

Invacare[®] Platinum[®] 5NXG Oxygen Concentrator

P5NXG1, P5NXGC1

en Stationary Oxygen Concentrator User Manual





This manual MUST be given to the user of the product. BEFORE using this product, this manual MUST be read and saved for future reference.

Yes, you can:

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Invacare reserves the right to alter product specifications without further notice.

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1 General

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1.1 Quick Start Guide

1.1.1 Quick Start Label

IMPORTANT!

-The Quick Start Label is for reference ONLY. It is imperative to read the manual in its ENTIRETY for full instructions.

The Quick Start Label is on the side of the device. This section of the manual provides additional information about this label.

- 1. Plug in the device.
- 2. The start/stop button will illuminate on the display.

3. Press the start/stop button on the display.

- 4. Adjust the flowmeter to the prescribed setting.
- The start-up symbol and blue light will illuminate when the start/stop button is pressed. When the device is ready, the check mark and green light will illuminate.



1.2 Symbols in this Manual or on the Packaging

Signal words are used in this manual and apply to hazards or unsafe practices which could result in personal injury or property damage. See the information below for definitions of the signal words.



DANGER!

-Danger indicates an imminently hazardous situation which, if not avoided, will result in death or serious injury.



WARNING!

-Warning indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.



CAUTION!

-Caution indicates a potentially hazardous situation which, if not avoided, may result in property damage or minor injury or both.

j Gives useful tips, recommendations and information for efficient, trouble-free use.

Read manual



j The color of the symbol background is blue on product labels.



No Smoking

<u>ຶ</u> The color of the circle with diagonal bar is red on product labels.

No Open Flame

j The color of the circle with diagonal bar is red on product labels.



Indoor Use ONLY



Keep Dry



Transport and Storage Temperature



Transport and Storage Humidity



Manufacturer

Recycle



Serial Number



Reference Number

1.3 Intended Use

The Invacare[®] Platinum[®] 5NXG oxygen concentrator is intended for patients with respiratory disorders requiring supplemental oxygen at flow rates of 1 to 5 liters per minute. For flow rates below 1 liter per minute use with Invacare Pediatric Flowmeter accessory. It is not intended to sustain or support life.



DANGER! Risk of Injury or Death

This product is to be used as an oxygen supplement and is not intended to be lifesupporting or life-sustaining. ONLY use this product if the patient is capable of spontaneous breath, able to inhale and exhale without the use of a machine. -DO NOT use in parallel or series with other oxygen concentrators or oxygen therapy devices.

DANGER!

Risk of Injury or Death

Depending on their medical condition, patients on flow rates greater than 5 L/min may be at an increased risk for serious injury or death in the event of failure. -ALWAYS discuss this increased risk with your home care provider BEFORE using this product if you are prescribed a flow rate greater than 5 L/min.

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WARNING! Risk of Injury or Damage

Use of this product outside of the intended use and specifications has not been tested and may lead to product damage, loss of product function, or personal injury. -DO NOT use this product in any way other than described in the Specifications and Intended Use sections of this manual.

DANGER!

Risk of Injury or Death

While Invacare strives to produce the best oxygen concentrator in the market today, this oxygen concentrator can fail to produce oxygen due to power failure or device malfunction.

-ALWAYS have a backup source of oxygen readily available.

-In the event the concentrator fails to produce oxygen, the concentrator will briefly alarm signaling the patient to switch to their backup source of oxygen. Refer to Troubleshooting for more detail.

1.4 Indications For Use

The Invacare[®] Platinum[®] 5NXG oxygen concentrator is indicated for patients with respiratory disorders requiring supplemental oxygen at flow rates of 1 to 5 liters per minute. For flow rates below 1 liter per minute use with Invacare Pediatric Flowmeter accessory. It is not intended to sustain or support life.

1.5 Contraindications

There are no known contraindications.

1.6 Prescription Statement

Per 21 CFR 801.109(b)(1) the device is labeled for prescription use only.



CAUTION!

Federal (statutory) law restricts this device sale to or on the order of a medical practitioner licensed by a governmental agency where he/she practices. -ONLY a licensed medical practitioner may order the purchase or use of this device.

1.7 Patient Population

Patients requiring supplemental oxygen at flow rates of 1 to 5 liters per minute.

1.8 Description

The Invacare Platinum[®] 5NXG concentrator is used by patients with respiratory disorders who require supplemental oxygen. The device is not intended to sustain or support life.

The oxygen concentration level of the output gas ranges from 87% to 96%. The oxygen is delivered to the patient through the use of a nasal cannula.

The Invacare Platinum[®] 5NXG concentrator uses a molecular sieve and pressure swing adsorption separation methodology to produce the oxygen gas output. Ambient air enters the device, is filtered and then compressed. This compressed air is then directed toward one of two nitrogen adsorbing sieve beds.

Concentrated oxygen exits the opposite end of the active sieve bed and is directed into an oxygen reservoir where it is delivered to the patient.

The Invacare Platinum[®] 5NXG oxygen concentrator is capable of operation by the patient in a home environment or in an institutional environment. Device operates at a nominal 120 VAC/60 Hertz supply.

The power supply cord is replaceable by qualified personnel only.

Service information will be available upon request to qualified technical personnel only.

1.9 Limited Warranty

Terms and conditions of the warranty are part of the general terms and conditions particular to the individual countries in which this product is sold.

Contact information for your local Invacare office is located on or inside the back cover of this manual.

2 Safety

2.1 General Guidelines

In order to ensure the safe installation, assembly and operation of the concentrator these instructions MUST be followed.



DANGER! Risk of Death, Injury, or Damage

Improper use of the product may cause death, injury or damage. This section contains important information for the safe operation and use of this product.

-DO NOT use this product or any available optional equipment without first completely reading and understanding these instructions and any additional instructional material such as user manuals, service manuals or instruction sheets supplied with this product or optional equipment.

-If you are unable to understand the warnings, cautions or instructions, contact a healthcare professional, dealer or technical personnel before attempting to use this equipment.

-Check ALL external components and carton for damage. In case of damage, or if the product is not working correctly, contact a technician or Invacare for repair.

-THE INFORMATION IN THIS DOCUMENT IS SUBJECT TO CHANGE WITHOUT NOTICE. -This product is intended to be set up by adults or under adjult supervision only after reading and understanding the instructions and warnings of this user manual.

DANGER!

Risk of Death, Injury or Damage from Fire

Textiles, oil or petroleum substances, grease, greasy substances and other combustibles are easily ignited and burn with great intensity in oxygen enriched air and when in contact with oxygen under pressure. Smoking during oxygen therapy is dangerous and is likely to result in burns or death. To avoid fire, death, injury or damage:

-DO NOT SMOKE while using this device. -DO NOT use near OPEN FLAME or IGNITION SOURCES.



-NO SMOKING signs should be prominently displayed.

-Keep all open flames, matches, lighted cigarettes, electronic cigarettes or other sources of ignition at least 10 ft (3 m) away from this concentrator or any oxygen carrying accessories such as cannulas or tanks.

DANGER!

Risk of Death, Injury or Damage from Fire Textiles, oil or petroleum substances, grease, greasy substances and other combustibles are easily ignited and burn with great intensity in oxygen enriched air and when in contact with oxygen under pressure. Smoking during oxygen therapy is dangerous and is likely to result in burns or death. To avoid fire, death, injury or damage:

-DO NOT allow smoking within the same room where the oxygen concentrator or any oxygen carrying accessories are located.

-If you disregard these warnings about the severe hazard of oxygen use while you continue to smoke, you must always turn off the concentrator, remove the cannula and then wait ten minutes before smoking or leave the room where either the concentrator or any oxygen carrying accessories such as cannulas or tanks are located.

DANGER!

Risk of Death, Injury or Damage from Fire Textiles, oil or petroleum substances, grease, greasy substances and other combustibles are easily ignited and burn with great intensity in oxygen enriched air and when in contact with oxygen under pressure. Smoking during oxygen therapy is dangerous and is likely to result in burns or death. To avoid fire, death, injury or damage: -Use only oxygen compatible water-based lotions or salves before and during oxygen therapy. To verify, refer to the lotion/salve container for the oxygen compatible water-based statement. If necessary, contact the manufacturer. DO NOT use any lubricants on concentrator

unless recommended by Invacare. -Avoid creation of any spark near oxygen equipment. This includes sparks from static electricity created by any type of friction.

