USER MANUAL

EASYPULSE TOC

TOTAL OXYGEN CONCENTRATOR

Model: PM4400 Series

SAVE THESE INSTRUCTIONS

℞ ONLY

Federal (USA) law restricts this device to sale by or on the order of a physician.

Read this manual before operating the device,
save this manual for future reference.

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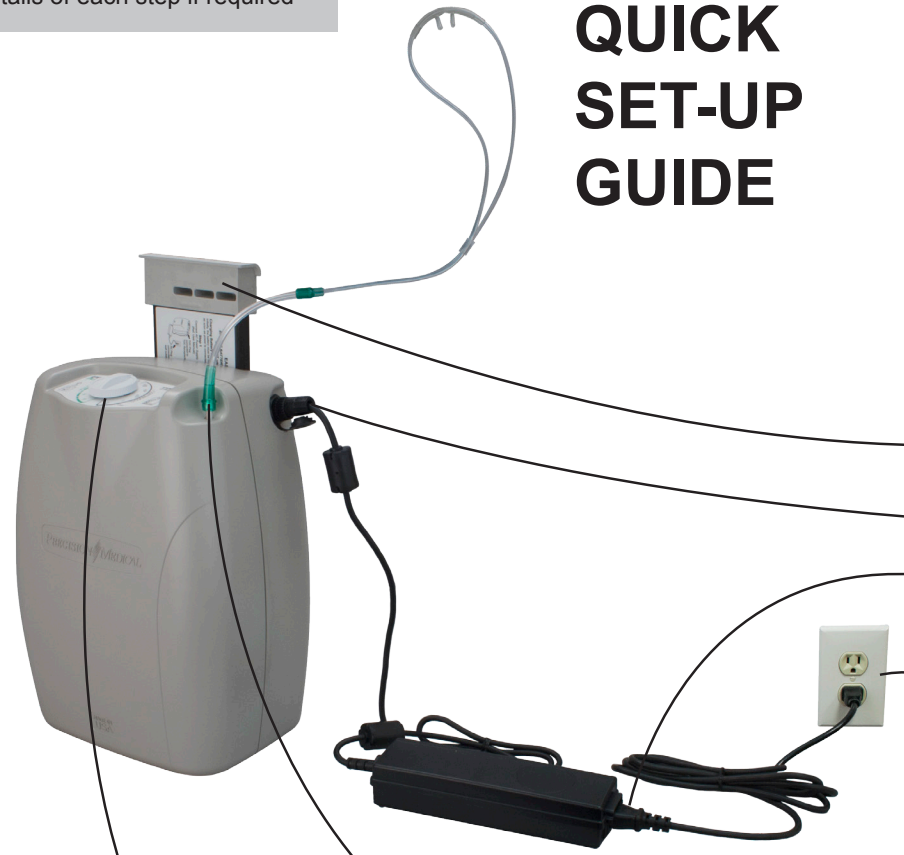
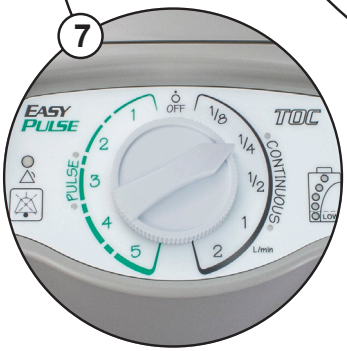
LET'S GET STARTED
We have referenced page numbers for details of each step if required

QUICK SET-UP GUIDE





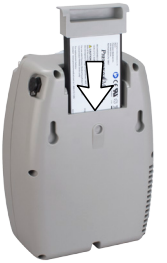
Turn Control Knob to Prescribed Setting.
(Ref. pg 12)

Connect Nasal Cannula to Oxygen Outlet Fitting.
(Ref. pg 10)

1

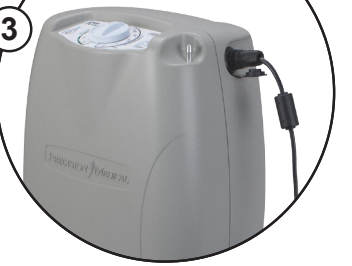
Place your EasyPulse TOC in the area of intended use near a wall outlet.

2



Insert Battery into back of EasyPulse TOC. (Ref. pg 7)

3

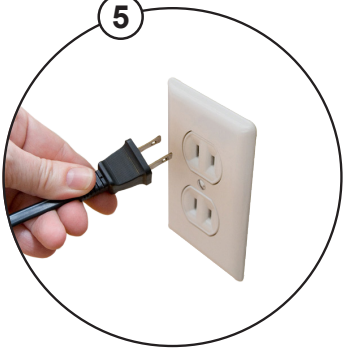


Connect AC Power Supply to EasyPulse TOC Receptacle. (Ref. pg 7)

4

Connect AC Power Cord into AC Power Supply.

5



Connect AC Power Cord to Wall Outlet.

DON'T STOP HERE
Please read entire manual

CONTENTS

RECEIVING/INSPECTION

Remove the Precision Medical, Inc. PM4400 Series EasyPulse Total Oxygen Concentrator (TOC) from the packaging and inspect for damage. Inspect for damage prior to each use of the TOC. If there is any damage, DO NOT USE and contact your Provider.

INDICATIONS FOR USE

The Precision Medical Inc. TOC is indicated on a prescription basis for the administration of supplemental oxygen. It supplies a high concentration of oxygen and is used with a nasal cannula to channel oxygen from the TOC to the patient. The TOC may be used in home, institution, vehicle and various mobile environments.

CONTRAINDICATIONS

- TOC is not to be used for life/support sustainment.
- Patients unable to communicate discomfort while using this TOC may require additional monitoring.
- Patients with hearing and/or sight impairment(s) may need assistance with using TOC.
- Under certain circumstances, the use of non-prescribed oxygen therapy can be hazardous. This TOC should only be used when prescribed by a physician.
- TOC is not intended for newborn and infant use.
- Patients who breathe from their mouths or through an oxygen mask should not use the TOC in Pulse Mode.

READ ALL INSTRUCTIONS BEFORE USING

This manual is provided for your safety and to prevent damage to the TOC. If you do not understand this manual, DO NOT USE the TOC and contact your Provider.

EXPLANATION OF ABBREVIATIONS

L/min	Liter Per Minute
mL/min	Milliliter Per Minute
B/min	Breaths per Minute
LED	Light Emitting Diode
TOC	Total Oxygen Concentrator

PRODUCT DESCRIPTION

EasyPulse TOC System

The **EasyPulse TOC** comes with the following items.

