



Model: **RespiAid** P2














PORTABLE OXYGEN CONCENTRATOR
TAŞINABİLİR OKSİJEN KONSANTRATÖRÜ
CONCENTRATEUR D'OXYGÈNE PORTABLE
CONCENTRADOR PORTÁTIL DE OXÍGENO
CONCENTRATORE DI OSSIGENO PORTATILE
CONCENTRADOR DE OXIGÊNIO PORTÁTIL









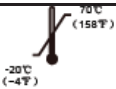


EN **Instruction Manual**

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Symbol	Meaning
WARNING	A warning indicates that the personal safety of the patient may be involved. Disregarding a warning could result in significant injury.
CAUTION	A caution indicates that a precaution or service procedure must be followed. Disregarding a caution could lead to a minor injury or damage to equipment.
	See User Manual for Instructions.
	AC Power
	DC Power
	U.S. Federal Regulation Restricts this Device to Sale by Order of Physician. May also be applicable in other Countries
	No Smoking
	Keep away from open flames
	Keep Dry
	Use No Oil or Grease
	Do Not Disassemble (contact your equipment provider for servicing by authorized personnel)
	Do Not Dispose of In Unsorted Municipal Waste
	Type BF Applied Part
	Class II (Double Insulated)
	Complies With Applicable EU Directives ; Including Medical Device Directive

	See Instructions for Use
	Manufacturer
	Authorised representative in the European Community
IP22	Protection against vertically falling water drops
	Date of manufacture
	Serial Number
Symbol	Meaning
	This side up
	Fragile
	Storage Humidity (Non-condensing)
	Storage Temperature
	MR unsafe
	The manufacturer of this POC has determined this device conforms to all applicable FAA requirements for POC carriage and use on board aircraft.

I .USE INTENTION ,CONTRAINDICATIONS AND GENERAL PRECAUTION

Use Intention

Intended use: The Plusmed RespiAid P2 Oxygen Concentrator is used on a prescriptive basis by patients requiring supplemental oxygen .It supplies a high concentration of oxygen to the patients .

It supplies a high concentration of oxygen and is used with a nasal cannula to channel oxygen from the concentrator to the patient. The Plusmed RespiAid P2 is small, portable and may be used in home, institution and various mobile environments.

WARNING

A backup oxygen source is recommended for power outages or mechanical problems. Please provide your device with a backup system type recommended by the business consultant.

CAUTION

This device restricted to sale by or on the order of a physician in many countries. May also be applicable in your country.

CAUTION

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

WARNING

This device is not intended to be life-sustaining or life-supporting. This device is not intended for newborn and infant use.



CAUTION

The expected life is depending on the environment of usage and the maintenance. The bad condition will short the life time of the concentrator.

Service Item

Expected Life

Plusmed RespiAid P2 Oxygen System	5 Years
Molecular Sieve Beds	1 Years
Batteries	500 full charge/discharge cycles



WARNING

The operator should read and understand this entire manual before using the device.

Contraindications

CAUTION

This device is not intended to be life sustaining or life supporting.

CAUTION

Patients who use this device may require additional monitoring or attention, and these patients cannot hear or see an alert or communicate discomfort. If the patient has any symptoms, consult a physician immediately.

CAUTION

In certain circumstances, oxygen therapy can be hazardous. Please seek medical advice before using this device.

CAUTION

The Plusmed RespiAid P2 is not designed or specified to be used in conjunction with a humidifier, nebulizer or connected with any other equipment. Do not modify the Plusmed RespiAid P2 Concentrator. Any modifications performed on the equipment may impair performance or damage equipment and will void your warranty.

General Precaution



WARNING

Oxygen supports combustion. Oxygen should not be used while smoking or smoking in the same room ,or in the presence of an open flame.



WARNING

Do not submerge the Plusmed RespiAid P2 or any of the

accessories in liquid.

Do not expose to water or precipitation.

Do not operate in exposed rain.

This could lead to electrical shock and/or damage.

CAUTION

Do not use oil or grease on the concentrator or its components as these substances, when combined with oxygen, can greatly increase the potential for a fire hazard and personal injury.

CAUTION

Never leave the Plusmed RespiAid P2 in an environment which can reach high temperatures or high humidity, such as an unoccupied car in high temperature environments or bathroom with high humidity. This could damage the device.



WARNING

Geriatric or any other patient unable to communicate discomfort, or hear or see the alarms while using this device, may require additional monitoring

General Precaution---Continued



WARNING

If you feel discomfort or are experiencing a medical emergency while undergoing oxygen therapy, seek medical assistance immediately to avoid harm



WARNING

The oxygen delivery settings of the oxygen concentrator should be periodically reassessed for the effectiveness of the therapy



WARNING

Set the device at the prescribed level and do not increase or decrease your flow rate from the prescribed level until you first consult with your physician or healthcare professional



WARNING

Only use this device as prescribed.