DANGER! Bisk of Death

Risk of Death, Injury or Damage from Fire Textiles, oil or petroleum substances, grease, greasy substances and other combustibles are easily ignited and burn with great intensity in oxygen enriched air and when in contact with oxygen under pressure. Smoking during oxygen therapy is dangerous and is likely to result in burns or death. To avoid fire, death, injury or damage:

-Keep the oxygen tubing, cord, and concentrator out from under such items as blankets, bed coverings, chair cushions, clothing, and away from heated or hot surfaces including space heaters, stoves, and similar electrical appliances.

-Turn the concentrator off when not in use to prevent oxygen enrichment.

Λ [

DANGER!

Risk of Death, Injury, from Electric Shock To reduce the risk of burns, electrocution, death or injury to persons:

-DO NOT disassemble. Refer servicing to qualified service personnel. There are no user serviceable parts.



-Avoid using while bathing. If continuous usage is required by the physician's prescription, the concentrator must be located in another room at least 7ft (2.1m) from the bath.

-DO NOT come in contact with the concentrator while wet.

-DO NOT place or store concentrator where it can drop into water or other liquid.
-DO NOT reach for concentrator that has fallen into water. Unplug IMMEDIATELY.
-DO NOT use frayed or damaged AC power cords.

WARNING!

Risk of Injury or Damage

-Invacare products are specifically designed and manufactured for use in conjunction with Invacare accessories. Accessories designed by other manufacturers, which are NOT listed in this manual have not been tested by Invacare and are not recommended for use with Invacare products.

-No modification of this equipment is allowed.

-There are many different types of humidifier bottles, oxygen tubing, cannulas and masks that can be used with this device. You should contact your home care provider for recommendations on which of these devices will be best for you. They should also give you advice on the proper usage, maintenance, and cleaning.

DANGER!

Risk of Injury or Death

To avoid choking or ingestion of chemicals from airway contamination:

-DO NOT use the concentrator in the presence of pollutants, smoke, fumes, flammable anesthetics, cleaning agents, or chemical vapors.

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WARNING! Risk of Injury or Death

To prevent injury or death from product misuse:

-Closely supervise when this concentrator is used by or near children or impaired individuals.

-Monitor patients using this device who are unable to hear or see alarms or communicate discomfort.

WARNING! Risk of Injury or Damage

To prevent injury or damage during use: -If you feel ill or uncomfortable, or if you are unable to feel the oxygen flow, consult your home care provider and/or your physician IMMEDIATELY.

| Λ | |
|-----------|--|
| | |

WARNING! Risk of Injury

A change in altitude may affect total oxygen available to you. To prevent oxygen deprivation:

-Consult your physician before traveling to higher or lower altitudes to determine if your flow settings should be changed.

WARNING!

Risk of Injury or Damage

To prevent injury or damage from cord misuse:

-DO NOT move or relocate concentrator by pulling on the cord.

-DO NOT use extension cords with AC power cords provided.

-Properly store and position electrical cords and/or tubing to prevent a tripping hazard.

WARNING!

Risk of Injury or Damage

To prevent injury or damage from misuse: -NEVER leave concentrator unattended when plugged in.

-Make sure concentrator is off when not in use.



CAUTION!

Risk of Minor Injury, Discomfort or Damage -Use of this device at an altitude above



13,000 ft (3,962 m) or outside a temperature of 50° F to 95° F (10° C to 35° C) or a relative humidity above 60% is expected to adversely affect the flowrate and the percentage of oxygen and consequently the quality of therapy.



WARNING! Risk of Injury or Damage

Invacare oxygen concentrators are specifically designed to minimize routine preventative maintenance. To prevent injury or damage: -Only professionals of the healthcare field or persons fully conversant with this process such as factory trained personnel should perform preventative maintenance or performance adjustments on the oxygen concentrator, except for tasks described in this manual.

-Users should contact your dealer or Invacare for service.

CAUTION!

Risk of Damage

To prevent damage from liquid ingress: -If the concentrator is not working properly, if it has been dropped or damaged, or dropped into water, call home care provider/qualified technician for examination and repair. -NEVER drop or insert any object or liquid

into any opening.

-For indoor use ONLY.

3 Components

3.1 Component Identification



Fig. 3-1 Front View



Fig. 3-2 Side View

| A | Oxygen Outlet |
|---|-------------------------|
| B | Flowmeter |
| © | Display |
| D | Circuit Breaker |
| Ē | Cabinet Filters |
| Ē | Power Cord |
| G | HomeFill Outlet Fitting |
| Θ | Retractable Handle |

¹ The HomeFill outlet fitting ^C is to be used only for filling oxygen cylinders with the HomeFill Home Oxygen Compressor. The outlet fitting does not affect concentrator performance. Refer to the HomeFill System user manual for connection and operating instructions. When not in use, the plug provided with the concentrator should be inserted into the outlet fitting. For more information about the HomeFill System, contact your Invacare dealer.

3.2 Display

This section of the manual provides additional information about the display.

| | $A \qquad () A \\ () $ | | | | | |
|--|--|---------------------------------|---------------------|--|--|--|
| lcon | Indicator Light Color | O ₂ Concentration | Description | Actions/Info | | |
| Ċ | WHITE | N/A | Start/Stop | Press the Start/Stop button to start or stop the unit. | | |
| | WHITE | N/A | Mute | Press the Mute button to mute alerts and alarms. | | |
| $\mathbf{\mathbf{\mathbf{\mathbf{\mathbf{\mathbf{\mathbf{\mathbf{\mathbf{\mathbf{\mathbf{\mathbf{\mathbf{\mathbf{\mathbf{\mathbf{\mathbf{\mathbf{$ | WHITE WITH BLUE DOT | < 82% | Start-up | The start-up symbol will rotate clockwise when illuminated. Refer to 5.4.7 Initial Start-up of the Concentrator, page 28. | | |
| / . | WHITE WITH GREEN DOT | >82% | System OKAY | No action is needed. Normal for operation. | | |
| [] | WHITE WITH YELLOW DOT | 50% - 82% | Running Alarms | Continue to use the concentrator, unless the unit has shut down. Inspect the device: Check cannula for kinks and check cannula connection to concentrator. Refer to 1.1 Connecting/Positioning the Nasal Cannula, page 1. Check humidifier bottle connection. Refer to 1.1 Setting Up the Humidifier (If Prescribed), page 1. | | |
| X | WHITE WITH RED DOT | <50% | Shut Down Alarms | Check and clean filter. Refer to 1.1 Cleaning the Cabinet Filter, page 1. Refer to 8 Troubleshooting, page 35 for information about specific error codes. If the Alert continues after inspection, call provider. Be certain that backup oxygen is nearby. | | |

| | $A \Rightarrow \# \blacksquare$ | | | | | |
|------|---------------------------------|---------------------------------|-------------------------------|---|--|--|
| lcon | Indicator Light Color | O ₂ Concentration | Description | Actions/Info | | |
| | WHITE | N/A | Menu | Press the Menu button to cycle through the data categories: Run Time Hours, Error Code, Firmware Version, Serial Number. Descriptions of the data categories are in this table. | | |
| | | | Per User Run Time Hours | Press the Menu button and continue to hold for at least 3 seconds to view the per user run time hours. | | |
| C | WHITE | N/A | Run Time Hours | Press the Menu button to cycle through the options and highlight Run Time Hours icon and view the cumulative number of hours the unit has operated. | | |
| | WHITE | varies | Error Code | Press the Menu button to cycle through the options and highlight the Error Code icon. If there is no active error, the display will show the last active error code. Refer to 8.4 Error Codes, page 37 for more information. | | |
| ₿ | WHITE | N/A | Firmware Version | Press the Menu button to cycle through the options and highlight the Firmware Version icon and view the current Firmware version of the device. | | |
| # | WHITE | N/A | Serial Number | Press the Menu button to cycle through the options and highlight the Serial Number icon and view the Serial Number of the device. The serial number will flash on the display in several segments until the entire serial number has been shown. | | |
| | WHITE | N/A | Data | This area displays the menu data and device data, including the | | |

error codes.

