EMMA™ Emergency Capnograph

USER'S MANUAL

Masimo

Important user information

All users must read this entire manual to fully understand the safe use of EMMA.

Declaration of conformity

CE 0413

Complies with 93/42/EEC Medical Device Directive.

FDA Approval reference number K072813 and K063167.

MEDICAL EQUIPMENT
WITH RESPECT TO
ELECTRICAL SHOCK,
FIRE AND MECHANICAL
HAZARDS ONLY
IN ACCORDANCE WITH
UL 60601-1
3JSV

Safety notices

This user manual contains Warning notices and Caution notices. These notices shall be followed.

WARNING! Warnings indicate a potential harmful condition that can possibly lead to injury or death.

CAUTION! Cautions indicate conditions which may lead to the damage or malfunction of the device.

NOTE! Alert the user to relevant facts and conditions.

Disclaimer

Masimo Sweden AB shall in no event be liable for any direct, indirect, special or consequential damages including without limitation damages for loss of business profits, loss of income, business interruption, loss of business information, loss of use or other related exposures, however caused, arising from the faulty or incorrect use of the product.

Liability

Masimo Sweden AB guarantees that the product delivered has been thoroughly tested to ensure that it meets its published specifications.

Warranty

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

Use of the equipment for other than its intended use, or if it has been repaired by anyone except Masimo Sweden AB or a Masimo Sweden AB authorized service center, or altered or modified or used without following the instructions in the user manual, will void the warranty.

Trademarks

Masimo Sweden AB owns the following licensed trademarks: Masimo EMMA and Masimo XTP Windows.

Patents

Masimo Sweden AB holds the following patents regarding products described in this manual: SE519766; SE519779; SE523461; SE524086. Other patents pending.

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The information in this document is subject to change without notice.

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Edition: 03
Released: April 2013

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

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

Revision history

Edition	Date	Description
03	April 2013	EMMA Analyzer removed (EOL). Revised for EMMA Emergency Capnograph and company name change.

Contents

1 Intended use

EMMA 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.

2 Safety Information

Adhere to the following warnings, cautions and notes for safe operation of EMMA.

2.1 Warnings

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! Use only EMMA Airway Adapters manufactured by Masimo.

WARNING! EMMA Airway Adapter shall not be reused. Reuse of the single use Adapter can cause cross infection. Used Airway Adapters shall be disposed of in accordance with local regulations for medical waste.

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 as this may cause excessive flow resistance.

WARNING! Measurements can be affected by mobile phones and RF communications equipment. It should be assured that EMMA is used in the specified electromagnetic environment.

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

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! 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 taken 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 volume 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! 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. The remaining lifetime for lithium batteries may be significantly less than 30 minutes when the Battery Status Indicator starts blinking.

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

2.2 Cautions

CAUTION! If EMMA is used in a manner other than that for which it was intended, unpredictable behavior could result.

CAUTION! The EMMA Airway Adapters are non-sterile devices. Do not autoclave the devices as this will damage them.

CAUTION! Never sterilize or immerse EMMA in liquid.

CAUTION! Do not operate EMMA at ambient temperatures less than -5°C (23°F) or greater than 50°C (122°F).

CAUTION! Remove batteries if EMMA is not likely to be used for a period of time longer than 90 days.

2.3 Notes

NOTE! Throughout this User's Manual:
EMMA Airway Adapter refers to both Airway Adapter Adult/Pediatric and Airway Adapter Infant if not otherwise mentioned.

NOTE! Always carry spare batteries in the EMMA pouch.