The use of oxygen therapy can be hazardous in some circumstances, so consult your health care practitioner before using Plusmed RespiAid P2



WARNING

To ensure that you receive the correct therapeutic amount of oxygen delivery according to your medical condition, the Plusmed RespiAid P2 must be used:

- Only after one or more settings have been individually determined or prescribed for you at your specific activity levels
- only use the parts and accessories that are provided by oxygen concentrator manufacturer Plusmed .

**WARNING**

The settings of the Plusmed RespiAid P2 might not correspond with continuous flow oxygen

**WARNING**

The settings of other models or brands of oxygen therapy equipment do not correspond with the settings of the Plusmed RespiAid P2

**WARNING**

There is a risk of fire associated with oxygen equipment and therapy. Do not use near sparks or open flames

General Precaution---Continued



WARNING

Use only water-based lotions or salves that are oxygen compatible during setup or use during oxygen therapy. To avoid the risk of fire and burns, never use petroleum or oil-based lotions or salves.



WARNING

Smoking during oxygen therapy is dangerous and is likely to result in serious injury or death of the patient and others from fire.



WARNING

To ensure receiving the therapeutic amount of oxygen delivery according to your medical condition Plusmed RespiAid P2 must

- be used only after one or more settings have been individually determined or prescribed for you at your specific activity levels.
- be used with the specific combination of parts and accessories that are in line with the specification of the oxygen conserver manufacturer and that were used while your settings were determined.



WARNING

Do not lubricate replaceable fittings, connections, tubing, or other accessories of the oxygen conserver to avoid the risk of fire and burns.



WARNING

Use only spare parts recommended by the manufacturer to ensure proper function and to avoid the risk of fire and burns.



WARNING

Wind or strong draughts can adversely affect accurate delivery of oxygen therapy.

EXAMPLE 1 Using this equipment beside an open window or in front of a fan can affect the accuracy of delivery of

oxygen.

EXAMPLE 2 Using this equipment in the back seat of an open convertible car can affect the accuracy of delivery of oxygen.

General Precaution---Continued



WARNING

If you notice any of the following, STOP use immediately and contact your equipment provider :

- unexplained changes in the performance of this device
- unusual or harsh sounds
- dropped or mishandled device or the power supply
- water spilled into the enclosure
- broken enclosure



WARNING

Oxygen is a combustion-supporting gas, a fire will start easier and spread quickly.

Do not leave the nasal cannula on bed coverings or chair cushions if the oxygen concentrator is turned on, but not in use; Turn the oxygen concentrator off when not in use



WARNING

To ensure proper function and to avoid the risk of fire and burns:

- Use only with Plusmed RespiAid P2 AC power supply
- Use only with Plusmed RespiAid P2 batteries
- Use only approved Plusmed RespiAid P2 accessories



WARNING

Remove the battery from the device if Plusmed RespiAid P2 will not be used for a long period of time



WARNING

Device operation exceed the voltage, breath rate, temperature, humidity and/or altitude values specified may decrease oxygen concentration levels

**WARNING**

Do not modify this system or equipment in any way .