3.3 Pneumatic Diagram

WHITE



N/A

Readout

Fig. 3-3 Concentrator without Humidifier Bottle



Fig. 3-4 Concentrator with Humidifier Bottle

3.4 Label Locations



Î (A) The serial number label is located on the control panel of the concentrator.

B Refer to 3.2 Display, page 10 for a description of the symbols on the display.
C Specification Label is located on the side of the concentrator at the base.

3.4.1 Symbols on the Labels



DO NOT use oil, grease, or any other lubricants, including hand lotion.

ຖິ The color of the circle with diagonal bar is red on product labels.



Not to be serviced by users

ຖິ The color of the circle with diagonal bar is red on product labels.

QR Code



j Scan using a QR scanning app on a smart device to get more product information online, including user manuals.

D Refer to 1.1.1 Quick Start Label, page 3 for a description of the symbols on the Quick Start label.

(E) Texture-free surface for provider labeling.

• Refer to *8.1 Troubleshooting Label, page 35* for a description of the symbols on the Troubleshooting label.



Class II, Double Insulated

Protected against solid foreign objects of 12.5 mm (0.5 in) diameter and

IP21 greater. Protected against vertically falling water drops.



Indoor Use ONLY



Read Manual

ັງ The color of the symbol background is blue on product labels.

No Smoking



No Open Flame

j The color of the circle with diagonal bar is red on product labels.



DO NOT dispose of in household waste





R-ONLY

Y For prescription use ONLY

3.5 Optional Accessories

Flow

There are many different types of humidifier bottles, oxygen tubing, cannulas and masks that can be used with this device. You should contact your home care provider for recommendations on which of these devices will be best for you. They should also give you advice on the proper usage, maintenance, and cleaning.

The supply accessories (nasal cannula, mask, tubing, humidifier bottle, etc.) used to deliver oxygen to the patient need to include a means to reduce the propagation of fire in the accessories for the safety of the patient and others. If a commercially available, fire-activated flow stop device is used in the accessories setup, it should be placed as close to the patient as practicable.

The following optional accessories are also available:

- PreciseRx[™] Pediatric Flowmeter Invacare IRCPF16
- HomeFill Home Oxygen Compressor Invacare IOH200
- HomeFill Ready Rack (for Platinum 5NXG) -Invacare IOH280
- Accessory Bag Invacare 60127483

The following optional accessories are recommended:

- Standard Adult Nasal Cannula, 7 ft (2.1 m) -WestMed - M3120
- Standard Humidifier Bottle Westmed 0480
- Prefilled Humidifier Bottle Teleflex AquaPak[®] 005-01
- Oxygen Supply Tubing 7 ft (2.1 m) WestMed MS4107
- Oxygen Supply Tubing 21 ft (6.3 m) WestMed MS4121
- Firesafe Cannula Valve Sunset Healthcare BPR RES010

4 Setup

4.1 Unpacking



- A Humidifier Bottle Tube Adapter
- B Tear Strip
- 1. Check for any obvious damage to the carton or its contents. If damage is evident, notify the carrier, or your local provider.
- 2. Remove the concentrator and contents of the packaging using one of the following methods:
 - Open the top of the carton and carefully remove any loose contents. Remove the concentrator, or
 - Using the tear strip (as indicated on the front of the carton), pull the strip around the entire carton. Carefully lift off the top portion of the carton and remove any loose contents. Remove the concentrator.
 - j Unless the oxygen concentrator is to be used IMMEDIATELY, leave concentrator in its packaging for storage until use is required.

4.2 Inspection

- 1. Inspect/examine exterior of the concentrator for nicks, dents, cracks, scratches or other damage.
- 2. Inspect all components.

4.3 Storage

- 1. Store the repackaged oxygen concentrator in a dry area. Refer to *9 Technical Data, page 41* for storage temperature parameters.
- 2. DO NOT place objects on top of repackaged concentrator.

4.4 Stacking Concentrators



WARNING! Risk of Injury or Damage

This feature must only be used in a commercial environment for storage purposes only. As such, this feature has been evaluated only under the following conditions:

- In low traffic areas and on flat, smooth, unbroken, hard ground-level surfaces
- Subject to no external disturbances, or being bumped, moved, shaken, or subject to external force
- Stacked no more than two units high, including the lowest level units, as shown in the instructions for use
- Stacked only with the same units and not mixed with other models
- Properly nested as shown in the instructions for use
- Stacked units in non-operating state/no power applied
- Not moved, transported, or repositioned when stacked

Any other use of stacking feature is considered misuse of the product and may cause instability, damage, or injury.

Units shall not be operated while in a stacked position.

These directions do not alter, replace, modify, or displace safe work practices, which include:

- Keeping a safe distance between people and the stacked concentrators
- The need for safety equipment, such as reinforced-toe shoes
- Periodic inspection to ensure proper storage conditions are present
- Storage in a place not subject to conditions that would make stacking unsafe
- $\hat{\eta}$ This procedure is for providers and qualified service personnel only.
- 1. Position two units side-by-side with the front of the each unit facing toward you. The units shall be positioned so that a small gap exists between units.



Fig. 4-1 Position units side-by-side



Fig. 4-2 Lifting hand positions



Fig. 4-3 Aligning the top unit

2. Lift a single unit by the top handle (in locked and retracted position) and front base hand cavity.

3. Place the unit on top of both units using alignment posts on the base of the top unit to nest the unit into the shroud indentations of the bottom two units.





Fig. 4-4 Confirming contact points

5. For more than 3 units: Units can interlock as shown in the following image. Increase in the horizontal direction, never stacking units more than 2 high (3 on bottom - 2 on top, 4 on bottom - 3 on top, etc.).

Follow steps 1-4 for correct placement of additional units.



j Units shall be placed on a flat surface and in a low traffic area to prevent any potential impact, while following proper placement guidelines.

5 Usage

5.1 Introduction

Your oxygen concentrator is intended for individual use indoors. It is an electronically operated device that separates oxygen from room air. It provides high concentration of oxygen directly to you through a nasal cannula. Clinical studies have documented that oxygen concentrators are therapeutically equivalent to other types of oxygen delivery systems.

Your provider will show you how to use your oxygen concentrator. He/She should be contacted with any questions or problems regarding your oxygen concentrator. This user manual will tell you about your concentrator and will serve as a reference as you use your concentrator.

5.2 Transport

The rear casters (A) and handle (B) allow for easy transport of the concentrator. The handle adjusts and locks in each of the following 3 positions.



Fig. 5-1 Handle Lowest Position

- 1. Press and hold the button \mathbb{C} on the handle \mathbb{B} .
- 2. Adjust the handle height to the desired position.
- 3. Release the button.
- 4. Raise or lower the handle to ensure the handle locks into place.
- 5. Tip the concentrator back onto the rear casters (A) and roll it to the desired location.
- 6. Tip the concentrator forward to rest on the front pegs \mathbb{D} .
- 7. Repeat STEPS 1-4 to lower the handle and lock it in place when not in use.



Position



Fig. 5-3 Handle Highest Position

5.3 Selecting a Location

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WARNING! Risk of Injury

To avoid injury during therapy:

- -The oxygen concentrator MUST be placed on a level surface for use.
- -DO NOT relocate the oxygen concentrator while in use.



WARNING!

Risk of Injury or Damage

To avoid injury or damage from airborne pollutants and/or fumes and for optimal performance: -Locate and position the concentrator in a well ventilated space so that the air inlet and the air outlet openings are not obstructed.

-NEVER block the air openings of the concentrator or place it on a soft surface, such as a bed or couch, where the air opening may be blocked.

-Keep the openings free from lint, hair and similar foreign items.

-Keep concentrator at least 12 in (30.5 cm) away from walls, draperies and furniture.

-Avoid use in presence of pollutants, smoke or fumes, flammable anesthetics, cleaning agents or chemical vapors.

-Place concentrator in a well ventilated area to avoid airborne pollutants and/or fumes.

-DO NOT use in a closet.

You may select a room in your house where using your oxygen concentrator would be most convenient. Your concentrator can be easily rolled from room to room on the rear casters, using the retractable handle.

Your oxygen concentrator will perform best when operated under the conditions outlined in *9 Technical Data, page 41*.

Usage in environments other than those described may result in the need for increased equipment maintenance. The air intake of the unit should be located in a well ventilated area to avoid airborne pollutants and/or fumes.

