

# V-Pod CapOx

# **Capnograph and Oximeter**

**User Manual** 

#### **GENERAL DISCLAIMER**

The intended use of the VPOD CapOx is to monitor a patient nocturnally and/or continuously for their End Tidal Capnography (ETCO2), Oxygen Saturation (SPO2), Respiratory Rate (RR), and Heart Rate (HR) non-invasively in hospitals, at a patients home, and all other various medical facilities.

# VirtuOx Inc., User Instructions

Thank you very much for your purchase.

This manual includes materials that are copyright reserved. Do not copy, reproduce or translate into other languages without the express permission of VirtuOx Inc..

Please read this manual carefully and then proceed based on the information contained here.

Do not open the V-Pod CapOx's cabinet without express written permission or any warranty will be considered null and void

We reserve the right to change certain aspects of the menu, firmware and options as technologies evolve and needs arise, we will do our best to inform when this happens and subsequently make changes or addendum to this manual as needed.

Furthermore please pay attention to the difference between the parts and or sections and this manual.

You may contact VirtuOx for technical documents about the electric circuit diagram relevant batch lists of parts or components etc. because of the continuing evolution of the device these may change.

You may contact us in the following manners:

Telephone: 877-337-7111 M-F 9am to 5pm EST.

Internet: <u>www.virtuox.net</u> Daily hours chat support, email support and direct product information.

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#### **CHAPTER 1 PREFACE**

#### I. Quick Start

The purpose of this manual is to present a brief instructional so the user has a solid working understanding of the characteristics, functions, and operation of the monitor, preventing improper results and mistakes.

This monitor can read four physical parameters of the patient simultaneously: concentration of EtCO2, respiration rate, pulse and saturation of SPO2.

#### **Warranty and Maintenance Warranty**

The following will void warranty:

- 1. The monitor is damaged due to misuse or incorrect procedure adaptation. (not following the instructions and recommendations in this manual).
- 2. The monitor is damaged due to incorrect connection with other components or devices.
- 3. The monitor is damaged due to accident or circumstance beyond normal limits (Force Majeure).
- 4. The user modifies the monitor on his/her own will without written consent of VirtuOx.
- 5. The series number, identification panel or Serial # are torn off or unreadable.

#### Maintenance

If the monitor is broken outside the warranty period, the manufacturer or distributor will maintain for additional charge. The maintenance price and conditions depend on actual circumstance.

#### II. Re-packing for shipment

Remove all sensors and accessories, then pack them in plastic bag.

It is recommended that you use the original packing boxes and packing materials.

A detailed description of the failure is required for faster service.

#### **III. Safety Procedures**

For the purpose of safety, please read the following and abide by the instructions regarding medical instruments.

Warning: The following may result in injury to patient or operator.

- This monitor is not be used to monitor a patient for suffocation, and also is not to be used during an MRI or CT.
- Always use the designated accessories, which comply with the standards of the manufacturer.
- Never remove the cover of the device.
- This monitor provides concentration of EtCO2, Respiration rate or Oximetry saturation and Pulse. This data only suggests further issues true diagnosis must be made by a doctor or trained medical professional.
- In order to prevent skin irritation, the SpO2 sensor may be moved or reapplied periodically; we recommend at least every 12 hours

#### **Chapter II Technical Specifications and Characteristics**

#### 1. Normal operating conditions:

Environmental temperature: 10ć~40ć

Relative humidity: 30%~75%

Voltage: AC 100V~250V, Frequency: 50Hz/60 Hz

Air pressure: 86kPa~106 kPa

#### 2. Concentration of EtCO2 (see note 1)

Range: 0.0-19.7% (V/V), 0-150mmHg, or 0-20kPa

Accuracy: deviation  $\pm 2$ mmHg when EtCO2 concentration in 0-40mmHg deviation  $\pm 5\%$  (reading) when EtCO2 concentration in 41-70mmHg deviation  $\pm 8\%$  (reading) when EtCO2 concentration in 71-100mmHg deviation  $\pm 10\%$  (reading) when EtCO2 concentration in 101-150mmHg range

Alarm accuracy: accuracy ~±0.2%

#### 3. Total System response time

< 1second

#### 4. Respiration rate

Range: 3 ~150 times/min.

