Hemodialysis Handbook

Copies of this handbook may be ordered from Transonic Systems Inc.
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I. Introduction: Hemodialysis: Flow-based Best Practices

A. 2019 KDOQI Life-Plans

The National Kidney Foundation's Kidney Disease Outcomes Quality Initiative (KDOQI) provides evidence-based guidelines for hemodialysis vascular access intended to assist multi-disciplinary practitioners' care for chronic kidney disease patients and their vascular accesses.

Three years in development, the 2019 Update of the KDOQI Clinical Practice Guideline for Vascular Access offers a different approach to vascular access care than in the past. These Guidelines emphasize a more patient-focused approach and recommend development of an End-Stage Kidney Disease (ESKD) Life-Plan that takes each patient's individual needs and preferences into consideration when choosing an access. The Guidelines also call for planning proactively for the likely complications and remediations of a current access.

Along with a LifePlan, the Guidelines also include new topics such as guidance on vascular access choice, new targets for arteriovenous (AV) fistulas and grafts and central venous catheters, management of specific complications, and renewed approaches to some older topics such as surveillance. The Guidelines readdress some of the practices previously considered "Best Practices." This paradigm shift in emphasis away from recommendations of standardized "Best Practices," such as encouraging a "Fistulas First" approach, now urge providers to think, during planning the first access, not only about what type of access should be first, but what type of accesses will follow. In other words, the updated Guidelines call for a customized approach for each patient that includes a map of care for the present and into the future - a Life-Plan.

The Guidelines call for the planning for dialysis modalities and vascular accesses over the course of the patient's life to ensure that future needs are always being considered. For instance, a patient may initiate dialysis with peritoneal dialysis (PD), but then receives a kidney transplant. If the kidney transplant fails, the patient may then transition to an in-center hemodialysis facility, while becoming trained for home hemodialysis. Such forward planning can have many benefits, including helping preserve vessels needed for successful future AV access creation and use, and avoiding unnecessary procedures and complications.

Summary

The 2019 Update of KDOQI Guidelines has refocused recommending creation of a patient's Life-Plan first that incorporates his or her corresponding access needs. Addressed are the preparation for and creation of vascular accesses, the care and management of each type of vascular access, and the prevention and treatment of complications. While continuing to emphasize high-quality standards, there is a greater emphasis on the need for improved training and application of physical vascular access monitoring, and a corresponding de-emphasis on the need for AV access surveillance.

The Guidelines present primary targets for use in tracking performance reasonably. The primary target is that each patient has a regularly updated Life-Plan designed with his/her goals in mind to achieve the most suitable dialysis access type and with consideration of changes in circumstances. Its goal is to support practices that will lead to the ideal vascular access that is reliable, complication-free, able to deliver prescribed dialysis, and is suitable for each patient's needs.

B. Physical Exam - A Primary Component of a Life-Plan

A primary component in the 2019 KDOQI proposed Life-Plan is to have a regular physical examination or check of an arteriovenous fistula (AVF) or graft (AVG) by a knowledgeable and experienced healthcare practitioner in order to detect clinical indicators of flow dysfunction in an AVF or AVG.

Guideline 13. AV Access Flow Dysfunction — Monitoring/Surveillance
Appropriate use of Monitoring/Surveillance for AV Access Flow Dysfunction

13.1 KDOQI recommends regular physical examination or check of the AVF, by a knowledgeable and experienced health practitioner, to detect clinical indicators of flow dysfunction of the AVF. (Conditional/Strong Recommendation, Moderate Quality of Evidence)

13.2 KDOQI recommends regular physical examination or check of the AVG, by a knowledgeable and experienced health practitioner, to detect clinical indicators of flow dysfunction of the AVG. (Conditional/Strong Recommendation, Moderate Quality of Evidence)

13.4 There is inadequate evidence for KDOQI to make a recommendation on routine AVF surveillance by measuring access blood flow, pressure monitoring, or imaging for stenosis, that is additional to routine clinical monitoring, to improve access patency.

Note: In other words, monitoring of vascular access is primary, while surveillance findings are supplementary, and action should not be based solely on surveillance findings.

13.5 KDOQI does not suggest routine AVG surveillance by measuring access blood flow, pressure monitoring, or imaging for stenosis, that is additional to regular clinical monitoring, to improve AVG patency. (Conditional Recommendation, Low Quality of Evidence)

Note: In other words, monitoring of vascular access is primary, while surveillance findings are supplementary, and action should not be based solely on surveillance findings.

C. Transonic HD03 Surveillance

Vascular Access Flow: Transonic vascular access surveillance measures access flow directly for an immediate snapshot of access function. Trending of these measurements over time provides data to indicate flow-limiting conditions anywhere in the circuit. A drop in access flow may signal formation of a stenosis in time for proactive minimally invasive intervention by the dialysis care team.

Of note: the Achilles Heel in intervention is actually the lack of practice by most physicians outside of the University setting, to quantitatively measure access flow before, during and post intervention. Due to this, many interventions fail

due to lack of adequate measurements and quality controls of the intervention. One cannot verify intervention success based on subjective metrics and thus, many studies have pointed to a failure of intervention success.

Dialysis Adequacy: The Hemodialysis Monitor also can be used to optimize dialysis delivery by measuring true delivered pump blood flow and recirculation in AV fistulas, grafts and catheters to ensure optimal delivery of a KT/V prescription. By measuring true delivered blood flow through dialysis tubing and then comparing this true flow to the pump's reading, any flow limiting cause can be identified and corrected on the spot. The Hemodialysis Monitor also detects and quantifies access recirculation in AV fistulas, grafts and catheters. Measurements in catheters (page 19) are used to establish a maximum dialysis pump setting before recirculation occurs. Known flow and recirculation values can also be used to adjust the length of dialysis, identify flow restrictions and failing CVCs, and determine the best connections between a CVC and the blood lines.

ESRD Life-Plans Supported by HD03 Measurements

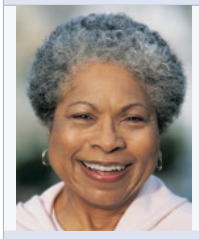
Examples of customized ESKD Life-Plans for vascular access with inclusion of Transonic HD03 measurements include the following: a young patient, an elderly patient, an acute start patient and a home dialysis patient.

I. Flow-based Hemodialysis Best Practices cont.

Young Patient: 28-year-old male	Description	ESRD Life-Plan Modality Choice	Dialysis Access	Comments
	Alport syndrome with rapid CKD progression requiring dialysis initiation, multiple abdomen surgeries related to a trauma, R handed, plays guitar/drums in a band.	1. HD outpatient 2. Evaluation for living related Tx or Tx waiting list 3. Return to HD if needed to return to dialysis post-transplant	1. Lower arm endovascular AVF (left) 2. BC-AVF (left) if endovascular AVF fails	* Endovascular AVF preferred to reduce steal syndrome risk or mega fistula to avoid impairment of his ability to play guitar or drums. Reduce physical disfigurement from a surgical AV access. * Follow closely, lifelong anticipated

Transonic Measurement Clinical Application:

- Routine clinical examination (look, listen, feel, arm elevation and augmentation) should be used regularly as part of the pre-cannulation process.
- Transonic Access Flow measurements can be used with with a clinical examination to detect/confirm indications of access dysfunction.
- A potential for cardiac overload exists if the Access Flow is > 1600mL/min. Evaluate patient for signs and symptoms of high-output cardiac failure if Access Flow reaches the high range.

