BELMED INC.

PC7-C Flowmeter O2/N2O Sedation Unit
Instruction Manual

WARNING

IMPORTANT:

READ MANUAL COMPLETELY BEFORE OPERATING THIS DEVICE

This manual contains instructions on periodically required checks to be performed by the user. These checks are necessary to ensure the proper performance of this device and its safety features.

RETAIN THIS MANUAL FOR FUTURE REFERENCE

CAUTION: Federal law requires this device for use by or on the order of a physician or dentist.

CAUTION: Do not attempt to repair, alter, or calibrate this device. Unauthorized repair, alteration or misuse of this device is likely to adversely affect the performance and will void the warranty.

WARNING: The PC7-C and its accessories, in need of repair, should ONLY be repaired by Belmed, Inc. or an authorized Belmed, Inc. dealer.

WARNING: The PC7-C and its accessories are designed to perform in accordance with the product specifications when installed, operated and maintained as instructed in this manual.

The National Institute for Occupational Safety and Health has issued a warning for dental workers exposed to N2O during administration of N2O/O2 conscious sedation analgesia. NIOSH has recommended that exposures should be minimized. Contact NIOSH to receive NIOSH Publications on Control of Nitrous Oxide in Dental Operatories at 1-800-232-4036. Exposure can be minimized by effective controls, including System Maintenance, Ventilation, and Work Practices can effectively reduce N2O concentrations in dental operations. A scavenger system is a significant part of exposure control.

Your sedation machine includes a fail-safe and other safety features. It also includes the required and accepted specifications by the ADA Council on Dental Materials and Devices. Which includes Emergency Air Valve, Rebreathing Check Valve, and Resuscitator Quick Connect. The ADA also requires the system be installed by a competent supplier of gases and equipment. The gas storage and delivery system should meet the recommendations for the National Fire Protection Association (See NFPA Code).

Index

PC7-C Flushmount Flowmeter

The PC7-C has been reconfigured to fit flush into today's cabinetry and provides the same time proven precision and dependability as our stand PC-7 unit.

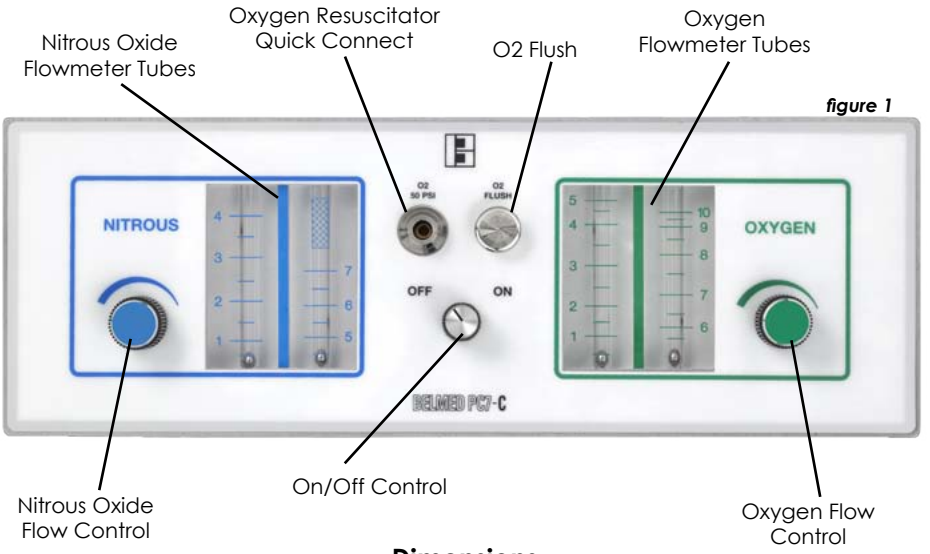


figure 1

Dimensions
4.25" H x 12.187" W x 4.687" D

On/Off Control simple 1/4 turn, establishes a 3 liter minimum O2 flow.

O2 Flush provides a rapid flow of oxygen directly into patient breathing circuit.

Flow Control Valves Micrometer needle valves allow quick responsive flow adjustments. Needle valve design prevents seat damage.

Dual Cascading Flowmeter Tubes are calibrated in liters per minute at ½ liter increments.

