# **Creative PC-900B** Hand Held Capnograph and Oximeter

# **USER INSTRUCTION MANUAL**



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# Notice

Welcome to Creative PC 900B Capnograph and Oximeter manual.

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

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

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

You may contact your local supplier or the manufacturer at the following address:

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# 1 Preface

# 1.1 Brief

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

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

# 1.2 Warranty and Maintenance

#### Warranty

This monitor has a warranty of 12 months from the date of purchase. Reusable  $SpO_2$  sensors and the battery included have a 12 month warranty. All other accessories have a warranty of 3 months or an "out of box" warranty for disposable items.

The following will invalidate the warranty:

- if the monitor is damaged due to misuse or incorrect operation (i.e. without following the user manual instruction)
- the monitor is damaged due to incorrect connection with another instrument
- the monitor is accidently damaged or dropped
- if the user modifies or changes the monitor without written authority of the company
- if the serial number is deliberately damaged, tom 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 PROACT Medical Ltd UK, unless detailed in a specific written agreement.

#### Re-packing for Repair or Calibration

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

## **1.3 Safety Requirements**

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

Warning: Indicating the possible injury on patient or operator.

- 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 use of accessories and cable other than those specified, with the exception of cables sold by the manufacturer of the device as replacement parts for internal component, may result in increased emissions or decreased accuracy of the device.
- Only use manufacturer designated accessories to ensure compliance with appropriate standards
- It is not allowed to remove the cover of the monitor.
- This monitor provides concentration of EtCO<sub>2</sub>, respiration rate, oxygen saturation and pulse rate. This data only provides assistance for diagnosis and actual diagnosis shall be made by suitably qualified clinical staff using all the clinical information and symptoms.
- In order to prevent pressure sores and correct circulation the SpO<sub>2</sub> sensor must be repositioned regularly, depending on the type of sensor used.

# 2 Technical specifications and characteristics

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

Note: The accuracy of  $CO_2$  concentration measurement is influenced by any interfering gas and/or vapour, for example N<sub>2</sub>O gas can raise the  $CO_2$ reading (2-10%), and Helium and O<sub>2</sub> can reduce the CO<sub>2</sub> reading (1-10%), so compensation should be set in the balance gas MENU to meet the accuracy requirements if such gases or vapours are present.

Update/Averaging T	ime: Option of every breath or 10, 20 or 30 seconds
Warm Up Time:	<20 seconds
Sample Flow Rate:	50–250ml/min User Adjustable. Default=100ml/min
Patient Modes:	Adult and Pediatric
Memory:	24 hours on Screen Trend and Numeric
Sensor:	<25g Single Use Gas Sample Line and Adaptor for
	Intubated and /or Non Intubated Patients
Colour Change:	Connector housing has additional LED ETCO <sub>2</sub> colour
	change feature built-in and will glow purple during
	expiration and orange during inspiration.

#### **Respiration Rate**

Range:	3 - 150 breaths/minute
Accuracy:	$\pm1\%$ of reading or $\pm1$ breaths/min whichever is greater
Memory:	24 hours on Screen Trend and Numeric

SpO <sub>2</sub> (optional)	
Method:	Creative Patented Proprietary Pulse Oximetry
Range:	0 - 100%
Accuracy:	$\pm 2\%$ for SpO <sub>2</sub> range from 70 - 100%,
	$\pm 3\%$ for SpO <sub>2</sub> range from 50 - 69%
Memory:	24 hours on Screen Trend and Numeric

### Pulse Rate (optional)

Range:	30 – 250bpm
Accuracy:	±2% for PR range from 30 - 250bpm
Memory:	24 hours on Screen Trend and Numeric

#### Power

AC Input:	100V - 250V, 50Hz/60 Hz to 5VDC Adapter with
	5V mini USB adapter Cable.
	Optional Vehicle 12V to 5V Mini USB Charger Lead

#### Battery

Туре:	Built-in rechargeable lithium battery pack		
	(3.6V, 3000mAH)		
Charging Time:	4 hours from flat		
Operating Time:	10 hours on full charge		

### **Operating Conditions**

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

#### **Storage Conditions**

Temperature:-30 to +70°CRelative Humidity:<93% (non-condensing)</td>Atmospheric pressure:50 - 120 kPa

#### **Dimensions of Monitor**

Size:70 x 160 x 40mm (W x H x D)Weight:Weight on Airway ETT/LMA <25g. Monitor 380g</td>

#### Warranty & Maintenance/ Calibration

One year warranty on main unit and lithium ion rechargeable battery Auto self-zeroing calibration, annual calibration check recommended

#### **IP** rating

IP32 when used in specified carry case.

#### **CE & Product classification**

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

#### **Type of Protection**

Class II (When used with UK/EU Power Supplies) Degree of Protection: Type BF-Applied Part Mode of Operation: Continuous Electro-Magnetic Compatibility: Group I, Class A

93/42/EEC Medical Device Directive Compliant

EC-Representative: Shanghai International Holding Corp. Gmbh (Europe)

Eiffestraβe 80, 20537 Hamburg Germany

**CE** 0123



# **3 Introduction of Monitor**

Figure 1

- (1) Screen: Displays waves, menu, alarm and all measuring parameters.
- (2)  $\blacktriangle$  /  $\bigstar$ : 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

 ${\it i}$  On the main display, to press this button to silence alarms for 2 minutes.

- (3)  $\mathbf{\nabla}$ : 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 (EtCO2, RR, SpO2, PR).

(7)  $\dot{\Box}$  Press this button to enter or quit menu or change display

(8)  $\bigcirc$  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 yellow LED is lit, the internal battery is being charged.

(10) CO2: The faucet of filter, blue color indicator flashes if the filter T3 is

off. When the filter T3 is plugged in, the indicator color will change to

blue, and it will change to red during occlusion or pump err.

(11) **SpO<sub>2</sub>:** The socket of SpO<sub>2</sub> (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.

# **4** Patient connection

# 4.1 CO<sub>2</sub> measurement

Push in and twist  $45^{\circ}$  clockwise to connect the Filter/Water Trap T3 to the Connector on the top of the Monitor. Attach the selected Gas Sampling Line to the CO<sub>2</sub> filter/Water Trap 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.





Filter/Water Trap T3:

Do not use the Monitor if the filter/water trap T3 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/Water Trap T3.



Figure 3

## Instruction for use of the Filter/Water TrapT3:

1) Insert the convex cleat of Filter/water Trap T3 into the notch of the inlet port of device and turn T3 45° clockwise.

2.) Attach male luer lock sample line connector to Filter/Water Trap T3 (Use a Male to Male Luer adapter if the sample line has Female Luer connector)

3.) Connect the other end of the Sample line to the chosen sampling point of Patient or Ventilator Circuit.

4.) Change the Filter/Water Trap T3 as needed. If the Filter/Water Trap T3 becomes dirty or the occlusion alarm is activated when it is dry then the Filter/Water Trap must be replaced.

 $\triangle$  WARNING  $\triangle$ : Ensure that connections are air tight as if

there is leakage, measured values are likely to be inaccurate.

 $\triangle$  WARNING  $\triangle$ : Use only recommended original bespoke

Filter Water Trap T3 to ensure accuracy.

# 4.2 Respiration rate measurement

The calculation of respiration rate derives from monitoring the CO2

waveform.

#### Theory introduction

1 The measure principle:

The device working theory is NON-DISPERSIVE INFRA GAS ANALYZER. The device has an AUTO ZERO ADJUSTMENT SYSTEM and GAIN CONTROL

2 Automatic Offset Calibrations

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

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

3 The Moisture Separation System:

This instrument uses a patented filter/water trap T3 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/Water Trap becomes full of water or dirt the display will show "OCCLUSION ', the operator needs to change the filter/water trap T3. The old filter can be reused after natural drying in a ventilated and dry environment. Discard the old filter/water trap if dirty.

## 4.3 Oximeter density measurement (optional)

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<sub>2</sub> 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.





#### The use of different SpO<sub>2</sub> sensors

There are a number of different SpO<sub>2</sub> Sensors for use with this monitor. Please see brochure or listing at rear of Manual for details. PLEASE NOTE: when SpO<sub>2</sub> 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".

## 4.4 Notice

## 1. Caution:

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

This device is not MRI/CT Compatible.

The filter/water trap T3 should be taken off and replaced when it is nearly full of water, otherwise water ingress may cause irreversible damage for IR measurement detector cell. Be sure that the collecting pipe is not occluded to avoid stressing the inner sampling pump and reduction of pump life.

2. Attention: other important information.

# 1). CO<sub>2</sub>:

The approved sampling lines provided by or specified by the

manufacturer or distributor, shall be used, otherwise readings may be inaccurate.

Fast changes in ambient Temperature may cause inaccuracy and in this instance the Display will show "TEMP IMBALANCE".

The measured data may be influenced by different kinds of anaesthetic gases. If it is required to calibrate interference gases please refer to Appendix 2.

