PiCCO-Technology

Intelligent diagnosis and therapy management
Trend-setting monitoring for the patient's benefit

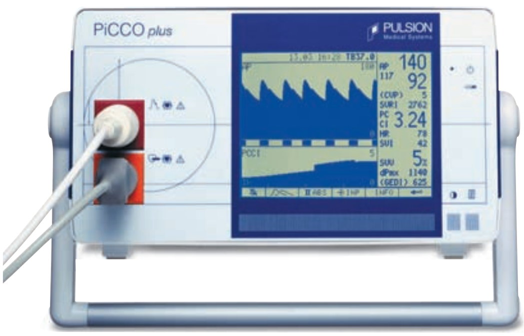
PULSION Device

PULSION
Medical Systems

PiCCO

...we find ourselves increasingly abandoning the PAC in favour of the PiCCO system, because the data on volume and extravascular lung water seem more physiologically and clinically relevant... [8]

Monitoring physiological parameters is essential for the goal directed management of critical care patients. Highly invasive monitoring methods have been established in clinical practice for many years, but are increasingly the centre of critical discussion. The PiCCO-Technology is the solution.



Indications and fields of application

PiCCO-Technology is the easy, less invasive and cost-efficient tool for determining the main hemodynamic parameters of critically ill patients.

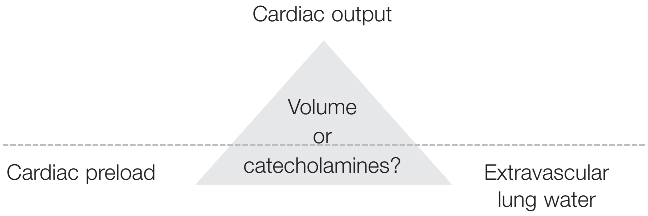
Diagnosis → Patient monitoring → Therapy guidance

In the intensive care unit:
Advanced monitoring of:
- Hemodynamic instability
- Shock
- Sepsis
- Lung injury
- Pulmonary edema
- Organ failure

In the Operating Room (OR):
Advanced monitoring of:
- High risk patients
- High risk interventions
- Extreme volume shifts

Prevention of
- Perioperative circulatory complications and pulmonary edema

PiCCO-Technology monitors the “hemodynamic triangle” of the patient and answers the key question “volume or catecholamines?”



Correct monitoring enables correct therapy

The principal objective of intensive therapy is to ensure optimal oxygenation of the organism [6]. Physiological metabolism, adequate delivery of substrates and pharmaceuticals and eventually recovery of organs and tissues is only possible when this is the case. On one side, intensive care treatment is achieved by ensuring optimal gas exchange. On the other side, the circulatory status and fluid management is of vital importance.

What is the circulatory status?
Is cardiac preload sufficient to achieve adequate cardiac output, and does this correspond to the clinical situation of the patient?
Does the patient need fluid or should fluid volume be reduced?
Can mechanical ventilation be ceased, shortened or avoided altogether?
What is the cardiac function? Does the patient need inotropes or vasoactive medication?
What is the afterload?

Correct answers to these questions ensure the maintenance of a stable hemodynamic state which also applies in the operating room. The following stay in anesthetic recovery rooms or in intensive care units can be shortened or avoided. [33]

The PiCCO-Technology parameters give answers to the following questions:

What is the cardiovascular status?
Cardiac Output (CO)

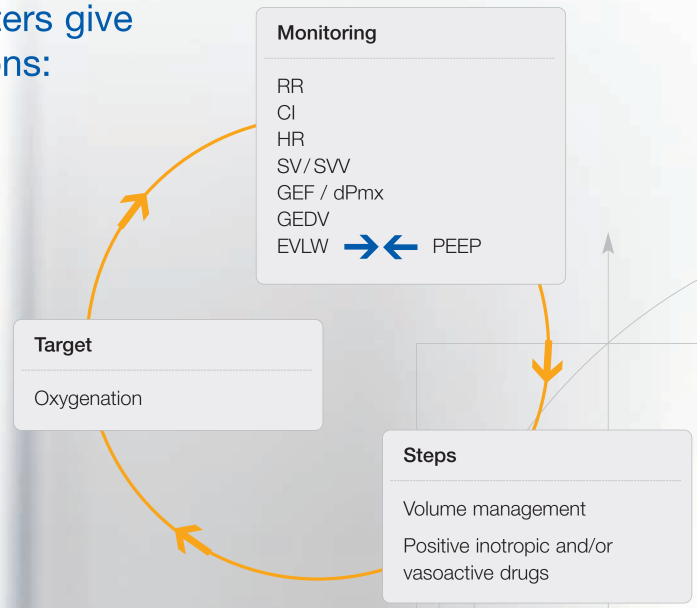
What is the cardiac preload?
Global End-Diastolic Volume (GEDV)

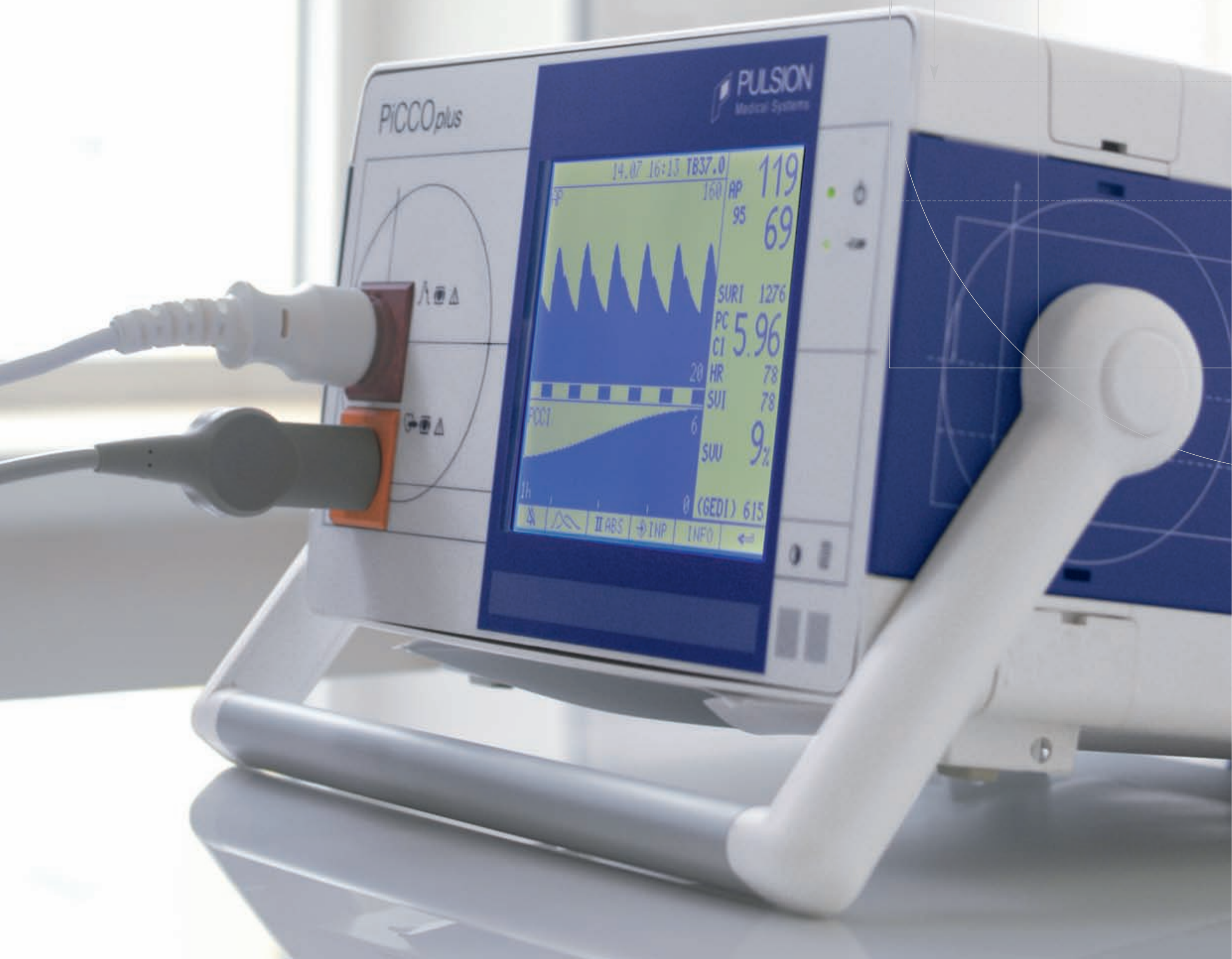
Will volume loading increase cardiac output?
Stroke Volume Variation (SVV)

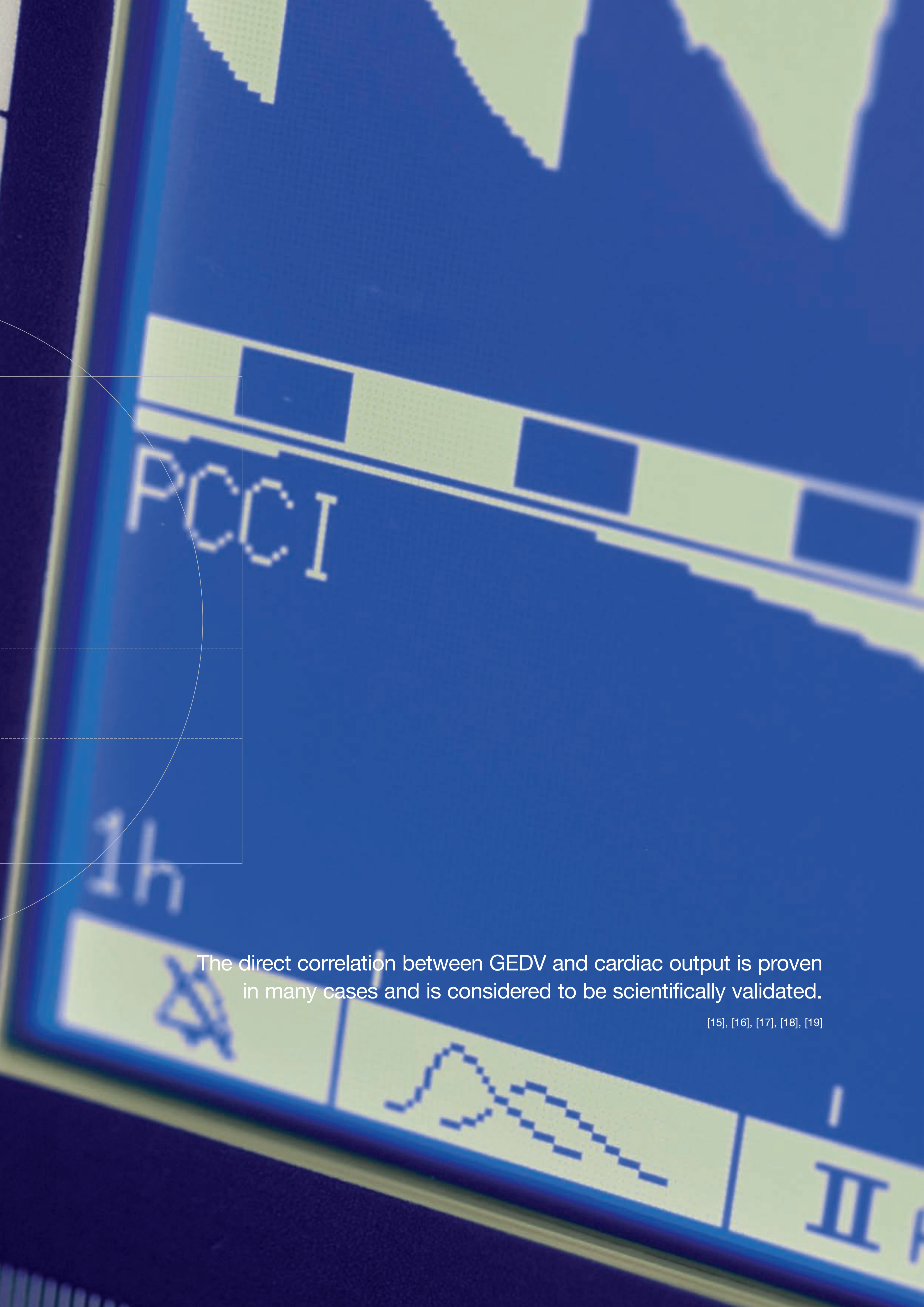
What is the afterload?
Systemic Vascular Resistance (SVR)

What is the cardiac contractility?
Pressure Velocity Increase (dPmx),
Global Ejection Fraction (GEF)

Is lung edema developing or already present?
Extravascular Lung Water (EVLW)







The direct correlation between GEDV and cardiac output is proven in many cases and is considered to be scientifically validated.

[15], [16], [17], [18], [19]

Volume Management and Preload

Preload is a significant component of cardiac output and depends on an adequate intravascular volume state, according to the Frank-Starling-mechanism. Knowledge of the exact amount of preload is indispensable as is knowledge regarding whether additional volume loading will optimize preload and therefore increase cardiac output. However, if excessive volume loading leads to pulmonary edema, oxygenation can be affected.

