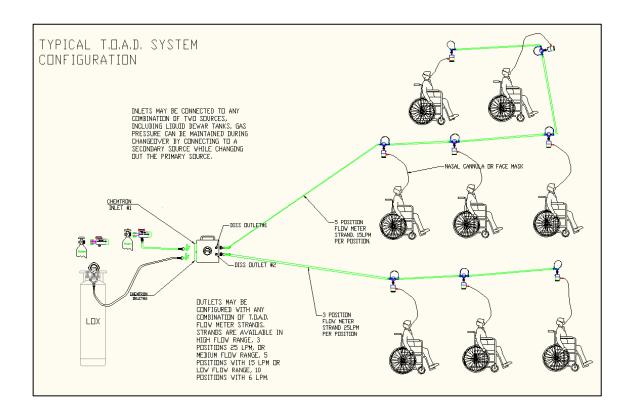


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### **Instructions for Use – Total Oxygen Administration Device**

Flotec's TOAD system is intended for use by patients up to 25 Liters Per Minute of Oxygen. The TOAD is intended for use in pre-hospital applications, alternative care centers, mass casualty field applications, and augmentation of oxygen administration during existing system failures.



#### **Contraindications:**

Patients undergoing procedures with flammable anesthetic gases.

**Specifications**:

Oxygen Supply Connections: CGA-540 and CGA-440

Oxygen Supply Requirements: 40 – 60 PSIG Oxygen @150 LPM

**Temperature range:** Use between -26 to 60° C (-15 to 140° F)

Inlet Supply Outlet Fitting: DISS-1240
Settings for Oxygen Flow: 2, 4, 6 LPM

2, 4, 8, 10, 15 LPM

2, 4, 8, 10, 15, 20, 25 LPM

21 CFR 801, 803, 806, 807, 820, & 821 ISO 13485:2016 MDSAP

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## Instructions for Use – Total Oxygen Administration Device

Warnings!	Read all safety warnings in this document before using the device.  Obey all safety warnings at all times.
Installation	<ol> <li>Device Setup         <ol> <li>Locate the TOAD Interface Box in a location which facilitates the monitoring of the system pressure gauge and convenient connection to the oxygen source(s) regulator using the hose assemblies with DISS style quick connects.</li> <li>The connection to the regulator is through a DISS port on the regulator.</li> <li>Do Not attach the supply hoses to a flow meter connection.</li> <li>The Interface box must be connected directly to a 50 PSI accessory port on the regulator.</li> <li>Attach a flow meter circuit (Patient Flow Strand) to the outlet of the Interface box using one or more of the DISS ports located on the face of the TOAD Interface box.</li> <li>The liquid regulator has been preset at 50 PSIG ± 5 PSIG for correct flow values at the patient stations.</li> <li>Turn on the oxygen supply and check that the system pressure is about 50 PSIG.</li> <li>Patient Circuit</li> <li>The patient circuit for use with the TOAD is a variety of single use disposable nasal cannula, face masks, nebulizers, etc. compatible with DISS Oxygen flow meter barb connections.</li> </ol> </li> </ol>
Use	<ul> <li>The TOAD System consists of a set of regulators for connection to both Liquid Oxygen and High-Pressure Tank Oxygen sources. The regulators are connected via either a CGA 540 fitting for high pressure gas tanks or a CGA 440 fitting for liquid systems.</li> <li>The TOAD Interface Box has internal control valves to prevent backflow when multiple sources are connected. This feature also allows multiple sources to be connected for backup and allows connection of a new tank to the system when the primary tank is close to empty, without shutting down the system.</li> <li>The TOAD Interface Box has a pressure gauge for a system pressure.</li> <li>The flow meter assemblies are connected to the TOAD Interface Box via two DISS outlets. Each flow meter strand is sized to allow the system to supply full flow to all stations without exceeding the capacity of the regulator.</li> <li>Lower flow assemblies will have more patient outlets than higher flow strands.</li> <li>Warning: Do Not interchange the flow controls from one strand to another. They are sized for a total flow of less than 75 LPM/strand and interchange of flow meters of a higher flow could cause the regulator to be overloaded, resulting in loss of flow to the patient.</li> </ul>
Cleaning & Maintenance	<ul> <li>Use only mild detergent or disinfectant and water.</li> <li>Do Not use solvents or abrasive cleaners (Solvents with hydrocarbons can react with oxygen and abrasive cleaners can damage the finish of the unit)</li> <li>Do Not immerse in water. Water can be trapped inside the unit and may cause erratic operation.</li> <li>The TOAD system should be inspected for damage monthly.</li> </ul>
Storage	<ul> <li>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.</li> <li>Storage temperatures must stay between -40 to 160° F (-40 to 70° C)</li> <li>40 – 90% Relative Humidity</li> </ul>

