AneSure-H

Multigas Monitor

USER MANUAL

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 ANESURE multigas monitor.

The Manual describes, in accordance with the device'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 Kingst Medical have the ultimate right to revise or modify 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:
In some countries Federal law restricts this device to sale by or on the order of a physician.

Notice

Welcome to user manual for the AneSure^{TM}-H multigas monitor.

This manual includes the materials and copyright is reserved. It is not allowed to copy, reduplicate, or translate into other languages without our written permission. Please to read this manual carefully before use and then operate this device by following the instructions 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 manufacturer/factory. Software cannot be altered by the built-in user interface. Some changes to the product due to the technology updates or improvements or due to the special demands of the user which do not influence the monitor's key functions will not be informed further. Furthermore, please pay attention to the difference between the parts or components and this manual. Please contact our company for technical documents or electric circuit diagram or relevant batch and lists of parts or components etc.

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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 device can monitor the respiratory rate, $EtCO_2$, $FiCO_2$,inhalation and exhalation concentrations of N_2O (FiN_2O and EtN_2O), inhalation and exhalation concentrations of the selected anesthetic gas one of the five anesthetic gases (halothane, enflurane, isoflurane, sevoflurane, or desflurane).
This device can also provide oxygen saturation (SpO_2), and pulse rate of adult, pediatric, or infant patients.

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 accidentally 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 Intended use

This device is intended to provide a means of simultaneously measuring end tidal carbon dioxide ($EtCO_2$), inhalation carbon dioxide ($FiCO_2$), respiration rate, inhalation, and exhalation concentrations of N_2O, inhalation and exhalation concentrations of the selected anesthetic gas one of the five anesthetic gases (halothane, enflurane, isoflurane, sevoflurane, or desflurane), oxygen saturation (SpO_2), and pulse rate of adult, pediatric, or infant patients.

It is intended for use in environments where patients require continuous, non-invasive monitoring of these parameters by a qualified medical professional, e.g., hospitals, medical facilities, post-operative care.

1.4 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.

Warning: Indicating the possible injury on patient or operator.

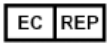
- Before use, Check the monitor for any mechanical damage; Inspect the exposed parts and the inserted parts of all the leads, and the accessories; Examine all the functions of the monitor that are likely to be used for patient monitoring, and ensure that it is in good working condition.
- This monitor 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, power adapter 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 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 Multigas Monitor is 5 years. The Multigas Monitor shall be collected and recycled in accordance with local law after 5 years. Please contact with local agency or manufacture for any questions.
- The SpO_2 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.

1.5 Equipment Symbols

Symbols	Meaning	Symbols	Meaning
	Date of manufacture		Manufacturer
	Serial number		Caution
	Type BF applied part		Refer to manual
	Authorized representative in the European Community		Indicates separate collection for electrical and electronic equipment (WEEE).

	Use-by date	MD	Indicates that the product is a medical device.
	General warning sign	IP32	Degree of protection provided by enclosures

2 Technical specifications and characteristics

Technique: NDIR (Non-dispersive infrared gas analysis)
Sampling Mode: Sidestream

$EtCO_2/FiCO_2$

Range: 0 – 150mmHg or 0 – 20kPa or 0 – 19.7% (v/v)
Accuracy: ±2mmHg for CO_2 range 0 - 40mmHg
±5% for CO_2 range from 41 - 70mmHg
±8% for CO_2 range from 71 - 100mmHg
±10% Over 100mmHg
Update/Averaging Time: Option of every breath or 10, 20 or 30 seconds
Sample Flow Rate: 50–250ml/min User Adjustable. Default=100ml/min
<±20% for sample flow rate ranges from 50–250ml/min
Patient Modes: Adult and Neonatal
Memory: 24 hours on Screen Trend and Numeric

FiN_2O/EtN_2O

Range: 0-100%
Accuracy: ± (2 vol% + 2% of reading)

FiHAL/EtHAL, FiENF/EtENF, FiISO/EtISO

Range: 0-12%
Accuracy: 0-8%: ± (0.15 vol% + 5% of reading); 8-12%: unspecified

FiSEV/EtSEV

Range: 0-15%
Accuracy: 0-10%: ± (0.15 vol% + 5% of reading); 10-15%: unspecified

FiDES/EtDES

Range: 0-25%
Accuracy: 0-18%: ± (0.15 vol% + 5% of reading); 18-25%: unspecified

All FiAG update: every 2-3 breath
All FiAG Trends: 24 hours on Screen Trend and Numeric *

Atmospheric Pressure Compensation

Auto-compensation for atmospheric pressure variation

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 SpO_2 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 *

TOTAL SYSTEM RESPONSE TIME and rise time

The total response time is less than 3s.

The rise time of 10%-90%:

CO_2 is less than 200ms;

N_2O is less than 300ms;

Anesthetic gases (halothane, enflurane, isoflurane, sevoflurane, or desflurane) are less than 300ms.

Warm Up Time

Warm Up Time: <15 seconds

Agent threshold

0.2%, When an agent is identified, concentrations will be reported even below 0.2 % as long as apnea is not detected.