Do not position the oxygen concentrator where it is difficult to disconnect the power cord from the wall outlet.

5.3.1 Radio Frequency Interference



WARNING!

Risk of Injury or Damage

To reduce the risk of injury or product damage from interference with wireless equipment: -Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Platinum[®] 5NXG Concentrator, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

-A risk of increased emissions or decreased immunity may result if any additional cables are attached. -Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

-Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

This equipment has been tested and found to comply with EMC limits specified by IEC/EN 60601-1-2 for Type BF equipment. These limits are determined to provide reasonable protection against electromagnetic interference in a typical home healthcare environment. Use of this equipment in an environment with higher levels of interference could affect the accuracy of the oxygen concentration being delivered. This equipment is not intended for use in a professional healthcare environment.

Other devices may experience interference from even the low levels of electromagnetic emissions permitted by the above standards. To determine if the emissions from the concentrator are causing the interference, turn the concentrator Off. If the interference with the other device(s) stops, then the concentrator may becausing the interference. In such rare cases, interference may be reduced or corrected by one of the following measures:

- Reposition, relocate, or increase the separation between the equipment.
- Connect the equipment into an outlet on a circuit different from that to which the other device(s) is connected.
 - \parallel For additional information, refer to 9.2 *Electromagnetic Compatibility (EMC), page 43*.

5.4 Setting Up the Concentrator

5.4.1 Setting up the Humidifier Bottle (If Prescribed)

WARNING!

Risk of Injury or Damage

To avoid burns from steam or hot water, inhalation of water and/or water damage to the concentrator: -DO NOT fill humidifier bottle with hot water.

-DO NOT overfill humidifier bottle.

-Replace the humidifier bottle cap and securely tighten. Confirm that the cap is not cross-threaded on the humidifier bottle.

-DO NOT reverse the oxygen input and output connections. Water from the humidifier bottle will travel through the cannula back to the patient if input and output connections are reversed.

-When using tubing connections longer than 7 ft (2.1 m) in length, position the humidifier bottle as close to the patient as possible to allow for maximum humidification output.

The humidifier bottle delivers humidified air to the patient. Air will flow out of the concentrator oxygen outlet port, through the humidifier bottle adapter tube, into the humidifier bottle, and out the humidifier bottle outlet port to the patient.



Fig. 5-4 Oxygen flow with humidifier bottle

1. If the humidifier bottle is unfilled, remove cap from bottle.

2. Fill humidifier bottle with distilled water to the level indicated by the manufacturer.



Fig. 5-5 Remove the cap



Fig. 5-6 Fill the humidifier bottle

3. Thread the cap onto the humidifier bottle.



CAUTION!

Risk of Damage -Confirm the humidifier bottle cap is not cross-threaded on the humidifier bottle.



Fig. 5-7 Thread the cap onto the bottle



4. Using the adapter tube provided in the device packaging or by your provider, attach the humidifier bottle adapter tube to the humidifier bottle cap.

5. Turn the wing nut on the humidifier bottle counterclockwise until the adapter tube is securely fastened.



Fig. 5-9 Tighten the wing nut



Fig. 5-10 Install the bottle



Fig. 5-11 Connect the bottle tubing

6. Place the humidifier bottle in the recessed shelf on the concentrator. Secure with the elastic band.

- 7. Attach the humidifier bottle/adapter tube to the oxygen outlet connector on the concentrator.
 - ິງ When using tubing connections longer than 7 ft (2.1 m) in length, position the humidifier bottle as close to the patient as possible to allow for maximum humidification output.

For optional accessories, refer to 3.5 *Optional Accessories, page 13*.

8. Connect the nasal cannula. Refer to *5.4.2 Connecting/Positioning the Nasal Cannula, page 23.*

5.4.2 Connecting/Positioning the Nasal Cannula



DANGER! Risk of Injury or Death

The cannula can cause tripping, falling, or other injury if improperly positioned and secured. To avoid injury or death:

-The cannula MUST be routed and secured properly.

-DO NOT position the cannula around the neck. Ensure the patient can move freely while wearing the cannula.

-Avoid positioning cannulas across areas of high foot traffic (i.e. aisles, doorways, hallways, etc.)

\triangle

WARNING! Risk of Injury or Death

To avoid choking and/or strangulation from tubing entanglement:

-Keep children and pets away from nasal cannula and tubing.

-Close supervision is necessary when the nasal cannula is used by impaired individuals or near children and/or impaired individuals.



WARNING!

Risk of Injury or Death

To reduce the risk of injury or death from illness:

-Replace the nasal cannula on a regular basis. Check with your home care provider or physician to determine how often the cannula should be replaced.

-DO NOT share cannulas between patients. Cannulas are for single patient use only.



CAUTION!

Risk of Minor Injury or Discomfort

To ensure proper oxygen delivery:

-Ensure the cannula prongs are positioned properly in your nose. This is critical to the effectiveness of the oxygen therapy.

-DO NOT use tubing/cannula length exceeding 15 m (50 ft).

-DO NOT place tubing on a cold floor when using a humidifier bottle, or condensation could occur and travel to your nasal passages.

-Use crush-proof oxygen tubing.

-Check for oxygen flow at the outlet of the cannula.



Fig. 5-12 Concentrator without Humidifier Bottle



Fig. 5-13 Concentrator with Humidifier Bottle

- 1. Remove the cannula from its packaging.
- 2. Perform one of the following:
 - For use without a humidifier bottle—Attach the patient's nasal cannula supply tube [®] to the oxygen outlet connector [©] on the concentrator.
 - For use with a humidifier bottle—Attach the patient's nasal cannula supply tube ^(B) to the humidifier bottle outlet ^(D).
- 3. After assembly, turn on the concentrator. Refer to 5.4.3 Turning the Concentrator On, page 24

WARNING!

Risk of Injury or Damage

Failure to properly install the humidifier bottle or other accessories to the concentrator will impact the flow of oxygen.

5.4.3 Turning the Concentrator On





- 1. Plug in power cord to an electrical outlet.
- 2. Press the start/stop button (A) on the display to turn the unit on.
 - ງິ The panel lights will come on and the concentrator will beep, confirming that the indicators are functioning properly. The start/stop button LED on the display will remain on.

The start-up symbol will rotate clockwise and blue light will illuminate when the start/stop button is pressed. Allow between 5 and 30 minutes for the unit to achieve full oxygen concentration. When the device is ready, the check mark and green light will illuminate.

If the concentrator is moved into an ambient temperature of 68° F (20° C) after being stored at its minimum storage temperature of -13° F (-25° C) or at its maximum storage temperature of 158° F (70° C) it may take up to 20 minutes to begin operating.

5.4.4 Setting the Prescribed Flowrate



Risk of Minor Injury or Discomfort

It is very important to select the prescribed oxygen flow setting. This will ensure you will receive the therapeutic amount of oxygen according to your medical condition.

-DO NOT increase or decrease the L/min flow setting unless a change has been prescribed by your physician or therapist.

-The therapeutic effectiveness of the prescribed oxygen flow setting should be periodically reassessed.

-Use only the tubing and accessories that were used to determine the prescribed oxygen flow setting.







Fig. 5-16 Example - Setting and reading the flow rate at 2 L/min

- n Do not set the flow above the RED line (E). An oxygen flow greater than 5 L/min will decrease the oxygen concentration.
- 1. Turn the flow knob A to the setting prescribed by your physician or therapist -
 - CLOCKWISE Decrease the flow rate.
 - COUNTERCLOCKWISE Increase the flow rate
 - j To properly set the flowmeter [®], locate the prescribed flowrate line on the flowmeter. Next, turn the flow knob until the ball [©] rises to the line. Now, center the ball on the L/min line prescribed.
- If the flowrate on the flowmeter ever falls below 0.5 L/min D for more than one minute, the Potential Obstruction Alert will be triggered. This is a rapid beeping of the audible alarm. Check your tubing or accessories for blocked or kinked tubing or a defective humidifier bottle. After flowrate is restored to above 0.5 L/min, the Potential Obstruction Alert will turn off.
 - n A Potential Obstruction Alert indicates a condition that may be associated with a partial or complete obstruction of oxygen output.

The use of some accessories such as the $PreciseR_X^{\text{TM}}$ pediatric flowmeter and the HomeFill compressor will deactivate the Potential Obstruction Alert.

