

CapnoEasyTM Capnograph

User's Manual

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Contents

1. Intended use.....	- 4 -
2. Safety.....	- 5 -
2.1. Warnings.....	- 5 -
2.2. Cautions.....	- 6 -
2.3. Notes.....	- 7 -
2.4. Symbol description.....	- 8 -
3. Device description.....	- 9 -
3.1. overview.....	- 9 -
3.2. Principle of operation.....	- 9 -
4. Preparations for use.....	- 10 -
4.1. Setting Up.....	- 10 -
4.2. Starting up.....	- 11 -
4.3. Shut down.....	- 12 -
4.4. Connecting to the CapnoEasy Capnograph.....	- 12 -
5. User interface.....	- 13 -
5.1. Buttons.....	- 13 -
5.2. Bluetooth.....	- 13 -
5.2.1. Bluetooth Settings.....	- 13 -
5.3. Monitoring.....	- 14 -
5.3.1. ETCO ₂	- 15 -
5.3.2. Respiratory Rate.....	- 15 -
5.3.3. Capnogram.....	- 15 -
5.3.4. CO ₂ Settings.....	- 16 -
5.4. Indicators and alarms.....	- 16 -
5.4.1. Alarm signals.....	- 16 -
5.4.2. Default limits for alarms.....	- 18 -
5.4.3. Alarm silence.....	- 19 -
5.4.4. Battery Status Indicator.....	- 19 -
5.4.5. Adjusting the alarm limit.....	- 19 -
6. CapnoEasy and accessories.....	- 21 -
7. Maintenance.....	- 22 -
7.1. Battery replacement.....	- 22 -
7.2. Cleaning.....	- 22 -
7.3. Airway Adapter.....	- 22 -
7.4. Zeroing procedure.....	- 23 -
7.5. Gas span check.....	- 23 -
7.6. Troubleshooting.....	- 25 -
8. Specifications.....	- 26 -
8.1. General specifications.....	- 26 -
8.2. Compliance.....	- 28 -
8.3. Classifications.....	- 28 -
8.4. Electromagnetic compatibility (EMC)	- 28 -
8.5. Bluetooth Information.....	- 32 -

1. Intended use

CapnoEasy 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

2.1. Warnings



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

- **WARNING!** CapnoEasy should only be used for the purpose and in the manner described in this manual.
- **WARNING!** CapnoEasy is intended for use by authorized health care professionals only.
- **WARNING!** CapnoEasy must not be used with flammable anesthetic agents. Use of the CapnoEasy in such environment may present an explosion hazard.
- **WARNING!** Use only CapnoEasy Airway Adapters manufactured by Winland.
- **WARNING!** No modification of the CapnoEasy probe or the CapnoEasy Airway Adapters is allowed.
- **WARNING!** CapnoEasy 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 CapnoEasy Adult/Pediatric Airway Adapter with infants as the Adapter adds 6 ml dead space to the patient circuit.
- **WARNING!** Do not use the CapnoEasy 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 CapnoEasy is used in the specified electromagnetic environment.
- **WARNING!** CapnoEasy 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 CapnoEasy is used with a respirator or with harmful gases such as N₂O, always perform a pre-use tightness check of the patient circuit.
- **WARNING!** Light transmission can be affected by secretions and moisture pooling on the CapnoEasy Airway Adapter 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 CapnoEasy with nebulized medications as this may affect the light transmission of the CapnoEasy Airway Adapter windows.
- **WARNING!** Do not operate the CapnoEasy when it is wet or has exterior condensation.
- **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 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

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



















- **CAUTION!** Use only approved accessories.
- **CAUTION!** If CapnoEasy is used in a manner other than that for which it was intended, unpredictable behavior could result.
- **CAUTION!** The CapnoEasy Airway Adapters are non-sterile devices. Do not autoclave the devices as this will damage them.
- **CAUTION!** Never sterilize or immerse CapnoEasy in liquid.
- **CAUTION!** Do not operate CapnoEasy at ambient temperatures less than 0°C or greater than 40°C.
- **CAUTION!** DO not store the CapnoEasy at temperatures less than -40°C or greater than 70°C .
- **CAUTION!** DO not clean the CapnoEasy and accessories except as directed in this guide.
- **CAUTION!** Federal law restricts this device to sale by or on the order of a physician.
- **CAUTION!** Remove batteries if CapnoEasy is not likely to be used for a period of time longer than 90 days.

