

Operator's Manual



Transonic® HT312 Surgical Flowmeter



Transonic® HT322 Surgical Flowmeter

Transonic® Flowmeters Model HT312/HT322(-CS)

FLOWMETER SERIAL # _____

AUHT312/322 Rev B, 2/02

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Transonic Systems Inc.

Tel 800-353-3569 • www.transonic.com • Fax 607- 257-7256

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Warnings & Precautions

- 
 The HT300(-CS) Series of Surgical Flowmeters is intended for use with adult and pediatric patients for:


Measurement of blood or liquid volume flow with PERIVASCULAR FLOWPROBES,


 - on major and peripheral arteries, veins and ducts (*not on synthetic vessel grafts and shunts*);
 - where surgery is medically indicated;
 - intraoperatively, rather than in chronic implant;
 - at intraoperative sites which admit and retain acoustic couplant;
 - with minimal vessel manipulation or constriction (to avoid vessel spasm);
 - where application does not unnecessarily lengthen surgical procedure.


Measurement of blood or perfusate volume flow with Sterile Tubing Flowsensors


 - on flexible 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 an IEC0601 Class I instrument. Only the power cord supplied by Transonic Systems should be used.








- 
 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 the serial numbers starting with "HQ" (as HQD4MP, HQB8XL). Other Transonic flowsensors are not compatible.

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

- 
 The flowmeter is fragile. It must be transported and stored at temperatures ranging from -40°C to 70° C.

- 
 Perivascular flowprobes may be used in pericardiac applications such as ascending aorta and coronary graft flow measurement, but are neither designed nor approved for intracardiac flow measurement.

Warning	Definition	Transonic Notation
	Attention, consult accompanying 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 Conformity Mark	This flowmeter conforms to 93/42 EEC, Annex II. Transonic Systems is an ISO9001/EN46001-certified facility.
	ETL Testing Mark	Electrical Safety Compliance Certification
	Defibrillator proof type CF equipment	This flowmeter employs line-to-meter, meter-to-probe and probe-to-patient ("cardiac floating") isolation to yield a high degree of patient electrical protection.
	Not category AP equipment	Danger-Explosion risk if used with flammable anesthetics.
	Equipotentiality pin	This ground pin is connected to the metal cabinet of the monitor. It provides the User with a means to monitor to other equipment.

Declaration of Conformity



Declaration of Conformity

Product: Intraoperative Flowmeters HT312(-CS), HT322(-CS),
HQ-perivascular flow sensors, and HQ-sterile tubing (clamp-on) flowsensors

Manufacturer's name: Transonic Systems Inc.

Manufacturer's address: 34 Dutch Mill Road, Ithaca, NY 14850 USA

Contact in the EEC: Transonic Systems Europe B.V.
Punterweg 31
6222 NW Maastricht
The Netherlands
31 43 407 7200

Applicable Council Directive: 93/42 EEC, Annex II

Notified Body: BSI Product Certification

Notified Body Identification #: 0086

Medical Device Directive Classification of this Product:

Meter: Class IIb, Perivascular Probe: Class III, Sterile Tubing (clamp-on) Flowsensor: Class IIb

I, the undersigned, hereby declare that as of meter series # HT312-A1-0037 and HQ-Probe serial # as of 4/17/97, the equipment specified in this owner's manual and on the data sheet enclosed with this shipment conforms to 93/42 EEC Annex II.

Signature Mark S. Alsberge Date: 3/24/00

Name: Mark S. Alsberge

Position: Vice President
Medical and Regulatory Affairs
Transonic Systems Inc.



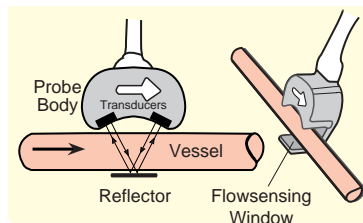
34 Dutch Mill Road, Ithaca, NY 14850 USA; Tel: 800-353-3569, 607-257-5300;
Fax: 607-257-7256; Internet: www.transonic.com

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I. Introduction

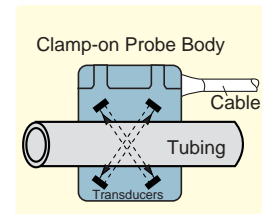
Transonic® HT300(-CS) Series Flowmeters consist of an **electronic flow detection unit** for use with perivascular probes and sterile tubing flowsensors.

