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 075182 0006 Rev. 00

Manufacturer:
PULSION Medical Systems SE
Hans-Riedl-Straße 17
85622 Feldkirchen
GERMANY

Facility(ies):
PULSION Medical Systems SE
Hans-Riedl-Straße 17, 85622 Feldkirchen, GERMANY

Product Category(ies):
Patient monitors including compatible modules, accessories and disposables for hemodynamic monitoring and measurement of blood pressure, cardiopulmonary, circulatory and organ function variables

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.: 713153619

Valid from: 2019-05-17
Valid until: 2023-05-24

Date, 2019-05-17

Stefan Preiß

Digitally signed by Dubalari Pavel
Date: 2022.01.19 09:20:44 EET
Reason: MoldSign Signature
Location: Moldova

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

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

Benannt durch/Designated by
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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 072017 0014 Rev. 01

Manufacturer:

MAQUET CRITICAL CARE AB
Röntgenvägen 2
171 54 Solna
SWEDEN

Facility(ies):

MAQUET CRITICAL CARE AB
Röntgenvägen 2, 171 54 Solna, SWEDEN

Product Category(ies): **Anaesthesia, Monitoring, Ventilator and Perfusion Systems**

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.: 713161324

Valid from: 2020-01-22
Valid until: 2024-05-26

Date, 2020-01-22

Christoph Dicks
Head of Certification/Notified Body

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

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TÜV®

EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60147519 0001

Report No.: 21197407 023

Manufacturer:

HUM Gesellschaft für
Homecare und Medizintechnik mbH
Zum Pier 79
44536 Lünen
Deutschland

Products:

Medical devices for ventilation, respiratory therapy,
emergency medicine and patient monitoring
(see attachment for products included)

Replaces Certificate, Registration No.: HD 60129649 0001

Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2020-04-15

Date: 2020-04-15

Notified Body

Dipl.-Ing. I. Munkler

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

TÜVRheinland®

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60147519 0001
Report No.: 21197407 023

Manufacturer:
HUM Gesellschaft für
Homecare und Medizintechnik mbH
Zum Pier 79
44536 Lünen
Deutschland

Products included:

- Sterile water for irrigation and inhalation
- Pulse oximeters
- Breathing tubing and breathing tubing systems
- Oxygen cannulas, -masks and -tubings
- Humidifiers
- High pressure regulators
- Flowmeters
- Suction regulators
- Devices for respiratory home care therapy
- Resuscitator bags
- Resuscitator masks
- Airway tubes
- PEEP-valves
- CPR Pocket masks
- Tubing extensions

Notified Body

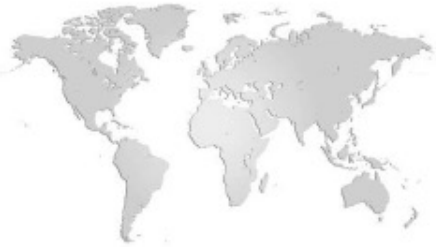
TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Date: 2020-04-15

Dipl.-Ing. I. Munkler

EC CERTIFICATE

for the Quality Assurance System



according the Directive 93/42/EEC, Annex II excluding section (4)

As a Notified Body of the European Union, DEKRA Certification GmbH certifies, that the company

Richard Wolf GmbH

Pforzheimer Straße 32, 75438 Knittlingen, Germany

Certified location:

Pforzheimer Straße 32, 75438 Knittlingen, Germany

applies a quality assurance system according to the Directive 93/42/EEC Annex II for the medical devices listed in the annex. The approval is based on the result of the re-certification audit report no. 50593-Z7-00, the decision dated 2020-04-01 and is only valid in connection with the successful performance of the annual surveillance audits.

This certificate is valid from 2020-04-01 to 2024-05-26

Registration No.: 50593-16-05

DEKRA Certification GmbH * D-70565 Stuttgart, Handwerkstraße 15 *

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-295.10.02

Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart; 2020-04-01
Notified Body ID-number: 0124

Annex to the EC Certificate No. 50593-16-05

Valid from 2020-04-01 to 2024-05-26

Revision status of the annex: 0 dated 2020-04-01

Devices/device categories included in the certificate:

Class I s:

For the products listed below, review of the Quality Assurance System refers exclusively to aspects of manufacture concerned with securing and maintaining sterile conditions.

- Endoscopic suction valve, single-use, sterile
- Suction system filter, plume particulate
- Suction/irrigation tubing, single use

Class II a:

- Basic endotracheal tube, reusable
- Basic roller pump
- Bone cutting forceps
- Bone graft funnel
- Bronchoscopy tube
- Cannulated surgical drill bit, reusable
- Endoscope assembly adaptor
- Endoscope sheath, reusable
- Endoscopic electrosurgical handpiece/electrode, bipolar, reusable
- Endoscopic electrosurgical handpiece/electrode, monopolar, reusable
- Endoscopic insufflation tubing set, single-use
- Endoscopic insufflation tubing set, sterile, reusable
- Flexible fibreoptic cystourethroscope
- Flexible fibreoptic hysteroscope
- Flexible fibreoptic nasopharyngoscope
- Flexible fibreoptic ureterorenoscope
- Flexible video bronchoscope, reusable
- Flexible video cystoscope, reusable
- Flexible video ureterorenoscope, reusable
- Fluted surgical drill bit, reusable
- General-purpose endoscopic needle, reusable
- General-purpose endoscopic needle, single-use
- Haemorrhoid ligator
- High-pressure medical gas tubing
- Laparoscopic access cannula, reusable
- Laparoscopic multi-instrument access port, reusable
- Laparoscopic multi-instrument access port, single-use
- Laser fibre
- Line-powered surgical power tool system motor
- Medical air low pressure tubing
- Microbial medical gas filter, sterile, single-use
- Operating room audiovisual data/device management system application software
- Orthopaedic bur, reusable
- Orthopaedic bur, single-use
- Resectoscope
- Rigid bronchoscope
- Rigid cystourethroscope
- Rigid endoscope telescope
- Rigid endoscopic grasping forceps, reusable
- Rigid optical hysteroscope
- Rigid intubation laryngoscope, reusable

Annex to the EC Certificate No. 50593-16-05

Valid from 2020-04-01 to 2024-05-26

Revision status of the annex: 0 dated 2020-04-01

Devices/device categories included in the certificate:

- Rigid mediastinoscope
- Rigid nephroscope
- Rigid optical laparoscope
- Rigid ureterorenoscope
- Spinal needle, single-use
- Spring-loaded pneumoperitoneum needle, reusable
- Surgical drill guide, reusable
- Surgical fluid/smoke waste management system suction unit
- Surgical guillotine
- Surgical irrigation tubing set, reusable
- Surgical irrigation tubing set, single-use
- Surgical irrigation/aspiration handpiece, reusable
- Surgical irrigation/aspiration tubing set
- Surgical power tool system control unit, line-powered
- Tissue extraction bag
- Tissue morcellation system
- Tissue morcellation system handpiece, line-powered
- Uterine manipulator cervical cup/transilluminator
- Uterine manipulator, reusable
- Uterine probe

Class II b:

- Electrosurgical system generator
- Endoscopic electrosurgical electrode, bipolar, reusable
- Endoscopic electrosurgical electrode, bipolar, single-use, sterile
- Endoscopic electrosurgical handpiece/electrode, monopolar, reusable
- Endoscopic electrosurgical electrode, monopolar, single-use
- Endoscopic electrosurgical handpiece/electrode, bipolar, reusable
- Endoscopic electrosurgical handpiece/electrode, monopolar, reusable
- Endoscopic electrosurgical handpiece/electrode, monopolar, single-use
- General/multiple surgical diode Laser system
- Hysteroscopic irrigation/insufflation system
- Laparoscopic insufflator
- Laser lithotripsy system
- Operating room audiovisual data/device management system application software
- Piezoelectric lithotripsy system
- Soft-tissue/mesh anchor, non-bioabsorbable
- Ultrasonic lithotripsy system
- Electromechanical orthopaedic extracorporeal shock wave therapy system

DEKRA Certification GmbH * Stuttgart, Handwerkstraße 15 * D-70565

Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2020-04-01
Notified Body ID-number: 0124

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
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BS-MDR-099

TÜV SÜD Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)

No. G10 016316 0022 Rev. 00

Manufacturer:

BOWA-electronic GmbH & Co. KG
Heinrich-Hertz-Strasse 4-10
72810 Gomaringen
GERMANY

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).
The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples.

