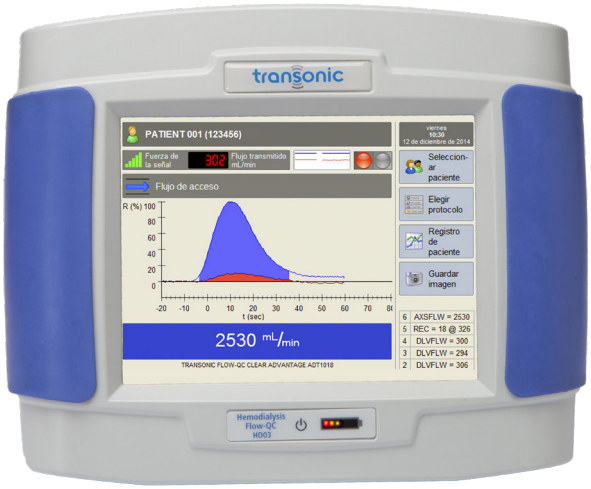
Transonic® HD03 Hemodialysis Monitoring

Delivered Flow • Recirculation Access Flow



HD03 Monitor displays vascular access flow results

Measure Dialysis Adequacy

Delivered Flow and Recirculation results identify dose delivery problems in the AV Access and Central Venous Catheters allowing the nurse to optimize the treatment on-the spot!

Trend Vascular Access Flow

A drop in Access Flow signals the onset of a stenosis, in time for proactive minimally invasive intervention. A high Access Flow can signal a potential high-output cardiac failure.

HD03Monitoring(DL-101-ds)RevC2022USltr

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HD03 Features & Benefits

HD03 Measurements

HD03 measurements can be performed on all Chronic or Acute Adult, and Pediatric Hemodialysis patients' AV fistulas, grafts and catheters during routine dialysis.

Easy to Use
The HD03 is operator independent and very easy to use with on-screen step-by-step procedure.

Quick and Accurate
Results are displayed immediately on the HD03 monitor screen.

Choice of Results
You have a choice of:

1) HD03 Patient-less Measurement Module (PMM) that displays measurement results to be manually recorded in a patient's chart.

Or

2) HD03 Administrator Management Software (DTM) that trends and archives measurement results under a patient's name. **Note:** This device is not available in countries requiring European Medical Device Regulation (MDR) clearance.

HD03 Monitor

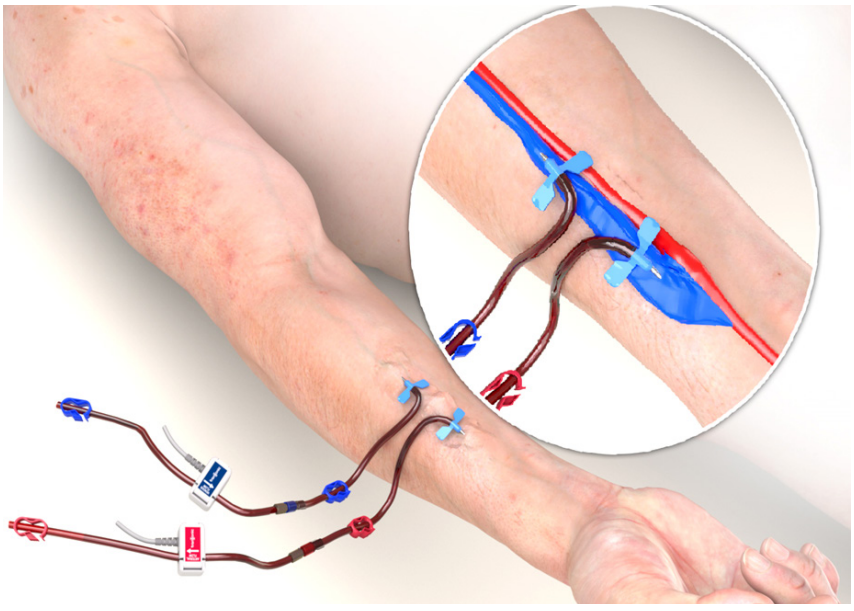
Portable
Rechargeable battery permits portable, easy mobility between patients.