Oxygen Fail-Safe Automatically and proportionally reduces N2O in the event O2 is reduced or shut off.

Non-Rebreathing Check Valve Prevents the rebreathing of expired gases and guards against CO2 build-up.

Air Intake Valve entrains ambient air into the breathing circuit in the event flow from the machine is lost for any reason.

Solid Gas Control Block Designed to eliminate internal gas leaks

Oxygen Resuscitator Quick Connect provides connection of auxiliary resuscitation equipment.

Test Procedures

Note: Failure of the following test will require unit to be returned for service. These tests must be conducted periodically to ensure proper operation. (Refer to figure 1)

Test: Connect unit to a 50psi gas source. Check to make sure control valves are turned off. Gently turn both valves clockwise until unit resistance is felt.

1. Minimum oxygen: Turn on unit by pushing and turning on/off knob. A 3 liter flow of oxygen should be produced through O2 tube.

2. Oxygen flush: Depress O2 flush button to determine a rapid flow of oxygen into breathing circuit. Flow should stop when button is released.

3. Maximum nitrous: Turn N2O needle valve wide open. N2O flow should not exceed 7 LPM.

4. Fail safe test: Establish a 7 LPM N2O flow and 3 LPM O2 flow. Disconnect O2 supply source or turn off O2 shut-off valve. Both O2 and N2O flows should stop flowing.

5. Air intake valve: Attach breathing bag and corrugated breathing tube to proper ports of tee. Unit should be turned off and bag flattened. Inhale through breathing tube. Room air must enter through air intake located on bottom of breathing circuit tee.

6. Non-Rebreathing valve: Connect corrugated tube to front of tee and attempt to exhale through tube. Valve should be closed preventing exhaled air from going into tube.

Operation

1. Turn unit on (100% O2) and set the oxygen flow rate to equal total gas flow (minute volume) to be administered to patient. Maintain breathing bag about ⅔ full.

2. Apply nasal hood to patient.

3. Gradually introduce nitrous oxide flow rate while proportionally decreasing oxygen flow rate (maintaining total gas flow) until determined patient ratio is reached.

4. If oxygen is required, press oxygen flush button.

5. To remove patient from conscious sedation, return to 100% oxygen flow rate established at beginning of procedure.

Maintenance

1. Ascertain a proper gas supply pressure of 50psi.

2. Inspect machine hoses and connections for damage, wear and leaks daily.

3. Perform functional test periodically.

4. Keep unit clean. Unit and accessories may be cleaned with activated dialdehyde (Cidex). Follow manufacturers directions for use.

Service: All Service and repair must be completed at Belmed, Inc. Have your dealer return the unit to our facility for service.

Installation

IMPORTANT: PRIOR TO INSTALLATION, TURN OFF CENTRAL GAS SUPPLY SYSTEM AND CLOSE ALL GAS TANK VALVES IN TANK ROOM. DISS SHUT-OFF VALVES SHOULD BE IN CLOSED POSITION THROUGHOUT INSTALLATION OF THE FLOWMETER.

Install the gas lines: A qualified plumber can install the delivery piping up to and including the DISS shut-off valves.

The dental dealer is responsible for the final connections to the flowmeter, the details of flowmeter installation checking for crossed-lines, leak testing of connections to the flowmeter, and basic flowmeter operation.

1. Determine desired location of the flowmeter. Use the provided cut-out dimensions to cut an opening in the cabinet or mounting apparatus.

> **Note:** Flowmeter location needs to accommodate 5 feet DISS hose-to-shut-off valve distance, and 10 feet mixed gas hose-to-remote bag tee distance.

2. Determine the location of the remote bag tee that accommodates visual monitoring of the breathing bag during patient treatment. Use the provided diagram to pre-drill and mount the remote bag tee block. Insert tee and tighten set screw with provided Allen wrench. (MAKE SURE SET SCREW IS ACCESSIBLE).

> **Note:** Bag Tee ideally is to be installed within 10 feet of the flowmeter.

3. Connect the O2 DISS hose (green) to the O2 shut-off valve and the N2O DISS hose (blue) to the N2O shut-off valve.

4. Connect 10 feet mixed gas hose to the hose barb on the Remote Tee. Shorten the hose if desired and attach the ferrules to the ends. Moisten the hose barb to ease installation.

