Operator's Manual

EMMA® Capnograph

Masimo

These operating instructions provide the necessary information for proper operation of all models of the EMMA. There may be information provided in this manual that is not relevant for your system. General knowledge of capnography and an understanding of the features and functions of EMMA are prerequisites for its proper use. Do not operate EMMA without completely reading and understanding these instructions. If you encounter any serious incident with product, please notify the competent authority in your country and the manufacturer.

Note: Cleared Use Only: The device and related accessories are cleared by the Food and Drug Administration (FDA) and are CE Marked for noninvasive patient monitoring and may not be used for any processes, procedures, experiments, or any other use for which the device is not intended or cleared by the applicable regulatory authorities, or in any manner inconsistent with the directions for use or labeling.

Notice: Purchase or possession of this device does not carry any express or implied license to use with replacement parts which would, alone or in combination with this device, fall within the scope of one of the relating patents.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician. See instructions for use for full prescribing information, including indications, contraindications, warnings and precautions.

For professional use. See instructions for use for full prescribing information, including indications, contraindications, warnings, and precautions.

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MEDICAL – GENERAL MEDICAL EQUIPMENT AS TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH ANSI/AAMI ES60601-1: A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012, CSA CAN/CSA-C22.2 NO. 60601-1:14

Patents: www.masimo.com/patents.htm

Contents

About this Manual

This manual explains how to set up and use EMMA® Capnograph. Important safety information relating to general use of EMMA appears in this manual. Read and follow any warnings, cautions, and notes presented throughout this manual. The following are explanations of warnings, cautions, and notes.

A *warning* is given when actions may result in a serious outcome (for example, injury, serious adverse effect, death) to the patient or user.

WARNING: This is an example of a warning statement.

A *caution* is given when any special care is to be exercised by the patient or user to avoid injury to the patient, damage to this device, or damage to other property.

CAUTION: This is an example of a caution statement.

A *note* is given when additional general information is applicable.

Note: This is an example of a note.

Product Description, Features and Intended Use

Product Description

The EMMA® Capnograph is a quantitative mainstream carbon dioxide monitor comprised of a Sensor Body that fits on top of a disposable EMMA Airway Adapter.

Intended Use

EMMA® Capnograph measures, displays and monitors carbon dioxide partial pressure and respiratory rate during anesthesia, recovery and respiratory care. It may be used in the operating suite, intensive care unit, patient room, clinic, emergency medicine and emergency transport settings for adult, pediatric and infant patients.

Safety Information, Warnings and Cautions

CAUTION: EMMA is to be operated by, or under the supervision of, qualified personnel only. Read the manual, accessories directions for use, all precautionary information, and specifications before use.

Safety Warnings and Cautions

WARNING: EMMA should only be used for the purpose and in the manner described in this manual.

WARNING: EMMA is intended for use by authorized health care professionals only.

WARNING: EMMA must not be used with flammable anesthetic agents.

WARNING: If EMMA is used with a respirator or with harmful gases such as N_2O, always perform a pre-use tightness check of the patient circuit.

WARNING: EMMA Airway Adapters shall not be reused. Reuse of single use Adapters can cause cross infection.

WARNING: Do not use the EMMA Adult/Pediatric Airway Adapter with infants as the Adapter adds 6 ml dead space to the patient circuit.

WARNING: Do not use the EMMA Infant Airway Adapter with adults/pediatrics as this may cause excessive flow resistance.

Performance Warnings and Cautions

WARNING: EMMA is intended only as an adjunct in patient assessment. It shall be used in conjunction with the assessment of clinical signs and symptoms.

WARNING: Use only EMMA Airway Adapters manufactured by Masimo.

WARNING: No modification of the EMMA probe or the EMMA Airway Adapters is allowed.

WARNING: Light transmission can be affected by secretions and moisture pooling on the EMMA Airway Adapter XTP™ windows. When using heated humidifiers special care should be paid to position the Airway Adapter in a vertical position and to change Airway Adapter if necessary.

WARNING: Do not use EMMA with nebulized medications as this may affect the light transmission of the EMMA Airway Adapter windows.

WARNING: Audible alarm of any monitor may not be heard in some loud environments, such as when sirens are in use and the care provider is more distant from the alarm source. Alarm volume should be tested with the extremes of your noise environment to confirm ability or limitations to hear an alarm in all circumstances of the environment.

WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating properly.

WARNING: Make sure that EMMA is used in the electromagnetic environment specified in this manual.

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the EMMA. Otherwise, degradation of the performance of the EMMA could result.

Note: To preserve and maximize battery life, make sure alarm conditions are addressed promptly and the unit is turned off when not in use, especially prior to storage.

Note: A trained medical professional must determine the proper EMMA Airway Adapter model for each patient application. No hardware or software configuration changes result from the EMMA Airway Adapter model selected.

Note: The alarm limits will be reset to default values after EMMA powers off.

Cleaning and Service Warnings and Cautions

WARNING: Properly use and dispose of batteries or they may leak or explode.

WARNING: Lithium batteries may present a fire or chemical burn hazard if mistreated. Do not disassemble, heat above 100°C (212°F) or incinerate. Dispose of used cells promptly. Keep away from children.

WARNING: Use only Alkaline batteries or Energizer Ultimate Lithium L92 batteries. Use of other Lithium batteries may present a risk of fire or explosion.

WARNING: Replace batteries immediately when the Battery Status Indicator starts blinking. Remaining battery time depends on battery type and other circumstances and cannot be reliably predicted.

CAUTION: Remove alkaline batteries when the EMMA will not be in use for more than 30 days to avoid damage to the device due to batteries that may leak.