Deviation: the larger of ±1% or ±1bpm

#### 5. Oximeter Saturation

Range: 0% 100%

Accuracy:

When within 50%~79%, ±3% (absolute value);

When within 80%~100%, ±2 %( absolute value)

#### 6. Pulse

Range: 30 times/min~250times/min

Deviation:

When within 30times/min~40times/min, ±2times/min (absolute value); when within 41times/min~250times/min, ±5 %( relative value)

#### 7. Trend

Parameter: EtCO2 concentration, respiration rate, SpO2 and Pulse

Maximum timespan: 24 hours

#### 8. Power consumption/requirements

Voltage: AC 100V-250V, Frequency 50Hz/60 Hz, DC5V

Unit requires: 5VA

#### 9. Battery

Battery pack 3.6Volt, 3AH

Battery fully charged time: 4 hours

#### 10. Transport and Storage recommendations:

Transportation: device is susceptible to sharp impact, violent vibration and

humidity.

Transport in an airtight bag or box with desiccant, allow temperature to equalize 20 minutes before application to a patient.

Environment temperature range: -40c - +55c

Relative humidity range: <93%

Storage requirements: In a dry and well ventilated room without corrosive gases or a strong magnetic field.

#### 11. Size and weight

Size: 72mm (W) x 155mm (H) x40mm (D)

Weight: approximately 600g

**Note:** The accuracy of the CO2 concentration measurement is influenced by interfering gas and vapor, for example N2O, presence can raise the CO2 reading(2-10%), and He and O2 can reduce the CO2 reading(1-10%), so adjustment should be made to the balance gas menu to meet the accuracy requirements when interfering gases exist.

# **Chapter III Chassis and Controls**



- 1.) Screen: It can display waves, menu, alarm and all measuring parameters.
- 2.) Dual Function button:
  - a) When menu (except the TREND menu) is activated, to press this button to move cursor.
  - b) When the TREND menu is activated, this button is to change between the trend graph and date table
  - when on the main display, to press this button to silence alarm for 2
- 3.) ▼ Press this button to move the cursor when in menu mode.
- 4.) Press this button to increase value.

- 5.) ◀ Press this button to decrease selected values.
- 6.) **ENTER**: Confirmation button: Press this button to enter sub menu. In the main menu, to press this button to turn on the pump directly when it is off.
- 7.) Press black button with white frame to enter or quit a menu or sub menu.
- 8.) Power button.
- 9.) Indicator **POWER**: If yellow LED is lit, the AC/DC is connected and the unit is charging, if blue LED is lit the machine is operating.
- 10.) CO2: The input/port for the moisture filter . (Required for use)
- 11.) SpO2: The socket for SpO2 probe.
- 12.) DC5V and data interface. *Note*: this is a dual purpose interface used for both data transfer to PC AND for DC charging.
- 13.) CO2 (Breath) Exhaust outlet.
- 14.) Speaker.
- 15.) Battery access.
- 16.) For wrist strap or Kensington Lock

# Chapter IV Using the device and application of sensors on a patient

#### I.CO2 measurement

The data collected will be more accurate if the monitor has a minimum of 10 minutes to acclimate to the ambient temperature up to 45 minutes in extreme freezing or heat conditions. To connect the CO2 filter use the 3-way joint loop for any anesthetic delivery device, or to directly connect patient's nasal delivery system using a direct link.

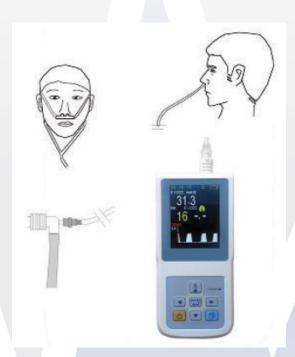


Figure 2

WARNING! The Elbow pictured in figure 2 is specifically used for patients under local anesthesia.

Installation of filter:

WARNING! Do not use the V-Pod CapOx when filter is not installed, this will void warranty and damage the CO2 pump/sensor.

Contact VirtuOx for replacement filters for testing use.

Note: For control of infectious disease we strongly recommend a new filter be used for each patient or test.

#### Instruction for use of the moisture filter:



FIGURE 3

- 1.) Put the connecting end of the moisture filter into the notches on top of the V-Pod CapOx and gently but firmly press filter downward and turn clockwise 1/8 turn until you will feel some resistance do not force or you may break the retaining tabs.
- 2.) Attach sample line to Moisture Filter.
- 3.) Connect the other end of the sample line with breathing loop of ventilator, anesthetic machine or nasal breathing tube.
- 4.) Change the moisture filter as needed.

