QUADROX PLS
- ECMO AND LIFE SUPPORT SYSTEM -

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Presentation Overview:

1. History of Quadrox PLS System
2. Advantage of CE - Certification
3. Set-up and technical data
4. Hardware, accessories & additional equipment
5. Clinical applications
6. Clinical references, case reports and hospitals that can accept visits
7. Demonstration film „Priming procedure“ & hands-on demonstration
8. Discussion

1. History of Quadrox PLS System

- Excellent publications and case reports on the reliability of the former Quadrox D
- Target → reliable product with official CE-certification for 14 day application
- Responsible authority requires clinical evidence **and** proof by laboratory tests
- Research in innovative stronger materials
- Reinforced housing fulfills requirements for fatigue strength

Quadrox PLS is different to Quadrox D

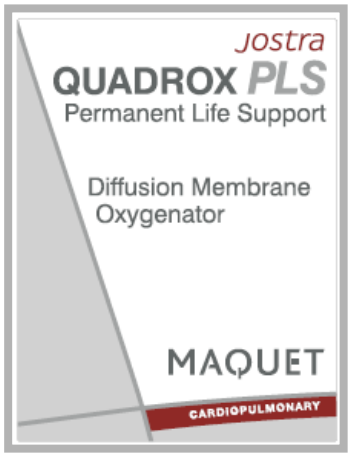
Quadrox PLS is an improved and reinforced oxygenator

2. Advantages of CE - Certification

- Proven and certified products
- Legalized procedure
- Using a „state of the art“ product for such sophisticated procedures
- Responsibility in case of product failure is at the manufacturer´s cost
- Well established components
- Working confidentially with a high performing and reliable product

3. Set-up and technical data

Diffusion Membrane



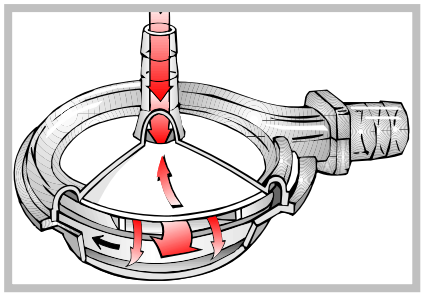
Oxygenator Quadrox PLS

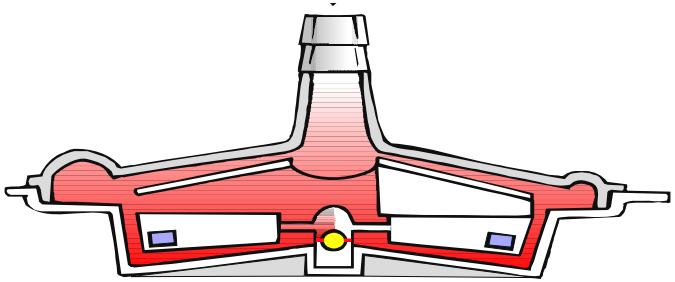
- Diffusion membrane → No plasma leak possible
- Very low pressure drop → Low resistance + low hemolysis
- Woven oxygenation mats → Homogenous blood flow without stagnant areas
- De-airing membrane → Easy and fast priming procedures
- High gas transfer performance → Great reserve for security
- No ¼” arterial outlet → Reduced risk of aggregation
- No temperature probe → Reduced risk of aggregation

3. Set-up and technical data

Centrifugal pumpe Rotaflow RF 32

- High efficiency → Low hemolysis, no heat generation
- Flow-Channel-Prinzip → No stagnant areas
- One-point bearing without seals → No leakage possible
  → High durability





3. Set-up and technical data

Bioline Coating

- Albumin-Heparin Coating → Biocompatibility
- Covalant bonding and electrostatic interaction → No ”wash-out” effect, Stability
- More than 10 years experience → Very good clinical results
  → High clinical acceptance

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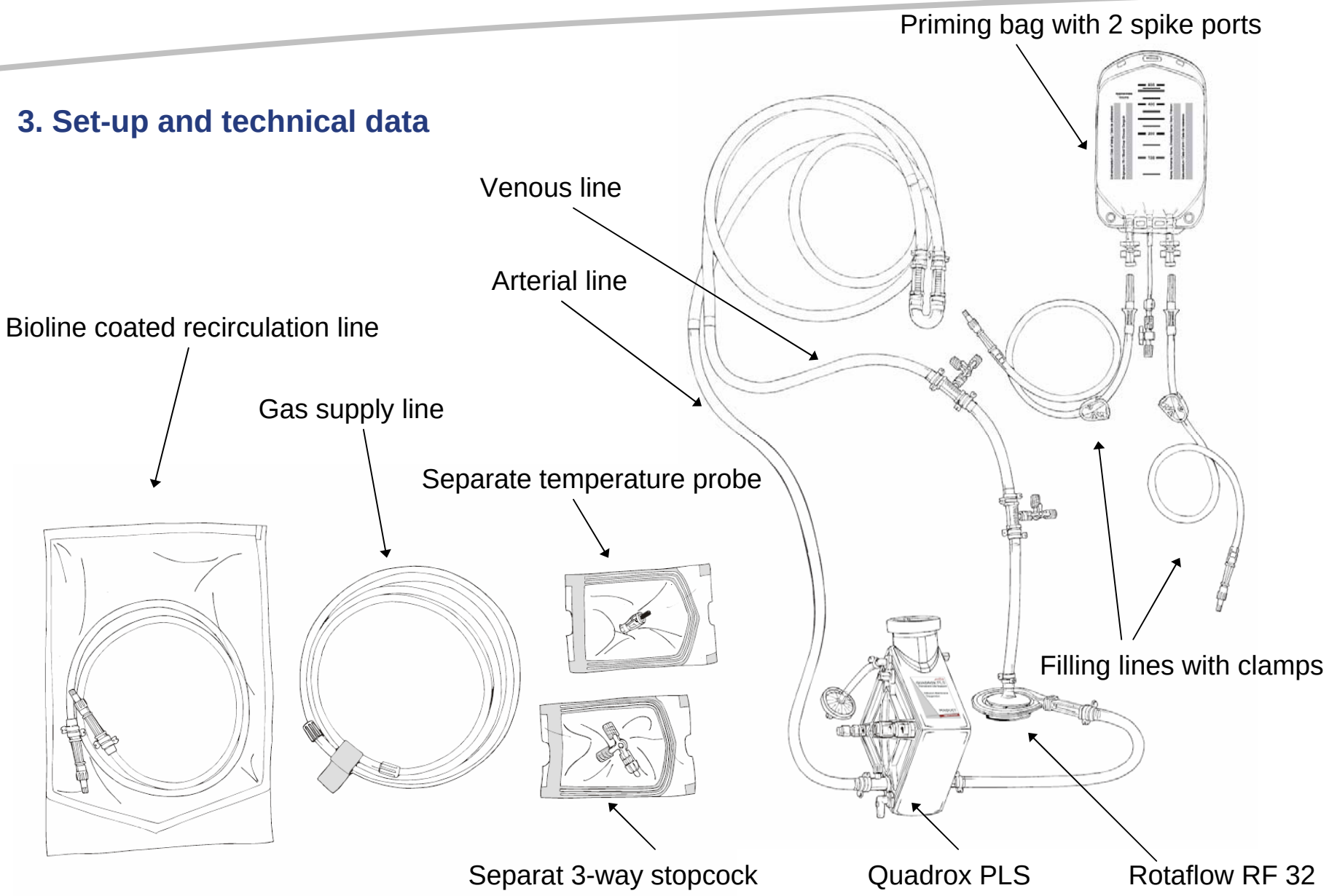
3. Set-up and technical data

Tubing Set

- ”Tip-to-tip” Bioline coated → mimicry of natural surface
- No-Dop® Tubes from Rehau → plasticizer-free tubes
- Minimized to the basic components → minimized aggregation risk
- Venous and arterial lines each 2,2 m 3/8” tubes → individual length can be adjusted
- Sterile tubes in hardshell cover → common priming procedure
- Priming volume incl. tubes 550 ml → starting procedure with approx. 400 ml
- Separate temperature probe → using as an option
- Separate Bioline coated recirculation line → recirculation during weaning period

