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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 072017 0015 Rev. 00

Manufacturer:

MAQUET CRITICAL CARE AB
Röntgenvägen 2
171 54 Solna
SWEDEN

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.: 713170827

Preceding certificate No.: This certificate is issued for the first time

Valid from: 2020-02-17
Valid until: 2025-02-16

Date of initial issuance / Rev.00: 2020-02-17

Issue date: 2020-02-17

Christoph Dicks
Head of Certification/Notified Body

Digitally signed by Ghereg Victor
Date: 2024.07.12 15:19:54 EEST
Reason: MoldSign Signature
Location: Moldova

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
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BS-MDR-099

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 072017 0015 Rev. 00

Device(s):	Risk classification	CND Code	Intended Purpose
INSTRUMENTS FOR ANESTHESIA AND PULMONARY VENTILATION SUPPORT	IIb	Z120301	Intended for respiratory support, administration of anesthetic and treatment of neonatal, pediatric and adult patients.

The validity of this certificate depends on conditions and/or is limited to the following: ./.

Revision History including Changes:

Revision / Issue Date / Report
Rev. 00 / 2020-02-17 / 713170827

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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

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

TÜV SÜD
Product Service

Certificate

No. Q5 072017 0013 Rev. 01

Holder of Certificate: **MAQUET CRITICAL CARE AB**
Röntgenvägen 2
171 54 Solna
SWEDEN

Facility(ies):
MAQUET CRITICAL CARE AB
Röntgenvägen 2, 171 54 Solna, SWEDEN

See Scope of Certificate

Certification Mark:

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

Scope of Certificate: **Design, development and manufacturing of Anaesthesia, Monitoring, Ventilator Systems and Perfusion Systems**

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

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 072017 0013 Rev. 01

Report No.: 713193727

Valid from: 2020-12-30

Valid until: 2023-12-29

Date, 2020-12-28

Christoph Dicks
Head of Certification/Notified Body

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

TÜV®

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

Temperature monitoring system

Lot : 13

This item is included in the Vario Single and Vario Twin versions.

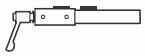
Quad temperature module (70101.0847)

* Maximum four temperatures.

This item is included in the Vario Single and Vario Twin versions.

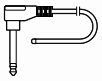
Temperature probe box, 4 probe connections (70101.0848)
- Includes:
  – 1.3 meter connection cable.

To be mounted on the Temperature box hold or placed in the console rack.

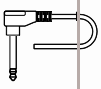


Temperature box holder (70101.0849)
- For mast mounting.

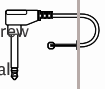
a/o



Getinge Temperature Probe TPO-D-HML L1.8 Adult (70105.4564)
Compatible with both, glue & screw connector variants of:
- Quadrox-i, Adult and Small Adult.
- Quadrox-iD, Adult.
- Quadrox-iR, Adult and Small Adult.
- Plegiox Cardioplegia Heat Exchanger.
- Venous Hardshell Cardiotomy Reservoirs.



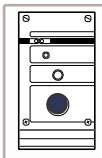
Getinge Temperature Probe TPO-D-HLM L1.8 Pediatric (70105.4565) Compatible with screw connector variants of:
- Quadrox-i, Pediatric and Neonatal
- Quadrox-iD, Pediatric.
- Venous Hardshell Cardiotomy Reservoirs.



Medtronic Affinity Tempera ATP210 Pediatric (70106.9
Compatible with screw con variants of:
- Quadrox-i, Pediatric and
- Quadrox-iD, Pediatric.
- Venous Hardshell Cardiot

Air emboli protection

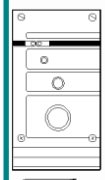
Level detection



Level detection kit (70101.0854)
Kit includes:
- Air protection module for level sensor (to be placed in the console rack).
- Capacitive level sensor with cable 2 meter **(70102.2206)**.
- Level sensor pad, 100 pieces **(70102.2208)**.

Level and bubble detection

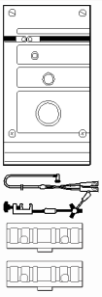
This item is included in the Vario Single and Vario Twin versions.



