The Impact of Advanced Hemodynamic Monitoring

Value-based decision making with PiCCO

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

GETINGE

Application Areas & Clinical Challenges

General hemodynamic questions

Patients in shock are in an acute medical condition. Early diagnosis and intervention are life-saving factors. Hemodynamic instability and an unclear volume status make treatment more difficult and also lead to therapeutic conflicts.

Value-based and comprehensive information about the patient's condition is, therefore, an essential aspect for tailoring an individual and goal-directed therapy, which can reduce complications.*

In order to ensure a broad foundation of information, a range of parameters can be provided and used as a basis for therapy decisions. Below are the questions that should be addressed and answered.

* Salzwedel C., et al. Perioperative goal-directed hemodynamic therapy based on radial arterial pulse pressure variation and continuous cardiac index trending reduces postoperative complications after major abdominal surgery: a multi-center, prospective, randomized study. Crit Care 2013;17(5):R191.

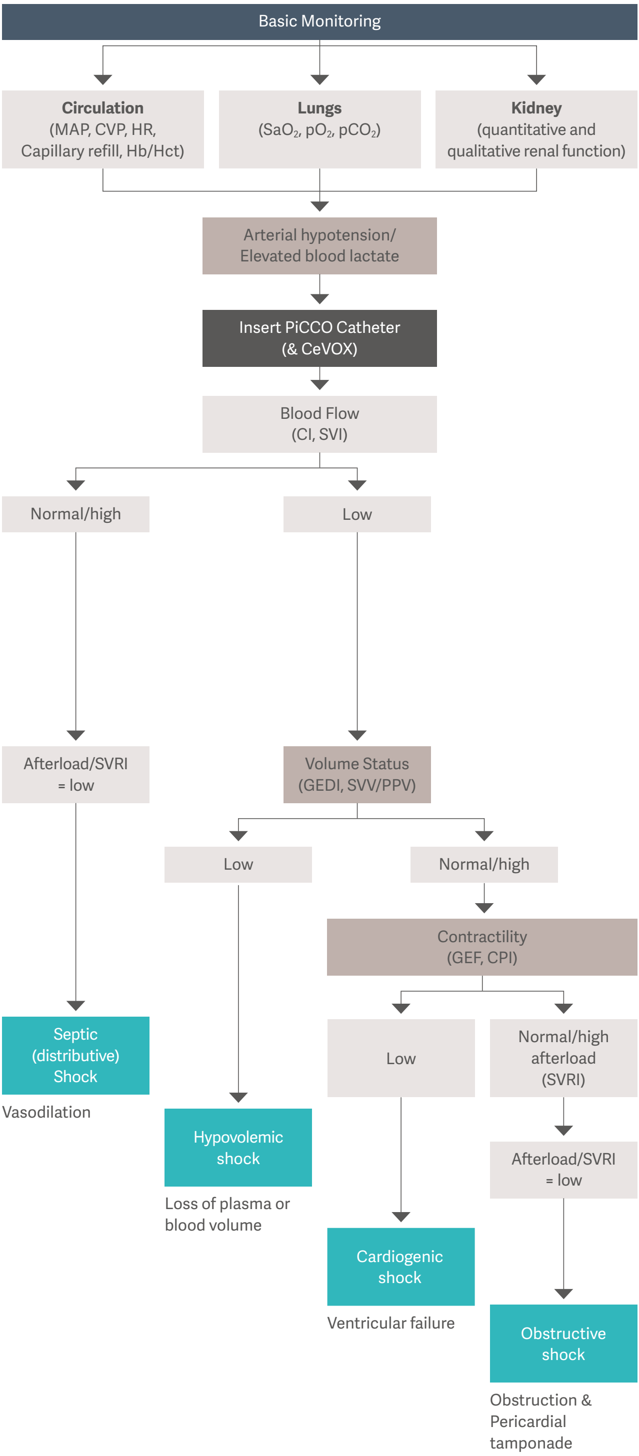
List of hemodynamic questions

General hemodynamic questions

Types of shock

Differentiation tree

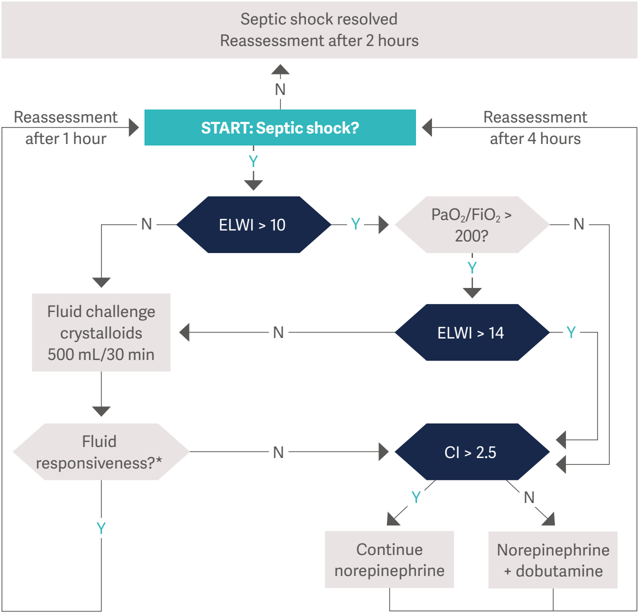
The following flow-chart can help identify the type of shock with the help of advanced hemodynamic parameters.



Based on Vincent JL et. al. J Med 2013; 369:1726-1734. DOI:10.1056/NEJMra1208943

Septic shock

Hemodynamic sepsis management within first 24 hours

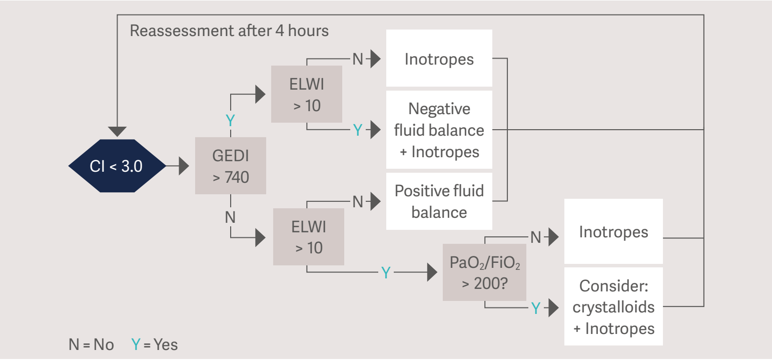


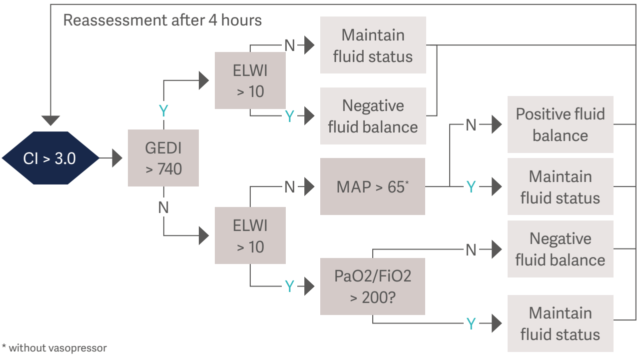
* Fluid responsiveness increase in CI ≥15% or increase in MAP ≥ 15% or increase in CI + increase in MAP ≥ 20%

▲▼ Based on Saugel et.al.; Advanced Hemodynamic Management in Patients with Septic Shock, Biomed Res Int. 2016;2016