3. Set-up and technical data



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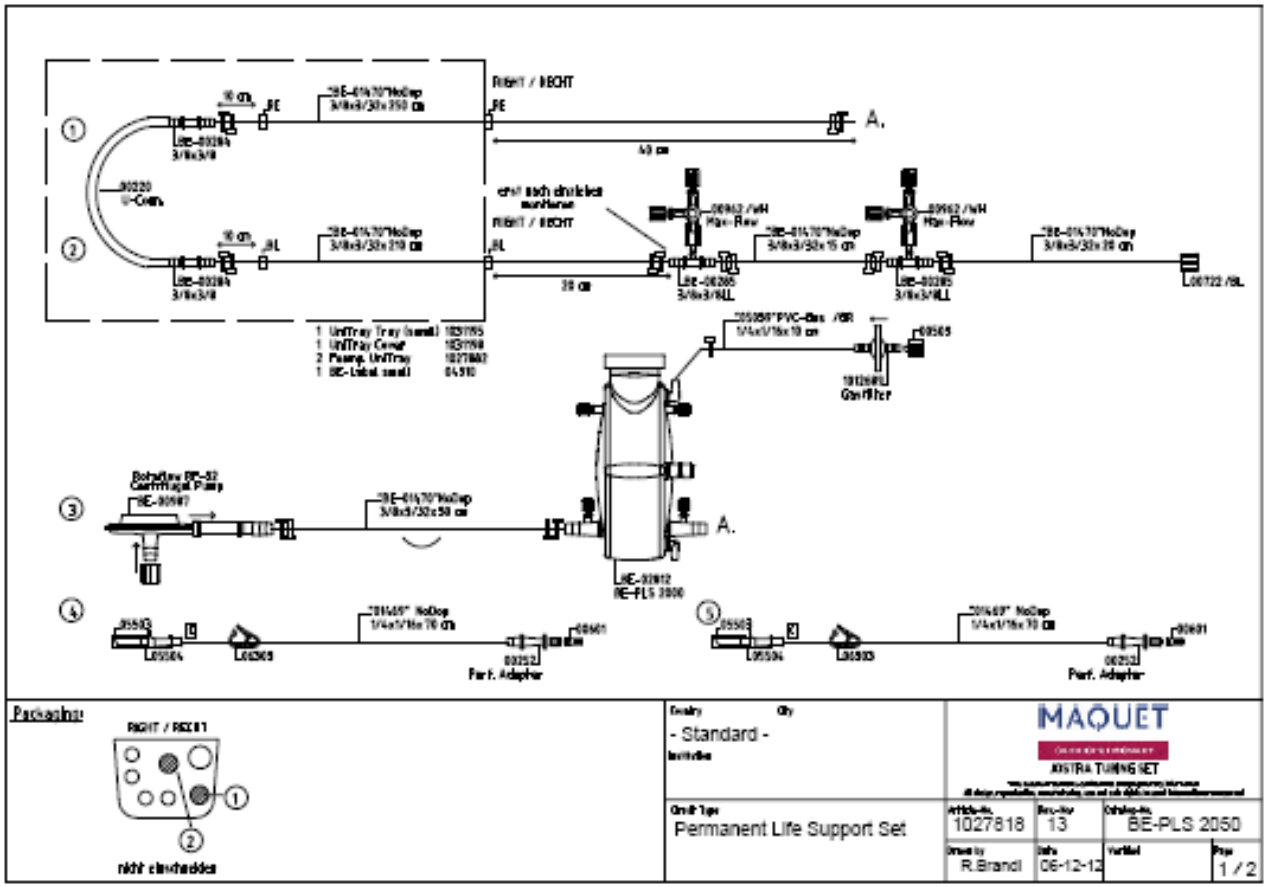

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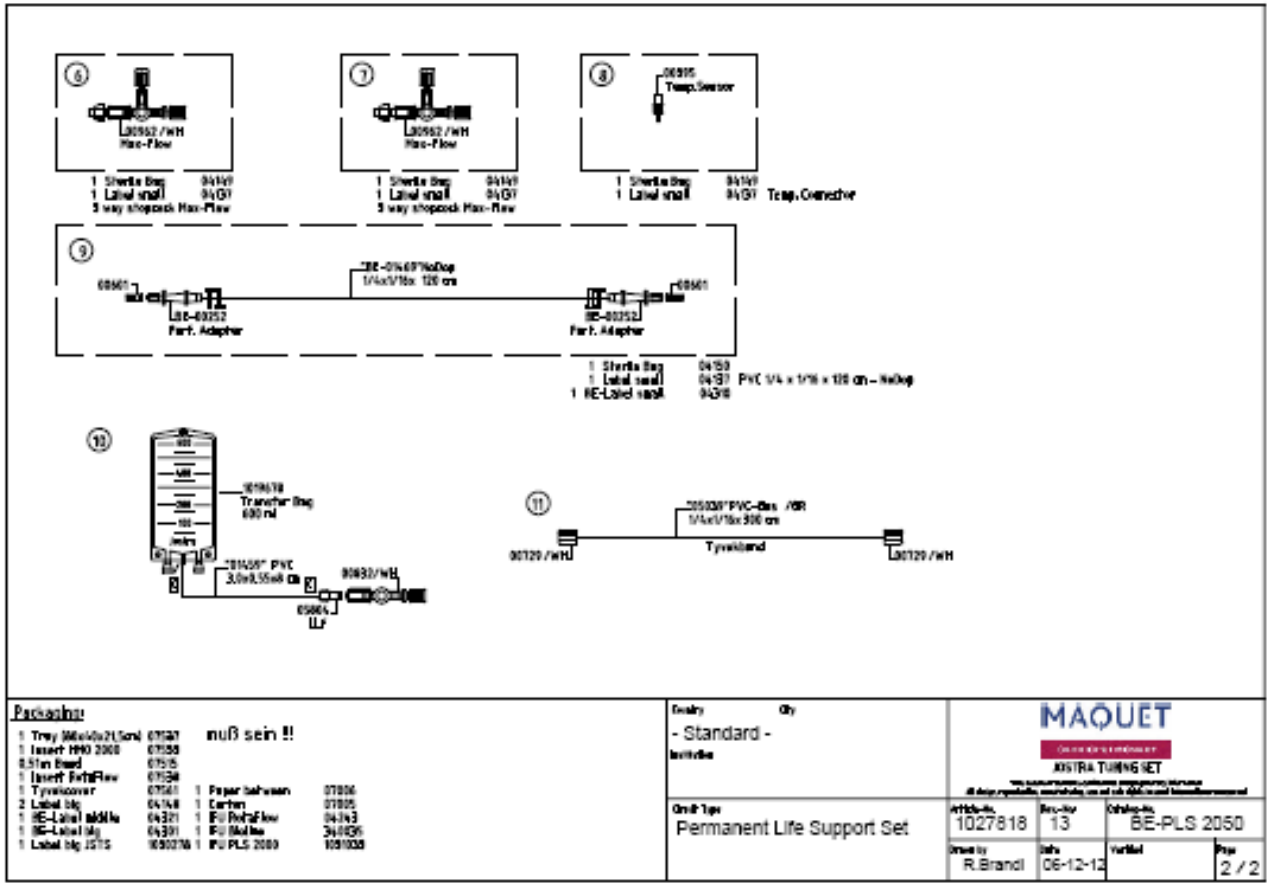
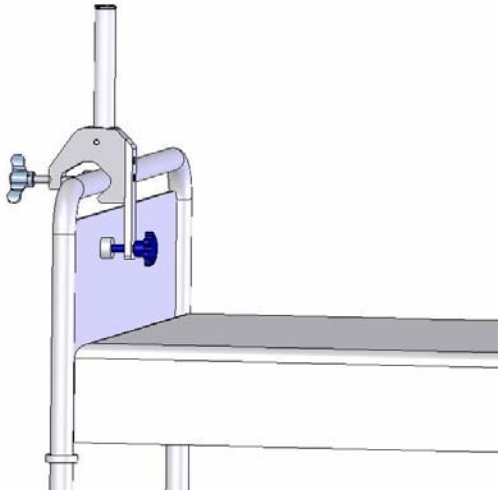


4. Hardware, accessories and additional equipment

Standard holders

HKH 7900

HKH 7910



HKH 7920

- Complet and flexible holder concept for individual working conditions
- Even transport and handling in narrow rooms possible

Pull relief

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ACCESSORIES – ECMO CART „SPRINTER“

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ACCESSORIES – ECMO CART „SPRINTER“ (FULLY EQUIPPED)

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ACCESSORIES – ECMO CART „SPRINTER“

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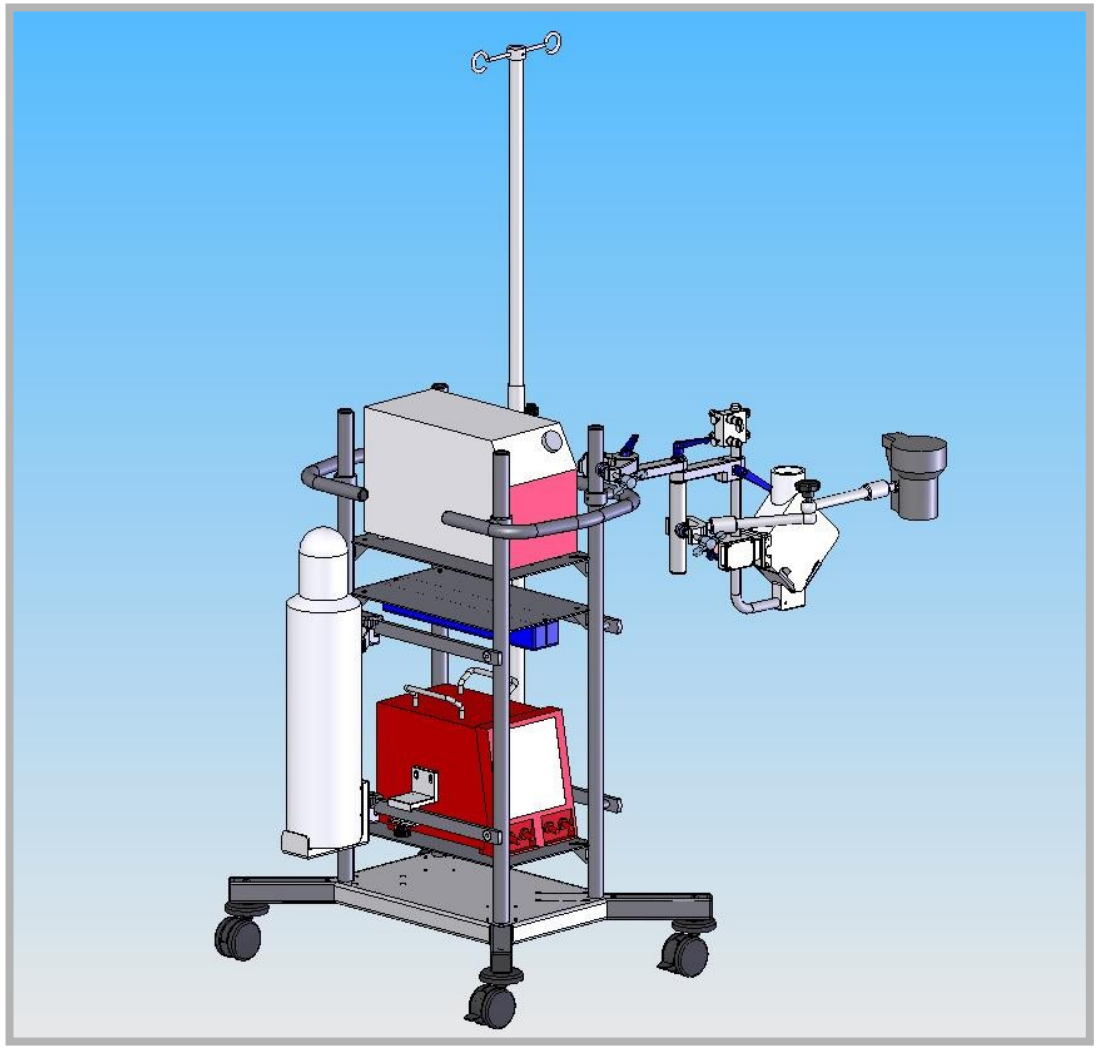
ACCESSORIES – HOLDER FOR GAS BOTTLES



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EQUIPMENT – ROTAFLOW HARDWARE

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Rotaflow Drive Unit

Rotaflow Stand Alone Unit

ACCESSORIES – HEATER UNIT HU 35

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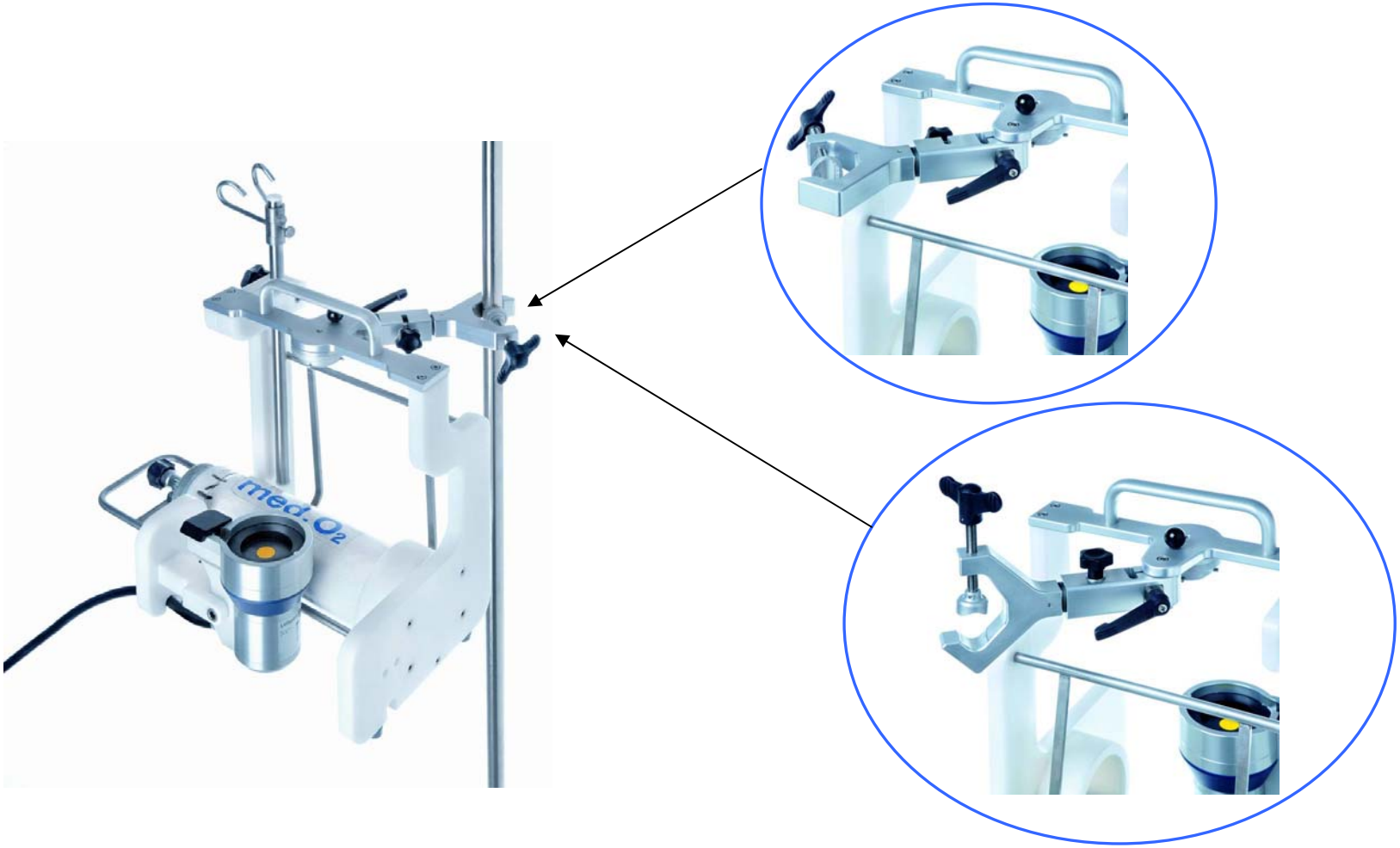
ACCESSORIES – TRANSPORT HOLDER HKH 8800



ACCESSORIES – TRANSPORT HOLDER HKH 8800

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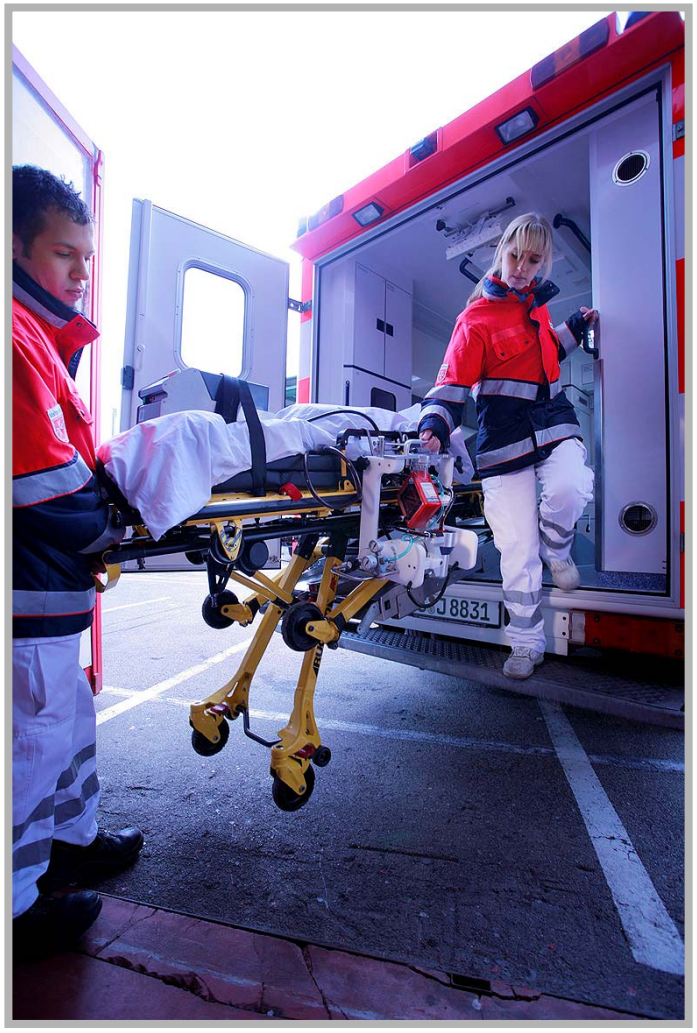

