3 Maintenance and checkout

To help ensure the equipment remains in proper operational and functional order, adhere to a good maintenance schedule.

WARNING Only perform maintenance procedures specifically described in the manual.

WARNING Planned maintenance should be carried out annually. Failure to implement the recommended maintenance schedule may cause equipment failure and possible health hazards.

CAUTION Do not apply pressurized air to any outlet or tubing connected to the module. Pressure may destroy sensitive elements.

NOTE: The manufacturer does not, in any manner, assume the responsibility for performing the recommended maintenance schedule, unless an Equipment Maintenance Agreement exists. The sole responsibility rests with the individuals, hospitals, or institutions utilizing the device.

Corrective maintenance

Service personnel shall perform the following checkout procedure after any corrective maintenance, before taking the module back into clinical use:

	Required checkout procedure	
Performed service activity	Visual inspections (section 3.2)	Functional check (section 3.3)
Front panel replacement	All steps	Check "Module Keys" only
OM Reference gas filter assembly	All steps	Check "Sample Flow Rate Check"
Module case opened either for troubleshooting purpose or for replacing any of the internal parts.	All steps	All steps

Planned maintenance

Service personnel shall perform the following checkout procedure completely every 12 months after installation:

- 1. 3.1. Replacement of planned maintenance parts
- 2. 3.2. Visual inspections
- 3. 3.3. Functional check

3.1 Replacement of planned maintenance parts

3.1.1 Required parts

Replace the following parts that wear in use at the recommended interval.

Description	Pieces	Replacement interval
Nafion Tube, 230 mm (mainflow)	1	Once a year
OM Reference gas filter assembly including O-ring	1	Once a year
PM sticker	1	Once a year
Nafion tube, 85 mm (zero line)	1	Once every 4 years
CO ₂ absorber	1	Once every 4 years

It is also recommended to replace the D-fend Pro water trap, the gas sampling line and the spirometry tube as part of the planned maintenance procedure.

NOTE: See the supplemental information manual for compatible accessories.

3.1.2 Planned Maintenance Kits

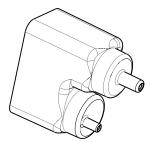
The required planned maintenance parts are included in a PM kit.

Part number	Description
M1206554	Planned Maintenance Kit for CARESCAPE E-sCxxx Respiratory modules.
	The PM kit includes the required Nafion tubes, the OM reference gas filter assembly with an O-ring and a PM sticker.
	NOTE: The PM kit does not include the CO_2 absorber. Order it separately.

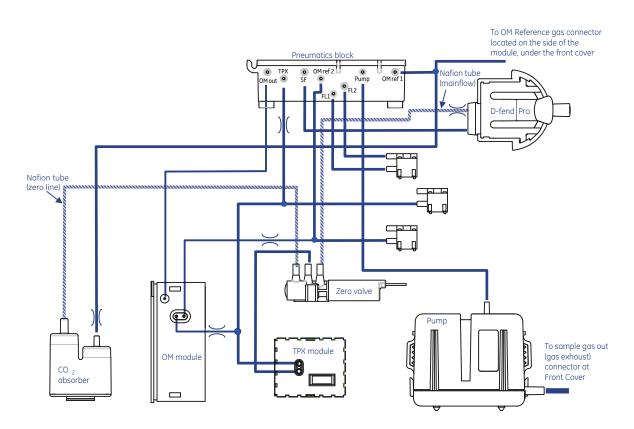
3.1.3 Replacement procedures

Replace the specified planned maintenance parts according to the chapter 6. Disassembly and reassembly.

1. Replace the CO₂ absorber every 4 years.



- 2. Replace the special tubes (Nafion) and check the condition of the internal tubing.
 - Check that the tubing inside the module is not contaminated. Any contamination inside the tubing may indicate that the valves or sensors are contaminated, too. This can increase a risk of faulty operation in valves or sensors. The valves or gas sensors are not possible to clean in the field. Therefore, if you noticed any contamination in the module tubing, send the module to GE Healthcare for factory service.



NOTE: The nafion tubes do not include the silicon fittings they connect to. Use the original silicon fittings unless they are damaged or leaking.

- 3. Replace the OM reference gas filter assembly.
- 4. Check that the fan and ventilation hole are not covered in dust.

3.2 Visual inspections

Detach the module from the module slot and check that:

- the front cover is intact
- all connectors are intact and are attached properly
- the module box and latch are intact
- the D-fend Pro and its connectors are clean and intact
- the module and the applied parts are clean

The cleaning precautions, cleaning requirements, cleaning procedures, and recommended cleaning solutions for the monitor are described in the CARESCAPE monitor user's manual. For details about cleaning, disinfecting and sterilizing the accessories, see the instructions for use in the accessory package.

3.3 Functional check

Turn the monitor on. Wait until the normal monitoring screen appears.

3.3.1 Test setup

Required tools

- A barometer
- A mass flowmeter for measuring air flow, minimum measurement range from 0 to 200ml/min, accuracy 5% or better in the 0 to 200 ml/min range.
- P/N: 755534-HEL Calibration Gas Regulator
- P/N: 755583-HEL Calibration gas, CO2, O2, N2O, DESF, package of 1 can (with E-sCAiO, E-sCAiOV modules)
- P/N: 755581-HEL QUICK CAL calibration gas, CO2, O2, N2O, package of 4 cans (with E-sCO, E-sCOV modules)
- P/N: M1006864, Calibration Gas Regulator, US only
- P/N: 755571-HEL, Calibration Gas, 5% CO2, 54.5% O2, 36.0% N2O, 2.0% DESFLURANE, BAL N2 (with E-sCAiO, E-sCAiOV modules) US only
- P/N: 755587, Calibration Gas, CO2, O2, Balance, 4 cans/pkg (with E-sCO, E-sCOV modules) US only
- D-fend Pro water trap
- 3 m / 10 ft anesthesia gas sampling line
- Spirometry tube, 3 m/10 ft (with E-sCOV and E-sCAiOV modules)
- Adult D-Lite sensor
- A pressure manometer with either an integrated or a separate pressure pump
- Tubing for spirometry leak tests
- Forceps

NOTE: See the supplemental information manual for compatible accessories.

Connections

• Disconnect the module from the monitor, if connected.

Monitor configuration

- 1. Configure the CO2, O2, AA, and Flow waveform fields to the monitor screen with adequate priority.
- 2. Configure the Spiro 1 split screen to the monitor screen.
- Select the Setup tab in the Spirometry and Gas Exchange menu and configure: Scaling: Auto Sensor Type: Adult

Show Volume: TV

3.3.2 Procedure

Mark each task as complete on the checkout form.

1. Gas Sampling System Leak Test

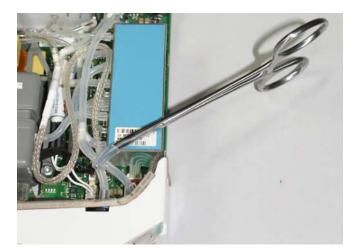
NOTE: The gas module shall be disconnected from the monitor during the leak test.

Check the gas sampling system for possible leakages.

a. Disconnect the module from the monitor.

- b. Detach the module front cover and casing, see chapters 6.2.1. Detaching the Front Cover and 6.2.2. Detaching the Module Casing.
- c. Block the OM reference tube with the forceps. Correct positioning of the forceps is indicated by the figure below.

NOTE: Be careful when attaching the forceps to the tube and avoid stretching the tube. Short pieces of silicone tubing on the forcep jaws can be used to protect the tube from breaks that may appear when the tube is compressed between the jaws.



- d. Connect a new D-fend Pro water trap to the module.
- e. Connect a new gas sampling line to the sampling line connector in the water trap.
- f. Connect the other end of the gas sampling line to a pressure manometer and a pressure pump.
- g. Block the sample gas out (gas exhaust) connector.
- h. Carefully pump 80 mmHg \pm 20 mmHg pressure to the gas sampling system. Let the pressure stabilize for 10 20 seconds.
- i. Check that the pressure reading does not drop more than 2 mmHg during 35 seconds.
- j. Release the forceps, and attach the module casing. Make sure that the tubing fits nicely into the module casing.
- 2. Spirometry System Leak Test

NOTE: Perform this test only for E-sCOV and E-sCAiOV modules.

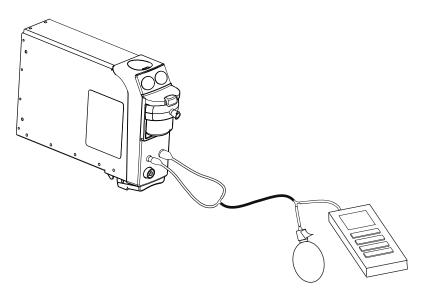
NOTE: The gas module shall be disconnected from the monitor during the leak test.

NOTE: The spirometry pressure transducers are very sensitive for differential overpressure. A momentary differential pressure between the two spirometry connectors exceeding $25 \text{ cmH}_2\text{O}$ (18 mmHg) may damage the pressure sensors. To ensure that both pressure channels are equally pressurized, make sure that the tubing between the manometer and the two spirometry connectors is connected tightly, the tubes are equally long and thick and not kinked.

NOTE: Do not overpressure the spirometry sampling system. A static pressure exceeding 300 cmH_2O (220 mmHg) may damage the pressure sensor.

Check the spirometry sampling system for possible leakages.

- a. Ensure the module is disconnected from the monitor.
- b. Connect a pressure manometer to the spirometry connectors.



- c. Pump ~68 cmH₂O (50 mmHg \pm 10 mmHg) pressure to the Spirometry sampling system. Let the pressure stabilize for approximately 10 seconds.
- d. Verify that the pressure reading does not drop more than 4 cmH $_2$ O (3 mmHg) during one minute.
- 3. Sample Flow Rate Check

Check the sample flow rate.

Connect the module to the monitor.

NOTE: Anesthetic gas measurement is not available during the first 1 to 5 minutes after the module is connected due to warming up. A message '*Calibrating Gas Sensor*' is shown in the waveform field. Wait until warm-up is completed before proceeding with the next steps.

NOTE: The ambient temperature and air pressure influence the flow rate measured by the flow meter. A flow meter, which has been calibrated at 21.11 °C (70 °F) and 760 mmHg (1033 cmH2O), measures the flow rate correctly under the same conditions, i.e. in room temperature at sea level. A flow rate correction as instructed by the manufacturer of the flow meter needs to be performed when measuring flow rate under other conditions, for example in high altitude.

- a. Connect the gas sampling line to the Sampling line connector.
- b. Connect the other end of the gas sampling line to a flowmeter.
- c. Check the sample flow rate reading from the flow meter. The flow rate shall be within the specification limit 120 \pm 20 ml/min.

NOTE: Readjustment is needed, if the measured value is not within the specification limit. Adjust the sample gas flow rate according to the instructions in section 4.1.2. Sample Flow Rate Adjustment.

4. Reference Gas Flow Rate Check

Check the flow rate in reference gas inlet:

- a. Connet the gas sampling line to the sampling line connector.
- b. Leave the other end of the gas sampling line open to room air.
- c. Connect the flowmeter to the OM reference gas inlet on the side of the module with a piece of tubing.

- d. Check that the *Reference Flow* is within the following range: 10 - 50 ml/min with E-sCO, E-sCOV, E-sCAiO and E-sCAiOV modules.
- e. Detach the water trap.
- f. Attach the front cover.
- 5. Fan
 - a. Check that the gas module's fan is running behind the D-fend Pro water trap.
 - b. Attach the water trap.
- 6. Module Keys

NOTE: Perform this test only for E-sCOV and E-sCAiOV modules.

