

**PULSION**  
Medical Systems

**PiCCO<sub>2</sub>**  
(PC8500)

Version 3.1

**Operator's Manual  
and  
Product Information**

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## About this Manual



**WARNING:** Important items of information, i.e. activities where operating personnel must proceed with extreme caution in order to avoid injury to themselves or the patient. These items of information are always shown in **BOLD**.



**CAUTION:** Items of information for which careful attention must be paid in order to avoid damage to the equipment or inaccurate data as well as operational errors. These items of information are always shown in **BOLD**.



**WARNING:** Read the operating instructions carefully before using the PiCCO<sub>2</sub> equipment!

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## A General Information

### 1 Intended Use

The PULSION PiCCO<sub>2</sub>'s intended use is the minimally invasive determination and monitoring of cardiopulmonary and circulatory variables. Along with other bedside monitors and the clinical evaluation, the PiCCO<sub>2</sub> detects the patient's status and evaluates the need for and the suitability of treatment methods for the care of critically ill patients in intensive care units as well as for perioperative monitoring. If a patient's correct weight and height are entered, the PiCCO<sub>2</sub> presents the derived parameters indexed to the patient's body characteristics.

The PiCCO<sub>2</sub> uses up to four technologies:

1. Transpulmonary thermodilution measurement for discontinuous determination of cardiac output and intra- and extravascular fluid volumes.
2. Arterial pulse contour analysis for the continuous determination of cardiac output, volume responsiveness and other derived parameters.
3. Fiberoptic reflective measurement for the determination of oxygen saturation in the blood.
4. Pulse oximetry for continuous monitoring of the functional oxygen saturation of arterial haemoglobin (SpO<sub>2</sub>) and pulse densitometry for the determination of the concentration of Indocyanine Green, a dye approved as a diagnostic drug.

The transpulmonary thermodilution technique and the arterial pulse contour analysis are not classified as measuring functions as stated in the Council Directive 93/42/EEC.

The PiCCO<sub>2</sub> is intended for use in hospitals and hospital-like facilities and by trained health care professionals.

The PiCCO<sub>2</sub> can be used in environments stated in the IEC 60601-1-1 Standard.

### 2 Indications

The use of the PiCCO<sub>2</sub> is indicated in patients where cardiovascular and circulatory volume status monitoring is necessary. This includes patients undergoing surgical interventions of such magnitude that cardiovascular monitoring is necessary.

Continuous monitoring of central venous oxygen saturation is indicated in all intensive care patients particularly in the case of sepsis and multi-organ failure; management of early goal directed therapy in severe sepsis; for intra-operative monitoring of high risk surgical patients and in emergency medicine and acute-care for fast track evaluation of the patient's haemodynamic condition.

The Indocyanine Green concentration and elimination measurement is indicated in all patients with persistent or expected limitations of the global liver function (cellular function or perfusion).

### 3 Contraindications

The invasive technologies in the PiCCO<sub>2</sub> should not be used in patients where the placement of an indwelling arterial catheter or a central venous catheter is contraindicated. The PiCCO<sub>2</sub> should only be used in patients where the expected results are reasonable in comparison to the risks. Patients on intra-aortic balloon counter pulsation (IABP) cannot be monitored with the pulse contour analysis of the device. Transpulmonary thermodilution however works during IABP support.



**WARNING:** Federal (USA) law restricts this device for sale by or on the order of a physician. The device is intended for use in hospitals and hospital-like facilities by trained and informed health care professionals.

For contraindications of the diagnostic drug, Indocyanine Green, please refer to the corresponding SPC (summary of product characteristics).

## 4 Warnings



### WARNING

#### General:

Federal (USA) law restricts this device to sale by or on the order of a physician.
The device is intended for use in hospitals and hospital-like facilities by trained and informed health care professionals.
Before using the PiCCO <sub>2</sub> equipment carefully read the operating instructions for the device and the used disposables. The use of the PiCCO <sub>2</sub> in contradiction to the instructions in this manual may cause undue equipment failure and possible health hazards.
For safety of operation and for accuracy of measurements, only disposables and accessories approved by PULSION Medical Systems may be used with the PiCCO <sub>2</sub> .
Explosion hazard when used in the presence of flammable anesthetics.
For safety of operation, only memory sticks and printers approved by PULSION Medical Systems may be used with the PiCCO <sub>2</sub> .

#### Positioning / Installation:

Position the equipment in such a manner that neither the device nor other equipment attached to the device can fall on the patient. Never lift or carry the device by the mains supply cable or the cable attached to the patient.
When using the provided assembly facilities pay attention to a correct installation. The used system must be sufficiently stable and tilt resistant as well as medically approved. In order to ensure a secure connection with the mounting system the locking mechanism of the universal adapter plate must be completely snapped in place.
Place the cables attached to the patient carefully so that the patient is not in danger of becoming entangled or strangulating him/herself with the cables.

#### Medical:

The device enables the monitoring of physiological parameters. The clinical significance of changes in the monitored parameters must be determined by a physician.
If a new patient is connected to the device without the device being shut down, the procedure "New Patient" must be selected. Otherwise data from the last patient is still displayed.
The PiCCO <sub>2</sub> may only be regarded as a device providing early warning. If there is an indication of a trend towards de-oxygenation of the patient, blood samples must be taken and tested on a laboratory oximeter in order to arrive at a decision concerning the condition of the patient.
The device must not be used for monitoring breathing.
The device must not be used for monitoring heart rate, arterial blood pressure and body temperature.
Before using the device the setting of the alarm limits and the alarm volume must be checked regarding their suitability for the respective patient.

If an alarm condition arises while the alarm is suppressed, only the optical warning will be given.
During the start up procedure an acoustic sound appears at the end of the activation time. If this sound does not appear no acoustic alarm can take place.
External influences: carboxyhaemoglobin can result in incorrect high values for SpO <sub>2</sub> . The degree of elevation is approximately equal to the amount of carboxyhaemoglobin present. Dye (e.g. Indocyanine Green) or other substances which contain dyes which usually modify the light absorption capacities, can lead to faulty measurement values of the oxygen saturation.
The measurement of SpO <sub>2</sub> is not recommended for patients weighing less than 20 kg (44lbs).
Do not use the device while a NMR scan is being carried out. An induced voltage can result in potential burns.

**Disposables:**

When placing the arterial catheter into a large artery (e.g. femoral, brachial or axillary artery) do not advance the tip of the catheter into the aorta.
An intracardiac blood pressure measurement is not allowed. This means that the measuring position (i.e. catheter tip) must not be in the heart.
Further use of disposable items is not allowed. Re-sterilization of disposables may cause infections in the patient.
Incorrect use of the ScvO <sub>2</sub> probe can lead to vessel perforation. Therefore check the correct position of the probe as indicated in the probe's instructions for use.

**Electrical:**

Do not use damaged probes or patient cables. Do not use any probes with exposed optical or electrical components.
Do not reconnect the PiCCO <sub>2</sub> to electrical power if liquid has entered the device. A short circuit may damage the device and cause hazardous conditions for patient and user.
Remove patient cables which are not needed. The used components are not galvanically isolated from each other.
The PiCCO <sub>2</sub> always has to be connected with the protective earth conductor. Never use mains supply cable or extension lines without protective earth conductor.
Connect the potential equalization at the back of the device with the potential equalization system of the treatment room.

## 5 Safety instructions



### CAUTION

#### General:

Do not expose the PiCCO<sub>2</sub> to temperatures above 40 °C (104 °F) or below 10 °C (50 °F). The accuracy of the measured values may be affected.

Do not pull on the probes or cables in order to remove them from the device. Observe the instructions for use for the probes in order to ensure that a technically correct procedure is carried out.

Do not place other equipment or containers with liquid on top of the PiCCO<sub>2</sub>.

Never place the cables in water or other cleaning solutions. The cables and connections are not water-tight. Never sterilize the cables by radiation, steam or gas.

Do not use abrasive or sharp-edged tools to clean the optical module as this may damage or destroy optical components.

If the device is not standing on a slip-proof surface and to prevent displacement, hold the unit securely while the function keys are being pressed.

#### Preparations for Use:

The user must assure him-/herself of the safe and fully functional condition of the equipment before using it.

If the PiCCO<sub>2</sub> appears to be damaged, contact your local PULSION representative. Do not use the PiCCO<sub>2</sub> if the device appears to be damaged.

If the system check detects a failure, no function will be available and "SERVICE" is displayed on the screen. Turn the PiCCO<sub>2</sub> off and contact your local PULSION representative. Do not attempt to use or repair the PiCCO<sub>2</sub>.

When the PiCCO<sub>2</sub> is connected to a bedside monitor, perform a zero adjustment of the PiCCO<sub>2</sub> before zeroing the bedside monitor.

#### Medical:

If the zero adjustment is not performed, the blood pressure values may be wrong. Zero adjustment of the pressure transducer is mandatory.

When restoring the calibration in the PCCO and ScvO<sub>2</sub> calibration menu an old calibration factor may be used. Ensure that the values are plausible after having used this option.

If the displayed pulse contour parameters are not plausible, they should be checked by a thermodilution measurement. The pulse contour cardiac output measurement will be recalibrated automatically.

As the pulse contour cardiac output of children has not been sufficiently validated so far the CO should be checked by thermodilution before therapeutic interventions.

Recalibration is recommended with significant changes in haemodynamic conditions, such as volume shifts or changes to medication.
If the option of the continuous CVP measurement is not used, CVP should be updated as soon as a new value is obtained to accurately calculate SVR and PCCO.
Faulty measurements can be caused by incorrectly placed catheters, interfering signal transmission e.g. of arterial pressure, defective connections or sensors or by electromagnetic interference (e.g. electric blankets, electric coagulation).
Due to an aortic aneurysm the displayed blood volume (GEDV/ITBV) derived by a thermodilution measurement can be erroneously high.

**Electrical:**

The PiCCO <sub>2</sub> is subject to specific precautions concerning EMC (Electromagnetic compatibility) and is only allowed to be installed and used according the EMC advice contained in this user's manual. Portable and mobile high frequency communication devices may influence the PiCCO <sub>2</sub> .
Any additional item of equipment which is connected to the digital interface must satisfy the EMC requirements of the IEC specification 60601-1-2.
Furthermore, all configurations have to meet the system standard IEC 60601-1-1. Any person who connects additional devices to the signal input or signal output of the PiCCO <sub>2</sub> is changing the system configuration and is responsible for observing the requirements of the IEC 60601-1-1 standard.
When high frequency devices are used during surgery, the applying standards for high frequency devices for surgery have to be followed.
Check the battery state of charge when using the device. Only when the battery is fully charged, the use of the device can be ensured for the stated time without being connected to the mains.
If the connection to the protective earth conductor cannot be ensured, separate the device from the mains supply and only use the device on battery power.

## **B Principles of Measurement and Parameters**

### **1 Introduction**

The PiCCO<sub>2</sub> is a device for continuous cardiac output measurement combined with monitoring of cardiac preload volume, extravascular lung water, arterial and central venous oxygen saturation and global liver function.

The PULSION PiCCO<sub>2</sub> computes the CO continuously, utilizing an improved arterial pulse contour analysis algorithm. The Pulse Contour Cardiac Output (PCCO) is calibrated by means of a transpulmonary thermodilution measurement. A cold or room-temperature bolus (e.g. normal saline 0.9%) is injected through a central venous catheter. A thermodilution curve is recorded by an arterial thermodilution catheter, which also serves for pressure monitoring. In addition to calibration of the PCCO, transpulmonary thermodilution also yields cardiac preload by means of global end-diastolic volume (GEDV) and an estimation of both, intrathoracic blood volume (ITBV) and extravascular lung water (EVLW).

Furthermore the PiCCO<sub>2</sub> continuously measures the central venous oxygen saturation (ScvO<sub>2</sub>) after calibration with blood gas analysis results and can continuously calculate oxygen delivery (DO<sub>2</sub>) and oxygen consumption (VO<sub>2</sub>).

Detection of concentration and determination of the elimination rate of a diagnostic drug, Indocyanine Green, provide information about the global liver function. The device indicates the Plasma Disappearance Rate (PDR) and the Retention Rate of ICG after 15 minutes (R15).

To derive parameters, the PiCCO<sub>2</sub> combines transpulmonary thermodilution technique with continuous arterial pulse contour analysis and fiberoptic oximetry and pulse oximetry/densitometry. Oximetry measurements use different wave lengths for the determination of the elimination rate of Indocyanine Green.

If a patient's weight, height, category and gender are entered, the PiCCO<sub>2</sub> presents the derived parameters indexed to the patient's body characteristics.

## 2 Transpulmonary Thermodilution Technique

### 2.1 Principle

To accomplish thermodilution determination a known volume of a suitable indicator (at least 10°C below blood temperature) is injected intravenously as quickly as possible. The recorded downstream temperature change is dependent on the flow and the volume through which the cold indicator has passed. As a result, a thermodilution curve can be recorded. The PiCCO<sub>2</sub> detects the cold indicator in the arterial system (preferably in the femoral artery).

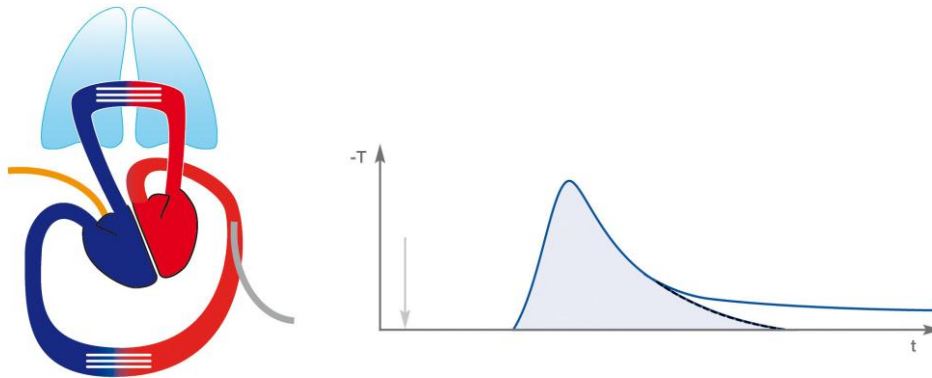


Figure 1: Heart-lung circulation and resulting thermodilution curve

### 2.2 Transpulmonary Cardiac Output

Cardiac Output (CO) is the volume of blood being pumped by the heart in one minute.

Cardiac output by thermodilution is calculated according to the Stewart-Hamilton formula (see Appendix) using the area under the thermodilution curve.

Parameter	Absolute Parameters		Indexed Parameters	
	Abbr.	Unit	Abbr.	Unit
Cardiac output, transpulmonary	CO	l/min	CI	l/min/m <sup>2</sup>



### 2.3 Transpulmonary volume determination

Specific volumes can be calculated by multiplying cardiac output with characteristic time variables of the thermodilution curve.

The parameters can alternatively be displayed as absolute parameters or indexed to the patient's body characteristics.

The PiCCO<sub>2</sub> uses predicted body weight (PBW) to index intrathoracic volumetric parameters.

Parameter	Absolute Parameters		Indexed Parameters	
	Abbr.	Unit	Abbr.	Unit
Global End-Diastolic Volume	GEDV	ml	GEDI	ml/m <sup>2</sup>
Extravascular Lung Water	EVLW	ml	ELWI	ml/kg
Global Ejection Fraction	GEF	%		
Pulmonary Vascular Permeability Index	PVPI	-		
Cardiac Function Index	CFI	l/min		
Intrathoracic Blood Volume	ITBV	ml	ITBI	ml/m <sup>2</sup>

#### 2.3.1 GEDV / ITBV

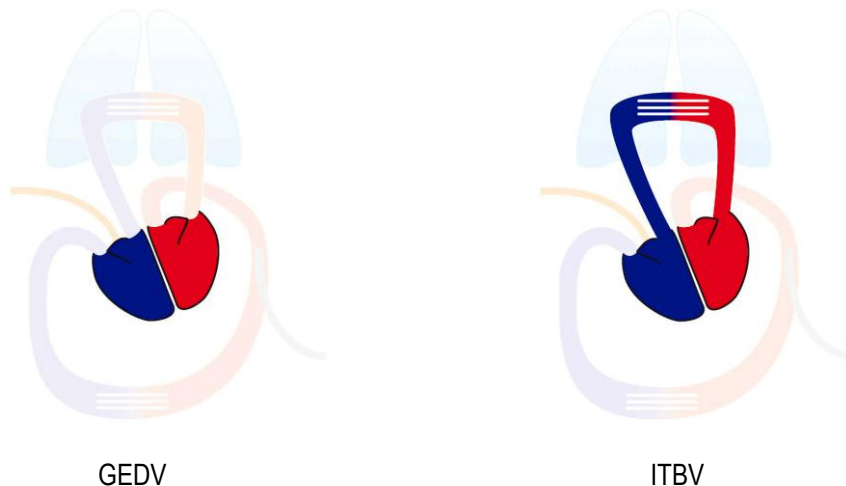


Figure 2: GEDV / ITBV

Global End-Diastolic Volume (GEDV) is the total amount of blood left in all four heart chambers, i.e. atria and ventricles, at the end of diastole.

Intrathoracic Blood Volume (ITBV) represents the total amount of blood in the thorax.

GEDV and ITBV reflect the circulatory volume status and are excellent indicators of cardiac preload. GEDV and ITBV are used for managing the patient's vascular filling status and guiding volume therapy.



**CAUTION:** Aortic aneurysms may cause the displayed blood volume (GEDV/ITBV) derived by thermodilution measurement to be erroneously high.

### 2.3.2 EVLW

EVLW quantifies the extravascular fluid volume in the lungs. It is used to alert the clinician to the existence or development of pulmonary edema. When measuring lung water the intra-alveolar, intracellular and interstitial lung water are considered. However, a pleural effusion does not influence measurements.



Figure 3: Extravascular Lung Water (EVLW)

### 2.3.3 Additional Thermodilution Parameters

#### 2.3.3.1 GEF:

GEF mainly depends on right and left ventricular contractility and can be used to detect right and/or left ventricular dysfunction. GEF is derived from the ratio of four stroke volumes divided by Global End-Diastolic Volume (GEDV).

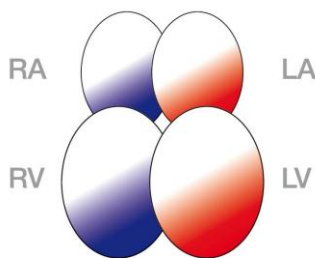


Figure 4: Global Ejection Fraction (GEF)

#### 2.3.3.2 CFI:

CFI represents the ratio between cardiac output and global end-diastolic volume (GEDV).

#### 2.3.3.3 PVPI

PVPI shows the relationship between EVLW and PBV (Pulmonary Blood Volume) and can help to distinguish between hydrostatic and permeability caused pulmonary edema.

### 3 Continuous Pulse Contour Analysis

#### 3.1 Principle

The relationship between blood flow out of the aorta and pressure measured near the aorta (femoral artery or other large artery) is determined by the compliance function. The compliance function can therefore be characterized by measuring blood pressure and blood flow (cardiac output) simultaneously. Transpulmonary thermodilution cardiac output determined simultaneously with continuous arterial pressure measurement is utilized to calibrate the pulse contour analysis to each individual patient's aortic compliance function.

#### 3.2 Calibration of the Pulse Contour Cardiac Output

To calibrate the measurement of continuous cardiac output, a reference thermodilution cardiac output is necessary. The PiCCO<sub>2</sub> uses the transpulmonary thermodilution as reference method.

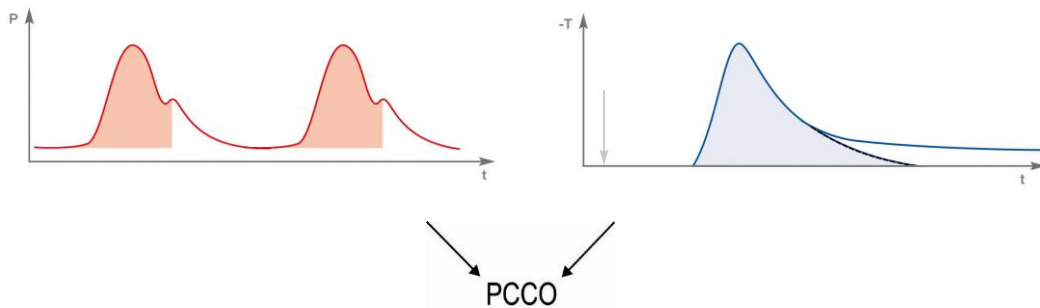


Figure 5: Calibration of pulse contour analysis by means of thermodilution

### 3.3 Continuous haemodynamic determination

The following parameters are derived by the PULSION PiCCO<sub>2</sub>, analyzing the arterial pressure curve beat by beat. The parameters can alternatively be displayed as absolute parameters or indexed to the patient's body characteristics.