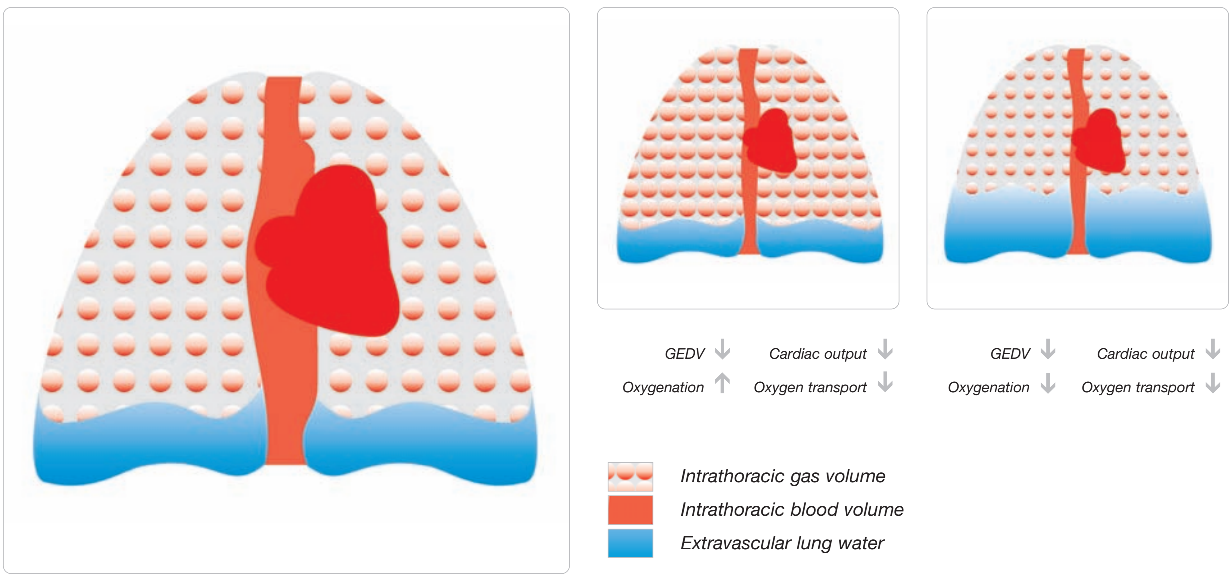
The amount of preload, volume responsiveness and water content in the lungs are closely related and interconnected. The thorax has only a limited ability to expand and three intra-thoracic compartments interact with each other: filling of the ventricles **(Global End-Diastolic Volume, GEDV)**, the **Extravascular Lung Water (EVLW)**, and the gas volume (tidal volume/PEEP). If one of these components changes under otherwise stable conditions it will inevitably influence the others.

An increase in tidal volume will, for example, cause a reduction in blood volume in the heart because blood is pressed out of the intra-thoracic circulation, and thus preload decreases. The Global End-Diastolic Volume of the PiCCO-Technology decreases and therefore correctly reflects the actual situation. The direct correlation between GEDV and cardiac output is proven in many cases and is considered to be scientifically validated. [15], [16], [17], [18], [19]

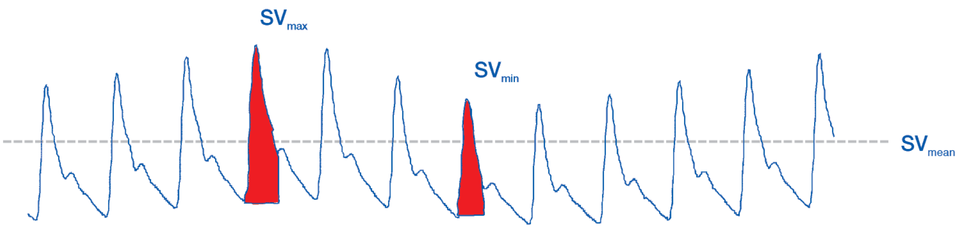
Another parameter of the PiCCO-Technology is of great value in directing volume management: The **Stroke Volume Variation (SVV)** gives – provided there is a fully ventilated patient with a stable heart rhythm – information as to whether an increase in preload will lead to an increased cardiac output.

The initial effect of a mechanical inspiration is to press blood out of the lungs into the left atrium, causing a short-term increase in preload. The increased gas volume in the thorax leads to the displacement of the end-diastolic volume and thus the preload decreases.

Interaction between the three thoracic compartments | **Increased intrathoracic pressure** | **Lung edema**

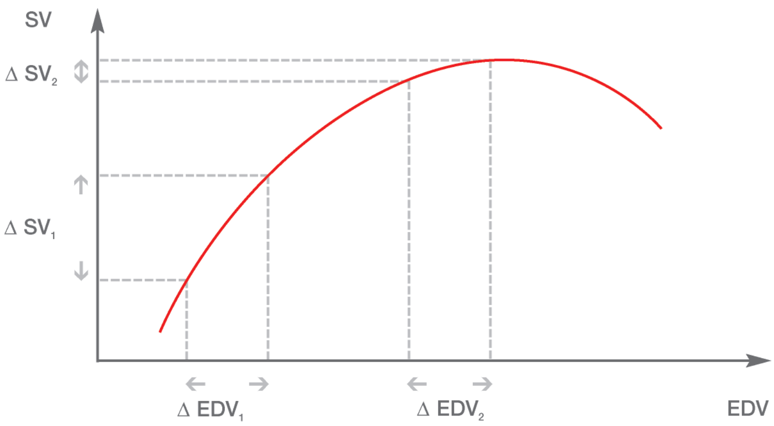


Change in preload leads to a variation in stroke volume in the case of a volume responsive heart.



Stroke Volume Variation (SVV)

The difference in preload between inspiration and expiration caused by mechanical ventilation leads to different stroke volumes. This depends on which part of the Frank-Starling curve the function of the heart is situated.



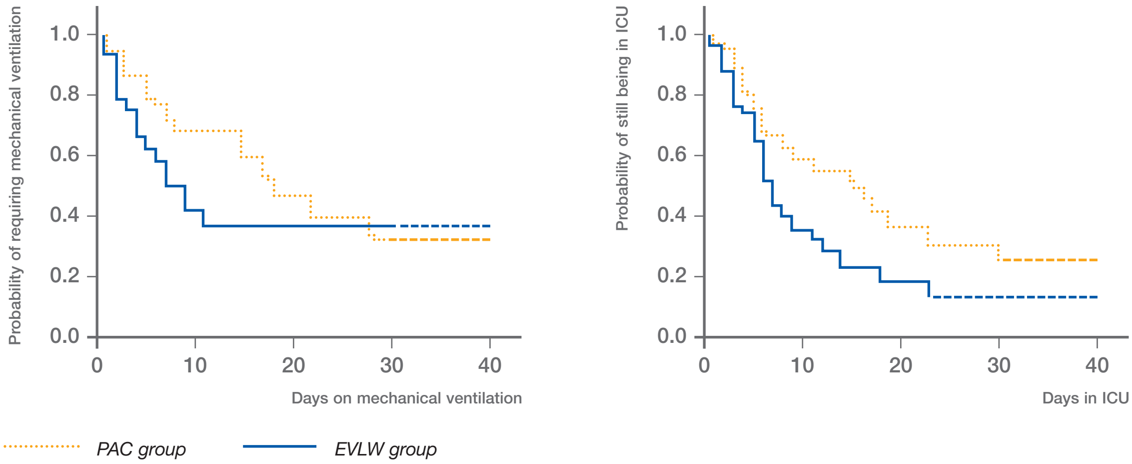
Stroke Volume (SV), End Diastolic Volume (EDV)

The increase in preload is identical: $\Delta EDV_1 = \Delta EDV_2$, but the influence of the stroke volume is different: $\Delta SV_1 >> \Delta SV_2$ [20], [21], [22], [23], [24], [25], [26]

Lung Water

Extravascular Lung Water (EVLW) describes the amount of liquid in the lung tissue and marks the point where further volume loading is no longer an advantage, or requires critical balancing. Volume loading with increasing lung water leads to pulmonary edema which has a negative influence on oxygenation and respiration. [28], [29]

The amount of lung water measured by the PiCCO-Technology is both an indication and therapy control for volume reduction, but should always be combined with monitoring of the Global End-Diastolic Volume. Even if cardiac output and oxygenation can be sustained by vasoactive medications, an inadequate Global End-Diastolic Volume can have a negative effect on the perfusion of other organs or in areas such as the splanchnic bed, the kidneys, or the brain. [29], [30], [31]



Comparison of fluid management guided either by pulmonary capillary wedge pressure (PAC group) or Extravascular Lung Water (EVLW Group) in 101 critically ill patients [29]. The Kaplan Meier plots of days on mechanical ventilation and duration of intensive care show a significantly shorter duration of mechanical ventilation and a significantly shorter length of ICU stay for the patients in the EVLW group.

