

# USER MANUAL

**SCALEO**  
M E D I C A L

Portable oxygen concentrator

**HORIZON**  
<sub>2</sub>  
**P5**



**CE**  
0459

MADE IN FRANCE



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# Safety Instructions and Warnings



***This user manual contains important safety information regarding the use of the Horizon® P5 oxygen concentrator. Please read this manual completely and carefully for a safe use of this product. Keep it for future reference. Do not use this product without reading and fully understanding these instructions. Injury or damage may result.***



***If you do not understand this user manual, please contact your service provider. SCALEO Medical offers consulting and training services. Make sure that the person handling the device understands this user manual and uses this product accordingly.***



***There is a risk of fire associated with oxygen enrichment during oxygen therapy. Keep the oxygen concentrator and its parts away from sparks and open flames.***



***The use of open flames during oxygen therapy is dangerous and may cause fire or death. The use of open flames less than 2 m from the oxygen concentrator or any accessory carrying oxygen is prohibited.***



***Only use water-based lotions or balms that are labeled as compatible with oxygen before and during oxygen therapy. Never use petroleum or oil based lotions or balms to avoid the risk of fire and burns.***



***Do not lubricate the device, fittings, tubing systems or other accessories of the oxygen concentrator to avoid the risk of fire and burns.***



***Oxygen facilitates the start and spread of a fire. Do not leave the nasal cannula or mask on bedspreads or seat cushions because if the oxygen concentrator is on but not in use, the oxygen will make the materials flammable. Turn off the oxygen concentrator when not in use to stop oxygen enrichment.***



***Always unplug the power outlet before cleaning the oxygen concentrator.***



***Smoking during oxygen therapy is dangerous and can cause facial burns or death. Smoking is prohibited in the room where the oxygen concentrator or any accessory carrying oxygen is located.***



***If you wish to smoke, you must always turn off the oxygen concentrator, remove the cannula and leave the room where the cannula / mask or oxygen concentrator is placed. If you cannot leave the room, you must wait 10 minutes after switching off the oxygen concentrator before smoking.***



***Use only replacement parts recommended by the manufacturer to ensure correct operation and to avoid the risk of fire and burns.***



***Oxygen therapy must strictly follow the doctor's prescription.***



***In order to ensure the delivery of a therapeutic amount of oxygen appropriate for your medical condition, the Horizon® P5 must:***

- ***Be used only after one or more settings have been individually determined or prescribed for you according to your own activity levels,***
- ***Be used with the specific combination of parts and accessories that meet the concentrator manufacturer's specifications and that were used in determining your settings.***



***It is recommended to have an alternate source of oxygen in the event of a power failure or mechanical failure. Consult your service provider for recommendations on the best type of backup system.***



***It is the patient's responsibility to make further arrangements for the supply of oxygen when traveling; SCALEO Medical assumes no responsibility for those who choose not to follow the manufacturer's recommendations.***



***The Horizon® P5 settings can differ from those with continuous-flow oxygen.***



***The Horizon® P5 settings do not match those of other brands or models of continuous flow oxygen therapy devices.***



***Do not connect the Horizon® P5 oxygen concentrator in parallel or in series with other oxygen therapy devices.***



***Wind or strong drafts can adversely affect the accuracy of the delivery of oxygen therapy.***



***Some breathing efforts of the patient may not trigger the concentrator and thus send a bolus. It is recommended to have a stress test with your doctor before using Horizon® P5.***



***Do not leave the Horizon® P5 connected to the power supply without its battery.***



**Never leave the Horizon® P5 in an environment which may reach high temperatures. It could damage the device.**



***In the event of a device failure, contact your authorized service provider or the manufacturer's service center immediately. Do not disassemble or repair it yourself.***



**In order to get the best performance from the oxygen concentrator, SCALEO Medical recommends using the oxygen concentrator for more than 30 minutes each time. Frequent use of the oxygen concentrator for a short time may shorten the life of the device.**



**Avoid the use of extension cords.**



**Do not drop or insert foreign objects into any openings. It is strictly forbidden to block the air inlet and exhaust port of this device or to place the device on a soft surface, such as a sofa or bed, which may cause the block the exhaust. Keep the air inlet away from lint, hair, or objects alike.**

# Symbols and Pictograms

## Symbols used in this manual



*This symbol indicates instructions and safety information, where an injury 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 observe this information may result in damage or malfunction of the device.**



















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

## Symbols and pictograms on the concentrator and the elements on the pack





Symbol	Signification
	Manufacturer
	No smoking while device is in use
	Refer to user manual
	AC power
	Direct current
	Indoor or dry location use only. Do not get wet.

Symbol	Signification
	This way up
	Fragile, handle with care
	Keep dry
	Temperature limit
	No Open Flames (Concentrator); Do not incinerate (Battery).
IP20	Protection against solid objects
IP22	Drip proof equipment (with carry bag)

	Complies with applicable EU Directives
	Caution, consult accompanying documents
	Use no oil or grease
	Do not disassemble
	Humidity rate
	Date of manufacture
	Catalogue number
	Battery charge indicator on the battery

	Do not dispose of in unsorted municipal waste
	Stacking limit by number
	Device serial number
	Type BF Applied Part, Not Intended for Cardiac Application
	Medical device
	Classe II equipment Double insulation
	« UL Recognized » battery
	Unique Device Identifier

## User interface

Symbol	Meaning
	ON / OFF button
	Increase Flow Setting
	Decrease Flow Setting
	Silent alarm button



**Device indentification**

“Horizon® P5” is a model of product range Horizon® GMN: 3664844HO2PRTXS.

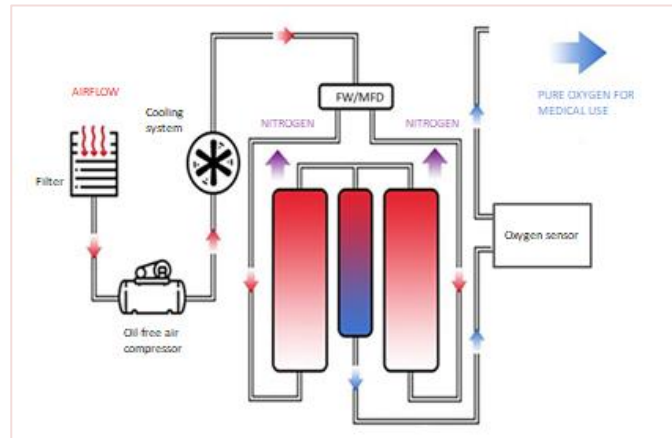
Reference	UDI-DI	Designation
R41 508	03664844000076	Pack Horizon® P5 portable concentrator - 8 cells
R41516	03664844000069	Pack Horizon® P5 portable concentrator – 16 cells
R41 10 020	03664844000038	Horizon® P5 portable concentrator
R41 10 010	03664844000021	Single Li-ion Battery for Horizon® P5 portable concentrator (6,5Ah)
R41 10 011	03664844000014	Dual Li-ion Battery for Horizon® P5 portable concentrator (6,5Ahx2)
R41 10 070	03664844000007	Carry Bag Horizon® P5 portable concentrator

# General Information about Horizon® P5

## About Horizon® P5

The Horizon® P5 is a portable oxygen concentrator that produces highly purified oxygen from ambient air.

Oxygen in the air is concentrated using sieves and a pressure swing adsorption process. The patient is the operator of his own machine.



## Intended use and Indications

The Horizon® P5 oxygen concentrators should be used by adult patients with a prescription, and presenting chronic respiratory failure, also called long-term oxygen supplementation: COPD or suffering from polycythemia, chronic pulmonary heart disease, pulmonary hypertension, non-apneic and in all cases when the partial pressure of oxygen is less than 60 mm of mercury.

The Horizon® P5 provides a high concentration of oxygen and is used with a nasal cannula to channel oxygen from the concentrator to the patient. The Horizon® P5 can be used in homes, institutions, vehicles, airplanes and a variety of mobile environments.

The Horizon® P5 can be used by a single patient or by several patients successively, if the disinfection procedures indicated in this user manual, as well as in the Technical Manual are followed.

