CONTRAINDICATIONS

- Do not use a flush device when monitoring intramuscular or intracranial pressures.
- Do not use the ACCUTRANS transducers with non-isolate pressure monitors.
- Do not use for left atrial pressure monitoring without an air eliminator filter between the cannula and the transducer prior to flushing.

PACKAGING AND STERILITY

Disposable Transducer Kits are supplied sterile and non-pyrogenic in undamaged, unopened packages. Do not use if package has been previously opened or damaged.

STORAGE

ACCUTRANS disposable transducer kits are recommended to be stored in a dark and cool place.

SHELF-LIFE

The recommended shelf-life is 3 years from the date of sterilization. Note that re-sterilization will not extend the shelf-life.

PRODUCT SPECIFICATIONS

Environmental Performance		Electrical Performance	
Operating Temperature	+15 ºC to +45 ºC	Transducer Excitation Voltage	1Vrms to 10 Vrms
Humidity	10% to 90% non condensing	Transducer Signal Frequency	DC to 5000 Hz
Operating Atmospheric Pressure	400 mmHg to 850 mmHg	Phase Shift	< 5 °
		Transducer Excitation Impedance	1200 Ω to 2200 Ω
		Transducer Signal Impedance	285 Ω to 375 Ω
Mechanical Specifications		Transducer Symmetry	- 5 % to + 5 %
Operation Pressure Range	-30 mmHg to 300 mmHg	Accuracy	Meets AAMI/ANSI BP22 (1994) standard
Overpressure Withstand	-400 mmHg to 4000 mmHg	Sensitivity	4.95 µV / V / mmHg to + 5.05 µV / V / mmHg
Mounting	Any axis	Zero Drift after 5 min warm-up	< 1 mmHg in 4 hrs
		Temperature Sensitivity Coefficient	< 0.1 % / ºC
Safety Features		Zero pressure offset voltage	- 20 mmHg to + 20 mmHg
Risk Current	Less than 5mA	Light Sensitivity	< 1 mmHg
Defibrillation Withstand	5 cycles in 5 minutes at 360J	Mechanical Shock (2ms sine, 3 axis)	500 g
		Vibration (20Hz to 2kHz, 1 octave / min, 3 axis)	20 g
		Warm-up time	60 s, 180 s is maximum
		Error band of sensitivity (25 ºC to 15 ºC)	+/- 1%
		Error band of sensitivity (25 ºC to 45 ºC)	+/- 2%
		Error band of sensitivity after warm-up time (25 ºC to 15 ºC)	+/- 1%
		Error band of sensitivity after warm-up time (25 ºC to 45 ºC)	+/- 2%

RECOMMENDED ACCESSORIES

- Pressure Tubing
- Adapter, Bifurated / Trifucated
- Cannula Adapter
- Female / Male Cap
- Drip Chambers
- Clamps
- Deadender
- IV Administrative Set
- In-line Sensor Spikes
- Monitor Adapter Cables
- Stopcocks
- Syringes
- Wrist Strap / Shealth
- Transducer Holder / Backplate
- Pole-mount

NOTE: Blood Pressure Monitor not provided in the system shall be approved accordance to IEC60601-1 and must be a CE approved device.

CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician or licensed practitioner.

WARRANTY

BIOPTIMAL warrants all its products free from defects in workmanship and materials under proper use and handling. This warranty is in lieu of all other warranties, whether expressed or implied, including any warranty of merchantability, suitability or fitness for a particular purpose since handling, storage as well as factors relating to the patient, his diagnosis, treatment, surgical procedures, and other matters beyond BIOPTIMAL'S control, directly affect BIOPTIMAL'S products and the results obtained from their use. BIOPTIMAL shall not be liable for any incidental or consequential loss, damage, or expense directly or indirectly arising from the use of its products. BIOPTIMAL neither assumes, nor authorizes any other person to assume for it, any other additional liability or responsibility in connection with its products.

