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Operator's Manual



Transonic Flow QC® Quality Care

Transonic® Bypass Flowmeter

HT110

FOR USE WITH STERILE TUBING FLOWSENSORS

CE 0086

AUHT110 *Rev. F, 6/11*

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Warnings & Precautions

✔ HT110 Ultrasonic Bypass Flowmeters are intended for use with adult and pediatric patients for: Measurement of liquid volume flow with STERILE-TUBING FLOWSENSORS,

- on flexible laboratory tubing specific to the flowsensor *(never on arteries, veins)*;
- for non-aerated media which are transparent to ultrasound;

The company disclaims responsibility for all other uses, and the user agrees to assume liability for damages resulting from non-intended use or operator-error by the user or user's employees.

✔ The flowmeter is not intended for use as the sole basis for diagnosis without confirmation by another established medical procedure.

✔ Use this flowmeter only with Transonic flowsensors having serial numbers starting with **"H"** and "H_XL" (such as H6XL). Other Transonic flowsensors are not manufactured for human use.

✔ 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;

It is the user's responsibility to review the meter and flowsensors use and conditions for compliance with local regulations.

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

Legends

Symbol	Definition	Transonic Notation
	Attention, consult accompany documents	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.
	Dangerous voltage	The flowmeter must not be modified or serviced except by qualified Transonic repair persons.
CE 0086	CE Conformity Mark	This flowmeter conforms to the requirements of applicable EU directives. See the Declaration of Conformity accompany this equipment for specific directives.
ETL	ETL Testing Mark	Electrical safety Compliance Certification
	Not category AP equipment	Danger-Explosion risk if used with flammable anesthetics.
	Equipotentiality	This ground stud is connected to the metal cabinet of the monitor. It provides the User with a means to monitor to other equipment.

Section A: Operator's Manual



This manual includes instructions for the two models of the HT110 flowmeter. Check the next page to determine which features are available with your model.

Introduction A-I.

The **Transonic® Bypass Flowmeter** (HT110) 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 HXL-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.

Sterile tubing flowsensors are intended for these uses:

a) In extracorporeal procedures (*ex.*, cardio-pulmonary bypass (CPB); extracorporeal membrane oxygenation (ECMO); hemodialysis; plasmapheresis; arterio-venous hemofiltration (CAVH);

b) In extracorporeal perfusion, infusion or transfusion procedures (*ex.*, allograft perfusion for pre-transplantation preservation; coronary reperfusion or retroperfusion; continuous total nutrient infusion, saline or dextrose infusion; blood transfusion);

c) On extracorporeal shunts (*ex.*, portal vein bypass shunts and lower body/upper body bypass shunts during liver transplants).



MODELS

HT110 (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.

HT110R (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-II. Specifications cont.

GENERAL FEATURES

Weight/Size	**HT110:** 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:	H_XL-Series sterile tubing flowsensors for extracorporeal tubing

ELECTRICAL SPECIFICATIONS

Power Amp fuse)	AC Input:	90 - 265 VAC; 50 - 60 Hz, single phase, 40 watts, (1.5
	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; HT110: filtered at 5Hz HT110R: 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	

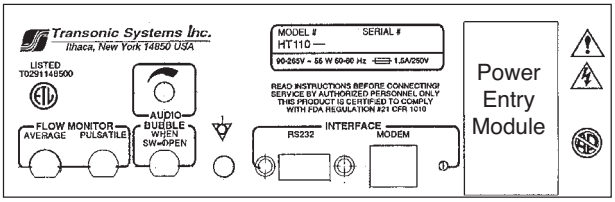
OPTIONAL FEATURES

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.

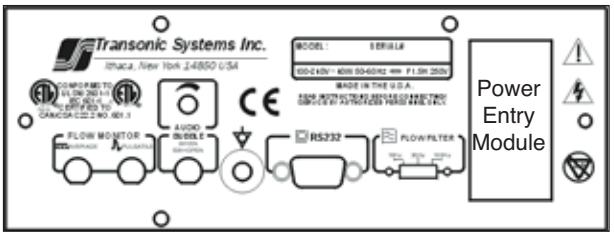
Package includes:
- Additional circuitry within the flowmeter cabinet;
- a standard RS-232 cable
- WINDAQ - PC compatible software to display & record flow data.

