E-COP, E-COPSv

Service Manual

Host software version 3
Module hardware version 01

E-COP, E-COPSv
English
3rd edition
2098086-002

Due to continuing product innovation, specifications in this manual are subject to change without notice.

For technical documentation purposes, the abbreviation GE is used for the legal entity names, GE Medical Systems *Information Technologies*, Inc. and GE Healthcare Finland Oy.

Contents

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About this manual

Intended use of this manual

This manual contains instructions for the planned and corrective maintenance of the acquisition module. This manual must be used together with the monitor's service manual for important safety and installation information.

Use the manual as a guide for maintenance procedures and repairs considered field repairable. Where necessary the manual identifies additional sources of relevant information and technical assistance.

See the monitor's service manual for an overview of the patient monitoring system, information needed for system installation and for planned and corrective maintenance of the monitor.

See the monitor's supplemental information manual for the technical specifications, default settings and compatibility information, including electromagnetic compatibility.

See the monitor's user manual for the instructions necessary to operate the device safely in accordance with its function and intended use.

Intended audience of this manual

This manual is intended for service representatives and technical personnel who maintain, troubleshoot, or repair this device.

Manual conventions

This manual uses the following styles to emphasize text or indicate an action. Also note the terminology conventions.

Item	Description
bold	Indicates hardware keys and connectors.
bold italic	Indicates menu options, software keys and messages.
italic	Indicates terms for emphasis.
>	Indicates menu options to select consecutively.
select	The word select means choosing and confirming.
supplemental information	In this manual, the phrase supplemental information refers to information that appears in the Supplemental Information Manual or supplements provided.
NOTE	Note statements provide application tips or other useful information.

Illustrations and names

This manual uses illustrations as examples only. Illustrations in this manual may not necessarily reflect all system settings, features, configurations, or displayed data.

Names of persons, institutions, and places and related information are fictitious; any similarity to actual persons, entities, or places is purely coincidental.

Related documents

- CARESCAPE monitor's service manual
- CARESCAPE monitor's user manual
- CARESCAPE monitor's supplemental information manual
- Cleaning and Disinfecting Supplement
- Supplies and Accessories Supplement

Product availability

NOTE Due to continual product innovation, design and specifications for these products are subject to change without notice.

Some of the products mentioned in this manual may not be available in all countries. Please consult your local representative for the availability.

Trademarks

GE, GE Monogram, and CARESCAPE are trademarks of General Electric Company.

Third party trademarks

All third party product and company names are the property of their respective owners.

Manufacturer responsibility

GE is responsible for the effects on safety, reliability, and performance of the equipment only if:

- Assembly operations, extensions, readjustments, modifications, servicing, or repairs are carried out by authorized service personnel.
- The electrical installation of the relevant room complies with the requirements of the appropriate regulations.
- The equipment is used in accordance with the instructions for use.
- The equipment is installed, maintained and serviced in accordance with the instructions provided in the related service manuals.

WARNING SAFETY HAZARD. To avoid risks to personnel and patient, or damage to the equipment, only perform maintenance procedures described in this manual. Unauthorized modifications can lead to safety hazards.

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Module introduction

Measurement parameters

This document provides information for the maintenance and service of the cardiac output modules, E-COP-01 and E-COPSv-01.

Cardiac output modules, E-COP-01 and E-COPSv-01 provide the following parameters:

- Cardiac output, C.O.
- Right ventricular ejection fraction, REF
- Invasive blood pressure, IP
- Blood temperature, Tblood

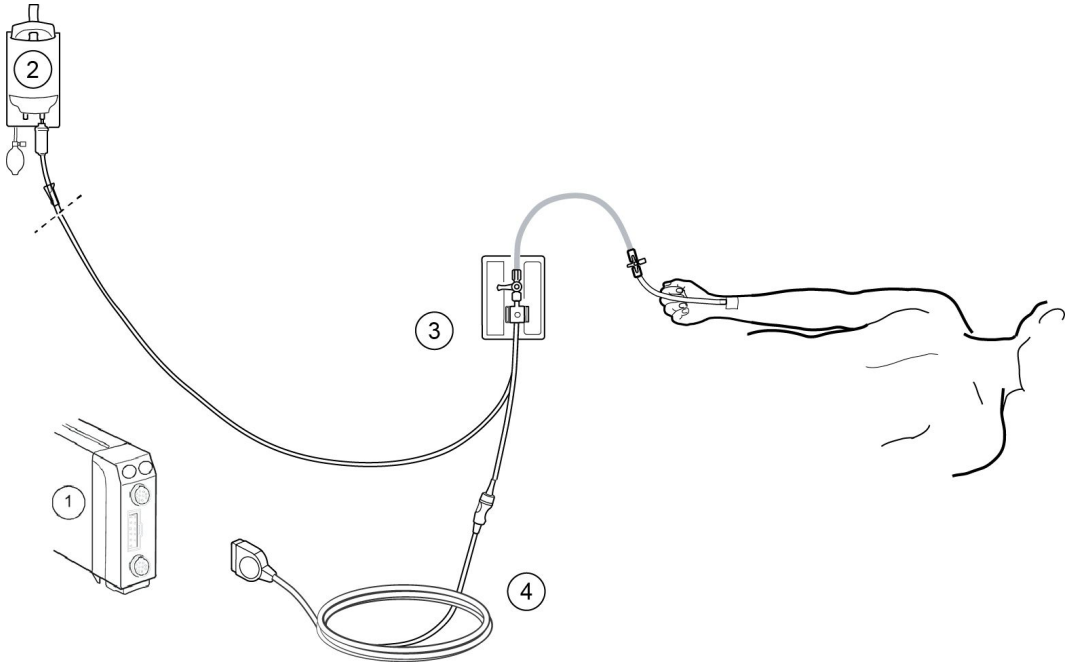
E-COPSv module provides additionally:

- Central venous oxygen saturation, $ScvO_2$ measurement
- Mixed venous oxygen saturation, SvO_2 measurement

Module compatibility

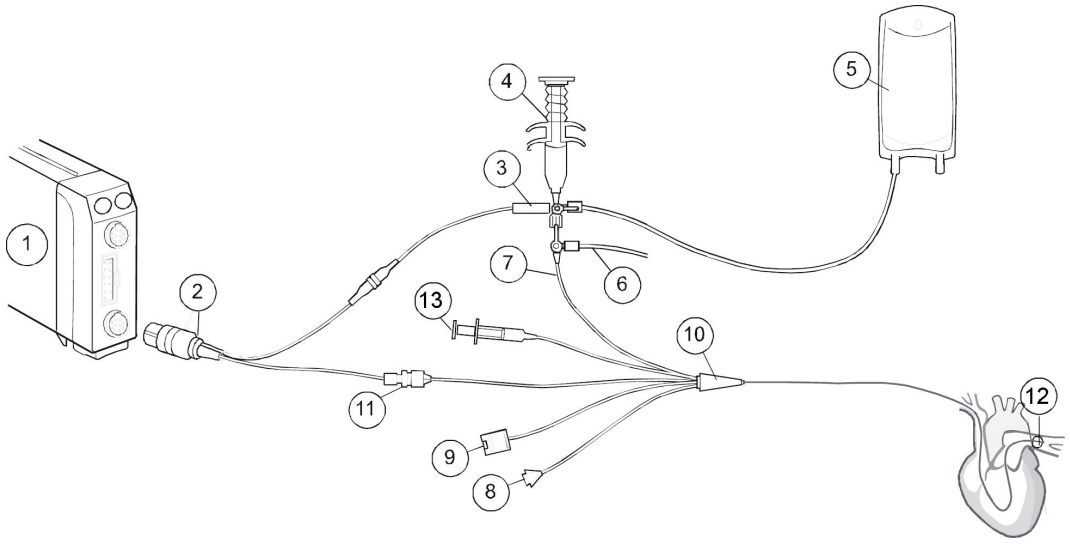
For detailed information regarding module, monitor, and accessory compatibility, see the supplemental information provided.

