User Manual v1.4Z / 1.1W

Rapid Intervention Capnograph (RICap®)

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RICap® User's Manual
Article number: WL-YF-ZG02-040
Version: V1.4Z / V1.1W
Released: 01/2021

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

Version Control Table

#	Version	Date	Changes
1	V0.2	September 5,2017	Initial released version
2	V0.3	May 15,2018	Update released version - SHO
3	V1.0Z	Oct 9,2018	Update Zug version – SHO Temporary Revision Before CE Approval
4	V1.4Z	Jan ,2021	Update Zug version – SHO Revision CE Approval

Declaration of Conformity

CE 0123

Complies with 93/42/EEC Medical Device Directive.

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Zug Medical Systems SAS guarantees that the product delivered has been thoroughly tested to ensure that it meets its published specifications

Warranty

Zug Medical Systems SAS warrants the products manufactured or distributed by them to be free from faulty materials and workmanship for a period of 12 months from date of original shipment to first end user except for disposable products or products which have a stated guarantee longer or shorter than 12 months. Zug Medical Systems SAS will perform warranty service at its factory. Use of the equipment for other than its intended use, or if it has been repaired by anyone except Zug Medical Systems SAS or a Zug Medical Systems SAS manufacturing site, or altered or modified or used without following the instructions in the user manual, will void the guarantee.

Patents

201410727985.8, 201420752681.2, Other patents pending.

Trademarks

RICap® is a trademark of Zug Medical Systems SAS.

Table of Contents

1 INTRODUCTION

1.1 Intended Use

RICap® CO_2 Monitor is intended to provide continuous monitoring of end tidal CO_2 concentration (EtCO2), Capnogram, Respiration rate (RR) of adult, pediatric and infant patients. It may be used in the operating theater, intensive care unit, patient room, clinic, for emergency medicine and emergency transport settings. . It can be used during patient transport inside and outside of the hospital environment.

1.2 Contraindications/ Hazards

There are no known contraindications for patient monitoring with RICap®, provided that the data obtained is evaluated with consideration given to the patient's clinical condition.

1.3 Warnings

Adhere to the following warnings for safe operation of RICap®.

⚠ Warning

- **RICap is to be operated only by trained personnel and is for attended monitoring only.**
- **RICap should only be used for the purpose and in the manner described in this manual.**
- **Do not make any clinical judgments based solely on RICap. RICap is intended only as an adjunct in patient assessment. It must be used in conjunction with the assessment of clinical signs and symptoms.**
- **Explosion hazard. Do not use the monitor in the presence of flammable anaesthetic mixtures with air, oxygen, or nitrous oxide.**
- **Use only RICap Airway Adapters manufactured by WITLEAF.**
- **RICap is transportable in a road ambulance .**
- **Disposable RICap 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.**
- **Do not use RICap Adult/Pediatric Airway Adapter adds 5 ml dead space to the patient circuit.**
- **Do not use RICap with nebulized medications as this may affect the light transmission of the RICap Airway Adapter windows.**
- **Replace the RICap airway adapter if the adapter window is clogged.**
- **A successful zeroing requires the presence of ambient air (21% O2 and 0% CO2) in the RICap airway adapter during zeroing. Incorrect zeroing of the RICap CO2 analyzer will result in false gas readings.**
- **The RICap may not meet the performance specifications due to degraded IR sensor and electrodes.A testing(chapter 6.4) should be performed regularly. If the performance of**

the equipment is degraded due to aging or environmental conditions, contact your service personnel.

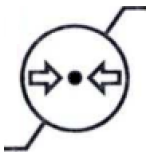
- **RICap detects respiratory effort via changes in CO2 concentration of exhaled air; therefore, the CO2 measurement can be used to detect apnea. The device however is unable to discriminate between a patient not breathing and a sensor that is disconnected from the patient circuit.**
- **Check all alarm settings and auditory alarm before use of the monitor.**
- **Measurements can be affected by mobile and RF communications equipment. Make sure that RICap is used in the electromagnetic environment specified in this manual.**
- **If RICap is used with a respirator or with harmful gases such as N2O, always perform a pre-use tightness check of the patient circuit.**
- **Do not silence the audible alarm function, or decrease the audible alarm volume if patient safety could be compromised.**
- **No modifications of RICap are allowed without authorization of the manufacturer.**
- **Do not use RICap during computed tomography (CT) or magnetic resonance imaging (MRI) scanning.**
- **Audible alarm volume of any monitor may not be heard in some loud environments, such as when sirens are in use or when 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.**
- **Replace batteries immediately when the Battery Status indicates a low battery. 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 is low battery.**
- **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.**
- **Use only Alkaline or Energizer Ultimate Lithium L92 batteries. Use of other Lithium batteries may present a risk of fire or explosion.**

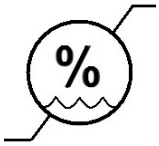
1.4 Cautions

Adhere to the following recommendations to avoid damage or malfunction of RICap®.