5.4.5 Checking the Oxygen Flow Out of the Cannula

Use one of these procedures to check for oxygen flow through the cannula.

Checking with Your Hand

- 1. Ensure the concentrator is on. Refer to 5.4.3 Turning the Concentrator On, page 24.
 - $\hat{\parallel}$ Oxygen flow can be checked while the concentrator is starting up.
- 2. Wave your hand in front of the nasal prongs. Check for the flow of oxygen on your hand.
 - Flow of oxygen—Place the cannula over your ears and position the prongs in your nose as instructed by your home care provider or cannula manufacturer.
 - No Flow of oxygen —Check all cannula connections (including humidifier bottle and accessories, if applicable) and repeat the procedure. Check with water (see next procedure) if you do not feel the flow of oxygen.



Fig. 5-17 Testing Oxygen Flow with Your Hand

Checking with Water

- 1. Ensure the concentrator is on. Refer to 5.4.3 Turning the Concentrator On, page 24.
 - $\hat{\parallel}$ Oxygen flow can be checked while the concentrator is starting up.
- 2. Place the end of the nasal cannula under the surface of a half-full cup of water
- 3. Look for bubbles indicating oxygen flow out of the nasal prongs:
 - Bubbles are present—Wipe off the nasal prongs. Place the cannula over your ears and position the prongs in your nose as instructed by your home care provider or cannula manufacturer.
 - No bubbles—Check all cannula connections (including humidifier bottle and accessories, if applicable) and repeat the procedure. Contact a provider if bubbles are not present.



Fig. 5-18 Testing Oxygen Flow with Water

5.4.6 Oxygen Concentration Indicator

This feature monitors the concentration of oxygen generated by the oxygen concentrator. If concentration falls below factory preset standards, indicator lights on the control panel (e.g. red or yellow) will illuminate. The symbol and error code associated with the condition will appear on the display. Refer to *8 Troubleshooting, page 35* for information about error codes.

5.4.7 Initial Start-up of the Concentrator

j Concentrator may be used during the initial start-up time (generally between 5-30 min.) while waiting for the oxygen concentration to reach an appropriate minimum concentration.

When the unit is turned on, the blue light will illuminate and the start-up symbol on the display will appear, indicating the unit is operating and is in the initial start-up period. When the green light comes on and a check mark is displayed on the display, the unit is in normal operating mode and has reached an oxygen concentration of greater than 82%. Once in normal operating mode, the lights will be controlled depending on the oxygen concentration values.

5.4.8 Elapsed Time Meter (Hour Meter)

The run time hours can be seen by pressing the Menu button to highlight the Run Time Hours icon. The display will show the cumulative number of hours the unit has operated.

The per user run time hours can be seen by pressing and holding the Menu button for at least 3 seconds.

Refer to 3.2 Display, page 10 for the location and description of the icons.

6 Maintenance

6.1 Service Life

The expected service life of this product is five years of operation when used in accordance with the safety instructions, maintenance intervals and correct use, stated in this manual. The effective service life can vary according to frequency and intensity of use. Refer to the procedures in this chapter.

6.2 Cleaning the Cabinet



DANGER! Risk of Injury or Damage

Invacare oxygen concentrators are specifically designed to minimize routine preventative maintenance. To prevent injury or damage:

- -Only qualified personnel should perform preventative maintenance on the oxygen concentrator.
- -DO NOT remove cabinet.



DANGER!

Risk of Injury or Damage

Liquid will damage the internal components of the concentrator. To avoid damage or injury from electrical shock:

- -Turn Off the concentrator and unplug the power cord before cleaning.
- -DO NOT allow any cleaning agent to drip inside the air inlet and outlet openings.
- -DO NOT spray or apply any cleaning agent directly to the cabinet.
- -DO NOT hose down the product.



CAUTION! Risk of Damage

Harsh chemical agents can damage the concentrator. To avoid damage: -DO NOT use products that contain ammonia on the brass patient outlet fitting.

At a minimum, preventative maintenance MUST be performed according to the maintenance record guidelines. In places with high dust or soot levels, maintenance may need to be performed more often.
 Refer to 1.1 preventative Maintenance Checklist, page 1.

Periodically clean the concentrator's cabinet as follows:

- 1. Use a damp cloth, or sponge, with a mild detergent such as Dawn dish washing soap to gently clean the exterior case.
- 2. Allow the concentrator to air dry, or use a dry towel, before operating the concentrator.

6.3 Disinfecting the Cabinet

The following disinfectants have been evaluated and may be used to disinfect the concentrator's cabinet:

- Barbacide
- Virex II 256
- MadaCide-FD
- Ethyl Alcohol (Up to 95%)
- Isopropyl Alcohol (Up to 99%)
 - \hat{n} Follow the manufacturer's disinfecting instructions for each disinfectant.

6.4 Cleaning the Cabinet Filter



CAUTION! Risk of Damage

To avoid damage to the internal components of the unit:

-DO NOT operate the concentrator without the filter installed or with a dirty filter.



CAUTION! Risk of Damage

To avoid breaking the filter assembly: -DO NOT remove the filter material from the filter holder.

 $\hat{\eta}$ There are two cabinet filters, one located on each side of the cabinet.

There are two ways to clean the cabinet filter:

- Vacuum the filter.
- Remove the filter door assembly and wash the filter.

6.4.1 Vacuum the Filter

- 1. Use the vacuum hose to remove the dirt from the filter.
- 2. If the dirt is not removed with the vacuum, follow the instructions in the next procedure for washing the filter.

6.4.2 Washing the Filter



Fig. 6-1 Washing the Filter

- 1. Press the filter assembly on both sides of the concentrator and slide up to remove to clean as needed.
 - j Environmental conditions that may require more frequent inspection and cleaning of the filter include, but are not limited to: high dust, air pollutants, etc.
- 2. Clean the cabinet filter assembly with a vacuum cleaner or wash with a mild liquid dish detergent (such as Dawn) and water. Rinse thoroughly. Thoroughly dry the filter assembly .
- 3. Inspect for fraying, crumbling, tears, and holes. Replace filter assembly if any damage is found.
- 4. Reinstall the cabinet filter assembly on both sides of the concentrator.

6.5 Humidifier Bottle Cleaning and Thermic Disinfection

- <u>1</u> Clean and disinfect the oxygen humidifier bottle daily to reduce limestone deposits and eliminate possible bacterial contamination. Follow the instructions provided by the manufacturer. If none are provided, follow these steps:
- 1. Wash humidifier bottle in soapy water and rinse with a solution of ten parts water and one part vinegar.
- 2. Rinse thoroughly with hot water.
- 3. Air dry thoroughly.
 - j To limit bacterial growth, air dry the humidifier bottle thoroughly after cleaning when not in use. Refer to 5.4 Setting Up the Concentrator, page 20.

6.6 Preventative Maintenance - Patient Checklist

Use the table below for routine maintenance.

| | Frequency | | |
|---|-----------|--------|-----------------------|
| | Daily | Weekly | Monthly |
| Clean Humidifier Bottle (if prescribed) | ✓ | | |
| Check that the fire break (if provided) is installed between the cannula and extension tubing | ~ | | |
| Clean humidifier bottle tubing and connector (if prescribed) | | ✓ | |
| Clean cannula/mask and tubing | | ✓ | |
| Clean cabinet filter | | ✓ | |
| Clean cabinet | | | ✓ |

6.7 For Providers and Service Technicians

6.7.1 Preventative Maintenance and Cleaning/Disinfection Between Patients



WARNING!

Risk of Injury or Damage

To prevent injury from infection or damage to concentrator: -Only qualified personnel should perform cleaning and disinfection of the oxygen concentrator and accessories between patients.

j Follow these instructions to eliminate possible pathogen exchange between patients due to contamination of components or accessories. Preventative maintenance should also be performed at this time if necessary.

Estimated Life and Replacement/Cleaning Intervals

| Component Estimated Life | | Replacement or Cleaning Interval | | |
|----------------------------|-------------------------|---|--|--|
| Cabinet Filter | 3 years or 26,280 hours | Clean/replace every 3 years or between patients | | |
| Compressor Inlet Filter | 3 years or 26,280 hours | Inspect/replace every 3 years or between patients | | |
| Patient Outlet HEPA Filter | 3 years or 26,280 hours | Replace every 3 years or between patients | | |

- j Estimated life and replacement/cleaning intervals can vary due to environmental conditions such as high dust, air pollutants, etc.
- 1. Dispose of and replace all patient side accessories not suitable for multiple patient use, including but not limited to:
 - Nasal Cannula and Tubing
 - Mask
 - Humidifier Bottle
 - User Manual
- 2. Perform maintenance and disinfecting procedures described in this manual and items on the 6.6 *Preventative Maintenance Patient Checklist, page 31* and 6.7.2 *Preventative Maintenance Provider Checklist and Record, page 33*.
- 3. Check concentrator for possible external damage or signs that it may require service or repair.
- 4. Ensure concentrator functions properly and all alarms are in working order.
- 5. Before repackaging and distribution to new patient, ensure packaging contents contain the concentrator and user manual.

6.7.2 Preventative Maintenance - Provider Checklist and Record

Perform the maintenance tasks in the table at each patient visit.

Check the box and enter data/notes for each maintenance task performed.



SN

- □ Check/replace humidifier bottle (if prescribed)
- □ Check that the fire break (if installed) is installed between the cannula and extension tubing
- □ Check/replace humidifier bottle tubing and connector (if prescribed)
- Check/replace cannula/mask and tubing
- Check/clean or replace cabinet filter(s)
- Inspect cabinet for damage
- Check/replace compressor inlet filter
- Check/replace patient outlet HEPA filter
- Record run time hours (total and per user)
- Check oxygen concentration (Green light)
- Check error code
- □ Check audible/LED indicators
- □ Ask patient for flow rate (L/min)
- □ Ask patient for use time (h/day)
- Check concentrator location
- Check concentrator environment

7 After Use

7.1 Recycling Information



This product may contain substances that could be harmful to the environment if disposed of in places (landfills) that are not appropriate according to legislation.

Follow local governing ordinances and recycling plans regarding disposal of the concentrator or components normally used in operation. The concentrator does not generate waste or residue in operation.

- DO NOT dispose of the concentrator in the normal waste stream.
- Any accessories not part of the concentrator MUST be handled in accordance with the individual product marking for disposal.

7.2 Wear and Tear

Invacare reserves the right to ask for any item back that has an alleged defect in workmanship. See Warranty that shipped with the product for specific warranty information.

Refer to this user manual for proper preventative maintenance schedule and use of the product.

This is just a general guideline and does not include items damaged due to abuse and misuse.

Normal wear and tear items and components for this product are listed below.

- All types of filters
- All types of tubing
 - j Sieve is a porous filtering material and is considered a wear item. Some factors that could affect sieve material life include humidity, temperature, particulates, air contaminants, air intake, vibration and other environmental conditions.

8 Troubleshooting

8.1 Troubleshooting Label

The Troubleshooting Guide Label is on the side of the device. The Troubleshooting Label covers the most common issues. Refer to 8.3 Alarm and Notification Types, page 36 and 8.4 Error Codes, page 37 for full details.

- 1. If there is an issue, the Alert indication (exclamation point and yellow light) or Alarm indication (X and red light) illuminate. Check the following items:
 - A Check the cannula for kinks, blockages, or obstructions.
 - ^(B) Check the filter. Clean the filter, if dirty.
- 2. If there is low or restricted oxygen flow, check the following items:
 - A Check the cannula for kinks or damage.
 - © Check the humidifier bottle. Ensure the cap is tightened securely. Check the cannula connection to the bottle.
 - D Check the cannula. Check that there is airflow through the cannula. Check the connection to the device.
- 3. If the device continues to have an issue or oxygen flow is low, check the troubleshooting section of the user manual. Refer to *8 Troubleshooting, page 35*.



8.2 Muting the Alarms



Press the Mute button to mute alerts and alarms.

 $\underline{\mathring{n}}$ Pressing the mute button will only silence the alarm for 24 hours if the alarm condition remains active during that time. If the alarm clears and returns, the alarm will sound. If a new alarm occurs the alarm will sound.

8.3 Alarm and Notification Types

 $\hat{\eta}$ All alarms generated are defined as low priority alarms.

The following table contains general descriptions and solutions for the categories of alarms.

| Туре | Error Code | Solution | Symbol | Indicator Light Color | Sound Indication |
|---------------------|---------------|--|--------|---------------------------|------------------------------|
| | | Check if flowmeter is set between 1.0-5.0 L/min | | | |
| | | Inspect cabinet filter Inspect for kinks or blockages (kinked cannula, blocked vents, etc.) | | White with | Beeping |
| Running Alarms | LXXXX | | | | |
| AldTITS | | 4. Restart unit using stop/start button | | yellow dot | |
| | | Ensure device is in specified operating environment | | | |
| | | m m m m m m m m m m m m m | | | |
| | нхххх | Check if flowmeter is set between 1.0-5.0 L/min | | White with red dot | Constant Audible Alarm |
| | | 2. Inspect cabinet filter | | | |
| Shut Down Alarms | | Inspect for kinks or blockages (kinked cannula, blocked vents, etc.) | X | | |
| Aldrins | | 4. Restart unit using stop/start button | | | |
| | | Ensure device is in specified operating environment | | | |
| | | m m m m m m m m m m m m m | | | |
| Notifications | LXXXX | Contact provider for service | /. | White with blue dot | N/A |
8.4 Error Codes

The following table contains detailed descriptions and solutions for the error codes and alarms.

| Alarm | Error Code | Solution | | Indicator Light Color | Sound Indication | |
|---|---------------|--|---|--------------------------------|--|--|
| Running Alarms | | | | | | |
| | | 1. Check if flowmeter is set between 1.0-5.0 L/min | | | | |
| | | 2. Inspect cabinet filter | | White with yellow dot | Single audible beep with | |
| Potential Obstruction Alert | L1000 | Inspect for kinks or blockages (kinked cannula, blocked vents, etc.) | • | | less than 2 second interval. | |
| | | If alarm is still present, contact provider | | | | |
| Oxygen Sensor Heater Open Failure | L2000 | | | | | |
| Oxygen Sensor Heater Short Failure | L2010 | 1. Restart unit using stop/start button | | White with yellow dot | Single audible beep wit less than 20 second interval. | |
| Oxygen Sensor Out of Range High Failure | L2020 | If alarm is still present, contact provider | | | | |
| Oxygen Sensor Out of Range Low Failure | L2030 | | | | | |
| | | 1. Check if flowmeter is set between 1.0-5.0 L/min | | | | |
| | L2040 | 2. Inspect cabinet filter | | White with yellow dot | Single audible beep with less than 20 second interval. | |
| Low Oxygen Concentration | | Inspect for kinks or blockages (kinked cannula, blocked vents, etc.) | | | | |
| | | 4. If alarm is still present, contact provider | | | | |
| | | 1. Check if flowmeter is set between 1.0-5.0 L/min | | | | |
| Low Oxygen Concentration Diagnostics | | 2. Inspect cabinet filter | | White with yellow dot | Single audible beep with | |
| | L204x | Inspect for kinks or blockages (kinked cannula, blocked vents, etc.) | | | less than 20 second interval. | |
| | | 4. If alarm is still present, contact provider | | | | |

| Alarm | Error Code | Solutio | Symbol | Indic Light | ator Color | Sound I | ndication | |
|---------------------------|---------------|----------------------------|---|----------------|------------------------------|---------|--------------------------|--------------------------------------|
| High Temperature Alert | L4000 | 2. Ensi ope 3. If al | Inspect for blocked vents Ensure device is in specified operating environment If alarm is still present, contact provider | | Whit with yello dot | 1 | less than | ole beep with 20 second erval. |
| Alarm | | Error Code | Solution | | S | Symbol | Indicator Light Color | Sound Indication |

Shut-Down Alarms

| Shut-Down Alarms | | | | | |
|---|-------|--|--------------|--------------------------|------------------------------|
| Power Loss 3 times in a row | H1000 | Restart unit using stop/start button If alarm is still present, contact provider | \mathbf{X} | White with red dot | Constant Audible Alarm |
| Low Oxygen Concentration Shut Down | H2040 | Check if flowmeter is set between 1.0-5.0 L/min Inspect cabinet filter Inspect for kinks or blockages (kinked cannula, blocked vents, etc.) If alarm is still present, contact provider | X | White with red dot | Constant Audible Alarm |
| Low Oxygen Concentration Shut Down Diagnostics | H204x | Check if flowmeter is set between 1.0-5.0 L/min Inspect cabinet filter Inspect for kinks or blockages (kinked cannula, blocked vents, etc.) If alarm is still present, contact provider | X | White with red dot | Constant Audible Alarm |
| Pressure Sensor Out of Range High | H3000 | Restart unit using stop/start button If alarm is still present, contact provider | \mathbf{X} | White with red dot | Constant Audible Alarm |
| Pressure Sensor Out of Range Low | H3010 | Restart unit using stop/start button If alarm is still present, contact provider | \mathbf{X} | White with red dot | Constant Audible Alarm |

| Alarm | Error Code | Solution | Symbol | Indicator Light Color | Sound Indication | |
|-------------------------------|---------------|--|-------------------|--------------------------|------------------------------|--|
| | | 1. Check if flowmeter is set between 1.0-5.0 L/min | | | | |
| | | 2. Inspect cabinet filter | | | _ | |
| High Pressure | H3020 | 3. Inspect for kinks or blockages (kinked cannula, blocked vents, etc.) | \mathbf{X} | White with red dot | Constant Audible Alarm | |
| | | 4. If alarm is still present, contact provider | | | | |
| High Presure Diagnostics | H302x | Contact provider/Refer to Service Manual | X | White with red dot | Constant Audible Alarm | |
| | | 1. Check if flowmeter is set between 1.0-5.0 L/min | | | | |
| | | 2. Inspect cabinet filter | | N /1 ·1 | Constant | |
| Low Pressure Diagnostics | H304x | Inspect for kinks or blockages (kinked cannula, blocked vents, etc.) | X Å | White with red dot | Audible Alarm | |
| | | 4. If alarm is still present, contact provider | | | | |
| | | 1. Inspect for blocked vents | | | | |
| High Temperature Shut Down | H4000 | 2. Ensure device is in specified operating environment | X | White with red | Constant Audible | |
| | | If alarm is still present, contact provider | | dot | Alarm | |
| Valve Coil Failure | H5000 | Restart unit using stop/start button | | White with red | Constant Audible | |
| | 115000 | 2. If alarm is still present, contact provider | Å | dot | Alarm | |
| Fan Not Connected | H6000 | 1. Restart unit using stop/start button | $\mathbf{\nabla}$ | White with red | Constant Audible | |
| | | 2. If alarm is still present, contact provider | | dot | Alarm | |
| Ean Spood Out of Pango | Ц6100 | 1. Restart unit using stop/start button | $\mathbf{\nabla}$ | White with rod | Constant Audible | |
| Fan Speed Out of Range | H6100 | 2. If alarm is still present, contact provider | X | with red dot | Alarm | |

| Alarm | arm Error Code Solution | | Symbol | Indicator Light Color | Sound Indication | |
|---|-------------------------|-------------|---|--------------------------|----------------------------|------------------------------|
| Calibration Failure | H700 | 00 | Restart unit using stop/start button If alarm is still present, contact provider | X | White with red dot | Constant Audible Alarm |
| Invalid State | H71(| 00 | Restart unit using stop/start button If alarm is still present, contact provider | X | White with red dot | Constant Audible Alarm |
| ງຳ x = numeric value (de | fined ir | n the s | service manual) | | | |
| Alarm | | Erro Cod | Solution | Symb | ol Indicator Light Colo | Sound or Indication |
| Notifications | | | | | | |
| Prediction Notification/Repla Sieve Bed | ice | L010 | 00 1. Contact provider for sieve bed replacement | / å | White with blue dot | N/A |
| Prediction Notification/Repla Compressor or Inlet Filter | ice | L011 | 1. Contact provider for compressor or inlet filter replacement | . | White with blue dot | N/A |

9 Technical Data

9.1 Specifications

| Electrical Requirements: | 120 VAC + 10, –15% (132 VAC/102 VAC), 60 Hz |
|---|---|
| Rated Current Input: | 3.0 A |
| Sound pressure level (typical) | < 44 dB(A) |
| Sound pressure level (per ISO 80601-2-69): | Max 60 dB(A) |
| Sound power level (per ISO 80601-2-69): | Max 60 dB |
| Altitude: | Up to 13,000 ft (3962 m) above sea level. While filling a HomeFill System: Up to 6,000 ft (1828 m) above sea level. Atmospheric Pressure Range: 101.3 kPa – 62.0 kPa |
| Oxygen Output Concentration Levels: | 87% to 96% at all patient flow rate settings <u>j</u> Concentration levels achieved after initial start-up period (between 5-30 minutes) |
| Maximum Outlet Pressure: | 5 psi ± 0.5 psi (34.5 kPa ± 3.45 kPa) |
| Flow Range: | 1 to 5 L/min (maximum). For flowrates less than 1 L/min, we recommend the use of the Invacare PreciseRx Pediatric Flowmeter (IRCPF16). |
| Potential Obstruction Alert: | 0 L/min to 0.5 L/min The concentrator detects a condition that may indicate a potential obstruction of the output oxygen. Rapid audible beeping alert (this alert is deactivated when accessories are connected) may be associated with flow setting of 0.5 L/min or less. |
| Power Consumption: | 245 W at ≤ 2 L/min 260 W at 2-3 L/min 285 W at > 3 L/min |
| Pressure Relief Mechanism Operational at: | 35 psi to 45 psi (242.3 kPa to 310.3 kPa) |
| Change in maximum recommended flow when back pressure of 7kPa is applied: | 0.7 L/min (Back Pressure of 7 kPa applied) |
| Filters: | Cabinet, Patient Outlet and Compressor Inlet |
| Safety System: | Current overload or line surge shutdown. High Temperature Alarm High Pressure Alarm |

| | Low Pressure Alarm Power Loss Alarm Oxygen Alarms Potential Obstruction Alert Refer to <i>8.4 Error Codes, page 37</i> for more information about the alarms. |
|--|---|
| Width: | 16 in ± 3/8 in (40.6 cm ± 1 cm) |
| Height: | 24 in ± 3/8 in (61 cm ± 1 cm) |
| Depth: | 12 in ± 3/8 in (30.5 cm ± 1 cm) |
| Weight: | ≤ 35 lbs (16 kg) |
| Shipping Weight: | ≤ 41 lbs (18.6 kg) |
| Operating Ambient Temperature and Humidity: | 50° F to 95° F (10° C to 35° C) at up to 60% non-condensing relative humidity |
| Cabinet: | Impact Resistant flame-retardant plastic cabinet that conforms to UL 94V–0 |
| Standards and Regulatory Listing: | Complying with AAMI ES60601-1, IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6, IEC 60601-1-11, CSA C22.2#60601-1, ISO 80601-2-69 |
| Placement: | No closer than 12 in (30.5 cm) from any wall, furniture, draperies or similar surfaces to assure sufficient air flow. Avoid deep pile carpets and heaters, radiators or hot air registers. Floor location only. No confined spaces (Example: No closets). |
| Tubing: | 7 ft (2.1 m) cannula with a maximum 50 ft (15 m) of Crush-Proof Tubing (DO NOT pinch) |
| Time of Operation: | Up to 24 hours per day |
| Recommended Storage and Transport Temperatures: | -13° F to 158° F (-25° C to 70° C) |
| Recommended Storage and Transport Humidity: | Up to 90% non-condensing relative humidity for temperatures of 41° F to 95° F (5° C to 35° C) Water vapor pressure up to 1.48 inHg (50 hPa) for temperatures of > 95° F (35° C) to 158° F (70° C) |
| Applied Parts per ISO 80601-2-69:2014: | Output oxygen gas Oxygen outlet* Cannula |

| 1 |
|--|
| Humidifier Bottle/water |
| Flowmeter |
| Control Panel/Display/Buttons* |
| Shroud/Base |
| Power Cord |
| Circuit Breaker Switch |
| Casters/Pegs |
| * Temperatures of these parts under a single fault condition of blocked air inlets can reach 144° F (62° C). |

<u>j</u> Measurement uncertainty is included in the device specification. All conditions at STPD (standard temperature and pressure, dry).