Report No.: 713175396

Valid from: 2020-08-10
Valid until: 2025-08-09

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2020-08-10

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

TÜV SÜD Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Class IIa and Class IIb Devices)

No. G10 016316 0022 Rev. 00

Device Group:	Z120109 - ELECTROSURGERY INSTRUMENTS
Classification:	IIb
Intended Purpose:	Generation of electrical power for monopolar and bipolar cutting and coagulation on tissue structures in surgical operations
Device Group:	K020101 - ELECTROSURGICAL INSTRUMENTARY, MONO- AND BIPOLAR, SINGLE-USE
Classification:	IIb
Intended Purpose:	Electrosurgical equipment for cutting and coagulation of tissue
Device Group:	K020102 - ELECTROSURGICAL PADS AND CABLES
Classification:	IIb
Intended Purpose:	Electrosurgical equipment for cutting and coagulation of tissue
Device Group:	K020480 - ARGON GAS SURGICAL DEVICES - ACCESSORIES
Classification:	IIb
Intended Purpose:	Electrosurgical equipment for cutting and coagulation of tissue
Device Group:	L180201 - SCISSORS, "OPEN SKY" ELECTROSURGICAL, REUSABLE
Classification:	IIb
Intended Purpose:	Electrosurgical equipment for cutting and coagulation of tissue
Device Group:	L180301 - HANDPIECES, "OPEN SKY" ELECTROSURGICAL, REUSABLE
Classification:	IIb
Intended Purpose:	Electrosurgical equipment for cutting and coagulation of tissue
Device Group:	L180401 - FORCEPS, "OPEN SKY" ELECTROSURGICAL, REUSABLE
Classification:	IIb
Intended Purpose:	Electrosurgical equipment for cutting and coagulation of tissue
Device Group:	L180402 - FORCEPS, ELECTROSURGICAL ENDOTHERAPY, REUSABLE

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www.zlg.de
BS-MDR-099

TÜV SÜD Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Class IIa and Class IIb Devices)

No. G10 016316 0022 Rev. 00

Classification:	IIb
Intended Purpose:	Electrosurgical equipment for cutting and coagulation of tissue
Device Group:	L180602 - ELECTRODES, ELECTROSURGICAL ENDOTHERAPY, REUSABLE
Classification:	IIb
Intended Purpose:	Electrosurgical equipment for cutting and coagulation of tissue
Device Group:	K020401 - ARGON GAS SURGICAL INSTRUMENTARY, SINGLE-USE
Classification:	IIb
Intended Purpose:	Electrosurgical equipment for cutting and coagulation of tissue
Device Group:	L180601 - ELECTRODES, "OPEN SKY" ELECTROSURGICAL, REUSABLE
Classification:	IIb
Intended Purpose:	Electrosurgical equipment for cutting and coagulation of tissue
The validity of this certificate depends on conditions and/or is limited to the following:	- none -

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TÜV®

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1622343-1

Organization:
HUM Gesellschaft für
Homecare und Medizintechnik mbH
Zum Pier 79
44536 Lünen
Germany

Scope: Design and development, production and distribution of medical devices for ventilation, respiratory therapy, emergency medicine and patient monitoring

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 1083603-40
Effective date: 2021-07-23
Expiry date: 2024-07-11
Issue date: 2021-07-23

TÜV Rheinland LGA Products GmbH
TÜVRheinland

D. Wiedemuth

Dipl.-Ing. (FH) D. Wiedemuth
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

CERTIFICATE

EN ISO 13485:2016

DEKRA Certification GmbH hereby certifies that the organization

Richard Wolf GmbH

Scope of certification:

Design and development, production, distribution, installation and service of systems, active medical devices (sterile, non-sterile), non-active medical devices (sterile, non-sterile) for human medicine, in particular for endoscopy and extracorporeal shockwave application.
Design and development, production, and distribution of non-active implants in urology and surgery as well as accessories for processing (cleaning, disinfection, sterilization).

Certified location:

Pforzheimer Straße 32, 75438 Knittlingen, Germany

(further locations see annex)

has established and maintains a quality management system according to the above mentioned standard. The conformity was adduced with audit report no. 50593-Z7-00.

Certificate registration no.:	50593-14-01	Certificate valid from:	2020-04-01
Validity of previous certificate:	2020-03-31	Certificate valid to:	2023-03-31

DEKRA Certification GmbH * Stuttgart, Handwerkstraße 15 * D-70565

DAkkS Deutsche Akkreditierungsstelle D-ZM-16029-08-00

Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2020-04-01

Annex to the Certificate No. 50593-14-01

Revision status: 0

valid from 2020-04-01 to 2023-03-31

The following locations / companies belong to the certificate above:

	Headquarter	Certified location	Scope of certification
	Richard Wolf GmbH	Pforzheimer Straße 32 75438 Knittlingen Deutschland	See page 1
	at the following locations / at the companies at the following locations		**Scope of certification**
1.	Richard Wolf GmbH	Reuchlinstraße 10-11 10553 Berlin Deutschland	Manufacture of flexible and rigid endoscopes

Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2020-04-01

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

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

TÜV SÜD Product Service

Certificate

No. Q5 016316 0021 Rev. 01

Holder of Certificate: **BOWA-electronic GmbH & Co. KG**
Heinrich-Hertz-Strasse 4-10
72810 Gomaringen
GERMANY

Certification Mark:

TÜV SÜD EN ISO 13485 tuv-sud.com/ps-cert

Scope of Certificate: **Design and development, production and distribution of sterile and non-sterile medical devices:
Electrosurgical Units and Accessories,
Argon Coagulation Units and Accessories,
Electrode Handles,
Active Electrodes and Instruments,
Monopolar and Bipolar Forceps,
Endoscopic and Laparoscopic Instruments,
Instruments for Vessel Sealing,
Neutral Electrodes and
Bipolar Scissors**

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 016316 0021 Rev. 01

Report No.: 713198949

Valid from: 2021-02-22
Valid until: 2022-02-28

Date, 2021-02-22

Christoph Dicks
Head of Certification/Notified Body

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

TÜV®

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

TÜV SÜD Product Service

Certificate

No. Q5 016316 0021 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):

BOWA-electronic GmbH & Co. KG
Heinrich-Hertz-Strasse 4-10, 72810 Gomaringen, GERMANY

Design and development, production and distribution of sterile and non-sterile medical devices:
Electrosurgical Units and Accessories,
Argon Coagulation Units and Accessories,
Electrode Handles,
Active Electrodes and Instruments,
Monopolar and Bipolar Forceps,
Endoscopic and Laparoscopic Instruments,
Instruments for Vessel Sealing and
Bipolar Scissors

Design and development and distribution of sterile and non-sterile medical devices:
Neutral Electrodes

BOWA Polska Sp. zo. o.
Zlotkowo, ul. Obornicka 10, 62-002 Suchy Las, POLAND

Production of sterile and non-sterile medical devices:
Instruments for Vessel Sealing and
Neutral Electrodes

./.

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TÜV®

SERVO-i v8.0

Data sheet

MAQUET
GETINGE GROUP

This document is intended to provide information to an international audience outside of the US.

SERVO-i ventilator family

SERVO-i v8.0

SERVO-i configurations

The SERVO-i® ventilator family consists of three configurations:

- Infant
- Adult
- Universal

- Standard configuration
- Options
- Not applicable

The SERVO-i ventilator family addresses the very different requirements of neonatal, pediatric and adult needs from a single ventilation platform. The SERVO-i family can also be upgraded with different options for future needs. The same ventilator can be used at the bedside, and in the MR-room* facilitating training, operation and maintenance, increasing efficiency and flexibility.

*An agreement with Maquet must be signed, see conditions in the SERVO-i MR declaration (Order no. 66 71 670).

	Infant	Adult	Universal
NIV NAVA®	■	■	■
NAVA®	■	■	■
Nasal CPAP	✕	■	■
NIV PC	■	■	■
NIV PS	■	■	■
Y Sensor Measuring	■	■	■
CO_2 Analyzer	■	■	■
Nebulizer	■	■	■
Alarm output connection	■	■	■
Heliox	■	■	■
STRESS INDEX	■	✕	■
Open Lung Tool®	■	■	■
Automode®	■	■	■
Bi-Vent/APRV	■	■	■
VS	■	■	■
PRVC (incl. SIMV (PRVC) + PS)	■	■	■
VC (incl. SIMV (VC) + PS)	■	■	■
PC (incl. SIMV (PC) + PS)	■	■	■
PS/CPAP	■	■	■
All patient category software	■	■	■

Key to abbreviations

NAVA	Neurally Adjusted Ventilatory Assist
NIV	Non-invasive ventilation
SIMV	Synchronized Intermittent Mandatory Ventilation
PRVC	Pressure Regulated Volume Control
VS	Volume Support
VC	Volume Control
PS	Pressure Support
PC	Pressure Control
CPAP	Continuous Positive Airway Pressure

Technical specifications

SERVO-i v8.0

Intended use - general	
The SERVO-i ventilator system is:	• Intended for treatment and monitoring of patients in the range of neonates, infants and adults with respiratory failure or respiratory insufficiency. • The added indications for use of the NAVA option is when the electrical signal from the brain to the diaphragm is intact; NAVA will improve synchrony between the ventilator and patients with no contraindication for insertion/exchange of a Naso-Gastric tube.
Instructions for use	Please carefully read the user's manual
Legal manufacturer	Maquet Critical Care AB
Other products	See separate data sheets. Contact your local Maquet supplier for more information.