Modifications could result in hazards to the user

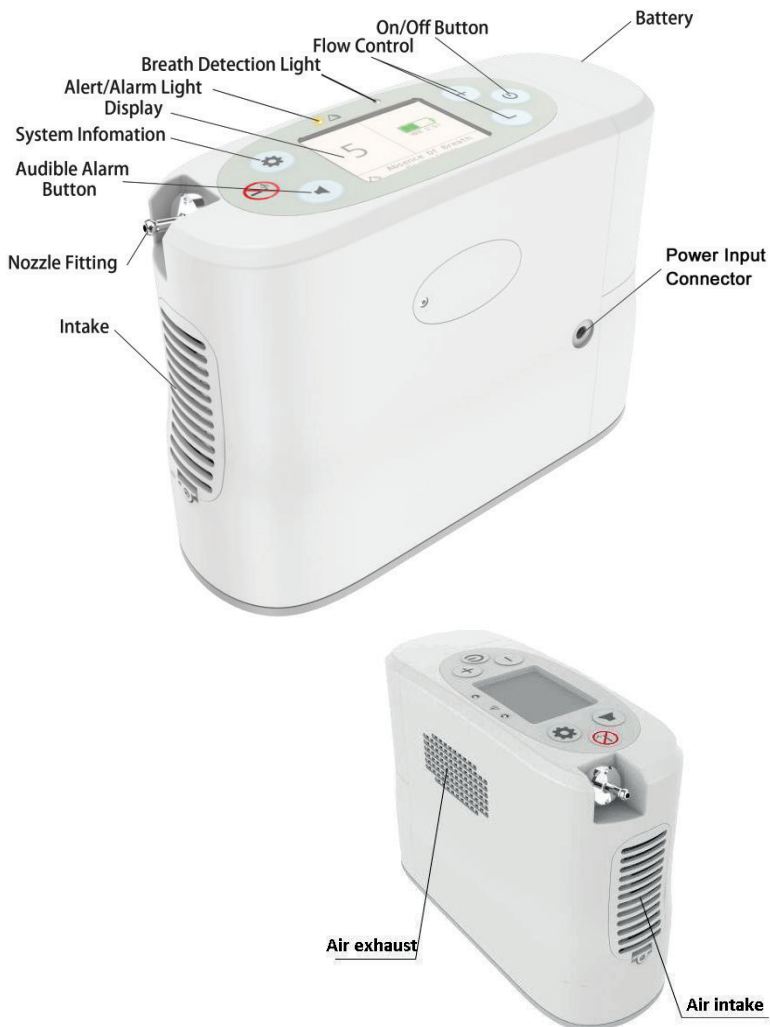
**WARNING**

Change in altitude may affect to actual oxygen supplied to you .Do consult your physician before travelling to a place with altitude changes.

Note: Additional warnings, cautions, and notes are located throughout the manual.

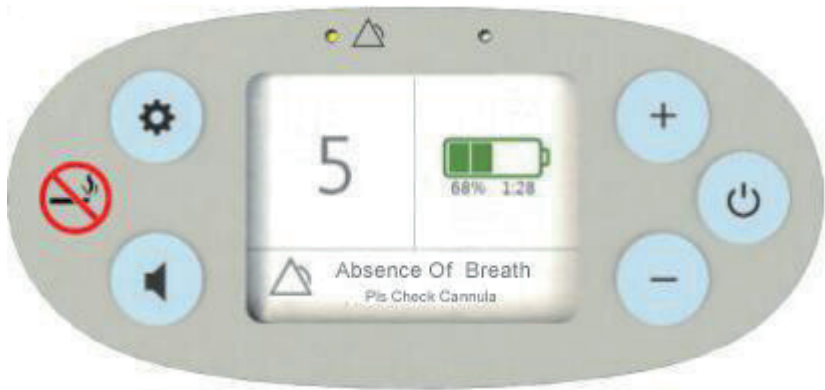
II. DESCRIPTION OF THE PLUSMED RESPIAID P2 OXYGEN CONCENTRATOR





Important Parts of the Plusmed RespiAid P2





User Interface Instruction and Symbols used on Plusmed RespiAid P2

User control:

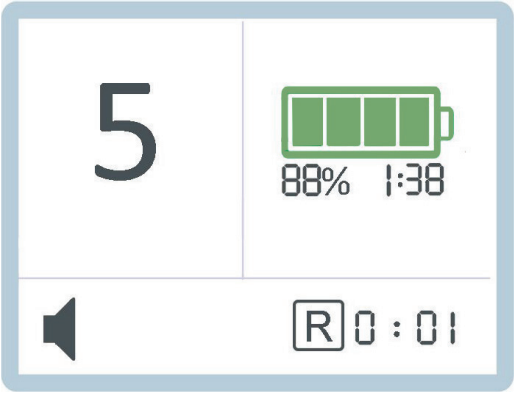


Symbol	Item	Description
	ON / OFF Button	Press once to turn “ON”; Press and hold for one second to turn “OFF”
	Audio Alarm Button	Pressing the button will toggle the Plusmed RespiAid P2’s audible alert on and off. The display’s mode indication area will show 2 different icons on mute & audible mode: on audible mode-----  On mute mode-----  and turn on yellow light, and display message when

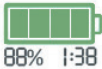



		<p>the alert is enable.</p> <p>Press this button to mute or unmute alarms .</p>
	Flow Setting Control Buttons	<p>Select the setting by pressing the – or + buttons ,swift from 1 to 5 different flow setting</p>
	Device Information	<p>Press this button to display the information of device.</p> <p>The information includes battery temperature,battery status,molecular temperature,molecular runtime, device model,device temperature,device runtime , firmware version, hardware version.</p>

Home Screen




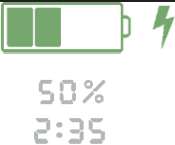




Home screen will show the icon as:



The icons mean:

Icon	Description
5	Flow Setting(from 1 to 5)
	Battery charge level: <ul style="list-style-type: none">•Battery percentage•Battery remaining time to use
	Device runtime (H:Min) (single time)
	Alert mute
	Alert audible

Additionally, screen will also display the following icons:

ICON	DESCRIPTION
	Powered by AC /DC only
	<ol style="list-style-type: none"> 1. Powered by battery only ,without AC & DC charge 2. Battery level and remaining time to use 3. Device ON
	<ol style="list-style-type: none"> 1. battery installed and with AC or DC charge 2. Battery level percentage and estimated time to fully charge the battery 3. Device ON
	<ol style="list-style-type: none"> 1. battery installed and with AC or DC charge 2. Battery level percentage and estimated time to fully charge the battery 3. Device OFF
	<p>Alarm Silence</p> <p>the device has detected an active alarm under mute mode</p>
	the device has detected an active alarm under unmute mode
	<p>Runtime of concentrator since started for single time</p> <p>(2H 35minutes)</p>
	More than one alert are rolling and will display.

