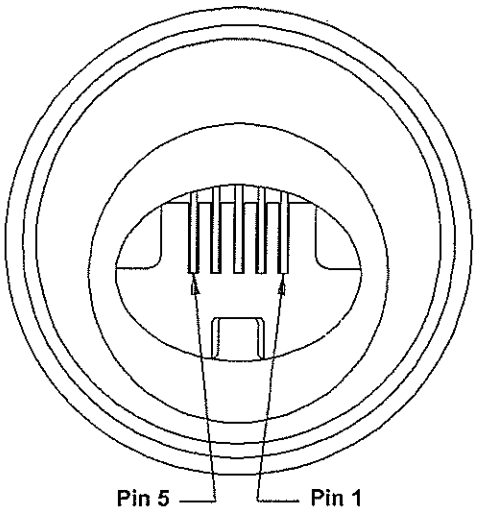
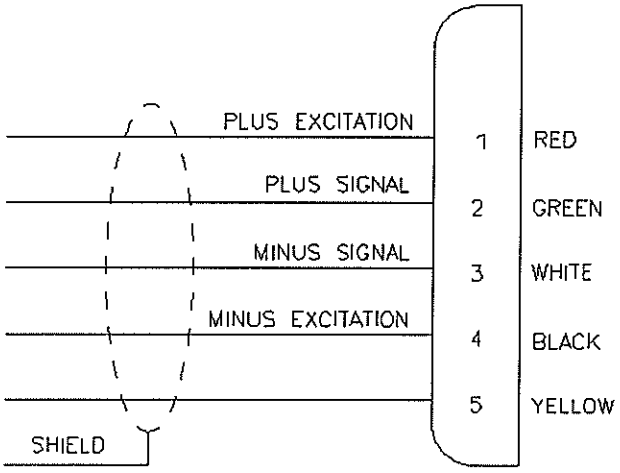
Pressure Monitoring

TruWave™ Transducer Pin Configuration



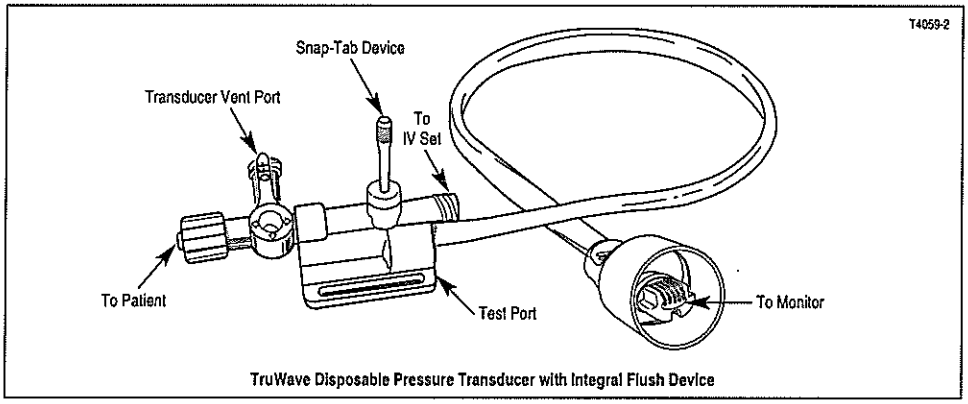
Transducer connector view



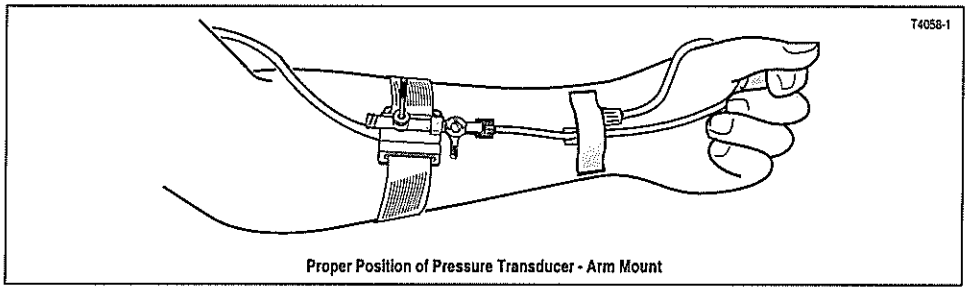
TruWave Schematic

Edwards Lifesciences

Pressure Monitoring Kit with TruWave Disposable Pressure Transducer



TruWave Disposable Pressure Transducer with Integral Flush Device



Proper Position of Pressure Transducer - Arm Mount

For single use only

These are general instructions for setting up a pressure monitoring system with the TruWave disposable pressure transducer. Since kit configurations and procedures vary according to hospital preferences, it is the responsibility of the hospital to determine exact policies and procedures.