The system - general	
CE 0123	The device complies with requirements and classification IIb of Medical Device Directive 93/42/EEC. CE Mark Notified Body number: 0123.
Classification:	IEC 60601-1: 2005, Class I, continuous operation
Standards:	• ISO 80601-2-12:2011 • ISO 80601-2-55:2011 • EN 13544-1:2007+A1:2009 • IEC 60601-1, Type B (base unit, nebulizer patient unit with cable and the gas path ways) • IEC 60601-1, Type BF (CO_2 analyzer) • IEC 60601-1, Type CF defibrillation proof (Edi catheter and cable)
A-weighted sound pressure level (L_{pA})	<41 dB, measured at 1 m distance.
IP classification	IP 21
Electromagnetic compatibility (EMC):	According to limits specified in IEC 60601-1-2:2007.
The '*EMC Declaration, Information to the Responsible Organization*' is available from Maquet.	
Patient range:	Weight:
• Adult, all ventilation modes:	10 - 250 kg
• Infant, invasive ventilation:	0.5 - 30 kg
• Infant, NAVA + NIV NAVA:	0.5 - 30 kg
• Infant, NIV PS+PC:	3 – 30 kg
• Infant, Nasal CPAP:	0.5 – 10 kg

Technical specifications

SERVO-i v8.0

Operating conditions	
Operating temperature:	+10 to +40°C
Relative humidity:	15 to 95% non-condensing
Atmospheric pressure:	660 to 1060 hPa
Lowest pressure in breathing system:	–400 cmH_2O

Non-operating conditions	
Impact:	• Peak acceleration: 15 g. • Pulse duration: 6 ms. • Number of impacts: 1000.
Storage temperature:	–25 to +60° C (–13 to 140° F)
Storage relative humidity:	< 95%
Storage atmospheric pressure:	470 to 1060 hPa

Power supply	
Power supply, automatic range selection:	100 – 120 V AC ±10%, 50 – 60 Hz, or 220 – 240 V AC ±10%, 50 – 60 Hz.
Plug-in battery module:	
• Battery backup:	Two battery modules are delivered with the ventilator. Up to six battery modules can be included.
• Battery capacity:	Rechargable, 12 V, 3.5 Ah each.
• Recharge time:	Approximately 3 h/battery.
• Battery backup time:	At least 3 h, when using six batteries.
External 12 V DC:	12.0 V – 15.0 V DC, 10 A
Max power consumption:	At 100 – 120 V: 2 A, 190 VA, 140 W. At 220 – 240 V: 1 A, 190 VA, 140 W.

Technical specifications

SERVO-i v8.0

The ventilator - general	
Dimensions:	(See dimensional drawings page 15)
• User interface:	W 355 x D 53 x H 295 mm
• Patient unit:	W 300 x D 205 x H 415 mm
Weight:	Approximately 20 kg (Patient Unit 15 kg, User Interface 5 kg)
Method of triggering:	Flow, pressure and Edi (optional)
Max. operating pressure:	Approximately 115 cmH_2O
Bias flow:	
• Adult:	2 l/min
• Infant:	0.5 l/min

Gas supply	
Inlet gas pressure Air/O_2:	200 – 600 kPa / 2.0 – 6.0 bar / 29 – 87 PSI
Connection standards available:	AGA, DISS, NIST, or French standard.
Unavailable gas/loss of gas pressure:	The flow from an unavailable gas (air or O_2) is automatically compensated for so that the patient gets the preset volume and pressure.

Patient system gas connectors	
Conical fittings:	Male 22 mm / female 15 mm. In accordance with ISO 5356-1.
Gas exhaust port:	Male 30 mm cone

User interface	
Weight:	Approximately 5 kg
Attachment:	Can be attached to the mobile cart, a table, rail or pole (15 – 30 mm diameter).

Screen	
Type:	TFT-LCD module
Size:	31 cm (12.1”) diagonal
Viewing area:	246.0 x 184.5 mm

Inspiratory channel	
Pressure drop:	Max. 6 cmH_2O at a flow of 1 l/s
Internal compressible factor:	Max. 0.1 ml/cmH_2O
Gas delivery system:	Microprocessor controlled valve
Inspiratory flow range:	
• Adult:	0 – 3.3 l/s
• Infant:	0 – 0.55 l/s

Expiratory channel	
Pressure drop:	Max. 3 cmH_2O at a flow of 1 l/s
Internal compressible factor:	Max. 0.1 ml/cmH_2O
PEEP regulation:	Microprocessor controlled valve
Rise time, expiratory flow measurement:	<12 ms for 10 – 90 % response at flow of 0.05 – 3.2 l/s
Expiratory flow range:	0 to 3.2 l/s

Technical specifications

SERVO-i v8.0

Alarms	
Airway pressure (upper):	
• Adult, Invasive ventilation	16 – 120 cmH_2O
• Adult, Non-invasive ventilation	16 - 70 cmH_2O
• Infant, Invasive ventilation:	16 – 90 cmH_2O
• Infant, Non-invasive ventilation	16 - 70 cmH_2O
Expired minute volume (Upper alarm limit):	
• Adult:	0.5 – 60 l/min
• Infant:	0.01 – 30 l/min
Expired minute volume (Lower alarm limit):	
• Adult:	0.5 – 40 l/min
• Infant:	0.01 – 30 l/min
It is possible to permanently silence this alarm (an option with infant version only)	
No patient effort (Apnea) alarm	
• Adult:	15 – 45 s
• Infant	1 - 45 s
Automatic return to support mode on patient triggering	
No consistent patient effort:	Yes, described in User's manual
Respiratory frequency:	1 – 160 breaths/min
High end expiratory pressure:	0 – 55 cmH_2O
Low end expiratory pressure:	0 – 47 cmH_2O. Note. Setting the alarm to 0 (zero) is equal to alarm off.
High continuous pressure:	Obstruction leading to constant high airway pressure (>PEEP +15 cmH_2O) during: > 2 breaths or 5 seconds, whichever is greater, 15 ±1.5 s if less than 2 breaths are triggered
O_2 concentration:	Set value ±5 vol% or ≤18 vol%
Gas supply:	Below 200 kPa / 2.0 bar / 29 PSI and above 600 kPa / 6.0 bar / 87 PSI

Alarms	
Battery:	• Limited battery capacity: 10 min. • No battery capacity: less than 3 min. • Low battery voltage.
End-tidal CO_2 (upper and lower limit):	• 0.5 – 20%. • 4 – 100 mm Hg. • 0.5 – 14 kPa.
Leakage out of range in NIV:	Yes. Described in the User's manual.
Technical:	Yes. Described in the User's manual.
Autoset (alarm limits) specification:	Invasive ventilation, controlled modes only.
• High airway pressure:	Mean peak pressure +10 cmH_2O or at least 35 cmH_2O.
• Upper minute volume:	Expiratory minute volume + 50%.
• Lower minute volume:	Expiratory minute volume – 50%.
• Upper respiratory frequency:	Breathing frequency + 40%.
• Lower respiratory frequency:	Breathing frequency – 40%.
• High end expiratory pressure:	Mean end expiratory pressure + 5 cmH_2O.
• Low end expiratory pressure:	Mean end expiratory pressure – 3 cmH_2O.
• Upper end tidal carbon dioxide concentration ($etCO_2$):	End tidal carbon dioxide concentration + 25%.
• Lower end tidal carbon dioxide concentration ($etCO_2$):	End tidal carbon dioxide concentration – 25%.

