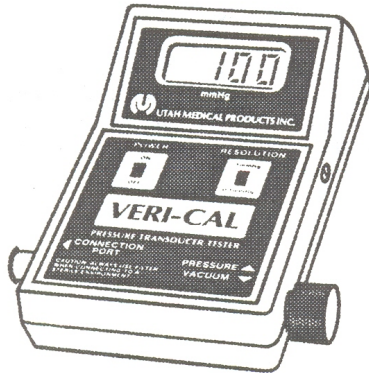


VERI-CAL™

PRESSURE TRANSDUCER TESTER

INSTRUCTION MANUAL



United States

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VERI-CAL™
PRESSURE TRANSDUCER TESTER
CERTIFICATE OF COMPLIANCE AND
CALIBRATION.

Catalog No. 650-900 Serial No. 111716-002

The accuracy and calibration of this instrument is traceable to the National Institute of Standards and Technology through equipment which is calibrated at planned intervals. The certification of all standards meet the requirements of the latest GMP'S.


Signature

8-31-01
Date

I

VERI-CAL™
PRESSURE TRANSDUCER TESTER

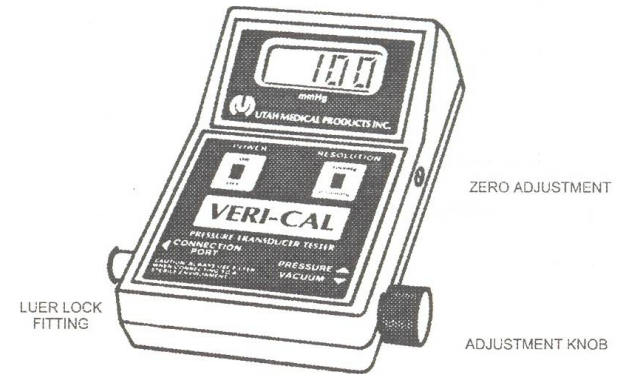


Figure 1

Utah Medical's Veri-Cal™ Pressure Transducer Tester incorporates a highly accurate digital pressure meter and pneumatic pressure generating cylinder into a small, hand-held package for determining the accuracy of most blood pressure measurement systems. Veri-Cal incorporates a specially designed pressure cylinder and precision solid-state transducer for generating and measuring static pressure from -300 to +300 mmHg. The adjustment knob is used to regulate the pressure, and the pressure value is shown on the liquid crystal display. A built-in luer lock fitting provides the external connection for stopcocks or pressure fittings.

II

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1.0 INTRODUCTION

In the hospital and laboratory settings, pressure measuring instruments are used for diagnostic and testing purposes. Devices such as mercury and water manometers, sphygmomanometers, and blood pressure transducers and monitors require periodic maintenance and calibration using a device capable of both generating and measuring pressures. The Utah Medical Veri-Cal Pressure Transducer Tester provides this capability and is especially useful in the area of pressure monitoring.

Until now, verification of proper calibration of both disposable and reusable blood pressure transducers has been difficult. Often, mercury or water manometers are used to generate known values of pressure while the transducer's response is monitored. However, it is difficult to interpret fluid levels in the manometer column. Calibration of the rule used to determine the fluid height may be inexact, and surface tension can cause height errors in the manometers. Therefore, manometers can introduce significant errors to the verification procedure. Because of these problems, clinicians and biomedical engineers have requested an easier, more reliable method of verification.

In the area of critical care, invasive blood pressure monitoring requires a properly calibrated monitoring system capable of linear operation over a wide range of pressures. In addition, the performance of a transducer may be questionable. In most cases, testing of calibration is required to insure that pressures at the catheter tip are reflected by the output voltage generated by the sensing diaphragm of the transducer.

Veri-Cal offers a preferred method of determining the accuracy of any direct blood pressure monitoring system. Positive and vacuum pressures of +300 to -300 mmHg can be generated within Veri-Cal and applied to a system under test. The pressure delivered is indicated on Veri-Cal's 3½ digit liquid crystal display for quick comparison to the monitor.

2.0 OPERATING INSTRUCTIONS

Occasionally a blood pressure transducer may not have the accuracy specified by the manufacturer. By matching gain adjustments on the monitor, deviations in accuracy can usually be compensated for. However, a transducer that is not performing as specified could have other problems, and accuracy measurements can be an early indication of performance deterioration.

