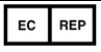
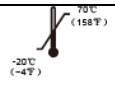
RHYTHM HEALTHCARE

ITEM# P2

P2 PORTABLE OXYGEN CONCENTRATOR

CONTENTS

Symbol	Meaning
WARNING	This warning label indicates that the personal safety of the patient may be at risk. Disregarding a warning could result in significant injury.
CAUTION	This caution label indicates a precaution or service procedure that must be followed. Disregarding a caution could lead to a minor injury or damage to equipment.
	See User Manual for details.
	AC Power
	DC Power
	U.S. Federal regulations restricts this device to be sold by prescription only. This restriction may also apply in other countries,
	Do not smoke while using this device.
	Keep this device away from open flames.
	Keep dry.
	Do not use oil or grease.
	Do not disassemble this unit. Contact your equipment provider for servicing by authorized personnel only.
	Follow local ordinances for proper disposal of this device. Do not dispose of in municipal waste.
	Applied Part - Type BF (BF applied parts are those that have conductive contact with patient, or medium or long-term contact with patient.)
	Complies with all applicable EU Directives; including the EU Medical Device Directive.

Symbol	Meaning
	Class II (Double Insulated)
	See instructions for use.
	Manufacturer
	Authorized representative in the European Community.
IP22	Device is protected against water spray <15 degrees from vertical.
	Date of manufacture
	Serial number
	This side up
	Fragile
	Storage humidity (Non-condensing)
	Storage temperature
	MR unsafe (should not enter MRI scanning rooms)
	Conforms to all applicable FAA requirements for POC storage and use onboard aircrafts.

Ⅰ. INTENDED USE, CONTRAINDICATIONS AND GENERAL PRECAUTIONS

Intended Use

The *P2 Oxygen Concentrator* is prescribed for patients requiring supplemental oxygen.

It supplies a high concentration of oxygen and is used with a nasal cannula to supply oxygen from the concentrator to the patient. The P2 is a small and portable device that can be used at home and can be taken with you while performing your daily activities.

WARNING	A backup oxygen source is recommended for power outages or mechanical problems. Be sure to have an available backup oxygen source that is recommended by your doctor or healthcare provider.
CAUTION	In most countries, this device must be purchased from a doctor or with a doctor's prescription.
CAUTION	It is the responsibility of the patient to arrange for an alternative oxygen supply when traveling. The manufacturer assumes no liability for persons who do not adhere to manufacturer recommendations.
WARNING	This device is not intended to be life-sustaining or life-supporting. This device is not intended for newborn babies or for infant use.
CAUTION	The expected lifespan of this device depends on proper usage and maintenance. Improper handling will shorten its lifespan.

Service Item	**Expected Life**
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 are unable to hear or see an alert from the device, or who are unable to communicate discomfort while wearing the device, will require additional monitoring to avoid injury or harm. If the patient experiences any new symptoms, seek medical attention immediately.
CAUTION	In certain circumstances, oxygen therapy can be hazardous. Please seek medical advice before using this device.
CAUTION	The P2 POC is not designed to be used in conjunction with a humidifier or nebulizer, nor is it designed to be connected to any other equipment. Do not modify the P2 POC. Any modification may impair performance or damage the unit. Modifications to the unit will void the warranty.

General Precautions

 **WARNING**	Oxygen supports combustion. To avoid risk of fire, oxygen therapy should never be used while smoking, while in the same room as someone who is smoking, or in the presence of an open flame.
 **WARNING**	Do not submerge the P2 POC or any of its accessories in liquid. Do not expose to water. Do not operate in the rain. Exposure to moisture can lead to electrical shock and/or damage.
CAUTION	Do not use oil or grease on the concentrator or any of its components as these substances, when combined with oxygen, can greatly increase the risk of fire and personal injury.
CAUTION	Never leave the P2 POC in an environment which can reach high temperatures or high humidity, such as an unoccupied car in high temperatures, or a bathroom with high humidity. This could damage the device.
 **WARNING**	Patients who are unable to communicate discomfort, or hear or see the alarms while using this device will require additional monitoring.
 **WARNING**	If you feel any discomfort or experience a medical emergency while using this product, stop using the product and seek medical attention immediately.

General Precautions---Continued

WARNING Reassess the oxygen delivery settings of this POC periodically to ensure the effectiveness of the oxygen therapy.

WARNING Set the device at the oxygen level prescribed by your doctor or healthcare provider. Do not increase or decrease the flow rate without first consulting with your doctor or healthcare provider.

Use this device only as prescribed.

WARNING The use of oxygen therapy can be hazardous in some circumstances. Always consult with your doctor or healthcare provider before using the P2 POC.

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

WARNING

- Must be used only after one or more settings have been individually determined or prescribed for you at your specific activity levels.
- Must use only the parts and accessories that were provided by the manufacturer, and those that were used while your personalized settings were configured.

WARNING The settings of the P2 might not correspond with a continuous flow of oxygen.

WARNING The settings of other models or brands of oxygen therapy equipment do not correspond with the settings of the P2 POC.

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

WARNING Use only water-based lotions or skin creams during device setup and while using oxygen therapy. To avoid the risk of fire and burns, never use petroleum or oil-based lotions or salves.

WARNING Smoking while using oxygen therapy is dangerous and may result in fire which can cause serious injury or death of the patient and others.

General Precautions---Continued

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

WARNING Use only replacement parts recommended by the manufacturer to ensure proper function and to avoid the risk of fire and burns,

WARNING Winds or strong drafts can adversely affect accurate delivery of oxygen therapy. Examples include:

- Using this equipment beside an open window or in front of a fan.
- Using this equipment in the back seat of an open convertible car.

WARNING If any of the following occurs, 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 power supply
- water spilled onto the device
- broken device enclosure

WARNING Oxygen supports combustion. A fire may start easily and spread quickly when the device is used improperly.

WARNING Do not leave the nasal cannula on bed coverings or chair cushions when the oxygen concentrator is turned on but not in use; Always turn off the oxygen concentrator when not in use.

WARNING To ensure proper function and avoid the risk of fire and injury:

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

WARNING Remove the battery from the device if it will not be used for an extended period of time.

General Precautions---Continued

WARNING	Operating the device while exceeding the specified values for voltage, breath rate, temperature, humidity and/or altitude 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	Changes in altitude may affect the amount of oxygen supplied by the device. Consult your doctor before travelling to a place with altitude changes.

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

Ⅱ. DESCRIPTION OF THE P2 OXYGEN CONCENTRATOR

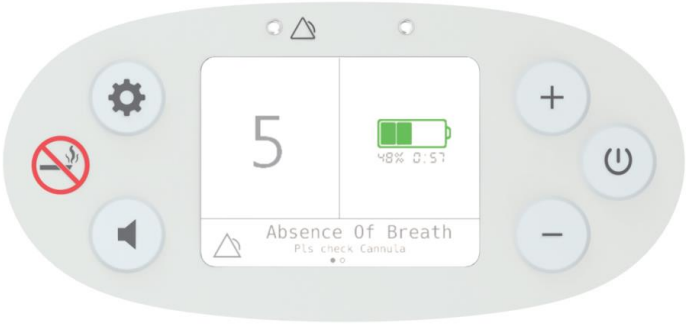
Components of the P2 Oxygen Concentrator

Battery Duration Chart

Setting	Duration
1	**5h 00min**
2	4h 00min
3	3h 00min
4	2h 14min
5	1h 50min

User Interface Instruction and Symbols used on P2

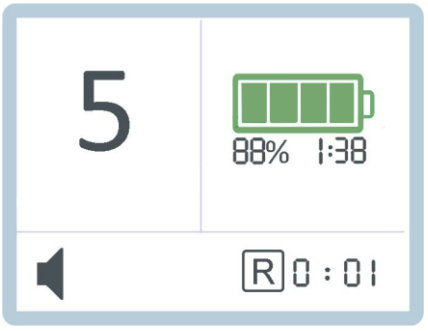
User Display Panel:



Symbol	Item	Description
	ON / OFF Button	Press once to turn **ON** Press and hold for one second to turn **OFF**
	Audio Alarm Button	Press once to toggle between **audible** and **silent** mode. The panel will display the appropriate icon to indicate which mode is enabled: Audible mode-- Silent mode-- When audible mode is enabled, a yellow light will turn on, and a message will display on the screen.
+ –	**Flow Setting Control Buttons**	Increase or decrease the oxygen flow setting by pressing **+** or **–**. Flow settings range from 1 to 5.
	Device Information	Press to display information about the device, including: battery temperature, battery status, molecular sieve temperature, molecular sieve runtime, device model, device temperature, device runtime, firmware version, hardware version.

Home Screen

The home screen will display the icons as in the example below:

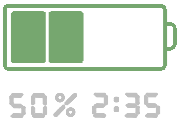
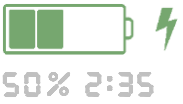
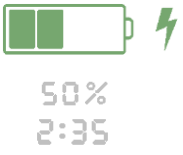


The icons on the display panel are described as follows:

Icon	Description
5	Current flow setting (range is from 1 to 5)
88% 1:38	Battery charge level: ● Battery percentage remaining ● Battery time remaining (in hours:minutes)
R 0:01	Device runtime since powered on (in hours:minutes)
	Alerts are silenced
	Alerts are audible

Additionally, the screen will also display the following icons:

Description of the P2 Oxygen Concentrator

Icon	Description
	Powered by AC
	1. Device is powered by battery without AC charger connected. 2. Battery level percentage and time remaining (in hours:minutes). 3. Device is ON.
	1. Battery is charging. 2. Battery level percentage and estimated time to fully charge the battery. 3. Device is ON.
	1. Battery is charging. 2. Battery level percentage and estimated time to fully charge the battery. 3. Device is OFF.
	The device has detected an active alarm while in silent mode.
	The device has detected an active alarm while in audible mode.
	Runtime of device (in hours:minutes) since it was powered on (sample shows 2 hours 35 minutes).
	Multiple alerts have been detected. Display will scroll to display all alerts.

Alert in Audible Mode:

The display below shows that the device has detected an active alarm while in Audible Mode (example below shows "Absence of Breath"):

Alert in Silent Mode:

The display below shows that the device has detected an active alarm while in Silent Mode (example below shows "Absence of Breath"):

Alerts

Adapter plug/unplug:

An adapter icon displays when adapter is plugged in and disappears when unplugged. An audible alarm (if enabled) will also be heard.

Battery plug/unplug

A battery icon displays when battery is connected and disappears when disconnected. An audible alarm (if enabled) will also be heard.

Alarm audio selection:

An alert will indicate when unit is turned on or off.

Alarm audio pulse duration:

An audible alert (if enabled) will pulse between 150ms on, then 150ms off, and repeat 2 times.

Alarm audio pulse group interval:

14.7s (until Alarm returns to normal)

Alarm details

Reference the table below for additional alarm details:

Alerts Table

Alarm item	Alarm condition	System process	Screen Display
Battery Exhausted	Battery cycles > 500 or battery health < 50%	Alarm only	Battery is exhausted. Replace battery
Replace Sieve Bed	Sieve bed expired or Sieve bed chip error	Alarm only	Replace Sieve Bed Please contact provider
Low Input Voltage	Adapter input < 17.0v	Auto-switch to battery until the adapter input > 18v	Low Input Voltage Please check adapter
Absence of Breath	No breath detected continuously for more than 15 seconds	Alarm only	Absence of Breath Please check cannula
Oxygen concentration <87%	Concentration < 87% continuously for more than 300 seconds	Alarm only	Low O_2:< 87% Please contact provider
Low Battery	5%≦RSOC≦20% without adapter	Alarm only	Low Battery Please charge
Oxygen concentration <50%	Concentration < 50% continuously for more than 300 seconds	Auto-shut down after 30 seconds	Low O_2:< 50% Please contact provider
Breath Sensor Fail	Breath Sensor failed	Auto-shut down after 30 seconds	Breath Sensor failed Please contact provider

Description of the P2 Oxygen Concentrator

Alarm item	Alarm condition	System process	Screen Display
Oxygen Sensor Fail	Oxygen Sensor failed	Auto-shut down after 30 seconds	Oxygen Sensor failed Please contact provider
Gas Delivery Fail	No delivery detected after injection	Auto-shut down after 30 seconds	Gas Delivery failed Please contact provider
Gas Obstruction	Pipe or nasal blocked	Auto-shut down after 30 seconds	Gas Obstruction Please contact provider
Tank Pressure Fail	Tank pressure failed	Auto-shut down after 30 seconds	Tank Pressure failed Please check cannula
Sieve Bed Fail	Sieve Bed failure or is invalid	Auto-shut down after 10 seconds	Sieve Bed failed Please contact provider
Compressor Fail	Compressor failed	Auto-shut down after 10 seconds	Compressor failed Please contact provider
Valve Check Fail	Valve switch failed	Auto-shut down after 10 seconds	Valve Check failed Please contact provider
Cooling Fan Fail	Cooling fan failed	Auto-shut down after 10 seconds	Cooling Fan failed Please contact provider
Battery Depleted	RSOC ≦ 5% without adapter	Auto-shut down after 10 seconds	Battery depleted Replace battery or connect to power adapter

Description of the P2 Oxygen Concentrator

Alarm item	Alarm condition	System process	Screen Display
System Cold	System temperature < 0℃ or 32°F	Auto-shut down after 10 seconds	System too cold for Operation Shut down, move to warmer place
Battery Cold	Battery temperature < 0℃ or 32°F	Auto-shut down after 10 seconds	Battery too cold for operation Shut down, move to warmer place
System Hot	System temperature > 60℃ or 140°F	Auto-shut down after 10 seconds	System too hot for operation Shut down, move to cooler place
Battery Hot	Battery temperature > 65℃or 149°F	Auto-shut down after 10 seconds	Battery too hot for operation Shut down, use only adapter until battery has cooled,
Gas Supply Fail	Flow or concentration below normal after injection	Auto-shut down after 10 seconds	Gas Supply failed Please contact provider
Sys Startup Fail	Concentration < 87% continuously for more than 15 seconds after system startup	Auto-shut down after 10 seconds	System Startup failed Please contact provider
Power Supply Fail	System voltage < 10.5v	Auto-shut down after 10 seconds	Power Supply failed Please contact provider

Power Supply

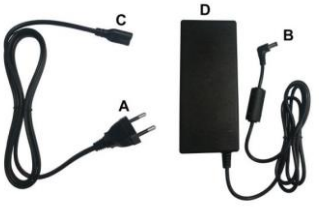
Standard Lithium Ion Battery - part # BA-P200

The P2 is powered by a standard lithium ion battery. When fully charged, the battery can last for up to 4 hours of operation. The battery is recharged by AC power when it's installed in the P2 and the power supply is connected. Recharging time is not more than 4 hours.

AC Power Supply - part # EM11012E

The AC power supply (EM11012E) is used to power the 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), allowing it to be used with most power sources throughout the world.

Connect plug (A) into the nearest AC power outlet. Then connect port (C) into port (D) of the power supply. Finally, connect plug (B) into the P2 device:



WARNING	Do not use power supplies or power cables other than those specified above. Do not use power supplies, power 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 P2 Oxygen Concentrator uses a single lumen nasal cannula to provide oxygen to the patient.

WARNING	Nasal cannulas should not be used by more than one person.DO NOT use a cannula that has a length exceeding 25ft (7,6m).