Any circumstances of blocking of the gas sampling line, such as bending, folding, contamination blocking the sampling tube and filter or water trap etc. may lead to inaccurate measurement.

Serious respiratory conditions leading to exhaled CO<sub>2</sub> concentration being extremely high or low, e.g. EtCO<sub>2</sub> lower than 0.5% or higher than 11%, may generate inaccurate measurement.

Any air leaks in the sampling line circuit will seriously influence accuracy of data measured and waveform shape.

# 2) Oximeter:

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.

Only use Creative  $SpO_2$  probes approved for use with this Monitor.

Always make sure that the sensor is not contaminated or broken before use. Always take care to check that the sensor is applied correctly.

## Warning:

Do not use the SpO<sub>2</sub> 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.



1. The first line of data shows time (hour, minute)/patient ID, patient type: Adult (ADULT) or Pediatric (PED), the memory area full indicator ( $\square$ ), alarm sound closing (!), silence ( $\bowtie$ ) or non silence ( $\square$ ), bluetooth symbol (\$) and battery indicator  $\blacksquare$ . 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. Alternatively, select AUTO LOOP to overwrite the oldest data when memory is full , please see the details in  $5.8\,\text{NEW}$  PATIENT

b) If the symbol 🏛 appears, the menu is locked, the setting menu will

be disabled unless user press the three buttons  $\square$ ,  $\checkmark$ , - 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 equipped. If this symbol is green, it indicates that no bluetooth equipment is connected (e.g, bluetooth printer). If this symbol becomes white, it indicates that some bluetooth equipment is connected (e.g, bluetooth printer).

d) The middle part of the screen shows results data: EtCO<sub>2</sub> concentration, respiratory rate, inhaling CO<sub>2</sub> concentration (optional), oxygen PLETH, exhaling or inhaling state (during exhaling, the becomes blue color).

The bottom area shows CO<sub>2</sub> respiratory wave. If it is equipped with SpO<sub>2</sub>, it will show SpO<sub>2</sub>, pulse, oxygen PLETH waveform and histogram. When the pump is not operating "PUMP OFF" will appear on the screen. If the filter/water trap 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 indication:

- If the EtCO<sub>2</sub>'s value exceeds the limit of high or low alarm level, the word 'EtCO<sub>2</sub>' will flash and alert with the audible high priority alarm. This high priority alarm will also sound for respiration rate, SpO<sub>2</sub> and pulse rate alarms.
- 2) If the battery level is almost fully depleted the battery indicates completely empty, the monitor will alarm continuously and will shut down automatically.
- 3) When the apnea alarm is turned on and apnea occurs the

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

- 4) When the SpO<sub>2</sub> 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. If the alarm volume is 0, the silence indicator in the main menu will show '!'
- 6) All the parameter alarms for over limits and apnea alarm, will lead to the flashing of the red alarm indicator on the panel.

# 5.2 Initial Monitoring Screen

Long press (about 3 seconds) power key " $\bigcirc$ " to start the monitor, the initial monitoring screen is as shown in figure 6.



Figure 6

In this menu, press  $\blacktriangle$  /+ button or  $\triangledown$ /- 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 7) and enter into main display screen directly (refer to Section 5.9 NEW PATIENT MENU for details).

# 5.3 The Main Menu

MAIN MENU			
CO2 SET			
SPO2 SET			
TREND			
TIME SET			
SOUND SET			
NEW PATIENT			
EXIT			

Figure 7

Press the MENU button  $\dot{\Box}$  to enter the Main Menu to set monitor parameters (as FIGURE 7).

WARNING A: All Menu Settings are LATCHING and remain

when the Monitor is powered off. Ensure that all necessary settings are reviewed and are suitable for the patient BEFORE use.

This menu includes the following options:

The setting menu for CO<sub>2</sub>: CO2\_SETUP

The setting menu for SpO<sub>2</sub>: **SPO2\_SETUP** The trend menu: **TREND** The time menu: **TIME\_SETUP** The sound menu: **SOUND\_SETUP** The new patient menu: **NEW PATIENT**.

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

# 5.4 CO<sub>2</sub> SET Menu

EtCO2 RESP	CO2 SE ALARM_H ALARM_L ALARM_H ALARM_L	ET 1 1	50.0mmHg 19.0 30 <b>RPM</b> 08
FLOW I APNEA UNIT CO2 PL AUTO 0 SWEEF WAVE EtCO2 LOAD I EXIT	RATE TIME JMP DFF TIME SCALE AVER DEFAULTS	100 m 30 S mmHg ON 10M FAST 54mm 1BRE/	nl/Min in IHg ATH

#### Figure 8

In this menu, press  $\blacktriangle$  or  $\checkmark$  button to move the cursor up or down, press + button or - button to change the data highlighted by the cursor.