Safety/Infection Control
Touch-screen input prevents cross contamination.
The screen can be cleaned with a diluted solution of bleach or soap.

H4FX Flow/Dilution Sensors

Paired sensors pass ultrasound waves through dialysis tubing to measure blood flow and other parameters.

- Sensors clip onto tubing connected to the patient's blood lines.
- Saline can be released directly from saline bag or infused into the dialysis circuit.



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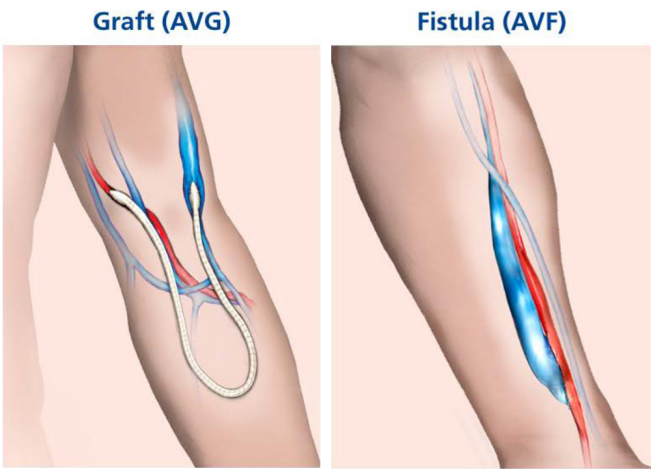
HD03 Monitoring of Dialysis Adequacy in Arteriovenous Grafts and Fistulas

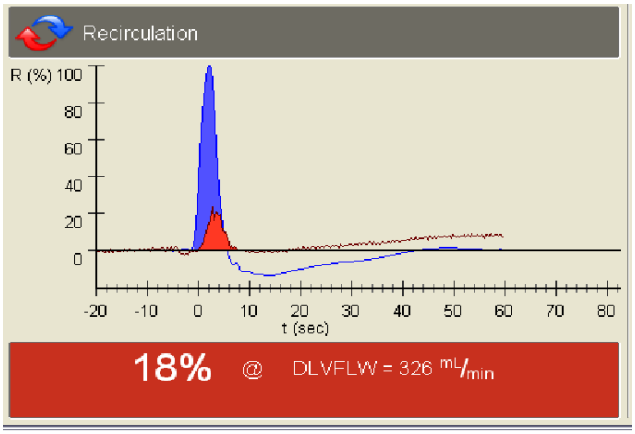
- Measure True Delivered Blood Flow to Optimize Dialysis Delivery
- Measure Recirculation to Identify Formation of Stenoses



Measure Access Recirculation

With a single infusion of saline, the Transonic Hemodialysis® Monitor detects and quantifies access recirculation, a late indicator of a failing access. Because Transonic® ultrasound dilution technology can separate cardiovascular recirculation from cardiopulmonary recirculation, 0% recirculation can be quantified. Measurement of recirculation will:

- Identify inadvertent reversal of blood lines (see box at right);
- Confirm proper needle placement;
- Confirm 0% recirculation, or identify recirculation percentage, if present.



Indicator concentration curves showing 18% access recirculation.

Measure Delivered Blood Flow

Pump flow errors and recirculation compromise dialysis delivery of a KT/V prescription. The Transonic® Hemodialysis Monitor measures true delivered blood flow through dialysis tubing using transit-time ultrasound technology. By comparing true delivered blood flow to the pump's reading, any flow limiting cause such as small needle diameter or incorrect needle placement can be identified and corrected. Delivered Blood Flow is used to:

- Determine the most appropriate blood pump setting for a low flow access when it is not feasible to increase access flow;
- Find the cause of excessive negative arterial pressure;
- Test blood pump calibration and its "effective flow" algorithm;
- Diagnose tubing set flow restrictions that could cause hemolysis.

Case Report:
Inadvertent Reversal of Blood Lines

When a routine Transonic® hemodialysis screening of a 41-year-old female ESKD patient with an AV graft reported a vascular access recirculation of 22%, the nurse reversed the blood lines and performed a second recirculation measurement. Zero percent recirculation registered. This demonstrated that the hemodialysis lines had been inadvertently reversed when they were first connected for hemodialysis. By leaving the lines in the correct position for the duration of the dialysis session, the patient received her prescribed dialysis prescription.