Technical specifications

SERVO-i v8.0

Ventilation modes – Invasive ventilation

Controlled ventilation:

- PC
- VC — Can be configured with alternative flow patterns
  - VC with flow adaptation,
  - VC without flow adaptation,
  - VC with decelerating flow
- PRVC

Supported ventilation:

- PS/CPAP
- VS — Optional with Infant and Adult

Combined ventilation:

- SIMV (VC) + PS: — Comes with the corresponding controlled ventilation mode
- SIMV (PC) + PS: — Comes with the corresponding controlled ventilation mode
- SIMV (PRVC) + PS — Comes with the corresponding controlled ventilation mode
- Bi-Vent/APRV — Pressure controlled ventilation on two independently adjustable levels, allowing unrestricted spontaneous breathing on both levels. (Optional with Infant and Adult)

Automode

- Control mode: VC <—> Support mode: VS
- Control mode: PC <—> Support mode: PS
- Control mode: PRVC <—> Support mode: VS
- (Optional)

Ventilation modes – Non-invasive ventilation (optional)

NIV PC

NIV PS

Nasal CPAP

Ventilation modes - NAVA (optional)

NAVA	Neurally Adjusted Ventilatory Assist via endotracheal tube or tracheostomy
NIV NAVA	Neurally Adjusted Ventilatory Assist via non-invasive patient interfaces

Waveform and loop presentations

Real time waveforms - up to 4 waveforms can be displayed simultaneously:

- Pressure
- Flow
- Volume
- CO_2 — Requires SERVO-i CO_2 Analyzer option
- Edi — Requires SERVO-i NAVA option

Loops:

- Volume / Pressure* — *A reference loop and three overlaying loops can be displayed.
- Flow / Volume* — *Displayed simultaneously with Open Lung Tool graphical trends, if requested.

Technical specifications

SERVO-i v8.0

Monitoring	Displayed value	Trended value*
Breathing frequency:	Yes	Yes
Spontaneous breaths per minute (RRsp):	No	Yes
Peak airway pressure:	Yes	Yes
Mean airway pressure:	Yes	Yes
Pause airway pressure:	Yes	Yes
End expiratory pressure:	Yes	Yes
CPAP pressure:	Yes	Yes
Inspired tidal volume:	Yes	Yes
Expired tidal volume:	Yes	Yes
Inspired minute volume:	Yes	Yes
Expired minute volume:	Yes	Yes
Leakage fraction in NIV (%):	Yes	Yes
Ti/Ttot:	Yes	No
I:E ratio:	Yes	No
Total PEEP:	Yes	No
Edi peak:	Yes	Yes
Edi min:	Yes	Yes
Switch to backup (b/min)	No	Yes
Backup (%/min)	No	Yes
O_2 concentration (measured):	Yes	Yes
CO_2 end tidal concentration ($etCO_2$):	Yes	Yes
CO_2 minute elimination (CO_2):	Yes	Yes
Tidal CO_2 elimination ($VTCO_2$):	Yes	Yes
MV_e sp / MV_e:	Yes	No
Spontaneous exp. minute volume (MV_e sp):	Yes	Yes
End expiratory flow:	Yes	Yes
Static compliance:	Yes	Yes
Dynamic compliance:	Yes	Yes

Monitoring	Displayed value	Trended value*
STRESS INDEX:	Yes	Yes
Inspiratory resistance:	Yes	Yes
Expiratory resistance:	Yes	Yes
Elastance:	Yes	Yes
Time constant:	Yes	No
P0.1:	Yes	Yes
Work of breathing patient:	Yes	Yes
Work of breathing ventilator	Yes	Yes
Shallow Breathing Index (SBI):	Yes	Yes
Supply pressure (O_2 and air):	Yes	No
Battery remaining time:	Yes	No
Barometric pressure:	Yes	No

**Stored trend values for up to 24 hours*

Log function	
Event log:	• Alarms. • Ventilator settings. • Apnea periods. • Immediate functions.
Service log:	• Technical alarms. • Test results. • Preventive maintenance. • Service history. • Configuration log.

Technical specifications

SERVO-i v8.0

Parameter settings Parameter:	Setting range: Infant	Adult
Inspiratory tidal volume (ml):	2 – 350	100 – 4000
Inspiratory minute volume (l/min):	0.3 – 20	0.5 – 60
Apnea, time to alarm (s):	1 - 45	15 – 45
Automode trigger timeout (s):	3 – 15	7 – 12
PC/PS above PEEP (cmH_2O)	0 – (80 -PEEP)	0 – (120 -PEEP)
PC/PS above PEEP in NIV (cmH_2O)	0 - (62 - PEEP)	0 - (62 - PEEP)
PEEP (cmH_2O)	0 – 50	0 – 50
PEEP in NIV (cmH_2O)	2 – 20	2 – 20
CPAP pressure (cmH_2O):	2 – 20	–
CMV frequency (breaths/min):	4 – 150	4 – 150
SIMV frequency (breaths/min):	1 – 60	1 – 60
Breath cycle time, SIMV (s):	0.5 – 15	1 – 15
P_{High} (cmH_2O)	(PEEP + 1) – 50	(PEEP + 1) – 50
T_{High} (s):	0.2 - 30 s	0.2 - 30 s
T_{PEEP} (s):	0.1 - 10 s	0.1 - 10 s
PS above P_{High} (cmH_2O):	0 – (80 - P_{High})	0 – (120 - P_{High})
O_2 concentration (%):	21 – 100	21 – 100
I:E ratio:	1:10 – 4:1	1:10 – 4:1
T_{Insp} (s):	0.1 – 5	0.1 – 5
NAVA level ($cmH_2O/\mu V$):	0 - 15	0 - 15
Edi trigger sensitivity (µV):	0.1 – 2.0	0.1 – 2.0
T_{Pause} (s):	0 – 1.5	0 – 1.5
T_{Pause} (% of breath cycle time):	0 – 30	0 – 30
Flow trigger sensitivity level:	0 – 10	0 – 10
Press. trigg sensitivity (cmH_2O):	-20 – 0	-20 – 0
Insp. rise time (% of breath cycle time):	0 – 20	0 – 20
Insp. rise time (s):	0 – 0.2	0 – 0.4

Parameter settings Parameter:	Setting range: Infant	Adult
End inspiration (% of peak flow):	1 – 70	1 – 70
End inspiration in NIV (% of peak flow):	10 – 70	10 – 70

Backup settings Parameter:	Setting range: Infant	Adult
Inspiratory tidal volume (ml):	2 – 350	100 – 4000
PC above PEEP (cmH_2O)	5 – (80 -PEEP)	5 – (120 -PEEP)
PC above PEEP in NIV	5 - (62 PEEP)	5 - (62 PEEP)
CMV frequency (breaths/min):	4 – 150	4 – 150
I:E ratio:	1:10 – 4:1	1:10 – 4:1
T_{Insp} (s):	0.1 – 5	0.1 – 5

Non-invasive ventilation (optional)	
Leakage compensation level	
• Adult:	Inspiratory, up to 200 l/min Expiratory, up to 65 l/min
• Infant:	Inspiratory, up to 33 l/min Expiratory, up to 25 l/min
• Infant, Nasal CPAP:	up to 20 l/min
Leakage overrange detection:	Automatic
Disconnect detection:	Automatic
Disconnect flow:	Configurable
• Low	7.5 l/min
• High	- 40 l/min (Adult) - 15 l/min (Infant)
• Disabled	Deactivates disconnect detection
Connect detection:	Manual, or automatic via bias flow

Technical specifications

SERVO-i v8.0

Open Lung Tool (OLT) (optional)	
Three simultaneous graphical trends, presented breath-by-breath:	1. EIP and PEEP (End Inspiratory Pressure and Positive End Expiratory pressure). 2. VT_i and VT_e (Inspiratory and Expiratory Tidal volume). 3. C dyn i and $VTCO_2$* (Dynamic inspiratory Compliance [= VTi/(EIP – PEEP)] and Tidal CO_2 elimination*). * Requires SERVO-i CO_2 Analyzer option.
Values stored breath by breath:	Up to 21.600 breaths.
Cursor function:	A cursor can be moved with the main rotary dial or via the touch screen. When moving it along the graph, the numeric parameter values valid for that actual moment will be shown.
Zoom function:	Time resolution of the x-axis can be selected in five different steps.
Time marking:	Hours and minutes (when values are measured).

Parameter:	Setting range
Oxygen breaths:	100% for 1 minute
Start breath:	Initiation of 1 breath (In SIMV mode initiation of 1 mandatory breath)
Pause hold:	Insp. or exp (0 – 30 seconds)
Alarm silence/reset:	2 minute silence and reset of latched alarms
Compliance compensation:	On/Off
Automode (optional):	Automode On/Off
Nebulizer (optional):	5 - 30 min./Continuous/Off
Backup ventilation:	Backup On/Off

Suction support	
Pre oxygenation time:	Max. 2 min
Post oxygenation time:	Max. 1 min
Suction phase time:	No maximum level
Adjustable oxygen level:	21 – 100 %

Technical specifications

SERVO-i v8.0

STRESS INDEX (optional)	
Presented values:	• SI (STRESS INDEX) • PEEP (Positive End Expiratory pressure). • VT_e (Expiratory Tidal volume).
Stored values:	• 120 values stored in graph • Stored trend values up to 24 hours
Cursor function:	A cursor can be moved with the main rotary dial. When moving it along the graph, the numeric parameter values valid for that actual moment will be shown.
Time marking:	Hours and minutes (when values are measured).