Parameter	Absolute Parameters		Indexed Parameters	
	Abbr.	Unit	Abbr.	Unit
Pulse Contour Cardiac Output	PCCO	l/min	PCCI	l/min/m <sup>2</sup>
Stroke Volume	SV	ml	SVI	ml/m <sup>2</sup>
Systemic Vascular Resistance	SVR	dyn•s•cm <sup>-5</sup>	SVRI	dyn•s•cm <sup>-5</sup> •m <sup>2</sup>
Stroke Volume Variation	SVV	%		
Pulse Pressure Variation	PPV	%		
Left Ventricular Contractility	dPmx	mmHg/s		
Cardiac Power Output	CPO	W	CPI	W/m <sup>2</sup>
Heart Rate	HR	min <sup>-1</sup>		
Mean Arterial Blood Pressure	MAP	mmHg		
Systolic Arterial Blood Pressure	APsys	mmHg		
Diastolic Arterial Blood Pressure	APdia	mmHg		

Moreover, central venous pressure (CVP) in mmHg can be measured continuously.

#### 3.3.1 MAP / CVP / HR

##### MAP (Mean Arterial Pressure)

Mean arterial pressure is the mean value of the blood pressure in the arterial system.

##### CVP (Central Venous Pressure)

Central venous pressure is the average blood pressure directly before the right heart.

##### HR (Heart Rate)

Heart rate is the number of heart beats per minute.

#### 3.3.2 PCCO

Pulse contour cardiac output is the continuously determined cardiac output from the pulse contour analysis.



**CAUTION:** As the pulse contour cardiac output of children has not been sufficiently validated thus far, the CO should be checked by thermodilution before therapeutic interventions.

Recalibration is recommended with significant changes in haemodynamic conditions, such as volume shifts or changes to medication.

### 3.3.3 SVV / PPV

SVV is the variation in stroke volume over a certain time.

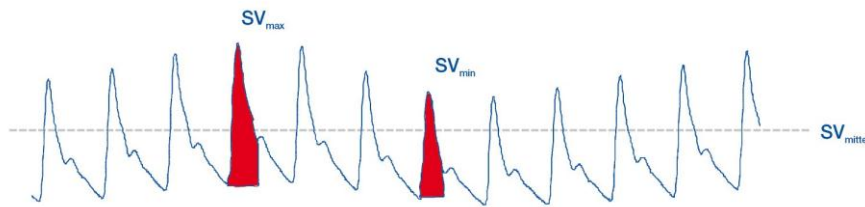


Figure 6: SVV

PPV is the variation in pulse pressure over a certain time.

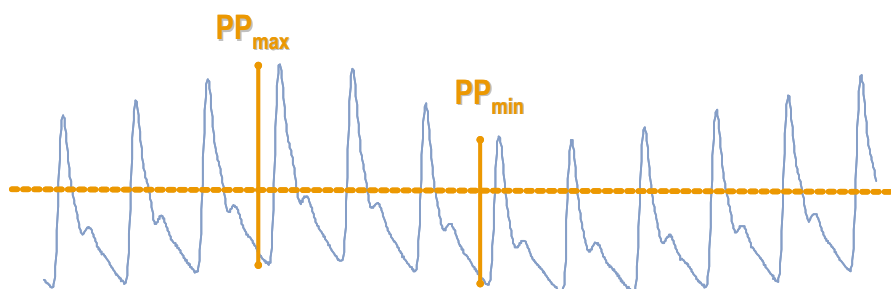


Figure 7: PPV

In mechanically ventilated patients without arrhythmias SVV and PPV enable an estimation of the volume responsiveness. Large variations in stroke volume or pulse pressure induced by mechanical ventilation indicate that volume loading will lead to an increase in cardiac ejection (volume responsiveness).

### 3.3.4 SVR

SVR represents the resistance the blood encounters as it flows through the vascular system. The SVR value is often used by clinicians as an estimate of afterload.

### 3.3.5 CPO

The CPO is the product of cardiac output and mean arterial pressure, thus reflecting the cardiovascular blood flow related to the counteractive resistance. CPO serves as an indicator for the overall performance of the heart.

### 3.3.6 dPmx

dPmx is the abbreviation for  $\Delta P_{max}/\Delta t$ . This parameter indicates how fast the aortic pressure is rising during systole. It allows a close approximation of the contractility of the left ventricle. In addition to CFI/GEF, dPmx can be used to manage the administration of positive inotropic and cardiovascular agents.

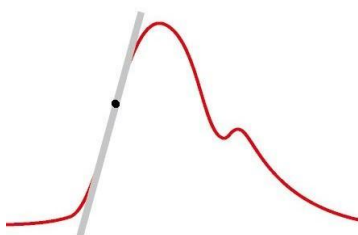


Figure 8: dPmx

## 4 Central venous oximetry

### 4.1 Principle

The PiCCO<sub>2</sub> measures central venous oxygen saturation (ScvO<sub>2</sub>) by spectrophotometry. Spectrophotometry involves the use of light emitting diodes (LED) that produce light of various wavelengths in red and infrared spectra. The light is transmitted to the blood through a fiberoptic in the probe, reflected off the red blood cells and transmitted back through a separate fiberoptic to an optical module.

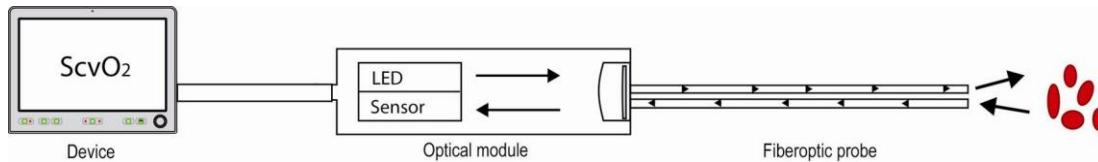


Figure 9: The principle of spectrophotometry

The wavelengths are selected in a way that the absorption characteristics of haemoglobin and oxyhaemoglobin are different. Given both the amount of total haemoglobin and the amount of haemoglobin bound to oxygen, oxygen saturation can be calculated.

### 4.2 Determination of ScvO<sub>2</sub>

ScvO<sub>2</sub> reflects the oxygen saturation of the haemoglobin in the blood in the superior vena cava directly before the right atrium. It is an early indicator of an imbalance between oxygen delivery and oxygen consumption. Thus this parameter early indicates a threat to global tissue oxygenation.

Parameter	Absolute Parameters	
	Abbr.	Unit
Central Venous Oxygen Saturation	ScvO <sub>2</sub>	(%)

### 4.3 Oxygen delivery and oxygen consumption: DO<sub>2</sub> and VO<sub>2</sub>

Parameter	Absolute Parameters		Indexed Parameters	
	Abbr.	Unit	Abbr.	Unit
Oxygen delivery	DO <sub>2</sub>	ml/min	DO <sub>2</sub> l	ml/min/m <sup>2</sup>
Oxygen consumption	VO <sub>2</sub>	ml/min	VO <sub>2</sub> l	ml/min/m <sup>2</sup>

#### 4.3.1 DO<sub>2</sub>

DO<sub>2</sub> is the amount of oxygen provided to the tissue per minute. It depends on the flow (cardiac output), the amount of haemoglobin in the blood and the arterial oxygen saturation.

#### 4.3.2 VO<sub>2</sub>

VO<sub>2</sub> is the amount of oxygen consumed by the tissue per minute.

## 5 Pulse oximetry and pulse dye densitometry

### 5.1 Principle of pulse oximetry

Pulse oximetry measures the percentage oxygen saturation of the haemoglobin. The principle of pulse oximetry is based on the transmission and absorption of light waves in the visible and near-infrared spectrum by haemoglobin. Light of different wavelengths is sent through the tissue non-invasively and is subsequently detected by a sensor. The received light signal is used to determine the oxygen saturation. This measurement is entirely non-invasive.

Pulse oximetry is used to measure the partial oxygen saturation of haemoglobin i.e. only oxygenated and deoxygenated haemoglobin is included. However, not included is e.g. carboxyhaemoglobin or methaemoglobin.



**WARNING:** External influences: carboxyhaemoglobin can result in incorrect high values for SpO<sub>2</sub>. The degree of elevation is approximately equal to the amount of carboxyhaemoglobin present. Dye (e.g. Indocyanine Green) or other substances which contain dyes which usually modify the light absorption capacities, can lead to faulty measurement values of the oxygen saturation.



**WARNING:** The measurement of SpO<sub>2</sub> is not recommended for patients weighing less than 20 kg (44lbs).

### 5.2 Principle of pulse dye densitometry

The principle of pulse dye densitometry and with it, the measurement of the plasma disappearance rate of Indocyanine Green (ICG) is based on pulse oximetry. The difference is that other light wavelengths are used than with pulse oximetry.

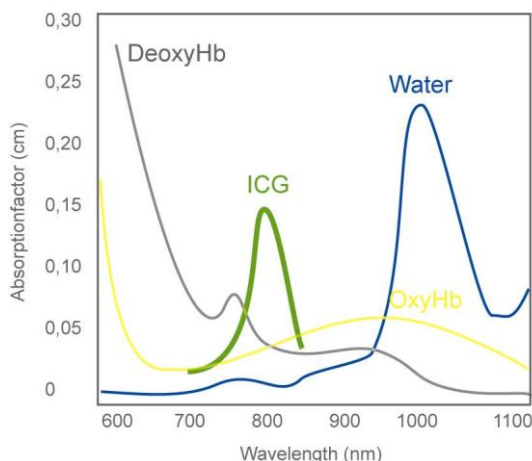


Figure 10: Absorption spectra of O<sub>2</sub>Hb, Hb and ICG (According to Britton Chance, University of Pennsylvania)

### 5.3 Principle of ICG elimination detection

ICG has an absorption maximum of approximately 805 nm. The determination of ICG concentration within this range (optical window) is not disturbed by other blood components.

The trend in ICG concentration over time is used to calculate the relative change in percent per minute. The plasma disappearance rate (PDR) of ICG is a measure of the excretory capacity of the liver and thus global liver function. It is influenced by the function of liver cells as well as the liver perfusion. Depending on the patients underlying disease the PDR helps to assess the patient's liver function and/or liver perfusion. As the liver is part of the splanchnic area, splanchnic perfusion can be indirectly estimated.

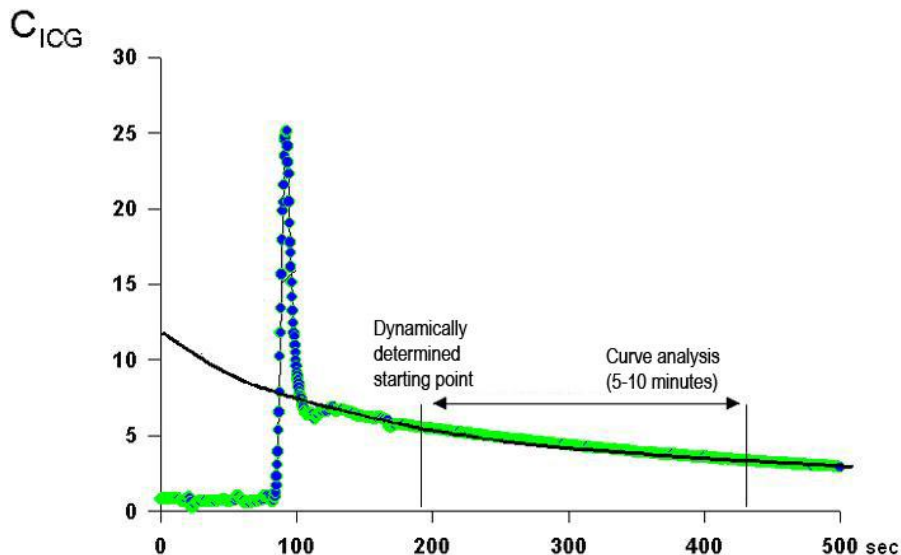


Figure 11: Schematic representation of the ICG elimination curve

The figure above shows a typical ICG concentration curve with the initial peak and its course over 500 seconds. The elimination measurement starts after thorough mixing of ICG with the circulating blood volume. The starting point of the PDR measurement is determined dynamically dependent on the circulation time derived from the first peak. The ICG curve analysis continues for five to ten minutes, dependent on the quality of the curve.

The starting point represents 100%. The algorithm detects a percentage decrease per minute and indicates the PDR in percent per minute.



#### NOTE

For information on the diagnostic drug, Indocyanine Green, please refer to the corresponding SPC (summary of product characteristics) or PIL (patient information leaflet) of ICG.

### 5.4 Parameters of pulse oximetry and pulse dye densitometry

The following parameters are measured by pulse dye densitometry and pulse oximetry:

- Arterial oxygen saturation SpO<sub>2</sub> (%)
- Plasma Disappearance Rate of ICG PDR (%/min)
- Retention Rate of ICG after 15 minutes R15 (%)



## 6 Parameter groups and ranges of normal values

The normal value ranges are based upon clinical experience and can vary from patient to patient. The stated values are therefore offered without guarantee. Indexed parameters are related to body surface area, predicted body weight or predicted body surface area (see Appendix) and can also be displayed as absolute values.

	Parameter	Normal Ranges	Unit
<b>Flow</b>	CI / PCCI	3.0 – 5.0	l/min/m <sup>2</sup>
	SVI	40 – 60	ml/m <sup>2</sup>
<b>Preload Volume</b>	GEDI	680 – 800	ml/m <sup>2</sup>
	ITBI	850 – 1000	ml/m <sup>2</sup>
	SVV	< 10	%
	PPV	< 10	%
<b>Afterload</b>	SVRI	1700 – 2400	dyn•s•cm <sup>-5</sup> •m <sup>2</sup>
<b>Contractility</b>	GEF	25 – 35	%
	CFI	4.5 – 6.5	1/min
	dPmx	-	mmHg/s
<b>Organ Function</b>	ELWI	3.0 – 7.0	ml/kg
	PVPI	1.0 – 3.0	-
	CPI	0.5 – 0.7	W/m <sup>2</sup>
	PDR	18 – 25	%/min
	R15	0 – 10	%
<b>Oxygenation</b>	ScvO <sub>2</sub>	70 - 80	%
	DO <sub>2</sub> l	400 – 650	ml/min/m <sup>2</sup>
	VO <sub>2</sub> l	125 – 175	ml/min/m <sup>2</sup>
	SpO <sub>2</sub>	90 – 100	%



**NOTE**

PULSION is a medical device manufacturer and does not practice medicine. PULSION does not recommend these values for use on a specific patient. The treating physician is in any case responsible for determining and utilizing the appropriate diagnostic and therapeutic measures for each individual patient.



**WARNING:** The PiCCO<sub>2</sub> equipment may only be regarded as a device providing early warning. If there is an indication of a trend towards de-oxygenation of the patient, blood samples must be taken and tested on a laboratory oximeter in order to arrive at a decision concerning the condition of the patient.

The device must not be used for monitoring breathing.

The device must not be used for monitoring heart rate, arterial blood pressure and body temperature.

## C Installation and setup



**CAUTION:** The user must assure him-/herself of the safe and fully functional condition of the equipment before using it.

### 1 Unpacking and inspection

Inspect the packaging for possible shipping damage. Use care when unpacking the PiCCO<sub>2</sub>. Retain the packing slip and save all packing material in case the device is damaged or fails the self test and has to be returned to the manufacturer.



**WARNING:** Before using the PiCCO<sub>2</sub> equipment carefully read the operating instructions for the device and the used disposables. The use of the PiCCO<sub>2</sub> in contradiction to the instructions in this manual may cause undue equipment failure and possible health hazards.

Position the equipment in such a manner that neither the device nor other equipment attached to the device can fall on the patient. Never lift or carry the device by the mains supply cable or the cable attached to the patient.

When using the provided assembly facilities pay attention to a correct installation. The used system must be sufficiently stable and tilt resistant as well as medically approved. In order to ensure a secure connection with the mounting system the locking mechanism of the universal adapter plate must be completely snapped in place.



**CAUTION:** If the PiCCO<sub>2</sub> appears to be damaged, contact your local PULSION representative.

Do not use the PiCCO<sub>2</sub> if the device appears to be damaged.

If the system check detects a failure, no function will be available and "SERVICE" is displayed on the screen. Turn the PiCCO<sub>2</sub> off and contact your local PULSION representative. Do not attempt to use or repair the PiCCO<sub>2</sub>.

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## 2 Functionality and user interaction

### 2.1 Screen elements

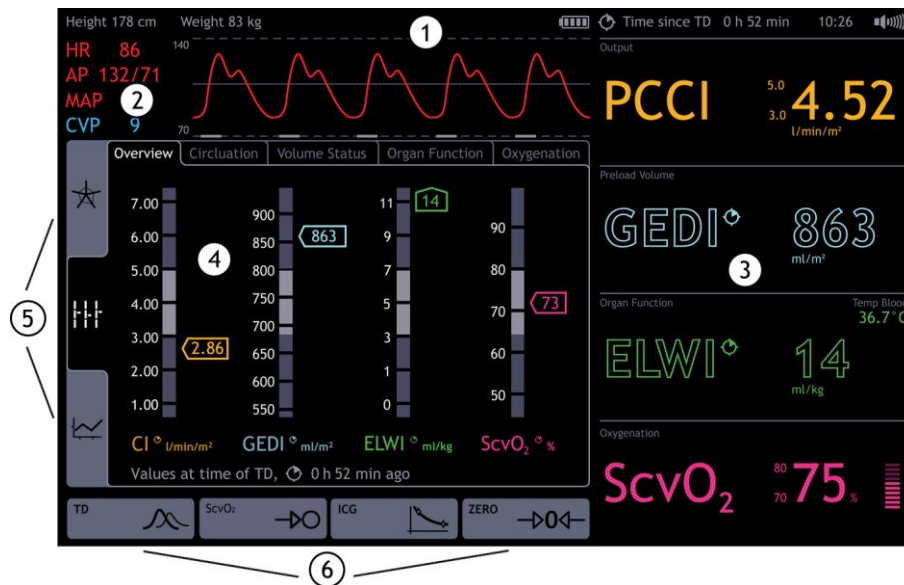


Figure 12: Screen elements

#### 1) Information bar

Information bar for patient and measurement specific information and error messages

#### 2) Real Time pressure curve

Permanent display of real time pressure curve of arterial pressure (AP) and central venous pressure (CVP)

#### 3) Parameter fields

Configurable parameter fields divided into parameter groups, permanent display of the selected parameters

#### 4) Patient screen

Function area for measurements, configuration and graphical display of parameters

#### 5) Display options

The determined parameters can be displayed in 3 different ways. (for details see chapter C4)

#### 6) Selection of actions

Direct access to thermodilution measurement, ScvO<sub>2</sub> calibration, ICG measurement and zero adjustment of blood pressure (dependent on setting and connected module)

### 2.2 User interaction

The PiCCO<sub>2</sub> provides an intuitive user interface and can be operated by both navigation dial and touch screen. In order to keep navigation as easy as possible, actions and settings can be done by direct activation of the respective screen element on the screen.

### 2.2.1 Touchscreen

Measurement and display options as well as any configuration can be reached directly by touching the respective element on the touch screen. All input can be directly made on the screen. Numerics can be directly entered on the screen by means of a touch keyboard.

To switch to another screen just select another element on the screen or use the Main button.

### 2.2.2 Function keys



Figure 13: Function keys



**ON/OFF key:** This key is used to switch the device on and off. As soon as the mains power switch is pressed at the rear side of the device, a green light appears. The green light indicates that the device is connected to the mains power supply. A blinking green light indicates that the battery is being charged. By pressing the key continuously for 4 seconds during operation, the device will shutdown and restart.