Item	Description/Function	
1	EasyPulse TOC	TOC with 1 to 5 Pulse Settings and 1/8 to 2 L/min Continuous Flow Settings **(P/N PM4400)**
2	Accessory Bag	Bag to carry all cords, extra batteries and other accessories **(P/N 508301)**
3	AC Power Supply	AC Power Supply with cord for attachment to TOC **(P/N 508188)**
4	AC Power Cord	Cord for attachment from AC Power Supply to wall outlet **(P/N 508291)**
5	DC Power Cord	DC Power Cord for charging and powering TOC from vehicle's DC electrical outlet **(P/N 508189)**
6	Battery	Rechargeable Lithium-Ion Battery Pack which supplies power for portability of TOC **(P/N 508016)**
7	User Manual	TOC System User Manual **(P/N 508217)**
8	Transportable Cart	Cart for transporting TOC **(P/N 508260)**

Additional Accessories available (not shown)

Description	Part Number
*Fire Stop Check Valve	507706
*2" Tubing Connector	507707
DC Power Cord Fuse	508320

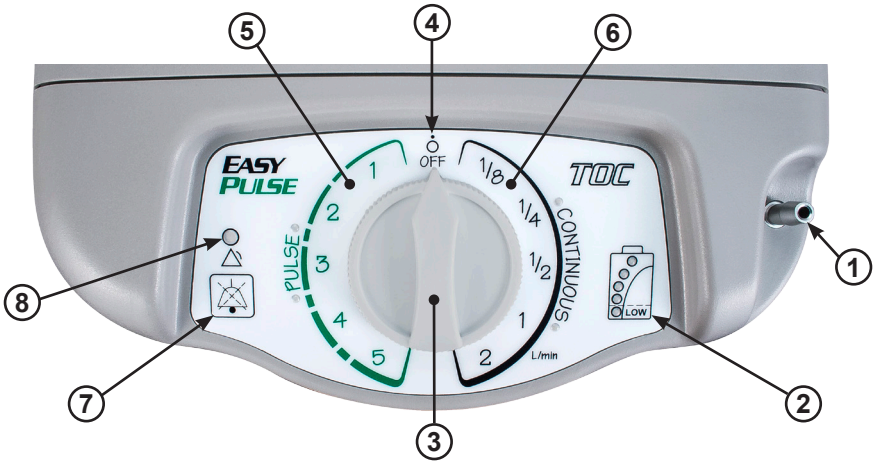
Description	Part Number
Connector, Humidifier	508333
Humidifier Bottle	PM500
Desktop Charger	508306

*ISO 80601-2-69, the standard for oxygen concentrators, highly recommends that the cannula delivering gas from the oxygen concentrator to the patient should include a Fire Stop Check Valve to stop the flow of gas towards the patient in the event the cannula becomes ignited. The Fire Stop Check Valve should be located as close to the patient as is reasonably practicable.

EasyPulse TOC Overview

Item	Description/Function	
1	Oxygen Outlet Fitting	Oxygen Outlet Connector for Patient Cannula
2	Control Panel	See EasyPulse TOC User Interface for detailed descriptions
3	TOC Handle	Integrated Handle for lifting TOC
4	TOC Receptacle with Dust Cap	TOC Receptacle for AC Power Supply and DC Power Cord attachments (see Charging (AC and DC Options) for detailed description)
5	Air Outlet Vent	Ventilation Exit - keep clear of obstructions
6	Cart Attachment Points	See TOC Attachment to Cart for detailed description
7	Battery	Rechargeable Lithium-Ion Battery with integrated handle to remove and install Battery
8	Air Inlet Filter	Air Inlet Filter - traps dust from entering TOC
9	Hour Meter/Fault Code Indicator	Behind Air Inlet Filter (No. 8) on left side.

EasyPulse TOC User Interface



Item	Description/Function		
1	Oxygen Outlet Fitting	Oxygen Outlet Connector for Patient Cannula	
2	Battery Indicator	Shows state of battery charge (See Battery ID for details)	
3	Control Knob	Starting at OFF position (12 o'clock): • Rotate counter-clockwise for 1 to 5 Pulse Mode Settings • Rotate clockwise for 1/8 to 2 L/min Continuous Mode Settings Note: The Control Knob does not rotate 360°. Rotating the Control Knob beyond the stops will damage the TOC. • **THERE IS NO FLOW BETWEEN SETTINGS.**	
4	OFF	TOC set to OFF position (no oxygen delivery)	
5	Pulse Mode Settings	Settings 1 to 5 Pulse Mode - LED lights are on when selection is made and blink to indicate a pulse delivery	
6	Continuous Mode Settings	Settings 1/8 to 2 Continuous Flow Settings - LED lights are on to indicate Continuous Flow in L/min	
7	Alarm Silence	Push button to silence audible alarm	
8	Alarm Light	Red Light - "Warning" Yellow Light - "Caution"	See Audible and Visual Alarm Signals for detailed description

EASYPULSE TOC BATTERY

ENSURE BATTERY IS FULLY CHARGED PRIOR TO FIRST USE.

NOTE: *See initial charging instructions on back of Battery.*

(DO NOT use the DC Power Cord for initial charge.)

Lithium Ion Battery Guidelines	
Proper Use: *In order to prolong life of the battery, it is best to charge the battery frequently rather than waiting until the battery is fully discharged.*	***Storage:*** *When storing for long periods of time without use (> 1 month) be sure to charge the battery to around 50% charge level to prolong life of battery.*

Battery ID

Charge Indicator

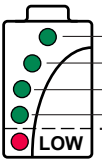
The Battery has it's own Charge Indicator. Momentarily activating the PUSH to Test Button will indicate the current state of battery charge. (Battery is NOT shipped fully charged.)

4 LED Lights - 75% to 100% Full Charge
3 LED Lights - 50% to 75% Charge
2 LED Lights - 25% to 50% Charge
1 LED Light - 15% to 25% Charge
(Blinking < 15%)

Control Panel Battery Indicator

When the TOC is not connected to any external AC or DC power source it will operate totally from the lithium-ion Battery.

It is imperative to monitor the status of the battery charge to ensure adequate available battery power/runtime. (see "EasyPulse TOC User Interface" for location of the Control Panel Battery Indicator).



4 Green LED's	75% to 100% Full
3 Green LED's	50% to 75% Full
2 Green LED's	25% to 50% Full
1 Green LED	15% to 25% Full
1 Red LED	Less than 15% - Low Priority Alarm
	Less than 7% - Medium Priority
	Less than 2% - High Priority

NOTE: Battery duration times will degrade with battery age, environmental operating conditions, and use over time. If the battery is near the end of its useful life, you may experience battery durations less than that of a new battery.

BATTERY INSTALLATION

Insert Battery into slot on the back of the TOC (insert until the bottom of the battery handle comes in contact with the TOC case).

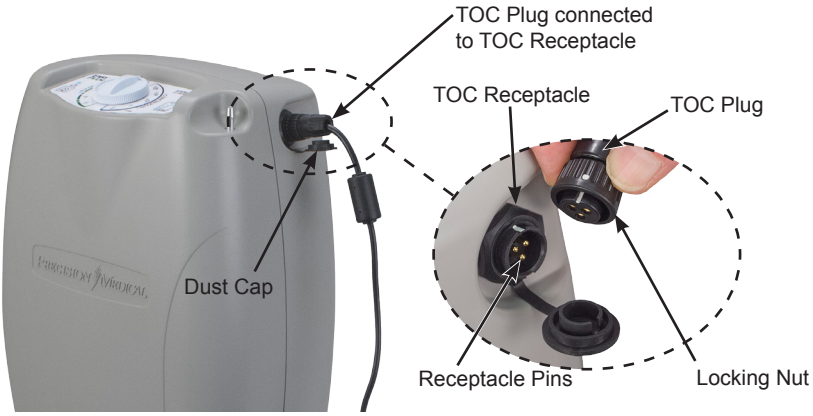
Battery shown
fully inserted

CHARGING (AC AND DC OPTIONS)

To prevent damage to the TOC, use only Precision Medical approved external power sources.

Connection of Power Cords to TOC

Unplug Dust Cap. Utilize “White” reference marks to help align TOC Plug with TOC Receptacle. Slightly push TOC Plug to engage into Receptacle Pins. Rotate Locking Nut clockwise to secure in place.



Charging Battery with AC Power Supply

AC Power Supply: The AC Power Supply connects the TOC to a 100-240 VAC, 50/60 Hz wall outlet. The AC Power Supply converts AC voltage to DC voltage in order to power the TOC. The AC Power Supply allows for running the TOC and simultaneously charging the battery. It is a good practice to attach the AC Power Supply when AC power is available.

Connection: Connect AC Power Supply to the TOC. (see Connection of Power Cords to TOC for details). Insert the AC Plug into a wall outlet.

NOTES:

- When TOC is first plugged into an AC outlet, all the lights on the Control Panel will illuminate then extinguish.

  The Battery Indicator will then illuminate and stay lit during charging to indicate the state of the battery charge.
- During charging, a blinking light on the Battery Indicator verifies that the Battery is being charged.
- When the Battery is fully charged all Battery Indicator lights will illuminate then extinguish if the TOC is NOT in use.
- Battery status can be checked at anytime by turning the TOC to any flow setting.
- If the TOC is in use, the Battery Indicator will constantly show the state of charge.
- The TOC fan may turn on and off during charging.
- It may take up to 4 hours to fully charge the Battery.
- Charging time may be longer if the TOC is being used while charging.

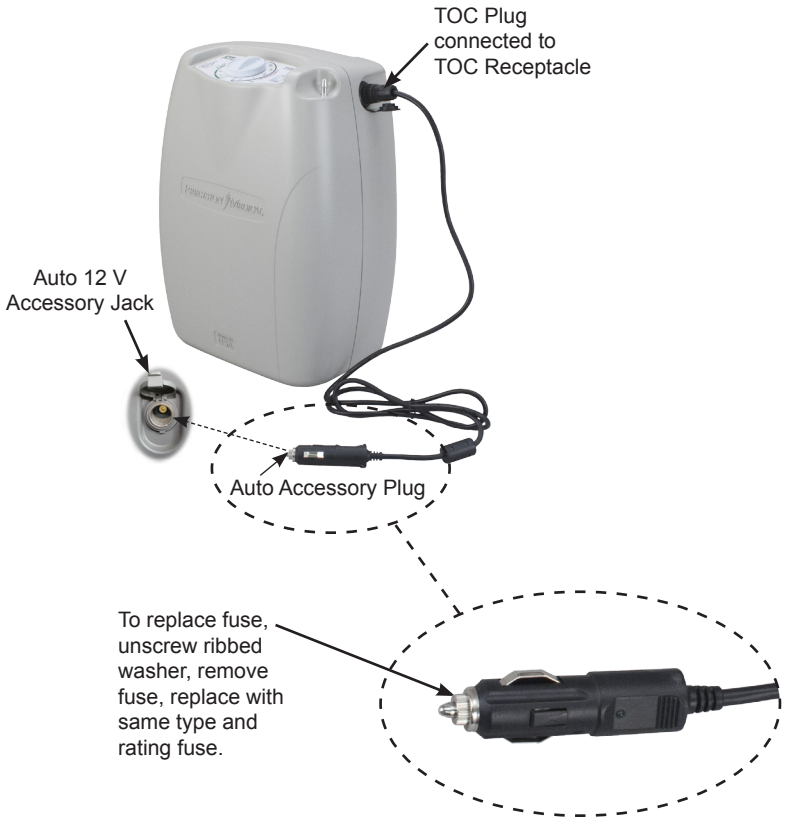
Charging Battery with DC Power Cord

⚠CAUTION

- Ensure the automobile power socket and the Auto Accessory Plug connect properly.
- When powering the TOC in an automobile, ensure the vehicle's engine is running first, before connecting DC Power Cord into Auto 12 V Accessory Jack. Operating the TOC without the engine running may drain the vehicle's battery.
- Ensure that the Auto 12 V Accessory Jack is adequately fused for the TOC power requirements (10 Amp). If the power socket cannot support a 10 Amp load, the automobile's fuse may blow and/or the socket may be damaged.
- It is not recommended to use a power inverter with the TOC.

DC Power Cord: The DC Power Cord connects the TOC to an automobile's 12 VDC outlet. The DC Power Cord will power the TOC and simultaneously charge the Battery.

Connection: Start the vehicle, connect the DC Power Cord to TOC (See Connection of Power Cords to TOC for details) . Insert the Auto Accessory Plug into automobile's 12 V Accessory Jack.



NOTE: The amount of power provided from the vehicle's DC electrical outlet is limited, the power available to charge the Battery is determined by the extra power available based on the operating demands of the TOC.

At high flow settings, the extra power available to charge the Battery may be limited and may increase the time to charge the Battery. At the highest settings, there may not be any extra power available to charge the Battery.

However, it is still a good practice to attach the TOC to a DC power source when available.

START UP PROCEDURE

Checking for Proper Operation:

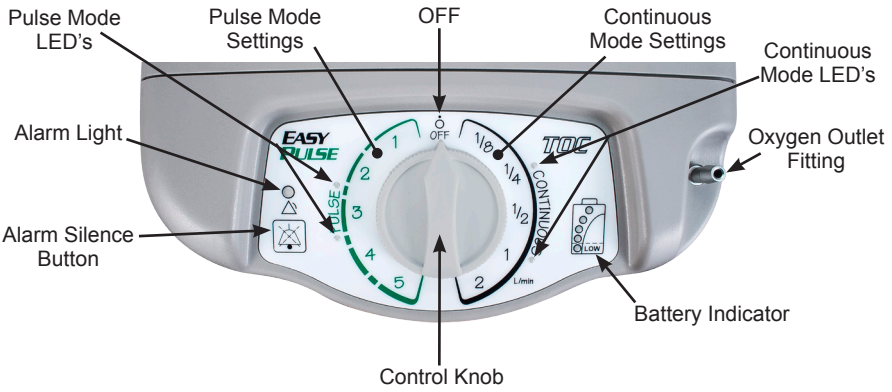
1. Connect the nasal cannula to the Oxygen Outlet Fitting of the TOC.
2. Turn on the TOC by selecting 2 L/min Continuous.
3. Verify that you hear an audible beep as the Control Knob is turned.
4. Verify the Battery Indicator LED's show the status level of the Battery.
5. Verify the Continuous Mode LED's are lit.
6. Gas should be flowing freely to the nasal cannula. You should be able to hear or feel the flow of gas through the prongs of the nasal cannula. Wave your hand in front of the prongs. If you do not feel the gas flowing, check the cannula connections for leaks.

Connecting Nasal Cannula to Oxygen Outlet Fitting

START UP PROCEDURE (continued)

⚠CAUTION

- Inspect the TOC for visual damage before use, DO NOT USE if damaged.
- Ensure Battery is fully charged prior to first use.
- To prevent damage to the TOC, DO NOT operate the TOC without the Air Inlet Filter or while the Air Inlet Filter is wet.
- The Control Knob does not rotate 360°. Rotating the knob beyond the stops will damage the TOC.
  Starting at OFF position (12 o'clock):
  - Rotate counter-clockwise for 1 to 5 Pulse Settings
  - Rotate clockwise for 1/8 to 2 L/min Continuous Flow Settings
  - **THERE IS NO FLOW BETWEEN SETTINGS.**
- When the Battery is low (red light) replace the Battery with a charged Battery or connect the TOC to AC or DC power source.
- Prior to operation, ensure the inlet and exhaust vents on the TOC are clear. Any blockage of the vents can inhibit performance.

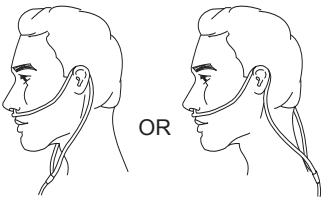


1. Choose a power option: AC Power Supply, DC Power Cord or Battery.
   - For AC Power Supply, see Charging Battery with AC Power Supply for connection instructions.
   - For DC Power Cord, see Charging Battery with DC Power Cord for connection instructions.
   - For Battery operation, verify battery status (level) prior to each use, charge as necessary. See label on back of Battery for initial charging and installation instructions. Ensure Battery is fully charged with AC Power Supply.
2. If running the TOC in PULSE mode:
   - Connect the end of a standard adult single lumen oxygen nasal cannula with a maximum length of 7 feet (2.1 m) to the TOC's Oxygen Outlet Fitting.

⚠CAUTION

- Do not use a humidifier bottle when pulse mode is selected.
- Irritation to the nasal passageways may occur with prolonged use of oxygen.

3. If running the TOC in Continuous Mode:
   - Connect the end of a standard adult single lumen oxygen nasal cannula with a maximum length of 30 feet (9.1 m) to the TOC's Oxygen Outlet Fitting.
   - NOTE: If using humidifier bottle, Precision Medical, Inc. highly recommends the PM500 Disposable Humidifier.
     - ○ Using tubing adaptor P/N 508333, connect tubing from TOC Oxygen Outlet Fitting to Humidifier Bottle Inlet Fitting.
     - ○ Connect Cannula to Humidifier Bottle Outlet Fitting.
4. Place the cannula over your ears and position the prongs in your nose as instructed by your Equipment Provider or cannula manufacturer.
   - NOTE: The proper placement and positioning of the prongs of the nasal cannula in the nose is critical to the amount of oxygen delivered to the patient.



5. Turn ON the TOC by selecting the setting for your prescribed flow and mode of operation.
   - Turn the Control Knob left to select a "PULSE" setting and to the right to select a "CONTINUOUS" setting.

6. Breathe normally through your nose.
   - If running the TOC in PULSE mode, a measured pulse of oxygen will be delivered each time the TOC senses an inhalation. To show the TOC is triggering properly, the Pulse Mode LED's will turn off briefly each time it senses an inhalation.
   - If running the TOC in CONTINUOUS mode, a measured continuous flow of oxygen will be delivered. To show the TOC is in the CONTINUOUS mode, the Continuous Mode LED's will be on steady.
7. To turn OFF the TOC, select the OFF position.

CART OVERVIEW

TOC ATTACHMENT TO CART

Step 1

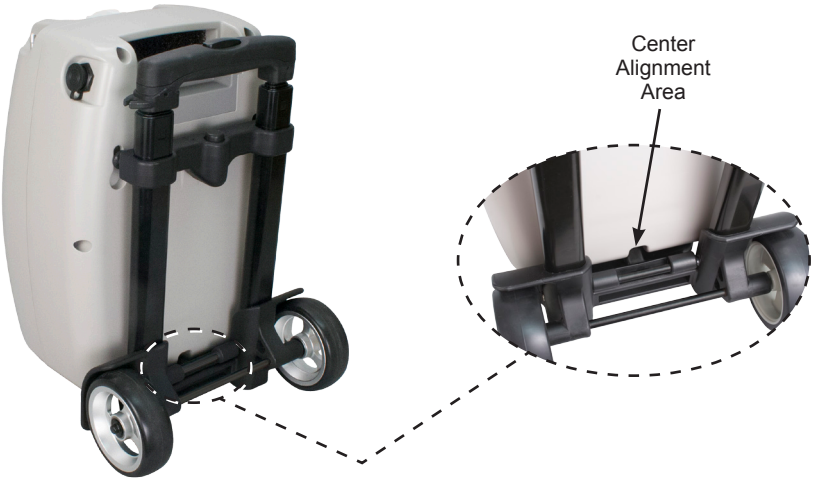
Release TOC Support Tray by grasping the side rails and pushing tray with thumbs.

Step 2

Swing TOC Support Tray down to flat position.

Step 3

Set TOC on center of TOC Support Tray utilizing Center Alignment Rib.



TOC ATTACHMENT TO CART (continued)

Step 4

Tilt Cart forward until it stops. (Attachment pins will insert into Mounting Holes of TOC.)

Step 5

Tilt Cart Handle backwards until TOC locks into position. (Release Button will return to elevated Position.)

TOC DETACHMENT FROM CART

Step 1

Push and hold Cart Release Button to deactivate lock-pin.

Step 2

Tilt Cart forward until it stops.

Step 3

Hold TOC in position and allow Cart to tilt away from TOC.

ALARM / INDICATORS / TROUBLESHOOTING

⚠CAUTION
Failure to resolve an alarm condition may cause the TOC to shut down.

NOTE: To view the alarm fault code, remove the Air Inlet Filter located inside the TOC Handle. The code will be displayed in window.

(Alarm fault code window “FC4” shown as an example)

If the TOC is producing an alarm fault code not listed in the alarm tables, contact your Healthcare Provider. If possible, switch to an alternate oxygen source.

TOC Alarms Functional Description

The TOC monitors various internal components and compares them to known acceptable limits. If a known acceptable limit has been exceeded, an alarm is generated.

Alarms are classified as Low, Medium, or High Priority. Classification is representative of the action required by the user.