Communication/interface	
Serial ports (2):	RS-232C - isolated. For data communication via the Communication Interface Emulator (CIE).
Alarm output connector (optional)	
Connector:	4-pole Modular connector
Ratings:	Max 40 V DC, Max 500 mA, Max 20 W
Data transfer (optional):	Via Ventilation Record Card
Screen picture transfer (optional)	Via Ventilation Record Card

Saving of data	
Recording of current waveform and parameter values:	20 seconds of data will be recorded (10 seconds before and 10 seconds after activation).

NAVA (optional)	
Size:	
• Edi module:	154 x 90 x 21 mm
• Edi catheter cable:	Length: 2 m
Weight - Edi module:	0.25 kg
Power source - Edi module supply voltage:	Powered from SERVO-i. <3 W at 12 V (normal operation)
Parameters:	• Edi waveform • ECG leads waveforms • NAVA estimated pressure waveform (Pest)
Edi catheters:	• 6 Fr, length 49 cm • 8 Fr, length 50 cm • 6 Fr, length 50 cm • 8 Fr, length 100 cm • 8 Fr, length 125 cm • 12 Fr, length 125 cm • 16 Fr, length 125 cm

Technical specifications

SERVO-i v8.0

SERVO-i CO_2 analyzer (optional)	
Size:	
• CO_2 analyzer module:	154 x 90 x 43 mm
• Sensor:	32.0 x 47.0 x 21.6 mm
Weight:	
• CO_2 analyzer module:	450 g
• Sensor:	20 g
• Airway adapter:	10 g
Connectors and cables:	
• Sensor cable:	2.8 m
Operating conditions	
• Operating temperature:	+10°C to + 33°C

SERVO-i CO_2 analyzer – performance	
Measuring method:	Mainstream, dual-wavelength, non-dispersive infrared.
Parameters:	• Capnogram. • CO_2 End tidal concentration ($etCO_2$). • CO_2 Minute elimination ($\dot{V}CO_2$). • Tidal CO_2 elimination ($VTCO_2$).
Measuring range:	• 0 to 100 mmHg CO_2 partial pressure. • 0 to 13.3 kPa CO_2 partial pressure. • 0 to 13.2% CO_2 volume (at a barometric pressure of 1013 hPa).
System response time CO_2	The total system response time of the CO_2 monitor when exposed first to air and then to a gas mix with 5.0 % CO_2 is <250 ms.
Warm-up time:	15 s to initial CO_2 indication, maximum 2 minutes to full specification
Oxygen concentration compensation:	Automatic. Values supplied from the SERVO-i Ventilator System.
Barometric pressure compensation:	Automatic. Values supplied from the SERVO-i Ventilator System.
Digitizing rate:	100 Hz
Airway adapter dead space:	
• Adult:	<5 ml
• Infant:	<1 ml

Technical specifications

SERVO-i v8.0

Y sensor measuring (optional)	
Size:	
• Y sensor module:	154 x 90 x 43 mm
• Y sensor adult:	Length 84 mm
• Y sensor infant:	Length 51 mm
Weight:	
• Y sensor module:	0.4 kg
• Y sensor adult:	10.5 g
• Y sensor infant:	7.5 g
Sensor material:	Makrolon polycarbonate.
Tubing:	2.0 m. Medical grade PVC.
Power source – Y sensor module supply voltage:	Powered from the SERVO-i. <5 W at 12 V (normal operation).

Y Sensor measuring – performance	
Measuring method:	Fixed orifice, differential pressure.
Parameters:	Airway pressure Airway flow Inspiratory and expiratory volumes
Measuring range:	
• Adult:	2 to 180 l/min
• Infant:	0.125 to 40 l/min
Airway adapter dead space:	
• Adult:	< 9.0 ml
• Infant:	< 0.45 ml

Aerogen nebulizer systems (optional)	
Weight - Aerogen module:	Approx. 216 g
Dimensions - Aerogen module:	H 105 mm x L 108 mm x W 60 mm
Connection cable length:	2.0 m
Particle size:	1 - 5 µm mass median aerodynamic diameter (MMAD)
Flow rate:	>0.2 ml/min
Volume - nebulizer unit	• Pro - 10 ml • Solo - 6 ml
Residual volume:	10 %

SERVO-i Mobile cart (optional)	
Weight:	21 kg
Dimensions:	H 992 mm x L 640 mm x W 560 mm (see dimensional drawing below)

SERVO-i Drawer kit (optional)	
Weight:	4.5 kg
Dimensions:	H 240 mm x L 210 mm x W 300 mm

SERVO-i Holder (optional)	
Weight:	3.5 kg
Dimensions:	H 352 mm x L 247 mm x W 159 mm (see dimensional drawing below)

SERVO-i Shelf base (optional)	
Weight:	1.2 kg
Dimensions:	H 29 mm x L 205 mm x W 159 mm (see dimensional drawing below)

Technical specifications

SERVO-i v8.0

Gas cylinder restrainer (optional)	
Max load:	2 x 5-liter bottles

SERVO-i IV pole (optional)	
Max load (total):	6 kg

Gas trolley (optional)	
Max load:	2x10 kg bottles
Docking:	Dockable to SERVO-i Mobile cart. Dockable to a separate wall clamp.

Compressor Mini (optional)
See separate data sheet.

Service	
Regular maintenance:	Once every 12 months or at least after 5000 operating hours.

Note
For inaccuracies and more detailed technical specifications please refer to the User's manual.

Ordering information

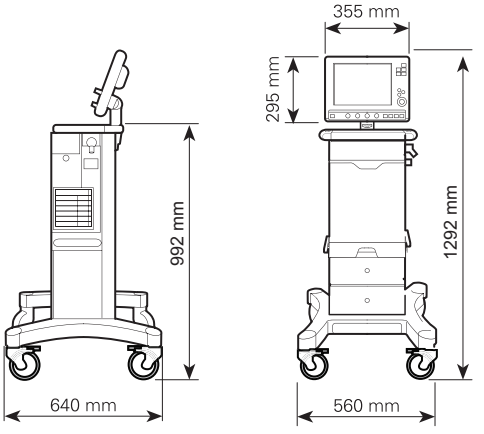
SERVO-i, Ventilator and accessories: See separate information: "SERVO-i System Flow Chart" (Order no: 66 70 102).

Technical specifications

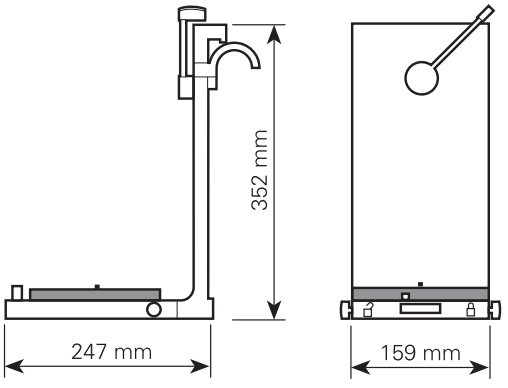
SERVO-i v8.0

Dimensional drawings

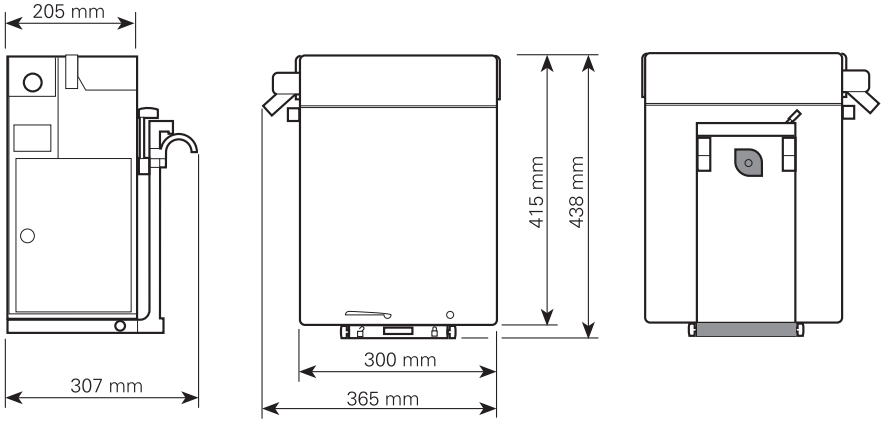
SERVO-i on Mobile cart



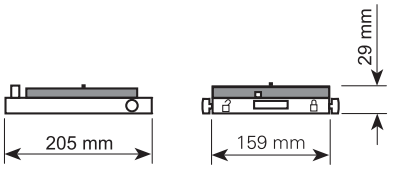
SERVO-i Holder



SERVO-i (patient unit) on SERVO-i Holder



SERVO-i Shelf base



Products may be pending regulatory approvals to be marketed in your country. Contact your Maquet representative for more information.

This document is intended to provide information to an international audience outside of the US.

