(4) If comparison demonstrates excessive damping, first check for and remove bubbles and obstructions from System according to included instructions or facility protocols.

PRECAUTIONS

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).**

(5) 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 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)**

(6) After efforts to improve performance, re-perform 'Square Wave Response Test'.

(7) If overdamped signal is still observed, check System as per above instructions or facility protocols until problem is resolved.

PACKAGING AND STERILITY

BIOTRANS™ Pressure Monitoring Kits is supplied sterile and non-pyrogenic if package is undamaged or unopened. Do not use if package is opened or damaged. BIOTRANS™ Pressure Monitoring Kits are for single use only. Do not clean or resterilize used BIOTRANS™ Kits.

STORAGE

Bioptimal BIOTRANS™ Pressure Monitoring System should be stored in dry location with the protective cap on diaphragm and protective adapter cap in place.

SHELF-LIFE

The recommended shelf-life is indicated on each package.

PRODUCT SPECIFICATIONS

Note: The Product Specification is a reference for BIOTRANS™ Reusable Sensor Base which is provided separately and not included in BIOTRANS™ Pressure Monitoring Kit. The same Product Specification is provided in Instruction for Use of BIOTRANS™ Reusable Sensor Bases.

Environmental Performance		**Electrical Performance**	
Storage Temperature	-25 °C to +70 °C	Transducer Excitation Voltage	4 to 8 volts RMS
Operating Temperature	+15 °C to +40 °C	Transducer Excitation Frequency	DC to 5000 Hz
Humidity	10% to 90% non condensing	Phase Shift	< 5 °
Operating Atmospheric Pressure	425 to 850 Torr	Transducer Excitation Impedance	300 Ω to 400 Ω
		Transducer Signal Impedance	250 Ω to 350 Ω
Mechanical Specifications		Transducer Symmetry	- 5 % to + 5 %
Pressure Range	-30 mmHg to +300 mmHg	Accuracy	Meets AAMI/ANSI BP22 (1994) standard
Overpressure Withstand	-400 mmHg to +4000 mmHg	Sensitivity	5µV / V / mmHg
Mounting	Any axis	Zero Drift after 5 min warm-up	< 2 mmHg in 4 hrs
		Temperature Sensitivity Coefficient	< 0.66 % / °C*
Safety Features		Zero Shift due to Temperature	±10 mm Hg maximum*
Risk Current	Less than 5 µA	Light** Sensitivity at 0 mmHg	< 1 mmHg
Defibrillation Withstand	5 discharges in 5 minutes at 360J	Mechanical Shock	Withstands 3 falls from 1 meter

* from 15 °C to 40 °C using 25 °C as reference
** 3000 foot-candles generated by 3,400K Tungsten source

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

WARRANTY

BIOPTIMAL warrants all its products free from defect 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 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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Tel: +65 6213 5777
Fax: +65 6213 5737
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Shanghai International Holding Corp. GmbH (Europe)

Eiffestrasse 80, 20537 Hamburg
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Email: shholding@hotmail.com

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Bioptimal™

INSTRUCTION FOR USE OF
BIOTRANS™ PRESSURE MONITORING KITS

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

READ ALL INSTRUCTIONS, WARNINGS AND PRECAUTIONS CAREFULLY PRIOR TO USE.

BIOTRANS™ Pressure Monitoring Kits include all Catalog Models beginning with "BT" (for BIOTRANS™ I model) and "BTR" (for BIOTRANS™ II model)

DEVICE DESCRIPTION

The BIOTRANS™ Pressure Monitoring System consists of the reusable BIOTRANS™ Sensor Base and Monitor Adapter Cable (both provided separately) and sterile, single-use BIOTRANS™ Pressure Monitoring Kit. All fluid contact occurs within the sterile, single-use kit components. Kits are provided with integral pressure relief valves or 3 or 30 cc/hr flush devices with integral pressure relief and fast flow features.