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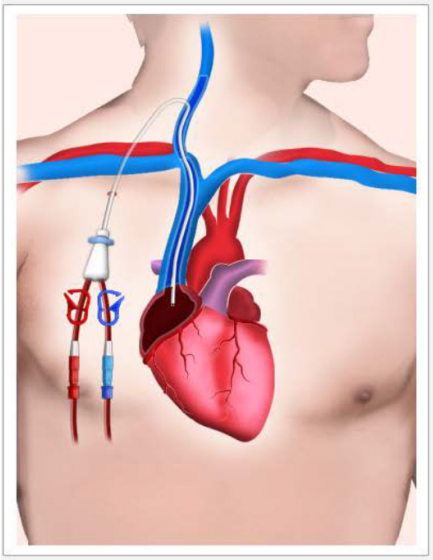
HD03 Monitoring of Dialysis Adequacy in Central Venous Catheters (CVCs)

Measure True Delivered Blood Flow and Recirculation in CVCs On-the-Spot to Optimize Dialysis Delivery



Catheter Adequacy

Most End-Stage Kidney Disease (ESKD) patients will undergo, at some point, dialysis administered through a Central Venous Catheter. Whether dialysis is emergent and temporary, acute or chronic, CVCs will often underdeliver dialysis due to:

- a discrepancy between a dialyzer's pump setting and its true delivered flow;
- and/or the presence of recirculation during dialysis delivery.

Example: Flow-QC Adequacy Test Detects Hemolysis Risk

75-year-old woman with Central Venous Catheter: Blood Lines: normal line position; Pump Setting: 300 mL/min; Delivered Blood Flow: 190 mL/min; Recirculation: 0%.

A 35% disparity between 300 mL/min pump setting and 190 mL/min delivered blood flow indicated significant hemolysis risk.

Response: Lines were checked to see that they were not kinked. Blood lines were then reversed; the pump was reset to 300 mL/min. Delivered blood flow & recirculation were again measured.

- Delivered Flow: 290 mL/min
- Flow-QC Recirculation: 2-3%

Results: The patient received better treatment with the lines in a reversed position and the pump delivering 290 mL/min.

Take Home: Treatment of patients with CVCs can be optimized with Flow-QC Delivered Flow and Recirculation measurements.

Transonic HD03 Flow-QC® Monitoring of Catheter Dose Delivery

Two potential pitfalls plague the use of catheters for dialysis delivery.

1. A fibrin sheath can occlude the lumen of the catheter's arterial entry port, impeding flow and causing a severe drop in dialysis dose delivery. This can be identified on the spot and often corrected with an HD03 measurement of true delivered blood flow.
2. The close proximity of the catheter's arterial entry and venous return ports make recirculation possible in some catheter designs. For instance, if there is 10% recirculation, the amount of blood cycled through the dialyzer is effectively 10% less and underdialysis can occur. Since the HD03 Monitor can measure recirculation, recirculation in catheters can be identified and optimized to provide the most efficient dialysis possible.

Transonic's HD03 Hemodialysis Monitor Measurements Optimize Dialysis Catheter Delivery by:

- Helping to establish a maximum dialysis pump setting before recirculation occurs;
- Using known values for flow and recirculation to adjust the length of dialysis;
- Identifying flow restrictions;
- Finding the best catheter configuration between the catheter blood lines (regular or reversed).

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HD03 Measurements of Vascular Access Flow in AV Grafts and Fistulas

Transonic® Hemodialysis Monitor identifies vascular access dysfunction and risk of thrombosis

