Mainstream

$EtCO_2$ MODULE

USER'S GUIDE

ENGLISH

Contents

Disclaimer

The manufacturer guarantees that the product delivered has been tested to ensure that it meets its published specifications.

Liability

The manufacturer shall in no event be liable for any direct, indirect, special or consequential damages, including without limitation, loss of profits, income, information, or use of the product, business interruption, other related damages, however caused, arising from the use of the product described in this manual.

Warranty

Please contact your local distributor for details regarding warranty and product returns.

Use of the product for other than its intended use, or if it is repaired by anyone except the manufacturer or a manufacturer authorized service center, or altered or modified or used without following the instructions provided with the product, voids the warranty.

Trademarks

Mainstream $EtCO_2$ Module is a trademark of the manufacturer.

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Contact information

Reference the end page or contact your local distributor.

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1. Intended use

The intended use of the Mainstream $EtCO_2$ Module is to provide carbon dioxide monitoring to a host monitoring system during anesthesia/recovery, in the intensive care unit (ICU), and in Emergency Medicine/Transport or Respiratory care.

The Mainstream $EtCO_2$ Module is to be used as prescribed by a physician or licensed medical practitioner trained in the use of the equipment.

- The Mainstream $EtCO_2$ Module is indicated for use in care areas such as, but not limited to critical care, intensive care, anesthesia, medical/surgical units, LTAC units, emergency department, sleep labs and during intra-hospital transport and inter-hospital transport.
- For use in monitoring patients in requiring ventilator support, receiving procedural sedation, during transport, during anesthesia or those in respiratory distress, respiratory arrest or that have asthma, COPD or other disorders where the patient's $EtCO_2$ and capnograph will benefit the caregiver in the treatment of the patient.
- For use in monitoring patients pre- and post-intubation.
- To assist in the setup, management and weaning of the patient that is connected to a “conventional” mechanical ventilator.

2. Safety

2.1 Warnings

⚠ *Indicates a potentially harmful condition that can lead to personal injury.*

WARNING! Explosion Hazard: DO NOT use in the presence of flammable anesthetics or other flammable gasses. Use of the Module in such environment may present an explosion hazard.

WARNING! Electrical Shock Hazard: Always disconnect the Module before cleaning. DO NOT use if it appears to have been damaged. Refer servicing to qualified service personnel.

WARNING! Electrical Shock Hazard; No user serviceable parts inside.

WARNING! No modification of this equipment is allowed.

WARNING! Device is to be used by licensed practitioner, or other qualified medical personnel properly trained in its use.

WARNING! Follow precautions for electrostatic discharge (ESD) and electromagnetic interference (EMI) to and from other equipment.

WARNING! Failure of Operation: If the Module fails to respond as described in this user guide; DO NOT use it until approved for use by qualified personnel.

WARNING! DO NOT position the Module cables or tubing in any manner that may cause entanglement or strangulation.

WARNING! Reuse, disassembly, cleaning, disinfecting or sterilizing the single patient use on-airway adapters may compromise functionality and system performance leading to a user or patient hazard. Performance is not guaranteed if an item labeled as single patient use is reused.

WARNING! Inspect the on-airway adapters for damage prior to use.

WARNING! DO NOT use the side stream on-airway adapters and side stream sampling kits if they appear to be damaged or broken.

WARNING! Replace the side stream on-airway adapters and side stream sampling kits if excessive secretions are observed.

WARNING! Monitor the CO_2 waveform (capnograph). If you see changes or abnormal appearance check the patient and the sampling line and water filter. Replace line or water filter if needed.

WARNING! DO NOT operate the $EtCO_2$ Module when it is wet or has exterior condensation.

WARNING! DO NOT apply excessive tension to any cable.

WARNING! DO NOT use device on patients with a respiration rate greater than or equal to 150 breaths per minute.

WARNING! DO NOT connect the exhaust tube to the ventilator circuit.

WARNING! Before use, carefully read the Operator's Guide and these operating instructions.

WARNINGS FOR OEM!

- The host system shall provide any required electrical isolation.
- The Mainstream $EtCO_2$ Module is not patient isolated. Use of the Module does not require direct patient contact. If isolation is desired or required, it is the responsibility of the Host system to provide the necessary isolation.

2.2 Cautions

⚠ *Indicates a condition that may lead to equipment damage or malfunction.*

CAUTION! Electrical Shock Hazard; the $EtCO_2$ Module is not user serviceable. Refer servicing to qualified personnel.

CAUTION! Follow precautions for electrostatic discharge (ESD) and electromagnetic interference (EMI) to and from other equipment.

CAUTION! Use only approved accessories.