WARNING! If there is excess moisture in the filter, measured values are likely to be inaccurate

WARNING! Use only approved cannula and tubes, or the results may be inaccurate.

#### II. Respiration rate measurement

The calculation of respiration rate derives from monitoring the wave of CO2.

#### III. Theory

The measurement theory and principle:

In working theory the device is a 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. At this moment, respiration wave becomes one straight line.

The air surrounding the device may have elevated concentrations of CO2 present (such as in an enclosed compartment or room with poor ventilation). We recommend cleaning the CO2 from the ambient air with a ventilator; otherwise, the device will cause deviation.

#### 3) The Moisture Separation System:

This instrument uses patented filter which can the filter a large amount of moisture while using a minimum of space and without affecting the waveform. But understand: if the filter becomes clogged or oversaturated, the screen will show the message "OCCLUSION". If this occurs, the operator needs to change the filter.

#### IV. Oximeter density measurement

PLEASE NOTE: only use proper probes sourced for the CapOx device, damage to delicate sensors can occur if the wrong compatibility probe is used.

1.) The finger sensor is included with the kit. Oximetry measurement will begin when your finger is put into the sensor clip properly as show in fig 4, meanwhile, the PLETH wave will appear on the screen, after several seconds the saturation and pulse rate appear also. The monitor will Beep when the each measurement occurs if the sound is on. The tone will vary if the values of SpO2 and Pulse Rate exceed the alarm setting and if the alarms are on. The higher the value of SpO2 and Pulse Rate exceeds the setting the sharper the tone will be.

NOTE: alarms are set default to off and silent for overnight testing



Figure 4

2.) The use of SpO2 sensor for neonatal (Optional, not included)

To use the neonatal probe please follow the application instructions found with the probe itself.

#### V. Important information.

1. Attention: Other important information.

#### 1). CO2:

The readings will be wrong if the monitor does not warm up.

A sampling cannula provided or recommended by VirtuOx needs to be used, otherwise the readings may be inaccurate.

Make sure to let the device settle to the ambient temperature of the testing environment before testing. In extreme cases the screen will show "TEMP IMBALANCE" when fast temperature ranges are at ex tremes (IE: hot vehicle to air conditioned environment). It is better to use the V-Pod CapOx in stable temperatures.

The measured data may be influenced a little bit if the patient is under the influence of any anesthetic gases. To calibrate based on some interferential gases, please refer to Appendix 2.

Any circumstances of blocking sampling gas, such as bending, folding, contaminations blocking sampling tube and filter or water trap etc. will lead to an inaccurate measurement.

Serious coughing etc. leading to exhaled CO2 concentration extremely high or low, e.g. EtCO2 lower than 0.5% or higher than 11%, will generate an inaccurate measurement.

#### 2). Oximeter:

The monitor's measurement to SpO2 may be influenced by strong ambient light therefore cover the probe (e.g. to use surgical tower etc.) if necessary.

Accuracy of oximeter readings will be influenced by any dyes in the blood.

Please use SpO2 probe provided with the unit or the one specially designed for this unit.

If the plethysmogram wave is abnormal the probe may be applied incorrectly. Confirm the proper placement of the probe and check for anything blocking the sensors such as nail polish or tape also inspect for broken or stressed wires and fittings.

#### Warning:

## DO NOT USE IF YOU SEE ANY EXPOSED WIRE OR SENSORS.

Pulse Oximetry signal can be negatively influenced due to:

- · extreme elevations in blood pressure
- · increased intrathoracic pressure

Pulse Oximetry should not be used in the following situations as the results will not be accurate:

- · shock
- · extremely low blood pressure
- · extreme anemia
- · hypothermia
- · known arterial blockage in hands

## **Chapter V Screen Display and Operation**

I. Screen Main Display



Figure 5

The first line of data shows time (hour, minute), Memory full Indicator □, Alarm status (!), silence (点) or active Charging mode (lightning bolt) and the battery charge indicator □.

NOTICE: When the memory full indicator displays , no more data will be stored. If you want to continue to store new data you need to clear the existing data in the NEW PATIENT menu. We recommend that you clear the device after EACH patient for best results.

The second area shows result data:

EtCO2 concentration, respiratory rate, inhaling CO2 concentration, oxygen PLETH, exhaling or inhaling state (during exhaling, becomes blue color).

The third area shows CO2 respiratory wave.

