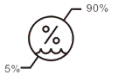
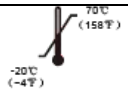
RHYTHM HEALTHCARE

ITEM# P2-E6

P2-E6 PORTABLE OXYGEN CONCENTRATOR

TABLE OF CONTENTS

Symbol	Description
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
	No Smoking
	Keep away from open flames
	Keep Dry
	Do not use 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)
	See Instructions for Use
	Manufacturer
IP22	Protection against falling water drops
	Date of manufacture

Symbol	Description
	Serial Number
	This side up
	Fragile
	Storage Humidity (Non-condensing)
	Storage Temperature
	MR unsafe

Intended use:

The P2-E6 Oxygen Concentrator is prescribed for patients requiring supplemental oxygen. It supplies a high concentration of oxygen and is used with a nasal cannula to deliver oxygen from the concentrator to the patient. The P2-E6 is a small and portable device that may be used at the home and can be taken with you while performing your daily activities.

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

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! Must have back up oxygen supply when traveling.
It is the responsibility of the patient to make back-up arrangements for alternative oxygen supply when traveling. We assume no liability for persons that do not adhere to manufacturer recommendations.

Service Item	**Expected Life**
P2-E6 Oxygen Concentrator:	5 Years
Molecular Sieve Beds:	1 Year
Batteries:	500 full charge/discharge cycles

CAUTION
The expected life is depending on the environment of usage and the maintenance. Bad conditions will shorten the lifetime of the concentrator.

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.

• 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.

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

• The P2-E6 is not designed or specified to be used in conjunction with a humidifier, nebulizer or connected with any other equipment. Do not modify the P2-E6 Concentrator. Any modifications performed on the equipment may impair performance or damage equipment and will void your 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-E6 or any of the accessories in liquid.
Do not expose to water or precipitation.
Do not operate in the rain/wet weather conditions.
Exposure to moisture can 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 P2-E6 in high temperatures/high humidity such as in a car in high heat or a bathroom with high humidity. This can damage the device.

WARNING ⚠
Geriatric patients or any other patients unable to communicate discomfort,
hear or see alarms while using this device, may require additional monitoring.

General Precautions - continued

WARNING
If you feel any discomfort or are experiencing a medical emergency while using this product, seek medical assistance immediately to avoid harm.

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

WARNING
Set the device at the prescribed level and do not increase or decrease your flow rate without first consulting with your doctor or healthcare professional.

WARNING
Use this device only as prescribed.
The use of oxygen therapy can be hazardous in some circumstances. Always consult your health care practitioner before using the POC.

WARNING
To ensure that you receive the correct therapeutic amount of oxygen delivery according to your medical condition, the P2-E6:

• Must be used only after one or more settings have been individually determined or prescribed for you at your specific levels.
• Must only use the parts and accessories that are provided by the manufacturer.

WARNING
The settings of the P2-E6 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-E6

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

General Precautions - continued

WARNING
Use only water-based lotions or skin creams that are oxygen compatible during setup or using 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 may result in fire which can cause serious injury or death of the patient and others.

WARNING
To ensure that you receive the correct therapeutic amount of oxygen delivery according to your medical condition, the P2-E6:
• 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
Do not lubricate replaceable fittings, connections, tubing, or other accessories of the oxygen concentrator 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 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.

General Precautions - continued

WARNING
If any of the following occurs, STOP using immediately and contact your equipment provider:
• Unexplained changes in the performance of this device
• Unusual or harsh sounds
• Dropping or mishandling the device or the power supply
• Water spilled into the enclosure
• Broken enclosure

WARNING
Oxygen is a combustion supporting gas, a fire may start easily if device is used improperly.
Do not leave the nasal cannula on bed coverings or chair cushions if the oxygen concentrator is turned on, but not in use. Always 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 P2-E6 AC and DC power supplys
• Use only with P2-E6 batteries
• Use only approved P2-E6 accessories

WARNING
Remove the battery from the device if the P2-E6 will not be used for an extended period of time.

WARNING
Device operation exceeding 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.

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

WARNING
Changes in altitude may affect the amount of oxygen supplied
by the device. Consult your physician before travelling to a place with altitude changes.

Parts Diagram

Setting	Battery Life
1	5.4h
2	4.8h
3	3.3h
4	2.5h
5	2.1h
6	1.7h

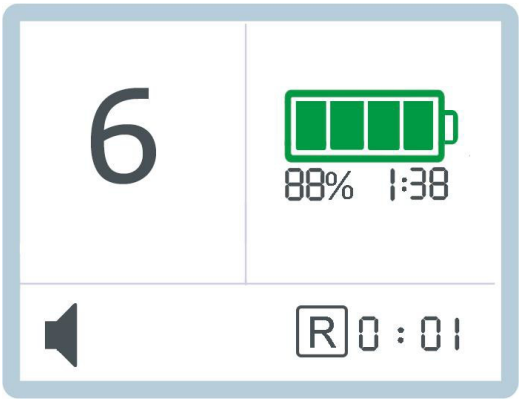
User Interface Buttons and Display Symbols

Display Panel:

Symbol	Description	Instructions
	ON I 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. Press this button to mute or unmute alarms.
+ —	**Flow Setting Control Buttons**	Increase or decrease the oxygen flow setting by pressing + or –. Flow settings range from 1 to 6.
	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.

User Interface Buttons and Display Symbols

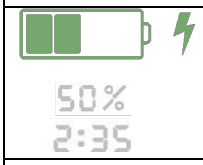
Home Screen
Home screen will show the icon as:



Icon	Description
	Current flow setting (range is 1 to 6)
	Battery charge level: • Battery percentage remaining • Battery time remaining (in hours:minutes)
	Device runtime since powered on (in hours:minutes)
	Alerts are silenced
	Alerts are audible

Additionally, screen will also display the following icons (see next page):

User Interface Buttons and Display Symbols

ICON	DESCRIPTION
	Powered by AC or DC only
	1. Powered by battery only (not plugged in and charging) 2. Battery level percentage and time remaining (in hours:minutes). 3. Device 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.

User Interface Buttons and Display Symbols

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, 150ms off, repeat 2 times.

Alarm audio pulse group interval:
15.5s (until Alarm returns to normal)

Alarm details
Reference the table below for additional alarm details.

Alerts-continued

Alarm item	Alarm condition	System process	Display of screen
Battery Exhausted	Battery cycle > 500 Or health < 50%	Alarm only	Battery Exhausted
Replace Sieve Bed	Sieve Bed expired or Sieve Bed chip error	Alarm only	Replace Sieve Bed Pls Contact provider
Low Input Voltage	Adapter input < 17 0v	Switch battery supply until adapter input >18	Low Input 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 injection	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
Sieve Bed Fail	Sieve Bed failure or invalid	shut down after 10s	Sieve Bed Fail Pls Contact provider
Compressor Fail	Compressor failed	shut down after 10s	Compressor Fail Pls Contact Provider

Alerts - continued

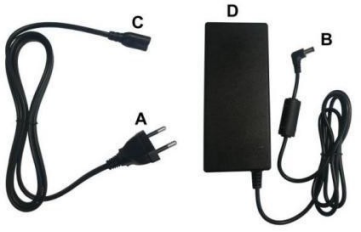
Alarm item	Alarm condition	System process	Display of screen
Valve Check Fail	Valve switch failed	shut down after 10s	Valve Check Fail: Pls Contact Provider
Cooling Fan Fail	Cooling fan failed	shut down after 10s	Cooling Fan Fail: Pls Contact Provider
Battery Depleted	RSOC: 5% Without adapter	shut down after 10s	Battery Depleted: Replace battery or connect to adapter
System Cold	System temperature < 32°F/0°C	shut down after 10s	System Cold: Pls Shut down, Move to warmer place
Battery Cold	Battery temperature < 32°F/0°C	shut down after 10s	Battery Cold: Pls Shut down, Move to warmer place
System Hot	System temperature > 140°F/60°C	shut down after 10s	System Hot: Pls Shut down, Move to cooler place
Battery Hot	Battery temperature > 149°F/65°C	shut down after 10s	Battery Hot: Pls Shut down, Only use adapter
Gas Supply Fail	Flow or concentration below normal after injection	shut down after 10s	Gas Supply Fail: Pls Contact Provider
System Startup Fail	Concentration less than 87% continuously > 15S after system startup	shut down after 10s	System Startup Fail: Pls Contact Provider
Power Supply Fail	System voltage < 10 5v	shut down after 10s	Power Supply Fail: Pls Contact Provider

Power Supply

Standard Lithium-Ion Battery # BA-P201
The P2-E6 is powered by a standard lithium-ion battery. When fully charged, the battery can last for up to 5.4 hours of operation. Recharge the battery with the AC or DC adapter. Recharging time is not more than 4 hours.

AC Power Supply # E M 11012E
The AC power supply (EM11012E) is used to power the P2-E6 Oxygen Concentrator from an AC power source. When using the AC charger, 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.

