

Invacare 1.7L (M9) Cylinder With Continuous Flow Regulator

For HomeFill® Oxygen System

en **HF2RE9ES**
User Manual

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



Yes, you can.®

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1 General

1.1 Symbols

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.



– Indicates a hazardous situation that could result in damage to property if it is not avoided.



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



Read the manual



No open flame



DO NOT Smoke



Oxidizer



Recycle



DO NOT dispose of in household waste



Manufacturer



EU Representative



This product complies with Directive 2002/96/CE concerning medical devices.

The launch date of this product is stated in the CE declaration of conformity.

1.2 Intended Use

This cylinder assembly is intended to store, regulate, and deliver supplemental oxygen to patients who may have difficulty extracting oxygen from the air they breathe. It is for patients who would normally receive the oxygen via a nasal cannula. This device delivers USP 93±3% oxygen at a number of different flow settings and may increase the drying out of airways. The product is to be used as an oxygen supplement and is not intended to be life supporting or life sustaining.



DANGER!

Risk of Injury or Death

This product is to be used as an oxygen supplement and is not intended to be life-supporting 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.



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.

1.3 User Profile

No specific product knowledge or training is required, other than what is contained in this manual, to operate the product. It is not intended for supplying oxygen therapy during refilling. This product is intended to be used by or under adult supervision only after reading and understanding the instructions and warnings of this user manual.

Only personnel instructed and trained in the use of the HomeFill® cylinder assembly should operate this product.

The use of this product is limited to the oxygen patient. Cylinder assemblies **MUST** be used only by the oxygen patient and are not to be distributed to any other individual for any purpose.

This product is **NOT** to be used by patients who breathe through their mouths.

1.4 Service Life

The expected service life of the regulator is five years when used in accordance with the safety instructions, maintenance intervals and correct use stated in this manual. Refer to the Maintenance section.

The expected service life of the cylinder is based on testing the cylinder every ten years and using it in accordance with the safety instructions, maintenance intervals and correct use stated in this manual. Refer to the following procedures:

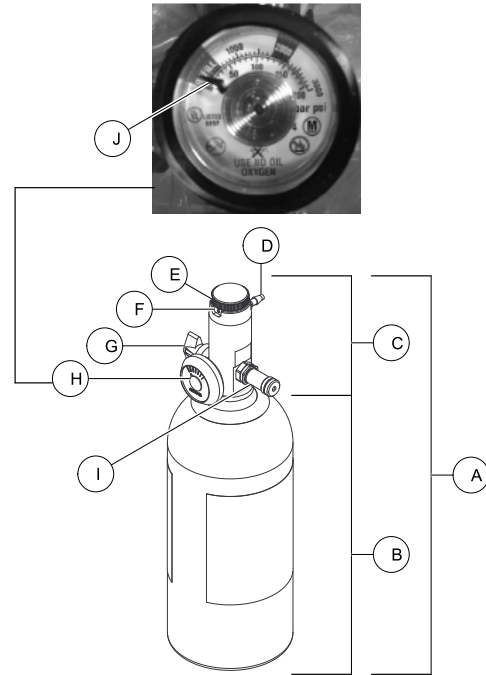
- The Hydrostatic Testing Date, External Examination, Maintenance

1.5 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.

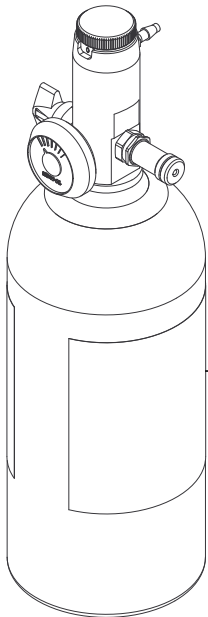
1.6 Component Identification

Item	Description
(A)	Cylinder Assembly
(B)	Cylinder
(C)	Continuous Flow Regulator
(D)	Outlet Connection
(E)	Flow Dial
(F)	Flow Setting Indicator Window
(G)	Shutoff Valve
(H)	Cylinder Gauge
(I)	Cylinder Fillport
(J)	Cylinder Gauge Needle