Elderly Patient 80-year-old female	Description	ESRD Life-Plan Modality Choice	Dialysis Access	Comments
	CDM, HTN, CHF, vision issues, CKD rapidly advancing with multiple hospitalizations, lives with her husband, active but does require the use of a walker, R handed	1.Hemodialysis outpatient	1. Forearm early cannulation AVG 2. Secondary upper arm AVF	* Patient likely has a limited life expectancy * Focus on AV access and limiting CVC dependency vs. preserving sites for future access

Transonic Measurement Clinical Application:

- Routine clinical examination (look, listen, feel, arm elevation, augmentation) should be used regularly as part of the pre-cannulation process.
- Transonic Access Flow measurements can be used with a clinical examination to detect/confirm indications of access dysfunction.
- A potential for cardiac overload exists if the Access Flow is > 1600mL/min. Evaluate patient for signs and symptoms of high-output cardiac failure if Access Flow reaches the high range.

I. Flow-based Hemodialysis Best Practices cont.

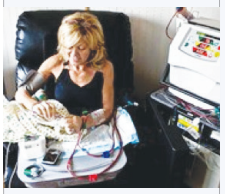
Acute Start Patient: 45-year-old male crash-lands on HD	Description	ESRD Life-Plan Modality Choice	Dialysis Access	Comments
	Acute start with no prior treatment of CKD; Urgent placement of HD catheter for hemodialysis, lives alone and lacks family support, R handed	1. Acute HD 2. HD outpatient 3. Evaluate for transplant and placement on the transplant waiting list	1. Tunnel Cuffed Catheter 2. RC-AVF (left) 3. Transplant while maintaining the vascular access if needed for return to hemo dialysis	* Follow closely, life-long anticipated * Flexibility required as Life-Plan may change * Life-Plan must consider multiple modalities and optimize dialysis access

Transonic Measurement Clinical Application:

- Utilize Delivered Flow and Recirculation as part of the hemodialysis catheter algorithm for "On The Spot" catheter adequacy check and adjustment of blood flow rate and or catheter connection configuration as needed. Utilize this in both the acute hospital setting and outpatient hemodialysis facility.

Once the RC-AVF is created and being utilized as the dialysis access:

- The routine clinical examination (look, listen, feel, arm elevation and augmentation) should be used regularly as part of the pre-cannulation process.
- The Transonic Access Flow measurements are intended to be utilized in conjunction with the clinical examination to detect/confirm indications of access dysfunction.

Home HD Patient: 55-year-old female	Decription	ESRD Life-Plan Modality Choice	Dialysis Access	Comments
	On hemodialysis for 3 years including home HD for past 2 years. CKD caused by nephrotoxic chemotherapy drugs to treat previous colon cancer, R handed.	1. Home Hemodialysis 2. Waiting to reach 5 plus years post cancer to be evaluated for a kidney transplant	1. PRC-AVF 2. Revision of her current AVF if fails or move up the arm for new AVF	* Maximize the lifespan of her current RC-AVF * Preserve R arm vessels above the current RC-AVF for any required revision of creation of a new AVF above the current RC location.

Transonic Measurement Clinical Application:

- Routine 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 the clinical examination to detect/confirm indications of access dysfunction.

Hemodialysis Vascular Access Trending

On-the-spot vascular access assessment with the HD03 helps you safeguard the health of your patients by ensuring dialysis adequacy through measurements of pump flow and vascular access recirculation in AVFs, AVGs and catheters. Vascular access flow can also be trended in AVFs and AVGs. This ultrasound dilution technology works by having paired flow/dilution sensors clip onto dialysis tubing and to measure flow within the tubing. Measurements take less than 10 minutes per patient.

Using the HD03 during Hemodialysis

Transonic HD03 Hemodialysis Monitor measures vascular access flow directly in AVFs and AVGs for an immediate snapshot of access function and detection of any flow limiting problems within the vascular access circuit.

The HD03 Hemodialysis Monitor is also used to optimize dialysis delivery by measuring delivered pump blood flow and recirculation in AVFs and AVGs. Delivered pump flow and recirculation can also be measured in central venous catheters to optimize dialysis by helping to establish a maximum dialysis pump setting before recirculation occurs.

How Does the HD03 Help the Dialysis Care Team?

With the best interests of their patients always at heart, the staff can quantify access recirculation in AVFs, AVGs and catheters; avoid inadvertent reversal of dialysis lines to prevent recirculation and/or underdialysis, and readily identify a discrepancy between pump setting & delivered blood flow. They can ensure correct needle placement during cannulation; confirm that there is 0% recirculation and readily detect inflow, outflow or between needle stenoses.

How Does the HD03 Help the Nephrologist?

The staff can alert the nephrologist to possible onset of access dysfunction and referral for early intervention. From HD03 measurement results, a nephrologist gleans myriad information that helps in the selection of an ideal treatment plan tailored to each patient. By knowing the actual function in arteriovenous grafts and fistulas, a nephrologist can identify a failing access and avert underdialysis and/or thrombosis. HD03 Trending will also exclude access dysfunction as a cause of underdialysis. It identifies a mid-access obstruction and in patients with access problems, it identifies whether the problem is from too much or too little flow which guides the choice for correction.

1. Hemodialysis Adequacy in AVFs, AVGs and Catheters[1]

- Tests calibration of the blood pump;
- Verifies true delivered blood flow; compares delivered blood flow to pump setting to identify flow disparity and avoid underdialysis. If disparity is significant, the HD03 assists in determining cause (blood pump calibration versus inflow restriction/excessive pre-pump negative arterial pressure);
- Detects and quantifies access recirculation in AVFs, AVGs, 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.

2. Vascular Access Measurements in AVFs, AVGs[1]

- Measures actual function in AVFs and AVGs in order to identify failing accesses and avert underdialysis and/or thrombosis;
- Indicates effectiveness of interventions (post-intervention Trending) 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 Trending to be performed by the clinic's staff who then can alert nephrologist to possible onset of access dysfunction;

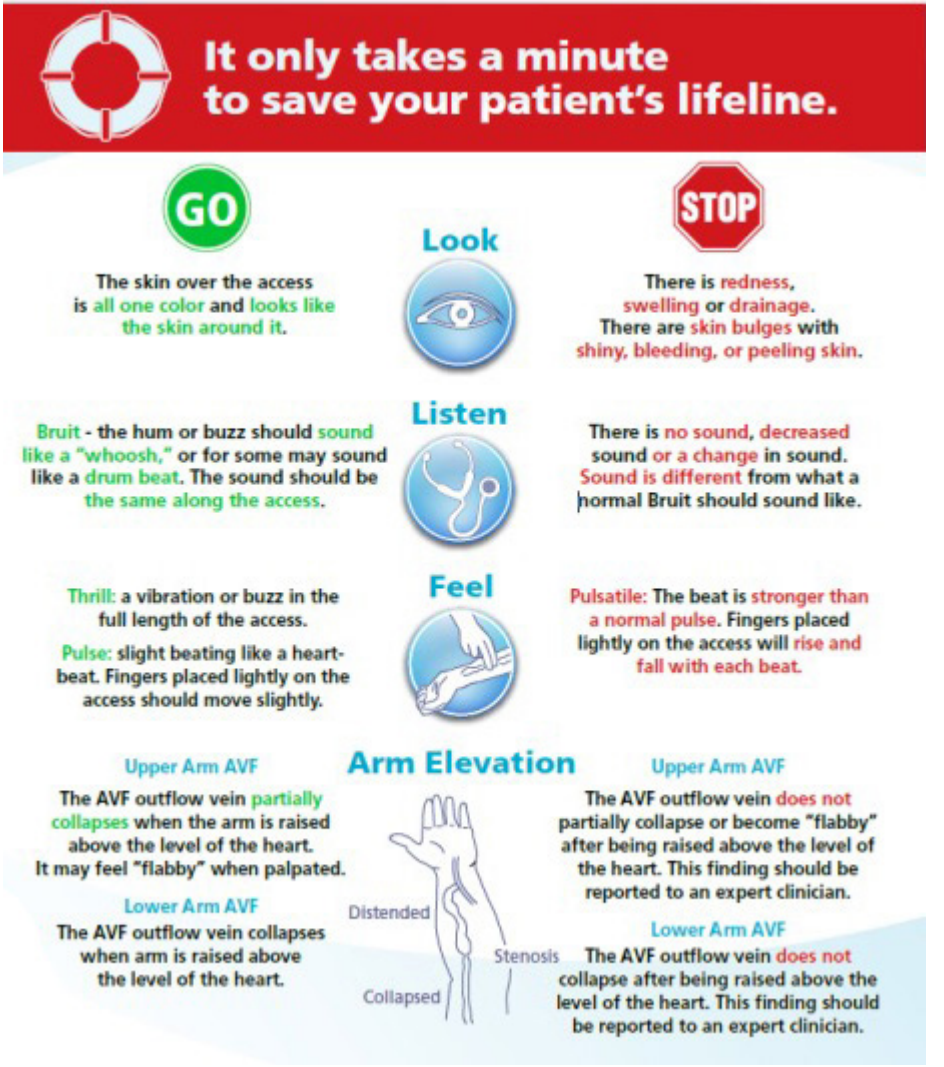
How Does HD03 Trending Help the Clinic?