## Contraindications



*The device was NOT designed for lifesaving or maintenance of vital functions.*



*Under certain circumstances, the use of non-prescribed oxygen therapy can be dangerous. The device should only be used when prescribed by a physician.*



*Using this device at an altitude above 3000 meters or at a temperature outside the range of 5 to 40°C or at a relative humidity above 95% without condensation, is likely to have an adverse impact on the flow rate and percentage of oxygen and therefore on the therapy.*



*A geriatric or any other type of patient unable to communicate their discomfort may require additional monitoring and / or a distributed alarm system to communicate information regarding discomfort and/or medical urgency to responsible caregivers to prevent harm.*



*This product is not suitable for babies or patients severely poisoned by carbon monoxide.*



*The Horizon® P5 should not be used by more than one patient at the same time. Complete disinfection must be performed between the different patients.*



**The Horizon® P5 is not designed nor intended for use with a humidifier, nebulizer, or connected to any other equipment. Using the device with a humidifier, nebulizer, or connected to other equipment may adversely affect performance and / or damage the equipment.**



**Do not modify the Horizon® P5. Any modification made to the equipment may adversely affect performance or damage the equipment and will void your warranty.**

# Horizon® P5 Description

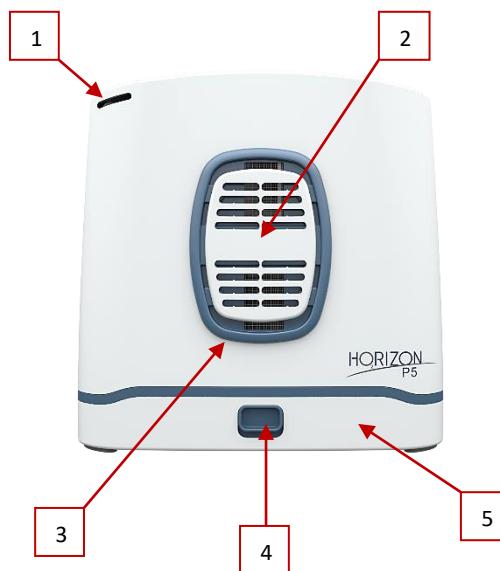
The Horizon® P5 packs come with the following elements:

- Horizon® P5 Concentrator – reference R41 10 020
- Horizon® P5 Carry Bag - reference R41 10 070
- Cable and Power Supply - reference R41 10 015
- Single or double battery, depending on the chosen pack:
  - Horizon® P5 pack R41508: Horizon® P5 single battery – reference R41 10 010
  - Horizon® P5 pack R41516: Horizon® P5 dual battery - reference R41 10 011

## Parts of your Horizon® P5 Oxygen Concentrator

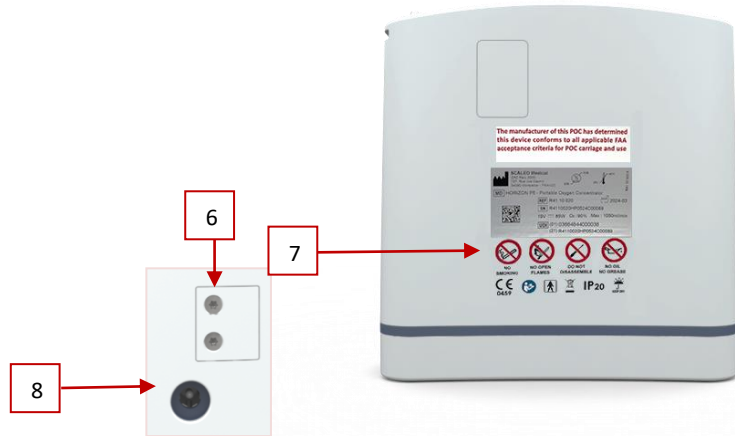
### Front

1. Ventilation opening
2. Particle filter cover
3. Air inlet and outlet
4. Battery release latch
5. Battery



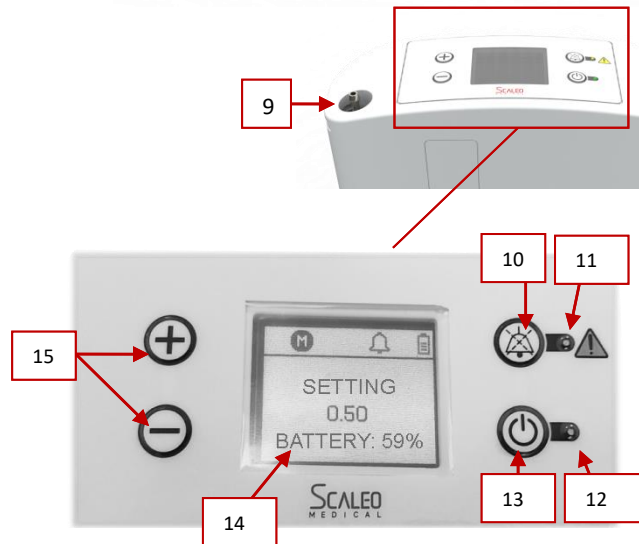
## Back

- 6. USB Port
- 7. Product identification label
- 8. Power supply input



## Upper side

- 9. Cannula nozzle
- 10. Audible alarm button
- 11. Alert / alarm LEDs
- 12. Breathing detection LED
- 13. On / Off button
- 14. Screen
- 15. Flow control



## Main parts description

- **Particulate filters.** Filters must be placed at the inlet of the concentrator during operation to keep the incoming air clean.
- **USB port.** Used only for maintenance by your service provider. Do not connect any unknown storage device.
- **Power supply input.** Allows connection to external power from the AC power supply.
- **Cannula nozzle.** The cannula must be connected to this nozzle, as this is where the Horizon® P5 releases the concentrated oxygen.
- **Audible alarm button.** By pressing on this button, the Horizon® P5 Breath Detection audible alarm will be enabled or disabled.
- **Alert / alarm LED.** An orange light indicates either a change in operating status or a condition that may require action (alarm). A flashing light has priority over a non-flashing light.



*The Horizon® P5 is also equipped with an audible signal (beep) that indicates either a change in operating status or a condition that may require action (alarm). More frequent beeps indicate higher priority conditions.*

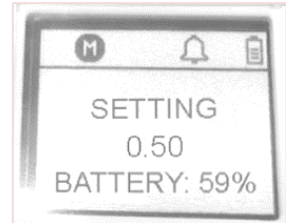
- **Breath detection LED.** The Horizon® P5 alerts with audible and visual "no breath detected" signals when this mode is activated and no breath has been detected for 15 seconds. After 15 seconds, the device enters automatic heartbeat mode. When another breath is detected, the device switches out of the automatic pulse mode and delivers normally on inspiration. The screen mode indication area displays a bell icon, a blinking orange light, and a message when the alert is triggered.



- **On / Off button.** Press the button once to activate the "On" function; hold the button down for one second to deactivate the function "Off".



- **Display.** This display shows information about the current setting, power status, battery life and malfunctions.



*The display turns on automatically when any of the control buttons are pressed. It also turns off automatically.*



*Contact your service provider to learn how to change the language of the Horizon® P5 display.*

- **Settings adjustment buttons.** Use settings buttons “-” or “+” to select the desired value as indicated on the display. Settings range from 0.25 to 5.



- **Rechargeable single and dual lithium-ion batteries.** The battery powers the Horizon® P5 without connection to an external power source. When fully charged, in flow setting 1, a single battery can provide up to 4 hours  $\pm$ 15 minutes of operation; a dual battery can provide up to 8 hours  $\pm$ 30 minutes of operation. The battery recharges when it is correctly installed in the Horizon® P5 and the concentrator is connected to AC power. The batteries can be replaced by the patient in the event of a low battery alarm.



Recharge time is up to 2 hours 30 minutes for a single battery and 4 hours 30 minutes for a dual battery. See the information in the "Battery Maintenance" section.



*The Horizon® P5's lithium battery is supplied charged to approximately 40% of its capacity. The concentrator can be used immediately, but a full charge is recommended before first use. SCALEO Medical recommends charging the batteries in a temperate room. SCALEO Medical recommends disconnecting the battery from the device when it is not used for a long period. If the device is not to be used for a long period (more than two weeks), SCALEO Medical recommends running the device for at least 30 minutes with the trigger activated at least once.*



*The Horizon® P5's batteries must not be stored at extreme temperatures above 60°C or below -20°C, even for a short time. The patient should follow charging instructions displayed by the device during use, especially when charging the battery. A completely discharged battery should not be left on a machine.*

- **Supplementary battery for the Horizon® P5.** The Additional battery allows extended use of the concentrator in the event of absence of a power outlet (outdoor use such as travel, walking, etc.).
- **Carry bag.** The Horizon® P5 carry bag provides protection when transporting the concentrator with a handle and adjustable shoulder strap.