CAUTION: Replace both batteries at the same time to avoid mixing fully and partially charged batteries. These actions may cause the batteries to leak; resulting in possible damage to the device.

CAUTION: Do not immerse EMMA in any liquid.

CAUTION: Do not apply excessive pressure on the IR-windows.

CAUTION: Never saturate EMMA completely with any disinfection solution.

CAUTION: Only perform maintenance procedures specifically described in the manual; otherwise, return EMMA for servicing. Improper maintenance may result in damage to the internal parts. Damage to internal parts may result in no or inaccurate readings.

CAUTION: Do not clean EMMA with any chemical other than those specified in Maintenance and Cleaning of this manual. These substances may affect the device's materials and damage internal parts.

CAUTION: The EMMA and EMMA Airway Adapters are non-sterile devices. Do not submerge EMMA or EMMA Airway Adapters in any cleaning solution or attempt to sterilize by autoclave, irradiation, steam, gas, ethylene oxide or any other method. This will seriously damage the device.

CAUTION: Do not use undiluted bleach (5% - 5.25% sodium hypochlorite) or any cleaning solution other than those recommended in Maintenance and Cleaning of this manual. Permanent damage to EMMA may occur if other unspecified solutions are used.

CAUTION: Never submerge EMMA in water or any other liquid solution this may cause permanent damage to the EMMA.

Note: Before cleaning EMMA, remove the batteries and make sure the battery cover is re-attached correctly.

Note: The presence of ambient air (0% CO_2) in the EMMA Airway Adapter is of crucial importance for a successful Zeroing. Special care should be taken to avoid breathing near the EMMA Airway Adapter before or during the Zeroing procedure.

Compliance Warnings and Cautions

WARNING: Any changes or modifications not expressly approved by Masimo shall void the warranty for this equipment and could void the user's authority to operate the equipment.

CAUTION: Disposal of Product: Comply with local laws in the disposal of the device and/or its accessories.

CAUTION: EMMA Airway Adapters shall be disposed of in accordance with local regulations for bio hazardous waste.

Note: This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

Note: This equipment has been tested and found to comply with the Class B limits for medical devices according to the EN 60601-1-2: 2015, Medical Device Directive 93/42/EEC. These limits are designed to provide reasonable protection against harmful interference in all establishments, including domestic establishments.

Note: This Class B digital apparatus complies with Canadian ICES-003.

Note: This device complies with Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

Chapter 1: Technology Overview

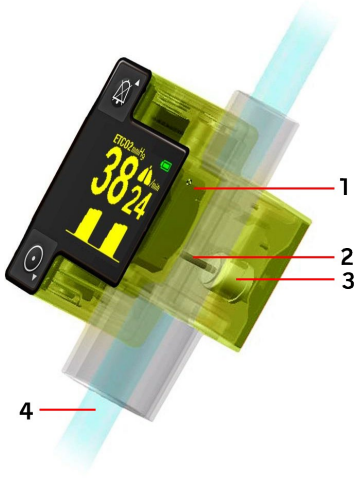
The following chapter contains general descriptions about parameters, measurements, and the technology used in EMMA.

Principles of Operation

The measurement of CO2 in the breathing gas mixture is based on the fact that different gas components absorb infrared light at specific wavelengths. A beam of invisible infrared light is directed through the respiratory gas flow in the EMMA Airway Adapter. As the beam passes through the EMMA Airway Adapter, some of the light is absorbed by the gas mixture. The amount of absorbed light is measured by a miniaturized two channel spectrometer positioned to receive the infrared light beam.

The spectrometer incorporates a filter wheel fitted with two different optical "color" filters. The wavelength ranges of these filters are chosen such that one filters out colors where carbon dioxide has very strong absorption and the other filters out colors where carbon dioxide has no absorption.

The spectrometer also incorporates an infrared detector that converts the light beam to an electrical signal. The electrical signal is converted to a digital value that is fed to a microprocessor. The ratio of the light measured through the two filters is then used by the microprocessor to calculate the carbon dioxide concentration in the breathing gas mixture.



1 Spectrometer with optical filter wheel and infrared detector

2 Infrared light beam

3 Infrared light source

4 Respiratory gas

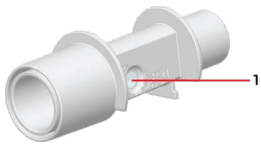
EMMA Airway Adapter

Respiratory gas measurements are, as described in the previous section, obtained by continuously measuring the infrared light absorption through the EMMA Airway Adapter. The Airway Adapter is fitted with optical XTP™ windows that are transparent to light in the wavelength ranges of interest. The Airway Adapter may, for example, be inserted between the endotracheal tube and the resuscitation bag or between the resuscitation bag and the patient mask.

The Airway Adapter is available in two models: Adult/Pediatric and Infant. EMMA operates to specification with either Airway Adapter model when used with its appropriate patient population.

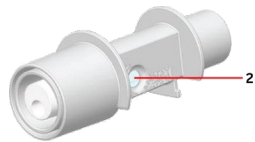
- The Airway Adapters are intended for single patient use. They are disposable and shall not be re-used. Reuse of single patient use Adapters can cause cross infection.
- Airway Adapters shall be disposed of in accordance with local regulations for bio hazardous waste.

EMMA Airway Adapter Adult/Pediatric (REF 100620)



1. XTP window (Adult/Pediatric)

EMMA Airway Adapter Infant (REF 100660)



2. XTP window (Infant)

Note: A trained medical professional must determine the proper EMMA Airway Adapter model for each patient application. No hardware or software configuration changes result from the Airway Adapter model selected.

Chapter 2: Description

This chapter contains the description of the EMMA physical features.

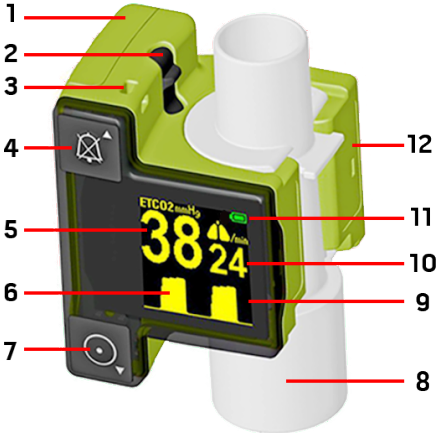
General System Description

The EMMA system includes the following:

- EMMA Device
- Two (2) AAA Batteries

For a complete list of compatible EMMA Airway Adapters, visit www.masimo.com.

Features



1 Battery Cover

2 Battery Cover release button

3 Lanyard attachment

4 Alarm Silence button

5 EtCO2 Value

6 Capnogram

7 Power On button

8 EMMA Airway Adapter

9 Alarm Status

10 Respiratory Rate Value

11 Battery Status Indicator

12 EMMA Sensor Body

Chapter 3: Basic Setup and Use

This chapter contains information about setting up EMMA before use.

Installing Batteries

Unpack and inspect the EMMA for external damage. Please contact your local distributor in case of damage.

1. Press the **Battery Cover** release button into the EMMA Sensor Body until the Battery Cover pops off.

2. Open the battery compartment and insert two (2) AAA batteries. Make sure the batteries are fitted according to the indicated polarity. After battery installation, snap the **Battery Cover** back into place.

Attaching Airway Adapter

Snap the Airway Adapter into the EMMA Capnograph.
It will click into place when properly inserted.

Connecting to a Tube or Mask

The EMMA Capnograph can be connected to a patient using an endotracheal tube or mask. The following pictures illustrate these two methods of connection.

Endotracheal tube

Mask

Power On

1. To power on EMMA, press the Power On button.

2. When the EMMA Capnograph is ready the $EtCO_2$ Value displays "0" and the Respiratory Rate Value displays dashes "- -".

The audible alarm sound may be checked by detaching the EMMA Airway Adapter to generate a *No Adapter* alarm.

If the $EtCO_2$ Value is non-zero, ensure that there has not been an accumulation of CO_2 between the EMMA Sensor Body and the EMMA Airway Adapter by removing and reattaching the EMMA Airway Adapter. If the $EtCO_2$ Value still displays a non-zero value after this procedure, perform a Zeroing procedure. See ***Zeroing Procedure*** on page 58.

Power Off

The EMMA Capnograph switches off automatically during following conditions:

- If no breath is detected within 2 minutes from power up.
- If no breath is detected for 2 minutes and the alarm has been silenced.
- 15 seconds after the EMMA Airway Adapter is removed.

Note: The device will not automatically power off if there is an alarm condition other than a No Adapter alarm detected (e.g. Clogged Adapter).

Chapter 4: Operation

The information in this chapter assumes that EMMA is set up and ready for use. This chapter provides necessary information for proper operation of the device. Do not operate EMMA without completely reading and understanding these instructions.

EMMA Display

The EMMA Capnograph is fitted with a graphic OLED-display that displays End-Tidal Carbon Dioxide ($EtCO_2$) and Respiratory Rate (RR) parameters as well as the CO_2 waveform (Capnogram).

1 $EtCO_2$ Parameter Value

2 Capnogram

3 RR Parameter Value

$EtCO_2$

The EMMA Capnograph is available in versions displaying End-Tidal Carbon Dioxide ($EtCO_2$) either in mmHg (0 - 99 mmHg) or kPa (0.0 - 9.9 kPa). $EtCO_2$ values are displayed after one breath and the averaged value is updated every breath.

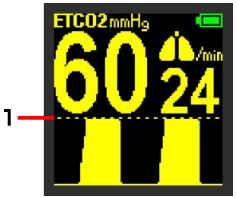
Respiratory Rate

Respiratory Rate (RR) is displayed as breaths per minute (3 - 150 bpm). RR is displayed after two breaths and the value is updated every breath.

Capnogram

The Capnogram is displayed as a filled graph with a 14.4 sec horizontal sweep and a fixed 0-53 mmHg/0-7 kPa scale.

If the CO_2 level reaches or exceeds 53 mmHg/7 kPa, a horizontal dashed line (1) will be displayed to indicate that the capnogram is saturated.



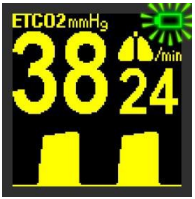
Auto Brightness

To extend battery life time the EMMA display has an automatic brightness control which will be activated during stable conditions. Any change in displayed vital parameters, alarm or pressing any button will return the EMMA display to normal brightness.

Battery Status Indicator

The *Battery Status Indicator* is  normally lit with a steady green light in the upper right corner of the display (Battery OK or Weak). When batteries are low, the Battery Status Indicator starts blinking.

Battery Status	Battery Voltage*	Battery Status Indicator
OK	>2.4V	
Weak	2.2V to 2.4V	

Battery Status	Battery Voltage*	Battery Status Indicator
Low	<2.2V	

* Typical values.

There will be an audible tone beep repeated every 80 seconds when batteries are low.

The terminal voltage of alkaline batteries recovers when the batteries are not in use. The remaining time prediction is thus unreliable during the first period after power on. Nearly depleted batteries may still be able to provide a voltage above the threshold for battery low indication, even if the internal battery resistance is too high to provide sufficient current to start up the device next time the power on button is activated.

To extend battery life time the EMMA display has an automatic brightness control, which will be activated during stable conditions. Any change in displayed vital parameters, alarm or pressing any button will return the EMMA display to normal brightness.

Controls

The EMMA Capnograph has one Power On and one Alarm Silence button. These buttons are also be used for adjusting the high and low $EtCO_2$ alarm limits up and down.

1 Power On/Adjust Down button

2 Alarm Silence/Adjust Up button

Parameter Settings

The following information contains default alarm limits and information for adjusting $EtCO_2$ alarm limits.

Default Alarm Limits

The default factory settings for the RR and the $EtCO_2$ alarms are as follows:

	Lower Limit	**Upper Limit**
RR (No Breath)	3 bpm (20 seconds)	NA
$EtCO_2$	OFF	50 mmHg (7.0 kPa)

EtCO2 Settings

The adjustment ranges for the $EtCO_2$ alarm limits are as follows:

	Lower range	**Upper range**
$EtCO_2$ (mmHg)	OFF; 1 – 89 mmHg	11 – 99 mmHg; OFF
$EtCO_2$ (kPa)	OFF; 0.1 – 8.9 kPa	1.1 – 9.9 kPa; OFF

Note: The alarm limits will be reset to default values after EMMA powers off.

If the high $EtCO_2$ limit is decreased close to the low $EtCO_2$ limit, the low limit will be automatically adjusted in order to maintain a minimum difference of 10 mmHg (1.0 kPa) between the high and low alarm limit. Similarly, if the low $EtCO_2$ limit is increased close to the high $EtCO_2$ limit, the high limit will be automatically adjusted to maintain a minimum difference of 10 mmHg (1.0 kPa) between the high and low alarm limit.

If no buttons have been activated for a short period during alarm limit adjustment, the EMMA Capnograph will automatically resume normal operation.

Low EtCO2 Alarm

1. Press and hold the Power On button until the display shows the "Lo ETCO2 Screen" and the $EtCO_2$ display shows the current low $EtCO_2$ alarm limit. See ***Controls*** on page 29.
2. Release the Power On button.
3. To adjust the alarm limit: press the Alarm Silence button (▲) to increase, or the Power On button (▼) to decrease the value. It is possible to switch off the low $EtCO_2$ alarm by adjusting the limit down to 0. The EMMA will indicate this setting by showing "- -" on the $EtCO_2$ display during the adjustment routine.

   If no button has been activated for a short period, the EMMA will automatically resume normal operation.

High EtCO2 Alarm

1. Press and hold the Alarm Silence button until the display shows the **Hi ETCO2 Screen** and the $EtCO_2$ display shows the current high $EtCO_2$ alarm limit. See ***Controls*** on page 29.
2. Release the Alarm Silence button.
3. To adjust the alarm limit: press the **Alarm Silence** button (▲) to increase, or the **Power On** button (▼) to decrease the value. It is possible to switch off the high $EtCO_2$ alarm by adjusting the limit above 99 mmHg (9.9 kPa). The EMMA will indicate this setting by showing "- -" on the $EtCO_2$ display during the adjustment routine.

   If no button has been activated for a short period, the EMMA will automatically resume normal operation.

Chapter 5: Alarms and Messages

Silencing Alarms

The EMMA Capnograph is equipped with an Alarm Status Indicator and an audible alarm. The audible alarm can be silenced for 2 minutes by pressing the **Alarm Silence** button. See ***Controls*** on page 29.

- When the audible alarm is silenced, the yellow silence alarm indicator in the bottom right corner of the display, i.e. the *Alarm Status Silence Indicator*, will be lit.
- Pressing the Alarm Silence button again during the 2 minutes mute period will reactivate the audible alarm.
- If a No Breath alarm is muted by pressing the Alarm Silence button, the EMMA Capnograph will automatically switch off after 2 minutes provided that no new breaths are detected.
- If the alarm situation passes while the audible alarm is silenced, the alarm icon turns green.
- Pressing the Alarm Silence button during no alarm will also show a green silence alarm indicator in the bottom right corner of the display.

Alarm Signals

Alarm	at t = 0 Alarm Priority: Low	at t = 20 Alarm Priority: Low	t = 40, 60, 80, ... Alarm Priority: Medium
No Breath	 (((•)))	 (((•))) (((•)))	 (((•))) (((•))) (((•)))
Low $EtCO_2$		n/a	
High $EtCO_2$		n/a	
Clogged Adapter [1]	 (((•)))	n/a	n/a

Alarm	at t = 0 Alarm Priority: Low	at t = 20 Alarm Priority: Low	t = 40, 60, 80, ... Alarm Priority: Medium
No Adapter [1]		n/a	n/a
Zero point adjustment [1]		n/a	n/a

[1] See ***Chapter 6: Troubleshooting*** on page 37.

Note: t = 0 is defined as the time when the alarm condition first is indicated. t = 40, 60, 80, ... shall be interpreted as "40 sec later than t = 0", "60 sec later than t = 0", "80 sec later than t = 0" etc. For Low $EtCO_2$ and Hi $EtCO_2$, there is a 20 sec delay before t = 0 when the alarm condition is indicated (i.e. the Alarm Signal Generation Delay is 20 sec).

Alarms and Messages

Active alarms are further displayed according to the following table:

Alarm	Screen	ETCO2 Value	RR Value
No Breath	NORMAL	value steady [1]	"- -" flashing [2]
Low $EtCO_2$	NORMAL	value flashing	value steady
High $EtCO_2$	NORMAL	value flashing	value steady
Clogged Adapter	ADAPTER	n/a	n/a
No Adapter	ADAPTER	n/a	n/a
Zero point adjustment [3]	NORMAL	value steady	value steady

Note 1: $EtCO_2$ value displays momentary CO_2 during No Breath.

