

Bonsai®

Oxygen Conserving Device

OM-812 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.

drive™

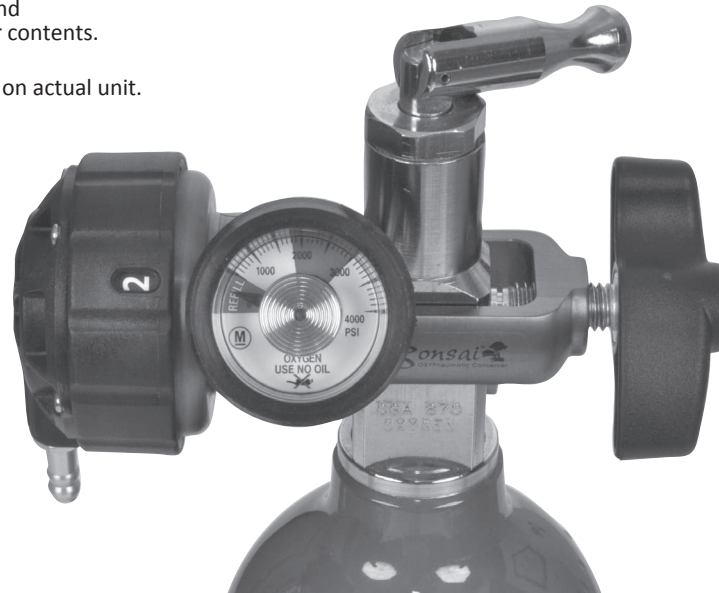


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






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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		Type B Applied Parts
	No Smoking		Contains Natural Rubber Latex
	Use no oil or grease		Serial Number
	Keep away from open flame		Catalog Number
	Use No Oil (on gauge face)		Manufacturer
	Keep dry, protect the device from moisture		Date of Manufacture
cf	Continuous flow		



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.









NOTE: These symbols may be used in the user manual and also on the device, packaging and other material.

IMPORTANT SAFEGUARDS, DANGERS, WARNINGS AND CAUTIONS

Read and understand this manual before operating your oxygen conserving 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: Danger indicates an imminently hazardous situation which, if not avoided, will result in death or serious injury.

- 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 conserver is turned on but not in use, the oxygen will vigorously accelerate the burning of any flammable material. Turn the oxygen conserver 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 conserver or any oxygen carrying accessories.
 - If you intend to smoke, you must always turn the oxygen conserver off, remove the cannula and leave the room where either the cannula or oxygen conserver 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 conserver to avoid the risk of fire and burns.
 - Never use aerosol sprays near the equipment.



WARNING: Warning indicates a potentially hazardous situation which, if not avoided, will result in death or serious injury.

- Under certain circumstances, oxygen therapy can be hazardous. Seek medical advice before using a OM-812 pneumatic oxygen conserver with built-in 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.
- Use of this device at an altitude above 9,800 ft. or outside temperature of 104° F is expected to adversely affect accurate delivery of oxygen therapy.
- Wind or strong drafts can adversely affect accurate delivery of oxygen therapy.
- This device is not intended to be used during sleep or by patients who breathe more than 40 breaths per minute or consistently fail to trigger equipment.
- The settings of this device may not correspond with continuous flow oxygen.



WARNING (Cont.)

- The conserver 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 conserver 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.
- The settings of other models or brands of oxygen therapy equipment do not correspond with the settings of the OM-812 Pneumatic Oxygen Conservor.
- Use only parts and accessories recommended by the manufacturer to ensure proper function and to avoid the risk of fire and burns.
- 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 (i.e. compressed cylinders and regulator).
- Not intended for use with any humidification devices.
- 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 (Cont.)

- The proper placement of the nasal cannula in the nose is critical to the consistent operation of this equipment.
- Do not use cannula tubing that is longer than 7 ft. (2.13 m).
- 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 conservor 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: Caution indicates a potentially hazardous situation which, if not avoided, may result in property damage or minor injury or both.

- Prevent water or any other liquid substances from entering the unit.
- Prevent dust, lint or any small particles from entering the unit, as these may degrade performance or cause oxygen leaks.
- Do not expose the unit to extreme temperatures or heat sources such as fireplaces and radiant heaters.
- Do not use humidifier bottles.
- 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 OM-812 should not be used to supply anything other than medical oxygen.
- Remember that in continuous flow mode, the Oxygen will be consumed at a much faster rate. Switch to another oxygen source before depleting the oxygen cylinder. The continuous flow function on the OM-812 pneumatic oxygen conserver is factory preset at 2 LPM.
- 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 OM-812 pneumatic oxygen conserver 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 Bonsai pneumatic oxygen conserver with built-in regulator. The Bonsai 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.