Veri-Cal can be used at the bedside to test any blood pressure transducer, reusable or disposable, for linearity and accuracy.

2.1 SETUP FOR CONVENTIONAL TRANSDUCERS WITHOUT A TEST PORT ON THE CABLE CONNECTOR

When using Veri-Cal to test a conventional transducer, a sterile bacteriostatic filter must be used between the test system and the sterile monitoring line to avoid violating sterility.

2.1.1 ZEROING THE SYSTEM

Properly zeroing the measurement system is important for determination of transducer accuracy. To zero:

- a. Remove the connecting stopcock and replace with a sterile filter.
- b. Position the handles on the stopcocks as shown in Figure 2 in order to vent the transducer and Veri-Cal to atmosphere.
- c. "Zero" or "Balance" the monitor.
- d. If Veri-Cal's display does not read 000, turn the zero adjustment (located on the right side - Figure 1) using a small screwdriver.
- e. When both the monitor and Veri-Cal read zero, position the handles on the stopcock as shown in Figure 3.

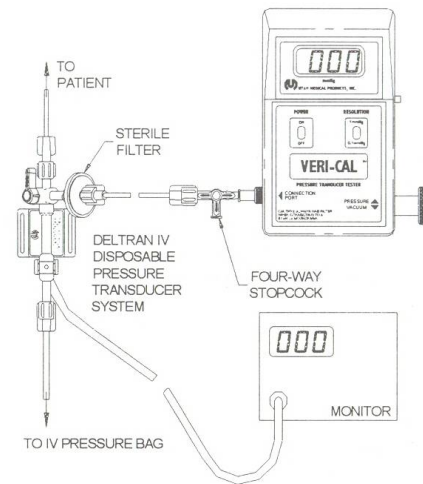


Figure 2

This figure illustrates both the Veri-Cal and Transducer being vented to atmosphere, for zeroing the system.

WARNING: IMPROPER USE OF THIS DEVICE ON A SYSTEM WHICH IS CONNECTED TO A PATIENT COULD CAUSE AIR EMBOLISM. TO AVOID AIR EMBOLISM, ALWAYS TEST THE SYSTEM PRIOR TO USE OR AFTER DISCONNECTING THE PATIENT FROM THE SYSTEM BY TURNING THE STOPCOCK OFF TO THE PATIENT AS SHOWN. ALWAYS USE A STERILE FILTER WHEN CONNECTING TO A STERILE ENVIRONMENT.

2.1.2 TESTING THE SYSTEM

With the stopcocks positioned as shown in Figure 3, the system is now ready for testing. A series of static pressure is generated by turning Veri-Cal's adjustment knob. The applied pressure is indicated on the digital display.

This reading should be compared to the reading on the monitor to determine the accuracy of the measurement system. Interpretation of the results is explained in sections 2.3 and 2.4.

Note: The indicator line on the smooth shaft of the adjustment knob, marks the pressure/vacuum midpoint. Starting with this groove lined up with the edge of the instrument case at zero pressure and adjusting to the maximum in either direction will generate approximately 300 mmHg pressure or vacuum, depending on the direction of rotation.

CAUTION: IF THE SYSTEM APPEARS TO BE LOSING PRESSURE, CAREFULLY CHECK ALL FITTINGS AND CONNECTIONS.

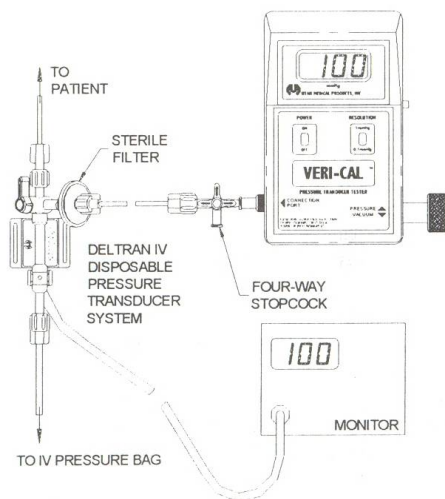


Figure 3

Veri-Cal, as shown in Figure 3, has generated a pressure of 100 mmHg which is measured by the blood pressure transducer under test and indicated on the monitor. Veri-Cal has its own internal precision pressure transducer. Pressures received from a pressure generating source or generated internally by Veri-Cal are measured.

