

## Invacare<sup>®</sup> HomeFill<sup>®</sup> System

HF2ECE9, HF2ECE6

Oxygen Conserving Cylinders 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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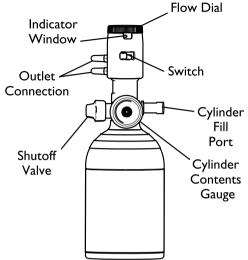
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## General

### I.I Intended Use

This cylinder 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. The device delivers USP 93±3% oxygen at a number of different flow settings. It is intended to be used as an oxygen delivery device and may increase the drying out of airways.

### I.2 Features



## 2 Safety

## 2.1 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.

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

This product complies with Directive 93/42/EEC concerning medical devices.

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

## 2.2 General Guidelines

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### WARNING!

- 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 - OTHERWISE, INJURY OR DAMAGE MAY OCCUR.
  - GENERAL GUIDELINES contains important information for the safe operation and use of this product.

### **ACCESSORIES WARNING**

 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.

#### DANGER!

- This product is not intended as a life-sustaining or life-supporting device.
- DO NOT SMOKE while using this device. Keep all matches, lighted cigarettes or other sources of ignition out of the room in which this product is located and away from where oxygen is being delivered.
- NO SMOKING signs should be prominently displayed. Textiles and other materials that normally would not burn are easily ignited and burn with great intensity in oxygen enriched air. Failure to observe this warning can result in severe fire, property damage and cause physical injury or death.

 The information contained in this document is subject to change without notice.

### **Operating Information**

Cylinder MUST be emptied of gas prior to shipping by courier or postal service.

Only personnel instructed and trained in the use of the HomeFill Conserving Cylinder should operate this product.

Product contains magnetic, ferrous material that may affect the results of an MRI.

Be sure all connections are tight and leak free.

DO NOT use a liquid leak detector to test for leaks.

DO NOT autoclave.

DO NOT gas sterilize with ethylene oxide.

DO NOT clean with aromatic hydrocarbons, including, but not limited to benzene and toluene.

DO NOT attempt to repair product.

DO NOT immerse product in any kind of liquid.

Store product in a clean area when not in use.

Only use Invacare Corporation carrying bag.

NEVER smoke in an area where oxygen is being administered.

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

DO NOT use if dirt or contaminants are present on or around cylinder, valve, product or connecting devices.

NEVER use near any type of flame or flammable/explosive substances, vapours or atmosphere.

NO OXYGEN is delivered when the pointer is aligned with "O".

DO NOT block the outlet fitting or kink the cannula when the product is in use, as this may damage the unit.

The use of this device is limited to the oxygen patient. Cylinders 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.

DO NOT allow oil from your hands or other sources to come into contact with the compressor coupling or bottle fittings. These substances may become flammable in the presence of oxygen and cause injury. Avoid touching the bottle fitting whenever possible. Example of items to avoid are hand creams or lotions, cooking oils, suntan oils or sunblocks and similar oily products. If you use these types of products Invacare suggests you wash your hands prior to using the HomeFill unit. If the bottle fitting should come in contact with such substances it should be cleaned off with a dry cloth prior to connecting it to the compressor.

NEVER oil or lubricate the compressor coupler or bottle fittings. NEVER use any penetrating oil or lubricant such as WD-40<sup>®</sup> or 3-IN-ONE<sup>®</sup>. If connection difficulty is experienced, verify that the bottle fitting is being inserted straight down into the compressor coupler. If continued difficulty is experienced, contact your supplier for assistance.

DO NOT use a humidifier with this product.

DO NOT allow cylinders to tip or fall. Secure gas cylinders so they cannot fall. Ensure cylinder is always in upright position.

DO NOT store cylinders near sources of heat or flame.

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 selector to the "O" position, and contact your dealer/Home Care equipment provider.

DO NOT use while sleeping without consulting your healthcare provider.

This product is designed to operate with a standard or high flow dual 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.

DO NOT place the unit under clothing while in use. When this product is in use a small amount of oxygen is vented. Wearing the unit under clothing may saturate fabrics with oxygen and cause them

to burn rapidly if exposed to sparks or flame. It may take several hours for oxygen levels in fabrics to return to normal.

