

Transonic Systems T110R

Laboratory Tubing Research Flowmeter



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Operator's Manual



Transonic® Laboratory Tubing Flowmeter T110

FLOWMETER SERIAL # _____

FOR USE WITH STERILE TUBING FLOWSENSORS

AUT110 Manual
Rev C 2/04

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Warnings & Precautions



This flowmeter achieves a high degree of patient electrical isolation through the use of:

- hospital-grade isolation between power line and meter
- double insulation between electronics within flowsensor and flowsensor cable and its user-accessible parts.

Many factors may degrade or bypass this insulation:

- connections between the meter and any external line-powered devices;
- connection of meter to power line via non-hospital-grade power cord;
- connection between the meter and patient or patient circuits other than via the supplied accessory flowsensors;
- damage to the electrical isolation of flowsensor or flowsensor cable;



Safe and effective use of the Transonic flowmeter depends on correct application technique, adequate precaution and readiness for emergencies.



The specific directions in this manual and in the package inserts included with each flowsensor must be observed. Periodic bench-testing of flowsensors must be performed as described to assure the validity of flow measurements.



Danger - Explosion risk if used with flammable anesthetics.



The flowmeter must not be modified or serviced except by qualified Transonic Systems repair persons.



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Section A: Operator's Manual



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Introduction A-I.

The **Transonic® Lab Tubing Flowmeter (T110)** package consists of a bench-top **electronic flow detection unit** and **sterile tubing flowsensors** for extracorporeal use with extracorporeal laboratory tubing. Patented by Cornell University, the flowmetering system uses an ultrasonic transit-time principle to sense liquid volume flow in tubing.

- A. ELECTRONIC FLOW DETECTION UNIT:** Designed for ease of use in the critical care setting the line-powered flowmeter has two functional modes that are operated by touch-sensitive membrane switches. In the MEASUREMENT MODE, the text display will show flowsensor information and current sensor status while the digital display will show monitored flow. The PROGRAM MODE will allow you to set parameters and alarms for a measurement run.

Volume flow is displayed on the easy-to-read LED digital display.

- B. STERILE TUBING FLOWSENSORS:** Transonic HX-Series sterile tubing flowsensors apply ultrasound energy through standard extracorporeal tubing to monitor instantaneous and average volume flow of blood or other priming solutions. With only ultrasonic contact required between probe and monitored flow, sterile tubing flowsensors maintain total physical and electrical isolation between sensor and liquid under study.



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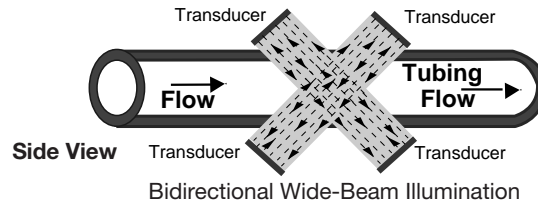
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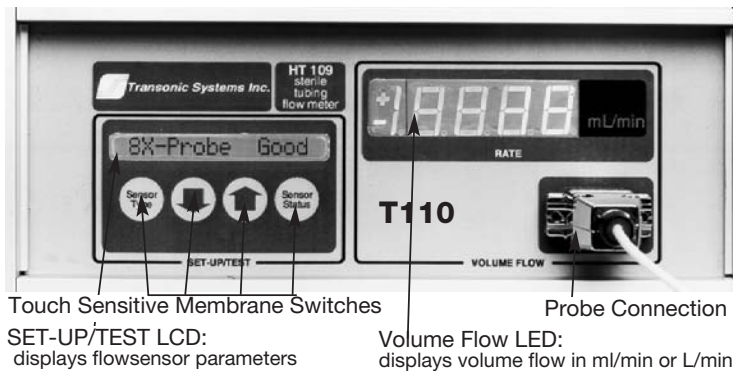
A-II. Theory of Operation

A Transonic X series flowsensor (Fig. 1) consists of a probe body which houses four ultrasonic transducers positioned on both sides of the tube.



The tubing is placed in two ultrasonic beams that fully and evenly illuminates the area. The four transducers pass ultrasonic signals back and forth, alternately intersecting the flowing liquid in upstream and downstream directions. The flowmeter derives an accurate measure of the changes in "transit time" (time it took for the wave of ultrasound to travel from one transducer to the other) resulting from the motion of the liquid in the vessel. The integrated difference between the two upstream and downstream transit times is a measure of volume flow.

A-III. Specifications



MODELS

T110 (Base Flowmeter)

All units have an LCD to display flowsensor parameters; for example, size of probe, tubing for which it is calibrated, fluid type, etc. Touch-sensitive membrane switches adjust zero offset and allow display of flowsensor status on the LCD. This unit simply measures flow.

T110R (Research Flowmeter)

This model allows the user to program variable parameters when it is desirable to adjust probe calibration and for different fluids or different tubing. Original calibration data is retained. In addition to the Bubble Detection Alarm, thresholds may be set separately for a Low and High Flow Alarms.

A-III. Specifications cont.



GENERAL FEATURES

Weight/Size	T110: single channel 7 lbs. (3.2 Kg), 8 1/2" w x 3 1/2" h x 13" d
Electrical Isolation	Flowmeter complies with USA standards for medical and dental equipment (UL544), and with European standards for medical and ultrasonic apparatus (DIN IEC 601-1, VDE 0750 -1/5.82, IEC 62D Sec. 31).
Alpha-Numeric Display	Single row by 16 character liquid crystal that displays error conditions, calibration and probe parameters.
Flowmeter Display	0.1 ml/min to 200l/min (typical), displayed by a 4 1/2 digit, 7 segment LED.
Flow Monitor Outputs	Analog mean and pulsatile flow
Probe Connector	15 pin, high density D-Sub connector
Digital Identification	Probe identification & calibration parameters programmed into flowprobe connector
Ultrasonic Frequency	300 KHz to 7.2 MHz
Accepts:	C-Series & X-Series sterile tubing flowsensors for extracorporeal tubing

