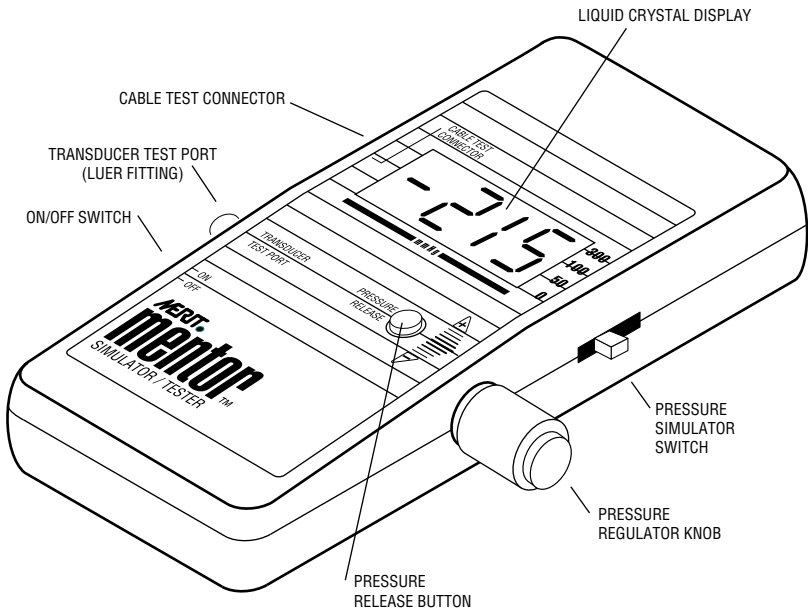


MERT[®] mentor[™]

SIMULATOR / TESTER

I N S T R U C T I O N S F O R U S E



PHYSIOLOGICAL PRESSURE TRANSDUCER SIMULATOR/TESTER OPERATORS MANUAL

T A B L E O F C O N T E N T S

INTRODUCTION	PAGE 1
SECTION I	PAGE 2
▪VERIFYING THE CALIBRATION OF THE MERITRANS™ TRANSDUCER USING THE MENTOR™	
SECTION II	PAGE 3
▪VERIFYING THE CALIBRATION OF THE PHYSIOLOGICAL PRESSURE MONITORING SYSTEM WHEN USING TRANSDUCERS WITH BACKSIDE CALIBRATION PORTS OR CALIBRATION PORTS LOCATED IN THE DISPOSABLE CABLE	
SECTION III	PAGE 4
▪VERIFYING THE CALIBRATION WHEN USING MORE THAN ONE TRANSDUCER	
SECTION IV	PAGE 4
▪TROUBLESHOOTING TRANSDUCERS, MERITRANS REUSABLE CABLES AND MONITORING SYSTEMS	
SECTION V	PAGE 5
▪PRODUCT SPECIFICATIONS	
SECTION VI	PAGE 6
▪ MAINTENANCE	
▪Low battery indicator	
▪Error messages	
▪Battery replacement	
▪Cleaning	
▪Checking Mentor calibration	
▪Returned goods authorization	
SECTION VII	PAGE 7
▪LIMITED WARRANTY	
SECTION VIII	PAGE 8
▪ORDERING INFORMATION	

●●●●●●● INTRODUCTION ●●●●●●●

Description

The Mentor is a transducer simulator/tester which can be used to verify the proper function of physiological pressure transducers, the integrity of Meritran[®] Reusable Cables and the proper calibration of related monitoring devices. It is a convenient, hand-held device capable of generating and measuring pressures ranging from -300 to +300 millimeters of mercury (mmHg). The Mentor's Liquid Crystal Display indicates the pressure at the Transducer Test Port .

Indications & Usage

The Mentor is designed to be used in the non-sterile field in environments where physiological pressure transducers and their monitoring systems are used. The Mentor tests and/or simulates both disposable and reusable pressure transducers and related cabling. It can be used to check linearity, hysteresis, gain and offset of transducers and also the reliability and signal integrity of Meritran Reusable Cables. When used as discussed in Section I, it allows verification of calibration without compromising the sterility of the pressure monitoring set-up.

WARNING: If the system is open to atmospheric pressure and the display fails to read "000", check mentor calibration as outlined in Section VI .

WARNING: Improper use of this device in a physiological pressure monitoring system by connecting to a patient during testing could cause an air embolism.

WARNING: Unless using the backside calibration port, test the pressure monitoring system prior to patient hook up or after disconnecting the patient from the pressure monitoring system.