DO NOT use HomeFill compressor unit, to fill cylinder outdoors or anywhere below 13°C (55°F).

NEVER attempt to fill cylinder with anything other than the HomeFill compressor.

2.3 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 device 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.

## 3 Setup

## **3.1 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.

## **3.2 Cylinder Prefill Inspection**

- Refer to the HomeFill owner's manual for compressor
- operating instructions.

### DANGER!

- Improper filling or abuse of this cylinder, 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 or related components.
- DO NOT use oil or grease. Keep cylinder, cylinder valve, all equipment and connections free of oil and grease to avoid violent ignition resulting in serious bodily injury or death.

### WARNING!

 For medical applications, use only as directed by a licensed practitioner. Uninterrupted use of high concentrations of oxygen over a long duration, without monitoring its effect on oxygen content of arterial blood, may be harmful.

### WARNING!

- Oxygen cylinders filled by the HomeFill 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 HomeFill system. This cylinder contains 93±3% oxygen produced by an oxygen concentrator using the pressure swing adsorption process.
- DO NOT handle cylinder or use contents until you are professionally trained, including emergency procedures.
- Use this cylinder in accordance with the HomeFill owner's manual. Open valve slowly, Close valve after each use and when empty. Secure cylinder during storage and use. No smoking in cylinder area. Keep away from heat, flame or spark. Keep out of the reach of children. DO NOT drop.
- Filling of cylinder is performed by Invacare HomeFill oxygen system only.



### WARNING!

- Cylinders that have been refinished and/or exposed to elevated temperatures MUST be hydrostatically tested before filling. Cylinder temperature should not exceed 52° C (125° 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.
- NEVER smoke in an area where oxygen is being administered.
- NEVER use near any type of flame or flammable/explosive substances, vapours or atmosphere.

## 3.3 The Hydrostatic Testing Date

Aluminum cylinders MUST undergo testing every five years.

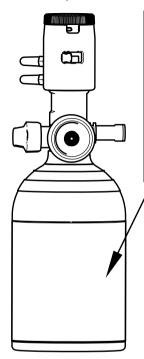
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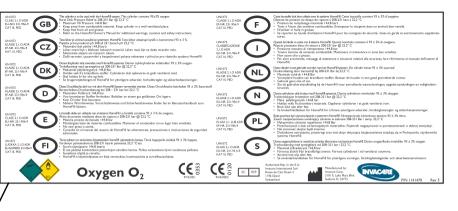
### WARNING!

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

### **3.4 External Examination**

- 1. Examine the outside of the cylinder for the following conditions, and replace the cylinder if they exist:
  - 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, replace the cylinder.
- 3. Inspect the cylinder fillport for the following:
  - Debris, oil or grease
  - Noticeable signs of damage
  - Signs of corrosion inside the valve
  - Signs of excessive heat or fire damage
  - Signs of pressure leaks
    - $_{\Pi}^{\circ}$   $\,$  DO NOT use the cylinder if any of these items are
    - found. Contact your dealer/Home Care equipment provider for replacement.





This cylinder is to be used with the HomeFill system. This cylinder contains 93±3% oxygen. Burst Disk Pressure Relief at 208-231 Bar @ 22.2°C. Keep cylinder in a well ventilated place Keep away from combustible material. Keep free from oil and grease. Refer to the HomeFill Owner's Manual for additional warnings, cautions and safety instructions.

## 4 Usage

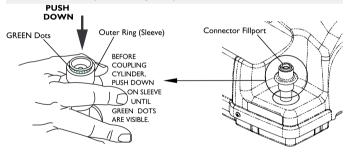
# 4.1 Connecting/Disconnecting the Cylinder to/from the Compressor

Connecting the Cylinder to the Compressor



### WARNING!

- NEVER use tools of any kind to connect/disconnect the cylinder and the compressor. Otherwise, severe injury and/or damage may occur.
- DO NOT drop oxygen cylinders. Use two hands when handling/transporting oxygen cylinders. Otherwise, injury or damage may occur.