2 Safety

2.1 Label Locations



<p>GB UN1072 CLASS 2.1 OADR BADR 314-654-9 CAT III FSD</p>	<p>This cylinder is to be used with the Homeofil system. This cylinder contains 93% oxygen. Borne Diox. Pressure Relief at 208-231 Bar @ 22.2 °C</p> <ul style="list-style-type: none"> Maximum Fill Pressure 144.8 bar Keep away from combustible material. Keep cylinder in a well ventilated place. Keep free from oil and grease. 	<p>F UN1072 CLASS 2.1 OADR BADR 314-654-9 CAT III FSD</p>	<p>Cette bouteille doit être utilisée avec le système Homeofil. Cette bouteille contient 93 % de l'oxygène. Distance de pression de décharge de rupture à 208-231 bars à 22,2 °C</p> <ul style="list-style-type: none"> Pression de remplissage maximale 144,8 bars Tenir à l'écart des matières combustibles. Envelopper le récipient dans un endroit bien ventilé. Ne pas lubrifier à l'huile ou à la graisse. Le produit doit être utilisé pour assurer un complément d'oxygène et non pour servir d'appareil de réanimation et de maintien des fonctions vitales.
<p>CZ UN1072 CLASS 2.1 OADR BADR 314-654-9 CAT III FSD</p>	<p>This product is to be used as an oxygen supplement and is not intended to be life-supporting or life-sustaining. Borne Diox. Pressure Relief at 208-231 bar @ 22.2 °C</p> <ul style="list-style-type: none"> Maximum fill pressure 144.8 bar Keep away from combustible material. Keep cylinder in a well ventilated place. Maximum fill pressure 144.8 bar Lihevi nesti 144,8 bar Ne smeo biti u kontaktu sa materijom koja se zapaljuje. Ne koristiti za održavanje života. Proizak je namenjen samo kao dopuna kiseonika i ne treba koristiti kao sredstvo za održavanje života. 	<p>I UN1072 CLASS 2.1 OADR BADR 314-654-9 CAT III FSD</p>	<p>Questo prodotto va usato con il sistema Homeofil. Questo prodotto contiene 93 % di ossigeno. Pressione massima di riempimento 144,8 bar</p> <ul style="list-style-type: none"> Tenere lontano da sostanze combustibili. Mantenerlo in contenitori in zone ben ventilate. Non usare olio o grasso. È destinato non solo a essere usato come integrazione d'ossigeno e non va considerato come un dispositivo di supporto o di sostegno vitale.
<p>DK UN1072 CLASS 2.1 OADR BADR 314-654-9 CAT III FSD</p>	<p>This cylinder is to be used with the Homeofil system. This cylinder contains 93% oxygen. Borne Diox. Pressure Relief at 208-231 Bar @ 22.2 °C</p> <ul style="list-style-type: none"> Maximum Fill Pressure 144.8 bar Keep cylinder in a well ventilated place. Maximum fill pressure 144.8 bar Lihevi nesti 144,8 bar Ne smeo biti u kontaktu sa materijom koja se zapaljuje. Proizak je namenjen samo kao dopuna kiseonika i ne treba koristiti kao sredstvo za održavanje života. 	<p>NL UN1072 CLASS 2.1 OADR BADR 314-654-9 CAT III FSD</p>	<p>Cette bouteille doit être utilisée avec le système Homeofil. Cette bouteille contient 93 % de l'oxygène. Distance de pression de décharge de rupture à 208-231 bars à 22,2 °C</p> <ul style="list-style-type: none"> Pression de remplissage maximale 144,8 bars Tenir à l'écart des matières combustibles. Envelopper le récipient dans un endroit bien ventilé. Ne pas lubrifier à l'huile ou à la graisse. Le produit doit être utilisé pour assurer un complément d'oxygène et non pour servir d'appareil de réanimation et de maintien des fonctions vitales.
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Oxygen O₂



Serial number located above product label shown here.

2.2 General Guidelines

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



DANGER!

Risk of Death, Injury or Damage

- Improper use of this 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.



DANGER!

