

End Tidal Carbon Dioxide (EtCO₂)

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END-TIDAL CARBON DIOXIDE (EtCO₂)

General Information

Product Description

M Series™ units, equipped with software revision 38.25 or higher, and M Series CCT units, equipped with software revision 57.50 or higher, support two End Tidal Carbon Dioxide (EtCO₂) monitoring options for the continuous measurement of respiratory carbon dioxide (CO₂) and respiration rate. These options use the same connector on the M Series unit and may be used interchangeably.

The first option uses a unique mainstream, solid-state infrared sensor called the CAPNOSTAT® 3 Mainstream CO₂ sensor. The CAPNOSTAT 3 sensor is attached to an airway adapter that connects to an endotracheal (ET) tube or other airway and measures gases flowing through these breathing circuit components. A disposable mouthpiece may be connected to the adapter for monitoring non-intubated patients. A Capno₂mask is also available for use with non-intubated patients. This option provides for O₂ delivery while monitoring expired CO₂.

The second option is a sidestream sampling system called the LoFlo™ Sidestream CO₂ Module. The LoFlo module contains a gas sampling pump, which draws small samples of gas from the patient's airway via a nasal/oral cannula or airway adapter, and passes these gases through a solid state infrared sensor (located away from the patient's airway) that measures CO₂. While the sidestream system is typically used on non-intubated patients, it can also be used for EtCO₂ measurement on intubated infant, pediatric, and adult patients. The sidestream system should not be used, however, on intubated patients who cannot tolerate the 50ml/min removal of the sample gases from their breathing circuit. The sidestream module uses specially designed sampling cannulae and airway adapters for sampling airway gases and passing them through an integrated sample cell, which connects to the LoFlo Module's CO₂ sensor. These cannulae incorporate a filter and sample cell, providing maximum filtration of fluids and contaminants, and protecting the system from aspiration of these fluids.

In both systems, the CO₂ sensor generates infrared light and beams it through the airway adapter or sample cell to a detector on the opposite side. CO₂ from the patient, flowing through the mainstream airway adapter or aspirated into the sample cell, absorbs some of this infrared energy. The M Series unit determines CO₂ concentration in the breathing gases by measuring the amount of light absorbed by gases flowing through the airway or sample cell.

The M Series unit displays EtCO₂ (the concentration of carbon dioxide detected at the end of each exhalation) as a numerical value in millimeters of mercury (mmHg), percent (%), or kilopascals (kPa). In addition, the unit can display a capnogram waveform. This waveform is a valuable clinical tool that can be used to assess patient airway integrity and proper endotracheal (ET) tube placement. The unit calculates respiration rate by measuring the time interval between detected peaks of the CO₂ waveform. The technology differentiates between waveforms caused by breathing and those caused by cardiogenic oscillations and artifact.

How to Use This Manual

This section explains how to set up and use the M Series End-Tidal Carbon Dioxide option. Important safety information relating to general use of the M Series End Tidal Carbon Dioxide monitor appears in the "Safety Considerations" section of this manual.

The *M Series Operator's Guide* provides information operators need for the safe and effective use and care of the M Series unit. It is important that persons using this device read and understand all the information contained therein.

Please thoroughly read both safety considerations and warnings sections before operating your M Series unit.

All CAPNOSTAT 3, LoFlo, airway adapter and cannula questions with regards to the Declaration of Conformity with European Union Directives should be directed to the authorized representative for Respiration Novamatrix LLC:

Respiration Novamatrix LLC
Authorized European Contact

Respiration Deutschland
Gewerbestr. 17
82211 Herrsching
Germany
+49 8152 93060

Safety Considerations

WARNINGS

General

- Carefully read the *M Series Operator's Guide* and these operating instructions before operating the EtCO₂ monitoring option.
- Ensure that the M Series EtCO₂ option is operated by qualified personnel only.
- Do NOT use the M Series EtCO₂ option as an apnea monitor.
- Do NOT immerse the M Series unit, patient cables or sensors in water, solvents, or cleaning solutions.
- If the accuracy of any reading is suspect, first check the patient's vital signs by alternate means and then check the M Series EtCO₂ option for proper operation.
- If an alarm condition occurs while the alarms are suspended, the suspended alarm indications will only be visual displays and symbols. No audio alarm indications will occur.
- To ensure patient safety, ensure that the ECG-out jack and modem (if available) are only connected to other equipment with galvanically isolated circuits.
- Elevated oxygen levels, nitrous oxide or halogenated agents contained in the breathing gases may degrade the accuracy of measurements made with the M Series EtCO₂ option. Activate oxygen compensation if O₂ levels in excess of 60% are introduced. Activate N₂O compensation if nitrous oxide is introduced into the airway circuit. The presence of Desflurane beyond 5% may positively bias the carbon dioxide reading by up to 3 mmHg.
- Do NOT use the LoFlo module on patients who cannot tolerate the removal of 50ml/min from the airway.
- Carefully route patient cabling and gas sampling tubes to reduce the possibility of patient entanglement or strangulation.
- Do not touch the bed, patient, or any equipment connected to the patient during defibrillation. A severe shock can result. Do not allow exposed portions of the patient's body to come in contact with metal objects, such as a bed frame, as unwanted pathways for defibrillation current may result.

CAPNOSTAT 3 and LoFlo Sensor and Accessories

- Always ensure the integrity of the patient breathing circuit after insertion of the mainstream or sidestream airway adapter by verifying a proper CO₂ waveform (capnogram) on the monitor display.
- Do NOT use CAPNOSTAT 3 or LoFlo sensors in the presence of flammable anesthetics or other flammable gases.
- Do not attempt to open the sensor. An electrical shock hazard exists internally. Refer servicing to qualified personnel.

CAUTIONS

- CAUTION: Federal (U.S.A.) law restricts this device to sale, or use by or on the order of a licensed medical practitioner.
- Use only ZOLL/Respironics Novamatrix CAPNOSTAT 3 sensors and LoFlo modules, airway adapters, nasal and nasal/oral cannulae with the M Series EtCO₂ option.
- The device is protected against interference from radio frequency emissions typical of two-way radios and cellular phones (digital and analog) used in emergency service/public safety activities. Users should assess the device's performance in their typical environment of use for the possibility of radio frequency interference from high-power sources. Radio Frequency Interference (RFI) may be observed as shifts in monitor baseline, trace compression, display brightness changes or transient spikes on the display.
- Do NOT sterilize or immerse the CAPNOSTAT 3 sensor or LoFlo module.
- Do NOT reuse or sterilize the disposable airway adapter, airway adapter with mouthpiece, Capno₂mask, nasal or nasal/oral sampling cannulae, or airway adapters, as system performance will be compromised. These items are intended for single patient use only.
- Do NOT use a damaged sensor or airway adapter.
- Do NOT use the device if it fails to operate properly.
- Do NOT place the mainstream or sidestream airway adapters between the ET tube and the breathing circuit elbow, as this may allow patient secretions to accumulate in the adapter.
- Position mainstream airway adapters with windows in a vertical, NOT a horizontal, position. This helps keep patient secretions from pooling on the windows.
- Do NOT insert any object other than the sample cell into the sample cell receptacle on the LoFlo module.
- ZOLL Medical Corporation recommends that the CAPNOSTAT 3 airway adapter be removed from the circuit whenever aerosolized medication is delivered. The increased viscosity of the medications may contaminate the adapter windows, requiring premature cleaning or replacement of the adapter.
- In order to eliminate the potential buildup of CO₂ inside the storage bag, ensure that the LoFlo module exhaust tube vents gasses away from the module environment.
- To avoid injury to the patient, remove the nasal/oral cannula from the patient before cutting the oral cannula tip.
- Do NOT apply tension to the sensor or module cable.
- Periodically inspect the sampling tubing for kinks.
- Monitor the capnogram for an elevated baseline. If an elevated baseline is observed, verify patient condition first. If the care giver determines that the patient condition is not contributing to the elevated baseline, follow the instructions for zeroing the sensor or module detailed in this manual.
- Do NOT store sensors, modules, airway adapters, or cannulae at temperatures less than -10° C or greater than 55° C.
- Do not operate sensors or modules at temperatures less than 10° C or greater than 40° C.
- Refer servicing to qualified personnel.
- Do not use the LoFlo module with M Series units that have a software version lower than 38.25, or with M Series CCT units that have a software version lower than 57.50.
- Make sure to insert the protective cap into the LoFlo module when it is not in use.