Caution: The use of lipids with the TruWave disposable pressure transducer may compromise product integrity.

Concept/Description

The Edwards pressure monitoring kit with the TruWave disposable pressure transducer (model series PX) is a sterile, single-use kit that monitors pressures when attached to pressure monitoring catheters. The disposable sterile cable (available in 12-inch/30 cm and 48-inch/120 cm lengths) interfaces exclusively with an Edwards cable that is specifically wired for the monitor being used.

The TruWave disposable pressure transducer has a straight, flow-through design across the pressure sensor, and is available with or without the integral flush device.

Indications

The pressure monitoring kit with TruWave disposable pressure transducer is for use on patients requiring intravascular, intracranial, or intrauterine pressure monitoring.

Contraindications

There are no absolute contraindications for using the TruWave disposable pressure transducer in patients requiring invasive pressure monitoring.

Flush devices should not be used when monitoring intracranial pressures.

Procedure

1. Ensure that the cable is compatible with the monitor being used. Connect the reusable cable to the monitor, and turn the monitor on to allow the electronics to warm up.
2. Using aseptic technique, remove the transducer and kit from the sterile packaging.
3. Add additional components as needed to complete the monitoring system per hospital policy.
4. Ensure that all connections are secure.
5. Connect the transducer cable to the reusable cable.
6. Remove all air from the heparinized IV flush solution bag per hospital policy.

   Caution: If all air is not removed from the bag, air may be forced into the patient's vascular system when the solution is exhausted.
7. Close the roller clamp on the IV set and connect the IV set to the IV flush bag. Hang the bag approximately 2 feet (60 cm) above the patient. This height will provide approximately 45 mmHg of pressure to prime the setup.
8. Fill the drip chamber halfway with flush solution by squeezing the drip chamber. Open the roller clamp.
9. To fill system:
   a. For transducers without integral flush device (Snap-Tap device), fill system per hospital policy.
   b. For transducers with integral flush device, flow is provided by pulling on the Snap-Tab device and discontinued by releasing the Snap-Tab device.
10. For kits with IV sets attached, open the transducer vent port by turning the stopcock handle. Deliver flush solution first through the transducer and out through the vent port, then through the remaining kit by turning the appropriate stopcocks. Remove all air bubbles.

    Caution: Significant distortion of the pressure waveform or air emboli can result from air bubbles in the setup.
11. Replace all vented caps on sideports of the stopcocks with nonvented caps.
12. Mount the transducer either on the patient's body per hospital procedure or on an IV pole using the appropriate clamp and holder. If holder is used, snap transducer into place.
13. Pressurize the IV flush solution bag. Flow rate will vary with pressure across the flush device. The flow rates with the IV bag pressurized to 300 mmHg are as follows:

    3 ± 1 ml/hr (DPT with blue Snap-Tab device)

    30 ± 10 ml/hr (DPT with yellow Snap-Tab device).
14. Connect pressure tubing to the catheter per manufacturer's instructions.
15. Flush system per hospital policy.

    Caution: After each fast-flush operation, observe the drip chamber to verify that the continuous flush rate is as desired (see **Complications**).

Zeroing and Calibration

1. Adjust the level of the transducer vent port (the fluid-air interface) to correspond to the chamber where pressure is being measured. For example, in cardiac monitoring, zero at level of the right atrium. This is at the phlebostatic axis, determined by the intersection of the midaxillary line and the fourth intercostal space.
2. Remove the non-vented cap and open the vent port to the atmosphere.
3. Adjust the monitor to read zero mmHg.
4. Check monitor calibration using procedure recommended by the monitor manufacturer.
5. Use the Model 59-UCAL Pressure Transducer Simulator/Tester in conjunction with the Model PXSIM (TruWave Pressure Transducer Simulator/Tester tubing set) to verify pressure readings without compromising sterility of the system (**Figure 1**).

