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Trasonic Systems Inc.

Excellence in Quantitative Hemodynamics

34 Dutch Mill Road, Ithaca, NY 14850 USA; Tel: 800-353-3569, 607-257-5300;

Fax: 607-257-7256; Internet: www.trasonic.com

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Section B: Operational Tests

Operational tests should be performed periodically to safeguard the success of each new application. A record of the flowprobe's received signal amplitude (sample form, see page B 6) is the basis for assessing whether an intraoperative application will meet probe specifications for accuracy.

I PERIVASCULAR PROBES

1. TESTING A PERIVASCULAR FLOWPROBE BEFORE REUSE

- a. **Inspect** the silicone cable jacket for superficial cuts. These can be repaired with Dow Corning's Brand Medical Adhesive, Silicone Type A, Catalog no. 891. If internal teflon insulation is also damaged, return probe to the factory or refer repair to factory-authorized personnel.

- b. **Submerge probe** in degassed water or saline in a soft-plastic container (*not glass, metal, styrofoam etc*). Connect flowprobe to flowmeter. Dislodge air bubbles from flowprobe's acoustic window. In "TEST" mode, the DIGITAL DISPLAY should identify the correct probe size. The probe's received signal amplitude as shown on the ANALOG METER increases during the initial 5-minute soaking period. When it has stabilized, verify that no air bubbles are in the probe's acoustic field because they reduce the received signal amplitude. The signal amplitude is then recorded on a Record of Use form found in pages B and B of the manual. For a new probe this reading is 1.0 V. During the life of a probe, the reading may slowly increase or decrease without indicating degradation of probe performance. The DIGITAL DISPLAY should register the received signal as "Gd," when the above conditions are met. If the ANALOG METER reading drops to 0.3 V or below (*coinciding with a "Lo" reading on the digital panel meter*) a defect in probe or probe wiring is indicated which must be diagnosed before the probe can be reused.

- c. **Engage "MEA" mode** and observe zero flow offset. During the initial probe immersion period, the meter may indicate a fluctuating zero offset. By the end of the soaking period, this reading will stabilize if the water bath is still. This reading must fall within "maximum unadjusted zero flow error" specification recorded on the flowprobe package insert sheet if the water bath in which the probe is submerged has sufficient ultrasonic absorption. If the probe has a zero offset error larger than stated in the probe's specifications sheet, move the probe to different locations within the water bath and wait for water motions to stop again. If the zero offset readings are all similar and too large, a defect in the probe is indicated which must be diagnosed before the probe can be reused. If the zero offset is position dependent, it is the result of ultrasonic echoes within the water bath. More ultrasonic absorbent material would have to be added to the container before diagnosing zero offset performance of that probe.

- d. **Record data** on Record of Probe Use sheet, page B 6.

- e. In case of problems: 1) Contact factory; 2) See next section: Troubleshooting.

B. Operational Tests, Troubleshooting *cont.*



I. PERIVASCULAR PROBES *cont.*

2. CUSTOMER TROUBLESHOOTING OF PERIVASCULAR PROBES

a. PROBE WIRING DATA

Figure a.1 presents a connection diagram for perivascular probes for use with the T106/T206 flowmeters. The "ROM" is a computer memory chip, mounted within the probe connector, which contains probe identification information such as probe size and style, its signal drive requirements, received signal strength and flow calibration factor. The transducer cabling consists of two twisted-pair wires between the connector and ultrasonic transducers within the flowsensor body.

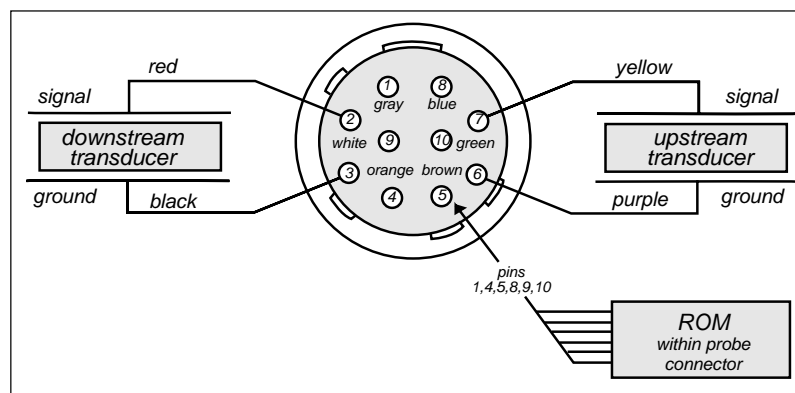


Fig. a.1: Probe wiring diagram for 10-pin self-aligning connector (*pin-side view of male connector*). Probes wired for other Transonic flowmeter models use the same connector, but are wired differently internally to avoid false readings.