An additional parameter of the PiCCO-Technology, the **Pulmonary Vascular Permeability Index (PVPI)**, determines the cause of pulmonary edema. A high permeability index indicates capillary leakage due to an inflammatory process. If this index is normal, it is very likely a congestive-caused or cardiac-caused edema. [32]
EVLW and PVPI are of great significance in the treatment of cardiac or septic shock. When using EVLW-based therapy, length of ICU stay and duration of mechanical ventilation can be significantly reduced. [33]

Contractility and Afterload

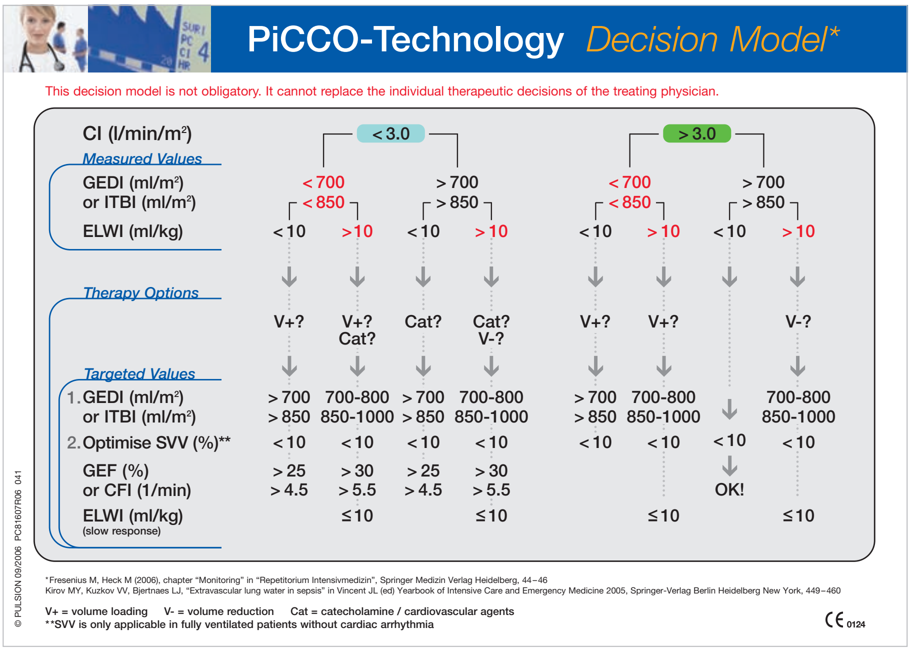
Often, optimization of fluid balance alone is not sufficient to stabilize the hemodynamic situation and to ensure adequate organ perfusion. Cardiac contractility and afterload are also important determinants of the Frank-Starling-mechanism. The PiCCO-Technology provides the possibility of monitoring and managing the interaction between cardiac output and vascular resistance by continuously calculating both the cardiac output and the **Systemic Vascular Resistance (SVR).** The possible cardiac effects caused by different therapies are highlighted by the **Global Ejection Fraction (GEF)** and by measurement of the **Left Ventricular Contractility (dPmx).** [34]
Furthermore, measuring the Global Ejection Fraction can reduce the necessity for echocardiography. [35]

Intracardiac Right-Left Shunt

The PiCCO-Technology allows the detection and quantification of a possible shunt between the right and the left heart. The accuracy of the volumetric parameters and the lung water is not affected by the presence of a shunt. Intracardiac R-L-shunts are more common than most physicians are aware of, especially in patients with increased pulmonary pressure or PEEP. [10]

PiCCO-Technology Decision Model

This decision model is not obligatory. It cannot replace the individual therapeutic decisions of the treating physician.



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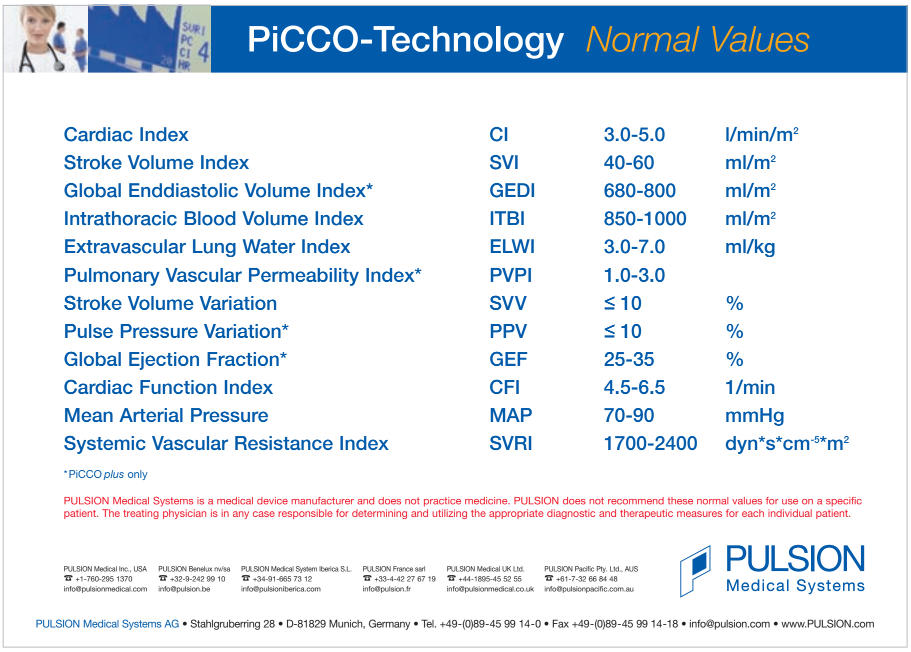

PiCCO-Technology Normal Values

Cardiac Index	CI	3.0-5.0	l/min/m²
Stroke Volume Index	SVI	40-60	ml/m²
Global Enddiastolic Volume Index*	GEDI	680-800	ml/m²
Intrathoracic Blood Volume Index	ITBI	850-1000	ml/m²
Extravascular Lung Water Index	ELWI	3.0-7.0	ml/kg
Pulmonary Vascular Permeability Index*	PVPI	1.0-3.0	
Stroke Volume Variation	SVV	≤ 10	%
Pulse Pressure Variation*	PPV	≤ 10	%
Global Ejection Fraction*	GEF	25-35	%
Cardiac Function Index	CFI	4.5-6.5	1/min
Mean Arterial Pressure	MAP	70-90	mmHg
Systemic Vascular Resistance Index	SVRI	1700-2400	$dyn*s*cm^{-5}*m^2$

