PROFESSIONAL MEDICAL PRODUCTS

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PC-900B CAPNOGRAPH AND OXIMETER

User Manual

REF PC900B (Gima 33698)

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CE 0123

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Notice

Thanks for buying PC -900B Capnograph and Oximeter.

Please read this manual carefully and then follow its instructions when operating this monitor.

It is not permitted to open the monitor's main cover, modify or disassemble it without our permission or official service training.

The buyer will not be advised of technology updates which do not influence the monitor's key functionality. Furthermore, please pay attention to the difference between the parts or components provided as information in this manual.

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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 monitor can measure four physical parameters at the same time: concentration of $EtCO_2$/$FiCO_2$, respiration rate, heart pulse rate and saturation of SpO_2 (optional). The monitor you bought may have two or more functions mentioned above but this manual can be used in common for the applicable functions.

1.2 Warranty and Maintenance

Warranty

This monitor has a warranty of 12 months from the date of purchase. Reusable SpO_2 sensors and the battery included have a 12 month warranty. All other accessories have a warranty of 3 months or an "out of box" warranty 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 accidently damaged or dropped
- if the user modifies or changes the monitor without written authority of the company
- if 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 or calibration would be carried out at local distributor, unless detailed in a specific written agreement.

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 for medical instrumental products.

Contraindications

Do not use the device in an MR environment.

Do not use the device during defibrillation.

Do not use the device in an explosive atmosphere or in the presence of flammable anaesthetics or gases.

Warning: Indicating the possible injury on patient or operator.

- Before use, Check the monitor for any mechanical damage; Inspect the exposed parts and the inserted parts of all the leads, and the accessories; Examine all the functions of the monitor that are likely to be used for patient monitoring, and ensure that it is in good working condition.
- This monitor is not MRI compatible and is not suitable for use within the magnetic field during the operation of MRI or CT. However, the sample lines supplied alongside the unit by the distributor are MRI compatible and may be extended into the MR or CT field. In this case, the monitor must remain outside of the room.
- The monitor is not intended to be used as a primary diagnostic apnea monitor.
- The use of accessories and cable other than those specified, with the exception of cables sold by the manufacturer of the device as replacement parts for internal component, may result in increased emissions or decreased accuracy of the device.
- Only use manufacturer designated accessories to ensure compliance with appropriate standards.
- It is not allowed to remove the cover of the monitor.
- This monitor provides End tidal CO_2 ($EtCO_2$) concentration, inhalation carbon dioxide ($FiCO_2$), respiration rate, oxygen saturation and pulse 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.
- In order to prevent pressure sores and correct circulation the SpO_2 sensor must be repositioned regularly, depending on the type of sensor used.
- When selecting a sensor application site use an extremity without a catheter,

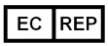
blood pressure cuff or intravascular infusion line.

- Do not use a damaged Sensor.
- The monitor should only be operated by trained licenced practitioners.
- The machinery life of Capnograph and Oximeter is 8 years. The Capnograph and Oximeter shall be collected and recycled in accordance with local law after 8 years. Please contact with local agency or manufacture for any questions.
- The SpO2 waveform has been normalized.
- Dispose of the device, accessories and its packing, the local law should be followed.
- Do not maintain the monitor and its accessories when patients use it.
- The use of the monitor is restricted to one PATIENT at a time.
- When using a defibrillator on a patient, ensure that the monitor is reliably grounded.
- When used with HIGH - FREQUENCY (HF) SURGICAL EQUIPMENT, the monitor measurement probe should be kept away from the surgical area. In particular, avoid the surgical current channel (from the tip to the pole plate) to prevent interference.
- When the network power is accidentally disconnected exceeding 30 s, the device is enabled to work on battery, at this time, the alarm function and working status should be checked. Check whether the alarm function and working status are normal, and connect the device to the network power as soon as possible.
- Alarm volume and alarm limits should be set for the actual patient situation. You cannot rely solely on the audible alarm system to monitor the patient. The alarm sound adjusted to a lower volume may lead to a dangerous patient. The actual clinical condition of the patient should be closely related.
- Please do not place the monitor in an area where it is difficult to operate the Isolation. The power adapter has an appliance coupler and the network power plug can be used as the Isolation from the SUPPLY MAINS measure.
- To ensure patient safety, do not place the monitor in any position that may cause it to fall on the patient.
- 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.
- DO NOT position the sensor cables or tubing in any manner that may cause entanglement or strangulation.
- 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.

- Do not modify the monitor without authorization of the manufacturer.

1.4 Symbols on the Monitor

Symbols	Meaning	Symbols	Meaning
	Date of manufacture		Manufacturer
	Serial number		Caution
	Type BF applied part		Refer to manual
	Authorised representative in the European Community		Indicates separate collection for electrical and electronic equipment (WEEE).
	Use-by date		Indicates that the product is a medical device.
	General warning sign	IP32	Degree of protection provided by enclosures

2 Technical specifications and characteristics

Intended Use

The Capnograph and Oximeter is designed for monitoring the vital physiological signs of the patient. It is used for non-invasive continuous monitoring of oxygen saturation (SpO2), pulse rate, CO2 and respiration rate.

The Capnograph and Oximeter is intended for use in adults, pediatrics and infants in a hospital environment. It is intended to be used only under regular supervision of clinical personnel.

$EtCO_2$/$FiCO_2$

Sampling Mode: Sidestream

Method: Non-dispersive Infrared Spectroscopy

Range: 0 – 150mmHg or 0 – 20kPa or 0 – 20% (v/v)

Accuracy: ±2mmHg for $EtCO_2$ range 0 - 40mmHg

±5% for $EtCO_2$ range from 41 - 70mmHg

±8% for $EtCO_2$ range from 71 - 100mmHg

±10% Over 100mmHg

Update/Averaging Time: Option of every breath or 10, 20 or 30 seconds

Warm Up Time: <15 seconds

Sample Flow Rate: 50–250ml/min User Adjustable. Default=100ml/min

<±20% for sample flow rate ranges from 50–250ml/min

TOTAL SYSTEM RESPONSE TIME and rise time: The total response time is less than 3s, and the rise time of 10%-90% is less than 200ms

Patient Modes: Adult and pediatric

Memory: 24 hours on Screen Trend and Numeric

Sensor: <25g Single Use Gas Sample Line and Adaptor for Intubated and /or Non Intubated Patients

Respiration Rate

Range: 3 - 150 breaths/minute

Accuracy: ±1% of reading or ±1 breaths/min whichever is greater

Memory: 24 hours on Screen Trend and Numeric

SpO_2 (optional)

Transducer: Dual-wavelength LED
Range: 0 - 100%
Accuracy: ±2% for SpO_2 range from 70 - 100%,
70% of the following does not require
Memory: 24 hours on Screen Trend and Numeric
Patient Modes: Adult and Pediatric
Data Update Time: 1s
The functional tester cannot be used to assess the accuracy of the SpO2 probe or the device.

Pulse Rate (optional)

Range: 30 – 250bpm
Accuracy: 30 Beats/min~40 Beats/min, error±2 Beats/min;
41 Beats/min~250 Beats/min, error±2 Beats/min (Absolute value)
or maximum of ± 2% (Relative value)

Memory: 24 hours on Screen Trend and Numeric

Power

AC Input: 100V - 240V, 50Hz/60 Hz to 5VDC Adapter with
5V type-C USB adapter Cable.
Optional Vehicle 12V to 5V Mini USB Charger Lead.

Battery

Type: Built-in rechargeable lithium battery pack,(3.7V, 3500mAH)
Charging Time: 4 hours from flat
Operating Time: 10 hours on full charge

Operating Conditions

Temperature: +5 to +50°C
Humidity: < 93% % (non-condensing) = < 29.45 hPa
Atmospheric pressure: 70 - 120 kPa

Storage Conditions

Temperature: -30to +70°C
Relative Humidity: <93% (non-condensing)

Atmospheric pressure: 50 - 120 kPa

Dimensions of Monitor

Size: 70 x 160 x 40mm (W x H x D)

Weight: Monitor 380g, Weight on Airway ETT/LMA <25g.

Warranty & Maintenance/ Calibration

One year warranty on main unit and lithium ion rechargeable battery

Auto self-zeroing calibration, annual calibration check recommended

IP rating

IP32 when used in specified carry case.