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

This menu includes the following setups:

1).The high alarm limits of EtCO<sub>2</sub>: **EtCO2 ALARM\_H:** 22-99mmHg, off

2).The low alarm limits of EtCO<sub>2</sub>: **EtCO2 ALARM\_L:** off, 10-60mmHg

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

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

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

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

7). The unit of CO2: CO2 UNIT: %, mmHg or kPa

8).Pump switch: ON or Off

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

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

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

12).EtCO<sub>2</sub> average computation time: **EtCO<sub>2</sub> Averaging:** every breath, 10sec, 20sec, 30sec

13).Default reload: LOAD-DEFAULTS

14). Exit: **EXIT** 

Attention:

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

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

Default values are as follows:

EtCO<sub>2</sub> alarm high limit: 50 mmHg

EtCO<sub>2</sub> alarm low limit: 19 mmHg

RESP alarm high limit: 30 breaths/min RESP alarm low limit: 08 breaths/min FiCO<sub>2</sub> alarm high limit: OFF FLOW\_SET: 100 CC/Min Apnea time: 30S CO<sub>2</sub> unit: % CO<sub>2</sub>\_PUMP: ON AUTO\_OFF\_TIME: 10 Min SWEEP SPEED: NORMAL EtCO<sub>2</sub> Averaging: 1 Breath WAVE SCALE: 54mmHg

# 5.5 SpO<sub>2</sub> SET Menu



Figure 9

In this menu, press  $\blacktriangle$  or  $\checkmark$  button to move the cursor up or down, press + button or - button to change the data highlighted by the cursor.

To return to the main menu highlight EXIT and press the **ENTER** button.

If you want to return the monitor to its default settings highlight LOAD DEFAULTS and Press the **ENTER** button.

This menu includes the following setups:

1). The low alarm limits of SpO<sub>2</sub>: SPO2 ALARM\_L: off, 50%-99%

2). The high alarm limits of pulse rate:

P\_RATE ALARM\_H: 70-250 beats/m, OFF

3). The low alarm limits of pulse rate:

P\_RATE ALARM\_L: OFF, 40-100 beats/m

4). Wave curve selection: CURVE WAVE: FILL or LINE

5). Renewing of defaults. LOAD DEFAULTS

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

photoplethysmogram is drawn in curve line.

Default values as follow:

SpO<sub>2</sub> alarm low limit: 92% (adult),95% (pediatric)

Pulse Rate alarm high limit: 130bpm (adult), 160bpm (pediatric) Pulse Rate alarm low limit: 50bpm (adult),60bpm (pediatric)

Curve: Line

# 5.6. TIME SET Menu

TIME SET			
YEAR MONTH DATE HOUR MINUTE SAVE EXIT	13 01 10 21 18		

In this menu, press  $\blacktriangle$  or  $\blacktriangledown$  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 following menu FIGURE 10.;
- 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 11

# 5.7. Sound SET Menu

SOUND SET BEEP VOLUME 08 ALARM VOLUME 08 EXIT

Figure 12

In this menu, press  $\blacktriangle$  or  $\checkmark$  button to move the cursor up or down, press + button or - button to change the data highlighted by the cursor.

This menu includes following setups:

Pulse sound volume: **BEEP\_VOLUME:** 0(OFF)-8

Alarm sound volume: ALARM\_VOLUME: 0(OFF)-8

If the alarm volume is 0, the top line in the main menu will show '!'

# 5.8. Trend

#### 1. The graph trend



Figure 13

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

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

1) Change patient ID under NEW PATIENT menu.

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

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

This figure shows that the time base for the trend page is 1 hours and

every point indicates the result of every 12 second. The top line of this page indicates patient's ID number, the start time of this page (date/month/year hour : minute), current page no. and sum pages (24 pages in total).

If in the corresponding time to the one page of trend table, the user turns off and turns on the device once or more times the trend table will show one or several blue vertical lines with full amplitude, at this time press  $\mathbf{V}$ , 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  $\mathbf{V}$  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  $\blacktriangle/\textcircled{A}$  button to change graph trend to table trend (see Figure 14).

In this menu, press MENU button to quit this menu and return to the main display.