Risk of Death, Injury or Damage

- Use this cylinder in accordance with the HomeFill compressor user manual.
- DO NOT handle the cylinder assembly or use the contents until you are professionally trained, including emergency procedures. Training required to operate the product is contained in the user manual.
- This product is not intended for supplying oxygen therapy during refilling.
- This product is intended to be used by or under adult supervision.
- Oxygen Cylinders filled by the Invacare HomeFill oxygen system shall be used for personal use only. “Not to be filled for resale or use by professional users.”
- This cylinder is to be used with the Invacare HomeFill oxygen system. This cylinder contains 93±3% oxygen produced by an oxygen concentrator using the pressure swing adsorption process.
- ALWAYS open the valve slowly and close the valve after each use and when empty.

**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. To avoid fire, death, injury or damage:

- DO NOT SMOKE while using this product.
- DO NOT use near OPEN FLAME or IGNITION SOURCES.
- DO NOT use any lubricants on the cylinder unless recommended by Invacare.
- NO SMOKING signs should be prominently displayed.
- Avoid creation of any spark near oxygen equipment. This includes sparks from static electricity created by any type of friction.
- Keep all matches, lighted cigarettes, electronic cigarettes or other sources of ignition out of the room in which this cylinder is located and away from where oxygen is being delivered.
- Keep the oxygen tubing, cord, and cylinder 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.

**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.

Operating Information



DANGER!

Risk of Fire

Dirt or contaminants on the cylinder assembly or regulator can cause fire, injury or death.

- DO NOT use if dirt or contaminants are present on or around cylinder or regulator.
- DO NOT use or fill cylinder assembly if the cylinder fillport is dirty or contaminated. Contact your provider for service or repair.
- DO NOT allow oil from your hands or other sources to come into contact with the compressor coupling or cylinder assembly fittings. These substances may become flammable in the presence of oxygen and cause injury. Examples of items to avoid are hand cream or lotion, cooking oil, suntan oil or sunblock and similar oily products. If you use these types of products Invacare suggests you wash your hands prior to using the HomeFill system. If the cylinder fillport should come in contact with such substances, contact your provider for service. Avoid touching the cylinder fillport.



DANGER!

Risk of Fire

Dirt or contaminants on the cylinder assembly or regulator can cause fire, injury or death.

- NEVER oil or lubricate the compressor coupler or cylinder fillport. NEVER use any penetrating oil or lubricant such as WD-40® or 3-IN-ONE®. If connection difficulty is experienced, verify that the cylinder fillport is being inserted straight down into the compressor coupler. If continued difficulty is experienced, contact your provider for assistance.
- DO NOT clean with aromatic hydrocarbons, including, but not limited to benzene and toluene.

**DANGER!****Risk of Fire**

Dirt or contaminants on the cylinder assembly or regulator can cause fire, injury or death.

- DO NOT use cleaning/disinfecting solutions on the fillport fitting.
- DO NOT immerse product in any kind of liquid.
- DO NOT allow any kind of liquid to get inside openings of the regulator.
- DO NOT spray cleaning/disinfecting solutions on product.
- DO NOT autoclave.
- DO NOT gas sterilize with ethylene oxide.
- DO NOT attempt to repair cylinder assembly. All repairs **MUST** be performed by Invacare Corporation or in an Invacare approved repair center.
- Store cylinder assembly in a clean, dry and cool area when not in use.

**DANGER!****Risk of Injury or Death**

To avoid choking or ingestion of chemicals from airway contamination:

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

**WARNING!****Risk of Injury or Death**

Contaminants in the oxygen may cause injury or death.

- DO NOT use if the oxygen has an unusual odor.
- DO NOT use if particulates are inhaled.
- Contact Invacare or dealer for service.

**WARNING!****Risk of Injury or Damage**

To avoid injury or damage from product misuse:

- The flow dial should be turned with normal pressure from one's hand. If the flow dial is stiff to turn, do not force, otherwise damage could occur.
- DO NOT use a flow outlet for driving any medical equipment.



CAUTION!

Risk of Injury or Damage

- To reduce the risk of injury or damage from dropped or impacted cylinder assemblies:
- Use two hands when handling/transporting oxygen cylinders.
 - Only use Invacare Corporation carrying bag.
 - DO NOT allow cylinder assemblies to tip or fall. DO NOT drop cylinder assemblies.
 - Secure gas cylinders so they cannot fall.
 - Ensure cylinder is always in upright position when not connected to the HomeFill compressor.
 - DO NOT allow cylinders to impact inanimate objects.



CAUTION!