*The carry bag helps protect your concentrator against liquid penetration, and it is classified IP22.*



- **Power cable and power supply.** The Horizon® P5 concentrator is powered by an alternating current (AC) source. The Horizon® P5 AC power supply provides the current and voltage required to safely power the Horizon® P5. It is designed to operate from a variety of AC power sources, automatically adjusting to input voltages from 100V to 240V (50-60Hz), allowing it to be used with most power sources in the world.



*The AC power supply charges the Horizon® P5's batteries when used with AC input power.*

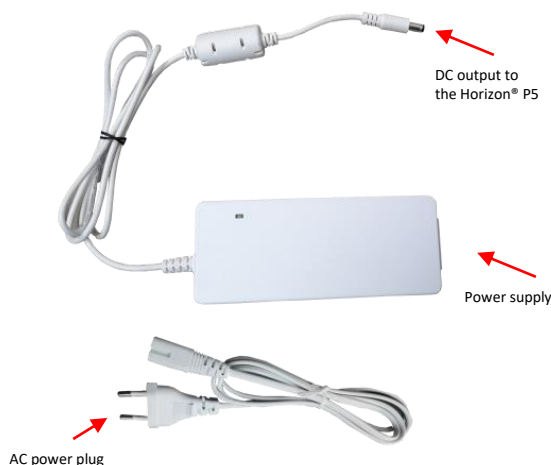




***Do not use power supplies or power cables other than those specified in this user manual. The use of unspecified power supplies or cables may present a safety hazard and/or adversely affect the performance of the device.***



***Do not wrap cords around the power source for storage. Doing so may damage the cords and prevent power from being supplied to the concentrator. To avoid choking or strangulation, keep cords and tubes out of the reach of children and pets.***



## Spare Parts

- Outlet filters - reference R41 10 156
- Outlet filter replacement kit - reference R41 10 025
- Horizon® P5 sieve beds - reference R41 10 060



*For assistance, if needed, with set-up, operation, maintenance, or to report unexpected operation or events, contact your service provider or SCALEO Medical.*



**The Horizon® P5 and its parts, recommended by SCALEO Medical, are compatible and allow optimal use of the concentrator.**

## Parts Non-included on the Horizon® P5 Pack

- **Nasal cannulas.** They should be used with the Horizon® P5 to deliver oxygen from the concentrator.



*To ensure accurate breathing detection and oxygen delivery, it is recommended to use low-flow oxygen cannulas with a flow rate of 0 to 6 L/min with a rate pressure of 5 to 50 PSI and a maximum length of 7.6 meters.*



***SCALEO Medical recommends single inlet cannulas (e.g., Salter 16SOFT) to ensure proper oxygen use and delivery to the patient.***



***The use of unspecified accessories may create a safety hazard and/or impair the performance of the equipment.***

# Instructions for Use

## How to Use the Horizon® P5



***Avoid using the Horizon® P5 in the presence of pollutants, smoke, or fumes. Do not use the Horizon® P5 in the presence of flammable anesthetics, cleaning agents or other chemical vapors.***



***Use of accessories that are incompatible with the Horizon P5 may result in a degradation of performance. Refer to the Accessories section of this manual for more information on the recommended accessories for your concentrator.***



**The responsible body:**

- must ensure the compatibility of the oxygen concentrator and all parts and accessories used to connect to the patient before use;
- must ensure that oxygen delivery parameters have been determined and registered for the individual patient along with the configuration of equipment to be used, including accessories; and
- should periodically reevaluate the therapy parameter(s) for effectiveness.



**The Horizon® P5 oxygen concentrator is designed for continuous use. For optimum sieve beds life, the product should be used frequently.**



**Do not obstruct the air inlet or outlet when using the device. Obstruction of air flow or proximity to a heat source may result in internal heat build-up and shutdown or damage to the concentrator.**



***The air inlet and outlet area must be freely accessible. Position the Horizon® P5 so that any audible alarm can be heard.***

Air inlet and  
outlet



1. Place the Horizon® P5 in a well-ventilated area.
2. Install the battery.

Insert the Horizon® P5 battery into the bottom of the concentrator by sliding it until the latch returns to the top position.



**i** *The Horizon® P5 battery acts as a secondary power supply in the event of loss of external AC power. When using the Horizon® P5 connected to AC power, a properly inserted Horizon® P5 battery must be maintained in the device. This procedure will ensure uninterrupted operation and will trigger all alarms and alerts in the event of loss of external power.*

3. Plug in the power source.

Connect the AC power plug to the AC outlet and plug the power output plug into the Horizon® P5. A beep will sound from the concentrator, the display light and control panel LED will turn on and then turn off after a few seconds.



**i** *A beep will be heard, then the "SCALEO Medical" logo will appear on the screen for 2 seconds. The screen then goes blank.*



**Do not disassemble the power source. Doing so may result in failure of the parts and/or a safety hazard.**



**Make sure the power supply is well ventilated, as it relies on air circulation for heat release. The power supply can become hot during operation. Make sure the power supply cools down before handling it.**



**The power supply is not water resistant.**



**Do not place anything in the power supply port other than the supplied wall cord.**



**Avoid using extension cords with the Horizon® P5. If an extension cord must be used, use an extension cord that is *Underwriters Laboratory (UL)*. Do not connect any other device to the same extension cord.**



*Under certain conditions (see technical specifications), the power supply may be shut off. The green light will blink or fail to illuminate. If this happens, unplug the power supply for at least 10 seconds and plug it back in.*



*When the power supply is disconnected from the AC outlet, also disconnect it from the concentrator to avoid unnecessary discharge of the battery.*



*When charging a fully discharged battery, the charging process may start and stop for the first few minutes. The fan will also stop.*

4. Connect the nasal cannula to the cannula nozzle fitting.

The nozzle fitting is located on top of the Horizon® P5. The use of a single inlet cannula up to 7.6 meters in length is recommended to ensure proper breath detection and oxygen delivery. Additional titration may be required to ensure proper oxygen delivery when using a particular cannula.



***When using a 7.6 m (25 ft) long cannula with the Horizon® P5, an increase in flow setting may be required.***



*Increasing the length of the nasal cannula may reduce the perceived noise during oxygen bolus delivery.*



*To ensure oxygen flow, ensure that the nasal cannula is properly connected to the nozzle fitting and that the tubing is not kinked or pinched in any way.*



*To confirm that air is being delivered to the end of the cannula, simply place your hand*

*near the air outlet at the end of the cannula; if you feel a puff, the air system is working properly. If you do not feel gas flowing, check the cannula connections for leaks. Please contact your supplier if this is the case.*



***Correct installation and positioning of the nasal cannulas in the nose is a critical stage for correct operation of this device. This device is not suitable for use on tracheostomised patients.***



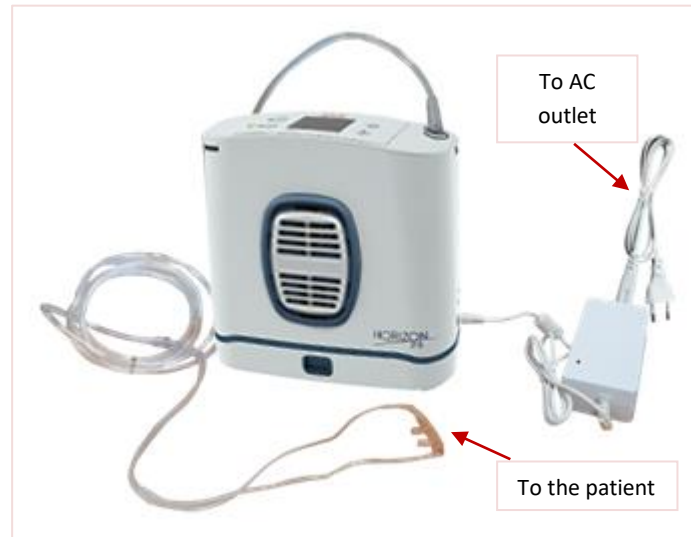
***To avoid choking and strangulation, keep tubes out of reach of children and pets.***



***Replace nasal cannulas regularly. Check with your supplier or physician to determine how often the cannula should be replaced.***

5. Make sure the removable parts of the concentrator are connected according to the following connection diagram:

*Connection Diagram  
Horizon® P5 Removable Parts*



6. Turn on your Horizon® P5.

To turn the device on, press the "On/Off" button. The device will turn on when the "SCALEO Medical" logo appears on the screen and the buzzer beeps.