Values measured in: CI = L/min/m² · GEDI = mL/m² · ELWI = mL/kg · MAP = mmHG

Hemodynamic sepsis manangement after first 24 hours





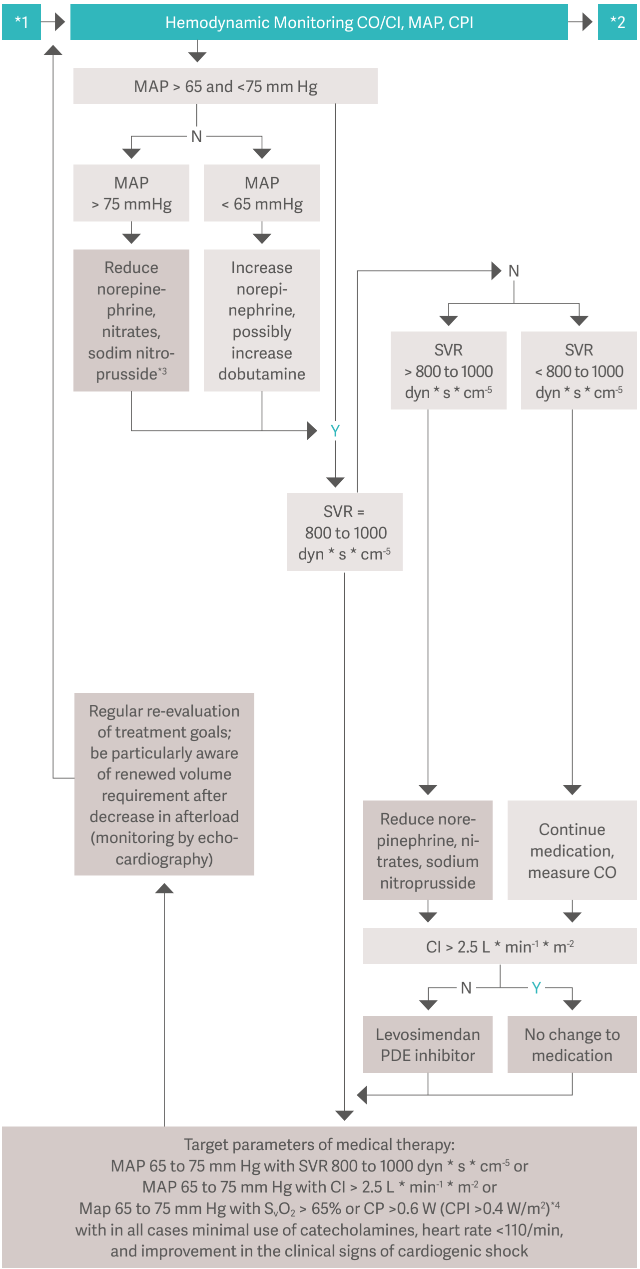
* without vasopressor

Septic shock

Cardiogenic Shock

Hemodynamic shock therapy

Hemodynamic shock therapy focuses on achieving adequate organ perfusion using the minimum of catecholamines.

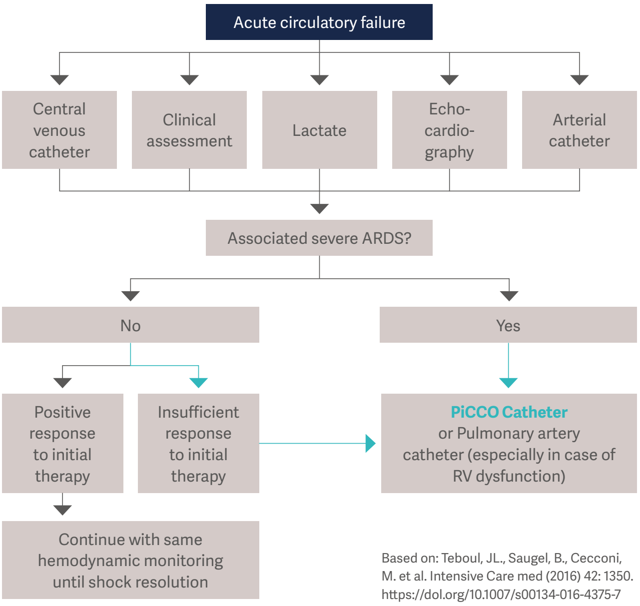


*1 Shock after revascularizatioin
*2 Treatment of MODS
*3 In patients with raised SVR, norepinephrine treatment is always ended before treatment with nitrates or sodium nitroprusside is started. ÖKG and ÖGIAIM (see Box 1) prefer treatment with nitroglycerine rather than sodium nitroprusside in patients with raised SVR, even though catecholamine treatment has been stopped
*4 CP > 0.6 W corresponds to a cardiac output of 5 L7min with an MAP of 65 mm Hg and SVR of 880 dyn x s x cm^{-5v}

Based on Werdan et. al. Dtsch Arztebl Int 2012; 109(19): 343–51; Cardiogenic Shock Due to Myocardial Infarction: Diagnosis, Monitoring and Treatment A German-Austrian S3 Guideline

ARDS

The following is the ESICM's recommended evaluation process regarding less invasive hemodynamic monitoring in critically ill patients:



Based on: Teboul, JL., Saugel, B., Cecconi, M. et al. Intensive Care med (2016) 42: 1350. https://doi.org/10.1007/s00134-016-4375-7

Getinge ICU algorithm

Targeted Values

• GEDI (ml/m2) (if ELWI >10 → 700-800)	> 700
• GEF (%)	> 25
• CFI (1/min)	> 5
• ELWI (ml/kg) (slow response)	≤ 10

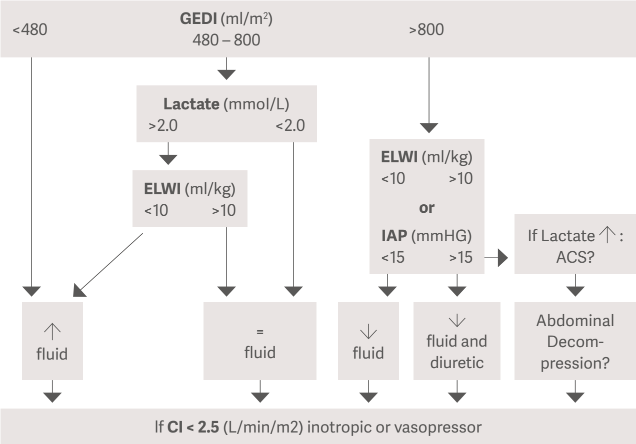
• Volume Responsiveness? (Passive Leg Raising / Endexpiratory Occlusion Test / Volume Challenge / SVV / PPV?)

• Contractility Problem? (GEF / CFI / Echo?)

V+ = volume loading V- = volume withdrawal Cat = cardiovascular agents
Please reevaluate your clinical decisions and the set target parameters.

Severe burn injuries

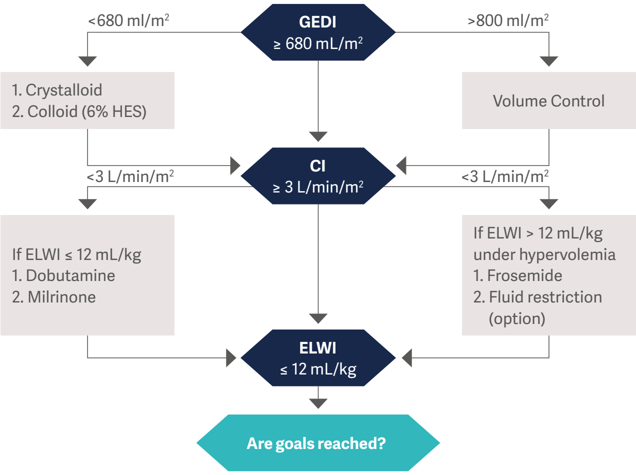
Diagram of a decision tree for the adjustment of fluid and catecholamine therapy according to a permissive hypovolemia protocol with lower preload targets and lactate measurements to ensure tissue perfusion.



