GIMA

PROFESSIONAL MEDICAL PRODUCTS

CAPNO CUBE CAPNOGRAPH

User manual




IP33 CE 0482

REF CAPNO-T **(GIMA 33831)**

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This Manual is written and compiled in accordance with the IEC 60601-1 (Medical electrical equipment Part1: General requirements for safety) and the General Principles of GB/T9969-2008 User Manual for Industrial Products issued by the State Technological Supervision Bureau of China. It complies with both international and enterprise standards and is also approved by State Technological Supervision Bureau. The Manual is written for the current Capno-T Capnograph.

The Manual describes, in accordance with the Capnograph's features and requirements, main structure, functions, specifications, correct methods for transportation, installation, usage, operation, repair, maintenance and storage, etc. as well as the safety procedures to protect both the user and equipment. Refer to the respective chapters for details.

The Manual is published in English and we have the ultimate right to explain the Manual.

 Marks in the Manual:

Warning: must be followed to avoid endangering the operator and/or the patient.

Attention: must be followed to avoid causing damage to the monitor.

Note: some important information and tips about operations and application.

Caution:

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

Notice

Welcome to use the Capnograph

Please to read this manual carefully and then to operate by the instruction of this manual.

It is not allowed to open the monitor's cover without our permission. If any software revisions are made, it must be updated by the factory. And the software cannot be altered by the keyboard.

Some changes on the product due to the technologies' promotion or due to the special demands of user which do not influence the monitor's work will not be informed further. Furthermore please pay attention to the difference between the parts or components and this manual. You may apply to our company for technical documents about the electric circuit diagram relevant batch and lists of parts or components and so on because the continuous promotion of the product. You may contact us by means of the following address.

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Chapter 1 - Preface

1.1 Brief

The purpose of this manual is to provide the User with a brief understanding of the characteristics, functions and operation of the monitor thereby preventing incorrect operation and user error.

This device can monitor two physiological parameters for the patient at the same time: End tidal CO2 concentration (EtCO2), Respiration Rate (RR).

1.2 Warranty and Maintenance

Warranty 1 Year Warranty on Hardware and Battery

This Monitor has a warranty of 12 Months from the date of purchase.

All the Accessories have a warranty of 3 months or “out of box” for Disposable Items.

The following will invalidate the warranty:

• If the monitor is damaged due to misuse or incorrect operation (i.e. without following the User manual instruction).

• The monitor is damaged due to incorrect connection with another instrument.

• The monitor is accidentally damaged or dropped.

• If the user modifies or changes the monitor without written authority of the company.

• The serial number is deliberately damaged, torn off or unreadable.

Maintenance

If the monitor is non-functional outside of the warranty period, the manufacturer or distributor will offer an estimate for repair. The maintenance/repair/calibration place depends on actual conditions.

Re-packing for Repair or Calibration

It is recommended to use the original packing boxes and packing materials when returning for repair or maintenance.

1.3 Safety Requirements

For the purposes of safety, please read the following and abide by these instructions of medical instrumental products.

Warning: Indicating the possible injury on patient or operator.

General

• **Warning:** To ensure accurate performance and prevent device failure, do preventive maintenance inspection (including performance and safety check) each 6 or 12 months to verify that the monitor operate functionally in good condition as ensuring patient and medical personnel safety.

• **Warning:** Check the safety and performance of this monitor every time before using it to ensure it works normally and safely.

• **Warning:** This monitor should be used for only one patient at the same time.

• **Warning:** This capnograph is intended only as an adjunct in patient assessment, not a treatment device, nor an equipment used in home.

• **Warning:** If uncertain about the accuracy of any measurement, first check the patient's vital signs by any alternate means, and then make sure the monitor is functioning properly.

• **Warning**: To ensure patient safety, do not place the monitor in any position that may cause it to fall on the patient.

• **Warning**: DO NOT lift the monitor by the cables and hoses of the applied parts, as they could disconnect from the monitor, causing the monitor to fall on the patient.

• **Warning**: If the monitor falls off accidentally, please do not operate it until its safety and performance have been carefully tested and positive testing results obtained.

• **Warning**: DO NOT position the sensor cables or tubing in any manner that may cause entanglement or strangulation.

• **Warning**: To ensure accurate performance and prevent device failure, do not expose the monitor to extreme moisture, such as rain.

• **Warning**: The use of accessories, sensors power adapter and cable other than those specified with the equipment may result in increased emission and/or decreased immunity of the equipment or other systems.

• **Warning**: CO2, respiratory rate readings and signals can be affected by sensor application errors, certain ambient environmental conditions, and certain patient conditions.

• **Warning**: The monitor is a prescriptive device and is to be operated by qualified healthcare personnel only.