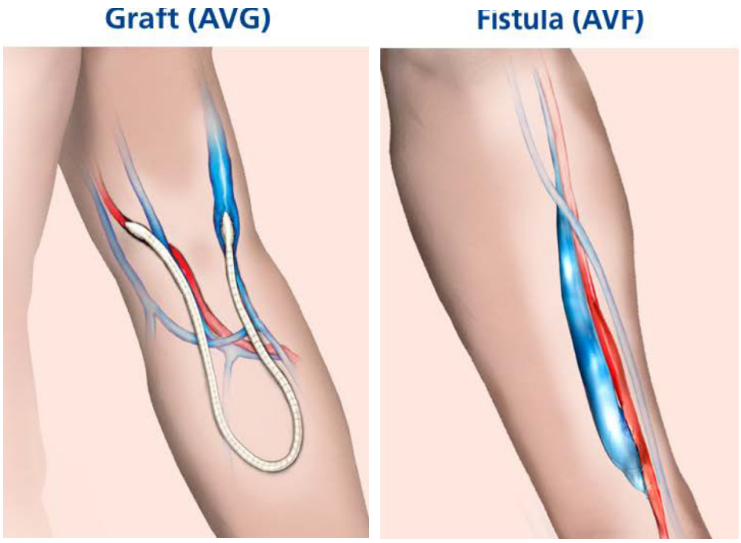
Vascular Access Flow

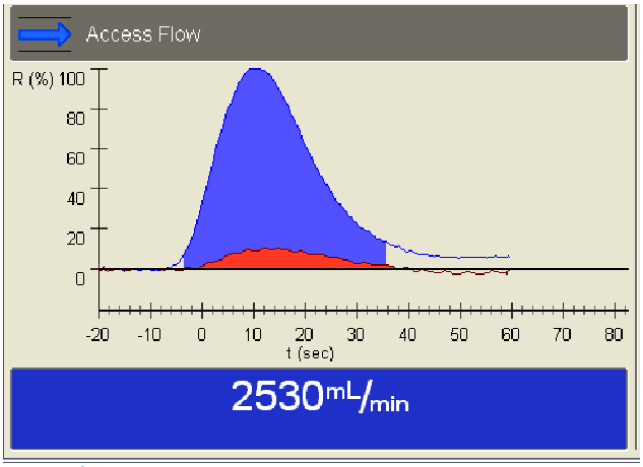
Access flow is the quintessential vital sign for an AV Access. Insufficient flow causes underdialysis. Still lower flow invites thrombosis. Too much flow can lead to heart problems. Each condition harbors associated morbidities.

Transonic® ultrasound dilution technology is an intra-access flow measurement technology to detect flow limiting problems wherever they occur within a vascular access during the dialysis session. The method uses Transonic® Hemodialysis Monitors and Flow/Dilution Sensors to measure access flow directly for an instant snapshot of access function.

By measuring vascular access flow routinely and trending the results over several months, a record of access patency is created. A drop in access flow signals formation of a stenosis, in time for proactive minimally invasive intervention.

Access Flow enables clinicians to detect onset of stenosis before thrombosis occurs.





Access flow measurement with the Transonic® Hemodialysis Monitor.

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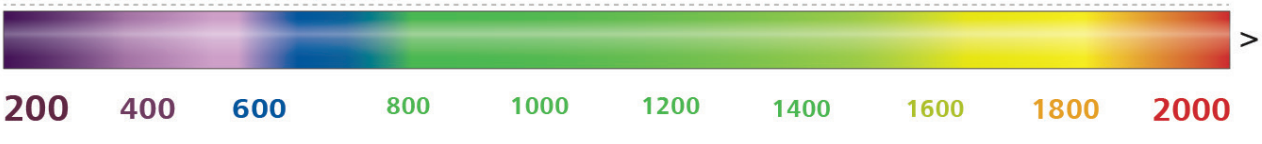
Fistula and Graft Access Flow Interpretation

Lower Arm AVF (wrist and above)

Upper Arm AVF (elbow and above)

AV Graft (forearm loop graft)



CLINICAL INTERPRETATION KEY:

Probable risk for Hemodynamically Significant Stenosis/Recirculation as flow decreases (indicated by color progression from blue to purple)	**Expected Access Flow Range** Expected flow range is ideal. However, a sudden drop of 25% in this range may signal a potential onset of stenosis.	**Probable risk for Cardiac Failure as flow increases** (indicated by color progression from yellow to red)
Action: Consider Clinical Examination & Imaging	**Action: If Flow Is Steady, Continue Monitoring. If 25% Decrease Occurs, Consider Clinical Exam & Imaging**	**Action: Evaluate the patient for signs and symptoms of high output cardiac failure.**