Based on Sánchez et al. Critical Care 2013, 17:R176
http://ccforum.com/content/17/4/R176

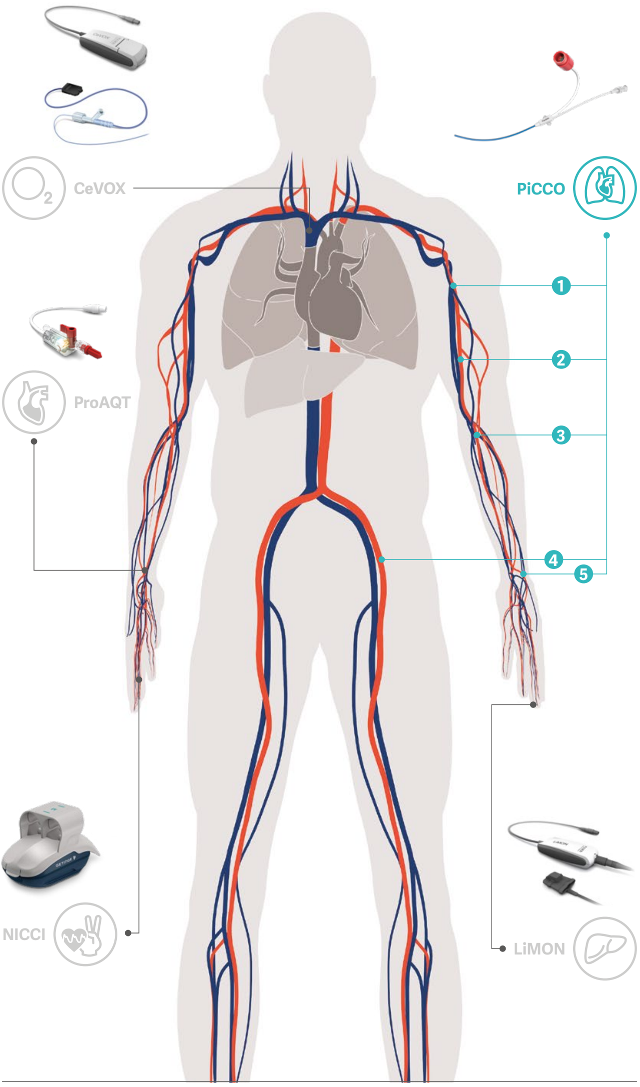
Subarachnoid hemorrhage

Algorithm for baseline hemodynamic management during early goal-directed fluid therapy (EGDT) guided by transpulmonary thermodilution using the PiCCO Technology.



Based on Mutoh T et.al. Early intensive versus minimally invasive approach to postoperative hemodynamic management after subarachnoid hemorrhage. Stroke, 2014;45:1280-4

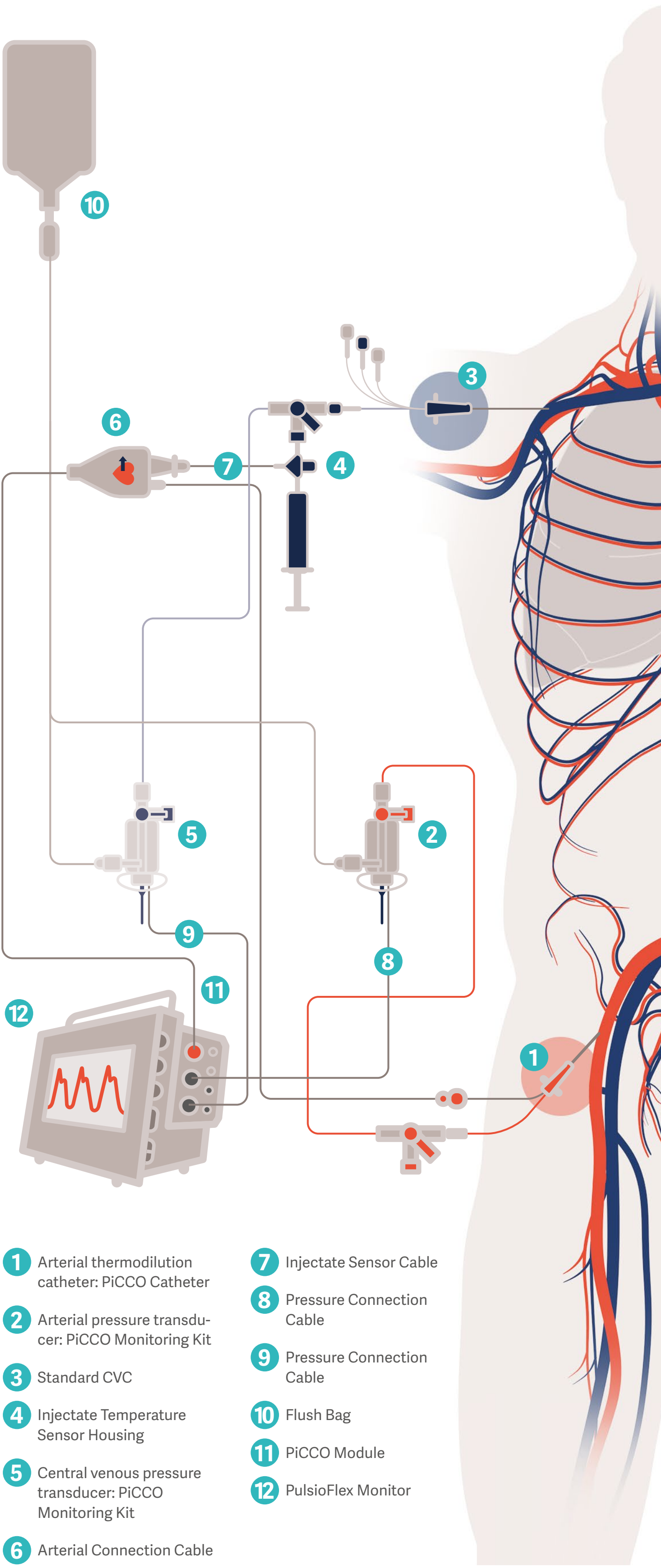
Recommended application sites of PiCCO



1. **A. axillaris**
   PiCCO Catheter 4F 8 cm
2. **A. brachialis, proximal**
   PiCCO Catheter 4F 16 cm
3. **A. brachialis, cubital**
   PiCCO Catheter 4F 22 cm
4. **A. femoralis**
   PiCCO Catheter 5F 20 cm
   PiCCO Catheter 3F 7 cm (children & infants)
5. **A. radialis**
   PiCCO Catheter 4F 50 cm

