

Instructions for Use – Regulator with or without Flowmeter

Flotec Regulators are designed for ease of use and durability. They are intended for use in homecare, professional care, and emergency medical services. They provide a constant flow of medical gas at a specified pressure. Regulators fitted with Flowmeters can deliver a metered flow through the twelve-position flow selector. Appropriate fittings are used to prevent connection of the wrong medical gas. Each Regulator has an internal safety relief valve to prevent over pressurization. They are available in a wide range of colors and inlet/outlet configurations. Flotec products contain no latex or latex byproducts.

Specifications	See engraving for specifics per device	Replacement Parts	
Operating Range:	See engraving for specifics per device	Inlet and outlet connections	Rotor & Flowmeter assembly
Flow Capacity:	See engraving for specifics per device	Dome or T-handles	Piston / manifold assembly
Outlet capacity:	See engraving for specifics per device	Filter disk	O-rings
Temperature Range:	-20 to 150F (-28.9 to 65.6C)		

Available medical gas configurations

Oxygen, Medical Air, Nitrogen, Nitric oxide, Nitrous Oxide, Heliox, Carbon Dioxide, and various mixes thereof.

Warnings

- Medical gases can be dangerous. Aside from dangers to specific gasses, large quantities of medical gases can reduce the availability of oxygen which can cause a person to faint and/or asphyxiate.
- Disassembly, assembly, and testing of Devices should be performed only by trained personnel. The work area must be free of hydrocarbon contaminants and residues because of the danger of spontaneous combustion when residues are exposed to medical gases.

Installation

- Connect the inlet and outlet of the Device to the correct fittings using the methods specific to the fitting used.
- If thread tape is required then
 - be sure only use PTFE tape;
 - do not tape the first thread; and
 - use no more than two turns of tape.
- If there is any confusion on installing a device, contact Flotec.

Preventative Maintenance

- All Devices should be cleaned and evaluated periodically to ensure proper performance. Clean as appropriate to the use and exposure of the device, for general use alcohol wipes are sufficient. The frequency of testing should be established according to usage and importance of the device. Testing should be performed at least once per year to evaluate for damage, contamination, leakage, and performance.

Device Evaluation

Damage

- Visually inspect the device for damage.
- While device is NOT attached to a medical gas system, dial each flow position. Each position should have a distinct click and a decal indicating the flow at that position. The device should not be capable of directly turning from off to full flow or full flow directly to off.
- If damage other than normal wear and tear is found, do not use the device, contact Flotec

Contamination:

- If there is any reason to believe that the device has been contaminated, do not use the device, contact Flotec.

Leak

- Plug all Device outlets.
- If Flow is selectable then turn the flow selector to "OFF".
- Attach the Device to the medical gas system.
- Slowly open outlet medical system valve.
- Apply a compatible leak test solution to all outlets, fittings, and Device body. Watch for bubbles.
- If a leak is found, do not use the device, contact Flotec.

Flow test


- Attach the device to an appropriate cylinder, plug all outlets, turn the flow selector to "OFF" and slowly open the cylinder valve.
- Apply compatible leak test solution to all outlets, fittings, and the junction of the gauge and regulator body to check for bubbles.
- Tighten fittings as required to eliminate all external leaks. DO NOT over tighten threaded connections.
- Replace yoke washer if required. Close cylinder valve.


Safety Warnings:


1. The use of Flotec devices for gases and pressures other than the specified gas and pressure is expressly prohibited. The user assumes all liabilities.
2. Do not use oil or grease.
3. Never administer medical gases while smoking, near an open flame, or near any other ignition source.
4. Never use medical gases from a cylinder without reducing the pressure through a suitable regulator intended for that gas.
5. Ensure that the threaded fittings on all devices are properly mated for the gas intended. Never attempt to force an incompatible connection.
6. Never permit compressed carbon dioxide to enter a flowmeter suddenly. Always open the valve slowly.
7. Fully open the medical gas system valve when a flowmeter is attached and in use.
8. Never leave a medical gas system valve open with flowmeter attached when flowmeter is not in use.
9. Before a device is removed, fully close the medical gas system valve, and release all residual gas pressure from within the device.
10. Never interchange devices, hoses, or other equipment with similar equipment intended for use with other gases. Flotec devices 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 medical gases as a pressure medium to purge obstructed pipelines or equipment, or to build up pressure in a tank.
12. Only use medical gases for equipment intended for use with the specified medical gas.
13. Do not stand in front of a flowmeter outlet when opening the medical gas system valve in case foreign particles are present which could cause a hazardous malfunction of the flowmeter.
14. Medical gas therapy may be critical treatment. All the devices must be used in strict accordance with the prescription and instructions of a physician.
15. Secure cylinders to wall, stand, or cart in accordance with local fire codes.
16. Downstream equipment used in conjunction with devices must be equipped with suitable safety valves to prevent over pressurization and damage.
17. Do not use or store medical gas equipment near excessive heat (>150 F or 65.5 C) or open flame.
18. CAUTION: Do not use organic-based threaded sealants on any portion of the regulator. Use only PTFE thread tape or carbon dioxide service compound.
19. Never leave devices pressurized with medical gases while not in use.