*PiCCO *plus* only

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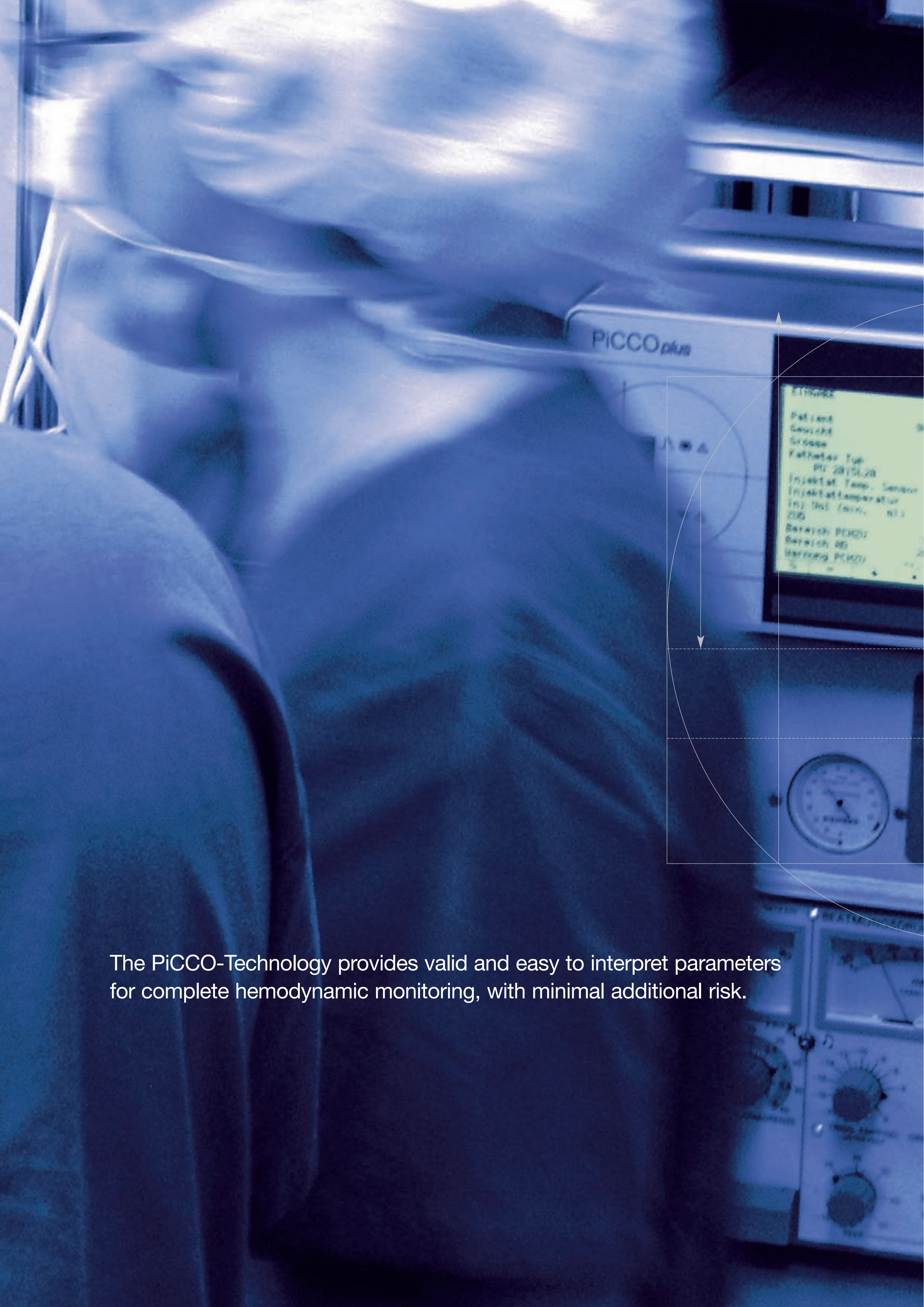


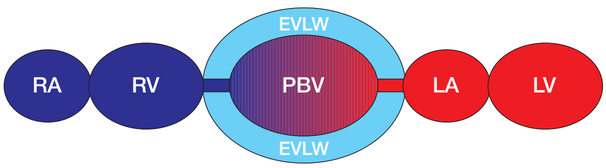
The PiCCO-Technology provides valid and easy to interpret parameters for complete hemodynamic monitoring, with minimal additional risk.

Accurate continuous measurement of physiological trends and the titration of the different therapies are therefore possible at the bedside and beat by beat.

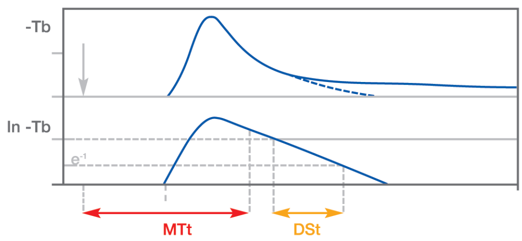
[11], [12], [13], [14]

Transpulmonary thermodilution

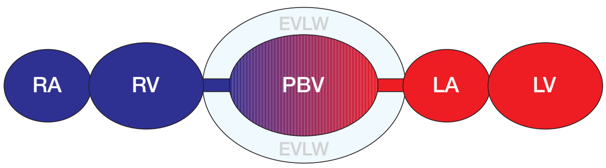
For determination of cardiac output a central venous injection of a saline bolus is required. After the indicator has been injected and passed through the cardiopulmonary system, the thermistor on the tip of the arterial PiCCO catheter measures the downstream temperature changes.



RA = Right Atrium, RV = Right Ventricle, LA = Left Atrium, LV = Left Ventricle,
PBV = Pulmonary Blood Volume

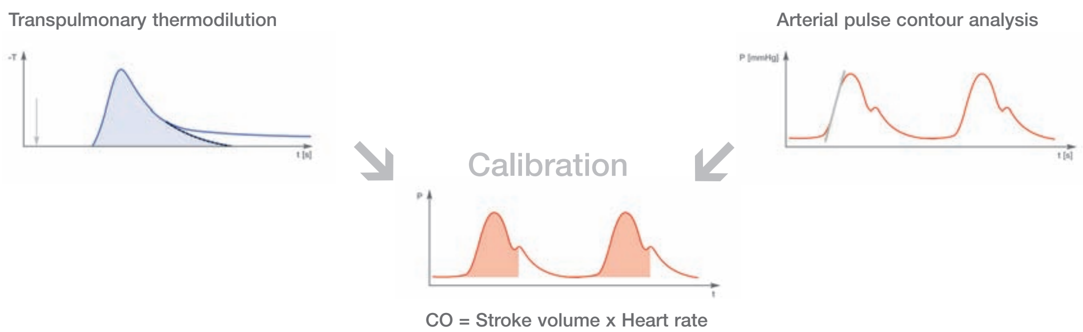


The **cardiac output** is calculated by means of the Stewart-Hamilton-equation from the area below the transpulmonary thermodilution curve. From the **Mean Transit time (MTt)** and the **Down Slope time (DSt)** of the thermodilution curve, **preload** and **lung water** are determined. When an intra-cardiac right-left-shunt is present, the thermodilution curves of both the shunt and the physiological blood flow are determined and analyzed separately.