ELECTRICAL SPECIFICATIONS

Power	AC Input: 90 - 265 VAC; 50 - 60 Hz, 40 watts Fuses: Two, 1.5A / 250V, 5 x 20 mm Connector: International 3 conductor type IEC 320
Flow Monitor	Average: Grounded BNC fitting ± 5.0 volts peak, Output impedance 500 Ω ; Filtered at .1Hz Pulsatile: Grounded BNC fitting ± 5.0 volts peak, Output impedance 500 Ω ; Filter Selectable 10/30/100 Hz
Bubble Switch	Isolated ground BNC fitting connected to SPST solid state relay, optically coupled, normally closed Voltage Isolation: 1000 Vdc Max switch voltage: 40 Vdc Max switch current: 0.5 Amps continuous Max switch power: 0.35 watts Typ. ON resistance: 1 ohm
RS-232	9-pin D-Sub connector, standard RS232 parameters Isolated ground: pin 5; Transmit: pin 2; Received: pin 3

OPTIONAL FEATURES

The (-P) Personal Computer Interface Option allows the user to interface the flowmeter to a standard IBM-PC computer to display, record and playback flow waveforms and data. The analog flow signal from the meter is digitized by an A to D converter providing 12 bits of resolution at a sampling rate of 100 samples per second. The resulting 2-byte packet is then transmitted serially at 9600 baud to the IBM-PC computer via its RS-232 port.

Package includes:

- Additional circuitry within the flowmeter cabinet;
- a standard RS-232 cable
- WINDAQ - PC compatible software to display & record flow data.



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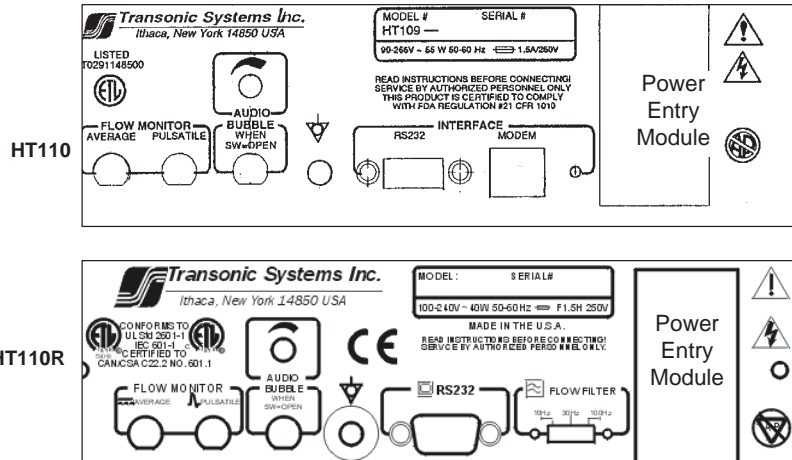
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A-IV. Functions and Controls

REAR PANELS



Power Entry Module This module contains the power switch and fuses and accepts a standard IEC 320 computer cord set.

Flow Monitor

Average This BNC fitting provides an output voltage proportional to flow rate. It is filtered at 0.1Hz to provide an average output value.

Pulsatile This BNC fitting provides an output voltage proportional to flow rate. It is filtered at 5 Hz.

Audio This potentiometer allows the user to adjust the alarm volume. Full counterclockwise rotation reduces the volume to inaudible.

Bubble This electrically isolated BNC fitting is connected to a single-pole, single throw (SPST) switch and is closed during normal flowmeter operation. Upon activation of the Bubble or Low/Hi flow alarms, the switch opens. It can be used to provide external indication that an alarm condition exists.

Interface

RS232 The 9-pin, D-Sub female connector is the serial data I/O port of the P-option within the flowmeter. Connection to the Personal computer via the appropriate cable will allow the PC to communicate with the flowmeter. The electrical "ground" of this interface is isolated from chassis ground.

Modem Reserved for future use.

Legend

Symbol



Definition
Attention, consult accompany documents



Dangerous voltage



Not category AP equipment



Equipotentiality

Transonic Notation

The specific directions in this manual and in the package inserts included with each flowsensor must be observed. Periodic testing of flowsensors must be performed to assure the validity of flow measurements.

The flowmeter must not be modified or serviced except by qualified Transonic repair persons.

Danger-Explosion risk if used with flammable anesthetics.

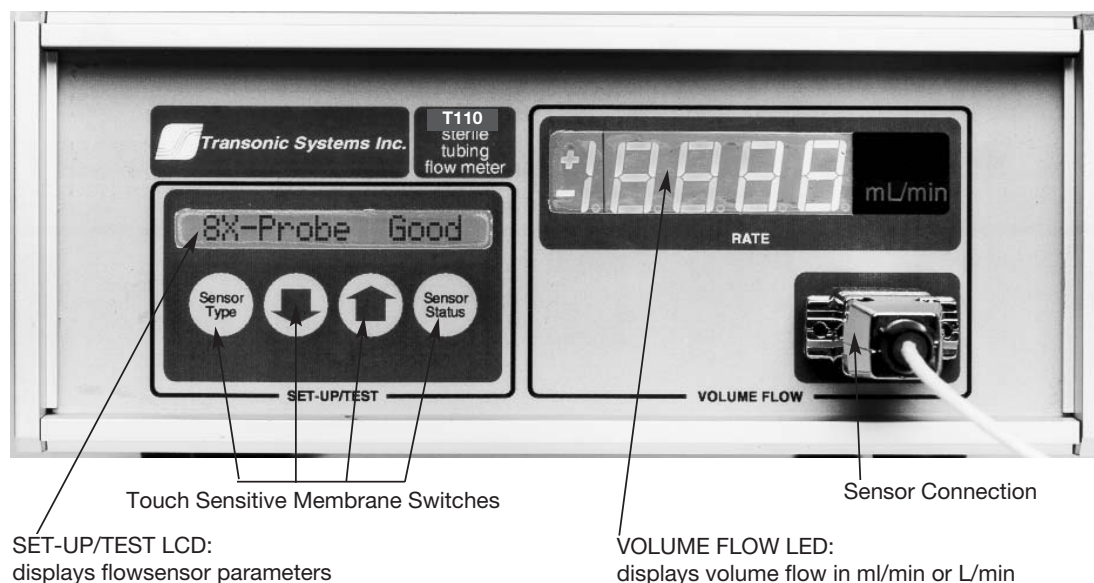
This ground stud is connected to the metal cabinet of the monitor. It provides the User with a means to monitor to other equipment.