Audible Mode:

the device has detected an active alarm under unmute mode



Mute Mode:

Alarm Silence

the device has detected an active alarm under mute mode



Alerts

Adapter plug / unplug:

System automatic switch power supply and adapter icon appears/disappears with audio.

Battery plug / unplug

System automatic switch power supply and battery icon appears/disappears with audio.

Alarm audio selection:

Global off/on (Audio Alarm Button)

Alarm audio pulse duration:

150ms On, 150ms Off , Repeat 2 times

Alarm audio pulse group interval:

14.7s (until Alarm returns to normal)

Alarm details

Reference the table below

Alerts

Alarm item	Alarm condition	System process	Display of screen
Battery Exhausted	Battery cycle > 500 Or health < 50%	Alarm only	Battery Exhausted
Replace SieveBed	SieveBed expired Or SieveBed chip error	Alarm only	Replace SieveBed Pls contact provider
Low Input Voltage	Adapter input < 17.0v	Switch battery supply until adapter input >18	LowInput Voltage Pls Check Adapter
Absence Of Breath	No breath detected continuously > 15S	Alarm only	Absence of Breath Pls Check cannula
Oxygen concentration<87	Concentration < 87% continuously > 300S	Alarm only	Low O2:< 87% Pls contact provider
Low Battery	5% ≤ RSOC ≤ 20% Without adapter	Alarm only	Low Battery Pls charge now
Oxygen concentration <50	Concentration < 50% continuously > 300S	shut down after 30s	Low O2:< 50% Pls contact provider
Breath Sensor Fail	Breath Sensor failed	shut down after 30s	Breath Sensor Fail Pls contact provider
Oxygen Sensor Fail	Oxygen Sensor failed	shut down after 30s	Oxygen Sensor Fail Pls contact provider
Gas Delivery Fail	No delivery detected After iniecton	shut down after 30s	Gas Delivery Fail Pls contact provider
Gas Obstruction	Pipe Or nasal blocked	shut down after 30s	Gas Obstruction Pls contact provider
Tank Pressure Fail	Tank pressure failed	shut down after 30s	Tank Pressure Fail Pls Check cannula
SieveBed Fail	SieveBed failure or invalid	shut down after 10s	SieveBed Fail Pls contact provider
Compressor Fail	Compressor failed	shut down after 10s	Compressor Fail Pls Contact Provider

Alerts -- Continued

Alarm item	Alarm condition	System process	Display of screen
Valve Check Fail	Valve switch failed	shut down after 10s	Valve Check Fail Pls Contact Provider
Cooling Fan Fail	Cooling fan failed	shut down after 10s	Cooling Fan Fail Pls Contact Provider
Battery Depleted	RSOC \leq 5% Without adapter	shut down after 10s	Battery Depleted Replace battery or connect to adapter
System Cold	System temperature $< 0^{\circ}\text{C}$	shut down after 10s	System Cold Pls Shut down, Move to warmer place
Battery Cold	Battery temperature $< 0^{\circ}\text{C}$	shut down after 10s	Battery Cold Pls Shut down, Move to warmer place
System Hot	System temperature $> 60^{\circ}\text{C}$	shut down after 10s	System Hot ; Pls Shut down, Move to cooler place
Battery Hot	Battery temperature $> 65^{\circ}\text{C}$	shut down after 10s	Battery Hot; Pls Shut down ,
Gas Supply Fail	Flow or concentration below normal after injection	shut down after 10s	Gas Supply Fail Pls Contact Provider
Sys Startup Fail	Concentration $< 87\%$ continuously $> 15\text{S}$ after system startup	shut down after 10s	Sys Startup Fail Pls Contact Provider
Power Supply Fail	System voltage $< 10.5\text{v}$	shut down after 10s	Power Supply Fail Pls Contact Provider

Power Supply

Standard Lithium Ion Battery # BA-P200

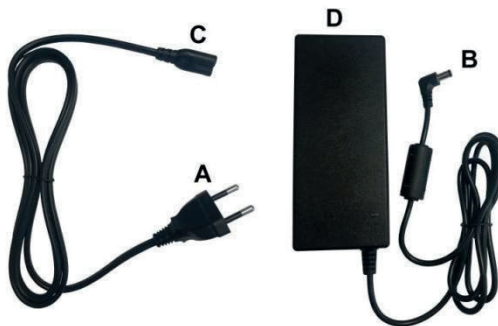
The Plusmed RespiAid P2 will be powered by standard lithium ion battery. When full charged, the battery can serve for up to 4 hours of operation. Recharge the battery by AC or DC power when installed in the P2. Recharging time is not more than 4 hours.



