

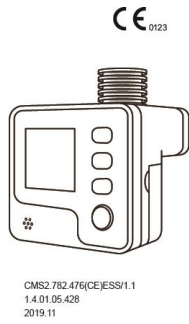
CA10M

Capnograph

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Preface

Dear user, thank you very much for purchasing the Capnograph. This device is a kind of medical product that can be used repeatedly. This user manual contains instructions for use and technical notes of the device, and describes its features and requirements, main structure, performance, specification, as well as correct method of transportation, installation, operation, maintenance, repair and storage, and also the safety precautions of protecting the operator and device. Refer to the following chapters for details. Please read the User Manual carefully before using this product. The operating procedures specified in this User Manual should be followed strictly. This manual describes in detail the operation steps must be noted, the procedures may result in abnormal, and possible damage to the product or users. Failed to follow the User Manual may cause measuring abnormality, device damage and personal injury. The manufacturer is NOT responsible for the safety, reliability and performance issues of such results due to user's negligence of this manual for using, maintenance or storage. The free services and repairs does not cover such faults either.

Upon request, our company may provide, with compensation, necessary circuit diagrams to help qualified technician to maintain and repair the parts that our company defined as user serviceable.

For product upgrade, the device you received may not exactly in keeping with the description in this user manual, and we sincerely apologize for that.

Content of this manual is subject to change without prior notice. Our company reserves the final explanation right to this user manual.

Warning

Reminding the things that may cause severe consequences to the patient, operator or environment:

- Do not use the device under flammable gases existing, such as anesthetic gas.
- Do not throw battery into fire to avoid explosion.
- Do not charge the dry battery to avoid current leakage, then causing fire or even explosion.
- The device can be only operated by the professional personal who has been trained and familiar with the user manual.
- Nitric oxide, high concentration of nitrogen, helium, xenon, halogenated gases and atmospheric pressure may affect the CO2 measurement.
- The device is not intended for use with parts, accessories or adapters that are not approved by the manufacturer. Do not use adult gas path adapter for newborns, as it will introduce additional dead space to the gas path.
- Do not apply the newborn gas path adapter on adults, otherwise the airflow may be blocked.
- The measurement accuracy of CO2 is influenced by the following factors: gas path blockage, air leakage and sharp temperature changes.
- Avoid electrostatic discharge (ESD) and electromagnetic interference (EMI) from other equipment.
- In the presence of equipment with electromagnetic interference, such as MRI, the device may be subject to electromagnetic interference. When the electromagnetic field is higher than 20V/m, the performance of the module will be seriously affected.
- If the device is used in conjunction with a ventilator or with hazardous gas, such as N2O, it is necessary to check the air tightness of the gas path connection before use.
- Moisture and secretions in the gas path adapter can affect the optical transmission. When using the device in a hot and humid environment, keep the adapter upright, and replace it if necessary.
- Do not use the device together with a nebulizer, or else the optical transmission of the gas path adapter will be affected.
- The disposal of waste and residue should comply with corresponding national laws and regulations, otherwise it will cause pollution to the local environment.
- For the details of clinical limitations and contraindications, please refer to relevant medical literature carefully.
- Do not set the alarm limit to the value beyond the device limits, or it may disable

the alarm system.
Unauthorized modification may result in danger.

Chapter 1 Overview

1.1 About the Capnograph

Capnograph adopts mainstream method to measure the end-tidal carbon dioxide, airway respiration rate and other parameters. It can detect pulmonary ventilation function and reflect the circulation and pulmonary blood flow condition, as well as indirectly reflect the alveolar ventilation, which is applicable for use in pre-hospital emergency transfer, emergency department, ICU, operating room, neonatology, respiratory department and other occasions. The application population is adult, pediatric and neonate patients. The Capnograph connects with patient's respiratory tract by the airway adapter (applied part) and breathing tube.