#### 2. The table trend

patient ID the beginning time of the large page				arge page(o	one hour):v	white color		
	\ \			the page No./the pages sum		e pages sum		
		1		1		ł		
the ta	able No.in one	ID 05	06/0	$\frac{12}{20}$	4 07:	12 09	9/23	the abbreviation
page		00/14	Et	PR	SPC	2 P	R 🖛	of parameter
		07:28:	12 0	0 00	00	00		or paramater
time		- 07:28:	24 0	0 00	00	00		the naramater
(hou	r:min:sec)	07:28:	36 0	0 00	00	00		data results:
		07:28:	48 3	6 12	99	78		if all zero.blue color:
		07:29:	10 3		98	70		otherwise, green color
		07.29.	12 3		90	70		<i>,</i> <b>,</b>
		07.29.	24 3		90	77		
		07.29.	18 3	7 12	90	76		
		07.20		6 12	90	70		
		07:30	12 3	6 12	aq	78		
		07:30	24 3	8 12	98	70		
		07.30	36 3	6 12	98	76		
		07:30	48 3	7 12	98	77		
		07:31:	12 3	9 12	98	77		
		07:31:	24 3	7 12	98	76		
		07:31:	36 3	6 12	98	79		
		07:31:	48 3	9 12	98	77		
		07:32:	00 3	7 12	98	76		
		07:32:	12 3	6 12	98	79		

Figure 14

In this graph trend menu, press  $\blacktriangle/\cancel{\alpha}$  button to change graph trend to table trend. Press  $\blacktriangle/\cancel{\alpha}$  button again, to return to graph trend (Figure 13).

Every trend table shows **20** groups of data, including time, EtCO<sub>2</sub> (Et), respiration rate (RR), SpO<sub>2</sub>, pulse rate (PR). The store interval is adjustable at 12econds in STORE INTERVAL under NEW PATIENT menu.

There are 24 sum pages when the storage is full. Each page contains **15** trend table and each trend table contains **20** groups data. The **15** trend table in one page can be reviewed by  $\checkmark$  button. The table no. is indicated on left top of the screen in Figure 14.

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 in Figure 14. To quickly check if the four parameters of a data group are all zero, the display will display the parameter columns in blue.

# 5.9. NEW PATIENT Menu

NEW PATIENT

CLEAR MEMORY MEM MODE AUTO LOOP ID GEOGE234 TYPE ADULT STORE INTERVAL 12S POWER ON ID PROMPT YES SAVE EXIT

Figure 15

In this menu, press  $\blacktriangle$  or  $\checkmark$  button to move the cursor up or down, press + button or - button to change the data highlighted by the cursor.

In this menu, press MENU button, then to exit this menu and enter the main menu.

This menu includes the following setups:

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

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

3). ID: patient's ID, press "Enter" key to enter or exit from the Set menu.

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

4). TYPE: patient type, ADULT or PEDIATRIC options

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

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

7). **SAVE:** to store the changes made (this needs to be confirmed by

the new menu due to possibly substitution to the original data of the same ID of patient)

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

# 6 Charging, Maintenance, Cleaning

# 6.1 Charging

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

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

After DC power is connected, the monitor will recharge the battery, and will stop charging after the battery has fully recharged. Operation time for a fully charged unit is > 10 Hours. Charge time is approx. 4 Hours.

## Battery replacement method:

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

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

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

# 6.2 Maintenance

If the monitor appears abnormal (e.g. 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/water trap. Check that the filter/water trap is dry and clean before it is used. Replace the filter/water trap if it is dirty, shows any sign of contamination or if in any doubt about its condition.

# 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<sub>2</sub> 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.

### 3. Cleaning of filter/water trap T3

Only the filter surface 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.

Replace the filter/water trap if it is dirty, shows any sign of contamination or if in any doubt about its condition.