• **Warning**: Dispose of the device, accessories and its packing, the local law should be followed.

• **Warning:** This monitor provides End tidal CO2 (EtCO2) concentration, Respiration Rate. This data only provides assistance for diagnosis and actual diagnosis shall be made by suitably qualified clinical staff using all the clinical information and

symptoms.

• **Warning:** Biocompatibility tests have been performed on all the applied parts, some exceptional allergic patients may still have anaphylaxis. Do not apply to those who have anaphylaxis.

• **Warning:** do not modify this equipment without authorization from the manufacturer.

• **Warning:** The setting of alarm could be restored automatically within 30 seconds of loss of power.

• **Warning:** The machinery life of capnograph is 5 years. The capnograph shall be collected and recycled in accordance with local law after 5 years. Please contact with local agency or manufacture for any questions.

MRI scanning

• There are some electromagnetic or inductance circuit designed in the device, use during MRIenvironment could burns or adversely affect the MRI image or the device's accuracy. So the device is MR unsafe.

• **Warning**: Turn off the monitor and take away the sensors from the patient during MRI scanning. Use during MRI scanning may cause a burn to the patient and affect the quality of MRI image or the measurement accuracy of the monitor.

• **Warning**: MR-unsafe!

• Do not expose the device to a magnetic resonance (MR) environment.

• The device may present a risk of projectile injury due to the presence of ferromagneticmaterials t hat can be attracted by the MR magnet core.

• Thermal injury and burns may occur due to the metal components of the device that canheat du ring MR scanning.

• The device may generate artifacts in the MR im age.

• The device may not function properly due to the strong magnetic and radiofrequency

fields generated by the MR scanner.

Alarms

• **Warning**: Do not silence the audible alarm if patient safety may be compromised.

• **Warning**: Always respond immediately to a system alarm since the patient may not be monitored during certain alarm conditions.

• **Warning**: Before each use, verify that the alarm limits are appropriate for the patient being monitored.

• **Warning**: Check the audible alarm silence duration before temporarily silencing audible alarms.

Fire Hazard

• **Warning**: The monitor is not suitable for use in the presence of flammable anesthetic mixture with air, oxygen or nitrous oxide.

Electrical

• **Warning**: To protect against electric shock hazard, the monitor's cover is to be removed only by qualified service personnel. There are no user- serviceable parts inside.

• **Warning**: To ensure patient electrical isolation, connect only to other equipment with circuits that are electrically isolated.

• **Warning**: Refer service to qualified service personnel.

• **Warning**: Do not open the sensor cabinet at will, as electric shock hazard may occur.

• **Warning**: Measure the device's leakage current whenever an external device is connected to the serial port. Leakage current must not exceed 100 microamperes.

• **Warning**: Electrical installation of the room or the building in which the monitor is to be used must comply with regulations specified by the country in which the equipment is to be used.

Electro-Magnetic Interference

• **Warning**: Operating high frequency electrosurgical equipment in the vicinity of the monitor can produce interference in the monitor and cause incorrect measurements.

Indication for Use

The Capnograph is designed for monitoring the vital physiological signs of the patient. It is use for non-invasive continuous monitoring of EtCO2 and Respiration Rate.

The Capnograph is indicated for in patients from newborn (neonate) to adult in a hospital

environment. It is intended to be used only under regular supervision of clinical personnel

Contraindication

• The device should not be used as an apnea monitor.

• Do not use the monitor with nuclear spin tomography (MRT, NMR, NMT) as the function of the monitor may be disturbed.

Chapter 2 - Technical specifications and characteristics

EtCO2

Method:	Creative proprietary non-dispersive InfraRed Spectroscopy
Range:	0 – 150mmHg or 0 – 20kPa or 0 – 20% (v/v)
Accuracy:	±2mmHg for EtCO2 range 0 - 40mmHg ±5% for EtCO2 range from 41 - 70mmHg ±8% for EtCO2 range from 71 - 100mmHg Over 100mmHg ±10%

Note 1: The accuracy of CO2 concentration measurement is influenced by any interfering gas and/or vapour, for example N2O gas can raise the CO2 reading (2-10%), and Helium and O2 can reduce the CO2 reading (1-10%), so compensation should be set in the balance gas MENU to meet the accuracy requirements if such gases or vapours are present.

Note 2: The accuracy of CO2 concentration measurement is also influenced by Respiration rate. The corresponding relationship is as follows:

Table1 EtCO2/ Respiration Rate Accuracy

EtCO2 (mmHg)	Respiration Rate (bpm)	Accuracy
0 - 40	0-79	± 2 mmHg
	>80	±12%
41 - 70	0-79	±5%
	>80	±12%
71 - 100	0-79	±8%
	>80	±12%
>100	0-79	±10%
	>80	±12%

Test method:

As shown in table 1, test the accuracy of different concentrations of gas at different respiratory rates. Set up the gas flow rate of 1 L/min, the sampling rate is 100ml/min. And then record the data.

The device in real time measures CO2 in the breathing loop, when inhaling, CO2

in the gas loop is evacuated and its concentration measured is decreased and reaches zero, when exhaling, CO2 enters the breathing loop and its concentration rises rapidly and is kept at a certain platform, at the end tidal breathing it reaches maximum. In this repeated way, a real-time and high or low waveform is formed and by the virtue of this waveform, the device calculates the respiration status and also by me asuring respiration cycle, the device meantime calculates the respiration rate.

Update/Averaging Time: Option of every breath

Warm Up Time: <15 seconds

Total system response time: < 1s

Memory: 24 hours on Screen Trend and Numeric

Respiration Rate

Range: 3 - 150 rpm

Accuracy: ±1% of reading or ±1 rpm whichever is greater

Memory: 24 hours on Screen Trend and Numeric

Sensor: Adapter for intubated Patients

Alarm limit

The high alarm limits of EtCO2: 22-99mmHg

The low alarm limits of EtCO2: 10-60mmHg

The high alarm limits of respiration rate: 5-60 breaths/min

The low alarm limits of respiration rate: 4-40 breaths/min

Power

AC Input: 100V - 240V, 50Hz/60 Hz to 5VDC Adapter with 5V mini USB adapter Cable.

Battery

Type: Built-in rechargeable lithium battery pack (3.7V, 1200mAH)

Charging Time: 4 hours from flat

Operating Time: 6 hours on full charge

Operating Conditions

Temperature: 5 to 40 °C

Humidity: 30%~75%

Atmospheric pressure: 86-106 kPa

Storage Conditions

Temperature: -20 to +55oC

Relative Humidity:<93% (non-condensing) = < 29.45 hPa

Atmospheric pressure: 50 - 120 kPa

Dimensions of Monitor

Size: 38 x 42 x 44mm (W x H x D)

Weight: 80g (including lithium battery and adult airway adapter)

Warranty & Maintenance/ Calibration

One year warranty on Main Unit and Lithium Ion Rechargeable Battery

IP rating

IP33

93/42/EEC Medical Device Directive Compliant EC-Representative:

SUNGO Europe B.V. Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

CE 0482

Type of Protection

Class II

Degree of Protection: Type BF-Applied Part

Mode of Operation: Continuous

Chapter 3 - Introduction of Monitor

Figure 1

(1) Screen: Displays waves, menu, alarm and all measuring parameters.

(2) S button: Press this button to move the cursor when menu is activated.

(3) **+/↵** Multifunction button

a) When menu is activated, to press this button as confirmation button or increase (+) button.

b) In the main screen, if the bluetooth printer is equipped, to press this button for two seconds to drive the printer to print CO2 reaction curve and result data of all parameters.

(4) Multifunction button

a) When menu is activated, to press this button to decrease data selected.

b) In the main display screen, to press this button to silence alarm for two minutes.

c) In the main display screen, to press this button over 2 seconds, the display screen will change to big font display mode as the figure showing:

Figure 2

(5): Multifunction button

a) Power switch, to press this button for two seconds to turn on or turn off power.

b) To press this button and quickly be off the button to enter or quit the menu.

(6) Light indicator: Flickering green light indicates power adapter is connected and green light indicates the device begins to work.

(7) Battery compartment location

(8) DC5V Mini USB Charging interface. Note: this interface must only be connected to a device which meets safety standards.

(9) Hanging Point for Lanyard if required.

(10) Airway adapter

Note: The direction sensor is installed in the device so the screen display direction will be automatically adjusted according to the vertical direction of the device.

Chapter 4 - Patient connection

4.1 CO2 measurement

Usage of the monitor

The device is a solid mainstream CO2 sensor and user can use it immediately without calibration.

Theory introduction

The principle is based on the fact that CO2 molecules absorb infrared light energy of specific wavelengths, with the amount of energy absorbed being directly related to the CO2 concentration. When an IR light beam is passed through a gas sample containing CO2, the electronic signal from a infrared sensor (which measures the remaining light energy), can be obtained. This signal is then compared to the energy of the IR source, and calibrated to accurately reflect CO2 concentration in the sample. To calibrated, the infrared sensor's response to a known concentration of CO2 is stored in the monitor's memory.

In addition, the circuit module has the atmospheres absolute pressure sensors. Modules can measure atmospheric pressure, and atmospheric pressure can compensate the calculation for the concentrations of carbon dioxide which improve the design accuracy.

