REV	EFFECTIVE DATE	ECN#	DESCRIPTION	APPROV'D
A	2018-10-18	N/A	The first release	Chevy xu
B			1. 更改Caution为Remark--P7 2. 更改上壳丝印LOGO颜色	Chevy xu

此文件为：电子空氧混合器说明书（英文版）技术资料。

Electronic Air-Oxygen Blender instruction (English version) technical information.

1. 尺寸：A5 (公差±2mm)

   Size: A5 (tolerance ±2mm)

2. 封面材质：250g双铜

   Cover material: 250g two coated paper

   内页材质：105g双铜

   Inner material: 105g two coated paper

3. 印刷：

   LOGO颜色：参照LOGO颜色图示；其他颜色：参照文档

   LOGO color: refer to here; Other color: refer to the document.

4. 表面处理：说明书封面、封底哑胶；

   Surface treatment: the manual cover, back cover rubber;

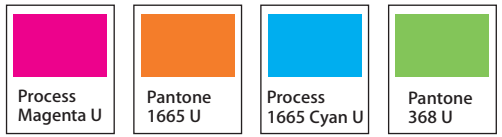
5. 装订方式：骑马钉

   Binding way: Nail

6. 印刷内容需清晰无误；

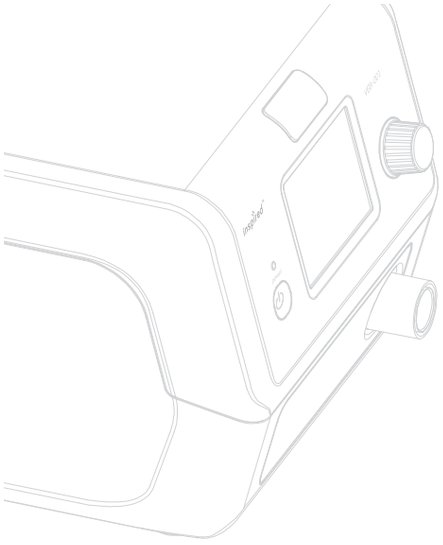
   Printing content must be clear and correct.

LOGO 颜色图示



永胜医疗技术资料
Vincent Medical Technical Information

预备 Prepared By	包装工程师 Packaging Engineer	
会　签 Reviewed By	项目工程师 Project Engineer	
	项目主管 Project Supervisor	
	市场部主任Marketing Executive	
	PE工程师 PE Engineer	
	RA工程师 RA Engineer	
批准 Approved By	工程经理 Engineering Manager	
文件版本 Version	B	Page: 1 of 25
文件编号 Doc.No.	A10021628	



inspired™

O2B Electronic Air-Oxygen Blender

Operator Manual

Vincent Medical Manufacturing Co., Ltd.
Flat/RM B2, 7/F., Hang Fung Industrial
Building, Phase 2, 2G Hok Yuen Street,
Hung Hom, Kowloon, Hong Kong
Tel: +852 2365 5688
Fax: +852 2765 8428
Email: service@inspired-medical.com
Website: www.inspired-medical.com

Website: www.inspired-medical.com

Sales inquiry:
+852 2365 5688
info@inspired-medical.com

Service support:
+852 2186 1010
service@inspired-medical.com

Vincent Medical Manufacturing Co., Ltd

Thank you for purchasing the Inspired™ O2B Electronic Air-Oxygen Blender (O2B for short) (model number VEB-001/ VEB-002).

This O2B mixes high pressure oxygen with high pressure air to deliver an operator set flow and oxygen concentration or dynamically blend high pressure oxygen into variable airflow for patient spontaneously breathing and delivers the set oxygen concentration independent of the patient's inspiratory flow.

ASSISTANCE:

For further information please refer to our website:
www.inspired-medical.com
If you need assistance using your O2B, contact the Vincent Medical authorized distributor or contact Vincent Medical directly at +852 2186 1010 or email service@inspired-medical.com

P/N.: 10021628 Rev.B

Release Date: 2018-11-08

Contents

Warnings and Cautions

Please read the following carefully before using.
The warning signs and the sample icons shown here are listed for you to use this product safely and correctly as well as to prevent the risk of injury to you and others.

CAUTION: Read this manual before use. Keep this instruction manual available for future reference.

Warnings

- Failure to set the oxygen concentration and delivery gas flow as prescribed and instructed by your physician may have an adverse effect on the patient.
- Failure to use a medical grade oxygen gas source that is dry and clean may cause damage to the O2B or cause the O2B not to deliver the set oxygen concentration.
- Use of an oxygen source (including oxygen concentrators) that is less than 99.5% oxygen may cause the O2B not to deliver the set oxygen concentration.
- Failure to use an air filter may contaminate the O2B air flow meter and could damage it or cause the sensor to inaccurately measure flow.
- Turn off gas to the O2B before removal of the gas connectors. Failure to do so could cause serious injury to operator.
- Failure to have an identified gas leak repaired by Vincent Medical or its authorized distributor can cause serious injury.
- Failure to keep the gas inlets and outlet clean and room air inlet cover closed when not in use may result in contamination of the O2B.
- The percentage of oxygen saturation (hemoglobin) should be continuously monitored when using O2B.
- It is not recommended to use gases other than oxygen and air as these may damage the O2B and may affect the set oxygen concentration and may harm the patient.
- The O2B is not designed to blend helium containing gas mixtures. Use with helium will cause the O2B to not deliver the set oxygen concentration and may harm the patient.
- Do not place liquid containers on top of the O2B. Liquid spilt on the O2B may cause damage to, or malfunction of the O2B.

- Disassembling, repair can only be carried by an authorized trained service Engineer. Any unauthorized repairs or modification may cause malfunction or cause patient injury.
- Contact with a leaking battery can cause serious burns to the skin.
- Do not let the battery get wet. A wet battery can short circuit and result in a system failure or create an electrical hazard.
- Do not set alarm volume too low when background noise is high.
- Do not apply strong shocks/impact to, or drop the main unit.
- Do not blow into the air inlet or outlet of the device. Doing so could lead to contamination of the device.
- Do not immerse the main unit into liquid.

⚠ Unauthorized repair by unqualified technician could lead to oxygen leakage into the electronics housing, potentially causing system failure or fire.

⚠ Do not expose the unit to an open flame when use oxygen gas. Exposure to an open flame could lead to fire or explosion.

⚠ Do not use the device near the presence of a flammable anesthesic gas. Exposure could lead to fire or explosion.

⚠ Do not expose the battery to open flames. Exposure to an open flame could lead to fire and/or explosion.

⚠ Cautions

- The device should only be operated by trained personnel under the guidance of a physician.
- To maintain device performance, the inlet filter should be replaced every 12 months. Failure to do so could cause the gas pathway to become blocked or obstructed which may impair device performance and may set off the loss of gas alarm.
- This device can be used on desktop, pole mount and wall mount; This device can be used on a flat surface, pole mount or wall mount. Please ensure that the position of the O2B is less than 10 degrees from horizontal.
- Do not use any parts other than the accessories or optional parts listed in this manual which are supplied exclusively by Vincent Medical. Otherwise, the performance of the device may be disrupted and can cause safety and performance issues.
- Federal Law (USA) and regulatory requirements (country basis) restricts this device to sale by or on the order of a physician.
- Do not remove the low-pressure hose from the device unless completely necessary. Frequent removal will negatively affect the service life of the connectors.

- Ensure that gas source pressure is within the working pressure shown in 3.1 Specification table.
- When the product is not being used, keep the inlets clean, and cover the room air inlet with its cover.
- Do not use organic solvents to clean the surface of the main unit.
- Do not scratch, tear, modify, forcibly bend, pull, twist, or bundle the power cord.
- Do not place heavy objects on the power cord.
- Keep power cord away from heated or hot surfaces.
- Keep the device away from radiation fields and magnetic fields when it is running.
- Ensure that the AC electrical outlet (wall end) is unobstructed and that it can be easily removed.
- Ensure that the device is powered off and disconnected from power supply before cleaning or performing maintenance.
- If the O2B loses power from the AC adapter, it will automatically switch to battery power. The battery will power the O2B for approximately 4 hours when it is fully charged. The battery alarm will be triggered if the battery has only 10% capacity remaining. It is critical to restore power to the O2B via the AC adapter. Failure to restore power will cause the O2B to either stop delivery of all gas (high pressure mode) or stop adding oxygen (low pressure mode). Either condition can have life threatening and/or adverse effects on the patient.
- The battery should be charged every 3 months even if it is not used. It needs 8 hours to fully charge from full discharge status. Failure to charge the battery may reduce the battery life or performance. It is recommended that the battery is replaced with a new one annually.
- An external detector (oxygen concentration analyzer) should be used to monitor the oxygen concentration accuracy at any time. An external detector (oxygen concentration analyzer) should be used to monitor the oxygen concentration accuracy at any time. It is recommended that a Vincent Medical oxygen module is used for this as it does not require calibration. A standard medical gas source must be used.
- Avoid direct exposure to sunlight or high temperature environments.
- Do not allow unsupervised children or untrained persons use the unit.
- The default alarm settings and records do not change with environmental changes. When the device is powered off, the alarm settings do not change.
- The O2B has an alarm history record of the last 100 alarms. After 100 alarms have been recorded, any new alarm recorded will replace the oldest alarm in this record.

