



AerX

USER MANUAL

myAerX.com

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1. INTENDED USE

The Aer X oxygen concentrator device is used on a prescriptive basis by patients requiring supplemental oxygen. It supplies a high concentration of oxygen and is used with a nasal cannula to channel oxygen from the concentrator to the patient. The 3B Aer X may be used in home, institution, vehicle and various mobile environments. The Aer X is not intended to be life supporting or life sustaining.

CAUTION USA Federal law restricts this device to sale by or on the order of a physician. May also be applicable in other countries.

CAUTION Use of a cannula other than a 3B approved may restrict oxygen delivery and / or attachment to cannula adapter.

WARNING Availability of an alternative source of oxygen is recommended in case of power outage or mechanical failure. Consult your equipment provider for type of back-up system recommended.

CAUTION It is the responsibility of the patient to make back-up arrangements for alternative oxygen supply when traveling; 3B Medical assumes no liability for persons choosing not to adhere to manufacturer recommendations.

CONTRAINDICATIONS

WARNING This device is NOT INTENDED to be life sustaining or life supporting.

CAUTION Under certain circumstances, the use of non-prescribed oxygen therapy can be hazardous. This device should be used only when prescribed by a physician.

CAUTION Additional monitoring or attention may be required for patients using this device who are unable to hear or see alarms or communicate discomfort. If the patient shows any signs of discomfort, a physician should be consulted immediately.

CAUTION Do not change your prescribed oxygen setting except on the advice of a physician or other healthcare professional.

CAUTION The 3B Aer X™ is not designed or specified to be used in conjunction with a humidifier or nebulizer. Use of this device with a humidifier or nebulizer may impair performance and / or damage the equipment.

CAUTION To avoid danger of choking, swallowing or strangulation hazard, keep cords, Cannula adaptor away from children and pets.

CAUTION The Aer X is not a Toy so don't let children or pets touch or turn on the device.

GENERAL PRECAUTIONS

WARNING This device produces enriched oxygen gas which accelerates combustion. DO NOT ALLOW SMOKING OR OPEN FLAMES within 10 feet of this device while in use.

CAUTION Do not use oil, grease, or petroleum-based products on or near the Aer X™.

WARNING If you begin to feel ill or are experiencing discomfort while using this device, consult your physician immediately.

CAUTION Do not use the Aer X™ in an oxygen rich environment such as an oxygen tent.

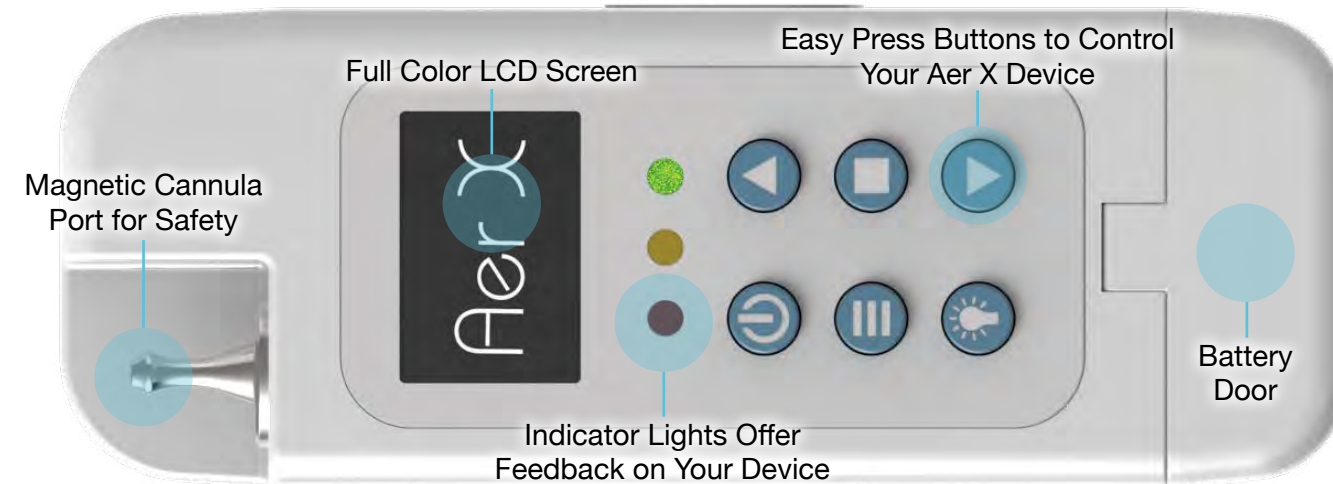
CAUTION Double check battery casing at each use, do not use if casing is torn or cracked.