Recommended application sites

PiCCO connection scheme



1 Arterial thermodilution catheter: PiCCO Catheter

2 Arterial pressure transducer: PiCCO Monitoring Kit

3 Standard CVC

4 Injectate Temperature Sensor Housing

5 Central venous pressure transducer: PiCCO Monitoring Kit

6 Arterial Connection Cable

7 Injectate Sensor Cable

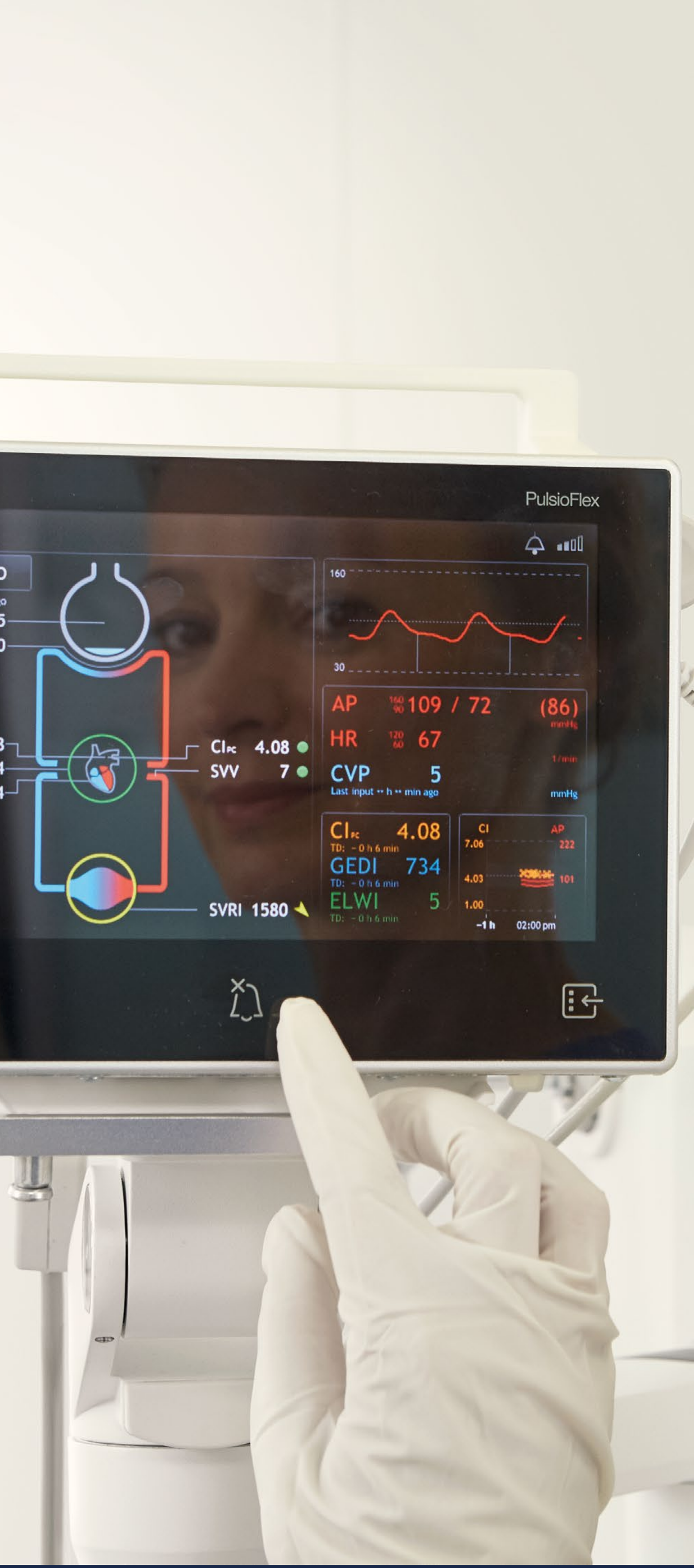
8 Pressure Connection Cable

9 Pressure Connection Cable

10 Flush Bag

11 PiCCO Module

12 PulsioFlex Monitor

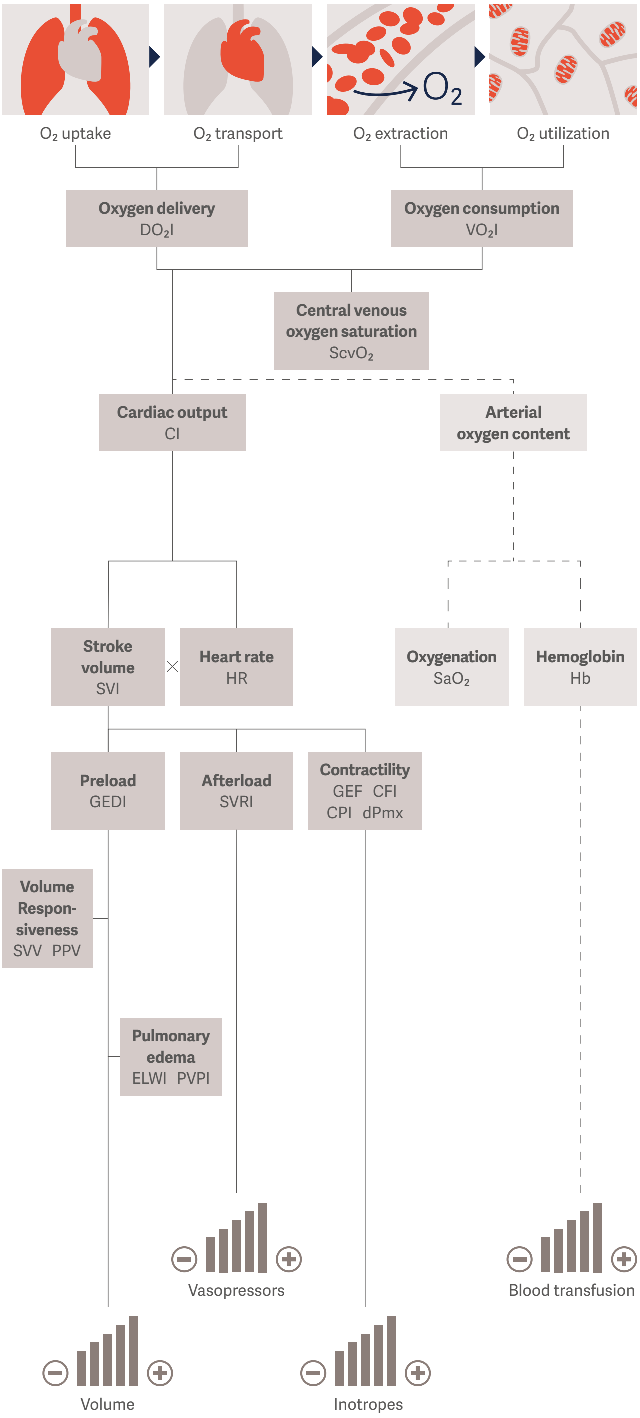


Basics of Hemodynamic Monitoring

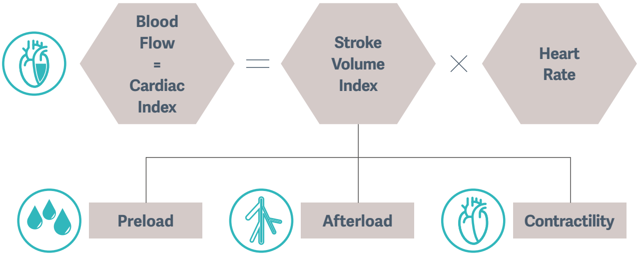
PiCCO Parameter

Basic physiology
Hemodynamic parameters

PiCCO provides a complete picture of the hemodynamic situation of your patients. The PiCCO parameters such as cardiac output and its determinants (preload, afterload, contractility) as well as the quantification of pulmonary edema contribute to optimal and patient-oriented treatment.



