

HD02 Repair & Maintenance Manual



Transonic[®]

HD02

Hemodialysis Monitor

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USA Technical Support
Call # 1-800-353-3569 (USA)

AUSD02 Service Manual
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I-a. Introduction

1-a: SCOPE OF THIS MANUAL

The intent of this service manual is to teach flowmeter Users and their Biomedical Engineering Service Departments how to maintain HD02 flowmonitor and flowsensor for performance to factory specifications, and how to make elementary repairs, if necessary.

Physical care of the flowmeter and flowsensor, including sterilization and cleaning procedures, is also described in the Operator's Manual. In any instance of equipment malfunction, the User is asked to return the equipment to Transonic Systems Inc. or to its authorized agents for repair or recalibration.

**CAUTION: SERVICE BY NON-AUTHORIZED PERSONNEL WILL VOID
THE FACTORY WARRANTY AND MAY VOID THE SAFETY RATING.**

Transonic Systems Inc. offers a liberal factory warranty on its flowmeters and flowsensors (*see next page*). In no event, should the User attempt to modify the flowmeter or flowsensor.



I-b. Factory Guarantee, Service & Warranty

A. CALIBRATION GUARANTEE

Transonic Systems Inc. certifies that HD02 Hemodialysis Monitor and its software are calibrated by methods traceable to the USA National Institute of Standards and Technology ("NIST"). Transonic Systems Inc. guarantees that the HD02 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 HD02 Hemodialysis Monitor 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 one (1) year from the date of shipment that H4E sterile tubing sensor will remain free from defects which are the result of faulty material or workmanship.

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.



I-c. Equipment Return Instructions



A. METERS

1. Call Transonic Systems Customer Service (1-800-353-3569) with a description of the problem and the Service Technician will give you a RMA (return material authorization) number.
2. Please use the shipping carton supplied with the meter for returning the meter for repair. If you need a carton, contact Customer Service at 1-800-353-3569.
3. Place the two foam packing pieces over the front and back ends of the flowmeter to protect the meter from damage. Notches in the foam should correspond to the cable exiting the front of the meter.
4. Lift the instrument with its foam padding into the box.
5. On top of the foam, place the cardboard insert along with all correspondence, cables, manuals etc. Seal the box for shipping.
6. With a carrier of your choice, ship the meter back to the factory. The address is:
Transonic Systems Inc.
34 Dutch Mill Road.
Ithaca, NY 14850, USA
7. Direct all questions to Customer Service at @ 800-353-3569 (USA) or fax us @ 607-257- 7256.

B. REUSABLE FLOWSENSORS/PROBES

1. Call Customer Service (1-800-353-3569USA) with a description of the problem and the Service Technician will give you a RMA (return material authorization) number.
2. Thoroughly clean all sensors. **Any sensor that has not been cleaned will be immediately returned without repair.**
3. Package all parts of the flowsensor in the original packaging along with any correspondence you wish to include.
4. With a carrier of your choice, ship the meter back to the factory. The address is:
Transonic Systems Inc.
34 Dutch Mill Road.
Ithaca, NY 14850, USA
7. Direct all questions to Customer Service at @ 800-353-3569 (USA) or fax us @ 607-257- 7256.



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 accidentally 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 FLOW/DILUTION SENSORS

Flow/Dilution Sensors: 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 ($\leq 60^{\circ}\text{C}$, 140°F) 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.



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 sensor recognition and re-scaling of the meter.
- USB Port
- 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.
- USB Port
- 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 Check the AC fuses in the power entry module	Ensure that all power cord connections are fully seated If blown, replace the TSI P/N TF1A5M5X20 fuses
The monitor does not measure flow	Call Technical Support Service 1-800-353-3569 (USA)	
HD02 Acquisition does not work	Consult the HD02 Operator's Manual	
Any other problem	Call Technical Support Service 1-800-353-3569 (USA)	



IV. Replacement Parts

<u>DESCRIPTION</u>	<u>TRANSONIC SYSTEMS INC. P/N</u>
1. Sensor 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. USB Cable	AEUSB-2
12. USB Upgrade Kit	AMUSBK-1

V. Ultrasound Dilution Theory of Operation



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.