A-IV. Functions and Controls *cont.*



FRONT PANEL

T110



SET-UP/TEST Liquid Crystal Display (LCD)

Power On Indicator When power is applied to the flowmeter and the rear power switch is turned on, the LCD background will glow light green.

Messages The LCD screen provides the user with all status and error messages. It can display up to 16 alpha-numeric function characters simultaneously.

Flow Display Flow is displayed through an array of 4 1/2 7-segment light emitting diodes (LEDs) and a preceding polarity / overflow indicator. The L/min and mL/min flow rate LEDs are selected and lighted depending on the scale value stored in the flowsensor's ROM.

Membrane Switches These four membrane switches allow the user to scroll through the menu of flowmeter functions and set flowsensor parameters to the flowmeter. Under alarm conditions depression of any one switch will reset the alarm.

Sensor Connector This 15-pin, female, high-density D-Sub connector mates with the flowsensor's 15-pin, male connector.

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A-V. Directions for Use, Sensor Operation

USE OF STERILE TUBING FLOWSENSOR

Sensor Selection

Flowsensor size and calibration is determined by the tubing on which it will be used. Each Transonic sterile tubing flowsensor is custom designed and calibrated for use on particular tubing (*silicone rubber, latex, polyurethane, or polyvinyl chloride [pvc]*). Use on tubing other than specified generally yields inaccurate measurements and may cause erratic zero baseline drift.

Cleaning and Sterilization

A sterile tubing (clamp-on) flowsensor may be cleaned by wiping with a solution of soap and water (60°C, 140°F) followed by a ethyl alcohol rinse to promote drying. Because no physical contact is required between the liquid under observation and the flowsensor, sterilization for hospital use is not usually necessary. STERRAD or standard hospital cold (*ethylene oxide*) **gas** sterilization may be used ($\leq 60^{\circ}\text{C}$, 140°F).

The sterile-tubing flowsensor can be damaged by saline immersion or wet storage and should not be boiled, autoclaved, or sterilized by cold liquid sterilization.

Sensor Calibration

Flowsensors are precalibrated for a particular liquid at a certain temperature (*see flowsensor's data sheet*). Recalibration is necessary for accurate measurements at other temperatures or in other liquids. If a more precise zero baseline than that specified is needed, the meter must be zeroed by stopping the flow momentarily and re-zeroed every time operating conditions change (*change in fluid temperature, re-mounting probe on tube, etc*).

Site Selection

The flowsensor may be applied on straight tubing segments, near side branches or on curved tubing segments to produce measurements within its accuracy specifications. The best application site for the flowsensor is a point well below the highest elevation of the tubing (*where gas bubbles might lodge*). The flowsensor will deform the tube slightly. If the tubing site becomes permanently deformed at one clamping position, choose another site to achieve better ultrasonic (acoustic) coupling.

Tubing Preparation

Apply a layer of petroleum jelly, or silicone grease over the tubing surface to enable ultrasonic transmission between tube and sensor.

Sensor Application

To apply the flowsensor to tubing, open the flowsensor's hinged lid, insert **lubricated** tubing into the sensing cavity, and close the lid. Fit should be tight, with the full tubing cross section contacting all inner surfaces of the sensing window. Once the tubing is filled with the liquid to be measured, signals from the flowmeter circuit board can be accessed to verify proper operation and to adjust received signal trip levels for bubble detect purposes. Since gas bubbles block ultrasonic transmission, tilt the tubing and flowsensor vertically before operating the flowmeter to **flush** any bubbles from the sensing window.

A-V. Directions for Use, Flowmeter Operation



MEASUREMENT MODE

Mount the sterile tubing sensor on a liquid-filled tube:

Connect flowmeter to hospital grade power source via medical grade power cord.

Turn on "Power" switch (rear panel, power entry module).

The meter starts up in MEASUREMENT MODE when powered up. (From the PROGRAM MODE, the MEASUREMENT MODE is engaged by depressing the "Exit" key several times.

With no sensor connected, the SET-UP/TEST display will read "Flowsensor?"

Plug Flowsensor into the "SENSOR" connector on the front panel of the flowmeter.

The flowmeter will read specific sensor information stored in the sensor connector about the indications and calibration of the sensor.

Within Measurement Mode, the Set-up/Test display offers three monitor functions:

Sensor type

Sensor status

Ultrasonic signal



SENSOR TYPE Monitoring

At any time within the MEASUREMENT MODE you may review the "Sensor Type" information by depressing the "Sensor Type" key. The SET-UP/TEST display will scroll through the following:

Sensor size, type, serial number

Tubing Type

Tubing dimensions

Fluid type and temperature

The VOLUME FLOW display will indicate flow in milliliters or liters per minute.

After the scroll of the "Sensor Type" information, the meter automatically defaults to the "Ultrasound Signal Monitor" condition (*below*).



SENSOR STATUS Monitoring

At any time during the measurement run, you may review the programmed parameters by depressing the "SENSOR STATUS" key. The SET-UP/TEST display will scroll through programmed settings. For example: "Offset adjusted 1 ml/min, Bubble alarm OFF".

After the scroll of the "Sensor Status" information, the meter automatically defaults to the "Ultrasound Signal Monitor" condition (*below*).

To SET or ADJUST sensor parameters for a measurement run, access the PROGRAM MODE and follow the procedure using the menu flow chart for your flowmeter model.

Note: For greatest accuracy, the zero offset adjustment and bubble alarm setting should be checked and reset each time the flowsensor is unclamped and remounted on the tubing.



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A-V. Directions for Use, Flowmeter Operation cont.

ULTRASOUND SIGNAL Monitoring

Default condition

The flowmeter will continually monitor the quality of the flowsensor's ultrasound signal coupling and display this on the SET-UP/TEST display.

This signal coupling quality is an important indication of flow and flowsensor functioning, flow measurement accuracy and, when the meter is properly set up is expressed as a percentage of the initial factory value.

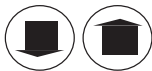
For example "*Ultrasound = 95%*". The flowmeter detects 95% of the original ultrasound signal at this clamping.

Error Message

The SET-UP/TEST display will scroll error messages "*No Ultrasonic signal!...No tube?...Air In Tube?...Bad Cable?*" when there is a gross interruption of the ultrasound signal.