2.3. Notes

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

- **NOTE!** Throughout this User's Manual: CapnoEasy 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 CapnoEasy Airway Adapter model for each patient application. No hardware or software configuration changes result from the CapnoEasy Airway Adapter model selected.
- **NOTE!** The CapnoEasy contains no user serviceable parts. Refer service to qualified service personnel.
- **NOTE!** This product and its accessories are latex free.
- **NOTE!** After the life cycle of the CapnoEasy and its accessories have been met, disposal should be accomplished following national and/or local requirements.
- **NOTE!** The alarm limits will be reset to default values after power off.
- **NOTE!** Always carry spare batteries in the CapnoEasy pouch.
- **NOTE!** The presence of ambient air (0% CO₂) in the CapnoEasy Airway Adapter is of crucial importance for a successful Zeroing. Special care should be taken to avoid breathing near the CapnoEasy Airway Adapter before or during the Zeroing procedure.
- **NOTE!** CapnoEasy 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!** CapnoEasy 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
	Date of manufacture
	Serial number
	Batch code
	Catalog number
	Defibrillation-proof type BF applied part
	Refer to instruction manual
	Manufacturer
	Symbol for CE mark. This symbol certifies that a product has met European Union consumer safety, health or environmental requirements.
	Authorized representative in the European Community
	Symbol for temperature limitation/temperature range
RxOnly	Caution (U.S.): Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.
	For EU only: Waste Electrical and Electronic Equipment (WEEE)
	WARNING
	Alarm Mute button
	Menu button
	Power button
	Battery bay locked
	Battery bay unlocked
	Bluetooth

3. Device description

3.1. overview

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



Figure 1 CapnoEasy Capnograph.

3.2. Principle of operation

The CapnoEasy CO₂ monitor measures the concentration of CO₂ in the breathing gas based on the NDIR technology. Different gases absorb infrared light of a specific wavelength.

The stationary infrared light source emits a beam of invisible infrared light through the airway adapter, and the respiratory airflow flows in the airway adapter. As the beam passes through the airway adapter, some light is absorbed by the gas mixture. The absorbed beam reaches the infrared detector fixed at the other end. The infrared detector is equipped with two filters of different wavelengths, one of which has very strong absorption of carbon dioxide, and the other wavelength of carbon dioxide has no absorption.

The infrared detector converts the beam into an electrical signal, which is converted to a digital value and sent to the microprocessor. The microprocessor then calculates the carbon dioxide concentration in the breathing gas mixture using the ratio of the light of the two measurement channels.

4. Preparations for use

4.1. Setting Up

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

1. Push the battery cover release button to the  position, then push down the battery cover and remove the battery cover.

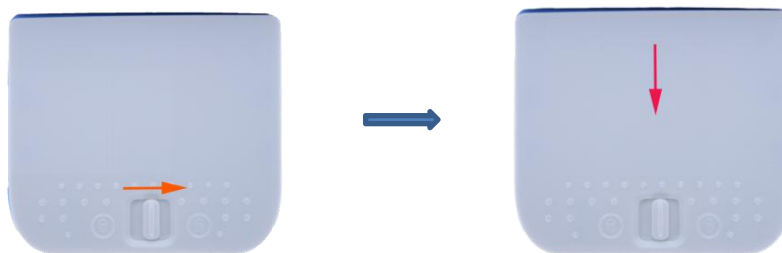


Figure 2. Releasing the Battery Cover

2. Open the battery compartment and insert two (2) AAA batteries. Make sure the batteries are fitted according to the indicated polarity.

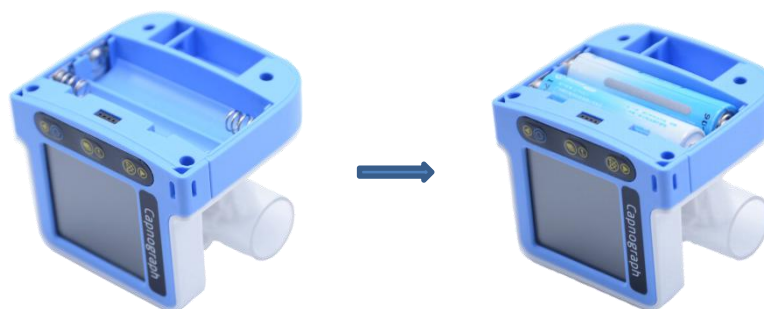



Figure 3. Install batteries

3. After battery installation, put the Battery Cover back into place, and then push the battery cover release button to the  position.

