USER MANUAL

SCALEO MEDICAL

Oxygen concentrator Horizon® S5

CE 0123

Content

Warnings and safety instructions

Safety notes

Please read this manual carefully before using this product and save it for future reference. Do not use this product without fully reading and understanding these instructions. Injury or damage may result.

If you cannot understand this user manual, please contact your service provider or after-sales service center. SCALEO Medical provides consulting and training services. Make sure that the user understands this user manual and uses this product accordingly.

Users of home oxygen therapy should strictly follow the doctor's prescription. Oxygen therapy is performed according to the doctor's daily oxygen flow and oxygen inhalation at rest, sleep and during exercise. It is strictly forbidden to adjust the oxygen flow rate and adjust the time by yourself, in order to avoid insufficient oxygen supply or oxygen poisoning.

Patients who are in urgent need of oxygen, critically ill patients and patients under continuous oxygen inhalation, shall have other oxygen supply devices (such as compressed oxygen cylinders or liquid oxygen systems) as a backup product when using the Horizon® S5 oxygen concentrator.

If an adverse reaction appears when inhaling oxygen, stop using it and contact your service provider or your doctor immediately.

If there is an eventual device failure, contact your service provider or the manufacturer's after-sales service center immediately and do not disassemble it or repair it.

This device is not intended to be life sustaining or life supporting. Additional monitoring or attention may be required for pediatric patients, elderly patients or patients using this device who are unable to hear or see alarms or communicate discomfort. This product is not suitable for babies.

Severe carbon monoxide poisoned patients are banned from using this device.

The nasal cannula is dedicated to one person and should be cleaned and replaced regularly. Be careful not to adjust the flow meter float (middle part) beyond the red line position. Long-term use will reduce the efficiency of the oxygen concentrator.

If the product has been stored for 6 months by the dealer, the product must be returned to the factory for inspection.

Warning

Please read the following information carefully before operating the oxygen concentrator.

Special attention should be given to reducing the risk of fire when using oxygen therapy. When the oxygen concentration is high, any material becomes extremely flammable and burns quickly, regardless of whether it is flammable or not. For safety reasons, all ignitions should be kept away from the oxygen concentrator and preferably shall not be in the same room as the oxygen concentrator.

Oil, grease or petroleum-based products are prone to strong spontaneous combustion when exposed to oxygen under pressure. These materials must be kept away from oxygen concentrators, piping, connections and other oxygen concentrator components. Do not use any lubricant.

Oxygen concentrators are strictly prohibited from being inverted or positioned horizontally during use and displacement, and should avoid an environment of pollution and smoke. The oxygen concentrator requires an ambient temperature of 10 to 37°C. When the temperature is lower than 10°C, the compressor may have difficulties starting. Above 37°C will cause the compressor to overheat and shorten the life of the machine.

It is strictly forbidden to use oxygen concentration in an environment above 3000 meters. Such an environment will reduce the quality of patient treatment.

Please do not move the oxygen concentration while it is in use. Do not turn on the oxygen concentrator with the flow meter turned off. During use, the oxygen concentrator produces a regular exhaust sound when oxygen is produced, which is a normal phenomenon. It is normal for the exhaust vent at the bottom of the oxygen concentrator to discharge hot air.

Please do not block the exhaust vent during use. In order to achieve the best performance of the oxygen concentrator, SCALEO Medical recommends to use the oxygen concentrator for more than 30 minutes each time. Frequent use of the oxygen concentrator for a short period of time may reduce the lifespan of the machine.

If the oxygen compressor power cord or plug is damaged, if the machine is working abnormally or if it falls into water, please contact your authorized service provider for inspection. Keep the power cord away from heat or high temperature surfaces. Do not use extension cords.

Do not move the oxygen concentrator by dragging the power cord. Do not drop or insert foreign objects into any openings. It is strictly forbidden to block the air inlet and exhaust port of the device or place the machine on a soft surface, such as a sofa or a bed, which can cause the exhaust port to be blocked. Keep the air intake away from plush, hair or similar.

When adding water into the humidifier, do so according to the amount calibrated by the humidifier. Do not add excessive water.

Oxygen concentrator must be at least 40 cm away from walls, tapestries, furniture and similar objects.