The message "Please wait, starting in progress" will appear when the concentrator starts up.

The main screen shows the selected flow settings and the battery status. After a brief start-up sequence, there is a warm-up period of up to 5 minutes.



*During this period, the oxygen concentration is building up but may not reach specifications. Additional warm-up time may be required if your Horizon® P5 has been stored in extremely cold temperatures.*

## Flow Setting Adjustment

7. Adjust the Horizon® P5 oxygen concentrator according to your physician's prescription.

Use the "+" or "-" flow setting control buttons to set the Horizon® P5 to the desired setting. The current setting can be viewed on the display.

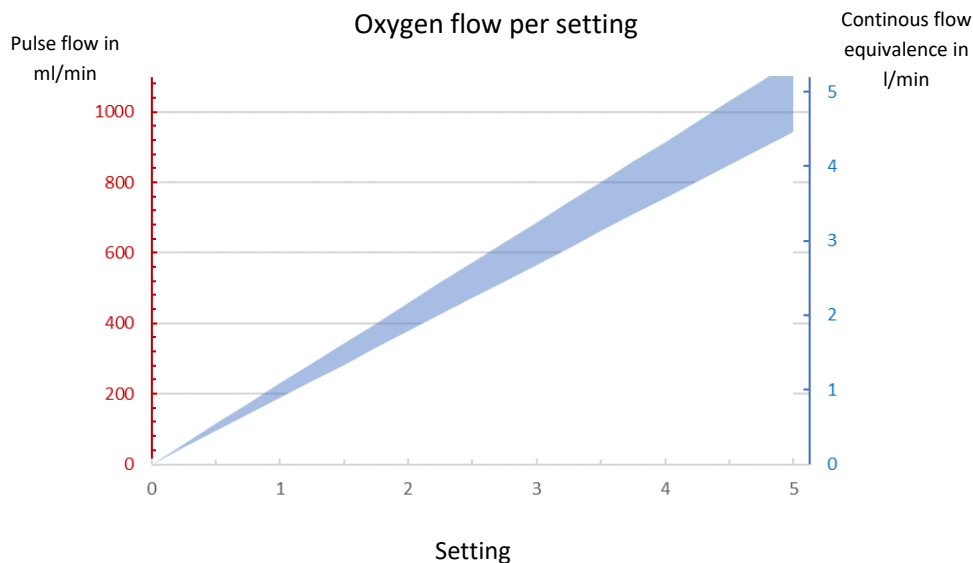
A short press of the "+" button increases the setting by 0.25 each time. A long press increases the setting in intervals of 1.

On the contrary, a short press on the "-" button will decrease the setting by 0.25. A long press will decrease the setting by 1 each time.

Under the environmental conditions recommended for its use, the Horizon® P5 will deliver an oxygen concentration between 87% and 96%, whatever the setting chosen (when the sieve bed is new, the oxygen concentration can temporarily rise to 98%).



*The bolus volume of the oxygen concentrator can be adjusted according to the physician's prescription, using the table above.*



Setting	Flow rate (ml/min $\pm 15\%$ )	Oxygen concentration % (-3+6%)
1	210	90
2	420	90
3	630	90
4	840	90
5	1050	90



*Gas flow rates are measured and indicated under STP (standardised temperature and pressure, in dry conditions). For each setting, Horizon® P5 delivers a constant flow rate in 210 ml increments, regardless of temperature, pressure and humidity conditions. The flow rate per setting remains constant, whatever the breathing rate, from 15 to 40 breaths per minute, thanks to automatic adjustment of the boluses delivered.*

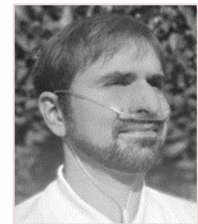


The table below summarises the bolus volumes delivered by the Horizon® P5 at 20°C at sea level, producing an oxygen concentration of 90%  $\pm$  (+6 / -3).

Setting	Flow rate (ml/min $\pm$ 15%)	Oxygen % (-3+6%)	15 BPM ( $\pm$ 15%)	20 BPM ( $\pm$ 15%)	25 BPM ( $\pm$ 15%)	30 BPM ( $\pm$ 15%)	35 BPM ( $\pm$ 15%)	40 BPM ( $\pm$ 15%)
0.25	52.5	90	3,5	2,6	2,1	1,8	1,4	1,3
0.5	105	90	7	5,2	4,2	3,5	2,8	2,6
0.75	157.5	90	10,5	7,9	6,3	5,3	4,2	3,95
1	210	90	14	10,5	8,4	7	5,6	5,25
1.25	262.5	90	17,5	13,1	10,5	8,8	7	6,55
1.5	315	90	21	15,7	12,6	10,5	8,4	7,85
1.75	367.5	90	24,5	18,3	14,7	12,3	9,8	9,15
2	420	90	28	21	16,8	14	11,2	10,5
2.25	472.5	90	31,5	23,6	18,9	15,8	12,6	11,8
2.5	525	90	35	26,2	21	17,5	14	13,1
2.75	577.5	90	38,5	28,8	23,1	19,3	15,4	14,4
3	630	90	42	31,5	25,2	21	16,8	15,75
3.25	682.5	90	45,5	34,1	27,3	22,8	18,2	17,05
3.5	735	90	49	36,7	29,4	24,5	19,6	18,35
3.75	787.5	90	52,5	39,3	31,5	26,3	21	19,65
4	840	90	56	42	33,6	28	22,4	21
4.25	892.5	90	59,5	44,6	35,7	29,3	23,8	22,3
4.5	945	90	63	47,2	37,8	31,5	25,2	23,6
4.75	997.5	90	66,5	49,8	39,9	33,3	26,6	24,9
5	1050	90	70	52,5	42	35	28	26,25

#### 8. Place the nasal cannula over your face and breathe through your nose.

The Horizon® P5 detects the beginning of inhalation and delivers a puff of oxygen at a specific time during inhalation. The concentrator will detect each breath and continue to deliver oxygen in this manner.



As your breathing rate changes, the Horizon® P5 detects these changes and delivers oxygen only when you need it. Sometimes, if you inhale very rapidly between breaths, the Horizon® P5 may ignore one of the breaths, giving the appearance of a missed breath. This can be normal because the Horizon® P5 detects and monitors changes in your breathing pattern. The Horizon® P5 normally detects the next breath and delivers oxygen accordingly.

A green light flashes whenever a breath is detected.



*Ensure that the cannulas are aligned with your face and that you are breathing through your nose.*



*Correct installation and positioning of the user interface is critical to oxygen delivery.*



***If you feel unwell or experience a medical emergency while on oxygen therapy, seek medical assistance immediately to avoid harm.***



***The Horizon® P5 is designed to provide a flow of high-purity oxygen. An advisory alarm, "Oxygen Low," will inform you if the oxygen concentration drops. If the alarm persists, contact your service provider.***

9. When you are finished using the device, turn it off.

To turn off the power, unplug the input cord from its source (i.e., the AC wall outlet) and disconnect it from the Horizon® P5.



*Oxygen delivery settings are determined individually for each patient with the accessories recommended by SCALEO Medical.*

## Using the Horizon® P5 Carrying Bag



*The carrying bag is designed to be used with either a single or a dual battery. To adjust the bag, simply insert or remove the spacer inside the bag.*

1. Insert the Horizon® P5 so that the display is visible through the top window and the cannula nozzle assembly is accessible through the open slot at the top of the bag.





*The inlet and outlet openings of the Horizon® P5 should be visible through the mesh fabric on the front.*

The Horizon® P5 can be used on battery power while in the carrying bag. It can also be connected to AC power through the bag's power outlet.



*Refer to the Operating Instructions section of this manual for more information.*

2. Adjust the strap to your size using the buckles.
3. Use your concentrator as usual, following the guidelines previously given in the Instructions for Use section of this manual.

## Using the Horizon® P5 while Traveling



***Due to power limitations on airplanes, AC power cannot be used to charge the Horizon® P5 battery when used on an airplane. We recommend using a spare battery during the entire duration of the flight. The Horizon® P5 can be used up to 3000 meters.***

It is possible to travel with the Horizon® P5 oxygen concentrator. Be sure to pack all the essentials for a safe trip:

- Your Horizon® P5 oxygen concentrator.
- The power supply and power cord.
- Extra batteries, to provide power for the duration of the trip.
- Important contact information, such as the phone number of your physician, local service provider, and/or those at your destination.
- Always have a backup source of oxygen.