Symbols Explanation

	Type B applied part		Refer to instruction manual		Shelf time
	Class II equipment		date of manufacture		Upward
IPX1	Dip proof protection to IPX1		Lot No.		Fragile
	Attention: consult accompanying documents		Serial No.		Keep dry
	Humidity limitation (Transportation and storage)		Power On/Off (Stand-by)		Keep away from sunlight
	Temperature limit (Transportation and storage)		Flammable material		Warning sign
	Do not discard WEEE collection (EU only)		Alternating current		
CE 0197	CE marking		Direct current		

Safety Classification

- Type of protection against electric shocks: Class Ⅱ and internal power supply device.
- Degree of protection against electric shock: Type B applied parts.
- Degree of protection against harmful ingress of water: IPX1.
- Degree of safety of application in the presence of a flammable anesthetic mixture with air or oxygen or nitrous oxide: Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or oxygen or nitrous oxide.
- Mode of operation: Continuous operation device.

Environmental Conditions

This product should not be exposed to excessive vibration, dust, corrosive or explosive gas environments. During device operation, it should be placed in a horizontal position. Suitable environmental conditions for operation are:

—> Ambient temperature range: 10 ~ 40°C
—> Relative humidity: 30 ~ 75%, non-condensing
—> Atmospheric pressure: 70 ~ 101kPa
—> Altitude: up to 3000m above mean sea level

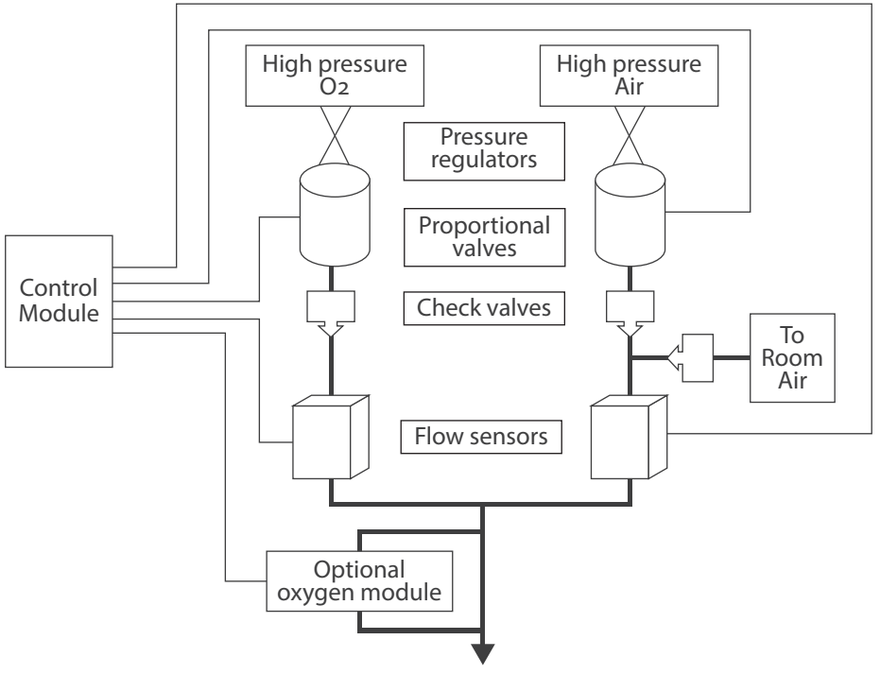
Environmental Protection

At the end of service life, disposal of the device and its accessories should be in accordance with local laws and regulations.

1. Introduction

1.1 Product Principle

The O2B is developed with two electronic flow channels controlled by a microprocessor. The Principle is shown in the following diagram:



The O2B has two modes of operation including a high pressure mode and a low pressure mode.
In the high pressure mode, the operator sets the inspired oxygen concentration and the desired delivered flow rate. The microprocessor in the O2B independently controls each proportional-control flow valve for the high pressure oxygen and air so that the total flow matches the set value and the proportions of each flow is set to match the required FiO_2, accounting for the 20.9% oxygen in the air gas stream. Flow sensors on the outlets of each flow valve measure the actual flow from each and provide closed loop feedback control to the microprocessor to make adjustments to the proportional

flow valves. The sum of the two flow sensors is used to display the actual total flow.
In low pressure mode, only the oxygen supply line is pressurized. The operator sets only the inspired oxygen concentration. A low resistance spontaneously breathing port is opened on the air source side between the air flow valve and the air flow meter. As a patient inhales from the system, the flow of air is measured that is drawn into the port by the patient or pushed in from a low pressure air source. The microprocessor uses that instantaneous flow rate to control the oxygen proportional flow valve to dynamically inject oxygen into the patient's air stream to deliver the set FiO_2.

1.2 Features

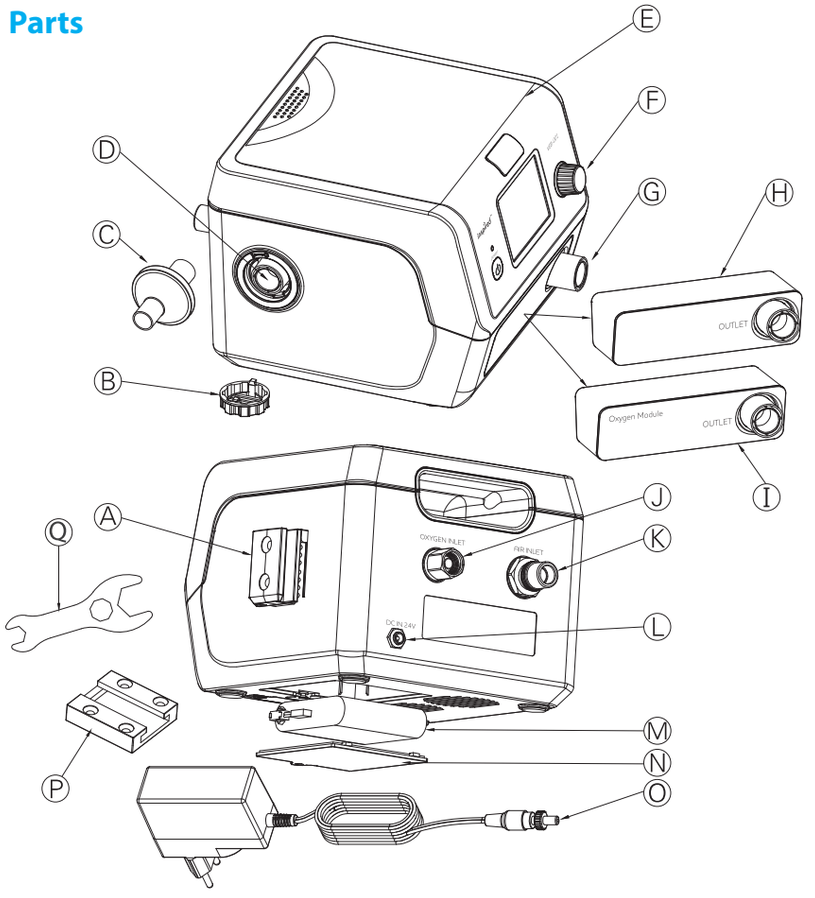
—> Highly accurate flow and oxygen blending with a rapid response.
—> Easy to use with a 2.8 inch LCD screen and a rotary control knob.
—> No need for an additional oxygen sensor for calibration.
—> Operates with a wide working pressure range.
—> Connecting an optional oxygen sensor module enables the setting of O_2 alarm limits and real-time display of the oxygen concentration.
—> Multiple safety alarms and indicators monitor the O2B function: System failure, Loss of gas, High FiO_2, Low FiO_2, Low battery.
—> The device can be powered by its internal rechargeable battery that can operate for 4 hours between charges. The DC power adapter can also be directly plugged into an AC wall outlet to charge the battery or provide primary power to the O2B.
—> The unique low pressure mode can be used for patients who can spontaneously breathe; this application can eliminate the need for a compressed air supply and save oxygen gas consumption.