Notes:

- Actual flow levels for AV fistula and graft patients should be customized by the nephrologist.
- A clinical examination (look, listen, feel, arm elevation and augmentation) should be used routinely as part of the pre-cannulation process.
- Transonic access flow measurements are intended to be utilized in conjunction with a clinical examination to detect/confirm indications of access dysfunction.
- Snuffbox or endovascular fistulas may have a lower access flow range depending on the location of the anastomosis and the vessel's outflow configuration.
- Upper arm AV fistulas typically have a higher access flow range due to the larger artery size.
- A potential for cardiac overload exists at flow >1600-3000 mL/min. Evaluate patient for signs and symptoms of high-output cardiac failure.

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Transonic Systems Inc. is a global manufacturer of innovative biomedical measurement equipment. Founded in 1983, Transonic sells "gold standard" transit-time ultrasound flowmeters and monitors for surgical, hemodialysis, pediatric critical care, perfusion, interventional radiology and research applications. In addition, Transonic provides pressure and pressure volume systems, laser Doppler flowmeters and telemetry systems.

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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 (±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	± 6% of the flow reading ± the zero offset	> 2% Recirculation detected ± 3% of displayed value. For example: a 15% reading is between 12% and 18%	The larger of:±100 ml/min ±15% of reading
Repeatability		Clinical correlation coefficient = 0.98	Clinical correlation coefficient = 0.98
Maximum zero flow offset:	± 10 ml/min		

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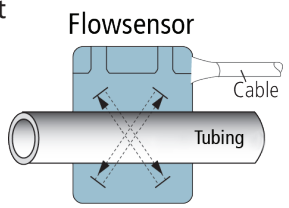
HD03 Theory of Operation

Transit-Time Ultrasound Technology: Delivered Flow

A Transonic® Clamp-on Flow/Dilution Flowsensor houses ultrasonic transducers and a tubing channel which holds the dialysis tubing containing the fluid being measured. The transducers in the sensor are positioned on opposite sides of the tubing. An electrical excitation from the flowmeter causes the transducers to emit ultrasound waves that intersect the tubing in both upstream and downstream directions. The ultrasound waves are received by the opposing transducers where they are converted into electrical signals. As the ultrasound waves travel downstream or with the flow within the tube, its velocity increases. As ultrasound waves travel upstream or against the flow, its velocity decreases. From these velocity signals, the Flowmeter derives an accurate measure of the "transit time" it takes for the ultrasound wave to travel from one transducer to the other from which it then derives volume flow.



Schematic representation of a Flow/ Dilution Sensor showing the paths of ultrasound signals across the tubing.

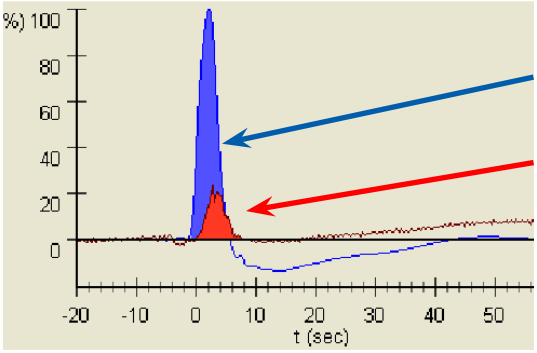
Paired arterial & venous Flow/Dilution Sensors.

A touch screen HD03 Monitor attached to an IV pole with paired arterial and venous Flow/Dilution Sensors clamped onto respective arterial and venous lines of Flow-QC tubing. Sensors can be clipped directly on the arterial and venous lines for most measurements and options. This schematic demonstrates the option for saline release into the arterial line for recirculation and access flow measurements.

Ultrasound Indicator Dilution Technology: Recirculation and Access Flow

The Transonic Hemodialysis Monitor with its Flow/Dilution Sensors measure ultrasound velocity. The velocity (1560-1590 m/sec) of ultrasound in blood is determined primarily by its blood protein concentration. A bolus of isotonic saline (ultrasound velocity: 1533 m/sec) introduced into the blood stream dilutes the blood and, thereby, reduces its ultrasound velocity. When a bolus of saline indicator is introduced into the blood line, arterial and venous Flow/Dilution Sensors record this saline bolus as a conventional indicator dilution curve.