AC Power Supply # EM11012E

The concentrator AC supply (EM11012E) is used to power the Plusmed RespiAid P2 Oxygen Concentrator from an AC power source. when used with AC power sources, the power supply automatically adapts to input voltages from 100V to 240V(50-60HZ) permitting use with most power sources throughout the world.

Connect A plug to nearest AC power outlet→connect C plug to D port →connect B plug to Plusmed RespiAid P2



**WARNING**

Do not use power supplies or power cable other than the specified above.

Do not use power supplies /adapters or accessories other than those specified above.

The use of non-specified accessories may create a safety hazard and/or impair equipment performance.

Accessories

Nasal Cannula

The Plusmed RespiAid P2 Oxygen Concentrator must use a single lumen nasal cannula to provide oxygen to the patient.

**WARNING**

One single lumen nasal cannula should not be used by two or more persons.

DO NOT use cannula length exceeding 25ft (7,6m)

CAUTION

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

CAUTION

When using a long cannula, the flow setting may be increased.

CAUTION

When using a long cannula, the flow setting may be increased.

CAUTION

Disposable usage for the cannula.

CAUTION

Choose the CE marked nasal cannula (e.g. Runmai NOC-DAW0721)

Carry bag # CB-P200

Plusmed RespiAid P2 carry bag allows you to go out for daily activities with the Plusmed RespiAid P2 concentrator. The bag is convenient to the patient.



Accessories List

Item	Qty	NO#
Nasal Cannula	1 pc	NOC-DAW0721
Carry Bag	1 pc	CB-P200
AC power supply	1 pc	EM11012E
Intake Filter	5 pc	FI-P201
Battery	1 pc	BA-P200

III. OPERATING INSTRUCTIONS

General Operation

1. Find a well ventilated location to place the Plusmed RespiAid P2, make sure it's turned off.

Be Sure to keep the Intake and exhaust with clear access. Try to locate the Plusmed RespiAid P2 in a suitable place where any auditory alarms may be heard.



WARNING

Do not use Plusmed RespiAid P2 in the presence of flammable anesthetics, detergents or other chemical vapors.

CAUTION

Do not block the air intake or air exhaust when operating the equipment.

Blocked air circulation or proximity to the heat source can cause internal heat build-up, shut down, or damage to the concentrator.

CAUTION

The Plusmed RespiAid P2 Concentrator is designed for continuous use. It is useful to operate the product frequently for optimal sieve bed life.

CAUTION

Plusmed RespiAid P2 is shipped from factory with battery removed.

2. Ensure the particle filter is in place.



CAUTION

Do not operate the Plusmed RespiAid P2 without intake filter. Inhalation of system particles can damage the device.

3. Install the battery.

Flat slide the battery into place until the latch returns to the upper position along with a audible sound .

**4. Connect the AC power to Plusmed RespiAid P2 .**

The green LED on the power adapter will be on and the concentrator will generate a sound of beep.



5. **Join the nasal cannula to the nozzle fitting by end connector.**



Nozzle fitting is located on the top side of the Plusmed RespiAid P2 near the pre-filter.

Connect a nasal cannula to the nozzle fitting.

CAUTION

Ensure that the cannula is routed to prevent it from being pinched or kinked to avoid a disruption of oxygen flow.

CAUTION

Disposable usage for the cannula.

CAUTION

Do not place anything in the power supply port other than the supplied wall cord. Avoid the use of electrical extension cords with the Plusmed RespiAid P2.

CAUTION

Power supply is not waterproof.
Do not disassemble the power supply.

CAUTION

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



6. Switch on Plusmed RespiAid P2 by short pressing the ON/OFF Button.

Pressing the ON/OFF button for one second, a sound of beep and the indicator light's flashing will turn on.

"Welcome" will appear on the display while the concentrator starts up. The display will indicate the selected flow setting and power condition. A two-minute warm up time will initiate. During this period the oxygen concentration is building to but may not have reached specification. Under special conditions, longer warm up time may be necessary, such as an extremely cold temperature of storage or operation of Plusmed RespiAid P2

CAUTION	Oxygen concentration may not reach specification during the one-minute warm up time.
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CAUTION	Plusmed RespiAid P2 will enter mandatory Auto pulse mode after 30 seconds of starting up and lasts for 30 seconds. No inhalation will work during the 30 seconds.
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7. Change the Plusmed RespiAid P2 Concentrator setting to the flow rate prescribed by your physician or clinician.

