USER MANUAL

Stratus 5

OXYGEN CONCENTRATOR

3B™ Medical, Inc.

www.3Bproducts.com

CE 0123

Symbol Key

MARK	DEFINITION
I	Power on
○	Power off
	Follow Instruction for Use
	No smoking
	Caution, consult accompanying documents.
	Class II (Double Insulated)
	Type BF Applied Part
CE 0123	CE certification mark
	AC Power
	Stacking Limit by Number
	This Way Up
	Fragile, handle with care
	Keep dry
	Temperature limit
	No open flames
IP21	IP21 Drip Proof Equipment
	Consult instructions for use
	Stand-by
	Warning, electricity

SPECIAL NOTES

- **Please read this manual carefully before using this product and save it for future reference.**
- **If you need assistance with this manual, Please contact your local DME or home health provider**
- **The Stratus 5 is a prescription device. Use only the liter setting prescribed for you.**
- **It is always recommended for critically ill patients to have a backup oxygen source in case of malfunction.**
- **If patient experiences an adverse reaction contact physician or call 911 immediately.**
- **In case of machine malfunction, contact the home medical equipment provider; do not attempt to disassemble the Stratus 5.**
- **The Stratus 5 is not intended as life support, it is for supplemental oxygen use only. Patients with special needs may be unable to understand the alarm features and should be well supervised while using an oxygen concentrator.**
- **The Stratus 5 is for single patient use.**
- **Do not adjust the flowmeter float beyond the red line position. Long-term use out of range will reduce the efficiency of the oxygen generator.**

SAFETY NOTICE

Please read the following information carefully before
Operating the oxygen concentrator

Warning

Special attention should be paid to reducing the risk of fire when using oxygen therapy. Any material that is flammable in the air becomes extremely combustible and burns quickly when the oxygen concentration is high. For safety reasons, all ignitions should be kept away from the oxygen concentrator.

Oil, grease or petroleum substances are prone to strong spontaneous combustion when exposed to oxygen under pressure. These materials must be kept away from oxygen concentrators, cannulas, connections, and other oxygen concentrator components. Do not use any lubricant unless recommended by 3B MEDICAL, INC. Do not smoke while using an oxygen concentrator.

Tips for Optimal Performance of the Stratus 5

- The Stratus 5 should remain upright during use and storage.
- The Stratus 5 should be operated in a clean environment. Excessive dust and moisture can affect optimal performance.
- Environmental temperatures for operation should remain between 50°F and 99°F. •
- The Stratus 5 should not be moved while in operation.
- The Stratus 5 should not be turned on with the flow meter turned off or less than “0”.
- The Stratus 5 will make an exhaust sound while in operation.
- The Stratus 5 will vent hot air from the bottom of the unit; please do not block the vent. Blocking the vent increases risk of fire.
- The Stratus 5 should be used for 30+ minutes at each session.
  Running the concentrator for short bursts can damage the components over time.
- Do not use the Stratus 5 if the power cord is damaged, the concentrator has fallen or has been submerged in water.
- If any of the above occurs, the unit is working incorrectly or abnormally, please contact your DME or home health company.
- Do not move the Stratus 5 by pulling the power cord.
- Do not insert foreign objects into any openings.
- Do not block inlets, vents or exhaust ports of the Stratus 5.
- Do not place the Stratus 5 on soft surfaces such as beds, sofas, blankets or cushions, this is a fire hazard.
- Do not overfill the humidifier water bottle. This may cause water to enter the cannula or oxygen outlet port.
- Please place the Stratus 5 at least 15 inches away from walls, curtains and other solid surfaces.
- Do not stack objects on top of the Stratus 5.
- Do not use parts, accessories, or equipment not approved by 3B MEDICAL, INC.
- Do connect the concentrator in parallel or series with other oxygen concentrators or oxygen therapy devices.
- Only use the Stratus 5 power cord made specifically for this device.
- Oxygen therapy is a prescription. Flow rates are patient specific. Please do not change your flow without consulting your physician.
- This machine is designed to supplement oxygen, not for first aid or to sustain life.

- Avoid creating sparks near medical oxygen equipment, including static sparks generated by friction.
- Extended use in sub-optimal conditions can affect oxygen purity. This may cause oxygen levels lower than the patient requires.
- If you feel your oxygen therapy is not sufficient please contact your physician. DO NOT attempt to change your prescribed liter flow.
- The power plug must be unplugged while the Stratus 5 concentrator is not in use.
- Contact the physician immediately, if the patient or caregiver finds insufficient oxygen supply. Do not adjust the oxygen flow unless directed by a physician or healthcare professional.
- Always unplug the Stratus 5 when performing any routine maintenance to avoid electric shock.

Maintenance

The 3B Stratus 5 is designed to minimize routine maintenance. Yearly maintenance must be performed by an authorized dealer or certified personnel only.

Radio frequency interference

- The use of portable communication equipment near the oxygen concentrator may cause interference to the machine.
- This product cannot be used in environments such as electrocautery, electrosurgery, defibrillation, X-ray (gamma ray), infrared radiation and transient electromagnetic fields, including magnetic resonance (MRI) and radio interference.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be more than 12 inches from any part of the equipment. Otherwise, the performance of the device may be affected.
- This oxygen concentrator cannot be stacked with other equipment. This may result in improper operation.

Water Safety

- Do not use while bathing. If the patient requires continuous O2, the Stratus 5 concentrator must be placed at least 10 feet from the bathroom.
- Do not touch the oxygen concentrator while wet. Do not use or store this oxygen concentrator near liquids or other electrically conductive materials.
- Do not touch the Stratus 5 if it should fall into water or other conductive liquid. If this should occur, unplug the power cord immediately.

Table of Contents

Chapter 1: Introduction

Your physician has prescribed an oxygen concentrator set at a specific flow setting to meet your needs. DO NOT change the flow settings unless your health care professional tells you to do so. Please read and understand this entire manual before using the device.

Intended Use

The 3B Medical Stratus 5 Oxygen Concentrator is intended to provide supplemental oxygen to persons requiring oxygen therapy. The device is not intended to be life supporting or life sustaining.

About Stratus 5

The Stratus 5 produces concentrated oxygen from room air for delivery to a patient requiring low flow oxygen therapy. The oxygen from the air is concentrated using a molecular sieve and a pressure swing adsorption process. Your home care provider will show you how to operate the concentrator and will be available to answer any questions.

Parts of Oxygen Concentrator

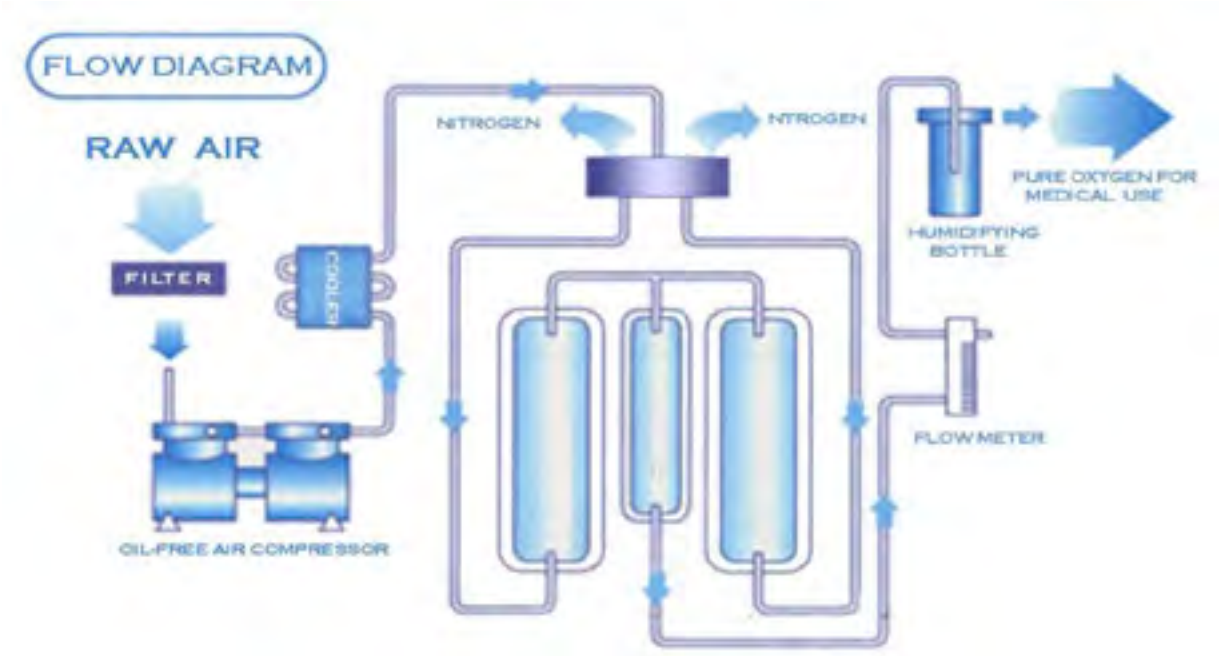
- Humidifier Band: The humidifier band secures the humidification bottle to the Stratus 5.
- Oxygen outlet: the oxygen flows from this port
- Oxygen flow meter: The flow meter indicates the liters per minute (lpm) that the oxygen is flowing from the oxygen outlet port
- Power switch
  " I " indicates the unit is running
- " O " indicates the power is off and oxygen is no longer being delivered to the patient