b. PROBE ELECTRICAL CHECKS AND MEASUREMENTS

1. Inspect cable for cuts through its silicone jacket. Repair (see "Cable Repair" Section , page B 15).
2. A broken transducer wire/connection can be identified from the probe connector pins as a low transducer capacitance. This capacitance is probe dependent, but will generally lie in the range of 200-1200 Pf; a value below 100 Pf indicates a faulty connection. Capacitance measurements for individual probes are recorded during initial factory calibration and may be obtained by contacting the factory. Capacitance is measured between pins 2 and 3 and between pins 6 and 7.
3. Pins 1, 4, 5, 8, 9 and 10 attach to an electronic memory device (ROM) mounted within the probe connector. Disassembly of this connector requires special tools and should not be attempted. The steps under I. PERIVASCULAR PROBES, 2d. will identify whether the ROM is at fault. Alternately, a flowmeter with the Computer Interface (-P) Option installed can read the content of this ROM, and thus verify whether it is connected and functioning properly.



B. Operational Tests, Troubleshooting *cont.*

I. PERIVASCULAR PROBES *cont.*

2. CUSTOMER TROUBLESHOOTING OF PERIVASCULAR PROBES *cont.*

c. PROBE-METER INTERFACING MEASUREMENTS

1. **ENGAGE FLOWMETER'S TEST MODE WITH NO PROBE PLUGGED IN. THE DIGITAL DISPLAY SHOULD READ "NO.PR" (NO PROBE PLUGGED IN).**

2. **Plug in the probe to be tested.**

If the DIGITAL DISPLAY reads "probe size-no" (where "probe-size" equals the first numerals from the probe serial number) then the meter reads the ROM properly, go to step 3. If the message remains "no-Pr," then either the probe's ROM could be at fault or the meter could be malfunctioning. Plug in another (working) probe to test the possibility of a malfunctioning meter. Return the probe to the factory if the problem is localized in its ROM, return the meter if the meter is at fault.

3. **With the ROM functioning properly, perform the following "wet test:"**

Submerge the probe in water or saline: If the "probe size - no" message changes to "probe size - Gd" and the ANALOG METER indicates 0.5 or more, the probe is O.K. If the received signal amplitude is lower, check for air bubbles within the acoustic window; clean all surfaces in the acoustic path. Proceed to Section B-VI-D if these steps do not bring the received signal amplitude above the 0.5 reading on the ANALOG METER.

d. ULTRASONIC CHECKS AND MEASUREMENTS ON PERIVASCULAR PROBES

If a perivascular probe passes all the above electrical tests and the flowmeter and extension cable work correctly with other probes, but the received signal has diminished more than 30% from its initial bench calibration value, check probe for a bent or misaligned reflector bracket (*see diagrams on next page*). These measurements are tricky to make. Please feel free to call the Transonic Systems Probe Repair department at 800-353-3569, 607-257-5300 for over-the-phone assistance.

Remove reflector from probe. Position probe underwater on its side so that the ultrasonic beam radiates in a horizontal plane. Position a steel/brass reflector block facing the ultrasonic transducers, at a distance similar to the probe's reflector. In "TEST" Mode, monitor the probe's received signal strength on the ANALOG METER. Maneuver reflector block to maximize received signal strength by moving the block in/out; rotating around its axis; and tipping it forwards/backwards (*Fig. d.1, on next page*).

