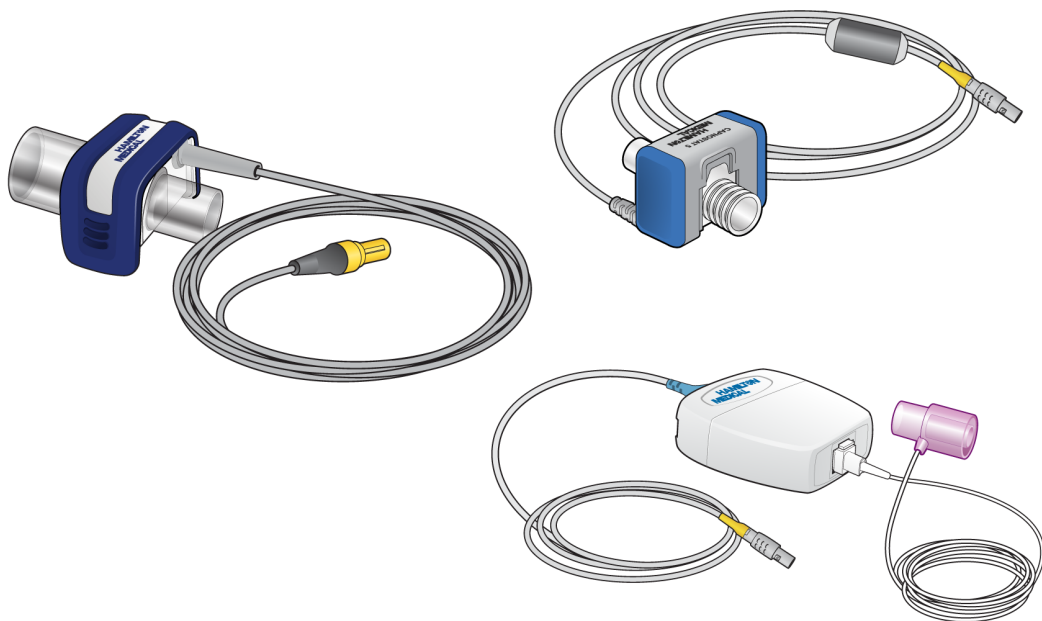




CO₂ monitoring

Instructions for use

HAMILTON-C6

REF

ProxyCo: 10169182, 10169159, 10083174, 10100344

CAPNOSTAT-5: 1149335, 281719, 281720, 281721, 281722, 281803

LoFlo: 281928, 281929, 281931, 281930, 281932

Software version 2.0.1 and later

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HAMILTON
MEDICAL

Instructions for use

CO2 monitoring

2026-03-15

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Manufacturer

Hamilton Medical AG
Via Crusch 8, 7402 Bonaduz
Switzerland
Phone: +41 (0) 58 610 10 20
info@hamilton-medical.com
www.hamilton-medical.com

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About this guide

When a supported CO2 sensor is connected to the device, the ventilator provides integrated monitoring of measured CO2 in the breathing gas, and uses this data to calculate end-tidal CO2 (etCO2).

This guide provides information about CO2 monitoring setup and operation. It is designed for use together with your *HAMILTON-C6 Operator's Manual*, and refers to information provided therein.

Be sure to read all relevant documentation, including safety information, before using the device or accessories. For the list of related Hamilton Medical documentation, see the *Documentation suite* table in the device *Operator's Manual*.

Documentation downloads and training

To download the latest version of this manual or other documents, visit the Hamilton Medical Resource Center: <https://www.hamilton-medical.com/Resource-center>

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Conventions used in this guide

In this manual:

- Button and tab names are shown in a **bold** font.
- The notation **XX > XX** shows the sequence of buttons/tabs to touch to open the associated window.

For example, the text "Touch **System > Settings**" means touch the **System** button, then touch the **Settings** tab.

- The notation **ICON > ICON** shows the following sequence:

Icon to touch in the toolbar on the bottom of the display, followed by the icon/element to touch in the window that is opened.

For example,  >  means touch the Applications icon in the toolbar to open the Applications window, then touch the P/V Tool icon.

For a description of the icons, see Chapter 2 of the ventilator *Operator's Manual*.

- Window names are shown using the sequence of buttons/tabs used to open them.

For example, "Alarms > Limits 2 window" means the window is accessed by touching the **Alarms** button, then the **Limits 2** tab.

- Pressure is indicated in cmH2O, length in cm, and temperature in degrees Celsius (°C). 1 cmH2O equals 0.981 mbar, which equals 0.981 hPa.

- A green check mark  or button  indicates a selected item or feature.
- The graphics shown in this manual, including the sensors and cables, may not exactly match what you see in your environment.
- Some figures use callouts in a white circle with a blue border.
 - ① These figures may have an associated legend table, or may provide the legend in the figures title, if a single item. Callouts may be numeric or alphabetic. Callouts are *unrelated* to any nearby procedures and refer only to the figures themselves and their associated legend.
- Some figures use small dark blue callouts.
 - A These callouts show the sequence of steps. Note that any numbering is *not* directly related to the numbering of any associated procedure.
- Not all features or products are available in all markets.
- Product description and order number may differ depending on region.
- The CO2 sensor technologies offered with the HAMILTON-C6 ventilators are provided by Hamilton Medical (ProxyCo) and Respironics Novamatrix (CAPNOSTAT-5 and LoFlo).

Safety messages are displayed as follows:

WARNING

A **WARNING** statement provides important information about a potentially hazardous situation which, if not avoided, could result in death or serious injury.

CAUTION

A **CAUTION** statement provides important information about a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or patient, or in damage to the medical device or other property.

NOTICE

A **NOTICE** provides additional information intended to avoid inconvenience during operation.

In tables, safety messages are indicated as follows:

 **WARNING!**

 **CAUTION!**

 **NOTICE!**

Safety information

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1.1 Overview

CO₂ sensors and related components are to be operated by, or under the supervision of, qualified personnel only.

Before using the CO₂ sensor and airway adapters, be sure to review the ventilator *Operator's Manual*, the CO₂ sensor and accessories instructions for use, and this guide, including all precautionary information and specifications.

Safety information is organized by general area of application:

- General safety information
- Sensor/airway adapter safety information
- Maintenance safety information (see Chapter 3)

1.2 General safety information

This section provides general safety information.

Be sure to also read the safety information provided in the ventilator *Operator's Manual* and in the CO₂ component manufacturers' instructions for use.

WARNING

- If the capnogram appears abnormal, inspect the CO₂ airway adapter and replace if needed.
- In NIV and neonatal ventilation, leaks may influence the capnogram and the measured values.

- During use, a system leak, such as that caused by an uncuffed ET tube or damaged airway adapter, may significantly affect sensor readings, including flow, volume, pressure, and other respiratory parameters.
- Monitor the capnogram for elevated baseline. Elevated baseline can be caused by sensor problems or by the patient's condition.

CAUTION

- *To ensure valid measurements:*
 - Always perform a zero calibration when changing the airway adapter.
 - Always perform a zero calibration with the CO₂ sensor connected to the airway adapter.
 - Calibrate the flow sensor after connecting the airway adapter to the breathing circuit.
 - If there are any questions about the CO₂ values from the sensor, review the CO₂ values from a blood gas analysis (BGA), if applicable.
- *The CO₂ sensors have no user serviceable parts. Refer servicing to qualified technical personnel.*

NOTICE

- Any incident with the device leading to serious patient injury, death, or a potential threat to public health must be reported to the manufacturer and the relevant authorities.
- Use only CO₂ monitoring equipment specified by Hamilton Medical as being compatible. This equipment complies with ISO 80601-2-55:2018.

- We recommend additional independent monitoring devices, including pulse oximeters measuring SpO₂, to be used during therapy. The operator assumes full responsibility for proper therapy and patient safety in all situations.

1.3 Sensor safety information

This section provides CO₂ sensor and related component safety information.

For details on connection and use of the sensors, see Chapter 2.

Additional information related to a specific sensor is provided in the sensor-specific subsections.

Be sure to also read the safety information provided in the CO₂ sensor component manufacturers' instructions for use.

WARNING

- Visually inspect the sensor and airway adapter for damage prior to use.
Do *not* use any component if it appears to be damaged, fails to operate properly, or fails preoperational checks. Replace the components immediately.
- If an airway adapter is dropped or has been in contact with contaminated surfaces, it must be discarded; use a new airway adapter.
- Do *not* combine the neonatal CO₂ airway adapter and the adult flow sensor. Doing so can increase resistance, create artifact, or lead to hypoventilation, AutoPEEP, or over-inflation.