- 1. Examine the cylinder gauge. If the cylinder pressure is less than 1500 psig (10342 kPa), proceed to STEP 2.
  - $_{\odot}$  If the cylinder pressure is greater than 1500 psig (10342
  - kPa), DO NOT attempt to top off this cylinder. It may not fill.
- 2. Set the conserver flow dial on the cylinder to "O".
- 3. Slowly open the shutoff valve fully (counterclockwise).
- 4. Remove the cylinder and connector fillport covers.

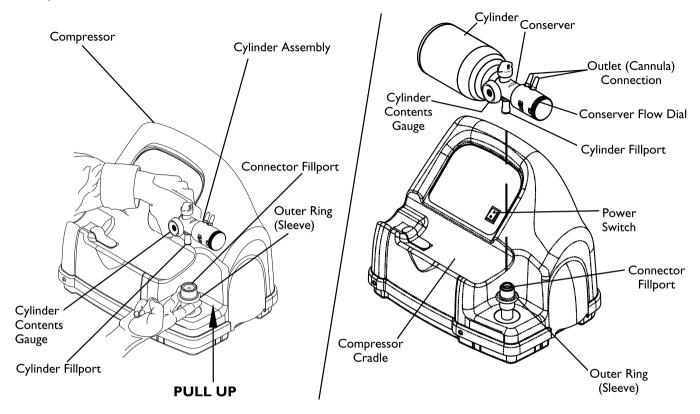
#### 1176148-A



## CAUTION!

 DO NOT connect the outlet (cannula) connection to the HomeFill unit, otherwise the conserving cylinder will not work properly.

- 5. Momentarily push DOWN on the outer ring (sleeve) of the connector fillport until GREEN dots are visible to reset the connector.
  - $\stackrel{\circ}{_{\rm I}}$  If the outer ring (sleeve) is in the UP position (GREEN
  - dots not visible), the connector fillport will not be able to accept the cylinder fillport. Pushing DOWN momentarily will reset the connector fillport (GREEN dots visible) to accept the cylinder fillport.

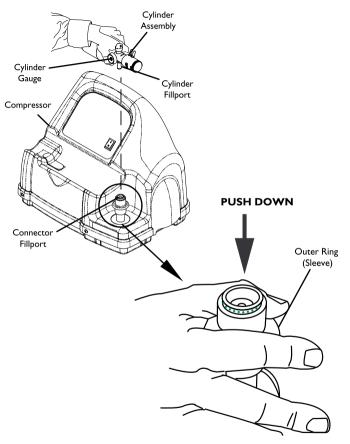


- $\stackrel{\circ}{]]}$  Fillport covers not shown for clarity.
- 6. Grasp the cylinder/regulator assembly in the area behind the cylinder gauge.
- 7. Position the cylinder in the compressor cradle.
- 8. Align the cylinder fillport with the connector fillport.
- 9. Pull UP on the outer ring (sleeve) of the connector fillport while pushing DOWN on the cylinder/regulator assembly to couple the cylinder fillport into the connector fillport.
  - $\overset{\circ}{\underline{\mathbb{I}}}$  The cylinder is properly connected when an audible "click" is heard.

**Disconnecting the Cylinder from the Compressor** 

### WARNING!

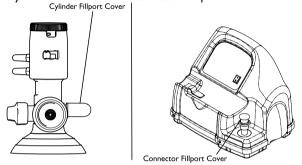
 NEVER use tools of any kind to connect/disconnect the cylinder and the compressor. Otherwise, severe injury and/or damage may occur.



- 1. Press the compressor power switch to the Off (O) position.
- 2. Grasp the cylinder/regulator assembly in the area behind the cylinder gauge.

#### HomeFill® System

- 3. With the other hand, grasp the outer ring (sleeve) of the connector fillport and push DOWN.
- Lift up on the cylinder/regulator assembly to remove from the connector fillport.



5. When the cylinder fillport is disconnected from the connector fillport, release the outer ring (sleeve) of the connector fillport and use two hands to remove the cylinder from the compressor cradle.