PRODUCT INFORMATION

For further information or assistance relating to the BIOPTIMAL products, please contact:

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Fax: +65 6213 5737
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CE 0344

DLBD-0002-001 REV. B1

Bioptimal™

ACCUTRANS
Disposable Pressure Transducer Kits

Read Instruction Manual Before Use
STERILE EO Sterile And Non-Pyrogenic
For Single Use Only
Do Not Re-sterilize
MR Conditional
Keep Dry
Do Not Use If Package Is Damaged
Keep From Direct Sunlight
PHT Presence of Phthalates DEHP (DEHP)
Non-Pyrogenic

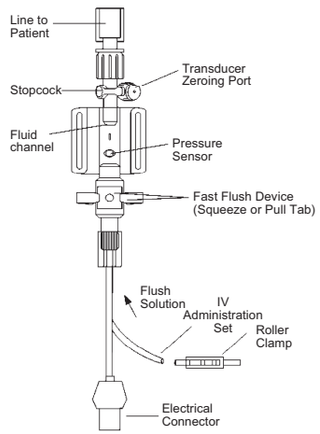
DEVICE DESCRIPTION

Bioptimal's ACCUTRANS Disposable Pressure Transducer Kit consists of a pressure monitoring kit connected to the single-use disposable transducer with an integrated pressure sensor and a stopcock.

ACCUTRANS Disposable Pressure Transducer is provided with or without an integral 3cc/hr or 30cc/hr flush devices, where with integral flush device, requires continuous flow to maintain the catheter patency. Kits with 3cc/hr flush devices deliver a nominal flow rate of 3cc/hr with a differential pressure of 200mmHg (Infusion bag pressure minus mean physiological pressure of 100mmHg being monitored). Kits with 30cc/hr flush devices are designed exclusively for use with a calibrated pump for neonatal applications.

The flush device has a squeeze tab and a pull flush. The squeeze tab can be activated by squeezing the butterfly wing towards each other. The pull flush is activated when it is pulled in the direction away from the ACCUTRANS transducer. The complete configuration is fully sterile.

Figure 1 shows an ACCUTRANS Disposable Transducer with integral flush device and attached IV Administration Set.



As customer designated kit configurations vary from institution to institution, it is the responsibility of the institution to establish its specific policies and procedures governing the use of the kit including safety measures to supplement those described in this instruction sheet.

INTENDED USE

Bioptimal's ACCUTRANS Disposable Pressure Transducer Kit provides the fluid pathway components that are intended to convert the hemodynamic waveform from the patient's catheter, through the disposable pressure transducer with integrated pressure sensor, into electrical signals which can be displayed using separate monitoring equipment. The disposable pressure transducer, with the integrated pressure sensor, is intended for direct coupling to sterile catheters with fluid (saline) flows in contact with the patient bloodstream.

The flush device has a squeeze tab and a pull flush. The flush device prevents clotting and backflow of blood through the catheter and provides a means of intermittent and rapid manual flushing of the system.

ACCUTRANS fast-flush actuator (squeeze or pull flush) offers convenience in fluid filling, debubbling and fast-flushing. Another feature of the pull tab is that it facilitates a "square wave response test" to be performed. This can be used to assess the dynamic performance of the system.

GENERAL PRECAUTIONS

Universal precautions and sterile techniques should be practiced in accordance with facility protocols and CDC guidelines during the connection and disconnection of all fluid-filled components. Be especially careful with low volume syringes which produce the highest pressures.

All personnel are advised to handle all components of the transducer kits with care. Excessive force used may damage the components of the transducer kits.

DO NOT use the disposable transducer if it is damaged or if it has expired.

DO NOT use the disposable transducer if the packaging is damaged.

DO NOT use excessive force on any syringes which will produce the highest pressures.

DO NOT kink cables or route them in heavy traffic areas as they can be crushed by rolling equipment.

Do NOT attempt to use damaged or defective cables. Use may result in incorrect pressure readings or electrical hazards. Return defective cables to Bioptimal or its designee.

