

Specificatie tehnică completată

Model: EPK-i7010/Optivista Producător: HOYA Corporation / PENTAX Medical; Țara: Japoni; PN: A010107

Lot 2. Sistem videoendoscopic pentru videogastroscopie			
Pozitia 2.1 Sistem video pentru investigarea și tratamentului căilor gastrice			
Descriere	Sistem video pentru investigarea și tratamentului căilor gastrice		
Parametrul		Specificația	Specificatia tehnica propusă de catre ofertant
Videoprocessor	Intrări cameră	≥1	DA
	Caracteristici	Ajustare nuanță	da
		Iluminare	auto
		Balans de alb	auto
		Acuitate	da
		Videocompensare	da
		Ajustarea culorilor	da
		Zoom Electronic	da
		Suporta tehnologie cromoscopie digitală sau analogica in 3 nivele	da
		Protocol de amplificarea adaugator pentru fiecare regim de cromoscopie digitala sau analogica.	da
		Inclus posibilitatea de inregistrare video direct pe USB sau HDD Extern / alt sistem de inregistrare video de inalta rezolutie cu transmitere la PC, in acest caz să fie inclus PC cu parametri recomandați de producător.	da
		Inscrierea pacientilor in baza interna	da
		Programarea protocolului pentru fiecare utilizator	da
		Afisarea datelor video endoscopului atasate la procesor la necesitatea utilizatorului.	da
			DA Tehnologie i-Scan 1,2,3 si disponibil filter optice care tip OE, OPTIVISTApplus Brochure pag. 3
			DA este disponibil, Operation manual EPK-i7010 pag. 29-38
			DA Operation manual EPK-i7010 pag. 71, 73, 91
			DA Operation manual EPK-i7010 pag. 75-76
			DA Operation manual EPK-i7010 pag. 77-79
			DA odata ce se apasa tasta space bar de pe tastiera alfanumerica pe monitor apare SN si Modelul Video endoscopului folosit
	Control	Tastatura Alfa numerica	da
		Ecran tactil cu meniu minim in limba romana/limba rusa	da
		Dimensiunile pentru ecran tactil	≥
	Ieșiri Video semnal live/real	Digital (DVI, HD-SDI,)	≥ 1
		Rezolutia de iesire	≥ 1080i
	Iesire date si	RJ45	≥1

	control	RS-232C sau anlogic	≥1	DA Operation manual EPK-i7010 pag. 91
	Compatibil cu video endoscoape	Video gastroscop	da	DA Operation manual EPK-i7010 pag. 91
		Video Colonoscop	da	DA Operation manual EPK-i7010 pag. 91
		Video Duodenoscop	da	DA Operation manual EPK-i7010 pag. 91
		Video Bronhoscop	da	DA Operation manual EPK-i7010 pag. 91
		de clasa joasa si inalta	da prezentarea listei cu care vide endoscoape este compatibil - obligatoriu	DA Operation manual EPK-i7010 pag. 91 seria 70K, 80K sint considerate seriile cele mai vechi.
	Sistema de irigare integrat a în procesor	Control	Direct de pe procesor	DA Operation manual EPK-i7010 / Air Supply pag. 26-27, 91
		nivele de irigare	pompa aer/apa cu atingerea în minim 4 nivele.	DA in 5 nivele active si oprire
Sursa de lumină	Tip		integrată in procesor	DA
	Tip lampă		Xenon/Led	DA Xenon de baza 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	DA Operation manual EPK-i7010 pag. 6, 26 prin intermediul butonului BRIGHTNESS este posibil modificari intensitati
	Mod standby		da	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 incat video procesorul ramine in stare de asteptare pentru conectarea urmatorului endoscop.
	Lampă de rezervă		da	DA
	Lampa de rezervă integrata in video procesor, pentru Tip lampă Xenon		LED	Tip LED DA Operation manual EPK-i7010 pag. 91
Periferice disponibile	Display medical		≥ 32 inch	DA Model : Radiance Ultra 32 prading PENTAX MEDICAL vezi pagina 2 din Radiance_Ultra_32_Sales_Sheet
	Rezolutia minima		≥ 1080i	DA 1080i pagina 2 din Radiance_Ultra_32_Sales_Sheet

	Suport cu brat articulat pe perete sau tavan		da solutia vine din partea vinzatorului dupa inspectarea spatiului beneficiarului final	DA este inclusa in oferta si va fi instalata.
Sistem de furnizare a aerului/apei			minim 4 nivele	DA 5 nivele active si unul de oprire completa Operation manual EPK-i7010 / Air Supply pag. 26-27, 91
			volumul vasului pentru apă minim 200 ml	DA Operation manual EPK-i7010 pag. 91
Sistem de aspirație endoscopic	Tip		Separat de procesor	DA Fazzini F60-F Broshura atasata
	Volumul rezervorului		≥ 2 litri	DA 2 L
	Vid		da	DA
	Dirijarea nivelului de aspirare		în trepte	DA
	Puterea de aspiratie a aspiratorului		minim 60 L/min	DA
	Control		Prin buton	DA
			Prin pedala	DA
Insuflator CO2	Cu sistema de incalzire		da	DA EGA-501P
	Debitul CO2 in 3 nivele minim		Nivel de Jos ≥ 1,0 L/min	DA pag. 10 din Instruction for USE CO2 Insufflator.
			Nivel Mediu ≥ 2,0 L/min	DA pag. 10 din Instruction for USE CO2 Insufflator.
			Nivelul Maxim ≥ 3,0 L/min	DA pag. 10 din Instruction for USE CO2 Insufflator.
	Spatiul pentru butelia de apa		da	DA pag. 13 din Instruction for
	Furtun pentru conecatare la butelia de CO2		da	DA
	Butelie cu CO2 cu toate componnetle de comunicare la pompa CO2		da	DA
			Volumul butelie ≥ 10 L	DA 10 L
	Accesori pentru conectarea la video endoscoape de unica folosita		≥ 1 set	DA
Pompa de irigatie	Cu sistema de incalzire		da	DA EGA-500P
	Spatiul pentru butelia de apa		da	DA pag. 12 din Instructions for USE Irrigation Pump
	Debitul de apă maxim prin canalul de video endosocopie		≥ 600 mL/min	DA 0-650ml/min (prin canalul de biopsie) pag. 9 din Instructions for USE Irrigation Pump
	Accesori pentru conectarea la video endoscoape de unica folosita		da	DA ITD Troleu reprading PENTAX MEDICAL (endo-cart)
Troleu	Polițe reglabile la înălțime		minim 4 unit	DA
	Transformator electric integrat		da	DA Operation manual ITD English, pag38
	Numarul de prize integrate in troleu		minim 5	DA este inclus
	Suport pentru 2 video endoscoape		da	DA este inclus
			reglabil pe inaltime	DA este inclus
	Sertar pliant pentru tastiera		da	DA cu posibilitate de schimbarea a positie minerului la necsitate
	Suport pentru butelie CO2		1 unit	DA
			Volumul maxim admisibil 10 L	DA
	Miner pentru controlul in timpul deplasarii		da	DA
	Roti	Pentru pozitionarea si deplsarea troleului	minim 4 buc	DA
		Frine	minim 2	DA
		Piesă bucală	minm 2 unit.	DA OF-Z5 accessories Pentax