## $\triangle$

### WARNING!

- The fillport cover on the connector fillport and the cylinder fillport MUST be replaced after filling and whenever not in use. If either of the fillport covers are missing contact your healthcare provider before using.
- 6. Place the fillport covers onto the connector fillport and cylinder fillport.
- 7. Examine the cylinder gauge to ensure cylinder is full (needle pointing into GREEN area). If the cylinder is not full, perform the following:

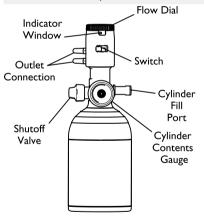
- Repeat STEPS 1–9 of Connecting the Cylinder to the Compressor, page 11.
- If cylinder is not full after second attempt to fill, contact the provider.
- 8. Slowly close the shutoff valve fully (clockwise).

## 4.2 Cylinder Operation



### WARNING!

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



 Prior to each use, inspect product for visible damage. Refer to 3.4 External Examination, page 9. DO NOT use if any damage is found.

- If for any reason, any label becomes illegible or lost, ĵ
  - contact your dealer/Home Care equipment provider.
- Inspect the cylinder contents gauge to ensure the pressure is at 2. least 500 psig (3447 kPa). If below 500 psig (3447 kPa), then refill the cylinder using the HomeFill system.



#### WARNING!

- When pointer on contents pressure gauge enters red zone, it is recommended to refill the cylinder on the Invacare HomeFill Compressor.
- 3. Position the cylinder so the oxygen cylinder valve outlet is pointing away from the user and any other person(s).



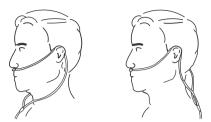
### WARNING!

- DO NOT direct flow of oxygen at any person, or flammable material when adjusting the flow dial.

- Be sure the flow dial is in the "O" position. Align "O" with the 4. indicator window.
- Attach a dual lumen adult oxygen nasal cannula with a maximum 5. length of 2.1 m (7 feet) to the product's two outlet connections according to the cannula manufacturer's instructions.
  - It does not matter which tube is installed on which outlet connection.

DO NOT use pediatric, low flow nasal cannulas or oxygen masks with this product.

Place the cannula over your ears and position the prongs in your 6. nose as instructed by your Health Care provider or cannula manufacturer.





### DANGER! **Risk of Death**

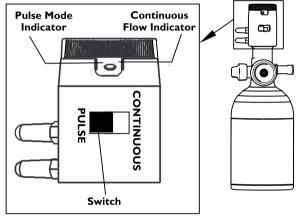
The cannula can cause injury if improperly positioned and secured

- 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 traffic.
- Ensure there are no kinks or twists in the cannula tubing. 7.
- Slowly turn the shutoff valve knob in the ON direction 8. (counterclockwise).
  - This will allow cylinder pressure to travel through the Ц regulator.
- Use the switch to select one of the following modes: 9.
  - Continuous Flow
  - **Conserving Pulse**

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The regulator is labeled "CONTINUOUS" and "PULSE".

The first three flows (0.25, 0.50 and 0.75 L/min) are in continuous mode at all times, regardless of the switch position.



- 10. Turn flow dial until the indicator window is aligned with the prescribed setting.
  - When there are two numbers displayed in the indicator
  - window, the larger number is the PULSE flow setting and the smaller number is the CONTINUOUS flow setting.



### WARNING!

- NO OXYGEN is delivered between settings.
- 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 pulse of oxygen as you inhale.
  - When on a pulse setting, there is flow, or a pulse, only at
  - ĵ the beginning of each breath. If you do not feel the pulse at the beginning of each breath, check the setting.

Because each patient's breathing pattern is different and the environment varies, it may be difficult to feel some low setting pulses.

If operating the cylinder below 1.7 ° C (35° F) use the 2 L/Min continuous setting only.

When the unit is first switched from pulse to continuous flow, a single inhalation is required to initiate the continuous flow.

- 12. When finished using the cylinder, perform the following steps:
  - Turn the flow dial to the "O" position. a.
  - Turn the shutoff valve clockwise to turn off the regulator. b.

## **5** Maintenance

### 5.1 Maintenance



### CAUTION!

- DO NOT use cleaning solutions on the coupler or fillport fitting.
- DO NOT immerse product in any kind of liquid.
- All repairs MUST be done by Invacare Corporation or in an Invacare approved repair center.
- 1. As required when dirty, clean exterior of the product with a dry, lint free cloth only.
- 2. Store product in a clean area free from grease, oil, and other sources of contamination.