REAR PANELS

HT110



HT110R



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 .1 HZ 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 date 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	Transonic Notation
	Attention, consult accompany documents	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.
	Dangerous voltage	The flowmeter must not be modified or serviced except by qualified Transonic repair persons.
	Not category AP equipment	Danger-Explosion risk if used with flammable anesthetics.
	Equipotentiality	This ground stud is connected to the metal cabinet of the monitor. It provides the User with a means to monitor to other equipment.

FRONT PANEL

HT110



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 displays 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.

USE OF STERILE TUBING FLOWSENSOR

Sensor Selection

Flowsensor size and calibration is determined by the tubing. 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 70% alcohol rinse to promote drying. Sterilization for hospital use is not usually necessary. STERRAD or standard hospital cold *(ethylene oxide)* **gas** sterilization may be used (≤ 60°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-zeroing 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. Tilt the tubing and flowsensor vertically before operating the flowmeter to **flush** any bubbles from the sensing window.

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

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

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.

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.

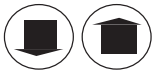
This signal coupling quality is an important indication of flow and flowsensor functioning, flow measurement accuracy and, when the meter is properly set up is expressed as a percentage of the initial factory value.

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

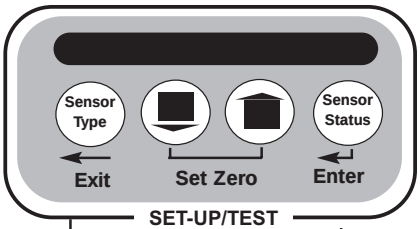


The PROGRAM MODE is engaged by depressing both arrow buttons simultaneously.

Programmable features offered in your HT110 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



Used to *enter* a function and *save or accept* the chosen setting.
Pointer Brackets ">....<" will indicate an accepted setting.

Used to scroll through functions and variable settings within functions.

Used to *exit* the menu or exit a function without changing settings.

PROGRAM MENU flow charts for each HT110 flowmeter model are on pages 12-14.

Descriptions and specific directions follow for each feature.

REVIEW OF PROGRAMMED SENSOR STATUS

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 though 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 equivalant 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.

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.

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.

HIGH FLOW ALARM

HT110R Research 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 Research 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 Research 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*