Accesorii	Tester manual		1 unit.	DA SHA-P5
	Vas de rezervă pentru aspirator	≥ 2l		DA
		minim 1 unit		DA 1 unit
	Filtre pentru aspirator		5 unit.	DA inclus 5
	Monitor medical		1 unit.	DA Model: Radiance Ultra 32
Videogastroscoop	Compatibil cu video procesorul de mai sus		da	DA EG29-i10 PN: A113584
	Compatibil cu tehnologia de cromoscopie digitala sau analogica in minim 3 nivele		da	DA
	Tip		Rezolutie inalta HD	DA HD+ Brosura PENTAX Medical - i10 endoscope series
	Tubul de inserție	Lungime totală	≥ 1300 mm	1366 mm pag. 2din Brosura PENTAX Medical - i10 endoscope series
		Lungime de lucru	≥ 1000 mm	1050 mm pag. 2din Brosura PENTAX Medical - i10 endoscope series
		Diametrul exterior	≤ 10 mm	9,8 mm pag. 2din Brosura PENTAX Medical - i10 endoscope series
		Marcaj de lungime	da	DA
	Canal de lucru	Numărul de canale	≥1	DA
		Diametrul	nu mai mic de 2,8mm	3,2 mm pag. 2din Brosura PENTAX Medical - i10 endoscope series
	Canal adaugator pentru jetul de apa		da	DA Water Jet system – 2021 Producut Overview brochure pag 8-9
	Optica	Unghiul câmpului vizual	≥ 140 grade	da 140 grade pag. 2din Brosura PENTAX Medical - i10 endoscope series
		Înclinația câmpului vizual	0 grade	da 0 grade
		Adâncimea câmpului vizual in regim normal	2-100 mm	2-100 mm pag. 2din Brosura PENTAX Medical - i10 endoscope series
	Tipul și unghiurile de deflecție	Sus/jos	≥210/90 grade	210/120 grade pag. 2din Brosura PENTAX Medical - i10 endoscope series
		Stînga/dreapta	≥100/100 grade	120/120 pag. 2din Brosura PENTAX Medical - i10 endoscope series
	Spălarea obiectivului		da	da Operation manual EPK-i7010 (Customize > Assign scope button) pag. 44-45
	Metode de sterilizare	Chimic		da
		Etilen oxid opțional		da
		Posibilitatea de a se efectua multiple proceduri de sterilizare		da
		Compatibil cu masina audmate de dezinfectare		da
	Programarea butoanelor		da	da

	Accesori	Pensa pu biopsie de mutipla folosinta compatibil cu canalul de de lucru a videogastroscofului cu lungimea maxima de 1600 mm	minim 2 unitati	da 2 unitati PN KH2415S – Single and Reusable Accessory Pentax Medical
Prezent certificatul CE sau declaratie de conformitate			da	DA
Garantia			minim 24 luni	DA 24 luni

Model: EW 1; Poduător: Steelco SPA; Țara: Italia

2.2 Dispozitiv pentru reprocesarea automata a sistemelor de endoscopie cu un singur loc				
Descriere	Concepute pentru a dezinfecta sau steriliza folosind un sistem automat de umezire si curatare a canalelor endoscopului.			
Parametru	Specificația		Specificatia tehnica propusă de catre ofertant	
Configuratie	Integrat pe suport pe roti dotat cu frine.		DA pagina 4 din EW 1 Automated endoscope reprocessor (AER) - Stand on wheels (only for single door machine)	
			DA pagina 3 din EW 1 Automated endoscope reprocessor (AER) - The endoscope washer EW 1 allows the storage of chemical tanks inside its frame	
	minim 1 loc pentru video endoscop		DA pagina 3 din EW 1 Automated endoscope reprocessor (AER)	
Control	Prezenta butoanelor		da	DA de tip soft touch, find impermeabile la lichide, asigurînd o siguranta maxima pentru utilizator. pagina 3 din EW 1 Automated endoscope reprocessor (AER)
Display	tip color		da	DA pagina 3 din EW 1 Automated endoscope reprocessor (AER)
	diagonala		≥ 3,5 inch	DA 3,5 inch pagina 3 din EW 1 Automated endoscope reprocessor (AER)
Ciclu	Numarul de cicluri		≥ 1	DA pagina 37 din User Manual 10/ 05/2022 _REV.1.27_ COD.671064_A4
	Timp de procesare, pentru un ciclu complet		Maxim 40 minut	DA 17 min pag. 49
	Prezenta ciclului de autodizinfecare		da	DA pagina 37 din User Manual 10/ 05/2022 _REV.1.27_ COD.671064_A4 - Self-disinfection cycle
	Sistem de bracadare sau prin taguri RF endoscop cu inscrierea modelului si serie numerece a endoscopului		da	DA Barcodare pagina 4 din EW 1 Automated endoscope reprocessor (AER)

Monitoring si control

Sistem de siguranta prin barcodare sau prin taguri RF a fiecarui utilizator pentru controlul personalului care va utiliza sistemul de sterilizare		da	DA Barcodare pagina 4 din EW 1 Automated endoscope reprocessor (AER)
Prezentare pe ecran a informatie referitor la endoscop, program, etapa a ciclului, timpul ramas pina la finisarea ciclului, temperatura.		da	DA pagina 34,35, 38 din User Manual 10/ 05/2022 _REV.1.27_COD.671064_A4 - Self-disinfection cycle
Prezenta alarmelor vizuale si auditive		da	DA pagina 40 din User Manual 10/ 05/2022 _REV.1.27_COD.671064_A4 - Self-disinfection cycle
Senzor de control pentru nivelu de apa		da	DA pagina 3 din EW 1 Automated endoscope
Termo-printer integrat pentru prezentarea timpului ciclului complet sterilizat cu indicare modelului si serie numerece a endoscopului		da	DA pagina 4 din EW 1 Automated endoscope reprocessor (AER) - Built-in printer
Port USB pentru transferul datelor referitoare la istoricul ciclurilor.		da	DA pagina 3 din EW 1 Automated endoscope reprocessor (AER)
RJ-45 / LAN conectare pentru transmiterea datelor (ciclu, endoscop, eror, utilizator etc) pe un server local cu soft specializat pentru citire.		optional	DA pagina 3 din EW 1 Automated endoscope reprocessor (AER)
Numaru de programe		minim 2 progame predifinite de producator	DA STANDART PAA si SELF-DISINFECTION 80 pagina 37 din User Manual 10/ 05/2022 _REV.1.27_COD.671064_A4
		minim 2 programe care pot fi programte de utilizator la necesitate	DA
Fazele minime ale ciclului	Test de scurgere sau ermetic	da	DA pagina 49 din User Manual 10/ 05/2022 _REV.1.27_COD.671064_A4 - <i>pe Cek - leak test h: 10:14</i>
	Prespalare	da	DA pagina 49 din User Manual 10/ 05/2022 _REV.1.27_COD.671064_A4 - <i>pe Cek - preawsh h: 10:15</i>
	Spalare cu detergent	da	DA pagina 49 din User Manual 10/ 05/2022 _REV.1.27_COD.671064_A4 - <i>pe Cek - Treatment h: 10:21</i>
	Clatire	da	DA pagina 49 din User Manual 10/ 05/2022 _REV.1.27_COD.671064_A4 - <i>pe Drain test h: 10:22</i>
	Dezinfectie la temperatura joasa (minim 35 °)	da	DA pagina 49 din User Manual 10/ 05/2022 _REV.1.27_COD.671064_A4 - <i>pe Disinfect h: 10:29</i>
	Clatire	da	DA pagina 49 din User Manual 10/ 05/2022 _REV.1.27_COD.671064_A4 - <i>pe Cek - leak test h: 10:30</i>

