

Servo-i Ventilator

Spare Parts List

Table 3: Patient unit, Inspiratory section

ID	Part no.	Description	Comments
60	6671137	Gas module O2, Type III	
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 III	
61A	6693792	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 with 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	

Lot : 9

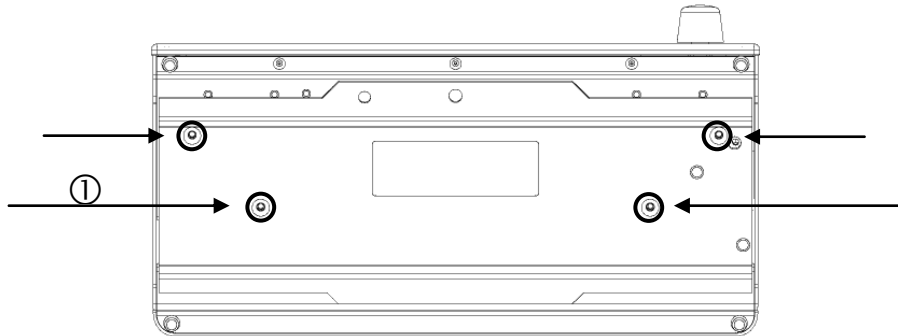
ref: 315170-P

4 Replacing the battery

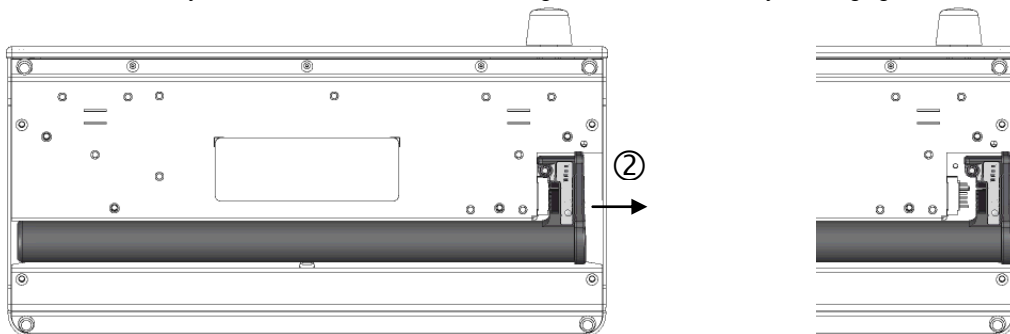
The battery should be changed, if the operating time of the fully charged battery drops below 30 minutes. In order to change the battery of the device, the device must be opened on the bottom side.

Therefore, the four marked screws must be removed with a hex key (2.5 mm), then the bottom plate can be demounted.

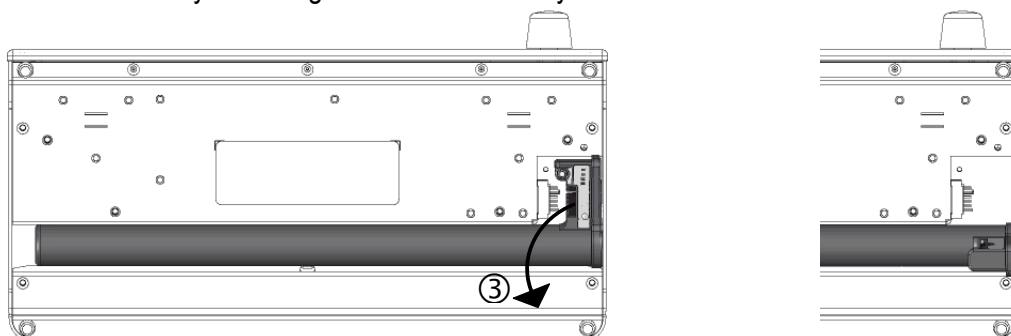
1. Demount the bottom plate of the device by removing the four screws (marked below).



2. Press the battery  to the right side. The battery disengages.




3. Rotate the battery at an angle of 90°. The battery can be removed.



4. Insert the battery the other way around.
5. Mount the bottom plate by using the four screws.

In order to check if the battery works properly, connect the device to mains power, switch on mains power switch on the back of the device and start the device. If the device shows a loading battery in the information bar, the battery works properly. If the battery does not work the symbol of a crossed battery

 is shown.