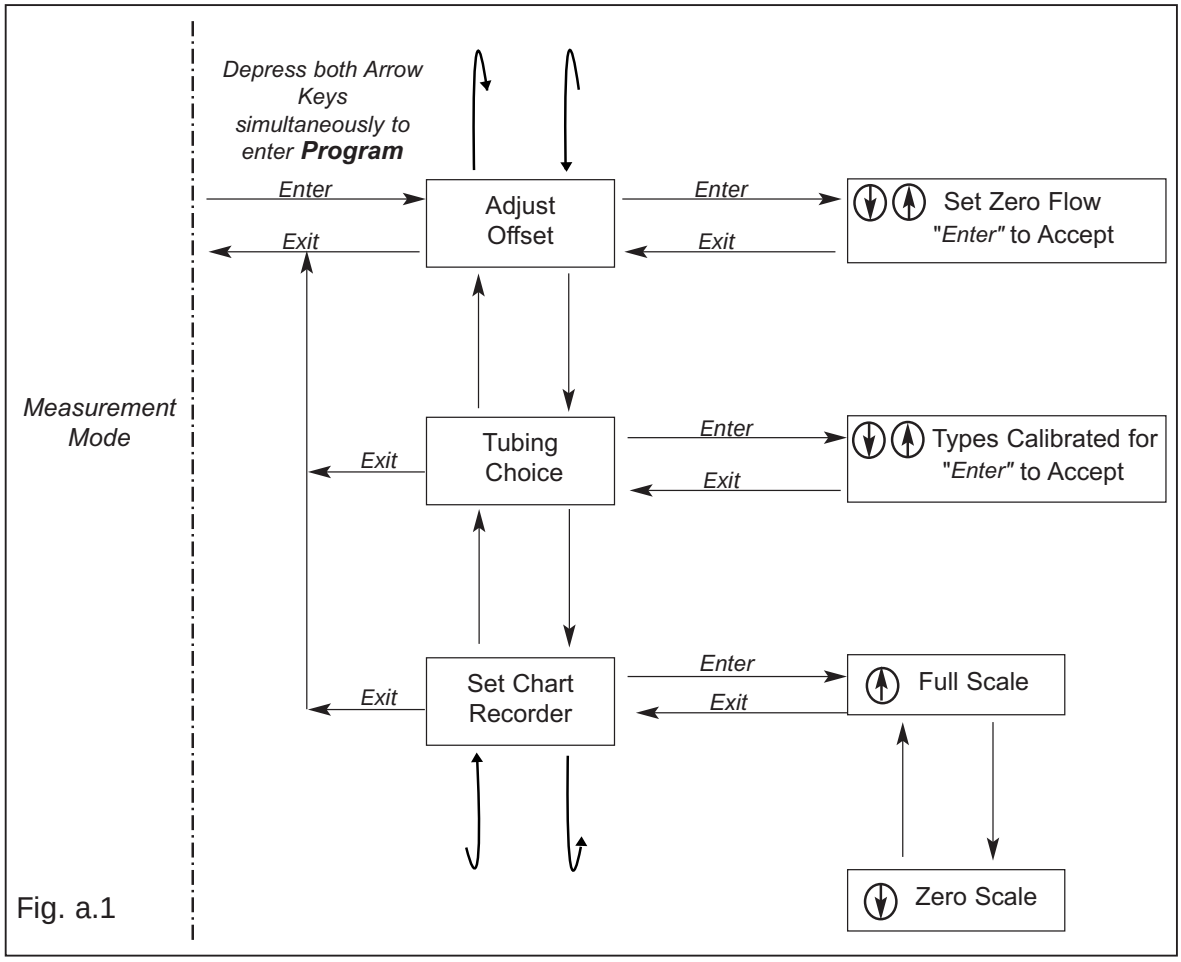

Depress both Arrow Keys simultaneously to enter **Program**
Measurement Mode
Adjust Offset
Enter
Exit
Enter
Exit
Set Zero Flow "Enter" to Accept
Tubing Choice
Enter
Exit
Exit
Types Calibrated for "Enter" to Accept
Set Chart Recorder
Enter
Exit
Exit
Full Scale
Zero Scale