It shows SpO2, pulse oxygen PLETH and histogram.

When the pump is not operating, "PUMP OFF" will appear on the screen. When the filter is not inserted into the inlet port, the screen will show "FILTER OFF", and the pump will also be automatically shut down.

#### Alarm indication: (If needed)

- 1. If the EtCO2's value exceeds the limit of high or low alarm level, the word 'EtCO2' will flash and alert with 'short double tone' .The same situation will happen if respiration rate, SpO2 and pulse settings are exceeded.
- 2. If the battery level is so low that the battery indicates completely empty, and the V-Pod CapOx will sound a warning tone continually. At this point the device will shut down automatically and may not respond until the device is charged for at least 20 minutes.
- 3. When the apnea alarm is turned on and the apnea happens and alerts, the screen center will appear with 'APNEA' (It means stoppage of breathing) flashing, and if the sound alarm is turned on, it will notify you 'double tone'.
- 4. When the SpO2 sensor is disconnected or off from finger, the screen will flash the word 'SENSOR OFF'. If the saturation could not be detected for long time, the screen will flash the words 'FAIL SEARCH'.
- 5. The volume of continuous or interval alarms as mentioned above can be modulated and closed down by the item of **ALARM\_VOLUME**. The sound will disappear under the silent condition. If the alarm volume is 0, the silence indicator in the main menu will show '!'
- 6. All the parameters ' alarm for over limits and apnea alarm, will lead to flashing of red alarm indicator on the panel

#### II. The Main Menu

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

Figure 6

When the main menu is open, press the MENU button to enter the setting menu as shown in figure 6.

In this menu press the Up or Down button to move the cursor up or down, Press the ENTER button to enter the next sub menu.

This menu includes the following sub menus:

The setting menus for:

CO2: CO2\_SETUP the setting menu for SpO2: SPO2\_SETUP

The trend menu: TREND

The time menu: TIME\_SETUP

The sound menu: SOUND\_SETUP

Patient reset: **NEW PATIENT** . Warning, if you change anything in this menu the patient data will be deleted and not be recoverable, the device will force you to con-

firm.

#### III. CO2 Set Menu

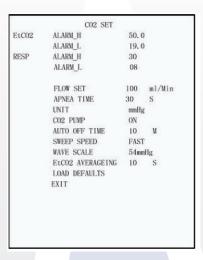


Figure 7

In this sub menu press the ▲ or ▼ button to move the cursor up or down press enter to select a parameter. Press the ◀ and ▶ arrows to change the data highlighted by the cursor once selected.

If you do not wish to modify certain values pass them over and use either LOAD DE-FAULTS or EXIT, press the **ENTER** button to make either of these changes.

Press the MENU button, then to exit this sub menu and enter the main menu area.

This menu includes the following setups:

1). The high alarm limits of EtCO2:

EtCO2 ALARM\_H: off or 22-99mmH

2). The low alarm limits of EtCO2:

EtCO2 ALARM\_L: off or 10-60mmHg

3). The high alarm limits of respiration rate:

**RESP ALARM\_H:** Off or 5-60t/m

4). The low alarm limits of respiration rate:

RESP ALARM\_L: off or 4-40t/m

5).Pump flux setup:

**FLOW-SET:** 50cc/min-250cc/min

6). The setup of apnea time:

**APNEA TIME:** 15s-44s or off

7). The unit of CO2:

CO2 UNIT.%, mmHg or kPA

8).Pump switch:

AUTO. (hard coded, no adjustment possible)

9).Pump auto-off time:

OFF (hard coded, no adjustment possible)

10). Screen speed of Capnograph SWEEP SPEED:

SLOW, NORMAL or FAST

11).CO2 Wave scale:

WAVE SCALE: 54mmHG or 76mmHG

12).EtCO2 average computation time:

**EtCO2 Averaging:** every breath, 10sec, 20sec, 30sec

13). Default reload:

**LOAD-DEFAULTS** 

14). Exit:

**EXIT** 

#### **PLEASE NOTE:**

Pump auto means that the pump will automatically be shut off if no respiration is detected.

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

#### IV. SpO2 Set Menu

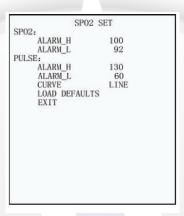


Figure 8

In this sub menu press the ▲ or ▼ button to move the cursor up or down press enter to select a parameter. Press the ◀ and ▶ arrows to change the data highlighted by the cursor.

