PulsioFlex Monitoring Platform

Flexible and patient-focused advanced hemodynamic monitoring

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

GETINGE

Making therapeutic decisions is not easy

Let us help

The PulsioFlex Platform for advanced hemodynamic patient monitoring is easily adaptable to every patient's individual needs and specific physician requirements, at all times.

- Adjustable to various clinical settings (OR, ER, ICU)
- Specific to the physicians need for information
- Easily scalable to patient's risk level

Intelligent visualization for advanced patient monitoring

- Brilliant 8" LED color touch screen with high resolution
- Glass touch screen and intuitive user interface
- Space saving thanks to minimal dimensions and low weight
- Flexible mounting and installation possibilities
- Modular expandability with automatic module detection
- Network compatible e.g. print function via clinic network

By your side

Patient-centered flexibility

The PulsioFlex Monitoring Platform is a flexible, patient-focused hemodynamic monitoring device. This convenient and compact bedside monitor is easy to set up and assists users through smart and intuitive handling – to help guide the next therapeutic steps.

Identify your patients' risk level continuously and intuitively

PulsioFlex offers the possibility to choose between different pre-configured displays which can be individually adjusted. The special color concept provides a comprehensive picture of the measured parameters. An example is the 'Spider-View' feature which shows an overview of the most important parameters at a glance. When the spider changes color, the patient's condition has changed.

Stay continuously updated about any change in your patient's condition – enable immediate and purposeful adjustment of treatment.

Additional benefits:

- Expandable modular design – ready for future technologies
- Usable as stand-alone monitor
- Simple set-up through individually coded cables
- Intuitive menu guidance

PulsioFlex

Platform setup

At a certain point you will need more information about your patient's hemodynamic condition.

The PulsioFlex Monitoring Platform combines the technologies of PiCCO, ProAQT, CeVOX and LiMON. This will give you the information you need to help assess the hemodynamic status of your critically ill patient, on-site.

Get the complete picture with:

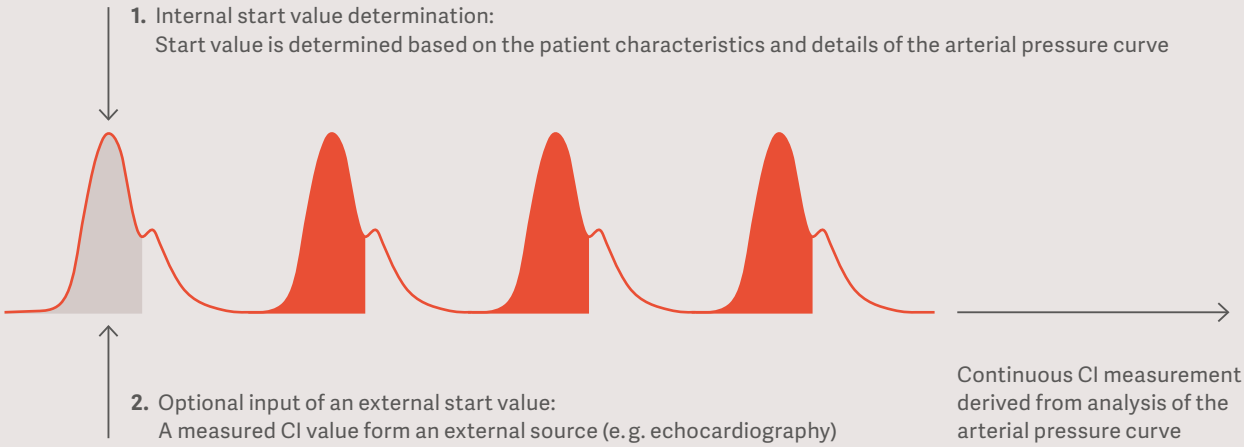
- Calibrated cardiac output monitoring with PiCCO
- Minimally invasive peri-operative cardiac output trend monitoring with ProAQT
- Continuous central venous oxygen saturation monitoring with CeVOX
- Non-invasive global liver function monitoring with LiMON