1.2 Accessories

- User Manual (1)
- Adult gas path adapter (1)
- Neonate gas path adapter(1) (optional)

1.3 Working environment

- Temperature: 5°C ~ 40°C
- Relative humidity: 30% ~ 75%, no condensation
- Atmospheric pressure: 700hPa ~ 1060hPa
- Waterproof degree: IP22
- Input voltage: DC 3V (2 AAA batteries)

1.4 Attentions

- The device should be inspected regularly in order to ensure there is no obvious damage that may affect the safety or monitoring performance. It is recommended to inspect the device at least once a week. Stop using the device if any damage found.
- Only the qualified maintenance person appointed by the manufacturer has the authority to maintain the device. Do not repair the device by yourself.
- The device is calibrated when leaving the factory.
- If the device alarms for low battery, it is recommended not to start the CO2 measurement function, otherwise the device may shutdown.
- Do not soak he device into liquid or directly spill liquid on the device.
- The device has automatic atmospheric pressure compensation.
- If the airway respiration rate or the ratio of expiratory time to inspiratory time exceeds specified range, the measurement accuracy of end-tidal CO2 may be reduced.

Chapter 2 Working Principle

When the device is working, the infrared light source emits periodic infrared light according to the preset modulation frequency, the emitted infrared light can incidence to the sampling window of gas path adapter, the CO2 gas in the adapter absorbs the infrared light of a specific wavelength. Then the infrared light of other wavelength that goes through the sampling window will be regarded as measurement signal and obtained by the light-sensitive element, after by electronic circuit and microprocessor processing, the measured result is displayed on the screen.

Chapter 3 Technical Specification

3.1 Main functions

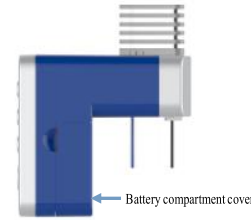
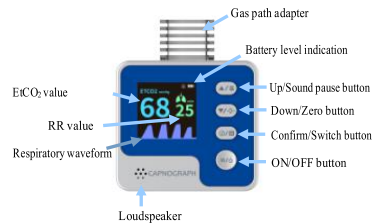
- Able to measure the EtCO2
- Able to measure the respiration rate
- With over-limit alarm function for EtCO2 and RR
- With low battery alarm function (battery voltage lower than 2.35V)

3.2 Main parameters

- A. End-tidal CO2**
Range: 0~150mmHg
Resolution: 1mmHg
Accuracy:
0~40 mmHg: ±2 mmHg
41~70 mmHg: ±5% of reading
71~100 mmHg: ±8% of reading
101~150 mmHg: ±10% of reading
- B. Respiration rate**
Range: 2 ~ 150 rpm
Resolution: 1rpm
Accuracy: ± 1rpm

Chapter 4 Operation Guide

4.1 Device structure



4.2 How to operate

4.2.1 Battery installation

A. Remove the battery compartment cover on the rear of the device, as shown in Figure 1.

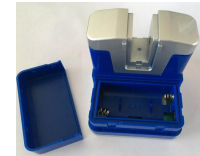


Figure 1

B. Gently press two 1.5V AAA alkaline batteries into the battery compartment according to the positive and negative marks (consistent with the polarity marks in the battery compartment). As shown in Figure 2.



Figure 2

C. Install the battery compartment cover, as shown in Figure 3.



Figure 3

Note: Batteries must be installed in accordance with "+" "-" marks, otherwise the device may be damaged.

Note: It is required to replace 2 new batteries of the same type at the same time.

4.2.2 Gas path adapter connection

Select a proper gas path adapter and connect it to the slot on the device. The connection will be appropriate if the gas path adapter is correctly connected.

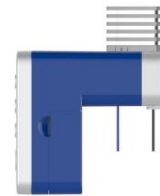


Figure 4

4.2.3 Startup

Long press the ON/OFF button to enter the measuring interface. The interface after

startup is shown as Figure 5.

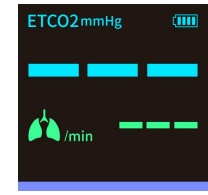


Figure 5

4.2.4 Alarm limits setup

Under the measuring interface, long press the Confirm/Switch button to enter the setup interface. Short press Up or Down button to choose the item that need to be adjusted, and short press the Confirm/Switch button to confirm the selection, then use Up/Sound pause button and Down/Zero button to adjust the alarm limit value, as shown in Figure 6.

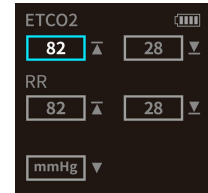


Figure 6

4.2.5 Switch unit

Under the setup interface, short press Up/Sound pause button or Down/Zero button to move the cursor to the unit, short press the Confirm/Switch button to confirm the selection, then use Up/Sound pause button and Down/Zero button to change the unit, the options are "mmHg", "kPa" and "%".