The Base consists of a pressure sensor mounted on a rigid support. (SEE Fig.1) The sensor is electrically isolated from the patient, which the sensor cable allows connection to the patient monitor via a monitor adapter cable. Cable models specific for use with all major monitor suppliers are available from Bioptimal International (Bioptimal).

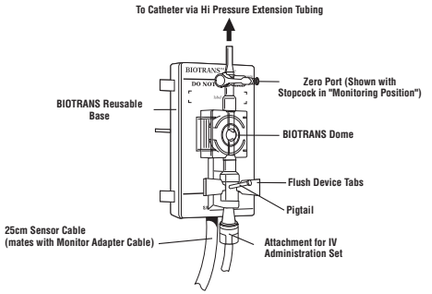

Fig. 1: BIOTRANS™ Pole-mount Base, shown with Disposable Dome in place

All Kits include the sterile, single-use, disposable Biotrans™ I Snap-On Dome or Biotrans™ II Twist-On Dome with integral Flush Device/ Pressure Relief Valve and 3-way stopcock. The Dome houses a diaphragm that contacts the Base sensor diaphragm during use. Additional sterile fluid pathway components provided in Kits include IV administration tubing, drip chamber, spike and roller clamp, extension tubing, and stopcocks; with ancillary vented and non-vented caps (SEE Fig.2). All fluid contact components meet ISO and FDA biocompatibility requirements.

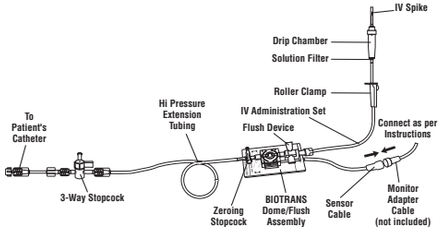

Fig. 2: Typical BIOTRANS™ Disposable Pressure Monitoring Kit, shown without BIOPORT™ Accessory. See Instructions for Assembly and Use.

Kits may be provided with BIOPORT™ Closed Blood Sampling System components which can be used to access arterial and/or venous blood via a needle-free connection, or accessories for mounting the sensor on the patient.

INDICATIONS AND INTENDED USE

Bioptimal BIOTRANS™ Pressure Monitoring Kits are designed for use with BIOTRANS™ Reusable Sensor Bases for pressure monitoring applications. BIOTRANS™ kits contain a second diaphragm which provides isolation between fluid (saline) contacting the patient's bloodstream and the transducer's pressure sensing diaphragm. BIOTRANS™ bases convey hemodynamic pressure waveforms from the patient's catheter to a reusable sensor which signal can be displayed using separate monitoring equipment.

- Kits containing an integral 3 cc/hr flush device are designed for use in physiologic pressure measurements while continuous flow is required to maintain catheter patency.
- Kits with integral 30 cc/hr (yellow banded) flush devices are designed exclusively for use with a calibrated pump for neonatal applications.
- Kits supplied without flush devices are intended for monitoring applications where continuous saline flush is not required.

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 Embolism

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 loss of proper calibration, loose connections, or air in the system.

CONTRAINDICATIONS

DO NOT use kits equipped with a Flush Device for monitoring intramuscular or intracranial pressures.

WARNING

- This product is designed for single use only. DO NOT resterilize or reuse Kit components, as cleaning and sterilization may result in damage.
- This device is intended for single patient use only.
- **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.

CAUTION

DO NOT use Kit components if package is opened or damaged as contents may lose sterility. The use of non-sterile components may result in patient infection. Inspect all packages prior to use.

PRECAUTIONS

- DO NOT use the kit components after indicated expiration date on the packaging.
- The product is designed for single use only. DO NOT reuse or resterilise the kit's components.
- DO NOT use kit components if packaging is opened or damaged as contents may loses sterility. Use of non-sterile components may result in patient infection. Inspect all packages prior to use.

