EMMA™ Emergency Capnograph

605100, 605102, 655100, 655102

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.

CLASSIFIED C UL US

MEDICAL – GENERAL MEDICAL EQUIPMENT AS TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH ANSI/AAMI ES60601-1 (2005) and CAN/CSA-C22.2 No. 60601-1 (2008)

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.

Liability

Masimo Sweden AB 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.

Disclaimer

Masimo Sweden AB guarantees that the product delivered has been 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 product for other than its intended use, or if it is repaired by anyone except Masimo Sweden AB or a Masimo authorized service center, or altered or modified or used without following the instructions provided with the product, voids the warranty.

Patents

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

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Contact information

Masimo Sweden AB
Svärdvägen 15
SE-182 33 Danderyd
Sweden
Telephone: +46 8 544 98 150
Fax: +46 8 544 98 169
Web site: www.masimo.com

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01	September 30th 2016	Revised for EMMA Capnograph with Bluetooth functionality.
02	March 20th 2017	Ch.2.3: Added statement that EMMA Bluetooth complies with Canada RSS standards.

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

WARNING! EMMA Airway Adapters shall not be reused. Reuse of single use Adapters 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 shall 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 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! 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.

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.

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

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! 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 power off.

NOTE! Always carry spare batteries in the EMMA pouch.

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.

NOTE! EMMA Bluetooth 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. Changes or modifications not expressly approved by the manufacturer could void the user's authority to operate the equipment.

NOTE! EMMA Bluetooth complies with Industry Canada license-exempt RSS standard(s). 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.

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	
REF	Catalog number	
SN	Serial number	
LOT	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.
CE 0413	Conformité Européenne	Complies with 93/42/EEC Medical Device Directive.
CLASSIFIED C UL US 3JSV	UL classification mark	Classified by Underwriters Laboratories Inc. for Canada and US with respect to electrical shock, fire and mechanical hazards in accordance with ANSI/AAMI ES60601-1 (2005) and CAN/CSA-C22.2 No. 60601-1 (2008) 3JSV = Control number assigned by UL.
IP33	IP classification indicating degree of protection against water and	IP33 =“Spray-proof” and “Tool-proof”.

Symbol	Title	Explanation
	solid foreign objects.	
Rx ONLY	Rx only	Caution (U.S.): Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.
	Power on button	
	Alarm silence button	
→0←	Zero-point adjustment	Indicating that an offset in gas readings is discovered and performing zeroing is required. See ch 7.4.
	Bluetooth	Device equipped with Bluetooth.
	Radio transmitter	Indicates that the device has a radio transmitter.
FC		Federal Communications Commission (FCC) licensing.
FCC ID, IC Model IC		Identifies unit has been registered as a radio device.

3 Device description

3.1 EMMA Capnograph overview

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.

Figure 1. EMMA Capnograph

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 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.