By proactively being able to address vascular access or treatment problems of patients, a clinic is able to retain patients and keep their chairs filled. Appointments are not missed because emergencies are averted before a patient needs to go to a hospital. This translates into significant cost savings for a clinic.

Secondly, a clinic benefits because its best practices comply with Medicaid ESRD Conditions for Coverage requirement for access monitoring and surveillance to detect access dysfunction.

Access Monitoring

KDOQI defines monitoring, as "applying physical examination techniques to detect access dysfunction." When performed correctly, monitoring can identify most access dysfunction.



How Does HD03 Trending Help the Patient?

A hemodialysis patient's link to life is his or her vascular access. It is also the Achilles heel of hemodialysis, for the consequences of a thrombosed or failing access are dire. HD03 Trending ensures the maintenance of a healthy access. With HD03 Trending the formation of a stenosis is readily identified so that a problem can be proactively addressed, rather than having the patient rushed to a hospital for emergency treatment or a thrombectomy. Patients experience less morbidity. Ultimately, HD03 Trending can help extend a patient's life.

2018 ESVS Clinical Practice Guideline Recommendations

#45	Vascular access Trending is performed by flow measurement in AVGs monthly and AVFs every 3 months.
#46	When AVF blood flow measurements during dialysis indicate the presence of a vascular access stenosis based on a Qa < 500 mL/min, angiographic assessment of the access should be considered.
#47	Venous pressure adjusted for the mean arterial pressure >.50 (or derived static venous pressure adjusted for the mean arterial pressure .>55) is not a reliable indicator of stenosis and intervention based on this finding is not recommended.
#48	When hemodialysis efficiency is impaired, investigation and correction of an underlying vascular access stenosis should be considered.

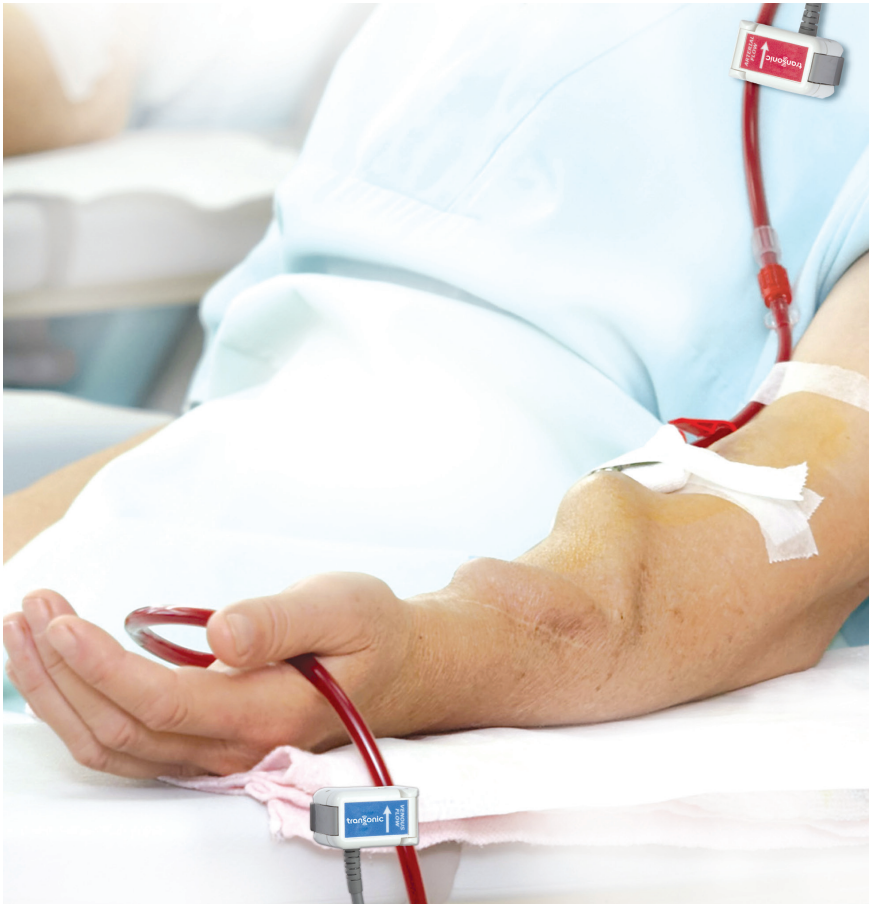
Schmidli J *et al*, Vascular Access: 2018 Clinical Practice Guidelines of the European Society for Vascular Surgery (ESVS), Eur J of Vasc & Endovasc Surg May 2018., page 33.

2019 KDOQI Guidelines for Monitoring of AV Grafts and Fistulas

The 2019 KDOQI Vascular Access Guidelines call for an "End-Stage Kidney Disease Life-Plan" (an individualized and comprehensive map for dialysis modalities and vascular access for the lifetime of the patient).

- Primary in the Life Plan is to have a regular physical examination or check of an AVF or AVG in every patient by an experienced health practitioner in order to detect clinical indicators of flow dysfunction in the AVF or AVG.
- If clinical indicators of flow dysfunction present, they can be corroborated and quantified in true mL's/min to remove any reasonable doubt by Transonic HD03 flow monitoring and trending of vascular access flow data.

II. Flow-based Vascular Access Management



II. Flow-based Vascular Access Management cont.

A. Ultrasound Dilution Technology

1. Vascular Access Flow Methodology

The Transonic® Hemodialysis Monitor utilizes two technologies: ultrasonic transit time and indicator dilution[9-11]. Transonic transit-time ultrasound flow measurements through sterile tubing for blood flow verification. Transonic ultrasound dilution access flow measurement, the "Krivitski Method®," is the technology for access flow measurements in dialysis patients. The Krivitski Method calls for the temporary reversal of arterial and venous blood lines at their respective needle connections to create mixing conditions conducive for an indicator dilution flow measurement when a bolus of isotonic saline is injected into the blood circuit (Fig. 2.1). Classic dilution equations are used to calculate vascular access flow.[10-12]

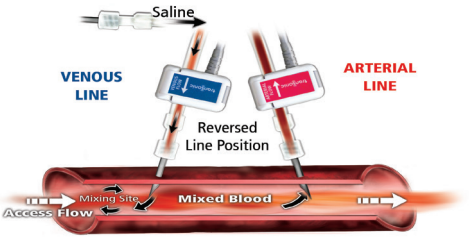


Fig. 2.1: "Krivitski Method"is the temporary reversal of blood lines at needle connections to create proper indicator dilution mixing conditions. When dialysis lines are reversed to induce recirculation, vascular access flow (Q_a) can be calculated.[10]

2. Vascular Access Flow Measurements

Access flow measurements can be performed in either prosthetic grafts or fistulas created with an end-to-side anastomosis (Fig. 2.1).[11-13] The dialyzer removes blood from the venous side of the access and returns the blood to the arterial side to create the mixing conditions needed for an indicator dilution measurement of access flow (Fig. 2.2).

When saline is introduced into the venous line, it dilutes the blood's protein concentration and reduces ultrasound velocity. This diluted blood is first detected by the flow/dilution sensor clipped onto the venous blood line and the Monitor's software generates a venous dilution curve. The diluted blood from the venous line then enters the access and

mixes with incoming access flow. Upon reaching the arterial needle, a portion of mixed blood is removed from the access by the dialyzer. This mixed (diluted) blood is detected by the arterial flow/dilution sensor and the Hemodialysis Monitor's software generates an arterial dilution curve. Access flow is calculated from the ratio of the area under the venous curve to the area under the arterial curve (Fig. 2.4). The use of two sensors effectively eliminates multiple factors, such as viscosity that can influence ultrasound velocity.

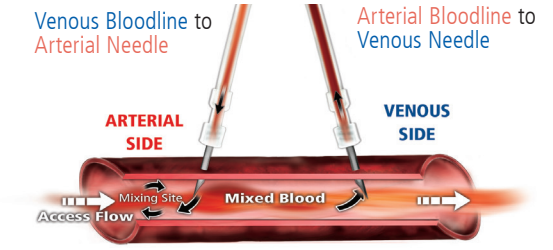


Fig. 2.2: Hemodynamics of access flow measurement with lines reversed by Krivitski Method. Line reversal creates an artificial recirculation loop with a mixing site at the arterial side of the access.

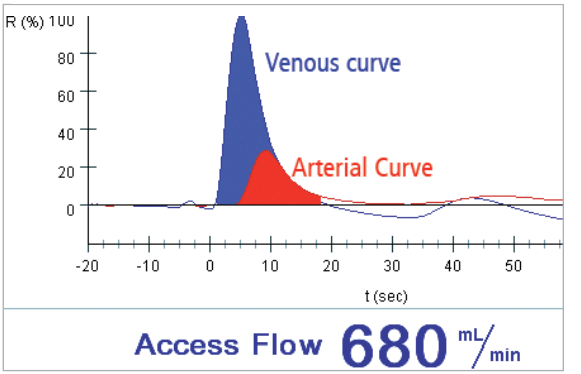


Fig. 2.3: Result showing flow/dilution curves and access flow measurement of 680 mL/min flow.

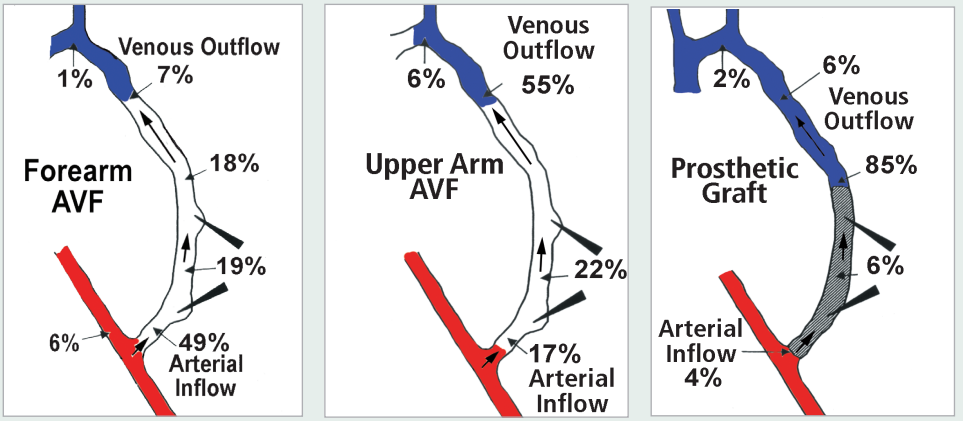
Tips for Adequate Saline Mixing in Fistulas

1. If delivered blood flow is 200-300 mL/min, any needle orientation (toward or away from incoming access flow) produces adequate mixing for up to 2 liters of flow.
2. In fistulas with a large aneurysm, or in upper arm fistulas with >2 L/min of flow, the arterial needle should be positioned so that it faces incoming access flow.

Transonic® Vascular Access Measurements

Transonic vascular access measurements detect hemodynamically significant stenoses at all sites within an access circuit (arterial inflow, between the dialysis needles, venous outflow) in both AV fistulas and prosthetic grafts. While other technologies can detect venous outflow stenoses, the site where most stenoses form in prosthetic grafts, they do not detect stenoses at all sites within the circuit.

In prosthetic grafts, most stenosis occur at the venous outlet. This is not the case in fistulas where a significant number of stenoses may also occur at the arterial inlet and/or between the needles. This makes the Transonic Monitor's capability to measure flow to detect stenoses anywhere in the circuit unique. KDOQI Guidelines acknowledge that inflow stenoses are more common than previously believed and occur in up to one-third of patients with clinical symptoms of venous stenosis or thrombosis.[1,20-21]



Arterial inflow	49%	Arterial inflow	17%	Arterial inflow	4%
Between Needles	19%	Between Needles	22%	Between Needle	6%
Venous Outflow	18%	Venous Outflow	55%	Venous Outflow	85%

Stenosis Sites in AV Fistulas and Grafts: The figures above show the sites of most frequent stenoses for AV fistulas and prosthetic grafts. Note that in forearm fistulas, 49% of stenoses are inflow stenosis. Adapted from Turmel-Rodrigues *et al*, Nephrol Dial Transplant 2000; 15: 2029-2036.[22]

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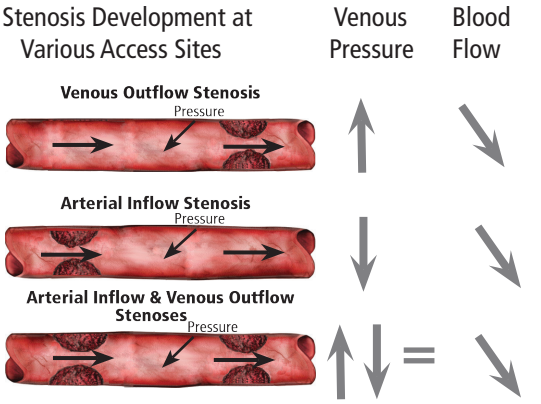
3. Venous Pressures Do Not Correlate with Flow Measurements[7-8]



The top graphic demonstrates increased resistance caused by a stenosis located past the venous pressure measurement site. Venous pressure increases; flow decreases. With an inflow stenosis, before the point where pressure is measured (middle graphic), venous pressure decreases. If multiple stenoses occur (bottom), one before the pressure measurement site, and another after, the two pressure components can cancel one another out, and result in no change in venous pressure. However, stenoses that decrease access flow can form at all sites within an access.

