Best Practices: Transonic® Hemodialysis Surveillance

- Vascular Access Flow
- Dialysis Adequacy
- Cardiac Function

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transonic
THE MEASURE OF BETTER RESULTS.
Flow-based Vascular Access Management

Vascular Access Surveillance
Flow-based surveillance per KDOQI Guidelines alerts a patient care team to patients at risk for underdialysis, thrombotic events and cardiac failure.

“The [HD03] allows you to proactively manage your patients as part of a multidisciplinary vascular access care program to reduce complications and costs of end-stage renal disease.” Duda, CR et al, Nephrology News & Issues, 2000; 14(5).

Dialysis Adequacy
Ensure adequate dose delivery by direct, accurate measurement of pump blood flow and access recirculation in AV accesses and catheters.

“Recirculation and delivered blood flow measurements provide important information about the most appropriate and effective therapies for your patients.” Sands, JJ et al, ASAIO, 1996; 42(5). Depner, TA et al, ASAIO 1995; 41(3).

Cardiac Function
Cardiac Output profiling with a Transonic® HD Monitor identifies patients with dangerously low Cardiac Index due to inadequate dry weight estimation.

“Integration of cardiac output measurements into an ESRD treatment program forestalls the devastating progression of cardiovascular disease.” MacRae, JM et al, Am J Kid Dis 2004; 43(5).

“Transonic flow monitoring is the cornerstone of my Vascular Access Management Program (VAMP).” Spergel, LM, MD, FACS, Dialysis Management Medical Group, San Francisco

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.
The battery-operated, portable HD03 Monitor & Flow/dilution Sensors Measure:

- Delivered Blood Flow
- Vascular Access Recirculation
- Vascular Access Flow
- Cardiac Output (optional)

Measurements take less than 10 minutes per patient. Results are displayed immediately on the Monitor.
HD03 Features & Benefits

HD03 Monitor

Measurements
Performed on AV fistulas, grafts and catheters during routine dialysis.

Easy to Use
Measurements are operator independent. Software guides user step-by-step through procedure.

Easy Set-up
Simply clip the arterial and venous flow/dilution sensors onto the respective blood lines.

Portable
Rechargeable battery permits easy mobility between patients.

Safety/Infection Control
Touch-screen input prevents cross contamination. The screen can be cleaned with a dilute 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.

Administrative Software

Data Management
A removable Data Transfer Module can be uploaded to a computer with HD03 Administration software, and information is synchronized between the Monitor and computer.

Powerful
- Documents and trends interventions and access history
- Generates High Risk Thrombosis “Alert” List
- Permits schedule planning
- Calculates individual patient and clinic statistics
- Displays comprehensive Patient Status Reports
Best Practice: Dialysis Adequacy

Optimize efficient dialysis delivery and assess measurement of delivered pump blood flow and recirculation.

DELIVERED BLOOD FLOW

Pump (delivered blood) 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 Gold Standard transit-time ultrasound technology. By comparing actual 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-QC® is used to:

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

AV 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;
- Confirm proper needle placement;
- Confirm 0% recirculation.

CATHETER ADEQUACY

Central venous catheters often under deliver dialysis due to a discrepancy between a pump’s setting and its actual delivered flow and/or the presence of recirculation. The Transonic® Hemodialysis Monitor optimizes dialysis catheter delivery by:

- Establishing 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 connections between a catheter and blood lines;
- Identify failing catheters through high recirculation rates.

CASE REPORT: INADVERTENT REVERSAL OF BLOOD LINES

A routine Transonic® hemodialysis screening of a 41 year-old female ESRD patient reported a vascular access recirculation of 22%. The nurse reversed the blood lines and performed a second recirculation measurement. 0% recirculation registered. This demonstrated that the hemodialysis lines had been inadvertently reversed when they were initially connected for hemodialysis. The lines were left in the correct position for the duration of the dialysis session and the patient received her prescribed dialysis prescription unimpeded by inadvertent reversal of the blood lines.

KDOQI GUIDELINES

“Any access recirculation is abnormal. Recirculation … should have prompt investigation of its cause. … If access recirculation values exceed 20%, correct placement of needles should be confirmed before conducting further studies.”


Fig. 1: Typical indicator concentration curves showing 18% access recirculation.
Best Practice: Dialysis Adequacy Cont.