NOTE: The OM-812 Pneumatic Oxygen Conserving will be referred to as the Bonsai in the remainder of the guide.

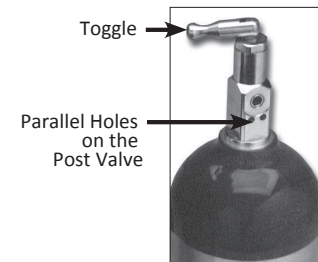


FIGURE A
Post-Valve Cylinder

PURPOSE:

The Bonsai pneumatic oxygen conserver includes a combination of a low-pressure regulator and an oxygen conserver. It is designed for use with a cylinder as an ambulatory oxygen system and is capable of delivering a specific amount of supplemental oxygen at the optimal point in the breathing cycle. The Bonsai increases the efficiency in the delivery of oxygen, maximizing the beneficial effects and eliminating unnecessary oxygen waste.

FUNCTION:

When we breathe, approximately one-third of the time is spent inhaling and two-thirds exhaling. As a result, oxygen delivered by continuous flow is wasted during exhalation. By eliminating oxygen flow during exhalation, a two-thirds saving is possible. Additionally, the oxygen available during the very first part of inhalation contributes most to meeting oxygen needs. The Bonsai conserver takes advantage of these facts to provide maximum efficiency in the delivery of oxygen. This device is designed to be an integral component of a lightweight, long-lasting supplemental ambulatory oxygen system.

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:

The Bonsai pneumatic oxygen conserver 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 Bonsai should not be used to supply anything other than medical oxygen.

CONTRAINDICATIONS:

- This device is not to be used for life support applications.
- This device is not intended for use by patients who breathe more than 40 breaths per minute.
- This device is not to be used by patients who consistently fail to trigger the device.
- 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 Bonsai. 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. cf Settings:** Enable the user to switch from pulse mode (oxygen delivery on demand) to continuous flow mode in the unlikely event of unit malfunction. The cf settings are designed for emergency use only.



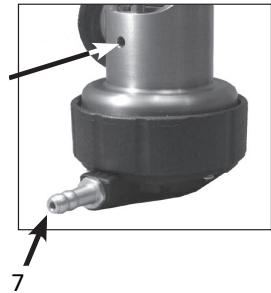
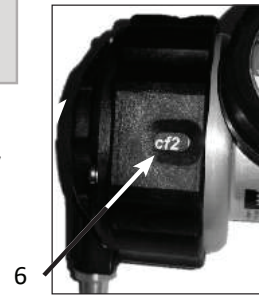
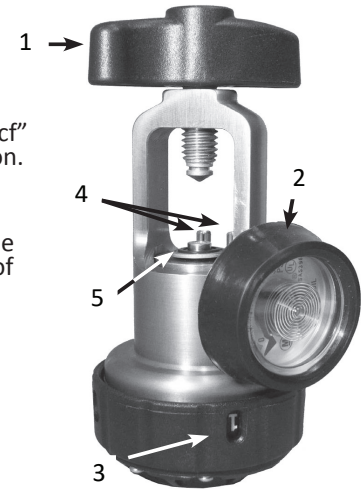
CAUTION: Remember that in continuous flow mode, the oxygen will be consumed at a much faster rate. Switch to another oxygen source before depleting the oxygen cylinder. The continuous flow functions on the Bonsai are factory preset at 2 LPM and 4 LPM

- 7. Oxygen Supply Outlet:** Use this fitting to attach a standard cannula.
- 8. 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).



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.



STANDARD PRODUCT

ORDER NUMBER	DESCRIPTION
OM-812	Bonsai pneumatic oxygen conserving device for 870 Post Cylinder Valve

REPLACEMENT PARTS

ORDER NUMBER	DESCRIPTION
SEAL-100	870 Post Seal Washer (Gasket)

SETTING UP YOUR CONSERVER



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 Bonsai is designed to extend the life of portable oxygen supplies when away from the primary source. While the conserver may be used with stationary oxygen sources, the unit should be used only while awake. The conserver is not intended for use while asleep.

Conditions in the home healthcare environment that can affect the performance of your device:



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.

- Degraded sensors due to rough handling, extreme temperatures or humidity can affect the device's ability to dose oxygen. To avoid this, operate the device within the rated environmental conditions listed in the Specifications section of this guide, found on page 19.

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 Bonsai 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 Bonsai conserver 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.



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].



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

STEP 5: Attach a standard cannula (7 ft. [2.13 m] or less in length) to the oxygen supply outlet. See Figure E on pg. 12 for an illustration demonstrating the proper positioning of the nasal cannula.