# 7 Trouble Shooting Analysis

# Simple analysis of problems

No.	Phenomena	Causes	Solution
1	The values of CO <sub>2</sub> is	1.Leaking of filter or	1. Check and
	reading too low, or	sampling tube	replace filter T3 or
	'OCCLUSION' appears on	2. Occlusion of filter	sample line
	the screen.	or sampling line	2. Clear the gas
		3. Out of Calibration	loop Occlusion
			3. Re-calibrate
			using standard gas.
2	The values of CO <sub>2</sub> is zero	1.Internal leaking	Contact the
	1. Screen indicating PUMP	inside the Pump gas	Distributoror
	ERR and big noise.	loop	manufacturer for
	2. Screen indicating	2.The IR lamp	repair.
	IR-LAMP-BAD	resource of sensor	
	3. Screen indicating CO <sub>2</sub>	damaged	
	SENSOR ERR	3.IR Sensor broken	
3	Screen indicating CAL-ERR	The last calibration	Re-calibrate using
		has failed.	standard gas.
4	Screen indicating	Damaged or incorrect	Contact Distributor
	POWER-ERR	power supply.	or manufacturer.
5	The $CO_2$ wave is not normal.	1. Temperature too	Use in normal
	1. Screen indicating	high.	environmental
	TEMP-HIGH	2. Temperature too	temperature range
	2. Screen indicating	low.	
	TEMP-LOW	3. Sharp ambient	
	3. Screen indicating	Temperature change	
	TEMP-IMBALANCE		
6	No values of SpO <sub>2</sub> or no	1.Finger too cold	1.Warm up finger
	wave	2. Interference of very	2. Avoid strong
		strong external light	external light.

		3. The measurement	3. Place SpO <sub>2</sub>
		test of SpO2 and	sensor on other arm
		blood pressure are	or position.
		done on the same	4.Renew SpO <sub>2</sub>
		arm.	sensor
		4. Red light in the	5.Clean internal
		sensor no flashing.	parts of SpO <sub>2</sub>
		5. Infrared and	Sensor
		collector of sensor is	
		not clean	
7	Flashing red color and	1. No Battery Charge.	1. Connect to
	closed down automatically.		Battery Charger.
8	Still flashing red color	1. Battery Charger	1. Check battery
	□_after the power is	power working	charger and
	supplied and AC indicator	abnormally.	cable and
	no light.		replace as
			necessary.

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

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# APPENDICES

## Appendix 1. Explanations of Terms in this Manual

MENU	Menu			
EtCO <sub>2</sub>	The CO <sub>2</sub> concentration of expiration end phase			
INCO <sub>2</sub>	The CC	D <sub>2</sub> concentration of inspiration phase		
SPO <sub>2</sub>	Oxyge	n saturation		
RR or R-RAT	E	Respiration rate		
PR or P-RAT	E	Pulse rate		
mmHg		Millimeters Mercury		
kPa		Kilopascal		
ALARM-H		Alarm high limit		
ALARM-L		Alarm low limit		
LINE		Line curve		
FILL		Filled or solid under waveform		
BEEP_VOLU	JME	Pulse volume		
ALARM_VO	LUME	Alarm volume		
LOW BATTE	RY	Low battery charge		
APNEA		Apnea or breathing stopped for a set period of time		
Breaths/Min		Breaths per minute		
CAL		Offset Calibration		
SET		Setup		
N <sub>2</sub> O:		Nitrous oxide		
HELIUM		Helium gas		
O2 CONCEN	ITRATIO	ON O <sub>2</sub> concentration compensation		
ANAESTHETIC GAS Anaesthetic gas		S Anaesthetic gas		
ZERO GAS		Base point or Zero point		
BTPS	Ter	nperature and deep lung air pressure compensation		
CALIBRATE		Calibration		
CANCEL:		cancellation		
OCCLUSION	N	Blocked filter/water trap or gas sample line		

# Appendix 2. ENGINEER MENU: Changing compensation of balance gas

**Attention:** Only the trained personnel may carry out the following the procedure. Contact your Supplier for training and advice.

Enter the engineer menu as follows:

Press + and  $\mathbf{T}$  two buttons simultaneously to enter the following menu.

ENGINEER MENU			
BALANCE GAS O2 CONCENTRATION ANESTHETIC GAS ZERO GAS BTPS MENU LOAD DEFAULTS CALIBRATE EXIT	AIR N 20% 00% AIR DISABLE UNLOCK		

Figure 16

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

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

This menu includes the following setups:

BALANCE GAS: AIR, N<sub>2</sub>O, and HELIUM O2 CONCENTRATION: 20%-99% ANAESTHETIC GAS: 0-20% ZERO GAS: AIR, N<sub>2</sub> BTPS: ENABLE, DISABLE MENU: UNLOCK,LOCK LOAD DEFAULTS CALIBRATE

#### Attention:

1. When the menu is locked, this menu is disabled. To unlock the menu,

press + and "T 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 CO2 concentration recalibration. Long press ENTER button for 8 seconds to enter this menu.