Note 2: RR value displays "- -" steady if no breath at all detected from power on.

Note 3: Perform Zeroing procedure. See ***Zeroing Procedure*** on page 58.

Chapter 6: Troubleshooting

Troubleshooting EMMA

Error	Possible Causes	Recommended Solutions
No Adapter alarm is displayed	Indicates that an EMMA Airway Adapter needs to be installed.	Connect an EMMA Airway Adapter. See ***Attaching Airway Adapter*** on page 20.
Clogged Adapter alarm is displayed	Indicates that the EMMA Airway Adapter needs to be replaced with a new one.	Replace the EMMA Airway Adapter with a new one.
Zero point adjustment alarm is displayed	A zero point adjustment is required.	Perform a Zeroing procedure. See ***Zeroing Procedure*** on page 58.
The unit does not complete the turn on sequence	Low battery	Replace the batteries.
The unit does not turn on	• No battery • Low battery	Replace the batteries.

Error	Possible Causes	Recommended Solutions
The measured values of ETCO2 are out of specified accuracy	Incorrect zero reference	Perform a Zeroing procedure and verify the measurement with reference gas. See ***Chapter 8: Service and Maintenance*** on page 55.
Numbers appear dim	• Automatic brightness control is activated. • Exposed to bright lights or sunlight.	Pressing any button will return the EMMA display to normal brightness. See ***Controls*** on page 29.

Chapter 7: Specifications

Display Range

Measurement	Display Range
$EtCO_2$ (End-Tidal CO_2) [1], [2] *	0 mmHg to 99 mmHg 0 kPa to 9.9 kPa
RR (Respiration Rate)	3 BPM to 150 BPM

* ETCO2 will be within specification for respiration rates up to 150 bpm [3]

Accuracy (ARMS)

Carbon Dioxide (CO_2) [4]	
Range 0 mmHg to 99 mmHg	0-40 mmHg ± 2 mmHg, 41-99 mmHg 6% of reading during standard conditions
Range 0 kPa to 9.9 kPa	0-5.3 kPa ± 0.3 kPa, 5.4-9.9 kPa 6% of reading during standard conditions

Respiration Rate (RR)	
Range 3 to 150 bpm	±1 bpm

Electrical

Battery	
Type	Two (2) AAA Cell Batteries, Alkaline or Lithium
Capacity - Alkaline [5]	Approx. 5 hours
Capacity - Lithium L92 [5]	Approx. 10 hours

Environmental

Environmental Conditions	
Operating Temperature	-5 to 50°C (23 to 122°F) -20 to -5°C for 20 minutes [6]

Environmental Conditions	
Storage/Transport Temperature	-40 to 70°C (-40 to 158°F)
Operating Humidity	< 50 hPa H2O (non-condensing) (41% RH at 50 °C)
Storage Humidity	10 to 95% RH (condensing) at a water vapor partial pressure not exceeding 50 hPa (95 % RH at 32 °C)
Operating Atmospheric Pressure	60 to 120kPa [1] (i.e. Altitude up to 4000 m)
Storage Atmospheric Pressure	50 to 120 kPa

Physical Characteristics

Physical Characteristics	
Dimensions	52 mm x 39 mm x 39 mm (2.1" x 1.6" x 1.6")

Physical Characteristics	
Weight	Approx. 65 g (2.1 oz.) with batteries
Display Type	96 x 96 pixel RGB OLED-display

Alarms

Audio Alarm Description
No Breath, Low ETCO2, High ETCO2, Clogged Adapter, No Adapter, Zero point adjustment, Low Battery

Alarm Characteristic	Description
Alarm Volume	v≥ 57 dB(A); ≤ 67 dB(A)

Compliance

Safety Standards Compliance	
EN 60601-1:2006/AMD1:2013	EN ISO 80601-2-55:2018
EN 60601-1-2:2015	EN ISO 5356-1:2015
EN 60601-1-8:2007, C1:2010, A1:2013	EN ISO 14971:2012
EN 60601-1-12:2015	EN ISO 15223-1:2016

Equipment Classification per IEC 60601-1	
Type of Protection	Internally powered (Battery power)
Degree of Protection of Electrical Shock	Defibrillation proof BF-Applied Part
Protection against harm from solid and liquid ingress	IP44, Protection from tools and small wires greater than 1mm and from water spray from any direction.
Mode of Operation	Continuous operation
Sterility	No part of EMMA is sterile

Additional Specifications

General	Specifications
Description	Compact, battery powered, quantitative capnograph for mainstream CO_2 monitoring of adult, pediatric and infant patients.
Measurements [1]	The CO_2 partial pressure is measured based on a 2 channel NDIR type gas analyzer at 4–5 μm with data acquisition rate at 10 kHz (sample rate 20 Hz / channel).
Models	CO_2 displayed in kPa or mmHg
Drift of measurement Accuracy	No drift
Recovery Time After Defibrillator Test	Unaffected
Highest Surface Temperature	
At Ambient Temperature	Surface Temperature
23°C / 73°F	30°C / 86°F

General	Specifications
50°C / 122°F	57°C / 135°F

Data Output	Specifications
Breath Detection	Adaptive threshold, minimum 1kPa CO_2 change.
Adult/Pediatric	Dead space 6 ml, Flow resistance < 0,3 cm H2O (@ 30 LPM)
Infant	Dead space 1 ml, Flow resistance < 1,3 cm H2O (@ 10 LPM)

Gas Analyzer	Specifications
Warm-up	In operation and full accuracy within 15 seconds.
Warm-up time after storage at -40°C	A warm up period of 15 minutes is required before EMMA is ready for use after being stored with batteries mounted at –40°C when the ambient temperature is 20°C.