- Periodically check the CO₂ sensor, and flow sensor and tubing for excessive moisture or secretion build-up, and replace if needed. Excessive moisture can affect measurements.
- Do *NOT* use the CO₂ sensor when it is wet or has exterior condensation. Condensation may harm the patient.
- Replace the CO₂ airway adapter if excessive secretions are observed.
- Keep all fluids away from any electrical connections.
- Positioning of tubing and cables:
 - Do *not* position the cables in any manner that may cause patient entanglement or strangulation.
 - Support the tubing to avoid stress on any tubing or cables.
 - Do *not* apply excessive tension to any cable.
- Handle used products as contaminated, and dispose of all parts removed from the device according to your institution's protocols. Comply with all local, state, and federal regulations with respect to environmental protection, especially when disposing of the electronic parts.

CAUTION

- *Do not place the CO₂ sensor directly on the patient's skin; ensure a cloth barrier is between the sensor and skin at all times. The sensor can reach temperatures exceeding 43°C (109°F) depending on ambient temperature.*
- *Always connect components securely and check for leaks in accordance with standard clinical procedures.*

- Always use the correct CO₂ airway adapter for the patient group.
In adult patients, smaller geometrics increase airway resistance and induce low tidal volumes and AutoPEEP.
In neonatal patients, larger geometrics impede effective CO₂ removal and add dead space.
- Use during nebulization may influence the CO₂ measurements. In addition, the medication can contaminate the airway adapter windows, causing the sensor to fail prematurely.
- (USA only) Federal law restricts this device to sale by or on the order of a physician.

NOTICE

- The CO₂ sensors and accessories that have contact with the patient are *not* made with natural rubber latex.
- Do *not* place the CO₂ sensor/airway adapter between the ET tube and any connected adapter, as this may allow patient secretions to enter the tubing and block the adapter windows.
 - If pooling occurs with a single use airway adapter, replace the adapter.
 - If pooling occurs with a reusable airway adapter, proceed as directed in the manufacturer's Instructions for use or the Respirationics *Reprocessing Guide*, available at www.philips.com/ifu.

1.3.1 ProxyCo sensor/airway adapter safety information

The following safety information applies to the ProxyCo components.

For connection and use details, see Chapter 2. For cleaning and disinfection information, see Chapter 3.

WARNING

- Read your ventilator's *Operator's Manual* and the CO₂ monitoring Instructions for use before using the ProxyCo CO₂ sensor and airway adapters.
- **MR UNSAFE.** Keep the ProxyCo CO₂ sensor set away from magnetic resonance imaging (MRI) equipment. The device poses unacceptable risks to the patient, medical staff, and other persons within the MRI environment.
- The ProxyCo CO₂ sensor set must *not* be used in an oxygen-rich environment, with flammable anesthetics, or in insufficiently ventilated areas. **Danger of fire.**
- Use only Hamilton Medical-approved parts and accessories that are specified in this document and in the product e-catalog. Modifications to any components of the ProxyCo CO₂ sensor and airway adapter are *not* permitted.
- Use of accessories, transducers, and cables other than those specified by Hamilton Medical can result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment, and may result in improper operation.

- Portable radio frequency (RF) communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm to any part of the breathing gas sensor, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- Correct function of the device may be impaired by the operation of high-frequency surgical equipment, shortwaves, or strong magnetic fields in close proximity.
- *Do NOT use with anesthetic agents, as this may result in incorrect CO₂ readings. The influence of isoflurane, sevoflurane, and norflurane on measurements is provided in Chapter 5.*
- *If the sensor is dropped, do the following, in order:*
 - *Clean the sensor.*
 - *Visually check the sensor for damage.*
 - *Perform a zero calibration to ensure it is still functioning properly.*

CAUTION

- *The ProxyCo CO₂ sensor is NOT protected against reanimation with a defibrillator. Disconnect the CO₂ sensor before using a defibrillator on the patient.*
- *Always connect all components securely and check for leaks according to standard clinical procedures.*
- *Adding attachments or other parts/assemblies to the device not listed in this guide can adversely affect device performance and may lead to patient injury.*
- *Position airway adapters with windows in a vertical, NOT horizontal, position. This helps keep patient secretions from pooling on the windows.*
- *Check for breath sounds over the stomach if the pCO₂ curve shows (very low) values that do not correlate with the patient's breaths after tracheal intubation.*
- Use of an oxygen concentrator may result in an increased baseline (up to a reading of 0.2% CO₂ during inspiration).
- The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment. The ProxyCo CO₂ sensor complies with the IEC 60601-1-2 EMC (Electro-magnetic Compatibility) Collateral Standard.

1.3.2 CAPNOSTAT-5 sensor/airway adapter safety information

The following safety information applies to the CAPNOSTAT-5 components.

For connection and use details, see Chapter 2. For cleaning and disinfection information, see Chapter 3.

WARNING

- Do not use in the presence of flammable anesthetics. Use of the CAPNOSTAT-5 CO₂ sensor in such an environment may present an explosion hazard.
- If the CAPNOSTAT-5 CO₂ sensor fails to respond as described in this guide, *do not* use it until approved for use by qualified personnel.

CAUTION

- *The CAPNOSTAT-5 sensor is NOT protected against reanimation with a defibrillator. Disconnect the CO₂ sensor before using a defibrillator on the patient.*
- *In the presence of electromagnetic devices (for example, electrocautery), patient monitoring may be interrupted due to electromagnetic interference. Electromagnetic fields up to 20 V/m between 80 MHz and 2.7 GHz will NOT adversely affect system performance.*
- *Excessive moisture in the sensor may affect the accuracy of measurements.*

- *Note the following when working with the CAPNOSTAT-5 sensor cable:*
 - *Do NOT pinch or stretch the cable during cleaning, handling, or use.*
 - *Do NOT coil or bend the cable tighter than 7.6 cm (3 in) in diameter.*
 - *Do NOT wind the cable on any object smaller than 7.6 cm (3 in) in diameter*
 - *Do NOT wind the sensor cable around the sensor head.*
 - *Do NOT fold the cable upon itself.*
 - *Do NOT wind the cable opposite the natural cable coil.*
- *Follow precautions for electrostatic discharge (ESD) and electromagnetic interference (EMI) to and from other equipment.*
- *Do NOT store the sensor at temperatures less than -40°C (-40°F) or greater than 70°C (158°F).*
- *Do NOT use the sensor at temperatures less than 0°C (32°F) or greater than 45°C (113°F).*
- *Use only Respironics Novamatrix-approved accessories with the CAPNOSTAT-5 sensor.*
- *The CAPNOSTAT-5 sensor is NOT user serviceable.*

NOTICE

- Position airway adapters with windows in a vertical, NOT horizontal, position. This helps keep patient secretions from pooling on the windows.
- Nitrous oxide, elevated levels of oxygen, helium, and halogenated hydrocarbons can influence the CO2 measurement.

1.3.3 LoFlo sensor/airway adapter safety information

The following safety information applies to the LoFlo sidestream components¹.

For connection and use details, see Chapter 2. For cleaning and disinfection information, see Chapter 3.

⚠ WARNING

- Do *not* use with patients who cannot tolerate the removal of 50 ml $\pm$ 10 ml/min from their total minute volume. In adaptive modes (such as ASV, APVcmv, and APVsimv), the removal is fully compensated.
- Use of devices containing PVC plasticized with DEHP should be limited to the amount of time treatment is medically necessary, especially for neonates and pregnant or nursing mothers.

- Monitor the CO2 waveform (capnogram) on the ventilator display. If it appears abnormal, check the patient, settings, and the breathing circuit set components, including the CO2 sensor sampling line. Adjust and replace components as appropriate.

⚠ CAUTION

- *Remove the sampling kit sample cell from the module when not in use.*
- *Monitor the CO2 waveform (capnogram) on the ventilator display. If it appears abnormal, check the patient, settings, and the breathing circuit set components, including the CO2 sensor sampling line.*
Adjust and replace components as appropriate.

1.4 Cleaning and disinfection safety information

For detailed cleaning/disinfection and maintenance procedures, including associated safety information, see Chapter 3.

¹ Not available in all markets.

2

CO2 monitoring

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2.4	About the CO2 monitoring parameters.....	29
2.5	Viewing CO2 capnography data	31
2.6	Working with alarms.....	34

2.1 Overview

CO2 monitoring data is helpful for the assessment of the patient's airway integrity and ensuring proper endotracheal tube placement, among other applications.

Two CO2 measurement options are available: mainstream and sidestream. Which option you use depends on the clinical setting.¹

For calibration information, see Section 2.2.3.