The Horizon® S5 medical oxygen concentrator is equipped with a set of oxygen nasal cannula. Patients can also choose other anti-extrusion registered oxygen cannula to be purchased as needed. However, the length of the nasal cannula should not exceed 14 meters. Oxygen nasal cannula should be placed correctly to avoid the risk of wringing the head or neck.

Do not use parts, accessories, or equipments that are not approved by the manufacturer. The use of unspecified humidifiers or other accessories may reduce the performance of this concentrator.

Do not connect the concentrator in parallel or series with other oxygen concentrators or oxygen therapy devices.

Do not use any power cord other than the original. Non recommended power cords can cause increased electromagnetic radiation or reduce electromagnetic immunity, resulting in operational failure.

Oxygen therapy is harmful under certain conditions. SCALEO Medical recommends the use of the Horizon® S5 oxygen concentrator under medical prescription only. Oxygen therapy should be performed according to the prescription of the doctor. Unauthorized adjustment of oxygen flow is strictly prohibited as it may cause oxygen poisoning or carbon dioxide retention. This medical device is designed to supplement oxygen, not for first aid or sustain life.

Avoid creating sparks near medical oxygen equipment, including static sparks generated by friction.

If the oxygen concentrator is used under abnormal conditions for a long time (in terms of humidity, temperature, dust... outside of its normal range) this will reduce its efficiency. Please contact your service provider or the after-sales service of the manufacturer.

Regularly evaluate your treatment and contact your doctor if you have uncomfortable symptoms when using this device.

Maintenance

The Horizon® S5 oxygen concentrator is designed to minimize the number of maintenance routine. The maintenance period is approximately once a year. Only an authorized after sales service can disassemble, repair or commission the equipment.

Radiofrequency interference

Most appliances are susceptible to interference with radio frequencies. Therefore, the use of portable communication equipment near the oxygen concentrator will cause interference to the machine.

This product cannot be used in environments such as electrocautery, electro surgery, defibrillation, X-ray, gamma ray, infrared radiation, 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 40 cm away from any part of the equipment. Otherwise, the performance of the device will decrease.

This oxygen concentrator should be avoided from being adjacent to or stacked with other equipment. This may result in improper operation. If you must be near or stacked, observe and verify the equipment and other equipment to ensure that it is working properly.

To reduce the burning, electric shock, fire hazard and personal injury, please do the following:

Do not use this device while bathing. If you need to use it continuously, the oxygen concentrator must be placed at least 3 meters away from the bathroom.

Do not touch the oxygen concentrator while your body is wet.

Do not use or store this oxygen concentrator near liquids or other electrically conductive materials.

Do not touch the oxygen concentrator that falls into the water or other easily conductive liquid. If it falls into it, unplug the power cord immediately.

The power plug must be unplugged when not using this oxygen concentrator.

If you find the supply of oxygen insufficient, contact your service provider or your doctor immediately. Do not adjust the oxygen flow unless directed by a healthcare professional.

Be careful not to place the device in an environment where it can easily collide or where other people can easily trip over the power cord. Small parts that fall off the device can cause suffocation if eaten or inhaled. Keep out of reach of children.

Do not perform maintenance while the device is running.

Warning

- ***Oxygen is a combustion-supporting gas. Oxygen compressors should be kept away from any source of ignition and flammable materials. Smoking and open flames near people who absorb oxygen are strictly prohibited.***

- ***Smoking is strictly prohibited during oxygen inhalation. Patients under oxygen therapy must quit smoking.***

- ***The power cord should be kept away from heat or fire sources.***

- ***The power switch must be turned off when no oxygen therapy is performed.***

- ***Do not place the nasal cannula under the covers or upholstery.***

- ***Before cleaning the oxygen concentrator housing or replacing the fuse, the power plug must be unplugged to avoid electric shock.***

Symbols and pictograms

Symbols used in this manual

This symbol indicates instructions and safety information, when injuries may occur if warnings are ignored or partially followed. It is important to carefully follow the advice and warnings.

This symbol indicates important information regarding the use of the equipment. Failure to follow this information may result in damage or malfunction of the device or other equipment.

This symbol indicates important and useful information. This information will help the user and optimize the use of the material. It will simplify routine operations and provide solutions to complex operations.

Pictograms on product and labels

Mark	Definition
	Power ON
	Power OFF
	Follow instruction for use
	No smoking
	Caution, consult accompanying documents.
	Class II (double Insulated)
	Type BF applied part
	CE certification mark
	AC power

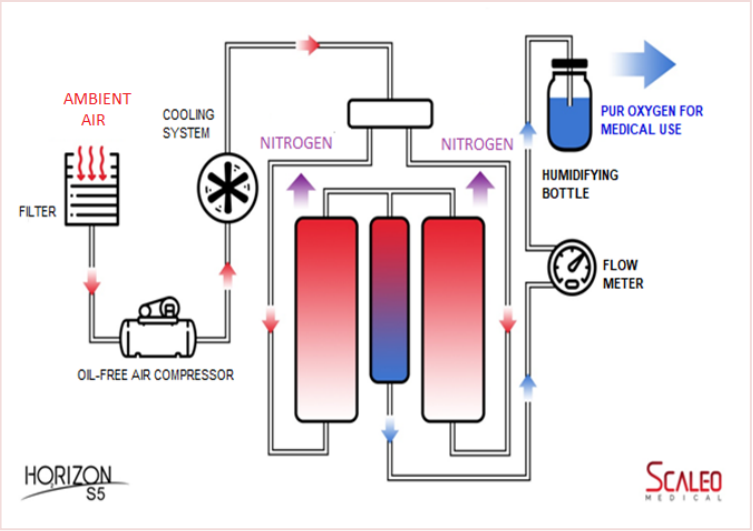
Mark	Definition
	This way up
	Fragile, handle with care
	Keep dry
	Temperature limit
	No open flames
IP21	Drip proof equipment
	Consult instructions for use
	Stand-by
	Warning, electricity
	Stacking limit by number

General information about the Horizon® S5

Your health care professional has determined that supplemental oxygen is beneficial to your health and 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.

About the Horizon® S5

The device produces concentrated oxygen from ambient air to patients requiring low flow oxygen therapy. The oxygen from the air is concentrated using molecular sieves 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.



Intended use

The Horizon® S5 oxygen concentrator is intended for the administration of supplemental oxygen. This device is not intended for life supporting and does not allow any type of patient monitoring. The system is intended to be operated at home, in community health care centers and medical institutions.

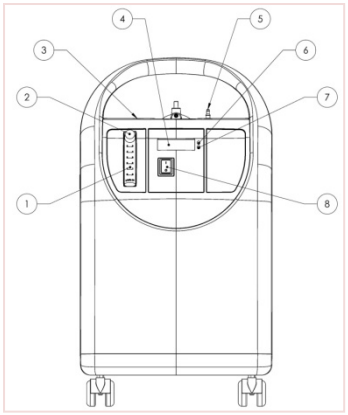
The Horizon® S5 oxygen concentrator is suitable for adults and children.

Contraindications

This product is not suitable for patients with severe carbon monoxide poisoning.

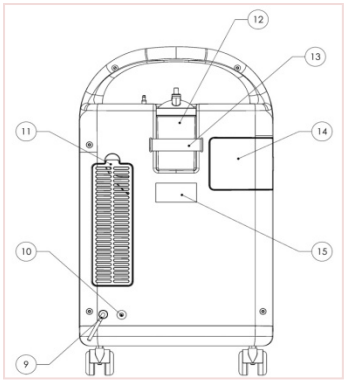
Parts of the Horizon® S5 oxygen concentrator

Front panel



1. Oxygen flow meter
2. Flow rate setting knob
3. USB port
4. LCD display
5. Oxygen outlet
6. Power indicator
7. Warning light
8. Power switch

Rear panel



9. Power cable
10. Circuit-breaker
11. Air inlet grid
12. Humidifier bottle
13. Humidifier loop fastener
14. Compressor filter cover
15. Product label

Description of the main parts

- **Flow meter:** the floating ball level indicates the magnitude of the output oxygen flow.
- **Oxygen outlet:** output oxygen.
- **Alarm indicator:** code appears on the display.
- **Power switch:** " I " ON; "o" OFF. A green light is on when the machine starts running.
- **Humidifier bottle:** it is used to prevent the dry oxygen to irritate the throat or the nasal mucosa. Also prevents phlegm from drying.
- **Humidifier loop fastener:** the loop fastener is used to fit the humidifier bottle.
- **Air intake grid and filter:** filters dust from the air.
- **Compressor filter cover:** contains the compressor filter.