Fig. a.1

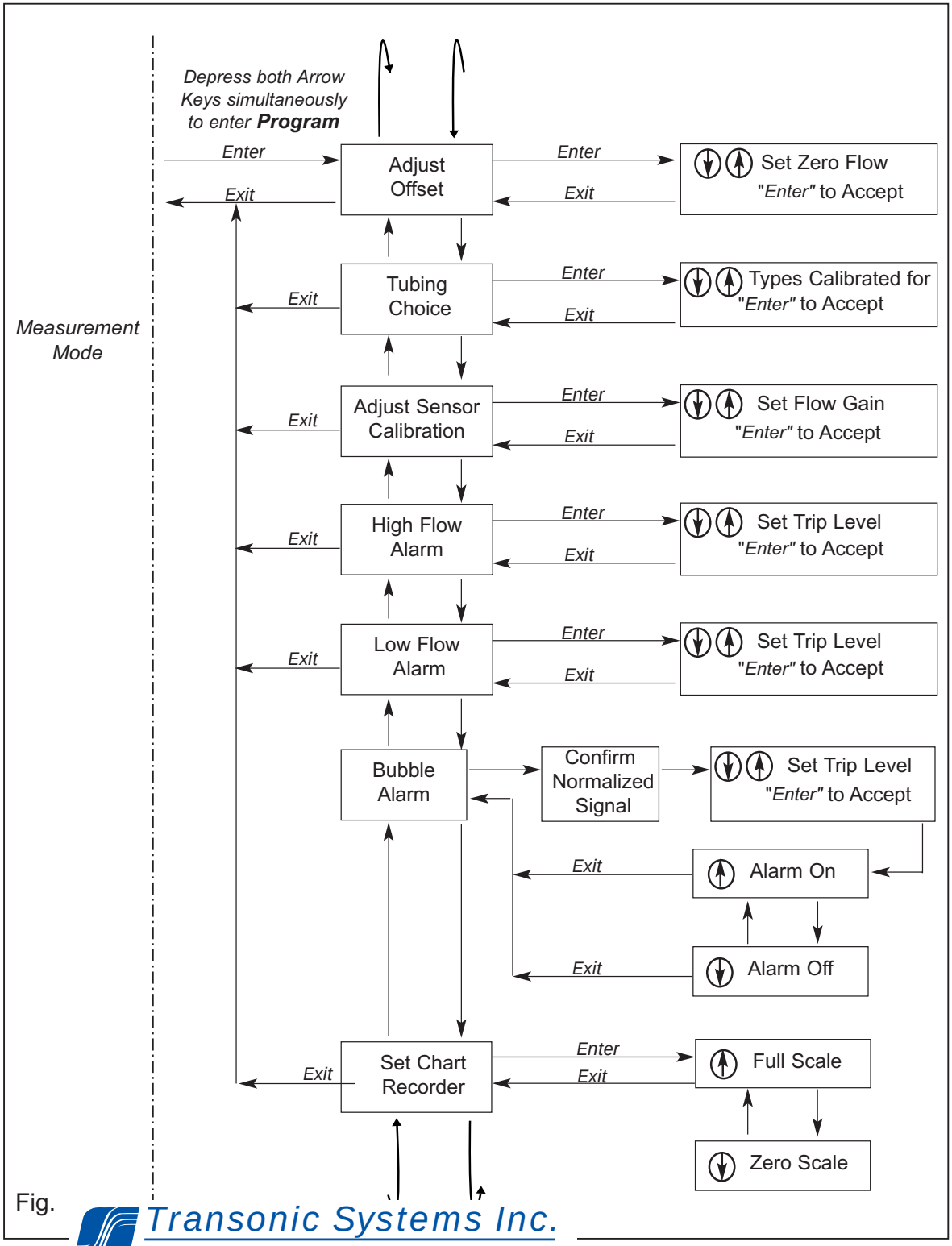

Depress both Arrow Keys simultaneously to enter Program
Measurement Mode
Adjust Offset
Set Zero Flow "Enter" to Accept
Tubing Choice
Types Calibrated for "Enter" to Accept
Adjust Sensor Calibration
Set Flow Gain "Enter" to Accept
High Flow Alarm
Set Trip Level "Enter" to Accept
Low Flow Alarm
Set Trip Level "Enter" to Accept
Bubble Alarm
Confirm Normalized Signal
Set Trip Level "Enter" to Accept
Alarm On
Alarm Off
Set Chart Recorder
Full Scale
Zero Scale
Enter
Exit

Fig.

FLOWSENSOR MAINTENANCE

Examine the sterile tubing flowsensor after use for moisture—particularly for saline or corrosive fluid. The flowsensor can be wiped with 70% alcohol. 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.**

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 A20).*

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 A20)*.

   If the new sensor works properly, then the previous sensor has failed and the failure recorded on the Flowsensor Repair Return Form *(page A19).*

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 A20)*.

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 %".

FACTORY REPAIR

Telephone assistance is available to help customers analyze problems. Factory repair service is available for malfunctioning equipment. 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.

EQUIPMENT RETURN INSTRUCTIONS

(1) Call Local authorized Transonic Sales Agent for a RMA #.

(2) Complete a FACTORY RETURN FORM (pages A19, A20)with information for repair service personnel.

(3) Use the Transonic Systems shipping carton for returning meter equipment. If you need a carton, contact your local authorized Transonic agent.

(4) Place the two foam packing pieces over the front and back ends of the flowmeter to protect front and rear panel controls. Lift the instrument with its foam padding into the box.

(5) In the space around the monitor, place power cords, and flowsensors, individually packaged with their parts).

(6) On top of the flowmeter place Factory Return Form (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) Ship to the address as advised by your Transonic agent.