ProAQT Technology

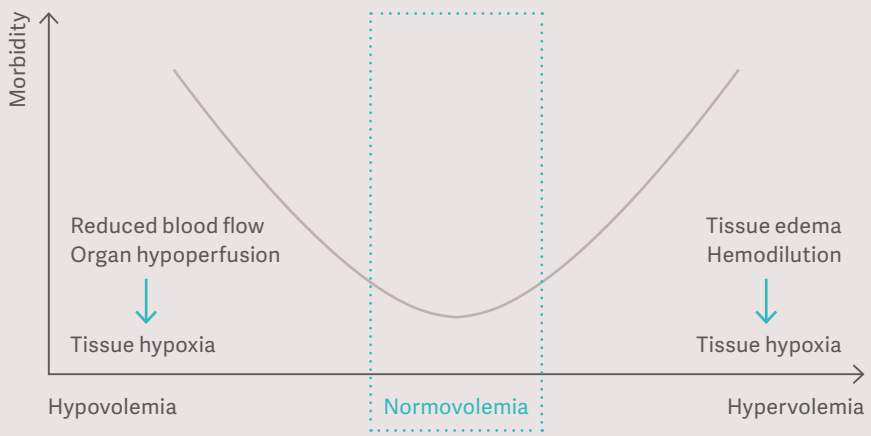
Peri-operative fluid optimization

Beat-to-beat cardiac output and volume responsiveness based on arterial pulse contour analysis with ProAQT.

ProAQT principle and calibration procedure



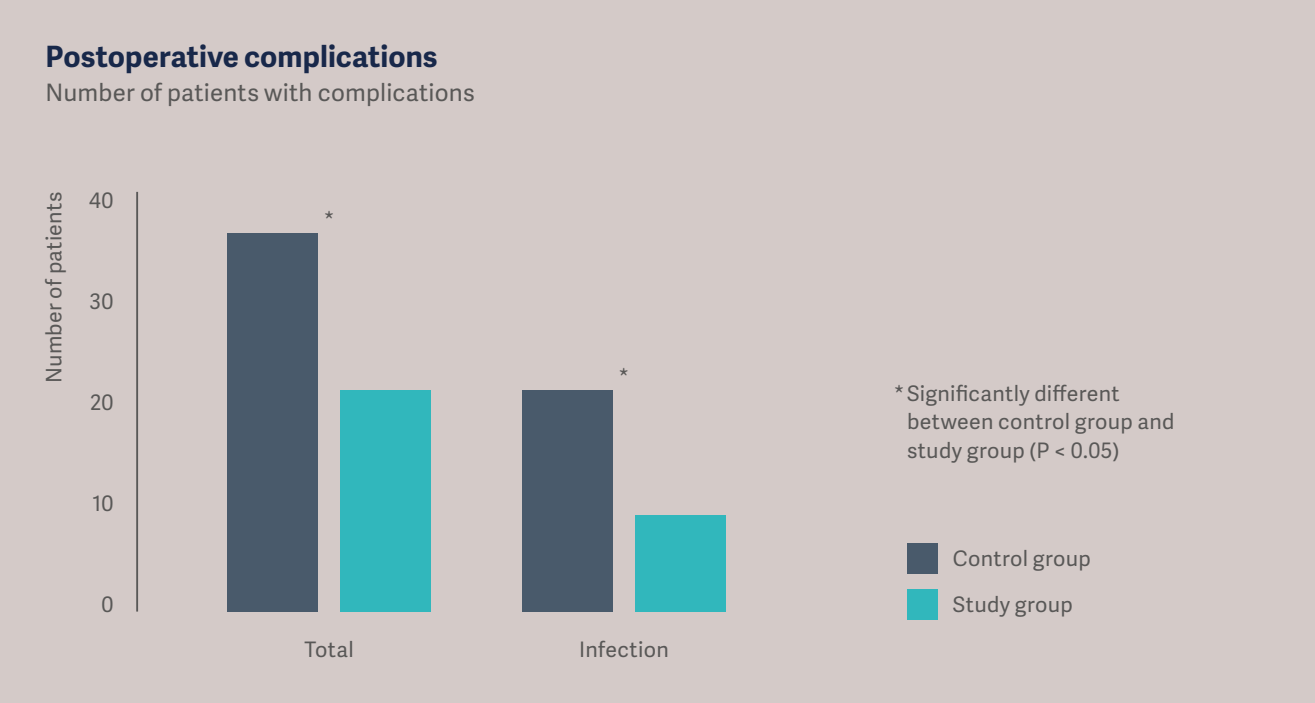
Individualized fluid therapy helps avoid hypervolemia or hypovolemia (and) related complications [1]