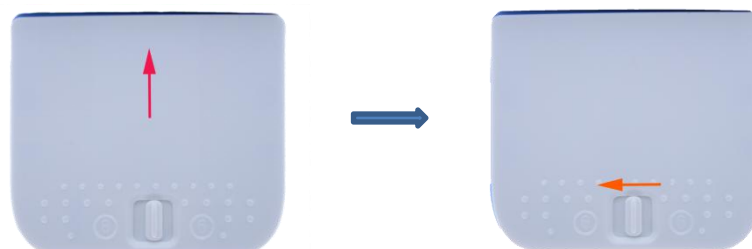


Figure 4. Installing the Battery Cover

4.2. Starting up

1. Press the Airway Adapter into the CapnoEasy Capnograph. It will click into place when properly seated.

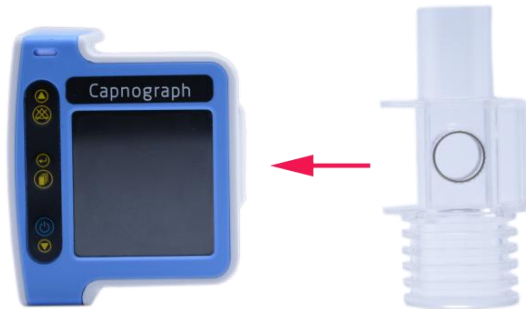


Figure 5. Connect CapnoEasy with airway adapter

2. Press the Power button.



Figure 6. Power on CapnoEasy

3. When the CapnoEasy Capnograph is ready the ETCO₂ Value indicates “0” and the Respiratory Rate Value indicates “--”.



Figure 7. Normal monitor interface

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

If the ETCO₂ Value is non-zero, ensure that there has not been an accumulation of CO₂ between the CapnoEasy Sensor Body and the CapnoEasy Airway Adapter by removing and reattaching the CapnoEasy Airway Adapter. If the ETCO₂ Value still displays a non-zero value after this procedure, perform a Zeroing procedure as described in chapter 7.4 prior to using the CapnoEasy Capnograph with a patient.

4.3. Shut down

When the screen not shows the menu interface, long press the power button for more than 3 seconds, the CapnoEasy Capnograph will shut down.

The CapnoEasy 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 60 seconds if the Airway Adapter is removed.

4.4. Connecting to the CapnoEasy Capnograph

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



Figure 8. CapnoEasy connected to an endotracheal tube






Figure 9. CapnoEasy connected to a mask

5. User interface

5.1. Buttons

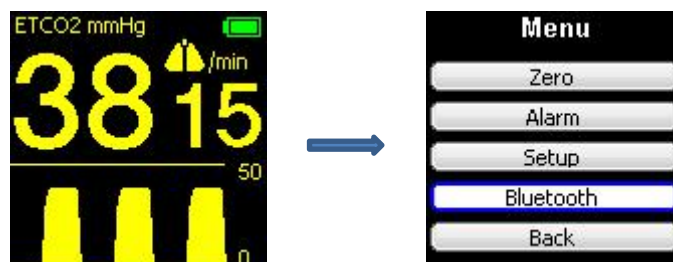
CapnoEasy has three multi-function buttons with different functions in different display interfaces:

Screen display	Alarm Mute button 	Menu button 	Power button 
Monitoring	Mute/Clear Mute	Enter Menu	Long press more than 2s, power off
Menu	Up/ plus	confirm	Down/ Minus
Bluetooth	Enable Bluetooth	Back	Disable Bluetooth

5.2. Bluetooth

The CapnoEasy Bluetooth provides a Bluetooth Low Energy (LE) wireless option to allow connection to a compatible smart device or host. CapnoEasy Bluetooth can only communicate to a single smart device at a time to minimize the risk of unauthorized access. The Bluetooth device is default disabled when the CapnoEasy power on.