5. Pull O2 and N2O DISS hoses and mixed gas hose through the cut-out for the flowmeter and attach O2, N2O and mixed gas hose to the back-side of the flowmeter.

> **Note:** Make certain hoses are not crimped. Check O2 and N2O hose connections for leaks.

Caution: Be sure to use two wrenches when tightening or removing hoses from the gas fittings.

6. Position flowmeter over opening and line up screws on the flowmeter with the pre-drilled holes of the cut-out. Secure the flowmeter by tightening the provided nuts.

7. Perform the Check for Crossed Lines, The Leak Test of the Flowmeter Installation, and the Flowmeter Function Test.

CHECK FOR CROSSED LINES: (Refer to NFPA Gas and Vacuum Systems for Type II Systems Crossguard Warning.) Open both the O2 and N2O shut-off valves to allow gas to the flowmeter. Before using flowmeter, check for crossed lines by opening the O2 valve and making certain that only oxygen flows through the flowmeter.

LEAK TEST OF THE FLOWMETER INSTALLATION: After all hose connections are tightened, turn the flow control knobs to the off position and the on/off knob to the off position. Confirm that the DISS shut-off valves are in the open position. Pressurize the sedation gas supply lines with 50psi. Observe any pressure decay after an overnight time period. (5psi drop allowed.)

PC7-C Flushmount Flowmeter

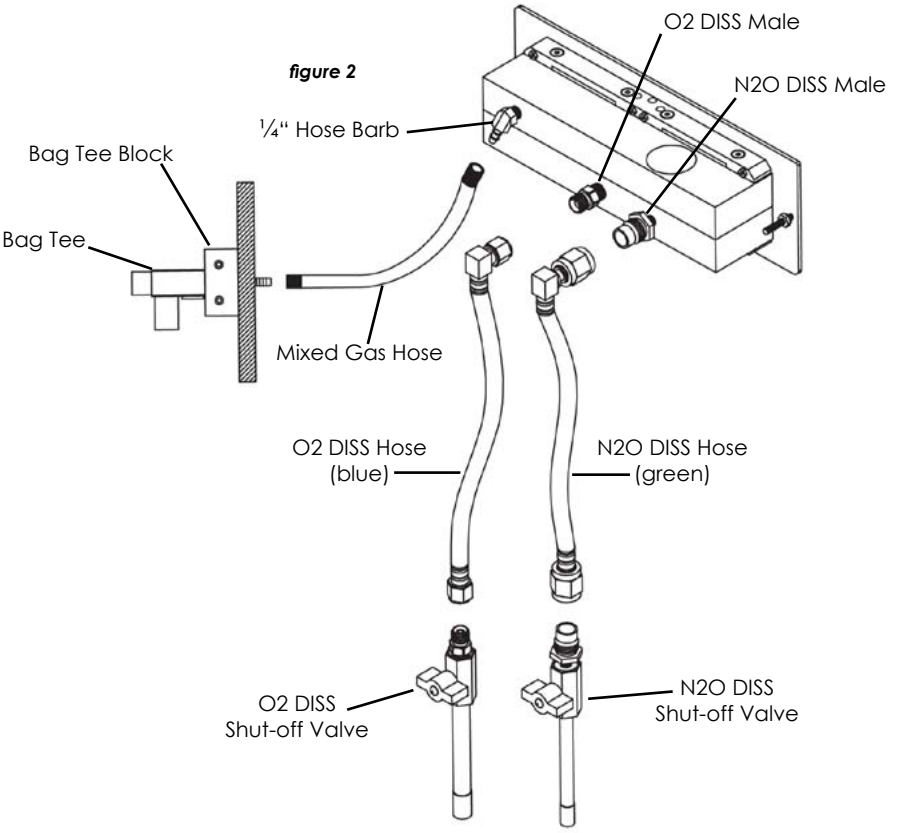


figure 2

Parts List

Description	Part Number
Accessory Angle	5500-600
Flushmount Flowmeter (includes Remote Tee)	5500
Mixed Gas Hose (10ft)	5500-76
N2O DISS Hose (5ft)	8031
N2O DISS Shut-Off Valve	7302
O2 DISS Hose (5ft)	8030
O2 Diss Shut-Off Valve	7304
Remote Tee Block	5500-500
Sliding Bracket	5500-700