All alarm conditions are presented in an auditory and visual format. Auditory presentation is dependent on the alarm classification. The following table classifies Alarm priority presentation:

Alarm Priority	Auditory Pattern	Repeat Interval	LED Color
Low	Double	None	Yellow
Medium	Triple	25 Sec.	Yellow
High	Triple-Double	10 Sec.	Red

When an alarm condition occurs, the user may press the Alarm Silence push button. Pressing the button will silence the alarm and transition the LED from a flashing state to a continuous on state; the auditory silence period is five (5) minutes. During this silence period, if the condition that created the alarm is rectified, the LED will extinguish. If the alarm condition is not rectified by the end of this silence period, the alarm condition will reoccur. The Alarm Silence push button may be pressed again and the period will repeat itself. This cycle will repeat until the alarm condition has been rectified.

If any additional alarm conditions are generated during an Alarm Silence period; the period is terminated and the additional alarm is presented with an audible and visual LED. This feature is independent of the priority classification of an alarm.

If a High Priority alarm is ongoing, no additional alarms will occur. High Priority Alarms result in the TOC shutting down and not producing oxygen; as a result, the TOC stops monitoring for additional alarm conditions. High Priority Alarms are reset by pressing the alarm silence button and turning the TOC off, rectifying the alarm condition and turning the TOC back on.

The specific condition that generated the alarm is available by viewing the alarm fault code in the display window.

If operating outside the “Operating Environment Ranges” (reference Specifications section of the manual), an alarm may occur and the TOC may shut down.

Operator’s Position

Visual alarms are best viewed at a distance of 3 feet (1m) or less along with the following conditions;

- the Operator shall be positioned in view of the top panel to view the visual alarm.
- the Operator line of sight shall be positioned to view the display window located behind the inlet filter to view the fault code

Low Priority Alarms:
The following low priority alarm messages are accompanied by a **double beep** and a **solid yellow light.**

Alarm Condition	Fault Code(s)	Possible Cause / Recommended Solution
Battery Low (15%)	FC1	Battery near depletion / Replace with charged battery or switch to alternate power source.
Battery Charge Temperature Low	FC5	1. Allow battery to warm up and charging will start automatically after alarm is acknowledged. 2. Replace with another battery. 3. If alarm condition persists, contact your Healthcare Provider. Switch to an alternate oxygen source.
Battery Charge Temperature High	FC6	1. Allow battery to cool, charging will start automatically after alarm is acknowledged. 2. Replace with another Battery. 3. I If alarm condition persists, contact your Healthcare Provider. Switch to an alternate oxygen source.

Medium Priority Alarms:
The following medium priority alarm messages are accompanied by a **triple beep** repeated every 25 seconds and a **flashing yellow light**.

Alarm Condition	Fault Code(s)	Possible Cause / Recommended Solution
Oxygen Less than 83%	FC17	Oxygen Concentration is below 83% / Continue to use TOC and contact your Healthcare Provider. Switch to an alternate oxygen source.
High Temp Warning	FC7, FC8, FC9	TOC or parts of TOC are overheating / Power off TOC and allow to cool. Ensure the TOC is well ventilated. Return the TOC to your prescribed dose. If alarm condition persists, contact your Healthcare Provider. Switch to an alternate oxygen source.
Cannula Blocked	FC15	Cannula blocked or pinched / Verify the cannula is not blocked or pinched. Replace cannula if damaged.
No Breath Detected	FC13	TOC is unable to detect patient's breath with TOC in Pulse mode / Verify cannula length is a maximum of 7 feet. Verify cannula connection is tight. Verify cannula nasal prongs are properly placed into nostrils. Breathe through the nose and not the mouth. Use "nasal cannula" only; do not use cannula with mask. If alarm condition continues, contact your Healthcare Provider. Switch to an alternate oxygen source.
Battery Weak (7%)	FC2	Battery near depletion / Replace with charged battery or switch to alternate power source.
Breath rate exceeding 35 breathes / minutes	FC14	1. Reduce level of activity to lower breath rate. 2. If alarm persists, change to alternate oxygen source and contact your Equipment Provider.

High Priority Alarms:
The following high priority alarm messages are accompanied by a **triple-double beep** pattern repeated every 10 seconds and a **flashing red light.**

Alarm Condition	Fault Code(s)	Possible Cause / Recommended Solution
High Temp Shutdown	FC10, FC11, FC12	TOC or parts of TOC are overheating. TOC will shutdown if condition cannot be resolved./ Power off TOC and allow to cool 5 to 10 minutes . Ensure the TOC is well ventilated. Return the TOC to your prescribed dose. If alarm condition persists, contact your Healthcare Provider. Switch to an alternate oxygen source.
Switch Position	FC16	TOC does not recognize the position of the Settings Dial / Ensure Settings Dial pointer is not between settings. Verify dial is pointing directly at setting. If alarm condition persists, select a different setting and then return to prescribed setting. If alarm condition persists, contact your Healthcare Provider. Switch to an alternate oxygen source.
Battery Communication	FC4	TOC does not recognize installed battery / Verify battery is fully inserted into the TOC. Remove and reinstall battery. Verify battery is for use with the PM4400 TOC. Replace battery with new battery. If alarm condition persists, contact your Healthcare Provider. Switch to an alternate oxygen source.
Battery Depleated (2%)	FC3	Battery Depleted / Replace with charged battery or switch to alternate power source

TROUBLESHOOTING

Problem	Possible Cause	Recommended Solution
Device will not power On or Run	**Battery Mobile Mode** 1. Dead Battery 2. Missing battery 3. Battery not seated correctly 4. Incorrect Battery **DC Power Mode** 1. DC power cord not connected correctly 2. DC power cord fuse is blown 3. Automobile Accessory fuse is blown **AC Power Mode** 1. AC power cord not connected correctly 2. No AC voltage on wall outlet **Other** 1. Knob not positioned at setting	**Battery Mobile Mode** 1. Charge Battery or replace with charged Battery 2. Install charged Battery 3. Ensure Battery if fully inserted into TOC 4. Use only Precision Medical Inc. Battery **DC Power Mode (Auto Plug)** 1. Ensure DC Plug is fully inserted into Accessory Jack. Verify power cord connection to TOC is tight. 2. Replace fuse. If fuse blows again, contact your Provider and/or Healthcare Professional. 3. Replace Automobile Accessory fuse with same amperage rating as original. If the amperage rating of the Automobile Accessory power outlet is less than 10 Amps, the TOC may not be suitable for use in that vehicle. **AC Power Mode** 1. Ensure AC Plug is fully inserted into outlet. Verify power cord connection to TOC is tight. 2. Find another outlet with AC power available. **Other** 1. Ensure Knob is not set between settings.