5.2.1. Bluetooth Settings



- 1) Enter Menu: Press the menu button to enter the menu in the monitoring interface.
- 2) Enter Bluetooth Menu: Press the alarm mute button (▲) or the power button (▼) to select the Bluetooth menu and press the menu button to confirm.
- 3) Press the mute button (▲) to turn on the Bluetooth module. press the power button (▼) to turn off the Bluetooth module.
- 4) Press the menu button to return to the previous menu.



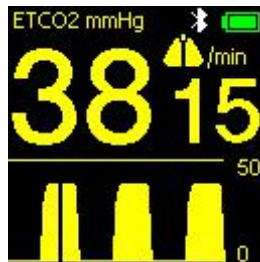
BLE Disabled



BLE connecting



BLE Connected



BLE Connected(monitored)

Note! If the connection is disconnected during use, the power of the Bluetooth module remains on, and the Bluetooth icon on the monitoring interface flashes. The host can connect again.




5.3. Monitoring

The CapnoEasy Capnograph is equipped with a 128*128 pixel graphic TFT display that shows the end-tidal carbon dioxide value, respiratory rate value, and the capnogram.

5.3.1. ETCO₂

The unit of end-tidal carbon dioxide (ETCO₂) defaults to millimeters of mercury (mmHg) and can be set to kPa or volume percent (%) by menu. The ETCO₂ value is shown after one breath and the averaged value is updated every breath.

The display range is as follows:

CO ₂ Unit	Value Range	Monitoring shows
mmHg	0-99 mmHg	
kPa	0-9.9 kPa	
%	0-9.9 %	

5.3.2. Respiratory Rate

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

5.3.3. Capnogram

The horizontal scanning speed and the scale of the capnogram can be set via the menu. The default values are as follows:

- Default scan speed: 2mm/s
- Default display scale: 0-50mmHg

5.3.4. CO₂ Settings

The CO₂ display unit, CO₂ waveform scale and scan speed can be set on the setup menu.

- 1) Enter the main menu: Press the "menu button " in the monitoring interface to enter the menu.
- 2) Enter the setup menu: Press the alarm mute button (▲) or the power button (▼) to select the setup menu, press the menu button to enter setup menu.
- 3) Select the setting item: Press the alarm mute button (▲) or the power button (▼) to select items.
- 4) Enter editing mode: press menu button to enter editing mode.
- 5) Adjust the setting value: Press the alarm mute button (▲) or the power button (▼) to adjust the values.
- 6) Exit the edit mode: press the menu button to exit the edit mode.



Parameters		Options	Default
CO ₂ Unit		mmHg; kPa; %	mmHg
CO ₂ Scale	mmHg	50; 60; 75	50
	kPa	6.7; 8.0; 10.0	6.7
	%	6.6; 7.9; 9.9	6.6
Waveform Speed		4mm/s; 2mm/s; 1mm/s	2mm/s

5.4. Indicators and alarms



The CapnoEasy 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 Status Indicator in the upper 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 Priority	Indicator	Audible	Alarm
Low	Yellow,steady	One beep, repeated every 20s	Zero point adjustment
Medium	Yellow,steady	Two beeps, repeated every 20s	ETCO ₂ Low
			ETCO ₂ High
			RR Low
			RR High
			No Adapter
			Clogged Adapter
High	Yellow,steady	Three beeps, repeated every 20s	Apnea

Active alarms are further displayed according to the following table:

Alarm	Screen	ETCO ₂ Value	RR Value
Apnea		value steady	"- -" flashing
ETCO ₂ Low		value flashing	value steady
ETCO ₂ High		value flashing	value steady
RR Low		value steady	value flashing
RR High		value steady	value flashing
No Adapter		n/a	n/a
Clogged Adapter		n/a	n/a

Battery Low		Depend on other alarm signal	
Zero point adjustment		n/a	n/a

5.4.2. Default limits for alarms

The default factory settings for the Apnea and the Low/High ETCO₂ and RR alarms are as follows:

	Lower Limit	Upper Limit
Apnea	20s	-
ETCO ₂	25mmHg	50mmHg
RR	5bpm	30bpm

5.4.3. Alarm silence



By pressing the mute button, the audio alarm can be muted for 2 minutes. When the alarm is muted, the yellow alarm mute indicator is located in the upper right corner of the display, ie the alarm status silence indicator will light.