2.1.1 About mainstream capnography

The HAMILTON-C6 ventilator supports the following mainstream CO2 sensors:

- ProxyCo
- CAPNOSTAT-5

The ventilator displays the following CO2 measurements:

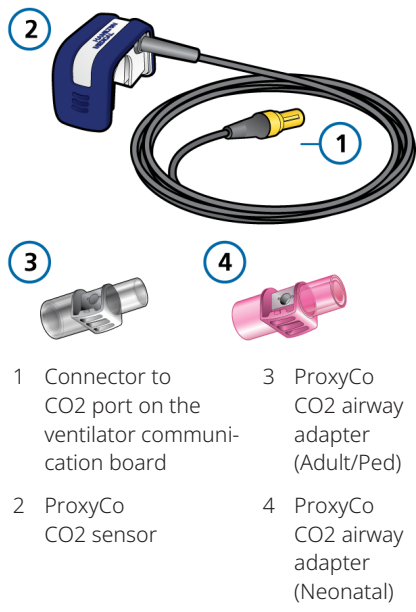
- Numeric values
- Waveforms
- Trends
- Loops

2.1.1.1 About the ProxyCo CO2 sensor

The ProxyCo CO2 sensor is a proximal mainstream sensor using infrared (IR) absorption spectrometry to continuously measure CO2 in the breathing gas. Measurements are taken at the patient's airway.

The sensor is restricted for use on a single patient at a time.

Figure 2-1. ProxyCo CO2 monitoring components



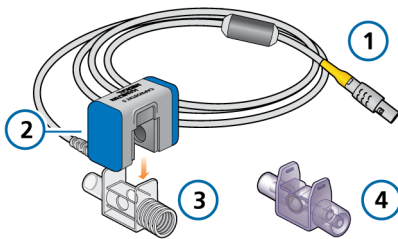
¹ The volumetric capnogram is only available when using a mainstream CO2 sensor.

2.1.1.2 About the CAPNOSTAT-5 CO2 sensor

The CAPNOSTAT-5 CO2 sensor is a proximal mainstream sensor using infrared (IR) absorption spectrometry to continuously measure CO2 in the breathing gas. Measurements are taken at the patient's airway.

The sensor is restricted for use on a single patient at a time.

Figure 2-2. CAPNOSTAT-5 mainstream CO2 monitoring components



- | | |
|---|----------------------------------|
| 1 Connector to CO2 port on the ventilator communication board | 3 CO2 airway adapter (Adult/Ped) |
| 2 CAPNOSTAT-5 CO2 sensor | 4 CO2 airway adapter (Neonatal) |

Reusable airway adapters not shown

2.1.2 About sidestream capnography

The LoFlo CO2 module is a sidestream CO2 monitoring system comprising the following components:

- Communication board
- Airway sampling adapter
- Sampling cell
- CO2 module

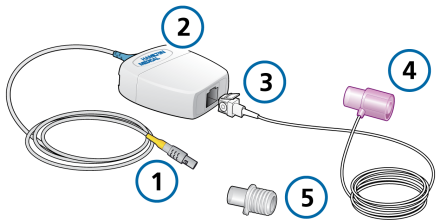
The HAMILTON-C6 ventilator supports the LoFlo sidestream CO2 sensor.

The module generates infrared light and beams it through the sample cell to a detector on the opposite side. CO2 from the patient that is aspirated into the sample cell absorbs some of this energy. The system uses a sampling rate of 50 ml/min.

The system determines CO2 concentration in the breathing gases by measuring the amount of light absorbed.

The ventilator displays CO2 measurements as numeric values, waveforms, trends, and loops.

Figure 2-3. LoFlo sidestream CO2 monitoring components



- | | |
|---|--------------------------------------|
| 1 Connector to CO2 port on the ventilator communication board | 4 Airway sampling adapter (Neonatal) |
| 2 CO2 module | 5 Adapter ID15/OD15 |
| 3 Sampling cell | |

2.2 Setting up CO2 monitoring

Before proceeding, review the safety information in Chapter 1.

Working with CO2 measurement on the ventilator requires the following tasks.

Table 2-1. Setting up CO2 monitoring

For details about ...	See ...
Enabling the CO2 hardware	Chapter 4
Connecting a mainstream CO2 sensor	
ProxyCo	Section 2.2.1.1
CAPNOSTAT-5	Section 2.2.1.2
Connecting a sidestream CO2 sensor	Section 2.2.1.3
Enabling the CO2 sensor on the ventilator	Section 2.2.2
Performing zero calibration of the adapter	Section 2.2.3

2.2.1 Connecting the components

This section describes the setup and connection of the CO2 sensor and airway adapter for CO2 monitoring.

For zero calibration information, see Section 2.2.3.

2.2.1.1 Connecting the ProxyCo mainstream sensor

Before proceeding, review the safety information in Chapter 1, and the ProxyCo CO2 sensor set Instructions for use.

Ensure the CO2 sensor and airway adapter are clean and dry before connection.

To set up ProxyCo CO2 monitoring

1. Connect the CO2 sensor connector to the CO2 port on the ventilator (Figure 2-4).
2. Attach the ProxyCo CO2 sensor to the appropriate airway adapter for the patient (Figure 2-5).

Align the narrow end of the airway adapter with the narrow end of the sensor, and press the components together until they click into place.

3. Perform a zero calibration of the airway adapter as described in Section 2.2.3.
4. Connect the CO2 sensor/airway adapter to the breathing circuit proximal to the patient, with the airway adapter windows in a vertical position (Figure 2-6).

Do *not* place the airway adapter between the ET tube and any connected adapter, as this may allow patient secretions to accumulate in the adapter.

5. Ensure the sensor cable faces away from the patient, and secure the cable safely out of the way.

6. Perform the rest of the preoperational checks on the ventilator. For details, see your ventilator *Operator's Manual*.
 7. Start ventilation.
 8. Verify the quality of the connection, as described next.
- Note that full specifications are available within two (2) minutes; the capnogram is displayed after a warm-up time of 30 seconds.

Figure 2-4. Connect CO2 sensor to ventilator CO2 port

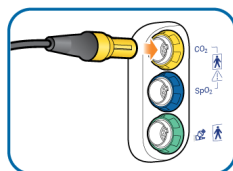


Figure 2-5. Connect ProxyCo sensor to airway adapter (one-way attachment)

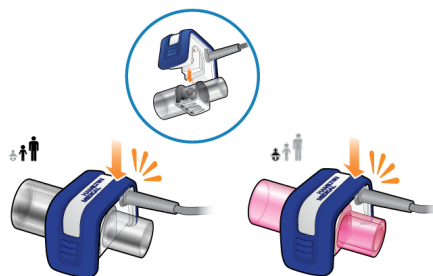
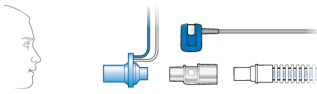
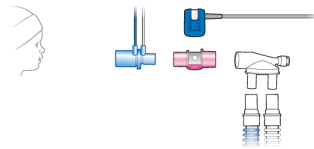


Figure 2-6. Connect CO2 sensor/airway adapter to breathing circuit

Adult/Ped



Neonatal



To verify the quality of the connection

- ▶ Check the capnogram (CO2 waveform) on the ventilator display.
If CO2 levels are higher than expected:
 - Check the CO2 airway adapter for condensation/moisture.
 - Check the patient condition.
 - If you determine that the patient's condition is not contributing to the issue, zero calibrate the sensor/airway adapter (Section 2.2.3).

To disconnect the sensor cable from the ventilator

- ▶ Gently pull the connector straight back and disengage from the CO2 connection port on the ventilator.

2.2.1.2 Connecting the CAPNOSTAT-5 mainstream sensor

Before proceeding, review the safety information in Chapter 1.

NOTICE

You must use an appropriate adapter to connect the mainstream CO2 neonatal airway adapter to a neonatal flow sensor.

Ensure the CO2 sensor and airway adapter are clean and dry before connection.

To set up CAPNOSTAT-5 CO2 monitoring

1. Connect the CO2 sensor connector to the CO2 connection port on the ventilator (Figure 2-7).
2. Attach the CO2 sensor to the airway adapter, aligning the arrows on both components (Figure 2-8).
Press the components together until they click.
3. When connecting a CO2 sensor for the first time, perform the zero calibration of the sensor/airway adapter, if needed, as described in Section 2.2.3.
4. Connect the CO2 sensor/airway adapter to the breathing circuit proximal to the patient, with the airway adapter windows in a vertical position (Figure 2-9).
An ID15/OD15 adapter is required between the CO2 airway adapter and the neonatal flow sensor (see Figure 2-3)

Do *not* place the airway adapter between the ET tube and any connected adapter, as this may allow patient secretions to accumulate in the adapter.¹

5. Ensure the sensor cable faces away from the patient, and secure the cable safely out of the way.
6. Perform the rest of the preoperational checks on the ventilator. For details, see your ventilator *Operator's Manual*.
7. Start ventilation.
8. Verify the quality of the connection, as described next.