2.4 Symbol Description

Symbol	Title	Explanation
	Follow instructions for use	This symbol replaces, and has the same meaning, as the previously used symbol ISO7000-0434.
	Defibrillation-proof type BF applied part	
	Catalog number	
	Serial number	
	Batch code	
	Manufacturer	Accompanied by the name and address of the manufacturer.
	Use by date [YYYY-MM-DD]	Indicates that the device should not be taken into operation after the date accompanying the symbol (EMMA airway adapters).
	Temperature limitation	
	Pressure limitation	
	Humidity limitation	
	Do not re-use	Intended for single patient use (EMMA airway adapters).
	For EU only: Waste Electrical and Electronic Equipment (WEEE)	For EU only: Electrical and electric equipment shall be collected and recycled in accordance with Directive 2002/96/EC.
	Conformité Européenne	Complies with 93/42/EEC Medical Device Directive.
	UL classification mark	Classified by Underwriters Laboratories Inc. for Canada and US with respect to electrical shock, fire and mechanical hazards in accordance with UL60601-1 and CSA 22.2 No.601.1-M90. 3JSV = Control number assigned by UL.
IP33	IP classification indicating degree of protection against water and solid foreign objects.	IP33 =“Spray-proof” and “Tool-proof”.

Symbol	Title	Explanation
Rx ONLY	Rx only	Caution: Federal (U.S.) law restricts this device to sale by or on the order of a licensed healthcare practitioner.
	Power on button	
	Alarm silence button	

3 Device Description

3.1 EMMA overview

EMMA is a quantitative mainstream carbon dioxide monitor comprised of a sensor body that snaps in place on top of a disposable EMMA Airway Adapter.

Figure 1. EMMA

3.2 Principle of operation

The measurement of CO_2 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 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.