CAUTION! DO NOT use the $EtCO_2$ Module if it fails to operate properly, appears to have been damaged, is wet or has exterior condensation.

CAUTION! DO NOT sterilize or immerse the $EtCO_2$ Module in liquids.

CAUTION! DO NOT clean the $EtCO_2$ Module and accessories except as directed in this guide.

CAUTION! DO NOT apply excessive tension to the $EtCO_2$ Module cable.

CAUTION! DO NOT store the $EtCO_2$ Module at temperatures less than -40 ºC or greater than 70 ºC.

CAUTION! DO NOT operate the $EtCO_2$ Module at temperatures less than 0 ºC or greater than 40 ºC.

CAUTION! Remove the sampling kit from the receptacle when not in use.

CAUTION! DO NOT stick appendage into sample receptacle.

CAUTIONS FOR OEM!

- The host system shall monitor for $EtCO_2$ Module connectivity and report the status and messages as required.
- In the presence of electromagnetic devices (i.e., electro cautery), patient monitoring may be interrupted due to electromagnetic interference. Electromagnetic fields up to 20 V/m will not adversely affect Module performance.
- Precautionary statement to use only approved accessories.

2.3 Notes

⚠ *A point of particular interest or emphasis intended to provide more effective or convenient.*

NOTE! Recommended operating temperature is 0 ºC to 40 ºC.

NOTE! The Mainstream $EtCO_2$ Module contains no user serviceable parts. Refer service to qualified service personnel.

NOTE! This product and its accessories are latex free.

NOTE! After the life cycle of the $EtCO_2$ Module and its accessories have been met, disposal should be accomplished following national and/or local requirements.

NOTE! Nitrous oxide, elevated levels of oxygen, helium, xenon, halogenated hydrocarbons, and barometric pressure can influence the $EtCO_2$ measurement. Levels to be supplied by host monitor.

2.4 Symbols

Symbol	Title
	Gas input.
	Gas output.
	Date of manufacture.
	Serial number.
	Batch code.
	Catalog number.
	Type B applied part.
	Follow instruction for use.
RxOnly	Caution (U.S.): Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.
	For EU only: Waste Electrical and Electronic Equipment (WEEE).
	Non sterilization.

	Consult instructions for use.
	Manufacturer.
	Symbol for temperature limitation/temperature range.
	Caution.

For the complete list of symbols see technical specification.

3. Device description

3.1 Overview

$EtCO_2$ Module is a mainstream end tidal CO_2 Module that using advanced dual channel non dispersive infrared absorption spectrum technology. The $EtCO_2$ Module is used to monitor continuous carbon dioxide and report the End Tidal carbon dioxide ($EtCO_2$), inspired CO_2 and respiratory rate values of the intubated adult, pediatric, infant and neonatal patient. Because of its unique design, response is fast, stability, and excellent price-performance.

3.2 Principles of operation

The Mainstream $EtCO_2$ Module is used for the continuous measurement of CO_2 (carbon dioxide) and respiratory rate.

Mainstream $EtCO_2$ Module is a non-dispersive infrared analyzer. In Module, infrared light is generated by the Module and beamed through the sample cell to a detector on the opposite side. CO_2 from the patient that is aspirated into the sample cell absorbs some of this infrared energy. The Module determines CO_2 concentration in the breathing gases by measuring the amount of light absorbed by these gases. The Module contains a reference channel, used to compensate for optical changes, so that the system is in a state of calibration. $EtCO_2$ is displayed as a numerical value in millimeters of mercury (mmHg), percent (%), or kilopascals (kPa). In addition, a CO_2 waveform (capnograph) may be displayed which is a valuable clinical tool that can be used to assess patient airway integrity and proper endotracheal tube (ETT) placement. Respiration rate is calculated by measuring the time interval between detected breaths.

4. Preparations for use

This section provides information how to setup the $EtCO_2$ Module.

Mainstream $EtCO_2$ Module is a rugged, solid-state, main stream module.

It is factory calibrated and does not require further calibration.

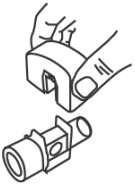
4.1 Setting up

1. Connect the module to the host monitor.
2. Install the airway adapter. Zero the module. Refer to the monitor operator's manual for calibration information.
3. Position the adapter and module in the patient respiratory circuit as close to the patient as possible. A location between the endotracheal tube and the ventilator circuit is common.

Warning: *Always position the module with the adapter in an upright position to avoid collection of fluids on the windows of the adapter. Large concentrations of fluids at this point will obstruct gas analysis.*

4.1.1 Combine with the airway adapter

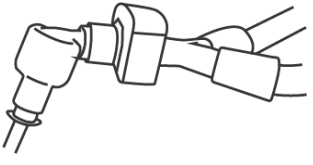
1. Verify the adapter is intact.
2. Press the Mainstream EtCO2 Module onto the airway adapter. It will “click” when properly seated.