Opening the help screen



**Print key:** Starts a printout, depending on the connected printer device (USB or thermal transfer printer)



**Mute key:** Pausing of the alarm for 2 minutes. The orange light indicates an alarm even if there is an acoustic alarm pause.

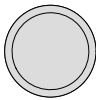
### 2.2.3 Navigation dial and navigation keys



Back key: Back to previous interaction level.



Main key: Back to the last active display screen



Navigation dial:

The navigation dial can be used alternatively to the touch screen. The currently active position will be displayed by a white frame on the screen. Pressing the navigation dial confirms the selection.

### 3 Setup and measurement: Step by step

#### 3.1 Connectors and connections

##### 3.1.1 Patient cables



**SO<sub>2</sub>**

Connection of the CeVOX module or LiMON module



**CO**

Connection of temperature interface cable for arterial thermodilution catheter and injectate temperature sensor.



**AP**

Connection of pressure transfer cable for arterial pressure (AP)



**CVP**

Connection of pressure transfer cable for central venous pressure (CVP)



Figure 14: Patient cables socket with equipment class (defibrillator protection)



**NOTE**

PiCCO<sub>2</sub> is protected against electric shock in case of defibrillation.



**WARNING:** Do not use damaged probes or patient cables. Do not use any probes with exposed optical or electrical components.

Do not reconnect the PiCCO<sub>2</sub> to electrical power if liquid has entered the device. A short circuit may damage the device and cause hazardous conditions for patient and user.

Remove patient cables which are not needed. The used components are not galvanically isolated from each other.

Place the cables attached to the patient carefully so that the patient is not in danger of becoming entangled or strangulating him/herself with the cables.



### 3.1.2 Monitor connections



Figure 15: Monitor connections

**1)  AP / CVP**

Transfer of continuous arterial pressure (AP) and central venous pressure (CVP) signal to bedside monitor

**2) Serial Interface RS232**

Connection for patient data acquisition systems (PDMS)

**3) LAN**

Connection for network devices for printing and data transfer

**4) USB ports (2)**

Connection for external printer and PULSION memory stick

**5) Potential equalization**

Connection for potential equalization cable

**6) Mains power connector**

Connects the monitor to the power socket

**7) Mains switch**



**WARNING:** Connect the potential equalization at the back of the device with the potential equalization system of the treatment room.



**CAUTION:** Any additional item of equipment which is connected to the digital interface must satisfy the requirements of the current IEC specification.

### 3.2 Patient and monitor wiring

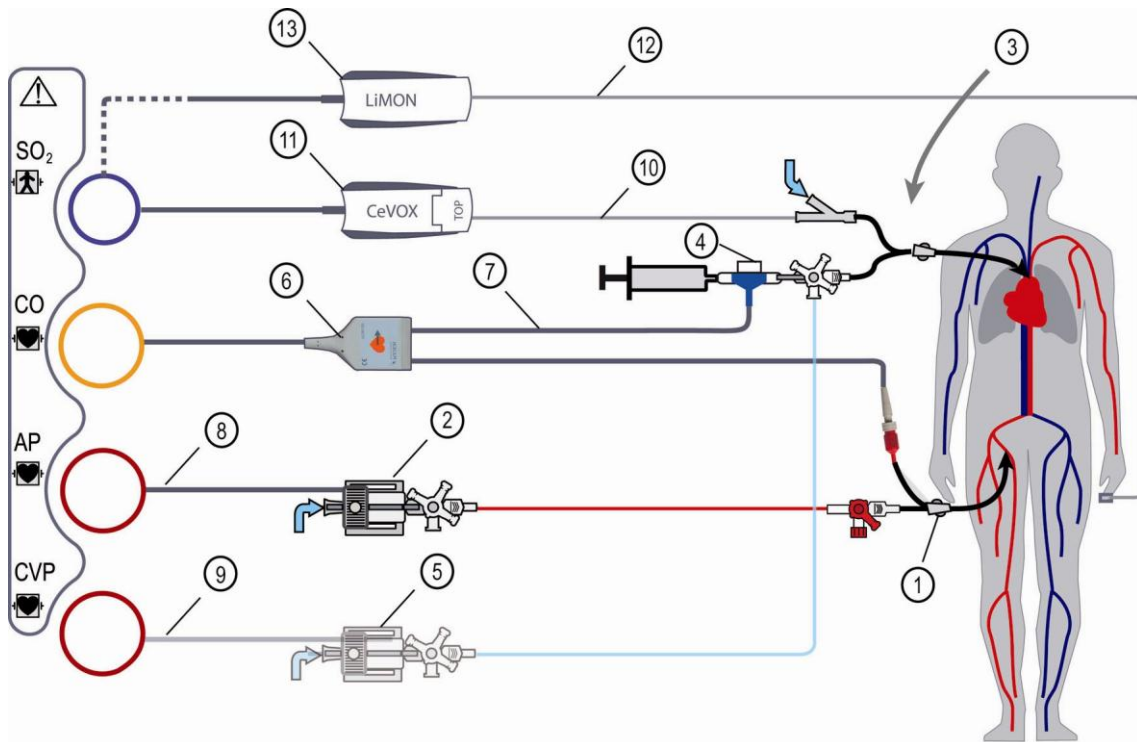



Figure 16: Patient and monitor wiring

Thermodilution measurement, pulse contour analysis and pulse oximetry/densitometry can work independently from central venous oxygen saturation measurement.

 **WARNING:** Please consult the instructions for use accompanying the disposables and accessories.

### 3.2.1 Thermodilution and Pulse Contour Analysis

#### **Disposables:**

##### **(1) Arterial Thermodilution Catheter: PiCCO catheter**

Insert thermodilution catheter according to instructions for use. Please ensure that the pressure lumen is completely filled with liquid and that all air is evacuated prior to insertion.

##### **(2) Arterial pressure transducer: PiCCO Monitoring kit**

To be installed according to instructions for use. Any other components (e.g. extensions or 3-way-stopcock) should not be added. Please ensure that the system is completely filled with liquid and that all air is evacuated prior to connection to the patient.

##### **(3) Standard CVC**

To be installed according to instructions for use.

##### **(4) Injectate temperature sensor housing PV4046, included in PiCCO Monitoring Kit**

Connection to distal (preferred) lumen of the central venous catheter (CVC) by means of a 3-way-stopcock (if a CeVOX probe is applied please refer to chapter 3.2.3). Do not measure the central venous pressure (CVP) through the sensor housing and/or do not apply glucose or lipid containing substances by the sensor housing. Before installation air must be completely removed from all components.

##### **(5) Central venous pressure transducer (optional)**

In order to ensure transmission of the CVP install 3-way-stopcock in front of the injectate temperature sensor housing. Please ensure that the system is completely filled with liquid and that all air is evacuated prior to connection to the patient.



**WARNING:** The PiCCO catheter must not be advanced into the aorta.

#### **Cables**

##### **(6) Temperature interface cable PC80150**

For connection of injectate temperature sensor cable PC80109 and the PiCCO catheter to the PiCCO<sub>2</sub>

##### **(CO port)**

##### **(7) Injectate temperature sensor cable PC80109**

For connection of the temperature interface cable PC80150 to the injectate temperature sensor housing PV4046.

##### **(8) Arterial pressure cable PMK-206**

For connection of arterial pressure transducer with the PiCCO<sub>2</sub> (**AP port**)

##### **(9) Central venous pressure connection cable PMK-206 (optional)**

For connection of central venous pressure transducer with the PiCCO<sub>2</sub> (**CVP port**)

### 3.2.2 Central venous oxygen saturation

#### Disposables:

##### **(3) Standard CVC**

To be installed according to instructions for use. The distal lumen of the central venous catheter (CVC) has to be designed for guide wires with  $\varnothing$  0.032". Thermodilution injection, infusions and measurement of CVP through the distal port is not recommended when a CeVOX probe is placed (see chapter C3.2.3)

##### **(10) CeVOX fiberoptic probe:**

Carefully place the probe through the distal lumen of the central venous catheter (CVC) according to the instructions for use. Do not install a 3-way-stopcock between the probe and the hub of the distal lumen of the central venous catheter (CVC). Remove the clamp on the CVC lumen in any case in order to avoid damage of the probe.

#### Modules:

##### **(11) CeVOX module (PC3010 / PC3015)**

For connection of the CeVOX probe with the PiCCO<sub>2</sub> (SO<sub>2</sub> port)

##### **(13) LiMON module (PC5100)**

For connection of the LiMON reusable sensor with the PiCCO<sub>2</sub> (SO<sub>2</sub> port)

#### Sensors:

##### **(12) LiMON reusable sensors (PC51100/PC51200/PC51300)**

For connection of the patient to the LiMON module


### 3.2.3 Application of injectate temperature sensor housing and CeVOX probe at the same time

As the CeVOX probe is placed through the distal lumen of the central venous catheter, the next largest lumen of the CVC catheter has to be used for injection of the thermodilution indicator and the central venous pressure (CVP) measurement.

### 3.2.4 Transmission of continuous pressure to bedside monitor

The PiCCO<sub>2</sub> allows the transfer of continuous arterial and central venous pressure to all conventional bedside monitors with standard excitation voltage of 5 $\mu$ V/V/mmHg.

##### **(14) Adapter cable for pressure transfer to bedside monitor (PC85200)**

For connection of the individual pressure transfer cable with the PiCCO<sub>2</sub> ( AP / CVP at rear side of device)

##### **(15) Pressure cable to bedside monitor**

Transmission of arterial pressure (AP) and central venous pressure (CVP) to patient bedside monitor. This cable is available for all conventional patient monitors.



#### **NOTE**

Set the pressure input channel of bedside monitor to 5 $\mu$ V/V/mmHg. Other settings will lead to incorrect blood pressure values being displayed on the bedside monitor.

Also set the pressure input channel of bedside monitor to 5 $\mu$ V/V/mmHg when using PULSION monitoring kits directly connected to the bedside monitor.



**CAUTION** When the PiCCO<sub>2</sub> is connected to a bedside monitor, perform a zero adjustment of the PiCCO<sub>2</sub> before zeroing the bedside monitor.

### 3.3 Setup and start

#### 3.3.1 Mains voltage

For connection to mains power only the supplied cable with protective connector may be used and connected to a corresponding power socket with an intact protective earth conductor.

Ensure the connection to the potential equalization cable and switch on the device by pressing the mains switch at the back of the device (position I). Connection to the mains power supply is indicated by the green light at the ON/OFF key at the front of the device.



**WARNING:** Do not reconnect the PiCCO<sub>2</sub> to electrical power if liquid has entered the device. A short circuit may damage the device and cause hazardous conditions for patient and user.  
The PiCCO<sub>2</sub> must always be connected to the protective earth conductor. Never use mains supply cable or extension lines without protective earth conductor.



**CAUTION:** If the connection to the protective earth conductor cannot be ensured, disconnect the device from the mains supply and only use the device on battery power.

#### 3.3.2 Switch on the device

Press the ON/OFF key for 1 second. The device needs a short activation time. This is indicated by the blinking of all LEDs.

After having switched on the device, the PiCCO<sub>2</sub> automatically leads through the necessary screens, depending on the connected patient cables.

During the start procedure, the  button will lead to the next screen.

While in actual operation each respective screen can be exited with the  button.



**WARNING:** During the start up procedure an acoustic sound appears at the end of the activation time. If this sound is not heard no acoustic alarm is available.



**CAUTION:** If the device is not standing on a slip-proof surface and to prevent displacement, hold the unit securely while the function keys are being pressed.

If the system check detects a failure, no function will be available and "SERVICE" is displayed on the screen. Turn the PiCCO<sub>2</sub> off and contact your local PULSION representative. Do not attempt to use or repair the PiCCO<sub>2</sub>.

### 3.4 Enter patient data



Last Patient

Height	178	cm	Name	Mr. X
Weight	75	kg	Patient ID	John
Category	Adult			
Gender	Male			

Monitoring stopped: 05.03.2007 10:25

New Patient?

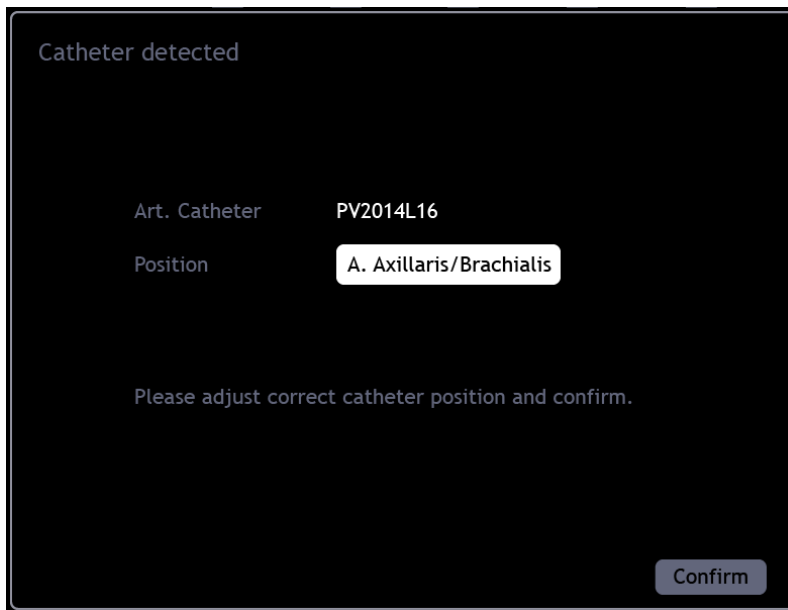
Figure 17: Start screen

Monitoring of the previous patient can be continued. In this case all previous measurement results will be stored by the monitor. PCCO calibration can be restored up to 15 minutes after the last shutdown of the device. ScvO<sub>2</sub> calibration can be restored up to 24 hours after the last calibration.



**CAUTION:** When restoring the calibration in the PCCO and ScvO<sub>2</sub> calibration menu an old calibration factor may be used. Ensure that the values are plausible after having used this option.

### Confirm catheter position



*Figure 18: Catheter position*

When selecting a new patient, and provided that a catheter has already been connected, the "Catheter Position" screen appears.

The catheter position must be confirmed and, if necessary, changed.

If monitoring of a new patient has been started, all previous results will be cleared from the system memory.

The screenshot shows a patient input screen with the following fields and values:

- Height: 175 cm
- Weight: 75 kg
- Category: Adult
- Gender: Male
- Name: [Empty field]
- Patient ID: [Empty field]


Calculated values:

- BSA: 2.01 m<sup>2</sup>
- PBW: 73.3 kg
- PBSA: 1.91 m<sup>2</sup>


Note: Correct input of height, weight, category and gender is mandatory for accuracy of the parameters displayed.

Buttons: New Patient, Next

Figure 19: Input screen

 **NOTE:** Correct input of height, weight, category and gender is mandatory for the accuracy of the displayed parameters as well as for the correct indexing of some parameters.

Patient name and ID can be entered optionally.

 **WARNING:** If a new patient is connected to the device without the device being shut down, the procedure "New Patient" must be selected. Otherwise data from the last patient is still displayed.

For further details please refer to chapter C5.1.1 Information input.



### 3.5 Zero adjustment

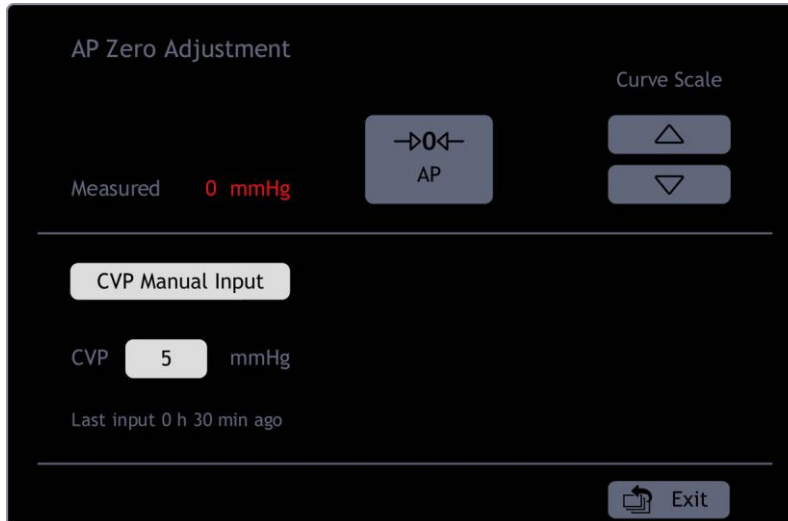



Figure 20: "Zero adjustment" screen

#### 3.5.1 Zero adjustment of arterial pressure (AP) and central venous pressure (CVP)

**Procedure:**

- Open 3-way-stopcock between pressure transducer and pressure line to ambient pressure.
- Confirm with the  button as soon as a stable value is displayed.
- Perform the zero adjustment at the bedside monitor.
- Set the 3-way-stopcock so that the invasive pressure is transferred to the pressure transducer by the pressure line.
- Adjust curve scaling with the respective buttons.
- If necessary repeat this procedure for the central venous pressure.
- In cases where continuous central venous pressure is not measured, manually update the value for the central venous pressure regularly.



**CAUTION:** If the option of the continuous CVP measurement is not used, CVP should be updated as soon as a new value is obtained to accurately calculate SVR and PCCO.

If the zero adjustment is not performed, the blood pressure values may be wrong. Zero adjustment of the pressure transducer is mandatory.

When the PiCCO<sub>2</sub> is connected to a bedside monitor, perform a zero adjustment of the PiCCO<sub>2</sub> before zeroing the bedside monitor.

### 3.6 Central venous oxygen saturation



#### 3.6.1 ScvO<sub>2</sub> calibration

Regular in vivo calibration is required using blood gas analysis of a central venous blood sample to ensure accurate measurement of continuous ScvO<sub>2</sub>.

For optimal accuracy, it is recommended that an in vivo calibration be performed at least every 24 hours.

The Signal Quality Indicator (SQI) is used for assessing the quality of fiberoptical signals during probe placement, calibration and measurement.

##### Signal Quality Indicator (SQI):

In the ScvO<sub>2</sub> calibration screen as well as in the parameter field the PiCCO<sub>2</sub> provides a Signal Quality Indicator to assist in proper probe placement.

The signal quality is indicated by bars of different height levels. Generally, the higher the level the better the signal.

Signal quality may be compromised by the following:

- Strong pulsation / motion artifacts
- Signal intensity (e.g. kinking of probe, blood clot or haemodilution)
- Intermittent wall contact by the tip of the probe



##### NOTE

The SQI signal can be affected by the presence of electrosurgical units. Attempt to distance electrocautery equipment and cables from the monitor and plug the power cords into separate circuits if possible. If signal quality problems persist, contact PULSION Medical Systems for assistance.

To achieve optimal accuracy, it is recommended that the entered haemoglobin and haematocrit values be updated when there is a change of 6 % or more in haematocrit or of 1.8 g/dl (1.1 mmol/l) or more in haemoglobin. A change in haemoglobin may also affect SQI.



Dye (e.g. Indocyanine Green) or other substances which contain dyes which usually modify the light absorption capacities, can lead to faulty measurement values of the oxygen saturation.

In case of ICG measurement ScvO<sub>2</sub> calibration is not possible for a maximum time span of 90 minutes.