Air emboli protection system (70101.0853)
Complete system for level and bubble sensors includes:
- Air protection module (to be placed in the console rack).
- Bubble sensor complete with cable 2.1 meter **(70101.0858)**.
- Insert (one pair) for 3/8" x 3/32" tubing **(70101.0861)**.
- Capacitive level sensor with cable 2 meter **(70102.2206)**.
- Level sensor pad, 100 pieces **(70102.2208)**.
- Ultrasonic gel dispenser **(70101.0859)**.

* Alternative inserts can be ordered separately (see below).

Bubble detection

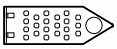


Bubble detection kit (70103.1541)
Kit includes:
- Air protection module (to be placed in the console rack).
- Bubble sensor complete with cable 2.1 meter **(70101.0858)**.
- Insert (one pair) for 3/8" x 3/32" tubing **(70101.0861)**.
- Ultrasonic gel dispenser **(70101.0859)**.

* Alternative inserts can be ordered separately (see below).

a/o

Extra sensor pads



Level sensor pad, 100 pcs (70102.2208)
Disposable level sensor pad, quantity 100.
- To be surface mounted on the reservoir at the level of supervision.

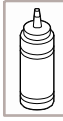
Inserts

Bubble sensor insert (one pair)

For 1/4" x 1/16" tubing	**(70101.0864)**
For 1/4" x 3/32" tubing	**(70101.0865)**
For 3/8" x 1/16" tubing	**(70101.0860)**
For 3/8" x 3/32" tubing *	**(70101.0861)**
For 1/2" x 1/16" tubing	**(70103.4514)**
For 1/2" x 3/32" tubing	**(70101.0863)**

* Included in Bubble detection kit **(70103.1541)** and Air emboli protection system **(70101.0853)**.

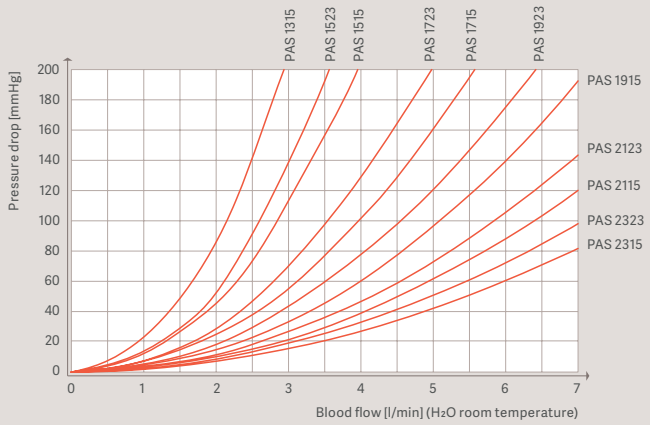
Extra gel



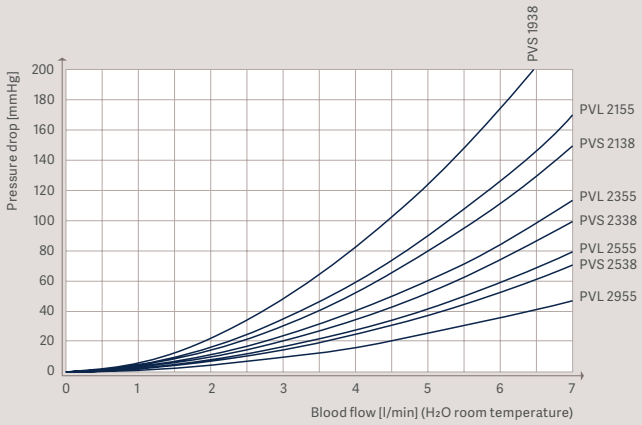
Ultrasonic gel dispenser (70101.0859)
- Gel to improve the sensitivity of the bubble sensor.