B. Vascular Access Trending Program

Many guidelines advise that periodic access flow measurement is an effective tool for predicting ow limiting stenoses and declining access health.[1-4] To establish a Vascular Access Trending program, the nephrologist sets a:

Monthly measurements are ideal to spot the onset of stenosis. For native fistulas, the thresholds are located in the graph on the next page.

Nephrologists should also consider a patient's history when setting flow thresholds to ensure that the level is set high enough to permit proactive action before access failure.

Upper Access Flow Threshold: A third threshold to be observed is the Upper Access Flow Threshold. It is generally accepted that in both fistulas and grafts, 2000 mL/min is a valid upper access flow threshold. Above 1500 mL/min, the patient may be at risk for cardiomegaly or other conditions resulting from cardiac overload.

II. Flow-based Vascular Access Management cont.

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.**

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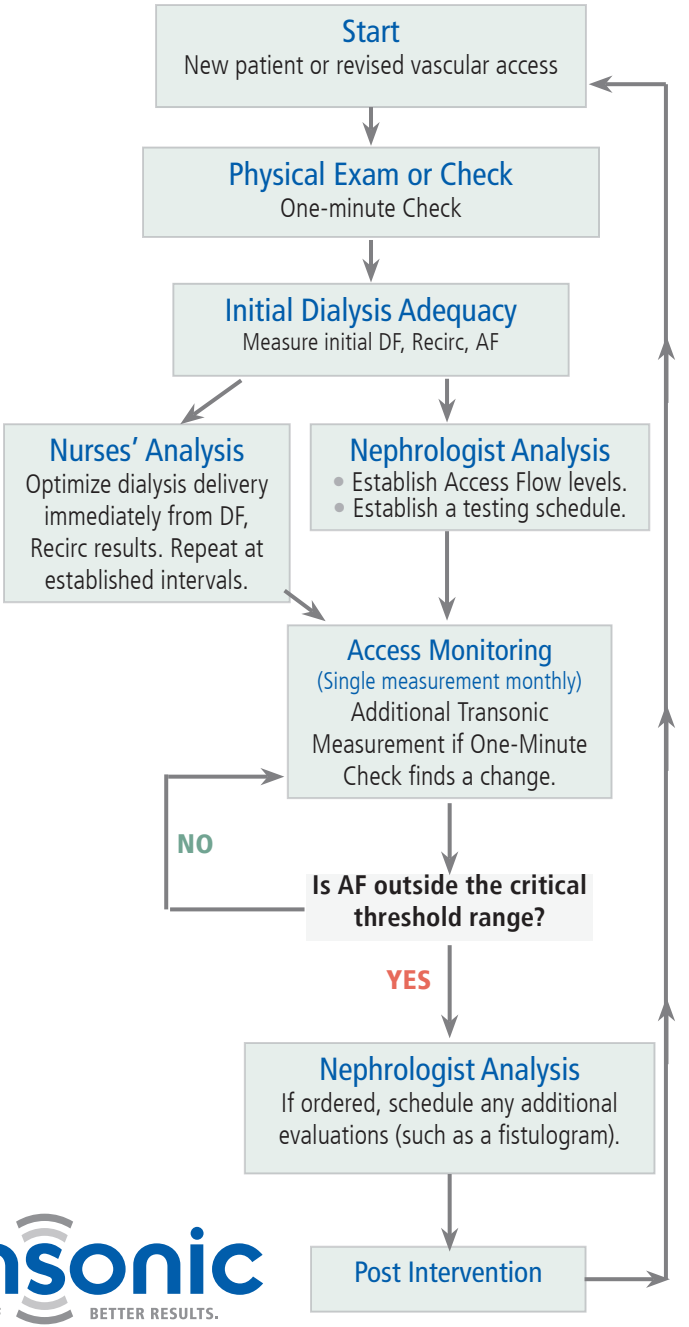
Minimizing Access Flow Measurements Errors

Published data[15-18] suggest the application of some simple rules during access flow data analysis. The following recommendations are advised to improve outcome quality:

- For AV grafts, examine two criteria: an absolute threshold et by the nephrologist and a dynamic threshold of a 25% decrease within four months. Using both these thresholds should decrease false-positive rates. The dynamic threshold may be more predictive of stenosis. Using only one threshold may not be as effective and may lead to a misleading message about the effectiveness of flow trending.[18]
- It is recommended that access flow measurements be performed during the first hour and one-half to two hours of a dialysis session. However, this approach may not always avoid hypotensive episodes or other abnormal situations. If a 20-30% decrease in flow is observed, it may be the result of significant stenosis, or a decrease in systemic pressure. If a significant decrease in mean arterial pressure (MAP) is observed, the patient's previous access flows and MAPs should be reviewed.[16-17] Before the patient is referred for angiography, the access flow measurement should be repeated at the patient's next session to confirm that the decrease also exists when the patient's MAP is normal.
- Flow measurements should be performed at least once a month in AV grafts to avoid thrombosis events.[18]

