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

TÜV SÜD Product Service

EC Certificate

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

No. G1 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

Digitally signed by Dubalari Pavel
Date: 2022.05.30 11:42:14 EEST
Reason: MoldSign Signature
Location: Moldova

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

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 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

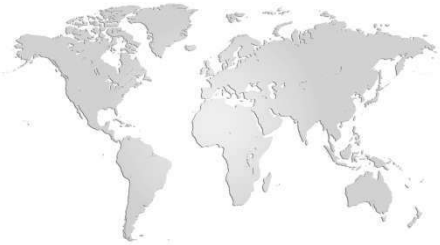
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

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

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

Maquet Cardiopulmonary GmbH

Kehler Straße 31, 76437 Rastatt, Germany

Certified location:

Kehler Straße 31, 76437 Rastatt, 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. 5008-Z7-00, the decision dated 2020-03-03 and is only valid in connection with the successful performance of the annual surveillance audits.

This certificate is valid from 2020-03-03 to 2024-05-26

Registration No.: 50008-16-10

DEKRA Certification GmbH Stuttgart, Handwerkstraße 15, D-70565

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; 2020-03-03
Notified Body ID-number: 0124

Annex to the EC Certificate No. 50008-16-10

Valid from 2020-03-03 to 2024-05-26

Revision status of the annex: 1 dated 2020-07-07

Devices/device categories included in the certificate:

Class II a:

- Oxygenators with SOFTLINE Coating:
  - QUADROX-i
    - Adult / Small Adult, microporous membrane
    - Option: with integrated arterial filter
  - QUADROX-iD
    - Adult, diffusion membrane
    - Option: with integrated arterial filter
  - QUADROX-i
    - Neonatal, microporous membrane
    - Option: with integrated arterial filter
  - QUADROX-i
    - Pediatric, microporous membrane
    - Option: with integrated arterial filter
- Venous Hardshell Cardiotomy Reservoir with or without SOFTLINE Coating:
  - Adult
  - Pediatric
  - Neonatal
- Heat Exchanger PLEGIOX with or without SOFTLINE Coating
- Centrifugal Pump ROTAFLOW with or without SOFTLINE Coating
- HIT Set (Heparin-induced thrombocytopenia Set) Advanced 5.0 / 7.0 with SOFTLINE Coating
- HIT Set PLS Plus with SOFTLINE Coating
- Tubing Sets and components with or without SOFTLINE Coating
  - Optional including Venous Softbag Reservoir with or without SOFTLINE Coating
  - Optional including Arterial Filter QUART with SOFTLINE Coating
  - Optional including Transfer Bag with SOFTLINE Coating
- Tubing Set with Centrifugal Pumps with or without SOFTLINE Coating
  - MECC Set with or without SOFTLINE Coating
  - Tubing Sets for CARDIOHELP-i with or without SOFTLINE Coating
    - Cardiac Intervention Set (CI Set)
    - Organ Donor Perfusion Set (ODP Set) with SOFTLINE Coating
- Transfer Bags
- AVALON ELITE Bi-Caval Dual Lumen Catheters
- HLS Cannulae with or without SOFTLINE Coating
- BMU Sensor
- BMU Cell
- Percutaneous Insertion Kits
- Guidewires
- Dilators

Annex to the EC Certificate No. 50008-16-10

Valid from 2020-03-03 to 2024-05-26

Revision status of the annex: 1 dated 2020-07-07

Devices/device categories included in the certificate:

Class II b:

- Hemoconcentrators
- ROTAFLOW Console
- ROTAFLOW Drive Unit
- CARDIOHELP Base Unit
- CARDIOHELP–i
- Capacitive Level Sensor CLS with accessory Level Sensor Pad LSP
- Flow-Bubble Sensor FBS
- Bubble Sensor BS
- Temperature Probe
- Venous Probe
- Heart-Lung Machine HL 20
- Pump modules for Heart-Lung Machine HL 20, Types TPM, RPM
- Heater Unit HU 35
- Heater-Cooler Unit HCU 40
- Blood Monitoring Unit BMU 40
- Tubing Set with Hemoconcentrators with or without SOFTLINE Coating

Annex to the EC Certificate No. 50008-16-10

Valid from 2020-03-03 to 2024-05-26

Revision status of the annex: 1 dated 2020-07-07

Devices/device categories included in the certificate:

Class III:

For the placing on the market of class III devices covered by this certificate an EC design-examination certificate according to directive 93/42/EEC annex II (4) is required.

- Oxygenators with BIOLINE Coating:
  - QUADROX-i
    - Adult / Small Adult, microporous membrane
    - Option: with integrated arterial filter
  - QUADROX-iD
    - Adult, diffusion membrane
    - Option: with integrated arterial filter
  - QUADROX-i
    - Neonatal, microporous membrane
    - Option: with integrated arterial filter
  - QUADROX-i
    - Pediatric, microporous membrane
    - Option: with integrated arterial filter
  - QUADROX-iD
    - Pediatric, diffusion membrane
- Venous Hardshell Cardiotomy Reservoir with BIOLINE Coating
  - Adult
  - Pediatric
  - Neonatal
- Heat Exchanger PLEGIOX with BIOLINE Coating
- Tubing Sets and components with BIOLINE Coating
  - Optional including Venous Softbag Reservoir with BIOLINE Coating
  - Optional including Arterial Filter QUART with BIOLINE Coating
  - Optional including Venous Bubble Trap with BIOLINE Coating
- Tubing Set with Hemoconcentrators with BIOLINE Coating
- Tubing Set with Centrifugal Pumps with BIOLINE Coating
  - MECC Set with BIOLINE Coating
  - Tubing Sets for CARDIOHELP-i with BIOLINE Coating
    - Organ Donor Perfusion Set (ODP Set) with BIOLINE Coating
    - Minimized Extra Corporeal Circulation Set (MECC-i Set) with BIOLINE Coating
- HLS Cannulae with BIOLINE Coating
- Centrifugal Pump ROTAFLOW with BIOLINE Coating
- PLS Set (Permanent Life Support Set) / PLS Set Plus with BIOLINE Coating
- HLS Set (Heart-Lung Support Set) Advanced 5.0 / 7.0 with BIOLINE Coating

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

Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2020-07-07
Notified Body ID-number: 0124

CERTIFICATE

EN ISO 13485:2016

DEKRA Certification GmbH hereby certifies that the organization

Maquet Cardiopulmonary GmbH

Scope of certification:

Design, manufacturing, distribution and service of medical devices for the scopes heart surgery, intensive care, cardiology and emergency medicine

Certified location:

Kehler Straße 31, 76437 Rastatt, 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. 50008-Z7-00.

