

# OXYGEN REGULATOR DEVICE

## Product Information and Instructions

**i NOTE:** *Healthcare Equipment Providers shall provide the end user with instructions for use and instructions for determining gas cylinder contents.*

**i NOTE:** *The gauge face may be different on actual unit.*



Device may be different than image shown.

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## IMPORTANT INFORMATION TO RECORD

Your Name: \_\_\_\_\_

Date You Received Your Unit: \_\_\_\_\_

Prescribed Oxygen Flow Setting:

    At Rest: \_\_\_\_\_

    During Exercise: \_\_\_\_\_

Home Care Provider's Name: \_\_\_\_\_

Home Care Provider's Phone Number: \_\_\_\_\_

Physician's Name: \_\_\_\_\_

















Physician's Phone Number: \_\_\_\_\_

Notes: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

## SYMBOL DEFINITIONS

	Consult instructions for use		Humidity Limit
	Consult accompanying documents		Temperature Limits
	Prescription only		Contains Natural Rubber Latex
	No Smoking		Catalog Number
	Use no oil or grease		Serial Number
	Keep away from open flame		Manufacturer
	Use No Oil (on gauge face)		Date of Manufacture
	Keep dry, protect the device from moisture		These symbols may be used in the user manual and also on the device, packaging and other material.



### **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, will 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.



### **NOTE**

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

## **IMPORTANT SAFEGUARDS, DANGERS, WARNINGS AND CAUTIONS**

Read and understand this manual before operating your oxygen regulator. Important safeguards are indicated throughout this guide. Pay special attention to all safety information. Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.



## DANGER



- Oxygen will not burn; however, it does vigorously accelerate the burning of any flammable material.
- Oxygen makes it easier for a fire to start and spread. Do not leave the nasal cannula on bed coverings or chair cushions. If the oxygen regulator is turned on but not in use, the oxygen will vigorously accelerate the burning of any flammable material. Turn the oxygen regulator off when not in use.
- Smoking during oxygen therapy is dangerous and is likely to result in burns or death. Do not allow smoking or open flames within the same room of the oxygen regulator or any oxygen carrying accessories.
  - If you intend to smoke, you must always turn the oxygen regulator off, remove the cannula and leave the room where either the cannula or oxygen regulator is located.
- There is a risk of fire associated with oxygen equipment and therapy. Do not use near sparks or open flames.
- Avoid creation of any spark caused by any type of friction, near oxygen equipment.
- Not suitable for use in the presence of flammable anesthetic mixture with air, oxygen or nitrous oxide.
- Never use oil, grease or petroleum-based products on or near the system to avoid the risk of fire and burns. Wash and dry hands before operating oxygen equipment. Use only water-based lotions or salves.
- Do not lubricate replaceable fittings, connections, tubing or other accessories of the oxygen regulator to avoid the risk of fire and burns.
- Never use aerosol sprays near the equipment.



## WARNING



- Under certain circumstances, oxygen therapy can be hazardous. Seek medical advice before using a oxygen regulator.
- The use of oxygen requires a prescription from a physician or other appropriately licensed healthcare practitioner.
- The oxygen delivery setting has been determined for each patient individually with the configuration of the equipment to be used, including accessories.
- If you feel discomfort or are experiencing a medical emergency, seek medical assistance immediately to avoid harm.
- Geriatric or any other patient unable to communicate discomfort may require additional monitoring to avoid harm.
- Be sure to turn off the oxygen supply by setting the flow control knob to "OFF" when not in use.
- Oxygen flow is only present when flow indicator is clicked into place. No oxygen will flow if knob is set between liter flow settings.



## WARNING

- The regulator must:
  - Be used only after one or more settings have been individually determined or prescribed for you at your specific activity levels.
  - Be used with a specific combination of parts and accessories (i.e. cannulas, tubing) that meet the specifications of the manufacturer, and that were used while your settings were determined.
- Your prescribed settings should be periodically reassessed by a physician or other appropriately licensed healthcare practitioner for effectiveness of therapy.
- Use only parts and accessories recommended by the manufacturer to ensure proper function and to avoid the risk of fire and burns.



