

# FLOTEC INC

Web Site: <http://www.floteco2.com>7625 West New York Street 317-273-6960  
Indianapolis, Indiana 46214-4911

Fax 317-273-6979

e-mail: [flotec@ix.netcom.com](mailto:flotec@ix.netcom.com)

Order desk: 800-401-1723

Order desk Fax 800-515-9254

The FLOTEC medical nitric oxide mix regulator is designed to provide specified flows at approximately 20 or 50 PSI. The FLOTEC regulator is preset to deliver the specified flows using pure nitrogen. Every FLOTEC regulator design has an internal safety relief valve to prevent overpressurization of the regulator. FLOTEC products contain no latex or latex byproducts.

**SPECIFICATIONS:**

Operating Pressure: 250-3000 PSI  
 Outlet Pressure: Nominal 20 or 50 PSI  
 Inlet Configuration: CGA 626 Nut & Nipple  
 Outlet Configuration: S.S. Hose Barb

**REPLACEMENT PARTS:**

CGA 626 Nut & Nipple  
 Stainless Steel Gauge  
 CGA 626 Washer (Teflon Tip)  
 Vent Port S.S. Hose Barb (s)

**INSTALLATION; CGA 626 Connector:**

When connecting the CGA 626 connection use the appropriate wrench to tighten the nut. Tighten further if leakage occurs at the CGA 626 connection.

**INSTALLATION REGULATOR:**

The Flotec regulator has an internal safety valve to prevent overpressurization of the regulator. Point of installation, local and state regulations may require venting of the relief valve to outside of the use/storage area. The regulator can be placed in an enclosed, ventilated closet, or the extra hose barbs can be mounted in the vent/relief valve ports and the unwanted gas is piped away using 3/16" tubing.

**WARNING:** If the internal safety relief valve should open because of a malfunction, large quantities of gas can be released. Some medical nitric oxide mix gases can be dangerous. Large quantities of medical nitric oxide mix gases can push the oxygen out of a room. A room filled with medical nitric oxide mix gases can cause a person to faint and/or asphyxiate.

**PREVENTIVE MAINTENANCE:** All medical nitric oxide mix regulators should be tested and cleaned periodically to insure proper performance. The frequency of testing should be established according to usage, but it should be performed at least once per year to evaluate for damage, contamination, wear and performance.

**LEAK TEST:** Attach the regulator to an appropriate cylinder, plug all outlets, turn the flow selector to "OFF" and slowly open the cylinder valve. Apply a 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 overtighten threaded connections. Close cylinder valve.

**WARNING:**

Nitric oxide mixed gas at room temperature is a colorless, nonflammable, toxic gas. Nitric oxide mixed gas in the presence of air forms brown fumes of nitrogen dioxide, which is extremely reactive and a strong oxidizing agent.

Nitric oxide mixed gas, with the attendant formation of nitrogen dioxide, results in a strong respiratory irritant which may be fatal.

When nitric oxide mixed gas is in the presence of moisture and oxygen, corrosive conditions will develop as a result of the formation of nitric and nitrous acids, therefore aluminum or stainless steel fittings and components should be used, do not use brass fittings or components.

Disassembly, assembly, and testing of regulators 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 gaseous medical nitric oxide mix.

### SAFETY WARNINGS:

1. The use of FLOTEC nitric oxide mixed gas regulators for gases other than compressed nitric oxide mixed gas is expressly prohibited by FLOTEC and the user must assume all liabilities.
2. Storage areas should be dry, cool and well ventilated. Where practical, storage areas should be fireproof. Storage in sub-surface locations should be avoided. Storage conditions should comply with local and state regulations.
3. Never administer oxidizing gases when smoking or when near an open flame.
4. Never use medical gases from a cylinder without reducing the pressure through a suitable regulator intended for that gas.
5. Make sure that the threaded fittings on regulators are properly mated for the gas intended. Never attempt to force an incompatible connection.
6. Never permit compressed medical gases 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 medical nitric oxide mixed gas 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. Medical nitric oxide mixed gas therapy may be critical treatment. The application of the regulator should be made in strict accordance with the prescription and instructions of a physician.
14. Secure cylinders to wall, stand, or cart in accordance with local fire codes.
15. The regulator is equipped with an internal safety, 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. Medical nitric oxide mixed gas must never be allowed to contact oil, grease or other petroleum-based substances. Therefore, do not use oil or grease on nitric oxide/nitrogen mix regulators, cylinders, valves or other related equipment. Do not use or store nitric oxide mixed gas 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 medical nitric oxide mixed gas service thread compound.
18. The regulator must be tight to prevent leaking from the seal on the CGA 626 nipple.
19. The regulator must NOT be twisted or turned when it is tight on the cylinder valve and/or under pressure to prevent seal abrasion.

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

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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  
Indianapolis, IN 46214-4911  
Country : USA  
Representative : Brian Davidson  
Tel : +1 317-273-6960  
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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## Authorized Representative

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Address : Molenstraat 15  
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Country : The Netherlands  
Tel : (31) (0) 70 345-8570

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<u>Symbols</u>	<u>Symbols</u>	<u>Definition</u>
PSI		POUNDS PER SQUARE INCH
KG/CM2		KILOGRAMS PER SQUARE CENTIMETER
BAR		KILOGRAMS PER SQUARE CENTIMETER
MPA		MEGA PASCAL
HP		HIGH PRESSURE PORT
LPM		LITERS PER MINUTE
SN		SERIAL NUMBER
		USE NO OIL
	-	CONSULT INSTRUCTIONS FOR USE

EC	REP
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 - AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY