
ED32-i10 Video DEC™ Duodenoscope	10.8	3.2	1250	120/90	105/90	105 (retro 15)	HD, DEC™ (Disposable Elevator Cap)
ED34-i10T2 Video DEC™ Duodenoscope	11.6	4.2	1250	120/90	105/90	100 (retro 10)	HD, DEC™ (Disposable Elevator Cap)
ED34-i10T Video Duodenoscope	11.6	4.2	1250	120/90	105/90	100 (retro 10)	HD, detachable distal-end cap

Endoscopic Ultrasound (EUS) Endoscopes

Product	Insertion Tube ø (mm)	Min. Instrument Channel ø (mm)	Working Length (mm)	Tip angulation up/down (°)	Tip angulation right/left (°)	Field of view (°)	Remarks
EG34-J10U Ultrasound Video Gastroscope	11.6	2.8	1250	160/130	120/120	120	Convex, RTE**, dCHI***, Frequency (MHz) 5 –13, Scan angle (°) 150
EG38-J10UT Ultrasound Video Gastroscope	12.8	4.0	1250	160/130	120/120	120	Convex, RTE**, dCHI***, Frequency (MHz) 5 –13, Scan angle (°) 150
EG36-J10UR Ultrasound Video Gastroscope	12.1	2.4	1250	150/70	70/70	140	Radial, RTE**, dCHI*** Frequency (MHz) 5 –13, Scan angle (°) 360

Processor

EPK-i7010 OPTIVISTA plus Video Processor with i-scan and i-scan OE	
Light source	300W Xenon
Advanced imaging modalities	Digital image enhancement (i-scan SE, CE, TE) Optical image enhancement (i-scan OE)
Digital output	HD-SDI, DVI
Analog output	RGB, S-Video, composite video
User interface	Touch screen, TwinMode
Digital zoom	yes
Dimensions (W x H x D)	400 x 205 x 520 mm

**Real-time Tissue Elastography
***Dynamic Contrast Harmonic Imaging

Biliopancreatic

Diagnostic and standard therapeutics

ERCP Endoscopes

Product	Insertion Tube ø (mm)	Min. Instrument Channel ø (mm)	Working Length (mm)	Tip angulation up/down (°)	Tip angulation right/left (°)	Field of view (°)	Remarks
ED34-i10T2 Video DEC™ Duodenoscope	11.6	4.2	1250	120/90	105/90	100 (retro 10)	HD+, DEC™ (Disposable Elevator Cap)
ED34-i10T Video Duodenoscope	11.6	4.2	1250	120/90	105/90	100 (retro 10)	HD+, detachable distal-end cap

Endoscopic Ultrasound (EUS) Endoscopes

Product	Insertion Tube ø (mm)	Min. Instrument Channel ø (mm)	Working Length (mm)	Tip angulation up/down (°)	Tip angulation right/left (°)	Field of view (°)	Remarks
EG34-J10U Ultrasound Video Gastroscope	11.6	2.8	1250	160/130	120/120	120	Convex, RTE*, dCHI**, Frequency (MHz) 5 –13, Scan angle (°) 150
EG38-J10UT Ultrasound Video Gastroscope	12.8	4.0	1250	160/130	120/120	120	Convex, RTE*, dCHI**, Frequency (MHz) 5 –13, Scan angle (°) 150
EG36-J10UR Ultrasound Video Gastroscope	12.1	2.4	1250	150/70	70/70	140	Radial, RTE*, dCHI**, Frequency (MHz) 5 –13, Scan angle (°) 360

Processors

EPK-i7010 OPTIVISTA plus Video Processor with i-scan and i-scan OE	
Light source	300W Xenon
Advanced imaging modalities	Digital image enhancement (i-scan SE, CE, TE) Optical image enhancement (i-scan OE)
Video output	HD-SDI, DVI
Analog output	RGB, S-Video, composite video
User interface	Touch screen, TwinMode
Digital zoom	yes
Dimensions (W x H x D)	400 x 205 x 520 mm

EPK-i5000	
Digital output	SXGA (native resolution) via DVI-D
Analog output	RGB, Y/C, composite, VGA
User interface	Control panel, keyboard
i-scan virtual chromoendoscopy	Quick access via i-scan keys 1, 2, 3
Light source	300W Xenon
Dimensions (W x H x D / weight)	400 x 205 x 485 mm / 22.0 kg

*Real-time Tissue Elastography
**Dynamic Contrast Harmonic Imaging

Biliopancreatic

Basic diagnosis and treatment

ERCP Endoscope

Product	Insertion Tube ø (mm)	Min. Instrument Channel ø (mm)	Working Length (mm)	Tip angulation up/down (°)	Tip angulation right/left (°)	Field of view (°)	Remarks
ED34-i10T Video Duodenoscope	11.6	4.2	1250	120/90	105/90	100 (retro 10)	HD, detachable distal-end cap

Endoscopic Ultrasound (EUS) Endoscopes

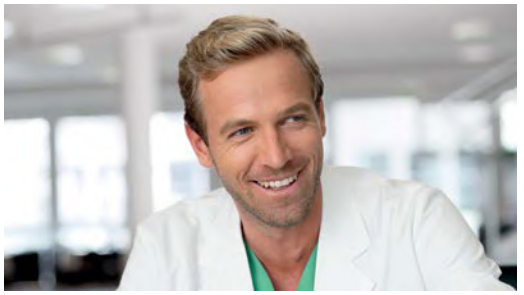
Product	Insertion Tube ø (mm)	Min. Instrument Channel ø (mm)	Working Length (mm)	Tip angulation up/down (°)	Tip angulation right/left (°)	Field of view (°)	Remarks
EG34-J10U Ultrasound Video Gastroscope	11.6	2.8	1250	160/130	120/120	120	Convex, RTE*, dCHI**, Frequency (MHz) 5 –13, Scan angle (°) 150
EG38-J10UT Ultrasound Video Gastroscope	12.8	4.0	1250	160/130	120/120	120	Convex, RTE*, dCHI**, Frequency (MHz) 5 –13, Scan angle (°) 150
EG36-J10UR Ultrasound Video Gastroscope	12.1	2.4	1250	150/70	70/70	140	Radial, RTE*, dCHI**, Frequency (MHz) 5 –13, Scan angle (°) 360

Processor

EPK-i5000	
Digital output	SXGA (native resolution) via DVI-D
Analog output	RGB, Y/C, composite, VGA
User interface	Control panel, keyboard
i-scan virtual chromoendoscopy	Quick access via i-scan keys 1, 2, 3
Light source	300W Xenon
Dimensions (W x H x D / weight)	400 x 205 x 485 mm / 22.0 kg

*Real-time Tissue Elastography
**Dynamic Contrast Harmonic Imaging

Biliopancreatic



Peripherals and Accessories

Recommended Leak Tester

Product	Remarks
SHA-P6 Automatic Leakage Tester	

Recommended Trolleys

Product	Remarks
Classic Cart with Insulation Transformer	

Recommended Monitor

Product	Remarks
27" Radiance Ultra Monitor NDS	

Accessories

Product	Remarks
OE-A65 Sterile Disposable Elevator Cap (DEC™)	DEC™ (Disposable Elevator Cap). To be used with ED32-i10 Video DEC™ Duodenoscope
OE-A63 Sterile Disposable Elevator Cap (DEC™)	To be used with ED34-i10T2 Video DEC™ Duodenoscope
OE-A55 Detachable Distal-End Cap	To be used with ED34-i10T Video Duodenoscope

Pumps

Product	Remarks
EGA-500 - irrigation pump	
EGA-501 - CO_2 insufflator	
Senator30 - suction pump	

Electrosurgery

Main Units

Product	Remarks
ARC PLUS Unit for ARC 400	
ENDO ARC Electrosurgical Unit	
ENDO PLUS Unit for ENDO ARC	
Fuego Basic Trolley II	

Basic Accessories for ENDO ARC

Product	Remarks
Monopolar Cable Endoscopy 2,8 mm Socket 4 mm	
Single Use Cable Return Plate 4,5 m	
Split Neutral Electrode, 90 cm^2, EASY (100 pieces)	

Basic Accessories for ARC 400

Product	Remarks
Monopolar Cable Endoscopy 2,8 mm Socket Comfort	
Single Use Cable Return Plate 4,5 m	
Split Neutral Electrode, 110 cm^2, EASY (100 pieces)	

Consumables for ENDO PLUS and ARC PLUS

Product	Remarks
Set of Sterile Filters (50 pieces)	
Cable for Flexible Argon Probe Comfort 2,5 m (Reusable)	
Flexible Argon Probe, Ø 2,3 mm, 2.2 m (10 pieces)	
Flexible Argon Probe, Ø 3,2 mm, 2.2 m (10 pieces)	
Flexible Argon Probe, Ø 1,5 mm, 3 m (10 pieces)	
Flexible Argon Probe, Ø 2,3 mm, 3 m (10 pieces)	
Flexible Argon Probe, 90°, Ø 2,3 mm, 2.2 m (10 pieces)	

Pulmonology

Advanced diagnosis and treatment

Endoscopes

Product	Insertion Tube ø (mm)	Min. Instrument Channel ø (mm)	Working Length (mm)	Tip angulation up/down (°)	Field of view (°)	Remarks
EB11-J10 Video Bronchoscope	3.9	1.2	600	210/130	120	HD, STERRAD® compatible
EB15-J10 Video Bronchoscope	5.2	2.0	600	210/130	120	HD, STERRAD® compatible
EB19-J10 Video Bronchoscope	6.4	2.8	600	180/130	120	HD, STERRAD® compatible
EB19-J10U Ultrasound Video Bronchoscope	6.3	2.2	600	120/90	100	Convex, Frequency [MHz] 5-13**, Scan angle 75°, RTE*

Processors

EPK-i7010 OPTIVISTA plus Video Processor with i-scan and i-scan OE	
Light source	300W Xenon
Advanced imaging modalities	Digital image enhancement (i-scan SE, CE, TE) Optical image enhancement (i-scan OE)
Digital output	HD-SDI, DVI
Analog outputs	RGB, S-Video, composite video
User interface	Touch screen, TwinMode
Digital zoom	yes
Dimensions (W x H x D)	400 x 205 x 520 mm

EPK-3000 DEFINA Video Processor with i-scan	
Light source	150W Xenon
Advanced imaging modalities	Digital image enhancement (i-scan SE, CE, TE)
Digital output	DVI-D
Analog outputs	RGB, Y/C, composite
User Interface	Control panel, keyboard
Digital Zoom	yes
Dimensions (W x H x D)	350 x 180 x 485 mm

*Real-time Tissue Elastography
**For details on frequency, refer to the instructions for use provided with the ultrasound scanning unit

Pulmonology

Diagnostic and standard therapeutics

Endoscopes

Product	Insertion Tube ø (mm)	Min. Instrument Channel ø (mm)	Working Length (mm)	Tip angulation up/down (°)	Field of view (°)	Remarks
EB15-J10 Video Bronchoscope	5.2	2.0	600	210/130	120	HD, STERRAD® compatible
EB19-J10U Ultrasound Video Bronchoscope	6.3	2.2	600	120/90	100	Convex, Frequency [MHz] 5-13*, Scan angle [°] 75, RTE*
EB19-J10 Video Bronchoscope	6.4	2.8	600	180/130	120	HD, STERRAD® compatible

Processor

EPK-3000 DEFINA Video Processor with i-scan	
Light source	150W Xenon
Advanced imaging modalities	Digital image enhancement (i-scan SE, CE, TE)
Digital output	DVI-D
Analog output	RGB, Y/C, composite
User Interface	Control panel, keyboard
Digital Zoom	yes
Dimensions (W x H x D)	350 x 180 x 485 mm

*Real-time Tissue Elastography

Pulmonology

Basic diagnosis and treatment

Endoscopes

Product	Insertion Tube ø (mm)	Min. Instrument Channel ø (mm)	Working Length (mm)	Tip angulation up/down (°)	Field of view (°)	Remarks
FB-8V Fiber Bronchoscope	2.8	1.15	600	180/130	100	Suction Control Valve
FB-15V Fiber Bronchoscope	4.9	2.1	600	180/130	120	Suction Control Valve
FB-18V Fiber Bronchoscope	6.0	2.7	600	180/130	120	Suction Control Valve
FB-19TV Fiber Bronchoscope	6.2	3.0	600	180/130	120	Suction Control Valve
FB-15RBS Portable Fiber Bronchoscope	4.9	1.95	600	180/130	100	Portable, LSV Solutions (Light Source Versatility), Plastic Suction Control Valve
FB-18RBS Portable Fiber Bronchoscope	6.0	2.55	600	180/90	100	Portable, LSV Solutions (Light Source Versatility), Plastic Suction Control Valve

Light Source

BS-LL1 LED Light Source Battery-type - for BS series only

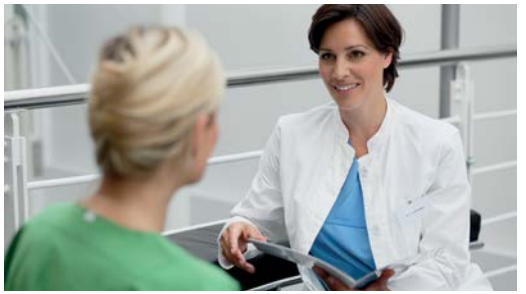
Dimensions	32 mm (W) × 32 mm (H) × 88 mm (D)
Weight	0.11 kg
Power supply	Lithium Battery DC3V
Power consumption [W]	250 mW max.
Lamp	White LED
Pressure [hPa]	700-1060

Endoscopic camera

S181P USB Camera

Sensor	CCD 1/4" high sensitivity
Resolution of the sensor	(725 x 582) PAL / (768 x 494) NTSC
Weight [g]	210
Cable length	3m, Ø 5mm
iCe Technology, Electronic anti-moiré filter for flexible fiberscope, 2 x programmable buttons, 1 x USB 2.0 output	

Pulmonology



Peripherals and Accessories

Recommended Leak Tester

Product	Remarks
SHA-P6 Automatic Leakage Tester	

Recommended Trolley

Product	Remarks
Classic Cart with Insulation Transformer	

Recommended Monitor

Product	Remarks
27" Radiance Ultra Monitor NDS	

Accessories

Product	Remarks
OF-B205 Single Use Suction Control Valves (10 pieces)	To be used with EB11-J10, EB15-J10, EB19-J10 and EB19-J10U

Intubation

Advanced diagnosis and treatment

Endoscope

Product	Insertion Tube ø (mm)	Min. Instrument Channel ø (mm)	Working Length (mm)	Tip angulation up/down (°)	Field of view (°)	Remarks
EB11-J10 Video Bronchoscope	3.9	1.2	600	210/130	120	HD, STERRAD® compatible
EB15-J10 Video Bronchoscope	5.2	2.0	600	210/130	120	HD, STERRAD® compatible
EB19-J10 Video Bronchoscope	6.4	2.8	600	180/130	120	HD, STERRAD® compatible

Processor

EPK-3000 DEFINA Video Processor with i-scan	
Light source	150W Xenon
Advanced imaging modalities	Digital image enhancement (i-scan SE, CE, TE)
Digital output	DVI-D
Analog output	RGB, Y/C, composite
User Interface	Control panel, keyboard
Digital Zoom	yes
Dimensions (W x H x D)	350 x 180 x 485 mm

Intubation

Basic diagnosis and treatment

Endoscopes

Product	Insertion Tube ø (mm)	Min. Instrument Channel ø (mm)	Working Length (mm)	Tip angulation up/down (°)	Field of view (°)	Remarks
FI-7RBS Portable Fiber Intubation Scope	2.4	-	600	130/130	95	portable, LSV (Light Source Versatility) Solution
FI-9RBS Portable Fiber Intubation Scope	3.1	1.15	600	130/130	90	portable, LSV (Light Source Versatility) Solution, Suction Control Valve
FI-10RBS Portable Fiber Intubation Scope	3.5	1.31	600	130/130	90	portable, LSV (Light Source Versatility) Solution, Suction Control Valve
FI-13RBS Portable Fiber Intubation Scope	4.2	1.72	600	160/130	95	portable, LSV (Light Source Versatility) Solution, Suction Control Valve
FI-16RBS Portable Fiber Intubation Scope	5.2	2.55	600	160/130	95	portable, LSV (Light Source Versatility) Solution, Suction Control Valve

Light Source

BS-LL1 LED Light Source Battery-type - for BS series only	
Dimensions	32 mm (W) × 32 mm (H) × 88 mm (D)
Weight	0.11 kg
Power supply	Lithium Battery DC3V
Power consumption	250 mW max.
Lamp	White LED
Pressure [hPa]	700-1060

Endoscopic camera

S181P USB Camera	
Sensor	CCD 1/4" high sensitivity
Resolution of the sensor	(725 x 582) PAL / (768 x 494) NTSC
Weight [g]	210
Cable length	3m, Ø 5mm
iCe Technology, Electronic anti-moiré filter for flexible fiberscope, 2 x programmable buttons, 1 x USB 2.0 output	

Intubation

Peripherals and Accessories

Recommended Leak Tester

Product	Remarks
SHA-P6 Automatic Leakage Tester	

Recommended Trolley

Classic Cart with Insulation Transformer	
Weight [kg]	70
Dimensions - H x W x D [mm]	1309 x 614 x 625
Cart load capacity	150

Recommended Monitor

Product	Remarks
27" Radiance Ultra Monitor	

ENT

Advanced diagnosis and treatment

Endoscopes

Product	Insertion Tube ø (mm)	Min. Instrument Channel ø (mm)	Working Length (mm)	Tip angulation up/down (°)	Field of view (°)	Remarks
VNL8-J10 Video Naso-Pharyngo-Laryngoscope	2.9	-	300	130/130	80	HD, STERRAD® compatible
VNL11-J10 Video Naso-Pharyngo-Laryngoscope	3.6	-	300	130/130	80	HD, STERRAD® compatible
VNL15-J10 Video Naso-Pharyngo-Laryngoscope	4.9	2.0	300	130/130	80	HD, STERRAD® compatible

Processor

EPK-i7010 OPTIVISTA plus Video Processor with i-scan and i-scan OE	
Light source	300W Xenon
Advanced imaging modalities	Digital image enhancement (i-scan SE, CE, TE) Optical image enhancement (i-scan OE)
Digital output	HD-SDI, DVI
Analog output	RGB, S-Video, composite video
User interface	Touch screen, TwinMode
Digital zoom	yes
Dimensions (W x H x D)	400 x 205 x 520 mm

Light Source

Product	Remarks
Laryngeal Strobe	

Digital Capturing Module

KAY9372HD Digital Capture	
Product Name	9372HD Digital Capture
Processor and Memory	Intel® Core™ i7 CPU 2.6 GHz; 16GB system RAM
Storage	Four removable hard drives (1 TB each); internal hard drive (1 TB)
Operating System	Microsoft® Windows 10 and Microsoft® Word for reports
Additional Hardware	DVD+RW drive with CD-R/RW writing capability
Connectivity	DICOM (option)
Software	Video and audio capture, processing, and playback; patient examination database management features; printing
Flouroscopy	Optional scan converter allows conversion of various and specialized input video formats to standard formats for recording and processing
Dimensions (W x H x D / weight)	211 x 444 x 495mm / 13.7kg

ENT

Diagnostic and standard therapeutics

Endoscopes

Product	Insertion Tube ø (mm)	Min. Instrument Channel ø (mm)	Working Length (mm)	Tip angulation up/down (°)	Field of view (°)	Remarks
VNL8-J10 HD Video Naso-Pharyngo-Laryngoscope	2.9	-	300	130/130	80	HD, STERRAD® compatible
VNL11-J10 HD Video Naso-Pharyngo-Laryngoscope	3.6	-	300	130/130	80	HD, STERRAD® compatible
VNL15-J10 HD Video Naso-Pharyngo-Laryngoscope	4.9	2.0	300	130/130	80	HD, STERRAD® compatible
VNL9-CP VIVIDEO Video Naso-Pharyngo- Laryngoscope	3.3	-	300	120/120	90	Only compatible with CP-1000 Video processor

Processors

EPK-3000 DEFINA Video Processor with i-scan

Light source	150W Xenon
Advanced imaging modalities	Digital image enhancement (i-scan SE, CE, TE)
Digital output	DVI-D
Analog output	RGB, Y/C, composite
User Interface	Control panel, keyboard
Digital Zoom	yes
Dimensions (W x H x D)	350 x 180 x 485 mm

CP-1000 VIVIDEO Video Processor

Video output	DVI-D, VGA
Image Format	SXGA [1280 x 1024@60p], XGA [1024 x 768@60p], 720p [1280 x 720@60p] HDTV, 1080p [1920 x 1080@30p] HDTV
Image Recording	Integrated function, external USB storage device
Dimensions (W x H x D)	75 x 340 x 380 mm

Digital Capturing Module

KAY9372HD Digital Capture

Product Name	9372HD Digital Capture
Processor and Memory	Intel® Core™ i7 CPU 2.6 GHz; 16GB system RAM
Storage	Four removable hard drives (1 TB each); internal hard drive (1 TB)
Operating System	Microsoft® Windows 10 and Microsoft® Word for reports
Additional Hardware	DVD+RW drive with CD-R/RW writing capability
Connectivity	DICOM (option)
Software	Video and audio capture, processing, and playback; patient examination database management features; printing
Flouroscopy	Optional scan converter allows conversion of various and specialized input video formats to standard formats for recording and processing
Dimensions (W x H x D / weight)	211 x 444 x 495mm / 13.7kg

Light Source

Product	Remarks
Laryngeal Strobe	

ENT

Basic diagnosis and treatment

Endoscopes

Product	Insertion Tube ø (mm)	Min. Instrument Channel ø (mm)	Working Length (mm)	Tip angulation up/down (°)	Field of view (°)	Remarks
FNL-7RP3 Fiber Naso-Pharyngo-Laryngoscope	2.4	-	300	130/130	75	
FNL-10RP3 Fiber Naso-Pharyngo-Laryngoscope	3.5	-	300	130/130	75	
FNL-10RBS Fiber Naso-Pharyngo-Laryngoscope	3.5	-	300	130/130	85	portable

