

Introduction

This guide provides instruction for operation, maintenance, and troubleshooting procedures for the Tumescence Measuring Device - the **TMD**. All users should be versed in its use and application before actual use and application.

Warnings and Cautions

All personnel should review and be familiar with the following warnings and cautions prior to using the TMD.

- a **Caution:** *Do not immerse the TMD. Immersion will cause permanent damage to the circuitry. Do not use an excessive amount of liquid when cleaning. Never allow liquids to enter the TMD case.*
- a **Caution:** *A specified power supply must be used. Power may be taken from a MD Resource tumescence delivery pump that has an auxiliary DC (direct current) outlet or from separate medical grade power supply with a standard barrel connector (5.5 x 2.1 x 9.9 mm, straight female, positive center) with an output voltage of 8 VDC to 32 VDC at 100mA.*
- a **Caution:** *When loading TMD use gentle motion. Never roughly pull on hook.*
- a **Caution:** *Maximum load on hook should never exceed 4,000ml.*
- a **Caution:** *The TMD weighs enough that its falling off the IV Pole due to incomplete or otherwise faulty mounting could do serious bodily damage. Take care in its set up; making sure that the mounting is complete and correct.*
- a **Caution:** *The TMD is designed to be mounted on a 7/8" diameter pole that is mounted vertically. Accuracy of measurement is compromised with any non-rigid mounting. Other mounting options are available: consult Medical Device Resource Corp.*

Modification

Changes made to the TMD or it's advised procedural usage may adversely affect its performance or accuracy. Any requests for changes in its design or use should first be communicated with the proper Medical Device Resource Corporation (MDRC) personnel.

Setup Instructions

1. Extend pole (no larger than 7/8" diameter) to desired height.
2. Make sure nylon pole mount tightener is loosened that TMD may be slid fully over pole.
3. Place TMD so pole inserts fully into the mounting cylinder. This is slightly more than 2" of insertion. **Total insertion is important for operator safety, device accuracy, and potential device damage abatement!**
4. After putting TMD in the desired viewing position, fix this location with the nylon pole mount screw. **Not tightening this set screw may lead to poor viewing and/or scale inaccuracy! Not using the set screw may lead to device damage or operator injury!**
5. Connect power plug from the universal AC adapter to the power inlet on the rear panel. Alternatively, the DC power may be supplied with an umbilical connected from the auxiliary DC outlet on a Medical Device Resource K-pump. (DC power into the TMD may be from 8 to 32 VDC at 100 mA.) *Diagram 1* shows a power umbilical route with the supplied Velcro ties.
6. Place the needed tumescent bag(s) on the hook, connect the tubing that will connect this (these) to the infiltration pump.
7. Use included Velcro tie(s) to secure this (these) tubes so that the weight of the tubing further down and the inevitable movement of these tubes do not bear on the TMD. *See *Diagram 1*. The TMD hook must not rub on the hole through which it is positioned. It is important that the Velcro ties are used, as the infiltration device and changing weight of the tubing as tumescent is being displaced will otherwise make for an erratic delivery display.
As tumescent is withdrawn from the bags the display will show an increasingly negative number. This is the amount of liquid delivered in CCs. The display takes a moment (1 to 3 seconds) to stabilize after delivery is temporarily halted or completed.

Note: This section does not include the particulars for the setup and usage of the infiltration pump that will be used in conjunction with the TMD. These instructions are specific to the device being used and should be followed as per its manufacturer's instruction.

a Conditions of Limited Warranty

All claims for defective products must be made in writing within the warranty period, and any claims not made within that period shall be deemed waived and released. Medical Device Resource Corporation may, at its discretion, replace a product in whole or in part with comparable equipment and may use re-manufactured and reconditioned parts in performing service.

Transportation charges on parts submitted for repair or replacement under this Limited Warranty must be borne by registered user.

Medical Device Resource Corporation shall have no liability for delay or failure to provide service to a product due to war, civil commotion, acts of public enemies, acts of terrorism, blockade, embargo, strikes, acts of God, inability to secure raw materials, transportation facilities, fuel or energy shortages, acts or omissions of communications carriers, or any other act whatsoever, whether similar or dissimilar to those referenced above, which is beyond Medical Device Resource Corporation's reasonable control.

This Limited Warranty is for a commercial, non-consumer product and is valid only in the United States.

The Limited Warranty shall be governed by the laws of The Commonwealth of Massachusetts, without regard to its conflict of laws and provisions.

This Limited Warranty applies only to the original registered user and is not transferable to a third party without Medical Device Resource Corporation's prior written consent.

This Limited Warranty constitutes the entire agreement between parties and shall not be amended except by written agreement. If any provision of this Limited Warranty is found invalid or unenforceable, the remaining provisions shall remain in effect.

This Limited Warranty gives the registered user specific legal rights. The registered user may also have other rights which vary depending upon local laws. In some areas, local laws do not apply limitations on warranties, remedies or liabilities, therefore some of the above limitations may not apply.

aid you in any way possible to achieve a satisfactory outcome for your damage claim. Filing and handling the claim is your responsibility.

Technical Specifications for TMD

- a Power input: 8 to 32 VDC @ 100mA, maximum. Typical usage is 8 to 32 VDC @ 30mA while on and 8 to 32 VDC @ 10mA while off.
- a Display: 5 digits, 0 to 6000g, backlit with blue panel light.
- a Accuracy: < 1% error, +/- 1 gram given reasonably level TMD mounting (level +/- 7 degrees).
- a NOTE ON ACCURACY: TMD accuracy reflects the loss of weight in the suspended tumescent bag(s). All tumescent displaced from the suspended mass will be measured. There is no way it can 'know' the amount of tumescent not delivered to the patient.

Technical Manuals

Repairs are only authorized by the manufacturer or a factory approved repair facility. Technical service manuals are not available to users for this reason.

Concealed Shipping Damage

Please set up and operate the product as soon as possible to discover any hidden shipping damage. If damage is revealed contact the carrier to have an agent inspect the damage. Most freight and shipping companies have a limited time period for accepting this type of loss or claim. Contact your carrier immediately. The carrier reserves the right to refuse any loss or concealed damage claim made beyond that time. Medical Device Resource Corporation is not responsible for the collection of claims or replacement of damaged merchandise. We will

Return Procedure

Contact Medical Device Resource Corporation before returning any merchandise. Have the following information available at that time.

- a Invoice or relevant information to invoice.
- a Contact person and phone number.
- a Serial number
- a Reason for return

If the product has been exposed to any bio-hazardous material or used in surgery or surgical related area, it must be **cleaned and sterilized** and **have a written statement of confirmation of sterility accompanying the returned product.**

Limited Warranty

Medical Device Resource Corporation products are manufactured for use by qualified medical personnel trained and skilled as medical professionals.

a Scope of Limited Warranty

The TMD Pump is warranted to be free from manufacturing defects in materials and workmanship for a period of one year from date of purchase. The Limited Warranty shall apply between Medical Device Resource Corporation and the registered user of the TMD Pump.

a Exclusions

This Limited Warranty does not cover routine maintenance or expendable parts.

a Circumstances rendering Limited Warranty Invalid

This Limited Warranty will become invalid in respect of any product if:
(1) the product has been damaged in any way (other than by Medical

Device Resource Corporation) by misuse, mishandling, improper operation, abuse of the product or otherwise;

(2) The product has been installed, stored, maintained, used or adjusted otherwise than in accordance with instructions provided by Medical Device Resource Corporation in these Instructions For Use;



M.D. RESOURCE
medical device resource corporation

TMD

Tumescent Measuring Device

Instructions For Use

Rev 2.0
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3. DO NOT IMMERSE TMD. DO NOT USE AN EXCESSIVE AMOUNT OF LIQUID WHEN CLEANING. NEVER ALLOW FLUIDS TO ENTER TMD CASE.

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User Maintenance

1. The TMD is factory calibrated- if calibration becomes necessary, return for service.
2. The hospital grade power adapter is included with the TMD, includes a detachable AC power cord. This should be inspected periodically for damage and should be replaced when worn. If the DC connector or its cable becomes damaged, the power adapter should be replaced.
3. If the nylon pole mounting screw or the start switch button get misplaced they are available from the factory.

Cleaning TMD

1. Ammoniated Cleaners may be used to gently clean the TMD case.
2. Use only a soft cotton cloth to gently clean the digital display face.

General Description

The TMD is a digital scale based on load cell technology with associated circuitry and display mounted with a load bearing steel foundation and assembled in an ABS package. It is designed and configured to measure 1 to 4,000 grams: corresponding to the usage of 1 to 4,000 ml of tumescent. The configuration is such that as tumescent is delivered to the cannula via tumescent delivery pump, the digital display shows the amount of tumescent displaced.

Description of Device

Front Panel:

1. 5 digit LCD display with blue backlighting. It is visible with a 60 degree viewing window for up to 10 ft.
2. **Start switch. Push once for “on” and once for “off.”**

Rear Panel:

1. Power plug that accepts a standard barrel jack (5.5 x 2.1 x 11 mm, straight female, positive center). Power in may be from 8 to 32 VDC at 100 mA, positive center.
2. Nylon pole mount screw for fixing the TMD’s position on its pole.

Bottom:

1. Hook for hanging tumescent bags: up to 3 liters of tumescent. It is free hanging and may be rotated 360 degrees.
2. Pole insertion cylinder: mount TMD to pole here. This cylinder will accept a 7/8" (0.875") OD pole. An adapter for 3/4" standard IV Poles is available.

Inside:

1. Load cell and associated circuitry.
2. Tool foundation for load cell monitoring. Patent Pending.

(3) The product has been repaired, serviced, replaced, worked on or altered by any person not authorized by Medical Device Resource Corporation;

(4) The product has been used for a purpose which is not intended for it;

(5) The serial number on the product has been altered or defaced.

a Sole Remedy

Medical Device Resource Corporation will repair or replace, free of charge, any parts that are defective in material or workmanship during the time period of the Limited Warranty. Medical Device Resource Corporation's obligations under this Limited Warranty are limited to repair or replacement of the part or parts found to be defective and such repair or replacement shall be a registered user's sole and exclusive remedy.

a Disclaimers and Limitations of Liability

Medical Device Resource Corporation's obligations under this Limited Warranty shall under no circumstances exceed the cost of the product or part for which the claim under this Limited Warranty is made.

This Limited Warranty contains all the warranties which Medical Device Resource Corporation gives in respect of the TMD Pump and related parts, and Medical Device Resource Corporation expressly disclaims all other warranties, either express or implied, including

without limitation any implied warranties of merchantability or fitness for particular purpose.

In no event shall Medical Device Resource Corporation be liable for consequential, indirect, special or incidental damages (including without limitation damages for loss of profits, loss of use, or any other indirect damages of any kind), but Medical Device Resource Corporation does not exclude its liability for death or personal injury caused by its negligence.

Diagram 1

1. Hook must not touch enclosure exit hole. It may be swung left and right, forward and back to assure this is the case.
2. Tubing doubled up and down, not overly pinched, and Velcro fastened to pole. Assure tubing will not slip down pole by giving it a sample tug downward.

These two steps assure stable and accurate measurement of tumescent delivery.

