RWD

Veterinary Capnograph

User Manual A

RWD Life Science Co.,Ltd

Intellectual Property Right

The intellectual property rights of this product and its instruction manual belong to RWD Life Science Co., Ltd (hereinafter referred to as the RWD), including, but not limited to patent, trademark, copyright etc.
RWD reserves final interpretation right of this instruction manual.
RWD have the right to use the instruction as confidential information. Any individual and/or organization shall not disclose the instruction of all or part of the information by any means without RWD's written permission. Nor shall any other person or organization be allowed to obtain all or part of the information of this instruction manual by any means.

No individual and/or organization shall publish, modify, reproduce, issue, rental, adapted, and translated into other languages without RWD's writen permission.

RWD is RWD's registered trademark or mark, these trademarks and the related security mark belong to RWD's intangible property. The use of non RWD's trademark or mark in this instruction manual are only for editing purposes, without other purposes, the rights belong to their respective rights owners.

Statement

RWD reserves the right to modify the content of this manual without prior notice.

RWD reserves the right to change the technology without prior notice.

RWD reserves the right to modify the product specifications without prior notice.

RWD does not guarantee the information in any forms, including (but not limited to) the responsibility of proposing the implied merchantability and suitability for a specific purpose.

RWD in only the following conditions is considered to be responsible for the safety, reliability and performance of the instruments, i.e.:

Assembly operation, expansion, adjustment, improvements and repairs carried out by RWD authorized personnel;

Relevant electrical equipment in line with national standards;

The instrument is operated according to the instruction manual.

RWD is not responsible for the products' safety, reliability or operation status in the following conditions:

Components are disassembled, stretched or debugged;

Non RWD authorized personnel repairs or alterations to the instruments;

Product may not in accordance with the manual.

Contents

1-Introduction

1.1 Overview

Thank you first for choosing the RM-C1 Veterinary Capnograph manufactured by the RWD Life Science Co., Ltd (hereinafter referred to as the RWD)!

For better use of this product, please read the supplied instructions carefully before the initial installation and use of this product.

RWD Life Science Co., Ltd. is endeavored to improve the product function and service quality. RWD reserves the right to change or alter the contents of user manual without prior notice.

If you would like the latest product information, you are welcome to call us or visit our website (http://www.rwdstco.com/). If you find any discrepancy between the instruments and this manual during the practical use of our product, or if you have any questions or suggestions, you are welcome to contact us.

1.2 Safety

In order to avoid the harm to the animal or operator and the damages to the device, please refer to chapter "***2-System Safety***".

If you have any questions or suggestions related to safety, please contact our company for after-sales service support.

This device is only used for clinical or scientific research of animals and is not allowed to be used on humans!

The veterinary capnograph should only be operated by trained personel.

1.3 Comprehensive description

The Capnograph is comprised of an airway adapter and a sensor body that fits on top of the adapter.

1.4 Application

Capnograph measures, displays and monitors CO_2 partial pressure and respiratory rate during anesthesia, recovery and respiratory care. It may be used in the operating suite, intensive care unit, patient room, emergency medicine and emergency transport settings.

1.5 Working principle

The Capnograph measures the concentration of CO_2 in the breathing gas based on the NDIR technology. Different gases absorb infrared light of a specific wavelength.

The stationary infrared light source emits a beam of invisible infrared light through the airway adapter, and the respiratory airflow flows in the airway adapter. As the beam passes through the airway adapter, some light is absorbed by the gas mixture. The absorbed beam reaches the infrared detector fixed at the other end. The infrared detector is equipped with two filters of different wavelengths, one of which has very strong absorption of CO_2, and the other one has no absorption of CO_2.

The infrared detector converts the beam into an electrical signal, which is converted to a digital value and sent to the microprocessor. The microprocessor then calculates the CO_2 concentration in the breathing gas mixture using the ratio of the light of the two measurement channels.