Flow measurement will be interrupted and the VOLUME FLOW display will show "- - - -" (no numbers).

PROGRAM MODE

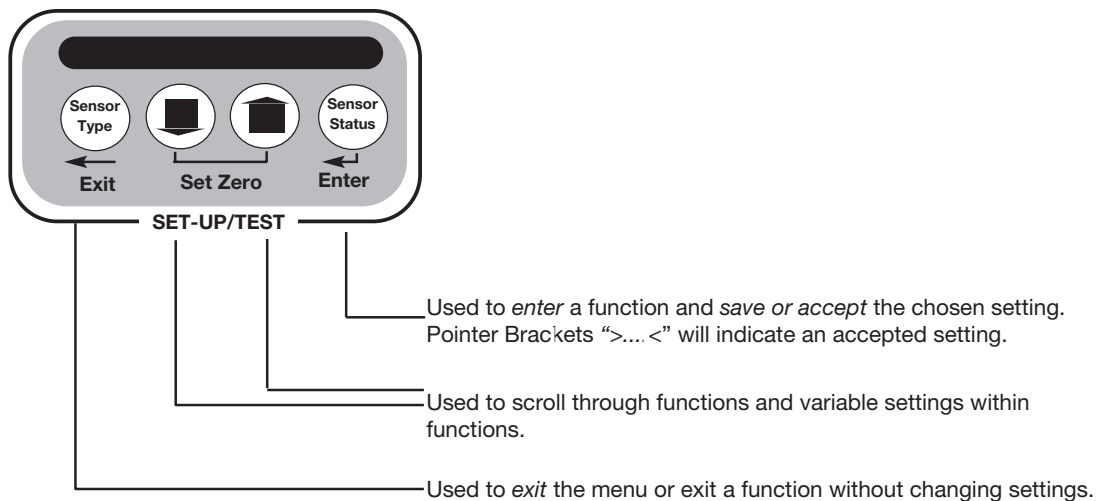


The PROGRAM MODE is engaged by depressing both arrow buttons simultaneously.

Programmable features offered in your T110 vary depending upon your flowmeter model. Once engaged in the program mode you may review the features of your meter by depressing the

the  or the  keys. The meter will roll through its installed features and allow you to set the value for each.

Programmable features are entered by pressing the "Enter" key and are exited by pressing the "Exit" key



A-V. Directions for Use, Flowmeter Operation cont.



PROGRAM MENU flow charts for each T110 flowmeter model are on pages 12-13.

Descriptions and specific directions for each feature follow.

REVIEW OF PROGRAMMED SENSOR STATUS



After you return to MEASUREMENT MODE, you may review the program settings by depressing the "SENSOR STATUS" key.

The SET-UP/TEST display will scroll through programmed settings.

For example: "Offset adjusted 1 ml/min, HI=2000 ml/min, LO=40 ml/min, Bubble alarm OFF, Flow gain 105%."

Note: All adjustments, except the zero offset adjustment, are stored in the connector ROM and remain the default setting after power off or disconnection of the sensor from the flowmeter. The zero offset adjustment should be reset for each measurement run.

ADJUST OFFSET

HT110, HT110R flowmeter models

This function allows you to adjust the flowmeter reading for the zero offset of the flowsensor. The flowsensor should be mounted on the tubing and flow through the tubing should be stopped to set zero flow.

Depress ARROW keys to adjust the VOLUME FLOW display to read "0" or near zero. The SET-UP/TEST display will indicate the *Zero Offset Adjustment in ml/min*. ENTER to accept the value.

EXIT to continue the program.

TUBING CHOICE

HT110, HT110R flowmeter models

ENTER to display the tubing type for which the sensor was calibrated. If the sensor was calibrated for more than one tubing type, use the ARROW keys to scroll through choices.

ENTER to *accept* the one that matches the tubing the flowsensor is mounted on. *(If the tubing in use is not a choice for this sensor, a calibration adjustment or signal timing change may be required for accurate measurements; factory consultation is recommended.)*

EXIT to continue the program.

SET CHART RECORDER

HT110, HT110R flowmeter models

This function allows the user to calibrate an *external recording device* such as a chart recorder or computer with the appropriate scale for the flowsensor. Flow measurement is temporarily suspended.

ENTER to display "FULL SCALE". The value indicated on the VOLUME FLOW display is equivalent to the 1 volt analog signal output of the BNC connectors on the back panel of the flowmeter.

Press the ARROW to display "ZERO SCALE". The VOLUME FLOW display will now read 0 ml/min and produces an electrical output of 0 volts.

EXIT to continue flow measurement.



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A-V. Directions for Use, Flowmeter Operation cont.

BUBBLE ALARM

HT110R flowmeter model only

When the sterile tubing flowsensor is properly mounted and functioning (as indicated by *ultrasound signal strength*), the **Bubble Detection Alarm** allows you to set a sensitivity threshold for bubble detection. This function is then triggered by a drop in the ultrasound signal caused by, for instance, air bubbles passing through the flowsensor.

Note: The connection between a drop in ultrasound signal strength and bubble diameter depends on the sterile tubing flowsensor style and size being used. Please request the appropriate application support information for your flowsensor.

ENTER the "BUBBLE ALARM" menu.

The SET-UP/TEST display indicates the percentage of the initial factory ultrasound signal at that clamping and asks you to confirm the quality of the signal.

For example: "90% Usound OK?" Too low a signal may indicate an incorrect tubing choice, a failing sensor, an inadequate clamping or air in the tube. After you have confirmed that all these conditions are not present, you push ENTER to confirm and accept this value. This value now becomes the "normalized" 100% ultrasound signal for bubble detect purposes.

Next, the program lets you adjust the **"BUBBLE TRIP LEVEL,"** that is, the relative drop in ultrasound signal strength at which the bubble alarm will sound.

Use the ARROW keys to set the BUBBLE TRIP LEVEL. This level is a percentage of the "normalized" ultrasound signal. Increasing the percentage increases sensitivity to bubbles so that smaller diameter bubbles will trip the alarm.

For example: "@ 80%U-son.sig" indicates that a 20% drop in the normalized ultrasound signal at that clamping will sound the alarm.

ENTER to accept the value of the chosen bubble trip level.

EXIT to continue. The SET-UP/TEST display will indicate ">Alarm On<".