CAUTION Never leave the Aer X™ in an environment which can reach high temperatures, such as an unoccupied car in high temperature environments. This could damage the device.







CAUTION Use of some accessories not specified for use with the Aer X™ may impair the performance.

CAUTION The Aer X is designed to provide a flow of high purity oxygen. An advisory yellow light will inform you if oxygen concentration drops below 85%. If the yellow light persists, contact your equipment provider. See the section "Indicator Lights" for additional information.

2. MAIN COMPONENTS AND FUNCTIONS




USER CONTROLS


BUTTON	MEANING	DIRECTIONS
	ON/OFF	Press once to turn "ON"; Press to turn "OFF".
	MENU	
	SELECT	
	UP	Use the Up and Down arrow to select your O ₂ pulse setting. Settings are available in 1-5 lpm increments. Please do not change settings unless you have been advised by a medical professional.
	DOWN	
	DISPLAY BACKLIGHT	

USER INTERFACES

Display



Indicator Lights



Green Light
Your Aer X device is operating correctly

Yellow Light
Warning status that may affect use or effectiveness

Red Light
Alerts you to error states which require maintenance

All 3 lights will blink during device start up and shut down.
Please See Troubleshooting Chart on page 28 for more details

Audible Signals

An audible signal (beep) indicates either a change in operating status or a condition that may need response (alarm). Your 3B Aer X will sound a long beep upon start up and shut down. When you press menu buttons a short audible beep will sound. Turning the volume off or low may interfere with alerts and alarms, please use caution. *Please refer to the Trouble Shooting guide on page 28 for detailed information.*

INPUT / OUTPUT CONNECTIONS

Inlet Air Filter Cartridge



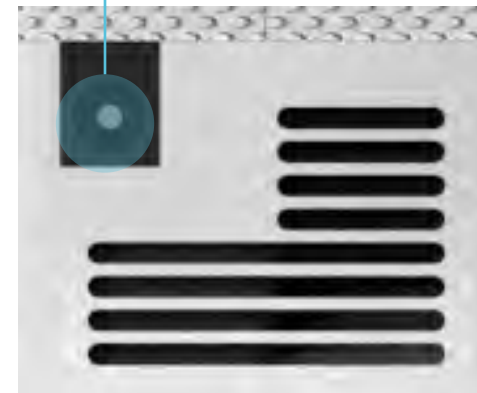
The user changeable inlet air filter should be checked and cleaned weekly.
The Inlet air filter should be changed every 6 months or as needed



CANNULA ADAPTER

The nasal cannula adapter connects to the top port on the 3B Aer X™. The port outputs oxygenated air. The port is magnetized and will detach from the device for your safety.

DC POWER IN



Connection for external power from the Power Supply.

POWER OPTIONS

Lithium Ion Batteries

The battery will power the 3B Aer X without connection to an external power source. When fully charged, a single battery will provide approximately 4 hours of operation at a setting of 2.

Recharging time is up to 3 hours for a fully depleted battery. See information in the “Battery Care and Maintenance” section.



WARNING Check Battery case before use, don't use cracked case.

Power Supply

The 3B Medical Power Supply (Model:GSM90B15-P2LR (90 degree) Mean Well) is used to power the Aer X concentrator from an AC power source. This allows the user to power the concentrator where AC power is available. The Aer X device will charge the battery during use when the device is plugged into a power source.