2-System Safety

2.1 Warnings

- WARNING! Capnograph should only be used for the purpose and in the manner described in this manual.
- WARNING! Capnograph only be used by trained professionals.
- WARNING! Capnograph must not be used with flammable anesthetic agents.
- WARNING! Use only Airway Adapters supplied by RWD.
- WARNING! No modification of the Capnograph probe or the Capnograph Airway Adapters is allowed.
- WARNING! Capnograph Airway Adapters shall not be reused. Reuse of single use Adapters can cause cross infection. Used Airway Adapters shall be disposed of in accordance with local regulations for medical waste.
- WARNING! Measurements can be affected by mobile phones and RF communications equipment. It should be assured that Capnograph is used in the specified electromagnetic environment.
- WARNING! Capnograph is intended only as an adjunct in animal assessment. It shall be used in conjunction with the assessment of clinical signs and symptoms.
- WARNING! If Capnograph is used with a respirator or with harmful gases such as N_2O, always perform a pre-use tightness check of the animal circuit.
- WARNING! Light transmission can be affected by secretions and moisture pooling on the Capnograph Airway Adapter windows. When using heated humidifiers special care should be paid to position the Airway Adapter in a vertical position and to change Airway Adapter if necessary.
- WARNING! Do not use Capnograph with nebulized medications as this may affect the light transmission of the Capnograph Airway Adapter windows.
- WARNING! Do not operate the Capnograph when it is wet or has exterior condensation.
- WARNING! Audible alarm of any monitor may not be heard in some loud environments, such as when sirens are in use and the care provider is more distant from the alarm source. Alarm volume should be tested with the extremes of your noise environment to confirm ability or limitations to hear an alarm in all circumstances of the environment.
- WARNING! Replace batteries immediately when the Battery Status Indicator starts blinking. Remaining battery time depends on battery type and other circumstances and cannot be reliably predicted.
- WARNING! Lithium batteries may present a fire or chemical burn hazard if mistreated. Do not disassemble, heat above 100°C or incinerate. Dispose of used cell promptly. Keep away

from children.

- WARNING! Use only Alkaline batteries or Energizer Ultimate Lithium L92 batteries. Use of other Lithium batteries may present a risk of fire or explosion.

2.2 Cautions

- CAUTION! Use only approved accessories.
- CAUTION! If Capnograph is used in a manner other than that for which it was intended, unpredictable behavior could result.
- CAUTION! The Capnograph Airway Adapters are non-sterile devices. Do not autoclave the devices as this will damage them.
- CAUTION! Never sterilize or immerse Capnograph in liquid.
- CAUTION! Do not operate Capnograph at ambient temperatures less than 0°C or greater than 40°C.
- CAUTION! DO not store the Capnograph at temperatures less than -40°C or greater than 70°C.
- CAUTION! DO not clean the Capnograph and accessories except as directed in this guide.
- CAUTION! Remove batteries if Capnograph is not likely to be used for a period of time longer than 90 days.

2.3 Notes

- NOTE! The alarm limits will be reset to default values after power off.
- NOTE! The presence of ambient air (0% CO_2) in the Capnograph Airway Adapter is of crucial importance for a successful Zeroing. Special care should be taken to avoid breathing near the Capnograph Airway Adapter before or during the Zeroing procedure.
- NOTE! Capnograph Bluetooth device complies with part 15 of the FCC rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation. Changes or modifications not expressly approved by the manufacturer could void the user's authority to operate the equipment.

2.4 The icon means

Symbol	Title
	Date of manufacture

SN	Serial number
LOT	Batch code
REF	Catalog number
	Defibrillation-proof type BF applied part
	Refer to instruction manual
	Manufacturer
CE 0197	Symbol for CE mark. This symbol certifies that a product has met European Union consumer safety, health or environmental requirements.
EC REP	Authorized representative in the European Community
	Symbol for temperature limitation/temperature range
	For EU only: Waste Electrical and Electronic Equipment (WEEE)
	WARNING
	Alarm Mute button
	Menu button
	Power button
	Battery bay locked
	Battery bay unlocked
	Bluetooth

3-Preparations for use

3.1 Setting Up

Unpack and inspect the Capnograph for external damage. Please contact RWD After-sales personnel in case of damage.