Default values are as follows:

BALANCE GAS: AIR O₂ CONCENTRATION: 20 % ANAESTHETIC GAS: 0 % ZERO GAS: AIR BTPS: DISABLE MENU: UNLOCK

# Appendix 3. Calibration of EtCO<sub>2</sub> Accuracy

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

#### 1. Attentive items and preparative work

The monitor has been calibrated before being shipped by the manufacturer. On each occasion that the monitor is switched on it will do a self-check and gain adjustment according to working environmental temperature, pressure and balance gas etc. Generally the user does not need to calibrate this device other than the recommended annual check. To check the unit using Cal Gas the following procedure must be obeyed.

#### 1.1 Required Parts and Items:

CO2 standard gas - Concentration is normally 5-8%

**Three-way connector:** A three way connector with an inner diameter of 1-3 mm (one connection vented to open air) must be used to protect the monitor when calibrating using a CO<sub>2</sub> standard gas bottle see figure 17. The device **will be damaged** by the high pressure of the standard Cal Gas Bottle if the connector is not used. It is strictly forbidden to connect the cal gas bottle directly to the device. One end of three-pass connector must be directly open to air to release gas pressure and protect the monitor.

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

#### 1.2 Connect as follows:



#### Figure 17

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

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

 Enter the engineer menu (procedure given at Appendix 2, Figure 16), highlight CALIBRATE, long press ENTER button for 8 seconds to enter the next menu.



#### Figure 18

Highlight STANDARD GAS and adjust the value to that of the concentration of CO<sub>2</sub> standard gas. If the standard gas concentration precision is to 2 decimal places numbers round up accordingly. Then highlight CAL-BEGIN and long press the ENTER button for 8 seconds, at the same time, open the standard gas as set per Figure 18 and the device will begin to calibrate. The screen will display the message 'ADJUSTING!' as sown in FIGURE 19.



Figure 19

The thick cross bars in the display will be erased as time passes and the

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

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

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

# Appendix 4. Part Numbers and Consumables listing

CR-ASK900B	Intubated Adult/Paediatric Airway Sampling Kits x 10 Pack - each kit includes 1 of each item:			
	Water Trap/Filter T3 for Creative PC-900B Monitor			
	CircuitAdaptor, 22F/15M with Gas Sample Port			
	Gas Sampling Tee, Male/Male Luers, 1.27mm ID x 3.0m			
CR2500-0000218	Water Trap/Filter T3 for Creative PC-900B Monitor	Pack of 10		
WL99370010	Elbow Connector Sampling Tee,	Pack of 50		
	22F/15M with Port & and Cap, Adult/Paed			
QPS8003-50	Gas Sampling Line, Male/Male Luers, 1.27mm ID x 3.0m	Pack of 50		
QO51035	Straight Connector Sampling Tee, 22F/15M with Port and Cap	Pack of 100		
QO12090	Male to Male Luer Lock Connector to convert Water Trap/Filter T3 to	Pack of 10		
	Male Luer-allows use of Female Luerended Sample Lines			

PLEASE NOTE: You will need to adjust the Flowrate of the sample pump down to 50 ml/min to allow the use of narrow bore very low flow Samples lines. Failure to do so may result in the Occlusion Alarm becoming active and/or premature Pump failure due to high resistance over stressing. Please call PROACT Medical Ltd for advice on Pump settings for Narrow Bore sample tubes and compatibility settings.

PB-331010 PRO-Breathe® CO2 Sampling Mask with O2 Delivery, Adult		Pack of 50
	with 2.1m O2 Tubing, Female Luer connector	
MA4000	Nasal CO2 Sample Line, Adult, 2.1m with Male Luer	Pack of 25
MA4100	Nasal CO2 Sample Line, Paediatric, 2.1m with Male Luer	Pack of 25
MA4707	Nasal CO2 Sample Line with O2 Delivery, Adult, 2.1m with Male Luer	Pack of 25
MA4703	Nasal CO2 Sample Line with O2 Delivery, Paediatric, 2.1m with Male Luer	Pack of 25
CR15040050	Creative SpO2 Sensor (Sub-D), Silicone, Adult, 2m	Pack of 1
CR15040051	Creative SpO2 Sensor (Sub-D), Silicone, Paediatric, 2m	Pack of 1
CR15040022	Creative SpO2 Sensor (Sub-D), Finger Clip, Adult, 2m Cable	Pack of 1
CR15040055	Creative SpO2 Sensor (Sub-D), Finger Clip, Paediatric, 2m Cable	Pack of 1
CR15040017	Creative SpO2 Sensor (Sub-D), Silicone Wrap, Neonate	Pack of 1
CR2302-0000013	Replacement Lithium Battery for PC-900B Capnograph	Pack of 1

