

Cardiac Output Module

The M1012A module measures Cardiac Output (C.O.) and Continuous Cardiac Output (CCO). It offers a choice of two measurement methods, the Transpulmonary Thermodilution (PiCCO™¹) method, and the Right Heart Thermodilution method. Both measurement methods are suitable for adults, pediatric and neonatal patients (above 2 kg) in a range of Critical Care environments.

The module can be connected with plug-and-play convenience to these patient monitor families:

- V24 (M1205A)
- CMS (M1165A/66A/75A and M1175A/76A/77A)
- IntelliVue (M8005A, M8007A, M8010A).

The module sends a thermodilution curve, cardiac output numerics, and cardiac index values to the patient monitor display.

CCO Features

- CCO can be measured using the Transpulmonary Thermodilution, or PiCCO™ method. CCO measurement technology using the PiCCO™ method was developed by Philips in cooperation with Pulsion Medical Systems.

In Canada, a version of the module without Continuous Cardiac Output functionality is shipped.

- Values for Intrathoracic Blood Volume (ITBV) and Extravascular Lung Water (EVLW) can be derived from the Transpulmonary Thermodilution C.O. measurement (not USA).
- CCO alarms can be generated from Pulse Contour Analysis when the arterial catheter used for the Transpulmonary Thermodilution is connected to

1. PiCCO™ is a trademark of Pulsion Medical Systems AG.



the module.

- Continuous Systemic Vascular Resistance values can be derived from the CCO.

C.O. Features

- Absolute and indexed hemodynamic values are shown.
- Alarm generation from blood temperature measurement.
- Patient isolation by internal optical coupling.
- Hard keys on the module for direct access to the most commonly performed functions.
- Light indicators identify the module in use during monitoring tasks.
- Color-coded patient cable connectors for quick and easy identification.
- Compact size due to surface mount technology.

Description

The M1012A C.O. Module is a Cardiac Output measurement unit that can use the following thermal dilution methods:

- Transpulmonary Thermodilution (PiCCO Method)
- Right Heart Catheter Thermodilution.

It is designed to be used with adult, pediatric or neonatal patients (above 2kg when using the Transpulmonary Thermodilution method), in a range of Critical Care environments.

The module produces a thermodilution curve and numerics for the cardiac output, cardiac index, blood temperature, and injectate temperature values.

CCO only

Intrathoracic Blood Volume (ITBV) and Extravascular Lung Water (EVLW) (not USA) can be derived from the Transpulmonary Thermodilution (PiCCO) C.O. measurement using an arterial thermodilution catheter placed downstream of the heart, in or near the aorta.

Using the same arterial catheter, in conjunction with the M1006B invasive pressure modules, it is possible to calculate Continuous Cardiac Output (CCO) values from Pulse Contour Analysis of the pressure measured. Systemic Vascular Resistance (SVR) is continuously calculated with the CCO measurement.

Independent alarms are generated for CCO and Blood Temperature.

Compatibility

If you use the module in a monitor that does not include the PiCCO functionality (for example a CMS monitor release earlier than C.0, or a V24/ V26 monitor), only the right heart method can be used.

Module Specifications

Physical	
Size (HxWxD)	99.6 x 36 x 97.5 mm (3.9 x 1.4 x 3.8 inches).
Weight	225 g (7.9 oz.).
Safety	
Complies with UL544, IEC 601-1, CSA C22.2 No. 125. Patient leakage current less than 10 μ A at 120 V/ 60 Hz. Protected against damage from defibrillation and electrosurgery. USA Federal Law restricts this device to sale by or on the order of a physician.	
Temperature Range	
Operating	0 to 55°C (32 to 131°F)
Storage	- 40 to 70°C (- 40 to 158°F)
Humidity	
Operating	95% RH max. at 40°C (104°F)
Storage	95% RH max. at 65°C (150°F)
Altitude Range	
Operating	Up to 4,600m (15,000ft).
Storage	Up to 15,300m (50,000ft).