Risk of Damage

- To avoid product damage:
- DO NOT block the outlet fitting or kink the cannula when the product is in use, as this may damage the unit.
 - DO NOT fill the cylinder assembly outdoors or anywhere below 13°C (55°F).



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.)



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 or near children and/or disabled persons.

**WARNING!****Risk of Injury or Death**

To reduce the risk of injury or death from illness:

- Before the first patient use, the provider **MUST** disinfect the product. Refer to the Disinfecting section.
- Replace the nasal cannula on a regular basis. Check with your equipment provider or physician to determine how often the cannula should be replaced.
- **DO NOT** share cannulas between patients.



The cylinder poses no biocompatibility hazards and is latex and phthalate free. The biocompatibility of cylinder accessories may vary by manufacturer. Invacare accessories such as the cylinder bag and Invacare oxygen tubing are latex and phthalate free. Refer to the packaging on any cylinder accessories to determine the biocompatibility hazard.

The cylinder assembly **MUST** be emptied of gas prior to shipping by courier or postal service. Refer to Emptying the Cylinder Assembly.

Because the cylinder contains magnetic, ferrous material, it is not suitable to be in an MRI room.

Be sure all connections are tight and leak free. **DO NOT** use a liquid leak detector to test for leaks. Leaks are indicated by loss of pressure when the cylinder assembly is not in use and by hissing sounds. This product is equipped with a relief valve. If you hear a loud hissing or popping sound coming from the product, discontinue use of product, turn the flow dial to the “0” setting, and contact your dealer/Home Care equipment provider.

ALWAYS confirm prescribed dose before administering to patient and monitor on a frequent basis.

NO OXYGEN is delivered when the regulator flow dial setting is “0”.

DO NOT use a humidifier with this product.

Keep cylinder in a well ventilated place.

This product is designed to operate with a standard or high flow single lumen, adult oxygen nasal cannula with a maximum length of 2.1 m (7 ft).

The cannula is for single patient use only.

Cannula **MUST** be installed on outlet connection prior to use.

Refer to the HomeFill User Manual for additional warnings, cautions and safety instructions.

3 Setup

3.1 Dealer Setup

**WARNING!**

- Before the first patient use, the provider **MUST** disinfect the product. Refer to the Disinfecting section.
- Before patient use, the provider **MUST** check the hydrostatic testing date. Refer to the Hydrostatic Testing Date section.

**WARNING!****Risk of Injury**

- For medical applications, it is very important to select the prescribed level of oxygen flow. Uninterrupted use of high concentrations of oxygen over a long duration, without monitoring its effect on oxygen content of arterial blood, may be harmful.
- Use **ONLY** as directed by a licensed practitioner.
 - **DO NOT** increase or decrease the flow unless a change has been prescribed by your physician or therapist.

3.2 User Setup

**WARNING!**

- When receiving the cylinder assembly from the provider, the user/patient **MUST** perform a receiving inspection. Refer to the Receiving Inspection section.

3.3 Receiving Inspection

Remove product from package and inspect for damage. If there is any damage, **DO NOT** use. Contact your dealer/Home Care equipment provider.

3.4 Cylinder Prefill Inspection

**WARNING!****Risk of Injury or Damage**

- Oxygen cylinder assemblies shall be used for personal use only. Not to be filled for resale or use by professional users.
- Filling of cylinder assemblies is performed by Invacare HomeFill oxygen system only.
- This cylinder assembly is to be used with the HomeFill system. This cylinder contains 93±3% oxygen produced by an oxygen concentrator using the pressure swing adsorption process.
- **DO NOT** handle the cylinder assembly or use contents until you are professionally trained, including emergency procedures.
- Use this cylinder assembly in accordance with the HomeFill user manual.
- Open and close the shutoff valve slowly. Close the shutoff valve after each use and when empty.
- Secure the cylinder assembly during storage and use. **DO NOT** drop.
- No smoking in cylinder assembly area. Keep away from heat, flame or spark.
- Keep out of the reach of children.

**DANGER!****Risk of Injury or Death**

Improper filling or abuse of this cylinder assembly, or failure to follow these safety instructions may cause serious bodily injury or death. High pressure oxidizing gas vigorously accelerates combustion.

