



## HD03/HD03-E Hemodialysis Monitor

**Delivered Blood Flow, Recirculation,  
Vascular Access Flow  
Measurements during Hemodialysis  
(with Cardiac Output Option)**

For use with Transonic® HD03 meter, H4FX Flow/Dilution Sensors and HD03 software.  
One or more of the following US and foreign patents cover this product: 5,453,576; 5,595,182; 5,685,989;  
6,210,591; 6,514,419; 6,926,838; 6,153,109; EP 0781161; CA2,198,601; JP3,627,042; as well as  
pending patent applications.



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## I. Components & Specifications

The Transonic HD03 Hemodialysis Monitoring System (Figure 1) consists of a portable, battery-operated electronic flowmeter, clamp-on flow/dilution sensors (Figure 2) for extracorporeal use on dialysis tubing, and an Administrator software package (Figure 3).

### HD03 Monitor (Figure 1)

The HD03 Monitor measures delivered blood flow, vascular access recirculation, vascular access flow and cardiac output (optional capability), and analyzes and displays the results of these measurements. The monitor can be carried from station to station within the dialysis clinic or easily mounted on a pole, as shown on the next page, to be wheeled from dialysis station to station.



Figure 1: HD03 Monitor

### H4FX Flow/Dilution Sensors (Figure 2)

Paired Transonic H4FX Flow/Dilution Sensors use an X configuration, four-crystal design to pass ultrasound waves through dialysis tubing to measure blood flow and other hemodynamic parameters.



Figure 2: H4FX Flow/Dilution Sensors

### HD03 Administrator (Figure 3)

A companion Administrator software package is provided for installation on a Windows 2000 (or later) personal computer. The HD03 Administrator allows the user to organize, review, edit, manage, print, and schedule patients

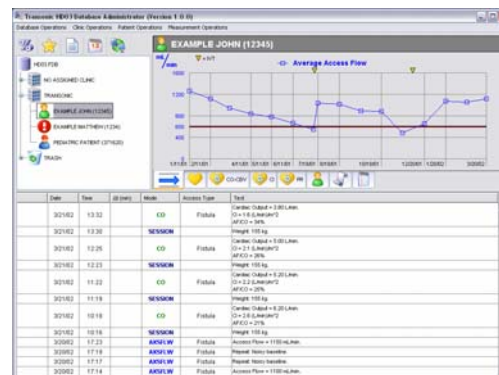


Figure 3: HD03 Administrator



## Components & Specifications (cont.)



Figure 4: HD03 Monitor Front



Figure 5: HD03 Monitor on pole. Pole is shown as an example only. Pole is not available from Transonic Systems Inc.

# HD03/HD03-E Operator Manual



Figure 6: HD03 monitor

## Battery Replacement

The HD03 Hemodialysis Monitor runs on a rechargeable Li-ion battery. To replace the battery, remove the battery from the battery pack compartment located on the left rear side of the HD03 (using a screwdriver), as shown in Fig. 6. Replace the battery and return to the battery pack compartment. The battery can be recharged while installed in the HD03.

## Accessories & Replacement Parts Listing

Catalog #	Model Description
ASCDHD03	HD03 Administrator Software
TPS1001	Rechargeable Battery
TPS1002	Power Adapter
FOS1008	Pole Mount Adapter
FB1001	Mounting Plate
FOS1009	IV Pole Mounting Pin
AUTHD03-EN	HD03 Operator's Manual Available in additional languages
AUTHD03-AD-EN	HD03 Administrator's Manual Available in additional languages
QRGHD03-EN	HD03 Quick Reference Guide Available in additional languages
AUTHD-DG5	Hemodialysis Training Guide
ZC100	Ultrasonic couplant, Vaseline 3.25oz. tube
H4FX	H4FX Hemodialysis Flowsensor
DTM1000	Data Transfer Module (Standard – non Cardiac Output Option)
TCHD03	HD03 Transport Case
DTM2000	Cardiac Output Data Transfer Module (DTM-CO)
HWF1000	Saline Bag Warmer
ADT1010-40	40 Flow-QC tubing sets
ADT1018-50	50 Flow-QC tubing sets (Asia)



## II. Accuracy Specifications

The HD03 measures Delivered Blood Flow, Access Recirculation and Vascular Access Flow. Cardiac output measurement, including calculated Central Blood Volume, Peripheral Resistance, and Cardiac Index, is available as an option. Accuracy specifications for measurement of these parameters are listed below.