Alarm limits

Apnea alarm limits: 15-40 sec

High alarm limits $EtCO_2$/ $FiCO_2$: 22-150mmHg

Low alarm limits $EtCO_2$/ $FiCO_2$: 00-60mmHg

High alarm limits FiHAL/EtHAL, FiENF/EtENF, FiISO/EtISO: 1.0-8.0%

Low alarm limits FiHAL/EtHAL, FiENF/EtENF, FiISO/EtISO: 0-6.5%

High alarm limits FiSEV/EtSEV: 1.0-10.0%

Low alarm limits FiSEV/EtSEV: 0-6.5%

High alarm limits FiDES/EtDES: 1.0-18.0%

Low alarm limits FiDES/EtDES: 0 -6.5%

High alarm limits FiN_2O/EtN_2O: 26-100%

Low alarm limits FiN_2O/ EtN_2O: 01-78%

The high alarm limits of respiration rate: 4-150 breaths/min

The low alarm limits of respiration rate: 0-140 breaths/min

The high alarm limits of SpO_2: off

The low alarm limits of SpO_2: 50-100%

The high alarm limits of Pulse Rate: 70-250 bpm

The low alarm limits of Pulse Rate: 30-100 bpm

Power

AC Input: 100V - 240V, 50Hz/60 Hz to 5VDC Adapter with
5V mini 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 +50ºC

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

Atmospheric pressure: 70 - 120 kPa

Storage Conditions

Temperature: -30to +70ºC

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 / 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

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°C, 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

$EtCO_2$（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 $EtCO_2$ reading measurements can also be affected by expiratory time, and $EtCO_2$ data

can drop when the expiration time is too short. For example, at a respiratory rate of 10 breaths/min, $EtCO_2$ values may drop by 12% when the inspiration-to-expiration ratio (I:E) is greater than 5:1.

Note2:

The accuracy of gas concentration measurement is influenced by any interfering gas and/or vapour, for example N_2O gas and halogenated anaesthetic gas can raise the CO_2 reading (2-10%), Helium and O_2 can reduce the CO_2 reading (1-10%), so compensation should be set in the balance gas MENU (Detail see Appendix 2) to meet the accuracy requirements if such gases or vapours are present.

If the concentration of one of the interfering gases listed in Table 2 can be measured by the device, its interference to $EtCO_2$ will be compensated automatically without manual intervention.

Table2: Interfering gases and vapours effects

Gas or vapour	Interference to CO_2	Interference to AGENT	Interference to N_2O
60% Nitrous Oxide	Note 2.1	Note 2.2	Note 2.2
4% Halothane	Note 2.2	Note 2.2	Note 2.2
5% Enflurane	Note 2.2	Note 2.2	Note 2.2
5% Isoflurane	Note 2.2	Note 2.2	Note 2.2
5%Sevoflurane	Note 2.2	Note 2.2	Note 2.2
15% Desflurane	Note 2.1	Note 2.2	Note 2.1
80% Xenon	-8% of reading	Note 2.2	Note 2.2
50% Helium	-6% of reading	Note 2.2	Note 2.2
0.1% Ethanol	Note 2.2	Note 2.2	Note 2.2
0.1% Isopropanol	Note 2.2	Note 2.2	Note 2.2
0.1% Acetone	Note 2.2	Note 2.2	Note 2.2
1.0% Methane	Note 2.2	Note 2.2	Note 2.2
100% O_2	Note 2.1	Note 2.1	Note 2.1

Note2.1: The measurement accuracy can be satisfied through automatic compensation.

Note2.2: The impact is low and negligible.

Note3:

The accuracy of gas 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

SpO_2 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).