II. Flow-based Vascular Access Management cont.



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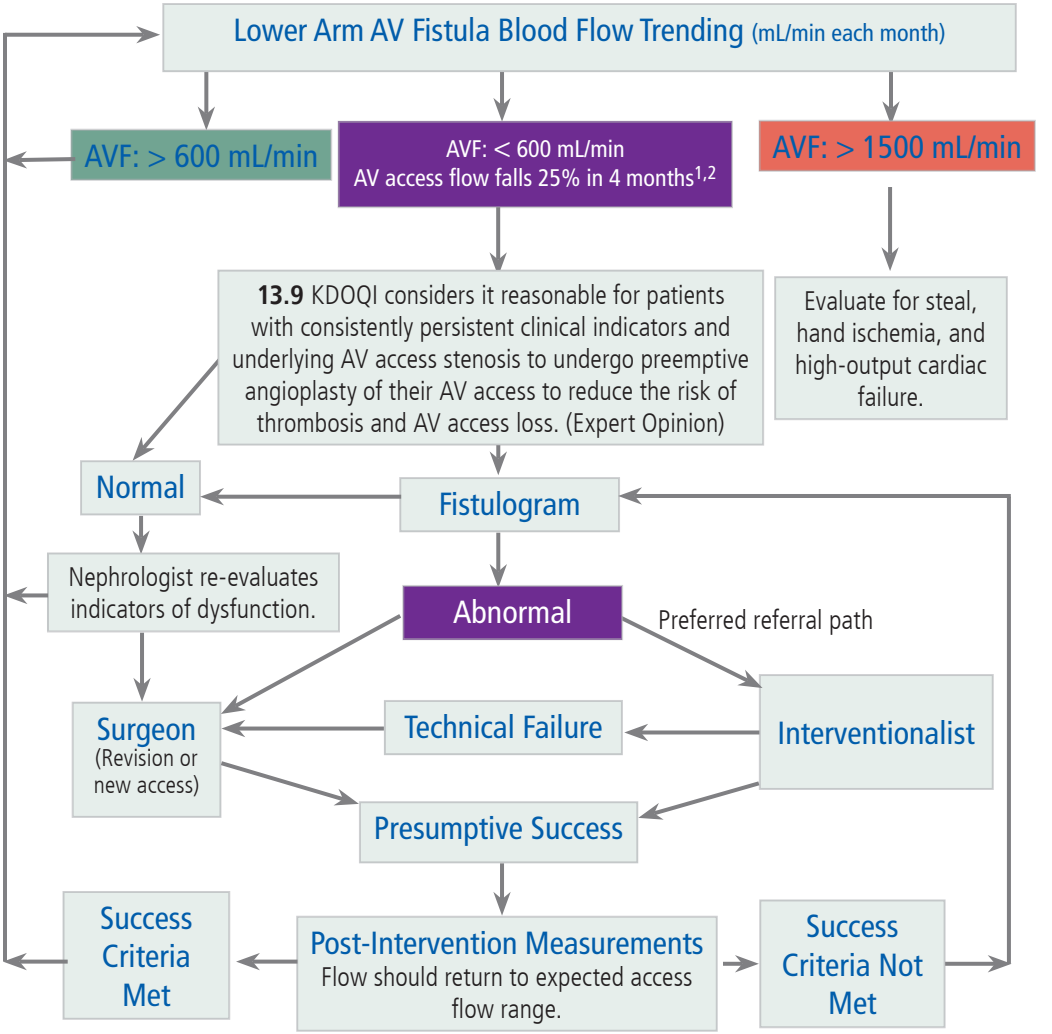
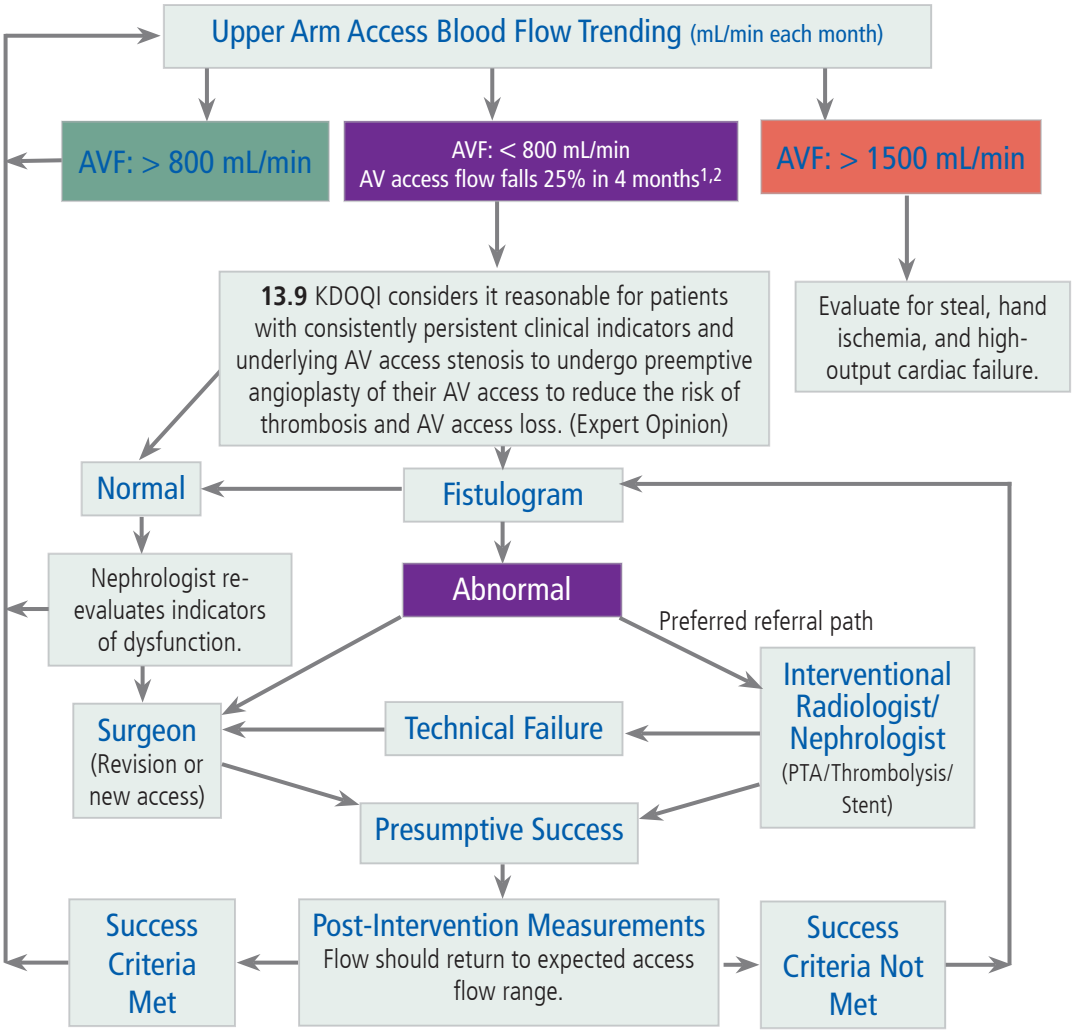
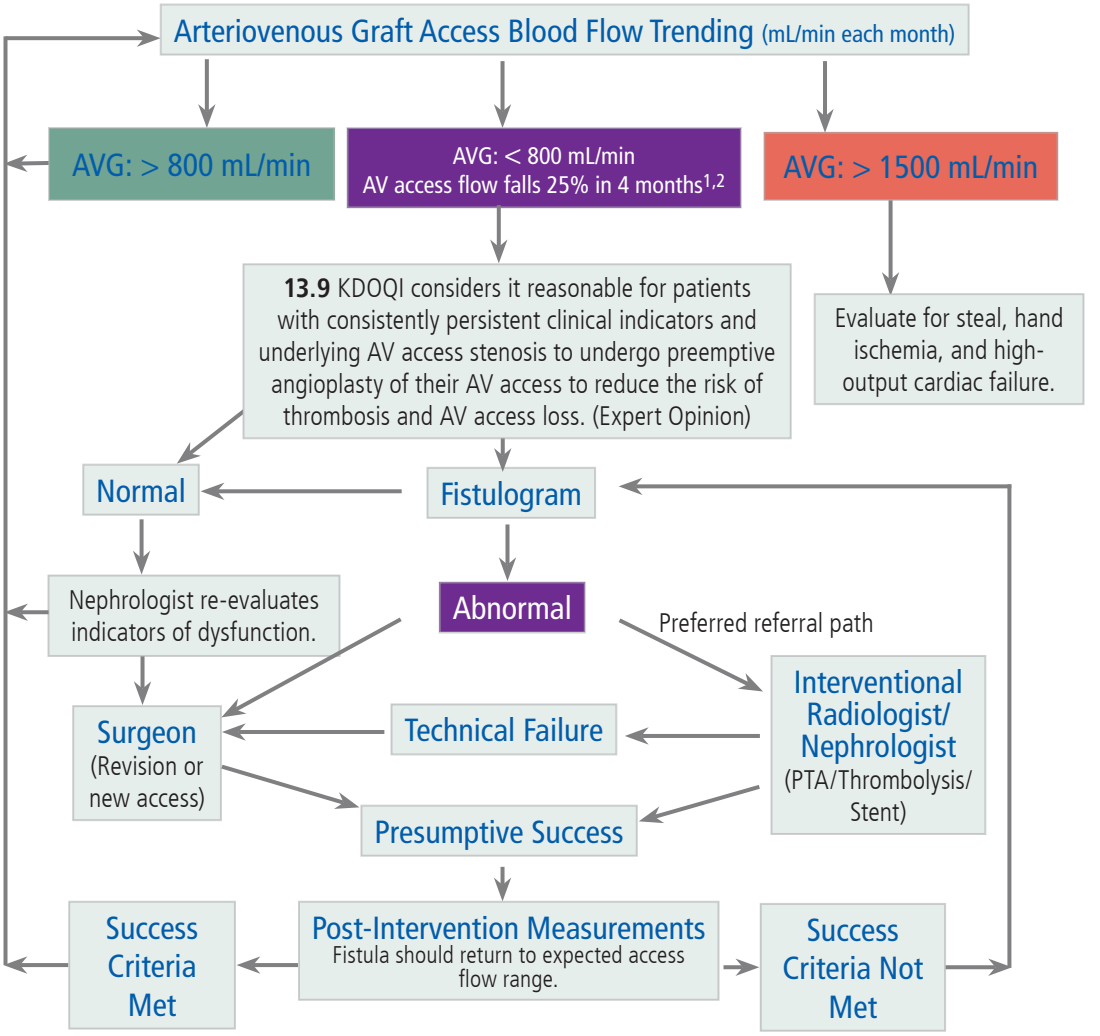
II. Flow-based Vascular Access Management cont.