- **If RICap is used in a manner other than that for which it was intended, unpredictable behavior could result.**
- **Do not autoclave or steam sterilize RICap or its airway adapter.**
- **Do not immerse RICap or its airway adapter in liquid.**
- **Do not operate RICap outside the specified operating temperature environment.**
- **RICap requires no routine calibration. A basic maintenance plan conducted by qualified service personnel is recommended. Please refer to the Service Manual for detailed information.**
- **Remove batteries if RICap is not likely to be used for a period of time longer than 90 days.**

1.5 Symbol Description

Symbol	Title
	Follow operator's guide
	Warning: Protection against effects of discharge of a cardiac defibrillator depends on use of proper cables included in instructions for use
	Caution, refer to accompanying documents
	Defibrillation-proof type BF applied part
	Catalog Part number
	Serial number
	Batch code
	Manufacturer
	Date of manufacture
	Temperature limitation
	Pressure limitation

	Humidity limitation
	Do not re-use
	Do not dispose of equipment as unsorted municipal waste
CE 0123	Complies with 93/42/EEC Medical Device Directive
IP33	IP Code (International Protection Rating)

1.6 Terms and Definitions

RICap®	Rapid Intervention Capnograph
IR	Infrared
CO2	Carbon dioxide
BTPS	Body Temperature and Pressure Saturated
EtCO2	End tidal CO2 gas concentration
AwRR	Air Way Respiration Rate
Rise time	Time required achieving an increase from 10% to 90% of final value when step function change in concentration occurs at the sampling site.
Total system response time	Time from a step function change in gas level at the sampling site to the achievement of 90% of the final gas reading of the capnograph. Total system response time = Delay time + Rise time
Zeroing	Ambient gas reference measurement used to establish zero concentration level for CO2. Zeroing needs to be performed ONLY when an offset in gas measurement values is observed, or when an unspecified accuracy message is displayed.

2 DEVICE DESCRIPTION

2.1 RICap® overview

RICap® is a quantitative carbon dioxide mainstream monitor. It is comprised of RICap® sensor body and RICap® Airway Adapter. RICap® can make real-time measurements of EtCO2, AwRR and Capnogram.

2.2 RICap® Airway Adapter

RICap® airway adapters are available in two models: Adult/Pediatric (**Figure 2a**) and Infant (**Figure 2b**). A trained medical professional must determine the proper Airway Adapter for each different type of patient. When replacing different model of adapter, there is no software or hardware configuration to change.

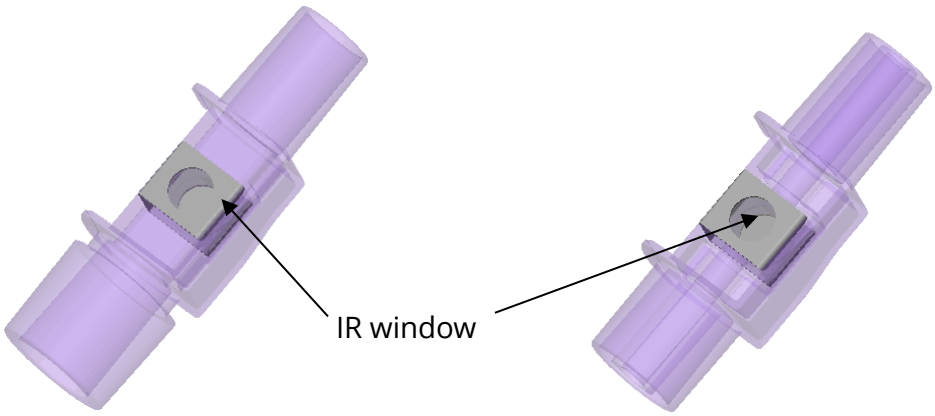


Figure 2a. RICap® Airway Adapter Adult/Pediatric **Figure 2b.** RICap® Airway Adapter Infant

2.3 Principle of operation

The measurement of CO2 in gas mixtures with RICap® is based on the fact that different gases absorb infrared light at specific wavelengths. The absorption spectrum for CO_2 is shown in the figure below.

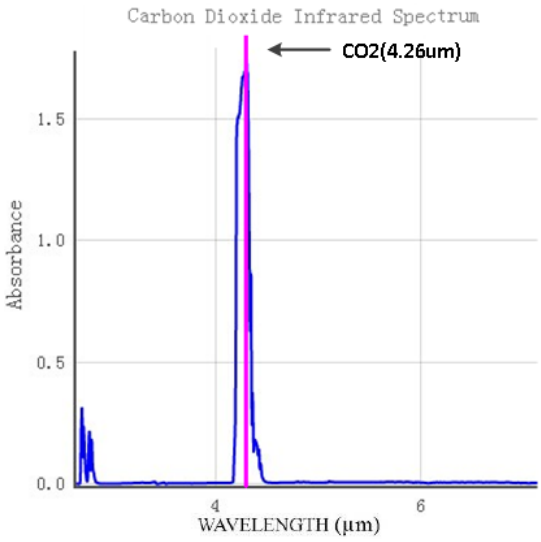


Figure 3. CO_2 absorption spectrum

On one side of the airway adapter windows, an IR source emits a beam of invisible IR light (2 to 14μm), which goes through the windows while some of the IR light is absorbed by the CO_2 in the respiratory gas. The amount of absorbed light is measured by a two-channel spectrometer at the end of the light path located behind the opposite window. This spectroscope can convert optical signals into electrical signals, which are digitalized and transferred to the CPU. The CPU will operate a digital signal processing to analyze, calculate, compensate and identify the EtCO2, and AwRR parameters, while producing a series of data allowing drawing a capnogram.
The Rating infrared radiation power is 5.1mW.

Parameters:
Capnogram: it is a graph representing the concentration or partial pressure of CO_2 in the respiratory gases plotted against time.

$EtCO_2$: The CO_2 concentration or partial pressure of point B.

AwRR: The time between point A and C.

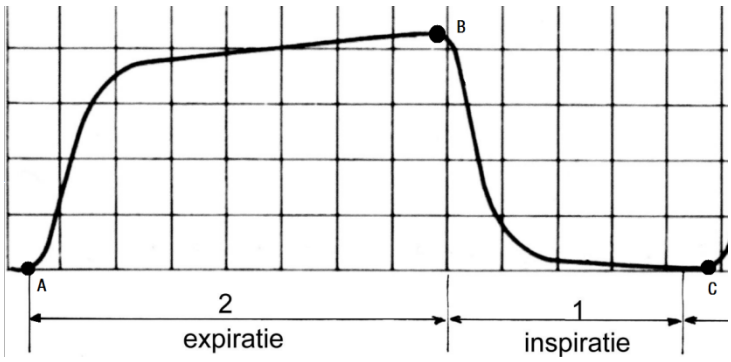


Figure 4. Capnogram

3 PREPARATION FOR USE

3.1 Setting up

Unpack and inspect RICap® for external damage.

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

2. After battery installation, slide the battery cover back into place until it locks.

Figure 5. Inserting batteries

3.2 Starting up

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

2.Press and hold the Power button for 3s. RICap® will turn on and start its warming process.

3.When RICap® is ready the ETCO2 value will be displayed as zero.

Figure 6. Starting up RICap® – Rapid Intervention Capnograph

3.3 Switching off

When RICap® is On, Press and hold the Power button for 3 Sec.

3.4 Connecting RICap® to a breathing circuit

RICap® can be connected to a patient circuit in different ways. The following pictures illustrate the most common methods of connection.

Figure 7. RICap® connected between an endotracheal tube and a resuscitation bag

Figure 8. RICap® connected to a mask

4 User Interface

4.1 Controls

RICap® has a Power button, an Alarm Silence button, an Up button and a Down button. These buttons are also used for adjusting menu settings or starting a zero calibration process.

4.2 Monitoring

RICap® OLED screen shows the $ETCO_2$ value, Airway Respiratory Rate, CO_2 waveform (the capnogram), Alarm information, Bluetooth status and Battery status indicator.

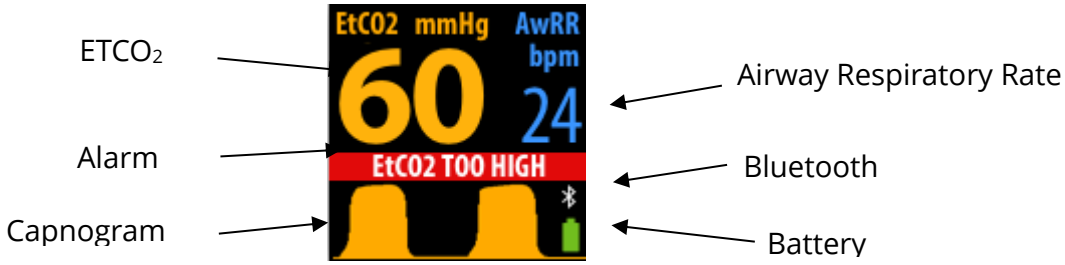


Figure 9. RICap® Display

4.2.1 $ETCO_2$

$ETCO_2$ concentration value can be displayed in the following 3 different units: mmHg (0 - 99 mmHg) , kPa (0.0 - 9.9 kPa) or percent (0.0 - 9.9%). The $ETCO_2$ value is displayed after warm up has complete. The averaged value is updated when it changes.

4.2.2 Respiratory Rate

Airway Respiratory Rate (AwRR) is displayed as breaths per minute (2 - 150 bpm). AwRR is displayed after one breath. The value is updated when it changes.

4.2.3 Capnogram

The capnogram is displayed as a filled graph with an 18mm horizontal sweep and a fixed vertical 0-53 mmHg/0-7 kPa/0-7% scale. The sweep speed can be selected as 2.25mm/s, 6.3mm/s, 12mm/s or 25mm/s. Only EtCO2 level below or equal to 53 mmHg/7 kPa/7% limit will appear on the display. Values exceeding this limit will produce a graph similar to the following figure with a top cut off.

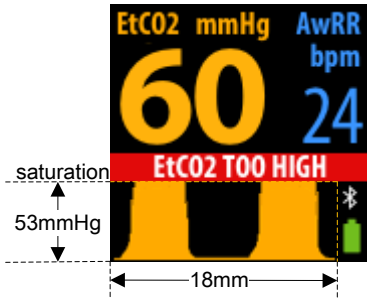


Figure 10. Capnogram Display

4.2.4 Battery Status Indicator

The Battery Status Indicator is normally lit with a steady green light in the bottom right corner of the display (Fig. 11a). When batteries are 10% to 30% remaining, the green light of the battery turns yellow (Fig. 11b). When batteries are 0% to 10% remaining, the yellow light of the battery turns red and a low priority alarm "LOW BATTERY" is triggered and displayed (Fig. 11c).

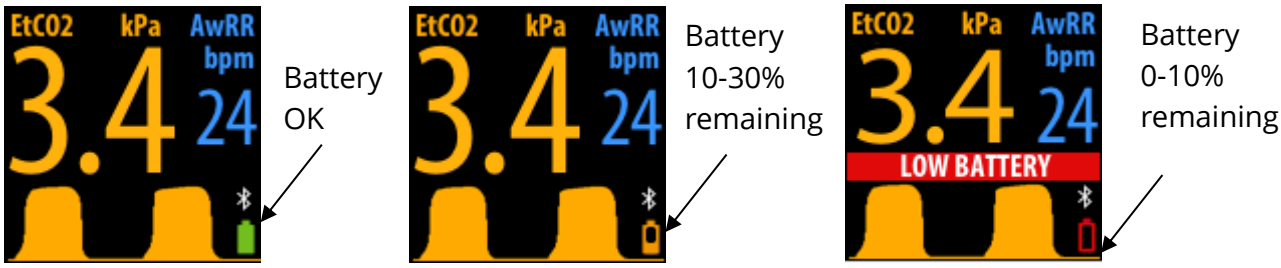


Figure 11a. 11b. 11c. Battery Status Indicator

4.3 Menu control

4.3.1 Settings menu

1.All important and frequently used settings are accessible through the Settings menu, which can be accessed by pressing and holding on the Alarm Silence button ( ) for 2 sec and the the Increase button ( ) for 2 sec.
Once in the Settings menu, the Alarm Silence button is used to validate an entry with a short press, or to exit the menu with a long press (2 sec).