   Instructions are included with the TruWave Pressure Transducer Simulator/Tester tubing set.
6. Close the vent port to the atmosphere and replace the nonvented cap.
7. System is ready to begin monitoring pressure.

Testing Dynamic Response

The assembly may be tested for dynamic response by observing the pressure waveform on an oscilloscope or monitor. Bedside determination of the dynamic response of the catheter, monitor, kit, and transducer system is done after the system is flushed, attached to the patient, zeroed, and calibrated. A square-wave test may be performed by pulling the Snap-Tab device and releasing quickly.

Note: Poor dynamic response can be caused by air bubbles, clotting, excessive lengths of tubing, excessively compliant pressure tubing, small bore tubing, loose connections, or leaks.

Routine Maintenance

Follow hospital policies and procedures for frequency of zeroing the transducer and monitor and for replacing and maintaining pressure monitoring lines. The TruWave disposable pressure transducer is precalibrated and has a negligible drift with time (see **Specifications**).

1. Adjust zero pressure reference each time level of the patient is changed.

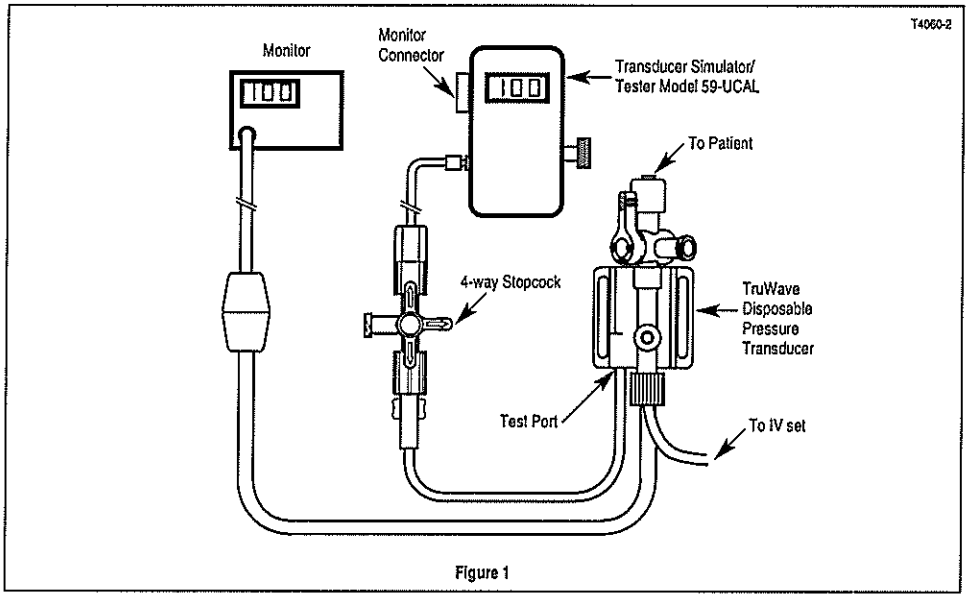


Figure 1

Caution: When rechecking zero or verifying accuracy, ensure that the non-vented cap is removed before opening the transducer vent port to the atmosphere.

2. Periodically check fluid path for air bubbles. Ensure that connecting lines and stopcocks remain tightly fitted.
3. Periodically observe the drip chamber to verify that the continuous flush rate is as desired.
4. The Centers for Disease Control recommends replacing disposable or reusable transducers at 96-hour intervals. Reface other components of the system, including the tubing, continuous-flush device, and flush solution, at the time the transducer is replaced.

Warnings

- **Do not use the flush device during intracranial pressure monitoring.**
- **For severely fluid-restricted patients such as neonates and children, use an infusion pump in series with the flush device to accurately regulate the minimum amount of flush solution needed to maintain catheter patency while allowing continuous pressure monitoring. High pressures, which may be generated by an infusion pump at certain flow rates, may override the flush device restriction, resulting in fast flushing at the rate set by the pump.**
- **Do not allow air bubbles to enter the setup, especially when monitoring atrial pressures.**
- **Avoid contact with any topical cream or ointment that attacks polymeric materials.**
- **Do not expose electrical connections to fluid contact.**
- **Do not autoclave the reusable cable.**

Complications

Sepsis/Infection

Positive cultures can result from contamination of the pressure setup. Increased risks of septicemia and bacteremia have been associated with blood sampling, infusing fluids, and catheter related thrombosis (Refs. 1, 2 & 7).