Lot : 110

Pressure drop for all arterial HLS Cannulae ⅜"



Pressure drop for all venous HLS Cannulae ⅜"



Product order details arterial HLS cannulae

Type	Outer diameter	Insertion length	Side holes	Perforation length	Connector	Bioline Coating
PAS 1315	13 Fr (4.3 mm)	15 cm	2	1 cm	3/8" LL	BE-PAS 1315
PAS 1515	15 Fr (5.0 mm)	15 cm	2	1 cm	3/8" LL	BE-PAS 1515
PAS 1715	17 Fr (5.7 mm)	15 cm	2	1 cm	3/8" LL	BE-PAS 1715
PAS 1915	19 Fr (6.3 mm)	15 cm	2	1 cm	3/8" LL	BE-PAS 1915
PAS 2115	21 Fr (7.0 mm)	15 cm	2	1 cm	3/8" LL	BE-PAS 2115
PAS 2315	23 Fr (7.7 mm)	15 cm	2	1 cm	3/8" LL	BE-PAS 2315
PAL 1523	15 Fr (5.0 mm)	23 cm	2	1 cm	3/8" LL	BE-PAL 1523
PAL 1723	17 Fr (5.7 mm)	23 cm	2	1 cm	3/8" LL	BE-PAL 1723
PAL 1923	19 Fr (6.3 mm)	23 cm	2	1 cm	3/8" LL	BE-PAL 1923
PAL 2123	21 Fr (7.0 mm)	23 cm	2	1 cm	3/8" LL	BE-PAL 2123
PAL 2323	23 Fr (7.7 mm)	23 cm	2	1 cm	3/8" LL	BE-PAL 2323

One cannula per carton

Product order details venous HLS cannulae

Type	Outer diameter	Insertion length	Side holes	Perforation length	Connector	Bioline Coating
PVS 1938	19 Fr (6.3 mm)	38 cm	12	10 cm	3/8"	BE-PVS 1938
PVS 2138	21 Fr (7.0 mm)	38 cm	12	10 cm	3/8"	BE-PVS 2138
PVS 2338	23 Fr (7.7 mm)	38 cm	16	10 cm	3/8"	BE-PVS 2338
PVS 2538	25 Fr (8.3 mm)	38 cm	20	10 cm	3/8"	BE-PVS 2538
PVL 2155	21 Fr (7.0 mm)	55 cm	20	20 cm	3/8"	BE-PVL 2155
PVL 2355	23 Fr (7.7 mm)	55 cm	20	20 cm	3/8"	BE-PVL 2355
PVL 2555	25 Fr (8.3 mm)	55 cm	24	20 cm	3/8"	BE-PVL 2555
PVL 2955	29 Fr (9.7 mm)	55 cm	32	20 cm	3/8"	BE-PVL 2955

One cannula per carton

2

HLS Set Advanced & CARDIOHELP device
Technical data

Lot 109

Technical Data	HLS Set Advanced 5.0	HLS Set Advanced 7.0
Flow rates	0.5–5 l/min	0.5–7 l/min
Gas exchange surface area	1.3 m2	1.8 m2
Heat exchange surface area	0.3 m2	0.4 m2
Priming volume HLS Module Advanced	240 ml	273 ml
Priming volume HLS Set Advanced with 2 x 2.3 m tubing length	570 ml	600 ml
Gas exchange fibers	Diffusion membrane (PMP)	Diffusion membrane (PMP)
Duration of use with BIOLINE Coating	Max. 30 days	Max. 30 days
Duration of use with SOFTLINE Coating	Max. 5 days	Max. 5 days
Integrated venous measuring cell	– oxygen saturation SvO2 – hemoglobin (Hb) – hematocrit (Hct) – temperature	– oxygen saturation SvO2 – hemoglobin (Hb) – hematocrit (Hct) – temperature
Integrated sensors	– 3 pressures (venous, arterial, internal) – arterial temperature	– 3 pressures (venous, arterial, internal) – arterial temperature
	70106.9076	70106.9073

Technical Data	CARDIOHELP-i
Dimensions (H x W x D) with guard closed	315 x 255 x 427 mm (without holder/disposable)
Weight	Approx. 10 kg
Display	5.7" LCD touchscreen
Sensors	4 x External pressures 3 x Internal pressures 2 x External temperatures 2 x Internal temperatures 1 x Venous oxygen saturation 1 x Hemoglobin 1 x Hematocrit 1 x Flow/Bubble sensor 1 x Bubble sensor 1 x Level sensor
Operating voltage range	11–28 Volt DC 100–240 Volt AC/50–60 Hz
Interfaces for	1 x USB port type A (for data export on USB stick) 1 x USB port type B (for data recording system and service purposes) 1 x Connection for alarm output (ward call)
Battery operating time	Min. 90 min (fully charged batteries)

Sensation Plus Fiber-optic IAB Catheters

Give patients the clinical effectiveness of a larger volume IAB in an easy-to-use balloon.