# Alerts and Troubleshooting

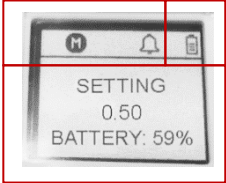
## Display Icons

The Horizon® P5 screen is divided into three areas: the "Mode" section, the "Power Status" section, and the "Text" section.

The "Mode" section is located in the upper left corner of the screen and indicates the operating mode.

The "Power Status" section is located in the upper right corner and shows the power source and battery level.

The lower part of the screen contains the "text" section and displays important information, such as the setpoint setting, remaining battery time and error notifications.



Mode	Battery level
Text	









## Power status icons

These icons are examples of those displayed in the "Power Status" section of the screen when the Horizon® P5 is operating on battery power or from an external power supply while charging the battery.








*The Horizon® P5 continuously displays the battery life. The displayed time is an estimation and the actual time remaining may vary from this value.*

The lightning flash indicates that an external power supply is connected.

Icon	Meaning
	Battery is empty.
	The battery's remaining charge is less than 10%.
	The battery's remaining charge is approximately 15-25%.
	The battery's remaining charge is approximately 45% to 50%.
	The battery's remaining charge is 75% to 80%.
	The battery is 100% full.
	The Battery is charging.
	The Horizon® P5 operates on an external AC power source.

## Function icons

These are the icons displayed in the "Mode" section of the screen:

Icon	Meaning
	Breath Detection Alert is on.
	The breath detection sound alert is off. This is the default mode when the concentrator is on.
	The Horizon® P5 operates in manual mode. This means that the user will be able to manually change the oxygen concentrator settings using the "+" and "-" buttons.
	Indicates an alarm.
	Required maintenance.

## Information about the text sections

Messages may be displayed in this section. They are intended to guide the user on the status of this device. The following section is devoted to presenting these messages and explaining their meaning.



*When two conditions occur simultaneously, the condition with the higher priority will be displayed.*

## Notifications & Alerts

### Information messages

The following information is NOT accompanied by an audible alarm or visual change in the indicators:

Message	Condition / Action / Explanation
Startup in progress Please wait	Displayed when the power button has been pressed for two seconds. The concentrator is starting the system.
Setting X Battery XX%	"X" represents the selected setpoint setting. "XX%" represents the approximate percentage remaining on the battery charge.

Audible notifications, alert the user of problems. In order for the auditory notifications to be heard, the maximum distance the user can move away from the notification should be determined based on the ambient noise level.

The Horizon® P5 monitors various parameters during operation and uses an intelligent alarm system to signal a malfunction of the concentrator. Mathematical algorithms and time delays are used to reduce the likelihood of false alarms while ensuring proper notification of an alarm condition.

If a low or medium level alarm is triggered, the buzzer will emit two or three sounds depending on the priority level, the LED next to the "alarm" button will flash or be steady, the alarm logo and the error message will appear on the display.




*It is possible to deactivate the buzzer by briefly pressing the "Alarm" button. This locks the buzzer on the screen and thus inhibits the alarm sound. The logo and the flashing LED will still be active, and the error message will still be displayed on the screen.*

It is always possible to change the setting when an alarm is active. The setting menu is displayed for 3 seconds, then the alarm message is displayed again. When the alarm indicating a change in the column is active, a maintenance key flashes every 2 seconds at the top of the screen.

If a medium priority alarm occurs, it will shut down the device. Before the concentrator is completely shut down, the corresponding error message is displayed for 10 seconds.

The following notification messages are accompanied by a single, short beep.

Message	Condition / Action / Explanation
	The SCALEO Medical logo is displayed when the device is turned on. The On/Off button has been pressed for two seconds and the system starts up.
Please wait Shutdown in progress	The On/Off button has been pressed for two seconds. The system will shut down.

## Low priority alerts

The following low priority alerts are accompanied by a double beep every minute and a solid yellow light.

Message	Condition / Action / Explanation
Low Battery Charge Battery	Battery charge is low, between 5 and 10 %. Connect an external power supply or turn off the power and insert a fully charged battery.
Replace Column	Column (sieve beds) maintenance must be performed within 30 days. Contact your service provider.
Low oxygen	The concentrator produces oxygen at a slightly low level (between 82 and 87%) for 30 minutes. If the condition persists, contact your service provider.
Warning Hot battery	The temperature of the battery is above 40°C. Remove the battery from the concentrator and allow it to cool in an open area for approximately 10-15 minutes. Then reinsert the battery into the device. If the problem persists, contact your service provider.
Battery communication error	The concentrator is producing oxygen but cannot indicate the battery's state of charge. Check that the battery is connected to the device. If the problem persists using the same battery, replace it with a new one, or remove the battery and connect the concentrator to the external power source.
Insufficient ventilation	The concentrator's temperature is above 50°C. Turn off the concentrator, move it to a cooler room, and let it cool for 20 minutes. If the alarm persists, check that the fan is running or call your service provider.
Cold system	The concentrator's temperature is below 0°C. Turn the device off, move it to a warmer room, and let it warm up for 20 minutes before turning it on. If the alarm persists, call your service provider.



## Medium priority alerts

The following medium priority alerts are accompanied by a triple beep, repeated every 30 seconds, and a yellow light flashing at 0.5 Hz.

Message	Condition / Action / Explanation
Breathing not detected Check cannula	The concentrator has not detected a breath for 15 seconds. Check that the cannula is connected to the concentrator, that there are no bends in the tube and that the cannula is correctly positioned in your nose.
Low oxygen	Oxygen concentration has been between 60% and 82% for 10 minutes. If the situation persists, switch to your backup oxygen source and contact your service provider.
Remove battery	The battery has exceeded the temperature limit and charging has stopped. Connect the device to an external power source and remove the battery to cool it down. If possible, move the concentrator to a cooler location. If the condition persists, contact your service provider.
Cold battery	The battery temperature is below 0°C. Move the concentrator to a warmer location and wait for the device to reach recommended operating temperatures before turning it on.
Failed pressure sensor	Check your filters for blockages. If the pressure sensor is defective or out of order, an alarm will be triggered by the device. Contact your service provider.
Failed piping	Nozzle failure (hoses or control valves). Contact your service provider.



*Reminder: If you are not in close proximity to the Horizon® P5, you may not be able to hear or see medium priority alerts. Make sure the Horizon® P5 is in a location where alerts and alarms will be recognized if they occur.*

Message	Condition / Action / Explanation
Malfunctioning pneumatic valves	Defective or out of order Solenoid valves. Contact your service provider.
Tank pressure too high	The pressure is above 32 PSI because of the sieves, but the compressor is not overspeeding. If the situation persists for 30 seconds, shut down the equipment and contact your service provider.
Charge battery immediately	Battery level is below 2%. Charge the battery immediately by connecting the device to an external power source.
Battery TOO HOT System shutdown	The battery temperature is above 45°C and the equipment has stopped producing oxygen. Turn off the equipment and allow it to cool. Move the concentrator to a cooler location. Then turn the power back on. Make sure the unit is well ventilated and that the particle filters are clean. If the situation persists, switch to a backup oxygen source and contact your service provider.
HOT System	The concentrator temperature has been above 55°C for more than 30 seconds. Turn off the unit and allow it to cool. Move the concentrator to a cooler location. Do not turn on the concentrator until the temperature has dropped below the critical values. If the temperature does not drop, contact your service provider.
System COLD	The concentrator temperature has been below 0°C for more than 30 seconds. Move the device to a warmer location. Do not start the concentrator until the temperature has risen above the critical values. If the condition persists, switch to a backup oxygen source and contact your service provider.
System error	The concentrator has stopped producing oxygen and is shutting down. Please contact your service provider.
Oxygen error	The oxygen concentration is below 60%. The oxygen concentrator stops after 10 minutes if the compressor cannot compensate in terms of volume and stops the alarm. If this happens, use your backup source and contact your service provider.

Message	Condition / Action / Explanation
Memory error	Flash memory failed to read. Contact your service provider.
Sensor error	There is no communication with the oxygen sensor. Contact your service provider.
Fan error	The fan speed is different from the expected speed. Turn off the concentrator and do not turn it on until it has been serviced by your service provider.
Compressor error	The compressor is overspeeding or the pressure is above 32 PSI due to the sieves beds. Turn off the concentrator and do not turn it on until it has been checked by your service provider.