Then the monitor (CO2 module) determines CO2 concentration in the breathing gases by measuring the amount of light absorbed by these gases. EtCO2 is display as a numerical value in millimeters of mercury (mmHg), percent (%), or kilopascals (kPa). In addition, a CO2 waveform (capnogram) may be displayed which is a valuable clinical tool that can be used to assess patient airway integrity and proper endotracheal tube placement. Respiration rate is calculated by measuring the time interval between detected breaths.

Connection and Installation

1) Install the airway adapter on the monitor

2) Install the monitor in the patient's gas loop

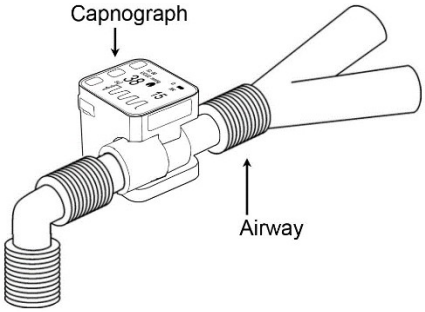

Figure 3

4.2 Respiration rate measurement

The calculation of respiration rate derives from monitoring the wave of CO2.

4.3 The sensor's zero

1). Zero

The vapour-prevent window of the airway adapter has a certain attenuation to infrared signal but due to individual diversity, its attenuation is different. So the sensor needs to be zeroed when changing new adapter. In addition, the sensor and in fared source have a certain of drifting, the sensor need to be zeroed after long usage, if the data is not correct, sensor also needs zero.

Attention: Zero needs to be careful, otherwise the false zero calibration will cause deviation of measurement data. 2). Zero method:

Connect the probe with host and warm up 5-10 minutes. Input the device into space without CO2 and attention, do not breathe near it. Then, enter CO2 setting submenu, move cursor to'ZERO', if this item is high-luminance colour, that means the sensor's data is stable and can make zero. Then press **+/↵** button, send zero order and 'ZEROING' will be shown and wait for 15-20 seconds till 'ZEROING' disappears.

4.4 Notice

Caution: Under the conditions of electromagnetic influence, for example: electrosurgical devices, MRI, CT etc. will cause negative impact.

Attention: indicating other important information.

The readings of CO2 may be wrong if the monitor does not warm up.

Use the airway adapter only provided by the manufacturer otherwise, measurement data might be not correct.

Measurement data might not be correct if under strenuous temperature changing surrounding. Therefore, if short temperature change comes beyond a certain range, 'TEMP IMBALANCE' will be shown on the screen, so should better use under stable temperature surrounding. When patient is used with anaesthesia gas, the measurement data will be a little bit influenced. If needs to calibrate on anaesthesia gas, please refer to Appendix 2. Warning:

The power adapter with naked electric point must not be applied- Dangerous for electric shock!

Chapter 5 - Screen display and Operation

5.1 Screen main display menu

Figure 4

1. The first line of data shows time (hour, minute)/patient ID, the memory area full indicator), silence ( ) or non silence ( ), bluetooth symbol ( ) and battery indicator

Attention:

a) When the memory full indicator is displayed, further patient data cannot be stored. If you want to save the new data effectively, you need to enter the NEW PATIENT menu to delete the data in the storage area, or to change patient ID., beside you can set up trend RENEW into AOTO mode, please see the details in 5.5 NEW PATIENT

b) The symbol ( ) appears if the bluetooth module is equipped. If this symbol is green, it indicates that no bluetooth equipment is connected (e.g, bluetooth printer), if this symbol becomes white, it indicates that some bluetooth equipment is connected (e.g, bluetooth printer).

2. The other part of the screen shows results data and waves: EtCO2 concentration, respiratory rate, exhaling or inhaling state (during exhaling, becomes blue colour),CO2 respiratory wave.

3. It also shows the status, e.g. when take out airway adapter, '**NO ADAPTER**' will be shown on the screen, when the probe needs zero calibration, 'ZERO REQ' will be shown on the screen to indicate that probe might need zero calibration.

Alarm setting:

The alarm settings of the system will not change after shutting down the power of capnograph.

Alarming level:

There are two types of alarming: physiological alarm and technical alarm. Physiological alarm refers to the alarm causing by physiological change of patient, patient's life may in danger. Technical alarm refers to system fault which cause capnograph working unproperly or providing unreliable readings. This capnograph adopt only medium priority alarm as there are three level of alarming. Level of alarm is preset by system, which cannot be changed by medical personnel.

Medium priority alarm means serious warning.

Warning: Medical personnel should set alarm limit based on clinical experience. DO NOT set value over maximum limit of alarm.

Warning: Same or similar device with different setting of alarm may cause potential danger in isolated area like ICU or operating room.

Please refer to the content of menu setting of CO2.

It is critical to set alarm of physiological parameter which gives alarm clinical significance.