The Aer X Power Supply is specifically designed for use with the Aer X Oxygen Concentrator. The Power Supply provides the precise current and voltage required to safely power the Aer X and is designed to operate from specified AC sources. The power supply automatically adapts to input voltages from 100V to 240V (50-60HZ) permitting use with most power sources throughout the world.

Battery Charger

The 3B Medical Battery Charger is used to charge the 3B Aer X concentrator battery(s) from an AC power source. This allows the user to charge batteries where AC power is available.

The Aer X Battery Charger is specifically designed for use with the Aer X Oxygen Concentrator Batteries. The Battery Charger provides the precise current and voltage required to safely charge the Aer X batteries and is designed to operate from specified AC sources. The battery charger automatically adapts to input voltages from 100V to 240V (50-60HZ) permitting use with most power sources throughout the world. The Aer X Battery Charger is a stand-alone accessory that is sold separately. It is not included in your Aer X purchase.

ACCESSORIES

Nasal Cannula



A nasal cannula must be used with the Aer X to provide oxygen

from the concentrator. Please use only 3B Medical recommended cannulas for the most efficient oxygen delivery.

Carry Case

The Carry Case provides a protective cover, comfortable padded shoulder strap, and extra storage for batteries and accessories. The Carry Case is specifically designed to allow proper airflow around the Aer X and battery during operation. Use caution when utilizing any other carrying case or pack with your Aer X device, improper venting may cause a fire hazard.

Adsorbent Cartridges

The Aer X has patient changeable sieve bed cartridges. These cartridges siphon out the oxygen in the room air to provide you with consistent high-quality oxygen delivery. These cartridges should be changed once a year or if oxygen purity is under 85%.



3. OPERATING INSTRUCTIONS

General Instructions

1. Place the Aer X in a well-ventilated location

The Carry Case is recommended to allow proper airflow. Air intake and exhaust must have clear access. Place the 3B Aer X in such a way that auditory alarms may be heard.

2. Ensure the Inlet air filter cartridge is in place.

The Carry Case is recommended to allow proper airflow. Air intake and exhaust must have clear access. Place the 3B Aer X in such a way that auditory alarms may be heard.

WARNING Avoid use of the Aer X in the presence of pollutants, smoke or fumes. Do not use the Aer X in the presence of flammable anesthetics, cleaning agents, or other chemical vapors.

CAUTION Do not obstruct air intake or exhaust when operating the device. Blockage of air circulation or proximity to a heat source may lead to internal heat buildup and shutdown or damage the concentrator

CAUTION Do not operate the Aer X without the inlet air filter cartridge in place. Particles drawn into the system may damage the equipment.

3. Power the Aer X

Install the battery

Slide the battery cover out and up to open.
Insert the battery and close the cover.

Connect the power supply

- Connect the AC Power plug to the Power Supply.
- Connect the AC Power Output Plug to the power source.
- Connect the Power Plug to the Aer X.

CAUTION Ensure the Power Supply is in a well-ventilated location as it relies on air circulation for heat dissipation. The Power Supply may become hot during operation. Make sure the Power Supply cools down before handling.

CAUTION The Power Supply is not intended to be used near water sources. Doing so will put you at risk of damage to your unit and electric shock.

CAUTION Do not disassemble the Power Supply. This may lead to component failure and/or safety risk.

CAUTION Do not place anything in the Power Supply port other than the supplied wall cord. Avoid the use of electrical extension cords with the Aer X. If an extension cord must be used, use an extension cord that has an Underwriters Laboratory (UL) Mark and a minimum wire thickness of 18 gauge. Do not connect any other devices to the same extension cord.

4. Connect the nasal cannula to the magnetic port.

The cannula tubing connects to the magnetic port. To ensure proper sealing and purity, only use cannulas and accessories approved or sold by 3B Medical, Inc Replacement Magnetic Ports are available should yours become lost or damaged.

CAUTION To facilitate oxygen flow, ensure the nasal cannula is properly connected to the port, the port is properly connected to the Aer X, and that the tubing is not kinked or pinched in any way.