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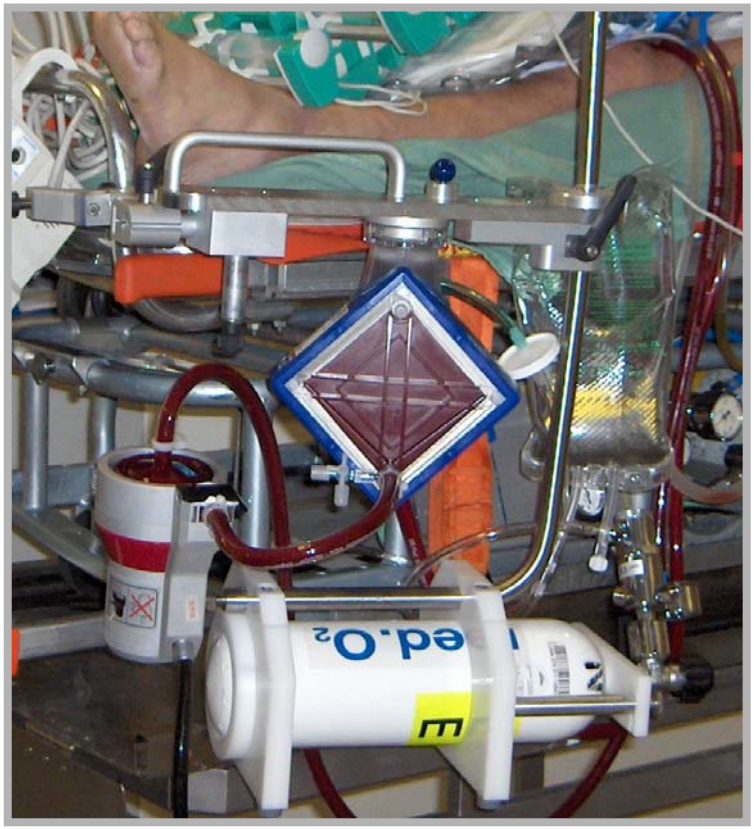

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ECMO AND LIFE SUPPORT SYSTEMS
QUADROX PLS AND ROTAFLOW RF32
HARDWARE AND ACCESSORIES
CARDIOPULMONARY
QUADROX PLS
MAQUET

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ECMO AND LIFE SUPPORT SYSTEMS
QUADROX PLS AND ROTAFLOW RF32
HARDWARE AND ACCESSORIES

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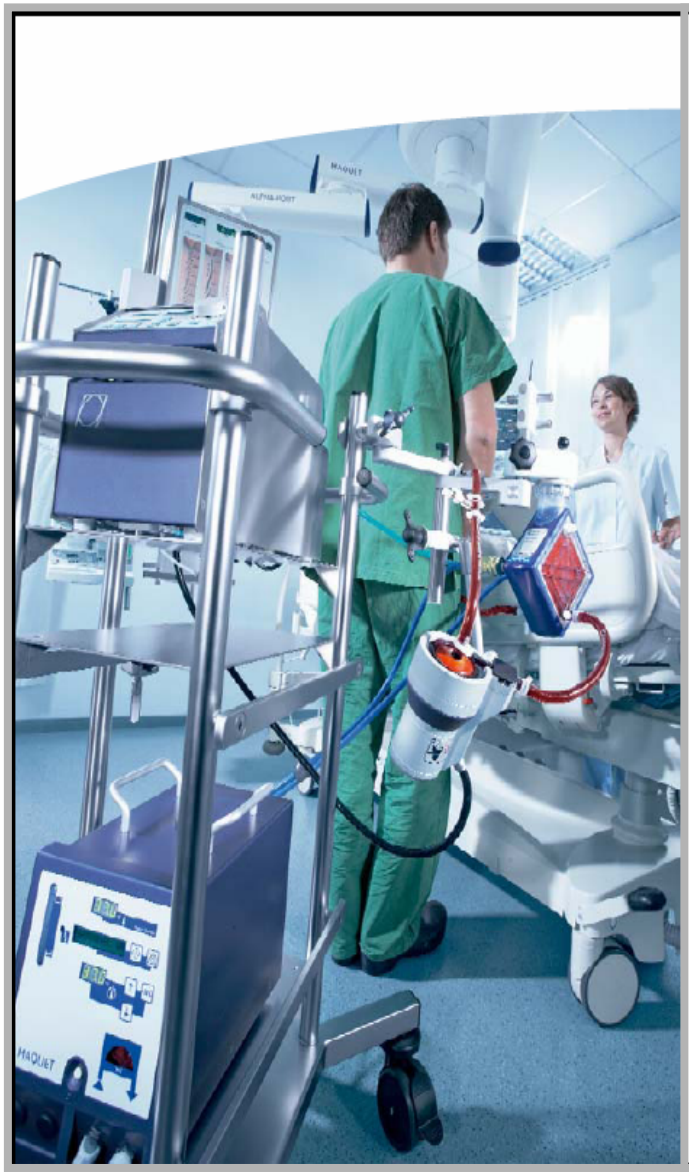
QUADROX PLS AND ROTAFLOW RF32
INNOVATIVE PERFORMANCE AND RELIABILITY
MAQUET – THE GOLD STANDARD

Extracorporeal circulation for extended life support:
The extremely demanding requirements for extended life support call for technology with outstanding features. The BIOLINE coated QUADROX PLS oxygenator and the ROTAFLOW RF32 centrifugal pump with their in-vitro CE certification are designed for treating patients in need of extended respiratory and/or circulatory support. This PLS system provides a unique specification triad – consistent performance, functional reliability and biocompatibility.

Products from MAQUET Cardiopulmonary are the result of innovative engineering and extensive clinical experience. With QUADROX PLS, ROTAFLOW RF32 and a tubing set, MAQUET offers a combination for long-term extracorporeal support applications.

It's the only system validated with CE certification for 14 days continuous use.

MAQUET – The Gold Standard.



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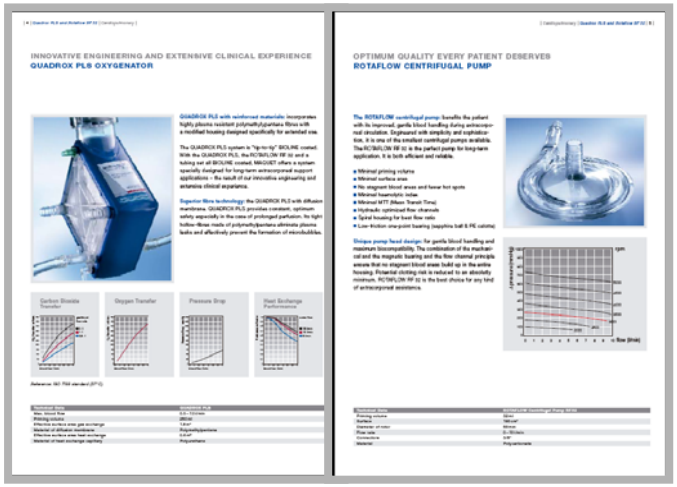
INNOVATIVE ENGINEERING AND EXTENSIVE CLINICAL EXPERIENCE
QUADROX PLS OXYGENATOR
QUADROX PLS with reinforced materials: incorporates highly plasma resistant polymethylpentene fibres with a modified housing designed specifically for extended use.
The QUADROX PLS system is "hip-to-hip" BIOLINE coated. With the QUADROX PLS, the ROTAFLOW RF 32 and a tubing set all BIOLINE coated, MAQUET offers a system specially designed for long-term extracorporeal support applications – the result of our innovative engineering and extensive clinical experience.
Superior fibre technology: the QUADROX PLS with diffusion membrane. QUADROX PLS provides constant, optimum safety especially in the case of prolonged perfusion: its tight hollow-fibres made of polymethylpentene eliminate plasma leaks and effectively prevent the formation of microbubbles.
Carbon Dioxide Transfer
Oxygen Transfer
Pressure Drop
Heat Exchange Performance
OPTIMUM QUALITY EVERY PATIENT DESERVES
ROTAFLOW CENTRIFUGAL PUMP
The ROTAFLOW centrifugal pump: benefits the patient with its improved, gentle blood handling during extracorporeal circulation. Engineered with simplicity and sophistication, it is one of the smallest centrifugal pumps available. The ROTAFLOW RF 32 is the perfect pump for long-term application. It is both efficient and reliable.
Minimal priming volume
Minimal surface area
No stagnant blood areas and fewer hot spots
Minimal haemolytic index
Minimal MTT (Mean Transit Time)
Hydraulic optimised flow channels
Spiral housing for best flow ratio
Low-friction one-point bearing (sapphire ball & PE calotte)
Unique pump head design: for gentle blood handling and maximum biocompatibility. The combination of the mechanical and the magnetic bearing and the flow channel principle ensure that no stagnant blood areas build up in the entire housing. Potential clotting risk is reduced to an absolute minimum. ROTAFLOW RF 32 is the best choice for any kind of extracorporeal assistance.