### **WARNING (CON'T)**

- It is unsafe to use accessories, detachable parts and materials not described in the instructions for use, interconnect this equipment with other equipment not described in the instructions or modify the equipment.
- Cannula tubing can pose a strangulation risk and tripping hazard. Locate tubing away from areas of high foot traffic and keep children and pets away from cannula tubing.
- Always maintain a backup supply of oxygen.
- Not for use with an endotracheal tube or tracheostomy.
- Close supervision is necessary when the nasal cannula is used by impaired persons or near children.



### **WARNING**

- Before using this unit, make certain that your hands are free of oil, grease and other contaminants, and that the cylinder is secure in an upright position.
- Lint and dust can contaminate the oxygen path and create a fire hazard. Keep all oxygen connections clean and free from lint and dust.
- Make sure the fill valve, if equipped, is clean and free of dirt, debris, oil or other contaminants.
- To reduce the risk of rapid oxygen recompression and fire, open the cylinder valve slowly and completely so the pressure gauge moves slowly as it indicates the cylinder pressure.
- Do not wet the area of the oxygen inlet connection, the disinfectant residue may create a risk of fire.
- Do not submerge the regulator in the disinfectant, wipe disinfect only.
- Do not attempt to open or remove enclosure. There are no user-serviceable internal components.
- Choking Hazard - The 870 post seal washer may pose a choking hazard. Small parts not for children under 3 years or any individuals who have a tendency to place inedible objects in their mouths.



### **CAUTION**

- Prevent water or any other liquid substances from entering the unit.
- Do not expose the unit to extreme temperatures or heat sources such as fireplaces and radiant heaters.
- Do not use if leaking or damaged.
- Refer repairs to authorized service personnel.
- Do not use the flow outlet for driving any medical equipment.
- This product contains natural rubber latex (oxygen pressure gauge rubber guard) which may cause allergic reactions. Oxygen supplied by this equipment is supplemental only and is not intended for life support applications.
- The regulator should not be used to supply anything other than medical oxygen.
- Tighten only by hand. The use of a tool to tighten the knob may damage the unit.
- Checking for leaks should be performed before each use.
- To help prevent possible damage to the unit and to maintain its cleanliness, keep the oxygen regulator in a carrying bag. Several bags are available for use with different cylinder sizes and configurations. Contact your Home Care provider for more information about carry bags.

**SAVE  
THESE INSTRUCTIONS**

## INTRODUCTION

This manual provides information necessary to operate the oxygen regulator. The device can be used with a CGA 870 post-valve cylinder [see Fig. A] at home or away from home to provide your specific oxygen requirements.

### PURPOSE

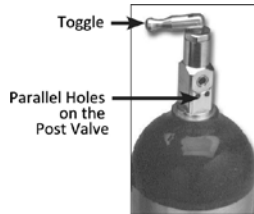
The device is intended to be used as part of a portable or stationary oxygen delivery system for patients that require supplemental oxygen in their home and for ambulatory use.

### FUNCTION

The principle operation of the device is to deliver continuous flow oxygen to a patient through means of a respiration demand system. The device is situated at the output of the oxygen cylinder and has the following characteristics:

- The device works with gaseous supply sources fitted with the following valve connections (CGA 870 or DIN 477).
- The device accomplishes the delivery through a single-lumen cannula. Flow is set in Liter per minute setting marked on the devices control knob.
- The device is non-sterile and reusable, having a service life of five years.

This accounts for the expected actual usage cycle, which includes actual use and storage once removed from the packaging.



**FIGURE A**  
*Post-Valve Cylinder*

### USER QUALIFICATION

Prior to beginning therapy, patients must be given instruction by qualified personnel in how to operate this unit.