Figure 12. RICap® Settings menu screen

2.Use the Up button (^) or Down button (v) to scroll through menu items. The currently selected menu item appears highlighted by a light grey background color. Press the Alarm Silence button to confirm your selection and press the Alarm Silence button again to return to the previous menu level.

3.Pressing and holding the Alarm Silence button ( ) for 2 sec or not pressing any button for over 10 sec will make RICap® return to normal monitor screen.

4.3.2 Submenu

Enter the Settings menu screen in accordance with 4.3.1.
If no button has been activated for 10 Sec, RICap® will automatically return to normal monitor screen regardless it is in Settings menu or submenu screens.

1.Adjusting the High $ETCO_2$ Alarm Limit
When the "EtCO2 High" menu item appears highlighted by a light grey background, press the Silence button to confirm your selection and enter the submenu.

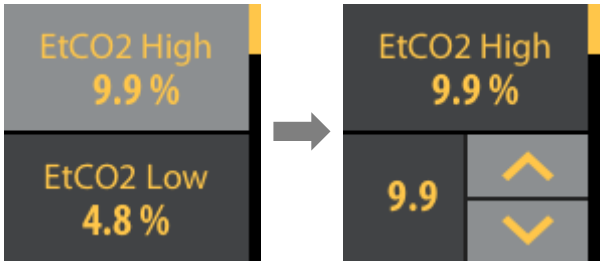


Figure 13a.

Press the Up button (^) to increase, or the Down button (v) to decrease the value. After you complete your selection, press the Alarm Silence button to confirm and return to the previous menu level or press and hold the Alarm Silence button for 2 Sec to return to normal monitor screen.
Note: Short presses on the Up/Down buttons will only increase/decrease by 1 step at a time the selection, while longer presses will speed up the selection with bigger steps between values.

It is possible to switch off the $ETCO_2$ High Alarm by adjusting the limit above 99 mmHg (9.9 kPa, 9.9%). In that particular case, the background colors will change to Red/Pink reminding the user of the Danger to disable this alarm (Fig. 13b). Backgrounds for that particular setting will remain with those colors until the Alarm is re-enable with a value equal or lower than 99 mmHg (9.9 kPa, 9.9%).

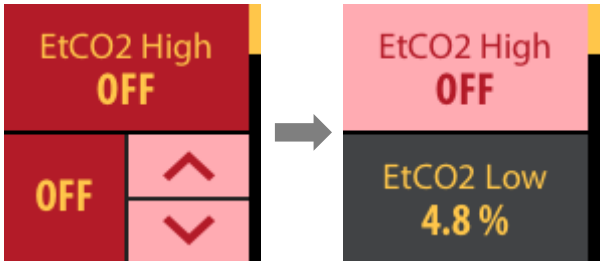


Figure 13b.

Note: Short presses on the Up/Down buttons will only increase/decrease by 1 step at a time the selection, while longer presses will speed up the selection with bigger steps between values.

2.Adjusting the Low $ETCO_2$ Alarm Limit

When the "EtCO2 Low" menu item appears highlighted by a light grey background, press the Silence button to confirm your selection and enter the submenu.

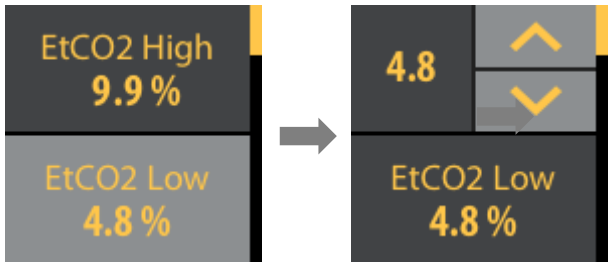


Figure 14a.

Press the Up button (^) to increase, or the Down button (v) to decrease the value. After you complete your selection, press the Alarm Silence button to confirm and return to the previous menu level or press and hold the Alarm Silence button for 2 Sec to return to normal monitor screen.

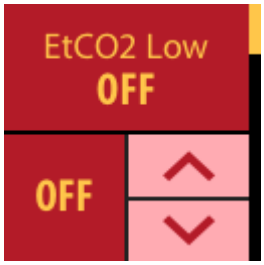


Figure 14b.

It is possible to switch off the $ETCO_2$ Low Alarm by adjusting the limit below 1 mmHg (0.1 kPa, 0.1%). In that particular case, the background colors will change to Red/Pink reminding the user of the Danger to disable this alarm (Fig. 14b). Backgrounds for that particular setting will remain with those colors until the Alarm is re-enable with a value equal or higher than 1 mmHg (0.1 kPa, 0.1%).

3.Adjusting the Respiratory Rate Upper Alarm Limit

When the "AwRR High" menu item appears highlighted by a light grey background, press the Silence button to confirm your selection and enter the submenu.

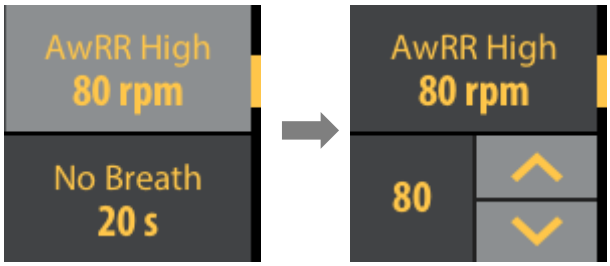


Figure 15a.

Press the Up button (^) to increase, or the Down button (v) to decrease the value. After you complete your selection, press the Alarm Silence button to confirm and return to the previous menu level or press and hold the Alarm Silence button for 2 Sec to return to normal monitor screen.

