Cardiac Intervention

Two choices – one goal

MAQUET
GETINGE GROUP

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

Two choices – one goal
Safe support during **cardiac intervention**

A trusted partner for hospitals and clinicians since 1838: Maquet Cardiovascular is a leading manufacturer of products for intra-aortic balloon counterpulsation (IABC) therapy and extracorporeal circulation. With the proven HLS Set Advanced and the Cardiac Intervention Set (CI Set), both powered by CARDIOHELP-i, Maquet now offers interventional cardiologists two choices of back-up systems with the same goal: safe and effective life support during cardiac interventions.

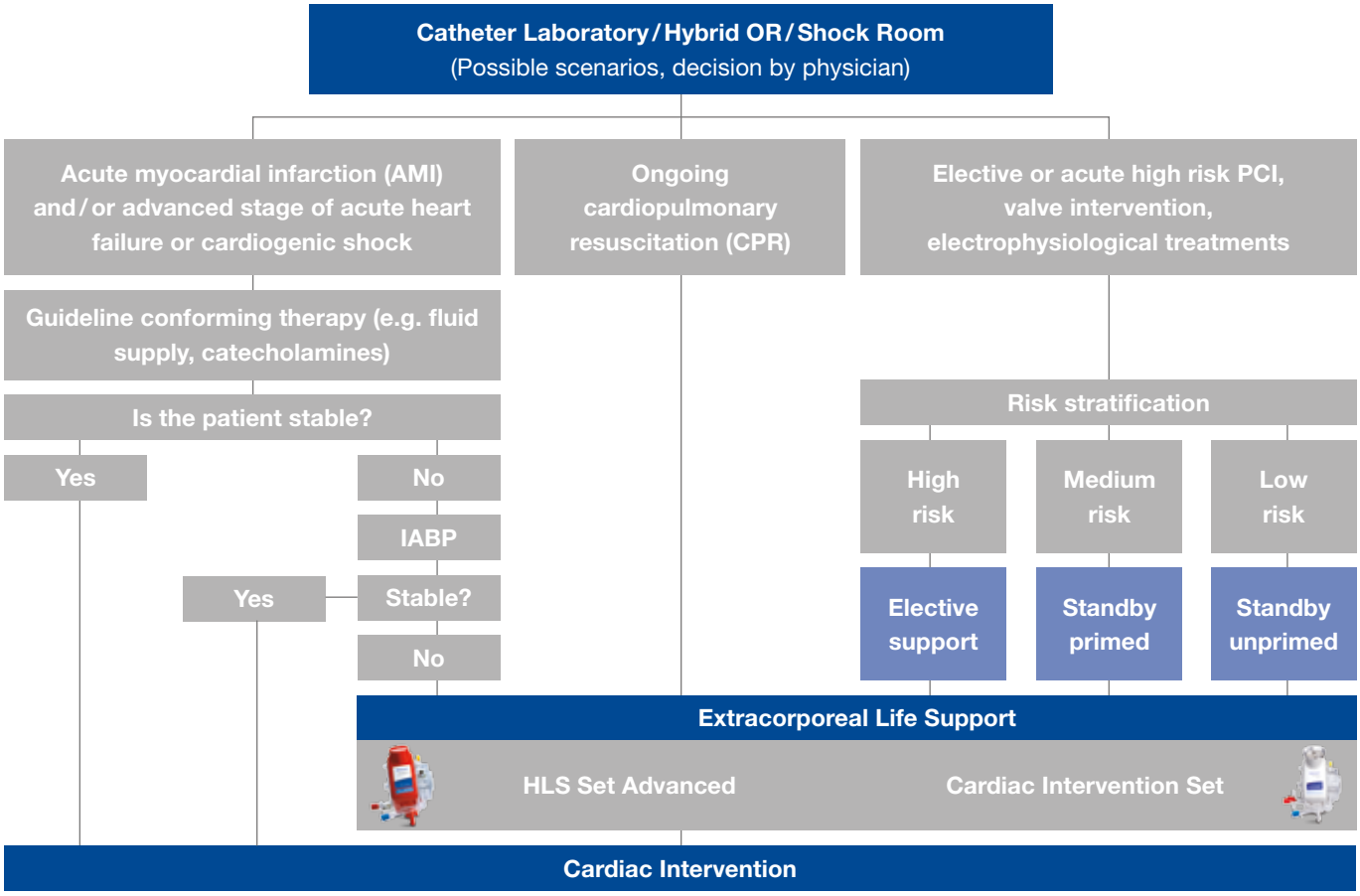
In recent years the number of percutaneous coronary interventions (PCI) has increased significantly and have become one of the most common medical interventions performed. However, despite this continuing success, the residual risk of complications can never be ruled out completely, especially since the number of so called high-risk PCI's is steadily increasing. What if there was a back-up system to save patients' lives in case of complications or in emergency situations? With the HLS Set Advanced and the CI Set interventional cardiologists are now prepared to face these challenges successfully.