B. Operational Tests, Troubleshooting



I. PERIVASCULAR PROBES *cont.*

2. CUSTOMER TROUBLESHOOTING OF PERIVASCULAR PROBES *cont.*

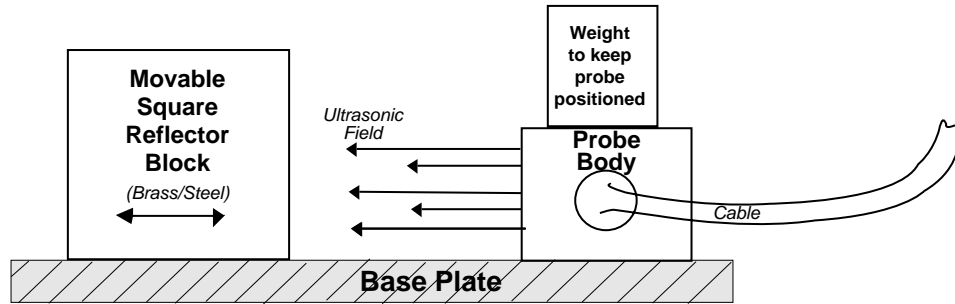


Fig. d.1 Underwater Test Fixture to measure a reference level for a perivascular probe's ultrasonic received signal strength. The reflector block is moved and tilted to maximize the received signal as monitored on the meter's analog meter in the "Test" mode.

The maximum received signal strength thus measured should be within 25% of the factory-calibrated received signal strength. The underwater signal strength attained with the probe's own reflector bracket assembly should be no less than 90% of the strength measured on the solid block, above, for bare reflectors, or 85% of the signal strength for silicone-covered reflector surfaces.

Common Sources of Error:

- Reflector is not seated properly in its groove;
- Reflector surface is bent (concave);
- Reflector arm is bent;
- Silicone covering of reflector bracket (the area facing the probe's ultrasonic transducers) has come partially loose from the bracket and now contains an air pocket. Air pockets in a dry reflector look like a slight reduction in transparency of the silicone. When the pocket contains liquid, one can see the liquid move by pushing on the surface.

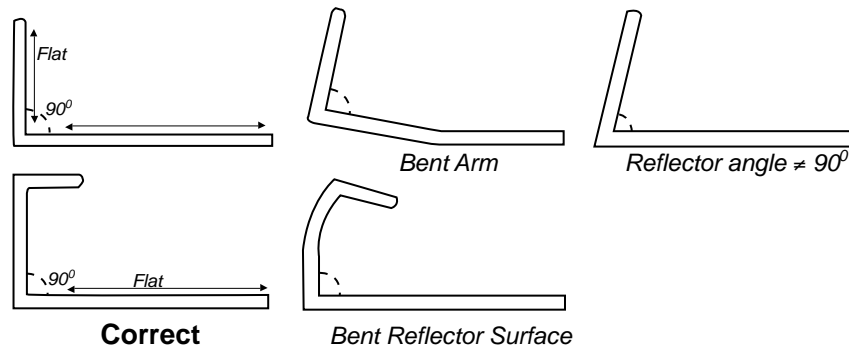


Fig. d.2 Common mis-alignment problems in a reflector. The smaller the probe size, the more critical its reflector alignment.



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B. Operational Tests, Troubleshooting *cont.*



II. STERILE TUBING (CLAMP-ON) FLOWSENSORS

1. TESTING A STERILE TUBING (CLAMP-ON) FLOWSENSOR (C-SERIES)

- a. **Inspect** the silicone cable jacket for superficial cuts. These can be repaired with Dow Corning's "Silastic" Brand Medical Adhesive, Silicone Type A, Catalog no. 891. If internal teflon insulation is also damaged, return probe to factory or refer repair to factory-authorized personnel.
- b. **Connect** flowsensor to flowmeter. Engage the TEST mode. Apply flowsensor to a water-filled tube for which it is calibrated. Verify that the DIGITAL DISPLAY identifies the correct probe size. If the DIGITAL DISPLAY always reports "no" or "Lo" received signal the electro-acoustic signal path is interrupted; proceed to next section: Troubleshooting.
- c. **Read received signal amplitude on ANALOG METER** while still in "TEST" mode. If the flowsensor is operating properly on the specified tubing, the received signal stabilizes after a few minutes of operation to read within 30% of the calibrated 1.0 reading. If the reading is less than 0.7, there is probably air in the sensor, reducing signal amplitude and causing erroneous flow readings. Remove any bubbles from the acoustic field by tilting the flowsensor/tubing to vertical and tapping the tubing.
- d. **Engage "MEA" mode** and observe zero flow offset. Zero-offset must be within the limits specified on the flowsensor's data sheet and small enough so the front panel "zero offset adjust" control can correct for it.
- e. **Record data** on Record of Probe Use sheet, page B 9 .
- f. In Case of Problems: 1) Contact factory; 2) See next section: Troubleshooting.