TROUBLESHOOTING (continued)

Problem	Possible Cause	Recommended Solution
Battery will not charge in TOC	**TOC connected to AC or DC** 1. Battery not seated correctly 2. Incorrect Battery 3. Defective Battery 4. TOC not connected to external power source 5. Device needs service (TOC) **TOC connected to DC (Auto Plug)** 1. DC plug not fully inserted into Auto Accessory Jack 2. Fuse in DC plug is blown 3. Fuse blown in automobile 4. Available power from Auto Accessory Jack is limited based on operating demands of the TOC	**TOC connected to AC or DC** 1. Ensure Battery is fully inserted into TOC 2. Use only Precision Medical Inc. Battery 3. Replace with new Battery 4. Ensure TOC is connected to a external power source. Verify all connections are tight. 5. Run TOC from AC or Auto DC power source. If Mobile, switch to an alternate oxygen source and contact your Healthcare Provider. **TOC connected to DC (Auto Plug)** 1. Ensure DC Plug is fully inserted into Auto Accessory Jack. Verify power cord connection to TOC is tight. 2. Replace fuse. If fuse blows again,contact your Healthcare Provider. 3. Replace Automobile Accessory power outlet fuse with same amperage rating as original. If the amperage rating of the Automobile Accessory power outlet is less than 10 Amps, the TOC may not be suitable for use in that vehicle. 4. See “Charging Battery with DC Power Cord” section of this manual.
Breath not detected in Pulse Mode	1. Patient breathing through mouth 2. Humidifier bottle being used 3. Cannula is longer than 7 ft 4. Cannula not positioned correctly 5. Cannula kinked or damaged	1. Breathe through the nose and not the mouth. 2. Do not use humidifier bottle with the device in the pulse mode. Connect cannula directly to device outlet. 3. Verify cannula length is less than 7 feet. Verify cannula connection is tight. 4. Verify cannula nasal prongs are properly placed into nostrils. Use “nasal cannula” only; do not use cannula with mask. 5. Verify the cannula is not kinked. If none of the above resolve the problem, perform the following: If Pulse setting is 1 or 2, switch TOC to the equivalent continuous setting. If possible, switch to an alternate oxygen source. Contact your Healthcare Provider.
Alarm Occurs	The device needs your attention	See the alarm conditions for information. If the alarm continues after performing the recommended solution, change to alternate oxygen source and contact your Equipment Provider.

CLEANING, CARE and MAINTENANCE

⚠CAUTION

- Prior to cleaning, ensure the TOC is turned off, unplug any external power sources and remove Battery.
- DO NOT disassemble or attempt to repair. There are no user serviceable parts inside. Contact your Provider and/or Healthcare Professional for service.
- DO NOT spray or apply any cleaners directly onto the case.
- DO NOT allow any liquids to enter inside case.
- DO NOT use harsh and/or flammable chemicals to clean the TOC.
- DO NOT run the TOC until it is thoroughly dry.
- To prevent damage to the TOC, DO NOT operate the TOC without the inlet filter or while the inlet filter is wet.

Perform cleaning as needed:

1. The patient should connect to an alternate oxygen source.
2. Select the **OFF** position on the TOC.
3. Unplug the external power source and remove battery before cleaning.
4. Clean exterior surfaces of the TOC with a cloth dampened with mild detergent.
5. Wipe and allow TOC to air dry.

Note: When not in use, store the TOC in a clean dry area free from grease, oil and other sources of contamination.

Inlet Filter:

1. Remove the inlet filter.
2. Wash filter with mild detergent. Rinse thoroughly with water and allow to dry completely.
3. Once filter is dry, push the filter back into the case so only the small tab is protruding.

SPECIFICATIONS

GENERAL SPECIFICATIONS

- When measuring any published tolerance, be sure to consider the tolerance of accuracy of the measuring equipment.
- Gas volume and flowrate specifications for gas delivered to the patient are expressed at ATPD (ambient temperature and pressure, dry).

For technical specifications call Precision Medical or visit www.precisionmedical.com

Dimensions:

Height: 14.63 in (37.16 cm)
Width: 10.50 in (26.67 cm)
Depth: 7.00 in (17.78 cm)

Weight: 11.40 lbs (5.17 kg)

Cart Maximum Safe Working Load:
17.00 lbs (7.71 kg)

Sound Level: On Setting 2 Continuous: 42 dBa

Alarm: >45 dBa @ 1m

Modes of Operation

Continuous: 1/8 L/min (±10cc), 1/4, 1/2,1,2 L/min (±10%)
Pulse Dose: Setting 1: 240 mL/min (±15%)
Setting 2: 380 mL/min (±15%)
Setting 3: 520 mL/min (±15%)
Setting 4: 660 mL/min (±15%)
Setting 5: 780 mL/min (±15%)

Oxygen Concentration: 87% to 95% on all settings

Start Up Time: 87% O2 Concentration ≤ 10 min

Breath Rate Range: 15 – 35 B/min

Maximum Limited Pressure (Outlet Pressure):
10 PSI (0.69 Bar)

Power Supply

AC Input: 100-240 VAC, 47-63 Hz, 2.5A
DC Output: 15 VDC, 10A

DC Power Cord: 10 amp Fuse

Battery: 14.4 VDC 6.6 Ah (Amp hours)

Battery Duration:

Pulse Mode	Continuous Mode	
Setting 1: 3.3 Hours	1/8	5.0 hours
Setting 2: 3.0 Hours	1/4	4.3 hours
Setting 3: 2.8 Hours	1/2	3.3 hours
Setting 4: 2.5 Hours	1	1.8 hours
Setting 5: 2.3 Hours	2	0.8 hours

Note: Battery run times may vary according to battery age.
Battery Charging Time: Up to 4 Hours (Completely depleted to full charge)

Operating Environment Ranges

Temperature:	TOC: 41°F to 104°F (5°C to 40°C)
Humidity:	0% to 95%, non-condensing but not requiring a water vapour partial pressure greater than 50 hPa
Atmospheric Pressure:	700 hPa to 1060 hPa
Altitude:	0 to 10,000 ft (0 to 3048 m)

Shipping and Storage Environmental Ranges

Temperature:	-4˚F to 140˚F (-20˚C to 60˚C)
Humidity:	0% to 95%, non-condensing 95°F (35 °C) at a water vapour pressure up to 50 hPa

Cannula

Pulse Mode:	Maximum 7 ft (2.1 m) long standard adult single lumen nasal cannula. Maximum oxygen flow ≥ 2 L/min
Continuous Mode:	Maximum 30 ft (9.1 m) long standard adult single lumen nasal cannula. Maximum oxygen flow ≥ 2 L/min

Expected Service Life of the device and accessories:

5 Years

Classifications

Mode of Operation:	Continuous Duty
Type of Protections against Shock:	Class II
Degree of Protection against Electrical Shock:	Type BF
Degree of Protection against Ingress of Water:	IP22

VOLATILE ORGANIC COMPOUND (VOC) AND PARTICULATE REQUIREMENTS

The oxygen delivered from the TOC meets the following requirements for particulate levels, VOC levels, carbon monoxide levels, carbon dioxide levels and ozone levels.

EPA PM 2.5:	Particulate Matter
ASTM D5466:	VOC Levels
21 CFR 801.415:	Ozone Levels
EPA NAAQS:	Carbon Monoxide Levels
OSHA Permissible Exposure Limits:	Carbon Dioxide Levels

Standard Test Method for Determination of Volatile Organic Chemicals in Atmospheres (Canister Sampling Methodology)

SAFETY INFORMATION - WARNINGS AND CAUTIONS

⚠ DANGER Indicates an imminently hazardous situation which, if not avoided, will result in death or serious injury.