Cardiopulmonary Support
A life saving decision

When treating patients with high-risk PCI, the physician should take into account a 7–10 % risk of acute hemodynamic instability which almost always leads to the need for urgent circulatory support1. Cardiac assist devices can be used to regain stability and to support the patient as quickly and effectively as possible.

Facts:

- Rising numbers of cardiac interventions especially in older and sicker patients [2,3,4]
- Increase of more complex cardiac interventions after the introduction of new stent variations (e. g. drug eluting stent, dissolving stent) and evolving technologies (e. g. minimal invasive valve-replacement) [5]
- Increased need for, and acceptance of circulatory support during high-risk PCI [1,6,7]



According to ESC and ACC / AHA guidelines

[1] *Briguori C et al. Elective versus provisional intra-aortic balloon pumping in ULMS. Am. Heart J. 2006; 152 (3): 565-572*

[2] *Vainer J et al. Elective high-risk percutaneous coronary interventions supported by extracorporeal life support. Am. J. Cardiol. 2007; 99 (6): 771-3*

[3] *Anastasiadis K et al. Successful high-risk percutaneous coronary intervention with the use of minimal extracorporeal cirulation system. Catheter Cardiovasc Interv. 2012; 80 (5): 845–9*

[4] *Tsao et al. Extracorporeal membrane oxygenation-assisted primary percutaneous coronary intervention may improve survival of patients with acute myocardial infarction complicated by profound cardiogenic shock. J. Crit. Care. 2012; 27 (5): 530.e1-530.e11*

Cardiopulmonary Support for cardiac interventions **Powered by CARDIOHELP-i**

CARDIOHELP-i as the central component for cardiac intervention support is a combined drive and control unit that comes with a compact, functional design. The disposable HLS Set Advanced and CI Set are easily attached to the CARDIOHELP-i. Weighing just approximately 10 kg, with a pump performance of up to 7 l/min and its user-friendly touchscreen, CARDIOHELP-i is a compact life-saver. Moreover, the CARDIOHELP-i life support system is an intuitively operated system, which can be deployed rapidly in emergency situations. Thanks to the system's mobility, the patient can undergo further therapeutic procedures and diagnostic investigations during ongoing cardiopulmonary support.

CARDIOHELP-i

Disposable	HLS Set Advanced	Cardiac Intervention Set
thApp		
Duration of use	Up to 30 days	Up to 6 hours
Flow rates	0.5–7.0 l/min	0.5–7.0 l/min
Temperature regulation	15–40 °C	15–40 °C
Place	Cath Lab/Hybrid OR/ICU/ER/OR	Cath Lab/Hybrid OR
Integrated centrifugal pump	■	■
Transport approval	Air/Ground	No
BIOLINE Coating	■	
Integrated measuring cell	■	■
Arterial temperature measurement	■	
Integrated pressure monitoring	■	

[5] *Dardas P et al. ECMO as a bridge to high-risk rotablation of heavily calcified coronary arteries. Herz. 2012; 37 (2): 225-30*