Warranty (U.S. Only)

(a) ZOLL Medical Corporation warrants to the original equipment purchaser that beginning on the date of installation, or thirty (30) days after the date of shipment from ZOLL Medical Corporation's facility, whichever first occurs, the equipment (other than accessories and electrodes) will be free from defects in material and workmanship under normal use and service for the period of one (1) year. During such period ZOLL Medical Corporation will, at no charge to the customer, either repair or replace (at ZOLL Medical Corporation's sole option) any part of the equipment found by ZOLL Medical Corporation to be defective in material or workmanship. If ZOLL Medical Corporation's inspection detects no defects in material or workmanship, ZOLL Medical Corporation's regular service charges shall apply. (b) ZOLL Medical Corporation shall not be responsible for any equipment defect, the failure of the equipment to perform any function, or any other nonconformance of the equipment, caused by or attributable to: (i) any modification of the equipment by the customer, unless such modification is made with the prior written approval of ZOLL Medical Corporation; (ii) the use of the equipment with any associated or complementary equipment, (iii) installation or wiring of the equipment other than in accordance with ZOLL Medical Corporation's instructions, (iv) abuse, misuse, neglect or accident. (c) This warranty does not cover items subject to normal wear and burnout during use, including but not limited to lamps, fuses, batteries, patient cables and accessories. (d) The foregoing warranty constitutes the exclusive remedy of the customer and the exclusive liability of ZOLL Medical Corporation for any breach of any warranty related to the equipment supplied hereunder. (e) Limitation of Liability: ZOLL shall not in any event be liable to Purchaser, nor shall Purchaser recover, for special, incidental or consequential damages resulting from any breach of warranty, failure of essential purpose, or under any other legal theory including but not limited to lost profits, lost savings, downtime, goodwill, damage to or replacement of equipment and property, even if ZOLL has been advised of the possibility of such damages.

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For additional information, please call ZOLL Medical Corporation at 1-800-348-9011. International customers should call the nearest authorized ZOLL Medical Corporation service center.

Software License

Read this Operator's Manual and License agreement carefully before operating any of the M Series products.

Software incorporated into the system is protected by copyright laws and international copyright treaties as well as other intellectual property laws and treaties. This software is licensed, not sold. By taking delivery of and using this system, the Purchaser signifies agreement to and acceptance of the following terms and conditions:

1. **Grant of License:** In consideration of payment of the software license fee which is part of the price paid for this product ZOLL Medical Corporation grants the Purchaser a non-exclusive license, without right to sublicense, to use the system software in object-code form only.
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EtCO₂ Indications for Use

The ZOLL M Series EtCO₂ option is indicated for the continuous noninvasive monitoring of end tidal carbon dioxide (EtCO₂) and respiration rate in patients requiring ventilator support, transport, or anesthesia. The M Series EtCO₂ option with Respironics Novamatrix technology supports two methods for continuous measurement of end tidal carbon dioxide (EtCO₂) and respiration rate.

The first method uses the CAPNOSTAT 3 Mainstream CO₂ Sensor attached to an airway adapter that connects to an endotracheal tube, mask or disposable mouthpiece.

The second method uses the LoFlo Sidestream CO₂ Module to monitor both non-intubated and intubated patients using specially designed sampling cannulae and airway adapters.

The M Series EtCO₂ option is designed to monitor adult, pediatric, and neonatal patients.

The following substances can influence CO₂ measurements made with the CAPNOSTAT 3 Sensor:

- elevated oxygen levels
- nitrous oxide
- halogenated agents

The M Series EtCO₂ option allows the user to enable high oxygen and/or nitrous oxide compensation. Halogenated anesthetic agents alter CO₂ readings, but the M Series unit will monitor CO₂ within specifications when these agents are present at normal clinical levels. The presence of Desflurane in the exhaled breath beyond normal values (5-6%) may positively bias measured carbon dioxide values by up to an additional 2-3 mmHg.

The M Series EtCO₂ option is intended for use only with the ZOLL/Respironics Novamatrix CAPNOSTAT 3 Mainstream CO₂ sensor and the LoFlo Sidestream CO₂ Module, mainstream airway adapters, nasal and nasal/oral sampling cannulae, and sidestream on-airway adapters.

Mainstream EtCO₂ Setup

There are several steps involved with mainstream EtCO₂ setup, as follows:

- Attaching the CAPNOSTAT 3 sensor cable.
- Selecting a mainstream airway adapter.
- Attaching the airway adapter to the CAPNOSTAT 3 sensor.
- Zeroing the mainstream sensor/airway adapter.
- Attaching the airway adapter to the airway circuit.
- Applying an airway adapter with mouthpiece.

Attaching the CAPNOSTAT 3 Sensor Cable

To attach the CAPNOSTAT 3 sensor cable, plug the cable into the CO₂ connector at the back of the M Series unit.

Note Effective with M Series software revision 38.35 and M Series CCT software revision 57.50, the “0” and “REF” cells on the sensor cable are no longer used. However, they remain on the sensor cable for backwards compatibility with earlier versions of the software.

Selecting a Mainstream Airway Adapter

Select an airway adapter based on the patient's size, ET tube diameter and monitoring situation. For more information refer to the following table or contact ZOLL Medical Corporation.

Airway Adapter Type	ET Tube Diameter
SPU Pediatric/Adult	> 4.0 mm
Adult Reusable	> 4.0 mm
SPU Neonatal/Pediatric	≤ 4.0 mm
Neonatal Reusable	≤ 4.0 mm

*SPU = Single Patient Use

Attaching the Airway Adapter to the CAPNOSTAT 3 Sensor

Before attaching the airway adapter to the CAPNOSTAT 3 sensor, verify that the airway adapter windows are clean and dry. Clean or replace the adapter if necessary.

CAUTION! The disposable (SPU) Pediatric/Adult and the Neonatal/Pediatric airway adapters are intended for single patient use. Do NOT reuse or sterilize these adapters as system performance will be compromised.

1. Attach the airway adapter to the CAPNOSTAT 3 sensor, as follows:
 - a. Align the arrow on the bottom of the airway adapter with the arrow on the bottom of the CAPNOSTAT 3.
 - b. Press the sensor and airway adapter together until they click.
2. If the unit displays the “CHECK CO2 ADAPTER” message, follow steps a through c, or else go to step 3.
 - a. Verify proper connection of the adapter to the sensor.
 - b. Verify that the airway adapter windows are clean and dry.

- c. If the adapter is properly connected, and the windows are clean and dry, then zero the adapter as described in the next section, "Zeroing the Mainstream Sensor/Airway Adapter".
3. Turn the Selector switch on the M Series unit to MONITOR (ON for AED units).
4. Wait for the airway adapter and sensor to warm up. The unit will display a "WARM UP" message for approximately one minute while the sensor and adapter warm to operating temperature. The message disappears when the sensor is ready to use.

Note Warm-up time varies with ambient temperature of the sensor.