Note that the capnogram is displayed in < 15 seconds at an ambient temperature of 25°C; full specifications are available within 2 minutes

Figure 2-7. Connect CO2 sensor to ventilator CO2 port

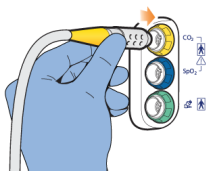


Figure 2-8. Connect CAPNOSTAT-5 CO2 sensor to airway adapter

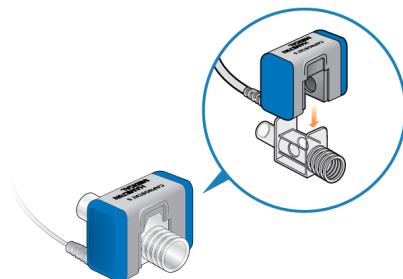
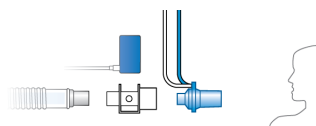
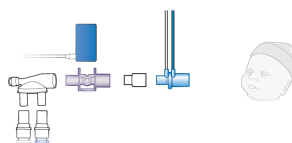


Figure 2-9. Connect CO2 sensor/airway adapter to breathing circuit set

Adult/Ped



Neonatal



To verify the quality of the connection

- Check the capnogram (CO2 waveform) on the ventilator display. If CO2 levels are higher than expected:
 - Check the CO2 airway adapter for condensation/moisture.
 - Check the patient condition.
 - If you determine that the patient's condition is not contributing to the issue, zero calibrate the sensor/airway adapter (Section 2.2.3).

¹ You can connect the CO2 sensor in front of or behind the flow sensor according to your institution's protocol.

To disconnect the sensor cable from the ventilator

- ▶ Pull back on the connector sheath and disengage from the CO2 connection port on the ventilator.

2.2.1.3 Connecting the LoFlo sidestream CO2 sensor

WARNING

Connect the CO2 airway adapter according to your institution's policy and procedures. Connecting the airway adapter between the flow sensor and the endotracheal tube increases dead space and may contribute to incorrect volume measurements.

Before proceeding, review the safety information in Chapter 1.

To set up LoFlo CO2 monitoring

1. Connect the CO2 module cable to the CO2 connection port on the ventilator (Figure 2-10).
2. Insert the sample cell into the CO2 module. The sample cell clicks into place (Figure 2-11).

Inserting the sample cell into the module automatically starts the sampling pump.

Removing the cell turns the pump off.

3. Perform the zero calibration of the airway adapter, if necessary, as described in Section 2.2.3, before connecting the breathing circuit.

4. Connect the airway adapter between the breathing circuit limb and the flow sensor (or between the breathing circuit limb and HMEF, if used) (Figure 2-12).
5. Ensure the sensor cable faces away from the patient, and secure the cable safely out of the way.
6. Perform the rest of the preoperational checks on the ventilator. For details, see your ventilator *Operator's Manual*.
7. Start ventilation.
8. Verify the quality of the connection, as described next.

Note that the CO2 sensor has a 2-minute warm-up time.

Figure 2-10. Connect CO2 module to ventilator CO2 port

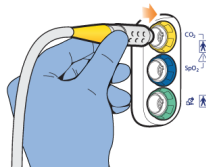


Figure 2-11. Insert sample cell into the CO2 module

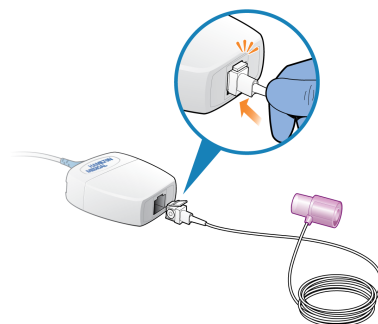
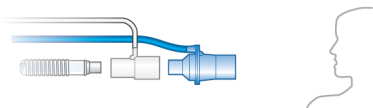
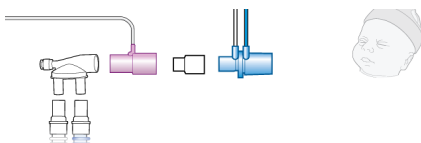


Figure 2-12. Connect CO2 airway adapter to the breathing circuit

Adult/Ped



Neonatal



To remove the sample cell

1. Remove the airway adapter from the breathing circuit.
2. Press down on the locking tab and remove the sample cell from the CO2 module.

2.2.2 Enabling the CO2 sensor on the ventilator

Before proceeding, review the safety information in Chapter 1.

The CO2 sensor must be enabled for CO2 monitoring data to be available.

To enable the CO2 sensor

1. Touch  > .

The Sensors On/Off window is displayed (Figure 2-13).

2. Select the CO2 sensor checkbox to enable CO2 monitoring.¹

 indicates a sensor is enabled

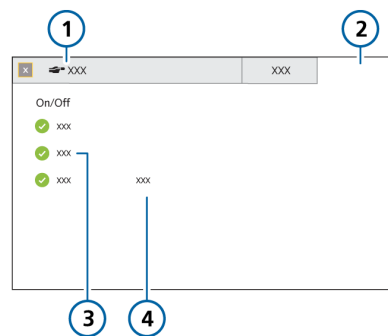
 indicates a sensor is disabled

If you disconnect a sensor, deactivate the corresponding alarm by disabling the sensor.

To disable the CO2 sensor

- Touch  > , and clear the CO2 sensor checkbox.

Figure 2-13. System > Sensors > On/Off window



- | | |
|-----------|--------------------------|
| 1 Sensors | 3 CO2 sensor |
| 2 On/Off | 4 CO2 sensor information |

¹ If the CO2 sensor entry is *not* displayed in the window, the option must be installed/activated. See Section 4.3.

2.2.3 Performing a zero calibration of the CO2 airway adapter

 **CAUTION**

- *Always perform zero calibration with the CO2 sensor (mainstream) or CO2 module (sidestream) connected to the airway adapter.*
- *Be sure NOT to cover both ends of the airway adapter with your fingers.*

Before proceeding, review the safety information in Chapter 1.

The CO2 airway adapter zero calibration compensates for optical differences between airway adapters and for sensor drift.

The mainstream CO2 sensors and sidestream CO2 module are calibrated at the factory. You must only zero calibrate the airway adapter, as described in this section.

Perform zero calibration according to the requirements listed in Table 2-2.

Table 2-2. CO2 airway adapter zero calibration requirements

CO2 measurement type	Perform a zero calibration ...
Mainstream	• With the first use of the sensor • CAPNOSTAT-5: When changing between airway adapter types (for example, from single use to reusable) • ProxyCo: When changing airway adapter • When the CO2 calibration needed alarm is generated
Sidestream	When the CO2 calibration needed alarm is generated

To perform zero calibration of the CO2 airway adapter

Calibration is performed in Standby, with the CO2 sensor/module and airway adapter connected to each other, disconnected from the breathing circuit and the patient.

1. Connect the CO2 sensor or module to the CO2 connection port on the ventilator (Figure 2-14).

If this is the first time the CO2 sensor/module is connected, wait at least two (2) minutes for the device to warm up.

2. Enable the CO2 sensor/module (Section 2.2.2).
3. Attach components as follows:

Mainstream: Connect the CO2 sensor to the airway adapter (Figure 2-15).

Sidestream: Insert the sampling cell into the CO2 module (Figure 2-16).

To ensure all CO2 is dissipated, wait two (2) minutes after removing the airway adapter from the patient breathing circuit set before starting the zero calibration.

Keep the components away from all sources of CO2, including the patient's and your own exhaled breath, as well as the ventilator exhaust port.

4. Touch  >  to open the Tests & calib window.

As an alternative, in the Standby window, touch **Preop check**.

5. Touch **CO2 sensor**.

Ensure there is no movement or vibration during zero calibration.