It is possible to switch off the AwRR High Alarm by adjusting the limit below 3 rpm or above 150 rpm. In that particular case, the background colors will change to Red/Pink reminding the user of the Danger to disable this alarm (Fig. 15b). Backgrounds for that particular setting will remain with those colors until the Alarm is re-enable with a values equal or within the range of 3 to 150 rpm.

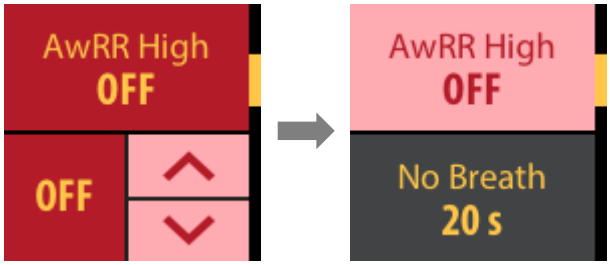


Figure 15b.

4.Adjusting the Apnea Alarm

When the "No Breath" menu item appears highlighted by a light grey background, press the Silence button to confirm your selection and enter the submenu.

Figure 16.

Press the Up button (^) to increase (up to 60sec maximum), or the Down button (v) to decrease the value (down to 20sec minimum). After you complete your selection, press the Alarm Silence button to confirm and return to the previous menu level or press and hold the Alarm Silence button for 2 Sec to return to normal monitor screen.

5.Adjusting the Sweep Speed

When the "Sweep Speed" menu item appears highlighted by a light grey background, press the Silence button to confirm your selection and enter the submenu.

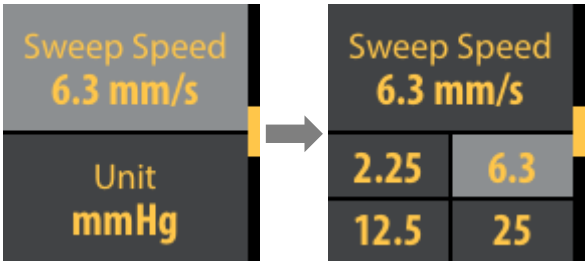


Figure 17.

Press the Up button (^) or the Down button (v) to select the desired value. After you complete your selection, press the Alarm Silence button to confirm and return to the previous menu level or press and hold the Alarm Silence button for 2 Sec to return to normal monitor screen.

6.Adjusting the Unit

When the "Unit" menu item appears highlighted by a light grey background, press the Silence button to confirm your selection and enter the submenu.

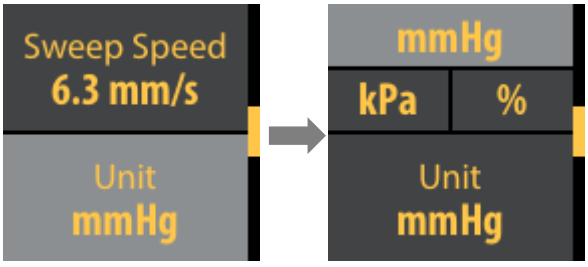


Figure 18.

Press the Up button (^) or the Down button (v) to select the desired unit. After you complete your selection, press the Alarm Silence button to confirm and return to the previous menu level or press and hold the Alarm Silence button for 2 Sec to return to normal monitor screen.

7.Adjusting the Alarm Volume

When a light background highlights the Alarm Volume menu item, press the Silence button to confirm your selection.

Figure 19a.

Press the Up button (^) to increase, or the Down button (v) to decrease the value. After you complete your selection, press the Alarm Silence button to confirm and return to the previous menu level or press and hold the Alarm Silence button for 2 Sec to return to normal monitor screen.

It is possible to switch off the Alarm Volume by set value at 0 (OFF). In that particular case, the background colors will change to Red/Pink reminding the user of the Danger to disable this alarm (Fig. 19b). Backgrounds for that particular setting will remain with those colors until the Alarm is re-enable with a value above 0.

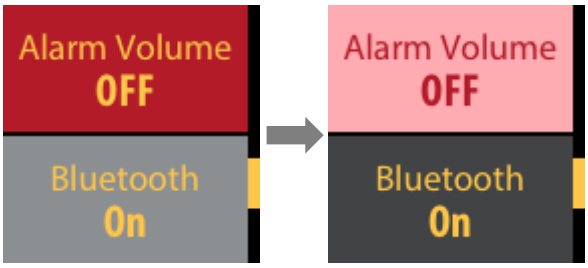


Figure 19b.

8.Turning On/Off the Bluetooth function

When a light background highlights the Bluetooth menu item, press the Alarm Silence button to confirm your selection.

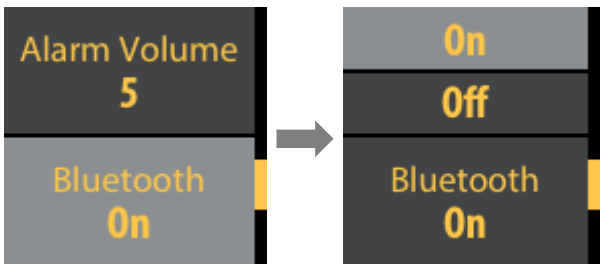


Figure 20.

Press the Up button (^) or Down button (v) to turn On or Off the Bluetooth function. After you complete your selection, press the Alarm Silence button to confirm and return to the previous menu level or press and hold the Alarm Silence button for 2 Sec to return to normal monitor screen.

9.Selecting the language

When a light background highlights the language menu item, press the Silence button to confirm your selection.