CAUTION	Increasing the cannula length may reduce the noise during oxygen delivery.

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

CAUTION	The nasal cannula is designed for disposable use.

CAUTION	Select only CE-marked replacement nasal cannulas (e.g. Runmai NOC-DAW0721)

Carry Bag - part # CB-P200

The P2 carry bag makes it convenient to go out for your daily activities:

Accessories List

Item	Qty	Part #
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. Keep the P2 in a well-ventilated area

Be sure to keep the intake and exhaust areas of the device clear of obstructions to allow for proper air flow. Find a location for the P2 such that auditory alarms can be heard. Turn off device when not in use.

WARNING	Do not use 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 close proximity to a heat source can cause internal heat build-up. This can cause the device to shut down, or damage to the concentrator.

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

CAUTION	P2 is shipped from factory with battery removed.

2. Ensure the particle filter is in place.

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

3. Install the battery

Slide the battery into place until the latch returns to the upper position. There will be an audible sound when the battery is in position.

4. Connect AC power to P2

The green LED on the power adapter will turn on and there will be an audible sound when power is connected.

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

CAUTION	The 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.

5. **Connect the nasal cannula to the nozzle fitting**

The nozzle fitting is located on the top of the P2 near the pre-filter.

Connect a nasal cannula to the nozzle fitting on the device

.

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

CAUTION	The cannula is designed for disposable use

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

Press the ON/OFF button to turn on the concentrator. The device will beep, and the indicator light will flash.

“Welcome” will appear on the display while the concentrator starts up. The display will indicate the selected flow setting and the power condition. A two-minute warm-up time will initiate. During this period, the oxygen concentration level is building to the specified value but may not have yet reached specification. Under special conditions, a longer warm-up time may be necessary, such as in extremely cold temperatures where the unit was stored or is being operated.

CAUTION	Oxygen concentration may not reach specification during the two-minute warm up time.

CAUTION	30 seconds after startup, the P2 will enter auto-pulse mode. During this 30 seconds inhalation will not work.

7. Set to the flow rate prescribed by your physician or clinician

Press the **+** or **–** buttons to adjust the P2 to the desired flow rate. The current setting can be viewed on the display and ranges from 1 to 5.

CAUTION	Make sure the power supply is located in a well-ventilated area. 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 P2 will sense if you are breathing from it. If you are not yet breathing through the cannula, the 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 P2 will sense these changes and adjust the amount of oxygen at the next inhale.

WARNING	If you feel any discomfort when using the device, consult your doctor immediately

CAUTION	A "**Low O2： < 87%**" alert will display on the screen if the oxygen level drops below recommended levels. If the alarm persists, contact your device provider.

CAUTION	The display will dim if there is no operation for 30 seconds. You can press any button to light up the display.

CAUTION	The P2 will notify you with audible alert (if enabled) and a display showing "**Absence Of Breath**" if no breath has been detected for 15 seconds. After 15 seconds, the device will enter auto-pulse mode until breath is detected. Once breath is detected, the device will resume normal delivery of oxygen.

General Information

To disconnect power, unplug the power cord from the wall outlet and disconnect it from the 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 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 not connected.	Check power supply connection and verify the green light on the power adapter is turned on.
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 to warm up. If the problem is not resolved, please contact your equipment provider.
	The sieve beds may require servicing.	Contact your equipment provider to change the sieve beds.
Alarm Occurs	Various causes	Refer to **Alerts Section** for full descriptions

Ⅴ. MAINTENANCE AND CLEANING OF 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 case or particle filters.

Cannula Replacement

The nasal cannula is designed for disposable use. Replacements can be purchased from your doctor and/or concentrator equipment providers.

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

Filter Cleaning and Replacement

Filters are designed to provide adequate air flow through the device and are located at the front of the P2.

Pre-Filter - part # FI-P200

This pre-filter 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 completely dry before reinstalling.