Scavenger Rubber Goods Assembly

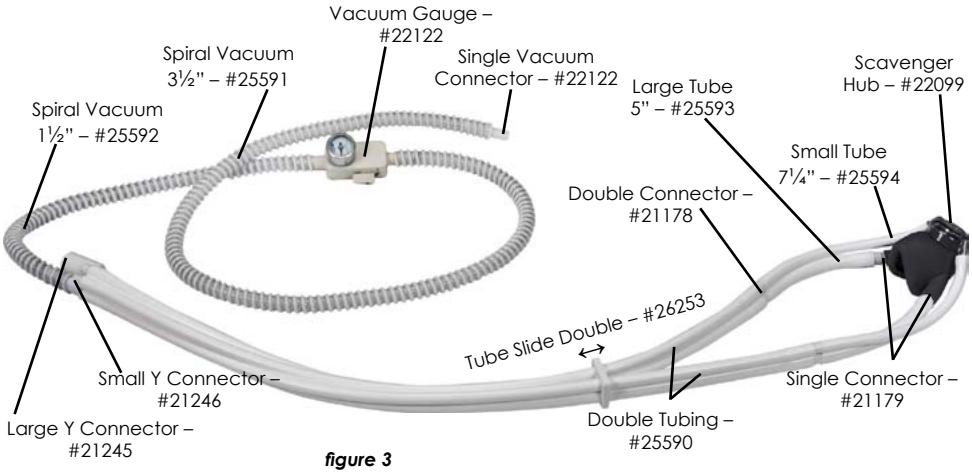


figure 3

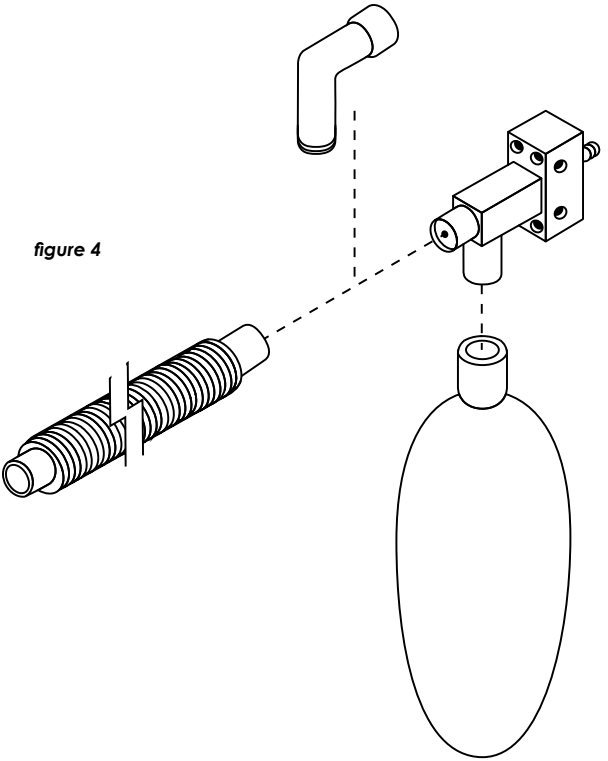


figure 4

Remote Tee Block Hose Barb Option

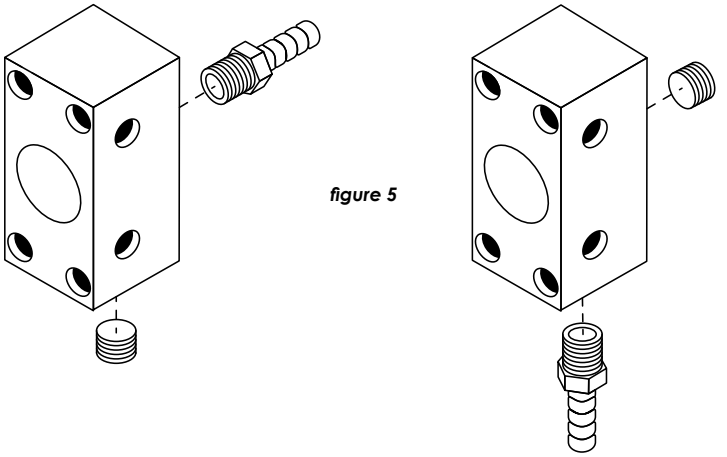


figure 5

The hose barb can be moved from the back location to the down location in a few simple steps.