CE & Product classification

As per IEC 60601- 1 / CSA601.1 / UL2601-1

Type of Protection

Class II (When used with UK/EU Power Supplies)

Degree of Protection: Type BF-Applied Part

Mode of Operation: Continuous

Electro-Magnetic Compatibility: Group I, Class A

93/42/EEC Medical Device Directive Compliant

EC-Representative:

Shanghai International Holding Corp. Gmbh (Europe)

Eiffestraße 80, 20537 Hamburg Germany

CE 0123

Note1:

1) $EtCO_2$ calculated by atmospheric pressure compensation is the maximum of each exhaled carbon dioxide. In order to reduce display fluctuation, the device can also be set to the average of multiple $EtCO_2$ measured in every 10 seconds, every 20 seconds or every 30 seconds.

2) The CO_2 concentration measured by the device is the measurement result under the circumstances of

ambient temperature and humidity at that time. If the heat and humidity exchanger is added to the pipeline to filter part of moisture, the relative difference between the CO_2 concentration measured by the device and the dry CO_2 concentration is less than 1%.

If converted to CO_2 concentration in human alveoli (temperature 37℃, tidal pressure 47mmHg, BTPS), a compensation calculation is required. BTPS CO_2 concentration is about 94% of the measured value.

3) The accuracy of CO_2 concentration measurement is also influenced by Respiration rate. The corresponding relationship is as follows：

Table1 $EtCO_2$/ Respiration Rate Accuracy

EtCO2（mmHg）	Respiration Rate（bpm）	Accuracy
0 - 40	0-79	±2mmHg
	>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 ensures CO_2 in the breathing loop, when inhaling, CO_2 in the gas loop is evacuated and its concentration measured is decreased and reaches zero, when exhaling, CO_2 enters the breathing loop and its concentration rises rapidly and is kept at a certain platform, at the end of expiration (end tidal) 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 measuring respiration cycle, the device meantime calculates the respiration rate.

4）The accuracy of EtCO2 reading measurements can also be affected by expiratory time, and EtCO2 data can drop when the expiration time is too short. For example, at a respiratory rate of 10 breaths/min, EtCO2 values may drop by 12% when the inspiration-to-expiration ratio (I:E) is greater than 5:1.

Note2:

The accuracy of CO_2 concentration measurement is influenced by any interfering gas and/or vapour, for example N_2O gas can raise the CO_2 reading (2-10%), and Helium and O_2 can reduce the CO_2 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.

Table2: Interfering gas and vapour effects

Interfering Gas or vapour	Interference to $EtCO_2$
60% N_2O	+5% of reading Need to send N_2O concentration to the device to correct the data by compensation
4% Halothane	Negligible interference
5% Enflurane	Negligible interference
5% Isoflurane	Negligible interference
5% Sevoflurane	Negligible interference
15% Desflurane	+4% of reading Need to send Agent concentration to the device to correct the data by compensation
80% Xenon	-8% of reading
50% Helium	-6% of reading
0.1% Ethanol	Negligible interference
0.1% Isopropanol	Negligible interference
0.1% Acetone	Negligible interference
1.0% Methane	Negligible interference
100% O_2	-8% of reading Need to send O_2 concentration to the device to correct the data by compensation

Note3:

The accuracy of CO_2 concentration measurement is not influenced by cyclical pressure of up to 10 kPa (100 cmH_2O)

Note4:

Explanation of the data update cycle of SpO_2 and PR

The data update time of SpO_2 and PR is ≤10s, the calculation update time of SpO_2 and PR values is 8s, and the display update time is 1s. The measurement of SpO_2 and PR is to judge and calculate the most recently collected multiple sets of data every 1s, and then average the newly calculated value queue to obtain the value to be displayed. The SpO_2 and PR values on the monitor will be updated and displayed at intervals of 1s according to the latest calculated data. The photoplethysmography waveform displayed is normalized and cannot be used as an indicator of signal incompleteness. When the signal is incomplete (such as excessive signal noise, poor or missing signal quality), the SpO_2 and PR display values will become invalid values, that is, the numerical value disappears, and the display screen displays "--".

Note5:

Arms is defined as root-mean-square value of deviation according to ISO 80601-2-61.

The table 3 with measured SpO_2 accuracy specification in the discrete SpO_2 ranges:

Table 3

SpO2 range	Arms
70%~80%	1.37
80%~90%	1.33
90%~100%	1.48
70%~100%	1.38

The graphical plot of all sampled data points, as shows in Figure 2.1:

The above data (table 3 and Figure 2.1) is obtained from clinical validation study of the PC-900A (K093016) through a controlled, induced hypoxia study conducted with healthy adult volunteers. The monitor uses the same SpO_2 measurement technology provided in the PC-900A (K093016).

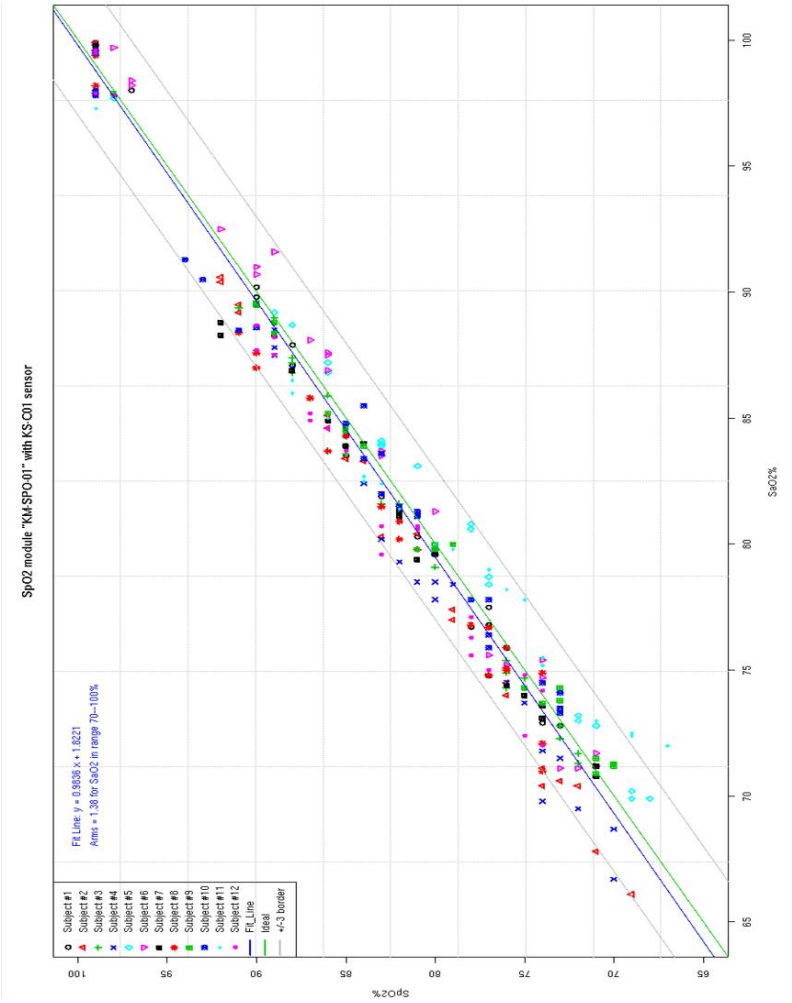


Figure 2.1

Note6:

Reference method for pulse rate accuracy:

Connect the monitor and the pulse oximeter simulator, set the SpO_2 value of the simulator to 96%, and then set the pulse rate of the simulator to 30bpm, 60bpm, 120bpm, 200bpm, and 250bpm respectively. Observe the pulse rate value displayed by the monitor. The range and accuracy should meet the described above.

3 Introduction of Monitor

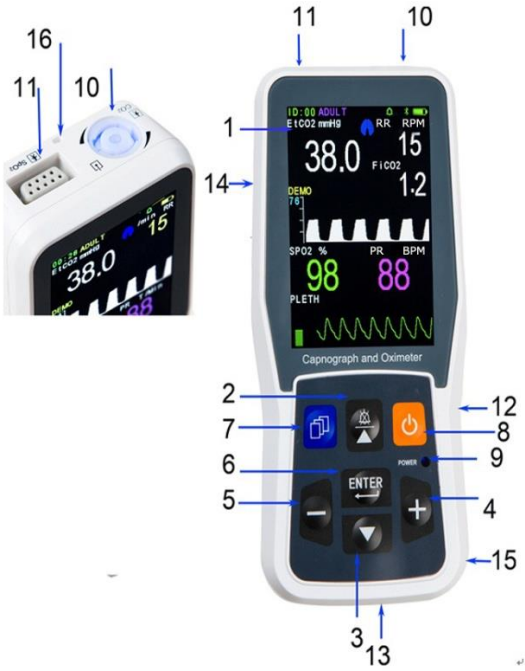


Figure 3.1

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

(2) / ▲: Function button:

▲ a) When menu (except the TREND menu) is activated, press this button to move the cursor.

b) When the TREND menu is activated, this button changes between the trend graph and data table

On the main display, to press this button to silence alarms for 2 minutes.