Invasive pressure equipment to patient connection



1. Module with IP measurement capability
2. Fluid bag with pressure infusor
3. Transducer setup
4. Invasive blood pressure adapter cable

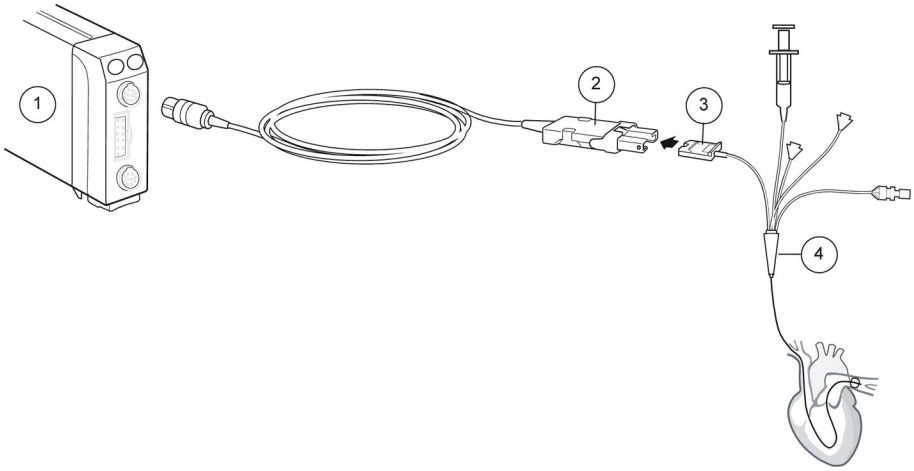
C.O. equipment to patient connection with an in-line probe



1. Module with C.O. measurement capability

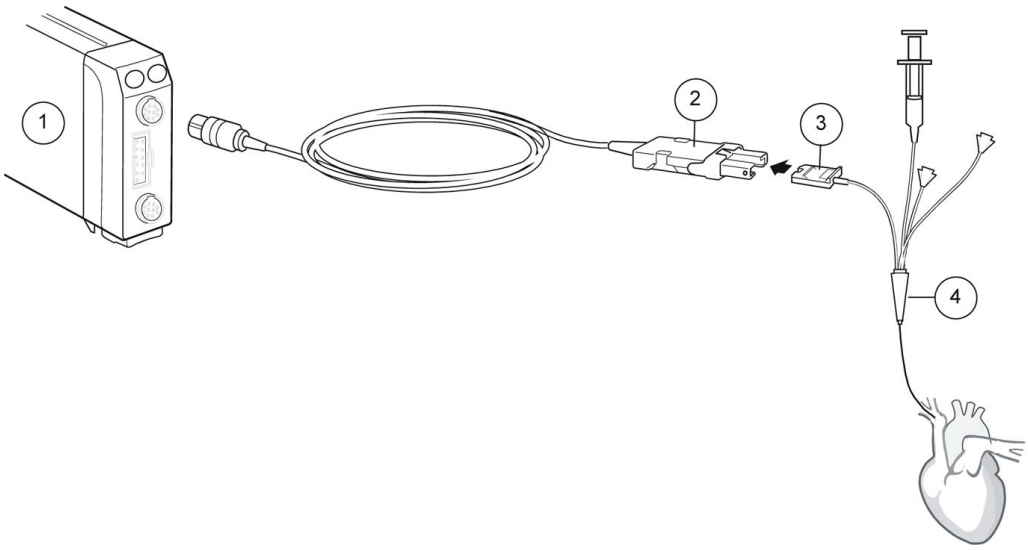
2. Cardiac output cable
3. In-line injectate probe
4. Injectate syringe
5. Injectate solution
6. CVP line to IP transducer or fluid infuser
7. Proximal injectate port
8. PA distal port
9. Optical module connector (used for SvO_2 measurement)
10. Swan-Ganz thermodilution catheter
11. Thermistor connector
12. Balloon
13. Balloon inflation valve

SvO_2 equipment to patient connection



1. Module E-COPSv
2. Optical module
3. Optical connector
4. Swan-Ganz thermodilution catheter

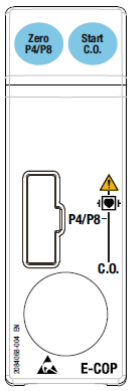
$ScvO_2$ equipment to patient connection

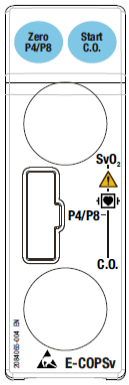


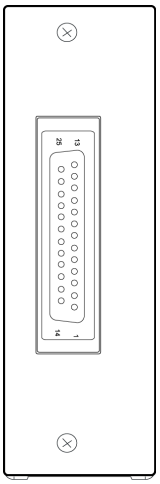
1. Module E-COPSv-01
2. Optical module
3. Optical connector
4. Central venous oximetry catheter

Controls and connectors of E-COP and E-COPSv

Front panels of Cardiac Output Modules, E-COP and E-COPSv, and the back of the module:







Equipment safety symbol

This symbol on the module refers to defibrillator precautions. To ensure protection against the effects of cardiac defibrillator discharge, always use the recommended cables and leadwires only (see the supplemental information provided). Using other cables or leadwires may result in damage to the equipment and compromise patient and/or user safety.

NOTE The invasive pressure connector in the E-COP and the E-COPSv module is labelled either as a P4 or as a P4/P8. However, the monitor software always identifies this invasive pressure port as a P8 channel.

Connector	Module	Description
SvO_2	E-COPSv	Connector for SvO_2 measurement
C.O.	E-COP, E-COPSv	Connector for C.O. measurement
P4 or P4/P8	E-COP, E-COPSv	Connector for invasive blood pressure measurement
D25 connector	E-COP, E-COPSv	Module bus connector

E-COP, E-COPSv module keys

There are two module keys on the E-COP and E-COPSv modules:

Module keys	Module	Description
Zero P4/P8	E-COP, E-COPSv	Zeros the reference for the pressure measurement.
Start C.O	E-COP, E-COPSv	Starts and stops the cardiac output measurement.

Measurement principles

Measurement principles of Cardiac output and REF

Cardiac output measurement is performed 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 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 the figure below.

The cardiac output is calculated from the equation:

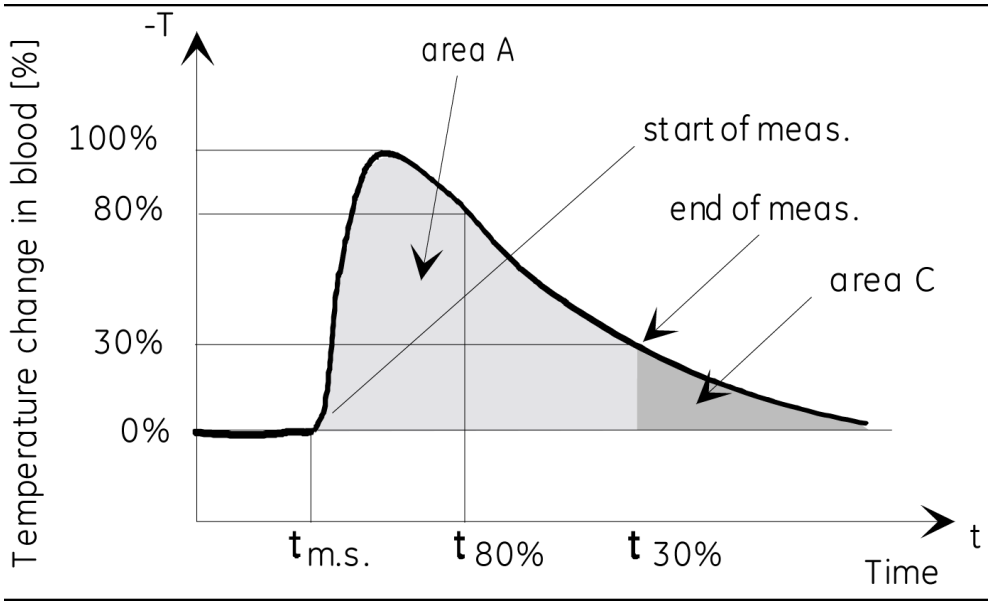
$C.O.= (1.08\ C_T\ 60\ V_i(T_b-T_i))/(T_b dt + C)$

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 (°C)
$T_b dt$ =	Area under time-temperature curve between time 0 and $t_{30\%}$, where $t_{30\%}$ is the time when the curve has dropped to 30% of its peak value
C =	Area beneath time-temperature curve between $t_{30\%}$ and the end of the curve

The following illustrates the 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.

Invasive blood pressure measurement principle

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

SvO_2 measurement description

The SvO_2 value is measured continuously by spectrophotometry. The algorithm consists of five different parts:

- Initialization: When connected, a number of startup procedures are performed prior to normal operation. These procedures include transfer of calibration factors and initialization of LED currents.
- Calibration
- Signal processing and SvO_2 calculation: Light of various wavelengths (red 660 nm and infrared 810 nm) 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. The light is electrically transmitted and analyzed. From the amount of reflected light it is possible to measure the amount of light absorbed by hemoglobin and oxyhemoglobin, resulting in the SvO_2 value. The SvO_2 value is displayed as a percentage.
- 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

$ScvO_2$ measurement description

Central venous oxygen saturation ($ScvO_2$) is a continuous measurement of venous oxygen saturation in central venous blood. $ScvO_2$ measures the percentage of hemoglobin carrying oxygen in the venous blood compared to the total binding capacity measured in central venous blood. It reflects how much oxygen was consumed by body tissues. In contrast, SpO_2 reflects the oxygen content of arterial blood, which has not yet given up its oxygen to body tissues (reflects the amount of O_2 available to tissues).