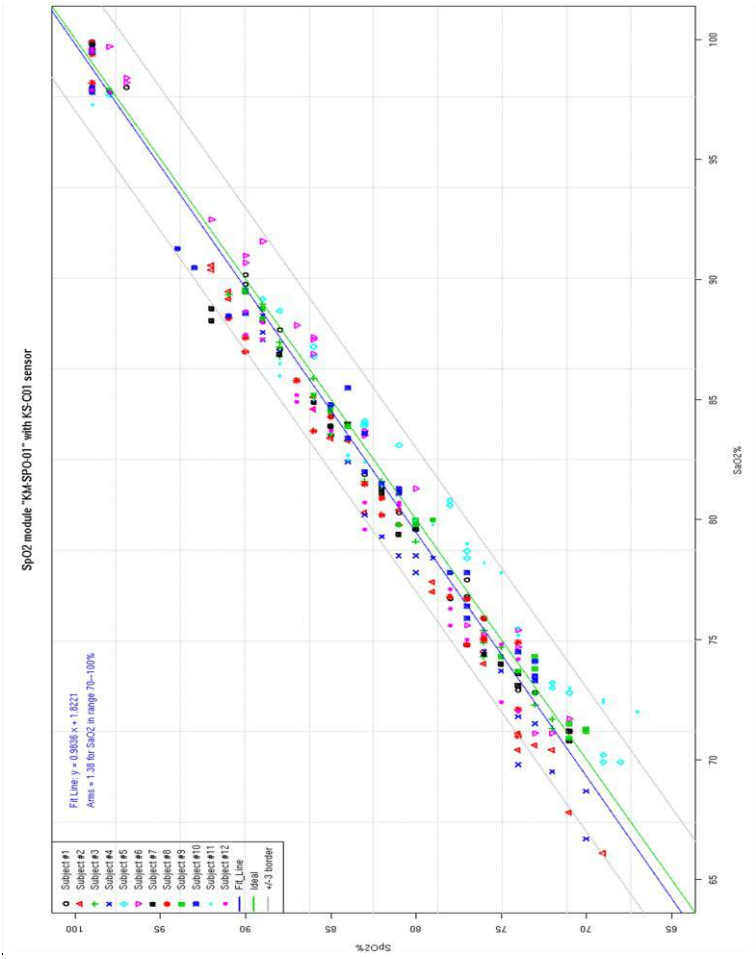


Figure 2.1

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

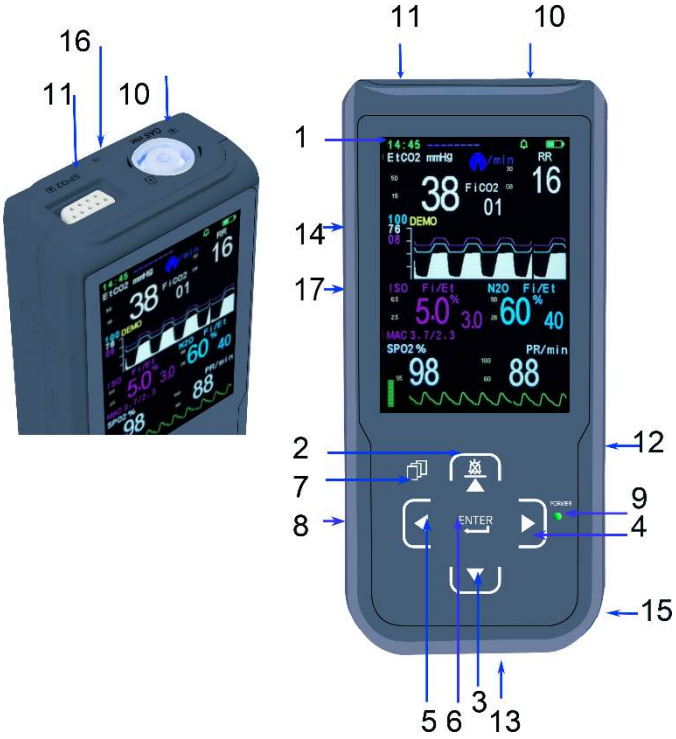


Figure 3.1

(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.

c) If the device is connecting with Bluetooth printer, press this button for 2 seconds to print capnography and other result parameters

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

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

(9) Indicator POWER: Blue LED is lit when the Monitor is either switched ON or subject to external power when not switched ON.

If the green LED is lit, the internal battery is being charged.

(10) **GAS inlet:** 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 orange during occlusion or pump err.

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

(12) DC5V Mini 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.

(17) Oxygen sensor's socket (optional).

4 Patient connection

4.1 Gas measurement

1). Connection and 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 gas 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.

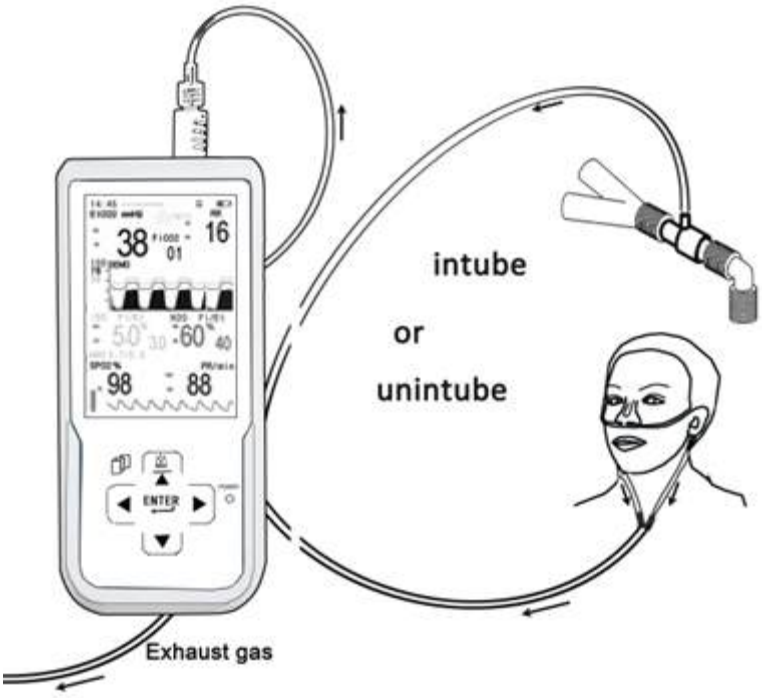


Figure 4.1

⚠ WARNING ⚠:

When N_2O and/or anesthetic agents are being used, pollution of the operating

room by these gases should be prevented. The gas exhaust should normally be connected via an exhaust line(OD:4mm, ID:2mm), to:

- a scavenging system (for evacuation of the sampled gas), or
- the patient circuit (for return of the sampled gas.

2). 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.

⚠ 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.

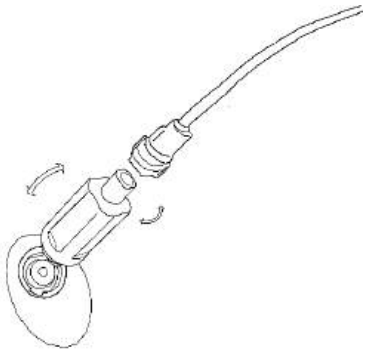


Figure 4.2

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 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 to ensure accuracy.