ProAQT is applicable for:

- Complex procedures with high-risk of intra- and post-operative complications
- Anticipated high blood loss (> 20%) and volume shifts during procedure which can result in hypo- or hypervolemia
- Protracted surgery time (> 120 min)

Improve outcome in major abdominal surgery



»... hemodynamic goal-directed therapy using pulse pressure variation, cardiac index trending and mean arterial pressure as the key parameters leads to a decrease in postoperative complications in patients undergoing major abdominal surgery« [2]

PiCCO Technology

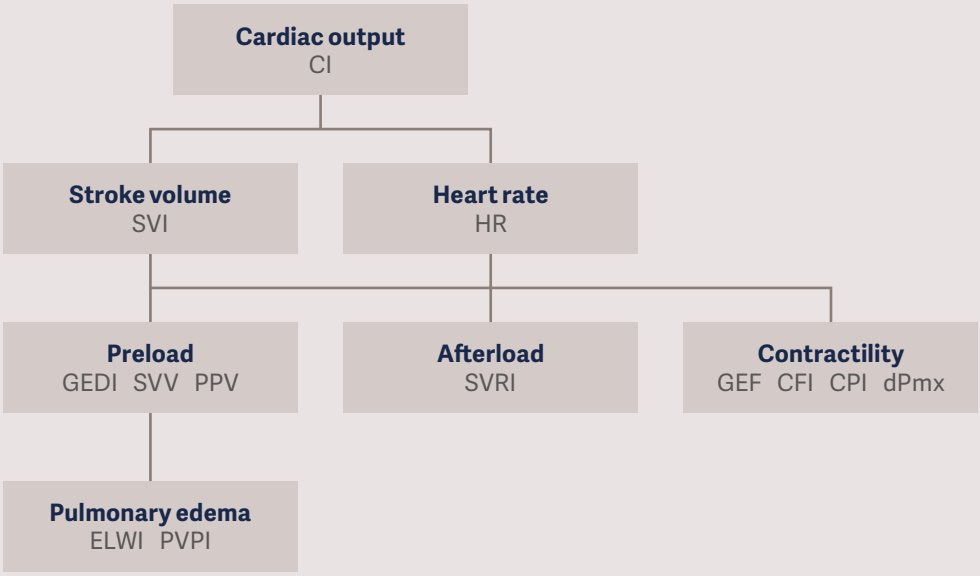
Get the complete picture of the hemodynamic situation in critically ill patients

PiCCO Technology is based on two physical principles: transpulmonary thermodilution and pulse contour analysis. Both principles allow the calculation of advanced hemodynamic parameters and have been clinically tested and established for more than 20 years.[3,4]

PiCCO helps you to answer these questions:

- What is the current cardiovascular situation?
- What is the cardiac preload and afterload?
- Is the patient fluid responsive?
- Is the patient developing lung edema?

Hemodynamic parameters



Simplify hemodynamics

- Clinically proven and widely accepted minimally-invasive alternative to the pulmonary artery catheter
- The precise PiCCO parameters allow physicians to perform patient-individualized therapy with optimal use of inotropes and vasopressors
- PiCCO enables the measurement of extra-vascular lung water for pulmonary edema assessment

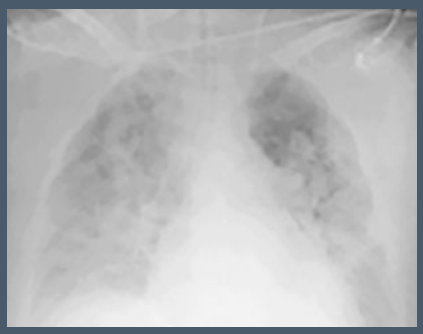
»PiCCO provides a comprehensive picture of the haemodynamic condition through relevant information on preload responsiveness indexes, cardiac output and extravascular lung water. In critically ill patients and particularly in those with both cardiovascular and respiratory disorders, PiCCO thus allows clinicians to take rapidly appropriate decisions on when to start, to continue and to stop fluid administration.«