4.1.2 Install the airway adapter

1. Install at the proximal end of the circuit between the elbow and the ventilator wye. If using an HME, place adapter between HME and wye.

2. The cord of the module should be facing away from the patient.
3. For optimal results, do not place the adapter between the ET tube and the elbow.



4.2 Zeroing the Module

The zero allows the $EtCO_2$ Module to adjust to the optical characteristics of Airway adapter, to reduce the measurement error. A Zero is necessary before each measurement or when requested. The following conditions may cause errors during a zero procedure.

- Breath is detected in the last 20 seconds.
- The temperature is not stable.

4.2.1 To perform Zero

1. Connect the $EtCO_2$ Module to the host monitor and connect the airway adapter to the $EtCO_2$ Module. Make certain that the airway adapter stays away from all sources of CO_2, including the ventilator, the patient's breath and your own.

2. Once the host monitor is turned on, wait for at least 2 minutes for the $EtCO_2$ Module to warm up.

3. Set the host monitor to the zeroing function.

4. Start the Zero. The maximum time for a module zero is 40 seconds. The typical time for a zero is 15-20 seconds.

Note: *For best results, wait 5 minutes to allow the $EtCO_2$ Module to warm up before performing the Zero procedure.*

4.3 Alarms

Status LED on the Mainstream $EtCO_2$ Module:

Indication	Status
Steady blue light	System OK
Steady yellow light	Module error
Blinking yellow light	Airway adapter error

5. Module and Accessories

Below is a list of device models, versions and approved accessories. For an up to date list of accessories visit:

Catalog Number (REF.NO.)	Product	Description
CMZ20A	Mainstream $EtCO_2$ Module	Compatible with Phasein/Masimo
CSM01A	Airway Adapter Adult	Airway adapter is needed in order for $EtCO_2$ to provide readings.

6. Maintenance

6.1 Cleaning

Cleaning the $EtCO_2$ Module case, Cable and connector:

1. Use a cloth dampened with isopropyl alcohol 70%, a 10% aqueous solution of sodium hypochlorite (bleach), a 2% glutaraldehyde solution, ammonia, mild soap or disinfectant spray cleaner.
2. Wipe down with a clean water-dampened cloth to rinse and dry before use.

Note: *Do not immerse or sterilize the Module.*

Note: *The Side stream on-airway adapters and side stream sampling kits are single patient use. Treat in accordance with hospital protocols for handling single patient use devices.*

6.2 Airway adapter

- The airway adapters are intended for single patient use. They are disposable and shall not be re-used. Reuse of single patient use adapters can cause cross infection.
- The airway adapters shall be disposed of in accordance with local regulations for bio-hazardous waste.

7. Specifications

The Mainstream $EtCO_2$ Module specifications are subject to change without notice. Unless otherwise stated, all CO_2 measurements are made following a zero, with 5% CO_2 gas, balance N_2 at 25 degrees Celsius, and Pb. = 760 mmHg with 2 liters per minute flow. The stabilization time for full specification testing of the $EtCO_2$ Module over the entire temperature range is 20 minutes.

7.1 General specifications

Mode of Sampling	Main stream.
Principle of Operation	Non-dispersive infrared, dual wavelength， no moving parts.
Initialization Time	Capnograph displayed in less than 4 seconds, At an ambient temperature of 25 °C, full specifications within 2 minutes.
CO_2 Measurement Range	0 - 114 mmHg. 0 - 15 %. 0 - 15.2 kPa.
CO_2 Response Time	Less than 60 ms - Adult Reusable or Single-Patient-Use Airway Adapter. Less than 60 ms - Infant Reusable or Single-Patient-Use Airway Adapter.
CO_2 Resolution	0.2 mmHg @ 0 - 59 mmHg. 0.5 mmHg @ 60 - 114 mmHg.
CO_2 Accuracy*	0 - 40 mmHg ±2 mmHg. 41 - 70 mmHg ±5% of reading. 71 - 100 mmHg ±8% of reading. 101 - 114 mmHg ±10% of reading. Above 80 breaths per minute ±12% of reading. * Note: Gas temperature at 25 °C.