WARNING: Do not use this device in the presence of flammable anesthetic gases.

WARNING: Discontinue use if liquid is spilled on device.

WARNING: Unless using a transducer that allows calibration verification without accessing the sterile fluid path, do not connect the patient to the physiological pressure monitoring system while verifying the calibration of the system.

WARNING: With a cable attached to the Cable Test Connector and in the presence of strong electromagnetic fields (e.g. nearby radio or television antennae, power cables, etc.), the displayed pressure reading may be inaccurate. Before reading pressures on the Mentor, remove cable from the Cable Test Connector.

WARNING: Pressures in excess of 1000mmHg can be generated by the Pressure Regulator Knob. Always turn device on before adjusting knob. If display reads "OPr", stop adjusting knob. Adjustments made after "OPr" reading can generate pressures (>1000 mmHg) high enough to cause sensor failure.

PRECAUTION: Check that all fittings and connections are secured to prevent loss of pressure and erroneous test results.

PRECAUTION: For best results, allow time for transducer to warm up (30 seconds).

PRECAUTION: Extreme differences in atmospheric pressure or the use of a test tubing set which is of much greater volume may effect the Mentor's ability to achieve a desired pressure. To compensate, first open the Mentor to atmospheric pressure. To gain more positive pressure capability, move the Pressure Regulator Knob to a starting position which is further away from the Mentor's housing. To gain more negative pressure capability, move the Pressure Regulator Knob to a starting position which is closer to the Mentor's housing.

●●●●●●●● SECTION I ●●●●●●●●

VERIFYING THE CALIBRATION OF THE MERITRANS TRANSDUCER USING THE MENTOR

Some conventional transducers have calibration ports located in their disposable cable or on the backside of the transducer. This design allows verification of calibration to be accomplished without accessing the sterile fluid path. When using a transducer of this design, the steps for verification of calibration with the Mentor are described in Section II.

As verification of calibration on the Meritran must be done by accessing the sterile fluid path, a sterile, 0.2 micron bacteriological filter (Catalog item #MER555) should be fitted between the Mentor test system and the sterile fluid path to avoid contamination of the pressure monitoring system. See Diagram A below.

WARNING: Disconnect the patient from the pressure monitoring system when verifying calibration through the transducer's fluid path.

PRECAUTION: Allow the transducer to warm-up for one minute prior to taking measurements.

1. Attach the sterile, bacteriological filter directly to the transducer or to its stopcock to ensure that the fluid path remains sterile. Do not connect any tubing between filter and transducer. See Diagram A below.

2. Prior to connecting the Mentor to the transducer, turn the ON/OFF button to the ON position to automatically zero the Mentor to atmospheric pressure.

3. Connect the pressure monitoring tubing (suggested for use with the Mentor - Catalog # PM6012P) between the bacteriological filter and the Mentor's Transducer Test Port luer fitting.

4. Open the transducer to air. Zero the monitor by using the "balance" or "zero" button on the monitoring system's control panel.

PRECAUTION: If the transducer signal does not appear on the zero reference line after using the monitor's zero button, adjust the position of the signal trace so that it is exactly on top of the zero reference line by adjusting the offset or signal position control knob of the amplifier (as outlined in the monitoring equipment's Operator Manual).

5. For calibration, set a standard reference display on the monitor screen. For example, a common reference display is a 0 to 300 mmHg scale with full deflection equaling 300 mmHg.