WARNING: IMPROPER USE OF THIS DEVICE ON A SYSTEM WHICH IS CONNECTED TO A PATIENT COULD CAUSE AIR EMBOLISM. TO AVOID AIR EMBOLISM, ALWAYS TEST THE SYSTEM PRIOR TO USE OR AFTER DISCONNECTING THE PATIENT FROM THE SYSTEM BY TURNING THE STOPCOCK OFF TO THE PATIENT AS SHOWN. ALWAYS USE A STERILE FILTER WHEN CONNECTING TO A STERILE ENVIRONMENT.

2.2 SETUP FOR DISPOSABLE TRANSDUCERS WITH TEST PORTS

When used in conjunction with certain disposable pressure transducers incorporating cable connector fittings which vent the backside of the sensor to atmosphere, Veri-Cal's unique design allows calibration of sterile blood pressure transducers without upsetting sterility of the pressure monitor system. Veri-Cal can be connected to the cable fitting; and by applying a vacuum, the linearity, gain, and accuracy of the blood pressure transducer can be tested. Since the blood pressure transducer is a true differential device, this is equivalent to applying a pressure to the patient monitoring port; and the system can be checked for calibration very easily without breaking into the sterility of the patient monitoring system.

2.2.1 ZEROING THE SYSTEM

Properly zeroing the measurement system is important for determination of transducer accuracy. To zero:

- Position the handles on the stopcocks as shown in Figure 4 in order to vent the transducer and Veri-Cal to atmosphere.
- "Zero" or "Balance" the monitor.
- If Veri-Cal's display does not read 000, turn the zero adjustment (located on the right side - Figure 1) using a small screwdriver.
- When both the monitor and Veri-Cal read zero, position the handles on the stopcocks as shown in Figure 5.

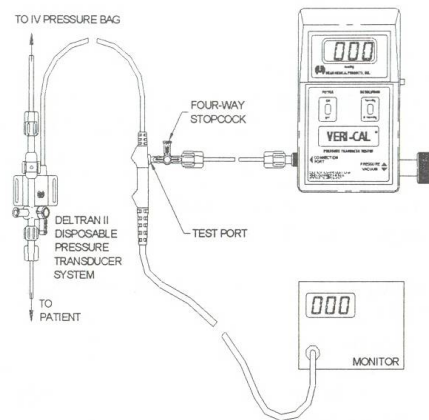


Figure 4

This figure illustrates both the Veri-Cal and the disposable pressure transducer with test port being vented to atmosphere for zeroing the system

CAUTION: DO NOT LEAVE THE VERI-CAL CONNECTED TO THE TEST PORT WHILE MONITORING PATIENT PRESSURES.

2.2.2 TESTING THE SYSTEM

With the stopcocks positioned as shown in Figure 5, the system is now ready for testing. A series of static pressure is generated by turning Veri-Cal's adjustment knob. The applied pressure is indicated on the digital display. This reading should be compared to the reading on the monitor to determine the accuracy of the measurement system.

Interpretation of the results is explained in sections 2.3 and 2.4. **With this setup, a negative (vacuum) reading on Veri-Cal™ is equivalent to a positive (pressure) reading on the monitor.**

NOTE: The indicator line on the smooth shaft of the adjustment knob, marks the pressure/vacuum midpoint. Starting with this groove lined up with the edge of the instrument case at zero pressure and adjusting to the maximum in either direction will generate approximately 300 mmHg pressure or vacuum, depending on the direction of rotation.

CAUTION: IF THE SYSTEM APPEARS TO BE LOSING PRESSURE, CAREFULLY CHECK ALL FITTINGS AND CONNECTIONS.