Pressing the alarm mute button again during 2 minutes of silence will reactivate the audible alarm.

If a No Breath alarm is muted by pressing the Alarm Silence button, the CapnoEasy Capnograph will automatically switch off after 2 minutes provided that no new breaths are detected.

If the alarm signal disappears when the audible alarm is muted, the alarm icon will turn green. Pressing the alarm mute button during no alarm will also show a green mute alarm indicator in the upper right corner of the display.

5.4.4. Battery Status Indicator

There is a battery status indicator in the upper right corner of the screen. The display status of the indicator changes according to the battery power:

- When the battery is normal, the battery status indicator lights up with a steady green light
- When the battery is low, the battery status indicator begins to flash.



Battery Normal

Battery Low

5.4.5. Adjusting the alarm limit

- 1) Enter the main menu: press the menu button in the monitoring interface to enter the menu.
- 2) Enter the alarm setting menu: Press the alarm mute button (▲) or the power button (▼) to select the

Alarm menu, and then press the menu button to enter the selected menu.

- 3) Select the alarm setting item: Press the alarm mute button (▲) or the power button (▼) to select.
- 4) Enter editing mode: press menu button to enter editing mode.
- 5) Adjust the alarm limit: Press the alarm mute button (▲) to increase or the power button (▼) to decrease the limit value.
- 6) Exit the edit mode: press the menu button to exit the edit mode.



The adjustment ranges for the ETCO₂ and RR alarm limits are as follows:

Alarm item	Lower range	Upper range
ETCO ₂ displayed in mmHg	0-99mmHg	1-99mmHg
ETCO ₂ displayed in kPa	0-13.2kPa	0.1 - 13.2kPa
ETCO ₂ displayed in %	0-13%	0.1-13%
RR	3-150bpm	3-150bpm

NOTE! After restart, the alarm limit is reset to the default value.

6. CapnoEasy and accessories

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

www.wldyq.com.

Catalog Number (REF)	Product	Description
301000	CapnoEasy	CapnoEasy Capnograph
301001	CapnoEasy Bluetooth	CapnoEasy Capnograph with Bluetooth
2101-00	Airway Adapter Adult	Airway adapter is needed in order for CapnoEasy to provide readings.
2102-00	Airway Adapter Pediatric/Infant,	Airway adapter is needed in order for CapnoEasy to provide readings.

7. Maintenance

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 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. Push the battery cover release button to the  position, then push down the battery cover and remove the battery cover.
2. Gently remove the depleted batteries. And Then Insert two new AAA type batteries into the battery compartment. Make sure that the batteries are fitted according to the polarity marking.
3. When the batteries are properly fitted, gently snap the battery cover back into place, and then push the release button to  .

NOTE! Always carry spare batteries with CapnoEasy.

7.2. Cleaning

1. Remove the batteries before cleaning.
2. The CapnoEasy Capnograph can be cleaned using a cloth moistened with 70% isopropyl alcohol.
3. Wipe down with a clean water-dampened cloth to rinse and dry before use.

CAUTION! DO NOT immerse CapnoEasy in any liquid.

7.3. Airway Adapter

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

7.4. Zeroing procedure

Zeroing is recommended after replaced airway adapter or whenever an offset in gas readings is discovered.

Zeroing of the CapnoEasy Capnograph is performed by the following procedure:

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

- 1) Start the CapnoEasy Capnograph by pressing the Power button.
- 2) Make sure that a new airway adapter is properly installed.
- 3) Press the menu button to enter the menu interface.
- 4) Press the alarm mute button (▲) or the power button (▼) to select the Zero menu. When the zero countdown shows "0", the zero operation is completed.
- 5) Press the menu button to start zeroing. When "Zeroing" and countdown digits are displayed on the screen, it means that zero is being executed. If Zero Fails, "Zero failed" will be displayed on the screen.
- 6) When the zero countdown shows "0", the zero operation is completed.