		Test ermetic sau de scurgere pe toata durata ciclului cu monitorizare continua a presiuni iar in caz de scurgere oprirea automat indiferent de etapa ciclului.	da	DA pagina 3 din EW 1 Automated endoscope reprocessor (AER) - <i>Leakage test</i>
		Blocarea Usei in timpul ciclului pentru siguranta procesului si a prevenirii deschiderii neautorizate	da	DA pagina 2 din EW 1 Automated endoscope reprocessor (AER) - <i>Loading/unloading doors</i>
		Sistem automat de dozare cu pompa separata pentru preparatele folosite in spalarea si dezinfectare endoscoapelor	da	DA pagina 3 din EW 1 Automated endoscope reprocessor (AER) - <i>Chemical dosing system</i>
		Sistem automat de transmitere a informatie in caz ca solutia folosita pentru dezinfectie s-a finisat.	da	DA pagina 3 din EW 1 Automated endoscope reprocessor (AER) - <i>Channels tratment and monitoring</i>
		Sistem intern de filtre in minim 2 nivele	1 nivel filtru de apa maxim de 0,45 µm	DA pagina 2 din EW 1 Automated endoscope reprocessor (AER) - <i>Water connections and filtration</i>
			2 nivel filtru de apa maxim de 0,1 µm	DA pagina 2 din EW 1 Automated endoscope reprocessor (AER) - <i>Water connections and filtration</i>
		Filtru intern pentru aer minim 1	minim de 0,2 µm	DA pagina 2 din EW 1 Automated endoscope reprocessor (AER) - <i>Channels purging/drying system</i>
Tipuri agenti folositi in desivectare			Recomandati de producatori (prezentarea certificatelor microbiologice de la producatorul utilajului pentru agenti propusi)	DA pagina 9 din User Manual 10/ 05/2022 _REV.1.27_COD.671064_A4 Rezultatele si institutia carea a facut testele microbiologice pot fi vazute la pagina 7 din Technical Data Sheet SteelcoXide
Compatibilitatea cu endoscoape	Multipla	Obligatoriu prezenta conectoarelor pentru video endoscoapele Olympus prezente in dotare - minim 1 set	DA va fi inclus	
		Obligatoriu cu conectoarele pentru video gastroscopul propus in lotul precedent	DA va fi inclus	
Volum maxim de apă incarcat pentru etapa a unui ciclului			< 10 litri	DA 6 litri pagina 2 din EW 1 Automated endoscope reprocessor (AER)
	Termo printer	1 buc	DA	
	Hirtie pentru termo printer	≥ 10 buc	DA	
	Cititor de barcoduri	1 buc	DA	
	Barcoduri care pot fi programate pe dispozitivul de reprocesare	minim 1 set (minim 10 endoscopae si 5 utilizatori) (poate fi prin barcoduri sau prin TAG-uri RF)	DA	

Accesori prezente la livrare	Sistem de prefiltrare a apei seprata de dispozitivul de reprocesare	da recomandat de producator	DA
	Sistem de durizare a apei separata de dispozitivul de reprocesare in caz ca sistemul are nevoie de apa dedurizta	da	DA
	Set de conectoare necesare de conectat la Video gastroscopul din Pozitia 2.1	1 set	DA
	Set de conectoare necesare de coenctata la Video endoscopelor prezente in dotare producator OLYMPUS	1 set	DA
	Set de solutie pentu sterilizare	Cu minimul necesar pentru a începe activitatea	DA
Constructia	Otel inoxidabil tip medical	minim standard AISI 316L sau alt material calitativ compatibil conform standardului ISO 15883-5	DA AISI 316L otel inoxidabil interiorul camerei exteriorul AISI 304
Alimentare electrica		220/230V , 50/60 Hz	DA

Model: EPW 100 S; Poduător: Steelco SPA; Țara: Italia

2.3 Dispozitiv pentru spalarea semi-automat a sistemelor de video endoscopie vlexibila				
Descriere		Utilizata pentru sustinerea curatirei manuale a video endoscoapelor flexibile		
Parametru			Specificația	Specificatia tehnica propusă de catre ofertant
Conexiuni Inviduale pentru curatarea separata a fiecarui canal a			da	DA
Control	Display	Tip TFT grafic color	da	DA TFT pagina 3 din EPW 100 S
		Diagonala	≥ 4 inch	DA 4.3 inch pagina 3 din EPW 100 S
	Butoane		da tip " soft touch" - cu membran de protectie nu vor fi acceptate.	DA pagina 3 din EPW 100 S
Monitorizarea procesuluui	Registru intern pentru fiecare endoscop supus procesulul de spalare		da	DA pagina 3 din EPW 100 S
	Cititor de barcod sau alta metoda de citire fiecarui endoscop care va trece prin procesul de spalare.		da	DA pagina 3 din EPW 100 S
	Printarea rezultatului final dupa finisarea ciclului de spalare		da	DA pagina 3 din EPW 100 S
	Indicarea ficarui pas de ciclu de spalare pe ecran		da	DA pagina 2 din EPW 100 S

	Prezenta semnalului audio		da	DA pagina 3 din EPW 100 S
	Prezenta regimului testare ermetica automat pentru endoscop		da	DA
Etaple minime pentru un cilcu de sterilarea	Test de scurger care va fi activ pe tot parcursul procesului		da	DA
	Informarea Operatorului necesitate de umplere a chivetei unde este pus endoscopul		da	DA
	Activarea dozarii de dergent		da	DA
	Informarea operatorului privin curatarea ficarui canal cu perie		da	DA
	Pornire autoamta a spalari endoscopului cu solutie de curatare		da	DA
	Informarea Operatorului privind golirea chiuvetei de apa si dupa umplerea cu apa curata		da	DA
	Pornire autoamta a procesului de clatire cu apa curata		da	DA
	Informarea Operatorului privind golirea chiuvetei de apa		da	DA
	Pornirea automata a procesului de evacuare forta a rezdurilor de detergent incaz ca sint prezente in canale endoscopului		da	DA
	Informarea operatoruluu privind finisarea procesului de splare cu printarea timpului folosit pentru endoscop cu informatie model, serie numerica, data si ora.		da	DA
Prezenta ciclului de autodezinfectare a dispozitivului			da	DA Self Test
Compatibilitatea	Video endoscoapele producator Olympus		da	DA
	Video gastrocpul din Pozitia 2.1		da	DA
Prezenta popei de dozaj a detergentului			da	DA
Prezenta popei de control a presiunie cu valva de sigurant pentru suprapresiune			da	DA
Filtru intern pentru Aer folosit la testare ermeticitati endoscopului			da	DA
Pompa de recirculare a apei pentru spalarea canalelor			da	DA
Accesori si consumabile	Hirtie pentru termoprinter		minim 10 buc	DA
	Detergent		minim 100 de reprocesări	DA
	Furtune cu sistema de conectare la endoscoape		1 set pentru fiecare producator	DA
Alimentare			220/230 V si 50/60 Hz	DA

Model: ED 150/1; Poduător: Steelco SPA; Țara: Italia

Poziti 2.4 Dispozitiv pentru uscarea vertical si mentinrea endoscopului in stare sterila			
Descriere	Conceput pentru uscarea dupa procesul de sterilizare cu posibilitate de mentinere a stari sterile pe parcursul a		
Parametru	Specificația		Specificatia tehnica propusă de catre ofertant
Configuratie	Static pe podea		DA
	Numarul de locuri		≥ 6 locuri
			DA 9 locuri pagina 1 din ED 150

Locuri pentru video endoscop	Conectori	Obligativ minim 3 conectoare pentru producatorul Olympus	DA 3 pentru conectarea olympus va fi dotate
		Obligativ minim 3 conform producatorului de la Pozitia 2.1	DA 6 vor fi totdate conform necesitatiilor
	Cu incarcare verticala	da	DA pagina 2 din ED 150
	Dotat cu sertar tip culisant vertical pentru extractia comoda a video endosocpului sau alta metoda care permite extragerea video endoscopului necesar, fara a fi nevoie extragerea a altor endoscoape din fataa sau prin partile laterale.	da	DA pagina 2 din ED 150
Timpul de pastrare minim in stare sterila si gata de utilizare		≥ 20 zile	30 zile = 720 ore pagina 1 din ED 150
Usa	Numarul de usi	minim 1	DA 1
	Rama din otel inoxidabil	da	DA AISI 304 pagina 2 din ED 150
	Partea interna a ramei din sticla rezistena	da	DA AISI 304 pagina 2 din ED 150
	Prezenta lacata	da	DA
Filtru de aier intern		Minim standart HEPA H13 sau HEPA H14	DA pagina 2 din ED 150
Sistem de tratare aerului tip UV/ultraviolet de tip inchis		da	DA pagina 3 din ED 150
Temperatura de uscare		minim 40 °C	DA pagina 3 din ED 150
Posibilitate de reglarea a timpului de expunere la regimul de uscare cu pompare a aerului subpresiune sau flux intensiv. In dependentă de endoscop		da	DA
Temperatura de păstrare minim 37 °C		da	DA
Display		minim tip LED, oLED, LCD	DA LED
Control	Prin intermediul butoanelor cu protectie la lichide	da	DA
Compresor de aer integrat		da	DA
Alimentare electrica		220/230V , 50/60 Hz	DA