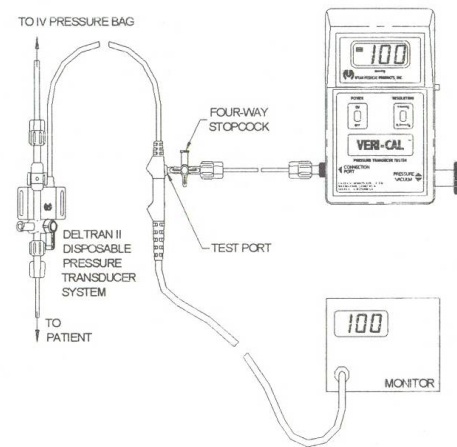


Figure 5

Veri-Cal™, as shown in Figure 5, is used in conjunction with a disposable transducer incorporating a test port located on the backside of the transducer's cable connector. In this case, Veri-Cal™ has generated a

vacuum of -100 mmHg on the backside of the disposable transducer which is equivalent to a pressure of 100 mmHg measured by the pressure transducer under test and indicated on the monitor. Because there is no need to break into the sterile monitoring system, there is no need to use a filter between the transducer's test port and Veri-Cal's tubing connector. Note that the vent port must be vented to atmosphere and off to the patient.

CAUTION: DO NOT LEAVE THE VERI-CAL™ CONNECTED TO THE TEST PORT WHILE MONITORING PATIENT PRESSURES.

2.3 TESTING TRANSDUCER LINEARITY

To determine whether a transducer is linear over a range of pressures, several measurements are required. For example, to test a transducer for linear operation in the range of 50 to 300 mmHg, measurements should be taken at 50 mmHg increments starting at 50 mmHg and ending at 300 mmHg. For each pressure level, readings from the monitor and Veri-Cal display may be recorded. Results can be plotted on a graph with Veri-Cal readings on one axis and the monitor readings on the other. If a line is drawn through the plotted points and the transducer is linear, the line will be straight. If the transducer is not linear, the line will be curved. In either case, the actual measurements should be compared to the manufacturer's specifications for linear operation.

2.4 TESTING TRANSDUCER ACCURACY

Determining if a transducer has the accuracy specified by the manufacturer requires only one measurement at a known amount of applied pressure. Transducer accuracy is calculated as follows:

- a. Apply 300 mmHg to the transducer as indicated on Veri-Cal's display.
- b. Record the pressure on the monitor's display.
- c. From the accuracy tolerance specification of the transducer, monitor and Veri-Cal readings, calculate maximum and minimum deviations in pressure.
- d. Compare the results from step "b" with step "c". If the results from "b" fall into the range calculated in "c", the transducer is within the manufacturer's specification.

3.0 THEORY OF OPERATION

Veri-Cal is a precision pressure monitoring system tester, with the unique feature of combining into a small hand-held enclosure a precision pressure transducer with associated circuitry, a digital display, and a pneumatic pump. Refer to the Block Diagram (see page 14).

3.1 POWER SUPPLY AND LOW BATTERY INDICATOR

The solid state electronics of Veri-Cal are powered by a 9 volt alkaline battery. Because Veri-Cal uses state-of-the-art CMOS circuitry, a 9 volt alkaline battery will last over a year in normal use. A low battery indicator is activated to alert the user when battery voltage drops below 7.2 VDC. When the "BAT" (low battery indicator) comes on, the battery must be replaced within a couple of hours of use for operation within specifications. Slide the battery compartment door open and replace the battery with an equivalent 9 volt alkaline transistor battery.

3.2 PRESSURE TRANSDUCER

A miniature piezoresistive transducer is used to generate electrical signals proportional to the applied pressure at the input of Veri-Cal. Pressure levels from -300 to +300 mmHg result in transducer output voltages in the safe operating range. The maximum allowable (over pressure) is 750 mmHg. If more than 750 mmHg is applied to, or generated by the Veri-Cal, its calibration accuracy could be affected and its precision pressure transducer may be permanently damaged.

To test the transducer, place the resolution switch in the 1 mmHg position, apply a known pressure to the pneumatic port of the unit and measure the voltage between pins 3 and 4 of the display connector (J1). The voltmeter should read 0.1 mV per mmHg of pressure displayed on the Veri-Cal. The 3 ½ digit display may change slightly as the voltmeter is connected to pins 3 and 4 of J1, due to meter loading effects.

3.3 DISPLAY

The PCIM 176 Digital Panel Meter is a multi-purpose device that converts analog voltages from the transducer into digital information and simultaneously displays it on the 3 ½ digit liquid crystal display. The PCIM 176 also contains the low battery voltage detection circuit.