Functions that are frequently used include:

- Installing the device by connecting to a portable oxygen cylinder post valve.
- Selecting prescribed oxygen setting on the selector dial.
- Attaching standard oxygen cannula and tubing to gas port and securing cannula to user.
- Monitoring the pressure gauge for remaining oxygen in cylinder.
- Disconnecting the device from the portable oxygen cylinder.

### INTENDED USE

Oxygen Regulator is intended for prescription use only, to be used as part of a portable oxygen delivery system for patients that require supplemental oxygen in their home and for ambulatory use.

The patient is the intended operator.



### CAUTION

Oxygen supplied by this equipment is supplemental only and is not intended for life support applications. The device should not be used to supply anything other than medical oxygen.

### CONTRAINDICATIONS

- This device is not to be used for life support applications.
- The device is not for use while asleep.

## IMPORTANT PARTS

1. **Cylinder Attachment Knob:** This is used to attach the unit to any CGA 870 post-valve cylinder
2. **Oxygen Pressure Gauge:** Enables the user to monitor the contents of the compressed oxygen cylinder and is protected by a rubber guard. The gauge displays maximum pressure of 4000 psi.
3. **Selector Switch:** Enables the user to select the desired setting, as well as “OFF” and “cf” (continuous flow). When not in use, the switch should be turned to the “OFF” position.
4. **Cylinder Alignment Pins:** When assembling the unit, these parallel pins must be inserted into the holes on the CGA 870 post valve.
5. **Seal Washer (Gasket, SEAL 100):** Creates the interface between the post valve and the device. Besides offering a rugged interface, it also surrounds the oxygen path in a ring of stainless steel or brass.



### WARNING

Use only a manufacturer-specified seal washer (gasket).

6. **Oxygen Supply Outlet:** Use this fitting to attach a standard cannula.
7. **Vent Hole:** Maintains proper internal pressure. Do not obstruct with any object, such as a label or tight-fitting carrying bag (located directly behind the gauge).
8. **DISS Fitting (ISO 1240):** Enables user to connect other device to regulated pressure with no flow restriction. User should not connect unsupported devices to this fitting.

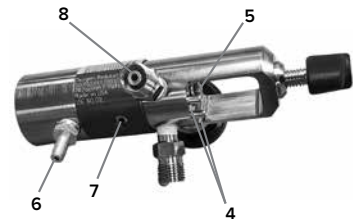
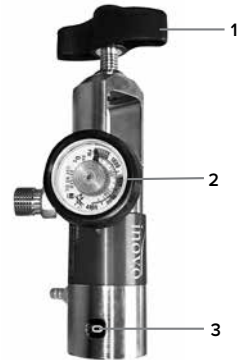


### WARNING: FIRE HAZARD

Lint and dust can contaminate the oxygen path and create a fire hazard. Keep all oxygen connections clean and free from lint and dust.

## REPLACEMENT PARTS

Order Number	Description
SEAL-100	870 Post Seal Washer (Gasket)



Device may be different than image shown.

## SETTING UP YOUR DEVICE



### WARNING: FIRE HAZARD

Before using this unit, make certain that your hands are free of oil, grease and other contaminants, and that the cylinder is secure in an upright position.

## NON-PORTABLE USE

The device should be used only while awake. The Oxygen Regulator is not intended for use while asleep.



### WARNING: FIRE HAZARD

Lint and dust can contaminate the oxygen path and create a fire hazard. Keep all oxygen connections clean and free from lint and dust.

## ASSEMBLY AND USE



### WARNING: FIRE HAZARD

Make certain that your hands are free of oil, grease and other contaminants.

- Inspect the unit to ensure the seal washer (gasket) is in good working condition and attached to the inlet nozzle.
- Secure the cylinder in an upright position.



### WARNING: FIRE HAZARD

- Inspect the valve of the cylinder and the device to ensure they are free of contaminants and damage.
- If any indication of damage or contamination is detected, DO NOT use the equipment and contact your Home Care Provider.