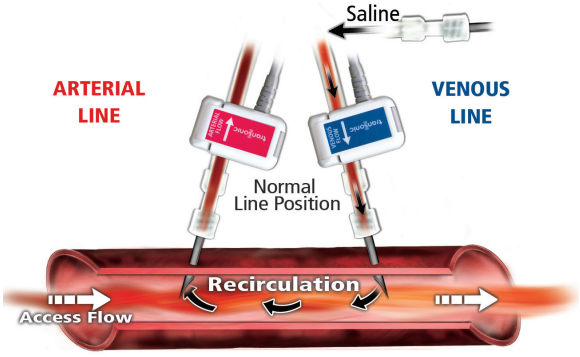
The following measurements can be selected:



Bell-shaped saline indicator dilution curve.

RECIRCULATION

The Hemodialysis Monitor identifies the direct reflux of the venous saline indicator bolus into the arterial line. The ratio of indicator concentrations equals access recirculation. The HD03 Monitor's high timing resolution separates cardiopulmonary circulation from systemic circulation and allows identification of zero access recirculation.



Normal sensor and reverse line position for access recirculation measurement.

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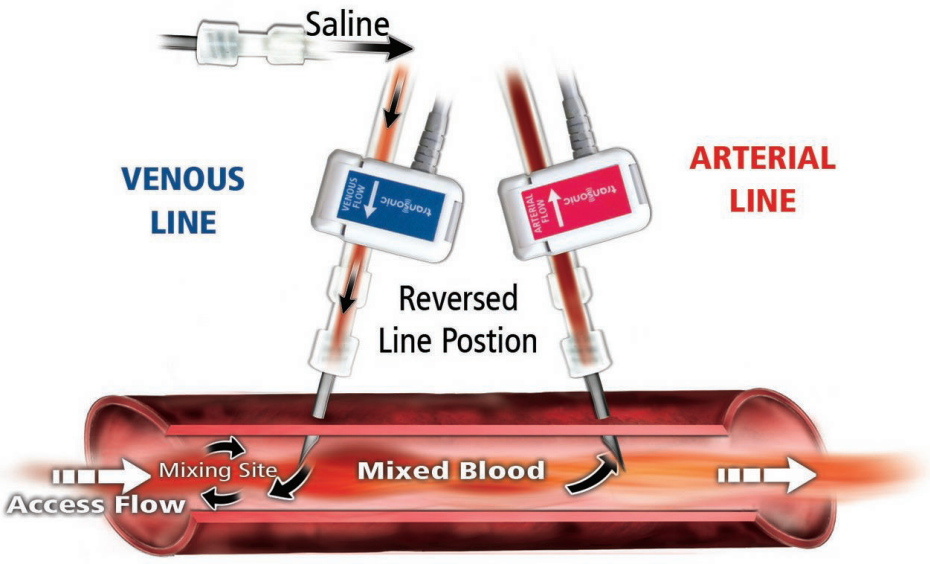
HD03 Theory of Operation cont.

ACCESS FLOW

Access Flow is measured by The Krivitski Method®, a pioneering Transonic® contribution to vascular access management. After reversing the blood lines at the needle connections, 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.



Reversed line position for access recirculation measurement. Saline injection is still made into the venous line which is now the upstream line.

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Hemodialysis Annotated References

Theory & Validations (UDT, TTFM)

Ultrasound Dilution (UDT)

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Predictive Power of Arteriovenous Access Flow Measurements

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Aragoncillo I *et al,* **"Adding access blood flow surveillance reduces thrombosis and improves arteriovenous fistula patency: a randomized controlled trial,"** J Vasc Access. 2017; 18(4): 352-358. *"QA-based surveillance combining Doppler ultrasound and ultrasound dilution reduces the frequency of thrombosis, is cost effective, and improves thrombosis-free and secondary patency in autologous AV."*

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Zero Vascular Access Recirculation - A New Reality

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Measurements of Recirculation and Delivered Flow in Catheters

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