Light Source

Product	Remarks
BS-LL1 LED Light Source Battery-type	
Laryngeal Strobe	

Endoscopic Camera

S181P USB Camera

Sensor	CCD 1/4" high sensitivity
Resolution of the sensor	(725 x 582) PAL / (768 x 494) NTSC
Weight	210g
Cable length	3m, Ø 5mm
iCe Technology, Electronic anti-moiré filter for flexible fiberscope, 2 x programmable buttons, 1 x USB 2.0 output	

ENT

Peripherals and Accessories

Recommended Leak Tester

Product	Remarks
SHA-P6 Automatic Leakage Tester	

Recommended Trolleys

Product	Remarks
Cart for VIVIDEO with Insulation Transformer	
PENTAX SVS Trolley	

Recommended Monitors

Product	Remarks
21″ EndoVue Monitor	
24″ EndoVue Monitor	
27″ Radiance Ultra Monitor NDS	

Accessories

Product	Remarks
OF-B205 Single Use Suction Control Valves (10 pieces)	To be used with VNL15-J10

Urology

Diagnostic and standard therapeutics

Endoscope

Product	Insertion Tube ø (mm)	Min. Instrument Channel ø (mm)	Working Length (mm)	Tip angulation up/down (°)	Field of view (°)	Remarks
ECY-1575K Video Cystoscope	5.2	2	400	210/130	120	STERRAD® compatible

Processor

EPK-3000 DEFINA Video Processor with i-scan	
Light source	150W Xenon
Advanced imaging modalities	Digital image enhancement (i-scan SE, CE, TE)
Video output	DVI-D
Analog output	RGB, Y/C, composite
User Interface	Control panel, keyboard
Digital Zoom	yes
Dimensions (W x H x D)	350 x 180 x 485 mm

Urology

Basic diagnosis and treatment

Endoscope

Product	Insertion Tube ø (mm)	Min. Instrument Channel ø (mm)	Working Length (mm)	Tip angulation up/down (°)	Field of view (°)	Remarks
FCY-15RBS Fiber Cystoscope	4.9	2.1	400	220/120	125 (A), 83 (W)	portable

Light Source

Product	Remarks
BS-LL1 LED Light Source Battery-type	
Laryngeal Strobe	

Urology

Peripherals and Accessories

Recommended Leak Tester

Product	Remarks
SHA-P6 Automatic Leakage Tester	

Recommended Trolley

Product	Remarks
ITD Classic Trolley With Insulation Transformer	

Recommended Monitors

Product	Remarks
PENTAX ZeroWire G2 Pair, for 27" Monitor	
27" Radiance Ultra Monitor	

Endoscope Drying and Storage

Endoscope Drying and Storage

PlasmaTYPHOON

Characteristic / Parameter	Value
Reference	Typhoon V2TD
Power supply / electrical network	220-240V
Frequency	50 Hz
Dimensions (length / width / height)	250 / 250 / 250 mm (9.8 / 9.8 / 9.8 in)
Pressure regukator - delivery pressure	0 to 5 bar (72.52 psi)
Pressure of the medical air at the gas inlet	3 bar (43.51 psi)
Minimal gas flowrate	60 l/min
Weight	7.5 kg

PlasmaTYPHOON* Drying Cycles

Endoscope type	Drying cycle time
Gastroscope, duodenoscope, enteroscope, colonoscope	2 min 30 s
Bronchoscope, ultrasound bronchoscope (EBUS), nasoscope, ureteroscope, cystoscope (channel diam. > 1.5mm)	1 min 30 s
Pediatric bronchoscope, nasoscope, ureteroscope, cystoscope (channel diam. <1.5mm)	1 min
Gastrointestinal ultrasound endoscope (EUS)	5 min

PlasmaBAG**

Description	Reference	Characteristics
Standard PlasmaBAG	PBag	size: 60cm x 50cm, packaging: 400 units
XL PlasmaBAG	PBagXL	size: 70cm x 64cm, packaging: 250 units
XXL PlasmaBAG	PBagXXL	size: 84cm x 60cm, packaging: 300 units

PlasmaBAG is a single-use bag specifically designed for endoscope storage using the PlasmaTYPHOON system. PlasmaBAG must be used in combination with PlasmaTYPHOON.

*Compatible with Olympus, Storz, Wolf and Fujifilm endoscopes. Compatible also with cystoscopes.
** For Urology endoscopes storage in PlasmaBAG, please check local regulations regarding need to reprocess after storage.

Product Compatibility Chart

			Processors / Lightsources									
Discipline	**Market/Application**	**Endoscope Series**	**EPK-i7010 OPTIVISTA plus**	**EPK-3000 DEFINA**	**EPK-i5000**	**EPK-i5500c IMAGINA**	**EPK-V1500c VERSA**	**CP-1000 VIVIDEO Video Processor**	**KAY9372HD Digital Capture**	**BS-LL1 LED Light Source Battery-type**	**USB camera head**	**PlasmaTYPHOON and PlasmaBAG**
Upper GI and Lower GI	Advanced diagnosis and treatment	i10	**X**		**X**							**X**
		K10	**X**	**X**	**X**							**X**
		90i	**X**		**X**							**X**
		90K	**X**	**X**	**X**							**X**
	Diagnostic and standard therapeutics	i10c				**X**						**X**
	Basic diagnosis and treatment	V10c					**X**					**X**
Biliopancreatic	Advanced diagnosis and treatment	i10, J10U	**X**									**X**
	Diagnostic and standard therapeutics	i10, J10U	**X**	**X** (J10U)	**X**							**X**
	Basic diagnosis and treatment	i10, J10U	**X**	**X** (J10U)	**X**							**X**
Pulmonology	Advanced diagnosis and treatment	i10, J10, J10U	**X**	**X** (J10, J10U)								**X**
	Diagnostic and standard therapeutics	J10, J10U, 70K	**X**	**X**								**X**
	Basic diagnosis and treatment	V, RBS								**X** (RBS-series)	**X** (V-series) **X** (RBS-series)	**X**
Intubation	Advanced diagnosis and treatment	70K		**X**								**X**
	Basic diagnosis and treatment	RBS								**X**	**X**	**X**
ENT	Advanced diagnosis and treatment	J10	**X**	**X**								**X**
	Diagnostic and standard therapeutics	J10, CP	J10	J10				CP				**X**
	Basic diagnosis and treatment	RP3, RBS		**X**						RBS	RP3, RBS	**X**
Urology	Diagnostic and standard therapeutics	75K										**X***
	Basic diagnosis and treatment	RBS								**X**	**X**	**X***

*For storage in PlasmaBAG please check local regulations regarding need to reprocess after storage in PlasmaBAG

