

Instructions for Use – Oxygen Regulator Test Kit

Flotec Oxygen Regulator Test Kits are multiuse devices with 10-year shelf lives from initial delivery date. They are designed to provide means for field personnel to evaluate a regulator for proper function. Flotec products contain no latex or latex byproducts.

Specifications: see engraving for specifics per device	Medical Gases: Oxygen
Operating Pressure: 0 - 3000 psig	Replacement Parts:
Flow Capacity: 30 LPM maximum	RTA – 540 Oxygen Regulator Test Kit
Storage Temperature: -20 to 150 F (-28.9 to 65.6 C)	RTA – 870 CGA 870 Adapter
Operating Temperature: 65 to 75 F (18 to 24 C)	RTA – 1240 DISS 1240 Adapter
Gauge accuracy: 3%, 2%, 3% as per ASME B40.1	008-1000-001 Mass Flow meter
Inlet Configuration: CGA 540 & CGA 870	405-0101-102 Tygon Tubing
Outlet Configuration: Hose Barb or DISS 1240	3/16" X 1/16 wall 48" long (2 required)

Note: When present, the readout of the flow control knob designates the flow setting. It is not a measurement of the current flow

Warnings

Should the device appear to not be operating as specified, immediately stop using the device, depressurize the device, then remove it from the gas source (if safe to do so). Contact Flotec. Medical gases under high pressure can be dangerous, this equipment should only be used by personnel trained in the use of high pressure gases and equipment. Make sure that high pressure tanks are secure during use and any time that the protective cap is removed.

Installation

Connect the high-pressure supply regulator to the supply tank. For testing CGA 870 regulators, a special adapter (RTA-870) should be attached to the outlet of the supply regulator. The RTA-870 adapter is equipped with a hand tight nut and should not be tightened with a tool. Attach the 870 regulator to the post of the adapter and tighten the clamp. CGA 540 regulators can be directly connected to the supply regulator. CGA 540 connections with hex nuts should be tightened with a 1-1/8" or adjustable wrench. Most 540 connections can seal with a light tightening of the nut. Over tightening the connection can cause premature wear of the connection. If the nut does not turn smoothly when starting the thread, check the nut and thread for damage or cross threading that can damage the connection. Open the tank valve slowly and check for leaks. If leakage is detected in the tank connection, try tightening the nut. If there is still leakage, then check the sealing surface for damage.

Testing regulators

There are three different configurations for connecting the unit under test to the test equipment. Units with one or more DISS 1240 outlets can be pressure tested by connecting the pressure gauge (RTA-1240) to one of the outlets. Units with a hose barb outlet may be connected using the RTA-HB attached to the RTA-1240. Refer to drawing 707-0195-000 for connection configurations. Set the Supply Regulator to 1250 PSIG for regulator testing. The outlet pressure of the unit under test should be within the range of 49 to 54 PSIG. To check the flows, connect the Mass Flow Meter to the hose barb using the tubing supplied. Starting from the lowest flow to the highest flow, select the flow setting then read the flow value on the flow meter.

Note: Mass flow meters are temperature dependent and readings will fluctuate with temperature variations. The meter should be powered up for 30 minutes before readings are taken for the most accurate readings and used in ambient conditions as close to 70 degrees F as possible. Readings should be taken after the meter stabilizes after changing the flow setting. A true reading is when the displayed value fluctuates above and below a particular value or remains the same. When large changes in flow occur, it may take some time for the unit to recover and display a true reading. It is also best to have a straight line of at least four inches before the flow meter to straighten the flow before measurement.

Flow readings should be within +/- 20% for readings between 0 and 0.5 LPM and +/- 10% for greater than 0.5 to 25 LPM.

Preventative Maintenance

The Flow meter should be tested and cleaned periodically to insure proper performance. Annual calibration should be performed to ensure accurate readings. The frequency of cleaning should be established according to usage, but it should be performed at least twice per year.

Leak Test

While connected to the supply, the flow selection set to zero, and nothing connected to the unit, turn the post valve off for 870 units or the supply tank valve off for 540 units. Observe the pressure gauge of the unit under test. If it drops to zero within ten seconds then there is a leak in the system. If a leak is indicated, open the supply valve, and apply an oxygen compatible leak test solution to all outlet fittings and check for bubbles. Tighten fittings as required to eliminate all external leaks. DO NOT over tighten threaded connections. Check the vent hole located on the body with a short hose with one end submerged in a glass of water and the other over the vent hole. Some venting is normal in a regulator; however, a continuous leak indicates an internal seal problem. Close the supply tank valve, then remove the unit for use or repair.