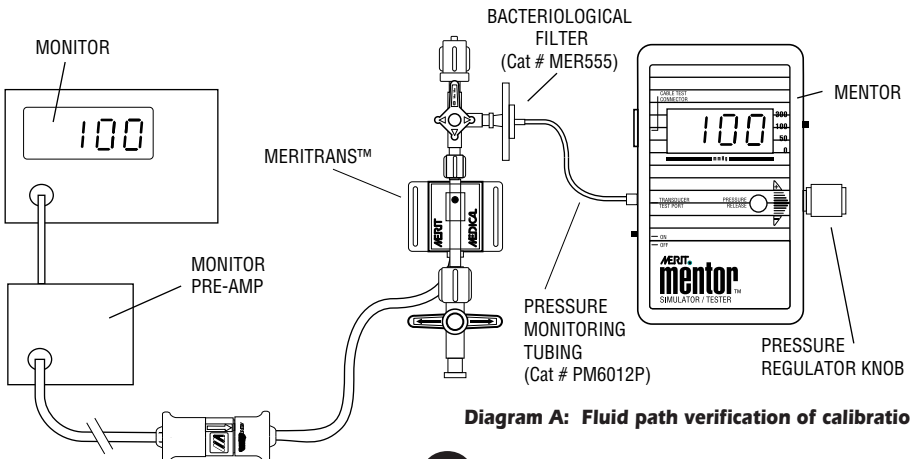


Diagram A: Fluid path verification of calibration

6. Generate a positive pressure on the monitor screen by rotating the Pressure Regulator Knob on the Mentor toward the (+) sign. For example, apply a pressure of 100 mmHg to the transducer so the Mentor LCD reads 100 mmHg. Now check that the signal displayed on the monitor screen reads 100 mmHg. If it is slightly above or below 100 mmHg, adjust the gain control of the monitor to move the signal tracing to the 100 mmHg position.

7. After any adjustments of the gain control, re-check the zero reference line. Compare the readings displayed on the Mentor and the monitor screen. If the measurements are the same, the system is calibrated correctly. If not, zero the monitor and repeat steps 6 and 7.

PRECAUTION: If, after following these calibration verification procedures, the pressure readings on the monitor screen and the Mentor LCD are not the same and greater than the sum of the accuracy specifications of both the transducer and the monitor, start the troubleshooting procedures outlined in Section IV.

8. Disconnect the Mentor from the physiological pressure monitoring set-up prior to measuring patient pressures. Also check that the fluid lines are thoroughly flushed and debubbled prior to measuring the patient's physiological pressures.

●●●●●●●●SECTION II●●●●●●●●

VERIFYING THE CALIBRATION OF THE PHYSIOLOGICAL PRESSURE MONITORING SYSTEM WHEN USING TRANSDUCERS WITH BACKSIDE CALIBRATION PORTS OR CALIBRATION PORTS LOCATED IN THE DISPOSABLE CABLE

1. Prior to connecting the Mentor to a transducer, turn the On/Off button to the On position to automatically zero the Mentor to atmospheric pressure.

2. Open the transducer to air. Zero the monitor by using the "balance" or "zero" button on the monitoring system's control panel.

PRECAUTION: If the transducer signal does not appear on the zero reference line after using the monitor's zero button, adjust the position of the signal trace so that it is exactly on top of the zero reference line by adjusting the offset or signal position control knob of the amplifier (as outlined in the monitoring equipment's Operator Manual).

3. For calibration, set a standard reference display on the monitor screen. For example, a common reference display is a 0 to 300 mmHg scale with full deflection equalling 300 mmHg.

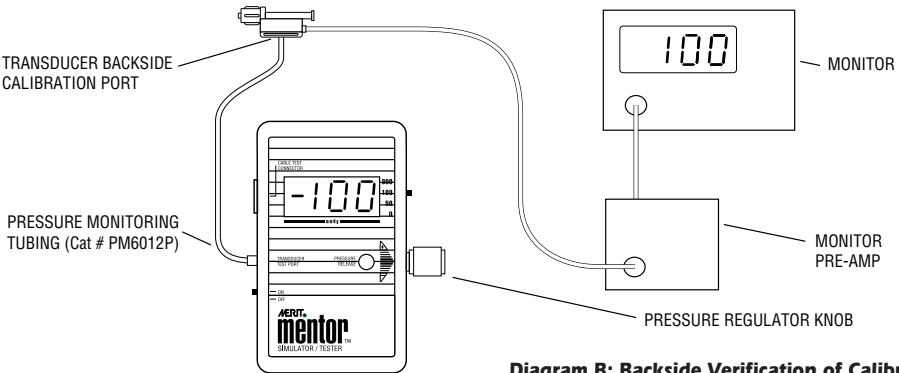


Diagram B: Backside Verification of Calibration

4. Connect the pressure monitoring tubing (suggested for use with the Mentor - Catalog # PM6012P) to the Mentor's Transducer Test Port luer fitting. Attach the other end to the backside calibration port (or the calibration port located in the disposable cable) of the transducer. See Diagram B on page 3.

5. Generate a positive pressure on the monitor screen by rotating the Pressure Regulator Knob toward the (-) sign. (Please note that a negative pressure reading on the Mentor's LCD is equivalent to a positive pressure reading on the monitor screen).

For example, apply a negative pressure of 100 mmHg to the transducer so the Mentor LCD reads -100 mmHg. Now check that the signal displayed on the monitor screen reads 100 mmHg. If it is slightly above or below 100 mmHg, adjust the gain control of the monitor to move the signal tracing to the 100 mmHg position.

6. After any adjustments of the gain control, re-check the zero reference line. Compare the readings displayed on the Mentor and the monitor screen. If the measurements are the same, the system is calibrated correctly. If not, zero the monitor and repeat steps 5 and 6.

PRECAUTION: If, after following these calibration verification procedures, the pressure readings on the monitor screen and the Mentor LCD are not the same and greater than the sum of the accuracy specifications of both the transducer and the monitor, start the troubleshooting procedures outlined in Section IV.

7. Disconnect the Mentor from the physiological pressure monitoring set-up prior to measuring patient pressures. Also check that the fluid lines are thoroughly flushed and debubbled prior to measuring the patient's physiological pressures.

●●●●●●● SECTION III ●●●●●●●

VERIFYING THE CALIBRATION WHEN USING MORE THAN ONE TRANSDUCER

If more than one transducer is to be used simultaneously in a procedure, calibration should be verified simultaneously. To accomplish this, connect all transducers to the Mentor's Transducer Test Port luer fitting by "piggy-backing" one transducer to another or by using a manifold. This will ensure that all transducers sense the same pressure at the same time. Follow the steps (depending on transducer type) as outlined in Sections I or II for calibrating transducers.

●●●●●●● SECTION IV ●●●●●●●

TROUBLESHOOTING TRANSDUCERS, MERITRANS REUSABLE CABLES AND MONITORING SYSTEMS

In the event that the pressure measurements differ by more than the sum of the accuracy specifications of both the Mentor and the monitor, the Mentor can be used to determine the source of the problem whether it be a faulty cable, the monitor or the transducer.

When the transducer pressure readings on the monitor screen differ from the Mentor LCD by more than the sum of the accuracy specifications of both the Mentor and the monitor, check the Meritran Reusable Cable to isolate the source of the problem:

WARNING: Remove Meritran Reusable Cable from the Cable Test Connector after completing this test.

1. Plug the Meritran Reusable Cable into the Cable Test Connector found on the left side of the Mentor housing.

2. Simulate a pressure signal by selecting one of the four pressure values (0, 50, 100, 300 mmHg) using the Pressure Simulator Switch on the right side of the Mentor housing.

3. Observe that the monitor waveform values match the pressure values on the Mentor.

If the pressure readings continue to differ by more than the sum of the accuracy specifications of both the Mentor and the monitor, the problem resides in the cable or the monitor. Replace the Meritans Reusable Cable to determine whether it is the fault of the cable or the monitor.

If the pressure readings on the Mentor and the monitor are the same, then the cables and the monitor are functioning correctly and the transducer is faulty. Replace the transducer and repeat directions one through eight as described in Section I.

If there is still a discrepancy between the readings on the Mentor and the monitor after replacing both the Meritans Reusable Cable and/or the transducer, check the calibration of the Mentor using a Sphygmomanometer as outlined in Section VI.

If the Mentor demonstrates proper calibration, the monitor is at fault. Have the hospital's biomedical engineer or the monitoring equipment's technical support team check the monitor.

In the event that the Mentor is dropped, physically damaged or misused in any way, please check the calibration accuracy.

●●●●●●● SECTION V ●●●●●●●

PRODUCT SPECIFICATIONS

Accuracy :

$\pm 1\%$ of Reading Or ± 1 mmHg,
Whichever Is Greater

Sensor Overpressure:

1000 mmHg

Mentor Working Pressure Range :

± 300 mmHg
Displays "OPr" when outside this range

Operating Temperature:

5°C to 40°C (41°F - 105°F)

Storage Temperature :

-20°C to 60°C (-5°F to 140°F)

Operating Humidity :

95% Relative Humidity Max., Non-Condensing

LCD Display :

3 1/2 Digit, 1/2" High

Low Battery Indicator:

Approximately 5.5 Volts DC

Dimensions :

6.30" High x 3.75" Wide x 1.40" Deep

Weight:

12.3 Ounces (350 grams)

Power Source :

9 Volt Alkaline: (Life: \approx 80 Hours Continuous)

Transducer Simulator:

- Sensitivity: $5 \mu\text{V/V/mmHg}$, $\pm 1\%$
- Excitation: 2 to 10 vdc, or vac rms to 5 khz
- Input Impedance: 2300Ω , 330Ω with reusable cable
- Output Impedance: 300Ω
- Asymmetry: Less than 1%

MAINTENANCE

Low Battery Indicator

When the Mentor LCD begins to flash, it is an indication the battery voltage is low and it should be replaced or recharged (See maintenance instructions for battery replacement information).