**HOW IT WORKS: DIFFERENTIAL TRANSIT-TIME ULTRASOUND**

A 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 Transonic® Hemodialysis Monitor derives an accurate measure of the changes in the time it takes for the wave of ultrasound to travel from one transducer to the other ("transit time") resulting from the flow of blood in the vessel. The difference between the upstream and downstream transit times is a measure of volume flow.

**HOW IT WORKS: 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 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.

When a bolus of saline indicator is introduced into the blood line, the arterial and venous sensors each register an indicator dilution curve (Fig. 1). The Hemodialysis Monitor identifies the direct reflux of the venous saline indicator bolus into the arterial line (Fig. 2). The ratio of indicator concentrations equals access recirculation. High timing resolution enables identification of zero access recirculation (Fig. 3).

**SELECT REFERENCES**


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.
Best Practice: Vascular Access Surveillance

Identify ESRD patients at risk for underdialysis, thrombotic events and cardiac failure with Transonic® Hemodialysis Surveillance

**FLOW-BASED ACCESS SURVEILLANCE**

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 recognized as the “gold standard” intra-access flow measurement technology for hemodialysis patient surveillance 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. Vascular access flow measurements detect flow limiting problems wherever they occur within a vascular access.

By measuring vascular access flow routinely and trending the results over several months, a record of access patency is created (Fig. 1). A drop in access flow signals formation of a stenosis, in time for proactive minimally invasive intervention.

**KDOQI GUIDELINES: GRAFTS AND FISTULAS**

- Intra-access flow measurements (such as Transonic® ultrasound dilution) are the preferred method for A-V graft and fistula surveillance.
- Low-flow Thresholds:
  - Grafts: < 600mL/min
  - Fistulas: 400-500 mL/min
- When access flow is less than 1000 mL/min and has decreased by more than 25% over four months, the patient should be referred for a fistulogram.

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**Fig. 1:** Trending of vascular access flow over a one year time frame with PTA interventions noted by arrows. Several technologies can monitor low AV access flow, but only fast-response blood-line reversal indicator dilution methods can trend flow. Their fast-response capability eliminates possible error stemming from cardio-pulmonary recirculation.

**Fig. 2:** Access flow measurement with the Transonic® Hemodialysis Monitor.

“ADEQUATE BLOOD FLOW IN PERIPHERAL HEMODIALYSIS FISTULAE AND GRAFTS IS VITAL TO THE SUCCESS OF HEMODIALYSIS AND TO THE SURVIVAL OF THE PATIENT. REDUCTION IN FLOW ... PRESAGES FAILURE OF THE ACCESS DEVICE ITSELF. ACCESS FLOW CAN THEREFORE BE CONSIDERED A FUNDAMENTAL PROPERTY OF THE ACCESS THAT SHOULD BE MONITORED.”

Depner, TA et al
Best Practice: Vascular Access Surveillance Cont.

HOW IT WORKS: ULTRASOUND INDICATOR DILUTION
(Patient Blood Flows & Recirculation)

The Krivitski Method® to measure vascular access flow is a pioneering Transonic® contribution to vascular access management (Fig. 2). A saline indicator is introduced via the upstream (venous) access needle into the access flow stream. The downstream (arterial) access needle samples the blood concentration diluted by the indicator from which vascular access flow is calculated (Fig. 3).

WHY PREVENTION OF FISTULA THROMBOSIS THROUGH ACCESS SURVEILLANCE IS WORTHWHILE

A thrombosed vascular access is problematic for:
- **Dialysis Staff who need to:**
  - Assist patient in coping
  - Arrange for transportation
  - Interface between patient and physicians
  - Rearrange dialysis schedule
- **Nephrologist who needs to:**
  - Console unhappy patient & family
  - Arrange logistics to resolve AVF failure
- **Patient who copes with:**
  - Discomfort, pain, anxiety and fear
  - Delay of dialysis
  - Concerns about K+ and fluid
  - Disruption to schedule
  - Decreased quality of life


Select References

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Best Practice: Cardiac Function

Forestall ESRD patients’ cardiovascular complications by routine clinical exams supported by hemodialysis cardiac function screening.

Cardiovascular disease (CVD) is the leading cause of morbidity and mortality in patients with End-Stage Renal Disease (ESRD). Transonic® Cardiac Function Monitoring provides a way to integrate cardiac function studies into a hemodialysis clinic’s treatment protocol and forestall the devastating effects of CVD.