3.4 PRESSURE GENERATING CYLINDER

Static pressure levels are generated using a unique piston and cylinder arrangement. Turning the adjustment knob clockwise will generate pressure. Turning the adjustment knob counterclockwise will generate vacuum at the connection port. The pressure generating cylinder incorporates precision parts with controlled assembly techniques and testing, therefore, if defective, it is not user serviceable and should be returned to the factory for repair or replacement.

4.0 SERVICE INFORMATION

Veri-Cals which are under warranty must be returned to Utah Medical or the Ireland location for repair. Veri-Cals which are out of warranty may be serviced by users knowledgeable in electronic repair and with the proper anti-static precautions for sensitive CMOS circuitry. Refer to the Theory of Operation (section 3.0), and the Block Diagram (see page 14). Before attempting to service out of warranty instruments, the user should call the factory for free over-the-phone assistance. Our service staff will help determine if the unit can be fixed in the field or should be returned for repair.

Veri-Cal should be checked for calibration every six months, or as often as hospital policy requires. For factory service or calibration, pack the unit carefully, in the original shipping container, insure for \$400, and ship UPS to:

United States

Utah Medical Products, Inc.
7043 South 300 West
Midvale, Utah 84047
(800) 533-4984 - Toll Free
(801) 566-1200 - Local
(801) 566-2062 - Fax

EU Representative

Utah Medical Products, Ltd.
Garrycastle Industrial Estate
Athlone, County Westmeath
Ireland
+353 (902) 73932

5.0 SPECIFICATIONS

Operating Pressure Range: ± 300 mmHg, 1 mmHg Resolution
 ± 199.9 mmHg, 0.1 mmHg Resolution

Temperature: Operating 15° C to 40° C (60° F to 105° F)
Storage -20° C to 65° C (-5° F to 145° F)

Operating Humidity: 80% RH Max. Non-Condensing

Accuracy: $\pm 1\%$ of Reading or ± 1 mmHg, whichever is greater

Repeatability and Hysteresis: $\pm 0.15\%$ Full Scale Output

Over pressure: 750 mmHg

Power Requirements: One 9 Volt Alkaline Battery

Battery Life: 150 Hours Constant Use, 15 Months Intermittent Use,
Low Battery Indicator ("BAT") appears when battery
voltage drops below 7.2 volts.

Display: 3½ Digit LCD (.5" High Digits) with "BAT" (Low Battery
Indicator) and Negative Polarity Indicator (for Vacuum
Indication)

Dimensions: 5 3/4" Long x 2" Deep x 3 ½" Wide
(146 mm Long x 51 mm Deep x 89 mm Wide)

Weight: 10 Ounces (284 Grams)

6.0 LIMITED WARRANTY

Utah Medical Products 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 material defects in workmanship and materials. 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 a new or equal part in exchange or, at our option, to refund the purchase price. All warranty work must be done through our authorized Service Centers.

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 Centers.

This warranty entitles the original purchaser to have the warranted parts repaired or replaced and labor rendered at no cost for the period of the warranty described above when the product is delivered or shipped at the purchaser's expense to our authorized Service Centers 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. WE MAKE NO WARRANTY OF MERCHANTABILITY OR WARRANTY THAT THE PRODUCT IS FIT FOR ANY PARTICULAR PURPOSE OR USE.

In no event shall Utah Medical Products, 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.

7.0 SUPPLIES

To order Veri-Cal supplies, call or write:

Utah Medical Products, Inc.
Attn: Customer Service
7043 South 300 West
Midvale, Utah 84047
(800) 533-4984 - Toll Free
(801) 566-1200 - In Utah
www.utahmed.com
www.order.utahmed.com

Ireland Office:
Garrycastle Industrial Estate
Athlone, County Westmeath
Ireland
+ 353 (902) 73932

VERI-CAL PRESSURE TRANSDUCER TESTER

<u>CATALOG NUMBER</u>	<u>DESCRIPTION</u>	<u>QUANTITY PER CASE</u>
650-900	Veri-Cal Pressure Transducer Tester Includes: one each Catalog No. 650-905 and 650-915.	1
650-905	4' Connecting Tube and 4-Way Stopcock with Luer Slip - Packaged Individually, Non-Sterile.	10
650-915	Instruction Manual	1

VERI-CAL BLOCK DIAGRAM