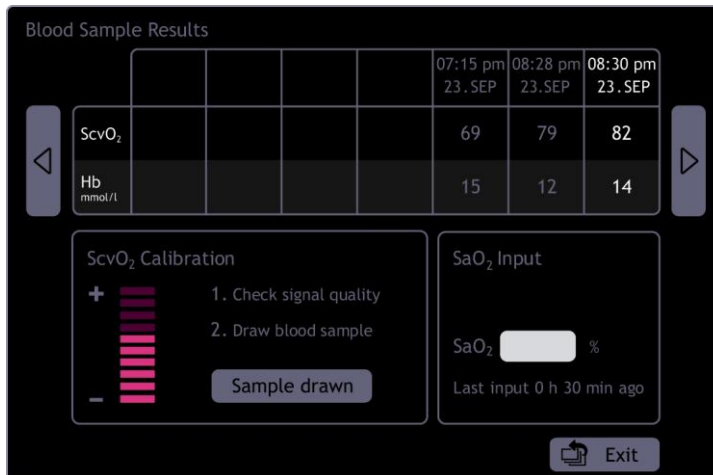


Figure 21: "ScvO<sub>2</sub> calibration" screen: Blood sample withdrawal

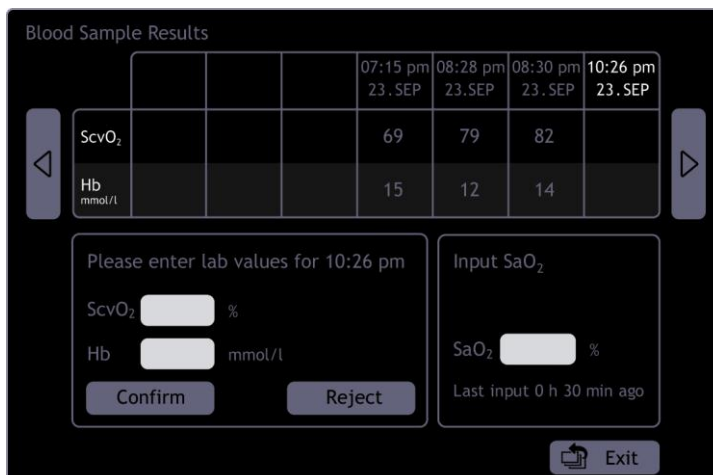


Figure 22: "ScvO<sub>2</sub> calibration" screen: Input of lab values

**Procedure:**

- 1 Check proper placement of central venous catheter and CeVOX probe.
- 2 Check the quality of the signal.
- 3 Withdraw a sufficient amount of central venous blood from the sideport of the CeVOX probe to avoid intermixture of infusion/injection with the withdrawn blood.
- 4 Slowly withdraw 2 ml blood from the sideport of the CeVOX probe. Do not pull too strongly in order to avoid a haemolysis.
- 5 Immediately confirm with button "Sample drawn".
- 6 If necessary put blood sample on ice and perform an analysis by a blood gas analysis device or a laboratory oximeter.
- 7 Input lab values for Hb/Hct and ScvO<sub>2</sub> and confirm.

The units g/dl or mmol/l can be used for Hb. Alternatively input of Hct is possible (adjustment in measurement configuration, chapter C5.6). During blood gas analysis, all other monitor functions can be operated. When returning to the ScvO<sub>2</sub> screen, the lab values for the respective measurement can be entered. In cases where the lab results are invalid, press "Reject" button and withdraw a new blood sample.

### 3.6.2 SaO<sub>2</sub> Input

Input of arterial oxygen saturation is required for display of parameters DO<sub>2</sub> and VO<sub>2</sub> (oxygen delivery and oxygen consumption).

SaO<sub>2</sub> input can be done independently from ScvO<sub>2</sub> calibration.

### 3.7 Indocyanine Green (ICG) measurement



This option needs to be activated in the measurement configuration tab (refer to chapter C5.6 Measurement configuration) and is only available if a LIMON module is connected to the PiCCO<sub>2</sub>.

The measurement of Indocyanine Green elimination is non-invasive.

The PiCCO<sub>2</sub> automatically detects the connected module.



#### NOTE

To avoid signal artifacts or insufficient curves please note that the patient should not be moved or treated during ICG measurement. No other PiCCO<sub>2</sub> measurement options are available during the ICG measurement.

#### 3.7.1 Non-invasive ICG measurement

Non-invasive ICG measurement is based on pulse oximetry. For detailed information please refer to chapter B5.1 Principle of pulse oximetry.



#### NOTE

The non-invasive ICG measurement is not recommended for use on patients weighing less than 20 kg (44lbs).



Manual input of ScvO<sub>2</sub> is required for the optional calculation of oxygen consumption (VO<sub>2</sub>). For further information please refer to chapter C3.7.1.1 ScvO<sub>2</sub> Input.



#### NOTE


To avoid signal artifacts or insufficient curves please note that the patient should not be moved or treated during ICG measurement. No other PiCCO<sub>2</sub> measurement options are available during the ICG measurement.


#### Procedure

- 1 Press direct access button .
- 2 Prepare the Indocyanine Green injection with 0.25mg/kg or 0.5mg/kg. If desired you can use the ICG Calculator by pressing the  button. For further information please refer to chapter C3.7.3 Calculation of ICG.
- 3 Check the quality of the SpO<sub>2</sub> signal in the parameter box. Strong pulsation indicates a good signal.

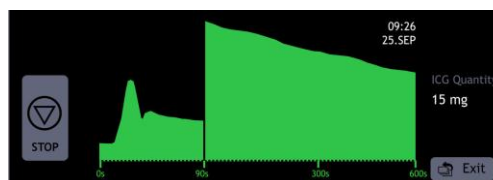
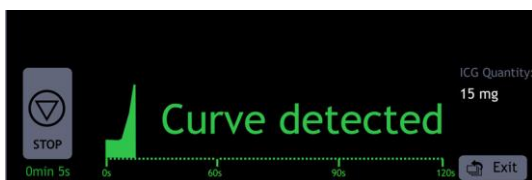
- 4 Press the START button and wait. The button label changes to STOP and a counter is displayed below the button indicating the remaining time needed for baseline analysis, this will last at least one minute.
- 5 When message “Inject XXmg” appears, inject the prepared ICG solution into a central or peripheral vein.




 **NOTE**  
After peripheral injection, immediate flushing of the cannula or catheter with saline solution is recommended.

 **WARNING:** During ICG measurement oxygen saturation cannot be determined i.e. SpO<sub>2</sub> is not available during non-invasive ICG measurement. This is indicated by blinking asterisk symbols (\*\*\*)  
As the SpO<sub>2</sub> value may still be affected by ICG after the measurement, the device will display corrected values. This is indicated by a question mark “?” next to the value. This corrected value is displayed for a maximum of 90 minutes.

- 6 The message “Curve detected” is displayed. A time counter appears below the STOP button indicating the remaining measurement time. The curve scale changes after 120 seconds.



- 7 Once the measurement is completed the PDR result is displayed in the table (please refer to chapter C3.7.2 Display of results)
- 8 To stop an ongoing ICG measurement, press the STOP button.

 **NOTE**  
If an ongoing ICG measurement is stopped and no PDR value is available within the last 6 hours, blinking asterisk symbols (\*\*\*) are displayed instead of a SpO<sub>2</sub> value for a maximum of 90 minutes.

### 3.7.1.1 ScvO<sub>2</sub> Input

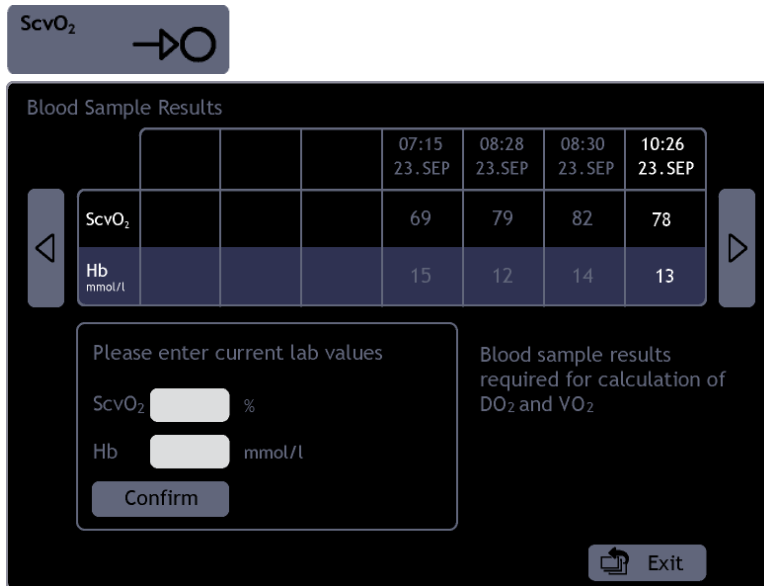


Figure 23: ScvO<sub>2</sub> input screen

During non-invasive ICG measurement manual input of ScvO<sub>2</sub> and Hb are required for the optional calculation of VO<sub>2</sub>. In this case the **ScvO<sub>2</sub>CAL** button automatically changes to the **ScvO<sub>2</sub>** button. For calculation of DO<sub>2</sub> only input of haemoglobin (Hb) is necessary.

### 3.7.2 Display of results

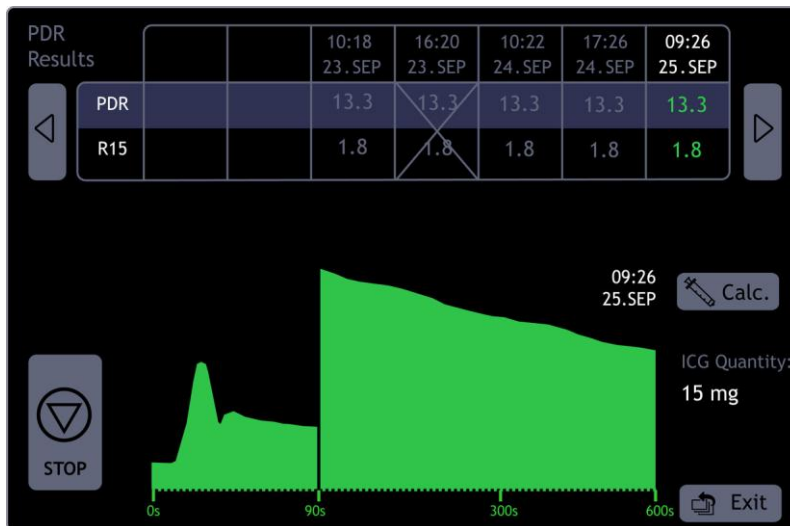


Figure 24: PDR curve and results

Single PDR results are displayed in a table. Current values are displayed in white on the right side of the table. These values are also displayed in the parameter field. The last 6 measurements can be reviewed. During the review the values appear in green colour and the corresponding ICG curve is displayed. Older measurements are displayed in grey and cannot be reviewed.

The current measurement can be deactivated / crossed out by touching the respective value in the table.

Asterisk symbols (\*\*\*) for PDR/R15 are displayed in the parameter field. Only the last measurement can be reactivated again.

### Following ICG injections

A new ICG measurement is only possible when the ICG concentration has decreased to a certain level. The message “**Next ICG injection possible hh:mm**” is displayed on the screen indicating the time the next ICG measurement is possible. The START button will remain grey during this time.

#### 3.7.3 Calculation of ICG quantity

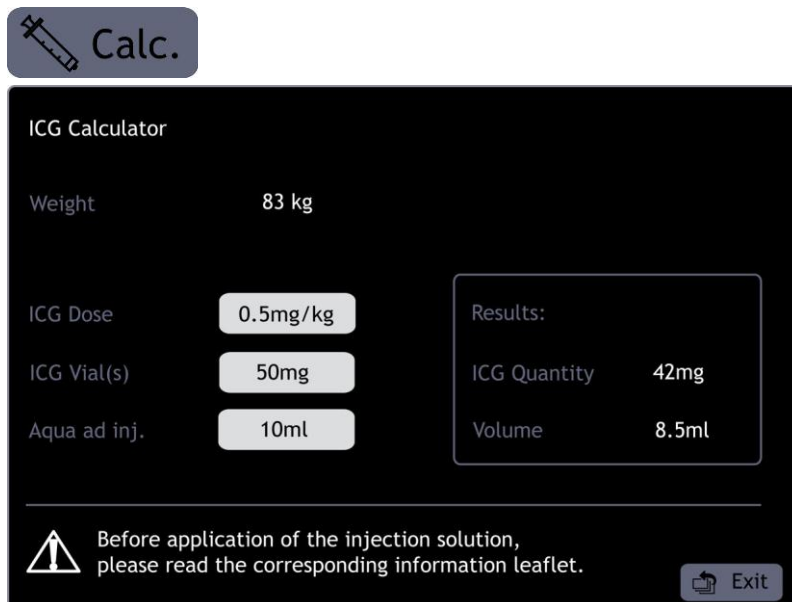




Figure 25: ICG calculator screen

The ICG Calculator screen appears by pressing the  button in the PDR measurement screen (refer to Figure 24). The necessary ICG quantity and injectate volume will be calculated according to the data input.

<b>Weight</b>	<b>kg</b>
Actual body weight of patient used for the calculation	
<b>ICG Dose</b>	<b>0.25mg/kg / 0.5mg/kg</b>
Setting of the individually used ICG dose	
<b>ICG Vial(s)</b>	<b>25mg / 50mg / 2x50mg / 3x50mg</b>
Setting of the individually used ICG Vial(s)	
<b>Aqua ad inj.</b>	<b>5ml / 10ml / 20ml / 30ml</b>
Setting of the individually used volume of water for injection	
<b>Results</b>	
Calculated values of ICG quantity and volume dependent on the entered data. Calculated values are recommendations for the minimum amounts.	

 **NOTE**  
For information on the diagnostic drug, Indocyanine Green, please refer to the corresponding SPC (summary of product characteristics) or PIL (patient information leaflet) of ICG.



### 3.8 Thermodilution and calibration of pulse contour analysis



Figure 26: "Thermodilution" screen

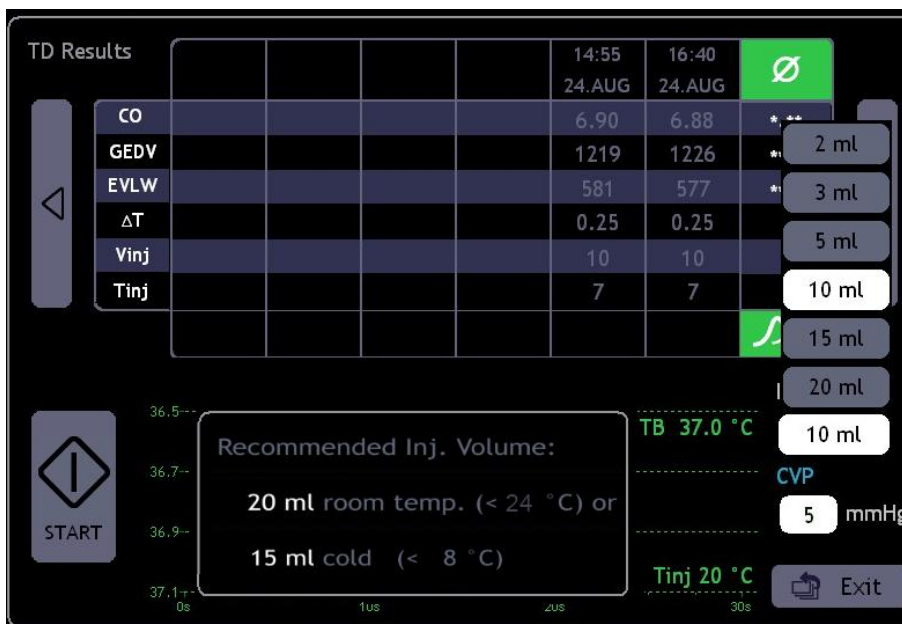


Figure 27: Selection of "Inj. Volume" option with help screen "Recommended Inj. Volume"

A thermodilution measurement is necessary to determine the patient's volume status and to calibrate the pulse contour analysis with reference to the CO value. Three to five single thermodilution measurements within 10 minutes are recommended.

With a stable patient it is recommended to perform a thermodilution measurement every 8 hours. With an unstable patient it may be necessary to perform thermodilution measurements more frequently in order to determine the patient's volume status and to recalibrate the continuous determination of CO.

**NOTE**

Central venous pressure (CVP) is required for calibration of continuous cardiac output (PCCO). Before performing a thermodilution measurement, pay attention to a current and plausible value. In cases of a continuous CVP measurement with the PiCCO<sub>2</sub>, the CVP value from the beginning of the thermodilution measurement is used in order to avoid errors due to, for e.g., adjusting the 3-way-stopcock to which the central venous pressure transducer is connected. The value of the CVP which is used for calibration is displayed on the thermodilution screen and can be changed if necessary.


**NOTE**

Before initial calibration you need to ensure that a zero adjustment for the arterial pressure is performed and that the pressure transfer works correctly.



**CAUTION:** If the displayed pulse contour parameters are not plausible, they should be checked by a thermodilution measurement. The pulse contour cardiac output measurement will be recalibrated automatically.

**Procedure:**

- 1 Press direct access button .
- 2 Check the blood pressure signal and if necessary flush the PiCCO catheter. If necessary perform a zero adjustment. Manually input central venous pressure (CVP) if not using continuous CVP measurement.
- 3 Prepare appropriate injectate solution e.g. 20 ml of room-tempered (<24°C) saline 0.9 %.
- 4 Check the setting for the used injectate volume and if necessary adjust the volume (Inj. Volume) (see Figure 26).  
① New in version 3.1: The recommended injectate volume is displayed in a help window when the "xx ml" button is pressed (see Figure 27).
- 5 Press the START button.
- 6 When message "Inject XX ml" appears, inject the prepared injectate through the injectate temperature sensor housing rapidly (< 7 s) and smoothly.
- 7 To stop an ongoing cardiac output measurement, press the STOP button.
- 8 Perform 3 to 5 single measurements within 10 minutes as described under points 1 to 6.

If necessary reject invalid measurements: the respective measurement can be activated by selection from the table, after selecting it once more the measurement is rejected and not included in the PCCO calibration. Irregular measurements are marked with a "?" and should be reviewed carefully. The remaining measurements should be distinct, without a high dispersion and they should have a regular and comparable curve shape (see next page: quality of a thermodilution measurement).



**NOTE**

The rejection of measurement values is only possible within 10 minutes after the measurement.



**NOTE**

In case of  $\Delta T < 0.1^{\circ}\text{C}$ , the precision of the thermodilution measurement should be further optimized by using cold ( $< 8^{\circ}\text{C}$ ) and/or more injectate.

If no plausible arterial pressure signal is available during a thermodilution measurement, the measurement is not used to calibrate PCCO, but is included in the average for the thermodilution parameters.

The results of such measurements are displayed in the table and marked by a curve highlighted in red. Additionally a message is displayed in the information bar.

Check the arterial pressure signal before the next thermodilution measurement in order to calibrate the pulse contour analysis.

Body weight [kg]	Cold ( $< 8^{\circ}\text{C}$ )	Room temperature ( $< 24^{\circ}\text{C}$ )
$< 3$	2 ml	3 ml
$< 10$	3 ml	5 ml
$< 25$	5 ml	10 ml
$< 50$	10 ml	15 ml
$< 100$	15 ml	20 ml
$\geq 100$	20 ml	20 ml

Figure 28: Recommended injectate volume depending on body weight

**Auto TD**

The function "Auto TD" can be selected via the configuration tab "Measurements". The Auto TD function allows a pre-selected number of TD measurements to be performed consecutively, without the need for pressing the START button between measurements.

A new thermodilution measurement is possible as soon as "Inject XX ml" is displayed on the screen. The PiCCO<sub>2</sub> patient monitor automatically detects further thermodilution measurements.

The number of measurements to be automatically detected can be selected via the configuration tab "Measurements". The current status is displayed below the STOP button.

Measurements can be stopped at any stage by pressing the STOP button.



### Display of results

The single TD results are displayed in table form. All measurements of one set must be done directly following each other. The maximum time frame for the measurements is 10 minutes.

Older measurements are displayed in grey and not included in the current average. Active values are displayed in white. Measurements which are excluded from the average are crossed out.

All active curves can be displayed at a later time by selection. Older measurements are still available in table form.

Scaling of a thermodilution curve can be changed in two steps by touching the curve.

- ① **New in version 3.1:** The values for injectate volume ( $V_{inj}$ ) and injectate temperature ( $T_{inj}$ ) are both displayed in the thermodilution table.