- DO NOT alter or modify cylinder assembly or related components.
- DO NOT use oil or grease. Keep cylinder, shutoff valve, all equipment and connections free of oil and grease to avoid violent ignition resulting in serious bodily injury or death.

3.4.1 The Hydrostatic Testing Date

Aluminum cylinders MUST undergo testing every ten years.

**DANGER!****Risk of Death, Injury or Damage from Fire**

To avoid fire, death, injury or damage:

- Cylinders that have been refinished and/or exposed to elevated temperatures MUST be hydrostatically tested before filling. Cylinder temperature should not exceed 60° C (140° F). Aluminum cylinders subject to the action of fire or heated temperatures in excess of 177° C (350° F) MUST be withdrawn from service and condemned by trained personnel. DO NOT use caustic paint strippers. Valve and safety relief devices MUST be removed and replaced by trained and authorized personnel. DO NOT alter or change valve assembly.
- All cylinders MUST be inspected before attempting to fill; otherwise, injury or damage may occur.

**WARNING!****Risk of Injury**

To reduce the risk of injury:

- DO NOT fill cylinders that have not been tested in the past ten years. Otherwise, serious personal injury may result. Contact your dealer/Home Care equipment provider for replacement.

3.4.2 External Examination



WARNING!

Risk of Injury or Damage

To reduce the risk of injury or product damage:

- DO NOT use the cylinder if any of the following items are found. Contact your dealer/Home Care equipment provider for replacement.

1. Examine the outside of the cylinder for the following conditions. If they exist, contact your provider for service.
 - Dents or dings, arc burns, oil or grease, any other signs of damage that might cause a cylinder to be unacceptable or unsafe for use
2. Examine the cylinder for evidence of fire or thermal damage. Evidence includes charring or blistering of the paint, or other protective coating or heat sensitive indicator. If fire or thermal damage is found, contact your dealer/Home Care equipment provider for a replacement.
3. Inspect the cylinder assembly for the following conditions. If they exist, contact your provider for a replacement.
 - Debris, oil or grease, noticeable signs of damage, signs of corrosion, signs of excessive heat or fire damage, signs of pressure leaks

4 Usage

4.1 Before Use



WARNING!

Risk of Injury or Damage

Defective or inoperable cylinders may cause injury or damage.

- All cylinders **MUST** be inspected before attempting to fill.
- If the cylinder is found to be defective or does not work properly, contact an Invacare dealer or qualified technician for service or replacement.

Before filling a cylinder assembly, read and follow the information in the following sections:

- Cylinder Prefill Inspection
- External Examination

4.2 Connecting/Disconnecting the Cylinder Assembly to/from the Compressor



Refer to the HomeFill Compressor user manual for operating instructions to connect and disconnect the cylinder to the HomeFill Compressor.

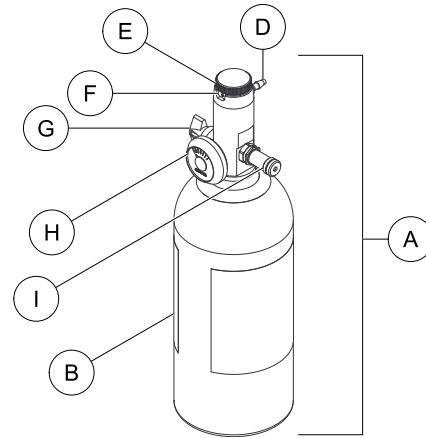
4.3 Cylinder Assembly Operation




DANGER!


Risk of Fire

- NEVER smoke in an area where oxygen is being administered.
- NEVER use near any type of flame or flammable/explosive substances, vapors or atmosphere.



1. Prior to each use, inspect product for visible damage. Refer to the External Examination section. DO NOT use if any damage is found.



 If for any reason, any label becomes illegible or lost, contact your dealer/Home Care equipment provider.

2. Inspect the cylinder gauge  to ensure the pressure is at least 1500 psig (10342 kPa). If below 1500 psig (10342 kPa), then refill the cylinder assembly using the HomeFill system.



WARNING!


– When needle on cylinder gauge enters red zone, it is recommended to refill the cylinder assembly on the Invacare HomeFill Compressor.


3. Position the cylinder assembly  so the outlet connection  is pointing away from the user and any other person(s).



WARNING!