⚠ WARNING Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.

⚠ CAUTION Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury.

CAUTION Used without the safety alert symbol indicates a potentially hazardous situation which, if not avoided, may result in property damage.


General Warning Sign


No Smoking


Follow Instructions for Use


Do Not Disassemble


General Mandatory Action Sign


No Oil or Grease


Class II Equipment


Type BF applied part


Direct Current


OFF for part of equipment


General Alarm


Single Use


Pause Alarm

Battery Level Indicator

PM4400 WITH RESPECT TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH ANSI/AAMI ES60601-1 (2005, 3RD ED), CAN/CSAC22.2 NO. 60601-1 (2008) 62NA

Caution! U.S. Federal Law restricts this TOC to sale by or on the order of a physician.


This TOC may contain electrical components that are hazardous to the environment. DO NOT dispose TOC into standard trash. Contact your local waste Management for disposal of Electronic Equipment.

CE 0473 Symbol indicates the TOC complies with the requirements of Directive 93/42/EEC concerning medical TOCs and all applicable International Standards.


The manufacturer of this POC has determined this device conforms to all applicable FAA acceptance criteria for POC carriage and use on board aircraft.

The TOC, gas pathways, components and accessories do not contain any natural rubber latex.

IP22 Protected from touch by fingers and objects greater than 12 millimeters. Protected from direct sprays of water up to 15° from the vertical.

GENERAL PRECAUTIONS

- TOC, it's parts or accessories do not contain known phthalates which are classified as carcinogenic, mutagenic or toxic.
- TOC, it's parts and accessories are intended for use by a single patient and should be cleaned/disinfected before use on a new patient.
  Note: The nasal cannula cannot be cleaned and should be disposed of.

⚠ DANGER

- Smoking during oxygen therapy is dangerous and is likely to result in facial burns or death. Do not allow smoking within the same room where the TOC or any oxygen carrying accessories are located. If you intend to smoke, you must always turn the TOC off, remove the cannula and leave the room where either the cannula or mask or the TOC is located. If unable to leave the room, you must wait 10 minutes after you have turned the TOC off before smoking.
- Use only water-based lotions or salves that are oxygen-compatible before and during oxygen therapy. Never use petroleum or oil-based lotions or salves to avoid the risk of fire and burns.
- DO NOT lubricate fittings, connections, tubing, or other accessories of the TOC to avoid the risk of fire and burns.
- Open flames during oxygen therapy are dangerous and are likely to result in fire or death. Do not allow open flames within 6.5 ft (2 m) of the TOC or any oxygen carrying accessories.
- TOC is not suitable for use in an enriched environment of flammable anesthetic mixture with air, oxygen or nitrous oxide.
- There is a risk of fire associated with oxygen enrichment during oxygen therapy. Do not use the TOC or accessories near sparks or open flames.
- DO NOT use near any type of flame or flammable/explosive substances.
- Oxygen makes it easier for a fire to start and spread. Do not leave the nasal cannula or mask on combustible materials such as bed coverings or chair cushions, if the TOC is turned on, but not in use; the oxygen will make the materials flammable. Turn the TOC off when not in use to prevent oxygen enrichment.
- Charging the battery in an environment below 32°F (0°C) may damage the battery and increase risk of fire.
- DO NOT use while bathing.
- DO NOT reach for the TOC if it has fallen into water. Unplug immediately.
- The TOC is designed to be used in dry conditions and is not to be submerged, operated under water or used while swimming.
- Be aware that the electrical cord and/or tubing could present a tripping or strangulation hazard.

⚠WARNING

- The Nasal Cannula is intended for single patient use only. Use on more than one patient may cause cross contamination.
- Use of accessories or replacement parts not listed in this User Manual may cause adverse effects to basic safety or essential performance of the TOC.
- **Use humidifier bottle with TOC in the Continuous Flow mode only.** Use of the humidifier bottle in the Pulse mode will cause the TOC to go into an alarm condition.
- Prior to operation, ensure the inlet and exhaust vents on the TOC are clear. Any blockage of the vents can inhibit performance.
- DO NOT place the TOC in a small closed space such as a closet.
- DO NOT cover the air vents, the TOC requires proper ventilation.
- ALWAYS keep at least 6 in. (15.24 cm) away from walls, furniture, and especially curtains that could prevent adequate airflow to the TOC.
- In the event of an audible alarm or if you are experiencing any signs of discomfort, connect to another oxygen source. DO NOT attempt to repair the TOC. Contact your Provider and/or Healthcare Professional immediately.
- To ensure receiving the therapeutic amount of oxygen delivery according to your medical condition, the TOC must be used only after one or more settings have been individually determined or prescribed for you at your specific activity levels by your Healthcare Provider.
- Use only parts recommended by the manufacturer to ensure proper function and to avoid the risk of fire and burns.
- Use of this TOC at an altitude above 10,000 ft (3048 m) or outside a temperature of 41°F to 104°F (5°C to 40°C) or a relative humidity above 95% is expected to adversely affect the flowrate and the percentage of oxygen and consequently the quality of therapy.
- ALWAYS confirm prescribed dose before use and monitor on a frequent basis.
- For proper oxygen flow, be sure that cannula is not kinked or obstructed before or during use.
- Patients unable to communicate discomfort can require additional monitoring and/or a distributed alarm system to alert caregiver of discomfort, medical urgency or impending harm.
- The TOC contains magnetic, ferrous material that may affect the results of an MRI.
- Ensure TOC is properly engaged onto Cart before transporting.
- While transporting the TOC on the Cart avoid rough surfaces, holes and bumps.
- Use transportable Cart designed for TOC only. Do not use transportable Cart to move other objects such as luggage.
- Do not modify the TOC or Cart in any way. Modifications could result in hazards to the user.

⚠WARNING (continued)

- Before each use, verify all connections are tight.
- To ensure receiving the therapeutic amount of oxygen delivery according to your medical condition, the TOC must be used with the specific combination of parts and accessories that were in place when your settings were determined.
- Where the prescribing Healthcare Professional has determined that an interruption in the supply of oxygen, for any reason, may have serious consequences to the user, an alternative source of oxygen should be available for immediate use.
- DO NOT place any liquids on or near the TOC. If any liquid gets on the TOC, immediately turn OFF the power switch, unplug from the electrical outlet, remove Battery and connect to another oxygen source. Contact your Provider and/or Healthcare Professional immediately.
- DO NOT attempt to lift the TOC using the battery handle.
- TOC is not appropriate for any patient who would experience adverse health consequences as a result of a temporary interruption in oxygen therapy.
- The availability of an alternate source of supplemental oxygen is strongly recommended in the case of power interruption or in the event the TOC stops functioning for any reason.
- To prevent damage, care should be taken when transporting TOC in a wet environment.
- The Pulse settings of the TOC might not correspond with continuous flow oxygen.
- The settings of other models or brands of oxygen therapy equipment may not correspond with the settings of the TOC.
- Using the TOC around wind or strong draughts can adversely affect accurate delivery of oxygen therapy.