Zeroing the Mainstream Sensor/Airway Adapter

Adapter zeroing compensates for the optical differences between airway adapters and should be performed after switching between different airway adapter types, in order to obtain accurate readings.

Zeroing is also necessary the first time a particular CAPNOSTAT 3 sensor is connected to the unit.

The M Series unit retains the CAPNOSTAT 3 sensor's zero settings during and after its use. When a previously used sensor is reconnected to the M Series unit, sensor zeroing does not need to be repeated, as long as no other CAPNOSTAT 3 sensor or adapter type has been connected and zeroed during the interim period.

1. Place the sensor with the adapter installed away from all sources of CO₂ (including the patient's – and your own – exhaled breath and ventilator exhaust valves).
2. Press the **Param.** softkey and select the EtCO₂ menu item, then press **Enter**.
3. Press the **Zero** softkey until the **Start** menu item is highlighted, then press **Enter**.

The unit zeroes the adapter and displays the "ZEROING CO₂ ADAPTER" message for approximately 15 seconds.

The unit displays the message "ZERO DONE" upon completion of the zeroing.

Note Do not attempt zeroing for 20 seconds after removing the adapter from the patient's airway. This time allows any CO₂ remaining in the adapter to dissipate before zeroing. Do not attempt to zero the adapter while it is in the patient's airway. Zeroing with CO₂ in the adapter can lead to inaccurate measurement and/or other error conditions. If you attempt zeroing while CO₂ remains in the adapter, the time required to zero the adapter may be increased. If zeroing cannot be completed, the message "ZERO FAILED" will be

displayed. If this occurs, clear any occlusion in the adapter, remove the source of CO₂, wait 20 seconds, and try zeroing again.

Attaching the Airway Adapter to the Airway Circuit

If you have not yet done so, you must attach the airway adapter to the CAPNOSTAT 3 sensor before attaching the airway adapter to the airway circuit. Refer to "Attaching the Airway Adapter to the CAPNOSTAT 3 Sensor" on page 5 if necessary.

Attach the airway adapter to the airway circuit as follows:

1. Place the CAPNOSTAT 3/airway adapter assembly at the proximal end of the airway circuit between the elbow and the ventilator circuit wye. Do NOT place the airway adapter between the ET tube and the elbow, as this may allow patient secretions to accumulate in the adapter.

Position the airway adapter with its windows in a vertical, NOT a horizontal, position. This helps keep patient secretions from pooling on the windows. If pooling does occur, the airway adapter may be removed from the circuit, rinsed with water and reinserted into the circuit. To prevent moisture from draining into the airway adapter, do NOT place the airway adapter in a gravity dependent position. See Figures 1 and 2.

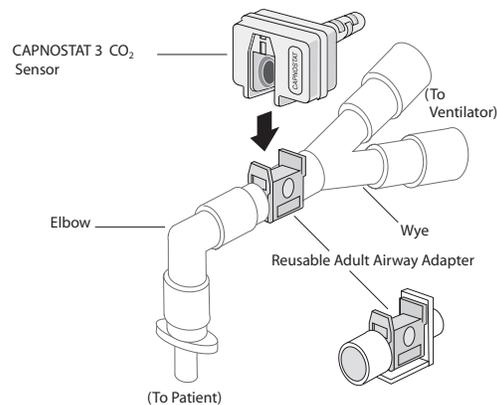


Figure 1

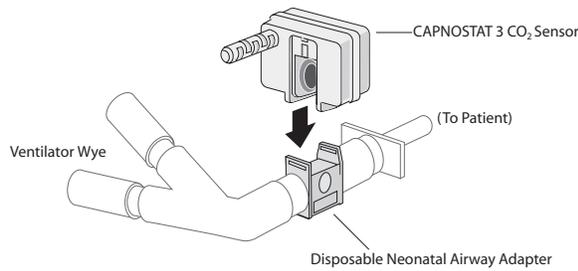


Figure 2

2. Check that connections have been made correctly by verifying the presence of a proper CO₂ waveform on the M Series display.
3. The sensor cable should face away from the patient. To secure the sensor cable safely out of the way, attach Sensor Cable Holding Clips to the airway tubing, then connect the sensor cable to the clips.

Applying an Airway Adapter with Mouthpiece

The disposable Pediatric/Adult airway adapter with mouthpiece can be used for spot checking CO₂ on non-intubated adult or pediatric patients.

CAUTION! The disposable Pediatric/Adult Airway Adapter with mouthpiece is intended for single patient use. Do NOT reuse or sterilize the adapter, as system performance will be compromised.

1. Remove adapter with mouthpiece from the package. Verify that the adapter and mouthpiece are intact and securely fastened to each other.
2. Attach the airway adapter to the CAPNOSTAT 3 sensor, as follows:
 - a. Align the arrow on the bottom of the airway adapter with the arrow on the bottom of the CAPNOSTAT 3.
 - b. Press the sensor and airway adapter together until they click (see Figure 3).

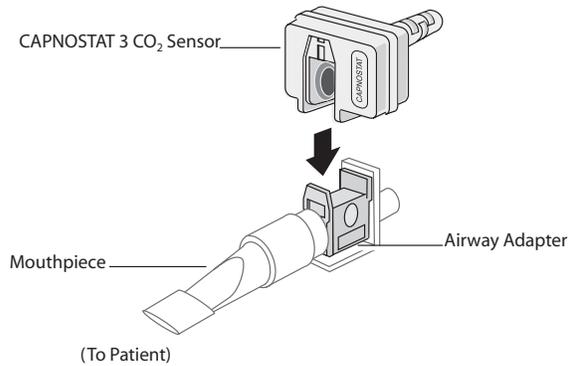


Figure 3

3. If the unit displays the "CHECK CO2 ADAPTER" message, follow steps a through c, else go to step 4.
 - a. Verify proper connection of the adapter to the sensor.
 - b. Verify that the airway adapter windows are clean and dry.
 - c. If the adapter is properly connected, and the windows are clean and dry, then zero the adapter as described in "Zeroing the Mainstream Sensor/Airway Adapter" on page 6.
4. Ensure the patient seals his or her mouth completely around the mouthpiece and breathes normally.

Note A nose clip may be needed if the patient is exhaling through the nose. It is important that all, or most, of the exhalation be routed through the airway adapter.

Sidestream EtCO₂ Setup

There are several steps involved with sidestream EtCO₂ setup, as follows:

- Selecting a Sidestream Airway Adapter Kit or Cannula
- Attaching the LoFlo Module Cable and Inserting the Sample Cell
- Zeroing the LoFlo CO₂ Module
- Applying a Sidestream Airway Adapter Kit
- Applying a Nasal or Nasal/Oral Cannula

Selecting a Sidestream Airway Adapter Kit

Select an airway adapter kit based on the patient's size, ET tube diameter, and monitoring situation. Airway adapter kits are disposable and single patient use.

Airway Adapter Kit	ET Tube Diameter
Adult/Pediatric Airway Adapter Kit	> 4.0 mm
Adult/Pediatric Airway Adapter Kit with Nafion® tubing	

Airway Adapter Kit	ET Tube Diameter
Pediatric/Infant Airway Adapter Kit	≤ 4.0 mm
Pediatric/Infant Airway Adapter Kit with Nafion tubing	

Note For monitoring times exceeding 6 hours, Nafion tubing is recommended.

Selecting a Sidestream Cannula

Select a sidestream cannula based on the patient's size and monitoring situation. Nasal and nasal/oral cannulae are disposable and single patient use.