(3) ▼: Press this button to move the cursor when menu is activated.

(4) **+**: Multifunction button.

a) Press this button to increase figures on the menu.

b) In the main display screen, press this button to freeze the display waveform (if frozen, the data which prints will be that shown on the screen).

(5) **-**: Press this button to decrease figures.

(6) **ENTER**: Confirmation button;

a) Press this button to "Confirm" on the menu.

b) In the main menu, press this button restart the pump if it has automatically switched OFF.

(7) Press this button to enter or quit menu or change display.

(8) Power button: hold for >2 seconds to activate.

(9) Indicator **POWER**: Green LED is lit when the monitor is power on; Blue LED is lit when the internal battery is being charged.

(10) **CO2:** The faucet of filter, blue color indicator flashes if the filter is off. When the filter is plugged in, the indicator color will change to blue, and it will change to be orange during occlusion or pump err.

(11) **SpO_2:** The socket of SpO_2 (optional).

(12) DC5V Type-C USB Charging interface. Note: this interface must only be connected to a device which meets safety standards.

(13) Exhaust outlet: Do not occlude.

(14) Speaker location.

(15) Battery Compartment with clip on Battery Door.

(16) Hanging Point for Lanyard if required.

4 Patient connection

4.1 CO_2 and Respiration rate measurement

Push in and twist 45° clockwise to connect the Filter to the Connector on the top of the Monitor. Attach the selected Gas Sampling Line to the CO_2 filter Female Luer Connector (Use a Male to Male Luer adapter if necessary) and then select a sampling point as close as possible to either the patient or the Ventilator Breathing Circuit.

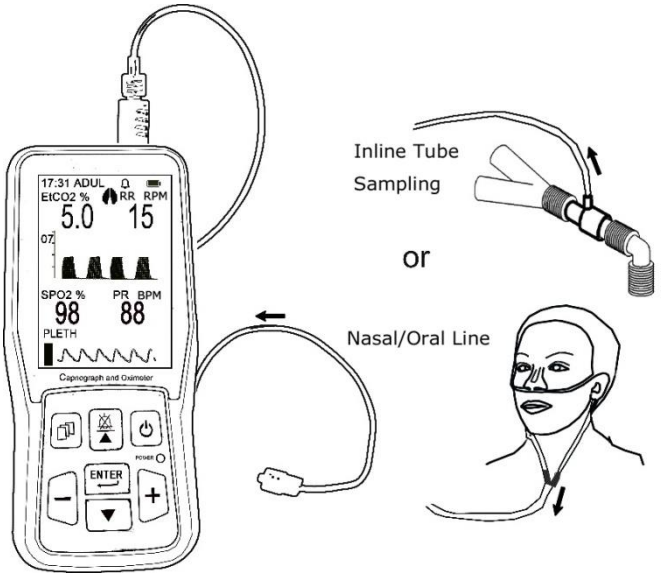


Figure 4.1

⚠WARNING ⚠:

Do not use the Monitor if the filter is not installed to avoid contamination and damage to the IR measurement cell.

In order to avoid vapor and respiratory mucus entering into the IR Cell, the machine must be used with the Filter .

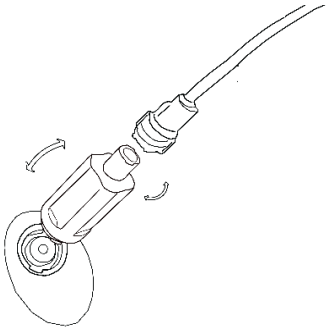


Figure 4.2

Instruction for use of the Filter

1.) Insert the convex cleat of Filter into the notch of the inlet port of device and turn 45°clockwise.
2.) Attach male luer lock sample line connector to Filter (Use a Male to Male Luer adapter if the sample line has Female Luer connector)
3.) Connect the other end of the Sample line to the chosen sampling point of patient or Ventilator Circuit.
4.) Change the Filter as needed. If the Filter becomes dirty or the occlusion alarm is activated when it is dry then the Filer must be replaced.
5.) The maximum specified intervals between any necessary OPERATOR interventions to the filter, based on a sample gas temperature of 37°C, a room temperature of 23°C and sample relative humidity of 100 %, are as follows:
24h @50ml/min;
15h @ 100ml/min;
10h @ 250ml/min.

⚠WARNING ⚠:

Ensure that connections are air tight as if there is leakage, measured values are likely to be inaccurate.

⚠WARNING ⚠:

Use only recommended original bespoke Filter Water Trap to ensure accuracy.

4.2 CO_2 Measure principle

1). Theory introduction

The device working theory is NON-DISPERSIVE INFRA GAS ANALYZER.

The principle is based on the fact that CO_2 molecules absorb infrared light energy of specific wavelengths, with the amount of energy absorbed being directly related to the CO_2 concentration. When an IR light beam is passed through a gas sample containing CO_2, 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 CO_2 concentration in the sample. To calibrated, the infrared sensor's response to a known concentration of CO_2 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 can compensate the calculation for the concentrations of carbon dioxide which improve the design accuracy.

Then the monitor(CO2 module) determines CO_2 concentration in the breathing gases by measuring the amount of light absorbed by these gases.EtCO_2 is display as a numerical value in millimeters of mercury (mmHg), percent (%), or kilopascals (kPa). In addition, a CO_2 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.

2). Automatic Offset Calibrations:

The device was designed to automatically perform calibrations in order to correct for changes in temperature, altitude and electronic component drift.

The air surrounding the device may have elevated concentrations of CO_2 present (such as in an enclosed compartment or room with poor ventilation). Therefore, we recommend use in well ventilated locations to ensure that the CO_2 baseline does not cause inaccuracy.

3). The Moisture Separation System:

This instrument uses a patented filter which can filter a large amount of moisture whilst maintaining a minimum dead space thereby improving the accuracy of the waveform. Please note that if the Filter becomes full of water or dirt the display will

show "OCCLUSION ', the operator needs to change the filter.

4.3 Oximeter density measurement (optional)

1). Theory introduction

SpO2 is measured by Pulsating oximetry. This is a continuous, non-invasive method to measuring hemoglobin oxygenation saturation. It is determined the number of sensor light emitted from the light source side penetrating the patient tissue (such as a finger or ear), to the receiver sensor. Sensors measure the wavelength of the red LED is typically 663nm, infrared LED is 890nm. The maximum output power of the optional LED is 2mW.

The amount of light passing through depends on several factors, most of which is constant. However, the arterial blood flow that is one of these factors varies with time, because it is pulsating. By measuring the light absorption of the pulsation period, it is possible to obtain the oxygen saturation of arterial blood. Detect pulsating itself can give a "plethysmography" wave and pulse rate signal.

It is also recommended to use Pulse Oximetry for ventilated or sedated patient s. Measurement will begin when a finger is put into the sensor clip, meanwhile, the photoplethysmogram wave will appear on the screen, after several seconds the oxygen saturation and pulse rate appear. The monitor will give a pulse tone sound when each heart beat happens. The tone will change to an alarm tone if the values of SpO_2 and Pulse Rate breach the alarm level settings. The volume of pulse beep can be adjusted by the item **BEEP VOLUME** in the SOUND SET menu. The pulse beep tone will disappear under the silent condition.

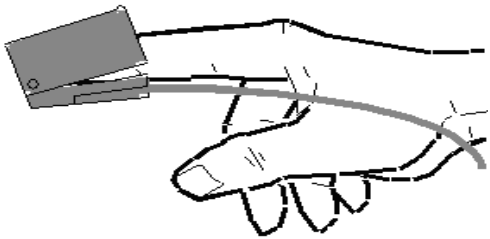


Figure 4.3

2). The use of different SpO_2 sensors

There are a number of different SpO_2 Sensors for use with this monitor. Please see brochure or listing at rear of Manual for details.

PLEASE NOTE: when SpO_2 is not being monitored the probe should be disconnected from the monitor to save battery life, or the two windows of sensor should be kept face to face, otherwise the light window will remain operational and the photoplethysmogram wave will be disordered and the screen will display "**FAIL SEARCH**".

3). Data averaging and update

The displayed SpO_2 and Pulse Rate values are the average of data collected within a specific time. The SpO_2 is calculated every second by the data collected in recent 5 seconds, the Pulse Rate is calculated for every beat. The averaging method depends on the pulse rate value, for pulse rates below 50bpm, the SpO_2 is averaged by 16-second sliding average, the Pulse Rate is averaged by 4-beat sliding average; for pulse rates between 50bpm and 120bpm, the SpO_2 is averaged by 8-second sliding average, the Pulse Rate is averaged by 8-beat sliding average; for pulse rates above 120bpm, the SpO_2 is averaged by 4-second sliding average, the Pulse Rate is averaged by 16-beat sliding average.