6. When the zero calibration is complete, verify that there is a checkmark  in the CO2 sensor checkbox.

Figure 2-14. Connect CO2 sensor to ventilator CO2 port

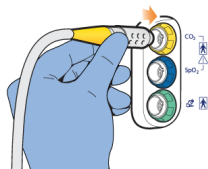


Figure 2-15. Connect CO2 sensor to airway adapter (mainstream)

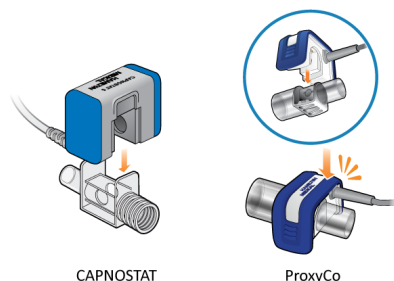
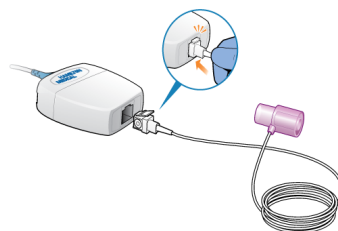


Figure 2-16. Insert sample cell into CO2 module (sidestream)



In case of zero calibration failure

If the zero calibration fails,  is displayed in the CO2 sensor checkbox. Perform the following checks, repeating the zero calibration after each one, until it is successful:

- Check the airway adapter and clean if necessary.
- If the zero calibration still fails, ensure there is no source of CO2 near the airway adapter.
- If the zero calibration still fails, connect a new airway adapter.
- If the zero calibration still fails, connect a new CO2 sensor (main-stream) or CO2 module (sidestream).

If the problem persists, have the ventilator serviced.

2.3 Verifying sensor measurements

When CO2 monitoring is enabled on the ventilator and the sensor is connected to the ventilator and breathing circuit, measurements recorded by the sensor are displayed in the Monitoring > CO2 window.

For a description of the CO2-related parameters, see Section 2.4.

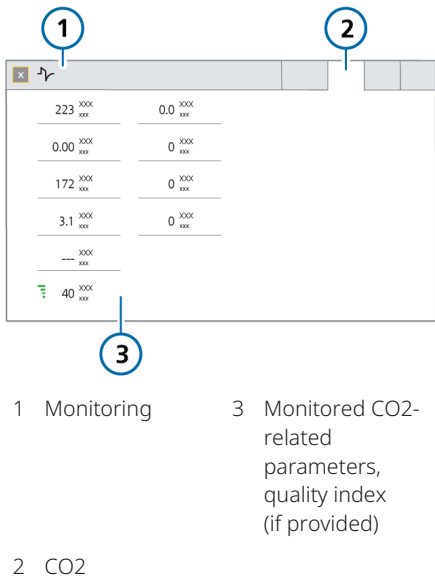
To verify that measurements are being recorded

1. Start ventilating the patient.
2. On the ventilator, touch  > CO2 (Figure 2-17).

Parameter values may take up to 30 seconds to be displayed.

If you do not see any CO2-related measurements, ensure that the CO2 sensor is enabled in the Sensors > On/Off window. See Section 2.2.2.

Figure 2-17. Capnography data, Monitoring window



2.4 About the CO2 monitoring parameters

The following table lists CO2-related monitoring parameters available when a CO2 sensor is connected and enabled. All parameter values are displayed in the Monitoring window (Section 2.5.2).

Monitored parameter values are either updated every breath or are time driven.

For parameter specifications, see

- Section 5.1 (ProxyCo)
- Section 6.1 (CAPNOSTAT-5)

Table 2-3. Monitoring parameters

Parameter (unit)	Definition
FetCO2 (%)	Fractional end-tidal CO2 concentration. Allows the assessment of PaCO2 (arterial CO2). Note that the measurement is inaccurate in cases of pulmonary embolism.
PetCO2 (mmHg)	End-tidal CO2 pressure. The maximum partial pressure of CO2 exhaled during a tidal breath (just before the start of inspiration). It represents the final portion of air that was involved in the exchange of gases in the alveolar area, thus providing a reliable index of CO2 partial pressure in the arterial blood under certain circumstances. PetCO2 does not reflect PaCO2 in the case of a pulmonary embolism. When PetCO2 is < 10, the quality index is red and the CO2 poor signal alarm is generated.
slopeCO2 (%CO2/l)	Slope of the alveolar plateau on the FCO2 / Volume curve.
Valv (l/min)	Alveolar minute ventilation. Allows the assessment of actual alveolar ventilation (as opposed to minute ventilation). $\text{Valv} * f$ (normalized to one (1) minute)

Parameter (unit)	Definition
$\dot{V}CO_2$ (ml/min)	CO2 elimination. Net exhaled volume of CO2 per minute. Permits assessment of metabolic rate (for example, it is high with sepsis) and treatment progress.
V_{Daw} (ml)	Airway dead space. Gives an effective, in-vivo measure of volume lost in the conducting airways. A relative increase in dead space points to a rise in respiratory insufficiency and can be regarded as an indicator of the current patient situation. Patients with high dead space values are at particular risk if the muscles also show signs of fatigue.
V_{Daw}/V_{TE} (%)	Airway dead space fraction at the airway opening.
$\dot{V}_{eCO_2}$ (ml)	Exhaled CO2 volume, updated breath by breath.
$\dot{V}_{iCO_2}$ (ml)	Inspired CO2 volume, updated breath by breath.
$\dot{V}_{talv}$ (ml)	Alveolar tidal ventilation. $V_{TE} - V_{Daw}$

2.5 Viewing CO2 capnography data

CO2-related data is readily available on the ventilator as follows:

View CO2-related data ...	See ...
On the main display (waveform and/or MMP)	Section 2.5.1
In the Monitoring window	Section 2.5.2
In a capnogram	Section 2.5.3
As a Trend graph	Section 2.5.4
As an SMP	Section 2.5.5

For a description of the parameters, see Section 2.4.

2.5.1 Viewing data on the main display

As with other parameters, any of the monitoring CO2 parameters can be configured as a main monitoring parameter (MMP). For configuration details, see your ventilator *Operator's Manual*.

Figure 2-18. Main display showing PetCO2 as MMP (1)



2.5.2 Viewing data in the Monitoring window

The Monitoring > CO2 window provides access to the capnography data. See Section 2.3.

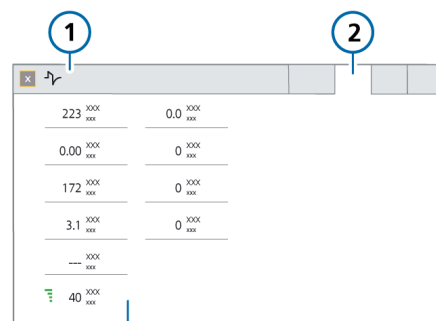
Sensor measurements are displayed on the ventilator using:

- Capnograms, both time based and volume based (single-breath CO2)
- CO2-related monitoring parameters

The quality index shows the sensor's evaluation of the signal quality. A low quality index indicates a poor signal due to interference from excessive motion or other cause.

For troubleshooting information when the quality index is poor, see Section 2.6.2.

Figure 2-19. Capnography data, Monitoring window



1 Monitoring

3 Monitored CO2-related parameters, quality index (if provided)

2 CO2

Table 2-4. Quality index display

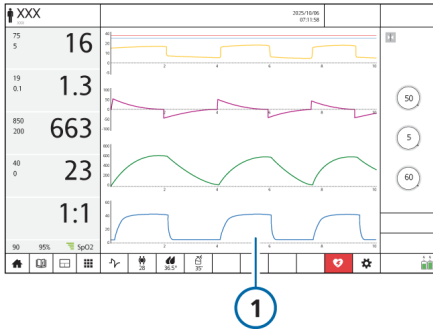
Quality indicator	Confidence value
4 gray (or blue) bars, no data 	OFF (no information).
1 red bar, poor quality 	The data from the sensor is not usable or the parameter measurement is still initializing.
2 orange bars, medium quality 	The data from the sensor is acceptable for most uses. An alarm may be active that could affect how accurately this parameter is currently measured.
3 green bars, good quality 	The data from the sensor is reliable.
4 green bars, best quality 	The data from the sensor is highly stable and reliable.

2.5.3 Reviewing the capnogram

A capnogram represents CO2 levels throughout a breath cycle. It can be time based or volume based. A volume-based capnogram is also referred to as a *single-breath CO2 curve*.

Time-based capnograms are available using the Waveform display option on supported ventilators.

Figure 2-20. Main display with capnogram (1)



To display the capnogram

1. Touch the area of the display where you wish to show the capnogram as described in your ventilator *Operator's Manual*.
The graphics selection window is displayed.
2. Touch the **Waveforms** tab, and then the **PCO2** or **FCO2** button.

The selected capnogram is displayed.

2.5.4 Viewing data as trends

You can view trend data for the following CO₂-related parameters: VDaw, slopeCO₂, Vtalv, VDaw/VTE, PetCO₂, FetCO₂, VeCO₂, ViCO₂, and V'CO₂.