CAUTION Replace the nasal cannula on a regular basis. Check with your equipment provider or physician to determine how often the cannula should be replaced.

5. Turn on your Aer X by pressing the ON/OFF button.

Upon startup a long audible beep will sound. Begin breathing normally and the Aer X will begin to deliver oxygen. Set the Aer X Concentrator to the output setting prescribed by your physician or clinician. Use the arrow keys, to adjust the Aer X to the desired output setting. The current setting can be viewed on the display.

6. Position the nasal cannula on your face and breathe through your nose.

The Auto X will sense the onset of inhalation and deliver a burst of oxygen at a precise time when you inhale. The Auto X will sense each breath and continue to deliver oxygen in this manner. As your breathing rate changes, the Auto X will sense these changes and deliver oxygen only as you need it. At times, if you inhale very quickly between breaths the Auto X may ignore one of the breaths, giving the

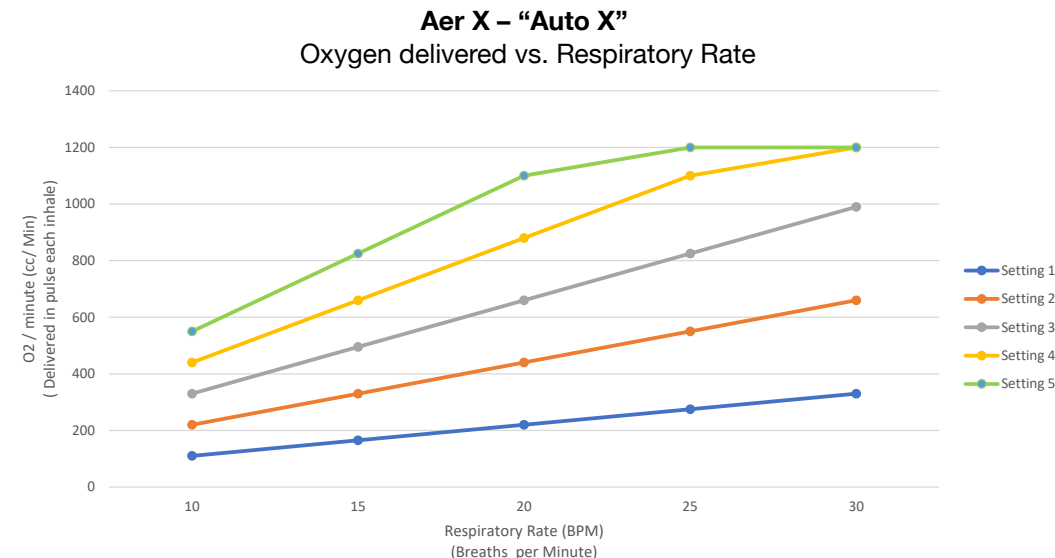
appearance of a missed breath. This may be normal as the Auto X senses and monitors the changes in your breathing pattern. The Auto X will normally sense the next breath and deliver oxygen accordingly.

Make certain that the nasal cannula is properly aligned on your face and you are breathing through your nose.

If no breath is detected for 3 minutes, your Aer X will power off.

AUTO X

During physical activity that requires more oxygen, your Aer X uses Auto X technology to detect your breaths per minute and increase your oxygen intake according to those needs.



7. Aer X Screen Options

Start Up Screen



Aer X Device Info



Main Screen



Settings Menu Options



TRAVELING BY AIR



The FAA allows the Aer X onboard all U.S. aircraft; here are a few points to make air travel easy.

Planning Your Flight

When flying with your Aer X, you must inform the airline that you will be using your Aer X onboard the aircraft. You must always keep a signed statement from your physician with you that includes:

- Your ability to see/hear alarms and appropriately respond.
- When oxygen use is necessary (all or a portion of the trip).
- Maximum flow rate corresponding to the pressure in the cabin under normal operating conditions.
- A new statement will not be necessary each time you fly, but the statement should be available during every flight.
- Some airlines may equip their aircraft with onboard electrical power. You may have an opportunity to request a seat with a power port which can be used to power your Aer X. However, availability varies by airline, type of aircraft and class of service. You should check with your airline for availability and always plan on having sufficient battery power for the duration of your flight, plus a conservative estimate of unanticipated delays.