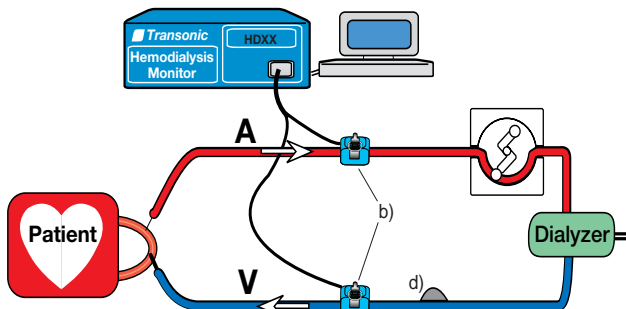


Fig. 1: Transit-time flow/dilution sensing during hemodialysis.

System Components

- Hemodialysis Monitor
- Transonic Arterial & Venous Flow/Dilutions Sensors
- Laptop computer for automated calculations
- 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

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.

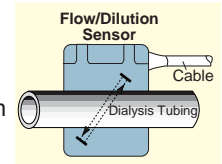


Fig. 2: Clip-on Flow/Dilution Sensor

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:

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



V. Ultrasound Dilution Theory of Operation

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).

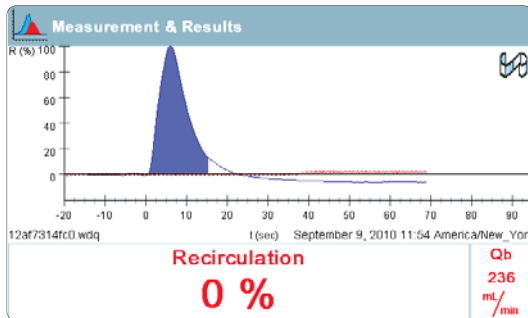


Fig. 3: Typical forward-line indicator concentration curves showing 0% access recirculation.

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).

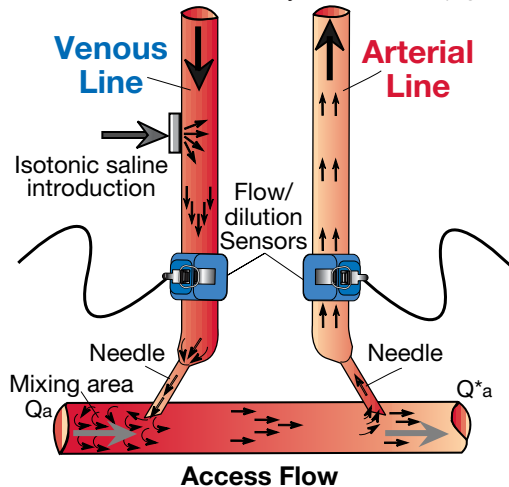


Fig. 4: Krivitski Method: Access Flow Measurement. Dialysis lines are reversed to induce recirculation from which vascular access flow (Q_a) is calculated.

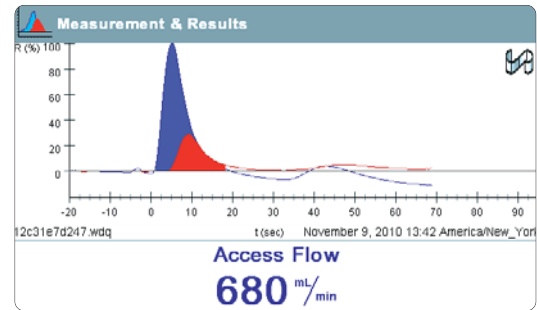


Fig. 5: Typical induced recirculation curves for the Krivitski Method® for calculating Q_a .

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.