1. Push the battery cover release button to the position, then push down the battery cover and remove the battery cover.

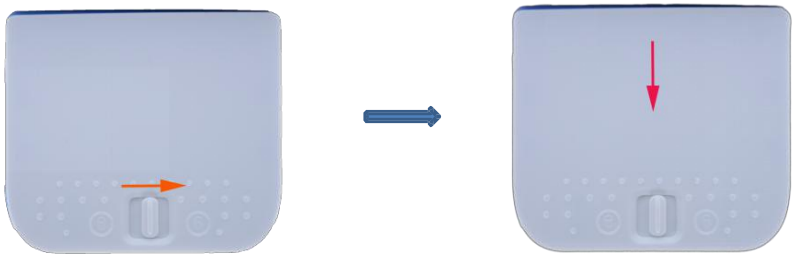

Figure 2. Releasing the Battery Cover

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

Figure 3. Install batteries

3. After battery installation, put the Battery Cover back into place, and then push the battery cover release button to the position.

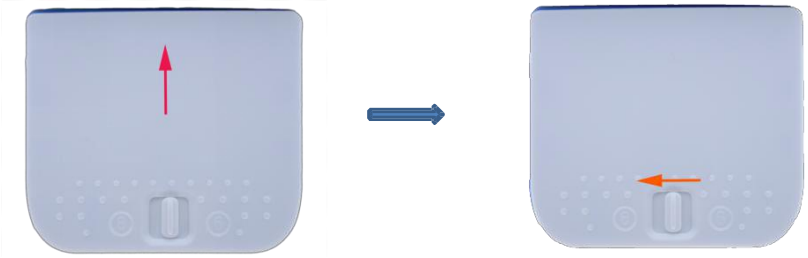

Figure 4. Installing the Battery Cover

3.2 Starting up

Press the Airway Adapter into the Capnograph. It will click into place when properly seated.

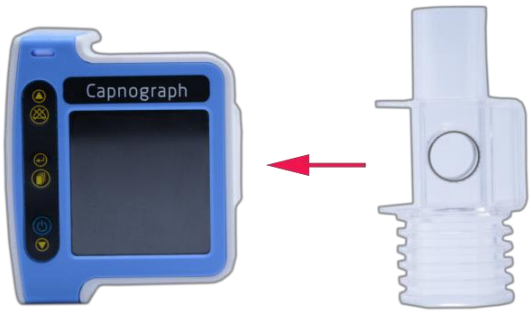

Figure 5. Connect Capnograph with airway adapter

Press the Power button.

Figure 6. Power on Capnograph

When the Capnograph is ready the $ETCO_2$ Value indicates “0” and the Respiratory Rate Value indicates “- -“.

Figure 7. Normal monitor interface

The audible alarm sound may be checked by detaching the Capnograph Airway Adapter to generate a “No Adapter” alarm.

If the $ETCO_2$ Value is non-zero, ensure that there has not been an accumulation of CO_2

between the Capnograph Sensor Body and the Capnograph Airway Adapter by removing and reattaching the Capnograph Airway Adapter. If the $ETCO_2$ Value still displays a non-zero value after this procedure, perform a Zeroing procedure as described in chapter 6.4 prior to using the Capnograph with an animal.

3.3 Shut down

When the screen not shows the menu interface, long press the power button for more than 3 seconds, the
Capnograph will shut down.

The Capnograph switches off automatically during following conditions:

- After 2 minutes if no breath is detected.
- After 2 minutes if No Breath condition is detected and the Alarm Silence is activated.
- After 60 seconds if the Airway Adapter is removed.

