

FLOTEC INC

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The FLOTEC Oxysavrr™ is an oxygen conserving module, which provides intermittent flow by sensing inspiration and exhalation during the user's respiratory cycle. It is simply a 2 position, 2 way valve, which allows flow at the beginning of the inhalation and stops flow as exhalation begins. The module fits between the body and flowmeter of FLOTEC's RW or Ingage Line series regulator. Only factory installation is authorized. The device is actuated by the negative or positive pressure produced by the user's breathing, acting upon a diaphragm which shifts the flow valve from the open to the closed position. FLOTEC's double lumen hose and cannula is required for reliable operation of the Oxysavrr™. If the fittings on both hoses are alike, then either hose may be connected to either hose barb on the Oxysavrr™ regulator. If one hose fitting is smaller than the other, then the smaller fitting goes on the diagonal hose barb located on the Oxysavrr™ module. The larger fitting goes on the outlet of the flowmeter module. Only qualified and authorized professional caregivers may prescribe the use of the Oxysavrr™ for use by patients. An analysis of the patient's breathing patterns must be done to insure that tidal volume and sensor pressures are adequate to insure reliable operation of the device. **FLOTEC products contain no latex or latex byproducts.**

SPECIFICATIONS:

Regulator Inlet Pressure:	250-3000 PSI
Outlet Pressure:	Nominal 20 PSII
Flow Range:	Minimum: 2.0 LPM, Maximum: 25 LPM
Maximum Cycle Rate:	120 Cycles per minute
Inlet Configuration:	CGA 870 Yoke or CGA 540 Nut & Nipple
Outlet Configuration:	Hose Barb or DISS 1240 fitting
Replacement Cannula:	CN106 (CN206 for DISS Fitting outlets)

Caution: Federal law restricts this device to sales by or on the prescription order of a physician. Device is provided clean non-sterile.

This device is only intended to be used with **FLOTEC** regulators, flowmeters and double lumen cannula

PREVENTIVE MAINTENANCE: Oxysavrr™ regulators should be tested periodically to insure proper performance. The frequency of testing should be established according to usage, but it should be performed at least every six months to evaluate for damage, contamination, wear and performance. Do not disassemble Oxysavrr™ regulators. Only the FLOTEC staff is qualified to clean internally or make repairs.

INSTALLATION:

Attach regulator/conservator to the cylinder.

Do not use a tool to tighten the Tee handle or Dome handle. If leakage occurs inspect and, if necessary, replace the yoke washer or O-ring.

Attach Flotec's dual lumen cannula to (1) hose barb on the silver conservator and (2) hose barb or DISS-1240 fitting on the flow meter portion of the regulator. Flotec's dual lumen cannula must be used and both connectors must be attached. Turn cylinder to on position and flow meter to the 2 LPM position.

Place cannula in normal breathing position and breathe or inhale as deeply as possible for several inspirations to properly initialize cycle. Upon completion of cycling inspirations adjust Flowmeter to the desired flow and resume normal breathing pattern for proper function.

LEAK TEST: Attach the regulator to an appropriate cylinder, plug all outlets, turn the flow selector to "OFF" and slowly open the cylinder valve. Do not immerse in water. Apply an oxygen compatible leak test solution to all outlets, fittings, windows, and connections. Tighten fittings as required to eliminate all external leaks. DO NOT overtighten threaded connections. Replace yoke o-ring if required.

WARNING: Never install a regulator to a post-type valve with more than one o-ring between the valve and the regulator inlet. Before attaching the regulator to the post valve, verify that the valve is not already equipped with a yoke washer.

SAFETY WARNINGS:

1. The use of FLOTEC Oxysavrr™ oxygen regulators for gases other than compressed oxygen of up to 3000 psi is expressly prohibited by FLOTEC and the user must assume all liabilities.
2. Use no oil or grease.
3. Never administer oxidizing gases when smoking or when near an open flame.
4. Never use oxygen from a cylinder without reducing the pressure through a suitable regulator intended for that gas.
5. Make sure that the threaded fittings on regulators or the indexing pins on yokes are properly mated for the gas intended. Never attempt to force an incompatible connection.
6. Never permit compressed oxygen to enter a regulator suddenly. Always open the cylinder valve slowly.
7. Fully open the cylinder valve when a regulator is attached and in use.
8. Never leave a cylinder valve open with regulator attached when regulator is not in use.
9. Before a regulator is removed from a cylinder, fully close the cylinder valve and release all gas from the regulator.
10. Never interchange regulators, hoses, or other equipment with similar equipment intended for use with other gases. Pressure regulators and related fittings should never be handled with oily or greasy hands or gloves. Never hold hand over the outlet(s) to test for the presence of pressure.
11. Never use oxygen as a pressure medium to purge obstructed pipelines or equipment, to operate pneumatic tools, or to build up pressure in any tanks.
12. Do not stand in front of a regulator outlet when opening the cylinder valve in case foreign particles are present which could cause a hazardous malfunction of the regulator.
13. The Oxysavrr™ therapy is not intended for critical treatment. The application of the regulator should be made in strict accordance with the prescription and instructions of a physician. The Oxysavrr™ is not intended for patients that are mouth breathers, or have low tidal volume or chronically congested nasal passages or are subject to fainting spells & other high-risk conditions.
14. Secure cylinders to wall, stand, or cart in accordance with local fire codes.
15. The regulator is equipped with an internal safety relief valve, which is designed to protect the regulator. Downstream equipment used in conjunction with the regulator should be equipped with suitable safety valves to prevent overpressurization and damage.
16. Oxygen must never be allowed to contact oil, grease or other petroleum-based substances. Therefore, do not use oil or grease on oxygen regulators, cylinders, valves or other related equipment. Do not use or store oxygen equipment near excessive heat (>125 F or 51.5 C) or open flame.
17. CAUTION: Do not use organic-based threaded sealants on any portion of the regulator. Use only Teflon threaded-sealing tape or oxygen services compound.
18. **DANGER: Never install a regulator w/Oxysavrr to a post-type valve with more than one yoke washer between the valve and the regulator inlet. The use of plastic yoke washer seals on Flotec regulators is prohibited.**
19. Never leave pressurized oxygen within a regulator. Always purge residual gases when not in use.
20. The regulator with Oxysavrr must be tight to prevent O-ring extrusion. (When using CGA 540 Nipple with O-ring).
21. The regulator with Oxysavrr must be tight to prevent leaking around the CGA 540 Nipple and those using a tip seal or face washer.
22. The regulator with Oxysavrr must NOT be twisted or turned when it is tight on the cylinder valve and/or under pressure to prevent O-ring, tip seal, or face washer abrasion.

Flotec Patent #'s: 4909476, 5785050, 6026854, 6082396, 6328280, 7089956, 4982760, 6148841, 7255127

TROUBLE SHOOTING:

Conservor runs continuously:

Turn cylinder to on position and flow meter to the 2 LPM position.

Place cannula in normal breathing position and breathe or inhale as deeply as possible for several inspirations to properly initialize cycle.

The Flotec Oxysavrr has a normal pilot flow of 1/16 LPM which can be detected only by submerging the nasal end of the cannula in water. During inhalation, the flow selected will flow from the cannula. During exhalation, the flow of 1/16 LPM will flow from the cannula.

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Declaration of Conformity

Product identification

Product name : Regulators & Flow meters, Regulators with Flow meter.
Brand : Flotec
Cat. Number : RXXXX-XXXXX, FXXX-XXXXX, MXXXX-XXXXX, DXXXX-XXXXX
Batch/Serial Nr. : Numbered Sequentially

Manufacturer

Name : Flotec
Address : 7625 West New York Street
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Representative : Brian Davidson
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Fax : +1 317-273-6979

Authorized Representative in Europe

Name : Emergo Europe
Address : Molenstraat 15
2513 BH
The Hague
Country : The Netherlands
Tel : (31) (0) 70 345-8570
Fax : (31) (0) 70 346-7299

Notified Body

Name : UL International (UK) Ltd
Address : Womersley House, The Guildway
Old Portsmouth Road
Country : UK-Guildford, Surrey, GU3 1LR
I.D. Number : CE 0843

Means of conformity

Flotec Inc. declares that the product listed has been classified as Class IIb - Annex IX, Rule 11 and is in conformity with the essential requirements and provisions of Council Directive: 93/42/EEC

Signature

Place and date : Flotec Inc 9-22-03

Signature :



Name : Brian Davidson
[Name and Signature of authorized person within organization]

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Country : The Netherlands
Tel : (31) (0) 70 345-8570

Symbols

PSI
KG/CM2
BAR
MPA
HP
LPM
SN



Symbols

Definition

POUNDS PER SQUARE INCH
KILOGRAMS PER SQUARE CENTIMETER
KILOGRAMS PER SQUARE CENTIMETER
MEGA PASCAL
HIGH PRESSURE PORT
LITERS PER MINUTE
SERIAL NUMBER

USE NO OIL

CONSULT INSTRUCTIONS FOR USE

AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY