

Datex-Ohmeda Cardiac Output Modules

S/5™ Cardiac Output and SvO₂ Module, M-COPsv (Rev. 01)

S/5™ Cardiac Output Module, M-COP (Rev. 03)

Technical Reference Manual Slot



All specifications are subject to change without notice.

Document No. 800 1012-1

June 2001

Datex-Ohmeda Inc.
3030 Ohmeda Drive
53707-7550 MADISON, WIS
USA
Tel. +1-608 -221 1551, Fax +1-608-222 9147
www.us.datex-ohmeda.com

Datex-Ohmeda Division,
Instrumentarium Corp.
P.O. Box 900, FIN-00031
DATEX-OHMEDA, FINLAND
Tel. +358 10 394 11 Fax +358 9 146 3310
www.datex-ohmeda.com
© Instrumentarium Corp. All rights reserved.

TABLE OF CONTENTS

Cardiac Output Modules, M-COP and M-COPsV

TABLE OF CONTENTS	i
TABLE OF FIGURES	ii
Introduction	1
1 Specifications	2
1.1 General specifications	2
1.2 Typical performance	2
1.2.1 C.O.	2
1.2.2 SvO ₂	2
1.2.3 InvBP	2
1.3 Technical specifications	3
2 Functional Description	4
2.1 Measurement principle	4
2.1.1 Cardiac output and REF	4
2.1.2 SvO ₂ measurement	5
2.1.3 Invasive blood pressure measurement	6
2.2 Main components	6
2.2.1 COP board	7
2.2.2 COPSv board	10
2.3 Connectors and signals	11
2.3.1 Module bus connector	11
2.3.2 Front panel connectors	12
3 Service Procedures	14
3.1 General service information	14
3.2 Service check	15
3.2.1 Recommended tools	15
3.3 Disassembly and reassembly	20
3.4 Adjustments and calibrations	20
3.4.1 Cardiac output calibration	20
3.4.2 Invasive pressure calibration	20
4 Troubleshooting	22
4.1 Troubleshooting charts	22
4.1.1 Cardiac Output	22
4.1.2 SvO ₂	22
4.1.3 InvBP	23
4.2 Troubleshooting flowchart	24
5 Service Menu	25
5.1 COP Menu	26
5.1.1 COP calibration menu	28
6 Spare Parts	29
6.1 Spare parts list	29

6.1.1 Cardiac Output Module, M-COP Rev. 00.....	29
6.1.2 Cardiac Output Module, M-COP Rev. 01.....	29
6.1.3 Cardiac Output Module, M-COP Rev. 02.....	30
6.1.4 Cardiac Output Module, M-COP Rev. 03.....	30
6.1.5 Cardiac Output and SvO ₂ Module, M-COPSv Rev. 00	30
6.1.6 Cardiac Output and SvO ₂ Module, M-COPSv Rev. 01	31
6.1.7 Front panel stickers for AS/3 modules (square buttons).....	31
6.1.8 Front panel stickers for S/5 modules (round buttons).....	31
7 Earlier Revisions	32
APPENDIX A	33
Service check form	A-1

TABLE OF FIGURES

Figure 1 Cardiac Output Module, M-COP, and Cardiac Output and SvO ₂ Module, M-COPSv	1
Figure 2 Cardiac output measurement curve.....	5
Figure 3 Front panels of Cardiac Output Modules, M-COP and M-COPSv	6
Figure 4 COPSv board block diagram, on COP board the SvO ₂ section is excluded.....	8
Figure 5 Pressure transducer principle of operation.....	8
Figure 6 Serial communication and opto isolation.....	9
Figure 7 Cardiac Output Module troubleshooting flowchart.....	24
Figure 8 Module box and Cardiac Output Module, M-COP	29
Figure 9 Cardiac Output and SvO ₂ Module, M-COPSv.....	30

INTRODUCTION

This section provides information for the maintenance and service of Cardiac Output Modules, M-COP and M-COPSv. Cardiac Output Modules, M-COP and M-COPSv are single width plug-in modules designed for use with the S/5 monitors. Later in this manual modules can be called w/o system name S/5.

Both modules provide

- Cardiac output (C.O.)
- Right ventricular ejection fraction (REF)
- Invasive blood pressure (InvBP) measurement

Additionally, the COPSv module provides venous oxygen saturation (SvO₂) measurement.

NOTE: Do not use identical modules in the same monitor simultaneously. These modules are considered as identical and would cause communication errors if used in the same system.



Figure 1 **Cardiac Output Module, M-COP, and Cardiac Output and SvO₂ Module, M-COPSv**

1 SPECIFICATIONS

1.1 General specifications

Module size (W × D × H)	37 × 180 × 112 mm / 1.5 × 7.1 × 4.4 in
Module weight	0.35 kg / 0.8 lbs
Power consumption, M-COP	Approximately 3.5 W
Power consumption, M-COPSv	Approximately 5 W

1.2 Typical performance

1.2.1 C.O.

Measurement range	0.1...20 l/min
Display resolution	0.01 l/min
Repeatability	±2 % or ±0.02 l/min whichever is greater (measured from electrically generated flow curves)
Max. change in blood temp	2.99 °C
Injectate temp range (with Edward's compatible probes)	0...25.5 °C ±0.3 °C 25.5...27.0 °C ±0.5 °C
Blood temp range (with Edward's compatible catheters)	17.5...30.9 °C ±0.5 °C 31.0...43.0 °C ±0.3 °C
Protection against electric shock	type CF defibrillation proof
REF	
Repeatability (Measuring range 10-60 %)	±2 %

1.2.2 SvO₂

Accuracy	±2 %
(Measuring range 30-95 %)	
Equal to standard deviation when using in-vivo calibration.	

1.2.3 InvBP

Measurement range	-40...+320 mmHg
Zero adjustment range	±150 mmHg
Calibration range	±20 %

Scales	Upper limit is adjustable between 10 and 300 mmHg in steps of 10. Lower limit is 10 % of selected upper limit below zero.
Sweep speed	12.5, 25, 50 mm/s
DIGITAL DISPLAY	
Range	-40...+320 mmHg
Resolution	±1 mmHg
WAVEFORM DISPLAY	
Range	-30...+300 mmHg
PULSE RATE	
Measurement range	30...250 bpm
Resolution	1 bpm
Accuracy	±5 % or ±5 bpm whichever is greater
Respiration artifact rejection	

1.3 Technical specifications

The digital display is averaged over 5 seconds and updated at 5 second intervals.

Accuracy	±5 % or ±2 mmHg, whichever is greater
Transducer and input sensitivity	5 µV/V/mmHg, 5 VDC 20 mA max current
Nonlinearity	<1 %, 0 to 200 mmHg <2 %, -40 to 0 and 200 to 320 mmHg
Filter adjustable upper limit	0...22 Hz (-3 dB), 4...22 Hz
Zero set accuracy	±1 mmHg
Calibration resolution	±1 mmHg
Zero time	< 15 sec
Protection against electric shock	type CF defibrillation proof

NOTE: The accuracy of the measurement may be different from the specified accuracy, depending on the transducer/probe used. Please check the transducer/probe specification.

2 FUNCTIONAL DESCRIPTION

2.1 Measurement principle

2.1.1 Cardiac output and REF

Cardiac output measurement is made using the principle of thermodilution. During measurement the catheter lies in the heart, with an injection port in the right atrium (RA) and a thermistor, which is to monitor blood temperature, in the pulmonary artery (PA). A small, known amount of thermal indicator is injected into the RA and is mixed with the blood on its way to the PA. The catheter thermistor measures the decrease in blood temperature as the blood flows past the thermistor in the PA.

The information is stored in the module and the cardiac output is calculated from the area beneath the time-temperature Cardiac Output Measurement Curve, as shown in figure 2.

The area under the time-temperature curve is inversely proportional to the flow rate which corresponds to cardiac output.