FIGURE B
*Attaching the
Bonsai
conservar to
the cylinder*



FIGURE C
*Connection
View of
the Bonsai
conservar*

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 conserver by inhaling several times using the nasal cannula.
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 Bonsai 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" section on previous page), 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 conserver to the appropriate delivery setting (see example in Fig. D).

STEP 5: Ensure cannula is properly attached to the Bonsai.

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 Bonsai will now start to deliver oxygen. The amount of oxygen delivered per pulse is determined by the setting. A sound may be heard each time the unit delivers a pulse of oxygen. Adequate saturation will be achieved because of the precise time in the breathing cycle in which the pulse of oxygen is delivered.



CAUTION: To help prevent possible damage to the unit and to maintain its cleanliness, keep the Bonsai in a carrying bag. Several bags are available for use with different cylinder sizes and configurations: contact your HomeCare 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.

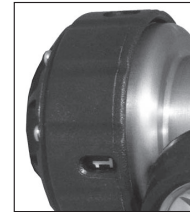



FIGURE D



FIGURE E

DISASSEMBLY INSTRUCTIONS:

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

To remove the Bonsai from the oxygen cylinder:

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

STEP 2: Deplete residual pressure in the conserver by continuing to breathe through the nasal cannula or by setting the conserver to continuous flow mode until no further oxygen is detected and the gauge reads "Refill".

STEP 3: Remove the nasal cannula from the Bonsai 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 10).

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 CONSERVER



The Bonsai should be kept clean and free from moisture and dust, as well as extreme temperature. Clean the Bonsai 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 pulse.	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.
Unit pulses or flows continuously.	Unit is set to the "cf" position.	Turn the selector switch to the appropriate delivery setting.
	Unit was not set to "OFF" prior to opening the cylinder valve.	Turn the selector switch to "OFF," wait a few moments, then set at proper delivery setting.
	Vent hole is obstructed.	Remove obstructions, such as labels or a tight-fitting carrying bag, and resume use as usual.
No oxygen delivery.	Fault in the unit.	Continue the therapy by setting the selector switch to "cf" (continuous flow). This setting increases the oxygen consumption, so you should regularly check how much oxygen you have left.

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

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

OXYGEN CYLINDER DURATION

Because the total delivery of oxygen via the Bonsai is related to breathing rates, it is user adaptive. The total oxygen delivered per minute will automatically adjust with user need, as expressed by increased or decreased breathing rates. For example, at all settings, twice as much oxygen per minute will be delivered if one breathes twenty (20) times per minute as compared with ten (10) times per minute. Please refer to the table below as a guide.

BONSAI®	SETTING	1	2	3	4	5	6	CF 2LPM	CF 4LPM
Cylinder Type	Cylinder Volume (Liters)	Estimated Cylinder Duration in Hours (based on 20 breaths per minute)							
M6(B)	164 liters	8.8	5.6	4.0	3.4	3.0	2.6	1.4	0.7
ML6	171 liters	9.2	5.8	4.1	3.5	3.2	2.7	1.4	0.7
M9(C)	246 liters	13.2	8.4	5.9	5.1	4.6	3.9	2.1	1.0
D	425 liters	22.8	14.5	10.3	8.7	7.9	6.7	3.5	1.8
E	680 liters	36.6	23.1	16.4	14.0	12.6	10.7	5.7	2.8

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:

- Clean the exterior of the device with:
 - a clean, lint-free cloth to remove surface dirt and soil.
 - a clean, lint-free cloth dampened with water to remove heavy soil.
 - a soft-bristled brush dampened with water to remove stubborn soil.
- Dry the device with a clean, lint-free cloth.



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

STEP 3: Disinfection Instructions:

- 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.



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 conserver 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 conserver 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.



NOTE: There is no portion of the gas pathways through the conserver 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.



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 conserver and regulator do 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 Bonsai 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.

SPECIFICATIONS

DELIVERED OXYGEN VOLUME PER BREATH (ml)						
	Breath Rate (breaths/min)					
Setting	15	20	25	30	35	40
1	14	11	9	7	6	5
2	31	29	27	23	19	16
3	42	41	39	37	32	27
4	50	50	48	47	44	38
5	56	56	55	54	53	49
6	59	58	58	57	56	56

Deviation of delivered oxygen per breath =
 +/- (1 ml/breath + 10% of the set initial value
 per breath)
 Tested per ISO 80601-2-67:2014 Sec 201.12.1.101

Continuous Flow Rate Settings
 cf2=2 LPM +/- 0.4 LPM
 cf4=4 +/- 0.4 LPM

Tolerance on measurements = +/- 15%
 (including measurement uncertainty)

All volumes and flows are expressed at STPD
 (standard temperature and pressure, dry)

