

Instructions for Use – Regulator, Sulfur Hexafluoride

Flotec Sulfur Hexafluoride Regulators are multiuse devices with 10-year shelf lives from initial delivery date. They are intended for use with pure Sulfur Hexafluoride (SF6) only. They are designed for ease of use and durability. They are intended for professional care only. They provide a 5 liter per minute flow at approximately 21 +/- 5 psig (1.4 ± 0.3 bar) when attached to a cylinder with a maximum pressure of 320 psig (22.1 bar). They are designed with an internal safety relief valve to prevent over pressurization.

	Specifications:	Medical gases:
Inlet pressure to regulator:	320 psig (22.1 bar) maximum	Sulfur Hexafluoride
Pressure regulated to:	21 ± 5 psig (1.4 ± 0.3 bar)	Replacement parts:
Inlet configuration:	CGA 170 nut & nipple	Brass Piston
Outlet configuration:	MC 10-02	Manifold
Temperature range:	-20 to 150° F (-28.9 to 65.6° C)	O-rings
	±3% of span, over the first quarter of the scale	Gauge
Gauge accuracy:	±2% of span, over the middle half of the scale	CGA 170 Inlet Nut & Nipple
	±3% of span, over the last quarter of the scale	MC 10-02 Outlet

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 for assistance.
- 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 CGA 170 Nut & Nipple with the appropriate wrench. Tighten further if leakage occurs at the CGA 170 connection.
- Mount the regulator to the small cylinder valve.
 - Be sure that the cylinder pressure is not above 320
 - Be careful to not cross thread the connection
- 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, isopropyl 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.
- 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 regulator to an appropriate cylinder, turn the flow selector to "OFF" and slowly open the cylinder valve.
- Select each sequential flow and verify that gas is flowing from the outlet.
- Return the flow selector to "OFF".
- If the device did not flow contact Flotec.

Warning



Do not remove this device from a gas source without first venting the pressure inside the device. Failure to vent this gas may result in injury such as a burn.

Warning



Do not use this device while smoking, around open flames, or around sparks. Smoking and supplemental oxygen can result in death.

End of device life



Flotec cannot guarantee correct operation after the 10-year shelf life.

After the 10-year shelf life of the device, the device should be returned to Flotec or disposed of.

Flotec can service devices to extend their shelf life. Contact Flotec for details.

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.