Cannula	Application
Nasal CO ₂ Sampling Cannula, Adult	Nasal CO ₂ sampling only
Nasal CO ₂ Sampling Cannula, Pediatric	
Nasal CO ₂ Sampling Cannula, Infant	
Oral/Nasal CO ₂ Sampling Cannula, Adult	Oral/Nasal CO ₂ sampling only
Oral/Nasal CO ₂ Sampling Cannula, Pediatric	
Nasal CO ₂ Sampling with O ₂ Delivery Cannula, Adult	Nasal CO ₂ sampling with oxygen delivery
Nasal CO ₂ Sampling with O ₂ Delivery Cannula, Pediatric	
Oral/Nasal CO ₂ Sampling with O ₂ Delivery Cannula, Adult	Oral/Nasal CO ₂ sampling with oxygen delivery
Oral/Nasal CO ₂ Sampling with O ₂ Delivery Cannula, Pediatric	

Attaching the LoFlo Module Cable and Inserting the Sample Cell

Follow these steps:

1. Attach the LoFlo module cable to the CO₂ connector at the back of the M Series unit.
2. Remove the LoFlo sampling cannula or airway adapter kit from the package.

3. Insert the LoFlo sample cell into the LoFlo sample cell receptacle and ensure that it clicks into place.

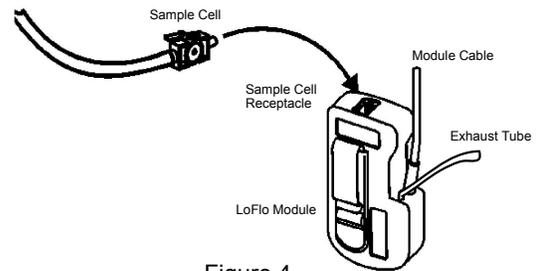


Figure 4

4. Ensure that the LoFlo module exhaust tube vents gasses away from the module environment.
5. Turn the selector switch on the M Series to MONITOR (ON for AED units).
6. Wait for the CO₂ module to warm up.

The unit will display the "WARM UP" message for approximately one minute while the module and accessory warm to operating temperature. The message disappears when the module is ready for use.

Note Warm up time varies with ambient temperature of the module.

Zeroing the LoFlo CO₂ Module

The first time a particular LoFlo module is connected to the M Series, the unit displays the message "ZERO CO₂ MODULE" following the warm up period.

The unit retains the LoFlo module zero settings during and after its use. When the previously used module is reconnected to the M Series unit, module zeroing does not have to be repeated, as long as no other LoFlo module has been connected and zeroed during the interim period.

Note After the initial zero procedure, the LoFlo module may be used during the warm up period. The capnogram, EtCO₂, and respiratory rate will be displayed; however, full product specifications are not achieved until the warm up period has completed.

CAUTION! Always ensure that the sample cell is properly connected to the LoFlo module before zeroing.

1. Ensure that the nasal cannula or on-airway adapter is not connected to the patient or close to any source of CO₂ (including the patient's -- and your own -- exhaled breath and ventilator exhaust valves).

2. Press the **Param.** softkey and select the EtCO₂ menu item, then press **Enter**.
3. Press the **Zero** softkey until the **Start** menu item is highlighted, then press **Enter**.

The unit zeros the module and displays the "ZEROING CO₂ MODULE" message for approximately 15 seconds.

The units displays the message "ZERO DONE" upon completion of the zeroing.

Note Do not attempt zeroing for 20 seconds after removing the adapter or cannula from the patient's airway. This time allows any CO₂ remaining in the adapter or cannula to dissipate before zeroing. Do not attempt to zero the module while the adapter or cannula is in the patient's airway. Zeroing with CO₂ in the adapter or cannula can lead to inaccurate measurements and/or other error conditions. If you attempt zeroing while CO₂ remains in the adapter or cannula, the time required to zero the module may be increased. If zeroing cannot be completed, the message "ZERO FAILED" will be displayed. If this occurs, clear any occlusion in the adapter or cannula, remove the source of CO₂, wait 20 seconds, and try zeroing again.

Applying a Sidestream Airway Adapter Kit

The sidestream airway adapter kit is intended for monitoring the EtCO₂ of intubated patients.

Before attaching the airway adapter to the breathing circuit, verify that the adapter is clean, dry, and undamaged. Replace if necessary.

CAUTION! The disposable (SPU) Adult/Pediatric and Pediatric/Infant airway adapter kits are intended for single patient use. Do NOT reuse or sterilize these adapters as system performance will be compromised.

1. Attach the airway adapter kit's sample cell to the sample cell receptacle on the LoFlo module, and ensure that it clicks into place.
2. If the unit displays either of the following messages take the appropriate action.

If you see this message:	Take this action:
CHECK CO ₂ LINE	Verify that the sample cell is plugged into the module and seated properly. Verify that neither the sample line nor the exhaust tube are blocked, kinked, or pinched. Verify that the airway adapter is not blocked. If the sample line, exhaust tube, or the airway adapter is blocked or otherwise compromised, the pump shuts off in approximately 15 seconds. To restart the pump, correct the blockage, then remove and reinsert the sample cell into the sample cell receptacle. If the problem persists, replace the sample line.
CHECK CO ₂ MODULE	Check that module cable is plugged in and seated properly. Check that module is not exposed to excessive heat. If problem persists, replace module.

3. Place the airway adapter assembly at the proximal end of the airway circuit between the elbow and the ventilator circuit wye. Do NOT place the airway adapter between the ET tube and the elbow as this may allow patient secretions to accumulate in the adapter.

If pooling does occur, the airway adapter may be removed from the circuit, rinsed with water and reinserted into the circuit. To prevent moisture from draining into the sample tubing, ensure that the sampling tube exits from the top of the airway adapter, not its bottom or sides. See Figure 5.

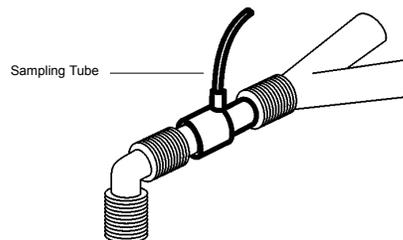


Figure 5

4. Check that connections have been made correctly by verifying the presence of a proper capnogram on the M Series display.

Applying a Nasal or Nasal/Oral Cannula

The nasal and nasal/oral cannulae are intended for monitoring EtCO₂ in non-intubated patients.

Oral/nasal sampling cannulae should be used on patients who are prone to mouth breathing, since most (if not all) of the CO₂ is exhaled through the mouth. If a

standard nasal CO₂ sampling cannula is used on such patients, the EtCO₂ values and capnogram waveform displayed will be substantially lower than the actual CO₂ levels present in the patient's expired breath.

CAUTION! The disposable Nasal and Nasal/Oral Cannulae are intended for single patient use. Do NOT reuse or sterilize the cannula, as system performance will be compromised.

1. Remove the cannula from the package. Verify that the cannula is clean, dry, and undamaged. Replace if necessary.
2. Attach the cannula's sample cell to the sample cell receptacle on the LoFlo module, and ensure that it clicks into place.
3. If the unit displays either of the following messages take the appropriate user action.

If you see this message:	Take this action:
CHECK CO2 LINE	Verify that the sample cell is plugged into the module and seated properly. Verify that neither the sample line nor the exhaust tube are blocked, kinked, or pinched. Verify that the airway adapter is not blocked. If the sample line, exhaust tube, or the airway adapter is blocked or otherwise compromised, the pump shuts off in approximately 15 seconds. To restart the pump, correct the blockage, then remove and reinsert the sample cell into the sample cell receptacle. If the problem persists, replace the sample line.
CHECK CO2 MODULE	Check that module cable is plugged in and seated properly. Check that module is not exposed to excessive heat. If problem persists, replace module.