The screen display of SpO_2 and Pulse Rate are updated every second with the most recent value, if the signal is noisy or missing, the display will hold the last value for at most 15 seconds before showing "--".

4.4 Notice

1). Caution:

Conditions of electromagnetic influence, for example: electrosurgical devices, MRI, CT etc., may cause incorrect operation.

This device is not MRI/CT Compatible.

The filter should be taken off and replaced when it is nearly full of water, otherwise water ingress may cause irreversible damage for IR measurement detector cell. Be sure that the collecting pipe is not occluded to avoid stressing the inner sampling pump and reduction of pump life.

2). Attention: other important information.

(1) CO_2:

The approved sampling lines provided by or specified by the manufacturer or distributor, shall be used, otherwise readings may be inaccurate.
Fast changes in ambient Temperature may cause inaccuracy and in this instance the Display will show "TEMP IMBALANCE".
The measured data may be influenced by different kinds of anaesthetic gases. If it is required to calibrate interference gases please refer to Appendix 2.
Any circumstances of blocking of the gas sampling line, such as bending, folding, contamination blocking the sampling tube and filter or water trap etc. may lead to inaccurate measurement.
Any air leaks in the sampling line circuit will seriously influence accuracy of data measured and waveform shape.

(2) Oximeter:

The monitor is calibrated to display FUNCTIONAL OXYGEN SATURATION.
The monitor's measurement of SpO_2 may be influenced by strong ambient light. Therefore the user should unplug the SpO_2 Sensor when it is not being used.
Accuracy of oximeter readings will be influenced if there is imaging dye in the blood or if CO has been inhaled by the Patient.
Always make sure that the sensor is not contaminated or broken before use. Always take care to check that the sensor is applied correctly.
The accuracy of the measurement may be affected when clinicians operate devices involving peak wavelengths (such as: photodynamic therapy devices).

Warning:

Only use original SpO_2 probes approved for use with this Monitor.
Do not use the SpO_2 sensor if it is damaged or dirty.
If shock, low blood pressure, serious blood vessel constriction, serious anemia, very body low temperature, artery block near sensor or incomplete heart asystole occur the pulse signal may disappear.
Continuous use of finger clip SpO_2 sensor may result in discomfort or pain, especially for those patients with microcirculatory problem. It is recommended that the sensor should NOT be applied to the same finger for over two hours，change the measurement site periodically and when necessary.

5 Screen display and Operation

5.1. Screen main display menu

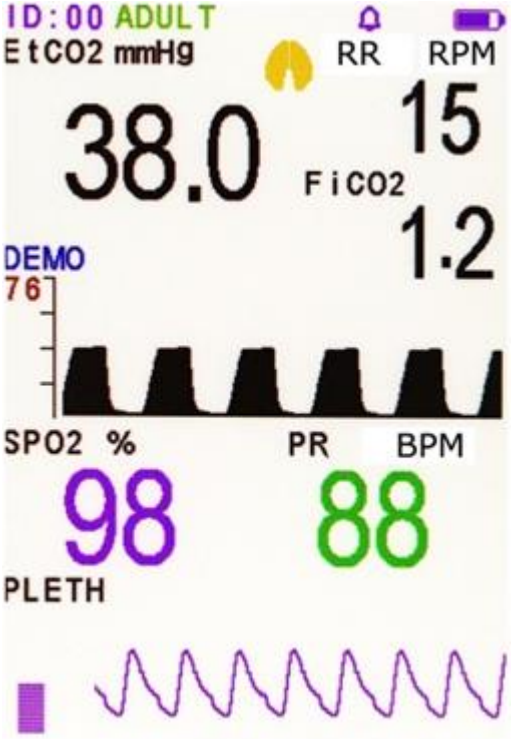


Figure 5.1

The monitor is designed as a portable device, with the operator usually standing by the patient's bed and holding the device in their hands.

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

Attention:

1.) When the memory full indicator is displayed, further 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. Alternatively, select AUTO LOOP to overwrite the oldest data when memory is full , please see the details in 5.9 NEW PATIENT

2.) If the symbol appears, the menu is locked, the setting menu will be disabled unless user press the three buttons , ▼, - at the same time, or enters engineer menu to unlock the menu (Refer to Appendix 2. ENGINEER MENU: Changing compensation of balance gas)

3.)The middle part of the screen shows results data: $EtCO_2$ concentration, respiratory rate, inhaling CO_2 concentration (optional), oxygen PLETH, exhaling or inhaling state (during exhaling, becomes blue color).

2. The middle part of the screen shows results data: $EtCO_2$ concentration, respiratory rate, inhaling CO_2 concentration (optional), exhaling or inhaling state (during exhaling, becomes blue color).

3. The bottom area shows CO_2 respiratory wave. If it is equipped with SpO_2, it will show SpO_2, pulse, oxygen PLETH waveform and histogram.

4.When the pump is not operating "PUMP OFF" will appear on the screen. If the filter is NOT inserted into the inlet port, the screen will show 'LINE OFF, the pump will also be automatically switched off to prevent ingress to the unprotected IR detector cell.

Alarm:

Alarm setting:

The alarm settings of the system will not change after the power interruption of the device.

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 and Oximeter working unproperly. This Capnograph and Oximeter adopt only medium priority alarm.

Medium priority alarm means serious warning.

Physiological alarm includes physiological parameters exceeding alarm limits, APNEA alarm.

Technical alarm will be displayed in text on the screen, including the following situations:

Technical alarm	Adverse effect
SENSOR OFF	Causing inability to provide gas measurement data.
TEMP UNSTABLE	Causing inability to provide gas measurement data.
IRS ERR	The gas measurement data cannot be provided.
TEMP LOW	May cause gas measurement error.
TEMP HIGH	May cause gas measurement error.
CAL ERR	May cause gas measurement error.
SENSOR ERR	Causing inability to provide gas measurement data.
OCCLUSION	Causing inability to provide gas measurement data.
LINE OFF	Causing inability to provide gas measurement data.
PUMP OFF	Causing inability to provide gas measurement data.
PUMP ERR	Causing inability to provide gas measurement data.
ZERO REQ	May cause gas measurement error.
SpO_2 SENSOR OFF	Causing inability to provide SpO_2 measurement data.
FAIL SEARCH	Causing inability to provide SpO_2 measurement data.

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 CO_2.

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.
The sum of the mean ALARM CONDITION DELAY plus the mean ALARM SIGNAL GENERATION DELAY is less than 5 seconds.

Alarm indication:

1.) If the $EtCO_2$'s value exceeds the limit of high or low alarm level, the data will be yellow and flashing and alert with alarm. This high priority alarm will also sound for respiration rate, SpO_2 and pulse rate alarms.

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 apnea alarm is turned on and apnea occurs the monitor will give a audio/visual alarm. The screen will flash the message 'APNEA' (meaning no $EtCO_2$ has been detected for a certain time period) and if the sound alarm is turned on, it will alert a audible alarm.

4.) When the SpO_2 sensor is disconnected or not applied, the screen will flash the message '**SENSOR OFF**'. If a heart beat pulse is not detected for a period of time, the screen will flash the message '**FAIL SEARCH**'.

5.) The volume of continuous or interval alarm tone sounds mentioned above can be adjusted up and down by the menu item **ALARM_VOLUME**. The sound will inaudible under the silent condition.

6.) The screen will show '', when an alarm is generated due to parameters out of range or APNEA.

7.) When the monitor is not able to maintain the NORMAL USE flowrate, the display will show '**OCCLUSION**' or 'PUMP ERR', the gas inlet indicator will change to orange.

Alarm sound:

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

Level of alarm	Sound	Sound pressure	Hemisphere Radius

Medium priority alarm	“Beep-Beep-Beep”, triggered each 8 seconds	45 ~ 70dB	1 m from the geometric center of the device

Alarm light:

Alarm light looks like following description.

Level of alarm	Light
Intermediate alarm	Parameter data turn yellow, the screen will show '', and 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.

Verification of alarm system function

The device startup self-test to verify the function of the alarm system. The operator can also restart to verify whether the alarm signal is inactivated.

After the device is turned on and before entering the main display screen, if you see ’

’ flashing once on the screen and hear a beep, it indicates that the system alarm function is normal.