Accessories and spare parts

If you have questions or concerns about this device, please contact your home care provider. Please use only the following manufacturer's accessories and spare parts:

- Compressor filter
- Humidifier connection tube

Unpacking the Horizon® S5 oxygen concentrator

1. Check for any obvious damage to the box or its contents. If damage is evident, notify the carrier, or your local distributor.
2. Remove the foam block from the packaging and the box.
3. Carefully take out all the parts and the machine from the carton. Inspect/examine the exterior of the oxygen concentrator for nicks, dents, scratches or other damages.

If there are parts or quality issues, please contact your local distributor. Keep the box and packaging materials for future storage and transportation.

Instructions for use

Operating instructions

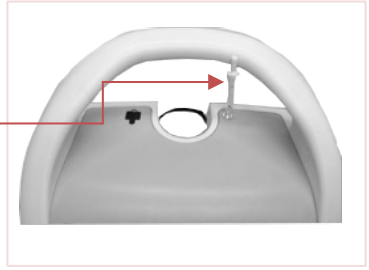
Do not use extension cords or electrical adapters.

1. Select a location that allows the concentrator to draw in room air without being restricted. Make sure the device is at least 40 cm away from walls, furniture and especially curtains that could impede adequate airflow to the device. Do not place the device near any heat source.
2. After reading this entire manual, plug the power cord into an electrical outlet.
3. Do either step A or step B below.

A. If you are NOT using a humidifier, follow these steps:

Diagram: 1-A1

A. 1. Connect the fire damper to the oxygen outlet according to the "1-A1" diagram.



A. 2. Connect your nasal cannula to the fire damper according to the "1-A2"diagram.

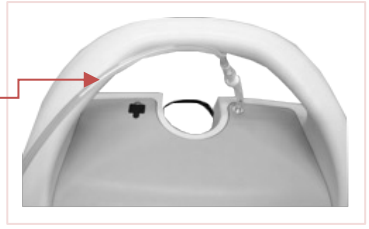


Diagram: 1-A2

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

B. 1. Take out the humidifier bottle from the plastic package.

B. 2. Unscrew the brown lid in a counterclockwise direction. Inject a proper amount of distilled water on the transparent humidification cup and then tighten the brown lid clockwise.

Use distilled water, purified water or previously boiled (and then cooled) water for the

humidifier water. Replace the water once a day. Fill the water up to half of the maximum and minimum tick marks, or slightly lower to cover the bubble outlet in the humidifier.

When disassembling, rotate the cup counterclockwise to remove the cup. When installing, align the humidification cup with the cup cover, rotate the cup clockwise and tighten the cup to avoid air leakage.

B. 3. Install the humidifier with water in the place dedicated to this purpose on the top of the Horizon® S5, according to the "2-B1"diagram.

Diagram: 2-B1

B. 4. Use the loop fastener to tighten the bottle and secure it.

B. 5. Connect the PVC hose to the oxygen concentrator outlet and the humidifier inlet according to the "2-B2" diagram.

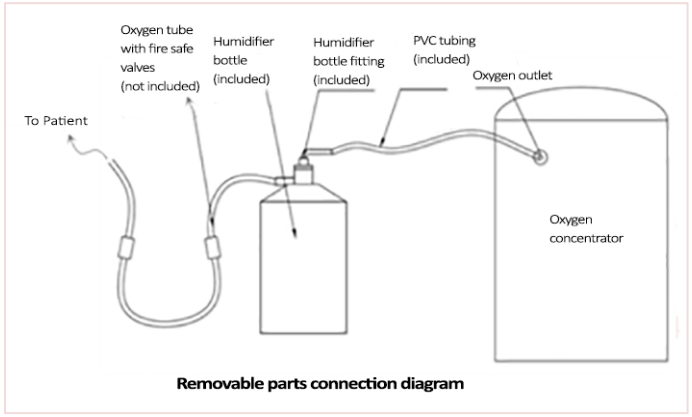
Diagram: 2-B2

B. 6. Connect the fire damper to the outlet end of the humidifier according to the "2-B3" diagram.

B. 7. Please connect the nasal cannula to the fire damper according to the "2-B4" diagram.

Diagram: 2-B3

B. 8. The air path connection is in the removable parts connection diagram below:



Removable parts connection diagram

Diagram: 2-B4

This product must be connected to the fire damper according to the above instructions, otherwise the manufacturer does not assume responsibility of the potential consequences.