BEFORE YOUR FLIGHT

Here are some things to keep in mind the day your flight departs:

- Ensure your Aer X is clean, in good condition and free from damage or other signs of excessive wear or abuse.
- Bring enough charged batteries with you to power your Aer X for the duration of the flight plus a conservative estimate for any unanticipated delays.
- Regional / Commuter airlines do not offer onboard electrical power. If your travel plans call for flights on regional airlines, you will need sufficient battery power for the duration of the flight, plus a conservative estimate of unanticipated delays.

CAUTION Airlines may not be equipped to provide backup oxygen.

- Arrive at the airport early. Airport Security screening personnel may require extra time to inspect your Aer X.
- While waiting to board your flight, you may be able to conserve battery power by using the Power Supply to power your Aer X from an electrical outlet in the airport terminal if available.
- You should inform the airlines you will be using your Aer X. Have a physician letter with you and ready for inspection if requested.

DURING YOUR FLIGHT

- If using airline power port, you do not need to remove the Battery from the Aer X oxygen concentrator.
- Connect the Power Plug for available airline power. Check with airline personnel to ensure compatibility.
- During taxi, takeoff and landing, stow your Aer X under the seat in front of you. Your Aer X will fit upright under most airline seats. However, if it doesn't fit you may turn it on its side.
- It is not necessary to turn off your Aer X during taxi, takeoff and landing if your physician's written statement requires you receive oxygen during these periods.



BATTERY OPERATING INSTRUCTIONS

Ensure that the battery is in place and charged. While the Aer X is operating on battery power, the battery will discharge. The display will indicate the estimated remaining battery charge. When the Aer X detects that the battery life is low the yellow indicator light will illuminate.

When battery life is low, do one of the following:

- Plug the Aer X into an AC power source using the Power Supply (wall or car outlet).
- Replace the battery with a charged battery after turning off the Aer X (by pressing the ON/OFF button).
- If the battery is drained, charge the battery.

Normal Battery Charging



To ensure that your battery is properly charging make sure the battery charger is properly connected to the AC wall outlet and to the battery being charged. Observe the battery charger icon that indicates the unit is charging.

BATTERY CARE AND MAINTENANCE

Your Aer X Lithium Ion Battery requires special care to ensure proper performance and long life. Use only 3B Aer X Batteries with your 3B Aer X Concentrator. The Aer X battery comes pre-charged from the factory.



Battery Time Remaining

The Aer X continuously displays battery level remaining.

The on-screen battery display reflects the battery power left in the battery. The Battery Level Display will show a circle with a value of 10%-100%. At 10% battery life, the RED INDICATOR light will blink on and off as a warning.

When the battery life reaches a critically low level the Aer X device will beep and the indicator light will blink red 7 times. This is to alert you that shut down is imminent. The Aer X will save your settings for your next use.

Replacement Part Numbers:

Lithium-Ion Batteries (RRC-Model: RRC2040-2)
Power Supply: GSM90B15-P2LR (90 degree) Mean Well
Battery Charger: (ACD200)
Nasal Cannula (3B Ultra Soft-Item No. 02SCR)
Magnetic Port Part No. D-03273
Adsorbent Cartridges (Aer3057)
Carry bag: T272

4. AUDIBLE AND VISIBLE SIGNALS

Display Settings



Output Setting Display 1, 2, 3, 4, 5 (lpm)