The cardiac output is calculated from the equation:

$$C.O. = (1.08 C_T 60 V_i (T_B - T_i)) / (T_B dt + C)$$

where:

C.O. = cardiac output in liters/minute

1.08 = factor comparing the density and specific heat of 5% dextrose solution in water to those of blood.

C_T = correction factor for the injectate temperature rise as it passes through the catheter and its dead space

60 = seconds/minute

V_i = injectate volume in liters

T_B = baseline blood temperature (°C)

T_i = injectate temperature

$T_B dt$ = area under time-temperature curve between time 0 and x, where x is the time when the curve has dropped to 30% of its peak value.

C = area beneath time-temperature curve between x and the end of the curve.

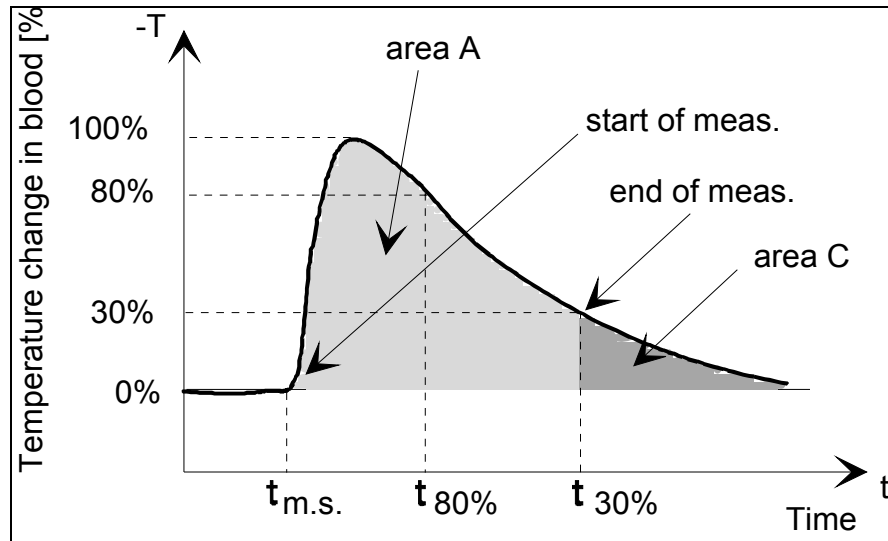


Figure 2 Cardiac output measurement curve

A = area derived by integration of the time-temperature curve

C = area beneath the time-temperature curve between $t_{30\%}$ and end of the curve. Computation based on an exponential fit to the curve between $t_{80\%}$ of the peak and $t_{30\%}$.

REF (right ventricular ejection fraction) measurement is a part of the time-temperature (thermodilution) cardiac output measurement. Ejection fraction is determined using an exponential technique by synchronizing sensed R-waves with points of temperature changes on the time-temperature curve. Once ejection fraction, cardiac output, and heart rate are known, right ventricular volumes may be calculated. The measurement requires a Baxter-Edwards fast response thermistor catheter and an ECG module to synchronize R-wave detection to the time-temperature curves.

2.1.2 SvO₂ measurement

The COPSv module measures SvO₂ when coupled with a Baxter-Edwards OM-2E optical module and a Swan-Ganz oximetry catheter. To measure SvO₂, the system utilizes a spectrophotometric technique involving the use of light emitting diodes (LEDs) that produce red (660 nm) and infrared (810 nm) light. The light is transmitted to the blood through a single plastic optical fiber in the oximetry catheter and reflected back through a separate optical fiber to a photodetector in the optical module. The light is electrically transmitted to the COPSv module and analyzed to determine SvO₂.

The oximetry portion of the system measures SvO₂ in the pulmonary artery by detecting color changes in the red blood cells. When pulses of red and infrared light are transmitted through the oximetry catheter, the light is reflected from the red blood cells and transmitted back through the catheter to the optical module. The amount of light reflected at each wavelength depends primarily on the color of the blood and the number of red blood cells. Since the number of red blood cells in the blood affects the amount of reflected light, the differences are compensated for when the patient's total hemoglobin value is entered. The optical module stores and transfers SvO₂ calibration data. SvO₂ values can be affected by the presence of methemoglobin or carboxyhemoglobin which imitate the absorption characteristics of HbO₂. Large concentrations of methemoglobin or carboxyhemoglobin could then cause a falsely elevated SvO₂. In cases where dysfunctional hemoglobins are suspected, SvO₂ should be interpreted with caution.

2.1.3 Invasive blood pressure measurement

To measure invasive blood pressure, a catheter is inserted into an artery or vein. The invasive pressure setup, consisting of connecting tubing, pressure transducer, an intravenous bag of normal saline all connected together by stopcocks, is attached to the catheter. The pressure transducer is placed at the same level with the heart, and electrically zeroed.

The pressure transducer is a piezo-resistive device that converts the pressure signal to a voltage. The monitor interprets the voltage signal so that blood pressure data and blood pressure waveforms can be displayed.

2.2 Main components

The Cardiac Output Module, M-COP consist of a COP circuit board and two input boards - a CO input board and a P input board, attached to the front panel.

The Cardiac Output and SvO₂ Module, M-COPSv, consist of a COPSv circuit board and three input boards - a CO input board, a SvO₂ input board and a P input board, attached to the front panel.

The front panels are shown in figure 3.

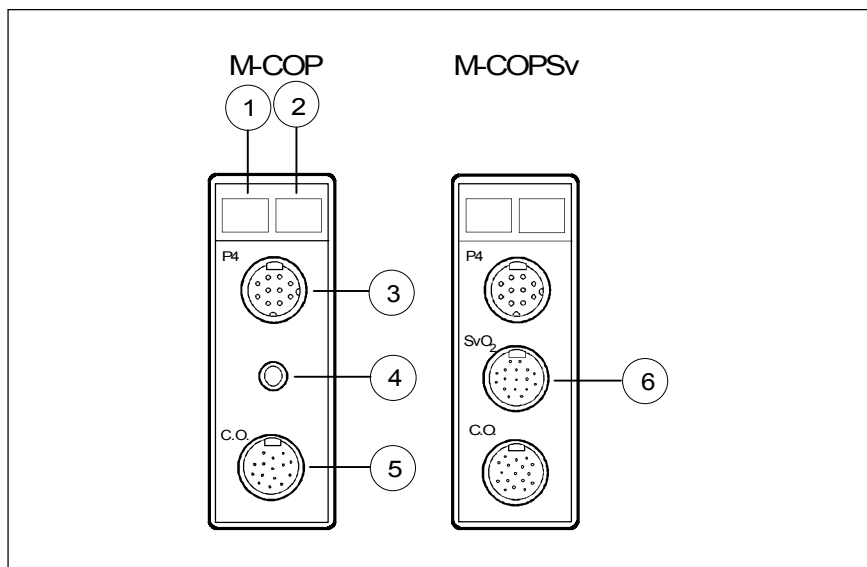


Figure 3 Front panels of Cardiac Output Modules, M-COP and M-COPSv

- (1) Key for pressure zeroing (Zero P4)
- (2) Key for cardiac output measurement (Start C.O.)
- (3) Connector for invasive blood pressure measurement
- (4) Connector for C.O. self test
- (5) Connector for C.O. measurement
- (6) Connector for SvO₂ measurement

2.2.1 COP board

The COP board consists of the following functional sections.

- Processor
- Cardiac output measurement
- Cardiac output self test
- Invasive blood pressure measurement
- Serial communication
- Isolation
- Power supply

Processor section

The microprocessor uses the Intel 80C196KC-16 CPU which includes three A/D converters and a UART. The microprocessor uses external memories, an 8-bit data bus, a 16 MHz oscillator, and a watchdog timer. The three A/D-converters within the CPU convert the analog input signals to digital. The internal UART communicates and transfers data between the module and the CPU board in the monitor.

Cardiac output measurement section

The catheter and the probe contain an NTC resistor that reacts to temperature change.

The temperature dependent voltage across the NTC resistor is amplified and an offset value is added to it. The resultant signal is then regulated into a ± 5 V range by voltage slicing and sent to an A/D converter.