4. Turn on the power switch.

The power cord plug must be securely inserted into a safe and qualified socket.

5. Block the vent of the brown tip of the humidified bottle with your finger for about 20 seconds. Observe whether the float in the flow meter drops, or if the humidification cup issues a "qiu" sound. If yes, there is no air leakage.

6. Adjust the oxygen output flow by taking the eye line of sight, the midline of the ball and the scale of the flow meter on the same horizontal line.

The flow meter adjustment knob increases the flow rate counterclockwise and decreases the flow rate clockwise. For health care, it is recommended to set the flow rate at 1- 2L/min for a period of 45 to 60 minutes per day. For long term oxygen therapy (LTOT), it is very important to strictly follow the advice of your physician. Take oxygen treatment according to the flow rate and time prescribed by your doctor. Never adjust the flow rate or time at will.

7. Insert the nasal cannula into the nostrils to start the oxygen therapy.

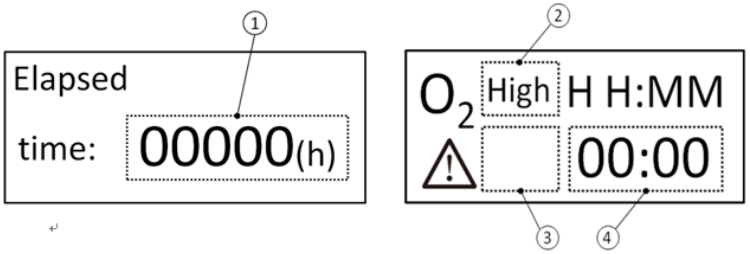
8. When the oxygen therapy is finished, turn off the power switch.

When not in use, unplug the power cord.

Alerts and troubleshooting

Alerts

LDC indication



Area	Indicators	Possible cause	Status prompt	Test method	Alarm delay time	Priority
①	000000	Accumulate working hours.	It will show working interface in 10 seconds.	Visualization.		----
②	High	High oxygen purity.	----	Visualization.		----
	Low	Low oxygen purity: 82%.	Solid red LED and the audible alarm is sounding hurriedly. ⚠	Adjust the oxygen flow-meter to the maximum level until alarm.	Less than 1 minute.	High.
③	H01	Output flow is too low.	Flashing yellow LED and the audible alarm is sounding intermittently. ⚠	Adjust the oxygen flow-meter to the minimum level until alarm.	Less than 1 minute.	Medium.
	H02	Abnormal temperature rise.	Solid red LED and the audible alarm is sounding hurriedly. The device is not working. ⚠	Unplug the blower connector.	Less than 2 minutes.	High.
③	H08	Abnormal working pressure.	Solid red LED and the audible alarm is sounding hurriedly. The device is not working. ⚠	Use the variable frequency power supply to adjust the supply voltage to less than 85% of the rated voltage.	Less than 1 minute.	High.
③	E01	Temperature sensor failure.	Flashing yellow LED and the audible alarm is sounding intermittently. ⚠	Unplug the temperature sensor connector.	Less than 1 minute.	Medium.
④	“00:00”	Current working time.	----	Visualization.		---
	PWR	Power failure alarm.	Audible alarm is sounding continuously and the sound is ≥ 60dB.	Unplug the power plug while in operation.		----

- *When multiple troubleshooting alarms, they will show alternately. Alarms and indicators depend on the highest priority.*
- *The above alarms are technical alarms.*
- *Within 3 minutes after power is on, the oxygen concentration of less than 82% will not alarm.*
- *When a troubleshooting alarm occurs, identify the type of failure that is displayed on the LCD and contact your service provider immediately.*
- *The recommended test interval of the alarm system is 18 months.*
- *The alarm sound pressure level is of 60~80 decibels*