- Intake filter: filters dust particles, this filter must not be removed by the patient
- Filter Access Panel: allows authorized personnel to access the intake filter

Accessory Equipment and Spare Parts

Please use only 3B MEDICAL, INC. accessories and spare parts for this device

Workflow Chart



Chapter 2: Conditions of Use

Operating Environmental

- Operating Temperature: 50-99° F
- Operating Relative Humidity: 20%RH-65%RH
- Operating Pressure atmosphere: 80kPa ~ 101kPa
- The operating environment should be dry and well ventilated. The Stratus 5 should never be run in environments that are dusty. Avoid electromagnetic interference when possible

Storage and Transportation Environment

- This product must be placed upright and vertical during transportation.
- Transport & Storage Temperature: -30°C-70°C.
- Transport & Storage Relative Humidity: 15-95%RH, No condensation.
- Transport & Storage Pressure Atmosphere: 500-1060hPa.

Classification

The Stratus 5 Oxygen Concentrator is classified as:

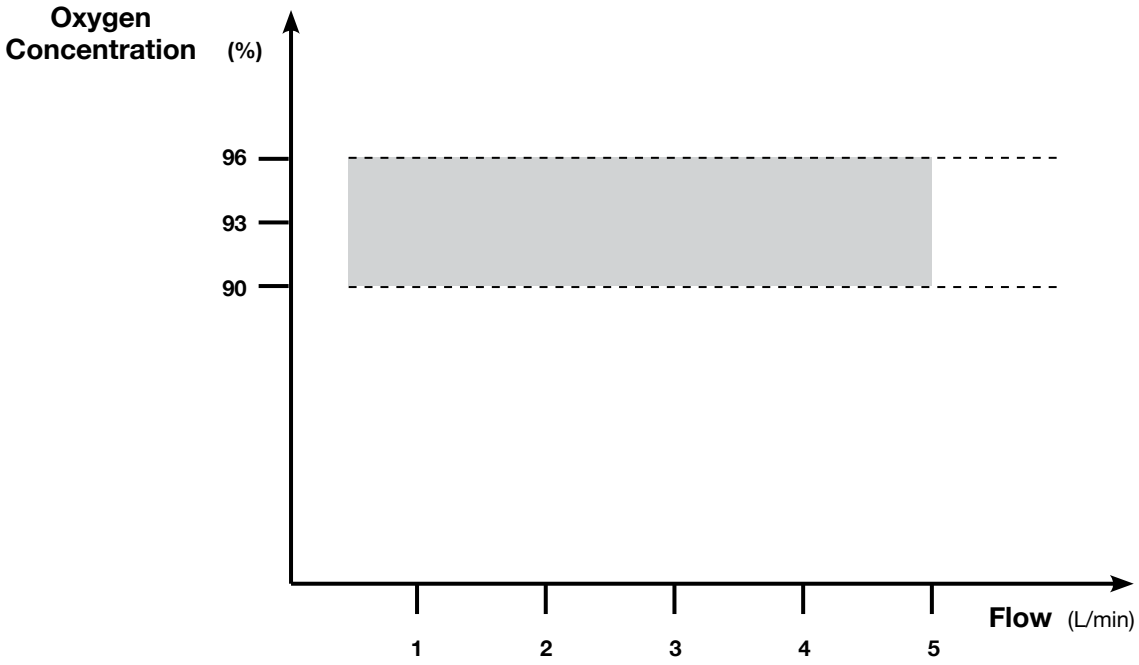
- IEC Class II Equipment
- Type BF Applied Part
- IP21 Drip Proof
- When the AC power supply voltage exceeds -15% to +10% of the rated voltage, the voltage is too high, which may result in damage to the equipment. If the voltage is too low, the equipment may not start. If the grid is unstable, please install a voltage regulator before use.
- The optimal temperature of the environment for Stratus 5 is 50-99°F. Below 50°F, compressor start-up may be difficult. Above 99°F, the compressor may overheat and shorten the service life of the compressor.
- During continuous operation, the time for reaching the specified oxygen content should not exceed 30 minutes.
- Not suitable for use in the presence of a flammable anesthetic mixture or nitrous oxide.
- Air outlet pressure: 0.05±10% MPa
- The expected service life of the product is 5 years.
- If the device is stored in a very cold or very hot environment, it should be allowed to stabilize at room temperature for 5 hours before use.