DO NOT allow saline or other fluids to contact surfaces of electrical connectors or contacts.

DO NOT autoclave or ETO sterilize Cables and Clamps.

DO NOT attach a non-vented cap to any port of the fluid-filled system unless stopcock is OFF to port you are capping. Doing so may create excessive internal pressure and result in excessive high pressure reading.

DO NOT use of the device with lipids.

DO NOT over-infuse the transducer kits.

DO NOT resterilize and/ or reuse this device, as this can compromise its performance and can lead to device failure and procedure complications with severe injury or patient death. Reuse and resterilisation bear the risk of cross contamination and patient infection and may also cause transmission of infectious diseases from patient to patient.

This device is intended for single patient use only.

Accessories supplied and intended to be non-sterile do not need special sterilization; however, user is recommended to maintain adequate aseptic condition according to facility protocol.

Used transducer kits must be properly disposed of as biohazardous material and processed according to facility protocol.

MAGNETIC RESONANCE IMAGING (MRI)

Non-clinical testing has demonstrated that Bioptimal ACCUTRANS Disposable Transducer Kit is MR Conditional. A patient with ACCUTRANS Disposable Transducer Kit can be scanned safely immediately after placement under the following conditions:

- Static magnetic field of 1.5-Tesla and 3-Tesla, only
- Spatial gradient field of 3000-Gauss/cm or less
- Whole body averaged specific absorption rate (SAR) of 2-W/kg for 15-minutes of scanning in the Normal Operating Mode of operation for the MR system

Bioptimal ACCUTRANS Disposable Transducer Kit is not

intended for use inside the bore of the MR system and should not be in contact with the patient during MR procedure.

INSTRUCTION FOR USE

A. Set Up Procedures

1. Ensure the monitor is turned on prior to setting up the ACCUTRANS Disposable Transducer Kit. Ensure the monitor is calibrated according to the manufacturer's instructions.
2. Open package and maintain sterility of monitoring kit. Tighten all connections and ensure that all stopcock handles are closed to atmosphere.
3. All side ports of the stopcocks in the kit are protected by vented caps which should remain in place until the system is filled with flush solution and debubbled. These vented caps should always be replaced with non-vented caps provided in a separate pouch in the kit after it is ready for use.
4. Connect transducer to reusable interface cable by aligning connector arrows and pushing them together (see Figure 2).

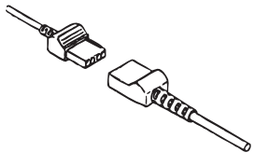


Figure 2: Transducer Cable to Reusable Interface Cable Connection.

B. Filling The ACCUTRANS Disposable Transducer Kit

1. Prepare sterile heparinized flush solution in a non-vented solution bag (usually 0.9% normal sterile saline with 1 to 2 units of aqueous heparin per 1 cc of solution), as prescribed by a properly licensed practitioner.
2. Evacuate air from the non-vented solution bag. Insert IV Administration Set and open roller clamp. Invert bag such that spike and associated tubing are at bag's top so that air will rise and escape into spike.

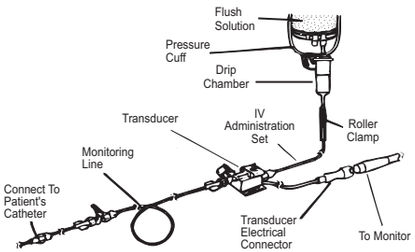


Figure 3: Filling Administration Set

NOTE: *Eliminating air from solution bag will prevent air from entering monitoring system and patient when solution is exhausted or when bag is inverted.*

3. Open package but maintain sterility of IV Administration Set. Close roller clamp. Place bag in pressure cuff and hang on IV pole. To preserve sterility, keep non-vented caps on connectors till ready for use.

NOTE: *To minimize air bubble formation, do not pressurize bag yet but fill monitoring system by gravity as per Step 5 below.*

4. With the roller clamp still closed, squeeze bag slightly to allow solution into drip chamber (fluid level in chamber should be about 1/3 filled only).

