# II. Periodic Maintenance Requirements

## II-a MONITOR

**Maintenance Check:** A routine maintenance check of the meter consists of exercising all of the functions of the meter with a sampling of flowsensors, and verifying that all features respond as described in the “Functional Tests” section of the Operator’s Manual. If any of these functions do not respond as described, contact Transonic Systems Technical Support Service (1-800-353-3569 USA).

**Cleaning:** 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 at room temperature in a dry place. **Warning** - Do not drip liquids into the meter cabinet. A flowmeter accidently exposed to spillage should be immediately unplugged from its power source. Remove the cover. If the spilled liquid is potentially corrosive or may leave a residue, flood the area with clean water, using care not to disturb components or components. Compressed air may be used to blow liquid off components. Remove the remaining liquid from the unit with a heat gun or a hair dryer. **Do not operate the flowmeter in a wet condition. Extreme damage may occur to the unit.**

## II-b FLOWSENSORS/PROBES

**Sterile Tubing Flowsensors:** After use of a sterile tubing flowsensor, wash and sterilize the sensor according to the instructions in the Operator’s Manual. If the connector becomes wet, drying overnight in an incubator oven (≤60ºC, 140ºF) is recommended. Transcribe the flow data to the Record of Sensor/Probe Use available in this manual, along with observations of the sensor’s received quality strength. Signal quality usually diminishes as the sensor increases in age. If the received signal quality drops below the 50% level, the sensor should not be used. Inspect the cables and connectors routinely for damage. Store the sensors at room temperature.

# Record of Sterile Tubing Flowsensor Use

Maintaining a record of probe received signal quality is part of routine probe maintenance. The sterile tubing flowsensor's received signal is normalized to 1.0 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 probe is used with the tubing specified on its Transonic Flowprobe Specifications sheet. As signal degradation may indicate improper mounting of the probe or deterioration of probe function, performance tracking is helpful in diagnosing problems before flow readings become questionable.

**User/contact person** ______________________________ **phone #** ___________________

**Sterile-tubing (clamp-on) probe #** ___________________ **date received** ______________

**Made for tubing material** ___________________________ **O.D.** _________ **I.D.** ________

| Date | Rec'd Signal Amplitude | √ How Used | | Notes (Describe tubing if different) |
|---|---|---|---|---|
| | | Bench | In Patient Circuit | |
| *Example* | *12/9/97* | *good** | ✔ | |
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** Good = Signal Quality indicator on meter's front panel is fully lit.*

Bench-test procedures are described Section C of this manual. When returning sensors for factory examination, call the factory beforehand for a Return Material Authorization (RMA) number and include this page along with the sensor.

**Transonic Systems Inc.**
*Excellence in Quantitative Hemodynamics*
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# III. HD02 Flow Monitor Specifications

**HD02 FLOW MONITOR -** Ultrasonic transit-time volume flowmeters

- Weight - 10 lbs.
- Case size 11” wide x 14 “ deep x 4” high (27.8 cm x 35.4 cm x 9.12 cm)

## General Features

- Automatic probe recognition and re-scaling of the meter.
- RS232 port for flow data collection with HD02 software and an IBM compatible computer.
- High visibility red LED display.
- Convenient ground connection on rear of unit.
- Pull cart mounting system available for system mobility.

## General Specifications

- Input power - 100-249 VAC 50-60 HZ
- Detachable medical grade grounded power cord.
- Fuses - 2 each 1.5A fast-blo 250 VAC 5 x 20 mm.
- Patient electrical isolation - IEC601 - 1 defibrillation proof @ 5000V.
- RS232 port - 19200 baud, isolated to 2500V .8 bit word, 1 stop bit, and no parity
- Agency listed with ETL, CSA, IEC601-1, MDD and CE mark tested and approved.

# IV. Troubleshooting Guide

**Warning:** **Dangerous voltages are present in the unit when the covers are removed and power is applied.**

**Only Factory Authorized Personnel are permitted to work inside the meter.**

| SYMPTOM | WHAT TO CHECK | CORRECTIVE ACTION |
|---|---|---|
| *Unit will not turn on.* | *Check the AC power cord*<br><br>*Check the AC fuses in the power entry module* | *Ensure that all power cord connections are fulled seated*<br><br>*If blown, replace the TSI P/N TF1A5M5X20 fuses* |
| *The meter does not measure flow* | *Call Technical Support Service 1-800-353-3569 (USA)* | |
| *HD02 Aquisition does not work* | *Consult the HD02 Acquisition Manual* | |
| *Any other problem* | *Call Technical Support Service 1-800-353-3569 (USA)* | |