Press the + or – setting buttons to adjust the Plusmed RespiAid P2 to the desired setting. The current setting can be viewed on the display from 1 to 5.

CAUTION

Make sure the power is in a well-ventilated place. During operation, the power supply may get hot. Make sure the power supply is cool before handling.

8. Wear the nasal cannula on your face and breathe through your nose.



The Plusmed RespiAid P2 will sense if you are breathing from it. If you are not yet breathing through the cannula, the Plusmed RespiAid P2 will begin to pulse automatically about once every 3 seconds. As soon as you begin breathing through the cannula, the device will begin delivering pulses based on your breathing. As your breathing rate changes, the Plusmed RespiAid P2 will sense these changes and adjust

the amount of oxygen at next inhale.



WARNING

If you feel uncomfortable or uncomfortable using the device, consult your doctor right now.

CAUTION

A Low O₂: < 87% alert will notify you if the oxygen level drops. If the alarm persists, contact your device provider.

CAUTION

The display could become darker if there is no operation of the device after 30 seconds. You can press any button to light up the display.

CAUTION

The Plusmed RespiAid P2 will alert with audible and visual signals (such as "Absence Of Breath ") when this mode is enabled and no breath has been detected for 15 seconds. At 15 seconds, the device will enter into auto pulse mode and once another breath is detected, the device will exit auto pulse mode and deliver normally on inspiration.

General

To remove power, disconnect the input cord from AC or DC power source (like AC wall outlet) and disconnect it from the Plusmed P2.

IV.TROUBLESHOOTING

The table below lists some common problems and actions you can take. If you can't resolve a problem, please contact your equipment provider.

Problem	Possible Cause	Recommended Solution
Device Won't Turn On	Battery is not installed correctly	Remove the battery and re-install it correctly.
	Battery is depleted.	Use the AC or DC power adapter to operate the device (with the battery inserted) to recharge the battery. If this does not resolve the problem, contact your equipment provider.
	the AC supply is poor contact.	Check power supply connection and verify green light on adapter is solid.
	the DC adapter is not connected properly	Check DC adapter connection
No Oxygen	The device is not turned on.	Turn on the concentrator.
	Cannula is kinked or obstructed.	Check cannula and its connection to the oxygen outlet port.
	Equipment failure.	Contact your equipment provider.
Oxygen Not At Full Concentration	The device is warming-up.	Wait 2 minutes for the device. If the problem is not solved, please contact your equipment provider.
	The sieve beds may require servicing.	Contact your equipment provider to change the sieve beds.
Alarm Occurs	Refer to Previous section-Alerts.	Refer to Previous section -Alerts.

V.MAINTENANCE AND CLEANING OF PLUSMED RESPIAID P2

Cleaning the Case

The outside case should be cleaned using a cloth dampened with a solution of mild detergent and water.

CAUTION

Do not allow liquids into any of the controls, the interior of the case, or the oxygen tubing connector. If this occurs, contact your equipment provider for assistance.



WARNING

Do not use alcohol, isopropyl alcohol, ethylene chloride or petroleum based cleaners on the cases or on the particle filters.

Cannula Replacement

The nasal cannula is designed for disposable usage. You can buy it from physician and/or equipment provider and/or cannula manufacturer's instructions.

CAUTION

Nasal cannula should be rated for 5 liters per minute to ensure proper patient usage and oxygen delivery.

Filter Cleaning and Replacement

Filters are designed to adequate air flow through the device at the front of the Plusmed RespiAid P2.

Pre Filter # FI-P200

This particle screen must be cleaned on a weekly basis to ensure adequate air flow through the device. Clean the pre filters with a mild liquid detergent and water; be sure that the filter is dried without water before reuse.

**CAUTION**

It may be necessary to clean the particle filters more often in dusty or bad environments/conditions.

Intake Filter # FI-P201

The intake filter is designed to ensure the clean air into the compressor.

1. screw off the screw on the bottom of pre-filter by a Philips screwdriver.
2. Lift the particle screen up by the bottom end then remove it.
3. take out of the intake filter from the intake chamber;
4. put a new intake filter into the chamber;
5. Install pre filters.



Pre and intake filters can be purchased from your equipment provider.

Battery Care and Maintenance

The Plusmed RespiAid P2 Lithium Ion Battery requires special care to ensure proper performance and long life. Use only PlusmedP2 batteries # BA-P200 with your concentrator.

CAUTION

Keep liquids away from batteries.

If batteries become wet, stop use immediately and dispose of battery properly.

Battery Replacement

1. Press down the latch, and flat slide the battery off



2.Insert the Plusmed RespiAid P2 battery by sliding battery into place until the latch returns to the upper position.