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

This menu includes the following options:

1). The high alarm limits of SpO2:

**SPO2 ALARM\_H:** off or 50%-100%

2). The low alarm limits of SpO2:

**SPO2 ALARM\_L:** off or 50%-99%

- 3). The high alarm limits of pulse rate:
  - P\_RATE ALARM\_H: off or 70-250t/m
- 4). The low alarm limits of pulse rate:

P\_RATE ALARM\_L: off or 40-100t/m

5). Wave selection:

**WAVE:** FILL or LINE 6).reload of default settings:

**LOAD DEFAULTS** 

The wave selection means that:

FILL indicates the wave of plethysmogram is solid. LINE indicates the wave of plethysmogram is linear.

Default values as follow:

Saturation of SPO2 alarm high limit: OFF Saturation of SPO2 alarm low limit: OFF

Pulse alarm high limit: OFF Pulse alarm low limit: OFF

Wave: Line

#### V. The Time Set Menu



Figure 9

In this sub menu press the ▲ or ▼ button to move the cursor up or down press enter to select a parameter. Press the ◀ and ▶ arrows to change the data highlighted by the cursor

**Attention:** Any time adjustment will delete any saved trend, so time adjustment needs to be done before start of use or treatment.

The procedure is as follows:

- 1. Change time
- 2. Move the cursor and manipulate the values as necessary select "SAVE to access the FIGURE 9.1 which will confirm the changes and reset the trend data.
- 3. Move the cursor to YES, then press and hold ENTER button until the device returns to the "Idle" page to confirm.
- 4. Only once confirmed will the changes take effect (See figure 10)

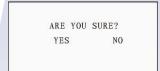


Figure 10

5. If you are only confirming the time and date are set correctly simply scroll down the menu to the "Exit" option and select. This will return you to the main menu.

#### VI. Sound Menu

SOUND SET

BEEP VOLUME 08

ALARM VOLUME 08

EXIT

Figure 11

In this sub menu press the ▲ or ▼ button to move the cursor up or down press enter to select a parameter. Press the ◀ and ▶ arrows to change the data highlighted by the cursor.

This menu includes following options:

1. Pulse sound volume:

BEEP\_VOLUME: 0(OFF)-8

2. Alarm sound volume:

ALARM\_VOLUME: 0(OFF)-8

Note: If the alarm volume is 0, the top line in the main menu will show "!"

#### VII. Trend

#### 1.) The Trend Graph

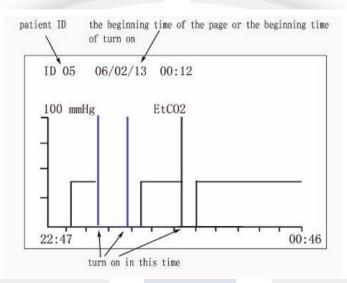


Figure 12

The V-Pod CapOx stores one group data every 12 seconds and maintains the data even after power is off. It will store trend data for up to 24 hours.

When memory storage reaches 24 hours, full memory indicator will display on the top line in the home screen, the user should upload any existing data for further analysis or reset the memory to take a trend reading of the next day's data.

As Figure 12 shows, the time span of each trend page is 1 hour and every point represents 12 seconds of data. The top line of this page indicates patient's ID number, the start time of this page (date/month/year hour: minute).

If during the displayed time the patient has turned the device off and on once or multiple times, the trend table will show one or several blue vertical lines from the top to bottom of the table, from this point press the down button, the top row will display the initial information in that segment: patient's ID number and initial time. The first blue vertical line will become white. Press down again, the second segment start time will display (if turned off and on several times).

The time at the beginning and end portion of the data pictured indicates the beginning and ending time for trend table on this page.

At times the data may be incomplete, it will show the monitor as having been turned off during longer periods of little of no data collection. (The device may be on and operational during these times but the probes/sensors will not have received sufficient signal)

#### TREND GRAPH CONTROLS:

Press the ENTER button to change the CO2 concentration trend, respiration rate, SpO2 and pulse (the latter 2 parameters are selectable).

Press the Down Page through the trend readings hour by hour.

Press the 🛦/ 🎉 button to change graph trend to table trend (see Figure 13).

Press MENU button to quit this menu and return to the main menu.