For more information, see the measurement description for SvO_2 .

Main components

E-COP and E-COPSv modules

The Cardiac Output Module, E-COP, consists of a COP circuit board and two input boards: a CO input board and a P input board, attached to the front chassis unit.

The Cardiac Output and SvO_2 Module, E-COPSv, consist of a COPSv circuit board and three input boards: a CO input board, a SvO_2 input board, and a P input board, attached to the front chassis unit.

E-COPSv measurement board

The measurement board consists of the following functional sections:

- Processor
- Cardiac output measurement
- Invasive blood pressure measurement
- Serial communication
- Isolation
- Power supply
- SvO_2 measurement (available only in E-COPSv)

Processor section of E-COP and E-COPSv

The CPU has a 32-bit high-speed H8SX single-chip microcomputer. It contains 768 Kbytes of flash memory and 24 Kbytes of RAM.

The clock frequency is 35 MHz.

Cardiac output measurement section E-COP and E-COPSv

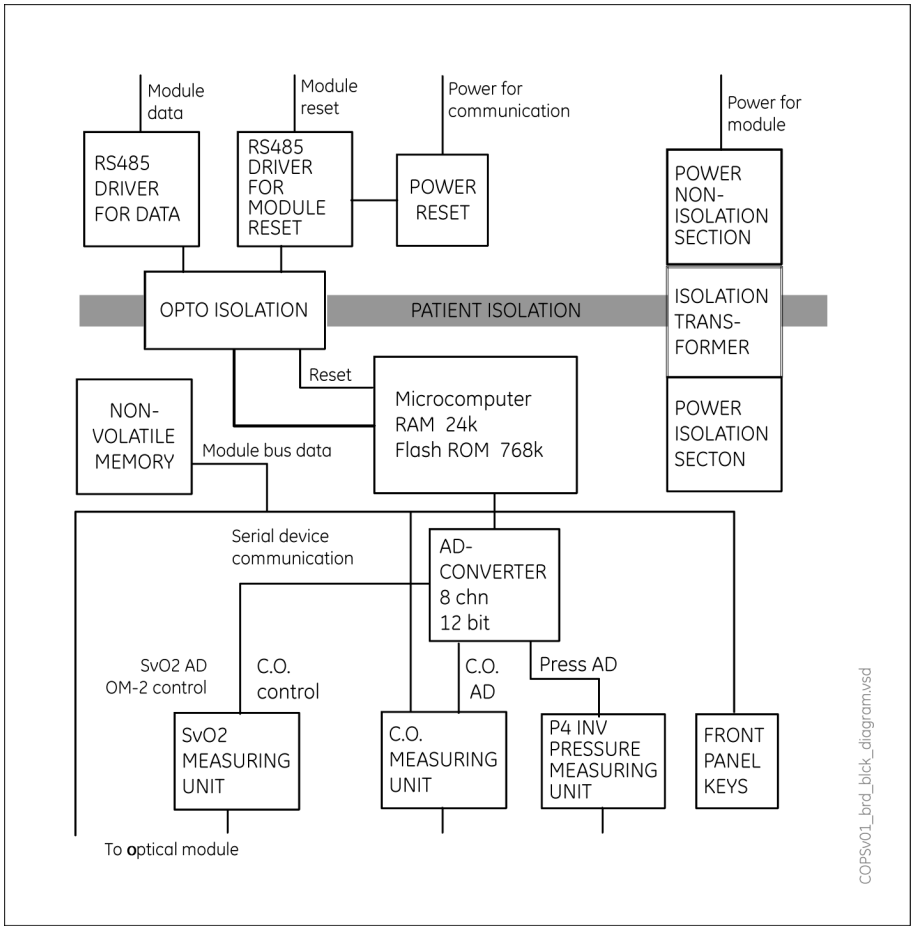
The catheter and the probe contain an NTC resistor that reacts to temperature change.

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 the non-linearity of catheter/probe is compensated for by software, ambient temperature change after calibration is the only factor that may influence the measurement.

The following illustrates the measurement board block diagram of E-COP and E-COPSv. Note that the SvO_2 section is excluded in the E-COP module.



Invasive blood pressure measurement section of E-COP and E-COPSv

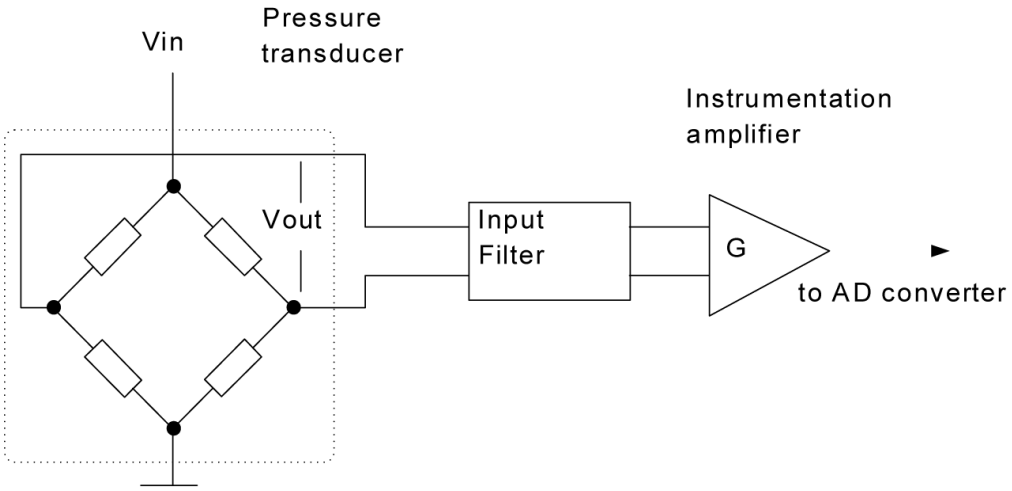
An isolated +5 V supply is connected to the input of the pressure transducer bridge circuit. A differential voltage, which depends on blood pressure and input supply voltage, is calculated from the bridge circuit output using the following formula:

$U_{out} = U_{in} \times Pressure \times 5\ V$, where $U_{in} = 5\ V$ ® $U_{out} = 25\ V \times Pressure$ [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.

The following diagram illustrates the pressure transducer's principle of operation:



SvO_2 measurement section

The SvO_2 algorithm is part of the measurement board software. The algorithm consists of five different parts: initialization, calibration, signal processing and SvO_2 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 SvO_2 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 SvO_2 parameter window.

Signal processing and SvO_2 calculation

The reflected red and infrared signals transferred from the optical module to the COPSv module are filtered, and SvO_2 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.

Serial communication

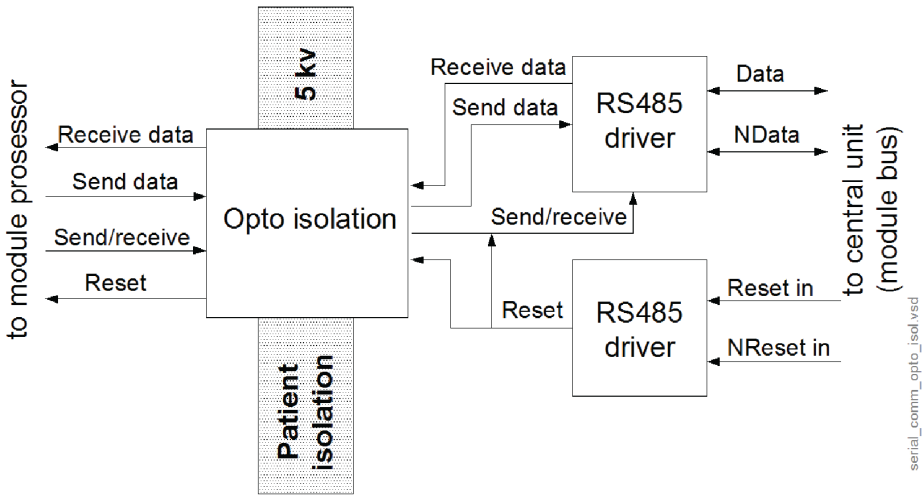
Serial communication between the module and the Ethernet to Module Bus Controller (EMBC) unit is established via an RS485 type bus. The communication bus drivers are powered from the Module Bus. The module isolation section is powered (+5 V) from the isolated power supply.