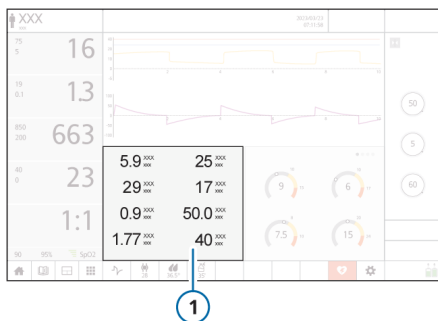
For details about viewing trend data, see your ventilator *Operator's Manual*.

2.5.5 Viewing data as an SMP

In Configuration, you can select the CO₂-related data to display in the Monitoring window.

For details, see the ventilator *Operator's Manual*.

Figure 2-21. Main display showing PetCO₂ as SMP (1)



2.6 Working with alarms

Operator-adjustable and nonadjustable alarms, together with a visual alarm indicator, help ensure your patient's safety. These alarms notify you of conditions that require your attention. They are categorized as high, medium, or low priority.

During an active CO2 alarm, the CO2-related parameter is displayed in the color corresponding to the associated alarm priority, together with a colored bar to the right of the parameter.

For the list of alarms, see Table 2-5.

See the ventilator *Operator's Manual* for details about reviewing and working with alarms.

To verify CO2-related alarms are operational

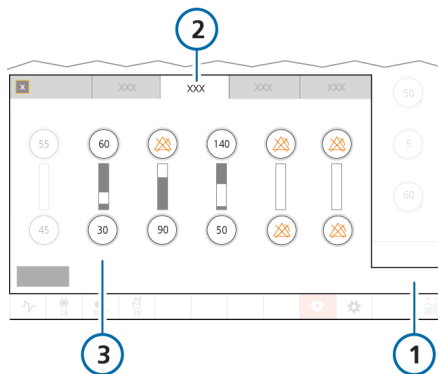
Check for the low-priority CO2 sensor warmup alarm during the first 30 seconds after connecting the sensor.

- ▶ If the alarm is not generated, disconnect and reconnect the sensor.

2.6.1 Setting alarm limits

CO2-related alarm limits are displayed in the Alarms > Limits 2 window.

Figure 2-22. Alarms > Limits 2 window



- | | |
|------------|-----------------------|
| 1 Alarms | 3 PetCO2 alarm limits |
| 2 Limits 2 | |

2.6.2 CO2-related alarms troubleshooting

Table 2-5 lists alarm messages displayed by the ventilator, along with their definitions and suggested corrective actions.

These corrective actions are sequenced to correct the most probable issue or to present the most efficient corrective action first. The proposed actions, however, may not always correct the particular problem.

If your issue is not resolved after performing the recommended tasks, contact your Hamilton Medical authorized service personnel.

Table 2-5. CO2-related alarms, priority, and corrective actions

Alarm	Definition	Action needed
Check CO2 airway adapter	<i>Low priority.</i> Adapter disconnection, optical block, or adapter type changed. Alarm delay: 1 second	• Check patient condition. • Check the airway adapter for excess moisture accumulation / contamination by secretions. • Replace / perform zero calibration on airway adapter.
Check CO2 sampling line	<i>Low priority.</i> The CO2 sidestream sensor sampling line is occluded by water. Alarm delay: 1 second	• Check patient condition. • Replace sampling line.
CO2: Poor signal	<i>Low priority.</i> The CO2 sensor signal quality is poor. Alarm delay: 60 seconds	• Check patient condition. • Check CO2 sensor and adapter connections. • Ensure that airway adapters are not in a horizontal position relative to the floor to reduce accumulation of patient secretions. If accumulation occurs, remove the adapter, rinse with sterile water, and reconnect. <i>Do not</i> rinse and reconnect adapter if it is designated as single-use.
CO2 calibration needed	<i>Low priority.</i> A previous sensor zero calibration failed. Alarm delay: 1 second	Perform the following checks, repeating the calibration after each one, until calibration is successful: • Clean or replace airway adapter. • Perform a zero calibration of the sensor, making sure there is no source of CO2 near the airway adapter. • Replace the airway adapter. • Replace the CO2 sensor. • If the problem persists, have the ventilator serviced.

Alarm	Definition	Action needed
CO2 sensor disconnected	<i>Low priority.</i> The CO2 module is installed, but there is no signal from the CO2 sensor. CO2 monitoring is enabled. Alarm delay: 6 seconds	• Make sure a CO2 sensor is connected. • Check CO2 sensor connections (CO2 sensor cable to module, CO2 module to ventilator). • Replace the CO2 sensor. Make sure the sensor is a genuine Hamilton Medical part. • If the problem persists, have the ventilator serviced.
CO2 sensor faulty	<i>Low priority.</i> The CO2 sensor signal indicates a hardware error or a third-party sensor is installed. Alarm delay: 1 second	• Disconnect the sensor from the CO2 module. Wait a few seconds, and reconnect. • Perform a zero calibration of the sensor. Ensure the sensor is attached to the airway adapter during zero calibration. • Replace the CO2 sensor. Make sure the sensor is a genuine Hamilton Medical part. • If the problem persists, have the ventilator serviced.

Alarm	Definition	Action needed
CO2 sensor over temperature	<i>Low priority.</i> The temperature at the CO2 sensor is too high. Alarm delay: 1 second	⚠ CAUTION! <i>Do not place the CO2 sensor directly on the patient's skin; ensure a cloth barrier is between the sensor and skin at all times. The sensor can reach temperatures exceeding 43°C (109°F), depending on ambient temperature.</i> • Check whether the sensor is affected by an external heating source. • Remove the sensor from the airway, and disconnect the sensor from the CO2 module. Reconnect. • Verify that system is running within the specified environmental conditions. Check for excessive airway temperature, which could be caused by defective humidifier, heater wire, or probe.
CO2 sensor warmup	<i>Low priority.</i> The CO2 operating temperature has not yet been reached or is unstable. Alarm delay: 1 second	Wait for the sensor to warm up (approx. 2 minutes).
PetCO2 high	<i>Medium priority.</i> PetCO2 exceeds the set alarm limit. Alarm delay: 2 or 3 consecutive breaths	• Check patient condition. • Check and confirm settings, including alarms.
PetCO2 low	<i>Medium priority.</i> PetCO2 is below the set alarm limit. Alarm delay: 2 or 3 consecutive breaths	• Check patient condition. • Check the breathing circuit and flow sensor/artificial airway of the patient for leaks. • Check airway adapter and replace if necessary. • Check and confirm settings, including alarms.

3

Maintenance

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3.1 Safety information

The following sections provide safety information related to cleaning/disinfection of the CO2 sensor and airway adapters.

For additional device cleaning, disinfection, and maintenance information, refer to the ventilator *Operator's Manual*.

3.1.1 General maintenance, surface cleaning, and disinfection safety information

WARNING

- Reprocessing of single-use CO2 airway adapters can affect the product properties and may cause injury to the patient. For example, a change to the surface structure during reprocessing may lead to a change in the tear strength or cause actual cracking. Furthermore, an altered surface structure may result in a microbial aggregation of spores, allergens and pyrogens, for example, or cause an increase in the number of particles released as a result of chemical changes in the material properties.
- Hamilton Medical does *not* assume any liability for the proper functioning of single-use items if they are reprocessed and reused by the user.
- Performance is not guaranteed if an item labeled as single use is reused.
- To reduce the risk of fire and electric shock, before cleaning and disinfecting components, always disconnect the CO2 sensor from electrical power and the patient, and ensure it has cooled down to room temperature.
- To prevent premature deterioration of parts, ensure the disinfecting chemical is compatible with the part material. Use only registered/ approved cleaning and disinfection solutions, as approved by your institution's protocol, after each patient use, according to the cleaning agent manufacturer's recommendations. See Table 3-1.
- To prevent patient exposure to sterilizing agents, sterilize parts using only the techniques recommended in Chapter 3 and in any associated Reprocessing guide or Instructions for use provided with each part.
- Do *not* clean or perform maintenance/service on any components while a patient is connected. As sanitation practices vary among institutions, Hamilton Medical cannot provide specific practices that will meet all needs, nor be responsible for the effectiveness of these practices.
- Do *not* sterilize the CO2 sensor.
- Do *not* immerse the CO2 sensor in liquid.

- Keep all fluids away from any electrical connections.
- Do *not* pour or spray fluids onto the device surfaces. Intrusion of fluids, or immersing parts in fluids, will damage the device.
- Follow the cleaning and disinfecting procedures for the CO2 sensor as described in this guide, and in the cleaning agent manufacturer's *Instructions for Use*.
- Clean the components using only the approved cleaning and disinfection agents listed in Table 3-1 before and after each patient use, or according to your institution's protocols.

