

Instructions for Use - Flowmeter

The intended use of a Flotec Flowmeters is to modify the flow rate of a medical gas blend (consisting of one or more gases), provided that the medical gas blend:

- Is the same gas blend for which Flotec designed the device;
- Is used legally; and
- Is used as intended by the medical gas manufacturer or medical professional.

The intended medical gas blend is directly marked on the device.

Flotec Flowmeters are intended to be utilized by general medical practitioners, Emergency Medical Services (EMS) and homecare personnel.

Specifications: see engraving on each device for specifications



UDI-DI +B741FM0

Available configurations:		Medical gases: Oxygen, other gases available upon request
Inlet pressure:	10 - 116 psig (0.7 to 8.0 Bar)	Replacement Parts:
Knob positions:	2, 3, 8, or 11 positions	Inlet Connection
Flow capacity:	0.02 to 60 Lpm	Outlet Connection
Window angle:	0, 60, 90, 180, 270, or 300°	Filter Disk
Temperature range:	0 to 120° F (-18 to 49° C)	Rotor Assembly
Flow accuracy:	±20% for flows 1.5 Lpm and below	Hose Barb
	±10% for flows above 1.5 Lpm	O-rings

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

Note: Ambient conditions for calibration of flows were 14.7 psia and 70° F (1 Bar and 21° C).

Available medical gas configurations:

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

Warnings! 	<p>Do not use this device while smoking, around open flames, or around sparks or while welding. Smoking and supplemental oxygen can result in death.</p>
	<p>Do not remove from its gas source without first venting the pressure inside the device. Failure to vent this gas may result in injury such as burn.</p>
	<p>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), then contact Flotec.</p>
	<p>Disassembly, assembly, and testing of devices should be performed only by trained personnel.</p>
Installation	<ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> ○ be sure only use PTFE tape; ○ do not tape the first thread; ○ and use no more than two turns of tape. <p>If there is ANY confusion on installing a device, contact Flotec.</p>
Use	<ul style="list-style-type: none"> • Before each use, check for damage, contamination, leakage, and correct flows. If there are any signs that the device is not working correctly, do not use the device and contact Flotec. • Rotate the knob to increase or decrease the flow, there will be a satisfying click as the device lines up to each flow position. The flow setting can be identified by the decal that can be seen through the window in the Flowmeter body. So long as adequate gas pressure is applied through the inlet, the outlet will maintain its designated flow. Be aware that: <ul style="list-style-type: none"> ○ It is not possible to turn the flow setting from the zero position directly to the full-open position in a single click; ○ Flotec Flowmeters only intended to be used at the indicated positions. Do not attempt to set them between positions; ○ It is possible to set the Flowmeter between positions, but the flow will not be correctly metered between positions; & ○ Do not use Flotec devices for unintended medical gases. They are configured only for the gas identified. • Please note that while the device will work over the temperature range of 0 °F to 120 °F (-188 °C to 49 °C), the flows were calibrated to 70 °F and 14.7 psia (21 °C and 1 Bar). The further the atmospheric conditions are from the calibration conditions, the less accurate the flows will be. <p>If there are ANY questions about the device, do not hesitate to contact us using the contact information above.</p>
Maintenance	<ul style="list-style-type: none"> • All devices should be cleaned periodically. Clean as appropriate to the use and exposure of the device; for general use alcohol wipes are sufficient. • We strongly suggest returning these devices every five years for a complete review and servicing. Device serving a more critical role may be returned more often, if needed, to ensure safety.
Storage	<ul style="list-style-type: none"> • For longest device life, while the device is not in use, store inside an airtight, opaque container. This can be easily achieved by placing the device inside a sealable plastic bag then inside a cardboard box. • Storage temperatures must stay between 0 °F and 120 °F (-18 °C to 49 °C).

Safety Warnings:

- 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.**
 - Never interchange devices, hoses, or other equipment with similar equipment intended for use with other gases.
 - Only use medical gases for equipment intended for use with the specified medical gas.
 - Medical gas therapy may be critical treatment. All the devices must be used in strict accordance with the prescription and instructions of a physician.
 - Never use medical gases from a cylinder without reducing the pressure through a suitable regulator intended for that gas.
 - Devices marked as MR Conditional have been approved for use in MRI environments up to 3 Tesla. Do not exceed 3 Tesla MRI environments.
- 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

- Do not use oil or grease in any way shape or form with this device
 - 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.
 - Never administer medical gases while smoking, near an open flame, or near any other ignition source.
 - Ensure that the threaded fittings on all devices are properly mated for the gas intended. Never attempt to force an incompatible connection.
 - Always open valves slowly.
 - Fully open the medical gas system valve when in use.
 - Never leave a medical gas system valve open when not in use.
 - Never leave devices pressurized with medical gases while not in use.
 - Before a device is removed, fully close the medical gas system valve, then release all residual gas pressure from within the device.
 - Never use medical gases as a pressure medium to purge obstructed pipelines or equipment, or to build up pressure in a tank.
 - Do not stand in front of an outlet when opening the medical gas system valve.
 - Secure cylinders to wall, stand, or cart in accordance with local fire codes.
 - Downstream equipment used in conjunction with devices must be equipped with suitable safety valves to prevent over pressurization and damage.
 - Do not use or store medical gas equipment near excessive heat greater than 120° F (49° C) or open flame.
 - 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

Only devices labeled with the MR Conditional symbol are MRI Conditional. Flotec devices with the MR Conditional symbol have only been tested up to a 3 Tesla MRI environment. Do not use Flotec devices in MRI environments above 3 Tesla

Meanings of symbols used.



MR Conditional



Authorized Representative in the European Community



Manufacture in the United States of America



Medical Device



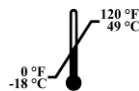
Manufacturer



Part Number



Consult Instructions for Use (IFU) prior to use



Storage temperature upper (120°F, 49°C) and lower (0°F, -18°C) limits in Celsius and Fahrenheit



Serial Number



No Smoking – Do not smoke at any time around this device



Caution



Universal Device Identifier



Do not use near open flames or ignition sources of any sort





CE symbol affirms conformity with appropriate European standards



Use No Oil – Do not use oil with this device

Product Name	Part Number	UDI-DI
Flowmeter	FXXX-XXXXX	+B741FM0

Manufacturer	Address	Contact information
Flotec 	7625 West New York Street Indianapolis, Indiana 46214-4911 United States of America	☎ +1 317-273-6960 📠 +1 317-273-6979 ✉ Orderdesk@floteco2.com

Notified Body (EU)	Address	Contact information
Polskie Centrum Badań i Certyfikacji S.A. z siedzibą w Warszawie (PCBC) (Polish Center for Testing and Certification)  1434	ul. Puławska 469 02-844 Warszawa Poland	☎ +48 (22) 46 45 200 📠 +48 (22) 46 45 251 ✉ pcbc@pcbc.gov.pl

Authorized Representative (EU)		
<table border="1"> <tr> <td>EC</td> <td>REP</td> </tr> </table> <p>MDSS GmbH Schiffgraben 41 D-30175 Hannover Germany</p>	EC	REP
EC	REP	

Flotec Five Year Product Warranty - Flotec 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.

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 specified purpose, by operation of 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.
- This warranty becomes void immediately should any repairs of, or alterations to this warranted product be made without authorization by Flotec.
- 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 is extended by Flotec only to the first purchaser of the product from either Flotec or from an authorized Flotec Distributor