- A. ELECTRONIC FLOW DETECTION UNIT:** The line-powered flowmeter houses the electronic circuitry for processing ultrasonic transit time flow signals.
- B. FLOWSENSORS:** Transonic flowsensors connect to an extension cable attached to the flowmeter. Two or four ultrasonic transducers within the flowprobe body transmit a minimum level of ultrasound through a rectangular sensing window. All liquid volume flow passing through the sensing window is measured.
- 1. PERIVASCULAR FLOWPROBES:** Transonic HQ-Series intraoperative, perivascular flowprobes work with HT312/HT322(-CS) flowmeters to measure instantaneous and average volume flow in blood vessels or grafts, 0.5 mm to 36 mm in diameter. Perivascular flowprobes measure blood flow in exposed vessels before and after vascular reconstructive procedures:
 - a) at the beginning of a procedure, for accurate assessment of volume flow.
 - b) at the conclusion of surgical procedures, prior to patient closing, on newly implanted natural and artificial bypass grafts, on vessels supplying restored or reconstructed organs and tissues, and on vessels supplying transplanted organs.
 - 2. STERILE TUBING (CLAMP-ON) FLOWSENSORS:** Transonic HQ - XL-Series sterile tubing flowsensors apply ultrasound energy through flexible tubing to monitor instantaneous and average volume flow of blood, cardioplegia or other perfusates in:
 - a) Extracorporeal procedures such as cardio-pulmonary bypass (CPB); extracorporeal membrane oxygenation (ECMO); hemodialysis; plasmapheresis; arterio-venous hemofiltration (CAVH)
 - b) Extracorporeal perfusion, infusion or transfusion procedures (such as allograft perfusion for pre-transplantation preservation; coronary reperfusion or retroperfusion; continuous total nutrient infusion, saline or dextrose infusion; blood transfusion)
 - c) Extracorporeal shunts (ex., portal vein bypass shunts, lower body/upper body bypass shunts during liver transplants, and carotid shunts).
- C. PRINCIPLES OF OPERATION: 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.



Perivascular Flowsensor

Loose-fitting probe is applied around a vessel exposed during surgery. Ultrasound couplant (saline or gel) provides full ultrasound passage within the flowsensing window.



Sterile Tubing Flowsensor

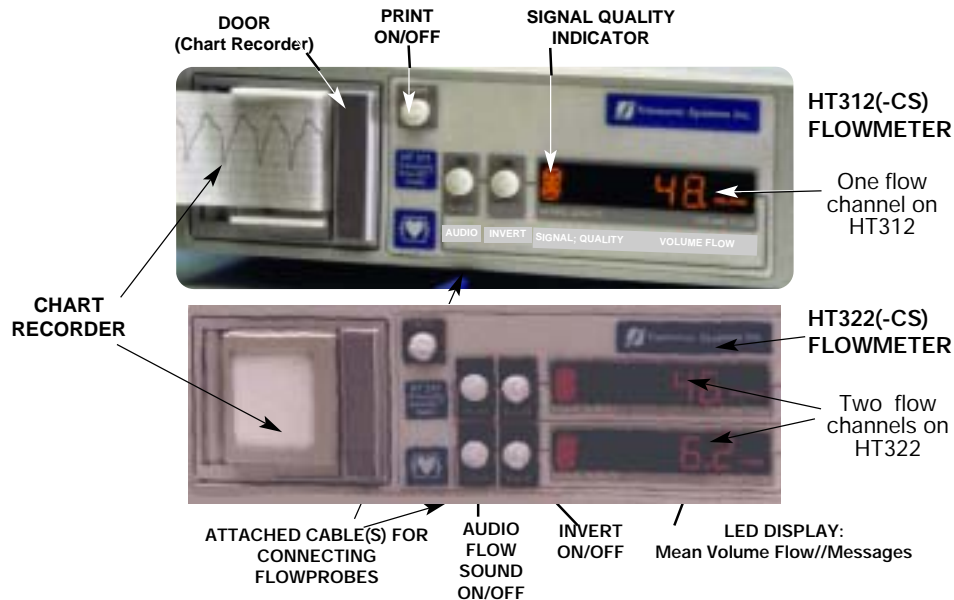
Ultrasonic transducer shell clamps onto the sterile tubing. Volume flow is sensed by X-pattern insonification of full cross section of flow.