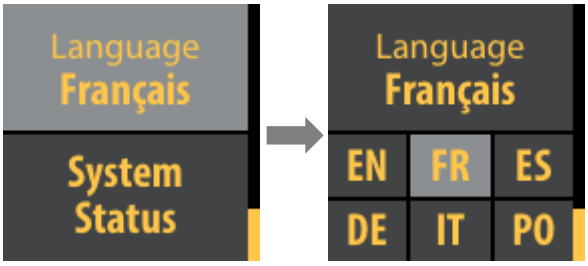


Figure 21.

Press the Up button (^) or Down button (v) to select the desired language.
EN = English, FR = French, ES = Spanish, DE = German, IT = Italian, PO = Polish

After you complete your selection, press the Alarm Silence button to confirm and return to the previous menu level or press and hold the Alarm Silence button for 2 Sec to return to normal monitor screen. All menus will appear now in the selected language.

10.Check System Status

When a light background highlights the System Status menu item, press the Silence button to confirm your selection.

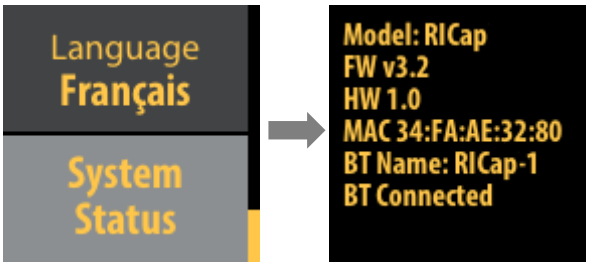


Figure 22.

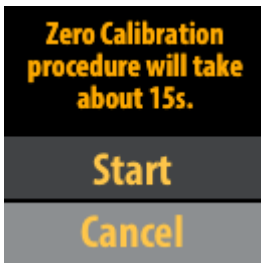
The System Status screen indicates device model number, firmware revision number (FW), hardware revision number (HW), the MAC address assigned for the Bluetooth function, the Bluetooth name as it will appear on search, and the Bluetooth connection status (Connected, Disconnected, Off, Waiting for Connection)

Press the Alarm Silence button return to the previous menu level or press and hold on the Alarm Silence button 2 Sec to return to normal monitor screen.

4.3.3 Zero Calibration

RICap® use air to complete Zero Calibration. The presence of ambient air in RICap® Airway Adapter is of crucial importance for a successful Zero Calibration. Check that RICap® Airway Adapter is inserted and kept away from a source of CO_2.

RICap® Zero Calibration is performed by the following procedure:
1. Press and hold down simultaneously the Increase button(^) and Decrease button(v) until the Zero Calibration screen shown below is displayed. By default, "Cancel" is highlighted.



2. Make sure that the RICap® Airway Adapter is properly inserted and kept away from a CO_2 source.

3.Press the Up button (^) once to highlight "Start".

4.When the "Start" menu item is highlighted by a light background, press the Silence button to initiate the Zero Calibration process. The following screen will then appear:

5.After about 15 Sec, the device will return to the standard monitoring screen.

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 replacing the RICap® airway adapter.

5 ALARM

5.1 Alarm Priority and Appearance

RICap has a high priority alarm.

Priority Level	Audio Signal Sequence	Condition	Maximum alarm status delay
High (Warning)	3 tone beeps + 1 second pause + 2 tone beeps and 5 seconds pause	For potentially life-threatening situations	＜2s

If more than one alarm with the same priority is generated, the alarm sound will still alarm according to the current highest priority sound, but there is still an alarm Indicate of this parameter in the display interface.

5.2 Audible Alarm Volume

The alarm volume is not adjustable; however, it is possible to silence the alarm for a period of two minutes using the button. It has an audibility of at least 55dB (A) at 1 meter away from the device.

5.3 Default Alarm Limits

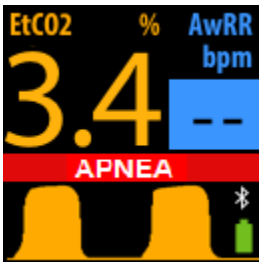
Limits	Units	Range	Default
$EtCO_2$ High	mmHg, kPa or %	From 11 to 99 mmHg From 1.1 to 9.9 kPa From 1.1 to 9.9 %	50mmHg 6.7 kPa 6.6 %
$EtCO_2$ Low	mmHg, kPa,or %	From 1 to 89 mmHg From 0.1 to 8.9 kPa From 0.1 to 8.9 %	1mmHg 0.1 kPa 0.1 %
AwRR High	bpm	From 3 to 150	30 bpm
Apnea	sec	From 20 to 60 sec	20 sec

Warning

- To avoid the failure of alarm system, do not set the maximum value of a parameter as the alarm limit.
- Please confirm whether the alarm limit is suitable for the patient before setup.
- Check all alarm settings and auditory alarm before use of the device.

5.4 Alarm Status Indicator

The table below shows the alarm limits, alarm conditions and priority of RICap®. Depending on the priority of the alarm, the respective measurement value will change color and an audible alarm will sound.

Alarm information	Indication	Condition	Priority	Verify and Solution
Apnea		No breath detected within defined time by "No Breath" setting	High	Please call the doctor
$EtCO_2$ High		$EtCO_2$ value above set alarm limit	High	Please Check the patient situation or change the alarm limit to avoid.
$EtCO_2$ Low		$EtCO_2$ value below set alarm limit	High	
AwRR High		Respiratory rate above set alarm limit	High	
Adapter Missing		Adapter missing	High	Please put on an new airway adpter and perform an zero calibration process

				
Clogged Adapter		Adapter window dirty	High	Please replace an new airway adpter and perform an zero calibration process

5.5 Alarm Silence

RICap® alarm is silent for 120 seconds after pressing the Alarm Silence button. The Alarm Silence status is indicated by a yellow silence alarm indicator in the alarm information display area as shown below:

If an alarm occurs during the silenced period, the alarm information area background will turn red as shown below:

6 MAINTENANCE AND SERVICE

6.1 Maintenance

RICap® monitor is permanently factory calibrated. The maintenance and calibration free technology integrated in RICap® ensures a robust measurement function throughout the lifetime of the device. No routine calibration is required. However, to meet any local or specific customer requirements, a basic maintenance plan is nevertheless highly recommended. More information regarding recommended maintenance tasks, see the Service Manual.