Jean-Louis Teboul, MD, Professor Service de Réanimation médicale, Centre Hospitalier Universitaire de Bicètre, Paris, France

PiCCO Technology offers direct and accurate bedside quantification of pulmonary edema by measuring extravascular lung water index (ELWI). This enables sensitive and early detection of the development of pulmonary edema and allows early therapeutic intervention before the pulmonary edema can cause alveolar damage or complications. The ELWI measurement is significantly more accurate than pulmonary edema estimation from chest X-rays.[5–7]

Examples of chest X-rays that do not reflect the level of pulmonary edema

ELWI = 21 ml/kg
Severe pulmonary edema



ELWI = 14 ml/kg
Moderate pulmonary edema

ELWI = 8 ml/kg
No pulmonary edema

Pulmonary edema is not easily detected by chest X-rays as shown above. ELWI is more sensitive than chest X-ray.[8]

O_2 CeVOX Technology

Sensitive continuous measurement of oxygen balance for early detection of tissue hypoxia

CeVOX Technology is based on spectrophotometry.

Infrared light of specific wave lengths is emitted by LEDs and transmitted through a fiber optic into the vessel.

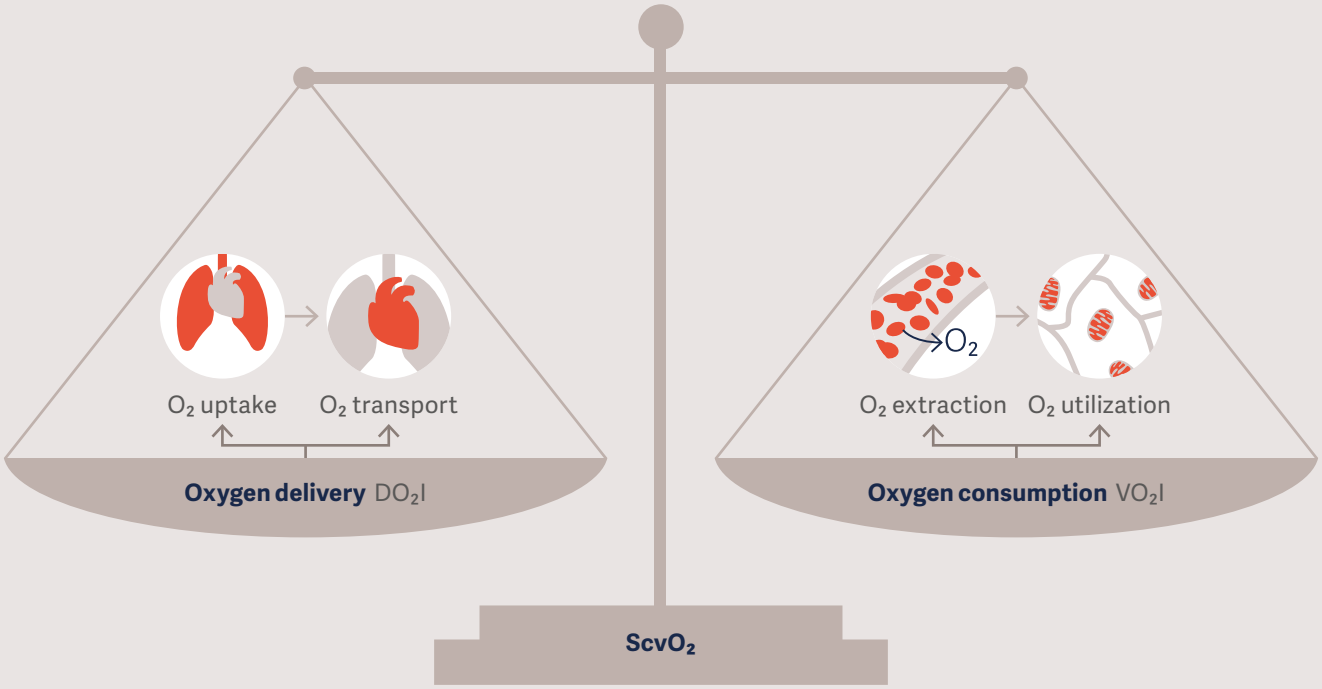
The light is then reflected by the red blood cells and transmitted back through a separate fiber optic to the optical module.