Improve patient comfort and safety with the Sensation Plus IAB. Sensation Plus brings innovative fiber-optic technology and greater hemodynamic support to adult patients 5'0" (152 cm) and above. Advanced fiber-optic technology provides accurate and consistent blood pressure indices, faster time to therapy and automatic *in-vivo* calibration.

- Greater hemodynamic support for more systolic unloading and more augmentation.[2]
- Needle-free securement with the StatLock® IAB Stabilization Device improves patient comfort and safety.

Sensation Plus IAB catheters

Sensation Plus 7.5 Fr. and 8 Fr. Fiber-optic IAB Catheters[3]

IAB volume	Introducer sheath length	Catheter extender compatible with:	Part Number
50 cc	6" (15 cm)	Getinge/Datascope Systems	0684-00-0576-01
40 cc	6" (15 cm)	Getinge/Datascope Systems	0684-00-0568-01

[3] Sensation Plus IAB catheters include Insertion Kits with Introducers and 2 StatLock® IAB devices.

Optional Accessories for Sensation Plus IAB Catheter Insertion Kit

Description	Part Number
Sensation Plus 8 Fr. 50 cc Insertion Kit only	0884-00-0019-23
Sensation Plus 7.5 Fr. 40 cc Insertion Kit only	0884-00-0019-22

Sensation Plus Insertion Kit includes:
- One 6" (15 cm) reinforced introducer sheath with hemostasis valve
- One introducer dilator
- One vessel dilator
- One 18 gauge angiographic needle
- One 0.025" x 145 cm 3 mm J PTFE stainless steel guidewire
- One male luer cap
- One three-way stopcock
- Two 4' pressure tubings
- One 6'0" catheter extender tubing (40 cc ONLY)
- One 5'7" catheter extender tubing (50 cc ONLY)

[2] Bench testing completed by Getinge. Data on file. Bench test results are not necessarily predictive of clinical results.

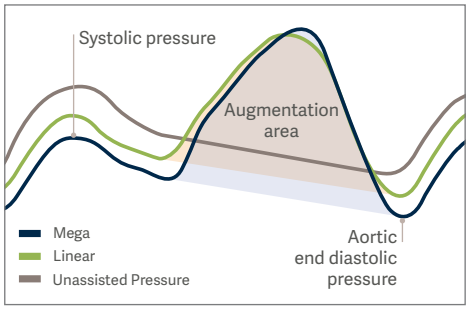
Mega IAB Catheters

Greater hemodynamic support and efficacy for all patients

With the Mega IAB, a larger patient population can now benefit from greater hemodynamic support. Consider a higher-efficiency IAB as your first choice for hemodynamic support.

- Larger-volume balloons displace more blood in the aorta during diastole for improved diastolic augmentation and systolic unloading.
- Eliminate suture-securement needle sticks and suture wound complications with StatLock® IAB, now included with Mega IAB for increased patient comfort and safety.
- Proprietary IAB membrane offers 43% more abrasion resistance, reduced insertion force and immediate inflation at start-up for better clinical outcomes.
- No step-down due to unique balloon wrap, reducing trauma to the vessel wall during insertion and removal.
- Co-lumen design provides optimal gas passage for faster inflation and deflation of the IAB.
- Large 0.027" inner lumen supports a reliable pressure transducer signal.