WARNING: The Mentor should not be used while a low battery condition is indicated. During a low battery condition, the pressure readings may not be within the operating specifications and results may be erroneous.

Error Messages

If the Mentor displays an error message it should be returned to Merit Medical for repair.

Er1 = Memory error detected

Er2 = General hardware/software error detected

“OPr” = Pressure is not within pressure range.
i.e. +/- 300 mmHg.

Battery Replacement

The access panel for the battery compartment is located on the back side of the Mentor. Remove the battery cover using a small slotted screwdriver and replace the battery with a 9 volt alkaline, non-rechargeable battery. Please note: If the Mentor is not going to be used for an extended length of time (30 days or more), the battery should be removed until reuse.

Cleaning

The outside surfaces of the Mentor may be cleaned with a soft cloth dampened with water or isopropyl alcohol.

Checking Mentor Calibration

Every six months the Mentor should be checked for proper calibration. This can be done by the following steps using a mercury sphygmomanometer with a scale in mmHg (millimeters of mercury).

1. Turn on and zero the Mentor Simulator/Tester.
2. Connect a short length of pressure monitoring tubing from the Mentor's Transducer Test Port luer fitting to the pressure inlet on the mercury sphygmomanometer.
3. Pump the bulb on the sphygmomanometer creating a pressure of 300 mmHg or as close as possible and check that the mercury level is fixed. If it is falling, check for tubing leaks.
4. Verify that the Mentor's LCD Display reads the same pressure as the sphygmomanometer to within 1% or 1 mmHg, whichever is greater. If the Mentor is out of calibration it should be returned to Merit Medical for service. Please see directions following for returning product.

Returned Goods Authorization

When returning a Mentor for service, please pack the unit carefully in its original shipping container or another similarly protective container. In the United States, call Merit's toll-free Customer Service telephone number below and obtain a Returned Goods Authorization number and further instructions.

USA Customer Service:
1-800-356-3748 (35-MERIT)

LIMITED WARRANTY

Merit Medical Systems, Inc. warrants to our immediate customer only that our products (other than products to which special warranties apply) will meet our published specifications and will be free from defects in materials and workmanship. This warranty shall extend for a period of one year commencing on the date of sale.

Our liability under this warranty is limited to repair or replacement of materially defective parts with new or equal parts in exchange or, at our option, to refund the purchase price. All warranty work must be done through our authorized Service Center.

This warranty does not apply to appearance items or to any product subjected to misuse, abnormal service or handling, or to any product altered or repaired by other than our authorized Service Center. This warranty does not apply to any product purchased outside the United States, its territories or possessions.

We make no warranty of merchantability or warranty that the product is fit for any particular purpose or use.

In no event shall Merit Medical Systems, Inc. be liable for consequential economic damage or consequential damage to property.

Some states do not allow a limitation on how long an implied warranty must last or an exclusion of consequential damages; thus the above limitation may not apply to you. In addition, this warranty gives specific legal rights. You may have other specific rights which vary from state to state.

This warranty entitles the original purchaser to have the warranted parts repaired or replaced and labor rendered at cost for the period of the warranty described above. The product must be delivered or shipped at the purchaser's expense to our authorized Service Center together with proof of purchase.

We agree to repair or replace defective parts and to return the product to the purchaser at our expense.

This shall be the exclusive written warranty of the original purchaser and neither this warranty nor any other warranty expressed or implied shall extend beyond the period of time indicated above.

ORDERING INFORMATION

The following Mentor accessories may be ordered by contacting Merit Medical Systems at 1-800-356-3748 or writing to the address below:

MER500 - Mentor Simulator/Tester with 12" pressure monitoring tubing.

MER555 - 0.2 micron bacteriological filter, box of 25.

PM6012P - 12" non-sterile pressure monitoring tubing, box of 25.

Stopcocks - wide selection available, call your Merit Sales Representative.

Merit Medical Systems, Inc.
1600 West Merit Parkway
South Jordan, Utah 84095
Utah: 1-801-253-1600
USA. Customer Service
Toll-Free: 1-800-356-3748

AERT[®]
mentor[™]
SIMULATOR / TESTER



Merit Medical Systems, Inc.

1600 West Merit Parkway

South Jordan, Utah 84095

Utah: 1-801-253-1600

U.S.A. Customer Service

Toll-Free: 1-800-356-3748