MAINTAINING DEVICE EFFECTIVENESS

Universal Precautions and Sterile Technique should be practiced in accordance with facility protocols and CDC Guidelines during the connection, disconnection, and exchange of all fluid pathway components. The Pressure Monitoring System should be zeroed/ rezeroed and calibration verified:

- when the system is initially set up
- when the temperature changes by more than 5˚C (9˚F)
- before any critical measurement
- when height of sensor in relations to patient's heart is altered (rezero only)
- when Dome has been disconnected from Base during monitoring of the patient. In such event, always turn Zero stopcock OFF to patient before reinstalling Dome on Base following procedures detailed in Section C; then rezero per Section F.

PRECAUTIONS

- Stopcock handles must be positioned in line with ports to be fully ON or OFF. Positioning at 45˚ angle to ports (or other intermediate angle) is not sufficient to prevent air embolism, patient bleedback, or fluid path contamination.
- Always check sensor diaphragm for cracks, holes, and tears before installing Dome. Do not use if damaged observed.
- To avoid applying excessive pressure to sensor, ALWAYS place Zeroing Stopcock handle in Monitoring Position (OFF to atmosphere) prior to placing non-vented caps on Zero Port.
- Do not prime system with catheter attached. Doing so may introduce air to the patient.
- Catheter patency must be verified, and air in the fluid pathway eliminated before connecting Extension Tubing to catheter.

Refer to Section F3 and F4 for troubleshooting procedures and precautions.

INSTRUCTIONS FOR USE

A. MOUNTING BASE POLE MOUNT APPLICATIONS

Following Instructions for Use provided with BIOTRANS™ Reusable Sensor Base, mount BIOTRANS™ Base(s) to IV poles and apply label(s). Position IV pole with BIOTRANS™ Base(s) in an appropriate location close to patient.

PATIENT MOUNT APPLICATIONS

1. Using sterile technique, carefully open Kit package on a flat work surface. Use inner surface of package as a sterile work site. Tighten all connections.
2. If sensor cable is already connected to monitor cable, thread previously cleaned sensor base through tubular section of protective sheath until entire sensor base extends beyond tube. (SEE Fig. 3A & 3B). If cables are not connected, connect before proceeding. Sensor cable and adapter junction will now be protected by sheath.
3. Position base at desired location on patient's arm or wrist and secure in place by engaging Velcro fastener. (Protected cable will extend up patient's arm.)
4. Connect required Monitor Adapter Cable to appropriate channel of monitor. Turn monitor ON.

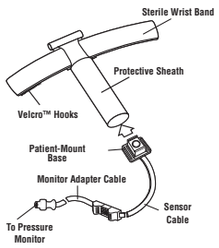

Fig. 3A: Insertion of patient-mount base and monitor adapter cable into sterile protective sheath.

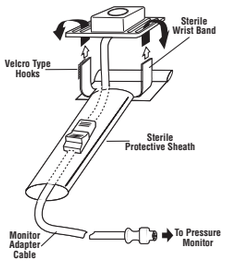

Fig. 3B: Attaching Wrist Strap to Patient Mount Base.

B. FILLING (PRIMING) THE BIOTRANS™ KITS (For Kits with BIOPORT™ system, refer to Instruction for Use for BIOPORT™ Closed Blood Sampling System)

CAUTION

All side ports of stopcocks and luer connectors are protected by white vented caps which are to be left in place until the system is filled with sterile solution and debubbled.

1. Prepare sterile heparinized flush solution (typically 0.9 N sterile saline containing 1 or 2 units of aqueous heparin per cc of solution), as prescribed by a properly licensed practitioner, in a non-vented solution bag.
   a. Evacuate all air from non-vented solution bag and fill IV Administration Set.
   b. On work surface, insert sterile spike of IV Set into solution bag.
   c. Open Roller Clamp.
   d. Invert bag so that spike and associated tubing are at bag's top so that air will rise into spike.
   e. Simultaneously squeeze bag and flush device until advancing heparinized solution just reaches drip chamber, forcing all air into drip chamber and distal tubing. Release pressure on bag and flush device.
   f. Hang IV solution from IV pole, approximately 60 cm (24˚) above work surface.

CAUTION

DO NOT fill the Pressure Monitoring System while Extension Tubing is connected to the patient's catheter or cannula. Doing so may introduce air into the patient.