1.3 Intended Use

Intended use: The O2B Electronic Air-Oxygen Blender is intended to deliver mixtures of air and oxygen to patients who require oxygen therapy.
Environments of Use: Emergency room, ICU, ambulances and other medical facilities where blended air-oxygen gas is required.
Intended Patients: Neonatal, Children and Adults who require supplemental oxygen therapy.
Intended Users: Doctors, Nurses, Respiratory Therapists, and other trained healthcare personnel.
Indications: Need for supplemental oxygen.

2. Composition of the Product

2.1 Parts



Ⓐ Bracket	Ⓖ Outlet	Ⓛ DC inlet
Ⓑ Air inlet cover	Ⓗ Ordinary outlet module	Ⓜ Rechargeable battery
Ⓒ Air filter	Ⓘ Optional oxygen module	Ⓝ Battery cover
Ⓓ Room air inlet	Ⓙ Oxygen inlet connector	Ⓞ Power adapter
Ⓔ Main unit	Ⓚ Air inlet connector	Ⓟ Mounting bracket
Ⓕ Knob		Ⓠ Wrench tool

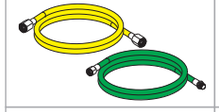
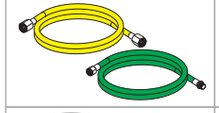
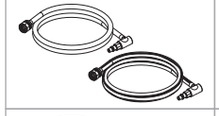
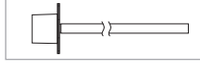
Remark: The picture is for reference only. Actual machine may vary slightly.

2.2 Pack Contents

Name	Amount
VEB-001 or VEB-002(with battery)	1 PC
Air filter	1 PC
Power adapter	1 PC
Mounting bracket	1 PC
22F Spared tube	1 PC
User manual	1 PC
Wrench tool	1 PC

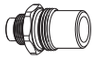
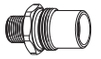
2.3 Optional Accessories

If you need to purchase any accessory, please contact the Vincent Medical authorized distributor or contact Vincent Medical directly at +852 2186 1010
or email service@inspired-medical.com

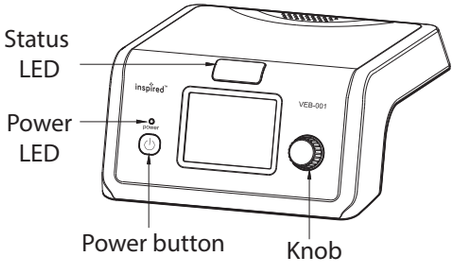
Picture	Product Name	Model	P/N
	Air Filter	BSF 103	31019914
	Low Pressure Hose Assembly (JP)	VLPH03	51006442
	Low Pressure Hose Assembly (US)	VLPH03	51006201
	Low Pressure Hose Assembly (EU)	VLPH02	51006443
	Low Pressure Hose Assembly (CN)	VLPH01	50006444
	22F Spared tube	N/A	31020123
	22F PVC Spared tube	N/A	31019320

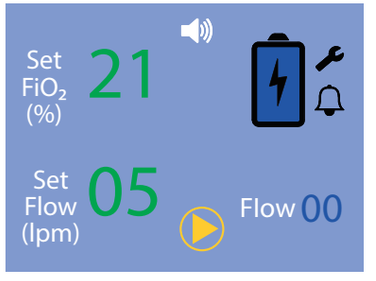
2.4 Detachable Parts

If you need to purchase any part, please contact the Vincent Medical authorized distributor or contact Vincent Medical directly at +852 2186 1010
or email service@inspired-medical.com

Picture	Product Name	P/N
	Oxygen Module	31020182
	Compressed Gas Inlet Filter	10020701
	NIST Oxygen Connector	10022283
	NIST Air Connector	10020822
	DISS Oxygen Connector	30018901
	DISS Air Connector	10020708
	Mounting Bracket	31019520
	Power Adapter	30020177 (EU) 30020178 (CN) 30020179 (US)
	Rechargeable Battery	10020731

2.5 Control Panel





Power button	Press and hold for 2 seconds to turn on or turn off the unit.	
Power LED	Green	On power off mode, it indicates the battery is fully charged. On running mode, it indicates the unit is being connected to the AC power.
	Green and blinking	On power off mode, it indicates that the battery is being charged.
	Yellow	It indicates that the unit is running on battery only.
Status LED	Green	Normal running status.
	Red and blinking	Alarm is active.
Knob	Clockwise rotation of the knob shall highlight the next item to be selected. Anticlockwise rotation shall highlight the previous item.	

2.6 List of Icons

Icon	Name	Function	Icon	Name	Function
	Lock icon	Press the icon for 2 seconds to unlock.		Settings icon	Select the mode, Adjust the alarm volume, Select screen language option, Set date and time of day and display device information.
	Unlock icon	Press the unlock icon to stop/pause the device.			
	Start icon	Press Start icon to start blending of gas and gas flow.		Volume icon	Indicates alarm volume.
	Audio paused	Alarm audio is paused for 120 seconds.		Audio off	Alarm audio off.
	Battery icon	Indicates the battery status and battery alarm.		High Pressure Mode icon	High pressure mode; requires pressurized air and oxygen gas supplies.
	Alarm icon	Alarm history records.		Low Pressure Mode icon	Low pressure mode; requires only a pressurized oxygen supply.

3. Specifications

3.1 Specifications

Modes	High pressure mode, Low pressure mode
Power adapter	Input: 100~240 VAC/50 -60Hz; Output: 24VDC/750mA
DC IN	24V/750mA
Rechargeable battery	14.4VDC, 2400mAH, Li-battery ⎓ ; Operate at least 4 hours when full charged
Power	18 W
Working pressure	VEB-001: 0.34~0.55Mpa(50 to 80psi), recommend 0.45Mpa(65psi) VEB-002: 0.21~0.55MPa(30 to 80psi), recommend 0.34Mpa(50psi)
Flow range	VEB-001: 1~60LPM VEB-002: 1~30+LPM, detail in table 1
FiO_2 range	High pressure mode: 21~100% Low pressure mode: 21~85%
Oxygen concentration accuracy	±3% of full scale
Delivery flow accuracy	VEB-001: ±0.5LPM (Delivery flow≤8LPM), ±8% (Delivery flow>8LPM) VEB-002: ±0.2LPM (Delivery flow≤2LPM), ±8% (Delivery flow>2LPM)
Inlet connectors	NIST (EU), DISS (US)
Outlets	22mm M/15mm F
Size	195x200x190mm with handle
Weight	≈2 Kg
Alarm volume	52dB (Low), 70dB (High)

Flow and FiO_2 Range for High Pressure Mode

Oxygen Concentration (%)	Delivery Flow (SLPM)	
	VEB-001	VEB-002
21%~29%	1~60	1~30
30%~39%		1~35
40%~49%		1~40
50%~59%		1~50
60%		1~60
61%~69%		1~50
70%~79%		1~40
80%~89%		1~35
90%~100%		1~30

Table 1

Flow and FiO_2 Range for Low Pressure Mode

Oxygen Concentration (%)	Spontaneous Respiration Peak Flow (SLPM)	
	VEB-001	VEB-002
21%~45%	100	100
46%~50%		80
51%~55%		70
56%~80%		60
61%~70%		50
71%~85%	80	40

Table 2

3.2 Alarms

Priority No.	Alarm Name	Alarm Description	Alarm Delay	Audio Paused/Off
1	System Failure	Sensor and/or software failures	＜3s	No
2	Loss of Gas	When delivered flow < 80% of system flow setting. (High pressure mode)	＜10s	No
		When O_2 flow < 50% of expected delivered O_2 flow. (Low pressure mode)	＜10s	
3	Low O_2 (Optional)	When the measured O_2 is lower than the set low alarm limit.(Optional)	＜10s	Yes
4	Low Battery	When the battery reaches approximately 10% remaining capacity.	＜10s	No
5	High O_2 (Optional)	When the measured O_2 is higher than the set high alarm limit.(Optional)	＜10s	Yes

The above alarms are all high priority. All alarms have three simultaneous alarm indicators. When an alarm is triggered, the alarm LED blinks red, an audible alarm will be triggered, and information in text describing the alarm appears on the LCD display.

Three of the alarms in the alarm table (System Failure, Loss of Gas Supply, and Low Battery) cannot be audio paused or audio off.

Press the knob to stop the O2B from operation and refer to Section 5.8 "Troubleshooting" to determine the possible causes and corrective actions.

When using the optional oxygen module, users can set the oxygen concentration alarm limits that enable alarm conditions for Low O_2 and High O_2. The 2 alarms can be silenced when the faults are eliminated. Refer to Section 4.5.3 on how to paused the audio.