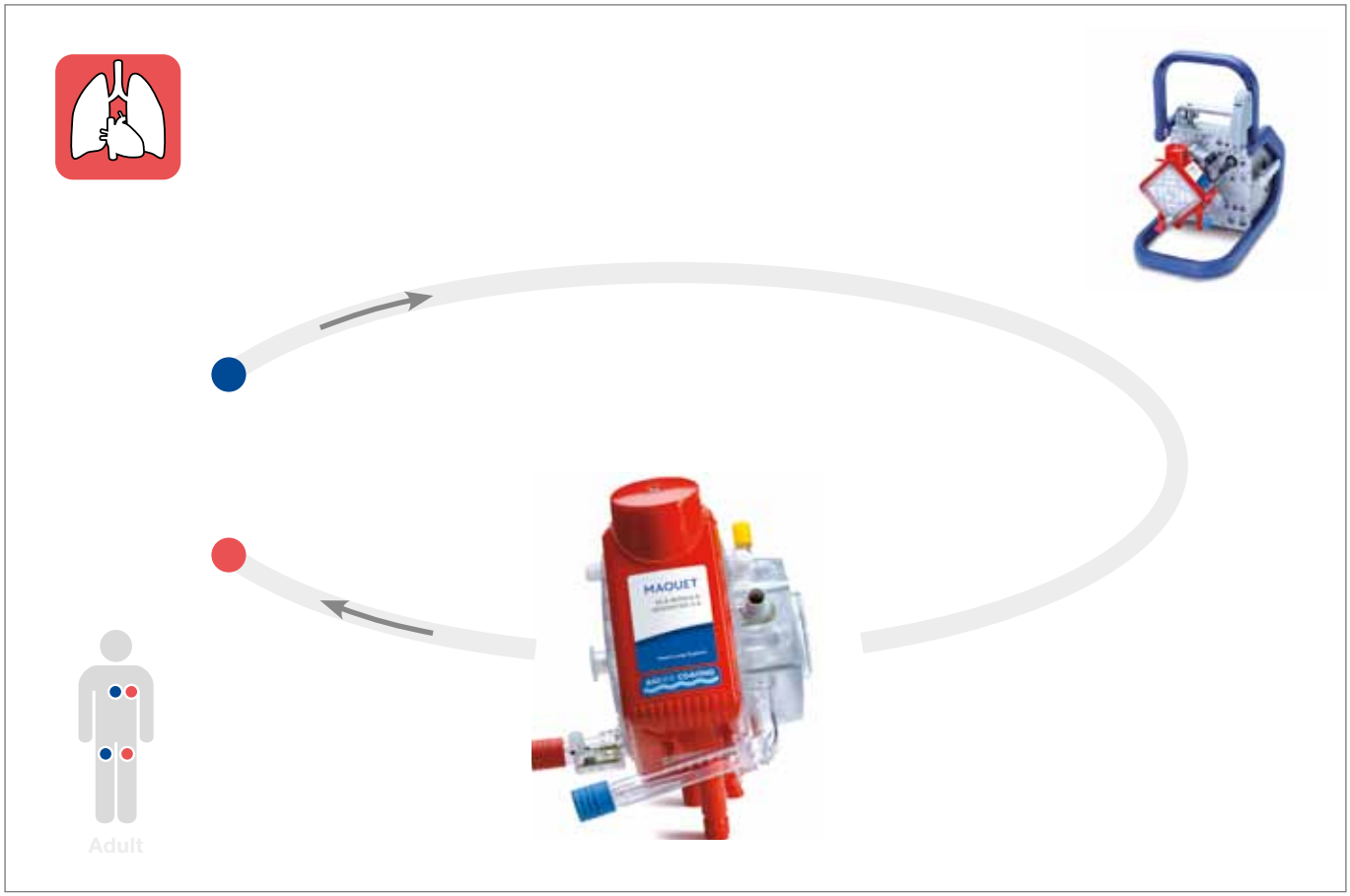
[6] *Bagai J et al. Efficacy and safety of percutaneous life support during high-risk percutaneous coronary intervention, refractory cardiogenic shock and in-laboratory cardiopulmonary arrest. J. Invasive Cardiol. 2011; 23 (4): 141-7*

[7] *Webb DP et al. Novel multi-functional life support system. J. Extra Corpor. Technol. 2010; 42 (3): 232-4*