#### 2.) The Trend Table.

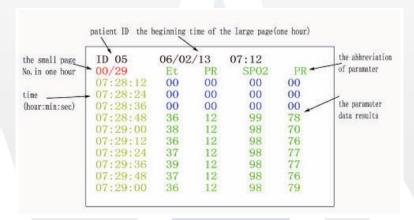


Figure 13

In this graph trend menu, to press  $\triangle/\varnothing$  button to change graph trend to Trend Table. Press  $\triangle/\varnothing$  button again, to return to graph trend (Figure 12).

Every Trend Table shows 10 groups of data with each about 120 seconds, including time, EtCO2 (Et), respiration rate (RR), SpO2, pulse rate (PR). Every hour covers 30 trend tables press the down button to scroll through them.

In this menu, press the down button to change the large page of trend table (to display the upper or lower hour trend table), it will be easier to see if there is no data to report the values will display in blue if there is no data for a specific time period.

#### **VIII. New Patient Menu**



Figure 14

In this sub menu press the ▲ or ▼ button to move the cursor up or down press enter to select a parameter. Press the ◀ and ▶ arrows to change the data highlighted by the cursor. Press the MENU button to exit this sub menu and access the main menu.

This menu includes the following options:

- 1). **ERASE ALARM:** Cancels the current alarm history
- 2). **ERASE MEMORY:** Deletes all data so new data can be collected.
- 3) **RENEW:** Controls the memory usage once full, "auto" overwrites memory and "manual" will stop recording when full set default to Manual.
- 4). ID: patient's ID, 00-99 (optional)
- 5). TYPE: patient type, adult or neonate (optional)
- 6). Store Interval: Set to 06s, no changes can be made to this setting.
- 7). **SAVE:** to store the changed data (this needs be confirmed so as to not allow a direct overlap of same patient data)
- 8). **EXIT:** quit the current menu but not store changes.

# Chapter VI: Charging, Maintenance, Sterilization and Cleaning I. Charging

After AC/DC power converter is connected and unit is turned on, this unit will charge the battery and operate power at the same time. The battery charging will stop when battery is full.

This unit is powered by a reusable lithium composite battery. In the case of only battery (without DC), the first column shows the battery's volume on the screen. When battery power is low, a red will be flashing, and DC power should be connected quickly.

After plugging in the DC power pack, the instrument will recharge the battery, and stop charging after the battery is at full capacity.

A depleted battery must be disposed of according to local laws and procedures.

#### Battery replacement:

Note: the V-Pod CapOx MUST be disconnected from charger/power supply and or PC before attempting a change of battery.

Press and move down the battery cover, once the cover is removed gently pull up the white plug, and insert the new battery's plug in the same location.

#### II. Maintenance

If the V-Pod CapOx locks up (e.g. system halted), press the power switch continually for 10 or more seconds to force power down.

Filtor:

If the screen shows 'occlusion', the moisture filter is blocked and needs to be replaced. See chapter IV figure 3

If it is contaminated the filter should be replaced (If the cannula has already been inspected and is in good condition).

To avoid transfer of infection it also should be replaced if it has been outside its sealed packaging in a previous test environment.

Please do not allow alcohol, cleaning agent or sterilizing agent into filter.

Visually inspect the filter for breakage or damage before installing or using for testing.

**Warning:** The Cannula and moisture filter should be not sterilized or used repeatedly they are disposable.

**Attention:** For the environment, disposable sample line or filter shall be treated suitably or recycled.

#### III. Sterilization, Cleaning

**Warning:** Before cleaning the monitor and probe, power needs to be turned off and the V-Pod CapOx needs to be disconnected from any charging OR PC.

1. Cleaning and sterilization of SpO2 probe.

#### **WARNING:**

DO NOT sterilize the probe using an autoclave.

DO NOT submerge the probe in liquid.

DO NOT use the probe if it has visible signs of wear or abuse

#### Cleaning and sterilization of probe:

Use a clean soft cloth moistened with medical alcohol, then wipe with dry cloth.

2. Cleaning and sterilization of the V-Pod CapOx device.

#### **WARNING:**

DO NOT sterilize the using an autoclave.

DO NOT submerge in any liquid.

DO NOT use if the device has visible signs of wear or abuse.

#### Cleaning and sterilization of the V-Pod CapOx:

Use clean soft lint free cloth with medical alcohol and wipe clean with a soft cloth. Do not spray CapOx directly with a spray bottle.