Arterial pulse contour analysis

At the same time as the thermodilution measurement, the arterial pulse contour is analyzed and the aortic compliance determined. With this, the PiCCO-Technology pulse contour algorithm is calibrated, which subsequently provides an individual stroke volume, cardiac output and stroke volume variation.



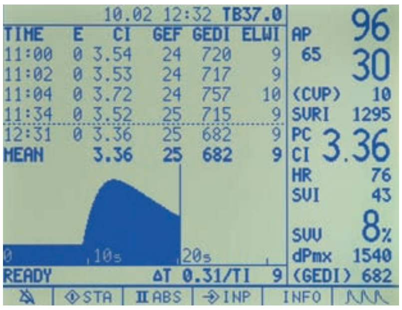
Accurate continuous measurement of physiological trends and the titration of the different therapies are therefore possible at the bedside and beat by beat. [11], [12], [13], [14]

The PiCCO *plus* parameters

Discontinuous parameters provided by transpulmonary thermodilution

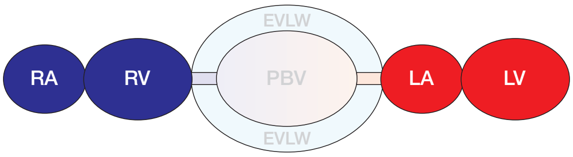
The **Cardiac Output (CO)** of the transpulmonary thermodilution is averaged over several respiration cycles while the bolus passes from the CVC to the arterial access and is therefore not subject to great deviation.

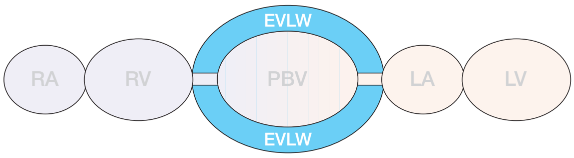
The **Global End-Diastolic Volume (GEDV)** represents the total of the 4 individual chambers of the heart and therefore reflects the cardiac preload.



Thermodilution

Extra Vascular Lung Water (EVLW) quantifies the liquid in the lung tissue outside the pulmonary capillaries. The complete interstitial, intra-alveolar and intra-cellular lung water is determined in all perfused areas. The mean value is calculated automatically using the single measurement results from the preceeding 10 minutes.



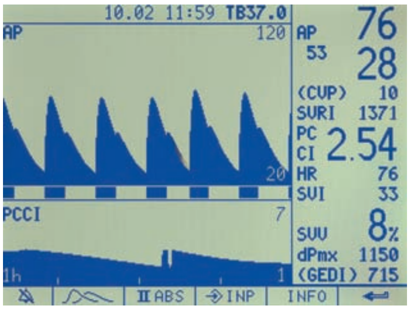


This is also used for calibrating the pulse contour analysis. 50 thermodilution measurements are stored in the memory of the PiCCO*plus*.

Continuous parameters provided by arterial pulse contour analysis

These are calculated from the shape of the arterial pressure curve in real time after the initial calibration through transpulmonary thermodilution. This is based on the 3rd generation PiCCO-pulse-contour-algorithm which calculates every single stroke volume. No other pulse contour technology has as much experience, gained from more than 400,000 applications (May 2005).

The multiplication of stroke volume with heart rate equals the continuous **Pulse Contour Cardiac Output (PCCO)**, which is displayed beat by beat.

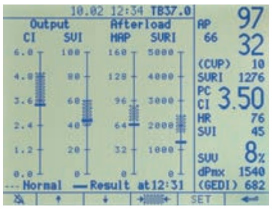


Pulse Contour

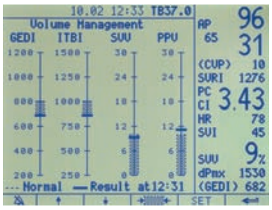
The PiCCO-Technology analyzes the minimum as well as the maximum stroke volumes within several respiratory cycles and calculates the **Stroke Volume Variation** from this. The **trend display** at the bottom of the screen can be scaled from 1 hour up to a maximum of 5 days.

Function and trend display

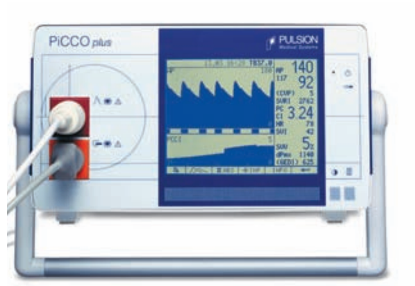
The PiCCO-Technology allows individualized and differentiated hemodynamic management, customized to organ specific functions.

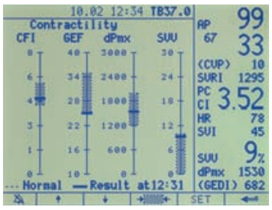


Flow / Afterload

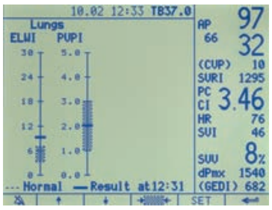


Volume Management

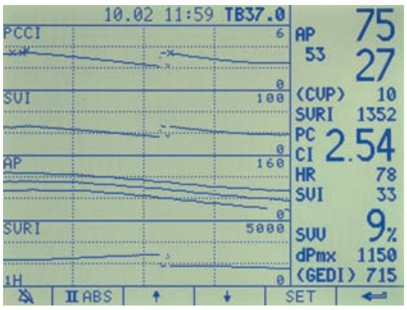




Contractilty



Lungs



Trend displays are able to track and record all parameters for up to 5 days. Continuous parameters are marked with a line, discontinuous parameters with a cross.

For documentation purposes, a custom-configured paper printout can be obtained.