4. Place the nasal cannula onto the patient as shown in Figure 6.

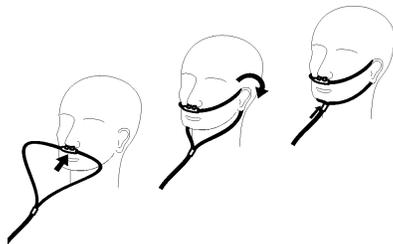


Figure 6

5. If necessary, cut the oral portion of the oral/nasal cannula (if you are using an the oral/nasal cannula) to an appropriate length to adequately fit the patient, as follows:

- a. Place the cannula onto the patient as shown in Figure 7.

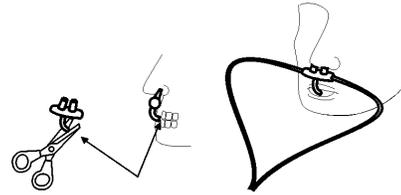


Figure 7

- b. Observe the length of the oral cannula tip. It should extend down past the teeth and be positioned in the mouth opening (see Figure 7).

CAUTION! To avoid injury to the patient, remove the cannula from the patient before you cut the oral cannula tip.

- c. Trim to the appropriate length.

Cleaning the CAPNOSTAT 3 Sensor and LoFlo Module

The CAPNOSTAT 3 sensor and LoFlo module (and rubber protective covering) can be cleaned and disinfected by wiping with one or more of the following solutions:

- 70% isopropyl alcohol
- 2% gluteraldehyde
- 10% bleach solution

Use a soft cloth dampened with one of the above listed solutions to clean the sensor or module. After cleaning, wipe with a clean, water-dampened cloth to rinse. Dry before use.

Note Do not immerse or attempt to sterilize the CAPNOSTAT 3 sensor or LoFlo module.

Cleaning Reusable Airway Adapters

Reusable airway adapters may be cleaned by rinsing in a warm soapy solution, followed by soaking in a liquid disinfectant such as Cidex® or System 1® (refer to the disinfectant manufacturer's instructions for use). Adapters should then be rinsed with sterile water and dried.

Reusable airway adapters may also be pasteurized or autoclaved. Autoclave at 121° C (250° F) for 20 minutes, unwrapped.

Before reusing the adapter, ensure the windows are dry and residue-free, and that the adapter has not been damaged during handling or by the cleaning process.

How EtCO₂ is Displayed

The M Series unit displays the numeric EtCO₂ value in units of mmHg, unless configured for percent or kPa. Refer to the *M Series Configuration Guide* (Part No. 9650-0201-01) for instructions on how to configure alternate units of measure. The unit also displays the number of breaths per minute, labeled "RR" for respiration rate. In addition, a capnogram waveform may be displayed using the **Wave2** softkey.

Monitor the capnogram for an elevated baseline. If an elevated baseline is observed, verify patient condition first. If you determine that the patient's condition is not contributing to the elevated baseline, follow the instructions for zeroing the CAPNOSTAT 3 sensor or LoFlo module, as described in this insert.

Displaying the Capnogram Waveform

The M Series unit can display one or two waveforms in Monitor, Defib, or Manual (AED) mode, as long as the defibrillator is not charging or ECG analysis is not in progress. The unit displays only one waveform in Pacer mode.

With EtCO₂ monitoring, the unit can display a capnogram waveform below the ECG trace for a visual indicator of the moment-by-moment CO₂ values. The unit displays the capnogram waveform at half the speed of the ECG display, and provides 8 seconds of data.



The unit temporarily removes the second waveform from the display when the user presses the **CHARGE**, **ANALYZE**, or **ENERGY SELECT** buttons, or the **Sync On/Off** softkey. The unit restores the second waveform to the display:

- 3 seconds after a shock is delivered
- 3 seconds after an analysis is completed, unless the defibrillator is charging
- 4 seconds after the last **Energy Select** button press
- 3 seconds after Sync mode is turned off

Pressing the **Wave2** softkey from the physiological monitoring menu cycles the display from the capnogram waveform, to the plethysmograph waveform (if SpO₂ is installed), to no second waveform displayed.

Use the **Zoom** softkey from the EtCO₂ submenu to adjust the waveform display size. Numbers shown on the left side of the capnogram display indicate the scaling.

Physiological Monitoring

The physiological monitoring menu includes the following softkeys: **Param**, **Wave2**, **ID#**, **Alarms**, and **12 Lead**.

Param Softkey

When the **Param** softkey is pressed, the following softkeys will be displayed: **Select**, **Enter**, and **Return**.



Pressing the **Select** softkey scrolls the highlighted area among the different available physiological parameters. Pressing the **Enter** softkey allows the user to select the parameter that is highlighted. Pressing the **Return** softkey allows the user to return to the physiological monitoring menu.

Selecting the EtCO₂ parameter causes the following softkeys to appear: **Zero**, **Average**, **Comp.**, **Zoom**, and **Return**. Note that the **Zoom** softkey is only displayed if the capnogram waveform is also displayed.



Pressing "**Return**" softkey returns the user to the physiological monitoring menu.

Zero Softkey

Adapter zeroing should be performed whenever the airway adapter type has been changed. Adapter zeroing may also be necessary if the unit displays "CHECK CO₂ ADAPTER." Module zeroing may be necessary if the unit displays the message "ZERO CO₂ MODULE."

Note Do not attempt zeroing for 20 seconds after removing the adapter or cannula from the patient's airway. This time allows any CO₂ remaining in the adapter or cannula to dissipate before zeroing. Do not attempt to zero while the adapter or cannula is in the patient's airway. Zeroing with CO₂ in the adapter or cannula can lead to inaccurate measurements and/or other error conditions. If you attempt zeroing while CO₂ remains in the adapter or cannula, the time required to zero may be increased. If zeroing cannot be completed, the message "ZERO FAILED" will be displayed. If this

occurs, clear any occlusion in the adapter or cannula, remove the source of CO₂, wait 20 seconds, and try zeroing again.

Pressing the **Zero** softkey causes the start/cancel menu to appear. Pressing the **Zero** softkey again toggles the highlight between **Start** and **Cancel**.



Pressing the **Enter** softkey with Start highlighted initiates zeroing of the adapter or module. The unit displays the "ZEROING CO2 ADAPTER" or "ZEROING CO2 MODULE" message during the zeroing process, which is typically finished in 15 seconds.

The unit displays the "ZERO DONE" message when the zeroing process is complete.

The unit displays the "ZERO FAILED" message if the zeroing process did not complete successfully. If this occurs, clear any occlusion in the adapter or sample line, remove the source of CO₂, and try zeroing again.

The **Cancel** selection halts the adapter zeroing process. Pressing **Enter** allows the user to enter the highlighted selection. Pressing **Return** returns the user to the EtCO₂ submenu.

Average Softkey

The M Series unit provides three (3) different time periods over which EtCO₂ values are averaged: 1 breath, 10 seconds (default), and 20 seconds.

The user can select the averaging period by pressing the **Average** softkey. When the **Average** softkey is pressed, the unit displays the **Average**, **Enter**, and **Return** softkeys.



Pressing the **Average** softkey scrolls the highlighted area among the different averaging periods of 1 breath, 10 seconds, and 20 seconds.

Pressing the **Enter** softkey allows the user to select the highlighted averaging period. Pressing the **Return** softkey returns the user to the EtCO₂ submenu.

Comp Softkey

The M Series unit can compensate for elevated levels of oxygen and/or the presence of nitrous oxide. Oxygen compensation should be activated when oxygen levels in excess of 60% are present in the airway circuit. Nitrous oxide compensation should be activated when nitrous oxide is present in the airway circuit. If the concentration

of oxygen in the breathing circuit exceeds 60% and nitrous oxide is in use, both O₂ and N₂O should be activated.

When the **Comp** softkey is pressed, the unit displays the **Comp.**, **Enter**, and **Return** softkeys.



Pressing the **Comp.** softkey scrolls the highlight among the different types of compensation available (either NONE, O₂, N₂O, or O₂ & N₂O).

The O₂&N₂O selection turns oxygen and nitrous oxide compensation on. The unit displays two asterisks (*) on the left side of the CO₂ field to indicate compensation for both oxygen and nitrous oxide. The left asterisk indicates oxygen compensation is active and the right asterisk indicates nitrous oxide compensation is active.

The O₂ selection turns oxygen compensation on and displays an asterisk in the far left of the CO₂ field. The N₂O selection turns nitrous oxide compensation on and displays an asterisk to the right of the O₂ asterisk. The NONE selection turns all compensations off and eliminates the asterisks from the display.

After selecting the appropriate compensation press **Enter** to activate the selected function. Pressing the **Return** softkey returns the user to the EtCO₂ submenu.

Zoom Softkey

The user can select the zoom level for capnogram waveforms by pressing the **Zoom** softkey. When the **Zoom** softkey is pressed, the scale for the displayed capnogram waveform scrolls among zoom levels:

- 0-12.5 mmHg
- 0-25 mmHg
- 0-50 mmHg
- 0-75 mmHg
- 0-100 mmHg

The scales are 0-1.7, 0-3.3, 0-6.6, 0-10, and 0-13.3 if units of kPa or % have been configured. (Refer to the *M Series Configuration Guide* for instructions on how to configure alternate units of measure.)

Alarms

The M Series EtCO₂ option provides user programmable "out of range" alarms for both EtCO₂ and respiration rate. See "Default Settings" on page 15 for low and high alarm limit default values and ranges.

The EtCO₂ and respiration rate alarms share the same State field in the Alarms Menu and cannot be enabled or disabled separately. Enabling the EtCO₂ alarms enables both EtCO₂ and respiration rate alarm functions;

disabling EtCO₂ or respiration rate alarms disables the other alarm function. See the *M Series Operator's Guide* for details on enabling, disabling, and suspending alarm functions on the M Series unit.

When the EtCO₂ and respiration rate alarm states are set to AUTO, the unit automatically sets the lower and upper limits for EtCO₂ and respiration rate.

For EtCO₂, the limits will be set to +/- 25% of the patient's currently measured EtCO₂ value. If the EtCO₂ value is greater than 40 mmHg (which is equivalent to 5.3kPa or 5.3% at a barometric pressure of 760 mmHg), then 10 mmHg (1.3 for kPa or %) will be added and subtracted from the current reading to set the upper and lower limits. The auto alarm limits are set only if valid measurements are present for the vital sign.

For the automatic respiration rate alarm limits, the unit sets the upper and lower limits for respiration by adding and subtracting the values shown in the following table to/from the patient's current breath rate.

Respiration Limits (Auto)		
Respiration Rate Average	High Limit	Low Limit
1-15 breaths/min.	+7 breaths/min.	-50% value
16-40 breaths/min.	+10 breaths/min.	-7 breaths/min.
> 40 breaths/min.	+15 breaths/min.	-10 breaths/min.

Recorder Operation

If EtCO₂ measurements have been taken, press the **RECORDER** button to print a stripchart that includes the following values across the top part of the paper:

- date and time
- ECG lead and size
- heart rate
- EtCO₂ value
- respiration rate

The recorder runs continuously until the button is pressed again. If displayed on the screen, the capnogram waveform will also be printed under the ECG trace. All waveforms printed by the recorder are delayed by six seconds relative to their occurrence.

Automated External Defibrillator (AED) Operation

M Series AED units equipped with the EtCO₂ option operate in a slightly different way than Manual and Advisory models equipped with EtCO₂, as outlined below.

Semi-Automatic Operation

The EtCO₂ monitoring parameters can be changed by pressing the **Param** softkey, as outlined in "Physiological

Monitoring" on page 11. The capnogram waveform cannot be displayed in semi-automatic mode.

Although EtCO₂ alarm functions are operational in semi-automatic mode, heart rate alarm functions are disabled. Background ECG analysis functions continue to operate as described in the "AED" section of the *M Series Operator's Guide*.

The **ALARM SUSPEND** button can be used to activate, deactivate, or audibly disable the EtCO₂ alarms (as described in the *M Series Operator's Guide*). The alarm limit settings cannot, however, be changed in semi-automatic mode; only the default alarm limits are available. See the *M Series Configuration Guide* for information on setting alarm limit defaults.

Manual Mode Operation

When the AED unit is in manual mode, the unit can display the capnogram waveform as described in "Displaying the Capnogram Waveform" on page 11.

Both heart rate and EtCO₂ alarms are operational. The alarm limits can be changed by pressing the **Alarms** softkey. The EtCO₂ monitoring parameters can be changed by pressing the **Param** softkey, as outlined in "Physiological Monitoring" on page 11.

Check Out Procedures

The following procedures verify that the EtCO₂ option is functioning properly.

Mainstream EtCO₂ (CAPNOSTAT 3 Sensor)

1. Connect the CAPNOSTAT 3 sensor cable to the EtCO₂ connector at the back of the M Series unit.
2. Connect an airway adapter to the sensor.
3. Turn the selector switch to **MONITOR** mode (**ON** for AED units and select **Manual Mode**).
4. Wait for the CO₂ sensor to warm up. The message "WARM UP" is displayed for approximately one minute.
5. Perform a zero procedure if necessary (see "Zeroing the Mainstream Sensor/Airway Adapter" on page 6).
6. Breathe normally into the adapter.
7. Verify that the unit displays EtCO₂ readings in the EtCO₂ display area of the monitor.
8. Verify the capnogram waveform is displayed by pressing the **Wave2** softkey.

Sidestream EtCO₂ (LoFlo Module)

Use an Adult/Pediatric Airway Adapter when performing this procedure.

1. Connect the LoFlo module cable to the EtCO₂ connector at the back of the M Series unit.
2. Insert the adapter sample cell into the LoFlo module sample cell receptacle.
3. Turn the selector switch to **MONITOR** mode (**ON** for AED units and select **Manual Mode**), and wait

approximately one minute while the module warms to operating temperature (unit displays "WARM UP" message).

4. Perform a zero procedure if necessary (see "Zeroing the LoFlo CO₂ Module" on page 8).
5. Breathe normally into the adapter.
6. Verify that the unit displays EtCO₂ readings in the EtCO₂ display area of the monitor.
7. Verify the capnogram waveform is displayed by pressing the **Wave2** softkey.

Default Settings

When the unit is turned on, the following default EtCO₂ settings are automatically selected and remain in operation until changed.

Parameter	Default Setting	Range
Averaging Mode	10 seconds	1 breath 10 seconds 20 seconds
High EtCO ₂ Alarm Limit	55 mmHg 7.2% 7.3 kPa	5 - 100 mmHg, OFF 0.6 - 13.1%, OFF 0.6 - 13.3 kPa, OFF
Low EtCO ₂ Alarm Limit	25 mmHg 3.2% 3.3 kPa	0 - 95 mmHg, OFF 0 - 12.5%, OFF 0 - 12.6 kPa, OFF
High Respiration Rate Alarm Limit	120 respirations per min.	5 - 150 respirations per min., OFF
Low Respiration Rate Alarm Limit	5 respirations per min.	0 - 100 respirations per min., OFF

Note The power on default settings for the capnogram waveform scale and CO₂ compensation are set in System Configuration, as are the power-on default settings for alarm limits. See the *M Series Configuration Guide* for more information.

EtCO₂ Accessories

The following tables list the accessories available for the M Series Mainstream and Sidestream EtCO₂ monitoring options.