Certificate registration no.:	50008-14-01	Certificate valid from:	2020-03-03
Validity of previous certificate:	2020-03-02	Certificate valid to:	2023-03-02

DEKRA Certification GmbH • D-70565 Stuttgart, Handwerkstraße 15

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

Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2020-03-03

Annex to the Certificate No. 50008-14-01

Revision status: 0

valid from 2020-03-03 to 2023-03-02

The following locations belong to the certificate above:

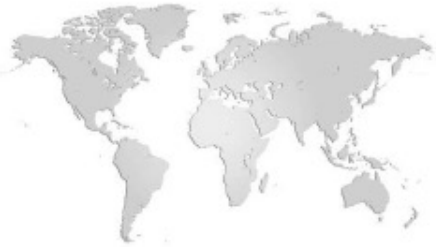
	Headquarters	Certified location	Scope of certification
	Maquet Cardiopulmonary GmbH	Kehler Straße 31 D-76437 Rastatt	Design, manufacturing, distribution and service of medical devices for the scopes heart surgery, intensive care, cardiology and emergency medicine
	Subsidiaries	**Certified locations**	**Scope of certification**
1.	Maquet Cardiopulmonary GmbH	Kehler Straße 31 D-76437 Rastatt	Design, manufacturing, distribution and service of active medical devices for the scopes heart surgery, intensive care, cardiology and emergency medicine Distribution of non-active medical devices for the scopes heart surgery, intensive care, cardiology and emergency medicine
2.	Maquet Cardiopulmonary GmbH	Neue Rottenburger Straße 37 D-72379 Hechingen	Design and manufacturing of non-active medical devices for the scopes heart surgery, intensive care, cardiology and emergency medicine
3.	Maquet Cardiopulmonary GmbH	Grabenstraße 25 D-72411 Bodelshausen	Design of non-active medical devices for the scopes heart surgery, intensive care, cardiology and emergency medicine