Measurement	Delivered Blood Flow	Access Recirculation	Access Flow	CO-(optional)
Range	-2 to +2 L/min	0 to 100%	0 to 4000 ml/min	1 to 16 L/min
Accuracy	± 6% of the flow reading ± zero offset	> 2% Recirculation detected ± 3% of displayed value. For example: a 15% reading is between 12% and 18%	The larger error of: ±100 ml/min ±15% of reading	The larger of: ±0.5 L/min; ±15% of flow reading
Repeatability		clinical correlation coefficient = 0.98	clinical correlation coefficient = 0.98	
Maximum zero flow offset:	± 10 ml/min			

## III. Installation & Testing

### A. Flow/Dilution Sensor

Each Transonic flow/dilution sensor is custom designed and calibrated for use on Flow-QC tubing. Use on other tubing is possible by using the 'Select Tubing' screen (Figure 14). **Note:** Model HD03-E only uses Transonic Flow-QC tubing.

#### Applying the Flow/Dilution Sensor

Mount the sensors on the dialysis tubing 5 to 10 cm (2 - 4 inches) from the connection to the needle. To apply the sensor to tubing, first push down on the sensor's gray latch and open the sensor. Apply a layer of petroleum jelly to the sensing cavity. Insert tubing into the sensing cavity, push down and close the lid. The fit should be tight, with the full tubing circumference contacting all inner surfaces of the sensing window.

### B. Monitor Setup

Plug sensors into the connector on the back of the HD03 monitor. Turn on the "power" switch on the rear side of the monitor.



## V. Specifications

### General

<b>Weight/Size, HD03</b>	6lbs (2.7 Kg); 9.5" x 11.5" x 7" (24cm x 29cm x 18cm)
<b>Alpha-Numeric Display</b>	VGA LCD Interactive Touch Screen (8.4") (21cm)
<b>USB Type A Port</b>	For connection to customer-supplied keyboard/mouse
<b>Sensor Connector</b>	36-pin high-density connector
<b>Ultrasonic Frequency</b>	Sensor dependent: (frequency fixed between 600 kHz & 7.2mHz).
<b>Ultrasonic Transducers</b>	H4FX dual channel flow/dilution sensors.

### Electrical

<b>Power-External Supply Input</b>	AC Input: nominal: 100 - 240 VAC ( $\pm 10\%$ ); 50-60 Hz, 1.0 A Connector: International 3 conductor type IEC 320						
<b>Output</b>	15 VDC, 2.6A						
<b>USB Port</b>	USB Type A						
<b>Electrical Isolation</b>	Hemodialysis monitor 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). Input leakage current < 50 uA; Patient leakage current < 10 uA ; Patient Isolation > 2500 V, double insulated.						
<b>Working Condition</b> (Monitor, ADT1010 & ADT1018)	<table> <tr> <td>Temperature</td> <td>15°C to 35°C</td> </tr> <tr> <td>Humidity</td> <td>45% to 75%</td> </tr> <tr> <td>Atmospheric Pressure</td> <td>400 hPa to 1060 hPa</td> </tr> </table>	Temperature	15°C to 35°C	Humidity	45% to 75%	Atmospheric Pressure	400 hPa to 1060 hPa
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### H4FX Ultrasound Output Specifications

<b>Frequency of Operation</b>	3.6 MHz
<b>Mode of Operation</b>	Transit-time burst excitation, 1.6% duty factor

The ultrasound output level of the H4FX sensor 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 "pre-amendment levels" which, in the USA, are generally recognized as acceptable isonification limits.

PARAMETER	MEANING	H4FX SENSOR	PRE-AMENDMENT MAX (for peripheral applications)
MI	Mechanical Index	0.012	1.9
$I_{max}$	Peak Intensity	0.023 W/cm <sup>2</sup>	310 W/cm <sup>2</sup>
$I_{spta,3}$	Spatial Peak, temporal average intensity	0.28 mW/cm <sup>2</sup>	720 mW/cm <sup>2</sup>
$I_{spta,3}$	Spatial Peak, pulse average intensity	0.018 W/cm <sup>2</sup>	190 W/cm <sup>2</sup>

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 cm-Hz. Measurement uncertainties do not exceed 30%.