4.2 Gas Measure principle

The Monitor is based on the principle that different gases absorb the infrared of a particular wavelength. For examples, CO_2 sensitive wavelength is 4.26 um, N_2O sensitive wavelength is 4.5 um, and the sensitive infrared wavelengths of the five anesthetic gases distribute between 7.5-10.5 um. We can choose one wavelength as reference which is not sensitive to these gases. When the concentration of the monitored gas changes, its absorbed dose of the sensitive infrared varies accordingly, but the reference infrared does not change. The monitor employs a four-channel sensor, with every channel having an optical filter that only allows a narrow band wavelength to pass through, and the central wavelength passing through each optical filter is different. Take CO_2 for example, when one beam of infrared passing through sampling gas with CO_2 molecule reaches infrared sensor, the CO_2 channel measures the residual infrared signal, while the reference channel measures initial infrared, then we use standard gas with known CO_2 concentration to calibrate the specific ratio between the two channels signal, then store the calibrated parameter into the internal storage and then we can measure CO_2

concentration in the rated range. Likewise, the principles for measuring the N_2O and selected anesthetic gas concentrations are same.

4.3 Respiration rate measurement

The calculation of respiration rate derives from monitoring the peak to peak time from the CO_2waveform.

4.4 MAC calculation

MAC (Minimum Alveolar Concentration) value is calculated according to following formula:

MAC=% A.G /K (A.G, age) + %N_2O/K (N_2O, age)

% A.G is percentage concentration of the Agent gas, %N_2O is percentage concentration of nitrous oxide.

k(HAL@40yr) =0.75%, k(ENF@40yr) =1.63%, k(ISO@40yr) =1.17%, k (SEV@40yr) =1.80%, k (DES@40yr) =6.6%;

k (N_2O@40yr) =100%.

K (A.G, age) and K (N_2O, age) decrease with patient age, so the MAC value increases with age.

The user can set the patient's age at 5.9 NEW PATIENT Menu

4.5 The sensor's Zero

1) Zeroing the calibration

The sensor and infrared source may have a small amount of natural drift with time. In this case the sensor may need to be zeroed after long usage, if the data is not correct.

Attention: Zeroing needs to be done carefully to prevent a false zero calibration causing a deviation of measurement data.

2) Zeroing method:

Turn on the device and allow to warm up for 5-10 minutes.

Place the device into a free air space without CO_2, N_2O and Agents and do not

breathe near it. Then, enter GAS setting submenu, move cursor to' ZERO'. If this item is high-luminance color that means the sensor's data is stable and it can be zeroed. Then press '**ENTER**' button, send the Zero command and 'ZEROING' will be shown. Wait for 15-20 seconds till 'ZEROING' disappears.

4.6 Oximeter density measurement (optional)

1). Theory introduction

SpO_2 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 patients. 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.

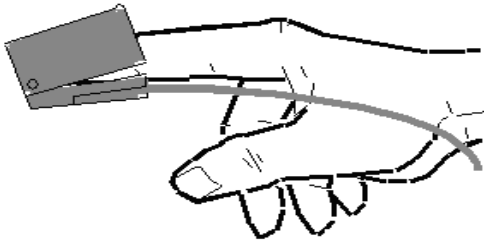


Figure 4.3

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 "--".

4.7 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.) Gas measure

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 interference gases. If it is required to compensate , 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 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).

3. 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 and age, 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. You can also set up trend RENEW into AUTO mode, please see the details in 5.9 NEW PATIENT Menu

b) 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)

c) The symbol ( ) appears if the bluetooth module is enabled. If this symbol glitters, it indicates that no bluetooth equipment is connected, if this symbol does not glitter, it indicates that some bluetooth equipment is connected.

2.The middle part of the screen shows results data and waves: $EtCO_2$, $FiCO_2$, respiratory rate, Agent and N_2O concentration, exhaling or inhaling state (during exhaling, becomes blue colour), CO_2, Agent and N_2O waves, so on.

3. This device can display MAC, the minimum alveolar concentration, pay attention, MAC correlates human age, if hope to get accurate MAC, please input patient's age into menu. Detail see 5.9 NEW PATIENT Menu.

4. If the device is equipped with SpO_2, it will show SpO_2, pulse, oxygen PLETH waveform and histogram.

5.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 the monitor working improperly. This device adopts 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 values 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 ALARM.

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 $EtCO_2$, Agent and N_2O's value exceeds the limit of high or low alarm level, their data will be yellow and flashing and alert with alarm. This alike 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 no CO_2 detected alarm is turned on and no CO_2 detected occurs the monitor will give an audio/visual alarm. The screen will flash the message 'no CO_2 detected' or 'APNEA' (meaning no $EtCO_2$ has been detected for a certain time period) and 'Beep' sound will also be heard.

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 protocol. Time interval cannot be changed.

Level of alarm	Sound	Sound	Hemisphere Radius

		pressure	
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), press the button to silence the alarm for two minutes and the Alarm icon becomes . Two minutes later, the Alarm silence will automatically clear and the alarm will activate normally again if there is an alarm condition.

If you wish to cancel the alarm silence during the two minutes period then press the button in this period. When the two minutes Alarm Silence alarm is on, both physical alarm and technical alarm will be silent.

Alarm counterplan:

WARNING: Always check status of patient if an 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 twice on the screen and hear a beep, it indicates that the system alarm function is normal.