Because the temperature measurements are calibrated digitally and non-linearity of catheter/probe is compensated by software, ambient temperature change after calibration is the only factor that may influence the measurement.

Cardiac output self test

The Cardiac Output Module, M-COP contains a C.O. Self Test connector.

When the cable is connected to the C.O. Self Test connector, the microprocessor starts the test program automatically. First, the microprocessor measures 30 °C, then it activates test circuits and measures 37 °C and 41 °C.

If the values are not correct 'Cable fault' is displayed and there is a fault is either in the module or in the catheter connecting cable.

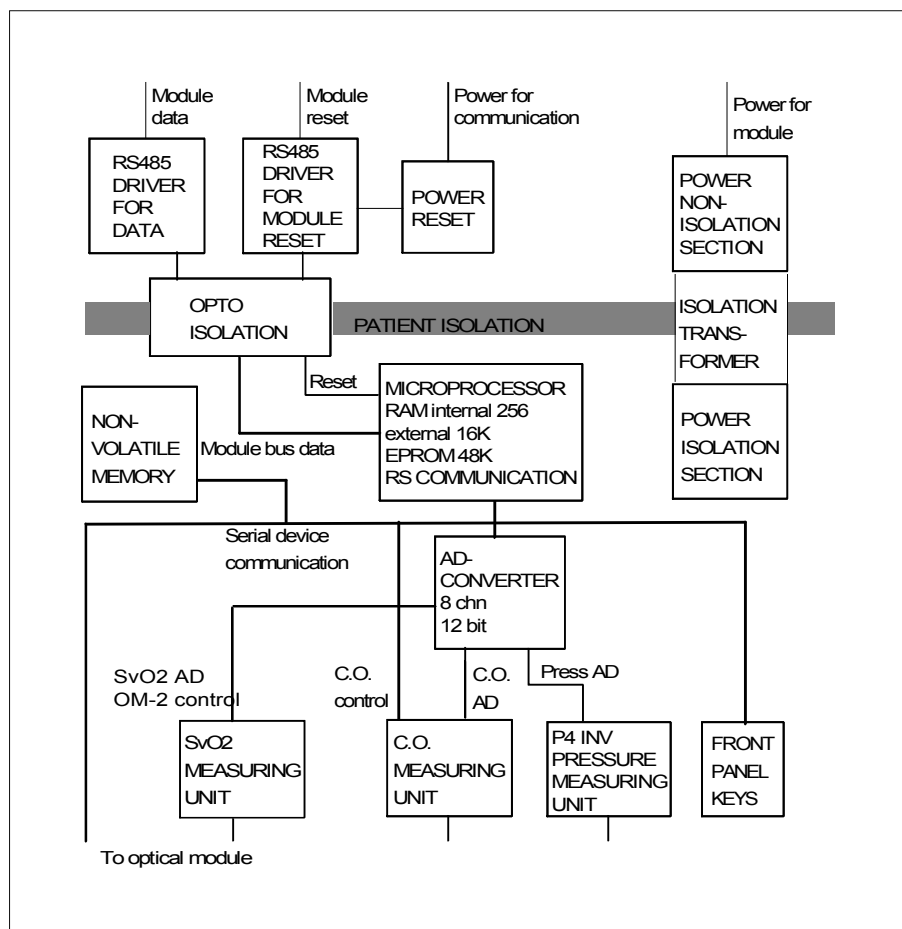


Figure 4 COPSv board block diagram, on COP board the SvO₂ section is excluded

Invasive blood pressure measurement section

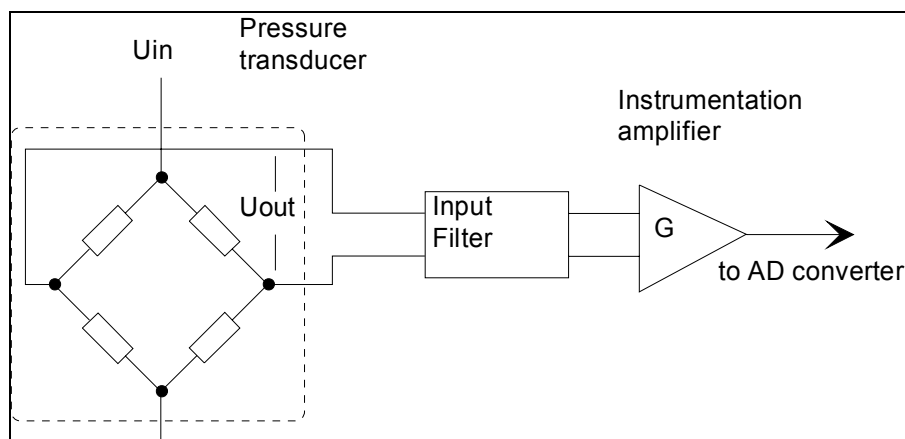


Figure 5 Pressure transducer principle of operation

An isolated +5 V supply is connected to the input of the pressure transducer bridge circuit. From the bridge circuit output a differential voltage, which depends on blood pressure and input supply voltage, is calculated using the following formula:

$U_{out} = U_{in} \times \text{Pressure} \times 5 \text{ V}$, where $U_{in} = 5 \text{ V} \Rightarrow U_{out} = 25 \text{ V} \times \text{Pressure} [\text{mmHg}]$

Pressure amplification is performed by the instrumentation amplifier. The gain of the amplifier is set so that the level of the signal transferred to the A/D converter stays within the measurement range even when there are circumstantial offsets or offsets caused by the pressure transducer. The input filter before the amplifier attenuates high frequency disturbances.

A FET switch cuts the measurement current and detects the existence of the pressure transducer. The existence of the pressure transducer is also checked digitally by a jumper next to the connector.

Serial communication

Serial communication between the Cardiac Output Module and the Central Unit Frame is via an RS485 type bus. The communication bus drivers are powered from the Module Bus. The module isolation section is powered (+5 V) from the isolated power supply.

The communication drivers are controlled by a Reset signal such that when the Reset is active the drivers do not transfer data.

In addition to the RS485 reset there is a logic power-up reset, which holds for approximately 500 ms regardless of the state of the RS485 reset. A time constant determines the power-up reset time. The power-up reset also prevents the module from sending data to the Module Bus. The data transmission rate is 500 kbps.

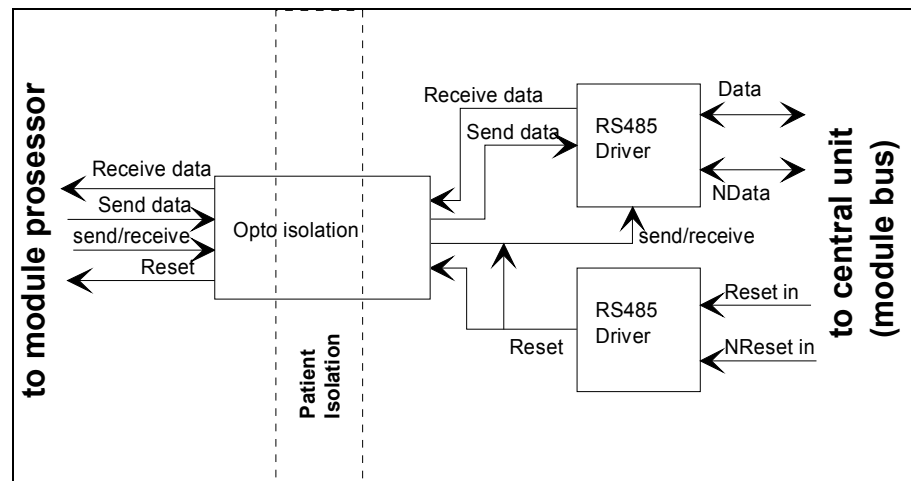


Figure 6 Serial communication and opto isolation

Isolation section

There are two opto isolators, one for data and one for the reset signal. Signals are processed on logical high-low levels even though the output of the opto isolators in the isolation section are analog signals.