You may use the ARROW to turn ▼ ">Alarm Off<", and ▲ ARROW to turn ">Alarm On<" again.

EXIT after setting the alarm.

When the bubble alarm is activated, the SET-UP/TEST display will read **"BUBBLE"** and an audible alarm will sound.

The loudness of the alarm is adjusted by the knob on the back panel of the flowmeter.

To cancel the alarm, DEPRESS ANY KEY.

Please note that the alarm will not clear until the condition is corrected. You may also need to RESET and RENORMALIZE the ultrasound signal after clearing the alarm, if there has been a change in the ultrasound signal quality or if you have reclamped the sensor.

For example: If you accepted "90% Usound OK" above as the normalized ultrasound signal from which the trip level alarm is derived, and your meter now indicates "Ultrasound = 70%" you need to examine why the signal has dropped and correct the error condition, or re-normalize the ultrasound signal level from which the bubble trip level is derived, if the drop in ultrasound signal is legitimate.

A-V. Directions for Use, Flowmeter Operation



HIGH FLOW ALARM

HT110R flowmeter model only

This function allows you to set an upper threshold for flow rates that will activate an alarm when the threshold is exceeded.

The upper limit is dependent upon sensor size and is 5 times the *FULL SCALE* for the sensor. (Full scale is described in "SET CHART RECORDER" and listed in the flowsensor specifications table.)

To disable this alarm, set it at 5 times the *FULL SCALE* value or maximum limit. At this level, the alarm will indicate when the meter will be taxed beyond its linear flow display capabilities.

ENTER the *HIGH FLOW ALARM* menu.

Use the ARROW keys to select the desired flow rate. Example: "*HI=2000 ml/min*".

ENTER to accept the value.

EXIT after setting the alarm.

When the alarm is activated, the SET-UP/TEST display will read "*HIGH FLOW*" and the VOLUME FLOW display will continue to indicate measured flow.

To cancel the alarm, DEPRESS ANY KEY.

Note that the alarm will not clear until the condition is corrected.

LOW FLOW ALARM

HT110R flowmeter model only

This function allows you to set a lower threshold for flow rates that will activate an alarm when the flow falls below the threshold.

To disable the alarm, set it at its maximum negative number (5 times the *FULL SCALE value*). At this level, the alarm will indicate when the meter will be taxed beyond its linear flow display capabilities.

ENTER the *LOW FLOW ALARM* menu.

Use the ARROW keys to select the desired flow rate. Example: "*LO= 40 ml/min*".

ENTER to accept the value.

EXIT after setting the alarm.

When the alarm is activated, the SET-UP/TEST display will read "*LOW FLOW*" and the VOLUME FLOW display will continue to indicate measured flow.

To cancel the alarm, DEPRESS ANY KEY.

Note that the alarm will not clear until the condition is corrected.

ADJUST CALIBRATION

HT110R flowmeter model only

This function allows the user to adjust the calibration gain of the flowsensor for different fluids, tubing or variable conditions.

Original factory calibration of the flowsensor is specified for fluid type and temperature and is programmed in the connector ROM.

(You may check this information by depressing "SENSOR TYPE" key when you are not in the program mode.)

The factory calibration is normalized and expressed as 100%. Adjustments to this value should be done only following a comparison of the flowmeter reading against a timed flow of a known volume under the true conditions requiring the calibration change. Several data points should be taken to establish a linear calibration curve.

Note: the OFFSET should be adjusted for zero flow prior to making the calibration adjustment.

ENTER the "*ADJ. CALIBRATION*" menu.

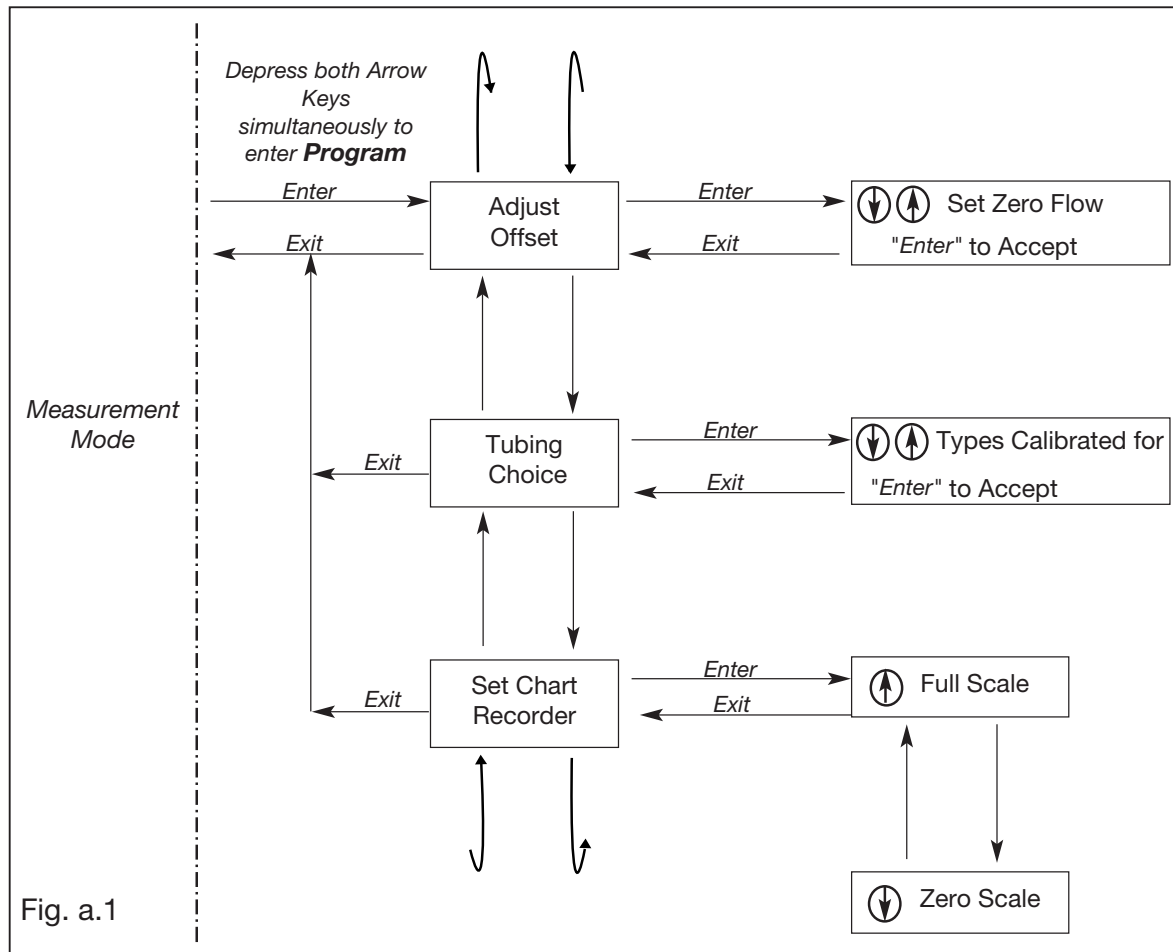
The original factory calibration is displayed as "*FLOW GAIN 100%*".