Device	Manufacturer	EC REP	Notified Body (if applicable) and Medical Device classes
All Others	HOYA Corporation 6-10-1 Nishi-shinjuku, Shinjuku-ku Tokyo 160-0023, Japan	PENTAX Europe GmbH Julius-Vosseler-Str. 104 22527 Hamburg, Germany	TÜV Süd CE0123 Medical Device classes I, Is, IIa, and IIb
Digital Capture 9372HD	PENTAX of America, Inc. 3 Paragon Drive, Montvale NJ 07645, USA	PENTAX Europe GmbH Julius-Vosseler-Str. 104 22527 Hamburg, Germany	Medical Device class I
VERSA System	PENTAX-Aohua Medical Technologies Co. Ltd. East of 3rd Floor, Block C, Building 1, No.5 Shenwang Road, Minhang District, 201108 Shanghai, P.R. China	PENTAX Europe GmbH Julius-Vosseler-Str. 104 22527 Hamburg, Germany	TÜV Rheinland CE0197 Medical Device classes I and IIa
G-EYE® System	Smart Medical Systems Ltd. 5 HaNofar St. Ra'anana 4366404, Israel	MedNet GmbH Borkstraße 10 48163 Münster, Germany	MEDCERT CE0482 Medical Device classes I and IIa
Medical Monitors and PENTAX ZeroWire	NDS Surgical Imaging LLC 5750 Hellyer Avenue San Jose, California 95138, USA	Novanta Europe GmbH Parkring 57-59, 85748 Garching, Germany	Medical Device class I
Trolleys	ITD GmbH Sportplatzstraße 3 84381 Johanniskirchen, Germany	—	Medical Device class I
PENTAX Medical USB Camera	SOPRO ZAC Athélia IV, Avenue des Genévriers 13705 La Ciotat, Cedex, France	—	Medical Device class I
Endo Stratus™ Endoscopic Irrigation Pump and CO_2 Insufflator	Medivators Inc. 14605 28th Ave N, Minneapolis MN 55447, USA	Cantel Medical (Italy) S.r.l., Vai Laurentina, 169, 00040 Pomezia (RM), Italy	NSAI CE0050 Medical Device class IIa
ARC PLUS, ARC 400, ENDO PLUS, ENDO ARC Units, Basic Accessories and Consumables	BOWA-electronic GmbH & Co. KG Heinrich-Hertz-Strasse 4-10 72810 Gomaringen, Germany	—	TÜV Süd CE0123 Medical Device classes I and IIb
Senator 30 Suction Pump	Ardo medical AG Gewerbestraße 19 6314 Unterägeri, Switzerland	Ardo medical GmbH Argelsrieder Feld 10 82234 Oberpfaffenhofen, Germany	TÜV Süd CE0123 Medical Device class IIa
PlasmaTYPHOON and PlasmaBAG	PLASMABIOTICS SAS 116 Quai de Bezons 95106 Argenteuil Cedex, France	—	Medical Device class I
ENDO PLUS and ARC PLUS filter set	Pall Medical - A Division of Pall International Sàrl Avenue de Tivoli 3, CH-1700 Fribourg, Switzerland	Pall Genedisc Technologies 1 Rue du Courtil Centre d'Affaires Cicea - Bat 1 35170 Bruz, France	ECM CE1282 Medical Device class IIa

Distributors

EMEA Headquarters Germany
PENTAX Europe GmbH
Julius-Vosseler-Straße 104
22527 Hamburg
T +49 40 / 5 61 92 - 0
F +49 40 / 5 60 42 13
info.emea@pentaxmedical.com

Spain
SIMMEDICA – Sistemas Integrales de Medicina, S.A.
Avenida del Sistema Solar 25
28830 San Fernando de Henares Madrid
T +34 91 / 301 62 40
F +34 91 / 751 31 15
sim@simmedica.com

France
PENTAX France Life Care S.A.S.
116 quai de Bezons
B.P. 204
95106 ARGENTEUIL CEDEX
T +33 1 / 3025 7575
F +33 1 / 3025 7445
clients.fr@pentaxmedical.com

Turkey
PENTAX Turkey
Veko Giz Plaza, Meydan Sokak
No:3/43 343396
Maslak – Istanbul
T +90 212 / 705 05 26
F +90 212 / 705 05 0

Italy
PENTAX Italia S.r.l.
Via Dione Cassio, 15
20138 Milano
T +39 / 02 50 99 58 1
F +39 / 02 50 99 58 60
marketing.lifecare@pentaxitalia.it

United Kingdom
PENTAX U.K. Limited
PENTAX House
Heron Drive, Langley
Slough SL3 8PN
T +44 17 53 / 79 27 33
F +44 17 53 / 79 27 94
medical.uk@pentaxmedical.com

Russia
Moscow Representative office of PENTAX Europe GmbH (Germany)
1-ya Tverskaya-Yamskaya ulitsa, 25, stroenie 1, 6th floor
125047, Moscow
T +7 495 995 10 91
F +7 495 995 10 91 (fax ext. 234)

Netherlands
PENTAX Nederland B.V.
Edisonring 6
6669NB Dodewaard
T +31 88 / 5 30 30 30
F +31 88 / 5 30 30 40
info.nl@pentaxmedical.com

These products must be used only by healthcare professionals. Before usage and for detailed product specifications, please refer to the instructions for use. In the interest of technical process, specifications may change without notice.

Latest update: July 2021

www.pentaxmedical.com

PENTAX MEDICAL

LCM/01/07/21/320002/02 MKGEN-3003EN-EMEA Rev 1

Reusable Biopsy Forceps with Window and Spike

Model Name	Compatible Endoscopes		Note	
	Instrument Channel Diameter [mm]	Working Length [mm]		
KH2411S	2.8	1100		Autoclavable
KH2415S	2.8	1500		
KH2418CS	2.8	1800	for ERCP scopes	
KH2422S	2.8	2200		
KH2430S	2.8	3000		

Reusable Biopsy Forceps with Mini Cups

Model Name	Compatible Endoscopes		Note
	Instrument Channel Diameter [mm]	Working Length [mm]	
KS1011CS	1.2	1100	Autoclavable
KS1022CS	1.2	2200	

Reusable Biopsy Forceps with Window and Extra Large Cups

Model Name	Compatible Endoscopes		Note
	Instrument Channel Diameter [mm]	Working Length [mm]	
KW3111S	3.2	1100	Autoclavable
KW3115S	3.2	1500	
KW3122S	3.2	2200	

Reusable Biopsy Forceps with Round Cups

Model Name	Compatible Endoscopes		Note
	Instrument Channel Diameter [mm]	Working Length [mm]	
KW2411R	2.8	1100	Autoclavable
KW2415R	2.8	1500	
KW2418R	2.8	1800	
KW2422R	2.8	2200	
KW2430R	2.8	3000	

PENTAX Europe GmbH
Julius Vosseler Strasse 104
22527 Hamburg
Germany
Tel: +49-40-561-920
Fax: +49-40-560-4213

PENTAX Medical Company
A Division of PENTAX of America, inc.
3 Paragon Drive Montvale
New Jersey 07645-1782
USA
Tel: +1-201-571-2300

PENTAX Medical (Shanghai) Co., Ltd.
Room 701
291 Fumin Road, Shanghai
China 200031
Tel: +86-21-6170-1555
FAX: +86-21-6170-1655

HOYA Corporation
PENTAX Lifecare Division
1-1-110 Tsutsujigaoka
Akishima-shi
Tokyo 196-0012
Japan

CE

Product availability cannot be guaranteed in all countries. For further information please contact your local sales representative.

