Flotec

7625 West New York Street Indianapolis IN 46214-4911 Phone: 317-273-6960 Fax: 317-273-6979 Email: QA@floteco2.com

Instructions for Use – InGage Regulator

The intended use of a Flotec InGage Regulator is to modify the pressure and or 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 InGage Regulators are intended to be utilized by general medical practitioners,

Specifications: see engraving for specifics per device



Note: A Flowmeter's flow settings decal 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).

Note: As inlet pressure decreases the Flow output will decrease as well.

Available medical gas configurations:

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

Warnings!	Do not use this device while smoking, around open flames, or around sparks or while wielding. Smoking and supplemental oxygen can result in death.
	Do not remove from its gas source without first venting the pressure inside the device.
	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.
	Disassembly, assembly, and testing of devices should be performed only by trained personnel.
	Nut and Nipple inlets:
	1. Inspect the inlet connections for damage, contact Flotec if damage is found.
	2. Line up the inlet connections and torque them down as per the instructions specific to the connector used.
	Post Valve inlets:
	1. Check for and remove the plastic dust cap and washer from the cylinder post if one is present.
	2. Loosen the InGage's I-Handle or Dome Handle.
	3. Inspect the exposed O-Ring on the inGage. If it is damaged, do not use the inGage, contact Flotec.
	4. Line up the incage perpendicular above the post valve. Slide it down until the pins engage.
	5. Hand-tighten the 1-handle of Dome Handle. Check that the inGage is securely connected to the post valve.
Installation	flow.
	7. Connect the outlet line to the InGage.
	8. Open the cylinder slowly and fully with a cylinder wrench. If a leak is heard or felt, close the cylinder valve.
	a. Check that the seal is not damaged or contaminated, wipe off if needed.
	b. Check that the T-Handle or Dome Handle are tight enough (Hand Tight).
	c. If the leak is not resolved, do not use the InGage, contact Flotec.
	9. Check that the pressure is reading the contents of the tank, If the gauge is not reading correctly, do not use the
	InGage, contact Flotec.
	10. If the InGage has a Flowmeter, check that the flows increase proportionally to the indicated flows.
	If there is ANY confusion on installing a device, contact Flotec.
	• 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, contact Flotec.
Use	Once the ingage is installed to the gas source turning on the source will engage the ingage.
	 Incages without howmeters or check valves will flow continually through the outlet so long as the specified pressure range is applied to the inlet.

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	 InGages with Flowmeters or check valves will require the flow setting to be increased or an output line to be attached before flow will begin. If the InGages includes a Flowmeter, 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: 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 (-18.8 °C to 49 °C), the flows and pressures 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. If an InGage with a Flowmeter is in use and the Flowmeter is moved to the zero position then there may be a small buildup of pressure inside the lnGage. This pressure buildup can reach several psi while at maximum inlet psi and may trigger a brief venting through the vent hole. Do not attempt to remove the regulator without having first closed the cylinder valve and venting regulator pressure. If there are ANY guestions about the device, do not hesitate to contact us using the contact information above.
Maintenance	 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	 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).

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InGage Regulator Examples

CGA Nut & Nipple Installed on a tank

CGA Yoke Body Installed on a Post Valve

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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





Medical Device



Consult Instructions for Use (IFU) prior to use



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



Authorized Representative in EC REP the European Community

Manufacturer

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

Caution



Use No Oil - Do not use oil with this device



Manufacture in the United States of America



Part Number



Serial Number



Unique Device Identifier





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Product Name	Part Number	UDI-DI
InGage Regulator	DXXXX-XXXXX	+B741DL0
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

Flotec Five Year Product Warranty - Flotec warrants this product to be free from defects in material and

workmanship for a period of <u>FIVE (5) YEARS</u> 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