DEKRA Certification GmbH, D-70565 Stuttgart, Handwerkstraße 15

Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2020-03-03

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

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

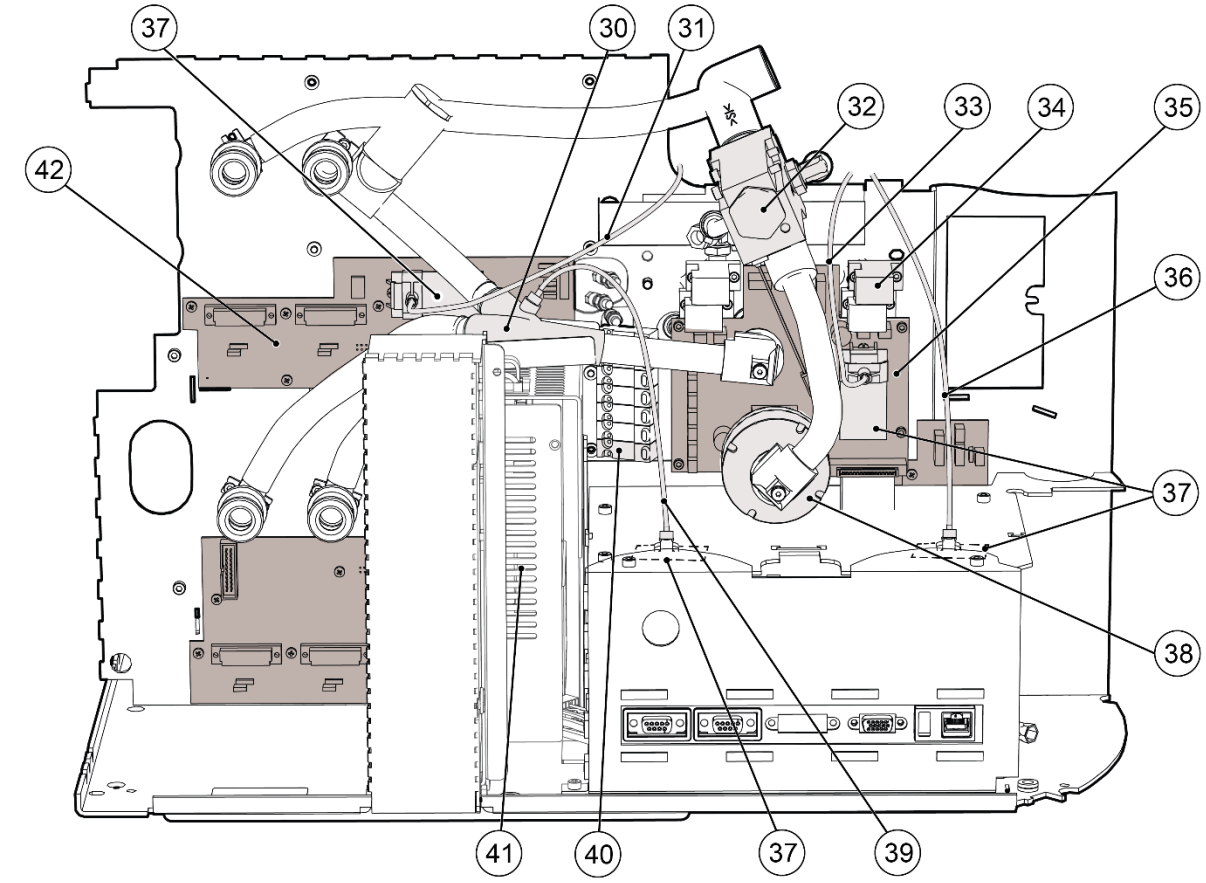
valid from 2020-04-01 to 2023-03-31

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

Figure 2: Gas control



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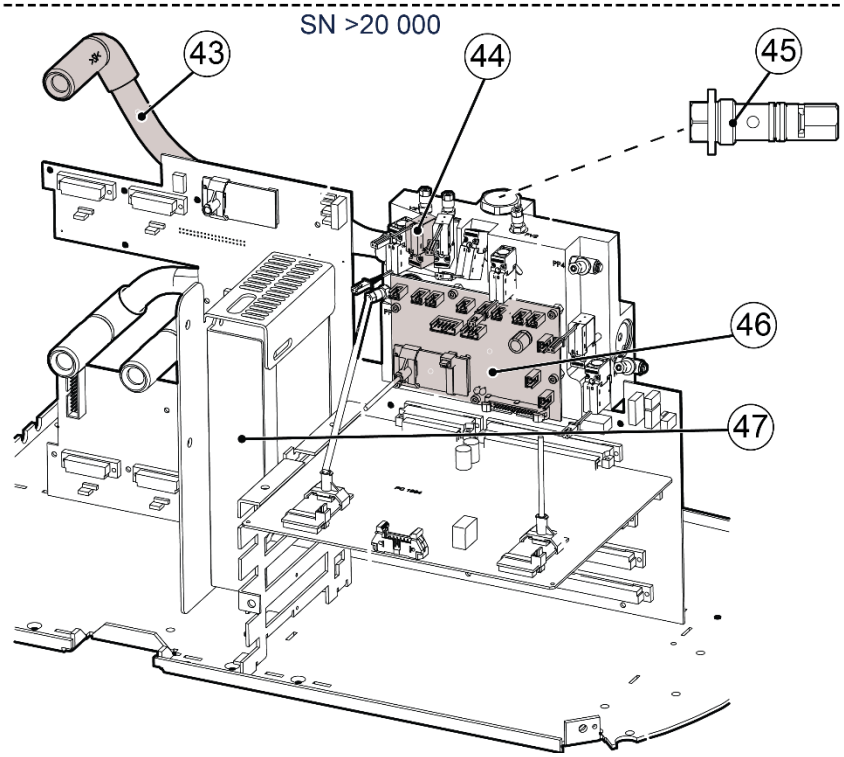
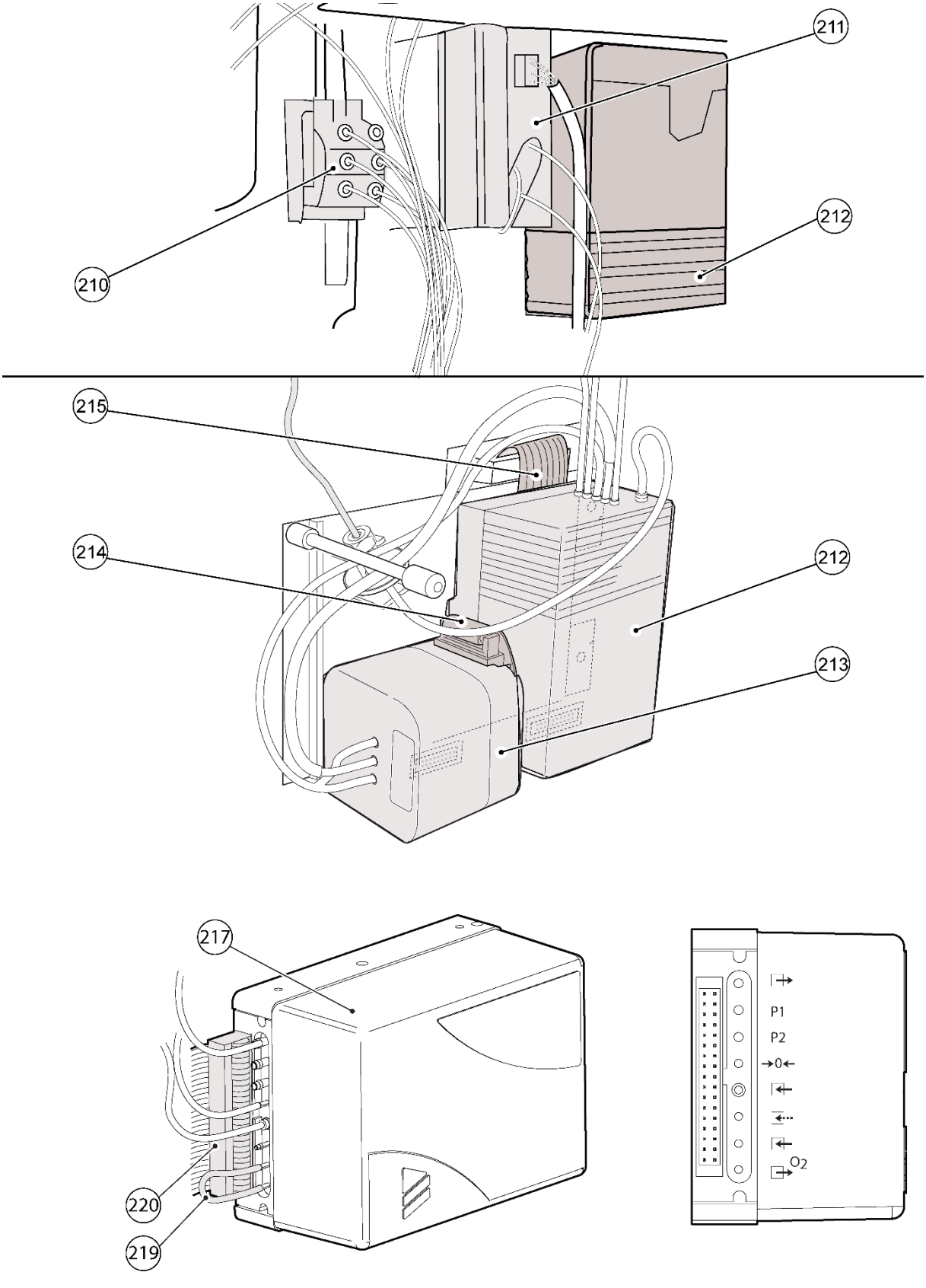


Lot: 64

Table 2: Gas control

ID	Part no.	Description	Comments
30	6884789	Collector incl. 6681232	
31	6693940	Press. trans. tube, Refl incl. 6880139	Tube to Reflector
32	6884787	AFGO valve cpl. incl. 6681432	
33	6693932	Press. trans. tube, Exp incl. 6880141	To expiratory pressure transducer
34	6693930	Vaporizer Valve incl. 6689562	EMV 9 - 12
35	6693805	Circuit board PC1907 incl. 6672860	Valve drivers
36	6693935	Press. trans. tube, Insp incl. 6880140	To inspiratory pressure transducer
37	6696967	Circuit board PC1781 incl. 6467893	Pressure transducer
38	6691192	Fresh Gas line filter	
39	6693937	Press. trans. tube, Fg incl. 6880142	To fresh gas pressure transducer
40	6693865	Pilot valve incl. 6674910	EMV 2 - 8
41	6889905	AC/DC Kit incl. PC1903 bracket	Including: • 1 PC2055 • 1 Contact frame • 1 Washer • 3 Types of screws • 2 Types of cables
42	6880465	Circuit board PC1900 incl 6672837	Non stock item, specify serial number of Flow-i when placing an order
		Only for SN > 20 000	
43	6887177	Collector incl. connections	Including: • 1 Angle connector • 1 Tube Insp. valves • 4 Docking seals • 1 Sealing and connection • 3 Insp. valve docking seals
44	6887174	Pilot valve incl. 6885845	EMV 2-5, 11-12 and 18
45	6890438	PV5	The cylinder bypass
46	6887175	Circuit board PC2057 incl. 6885800	Including 1 cable tie
47	6889766	AC/DC Converter incl. 6886451	