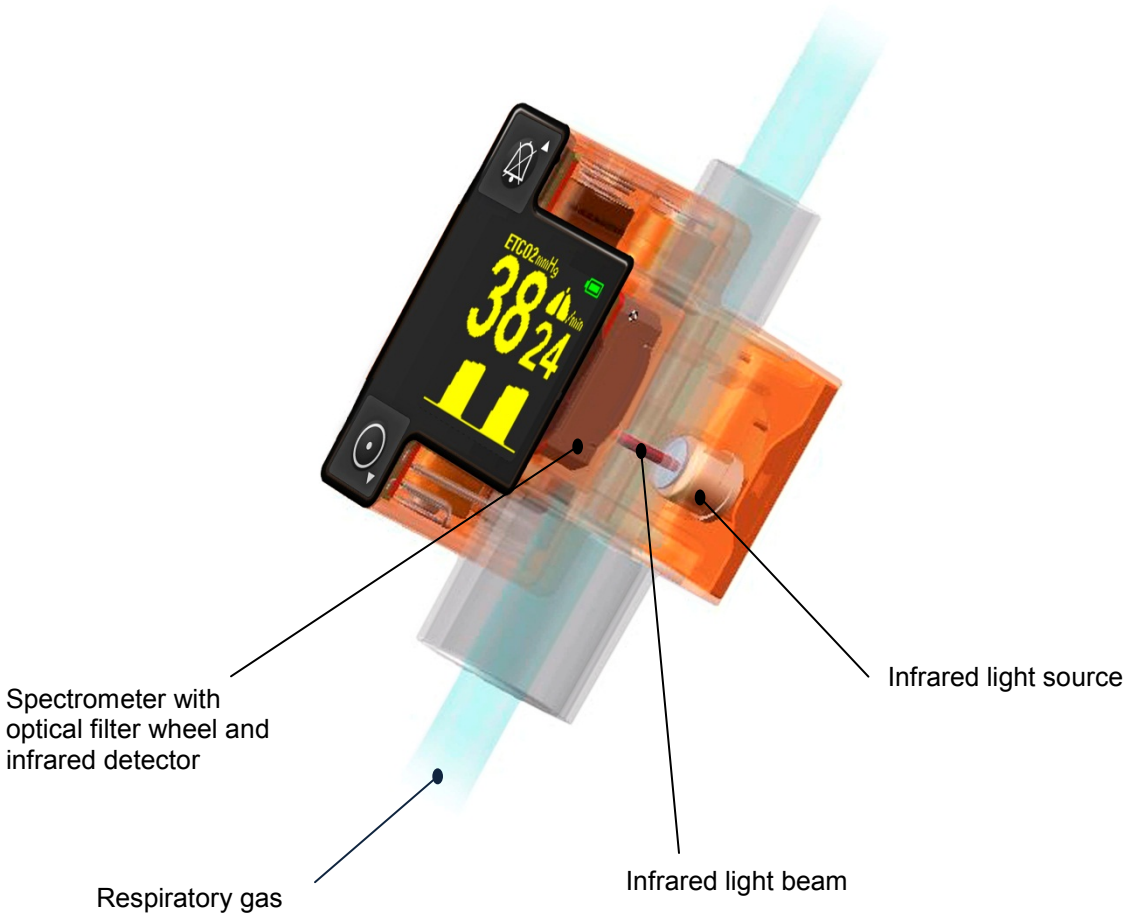


Figure 2. Principle of operation

3.2.1 EMMA Airway Adapter

The EMMA Airway Adapter is available in two models: Adult/Pediatric (Figure 3a) and Infant (Figure 3b). EMMA operates to specification with either Airway Adapter model when used with its appropriate patient population. A trained medical professional must determine the proper Airway Adapter model for each patient application. No hardware or software configuration changes result from the EMMA Airway Adapter model selected.

EMMA snaps in place on top of the EMMA Airway Adapter. 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. Respiratory gas measurements are, as described in the previous section, obtained by continuously measuring the infrared light absorption through the Airway Adapter. The EMMA Airway Adapter is fitted with optical XTP™ windows that are transparent to light in the wavelength ranges of interest.

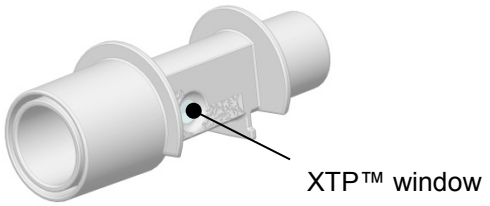


Figure 3a. EMMA Airway Adapter Adult/Pediatric

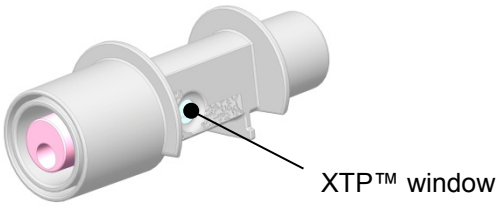


Figure 3b. EMMA Airway Adapter Infant

4 Preparations for Use

4.1 Setting up

Unpack and inspect 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.

Figure 4. Releasing the battery cover

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.

Figure 5. Inserting batteries

4.2 Starting up

1. Snap the EMMA Airway Adapter into EMMA. It will click into place when properly seated.

2. Press the Power On button.

3. When EMMA is ready the $ETCO_2$ value is zero.

The audible alarm sound may be checked by detaching the Airway Adapter to generate a “Check Adapter” alarm.

When EMMA is ready the end-tidal carbon dioxide ($ETCO_2$) display indicates 0 and the Respiratory Display indicates “- -“.

If the $ETCO_2$ display shows a non-zero value, ensure that there has not been an accumulation of CO_2 between EMMA and the EMMA Airway Adapter by removing and reattaching the EMMA Airway Adapter. If the $ETCO_2$ still displays a non-zero value after this procedure, perform a Zeroing procedure as described in chapter 7.4 prior to using EMMA with a patient.

4.3 Switching off

EMMA switches off automatically 15 Sec after that the EMMA Airway Adapter is removed or 2 min after a No Breath condition is detected and the Alarm Silence button is pressed.

4.4 Connecting EMMA to a tube or mask

EMMA can be connected to a patient in different ways. The following pictures illustrate two methods of connection.

Figure 7. EMMA connected to an endotracheal tube.

Figure 8. EMMA connected to a mask

5 User Interface

5.1 Controls

EMMA has one Power On and one Alarm Silence button. These buttons may also be used for adjusting the Low and High $ETCO_2$ alarm limits up and down.