### WARNING

Use ONLY a manufacturer-specified seal washer (gasket). An incorrect seal washer (gasket) may not be oxygen compatible or may cause an oxygen leak, creating an increased fire risk. DO NOT use the device if the manufacturer-specified seal washer (gasket) is missing.

## SETUP

**Step 1:** Loosen the cylinder attachment knob.

**Step 2:** Lower the Oxygen Regulator over any post-valve cylinder with the alignment pins toward the holes on the cylinder neck [see Fig. B].

**Step 3:** Line up the two pins and the seal washer (gasket) with the corresponding holes on the cylinder post valve.

**i NOTE:** *The cylinder attachment knob should be aligned with the indentation on the post valve.*

**Step 4:** While holding the unit in place, tighten the cylinder attachment knob by turning clockwise [see Fig. B].

**i NOTE:** *Tighten only by hand. The use of a tool to tighten the knob may damage the unit.*



**FIGURE B**  
Attaching the device to the cylinder



**FIGURE C**  
Connection View of the Oxygen Regulator

**Step 5:** Attach a standard cannula (7 ft. [2.13 m] or less in length) to the oxygen supply outlet. See Figure E on page 11 for an illustration demonstrating the proper positioning of the nasal cannula.

### SETUP - CGA 540 (DIN 477)

**Step 1:** Set the regulator to the OFF position (if equipped with a flow selector).

**Step 2:** Align regulator nipple with recessed hole in the cylinder valve. (see Fig. 1). Tighten the nut by rotating clockwise until tight (see Fig. 2).

**Step 3:** Slowly open the cylinder valve. Pressure should be indicated on the regulator pressure gauge.

Operation of the device is the same as CGA 870 device (see OPERATING INSTRUCTIONS on page 10).

### DISASSEMBLY INSTRUCTIONS

**Step 1:** Close the oxygen supply cylinder valve by turning the valve clockwise.

**Step 2:** Deplete residual pressure in the regulator by setting the flow selector to a flow setting. Pressure gauge will read zero when complete.

**Step 3:** Remove the nasal cannula from the device and turn the selector switch to the "OFF" position (if equipped with a flow selector).

**Step 4:** While holding the unit in place, slowly loosen the nut by turning counter-clockwise.

Operation of the device is the same as CGA 870 device (see OPERATING INSTRUCTIONS on page 10).

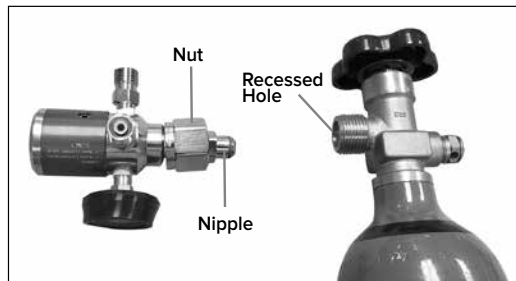


FIGURE 1

Device may be different than images shown.



FIGURE 2

## INSPECTION BEFORE EACH USE

**Step 1:** Examine the outside of the cylinder and regulator assembly for debris, oils or grease and noticeable signs of damage, dents or dings, corrosion, excessive heat or fire damage, pressure leak or any other sign of damage that might cause a cylinder to be unacceptable or unsafe for use.



### WARNING: FIRE HAZARD

If any of these conditions exist, DO NOT use the cylinder and contact your healthcare provider for a replacement cylinder.

**Step 2:** Check the flow selector knob to be sure it rotates and stops at each setting.



### WARNING: FIRE HAZARD

Make sure the fill valve, if equipped, is clean and free of dirt, debris, oil or other contaminants.

## CHECKING FOR LEAKS



### CAUTION

This should be performed before each use.