MAQUET
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GETINGE GROUP

Getinge Group is a leading global provider of innovative solutions for operating rooms, intensive-care units, hospital wards, sterilization departments, elderly care and for life science companies and institutions. With a genuine passion for life we build quality and safety into every system. Our unique value proposition mirrors the continuum of care, enhancing efficiency throughout the clinical pathway. Based on our first-hand experience and close partnerships, we are able to exceed expectations from customers – improving the every-day life for people, today and tomorrow.

Order No. 66 70 105 • Data sheet • Printed in Sweden • 16041 • Rev: 22 English •

Declaration of Conformity

Declares under our sole responsibility that the product to which this declaration relates is in conformity with the provisions of Council Directive 93/42/EEC (Medical Device Directive, MDD).

Manufacturer & address

PULSION Medical Systems SE
Hans-Riedl-Str. 17
85622 Feldkirchen
Germany

Product Name	PiCCO Catheter
Product Model Number	PV2015L20-A, PV2014L22-A, PV2013L07-A, PV2014L08-A, PV2014L16-A, PV2014L50-A
Device Classification	IIa according Annex IX, Rule 7.
GMDN Code	10689, Arterial blood pressure catheter

PULSION Medical Systems SE is assessed to
EN ISO 13485:2016 and MDD Annex II excluding section (4) by the following Notified Body:

DEKRA Certification GmbH
Handwerkstraße 15
70565 Stuttgart
Germany

Identification Number 0124

This declaration of conformity is valid in combination with the following certificates or until the next substantial change of the product:

- **the EC Certificate No. 50215-16-08**
  (expiration date 24 May. 2023**)**

PULSION Medical Systems SE
Feldkirchen, 30 May. 2018

Jens Anter
Head of Quality Management & Regulatory Affairs

Stephan Haft
Managing Director

EC DECLARATION OF CONFORMITY FOR MEDICAL DEVICES

Name and Address of the Manufacturer: Maquet Critical Care AB
Röntgenvägen 2
SE-171 54 Solna, Sweden

On our sole responsibility, we hereby declare that the product(s)

Product Description: Critical Care Ventilator

Product Identification: SERVO-i Ventilator System, see next page, Serial No. from 70 001

Product-No.: See Annex I of this document

Classification (acc. to Annex IX of MDD)**:** Class IIb

comply with the relevant provisions of the following Directive(s):

Directive 93/42/EEC on Medical Devices

Notified Body: TÜV SÜD Product Service GmbH
ID No. 0123
Zertifizierstelle, Ridlerstraβe 65
80339 München, Germany

Conformity Assessment Procedure: acc. to Annex II excluding (4) of Directive 93/42/EEC

Directive 2011/65/EU on the restriction of the use of certain substances in electrical and electronic equipment

This declaration is valid until the next change of the product or until the expiration date of the Certificate (No. G1 072017 0014, dated 2019-05-13, valid to 2021-12-29) issued by the notified body. Any modification of the medical device not authorized by us will invalidate this declaration

For the signature of the Manager for Product Compliance on behalf of Maquet Critical Care AB see left corner of page.

ANNEX I
TO THE EC DECLARATION OF CONFORMITY FOR MEDICAL DEVICES

Product(s) Covered:

Trade Name		Article No.
SERVO-i Base Unit		64 87 800
SERVO-i Universal	Software option	66 70 802
SERVO-i Infant	Software option	65 24 222
SERVO-i Adult	Software option	65 24 214
SW Service Release v8.00.01 SERVO-i		68 85 573
O_2 cell for SERVO-i		66 40 044
O_2 sensor		66 70 680
Y Sensor Module	Option (HW)	66 70 650
SW Y Sensor Software option		66 70 807
Y Sensor Adult	Single use device	66 70 660
Y Sensor Infant	Single use device	66 70 662
SW Nasal CPAP	Software option	66 70 805
SW Open Lung Tool	Software option	65 33 173
SW Bi-Vent/APRV	Software option	65 33 157
SW CO_2 analyzer, SERVO-i	Software option	65 33 462
Capnostat 5 mainstream CO_2 sensor		68 82 078
CO_2 Analyzer Module Capnostat 5		68 81 766
CO2 analyzer module Capnostat 5, Servo ventilators		68 87 050
$EtCO_2$ Airway adapter Neonatal		4721788
$EtCO_2$ Airway adapter Adult		4721796
$EtCO_2$ Airway adapter Neonatal disposable	Single use device	66 84 610

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ANNEX I
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$EtCO_2$ Airway adapter Adult disposable device	Single use	66 84 612
SW Automode SERVO-i	Software option	65 33 140
SW Volume Support SERVO-I	Software option	65 33 751
SW PRVC SERVO-i	Software option	65 33 744
SW Non Invasive ventilation NIV SERVO-i	Software option	66 67 187
SW Alarm output connector SERVO-i	Software option	66 49 748
Alarm output connector SERVO-i	Option (HW)	66 49 730
Loudspeaker booster kit SERVO-i	Option (HW)	66 51 280
Holder SERVO-i		64 87 313
Holder SERVO-i (low-magnetic)		66 71 717
Cart SERVO-i with drawers, mounted		64.86 729
Cart SERVO-i without drawers, mounted		65 94 845
Carrier SERVO-i, Robust, flatpack		66 71 675
Carrier SERVO-i, Robust, mounted		66 72 285
Gas cylinder restrainer SERVO-i		65 24 339
Shelf Base SERVO-i		65 94 639
SERVO-i Shelf Base (low-magnetic)		66 71 720
IV pole		64 81 738
Battery module		64 87 180
Support arm 177		64 81 720
Humidifier holder		65 23 935
User interface panel cover		65 67 130
Gas Trolley for Mobile Cart SERVO-i		65 32 910
Ventilation Record Card		65 33 181
Tryout option PC card without files		66 67 203

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ANNEX I
TO THE EC DECLARATION OF CONFORMITY
FOR MEDICAL DEVICES

Try out option PC card with files		66 67 195
MR Environment kit, SERVO-i upgrade	(field)	66 71 712
MR Environment kit, new SERVO-i	(factory installation)	66 72 287
MR Declaration[1]		66 71 670
Low minute volume alarm audio off software[2] SERVO-i		66 75 577
Edi Module 60 Hz		66 72 332
Edi Module 50 Hz		66 72 330
NAVA Software, SERVO-i	Software option	66 71 965
Heliox software, SERVO-i	Software option	66 75 580
Heliox adapter kit, New SERVO-i		
NIST/NIST		66 75 582
AGA/NIST		66 75 590
French/NIST		66 75 587
Heliox adapter kit, Onsite Upgrade		
NIST/NIST		66 77 555
AGA/NIST		66 55 560
French/ NIST		66 77 557
SERVO-i up to serial number 36703 also requires:		
PC board 1784 rev 16 or later		64 67 984
PC board 1785 rev 3 or later		64 68 016
High pressure Heliox hose NIST, 5m		66 75 607
SERVO-i User Interface, upgrade		66 72 527
NIV NAVA SW, SERVO-i	Software Option	66 83 412
SW Stress Index Software, SERVO-i	Software Option	66 82 897
SW Nebulizer Software, SERVO-i	Software option	65 33 033
Aeroneb Module, SERVO-i		66 85 342
Aeroneb Module Pro Kit, SERVO-i		66 85 345

ANNEX I
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Aeroneb Module Solo Kit, SERVO-i	66 85 347
Aeroneb Module Control Cable	66 87 685
HBO System	66 94 947
SW Service Release v8.00.40 SERVO-i	68 85 641
Drawer kit for Mobile Cart SERVO-i	66 32 611
Cart SERVO-i, w/o drawers, flatpack	66 82 722
Support Arm 176	64 05 976
Expiratory Cassette	66 96 947
SW Release v7.00.08 SERVO-i	68 89 447

Maquet Critical Care AB
Röntgenvägen 2
171 54 Solna, Sweden

Phone: +4610-335 73 00
Email: Regulatory.Affairs@maquet.com
www.getinge.com

Lot: 13;14;15

5.4 Cables

Power cord

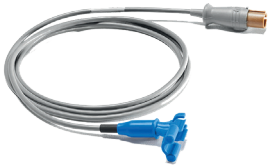
Included in initial shipment of PulsioFlex 6882747.

Product description	REF	Getinge order #
Power Cord	40109X (X=country specific number)	Country specific order number available upon request*

Arterial Connection Cable

For connecting the temperature sensor of the PiCCO Catheter to the device.
Included in initial shipment of PiCCO Module 6882748.

Product description	REF	Getinge order #
Arterial Connection Cable	PC80150*	6882742*



Injectate Sensor Cable

For clamping to the Injectate Temperature Sensor Housing 6882773.
Included in initial shipment of PiCCO Module 6882748.