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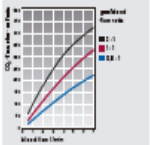
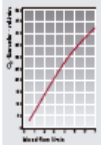
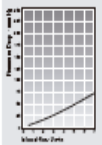
Carbon Dioxide Transfer



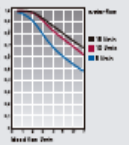
Oxygen Transfer



Pressure Drop



Heat Exchange Performance



Reference: ISO 7199 standard (37° C)

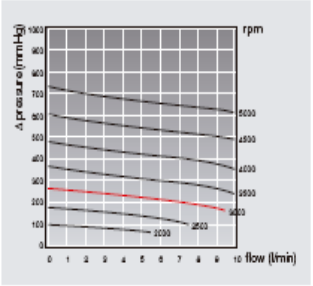
Technical Data	QUADROX PLS
Max. blood flow	0.5 – 7.0 l/min
Priming volume	250 ml
Effective surface area gas exchange	1.8 m²
Material of diffusion membrane	Polymethylpentene
Effective surface area heat exchange	0.6 m²
Material of heat exchange capillary	Polyurethane

OPTIMUM QUALITY EVERY PATIENT DESERVES
ROTAFLOW CENTRIFUGAL PUMP

The ROTAFLOW centrifugal pump: benefits the patient with its improved, gentle blood handling during extracorporeal circulation. Engineered with simplicity and sophistication, it is one of the smallest centrifugal pumps available. The ROTAFLOW RF 32 is the perfect pump for long-term application. It is both efficient and reliable.

- Minimal priming volume
- Minimal surface area
- No stagnant blood areas and fewer hot spots
- Minimal haemolytic index
- Minimal MTT (Mean Transit Time)
- Hydraulic optimized flow channels
- Spiral housing for best flow ratio
- Low-friction one-point bearing (sapphire ball & PE calotte)

Unique pump head design: for gentle blood handling and maximum biocompatibility. The combination of the mechanical and the magnetic bearing and the flow channel principle ensure that no stagnant blood areas build up in the entire housing. Potential clotting risk is reduced to an absolutly minimum. ROTAFLOW RF 32 is the best choice for any kind of extracorporeal assistance.



Technical Data	ROTAFLOW Centrifugal Pump RF32
Priming volume	32 ml
Surface	160 cm²
Diameter of rotor	50 mm
Flow rate	0 – 10 l/min
Connectors	3/8"
Material	Polycarbonate

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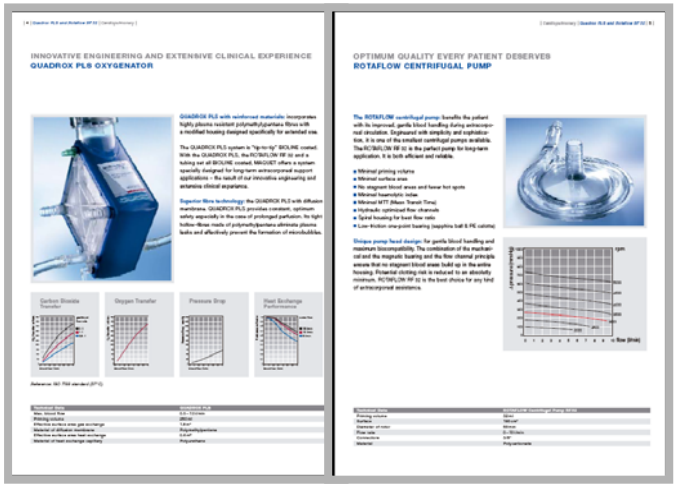
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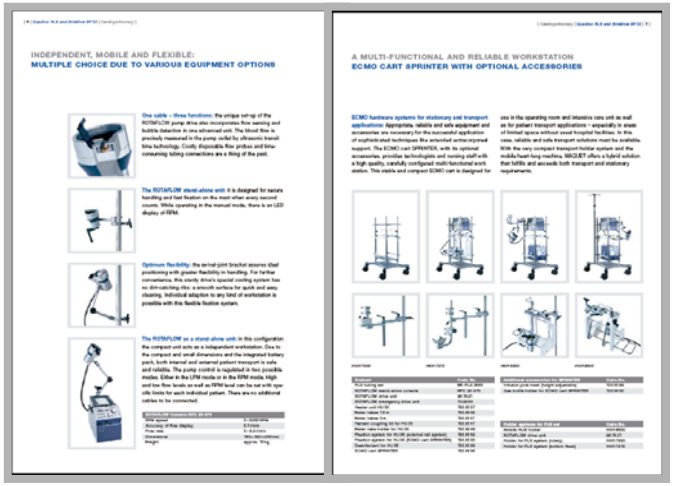
INDEPENDENT, MOBILE AND FLEXIBLE:
MULTIPLE CHOICE DUE TO VARIOUS EQUIPMENT OPTIONS
A MULTI-FUNCTIONAL AND RELIABLE WORKSTATION
ECMO CART &PRINTER WITH OPTIONAL ACCESSORIES

INDEPENDENT, MOBILE AND FLEXIBLE:
MULTIPLE CHOICE DUE TO VARIOUS EQUIPMENT OPTIONS

One cable – three functions: the unique set-up of the ROTAFLOW pump drive also incorporates flow sensing and bubble detection in one advanced unit. The blood flow is precisely measured in the pump outlet by ultrasonic transit time technology. Costly disposable flow probes and time-consuming tubing connections are a thing of the past.

The ROTAFLOW stand-alone unit: it is designed for secure handling and fast fixation on the mast when every second counts. While operating in the manual mode, there is an LED display of RPM.

Optimum flexibility: the swivel-joint bracket assures ideal positioning with greater flexibility in handling. For further convenience, this sturdy drive's special cooling system has no dirt-catching ribs: a smooth surface for quick and easy cleaning. Individual adaption to any kind of workstation is possible with this flexible fixation system.

The ROTAFLOW as a stand-alone unit: in this configuration the compact unit acts as a independent workstation. Due to the compact and small dimensions and the integrated battery pack, both internal and external patient transport is safe and reliable. The pump control is regulated in two possible modes. Either in the LPM mode or in the RPM mode. High and low flow levels as well as RPM level can be set with specific limits for each individual patient. There are no additional cables to be connected.

ROTAFLOW Console RFC 20-970	
RPM speed	0 – 5000 RPM
Accuracy of flow display	0.1 l/min
Flow rate	0 – 9.9 l/min
Dimensions	160 x 350 x 240 mm
Weight	approx. 15 kg

A MULTI-FUNCTIONAL AND RELIABLE WORKSTATION
ECMO CART SPRINTER WITH OPTIONAL ACCESSORIES

ECMO hardware systems for stationary and transport applications: Appropriate, reliable and safe equipment and accessories are necessary for the successful application of sophisticated techniques like extended extracorporeal support. The ECMO cart SPRINTER, with its optional accessories, provides technologists and nursing staff with a high quality, carefully configured multi-functional work station. This stable and compact ECMO cart is designed for use in the operating room and intensive care unit as well as for patient transport applications – especially in areas of limited space without usual hospital facilities. In this case, reliable and safe transport solutions must be available. With the very compact transport holder system and the mobile heart-lung machine, MAQUET offers a hybrid solution that fulfills and exceeds both transport and stationary requirements.