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| | DESCRIPTION | TRANSONIC SYSTEMS INC. P/N |
|---|---|---|
| 1. | Probe holder, HD02 | FEF1003 |
| 2. | Fuse 1.5A 240 VAC 5mm x 20 mm | TF1A5MX20 |
| 3. | AC power cord, medical grade, US | TPC101-H |
| 4. | AC power cord, medical grade, Europe | TPC101-EUR |
| 5. | AC power cord, medical grade, UK | TPC101-UK |
| 6. | AC power cord, medical grade, Australia | TPC101-AUS |
| 7. | Operator's Manual, HD02 | AUTHD02 |
| 8. | Standard rolling stand | AOS1000 |
| 9. | Laptop compatible rolling stand | AOS1002 |
| 10. | HD02 computer monitor software | ASCDHD02 |
| 11. | RS232 cable, 9 pin to 9 pin, 6 feet | PDB9M9F6 |
| 12. | RS232 cable, 25 pin to 25 pin, 6 feet | PDB25MF6 |
| 13. | RS232 adapter plug, 9 pin to 25 pin | PDB9M25F |


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## HD-Series Monitors Use Ultrasound Transit-time Technology to Measure

- **Delivered Blood Flow** (flow in the dialysis tubing, pump flow)**:** Ultrasound sensors clipped onto hemodialysis tubing blood lines transmit minute levels of ultrasound through the tubing wall into the blood stream. Sensitive electronics derive flow via transit-time ultrasound principles.
- **Access Recirculation:** Using indicator dilution principles, the same sensors sense the direct reflux of saline from the venous line back into the arterial line after a saline indicator change in the venous blood line.
- **Access Flow:** After reversing the blood lines, the sensors measure Access Flow by the patented Krivitski Method®.
- **Cardiac Output:** With blood lines in their normal position, the Transonic monitor analyzes cardio-pulmonary recirculation (CPR) to measure cardiac output.

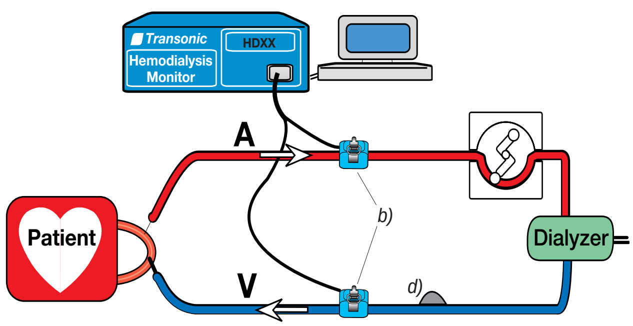



Fig. 1: Transit-time flow/dilution sensing during hemodialysis.

### System Components

a) Hemodialysis Monitor

b) Transonic Arterial & Venous Flow/Dilutions Sensors

c) Laptop computer for automated calculations

d) Isotonic saline (0.9% NaCl) released from the patient's saline bag or by direct injection into the blood line.

## Principle I:

### Differential Transit-Time Ultrasound

### Delivered Blood Flow

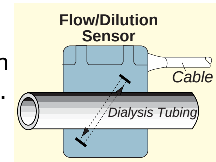



Fig. 2: Clip-on Flow/Dilution Sensor

The clip-on sensor transmits a beam of ultrasound through the blood line. Two transducers pass ultrasonic signals back and forth, alternately intersecting the flowing blood in upstream and downstream directions. The Hemodialysis Monitor derives an accurate measure of the changes in "transit time" (time it takes for the wave of ultrasound to travel from one transducer to the other) resulting from the motion of the blood in the vessel.
The difference between the upstream and downstream transit times is a measure of volume flow.

During hemodialysis two matched flow/dilution sensors are clipped onto the arterial and venous dialysis lines (Fig 1). The monitor continuously displays delivered blood flow. Comparison of this reading with the pump flow setting (i.e., the flow the pump ***tries*** to deliver) provides an opportunity to identify and correct dialysis delivery problems.

## Principle II:

### Ultrasound Indicator Dilution

### Patient Blood Flows & Recirculation

The velocity of ultrasound in blood (1560-1590 m/sec) is determined primarily by its blood protein concentration. The *Transonic*® Hemodialysis Monitor and clip-on Flow/dilution Sensors measure ultrasound velocity. A bolus of isotonic saline (ultrasound velocity: 1533 m/sec) introduced into the blood stream dilutes the blood and reduces the ultrasound velocity. The sensor records this saline bolus as a conventional indicator dilution curve.