5.2 Monitoring

EMMA is fitted with a graphic OLED-display that shows the $ETCO_2$ value, the Respiratory Rate and a CO_2 waveform (the capnogram).

5.2.1 $ETCO_2$

EMMA is available in two versions displaying $ETCO_2$ 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.

5.2.2 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.

5.2.3 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.

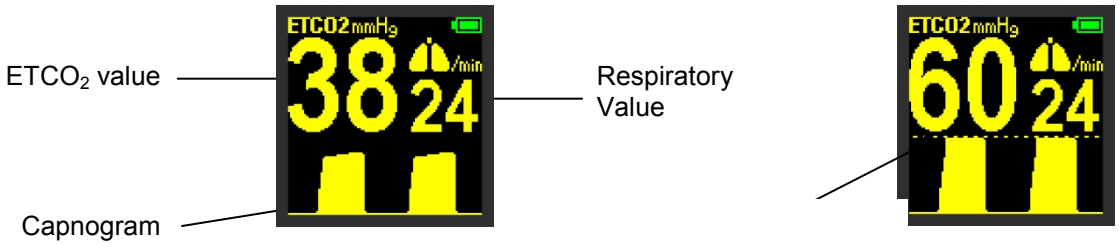


Figure 9. EMMA Display

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

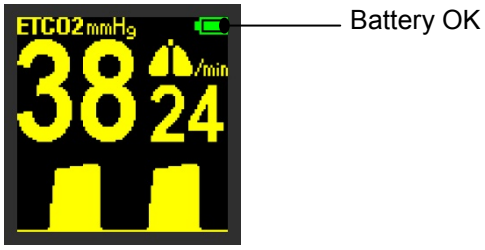
5.3 Default Limits for indicator and alarms

The default factory settings for the No Breath and the $ETCO_2$ alarms are as follows:

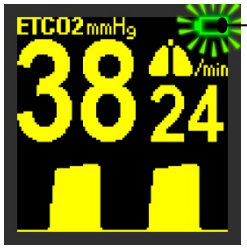
	Low	High
RR (No Breath)	3 bpm (20 s)	-
$ETCO_2$	OFF	50 mmHg (7.0 kPa)

5.3.1 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). When batteries are low, the Battery Status Indicator starts blinking (approximately 30 minutes before depletion for alkaline batteries).



Battery OK



Battery low (Blinking)

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.

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. The remaining lifetime for lithium batteries may be significantly less than 30 minutes when the Battery Status Indicator starts blinking.

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

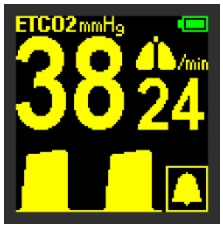
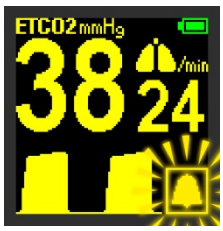
5.3.2 Alarm Status Indicator

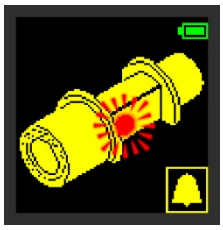
When an alarm is triggered, the indicator in the lower right corner of the display is lit with a steady or blinking yellow light depending on alarm priority.

Active alarms are displayed according to the following table:

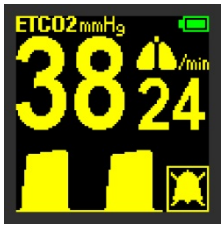
Alarm	Screen	$ETCO_2$ value	RR value
Apnea	NORMAL	value steady [1)]	"- -" flashing [2)]
Clogged Adapter	ADAPTER	n/a	n/a
No Adapter	ADAPTER	n/a	n/a
High $ETCO_2$	NORMAL	value flashing	value steady
Low $ETCO_2$	NORMAL	value flashing	value steady

Note 1: $ETCO_2$ value shows momentary CO_2 during apnea.
Note 2: RR value will show "- -" steady if no breath at all detected from power on.