Figure 8: Gas analyzer

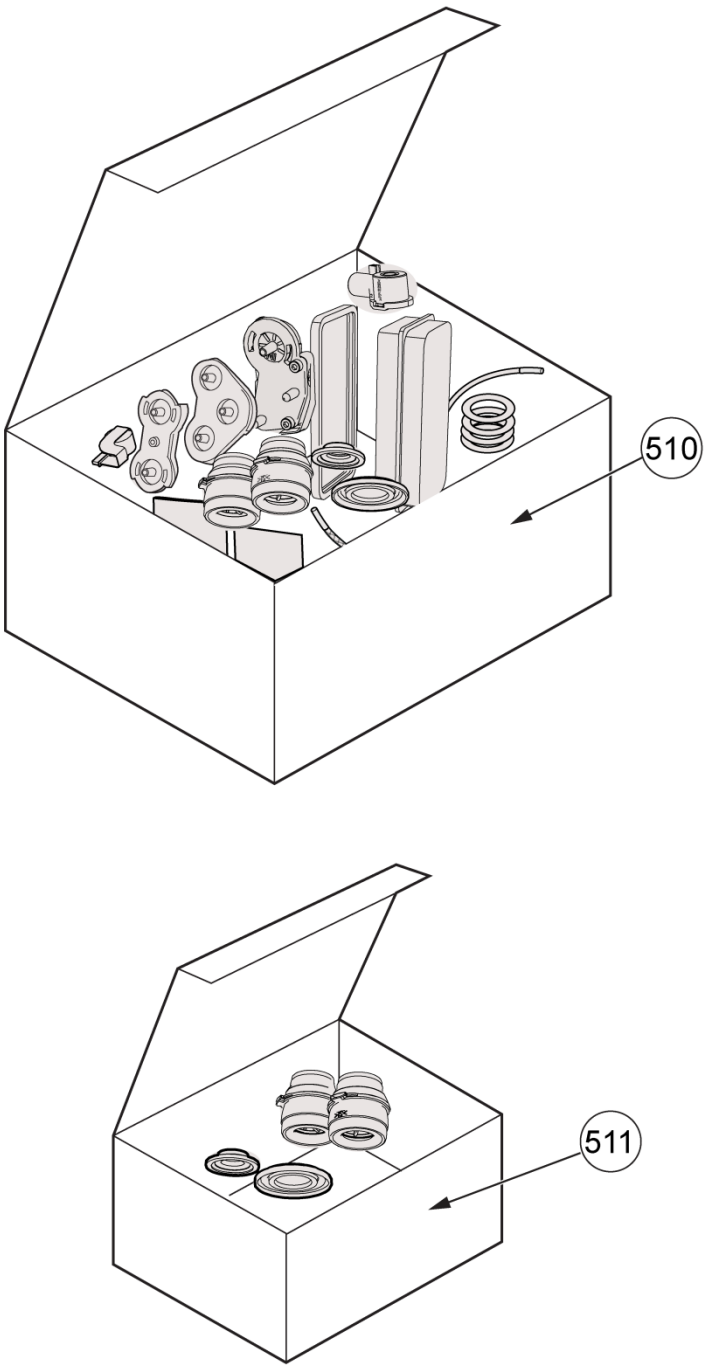


Lot: 68

Table 8: Gas analyzer

ID	Part No	Description	Comments
210	6688450	Sampling block cpl.	Including tubes S and R to AION and valve cables The S1, S2, R1 and R2 tubes are not included
211	6674822	Oxygen sensor, Servomex Pm1116	Calibrate after replacement
212	6678110	Multigas Analyzer AION	Only available for country with System SW Version ≤ 4.3 Proper software has to be loaded on site then calibrate with Servomex after replacement
213	6522820	Oxygen sensor, Servomex Pm1111E	Calibrate with AION after replacement
214	6884971	Cable PC1900:P31-O_2 transd. incl 6676287	
215	6884972	Cable PC1900 P32 PGA incl. 6676285	For AION ADS
216	6884973	PGA Tubing kit	Complete tubing setup for PGA and O_2 sensor. Not shown in picture
217	6886576	AION Platinum incl. 6886095	
218	6886574	Upgrade kit AION Platinum	Complete AION Platinum assembly for replacement of AION ADS. Contains the following parts: Patient gas analyzer AION Platinum, Mounting bracket, Cable for AION Platinum, Filter and tubing for zero calibration gas and tubing for O_2 interconnection. System SW Version 4.04.01 or higher must be installed. Not shown in picture
219	6886575	Tubing kit	For AION Platinum
220	6886577	Cable PC1900 P32 incl. 6886006	For AION Platinum

Figure 16: Maintenance kits



Lot: 60

Table 16: Maintenance kits

ID	Part No	Description	Comments
510	6684697	Flow family maintenance kit 24 months	Contains parts for one cassette, see Service Manual for more information
511	6684700	Flow family maintenance kit cassette 24 months	Necessary for each additional cassette on site, see Service Manual for more information
512	6882204	Flow family maintenance kit backup gas	Not shown in picture, see Service Manual for more information
513	6503648	Seal for yoke, 10 pcs	Not shown in picture, see Service Manual for more information

Lot: 61

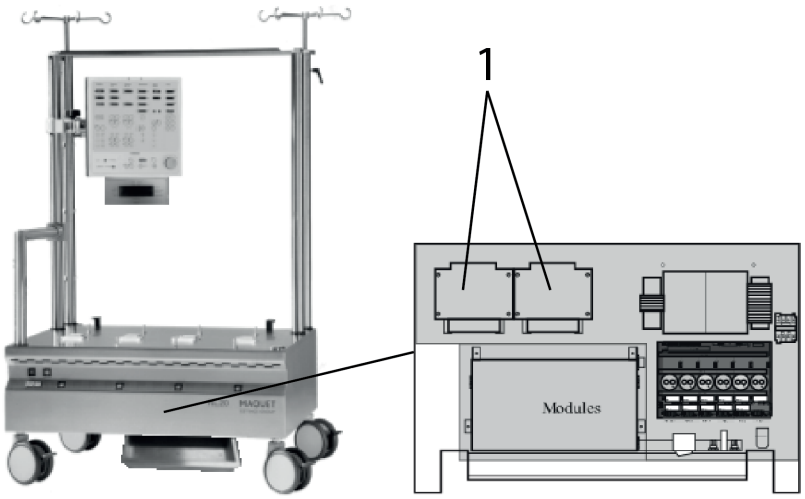
SPARE PARTS LIST

HEART-LUNG MACHINE

HL 20 Maintenance Parts Console 4/5 Pump

Version
13

Approval by
Service - 2022-03-09



ID	Order No.	Description	Comments	Qty	Additional Information
1	70100.7875	Backup Battery	4/5 pump console replacement every 12 month	1	4

1	ESD	ESD Protection must be considered
2	Calibration	Part needs special calibration
3	Storage Conditions	Be aware of special storage conditions
4	DMD	Part has date of minimum duration

Lot:61

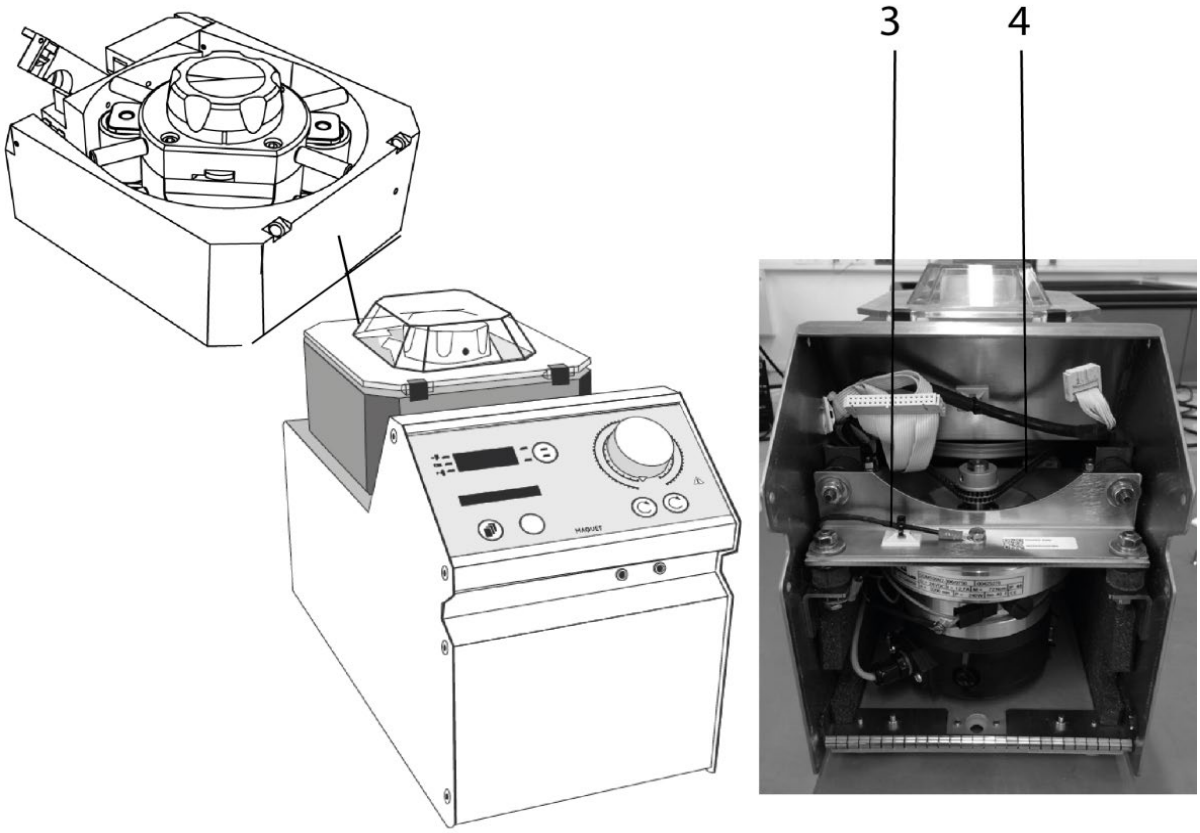
SPARE PARTS LIST

HEART-LUNG MACHINE

HL 20 Maintenance Parts RPM

Version
13

Approval by
Service - 2022-03-09



ID	Order No.	Description	Comments	Qty	Additional Information
3	70105.3805	RPM ESD Cable	replacement every 2 years	1	
4	70106.8194	HL20 Belt Kit	replacement every 12 month	1	

