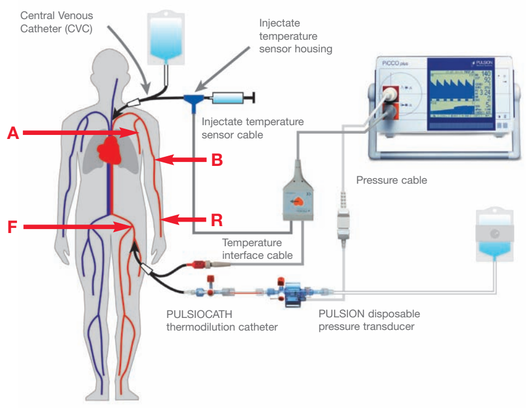



PULSION PiCCO *plus:* Setup & Method

Setup

The PiCCO-Technology initial setup

1. Connect the injectate-temperature sensor housing to the CV line already in place.
2. Insert a PiCCO arterial thermodilution catheter into a large artery, preferable femoral artery, but also brachial / axillary artery or radial artery (with long catheter).
3. Connect the injectate sensor, the arterial catheter's thermistor and pressure line to your PiCCO Monitor.
4. For blood pressure transfer to any bedside monitoring system, connect the cable at the back of the PiCCO Monitor.
5. Now the system is ready to work.
6. For information how to operate your PiCCO Monitor, please refer to your accompanying PiCCO Operator's Manual and Setup guide.



Standard Central Venous Catheter (CVC)	**A**xillary:	4F	(1,4 mm)	8 cm
	Brachial:	4F	(1,4 mm)	22 cm
PULSIOCATH thermodilution catheter	**F**emoral:	3-5F	(0,9-1,7 mm)	7-20 cm
with lumen for arterial pressure measurement	**R**adial:	4F	(1,4 mm)	50 cm

PULSIOCATH arterial thermodilution catheters

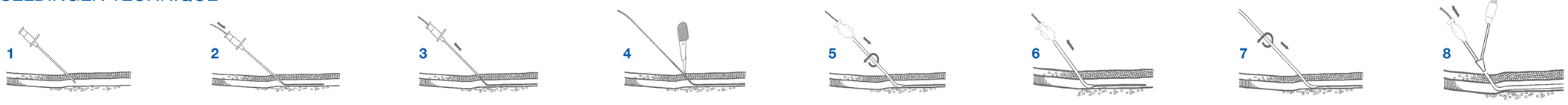
are specifically designed for less invasive volumetric hemodynamic monitoring with the PiCCO-Technology.
The catheters are placed with Seldinger Technique. Several versions and sizes are available.
They can remain in situ for up to 10 days.

Article number	PV2013L07	PV2014L08	PV2014L16	PV2014L22	PV2015L20	PV2014L50LGW
Outer diameter	3F (~20G) / 0,9 mm	4F (~18G) / 1,4 mm	4F (~18G) / 1,4 mm	4F (~18G) / 1,4 mm	5F (~16G) / 1,7 mm	4F (~18G) / 1,4 mm
Usable length	7 cm	8 cm	16 cm	22 cm	20 cm	50 cm
Common feature	Latex free / DEHP free	Latex free / DEHP free	Latex free / DEHP free	Latex free / DEHP free	Latex free / DEHP free	Latex free / DEHP free

The catheters are also available as complete kits (e.g. PVPK2015L20-46), including a disposable pressure transducer and the injectate temperature sensor housing. Optionally, these kits can be ordered with an additional pressure line for intermittent central venous pressure monitoring.
Catheters should be selected depending on patient size, weight and insertion site.