Indicator Lights & Troubleshooting

Green Light	<ul style="list-style-type: none"> • Device Operating Properly • Blinks on start up • Blinks during oxygen bolus delivery 	Green light will blink on start-up and during Oxygen inhalation. The Green light indicates your Aer X is running normally and no issues are detected
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Yellow Light	<ul style="list-style-type: none"> • Low O₂ • Warning status • Cartridge replacement • Cannula missing 	A yellow indicator light alerts you to a warning status. If no cannula is detected a solid yellow light will show. Low O ₂ purity between 70%-85% the yellow indicator light will blink while inhaling, the Aer X unit IS usable during this time, but will need to be checked by a service professional. Cartridge Replacement needed-the yellow light will blink and a message will show "change cartridge" in the machine log. Light will blink twice and beep if no breath is detected.
Red Light	<ul style="list-style-type: none"> • Error status unit requires servicing • Low battery (shut off impending) • Unit is overheating 	Solid red indicator light indicates the Aer X unit cannot complete a cycle and may not be delivering oxygen, this requires urgent servicing. Very low O ₂ purity >70% will cause the Aer X to blink a red indicator light 4 times while simultaneously beeping. Critically low battery power will cause the red-light indicator to blink and beep 7 times prior to the Aer X shutting down.

5. TROUBLESHOOTING

Problem	Possible Cause	Recommended Solution
Device does not operate	Battery low	<ul style="list-style-type: none"> Check & charge battery Change battery Use power supply
	Battery not installed correctly	Seat battery correctly
	Unknown mechanical electrical failure	Contact service provider check machine log if screen turns on

Problem	Possible Cause	Recommended Solution
Device skips a pulse dispense of oxygen	Did not sense inhale	Adjust cannula
	Breathing faster than 30 times per minute	Cannula disconnected
Battery pack appears to have no power	Battery completely discharged	Physically check battery gauge on bottom of battery

6. CLEANING, CARE AND MAINTENANCE

Cannula Replacement

Your nasal cannula should be replaced on a regular basis. Consult with your physician and/or equipment provider and/or cannula manufacturer's instructions for replacement

information. A single lumen cannula up to 4 feet in length is recommended to ensure proper breath detection and oxygen delivery.

CAUTION Use of a cannula other than what is recommended by 3B Medical may restrict oxygen delivery and may cause impurities in the delivered oxygen.

Carry Case and Device Case Cleaning

Turn off and disconnect power before cleaning/replacing parts. You may clean the outside case

and the carry case using a cloth dampened with a mild detergent (such as Dawn™) and water.

WARNING Do not submerge the 3B Aer X or its accessories in water or allow water to enter into the case; this may lead to electrical shock and/or damage.

Filter Cleaning and Replacement

The inlet air filter must be cleaned weekly to ensure the ease of air flow. Remove filter from device. Clean the particle filter with a mild liquid detergent (such as Dawn™) and water; rinse in water and dry before reuse.

NOTE It may be necessary to clean the particle filter more often in dusty environments.

To purchase additional particle filters, contact your equipment provider or 3B Medical.

Other Service and Maintenance

WARNING Do not disassemble the 3B Aer X or any of the accessories or attempt any maintenance other than tasks described in the troubleshooting section; disassembly creates a hazard of electrical shock and will void your warranty. Do not remove tamper evident labels. For events other than those described in this manual, contact your equipment provider for servicing by authorized personnel.

CAUTION Do not use lubricants on the 3B Aer X or its accessories.







DISPOSAL OF EQUIPMENT AND ACCESSORIES











Follow your local governing ordinances for disposal and recycling of the 3B Aer X and accessories.

MAINTENANCE ITEMS LIST

- Aer X battery
- Replacement inlet air filter
- Adsorbent cartridge

7. SYMBOLS USED ON CONCENTRATOR AND ACCESSORIES

SYMBOL	MEANING
WARNING	A warning indicates that the personal safety of the patient may be involved. Disregarding a warning could result in significant injury.
CAUTION	A caution indicates that a precaution or service procedure must be followed. Disregarding a caution could lead to a minor injury or damage to equipment.
	See User Manual for Instructions
	Risk of Electrical Shock
	U.S. Federal Regulation Restricts this Device to Sale by Order of Physician. May also be applicable in other Countries.
	AC Power
	DC Power
	Read instructions in User Manual