The reset line is an open collector type, with a pull-up resistor so that the microprocessor is able to use its internal watchdog function.

Power supply section

The module isolated power supply is developed from the +15 Vdirty (non isolated) supply from the Central Unit power supply.

The isolated power supply is a switched-mode circuit, where an FET switch is controlled by an oscillator using a bipolar timer. The frequency of the oscillator is approximately 30 kHz, with a pulse ratio of 50%; switching of the FET is slow to suppress spurious interference. A special isolation pulse transformer is used in the circuit. The transformer secondary circuit uses normal linear regulators except for +5 V which uses a low drop type linear regulator.

2.2.2 COPSv board

The COPSv board consists of the same functional sections as the COP board, except for the cardiac output self test section. Additionally, the COPSv board consists of the SvO₂ measurement section.

SvO₂ measurement section

The SvO₂ algorithm is a part of the COPSv module software. The algorithm consists of five different parts; initialization, calibrations, signal processing and SvO₂ calculation, automatic gain control, and signal quality analysis.

Initialization

When the optical module is connected to the COPSv module, a number of start-up procedures are performed prior to normal operation. These procedures include transfer of calibration factors from the optical module to the COPSv module and initialization of LED currents.

Calibration

The system is calibrated according to either in-vitro or in-vivo calibration. In-vitro calibration is performed before the oximetry catheter is removed from the package with the catheter tip still inside the calibration cup. The resulting calibration factor is calculated on the basis of the measured ratio of red and infrared signals and the ideal ratio for the calibration cup. In-vivo calibration is performed when the catheter is inserted into the patient's pulmonary artery. The resulting calibration factor is based on the measured ratio of red and infrared signal and the Hgb and SvO₂ values measured in a laboratory. If the calibration is skipped, the result of an old calibration is used instead and the "Not calibrated" message is displayed in the SvO₂ number field.

Signal processing and SvO₂ calculation

The reflected red and infrared signals transferred from the optical module to the COPSv module are filtered, and SvO₂ is calculated on the basis of the ratio of the two signals.

Automatic gain control

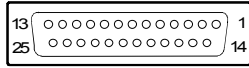
The intensity of the red and infrared signals can be amplified by four different gains. The gain is selected automatically to achieve optimal signal levels.

Signal quality

The reflected red and infrared signals are checked for wall contact artifacts, pulsatility and intensity shifts. An index is calculated to indicate the signal quality. 0 indicates a normal signal, 1 indicates an intermediate signal, 2 indicates a poor signal, and 3 indicates an unacceptable signal. Please refer to the service menu section for more information.

2.3 Connectors and signals

2.3.1 Module bus connector

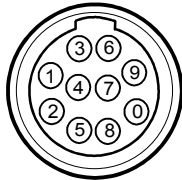


Pin	I/O	Signal
1	I	RESET_RS485*
2	I	-15 VDC*
3	I	+15 VDIRTY*
4	I	+15 VDC*
5	I/O	-DATA_RS485*
6	I/O	DATA_RS485*
7	-	Ground & Shield*
8	I	-RESET_RS485*
9	I	CTSB
10	O	RTSB
11	I	RXDB
12	O	TXDB
13	-	Ground & Shield*
14	I	+32 VDIRTY
15	I	GroundDIRTY*
16	I	CTSC
17	O	RTSC
18	I	RXDC
19	O	TXDC
20	-	ON/STANDBY
21	-	BITOIN
22	-	RXDD_RS232
23	-	TXDD_RS232
24	I	+5 VDC*
25	I	+5 VDC*

*Used in the M-COP module

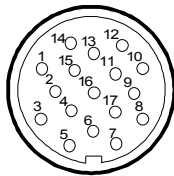
2.3.2 Front panel connectors

Invasive blood pressure connector (P4)



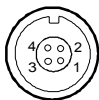
Pin	Signal
1	Pressure 4 +
2	Pressure 4 -
3	Polarization - (ground)
4	Polarization +
5	Not connected
6	Not connected
7	Not connected
8	Not connected
9	Ground
0	Cable detection

Cardiac output connector (C.O.)

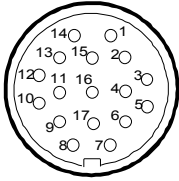


Pin	Signal
1	BAB
2	THB
3	BAC
4	Not connected
5	Shield
6	Not connected
7	THD
8	THA
9	THC
10	BAA
11	Not connected
12	Not connected
13	Not connected
14	FL
15	Not connected
16	Not connected
17	Not connected

C.O. Self Test connector (C.O. Test)



Pin	Signal
1	CTC
2	CTA
3	CTB
4	CTD

SvO₂ connector (SvO₂)

Pin	Signal
1	IR_CATHODE
2	CE
3	SK
4	DATA_OUT
5	CHASSIS_GND
6	SVO2_GND
7	HEATER_RTN
8	REMOTE_OUT
9	+V_OPT
10	TEMP_SENSOR
11	HEATER_HI
12	LOCAL_OUT
13	REF_RTN
14	LED_ANODE
15	RED_CATHODE
16	DATA_IN
17	-V_OPT

3 SERVICE PROCEDURES

3.1 General service information

Field service of the M-COP and M-COPsv modules is limited to replacing faulty mechanical parts. The COP board and the COPsv board cannot be replaced, and all calibrations can only be done at the factory.

Datex-Ohmeda is always available for service advice. Please provide the unit serial number, full type designation, and a detailed description of the fault.


CAUTION Only trained personnel with the appropriate tools and equipment should perform the tests and repairs outlined in this section. Unauthorized service may void warranty of the unit.

3.2 Service check

These instructions include complete procedures for a service check. The service check is recommended to be performed after any service repair. However, the service check procedures can also be used for determining possible failures.

The procedures should be performed in ascending order.

The instructions include a check form (*Appendix A*) which should be filled in when performing the procedures.

The mark  in the instructions means that the check form should be signed after performing the procedure.

The procedures are designed for monitors with S/5 monitor software of revision 01. However, most of the procedures also apply to monitors, which contain some other monitor software type/revision.

3.2.1 Recommended tools

Tool	Order No.	Notes
Patient simulator		
SvO ₂ simulator	890121	
Pressure manometer		
InvBP transducer		
Catheter connecting cable		
Screwdriver		

All modules

- Detach the module box by removing the two screws from the back of the module. Be careful with the loose latch and spring locking pin.

1. Check internal parts:

- screws are tightened properly
- cables are connected properly
- all socket mounted IC's are inserted properly
- EMC covers are attached properly
- there are no loose objects inside the module



2. Check external parts:

- the front cover and the front panel sticker are intact
- all connectors are intact and are attached properly
- the module box, latch and spring locking pin are intact



- Reattach the module box and check that the latch moves properly.
- Turn the monitor on and wait until the monitoring screen appears.
- Configure the monitor screen so that all the required parameters are shown, for example :

Monitor Setup - Screen 1 Setup - Waveform Fields - Field 4 - P4
Digit Fields - Field 4 - SvO₂

- Preset the C.O., SvO₂ and InvBP measurement settings:

Others - C.O. View - C.O. Setup - Scale - 1.0 °C
Injectate Volume - 10 ml
Measurement Mode - SET
SvO₂ - Update Hgb - 115 g/l

Invasive Pressures - P4 Setup - Label - PA

3. Plug in the module. Check that it goes in smoothly and locks up properly.



4. Check that the module is recognized by entering the C.O. View menu:

Others - C.O. View

Check that the message “No Catheter” is shown in the middle of the menu and the message “No cable” in the digit field for SvO₂, if it is an M-COPSv module.



5. Enter the service menu:

Monitor Setup - Install/Service (password 16-4-34) - **Service** (password 26-23-8)

Take down the information regarding COP software by selecting SCROLL VERS and turning the ComWheel.



6. Enter the COP module service menu:

Parameters - COP

Check that the “Timeouts”, “Bad checksums” and “Bad c-s by mod” values are not increasing faster than by 50 per second. Check that the module memories have passed the internal memory test, i.e. “RAM”, “ROM” and “EEPROM” all show OK.



