FLOTEC

7625 West New York Street, Indianapolis, IN 46214-4911 www.floteco2.com

Phone: 317-273-6960 Fax: 317-273-6979 Order Desk: 800-401-1723 e-mail: orderdesk@floteco2.com

Instructions for Use – Mass Casualty System

The Flotec pressure reducing oxygen regulator utilized with the Mass Casualty System Assembly is designed to provide a constant flow of oxygen at approximately 50 PSIG or 58 PSIG through the optional one or two DISS check valve(s). The Flotec regulator incorporates an internal safety relief valve to prevent over pressurization. The inlet connection is a CGA 540 nut and nipple. The Flotec oxygen Flowmeters utilized with the Mass Casualty System Assembly are designed to provide a constant flow of oxygen through the twelve-position selector knob at different flow rates. Flowmeters have a metal inlet filter and rotor filter body to eliminate downstream contamination. Flotec products contain no latex or latex byproducts.

Specifications:

Operating Pressure:	250-2216 PSIG
Outlet Pressure:	Nominal @ 50 PSIG; 58 PSIG
Flow Capacity:	50 ccm to 25 LPM through optional DISS-1240 regulator check valve(s)
Inlet Configuration:	CGA 540 Nut and Nipple Style
Outlet Configuration:	DISS-1240 check valve

Replacement Parts:

DISS-1240 Check Valve	O-rings
Inlet and Outlet Connections	Piston/Manifold sub-assembly
Rotor assembly	Flow Meter Hose barb or DISS-1240 outlet
Lead and Hose ASSY	Gauge w/Rubber Boot
316 S.S. Sintered Filter Disk	CGA 540 Nut and Nipple
CGA 540 Tee	

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:

Mount the CGA 540 Tee Port to the oxygen supply cylinder valve. Be careful to avoid cross-threading the connection. To achieve a proper seal for threaded cylinder and regulator connections, which use O-Rings, ensure that the O-Ring is properly positioned before tightening these connections. 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 manned by an operator who can shut off the tank if necessary.

- Connect the outlets of the Devices to the correct fittings using the methods specific to the fitting used.
- 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:

- Attach the Mass Casualty Assembly 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, hoses 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.
- Close cylinder valve and allow residual pressure to vent from system components prior to closing all outlets.
- If a leak is found, do not use the device, contact Flotec.

Flow test

- Attach the Device to the medical gas system.
- Select each sequential flow and verify that gas is flowing from the outlet.
- Return the flow selector to “OFF”.
- If all positions did not flow, do not use the device, contact Flotec.

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Safety Warnings:

1. Disassembly, assembly, and testing of MASS Casualty Assembly 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 oxygen.

2. The use of Flotec devices for gases and pressures other than the specified gas and pressure is expressly prohibited. The user assumes all liabilities.

3. Do not use oil or grease.

4. Never administer medical gases while smoking, near an open flame, or near any other ignition source.

5. Never use medical gases from a cylinder without reducing the pressure through a suitable regulator intended for that gas.

6. Ensure that the threaded fittings on all devices are properly mated for the gas intended. Never attempt to force an incompatible connection.

7. Never permit compressed carbon dioxide to enter a flowmeter suddenly. Always open the valve slowly.

8. Fully open the medical gas system valve when a flowmeter is attached and in use.

9. Never leave a medical gas system valve open with flowmeter attached when flowmeter is not in use.

10. Before a device is removed, fully close the medical gas system valve, and release all residual gas pressure from within the device.

11. 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.

12. Never use medical gases as a pressure medium to purge obstructed pipelines or equipment, or to build up pressure in a tank.

13. Only use medical gases for equipment intended for use with the specified medical gas.

14. 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.

15. Medical gas therapy may be critical treatment. All the devices must be used in strict accordance with the prescription and instructions of a physician.

16. Secure cylinders to wall, stand, or cart in accordance with local fire codes.

17. Downstream equipment used in conjunction with devices must be equipped with suitable safety valves to prevent over pressurization and damage.

18. Do not use or store medical gas equipment near excessive heat (>150 F or 65.5 C) or open flame.

19. CAUTION: Do not use organic-based threaded sealants on any portion of the regulator. Use only PTFE thread tape or carbon dioxide service compound.

20. Never leave devices pressurized with medical gases while not in use.

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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 CE 0843	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 EC REP	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	BS EN ISO 10524:2006	BS EN ISO 14971:2012
IEC 62366-1:2015	ASTM-G175-03	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

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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.