1 ESD	ESD Protection must be considered
2 Calibration	Part needs special calibration
3 Storage Conditions	Be aware of special storage conditions
4 DMD	Part has date of minimum duration

Lot:61

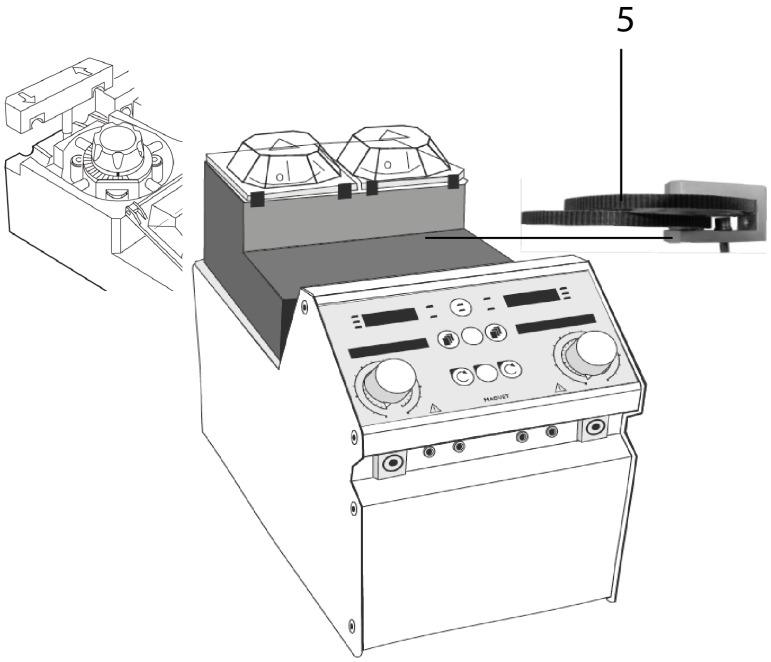
SPARE PARTS LIST

HEART-LUNG MACHINE

HL 20 Maintenance Parts TPM

Version
13

Approval by
Service - 2022-03-09



ID		Order No.	Description	Comments	Qty	Additional Information
5		70101.7253	Belt with pulley	replacement every 3 years	1	

1 ESD	ESD Protection must be considered
2 Calibration	Part needs special calibration
3 Storage Conditions	Be aware of special storage conditions
4 DMD	Part has date of minimum duration

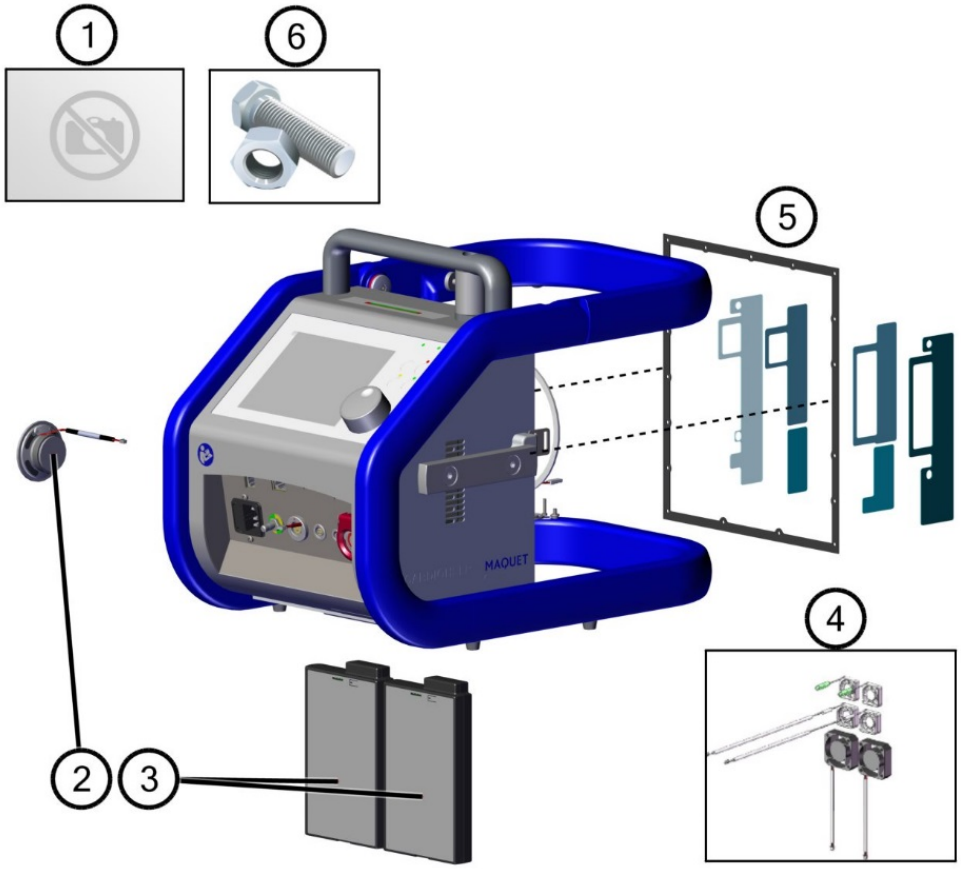
Lot: 62

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 *without illustration*	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 *without illustration*	1	
41	70105.1784	Cardiohelp Rubber Feet Kit	replacement as required 5 pieces of screws and feet Illustration see page 7	5	

1 ESD	ESD Protection must be considered
2 Calibration	Part needs special calibration
3 Storage Conditions	Be aware of special storage conditions
4 DMD	Part has date of minimum duration