1. Remove the hose barb with a 7/16" open end wrench.
2. Remove the plug with a 3/16" Allen wrench.
3. Wrap both the hose barb and plug with Teflon Tape.
4. Tighten the hose barb to the bottom of the block.
5. Tighten the plug to the back of the block.

Tee Installation

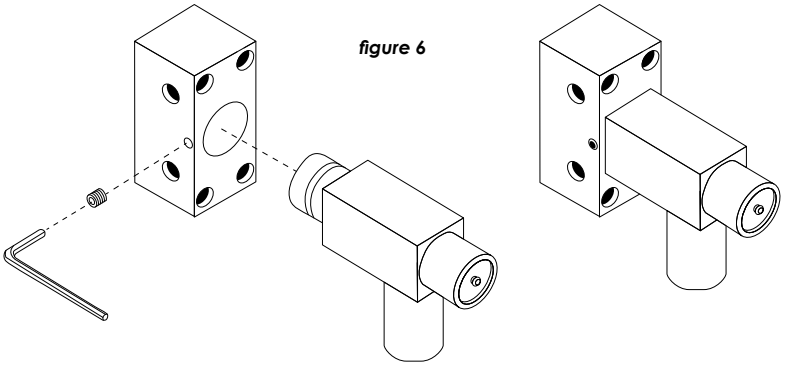
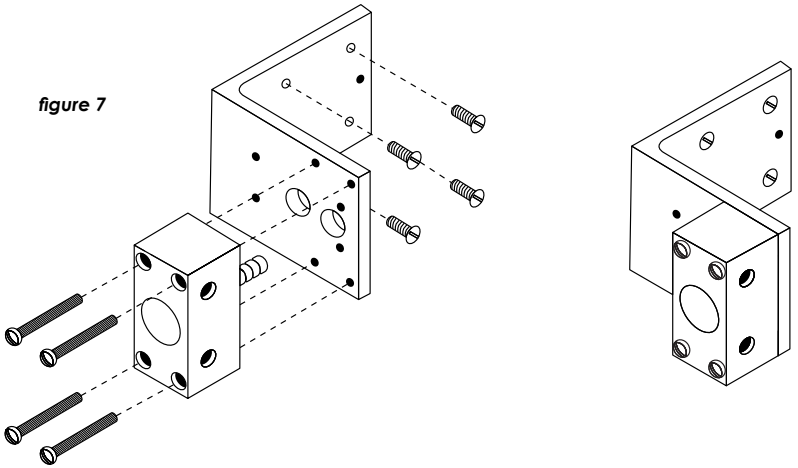


figure 6

Remote Tee Bracket Installation
Left or Right Side Installation

figure 7



1. Use Remote Tee Bracket as drilling guide.
2. Pre-drill all 4 holes 7/64"
3. Mount Bracket with #8 x 5/8 wood screws (4 included).
4. Attach Remote Tee Block to the Remote Tee Bracket with #8 x 1 1/2" machine screws (4 included).
5. Attach Mixed Gas hose to hose barb on block.
6. Insert Tee and tighten set screw with 3/32" Allen wrench.
7. Attach Rubber Goods.

Standard

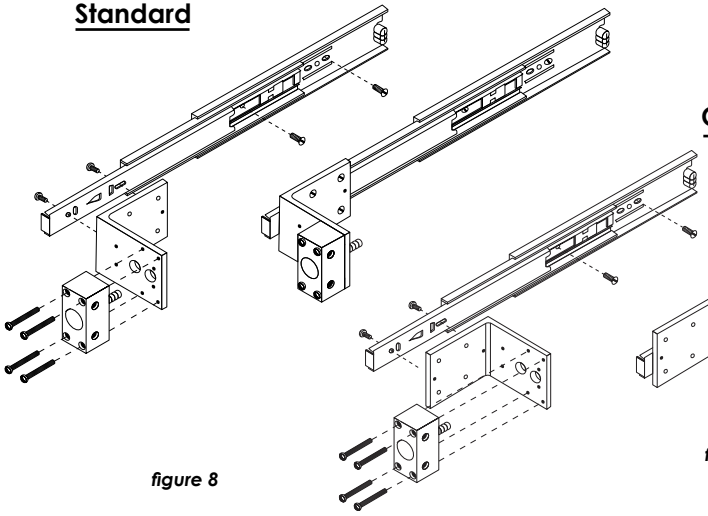


figure 8

Compact (save 3")