2. CUSTOMER TROUBLESHOOTING OF STERILE TUBING FLOWSENSORS

- a. **PROBE WIRING DATA:** Figure a.1 presents a connection diagram for sterile tubing (*clamp-on*) flowsensors for use with the T106/T206 meters. The "ROM" is a computer memory chip, mounted within the probe connector, which contains probe identification information such as probe size and style, its signal drive requirements, received signal strength and flow calibration factor. The transducer cabling consists of two twisted-pair wires between the connector and ultrasonic transducers within the flowsensor body.

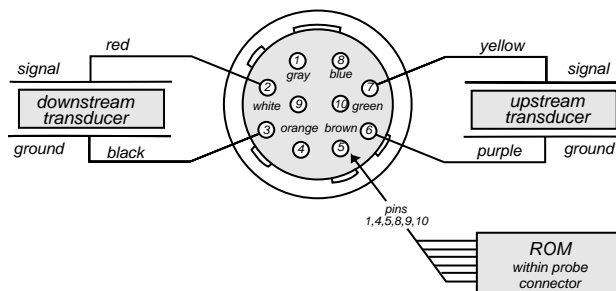


Fig. a.1:

Probe wiring diagram for 10-pin self-aligning connector (pin-side view of male connector). Probes wired for other Transonic flowmeter models use the same connector, but have different internal wiring to avoid false readings.



B. Operational Tests, Troubleshooting *cont.*

II. STERILE TUBING (CLAMP-ON) FLOWSENSORS *cont.*

B. PROBE ELECTRICAL CHECKS AND MEASUREMENTS

1. Inspect cable for cuts through its silicone jacket. Repair (see "Cable Repair" Section, page B 15).
2. A broken transducer wire/connection can be identified from the probe connector pins as a low transducer capacitance. This capacitance is probe dependent, but will generally lie in the range of 200-1200 pf; a value below 100 pf indicates a faulty connection. Capacitance measurements for individual probes are recorded during initial factory calibration and may be obtained by contacting the factory. Capacitance is measured between pins 2 and 3 and between pins 6 and 7.
3. Pins 1, 4, 5, 8, 9 and 10 attach to an electronic memory device (ROM) mounted within the probe connector. Disassembly of this connector requires special tools and should not be attempted. The steps in the next section will identify whether the ROM is at fault. Alternately, a flowmeter with the Computer Interface (-P Option) installed can read the content of this ROM, and thus verify whether it is connected and functioning properly.

C. PROBE-METER INTERFACING MEASUREMENTS

1. **Engage flowmeter's TEST mode with no probe plugged in.** The digital display should read "no.Pr" (no probe plugged in).
2. **Plug in the probe to be tested.** If the DIGITAL DISPLAY reads "probe size-no" where "probe-size" equals the first numerals from the probe serial number, then the meter reads the ROM properly; go to step 3. If the message remains "no-Pr", then either the probe's ROM could be at fault or the meter could be malfunctioning. Plug in another (working) probe to eliminate the possibility of a malfunctioning meter. Return the probe to the factory if the problem is localized in its ROM, return the meter if the meter is at fault.
3. With the ROM functioning properly, perform the following "wet test:"

Mount the sterile tubing flowsensor on its liquid-filled tube per standard instructions. If the "probe size - no" message changes to "probe size - Gd" and the ANALOG METER indicates 0.5 or more, the probe is O.K. If the received signal amplitude is lower, remount the sterile tubing flowsensor on a clean, smooth segment of lubricated tubing. Proceed to Section IV. Customer Repairs if these steps do not bring the received signal amplitude above the 0.5 reading on the ANALOG METER.