Transonic® Monitoring identifies:

1) Dangerously high and prolonged levels of access flow (>1,600-2,000 mL/min) stress the heart causing cardiomegaly and heart failure. This can be identified by an access flow to cardiac output ratio (AVF/CO) exceeding 25-30%.

2) Dangerously low cardiac output (CI < 2 L/min/m²) which places patients at high risk for cardiovascular complications and failure.

3) Dramatic 20 - 30% decreases of Cardiac Index during hemodialysis to dangerously low levels due to inaccurate dry weight estimation and/or inadequate medication that places patients at high risk for cardiovascular complications and sudden death following a dialysis session.

4) Dangerous decreases in Central Blood Volume during dialysis that may portend hypotensive episodes.

Transonic® proprietary ultrasound indicator dilution technology measures Cardiac Output and the following derived cardiac function parameters: Cardiac Output; Cardiac Index; Peripheral Resistance; Central Blood Volume; Central Blood Volume Index.

Central Hemodynamic Profiling (CHP) is the periodic assessment of cardiac function during the hemodialysis session in order to track the heart’s response to the stress of a dialysis treatment (Fig. 2). CHP identifies patients who leave hemodialysis sessions with dangerously low cardiac indices (CI ≤ 2.0), that increases their risk for death, stroke or myocardial infarction.

Fig. 1: Flow-QC screen reports Cardiac Output, Cardiac Index (CI) & Central Blood Volume (CBV). Software also displays Height, Weight, Heart Rate, Blood Pressure, Peripheral Resistance, Central Blood Volume Index, Systemic Cardiac Index & Stroke Volume.

Cardiovascular mortality in ESRD patients, depending on age, is 10 - 500 times greater than the general population.

Special Report: NKF Task Force on Cardiovascular Disease, AJKD 1999; 32(5)
Best Practice: Cardiac Function Cont.

HOW IT WORKS:
ULTRASOUND INDICATOR DILUTION
(Cardiac Output)

With blood lines in the normal line position and no direct recirculation present, cardiopulmonary recirculation represents a measure of cardiac output (Fig. 3). The complete bolus of saline indicator 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 using conventional Stewart-Hamilton analysis.

SELECT REFERENCES*
2. Cardiovascular Disease: An ESRD Epidemic, Am J Kid Dis 1998; 32(Suppl 3) 1

Fig. 3: Recirculation Measurement. Saline is introduced into the venous sensor with the dialysis lines in normal position. The arterial sensor measures the diluted concentration of blood from which recirculation is calculated.

* Numbers in parentheses ( ) are Transonic® reference numbers.

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Why Perform Surveillance?

7 Ways the HD03 Improves Outcomes for Your Patients

The Transonic® Gold Standard Hemodialysis Monitor Assures KDOQI Quality Compliance through:

- Dialysis Adequacy Optimization
- Vascular Access Surveillance
- Cardiac Function Assessment
1. **Identifies Discrepancy Between Pump Setting & Delivered Blood Flow As A Result of:**

- Negative pressure effects of the roller pump
- Condition of access
- Needle size
- Needle placement
- Kinked or occluded tubing
- Calibration of dialysis machine
- Change in type of dialysis tubing
- Calibration of Transonic® Flow/dilution Sensors

2. **Ensures Correct Needle Placement**

When Transonic® Hemodialysis Monitoring first shows vascular access recirculation (Fig. 1), which disappears after the blood lines are reversed and the recirculation measurement is repeated (Fig. 2), the hemodialysis lines have been inadvertently reversed.

Transonic® Hemodialysis Monitor screenings show that dialysis occurs with the needles inadvertently reversed in more than 4% of cases.

3. **Confirms 0 % Recirculation**

In contrast to measurement technologies that cannot separate vascular access recirculation from cardiopulmonary recirculation and, therefore, show false positives, Transonic® Hemodialysis Monitoring can separate access recirculation from the cardiopulmonary (the red curve in Fig. 3) and can report zero % recirculation.

4. **Optimizes Dialysis in Dual-lumen Catheters**

Catheter recirculation is an early sign of catheter failure and usually depends on dialysis blood flow. The patient in Fig. 4 was dialysed at flows up to 300 mL/min without any recirculation. At flows higher than 300 mL/min, such as 450 mL/min shown in Fig. 5, 19% recirculation occurred.

Therefore, increasing delivered blood flow (Qb) did not proportionally increase the quality of dialysis.