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#### **Instructions for Use – Total Oxygen Administration Device**

#### **Troubleshooting**

Problem	Cause	Correction
Device has no Output Flow	Low Supply Tank Bad Regulator	Replace Tank Repair/Replace Regulator
Leaking at the vent hole of the regulator	Damaged internal seal from rapid opening of the tank valve.	Repair/Replace regulator and train users on opening of the tank valve

#### **Safety Warnings:**

- Do not exceed the indicated temperature range.
  - Do not crush, kink, pull, or tightly bend the Hose Assembly.
- Do not use with gases or gas mixtures other than the specified gas or gas mixture.
- Do not attempt to force an incompatible connection.
- Do not use oil or grease in any way shape or form with this device.
- Do not use while smoking, near an open flame, or near any other ignition source.
- Do not connect Hose Assemblies in series, without validating that the resulting pressure and flow rate are suitable for the intended application.
- Do not apply lubricants to the threads that are incompatible with the hose material or medical gas used. If unsure, consult Flotec.
- Do not use humidifiers upstream of this device or otherwise introduce moisture above atmospheric levels into the device.
- Do not use the Hose Assembly beyond 10 years after the manufacture date
- Do not disassemble the Hose Assembly.
- Do not attempt to self-service Hose Assemblies beyond cleaning and O-ring replacement.
- Downstream equipment should have suitable safety valves, where appropriate, to prevent over pressurization and damage.
- Particulate matter and VOCs could be introduced into the breathing gas pathway from a device upstream or downstream of the hose assembly. Purchasers of medical gas systems should take caution to ensure that all components of the system are biocompatible.
- The user assumes all liabilities if instructions are not understood or warnings not followed. If any of these instructions are unclear, contact Flotec.

Failure to follow the above safety instructions may result in death or serious injury.

21 CFR 801, 803, 806, 807, 820, & 821 ISO 134

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## Instructions for Use - Total Oxygen Administration Device



The "High Pressure" regulators are intended for use with standard CGA 540 fittings. These fittings are commonly found on M, H, and T oxygen cylinders.

Tank pressure is reduced to an operating pressure of 50 PSI ± 5 PSI within these regulators.

These regulators DO NOT require a wrench to acquire a proper seal.

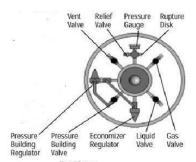
DO NOT attempt to force the regulator to tighten, as thread damage may occur.



The Low-Pressure regulator is intended for use with the "Gas Valve" discharge on the LOX VGL ONLY.

The regulator has been preset at the factory to the proper operating pressure of 50 PSI ± 5 PSI and then sealed.

DO NOT use any other regulators other than those supplied with the system as damage or injury may occur.



Top Views

This is a top view of a standard Variable Gas Liquid (VGL) vessel. The Total Oxygen Administration Device is designed to utilize the "Gas Valve" ONLY!

**Never** connect this device to any other connection on the **VGL!** 

Never operate any other valves/controls other than the "Gas Valve" unless you have specialized training in the system from your vendor.