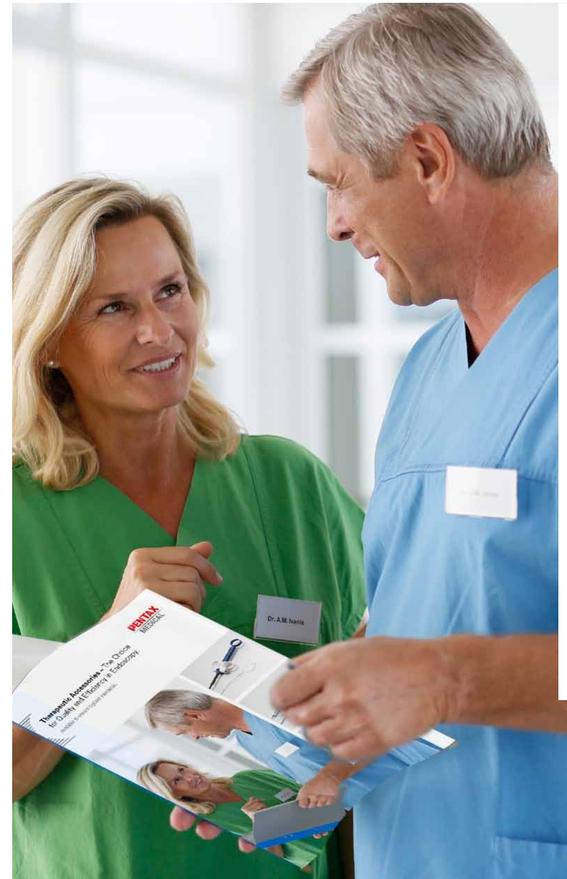
PENTAX MEDICAL
Excellence in Focus

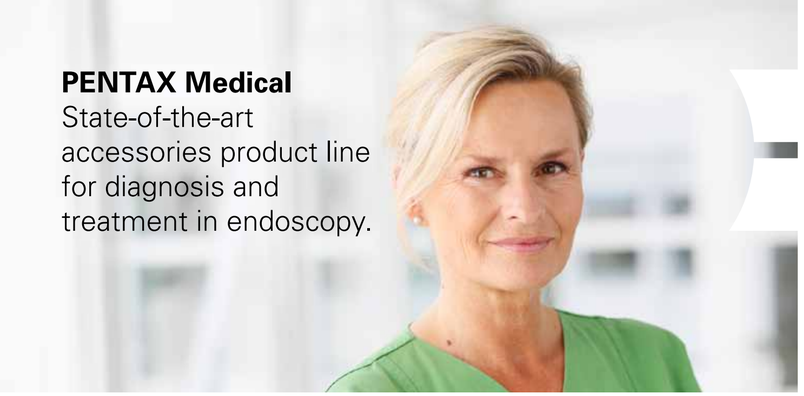
©2014 RICOH Corporation PENTAX Lifecare Div GPM-2014-002

PENTAX MEDICAL

Therapeutic Accessories – The Choice for Quality and Efficiency in Endoscopy.

Available to ensure highest standards.





PENTAX Medical
State-of-the-art accessories product line for diagnosis and treatment in endoscopy.

Our commitment to quality

Safe and successful endoscopy depends upon the use of a finely tuned endoscopic system of components. This is the underlying principle behind PENTAX Medical's commitment to a product line of therapeutic accessories with the highest possible level of quality. We invite you to examine our carefully selected and meticulously crafted therapeutic accessories for state-of-the-art diagnostic and treatment applications. All PENTAX Medical accessories have been tested in conjunction with PENTAX Medical endoscopes for function and compatibility.

How to select the correct accessories.

Before you select new accessories, please consider the following:

- The compatibility of your endoscope with the desired diagnostic/treatment application.
- The diameter of the instrument channel and working length of your endoscope.
- Use only accessories that are compatible with your endoscope to ensure the highest standards of endoscopic therapy.

PENTAX Medical
Single Use Accessories

Single Use Biopsy Forceps

Description	Model Name	Compatible Endoscopes	
		Instrument Channel Diameter [mm]	Working Length [mm]
with Windows	KW-D1810	2.0	1000
	KW-D1816	2.0	1600
	KW-D2416T	2.8	1600
	KW-D2423T	2.8	2300
with Windows/ Spike	KH-D2416T	2.8	1600
	KH-D2423T	2.8	2300
Crocodile	KA-D2416T	2.8	1600
	KA-D2423T	2.8	2300
Crocodile with Spike	KB-D2416T	2.8	1600
	KB-D2423T	2.8	2300

Single Use Retrieval Basket

Model Name	Compatible Endoscopes		Width of Basket [mm]
	Instrument Channel Diameter [mm]	Working Length [mm]	
GB-D1807L015	2.0	700	15
GB-D1810L020	2.0	1000	20
GB-D1819L020	2.0	1900	20
GB-D2415L030	2.8	1500	30
GB-D2419L020	2.8	1900	20
GB-D2423L035	2.8	2300	35

Single Use Polypectomy Snare

Description	Model Name	Compatible Endoscopes		Width of Snare Wire [mm]
		Instrument Channel Diameter [mm]	Working Length [mm]	
Oval	DO-D2416-15	2.8	1650	15
	DO-D2423-15	2.8	2300	15
	DO-D2416-20	2.8	1650	20
	DO-D2423-20	2.8	2300	20
	DO-D2416-25	2.8	1650	25
	DO-D2423-25	2.8	2300	25
Hexagonal	DH-D2416-15	2.8	1650	15
	DH-D2423-15	2.8	2300	15
	DH-D2423-20	2.8	2300	20
	DH-D2416-25	2.8	1650	25
	DH-D2423-25	2.8	2300	25

Single Use Injection Needle

Needle Size	Model Name	Compatible Endoscopes		Needle Length [mm]
		Instrument Channel Diameter [mm]	Working Length [mm]	
23G	NI-D1816-T2304	2.0	1650	4
	NI-D1816-T2305	2.0	1650	5
	NI-D1816-T2306	2.0	1650	6
	NI-D1816-T2308	2.0	1650	8
	NI-D2416-T2304	2.8	1650	4
	NI-D2416-T2306	2.8	1650	6
	NI-D2423-T2304	2.8	2300	4
	NI-D2423-T2305	2.8	2300	5
	NI-D2423-T2306	2.8	2300	6
25G	NI-D1816-T2504	2.0	1650	4
	NI-D1816-T2505	2.0	1650	5
	NI-D2416-T2504	2.8	1650	4
	NI-D2416-T2505	2.8	1650	5
	NI-D2416-T2506	2.8	1650	6
	NI-D2423-T2504	2.8	2300	4
	NI-D2423-T2505	2.8	2300	5
	NI-D2423-T2506	2.8	2300	6

Single Use Sprayer

Model Name	Compatible Endoscopes	
	Instrument Channel Diameter [mm]	Working Length [mm]
TJ-D2418PB	2.8	1800
TJ-D2423PB	2.8	2300

PENTAX Medical
Reusable Accessories (Autoclavable)

Reusable Crocodile Biopsy Forceps

Model Name	Compatible Endoscopes		Note
	Instrument Channel Diameter [mm]	Working Length [mm]	
KA1806S	1.8	600	Autoclavable
KA1811S	2.0	1100	
KA1815S	2.0	1500	
KA2411S	2.8	1100	
KA2415S	2.8	1500	
KA2422S	2.8	2200	

Reusable Biopsy Forceps with Window

Model Name	Compatible Endoscopes		Note	
	Instrument Channel Diameter [mm]	Working Length [mm]		
KW1511S	2.0	1100		Autoclavable
KW1806S	2.0	600		
KW1811S	2.0	1100		
KW1815S	2.0	1500		
KW1818S	2.0	1800		
KW1818CS	2.0	1800	for ERCP scopes	
KW2211S	2.4	1100		
KW2215S	2.4	1500		
KW2218CS	2.4	1800	for ERCP scopes	
KW2411S	2.8	1100		
KW2415S	2.8	1500		
KW2418S	2.8	1800		
KW2422S	2.8	2200		
KW2430S	2.8	3000		

PENTAX MEDICAL

PENTAX Medical – Stella line

Single-use standard accessories

Stella line

PENTAX Medical

Product line of state-of-the-art accessories for diagnosis and treatment in endoscopy.