If service is necessary, contact qualified service personnel or your local sales representative.

6.2 Battery Replacement

The Battery Status indicator in the lower right corner of the RICap® displays "  " when the remaining lifetime of the batteries is approximately 30 min (High quality Alkaline batteries).

To replace the batteries:

1. Open the battery compartment.
2. Gently remove the depleted batteries.
3. Insert two new AAA type batteries into the battery compartment. Make sure that the batteries are inserted according to the polarity marking.
4. When the batteries are properly in place, gently snap the battery cover back into place.

6.3 Cleaning

Remove the batteries and use a cloth moistened with isopropyl alcohol to clean the RICap®.

6.4 Testing

RICap® is permanently factory calibrated and does not require any routine calibration. In order to make sure the measurement is within accuracy levels, it is recommended that the test should be conducted once a year. The test method is as follows.

1. Attach a new Airway Adapter to RICap®.
2. Turn on RICap® and ensure that the $ETCO_2$ value reading is zero. Otherwise conduct a Zeroing procedure according to chapter 4.3.3 above before proceeding.
3. Adjusting the $EtCO_2$ unit to percent (%) according to chapter 4.3.2.
4. Let Calibration gas (5% CO_2, 21% O_2, Balance N_2) flow into RICap® airway adapter.
5. After 30 seconds, record the ETCO2 reading.

If the $EtCO_2$ value is reading within the range 4.7% to 5.3% then your RICap® has been successfully verified.
If the $EtCO_2$ value is not reading within this range, perform a Zeroing procedure according to the instructions in chapter 4.3.3 above and then repeat the test. If verification still fails, contact your local distributor for further instructions.

6.5 Troubleshooting

6.5.1 CO_2 Measurement Limitations

The following factors may influence the measurement accuracy:
1.Leaks or internal venting of sampled gas
2.Mechanical shock
3.Cyclic pressure up to 10 kPa (100 cmH_2O)
4.Other sources of interference, if any
Measurement accuracy may be affected by the breath rate and inspiration/expiration (I/E) ratio as follow:
1.$EtCO_2$ value is within specification for breath rate ≤ 60 bpm and I/E ratio ≤ 1:1
2.$EtCO_2$ value is within specification for breath rate ≤ 30 bpm and I/E ratio ≤ 2:1
Measurement accuracy is unspecified for breath rate larger than 60 bpm.

6.5.2 Error Message

Error Message	Cause	Corrective Action
Low Battery	Low batteries	Replace batteries
Adapter Missing	Adapter Missing	Check the adapter
Clogged Adapter	Adapter window is dirty	Check the adapter and replace if required
Atmospheric pressure / Temperature out of range	Atmospheric pressure / environment temperature is outside of the device operating range.	Ensure that device is used in an environment with a Atmospheric pressure / Temperature within the operating range

6.5.3 Failure

Failure	Cause	Corrective Action
No response to the power button	Low batteries	Replace batteries
	Power button is not fully depressed.	Ensure that the power button is fully depressed
The measured values of ETCO2 are out of specified accuracy	Incorrect Zero reference	Perform a Zeroing procedure and verify the measurement with reference gas

7 TECHNICAL SPECIFICATIONS

7.1 General Specifications

Transducer Type	Mainstream CO_2 Monitoring
Measuring method	Dual-wavelength, non-dispersive infrared spectroscopy
Initialization Time	Capnogram, displayed in less than 30 seconds at an ambient temperature of 25°C, full specifications within 2 minutes.
Certifications	CE
Dimensions	60 x 47 x 43 mm (2.36 x 1.85 x 1.69 inches)
Weight	~80 g (complete device with batteries)
Mechanical robustness	Meets the shock and vibration requirements for transport of SS-EN ISO 21647:2004 clause 21.102.
Temperature and Humidity	Continuous operating: 0 to 40°C, 15 to 90% RH, non-condensing Transient operating: -20 to 50°C, 15 to 90% RH, non-condensing Storage*: -30 to 70°C, <90% RH, non-condensing
*If the device storage in minimum or maximum temperature and bring to 20℃ it always needs 2hours to let the device temperature balance with the environment then the device can work nor mally.	
Atmospheric pressure	Operating: 50 - 120 kPa Storage: 40-120kPa
Display	Active OLED color graphic display, 65 000 colors, 128 x 128 pixels
CO_2 Measurement Range	0 to 99 mmHg, 0 to 9.9%, 0 to 9.9 kPa
CO_2 Accuracy*	±(0.2% + 2% of reading)
Accuracy drift	Meet the accuracy requirement within 6 hours
Compensations	Automatic compensation for pressure and temperature
*Accuracy applies for respiration rate up to 60 rpm. For respiration rate above 60 rpm, the accuracy is 4 mmHg or ±12% of the reading, whichever is greater.	
Total system response time	＜1s
Rise time	＜90ms
Recovery time after defibrillator test	Unaffected
Respiratory rate Range	2~150 Breaths Per Minute (BPM)
Respiration Rate Accuracy	±1BPM
Data sample rate	20Hz
Calibration	No routine user calibration required. An airway adapter zero is required when changing to a new airway adapter.
Breath detect	Adaptive threshold, minimum 1 % CO_2 change.
Airway Adapters	< 5 cc dead space (adult/Pediatric)
Alarms	No Adapter, Clogged Adapter, No Breath Detected, High AwRR, Low $ETCO_2$, High $ETCO_2$, Temperature out of range, Atmospheric pressure is over operating range, Low Battery
Sound Intensity Level	≥ 55 dB(A)
Batteries	Two AAA Cell batteries (2x1.5VDC): 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	Duracell Plus Alkaline: ~4 hours Energizer Ultimate Lithium L92: ~7 hours	
Lifetime	5 years	
Effect of interference gases on CO2 measurements		
Gas	Concentration(%)	Quantitive effect*
O_2	≤100	±1mmHg
Nitrous oxide	≤60	
Halothane	≤4	
Sevoflurane	≤5	
Isoflurane	≤5	
Enflurane	≤5	
Desflurane	≤15	±2mmHg
*: means an extra error should be added in case of gas interference when CO2 measurements are performed between 0 to 40mmHg. Inaccuracy specifications are affected by the breath rate and I:E change. The end-tidal gas reading is within specification for breath rate below 15BPM and I:E ratio smaller than 1:1 relative to the gas readings without breath.		