Servo-i Ventilator Spare Parts List

Figure 3: Patient unit, Inspiratory section

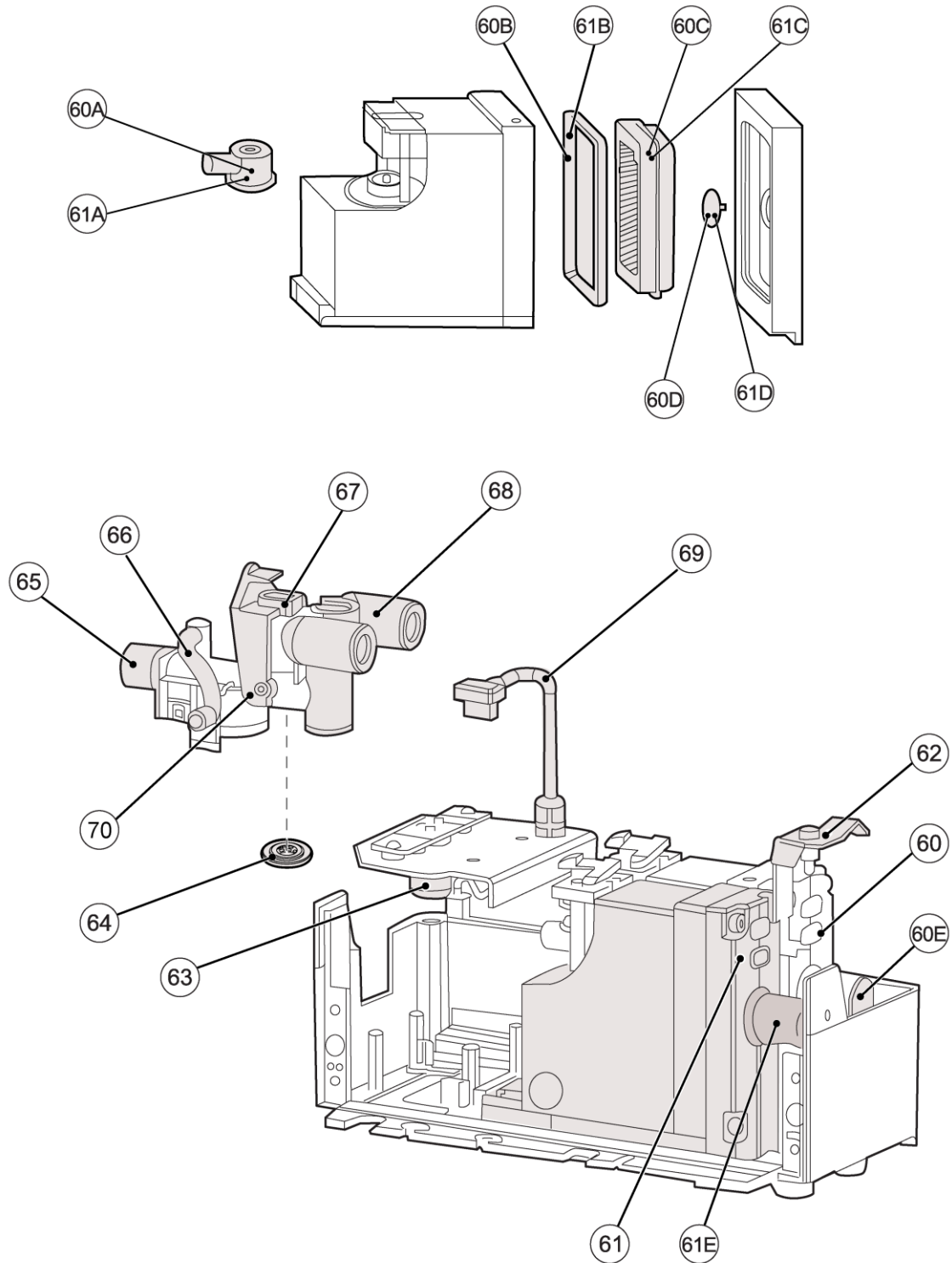
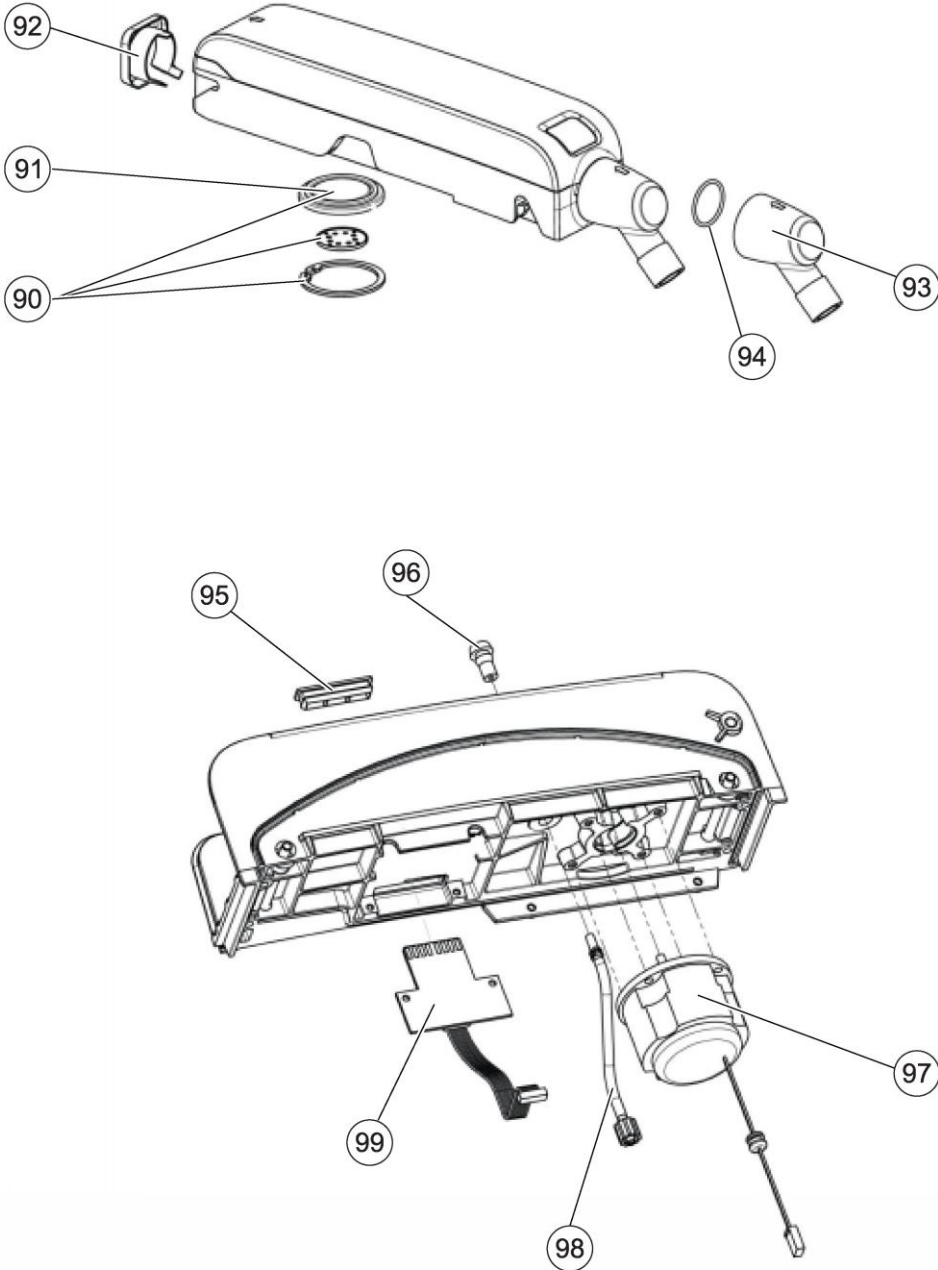


Figure 4: Patient unit, Expiratory section

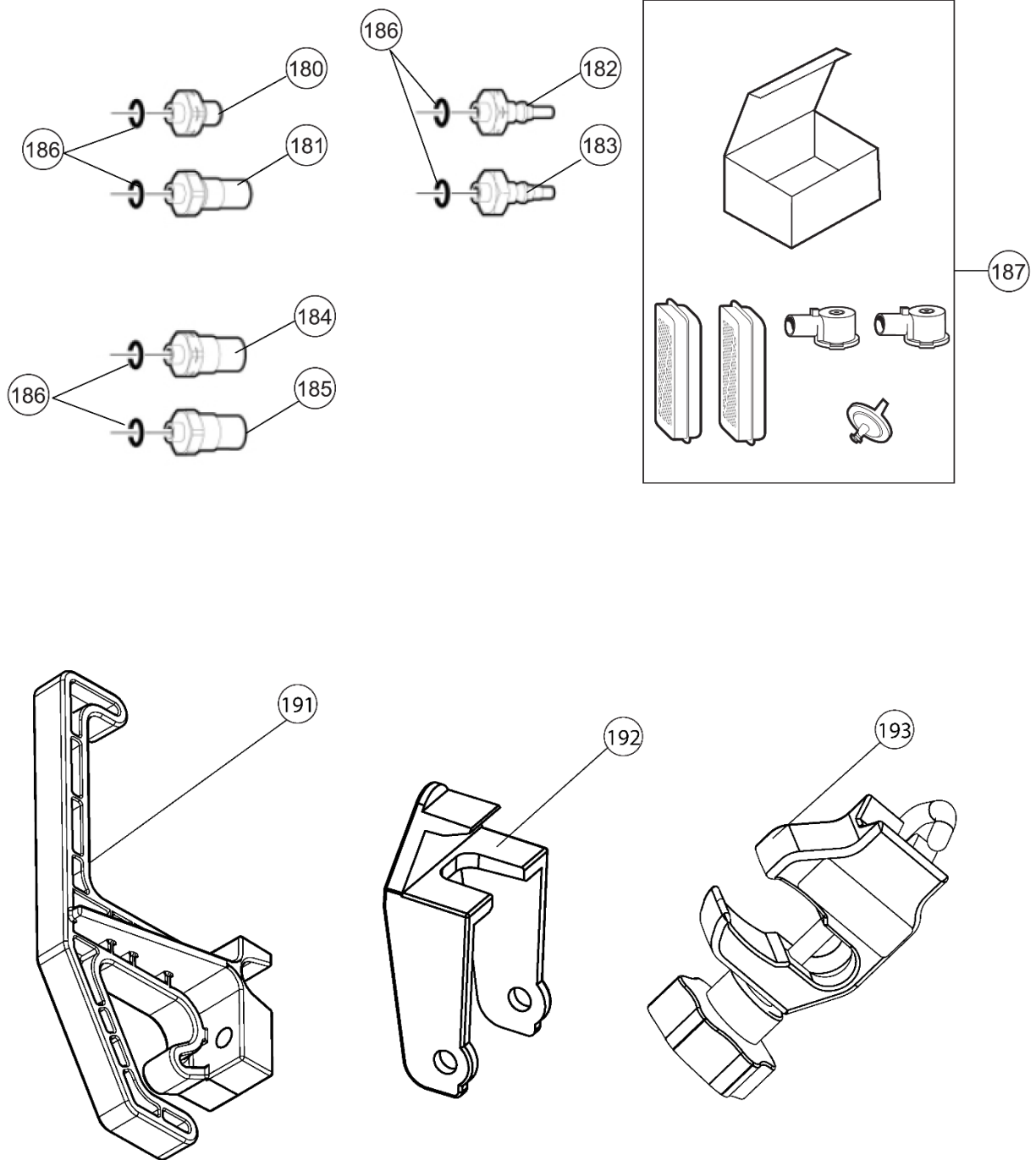


Servo-u/Servo-n/Servo-u MR Ventilator Spare Parts List

Table 4: Patient unit, Expiratory section

ID	Part no.	Description	Comments
90	6586791	Membrane with washer and ring, 1 pcs	
91	6670360	Membrane, 10 pcs	Membrane only
92	6880752	Thermo sleeve	
93	6880730	Moisture trap, Servo-u	Graphite gray color
	6880731	Moisture trap, Servo-n	Light gray color
94	9344144	O-Ring 26.2 X 3, 10 pcs	
95	6448166	Gasket	
96	6447895	Seal	
97	6696975	Expiratory valve coil incl. 6586742	
98	6533579	Expiratory pressure transducer tube	
99	6696972	Circuit board PC1785 incl. 6468016	Expiratory channel connector

Figure 7: Nipples, service kit, tools and miscellaneous



Servo-u/Servo-n/Servo-u MR Ventilator Spare Parts List

Table 7: Service kit, tools and miscellaneous

ID	Part no.	Description	Comments
180	6884593	NIST Connection O2 Servo-u/n	
181	6169242	NIST Connection AIR	
182	6169275	Male quick coupling O2, AGA	
183	6169283	Male quick coupling AIR, AGA	
184	6884592	DISS Connection O2 Servo-u/n	
185	6169267	DISS Connection AIR	
186	9131434	O-ring 12.1 X 1.6, 10 pcs	Included in positions 180-185
187	6532621	Maintenance kit 5000h	
188	6884594	French Connection O2 Servo-u/n	Not shown in picture
189	6883300	Isolation test cable kit	Including: <ul style="list-style-type: none"> • Test cable Y sensor module • Test cable Edi module • Test cable Nebulizer • Test cable CO2 analyzer module Capnostat 3 • Test cable CO2 analyzer module Capnostat 5 Not shown in picture
190	9573700	Grease ALEXOL STABOX (oxygen compatible)	Tube of 20 g Not shown in picture
191	6888731	Cable guide	
192	6888750	O2 cell holder	
193	6888289	Support clamp	To be used with Support Arm 178 & 179

Service information 014: Preventive maintenance.

Lot: 39.1

RevoLix DUO

Lisa laser products recommends to do once a year a preventive maintenance on the RevoLix DUO laser. This maintenance should be done only from a trained and authorized service engineer. The service engineer can only be trained and authorized from Lisa laser products.

The reason of this maintenance is to prevent later faults and to keep the reliability of the laser.

The preventive maintenance enfolded:

- Check the earth leakage current
- Open the laser module and check the drying agent of the laser diode (SI006)
- Check the protection window (SI015)
- Change the DI-Filter and the filter cartridge (SI010)
- Change the filter cartridge laser head (SI009)
- Fill up the cooling water (SI007)
- Measure the output power and compare with the displayed power
- Take a terminal report and read out the error list. (SI016)

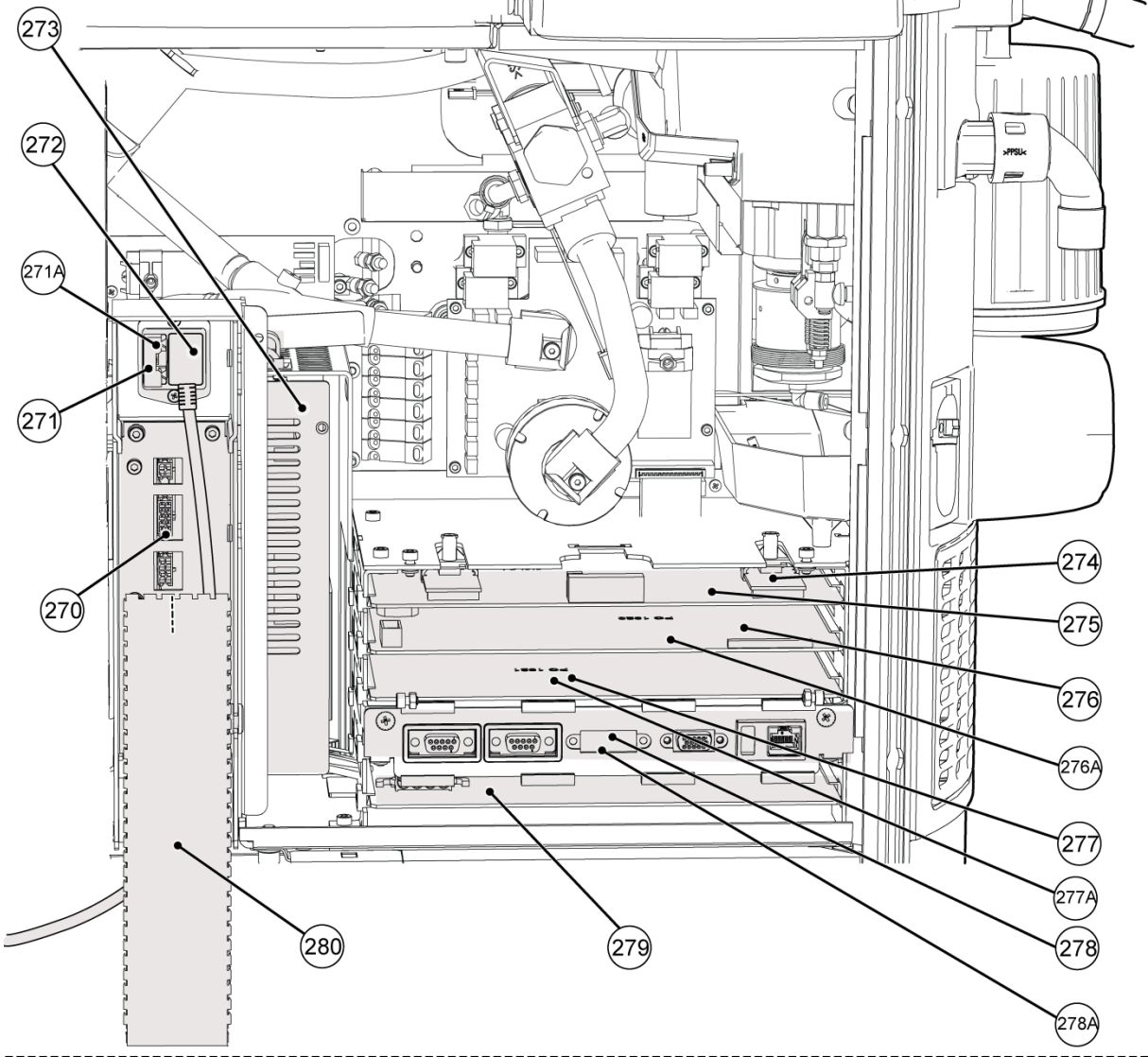
Needed PM parts:

QTY:	Name:	Order No.:
1	Desiccant cartrige for diode	101 630 030
1	Desiccant bag (internal) for resonator	101 600 188
1	DI Filter	101 630 045
1	Water filter 1µm for chiller	101 630 055
1	Water filter 25µm for Laserhead	101 630 031

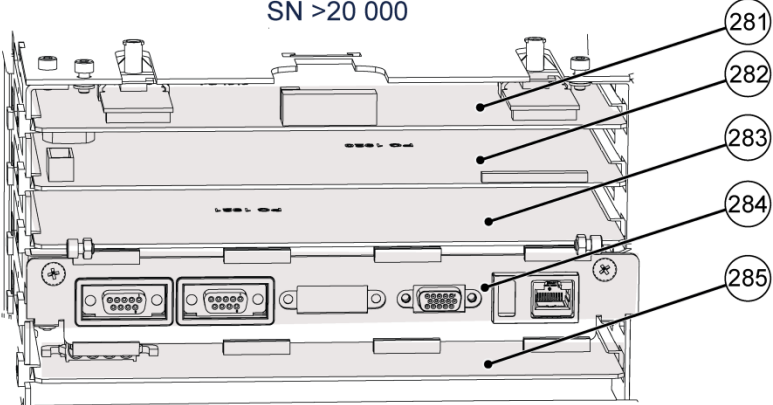
Complete the form at page two and send a copy to Lisa laser products.

Also a copy of the terminal report should be send to Lisa laser products.

Figure 10: Circuit boards



SN >20 000

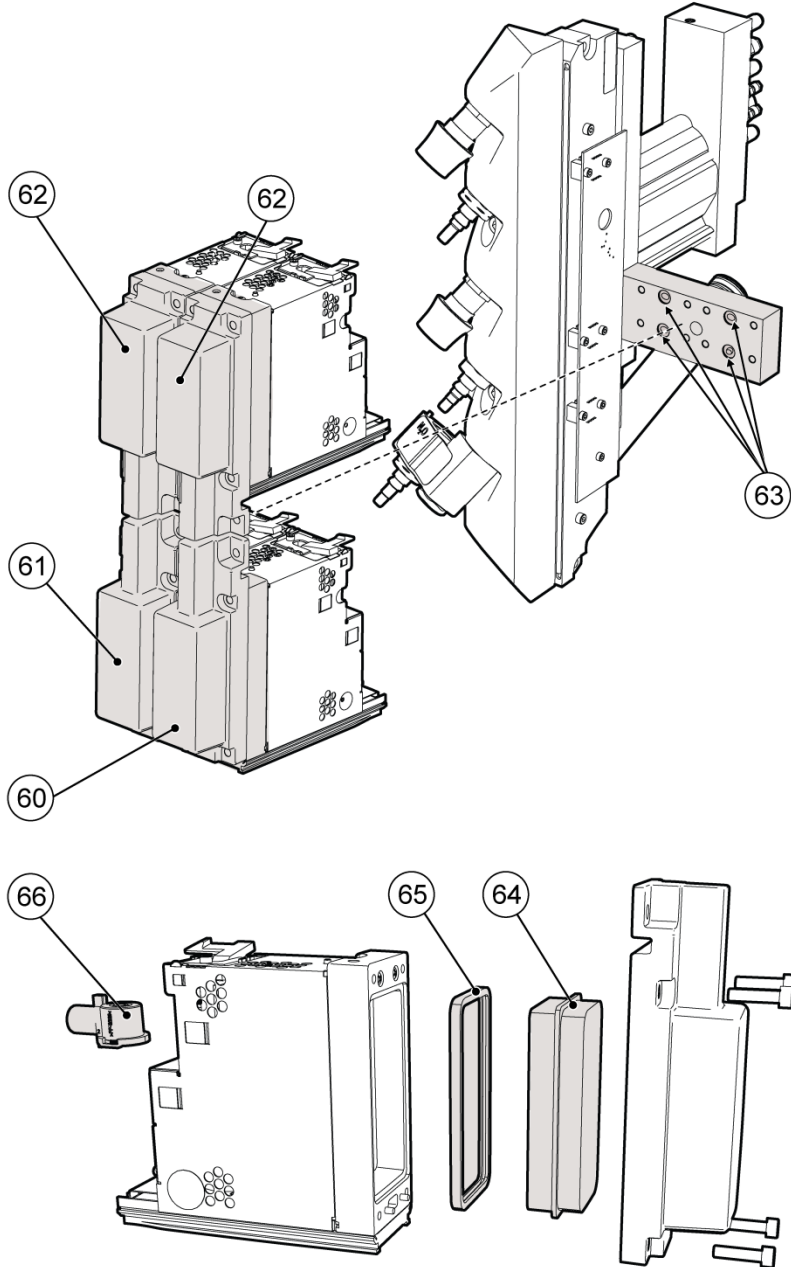


Flow-i Anesthesia Machine Spare Parts List

Table 10: Circuit boards

ID	Part No	Description	Comments
270	6693800	Circuit board PC1903 incl. 6672845	
271	6693875	Cable, IEC Inet to AC/DC (6676160)	
271A	9604059	Fuse, 6.3 AT, 5X20 MM, 10 pcs	
272	6693872	Connection internal incl. 6676085	
273	6889905	AC/DC Kit incl. PC1903 bracket	Including: <ul style="list-style-type: none"> • 1 PC2055 • 1 Contact frame • 1 Washer • 3 Types of screws • 3 Types of cables Shown in position 41 in picture on page 6
274	6696967	Circuit board PC1781 incl. 6467893	
275	6693812	Circuit board PC1919 incl. 6881564	
	6885506	Circuit board PC1984 incl. 6884636	Require system SW version 4.3.1 or later
276	6693825	Circuit board PC1920 Type1, incl. 6672970	Require system SW version lower than 4.3.1
	6887331	Circuit board PC1920 Type 2, incl. 6887112	Require system SW version 4.3.1 or later
276A	6194687	Battery	To be replaced every 4 years Not shown in picture
277	6693827	Circuit board PC1921 Type 1, incl. 6672972	Require system SW version lower than 4.3.1
	6887332	Circuit board PC1921 Type 2, incl. 6887113	Require system SW version 4.3.1 or later
277A	6194687	Battery	To be replaced every 4 years Not shown in picture
278	6887333	Circuit board PC1922 Type 2, incl. 6887114	
278A	6194687	Battery	To be replaced every 4 years Not shown in picture
279	6693817	Circuit board PC1923 incl. 6672945	
280	6883464	Cable cover	
Only for SN > 20 000			
281	6885506	Circuit board PC1984 incl. 6884636	
282	6887205	Circuit board PC2060 incl. 6885853	
	6194687	Battery	To be replaced every 4 years Not shown in picture

Figure 3: Gas supply



Flow-i Anesthesia Machine Spare Parts List


Table 3: Gas supply

ID	Part no.	Description	Comments
60	6693945	Gas module N ₂ O incl. 6685477	
61	6693915	Gas module AIR incl. 6679422	
62	6693910	Gas module O ₂ incl. 6678900	
63	9358425	O-Ring 6.1X1.6, 10 pcs	Included in the maintenance kit
64	6169416	Bacteria Filter for Gas Module	Included in the maintenance kit
65	6693757	Rubber seal filter, incl. 6039528	Included in the gas module
66	6693792	Nozzle unit incl. 6463496	Included in the maintenance kit
67	6888067	Ground spring, 2 pcs	Located under the gas modules Not shown in picture

Temperature monitoring system

Lot 111


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



Quad temperature module (70101.0847)

* Maximum four temperatures.

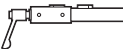
This item is included in the Vario Single and Vario Twin versions.



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.



Temperature Probe, oxygenator, adult (70105.4564)
Available from Q2/2021.

Compatible with:


- Quadrox-i, Adult and Small Adult.
- Quadrox-iD, Adult.
- Quadrox-iR, Adult and Small Adult.
- Plegiox Cardioplegia Heat Exchanger.
- Venous Hardshell Cardiotomy Reservoirs.



Temperature Probe, oxygenator, pediatric (70105.4565)
Available from Q2/2021.

Compatible with screw connector variants of:

- Quadrox-i, Pediatric and Neonatal.
- Quadrox-iD, Pediatric.
- Venous Hardshell Cardiotomy Reservoirs.



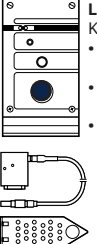
Temperature Sensor ATP210, oxygenator, pediatric (70106.9276)

Compatible with screw connector variants of:

- Quadrox-i, Pediatric and Neonatal.
- Quadrox-iD, Pediatric.
- Venous Hardshell Cardiotomy Reservoirs.

Air emboli protection

Level detection



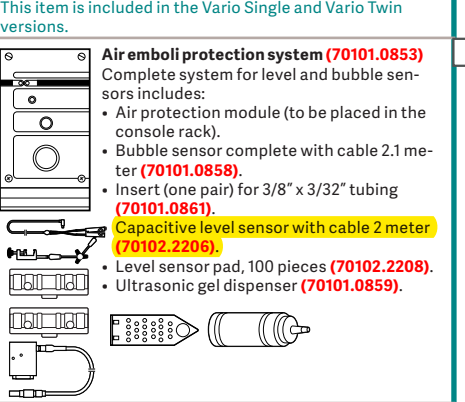
Level detection kit (70101.0854)

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.



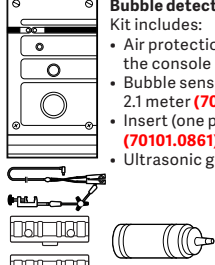
Air emboli protection system (70101.0853)

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)

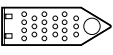
Kit includes:

- 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).

Lot :111

Extra sensor pads

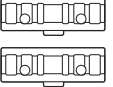


Level sensor pad, 100 pcs (70102.2208)

Disposable level sensor pad, quantity 100.

- To be surface mounted on the reservoir at the level of supervision.

Inserts

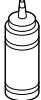


Bubble sensor insert (one pair)

- 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



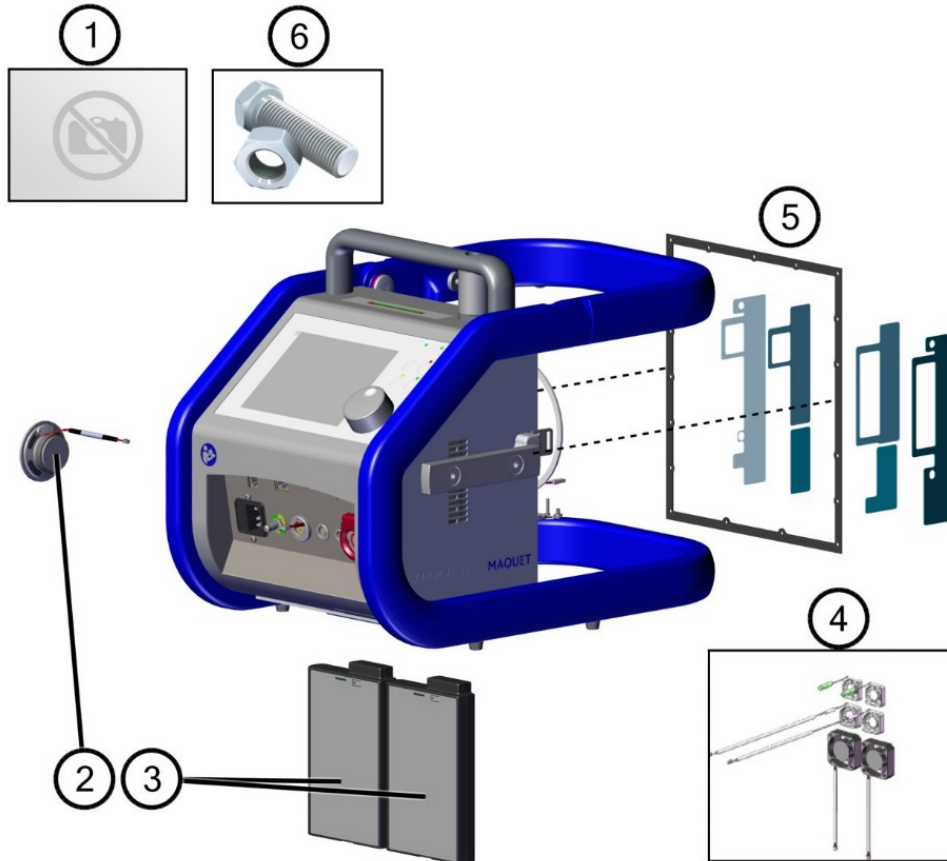
Ultrasonic gel dispenser (70101.0859)

- Gel to improve the sensitivity of the bubble sensor.

SPARE PARTS LIST

CARDIOHELP
Cardiohelp Maintenance Parts

Version 12
approved by Service 2022-01-31



ID	Order No.	Description	Comments	Qty	Additional Information
1	70104.7987	Label Safety Seal	replacement every 2 years <i>without illustration</i>	1	
2	70105.3582	Speaker	replacement every 2 years	1	1
3	70104.9130	Battery Pack (1 piece)	replacement every 3 years	1	3,4
4	70104.9299	2x Drive Fan. 2x Colling Element Fan 2x Power Supply Unit Fan	replacement every 2 years	1	1
5	70104.9301	Gasket Seal Kit	replacement every 2 years Include: 1x 701051821 Cardiohelp Screw Kit	1	
6	70105.1821	Cardiohelp Screw Kit	replacement every 2 years <i>without illustration</i>	1	
41	70105.1784	Cardiohelp Rubber Feet Kit	replacement as required 5 pieces of screws and feet <i>Illustration see page 7</i>	5	

1 ESD

2 Calibration

3 Storage Conditions

4 DMD

ESD Protection must be considered

Part needs special calibration

Be aware of special storage conditions

Part has date of minimum duration



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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

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ CERTIFICADO ◆ CERTIFICAT



Certificate

No. Q5 072017 0013 Rev. 01

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

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

See Scope of Certificate

Certification Mark:



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



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für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
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

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

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2020-02-17

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



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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

ZERTIFIKAT ◆ CERTIFICATE ◆ 認 證 證 書 ◆ CERTIFICADO ◆ CERTIFICAT

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 Module
	Product Model Number	PC4510
	Device Classification	IIb according Annex IX, Rule 10
	GMDN Code	36561, Patient monitoring system module, cardiac output

PULSION Medical Systems SE is assessed to EN ISO 13485:2016 and Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4) by the following Notified Body:

TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 Munich
Germany
Identification Number 0123

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. G1 075182 0006 (expiration date 26 May. 2024)**

PULSION Medical Systems SE
Feldkirchen, 17 Jun. 2020



Jens Anter
Head of Quality Management &
Regulatory Affairs



Stephan Haft
Managing Director



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