Invasive blood pressure measurement

7. Check the front panel membrane key ZERO P4.
Press the key for at least one second. Check that the key being pressed is identified, i.e. the information on the service menu under "Button" - "P4" changes from OFF to ON.



8. Check that "Cable" and "Probe" for P4 show OFF. Plug a cable with an invasive blood pressure transducer into the front panel connector P4 and check that "Cable" and "Probe" show ON and the corresponding pressure waveform appears on the screen.



9. Calibrate InvBP channel P4 according to the instructions in the Technical Reference Manual.



10. Return to the normal monitoring screen by pressing the "Normal Screen" key on the Command Board. Check the InvBP channel with a patient simulator.
The settings and checks with a Dynatech Nevada medSim 300 Patient Simulator are:

SENSITIVITY -switch; 5 μ V/V/mmHg

ECG - BASE - BPM - 60

BP - 3 - WAVE - ATM

Connect the cable from channel BP3 to module connector P4. Zero the InvBP channel P4 by pressing the ZERO P4 key on the module front panel.

BP - 3 - WAVE - PA

Check that appropriate InvBP waveforms are shown and the InvBP value is approximately 25/10 (± 2 mmHg) for channel P4 (PA).



SvO₂ measurement

11. Enter the COP module service menu. Check that the SvO₂ values "Meas. state", "OM fail" and "OM temp." all show NO OM.

Turn the SvO₂ simulator's pulsation switch to "Medium" and the range switch to "Normal pulse". Connect the simulator to the module and check that the messages "Initializing, please wait", "Warming up" and "Not calibrated" appear in the digit field for SvO₂.

Initializing, please wait --> Warming up --> Not calibrated

Check that “Meas. state” has changed to NORMAL and “OM fail” and “OM temp.” show OK.

NOTE: “OM temp.” may show UNSTABLE at first, but the message should change to OK within a half a minute.



12. Perform an In-Vitro -calibration. Keep the SvO₂ simulator connected to the module and turn the pulsation switch to “No pulse”.

Enter the SvO₂ -menu:

Others - SvO₂

Highlight the CALIBRATE IN VITRO text and press the ComWheel to start the calibration. Wait until the text “Start SvO₂” appears in the menu.

Turn the SvO₂ simulator pulsation switch to “Normal Pulse” and complete the calibration by pressing the ComWheel again. Wait until the text “Calibrating” disappears from the digit field for SvO₂.

Check that the calibration date for In-Vitro calibration was updated correctly and the SvO₂ reading on the screen is 81 % (±2).



13. Turn the SvO₂ simulator pulsation switch to “No pulse” and check that the message “Check cath. position” appears in the digit field for SvO₂ and the message “SvO₂ poor signal” appears in the message field within one minute.

Turn the pulsation switch to “High pulse” and check that the two messages remain on the screen.

Turn the pulsation switch back to “Normal pulse” and check that the messages disappear within one minute.



Cardiac Output measurement

14. Check the front panel START C.O membrane key.
Enter the COP module service menu. Press the key for at least one second and check that it is identified, i.e. the information on the service menu under “Button” - “C.O.” changes from OFF to ON.



- Enter the “C.O. View” menu:

Others - C.O. View

Connect a catheter connecting cable to module connector C.O.

15. If the module contains the C.O. Test connector (M-COP), attach the catheter connector of the connecting cable to the C.O. Test connector. Check that the message “Cable OK” appears on the menu after the self-test.

No Catheter --> Self Test in Progress --> Cable OK

If the message “Cable fault” appears, exchange the cable and perform the same again.



16. Check the C.O. measurement with a patient simulator.

The settings and checks with a Dynatech Nevada medSim 300 Patient Simulator are:

C.O. - BASE - 37 °
WAVE

Leave the WAVE menu open on the simulator. Connect the catheter connecting cable (both connectors) to the simulator’s C.O. box. Highlight the text START C.O. SET on the C.O. View menu.

Press the ComWheel to start the measurement. When the text “Inject now!” appears on the menu, select the setting 5 l/min (F3) from the medSim 300 simulator. Check that the thermodilution curve displayed returns to the base level on the screen. Complete all 6 measurements .

NOTE: The medSim 300 simulator may give an inaccurate C.O. signal immediately after it has been turned on and after each new simulator setting. This property of the simulator must be taken into account when interpreting the C.O. results.

17. When the set is complete, exclude the first measurement from the average using the C.O. View menu functions:

Edit Average - Exclude Curves - 1

Press the ComWheel to exclude the first curve. Check that each of the remaining results is within ± 2 % of the new average.



All modules

17. Perform an electrical safety check and a leakage current test.



18. Check that the module functions normally after performing the electrical safety check.



19. Clean the module with suitable detergent.



- Fill in all necessary documents.

3.3 Disassembly and reassembly

Disassemble the Cardiac Output Modules ,M-COP and M-COPsv, in the following way. (see the exploded view of the module.

1. Remove the two screws from the back of the module.
2. Pull the module box slowly rearwards and remove it from main body. Be careful with the loose latch and spring locking pin.

To reassemble the module, reverse the order of the disassembly steps.

CAUTION When reassembling the module, make sure that the cables are reconnected properly.

3.4 Adjustments and calibrations

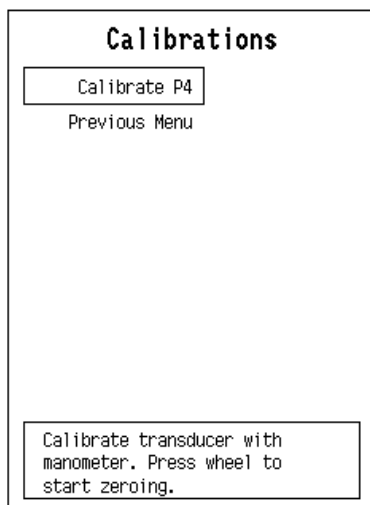
3.4.1 Cardiac output calibration

The cardiac output calibration can be performed only at the factory.

3.4.2 Invasive pressure calibration

Calibrate invasive pressure when the pressure transducer (probe) is replaced with a different type of transducer.

1. Enter the COP service menu (**Monitor Setup - Install/Service - Service - Parameters**)
2. Enter the **Calibrations** menu.



3. Connect a pressure transducer with a pressure manometer to the P4 connector. Select

'Calibrate P4' from the menu. Leave the transducer at room air pressure.

4. Press the ComWheel to start zeroing.
5. Supply a pressure of 100 mmHg to 300 mmHg to the transducer. The recommended pressure is 200 mmHg.
6. Set the pressure on the display to match the pressure reading on the manometer and press the ComWheel.
A tolerance of ± 1 mmHg is allowed.
7. The text 'calibrated' will appear on the display.

4 TROUBLESHOOTING

4.1 Troubleshooting charts

4.1.1 Cardiac Output

Trouble	Cause	Treatment
NO CATHETER-message	Catheter or cable not connected.	Connect catheter (cable).
	Catheter or cable faulty.	Check by self-test. Change catheter or cable.
	Blood temp out of range.	Check blood temp is within range.
Tinj OFF-message	No injectate temp probe.	Connect probe.
	Probe faulty.	Change probe.
	Wrong type of probe.	Use Baxter compatible inj. temp probe.
	Temp out of range.	Check blood temp is within range.

4.1.2 SvO₂

Trouble	Cause	Treatment
Faulty cable	Factory calibration of the optical module corrupted. Red or infrared transmit error, currents cannot be adjusted to factory defaults.	Replace optical module.
No cable	No optical module connected.	Connect optical module.
Insufficient signal	Loose catheter connection. Optical module failure. Catheter kinked or damaged.	Check connection. Replace optical module. Calibrate In vivo or replace catheter if necessary.
Warming up	Temperature of the optical module has not yet reached the optimum value or optical module failure or COPSv module failure.	Please wait. If it takes longer than 20 minutes replace optical module or COPSv module.
Poor SvO ₂ signal	Signal pulsatility, wall contact or intensity shift signal quality level at 3.	Check number field message for problem "Check catheter position" or "Intensity shift".