Blood Flow and it's determinants



CI – Cardiac Index

- Cardiac index is the amount of blood pumped by the heart per minute indexed to the body surface area (BSA).
- Cardiac index is the product of heart rate and stroke volume index and represents the global blood flow

OK **CI** 3.0 – 5.0 l/min/m^2

SVI – Stroke Volume Index

- Stroke volume is the ejection of blood per heart beat
- Stroke volume is determined by preload, afterload and contractility

OK **SVI** 40 – 60 ml/m^2

HR – Heart rate

- Heart Rate is the amount of heart beats per minute
- Heart rate (HR) ist the electrial conductive signal
- Pulse rate (PR) is the mechanical signal derived from the arterial pressure curve

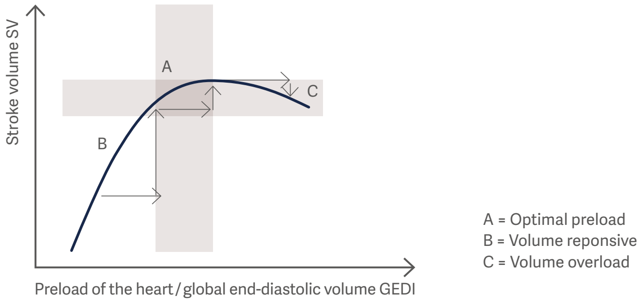
OK **HR/PR** 60 – 100 1/min

Blood flow and it's determinants

Preload

In the clinical setting, preload is referred to as the end-diastolic pressure or (more precisely) end-diastolic volume

Schematic Frank-Starling curve for verification of the preload status



GEDI – Global End-diastolic Volume Index

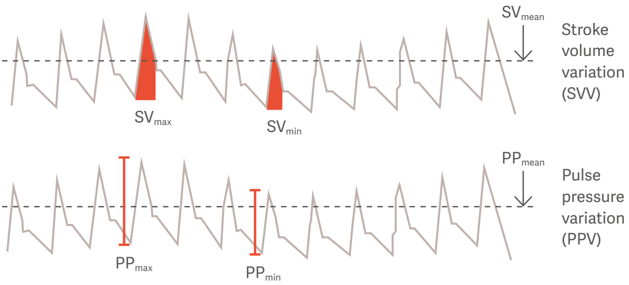
- Represents the end-diastolic filling volume of all four heart chambers before contraction and ejection
- Marker of preload volume

OK **GEDI** 680 – 800 ml/m²

Volume responsiveness

SVV – Stroke Volume Variation
PPV – Pulse Pressure Variation

- Predicts the reaction of cardiac output to volume loading
- Preconditions for the:
  - Fully controlled mechanical ventilation with a tidal volume ≥ 8ml/KG PBW (predicted body weight)
  - Sinus rhythm
  - No artifact on pressure curves

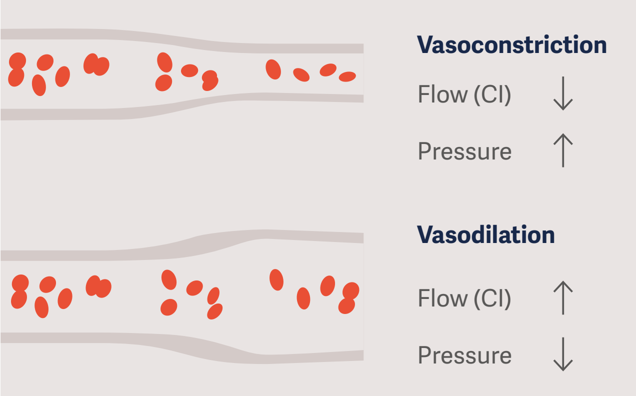


OK **SVV/PPV** < 10%

Afterload

SVRI – Systemic Vascular Resistance Index
Measurement of the vascular resistance which the heart has to pump against.

SVRI 1700 – 2400 dyn*s*cm^{-5}*m^{2}



Contractility

GEF – Global Ejection Fraction

- Percentage of volume ejected with every single contraction
- GEF provides information regarding global contractility of the heart (right and left)

CFI – Cardiac Function Index

- Calculated via the relation of cardiac output (CO) and global end-diastolic volume (GEDV)
- Preload related global cardiac performance parameter

GEF 25 – 35%
CFI 4.5 – 6.5 1/min

CPI – Cardiac Power Index

- Surrogate parameter for global cardiac performance
- Best predictive parameter for mortality in patients with cardiogenic shock

CPI 0.5 – 0.7 W/m^2

dPmx – Left Ventricular Contractility

- Surrogate parameter for left ventricular contractility
- Only to be used as trend information

dPmx Trend Information mmHg/s

Pulmonary edema

ELWI – Extravascular Lung Water Index

- Quantification of the intracellular, interstitial and intra-alveolar water content of the lung (not pleural effusion)
- Direct and easy bedside measurement
- Sensitive detection of pulmonary edema

ELWI 3.0–7.0 ml/kg

PVPI – Pulmonary Vascular Permeability Index

- Relationship between extra and intravascular fluids in the lungs
- Differentiation of the cause of the pulmonary edema (permeability or cardiogenic)

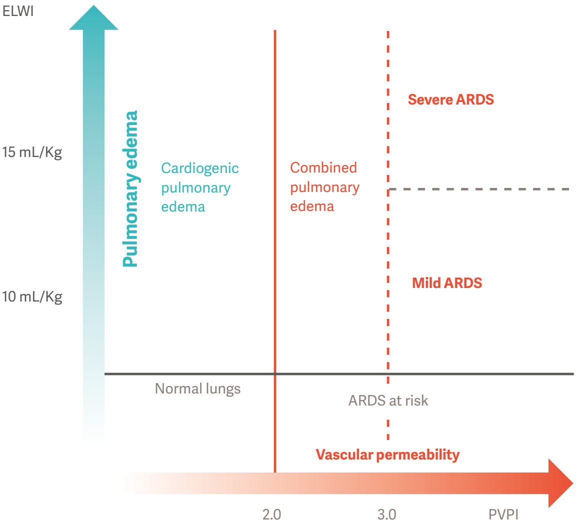
PVPI
<3 Cardiogenic pulmonary edema
>3 Permeability pulmonary edema

Contractility & Pulmonary edema

Accurate and objective diagnoses can be made for ARDS patients using ELWI and PVPI.

PVPI more than 3 with ELWI >10 ml/kg represents increased permeability pulmonary edema, or ARDS.

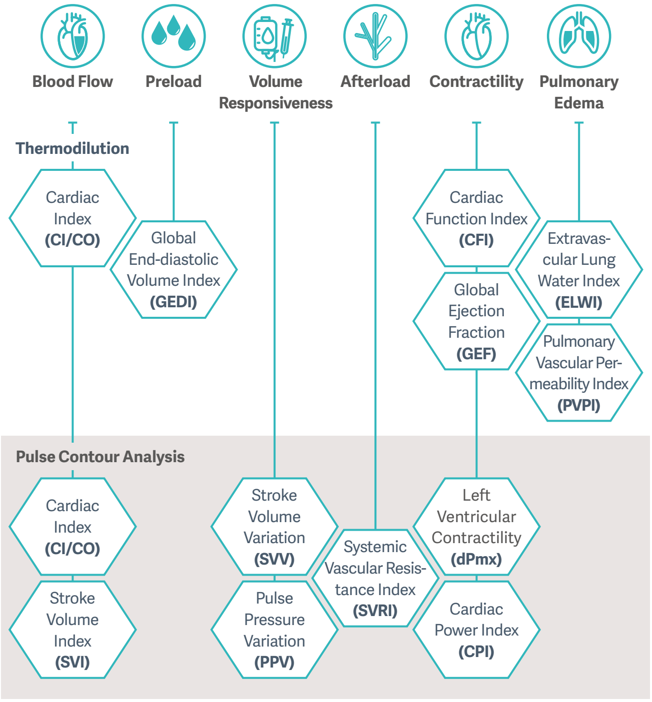
Diagnostic framework for pulmonary edema



Based on Tagami T, Ong MEH. Extravascular lung water measurements in acute respiratory distress syndrome: why, how, and when? Curr Opin Crit Care. 2018 Jun;24(3):209-215.