CAUTION

If drip chamber is filled completely, drip cannula would not be visible and drop-count (flow-rate determination) would not be possible. With a differential pressure of 200 mmHg (bag pressure of 300 mm HG minus mean physiological of 100 mmHG pressure monitored), 2-4 drops per minute from a micro-drip IV Administration Set or 2-4 drops per three minutes from a macro-drip IV set equates to 2-4 cc/hr flow-rate.

5. Fill the IV Administration Set using gravity flow by opening the roller clamp slowly. Tap lower portion of drip chamber to free any bubbles from the underside of the solution filter.
6. Close roller clamp.
7. Connect filled IV Administration Set to monitoring system and ensure all connections are tightened.

NOTE: *All pressure tubing connections in the kits are standard luer connections.*

8. Ensure that all distal stopcocks are closed to atmosphere. With the pressure cuff still deflated, open the roller clamp on the IV Administration Set.

NOTE: *Since transducer is filled by gravity; ensure bag is higher than transducer and monitoring system.*

9. Activate the fast flush by squeezing clip actuator to purge air from transducer chamber and ensure that the solution completely fill the transducer, zeroing stopcock and the extension tubing.

NOTE: *Transducer should not be tapped with metal objects such as hemostats to purge air bubbles as this may damage the transducer.*

10. Inspect monitoring system to verify that air bubbles have been completely purged through the side ports of all stopcocks and the distal ends of the extension tubing.
11. Pressurize bag to 300 mmHg. If air bubbles appear in transducer chamber, flush again using purging technique per Step 9 above.
12. With the zeroing stopcock closed to atmosphere (pointing right), use sterile technique to replace all white vented caps with yellow non-vented caps.

CAUTION

Never insert a yellow non-vented cap onto Zero Port of the Zeroing Stopcock with stopcock handle closed to patient (pointing up). Doing so may exert an extremely high fluid pressure on Sensor. To eliminate potential sensor failure, ALWAYS place stopcock handle closed to atmosphere (pointing right) prior to placing non-vented caps on Zero Port.

13. Mount the transducer kit as directed in the Section on Mounting the System.
14. Connect the monitoring line to the patient's cannula. Flush the system by squeezing the flush device to clear blood from the cannula.

CAUTION

DO NOT attempt to connect extension tubing to catheter or to flush catheter until you have verified that there are no bubbles remaining in fluid pathways of the system. Doing so may infuse air into the patient.

C. Mounting The System

Pole Mount

1. Insert ACCUTRANS transducer into the transducer holder.

NOTE: *In multiple transducer installation, a color coding system is used to identify the appropriate monitor input:*

Red	=	*Arterial Pressure*
Blue	=	*Central Venous Pressure*
Yellow	=	*Pulmonary Artery Pressure*
Green	=	*Left Atrial Pressure*
White (Blank)	=	*Miscellaneous Pressure*

Color coded labels are provided in the kit for identifying the use of each ACCUTRANS transducer. Affix appropriate labels to transducer holder or the monitoring line closest to each transducer.

2. Adjust height of transducer and manifold clamp on IV pole until zero port is level with the heart – i.e. "mid-heart level".
3. Tighten clamp to fix ACCUTRANS transducer system on IV pole.

Patient Mount

1. Mount the ACCUTRANS transducer on the patient per hospital's protocol.

NOTE: *The pressure readout will vary with changes in the height of the arm-mounted sensor in relation to mid-heart level.*

D. Zeroing And Calibration

1. Ensure that zero port is at mid-heart level.
2. Zero the monitoring system. Turn zeroing stopcock handle OFF to patient (pointing up). Remove non-vented cap from zero port. Zero monitor according to manufacturer's instructions. After zeroing monitoring system, verify that monitor reads zero, then return zeroing stopcock handle closed to atmosphere (pointing right). Recap zero port with sterile non-vented cap to continue monitoring.
3. Allow approximately one minute for the system to equilibrate to ensure that flush device is operating properly. Verify that the flow-rate is about 3cc/hr. A visual inspection for leaks should also be made. Thirty minutes after installation and periodically afterwards, check the system for correct bag pressure, flow rate and ensure no leaks. Leaks, however, small, may lead to inaccurate flow-rate readings. If this is observed, DO NOT USE the device. After each fast flush, it is recommended to reconfirm the flowrate.
4. Use sterile reference pressure source to check system calibration according to monitor manufacturer's instructions. Contact Bioptimal for more information.