CO_2 Stability	Short Term Drift: Drift over three hours shall not exceed 1 mmHg maximum. Long Term Drift: Accuracy specification will be maintained over a six hour period.
CO_2 Noise	RMS noise of the Module shall be less than or equal to 0.5 mmHg at 5% CO_2.
Sampling Rate	100 Hz.
Respiration Rate Range	2 to 150 breaths per minute.
Respiration Rate Accuracy	±1 breath.
Calibration	No routine user calibration required.
$EtCO_2$ Calculation	Method: Peak of the expired CO_2 waveform.
Inspired CO_2 Measurement	Method: lowest reading of the CO_2 waveform in the previous 20 seconds.
Compensations (Supplied)	Barometric Pressure 400 mm Hg to 850 mm Hg Operator selectable O_2, N_2O, HE and Agent compensation.
O_2 Compensation	Range: 0 - 100%. Resolution: 1%. Default:16%.
N_2O Compensation	Range: 0(off) or 1(on). Default: off.
He Compensation	Range: 0(off) or 1(on). Default: off.

Cross-sensitivity Compensation Error *	* Additional worst-case error when compensation for Pb, O_2, N_2O, anesthetic agents, or helium is correctly selected for the actual fractional gas constituents present. 0 - 40 mmHg: ±1 mmHg additional error. 41 - 70 mmHg: ±2.5% additional error. 71 - 100 mmHg: ±4% additional error. 101 - 114 mmHg: ±5% additional error.

7.2 Interfering gas and vapor effects

Gas or Vapor	Gas Level	Quantitative Effects
Nitrous Oxide	60	No additional effect.
Halothane	4	No additional effect.
Enflurane	5	No additional effect.
Isoflurane	5	No additional effect.
Sevoflurane	5	No additional effect.
Xenon	80	Negatively bias Carbon Dioxide values by up to an additional 5 mmHg at 38 mmHg.
Helium	50	No additional effect.
Metered dose inhaler propellants	Unspecified	Unspecified.
Desflurane	15	Concentrations greater than 5% will positively bias Carbon Dioxide values by up to an additional 3 mmHg at 38 mmHg.
Ethanol	0.1%	No additional effect.
Isopropanol	0.1%	No additional effect.

Acetone	0.1%	No additional effect.
Methane	1%	No additional effect.

(ISO 21647, Medical electrical equipment – Particular requirements for the basic safety and essential performance of respiratory gas monitors, Table 105.)

7.3 Environmental

Temperature	Operating: 0 to 40 °C. Storage: -40 to 70 °C. Transport: -40 to 70 °C.
Humidity	Operating: 10 to 90% RH, non-condensing. Storage: 10 to 90% RH, non-condensing. Transport: 10 to 90% RH, non-condensing.
Atmospheric Pressure	Operating: 400-800 mmHg. Storage: 400-800 mmHg. Transport: 400-800 mmHg.
Category AP/APG	AP - This device is not suitable for use in the presence of a flammable anesthetic mixture with air or nitrous oxide.
Water Resistance	IPX4 - Splash-proof - Module only.
Mode of Operation	Module is rated for continuous use. No marking is required.
Protection Against Electric Shock	The Module does not provide electrical isolation for enclosure leakage current, patient risk circuit, or patient auxiliary current. It is the responsibility of the Host System to ensure that the power supply conforms to applicable standards - Recommend IEC 60601-1 Type BF.

Shock Impact	IEC TR 60721-4-7 Class 7M3 (designed to withstand environments subject to significant vibrations or high shock levels). EN60068-2-27 Shock. EN60068-2-64 Random Vibration.
Radiated Emissions	Host system dependent, designed to meet the requirements of EN55011- CISPR 11 Class B 30 MHz to 1000 MHz.
Electrostatic Discharge Immunity	Host system dependent, designed to meet the requirements of IEC 61000-4-2 (2001-04) 6 kV conducted 8 kV air discharge.
Radiated Immunity	Host system dependent, designed to meet the requirements of IEC 61000-4-3 (2002-03) 80 MHz to 2.5 GHz, 20 V/m.
Immunity to Conducted Disturbances Induced by RF Fields	Host system dependent, designed to meet the requirements of IEC61000-4-6 (2001-04).

8. Host communication specifications

It is the responsibility of the host system to monitor connectivity to the EtCO_2 Module and provide status information and messages to the user. The Module will provide status information to the host via the communication protocol. It is the host's responsibility to provide any visual or audible indications of alert conditions to the end user.

Serial Communication Format	RS-232, bi-directional, 19200 baud, standard N-8-1.
Data Output	Real time CO_2 waveform, gas and barometric pressure compensated, End-tidal CO_2 Inspired CO_2, Respiratory Rate. Status information.

Serial Communications Protocol	The Mainstream CO_2 Module system shall use a proprietary protocol as the standard data communication protocol to the Host system. The signal levels shall conform to the RS-232 standard and be a in a bi-directional binary format.

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