Use the ARROW keys to adjust this percentage. ENTER to accept this value.

EXIT program. *Note: This new calibration value is stored in the sensor ROM and becomes the default calibration for the sensor until reset to 100%.*



A-V. Program Menu - Base Model



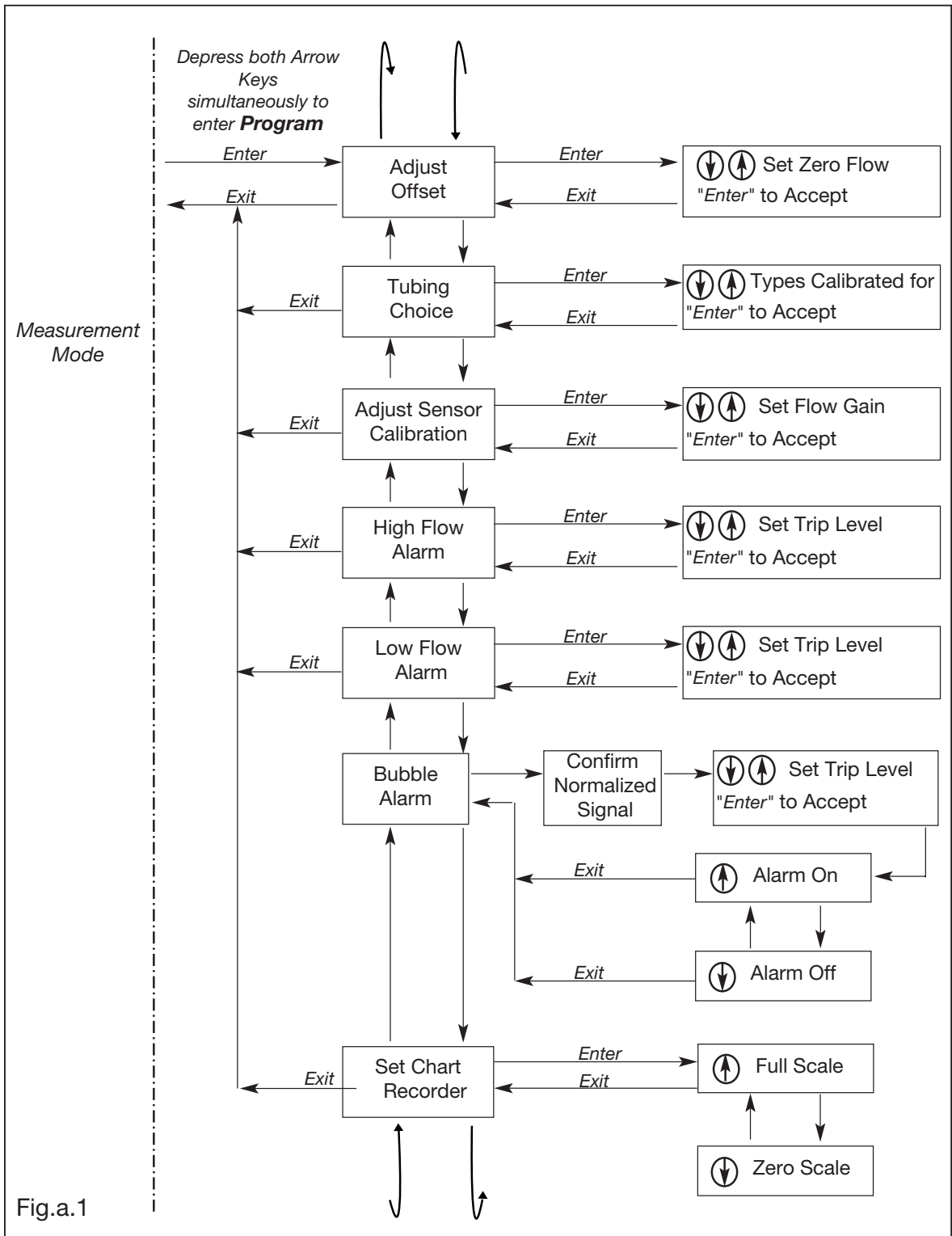


Fig.a.1



A-V. Directions for Use, Maintenance

FLOWSENSOR MAINTENANCE

Examine the sterile tubing flowsensor after use for moisture—particularly for saline or corrosive fluid. The flowsensor can be wiped with 90% ethyl alcohol. See sterilization instructions above. Inspect cables for damage; verify availability of correct tubing stock. Note performance data in Record of Probe Use (Section A-VI) and store flowsensor at room temperature in a dry place.

FLOWMETER MAINTENANCE

Exterior flowmeter surfaces can be cleaned using a cloth or brush dampened with soapy water, followed by damp wiping with clear water. Alternately, the surface can be damp-wiped clean with isopropyl alcohol instead of soapy water. Do not drip liquids into the meter cabinet. A flowmeter exposed to accidental spillage should be unplugged immediately from its power source. Remove the cover. If the spilled fluid is potentially corrosive or may leave a residue, flood the area of the spill with water, using care not to disturb components or wires. Compressed air may be used to blow liquid off components, repeating the rinse and air-blowing if the spilled liquid is other than water. Remove remaining moisture with a heat gun. **Do not operate the flowmeter in a wet condition; keep it in a dry environment.**

A-VI. Operational Tests, Troubleshooting



STERILE TUBING FLOWSENSORS

- a. Inspect the polyurethane cable jacket for superficial cuts. These can be repaired with any RTV Silicone Sealant / Adhesive. If internal teflon insulation is also damaged, return probe to factory or refer repair to factory-authorized personnel.
- b. With no probe installed, apply power to the flowmeter. The LED should display the message "----" and the LCD display "Flow Sensor?". If this is not displayed, there is a flowmeter malfunction and the failure should be reported on the Flowmeter Repair Return Form (*page A 27*).
- c. Install a flowsensor.
- d. The flowmeter will access the Read Only Memory (ROM) resident in the sensor's connector and display the sensor status, sensor size, tubing type, tubing size, fluid type, temperature at which the sensor was calibrated, and received ultrasound amplitude expressed as a % of the initial factory value.