**Step 1:** Close the valve on the oxygen cylinder by turning the valve clockwise.

**Step 2:** Depressurize the device by turning the flow selector to a setting. The gauge indicator should drop to zero.

**Step 3:** Check that all screwed unions and tube connections are tight. If necessary, tighten them **by hand**.



### CAUTION

Do not use a tool.

**Step 4:** Ensure that the unit is set to the “OFF” position.

**Step 5:** Slowly open the valve on the oxygen cylinder by turning the valve counter clockwise until the needle in the gauge indicator no longer moves.

**Step 6:** Close the cylinder valve again by turning the valve clockwise.

**Step 7:** Observe the needle in the gauge indicator for approximately one minute.

- If the needle remains in its position, there is no leak and the device is ready for use.
- However, if the contents indicator shows a continuous decrease in pressure, there is a leak in the system. In this event, contact your Home Care Provider.

## OPERATING INSTRUCTIONS

**Step 1:** Make sure that the device is set to the “OFF” position before opening the cylinder valve.



### WARNING: FIRE HAZARD

To reduce the risk of rapid oxygen recompression and fire, open the cylinder valve slowly and completely so the pressure gauge moves slowly as it indicates the cylinder pressure.

**Step 2:** If a leak is present (see “Checking for Leaks”), close the cylinder valve, check the seal washer (gasket) and reinstall. If the leak persists, DO NOT USE THE EQUIPMENT. Contact your Home Care Provider for repair or replacement.

**Step 3:** Check the oxygen pressure gauge to verify that the cylinder pressure is within the operating range.

**Step 4:** Select the setting on the device to the appropriate delivery setting (see example in Fig. D).

**Step 5:** Ensure cannula is properly attached to the device.

**Step 6:** Properly position the cannula with the nasal prongs facing upward and insert the prongs into nose. Wrap the cannula tubing over the ears and position in front of body (see Fig. E)

The regulator will now start to deliver oxygen. The amount of oxygen delivered is determined by the setting.



FIGURE D



FIGURE E



#### CAUTION

To help prevent possible damage to the unit and to maintain its cleanliness, keep the device in a carrying bag. Several bags are available for use with different cylinder sizes and configurations: contact your Home Care provider for more information about carry bags.

**Step 7:** When finished using the system, close the oxygen supply cylinder valve by turning the valve clockwise and continue breathing through the nasal cannula until no further oxygen is detected and the gauge reads “Refill”.

**Step 8:** Remove the nasal cannula and turn the selector switch to the “OFF” position.

**Step 9:** When not in use, store in a clean, dry location.

#### DISASSEMBLY INSTRUCTIONS

**NOTE:** *Tools are not required and not to be used to remove the regulator from the post valve.*

**To remove the Regulator from the oxygen cylinder:**

**Step 1:** Close the oxygen supply cylinder valve by turning the valve clockwise.

**Step 2:** Deplete residual pressure in the regulator by setting the flow selector to a flow setting. Pressure gauge will read zero when complete.

**Step 3:** Remove the nasal cannula from the device and turn the selector switch to the “OFF” position.

**Step 4:** While holding the unit in place, slowly loosen the cylinder attachment knob by turning counter-clockwise (see Figure B on page 8).

**Step 5:** Pull the unit away from the cylinder post valve until the two alignment pins are out of the holes on the cylinder post valve.

**Step 6:** Lift the unit off of the cylinder post valve. Use caution while lifting the unit off of the post valve, as the alignment pins can damage sealing surfaces on the post, increasing the chance of leakage.

**Step 7:** Store in a clean, dry location.

## CARING FOR YOUR DEVICE



The regulator should be kept clean and free from moisture and dust, as well as extreme temperature. Clean the device once a week by wiping the outer surface, cylinder fill valve and oxygen outlet port with a clean, dry cloth. Do not use oil or products containing oil.