A-VI. Guarantee, Service, Warranty

A. CALIBRATION GUARANTEE

Transonic Systems Inc. certifies that the HT110 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 HT110 Flowmeter will stay in calibration during its first year of use, if used and stored per standard clinical apparatus practices. Annual recalibration is recommended. 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 HT110 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 sterile tubing flowsensor is 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.

A-VII. Flowsensor Record of Use Form

STERILE TUBING FLOWSENSOR RECORD OF USE
HT110 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 your local Transonic agent 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, p. A19, along with this page.

A-VII. Flowsensor Repair Return Form

Before returning a product for repair, call your local Transonic agent 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. 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.
RMA#
34 Dutch Mill Road, Ithaca, NY 14850
Tel: 800-353-3569; Fax: 607-257-7256

A-VII. 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**

Address _____ **RETURN**

_____

_____

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.
RMA#
34 Dutch Mill Road, Ithaca, NY 14850
Tel: 800-353-3569; Fax: 607-257-7256

Section B: HXL-Sterile Tubing Flowsensors

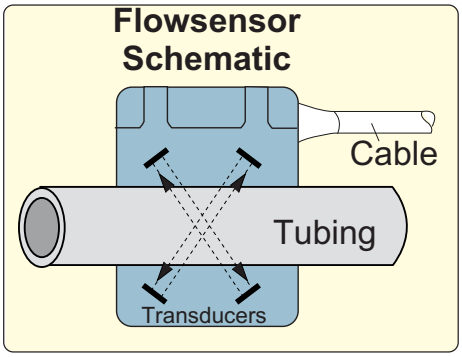
An Independent Measure of Absolute Volume Flow for Enhanced Safety of Extracorporeal Procedures

CP Bypass • ECMO • LVAH • Shunt Flows • Organ Preservation

Transonic sterile tubing flowsensors produce precise, accurate, volume flow measurements with no physical contact between the flowsensor and the liquid, thereby ensuring sterility and avoiding cross-contamination,

- Sterile tubing flowsensors clip around the outside of standard tubings to provide a non-invasive measure of volume flow.
- The integrity of non-thrombogenic surfaces is maintained.
- For use with blood, saline and other non-aerated aqueous solutions.





Transonic Sterile Tubing Flowsensors

- Molded clip-on design for easy care and handling.
- 'X'- pattern of ultrasound insonification to ensure precision measurements.
- Stable low zero offset and accurate under perturbed flow conditions.
- Compatible with a wide range of tubings sizes and materials.

PRINCIPLES OF OPERATION — ULTRASONIC TRANSIT TIME TECHNOLOGY

Ultrasound that Measures Volume Flow, Not Velocity

Using wide-beam illumination, transducers pass ultrasonic signals back and forth, alternately intersecting flowing blood in upstream and downstream directions. The transit time of the ultrasonic beam is decreased when traveling downstream with the blood flow and increased when traveling upstream against the flow.
The difference between the integrated transit times is a measure of volume flow.

Transonic Systems Inc.
The Flow Measurement Specialists
USA: Tel 800-353-3569; Fax 607-257-7256; www.transonic.com
Europe: Tel +3143 407-7200; Fax +3143 407-7201; info@transonic.nl
Asia: Tel +886 3399-5806; Fax +886 3399-5805; support@transonicasia.com

Specifications

Sensors are pre-calibrated for specific tubing type, fluid and temperature. Typical tubing brands are listed in the table below; flowsensors for tubing other than listed may be custom calibrated.