Alarm delay:

The sum of maximum delay of alarming state and signal generation is less than 10 seconds.

Alarm indication:

1) If the EtCO2's value exceeds the limit of high or low alarm level, the word 'EtCO2' will flash and alert with the audible high priority alarm. This high priority alarm will also sound for respiration rate.

2) ▭ if the battery level is almost fully depleted the battery indicates completely empty, the monitor will alarm continuously and will shut down automatically.

3) When the no CO2 detected alarm is turned on and no CO2 detected occurs the monitor will give a audio/visual alarm. The screen will flash the message 'APNEA' (meaning no EtCO2 has been detected for a certain time period) and 'Beep' sound will also be heard.

4) Symbol of parameter will turn yellow and blink if any over ranging parameter triggers alarm.

Alarm sound:

Alarm sounds as following description. Time interval cannot be changed.

Level of alarm	Sound	Sound pressure
Medium priority alarm	Beep-Beep Beep", triggered each 8 seconds	45-70dB

Alarm light:

Alarm light looks like following description

Level of alarm	Light
Intermediat alarm	Parameter indicator turn yellow, blinking with frequency of 0.5Hz

Alarm silence:

In the main display screen (menu is not open), to press the button  to silence alarm for two minutes and meantime, trumpet icon becomes  , two minutes later, trumpet icon becomes  , meanwhile, alarm begins to work if there is sound alarm. If to press the button  in this period, the silence alarm can be released. Silence alarm time will not vary with operator. When silence alarm is on, physical alarm and technical alarm both will be silent.

Alarm counterplan:

WARNING: Always check status of patient as alarm is triggered.

Check the alarm information displayed on the screen, correctly identify the alarm, and reasonably handle the alarm according to the cause of the alarm.

- Check patient's status.
- Identify type or parameter of alarming.
- Find the reason.
- Turn off alarming if necessary.
- Check alarm after removing alarming condition.

5.2 The Main Menu

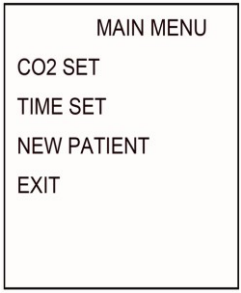

Figure 5

In the main display screen, to press the button ⏻/⮌ to enter the setup menu, see the picture above.

In this menu, to press button S to move the cursor to choose item.

In this menu, to press button **+/↵** to enter the next submenu, to press ⏻/⮌ again to go back to the main display screen.

This menu includes the following options:

The setting menu for CO2: **CO2_SETUP.**

The time menu: **TIME_SETUP**

The new patient menu: **NEW PATIENT.**

WARNING: All Menu Settings are LATCHING and remain when the Monitor is powered off. Ensure that all necessary settings are reviewed and are suitable for the patient BEFORE use.

5.3 CO2 SET Menu

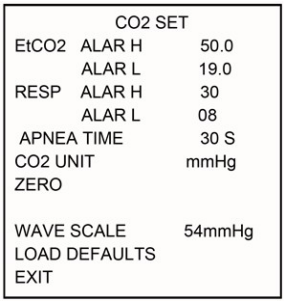

Figura 6

In this menu, to press button S to move the cursor to

choose item, to press button +/↵ or button −/🔕 to change data highlighted by the cursor.

Some items in this menu, if there are some actions not for changing data but just for direct operations such as

LOAD_DEFAULTS or EXIT, then to press button +/↵ to execute.

In this menu, to press ⏻/⮌ button, then to exit this menu return back to the main display screen.

This menu includes the following setups:

1). The high alarm limits of EtCO2: EtCO2 ALARM_H: 22- 99mmHg, off

2). The low alarm limits of EtCO2: EtCO2 ALARM_L: off, 10-60mmHg

3). The high alarm limits of respiration rate: RESP ALARM_H:5-60t/m, off

4). The low alarm limits of respiration rate: RESP ALARM_L: off, 4-40t/m

5). The setup of no CO2 detected time: APNEA TIME: 15s-44s, off

6). The unit of CO2: CO2 UNITÀ %, mmHg or kPA 7). Sensor zero Calibration

8). CO2 Wave scale: WAVE SCALE: 54mmHG or 76mmHG

9). Default reload: LOAD-DEFAULTS

10). Exit: EXIT

Attention:

a) When respiration wave comes and EtCO2 is not zero value, the zero instructive item 'ZERO' will be dark colour and zero calibration operation cannot be run;

Only when the sensor is in clean air without respiration wave and EtCO2 is zero value, can enter the sensor zero calibration item 'ZERO', press the +/↵ button then, the sensor can be zero calibrated, but must be sure without breathing near the sensor during zero calibration

b) The wave scale means the maximum value of waveform amplitude display but it does not mean data on full-scale. Data on full-scale still means 99mmHg.