Product description	REF	Getinge order #
Injectate Sensor Cable	PC80109*	6882741*

Pressure Output Adapter

For transferring the pressure signal from the PiCCO Module to an external device.
2 pieces included in initial shipment of PiCCO Module 6882748.

Product description	REF	Getinge order #
Pressure Output Adapter	PC85200*	6882745*

Pressure Connection Cable

For connecting the pressure transducer to the device.
2 pieces included in initial shipment of PiCCO Module 6882748.

Product description	REF	Getinge order #
Pressure Connection Cable	PMK-206*	6882743*

*Also suitable for $PiCCO_2$

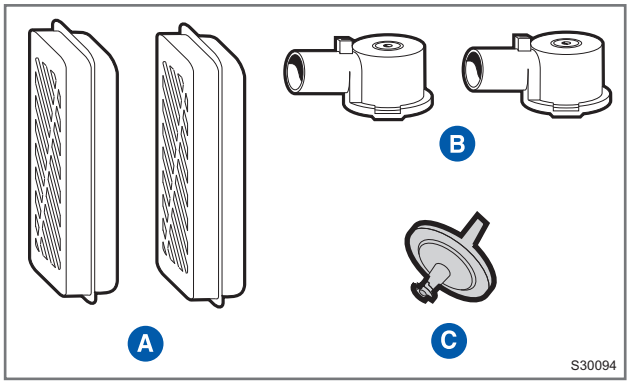
7.5 Maintenance kit 5000 hours

Only original parts from the manufacturer must be used. Spare parts and maintenance kits can be ordered from your local Getinge representative.

When performing this maintenance, a **Maintenance kit 5000 hours** should be used.

The following parts shall be replaced and they are included in the maintenance kit:

A. Filters for the gas modules
B. Nozzle units for the gas modules
C. Bacteria filter for the inspiratory pressure transducer



7.6 Performing the Preventive maintenance

- Disassembling and assembling of the system is required when replacing parts included in the maintenance kit. If not stated otherwise, refer to chapter Disassembling and assembling.
- All steps during Preventive maintenance should be documented in a protocol.
- The letters A – C in the text below refer to the description of the maintenance kit above.

7.6.1 Preparations

- Check and note Serial number, System SW version and Operating time.
- Check that a User's Manual corresponding to the installed System version is present.
- Make a general inspection/visual check of the system for external defects or damages. Replace defective or damaged parts.
- Make sure that gas supply hoses and connectors are correct.
- Check if there are any unexpected Technical alarms in the Service log available via the Biomed menu. Technical alarms are available also via the Field Service System (FSS).
- Perform a Pre-use check to make sure that the system works properly before the maintenance.
- Set the On/Off switch to Off.
- Disconnect the mains power cable.
- Disconnect the gas supplies (wall and/or cylinder).
- Remove patient tubing.
- If fitted, remove bacteria filter from the expiratory inlet.

Patient connection options

Lot: 49

Other accessories

Extra accessories

Connectivity

Remote service

Reusable

Tube connector 22-15 mm, angled, 5 pcs/pkg
90 37 730

Flex tube 15 mm Hytrel
66 92 455
• Including:
- Adapter 15 mm conn.

Loudspeaker booster, new Servo-i/Servo-s
66 66 593

Loudspeaker booster on-site upgrade: Order no 66 51 280.

User Interface panel cover, Servo-i/ Servo-s
65 67 130

Isolation shield with drip guard, 5 pcs/pkg
66 47 890
• For expiratory cassette.

Expiratory cassette, Servo-i/Servo-s
66 96 947

Test tube, grey
64 87 941
One Test tube is delivered with each base unit.

Test Lung 190, adult
60 06 832
One Test Lung 190 adult is delivered with each base unit.

Test Lung 191, neonatal
63 01 720
One Test Lung 191 neonatal is delivered with each base unit.

MCare Remote Service Box
66 87 825
• Including:
- Connection cables.
- Installation instructions.

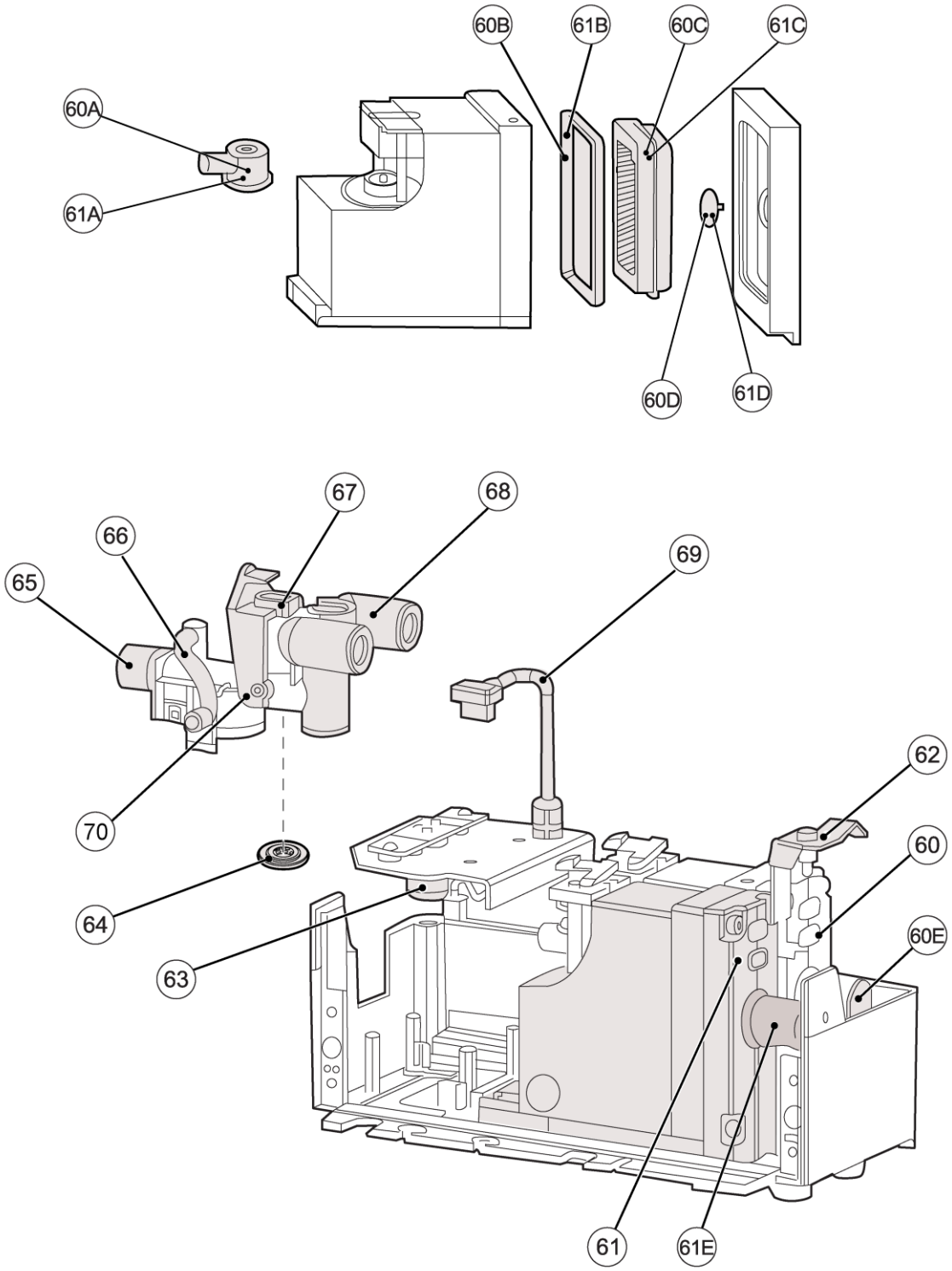
Ventilation Record Card
65 33 181

Data cable Servo ventilator to PC, 2.4 m
65 23 570
• 9 pin female PC plug.

PC card reader, USB connection
66 82 455
• Including:
- USB cable, 1.8 m.

MSync with holder for rail
68 81 603
• Including:
- PSU (power supply unit).
- RS232 cable (shielded), length 0.7 m.
- USB cable, length 1.8 m.