Troubleshooting

Problem	Why it happened	What to do
Power on, the equipment is not working.	The start capacity of the compressor is broken or the compressor is not working.	Call your service provider or dealer.
Power on, the equipment is not working, or works un-continuously.	The power cord may not be plugged correctly or there may be a bad contact.	* Check if the power cord is damaged. * Check if the power cord is plugged correctly. Call your service provider, if you still cannot solve the problem.
No oxygen outlet or the outlet flow is too low.	* Oxygen cannula kinked or blocked. * The humidifier bottle is not tighten.	* Unknit the cannula. * Re-install the humidifier lid. Call your service provider, if you still cannot solve the problem.
The ball in flow meter is uncontrolled by the knob.	* The flow knob is not tighten. * The knob was turned abruptly or too fast.	* To tight the knob, turn the knob slowly and softly. Call service provider, if still cannot solve the trouble.
Water goes back to the cannula.	* There is a temperature difference caused by the weather. * The device is too close to the wall, curtains or furniture. * The location of the equipment and cannula is different.	* Dry the inside of humidifier lid. * Do NOT use hot water. * Do NOT over-fill the humidifier. * Keep the equipment and cannula in the same room to maintain the same temperature.

Cleaning and maintenance

It is important to unplug the device before performing any cleaning.

Excess moisture may impair the proper operation of the device.

1. The sponge mesh filter:

The sponge mesh filter should be cleaned weekly to keep the oxygen concentrator running smoothly, or more frequently if the environmental conditions requires it.

In order to clean the sponge mesh filter, please follow the following instructions :

a. Open the air intake grid located on the back part of the concentrator. Remove the sponge mesh filter and shake it to let the dust fall.

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

c. The dry mesh filter may be replaced and the air intake grid reinstalled.

Having a second sponge mesh filter allows a quick replacement while the other filter is drying. Always use original spare parts. If the sponge filter needs to be replaced, please contact your local distributor.

Air intake grid

Sponge mesh filter

2. Compressor filter replacement:

The compressor filter is used to filter dust entering the compressor. It needs to be replaced regularly. It is recommended to replace the filter every 4000 hours. The compressor filter needs to be purchased from a SCALEO Medical distributor.

In order to replace the compressor filter, please follow the following instructions :

a) The compressor filter cover is in the back of the device (see figure 4-1 below). Open the compressor

filter cover (see figure 4-2 below) and unscrew the filter body clockwise (see figure 4-3 below) to remove the compressor filter (see figure 4-4 below).

Figure 4-1

Figure 4-2

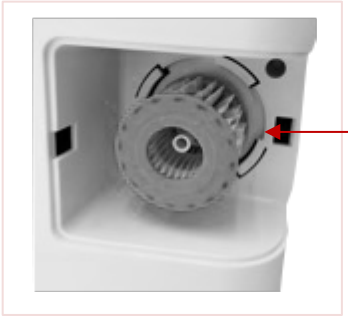


Figure 4-3

Figure 4-4

b) Replace the new compressor filter, install the filter body counterclockwise and install the filter cover.

3. Cleaning the nasal cannula:

Cleaning the cannula should be done every day with a detergent and then rinsing thoroughly with clean water, then allowing it to air dry.

It is recommended to replace the cannula once a month.

4. Cleaning the outside case :

With your oxygen concentrator turned off, clean the outer case once or twice per month. Use a damp towel

and a small amount of detergent and then wipe it up with a dry towel.

5. Humidifier bottle disinfection :

The humidifier water should be refreshed every day with cool water that is distilled or previously boiled (and then cooled).

Cleaning and disinfection should be done at least every 3 weeks by cleaning with a mild detergent (such as Dawn™) then rinsing with warm or hot water followed by soaking in a household disinfectant for 20-30 minutes, then rising thoroughly with warm or hot water and allowing it to air dry.

Keep the humidifier in a clean plastic bag if not using for extended periods of time.

Different disinfectant can be used :

- vinegar and distilled water in a ratio of 1 : 1,
- bleach and distilled water in a ratio of 1 : 10,
- or commercially available household disinfectant.

It is recommended to replace the humidifier bottle once a year.

