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

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 pump Rotaflow RF 32**

- High efficiency  \(\rightarrow\) Low hemolysis, no heat generation
- Flow-Channel-Prinzip  \(\rightarrow\) No stagnant areas
- One-point bearing without seals  \(\rightarrow\) No leakage possible
-  \(\rightarrow\) 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
3. Set-up and technical data

**Tubing Set**

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

- Bioline coated recirculation line
- Gas supply line
- Venous line
- Arterial line
- Separate temperature probe
- Priming bag with 2 spike ports
- Filling lines with clamps
- Separat 3-way stopcock
- Quadrox PLS
- Rotaflow RF 32
3. Set-up and technical data
3. Set-up and technical data
4. Hardware, accessories and additional equipment

**Standard holders**

- Complet and flexible holder concept for individual working conditions
- Even transport and handling in narrow rooms possible
ACCESSORIES – ECMO CART „SPRINTER“
ACCESSORIES – ECMO CART „SPRINTER“ (FULLY EQUIPPED)
ACCESSORIES – ECMO CART „SPRINTER“
ACCESSORIES – HOLDER FOR GAS BOTTLES
EQUIPMENT – ROTAFLOW HARDWARE
EQUIPMENT – ROTAFLOW HARDWARE

Rotaflow Drive Unit

Rotaflow Stand Alone Unit
ACCESSORIES – HEATER UNIT HU 35
ACCESSORIES – TRANSPORT HOLDER HKH 8800
ACCESSORIES – TRANSPORT HOLDER HKH 8800
4. Hardware, accessories and additional equipment

QUADROX PLS System – Permanent Life Support
QUADROX PLS AND ROTAFLOW RF32
INNOVATIVE PERFORMANCE AND RELIABILITY
MAQUET – THE GOLD STANDARD

Exceptional engineering for extended life support:

The extremely demanding requirements for extended life support ran technology with increasing frequency. The QUADROX PLS and the ROTAFLOW RF32 cartridge pump with their newly CE certifications are designed for treating patients in need of extended intubation and respiratory support. The PLS system provides a unique specification to offer consistent performance, functional reliability and interchangeability.

Products from MAQUET Cardiopulmonary are the result of innovative engineering and extensive clinical experience. With QUADROX PLS, ROTAFLOW RF32 and a rating as a S-ECG, MAQUET offers a combination for long-term and exception support applications.

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

INNOVATIVE ENGINEERING AND EXTENSIVE CLINICAL EXPERIENCE

QUADROX PL6 OXYGENATOR

QUADROX PL6 incorporates highly precise patented components designed specifically for extended use.

The QUADROX PL6 system is a "plug-and-play" solution, offering a reliable and easy-to-use option for long-term extracorporeal support applications.

Support your team to achieve the QUADROX PL6 with intuitive maintenance. QUADROX PL6 provides a constant, optimal safety, especially in cases of partial perfusion for high-volume flows or polymeric bypasses to eliminate pressure loss and effectively prevent the formation of microbubbles.

OPTIMUM QUALITY EVERY PATIENT DESERVES

ROTAFLOW CENTRIFUGAL PUMP

The ROTAFLOW centrifugal pump benefits the patient with its improved, gentle blood handling during extracorporeal support. Designed with simplicity and sophistication, it is one of the most efficient centrifugal pumps available.

The ROTAFLOW PF 60 is the perfect pump for long-term applications. It is both efficient and reliable.

- Minimal priming volume
- Minimal surface area
- No stagnant blood areas and reduced heat spots
- Minimal hemolytic index
- Minimal MTT (Mean Transit Time)
- Hydraulically optimized flow channels
- Spiral housing for low flow noise
- Less friction-one point bearing (sealing ball & PTFE soldated)

Unique pump head design for gentle blood handling and minimum hemolysis. The combination of this material and the magnetic-bearing and flow-channel principle ensures minimal stagnation blood area built up in the unison housing. Deteriorating speed is reduced to an absolute minimum. ROTAFLOW PF 60 is the best choice for any kind of long-term extracorporeal assistance.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>QUADROX PL6</th>
<th>ROTAFLOW Centrifugal Pump, PF 60</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max. usage</td>
<td>5 l/min</td>
<td>5 l/min</td>
</tr>
<tr>
<td>Priming volume</td>
<td>200 ml</td>
<td>200 ml</td>
</tr>
<tr>
<td>Blood flow rate</td>
<td>10 l/min</td>
<td>10 l/min</td>
</tr>
<tr>
<td>Minimum flow rate</td>
<td>0.5 l/min</td>
<td>0.5 l/min</td>
</tr>
<tr>
<td>Maximum flow rate</td>
<td>10 l/min</td>
<td>10 l/min</td>
</tr>
<tr>
<td>Exchanger volume</td>
<td>60 ml</td>
<td>60 ml</td>
</tr>
<tr>
<td>Flow rate</td>
<td>5 l/min</td>
<td>5 l/min</td>
</tr>
<tr>
<td>Temperature</td>
<td>37°C</td>
<td>37°C</td>
</tr>
<tr>
<td>Contact surface area</td>
<td>Polypropylene</td>
<td>Polypropylene</td>
</tr>
</tbody>
</table>
INDEPENDENT, MOBILE AND FLEXIBLE:
MULTIPLE CHOICE DUE TO VARIOUS EQUIPMENT OPTIONS

One capable, three functional: the unique setup of the ROTAFLOW pump drive also incorporates flow sensing and bubble detection in one automated unit. This front line is previously managed in the pump control by ultrasound or visual time technology. Courtesy disposable flow probes and time consuming testing connections are a thing of the past.