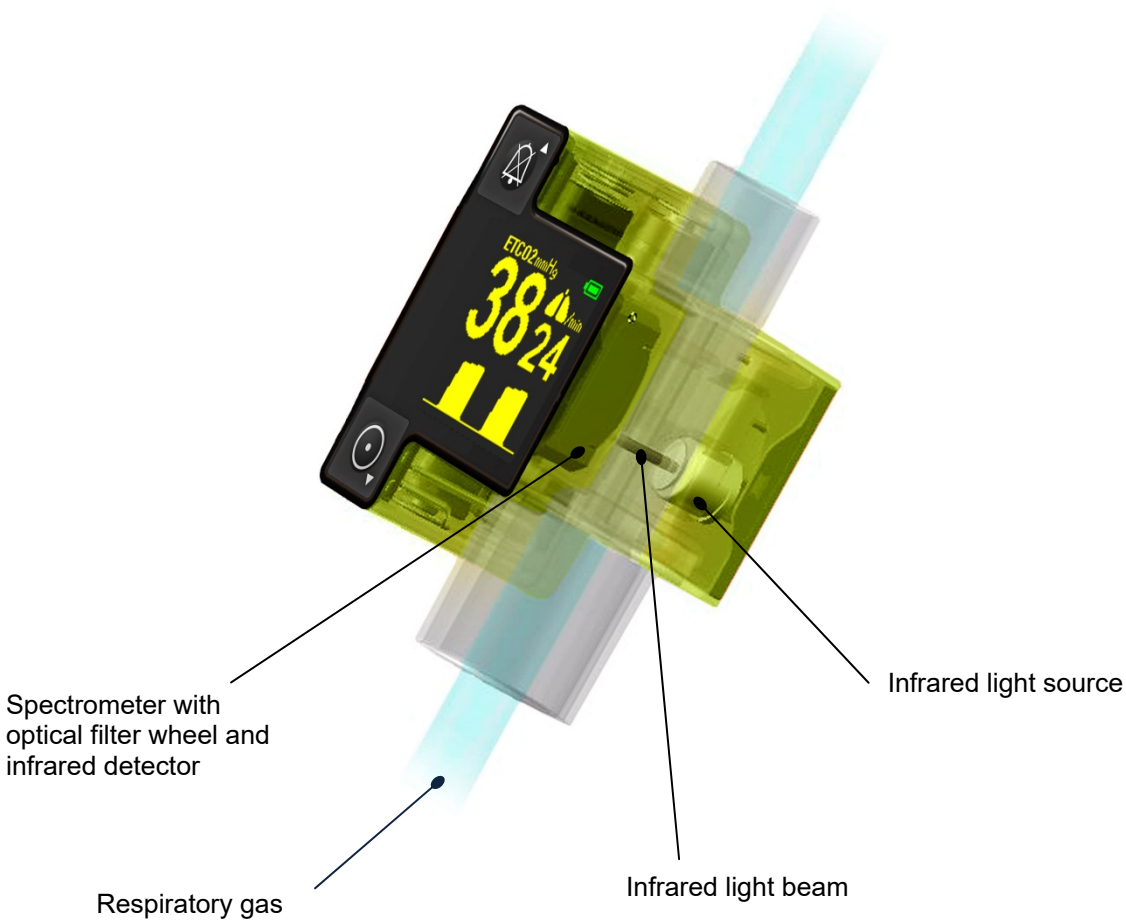


Figure 2. Principle of operation

3.2.1 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 EMMA Airway Adapter is fitted with optical XTP™ windows that are transparent to light in the wavelength ranges of interest. The EMMA 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 EMMA Airway Adapter is available in two models: Adult/Pediatric (Figure 3a) and Infant (Figure 3b). EMMA operates to specification with either EMMA Airway Adapter model when used with its appropriate patient population.

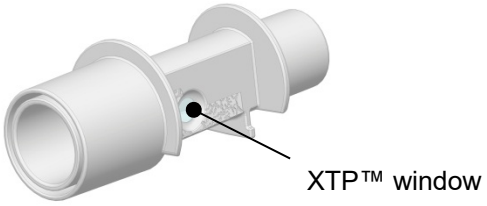


Figure 3a. EMMA Airway Adapter Adult/Pediatric

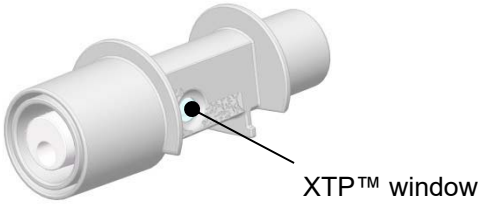


Figure 3b. EMMA Airway Adapter Infant

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 EMMA Airway Adapter model selected.

4 Preparations for use

4.1 Setting up

Unpack and inspect the EMMA Capnograph 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 the EMMA Capnograph. It will click into place when properly inserted.

2. Press the Power On button.

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

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

When the EMMA Capnograph is ready the $ETCO_2$ Value indicates “0” and the Respiratory Rate Value indicates “- -“.

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 as described in chapter 7.4 prior to using the EMMA Capnograph with a patient.

4.3 Switching off

The EMMA Capnograph switches off automatically during following conditions:

- After 2 minutes if no breath is detected.
- After 2 minutes if No Breath condition is detected and the Alarm Silence is activated.
- After 15 seconds if the EMMA Airway Adapter is removed.