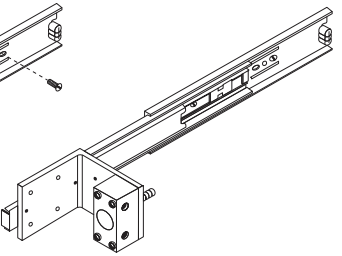
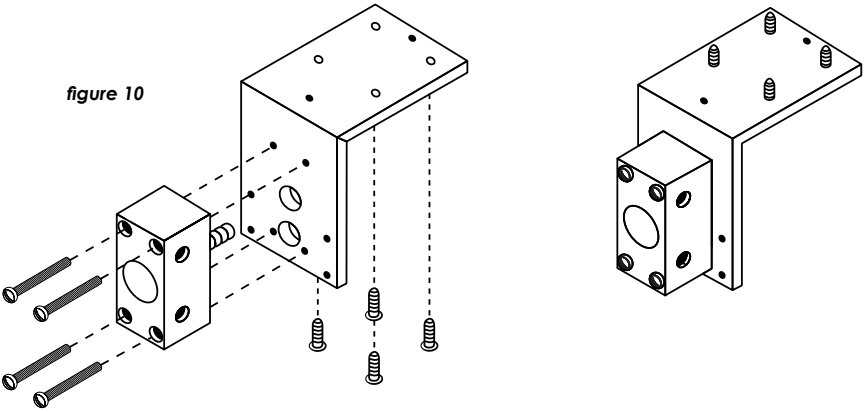


figure 9

Remote Tee Bracket Installation
Top Installation

figure 10



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Standard

Compact (save 3")