The communication drivers are controlled by a reset signal so 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.

The following illustrates serial communication and opto isolation:



Isolation section

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

Power supply section

The module isolated power supply is developed from the +15 V (non-isolated) supply received from the module bus. The isolated power supply is a switched-mode circuit where a Push-Pull type transformer driver is controlled by an oscillator circuit. The frequency of the oscillator is approximately 130 kHz with a pulse ratio of 50%. 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 switching regulator.

3 Planned and corrective maintenance

About the maintenance check procedures

This chapter describes the planned and corrective maintenance check procedures for the product. To help ensure the equipment remains in proper operational and functional order and maintains its essential performance and basic safety, follow the corrective and planned maintenance recommendations. The tests that are related to the essential performance and basic safety are marked with the *.

The cleaning precautions, cleaning requirements, cleaning procedures, and recommended cleaning solutions are described in the monitor's user manual or supplemental information provided.

For details about cleaning, disinfecting and sterilizing the accessories, see the instructions for use in the accessory package.

Record the results of the planned and the corrective maintenance check procedures to the eCheckforms delivered in the electronic manual media.

WARNING SAFETY HAZARD. To avoid risks to personnel and patient, or damage to the equipment, only perform maintenance procedures described in this manual. Unauthorized modifications can lead to safety hazards.

Planned maintenance

WARNING PATIENT SAFETY. Planned maintenance must be carried out at the specified interval. Failure to implement the maintenance schedule may cause equipment failure and possible health hazards.

Perform the planned maintenance procedure completely every 2 years after installation. Perform the procedure in the following order:

1. Visual inspection
2. Electrical safety tests *
3. Functional check

Corrective maintenance

Perform the following check procedure after any corrective maintenance, before taking the product back into clinical use:

Performed service activity	Required checkout procedure		
	Visual inspection	Electrical safety test	Functional check
Product casing opened either for troubleshooting purpose or for replacing any of the internal parts.	All steps	All steps	All steps
Front cover, or an other external part, replaced.	All steps	Not applicable	Not applicable

Performing visual inspection

1. Remove the module and check that:
   a. The front cover is intact.
   b. All connectors are intact, clean and attached properly.
   c. The module casing and the latch are clean and intact.
   d. The patient cables are clean and intact.

Performing electrical safety tests *

Perform the electrical safety tests described in the monitor's service manual, Checkout procedures chapter. Perform the following tests:

1. Patient (source) leakage current test
2. Patient (sink) leakage current test

Performing functional check

Required tools for E-COP, E-COPSv modules functional check

For a list of compatible accessories, see the supplemental information provided.

- A multiparameter patient simulator with adapter cables to GE invasive pressure and cardiac output connectors.
- Catheter connecting cable
- One of the following simulators depending on the module version:
  - P/N 2089334–001 SvO_2 simulator is compatible with all E-COPSv-00 and COPSv-01 modules.
  - P/N 890121 SvO_2 simulator is compatible with all the E-COPSv-00 modules, but only with those E-COPSv-01 modules with serial number SGQ14462015HA or lower.

Making connections for the functional check

1. Turn on or restart the monitor and wait until the normal screen appears.
2. Ensure that the module is connected to the monitor.

3. Connect the multiparameter patient simulator with its invasive blood pressure adapter cable to the red invasive pressure connector in the module.

   The invasive pressure connector in the E-COP and the E-COPSv module is labelled either as a P4 or as a P4/P8. However, the monitor software always identifies this invasive pressure port as a P8 channel.

4. Connect the C.O. cables:

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

   b. Connect the catheter connecting cable's injectate probe connector and blood catheter (blood temperature) connector to the simulator according to the instructions in the patient simulator's manual.

5. Connect the SvO_2 simulator cable to the red SvO_2 connector in the module.

   NOTE SvO_2 measurement is only available in E-COPSv.

Configuring monitor for E-COP, E-COPSv module functional check

1. Configure invasive pressure measurement:

   a. Select ***P8*** waveform field to the screen with adequate priority.

   b. In the ***Invasive Pressures*** menu, select ***Setup*** > ***P8*** and configure:

   - ***Label***: P8
   - ***Scale mmHg***: 0-200 mmHg
   - ***Display Format***: Sys/Dia (Mean)

2. Configure cardiac output measurement:

   a. Select ***C.O.*** and ***TBlood*** parameter windows to the monitor screen with adequate priority.

   b. In the ***Cardiac Output*** menu select the ***Setup*** tab and configure:

   - ***Manufacturer***: User defined
   - ***Computation constant***: 0.542
   - ***Measurement Type***: Manual
   - ***Injectate Volume***: 10 ml
   - ***Ref Measurement***: Deselect

3. Configure SvO_2 parameter window to the monitor screen with adequate priority.

Configuring simulator for E-COP, E-COPSv modules functional check

For instructions on how to use and configure the simulators, refer to the simulators' documentation.

1. Configure the invasive pressure channels of the simulator as follows:

   - ***Sensitivity***: 5 µV/V/mmHg
   - ***InvBP output***: 0 mmHg static pressure or atmosphere

2. Configure the cardiac output channels of the simulator as follows:
   - ***Baseline Temperature/Blood Temperature***: 37 °C
   - ***Injectate temperature***: 0°C or 2 °C
3. Configure SvO_2 parameter as follows:
   - Turn the SvO_2 simulator's pulsation switch to Normal pulse.
   - Turn the range switch to Medium.

Testing invasive pressure measurement *

Check the functionality of the measurement with a patient simulator.

1. Zero the tested pressure channel:
   a. Ensure that the simulator's invasive pressure output channel is configured to 0 mmHg static.
   b. Zero the P8 invasive pressure channel by pressing Zero P4/P8 key on the module.
   c. Check that a ***Zeroing*** message followed by a ***Zeroed*** message is shown in the related parameter window.
2. Test a static pressure:
   a. Configure the simulator's invasive pressure output channel to 200 mmHg static pressure.
   b. Check that a flat pressure line appears on the related waveform field.
   c. Check that the reading in the parameter window is 200 ± 10 mmHg.
   - If the measured value is not within the specification limits, recalibrate the measurement.
3. Check the pressure waveform:
   a. Configure the simulator's invasive pressure output channel to Arterial 120/80.
   b. Check that the pressure waveform for the P8 invasive pressure channel appears in the waveform window.
   c. Check that the Sys/Dia (Mean) pressure values are shown in the related parameter window.

Testing cardiac output measurement *

Check the functionality of the measurement with a patient simulator.

NOTE This test is for functional check purpose only. Results can't be used for accuracy checking.

NOTE Check that the ***T injectate*** and ***Tblood*** values in the C.O. menu are close to the set values to ensure successful measurement. Adjust simulator, if necessary.

1. Select ***Monitor Setup*** > ***Parameter Setup*** > ***Cardiac Output*** > ***Measurement***.
2. Select ***Start C.O. Serial*** to start a manual C.O. measurement.
3. Wait until the ***Inject now!*** message appears and inject a 5 l/min C.O. wave from the simulator.

4. Check that:
   a. A thermodilution curve appears on the C.O. menu and the curve returns to the base level after the measurement is completed.
   b. The measured C.O. value is updated and close to the simulator's set value.
   c. There are no error messages on the screen.

   NOTE To reject any noisy or erroneous measurement results, select the ***Cancel/Reject Injection***.

5. Repeat steps from 2) to 4) until you have 3 good measurement results.
6. Select ***Confirm C.O.*** to complete the C.O. measurement.
7. Check that the average of the measured C.O. values and the Tblood reading are updated to the ***C.O.*** and ***Tblood*** parameter windows.

Testing SvO_2 measurement *

Check the functionality of the measurement with a patient simulator.

1. Calibrate SvO_2 in vitro:
   a. Check that ***Not calibrated*** message is shown in the SvO_2 parameter window.
   b. Turn the SvO_2 simulator's pulsation switch to ***No pulse*** position and range switch to ***Medium*** position.
   c. Select the SvO_2 parameter window.
   d. Select the ***Calibration*** tab.
   e. Select ***In Vitro Calibration*** >***Calibrate*** to start in vitro calibration.

      Wait until ***In vitro calibrating*** message disappears from SvO_2 parameter window and the ***Start SvO2*** key is enabled.
   f. Select ***Start SvO2*** to complete the in vitro calibration.

      Wait until the ***Calibrating*** message disappears from SvO_2 parameter window.
   g. Check that the calibration date for in vitro calibration is updated correctly to the SvO_2 calibration menu.

2. Calibrate SvO_2 in vivo:
   a. Turn the SvO_2 simulator's pulsation switch to ***Normal pulse*** position.
   b. Select ***In Vivo Calibration*** > *Calibrate* to start in vivo calibration.

      Wait until the ***In vivo calibrating*** message disappears from SvO_2 parameter window and the ***Draw Blood Sample*** key is enabled.
   c. Select ***Draw Blood Sample***.
   d. Select ***Lab SvO2***: 81.
   e. Select ***Lab Hb***: 115.
   f. Select ***Save Lab Values***.

      Wait until the ***Calibrating*** message disappears from SvO_2 parameter window.
   g. Check that the calibration date for in vivo calibration is updated correctly in the SvO_2 calibration menu.
   h. Select ***Close*** .
3. Check that a SvO_2% reading appears to the SvO_2 parameter window.

Completing the functional check

1. Select ***Discharge Patient*** or ***Reset Case*** to discard any changes made to the monitor configuration during the functional check.
2. Disconnect the test setup.

4

Configuration and calibration

Configuration

There is no service configuration for this module.

Invasive pressure calibration

Invasive pressure calibration shall be performed:

- whenever the pressure transducer in use is replaced with a new type of transducer
- if the invasive pressure calibration check failed
- if the measured value is not within the specification limits.

Required tools

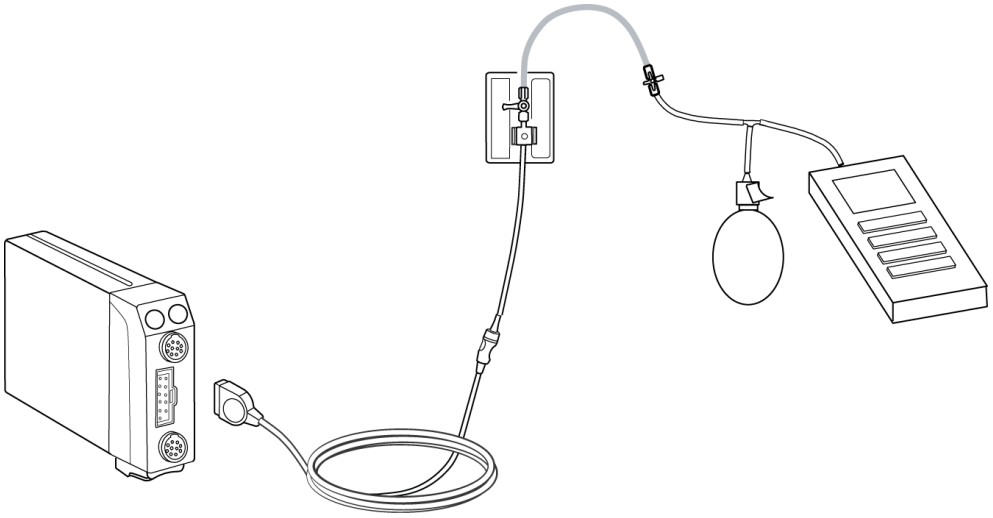
- Pressure manometer with a pressure pump
- Transducer adapter cable
- Invasive pressure transducer

NOTE See the supplemental information provided for compatible accessories.

NOTE The pressure transducer is a key component in the measurement setup. If possible, perform the invasive pressure calibration with the same type of pressure transducer that is used in daily clinical use.

NOTE Use only accurate, properly maintained, calibrated, and traceable calibration tools for the parameter calibration to ensure measurement accuracy.

Making connections

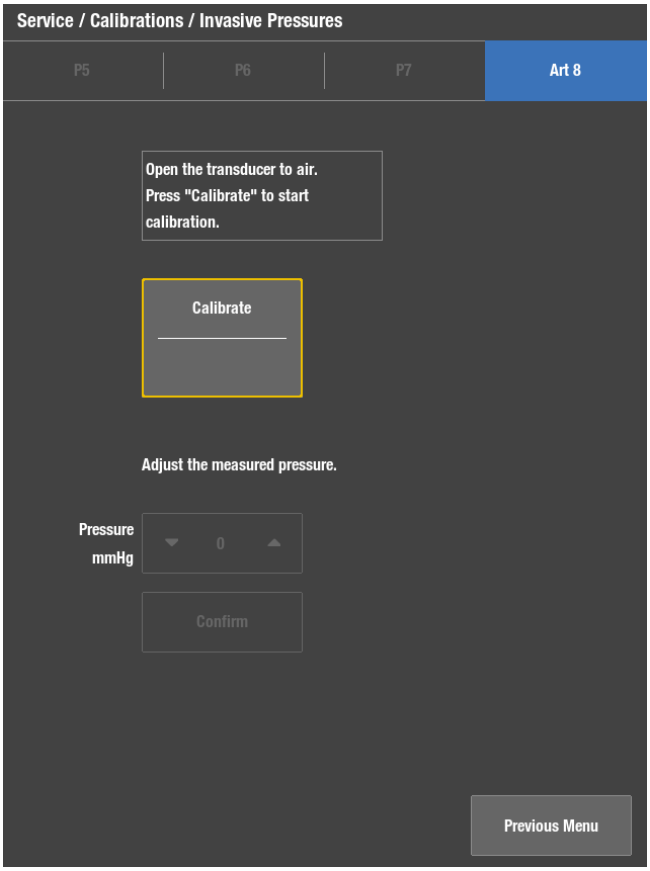


1. Ensure that the module is connected to the monitor.
2. Connect the transducer adapter cable to the red Inv BP connector in the module.
3. Connect the invasive pressure transducer to the transducer adapter cable.
4. Connect the pressure manometer with a pressure pump to the transducer's pressure line with a piece of tubing.

Calibrating invasive pressure

1. Select ***Monitor Setup*** > ***Defaults & Service*** > ***Service Calibrations***.
2. Enter the User Name and the Password and press ***Enter*** to get into the Calibrations menu.
3. Select ***Invasive Pressures***.
4. Select the ***P8*** tab to calibrate the Invasive Pressure channel for E-COP(Sv)

NOTE The invasive pressure connector in the E-COP and E-COPSv module is labelled either as P4 or as P4/P8. However, the monitor software always identifies this invasive pressure port as a P8 channel.



5. Prepare the transducer for the zeroing by opening the dome stopcock to room air.
6. Select ***Calibrate***.
7. The monitor will start automatic zeroing of the invasive pressure channel. Wait until the message ***Zeroing*** is replaced by the message ***Zero Ok***.
8. Pump a 200 mmHg ± 100 mmHg static pressure with the pressure pump when the message ***Create 200 mmHg pressure*** is shown. The pressure measured by the module is updated in real-time to the calibration menu.
9. When the pressure is stabilized, check the pressure reading from the manometer.
10. Use the up-down spinner control in the calibration menu to adjust the reading measured by the module to match with the manometer reading. Select ***Confirm*** to complete the calibration when the two readings match each other.
11. Wait until the message ***Calibrated*** is shown.

NOTE The ***Zero Failure*** message is shown if the zeroing fails.

NOTE The ***Calibration Error*** message is shown, if you do not start inflating the pressure within 45 seconds after the automatic zeroing is completed, or if the calibration fails.

5

Troubleshooting

Troubleshooting guidelines

This chapter focuses on troubleshooting technical problems. Refer to the user manual for troubleshooting monitoring problems and clinical configuration issues.

If a problem remains, contact technical support for service. To ensure accurate problem solving, please be prepared to provide the following information:

- Product name and serial number or UDI
- Hardware and software versions
- Detailed problem description
- Error messages, if any
- Configuration information (or settings file)
- Service Logs
- The troubleshooting you have done so far

Perform the specified corrective maintenance check after any corrective maintenance to the product.

Performing visual inspection

Before any detailed troubleshooting, complete a thorough visual inspection for the module.

1. Remove the module and check that:
   a. The front cover is intact.
   b. All the connectors are intact, clean, and attached properly.
   c. The module casing and the latch are clean and intact.
   d. The patient cables are clean and intact.
2. If you suspect that there are loose parts or cable connections inside the module, remove the two screws from the back of the module to detach the module box, and check that:
   a. All the screws are tightened properly.
   b. All the cables are connected properly.
   c. There are no loose objects inside the module.

Troubleshooting module functionality

Follow these instructions to identify the unit causing the functional problem.

Before you begin, ensure that the monitor is turned on, and all the modules are connected.

1. Check if there are any error messages shown in the message field.

   For a list of possible causes and solutions, see Messages related to the measurement.

2. Check the compatibility of each system component.

   For a list of the compatible monitors, modules, and accessories, see the supplemental information provided.

3. Check that there are no identical modules connected to the monitor.

   For a list of identical modules, see the supplemental information manual.

4. Visually check the accessories in use. Replace them, if necessary.

   For a list of compatible accessories, see the supplemental information provided.

5. Connect the accessories with a simulator to the module. Check that the parameters measured by the module are configured to the display with adequate priority.

6. Press one of the module keys.

7. Check that the correct menu opens or the activity starts. If nothing happens, check if there is a loose keypad cable or other problem in the module.

Viewing device information

To view the hardware, software and configuration information of the monitor, modules and/or connected devices:

1. Ensure that the module is connected to the monitor.
2. Log in to the service interface.
3. Select ***Information***.
4. Select an item on the side navigation menu or scroll down the page to view the information.

Service log files

The monitor collects information about different system events, errors and alarms to log files to help troubleshoot equipment problems. The following service logs may contain related useful information:

- ***System Logs*** records different system events, messages, clinical alarms, user interactions and internal communication events.
- ***EMBC Logs*** records module communication events and errors for E-series acquisition modules.

Viewing log files

1. Log in to the service interface.

2. Select ***Diagnostics*** > ***View Logs***.
3. Select the log you want to view. The contents of the selected log file are shown on the screen.

Downloading log files

For security reasons, the contents of the log file(s) will be encrypted with a user-selectable password before the download. Provide the password in a secure way only for the authorized receiver of the log file. Use 7-Zip open-source file archiver (http://7-zip.org/) and the password to decrypt the downloaded log file.

1. Log in to the service interface.
2. Select ***Diagnostics*** > ***Download Logs***.
3. Select the log(s) you want to download.
4. Provide a password to encrypt the contents of the log file. This password is user-selectable.
5. Depending on your access to the service interface:
   a. If you are using a service PC, you can save the log file to any storage device connected to the service PC.
      i. Select ***Download***.
      ii. Save the log file according to the instructions provided by the web browser.

      The steps to download the log file to a service PC depend on the web browser used. The web browser may also notify you about security issues. Refer to the web browser documentation for details.
   b. If you are using the local, integrated service interface, you can save the log file to a USB flash drive that is connected to one of the monitor's USB ports:
      i. Select ***Save to USB storage*** to save the log file to the USB flash drive.

      The log file is saved always to the root directory of the USB flash drive.

      NOTE Do not disconnect the USB flash drive until downloading is complete.
6. Send the log file and the password in a secure way to GE Service for further investigation.

Messages

Messages related to invasive pressures measurement

For information regarding alarm priorities and escalation times, see the supplemental information provided.

Make sure you are familiar with the generic layout of the screen. This will help you identify where on screen the following messages appear. The message location is indicated with the following abbreviations:

- al. area = alarm area
- param. = parameter window
- wavef. = waveform area

Message	Location	Possible causes	Suggested actions
• ***> 320 mmHg*** or ***> 43 kPa*** • ***P5 over range*** to ***P8 over range***	• param.	Measurement is over range, or the sensor or cable is faulty. If you pre-zero a line with the stopcock closed, it creates a high fluid bag pressure and triggers this message. In this case, you can acknowledge the alarm with the pause audio key. Transducer is not zeroed correctly.	• Check the cable and connections. • Rezero the transducer. • Replace the sensor. • Replace the transducer. • Replace the module. • Zero the invasive pressure channel.
• ***< -40 mmHg*** or ***< -5 kPa*** • ***P5under range*** to ***P8under range***	• param.	Measurement is under range, or the sensor or cable is faulty. Transducer is not zeroed correctly.	• Check the cable and connections. • Rezero the transducer. • Replace the sensor. • Replace the transducer. • Replace the module. • Zero the invasive pressure channel.
• ***Art*** 1 ***disconnect*** to ***Art*** 8 ***disconnect*** • ***Disconnected***	• al. area • param.	No arterial invasive pressure is detected.	• Check connections. • If pressure drops because of zeroing, perform the zeroing process.
• ***Calibrated***	• param.	Channel calibrated successfully.	• Wait until the message disappears (after 10 seconds) before starting a measurement. • No action required.
• ***Calibrating***	• param.	Calibration of a channel is in progress.	• No action required.
• ***Calibration error***	• param.	Pressure calibration failure due to time-out. Pulsating waveform detected during calibration. Gain is beyond the limits (± 20% of the default gain).	• Re-calibrate. Start inflating the pressure within 45 seconds after the automatic zeroing is completed. • Check the manometer reading to ensure that a static 100-300 mmHg pressure is present for calibration. • Replace the transducer and re-calibrate.
• ***Fem*** 1 ***disconnect*** to ***Fem*** 8 ***disconnect*** • ***Disconnected***	• al. area • param.	No arterial invasive pressure is detected.	• Check connections. • If pressure drops because of zeroing, perform the zeroing process.

Message	Location	Possible causes	Suggested actions
• ***Identical IP8 modules***	• al. area	There are two or more E-PiCCO or E-COPSv modules mapping to the same channel in the system.	• Remove identical IP modules mapping to the same channel. • Disconnect the IP cable from one of the modules providing identical IP channel.
• ***IP's not zeroed*** • ***P***X ***not zeroed***, where X = invasive pressure channel number 1 to 8.	• al. area • param.	There is at least one invasive pressure channel that has not been zeroed.	• Perform zeroing for all channels.
• ***P5 over range*** to ***P8 over range*** • ***> 320 mmHg*** or ***> 43 kPa*** • ***P5 under range*** to ***P8 under range*** • ***< -40 mmHg*** or ***< -5 kPa***	• al. area	The measurement value is over or under range, or the sensor is faulty. Transducer is not zeroed correctly.	• Check the cables. • Rezero the transducer. • Replace the sensor. • Replace the transducer. • Replace the module. • Zero the invasive pressure channel.
• ***P1 standby*** to ***P8 standby***	• param.	The IP channel has been set to standby.	• Reactivate the channel by selecting ***Activate P1*** to ***Activate P8***.
• ***P1 zeroing failed*** to • ***P8 zeroing failed***	• param.	Defective transducer. Offset is >150 mmHg.	• Open the transducer to room air and zero the channel. • Replace the transducer, open it to room air, and zero the channel.
• ***Pressure measurement removed***	• al. area	The acquisition device has been removed.	• Reconnect if necessary.
• ***Pressure Sensed***	• param.	Pressure pulsation has been sensed during zeroing.	• Open the venting stopcock to air. • Re-zero.
• ***Sensor*** • [Invasive pressure channel label] X ***sensor disconnected***, where [Invasive pressure channel label] = ***Art***, ***CPP***, ***CVP***, ***Fem***, ***FemV***, ***ICP***, ***LAP***, ***P***, ***RAP***, ***RVP***, ***UAC***, or ***UVC***, and X = invasive pressure channel number 1 to 8.	• param. • al. area	• The transducer detected a disconnection or the cable is disconnected from the module.	• Check connections. • Acknowledge the alarm if you are intentionally disconnecting the invasive pressure line.

Message	Location	Possible causes	Suggested actions
• ***UAC*** 1 ***disconnect*** to ***UAC*** 4 ***disconnect*** • ***Disconnected***	• al. area • param.	Invasive pressure line is disconnected.	• Check connections. • If pressure drops because of zeroing, perform the zeroing process.
• ***Zero adj >100 mmHg***	• param.	Offset during zeroing has exceeded 100 mmHg.	• Repeat the transducer zeroing. • Replace the sensor. • Replace the transducer. • Replace the module. • Check transducer. Re-zero the pressure channel.
• ***Zeroed***	• param.	Zeroing was successful.	• No action required. Message is automatically removed after 10 seconds.
• ***Zeroing***	• param.	IP channel is currently being zeroed.	• No action required. Message is automatically removed and replaced with the zeroing results after completion.
• ***Zero ICP separately***	• al. area	The ICP channel must be zeroed separately from all other invasive pressures.	• Zero the channel using the ***Zero*** option found under the ICP channel setup menu.

Messages related to C.O./CCO measurement

For information regarding alarm priorities and escalation times, see the supplemental information provided.

Make sure you are familiar with the generic layout of the screen. This will help you identify where on screen the following messages appear. The message location is indicated with the following abbreviations:

- al. area = alarm area
- param. = parameter window
- wavef. = waveform area
- C.O. menu = cardiac output menu, ***Measurement*** or ***Calibrate*** tab

Message	Location	Possible causes	Suggested actions
• ***Calibrating***	• param.	Calibration is in progress.	• No action required.
• ***Calibration fail***	• C.O. menu, param.	Unsuccessful calibration.	• Qualified service personnel should repeat the calibration procedure.
• ***CO measurement removed***	• al. area	The module is disconnected.	• Reconnect the module or select audio pause to reset the message.