Risk of Injury

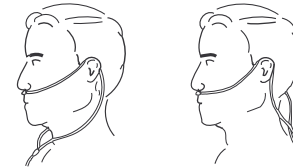
To reduce the risk of injury:
– DO NOT direct flow of oxygen at any person, or flammable material when adjusting the flow dial .

4. Turn the flow dial  to setting “0”.
5. Remove the outlet connection cap, if present.

6. Attach a standard or high flow single lumen adult oxygen nasal cannula with a maximum length of 2.1 m (7 feet) to the product’s outlet connection according to the cannula manufacturer’s instructions.



DO NOT use pediatric cannulas with this product.



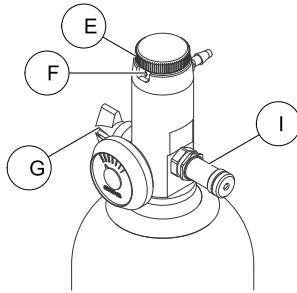
DANGER!

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.)

7. Place the cannula over your ears and position the prongs in your nose as instructed by your health care provider or cannula manufacturer.

8. Ensure there are no kinks or twists in the cannula tubing.



9. Slowly open the shutoff valve **G** fully.



Turn the shutoff valve **G** counterclockwise to open.

This will allow cylinder pressure to travel through the regulator.

10. Turn flow dial **E** until the prescribed setting is aligned with the flow indicator window **F**.



WARNING!

- To avoid injury to patient, ALWAYS confirm prescribed setting before administering to patient and monitor flow on a frequent basis.
- Only use the Invacare Corporation carrying bag.

11. Breathe through the nose and feel a flow of oxygen as you inhale.
12. When finished using the cylinder assembly, perform the following steps:

- a. Turn the flow dial **E** to setting “0”.
- b. Slowly close the shutoff valve **G** fully.



Turn the shutoff valve **G** clockwise to close.

5 Maintenance

5.1 Maintenance



WARNING!

Risk of Injury or Damage

Lack of product maintenance can lead to injury and loss of product function or damage.

- Maintenance **MUST** be performed **ONLY** by qualified personnel.
- Regular maintenance is necessary to assure proper operation.



WARNING!

Risk of injury or damage

- The cylinder assembly **MUST** be disconnected from the HomeFill and emptied of gas prior to cleaning or disinfecting. Refer to the Emptying the Cylinder Assembly section. The fillport cover **MUST** also be installed.
- All cylinders **MUST** be inspected before attempting to fill; otherwise, injury or damage may occur. Refer to the Cylinder Prefill Inspection section.



DANGER!

Risk of Fire

Dirt or contaminants on the cylinder assembly or regulator can cause fire.

- **DO NOT** use or fill cylinder assembly if the cylinder fillport is dirty or contaminated. Contact your provider for service or repair.
- **DO NOT** clean with aromatic hydrocarbons, including, but not limited to benzene and toluene.
- **DO NOT** use cleaning/disinfecting solutions on the fillport fitting.
- **DO NOT** immerse product in any kind of liquid.
- **DO NOT** allow any kind of liquid to get inside openings of the regulator.
- **DO NOT** spray cleaning/disinfecting solutions on product.
- All repairs **MUST** be performed by Invacare Corporation or in an Invacare approved repair center.

The cannula does not require maintenance and needs to be replaced at the manufacturer's recommended interval.

The aluminum cylinder must undergo hydrostatic testing every 10 years. Refer to The Hydrostatic Testing Date section.

5.2 Emptying the Cylinder Assembly



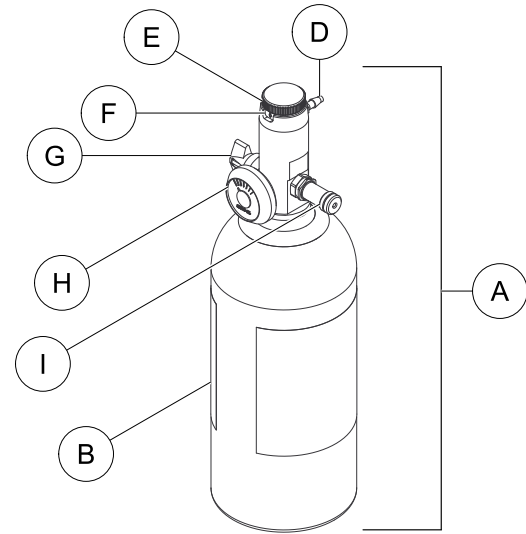
DANGER! Risk of Fire


- NEVER smoke in an area where oxygen is being administered.
- NEVER use near any type of flame or flammable/explosive substances, vapors or atmosphere.
- DO NOT direct flow of oxygen at any person, or flammable material when adjusting the flow dial.