4.2.6 Zero calibration

Each time the device uses a new gas path adapter, it should process zero calibration according to the following procedure:

Connect the gas path adapter with the respiratory circuit, then install the adapter on the device, and make sure the device is far away from all objects that may generate CO2,

including air conditioner, patient and the operator. Long press the Down/Zero button, the interface as shown in Figure 7 appears, and the device starts zeroing.

Normally, the zero calibration lasts 15~20 seconds. When it is finished, the interface as shown in Figure 8 appears. If the device does not reach the zero calibration condition (i.e. preheating is not finished, or the period of no breath detected is less than 12seconds), after pressing the Zero button, the failure interface of zero calibration appears, as shown in Figure 9.

Wait a few seconds under the failure interface, the device will jump to the measuring interface. At this moment, the device needs to wait to reach the zero calibration condition (i.e. preheating is finished and the period of no breath detected is over 12 seconds), then perform another zero calibration.

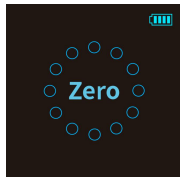


Figure 7

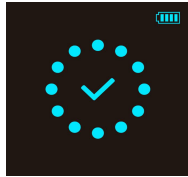


Figure 8

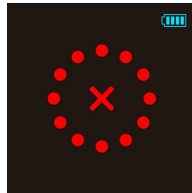


Figure 9

Note: The zero calibration can be performed only after the device has not detected breathing for 12 seconds.

4.2.7 Measurement

As shown in Figure 10, connect the gas path adapter with the respiratory circuit, and install the adapter on the device according to Section 4.2.2, after the zero calibration is finished, it is available to start the measurement.

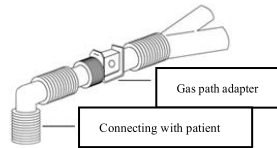


Figure 10

Note: The measurement can be affected by the following factors:

- ★ Leakage or internal leakage of sample gas
- ★ Mechanical shock;
- ★ Excessive circulation pressure and abnormal pressure change of the gas path;
- ★ Quantitative effect of temperature and condensation
- ★ Gas or steam interference
- ★ Periodic pressure rising to 10kPa(100 cmH2O)
- ★ Other interference sources

4.2.8 Alarms

4.2.8.1 Over-limit alarm

When the detected EtCO₂ or RR value exceeds the preset limit, the device generates over-limit alarm. On the display interface, the parameter turns red, at the same time, the corresponding upper limit or lower limit icon appears and flickers continuously.

Figure 11 shows the alarm status that the detected RR value exceeds its lower limit.

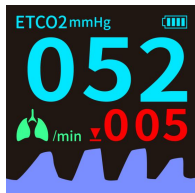


Figure 11

Figure 12 shows the alarm status that the detected CO₂ value exceeds its upper limit.



Figure 12

4.2.8.2 Alarm for gas path adapter falling off

When the gas path adapter falls off or the connection between adapter and the device is bad, the device alarms for gas path adapter falling off, as shown in Figure 13.

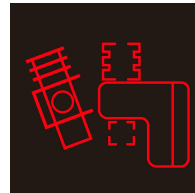


Figure 13

To verify the whether the alarm function is normal, user can remove the gas path adapter to see if the device generates an alarm.

4.2.8.2 Alarm sound pause


In the alarm state, long press the Sound pause button the icon  as shown in Figure 14 appears, at the same time, the alarm sound stops, and it automatically recovers 2 minutes later.



Figure 14 Physiological alarm

Alarm type	Causes	Alarm level	Delay
ETCO ₂ upper limit alarm	ETCO ₂ value exceeds the upper limit	High	Less than 30s
ETCO ₂ lower limit alarm	ETCO ₂ value exceeds the lower limit	High	Less than 30s
RR upper limit alarm	RR value exceeds the upper limit	High	Less than 30s
RR lower limit alarm	RR value exceeds the lower limit	High	Less than 30s

Technical alarm			
Alarm type	Causes	Alarm level	Delay
Disconnection alarm	Gas path adapter falls off from the device.	High	Less than 1s
Low battery alarm	Low battery	Low	Less than 1s

4.3 Software description

Software name: CA10M

Software specification: no

Release version: 1.0

Naming rule for version: <Major enhance software upgrade>.<Minor enhance software upgrade>.<Improvement software upgrade>.<construction>

Involved algorithm

Name: photoelectric ETCO₂ detection technology

Type: mature arithmetic

Purpose: be used to calculate user's ETCO₂ and respiration rate values.