Declaration of Conformity

Product Identification	
Product names	Model/number
Regulators, Flowmeters, and Regulators with Flowmeters	RXXXX-XXXXX FXXX-XXXXX MXXXX-XXXXX DXXXX-XXXXX SN numbered sequentially

Manufacturer		
Name of company	Address	Representative contact information
Flotec 	7625 West New York Street Indianapolis, Indiana 46214-4911 United States of America	Brian Davidson +1 317-273-6960 - telephone +1 317-273-6979 - fax Info@floteco2.com

Notified Body		
Name of company/CE number	Address	Contact information
UL International (UK) Ltd 	Wonersh House, The Guildway Old Portsmouth Road UK- Guildford, Surrey, GU3 1LR	+44 1483-302-130 - telephone +44 1483-376-4848 - fax Customerservice.uk@ul.com

Authorized representative		
Name of company	Address	Contact information
Medical Device Safety Service 	Medical Device Safety Service GmbH Schiffgraben 41 D-30175 Hannover Germany	+49 511-6262-8630 - telephone +49 511-6262-8633 - fax info@mdss.com

Conformity assessment		
Device classification	Route to compliance	Standards applied
Class IIb Rule 11	Annex IX MDD 93/42/EEC Council Directive	Council Directive 93/42/EEC ISO 13485:2012

Other standards applied		
SOR/98-282 IEC 62366-1:2015	BS EN ISO 10524:2006 ASTM-G175-03	BS EN ISO 14971:2012 RoHS Directive 2011/65/EU

Flotec declares that the above-mentioned products meet the provision of the Council Directive 93/42/EEC for Medical Devices and Directive 93/42/EEC as transposed in the national laws of the Member States.

Company representative: Brian Davidson

Title: President

Signature:



Date: 01/09/2017

DoC Rev D

Flotec, Inc. warrants this product to be free from defects in material and workmanship for a period of

Five (5) Years

from the date of manufacture. This warranty is expressly conditioned on compliance with all inspection and preventative maintenance requirements as set by applicable government agencies and as specified by Flotec.

This warranty is extended by Flotec only to the first purchaser of the product from either Flotec or from an authorized Flotec Distributor.

FLOTEC'S OBLIGATIONS AND PURCHASER'S REMEDIES UNDER THIS WARRANTY ARE LIMITED AS

FOLLOWS: In the event of a defect, malfunction or failure to conform to this warranty, purchaser shall return this product to Flotec, with shipping charges prepaid, within a reasonable time after discovery of such defect, malfunction or failure to conform. Flotec shall repair or replace (at Flotec's option) this product if it is defective, malfunctions or fails to conform to this warranty, and shall return it to purchaser with shipping charges prepaid and without any charges due to costs of repair or replacement.

In the event the product returned by purchaser is not defective, has not malfunctioned and does conform to this warranty, Flotec shall not be obligated to repair or replace the product and shall not be obligated for shipping charges for return of the product to the purchaser.

Flotec shall in no event be liable for any consequential damages, nor for loss, damages or expenses directly or indirectly arising from the use of this product.

Disclaimer of Other Warranties.

THIS WARRANTY IS IN PLACE AND IN LIEU OF ALL OTHER WARRANTIES OR REPRESENTATIONS, EXPRESSED OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, WARRANTIES OF MERCHANTABILITY OR FITNESS FOR SPECIFIC PURPOSE, BY OPERATION OR LAW OR OTHERWISE.

This warranty does not apply to malfunction or damage resulting from accident, alteration, misuse, abuse of the product, improper preventative maintenance, storage at extreme temperatures or extreme environments beyond design limits, or where appropriate, improper use of the product by untrained person. This warranty does not apply to any plastic or rubber components that have been affected adversely by undue exposures to heat, sun, water, ozone, or to other deteriorative elements.

Flotec has not authorized any other firm or person to make any representations concerning this product nor to assume on Flotec's behalf any liability in any way connected with the sale or use of this product.

This warranty becomes void immediately should any repairs of, or alterations to this warranted product be made without authorization by Flotec.