CAUTION

- *Incorrect concentrations or residence times of sterilization agents may lead to bacterial resistance.*
- *Clean parts after each patient use. See Table 3-1.*
- *Do NOT use abrasives materials (for example, steel wool or silver polish), hard brushes, pointed instruments, or rough materials on surfaces.*
- *Cleaning and disinfection methods that are not validated could cause blemishes and fine cracks.*
- *Do NOT attempt service procedures other than those specified in the ventilator's Service Manual.*
- *To ensure proper servicing and to prevent possible physical injury, only Hamilton Medical authorized service personnel may service the therapy device, using information provided in the ventilator's Service Manual.*

3.1.1.1 LoFlo components cleaning and disinfection safety information

CAUTION

- *To reduce the risk of infection, the module must be cleaned and disinfected between patients.*
- *Disconnect module and cool to room temperature before cleaning.*
- *Use only approved cleaners or disinfectant. Do not immerse or sterilize.*
- *Improper cleaning techniques can potentially lead to cross-contamination.*
- *Keep cleaners and disinfectant away from the sample cell receptacle and connectors.*
- *Do not pull or stretch the cable while cleaning and disinfecting.*

NOTICE

- Wear personal protective gear when cleaning and disinfecting the module.
- Do *not* pour liquids on the module while cleaning and disinfecting. Wipe around, not over, module ports.
- The module and windows must be clean and completely dry before reuse.

3.2 Cleaning and disinfecting the components

The CO2 sensor set must be regularly cleaned and disinfected using the cleaning methods and solutions specific to the individual component.

Cleaning/disinfection agents are tested as a specific composition of different chemicals by our certified laboratory to validate their materials compatibility and cleaning/disinfection efficacy. See Section 3.2.1.

Other surface cleaning/disinfection agents are used at your own risk. Hamilton Medical is not responsible for damages, incidents, or adverse events due to the use of any cleaning/disinfection agents that are not listed in Section 3.2.1.

3.2.1 Approved cleaning/disinfection agents

NOTICE

Use of cleaning and disinfectant wipes based on propanol, isopropylalcohol, and/or isopropanol may cause marginal color change in some materials. Marginal color change on its own is not an indicator of product malfunction.

Table 3-1. Approved cleaning/disinfection wipes for the CO2 sensors

Cleaning/ disinfection wipe	Contact time (min)
EPA-registered cleaning/disinfection wipe	
CaviWipes 2.0	2
Approved cleaning/disinfection wipe	
Incidin OxyWipes S	2
CaviWipes 2.0	2
mikrozid® universal wipes green line	1
Environmental Cross V-Lock	3

3.2.2 CO2 sensor, sensor holder, and cable cleaning and disinfection

Carefully follow the instructions provided here to clean/disinfect the components.

To surface clean a component

Surface clean each component before and after each patient use, or according to your institution's protocols.

1. Unfold a clean disposable cleaning and disinfectant wipe (from Table 3-1), and wipe off visible soil from the component surface.
2. Wet all surfaces, working from top to bottom, from clean to dirtier areas, in an S-shaped fashion.
Should your wipe dry out or become soiled, replace it with a new wipe to complete the area.
Ensure the surface is visually free of soil.
Do *not* overuse the wipe.
3. Dispose of the wipe.

To surface disinfect a component

After cleaning the surface as instructed previously, do the following.

1. Wipe cleaned surfaces again, until visibly wet, with a cleaning and disinfectant wipe listed in Table 3-1.
2. Dispose of the wipe.
3. Wait for the contact time of your chosen wipe.

4. Wait until the surfaces are dry.
5. Check the surfaces for visible damage.
If there is any damage, contact your Hamilton Medical technical representative.
6. After use of the wipes, ensure their packaging lid is firmly sealed.

3.3 Single-use (SU) CO2 airway adapters

Do *not* clean, soak or wash the single-use airway adapter.

Replace the product in accordance with your hospital infection control procedures and/or depending on the patient's secretions.

A single-use airway adapter can be used continuously on a single patient for a maximum of seven (7) days.

3.4 Reusable (RU) CO2 airway adapters

Reusable airway adapters are available for use with the CAPNOSTAT-5 CO2 sensor.

For reprocessing information, as well as specifications, refer to the manufacturer's instructions for use.

3.5 Preventive maintenance

The CO2 sensor is end-user maintenance free.

3.6 Disposal

Used components must be handled as contaminated. Follow all local, state, and federal regulations with respect to waste management and environmental protection when disposing of used parts.

4

Configuration

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4.1 Overview

Working with CO2 measurement on the ventilator requires the following configuration steps.

To ...	See ...
Access Configuration mode	Section 4.2
Activate the CO2 option in Configuration	Section 4.3
Select the sensor type in Configuration	Section 4.4
Enable the CO2 sensor for use during ventilation	Section 2.2.2

4.2 Accessing Configuration mode

You can access all Configuration mode settings when the ventilator is in Standby. Access requires a configuration code; contact your administrator.

To access Configuration mode

1. Touch  > .
2. Using the keys on the onscreen keypad, type the configuration code; then touch **Enter**.
The **Configuration** button is enabled.
3. Touch **Configuration**.

The Configuration window opens, displaying the General window.

You can now define settings and add options.

4.3 Activating the CO2 hardware option

CO2 communication board-related functions are activated at three levels:

- The hardware itself must be activated in configuration to make the functionality available to the user, described in this section.
- The sensor type you are using (ProxyCo or CAPNOSTAT-5/LoFlo) must be specified. See Section 4.4.
- Sensors that plug into the hardware are individually enabled by the user, as needed, in the System window. See Section 2.2.2.

To activate hardware options in Configuration

1. Touch **Options**.
2. In the Options window, touch the **HW options** tab.
The window lists hardware that requires activation.
3. Select the checkbox for options to activate.
A green checkmark indicates the option is activated.

The next step is to select the sensor type to use, as described in Section 4.4.

Upon exiting Configuration, the activated hardware is available for use.

4.4 Selecting the sensor type

The CO2 communication board must be enabled for the **Sensors** button to be available (Section 4.3).

In Configuration, you can select the desired sensor type.

To select the sensor type

1. In the Configuration window, touch **Sensors**.
2. Touch the **CO2** tab, if not already selected.
3. Touch the appropriate button for your CO2 sensor:
 - **CAPNOSTAT-5/LoFlo**
 - **ProxyCo**

You can now set the sensor acquisition settings appropriate for your device.

Upon exiting Configuration, the activated hardware is available for use.

5

Specifications: ProxyCo

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5.1 Parameter specifications

Table 5-1. ProxyCo monitored parameters, ranges, and accuracy

Parameter (units)	Range: Adult/Ped.	Range: Neonatal	Accuracy ¹
CO2 related²			
FetCO2 (%)	0-20	0-20	CO2 accuracy (in volume percent): ± (0.43% + 8% of gas level)
PetCO2 (mmHg)	0-165	0-165	
slopeCO2 ^{3,4} (%CO2/l)	0-99.9	0-99.9	--
Vtalv ^{3,4} (ml)	0-9999	0-9999	±10% or ±10 ml, whichever is greater
V'alv ^{3,4} (l/min)	0-20	0-20	±10% or ±0.3 l/min, whichever is greater
V'CO2 ^{3,4} (ml/min)	0-9999	0-9999	±10% or ±0.3 l/min, whichever is greater
VDaw ^{3,4} (ml)	0-999	0-999	±10% or ±10 ml, whichever is greater
VDaw/VTE ^{3,4} (%)	0-100	0-100	±10% or ±10 ml, whichever is greater
VeCO2 ^{3,4} (ml)	0-999	0-999	±10% or ±10 ml, whichever is greater
ViCO2 ^{3,4} (ml)	0-999	0-999	±10% or ±10 ml, whichever is greater

¹ The stated accuracy includes the tolerance interval for each measurement, except for measurements displayed from external sensors (CO2). See the Accuracy testing section in your ventilator *Operator's Manual* for details.

² Only available if the CO2 communication board is installed and the CO2 sensor is enabled.

³ Only for mainstream CO2.

⁴ All CO2-related values are displayed as dashes (--).

5.2 Alarm specifications

Table 5-2. Adjustable CO2-related alarm priority, range, defaults, and resolution

Alarm (units)	Priority	Range: Adult/Ped.	Range: Neonatal	Default	Resolution
PetCO2 (high) (mmHg)	Medium	11–100 / Off	11–100 / Off	60	1
PetCO2 (low) (mmHg)	Medium	Off / 10–99	Off / 10–99	30	1

5.3 Technical specifications

The following sections provide the technical specifications for the components.