Enables early intervention

- Traditional vital signs may be late indicators of inadequate oxygen delivery to tissue
- Detects acute changes in systemic balance between oxygen delivery and consumption
- Tracks therapeutic effects immediately and continuously

Reduces complications and mortality

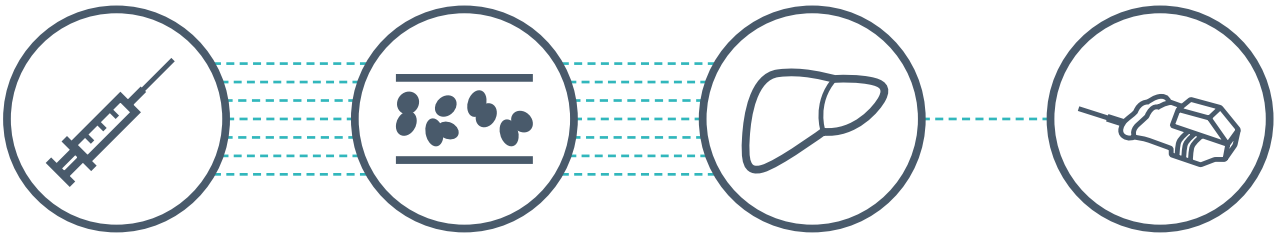
- Low $ScvO_2$ is related to an increased risk of post-operative complications in high-risk surgery[9]
- Decreases risk of infection by reducing frequency of BGA sampling
- Identifies early life-threatening drop in systemic oxygen delivery



LiMON Technology

Non-invasive global liver function assessment at the bedside

LiMON Technology detects the elimination of diagnostic dye indocyanine green (ICG) by modified pulse oximetry.



Intravenous injection of ICG

ICG binds immediately and completely to plasma proteins

ICG is exclusively eliminated by the liver into the bile

Non-invasive detection of the ICG signal by the LiMON Sensor

LiMON supports physicians in various applications

- Significantly better specificity and sensitivity than standard liver function tests [10]
- Quantification of remaining liver function before liver resection [11,12]
- Early identification of post-operative liver dysfunction in liver resection and transplantation [13–15]
- Identification of post-operative complications in liver surgery [16]

Overview

Technologies and parameters

Method		PiCCO	ProAQT	CeVOX	LiMON
Pulse contour analysis (continuous)	**Flow**	CI_{PC*}, SVI	$CI_{Trend/Cal**}$, SVI		
	Contractility	dPmx, CPI	dPmx, CPI		
	Afterload	SVRI	SVRI		
	Volume responsiveness	SVV, PPV	SVV, PPV		
Thermodilution (discontinuous)	**Flow**	CI_{TD***}			
	Preload	GEDI			
	Contractility	CFI, GEF			
	Pulmonary edema	ELWI, PVPI			
Oxymetry	**Oxygen saturation**			$ScvO_2$	
ICG elimination	**Liver function**				PDR, R15

* Cardiac index derived from pulse contour ** Calibrated from internal or external reference value
*** Cardiac index derived from thermodilution