4.4 Connecting the EMMA Capnograph to a tube or a mask

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

Figure 7. EMMA Capnograph connected to an endotracheal tube.

Figure 8. EMMA Capnograph connected to a mask

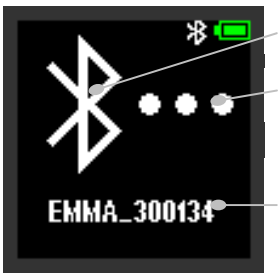
5 User interface

5.1 Controls

The EMMA Capnograph 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 Bluetooth (optional)

The EMMA Bluetooth (REF: 655100 and 655102) provides a Bluetooth Low Energy (LE) wireless option to allow connection to a compatible smart device or host. EMMA Bluetooth can only communicate to a single smart device at a time to minimize the risk of unauthorized access. Pressing the Power ON button twice when EMMA Bluetooth device is ON will enable the LE Bluetooth.



Bluetooth symbol

Connectivity indicator

Unique Bluetooth adress (EMMA_serial number)

Bluetooth enabled

Bluetooth disabled

Bluetooth may be enabled/disabled by repeatedly pressing the ON button. Bluetooth will as default be disabled and must be enabled each time by the user. The unique Bluetooth address contains the product name plus the serial number of the device and will be transmitted to the smart device or host. Confirm the correct connection by controlling that the appropriate serial number is displayed on the smart device or host.

If no button has been activated for a short period of time, the EMMA Bluetooth will automatically resume normal operation. If the Bluetooth is enabled the Bluetooth indicator will appear on the screen.

Normal operation with Bluetooth enabled

5.3 Monitoring

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

5.3.1 $ETCO_2$

The EMMA Capnograph is available in 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.

5.3.2 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.

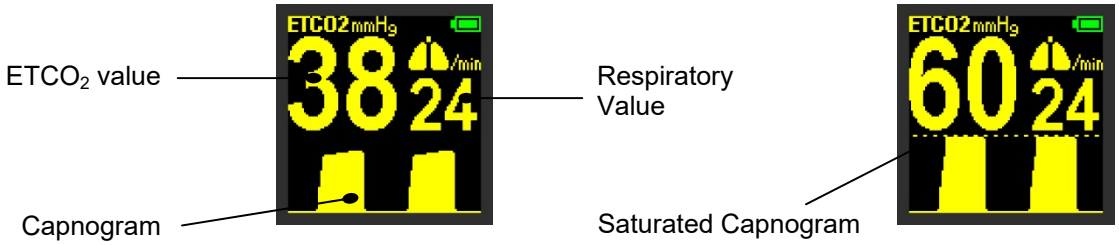


Figure 9. EMMA Capnograph display

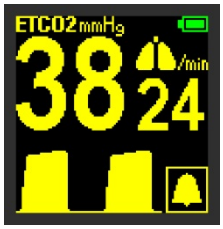
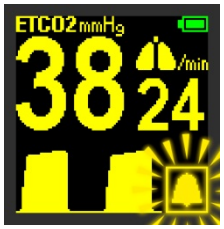
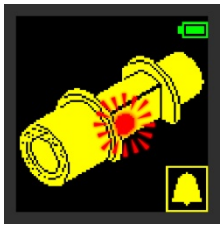
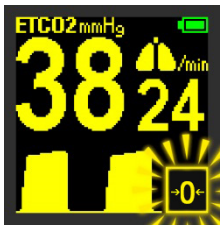
If the CO_2 level reaches or exceeds 53 mmHg/7 kPa, a horizontal dashed line will be displayed to indicate that the capnogram is saturated.

5.4 Indicators and alarms

The EMMA Capnograph is equipped with an Alarm Status Indicator and an audible alarm that may be silenced for a period of 2 minutes.

5.4.1 Alarm signals

When an alarm is triggered, an Alarm Satus Indicator in the lower right corner of the display is lit with a steady or blinking yellow light depending on alarm priority, together with an audible alarm beep ((•)) according to the following table:

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 $ETCO_2$			
Clogged Adapter	 ((•))		n/a
No Adapter	 ((•))		
Zero point adjustment	 ((•))		

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.