9.2 Electromagnetic Compatibility (EMC)

The Platinum[®] 5NXG Concentrator requires special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in these accompanying documents.

Guidance and manufacturer's declaration—electromagnetic emission

The Platinum[®] 5NXG Concentrator is intended for use in the electromagnetic environment specified below. The customer or the user of the Platinum[®] 5NXG Concentrator should assure that it is used in such an environment.

| Emissions test | Compliance | Electromagnetic environment - guidance |
|--|------------|--|
| RF emissions CISPR 11 | Group I | The Platinum [®] 5NXG Concentrator 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 | |
| Harmonic emissions IEC 61000-3-2 | Class A | The Platinum [®] 5NXG 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 |
| Voltage fluctuations IEC 61000-3- 3 | Complies | purposes. |

Guidance and manufacturer's declaration—electromagnetic immunity

The Platinum[®] 5NXG Concentrator is intended for use in the electromagnetic environment specified below. The customer or the user of the Platinum[®] 5NXG Concentrator should assure that 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 | +8kV contact +15kV air | +8kV contact +15kV 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 Fasttransient / burst IEC 61000-4-4 | +2kV for power supply lines | +2kV for power supply 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(2) ± 2 kV line(s) to earth | ± 1 kV line(s) to line(2) ± 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 | 0 % U_T ; 0,5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U_T ; 1 cycle and 70 % U_T ; 25/30 cycles h) Single phase: at 0° 0 % U_T ; 250/300 cycle | 0 % U_T ; 0,5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U_T ; 1 cycle and 70 % U_T ; 25/30 cycles h) Single phase: at 0° 0 % U_T ; 250/300 cycle | Mains power quality should be that of a typical commercial or hospital environment. If the user of the Platinum [®] 5NXG Concentrator requires continued operation during power mains interruptions, it is recommended that the Platinum [®] 5NXG Concentrator be powered from an uninterruptible power supply or a battery. | | | | | |
| Power frequency (50/60 Hz) 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 commercial or hospital environment. | | | | | |
| U _T is the a. c. m | U _T is the a. c. mains voltage prior to application of the test level. | | | | | | | |

Guidance and manufacturer's declaration—electromagnetic immunity

The Platinum[®] 5NXG Concentrator is intended for use in the electromagnetic environment specified below. The customer or the user of the Platinum[®] 5NXG Concentrator should assure that it is used in such an environment.

| Immunity test | IEC 60601 test level | Compliance level | Electromagnetic environment – guidance | Immunity test |
|--------------------------------------|---|---|--|--|
| Conducted RF IEC 61000-4- 6 | 3 Vrms 0,15 MHz – 80 MHz 6 Vrms in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz | 3 Vrms 0,15 MHz – 80 MHz 6 Vrms in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz | Portable and mobile RF communi equipment should be used no clo of the Platinum [®] 5NXG Concentra the recommended separation dis equation applicable to the freque Recommended separation distant d = [3.5/10] VP 80 MHz to 800 MH d = [7/10] VP 800 MHz to 2.7 GHz | ser to any part ator, including cables, than tance calculated from the ency of the transmitter. ce Hz |
| Radiated RF IEC 61000-4- 3 | 10 V/m 80 MHz to 2.7 GHz | 10 V/m 80 MHz to 2.7 GHz | where <i>P</i> is the maximum output p transmitter in watts (W) accordin manufacturer and <i>d</i> is the recomm distance in meters (m). Field stren transmitters, as determined by ar survey, ^a should be less than the co frequency range. ^b Interference ma equipment marked with the follow | g to the transmitter mended separation ngths from fixed RF n electromagnetic site ompliance level in each ay occur in the vicinity of |

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

 Field strengths 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 Platinum[®] 5NXG Concentrator is used exceeds the applicable RF compliance level above, the Platinum[®] 5NXG 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 Platinum[®] 5NXG Concentrator.

Guidance and manufacturer's declaration—electromagnetic immunity

The Platinum[®] 5NXG Concentrator is intended for use in the electromagnetic environment specified below. The customer or the user of the Platinum[®] 5NXG Concentrator should assure that it is used in such an environment.

| Immunity test | IEC 60601 test level | Compliance level | Electromagnetic environment – guidance | Immunity test |
|--|--|---|--|---|
| IMMUNITY to proximity fields from RF wireless communications equipment | $\begin{array}{r} MHz-\\Modulation-\\Field\\Strength\\385-18Hz-27\\V/m\\450-18Hz-28\\V/m\\710-217Hz-9\\V/m\\745-217Hz-9\\V/m\\780-217Hz-9\\V/m\\810-18Hz-28\\V/m\\870-18Hz-28\\V/m\\870-18Hz-28\\V/m\\930-18Hz-28\\V/m\\1720-217Hz-28V/m\\1720-217Hz-28V/m\\1845-217Hz-28V/m\\1845-217Hz-28V/m\\1970-217Hz-28V/m\\1970-217Hz-28V/m\\1970-217Hz-28V/m\\1970-217Hz-28V/m\\1970-217Hz-28V/m\\1970-217Hz-28V/m\\5240-217Hz-29V/m\\5500-217Hz-9V/m\\5500-217Hz-99V/m\\5785-217Hz-99V/m\\5785-217Hz-99V/m\\5785-217Hz-99V/m\\5785-217Hz-99V/m\\5785-217Hz-99V/m\\5785-217Hz-99V/m\\5785-217Hz-99V/m\\5785-217Hz-99V/m\\5785-217Hz-99V/m\\5785-217Hz-99V/m\\5785-217Hz-99V/m\\5785-217Hz-99V/m\\5785-217Hz-99V/m\\5785-217Hz-99V/m\\5785-217Hz-99V/m\\5785-217Hz-99V/m\\5785-217Hz-99V/m\\5785-217Hz-99V\\10$ | MHz – Modulation – Field Strength 385 - 18 Hz - 27 V/m 450 - 18 Hz - 28 V/m 710 - 217 Hz - 9 V/m 745 - 217 Hz - 9 V/m 780 - 217 Hz - 9 V/m 810 - 18 Hz - 28 V/m 870 - 18 Hz - 28 V/m 930 - 18 Hz - 28 V/m 930 - 18 Hz - 28 V/m 1720 - 217 Hz - 28 V/m 1845 - 217 Hz - 28 V/m 1845 - 217 Hz - 28 V/m 1970 - 217 Hz - 28 V/m 2450 - 217 Hz - 28 V/m 5240 - 217 Hz - 9 V/m 5500 - 217 Hz - 9 V/m | Portable and mobile RF comm equipment should be used no of the Platinum® 5NXG Concer than the recommended separa calculated from the equation a frequency of the transmitter. Recommended separation dist $E = [6/d] \lor P$ $d = [6/E] \lor P$ where <i>P</i> is the maximum output transmitter in watts (W) accord manufacturer and <i>d</i> is the reco distance in meters (m). Field st transmitters, as determined by site survey, should be less than each frequency range.Interference vicinity of equipment marked of symbol: | closer to any part ntrator, including cables, ation distance applicable to the ance to power rating of the ding to the transmitter ommended separation crengths from fixed RF y an electromagnetic the compliance level in ence may occur in the with the following |

NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Recommended separation distances between portable and mobile RF communications equipment as well as RF wireless communications equipment the Platinum[®] 5NXG Concentrator

The Platinum[®] 5NXG Concentrator is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Platinum[®] 5NXG Concentrator can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Platinum[®] 5NXG Concentrator as recommended below, according to the maximum output power of the communications equipment.

| | Separation distance according to frequency of transmitter [m] | | | |
|--|---|--|--|--|
| Rated maximum output of transmitter [W] | 80 to 800 MHz d = [3.5/10] VP | 800 MHz to 2.7 GHz d = [7/10] VP | 710, 745, 780, 5240, 5500, 5785 d = [6/9] √P | 385, 450,810, 870, 930, 1720, 1845, 1970, 2450 d = [6/28] √P |
| 0.01 | 0.035 | 0.070 | 0.067 | 0.021 |
| 0.1 | 0.110 | 0.221 | 0.211 | 0.070 |
| 1 | 0.350 | 0.700 | 0.667 | 0.214 |
| 10 | 1.107 | 2.213 | 2.108 | 0.700 |
| 100 | 3.500 | 7.000 | 6.670 | 2.143 |

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.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Contact Information

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