figure 11

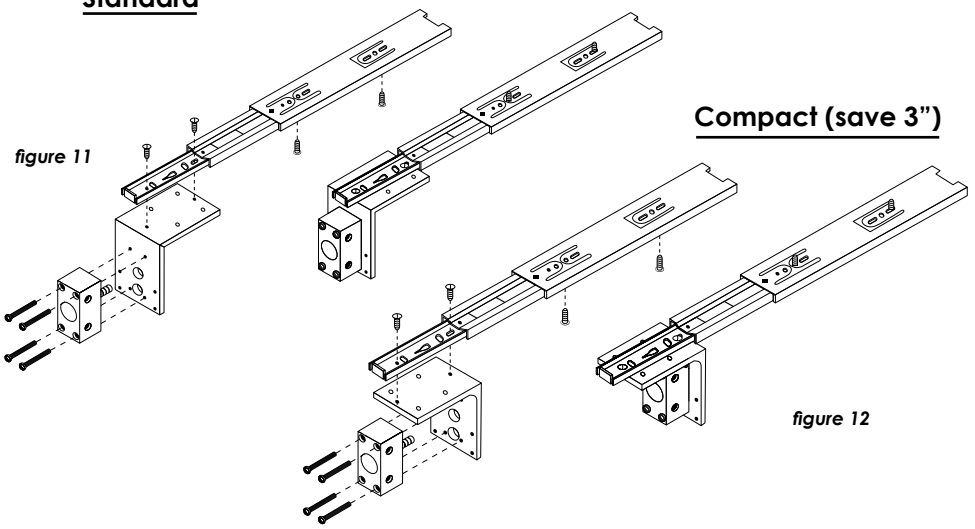


figure 12

PC7-C Flowmeter Dimensions

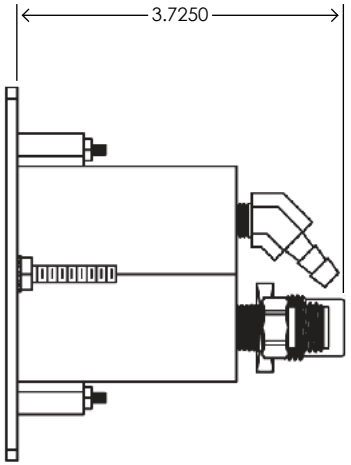


figure 13

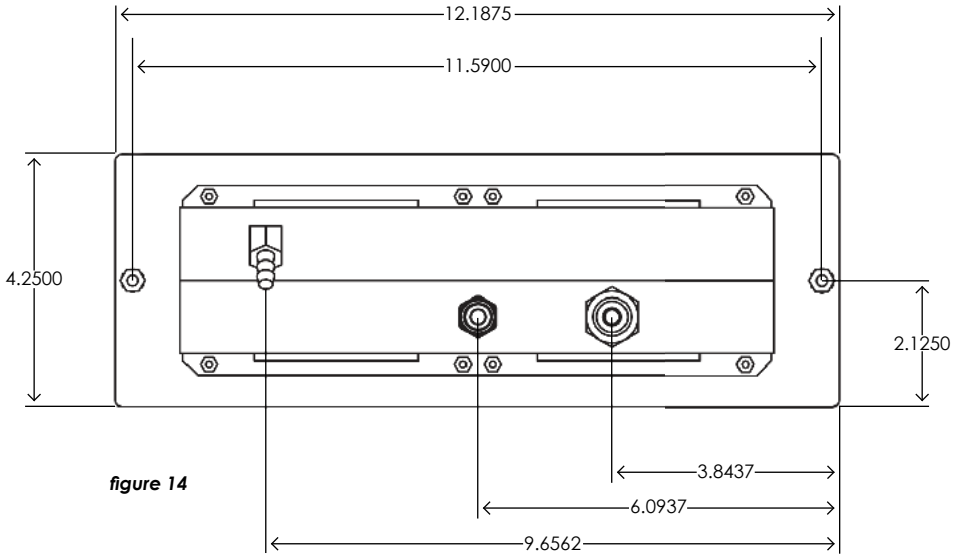
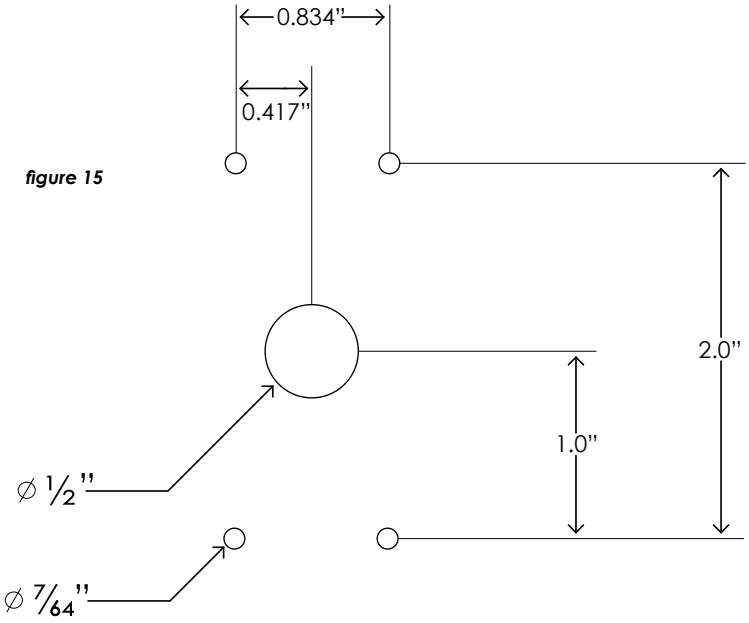


figure 14

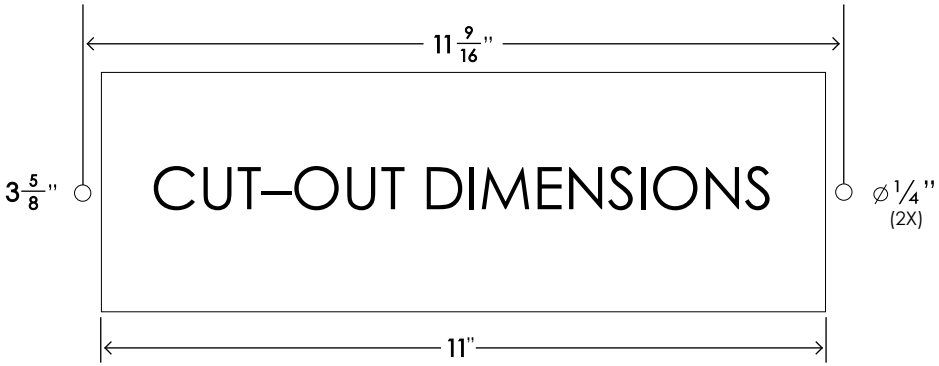
Remote Tee Block Template

figure 15



Cut-Out Dimensions

figure 16



Purchase Record

MODEL NO.	SERIAL NO.	PURCHASE DATE

Warranty

Definition of Warranty Return: A product or part covered by the Belmed, Inc. warranty, that fails while the terms of the warranty are in effect.

THIS WARRANTY IS GIVEN IN PLACE OF ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE.

No statement or claim about the product by any employee, agent, representative or dealer of Belmed, Inc. shall constitute a warranty by Belmed, Inc. or give rise to any liability or obligation of Belmed, Inc.

Subject to the next sentence, Belmed, Inc warrants that each product or part shall be free from defects in workmanship and materials, under normal use and with appropriate maintenance, for one (1) year from the date of delivery to customer. For plastic, rubber and disposable parts or items Belmed, Inc. warrants only that each such part and item shall be free from defects in workmanship and materials at the time of delivery to the customer.

Belmed, Inc.'s obligation for breach of this warranty, or for negligence or otherwise, shall be strictly and exclusively limited to Belmed Inc.'s choice of repair or replacement of the product or part. This warranty shall be void for any product on which the serial number has been altered, defaced or removed.

Belmed, Inc. shall not be liable for any damage, injury or loss arising out of the use of the product, whether as a result of a defect in the product or otherwise, if, prior to such damagve, injury or loss, the product was (1) damaged, misused, or misapplied; (2) repaired, altered or modified by persons other than Belmed, Inc. (3) not installed in strict compliance with applicable codes and ordinances; or (4) not installed by Belmed, Inc. or an authorized Belmed, Inc. dealer.

UNDER NO CIRCUMSTANCES SHALL BELMED, INC. BE LIABLE FOR INCIDENTAL OR CONSEQUENTIAL DAMAGES AS THOSE TERMS ARE DEFINED IN THE UNIFORM COMMERCIAL CODE.

Important: Traceability/Warranty Registration

Medical device legislation of 1976 mandates traceability of this equipment. Please fill out and return warranty card.

NITROUS OXIDE LPM	OXYGEN 0.5	1	1.5	2	2.5	3	3.5	4	4.5	5	5.5	6	6.5	7	7.5	8	8.5	9	9.5	10
0.5	50%	33%	25%	20%	17%	14%	13%	11%	10%	9%	8%	8%	7%	7%	6%	6%	6%	5%	5%	5%
1	67%	50%	40%	33%	29%	25%	22%	20%	18%	17%	15%	14%	13%	13%	12%	11%	11%	10%	10%	9%
1.5	75%	60%	50%	43%	38%	33%	30%	27%	25%	23%	21%	20%	19%	18%	17%	16%	15%	14%	14%	13%
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3	86%	75%	67%	60%	55%	50%	46%	43%	40%	38%	35%	33%	32%	30%	29%	27%	26%	25%	24%	23%
3.5	88%	78%	70%	64%	58%	54%	50%	47%	44%	41%	39%	37%	35%	33%	32%	30%	29%	28%	27%	26%
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5	91%	83%	77%	71%	67%	63%	59%	56%	53%	50%	48%	45%	43%	42%	40%	38%	37%	36%	34%	33%
5.5	92%	85%	79%	73%	69%	65%	61%	58%	55%	52%	50%	48%	46%	44%	42%	41%	39%	38%	37%	35%
6	92%	86%	80%	75%	71%	67%	63%	60%	57%	55%	52%	50%	48%	46%	44%	43%	41%	40%	39%	38%
6.5	93%	87%	81%	76%	72%	68%	65%	62%	59%	57%	54%	52%	50%	48%	46%	45%	43%	42%	41%	39%
7	93%	88%	82%	78%	74%	70%	67%	64%	61%	58%	56%	54%	52%	50%	48%	47%	45%	44%	42%	41%

* Greater than 70% N2O administered exceeds the amount able to be delivered by sedation machine.

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