1. Connect A plug to nearest AC power outlet
2. Connect C to D port
3. Connect B to the P2-E6



DC Power Supply # E D 1010C
The DC power supply (ED1010C) is designed for use with the P2-E6 Oxygen Concentrator. The DC power input cable connects directly to the car cigarette lighter or auxiliary DC power supply. The input DC power is 11-16Vdc, and fuse rating is 15A/125V, output is 19V 6.3A.

WARNING ⚠
Do not use power supplies or power cables 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 P2-E6 Oxygen Concentrator must use 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
When using a long cannula, the flow setting may need to be increased.
Increasing the cannula length may reduce the perceived noise during oxygen bolus delivery.

CAUTION
The nasal cannula is designed for disposable use.

CAUTION
Select only CE approved nasal cannula (e.g. Runmai NOC-DAW0721)

Carry bag # CB-P200
The P2-E6 carry bag allows you to go out for daily activities.

Accessories List

Item	Qty	NO#
Nasal Cannula	1 pc	NOC-DAW0721
Carry Bag	1 pc	CB-P200
AC power supply	1 pc	EM11012E
DC power supply	1 pc	ED1010C
Intake Filter	5 pc	FI-P201
Battery	1 pc	BA-P201

General Operation

1. **Find a well-ventilated location to place the P2-E6, make sure it's turned off.**
   Be sure the Intake and exhaust has clear access. Put the P2-E6 in a suitable place where any alarms can be heard.

   WARNING
   Do not use P2-E6 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 P2-E6 Concentrator is designed for continuous use. It is useful to operate the product frequently for optimal sieve bed life.

   CAUTION
   P2-E6 is shipped from factory with battery removed

   Ensure the particle filter is in place.

   CAUTION
   Do not operate the P2-E6 without intake filter. Inhalation of system particles can damage the device.

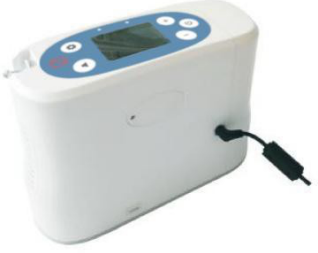
General Operation-continued

2. 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.

3. Connect the AC or DC power to P2-E6.

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 wall cord. Avoid the use of electrical extension cords with the P2-E6.

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.

General Operation-continued

4. Connect the nasal cannula to the nozzle fitting.

Nozzle fitting is located on the top side of the P2-E6 near the pre-filter.
Connect a nasal cannula to the nozzle fitting on the device. (pictured)

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.

5. Switch on P2-E6 with a short press of 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 power condition. A two-minute warm up time will initiate. During this period the oxygen concentration 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-E6 will enter auto-pulse mode. During these 30 seconds, inhalation will not work.

General Operation-continued

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

Press the + or - setting buttons to adjust the P2-E6 to the desired flow rate. The current setting can be viewed on the display from 1 to 6.

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.

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

The P2-E6 will sense if you are breathing from it. If you are not yet breathing through the cannula, the P2-E6 will begin to pulse automatically about 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-E6 will sense these changes and adjust the amount of oxygen at your next inhale.

WARNING
If you feel discomfort 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 provider.

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

CAUTION
The P2-E6 will notify you with an 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.

Troubleshooting

The table below lists some common problems and solutions. If you can't resolve a problem, please contact your 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.
	AC supply is not connected properly	Check AC power connection and verify solid green light on adapter.
	DC Cable is not connected properly	Check DC power connection and at cigarette lighter or auxiliary DC power source.
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 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 provider to change the sieve beds.
Alarm Occurs	Refer to previous section-Alerts	Refer to Previous section – Alerts.

Cleaning the Case

The outside case should be cleaned using a damp cloth 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 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 disposable. You can buy replacements from your physician or provider and follow the 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 for adequate air flow through the device at the front of the P2-E6.

Pre Filter # FI-P202
The particle screen/pre filter must be cleaned weekly to ensure adequate air flow. Clean the pre filters with a mild liquid detergent and water. Ensure that the filter is completely dry before use.

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

Intake Filter # FI-P201

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

1. Lift the particle screen up by the bottom end then remove it.
2. Take out of the intake filter from the intake chamber.
3. Put a new intake filter into the chamber.
4. Install pre filters.

Pre and intake filters can be purchased from your provider.

Battery Care and Maintenance

The P2-E6 Lithium-Ion Battery requires special care to ensure proper performance and long life. Use only P2-E6 batteries # BA-P201 with your concentrator.

CAUTION

Keep liquids away from batteries. If batteries get wet, stop using immediately and dispose of battery properly.