# **Chapter VII Connection to PC and Upload to VirtuOx.net**

#### Connection of CapOx to PC.

The CapOx is a digital USB native device and will plug into your PC and or charge using the same cable provided. (Do not attempt to upload or charge using the finger probe port at the top of the device you may damage delicate sensor components and void warranty)

1. To upload data from your CapOx first plug the device into your PC/Laptop using the provided USB 2.0 cable (See Fig 15 Below)

( If you have speakers you will hear a chime or sound as the driver and device are loaded.)



Figure 15

#### VirtuOx CapOx User Manual

2. Turn the device on, the display will show that the probe is not reading and that the other sensors are not reading. It will however show that the battery is charging in the upper right hand corner. (See figure 16 below)

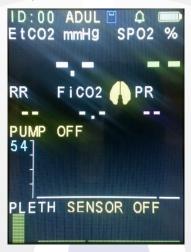


Figure 16

If this is the first time using the VirtuOx website or platform on this PC the drivers may need to be installed please contact your internal IT or VirtuOx for assistance if necessary.

3. Next step is to log into the VirtuOx platform and follow the required process based on your patient's needs.

(For complete upload instructions please see the VirtuOx website for screen shot based step by step instructions)

4. Once the data is uploaded and you have a printed report please clear the device as instructed either using the Website utility OR the instructions in Chapter V Section VIII. (New Patient Menu)

# **Appendix 1. Troubleshooting**

## Simple troubleshooting table

No.	Issue	Causes	Solution	
1	The value of the CO2 reading is lower than expected or normal	Leaking filter or cannula .     Blockage of filter or cannula.     Presence of interfering gasses.     Incorrect cannula used	1. Check and replace filter or cannula. 2. Clean or straighten the cannula. 3. Calibrate CapOx to environment. (Advanced Operation please leave to trained experienced personnel) 4. Replace with proper cannula.	
2	1.The value of CO2 is zero 2. Screen reads PUMP ERR with loud noise. 3. Screen reads IR-LAMP-BAD 4. Screen reads CO2 SENSOR ERR	1.Large leak inside the gas loop 2. Pump damaged 3. The lamp resource of sensor damaged 4.Sensor broken	Contact the manufacturer.	
3	Screen shows CAL-ERR	The last calibration failed.	Return to VirtuOx for proper calibration.	
4	Screen shows POWER-ERR	Incorrect power supply or battery used.	Contact the manufacturer.	
5	1. The CO2 wave is not normal. 2. Screen shows TEMP-HIGH 3. Screen shows TEMP-LOW 4. Screen shows TEMP- IMBALANCE	Temperature too high.     Temperature too low.     Temperature needs to equalize	Let device cool or warm in test environ- ment for up to 1 hour before use.	
6	No values of SPO2 or no wave	1. Poor circulation or cold temperature 2. Strong ambient light 3. Testing of SpO2 and blood pressure are being done on the same arm. 4. Red light in the sensor not flashing. 5. Infrared and collector of sensor is not clean	1. Massage and or warm up finger 2.  Protect hand from direct light sources. 3. Test blood pressure and SpO2 on different arms. 4. Inspect or replace finger probe. 5. Clean finger probe according to instructions.	
7	CapOx screen flashing "LOW BATTERY and shuts down automatically.	Battery discharged	Connect CapOx to correct AC power supply (Provided)	
8	CapOx screen still flashes "LOW BATTERY" plugged in to proper power supply.	AC power is not working normally.	Check AC power outlet, cable and Power adaptor.	

Attention: Please to contact our customer service center if these or any other problems occur repeatedly.

# Appendix 2. Explanation of terms used in this manual

EtCO2	-—— The co2 concentration during exhalation of subject		
INCO2	— The co2 concentration during inhalation of subject		
SPO2	————— Oxygen saturation		
RR or R-RATE ————	Respiration rate		
PR or P-RATE ————	Pulse rate mmHg		
KPA	————— Kilopascal		
ALARM-H ————-	Alarm high limit		
ALARM-L —————	Alarm low limit		
FILL	Filled or solid		
APNEA	Stoppage of breathing		
T/Min —————	Times/ minute		
CAL	—————————————Offset Calibration		
N2O	Nitrous oxide		
ZERO GAS ————	Base point or Zero point		
BTPS	-Temperature and deep lung air pressure compensation		

## **Appendix 3. Disclaimers and Statements**

#### 1. Calibration statement:

This device is of a digital nature and as such the digital portions are set by logarithm at the factory and under proper usage conditions will need no calibration for the life of the device. This statement does not include probes and other limited life components which need to be periodically replaced by the user, VirtuOx and the manufacturer assume no liability if these components are not inspected and replaced at recommended intervals suggested earlier in this manual.