## Self-Test

The Horizon® P5 oxygen concentrator is programmed to perform a self-test of alarm-related sensors at start-up. If one of the sensors is no longer functional, the corresponding error message will be displayed at start-up.

At each start-up:

- Check of solenoid valves,
- Presence of pressure sensors (tank and breathing),
- Presence of barometer,
- Fan speed,
- Presence of accelerometer,
- Presence of oxygen sensor.

## Troubleshooting

Solutions to some possible problems you may encounter are described in this section.

Problem	Possible cause	Recommended solution
Any problem that is associated with error messages on the concentrator, lights and/or beeps	Abnormal function detected	See the "Notifications and Alerts" section.
The concentrator does not turn on when the on/off button is pressed	The battery is discharged or there is no battery	Use an external power source or replace the battery with a fully charged one.
	AC power source is not properly connected	Check the connection to the power supply and verify that the display and control panel lights are on during the connection. Replace the AC power source.
	Malfunction	Contact your service provider.
	Power supply voltage outside the limits	Connect the power supply to a suitable source. Refer to the "Technical Data" section for the correct power supply voltage.
No oxygen	Concentrator is not turned on	Press the On/Off button to power the concentrator
	The cannula is not connected properly or is bent or obstructed	Check the cannula and its connection to the concentrator nozzle.
Battery not detected when connected to the concentrator (no screen display, no battery status indicator)	Battery safety shutdown to avoid deep discharge	Connect the AC adapter and wait a few hours until the battery level is sufficient to lift the safety shutdown.
	Battery sleep mode after a period of inactivity	Plug in the AC adapter to activate the battery immediately. Then charge the battery normally.

# Cleaning and Maintenance

## Cleaning and Disinfection



***Reminder: Use only water-based lotions or balms that are labeled as oxygen compatible before and during oxygen therapy. Never use petroleum or oil-based lotions or balms to avoid the risk of fire and burns.***



***Do not disassemble the Horizon® P5 or any of its parts or attempt to perform any maintenance other than that described in this user manual; disassembly creates a risk of electric shock and voids your warranty.***



***Do not remove the safety label. Contact your service provider for situations other than those described in this manual.***



***The tubing, inlet filter and cannula are parts of the gas pathways through the Horizon® P5 that are susceptible to contamination by body fluids or exhaled gases.***



***Regularly check your concentrator for housing damage, battery deformation, cable and power supply, air inlet obstructions and nasal cannula connections, to prevent any risk of failure.***

### 1. Replacing the cannula

The cannula should be replaced regularly. Consult your physician and/or service provider and/or the cannula manufacturer's instructions for replacement information.

### 2. Cleaning the case

You can clean the outer casing using a cloth dampened with a mild liquid detergent and water.



***Do not immerse the Horizon® P5 or its accessories in water or allow water to enter the housing; this may result in electrical shock and/or damage.***

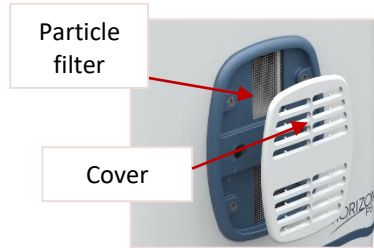
### 3. Cleaning and replacing the filter

The particle filter should be cleaned by the patient on a weekly basis to ensure easy airflow. The particle filter is located on the front of the Horizon® P5, behind the oval center section. The particle filter cover opens and closes with an intuitive clip system.

1. Using your fingers, remove the center oval (the cover).
2. Clean the particle filters with a brush.



*It may be necessary to clean the particulate filter more often in dusty environments. If the filter needs to be replaced, contact your service provider.*



### 4. Output filter

The outlet filter is designed to protect the user from inhaling small particles in the product gas stream. The Horizon® P5 includes an outlet filter conveniently located behind the removable cannula nozzle fitting. The Horizon® P5 requires that this filter be replaced between patients or every 3 months if the concentrator is used by the same patient. This output filter cannot be disinfected and must be replaced.



The output filter can be replaced by the patient using the tool wrench.



*The Horizon® P5 concentrator should be cleaned according to the above instructions if used by a single patient. No special maintenance should be performed by the patient. Any service other than that specified in this user manual should be performed by technicians trained and certified by the manufacturer.*



## Patient-to-patient Disinfection

If used by multiple patients, the same cleaning routine must be performed between each patient, and in addition, a complete disinfection procedure must be performed using a dry hydrogen peroxide mist system and the Horizon® P5 disinfection protocol outlined in the Technical Manual. The disinfection procedure is communicated to providers.

The cannula should be replaced routinely between patients.

## Battery Care

Your Horizon® P5 lithium-ion battery requires special care to ensure proper performance and long life. Use only Horizon® P5 batteries with your Horizon® P5 concentrator.



**Always keep the batteries dry with a 40-50% charge.**



**Always keep batteries away from liquids. If batteries become wet, discontinue use immediately.**



**To extend the life of your battery, avoid using it in temperatures below 5°C or above 40°C for extended periods of time.**



**When using multiple batteries, rotate them regularly.**



**A battery kept alone without being used for more than 48 hours goes into a sleep mode to limit its natural discharge. Plugging in the AC adapter allows the battery to wake up immediately: you can then recharge the battery.**

## Horizon® P5 Column Replacement Procedure



*Use only original columns. The use of unspecified columns may create a safety hazard and/or adversely affect the performance of the device and will void your warranty.*



*The column replacement instructions should only be used when maintenance is required and are not intended for training purposes. The column can be replaced by the patient by following the procedure below.*

### Remove the current column (sieve beds)

1. Turn off the Horizon® P5 concentrator by pressing the "On/Off" power button.
2. Remove the Horizon® P5 Concentrator from the carrying bag.
3. Remove the battery from the Horizon® P5 concentrator.
4. Turn the Horizon® P5 upside down, so that the display panel is facing down and the bottom of the Horizon® P5 is facing up.
5. The column is the silver colored part (see picture on the right).
6. Remove the column by pressing the lock button with a finger.
7. While holding the button open, slide the column out by grasping the handle provided with your other hand.
8. Remove the column completely from the Horizon® P5.



### Installing the new column

9. Remove the dust caps from the new column. Make sure there is no dust or debris where the dust caps were.



10. Insert the new column into the Horizon® P5 concentrator.



**Do not leave the column exposed; it must be inserted into the Horizon® P5 as soon as the dust caps have been removed.**

11. Push the column into the device so that it is fully inserted into the Horizon® P5 concentrator.



*The snap lock button should return to the closed position.*

12. Connect the power cord to the Horizon® P5 and plug it into the power outlet. Do not turn on the Horizon® P5 concentrator.

13. Press and hold the light button for 10 seconds. The display will show the message "Screen Reset". Release the button once the message is displayed on the screen.

14. Press the bell button once and the screen will display "Sieves reset success".

15. Press the power button to turn on the Horizon® P5, and operate it normally.

## Repair

Full repair instructions are available in the Technical and Service Manuals supplied to your healthcare provider.

Disassembly and replacement of internal parts of the oxygen concentrator and its battery must be carried out by trained and qualified personnel.

Software updates must be carried out using software authorized by the manufacturer and only by qualified personnel.

# Technical Specifications

## Horizon® P5 Technical Specifications

<b>Dimensions in cm (L x W x H)</b> <b>With single battery</b> <b>With dual battery</b>	21.6 cm x 8.8 cm x 18 cm (without battery) 21.6 cm x 8.8 cm x 22 cm 21.6 cm x 8.8 cm x 24 cm
<b>Weight</b>	2.54 kg (including single battery) 2.90 kg ( including dual battery)
<b>Noise level*</b>	37.3 dB(A) as per 14-1 10/2018 MDS-Hi at setting 2 and 5
<b>Power consumption</b>	85 W (1W in standby mode)
<b>Oxygen concentration**</b>	90% -3+6% V/VO2 (>87% at all settings)
<b>Trigger sensitivity</b>	-0.5 cm H2O (+/- 20%)
<b>Output pressure (maximum)</b>	<30 PSI
<b>Heating time</b>	5 minutes
<b>Flow settings</b>	20 settings: from 0.25 to 5
<b>Breathing frequency</b>	From 15 to 40 breaths per minute
<b>Volume of oxygen produced per minute</b>	Setting 1: 210 ml/min                      Setting 4: 840 ml/min Setting 2: 420 ml/min                      Setting 5: 1050 ml/min Setting 3: 630 ml/min
<b>AC/DC Power supply</b>	AC input: 100 to 240 VAC; 50 to 60 Hz DC output: 19VDC, 4.7A
<b>Rechargeable battery</b>	Voltage: 12V to 16.8 VDC
<b>Battery life*** at setting 1</b>	Up to 4 hours ± 15 minutes with single battery Up to 8 hours ± 30 minutes with dual battery
<b>Battery charging time</b>	Up to 2 hours 30 minutes with single battery Up to 4 hours 30 minutes with dual battery

\*37.3 dB(A) as per 14-1 10/2018 MDS-Hi at setting 2 and 5; Weighted sound pressure level of 47dB(A) at setting 5 and 44dB(A) at setting 2: at 1m as per ISO 80601-2-69:2014 §201.9.6.2.1.101; Calculated sound power level of 55dB(A) as per ISO80601-2-69:2014 §201.9.6.2.1.101.