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 shows momentary CO_2 during No Breath.
Note 2: RR value will show "- -" steady if no breath at all detected from power on.
Note 3: Perform Zeroing procedure as described in chapter 7.4.

5.4.2 Default limits for alarms

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

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

5.4.3 Alarm silence

The audible alarm can be muted for 2 minutes by pressing the Alarm Silence button. When the audible alarm is muted the yellow silence alarm indicator in the bottom right corner of the display, i.e. the Alarm Status Silence Indicator, will be lit.

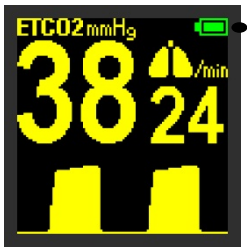
Pressing the Alarm Silence button again during the 2 minutes mute period will reactivate the audible alarm.

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.

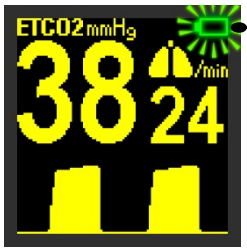
If the alarm disappears when the audible alarm is muted, the alarm icon will turn green. Pressing the Alarm Silence button during no alarm will also show a green silence alarm indicator in the bottom right corner of the display.

5.4.4 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.



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.

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.

5.4.5 Adjusting the $ETCO_2$ alarm limits

5.4.5.1 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). The EMMA Capnograph 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, the EMMA Capnograph will automatically resume normal operation.

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

5.4.5.2 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. The EMMA Capnograph 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, the EMMA Capnograph will automatically resume normal operation.

5.4.5.3 Alarm limit adjustment ranges

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

	Lower range	Upper range
$ETCO_2$ 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

Catalog number (REF)	EMMA and accessories	Description
605100	EMMA (kPa)	EMMA Emergency Capnograph (full-alarm, display in kPa). Color: green
605102	EMMA (mmHg)	EMMA Emergency Capnograph (full-alarm, display in mmHg). Color: green
655100	EMMA Bluetooth (kPa)	EMMA Emergency Capnograph with Bluetooth (full-alarm, display in kPa). Color: green
655102	EMMA Bluetooth (mmHg)	EMMA Emergency Capnograph with Bluetooth (full-alarm, display in mmHg). Color: green
606100	EMMA Capnometer (kPa)	EMMA Emergency Capnometer (full-alarm, display in kPa). Color: orange
606102	EMMA Capnometer (mmHg)	EMMA Emergency Capnometer (full-alarm, display in mmHg). Color: orange
3678	Kit EMMA (kPa)	Kit including EMMA Emergency Capnograph (kPa), EMMA Pouch and EMMA Lanyard.
3639	Kit EMMA (mmHg)	Kit including EMMA Emergency Capnograph (mmHg), EMMA Pouch and EMMA Lanyard.
4270	Kit EMMA Bluetooth (kPa)	Kit including EMMA Emergency Capnograph with Bluetooth (kPa), EMMA Pouch and EMMA Lanyard.
4271	Kit EMMA Bluetooth (mmHg)	Kit including EMMA Emergency Capnograph Bluetooth (mmHg), EMMA Pouch and EMMA Lanyard.
9633	Kit EMMA Capnometer (kPa)	Kit including EMMA Emergency Capnometer (kPa), EMMA Pouch and EMMA Lanyard.
9632	Kit EMMA Capnometer (mmHg)	Kit including EMMA Emergency Capnometer (mmHg), EMMA Pouch and EMMA Lanyard.
100620	EMMA Airway Adapter Adult/Pediatric, box of 25	EMMA Airway adapter is needed in order for EMMA to provide readings.
100660	EMMA Airway Adapter Infant, box of 10	EMMA Airway adapter is needed in order for EMMA to provide readings.
100681 **100682**	EMMA Pouch, Green EMMA Pouch, Orange	Easy to carry pouch for safe storage of EMMA.
100685 **100684**	EMMA Lanyard, Green, 10 pcs EMMA Lanyard, Orange, 10 pcs	Lanyard attaches to EMMA to be carried around your neck.

7 Maintenance and service

7.1 Battery replacement

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.