If the flowmeter cannot read the ROM, then the flowmeter will continue to display "Flow Sensor". This indicates that either there is a flowmeter malfunction or that the data in the ROM has changed.

By installing a different sensor known to be in working order, the user can determine which failure has occurred. If the new sensor also displays "Flow Sensor", then there is a flowmeter failure and it should be recorded on the Flowmeter Repair Return Form (*page A 27*).

If the new sensor works properly, then the previous sensor has failed and the failure recorded on the Flowsensor Repair Return Form (*page A 25*).
- e. Apply a working flowsensor to a water-filled tube for which it is calibrated. Verify that the LCD displays the correct sensor size. If the acoustic path is such that little or no ultrasound is received, the LCD will advise the user "No U-sonic Sig!" It will then display possible causes by a series of prompts: "No Tube?"; "Air In Tube?"; and "Bad Cable?"

If the meter continues to respond "No U-sonic Sig!" after the elimination of possible causes, there is a flowmeter failure. This failure should be recorded on the Flowmeter Repair Return form (*page A 27*).
- f. If the flowsensor is operating properly on the specified tubing, the flow readout on the LED will stabilize within a few seconds. The LCD will display the sensor status menu and end by displaying "Ultrasound %".



Transonic 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.transonic.com

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A-VI. Operational Tests, Troubleshooting *cont.*

FACTORY REPAIR

Telephone assistance is available 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 Return Material Authorization (RMA) 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 flowsensor defects. Any returned defective flowsensor covered under warranty will be repaired (or replaced) free of charge. If the sensor warranty has expired but the sensor is repairable, an estimated repair cost will be quoted. If the user then selects not to have the repair performed, or if the sensor 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 Return Material Authorization (RMA) 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 (607) 257-1185.
- (4) 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.
- (5) Lift the instrument with its foam padding into the box.
- (5) Place between meter and box, in the space around the flowmeter,
Power cords,
Flowsensors (individually packaged with their parts).
- (6) On top of the flowmeter place:
Factory Return Form, with your name and phone number
Instruction Manual
SENSOR RECORD OF USE and any correspondence that would help define the problem.
Seal the cover of the box.
- (7) 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
- (8) If you have any questions, please call Customer Service at:

Tel: 800-353-3569; or Fax: (607) 257- 7256.

A-VII. Guarantee, Service, Warranty



A. CALIBRATION GUARANTEE

Transonic Systems Inc. certifies that the T110 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 T110 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.

B. LIMITED WARRANTY

Transonic Systems Inc. warrants for a period of one (1) year from the date of shipment that the T110 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 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.

C. 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.



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A-VIII. Flowsensor Record of Use Form

STERILE TUBING FLOWSENSOR RECORD OF USE T110 FLOWMETERS

Maintaining a record of sensor received signal strength is an essential part of routine sensor maintenance. The flowsensor's received signal is normalized to 100% at the factory on the tubing for which the sensor is built and should vary only slowly over time (due to transducer "aging") when the sensor is used with the tubing specified on its Transonic Flowprobe Specifications sheet. As signal degradation may indicate improper mounting of the sensor or deterioration of sensor function, performance tracking is helpful in diagnosing problems before flow readings become questionable. Before returning a product for repair, call Transonic Customer Service for a RMA (return material authorization) number.

User/contact person _____ phone # _____
Sterile-tubing probe # _____ date received _____
Made for tubing material _____ I.D. _____ Wall _____

Date	Rec'd Signal	Bench	Patient Circuit	Notes (Describe tubing if different)

When returning flowsensors for factory examination, please include Flowsensor Repair Return Form on the next page.

A-VIII. 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 and properly liquid-filled (refer to Section V "Directions for Use) the SET-UP/TEST display indicates:

☐ "No U-sonic sig! No tube" etc. - go to 3, below
☐ Identifies flowsensor correctly

2. Please describe the problem:

☐ Flow readings are suspect (please explain)
☐ Other (please describe)

- 3.b 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; Fax: 607-257-7256



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A-VIII. Flowmeter Repair Return Form



Transonic Systems Inc. will return the repaired meter within 2 weeks of receipt or send you a temporary replacement meter, if all the information below is supplied. Before returning a product for repair, call Transonic Customer Service for a RMA (return material authorization) number.

CUSTOMER NAME _____ **DATE OF RETURN** _____
Address _____

METER SERIAL # _____

CONTACT PERSON *(familiar with reported problem, and available by phone)*

Name _____ **Fax #** _____

Phone # _____ **Best time to call** _____

DESCRIPTION OF THE PROBLEM(S)

Please complete the appropriate entry from the three below:

- ☐ Meter does not measure flow at all.
- ☐ Meter malfunctions erratically: intermittent problem shows up:
 - ☐ when meter is turned on; ☐ after ___ minutes of power on
- ☐ All meter functions operate, but readings are suspect.

Please describe the problem:

- ☐ Zero flow offset is too high with flowsensor # _____ plugged directly into the meter and properly liquid filled* (see below)

The zero offset was _____ ☐ ml/min; ☐ L/min; ☐ % of full scale on the

☐ Digital Meter ☐ Avg. flow Monitor BNC ☐ Pulsatile Flow monitor BNC.

* Refer to Section V on how to make proper zero flow measurements, and to diagnose whether the meter or the flowsensor is at fault. In case of doubt, include the flowsensor with this shipment.

- ☐ Noise in flow readings is too high as monitored on the
- ☐ Digital Meter ☐ Avg. flow Monitor BNC ☐ Pulsatile Flow monitor BNC.