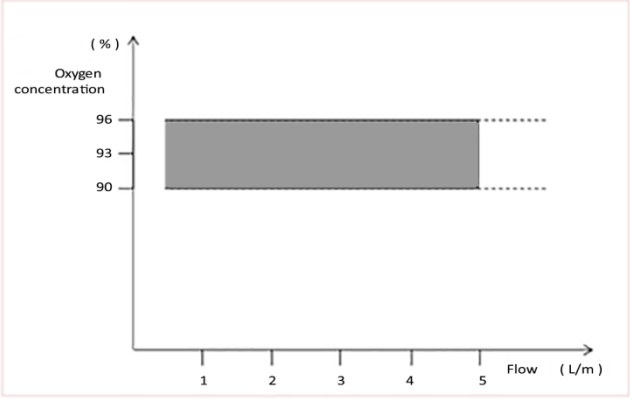
Technical specifications

Specifications

Flow control settings	0,5 to 5 liters
Rated power (W)	320
Voltage and frequency	220V±22V, 50Hz±1Hz / 110V±11V, 60Hz±1Hz, depending on the model.
Flow rate (L/min)	0,5 - 5
Concentration (rated flow)	93% ± 3%
Sound pressure level dB (A)	≤ 45
Sound power level dB (kg)	≤ 55
Net weight (kg)	14,96
Dimensions (mm)	380 x 240 x 660
Air outlet pressure	0.05 ± 10% MPa
Features	Abnormal temperature alarm; low oxygen content alarm; power failure alarm; timer: pressure alarm; low flow alarm; thermostat fault alarm.

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

When the nominal pressure of the oxygen output port is zero, the oxygen concentration is 93% ±3% under the operating environment and rated flow rate. See the following “Output oxygen concentration and flow rate diagram":



Relation of outlet oxygen concentration and flow

Classification

IEC class	Class II
Degree of protection to concentrator components against electrical shock	Type BF
Degree of protection to concentrator components against ingress of water while used	IP21
Mode of operation	Continuous mode
Degree of safety for application in the presence of a flammable anesthetic mixture with air or with oxygen or	Not suitable for such application
Expected service life of the product	5 years

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.

While in continuous operation, when the rated flow rate is reached, the time for reaching the specified oxygen content should not exceed 30 minutes.

Operating environment

Operating temperature	10 to 37°C
Operating relative humidity	20% RH - 65% RH
Operating atmospheric pressure	80 kPa ~ 101 kPa
Surrounding environment	Dry and ventilated, free from dust and any corrosive gases, without strong electromagnetic interference
Recommended altitude for use	Below 3000 meters

It is not recommended to use this concentrator in an environment above 3000 meters above sea level, which may result in a decrease in oxygen concentration.

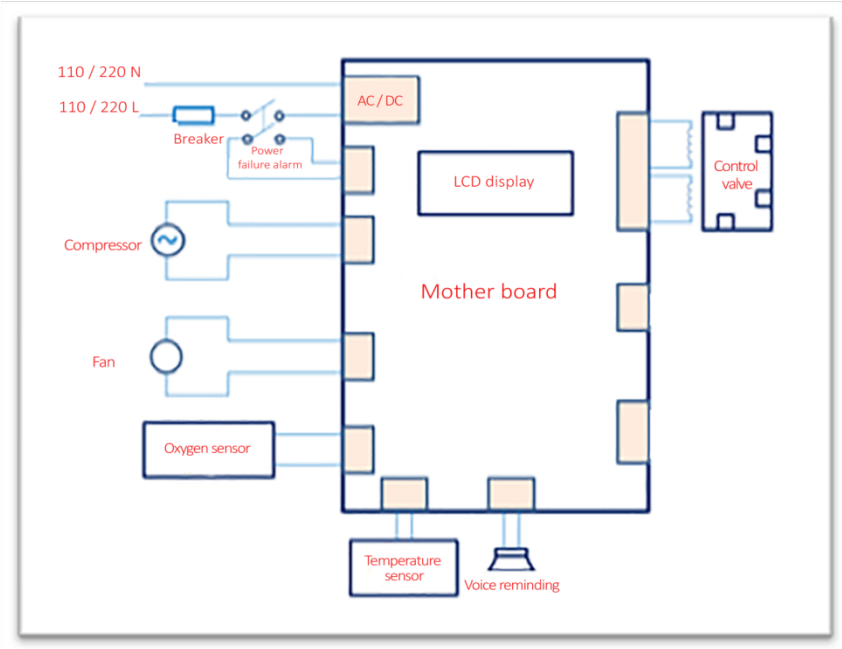
The ambient temperature of the oxygen machine is from 10°C to 37°C. Below 10°C, the compressor may have difficulties starting. Above 37°C, the compressor may overheat and shorten the service life of the compressor. If the device is stored in a very cold or very hot environment, it should be placed in the room intended for use for 5 hours before use.