Mega IAB catheters



Hemodynamic Comparison[5] Bench testing results

Mega 7.5 Fr. and 8 Fr. IAB Catheters[6]

IAB Volume	Introducer sheath length	Catheter extender compatible with:	Part Number
50 cc	6" (15 cm)	Getinge/Datascope Systems	0684-00-0296-01
40 cc	6" (15 cm)	Getinge/Datascope Systems	0684-00-0295-01
30 cc	6" (15 cm)	Getinge/Datascope Systems	0684-00-0294-01

[6]All Mega IAB catheters Include Insertion Kits with Introducers and 2 StatLock® IAB devices.

IAB Volume	Introducer sheath length	Catheter extender compatible with:	Part Number
50 cc	6" (15 cm)	Arrow (Kontron)	0684-00-0296-02
40 cc	6" (15 cm)	Arrow (Kontron)	0684-00-0295-02
30 cc	6" (15 cm)	Arrow (Kontron)	0684-00-0294-02

[6]All Mega IAB catheters Include Insertion Kits with Introducers and 2 StatLock® IAB devices.

Optional Accessories for Mega IAB Catheters Insertion Kit

Description	Part Number
Mega 8 Fr. 50 cc Insertion Kit for sheathless/sheathed insertion	0884-00-0019-17
Mega 7.5 Fr. 30 cc/40 cc Insertion Kit for sheathless/sheathed insertion	0884-00-0019-21

Mega Insertion Kits include:

- One 6" (15 cm) reinforced introducer sheath with hemostasis valve
- One introducer dilator
- One vessel dilator
- One 18 gauge angiographic needle
- One 0.025" x 145 cm 3 mm J PTFE stainless steel guidewire
- One male luer cap
- One three-way stopcock
- Two 4' (122 cm) pressure tubings
- One 5'6" catheter extender tubing (30 cc/40 cc ONLY)
- One 5'7" catheter extender tubing (50 cc ONLY)

[5] Bench testing completed by Getinge. Data on file. Bench test results are not necessarily predictive of clinical results.

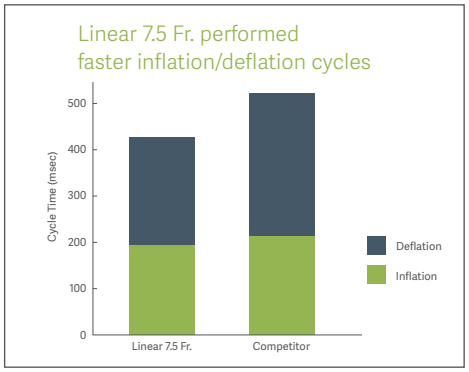
Linear IAB Catheters

Smaller profile, big performance[7]

In IAB therapy, proper timing of inflation and deflation within the cardiac cycle is critical to patient outcomes.

In bench testing, Linear 7.5 Fr. IAB catheters demonstrated faster inflation and deflation cycles than the competition.

- Linear has 19% faster cycle time in 80° bend test method compared to a competitor IAB catheter.
- Faster gas shuttle performance offers better support for rapid heart rates and arrhythmias.



Linear 7.5 Fr. IAB Catheters[8]

IAB Volume	Introducer sheath length	Catheter extender compatible with:	Part Number
40 cc	6" (15 cm)	Getinge/Datascope Systems	0684-00-0480-01
34 cc	6" (15 cm)	Getinge/Datascope Systems	0684-00-0479-01
25 cc	6" (15 cm)	Getinge/Datascope Systems	0684-00-0478-01

[8]All Linear IAB catheters Include Insertion Kits with Introducers

IAB Volume	Introducer sheath length	Catheter extender compatible with:	Part Number
40 cc	6" (15 cm)	Arrow (Kontron)	0684-00-0480-02
34 cc	6" (15 cm)	Arrow (Kontron)	0684-00-0479-02
25 cc	6" (15 cm)	Arrow (Kontron)	0684-00-0478-02

[8]All Linear IAB catheters include Insertion Kits with Introducers

Optional Accessories for Linear 7.5 Fr. IAB Catheters 40 cc and 34 cc Insertion Kit

Description	Part Number
Linear 7.5 Fr. 40 cc and 34 cc Insertion Kit for Sheathless/Sheathed Insertion	0884-00-0019-13

Linear 40 cc and 34 cc Insertion Kit includes:

- One 7.5 Fr. 6" (15 cm) reinforced introducer sheath with hemostasis valve
- One introducer dilator
- One vessel dilator
- One 18 gauge angiographic needle
- One 0.025" x 145 cm 3 mm J PTFE stainless steel guidewire
- One male luer cap
- One three-way stopcock
- Two 4' (122 cm) pressure tubings
- One 6' catheter extender tubing

[7] Bench testing completed by Getinge. Data on file. Bench test results are not necessarily predictive of clinical results.