4.1.3 InvBP

Trouble	Cause	Treatment
Abnormally low pressure	Transducer wrongly positioned.	Check mid-heart level and reposition transducer.
No pressure	Defective transducer. No pressure module plugged in. No waveform selected on screen.	Check transducer. Check the module. To select the desired pressure waveforms press Monitor Setup key and select modify waveforms. Check that the pressure transducer is open to the patient.
Not zeroed-message	Measurement on, channel not zeroed.	Zero the channel.
Zeroing failed-message	Unsuccessful zeroing of P4 (number field).	Possibly due to pulsating pressure waveform. Open the transducer to room air and zero the channel. Offset is > 150 mmHg. Open the transducer to room air and zero the channel. Defective transducer. Replace and zero the channel.
Calibration failed-message	Unsuccessful calibrating of P4 (number field).	Pulsating waveform. Turn the transducer to sphygmomanometer and try again (zeroing takes place first). Gain is beyond the limits ($\pm 20\%$ of the default gain) of the module. Replace the transducer.
Out of range ≤ 40 mmHg	Measurement pressure is beyond measurement range.	Check transducer level. Zero the channel.
Out of range > 320 mmHg	Measurement pressure is beyond measurement range.	Check transducer level. Zero the channel. The patient may also have high blood pressure.
Zero adj. > 100 mmHg	Offset when zeroing is > 100 mmHg (but < 150 mmHg) from the absolute zero of the module (with default gain).	Check transducer. The waveform may hit the top and the numeric display not shown.
Out of range	Measured pressure is beyond the internal measurement range of the module.	The waveform hits the top and the numeric display not shown. Check transducer and its level. Zero the channel.

See also the troubleshooting flowchart on the next page.

4.2 Troubleshooting flowchart

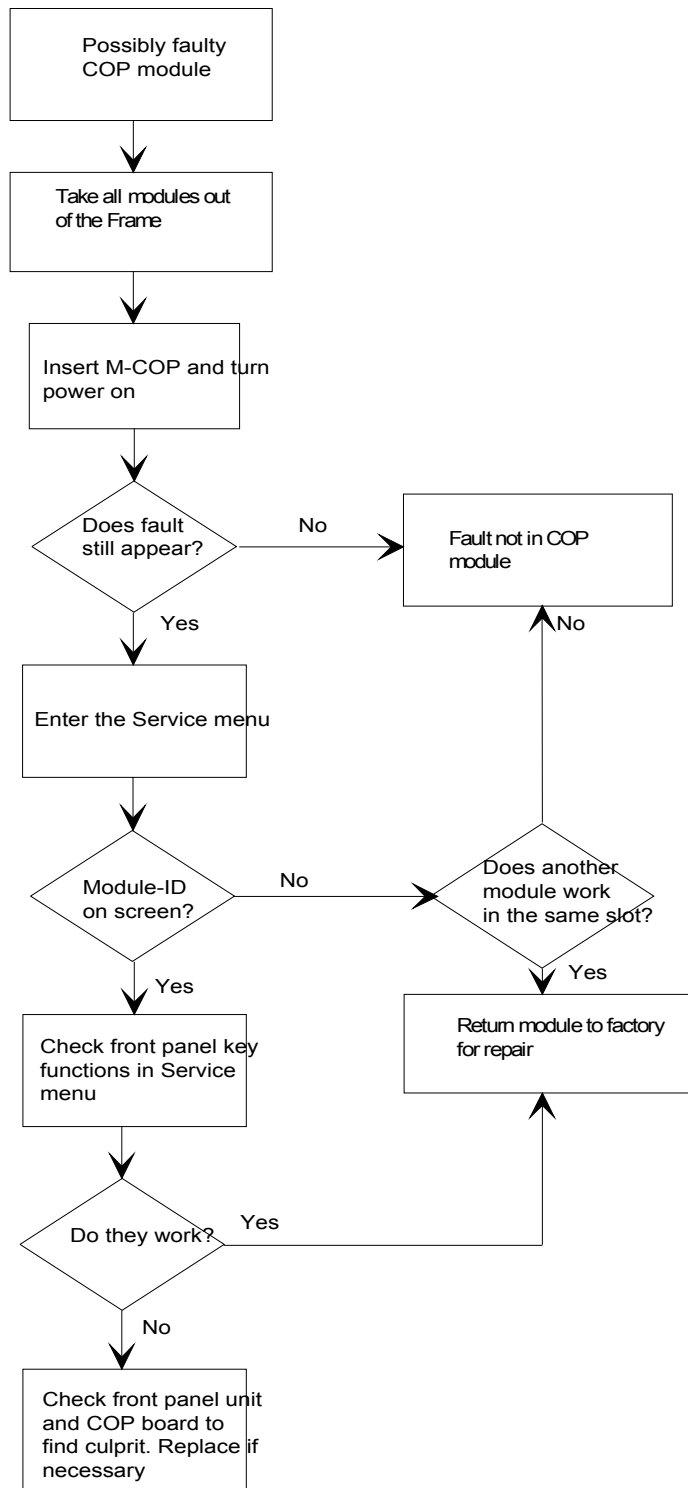
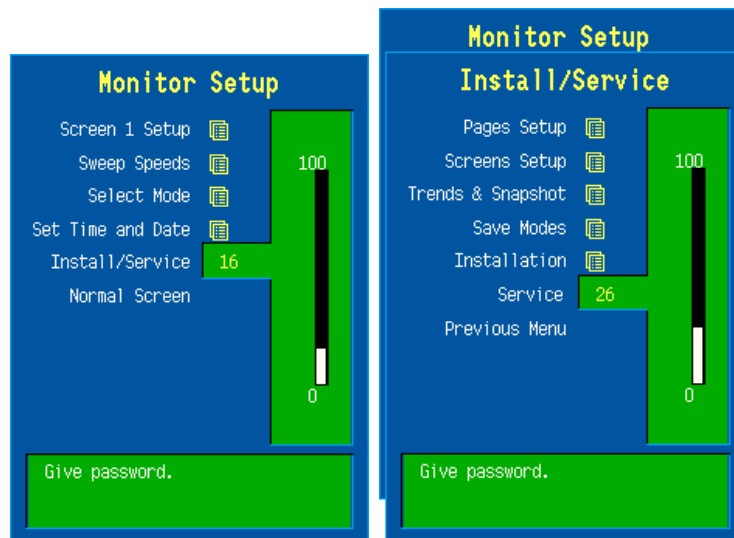


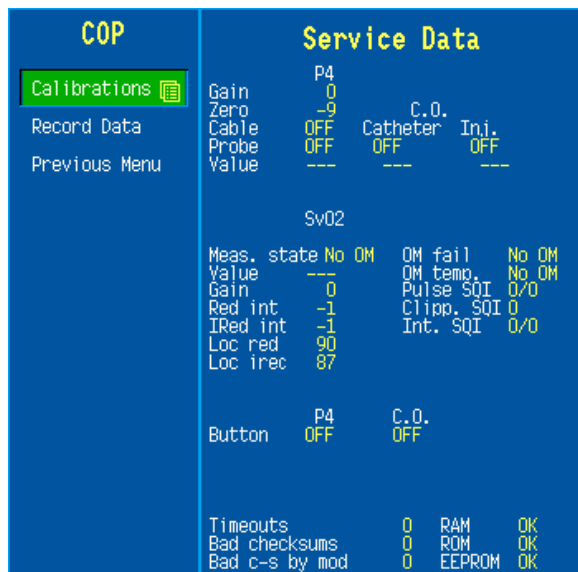
Figure 7 Cardiac Output Module troubleshooting flowchart

5 SERVICE MENU



1. Press the **Monitor Setup** key.
2. Select **Install/Service** (password 16-4-34).
3. Select **Service** (password 26-23-8).
4. Select **Parameters**.
5. Select **COP**.