### Quality of a thermodilution measurement:

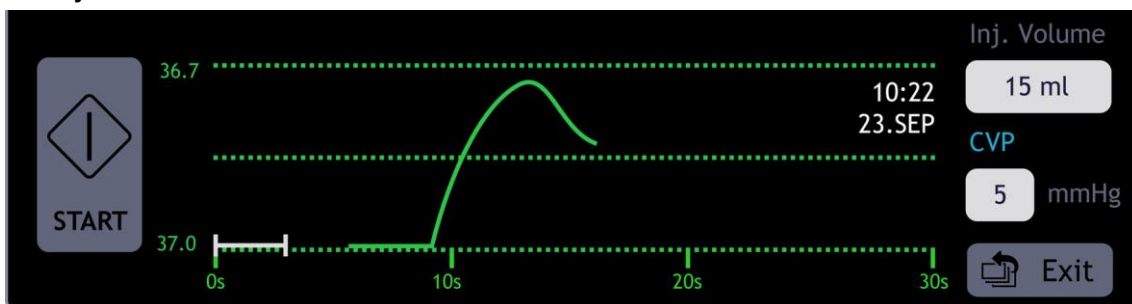


Figure 29: Thermodilution curve

- A normal curve has one smooth peak and then returns in direction to the baseline.
  - The maximum temperature difference ( $\Delta T$ ) should exceed  $0.10^{\circ}\text{C}$ .
  - The used injectate volume ( $V_{inj}$ ), the measured injectate temperature ( $T_{inj}$ ) and  $\Delta T$  can be verified in the table.
  - Good measurements within one set of measurements are in close agreement. In case of a dispersion of CO results of more than 20 %, the measurement is marked with a "?".
- Conspicuous measurements have to be rejected.



#### NOTE

In order to optimize the quality of the thermodilution curve you can use more and/or colder injectate and inject as rapidly as possible.

Throughout the measurement the patient should remain as still as possible, the position of the thermodilution catheter must not be moved and no further infusions or injections should be administered.



**CAUTION:** Faulty measurements can be caused by incorrectly placed catheters, interfering signal transmission e.g. of arterial pressure, defective connections or sensors, or by electromagnetic interference (e.g. electric blankets, electric coagulation).

## 4 Display Options

(see Figure 12: Screen elements)

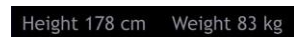
The parameter fields on the right, the information bar and the real time pressure curve are displayed permanently. Extended display options for parameters are accessible in the patient screen.

The default setting provides the basic and commonly used parameters. All necessary modifications and settings are effected by selecting the respective graphic element.



**WARNING:** The device enables the monitoring of physiological parameters. The clinical significance of changes in the monitored parameters must be determined by physician.

### 4.1 Information bar



Height and weight of patient

Selection takes you to "Patient configuration" screen



Time of last thermodilution measurement



System time

Selection takes you to "Monitor configuration" screen



Loudspeaker

Alarm / warning volume



Blinking: acoustic alarm paused

Not blinking: alarm volume muted



Selection takes you to alarm and volume setting



Battery status

Shows battery status in case system is not connected to mains



Error message (in case of error status)

## 4.2 Real time pressure curve

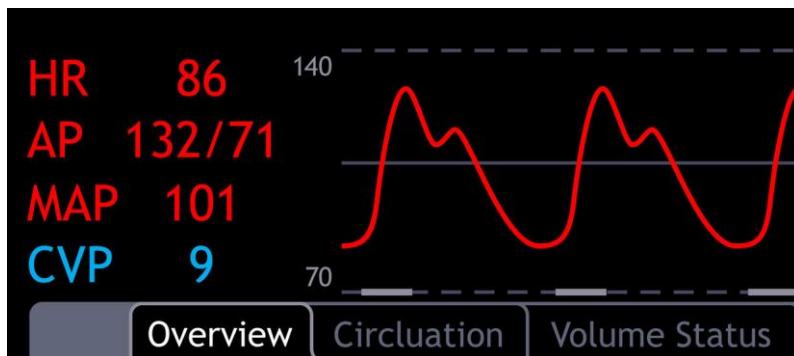


Figure 30: Real time curve of arterial pressure

### Curve and pressure display

Arterial pressure is continuously displayed as pressure curve. The numeric values for heart rate, systolic, diastolic and mean arterial pressure are displayed.

### Systolic marker of arterial pressure

The systolic part of each heart beat is marked by a bar under the curve. If all or some of these bars are missing, the PiCCO<sub>2</sub> cannot analyze the blood pressure curve and thus cannot display results for the continuous CO.

- ➔ Selection of the curve on the touch screen directly leads to zero adjustment and scaling of the curve.

### CVP value

Central venous pressure of a patient can either be recorded continuously as it is the case with arterial pressure or it can be entered manually. In the case of manual input the value is displayed in brackets.

- ➔ Selection of the CVP value on the touch screen displays the continuous CVP curve for 15 seconds. Selection of the curve leads to zero adjustment. Manual input is done by selection of the CVP value.

### 4.3 Parameter fields




Figure 31: Parameter fields

The arrangement of the PiCCO<sub>2</sub> parameter fields is function-specific. Additionally other parameters can be configured along side the main parameter of each group.

- ➔ Selection of the parameter field on the touch screen directly leads to parameter configuration.



#### NOTE

Discontinuous parameters are marked with the time indicator symbol . The time since determination of these values is displayed in the information bar on the right hand side.

Depending on the selected measurement function the parameter fields are automatically adapted.

## 4.4 Profiles

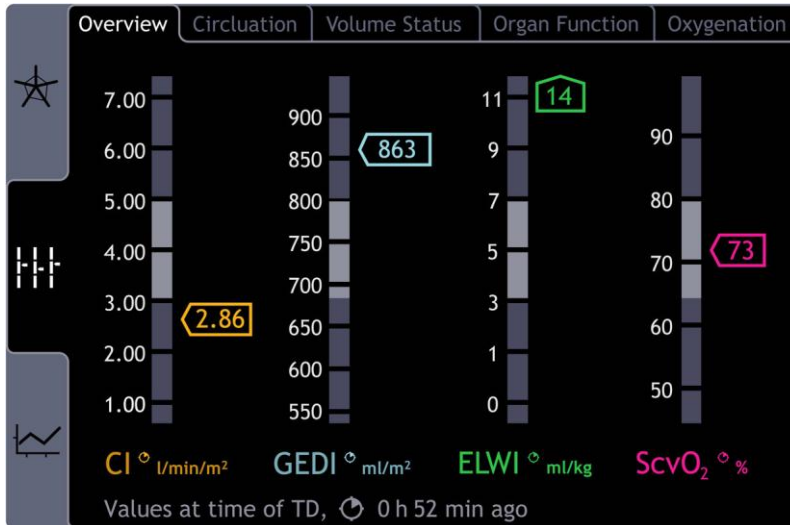


Figure 32: "Profiles" screen

Parameter profiles show the measured parameters in respect of their position to the normal value range which is highlighted.



**NOTE**

All values displayed in the profile correspond to the time of the last thermodilution measurement.

- ➡ The option "Overview" shows the main parameters. The organ specific parameters can be displayed by selection of the respective option.

The marked normal value ranges can be modified. Please contact your PULSION representative to individually modify the normal values range.

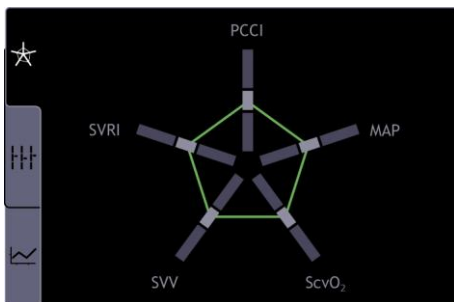


## 4.5 SpiderVision



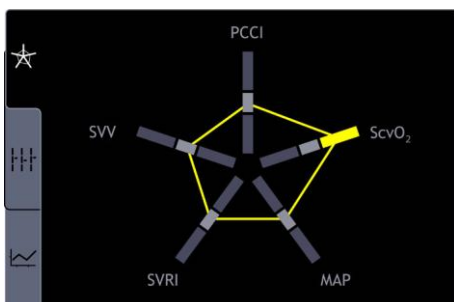
The PULSION SpiderVision diagram shows all continuous parameters in dynamic conjunction.

- ➔ Selection of the SpiderVision diagram on the touch screen directly leads to individual configuration.

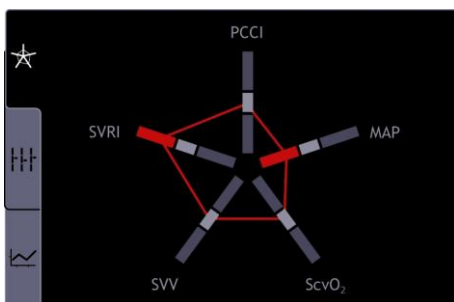


The brighter marked areas highlight the normal or target value for the respective parameter.

The diagram is displayed **GREEN** as long as all displayed parameters are within the normal or target value range.




The diagram is displayed **YELLOW** immediately one of the displayed parameters goes outside the normal or target value range.



If the diagram appears **RED**, two or more displayed parameters are outside the normal or target value range.

Figure 33: "Spider" screen

All parameters which were given a target value are marked with the target value symbol .

For details concerning the adjustment of normal values to target values please refer to chapter C5.7 Normal and Target Values.

## 4.6 Trend

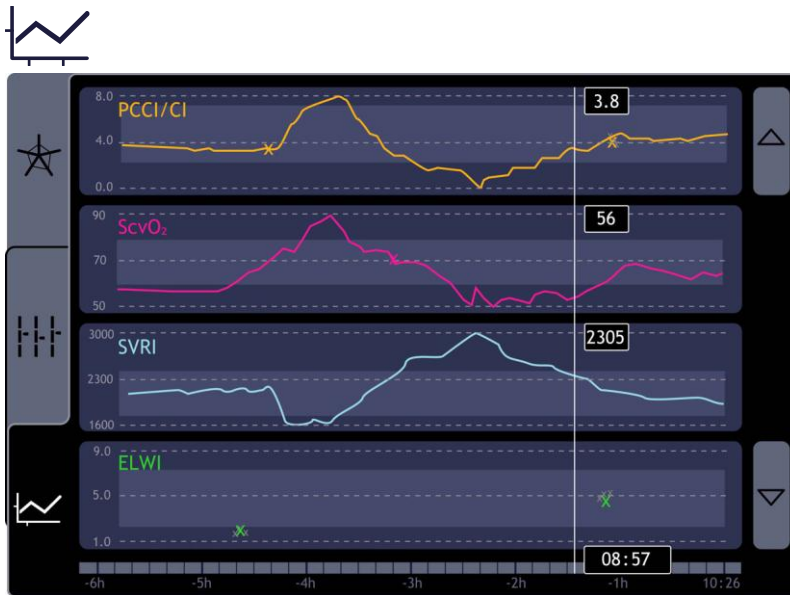


Figure 34: "Trend" screen

The number of trends as well as the trend time span of the PiCCO<sub>2</sub> parameters can be configured individually.

➡ Selection of a trend curve on the touch screen directly leads to individual configuration.

If more than 4 trends are configured at the same time, the arrow keys on the right side of the screen can be used for scrolling up or down the trends.

The vertical cursor, which can be activated and moved by the navigation dial, is used for accurate display of the numeric values at the respective time.

The trend can be displayed numerically or graphically. This selection can be done in the Trend Configuration screen.

## 5 Monitor and Display Configuration

The PiCCO<sub>2</sub> has a configuration level in order to arrange individual settings. By selecting the respective function the corresponding option in the configuration menu is opened. A direct change between the single configuration options is possible.

### 5.1 Patient settings

Figure 35: "Patient settings" screen

The required settings must be made before starting monitoring. When the PiCCO<sub>2</sub> is switched on the device automatically displays this option.



#### NOTE

Correct input of height, weight, category and gender is mandatory for the correct indexing of some parameters.

↻ Selection of height / weight display in the information bar at the top of the screen also opens this option.

The button **New Patient** allows the admission of a new patient. Existing trend information and calibrations will be erased. The PiCCO<sub>2</sub> automatically goes through the next screens which are required.

#### 5.1.1 Information input

##### Height, Weight

**20 – 250 cm / 2 – 300 kg**

Input of actual height and weight.

A short-term increase in body weight due to illness (e.g. edema) should be deducted. However, in patients with pre-existing obesity this weight should be entered.

**Category****adult / pediatric**

In marginal cases the decision about the correct category for the individual patient must be based on their anatomy and appearance (habitus). For further information please refer to chapter E5 Equations for Calculated Values.

**Gender****male / female****5.1.2 Predicted body weight**

Height, weight, category and gender are needed for the calculation of the Body Surface Area (**BSA**), Predicted Body Weight (**PBW**) and Predicted Body Surface Area (**PBSA**).

These calculated body characteristics are required for the indexing of PiCCO<sub>2</sub> parameters (details see Appendix, chapter E)

**5.2 Monitor settings**

Figure 36: "Monitor settings" screen

Settings of **date**, **time**, **language** and further device-related settings.

**NOTE**

Adjustment of date or time during patient monitoring deletes the complete trend information for this patient.

- ➡ Selection of the time or the loudspeaker symbol in the information bar at the top of the screen also opens this option.

### Keytones

The keytones (ON/OFF) are initiated when touching elements on the screen, the device or the navigation dial. The current setting is retained even if the equipment is switched off.

### Alarm

The volume of the acoustic alarm. For safety reasons the settings are adjusted to 75% with every new patient.

### Brightness

The selection of brightness of the screen can be done manually. The setting is retained even if the equipment is switched off.

## 5.3 Configuration of parameter display

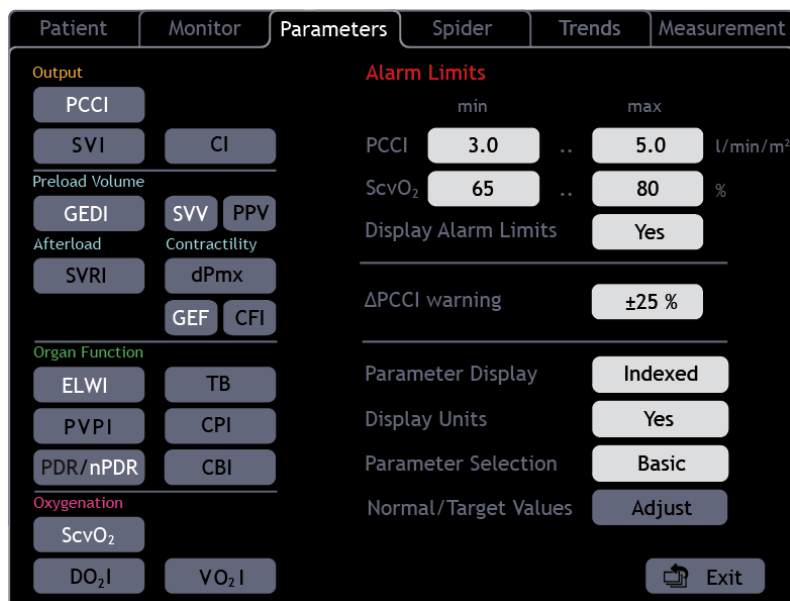


Figure 37: "Parameter configuration" screen

➔ Selection of a parameter field on the right side of the screen directly leads to the configuration screen.

The parameter display can be configured individually. The main parameters are always displayed and cannot be deselected. Active parameters are displayed in WHITE.

#### ① New in version 3.1:

In the "Preload Volume" group, the parameter buttons "SVV" and "PPV" are both displayed and can either be selected individually, both at the same time, or deselected. Default selection is "SVV".

In the "Contractility" group, the parameter buttons "GEF" and "CFI" are both displayed and can be selected individually or deselected. The buttons cannot be selected both at the same time. Default selection is "GEF".

➔ The parameters are activated or deactivated by selection of the respective parameter button and directly displayed or disabled in the parameter display.

### 5.3.1 Setting of alarm limits

#### Adjusting of alarm limits

Alarm limits can be set for the parameters PCCO and ScvO<sub>2</sub>. Upper and lower alarm limits have to be determined. These alarm limits are returned to the default setting with every new patient.

#### Display alarm limits

Yes / No

Display of alarm limits directly next to the respective parameter on the right side of the screen.

### 5.3.2 PCCI change warning

#### ① New in version 3.1:

#### Δ PCCI warning

Off / ± 15 % / ± 25 % / ± 35 %

Warning messages can be displayed when a change in PCCI since the last thermodilution has occurred that is greater than the threshold value defined in this option. Also, the amount of time elapsed since the last measurement and the change percentage (e.g. “ΔPCCI ↑ xx%” for positive values or “ΔPCCI ↓ xx%” for negative values) are alternately displayed in the right part of the information bar (for further information see chapter 6.2).

The PCCI change warning can be switched off using the “Confirm” button.

The PCCI change warning can be reactivated with a new thermodilution measurement (TD) or by changing the percentage setting.

Default setting is Off.

- ☞ The warning message “Significant change - Consider TD” will be displayed, if 80% of the relative change of PCCI values calculated within the last 2 minutes are above or below the user-defined threshold AND if the latest TD measurement took place more than 12 minutes ago.
- ☞ If the PCCI change warning and TD reminder are both activated, the messages in both sections alternate.
- ☞ Every time a new patient is entered, this setting is automatically reset to the default value Off.

### 5.3.3 Parameter settings

#### Absolute / Indexed

Depending on the setting of the entire device the PiCCO<sub>2</sub> shows the parameters as either absolute or indexed to the body characteristics of the patient. Exceptions are the patient profiles, SpiderVision and the trend display because the indication of normal value ranges is only reasonable for indexed parameters.

#### Display of units

Yes / No

The respective parameter units can be activated or deactivated with this option.

#### Parameter selection

Basic / Cardiac / Septic / Individual

The main parameters are shown in the basic display. In the case of individual parameter settings "Individual" is displayed.

① New in version 3.1:

Two additional settings "Cardiac" and "Septic" are available by default, containing the following parameters:

Cardiac	Septic
PCCI, SVI, CI	PCCI, SVI, CI
GEDI	GEDI, SVV
SVRI	SVRI
GEF, dPmx	---
ELWI, CPI, TB	ELWI, PVPI, CPI, TB
ScvO <sub>2</sub> , DO <sub>2</sub> , VO <sub>2</sub>	ScvO <sub>2</sub> , DO <sub>2</sub> , VO <sub>2</sub>

➔ Please contact your PULSION representative to individually modify the parameter profiles.

## 5.4 Spider configuration

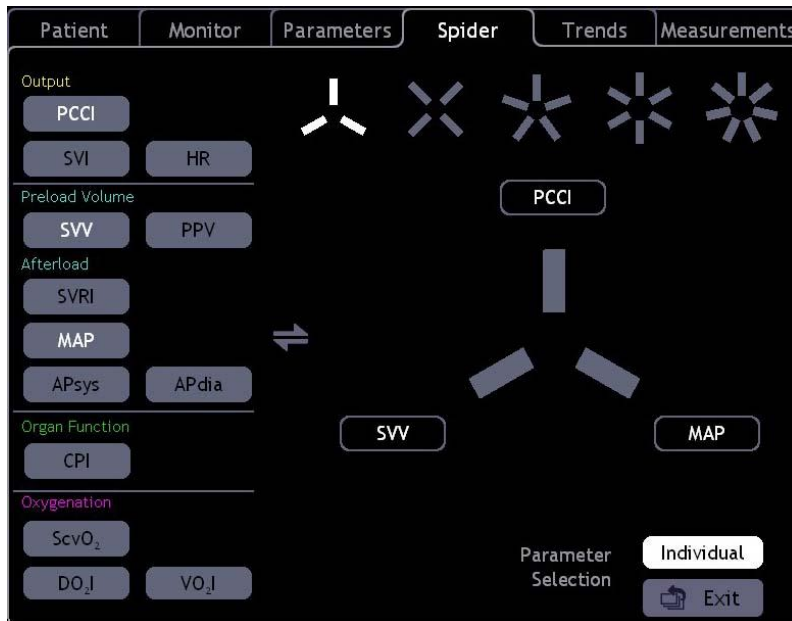


Figure 38: "Spider configuration" screen

The SpiderVision diagram can be configured individually:

- First select the number of spider legs (3 to 7)
- Select the parameter to be placed (left)
- Select the spider leg where the parameter should be placed

➡ The spider configuration can be opened by direct selection of the spider diagram.

① New in version 3.1: The buttons "SVV" and "PPV" are both available for selection.

### Parameter selection

### Basic / Individual

The "Basic" setting uses the default setting of the device which can be recalled at any time.