7.2 Electromagnetic Compatibility (EMC)


Warning

- Don't near active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances is high.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation."
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Rapid Intervention Capnograph. including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

If any：a list of all cables and maximum lengths of cables (if applicable), transducers and other ACCESSORIES that are replaceable by the RESPONSIBLE ORGANIZATION and that are likely to affect compliance of the ME EQUIPMENT or ME SYSTEM with the requirements of Clause 7 (EMISSIONS) and Clause 8 (IMMUNITY). ACCESSORIES may be specified either generically (e.g. shielded cable, load impedance) or specifically (e.g. by MANUFACTURER and EQUIPMENT OR TYPE REFERENCE).

If any：the performance of the ME EQUIPMENT or ME SYSTEM that was determined to be ESSENTIAL PERFORMANCE and a description of what the OPERATOR can expect if the ESSENTIAL PERFORMANCE is lost or degraded due to EM DISTURBANCES (the defined term "ESSENTIAL PERFORMANCE" need not be used).

Technical description

1.all necessary instructions for maintaining BASIC SAFETY and ESSENTIAL PERFORMANCE with regards to electromagnetic disturbances for the excepted service life.

2. Guidance and manufacturer's declaration -electromagnetic emissions and Immunity.

Table 1

Guidance and manufacturer's declaration - electromagnetic emissions	
Emissions test	**Compliance**
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class B
Harmonic emissions IEC 61000-3-2	Not application
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not application

Table 2

Guidance and manufacturer's declaration - electromagnetic Immunity		
Immunity Test	**IEC 60601-1-2 Test level**	**Compliance level**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Electrical fast transient/burst IEC 61000-4-4	Power supply lines：±2 kV input/output lines：±1 kV	N/A
Surge IEC 61000-4-5	line(s) to line(s)：±1 kV. line(s) to earth：±2 kV. 100 kHz repetition frequency	N/A
Voltage dips, short interruptions and voltage variations on power supply input lines	0% 0.5 cycle At 0º, 45 º, 90 º, 135 º, 180 º, 225 º, 270 º and 315 º 0% 1 cycle	N/A

IEC 61000-4-11	And 70% 25/30 cycles Single phase: at 0 0% 300 cycle	
Power frequency magnetic field IEC 61000-4-8	30 A/m 50Hz/60Hz	30 A/m 50Hz/60Hz
Conduced RF IEC61000-4-6	150KHz to 80MHz: 3Vrms 6Vrms (in ISM and amateur radio bands) 80% Am at 1kHz	N/A
Radiated RF IEC61000-4-3	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz
NOTE U_T is the a.c. mians voltage prior to application of the test level.		

Table 3

Guidance and manufacturer's declaration - electromagnetic Immunity							
	Test Frequency (MHz)	**Band** (MHz)	**Service**	**Modulation**	**Modulation** (W)	**Distance** (m)	**IMMUNITY TEST LEVEL** (V/m)
Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment)	385	380 – 390	TETRA 400	Pulse modulation 18 Hz	1,8	0.3	27
	450	380 – 390	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	2	0.3	28
	710	704 – 787	LTE Band 13, 17	Pulse modulation 217 Hz	0,2	0.3	9
	745						
	780						
	810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0.3	28
	870						
	930						
	1720	1700 – 1990	GSM 1800, CDMA 1900,	Pulse modulation	2	0.3	28
	1845						

	1970		GSM 1900, DECT, LTE Band 1, 3, 4, 25, UMTS	217 Hz			
	2450	2400 – 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28
	5240	5100 – 5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0,2	0.3	9
	5240						
	5785						

7.3 Compliance

MDD 93/42/EEC
IEC 60601-1:2012
IEC 60601-1-2:2015
IEC 60601-1-8:2012
IEC 60601-1-12:2014
ISO 80601-2-55:2018

7.4 Classifications

General

- The device is not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.
- No sterile parts are included.
- Mode of operation: Continuous operation.

Built : IP33 (spray proof and tool proof EQUIPMENT).

Classification (according to MDD 93/42/EEC) : Class IIb.

Electrical safety : Class of protection II / Type BF – Type and degree of protection against electrical shock.

8 ACCESSORIES

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

Name	PN / Order Number	Contact Material	Description
Airway Adapter adult /Paediatric	M401B-A SGMC-DA	Acrylonitrile butadiene Styrene copolymers	disposable, requires no sterilization

Note:The choice of adapter type depends on the size of the tracheal tube and not on the patient's weight or height.

9 WARRANTY AND CONTACT

9.1 Warranty

RICap® device: 1 year warranty

9.2 Contact

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