MERITRANS®

## DISPOSABLE PRESSURE TRANSDUCER - INSTRUCTIONS FOR USE

### DESCRIPTION

The Meritrans is a sterile, single use device for physiological pressure measurement. A separate reusable interface cable is used with this system to transmit the signal from 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.

### INTENDED PURPOSE/INTENDED USE

The Meritrans is a pre-calibrated, single use device for physiological pressure measurement.

### INDICATIONS FOR USE:

| Product Configuration | Indications |
|---|---|
| Meritrans | The Meritrans disposable pressure transducer is indicated for use in patients requiring invasive physiologic pressure monitoring. |
| Accessories | The Meritrans accessories are used with the Meritrans disposable pressure transducer in patients requiring invasive physiologic pressure monitoring. |
| Reusable Interface Cable | The Meritrans transducer interface cable connects the Meritrans disposable pressure transducer to a compatible pressure monitor in patients requiring invasive physiologic pressure monitoring |

### CLINICAL BENEFITS:

The indirect clinical benefit of the Meritrans Transducer and Accessories is physiologic pressure measurement to facilitate patient monitoring and/or medical management.

### USER / PATIENT / CLINICAL

**User:** Qualified nurses, clinicians and physicians

**Patient:** Pediatric and adult applications

**Clinical:** Hospitals or appropriate clinical environments

### PRECAUTIONS:

1. The Meritrans is an EO-Sterilized single use item. Contents sterile unless package is opened or damaged. Do not reuse or resterilize.
2. Do not autoclave the reusable cable.
3. If the transducer is used to measure left arterial pressure, an air eliminator filter must be installed between the solution source and the transducer.
4. Components of the pressure monitoring system in contact with the fluid path must be kept sterile.
5. This product is to be used in conjunction with a monitor that is compliant to applicable IEC 60601 electrical safety standards. If this product is being used in conjunction with other manufacturers' components, their instructions for use must also be reviewed.
6. The transducer is to be kept away from sunlight.
7. The transducer is to be kept dry from moisture.

**CONTRAINDICATIONS:** None known

In the EU, any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the applicable Member State.

### 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.

### POTENTIAL COMPLICATIONS

- Abnormal Pressure Readings
- Air Emboli
- Clotted Catheter and Bleed-Back
- Inflammation
- Overinfusion
- Sepsis/Infection
- Soft Tissue Injury

### INSTRUCTIONS FOR USE

The following instructions provide technical direction but do not obviate the necessity of formal training in the use of the device. The techniques and procedures described do not represent all medically acceptable protocols, nor are they intended as a substitute for the clinician's experience and judgment in treating any specific patient.

### SET-UP

### CONNECTIONS

1. Using aseptic technique, open the package containing the sterile transducer.
2. 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.

3. Ensure that the connectors are dry.
4. Connect the Meritrans disposable transducer cable to the reusable monitor cable.
5. Purge 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**

1. Remove caps (if any) from stopcock on transducer and open the system.
2. 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.

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

**ZEROING THE SYSTEM**

1. Zeroing should be performed after the system has been filled and mounted.
2. Turn the pressure monitoring system "off" to the patient.
3. Verify that the opening of the stopcock to be used for zeroing is positioned at the patient's mid-axillary level.
4. Being careful not to contaminate the zeroing port, turn the stopcock handle to open the port at the mid-axillary level to air.
5. Zero the transducer according to the monitor manufacturer's instructions.
6. Turn the stopcock handle "off" to the open port.
7. 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**

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

| MERITRANS SPECIFICATIONS | |
|---|---|
| Excitation Voltage | 4-8 Vdc-5kHz |
| Excitation Impedance | 240-350 Ω |
| Signal Impedance | 300 Ω ±30 Ω |
| Phase Shift | <5º |
| Sensitivity | 5 µV/V/mmHg |
| Operating Temperature | 15ºC to 40ºC |
| Storage Temperature | -25ºC to 70ºC |
| Shock Acceleration | 4500 G |
| Zero Drift | 1 mmHg/4 hours |
| Thermal Coefficient Offset | ±0.3 mmHg/ºC |
| Thermal Coefficient Span | ±0.1%/ºC |
| Light Sensitivity | <1 mmHg at 3000 ft-Candles |

**DISPOSAL**

After use, dispose of the Meritrans transducer in accordance with hospital protocol.

Device lifetime is 72-96 hours based on CDC & Joint Commission Intl (JCI) recommendation.

## MR MRI Safety Information

**MR Conditional**

Non-clinical testing has demonstrated the Meritrans device is MR Conditional. A patient with this device can be safely scanned in an MR system under the following conditions:

- Static magnetic field of 3-Tesla or less
- Maximum spatial gradient magnetic field of 4,000 Gauss/cm(40 T/m)
- The transducer and cable must not contact the patient during operation of the MR system
- The transducer and cable must not be placed inside the bore of the MR system during operation of the scanner
- The transducer is permitted in the MR system room, but must not be operational or connected to a monitoring system during the MRI procedure.

| SYMBOL | DESIGNATION |
|---|---|
| ℞ ONLY | Caution: Federal (USA) law restricts this device to sale by or on the order of a physician |
|  | Consult Instructions for use. For electronic copy scan QR code or go to www.merit.com/ifu and enter IFU ID Number. For printed copy available within 7 calendar days, call U.S.A or E.U Customer Service. |
|  | Single use |
|  | Caution |
|  | Do not resterilize. |
|  | Non-pyrogenic |
|  | Do not use if package is damaged. |
|  | Defibrillation-proof type CF applied part |
|  | MR Conditional |
| STERILE EO | Sterile Using Ethylene Oxide |
|  | Date of Manufacture |
|  | Use By Date |
| EC REP | Authorized Representative in the European Community |
| REF | Catalog Number |
| MD | Medical Device |
| UDI | Unique Device Identifier |
|  | Manufacturer |
|  | Single Sterile Barrier |
|  | Keep away from Sunlight |
|  | Keep Dry |

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