Zeroing



Zero not started

CapnoEasy will automatically return to normal measurement mode after zero completion

7.5. Gas span check

The CapnoEasy 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 CapnoEasy you will need:

1. A gas flow regulator with a plastic tube and a 15M connector
2. Calibration gas (5% CO₂, Balance N₂)
3. Two Airway Adapters



Figure 10. Gas span check connection

The process is as follows:

- 1) Connect the flow regulator to the calibration cylinder. Ensure that the valve is completely closed.
- 2) Install a new airway adapter to the CapnoEasy.
- 3) Turn on the CapnoEasy and make sure the ETCO₂ reading is zero. Otherwise conduct a zeroing procedure according to Chapter 7.4 above before proceeding.
- 4) Insert the 15M connector into one end of the airway adapter, and connect a second airway adapter to the other end of the first airway adapter (see **Figure 10**).
- 5) Turn on the regulator flow.
- 6) After 30 seconds, record the ETCO₂ reading.
- 7) Turn off the flow.
- 8) Determine and record the estimated ambient atmospheric pressure in mmHg.
- 9) Use the following table to determine if the device is reading within the specified limits.

Barometric Pressure mmHg	CapnoEasy Capnograph ETCO ₂ readings should be between		
	%	mmHg	kPa
660-679	4.7 - 5.3	31 - 36	4.1 - 4.8
680-699	4.7 - 5.3	32 - 37	4.3 - 4.9
700-719	4.7 - 5.3	33 - 38	4.4 - 5.1
720-739	4.7 - 5.3	34 - 39	4.5 - 5.2
740-759	4.7 - 5.3	35 - 40	4.6 - 5.4
760-779	4.7 - 5.3	36 - 41	4.8 - 5.5
780-799	4.7 - 5.3	37 - 42	4.9 - 5.6

If the reading of the device is within the above range, Then your CapnoEasy has been successfully verified.

If the device is not reading within the above range, disconnect the airway adapter from the cylinder and perform a Zeroing procedure according to the instructions in Chapter 7.4 above, and then repeat the gas range check procedure . If verification still fails, contact your local distributor for more information.

7.6. Troubleshooting

Error	Possible causes	Recommended Solutions
The unit does not turn on	No battery Low battery	Replace batteries
The unit does not complete the turn on sequence	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

8. Specifications

8.1. General specifications

Description	Compact, battery powered, quantitative capnograph for mainstream CO2 monitoring of adult, pediatric and infant patients. .
Measurements	CO2 partial pressure and respiratory rate
Measuring principle	2 channel NDIR type gas analyzer, No moving parts
Warm up	Waveform displayed within 10 seconds, meets specifications within 2 minutes (at 25°C room temperature)
Calibration	No routine calibration required
CO2 Range	0~99 mmHg 0~9.9 % 0~9.9 kPa
CO2 Resolution	1mmHg or 0.1kPa or 0.1%
CO2 accuracy	0~40mmHg ±2 mmHg 41~99mmHg ±8% of readings When RR is above 80 bpm ±12% of readings
Drift of CO2 measurement accuracy	Short drift: Less than 1 mmHg offset in 4 hours Long drift: Meet measurement accuracy requirements within 120 hours
CO2 noise	Noise RMS less than 1mmHg at 5% CO2
Total system response time	Less than 500ms
Recovery time after defibrillator test	Unaffected
Respiratory rate	3~150 bpm
Respiratory rate accuracy	±1 bpm
ETCO ₂ Calculation Method	Peak of the expired CO ₂ waveform
Compensation	Built-in atmospheric pressure sensor, automatic pressure compensation
Display	128 *128 pixels 1.44 inch TFT color display
Dimensions	51 x 43 x 45 mm
Weight	<65 g (Included 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: 0 - 40 °C Humidity: <90% (non-condensing) Atmospheric pressure: 50-120 kPa
Storage conditions	Temperature: -20 - 70 °C Humidity: <95% (non-condensing) Atmospheric pressure: 50-120 kPa