Table 1: CAPNOSTAT 3 Mainstream CO₂ Accessories

Accessory (ZOLL Reorder Part Number)	Application
CAPNOSTAT 3 CO ₂ Sensor and Cable (8000-0264-01)	
Sensor Cable Holding Clips, bag of 5 (8000-0266-01)	
SPU Pediatric/Adult Airway Adapter (8000-0260-01)	Single patient use, for ET tube sizes > 4.0 mm
SPU Neonatal/Pediatric Airway Adapter (8000-0261-01)	Single patient use, for ET tube sizes ≤ 4.0 mm
Reusable Adult Airway Adapter (8000-0262-01)	Reusable, for ET tube sizes > 4.0 mm
Reusable Neonatal/Pediatric Airway Adapter (8000-0263-01)	Reusable, for ET tube sizes ≤ 4.0 mm
SPU Pediatric/Adult Airway Adapter with Mouthpiece (8000-0265-01)	Single patient use, for non-intubated patients
Capno ₂ mask, Large Adult (8000-0761)	SPU, for non-intubated large adults
Capno ₂ mask, Standard Adult (8000-0760)	SPU, for non-intubated adults
Capno ₂ mask, Pediatric (8000-0762)	SPU, for non-intubated adults pediatric patients

* SPU = Single Patient Use

Table 2: LoFlo Sidestream CO₂ Accessories

Accessory (ZOLL Reorder Part Number)	Application
LoFlo Module and Cable (8000-0365)	
Nasal CO ₂ Sampling Cannula, Adult (8000-0351)	SPU, Nasal CO ₂ sampling only (adult)
Nasal CO ₂ Sampling Cannula, Pediatric (8000-0352)	SPU, Nasal CO ₂ sampling only (pediatric)
Nasal CO ₂ Sampling Cannula, Infant (8000-0353)	SPU, Nasal CO ₂ sampling only (neonate)
Oral/Nasal CO ₂ Sampling Cannula, Adult (8000-0354)	SPU, Oral/Nasal CO ₂ sampling only (adult)
Oral/ Nasal CO ₂ Sampling Cannula, Pediatric (8000-0355)	SPU, Oral/Nasal CO ₂ sampling only (pediatric)
Nasal CO ₂ Sampling with O ₂ Delivery Cannula, Adult (8000-0356)	SPU, Nasal CO ₂ sampling with O ₂ delivery (adult)
Nasal CO ₂ Sampling with O ₂ Delivery Cannula, Pediatric (8000-0357)	SPU, Nasal CO ₂ sampling with O ₂ delivery (pediatric)
Oral/Nasal CO ₂ Sampling with O ₂ Delivery Cannula, Adult (8000-0358)	SPU, Oral/Nasal CO ₂ sampling with O ₂ delivery (adult)
Oral/Nasal CO ₂ Sampling with O ₂ Delivery Cannula, Pediatric (8000-0359)	SPU, Oral/Nasal CO ₂ sampling with O ₂ delivery (pediatric)
Adult/Pediatric Airway Adapter Kit (8000-0362)	SPU, for ET tube sizes > 4.0 mm
Adult/Pediatric Airway Adapter Kit with Nafion tubing (8000-0363)	SPU, for ET tube sizes > 4.0 mm
Pediatric/Infant Airway Adapter Kit (8000-0361)	SPU, for ET tube sizes ≤ 4.0 mm
Pediatric/Infant Airway Adapter Kit with Nafion tubing (8000-0364)	SPU, for ET tube sizes ≤ 4.0 mm

* SPU = Single Patient Use

Note Components of this product and its associated EtCO₂ accessories that make patient contact are free of latex.

Note: The CAPNOSTAT 3, LoFlo and its accessories are covered by the following US patents:

- 4,859,858
- 4,859,859
- 4,914,720
- 4,958,075
- 5,146,092
- 5,153,436
- 5,206,511
- 5,251,121
- 5,369,277
- 5,616,923
- 5,693,944
- 5,793,044

Other patents pending.

Messages and Troubleshooting

The following three tables list the common (occur for both mainstream and sidestream), mainstream, and sidestream messages that may appear on the M Series unit, possible causes, and the action(s) to take if the message indicates a problem. You should become thoroughly familiar with this information before monitoring patients.

COMMON MESSAGES		
Message/Symptom	Possible Cause(s)	Recommended Action(s)
---- (dashed lines in EtCO ₂ field)	After a defibrillation discharge, the numeric value displays as "----" for approximately 10 seconds. When the respiration rate is zero, the numeric CO ₂ value will display "----". When the respiration rate is greater than zero, the actual CO ₂ numeric value will be displayed.	None, normal operation.
---- (dashed lines at top of capnogram waveform)	Scale value setting incorrect. Measured CO ₂ higher than scale limits.	Adjust to higher scale setting using the Zoom key.
CO2 COMM ERROR	No communication from the EtCO ₂ module or sensor.	Turn M Series unit off, then on again to reset. If problem persists, return for service.
CO2 DEVICE NOT READY	The zero operation cannot be initiated because: <ul style="list-style-type: none"> The sensor or module is still warming up. No sensor or module is attached to the unit. 	Wait for sensor or module to warm up. Attach sensor or module to the unit.
CO2 OUT OF RANGE (dashed lines for CO ₂)	Calculated CO ₂ value is greater than 100 mmHg.	If error persists, perform an adapter or module zero
CO2 UNIT ERROR	Defective EtCO ₂ module or sensor.	Turn M Series unit off, then on again to reset. If problem persists, contact Technical Support.
INVALID CO2 DEVICE	CAPNOSTAT 3 sensor or LoFlo Module is not responding to the M Series unit.	Turn M Series unit off, then on again to reset. Try another sensor/module. If problem persists, contact Technical Support.
WARM UP	Mainstream sensor or LoFlo sidestream module is warming up. This may take up to 5 minutes.	Wait for sensor or module to warm up (max 5 minutes). If message persists more than 5 minutes, replace the sensor, or module.
ZERO DONE	The mainstream sensor or adapter zero, or the LoFlo module zero, is finished.	No action required.
ZERO FAILED	The zero operation did not complete successfully.	Clear occlusion, remove source of CO ₂ , and try zeroing again. If problem persists, contact Technical Support.

MAINSTREAM MESSAGES		
Message/Symptom	Possible Cause(s)	Recommended Action(s)
Sensor not responding to breaths. CO ₂ waveform always at 0 mmHg with no messages displayed. or CO ₂ waveform baseline > 25 mmHg with no messages displayed.	Sensor/Adapter was zeroed with a low level of residual CO ₂ in the adapter. CO ₂ baseline is set below 0 mmHg. Airway adapter type was changed with unit powered off. New sensor/adapter combination has not been zeroed.	Perform a mainstream airway adapter zero as described in "Zeroing the Mainstream Sensor/Airway Adapter" on page 6.
CHECK CO2 ADAPTER displayed during each inhalation. Message disappears during exhalation. CHECK CO2 ADAPTER alternates with ZERO CO2 ADAPTER shortly after breathing stops.	Sensor/Adapter was zeroed with a low level of residual CO ₂ in the adapter. CO ₂ baseline is set below 0 mmHg.	Perform a mainstream airway adapter zero as described in "Zeroing the Mainstream Sensor/Airway Adapter" on page 6.
CHECK CO2 ADAPTER	Usually caused when the airway adapter is removed from the CAPNOSTAT 3, or when there is an optical blockage on the windows of the airway adapter. May also be caused by not having performed an adapter zero after changing the adapter type.	Clean airway adapter and reattach it. If the problem persists or the adapter type was changed, perform a mainstream airway adapter zero as described in "Zeroing the Mainstream Sensor/Airway Adapter" on page 6.
CHECK CO2 SENSOR	Sensor cable not properly plugged in or over temperature.	Check that sensor cable is plugged in and properly seated in the connector. Check that sensor is not exposed to excessive heat. If problem persists, replace sensor.
CO2 IN ADAPTER: WAIT	There is CO ₂ in the adapter when attempting to zero. Zeroing was attempted within 20 seconds of previous zero operation.	Remove adapter from CO ₂ source including the patient's - and your own - exhaled breaths, and ventilator exhaust valves. Wait up to 20 seconds before retrying adapter zero.
REPLACE CO2 SENSOR	Sensor is defective or incompatible (message appears when "WARM UP" message is displayed for more than 5 minutes).	Replace sensor.
USE AIRWAY ADAPTER	CO ₂ sensor is on the "REF" or "0" cell when zeroing is started.	Remove CO ₂ sensor from the "REF" or "0" cell and attach airway adapter to CO ₂ sensor.
ZERO CO2 ADAPTER	Sensor cable connected to M Series unit for the first time. Zeroing error or probe drift error detected.	Perform a mainstream airway adapter zero as described in "Zeroing the Mainstream Sensor/Airway Adapter" on page 6.
ZEROING CO2 ADAPTER	Adapter zeroing in progress.	Wait for adapter zeroing to finish.