Literature

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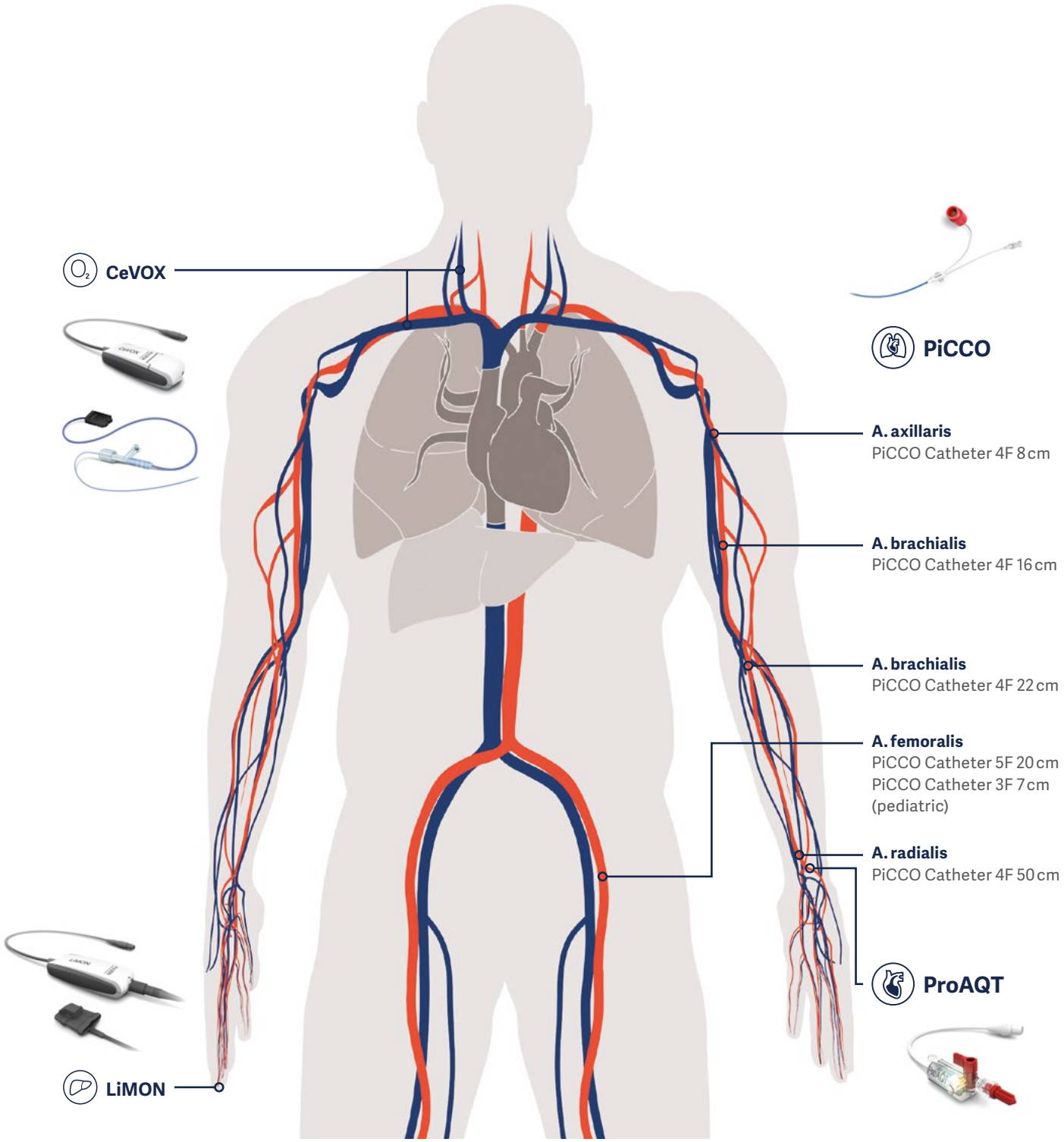
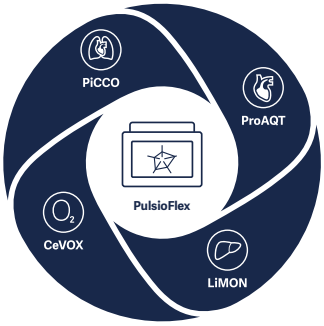
Recommended application sites

of PulsioFlex Technologies



Passion for life

Improving outcomes for critically ill patients



Advanced hemodynamic monitoring helps physicians understand complex conditions of patients in intensive care units and during high risk surgeries and helps to optimize their hemodynamic condition.

Pulsion's core competence is the development and production of medical devices for monitoring critically ill patients. Pulsion Medical Systems SE was founded in 1990 and is located in Feldkirchen, Greater Munich. Since 2014, Pulsion is wholly-owned by, and fully-integrated with, Getinge.

Getinge is a global provider of innovative solutions for operating rooms, intensive care units, sterilization departments and life science companies and institutions.

Based on our firsthand experience and close partnerships with clinical experts, healthcare professionals and medtech specialists, we are improving everyday life for people – today and tomorrow.

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