IV. CUSTOMER REPAIR

1. METER MESSAGES

When “no.Pr.” message is lit

- Probe is not connected to unit;
- Probe extension cable is defective or has cuts through insulation (see Cable Repair); connect probe directly to flowmeter without extension cable to continue testing of probe;
- Probe connector is defective or improperly wired; a trained technician can open the connector and check for wiring continuity, or return to factory.
- If error occurs with all probes, flowmeter is defective; contact factory.

When “probe size - no” (in TEST mode) or “Ac.Er” (in other modes) is lit

- An air bubble obstructs the acoustic signal path within the probe; other material unmatched in acoustic properties to the fluid of measurement is disrupting ultrasonic transmission.
- Perivascular probe is not submerged in water or its sensing window is not filled with an acoustic couplant surrounding the vessel.
- L-shaped metal reflector bracket on perivascular probe is bent, missing, improperly oriented, or poorly secured and misaligned on probe body.
- Sterile tubing (clamp-on) flowsensor is on tubing other than that for which it was calibrated or its tubing is not fluid filled.
- Probe cable is defective or has cuts through insulation (see Cable Repair, next page).
- Electro-acoustic circuitry of probe appears to be malfunctioning; if error persists with all probes, flowmeter is defective; contact factory.

When “probe size-Lo” message is lit in “TEST” mode

- Air partially obstructs acoustic path resulting in low received signal within probe. If a perivascular flowprobe has just been submerged in water and is in its initial soaking period, wait until zero-flow reading on flowmeter has stabilized. A cold sterile tubing (clamp-on) flowsensor may be unstable during initial operation.
- L-shaped metal reflector bracket on perivascular probe is bent, poorly secured to probe body, or improperly oriented.
- Tubing in sterile tubing flowsensor is not lubricated with petroleum jelly or improper tubing size/material is used.
- Probe cable defective, may have cuts through insulation (see Cable Repair on next page).
- Probe is defective. Contact factory for advice.

When “TEST” light is on

- Flowmeter displays an “Ac. Er” message. Follow troubleshooting instructions above.
- “Lo” message appears in “TEST” mode. Follow instructions above.
- Neither of the two above conditions apply; meter defective; contact factory.

When DIGITAL DISPLAY indicates wrong probe size in “TEST” mode

- Ultrasonic transducer coding inside the probe connector appears defective. Attach different probe to flowmeter. Flowmeter is likely to be defective if other probes fail in the same manner. Contact factory.

B. Customer Repair *cont.*



IV. CUSTOMER REPAIR *cont.*

2. METER REPAIR

Most flowmeter repairs must be performed by Transonic Systems or one of its authorized distributors. Certain repairs can be done by a institution's electronic maintenance and repair department in consultation with Transonic Systems Inc. Please call the company at 800-353-3569 or 607-257-5300 with a description of meter error messages (page B 17) and the probe style and sizes that give these meter error messages.

3. PROBE CABLE REPAIR

Note: Cuts in flowsensor cabling void the factory warranty. Probe cable repair must be done professionally to maintain the integrity of flow measurement.

Cuts in the outer jacket alone can be repaired, when the cable is thoroughly dry, with Dow Corning's "Silastic" Brand Medical Adhesive, Silicone Type A, Catalog no. 891. Such a repair can be finished smoothly with a sleeve of silicone tubing, slit from end to end and glued around the patched area with silastic. If the teflon inner insulation is also damaged, cut through the cable completely at the site of the damage.

- Clean wire with alcohol at site of intended repair.
- Remove approximately 2.5 cm of the silicone jacket from one of the cut ends, and 1 cm from the other end.
- Using a thermal wire stripper, remove approximately 1.5 mm of the teflon insulation from each wire.
- Pre-tin the stripped wires, using acid flux electronic solder available from Transonic Systems
- Clean tinned wire with alcohol.
- Push a piece of small diameter heat-shrink tubing, approximately 6 mm in length, over each of the 2.5 cm cut and stripped wire ends.
- Protect the heat-shrink tubing from premature shrinkage by using pliers to grasp each 2.5 cm wire end between its pre-tinned section and the tubing before soldering.
- Then solder the wire to its color match on the other half of the cable. Remove the pliers and push the shrink tubing over the solder joint.