**Note:** Discrepancies between pump flow and real delivered flow can also be more dramatic with catheters than with vascular accesses.
5. **Recirculation with Low Access Flow Detects Significant Inflow/Outflow Stenoses**

Unlike other technologies that can only identify outflow stenoses in AV accesses, HD03 Monitor surveillance can detect a stenosis wherever it occurs within the vascular access circuit: inflow, outflow or between the needles in both fistulas or grafts.

In the example on the right, access recirculation (Fig. 6), accompanied by low vascular access flow (Fig. 7), indicated the presence of a significant stenosis which was then confirmed by color Doppler and fistulogram.

6. **0% Recirculation & Low Access Flow Pinpoints Stenoses Between Needles**

When a significant stenosis is located between the hemodialysis needles, hemodialysis pump flow simply bypasses the stenosis without producing any recirculation.

When low access flow (Fig. 9) is accompanied by 0% recirculation (Fig. 8), a stenosis between the dialysis needles can be suspected. A stenosis between the needles can be confirmed by a color Doppler image.

7. **Cardiac Output Check Indicates Potential Cardiac Overload**

In the case example on the right, vascular access flow measured more than 3 L/min (Fig. 10). Cardiac output exceeded 10 L/min (Fig. 11). When the vascular access was briefly occluded by the tip of the examiner’s finger, the patient’s pulse rate dropped from 112 to 88 per min. This patient had complained of chest pains and had been diagnosed with cardiomegaly.

The access was surgically revised by banding. Following the revision, access flow then measured 1700 mL/min. Cardiac output dropped to 7-8 L/min. The patient exhibited fewer post-dialysis hypotensive episodes, his dry weight decreased, his chest X-Ray cleared and he reported significant improvement in his previous symptoms.
Hemodialysis Adequacy

- Tests calibration of the blood pump;
- Verifies true delivered blood flow and compares delivered blood flow to pump setting to identify flow disparity and avoid underdialysis. If disparity is significant, Flow-QC® assists in determining cause (blood pump calibration versus inflow restriction/excessive pre-pump negative arterial pressure);
- Detects and quantifies access recirculation in AV access and catheters;
- Identifies inadvertent reversal of dialysis lines to prevent recirculation and/or underdialysis;
- Determines proper needle placement;
- Identifies sources of large negative arterial blood line pressure (and its resulting underdialysis);
- Determines the most appropriate blood pump setting for a low flow access when it is not feasible to increase access flow;
- Provides delivered flow and recirculation measurements to maximize catheter function.

Vascular Access Measurements

- Tells actual function in AV grafts and fistulas in order to identify failing accesses and avert underdialysis and/or thrombosis;
- Indicates effectiveness of interventions (post-intervention surveillance) or limb ischemia;
- Excludes access dysfunction quickly as cause of underdialysis;
- Identifies a mid-access obstruction;
- Identifies high-flow versus low flow accesses to select ideal treatment plan for correction (flow-restricting versus re-vascularization procedure);
- Permits access surveillance to be performed by the clinic’s staff who then can alert nephrologist to possible onset of access dysfunction & referral for early intervention;
- Implements KDOQI Guidelines;

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Numbers in parentheses () are Transonic Reference #s.

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HemodialysisBibliography(DL-5-ref)Rev A 2013
Validations and Methodology of Vascular Access Flow Measurement


Predictive Power of Access Flow Measurements


**The Gold Standard**

**Dialysis Adequacy**

**Zero Vascular Access Recirculation - A New Reality**


**Discrepancy between Prescribed and Delivered Pump Flow (Qb) in the Vascular Access**


**Catheter Recirculation and Delivered Flow**


**Teruel LL et al, “Differences between Blood Flow”**


Cardiac Function

Methodology, Validations, Applications


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Pandeya S, Lindsay RM, "The Relationship between Cardiac Output and Access Flow during Hemodialysis," ASAIO J 1999; 45(3) 135-138. (HD89A, HD74, HD50A)


Ondocin PT et al, "The Influence of Beta Blockade on Autonomic Neuropa-thy and Cardiovascular Function in Patients on Hemodialysis (HD)," J Am Soc of Nephrol Abstr 2001; A2084. (HD243A)


Nikiforov UV et al, "Validation of a New Method to Measure Cardiac Output during Extracorporeal Detoxification," ASAIO J 1996; 42: M903-M905. (HD15V)


Vascular Access Management
“A Circle of Care®”

Proactive vascular access management depends upon a trio of Transonic® flow measurements that guide the surgeon, the nephrologist and the interventionalist throughout the natural history of a vascular access.