☐ Other: Please describe: _____

Please add any comment that may expedite the repair

Return the flowmeter with this form to:

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



Transonic Systems Inc.

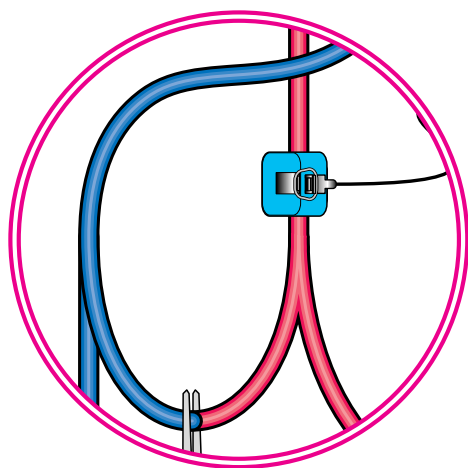
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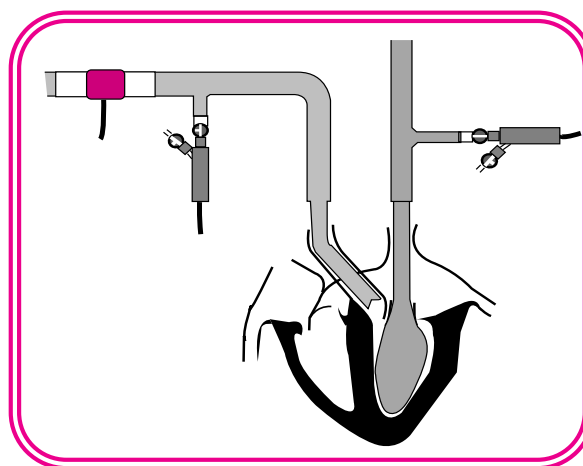
Section B: X-Sterile Tubing Flowsensors



HX-Sterile Tubing Flowsensor

Contents

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For extracorporeal applications, X-Series Sterile Tubing Flowsensors with the T110 Lab Tubing Flowmeter offer the highest accuracy.

The sensors clip around the outside of standard flexible tubing and measure the volume flow within. Measurements are bi-directional, largely independent of flow profile, and turbulence and cover a wide dynamic range. Because no physical contact with the liquid under study is necessary, the sensor is ideal for applications where non-thrombogenic surfaces must be maintained or where biohazardous liquids (radioactive, chemotherapeutic and infectious solutions) must be contained within tubing.

Sensors are pre-calibrated for specific tubing type, fluid and temperature. They may be factory programmed for use on up to 4 tubing choices of the same dimension. Typical tubing brands are listed in the table on the next page; flowsensors for tubing other than listed may be custom built.



XL-Sterile Tubing Flowsensors

Specifications

Sensor Model #	Tubing			Max. Zero Offset mL/min	Absolute Accuracy ¹ %	Relative Accuracy %	Bidirectional Flow Outputs			Ultrasound Frequency MHz
	ID	Wall Thickness	OD				Resolution ² mL/min	Scale L/min/Volt	Max Range L/min	
2XL	In sizes 2XL - 5XL ratio of tubing wall thickness to OD must not exceed 1:5 for PVC; 1:3 for silicone		1/8	± 5	± 10	± 4	0.5	.2	1	3.6
3XL			3/16	± 10	± 10	± 4	1.0	.4	2	3.6
4XL			1/4	± 10	± 10	± 4	1.0	.4	2	3.6
5XL			5/16	± 10	± 10	± 4	1.0	.4	2	3.6
6XL	1/4	1/16	3/8	± 30	± 10	± 4	2.5	1	5	2.4
7XL	1/4	3/32	7/16	± 60	± 10	± 4	5	2	10	1.8
8XL	3/8	1/16	1/2	± 60	± 10	± 4	5	2	10	1.8
9XL	3/8	3/32	9/16	± 60	± 10	± 4	5	2	10	1.8
10XL	1/2	1/16	5/8	± 120	± 10	± 4	10	4	20	1.2
11XL	1/2	3/32	11/16	± 120	± 10	± 4	10	4	20	1.2
12XL	1/2	1/8	3/4	± 120	± 10	± 4	10	4	20	1.2
14XL	5/8	1/8	7/8	± 300	± 10	± 4	25	10	50	1.2
16XL	3/4	1/8	1	± 300	± 10	± 4	25	10	50	1.2
20XL	1	1/8	1 1/4	± 600	± 10	± 4	50	20	100	0.9

Calibration is dependent on tubing material, wall thickness, ultrasound velocity of the liquid flowing through the tube, and temperature.

¹) Absolute Accuracy is composed of zero stability, sensitivity and linearity errors. Stated values apply when flow rate is greater than 5% of maximum range and zero offset is nulled.

^{1b}) If the sensor is calibrated on-site for the tubing and liquid in use, absolute accuracy is further improved to the value listed as "Relative Accuracy."

^{1c}) On-site calibration is recommended if the sensor is routinely used to measure flows less than 5% of the maximum range to account for non-linearities associated with flow profile.

Stocked Tubings

Tubings stocked at Transonic Systems for sensor calibration; for tubing other than listed, please send sample.

Probe Size	Tubing (inches)		Stock Tubing
	i.d.	wall	
2XL	3/32	1/32	Tygon S-50-HL, Tygon R-3603
3XL	1/8	1/32	Tygon R-3603
4XL			No stock tubing
5XL	3/16	1/16	Tygon R-3606
6XL	1/4	1/16	MEDIFLEX, Tygon R-3603, Tygon S-50-HL
7XL	1/4	3/32	MEDIFLEX, Tygon R-3603
8XL	3/8	1/16	Tygon R-3603, Tygon S-50-HL
9XL	3/8	3/32	BENTLY BYPASS, MEDIFLEX, Tygon R-3603, Tygon
10XL	1/2	1/16	Tygon R-3603, Tygon S-50-HL
11XL	1/2	3/32	BENTLY BYPASS 70, Tygon R-3603, Tygon S-50-HL
12XL	1/2	1/8	Tygon R-3603, Tygon S-50-HL
14XL	5/8	1/8	Tygon R-3603
16XL	3/4	1/8	Tygon R-3603
20XL	1	1/8	Tygon R-3603

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