Parameter Configuration

Model	STR1005
Rated power (W)	320
Voltage	120V ± 12V 60HZ ± 1HZ
Flow rate (L/min)	0.5~5
Concentration (Rated flow)	93%±5%
Sound pressure level dB (A)	≤45
Sound power level dB (A)	≤55
Net weight (kg)	15.5
Dimension (mm)	390×230×600
Features	Abnormal temperature alarm; Low oxygen concentration alarm; Power failure alarm; Timer; Pressure alarm; Low flow alarm; Thermistor fault alarm

* Device operation above or outside of the voltage, LPM, temperature and humidity values specified may decrease oxygen concentration levels.

* When the nominal pressure of the oxygen output port is zero, the oxygen concentration is 93%±5% under the operating environment and rated flow rate. See the “Output Oxygen Concentration and Flow Rate Diagram



Relation of outlet oxygen concentration and flow

Chapter 3: Operating Instructions

Warning: Do not use extension cords or electrical adapters.

1. Select a location that allows the concentrator to draw in room air without being restricted. Make sure that the device is at least 12 inches away from walls, furniture, curtains that could impede adequate airflow to the device.
2. Do not place the device near any heat source.
3. Plug the power cord into a grounded electrical outlet.
4. Follow step A or B depending on humidifier use:

   A. If you are not using a humidifier:

      I) Connect a cannula to the oxygen outlet.

   B. If you are using a humidifier, follow the steps below:

      I). Remove humidifier bottle from package.

      II). Unscrew the lid in a counterclockwise direction, remove the humidification cup, fill with proper amount of distilled water, and then tighten the lid clockwise.

Note:

- Please use distilled water only, and replace daily
- Please do not over fill the humidifier.

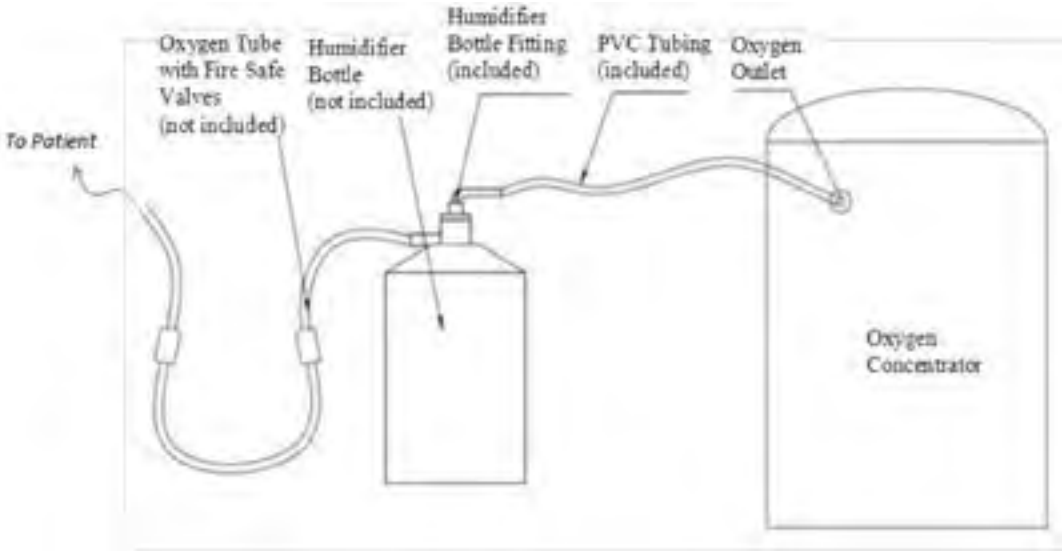
III). Install the humidifier with water in the hook and loop fastener on the top of the Stratus 5 according to the diagram.