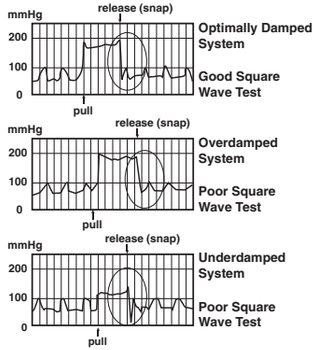


Figure 4: Waveform response to "square wave response test".

5. Check System Dynamic Response with "square wave response test". See Fig. 4.

The Snap Test indicates the dynamic response of the catheter, monitor, fluid path components, and sensor, and indirectly indicates the thoroughness of system debubbling and catheter patency. Perform "square wave response test" after system is fully operational and is properly zeroed and calibrated as follows:

i. While observing pressure waveform on patient monitor, pull and quickly release the pull flush on the flush device.
ii. Compare obtained pressure waveform to those presented in Fig. 4.
iii. Repeat the above steps as needed to obtain maximum dynamic response.
iv. If comparison demonstrates excessive damping, first check for and remove bubbles and obstructions from system according to included instructions or facility protocols.

PRECAUTION

Other factors that may cause overdamping (and possible corrective actions) include:

- **Incorrect positioning of stopcock handle (Reposition if necessary).**
- **Loose connection in fluid pathway (Check for leaks, tighten as required).**
- **Improperly calibrated monitor (Test and recalibrate per manufacturer's instructions).**
- **Kinked tubing or cannula (Inspect, straighten if necessary).**

6. After efforts to improve performance, re-perform "square wave response test".

WARNING

If damped waveform is still observed, it may be the result of one or more of the following factors: (Corrective actions appearing in parentheses may present a risk to the patient, and should be performed with extreme caution by an experienced professional in accordance with facility protocols or medically established practices.)

- **Blood clots in the fluid pathway, including catheter (Clear clots or replace catheter per facility protocols or catheter manufacturer's instructions).**
- **Catheter/cannula positioned against vessel wall (Reposition as per facility protocols or catheter manufacturer's instructions).**
- **Kinked catheter (Straighten or replace catheter per facility protocols or catheter manufacturer's instructions.)**

7. After efforts to improve performance, re-perform "square wave response test".
8. If overdamped signal is still observed, check system as per above instructions or facility protocols until problem is resolved.

POTENTIAL COMPLICATIONS

Sepsis/Infection

Positive cultures can result from contamination of the pressure system. Increased risks of septicemia and bacteremia have been associated with blood sampling, infusion fluids and catheter-related thrombosis.

Air Emboli

Air can enter the system and ultimately the patient through stopcocks that are inadvertently left open from accidental disconnection of the pressure system or from flushing residual air bubbles into the patient.

Clotted Catheter and Bleed-Back

If a flushed system is not adequately pressurized relative to the patient's own blood pressure, bleed-back as well as catheter clotting may occur.

Overinfusion

Excessive fluid may be infused into the patient if the bag pressure is greater than 300 mmHg. This may result in fluid overload and/or a potentially harmful increase in blood pressure.

Abnormal Pressure Readings

Pressure readings can change quickly and dramatically because of lack of proper calibration, loose connections, or air in the system.

WARNING

Abnormal pressure readings should correlate with patient's clinical manifestations. If not so, verify that the transducer is functioning correctly by using a known or calibrated pressure source.