Effect of Temperature on Battery Performance

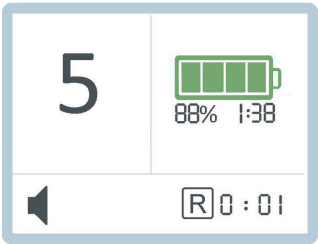
To extend the run-time of your battery, the device should be used in temperatures between 41° F(5°C) and 95° F(35°C) for extended periods of time. The number of cycles that the battery will last is highly dependent upon the temperature at which the battery is charged.

CAUTION

Plusmed suggests that the room temperature should not be exceeding 75°F (24°C) when batteries are charged.

Battery Time Remaining Clock

The Plusmed RespiAid P2 continuously displays battery time remaining. This displayed time is only an estimate and the actual time remaining may vary from this value.



CAUTION	Store battery in a cool, dry place. Store with a charge of 40-50%. Batteries should not be left dormant for more than 90 days at a time.
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CAUTION	If the device is not used in a long time, please remove the battery.
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Disposal of Equipment and Accessories

Follow your local governing ordinances for disposal and recycling of the Plusmed RespiAid P2 accessories. The battery contains lithium ion cells and should be recycled and must not be incinerated.



Maintenance Items Lists

Item	Model No.
Plusmed RespiAid P2 standard battery	BA-P200
Pre Filter	FI-P200
Intake Filter	FI-P201

For assistance, if there are some problems, contact your equipment provider, or manufacturer.

VI.SYSTEM SPECIFICATIONS

Concentrator Specification

Dimensions	L/W/H:8.70in.(22.1cm.)/3.35in.(8.5cm.)/6.30in.(16.0cm.)					
Weight	4.37 pounds 1.98Kg (with battery.)					
User Interface	2.8 inch large LCD color display screen					
Sound Level	49 dB (A) (on setting 2)					
Warm-Up time	2 minutes					
Oxygen Concentration	90% - 3% /+ 6% at all settings					
Flow Control Settings and Pulse Volumes	Settings					
		1	2	3	4	5
	Breath Rate	Pulse Volumes(ml)				
	10	21	42	63	84	100
	15	14	28	42	56	66.7
	20	10.5	21	31.5	42	50
	25	8.4	16.8	25.2	33.6	40
	30	7	14	21	28	33.3
	35	6	12	18	24	28.6
	40	5.3	10.5	15.8	21	25
	±15% at STPD*					
	+/-25% over the rated environmental range					
	*STPD is 101.3 kPa at an operating temperature of 20 °C, dry					

Breathing Frequency	10 to 40 BPM
Inspiratory Trigger Sensitivity	≤ 0.12 cm H ₂ O
Maximum Outlet Pressure	25 PSI
Use Mode	Continuous Use

Concentrator Specification--Continued

Power:	
AC Power supply	AC Input: 100 to 240VAC 50 to 60 Hz
Rechargeable Battery	Voltage: 14.4VDC Rated capacity:6.8Ah
Battery Duration	Up to 4 hours
Battery Charging Time	Not more than 4 hours
Environmental Ranges	Temperature: 41 to 104°F (5 to 40°C)
Intended for Operation	Humidity: 10% to 90%, non-condensing
	Altitude: 0 to 10,000 ft. (0 to 3048 meters,70kPa to 106 kPa)
Environmental Ranges	Temperature: -4 to 158°F (-20 to 70°C)
Intended for Shipping and Storage	Humidity: 5% to 90%, non-condensing
	Store in a dry environment
	Altitude: 0 to 10,000 ft (0 to 3048 meters,70kPa to 106 kPa)
Transportation	Keep Dry, Handle With Care

Classifications

Mode of Operation:	Continuous Duty
Type of Protection Against Electrical Shock:	Class II
Degree of Protection to Concentrator Components Against Electrical Shock:	Type BF Not intended for cardiac application
Degree of Protection to Concentrator Components Against Ingress of Water	IP22 - Not protected from dripping water. Protected against ingress of solid objects > 12.5 mm.

Standards Compliance

The device is designed to conform to the following standards:

- IEC 60601-1-2, 2014, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 60601 - 1: Medical Electrical Equipment - part 1: General Requirements for Basic safety & Essential Performance
- AAMI ES60601-1: Medical Electrical Equipment - Part 1: General Requirements for Basic safety and Essential Performance
- IEC 60601-1-8 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
- IEC 60601-1-11 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

- ISO 80601-2-67, Medical electrical equipment, Part 2-67: Particular requirements for basic safety and essential performance of oxygen conserving equipment
- ISO 80601-2-69, Medical electrical equipment, Part 2-69: Particular requirements for basic safety and essential performance of oxygen concentrator equipment
- ISO18562-1: 2017 Biocompatibility evaluation of breathing gas pathways in healthcare applications -- Part 1: Evaluation and testing within a risk management process
- ISO18562-2: 2017 Biocompatibility evaluation of breathing gas pathways in healthcare applications -- Part 2: Tests for emissions of particulate matter
- ISO18562-3: 2017 Biocompatibility evaluation of breathing gas pathways in healthcare applications -- Part 3: Tests for emissions of volatile organic compounds (VOCs)
- ISO 10993-1 Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
- AAMI/ANSI/ISO 10993-10:2010, Biological Evaluation of Medical Devices - Part 10: Tests for Skin Irritation
- AAMI/ANSI/ISO 10993-5:2009, biological Evaluation of Medical Devices - Part 5: Tests for in vitro Cytotoxicity

EMC Information

The device has been designed to meet EMC standards throughout its Service Life.