- Surgical creation of AV access: Transit-time ultrasound (intraoperative) flow measurements foretell successful maturation.
- During hemodialysis: Transonic® ultrasound dilution measurements provide ongoing surveillance and trending to detect development of hemodynamically significant stenoses.
- Intervention/Revision: When an access problem is identified, intragraft flow measurements guide the interventional radiologist during percutaneous transluminal angioplasty (PTA). Intraoperative flow measurements guide surgical revisions to resolve complications such as “steal” syndrome.
Access Creation: Intraoperative Blood Flow Measurements

The Centers for Medicare and Medicaid Services (CMS) Fistula First Break-through Initiative’s success has transformed the hemodialysis access in the United States from a “graft-oriented culture” to a “fistula-oriented culture.” Since 2012 more than 60% of American hemodialysis patients have AV fistulas.¹ Yet, the number of fistulas that do not mature (estimated to be between 28-50%)² continues to confound and challenge the hemodialysis care provider.

In his landmark 1998 study in Surgery, Johnson et al reported that for an AV fistula to mature, a venous outflow equal or greater than 100 mL/min at its creation is advised. For an AV prosthetic graft, an initial venous outflow of less than 250 mL/min is associated with a higher rate of initial graft failure.³ As the access matures and arterializes, flow generally increases to levels needed for hemodialysis (greater than 500 mL/min). To ensure adequate flow for hemodialysis, Transonic® intraoperative blood flow measurements provide the surgeon with quantitative flow values during creation of the access (Fig. 1). Johnson and others report that intraoperative blood flow rates at access creation directly correlate to access outcomes including: patency, number of interventions, and length of hospital stays.

“Adequate blood flow in peripheral hemodialysis fistulae and grafts is vital to the success of hemodialysis and to the survival of the patient. Reduction in flow ... presages failure of the access device itself. Access flow can therefore be considered a fundamental property of the access that should be monitored.” - Depner, TA et al,
Hemodialysis: Surveillance

The Kidney Disease Outcomes Quality Initiative (KDOQI) Clinical Practice Guidelines for Vascular Access and the National Kidney Foundation codified Dr. Depner’s advocacy of access flow monitoring by stating “prospective surveillance of AV grafts and fistulas for hemodynamically significant stenosis, when combined with correction, improves patency and decreases the incidence of thrombosis.”

Canadian, Australian and European Guidelines also call for surveillance during hemodialysis to forestall stenosis formation and prolong the life of the access. Intra-access measurements (ultrasound dilution technology) are cited as the preferred method for surveillance.

Transonic’s ultrasound dilution technology is recognized as the “gold standard’ intra-access flow measurement technology for hemodialysis patient surveillance. The method uses Transonic Flow-QC® Hemodialysis Monitors and Flow/dilution Sensors to directly measure dialysis adequacy (delivered blood flow, recirculation) for on-the-spot correction of problems during hemodialysis and to trend vascular access flow to detect flow limiting problems wherever they occur in a vascular access (Fig. 2). Cardiac output and associated parameters can also be measured with this technology during the dialysis treatment.
Vascular Access Revision

Intra- graft Flow Measurements

During angioplasty, a Transonic® ReoCath® Flow Catheter and Endovascular Flowmeter provide the interventionalist with immediate flow feedback (Fig. 3) for quantitative confirmation that a hemodynamically significant stenosis has been corrected or that elastic recoil has not compromised the flow correction.

Intraoperative Flow Measurements

When surgery is the access revision option, intraoperative flow measurements inform during the revision. Transonic® quantitative measurements replace guesswork especially when an access needs to be banded to mitigate ischemic steal syndrome.

Conclusion

In the outcomes-driven climate of proactive end-stage renal disease (ESRD) care, Transonic® quantitative flow measurements are integral to successful and comprehensive vascular access management. During creation of the access, during hemodialysis and/or during interventions or revisions, respective Transonic® flow measurements inform and guide the surgeon, nephrologist and/or interventionalist as they seek to create and maintain a healthy access for their patients. Transonic® flow-based “Circle of Care” is a cornerstone for proactive Vascular Access Management.

REFERENCES

1 http://www.fistulafirst.org/