IX). Secure the humidifier using the humidifier band.

X). Connect the PVC hose to the oxygen outlet and humidifier inlet according to the diagram.

XI). Attach the cannula to the humidifier

The Air Path:



5. Turn on the power switch
6. Adjust the oxygen output flow to prescribed liters per minute by centering flow meter ball on the proper number.

Note:

- The flow meter adjustment knob increases the flow rate counterclockwise and decreases the flow rate clockwise.

7. Always turn off the Stratus 5 when not using.

Chapter 4: Cleaning & Maintenance

Warning: It is important to unplug the device before you perform any cleaning.

Excessive moisture may impair the operation of the Stratus 5

1. The air intake filter should be cleaned weekly. If environmental conditions are less than optimal, clean more frequently
2. Cleaning steps are as follows:

   a) Remove the air intake cover on the side of the Stratus 5 and take out the sponge mesh filter.

(Left side of the body)

(sponge mesh filter)

   b) Rinse the sponge mesh thoroughly using clean water, then allow to air dry completely.

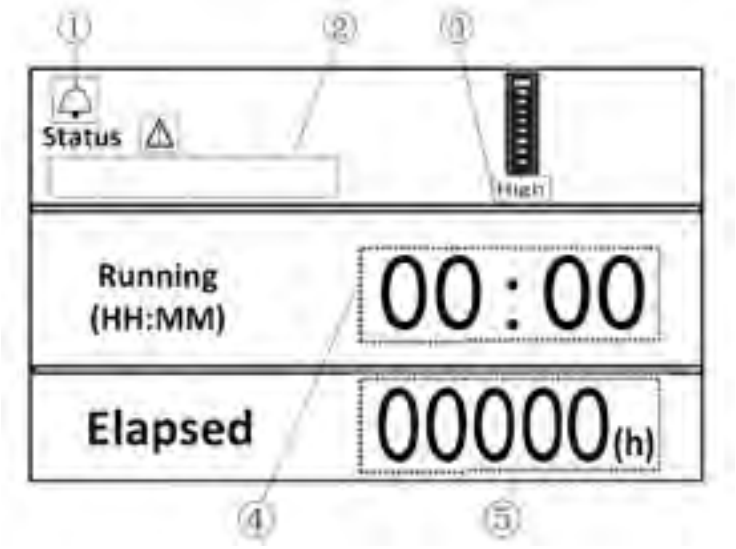
   c) Once dry, replace filter and air intake cover.

TIP: Having a second sponge mesh filter allows for quick replacement while the other filter is drying.

Cleaning Your Stratus 5 and Accessories:

1. Wash your cannula daily. Wash with mild soap and water and allow to air dry
2. Your cannula should be replaced once a month
3. To clean the body of the Stratus 5, wipe with a damp towel, mild soap may be used. Do not submerge the Stratus 5.
4. Humidification bottle: The humidifier water should be replaced every day with distilled water. Cleaning and disinfection should be done at least weekly with a mild soap and water, then allowing to air dry. To disinfect use one part white vinegar and one part distilled water. Once yearly replacement of the humidifier bottle is recommended.

Chapter 5: Alerts and Troubleshooting



The device has an audible alarm and LED indicators, as shown above.

LCD Indication

1		**Loudspeaker Alarm**		**Visualization**		
2	**System high temp**	Temperature rise abnormal	Red LED illuminates continuously and the Audible Alarms is beeping quickly. The device is not operating. ⚠ The sound level is 60~80dB	Block the air outlet of the oxygen concentrator, and alarm after a period of time	Less than 1 minute	High
	Pressure abnormal	Working pressure abnormal	Red LED illuminates continuously and the Audible Alarms is beeping quickly. The device is not operating. ⚠ The sound level is 60~80dB	Use the variable frequency power supply to adjust the supply voltage to less than 85% of the rated voltage	Less than 1 minute	High
	NTC Sensor Error	Temperature sensor failure	Yellow LED illuminates intermittent continuously and the Audible Alarm is sounding intermittently. ⚠ The sound level is 60~80dB	Unplug the temperature sensor connecter	Less than 1 minute	Medium
	Low Flow	Output flow is too low	Yellow LED illuminates intermittent continuously and the Audible Alarm is sounding intermittently. ⚠ The sound level is 60~80dB	Adjust the oxygen flow-meter to the minimum level until alarm stops	Less than 1 minute	Medium
3		High Oxygen Purity		visualization		
		Low Oxygen Purity: 82%	Red LED illuminates continuously and the Audible Alarms is beeping quickly. ⚠ The sound level is 60~80dB	Adjust the oxygen flow-meter to the maximum level until alarm stops		Medium