2. Using gravity flow, prime Pressure Monitoring System as follows:
   a. Assure heparinized solution bag is positioned at least 12 inches (30 cm) above height of Dome, and Zero, and distal stopcocks are OFF to atmosphere.
   b. Squeeze tabs on Flush Device to allow solution to completely fill Dome, Zeroing and Distal Stopcocks, and Extension Tubing.
   c. With white, vented caps remaining in place, fill and debubble side ports of all stopcocks.
3. For kit with Bioport ™ system, prime Bioport™ system according to Instruction for Use for BIOPORT™ Closed Blood Sampling System.

C. ATTACH DOME TO REUSABLE BASE (SEE Fig. 4A or 4B as applicable)

CAUTION

Inspect sensor diaphragm on Base for holes and tears prior to installing Dome. Replace Base if damaged.

CAUTION – BIOTRANS™ I

Engagement of only one Dome snap connector can occur if Dome is not properly mated with Base, resulting in incorrect pressure readings.

CAUTION – BIOTRANS™ II

Improper mating of the Dome to the Base results in incorrect pressure readings. This occurs when the rotating nut engages only on one side of the thread.

1. Loop capped distal end of primed Extension Tubing (the end to be connected to the catheter) over top of IV Pole.
2. Turn Zero stopcock OFF to Extension Tubing/ Patient Monitoring Line.
3. With white vented caps in place on Zero Port and distal Luer connector;

   Mate BIOTRANS™ I Dome on BIOTRANS™ I Base (SEE Fig. 4A) properly by press firmly on center of Dome with thumb or index finger. Simultaneously "clicks" will be heard when snap connectors on each side of Dome are engaged in base.
   Or
   Mate BIOTRANS™ II Dome on BIOTRANS™ II Base (SEE Fig. 4B) properly by holding Dome on the rotating nut between thumb and index finger, ensure that colour stripes on the rotating nut are under the Dome housing (i.e. the rotating nut is not in locking position) and mate it against Base. Turn the rotating nut 90 degree clockwise to lock them together (blue stripes on the rotation nut must appear between the windows on the Dome).
4. Rotate Zero stopcock handle to Normal Monitoring Position (OFF to atmosphere).
5. Install pressure cuff on IV solution bag and pressurize infusion bag to 300 mmHg by pumping cuff inflator.
6. Remove tubing from IV pole and hold distal end with attached vented cap over liquid waste receptacle.
7. Verify fast flush is operable by observing drip chamber while squeezing Flush Device or pulling on pigtail.
8. If any bubbles remain trapped in Dome or Extension Tubing, activate fast flush to assist in their removal.
9. Check system for leaks, and tighten any leaking connections.
10. Verify that all bubbles have been eliminated from the Monitoring System by inspecting all fluid-filled pathways carefully, including Extension Tubing, all stopcocks, and Dome. (If Bioport™ site is present in system, ensure that bubbles are removed by gentle tapping. Refer to the Instruction for Use for Bioport™. Note that bubbles may appear as shiny reflective surfaces lodged against the septum site.)
11. With Zeroing Stopcock handle in Monitoring Position (pointed away from Base surface), use sterile technique to replace all white, vented caps remaining on stopcocks with yellow, non-vented caps.

CAUTION

NEVER insert a yellow non-vented cap onto Zero Port or Zeroing Stopcock handle set in Zeroing Position (handle pointed away from Sensor.) Doing so may exert an extremely high fluid pressure on Sensor. To eliminate potential for sensor failure, ALWAYS place the stopcock handle in Monitoring Position prior to placing non-vented caps on Zero Port.