21 CFR 801, 803, 806, 807, 820, & 821

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### **Instructions for Use – Total Oxygen Administration Device**



The Total Oxygen Administration Device "Interface Box" Is intended for use with supply lines and patient strands provided with each system **ONLY!** 

The Interface Box will allow for the addition or replacement of either source, as well as the removal or addition of either Patient flow strand without interruption of already established Oxygen administration.

The Interface Box is weather resistant; however, it should be always kept free/clean of dirt debris just like any other Oxygen delivery system.



Do not interchange the flowmeters from one strand to another. They are sized for a total flow of less than 75 LPM/strand and interchange of flow meters of a higher flow could cause the regulator to be overloaded, resulting in loss of flow to the patient.

Each flowmeter connects to the strand via a standard DISS connector. This allows the user to remove a flowmeter should it become necessary without interrupting oxygen administration to the other patients.

Keep all hoses and connections out of any walking/working areas/surfaces. Each flowmeter connection is supplied with a cable lanyard for hanging the strand if needed.

This is a chart that gives **general operating times** for one VGL when the Total Oxygen Administration Device is operated continuously at maximum standard flow rates.

Liquid	Gas	@ 150 lpm
180 liters	154,800 liters	17.2 Hours
193 liters	165,980 liters	18.4 Hours
210 liters	180,600 liters	20.0 Hours
250 liters	215,000 liters	23.8 Hours
280 liters	240,800 liters	26. 8 Hours

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## **Instructions for Use – Total Oxygen Administration Device**

PART #	DESCRIPTION
009-1000-002	Liquid Oxygen Regulator
009-1000-003	Cap, Liquid Oxygen Regulator (REQUIRED)
DR5303-6003	InGage CGA 540 Pressure Reducer (for H Cylinder)
015-1021-001	TOAD, Interface Box
015-1022-001	Hose Assy HAG3-3SC1-240 20 feet
HAG3-3SC1-480	Hose Assy HAG3-3SC1-480 40 feet
015-1054-001	Hose Assy HAG3-3SC1-600 50 feet
015-1071-001	Hose Assy HAG3-3S3S-1500 125 feet
015-1021-101	TOAD, Interface Box (DISS-1240 Swivel Inlets (2))
HAG3-3S8S-240	Hose Assy HAG3-3SC1-240 20 feet (F DISS to M DISS CV)
HAG3-3S8S-480	Hose Assy HAG3-3SC1-480 40 feet (F DISS to M DISS CV)
HAG3-3S8S-600	Hose Assy HAG3-3SC1-600 50 feet (F DISS to M DISS CV)
HAG3-3S8S-1200	Hose Assy HAG3-3S3S-1200 100 feet (F DISS to M DISS CV)
015-1029-001	MCA-003P7-20BX0 (3 ea. 0-25 lpm, 240" (6 ft), Swivel)
015-1044-001	MCA-005H1-20D80 (5 ea. 0-8 lpm, 240" (8 ft), Swivel
015-1067-001	MCA-005M5-20D10 (5 ea. 0-15 lpm, 240" (10 ft), Swivel
015-1050-101	MCA-005M5-20D30 (5 ea. 0-15 lpm, 240" (2 ft), Swivel
015-1053-001	MCA-005M5-20D40 (5 ea. 0-15 lpm, 240" (16 ft), Swivel)
015-1028-001	MCA-005M5-20DX0 (5 ea. 0-15 lpm 240" (6 ft), Swivel)
015-1073-001	MCA-008M5-20D20 (8 ea. 0-15 lpm, 240" (12 ft), Swivel)
015-1027-001	MCA-008J1-20HX0 (8 ea. 0-10 lpm, 240" (6 ft), Swivel)
015-1031-001	MCA-00KH1-20KX0 (10 ea. 0-8 lpm 240" (6 ft), Swivel)
015-1030-001	MCA-00LF1-20QX0 (12 ea. 0-6 lpm 240" (6 ft), Swivel)
015-1072-001	MCA-00LF1-20Q20 (12 ea. 0-6 lpm 240" (12 ft), Swivel)

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### **Instructions for Use – Total Oxygen Administration Device**

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.

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