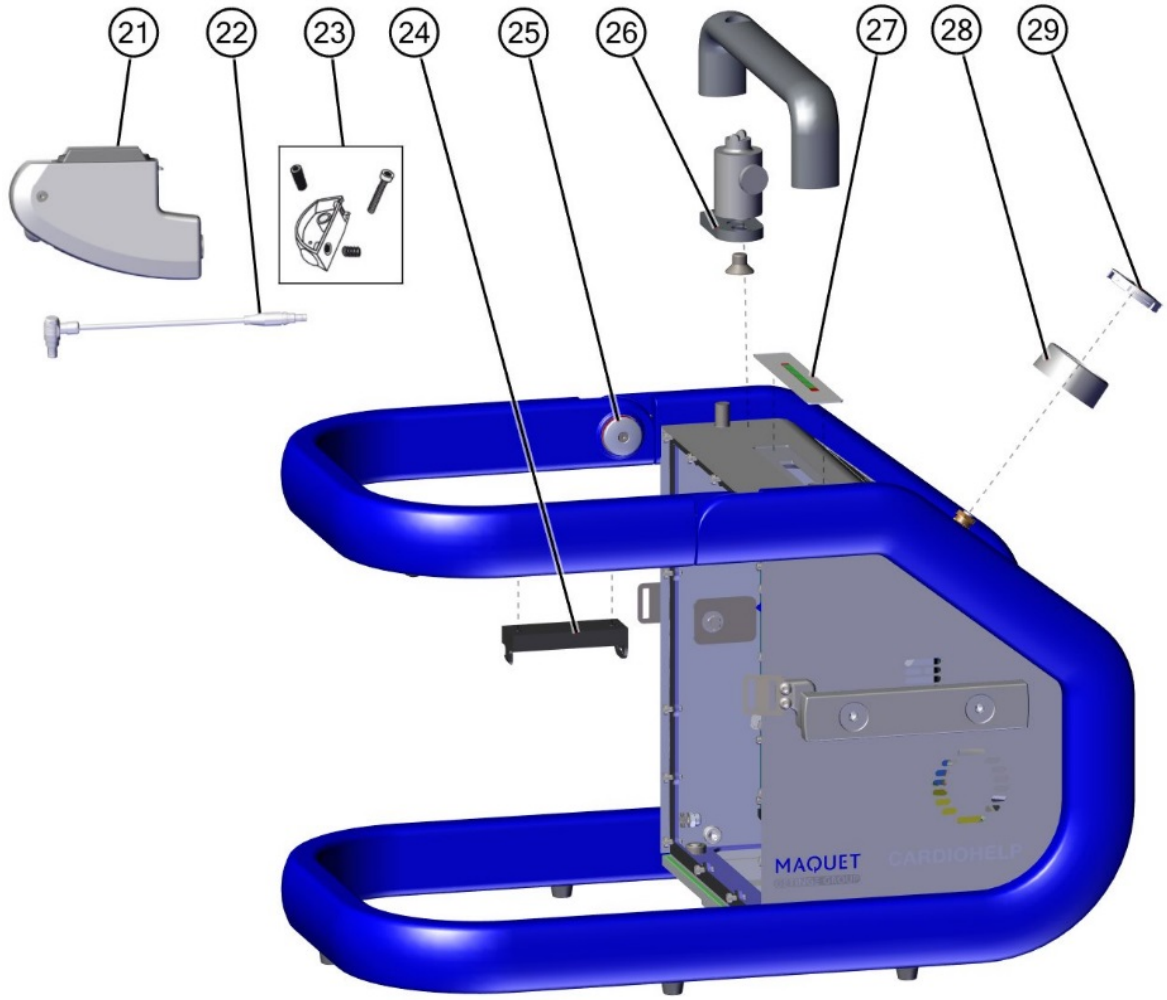
Lot: 63

SPARE PARTS LIST

CARDIOHELP

Cardiohelp Spare Parts Top Side

Version 12
approved by Service 2022-01-31



ID		Order No.	Description	Comments	Qty	Additional Information
21		70104.8803	Venous Probe	S_VO_2, Hb, Hct, T_{Ven}	1	
22		70107.2695	Venous Probe Cable	Length 0.32m	1	
23		70104.7584	Probe Pusher Kit		1	
24		70105.3569	Holder Venous Probe		1	
25		70104.9307	Unlocking Guard Kit	For both sides	1	
26		70105.1785	Cardiohelp Locking Kit	For Emergency Drive	1	
27		70105.3570	LED foil	LED Display	1	1
28		70105.3571	Rotary Knob		1	
29		70104.8800	Rotary Knob Cover	CARDIOHELP-i	1	

1 ESD	ESD Protection must be considered
2 Calibration	Part needs special calibration
3 Storage Conditions	Be aware of special storage conditions
4 DMD	Part has date of minimum duration