5.2 Initial Monitoring Screen

Long press (about 3 seconds) power key " " to start the monitor, the initial monitoring screen is as shown below:

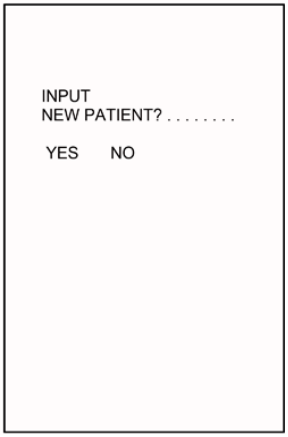


Figure 5.2

In this menu, press ▲ / + button or ▼/ - button to move the cursor, then press the **ENTER** button to select YES or NO. If selecting "YES" then the monitor enters the New Patient menu directly. If selecting "NO" or there is no any operation in 8 seconds, then the monitor enters main display screen.

To disable this prompt, enter the New Patient menu screen. If "POWER ON ID PROMPT" is set as "NO", the monitor will disregard the initial monitoring screen (see figure 5.2) and enter into main display screen directly (refer to Section 5.9 NEW PATIENT MENU for details).

5.3 The Main Menu

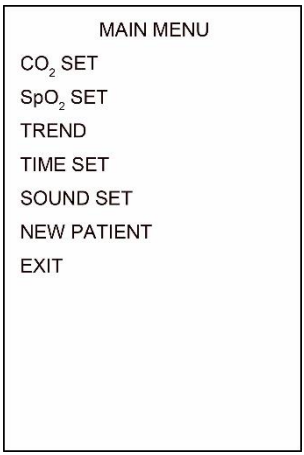


Figure 5.3

Press the MENU button to enter the Main Menu to set monitor parameters

⚠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.

This menu includes the following options:

The setting menu for CO_2: **CO_2_SETUP**

The setting menu for SpO_2: **SpO_2_SETUP**

The trend menu: **TREND**

The time menu: **TIME_SETUP**

The sound menu: **SOUND_SETUP**

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

In this menu, to press ▲ or ▼ button to move the cursor up or down to highlight an option and Press the ENTER button to select and enter the next level of the menu. To return to the Main menu select EXIT option and press ENTER (not available on Trend screen).

5.4 CO_2 SET Menu

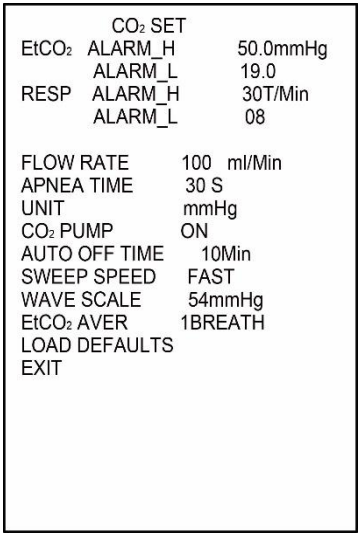


Figure 5.4

In this menu, press ▲ or ▼button to move the cursor up or down, press + button or - button to change the data highlighted by the cursor.

To return to the main menu highlight EXIT and press the **ENTER** button. If you want to return the monitor to its default settings highlight LOAD DEFAULTS and Press the **ENTER** button.

This menu includes the following setups:

1.) The high alarm limits of $EtCO_2$: **$EtCO_2$ ALARM_H:** 22-99mmHg, off

2.) The low alarm limits of $EtCO_2$: **$EtCO_2$ ALARM_L:** off, 10-60mmHg

3.) The high alarm limits of respiration rate: **RESP ALARM_H:**5-60 breaths/min, off

4.) The low alarm limits of respiration rate: **RESP ALARM_L:** off, 4-40 breaths/min

5.) Pump flow rate setup: **FLOW-SET:** 50 -250ml/min

6.) The setup of apnea time: **APNEA TIME:** 15s-44s, off

7.) The unit of CO_2:**CO_2 UNIT：** %, mmHg or kPa

8.) Pump switch: ON or Off

9.) Pump auto-closing time: **AUTO-OFF-TIME:** 10-30min

10.) Screen speed of capnograph：SWEEP SPEED: SLOW, NORMAL or FAST

11.) CO_2 Wave scale: **WAVE SCALE**: 54mmHG or 76mmHG

12.) $EtCO_2$ average computation time: **$EtCO_2$ Averaging:** every breath, 10sec, 20sec, 30sec

13.) Default reload: **LOAD-DEFAULTS**

14.) Exit: **EXIT**

Attention:

Pump auto-closing time means that the pump will automatically be closed down when no respiration occurs in the set period (default 10 min).

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 150mmHg.

Default values are as follows:

$EtCO_2$ alarm high limit: 50 mmHg

$EtCO_2$ alarm low limit: 19 mmHg

RESP alarm high limit: 30 breaths/min

RESP alarm low limit: 08 breaths/min

$FiCO_2$ alarm high limit: OFF

FLOW_SET: 100 CC/Min

Apnea time: 30S

CO_2 unit: %

CO_2_PUMP: ON

AUTO_OFF_TIME: 10 Min

SWEEP SPEED: NORMAL

WAVE SCALE: 54mmHg

$EtCO_2$ Averaging: 1 Breath

5.5 SpO_2 SET Menu

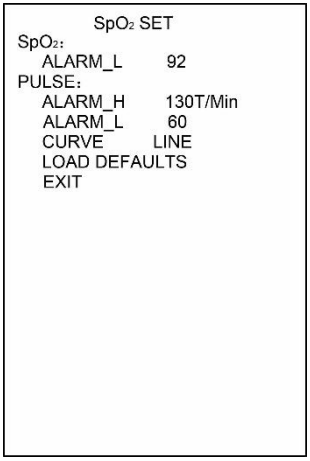


Figure 5.5

In this menu, press ▲ or ▼button to move the cursor up or down, press + button or - button to change the data highlighted by the cursor.

To return to the main menu highlight EXIT and press the **ENTER** button.
If you want to return the monitor to its default settings highlight LOAD DEFAULTS and Press the **ENTER** button.

This menu includes the following setups:
1.) The low alarm limits of SpO_2: **SpO_2 ALARM_L:** off, 50%-100%
2.) The high alarm limits of pulse rate: **P_RATE ALARM_H:** ***70-250***beats/m, OFF
3.) The low alarm limits of pulse rate: **P_RATE ALARM_L:** OFF, ***30-100***beats/m
4.) Wave curve selection: **CURVEWAVE:** FILL or LINE
5.) Renewing of defaults. **LOAD DEFAULTS**

The wave curve selection means that: FILL indicates the beneath part of photoplethsmogram is filled. LINE indicates the photoplethysmogram is drawn in curve line.

Default values as follow:
SpO_2 alarm low limit: 92%
Pulse Rate alarm high limit: 130bpm

Pulse Rate alarm low limit: 50bpm
Curve: Line

5.6. TIME SET Menu

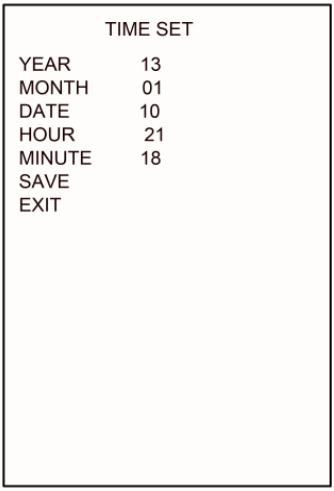


Figure 5.6

In this menu, press ▲ or ▼button to move the cursor up or down, press + button or - button to change the 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 ENTER button to enter the confirm menu, as the below figure showing.

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.

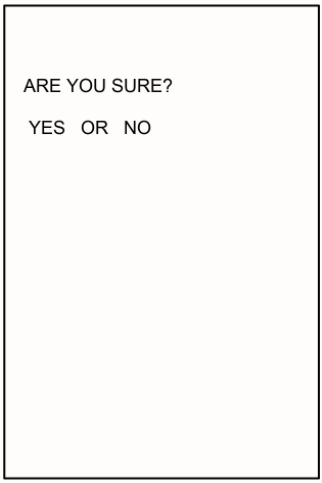


Figure 5.7

5.7. Sound SET Menu

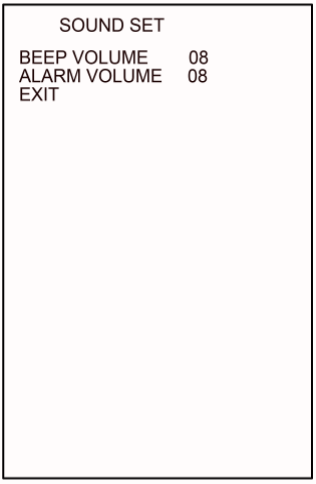


Figure 5.8

In this menu, press ▲ or ▼button to move the cursor up or down, press + button or - button to change the data highlighted by the cursor.