\*\* Used under normal pressure and temperature conditions.

\*\*\*Battery life will vary depending on flow setting and operating conditions.

#### Measurement uncertainty:

- Sound pressure level (K=2; 3.0db(A))
- Oxygen concentration (K=2; 0.03% V/V)

## Batteries Specification

Battery	Single Battery 8 cells	Dual Battery 16 cells
Calls types	LI-ion	LI-ion
Nominal voltage V	14.4 V	14.4 V
Max Capacity mAh	6.500 mAh	6.500 mAh x2
Standard current	0.2C	0.2C
Max. charging Current	3.0A	3.0A
UN38.3	YES	YES
IEC62133-2	YES	YES
Charging temperature	10°C to 45°C	10°C to 45°C
Storage temperature	0°C to 50°C	0°C to 50°C
Life expectancy 0.2C/0.2C at 21+/-2°C	500 cycles – 60% capacity	500 cycles – 60% capacity

## Classification

Operating mode	Pulse mode
Concentrator's protection degree of components against electric shock	Type BF Not intended for cardiac use
Electrical protection class	Class II
Concentrator components' degree of protection against water penetration when used outside the carrying bag	IP 20: Protection against penetration of solid matter (Horizon® P5 only)
Protection degree of the concentrator components against water penetration when used inside the carrying bag	IP 22: Protection against vertically falling water drops and solid objects (Horizon® P5 in its bag)
Degree of protection of the outer part of the concentrator provided by the carrying bag	IP X2: Drops of water falling vertically will have no effect
Safety degree for use in the presence of anesthetic gases	Not suitable for use in the presence of a mixture of flammable anesthetics and air or oxygen or nitrous oxide

## Operating Environment

Recommended environmental conditions for use	Temperature: 5 to 40°C Humidity: 20% to 95%, non-condensing Altitude: 0 to 3000 meters
Recommended environmental conditions for transport and storage	Temperature: -25 to 70°C Humidity: 0% to 95%, non-condensing Storage in a dry environment Altitude: 0 to 3000 meters
Transportation	Keep dry, handle with care


# Electromagnetic Compatibility

Guidelines and manufacturer's declaration - electromagnetic emissions		
The Horizon® P5 oxygen concentrator is intended for use in the electromagnetic environment specified below. The customer or user of the Horizon® P5 oxygen concentrator should ensure that it is used in such an environment.		
Emissions Testing	Compliance	Electromagnetic environment - guidelines
RF Emissions CISPR11	Group 1	The Horizon® P5 oxygen concentrator uses RF energy only for its internal functions. Therefore, its RF emissions are very low and are not likely to cause interference in any nearby electronic device.
RF Emissions CISPR11	Class B	The Horizon® P5 oxygen concentrator is suitable for use in all premises, including domestic premises and those directly connected to the public low-voltage power supply network supplying domestic buildings.
Harmonic emissions CEI 61000-3-2 A	A	
Voltage fluctuations / flicker IEC 61000-3-3 Compliant	Compliant	

Guidelines and manufacturer's declaration - electromagnetic immunity			
The Horizon® P5 oxygen concentrator is intended for use in the electromagnetic environment specified below. The customer or user of the Horizon® P5 oxygen concentrator should ensure that it is used in such an environment.			
Immunity Test	Test level IEC 60601	Compliance level	Electromagnetic environment - guidelines
Electrostatic Discharge (ESD) IEC 61000-4-2	± 8 kV in contact ± 15 kV in air	± 8 kV in contact ± 15 kV in air	The floors should be made of wood, concrete or ceramic tiles. If the floors are covered with synthetic materials, the relative humidity should be at

			least 30%.
Electrical fast transient / burst IEC 61000-4-4	$\pm 2$ kV for power supply lines $\pm 1$ kV for input/output lines	$\pm 2$ kV for power supply lines $\pm 1$ kV for input/output lines	The quality of the power supply system should be that of a typical commercial or hospital environment.
Overvoltage transient IEC 61000-4-5	$\pm 1$ kV phase to phase $\pm 2$ kV phase to earth	$\pm 1$ kV phase to phase $\pm 2$ kV phase to earth	
Voltage dips, short interruptions and voltage variations on power supply input lines power supply lines IEC 61000-4-11	$<0\%$ $U_T$ for 0.5 cycle $0\%$ $U_T$ for 1 cycle $70\%$ $U_T$ for 25 cycles $<0\%$ $U_T$ for 250/300 cycles	$<0\%$ $U_T$ for 0.5 cycle $0\%$ $U_T$ for 1 cycle $70\%$ $U_T$ for 25 cycles $<0\%$ $U_T$ for 250/300 cycles	The quality of the power supply should be that of a typical commercial or hospital environment. If the user of the Horizon® P5 oxygen concentrator requires continuous use during power outages, it is recommended that the Horizon® P5 oxygen concentrator be powered from an uninterruptible power supply or battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m - 50 or 60 Hz	30 A/m - 50 or 60 Hz	The quality of the power supply system should be that of a typical commercial or hospital environment.
<b>NOTE:</b> $U_T$ is the a.c. main voltage prior to application of the test level.			

Guidelines and manufacturer's declaration - electromagnetic immunity			
The Horizon® P5 oxygen concentrator is intended for use in the electromagnetic environment specified below. The customer or user of the Horizon® P5 oxygen concentrator should ensure that it is used in such an environment.			
			<p>Portable and mobile RF communications equipment should be used no closer to any part of the Horizon® P5, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance:</p>
Disturbances Conducted RF IEC 61000-4-6	3V / 0.15MHz -80MHz / 80% AM 1kHz + discrete frequencies in table 5 of standard 60601-1-2	3 Vrms	d = 1,2√P
Disturbances Radiated RF IEC 61000-4-3	3V/m / 80MHz - 2.7GHz / 80% MA 1kHz + discrete frequencies of §8.10 of standard 60601-1-2	3 V/m	<p>d = 1.2 √P</p> <p>d = 1.2 √P 80 MHz to 800 MHz</p> <p>d = 2.3 √P 800 MHz to 2.7 GHz</p>
	10V/m / 80MHz - 2.7GHz / 80% AM 1kHz + discrete frequencies of §8.10 of the standard 60601-1-2		<p>Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site</p>

			<p>survey <sup>a</sup>, should be less than the compliance level in each frequency range <sup>b</sup>.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
<p><b>NOTE 1:</b> At 80 MHz and 800 MHz, the highest frequency range applies.</p>			
<p><b>NOTE 2:</b> These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflections from structures, objects, and people.</p>			
<p><b>a:</b> The field strengths of fixed transmitters, such as base stations for radiotelephones (cellular/wireless) and land mobile radios, amateur radio, AM and FM broadcasting, and TV broadcasting, cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an on-site electromagnetic investigation should be considered. If the field strength, measured at the location where the Horizon® P5 oxygen concentrator is used, exceeds the applicable RF compliance level above, the Horizon® P5 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be required, such as reorienting or repositioning the Horizon® P5 oxygen concentrator.</p>			
<p><b>b:</b> In the frequency range of 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p>			



Recommended separation distances between portable and mobile RF communications devices and the Horizon® P5 oxygen concentrator			
<p>The Horizon® P5 Oxygen Concentrator is intended for use in an electromagnetic environment in which radiated RF interference is controlled.</p> <p>The customer or user of the Horizon® P5 Oxygen Concentrator can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Horizon® P5 Oxygen Concentrator as recommended below, based on the maximum transmit power of the communications equipment.</p>			
Maximum rated transmitter output power W	Separation distance according to the frequency of the transmitter m		
	from 150 kHz to 80 MHz	from 80MHz to 800 MHz	from 800MHz to 2,5G Hz
	d= 1,2vP	d= 1,2vP	d= 2,3vP
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

# Warranty & Liability

## Warranty

The Horizon® P5 oxygen concentrator is guaranteed for three (3) years, except for the battery, charger, adaptator, car charger and sieve beds which are guaranteed for one (1) year.