HLS Set Advanced
Integration meets innovation

Benefits at a glance

- Quick and easy set-up and priming for fast deployment in emergency situations
- Color-coded tubing for safe patient connection
- Special design features allow for up to 30 days continuous use* reducing the risk to patients when conventional sets need to be exchanged
- Ensures safe intra- and inter-hospital patient transport
- The sterile packaging contains all the necessary components and tubing
- Available in two versions: HLS Set Advanced 5.0 with a blood flow of up to 5 l/min and HLS Set Advanced 7.0 with a blood flow of up to 7 l/min
- Due to the non-invasive integrated sensor technology there are no hazards of air embolism, stagnant zones, clotting and cavitation from external pressure sensors
- There are no pressure lines that need flushing
- Rapid detection of cannulae misplacement and kinking by monitoring pressure changes
- Integrated cutting-edge centrifugal pump
- Integrated heat exchanger for precise temperature management
- Low priming volume for less hemodilution
- The HLS Set Advanced comes with the biocompatible BIOLINE Coating
- The HIT Set Advanced with SOFTLINE Coating is available for patients who are susceptible to heparin-induced thrombocytopenia

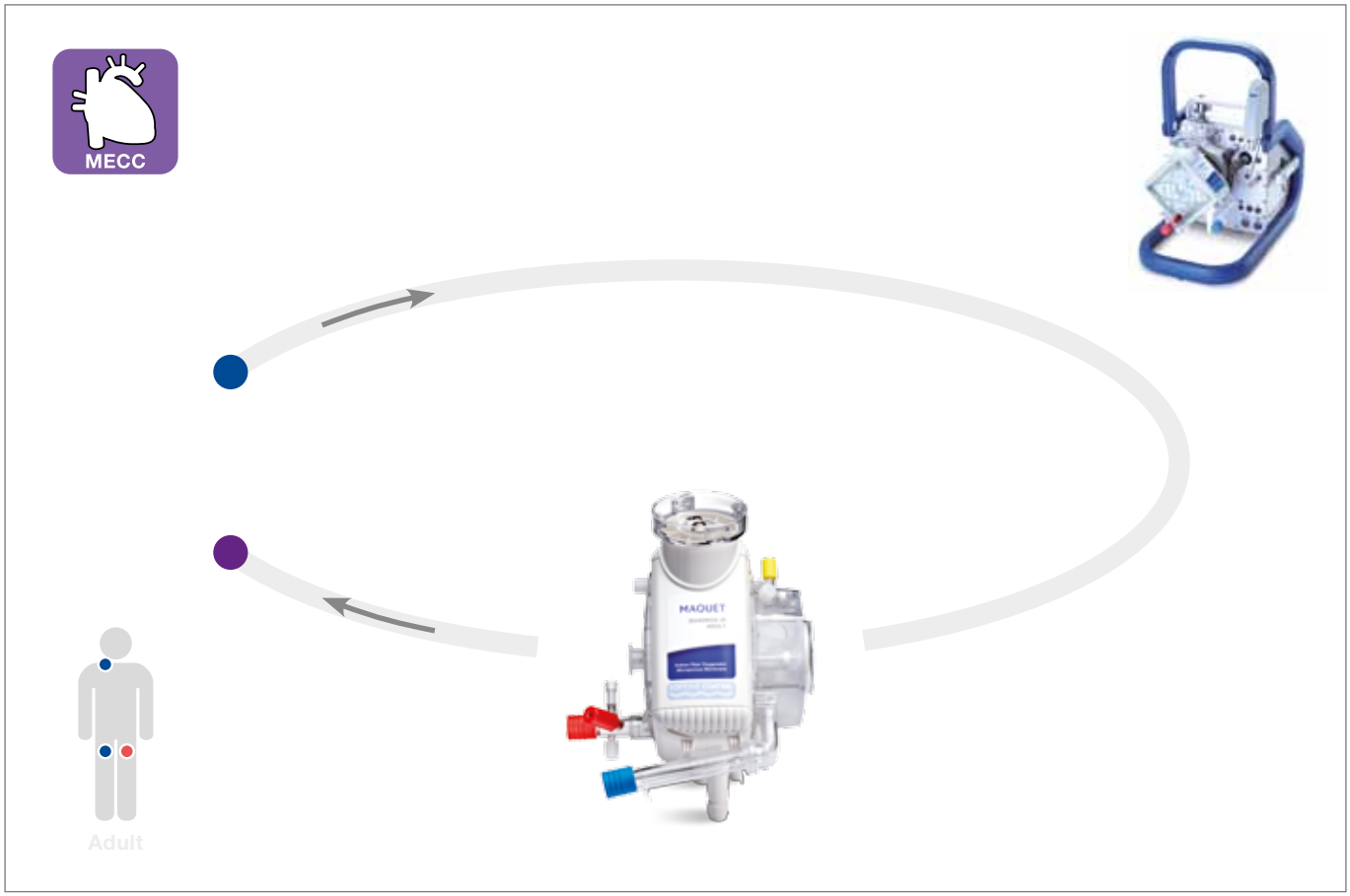


*When used with HLS Cannulae with BIOLINE Coating.

Cardiac Intervention Set
Short term support