Do not expose the unit to water, such as when bathing or swimming. It is advisable to keep the system in its carrying bag to afford a degree of protection. Clean the outside of the unit periodically with a clean, lint-free cloth. To remove heavy soil, wipe unit using a lint-free cloth, dampened with clean water, then dry unit with clean, dry, lint-free cloth. Pay special attention to the oxygen outlet to make sure it remains free of dust, etc.



### WARNING

There are no user serviceable parts. Do not attempt to service the device while it is in use.

## TROUBLESHOOTING

Problem	Probable Cause	Solution
Unit does not flow.	Cylinder valve is closed.	Turn cylinder valve counter clockwise to open.
	Cylinder is empty.	Check the oxygen gauge. Replace the cylinder, if empty.
	Oxygen cannula is blocked or kinked.	Remove kinks. Clean or replace, if necessary.
	Selector switch is set to the "OFF" position.	Make sure the selector switch is set to the appropriate delivery setting.

Non-functioning units are subject to warranty provisions and the manufacturer repair/return policy. If necessary, call your Home Care Provider.



**NOTE:** Do not attempt to open the unit. If the unit is opened or tampered with, the warranty is void.

## SPECIFICATIONS

Operating Temperature .....	41°F to 104°F (5°C to 40°C)
Operating Relative Humidity .....	15% to 93% non-condensing
Operating Inlet Pressure .....	34.5 to 206.8 bar (500 to 3000 psi)
Storage/Transportation .....	-13°F to 158°F (-25°C to 70°C)
Ingress Protection .....	Keep Dry

## INFORMATION FOR HOME AND HEALTHCARE PROVIDERS

### DISINFECTION BETWEEN PATIENTS

Drive Medical recommends that at least the following procedures be completed by an appropriately trained individual (i.e. biomedical technician, equipment technician, respiratory therapist, nurse) between uses by different patients.

**Step 1:** Dispose of nasal cannula.

**Step 2:** Cleaning Instructions:

A. Clean the exterior

1. a clean, lint-free cloth to remove surface dirt and soil.
2. a clean, lint-free cloth dampened with water to remove heavy soil.
3. a soft-bristled brush dampened with water to remove stubborn soil.

B. Dry the device with a clean, lint-free cloth.

**i** **NOTE:** *Ensure that the oxygen inlet remains free of dust, etc.*

**Step 3:** Disinfection Instructions:

A. Saturate a clean, lint-free cloth with a suitable disinfecting

agent (e.g., 1:5 chlorine bleach [5.25%] and water solution) and wipe the exterior of the device.

**i** **NOTE:** *Ensure that the device remains visibly wet for ten minutes, with the solution reaching all crevices and hard-to-reach areas.*



### WARNING

Do not wet the area of the oxygen inlet connection, the disinfectant residue may create a risk of fire. Do not submerge the regulator in the disinfectant, wipe disinfect only.

**Step 4:** Allow all parts to dry completely before checking for proper operation.

**Step 5:** Replace all damaged or worn components (cylinder attachment knob, seal washer).

**Step 6:** Check the oxygen device for proper operation.

- Ensure cylinder attachment knob is easy to adjust.
- Ensure flow selector knob rotates and clicks into each setting.
- Attach device to cylinder.
- Ensure pressure gauge is working.

- Ensure flow is working.
- Set device to each setting, and verify that oxygen pulses.

If the device is operating properly, it is ready to be used by another patient. If the device is not operating properly, the provider should return the device to Drive Medical for service.

**i NOTE:** *There is no portion of the gas pathways through the regulator that could be contaminated with body fluids or expired gas under normal or single fault conditions.*

## DISINFECTION INTERVALS



### WARNING

Do not attempt to open or remove enclosure. There are no user-serviceable internal components.

