TRAM P™

INSTRUCTIONS FOR USE

PRODUCT 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. A pressure monitor tubing line may be used as a compensation line with a pole mount organizer clip.

INTENDED USE
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.
- The compensation line must be completely filled with fluid to produce accurate pressure readings.
- The female luer end of the compensation line (placed in the Merit organizer bracket) must be positioned at the mid axillary level in order to produce accurate readings.
- 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.

CONTRAINDICATIONS: None known**.**

Merit's DeVos manifolds are a standard manifold with a check relief valve as the end port.

The DeVos manifolds are available with:

- 4 port wide
- Half body style
- Right port orientation
- 180º/360º (might need to be implemented depending on demand)
- 200 PSI (14 BAR) pressure rating
- OFF/ON handles (might need to be implemented depending on demand)

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. Attach the male end of the sterile compensation line to the transducer side port. Verify connection is tight but do not over tighten.
6. Turn the manifold handles so the transducer is open to the fluid source. Open the yellow stopcock and flush the transducer free of air. Continue fluid filling through the yellow stopcock and out the compensation line until completely full. Debubble the compensation line. Turn the manifold handle and yellow stopcock off to the transducer. **Note:** When filling the compensation line there will be an air space in the transducerhousing between the yellow handle and the transducer element. This is normal and has no effect on pressure readings or frequency response.
7. Mount a Merit organizer bracket on the pole. Place the compensation line mounting clip in the organizer bracket so that the slots of the plate are facing up and it snaps into the organizer. Place the female luer of the compensation line in the mounting clip. Adjust the bracket on the pole so that the top of the fluid column is at the mid axillary level.
8. Inspect the entire length of the compensation line to ensure it is completely fluid filled and bubble free.
9. Once the 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 atmosphere and the manifold transducer handle is closed to the patient.
10. Balance and calibrate the system according to the monitor manufacturer's instructions.
11. Once the system is balanced and has begun monitoring pressures, changes in elevation of the manifold will not affect the continued accuracy of pressure readings.
12. To monitor patient pressure, ensure the yellow stopcock is off to atmosphere. Turn the manifold handles so that the transducer lumen is open to the catheter. **Note:** Ensure all connections are securely tightened. Inspect carefully for air bubbles and flush the manifold lumen, if necessary.
13. If the patient position is changed, adjust the height of the compensation mounting clip so that the top of the fluid column is maintained at mid axillary level.

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.

MERITRANS SPECIFICATIONS

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

CAUTIONS

℞ Only	Federal (USA) law restricts this device to sale by or on the order of a physician.
②	Single Use Device. DO NOT REUSE
	Non-Pyrogenic
	Do not use if package is opened or damaged

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