TRANSPAC®

Monitoring Kit with Disposable Transducer
and **30 mL/hr** Flush Device
Intended for use with an Infusion Pump

Use Aseptic Technique. Single Use Only - Do not reuse/resterilize
Sterile, non-pyrogenic fluid path in unopened undamaged package

℞ only STERILE EO

Not made with DEHP • Do not use if package is open or

INSTRUCTIONS FOR USE

CAUTION: Care must be taken to keep electrical connections on the cable extension dry and fluids from entering the atmospheric vent on the transducer or erratic readings may result.

NOTE: These instructions are for setting up a typical monitoring system. Exact components and set-up procedure used in your kit may vary, depending on the kit's design. For components added to the monitoring system, refer to applicable manufacturer's instructions for set up and use.

I. Installation of Transducer Cable

Connect the transducer cable to the patient connection on monitor.

II. Kit Set Up

A. Set up the disposable transducer monitoring system using aseptic technique.
   1. Open package containing the sterile disposable transducer monitoring kit.
   2. Remove transducer monitoring kit assembly from package.
   3. Attach additional monitoring components as desired.
   4. Check all fittings to ensure tight connections.
   NOTE: If connections are bonded, do not attempt to tighten or disconnect. Doing so may damage or break the connections.
   5. Attach the reusable cable to the transducer.

B. Preparing Solution.
   1. Assemble pump administration set appropriate for the infusion pump that is to be used.
   2. If using heparin, add prior to air removal.
   CAUTION: If an air-free solution source is not used (i.e., air is not extracted from the fluid source), air may be forced into the monitoring line when solution is exhausted.
   3. Attach tubing to solution container and prime the tubing following pump manufacturer's instructions.

C. Connecting Kit to Infusion Pump.
   1. Remove vented cap from the female port of flush device and connect flush device fluid line to distal connector of infusion pump administration set.
   CAUTION: In this application, the flush device is not intended to control flow rate. Flow rate must be controlled by an infusion pump. Do not use with pressure administration cuff.

III. Purging Air From Monitoring Line

A. Remove vented caps from the stopcocks or verify the blue self-retaining cap spins freely on zero reference stopcock.

B. Adjust the pump delivery regulator to a fluid flow rate sufficient to flush solution through the system.

C. Carefully fill fluid lines of the monitoring kit with I.V. solution until all air has been removed from the system. Activate flush device to facilitate filling and to remove air from flush device. Turn stopcock handles as applicable to prime through side ports of stopcocks.

D. Cover all ports with nonvented caps provided in the spare parts bag and tighten the self -retaining cap.

NOTE: Take special care to ensure no air is trapped in any components of the fluid pathway. The monitoring system must be totally air-free for maximum performance, i.e., optimal dynamic response.

CAUTION: Pulling a vacuum to purge bubbles from the lines is not recommended. This practice may entrain air or release air from solution. If the line is primed in a forward manner under pressure, care must be taken to assure the maximum pressure specifications for the transducer are not exceeded.

IV. Zeroing, Leveling and Calibration

A. After the system has been primed and mounted, zero the transducer. The following procedure should be completed periodically.
   1. Turn the zero reference stopcock "off" to the patient. Remove white vented cap from the side port or verify the blue self-retaining cap spins freely on the side port.

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   1. Remove vented cap from the female port of flush device and connect flush device fluid line to distal connector of infusion pump administration set.
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   1. Remove vented cap from the female port of flush device and connect flush device fluid line to distal connector of infusion pump administration set.
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   1. Turn the zero reference stopcock "off" to the patient. Remove white vented cap from the side port or verify the blue self-retaining cap spins freely on the side port.

2. Zero the transducer according to monitor manufacturer's instructions.
3. Turn handle of zero reference stopcock "off" to the side port. Place a yellow nonvented cap onto the side port of the stopcock, or tighten the blue self-retaining cap.

—or—

1. Remove vented cap on distal end of monitoring kit and attach desired catheter. Prime by purging all air bubbles from catheter. (The catheter tip is now the system air-fluid interface.)
2. Place transducer in the position (horizontal plane) it will maintain during pressure measurement.
3. Place the catheter tip at the right atrial (mid-axillary) level.
4. Zero the transducer according to monitor manufacturer's instructions.

B. Transducers are precalibrated to industry standards. To verify monitor calibration, follow monitor manufacturer's calibration procedures. Do not apply pressure when connected to a patient.

NOTE: As long as relative level between catheter tip and transducer are maintained, zero leveling will be appropriate. Any significant change in relative level necessitates re-zeroing.

V. Connecting Monitoring System to Patient

CAUTION: If using a squeeze flush device, patient mounting is not recommended with the flush clip attached to the device as it may result in inadvertent activation of the fast flush mechanism by patient movement. If patient mounting is desired, the flush clip must be removed.

A. Remove nonvented cover at patient connector.

B. Set the infusion pump to deliver the desired flow rate. Continuous low flow flush should be observed at the patient connector and drip chamber (if provided) at this time.

CAUTION: Kits with a 30 mL per hour flush device are not intended to control flow rate. Flow rate must be controlled by an infusion pump. Do not use with pressure administration cuff.

C. For systemic arterial blood pressure line, activate pump delivery mechanism to pump solution through the flush device while allowing arterial cannula to back flow during attachment. For pulmonary artery catheters, the monitoring system should be attached to the catheter and the catheter filled with I.V. solution prior to insertion. Follow catheter manufacturer's insertion instructions.

CAUTION: Be certain not to introduce air into the system during connection procedure.

CAUTION: If this product is used with fat emulsions, they must be introduced through the lipid compatible stopcock that is distal to the flush transducer assembly to avoid cracking of the transducer line.

VI. Checking For Leaks

After approximately one minute has elapsed, check for proper flow rate. A visual inspection for leaks should also be made. The system should be checked periodically for proper flow rate and leaks. Any small leak can give misrepresentation of actual continuous flow rate through the catheter.

VII. Indications and Contraindications

A. Indications

- Umbilical artery catheterization of neonates
- Invasive pressure monitoring with infusion pump

B. Contraindications

- Left atrial monitoring without an air-eliminating filter between the solution source and continuous flush device
- Intracranial pressure monitoring
- Compartmental pressure monitoring
- Intrauterine pressure monitoring

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2. Zero the transducer according to monitor manufacturer's instructions.
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