CAUTION! Risk of Damage


- DO NOT completely empty the cylinder. Otherwise, damage to the cylinder could occur.



1. Position the cylinder assembly **A** so the outlet connection **D** is pointing away from the user and any other person(s).
2. Turn the flow dial **E** to setting “0”.
3. Slowly open the shutoff valve **G** fully.
 -  Turn the shutoff valve **G** counterclockwise to open.
4. Turn the flow dial **E** to setting “6”.

5. Examine the cylinder gauge  until the pressure is below 500 psig (3447 kPa).
 -  Cylinder pressure is below 500 psig (3447 kPa) when the cylinder gauge needle  is in the red zone.
6. Turn the flow dial  to setting “0”.
7. Close the shutoff valve  fully.
 -  Turn the shutoff valve clockwise to close.

5.3 Cleaning


-  Refer to the safety information in the Maintenance section before performing this procedure.

Follow the cleaning/disinfectant product manufacturer’s instructions for use, handling, storage and disposal of the product.

Follow this procedure to clean the cylinder assembly as required when visibly soiled.

1. Ensure the cover is installed on the fillport.
2. Clean exterior surfaces of the cylinder with a lint free cloth dampened with 70% isopropyl alcohol.
3. Clean the exterior surfaces of the regulator with a dry, lint free cloth.
4. If the regulator is still visibly soiled, clean with a lint free cloth dampened with 70% isopropyl alcohol. DO NOT wipe the fillport or outlet fitting.
5. Wipe the cylinder and regulator with a dry lint free cloth. Ensure the product is dry before using.

5.4 Disinfecting

-  Refer to the safety information in Maintenance before performing this procedure.

Follow the cleaning/disinfectant product manufacturer’s instructions for use, handling, storage and disposal of the product.

This procedure is for disinfecting the cylinder assembly and is to be performed by the provider prior to a patient change and as otherwise required. Recommended disinfectant products:

- Quaternary ammonium based wipes selected by the provider for the desired disinfecting characteristics
 - 70% isopropyl alcohol wipes
1. Ensure the cover is on the fillport.
 2. If heavily soiled, first clean the cylinder assembly. Refer to the Cleaning section.
 3. Use a wipe to disinfect the external surfaces of the regulator and cylinder. Follow the disinfectant manufacturer’s instructions. DO NOT wipe the fillport or outlet connection.
 4. Wipe the cylinder and regulator with a dry lint free cloth. Ensure the product is dry before using.

5.5 Reuse



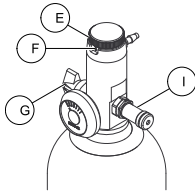
WARNING!

Before transferring the product to a different user, providers **MUST** inspect the product for damage and disinfect the product. Refer to the following procedures:

- Disinfecting, Cylinder Prefill Inspection, The Hydrostatic Testing Date, External Examination

The cylinder assembly can be transferred to a different patient. The cannula is for single patient use only.

5.6 Storage



1. Ensure the shutoff valve ③ is closed.
2. Ensure the flow dial ⑤ is turned to setting “0”.
3. Place the cover on the fillport ①.
4. Store product in a clean, dry and cool area free from grease, oil, and other sources of contamination.

5.7 Optional Accessories



WARNING!

Risk of Injury or Damage

Use of non-Invacare accessories may result in serious injury or damage.

- Invacare products are specifically designed and manufactured for use in conjunction with Invacare accessories. Accessories designed by other manufacturers have not been tested by Invacare and are not recommended for use with Invacare products.
- DO NOT use non-Invacare accessories.
- To obtain Invacare accessories, contact Invacare by phone or at www.invacare.com.

The following optional accessories are available for use with this product: HF2PC9BAG — Carrying Bag

6 After Use

6.1 Disposal

This product has been supplied from an environmentally aware manufacturer that complies with the Waste Electrical and Electronic Equipment (WEEE) Directive 2002/96/CE. 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 product or components normally used in operation. The device does not generate waste or residue in operation.