II. Functions & Controls

FRONT PANEL

HT312/HT322(-CS) FLOWMETER



FLOWPROBE CONNECTION

2 meter cable attached to accept HQ-style connector of flowprobe.

CHART RECORDER

The chart recorder automatically scales the paper to the flow being measured. For more information see "Getting Familiar with the Chart Recorder" on page 7.

PRINT ON/OFF starts and stops the chart recorder.

AUDIO FLOWSOUND ON/OFF

Turns Flow Sound on and off. Volume control knob is located on the rear panel



INVERT ON/OFF

Reverses the polarity of the flow signal on the chart recorder, front panel LED display, rear panel analog outputs and RS232 connector



DEFIBRILLATOR - PROOF TYPE CF
(cardiac-floating) equipment.

LED APHANUMERIC DISPLAY

• FLOW & ULTRASOUND SIGNAL QUALITY

during measurement
MEAN VOLUME FLOW in mL or L/min
and

SIGNAL QUALITY INDICATION

This indicator resembles a container, empty at low, full at 100% signal level.



- **STATUS/ERROR MESSAGES** during start-up and when measurement errors are diagnosed. Longer messages are displayed in 6-character segments:

NO PROBE - No probe connected to the meter

HQXN - Probe type and size (e.g., HQB8) is displayed when a probe is plugged in

MORE USES REMAIN - Countdown of number of surgeries, after the present surgery, remaining for this probe (for 8x, 12x use probes only)

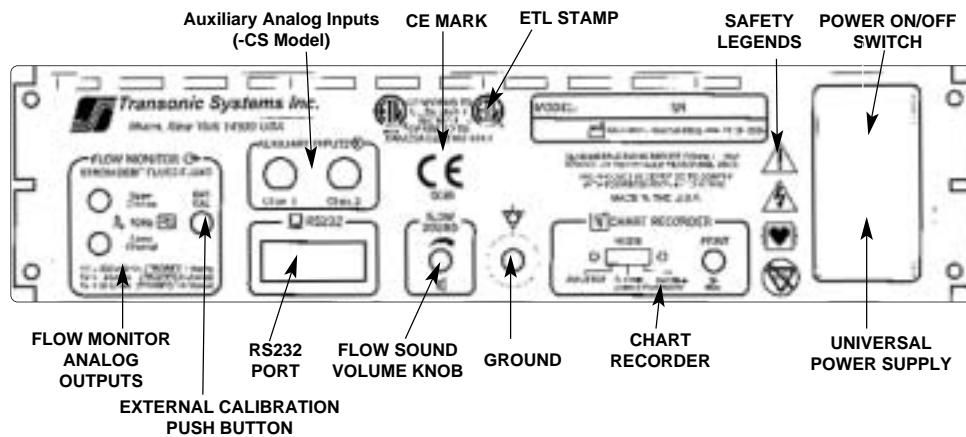
NO SIGNAL - Ultrasound signal quality is below the 15% threshold. Add ultrasound couplant to probe window.

0 → SCALE When the rear panel EXT. CAL button is pushed, the LED displays "0" and the probe's uniscale flow range (e.g. 200 ml/min) for 10 sec each, while the rear panel flow output signals switch to 0 Volt and 1 Volt

II. Functions & Controls *cont.*

BACK PANEL

HT312/HT322(-CS) FLOWMETERS



FLOW MONITOR ANALOG OUTPUTS

UNISCALE Output: 10 Hz low pass filtered; Automatic gain adjustment for fixed scaling of multiple probe sizes. Accepts miniphono connector.