3.4 Connecting to the Capnograph

The Capnograph can be connected to an animal in different ways. The following pictures illustrate two methods of connection.

Figure 8. Capnograph connected to an endotracheal tube

Figure 9. Capnograph connected to a mask

4-User interface

4.1 Buttons

Capnograph has three multi-function buttons with different functions in different display interfaces:

Screen display	**Alarm Mute button** 	**Menu button** 	**Power button** 
Monitoring	Mute/Clear Mute	Enter Menu	Long press more than 2s, power off
Menu	Up/ plus	confirm	Down/ Minus
Bluetooth	Enable Bluetooth	Back	Disable Bluetooth

4.2 Bluetooth（Optional Configuration）

The Bluetooth device is default disabled when the Capnograph power on.

4.2.1 Bluetooth Settings

Enter Menu：Press the menu button to enter the menu in the monitoring interface.

1) Enter Bluetooth Menu：Press the alarm mute button (▲) or the power button (▼) to select the Bluetooth menu and press the menu button to confirm.
2) Press the mute button (▲) to turn on the Bluetooth module. Press the power button (▼) to turn off the Bluetooth module.
3) Press the menu button to return to the previous menu.

BLE Disabled

BLE connecting

BLE Connected

BLE Connected (monitoring)

Note! If the connection is disconnected during use, the power of the Bluetooth module remains on, and the Bluetooth icon on the monitoring interface flashes. The host can connect again.

4.3 Monitoring

The Capnograph is equipped with a 128*128 pixel graphic TFT display that shows the end-tidal CO_2 value, respiratory rate value, and the capnogram.

4.3.1 $ETCO_2$

The unit of end-tidal CO_2 ($ETCO_2$) defaults to millimeters of mercury (mmHg) and can be set to kPa or volume percent (%) by menu. The $ETCO_2$ value is shown after one breath and the averaged value is updated every breath.

The display range is as follows:

CO_2 **Unit**	**Value Range**	**Monitoring shows**
mmHg	0-99 mmHg	

kPa	0-9.9 kPa	
%	0-9.9 %	

4.3.2 Respiratory Rate

Respiratory Rate (RR) is displayed as breaths per minute (3 - 150 bpm). RR is displayed after three breaths and the value is updated every breath.

4.3.3 CO_2 Capnogram

The horizontal scanning speed and the scale of the capnogram can be set via the menu. The default values are as follows:

- Default scan speed: 2mm/s
- Default display scale: 0-50mmHg

4.3.4 CO_2 Settings

The CO_2 display unit, CO_2 waveform scale and scan speed can be set on the setup menu.

1) Enter the main menu: Press the "menu button" in the monitoring interface to enter the menu.
2) Enter the setup menu: Press the alarm mute button (▲) or the power button (▼) to select the setup menu, press the menu button to enter setup menu.
3) Select the setting item: Press the alarm mute button (▲) or the power button (▼) to select items.
4) Enter editing mode: press menu button to enter editing mode.
5) Adjust the setting value: Press the alarm mute button (▲) or the power button (▼) to adjust the values.
6) Exit the edit mode: press the menu button to exit the edit mode.

Parameters		**Options**	**Default**
CO_2 Unit		mmHg；kPa；%	mmHg
CO_2 Scale	mmHg	50；60；75	50
	kPa	6.7；8.0；10.0	6.7
	%	6.6；7.9；9.9	6.6
Waveform Speed		4mm/s；2mm/s；1mm/s	2mm/s

4.4 Indicators and alarms

The Capnograph is equipped with an Alarm Status Indicator and an audible alarm that may be silenced for a period of 2 minutes.