Benefits at a glance

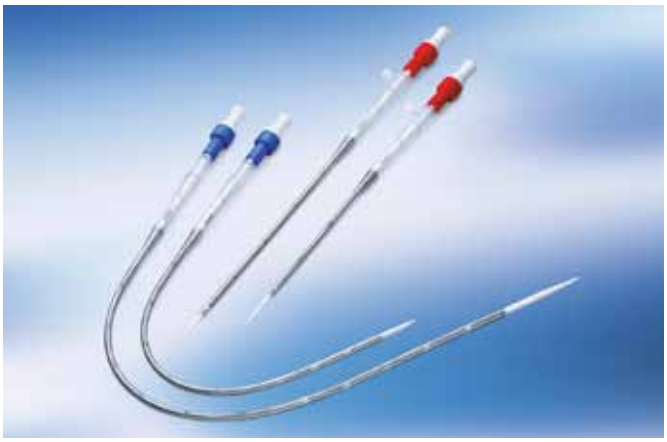
- First standardized tubing set for extracorporeal circulation during e.g. high-risk PCI
- Designed to be used for up to 6 hours this cost-efficient set can serve as a back-up solution to cover the phase of highest risk of instability and take over full support if necessary
- Quick and easy set-up and priming for fast deployment in emergency situations
- Low priming volume for less hemodilution
- Infrared measurement of venous oxygen saturation, hemoglobin (Hb)/hematocrit (Hct) and venous temperature for added patient safety
- Connection of external pressure measurement and arterial temperature is possible
- Integrated centrifugal pump as well as heat exchanger for precise temperature management
- Fewer tubing connectors result in reduced hemolysis



HLS Cannulae & Insertion Kit

For a less traumatic vessel access

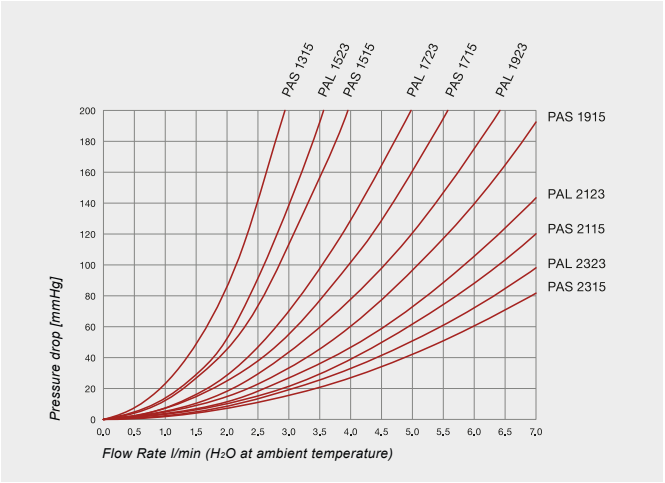
The specially developed HLS Cannulae from Maquet can be gently inserted into appropriate veins and arteries. The cannulae are available with various outer diameters and insertion lengths, thereby enabling the most appropriate cannulae to be used. HLS Cannulae are made of highly biocompatible polyurethane with thin walls to give the highest flows at lowest pressure drop. The Cannulae can be inserted percutaneously or with a surgical cut-down.