A bolus of saline indicator is introduced into the blood line. As the saline passes through the blood lines, the arterial and venous sensors each register an indicator dilution curve. The following measurements can be selected:

*Continued on next page 10*

Protected under USA patents # 5,453,576; 5,595,182; 5,685,989.
International patent #EP 0 781 161 B1

## Principle II: Ultrasound Indicator Dilution *cont.*

- **Access Recirculation:** the Hemodialysis Monitor identifies the direct reflux of the venous saline indicator bolus into the arterial line (Fig. 3). The ratio of indicator concentrations equals access recirculation. High timing resolution enables identification of zero access recirculation (Fig. 3).

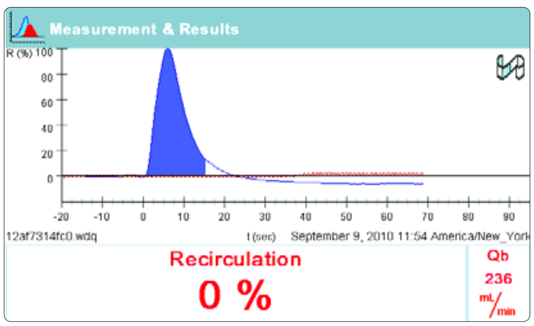
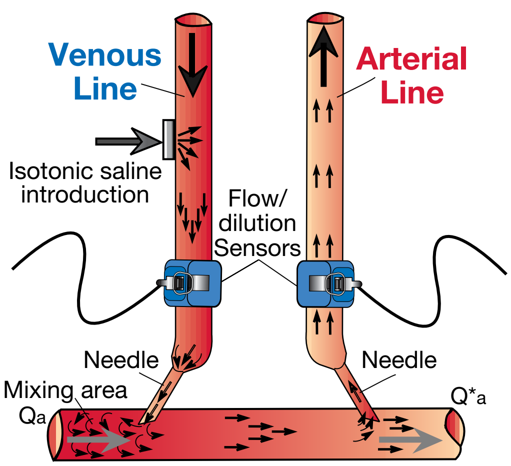



Fig. 3: Typical forward-line indicator concentration curves showing 0% access recirculation.

- **Access Flow** is measured by the The Krivitski Method®, a pioneering *Transonic*® contribution to vascular access management (Fig. 4). The upstream (venous) access needle introduces an indicator into the access flow stream. The downstream (arterial) access needle samples the blood concentration diluted by the indicator (Figs. 5).




**Access Flow**

Fig. 4: Krivitski Method: Access Flow Measurement. Dialysis lines are reversed to induce recirculation from which vascular access flow (Qa) is calculated.

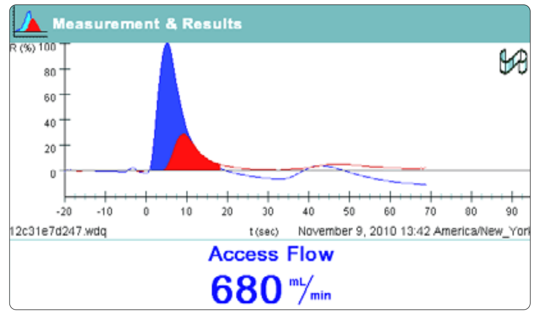



Fig. 4: Typical induced recirculation curves for the Krivitski Method® for calculating Qa.

- **Cardiac Output:** with blood lines in the normal configuration and no direct recirculation present, cardiopulmonary recirculation provides a measure of cardiac output (Fig. 6). The full saline indicator bolus travels into the heart where it is mixed (diluted) into the full cardiac output. Part of this diluted indicator then reappears at the *Transonic*® arterial sensor. Cardiac output and Cardiac Index are calculated via conventional Stewart-Hamilton analysis.

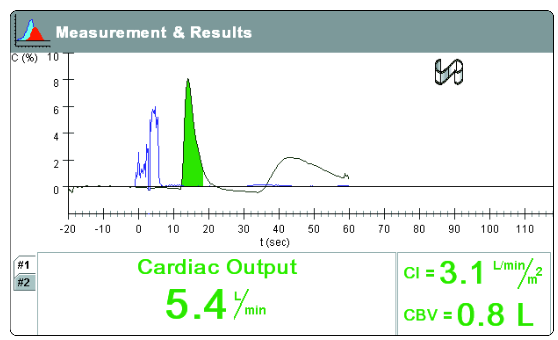



Fig. 6: Typical forward-line indicator concentration curves cardiac output.

# V. Circuit Operation & Block Diagram

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