PiCCO Parameter

The complete picture



Pulmonary edema & PiCCO parameters

Hemodynamic normal values

		Central Venous Oxygenation - Oxygenation Balance (Oxygen load of the venous blood after passing through the organs)	$ScvO_2$*	70-80 %
		O_2 Consumption (Consumption of O_2 by organs)	VO_2I	125-175 ml/min/m²
Oxygen Delivery		O_2 Delivery (Delivery of O_2 via blood to organs)	DO_2I	400-650 ml/min/m²
Oxygen Delivery		Hemoglobin (Oxygen transporter in blood)	Hb**	8.7-11.2 mmol/l (Male) 7.5-9.9 mmol/l (Female)
Oxygen Delivery		Arterial / capillary oxygen saturation (Oxygen load of arterial blood)	SaO_2 / SpO_2	96-100 %
Blood FLow	Flow	Cardiac Index (Trend, Cal, td, PC)	CI	3.0-5.0 l/min/m²
Blood FLow	Chronotropy	Heart Rate/ Pulse Rate	HR/PR	60-100 1/min
Stroke Volume	Preload	Stroke Volume Index (Output per heart beat)	SVI	40-60 ml/m²
Stroke Volume	Preload	Global Enddiastolic Volume Index (Volume of blood in the heart)	GEDI	680-800 ml/m²
Stroke Volume	Preload	Intrathoracic Blood Volume Index (Volume of blood in heart & lungs)	ITBI	850-1000 ml/m²
Stroke Volume	Preload	Stroke Volume Variation (Dynamic fluid responsiveness)	SVV***	<10 %
Stroke Volume	Preload	Pulse Pressure Variation (Dynamic fluid responsiveness)	PPV***	<10 %
Stroke Volume	Afterload	Systemic Vascular Resistance Index (Resistance of vascular system)	SVRI	1700-2400 dyn*s*cm⁻⁵*m²
Stroke Volume	Afterload	Mean Arterial Pressure	MAP	70-105 mmHg
Stroke Volume	Contractility	Global Ejection Fraction (Ratio of stroke volume & preload)	GEF	25-35%
Stroke Volume	Contractility	Left Ventricular Contractility (Increase of arterial pressure over time)	dPmx	Trend info - mmHg/s
Stroke Volume	Contractility	Cardiac Function Index (Ratio of CI and preload)	CFI	4.5-6.5 1/min
Stroke Volume	Contractility	Cardiac Power Index (Global cardiac performance)	CPI	0.5-0.7 W/m²
	Lung	Extravascular Lung Water Index (Lung edema)	ELWI	3.0-7.0 ml/kg
	Lung	Pulmonary Vascular Permeability Index (Permeability of lung tissue)	PVPI	1.0-3.0
	Liver	Plasma Disappearance Rate ICG (Performance of the liver)	PDR	18-25 %/min
	Liver	Retention rate of ICG after 15 minutes (Performance of the liver)	R15	0-10 %

Absolute values (non-indexed values) are only usable in trend screens and have no normal range.

* A high-normal / high $ScvO_2$ can be a sign of insufficient O2 utilization
** 14-18 g/dl (Male); 12-16 g/dl (Female)
*** SVV and PPV are only applicable in fully ventilated patients with a tidal volume ≥ 8 ml/kg PBW (predicted body weight) and without cardiac arrhythmias

OEM Partner modules

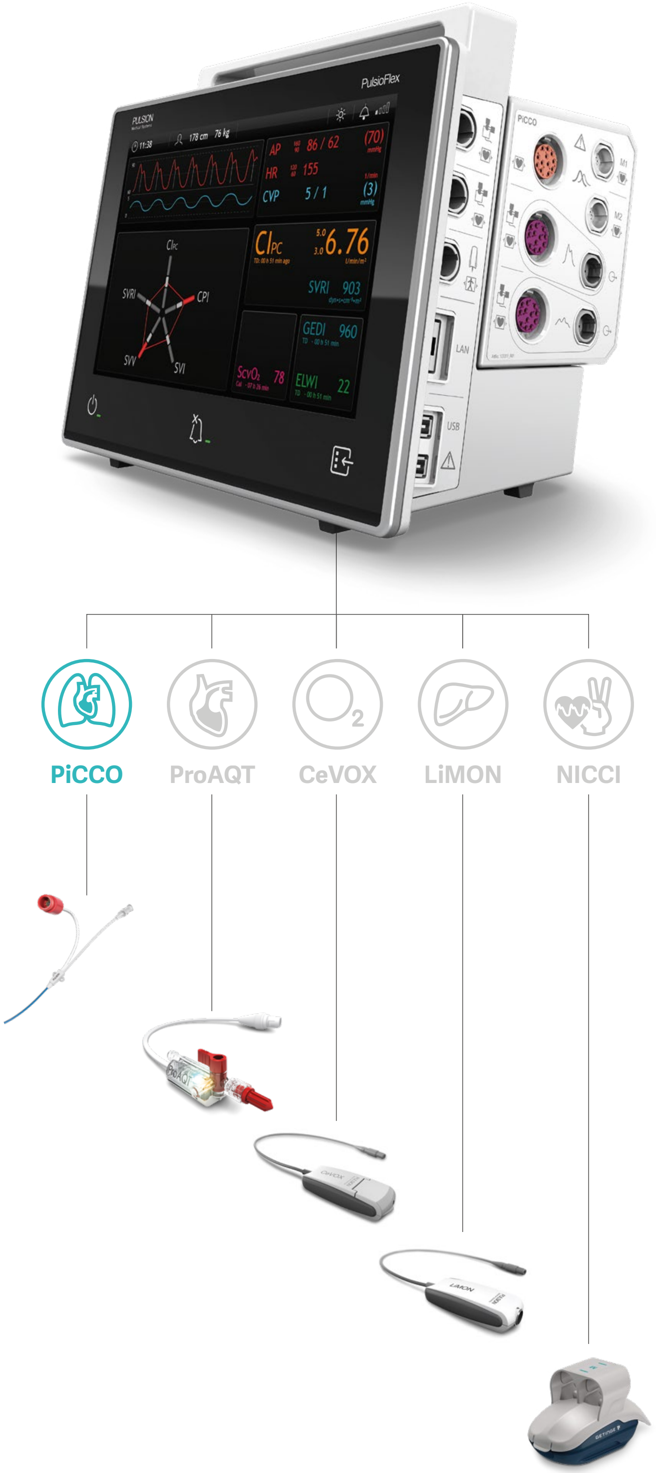
Patient centered flexibility

The versatile PiCCO Technology has been developed to match and adapt to different clinical settings.

To allow easy integration into your existing product portfolio, Getinge is partnering with various monitoring companies like GE, Philips, Dräger, Mindray, and Nihon Kohden.

Getinge modules can be implemented seamlessly with negligible footprint and maintaining the already familiar user interface. All while relying on the clinically well-proven and documented advantages of PiCCO Technology.

All OEM partner modules are fully compatible with the original PiCCO disposable products.



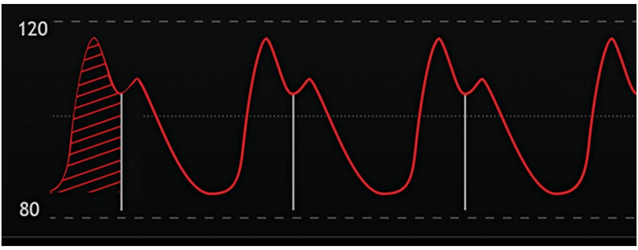
PiCCO Principle & Data Interpretation

Questions & Answers

PiCCO Technology measurement principle

Arterial pulse contour analysis

The pulse contour analysis provides continuous information, while transpulmonary thermodilution provides intermittent measurements. Transpulmonary thermodilution is used to calibrate the continuous pulse contour parameters.

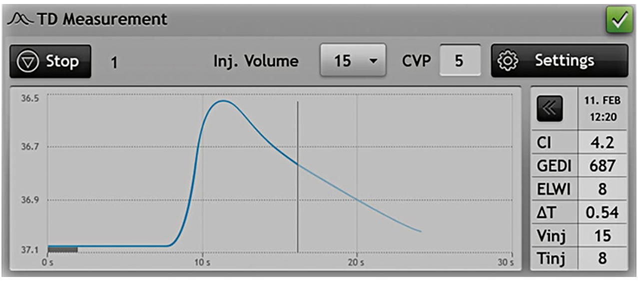


Arterial pulse contour analysis. The shaded area below the systolic part of the pressure curve is proportional to the stroke volume.

Transpulmonary thermodilution

For the transpulmonary thermodilution measurement, a defined bolus (e. g. 15 ml cold normal saline) is injected via a central venous catheter.

The cold bolus passes through the right heart, the lungs, the left heart and is detected by the PiCCO catheter, commonly placed in the femoral artery. This procedure should be repeated around three times in under 10 minutes to ensure an accurate average is used to calibrate the device and to calculate the thermodilution parameters. These thermodilution parameters should be checked whenever there is a significant change in the patient's condition or therapy. It is recommended to calibrate the system at least 3 times per day.



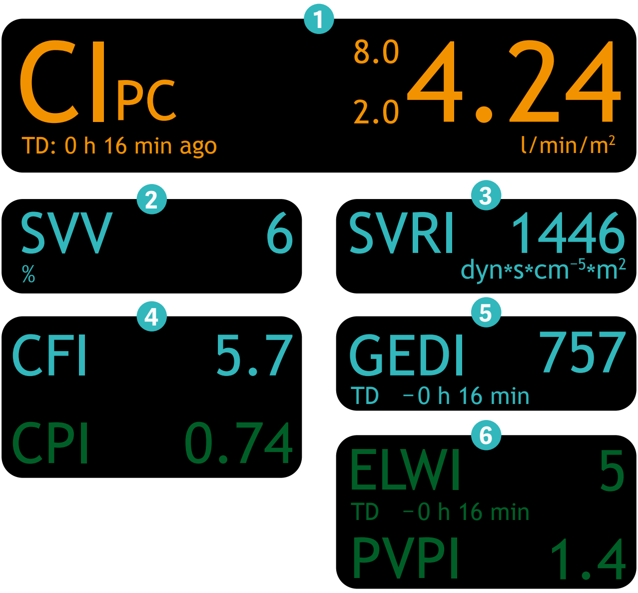
Transpulmonary thermodilution

Visualization

Graphical presentation of measurement results

Data interpretation

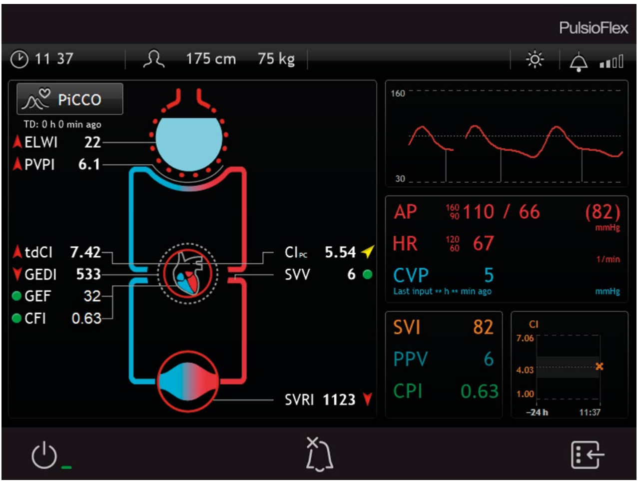
General physiological assignment of PiCCO parameters



1 Blood flow
2 Volume responsiveness
3 Afterload
4 Contractility
5 Preload
6 Pulmonary edema

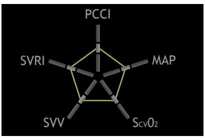
Organ View

The Organ View gives a graphical overview of the organ related parameters and can help identify values out of the normal range at a glance.

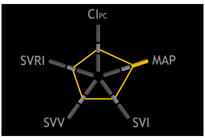


Spider Vision

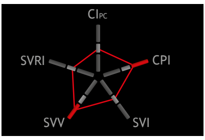
- Traffic light system for simple risk evaluation
- Configurable detection of dynamic changes



Green: all parameters in normal range



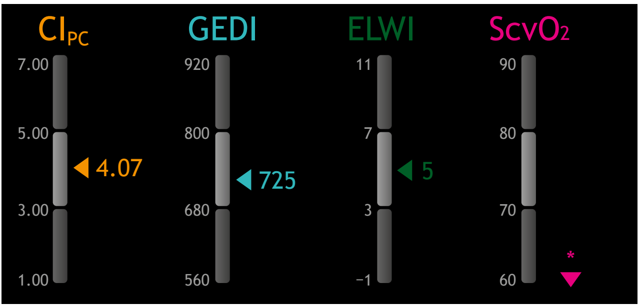
Yellow: one parameter outside the normal range



Red: more than one parameter outside the normal range

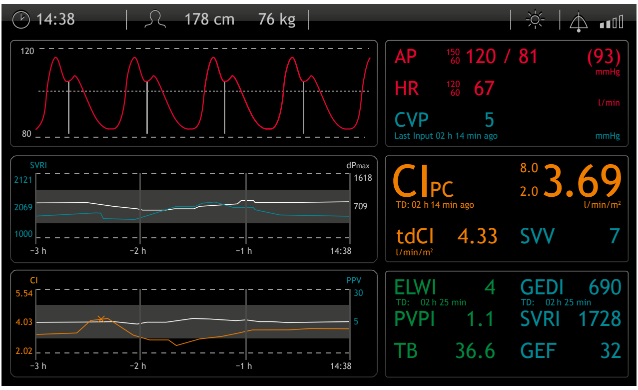
Profile

- Detailed parameter information in relation to normal ranges to support therapeutic decisions
- Selectable categories: circulation, volume status, organ function, oxygenation



Trends – clinical trends and therapy success

- Enables tracking of changes due to therapeutic interventions
- Flexible shifting & scaling options



Questions & answers

Contraindications
PiCCO Catheters are not intended for any use other than which is indicated. The catheter may not be used in patients where the placement of an indwelling arterial catheter is contraindicated e.g. in the case of arterial prostheses, insufficient perfusion, or tissue damages around the puncture site as well as severe peripheral vascular diseases. A PiCCO Catheter should only be used if the expected results are reasonable in comparison to the risks.