Measurement Specifications

Cardiac Output (Right Heart)	
C.O. Range	0.1 to 20.0 l/min
Instrument Specification (measured electronically)	
C.O. instrument accuracy	\pm 3% or 0.1 l/min
C.O. repeatability accuracy	\pm 2% or 0.1 l/min
System Specification	
C.O. instrument accuracy	\pm 5%.or 0.2 l/min (\leq 10 l/min) \pm 8% (\geq 10 l/min)
C.O. repeatability accuracy	\pm 3% or 0.1 l/min
Cardiac Output (Transpulmonary)	
C.O. Range	0.1 to 25.0 l/min
Instrument Specification (measured electronically)	
C.O. instrument accuracy	\pm 4% or 0.15 l/min
C.O. repeatability accuracy	\pm 2% or 0.1 l/min
System Specification	
C.O. instrument accuracy	\pm 5% or 0.2 l/min
C.O. repeatability accuracy	\pm 3% or 0.1 l/min
Blood Temperature	
Blood Temperature Range	17 to 43°C
Injectate Temperature	
Injectate Temperature Range	0 to 27°C
EVLW (not available in the USA)	
EVLW Range	10 to 5000 ml
Standard Deviation	10% or 1 ml/kg

ITBV	
ITBV Range	50 to 6000 ml
Accuracy	± 10% or 30 ml
Repeatability	± 5% or 20 ml
CCO	
CCO Range	0.1 to 25.0 l/min
Standard Deviation	10% or 0.3 l/min
Display Update:	2 seconds nominal

Cardiac Output Alarm Specifications

Tblood Alarms	
Alarm Limit Range	17 to 43°C
Adjustment	Steps of 0.1°C (T > 35 °C) Steps of 0.5°C (T < 35 °C)
Alarm Criterion	8 seconds after the value exceeds the set limit value.
Alarm	within 2 seconds after this criterion is met.
CCO Alarms	
Alarm Limit Range	0.1 to 25.0 l/min
Adjustment	Steps of 0.1 l/min (CCO < 10.0 l/min) Steps of 0.5 l/min (CCO > 10.0 l/min)
Alarm Criterion	8 seconds after the value exceeds the set limit value
Alarm	within 2 seconds after this criterion is met

Ordering Information

All accessories for modules are optional.



These accessories are designed to have special protection against electric shocks (particularly regarding allowable leakage currents), and are defibrillator proof.

Accessories		
C. O. Interface Cable		
2.4 m + 2.4 m cable		M1643A
C.O. Temperature Probes		
PiCCO method: PiCCO inline temperature probe for warm injectate, Latex free, compatible with housings from PULSION		M1646A
Right Heart method: 0.5m standard inline injectate temp. probe, compatible with Edwards/Baxter housings		23001B
Additional Accessories for both methods		
Set of ice buckets		14455A
Remote handswitch		15244A
Pulsion disposables		
Arterial Catheter 4F, 16 cm, or other compatible catheter as validated by Pulsion		PV 2014 L16
PiCCO Pressure Transducer Kits compatible with M1646A	PiCCO monitoring kit, (with M1646A, housing PV 4046) 30cm pressure line	PV 8103
	PiCCO monitoring kit, 150cm pressure line	PV8115
	PiCCO monitoring kit, (with M1646A housing, PV 4046, and central venous catheter): 150cm pressure line	PV8115 CVP
Pulsion Pressure Transducer Kits compatible with Edwards/Baxter housing (required for measuring CCO)	30cm pressure line	PV 8003
	100cm pressure line	PV 8010
	150cm pressure line	PV 8015
PULSION Pressure Interface Cable for disposable pressure transducer		PMK 206

Documentation

The Instructions for Use for this module is included in the documentation package shipped with the ordered system.

Philips Medical Systems is part of Royal Philips Electronics

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M1012A complies with the requirements of the Council Directive 93/42/EEC of 14 June 1993 (Medical Device Directive).

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