- Any intervention on the machine contrary to this manual will completely void the warranty.
- Any abnormal or improper use will void the warranty.
- Any modification made to the device will void the warranty.
- Any technical intervention carried out by unqualified personnel or an unauthorized distributor will void the warranty.

In the event of long-term storage (> 6 months), batteries should be stored with a minimum of 40% charge and recharged every 6 months to guarantee battery life.

If you store your portable oxygen concentrator for an extended period (2-3 weeks), make sure to keep it in a dry place to prevent moisture build-up in the cartridge. Such build-up can degrade the machine's performance. You should start the device for at least 30 minutes each time you use it, and at least once a week. However, if the sieves are still in their original sealed bag, you do not need to follow this recommendation.



## Liability

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

- Non-compliance with the instructions and recommendations provided in this user manual.

- Use of unsuitable spare parts.
- Assembly, adjustments and repairs carried out by unqualified personnel or by an unauthorized distributor.
- Abnormal use of the equipment, negligence, accident, human error, or maintenance and cleaning with unsuitable products.
- Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

# Product Life & Recycling

## Product Life

The Horizon® P5 oxygen concentrator has an expected lifespan of 5 years, with the exception of the batteries, which have an expected lifespan of 500 full charge/discharge cycles.

## Recycling

Please dispose of the device under local Waste Electrical and Electronic Equipment WEEE regulation.

When the product is at the end of its life and the user intends to dispose of it, it must be discarded separately from other household waste.

The battery contains lithium and must be recycled. The battery should not be incinerated.

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

# EC Declaration of Conformity



## EC Declaration of Conformity Déclaration CE de conformité

Manufacturer / Fabricant: SCALEO MEDICAL, 107 rue Joe Dassin, Parc 2000, 34080 Montpellier France

(SRN):FR-MF-000002929

We hereby declare that the following product(s)  
*Déclarons sous notre entière responsabilité que le(s) produit(s) suivant(s) :*

**Portable oxygen concentrator HORIZON P5, Ref : R41508 & R41516**  
**Concentrateur d'oxygène portable HORIZON P5, Ref : R41508 & R41516**

Basic UDI-DI: 3664844HO2PRTXS

Class IIa according to rule 11 of annex IX of the Directive 93/42/CE  
*Classe IIa en application de la règle 11 de l'annexe IX de la directive 93/42/CE*

Are compliant with / sont en conformité avec :

The council directives and amendments concerning medical devices **93/42/EEC** and the French Public Health Code, by compliance to the Harmonized European standards NF EN ISO 80601-2-69:2014 and NF EN ISO 80601-2-67:2014.

*Les directives du conseil et leurs amendements relatives aux dispositifs médicaux 93/42/CEE, et le Code de la Santé Publique, par conformité à la norme harmonisée européenne réf : NF EN ISO 80601-2-69 :2014 and NF EN ISO 80601-2-67 :2014.*

The European Directive 2015/863/EU on the use of certain hazardous substances and their restriction in electrical and electronic equipment.

*La Directive Européenne 2015/863/UE relative à l'utilisation de certaines substances dangereuses et leur restriction dans les équipements électriques et électroniques.*

This declaration is based on following elements:  
*Cette déclaration est basée sur les éléments suivants :*

- Technical data " DTCE HORIZON P5" proving conformity to the Directive Requirements  
*La Documentation technique « DTCE HORIZON P5 » démontrant la conformité du produit aux exigences de la Directive.*
- CE n° 38188 rev.1 certificate delivered by GMED approving the full quality assurance system according to the annex II.3 of the 93/42/EEC directive.  
*L'Attestation CE n° 38188 rev.1 délivré par GMED d'approbation du système qualité complet suivant l'annexe II.3 de la directive 93/42/CEE.*
- GMED additional document n°38189 rev.2 which attests to the validity of CE certificate n°38188 rev.1.  
*Le document complémentaire GMED n°38189 rev.2 qui atteste de la validité du certificat CE n°38188 rev.1.*
- Confirmation letter #39608-0 from GMED of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices.  
*Lettre de Confirmation #39608-0 du statut d'une demande formelle, d'un accord écrit et de la surveillance appropriée dans le cadre du règlement UE 2023/607 modifiant les règlements (UE) 2017/745 et (UE) 2017/746 en ce qui concerne les dispositions transitoires relatives à certains dispositifs médicaux.*

This declaration, made under the sole responsibility of SCALEO Medical, is valid for all devices identified in this declaration.  
*Cette déclaration, établie sous la seule responsabilité de SCALEO Medical, est valable pour tous les dispositifs identifiés dans la présente déclaration.*

P.J. : liste des références couvertes par la présente déclaration  
*Attachment: list of references covered by this declaration*

Expiry date / Date expiration : Dec 31<sup>st</sup>, 2028  
Released on / Fait à : Montpellier, July 31<sup>st</sup>, 2024

Michel MALGOUYRES  
Director

DDDT\_OXP5\_CE03\_Declaration Conformité CE V08

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Annex 1

DESIGNATION Désignation	REFERENCE Référence	CLASS Classe
PACK HORIZON P5 single battery PACK HORIZON P5 avec batterie simple	R41 508	Ila
PACK HORIZON P5 Dual battery PACK HORIZON P5 avec batterie double	R41 516	Ila
<b>PARTS IN THE PACK / COMPOSANTS DU PACK</b>		
Portable Oxygen concentrator « Horizon P5 » Concentrateur d'oxygène Portable « Horizon P5 »	R41 10 020	Ila
Single battery for « Horizon P5 » Batterie single pour « Horizon P5 »	R41 10 010	N/A
Dual battery for « Horizon P5 » Batterie double pour « Horizon P5 »	R41 10 011	N/A
AC/DC charger Chargeur AC/DC Horizon P5	R41 10 015	N/A
Carry bag Sacoche	R41 10 070	N/A
<b>CONSUMABLES / CONSOMMABLES</b>		
Zeolithe cartridge for « Horizon P5 »	R41 10 060	N/A
Aeration cover	R41 10 122	N/A
Outlet cannula filter	R41 10 156	N/A
<b>SPARE PARTS / PIECES DETACHEES</b>		
Casing P5	R41 10 120	N/A
Aeration	R41 10 121	N/A
USB cover	R41 10 125	N/A
Connector cover	R41 10 126	N/A
Envelope base	R41 10 130	N/A
Main internal structure	R41 10 131	N/A
High internal structure	R41 10 132	N/A
Support	R41 10 133	N/A
DC fixing	R41 10 134	N/A
Tubing	R41 10 135	N/A
Engine support	R41 10 136	N/A
Connector	R41 10 139	N/A
Inlet box	R41 10 140	N/A
Inlet cover	R41 10 142	N/A
Inlet filter	R41 10 144	N/A
Compressor THOMAS - 2110Z	R41 10 145	N/A
Manifold intake&exhaust	R41 10 150	N/A
Main manifold	R41 10 250	N/A
Accumulator	R41 10 153	N/A
Cannula out	R41 10 155	N/A
Compressor outlet pipe	R41 10 179	N/A
Cartridge inlet pipe	R41 10 181	N/A
Short cartridge outlet hose	R41 10 183	N/A
Long cartridge outlet hose	R41 10 184	N/A
Accumulator manifold hose	R41 10 185	N/A
Sensor inlet pipe	R41 10 186	N/A
Sensor outlet hose	R41 10 187	N/A
Screen keyboard	R41 10 400	N/A
Fan Sanyo Denki 9GA0412P6G001 modified	R41 10 500	N/A
Power outlet DC - HDTSCALJACK01	R41 10 501	N/A
Motherboard - HDTSCALAUORA02	R41 10 502	N/A
Screen card - HDTSCALECRAN01	R41 10 503	N/A
Connector motherboard-screen card	R41 10 504	N/A

## How to Contact Us



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MADE IN FRANCE



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