This menu includes following setups:

Pulse sound volume: **BEEP_VOLUME:** 0(OFF)-8

Alarm sound volume: **ALARM_VOLUME:** 0(OFF)-8

5.8. Trend

The graph trend

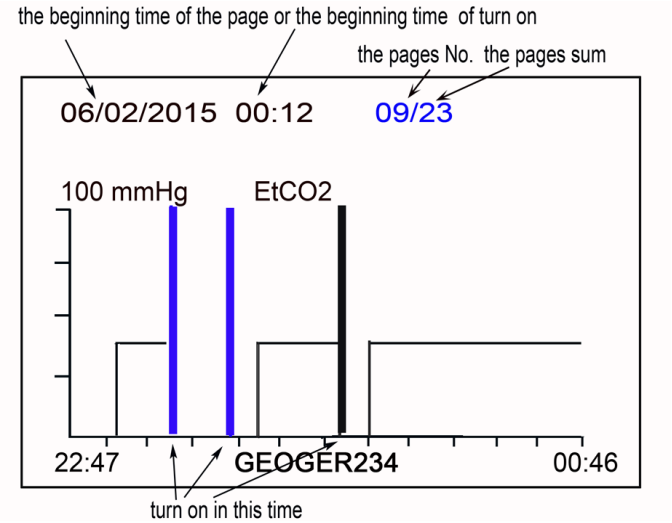


Figure 5.9

The monitor stores EtCO2, PR, SpO2 and PR as a group of data every 12seconds (Adjustable in Store Interval under New Patient menu) with accumulated trend up to 24hours respectively. The stored data is retained even the device is shut off.

The symbol will appear on screen when the storage is full. There are three options to further store the data.

1.) Change patient ID under NEW PATIENT menu.

2.) Change store mode to AUTO LOOP under NEW PATIENT menu, in auto loop mode new data will be stored and overwrite old data when reaches its limits.

3.) Select CLEAR MEMORY under NEW PATIENT menu to empty the stored data.

This figure shows that the time base for the trend page is 1 hours and every point indicates the result of every 12 second. The top line of this page indicates patient's ID number, the start time of this page (date/month/year hour: minute), current page no. and sum pages (24 pages in total).

If in the corresponding time to the one page of trend table, the user turns off and

turns on the device once or more times the trend table will show one or several blue vertical lines with full amplitude, at this time press ▼, then the top row will display the initial information at that turn on time: patient's ID number and initial time. The correspondingly initial blue vertical line will become white one. Press ▼ again, the second initial time will display (if turned off and on for several patients).

The time at beginning and ending parts of abscissa in this picture respectively indicates the beginning and ending time for trend of this page.

If the data is not complete, it shows the monitor was turned off although it has not completed 2 hours' record.

In this menu, press ENTER button to change the trends of CO_2 concentration, respiration rate, SpO_2 and pulse (the latter 2 parameters are selectable).

In this menu, press + button or - button to change the page of trend.
In this menu, press /▲button to change graph trend to table trend.
In this menu, press MENU button to quit this menu and return to the main display.

The table trend

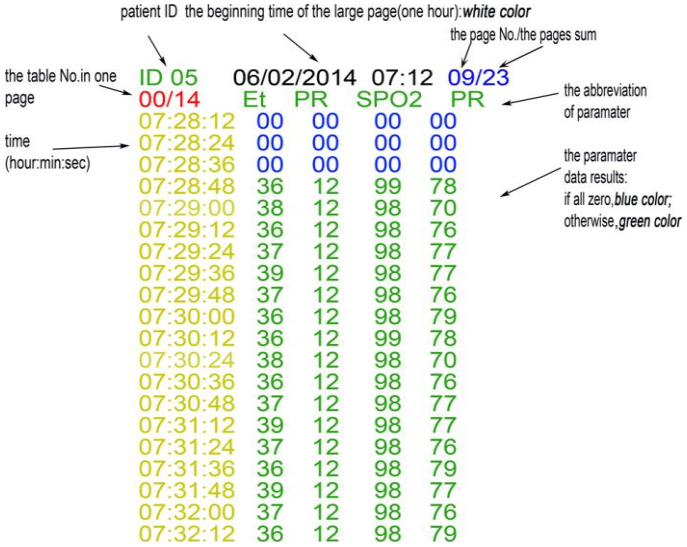


Figure 5.10

In this graph trend menu, press /▲ button to change graph trend to table trend.

Press / ▲ button again, to return to graph trend .

Every trend table shows ***20*** groups of data, including time, $EtCO_2$ (Et), respiration rate (RR), SpO_2, pulse rate (PR). The store interval is adjustable at 12econds in STORE INTERVAL under NEW PATIENT menu.

There are 24 sum pages when the storage is full. Each page contains ***15*** trend table and each trend table contains ***20*** groups data. The ***15*** trend table in one page can be reviewed by ▼ button. The table no. is indicated on left top of the screen as above figure showing.

In fully stored status, 24 pages can be paged up or down by + button or - button. The page no. is indicated on right top of the screen as above figure showing.
To quickly check if the four parameters of a data group are all zero, the display will display the parameter columns in blue.

5.9. NEW PATIENT Menu

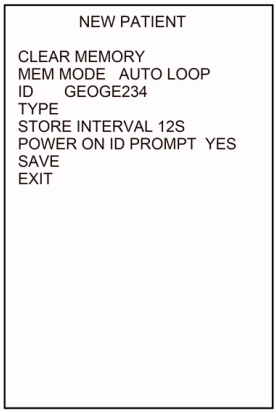


Figure 5.11

In this menu, press ▲ or ▼button to move the cursor up or down, press + button or - button to change the data highlighted by the cursor.
Press MENU button, then to exit this menu and enter the main menu.
This menu includes the following setups:
1.) **CLEAR MEMORY:** to delete all the historical data so as to store new data
2.) **MEM MODE:** 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,** press "Enter" key to enter or exit from the Set menu. Press + button or - button to move the cursor up or down， press ▲ or ▼button to change the data highlighted by the cursor.

4.) **TYPE:** patient type, Adult or pediatric options

5.) **STORE INTERVAL:** adjustable at 4/6/12 seconds

6.) POWER ON ID PROMPT: to set if the monitor enters into the "input new patient" menu when power on the monitor.

7.) **SAVE:** store the changes made (it needs to be confirmed by the new menu due to possibly substitution to the original data of the same ID of patient)

8). **EXIT:** to quit the current menu but not to store any changes to the setup

6 Charging, Maintenance, Cleaning

6.1 Charging

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 > 10 Hours. Charge time is approx. 4 Hours.

Battery maintenance method:

In order to avoid zero voltage or bulge damage due to self-discharge of the built-in lithium battery of the monitor that is not used for a long time, please ensure that the monitor is charged every 3 months and fully charged.

Note:

1. The charging time is not less than 4 hours； the monitor can be charged while being turned off, and the POWER indicator is on when charging.
2. The battery should be stored in a dry environment without static electricity, dust and moisture.

Battery replacement method:

To ensure the best performance and safety of the device, it is recommended that the lithium battery built into this device be replaced every 3 years.

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 r eplace 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. software system is halted), then to reboot the device hold the Power ON/OFF button down for 5 seconds.

OCCLUSION: **If the Display shows 'occlusion', check if the filter and/or sampling line tubing or connectors are blocked. Replace as necessary and clear the occlusion or switch OFF to prevent damage to the sampling pump.**

Please do not let alcohol, cleaning reagent or sterilizing reagent into filter. Check that the filter is dry and clean before it is used. Replace the filter if it is dirty, shows any sign of contamination or if in any doubt about its condition.
Please Note: It is advised to use the filter, sampling line and airway adapter as single use item so as to absolutely remove the risk of cross infection.

The SpO_2 simulator cannot be used to verify the SpO_2 measuring accuracy, which should be supported by the clinical study conducted by inducing hypoxia on healthy, non-smoking, light to dark skin n ed subjects in an independent research laboratory. However, it is necessary for the user to use SpO_2 simulator for routine verification of precision.
Please note that the specific calibration curve (so called R-curve) should be selected when use of SpO_2 simulator, e.g., for Index 2 series SpO_2 simulator from Fluke Biomedical Corporation, please set "Make" to "DownLoadMake: KRK", then the user can use this particular R-curve to test the SpO_2 function. If the SpO_2 simulator does not contain "KRK" R curve, please ask the manufacturer for helping to download the given R curve into the SpO_2 simulator.

Attention:
The filter, sampling line and airway adapter should be not sterilized and used repeatedly if the packing indication shows that it is disposable.
Attention: For the environment, disposable the filter, sampling line and airway adapter shall be treated suitably or recycled.