**i NOTE:** *The disinfection process can only be performed by an appropriately trained individual.*

Part/Accessory	Recommended Disinfection Interval	Compatible Disinfection Method
Outside surface of the conserver and controls	Between patients	1:5 chlorine bleach (5.25%) and water solution
Oxygen tubing, nasal cannula	Do not clean, replace between patients	N/A

## MAINTENANCE

The oxygen regulator does not need maintenance through the expected service life of the product. The device has an expected service life of 5 years, which is based on 1500 hours/year of use under normal operating and storage conditions.

## PREVENTIVE MAINTENANCE:

### Before attaching the regulator to a cylinder

- Examine the seal washer and replace if it is damaged or contaminated with dirt, debris, oil or other contaminants.
- Inspect the threads on the cylinder attachment knob, make sure that the knob turns freely through its full range of adjustment.

### To replace the SEAL 100 Seal Washer

1. Remove the old seal washer by lifting the edge of the brass washer and removing the seal washer from the oxygen inlet connection, discard old seal washer.
2. Wash and dry hands before handling the new seal washer.
3. Place the new seal washer over the oxygen inlet connection and press it against the body of the device to seat the seal washer in place.

## CALIBRATION

No calibration is necessary through the expected service life of the product.

## LIMITED WARRANTY

The device has been carefully manufactured and inspected and is warranted to be free from defects in workmanship and materials. Under this warranty, Drive Medical's obligation shall be limited to the replacement or repair of any such units or parts that prove, by Drive Medical's inspection, to be defective within two years from the date of purchase. Any abuse, operation other than the intended use of the product, negligence, accident or repair by other than authorized service professionals shall immediately void this warranty. This

warranty does not extend to spare parts or accessories.

Drive Medical will not accept damages or charges for labor, parts or expenses incurred in making field repairs, except upon written authorization prior to such action.

The foregoing warranty is exclusive and in lieu of all other express warranties. Implied warranties, if any, including but not limited to the implied warranties of merchantability and fitness for a particular purpose, shall not extend beyond the duration of the express warranty provided herein. In no event shall Drive Medical be liable for loss of use or profit or other collateral, special or consequential damages.

## DISPOSAL INSTRUCTIONS

The equipment, including accessories and internal components, does not belong in your regular household waste. Such equipment is manufactured from high-grade materials and can be recycled and reused. The plastic components should be recycled as plastics.

The device should be destroyed or made unusable prior to disposal, example: remove the cylinder contents gauge.

Dispose in accordance with local ordinances.

## TECHNICAL DESCRIPTION

### HOW THE DEVICE FUNCTIONS

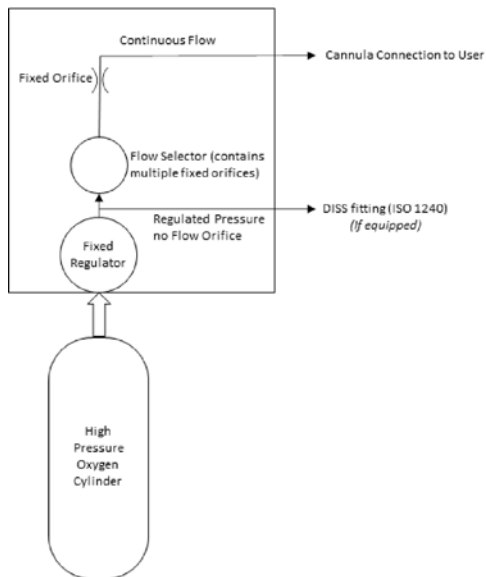
The device includes a low-pressure regulator. It is designed for use with a cylinder as an ambulatory oxygen system. This system takes high pressure Oxygen and reduces the pressure to a usable pressure. It provides continuous flow through a fixed orifice and is determined by the numerical settings on the flow selector (example: a setting of 2 is equal to 2 liters

per minute of oxygen flow). This oxygen is then delivered to the patient through a nasal cannula.

**i NOTE:** *The components in the medical gas path and the nasal cannula are considered applied parts.*

## PNEUMATIC DIAGRAM

**Pneumatic Diagram depicts device in conserving selection.**



***drive***

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