Lot : 111-112

The Quadrox-i product design

4 variants to cover all patient sizes

	Neonatal	Pediatric	Small Adult	Adult
	HMO 10000 / HMO 11000 (w. filter)	HMO 30000 / HMO 31000 (w. filter)	HMO 50000 / HMO 51000 (w. filter)	HMO 70000 / HMO 71000 (w. filter)
Edge length	45 mm	55 mm	90 mm	90 mm
Maximum blood flow	1.5 l/min	2.8 l/min	5.0 l/min	7.0 l/min
Gas transfer surface area	0.38 m²	0.8 m²	1.3 m²	1.8 m²
Heat exchanger surface area	0.07 m²	0.15 m²	0.3 m²	0.4 m²
Fiber diameter	300 µm	380 µm	380 µm	380 µm
Priming volume without filter	<41 ml	<190 ml	*181 ± 3 ml	*232 ± 4 ml
Priming volume with Filter	<43 ml	<107 ml	*303 ± 3 ml	*344 ± 5 ml

* Has been updated in IFU accordingly.

Perfusion simplified

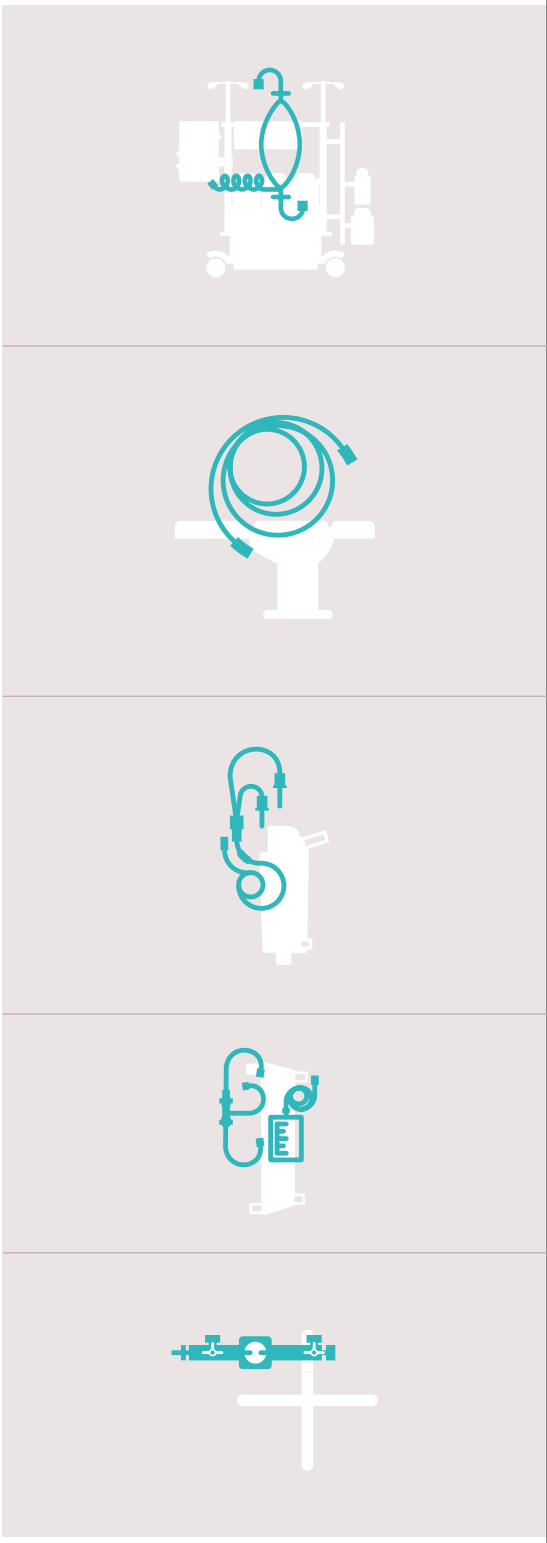
with the modular tubing set approach by Getinge