Message	Location	Possible causes	Suggested actions
• ***Identical C.O. modules***	• al. area	There are two or more of the following modules in the system: E-COP, E-COPSv, E-PiCCO. Also when there is one E-PiCCO and one E-COP-01 or E-COPSv-01 module in the system with their C.O. cables connected, or one with P8 and the other with C.O. cable connected. Also when there are more than one active C.O. sources.	• Connect only one of the listed modules at a time.
• ***Incompatible device: COP(Sv) module*** Not available with host software version 3.1 or earlier.	• al. area	The connected COP or COPSv module is not compatible.	• Replace with a compatible E-COP or E-COPSv module. For a list of compatible devices, refer to the supplemental information provided.
• ***No module***	• C.O. menu	No C.O. module connected.	• Connect a C.O. module to measure cardiac output.
• ***Service CO module*** Not available with host software version 3.1 or earlier.	• al. area	Blood temperature value is inaccurate.	• Replace the E-COP(Sv) module unit.

Messages related to venous oxygenation measurement

For information regarding alarm priorities and escalation times, see the supplemental information provided.

Make sure you are familiar with the generic layout of the screen. This will help you identify where on screen the following messages appear. The message location is indicated with the following abbreviations:

- al. area = alarm area
- param. = parameter window
- wavef. = waveform area

Message	Location	Possible causes	Suggested actions
• ***Re-calibrate ScvO2*** • ***Re-calibrate SvO2***	• al. area, param.	The calibration is over 24 hours old.	• Perform in vivo calibration.
• ***ScvO2 cable off*** • ***SvO2 cable off***	• al. area	The cable is disconnected from the module.	• Reconnect the cable to the module.

Message	Location	Possible causes	Suggested actions
• *ScvO2 faulty cable* • *SvO2 faulty cable*	• al. area, param.	Factory calibration of the optical module is corrupted. There is an error with the red/infrared transmitter. The currents cannot be adjusted to the factory defaults.	• Replace the optical module.
• *ScvO2 measurement removed* • *SvO2 measurement removed*	• al. area	The module is disconnected.	• Reconnect the module.
• *ScvO2 not calibrated* • *SvO2 not calibrated*	• al. area, param.	The optical module is connected to the monitor but the catheter has not been calibrated.	• Perform in vivo calibration or accept the old calibration.
• *ScvO2 signal poor* • *SvO2 signal poor*	• al. area, param.	There is signal pulsation, the catheter is touching the wall, or there is an intensity shift in the signal quality level.	• Reposition and/or flush the catheter. • Recalibrate.

Troubleshooting charts

Troubleshooting invasive pressure measurement

Problem	Possible causes	Recommended actions
Abnormally low pressure.	Transducer wrongly positioned.	Check mid-heart level and reposition transducer.
No pressure.	Defective transducer.	Check or replace transducer.
	Module not connected.	Connect module.
	Transducer adapter cable not connected to the module.	Connect the transducer adapter cable with the transducer to the module.
	Invasive pressure channel not configured to the screen (with adequate priority).	Configure the invasive pressure channel to the screen with adequate priority and check that it is active.
	Invasive pressure channel not zeroed.	Zero the invasive pressure channel.

Troubleshooting SvO2 measurement

Problem	Possible causes	Recommended actions
Unable to calibrate SvO_2.	E-COPSv-01 module with S/N lower than SGQ14529862HA is not compatible with Edwards Lifesciences Optical module OM2E/OM2 version AF and above.	Contact GE service for further information.

6

Disassembly and reassembly

Disassembly guidelines

Field repair of the device is limited to replacing field replaceable units (FRUs).

NOTE Only qualified service personnel should perform field replacement procedures.

NOTE Perform the specified corrective maintenance check after any corrective maintenance to the product.

ESD precautions

All external connectors of the device are designed with protection from ESD damage. However, if the device requires service, exposed components and assemblies inside are susceptible to ESD damage. This includes human hands, non-ESD protected work stations or improperly grounded test equipment. The following guidelines may not guarantee a 100% static-free workstation, but can greatly reduce the potential for failure of any electronic assemblies being serviced:

- Discharge any static charge you may have built up before handling semiconductors or assemblies containing semiconductors.
- Wear a grounded, antistatic wristband or heel strap at all times while handling or repairing assemblies containing semiconductors.
- Use properly grounded test equipment.
- Use a static-free work surface while handling or working on assemblies containing semiconductors.
- Do not remove semiconductors or assemblies containing semiconductors from antistatic containers until absolutely necessary.
- Do not slide semiconductors or electrical/electronic assemblies across any surface.
- Do not touch semiconductor leads unless absolutely necessary.
- Store the semiconductors and electronic assemblies only in antistatic bags or boxes.
- Handle all PCB assemblies by their edges.
- Do not flex or twist a circuit board.

Before disassembly

- Note the positions of any wires or cables. Mark them if necessary to ensure that they are re-assembled correctly.
- Save and set aside all hardware for reassembly.

Required tools

- Torx screwdriver, T10
- Flat blade screwdriver
- Antistatic wristband

Disassembly procedures

Disassemble the module in the order described in this section.

For reference, see the exploded view in Service parts chapter.

Detaching the front cover

1. Detach the front cover of the module by releasing the snaps that hold the front cover to the front chassis unit by using a small flat blade screwdriver. There are 2 snaps on both sides of the module and 1 snap on the top.

Disassembling the module

The measurement board and input boards are not field replaceable separately. In case of a faulty measurement board or input board, repair the module using FRUs listed in Service parts.

1. Detach the front cover of the module by releasing the snaps that hold the front cover to the front chassis unit by using a small flat blade screwdriver. There are 2 snaps on both sides of the module and 1 snap on the top.
2. Remove the two screws (T10) from the back of the module.
3. While pressing the release latch, pull the module casing slowly backwards and remove it from the main body.

Reassembling the module

1. Reassemble in reverse order. Make sure that you:
   a. Tighten all the screws properly.
   b. Connect all the cables properly.
   c. Check that there are no loose objects inside the module.

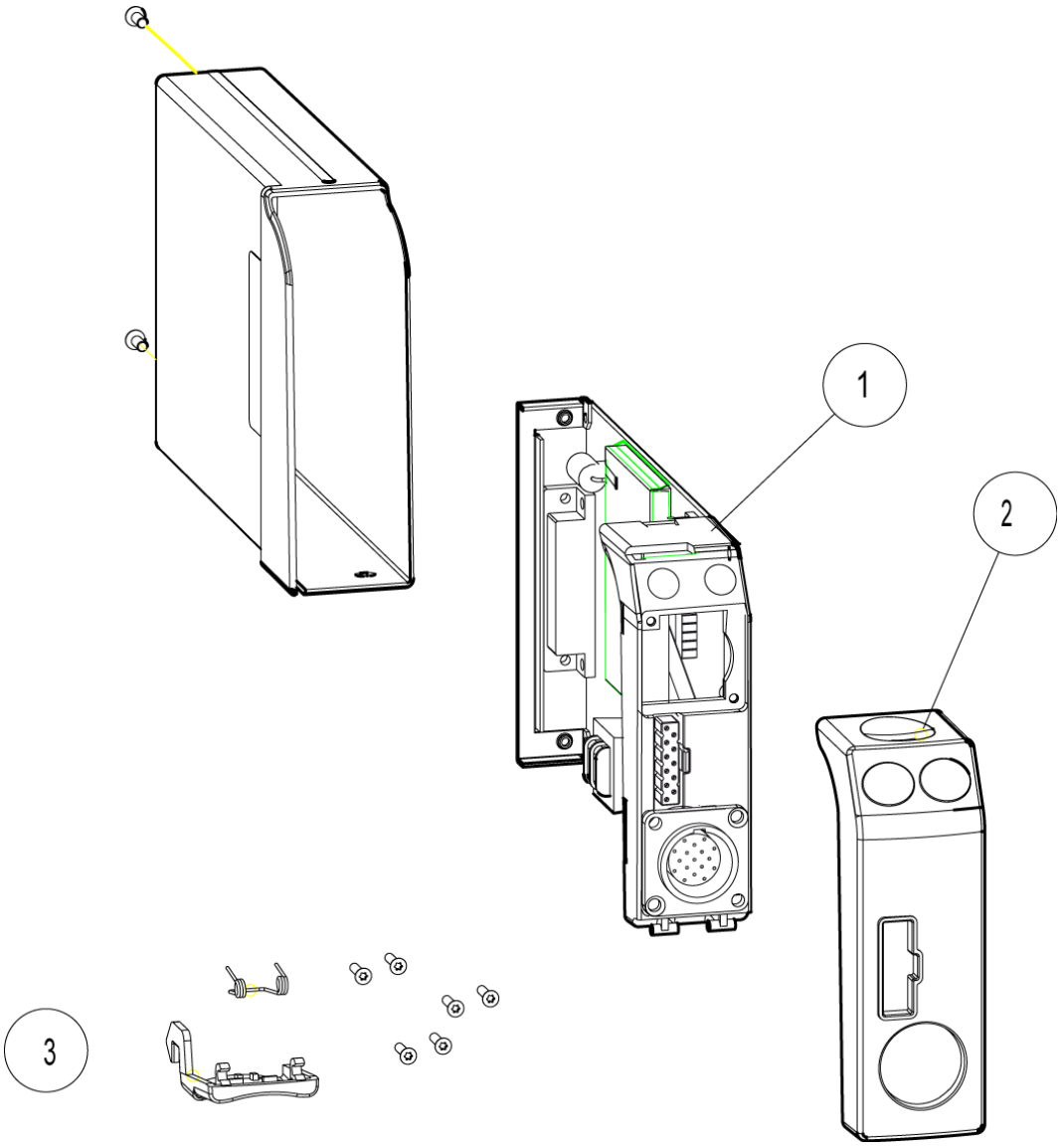
7

Service parts

Ordering parts

To order parts, contact your local GE representative. Contact information is available at www.gehealthcare.com. Make sure you have all necessary information at hand.