6.3 Cleaning

Warning：Before cleaning the monitor and probe, turn off power and remove 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 sterilize by high pressure, autoclave or washer

Do not dip or expose to liquid

Do not 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 sterilization.

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 the SpO_2 probe

Care:

Do not sterilize by high pressure, autoclave or washer

Do not dip the probe into liquid.

Do not use the probe if there is any sign of damage.

Use only PH Neutral Cleaning products.

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

Cleaning instructions:

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.

7 Trouble Shooting Analysis

Simple analysis of problems

No.	Phenomena	Causes	Solution
1	The values of CO_2 is reading too low, or 'OCCLUSION' appears on the screen.	1.Leaking of filter or sampling tube 2. Occlusion of filter or sampling line 3. Out of Calibration	1. Check and replace filter or sample line 2. Clear the gas loop Occlusion 3. Re-calibrate using standard gas.
2	The values of CO_2 is zero 1. Screen indicating PUMP ERR and big noise. 2. Screen indicating IR-LAMP-BAD 3. Screen indicating CO_2 SENSOR ERR	1.Internal leaking inside the Pump gas loop 2.The IR lamp resource of sensor damaged 3.IR Sensor broken	Contact the Distributor or manufacturer for repair.
3	Screen indicating CAL-ERR	The last calibration has failed.	Re-calibrate using standard gas.
4	Screen indicating POWER-ERR	Damaged or incorrect power supply.	Contact Distributor or manufacturer.
5	The CO_2 wave is not normal. 1. Screen indicating TEMP-HIGH 2. Screen indicating TEMP-LOW 3. Screen indicating TEMP-IMBALANCE	1. Temperature too high. 2. Temperature too low. 3. Sharp ambient Temperature change	Use in normal environmental temperature range
6	No values of SpO_2 or no wave	1.Finger too cold 2.Interference of very strong external light 3. The measurement test of SpO_2 and blood pressure are done on the same arm.	1.Warm up finger 2. Avoid strong external light. 3. Place SpO_2 sensor on other arm or position. 4.Renew SpO_2 sensor

		4. Red light in the sensor no flashing. 5. Infrared and collector of sensor is not clean	5.Clean internal parts of SpO_2 Sensor
7	Flashing red color and closed down automatically.	1. No Battery Charge.	1. Connect to Battery Charger.
8	Still flashing red color after the power is supplied and AC indicator no light.	1. Battery Charger power working abnormally.	1. Check battery charger and cable and replace as necessary.

Attention: Please contact your distributor if you require advice, replacement parts and/ or service.

Appendix 1. Explanations of Terms in this Manual

MENU	Menu
$EtCO_2$	The CO_2 concentration of expiration end phase
$FiCO_2$	The CO_2 concentration of inspiration phase
SpO_2	Oxygen saturation
RR	Respiration rate
PR	Pulse rate
mmHg	Millimeters Mercury
kPa	Kilopascal
ALARM-H	Alarm high limit
ALARM-L	Alarm low limit
LINE	Line curve
FILL	Filled or solid under waveform
BEEP_VOLUME	Pulse volume
ALARM_VOLUME	Alarm volume
APNEA	Apnea or breathing stopped for a set period of time
BPM	Breaths per minute
SET	Setup
N_2O:	Nitrous oxide
HELIUM	Helium gas
O_2CONCENTRATION	O_2 concentration compensation
ANAESTHETIC GAS	Anaesthetic gas
ZERO GAS	Base point or Zero point
BTPS	Temperature and deep lung air pressure compensation
CALIBRATE	Calibration
CANCEL	Cancellation
OCCLUSION	Blocked filter or gas sample line

Appendix 2. 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:

Press **+** and ▼ two buttons simultaneously to enter the following menu.

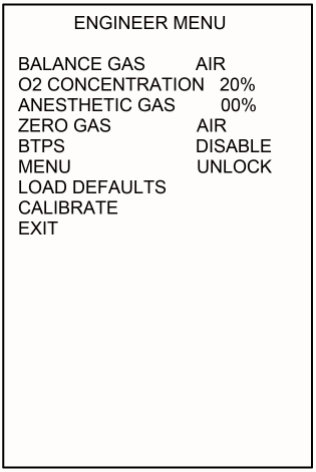


Figure A2.1

In this menu, press ▲ or ▼button to move the cursor up or down, press + button or - button to change the data highlighted by the cursor.

Some items of this menu can be directly adjusted, such as LOAD-DEFAULT or EXIT: to press ENTER button, exit without saving or changing data. In this menu, press MENU button, then to exit this menu and enter the main menu.

This menu includes the following setups:

BALANCE GAS: AIR, N_2O, and HELIUM

O2 CONCENTRATION: 20%-99%

ANAESTHETIC GAS: 0-20%

ZERO GAS: AIR, N_2

BTPS: ENABLE, DISABLE

MENU: UNLOCK, LOCK

LOAD DEFAULTS

CALIBRATE

Attention:

1.) When the menu is locked, this menu is disabled. To unlock the menu, press **+** and ▼ to enter engineer menu and change "unlock" to "lock" in the MENU setting. This is to avoid the misoperation of the patient against the preset of the doctor.

2.) CALIBRATE is for CO_2 concentration recalibration. Long press ENTER button for 8 seconds to enter this menu.

Default values are as follows:

BALANCE GAS: AIR

O_2 CONCENTRATION: 20 %

ANAESTHETIC GAS: 0 %

ZERO GAS: AIR

BTPS: DISABLE

MENU: UNLOCK

Appendix 3. Calibration of $EtCO_2$ Accuracy

Attention: Only trained personnel are allowed to carry out the following procedure. Contact your Supplier for training and advice.

The monitor has been calibrated before being shipped by the manufacturer. Generally the user does not need to calibrate this device other than the recommended annual check. To check the unit using Cal Gas the following procedure must be obeyed.

1. Required Parts and Items:

1.) CO_2 standard gas - Concentration is normally 5-8%

2.) Three-way connector: A three way connector with an inner diameter of 1-3 mm (one connection vented to open air) must be used to protect the monitor when calibrating using a CO_2 standard gas bottle see below figure . The device **will be damaged** by the high pressure of the standard Cal Gas Bottle if the connector is not used. It is strictly forbidden to connect the cal gas bottle directly to the device. One end of three-pass connector must be directly open to air to release gas pressure and protect the monitor.

3.) Two tubes (whose length can extend outside room): The standard gas flows into the air continuously through the three way connector and the module pump also vents the gas that is checked. During calibration CO_2 gas of a higher concentration can easily and quickly accumulate around the device. To prevent any potential of this affecting and influencing the calibration of the Zero base vent the connections from the three way adapter and the monitor to outdoor.

2. Connect as follows:

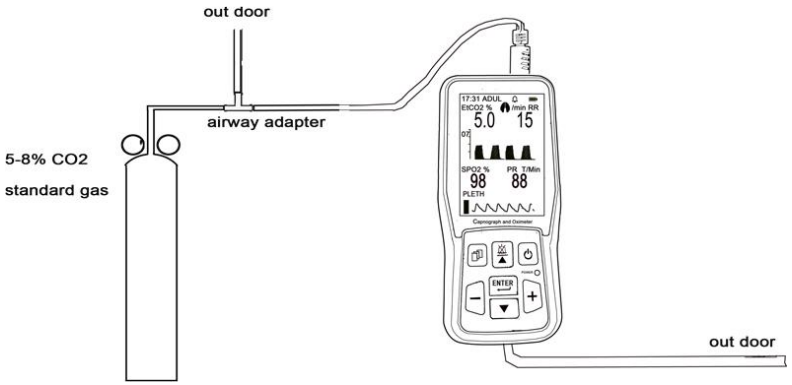


Figure A3.1

3. Warm-up

Turn on power and run the unit for 20-30 minutes and adjust the pump flow rate to over 120cc/min. To check if there is a leak use the following method: Squeeze the sampling tube by hand, the operating noise of the sampling pump will increase noticeably. If the sampling pump does not accelerate and its operating noise also does not change then there must be a leak in the gas loop. You must then find out where the leak is and solve it, otherwise, it will lead to incorrect calibration. After warming-up, open the flow of standard cal gas, and listen if the sound of pump is as same as original one. If the pump's turning is slow and its turning sound is weak, that means the standard gas pressure/flow is too large.

Turn down the Cal Gas flow rate until the sound of sampling pump resumes its original volume.

4. Calibrate

Enter the engineer menu (procedure given at Appendix 2,), highlight CALIBRATE, long press ENTER button for 8 seconds to enter the next menu.