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

GETINGE

Combined expertise
to make perfusion simpler

The combined expertise of perfusionists and Getinge is the basis for creation of the modular tubing sets. These sets comply with international standards of practice, adhering to minimum safety considerations for the safe conduct of surgical perfusion. Modular tubing sets are the first step to make perfusion easier, faster and safer.



Modular tubing sets ensure a quality standard in production, configuration and validation

The various modules have been intensively tested and validated at Getinge. Drawing approvals, documentation or verification for quality assurance are now a thing of the past.

In addition, Getinge ensures that the modular tubing sets comply with the guidelines for minimum system requirements and risk analysis for the Getinge Heart-Lung Machine HL 40. These guidelines have been developed by perfusionists and aligned with international perfusion recommendations in Europe, North America and Asia.

Modular tubing sets are pre-produced and available from stock

A further advantage of modular tubing sets is the continuous availability. Availability is normally given within two working days. This facilitates sustainable planning and inventory management.

When selecting modules, the new digital product catalog for modular tubing sets is available to help. The e-catalog contains a detailed overview of the individual modules and customized configuration of these modules is possible. Various calculators, such as priming volume or surface area in contact with blood, are also available.

Stay flexible with modular tubing sets

The modules contain all the essential components you need for an extra-corporeal circuit. The combination of modules is completely customizable.

Modules consists of table sets, machine sets, hemoconcentrator sets, cardioplegia sets and additional components and lines. Uncoated versions or with Softline Coating are available for adults and small adult patients.

Machine sets

Machine set consists of the disposables and the tubing, which are assembled on the heart-lung machine and carry the perfused blood between the table lines and reservoir, pump, oxygenator.

Main components include the reservoir, the oxygenator with integrated arterial filter and pump lines. Several variations are available as well as additional components and lines.

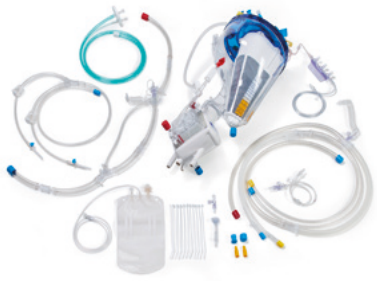


Table sets

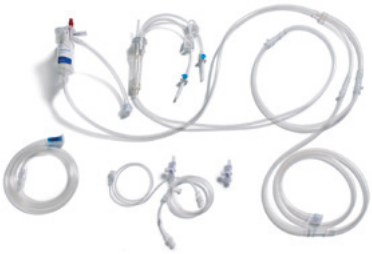
Table set consists of lines, which are connected between the patient and the heart-lung machine lines.

Main components include arterial line, venous line, suction lines, vent lines and pre-bypass filter, if needed. Several variations as well as additional components and lines are available in different lengths depending on where the heart-lung machine is located.

Cardioplegia sets

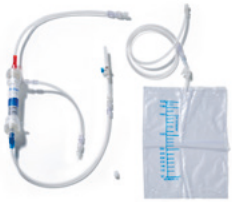
Cardioplegia set includes the tubing lines and disposable components, which are used for carrying the cardioplegia solution to the heart for myocardial protection.

Getinge has cardioplegia sets for standard cardioplegia solution delivery methods, like blood cardioplegia or crystalloid cardioplegia.



Hemoconcentrator sets

Hemoconcentrator set consists of the inlet and outlet tubing lines, a waste bag and the hemoconcentrator. Several variations are available as well as additional components and lines.



Additional components and lines

Additional components and lines are available for all modules and include accessories and lines such as a Rotaflow Centrifugal Pump RF-32, gas lines, suction lines, pre-bypass filter, pressure dome. Several variations are available depending on size / weight of the patient (tubing diameter).