Table 5-3. Technical performance data, ProxyCo CO2 sensor

Description	Specification
Sensor type:	Mainstream
Principle of operation:	Nondispersive infrared (NDIR) technology
Type of operation:	Continuous
Classification, according to IEC 60601-1:	Transportable Class II ME equipment
Insulation:	Applied part of type BF
CO2 measurement range:	0 to 220 hPa (0 to 165 mmHg) partial pressure
CO2 accuracy (in volume percent):	± (0.43% + 8% of gas level)
CO2 resolution:	0.1 hPa (0.07 mmHg)
Initialization time (time from turning on device to operating performance):	Full specifications within two (2) minutes; capnogram displayed within 30 seconds
Response time (sensor):	< 80 ms
Sampling rate:	PCO2: 100 Hz etCO2: 1 Hz
Flow rate:	0 to 260 l/min
Respiration rate range:	0 to 150 b/min
Dead space, airway adapter Adult/pediatric:	≤ 5.0 ml
Dead space, airway adapter Neonatal with flow sensor (PN 155500):	3.8 ml

Description	Specification
Compensation (using values provided by ventilator):	• Ambient pressure compensation • FiO2 compensation • Heliox compensation
Maximum housing temperature:	43°C (109°F) with ambient temperature up to 35°C (95°F)
Data output:	Measurement data and sensor status using a proprietary protocol
Data transmission protocol:	Proprietary protocol over a serial RS-232 connection. The nominal data rate is 38,400 baud.
Voltage requirements:	+ 5.00 VDC ± 5%
Power rating, total consumption:	0.7 W typical, steady state
Power loss:	After a power loss, the sensor restarts operation with the previous calibration values. The warm-up period is reset.
Usage time (airway adapter) PN 10083174, 10100344:	Seven (7) days maximum continuous use on a single patient
Lifetime (sensor) PN 10169182, 10169159:	5 years (44,000 hours)
Shelf life (airway adapter) PN 10083174, 10100344:	5 years

5.4 Influence of interfering gases

Influence on the measurement of 5% exhaled CO2 with a listed interfering gas present.

Table 5-4. Influence of interfering gases on the ProxyCo CO2 sensor measurements

Interfering gas and gas level	Relative influence on measured value
Isoflurane 5%	< 15% increase
Sevoflurane 5%	< 2% decrease
Norflurane 5% (as MDI propellant only)	< 2% decrease
Ethanol 0.1%	< 1% decrease
Isopropanol 0.1%	< 1% decrease
Acetone 0.1%	< 1% decrease
Methane 1%	< 1% decrease

5.5 Residual Risks

This product has been developed in accordance with Regulation (EU) 2017/745 and has undergone a detailed evaluation concerning its safety and effectiveness. All known risks have been mitigated with appropriate measures in accordance with ISO 14791.

It is recommended to periodically use blood gas analysis (BGA) to verify plausibility of the measured values and support clinical decision-making.

6

Specifications: Respironics

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6.1 Parameter specifications

Table 6-1. CAPNOSTAT-5 monitored parameters, ranges, and accuracy

Parameter (units)	Range: Adult/Ped.	Range: Neonatal	Accuracy ¹
CO2 related²			
FetCO2 (%)	0–20	0–20	CO2 (BTPS): 0–40 mmHg: ± 2 mmHg 41–70 mmHg: $\pm 5\%$ of reading 71–100 mmHg: $\pm 8\%$ of reading ³ 101–150 mmHg: $\pm 10\%$ of reading For sidestream CO2 sensor above 80 b/min: $\pm 12\%$ of reading
PetCO2 (mmHg)	0–150	0–150	
slopeCO2 ^{3,4} (%CO2/l)	0–99.9	0–99.9	--
Vtalv ^{3,4} (ml)	0–9999	0–9999	$\pm 10\%$ or ± 10 ml, whichever is greater
V'alv ^{3,4} (l/min)	0–20	0–20	$\pm 10\%$ or ± 0.3 l/min, whichever is greater
V'CO2 ^{3,4} (ml/min)	0–9999	0–9999	$\pm 10\%$ or ± 0.3 l/min, whichever is greater
VDaw ^{3,4} (ml)	0–999	0–999	$\pm 10\%$ or ± 10 ml, whichever is greater
VDaw/VTE ^{3,4} (%)	0–100	0–100	$\pm 10\%$ or ± 10 ml, whichever is greater
VeCO2 ^{3,4} (ml)	0–999	0–999	$\pm 10\%$ or ± 10 ml, whichever is greater
ViCO2 ^{3,4} (ml)	0–999	0–999	$\pm 10\%$ or ± 10 ml, whichever is greater

¹ The stated accuracy includes the tolerance interval for each measurement, except for measurements displayed from external sensors (CO2). See the Accuracy testing section in your ventilator *Operator's Manual* for details.

² Only available if the CO2 communication board is installed and the CO2 sensor is enabled.

³ Only for mainstream CO2.

⁴ All CO2-related values are displayed as dashes (--).

6.2 Alarm specifications

Table 6-2. Adjustable CO2-related alarm priority, range, defaults, and resolution

Alarm (units)	Priority	Range: Adult/Ped.	Range: Neonatal	Default	Resolution
PetCO2 (high) (mmHg)	Medium	11–100 / Off	11–100 / Off	60	1
PetCO2 (low) (mmHg)	Medium	Off / 10–99	Off / 10–99	30	1

6.3 Technical specifications

Table 6-3. Technical performance data, CAPNOSTAT-5 mainstream sensor

Description	Specification
Sensing position:	Mainstream
Principle of operation:	Nondispersive infrared (NDIR) technology
Measurements:	See Table 6-1
Total system response time:	≤ 1 second
Rise time:	< 60 ms
Initialization time:	Capnogram displayed in < 15 seconds at an ambient temperature of 25°C, full specifications within 2 minutes
Sampling frequency:	100 Hz
CO2 calculation method:	BTPS
CO2 stability ¹ :	Short-term drift: ≤ 0.8 mmHg over 4 hours Long-term drift: Accuracy specification maintained over 120 hours
CO2 noise (rms):	≤ 0.25 mmHg at 7.5% CO2
Operating conditions:	Temperature: 0°C to 45°C (32°F to 113°F) Humidity: 10% to 90% relative humidity, noncondensing Pressure (barometric + airway pressure): 400 mmHg to 850 mmHg
Storage conditions:	Temperature: -40°C to 70°C (-40°F to 158°F) Humidity: < 90% relative humidity, noncondensing Pressure (atmospheric): 375 mmHg to 795 mmHg

¹ Neither humidity (noncondensing) nor cyclical pressures have any effect on the stated accuracy of the device.

Table 6-4. Technical performance data, LoFlo sidestream sensor

Description	Specification
Sensing position:	Sidestream
Principle of operation:	Nondispersive infrared (NDIR) technology
Measurements:	See Table 6-1
Total system response time:	< 4 seconds
Rise time:	200 ms for on-airway adapter kits Additional 30 ms for sidestream sampling cannulas. Additional 80 ms for extension line and dehumidification tubing.
Initialization time:	Capnogram displayed in < 20 seconds at an ambient temperature of 25°C, full specifications within 2 minutes
Accuracy	0–40 mmHg $\pm$ 2 mmHg 41–70 mmHg $\pm$ 5% of reading 71–100 mmHg $\pm$ 8% of reading 101–150 mmHg $\pm$ 10% of reading Above 80 bpm $\pm$ 12% of reading
Sampling frequency:	100 Hz
Gas sampling rate:	50 ml/min $\pm$ 10 ml/min
CO2 calculation method:	Actual, corrected for temperature and pressure in the sample cell
CO2 stability ¹ :	Short-term drift: $\leq$ 0.8 mmHg over 4 hours Long-term drift: Accuracy specification maintained over 120 hours
CO2 noise (rms):	$\leq$ 0.25 mmHg at 5% CO2
Operating conditions:	Temperature: 0°C to 40°C (32°F to 104°F) Humidity: 10% to 90% relative humidity, noncondensing Pressure (barometric + airway pressure): 400 mmHg to 800 mmHg
Storage conditions:	Temperature: -40°C to 70°C (-40°F to 158°F) Humidity: 10% to 90% relative humidity, noncondensing Pressure (atmospheric): 400 mmHg to 800 mmHg

¹ Neither humidity (noncondensing) nor cyclical pressures have any effect on the stated accuracy of the device.

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For more information
www.hamilton-medical.com



HAMILTON
MEDICAL



Hamilton Medical AG
Via Crusch 8, 7402 Bonaduz, Switzerland
☎ +41 (0) 58 610 10 20
info@hamilton-medical.com
www.hamilton-medical.com



medin Medical Innovations GmbH
Adam-Geisler-Straße 1
DE – 82140 Olching
Germany