4.4.1 Alarm signals

When an alarm is triggered, an Alarm Status Indicator in the uper right corner of the display is lit with a steady or blinking yellow light depending on alarm priority, together with an audible alarm beep according to the following table:

Alarm Priority	**Indicator**	**Audible**	**Alarm**
Low	Yellow,steady	One beep，repeated every 20s	Zero point adjustment
Medium	Yellow,steady	Two beeps，repeated every 20s	$ETCO_2$ Low
			$ETCO_2$ High
			RR Low
			RR High
			No Adapter
			Clogged Adapter
			Battery Low
High	Yellow,steady	Three beeps，repeated every 20s	Apnea

Active alarms are further displayed according to the following table：

Alarm	**Screen**	**$ETCO_2$ Value**	**RR Value**
Apnea		value steady	"- -" flashing
$ETCO_2$ Low		value flashing	value steady
$ETCO_2$ High		value flashing	value steady
RR Low		value steady	value flashing
RR High		value steady	value flashing
No Adapter		n/a	n/a
Clogged Adapter		n/a	n/a

Battery Low		Depend on other alarm signal

Zero point adjustment		n/a	n/a

4.4.2 Default limits for alarms

The default factory settings for the Apnea and the Low/High $ETCO_2$ and RR alarms are as follows:

	Lower Limit	Upper Limit
Apnea	20s	-
$ETCO_2$	25mmHg	50mmHg
RR	5bpm	30bpm

4.4.3 Alarm silence

By pressing the mute button, the audio alarm can be muted for 2 minutes. When the alarm is muted, the yellow alarm mute indicator is located in the upper right corner of the display, i.e. the alarm status silence indicator will light.

Pressing the alarm mute button again during 2 minutes of silence will reactivate the audible alarm.

If a No Breath alarm is muted by pressing the Alarm Silence button, the Capnograph will automatically switch off after 2 minutes provided that no new breaths are detected.

If the alarm signal disappears when the audible alarm is muted, the alarm icon will turn green. Pressing the alarm mute button during no alarm will also show a green mute alarm indicator in the upper right corner of the display.

4.4.4 Battery Status Indicator

There is a battery status indicator in the upper right corner of the screen. The display

status of the indicator changes according to the battery power:

- When the battery is normal, the battery status indicator lights up with a steady green light
- When the battery is low, the battery status indicator begins to flash.

Battery Normal

Battery Low

4.4.5 Adjusting the alarm limit

1) Enter the main menu: press the menu button in the monitoring interface to enter the menu.
2) Enter the alarm setting menu: Press the alarm mute button (▲) or the power button (▼) to select the
   Alarm menu, and then press the menu button to enter the selected menu.
3) Select the alarm setting item: Press the alarm mute button (▲) or the power button (▼) to select.
4) Enter editing mode: press menu button to enter editing mode.
5) Adjust the alarm limit: Press the alarm mute button (▲) to increase or the power button (▼) to decrease the limit value.
6) Exit the edit mode: press the menu button to exit the edit mode.

The adjustment ranges for the $ETCO_2$ and RR alarm limits are as follows:

Alarm item	**Lower range**	**Upper range**
$ETCO_2$ displayed in mmHg	0-99mmHg	1-99mmHg
$ETCO_2$ displayed in kPa	0-13.2kPa	0.1 - 13.2kPa
$ETCO_2$ displayed in %	0-13%	0.1-13%
RR	3-150bpm	3-150bpm

NOTE! After restart, the alarm limit is reset to the default value.

5-Capnograph and accessories

Way of attachment	Name of accessories	Amo	Description
Standard	Capnograph	1	Capnograph
	Capnograph with Bluetooth	1	Capnograph with Bluetooth
Standard	Disposable airway adapter-large	1	Airway adapter is needed in order for Capnograph to provide readings.
Standard	Disposable airway adapter-small	1	Airway adapter is needed in order for Capnograph to provide readings.

6-Maintenance

6.1 Battery replacement

WARNING! Replace batteries immediately when the Battery Status Indicator starts blinking. Remaining battery time depends on battery type and other circumstances and cannot be reliably predicted.

WARNING! Lithium batteries may present a fire or chemical burn hazard if mistreated. Do not disassemble, heat above 100℃ or incinerate. Dispose of used cell promptly. Keep away from children.