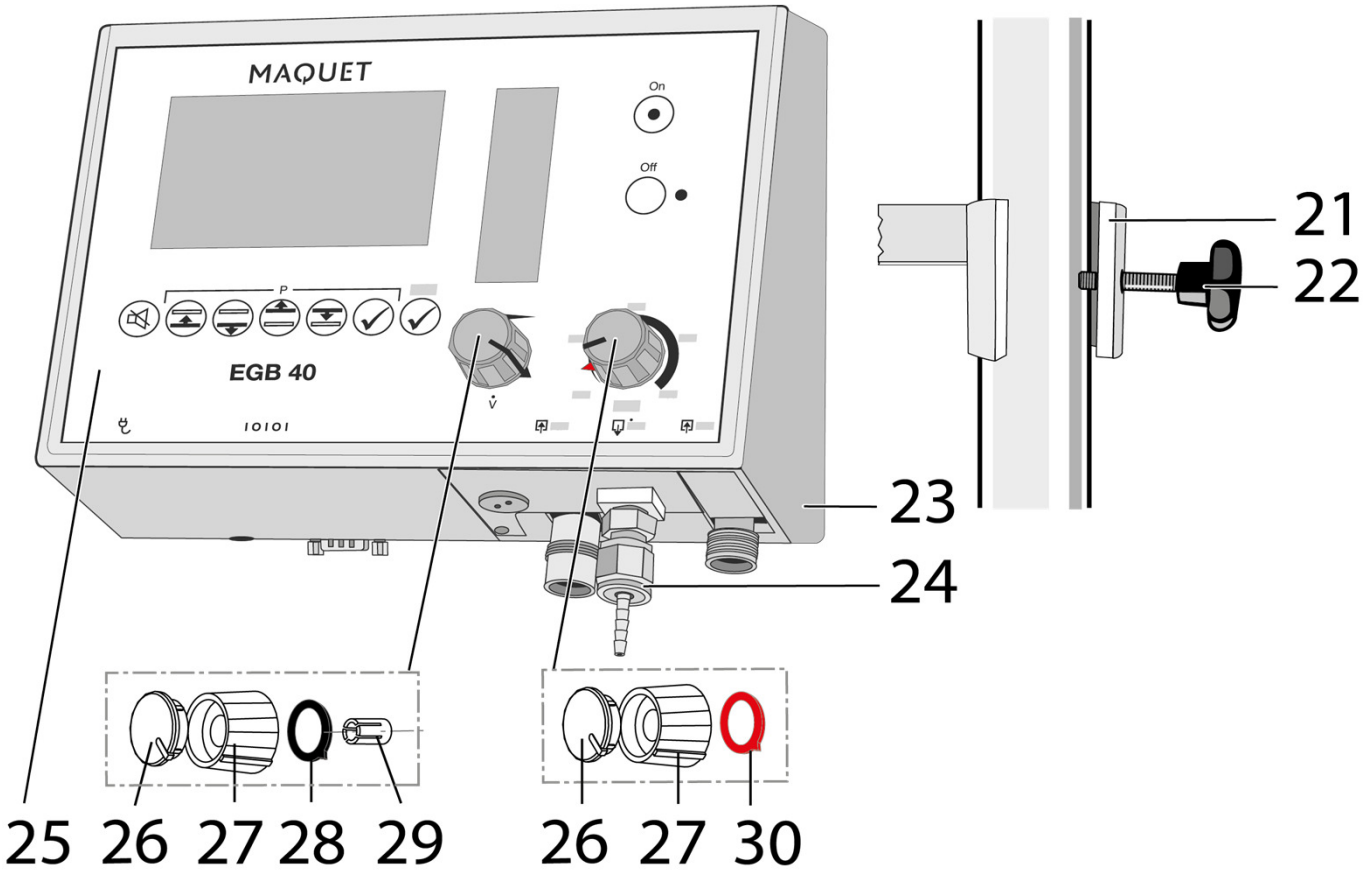
Lot: 65

SPARE PARTS LIST

ELECTRONIC GAS BLENDER

EGB 40 Spare Parts Front

Version
03
Approval by
Service - 2018.01.01



ID	Order No.	Description	Comments	Qty	Additional Information
21	70104.7099	Rail for Pole Holder		1	
22	70104.7100	Star Handle for Rail	M 8 x 30	1	
23	70104.7087	Enclosure Front		1	
24	70104.7088	Hose Connection 1/4"		1	
25	70104.7086	Front Foil		1	
26	70104.7308	Front Cap for Knob Flow / FiO_2		1	
27	70104.7089	Knop for Flow/FiO_2		1	
28	70104.7309	Arrow Plate for Knob, Black	(Flow)	1	
29	70104.7090	Clamping Sleeve for FiO_2 Knob		1	
30	70104.7310	Arrow Plate for Knob, Red	(FiO2)	1	

1 ESD	ESD Protection must be considered
2 Calibration	Part needs special calibration
3 Storage Conditions	Be aware of special storage conditions
4 DMD	Part has date of minimum duration

ENDOCAM Logic HD
3-chip HD camera head

- Digital image processing and digital signal transmission
- 2 programmable camera head buttons with 4 available functions
- Universal C-Mount lens connection
- Cable outlet angled at 30°
- Camera head cable can be replaced in the hospital by technicians
- Steam-sterilizable
- Can be reprocessed by machine
- Suitable for low-temperature procedure

ENDOCAM Logic HD camera head **85525922**
3-chip type, cable length 3 m

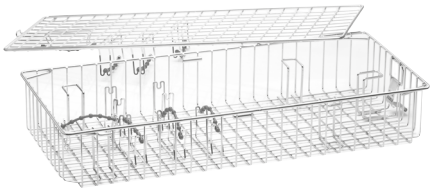
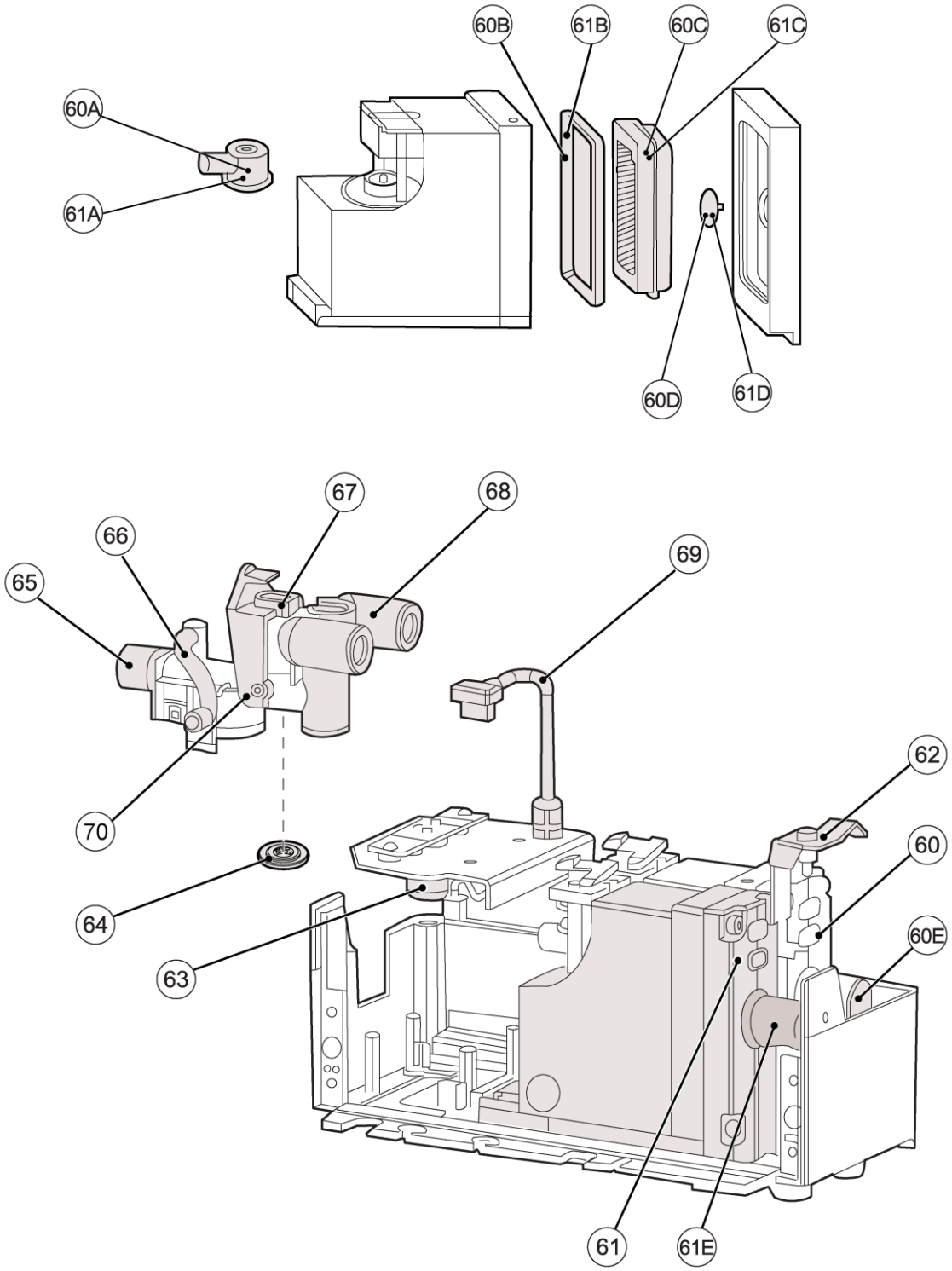
Recommended accessories		Product no.
RIWO lens	C-Mount, f = 14 mm	**85261144**
	C-Mount, f = 24 mm	**85261244**
RIWO zoom lens	C-Mount, f = 13 - 29 mm	**85261504**
	**Reprocessing basket for camera head** (L x W x H) 445 x 200 x 73 mm	**38047111**

Figure 3: Patient unit, Inspiratory section



Lot : 104

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	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 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	

Lot: 114;115;116

5.4 Cables

Power cord

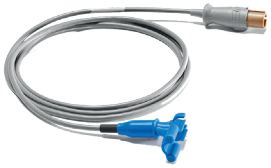
Included in initial shipment of PulsioFlex 6882747.