Storage and transportation environment

This product must be placed upright during transportation. It is strictly prohibited to place it horizontally or upside down.

Transport & storage temperature	-30°C to 70°C.
Transport & storage relative humidity	15 - 95% RH, no condensation.
Transport & storage atmospheric pressure	500 - 1060 hPa.

Circuit diagram



Electromagnetic compatibility

In order to ensure the electromagnetic compatibility of the Horizon® S5 oxygen concentrator, the Horizon® S5 oxygen concentrator needs to be installed, commissioned and used according to this user manual.

Portable and mobile RF communication devices may affect the electromagnetic compatibility of the Horizon® S5 oxygen concentrator. If this happens, please contact SCALEO Medical.

Electromagnetic compatibility refers to the ability of a device to suppress electromagnetic interference from other devices without causing similar electromagnetic radiation interference to other devices. The Horizon® S5 oxygen concentrator electromagnetically interferes with other equipment.

Solutions to common problems related to electromagnetic compatibility:

- Operate the Horizon® S5 oxygen concentrator in strict accordance with the instructions expressed in this manual.
- Keep it away from other devices 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.

The Horizon® S5 oxygen concentrator can only be connected to the cable mentioned in this manual. Connections using accessories and cables outside of the regulations may result in increased emissions or reduced immunity of the Horizon® S5 oxygen concentrator.

The Horizon® S5 oxygen concentrator 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.

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.

Emission 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 indicated here 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.

Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment-guidance
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 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) 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 device be powered from an uninterrupted 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.
U_T 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 than the recommended 40 cm separation distance to any part of the device, including cables. 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 user of this device can help preventing 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.

Terms of warranty & liabilities

The manufacturer 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 to the dealer. The sieve beds and the compressor are guaranteed for thirty six (36) months.

The manufacturer warrants that the Horizon® S5 oxygen concentrator serviced by themselves, or an authorized service center, will be free from defects for a period of 90 days from the time of service.

The accessories are warranted to be free of defects for a period of 90 days from the time of purchase. If the product fails to perform in accordance with the product specifications, the manufacturer 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.

The warranty is automatically canceled in the following cases:

- Any intervention on the device contrary to the present manual,
- Abnormal and non-compliant use of the equipment,
- Any modification of the equipment,
- Any technical intervention by unqualified personnel or an unauthorized reseller.

SCALEO Medical assumes no liability for any injury or harm and consequences thereof directly or indirectly caused to operators, patients, or any third party in the following cases:

- Non compliance of the instructions and recommendations supplied within the present user manual.
- The use of un-adapted spare parts.
- Assembling, adjusting and repairing service carried out by a non authorized distributor.
- Abnormal use of the equipment, negligence, accident, human error, or maintenance and cleaning with non-adapted products.

This warranty is given in lieu of all other express or implied warranties, including the implied warranties of merchantability and fitness for a particular purpose. In addition, in no event shall the manufacturer be liable for lost profits, loss of good will, or incidental or consequential damages, even if the manufacturer has been advised of the possibility of the same. Some countries do not allow the exclusion of limitation of implied warranties or the disclaimer of incidental and consequential damages. Accordingly, the laws of your country, the above limitation or exclusion may not apply. To exercise your rights under this warranty, contact your local authorized dealer or the manufacturer.

Lifespan and recycling

Lifespan

The expected service life of the Horizon® S5 oxygen concentrator is 5 years.

Waste disposal

Dispose of the device in accordance with local regulations.

WEEE/RoHS Recycling Directive

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 production waste. Please contact your local distributor or waste disposal service center for product recycling and reuse.

Applicable 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.

How to contact us

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