

DESCRIPTION

The Meritrans is a pre-calibrated, single use device for physiological pressure measurement. A separate reusable interface cable is used with this system to connect the transducer to a pressure monitor.

The Meritrans may be used with a manifold, pole mount organizer, or attached directly to the patient via a strap.

SET-UP

Connections

- Using aseptic technique, open the package containing the sterile transducer.
- Set-up according to hospital protocol for pressure monitoring procedures. Connect to other monitoring equipment (e.g. manifolds, stopcocks, flush devices, tubing administration sets, etc.)

CAUTION: Make sure that all connections are tight. To prevent stripping, do not overtighten.

- Ensure that the connectors are dry.
- Connect the Meritrans disposable transducer cable to the reusable monitor cable.
- Extract all air from the flush solution container.

CAUTION: If air is not extracted from the solution container, air may be forced into the system when the fluid is depleted.

FILL LINES

- Remove caps (if any) from stopcock on transducer and open the system.

- Fill all lines with sterile flush solution until free of air bubbles.

NOTE: Merit Medical recommends gravity filling the system rather than pressurizing the flush solution to avoid generating bubbles in the solution.

CAUTION: Verify that no air is trapped in any components of the fluid pathway. Air bubbles can cause serious patient harm and will negatively impact pressure wave forms.

- Turn stopcock off.
- Using sterile technique, replace vented caps with non-vented caps.
- Repeat steps 1-4 for any additional stopcocks or ports.
- Pressurize the I.V. solution source to 300 mmHg.

ZEROING THE SYSTEM

- Zeroing should be performed after the system has been filled and mounted.
- Turn the pressure monitoring system "off" to the patient.
- Verify that the opening of the stopcock to be used for zeroing is positioned at the patient's mid-axillary level.
- Being careful not to contaminate the zeroing port, turn the stopcock handle to open the port at the mid-axillary level to air.
- Zero the transducer according to the monitor manufacturer's instructions.
- Turn the stopcock handle "off" to the open port.
- Turn the pressure monitoring system "on" to the patient.

cautions: Before injecting, turn the manifold handle to the transducer off in order to isolate the transducer from pressure.

CONNECTING TO THE CATHETER

- Connect the monitoring kit pressure tubing carefully to the patient's catheter or sheath so that no air is introduced into the system.

CAUTIONS:

- The Meritrans is a single use item. Contents sterile unless package is opened or damaged. Do not reuse or resterilize.
- Federal (U.S.A.) Law restricts this device to sale by or on the order of a physician.
- Do not autoclave the reusable cable.
- If the transducer is used to measure left arterial pressure, an air eliminator filter must be installed between the solution source and the transducer.
- Components of the pressure monitoring system in contact with the fluid path must be kept sterile.

MERITRANS SPECIFICATIONS

Excitation Voltage	1.0 to 10 Vdc-5kHz	Excitation Impedance	240-350 Ω
Signal Impedance	300 Ω ±30 Ω	Phase Shift	<5°
Sensitivity	5 μV/V/mmHg	Operating Temperature	15°C to 40°C
Storage Temperature	-25°C to 70°C	Maximum Half-Sine Shock Acceleration	4500 G
Zero Drift	1 mmHg/8 hours	Thermal Coefficient Span	±0.1%/°C
Thermal Coefficient Offset	±0.3 mmHg/°C		
Light Sensitivity	<1 mmHg-		

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.

描述

Meritrans 是经过预先校准的一次性使用装置，用于生理压力测量。用一根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。

Meritrans 可与连通板、柱装管整理夹一起使用或者通过胶带直接与患者相连。

安装

连接

- 采用无菌技术，打开包有无菌传感器的包装。
- 按照医院关于压力监测程序的规程安装。连接至其他监测设备（如连通板、旋塞阀、冲洗装置、管路给药装置等）

警告： 确保所有连接件牢固连接。为防止折断，请勿过度紧固。

- 确保连接器干燥。
- 将 Meritrans 一次性传感器线缆与可重复使用的监测器线缆相连。
- 排尽冲洗液容器中的所有空气。

警告： 如果未排尽溶液容器中的空气，可能会迫使空气在液体用尽时进入系统内。

加注管路

- 取下传感器旋塞阀上的密封帽（如有）并打开系统。
- 将无菌冲洗液加注到所有管路中，直至没有气泡为止。

注意： Merit Medical 建议利用重力加注系统，而不是对冲洗溶液进行加压，从而避免溶液中产生气泡。

警告： 确认液体通路的任何组件中均没有空气。气泡会导致患者遭受严重伤害，并且会对压力波形产生负面影响。

- 关闭旋塞阀。
- 采用无菌技术，用非通气帽替换通气帽。
- 如有任何其他旋塞阀或接口，重复步骤 1-4。
- 将静脉输液溶液加压至 300 mmHg。

系统调零

- 应在系统已注满及安装好之后进行调零。
- 将患者的压力监测系统转至“off”位置。
- 确认用于调零的旋塞阀的打开位置是否处于患者的中腋窝水平。
- 小心不要污染调零接口；旋转旋塞阀手柄，打开位于中腋窝水平位置的接口进行通气。
- 根据监测器制造商的说明将传感器调零。
- 将打开的接口的旋塞阀手柄转至“off”位置。
- 将患者的压力监测系统转至“on”位置。

警告： 注射前，将连通板旋钮拧至传感器关闭位置，以使传感器不受任何压力。

连接至导管

- 小心地将监测工具包中的压力管与患者的导管或外鞘相连，从而确保没有空气进入系统内。

警告：

- Meritrans 是一种一次性使用装置。除非包装已打开或损坏，否则内容物是无菌的。请勿重复使用或重新消毒。
- 联邦（美国）法律限定本装置仅可由医师或凭医师处方销售。
- 请勿对可重复使用的线缆进行高压灭菌。
- 如果传感器被用于测量左动脉压，则必须在输液溶液与传感器之间增加一个排除空气的空气过滤器。
- 与液体通路接触的压力监测系统组件必须保持无菌状态。

MERITRANS 规格

励磁电压	1.0 至 10 Vdc-5kHz	励磁阻抗	240-350 Ω
信号阻抗	300 Ω ±30 Ω	相移	<5°
敏感度	5 μV/V/mmHg	工作温度	15° C 至 40° C
存放温度	-25° C 至 70° C	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
热膨胀系数偏差	±0.3 mmHg/° C		
感光度	<1 mmHg-		

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、重新处理或重新消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。

此产品使用后禁止随意丢弃，须放到指定地点，统一回收和销毁。

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

产品注册证号：SFDA (I) 20123213278

产品标准编号：YZB/USA 4104-2012

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