Default values as follow:

EtCO2 alarm high limit: 50 mmHg

EtCO2 alarm low limit: 19 mmHg

RESP alarm high limit: 30 rpm

RESP alarm low limit: 08 rpm

APNEA time: 30S

CO2 unit: %

WAVE SCALE: 54mmHg

5.4 TIME SET Menu

Figure 7

In this menu to press button **S** to move the cursor to choose item, to press button **+/↵** or button **−/🔔** to change data highlighted by the cursor.

Attention: Any time adjustment will delete any stored trend data, so please take care before making this adjustment.

The procedure is as follows:

1) Change time.

2) Move the cursor to SAVE then press the **+/↵** button to enter the following menu FIGURE 8;

3) YES is already selected (highlighted in white) and if you wish to confirm this change press Enter if you do not wish to confirm the change move the cursor and highlight NO and press Enter.

4) Only by confirming can the time adjustments be made.

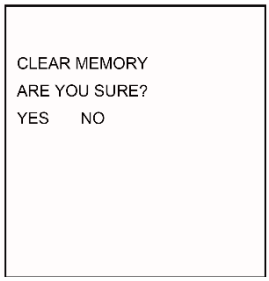

Figure 8

In the menu (Figure 7,8), to press ⏻/↩ button to exit this menu without saving or changing data.

5.5 NEW PATIENT Menu

Figure 9

In this menu to press button **S** to move the cursor to choose item, to press button **+/** ↵ or button −/☼ o change data highlighted by the cursor.

In this menu, press ⏻/↩ button, to exit this menu and enter the main display screen.

This menu includes the following setups:

1). CLEAR MEMORY: to delete all the historical data so as to store new data.

2). MEM: to change store mode between manual data deletion (STOP WHEN FULL) and automatic overwriting of the oldest data (AUTO LOOP).

3). ID: patient's ID, 00-99 optional.

4). SAVE: to store the changed data (this needs to be confirmed by the new menu due to possibly substitution to the original data of the same ID of patient).

5). EXIT: to quit the current menu but not to store the changed setup.

Chapter 6 - Charging, Maintenance, Cleaning

6.1 Charge

Connect the AC/DC power adapter via the Mini USB port turn on the unit. The unit will charge the battery with power at the same time as operating. The battery charge will end after battery is full.

The battery of this unit is a long life rechargeable lithium battery. When the unit is operated on battery only the battery indicator shows the battery's charge level on the screen. When the battery charge level is low, the indicator will flash red ▭, and the external 5VDC power must be connected as soon as possible.

After DC power is connected, the monitor will recharge the battery, and will stop charging after the battery has fully recharged. Operation time for a fully charged

unit is > 6 Hours. Charge time is approx. 4 Hours.

Battery replacement method:

Note that the operation must be done with the DC Charger disconnected ensuring that the operator's safety is not compromised.

Press down and slide off to remove the battery cover, then carefully disconnect and remove the battery. Reverse this procedure to replace the new battery and re-fit the battery cover.

NOTE: Any battery that is removed and no longer required must be properly disposed of by following national and local regulations.

6.2 Maintenance

If the monitor appears abnormal (e.g. system halted), to press the switch the monitor at least more than 5 seconds, then it can be turned off compulsively.

Adapter: If it is polluted or shown ADPTER ERR, it is needed to replace or zero calibration.

Attention: Check adapter before usage every time and check in fared window surface clean condition.

6.3 Cleaning

Warning: Before to clean the monitor, power shall be turned off and removed from any charging source.

1) Cleaning the Monitor

It is recommended that the Monitor is used in the supplied Carry Case which offers protection from both contamination, liquid ingress and damage.

Do not to disinfect the Monitor by high pressure, autoclave or washer.

Do not to dip or expose the Monitor to liquid.

Do not to use the Monitor if there is any sign of damage. Use only PH Neutral Cleaning products.

This product is not suitable for mechanical re-processing or disinfection.

Monitor Cleaning Instructions:

Only the Carry Case and if necessary the Monitor surfaces may be cleaned and/or disinfected. Use Moist (not dripping) wipes with 70% solution of isopropyl alcohol, or very dilute Chlor-clean (1000ppm) or Chlorohexidine (1000ppm) or mild detergent, then allow to air dry naturally.

2) Cleaning and disinfecting of the monitor's window and the airway adapter

a) The monitor's window:

Use cotton swab or cloth strip wetted by clean water to graze and remove blot and naturally air dried. Be sure it is dry before usage.

b) Cleaning and disinfecting of adapter:

Disinfection:

● For single use airway adapter (A3,A3N):

Reuse of the single use Adapter can cause cross infection.