The alarm sound can be set to high, medium and low level volume, please choose appropriate volume setting per section 4.5.2.

⚠ **Warning:** Do not set volume too low when background noise is high.
⚠ **Caution:** The default alarm settings and records do not change with environment changes. When the device is powerd off, the alarm settings do not change.
⚠ **Caution:** The O2B has an alarm history record of the last 100 alarms. After 100 alarms have been recorded, any new alarm recorded will replace the oldest alarm in this record.

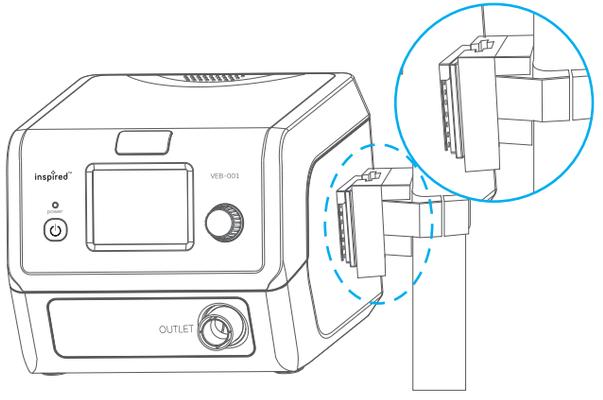
4. System Operation

4.1 Pre-Install Inspection

4.1.1 Ensure that the compressed air and compressed oxygen sources are clean and dry medical gas. Confirm that the gas sources are sufficient for use.
4.1.2 If the air supply contains water, it should be drained and a filter for water installed. Water entering the gas inlets may damage the O2B and void the warranty.
4.1.3 Before using the O2B, confirm that the O2B operates as intended.

⚠ **Warning:** Use of an oxygen source (including oxygen concentrators) that is less than 99.5% oxygen may cause the O2B not to deliver the set oxygen concentration.
⚠ **Caution:** Ensure that gas source pressure is within the working pressure which shown in 3.1 Specifications table.

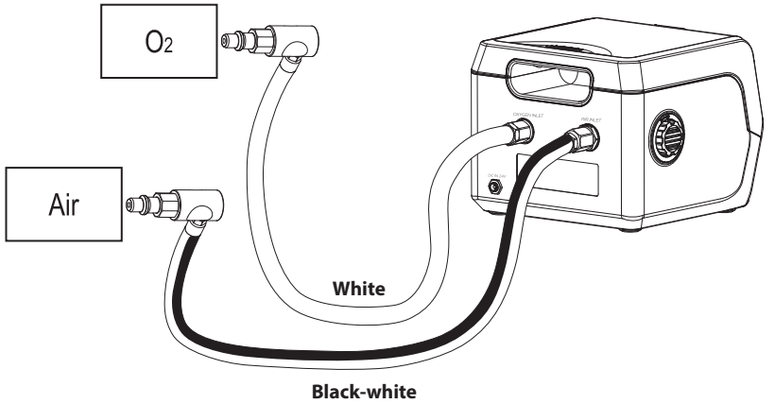
4.1.4 Place the device on horizontal surface or mount it on a pole or wall .



⚠ **Caution:** This device can be used on a flat surface, pole mount or wall mount. Please ensure that the position of the O2B is less than 10 degrees from horizontal.

4.2 Preparation before Use

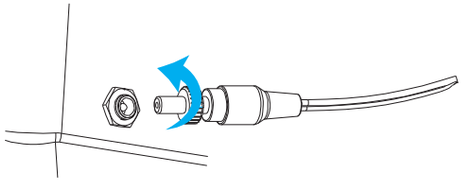
4.2.1 Connect Air and Oxygen Gas Sources
Step 1: Connect the standard medical air low pressure hose assembly* to the device air inlet. Rotate the nut of the NIST/DISS connector clockwise until hand tight;
Step 2: Connect the standard medical oxygen low pressure hose assembly* to the device oxygen inlet. Rotate the nut of the DISS (anticlockwise) or NIST (clockwise) connector until hand tight;
Step 3: Connect the air and oxygen standard medical air hoses to the air source and oxygen source respectively .

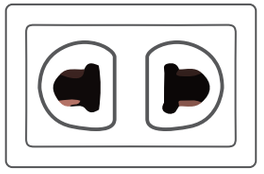


Step 4: Open the gas source valves and adjust the pressure to between 50psi to 80psi (recommended 0.45Mpa / 65 psi) for VEB-001 and 30 psi to 80 psi (recommended 0.34Mpa / 50 psi) for VEB-002.
**Note: medical hoses vary by country or region: EU (Air: Black-white, O_2: white), US and JP (Air: Yellow, O_2: Green), CN (Air: Black, O_2: Blue).*

⚠ **Warning:** Do not expose the unit to an open flame when using oxygen gas. Exposure to an open flame could lead to fire or explosion.
⚠ **Warning:** Do not use the device near the presence of a flammable anesthesic gas. Exposure could lead to fire and explosion.

4.2.2 Connect to Power
Step 1: Connect the power adapter to the O2B and rotate the locking nut to prevent accidental disconnection.
Step 2: Plug the Power adapter into an AC electrical outlet.

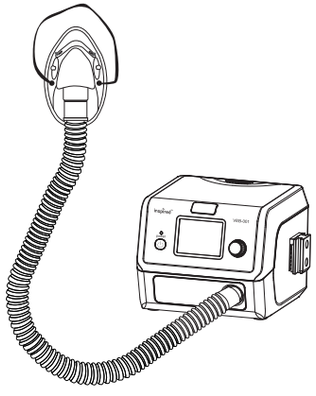




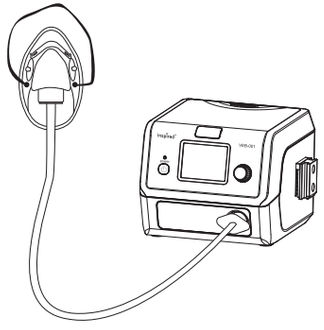
⚠ **Caution:** Ensure that the AC electrical outlet (wall end) is unobstructed and that it can be easily removed.

4.2.3 Connect to Patient Interface

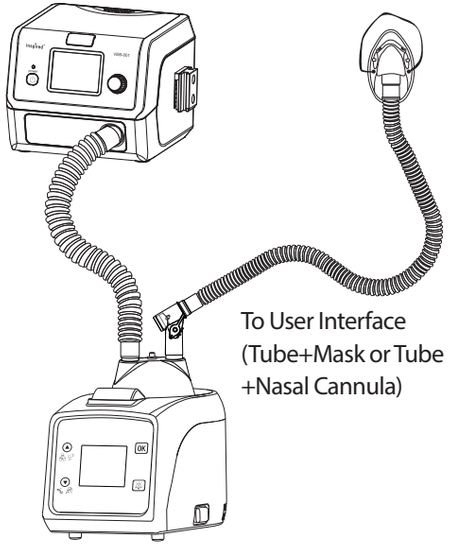
Before connecting the O2B to a patient, connect the outlet of the O2B to the patient interface such as a Mask, Humidification Chamber, Resuscitator, etc.



Connect to a mask with 22F spared tube

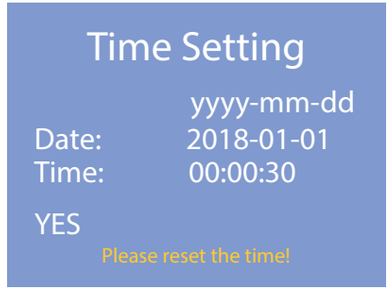


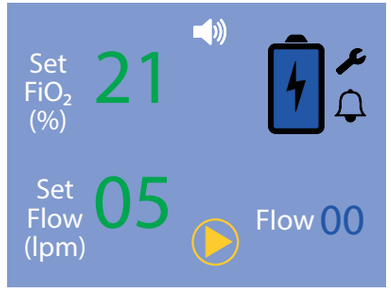
Connect to a mask with 22F PVC spared tube



Connect to Humidification System

4.3 Starting Use on a Patient



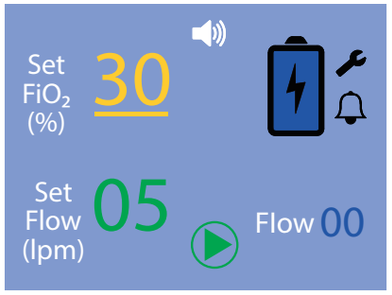


Step 1: Press the power button ⏻ for 2 seconds to start the O2B. The screen will display the logo and device information. The system will then perform a self-test.
** If there are alarms trigged when the device is turned on, refer to Section 5.8 for trouble-shooting.*
** If the system has a failure, the screen will show the system failure alarm. Press the power button for 2 seconds to turn off the O2B and contact professional maintenance personnel.*
** If the cause of the alarm conditions are cleared and the device is still alarming, turn off, then restart the device. If the alarm continues, please contact professional maintenance personnel.*

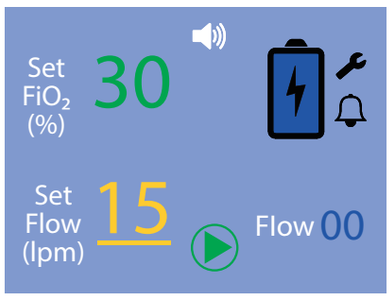
Step 2: The first time the O2B is started or after replacing the battery, you should first set the time. Rotate the knob to select "YES" and press knob to continue.