Guidance and Manufacturer's Declaration –Electromagnetic Immunity:

The Concentrator is intended for use in the electromagnetic environment specified below. The user of the Concentrator 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	±8 kV Contact ±15 kV Air	±8 kV Contact ±15 kV 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 Power Supply Lines ±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 Line to Line ±2 kV Line to Ground	±1 kV Line to Line ±2 kV Line to Ground	Mains power quality should be that of a typical home or hospital environment.
Voltage Dips, Short Interruptions and Voltage Variations on Power Supply Input Lines IEC 61000-4-11	<5% U_T (>95% Dip in U_T) for 0.5 Cycle at 45 degree increments 70% U_T (30% Dip in U_T) for 0.5 seconds <5% U_T (>95% Dip in U_T) for 5 Seconds	<5% U_T (>95% Dip in U_T) for 0.5 Cycle at 45 degree increments 70% U_T (30% Dip in U_T) for 0.5 seconds <5% U_T (>95% Dip in U_T) for 5 Seconds	Mains power quality should be that of a typical home or hospital environment. If the user of the Device required continued operation during power mains interruptions, it is recommended that the Device be powered from an uninterruptible power supply or battery.
Power Frequency	30 A/m	30 A/m	Power frequency magnetic fields should be at levels

(50/60Hz) Magnetic Field IEC 61000-4-8			characteristic of a typical location in a typical home or hospital environment.
Note: U_T is the A.C. mains voltage prior to application of the test level			

EMC Information-Continued

Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the Device, including cables, than the recommended 30 cm separation distance. Interference may occur in the vicinity of equipment marked with the  following symbol:
Radiated RF IEC 61000-4-3	6 Vrms Amateur Radio & ISM Bands between 150 kHz and 80 MHz	6 Vrms Amateur Radio & ISM Bands between 150 kHz and 80 MHz	
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m	

Guidance and Manufacturer's Declaration –Electromagnetic Emissions:

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

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF Emissions CISPR 11	Group 1	The Device uses RF energy only for its internal. Function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	The Device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage Fluctuations/Flicker Emissions IEC 61000-3-3	Complies	

VII.WARRANTY

Under our warranty conditions we assume the warranty for our Plusmed RespiAid P2 O2 Concentrator for perfect condition and function. The warranty term is 36 months and begins on the day of shipment. Please contact us by telephone or email for return of your defective equipment during the warranty term as well as smooth resolution of your problems. Well trained employees shall take up your concerns and support you in word and deed. Please make sure that your equipment is safe for transportation, if possible in its original packaging in order to avoid transport damages.

Excluded from the warranty are damages caused by improper usage, as well as to expendable parts and consumables, battery replacement .Sieve bed ,filters ,batterys in the equipment are expressly excluded from the 36 months warranty, except as provided below:

Description	Period
Plusmed RespiAid P2 Oxygen Concentrator	3 years
other accessories (battery ,carry bag,external battery charger,power suppliers,and power cord)	1 year
Sieve Bed	1 year
Disposables(Nasal Cannula,filters)	No Warranty

Further damage compensation claims of any kind, particularly owing to breach of obligations and unpermitted handling, as well as claims on repayment of expenses paid in vain, are not included in the warranty; the same shall apply to claims on repayments of consequential harm caused by a defect.

Any further claims are excluded in this warranty .The aforementioned limitations do not apply to claims on damages from harm to life, body or health or attributable to intent or gross negligence, or the product liability law.

This warranty does not cover damage or injury whether to Plusmed RespiAid P2 or to personal property or persons caused by accident, misuse, abuse, negligence, failure to

install in accordance with Plusmed Medical's installation instructions, failure to operate under conditions of normal use and in accordance with the terms of the operating manual and instructions, failure to maintain in accordance with the applicable service manuals, or alteration or any defects not related to materials or workmanship of Plusmed RespiAid P2. This warranty does not cover damage which may occur in shipment. This warranty does not apply to any product or individual part of a product that may have been repaired or altered by anyone other than Plusmed Medical or an authorized Plusmed Medical service center. This warranty does not apply to any product which is not purchased new.

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