⚠CAUTION

- The US Department of Transportation (DOT) and United Nations (UN) regulations require the removal of the battery from the TOC for all international airline travel when the TOC is checked as luggage. When shipping the TOC, the battery must also be removed.
- When setting dosage/mode of operation in a dark environment, visually verify dose setting is correct.
- Ensure transportable Cart handle is locked into place before transporting the TOC.
- Some respiratory efforts of the patient may not trigger the TOC while in the Pulse mode. If patient is unable to trigger the TOC while in the Pulse mode, switch to the nearest equivalent Continuous mode setting and contact your Provider and/or Healthcare Professional.
- Patients with tracheotomies should consult with their Respiratory Healthcare Professional to evaluate whether the TOC is appropriate for their treatment.

GUIDANCE and MANUFACTURER'S DECLARATION - ELECTROMAGNETIC IMMUNITY

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

Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 Vrms 80 MHz to 2.7GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the TOC, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d=1.2\sqrt{P}$ 150 kHz to 80 MHz $d=1.2\sqrt{P}$ 80 MHz to 800 MHz $d=2.3\sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey a, should be less than the compliance level in each frequency range b. Interference may occur in the vicinity of equipment marked with the following symbol: 
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 EC 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 commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial 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 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the [ME EQUIPMENT or ME SYSTEM] requires continued operation during power mains interruptions, it is recommended that the [ME EQUIPMENT or ME SYSTEM] be powered from an uninterrupted power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical hospital or home environment.

- At 80 MHz and 800 MHz, the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.
- UT is the a.c. main voltage prior to application of the test level.

[a] : Field strength from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the concentrator is used exceeds the applicable RF compliance level above, the concentrator should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the TOC.

[b] : Over the frequency range 150 kHz to 80 MHz, the field strengths should be less than 3V/m.

Recommended Separation Distances between Portable and Mobile RF Communications Equipment and This TOC:

This concentrator is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of the concentrator can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and this concentrator as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum Power Output of Transmitter (W)	Separation Distance According to Frequency of Transmitter (M)		
	150 kHz to 80 MHz $d=1.2\sqrt{P}$	80 MHz to 800 MHz $d=1.2\sqrt{P}$	800 MHz to 2.5 GHz $d=2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

- At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
- The guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

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 assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	The concentrator uses RF energy only for its internal function. Therefore its RF emissions are very low and not likely to cause any interference in nearby equipment.
RF emissions CISPR 11	Class B	The concentrator 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	

DISPOSAL OF TOC AND ACCESSORIES

Follow your local governing ordinances for disposal and recycling of the TOC and its accessories. If WEEE regulations apply, do not dispose of in unsorted municipal waste. Within Europe, contact the EU Authorized Representative for disposal instructions. The battery contains lithium ion cells and should be recycled. The battery must not be incinerated.

RETURNS

Returned products require a Returned Goods Authorization (RGA) number, contact Precision Medical, Inc. All returns must be packaged in sealed containers to prevent damage. Precision Medical, Inc. will not be responsible for goods damaged in transit. Refer to Precision Medical, Inc. Return Policy available on the Internet, www.precisionmedical.com.

LIMITED WARRANTY AND LIMITATION OF LIABILITY

Precision Medical, Inc. warrants that the Total Oxygen Concentrator TOC, (the Product), will be free of defects in workmanship and/or material for the following period:

Total Oxygen Concentrator - - - three (3) years from date of shipment

Battery - - - - - - - - - - - - - 180 days from date of shipment

Precision Medical, Inc. is NOT responsible for normal wear and tear, or any neglect or abuse of the product.

The customer is responsible for the shipping costs of repairs to Precision Medical, Inc.

Precision Medical, Inc. will have in its sole and absolute discretion, the final determination if your product is covered under this limited warranty.

Should any failure to conform to this warranty appear within the applicable period, Precision Medical, Inc. shall, upon written notification thereof and substantiation that the goods have been stored, installed, maintained and operated in accordance with Precision Medical, Inc.'s instructions and standard industry practice, and that no modifications, substitutions, or alterations have been made to the goods, correct such defect by suitable repair or replacement at it's own expense.

ORAL STATEMENTS DO NOT CONSTITUTE WARRANTIES.

The representatives of Precision Medical, Inc. or any retailers are not authorized to make oral warranties about the merchandise described in this contract, and any such statements shall not be relied upon and are not part of the contract for sale. Thus, this writing is a final, complete and exclusive statement of the terms of that contract.

THIS WARRANTY IS EXCLUSIVE AND IS IN LIEU OF ANY WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR OTHER WARRANTY OF QUALITY, WHETHER EXPRESS OR IMPLIED.

Precision Medical, Inc. shall not under any circumstances be liable for special, incidental or consequential damages including but not limited to lost profits, lost sales, or injury to person or property. Correction of non-conformities as provided above shall constitute fulfillment of all liabilities of Precision Medical, Inc. whether based on contract, negligence, strict tort or otherwise. Precision Medical, Inc. reserves the right to discontinue manufacture of any product or change product materials, designs, or specifications without notice.

Precision Medical, Inc. reserves the right to correct clerical or typographical errors without penalty.

DECLARATION OF CONFORMITY

Precision Medical, Inc.
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EC REP

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CE 0473

REF PM4400 Series

Classification: IIa

Classification criteria: Clause 3.2 Rule 11 of Annex IX of MDD

We hereby declare that an examination of the under mentioned production quality assurance system has been carried out following the requirements of the UK national legislation to which the undersigned is subjected, transposing Annex II, 3 of the Directive 93/42/EEC and Directive 2007/47/EC on medical devices.

We certify that the production quality system conforms to the relevant provisions of the aforementioned legislation, and the result entitles the organization to use the CE 0473 marking on those products listed above.

Applied Standards:

EN 1041:2008
ISO 15223-1:2016
ISO 15001:2010
EN ISO 14971:2012
IEC 60601-1: Ed. 3.0:2005
IEC 60601-1-2 Ed. 4.0:2014
IEC 60601-1-6 Ed. 3.1b:2013
IEC 60601-1-8 Ed.2.0b:2007
IEC 60601-1-11 Ed. 2.0b:2015
EN 62366:2008
EN ISO 3744:2010
ISO 80601-2-67:2014
ISO 80601-2-69:2014
EN ISO 15001:2011
2006/66/EC
2011/65/EU (RoHS 2)
ISO 13485:2003

Notified Body:	Intertek AMTAC Certification Services Limited CE 0473
Address:	Davy Avenue Knowlhill Milton Keynes MK5 8NL, UK
Certification Registration No's:	1126 A CE Date of Expiry: 26 July 2017
Devices already manufactured:	S/N traceability Device History Records
Validity of DOC:	31 August 2012 to Date of Expiry
Manufacture Representative:	Quality Manager
Position:	Quality Systems/ISO Representative
Date of Issue:	31 August 2012