SIDESTREAM MESSAGES		
Message/Symptom	Possible Cause(s)	Recommended Action(s)
<p>Breaths not registering (CO₂ and RR values remain dashed and the capnogram waveform remains at baseline);</p> <p>or</p> <p>CHECK CO2 LINE with sample cell connected and pump running;</p> <p>or</p> <p>ZERO CO2 MODULE with no sample cell connected.</p>	<p>Module improperly zeroed because pump stopped or sample cell was disconnected during zeroing.</p>	<p>Verify that the sample line and exhaust tube are not kinked or blocked. Disconnect the sample cell from the module. Reconnect the sample cell and verify pump is running. Perform module zero as described in "Zeroing the LoFlo CO2 Module" on page 8. Repeat the zeroing procedure a second time. The LoFlo module is now ready to use.</p>
<p>CHECK CO2 LINE displayed during each inhalation. Message disappears during exhalation.</p> <p>or</p> <p>Module not responding to breaths. CO₂ waveform always at 0 mmHg with no messages displayed.</p>	<p>LoFlo module was zeroed with residual CO₂ in the sampling line. CO₂ baseline is set below 0 mmHg.</p>	<p>Perform a sidestream module zero as described in "Zeroing the LoFlo CO2 Module" on page 8.</p>
<p>CHECK CO2 LINE</p>	<p>Sample line blockage</p>	<p>Verify that the sample line is plugged into the module and seated properly.</p> <p>Verify that neither the sample line nor the exhaust tube are blocked, kinked, or pinched. Verify that the airway adapter is not blocked. If the sample line, exhaust tube, or the airway adapter is blocked or otherwise compromised, the pump shuts off in approximately 15 seconds. To restart the pump, correct the blockage, then remove and reinsert the sample cell into the sample cell receptacle.</p> <p>If the problem persists, replace the sample line.</p>
<p>CHECK CO2 MODULE</p>	<p>Module not properly plugged in. Module over temperature.</p>	<p>Check that module cable is plugged in and seated properly in the connector.</p> <p>Check that module is not exposed to excessive heat.</p> <p>If problem persists, replace module.</p>
<p>CO2 IN LINE: WAIT</p>	<p>CO₂ in cannula/adaptor when attempting to zero.</p> <p>Zeroing was attempted within 20 seconds of a detected breath.</p>	<p>Wait up to 20 seconds before retrying module zero.</p> <p>Remove adaptor or cannula tip from CO₂ source including the patient's - and your own - exhaled breaths, and ventilator exhaust valves.</p>

REPLACE CO2 MODULE	Module defective, incompatible, under temperature, or temperature unstable for more than 5 minutes.	Replace module.
ZERO CO2 MODULE	Module cable connected to M Series unit for the first time. Probe drift error detected, or negative CO ₂ detected.	Perform module zero as described in "Zeroing the LoFlo CO2 Module" on page 8.
ZEROING CO2 MODULE	Module zeroing in progress.	Wait for module zeroing to finish.

Specifications

This section summarizes the specifications of the M Series End-Tidal Carbon Dioxide (EtCO₂) option.

	CAPNOSTAT 3	LoFlo
Transducer Type	Mainstream	Sidestream
Principle of Operation	Non-Dispersive Infrared (NDIR) single beam optics, dual wavelength, no moving parts.	
Warm Up Time	Full specifications within 60 seconds. Capnogram in 15 seconds.	
EtCO₂ Measurement Range	0 - 100 mmHg 0 - 13% 0 - 12.5 kPa	
EtCO₂ Accuracy (at 760 mmHg, ambient temperature of 25°C)	0 - 40 mmHg, ±2 mmHg 41 - 70 mmHg, ±5% of actual 71 - 100 mmHg, ±8% of actual	0 - 40 mmHg, ±2 mmHg 41 - 70 mmHg, ±5% of actual 71 - 100 mmHg, ±8% of actual ±12% for respiration rate above 80 BrPM
EtCO₂ Resolution	0.5 mmHg	
EtCO₂ Stability	Short Term Drift: Drift over four hours ≤ 0.8 mmHg. Long Term Drift: Accuracy specification will be maintained over a 120 hour period after zeroing.	
EtCO₂ Noise	RMS noise of the sensor ≤ 0.25 mmHg at 7.5% CO ₂ .	
EtCO₂ Rise Time (10-90%)	< 60 ms (Adult/pediatric adapters) < 50 ms (Neonatal adapters)	< 200 ms
Respiration Rate Range	0 - 150 breaths per minute	
Respiration Rate Accuracy	±1 breath per minute	
Sample Flow Rate	N/A	50 ml/min
Compensations	Barometric pressure 550 - 780 mmHg (automatic). Operator selectable O ₂ /N ₂ O compensation.	
EtCO₂ Alarm Limits	User selectable, High 5 - 100 mmHg, Low 0 - 95 mmHg, OFF.	
Respiration Rate (RR) Alarm Limits	User selectable, High 5 - 150 respirations per minute, Low 0 - 100 respirations per minute, OFF.	
Halogenated Agents	Specification allows for halogenated anesthetic agents that may be present at normal clinical levels. The presence of Desflurane in the exhaled breath beyond normal values (5-6%) may positively bias carbon dioxide values by up to an additional 2-3 mmHg.	
Airway Adapter Deadspace	Adult < 5 cc Infant < 1.0 cc	Adult 7.3 cc maximum Pediatric/Infant < 1 cc
Environmental	Operating Temperature: 10° C to 40° C Storage and Shipping Temperature: -10° C to 55° C The M Series unit may not perform to specifications when stored at the upper or lower extreme limits of storage temperature and immediately put into use.	
Electromagnetic Immunity	AAMI DF-39, IEC 60601-1-2, 20 V/m	

	CAPNOSTAT 3	LoFlo
Software Hazards	Minimized by compliance with EN1441	
Operating Time EtCO₂ and SpO₂ Options	<p>For a new fully charged PD4410 battery pack at 20° C:</p> <ul style="list-style-type: none"> • 35 defibrillator discharges at maximum energy (360J), or • 1.5 hours minimum of continuous ECG monitoring, or • 1.0 hour of continuous ECG monitoring/pacing at 60 mA, 70 beats/min. <p>For a new fully charged XL battery pack at 20° C:</p> <ul style="list-style-type: none"> • 60 defibrillator discharges at maximum energy (360J), or • 3.0 hours minimum of continuous ECG monitoring, or • 2.75 hour of continuous ECG monitoring/pacing at 60 mA, 70 beats/min. 	