Alarm Priority	Indication	Audible Alarm	Condition
Advisory	Steady yellow alarm indicator 	1 tone beep 2 tone beep	No breath (first 20 s) ET CO_2 Low (first 40 s) ET CO_2 High (first 40 s) No breath (20 - 40 s)
Caution	Blinking yellow alarm indicator 	3 tone beep repeated every 20 seconds	No breath (after 40 s) ET CO_2 Low (after 40 s) ET CO_2 High (after 40 s)
Advisory	Adapter flashing yellow Steady yellow alarm indicator 	1 tone beep	No Adapter

Advisory	Adapter steady yellow Flashing red adapter window Steady yellow alarm indicator 	1 tone beep	Clogged Adapter

5.3.3 Alarm Silence



If an alarm is active, pressing the Alarm Silence button will silence the alarm for a period of 2 minutes.

The Alarm Silence status is indicated by the yellow silence alarm indicator in the bottom right corner of the display.

If a No Breath alarm is turned off by pressing the Alarm Silence button, EMMA will automatically switch off after 2 minutes if no new breath takes are detected.

If the alarm disappears during the silence period, the alarm icon will turn 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.

5.3.4 Adjusting the $ETCO_2$ Alarm Limits

5.3.4.1 Adjusting the High $ETCO_2$ Alarm Limit

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.
2. Release the 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). 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 of time, EMMA will automatically resume normal operation.

Figure 10. Adjusting the High and Low $ETCO_2$ alarm limits

5.3.4.2 Adjusting the Low $ETCO_2$ Alarm Limit

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.
2. Release the 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. 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 of time, EMMA will automatically resume normal operation.

5.3.4.3 Alarm limit adjustment ranges

The adjustment ranges for the $ETCO_2$ alarm limits are as follows:

	Low	High
$ETCO_2$ displayed in mmHg	OFF; 1 – 89 mmHg	11 – 99 mmHg; OFF
$ETCO_2$ displayed in kPa	OFF; 0.1 – 8.9 kPa	1.1 – 9.9 kPa; 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.

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

6 EMMA and Accessories

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

EMMA and Accessories	Catalog number
EMMA (kPa)	605100
EMMA (mmHg)	605102
EMMA Airway Adapter Adult/Pediatric, box of 25	100620
EMMA Airway Adapter Infant, box of 10	100660
EMMA Pouch, Box of 10	100680
EMMA Lanyard, Bag of 10	100684

7 Maintenance and Service

7.1 Battery Replacement

The Battery Status indicator in the upper right corner of the EMMA display starts blinking when the remaining lifetime of the batteries is approximately 30 min (Alkaline batteries).

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. The remaining lifetime for lithium batteries may be significantly less than 30 minutes when the Battery Status Indicator starts blinking.

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 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.
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 in place, gently snap the battery cover back into place.

NOTE: Always carry spare batteries in the EMMA pouch.

7.2 Cleaning

1. Remove the batteries before cleaning.
2. EMMA can be cleaned using a cloth moistened with isopropyl alcohol.

CAUTION! DO NOT immerse EMMA in any liquid.

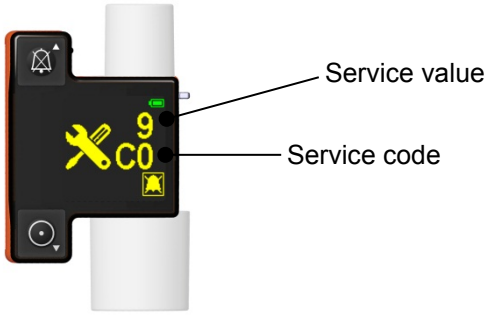
7.3 EMMA Airway Adapter

- 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.

7.4 Zeroing procedure

Zeroing of EMMA is performed by the following procedure. The presence of ambient air (0% CO_2) in the EMMA Airway Adapter is of crucial importance for a successful Zeroing.