Repeat these steps for the other wires within the cable. The shrink tubing will be the major barrier against corrosion. Position it so that no metal wire will be exposed, and shrink it using a heat gun or match flame. Be careful not to leave any sharp points when soldering because they may penetrate the heat-shrink tubing. The outer silicone jacket can be restored again by gluing a slit sleeve of silicone tubing around the patched area, as above.

4. EXTENSION CABLE REPAIR

The extension cable consists of a male and female 10-pin connector, interconnected via a 10-wire cable (pin 1 to pin 1, pin 2 to pin 2, etc.). The proper operation of the cable can be diagnosed with an Ohmmeter. Measure pin 1 to pin 1 continuity, pin 2 to pin 2 continuity, etc.; verify that no shorts exist between pins 1 and all other pins, pin 2 and all other pins, etc. Alternately, one can verify the proper functioning of an extension cable by operating a good probe from a good meter, both with and without extension cable. For 6 mm and larger flowsensors all messages and readings in the TEST mode are the same in both cases. For smaller flowprobes, the extension cable may reduce the received signal amplitude (*reported on the ANALOG METER*) somewhat; all other indications must be the same.

The connectors of the extension cable require special tools for their disassembly; repair must be referred to factory-authorized personnel.



B. Factory Repair

V. FACTORY REPAIR

Telephone assistance is provided to help customers analyze problems. Factory repair service is available for malfunctioning equipment. Before returning a product for repair, call Transonic Customer Service for a RMA (*return material authorization*) number. Equipment returned to manufacturer should include all parts and be accompanied by the Factory Return Forms at end of this section.

Transonic Systems provides no-cost analysis of suspected probe defects. Any returned defective probe covered under warranty will be repaired (*or replaced*) free of charge. If the probe warranty has expired but the probe is repairable, an estimated repair cost will be quoted. If the user then selects not to have the repair performed, or if the probe is damaged beyond repair, a \$35.00 credit will be applied to the next purchase.

EQUIPMENT RETURN INSTRUCTIONS

- (1) Call Transonic Systems Customer Service for a RMA (*return material authorization*) number.
- (2) Complete a FACTORY RETURN FORM (*see next pages*) with information for repair service personnel.
- (3) Please use the Transonic Systems shipping carton for returning meter equipment. If you need a carton, contact Customer Service at 800-353-3569 or 607-257-185.
- (4) For a single channel meter, place the two foam packing pieces over the front and back ends of the flowmeter to protect front and rear panel controls. Notches in the foam correspond to protrusions on the instrument.

For a dual-channel meter, the foam packing pieces are placed over the left and right sides of the meter, rather than the front and back panels. The foam ends with three notches are made to fit over the front corners of the meter; smaller indentations along the lengthwise horizontal of the foam indicate the bottom edge, fitted for flowmeter feet. Standing the flowmeter on its left side, slip the front end of the right foam packing piece over the right front end of the flowmeter and then drop the foam piece down over the back end. Repeat the procedure for the other side.

- (5) Lift the instrument with its foam padding into the box.
- (6) Place between meter and box, in the space around the flowmeter,
 - Extension cords,
 - Power cords,
 - Probes (individually packaged with their parts).
- (7) On top of the flowmeter place:
 - Factory Return Form, page
 - Instruction Manual,
 - PROBE RECORD OF USE and any correspondence you would like to include.Seal the cover of the box.
- (8) As a carrier for return, United Parcel Service (UPS) is recommended for all shipping.
 - Ship to our factory address:
 - TRANSONIC SYSTEMS INC.
 - 34 Dutch Mill Road
 - Ithaca NY 14850
- (89) If you have any questions, please call Customer Service at:
TEL: 800-353-3569 or 607-257-5300; or FAX: 607-257-7256.



B. Flowsensor Repair Return Form



Before returning a product for repair, call Transonic Customer Service for a RMA (*return material authorization*) number.

