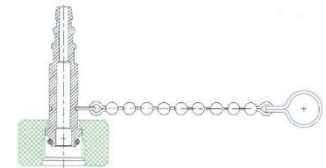



Instructions for Use – Resident Nipple Adapter

Flotec Resident Nipple Adapters are intended to connect through DISS 1240 connections, at specified pressure, in order to reduce the flow rate. Flotec Resident Nipple Adapters are intended to be utilized by general medical practitioners, Emergency Medical Services (EMS) and homecare personnel.

Specifications: Flotec Resident Nipple Adapters can be ordered in combinations of the specifications below.

| Typical configurations: | Typical Replacement Parts |
|---|---------------------------|
| Inlet pressure: 20, 50, or 58 psi | Hose Barb |
| Flow capacity: 0.5, 1, 2, 4, 6, 8, 10, 12, 15, 20, or 25 Lpm | Diss 1240 Knurled Nut |
| Temperature range: 0 to 120° F (-17.8 to 48.9° C) | O-Ring (210-6022-010) |
| Diss 1240 Nut Colors Green, Yellow, Blue, Red, Black, or Purple | Chain & Retainer Assembly |
| Chain Lengths No chain, 2 ½", 4", 6", 8" or 10" | Swivel Clip |
| Custom orifice configurations available upon request. | Orifice Insert |



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| Warnings!  | Do not use this device while smoking, around open flames, or around sparks or while welding. Smoking and supplemental oxygen can result in death. |
| | Do not remove from its gas source without first ensuring that the gas directly upstream of the device is depressurized. Failure to vent this gas may result in injury such as burn. |
| | Should the device appear to not be operating as specified, immediately stop using 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. |
| Installation | <ul style="list-style-type: none"> Connect the inlet of the device by hand-turning the nut around a DISS 1240 connection with male threads. If there is ANY confusion on installing a device, contact Flotec. |
| 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. Do not use Flotec Resident Nipple Adapters 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 101.3 kPa). 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> |
| Cleaning & 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 -40 °F and 140 °F (-40 °C to 60 °C0). |

Safety Warnings:

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| 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. |
| Use caution when interchanging 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. |
| Do not 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

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|---|
| 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 (>150 F or 65.5 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

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



MR compatible to 3 Tesla up to bore entry position

MRI conditional testing performed by,

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

Complete details can be provided upon request.

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.