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

6.2 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 the Maintenance section for proper preventative maintenance schedule and use of the product.

7 Troubleshooting

7.1 Troubleshooting

If the Regulating Cylinder fails to function, consult the Troubleshooting guide. If problem cannot be corrected, consult your Dealer/Home Care equipment provider.

Problem	Possible Cause	Solution
No flow.	<ol style="list-style-type: none"> 1. Flow dial at setting "0". 2. Cylinder empty. 3. Flow dial is between settings. 4. Kinked or blocked cannula. 5. Shutoff valve closed. 	<ol style="list-style-type: none"> 1. Adjust flow dial to prescribed setting. 2. Fill or replace cylinder. 3. Set dial so indicator points to a setting. 4. Check to see if the cannula is kinked. 5. Slowly open shutoff valve.
Cylinder will not fill.	<ol style="list-style-type: none"> 1. Shutoff valve closed. 	<ol style="list-style-type: none"> 1. Slowly open shutoff valve.

8 Technical data

8.1 Technical Description

The Invacare HF2RE9ES Oxygen Continuous Flow Regulator & Cylinder Assembly is an oxygen storage product that can deliver up to 6 L/min of continuous flow oxygen to the patient via a nasal cannula. The cylinder assembly is designed to store compressed oxygen up to 14479 kPa (2100 psig). The continuous flow regulator reduces the pressure at the cannula connection to 345 kPa (50 psig) and contains a rotary flow dial that is used to adjust the oxygen flow rate to the prescribed setting. The cylinder assembly is filled with USP 93±3% oxygen using its proprietary fill port that allows filling only through the use of an Invacare HomeFill System. The duration of oxygen flow between fills is dependent on the size of the cylinder and the flow setting.

8.2 Specifications

Flows

Flow Type	Continuous
------------------	------------

Flow Setting	Flow Rate (L/min)
0	0
.25	0.25 ± 0.075
.5	0.5 ± 0.10
.75	0.75 ± 0.10
1	1.0 ± 0.10

1.5	1.5 ± 0.15
2	2.0 ± 0.20
2.5	2.5 ± 0.25
3	3.0 ± 0.30
3.5	3.5 ± 0.35
4	4.0 ± 0.40
4.5	4.5 ± 0.45
5	5.0 ± 0.50
5.5	5.5 ± 0.55
6	6.0 ± 0.60

Pressures

Inlet Pressure Range	2068–14479 kPa (300-2100 psig)
Max Fill Pressure	14479 kPa (2100 psig)
Internal Regulated Pressure	345 kPa (50 psig)
Safety Burst Disk	Integrated in Flow Delivery Device (Serviceable)
Burst Pressure	20856–23166 kPa at 22.2°C (3025–3360 psig at 72°F)

Environmental Operating Temperature Range

Operating Temperature Range	-20°C to 60°C (-2°F to 140°F)
Max Operating Humidity	95% RH
Max Altitude	3071 m (10,000 ft)
Storage Temperature Range	-40°C to 60°C (-40°F to 140°F)
Max Storage Humidity	95% RH

Assembly Dimensions


Diameter	11.1 cm (4.4 in)
Weight	2.31 kg (5.1 lb)
Overall Length	35.5 cm (14.1 in)

Cylinders

Cylinder Size	M9
Volume (H₂O)	1.7 L (0.061 ft ³)
Oxygen Capacity	255 L (9 ft ³)

Fill Times

2 h 20 min*	
*With Concentrator flow rates to patient:	
Concentrator Model	Concentrator Flow Rate
Platinum 5, Platinum S Series and Perfecto ₂ Series	Up to 2.5 L/min

Platinum 9	Up to 5 L/min
 All filling times are approximate and may vary on environmental conditions.	

Accessories

Single Lumen Cannula	1.21 m (4 ft) recommended. 2.1 m (7 ft) tubing length maximum.
Carry Bag	HF2PC9BAG

Regulatory Compliance

93/42/EEC - Medical Device Directive (Class 2b)
2014/68/EU - Pressure Equipment Directive (Category 3)
ISO 10524-3 (applicable sections)

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