Exploded view of Cardiac Output Module, E-COP

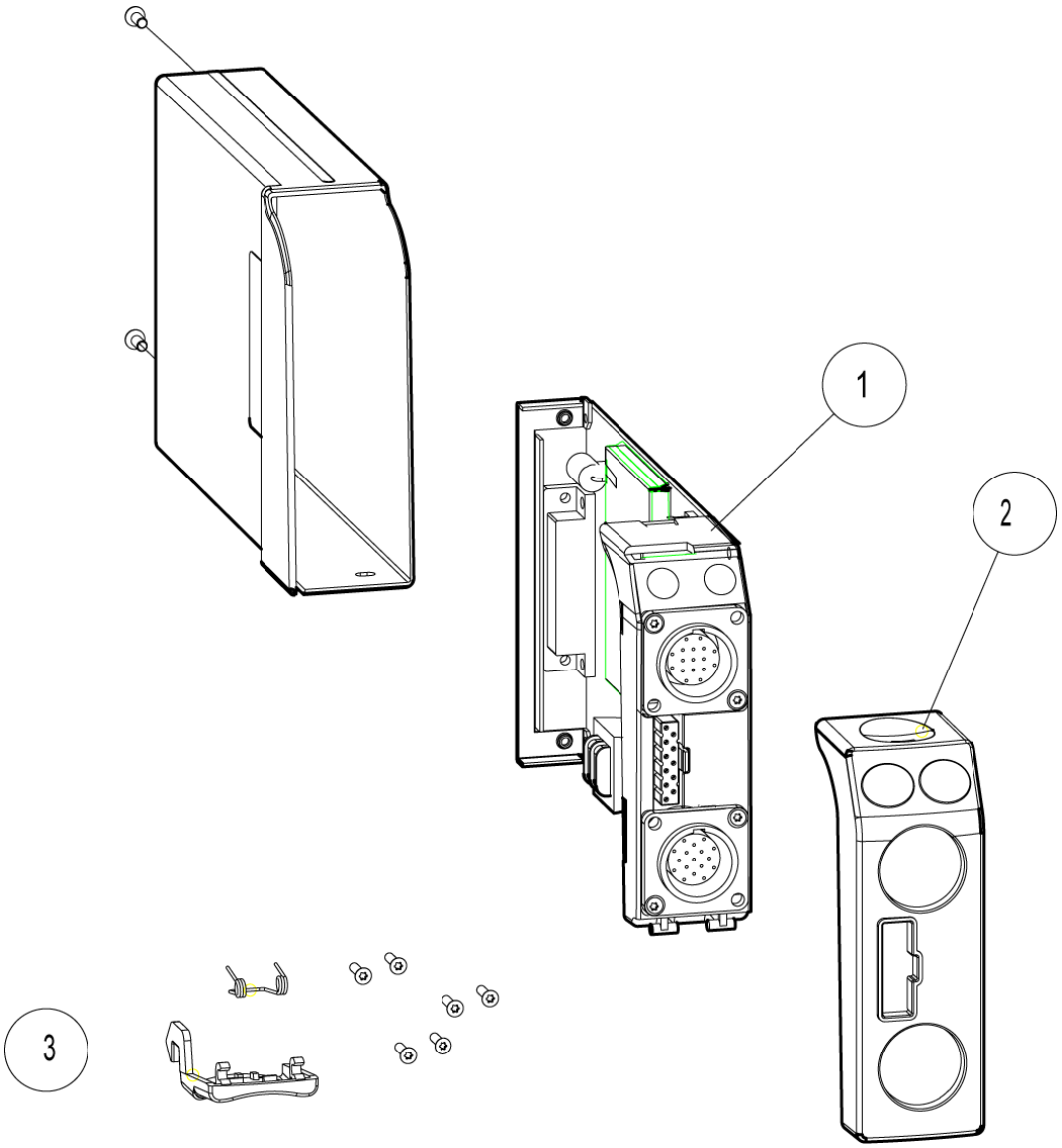


List of FRUs for E-COP

Part number	Description
5848126	FRU, E-COP module unit (#1) • Front chassis unit, FRU (inc. front chassis, membrane keyboard, connector unit, latch, torsion spring) • Measurement board, FRU (inc. Measurement board, metal frame, mounting screws)
2086151-001	FRU, Front Cover, CS, E-COP (#2)
2086171-001	FRU, Front Cover, DA, E-COP (#2)
2086172-001	FRU, Front Cover, DE, E-COP (#2)
2086173-001	FRU, Front Cover, EN, E-COP (#2)

Part number	Description
2086174-001	FRU, Front Cover, ES, E-COP (#2)
2086175-001	FRU, Front Cover, FI, E-COP (#2)
2086176-001	FRU, Front Cover, FR, E-COP (#2)
2086177-001	FRU, Front Cover, HU, E-COP (#2)
2086178-001	FRU, Front Cover, IT, E-COP (#2)
2086179-001	Front Cover, JA, E-COP (#2)
2086180-001	Front Cover, NL, E-COP (#2)
2086181-001	Front Cover, NO, E-COP (#2)
2086182-001	Front Cover, PL, E-COP (#2)
2086183-001	Front Cover, PT, E-COP (#2)
2086184-001	Front Cover, SV, E-COP (#2)
M1206392	FRU, Module Hardware Kit (#3) • 2 mounting screws for metal frame • 2 mounting screws for front chassis unit • 2 mounting screws for module casing • Latch • Torsion spring
NOTE	The parts listed in this table are also compatible with the E-COP-00 modules.

Exploded view of Cardiac Output Module, E-COPSv



List of FRUs for E-COPSv

Part number	Description
5848127	FRU, E-COPSv module unit (#1) • Front chassis unit, FRU (inc. front chassis, membrane keyboard, connector unit, latch, torsion spring) • Measurement board, FRU (inc. Measurement board, metal frame, mounting screws)
2086152-001	FRU, Front Cover Unit, CS, E-COPSV (#2)
2086185-001	FRU, Front Cover Unit, DA, E-COPSV (#2)
2086186-001	FRU, Front Cover Unit, DE, E-COPSV (#2)
2086187-001	FRU, Front Cover Unit, EN, E-COPSV (#2)

Part number	Description
2086188-001	FRU, Front Cover Unit, ES, E-COPSV (#2)
2086189-001	FRU, Front Cover Unit, FI, E-COPSV (#2)
2086190-001	FRU, Front Cover Unit, FR, E-COPSV (#2)
2086191-001	FRU, Front Cover Unit, HU, E-COPSV (#2)
2086192-001	FRU, Front Cover Unit, IT, E-COPSV (#2)
2086193-001	FRU, Front Cover Unit, JA, E-COPSV (#2)
2086194-001	FRU, Front Cover Unit, NL, E-COPSV (#2)
2086195-001	FRU, Front Cover Unit, NO, E-COPSV (#2)
2086196-001	FRU, Front Cover Unit, PL, E-COPSV (#2)
2086197-001	FRU, Front Cover Unit, PT, E-COPSV (#2)
2086198-001	FRU, Front Cover Unit, SV, E-COPSV (#2)
M1206392	FRU, Module Hardware Kit (#3) • 2 mounting screws for metal frame • 2 mounting screws for front chassis unit • 2 mounting screws for module casing • Latch • Torsion spring
NOTE	The parts listed in this table are also compatible with the E-COPSV-00 modules.

E-COP, E-COPSv

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