Figure 3: Patient unit, Inspiratory section



Lot: 50;51

Table 3: Patient unit, Inspiratory section

ID	Part no.	Description	Comments
60	6671137	Gas module O2, Type lll	
60A	6693792	Nozzle unit	
60B	6039528	Rubber seal for bacteria filter	
60C	6169416	Bacteria Filter for Gas Module	
60D	6169358	Non-return valve, 2 pcs	
60E	6532654	Module adapter O2, with O-rings	Fits only modules with 2 screws in end plate
61	6671135	Gas module Air, Type lll	
61A	6463496	Nozzle unit	
61B	6039528	Rubber seal for bacteria filter	
61C	6169416	Bacteria Filter for Gas Module	
61D	6169358	Non-return valve, 2 pcs	
61E	6532647	Module adapter AIR, with O-rings	Fits only modules wit 2 screws in the end plate
62	6488113	Module bracket	
63	6670330	Pull magnet incl. bracket	
64	9303892	Filter for O2 cell, 25 pcs	
65	6532662	Inspiratory pipe	
66	6532977	Tube	
67	6640044	O2 cell	
68	6448612	Connector muff	
69	6487958	Cable for O2 cell	
70	6888750	O2 cell holder	

AEROway® - DIN Couplings (DIN 13260)

DIN-couplings (DIN 13260) O_2, AIR and N_2O, for DIN-Plug (DIN 13260), inlet G 3/8" external thread sealed. Seal also available as spare part, single packed.

1

2

3

4

Lot: 102;103

5

Item No.	Gas Type
1 HVK02-O2-F	O_2
2 HVK02N-O2-F	O_2 (neutral labelling color)
3 HVK02-AIR-F	AIR
4 HVK02-N2O-F	N_2O
5 HDM01-AA0-38	Sealing ring for DIN-couplings with G 3/8" connector

AEROway® - Y-Couplings (DIN 13260)

Y-Couplings (DIN 13260) for O_2, AIR and N_2O, inlet DIN-plug (DIN 13260), 2 outlets DIN-couplings (DIN 13260) for DIN-plugs.

1

2

3

4

Item No.	Gas Type
1 HVK02-O2-F2	O_2
2 HVK02N-O2-F2	O_2 (neutral labelling color)
3 HVK02-AIR-F2	AIR
4 HVK02-N2O-F2	N_2O

AEROway® - Plugs (DIN 13260)

DIN-plugs (DIN 13260) for O_2, AIR, VAC and N_2O, 90°-angle, inlet DIN-plug (DIN 13260), outlet for 6 mm tubing.

1

2

3

4

5

6

Item No.	Gas Type
1 HVK02-O2-MW	O_2
2 HVK02N-O2-MW	O_2 (neutral labelling color)
3 HVK02-O2/AIR-MW	O_2 and Air
4 HVK02-AIR-MW	AIR
5 HVK02-VAC-MW	VAC
6 HVK02-N2O-MW	N_2O

RICHARD WOLF
spirit of excellence

HF Monopolar Connecting Cables HF-Monopolar Anschlusskabel

Anschluss Instrument *Connector for instrument*	Anschluss Gerät *Connector for unit*	Länge *Length*	Typen *Types*
WOLF - Resektoskope ***WOLF resectoscopes*** 	 ERBE (ACC / ICC) / BOWA (EU)	3 m	**815.032**
		5 m	**815.052**
	 ERBE (T-Serie) ERBE (T series)	3 m	**815.132**
		5 m	**815.152**
	 Martin (m-Version) / Berchtold / Aesculap	3 m	**815.031**
		5 m	**815.051**
	 Bovie / Valleylab / Erbe (Int.) / BOWA (Int.)	3 m	**815.033**
		5 m	**815.053**
HF-Elektroden, monopolar ***Monopolar HF electrodes*** 	 BOWA (Int. / EU) Eschmann und andere Geräte mit 4 mm Stecker *Eschmann and other devices with 4 mm connectors*	3 m	**815.034**
		5 m	**815.054**
WOLF - Instrumente **WOLF instruments** 	 ERBE (ACC / ICC) / BOWA (EU)	3 m	**8106.032**
		5 m	**8106.052**
	 ERBE (T-Serie) ERBE (T series)	3 m	**8106.132**
		5 m	**8106.152**
	 Martin (m-Version) / Berchtold / Aesculap	3 m	**8106.031**
		5 m	**8106.051**
	 Bovie / Valleylab / Erbe (Int.) / BOWA (Int.)	3 m	**8106.033**
		5 m	**8106.053**
HF-Elektroden, monopolar ***Monopolar HF electrodes*** 	 BOWA (Int. / EU) Eschmann und andere Geräte mit 4 mm Stecker *Eschmann and other devices with 4 mm connectors*	3 m	**8106.034**
		5 m	**8106.054**

15

Overview of the range

Lot: 133

RICHARD WOLF
spirit of excellence

Light Cables in new design

Fiber Light Cable Set	Color identification, endoscope-side	Ø Fiber bundle and color code	Length	Order number	Order number without adapter
 **Set bestehend aus:** Fiber Lichtleiter, Adapter projektorseitig (8095.07) und Adapter endoskopseitig (809509) * Die Lichtleiter können auch ohne Adapter bestellt werden. Adapter zum Anschluss an Fremdprodukte bieten wir separat an (siehe unten).		1,6 mm	1,8 m	806616181	80661618*
			2,3 m	806616231	80661623*
			3,0 m	806616301	80661630*
		2,5 mm	1,8 m	806625181	80662518*
			2,3 m	806625231	80662523*
			3,0 m	806625301	80662530*
		3,5 mm	1,8 m	806635181	80663518*
			2,3 m	806635231	80663523*
			3,0 m	806635301	80663530*
			3,5 m	806635351	80663535*
		5,0 mm	2,3 m	806650231	80665023*
			3,0 m	806650301	80665030*
			3,5 m	806650351	80665035*

Fused fusion light cables, resistant to high temperatures

fusion Light Cable Set	Color identification, endoscope-side	Ø Fiber bundle and color code	Length	Order number	Order number without adapter
 **Set comprises:** Fiber Light Cable, adapter projector-light source-end (8095.07) and adapter endoscope-end (809509) *The fusion light cables can also be ordered without adapters and they are compatible with the same adapters.		5,0 mm	2,3 m	806550231	80655023*
			3,0 m	806550301	80655030*
			3,5 m	806550351	80655035*

Adapters for light cables

for connection to **light sources** from the following manufacturers:

for connection to **endoscopes** from the following manufacturers:

Wolf, Stryker.....**8095.07**			**Wolf**.....**809509**
Storz	no adapter necessary		**Storz, Stryker, Olympus**.....**807001**
Olympus.....**8096.811**			**ACMI, Circon, Henke-Sass-Wolf**.....**807002**

Specifications subject to change without notice.

A 669.XI.17.en.3

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Fax: +49 7043 35-4300
info@richard-wolf.com

Co-CEOs:
Jürgen Pfab
Jürgen Steinbeck

Trade Register: Mannheim HRB 510031
VAT no.: DE144521586
Tax no.: 48020/00171

Lot : 135

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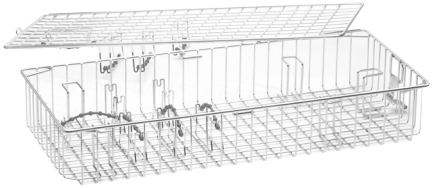
ENDOCAM Logic HD
Pendual camera head

- Bendable housing for two operating modes: 1: pivoting camera head, 2: straight camera head
- Freely rotating snap-on mechanism with lock function
- Integrated lens f = 17 mm
- Digital image processing and signal transmission
- 2 programmable camera head buttons with 4 available functions
- Camera head cable can be replaced in the hospital by technicians
- Can be reprocessed by machine
- Suitable for low-temperature procedure

ENDOCAM Logic HD pendual camera head **5525933**
1-chip type, cable length 3 m

Recommended accessories		Product no.
	**Reprocessing basket for camera head** (L x W x H) 445 x 200 x 73 mm	**38047111**

Lot: 143

134°C
Autoclave
273°F

	700-099	Dichtungskappe (5 Stck.) Sealing cap (5 pcs.) Capuchon d'étanchéité (5 pcs.) Tapón hermético (5 uds.) Guarnizione di tenuta (5 pz.)

3.2 Anschlusskabel monopolar
Connecting cables monopolar
Câbles de raccordement monopolaires
Cables de conexión monopolares
Cavi di collegamento monopolari

Stecker, Geräteseite Plug, generator side Connecteur, côté générateur Enchufe, parte generador Spinotto, parte generatore	Stecker, Instrumentenseite Plug, instrument side Connecteur, côté instrument Enchufe, parte instrumento Spinotto, parte strumento	Passend für Gerätetyp Fitting generator type Pour générateurs type Para generadores tipo Per generatori tipo	REF
	 6-Kant Hexagon coding Hexagonal Hexagonal Esagonale	Erbe VIO / ICC / ACC	101-060 (4.5 m)
		4 mm Ø Buchse 4 mm Ø socket Fiche 4 mm Ø Casquillo 4 mm Ø Presa 4 mm Ø	280-035 (4.5 m)
		BOWA ERBE International Martin International Valleylab Conmed	370-050 (4.5 m)