See page 9.

HT312: 1 uniscale output;
 HT322: 2 uniscale outputs;

AUXILIARY ANALOG INPUTS (-CS MODELS)

All -CS models incorporate 2 analog BNC inputs (i.e., pressure, EKG)

RS232 PORT

for serial connection to a PC-style computer



FLOW SOUND VOLUME KNOB

Adjusts the volume level of the audio output.

CHART RECORDER — 3 Modes of Operation

RUN/STOP: for continuous printing at 20 mm/sec

SLOW: Prints 20 cm (8.5") strip at 20 mm/sec

FAST: Prints 20 cm (8.5") strip at 40 mm/sec

Warning

Definition, see page c



Attention, consult accompany documents



Dangerous voltages inside: may be serviced by trained technicians only



CE Conformity Mark



Not category AP equipment



Equipotentiality Pin (instrument ground)



Electrical Safety Compliance Certification



III. Specifications

HT312/HT322(-CS)

single-channel (HT312), dual-channel (HT322) flowmeters with built-in chart recorders
HT312(-CS): 10 lb (4.5 Kg); HT322(-CS): 11 lb (5 Kg); 11" (27.8 cm) wide x 4" (9.12 cm) high x
14" (35.4 cm) deep
attached two meter flowprobe-to-flowmeter extension cable per channel
separate grounded medical grade power line-cord is supplied with the flowmeter.

INPUT POWER

Universal Power Supply; 50-60 Hz; 100 -240 V \pm 10% (automatic voltage adjustment)

FUSES 1.5A fast blo, mfg bussman: #GMA1.5, 250 VAC

Both power entry conductors are protected by size 5 x 20 mm fuses.

ELECTRICAL ISOLATION

Cabinet is grounded; line to ground leakage current: less than 50 μ A @100-120 V line;
less than 100 μ A @ 220-240 V line.

All electronic components and cabling of the probe extension cable, probe cable and probe are fully isolated from the meter electrical circuitry to meet IEC0601 "cardiac floating" specifications.

Defibrillator Protection: probes can be left attached to the patient during cardiac defibrillation for instantaneous report on the restoration of flow.

AUTOMATIC METER ADJUSTMENTS

- Ultrasound frequency and insonification parameters
- Probe size and corresponding flow output ranges
- Volume flow calibration of connected flowprobe
- Sampling rate optimized for local acoustic conditions

DIGITAL PROBE IDENTIFICATION

Probe identification and calibration parameters are programmed on an EEPROM housed inside the probe connector

COMPATIBLE FLOWPROBES

These meters accept a range of HQ-Series probes for intraoperative surgical use. See probe specification sheets or your local representative for models, sizes and recommended uses.

-CS OPTION FLOWMETER INPUTS

Two BNC connectors are provided on the rear panel as auxiliary inputs (i.e., pressure or EKG monitors). Each accepts a signal range of \pm 5 Volts.

RS232 OUTPUT PORT

Optically isolated output connector meeting IEC0601 patient isolation. Permits connection to a laptop or other data monitor computer. The \pm 5V analog flow signals (and pressure, EKG Signals for -CS option meters) are digitized at 100 sampling rate with 12-bit resolution. Data is supplied in FLOWTRACE software at 19200 Baud.

III. Specifications *cont.*



ULTRASONIC FREQUENCY/PARAMETERS

The ultrasound output level of the flowsensors is factory-set and does not incorporate any interactive system features. These settings are made using "ALARA" principles (*As Low As Reasonably Achievable*), and are orders of magnitude below the FDA "preamendment levels," the USA insonification safety limits.

Transducer excitation: Burst of 10 to 24 waves (*probe size dependent*).

Transducer excitation frequency: 900 MHz to 4.8 MHz (*probe size dependent*).

Transducer excitation rate: 900 KHz to 14 KHz (*probe size dependent*), automatically reduced down to 600 Hz when probe operates in adverse acoustic conditions that would degrade measurement accuracy.