Safety Warnings:

Improper Gas hazards

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 if instructions are not understood or warnings not followed. If any of these instructions are unclear, contact Flotec.
2. Never interchange devices, hoses, or other equipment with similar equipment intended for use with other gases.
3. Only use medical gases for equipment intended for use with the specified medical gas.
4. Medical gas therapy may be critical treatment. All the devices must be used in strict accordance with the prescription and instructions of a physician.
5. Never use medical gases from a cylinder without reducing the pressure through a suitable regulator intended for that gas.

Failure to follow the above safety instructions may result in improper use of medical gases, which may result in asphyxiation or fire hazards.

Fire hazards

1. Do not use oil or grease.
2. Flotec devices and related fittings should never be handled with oily or greasy hands or gloves.
3. Never hold hand over the outlet(s) to test for the presence of pressure.
4. Never administer medical gases while smoking, near an open flame, or near any other ignition source.
5. Ensure that the threaded fittings on all devices are properly mated for the gas intended. Never attempt to force an incompatible connection.
6. Always open valves slowly.
7. Fully open the medical gas system valve when in use.
8. Never leave a medical gas system valve open when not in use.
9. Never leave devices pressurized with medical gases while not in use.
10. Before a device is removed, fully close the medical gas system valve, then release all residual gas pressure from within the device.
11. Never use medical gases as a pressure medium to purge obstructed pipelines or equipment, or to build up pressure in a tank.
12. Do not stand in front of an outlet when opening the medical gas system valve.
13. Secure cylinders to wall, stand, or cart in accordance with local fire codes.
14. Downstream equipment used in conjunction with devices must be equipped with suitable safety valves to prevent over pressurization and damage.
15. Do not use or store medical gas equipment near excessive heat (>150 F or 65.5 C) or open flame.
16. CAUTION: Do not use organic-based threaded sealants. Use only PTFE thread tape or other approved compounds.

Failure to follow the above safety instructions may result in fire, explosion, rapid decompression, or other hazards.

MRI conditional compatibility of Flotec devices

Note: only devices labeled with the below symbol are MRI Conditional.



**MR compatible to 3 Tesla
up to bore entry position**

A test was completed by the following below. The complete details will be provided upon request.

Emanuel Kanal, MD, FACR
Director, MR Services
UPMC Presbyterian

Results:

The Flotec Oxygen Regulator S/N 421763 demonstrated 21 degrees of deflection on the deflection angle test; this is below the 45-degree threshold necessary for claims of MR safety/compatibility. Torque test was grossly negative for this model/device. No significant artifacts were observed in the image with this oxygen regulator/attached post valve positioned at the magnet bore entry location. Signal to noise measurements of the phantom with the above-noted post valve still attached to the Flotec Oxygen Regulator, S/N 421763 at the bore entry location, were comparable (150.6 for the baseline and 152.6 with the devices at the bore entry location) and well within one standard deviation of noise measurements (noise measurements were 23.18 for the baseline and 22.8 with the post valve/oxygen regulator at the bore entry location). Flow rates measured at increments of ≤ 1 l/m throughout the range of 0 to 6 l/m at both locations #1 and #2 measured consistently within roughly 0.5 l/m of that set on the wall control unit. Thus, no alteration of flow rate/function was identified or observed for this oxygen regulator S/N 421763 that appeared in any way dependent upon or modified by the presence or absence of the static magnetic field and static spatial magnetic field gradients of the 3T MR scanner.

Conclusions:

It is my [Emanuel Kanal] opinion that the present submitted Flotec Oxygen Regulator S/N 421763 model tested does meet the criteria for both MR safety as well as MR compatibility at 3 Tesla when used up to and including at the magnet bore entry position of this system on which it has been tested.

Please note that grossly detectable Lenz's Law related forces when torqued at bore entry and even greater such detectable forces at magnet isocenter are expected and predictable for metallic objects of this mass/geometry and should not be misconstrued as affecting present definitions of product labeling.

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.