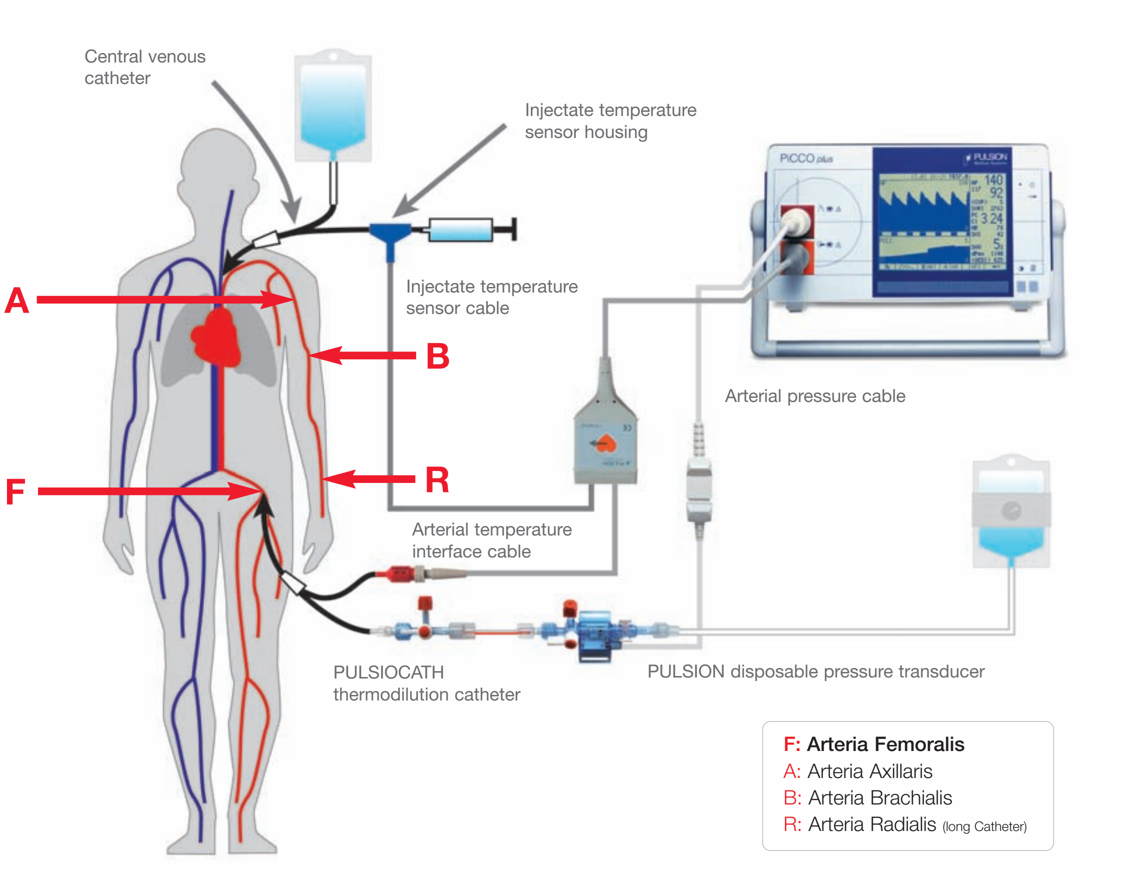
The individualized **parameter selection** helps to highlight the most important variables and rationalizes the display to the most relevant parameters.

Continuous parameters
Discontinuous parameters

Flow / Afterload	Cardiac Output	CO
	Stroke Volume	SV
	Heart Rate	HR
	Arterial Pressure	AP
	Systemic Vascular Resistance	SVR
Volume Management	Global End-Diastolic Volume	GEDV
	Intrathoracic Blood Volume	ITBV
	Stroke Volume Variation	SVV
	Pulse Pressure Variation	PPV
Lungs	Extravascular Lung Water	EVLW
	Pulmonary Vascular Permeability Index	PVPI
Contractility	Global Ejection Fraction	GEF
	Cardiac Function Index	CFI
	Left Ventricular Contractility	dP/mx

The PiCCO-Technology allows hemodynamic management individualized to each organ specific function.

Configuration



Schematic image of the PiCCO plus setup.
Allocation of the CVC lumen, CVP measurement and positioning of the stopcocks are subject to adaption to individual circumstances.

For the PiCCO-Technology any central venous catheter with a specific arterial PiCCO thermodilution catheter is required.

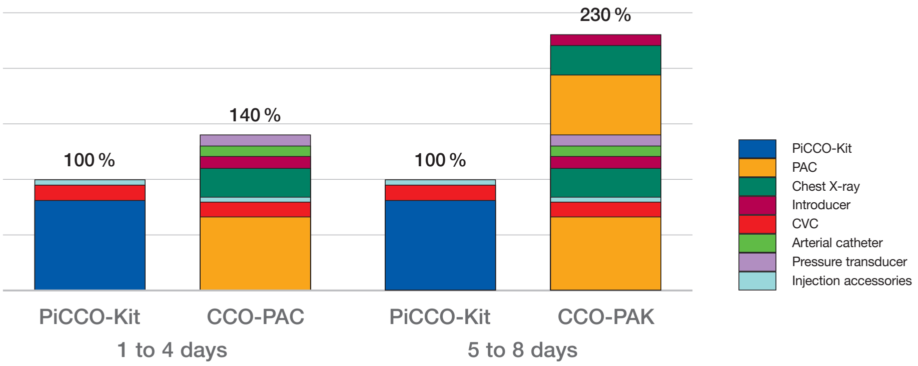
The specific PiCCO pressure transducer, validated and optimized for arterial pulse contour analysis.

A pulmonary catheter is not required for the measurement of cardiac output and all other PiCCO parameters.

PiCCO and the costs

Direct costs

As a result of low material and personal expenditures the PiCCO-Technology allows efficient monitoring at a reasonable price. Valid and rapidly available parameters facilitate the guidance of therapy and shorten patients' length of stay.

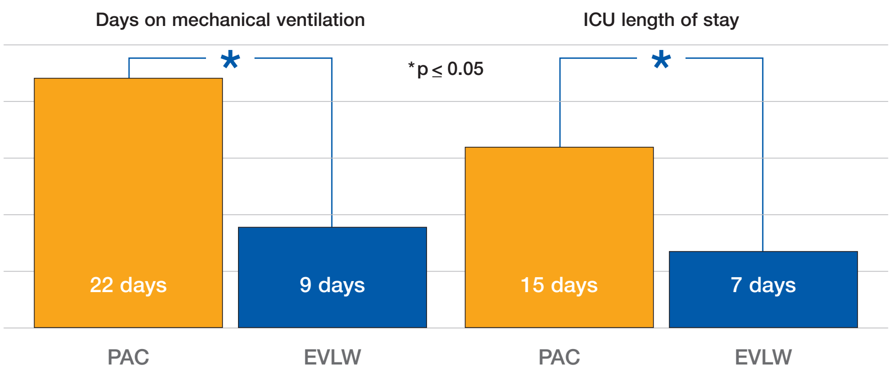


Percentage costs for the continuous-cardiac-output pulmonary artery catheter (CCO– PAC) as compared to PiCCO-monitoring dependent on length of use.

Due to the high follow-up costs the total expenditures for the previously gold standard right heart catheter may be more than double when compared to the PiCCO-Technology. In contrast to the right heart catheter, which has to be replaced after 4 days use incurring high additional costs, the PiCCO catheter can remain in situ for up to 10 days. Not included in this calculation are the higher personal expenditures caused by the use of the right heart catheter.

Indirect costs

The length of stay for intensive care patients can be shortened by the application of the PiCCO-Technology.