Clinical function: the algorithm adopts photoelectric ETCO₂ detection technology to calculate ETCO₂ and respiration rate values, to make the user know the his physical condition.

Chapter 5 Cleaning, Maintenance and Storage

5.1 Cleaning and Disinfection

Remove batteries before cleaning, and do not directly immerse the device into liquid. Wipe the surface of the device with 75% medical alcohol, then air dry or use a clean and dry cloth to clean. Do not directly spill liquid on the device to avoid the liquid entering the inside of device.

5.2 Maintenance

- The device should be inspected regularly in order to ensure there is no obvious damage that may affect the safety or monitoring performance. It is recommended to inspect the device at least once a week. Stop using the device if any damage found.
- Please clean and disinfect the device before or after using according to Section 5.1.
- Replace batteries when the device prompts low battery.
- Take out the batteries if the device is not used for a long time (over 3 months).














5.3 Transport and Storage









- The packed device can be transported by ordinary conveyance or according to transport contract. Avoid violent shock, vibration, rain and snow splash during transporting. Do not transport it mixed with toxic, harmful, corrosive material.
- The packed device should be stored in room with no corrosive gas and good ventilation. Atmospheric pressure: 500hPa ~ 1060hPa, Temperature: -40°C~+55°C; Relative Humidity: ≤95%

Chapter 6 Troubleshooting

No	Problems	Cause analysis	Solutions
1	Unable to turn on the device	1. Low battery or batteries run out. 2. Battery polarity is connected falsely. 3. Something wrong with the device.	1. Replace batteries. 2. Install the batteries correctly. 3. Contact the local customer service.
2	The display information disappears suddenly	1. Low battery. 2. Something wrong with the device.	1. Replace batteries. 2. Contact the local customer service.
3	The display of data is abnormal or unstable	1. The adapter of gas path is not properly installed. 2. Air leakage in the gas path. 3. The working environment does not satisfy the requirements in this user manual. 4. Something wrong with the device.	1. Check the connection of adapter. 2. Check the connection of gas path. 3. Use the device under normal working environment condition. 4. Contact the local customer service.
4	The device prompts that the adapter of gas path is not connected.	The adapter of gas path is not connected.	Check the connection of adapter.

Chapter 7 Symbols

Symbol	Meaning
	ON/OFF button
	Confirm/Interface switch button
	Down/Zero button
	Up/Sound pause button
	Alarm sound pause icon
	Battery level icon
	Exceeding upper limit
	Exceeding lower limit
	"Caution", please refer to the accompanying document (this user manual)
	ETCO ₂ concentration, unit: mmHg
	Respiration status indication
	WEEE (2002/96/EC)
	Serial number

	Date of manufacture
	Manufacturer
	Temperature limitation
	Humidity limitation
	This way up
	Fragile, handle with care
	Keep dry
	This item is compliant with Medical Device Directive 93/42/EEC of June 14, 1993, a directive of the European Economic Community.

Chapter 8 Specification

EtCO ₂	
Range	0 ~150 mmHg
Resolution	1mmHg
Accuracy	0~40 mmHg: ±2 mmHg 41~70 mmHg: ±5% of reading 71~100 mmHg: ±8% of reading 101~150 mmHg: ±10% of reading
Alarm range	Upper limit: 1~150 mmHg Lower limit: 0~149 mmHg
Measurement accuracy drift	Meet the requirement of measurement accuracy
Respiration rate	
Range	2~150 rpm
Resolution	1 rpm
Accuracy	±1 rpm
Alarm range	Upper limit: 1~150 mmHg Lower limit: 0~149 mmHg
Power requirement	
Two AAA batteries	
Working hour	
4 hours	
Total response time of system	
<0.5s	
Preheat time	
15s	
Dimension and Weight	
Dimension	55*52*59mm
Weight	97g (with batteries)
Service life	
3 years	
Alarm sound pressure level	
50dB	