WARNING! Use only Alkaline batteries or Energizer Ultimate Lithium L92 batteries. Use of other Lithium batteries may present a risk of fire or explosion.

To replace the batteries:

1) Push the battery cover release button to the  position，then push down the battery cover and remove the battery cover.
2) Gently remove the depleted batteries. And then insert two new AAA type batteries into the battery compartment. Make sure that the batteries are fitted according to the polarity marking.
3) When the batteries are properly fitted, gently snap the battery cover back into place, and then push the release button to  .

NOTE! Always carry spare batteries with Capnograph.

6.2 Cleaning

1) Remove the batteries before cleaning.
2) The Capnograph can be cleaned using a cloth moistened with 70% isopropyl alcohol.

CAUTION! DO NOT immerse Capnograph in any liquid.

6.3 Airway Adapter

- The Capnograph Airway Adapters are intended for single use. They are disposable and shall not be re-used. Reuse of single use Adapters can cause cross infection.
- Capnograph Airway Adapters shall be disposed of in accordance with local regulations for bio-hazardous waste.

6.4 Zeroing procedure

Zeroing is recommended after replaced airway adapter or whenever an offset in gas readings is discovered. Zeroing of the Capnograph is performed by the following procedure:

NOTE! The presence of ambient air (0% CO_2) in the Capnograph Airway Adapter is of crucial importance for a successful Zeroing. Special care should be taken to avoid breathing near the Capnograph Airway Adapter before

1) Start the Capnograph by pressing the Power button.
2) Make sure that a new airway adapter is properly installed.
3) Press the menu button to enter the menu interface.
4) Press the alarm mute button (▲) or the power button (▼) to select the Zero menu. When the zero countdown shows "0", the zero operation is completed.
5) Press the menu button to start zeroing. When "Zeroing" and countdown digits are displayed on the screen, it means that zero is being executed. If Zero Fails, "Zero failed" will be displayed on the screen.
6) When the zero countdown shows "0", the zero operation is completed.

Zeroing

Zero not started

Capnograph will automatically return to normal measurement mode after zero completion

6.5 Gas span check

The Capnograph does not require any routine calibration. A gas span check is recommended at regular intervals to make sure the measurement is within accuracy levels. The suggested interval for gas span check is once every year.

To perform a gas span check of Capnograph you will need:

1) A gas flow regulator with a plastic tube and a 15M connector
2) Calibration gas (5% CO_2, Balance N2)
3) Two Airway Adapters

Figure 10. Gas span check connection

The process is as follows:

1) Connect the flow regulator to the calibration cylinder. Ensure that the valve is completely closed.
2) Install a new airway adapter to the Capnograph.
3) Turn on the Capnograph and make sure the $ETCO_2$ reading is zero. Otherwise conduct a zeroing procedure according to Chapter 6.4 above before proceeding.
4) Insert the 15M connector into one end of the airway adapter, and connect a second airway adapter to the other end of the first airway adapter (see **Figure 10**).
5) Turn on the regulator flow.

6) After 30 seconds, record the $ETCO_2$ reading.
7) Turn off the flow.
8) Determine and record the estimated ambient atmospheric pressure in mmHg.
9) Use the following table to determine if the device is reading within the specified limits.

Barometric Pressure	**Capnograph $ETCO_2$ readings should be between**		
	%	**mmHg**	**kPa**
660-679	4.7 - 5.3	31 - 36	4.1 - 4.8
680-699	4.7 - 5.3	32 - 37	4.3 - 4.9
700-719	4.7 - 5.3	33 - 38	4.4 - 5.1
720-739	4.7 - 5.3	34 - 39	4.5 - 5.2
740-759	4.7 - 5.3	35 - 40	4.6 - 5.4
760-779	4.7 - 5.3	36 - 41	4.8 - 5.5
780-799	4.7 - 5.3	37 - 42	4.9 - 5.6

If the reading of the device is within the above range, then your Capnograph has been successfully verified.