HKH 7900

HKH 7910

HKH 8800

HKH 8600

Product	Code No.
PLS tubing set	BE-PLS 2050
ROTAFLOW stand-alone console	RFC 20-970
ROTAFLOW drive unit	98 76 21
ROTAFLOW emergency drive unit	70 25 65
Heater unit HU 35	103 35 57
Water tubes 1.5 m	103 36 46
Water tubes 3 m	103 35 51
Hansen coupling kit for HU 35	103 35 47
Water tube holder for HU 35	103 36 49
Fixation system for HU 35 (external rail system)	103 35 52
Fixation system for HU 35 (ECMO cart SPRINTER)	103 35 50
Desinfectant for HU 35	103 35 69
ECMO cart SPRINTER	103 34 56

Additional accessories for SPRINTER	Code No.
Infusion pole mast (height adjustable)	103 35 99
Gas bottle holder for ECMO cart SPRINTER	103 36 90

Holder systems for PLS set	Code No.
Mobile HLM holder	HKH 8600
ROTAFLOW drive unit	98 76 21
Holder for PLS system (rotary)	HKH 7900
Holder for PLS system (bottom fixed)	HKH 7910

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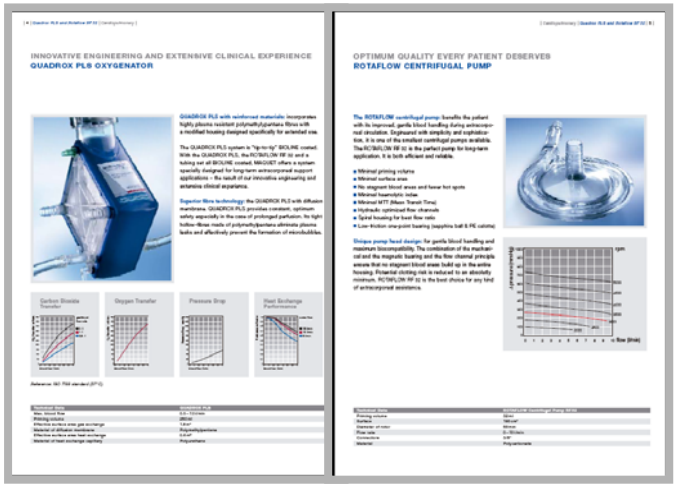
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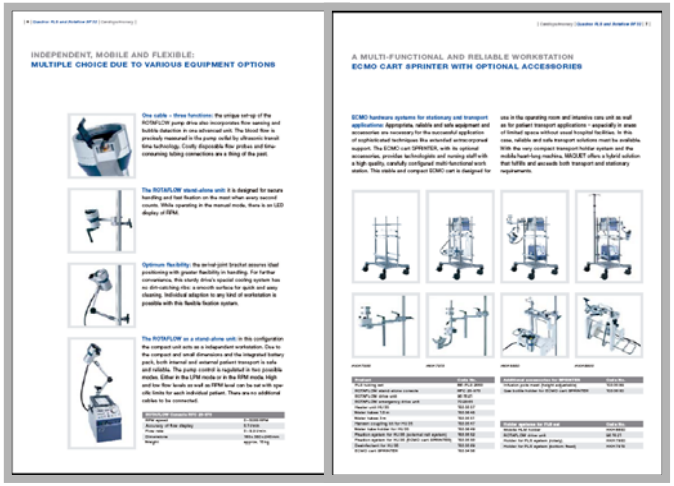
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THE OPTIMAL OXYGENATOR HEATER UNIT
MU 35 FOR ECMO PROCEDURE

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THE OPTIMAL OXYGENATOR HEATER UNIT
HU 35 FOR ECMO PROCEDURE

The HU 35 is the perfect companion to the QUADROX PLS Oxygenator or any appropriate oxygenator: with a footprint of only 200 x 330 mm and an approximate weight of 9 kgs it fits on the lower shelf of the ECMO cart SPRINTER. The HU 35 is a precise and reliable oxygenator water supply unit for maintaining patient temperatures between 35 and 39° C. Two different lengths of water supply lines are available. The HU 35 incorporates an automatic function test and water and temperature alarms with status displays to optimise operational safety and reliability.

- Accurate and reliable temperature control
- Function test and status alarms
- Compact, robust and easily transportable

Technical Data	HU 35
Operating voltage	220 – 240 V AC, 50/60 Hz
Power consumption	530 W
Setting range for water temperature	35 – 39° C
Water content	approx. 0.7/1.4 l (MIN/MAX)
Pumping level	10 W (max. 0.34 bar)
Heating capacity	500 W
Weight	approx. 9 kg
Noise rate	approx. 35 dB (A)
Alarm level	> 65 dB (A)
Dimensions (W x H x L):	approx. 200 x 290 x 330 mm

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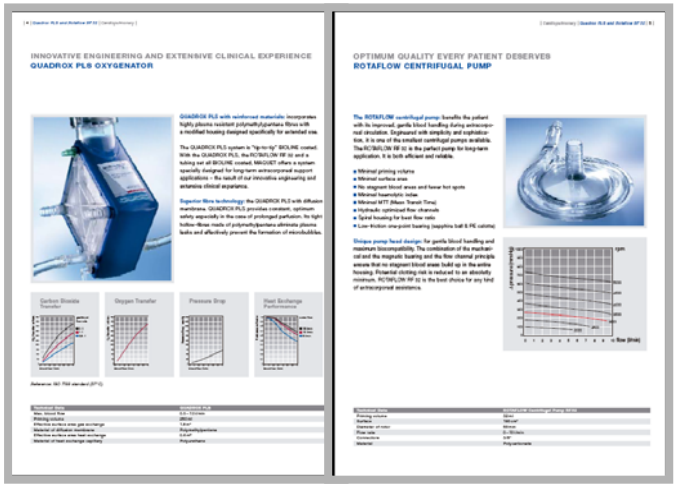
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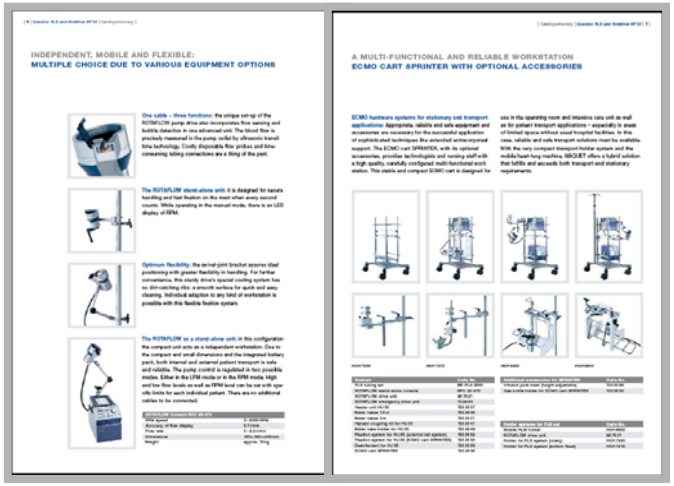
OPTIMUM QUALITY EVERY PATIENT DESERVES
ROTAFLOW CENTRIFUGAL PUMP


INDEPENDENT, MOBILE AND FLEXIBLE:
MULTIPLE CHOICE DUE TO VARIOUS EQUIPMENT OPTIONS
A MULTI-FUNCTIONAL AND RELIABLE WORKSTATION
ECMO CART &PRINTER WITH OPTIONAL ACCESSORIES

THE OPTIMAL OXYGENATOR HEATER UNIT
MU 35 FOR ECMO PROCEDURE

5. Clinical application

Acute Respiratory Distress Syndrome ARDS

Three quarters of all ARDS cases can be attributed to:

Sepsis
Polytrauma
Pneumonia
Aspiration

Inzidenz: 3-16 /100 000 inhabitants / year

Germany:	3-8
Scandinavia:	14
Great Britain:	4-5
Asia-Pacific:	8-16
Australia:	7-9

Mortality rate: more than 50% despite advanced critical care support

(Source: Bernard GR et al.: The American-European consensus conference on ARDS: Definitions, mechanisms, relevant outcomes and clinical trial conditions. Am J Respir Crit Care Med 1994;149:818-824)

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5. Clinical application

Sepsis and Septic Shock Syndrome

Epidemiology and costs:

- Mortality of 1400 patients / day worldwide
- Leading cause of death in the intensive care units
- Inzidenz 44 000 to 95 000 patients in Germany / year
- Inzidenz 750 000 patients in USA / year
- Mortality rate of 215 000 patients / year in USA
- Sepsis consumes considerable resources in the medical system and society
- Adding direct and indirect costs due to temporary or permanent morbidity, severe sepsis imposes annual costs of 16 milliards US $ per year in USA.