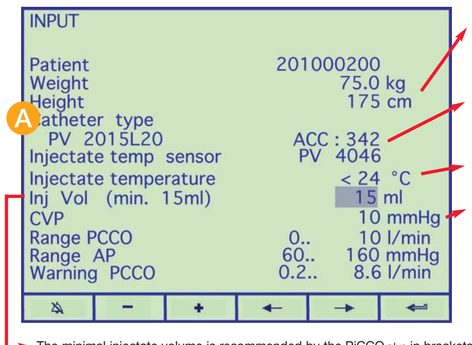
Catheter Placement

SELDINGER TECHNIQUE



1. Introduce the cannula at an angle of no more than 45° into a suitable artery.
2. Insert a part of the guidewire through the cannula into the artery.
3. Leave the guidewire in place and withdraw the cannula.
4. Enlarge the point of entry by performing a skin incision using a scalpel.
5. With a twisting motion, advance the dilator over the guidewire into the vessel.
6. Leave the guidewire in place and withdraw the dilator.
7. With a twisting motion, insert the catheter over the guidewire into the vessel.
8. Hold catheter at the desired position and withdraw guidewire.

Operation



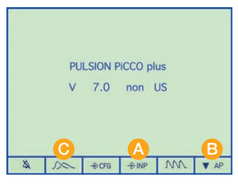
Enter Height and Weight of the patient for calculation of the indexed parameters

The Arterial Catheter Constant (ACC) will be detected automatically, if the PULSIOCATH is connected

< 24° C = room temp. injectate
< 8° C = cold injectate

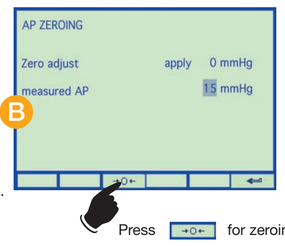
CVP should be manually updated when the CVP changes ± 5 to accurately calculate SVR

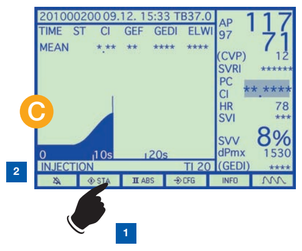
The minimal injectate volume is recommended by the PiCCO*plus* in brackets ( ). This parameter can be modified by highlighting the parameter using the inverse marker [←] [→]. The number can be changed by using the function keys [−] [+].



A INP Input Screen
B AP AP zeroing
C Thermodilution Screen

Open pressue transducer to atmosphere.





1. Press [STA] to perform a thermodilution measurement.
2. Wait until "STABLE" appears
3. Injection of the indicator should be done as fast (< 7 sec) and steadily as possible.

Perform zero adjustment initially on PiCCO*plus* then on bedside monitor!

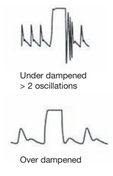
Weight of pat.	PV4046 For cold injectate	PV4046 For roomtemp. injectate
< 3 kg	2 ml	3 ml
< 10 kg	2 ml	3 ml
< 25 kg	3 ml	5 ml
< 50 kg	5 ml	10 ml
< 100 kg	10 ml	15 ml
≥ 100 kg	15 ml	20 ml

Recommendation:
15 ml of cold NaCl 0,9 % as the default setting for adults.

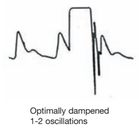
Square Wave Test Procedure:

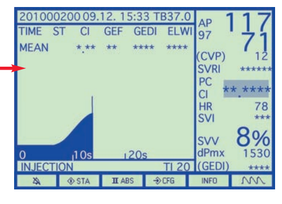
- Pull the Snap Tab™ of the flush device and release immediately.
- Observe the pressure signal on the patient monitor.
- Compare the wave form with the figures to determine the dynamic response.

If necessary repeat to verify maximum dynamic response.



CAUTION: An over- or under dampened wave may be the result of one or more of the following:
- 3 way stopcock partially closed pressure line kinked or squeezed
- Air in the pressure tubing and/or in the catheter
- Loose connections in the system
- Blood clots in catheter or in the pressure tubing
- Catheter tip touching the vessel wall
- Lumen too narrow
- Use of foreign or addition pressure tubing or material





Initially perform 3 thermodilution measurements

Press [STA] when performing further thermodilution measurements. Recalibrate 8 hourly or more frequently if patient condition unstable, if one measurement does not closely correspond to others, delete and re-perform.