5.2 Replacement Parts — Accessories HF2POST6BAG

HF2POST9BAG

## **6** Troubleshooting

### **6.1** Troubleshooting

If Conserving 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> <li>Regulator in "O" position.</li> <li>Cylinder empty.</li> <li>Dial not set at increment.</li> <li>Conserver not sensing breath.</li> </ol>	<ol> <li>Set to prescribed setting.</li> <li>Replace/fill cylinder.</li> <li>Set dial so indicator points to a setting.</li> <li>Check position of cannula in nose. Do not breathe through mouth.</li> <li>Check to see if the cannula is kinked.</li> </ol>

## 7 Technical Data

## 7.1 Typical Product Parameters

**Flows** 

Continuous Flow			Pulse Volumes (L)	
Setting	Equivalent Flow Rate	Minimum	Nominal	Maximum
	1/4 L/min setting:	0.213	0.250	0.288
	1/2 L/min setting:	0.425	0.500	0.575
	3/4 L/min setting:	0.638	0.750	0.863
	0.4 L/min setting:	0.340	0.400	0.460
	0.5 L/min setting:	0.425	0.500	0.575
	I L/min setting:	0.850	1.000	1.150
	1.5 L/min setting:	1.275	1.500	1.725
	2 L/min setting:	1.700	2.000	2.300
	2.5 L/min setting:	2.125	2.500	2.875
	3.5 L/min setting:	2.975	3.500	4.025
	4.5 L/min setting:	3.825	4.500	5.175

Pulse Setting	1, 1.5, 2, 2.5, 3, 4, 5, 6			
	Conserving (Savings) Ratio, Bolus Size and Accuracy @ 20 BPM		Pulse Volumes (L)	
	Equivalent Flow Rate	Minimum	Nominal	Maximum
	I L/min setting:	0.014	0.0165	0.019
	1.5 L/min setting:	0.021	0.0248	0.029
	2 L/min setting:	0.029	0.0330	0.038
	2.5 L/min setting:	0.036	0.0413	0.047
	3 L/min setting:	0.043	0.0495	0.057
	4 L/min setting:	0.056	0.0660	0.076
	5 L/min setting:	0.071	0.0825	0.095
	6 L/min setting:	0.084	0.0990	0.114
	Sensitivity	0.130 to 0.150 in (0.330 to 0.381 cm) H <sub>2</sub> O		
	Delivery	"ON" time	< 125 ms	
		"OFF" time	< 300 ms	

### 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	Bursts at 20.8 — 23.2 Mpa at 22°C (3025–3360 psig at 72°F)

### Environmental Operating Temperature Range

Storage Temperature Range	-20°C to 60°C (-4°F to 140°F)	
Operating Temperature Range	1.7°C to 40.6°C (35°F to 105°F)	
Max Operating Humidity	95% non-condensing	

### **Assembly Dimensions**

Model	HF2ECE6	HF2ECE9
Diameter	11.1 cm (4.4 in)	11.1 cm (4.4 in)
Weight	2.07 kg (4.57 lb)	2.75 kg (6.07 lb)
Overall Length	43.3 cm (17.03 in)	40.7 cm (16.03 in)

### Cylinders

Cylinder Size	M6	M9
Volume (H <sub>2</sub> O)	1.0 L (0.035 ft <sup>3</sup> )	1.7 L (0.061 ft <sup>3</sup> )
Oxygen Capacity	170 L (6 ft <sup>3</sup> )	255 L (9 ft <sup>3</sup> )

### HomeFill<sup>®</sup> System

### Fill Times

Model	HF2ECE6	HF2ECE9	
	l hrs 25 min*	2 hrs 20 min*	
*Concentrator flow rates to patient:			
Platinum 5, Platinum S Series and Perfecto2 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

Model	HF2ECE6	HF2ECE9
Dual Lumen Cannula	5' (1.524 m) or 7' (2.1336 m) tubing length (HUD 1850)	5' (1.524 m) or 7' (2.1336 m) tubing length (HUD 1850)
Carry Bag	HF2POST6BAG	HF2POST9BAG

## **Regulatory Compliance**

93/42/EEC - Medical Device Directive (Class 2b)
97/23/EC - Pressure Equipment Directive

## EC REP

### **EU** Representative

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