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.
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.

7.2 Cleaning

1. Remove the batteries before cleaning.
2. The EMMA Capnograph can be cleaned using a cloth moistened with 70% isopropyl alcohol.

CAUTION! DO NOT immerse EMMA in any liquid.

7.3 EMMA Airway Adapter

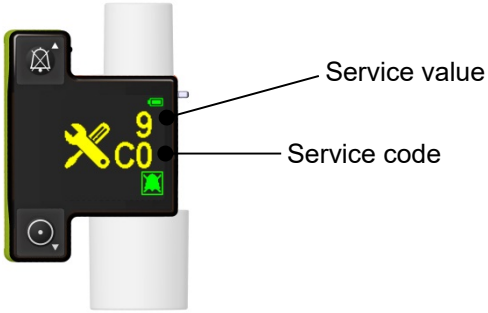
- The EMMA Airway Adapters are intended for single patient use. They are disposable and shall not be re-used. Reuse of single patient use Adapters can cause cross infection.
- EMMA Airway Adapters shall be disposed of in accordance with local regulations for bio hazardous waste.

7.4 Zeroing procedure

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

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.

1. Start the EMMA Capnograph 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 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 Capnograph is completed.



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

7.5 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 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 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.

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 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

Error	Possible causes	Recommended Solutions
The unit does not complete the turn on sequence	Low battery	Replace batteries
The unit does not turn on	No battery Low battery	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
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
Measurement does not display on the smart device or host using optional Bluetooth	Bluetooth not connected Smart device, host or EMMA Bluetooth out of range Compatible app not installed on smart device Smart device damaged EMMA Bluetooth damaged	Confirm Bluetooth is on for the EMMA Bluetooth and the smart device or host Move the EMMA Bluetooth, smart device or host closer to each other Check that EMMA Bluetooth is paired to the correct smart device or host Confirm a compatible app is installed on the smart device Close and re-launch the compatible app on the smart device Contact Masimo Technical Services

7.7 Service and product return requirements

Please contact Technical Services with any questions or assistance you may need regarding this product. Local contact information can be found at http://service.masimo.com.

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[1]	The CO2 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	
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	EMMA Capnograph: 52 x 39 x 39 mm (2.1 x 1.6 x 1.6 inches) EMMA Bluetooth: 52 x 44 x 39 mm (2.1 x 1.8 x 1.6 inches)	
Weight	<65 g (2.1 oz) with batteries	
Mechanical robustness	Withstands repeated 1 m drops. Meets the shock and vibration requirements for transport of EN ISO 80601-2-55:2011 clause 201.15.3.5.101.2 and EN 1789:2007 clause 6.3.4.2 and 6.4.1.	
Operating conditions	Temperature: -5 - +50°C (23 to 122°F) Humidity: < 40 hPa H_2O (non-condensing) (95% RH at 30 °C) Atmospheric pressure: 60 - 120kPa [1] (i.e. Altitude up to 4000 m)	
Highest surface temperature	At ambient temperature	Surface temperature
	23°C / 73°F	30°C / 86°F
	50°C / 122°F	57°C / 135°F
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	
$ETCO_2$ [1]	0 - 99 mmHg (0 - 9.9 kPa) [2] $ETCO_2$ will be within specification for respiration rates up to 150 bpm [4]	
CO_2 accuracy[3]	0-40 mmHg ± 2 mmHg, 41-99 mmHg 6% of reading 0-5.3 kPa ± 0.3 kPa, 5.4-9.9 kPa 6% of reading during standard conditions.	
Total system response time	< 0.5 s	
Drift of measurement accuracy	No drift	
Recovery time after defibrillator test	Unaffected	
Respiratory rate	3 - 150 bpm	
Respiratory rate 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 Breath, Low ETCO2, High ETCO2, Clogged Adapter, No Adapter, Zero point adjustment, Low Battery
Sound Intensity Level	≥ 57 dB(A); ≤ 67 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	EMMA Capnograph: Duracell Plus Alkaline: ~5 hours Energizer Ultimate Lithium L92: ~10 hours EMMA Bluetooth: Duracell Plus Alkaline: ~4 hours Energizer Ultimate Lithium L92: ~8 hours

Notes:

[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] 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 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] $ETCO_2$ 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.

[5] www.energizer.com

8.3 Electromagnetic compatibility (EMC)

Guidance and Masimo's declaration – electromagnetic emissions		
The EMMA gas analyzer is intended for use in the electromagnetic environment specified below. The customer or the user of the EMMA gas analyzer should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11 EN 55011	Group 1	The EMMA gas analyzer 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 EN 55011	Class B	The EMMA gas analyzer 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	

The EMMA gas analyzer will function according to general specification in chapter 8.1 and will not cause any safety hazard or false alarm when exposed to the following immunity test levels.

Guidance and Masimo's declaration – electromagnetic immunity			
The EMMA gas analyzer is intended for use in the electromagnetic environment specified below. The customer or the user of the EMMA gas analyzer 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	±8 kV contact ±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 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	Not applicable	Not applicable
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Not applicable	Not applicable
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	Not applicable
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			
The EMMA gas analyzer is intended for use in the electromagnetic environment specified below. The customer or the user of the EMMA gas analyzer should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the EMMA gas analyzer including cables than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz - 80 MHz	Not applicable	
Radiated RF IEC 61000-4-3	3 V/m 80%AM@2Hz 80 MHz - 2,5 GHz	3 V/m 80%AM@2Hz 80 MHz - 2,7 GHz	$d = 1{,}17\sqrt{P}$ 80 MHz to 800 MHz $d = 2{,}33\sqrt{P}$ 800 MHz to 2,7 GHz
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* and ETSI EN 301 489-1	20 V/m 80%AM@1kHz 80 MHz - 2,5 GHz	20 V/m 80%AM@1kHz 80 MHz - 2,7 GHz	$d = 0{,}18\sqrt{P}$ 80 MHz to 800 MHz $d = 0{,}35\sqrt{P}$ 800 MHz to 2,7 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 the EMMA gas analyzer is used exceeds the applicable RF compliance level above, the EMMA gas analyzer should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the EMMA gas			

analyzer.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the EMMA gas analyzer			
The EMMA gas analyzer 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]**		
	150 kHz to 80 MHz $d = 1{,}17\sqrt{P}$	**80 MHz to 800 MHz** $d = 0{,}18\sqrt{P}$	**800 MHz to 2.7 GHz** $d = 0{,}35\sqrt{P}$
0,01	**0,12**	**0,02**	**0,04**
0,1	**0,37**	**0,06**	**0,11**
1	**1,17**	**0,18**	**0,35**
10	**3,70**	**0,57**	**1,11**
100	**11,70**	**1,80**	**3,50**
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. **Note 3**: In the frequency band 80 MHz to 2.7 GHz the separation distance is based on the higher field strength 20 V/m 80%AM@1kHz.			

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.

8.4 Compliance

EN 60601-1:2006, Amendment 1 (2012)
EN 60601-1-2:2007, C1:2010
EN 60601-1-8:2007, C1:2010, A1:2013
EN 1789:2007, A1:2010
EN 13718-1:2008
EN ISO 80601-2-55:2012
EN ISO 5356-1:2004
EN ISO 14971:2012
EN ISO 15223-1:2012

8.5 Bluetooth LE Wireless Technology information

Bluetooth LE Wireless Technology Information	
Modulation Type	GFSK
Max. Output Power	-1 dBm
Frequency Range	2402-2480 MHz
Antenna Peak Gain	-7 dBi
Recommended Range	~10 feet (~3 meters) line-of-sight

Radio Compliance	
Radio Modes	Bluetooth LE
USA	FCC ID: VKF-EMMABT FCC parts 15.207 and 15.247
Canada	IC-7362A-EMMABT RSS-247
Europe	EN 300 328 ETSI EN 301 489-1 ETSI EN 301 489-17 R&TTE 1999/5/EC
Japan	Japanese Radio Law, Item 19 of Article 2-1

8.6 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 sterility
No part of EMMA is sterile

Masimo Sweden AB
Svärdvägen 15
182 33 Danderyd
Sweden
www.masimo.com

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