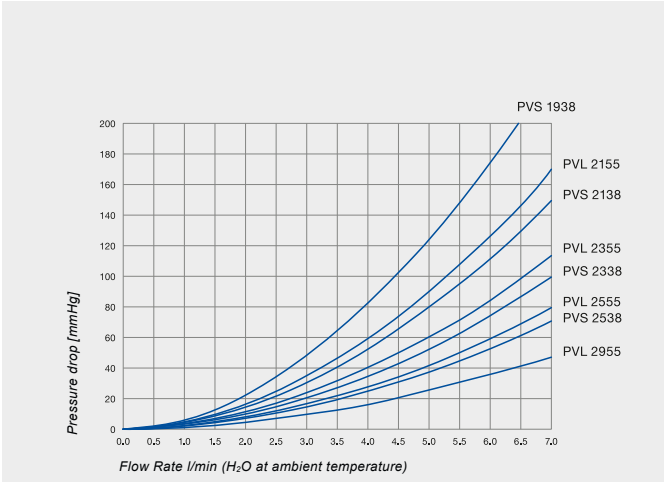
HLS Cannulae

Maquet also provides special insertion kits for gentle percutaneous vascular access. These kits are available with different guide wire lengths and fulfill the requirements for arterial and venous peripheral cannulation. The insertion kits also include dilators, a puncture needle, a scalpel as well as a syringe. This ensures that all the necessary cannulation components are readily available for both routine and emergency situations.

Insertion Kit



Flow rates vs. pressure drop for all Arterial HLS Cannulae



Flow rates vs. pressure drop for all Venous HLS Cannulae

Completely Equipped **Sprinter Cart XL**
a stable, compact and multi-functional Workstation

Infusion pole (height-adjustable)

Handle for pulling and pushing

CARDIOHELP Emergency Drive on holder

Gas bottle holder (part 1)

*Electronic Gas Blender EGB 40**

Top shelf kit (height-adjustable)

*Heater Unit HU 35**

Gas bottle holder (part 2)

Standard rail

Shelf kit for heater unit (height-adjustable and extendable)

Medical isolating transformer with fixation system

Base tray provided with holes for mounting the isolating transformer

Equipotential bonding pin

Electrically conductive wheels with parking brakes

*These products are currently pending CE certification

Technical Data
At a glance

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

Technical Data	Cardiac Intervention Set
Flow rates	0.5 – 7 l/min
Gas exchange surface area	1.8 m2
Heat exchange surface area	0.4 m2
Priming volume QUADROX-iR	273 ml
Priming volume CI Set with 2 x 2.3 m tubing length	600 ml
Gas exchange fibers	Microporous membrane
Coating	Not coated*
Duration of use	Max. 6 hours
Integrated measuring cell	– venous oxygen saturation SvO2 – hemoglobin (Hb) – hematocrit (Hct) – venous temperature
Integrated sensors	–

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

*Except for QUADROX-iR oxygentor with SOFTLINE Coating


Artis

This brochure contains information about products which may be pending regulatory approval to be marketed in your country.
Contact your local Maquet representative for more information.

See instructions for use for full prescribing information, including indications, contraindications, warnings, precautions and adverse events.

MAQUET
GETINGE GROUP

Maquet Cardiopulmonary AG
Kehler Str. 31
76437 Rastatt, Germany
Phone: +49 7222 932-0
Fax: +49 7222 932-1888
info.cp@maquet.com

www.maquet.com

GETINGE GROUP

Getinge Group is a leading global provider of products and systems that contribute to quality enhancement and cost efficiency within healthcare and life sciences. We operate under the three brands of ArjoHuntleigh, Getinge and Maquet. ArjoHuntleigh focuses on patient mobility and wound management solutions. Getinge provides solutions for infection control within healthcare and contamination prevention within life sciences. Maquet specializes in solutions, therapies and products for surgical interventions, interventional cardiology and intensive care.

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