If the device is not reading within the above range, disconnect the airway adapter from the cylinder and perform a Zeroing procedure according to the instructions in Chapter 6.4 above, and then repeat the gas range check procedure. If verification still fails, contact your RWD After-sales personnel for more information.

6.6 Troubleshooting

Error	**Possible causes**	**Recommended Solutions**
The unit does not turn on	No battery Low battery	Replace batteries
The unit does not complete the turn on sequence	Low battery	Replace batteries
The measured values of $ETCO_2$ are out of specified accuracy	Incorrect zero reference	Perform a Zeroing procedure and verify the measurement with reference gas

7-Specifications

7.1 General specifications

Description	Compact, battery powered, quantitative Capnograph for mainstream CO_2 monitoring of animals.
Measurements	CO_2 partial pressure and respiratory rate
Measuring	2 channel NDIR type gas analyzer，No moving parts
Warm up	Waveform displayed within 10 seconds, meets specifications within 2 minutes (at 25°C room temperature)
Calibration	No routine calibration required
CO_2 Range	0～99 mmHg 0～9.9 % 0～9.9 kPa
CO_2 Resolution	1mmHg or 0.1kPa or 0.1%
CO_2 accuracy	0～40mmHg ±2 mmHg 41～99mmHg ±8% of readings When RR is above 80 bpm ±12% of readings
Drift of CO_2 measurement	Short drift: Less than 1 mmHg offset in 4 hours Long drift: Meet measurement accuracy requirements within 120 hours
CO_2 noise	Noise RMS less than 1mmHg at 5% CO_2
Total system	Less than 500ms
Recovery time after	Unaffected
Respiratory rate	3～150 bpm
Respiratory rate	±1 bpm
$ETCO_2$	Peak of the expired CO_2 waveform
Compensation	Built-in atmospheric pressure sensor, automatic pressure compensation
Display	128 *128 pixels 1.44 inch TFT color display
Dimensions	51 x 43 x 45 mm
Weight	<65 g (Included batteries)
Mechanical robustness	Withstands repeated 1 m drops. Meets the shock and vibration requirements for transport of EN ISO 80601-2-55:2011 clause 201.15.3.5.101.2 and EN 1789:2007 clause 6.3.4.2 and 6.4.1.
Operating conditions	Temperature：0 - 40 ℃ Humidity：<90% (non-condensing) Atmospheric pressure：50-120 kPa
Storage conditions	Temperature：-20 - 70 ℃ Humidity：<95% (non-condensing) Atmospheric pressure：50-120 kPa

Alarms	No Breath, Low ETCO_2, High ETCO_2, Low RR, High RR, Clogged Adapter, No Adapter, Zero point adjustment, Low Battery
Batteries	Two AAA Cell batteries（2*1.5VDC） Alkaline IEC: LR03 or Energizer Ultimate Lithium L92 batteries. Use of other Lithium batteries may present a risk of fire or explosion
Battery life time	Bluetooth Disabled: Duracell Plus Alkaline: ~6 hours Energizer Ultimate Lithium L92: ~10 hours Bluetooth Connected: Duracell Plus Alkaline: ~4 hours Energizer Ultimate Lithium L92: ~8 hours

Interfering gas and vapor effects

Gas or Vapor	Gas Level	Quantitative Effects
Nitrous oxide	60	increases CO_2 readings 10%
Halothane	4	decreases CO_2 readings by 4%
Enflurane	5	increases CO_2 readings 5%
Isoflurane	5	increases CO_2 readings 5%
Sevoflurane	5	increases CO_2 readings 5%
Xenon	80	decreases CO_2 readings by 10%
Helium	50	decreases CO_2 readings by 6%
Metered dose inhaler propellants	Unspecified	Unspecified
Desflurane	15	increases CO_2 readings 12%
Ethanol	0.1%	No additional effect
Isopropanol	0.1%	No additional effect
Acetone	0.1%	No additional effect
Methane	1%	No additional effect
Gas or Vapor	Gas Level	No additional effect