4.3.1 High Pressure Mode

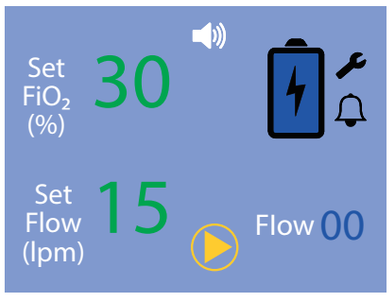
After startup, the O2B defaults to the high pressure mode:
Step 1: Ensure room air inlet is covered.



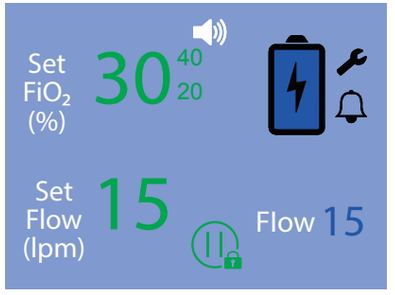
Step 2: Set O_2 Concentration
Rotate the knob to highlight the current "Set FiO_2" value and then press the knob to enable changes. Rotate the knob either clockwise or anticlockwise to increase or decrease the oxygen concentration to the desired setting value. Press the knob to select; if no response after 20 seconds, the current settings will be selected.



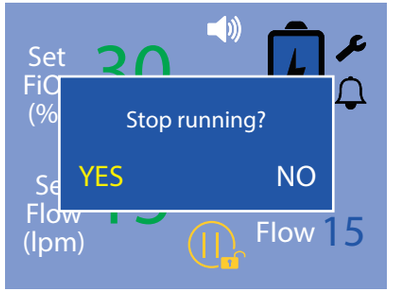
Step 3: Set Delivery Flow
Rotate knob to highlight the current "Set Flow" value and then press the knob to enable changes. Rotate the knob either clockwise or anticlockwise to increase or decrease the flow to the desired setting. Press the control knob to select; if no operation after 20 seconds, the current settings will be selected.
⚠ **Caution:** The gas source pressure shall be greater than 60psi when the flow was set greater than 50 LPM.



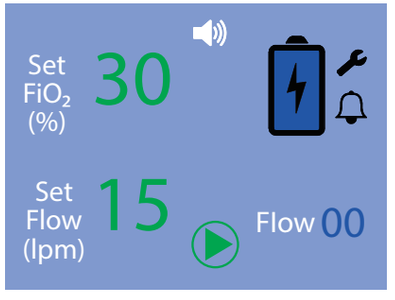
Step 4: Start Delivery
Rotate knob to highlight the Start icon , Press the knob to activate the Start icon , and the icon will change to the Lock icon . The O2B will start flowing blended gas at these settings. The screen will be locked automatically when the O2B is delivering gases. The actual flow will be shown in the lower right corner of the display.



Step 5:Set parameter when delivering gases
Press the knob for 2 seconds to unlock. The "Set FiO_2", "Set Flow", high and low oxygen alarm limits and battery icon can be highlighted when delivering gases. User can change these parameters and check battery capacity. If no response after 20 seconds, the screen will be locked again.



Step 6: Stop Delivery
Press the knob to enter "Stop running?" selection screen.



Step 7: Select "YES" to stop delivery of oxygen.

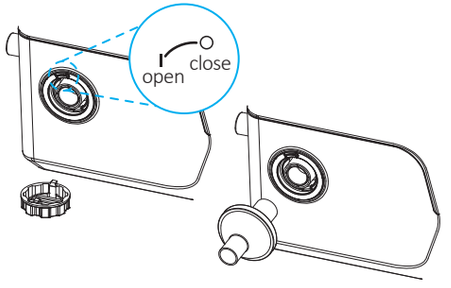
4.3.2 Low Pressure Mode
If the patient is spontaneously breathing with a closed system (e.g., a tight fitting mask, tee piece, etc.) with one way valves, the patient can be supported with low pressure mode. In the low pressure mode, the patient's breathing effort brings fresh air into the breathing circuit. The O2B measures the patient's inspiratory flow and matches the

instantaneous flow with injected oxygen proportionate to the instantaneous flow to deliver the set oxygen concentration. In the low pressure mode, only the oxygen concentration can be set.

Step 1: Select the Low Pressure Mode
From the main screen on the O2B, rotate the knob until the settings icon is highlighted; press the knob to select. The "Mode" will be highlighted. Press the knob to switch to the Low Pressure Mode. There will be a warning screen to open the room air inlet cover and intall the air filter, follow next step 2 to open the room air inlet then press "Yes" to low pressure mode screen.

—> Mode—>Low pressure mode —>Warning—>Low Pressure Mode screen.

Step 2: Rotate the cover anticlockwise to open the room air inlet cover. Insert an O2B Air Filter to the room air inlet. To close, rotate the cover clockwise.
⚠ **Warning:** Failure to use an air filter may contaminate the O2B air flow meter and could damage it or cause the sensor to inaccurately measure flow.



Step 3: Set O_2 Concentration and press the knob to activate the Start icon .

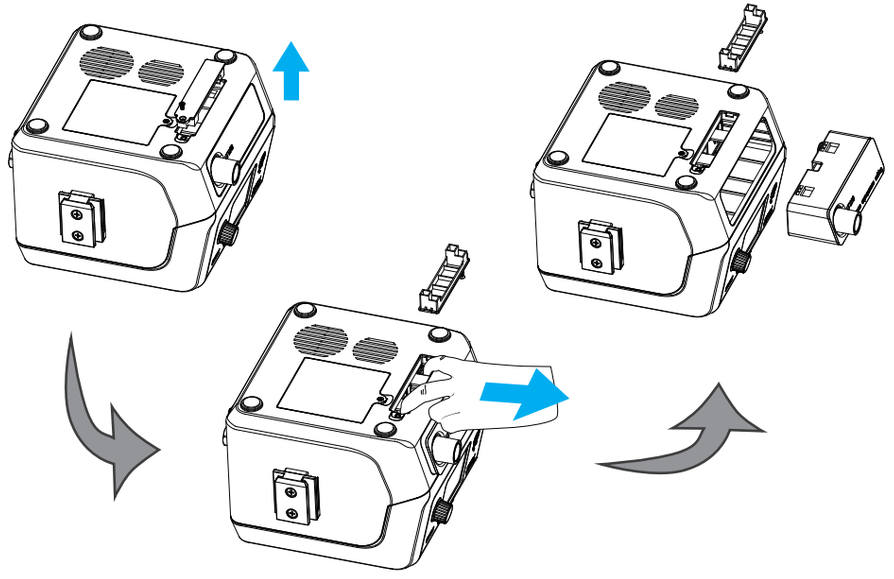
4.3.3 System Shutdown
To stop delivery and shut down the O2B:
Step 1: Remove the patient interface from the patient.
Step 2: Close the gas sources.
Step 3: Ensure that there is no gas out of the device; press the power button for 2 seconds to shut down the device.
Step 4: Remove the gas supply hoses.

⚠ **Warning:** Turn off gas to the O2B before removal of the gas connectors. Failure to do so could cause serious injury to operator.
⚠ **Caution:** Do not remove the low-pressure hose from the device unless completely necessary. Frequent removal will negatively affect the service life of the connectors.

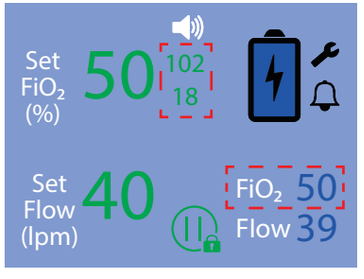
4.4 Using the Optional Oxygen Module

If real time-display of the oxygen concentration and the ability to set high and low alarm limits for the oxygen concentration is required, you can use the oxygen module (optional accessory) by following these steps:

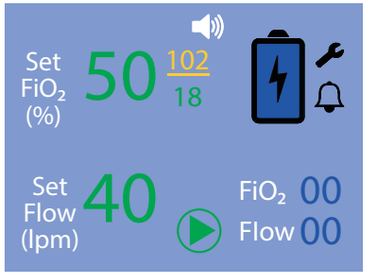
Step 1: Remove Standard Module
Turn the O2B over and remove the screw for the locking cover. Lift the locking cover and then push the standard module out of the device with 2 fingers.
Step 2: Insert the optional oxygen module into the O2B and replace the locking cover and screw.