Gas Analyzer	Specifications
Cool-down time after storage at 70°C	In operation and full accuracy within 15 seconds.
Calibration	No routine calibration is required.
Total System Response Time	< 0.7 seconds

Guidance and Manufacturer's Declaration-Electromagnetic Emissions

EMMA is expected to be used in a professional environment like intensive care unit, patient room and operating suite except near high frequency electro surgical equipment and magnetic resonance imaging (MRI) systems. EMMA is also intended to be used in emergency medical services as road ambulances.

EMMA is intended for use in the electromagnetic environment specified in the tables below. Customers or end users of EMMA should assure that the EMMA is used within the intended environment.

Guidance and Manufacturer's Declarations - Electromagnetic Emissions		
Emission Test	**Compliance**	**Electromagnetic Environment - Guidance**
RF Emissions CISPR 11	Group 1	ME Equipment uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B EUROCAE ED-14G or RTCA DO 160G, Section 21, category M levels	Suitable for use in all professional facility and home healthcare environments. Suitable for use in air ambulances.

Guidance and Manufacturer's Declaration-Electromagnetic Immunity

This section constitutes the guidance and Masimo's declaration regarding electromagnetic immunity for EMMA.

Essential performance of EMMA is gas measurement accuracy (see Citation [4]) including gas reading alarm conditions, or generation of technical alarm conditions, when exposed to the following immunity levels.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity		
Immunity Test	**Compliance Level**	**Electromagnetic Environment - Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	+/-8 kV contact +/-2 kV, +/-4 kV, +/-8 kV, +/-15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Power frequency (50 / 60 Hz) magnetic field. IEC 61000-4-8	30 A/m	Power frequency magnetic fields should be at levels characteristic of typical location in a typical hospital environment.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity		
Radiated RF IEC 61000-4-3	10 V/m 80%AM@1kHz 80 MHz to 2.7 GHz and Table 9 (60601-1-2:2015)	Portable and mobile RF communications equipment should be used no closer than 30 cm to any part of EMMA. Otherwise, degradation of the performance of this equipment could result.

WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating properly.

WARNING: Make sure that EMMA is used in the electromagnetic environment specified in this manual.

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the EMMA. Otherwise, degradation of the performance of the EMMA could result.

Recommended Separation Distances

Recommended separation distances between portable and mobile RF communications equipment and the EMMA	
The EMMA is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the EMMA gas analyzer can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the EMMA gas analyzer as recommended below, according to the maximum output power of the communications equipment.	
Rated maximum output power of transmitter [W]	**Separation distance according to frequency of transmitter [m]**
	80 MHz to 2.7 GHz $d = 0.6\sqrt{P}$
0,01	0.06
0,1	0.19
1	0.6
10	1.9
100	6

Recommended separation distances between portable and mobile RF communications equipment and the EMMA
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. **Note:** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Symbols

The following symbols are found on the EMMA, or packaging and are defined below.

Symbols	Definition	Symbols	Definition
	Follow Instructions for use		Defibrillation Proof Type BF
REF	Catalog number (model number)	SN	Serial number
LOT	Lot Code		Manufacturer
	Use by Date YYYY-MM-DD		Storage temperature range
	Atmospheric pressure limitation		Storage humidity limitation

Symbols	Definition	Symbols	Definition
	Do not Reuse		Separate collection for electrical and electronic equipment (WEEE)
CE 0413	Mark of Conformity to European medical device directive 93/42/EEC	CLASSIFIED c UL us 3JSV	UL LLC certification
IP44	Degree of protection against water and solid foreign objects.	**Rx ONLY**	**Caution:** Federal law restricts this device to sale by or on the order of a licensed physician.
	Instructions/Directions for Use/Manuals are available in electronic format @http://www.Masimo.com/TechDocs **Note:** eIFU is not available in all countries.		

Citations

[1] The EMMA Capnograph displays CO_2 in partial pressure units (kPa or mmHg) and compensates the displayed value for the actual barometric pressure. The $EtCO_2$ value is the max partial CO_2 pressure measured within a breath and the displayed value is:

– the latest EtCO2 values i.e. if $\Delta EtCO_2 \geq 25\%$ or

– the average of up to four $EtCO_2$ values measured within 30s given $\Delta EtCO_2 < 25\%$.

[2] Gas reading showing actual partial pressure at current humidity level. Partial pressure of CO_2 in the alveoli, where the breathing gas is saturated with water vapor at body temperature (BTPS), is typically 6% lower than the corresponding CO_2 partial pressure after removal of all water vapor (ATPD).

[3] EtCO2 was measured at I/E ratio 1:1 using breath simulator according to the test setup in EN ISO 80601-2-55 fig. 201.101. The measured $EtCO_2$ was within the accuracy range for all respiration rates up to 150 bpm.

[4] To include quantitative effect on gas reading from variations in environment conditions (outside STP, electromagnetic disturbances) and presence of Halothane, Ethanol, Isopropyl alcohol, He, Acetone and Methane, the CO_2 accuracy range should be increased to ±4 mmHg/ ±0.5 kPa or ±10% of reading whichever is the greater. In addition the following interference effects on CO_2 readings exists:

- *60 vol% of N2O typically increases CO_2-readings by 10%*
- *60 vol% of O2 typically decreases CO_2-readings by 4% (EMMA compensates CO_2-values for influence from 21% O_2 as default)*
- *5 vol% of ENF, ISO, SEV typically increases CO_2-readings by 8%*
- *15 vol% of DES typically increases CO_2-readings by 12%*
- *80% Xe typically decreases CO_2-readings by 10%*
- *50% He typically decreases CO_2-readings by 6%.*

[5] Battery life test was performed using Energizer brand batteries. www.energizer.com.