5.1 COP Menu



COP

Record Data **Record Data** prints out the service data and module information (id. serial number and software id.) on the Recorder Module, M-REC.

Service Data

P4

Gain is a coefficient to compensate for gain error. Typically the value is between 17000 and 25000. Calibrate if the zero and/or gain value is outside the ranges.

Zero indicates the offset compensation value of each parameter in the A/D converter. Usually the value is within ± 1000 .

Cable shows ON when the corresponding cable is connected to the front panel and **Probe** shows ON when the corresponding probe is connected to the cable.

Value shows the measured numeric values simultaneously. Pressure value is a real time value and shown in mmHg.

Probe items **Catheter** (ON/OFF) and **Inj.** (FT, BATH, or OFF) indicate connections and **Value** indicates the measured temperatures in 0.01 °C increments.

SvO2

Meas. state: Measurement status shows: No optical module (No OM) connected, initializing the optical module (Init OM), normal measurement state (Normal) and failed module (OM fail).

Value is a measured SvO₂ value.

Gain is the gain of the remote red and infrared signals (0, 1, 2 or 3)

Red int: Reflected red intensity

IRed int: Reflected infrared intensity

Loc red: Local red intensity

Loc ired: Local infrared intensity

OM fail: Reason why initialization OK (OK), can't read EEPROM of the optical module correctly (EEPROM), can't adjust LED current to get required local signal (Transmit).

OM temp: Temperature of the optical module OK (OK), temp under 43 °C (Under), temp over 47 °C (Over).

Pulse SQL: Signal quality index for pulsing (low pulse/high pulse). 0 indicates a normal signal, 1 indicates an intermediate signal, 2 indicates a poor signal, and 3 indicates an unacceptable signal.

Clipp. SQL: Signal quality index for wall artifact. 0 indicates a normal signal, 1 indicates an intermediate signal, 2 indicates a poor signal, and 3 indicates an unacceptable signal.

Int. SQL: Signal quality index for intensity shift from previous calibration or Hgb update (intensity decreased/increased) 0 indicates a normal signal, 1 indicates an intermediate signal, 2 indicates a poor signal, and 3 indicates an unacceptable signal.

Button: The front panel Zero P4 and Start C.O. key functions can be confirmed by pressing the key and checking that the relevant OFF message turns to ON.

Timeouts is a cumulative number that indicates how many times the module has not responded to the monitor's inquiry.

Bad checksums is a cumulative number that indicates how many times communication from the module to the monitor has failed.

Bad c-s by mod is a cumulative number that indicates how many communication errors the module has detected.

The monitor starts counting these items at power up and resets to zero at power off. The nonzero values do not indicate a failure, but the continuous counting (more than 50 per second) during normal operation indicates either serial communication failure or the module is not in place.

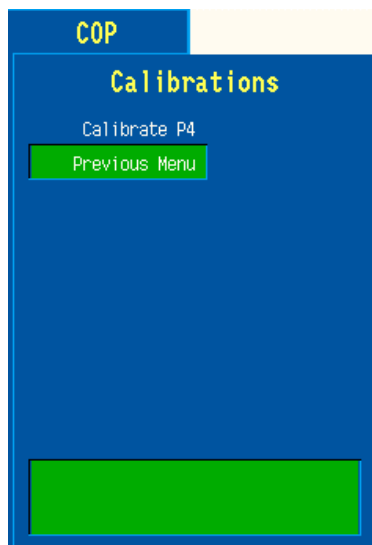
RAM indicates the state of the external RAM memory.

ROM indicates whether the checksum at the EEPROM is in accordance with the software calculated value.

EEPROM indicates if the values stored in the permanent memory are valid.

The state is either **OK**, **Fail** or **?** (module not in place or a communication error).

5.1.1 COP calibration menu



Calibrate P4

This function is for calibrating the invasive blood pressure channel P4.

The calibration requires a pressure transducer (with an appropriate cable) and a pressure manometer.

Calibration:

1. Connect the pressure transducer with the pressure manometer to the P4 connector. Select Calibrate P4. Leave the transducer at room air pressure.
2. Press the ComWheel to start zeroing.
3. Supply a pressure of 100 mmHg to 300 mmHg to the transducer. The recommended pressure is 200 mmHg.
4. Set the pressure on the display to match the pressure reading on the manometer and press the ComWheel.

6 SPARE PARTS

6.1 Spare parts list

NOTE: Only changed part numbers are listed under later revisions. To find the desired part: check first the list of the revision that corresponds your device. If the part is not listed there, check the previous revision, etc. until you find the right number.

NOTE: Accessories are listed in the *Patient Monitor Supplies and Accessories*.

6.1.1 Cardiac Output Module, M-COP Rev. 00

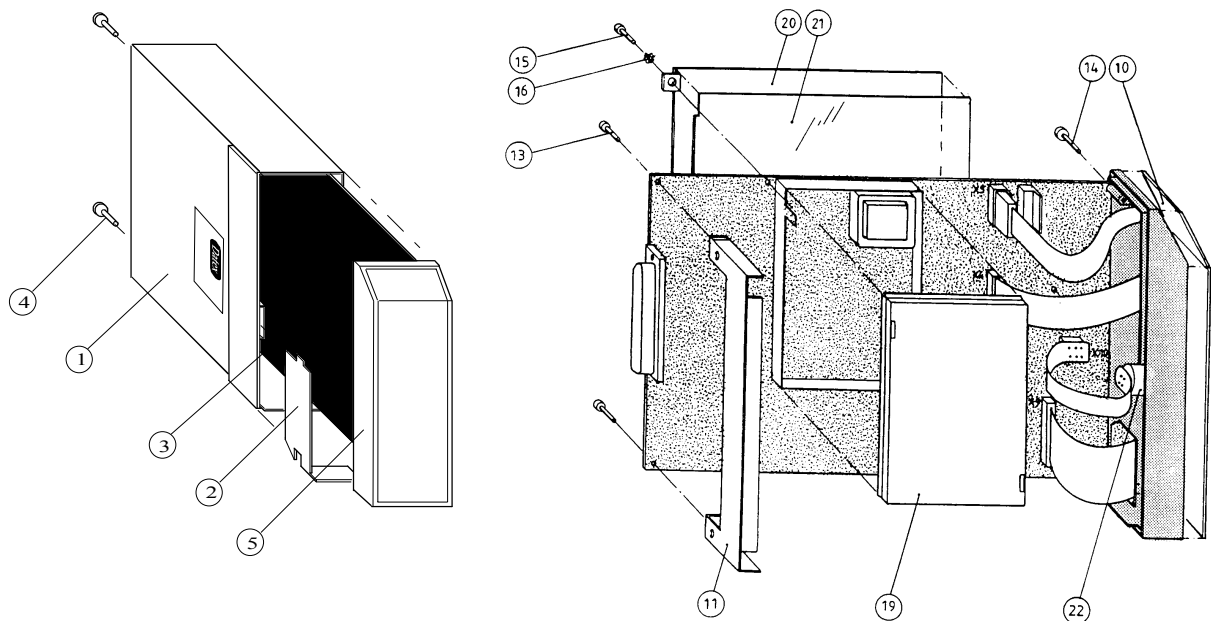


Figure 8 Module box and Cardiac Output Module, M-COP

Item	Description	Order No.	Item	Description	Order No.
-	Membrane keypad	880101	11	Metal frame	879184
1	Module box (single width)	886167	13	Cross cylinder-head screw M3x6	61721
2	Spring pin	879182	14	Cross cylinder-head screw M3x12	628700
3	Latch	879181	15	Cross cylinder-head screw M3x16	628710
4	Cross recess screw M3x8 black	616215	16	Star washer	63611
5	Front panel unit, M-COP	881191	22	C.O. Test connector, M-COP	546215

The front panel unit includes all the connectors and input boards.

6.1.2 Cardiac Output Module, M-COP Rev. 01

Item	Description	Order No.	Item	Description	Order No.
10	Front panel stickers	See 6.1.7	20	Protection plate	883946
19	EMC plate	884099	21	Insulation plate for 883946	884121

6.1.3 Cardiac Output Module, M-COP Rev. 02

No new spare parts.