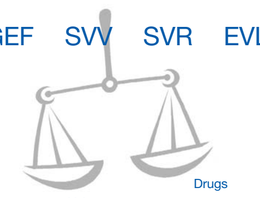
... change to [INFO] if you want to delete measurements

If ΔT < 0,2 % more/colder injectate might be necessary

Clinical Use & Benefit

PiCCO answers all relevant questions:

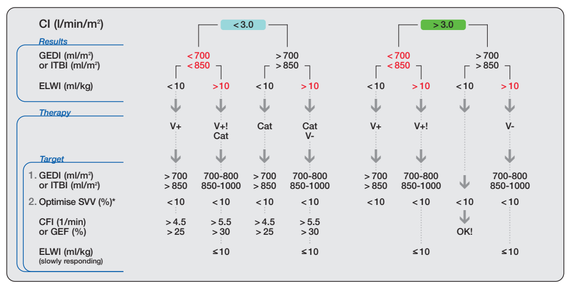
CO GEDV GEF SVV SVR EVLW*



What is the current situation?.....Cardiac Output
What is the preload?.....Global End-Diastolic Volume
Will volume increase CO?.....Stroke Volume Variation
What is the afterload?.....Systemic Vascular Resistance
What about contractility?.....Global Ejection Fraction
Are the lungs still dry?.....Extravascular Lung Water*

The PiCCO-Technology therapeutic decision tree and normal range table

(available as pocket guide)



V+ = volume loading (! = cautiously) V- = volume contraction Cat = catecholamine / cardiovascular agents *SVV only applicable in ventilated patients without cardiac arrhythmia
Without guarantee

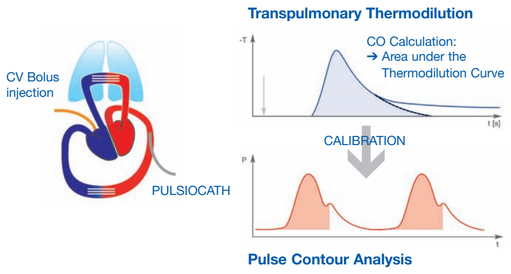
		Index	Range	Unit
Thermodilution Parameters				
Cardiac Output	CO	CI	3.0-5.5	l/min/m²
Global End-Diastolic Volume	GEDV	GEDI	680-800	ml/m²
Intrathoracic Blood Volume	ITBV	ITBI	850-1000	ml/m²
Extravascular Lung Water*	EVLW*	ELWI	3.0-7.0	ml/kg
Pulmonary Vascular Permeability Index	PVPI		1.0-3.0	-
Cardiac Function Index	CFI		4.5-6.5	1/min
Global Ejection Fraction	GEF		25-35	%
Pulse Contour Parameters				
Pulse Continuous Cardiac Output	PCCO	PCCI	3.0-5.5	l/min/m²
Arterial Blood Pressure	AP			
Heart Rate	HR			
Stroke Volume	SV	SVI	40-60	ml/m²
Stroke Volume Variation	SVV		<10	%
Pulse Pressure Variation	PPV		<10	%
Systemic Vascular Resistance	SVR	SVRI	1700-2400	dyn*s*cm^{-5}*m²
Index of Left Ventricular Contractility	dPmx			mmHg/sec

The PiCCO-Technology advantages:

→ Less Invasiveness	Only central venous and arterial access required No pulmonary artery catheter required Also applicable in small children
→ Short Set-up Time	Can be installed within minutes
→ Dynamic, Continuous Measurement	Cardiac Output, Afterload and Volume Responsiveness are measured Beat by Beat
→ No Chest X-ray	To confirm correct catheter position
→ Cost Effective	Less expensive than continuous pulmonary artery catheter Arterial PiCCO catheter can be in place for 10 days or more Potential to reduce ICU stay and costs
→ More Specific Parameters	PiCCO parameters are easy to use and interpret even for less experienced caregivers
→ Extravascular Lung Water*	Lung edema can be excluded or quantified at the bed-side

Underlying Principles

→ The PiCCO-Technology is a unique combination of 2 techniques for advanced hemodynamic and volumetric management without the necessity of a right heart catheter in most patients:

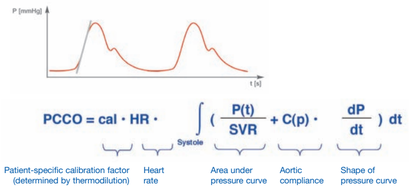


→ After central venous injection of the indicator, the thermistor at the tip of the arterial catheter measures the downstream temperature changes.
→ Cardiac output is calculated by analysis of the thermodilution curve using a modified Stewart-Hamilton algorithm:

$$CO_{TDa} = \frac{(T_b - T_i) \cdot V_i \cdot K}{\int \Delta T_b \cdot dt}$$

Tb = Blood temperature
Ti = Injectate temperature
Vi = Injectate volume
$\int \Delta T_b \cdot dt$ = Area under the thermodilution curve
K = Correction constant

→ For correct calculation of CO, only a fraction of the total injected indicator needs to pass the detection site. Simplified, only the change of temperature over time is relevant.
→ The algorithm is capable of computing each single stroke volume (SV) after being calibrated by an initial transpulmonary thermodilution.
→ After calibration, the pulse contour algorithm is able to follow the cardiac output Beat by Beat.



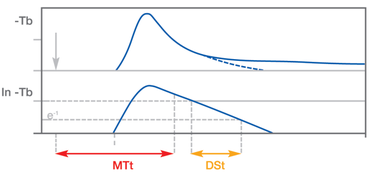
→ All volumetric parameters are obtained by advanced analysis of the thermodilution curve:

For the calculations of volumes…
MTt: Mean Transit time
= time when half of the indicator has passed the point of detection in the artery

…and…
DSt: Down Slope time
= exponential downslope time of the thermodilution curve

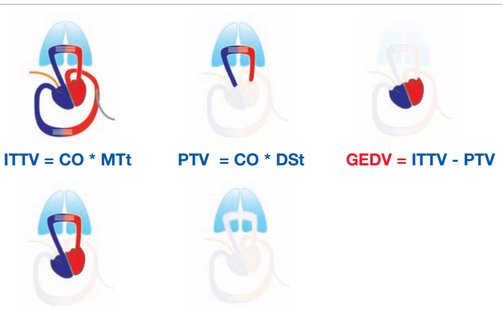
…are important.

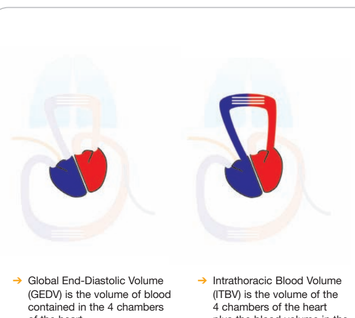
Advanced Thermodilution Curve Analysis



→ The intrathoracic compartments can be considered as a series of "mixing chambers" for the distribution of the injected indicator (intrathoracic thermal volume).
→ The largest mixing chamber in this series are the lungs, here the indicator (cold) has its largest distribution volume (largest thermal volume).

Underlying Principles





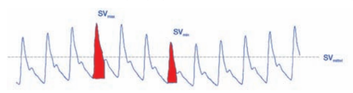
→ Global End-Diastolic Volume (GEDV) is the volume of blood contained in the 4 chambers of the heart.

→ Intrathoracic Blood Volume (ITBV) is the volume of the 4 chambers of the heart plus the blood volume in the pulmonary vessels.

→ ITBV and GEDV have been shown to be far more sensitive and specific to Cardiac Preload than the standard cardiac filling pressures CVP plus PCWP, and also right ventricular enddiastolic volume.

→ The striking advantage of ITBV and GEDV is that they are not adversely influenced by mechanical ventilation and give correct information regarding the preload status under any condition.

→ Stroke Volume Variation (SVV) represents the variation of stroke volume (SV) over the ventilatory cycle.



→ SVV reflects the sensitivity of the heart to the cyclic changes in cardiac preload induced by mechanical ventilation.
→ SVV can predict whether stroke volume will increase with volume expansion
→ SVV is only applicable in fully ventilated patients with regular heart rhythm

→ Extravascular Lung Water (EVLW*) is the amount of water content in the lungs. It allows bedside quantification of the degree of pulmonary edema.

→ EVLW* assessed by transpulmonary thermodilution has been validated against dye dilution and the reference gravimetric method.

→ EVLW* has shown to have a clear correlation to severity of ARDS, length of ventilation days, ICU-Stay and Mortality and to be superior to assessment of lung edema by chest x-ray and CT scan.