1. Start EMMA by pressing the Power On button.
2. Make sure that a new EMMA Airway Adapter is properly fitted.
3. Press and hold down simultaneously the Power On button and Alarm Silence button until the Service Screen display the Service Code “C0” and the Service value “9”. Keep both buttons depressed while the Service value starts "counting down" i.e. displaying "9" - "8" - "7" etc. until "0" is displayed.
4. Once the Service value display “0”, Zeroing of EMMA is completed.



Gas readings should be verified with a reference instrument at regular intervals. Zeroing should be performed whenever an offset in gas readings is discovered. Zeroing is recommended after 500 hours of operation.

EMMA will return to normal screen when the Service value has reached "0" or if any of the buttons are released.

Note: Special care should be taken to avoid breathing near the EMMA Airway Adapter before or during the Zeroing procedure.

7.5 Gas Span Check

EMMA 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 perform a gas span check of EMMA you will need:

1. A gas flow regulator with a plastic tube and a 15M connector
2. Calibration gas (5% CO_2, 21% O_2, Balance N_2)
3. Two EMMA Airway Adapters

Directions

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 EMMA.
2. Turn on EMMA 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.

Column A **Barometric Pressure**	**Column B** **EMMA $ETCO_2$ Readings should be between**	
mmHg	**mmHg 5% CO_2**	**kPa 5% CO_2**
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 has been successfully verified.

If the unit is not reading within the above range, disconnect the Airway Adapter from the gas bottle and perform a Zeroing procedure according to the instructions in chapter 7.4 above and then repeat the Gas span check procedure. If verification still fails, contact your local distributor for further instructions.

7.6 Troubleshooting

Failure	**Possible Cause**	**Troubleshooting action**
The unit does not complete the turn on sequence	Low batteries	Replace batteries
The unit does not turn on	Low batteries	Replace batteries
The measured values of $ETCO_2$ are out of specified accuracy	Incorrect Zero reference	Perform a Zeroing procedure and verify the measurement with reference gas

7.7 Service and Product Return Requirements

Please contact your local distributor for detailed instructions.

8 Technical Specifications

8.1 General Specifications

Description	Compact, battery powered, quantitative capnograph for mainstream CO_2 monitoring of adult, pediatric and infant patients.
Measurements	Non-dispersive IR absorption
Models	CO_2 displayed in kPa or mmHg
Warm up	In operation and full accuracy within 15 s.
Calibration	No routine calibration required
Certifications	CE marked per 93/42/EEC, FDA 510(k) and UL/CSA 60601-1
Dimensions	52 x 39 x 39 mm (2.1 x 1.5 x 1.5 inches)
Weight	~60 g (2.1 oz) with batteries
Mechanical robustness	Withstands repeated 1 m drops. Meets the shock and vibration requirements for transport of SS-EN ISO 21647:2004 clause 21.102 and SS-EN 1789:2007 clause 6.3.4.2.
Operating conditions	Temperature: -5 - +50°C (23 to 122°F) Humidity: < 40 hPa H_2O (non-condensing) (95% RH at 30 °C) Atmospheric pressure: 70 - 120 kPa (1)
Storage conditions	Temperature: -30 - +70°C (-22 to 158°F) Humidity: 5 - 100% RH (condensing) at a water vapor partial pressure not exceeding 74 hPa (100 %RH at 40 °C) Atmospheric pressure: 50 - 120 kPa
Display	96 x 96 pixel RGB OLED-display
$ETCO_2$	0 - 99 mmHg (0 - 9.9 kPa) (2)
CO_2 Accuracy	0-40 mmHg ± 2 mmHg, 41-99 mmHg 6% of reading, during standard conditions.(3) (4)
Total system response time	< 0.5 s
Recovery time after defibrillator test	Unaffected
Respiratory rate	3 - 150 breaths/min
Accuracy	± 1 bpm
Breath detect	Adaptive threshold, minimum 1 kPa CO2 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)
Alarms	No Adapter, Clogged Adapter, No Breath Detected, Low Battery, Low ETCO2, High ETCO2
Sound Intensity Level	≥ 80 dB(A)
Batteries	Two AAA Cell batteries (2x1.5VDC): Alkaline IEC:LR03 or Energizer Ultimate Lithium L92 batteries(5). Use of other Lithium batteries may present a risk of fire or explosion.

Battery life time	Duracell Plus Alkaline: ~6 hours Energizer Ultimate Lithium L92: ~10 hours

Notes:

(1) EMMA displays CO_2 in partial pressure units (kPa or mmHg) and compensates the displayed value for the actual barometric pressure.

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

- 60 vol% of N_2O typically increases CO_2-readings by 10%
- 60 vol% of O_2 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%

(4) CO_2 was tested at a RR of 40. As RR rates increases above 60 the accuracy range will also increase.

(5) www.energizer.com

8.2 Electromagnetic Compatibility (EMC)

Guidance and Masimo's declaration – electromagnetic emissions – for EMMA		
EMMA is intended for use in the electromagnetic environment specified below. The customer or the user of EMMA should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	EMMA 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	EMMA is suitable for use in all establishments including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Guidance and Masimo's declaration – electromagnetic immunity – for EMMA			
EMMA is intended for use in the electromagnetic environment specified below. The customer or the user of EMMA should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 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 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	Not applicable	Mains power quality should be that of a typical commercial or hospital environment. If the user of EMMA requires continued operation during power mains interruptions, it is recommended that EMMA be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and Masimo's declaration – electromagnetic immunity – for EMMA			
EMMA is intended for use in the electromagnetic environment specified below. The customer or the user of EMMA should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3 Radiated RF IEC 61000-4-3 20 V/m, 80% AM at 1kHz field strength is defined in EN-ISO 80601-2-55 in 202.6.2.3.1	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz 20 V/m 80 MHz to 2.5 GHz	Not applicable 3 V/m 20 V/m	Portable and mobile RF communications equipment should be used no closer to any part of EMMA including cables than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 0{,}17\sqrt{P}$ 80 MHz to 800 MHz $d = 2{,}33\sqrt{P}$ 800 MHz to 2.5 GHz $d = 0{,}18\sqrt{P}$ 80 MHz to 800 MHz $d = 0{,}35\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
Note 1: At 80 MHz and 800 MHz, the higher frequency range applies. **Note 2:** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which EMMA is used exceeds the applicable RF compliance level above, EMMA should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating EMMA. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.			

Recommended separation distances between portable and mobile RF communications equipment and the EMMA

EMMA is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of EMMA can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and EMMA 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		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 0.18\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 0.35\sqrt{P}$
0.01	**0.12**	**0.018**	**0.035**
0.1	**0.37**	**0.057**	**0.11**
1	**1.2**	**0.18**	**0.35**
10	**3.7**	**0.57**	**1.1**
100	**12**	**1.8**	**3.5**

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 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Warning: Measurements can be affected by mobile phones and RF communications equipment. It should be assured that EMMA is used in the electromagnetic environment specified.

8.3 Compliance

MDD 93/42/EEC
EN 60601:1990, Amendment 1 (1991), Amendment 2 (1995)
EN 60601-1-2:2001
EN 60601-1-8:2004
EN ISO 21647:2004
EN ISO 5356-1:2004
EN 1789:2007

8.4 Classifications

According to the type of protection against electric shock
INTERNALLY POWERED EQUIPMENT (Battery power)

According to the degree of protection against electric shock
DEFIBRILLATION-PROOF TYPE BF APPLIED PART

According to the degree of protection provided by enclosures
IP33 (spray proof and tool proof EQUIPMENT)

According to the mode of operation
CONTINUOUS OPERATION

According to the degree of safety of application in the presence of a FLAMMABLE ANESTHETIC MIXTURE WITH AIR, OR WITH OXYGEN OR NITROUS OXIDE
EQUIPMENT not suitable for use in the presence of FLAMMABLE ANESTHETIC MIXTURE WITH AIR; OR WITH OXYGEN OR NITROUS OXIDE

According to sterility
No part of EMMA is sterile.

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