7.2 Compliance

EN 60601-1:2006, Amendment 1 (2012)
EN 60601-1-2:2007, C1:2010
EN 60601-1-8:2007, C1:2010,
A1:2013 EN 1789:2007, A1:2010
EN 13718-1:2008
EN ISO 80601-2-55:2012
EN ISO 5356-1:2004
EN ISO 14971:2012
EN ISO 15223-1:2012

7.3 Classifications

Category AP/APG	AP - This device is not suitable for use in the presence of a flammable
The Type Of Protection Against Electric Shock	Internally Powered Equipment (Battery Power)
The Degree Of Protection	Defibrillation-proof type bf applied part
The Degree Of Protection	IP33 (spray proof and tool proof equipment)
Mode Of Operation	Continuous Operation
Sterility	No part of Capnograph is sterile

7.4 Electromagnetic compatibility（EMC）

Guidance and manufacturer's declaration – electromagnetic emissions		
The Capnograph is intended for use in the electromagnetic environment specified below. The customer or		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions	Group 1	The Capnograph 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
RF emissions CISPR 11	Class B	The Capnograph is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not Applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not Applicable	

Guidance and manufacturer's declaration – electromagnetic immunity			
The Capnograph is intended for use in the electromagnetic environment specified below. The customer or the user of the Capnograph should assure that it is used in such an environment.			
IMMUNITY test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC	± 6 kV contact ± 8 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the

Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output	Not Applicable	
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Not Applicable	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for	Not Applicable	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	30A/m	Note: The Capnograph does not contain components susceptible to magnetic fields, such as Hall elements or

Recommended separation distances between portable and mobile RF communications equipment and

The Capnograph is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Capnograph can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Capnograph as recommended below, according to the maximum output power of the

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** m		
	150 kHz to 80 MHz $d = 1.17\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.17\sqrt{P}$	**800 MHz to 2,5 GHz** $d = 1.17\sqrt{P}$
0.01	0.12	0.12	0.07
0.1	0.37	0.37	0.22
1	1.17	1.17	0.70
10	3.69	3.69	2.21
100	11.67	11.67	7.00

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated 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! Measurements can be affected by mobile phones and RF communications equipment. It should be assured that Capnograph is used in the electromagnetic environment

7.5 Bluetooth Information

Bluetooth LE Wireless Technology Information	
Modulation Type	GFSK
Max. Output Power	-1 dBm
Frequency Range	2402-2480 MHz
Antenna Peak Gain	0 dBi
Recommended Range	~3 meters line-of-sight
Radio Compliance	

Radio Modes	Bluetooth LE
USA	FCC ID: 2ABN2-RFBMS02A FCC parts 15.207 and 15.247
Europe	ETSI EN 300 328 ETSI EN 301 489-1 ETSI EN 301 489-17

8-Warranty

The warranty of this equipment starts from the date of leaving the factory. During the warranty period, the equipment cannot be used normally due to problems such as materials and process defects. RWD undertakes after-sales service such as equipment maintenance and parts replacement.

Any damage caused by improper use or over-range use is not covered by the warranty. If repair or replacement of parts is required, the cost will be borne by the user.

If the reworked equipment was found to have been unauthorised disassembly, RWD will not provide after-sales service such as warranty, free maintenance and parts replacement.

The warranty statement (including its restrictions) is exclusively issued by RWD and covers all other warranties.

RWD Life Science

Web: www.rwdstco.com
Add: 6540 Lusk Blvd, San Diego, CA 92121，USA
Add: Room201, Robeta Building, No.11 High Tech North 4th Road, Nanshan District, Shenzhen City, Guangdong Province, 518057, China
Tel: +001-858-900-6602　　+86-755-86111286
After-sales Service: +86-755-86111281
After-sales E-mail: service@rwdstco.com