- a. Press the Change Loop module key.
- b. Check that the spirometry loop is changed from *Flow / Vol* loop to *Paw/Vol* loop, or vice versa.
- c. Leave the *Flow / Vol* loop on the screen.
- 7. Zero Valve Operation

Test the zero valve functionality:

- a. Connect the gas regulator to the calibration gas container.
- b. Connect the gas sampling line to the sampling line connector.
- c. Connect the end of the gas sampling line to the regulator on the gas container. Leave the regulator overflow port open to room air.
- d. Select Monitor Setup > Service Calibrations.
- e. Enter the User Name and the Password and press *Enter* to get into the *Calibrations* menu.
- f. Select Gases.
- g. Start feeding the specified calibration gas. Wait until the gas values shown in the *Gas calibration* menu rise approximately to the level indicated in the labelling of the calibration gas container.

NOTE: The gas values in the *Gas Calibrations* menu is in percentages (%).

- h. Open the zero valve to room air by selecting Zero valve Off (zero position).
- i. Check that the **CO2**, **N2O** and **anesthesia agent** values drop back near 0% and the **O2** reading near 21% (room air).
- j. Stop feeding the calibration gas.
- k. Turn the zero valve back to the normal measurement position by selecting **Zero** *valve On* (measurement position).
- 8. Gas Calibration

Perform gas calibration according to the instructions in section 4.2. Gas Calibration.

9. Agent Identification

NOTE: Perform this test only for E-sCAiO and E-sCAiOV modules.

Check agent ID unreliability:

a. Feed the specified calibration gas for at least 30 seconds.

b. Check that the anesthesia agent is identified as Desflurane and the *IDu* value (=agent ID unreliability) shown in the *Monitor Setup / Service calibrations / Gases* menu is lower than 75.

If the value is higher, repeat the gas calibration and check the value again.

10. Ambient Pressure

Use a barometer to check the operation of the absolute pressure sensor.

• Check that the ambient pressure value shown in the *Gas Calibrations* menu does not differ more than ± 10 mmHg from the value shown by the barometer.

NOTE: The ambient pressure value in the Gas Calibrations menu is in mmHg.

- 11. Occlusion detection
 - a. Block the tip of the sampling line by your finger.
 - b. Check that a 'Sample line blocked' and a 'Low sample flow' message appear to the parameter window within 30 seconds.
- 12. Air Leak detection
 - a. Detach the D-fend Pro water trap.
 - b. Check that the message '**Check Water Trap**' appears to the parameter window within 30 seconds.
 - c. Attach the water trap.
- 13. Gas exhaust blockage
 - a. Block the gas exhaust connector with your finger.
 - b. Check that the message 'Sample gas out' appears to the parameter window within 30 seconds.
- 14. Airway Gases
 - a. Breathe a minimum of 5 times to the tip of the sampling line.
 - b. Check that a normal **CO2** waveform appears to the waveform field and the **EtCO2** and **FiCO2** values are updated to the parameter window.
- 15. Apnea detection
 - a. Stop breathing to the gas sampling line.
 - b. Check that an '**Apnea**' alarm appears to the message field within 30 seconds.
- 16. Flow waveform

NOTE: Perform this test only for E-sCOV and E-sCAiOV modules.

- a. Connect a clean spirometry tube and D-lite to the module.
- b. Breathe through the wider side of the D-lite.
- c. Check that the flow waveform responds when you breathe in and out. The setting of the inspiratory flow may be positive or negative.

3.3.3 Test completion

- Select *Discharge patient* or *Reset case* to discard any changes made to the monitor configuration during checkout.
- Disconnect and reconnect the module before starting a new case.
- Complete the "Maintenance check form" on page 63.