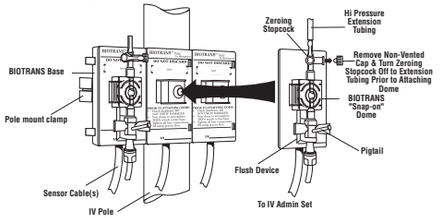

Fig. 4A: Snap Primed Biotrans™ I Dome to Sensor Base

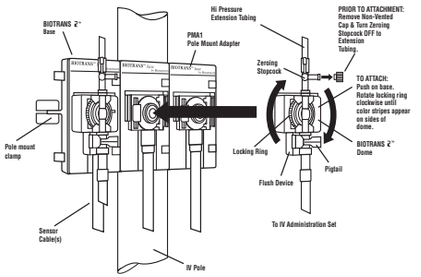

Fig. 4B: Attachment of Primed Biotrans™ II Dome to Biotrans™ II Sensor Base

D. CONNECT PRESSURE SYSTEM TO MONITORING CATHETER

NOTE: Follow your facility protocols for catheter and infusion line access, connect, disconnect, and exchange procedures, and disposal of waste.

WARNING: USE STERILE TECHNIQUE

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 system. Doing so may infuse air into the patient.

1. Remove cap from catheter hub.
2. Allow a few drops of blood out to flow out of the catheter hub to assure catheter is patent before attempting a sterile connection of extension tubing to catheter.

WARNING

DO NOT connect Extension Tubing to catheter if catheter is not patent. Doing so may force clots into patient's blood stream. If catheter is not patent, follow facility protocols and/ or instructions supplied with catheter to clear catheter before proceeding.

3. Remove yellow non-vented cap from distal and end of extension tubing and discard.
4. Following facility protocols or catheter manufacturer's Instructions make sterile, liquid/ liquid connection of extension tubing to catheter connector (hub).
5. Activate fast flush to clear any blood present in catheter lumen.

E. POSITION THE SENSOR BASE

Pole- Mount Bases

1. Adjust height of Base and manifold clamp on IV pole until Zero Port is level with heart i.e., at "mid-heart level".
2. Tighten clamp to fix BIOTRANS™ transducer system on IV pole.

CAUTION

Failure to appropriately align Zero Port height with heart will result in inaccurate pressure readings. If height of patient's chest is altered, loosen sensor mounting clamp and readjust height of Base until Zero Port is again at mid-heart or desired level. Retighten clamp.

Patient- Mount Bases

CAUTION: PATIENT MOUNT APPLICATIONS

The pressure readout will vary with changes in the height of the arm-mounted sensor in relation to mid-heart level. In order to obtain accurate readings, hold sensor base at mid-heart level, or, to account for the difference in height, employ appropriate correction factors. (NOTE: a 2.5 cm difference in level between the heart and zero stopcock results in approximately 2 mmHg zero shift.)

F. ZEROING AND CALIBRATION

1. Ensure that Zero Port is at mid-heart level.
2. Zero Monitoring System:
   a. Turn Zeroing Stopcock handle OFF to patient.
   b. Remove non-vented cap from Zero port.
   c. Zero monitor according to manufacturer's instructions.
   d. After zeroing Monitoring System, verify monitor reads zero, then return Zeroing Stopcock handle to Monitoring Position.
   e. 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 correct. A visual inspection for leaks should be made. Thirty minutes after installation and periodically afterwards check the system for correct bag pressure 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 flow rate.

Check Sensor Calibration

4. Use sterile reference pressure source to check system calibration according to monitor manufacturer's instructions. Contact facility Maintenance Department or Bioptimal for information.

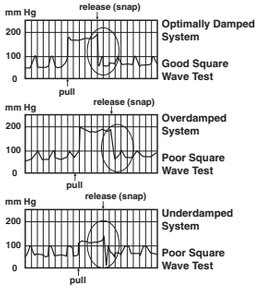

Fig. 5: Waveform response to 'Square Wave Response Test'. See text for details.

5. Check System Dynamic Response with the 'Square Wave Response Test'. SEE Fig. 5.

   NOTE: The 'Square Wave Response 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:

(1) While observing pressure waveform on patent monitor, pull pigtail on Flush Device and quickly release.

(2) Compare obtained pressure waveform to those presented in Figure 5.

(3) Repeat the above steps as needed to obtain maximum dynamic response.