● For reusable airway adapter (rA3)

Soak the adapter in disinfectant and dry it in a ventilated place for at least 30min after taking it out.

See the following table for specific disinfectant and soaking time requirements:

Disinfectant	Concentration	Soaking time
Chlorine disinfectant	500-1000ppm	30 min
glutaraldehyde	2.0%	20-90min
peracetic acid	0.2%	10min

Used and discarded adapters should be treated according to State regulation.

Be sure it is dry before its usage.

Chapter 7 - Trouble Shooting Analysis

Simple analysis of problems

No.	Phenomena	Causes	Solution
1	The values of CO2 is lower	1. Leakageofgas loop 2. Needzero 3.Theiwindowof adapterhas vapor (lowtemperature) 4. Long used parts drift.	1. Check and replacegasloopand adapter. 2. Sensorzeros. 3. Wait for the temperaturerising 4.Recalibrate by the standard gas.
2	CO2 concentration is zero: Show 'NO ADAPTER' or 'SENSOR ERR' or 'IR LAMPBAD' onthescreen	1. Without adapter 2. Sensor data wrong 3. Light source wrong.	1. Check adapter if plugged in 2. Check adapter if plugged into correct position or infrared window has blot. 3. Contact manufacturer
3	Screen indicating CAL- ERR	The last calibration is failed.	To recalibrate by the standard gas.
4	The CO2 wave isnotnormal. Screen indicating TEMP-HIGH Or TEMP- LOW Or TEMP-IMBALANCE	1. Temperature too high. 2. Temperature too low. 3.Temperature sharp change	To provide normal environmental temperature.

5	Flashing red colour ▭ and closed down automatically	1. Battery lack of power.	1. To connect AC/DC power adapter.
6	Still flashing red colour ▭ after the power is supplied and AC indicator no light.	AC/DC power adapter working abnormally.	1. To check the AC/DC adapter and cable.

Attention: Please to contact the client' service centre if some problems occurred repeatedly.

Appendix 1. Explanations of Terms in this Manual

MENU	Menu
EtCO2	The CO2 concentration of expiration end
RR	Respiration rate
mmHg	Millimeters Mercury
kPa	Kilopascal
ALAR H	Alarm high limit
ALAR	LAlarm low limit
No CO2	detected
No CO2	detected or breathing stopped for a set period of time

CAL	Offset Calibration
N2O	Nitrous oxide
HELIUM	Helium gas
O2 CONCENT	O2 concentration compensation
ANAESTHETIC	Anaesthetic gas
ZERO GAS	Base point or Zero point
BTPS	Temperature and deep lung air pressure compensation
CALIBRATE	Calibration
CANCEL:	Cancellation

Appendix 2. ENGINEER MENU:

Changing compensation of balance gas

Attention: Only the trained personnel may carry out the following the procedure. Contact your Supplier for training and advice. Enter the engineer menu as follows:

When the device is powered on, entering version display window, simultaneously to press both button S and button −/🔔 to enter the following menu

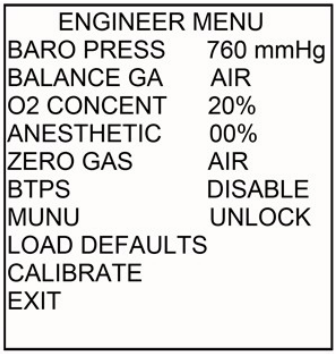

Figure 10

In this menu to press button **S** to move the cursor to choose item, to press button **+/** ↵ or button **–**/🔔 to change data highlighted by the cursor.

In this menu, press ⏻/↩ button, to exit this menu and enter the main display screen.

Some items of this menu can be directly adjusted, such as LOAD-DEFAULT or EXIT: to press button **+/** ↵ to execute.

This menu including the following setups

BARO PRESS: 760mmHg

BALANCE GAS: AIR, N2O, and HELIUM

O2 CONCENTRATION: 20%-99%

ANAESTHETIC GAS: 0-20%

ZERO GAS: AIR, N2

BTPS: ENABLE, DISABLE

MENU: UNLOCK, LOCK

LOAD DEFAULTS

CALIBRATE

Default values as follows:

BARO PRESS: 760mmHg BALANCE GAS: AIR

O2 CONCENTRATION: 20 % ANAESTHETIC GAS: 0 % ZERO GAS: AIR

BTPS: DISABLE

MENU: UNLOCK

Appendix 3. Guidance and manufacturer's declaration- Electromagnetic compatibility

Table 1 - Guidance and manufacturer's declaration- electromagnetic emission-for all EQUIPMENTAND SYSTEMS

<table>
<tr><td colspan="3">This device is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment or system should assure that it is used in such an environment.</td></tr>
<tr><td>Emissions test</td><td>Compliance</td><td>Electromagnetic environment-guidance</td></tr>
<tr><td>RF emissions CISPR 11</td><td>Group 1</td><td rowspan="3">This device 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.</td></tr>
<tr><td>RF emissions CISPR 11</td><td>Class B</td></tr>
<tr><td>Harmonic emissions IEC61000-3-2</td><td>Class A</td></tr>
<tr><td colspan="3">This device is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td></tr>
</table>

Table 2 - Guidance and manufacturer's declaration- electromagnetic immunity for all EQUIPMENTAND SYSTEMS

This device is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment or system should assure that it is used in such an environment.			
Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment-guidance
Electrostatic discharge (ESD) IEC61000- 4-2	±8 kV contact ±15kV air	±8 kV contact ±15kV air	Floors should be wood, concrete or ceramic tile. if floors are covered with synthetic material, the relative humidity should be at least 30%. If ESD interfere with the operation of equipment, counter measurements such as wrist strap, grounding shall be considered.
Electrical fast transient/bur st IEC61000- 4-4	±2kV for power Supply lines ±1 kV for input/ output lines	±2kV for power Supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Sovratensione IEC 61000-4-5	±1kV line (s) to line(s) ±2kV line(s) to earth	±1kV differential mode ±2kV common mode	Mains power quality should be that of a typical commercial or hospital environment.

Voltage dips, short interruptions and voltage variations on power supply input lines IEC61000- 4-11	0% UT (100% dip in UT) for 0,5 cycle 0% UT (100% dip in UT) for 1 cycles 70% UT (30% dip in UT) for 25/30cycles 0% UT (100% dip in UT) for 250/300 cycles	0% UT (100% dip in UT) for 0,5 cycle 0% UT (100 % dip in UT) for 1 cycles 70% UT (30% dip in UT) for 25/30cycles 0% UT (100% dip in UT) for 250/300 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the equipment or system requires continued operation during power mains interruptions, it is recommended that the equipment or system be powered from an uninterruptible power supply or a battery
Power frequency (50Hz/60Hz) magnetic field IEC61000- 4-8	30A/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.			

Table 3 Guidance and manufacturer's declaration

Electromagnetic immunity-for EQUIPMENT and SYSTEM that are not LIFE-SUPPORTING

Guidance and manufacturer's declaration – electromagnetic immunity This device is intended for use in the electromagnetic environment specified below. The customer or the user of this device should assure that it is used in such an electromagnetic environment.

IMMUNITY test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
RF condotta RF IEC 61000-4-6 RF irradiata IEC 61000-4-3	3 Vrms da 150 kHz a 80MHz (6V in ISM e bande radio amatoriali tra 0,15MHz e 80 MHz) 10 V/m da 80 MHz a 2,7 GHz	3 Vrms da 150 kHz a 80MHz (6V in ISM e bande radio amatoriali tra 0,15MHz e 80 MHz) 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of this device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance = 1,2√P = 1,2√P 80MHz a 800MHZ = 2.3√P 800 2,7 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 metres (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 Interference may occur in the vicinity of equipment marked with the following symbol. 

Table 4 Recommended separation distances

Recommended separation distances between portable and mobile RF communications equipment and the equipment or system for EQUIPMENT and SYSTEM that are not LIFE- SUPPORTING

Recommended separation distances between Portable and mobile RF communications equipment and the device			
This device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the equipment or system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the equipment or system as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter (W)	Distanza di separazione in base alla frequenza del trasmettitore (m)		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2,7 GHz
	= 1,2√P	= 1,2√P	= 2,3√P
0,01	1,2	0,12	0,23
0,1	3,8	0,38	0,73
1	12	1,2	2,3
10	38	3,8	7,3
100	120	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be determined 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.

Symbol

	Date of manufacture		Medical Device complies with Directive 93/42/EEC
SN	Serial number		Expiration date
	Manufacturer	REF	Product code
	Type BF applied part	LOT	Lot number
	Caution: read instructions (warnings) carefully		Don't use if package is damaged
IP33	Covering Protection rate		Humidity limit
	Follow instructions for use		Atmospheric pressure limit
EC REP	Authorized representative in the European community		Temperature limit
	WEEE disposal		

Accessories list

Accessory	Quantity
Adult/Pediatric Airway Adapter (Optional)	1
Neonatal/Pediatric Airway Adapter (Optional)	1
USB Cable	1
AC/DC Adapter	1

Disposal: The product must not be disposed of along with other domestic waste. The users must dispose of this equipment by bringing it to a specific recycling point for electric and electronic equipment

GIMA WARRANTY TERMS

The Gima 12-month standard B2B warranty applies