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 $PiCCO_2$

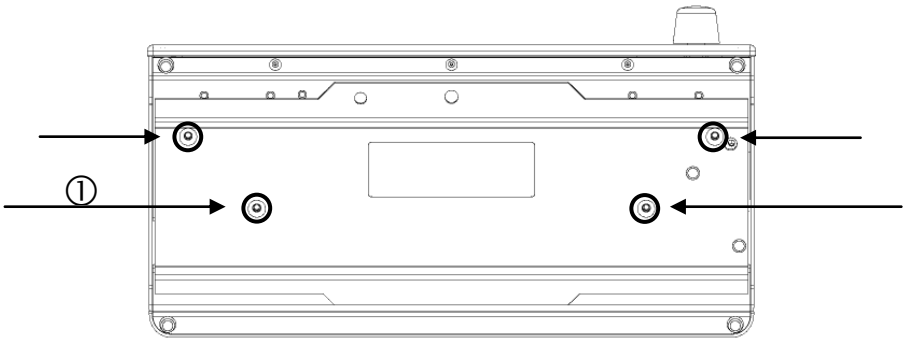
Lot : 120

ref: 315170-P

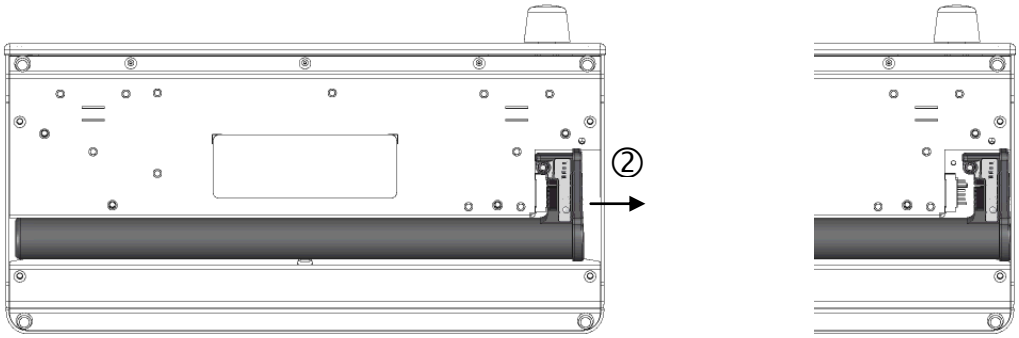
4 Replacing the battery

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.

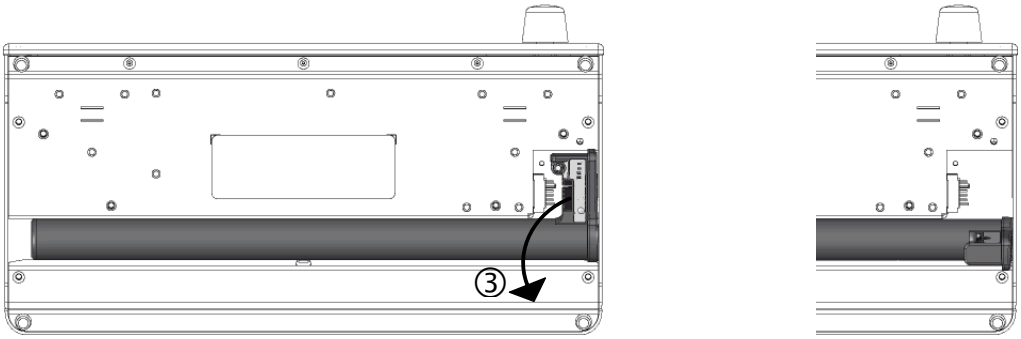
1. Demount the bottom plate of the device by removing the four screws (marked below).



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



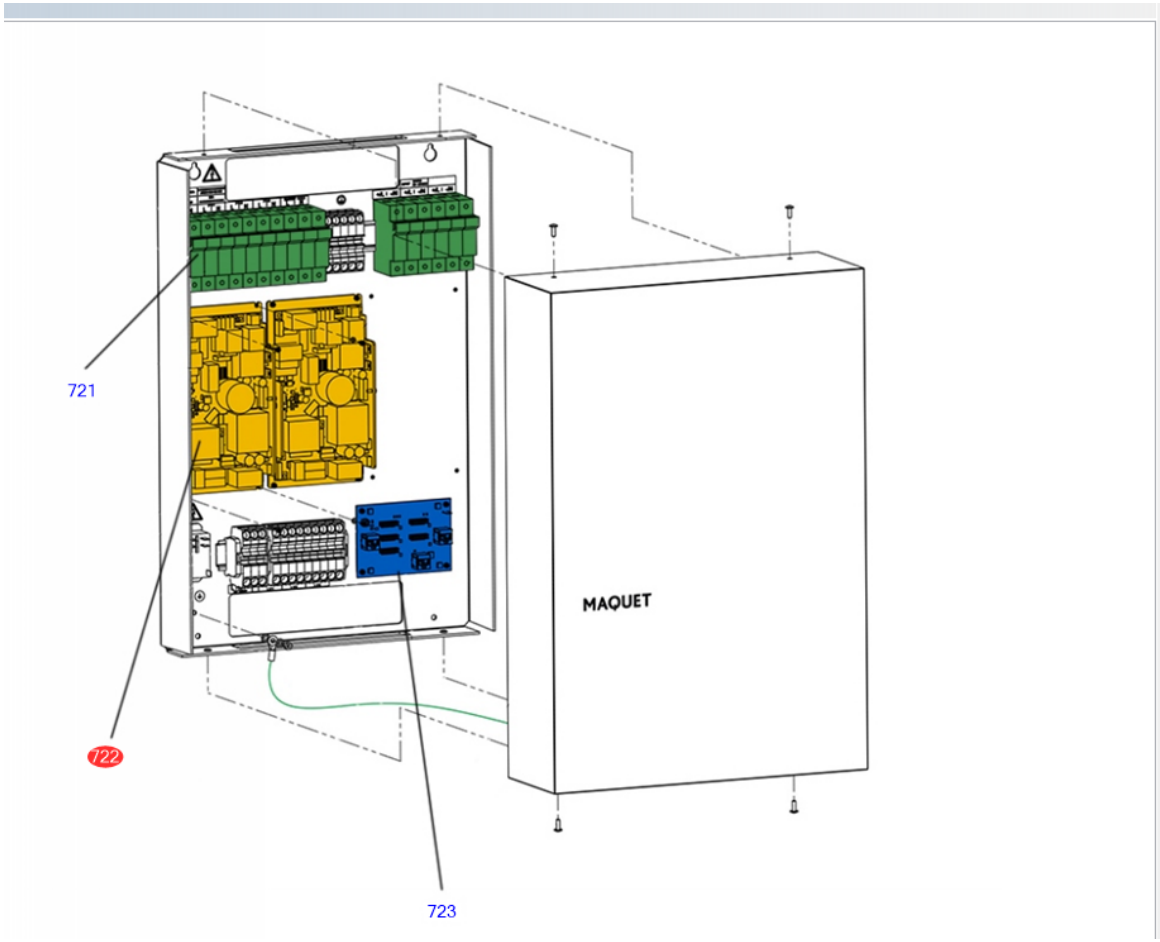
3. Rotate the battery at an angle of 90°. The battery can be removed.



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.

Lot : 206



Parts List

VOLISTA PWD

SUSYPOWER

VOLISTA PWD

MA GETIN

	ID	Part-No	Description
☐	721	ARD693502011	TRIOP - POWER SUPPLY 10X38 10A FUSE
☐	722	ARD568407565	VPS - EPS 24V AC/DC - POWER SUPPLY BOARD
☐	723	ARD368710555	VOLISTA - PS CHAINING BOARD
☐	751	ARD368711555	VPS SN>40 000 - PS COMMUNICATION BOARD
☐	752	ARD368717555	VPS SN<40000-COMMUNICATION+CHARGER BOARD
☐	841	ARD693502026	TRIOP - BATTERY PACK 10X38 25A FUSE
☐	843	ARD368712555	VPS SN> 40 000 - CHARGER BOARD