PRODUCT OVERVIEW

Discover the fascinating world of
PENTAX Medical endoscopy



PENTAX Medical innovation and responsibility

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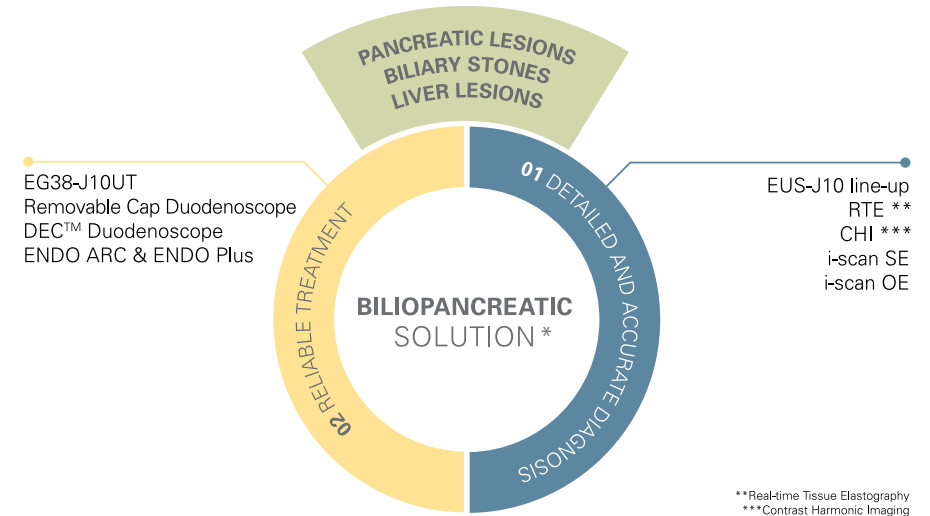
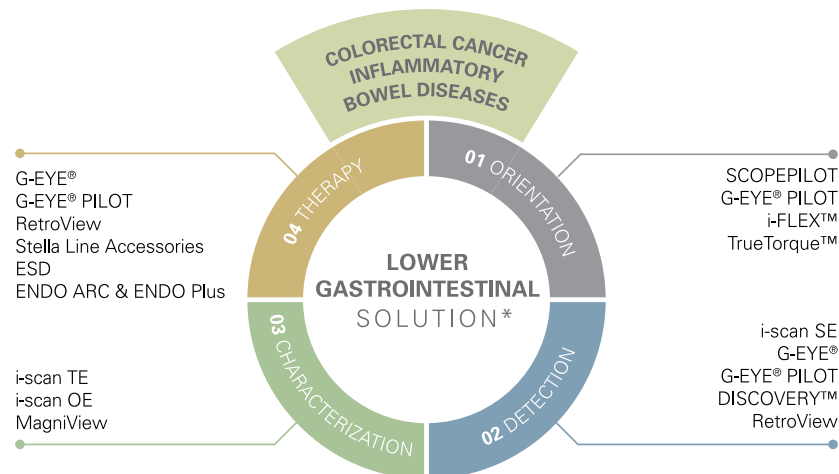
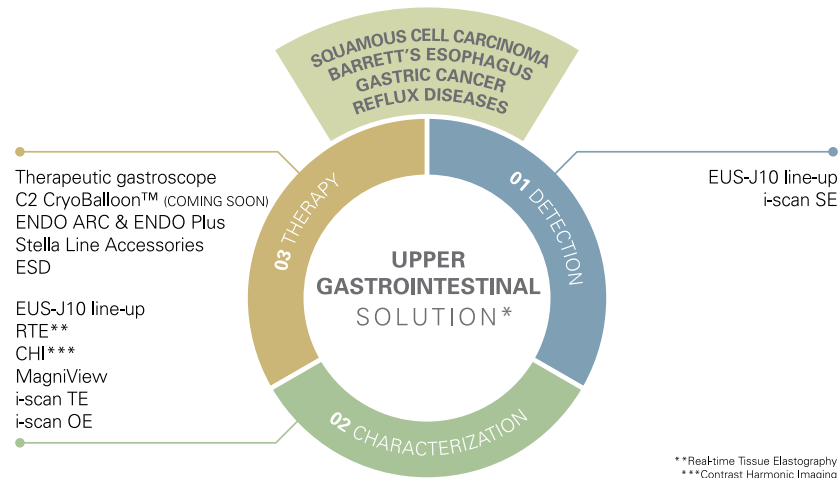
With a combination of technological innovations and medical responsibility, PENTAX Medical sets new standards for endoscopic diagnosis and therapy.

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.



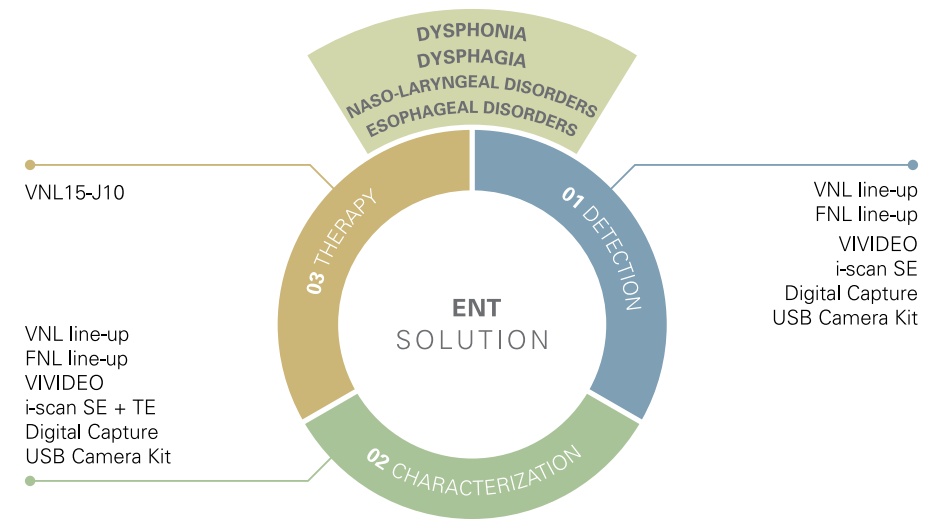
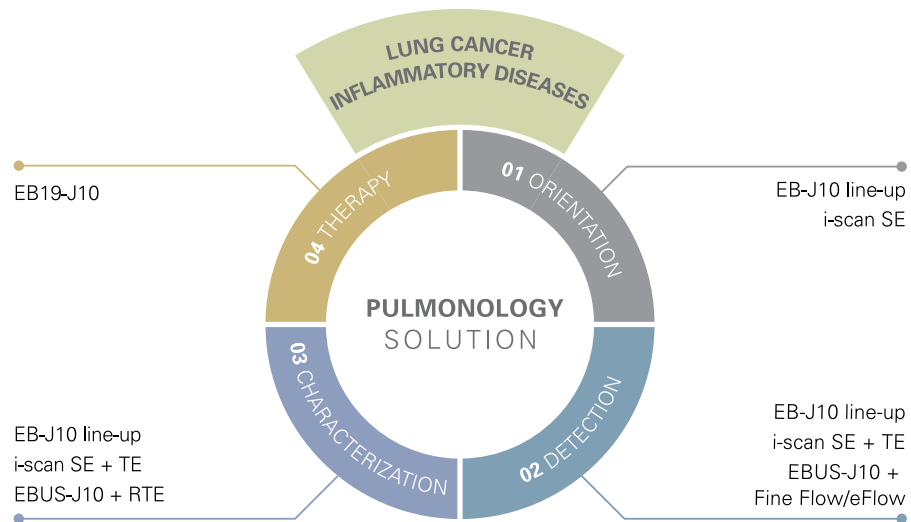
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Solutions for every discipline and market



* 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]
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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
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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	13.2	3.8	1500	Forward	180/180	160/160	140	HD+, Water Jet System, i-FLEX and TrueTorque, 3D navigation support
EC38-i10NL SCOPEPILOT Video Colonoscope	13.2	3.8	1700					
EC34-i10NF SCOPEPILOT	11.6	3.2	1500					
EC34-i10NL SCOPEPILOT	11.6	3.2	1700					