Figure A3.2

Highlight STANDARD GAS and adjust the value to that of the concentration of CO_2 standard gas. If the standard gas concentration precision is to 2 decimal places numbers round up accordingly.

Then highlight CAL-BEGIN and long press the ENTER button for 8 seconds, at the same time, open the standard gas and the device will begin to calibrate. The screen will display the message 'ADJUSTING' as sown in below figure.

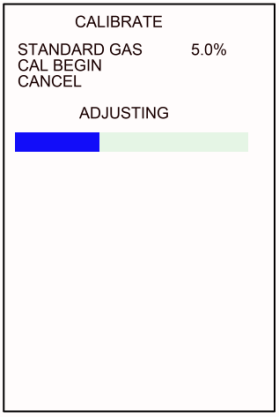


Figure A3.3

The thick cross bars in the display will be erased as time passes and the calibration will end when they are completely erased. If the calibration is successful, the menu will show ADJUST OK and subsequently exit into the main menu. If the calibration is unsuccessful, this menu will show ADJUST ERR. If this occurs the loop needs to be checked to determine if there is a leak or standard gas has run out (the pressure indicator of gas bottle shows 0). The Calibration menu will remain if

the calibration is unsuccessful.

If you require to exit this menu during the calibration press the MENU button or highlight CANCEL and press the ENTER button.

Note: Remember to close the valve of the standard gas to prevent wastage.

Appendix 4. Part Numbers and Consumables listing

CR-ASK900B Intubated Adult/Paediatric Airway Sampling Kit s x 10 Pack - each kit includes 1 of each item:

Water Trap/Filter T3 for PC-900B Monitor

Circuit Adaptor, 22F/15M with Gas Sample Port

Gas Sampling Tee, Male/Male Luers, 1.27mm ID x 3.0m

CR2500-0000218	Disposable Water Trap/Filter T4F (Female Luer Lock Connector)	Pack of 10
CR2500-0000240	Disposable Water Trap/Filter T4M (Male Luer Lock Connector)	Pack of 10
WL99370010	Elbow Connector Sampling Tee , 22F/15M with Port & and Cap, Adult/Paed	Pack of 50
15100110	Gas Sampling Line, Male/Male Luers, 1.27mm ID x 2.4m	Pack of 50
15100004	Nasal cannual, Male/Male Luers, Adult	Pack of 50
15100210	Straight Connector Sampling Tee, 22F/15M with Port and Cap	Pack of 100
QO12090	Male to Male Luer Lock Connector to convert Water Trap/Filter T3 to Male Luer – allows use of Female Luer ended Sample Lines	Pack of 10

PLEASE NOTE: You will need to adjust the Flowrate of the sample pump down to 50 ml/min to allow the use of narrow bore very low flow Samples lines. Failure to do so may result in the Occlusion Alarm becoming active and/or premature Pump failure due to high resistance over stressing.

PB-331010	PRO-Breathe® CO2 Sampling Mask with O2 Delivery, Adult with 2.1m O2 Tubing, Female Luer connector	Pack of 50
MA4000	Nasal CO2 Sample Line, Adult, 2.1m with Male Luer	Pack of 25
MA4100	Nasal CO2 Sample Line, Paediatric, 2.1m with Male Luer	Pack of 25
MA4707	Nasal CO2 Sample Line with O2 Delivery, Adult, 2.1m with Male Luer	Pack of 25
MA4703	Nasal CO2 Sample Line with O2 Delivery, Paediatric, 2.1m with Male Luer	Pack of 25

CR15040050	SpO2 Sensor (Sub-D), Silicone, Adult, 2m	Pack of 1
CR15040051	SpO2 Sensor (Sub-D), Silicone, Paediatric, 2m	Pack of 1
CR15040022	SpO2 Sensor (Sub-D), Finger Clip, Adult, 2m Cable	Pack of 1
CR15040055	SpO2 Sensor (Sub-D), Finger Clip, Paediatric, 2m Cable	Pack of 1
CR15040017	SpO2 Sensor (Sub-D), Y Type with Silicone Wrap, 0.9m Cable	Pack of 1

CR2302-0000013	Replacement Lithium Battery for PC-900B Capnograph	Pack of 1
CR2903-2000010	Charger Cable (USB to mini USB) 1.5m	Pack of 1

ACA-USB2UK	5V DC Mini USB to UK Plug Adapter for use with above	Pack of 1
CR-12VDC9B	12V DC Vehicle Power Adapter to 5V DC Mini USB 3m length	Pack of 1
PROBAG-CAP	Heavy Duty Cushioned Carry Case for PC-900B Monitor	Pack of 1

Warning:

PLEASE USE ONLY GENUINE RECOMMENDED SPARE PARTS AND ACCESSORIES OTHERWISE YOUR WARRANTY WILL BE INVALIDATED

Attention:

Please contact **your distributor if you require advice, replacement parts and/ or service.**

Appendix 5. Guidance and manufacturer's declaration - Electromagnetic compatibility

Table 1 Guidance and manufacturer's declaration-electromagnetic emission-for all EQUIPMENT AND 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>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. This device does not contain magnetically sensitive components or circuitry. Therefore, it is not affected much by proximity magnetic fields.</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Class A</td><td rowspan="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>
<tr><td>Harmonic emissions
IEC61000-3-2</td><td>N/A</td></tr>
<tr><td>Voltage fluctuations/flicker emissions
IEC61000-3-3</td><td>N/A</td></tr>
</table>

Table 2 Guidance and manufacturer's declaration-electromagnetic immunity for all EQUIPMENT AND 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/burst IEC61000-4-4	±2kV for power Supply lines	±2kV for power Supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1kV differential mode ±2kV common mode	±1kV differential mode ±2kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short	0 % UT (100 % dip in UT) for 0,5 cycle	0 % UT (100 % dip in UT) for 0,5 cycle	Mains power quality should be that of a

interruptions and voltage variations on power supply input lines IEC61000-4-11	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 1 cycles 70 % UT (30 % dip in UT) for 25/30cycles 0 % UT (100 % dip in UT) for 250/300 cycles	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	30A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Table 3 Guidance and manufacturer's declaration – electromagnetic immunity-for EQUIPMENT and SYSTEM that are not LIFE-SUPPORTING

<table>
<tr><td colspan="4">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.</td></tr>
<tr><td>IMMUNITY test</td><td>IEC 60601 test level</td><td>Compliance level</td><td>Electromagnetic environment - guidance</td></tr>
<tr><td>Conducted RF IEC 61000-4-6</td><td>3 Vrms 150 kHz to 80 MHz (6V in ISM radio bands between 0.15MHz and 80 MHz)</td><td>3 Vrms 150 kHz to 80 MHz (6V in ISM radio bands between 0.15MHz and 80 MHz)</td><td>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
$d = 1.2\sqrt{P}$
$d = 1.2\sqrt{P}$ 80MHz to 800MHZ
$d = 2.3\sqrt{P}$ $800MHz\ to\ 2.7\ GHZ$

Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).
Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a should be less than the compliance level in each frequency range.
Interference may occur in the vicinity of equipment marked with the following symbol:
  </td></tr>
<tr><td>Radiated RF IEC 61000-4-3</td><td>3 V/m 80 MHz to 2.7 GHz</td><td>3 V/m</td><td></td></tr>
</table>

Table 4 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)	Separation distance according to frequency of transmitter (m)		
	150kHz to 80MHz $d = 1.16\sqrt{P}$	80MHz to 800MHz $d = 1.16\sqrt{P}$	800MHz to 2,7GHz $d = 2.33\sqrt{P}$
0,01	0.12	0.12	0.23
0,1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (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.			

⚠WARNING:

- 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.

The following types of cable must be used to ensure compliance with interference remissions and immunity standards.

Table 5 overview of cable

No.	Name	Length of cable (m)	Shielded (Yes or No)	Remark
1	Power adapter cable	1.8	No	/
2	SpO_2 Probe cable	1.8	No	/

- 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.
- 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 equipment, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- The essential performance of the device is measurement accuracy and alarm conditions for the GAS READING, SpO_2 and pulse rate, or generation of a technical alarm conditions.
- The device is subject to special EMC precautions and must be installed and used in accordance with these guidelines.

	Manufacturer
	Date of manufacture
	Lot number
	Follow instructions for use
	Keep in a cool, dry place
	Imported by
	Product code
	Authorized representative in the European community
	WEEE disposal
	This item is compliant with Directive 93/42/EEC
	Caution: read instructions (warnings) carefully
	Keep away from sunlight
IPX1	Covering Protection rate
	Expiration date

GIMA WARRANTY TERMS

The Gima 12-month standard B2B warranty applies.

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.

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