## 5.5 Trend configuration

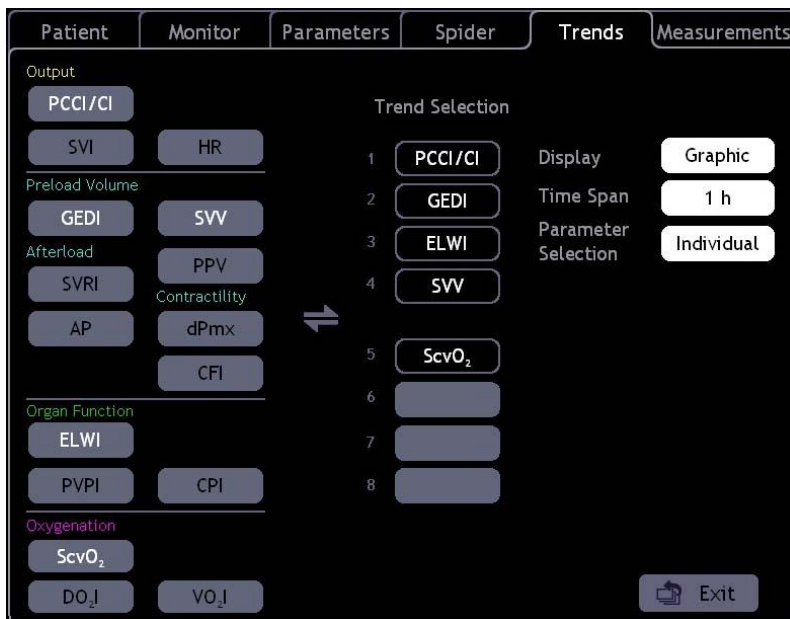


Figure 39: "Trend configuration" screen

The trend display can be configured individually. A maximum of 8 parameter trends can be displayed.

- Select the parameter which should be displayed as a trend.
  - Select the position where the parameter trend should be displayed.
- ➔ The trend configuration is opened by direct selection of the trend diagram.
- ① New in version 3.1: The buttons "SVV" and "PPV" are both available for selection.
- ① Depending on the selection in the "Parameters" configuration tab, either the "GEF" or the "CFI" button is displayed, respectively. If neither of the buttons is selected, the "GEF" button is displayed.

### Display

**Graphic / Numeric**

The trend display of individual parameters can be graphic or numeric.

### Time span

**10min / 1h / 6h / 24h / 2d / 6d / 12d**

Time span of trend display.

### Parameter selection

**Basic / Individual**

The "Basic" setting uses the default setting of the device which can be recalled at any time.

## 5.6 Measurement configuration

The screenshot shows the 'Measurement' tab of a medical device interface. It is divided into three sections:

- TD Measurement:**
  - Art. Catheter: PV2015L20
  - Position: A. Axillaris
  - Auto TD: off
  - TD Reminder: off
  - Central Venous Catheter: V. Jug./Subcl.
  - Inj. Site: V. Jug./Subcl.
  - Inj. Volume: 15 ml
  - Recommended Inj. Volume: 20 ml room temp. (< 24 °C) or 15 ml cold (< 8 °C)
- ScvO<sub>2</sub> Measurement:**
  - Hb / Hct: Hb
  - Hb unit: mmol/l
- ICG Measurement:**
  - ICG Dose: >0.25 mg/kg
  - ICG quantity: 19mg
  - Exit button

Figure 40: "Measurement configuration" screen

➡ The measurement configuration can be directly accessed from the respective measurement screen.

### 5.6.1 Configuration of thermodilution measurement

#### Art. Catheter

Automatic detection and display of the connected thermodilution catheter. If a new PiCCO catheter type is not automatically recognized by the device, it is necessary to enter the ACC (Arterial Catheter Constant, indicated on the connector of the PiCCO catheter).

#### Position

A. Axillaris / A. Brachialis / A. Femoralis / A. Radialis

The intended catheter position is displayed and can be changed if necessary.

#### Auto Thermodilution Mode (Auto TD)

Off / 3x / 4x / 5x

The number of TD measurements can be set automatically. The device will prompt the user to inject without the need to press the START button repeatedly.

Default setting is 3x.

- ① New in version 3.1: The selected value remains valid for every new patient.

#### TD Reminder

Off / 1h / 2h / 4h / 8h

Setting of the individual reminder to perform a thermodilution measurement. Default setting is 8h.

- ① New in version 3.1: When the selected TD reminder time has elapsed, the message "TD Measurement recommended" and the amount of time elapsed since the last measurement are displayed in the information bar (see also chapter 6.2).

The selected value remains valid for every new patient.

### 5.6.2 Configuration of central venous catheter

Setting of the individual injection site and injectate volume for the central venous catheter.

① New in version 3.1:

**Inj. Site:**

**V. Jug./Subcl. / V. Femoralis**

Selection of the injection site. Default setting is V. Jug./Subcl.

**Inj. Volume:**

**2ml / 3ml / 5ml / 10ml / 15ml / 20ml**

Setting of the individually required injectate volume. The recommended injectate volume will be displayed depending on body weight of the patient (see also Figure 40: "Measurement configuration" screen). Default setting for an adult patient is 15ml.

### 5.6.3 Configuration of ScvO<sub>2</sub> measurement

**Hb / Hct**

**Hb / Hct**

Optional input of Hb or Hct. Default setting is Hb.

**Hb Unit**

**g/dl / mmol/l**

Input of Hb can be made in the preferred unit. Default setting is g/dl.

### 5.6.4 Configuration of ICG measurement

The ICG measurement option only appears if a LiMON module is connected.

**ICG Dose**

**0.25mg/kg / 0.5mg/kg**

Default setting is 0.5mg/kg

**ICG quantity**

**mg**

The necessary quantity of ICG, dependent on the settings and the patient's body weight. The calculated value may not be altered.

### 5.7 Normal and Target Values

The allocation of target values is accessible via the menu "Normal values" of the help function or the parameter configuration. When pressing the "Adjust" button, a screen opens with a list of normal parameter values.

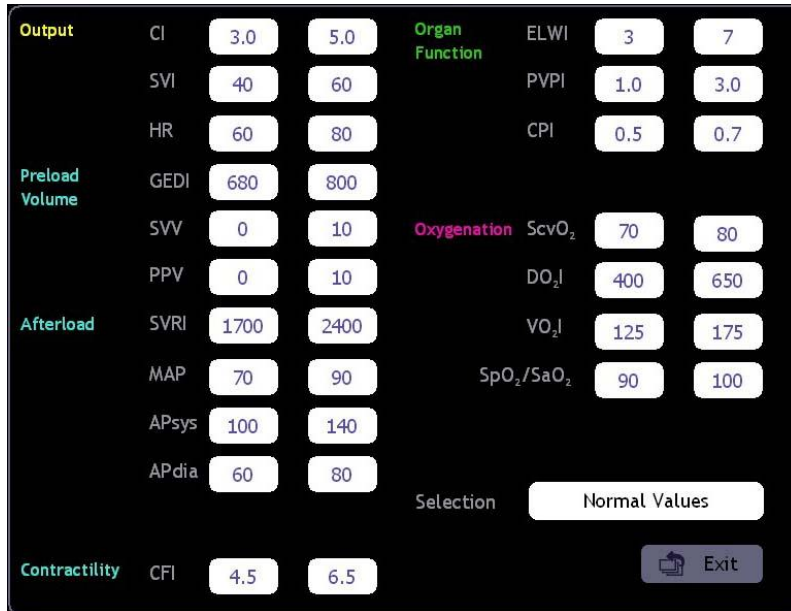
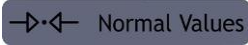


Figure 41: Normal- / Target value range

Adjustment of normal values to target values in the selection field is necessary in order to define target values. The allocation of target values applies for all display screens (Spider, Trends and Profile). In the SpiderVision diagram the target value symbol is displayed next to the respective parameter, if the target value is activated.

In order to restore normal values in the target selection press the  Normal Values button. All changes made will be cancelled and the default setting (normal values) will be restored.

When admitting a new patient normal values are automatically used.

- ① **New in version 3.1:** The buttons "SVV" and "PPV" are both available for selection.
- ① Depending on the selection in the "Parameters" configuration tab, either the "GEF" or the "CFI" button is displayed, respectively. If neither of the buttons is selected, the "GEF" button is displayed.

## 6 Alarms, messages and troubleshooting

The PiCCO<sub>2</sub> displays alarms, warnings and additional important information with different priorities.

### Categories:

Priority	Meaning	Display
1	Alarm: Emergency, immediate response necessary	Red blinking text display, acoustic alarm, blinking LEDs
2	Error messages, response necessary	Yellow text display
3	Additional information	Grey text display

Messages with the same priority are displayed alternately.

### Setting of acoustic alarm:

➔ Selection of the loudspeaker symbol directly leads to setting of the alarm volume.

The volume and the status of the acoustic alarm are displayed on the right side of the information bar.

Alarm muted (2 min / 5 min)		Blinking
Alarm volume, 6 steps		Turned down
		Loud
Alarm turned off		No acoustic alarm

### Suppression of acoustic alarm



The acoustic alarm can be temporarily paused. As long as the alarm condition exists the acoustic alarm can be heard again after:

- 2 minutes in case of parameter alarm
- 5 minutes in case of battery alarm



**WARNING:** Before using the device the setting of the alarm limits and the alarm volume must be checked for their suitability for the respective patient.

If an alarm condition arises while the alarm is suppressed, only the optical warning will be given.

## 6.1 Alarms

Alarms are displayed with priority 1, error messages with lower priority are overridden.

Alarm	Cause	Remedy
High PCCO / PCCI	PCCO / PCCI > alarm limit	-
Low PCCO / PCCI	PCCO / PCCI < alarm limit	-
High ScvO <sub>2</sub>	ScvO <sub>2</sub> > alarm limit	-
Low ScvO <sub>2</sub>	ScvO <sub>2</sub> < alarm limit	-
High SpO <sub>2</sub>	SpO <sub>2</sub> > alarm limit	-
Low SpO <sub>2</sub>	SpO <sub>2</sub> < alarm limit	-
Low Battery	Battery status < 25% and device is not connected to mains power	Connect device to mains power
Internal error - restart the device or SERVICE	No signals longer than 10 s (e.g. internal USB does not work)	Restart the device, if error exists further on, SERVICE necessary
Internal error - SERVICE necessary	Internal error	SERVICE necessary

## 6.2 Error Messages

Text error messages are displayed in the information bar (chapter C4.1). When viewing old measurements the respective error messages are displayed as well.

### General

Error Message	Cause	Remedy
Enter patient data for indexed values	Patient data (height / weight) etc. not entered	Enter patient data.

### Thermodilution

Error Message	Cause	Remedy
Invalid / Faulty catheter - Change catheter	Faulty catheter, not compatible or not connected	Connect compatible catheter
Unknown catheter - Enter ACC	Unknown catheter type with unknown resistor	Enter ACC in corresponding field
Injection Error - Repeat injection, rapid and smooth	Injection not smooth	Repeat injection rapidly and smoothly
Injectate Temp. Sensor Error - Check sensor cable and sensor housing	Defective injectate temp. sensor or sensor cable	Check and replace if necessary

Injection Error - Inject faster than 10 s	Time of injection longer than 10 seconds	Repeat injection rapidly and smoothly
TD Curve Error - Stabilize patient temperature and repeat injection	Calculation error of MTt / DSt caused by temperature interferences	Eliminate interference and repeat injection
Baseline Error - Stabilize patient temperature and repeat injection	Large temperature variations detected	Eliminate temperature variations and repeat injection
Time Out - Repeat fast injection with cold injectate	Thermodilution curve not finished within 90 seconds, possibly very high EVLW with low CO	Repeat injection with cold and/or more injectate, if necessary stabilize patient
Error: Injectate too warm	Injectate temperature above blood temperature	Use colder injectate (< 24°C)
Warning: Injectate too warm	Tinj > 26 °C	Use colder injectate (< 24°C)
ΔT small - Use more and/or colder injectate	ΔT < 0.1 °C	Use more and/or colder injectate
Invalid PCCO Calibration - Check AP signal and repeat injection	Implausible arterial pressure signal, signal interferences	Eliminate possible interferences and repeat injection

### ScvO<sub>2</sub> Measurement and Calibration

Error Message	Cause	Remedy
ScvO <sub>2</sub> Calibration Error - Check optical module and probe	Defective module, probe or connections	Check module and probe, if necessary replace and repeat calibration
Signal too high - Check probe and position	Artifact due to vessel wall contact of probe	Check probe, if necessary relocate and repeat calibration
Signal too low - Check probe and position	Probe or module damaged, defective connector	Check probe, if necessary replace it and repeat calibration
Too much ambient light - Check optical module	Optical module damaged, defective connector	Check module, if necessary replace it and repeat calibration. Avoid too much ambient light.
Optical module disconnected - Check optical module and probe connections	Optical module not connected	Connect optical module

Implausible ScvO <sub>2</sub> value - Recalibrate the monitor	Implausible value due to defect or interference	Check probe, position and optical module and repeat calibration.
Error Optical Module - Check/Replace optical module	Internal electronic problem in optical module	If necessary replace optical module

**SpO<sub>2</sub> / PDR**

<b>Error Message</b>	<b>Cause</b>	<b>Remedy</b>
Error LiMON Sensor - Check / Exchange LiMON sensor	Sensor error (for more than 5 seconds)	Use a compatible and correctly functioning sensor
Error LiMON Module - Check / Exchange LiMON module	Module error (for more than 5 seconds)	Use a compatible and correctly functioning module
Error LiMON Sensor - Connect LiMON sensor	Sensor not connected to device or patient (for more than 5 seconds)	Check connection of the sensor
Pulse not detected - Relocate LiMON sensor	Insufficient pulse signal (for more than 5 seconds)	Reposition the sensor to a place with better perfusion
Bad signal quality - Relocate LiMON sensor	Insufficient pulse signal (for more than 5 seconds)	Reposition the sensor to a place with better perfusion
Too much ambient light - relocate or cover LiMON sensor	Too much ambient light (for more than 5 seconds)	Cover the sensor with dark or non-transparent material. Employ a different sensor location better protected from ambient light
Strong movement artefacts - reduce LiMON sensor movement	Too much movement (for more than 5 seconds)	Avoid patient movement
LiMON module disconnected - Check module connection	Module not connected to device or patient	Check connection of the module
Bad signal quality - Check signal and repeat measurement	Low rate of perfusion	Relocate the sensor, repeat the measurement




### 6.3 Additional information

Helpful additional and status information are also displayed in the information bar after performed or expected action.

<b>Message / Display</b>	<b>Is displayed at following actions</b>
<b>Print key</b>	
Printout in process	Press print key
Printout ready	After printout is completed
USB device detected	After detection of a USB device
No USB device detected	Pressing the print button and no USB device is connected or detected
Printer error - Check printer	No paper or printer cartridge, paper jam
<b>Real Time Pressure</b>	
No continuous CVP available	Touching the CVP parameter field and when continuous CVP not available
<b>Thermodilution</b>	
Thermodilution in progress. Press "STOP" to cancel the thermodilution	Request another action during thermodilution
Measurement is rejected. Not included in average	Reject a TD measurement
Measurement included in average	Selection of an active TD measurement
TD Measurement recommended	TD reminder limit is reached
Significant change - Consider TD	$\Delta$ PCCI above selected threshold
<b>ScvO<sub>2</sub> Calibration</b>	
Draw blood sample and confirm	Request ScvO <sub>2</sub> calibration screen
Please enter ScvO <sub>2</sub> /Hb lab values	Request ScvO <sub>2</sub> calibration screen
	Outside of ScvO <sub>2</sub> calibration screen as long as lab values are not entered
Incorrect / Implausible Input	Input incorrect / not plausible
<b>PDR</b>	
Measurement in progress - Press „STOP“ to cancel	Request another action during PDR measurement
ICG influence: CAL not possible, please wait	Remaining ICG concentration in the blood too high
Sensor not connected - Connect LiMON sensor	Sensor not connected; pressing of (greyed) ICG button
<b>Zero adjustment</b>	
Zero adjustment failed - Pressure unstable	Unstable pressure (>2 mmHg/s) during zero adjustment

Zero adjustment failed - Close stopcock	Unstable pressure (>5 mmHg/s) during zero adjustment
Zero adjustment of AP successful	Pressing AP >0< button
Zero adjustment of CVP successful	Pressing CVP >0< button
Zero adjustment of PAP successful	Pressing PAP >0< button
Zero adjustment necessary	No initial zero adjustment of AP and CVP
<b>Trend</b>	
Move white marker by turning the navigation dial	Request TREND screen

## 7 Help Functions

The help function offers information relating to installation and operation. It can be accessed during monitoring by pressing the  key. Furthermore, information on monitor status (software or hardware version) can be obtained.


### Components:

- Setup: Setup Guide PiCCO<sub>2</sub> (see Figure 16)
- Normal Values/Target Values: This tab details the normal value ranges / target value ranges of the individual values.  
**① New in version 3.1:** Detailed "Parameter Explanations" are available for each of the framed parameter areas. The corresponding screen can be accessed by touching the respective area.
- Decision Model
- Physiological Overview
- Info: System information

## 8 Printout

For documentation purposes the PiCCO<sub>2</sub> results can be printed.

### 8.1 USB Virtual Printing Option

By means of an optional PULSION USB Memory Stick (MPI78), a PDF file is generated and automatically stored on the USB Memory Stick when pressing the "Print key"  on the device.

In doing so a file folder with the current date is automatically generated and the file with the time as file name is stored. The USB virtual printing option offers three different printing formats:

- **Basic:** The main parameters which are shown in the basic display are always printed. Additional parameters are printed according to the settings made in the parameter configuration screen.
- **Trend:** When pressing the "Print key" while the trend screen is displayed, the printout includes the trend curves that have been selected in the trend configuration screen.
- **Thermodilution:** When pressing the "Print key" while the thermodilution screen is displayed, the printout includes a table with the results of the last thermodilution measurements as well as the respective curves. Messages that occurred during a particular TD measurement are displayed on the respective curve of the printout.

① New in version 3.1: In addition to the printout, a screenshot of the current screen is stored in JPG format in a separate "Screenshots" folder. The file has the same timestamp as the corresponding PDF file.

### 8.2 Label Printer

By means of the optional PULSION Printer (PC85300) a printout can be made for filing or placing into the patient file.

The printer is connected at the USB port on the back of the PiCCO<sub>2</sub> and it is recognized automatically when starting the monitor.

All parameters which are selected in the parameter configuration screen will be printed on the label.

For information relating to replacement of printer cartridge and paper, please consult the accompanying instruction for use.


## 9 Battery Function

The device is equipped with a battery to ensure the maintenance of operations for at least 30 minutes without mains power supply.

The PiCCO<sub>2</sub> must be connected to the mains power supply for at least 6 hours in order to completely charge the battery.

In order to maintain the charging condition of the battery, the device must remain on mains power supply during storage and the main switch at the back of the device must remain on position "ON".

The battery symbol in the information bar shows the current state of charge:

Battery charging		Grey, last bar of status display is blinking
Fully charged, device connected to mains power		No battery symbol
Battery-powered, > 25% capacity		Grey, remaining capacity in 25% steps
Battery-powered, < 25% capacity		Red, blinking with acoustic alarm
No battery in device		Grey, crossed out symbol

**In cases of a battery alarm the acoustic alarm can be paused for 5 minutes.**



### NOTE

If the operating time of the fully charged battery drops below 30 minutes, or the remaining operating time after the battery alarm has started (a red blinking battery symbol) drops below 7 minutes, contact your PULSION representative to replace the internal battery.

Ensure that the batteries are disposed of correctly after expiration of battery life.



### NOTE

In case of a totally discharged battery the message "Battery totally discharged" appears on the screen. To ensure a fully charged battery, the device must be connected to mains power supply for up to 24 hours.



**CAUTION:** Check the battery state of charge when using the device. Only when the battery is fully charged, the use of the device can be ensured for the stated time without being connected to the mains.

## 10 Cleaning and Disinfection

For cleaning and disinfecting the PiCCO<sub>2</sub> patient monitor only PULSION approved substances and methods listed in this chapter may be used. PULSION makes no claims regarding the efficacy of the listed chemicals or methods as a means of controlling infection. Please consult your hospital's Infection Control Officer or Epidemiologist.