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

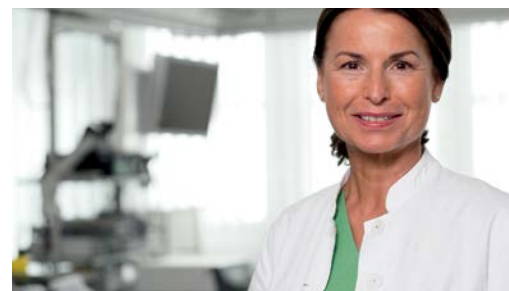
EPK-3000 DEFINA Video Processor with i-scan

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	



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

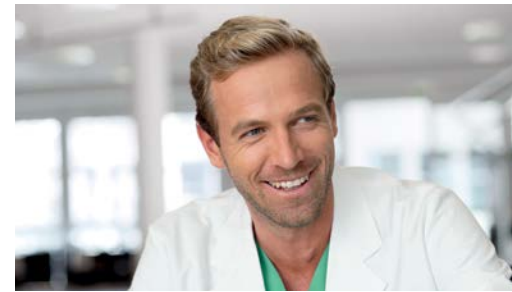
Product	Remarks
27" Radiance Ultra Monitor NDS	

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 × 582) PAL / (768 × 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	

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

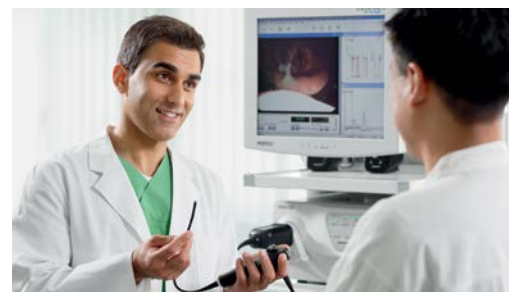
Product	Remarks
Laryngeal Strobe	



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
Fluoroscopy	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



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
Fluoroscopy	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	



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	



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	

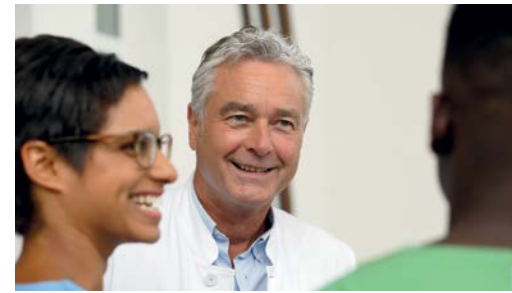
Recommended Monitors

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 regulator - 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, ureterscope, cystoscope (channel diam. > 1.5mm)	1 min 30 s
Pediatric bronchoscope, nasoscope, ureterscope, 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

Discipline	Market/Application	Endoscope Series	Processors / Lightsources									PlasmaTYPHOON and PlasmaBAG
			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	
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, Ila, 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 Ila
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 Ila
Medical Monitors and PENTAX ZeroWire	NDS Surgical Imaging LLC 5750 Hellyer Avenue San Jose, California 95138, USA	Novanta Europe GmbH Parking 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 Genèveviers 13705 La Ciotat, Cedex, France	—	Medical Device class I
Endo Stratus™ Endoscopic Irrigation Pump and CO₂ 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 Ila
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 Ila
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 Sarl 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 Ila

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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

PENTAX Medical
The i10 endoscope series.

High-Definition and high performance at its best.



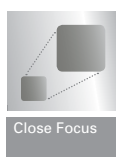
The high-end i10 endoscope series is the natural choice to meet your need for extraordinarily High-Definition image (HD+) and high endoscopic performance. The i10 series offers impressive visualisation and excellent therapeutic options. These endoscopes allow you to fully exploit their wide range of features to undertake the most sophisticated procedures. The graduated flexibility allows optimal insertion control of the endoscope, while the advanced ergonomics deliver increased maneuverability, control and comfort.

The i10 endoscope series at a glance.

High performance i10 series HD+ endoscopes

Next generation megapixel CCD for improved HD+ image quality

- Crisp, clear and bright endoscopic image combined with exceptional field of view for a superior visualisation of the mucosa. Gastrosopes, colonoscopes and, the first-to-market outstanding HD+ duodenoscope.



Exclusive Close Focus

- State-of-the-art endoscopy combined with Close Focus allows detailed examination and close visualisation of suspicious mucosal details.



Expanded Therapeutic Option

- Excellent Therapeutic Option in all standard and slim endoscopes – For your daily challenges, the best ratio of external diameter & working channel combined with Water Jet System.

Improved Graduated Flexibility (GDF)

- Improved flexibility of the insertion tube to increase patient comfort and examination performance during every colonoscopy.

Optimized control body

- Lighter weight and improved size to serve you during challenging procedures.

Product	Insertion tube [ø mm]	Instrument channel [ø mm]	Working length [mm]	Total length [mm]	Angle of view [mm]	Focal range [mm]	Tip deflection up/down [°]	Tip deflection right/left [°]
Gastrosopes i10								
EG16-K10	5.4	2.0	1,100	1,416	140	4-100	210/120	120/120
EG27-i10	9.0	2.8	1,050	1,366	140	2-100	210/120	120/120
EG29-i10	9.8	3.2	1,050	1,366	140	2-100	210/120	120/120
Duodenoscope i10								
ED34-i10T	11.6	4.2	1,250	1,566	100	4-60	120/90	105/90
Colonoscopes i10								
EC34-i10L	11.6	3.8	1,700	2,016	140	2-100	180/180	160/160
EC34-i10F	11.6	3.8	1,500	1,816	140	2-100	180/180	160/160
EC34-i10M	11.6	3.8	1,300	1,616	140	2-100	180/180	160/160
EC38-i10L	13.2	3.8	1,700	2,016	140	4-100	180/180	160/160
EC38-i10F	13.2	3.8	1,500	1,816	140	4-100	180/180	160/160
EC38-i10F2	13.2	3.8	1,500	1,816	140	4-100	180/180	160/160
EC38-i10M	13.2	3.8	1,300	1,616	140	4-100	180/180	160/160
EC38-i10M2	13.2	3.8	1,300	1,616	140	4-100	180/180	160/160

PENTAX Europe GmbH

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E-mail: medical@pentax.de . www.pentaxmedical.com

PENTAX
MEDICAL
Excellence in Focus



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



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
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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.

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20090 Vimodrone (MI)

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**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



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

A handwritten signature in black ink, reading "Kazunori Shimada".

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

List of products labeled with CE marking

Category : Endoscopes, video processors and accessories

MDD Class II a& II b / RoHS

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

List of products labeled with CE marking

Category : Endoscopes, video processors and accessories

MDD Class II a& II b / RoHS

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



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, Aug.29,2016

Yoshihiro HATAGUCHI

Vice President
Quality Assurance and
Regulatory Affairs, Japan
PENTAX Lifecare Division
HOYA Corporation

Authorized Representative in the European Union :