The mechanical CO2 pump/sensor assembly may require periodic calibration if used in environments of varying gaseous density and composition as stated earlier in this document. Please contact VirtuOx during normal business hours for assistance.

#### VirtuOx CapOx User Manual

SERIAL #	
Purchase Date/PO/Order #	
Notes:	
	A

# **Custom Manufactured for:**



As part of the V-pod series of solutions.

VirtuOx Inc.



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# Special Addendum A. ENGINEER MENU: Changing compensation of balance gas

**WARNING:** Only personnel skilled in electronics and clinical adjustments/calibrations should attempt the following, specialized equipment is necessary. Please contact VirtuOx for professional calibration and testing.

Enter the engineer menu by:

pressing Up the Down and Right arrow buttons simultaneously.

#### **ENGINEER MENU**

BALANCE GAS AIR

O2 CONCENTRATION 20%

ANESTHETIC GAS 00%

ZERO GAS AIR

BTPS DISABLE

MENU UNLOCK

LOAD DEFAULTS

CALIBRATE

EXIT

#### Figure 15

In this menu, use the ▲ or ▼buttons to move the cursor up or down, press ▶ button or ◀ button to change the data highlighted.

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

In this menu, Press the MENU button, to exit this menu for the main menu.

This menu including the following options

BARO PRESS: Displayed in mmHg

**BALANCE GAS:** AIR,  $N_2O$ , and or HELIUM

O2 CONCENTRATION: 20%-99%
ANAESTHETIC GAS: 0-20%

ZERO GAS: AIR, N<sub>2</sub>
BTPS: ENABLE, DISABLE

MENU: LOCK (set as default, no adjustment possible)

LOAD DEFAULTS
CALIBRATE

EXIT

# **Attention:** 1. When the MENU setting is locked, the main menu is disabled. To access the main menu, select "Menu", ◀ and ▼ at the same time. To unlock the main menu, press ▶ and to enter engineer menu and change "unlock" to "lock" in the MENU setting. We recommend leaving this setting in the mode it was in when the device was delivered. 2) CALIBRATE is for CO2 concentration recalibration. Hold the ENTER button for 8 seconds to enter this menu once all conditionals have been properly set.

## Special Addendum B. Calibration of EtCO<sub>2</sub> Accuracy

**Attention:** for preservation of warranty only authorized trained personnel are permitted to carry out the following procedure. Contact your Supplier for training and advice.

Required equipment and preparation.

The VirtuOx CapOx has been calibrated and a detailed regimen of quality control has been executed before being shipped by VirtuOx. On each time the device is switched on it will do a self-check and adjustment itself based on the environmental temperature, pressure and balance gas etc.(It is REQUIRED that the operator allow a minimum of 30 minutes to allow the device to equalize temperature if moving from one environment to another) Generally the user does not need to calibrate this device other than the recommended annual check. To check the unit using Calibration Gas the following procedure must be used.

#### A1 Required Items:

CO<sub>2</sub> standard gas - Concentration of 5%

**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 16. The device **will be damaged** by the high pressure of the standard Cal Gas Bottle if the connector is not used. It is easy for skilled personnel to identify if the cal gas bottle is attached directly to the device Warranty will not be honored if this is the case. One end of three-pass connector must be directly open to air to release gas pressure and protect the monitor.

Two tubes (whose length should 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 the outdoors.

#### 1.2 Connect as follows:



Figure 16

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 is a leak in the gas loop. You must then find out where the leak is and resolve it, otherwise, it will result in inaccurate 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.

3. Enter the engineer menu (procedure given at Special Addendum A., Figure 15), highlight CALIBRATE, press and hold the ENTER button for 8 seconds to enter the next menu.



Figure 17

Highlight STANDARD GAS and adjust the value to that of the concentration of CO<sub>2</sub> standard gas. If the standard gas concentration is 2 decimal places the 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 17 and the device will begin to calibrate. The screen will display the message 'ADJUSTING!' as sown in FIGURE 18.

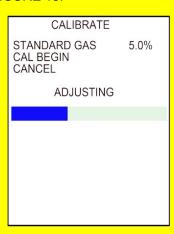


Figure 18

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 waste.