There is an urgent need for therapeutic standards and innovative therapies in the treatment of sepsis to improve outcome

(Source: European Society of Intensive Care Medicine, Society of Critical Care Medicine, International Sepsis Forum: Mission of the International Sepsis Forum 2007)

5. Clinical application

Sepsis

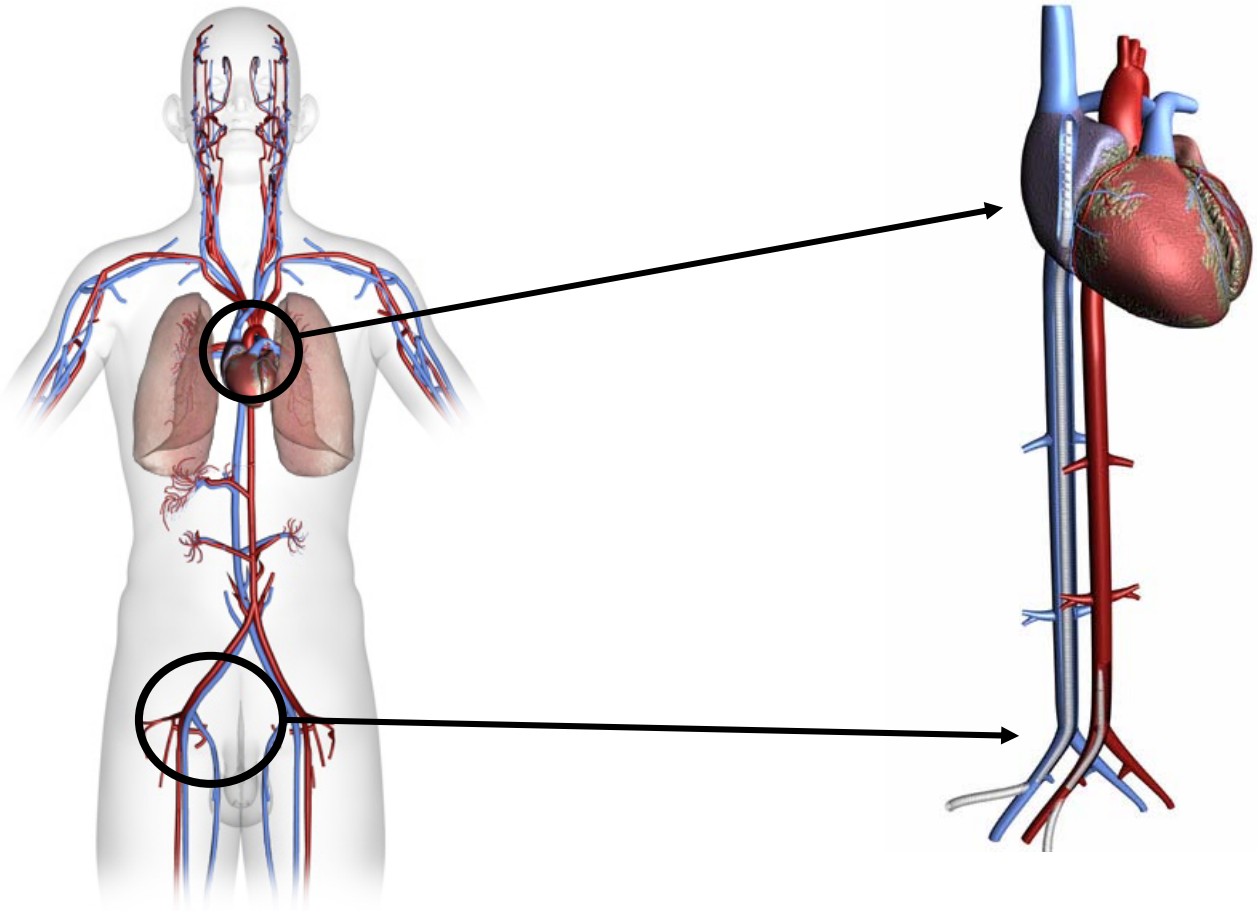
Definition:

The systemic response to infection, manifested by two or more of the following conditions as a result of infection:

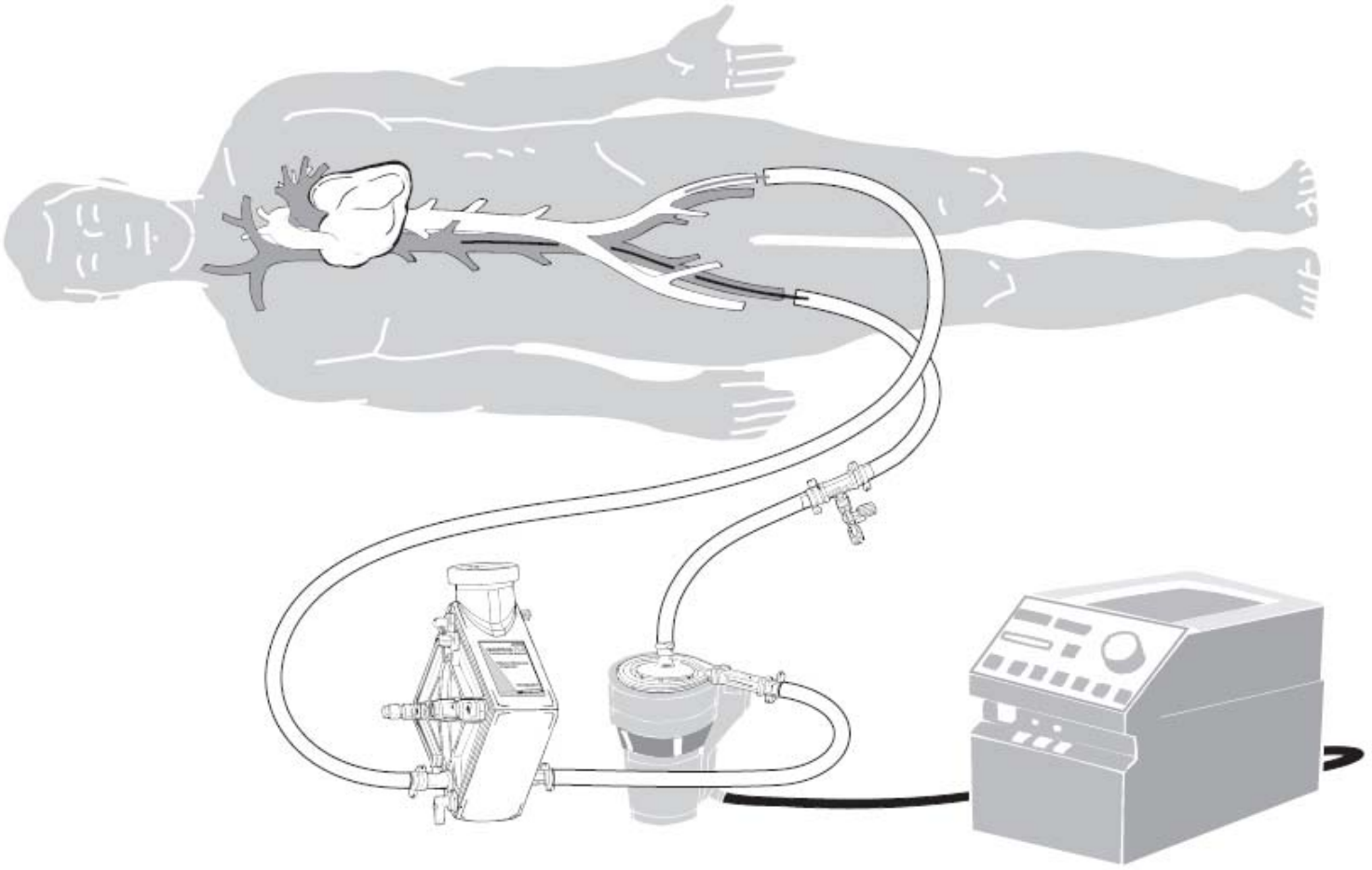
a) **temperature >38°C (100.4°F) or < 36°C (96.8°F)**
b) **Heart rate > 90 beats/min**
c) **Respiratory rate > 20 breaths/min or $PaCO_2$< 32 torr**
d) **White blood cell count > 12000/mm^3 or < 4000 mm^3**

(Source: Bone RC et al.: ACCP/SCCM consensus conference: Definitions for sepsis and organ failure and guidelines for the use of innovative therapies in sepsis. Chest 1992;101:1644-1645)