PENTAX Europe GmbH, Julius Vosseler Straße 104, 22527 Hamburg, Germany

PENTAX Life Care Division

List of products labeled with CE marking

Category : Endoscopes, video processors and accessories

MDD Class II a& II b / RoHS

Model Name	MDD Class	Rule	Initial date of declaration of conformity	Serial/Lot Number	Remarks
DC-D2618	II b	9	2016.8.29	B605459-	Revised 2016.8.29
DL-D2618	II b	9	2016.6.1	B501390-	
DL-D2622	II b	9	2016.6.1	—	
DN-D2718A	II b	9	2016.6.1	B602186-	
DN-D2718B	II b	9	2016.6.1	B502150-	
DN-D2722A	II b	9	2016.6.1	B601655-	
DN-D2722B	II b	9	2016.6.1	B601380-	
DO-D2618	II b	9	2016.8.29	B601086-	Revised 2016.8.29
DO-D2622	II b	9	2016.8.29	B501131-	Revised 2016.8.29
DP-D2518	II b	9	2016.8.29	B604468-	Revised 2016.8.29
DP-D2622	II b	9	2016.8.29	B604440-	Revised 2016.8.29
EB-1170K	II a	5	2016.6.1	H120632-	
EB-1570K	II a	5	2016.6.1	H122438-	
EB-1572K	II a	5	2016.6.1	G120015-	
EB-1575K	II a	5	2016.6.1	H121085-	
EB15-J10	II a	5	2016.6.1	A120008-	
EB-1970K	II a	5	2016.6.1	H121697-	
EB-1970TK	II a	5	2016.6.1	H120415-	
EB-1972K	II a	5	2016.6.1	G120011-	
EB-1975K	II a	5	2016.6.1	H120735-	
EB-1990i	II a	5	2016.6.1	H110146-	
EB19-J10	II a	5	2016.6.1	A120008-	
EC-2990Fi	II a	5	2016.6.1	H110034-	
EC-2990Li	II a	5	2016.6.1	H110198-	
EC-2990Mi	II a	5	2016.6.1	H110021-	
EC-3490Fi	II a	5	2016.6.1	—	
EC-3490FK	II a	5	2016.6.1	H120304-	
EC-3490Li	II a	5	2016.6.1	—	
EC-3490LK	II a	5	2016.6.1	H120245-	
EC-3490Mi	II a	5	2016.6.1	—	
EC-3490MK	II a	5	2016.6.1	H120052-	
EC-3490TFi	II a	5	2016.6.1	H110246-	
EC-3490TLi	II a	5	2016.6.1	H110591-	
EC-3490TMi	II a	5	2016.6.1	H110063-	
EC34-i10F	II a	5	2016.6.1	A110387-	
EC34-i10L	II a	5	2016.6.1	A110709-	
EC34-i10M	II a	5	2016.6.1	A110143-	
EC-380FK2p	II a	5	2016.6.1	H122904-	
EC-380FKp	II a	5	2016.6.1	H121099-	
EC-380LKp	II a	5	2016.6.1	H122680-	
EC-380MK2p	II a	5	2016.6.1	H120272-	
EC-3890Fi	II a	5	2016.6.1	H111703-	
EC-3890Fi2	II a	5	2016.6.1	H112559-	
EC-3890FK	II a	5	2016.6.1	H120749-	
EC-3890FK2	II a	5	2016.6.1	H121049-	
EC-3890FZi	II a	5	2016.6.1	H110084-	
EC-3890Li	II a	5	2016.6.1	H116211-	
EC-3890LK	II a	5	2016.6.1	H120935-	
EC-3890LZi	II a	5	2016.6.1	H110061-	
EC-3890Mi	II a	5	2016.6.1	—	
EC-3890Mi2	II a	5	2016.6.1	—	
EC-3890MK	II a	5	2016.6.1	H120120-	
EC-3890MK2	II a	5	2016.6.1	H120086-	
EC-3890MZi	II a	5	2016.6.1	H110044-	
EC-3890TFK	II a	5	2016.6.1	H120051-	
EC-3890TLK	II a	5	2016.6.1	H120108-	
EC38-i10F	II a	5	2016.6.1	A110999-	
EC38-i10F2	II a	5	2016.6.1	A110794-	
EC38-i10L	II a	5	2016.6.1	A111539-	
EC38-i10M	II a	5	2016.6.1	A110444-	
EC38-i10M2	II a	5	2016.6.1	A110111-	
EC38-i10NF	II a	5	2016.6.1	A110045-	
EC38-i10NL	II a	5	2016.6.1	A110036-	
ECY-1570K	II a	5	2016.6.1	H120415-	
ECY-1575K	II a	5	2016.6.1	H120438-	
ED-3490TK	II a	5	2016.6.1	H121416-	
ED34-i10T	II a	5	2016.6.1	A110621-	
EE-1580K	II a	5	2016.6.1	H120127-	
EG-1690K	II a	5	2016.6.1	—	
EG16-K10	II a	5	2016.6.1	A120318-	
EG-1870K	II a	5	2016.6.1	—	
EG-2490K	II a	5	2016.6.1	H120374-	
EG-2790i	II a	5	2016.6.1	—	
EG-2790K	II a	5	2016.6.1	H121177-	
EG27-i10	II a	5	2016.6.1	A110899-	

List of products labeled with CE marking

Category : Endoscopes, video processors and accessories

MDD Class II a& II b / RoHS

Model Name	MDD Class	Rule	Initial date of declaration of conformity	Serial/Lot Number	Remarks
EG-290Kp	II a	5	2016.6.1	H127399-	
EG-2990i	II a	5	2016.6.1	H118721-	
EG-2990K	II a	5	2016.6.1	H122541-	
EG-2990Zi	II a	5	2016.6.1	H110202-	
EG29-i10	II a	5	2016.6.1	A113584-	
EG-3490K	II a	5	2016.6.1	H120712-	
EG-3890TK	II a	5	2016.6.1	H120264-	
EPK-1000	II a	2	2016.6.1	H016084-	
EPK-100p	II a	2	2016.6.1	F013808-	
EPK-3000	II a	2	2016.6.1	A020033-	
EPK-i5000	II a	2	2016.6.1	E013560-	
			2016.6.22	A620014-	
EPK-i7000	II a	2	2016.6.1	C010936-	
EPK-i7000(A)	II a	2	2016.6.1	C010490-	
EPK-i7010	II a	2	2016.6.1	A010107-	
EPK-p(C)	II a	2	2016.6.1	B011594-	
ES-3870K	II a	5	2016.6.1	H120214-	
FB-10V	II a	5	2016.6.1	H110891-	
FB-15BS	II a	5	2016.6.1	—	
FB-15RBS	II a	5	2016.6.1	H111601-	
FB-15V	II a	5	2016.6.1	H113137-	
FB-18BS	II a	5	2016.6.1	—	
FB-18RBS	II a	5	2016.6.1	H110788-	
FB-18V	II a	5	2016.6.1	H112369-	
FB-19TV	II a	5	2016.6.1	H110737-	
FB-8V	II a	5	2016.6.1	H110744-	
FC-38FV	II a	5	2016.6.1	H110906-	
FC-38LV	II a	5	2016.6.1	H111645-	
FCN-15X	II a	5	2016.6.1	—	
FCP-9P	II a	5	2016.6.1	H110335-	
FCY-15RBS	II a	5	2016.6.1	H111082-	
FD-34V2	II a	5	2016.6.1	H110286-	
FG-16V	II a	5	2016.6.1	H110433-	
FG-24V	II a	5	2016.6.1	H112083-	
FG-29V	II a	5	2016.6.1	H117736-	
FHY-10RBS	II a	5	2016.6.1	H110282-	
FHY-15RBS	II a	5	2016.6.1	H110202-	
FI-10BS	II a	5	2016.6.1	—	
FI-10RBS	II a	5	2016.6.1	H111270-	
FI-13BS	II a	5	2016.6.1	—	
FI-13RBS	II a	5	2016.6.1	H110696-	
FI-16BS	II a	5	2016.6.1	—	
FI-16RBS	II a	5	2016.6.1	H111530-	
FI-7BS	II a	5	2016.6.1	—	
FI-7RBS	II a	5	2016.6.1	H110318-	
FI-9BS	II a	5	2016.6.1	—	
FI-9RBS	II a	5	2016.6.1	H110638-	
FNL-10RBS	II a	5	2016.6.1	H115649-	
FNL-10RP3	II a	5	2016.6.1	H141695-	
FNL-15RP3	II a	5	2016.6.1	H112263-	
FNL-7RP3	II a	5	2016.6.1	H115067-	
FS-34V	II a	5	2016.6.1	H111651-	
FUR-9RBS	II a	5	2016.6.1	H110218-	
HDB2418	II b	9	2016.6.1	—	
HDB2418W	II b	9	2016.8.29	to be fixed later	Revised 2016.8.29
HDB2422	II b	9	2016.6.1	—	
HDB2422W	II b	9	2016.8.29	to be fixed later	Revised 2016.8.29
H-S2518	II b	9	2016.8.29	to be fixed later	Revised 2016.8.29
H-S2522	II b	9	2016.8.29	to be fixed later	Revised 2016.8.29
HS-D2618	II b	9	2016.6.1	to be fixed later	
HS-D2622	II b	9	2016.6.1	to be fixed later	
LH-150PC	II a	2	2016.6.1	B043790-	
OF-B205	II a	5	2016.6.1	0011026-	
OS-H3	II a	2	2016.6.1	0021046-	
OS-H4	II a	2	2016.6.1	0051046-	
OS-H5	II a	2	2016.6.1	0081026-	
VNL-1070STK	II a	5	2016.6.1	H120233-	
VNL-1190STK	II a	5	2016.6.1	H120300-	
VNL11-J10	II a	5	2016.6.1	A120014-	
VNL-1570STK	II a	5	2016.6.1	H120446-	
VNL-1590STi	II a	5	2016.6.1	H110250-	
VNL15-J10	II a	5	2016.6.1	A120003-	
VNL8-J10	II a	5	2016.6.1	A120012-	
VSB-2990i	II a	5	2016.6.1	H110095-	

