TRAM®

INSTRUCTIONS FOR USE

Description
A manifold with integral transducer is a pre-calibrated, single use device for physiological pressure measurement and fluid delivery. A separate reusable interface cable is used with this system to connect the transducer to a pressure monitor.

Indications
The Merit manifold with integrated transducer is used in cardiovascular diagnostic, surgical, and therapeutic applications to interconnect tubing, catheters, or other devices. Also used for measurement of blood pressure.

℞ Only. Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

Warnings
- Ensure that you are making secure connections when using this device to prevent the introduction of air into the system. All connections should be finger tightened. Over tightening can cause cracks and leaks to occur.
- Check for fluid leakage before and during the procedure. Leaks can result in the loss of sterility, fluid or blood loss, and/or air embolism. If a product leaks before or during use, retighten the leaking connection or replace the product.
- Prior to pressure injecting through the manifold, open the zeroing port. This product does not incorporate protection from accidental over pressurization. Over pressurizing may permanently impair the accuracy of the device.

Precautions
- Contents supplied sterile. Do not use if sterile barrier is damaged. If damage is found, contact a Merit Medical representative.
- Carefully read instructions before using product. If product is being used in conjunction with other manufacturers' components, also read instructions for use.
- Use proper aseptic techniques while handling product.
- The presence of air in the system will damp the transmission of the patient's pressure to the transducer. Be sure to eliminate all air bubbles within the system.
- During fluid injection through the main lumen of the manifold, ensure proper orientation of the port handles so that fluid does not enter the side ports.
- Do not use yellow side port as an injection site for fluids.
- Inspect device prior to use to verify that no damage has occurred during shipping.

Instructions for Use
1. Using aseptic technique, open the package containing the sterile product.
2. Check all connections before use and finger tighten, if necessary. To prevent stripping, do not over tighten. Inspect for damage or improper assembly.
3. Begin set-up according to hospital protocol for catheterization/pressure monitoring procedures. Purge the system of air bubbles.
4. Ensure that all electrical connectors are dry. Connect the Meritrans® disposable transducer cable to the reusable monitor cable. Align the connector pins, firmly join the connectors together.
5. To complete the set-up, open the stopcock to atmosphere and flush the transducer port free of air. Once the entire system has been fluid filled and the air is removed, the system is ready to be zero balanced. Ensure the yellow stopcock is open to air and the manifold transducer handle is closed to the patient.
6. Balance and calibrate the system according to the monitor manufacturer's instructions.
7. To monitor pressure, orient the port handles so that the transducer lumen is open towards the catheter or patient. (Inspect carefully for air bubbles and reflush, if necessary.)

Note: Ensure all connections are securely tightened. Inspect carefully for air bubbles and flush the manifold lumen, if necessary.

8. The manifold should be returned to the original position used to zero balance the system. The reference point assures consistency as pressures can be affected by elevating the transducer.

REUSE PRECAUTION STATEMENT:
For single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

SPECIFICATIONS

Excitation Voltage	1.0 to 10 Vdc-5kHz	Excitation Impedance	240-350 Ω
Signal Impedance	300 Ω ±30Ω	Phase Shift	<5°
Sensitivity	5 µV/V/mmHg	Operating Temperature	15°C to 40°C
Storage Conditions	Store in a cool, dry place	Maximum Half-Sine Shock Acceleration	4500 G
Zero Drift	1 mmHg/8 hours		
Thermal Coefficient Offset	±0.3 mmHg/°C	Thermal Coefficient Span	±0.1%/°C
Light Sensitivity	<1 mmHg-		

MERITMEDICAL™

Manufacturer:
Merit Medical Systems, Inc. South Jordan, Utah 84095 www.merit.com
U.S.A. 1-801-253-1600 U.S.A. Customer Service 1-800-356-3748

EC REP Authorized Representative:
Merit Medical Ireland Ltd, Parkmore Business Park West, Galway, Ireland

401906003/C ID 053113

带压力传感器的连通板

使用说明

说明
带压力传感器的连通板是经过预先校准的一次性使用装置，用于生理压力测量和液体输送。将单独的可重复使用的连接线缆与该系统一起使用以将传感器连接至压力监测器。

产品结构
该产品由传感器外壳/安装板、压力传感器、电缆、连通板体、手柄及旋转鲁尔接头组成。

产品型号及标称压力

型号	承受压力	型号	承受压力	型号	承受压力
203LTPHN-R	200PSI	203LTPHWN-R	200PSI	203LTPHF-R	200PSI
203LTPHWF-R	200PSI	503LTPHN-R	500PSI	503LTPHWN-R	500PSI
503LTPHF-R	500PSI	503LTPHWF-R	500PSI		