Alarms	No Breath, Low ETCO ₂ , High ETCO ₂ , Low RR, High RR, Clogged Adapter, No Adapter, Zero point adjustment, Low Battery
Batteries	Two AAA Cell batteries (2*1.5VDC) Alkaline IEC:LR03 or Energizer Ultimate Lithium L92 batteries. Use of other Lithium batteries may present a risk of fire or explosion
Battery life time	Bluetooth Disabled: Duracell Plus Alkaline: ~6 hours Energizer Ultimate Lithium L92: ~10 hours Bluetooth Connected: Duracell Plus Alkaline: ~4 hours Energizer Ultimate Lithium L92: ~8 hours

Interfering gas and vapor effects

Gas or Vapor	Gas Level	Quantitative Effects
Nitrous oxide	60	increases CO ₂ readings 10%
Halothane	4	decreases CO ₂ readings by 4%
Enflurane	5	increases CO ₂ readings 5%
Isoflurane	5	increases CO ₂ readings 5%
Sevoflurane	5	increases CO ₂ readings 5%
Xenon	80	decreases CO ₂ readings by 10%
Helium	50	decreases CO ₂ readings by 6%
Metered dose inhaler propellants	Unspecified	Unspecified
Desflurane	15	increases CO ₂ readings 12%
Ethanol	0.1%	No additional effect
Isopropanol	0.1%	No additional effect
Acetone	0.1%	No additional effect
Methane	1%	No additional effect
Gas or Vapor	Gas Level	No additional effect

8.2. 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

8.3. Classifications

Category AP/APG	AP - This device is not suitable for use in the presence of a flammable anesthetic mixture with air or nitrous oxide
The Type Of Protection Against Electric Shock	Internally Powered Equipment (Battery Power)
The Degree Of Protection Against Electric Shock	Defibrillation-proof type bf applied part
The Degree Of Protection Provided By Enclosures	IP33 (spray proof and tool proof equipment)
Mode Of Operation	Continuous Operation
Sterility	No part of CapnoEasy is sterile


8.4. Electromagnetic compatibility (EMC)

Guidance and manufacturer's declaration – electromagnetic emissions		
The CapnoEasy is intended for use in the electromagnetic environment specified below. The customer or the user of the CapnoEasy should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The CapnoEasy 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	The CapnoEasy 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 manufacturer's declaration – electromagnetic immunity			
The CapnoEasy is intended for use in the electromagnetic environment specified below. The customer or the user of the CapnoEasy 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	
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Not Applicable	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 s	Not Applicable	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	30A/m	Note: The CapnoEasy does not contain components susceptible to magnetic fields, such as Hall elements or magnetic field sensors.

Guidance and manufacturer's declaration – electromagnetic immunity

The CapnoEasy is intended for use in the electromagnetic environment specified below. The customer or the user of the CapnoEasy should assure that it is used in such an electromagnetic environment.

IMMUNITY test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	Not Applicable	Portable and mobile RF communications equipment should be used no closer to any part of the CapnoEasy, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m 80 MHz to 2,5 GHz	<p>Recommended separation distance</p> $d = 1.17\sqrt{P}$ $d = 1.17\sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = 2.33\sqrt{P} \quad 800 \text{ MHz to } 2,5 \text{ GHz}$ <p>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).</p> <p>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</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 

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 CapnoEasy is used exceeds the applicable RF compliance level above, the CapnoEasy should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the CapnoEasy.

^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 CapnoEasy

The CapnoEasy is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the CapnoEasy can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the CapnoEasy 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	80 MHz to 800 MHz	800 MHz to 2,5 GHz
	$d = 1.17\sqrt{P}$	$d = 1.17\sqrt{P}$	$d = 1.17\sqrt{P}$
0.01	0.12	0.12	0.07
0.1	0.37	0.37	0.22
1	1.17	1.17	0.70
10	3.69	3.69	2.21
100	11.67	11.67	7.00

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 CapnoEasy is used in the electromagnetic environment

8.5. Bluetooth Information

Bluetooth LE Wireless Technology Information	
Modulation Type	GFSK
Max. Output Power	-1 dBm
Frequency Range	2402-2480 MHz
Antenna Peak Gain	0 dBi
Recommended Range	~3 meters line-of-sight
Radio Compliance	
Radio Modes	Bluetooth LE
USA	FCC ID: 2ABN2-RFBMS02A FCC parts 15.207 and 15.247
Europe	ETSI EN 300 328 ETSI EN 301 489-1 ETSI EN 301 489-17



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