### 10.1 General remarks

Keep the monitor, cables and accessories free of dust and dirt. After cleaning and disinfection, carefully check the equipment.

Do not use the equipment if signs of deterioration or damage are visible. If you need to return any of the equipment to PULSION, decontaminate it first.

### 10.2 Precautions

Please observe the following precautions:

- Do not sterilize the monitor, related products, accessories or supplies by steam, heat, radiation or ETO unless otherwise indicated in the instructions for use accompanying the accessories and supplies.
- Always dilute the used substances according to the manufacturer's instructions or use the lowest possible concentration.
- Take care that no liquid enters the PiCCO<sub>2</sub> case.
- Do not allow cleaning or disinfecting agents to remain on any of the equipment surfaces. Remove them immediately with a cloth dampened with water and dry with a clean cloth.
- Do not use abrasive material (e.g. steel wool or silver polish) or sharp objects (e.g. needles, paper clips, etc.) to clean the PiCCO<sub>2</sub>.
- Never use bleach.
- Before starting, turn off the PiCCO<sub>2</sub> and disconnect the mains power connection cable from the mains receptacle.



**WARNING:** Do not reconnect the PiCCO<sub>2</sub> to electrical power if liquid has entered the device. A short circuit may damage the device and cause hazardous conditions for patient and user.  
Allow disinfectants to evaporate for at least 15 minutes before the device is switched on again.



**CAUTION:** Never place the cables in water or other cleaning solutions. The cables and connections are not water-tight. Never sterilize the cables by radiation, steam or gas.  
Do not use abrasive or sharp-edged tools to clean the optical module as this may damage or destroy optical components.

### 10.3 Cleaning

When cleaning the PiCCO<sub>2</sub>, please proceed as follows:

- Clean the surface of the PiCCO<sub>2</sub> with a soft, lint-free cloth moistened with warm water (40°C/104°F maximum) and soap, a diluted non-caustic detergent, tenside, ammonia- or alcohol-based cleaning agent.
- Do not use strong solvents.
- Take special care when cleaning the touch screen of the PiCCO<sub>2</sub> as it is more sensitive to rough cleaning methods than the housing.
- Do not allow water or cleaning solution to enter the connectors of the monitor.

Recommended cleaning agents:

- Tensides Edisonite Schnellreiniger®
- Ammonias Dilution of Ammonia < 3%, Window Cleaner
- Alcohol Ethanol 70%, Isopropanol 70%

### 10.4 Disinfection

Disinfect the product as stated by your hospital's policy in order to avoid long-term damages.

Before disinfection clean the equipment.



**CAUTION:** Do not mix disinfecting solutions (such as bleach and ammonia) as hazardous gases may be the result.

Recommended disinfecting agents:

- Alcohol based: Ethanol 70%, Isopropanol 70%, Cutasept®, Kodan®, Sagrosept®, Sterilium Fluid®
- Aldehyde: Cidex®

- Blank page -



## D Disposables / Accessories

### 1 Disposables



**WARNING:** For safety of operation and for accuracy of measurements, only disposables and accessories approved by PULSION Medical Systems may be used with the PiCCO<sub>2</sub>.

Reuse of disposable items is not allowed. Re-sterilization of disposables may cause infections in the patient.

**Technical specifications are subject to change without further notice.**

#### 1.1 PiCCO Catheter (arterial thermodilution catheter)

The PiCCO catheters are specifically designed thermodilution catheters for use with the PiCCO<sub>2</sub>. Every catheter has a built-in thermistor and a distal lumen for arterial pressure measurement.

**PV2013L07-A / PV2013L07N / PV2013L07**

3F thermodilution catheter with a usable length of 7 cm and a distal lumen, 20/22 G cannula, guide wire.

**PV2014L08-A / PV2014L08N / PV2014L08**

4F thermodilution catheter with a usable length of 8 cm and a distal lumen, 20 G cannula, "J" guide wire, vessel dilator.

**PV2014L16-A / PV2014L16N / PV2014L16**

4F thermodilution catheter with a usable length of 16 cm and a distal lumen, 18/20 G cannula, "J" guide wire, vessel dilator.

**PV2014L22-A / PV2014L22N / PV2014L22**

4F thermodilution catheter with a usable length of 22 cm and a distal lumen, 18/20 G cannula, guide wire, vessel dilator.

**PV2015L20-A / PV2015L20N / PV2015L20**

5F thermodilution catheter with a usable length of 20 cm and a distal lumen, 18/20 G cannula, "J" guide wire, vessel dilator.

**PV2014L50LGW-A / PV2014L50LGWN / PV2014L50LGW**

4F thermodilution catheter with a usable length of 50 cm and a distal lumen, 22G/20G cannula, guide wire.



**NOTE**

Single packed guide wires are available for all catheters.



Consult accompanying instructions for use of disposables and accessories.



**WARNING:** When placing the arterial catheter into a large artery (e.g. femoral, brachial or axillary artery) do not advance the tip of the catheter into the aorta.

An intracardiac blood pressure measurement is not allowed. This means that the measuring position (catheter tip) must not be directly in the heart.

Reuse of disposable items is not allowed. Re-sterilization of disposables may cause infections in the patient.

## 1.2 PiCCO Monitoring Kits

The PV8115 / PV8215 monitoring kits (for arterial pressure) contain:

- pressure transducer with macro set, spike, line lock and flush device (flow rate 3 ml/h)
- 3-way-stopcock, injectate temperature sensor housing (PV4046)
- 150 cm red pressure line

The PV8115CVP / PV8215CVP monitoring kits (for central venous pressure or arterial pressure) contain:

- pressure transducer with macro set, spike, line lock and flush device (flow rate 3 ml/h)
- 3-way-stopcock, injectate temperature sensor housing (PV4046)
- 150 cm blue pressure line
- 150 cm red pressure line

## 1.3 Injectate Temperature Sensor Housing

The injectate temperature sensor housing PV4046 is required to determine the injection temperature during thermodilution measurements.

Single packed PV4046 are also available.

## 1.4 CeVOX probe

The PULSION CeVOX fiberoptic probes have been specifically developed for use with the PULSION optical module. The probes are equipped with fiberoptics to transfer light at a specific wavelength. For continuous oxygen saturation monitoring the probe is inserted into the distal lumen of an already placed central venous catheter. Dependent on the type of the central venous catheter an appropriate probe has to be selected.

PV2022-30	2F CeVOX probe (usable length: 30 cm)
PV2022-32	2F CeVOX probe (usable length: 32 cm)
PV2022-33	2F CeVOX probe (usable length: 33 cm)
PV2022-35	2F CeVOX probe (usable length: 35 cm)
PV2022-37	2F CeVOX probe (usable length: 37 cm)
PV2022-38	2F CeVOX probe (usable length: 38 cm)
PV2022-48	2F CeVOX probe (usable length: 48 cm)

Other lengths can be ordered with a delivery time of 6 weeks (packaging unit=50).

The CeVOX probes are designed for 15 cm, 20 cm and 30 cm central venous catheters with a distal lumen of  $\varnothing \geq 0.032''$  guide wires (0.8 mm). The tip of the probe has to exceed the distal tip of the central venous catheter by  $2.5 \pm 0.5$  cm.



**WARNING:** Incorrect use of the ScvO<sub>2</sub> probe can lead to vessel perforation. Therefore check the correct position of the probe as indicated in the probe's instructions for use.

## 2 Accessories

Article number	Description
PC8500	PiCCO <sub>2</sub> Monitor
PC80150	Arterial connection cable and injectate temperature interface cable
PC80109	Injectate sensor cable
PMK-206	Pressure connection cable
PC85200	PiCCO <sub>2</sub> AUX Adapter
401090	Mains power cable (240V)
401080	Potential equalization cable
PC3010 / PC3015	CeVOX module
PC5100	LIMON module
PC51100	LIMON Reusable Sensor, large
PC51200	LIMON Reusable Sensor, medium
PC51300	LIMON Reusable Sensor, small
PC85300	PiCCO <sub>2</sub> Thermotransfer printer
PC85350	Printer labels (565 labels per roll)
PC85355	Thermo-transfer ink ribbon
PC85230	PiCCO <sub>2</sub> cart
PC85231	Basket for cart
PC85232	Anchoring clip
PC85233	PiCCO <sub>2</sub> variable wall mounting arm for horizontal standard bar
PC856EN	PiCCO <sub>2</sub> Operator's Manual English



**CAUTION:** Do not pull on the probes or cables in order to remove them from the device. Observe the instructions for use for the probes in order to ensure that a technically correct procedure is carried out.

## E Appendix

### 1 Technical Data

<b>General</b>	
Equipment	PiCCO <sub>2</sub>
Article number	PC8500
Equipment Class	IIb
Equipment Type	Type BF: ScvO <sub>2</sub> ; Type CF: CO, AP, CVP; all defibrillation-proof
Protection Class:	I
<b>Accessories</b>	
PiCCO catheter and kits	Please consult accompanying instructions for use of the PiCCO catheter
Arterial connection cable and injectate temperature interface cable	Art. No.: PC80150
Injectate temperature sensor cable	Art. No.: PC80109
Pressure cable	Art. No.: PMK-206
PiCCO <sub>2</sub> AUX Adapter	Art. No.: PC85200
Mains power cable	Art. No.: 40109X (dependent on country)
Grounding cable	Art. No.: 401080
CeVOX module	Art. No.: PC3010 / PC3015
LiMON module	Art. No.: PC5100
<b>Screen</b>	
Type	13.3" (=338 mm) TFT LCD colour display, touch screen, active matrix
Size (W x H)	299 x 195 mm
Viewing Area (W x H)	286 x 178 mm
Resolution	1280 x 800 Pixel
<b>Electrical Specifications</b>	
Mains Voltage	100 to 240 VAC
Mains Frequency	50 to 60 Hz
Power Consumption	85 VA
Internal Battery	14.4V 36Wh
Cell Type	Lithium-Ion
Charging Time	3-5h

Battery Operating Time	> 30min
<b>Operating Conditions</b>	
Temperature Range	10 °C to 40 °C (50 °F to 104 °F)
Relative Humidity	75% (non-condensing)
Ambient Pressure	700 hPa to 1060 hPa
<b>Transport and Storage Conditions</b>	
Temperature Range	-20 to 60°C (-4°F to 140°F), (with rechargeable battery -20 to 50°C (-4°F to 122°F))
Relative Humidity	90% (non-condensing)
Ambient Pressure (Storage)	700 hPa to 1060 hPa
Ambient Pressure (Transport)	270 hPa to 1060 hPa
<b>Physical Attributes</b>	
Size (W x H x D)	328 mm x 248 mm x 180 mm (with navigation dial)
Weight	< 5 kg
<b>Standards</b>	
EN 60601-1:1990 + A1:1993 + A2:1995	
EN 60601-1-1:2001, EN 60601-1-2:2007, EN 60601-1-4:1996 +A1:1999, EN 60601-1-6:2007, EN 60601-1-8:2007, EN 60601-2-34:2000	
PiCCO <sub>2</sub> complies with directive 93/42/EEC (medical products) and bears the CE mark	
<b>User Interface</b>	
User Controls	Touch screen
	Navigation dial
	Function keys
<b>Data Transmission Capabilities</b>	
Interfaces	RS232
	LAN
	2xUSB
Printer	USB

**Measured Parameters:**

Label	Unit	Lower limit	Upper limit	Accuracy
PCCO	l/min	0.25	25.0	Coefficient of variation $\leq 2\%^*$
SV	ml	1	250	Coefficient of variation $\leq 2\%^*$
CO	l/min	0.25	25.0	Coefficient of variation $\leq 2\%^*$
GEDV	ml	40	4800	Coefficient of variation $\leq 3\%^*$
ITBV	ml	50	6000	Coefficient of variation $\leq 3\%^*$
EVLW	ml	10	5000	Coefficient of variation $\leq 6\%^*$
ScvO <sub>2</sub>	%	1	99	$\pm 3\%$ for 50 – 80 %
SpO <sub>2</sub>	%	45	100	70% < SpO <sub>2</sub> < 100%: $\leq 2\%$ SpO <sub>2</sub> < 70% not validated
PDR	%/min	0.0	50.0	$\pm 3\%$ / min (absolute) or 15 % relative
R15	%	0.0	99.9	n.a.
TB	°C	25	45	$\pm 0,1\ ^\circ\text{C}$
Tinj	°C	0	30	$\pm 0,1\ ^\circ\text{C}$
AP	mmHg	0	300	$\pm 4$ mmHg (absolute) or 4 % relative (acc. to EN 60601-2-34: 2000)
CVP	mmHg	-10	50	$\pm 4$ mmHg (absolute) or 4 % relative (acc. to EN 60601-2-34: 2000)

\*Coefficient of variation, measured using synthetic and/or database wave forms (laboratory testing)

**Technical specifications are subject to change without further notice.**

## 2 Maintenance and Service

### 2.1 Classification

This product is classified according to Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, annex IX:

**Class II b**

### 2.2 Maintenance

Before commencing monitoring of a patient, check the PiCCO<sub>2</sub> for any mechanical damage, check all input cables, connectors and accessories and check all functions necessary for patient monitoring.

The PULSION PiCCO<sub>2</sub> and its accessories are maintenance free and are not subject to special intervals of service if local medical law does not indicate this. For further details about potential difficulties, possible causes and suggested remedies see chapter C6.2.



**CAUTION:** If the PiCCO<sub>2</sub> appears to be damaged, contact your local PULSION representative. Do not use the PiCCO<sub>2</sub> if the device appears to be damaged. If the system check detects a failure, no function will be available and "SERVICE" is displayed on the screen. Turn the PiCCO<sub>2</sub> off and contact your local PULSION representative. Do not attempt to use or repair the PiCCO<sub>2</sub>.



#### **IMPORTANT**

Updates and all checks which require the PiCCO<sub>2</sub> to be opened must be made by a PULSION technician.

For telephone inquiries relating to service, technical support, accessories or other matters contact PULSION Medical Systems SE.

To respond to questions, PULSION Medical Systems SE will need the serial number of the device that is found on the rear panel of the PiCCO<sub>2</sub>.

PULSION Medical Systems SE

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### 2.3 Disposal of electrical and electronic equipment

The 2012/19/EU Directive aims to increase the separate collection, reuse, recovery and recycling of waste from electrical and electronic equipment. This directive applies to all electrical and electronic appliances as well as to medical devices.

**As a medical device, the PiCCO<sub>2</sub> is subject to this directive and is labelled with the symbol of the crossed-out wheeled bin.**



**NOTE**

Ensure that the included lithium-ion battery is removed from the device and disposed of correctly.

### 3 Interfaces

#### AP / CVP

Transfer of continuous arterial pressure (AP) and central venous pressure (CVP) signal to bedside monitor.

#### LAN

Connection for network devices for printing and data transfer.

#### Serial Interface RS232

Connection for patient data management systems (PDMS)

Please contact your PULSION representative for current technical information.

#### USB ports (2)

Connection for external printer and PULSION memory stick.

The interfaces are galvanically isolated by an isolation voltage of 1.5kV (IEC 60601-1).



**CAUTION:** Furthermore, all configurations have to meet the system standard IEC 60601-1-1. Any person who connects additional devices to the signal input or signal output of the PiCCO<sub>2</sub> is changing the system configuration and is responsible for observing the requirements of the IEC 60601-1-1 Standard.



**IMPORTANT:** For safety of operation, only memory sticks and printers approved by PULSION Medical Systems may be used with the PiCCO<sub>2</sub>.

## 4 EMC-Requirements


**Table 1 – Guidance and manufacturer’s declaration – electromagnetic emissions  
(EN 60601-1-2:2007; 5.2.2.1 c)**

<b>Guidance and manufacturer’s declaration – electromagnetic emissions</b>		
The PiCCO <sub>2</sub> is intended for use in the electromagnetic environment specified below. The customer or the user of the PiCCO <sub>2</sub> should assure that it is used in such an environment.		
<b>Emissions test</b>	<b>Compliance</b>	<b>Electromagnetic environment - guidance</b>
RF emissions CISPR 11	Group 1	The PiCCO <sub>2</sub> uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The PiCCO <sub>2</sub> is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

**Table 2 – Guidance and manufacturer’s declaration – electromagnetic immunity  
(EN 60601-1-2:2007; 5.2.2.1 f)**

<b>Guidance and manufacturer’s declaration - electromagnetic immunity</b>			
The PiCCO <sub>2</sub> is intended for use in the electromagnetic environment specified below. The customer or the user of the PiCCO <sub>2</sub> should assure that it is used in such an environment.			
<b>Immunity test</b>	<b>IEC 60601 test level</b>	<b>Compliance level</b>	<b>Electromagnetic environment - guidance</b>
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient / burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input / output lines	± 2 kV for power supply lines ± 1 kV for input / output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5% U <sub>T</sub> (>95 % dip in U <sub>T</sub> ) for 0,5 cycle	< 5% U <sub>T</sub> (>95 % dip in U <sub>T</sub> ) for 0,5 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the PiCCO <sub>2</sub> requires continued Operation during power mains interruptions, it is recommended that the PiCCO <sub>2</sub> is powered from an uninterruptible power supply or a battery.
	40% U <sub>T</sub> (60 % dip in U <sub>T</sub> ) for 5 cycles	40% U <sub>T</sub> (60 % dip in U <sub>T</sub> ) for 5 cycles	
	70% U <sub>T</sub> (30 % dip in U <sub>T</sub> ) for 25 cycles	70% U <sub>T</sub> (30 % dip in U <sub>T</sub> ) for 25 cycles	
	< 5% U <sub>T</sub> (> 95% dip in U <sub>T</sub> ) for 5 s	< 5% U <sub>T</sub> (> 95% dip in U <sub>T</sub> ) for 5 s	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U <sub>T</sub> is the a.c. mains voltage prior to application of the test level.			

**Table 3 – Guidance and manufacturer’s declaration – electromagnetic immunity  
(EN 60601-1-2:2007; 5.2.2.2)**

Guidance and manufacturer's declaration - electromagnetic immunity			
The PiCCO <sub>2</sub> is intended for use in the electromagnetic environment specified below. The customer or the user of the PiCCO <sub>2</sub> should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	<p>Portable and mobile RF communications equipment should be used no closer to any part of PiCCO<sub>2</sub>, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p><b>Recommended separation distance:</b>  <math>d = 1.17 \sqrt{1/V * \sqrt{P}}</math></p>
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	<p><math>d = 1.17 \text{ m/V} * \sqrt{P}</math> for 80 MHz to 800 MHz  <math>d = 2,33 \text{ m/V} * \sqrt{P}</math> for 800 MHz to 2,5 GHz</p> <p>where <math>P</math> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <math>d</math> is the recommended separation distance in meters (m).</p> <p>Field strength from fixed RF transmitters, as determined by an electromagnetic site survey,<sup>a</sup> should be less than the compliance level in each frequency range.<sup>b</sup></p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
NOTE 1	At 80 MHz and 800 MHz, the higher frequency applies.		
NOTE 2	These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection of structures, objects and people.		
<sup>a</sup>	Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the PiCCO <sub>2</sub> is used exceeds the applicable RF compliance level above, the PiCCO <sub>2</sub> should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the PiCCO <sub>2</sub> .		
<sup>b</sup>	Over the frequency range 150 kHz to 80 MHz, field strength should be less than 3 V/m.		

**Table 6 – Recommended separation distances between portable and mobile RF communications equipment and the PiCCO<sub>2</sub>**  
(EN 60601-1-2:2007; 5.2.2.2)

<b>Recommended separation distances between portable and mobile RF communications equipment and the PiCCO<sub>2</sub></b>			
The PiCCO <sub>2</sub> is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the PiCCO <sub>2</sub> can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the PiCCO <sub>2</sub> as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1.17 \sqrt{1/V * \sqrt{P}}$	80 MHz to 800 MHz $d = 1.17m/V * \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.33m/V * \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.70	3.70	7.37
100	11.70	11.70	23.3
For transmitters rated at a maximum output power not listed above, the recommended separation distance $d$ in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where $P$ is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
NOTE 1	At 80 MHz and 800 MHz, the higher frequency range applies.		
NOTE 2	These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection of structures, objects and people.		