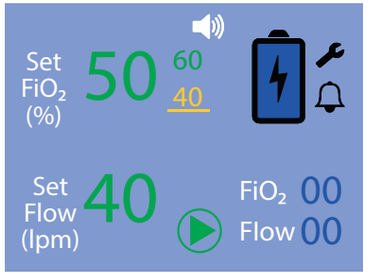


Step 3: After connecting the optional oxygen module, the display will now show alarm limits (default high oxygen alarm limit is 102, low oxygen alarm limit is 18) as shown below for high pressure mode:



Step 4: Set high and low oxygen alarm limits
Rotate the knob to highlight the default high oxygen alarm limit "102" and then press the knob to enable changes. Rotate the knob either clockwise or anticlockwise to increase or decrease the high oxygen alarm limit to the desired setting. Press the knob to confirm and exit the high O_2 alarm limit setting. Follow the same operation to set the low O_2 alarm limit.





4.5 Other Operations

4.5.1 Battery

Indicates the device is connected to AC power and that the battery is charging.

Indicates battery is fully charged.

Rotate the control knob to highlight the battery icon ; press the control icon, to reveal remaining battery capacity .

When the remaining battery capacity is only 10% , the system will alarm.
If this alarm is triggered the user should connect the power adapter to AC power.

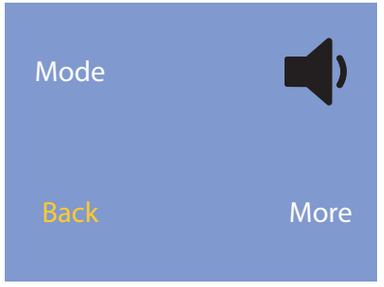
Indicates no battery is installed.

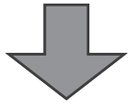
⚠ **Caution:** If the O2B loses power from the AC adapter, it will automatically switch to battery power. The battery will power the O2B for approximately 4 hours when it is fully charged. The battery alarm will indicate if the battery has only 10% capacity remaining. It is critical to restore power to the O2B via the AC adapter. Failure to restore power will cause the O2B to either stop delivery of all gas (high pressure mode) or stop adding oxygen (low pressure mode). Either condition can have life threatening and/or adverse effects on the patient.

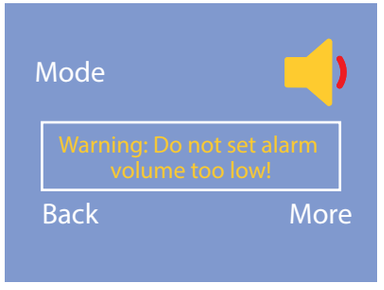
⚠ **Caution:** The battery should be charged every 3 months even if it is not used. It needs 8 hours to fully charge from full discharge status. Failure to charge the battery may reduce the battery life or performance. It is recommended that the battery is replaced with a new one annually.

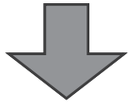
⚠ **Warning:** Do not expose the battery to an open flame. Exposure to an open flame could lead to explosion.

⚠ **Warning:** Do not let the battery get wet. A wet battery could short circuit and result in a system failure or create an electrical hazard.









4.5.2 Settings Menu

To get to the Settings Menu, rotate the knob until the Settings Icon is highlighted . Press the knob to select.

Mode setting

Rotate the knob to highlight the "Mode" icon, press the knob to select and choose high pressure or low pressure mode. Ref. to Section 4.3.2.

Volume setting

Rotate the knob to highlight the volume icon , rotate the knob clockwise or anticlockwise to increase or decrease the volume setting. Press the knob to select.

⚠ **Warning:** Do not set the alarm volume too low when the background noise is high.

Rotate the knob to the "More" icon and press the knob to go next page.

Language Selection

Rotate the knob to highlight the " Language " icon, then press the knob to select language.

Time Setting

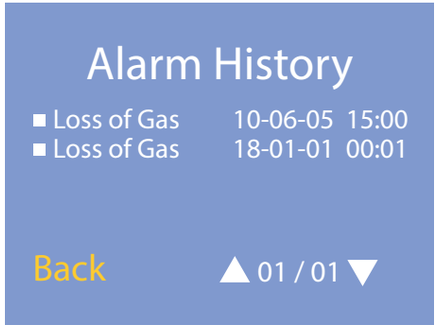
Rotate the control knob to highlight the "Time" icon, Set time Y-M-D-H-M-S.

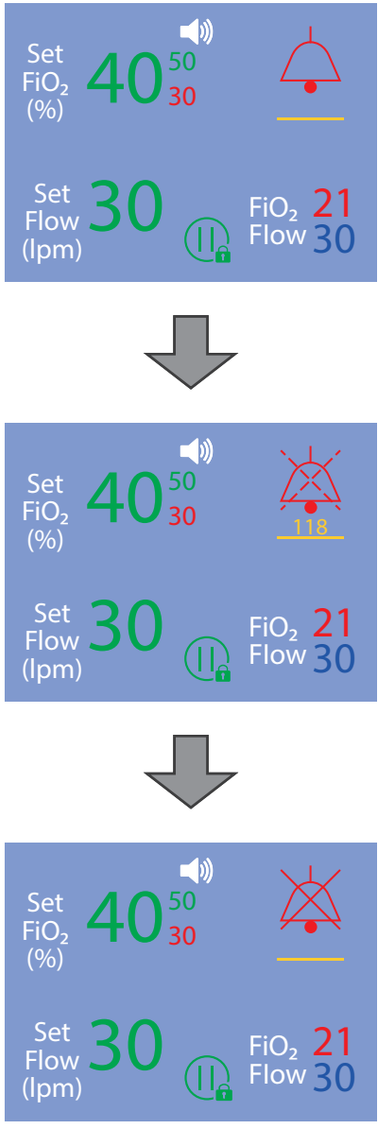
Device Information

Rotate the knob to highlight the "Info" icon. This will display device information including Logo, device name, model, software version, etc.

4.5.3 Alarm Information

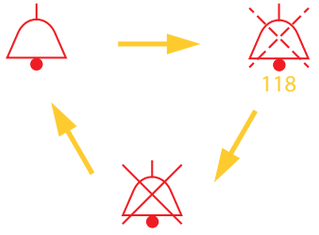
Rotate the knob to the alarm icon and press the knob to show the alarm records. The O2B has an alarm history record of the last 100 alarms. After 100 alarms have been recorded, any new alarm recorded will replace the oldest alarm in this record.





Alarm Audio Paused and Off: When the High Oxygen or Low Oxygen alarm is triggered, the O2B will simultaneously activate an alarm audio, alarm light (LED blinking red), and the oxygen concentration limit FiO_2 value will be red.

At this time, the alarm audio icon will be selected, press the knob to jump to alarm audio paused for 120 seconds, continue to press the knob to jump to alarm audio off.



5. Product Maintenance

The O2B should be inspected before each use. User should check for leakage, oxygen accuracy, inlet connectors, room air inlet & its check valve, battery capacity and all accessories. This should be performed by a trained person who is familiar with technical performance requirements of the VEB-001, VEB-002. These should be checked at least monthly. Any damaged parts should be replaced. Check the condition of the filter before using the O2B.

⚠ **Caution:** Ensure that the device is powered off and disconnected from the power supply before cleaning or performing maintenance.

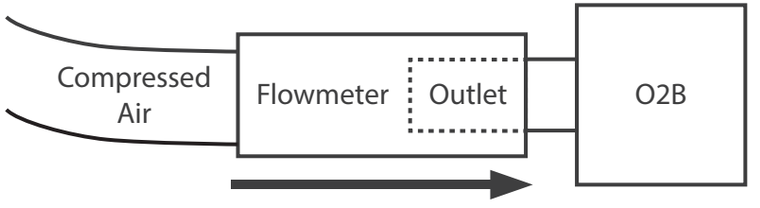
⚠ **Caution:** When the product is not being used, keep the inlets clean, and cover the room air inlet with its cover.

5.1 Leakage Inspection

The unit should be checked for gas path leakage by a trained qualified technician who is familiar with the performance of the O2B at least every month. The leakage inspection procedure is as follows:

5.1.1 Outlet Leakage Test

Step 1: Turn off the device, then connect a highly accurate (less than 1L/Hour or 0.01L/min) flow meter (recommend to use TST4000 series flow meter) to the device outlet as shown below.