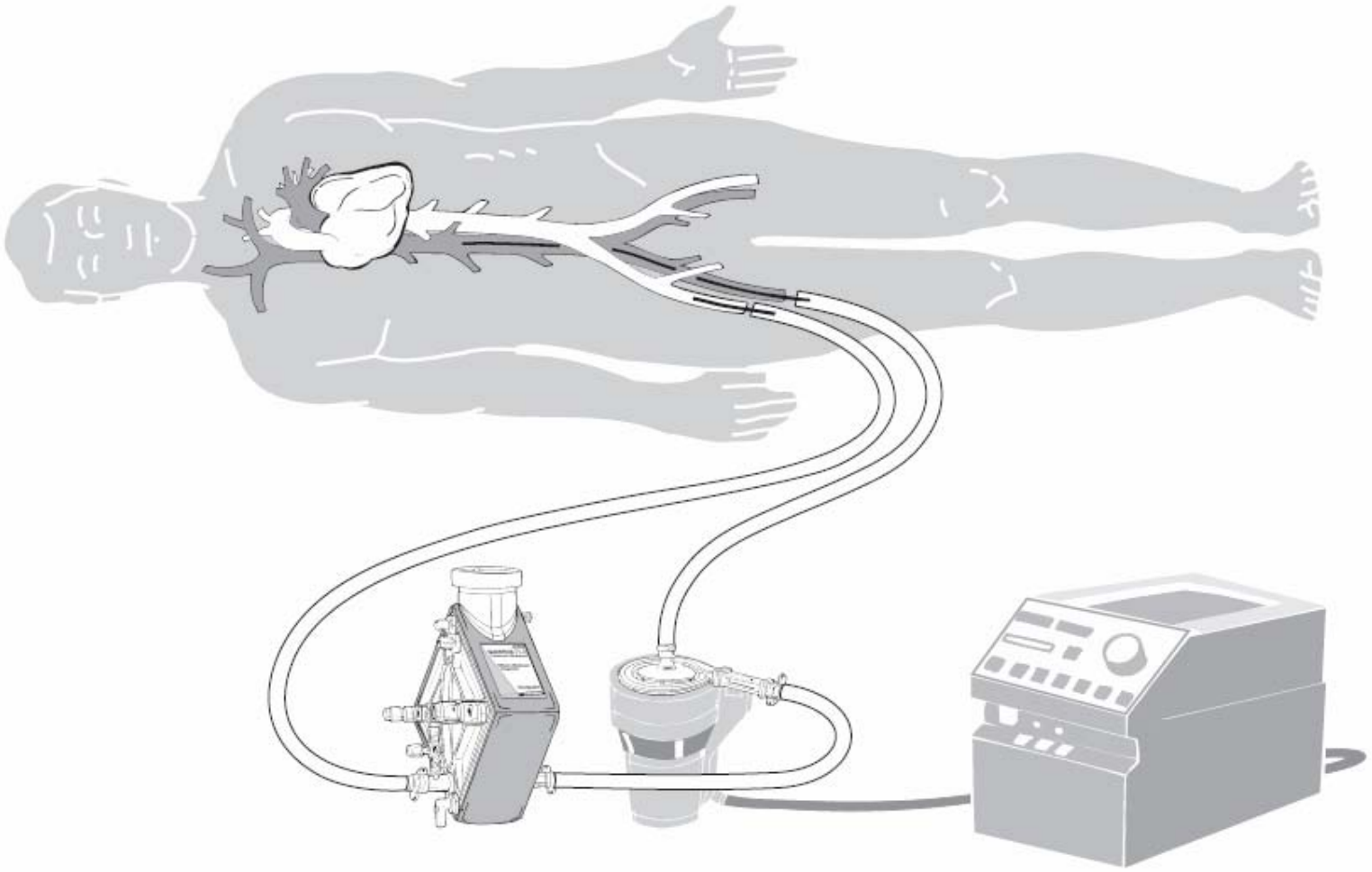
5. Clinical applications



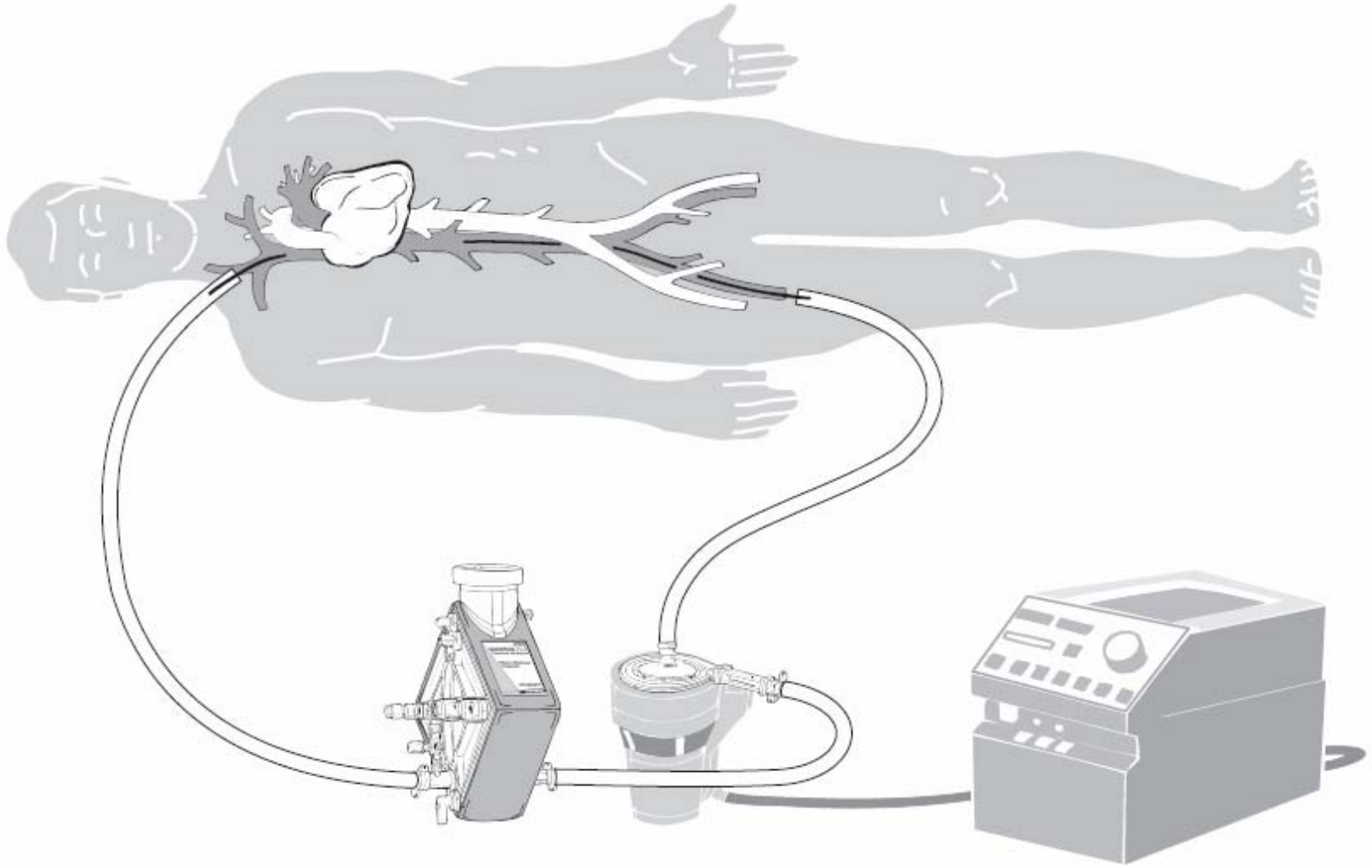
5. Clinical applications



5. Clinical applications



5. Clinical applications



6. Clinical references, case reports and hospitation:

▪ Royal Children Hospital, Melbourne	→ See report in Journal ”Perfusion”
▪ Oslo Rikshospital	→ Nationales ECMO center, Norway
▪ University Bochum	
▪ University Hospital, Jena	
▪ University Hospital, Regensburg	→ Hospitation possible
▪ Nieuwegein, Netherlands	→ Hospitation and clinical support
▪ University Hospital, Göttingen	
▪ University Hospital, Erlangen	
▪ Bad Oeynhausen	
▪ Bad Nauheim	

6. Clinical references, case reports and hospitation:

- Trümlihospital Zürich / Swiss
- University Hospital Vigo / Spain
- St. Gerardo di Monza Cardicsurgery & ICU
- Osp. ISMETT Palermo, Italy
- Osp. Liera Pisa, Italy
- Osp. San Giovanni Battista Torino, Italy

CONTACT

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Thank you for your attention!

Frank Stickel - Product Manager - August 2007

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The Gold Standard