Battery Replacement

1. Press down on the latch and slide the battery out.

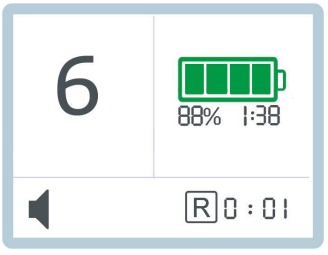
2. Insert the P2-E6 battery by sliding battery into place until the latch returns to the upper position and it clicks into place.

Battery Care and Maintenance-Continued

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). The number of cycles that the battery will last 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-E6 continuously displays the 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 is not used for an extended period of time, please remove the battery from the device.

Disposal of Equipment and Accessories

Follow your local governing ordinances for disposal and recycling of the P2-E6 accessories. The battery contains lithium-ion cells and should be recycled and must not be incinerated.

P2-E6 Replacement Items

Item	Model No.
P2-E6 standard battery	BA-P201
Pre Filter	FI-P202
Intake Filter	FI-P201

If you need assistance, contact your provider.

P2-E6 Portable Oxygen Concentrator Specifications

Dimensions	L/W/H:8.70" x 3.35" x 6.30" 22.1cm x 8.5cm x 16.0cm						
Weight	4.37 pounds 1.98Kg (with battery)						
User Interface	2.8" LCD color display screen						
Sound Level	49 dB (A) (on setting 2)						
Time from Turning on the Concentrator to Reach Stated Performance	2 minutes						
Oxygen Concentration	90% - 3% /+ 6% at all settings						
Flow Control Settings and Pulse Volumes	Settings						
		1	2	3	4	5	6
	Breath Rate	Pulse Volumes(ml)					
	10	21	42	63	84	100	120
	15	14	28	42	56	66.7	80
	20	10.5	21	31.5	42	50	60
	25	8.4	16.8	25.2	33.6	40	48
	30	7	14	21	28	33.3	40
	35	6	12	18	24	28.6	34
	40	5.3	10.5	15.8	21	25	30
	±15% at STPD* +/-25% over the rated environmental range *STPD is 101.3 kPa at an operating temperature of 68 °F, dry						
Breathing Frequency	10 to 40 BPM						
Inspiratory Trigger Sensitivity	≤ 0.12 cm H2O						
Time Delay from Onset of Inspiration	<10ms						
Delivery pressure at the device outlet	Maximum 25 PSI						
Use Mode	Continuous Use						
Available Mode	Triggered pulse delivery mode						

Concentrator Specifications-Continued

Power: AC Power supply DC Power supply Rechargeable Battery	 AC Input: 100 to 240VAC 50 to 60 Hz DC Input: 11-16VDC DC Output: 19V⎓ 6.3A Voltage: 14.4VDC Rated capacity:6.7Ah
Battery Duration	Up to 5.4 hours at setting 1 Up to 1.5 hours at setting 6
Battery Charging Time	Not more than 4 hours
Environmental Ranges Intended for Operation	Temperature: 41˚F - 104˚F (5˚C - 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˚F - 158˚F (-20˚C -70˚C) Humidity: 5% to 90%, No 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: Requirements for basic safety and essential performance of oxygen conserving equipment
- ISO 80601-2-69, Medical electrical equipment, Part 2-69: 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	Main power supply 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	Main power supply 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	Main power supply should be that of a typical home or hospital environment. If the user of the Device required continued operation during power outages, 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 A.C. mains voltage prior to application of the test level			

EMC Information-Continued

Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 6 Vrms Amateur Radio & ISM Bands between 150 kHz and 80 MHz 10 V/m 80 MHz to 2.7 GHz	3 Vrms 150 kHz to 80 MHz 6 Vrms Amateur Radio & ISM Bands between 150 kHz and 80 MHz 10 V/m	Portable and mobile RF communications equipment should not be used closer (to any part of the device, including cables) than the recommended 11.8"/30 cm separation distance. Interference may occur in the vicinity of equipment marked with the following symbol:

Guidance and Manufacturer's Declaration - Electromagnetic Emissions:

The P2-E6 is intended for use in the electromagnetic environment specified below. The user of the P2-E6 should ensure it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF Emissions CISPR 11	Group 1	The P2-E6 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 P2-E6 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	

Warranty

The P2-E6 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 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-E6 Oxygen Concentrator	3 years
Accessories (battery, carry bag, external battery charger, power supplies, 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 P2-E6 or to personal property or persons caused by accident, misuse, abuse, negligence, failure to install in accordance with 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 P2-E6. 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 Medical or an authorized Medical service center. This warranty does not apply to any product which is not purchased new.

RHYTHM
HEALTHCARE

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