Step 2: Connect dry clean compressed air at 6.0±0.3kPa.

Step 3: The flow meter reading should be less than 3L/hour or 0.05L/min. A higher flow reading indicates that the O2B has a leak. Contact Vincent Medical's authorized personnel for maintenance.

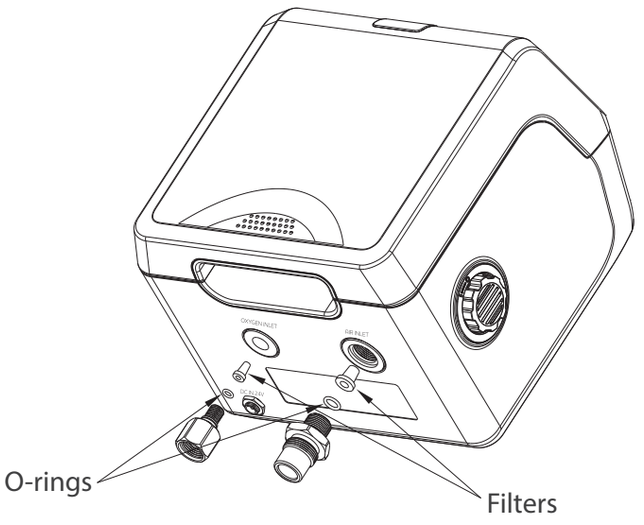
5.1.2 Inlet Leakage Test

Use the same method as 5.1.1 to inspect leakage from inlets. The flowmeter and test circuit should be connected to air or oxygen inlet with delivering compressed air.

⚠ **Warning:** Unauthorized repair by unqualified technician could lead to oxygen leakage into the electronics housing, potentially causing system failure or fire.

5.2 Inlet Filter Replacement

The compressed gas inlets have filters. It is recommended that these are replaced once a year. The cleaning and replacement steps are as follows:



Step 1: Remove the air/oxygen inlet connectors with a wrench; Do not over torque or tighten as this may cause damage to the threads or casing.
Step 2: Remove the O-rings and air and oxygen filters with tweezers (tilting the device will make it easier to remove the filters); ensure that the O-rings are in good condition, if not, replace with new O-rings.
Step 3: The filter has a 1 year life and a new filter should be installed annually.*
Step 4: Follow above steps in reverse order to reinstall the filters and inlet connectors.
Step 5: Connect the unit to air source and try to run the unit to check if it has leakage.

**Before installing the filters, make sure to check that the filters are in good condition without defects.*

⚠ **Caution:** To maintain device performance, the inlet filter should be replaced every 12 months. Failure to do so could cause the gas pathway to become blocked or obstructed which may impair device performance and may set off the loss of gas alarm.

5.3 Case Cleaning

Clean the dust on the case by wiping it with a lightly moistened cloth.

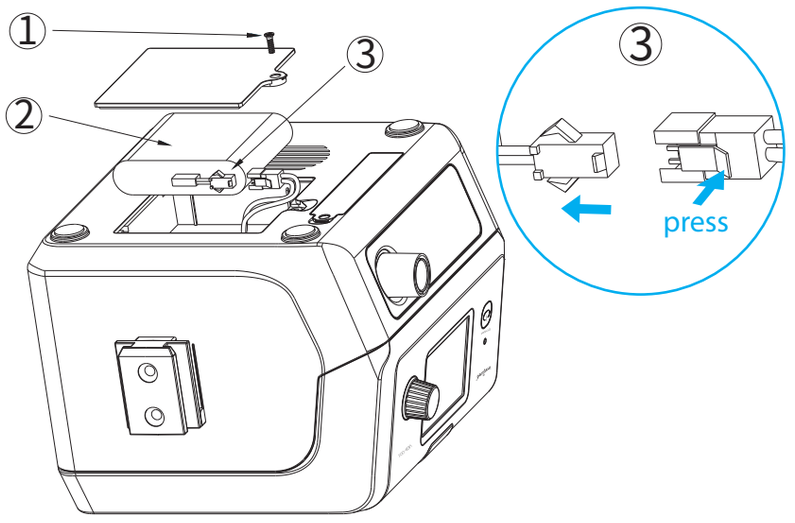
⚠ **Warning:** Do not immerse the O2B in liquid.
⚠ **Caution:** Do not use organic solvents to clean the surface of the main unit.

5.4 Battery Installation and Replacement

Before installing a battery, make certain that the battery is in good condition and within the shelf time (two years). Install or replace a battery as follows:
Step 1: Remove battery cover.
Step 2: Lift the battery out of the housing.
Step 3: Disconnect the battery cable from the battery connector.
Step 4: Connect the new battery to the battery cable.
Step 5: Install the battery* following the above steps in reverse order.

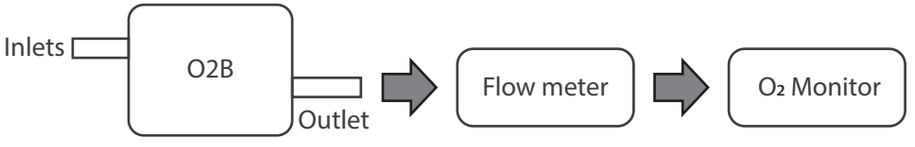
**The battery must be provided by Vincent medical, the P/N is shown on section 2.4.*
Use of other battery types will cause the device to malfunction.

⚠ **Caution:** Do not use any parts other than the accessories or the optional parts listed in this manual which are supplied exclusively by Vincent Medical. Otherwise, the performance of the device may be disrupted and can cause safety and performance issues.
⚠ **Warning:** Do not expose the battery to open flames. Exposure to an open flame could lead to fire and/or explosion.
⚠ **Warning:** Contact with a leaking battery can cause serious burns to the skin.



5.5 Oxygen Accuracy Inspection

Use a flow meter and an oxygen concentration monitor to check the delivery flow accuracy and FiO_2 accuracy every three months by following below connection process. If the flow and FiO_2 accuracy is out of specification (Section 3.1), contact professional maintenance personnel or Vincent Medical Customer Service.



5.6 Reverse Gas Inspection

The unit should be checked for reverse gas inspection by a trained qualified technician who is familiar with the performance of the O2B every three months. The check procedure is as follows:

1) Check reverse gas from air inlet to oxygen inlet

① Connect the low pressure hose assemblies to O2B. Connect terminal of air hose with compressed air(pressure approx. 50psi). Place terminal of oxygen hose into approx. 5mm of water (be careful to immobilize the hose to prevent it from becoming fully submerged, otherwise it would be difficult to dry hose).
② Turn on O2B and set FiO_2 as 21% and flow as 1L/min, then run the gas delivery.
③ Seal outlet of O2B. Wait for 5 seconds and then observe whether or not there are bubbles flowing continuously (more than 3 bubbles) from the end of the oxygen hose. If bubbles are observed there is a leak and a risk of decreased device functionality. Contact maintenance personnel for maintenance or replacement.
④ Dry terminal of hose after test.

2) Check reverse gas from oxygen inlet to air inlet

① Connect the low pressure hose assemblies to O2B, and connect terminal of oxygen hose with compressed oxygen(pressure approx. 50psi). Place terminal of air hose into approx. 5mm of water (be careful to immobilize the hose to prevent it from becoming fully submerged, otherwise it could be difficult to dry hose).
② Turn on O2B and set FiO_2 as 100% and flow as 1L/min, then run the gas delivery.
③ Seal outlet of O2B. Wait for 5 seconds and then observe whether or not there are bubbles flowing continuously (more than 3 bubbles) from the end of the air hose. If bubbles are observed there is a leak and a risk of decreased device functionality. Contact maintenance personnel for maintenance or replacement.
④ Dry terminal of hose after test.

5.7 Storage and Shipment

Storage and transportation conditions: -20°C ~ 45°C, 15% ~ 93% RH, non-condensing. Please keep the original packaging of the O2B to facilitate storage and protection during transportation.