CAUTION	It may be necessary to clean the pre- filters more frequently in dusty environments or conditions.

Intake Filter - Item # P2FC-1

In normal conditions of use, the air filter must be replaced after approximately 6 months of daily use. When conditions are subject to higher levels of dust or dirt, we recommend periodically checking the air filter and if the filter shows a grey or brown color, replace it.

The intake filter is designed to ensure clean air enters the compressor. To replace the intake filter:

1. Unscrew the bottom of the pre-filter with a Philips screwdriver.
2. Lift up the pre-filter from the bottom end, then remove it.
3. Remove the intake filter from the intake chamber.
4. Insert a new intake filter into the chamber;
5. Reinstall the pre filter.

Replacement pre-filters and intake filters can be purchased from your equipment provider.

Battery Care and Maintenance

The P2 Lithium Ion Battery requires special care to ensure proper performance and long life. Use only P2 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 slide the battery out.

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

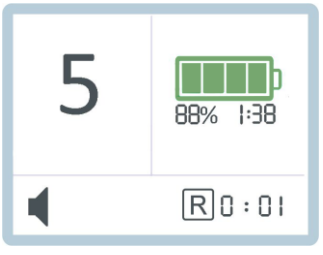
Effect of Temperature on Battery Performance

To extend the life of your battery, the device should be used in temperatures between 41˚F (5°C) and 95˚F (35°C). In addition, the number of battery cycles is highly dependent upon the temperature at which the battery is charged.

CAUTION	We suggest that the room temperature should not exceed 75°F (24°C) when batteries are being charged.

Battery Time Remaining Clock

The 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.

CAUTION	If the device will not used for an extended period of time, remove the battery from the device.

Disposal of Equipment and Accessories

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

Maintenance Items List

Item	**Model No.**
P2 standard battery	BA-P200
Pre-filter	FI-P200
Intake Filter	FI-P201

For assistance using the device or if there are problems with the device, contact your equipment provider, or manufacturer.

Ⅵ. SYSTEM SPECIFICATIONS

Concentrator Specifications

Dimensions	L/W/H: 8.70in (22.1cm) / 3.35in (8.5cm) / 6.30in (16.0cm)					
Weight	4.37 pounds / 1.98Kg (with battery installed)					
User Interface	2.8 inch 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_2O					
Maximum Outlet Pressure	25 PSI					
Use Mode	Continuous Use					

Concentrator Specification--Continued

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

- ISO 18562-1:2017 - Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 1: Evaluation and testing within a risk management process

- ISO 18562-2:2017 - Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 2: Tests for emissions of particulate matter

- ISO 18562-3:2017 - 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 requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or battery.
Power Frequency (50/60Hz) Magnetic Field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical home or hospital environment.
Note: U_T is the AC mains voltage prior to application of the test level.			

EMC Information---Continued

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
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 not be used near any part of the device, including cables. Recommended distance is 30 cm (or 1').
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	Interference may occur in the vicinity of equipment marked with the following symbol: 
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

The P2 Oxygen Concentrator warranty covers the repair or replacement of the unit. The warranty term is 36 months from the date of shipment. Please contact us by telephone or email to return defective equipment under warranty and to resolve any problems. Our trained technicians will help you with any questions or problems with your POC.

Please make sure that your returned equipment is packaged safely for transportation, if possible, in its original packaging in order to avoid damages during shipping.

Excluded from the warranty are damages caused by improper usage. Also excluded are replacements of batteries, disposable parts and consumables. Sieve bed, filters, batteries are expressly excluded from the 36 months warranty, except as provided below:

Description	Period
P2 Oxygen Concentrator	3 years
Accessories (battery, carry bag, external battery charger, power supply, 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 to P2 or injury to personal property or persons caused by accident, misuse, abuse, negligence, or failure to install in accordance with the 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 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 an authorized service center. This warranty does not apply to any product which is not purchased as new.

RHYTHM HEALTHCARE

EC REP

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