Our commitment to quality

Safe and successful endoscopy depends on the use of a finely tuned endoscopic system of components. This is the underlying principle behind PENTAX Medical's commitment to a product line of therapeutic accessories with the highest possible level of quality. We invite you to examine our carefully selected and meticulously crafted therapeutic accessories for state-of-the-art diagnostic and treatment applications. All PENTAX Medical accessories have been tested in conjunction with PENTAX Medical endoscopes for functionality and compatibility.

How to select the correct accessories.

Before you select new accessories, please consider the following:

- The compatibility of your endoscope with the desired diagnostic/treatment application.
- The diameter of the instrument channel and working length of your endoscope.
- The compatibility of the accessories with your endoscope to ensure the highest standards of endoscopic therapy.

Table of contents

1. Hemoclips ——— page 3
2. Injection needles ——— page 3
3. Polyp snares ——— page 4
4. Cold snares ——— page 4
5. Biopsy forceps ——— page 5
6. Spray catheters ——— page 6
7. Grasping forceps ——— page 6, 7
8. Polyp traps ——— page 7

Single-use

StellaClip Hemoclips

Usage

For endoscopic hemostasis and clamping the wound in the GI tract.

Features

- Synchronous rotation supports accurate positioning.
- Repositionable clips.
- The handle's security lock system helps prevent unexpected pain for the patient.
- MR conditional.
- Packaging: boxes of 5.

Description	Model name	Item number	Maximum outer diameter [mm]	Working length [mm]	Maximum opening of clip [mm]	Compatible endoscopes channel diameter* [mm]
Uncoated	VDK-CD-11-230-O	500063	2.7 mm	2300	11	≥ Ø 2.8
Coated	VDK-CD-11-230-P	500064	2.7 mm	2300	11	≥ Ø 2.8
	VDK-CD-13-230-P	500012	2.7 mm	2300	13	≥ Ø 2.8
	VDK-CD-16-230-P	500065	2.7 mm	2300	16	≥ Ø 2.8

*Figures are based on the validation tests done by PENTAX Medical

Single-use

StellaNeedle Injection needles

Usage

Endoscopic injection treatment of esophageal and gastric varices.
Endoscopic injection of submucosa in the GI tract.

Features

- Classic handle designed to easily control the needle movement.
- 3-bevel tip designed for precise injection and prevents lumen from clogging.
- Needle shield designed to prevent damage to endoscope working channel.
- Packaging: boxes of 10.

Needle size	Model name	Item number	Outer diameter [mm]	Working length [mm]	Needle length [mm]	Compatible endoscopes channel diameter* [mm]
19G	VDK-IN-23-230-1904-A	500016	2.3	2300	4	≥ Ø 2.8
22G	VDK-IN-18-120-2205-A	500013	1.8	1200	5	≥ Ø 2.0
	VDK-IN-23-180-2204-A	500068	2.3	1800	4	≥ Ø 2.8
	VDK-IN-23-230-2205-A	500069	2.3	2300	5	≥ Ø 2.8
25G	VDK-IN-23-230-2504-A	500017	2.3	2300	4	≥ Ø 2.8
	VDK-IN-23-230-2506-A	500019	2.3	2300	6	≥ Ø 2.8

*Figures are based on the validation tests done by PENTAX Medical

Single-use

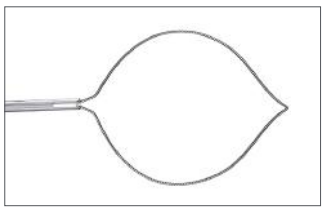
StellaLoop Polyp snares

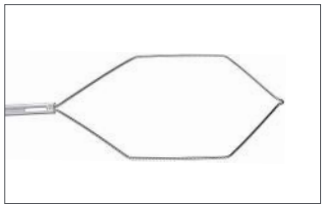
Usage

For excising polyps and other redundant tissues in the GI tract by high-frequency electricity in combination with an endoscope.

Features

- Synchronous rotation supports accurate positioning (rotatable snares).
- Made of medical stainless steel with good conductivity.
- Designed for safe and precise removal with effective coagulation.
- Braided snare loop.
- Packaging: boxes of 10.





Description	Model name	Item number	Outer diameter [mm]	Working length [mm]	Width of snare loop [mm]	Compatible endoscopes channel diameter* [mm]
Oval	VDK-SD-23-230-15-A1	500062	2.3	2300	15	≥ Ø 2.8
	VDK-SD-23-230-25-A1	500022	2.3	2300	25	≥ Ø 2.8
	VDK-SD-23-230-35-A1	500024	2.3	2300	35	≥ Ø 2.8
	VDK-SD-23-230-50-A1	500025	2.3	2300	50	≥ Ø 2.8
Oval rotatable	VDK-SD-23-230-20-A1R	500026	2.3	2300	20	≥ Ø 2.8
	VDK-SD-23-230-30-A1R	500027	2.3	2300	30	≥ Ø 2.8
Hexagonal	VDK-SD-18-160-20-C1	500028	1.8	1600	20	≥ Ø 2.0

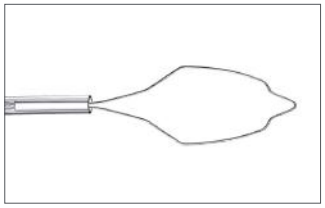
*Figures are based on the validation tests done by PENTAX Medical

Single-use

StellaCold Cold snares

Features

- To be used without electricity.
- Packaging: boxes of 10.



Description	Model name	Item number	Outer diameter [mm]	Working length [mm]	Width of snare loop [mm]	Compatible endoscopes channel diameter* [mm]
Rhombic	VDK-CS-23-230-10-C3	500030	2.3	2300	10	≥ Ø 2.8
	VDK-CS-23-230-15-C3	500031	2.3	2300	15	≥ Ø 2.8

*Figures are based on the validation tests done by PENTAX Medical

Single-use

StellaBite Biopsy forceps

Usage

Tissue sampling in GI and respiratory tracts.

Features

- Special cup sharpness designed for easy sampling.
- Wide cup opening enables massive tissue sampling.
- 4-bar linkage connecting structure of the jaws designed for good rigidity and accurate biopsy.
- Packaging: boxes of 10

Model name	Item number	Description				Jaw diameter [mm]	Working length [mm]	Compatible endoscopes channel diameter* [mm]
		Alligator-tooth jaws	Spike	Plastic screen printing scale	Coated			
VDK-FB-18-105-O-P-A1	500048	X			X	1.8	1050	≥ Ø 2.0
VDK-FB-23-230-W-P1-A1	500053	X	X	X	X	2.3	2300	≥ Ø 2.8
VDK-FB-23-230-O-P1-A1	500052	X		X	X	2.3	2300	≥ Ø 2.8
VDK-FB-18-105-O-P-B1	500039				X	1.8	1050	≥ Ø 2.0
VDK-FB-18-105-W-P-B1	500040		X		X	1.8	1050	≥ Ø 2.0
VDK-FB-18-160-O-P-B1	500041				X	1.8	1600	≥ Ø 2.0
VDK-FB-23-230-O-P1-B1	500045			X	X	2.3	2300	≥ Ø 2.8
VDK-FB-23-230-W-P1-B1	500046		X	X	X	2.3	2300	≥ Ø 2.8

*Figures are based on the validation tests done by PENTAX Medical

Single-use

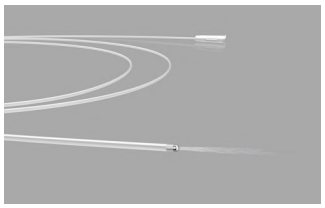
Spray catheters

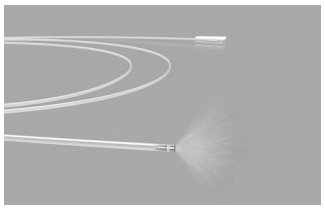
Usage

Used for conjunction with an endoscope to spray the gastrointestinal mucosa.

Features

- Two types of spray: straight (A type) and dispersive (B type: >120°) to meet various clinical requirements.
- Uniform spray application.
- Packaging: boxes of 10.





Model name	Item number	Spray type	Outer diameter [mm]	Working length [mm]	Compatible endoscopes channel diameter* [mm]
VDK-ST-23-230-A	500038	straight spray	2.3	2300	≥ Ø 2.8
VDK-ST-23-230-B	500070	dispersive spray	2.3	2300	≥ Ø 2.8

*Figures are based on the validation tests done by PENTAX Medical

Single-use

StellaNet Grasping forceps (net type)

Usage

Facilitates the removal of foreign bodies from the GI tract.

Features

- Packaging: boxes of 10.

Model name	Item number	Net size [mm]	Outer diameter [mm]	Working length [mm]	Compatible endoscopes channel diameter* [mm]
VDK-FG-25-230-C3	500056	30*60 mm	2.5	2300	≥ Ø 2.8
VDK-FG-25-230-C4	500057	40*75 mm	2.5	2300	≥ Ø 2.8
VDK-FG-25-230-C5	500058	40*65 mm	2.5	2300	≥ Ø 2.8

*Figures are based on the validation tests done by PENTAX Medical

Single-use

StellaGrasp Grasping forceps (jaw type)

Usage

Facilitates the removal of foreign bodies from the GI tract.

Features

- Variation of tooth design to facilitate the removal of a variety of foreign bodies.
- Packaging: boxes of 10.

Description	Model name	Item number	Jaw diameter [mm]	Working length [mm]	Compatible endoscopes channel diameter* [mm]
Alligator-teeth shape	VDK-FG-23-230-A1	500066	2.3	2300	≥ Ø 2.8
Rat-teeth shape	VDK-FG-23-230-A2	500067	2.3	2300	≥ Ø 2.8

*Figures are based on the validation tests done by PENTAX Medical

Single-use

StellaTrap Polyp traps

Usage

Allows for the quick and accurate retrieval of endoscopic tissue samples.

Features

- 5 numbered chambers designed to facilitate accurate identification of specimens.
- Packaging: boxes of 10.

Model name	Item number	Description
VDK-PT-05	500061	5 chambers

Manufacturer

Jiangsu Vedkang Medical Science & Technology Co., Ltd
No. 52, Guoxiang Road, Wujin
Economic Development Zone,
Changzhou, Jiangsu, China

Distributor

PENTAX Europe GmbH
Julius Vosseler Straße 104
22527 Hamburg, Germany
Tel.: +49 (0)40 561 920
Fax: +49 (0)40 560 4213
Email: info.emea@pentaxmedical.com

EC REP **Prolinx GmbH**
Brehmstr. 56
40239, Düsseldorf, Germany

CE 0197

TÜV Rheinland CE 0197 • Medical Devices Class: IIa, IIb & III • This product must be used only by healthcare professionals. Before usage and for detailed product specifications, please refer to the instructions for use. In the interest of technical process, specifications may change without notice. Product availability cannot be guaranteed in all countries. For further information please contact your local sales representative.

PENTAX MEDICAL
Excellence in Focus

LCM.K2/09/20/32061S/02

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 044963 0035 Rev. 01

Manufacturer:

Fazzini s.r.l.
SS Padana Superiore 317
20090 Vimodrone (MI)
ITALY

Product Category(ies):

Suction pumps, Powered nebulisers, diaphragm, piston and ultrasonic, Rebreathing bags and anesthesia masks, Reanimation bags and face masks, Nasal cannula and connecting tubes for oxygen and aerosol therapy

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class IIb and III devices an additional Annex III certificate is mandatory. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G2 044963 0035 Rev. 01

Report No.: ITA1466063

Valid from: 2021-03-29
Valid until: 2024-05-26

Date, 2021-03-29

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

F-60.00 / F-90.00

W 48cm **L** 46cm **H** 42cm

GB SUCTION PUMP

Mobile suction machine for professional use, with powerful double piston motor. ABS anti-shock case. Four antistatic castors, two of which with brakes. Vacuum gauge for the control of vacuum.Vacuum regulation. Two jars, 2 lt. capacity made of Makrolon autoclavable. Each jar with double security valve. Indipendent use of each jar. Supplied with disposable filter and set of tubes.

F ASPIRATEUR DE MUCOSITES

Aspirateur mobile avec puissant moteur à double piston. Boîtier en ABS antichoc avec quatre roulettes antistatiques, dont 2 avec freins. Livré avec 2 bocaux Makrolon autoclavables de 2 litres indépendants et double valve de reflux. Régulateur de dépression avec vacuomètre. Fourni avec filtre jetable et un jeu de tubes.

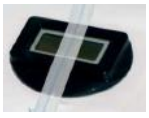
AVAILABLE CONFIGURATIONS / CONFIGURATIONS DISPONIBLES

Jar / Bocaux	230V 50-60Hz code	110V 60Hz code
2 x 2 lt.	F-60	F-60.20
2 x 2 lt. with footswitch / avec pédale	F-60/F	F-60/F.20
2 x 4 lt.	F-60/4	F-60/4.20
2 x 4 lt. with footswitch / avec pédale	F-60/F4	F-60/F4.20

Jar / Bocaux	230V 50/60Hz code	110V 60Hz code
2 x 2 lt.	F-90	F-90.20
2 x 2 lt. with footswitch / avec pédale	F-90/F	F-90/F.20
2 x 4 lt.	F-90/4	F-90/4.20
2 x 4 lt. with footswitch / avec pédale	F-90/F4	F-90/F4.20

TECHNICAL SPECIFICATIONS / SPECIFICATIONS TECHNIQUES

	F-60	F-90
Motor / Moteur	Maintenance-free Oil free piston pump	Maintenance-free Oil free piston pump
Weight / Poids	12 kg	14,5 kg
Power supply / Alimentation	230V/50-60Hz (0,260A)	230V/50-60Hz 120VA (0,93A)
Power consumption / Puissance absorbée	60 W	200W
Suction power / Débit	70 l/min	90 l/min
Max vacuum / Vide maximum	0,80 bar - 600 mmHg / -75 kPa	0,80 bar - 675 mmHg
Operating cycle / Cycle d'opération	60min ON / 30 min OFF	Continuous
Noisiness / Niveau sonore	61,2 dB	62,3 dB



SUCTION PUMP DIGITAL

Available digital diplay / Disponibles avec affichage digital
F-60 D / F-90 D / FX50 D / F100D

APPLICATIONS

Operating theatre, general surgery / Bloc opératoire, chirurgie générale