适应症
带压力传感器的MERIT连通板可用于心血管诊断治疗手术及外科手术过程中，用于连接输液管、导管。亦可用于测量动脉压及中心静脉压。

仅凭处方销售。警示：联邦（美国）法律限定本装置仅可由医师或凭医师处方销售。

警告
- 在使用该装置时，请确保连接牢固，以免将空气引入系统中。所有连接必须用手指紧固。过度紧固可能造成裂缝和泄漏。
- 在术前和术中，检查有无液体泄漏。泄漏可能导致丧失灭菌、流失液体或血液和／或引起气栓。若产品在使用之前或之中发生泄漏，应重新紧固发生泄漏的连接或更换产品。
- 在压力通过连通板注入之前，打开归零接口。本产品没有意外压力过高保护措施。压力过高可能会永久损害装置的精度。

注意事项：
- 内容物提供时已灭菌。如果灭菌屏障损坏，则不要使用。如发现损坏，请联系MERIT MEDICAL 代表。
- 使用本产品前，请认真阅读说明。若将本产品与其他制造商的产品联用，请阅读相应的使用说明。
- 处理本产品时须采用正确的无菌技术。
- 若系统内存有空气，将患者的压力传递到传感器时将被减弱。务必清除系统内的所有气泡。
- 在通过连通板的主管腔进行液体注入时，确保接口手柄朝向正确的方向，以防液体进入侧口。
- 请勿将黄色的侧口作为液体注入部位使用。
- 在使用前检查装置，以确认运输期间未造成任何损坏。

使用说明
1. 使用无菌技术，打开包有灭菌产品的包装。
2. 如有必要，请在使用及用手指紧固前，检查所有连接。为防止折断，请勿过度紧固。检查是否损坏或组装不当。
3. 按照医院关于插管／压力监测程序的规程开始安装。从系统中排出气泡。
4. 确保所有电气接头干燥。将 MERITRANS 一次性传感器线缆与可重复使用的监测线缆相连。校准插针，将其与插接件牢固接合。
5. 为完成安装，打开旋塞阀与大气相通，并冲洗传感器接口以排出空气。待整个系统充满液体并清除空气后，系统便可进行归零了。确保打开黄色旋塞阀与大气相连，并确保对患者关闭连通板传感器手柄。
6. 根据监视器制造商的说明归零和校准系统。
7. 为监测压力，调整接口手柄以使传感器管腔朝向导管或患者方向打开。（仔细检查是否存在气泡，如有必要，请重新冲洗。）
   注意：确保所有连接均紧固妥当。仔细检查是否存在气泡，如有必要，请冲洗连通板管腔。
8. 连通板应放回到系统实现归零的最初位置。该参考点可确保压力始终保持一致，因为抬高传感器会对压力产生影响。

灭菌方式：环氧乙烷灭菌，仅限一次性使用。

重复使用注意事项声明：
仅可用于一名患者。请勿重复使用、重新处理或重新消毒。重复使用、重新处理或重新消毒可能破坏装置的结构完整性，及／或导致装置故障，从而可能导致患者受伤、患病或死亡。重复使用、重新处理或重新杀毒也可能构成装置污染风险，及／或导致患者感染或交叉感染，包括但不限于在患者间传播传染病。装置污染可能导致患者受伤、患病或死亡。

增塑剂名称：邻苯二甲酸（2-乙基己基）酯（DEHP）
警示信息及药物相容性提示：1）本产品不宜贮存和输注脂肪乳等脂溶性液体和药物；2）临床医务人员应注意其对高风险人群（新生儿、青春期前的男性、怀孕期和哺乳期的妇女）的可能毒性，应尽量替代。3）不能用于输注与PVC不相容的药物，根据国内外研究资料临床医务人员应注意PVC管路会与所输注药物发生相互作用而致药效改变。4）企业未作药物的相容性试验，用本产品输注相关药物时的相容性信息是未知的

规格

励磁电压	1.0 至 10 VDC-5KHZ	励磁阻抗	240-350Ω
信号阻抗	300Ω ±30Ω	相移	<5°
敏感度	5 µV/V/mmHg	工作温度	15° C 至 40° C
贮存条件	存储于阴凉干燥处	最大半正弦冲击加速度	4500 G
零位偏移	1 mmHg/8 小时	热系数跨距	±0.1%/° C
热系数偏移	±0.3 mmHg/° C		
感光度	<1 mmHg-		

产品有效期：3年
储存条件： 室温，通风，干燥，避光；
运输条件：运输过程中，避免接触高温潮湿；

注册证号： CFDA (I) 20133213420
标准号：YZB/USA 4428-2013
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