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 TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD
ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ 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

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



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

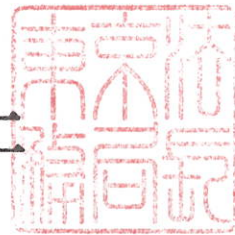
証 明

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. 21. 2019

7. by the Ministry of Foreign Affairs

8. 19- NO 065483

9. Seal/stamp:

10. Signature



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

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/ЕЕС о медицинских изделиях (MDD), Приложение II, исключая (4)
(Изделия Класса Па, Пб или III)
№: G1 068357 0028 Верс. 00

**Производственный(е)
объект(ы)**

ХОЯ Корпорейшн Фабрика ПЕНТАКС Мяги
30-2 Окада, Аза-Шимомияно, Цукидате, Курихара-Ши,
Мяги, 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

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/ЕЕС о медицинских изделиях (MDD), Приложение II, исключая (4)

(Изделия Класса Па, Пб 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 (Па, Пб)

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

Страница 1 из 2

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

TÜV SÜD Product Service GmbH-Сертификационный орган - Ридлерштрассе 65 - 80339 г.Мюнхен-Германия
TÜV®

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 Акимов 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.

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

ВРИО нотариуса

Е.Д. Ребрина



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. Independent use of each jar. Supplied with disposable filter and set of tubes.

F ASPIRATEUR DE MUCOSITES

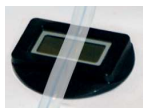
Aspirateur mobile avec puissant moteur à double piston. Boîtier en ABS antichoc avec quatre roulettes antistatiques, dont 2 avec freins. Livré avec 2 bocaux Makrolon autoclavables de 2 litres indépendants et double valve de reflux. Régulateur de dépression avec vacuomètre. Fourni avec filtre jetable et un jeu de tubes.

AVAILABLE CONFIGURATIONS / CONFIGURATIONS DISPONIBLES

Jar / Bocaux	230V 50/60Hz	110V 60Hz
2 x 2 lt.	code F-60	code 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	110V 60Hz
2 x 2 lt.	code F-90	code 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 display / Disponibles avec affichage digital
F-60 D / F-90 D / FX50 D / F100D

APPLICATIONS

Operating theatre, general surgery /
Bloc opératoire, chirurgie générale

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」

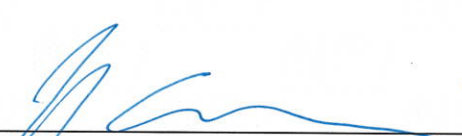
HOYA 株式会社
PENTAX ライフケア事業部
開発統括部長代理
兼 カスタマーソリューション開発部 部長
坂井 康弘

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



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:



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

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

-/-



囑託人 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 糸 懐
WATAHIKI Yutaka



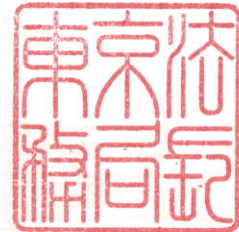
証 明

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



認

証

囑託人 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

綿永 懐



WATAHIKI Yutaka

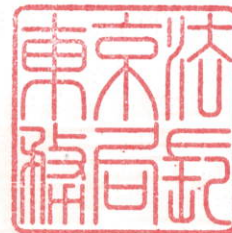
証 明

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

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



WATAHIKI Yutaka

NOTARY

9 - 21, 3 - CHOME, SHIBAZAKICHO

TACHIKAWA, TOKYO, JAPAN

TOKYO LEGAL AFFAIRS BUREAU

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

Страница 1 из 2

TÜV SÜD Product Service GmbH-Сертификационный орган - Ридлерштрассе 65 - 80339 г.Мюнхен-Германия

TÜV®

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 Мяги
30-2 Окада, Аза-Шимомияно, Цукидате, Курихара-ши, Мяги,
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, Сибасаки-тё, 3-тёме, 9-21

Нотариус, подведомственный Токийскому бюро по юридическим вопросам

Печать: Нотариус БАТАХИКИ Ютака.

Нотариус

[Подпись]

БАТАХИКИ 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 **БАТАХИКИ Ютака**
3. выступающим в качестве **нотариуса Токийского бюро по юридическим вопросам**
4. заверен печатью/штампом **БАТАХИКИ 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]

БАТАХИКИ 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.

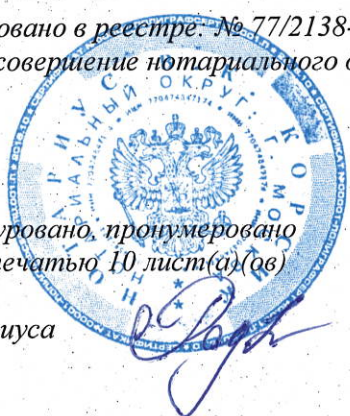
Подпись сделана в моем присутствии.

Личность подписавшего документ установлена.

Зарегистрировано в реестре: № 77/2138-н/77-2022-13-2453
Уплачено за совершение нотариального действия: 400 руб. 00 коп.

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

ВРИО нотариуса



У.А. Родина



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 – Expand your possibilities for optical diagnosis.

The PENTAX Medical platform for high-end endoscopy.

PENTAX
MEDICAL



Choose your system for success.

New possibilities for optical diagnosis with the unique premium series from PENTAX Medical.

High-Definition (HD+) endoscopy and optical diagnosis have become the new standard in clinical care. An increasing number of endoscopists regularly makes use of advanced technologies in their daily work. PENTAX Medical's imaging equipment can meet individual needs and technical requirements. The premium video processor EPK-i7000 and the high performance i10 series endoscopes offer the latest advances in endoscopic imaging technology.

PENTAX Medical provides the best solutions to support physicians all over the world in fulfilling their key roles in the health system. It provides aspiring endoscopists and leading physicians with highly sophisticated equipment and instruments to help sharing their latest findings with colleagues and fellows. Its innovative platform allows you to see better, achieve more and work more effectively.

See better

Exceptional image quality and full i-scan Management.

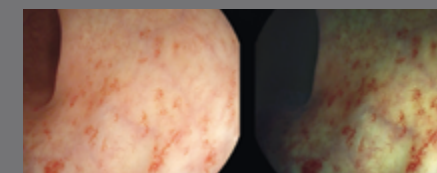
Achieve more

Double your information: more detailed information.

Work easier

With innovative features to support your daily challenges.

"An extraordinary product platform, designed to meet the needs of our customers."



Angiodysplasia rectum



- HD+ high resolution imaging across the full range of endoscopes for better orientation
- Full i-scan Management to support detection, demarcation and complete pattern characterisation
- Close view of the mucosa for diagnostic as well as therapeutic procedures
- State-of-the-art image resolution (HD+) and i-scan functions combined in the Twin Mode for improved assessment of lesions
- Expanded therapeutic options in a standard endoscope: ratio outer diameter-working channel
- Videos, images and voice can be collected at the same time
- Integrated HD+ Video Recording and freeze scan to collect and share clinical findings
- Ergonomic design for improved comfort for users and patients
- Graduated flexibility (GDF) for a smooth intubation of the caecum

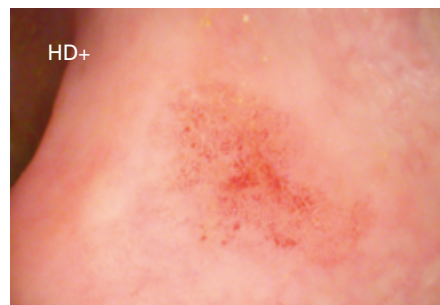
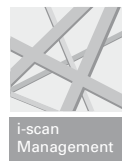


PENTAX Medical – The ultimate video processor: EPK-i7000.