PARAMETER	MEANING	TRANSONIC SENSORS THEORETICAL MAX	PRE-AMENDMENT MAX: (for cardiac applications)
MI	Mechanical Index	0.1	1.9
I _{MAX}	Peak Intensity	2.2 W/cm ²	310 W/cm ²
I _{SPTA,3}	Spatial peak, temporal average intensity	16 mW/cm ²	430 mW/cm ²
I _{SPPA,3}	Spatial peak, pulse average intensity	2.2 W/cm ²	190 W/cm ²

All these measurements were "derated" (*reduced from the actual water bath measurements*) by applying the conventional *in vivo* attenuation factor of 0.3 dB per cmHz. Measurement uncertainties did not exceed 30%.

REGULATORY COMPLIANCE

Transonic Systems flowmeters and sensors comply with USA standards for medical and dental equipment (UL2601-1), and with European standards for medical and ultrasonic apparatus (IEC0601-1). These products are CE marked per 93/42EEC Annex II. Transonic Systems is an ISO9001/EN46001-certified facility.



IV. Functional Tests

The following tests will acquaint the user with the operation of the flowmeter and flowprobes. If the apparatus does not function as described during this initial operation, please call your authorized Transonic Systems Service provider or sales representative.

A. SETTING UP THE FLOWMETER

- 1. Connect flowmeter's power cord to a grounded power receptacle.**
Do not operate unless flowmeter is electrically grounded via the supplied power cord.
- 2. Turn power switch to "1" (= on) (located on the rear panel within the Power Entry Module)**
The digital display will read **"NO PROBE"** which indicates that there is no flow probe connected.
- 3. Connect a flowprobe to the probe extension cable.**
The connection between the flowmeter, extension cable and the probe is made with 20-pin self-aligning push-lock connectors. Make sure connector is fully pushed in.
The meter LED first displays the series and size of the connected probe. If this is a limited-use probe, the remaining number of uses will be displayed next.
The digital display will then read **"NO SIGNAL"** which indicates Acoustic Error or no ultrasonic coupling.

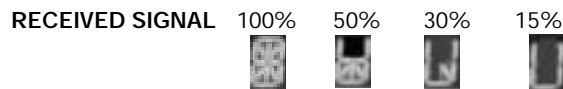
B. TESTING THE FLOWSENSORS

PERIVASCULAR FLOWPROBES

It is recommended that the scrub nurse perform this function test just prior to use.

- 1. Immerse the flowprobe** in a container filled with sterile saline.
- 2. Dislodge any air bubbles** from the probe's surfaces. It may be necessary to swish the probe back and forth in the water to remove all of the air bubbles.
- 3. Observe front panel LED digital display.**
The **"NO SIGNAL"** message will be replaced by a flow reading when acoustic conduction is established within the probe. Gently swish the probe back and forth in the beaker to confirm that the flowmeter registers a flow on the LED digital display.

The **"Signal Quality Indicator"** should be fully illuminated as shown below. If the received signal is below 20%, the flowmeter will revert to the **"NO SIGNAL"** (acoustic error) condition.



A properly functioning flowprobe will have 100% Signal Quality when immersed in water.
If Signal Quality falls during the initial saline test below 50%, **DO NOT USE THE PROBE.**

STERILE TUBING FLOWSENSORS

This test may be performed on a fluid filled tubing circuit or a 1 foot segment of tubing which is clamped at one end and filled with water.

- 1. Lubricate tubing** with a thin layer of petroleum jelly to promote ultrasonic transmission.
- 2. Place the tubing inside the flowsensor and close the door of the sensor.**
The tubing slot is dimensioned to squeeze the tubing to a fully rectangular shape.
- 3. Observe front panel LED digital display.**
 - The **"NO SIGNAL"** message will be replaced by a flow reading when acoustic conduction is established.
 - The Signal Quality Indicator should be fully illuminated.

Note: do not immerse a sterile tubing (clamp-on) flowsensor in liquid.