5.8 Troubleshooting

Symptom	Possible Cause	Remediation
The power LED does not illuminate.	Is the power plug securely plugged into the electric outlet?	Plug the power plug in the electric outlet correctly.
	Is the power adapter loose or not plugged into the unit?	Plug the power adapter into the device correctly and lock it. (Ref. to section 4.2.2)
	If the unit is working with battery only? The battery has no power or the battery connection cable is broken.	Use the power adapter to charge the battery (Ref. to section 4.2.2) or install a new battery. (Ref. to section 5.4).
	Equipment failure.	Contact qualified trained technician.
No gas flows when the device is started	A gas source is not open.	Open the valves of gas sources.
	The gas source pressure is lower than the working pressure of Section 3.1.	Increase the gas source pressure.
	The gas source is empty.	Change to new gas source.
	The gas inlet is block.	Replace inlet filters. (Ref. to Section 5.2)
	The room air inlet cover is not open when use low pressure mode.	Open the room air inlet cover. (Ref. to section 4.3.2)
	Equipment failure.	Contact qualified trained technician to change a new room air inlet.
Leakage sound	Gas inlet connectors are loose.	Tighten the gas inlet connectors with wrench.
	The room air inlet check valve is damaged.	Contact qualified trained technician to change a new room air inlet.
	Mixed gas outlet module or optional oxygen module is loose.	Make certain the mixed gas outlet module or optional oxygen module is tightly connected, secured and locked in place with screw. (Ref. to Section 4.4)
	Equipment failure.	Contact qualified trained technician.
Low oxygen concentration alarm	The compressed oxygen gas source pressure is lower than the working pressure of Section 3.1.	Increase the oxygen gas source pressure.
	Equipment failure.	Contact qualified trained technician.
High oxygen concentration alarm	The compressed air gas source pressure is lower than the working pressure of section 3.1.	Increase the air gas source pressure.
	Equipment failure.	Contact qualified trained technician.
Loss of gas alarm	The compressed air and oxygen gas source pressures are lower than their working pressure in Section 3.1.	Increase the gas source pressure.
	Gas supply is empty.	Replace gas supply.
	Equipment failure.	Contact qualified trained technician.
Low battery alarm	Less than 10% battery remaining capacity.	Use the power adapter to charge the battery (Ref to section 4.2.2).
System failure	Sensor failure.	Restart the device or contact qualified trained technician.

5.9 Maintenance Statement

For any repair or change of components, contact Vincent Medical or your local supplier.
Installers and operators must follow the instructions of the device installation, operation, inspection and maintenance. Only qualified trained technician can carry our repair and maintenance work.

Conduct inspections and maintenance in accordance with the recommended schedule. In any of the following circumstances, Vincent Medical will not be responsible for the safety and reliability of the device performance if the following.

- Unauthorized modification, or repairs by unqualified and trained technicians.
- Unauthorized specified components are used.
- Use of an electrical power source that is not compatible with local regulations.
- Use of the device which is not in accordance with the instruction manual or intended use.

It is recommended that the following information is recorded before performing maintenance or repairs:

- Nature and scope of maintenance or repairs conducted
- Changes in the scope of maintenance
- Maintenance date
- Name of staff or company who is providing the maintenance service
- Signature from the Maintenance operation

Maintenance conducted by non-qualified and trained people and any unauthorized repairs will void all warranties.

6. EMC Information

The electromagnetic compatibility (EMC) of the VEB-001, VEB-002 is designed according to Medical Electrical Equipment Part 1-2 General requirement on safety (IEC 60601-1-2), Collateral Standard: Requirements and Tests for Electromagnetic Compatibility and the device comply with the requirements.

6.1 Declaration - Electromagnetic Emissions

Guidance and Manufacturer's Declaration - Electromagnetic Emissions		
VEB-001, VEB-002 is intended for being used in the electromagnetic environment specified below. The customer or the user of the model VEB-001, VEB-002 should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The models VEB-001, VEB-002 use RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearly electronic equipment.
RF emissions CISPR 11	Class A	The models VEB-001, VEB-002 are suitable for used in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: Warning: The models VEB-001, VEB-002 are intended for use by health-care professionals only. The models VEB-001, VEB-002 may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the O2B or shielding the location.
Harmonic Emissions IEC 61000-3-2	N/A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	N/A	

6.2 Guidance & Declaration - Electromagnetic Immunity

Guidance & Declaration — Electromagnetic Immunity			
The model VEB-001, VEB-002 is intended for using in the electromagnetic environment specified below. The customer or the user of the model VEB-001, VEB-002 should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8kV contact ±2kV, ±4kV, ±8kV, ±15kV air	±8kV contact ±2kV, ±4kV, ±8kV, ±15kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient / burst IEC 61000-4-4	±2kV for power supply lines ±1kV for Input/output lines	±2kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±0.5kV, ±1kV line to line ±0.5kV, ±1kV, ±2kV line to earth	±0.5kV, ±1kV line to line	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11.	＜5% U_T (＞95% dip in U_T) for 0.5 cycle ＜5% U_T (＞95% dip in U_T) for 1 cycle 70% U_T (30% dip in U_T) for 25/30 cycles ＜5% U_T (＞95% dip in U_T) for 5/6 sec	＜5% U_T (＞95% dip in U_T) for 0.5 cycle ＜5% U_T (＞95% dip in U_T) for 1 cycle 70% U_T (30% dip in U_T) for 25/30 cycles ＜5% U_T (＞95% dip in U_T) for 5/6 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the models VEB-001, VEB-002 requires continued operation during power mains interruptions, it is recommended that the models VEB-001, VEB-002 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the a.c. mains voltage prior to application of the test level.			

6.3 Guidance & Declaration - Electromagnetic Immunity Concerning Radiated RF

Guidance & Declaration - Electromagnetic Immunity			
The model VEB-001, VEB-002 is intended for using in an electromagnetic environment specified below. The customer or the user of the model VEB-001, VEB-002 should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150kHz to 80 MHz 6 Vrms in ISM bands 3V/m 80 MHz to 2.7GHz 385MHz-5785 MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2: 2014)	3 Vrms 150kHz to 80 MHz 6 Vrms in ISM bands 3V/m 80 MHz to 2.7GHz 385MHz-5785 MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2: 2014)	Portable and mobile RF communications equipment should be used no closer to any part of the models VEB-001, VEB-002, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d=[3,5/V_1]\times P^{1/2}$ $d=1.2\times P^{1/2}$ 80MHz to 800 MHz $d=2.3\times P^{1/2}$ 800MHz to 2.7 GHz Where P is the maximum output power rating of the transmitter In watts (W) according to the transmitter manufacturer and d Is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [a] should be less than the compliance level in each frequency range. [b] Interference may occur In the vicinity of equipment marked with the following symbols: 
NOTE 1: At 80MHz 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, an electromagnetic site survey should be considered. If the measured field strength in the location in which the models VEB-001, VEB-002 are used exceeds the applicable RF compliance level above, the models VEB-001, VEB-002 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the models VEB-001, VEB-002. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

6.4 Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and The Model VEB-001, VEB-002

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and The Model VEB-001, VEB-002.

The model VEB-001, VEB-002 is intended to be used in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the model VEB-001, VEB-002 can help to prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the model VEB-001, VEB-002 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (M)		
	150kHz to 80MHz $d=1.2\times P^{1/2}$	80MHz to 800MHz $d=1.2\times P^{1/2}$	800MHz to 2,5GHz $d=1.2\times P^{1/2}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance **d** in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where **P** is the maximum output power rating of the transmitter in watts (W) accordable to the transmitter manufacturer.

NOTE 1: At the frequency 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.

7. Use and Warranty Period

The device is not disassembled by authorized trained qualified service engineer/technician certified by Vincent Medical.

The warranty period is 1 year for main unit from the date of purchase. For the shelf-life of accessories, please refer to their manual. During the warranty period, the warranty will be void under the following conditions:

(1) An error caused by operating the unit in any non-prescribed conditions or application not described in the intended use.
(2) Damage or broken components caused by using an incorrect power supply or performing installation or operation incorrectly.
(3) Damage or broken components caused by installation, modification or repair by non-authorized trained service engineers/technician.
(4) Damage or broken components caused by natural disasters such as fire, earthquakes, power surges, lightning, floods, etc.
If the Electronic Blender develops a fault, please contact your authorized supplier or Vincent Medical for maintenance.

Customer Service Contact Information

Vincent Medical Manufacturing Co., Ltd.
Flat/RM B2, 7/F., Hang Fung Industrial Building, Phase 2, 2G Hok Yuen Street, Hung Hom, Kowloon, Hong Kong
Tel: +852 2186 1010
Fax: +852 2765 8428
E-mail: service@inspired-medical.com
Website: www.inspired-medical.com

Vincent Medical Manufacturing Co., Ltd.
Flat/RM B2, 7/F., Hang Fung Industrial Building, Phase 2, 2G Hok Yuen Street, Hung Hom, Kowloon, Hong Kong
Tel: +852 2365 5688
Fax: +852 2765 8428

EC REP **Obelis s.a**
Bd Général Wahis, 53, 1030 Brussels, Belgium
Tel: +32 2 732 59 54
Fax: +32 2 732 60 03
E-Mail: mail@obelis.net

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