Application restrictions
No restrictions in adult patients. Minimum body weight at least 10 kg.

PiCCO catheter length of stay
The catheters for femoral, axillary, and brachial arteries are intended for the use of up to 10 days. In the case of complications, they have to be removed immediately (exception: long radial artery catheter PV2014L50-A max. 3 days). PiCCO monitoring kit length of stay: it is recommended to change the PiCCO monitoring kit every 4 days or as per the hospital's regulations.

MRI compatibility
The compatibility of the PiCCO catheter with MRI systems cannot generally be confirmed. The final decision to leave the PiCCO catheter in place during MRI is up to the attending physician.

Hypothermia
No influence on the thermodilution measurement, as long as the patient's temperature is stable. Cooled injectate should be used (approx. 4°C).

Fluctuating blood temperature
Will be compensated for by the device, as long as the temperature drift is less than 0.15° C per minute.

Find more frequently asked questions on our website:

Scan the QR-Code an download our PiCCO Technology Questions and Answers Brochure

Special clinical situations

Possible interference with the PiCCO measurement parameters

	CI_{TD}	GEDI	ELWI	CI_{PC}
Left-to-right heart shunt	?	▲	▲	?
Right-to-left heart shunt	?	?	?	?
Cross-talk phenomenon	✓	?	✓	✓
Continuous renal replacement therapy (CRRT)*	✓	✓	✓	✓
Extracorporeal membrane oxygenation (ECLS/ECMO in VV mode)	✓	▲	▲	✓
Severe cardiac valve insufficiency	✗	✗	✗	✗
Moderate cardiac valve insufficiency	✓	✗	✗	✓
Partial lung resection	✓	✓	▼	✓
Massive pulmonary embolism	✓	✓	▼	✓
Pleural effusion	✓	✓	✓	✓
Abdominal aortic aneurysm	✓	▲	✓	✓
Severe cardiac arrhythmia	✓	✓	✓	✗
Mild to moderate cardiac arrhythmia	✓	✓	✓	✓
Intra-aortic balloon pump (IABP)	✓	✓	✓	✗

✓ = Values will be correctly calculated
▲ = Value could be overestimated
✗ = Value is not calculated correctly
? = Value could be incorrectly calculated
▼ = Value could be underestimated

* Do not place CRRT catheter between between the point of injection and detection of PiCCO injectate solution.

PiCCO thermodilution measurements check list

Step-by-step approach

1. – Check arterial pressure signal, possibly flush pressure line
   – Check correct zeroing procedure

2. – Prepare cold saline solution (3x15ml minimum)
   – Start thermodilution at the device

3. – Observe screen messages and when recommended
   – Inject bolus rapidly and steadily into the distal lumen of the CVC

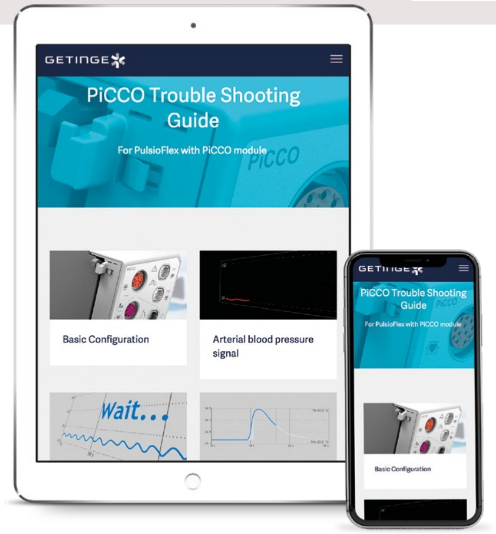
4. – Observe the thermodilution curve on the screen:
   – Check that ΔT≥ 0.2°, if not use more indicator (colder or more volume)

5. – Repeat STEP 2 to 4 until 3 satisfying measurements are obtained and confirm with calibrate (values deviations < 15% from the mean)

6. – Enter the CVP value (to calculate SVRI)

PiCCO practical help: visit the Trouble Shooting Guide

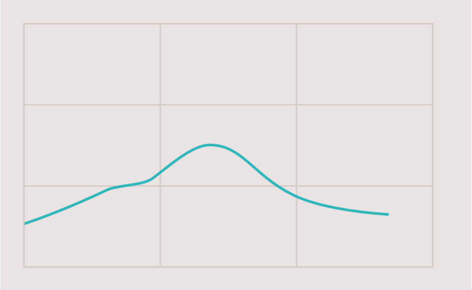
Scan the QR-Code an find our interactive PiCCO Trouble Shooting Guide



Interpretation of thermodilution curve

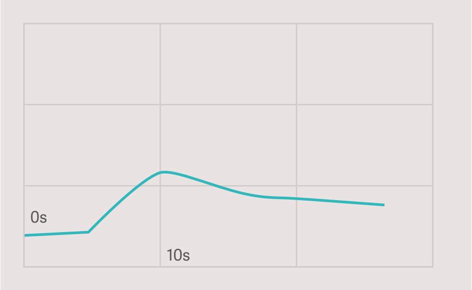
Cross-talk phenomenon

Venous and arterial catheters are placed on the same femoral side



Left-right cardiac shunt

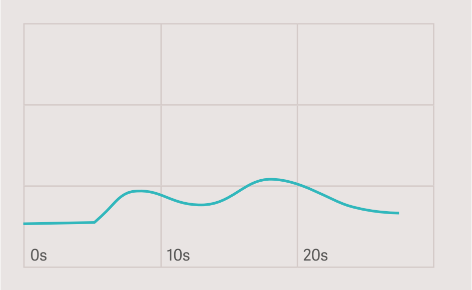
- Elongated downslope of the curve
- Volume parameters may be influenced (GEDI and ELWI overestimation)



Right-left heart shunt

Camel hump curve indicates a need for diagnosis via ultrasound/Echo

- Results of thermodilution questionable and should be considered carefully



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.

* Salzwedel C., et al. Perioperative goal-directed hemodynamic therapy based on radial arterial pulse pressure variation and continuous cardiac index trending reduces post-operative complications after major abdominal surgery: a multi-center, prospective, randomized study. Crit Care 2013;17(5):R191.

Simplify hemodynamics

Understand complex conditions with PiCCO

With a firm belief that every person and community should have access to the best possible care, Getinge provides hospitals and life science institutions with products and solutions aiming to improve clinical results and optimize workflows. The offering includes products and solutions for intensive care, cardiovascular procedures, operating rooms, sterile reprocessing and life science. Getinge employs over 10,000 people worldwide and the products are sold in more than 135 countries.

This document is intended to provide a general overview of the products and related information to an international audience outside the US. Indications, contraindictions, warnings and instructions for use are listed in the separate instructions for use. This document may be subject to modifications. Any reference values mentioned herein or any other product related information shall solely serve as a general information and are subject to modifications and updates according to the current state of science and do not replace the individual therapeutic decision of the treating physician. Products may be pending regulatory approvals to be marketed in your country. All graphics shown herein are produced by PULSION Medical Systems SE, unless otherwise noted.

Pulsion Medical Systems SE · Hans-Riedl-Str. 17
85622 Feldkirchen · Germany · +49 89 45 99 14-0
zentrale.pulsion@getinge.com

www.getinge.com