SYMBOL	MEANING
	No Smoking while the device is in use.
	No Open Flames (Concentrator); Do not incinerate (Battery)
	Keep Dry
	Indoor or Dry Location Only, Do Not Get Wet
	Use No Oil or Grease
	Do Not Disassemble
	Do Not Dispose of In Unsorted Municipal Waste
	Type BF Applied Part, Not Intended for Cardiac Application
	Class II Device
	Complies with Applicable EU Directives Including Medical Device Directive

8. SYSTEM SPECIFICATIONS

Dimensions: (with battery)	L / W / H: 7.22" X 8.38" X 2.64"
Weight:	4.25lb - 3.5lb without battery
Noise:	40 dBA
Warm-Up Time:	2 minutes
Oxygen Concentration:	87% to 94% on all settings
Output Settings:	5 settings: 1 to 5

System Specifications continued

Power:	Power Supply
	AC Input: 100 to 240 VAC 50 to 60 Hz Auto-Sensing: 1.35 A DC Output: 15 VDC, 5.35A max.
	Rechargeable Battery
	Voltage: 10.4-12.6 VDC
Battery Duration:	Up to 4 hours at output setting of 2
Battery Charging Time:	Up to 3 hours
Environmental Ranges Intended for Use:	Temperature: 38 °F to 100 °F (2 °C to 38 °C) Humidity: 0 to 60% non-condensing Altitude: 0 to 10,000 ft. (0 to 3,048 meters)

System Specifications continued

Environmental Ranges Intended for Storage:	Temperature: -4 °F to 140 °F (-20°C to 60°C) Humidity: 0 to 95% non-condensing Altitude: 0 to 10,000 ft. (0 to 3048 meters)
Transportation:	Keep Dry, Handle with Care

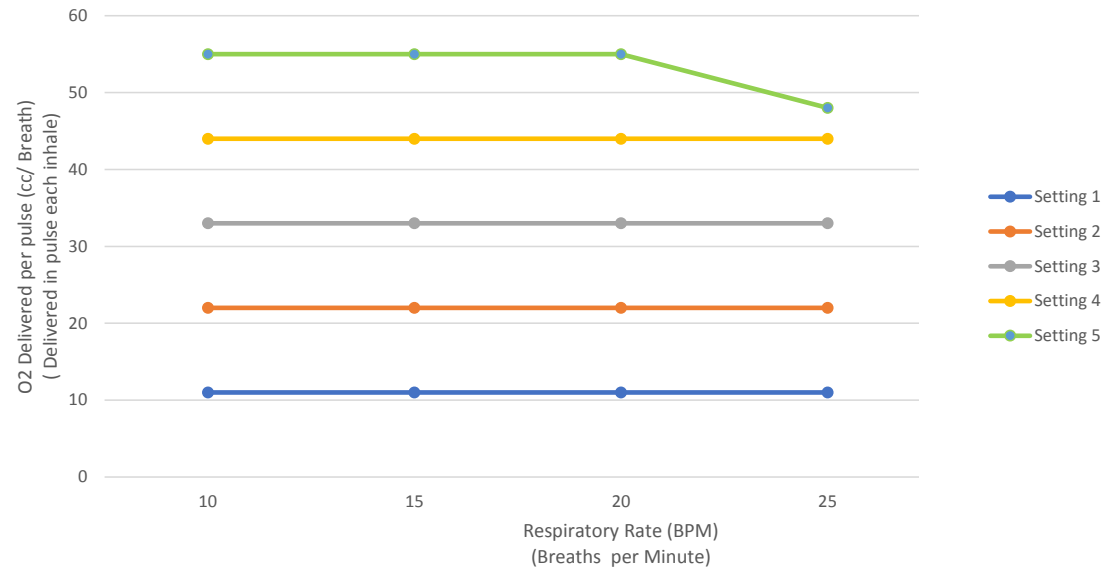
SETTING	DISPENSE VOLUME (CC)	MAXIMUM BREATH RATE (BPM)*
1	11	30
2	22	30
3	33	30
4	44	30*
5	55	30*

The Aer X will wait for the next breath when maximum breath rate is exceeded. Will slightly reduce the O2 output.