5.2 Initial Monitoring Screen (optional)

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

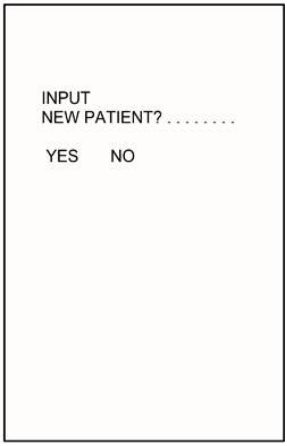


Figure 5.2

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 GAS: **GAS SET**

The setting menu for ALARM: **ALARM SET**

The trend menu: **TREND**

The time menu: **TIME SET**

The sound menu: **SOUND SET**

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 GAS SET Menu

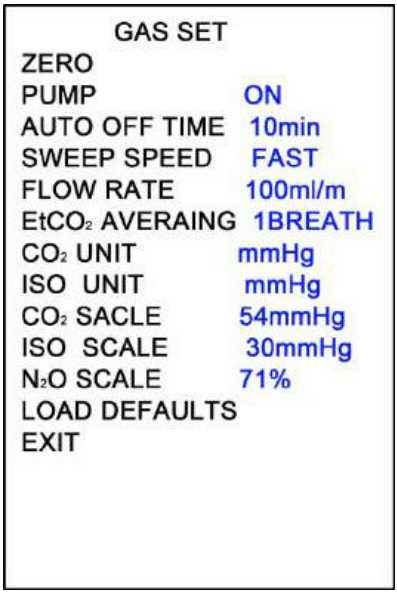


Figure 5.4

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) Sensor zero Calibration: **ZERO**

2) Pump switch: **PUMP:** ON or OFF

3) Pump auto-closing time: **AUTO-OFF-TIME:** 10-30min or OFF

4) Screen speed of capnography, agent gas wave and N_2O wave: **SWEEP SPEED:** SLOW, NORMAL or FAST

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

6) $EtCO_2$ average computation time: **$EtCO_2$ Averaging:** every breath, 10sec, 20sec,

30sec

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

8) The unit of Agent: **A.G UNIT:** %, mmHg or kPA

9) CO_2 Wave scale: **CO_2 SCALE:** 54mmHg or 76mmHg

10) Agent Wave scale: **HAL SCALE:** 30mmHg or 60mmHg

ENF SCALE: 30mmHg or 60mmHg

ISO SCALE: 40mmHg or 60mmHg

SEV SCALE: 54mmHg or 76mmHg

DES SCALE: 76mmHg or 114mmHg

11) N_2O Wave scale: **N_2O SCALE:** 70 or 100%

12) Default reload: **LOAD-DEFAULTS**

13) Exit: **EXIT**

Attention:

a) When respiration wave comes and $EtCO_2$ is not zero value, the zero instructive item 'ZERO' will be dark color and zero calibration operation cannot be run;

Only when the sensor is in clean air without respiration wave and $EtCO_2$, Agent and N_2O is zero value, can enter the sensor zero calibration item 'ZERO', press the **ENTER** button then, the sensor can be zero calibrated, but must be sure without breathing near the sensor during zero calibration

b) 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 99mmHg.

Default values are as follows:

PUMP: ON

AUTO_OFF_TIME: 10 Min

SWEEP SPEED: FAST

FLOW_SET: 100 ml/min

$EtCO_2$ Averaging: 1 Breath

CO_2 UNIT: mmHg

AGENT UNIT: mmHg

CO_2 WAVE SCALE: 54mmHg

HAL SCALE: 30mmHg
ENF SCALE: 30mmHg
ISO SCALE: 40mmHg
SEV SCALE: 54mmHg
DES SCALE: 76mmHg
N_2O WAVE SCALE: 71%

5.5 Alarm SET Menu

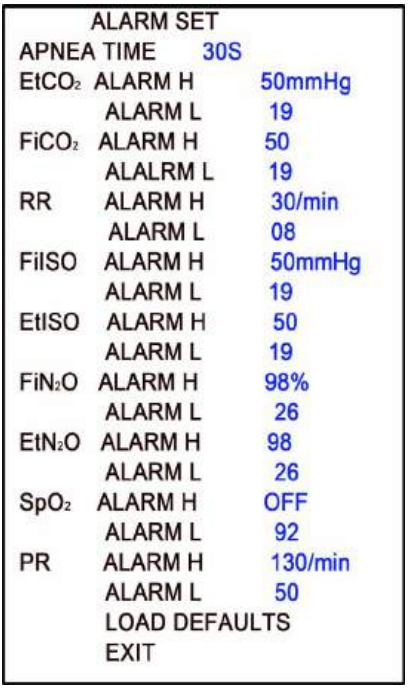


Figure 5.5

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.

Pressing the **ENTER** button for more than 3 seconds can directly change the alarm limit highlighted by the cursor to OFF.