II. Flow-based Vascular Access Surveillance cont.



II. Flow-based Vascular Access Surveillance cont.



C. Multi-disciplinary Vascular Access Care Program[23]

Multi-disciplinary vascular access care programs to proactively address access-related morbidity among hemodialysis patients. These programs are designed to improve all vascular access-related outcomes, prolong vascular access life, and reduce hospitalization costs associated with the vascular access.[6] Benefits include improved quality care and satisfaction outcomes, cost-effectiveness, optimizing seamless care delivery, and empowering the nephrologist in the delivery of vascular access care.

Duda *et al's* Process Implementation Model on the following pages presents the process and timetable for implementation and core competencies. An Assessment Phase evaluates the current access care and baseline data. This is accompanied by a thorough and ongoing Educational Phase to develop vascular access core competency among all team members. The heart of a vascular access care program is a fully integrated and proven Access Management Program and referral process. The objectives of these protocols are to:

- Detect and intervene when significant access stenosis is suspected to prevent access thrombosis;
- Prolong access life;
- Prevent inadequate dialysis;
- Reduce access-related morbidity and hospitalizations;
- The number of missed dialysis treatments.

Other components of the program include the Diagnosis Phase to identify patients at risk for vascular access stenosis or other causes of access dysfunction to determine whether an intervention should be radiologic or surgical. During the Intervention Phase the patient actually undergoes a procedure to correct the diagnosed complication. Finally, Documentation of vascular access care program indicators is essential for the success of the continuing quality improvement (CQI) process. CQI recommends monthly analysis of data and benchmarking of vascular access performance criteria.

This and other multi-disciplinary access management programs that prolong access life prevent inadequate dialysis and reduce access-related morbidity and hospitalizations.

II. Flow-based Vascular Access Surveillance cont.

Process Implementation Model[23]		
Purpose	Core Components	Time Line
Standardizes assessment criteria and provides VA benchmarks for the continuous improvement process (CIP).	1. Assess clinic staff and patient for vascular access care behavior and knowledge 2. Assess each patient's access each treatment	1st Month & Ongoing
Assure that all members of the VA Care team are knowledge-able and capable of providing VA care.	1. Access Care Basics and Techniques 2. How to apply VACP in my Center 3. Access evaluation techniques to assess potential stenosis 4. When to refer for diagnosis	1st Month & Ongoing
Detects access dysfunction early and to permit sufficient lead time for a planned access intervention as well as assess the "success" of any completed access intervention (radiological or surgical).	1. Identifies patients at risk with access problems 2. Defines access intervention required	1st Month & Ongoing
Provides a clear "road map" for any subsequent access intervention.	1. Identifies patients at risk with access problems 2. Defines access intervention required	1st Month & Ongoing
Intervention is planned and delivered specifically to correct a diagnosed access problem.	1. per Radiology 2. per Surgery	Ongoing per diagnosis
Facilitates the tracking of each patient's VA history and ensures center-specific and national data are collected, monitored and trended.	1. Access status for each patient each treatment 2. Access Clinical Indicators for each patient each treatment	Ongoing per intervention & flow
Evaluates each Centers own standards of care against the national goals and benchmarks to promote each Center's CIP to achieve best-demonstrated practices in VA care.	1. Trend and analyze VACP Clinical Indicators each month 2. Maintain and monitor center-specific VA care improvement.	Ongoing per monthly CQI meeting process

D. Select Vascular Access Measurements References

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D. Select Vascular Access Measurements References cont.

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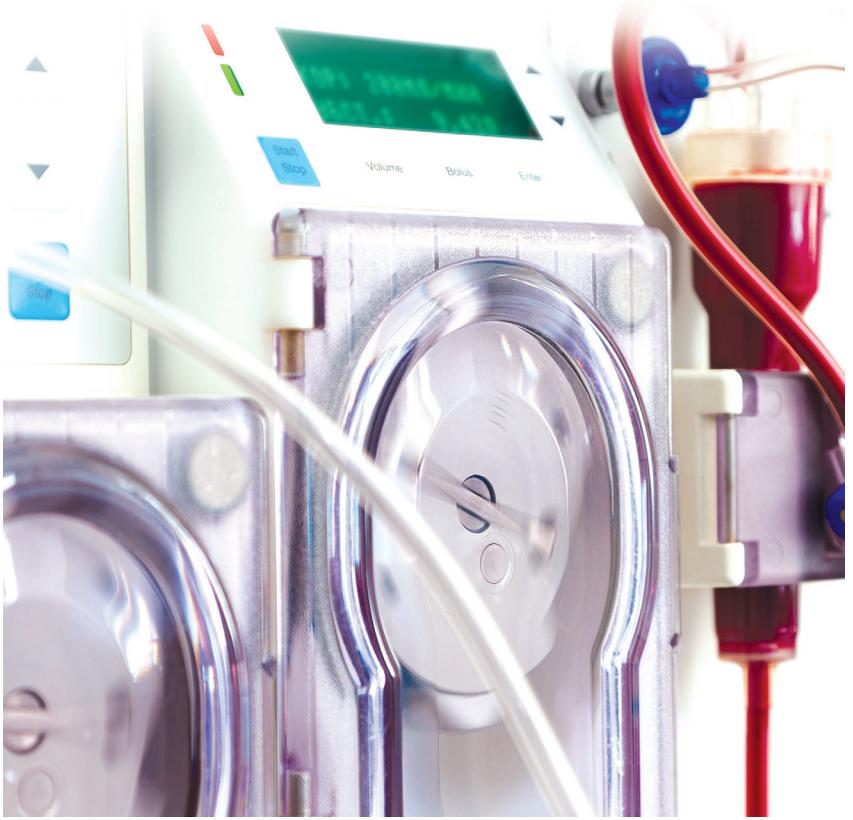
III. Flow-based Dialysis Adequacy



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III. Flow-based Dialysis Adequacy cont.

A. Hemodialysis Adequacy

The Transonic Hemodialysis Monitor is used to optimize efficient dialysis delivery through measurement of delivered pump blood flow and recirculation. Use of these measurements guarantee efficient and effect hemodialysis by:

- Testing the calibration of the blood pump;
- Verifying true delivered blood flow;
- Comparing delivered blood flow to pump setting to identify flow disparity and avoid underdialysis. If disparity is significant, measurements assist in determining cause (blood pump calibration versus inflow restriction/excessive pre-pump negative arterial pressure);
- Detecting and quantifying access recirculation in AV access, catheters;
- Identifying inadvertent reversal of dialysis lines to prevent recirculation and/or underdialysis;
- Determining proper needle placement;
- Identifying sources of large negative arterial blood line pressure (and its resulting underdialysis);
- Determining the most appropriate blood pump setting for a low flow access when it is not feasible to increase access flow;
- Using delivered flow and recirculation measurements to maximize catheter function.