4	**“00:00”**	Current working time		visualization		
5	**00000**	Accumulate working hours		visualization		
	_ _ _ _	Power outage alarm	Audible Alarm is sounding continuously. And the sound level is 60~80dB	Unplug the power plug while in operation		

Note:

1. When troubleshooting multiple alarms, they will alternate. Alarms and indicators depend on the highest priority. All of the above alarms are technical alarms, within 3 minutes after power on, oxygen concentration less than 82% will not alarm
2. When troubleshooting alarms, identify failure type from LCD and contact DME immediately.
3. Alarm system recommended test interval: 18 months.

Troubleshooting Guide

Problem	Cause	Troubleshooting
Power on, the equipment is not working	Start capacity of compressor is broken or compressor is not working	Call service provider or dealer.
Power on, the equipment is not working, or works intermittently	Power cord not plugged securely or bad contact	* Check the power cord for damage * check that plug is secure If not, call service provider
No oxygen outlet or the outlet flow is too small	* oxygen cannula kinked or blocked * humidifier bottle top not tightened against leaks	* unkink the cannula * re-install the humidifier cap Call service provider if problem persists
no control of the flow meter ball	* the flow knob is not tight * turning the knob to quickly can cause the ball to be bypassed	* tighten the knob * turn the knob slowly Call service provider if problem persists
Water backing in to cannula	* Temperature difference can cause rainout. The concentrator is too near the wall, draperies or furniture. excessive tubing separating the patient and the concentrator	* dry the inside of humidifier cap * Do NOT use hot water * Do NOT over-filled humidifier * keep the same temperature of equipment and cannula (place concentrator in the same room as patient)

Chapter 6: Implementing Standards and Waste Disposal

Executive Standards

This device is designed to conform to the following standards:

IEC 60601-1: 2012 Medical electrical equipment –Part 1: General requirements for basic safety and essential performance

IEC 60601-1-2: 2014 2nd edition, Medical Electrical Equipment, Part 1-2: General Requirement for Safety – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests.

IEC 60601-1-8: 2012 Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance — Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems +Amendment 1:2012

IEC 60601-1-11: 2015 Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.

BS EN ISO 80601-2-69: 2014 Medical electrical equipment Part 2-69: Particular requirements for basic safety and essential performance of oxygen concentrator equipment

Waste Disposal

Dispose of the device in accordance with local regulations.

When the product is at the end of its life and the user intends to discard the product, it must be disposed of separately from other waste. Please contact your local agency or waste disposal service center for instruction and local disposal laws.

Appendix A: EMC Information

Warning:

The Stratus 5 series oxygen concentrators can only be connected to the cables mentioned in the attached documents. The use of accessories and cables outside the specified connections to the Stratus 5 series oxygen machine may result in increased emissions or reduced immunity of the Stratus 5 series oxygen generators.

The Stratus 5 Series Oxygen Concentrators should not be used in close proximity or stacked with other equipment. If they must be used close to or stacked, they should be observed to operate properly in the configuration in which they are used.

Solutions to common problems with electromagnetic compatibility:

- Operate in strict accordance with the instructions of the Stratus 5 series oxygen concentrator instruction manual to ensure that the device is not subject to electromagnetic interference.
- Keep other devices away from this device to reduce the effects of electromagnetic interference.
- The effect of electromagnetic interference can be mitigated by adjusting the relative position/ mounting angle between the device and other devices.
- Reduce electromagnetic interference by changing the wiring location of other device power/ signal cables.
- Reduce electromagnetic interference by changing the power path of other devices.

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMISSIONS:

This device is intended for use in the electromagnetic environment specified below. The user of this device should make sure it is used in such an environment.

EMISSIONS TEST	COMPLIANCE	ELECTROMAGNETIC ENVIRONMENT-GUIDANCE
RF emissions CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/Flicker emissions IEC 61000-3-3	Complies	

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY:

This device is intended for use in the electromagnetic environment specified below. The user of this device should make sure it is used in such an environment.