The ROTAFLOW stand-alone unit is designed for secure handling and fast function on the maximum every cardiac output. While operating in the topical mode there is an LED display of RPM.

Optimum flexibility: the mini-ponent features several ideal positioning or lift, greater flexibility in handling. For further considerations, the custom designed and custom system has no flat undetachable keyboard, a smooth surface for quick and easy cleaning. Induction nozzles in any kind of maintenance is possible with this flexible system.

The ROTAFLOW as a stand-alone unit in this configuration the compact system is an independent workstation. Due to the compact and small dimensions and the integrated battery pack, both manual and automatic patient transport is easy and reliable. The pump control is equipped in two possible modes. Either in the OHM mode or in the RPM mode, high and low that lends as well as RPM level can be set with specific criteria for each individual patient. There are an additional cables to be connected.

<table>
<thead>
<tr>
<th>Feature</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flow monitor</td>
<td>RPM 100 - 1200</td>
</tr>
<tr>
<td>Accuracy of flow display</td>
<td>±15%</td>
</tr>
<tr>
<td>Temperature sensor</td>
<td>0°C - 40°C</td>
</tr>
<tr>
<td>Connections</td>
<td>WiFi, Bluetooth</td>
</tr>
<tr>
<td>Switches</td>
<td>1x, 2x</td>
</tr>
</tbody>
</table>

A MULTI-FUNCTIONAL AND RELIABLE WORKSTATION
ECMO CART SPRENTER 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 extracorporeal membrane oxygenation support. This ECMO cart SPRENTER with the specific accessories, provides telecontrol and nursing staff with a high-quality, fully integrated and multi-functional workstation. The stable and compact ECMO cart is designed for use in the operating room and intensive care units 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 well-laid modules, MAQUET offers a hybrid solution that fulfills all aspects both transport and stationary requirements.

<table>
<thead>
<tr>
<th>Accessory</th>
<th>Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>Foot controller</td>
<td>00X010200</td>
</tr>
<tr>
<td>Valve assembly for ECMO 1400</td>
<td>904001050</td>
</tr>
<tr>
<td>Waste bag holder</td>
<td>100201050</td>
</tr>
<tr>
<td>Accessory for ECMO 1400</td>
<td>00X010200</td>
</tr>
<tr>
<td>Accessory for ECMO 1400</td>
<td>904001050</td>
</tr>
<tr>
<td>Waste bag holder</td>
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<td>904001050</td>
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<td>Waste bag holder</td>
<td>100201050</td>
</tr>
</tbody>
</table>

MAQUET
THE OPTIMAL OXYGENATOR HEATER UNIT
HU35 FOR ECMO PROCEDURE

The HU 35 is the perfect companion to the SWANBOX
PLS Oxygenator or any appropriate oxygenator with a
volumetric flow rate of only 1000-3000 ml/min and an
operation weight of 6 kg (13 lbs) on the lower shelf of
the ECMO cart (MAQUET). The HU 35 is a passive and
reliable oxygenator-water supply unit for maintaining
patient temperatures between 36 and
350°C. Two different lengths of water supply hoses are
available. The HU 35 incorporates an automatic function
level and water temperature alarms with patient displays
to optimise operational safety and reliability.

- Accurate and reliable temperature control
- Operation time and status alarms
- Compact, robust, and easily transportable

<table>
<thead>
<tr>
<th>Technical Data</th>
<th>HU35</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operating voltage</td>
<td>220-240 V</td>
</tr>
<tr>
<td>Power consumption</td>
<td>140 W</td>
</tr>
<tr>
<td>Ambient temperature range</td>
<td>10°C to 40°C</td>
</tr>
<tr>
<td>Water supply</td>
<td>20°C to 40°C</td>
</tr>
<tr>
<td>Heating capacity</td>
<td>15 kW</td>
</tr>
<tr>
<td>Weight</td>
<td>approx. 65 kg</td>
</tr>
<tr>
<td>Dimensions (L x W x H)</td>
<td>approx. 390 x 650 x 450 mm</td>
</tr>
<tr>
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<td>approx. 390 x 650 x 450 mm</td>
</tr>
</tbody>
</table>
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**

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 PaCO₂< 32 torr
d) White blood cell count > 12000/mm³ or < 4000 mm³

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
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Thank you for your attention!

Frank Stickel - Product Manager - August 2007
The Gold Standard