Detect & define

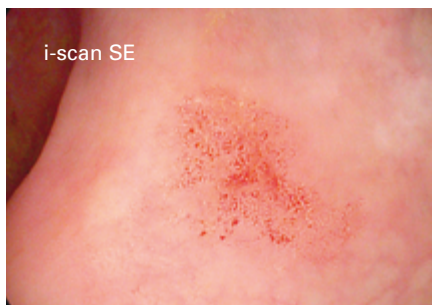
Enhance your endoscopic options with HD+ and full i-scan Management.

Tailor your i-scan settings to current and future needs for enhanced detection and complete pattern characterisation.



Extraordinarily High-Definition (HD+) images and excellent illumination

- Supports fast orientation and detection
- Significant improvement in the visibility and evaluation of minute lesions
- Integrated zoom function for more detailed inspection of suspicious surface structures



Detection and delineation support with i-scan Surface Enhancement (SE)

- i-scan SE retains the natural color tones
- Accentuation of tissue structures at the touch of a button
- Mucosal enhancement potentially supports the detection of flat lesions



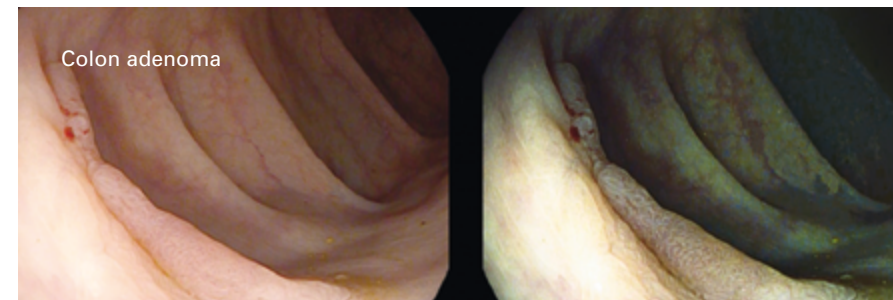
Support in characterisation with i-scan Tone Enhancement (TE)

- Specific imaging technology for further assistance in endoscopic procedures
- Allows more accentuated display of mucosal structures which may support lesion characterisation
- Virtual chromoendoscopy may help to improve endoscopic diagnosis

Teach & assess

Twin Mode: State-of-the-art endoscopy with two images side-by-side.

The PENTAX Medical Twin Mode is an advanced technology that combines leading-edge HD+ quality and i-scan images to support detection and characterisation of lesions.



- Twin Mode doubles your information: different lesion details can be seen and compared at the same time
- Twin Mode allows simultaneous comparison of side-by-side endoscopic images during the entire examination
- Twin Mode facilitates the assessment of detected lesions by direct evaluation of different i-scan modes

Among tutors and speakers, the new Twin Mode is highly appreciated as an educational tool for “building the bridge” between HD+ white light images and i-scan findings.

The simultaneous comparison of enhanced clinical images is useful in teaching the appropriate characterisation of lesions.

Collect & share

Capture your examinations with integrated HD+ Video Recording.

It is all about collecting and sharing the latest scientific findings in the same HD+ image quality as experienced in the endoscopy room.



The EPK-i7000 provides integrated HD+ Video Recording and freeze scan to:

- Collect High-Definition (HD+) videos, images and voice at the same time – at the touch of a button
- Share the most important findings within your scientific network
- Record your reports and personal comments on the HD+ video
- Save cost: built-in Video Recording provides easy & quick recording

Diagnostic proof

Improved support along the diagnostic pathway.

For better detection

	HD+	HD+ and i-scan	p-value	The use of i-scan increases overall polyp detection rates, adenoma detection rates, and increases the number of advanced lesions detected during screening colonoscopy.
n	931	1033		
Number of patients with an adenoma	27%	33%	P< .01	
Number of adenomas per examined patient	.45	.59	P< .01	
Number of non-adenomatous polyps/ examined patients	.51	.61	P=0.02	
Number of advanced polyps/ examined patients	.061	.095	P< .01	

“High-Definition Colonoscopy Combined With i-scan Imaging Technology is Superior in the Detection of Adenomas and Advanced Lesions Compared to High-Definition Colonoscopy Alone.”
Gagovic V. et al, Abstract DDW, 2011

For better detection

Results	HD+	Standard*	p-value	With PENTAX HD+ endoscopes, the adenoma detection rate is significantly superior to standard resolution endoscopes.*
Patients	100	100		
Patients with at least one adenoma	38	18	< .0001	
Total number of lesions	145	37	< .0001	
Total number of neoplasias	80	16	< .0001	
Number of flat adenomas	22	3	< .0001	
p<0.0001 Mann-Whitney Test				

“High-Definition Colonoscopy Combined With i-scan Imaging Technology is Superior in the Detection of Adenomas and Advanced Lesions Compared to High-Definition Colonoscopy Alone.”
Gagovic V. et al, Abstract DDW, 2011

For easier characterisation

Pit pattern	Hyperplasia	Neoplasia	Total	Histology could be predicted with a high sensitivity (98 %) and a high specificity (100 %) using i-scan TE.
Hyperplasia pit pattern I/II	63	2	65	
Neoplastic lesions pit pattern III/IV/V	0	80	80	

“High-definition colonoscopy combined with i-scan is superior in the detection of colorectal neoplasias compared to standard video colonoscopy.”
Hoffman A. et al, Endoscopy 2010

For more accurate diagnosis in GERD

	HD+	i-scan	Lugol's solution	i-scan as well as Lugol's solution (chromoendoscopy) significantly improve the identification of patients with oesophagitis.
Number of patients with macroscopically defined oesophagitis	9	12 ²	25 ¹	
Number of small lesions	21	58 ¹	85	
¹ Significant p<0.01 ² Not significant p<0.01				

“High-definition endoscopy with i-scan and Lugol’s solution for more precise detection of mucosal breaks in patients with reflux symptoms.”
Hoffman A. et al, Endoscopy 2009

For reliable surveillance in Barrett’s oesophagus

i-scan	Histolog. Barrett	Histolog. Ø Barrett	Total	Under the guidance of i-scan, targeted biopsies are reliable for predicting Barrett's epithelium.
Type III-IV	26	2	28	
Type I - II	2	13	15	
Sensitivity: 92,8%, Specificity: 86,7%, Accuracy: 90,1%				

“Acetic acid guided biopsies compared with high-definition endoscopy and i-scan guided biopsies in the detection of Barrett’s oesophagus.”
Hoffman A. et al, Poster Presentation, DDW 2010

A range that meets your individual needs.



EPK-i7000

The new premium HD+ video processor.

As fully equipped flagship model, the new EPK-i7000 video processor supports innovative and advanced endoscopic diagnosis. The EPK-i7000 is designed to provide individual solutions to master your daily challenges, to help with your research and to share your clinical findings.



i10 endoscope series

High-performance.

The PENTAX Medical i10 endoscope series delivers images of extraordinarily high resolution thanks to a high performance CCD chip. It enables you to fully exploit HD+ performance, offers expanded therapeutic options and gives a close view of mucosal details. The i10 series is the natural choice for endoscopic procedures.



EPK-i5000

From routine applications to challenging examinations.

The PENTAX Medical EPK-i5000 combines excellent illumination and HD+ quality at an optimal price-performance ratio. Ideal for practitioners who require routine functions offered by proven imaging technology in their day-to-day clinical work.



90i and 90K endoscope series

The redefinition of High-Definition.

The PENTAX Medical 90i and 90K endoscope series are the optimal choice for an exceptional high resolution image. Combined with excellent illumination, they support better orientation and detection in endoscopic procedures. With the 90i endoscope series you can fully experience HD+ during routine examinations.

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E-mail: medical@pentax.de

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E-mail: marketing.lifecare@pentaxitalia.it

**SIMMEDICA – Sistemas Integrales
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