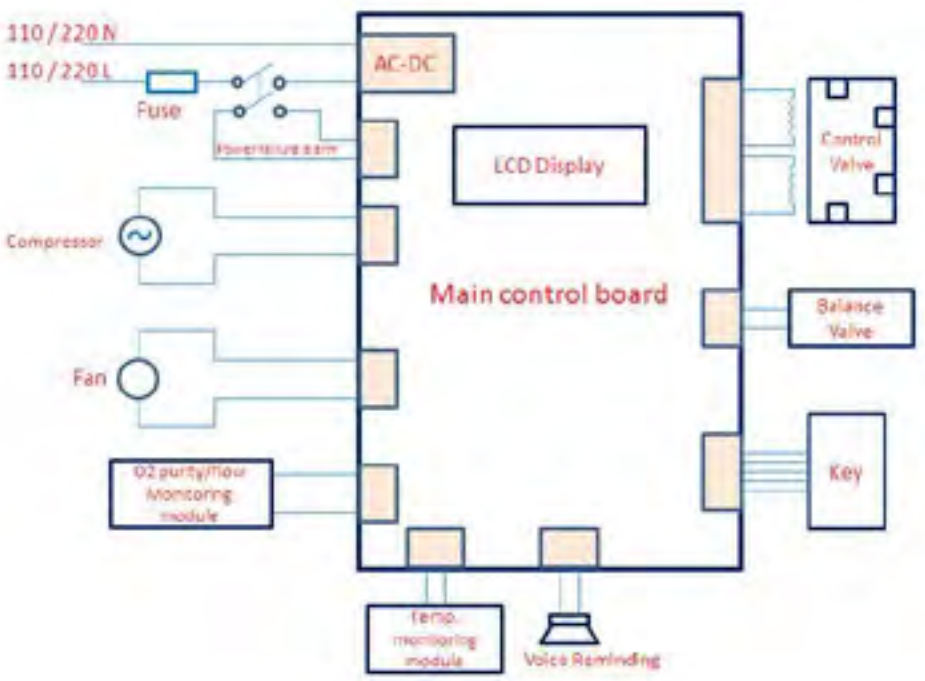
IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT-GUIDANCE
Electrostatic Discharge (ESD) IEC 61000-4-2	±8kV contact ±15 kV air	±8 kV contact ±15kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast Transient/Burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input-output lines	±2 kV for supply mains ±1 kV for input/output lines	Mains power quality should be that of a typical home or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV for common mode	±1 kV differential mode ±2 kV for common mode	Mains power quality should be that of a typical home or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	Mains power quality should be that of a typical home or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the

IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT-GUIDANCE
			device 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 hospital or home environment.
Note: UT is the a.c. mains voltage prior to application of the test level.			
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrm 150 kHz to 80 MHz 10V/m 80 MHz to 2.7 GHz	3 Vrm 10V/m	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the Recommended 12inch separation distance. Interference may occur in the vicinity of equipment marked with the following symbol: 

RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND THIS DEVICE: The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of this device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and this device as recommended below, according to the maximum output power of the communications equipment.

RATED MAXIMUM POWER OUTPUT OF TRANSMITTER (W)	SEPARATION DISTANCE ACCORDING TO FREQUENCY OF TRANSMITTER (m)		
	150kHz~80MHz d=1.2 $\sqrt{P}$	80MHz-800MHz d=1.2 $\sqrt{P}$	800MHz-2.5GHz d=2.3 $\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance (d) in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			

Attachment B: Circuit Diagram



Warranty Information

3B MEDICAL, INC. warrants that the system shall be free from defects of workmanship and materials and will perform in accordance with the product specifications for a period of three (3) years from the date of sale by 3B MEDICAL, INC. to the dealer.

If the product fails to perform in accordance with the product specifications, 3B MEDICAL, INC. will repair or replace – at its option – the defective material or part. This warranty does not cover damage caused by accident, misuse, abuse, alteration, and other defects not related to material or workmanship.

3B MEDICAL, INC. accessories are warranted to be free of defects in materials and workmanship for a period of 90 days from the time of purchase.

3B MEDICAL, INC. disclaims all liability for economic loss, loss of profits, overhead, or consequential damages which may be claimed to arise from any sale or use of this product. This warranty is given in lieu of all other express or implied warranties.

3B™ Medical, Inc.

www.3Bproducts.com

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