[6] Depending on battery type and status; 19 minutes when tested with new Alkaline batteries, >20 minutes when tested with new Lithium batteries.

Chapter 8: Service and Maintenance

The following chapter contains information about cleaning, battery operation, performance verification, service, repair, and warranty.

Cleaning

Device

CAUTION: Do not immerse EMMA in any liquid.

CAUTION: Do not apply excessive pressure on the IR-windows.

Note: Before cleaning EMMA, remove the batteries and make sure the battery cover is re-attached correctly.

To clean EMMA, follow the instructions below:

1. Remove the Airway Adapter.
2. Wipe each of the outer surfaces twice or until the surfaces are free of any visible residue, using one of the following solutions:
   - A cloth moistened with 70% Isopropyl Alcohol
   - A quaternary ammonium chloride solution wipe (for example CaviWipes™)

   Note: Pay particular attention to crevices and hard to reach areas of the device. Use a soft bristled brush to gently remove any visible residue from crevices as necessary.

3. Repeat the above cleaning step using a fresh cloth or wipe.
4. Allow the EMMA device to dry thoroughly before using again.

The surfaces of EMMA have been tested to be chemically resistant to the following disinfectants/solutions:

- 70% Isopropyl alcohol
- 70% Ethyl alcohol
- Quaternary ammonium chloride solution wipe
- Cidex Plus (3.4% glutaraldehyde)
- 0.5% Sodium hypochlorite (1:10 Bleach to water solution)
- Accelerated hydrogen peroxide

Always wipe off residues of disinfection solutions with a wet cloth after exposure.

CAUTION: Never saturate EMMA completely with any disinfection solution.

Airway Adapters

The EMMA Airway Adapters are not intended to be cleaned.

The EMMA 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.

EMMA Airway Adapters shall be disposed of in accordance with local regulations for bio hazardous waste.

Maintenance

Battery Replacement

WARNING: Lithium batteries may present a fire or chemical burn hazard if mistreated. Do not disassemble, heat above 100°C (212°F) or incinerate. Dispose of used cell promptly. Keep away from children.

WARNING: Use only Alkaline batteries or Energizer Ultimate Lithium L92 batteries. Use of other Lithium batteries may present a risk of fire or explosion.

To replace the batteries:

1. Open the battery compartment by pressing the release button. See ***Installing Batteries*** on page 19.
2. Gently remove the depleted batteries.
3. Insert two new AAA type batteries into the battery compartment. Make sure that the batteries are fitted according to the polarity marking.
4. When the batteries are properly fitted, gently snap the battery cover back into place.

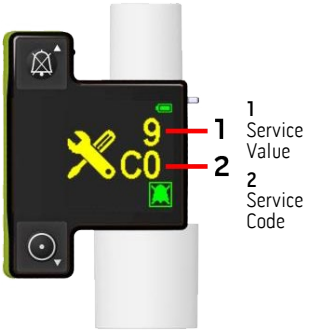
Note: Always carry spare batteries in the EMMA pouch.

Zeroing Procedure

Zeroing is recommended after 500 hours of operation or whenever an offset in gas readings is discovered. Zeroing of the EMMA is performed by the following procedure:

Note: The presence of ambient air (0% CO2) in the EMMA Airway Adapter is of crucial importance for a successful Zeroing. Special care should be taken to avoid breathing near the EMMA Airway Adapter before or during the Zeroing procedure.

1. Start the EMMA by pressing the Power On button. See ***Controls*** on page 29.
2. Make sure that a new EMMA Airway Adapter is properly fitted. See ***Attaching Airway Adapter*** on page 20.
3. Press and hold down simultaneously the Power On and Alarm Silence button until the Service Screen display the Service code “C0” and the Service value “10”. Keep both buttons depressed while the Service value starts "counting down" i.e. displaying "9" - "8" - "7" etc. until "0" is displayed.
4. When the Service value “0” is shown, zeroing of the EMMA is complete.*



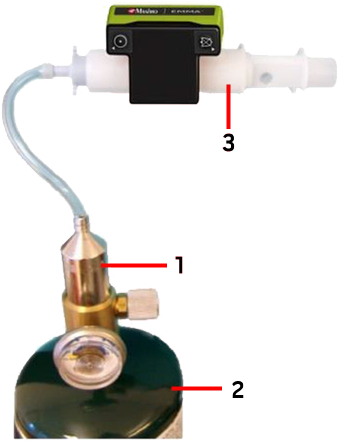
* The EMMA Capnograph will return to normal measuring mode when the Service value has reached "0" or if any of the buttons are released.

Gas Span Check

The EMMA Capnograph does not require any routine calibration. A gas span check is recommended at regular intervals to make sure the measurement is within accuracy levels. The suggested interval for gas span check is once every year. To following items are required to perform a gas span check of EMMA:

Attach the flow regulator to the calibration gas cylinder. Ensure that the valve is shut off completely.

1. Attach a new EMMA Airway Adapter to the EMMA Capnograph.
2. Turn on the EMMA Capnograph and ensure that the $EtCO_2$ reading is zero. Otherwise conduct a Zeroing procedure according to chapter 7.4 above before proceeding.
3. Insert the 15M connector into one end of the EMMA Airway Adapter, and connect a second EMMA Airway Adapter to the other end (see picture).
4. Turn on the regulator flow.
5. After 30 seconds, record the $EtCO_2$ reading.
6. Turn off the flow.
7. Determine and record an estimated ambient atmospheric pressure in mmHg.
8. Use the following table to determine if the unit is reading within specified limits.