**setting of 4 @30 pm dispenses 48*

Aer X

Pulse Volume Setting vs. Respiratory Rate



CLASSIFICATIONS

Mode of Operations:	Continuous Duty
Type of Protection Against Electrical Shock	Class II
Degree of Protection Against Electrical Shock:	Type BF Not intended for cardiac application
Degree of Protection Against Ingress of Water:	IP22
Degree of Safety for Application in Presence of Anesthetic Gases:	Not suitable for such application

ELECTROMAGNETIC COMPATIBILITY

The Aer X is designed to provide reasonable protection against harmful interference in a typical medical installation. The equipment generates uses and can radiate radio frequency energy and if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation.

If this equipment interferes with other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

1. Reorient or relocate the receiving device.
2. Increase the distance between the equipment.
3. Connect the equipment into an outlet on a circuit different from that to which the other device(s) is connected.
4. Consult 3B Medical or your equipment provider for assistance.

CAUTION Portable and mobile RF communications equipment can affect medical electrical equipment.

CAUTION Stacking or placing equipment adjacent to other devices is not recommended, where such configurations are necessary, all equipment in question should be carefully observed to ensure that EMI does not degrade performance.

CAUTION Use of accessories, transducers and cables other than those specified, with the exception of transducers and cables sold by the manufacturer of the equipment as replacement parts for internal components, may result in increased emissions and decreased immunity of the equipment or system.

GENERAL WARNING Keep the Aer X inside the Carry bag at all times, as it works like a barrier from any excessive heat, don't wear the carry bag while connecting the Aer X to the power supply to charge the battery.

During the running of the Aer X especially outdoor or in up normal environment, the patient doesn't need to touch hot parts like cannula port.

If a patient has the requirement for Oxygen at all times, then a backup source for oxygen supply is the responsibility of the patient as stated in the IFU. The Aer X is as stated in the "Indication for Use" "not life supporting or life sustaining". The Aer X is an adjunct machine in the care for a patient needing supplemental oxygen

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

The Aer X Oxygen Concentrator is intended for use in the electromagnetic environment specified below. The customer or the user of the Aer X Oxygen Concentrator should assure that it is used in such an environment.

EMISSIONS TEST	COMPLIANCE	ELECTROMAGNETIC ENVIRONMENT
RF Emissions CISPR 11	Group 1	The 3B Medical Aer X uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	The 3B Medical Aer X is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	Not Applicable	
Voltage Fluctuations/ Flicker Emissions	Not Applicable	

9. LIMITED WARRANTY

Limited Warranty Statement

The Aer X POC units come with a standard 5-year warranty.

Warranty begins from the date of shipment. The Standard Equipment Warranty covers only defects arising under normal use and do not include malfunctions or failures resulting from misuse, abuse, neglect, alteration, problems with electrical power, usage not in accordance with product instructions, acts of nature, or improper repairs made by anyone other than 3B Medical or a 3B Medical authorized third-party service provider.

Defective units will be repaired by a contracted third-party repair center, this center is acting as 3B Medical and has the authority to determine if misuse or neglect is resulting in a fraudulent replacement.

- If a confirmed malfunction or failure occurs it is at 3B Medical's discretion to provide a new or refurbished unit as a replacement. All refurbished units are professionally handled and are in "like new" condition.
- Warranty begins from date of shipment.

- The malfunctioning unit MUST be shipped within 30 days of receipt of the replacement unit, failure to do so may incur an invoice for the replacement unit at full price
- 3B Medical will provide a return shipment label to the nearest contracted repair center

Adsorbent Sieve Bed Cartridges and Rechargeable Batteries are covered for a period of 1 year only.

**Please see our 3B Medical Standard Warranty policy located at www.3bproducts.com for full warranty details.*