The front panel unit includes all the connectors and input boards.

6.1.4 Cardiac Output Module, M-COP Rev. 03

No new spare parts.

The front panel unit includes all the connectors and input boards.

6.1.5 Cardiac Output and SvO₂ Module, M-COPSv Rev. 00

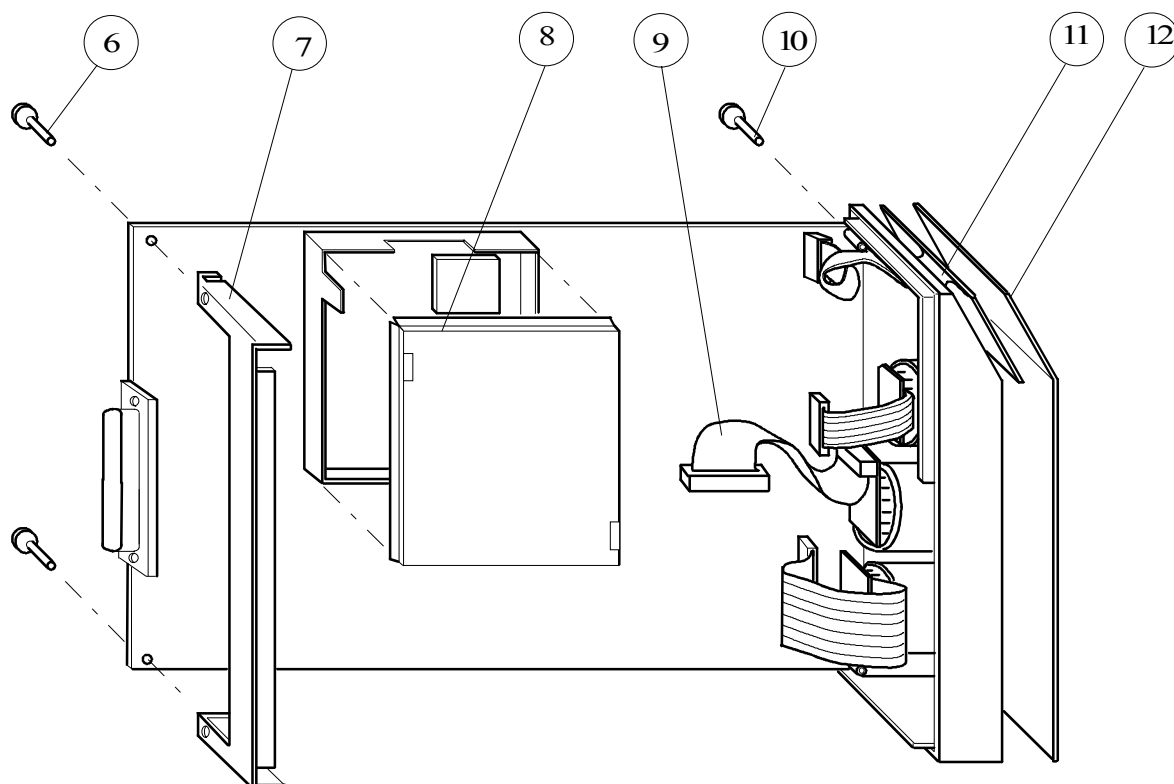


Figure 9 Cardiac Output and SvO₂ Module, M-COPSv

Item	Description	Order No.	Item	Description	Order No.
1	Module box (single width)	886167	7	Metal frame	879184
2	Latch	879181	8	EMC plate	884099
3	Spring pin	879182	9	SvO ₂ cable	888546
4	Cross recess screw M3x8 black	616215	10	Cross cylinder-head screw M3x12	628700
5	Front panel unit, M-COPSv	888540	11	Membrane keypad	880101
6	Cross cylinder-head screw M3x6	61721	12	Front panel sticker	see 6.1.7

The front panel unit includes all the connectors and input boards.

6.1.6 Cardiac Output and SvO₂ Module, M-COPsv Rev. 01

No new spare parts.

The front panel unit includes all the connectors and input boards.

6.1.7 Front panel stickers for AS/3 modules (square buttons)

Items 10 and 12

Adaptation	M-COP (Rev. 02) Order No.	M-COPsv (Rev. 00) Order No.
DA	892213	892214
DE	880978	889550
EN	880770	887376
ES	884387	889555
FI	888871	889554
FR	881271	889551
IT	886757	889556
JA	888309	890212
NL	886064	889552
NO	893557	893558
PT	895253	895239
SV	885871	889553

6.1.8 Front panel stickers for S/5 modules (round buttons)

Adaptation	M-COP (Rev. 03) Order No.	M-COPsv (Rev. 01) Order No.
DA	898732	898787
DE	898723	898778
EN	898722	898777
ES	898726	898781
FI	898729	898784
FR	898724	898779
IT	898727	898782
JA	898733	898788
NL	898725	898780
NO	898731	898786
PT	898728	898783
SV	898730	898785

7 EARLIER REVISIONS

This manual supports all earlier Cardiac Output Module revisions.

APPENDIX A

SERVICE CHECK FORM

Cardiac Output Modules, M-COP and M-COPsv

Customer			
Service	Module type	S/N	
Service engineer		Date	



OK = Test OK



N.A. = Test not applicable



Fail = Test Failed

All modules			
	OK	N.A.	Fail
1. Internal parts	<input style="width: 30px; height: 20px; border: 1px solid green;" type="checkbox"/>	<input style="width: 30px; height: 20px; border: 1px solid red;" type="checkbox"/>	<input style="width: 30px; height: 20px; border: 1px solid red;" type="checkbox"/>
3. Installation	<input style="width: 30px; height: 20px; border: 1px solid green;" type="checkbox"/>	<input style="width: 30px; height: 20px; border: 1px solid red;" type="checkbox"/>	<input style="width: 30px; height: 20px; border: 1px solid red;" type="checkbox"/>
5. Module software	COP		
6. Communication and memories	<input style="width: 30px; height: 20px; border: 1px solid green;" type="checkbox"/>	<input style="width: 30px; height: 20px; border: 1px solid red;" type="checkbox"/>	<input style="width: 30px; height: 20px; border: 1px solid red;" type="checkbox"/>
Notes			

InvBP measurement			
	OK	N.A.	Fail
7. Membrane keys	<input style="width: 30px; height: 20px; border: 1px solid green;" type="checkbox"/>	<input style="width: 30px; height: 20px; border: 1px solid red;" type="checkbox"/>	<input style="width: 30px; height: 20px; border: 1px solid red;" type="checkbox"/>
9. Calibration	<input style="width: 30px; height: 20px; border: 1px solid green;" type="checkbox"/>	<input style="width: 30px; height: 20px; border: 1px solid red;" type="checkbox"/>	<input style="width: 30px; height: 20px; border: 1px solid red;" type="checkbox"/>
Notes			

SvO ₂ measurement			
	OK	N.A.	Fail
11. Membrane keys	<input style="width: 30px; height: 20px; border: 1px solid green;" type="checkbox"/>	<input style="width: 30px; height: 20px; border: 1px solid red;" type="checkbox"/>	<input style="width: 30px; height: 20px; border: 1px solid red;" type="checkbox"/>
13. SvO ₂ messages	<input style="width: 30px; height: 20px; border: 1px solid green;" type="checkbox"/>	<input style="width: 30px; height: 20px; border: 1px solid red;" type="checkbox"/>	<input style="width: 30px; height: 20px; border: 1px solid red;" type="checkbox"/>
Notes			

C.O. measurement

14. Membrane keys

☐☐☐

15. Self test

☐☐☐

16. Test with patient
simulator

☐☐☐

Notes

17. Electrical safety check

☐☐☐

18. Functioning after
electrical safety
check

☐☐☐

19. Final cleaning

☐☐☐

Notes

Notes

Used Spare Parts

Signature