Continuous Flow Emergency Bypass System Settings:	Factory preset at 2 LPM and 4 LPM
Regulator:	Brass high-pressure with aluminum low-pressure materials
Dimensions (LxHxW):	Approximately 5.1" (13 cm) x 3.3" (8.3 cm) x 2.5" (6.4 cm) conserver only
Weight:	Approximately 12 ounces (340 grams) conserver only
Operating Temperature:	41°F to 104°F (5°C to 40°C)
Operating Relative Humidity:	15% to 93% non-condensing
Operating Altitude:	-1,200 to 9,800 ft.
Operating Atmospheric Pressure:	1,060 to 700 hPa
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) RH up to 93% non-condensing
Shock:	IEC 60601-1-11:2010
Vibration:	IEC 60601-1-11:2010
Pneumatic Inspiratory Trigger Sensitivity:	0.03-0.56 cm H ₂ O sensitivity: (0.01-0.22 in H ₂ O) (under test conditions in ISO 80601-2-67:2014 sec. 201.12.1.101)
Breathing Frequency Range:	1 to 40 bpm
Ingress Protection Rating:	Keep Dry


Technical Description:

How the device functions:

The Bonsai includes a combination of a low-pressure regulator and an oxygen conserver. It is designed for use with a cylinder as an ambulatory oxygen system and is capable of delivering a precise amount of supplemental oxygen at the optimal point in the breathing cycle. The Bonsai greatly increases the efficiency in the delivery of oxygen, maximizing the beneficial effects and eliminating unnecessary oxygen waste. The Bonsai is designed to sense the precise moment in the patient's breathing cycle when it has to deliver the oxygen pulse. It accomplishes its intended purpose by providing supplemental oxygen to a patient requiring nasal oxygen therapy in a manner that yields a high level of efficiency in the consumption of the oxygen administered. The Bonsai's responsive and rapid oxygen delivery time increases the oxygen concentration provided to the patient, thus increasing the ability to better maintain patient saturation levels.

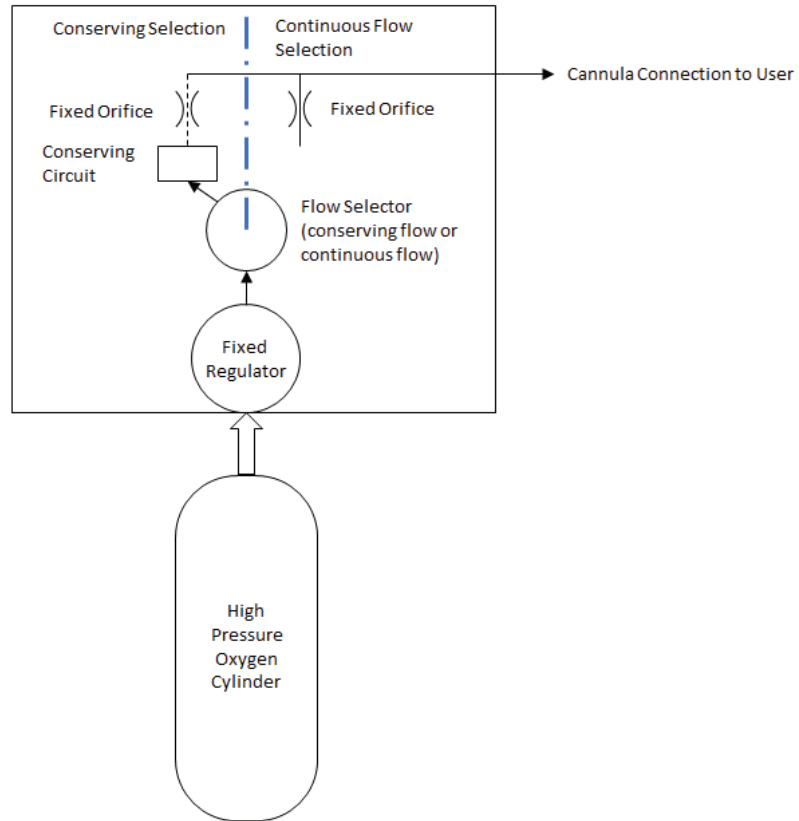
Principles of dosing, timing, triggering and settings:

The Bonsai delivers a uniform oxygen pulse which ensures that, if you breathe faster, you will still receive the same amount of oxygen with each breath. The device is pneumatically powered using springs and mechanical components. A pulse dose of oxygen is triggered by sensing a pressure drop at the beginning of inhalation and is timed to deliver the dose within the first half of the inhalation. A setting of 1 produces the smallest dose, and a setting of 7 produces the largest dose. The cf setting produces continuous flow of 2 liters per minute. The cf4 setting produces continuous flow of 4 liters per minute.

 **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.



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