CUSTOMER NAME _____ DATE OF
address _____ RETURN _____

FLOWSENSOR SERIAL # _____

CONTACT PERSON familiar with reported problem, and available by phone:

Name: _____ Fax #: _____
Phone #: _____ Best time to call: _____

DESCRIPTION OF THE PROBLEM(S)

1. With flowsensor plugged directly into the meter without extension cable and properly liquid-filled (refer to Section IV "Initial Bench-Top Operation", page 18) the meter indicates:
 - "No.Pr." - go to 3, below:
 - "Ac.Er" - go to 3, below:
 - Identifies probe: e.g. "4'Gd"
2. Please describe the problem:
 - Received signal reads below 0.5 on the ANALOG METER on T106, HT107 Series flowmeters (For T101 Series flowmeters, see respective manual)
 - Flow readings are suspect (please explain)
 - Other (please describe)

3. The defects in this flowsensor showed up:

- upon arrival
- after repeated uses, as a sudden gradual change in performance.
 - The flowsensor was used approximately _____ times.
 - The duration of each use was approximately _____ hours / days / weeks.
 - Sterilization method(s) used: _____.

4. Please add any additional comments that may expedite this repair.

* For flowsensors under factory warranty: Transonic Systems Inc. will, within 2 weeks of date of receipt of flowsensor, either repair it or replace it from available stock, or notify you of a delivery date for a replacement if not available from stock. For non-warranty repairs: Transonic Systems Inc. will, within 2 weeks of date of receipt of the flowsensor, either repair the flowsensor or notify you of the cost of repair (*depending on the repair cost level authorized herewith*).

Return flowsensor and this form to:

Transonic Systems Inc.
Attn. Probe Repair Department
34 Dutch Mill Road, Ithaca, NY 14850
TEL: 800-353-3569, 607-257-5300; Fax: 607-257-7256



Guarantee, Service, Warranty



A. CUSTOMER SATISFACTION GUARANTEE

The Transonic HT107 Flowmeter carries a 6-month money-back guarantee. Transonic Systems Inc. will reimburse the full purchase price to the original purchaser (for apparatus not bought under an institutional volume discount plan) if the product fails to perform to the expectations of the product end user. The Buyer pays shipping charges to the Transonic Systems' plant..

B. CALIBRATION GUARANTEE

Transonic Systems Inc. certifies that the HT107 Flowmeter and its software are calibrated by methods traceable to the USA National Institute of Standards and Technology ("NIST"). Transonic Systems Inc. guarantees that the HT107 Flowmeter will stay in calibration during its first year of use, if used and stored per standard clinical apparatus practices. Product users may purchase additional years of recalibration service and certification.

C. LIMITED WARRANTY

Transonic Systems Inc. warrants for a period of one (1) year from the date of shipment that the HT107 Flowmeter will remain free from defects which are the result of faulty material or workmanship. Product users may purchase additional years of warranty and repair service insurance. Transonic Systems Inc. warranty shall not apply to: a. defects caused by abuse, neglect or misuse; (e.g., cut cable, pulled cable broken sensor body due to mishandling); b. damage due to accident or casualty; or c. unauthorized repairs, alterations.

Transonic Systems Inc. warrants for a period of six (6) months from date of shipment that the perivascular ultrasonic flowprobe and the clamp-on tubing flowsensor are free from defects which are the result of faulty material or workmanship by Transonic Systems Inc.

Transonic Systems Inc. will, at no cost to the user, either repair or replace a monitor or sensor found defective within its warranty period. The Buyer pays shipping charges.

No other warranty is expressed or implied. Transonic Systems Inc. is not liable for incidental or consequential damages. Warranty is valid only if equipment is purchased through Transonic Systems or its duly appointed distributor or licensed representative.

D. WARRANTY CLAIM

The obligations of Transonic Systems Inc. under this warranty are limited to repairing or, at its option, replacing any goods determined to be defective. Buyer must notify Transonic Systems Inc. in writing within the warranty period of the reason Buyer believes that warranty repairs are required. Buyer is then required upon the request of Transonic Systems Inc. and at Buyer's expense, to return the goods to the Transonic Systems Inc. manufacturing plant. Freight for shipping the repaired goods from the Transonic Systems Inc. manufacturing plant to Buyer's place of business shall be paid for by the Buyer. Any goods repaired or replaced by Transonic Systems Inc. shall be warranted for the period of time remaining on the original warranty from its date of inception.