Indications:
Patients in whom cardiovascular and circulatory volume status monitoring are necessary. This includes patients in surgical, medical, cardiac and burn specialty units, as well as other specialty units where cardiovascular monitoring is desired, and patients undergoing major surgical interventions where cardiovascular monitoring is necessary. In short, every patient who requires a central venous and arterial catheter for monitoring.
Contraindications:
Patients in whom there are arterial access restrictions, for example due to femoral artery grafting or severe burns in areas where the arterial catheter would normally be placed.
Note: The Axillary or Brachial artery can be used as an alternative site.
Additionally a long radial artery catheter can also be placed for short term use.
The PiCCO-Technology may give incorrect thermodilution measurements in patients with intracardiac shunts, aortic aneurysm, aortic stenosis, mitral or tricuspid insufficiency, pneumonectomy, macro lung embolism and extracorporeal circulation (if blood is either extracted from or infused back into the cardiopulmonary circulation).
As is the case with all arterial catheters adequate perfusion downstream of the puncture site has to be assured. Adequacy of perfusion can be monitored using clinical inspection, surface temperature measurement, or by applying a pulse oximetry sensor to a digit downstream from the puncture site to continuously establish pulsatile flow.

Trouble-shooting

Troubleshooting:
If the device shows an error message (E), please confirm with [⇐] and check the system for correct setup and settings. Do a further Thermodilution Measurement. For detailed trouble shooting please refer to the PiCCO*plus* Operator's Manual or contact your PULSION representative. In the case where you observe any product defect on disposables or accessories, please keep the product to be handed to your PULSION representative for further investigation.

E	Interpretation
0	Technically good measurement
1	Error in determination of Tinj.
2	Injection error
3	Inject faster than 10 s
4-6	Error in calculation of thermodilution curve parameters
7	Time out (Thermodilution curve longer than 90s)
8	Blood temperature lower than injectate temperature
9	Invalid PCCO calibration

Injectate temperature problem	Possible cause	Suggested remedy
- Injection not detected	- No signal transfer	- Change injectate temp. sensor cable or housing
- Injectate temperature sensor error	- Blocked sensor housing	- Change sensor housing
Thermodilution signal problem	**Possible cause**	**Suggested remedy**
- TD curve does not appear	- Defective catheter / cable	- Remove catheter / cable
- No TB (Blood Temperature)	- Defective catheter / cable	- Remove catheter / cable
- TB incorrect	- Catheter / calibration of system defective	- Change cath. / call PULSION representative

Arterial blood pressure problem	Possible cause	Suggested remedy
- Arterial pressure dampened	- Air in arterial line	- Remove air from pressure line
	- Additional /foreign pressure line	- Remove additional / foreign line
- Arterial line flat or absent	- Catheter kinked	- Avoid bending of catheter
	- Catheter clotted	- Secure continuous flushing
- No pressure transfer	- No pressure in flush device	- Add pressure to flush device
- Invalid pressure values	- Defective cable	- Replace cable
	- Defective pressure transducer	- Replace pressure transducer
	- Calibration of system defective	- Call PULSION representative

PULSION Medical Systems AG • Stahlgruberring 28 • D-81829 Munich, Germany
Tel. +49-(0)89-45 99 14-0 • Fax +49-(0)89-45 99 14-18
info@pulsion.com
www.PULSION.com

PULSION Medical Inc., USA
☎ +1-760-295 1370
info@pulsionmedical.com

PULSION Benelux nv/sa
☎ +32-9-242 99 10
info@pulsion.be

PULSION Medical System Iberica S.L.
☎ +34-91-665 73 12
info@pulsioniberica.com

PULSION France sarl
☎ +33-4-42 27 67 19
info@pulsion.fr

PULSION Medical UK Ltd.
☎ +44-1895-45 52 55
info@pulsionmedical.co.uk

PULSION Pacific Pty. Ltd., AUS
☎ +61-7-32 66 84 48
info@pulsionpacific.com.au

PULSION Medical Systems

*Extravascular Lung Water (EVLW) is not yet available in the US, FDA clearance pending