This menu includes the following setups:

1) Apnea alarm: APNEA TIME: 15-40 sec，OFF

2) The high alarm limits of $EtCO_2$: $EtCO_2$_H: 22-99mmHg, OFF

3) The low alarm limits of $EtCO_2$: $EtCO_2$ _L: OFF, 10-60mmHg

4) The high alarm limits of $FiCO_2$: $FiCO_2$_H: 22-90mmHg, OFF

5) The low alarm limits of $FiCO_2$: $FiCO_2$ _L: OFF, 10-60mmHg

6)The high alarm limits of respiration rate: RR_H: 4-150 /min, OFF

8)The low alarm limits of respiration rate: RR_L: OFF, 0-140/min

9) The high alarm limits of FiA.G/EtA.G:

HAL _H: 21-60mmHg, OFF

ENF _H: 21-60mmHg, OFF

ISO _H: 21-60mmHg, OFF

SEV _H: 21-76mmHg, OFF

DES_H: 21-135mmHg, OFF

10) The low alarm limits of FiA.G/EtA.G:

HAL _L: OFF, 0-50mmHg

ENF _L: OFF, 0-50mmHg

ISO _L: OFF, 0-50mmHg

SEV _L: OFF, 0-50mmHg

DES _L: OFF, 0-50mmHg

Note: One of the five anesthetic gases manually selected by the user in the hidden menu, detail see Appendix 2. ENGINEER MENU

11) The high alarm limits of FiN_2O/ EtN_2O_H: 26-98%, OFF

12) The low alarm limits of EtN_2O: EtN_2O _L: OFF, 1-78%

13) The high alarm limits of SpO_2: SPO_2 ALARM_H**:** OFF

14) The low alarm limits of SpO_2: SPO_2 ALARM_L**:** OFF, 50%-99%

15) The high alarm limits of pulse rate: PR ALARM_H: 70-250/min, OFF

16) The low alarm limits of pulse rate: PR ALARM_L**:** OFF, 40-100/min

17) Default reload: LOAD-DEFAULTS

18) Exit: EXIT

Default values as follow:

APNEA time: 30S

$EtCO_2$ alarm high limit: 50 mmHg

$EtCO_2$ alarm low limit: 19 mmHg

$FiCO_2$ alarm high limit: 50 mmHg

$FiCO_2$ alarm low limit: OFF

RESP alarm high limit: 30 rpm

RESP alarm low limit: 08 rpm

Fi &EtHAL/ENF/ISO/SEV alarm high limit: 50 mmHg

Fi &EtDES alarm high limit: 84mmHg

Fi &EtHAL/ENF/ISO/SEV/DES alarm low limit: 19 mmHg

Fi &EtN_2O alarm high limit: 98%

Fi&EtN_2O alarm low limit: 26%

SpO_2 alarm low limit: 95%

PR alarm high limit: 160/min

PR alarm low limit: 60/min

5.6 Trend

The graph trend

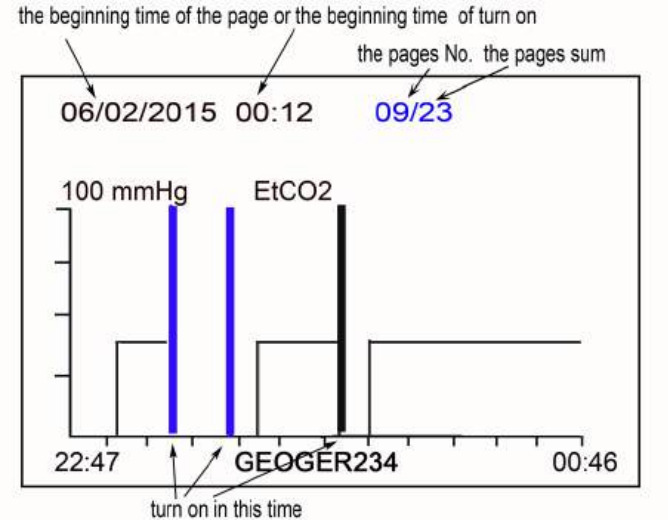


Figure 5.6

The monitor stores $EtCO_2$, RR, SpO_2 and PR or $EtCO_2$,RR,FiAG and FiN_2O as a group of data every 12seconds (Adjustable in STORE INTERVAL and STORE under New Patient menu, **detail see 5.9 NEW PATIENT SET 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 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

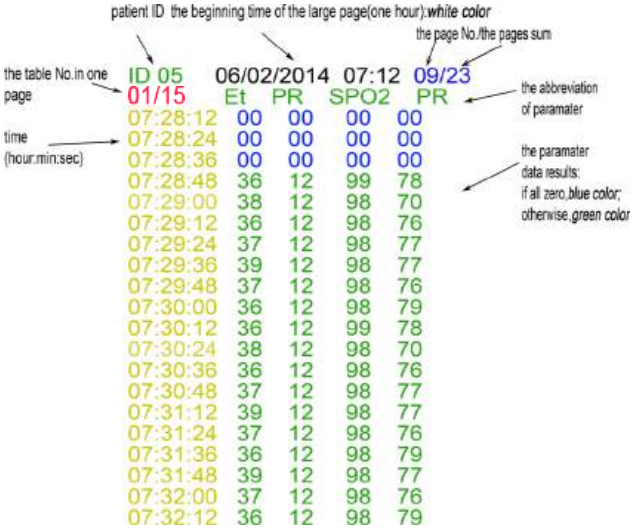


Figure 5.7

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 12 seconds 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.

5.7 TIME 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.

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.