CAT #	TUBING			BIDIRECTIONAL FLOW		ACCURACY[1]			ULTRA-SOUND
	ID inches	Wall thickness inches	OD inches	Resolution [2] ml/min	Maximum Range L/min	Zero Stability ml/min	Sensitivity %	Δ ml/min	Frequency MHz
H2XL	For these sensors the ratio of tubing wall thickness to OD must not exceed 1:5 for PVC tubes or 1:3 for silicone tubes		1/8-3/16	0.5	1	1.5	±5	1.5	3.6
H3XL			3/16-1/4	1.0	2	3	±5	3	3.6
H4XL			1/4-5/16	1.0	2	3	±5	3	3.6
H5XL			5/16	1.0	2	3	±5	3	3.6
H6XL	1/4	1/16	3/8	2.5	5	7.5	±5	7.5	2.4
H7XL	1/4	3/32	7/16	5	10	12	±5	15	1.8
H8XL	3/8	1/16	1/2	5	10	12	±5	15	1.8
H9XL	3/8	3/32	9/16	5	10	12	±5	15	1.8
H10XL	1/2	1/16	5/8	10	20	20	±5	30	1.2
H11XL	1/2	3/32	11/16	10	20	20	±5	30	1.2
H12XL	1/2	1/8	3/4	10	20	20	±5	30	1.2
H14XL	5/8	1/8	7/8	25	20	50	±5	75	1.2
H16XL	3/4	1/8	1	25	50	50	±5	75	1.2
H20XL	1	1/8	1 1/4	50	50	100	±5	150	0.9

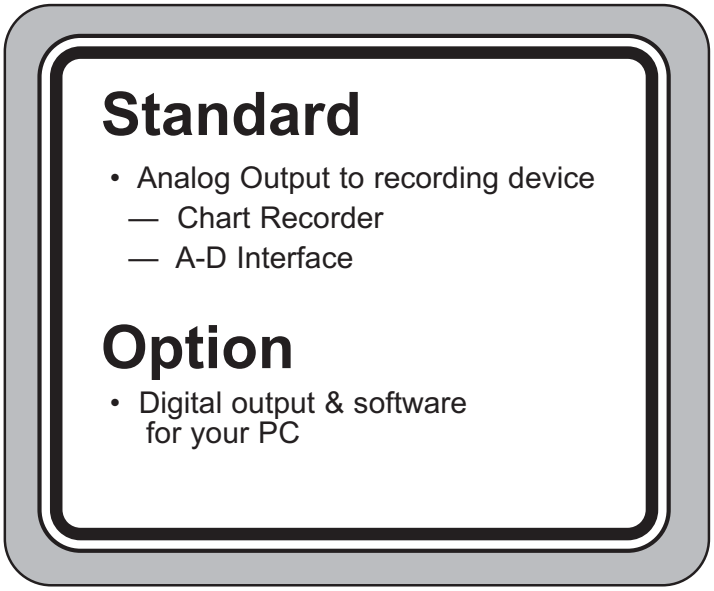
[1]These values represent the maximum observed error. Total accuracy (error) will be the sum of the zero offset, sensitivity error (percentage of flow reading) and the number "Δ" which affects flows in the low flow region and is positive. Stability is defined as the maximum zero offset drift over an 8 hour period. Sensitivity error can be decreased to < 2% by calibrating sensor directly on the tubing and fluid prior to measurement. Zero offset can be eliminated by zeroing sensor prior to measurement.

[2]Resolution indicated is at .1Hz filter (average flow output).

PROCEDURE	CAT #	TUBING (inches) Inner Diameter	Wall Thickness	STOCK TUBING If using tubing of different diameter or type, please discuss tubing with a customer service representative.
Carotid Shunts	H2XL			TYGON S-50-HL, Tygon R-3603
Carotid Shunts	H3XL	1/8 x	1/32	Tygon R-3603
Carotid Shunts	H4XL			none
Carotid Shunts	H5XL	1/8 x	1/16	
Ped CPB, ECMO	H6XL	1/4 x	1/16	MEDIFLEX, Tygon R-3603,TYGON S-50-HL,
Ped CPB, ECMO	H7XL	1/4 x	3/32	TYGON S-50-HL
Ped CPB, ECMO	H8XL	3/8 x	1/16	Tygon R-3603, TYGON S-50-HL
Adult CP Bypass	H9XL	3/8 x	3/32	BENTLEY BYPASS 70, Tygon R-3603, TYGON S-50-HL class VI, MEDIFLEX
Adult CP Bypass	H10XL	1/2 x	1/16	Tygon R-3603, TYGON S-50-HL
Adult CP Bypass	H11XL	1/2 x	3/32	Tygon R-3603, TYGON S-50-HL, BENTLEY BYPASS 70
Custom	H12XL	1/2 x	1/8	TYGON S-50-HL, Tygon R-3603
Custom	H14XL	5/8 x	1/8	Tygon R-3603
Custom	H16XL	3/4 x	1/8	Tygon R-3603
Custom	H20XL	1 x	1/8	Tygon R-3603 *Rev 2/06*