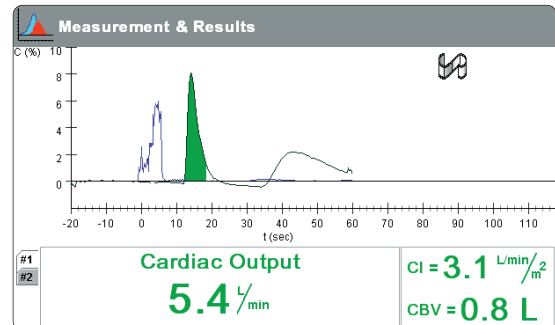
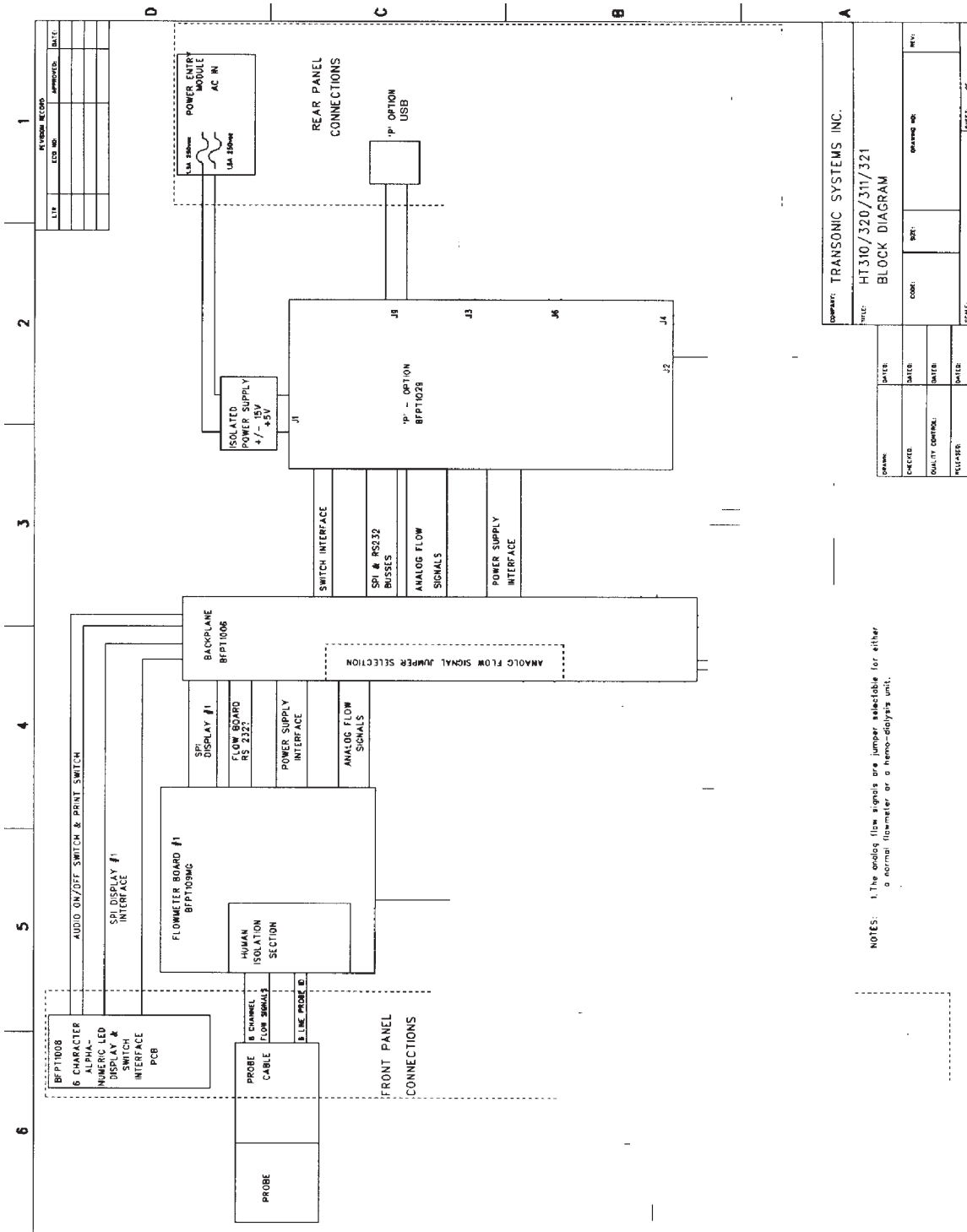


Fig. 6: Typical forward-line indicator concentration curves cardiac output.

V. Circuit Operation & Block Diagram



COMPANY: TRANSONIC SYSTEMS INC.	
DATE:	HT310/320/311/321
BLOCK DIAGRAM	
DESIGNER:	DATE:
CHECKER:	DATE:
QUALITY CONTROL:	DATE:
REVISION:	DATE:
SCALE:	SHEET: 01