1 A gas flow regulator with a plastic tube and a 15M connector

2 Calibration gas (5% CO2, 21% O2, Balance N2)

3 Two EMMA Airway Adapters

Barometric pressure [mmHg]	EMMA Capnograph $EtCO_2$ readings should be between	
	5% CO_2 [mmHg]	5% CO_2 [kPa]
660-679	31-36	4,1-4,8
680-699	32-37	4,3-4,9
700-719	33-38	4,4-5,1
720-739	34-39	4,5-5,2
740-759	35-40	4,6-5,4
760-779	36-41	4,8-5,5
780-799	37-42	4,9-5,6

If the unit is reading within the above range then your EMMA Capnograph has been successfully verified.

If the unit is not reading within the above range, disconnect the EMMA Airway Adapter from the gas cylinder and perform a Zeroing procedure and then repeat the Gas span check procedure. See ***Zeroing Procedure*** on page 58. If verification still fails, contact your local distributor for further instructions.

Service and Return Procedure

Contact Masimo for product support. If needed, an RMA will be provided for repair or replacement. Masimo can be reached at 800-326-4890. For customers outside the United States, local contact information can be found at http://service.masimo.com.

Clean contaminated/dirty equipment before returning per Maintenance and Cleaning instructions. Make sure the equipment is fully dry before packing. Package the device securely, in the original shipping box if possible, and enclose the following information and items:

- Include the RMA form provided, or a letter describing in detail any difficulties experienced with EMMA. Include the RMA number in the letter.
- Warranty information, a copy of the invoice or other applicable documentation must be included. Purchase Order number to cover repair if the device is not under warranty, or for tracking purposes if it is.
- Ship-to and bill-to information. Person (name, telephone/Telex/fax number and country) to contact for any questions about the repairs.
- A certificate stating that the device has been decontaminated for bloodborne pathogens.
- Return the device to Masimo at the address listed in ***Contacting Masimo*** on page 61 below.

Contacting Masimo

Masimo Corporation
52 Discovery
Irvine, California 92618

Tel:+1 949 297 7000
Fax:+1 949 297 7001

Limited Warranty

Masimo warrants to the original end-user purchaser the Masimo-branded hardware product EMMA and any software media contained in the original packaging against defects in material and workmanship when used in accordance with Masimo's user manuals, technical specifications, and other Masimo published guidelines for a period of 12 months from the original date the Product was obtained by the end-user purchaser.

Masimo's sole obligation under this warranty is the repair or replacement, at its option, of any defective Product or software media that is covered under the warranty.

To request a replacement under warranty, Purchaser must contact Masimo and obtain a returned goods authorization number so that Masimo can track the Product. If Masimo determines that a Product must be replaced under warranty, it will be replaced and the cost of shipment covered. All other shipping costs must be paid by purchaser.

Exclusions

The warranty does not apply to any non-Masimo branded product or any software, even if packaged with the Product, or any Product that was: (a) not new or in its original packaging when supplied to purchaser; (b) modified without Masimo's written permission; (c) supplies, devices, or systems external to the Product; (d) disassembled, reassembled, or repaired by anyone other than a person authorized by Masimo; (e) used with other products, like new sensors, reprocessed sensors, or other accessories, not intended by Masimo to be used with the Product; (f) not used or maintained as provided in the operator's manual or as otherwise provided in its labeling; (g) reprocessed, reconditioned, or recycled; and (h) damaged by accident, abuse, misuse, liquid contact, fire, earthquake or other external cause.

No warranty applies to any Product provided to Purchaser for which Masimo, or its authorized distributor, is not paid; and these Products are provided AS-IS without warranty.

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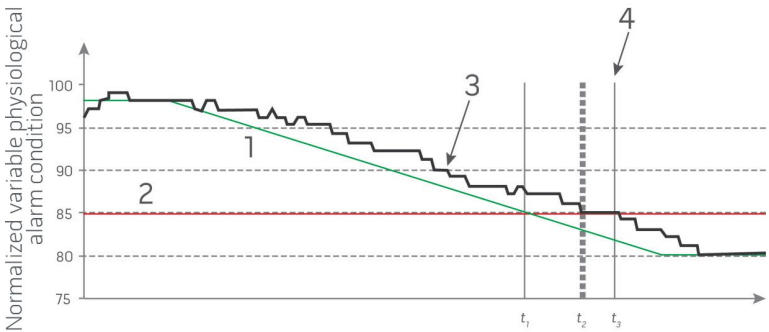
Appendix A: Concepts of Alarm Response Delay

Concepts of Alarm Response Delay

As with any monitoring equipment, the audible and visual alarms are subject to alarm response delay, which is composed of Alarm Condition Delay and Alarm Signal Generation Delay. Alarm Condition Delay is the time from the occurrence of the triggering event to when the alarm system determines the alarm condition exists. While Alarm Signal Generation Delay is the time from the onset of an alarm condition to the generation of its alarm signal. The graphic below is a simplified illustration of the concept of alarm response delay and does not reflect actual lengths of delays.



Ref	Definition	Ref	Definition	Ref	Definition
1	Instantaneous signal from the patient	3	Displayed Value	*t*	Time
2	Alarm Limit	4	Alarm Signal Generation	--	--

- The Alarm Condition Delay is graphically represented as $t_2 - t_1$ in the figure above to show the delay due to processing and averaging.
- The Alarm Signal Generation Delay is graphically represented as $t_3 - t_2$ in the figure above to show the delay due to alarm system strategy and communication time.
- The overall alarm system delay time is graphically represented as $t_3 - t_1$.

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