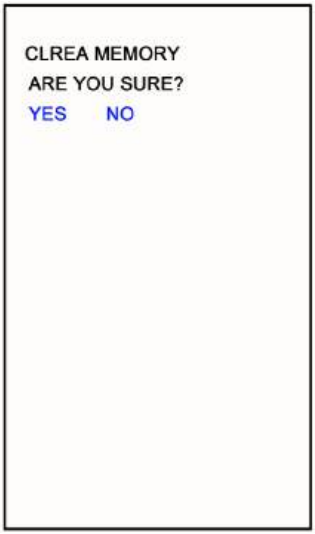


Figure 5.9

5.8 Sound SET Menu

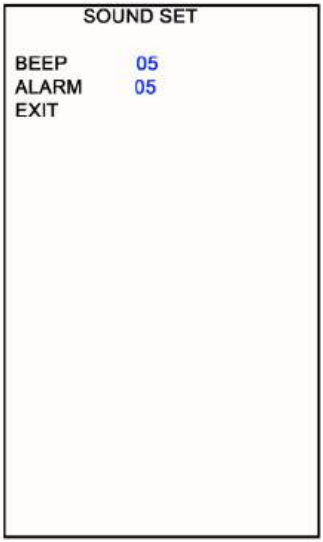


Figure 5.10

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:** 1(OFF)-8

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,** 0-99 optional

Press "Enter" key to enter or exit from the Set menu. Press ▲ or ▼button to move the cursor up or down, press ► or ◄ button to change the data highlighted by the cursor.

4.) **AGE: patient's** age, 00-80 optional

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

6.) **STORE:** adjustable stored parameters as $EtCO_2$, RR, $SpO_2$and PR or $EtCO_2$, RR, FiAG and FiN_2O

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

8.) **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)

9). **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 indicator flash red  in 5 minutes before battery depletion, 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 replacement method:

Battery life is one year, please replace the battery in time.

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.

Warning: Battery must be replaced by professionally trained personnel, otherwise it may result in fire or explode.

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 /water trap 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 sample line or filter should be not sterilized and used repeatedly if the packing indication shows that it is disposable.

Attention: For the environment, disposable sample line or filter 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 GAS are 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 GAS are zero 1. Screen indicating PUMP ERR and big noise. 2. Screen indicating IR-LAMP-BAD 3. Screen indicating 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 GAS 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. 4. Red light in the sensor	1.Warm up finger 2. Avoid strong external light. 3. Place SpO_2 sensor on other arm or position. 4.Renew SpO_2 sensor 5.Clean internal parts of SpO_2 Sensor

		no flashing. 5. Infrared and collector of sensor is not clean	
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.

8 Accessories list

Accessory	Quantity
Filter	6
Sampling line (optional)	1
Adult Nasal tube (optional)	1
Infant Nasal tube (optional)	1
Airway Adapter	1
SpO_2 Probe	1
USB Cable	1
AC/DC Adapter	1
User manual	1

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
EtHAL	The halothane concentration of expiration end phase
FiHAL	The halothane concentration of inspiration phase
EtENF	The enflurane concentration of expiration end phase
FiENF	The enflurane concentration of inspiration phase
EtISO	The isoflurane concentration of expiration end phase
FiISO	The isoflurane concentration of inspiration phase
EtSEV	The sevoflurane concentration of expiration end phase
FiSEV	The sevoflurane concentration of inspiration phase
EtDES	The desflurane concentration of expiration end phase
FiIDES	The desflurane concentration of inspiration phase
SPO_2	Oxygen saturation
RR	Respiration rate
PR	Pulse rate
MAC	Minimum Alveolar Concentration
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.

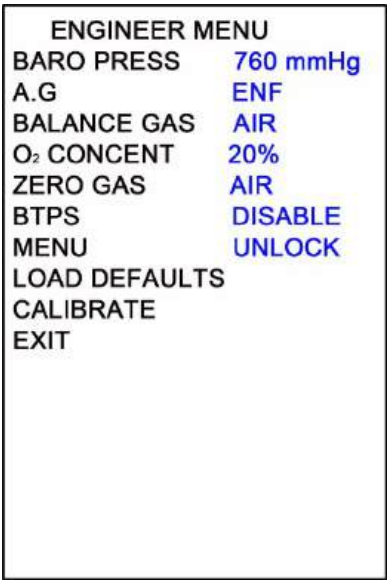


Figure A2.1

In this menu, press ▲ or ▼button to move the cursor up or down, press ► 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:

BARO PRESS: 760mmHg

A.G HAL, ENF, ISO, SEV or DES

BALANCE GAS: AIR, N_2O, and HELIUM

O_2 CONCENTRATION: 20%-99%

ZERO GAS: AIR, N_2

BTPS: ENABLE, DISABLE

MENU: UNLOCK, LOCK

LOAD DEFAULTS

CALIBRATE

EXIT

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 %

ZERO GAS: AIR

BTPS: DISABLE

MENU: UNLOCK

Appendix 3. Calibration with Standard Gas

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

All monitors have been calibrated before being shipped by the manufacturer. Moreover, during each Startup, Drift Suppression and Gain Adjustment will be performed according to many factors such as temperature, pressure, balance gas in the working environment. Generally, the user does not need to calibrate this device other than the recommended annual check. If it has been more than one year since the last calibration, and the readings are clinically suspected to be inaccurate, the following procedure can be followed to perform the calibration.