CR2903-2000010	Charger Cable (USB to mini USB) 1.5m	Pack of 1
ACA-USB2UK	5V DC Mini USB to UK Plug Adapter for use with above	Pack of 1
CR-12VDC9B	12VDC Vehicle PowerAdapter to 5VDC Mini USB 3m length	Pack of 1
PROBAG-CAP	Heavy Duty Cushioned Carry Case for Creative PC-900B Monitor	Pack of 1

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

Attention: Please contact

# your distributor if you require advice, replacement parts and/ or service.

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

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

This device is intended for use in the electromagnetic environment specified below. The customer or the user				
of the equipment or system should assure that it is used in such an environment.				
Emissions test	Compliance	Electromagnetic environment-guidance		
RF emissions CISPR 11	Group 1	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.		
RF emissions CISPR 11	ClassA			
Harmonic emissions IEC61000-3-2	ClassA	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		
Voltage fluctuations/flicker emissions IEC61000-3-3	Complies	supplies buildings used for domestic purposes.		

## User Manual of Capnograph and Oximeter 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.

Immunityteet		Compliance lovel	Electromagnetic
inimunity test	IECOUOUT lest level	Compliance level	environment -guidance
			Floors should be wood,
Electrostatio			concrete or ceramic tile.
discharge (ESD)	±6 kV contact	±6 kV contact	if floors are covered with
	±8kV air	±8kV air	synthetic material, the
IEC01000-4-2			relative humidity should
			be at least 30%
Electrical fast	±2kV for power	±2kV for power	Mains power quality
transient/burst	Supply lines	Supply lines	should be that of a
	±1 kV for	±1 kV for	typical commercial or
IEC61000-4-4	input/output lines	input/output lines	hospital environment.
	+110/line (a) to		Mains power quality
Surge		±1kV differential mode	should be that of a
IEC 61000-4-5	+2kV/line(s) to earth	±2kV common mode	typical commercial or
			hospital environment.
			Mains power quality
Voltago dina	<5 % UT	<5 % UT	should be that of a
short	for 0,5 cycle	for 0,5 cycle	typical commercial or
interruptions and	40 % UT	40 % UT	hospital environment. If
voltago	(60 % dip in $U_T$ )	(60 % dip in $U_T$ )	the user of the
voitage	70 % 11-	70 % //-	equipment or system
nower supply	(30 % dip in UT)	(30 % dip in U <sub>T</sub> )	requires continued
inputlines	for 25 cycles	for 25 cycles	operation during power
IEC61000_4_11	$<5\% U_{T}$ (>95\% din in U-)	<5 % U <sub>T</sub> (>95 % dip in U <sub>T</sub> ) for 5 s	mains interruptions, it is
	for 5 s		recommended that the
			equipment or system be

			powered from an	
			uninterruptible power	
			supply or a battery.	
			Power frequency	
Power			magnetic fields should	
frequency			be at levels	
(50Hz/60Hz)	3A/m	3A/m	characteristic of a typical	
magnetic field			location in a typical	
IEC61000-4-8			commercial or hospital	
			environment.	
NOTE: $U_T$ is the a.c. mains voltage prior to application of the test level.				

# User Manual of Capnograph and Oximeter 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 th	at it is used in such	an electromagnetic environment.		
	Compliance		Electromagnetic environment -		
	IEC 6060 I lest level	level	guidance		
			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		
Conducted RF	3 Vrms	3V	d = 12 /P		
IEC 61000-4-6	150 kHz to 80 MHz		$u = 1.2 \sqrt{1}$		
Padiated PF	3.\//m	3 \//m	$d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz		
IEC 61000-4-3	80 MHz to 2.5 GHz	5 0/11	$d = 2.3\sqrt{P}$ 800 MHz to 2,5 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 metres (m). b		
			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 .b
		Interference may occur in the
		vicinity of equipment marked with
		the following symbol.

NOTE 1: At 80 MHz and 800 MHz, 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.

a: Field strengths from fixed transmitters, such as base stations for radio (cellular / cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, and electromagnetic site survey should be considered. If the measured field strength in the location in which this device is used exceeds the applicable RF compliance level above, this device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating this device. b: Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.

## 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

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	Separation distance according to frequency of transmitter (m)			
maximum output power of	150kHz to 80MHz	80MHz to 800MHz	800MHz to 2,5GHz	
transmitter (W)	$d = 1.2 \sqrt{P}$	$d = 1.2 \sqrt{P}$	$d = 2.3\sqrt{P}$	
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 metres (m) can be determined using the equation applicable to the frequency of the transmitter, where p is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.