

HD03 Hemodialysis Monitor Specifications

Two HD03 system configurations address different user needs.

- Patient-less Measurement Module (PMM): does not save any patient information or measurement data.
- Data Transfer Module (DTM): records patient information & measurement data to be transferred to a computer loaded with HD03 Administrative software for further analysis.

VASCULAR ACCESS TYPE	TRANSONIC MEASUREMENT	CLINICAL APPLICATION
Catheter	Delivered Flow; Recirculation	Dialysis optimization with simple algorithm. Outcomes: improved adequacy; decreased use of thrombotic agents; decreased catheter exchange.
AV Fistula and/or graft	Delivered Flow; Recirculation; Vascular Access Flow	Detection of access dysfunction with customized AVF/AVG protocols. Detection of high flow access and related high flow cardiac failure. Outcomes: improved management of access intervention and measurement to manage intervention outcomes; Cardiac care intervention to reduce morbidity and mortality; Assist with kidney transplant listing.

HD03 Specifications

PHYSICAL PARAMETERS

Weight: 6 lbs (2.7 Kg)

Dimensions: 9.5" x 11.5" x 7" (24cm x 29cm x 18cm)

Display: VGA LCD Interactive Touch Screen (8.4") (21cm)

USB Port: Type A; For connection to Transonic DTM only

Sensor Connector: 36-pin high-density connector

POWER SUPPLY

External AC Input: 100 - 240 VAC ($\pm 10\%$); 50-60 Hz. nominal

External Connector: International 3 conductor type IEC 320

Output: 15 VDC, 2.6A

Battery: 12.6 VDC (max) 8.7 Ahr (min) Li-ion

ELECTRICAL ISOLATION

Hemodialysis monitor complies with USA standards for medical and dental equipment (IEC60601), 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. Meets IEC 60601-1 Cardiac Floating (CF) specification.

H4FX Flow/Dilution Sensors

Sensor pair transmits ultrasound waves through dialysis tubing to measure blood flow and other parameters

- Sensors clip onto tubing connected to a patient's blood lines.

H4FX ULTRASONIC SENSOR SPECIFICATIONS

- Frequency of Operation: 3.6 MHz
- Mode of Operation: Transit-time burst excitation, 1.6% duty factor
- Ultrasound Output Level: Factory-set, no interactive system features. Settings use "ALARA" principles (As Low As Reasonably Achievable) and are more than 30dB below FDA "pre-amendment levels," recognized as acceptable USA insonification limits.

HD03 ACCURACY

MEASUREMENT	DELIVERED FLOW	RECIRCULATION	ACCESS FLOW
Range	-2 to +2 L/min	0 to 100%	0 to 4000 ml/min
Accuracy	$\pm 6\%$ of the flow reading \pm the zero offset	> 2% Recirculation detected $\pm 3\%$ of displayed value. For example: a 15% reading is between 12% and 18%	The larger of: ± 100 ml/min $\pm 15\%$ of reading
Repeatability		Clinical correlation coefficient = 0.98	Clinical correlation coefficient = 0.98
Maximum zero flow offset:	± 10 ml/min		