Appendix A

Data Acquisition



Transonic®
HT110 Flowmeters

Transonic Flowmeters are equipped with standard analog voltage output of flow signals; digital output *(optional)* is also supported. The standard analog output connects directly to any of a wide range of physiological chart recorders to observe and record pulsatile waveforms or mean flow signals. This analog port can also be connected to your analog-to-digital interface board which you may use with any type of computer system.

Transonic Systems offers an optional computer interface with software to record, store and allow you to retrieve complete flow data on your Windows-equipped IBM-compatible PC.

Personal Computer (-P) Interface

Analog Outputs

to Chart Recorder

The analog output ports on Transonic transit-time flowmeters are BNC connectors with -5 to +5 volt DC signals *(0 to + 5 in laser Doppler flowmeters)*. This signal can be connected to the physiological recorder. The recording device can then be calibrated to the flowmeter and probe with procedures described in the instrument manual. *Contact Transonic Systems for specifications.*

to A - D Interface & Computer

If you are currently outfitted with an A-D board for your computer and have a software package that will support flow data, you may also acquire the flow information from Transonic flowmeters standard analog ports without any additional modifications required.

The analog output ports on Transonic transit-time flowmeters are BNC connectors with -5 to +5 volt DC signals. This signal can be connected to a computer's analog to digital interface board. The recording device can then be calibrated to the flowmeter and probe with the procedures described in the instrument's manual.

Personal Computer Interface Option

Flowmeters equipped with the the (-P) Personal Computer Interface Option will be indicated by a (-P) in the serial number on the back panel. All flowmeters may be upgraded for this option.

The Personal Computer Interface option provides the capability to record, store and playback flow data on an IBM-PC compatible computer. The Computer Interface Option turns your IBM-compatible personal computer into a low cost data acquisition system for up to 8 channels of data. If you do not currently have a computer-based data acquisition system, or if it is outdated or has no available channels for flow data, the Transonic computer interface option can provide you with stand-alone data acquisition simplicity.

The (-P) Personal Computer Interface consists of A/D converter circuitry, microprocessor and RS-232 circuitry and cable to connect the flowmeter to a standard IBM-PC via its serial RS-232 port.

Up to 8 channels of data are transmitted at 19200 baud to the computer via an on-board processor which continuously transmits instantaneous or mean FLOW data converted from analog to 12-bit digital values. Sample rate is 200 samples per second for 4 channels; 100 samples per second for 8 channels. The (-P) Option includes:

- a microprocessor board mounted within the flowmeter cabinet
- a female RS-232 connector on the flowmeter's rear panel
- an RS-232 cable to connect the the flowmeter to the serial port of your computer
- a 25-pin to 9-pin adapter needed for some computers
- WINDAQ Data Acquisition and WINDAQ Playback software

With the Computer Interface Option you can also designate channels of the (-P) Interface for data from other devices in addition to Transonic research flowmeters, thereby providing simultaneous recording of all parameters.

Appendix B

EMC Information Tables
per EN60601-1-2:2001-09 Section 6.

In accordance with EN 60601-1-2:2001 Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests

1) “Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the Accompanying Documents” (the following tables).
2) “Portable and Mobile RF Communications Equipment can affect Medical Electrical Equipment.”
3) “The equipment or system should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the equipment or system should be observed to verify normal operation in the configuration in which it is used.”

The following tables provide information regarding the EMC characteristics of this Medical Electrical Equipment.