Air Emboli

Air can enter the patient through stopcocks that are inadvertently left open, from accidental disconnection of the pressure setup, or from flushing residual air bubbles into the patient (Ref. 6).

Clotted Catheter and Bleed-Back

If the flush system is not adequately pressurized relative to the patient's blood pressure, blood bleed-back and catheter clotting may occur.

Overinfusion

Excessive flow rates may result from pressures greater than 300 mmHg. This may result in a potentially harmful increase in blood pressure and fluid overdose (Ref. 3).

Abnormal Pressure Readings

Pressure readings can change quickly and dramatically because of loss of proper calibration, loose connection, or air in the system (Refs. 3 & 6).

Warning: Abnormal pressure readings should correlate with the patient's clinical manifestations. Verify transducer function with a known amount of pressure before instituting therapy.

How Supplied

TruWave disposable pressure transducers are supplied sterile in preconnected monitoring kits (either standard design or special order). Contents sterile and fluid path nonpyrogenic if package is undamaged or unopened. Do not use if package is opened or damaged. Do not resterilize.

Technical Assistance

For technical assistance, please call Edwards Technical Support at the following telephone numbers:

Inside the U.S. and Canada
(24 hours) 800.822.9837

Outside the U.S. and Canada
(24 hours) 949.250.2222

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

Prices, specifications, and model availability are subject to change without notice.

References

1. Centers for Disease Control: National Nosicomial Infections Study Report. *Annual Summary* 1979. Issued 1982.
2. Maki, D.G., et al. Infection Control in Intravenous Therapy. *Ann. of Intern. Med.*, 79:867-887, 1973.
3. Morray, J., et al. A Hazard of Continuous Flush Systems for Vascular Pressure Monitoring in Infants. *Anesthesiology*, 58:187-189, 1983.
4. Murray, I.P. Complications of Invasive Monitoring. *Medical Instrumentation*, 15(2):85-89, 1981.
5. New Protocols for the Swan-Ganz Catheter. *RN*, October 1983, pp 54-59.
6. Peters, J.L. Current Problems in Central Venous Catheter Systems. *Intensive Care Medicine*, 8:205-208, 1982.
7. Simmons, B.P., et al. Guidelines for Prevention of Intravascular Infections. *Infection Control*, 3:61-67, 1981.

Specifications*

TruWave Disposable Pressure Transducer	
Operating Pressure Range	-50 to +300 mmHg
Operating Temperature Range	15° to 40°C
Storage Temperature Range	-25° to +70°C
Sensitivity	5.0μ V/V/mmHg ± 1%
Nonlinearity and Hysteresis	± 1.5% of reading or ± 1 mmHg, whichever is greater
Excitation Impedance	350 ohms ± 10% with typical Edwards Monitor Cable attached
Signal Impedance	300 ± 5%
Zero Offset	≤ ± 25 mmHg
Zero Thermal Drift	≤ ± 0.3 mmHg/°C
Output Drift	± 1 mmHg per 8 hours after 20 second warm-up
Sensitivity Thermal Drift	≤ ± 0.1%/°C
Natural Frequency	40 Hz nominal for a standard kit (48"/12"); >200 Hz for transducer alone
Defibrillator Challenge	withstands 5 repeated discharges of 360 Joules within 5 minutes delivered into a 50 ohm load
Leakage Current	<2μ amps at 120V RMS 60 Hz
Overpressure Tolerance	-500 to +5000 mmHg
Shock Resistance	withstands 3 drops from 1 meter
Light Sensitivity	< 1 mmHg at 6 volts excitation when exposed to a 3400°K tungsten light source at 3000 foot candles
Volumetric Displacement	≤ 0.03 mm^3/100 mmHg for transducer without flush device
Flow rate across flush device with IV bag pressurized to 300 mmHg	
Blue Snap-Tab device	3 ± 1 ml/hr
Yellow Snap-Tab device	30 ± 10 ml/hr

*at 6.00VDC and 25°C unless otherwise stated.

All specifications meet or exceed the AAMI Standard for performance interchangeability of resistance bridge type blood pressure transducers.

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