1. Required Parts and Items:

1.) Standard Gas

Standard Gas Concentration:

The standard gas concentration of CO_2 is about 5.0%, preferably between 5.0-7.0%

The standard gas concentration of N_2O is 50%-70%

The standard gas concentration of Halothane is 3%-5%

The standard gas concentration of Enflurane/Isoflurane/Sevoflurane is 4%-6%

The standard gas concentration of Desflurane is 6%-18%

The Oxygen concentration is 60-100%

2.) Three-way connector: The inner diameter is 1-3 mm, which is used to connect the "Standard Gas Bottle", "monitor" and "outdoor" for connection and protection. The device will be damaged by the high pressure of the standard Gas Bottle if the connector is not used. It is strictly forbidden to connect the 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. The 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:

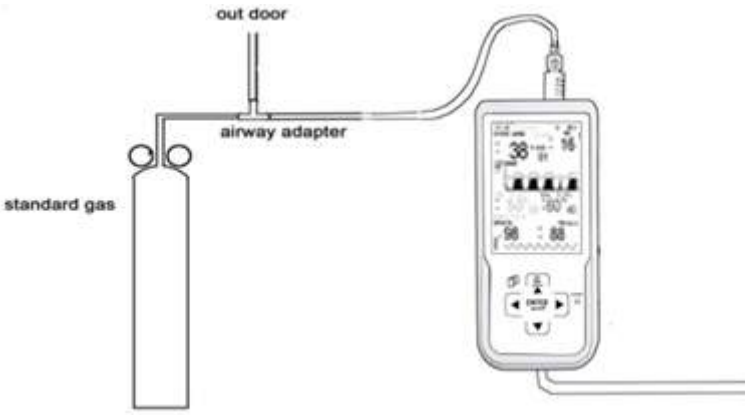


Figure A3.1

⚠ WARNING ⚠:

When N_2O and/or anesthetic agents are being used, pollution of the operating room by these gases should be prevented. The gas exhaust should normally be connected via an exhaust line(OD:4mm, ID:2mm), to:

- a scavenging system (for evacuation of the sampled gas), or
- the patient circuit (for return of the sampled gas.

3.Warm-up

Power on and run the unit for more than 5 minutes and adjust the pump flow rate to over 100cc/min. To check if there is a leak according to the following method: fold the sampling tube by hand, if the display screen shows ' occlusion ', there is no air leak. Otherwise, there is a leak somewhere in the pipeline, it is not suitable to do calibration. The leak point should be checked first and then calibrated after removing the leak point. Otherwise, the measured value will be lower due to air leakage.

4.Calibrate

Press and hold the ► and ▼ simultaneously for entering the engineer menu (procedure given at Appendix 2), move the cursor to CALIBRATE, long press ENTER button to enter the following menu.

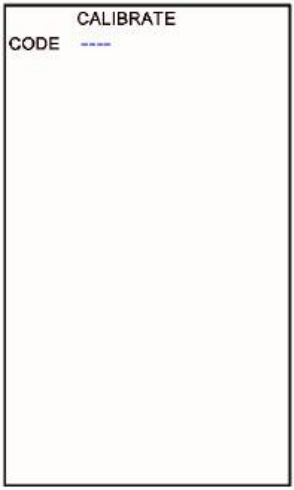


Figure A3.2

At this time, move the cursor to the CODE, and press the ENTER key to enter or exit the password setting. Press the ► or ◄ key to move the cursor position, and press the ▲ or ▼ key to change the letters or numbers at the cursor position to complete the password setting.

Enter the password XXXX to enter gas Calibration. If the password is incorrect, you cannot enter the calibration menu.

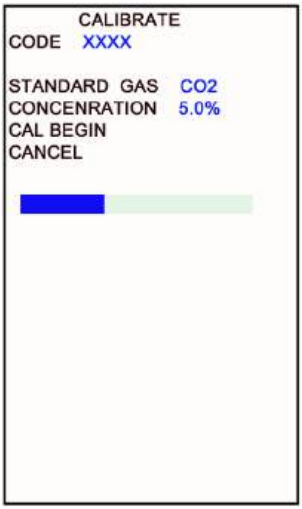


Figure A3.3

In the Multi-gas Calibration menu, move the cursor to the **STANDARD GAS** for selecting the type of standard gas. Under **CONCENTRATION,** adjust the value to the same concentration as the Standard Gas. If the standard gas concentration is accurate to two decimal places, to the nearest whole number.

Open the standard gas according to the above requirements and precautions, move the cursor to **CAL_BEGIN** and press the ENTER key to start the calibration. ADJUSTING! appears in the middle of the screen (calibrating).

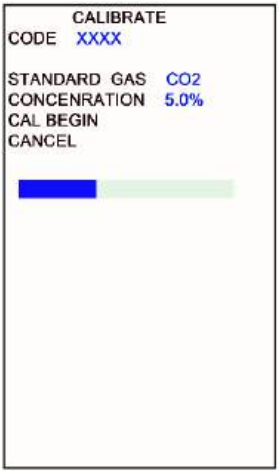


Figure A3.4

The Progress Bar 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.

If you want to stop the calibration process, move the cursor to CANCEL and press ENTER, or directly press MENU to exit.

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

Appendix 4. 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 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	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

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
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz (6V in ISM radio bands between 0.15MHz and 80 MHz)	3 Vrms 150 kHz to 80 MHz (6V in ISM radio bands between 0.15MHz and 80 MHz)	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
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m	

			vicinity of equipment marked with the following symbol. 

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.

Ver : 1.4

Date : 2024.01