**CAUTION:** The PiCCO<sub>2</sub> is subject to specific precautions concerning EMC (Electromagnetic compatibility) and is only allowed to be installed and used according the EMC advice contained in this user's manual.

Portable and mobile high frequency communication devices may influence the PiCCO<sub>2</sub>.

When high frequency devices are used during surgery, the applying standards for high frequency devices for surgery have to be followed.

## 5 Equations for Calculated Values

This chapter contains the equations the PiCCO<sub>2</sub> uses to calculate the displayed values.

### 5.1 General

For the indexing of volumetric parameters the PiCCO<sub>2</sub> uses the following calculated parameters, dependent on body characteristics:

BSA = Body Surface Area (m<sup>2</sup>)

Depending on the actual entered body weight (BW) different formulas are used for adult and pediatric patients:

BSA =  $(BW^{0.5378} \times \text{height}^{0.3964}) \times 0.024265$  Haycock, BW < 15kg

BSA =  $(BW^{0.425} \times \text{height}^{0.725}) \times 0.007184$  DuBois, BW ≥ 15kg

PBW = Predicted Body Weight (kg)  
Calculated according to height, gender and category

PBSA = Predicted Body Surface Area (m<sup>2</sup>).  
Calculated with PBW instead of actual body weight (BW)

Calculation	Category	Gender
PBW (kg) = 50 + 0.91 [height (cm) – 152.4]	Adult (habitus)*	male
PBW (kg) = 45.5 + 0.91 [height (cm) – 152.4]		female
PBW (kg) = 39 + 0.89 [height (cm) – 152.4]	Pediatric (> 152.4 cm), (habitus)*	male
PBW (kg) = 42.2 + 0.89 [height (cm) – 152.4]		female
PBW (kg) = ((height (cm)) <sup>2</sup> • 1.65) / 1000	Pediatric (< 152.4 cm)	both

\*In marginal cases the decision about the correct category for the individual patient must be based on their anatomy and appearance (habitus).

## 5.2 Output

$$\text{PCCO} = \text{cal} \cdot \text{HR} \cdot \int [\text{P}(t) / \text{SVR} + \text{C}(\text{P}) \cdot \text{dP}/\text{dt}] \text{ dt}$$

where	PCCO	=	Pulse Contour Cardiac Output (l/min)
	cal	=	Patient specific calibration factor (determined by thermodilution)
	HR	=	Heart Rate (1/min)
	$\text{P}(t) / \text{SVR}$	=	Area under pressure curve
	$\text{C}(\text{P})$	=	Characteristic compliance of the aorta (determined by thermodilution)
	$\text{dP}/\text{dt}$	=	Shape of pressure curve

$$\text{PCCI} = \text{PCCO} / \text{BSA}$$

where	PCCI	=	Pulse Contour Cardiac Output Index (l/min/m <sup>2</sup> )
	PCCO	=	Pulse Contour Cardiac Output (l/min)
	BSA	=	Body Surface Area (m <sup>2</sup> )

$$\text{SV} = (\text{PCCO} / \text{HR}) \cdot 1000$$

where	SV	=	Stroke Volume (ml)
	PCCO	=	Pulse Contour Cardiac Output (l/min)
	HR	=	Heart Rate (1/min)

$$\Delta\text{PCCI} = (\text{PCCO} - \text{TDCO}) / \text{TDCO} \cdot 100\%$$

where	$\Delta\text{PCCI}$	=	Relative Change of PCCI
	PCCO	=	Pulse Contour Cardiac Output (l/min)
	TDCO	=	Mean of all (selected) TDs used for PCCO-calibration (l/min)

➡ Note: The indexing factor BSA is irrelevant.

$$\text{SVI} = \text{SV} / \text{BSA}$$

where	SVI	=	Stroke Volume Index (ml/m <sup>2</sup> )
	SV	=	Stroke Volume (ml)
	BSA	=	Body Surface Area (m <sup>2</sup> )



$$CO = [(T_b - T_i) \bullet V_i \bullet K] / [\int \Delta T_b \bullet dt]$$

where	CO	=	Cardiac Output (l/min)
	T <sub>b</sub>	=	Blood temperature before the injection of cold bolus (°C)
	T <sub>i</sub>	=	Temperature of the injection solution (injectate) (°C)
	V <sub>i</sub>	=	Injection volume (ml)
	$\int \Delta T_b \bullet dt$	=	Area under the thermodilution curve
	K	=	Correction constants, made up of specific weights and specific heat of blood and injectate

$$CI = CO / BSA$$

where	CI	=	Cardiac Index (l/min/m <sup>2</sup> )
	CO	=	Cardiac Output (l/min)
	BSA	=	Body Surface Area (m <sup>2</sup> )

### 5.3 Preload Volume

$$GEDV = [CO \bullet 1000] \bullet [(MT_{t_{TDa}} - DSt_{t_{TDa}}) / 60]$$

$$GEDV = ITTV - PTV$$

where	GEDV	=	Global End-Diastolic Volume (ml)
	ITTV	=	Intrathoracic Thermal Volume (ml)
			where: ITTV = (CO • 1000) • MT <sub>t<sub>TDa</sub></sub>
	PTV	=	Pulmonary Thermal Volume (ml)
			where: PTV = (CO • 1000) • DSt <sub>t<sub>TDa</sub></sub>

and

	CO	=	Cardiac Output (l/min)
	MT <sub>t<sub>TDa</sub></sub>	=	Mean transit time of the cold indicator from the site of injection to the site of detection
	DSt <sub>t<sub>TDa</sub></sub>	=	Exponential downslope time of the arterial thermodilution curve

$$GEDI = GEDV / PBSA$$

where	GEDV	=	Global End-Diastolic Volume (ml)
	GEDI	=	Global End-Diastolic Volume Index (ml/m <sup>2</sup> )
	PBSA	=	Predicted Body Surface Area (m <sup>2</sup> )

$$ITBV = 1.25 \bullet GEDV$$

where	ITBV	=	Intrathoracic Blood Volume (ml)
	GEDV	=	Global End-Diastolic Volume (ml)

**ITBVI = ITBV / PBSA**

where	ITBVI	=	Intrathoracic Blood Volume Index (ml/m <sup>2</sup> )
	ITBV	=	Intrathoracic Blood Volume (ml)
	PBSA	=	Predicted Body Surface Area (m <sup>2</sup> )

**SVV = (SV<sub>max</sub> – SV<sub>min</sub>) / SV<sub>mean</sub>**

where	SVV	=	Stroke Volume Variation (%)
	SV <sub>max</sub>	=	Mean value of 4 maximum stroke volumes of the last 30 seconds (ml)
	SV <sub>min</sub>	=	Mean value of 4 minimum stroke volumes of the last 30 seconds (ml)
	SV <sub>mean</sub>	=	Mean value of stroke volumes over the last 30 seconds (ml)

**PPV = (PP<sub>max</sub> – PP<sub>min</sub>) / PP<sub>mean</sub>**

where	PPV	=	Pulse Pressure Variation (%)
	PP	=	Pulse Pressure (AP <sub>sys</sub> - AP <sub>dia</sub> )
	AP <sub>sys</sub>	=	Systolic Arterial Pressure
	AP <sub>dia</sub>	=	Diastolic Arterial Pressure
	PP <sub>max</sub>	=	Mean value of 4 maximum Pulse Pressures of the last 30 seconds (mmHg)
	PP <sub>min</sub>	=	Mean value of 4 minimum Pulse Pressures of the last 30 seconds (mmHg)
	PP <sub>mean</sub>	=	Mean value of pulse pressure over the last 30 seconds (mmHg)

## 5.4 Afterload

**SVR = [(MAP – CVP) / CO] • 80**

where	SVR	=	Systemic Vascular Resistance (dyn•s•cm <sup>-5</sup> )
	MAP	=	Mean Arterial Pressure (mmHg)
	CVP	=	Central Venous Pressure (mmHg)
	CO	=	Cardiac Output (l/min)

**SVRI = [(MAP-CVP) / CI] • 80**

where	SVRI	=	Systemic Vascular Resistance Index (dyn•s•cm <sup>-5</sup> •m <sup>2</sup> )
	MAP	=	Mean Arterial Pressure (mmHg)
	CVP	=	Central Venous Pressure (mmHg)
	CI	=	Cardiac Index (l/min/m <sup>2</sup> )

## 5.5 Contractility

$$\text{CFI} = \text{CO} \bullet 1000 / \text{GEDV}$$

where	CFI	=	Cardiac Function Index (1/min)
	CO	=	Cardiac Output (l/min)
	GEDV	=	Global End-Diastolic Volume (ml)

$$\text{GEF} = 4 \bullet \text{SV} / \text{GEDV}$$

where	GEF	=	Global Ejection Fraction (%)
	SV	=	Stroke Volume (ml)
	GEDV	=	Global End-Diastolic Volume (ml)

## 5.6 Organ Function

$$\text{EVLW} = \text{ITTV} - \text{ITBV}$$

where	EVLW	=	Extravascular Lung Water (ml)
	ITTV	=	Intrathoracic Thermal Volume (ml)
	ITBV	=	Intrathoracic Blood Volume (ml)

$$\text{ELWI} = \text{EVLW} / \text{PBW}$$

where	ELWI	=	Extravascular Lung Water Index (ml/kg)
	EVLW	=	Extravascular Lung Water (ml)
	PBW	=	Predicted Body Weight (kg)

$$\text{CPO} = \text{PCCO} \bullet \text{MAP} \bullet 0.0022$$

where	CPO	=	Cardiac Power Output (W)
	PCCO	=	Continuous Pulse Contour Cardiac Output (l/min)
	MAP	=	Mean Arterial Pressure (mmHg)

$$\text{CPI} = \text{PCCI} \bullet \text{MAP} \bullet 0.0022$$

where	CPI	=	Cardiac Power Index (W/m <sup>2</sup> )
	PCCI	=	Pulse Contour Cardiac Output Index (l/min/m <sup>2</sup> )
	MAP	=	Mean Arterial Pressure (mmHg)

$$\text{PVPI} = \text{EVLW} / \text{PBV}$$

where	PVPI	=	Pulmonary Vascular Permeability Index (no unit)
	EVLW	=	Extravascular Lung Water (ml)
	PBV	=	Pulmonary Blood Volume (ml) (ITBV - GEDV)

$$\text{PDR} = 100 \cdot \ln 2 / t^{1/2}$$

where	PDR	=	Plasma disappearance rate (%/min)
	$t^{1/2}$	=	Half life of ICG-PULSION

$$\text{R15} = C_{15} / C_0 \cdot 100 \%$$

where	R15	=	ICG Retention rate after 15 minutes (%)
	$C_{15}$	=	Concentration of ICG-PULSION after 15 minutes
	$C_0$	=	Back-extrapolated concentration of ICG-PULSION at Time 0

## 5.7 Oxygenation

$$\text{ScvO}_2 = [\text{HbO}_2 \cdot 100] / [\text{HbO}_2 + \text{Hb}_{\text{Des}}]$$

where	ScvO <sub>2</sub>	=	Central Venous Oxygen Saturation (%)
	HbO <sub>2</sub>	=	Concentration of oxygenated haemoglobin (g/dl)
	Hb <sub>Des</sub>	=	Concentration of deoxygenated haemoglobin (g/dl)

$$\text{DO}_2 = 1.34 \cdot \text{Hb} \cdot \text{SaO}_2 \cdot \text{PCCO} \cdot 10$$

where	DO <sub>2</sub>	=	Oxygen delivery (ml/min)
	Hb	=	Concentration of haemoglobin (g/dl)
	SaO <sub>2</sub>	=	Arterial Oxygen Saturation (%)
	PCCO	=	Continuous Pulse Contour Cardiac Output (l/min)

$$\text{DO}_2\text{I} = 1.34 \cdot \text{Hb} \cdot \text{SaO}_2 \cdot \text{PCCI} \cdot 10$$

where	DO <sub>2</sub> I	=	Oxygen Delivery Index (ml/min/m <sup>2</sup> )
	Hb	=	Concentration of haemoglobin (g/dl)
	SaO <sub>2</sub>	=	Arterial Oxygen Saturation (%)
	PCCI	=	Pulse Contour Cardiac Output Index (l/min/m <sup>2</sup> )

$$\text{VO}_2 = 1.34 \cdot \text{Hb} \cdot (\text{SaO}_2 - \text{ScvO}_2) \cdot \text{PCCO} \cdot 10$$

where	VO <sub>2</sub>	=	Oxygen Consumption (ml/min)
	Hb	=	Concentration of haemoglobin (g/dl)
	SaO <sub>2</sub>	=	Arterial Oxygen Saturation (%)
	ScvO <sub>2</sub>	=	Central Venous Oxygen Saturation (%)
	PCCO	=	Continuous Pulse Contour Cardiac Output (l/min)

$$VO_2I = 1.34 \cdot Hb \cdot (SaO_2 - ScvO_2) \cdot PCCI \cdot 10$$

where	VO <sub>2</sub> I	=	Oxygen Consumption Index (ml/min/m <sup>2</sup> )
	Hb	=	Concentration of haemoglobin (g/dl)
	SaO <sub>2</sub>	=	Arterial Oxygen Saturation (%)
	ScvO <sub>2</sub>	=	Central Venous Oxygen Saturation (%)
	PCCI	=	Pulse Contour Cardiac Output Index (l/min/m <sup>2</sup> )

$$SpO_2 = HbO_2 / [HbO_2 + Hb_{Des}]$$

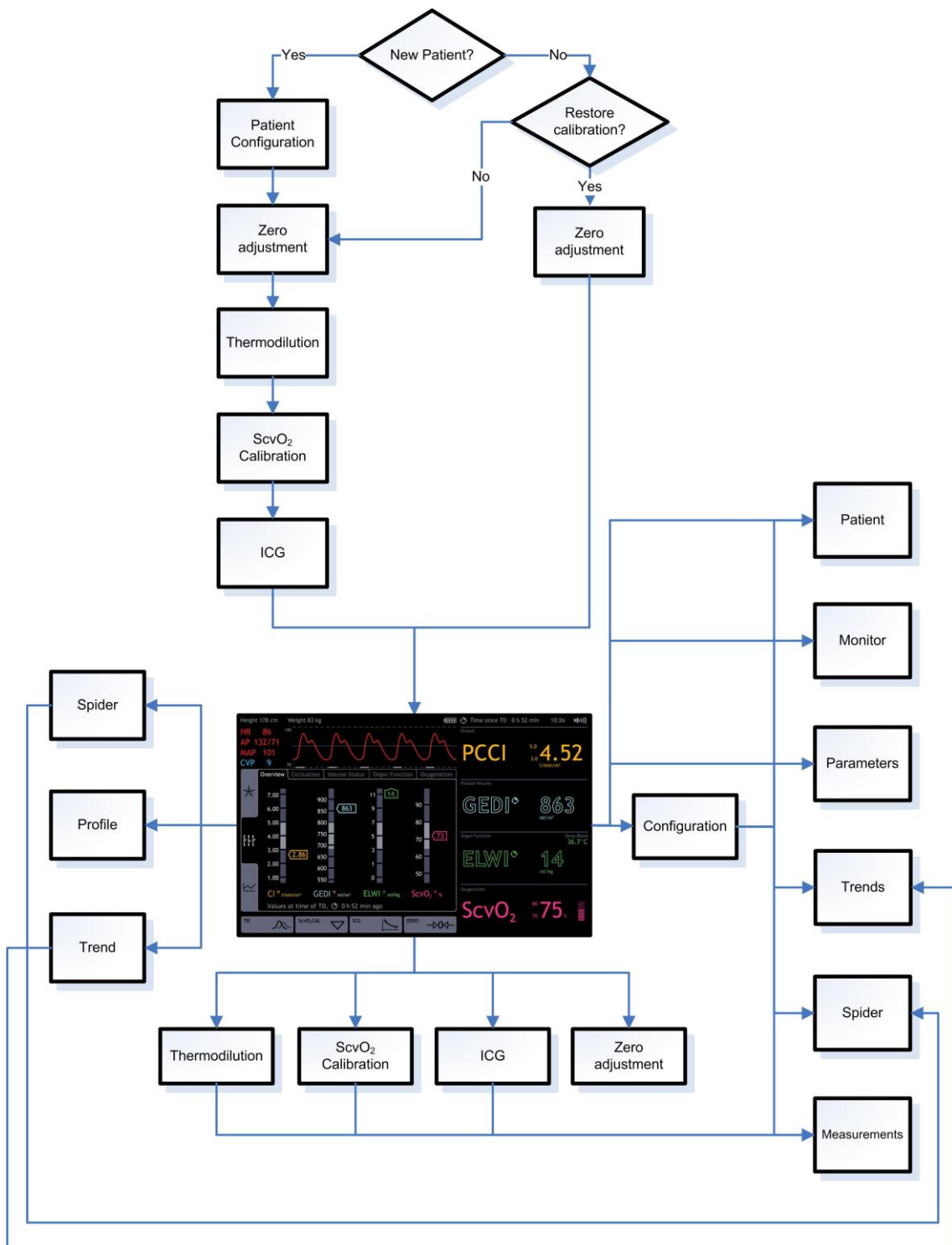
where	SpO <sub>2</sub>	=	Partial arterial oxygen saturation (%)
	HbO <sub>2</sub>	=	Concentration of oxygenated haemoglobin (g/dl)
	Hb <sub>Des</sub>	=	Concentration of deoxygenated haemoglobin (g/dl)























**NOTE**

Physically dissolved oxygen is neglected.

## 6 Flow chart



## 7 Symbols

	ON/OFF Key
	Help key
	Print key
	Mute key
	Main key: Back to the last active screen display
	Back key: Back to previous interaction level
	Attention, consult accompanying operator's manual
	Equipment Type BF, protected against defibrillation
	Equipment Type CF, protected against defibrillation
	Symbol for battery status
	Time indicator for parameters which are not continuously derived
	Loudspeaker
	
	Separate disposal of electrical and electronic equipment
	
	ETL certification for electrical safety
	
<b>RS232</b>	Serial interface
<b>LAN</b>	Local Area Network
	Arterial Pressure: analogue signal output
	Central Venous Pressure: analogue signal output
	Date of manufacture
<b>SN</b>	Serial Number

## 8 Warranty

Given the described objectives and indications and adherence to the Guidelines in the Operating Instructions, PULSION Medical Systems (hereafter called PULSION) guarantees the correct function of the PiCCO<sub>2</sub> for the agreed period after the date of purchase. If the PiCCO<sub>2</sub> is not used in accordance with the requirements of this Operator's Manual, the guarantee becomes null and void. No further explicit or implicit guarantee of performance exists such as re-sale or suitability of the PiCCO<sub>2</sub> for a particular purpose. Disposables and accessories which are used with the PiCCO<sub>2</sub> are not covered by this guarantee.

PULSION offers no guarantee for the function of the PiCCO<sub>2</sub>, if disposables and accessories are used with the PiCCO<sub>2</sub> which are not approved by PULSION. In the context of this guarantee, PULSION is not obliged to repair or replace a damaged or faulty PiCCO<sub>2</sub>, if the damage or the faulty performance results from the user employing disposables and accessories which are not approved by PULSION.

It is understood and acknowledged that any person other than a PULSION representative performing repair or service is not an authorized agent of PULSION.



For technical assistance or customer order entry, contact:

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Internet: [www.PULSION.com](http://www.PULSION.com)



**WARNING:** Explosion hazard when used in the presence of flammable anesthetics.

Do not use the device while a MRI scan is being carried out. Induced voltage can result in potential burns.



**ATTENTION:** Consult accompanying operator's manual.

Do not expose the PiCCO<sub>2</sub> to temperatures above 40 °C or below 10 °C. The accuracy of the measured values may be affected.

Do not place other equipment or containers with liquid on top of the PiCCO<sub>2</sub>.

**Patents:**

EP1598005, EP0947941, US6315735, JP3397716, US6200301, EP0637932, US5526817, JP3242655, EP1034737, US6491640, JP3375590, US6394961, EP0983745, US6264613, JP2000102622, EP0505918, EP0557492, EP1022984, US6640129, JP4322227, US7588542

Further patents pending



0124 Certification according to Annex II of Directive No. 93/42/EEC for medical devices.

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