Table 201 — Guidance and Manufacturer’s Declaration - Electromagnetic Emissions

GUIDANCE AND MANUFACTURER’S DECLARATION - ELECTROMAGNETIC EMISSIONS The HT110-Series meters are intended for use in the electromagnetic environment specified below. The customer or user of the HT110-Series meter should ensure that it is used in such an environment.		
EMISSIONS TEST	**COMPLIANCE**	**ELECTROMAGNETIC ENVIRONMENT-GUIDANCE**
RF emissions CISPR 11	Group 1	The HT110-Series meter uses RF energy in the flow measurement function. The equipment should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the equipment should be observed to verify normal operation in the configuration in which it is used.transmitters, as determined by an electromagnetic site survey, should be less than the compliance levels (V1 and E1).
RF emissions CISPR 11	Class B	The HT110-Series meter is suitable for use in all establishments, including those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations /Flicker emissions IEC 6100-3-3	Complies	

Table 202 — Guidance and Manufacturer's Declaration - Immunity
All Equipment and Systems

GUIDANCE AND MANUFACTURER'S DECLARATION - IMMUNITY

The HT110-Series meters are intended for use in the electromagnetic environment specified below. The customer or user of the HT110-Series meter should ensure that it is used in such an environment.

IMMUNITY TEST	EN 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT-GUIDANCE
ESD EN 61000-4-2	±6kV Contact ±8kV Air	±6kV Contact ±8kV Air	Floors should be wood, concrete or ceramic tile. If floors are synthetic, the r/h should be at least 30%.
EFT EN 61000-4-4	±2kV Mains ±1kV I/Os	±2kV Mains ±1kV I/Os	Mains power quality should be that of a typical commercial or hospital environment.
Surge EN 61000-4-5	±1kV Differential ±2kV Common	±1kV Differential ±2kV Common	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips/Dropout EN 61000-4-11	>95% Dip for 0.5 Cycle 60% Dip for 5 Cycles 30% Dip for 25 Cycles >95% Dip for 5 seconds	>95% Dip for 0.5 Cycle 60% Dip for 5 Cycles 30% Dip for 25 Cycles >95% Dip for 5 seconds	Mains power quality should be that of a typical commercial or hospital environment. The unit shut off during the >95% for 5 second disturbance. If the user of the HT300-series meter requires continued operation during power mains interruptions, it is recommended that the HT300-Series meter be powered from an uninterruptible power supply or battery.
Power Frequency 50/60Hz Magnetic Field EN 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be that of a typical commercial or hospital environment.

Table 204 — Guidance and Manufacturer's Declaration - Emissions Equipment and Systems that are NOT Life-Supporting

GUIDANCE AND MANUFACTURER'S DECLARATION - EMISSIONS

The HT110-Series meters are intended for use in the electromagnetic environment specified below. The customer or user of the HT110-Series meter should ensure that it is used in such an environment.

IMMUNITY TEST	EN 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT-GUIDANCE
Conducted RF EN 61000-4-6	3 Vrms±8kV Air 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 Vrms±8kV Air 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	Portable and mobile communications equipment should be separated from the HT300-Series meter by no less than distances calculated/listed below: D=(3.5/V1)(Sqrt P) D=(7/E1)(Sqrt P) 80 to 800 MHz D=(7/E1)(Sqrt P) 800 MHz to 2.5 GHz where P is the max power in watts and D is the recommended seperation distance in meters Field strengths from fixed transmitters, as determined by an electromagnetic site survey, should be less than the compliance levels (V1 and E1). Interference may occur in the vicinity of equipment containing a transmitter.

Table 206 — Recommended Separations Distances for the HT110-Series Meter

Guidance and Manufacturer's Declaration - Emissions The HT110-Series meter is intended for use in the electromagnetic environment in which radiated disturbances are controlled. The customer or user of the HT110-Series meter can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF Communications Equipment and the HT110-Series meter as recommended below, according to the maximum output power of the communications equipment.			
Max Output Power (Watts)	**Seperation (m) 150kHz to 80MHz** D=(3.5/V1)(Sqrt P)	**Seperation (m) 80MHz to 800MHz** D=(3.5/E1)(Sqrt P)	**Seperation (m) 800MHz to 2.5GHz** D=(7/E1)(Sqrt P)
0.01	.1166	.1166	.2333
0.1	.3689	.3689	.7378
1	1.1666	1.1666	2.3333
10	3.6893	3.6893	7.3786
100	11.6666	11.6666	23.3333

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