Randomized comparison of PCWP-guided volume management with fluid therapy oriented towards the extra-vascular lung water (EVLW) in 101 intensive care patients. The duration of mechanical ventilation and the ICU length of stay were significantly shorter in the EVLW-group than in the patients with the pulmonary artery catheter. [33]

Costs per intensive care day are currently approximately 2,300 USD per patient [36]. The theoretical savings by a reduction in ICU length of stay by 8 days is approximately 18,400 USD per patient. For an average intensive care unit with 600 patients per year, 25 % of whom receive PiCCO-Monitoring, a theoretical potential saving of approx. 2,760,000 USD annually is possible, purely by the reduction in ICU length of stay.

Among the currently applied hemodynamic monitoring systems the PiCCO-Technology boasts the most favourable cost-efficiency relationship. [2]

Unique advantages of the PiCCO-Technology

Specific parameters

The PiCCO parameters are physiologically relevant, easy to manage and interpret. The actual status of the patient can be recognized quickly and the correct decisions for the right therapies made. Continuous, fast reacting parameters work advantageously with therapy strategies, in which rapid volume loading and/or the application of highly potent pharmaceuticals are required. The anesthesist does not get distracted from the action around the patient caused by the use of high level technology in the operating room. The user receives information on the actual volume status and the water content of the lungs without having to rely on difficult to interpret utilities such as chest x-ray or pulmonary artery catheters.

Valid parameters

A large body of literature published in well known medical journals confirms the accuracy and the ease of use of the PiCCO parameters in clinical routine.

Complete range of hemodynamic parameters

The PiCCO-Technology unites all hemodynamic parameters necessary to stabilize and manage the patient effectively with goal directed therapies.

Minimal invasiveness

"There is no additional risk for a patient with a central venous catheter, who is already in need of an arterial catheter for blood pressure measuring." [8]

Applicable in pediatrics

The PiCCO-Technology allows precise hemodynamic monitoring in children and neonates when the application of other methods is not possible or contra-indicated. [37], [38], [39], [40]

Cost efficiency

Application of PiCCO parameters reduces intensive care stay and time on mechanical ventilation. [33]
The parameters are determined in a short time period, or are already continuously available. Costs for chest x-rays decrease. The time to place and manage disposables for the PiCCO-Technology is low thereby reducing expenses. The PiCCO thermodilution catheter can remain in situ as a conventional arterial catheter for up to 10 days and is cost effective. In addition, the avoidance of complications and low staff maintenance leads to cost reductions.

The PiCCO-Technology allows precise hemodynamic monitoring in children and neonates when the application of other methods is not possible or contra-indicated.

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PiCCO Parameters – Background Validation & Methodology

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Contractility (Global Ejection Fraction, Cardiac Function Index & Left Ventricular Contractility dPmx)

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Cost Effectiveness

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Ordering information

Monitor

PC8100	PiCCO*plus* Monitor

Accessories

401090-F	Hospital grade mains power connection cable (240 V / 115 V)
PC80150	Temperature interface cable
PC80109	Injectate temperature sensor cable for PV4046
PMK206	Interface cable for pressure signal
401080	Potential equalization cable (green/yellow)
PV6005	Thermal printer paper roll
PC81200	Adapter cable for connection of PiCCO*plus* to bedside monitor
PMK-XXX	Pressure transducer connection cable to be connected between the PC81200 adapter cable and the bedside monitor, where XXX depends on the type of the monitor used

Disposables

Arterial thermodilution catheter:

Art. No.:	**Size**	**Preferred location of placement**
PV2013L07	3F / 7 cm	A. Femoralis, children
PV2014L08	4F / 8 cm	A. Axillaris, adults
PV2014L16	4F / 16 cm	A. Femoralis, small adults
PV2014L22	4F / 22 cm	A. Brachialis, adults
PV2015L20	5F / 20 cm	A. Femoralis, adults
PVPK2014L50	4F / 50 cm	A. Radialis, adults (long catheter) (consists of catheter, cannula(s), dilatator and guide wire. Single packed guide wires available)

Pressure transducer systems:

PV8115	150 cm red pressure line incl. PV4046
PV8115CVP	150 cm red / 120 cm blue pressure line incl. PV4046

Injectate temperature sensor housing:

PV4046	Injectate temperature sensor housing

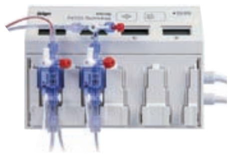
Disposable Kits can be ordered easily by using the ordering number PVPK201XLXX-46 (X) according to the desired catheter type. The kits contain all the PiCCO-Monitoring disposables necessary for one patient including catheter and pressure transducer set (includes injectate temperature sensor housing).

ATTENTION:
For safe operation and for accuracy of measurements, only disposables and accessories approved by PULSION Medical Systems may be used with the PiCCO.

The PiCCO-Technology is available as a stand-alone monitor and as a module for patient monitoring systems.

PULSION PiCCO plus

Philips IntelliVue Module



Dräger Medical Infinity® PiCCO SmartPod™

Stand-alone Monitor PiCCO *plus*

Parameter and display limits

Absolute: Parameter	Unit	Min.	Max.
CO	l/min	0.25	25
PCCO	l/min	0.25	25
GEDV	ml	40	4800
ITBV	ml	50	6000
EVLW	ml	10	5000
SV	ml	1	250
SVR	dyn*sec*cm^{-5}	1	9999
PPV / SVV	%	0	50
CFI	1/min	1	15
GEF	%	1	99
PVPI	–	0.1	9,9
dPmx	mmHg/sec	200	5000
HR	1/min	30	240
AD	mmHg	0	300
T Inj.	°C	0	30
T Blood	°C	25	45

Indexed: Parameter	Unit	Min	Max.
CI	l/min/m^2	0.1	15
PCCI	l/min/m^2	0.1	15
GEDI	ml/m^2	80	2400
ITBI	ml/m^2	100	3000
EVLWI	ml/kg	0	50
SVI	ml/m^2	1	125
SVRI	dyn*sec*$m^2$$cm^{-5}$	1	9999

Technical data

Protection classification / Device type:	I/CF defibrillator safe
Electrical and physical data:	
Power supply:	95 – 240 V~/ 50 – 60 Hz
Power consumption:	50 VA max.
Internal battery:	12 V / 2.5 Ah, sealed lead D-cells
Charging time:	15 hrs
Battery operating time:	30 min (minimum)
Operating conditions:	
Temperature range:	0 – +70°C
Relative Humidity:	20 – 90 %
Air pressure:	700 – 1060 hPa
Dimensions:	
Width / Height / Depth	260 mm / 158 mm / 250 mm
Weight:	4.8 kg
Interfaces:	
RS232	The RS232 interface serves as the data transmission between the PiCCO *plus* and the interface of the adapted system. For direct data recording, PULSION provides recording software.
AUX-Adapter	The Aux-Adapter enables the transmission of the arterial pressure curve to any bedside monitor.
Integrated thermal printer	

Related Patents:
EP0947941, US6315735, JP3397716, US6200301 , EP0637932, US5526817, JP3242655, EP1034737, US6491640, JP3375590, US6394961, EP1139867, US6537230, US6264613, P200010262, EP0666056, US5769082, JP3234462,
Further patents pending

Technical details subject to change

CE 0124

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