A. Hemodialysis Adequacy cont.

1. True Delivered Blood Flow Verified by Transit-Time Ultrasound[1]

Effective dialysis depends on delivery of the dialysis prescription through functional blood lines into a patent vascular access. Underdialysis is often caused by poor delivered blood flow. By comparing the flow reading of Transonic actual delivered blood flow through the dialysis lines, connected to either a graft, fistula or catheter, with the dialysis pump setting, dialysis delivery problems can be quickly identified and resolved.

To measure true delivered blood flow, matched Flow/dilution Sensors clip onto the arterial and venous dialysis lines during hemodialysis (Fig. 3.1) Each sensor emits an ultrasound beam that transects the tubing and blood in upstream and downstream directions. When the ultrasound beam travels in the direction of flow, the transit time it takes to traverse the distance through the tubing and blood is decreased by a flow-dependent amount. When the beam travels in the opposite direction, against the flow in the tubing, the beam's transit time is increased by a flow-dependent amount. By subtracting the integrated upstream and downstream transit times, volume flow is calculated.[1] The Hemodialysis Monitor continuously displays this delivered blood flow.

Prescribed delivered blood flow can be verified by comparing the reading of delivered blood flow on the Hemodialysis Monitor to the setting on the dialysis machine. At high blood pump settings, it is

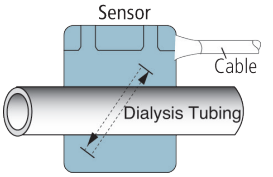


Fig. 3.1: Blood line inserted into the groove of the flow/dilution sensor body.

A. Hemodialysis Adequacy cont.

not uncommon to see a difference between the two due to the size of the access needles (Fig. 3.2). Larger diameter needles (15G) deliver flow more efficiently than smaller diameter needles (16G). Under-delivery of prescribed blood flow may also be caused by the site of needle placement in the access. The arterial needle tip may be too close to the vessel wall.

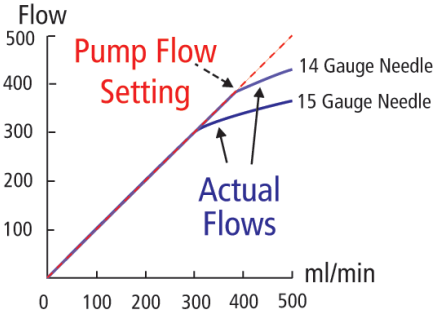


Fig. 3.2: Discrepancy between delivered blood flow and the pump setting can be caused by: negative pressure effects of the roller pump; access condition; needle size and placement; kinked or occluded tubing; calibration of dialysis machine or sensors.

If the arterial needle does not face the incoming access flow (needle is down rather than up), it may also be difficult to achieve high delivered blood flow. Other access factors may also limit delivery of prescribed delivered blood flow. They include:

Discrepancy between Delivered Blood Flow and Pump Setting[2-6]

To diagnose large delivered blood flow differences between the pump and the monitor, turn the pump speed to 200 mL/min. At this speed, pump errors due to high negative pressures are negligible and the Monitor's delivered blood flow reading should correspond to the dialysis pump setting. If the readings agree at this setting, the deviations at the high pump settings were due to one of the factors described above.

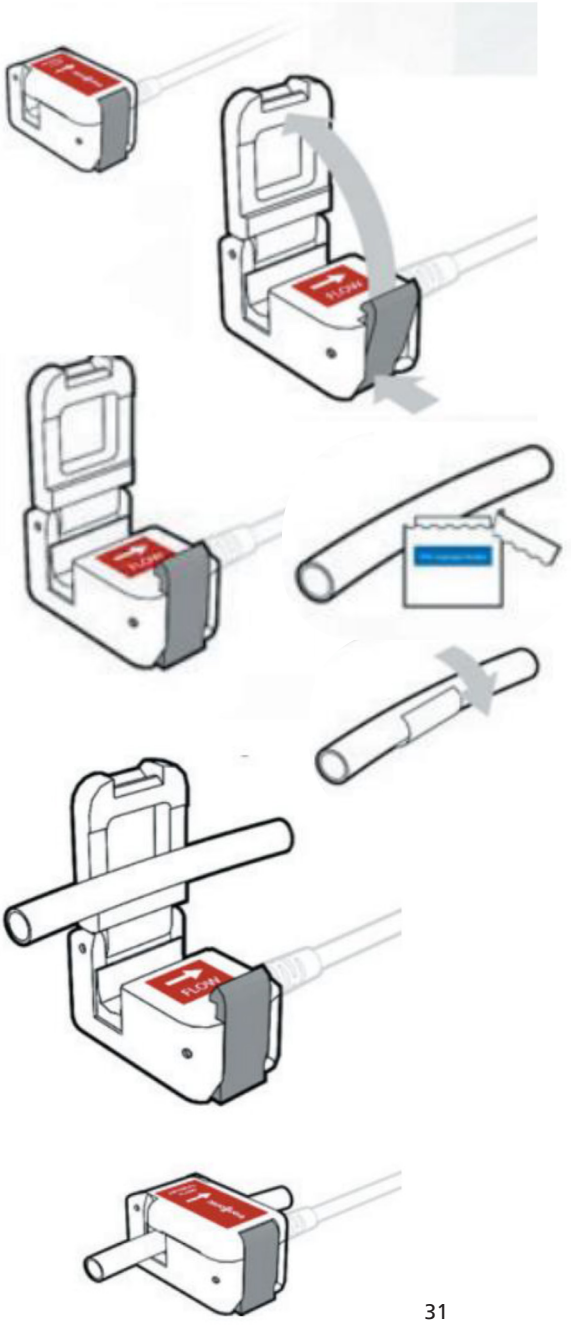
Delivered Blood Flow Disparity at Pump Speed 200 mL/min

If delivered blood flow readings do not agree with the monitor's at a pump setting of 200 mL/min, check the tubing selection on the monitor to ensure that it matches the dialysis tubing being used. Ultrasound dilution sensors are sensitive and accuracy decreases if the sensor is not calibrated for the specific tubing being used. In general, the accuracy of a Transonic Delivered Blood Flow reading is $\pm$ 6%. Other possible causes for pump and hemodialysis monitor blood flow discrepancies could be:

- the dialysis machine is not in calibration
- the arterial needle tip is too close to the vessel wall.

Flow/Dilution Sensor Set-up

1. Open the door of the first paired Flow/ dilution Sensor by pressing the silver level (see arrows in image).
2. Place the tubing segment to be inserted next to the Flow/dilution Sensor. The arrow on the Sensor must point in the direction of flow.
3. Open a 70% isopropyl alcohol wipe (prep pad).
4. Wipe the entire circumference of the tubing segment which will be inserted into the Flow/dilution Sensor.
5. Immediately insert this tubing segment into the Flow/dilution Sensor 5-10 cm (2-4") from the needle connection and close the door. The wetness from the alcohol acts as a couplant so it should be inserted immediately before it has a chance to evaporate. It is important to wipe, insert tubing, and close door [wipe-insert-close] as a quick, continuous sequence.
6. Repeat the same [Wipe, Insert, Close Door] sequence for the second paired Flow/dilution Sensor and tubing segment.
7. Verify Signal Strength indicator on the upper left of the Hemodialysis Monitor screen is green when the Monitor has been turned on. This means that the paired Flow/dilution Sensors have adequate contact with the tubing. If the Signal Strength indicator is not green, repeat the [Wipe-Insert-Close door] sequence to achieve proper contact.



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2. Access Recirculation

Measurement of Access Recirculation (Flow Chart, page 49) is the next step in the Hemodialysis Adequacy Flow Study. Most patients have zero percent access recirculation.[7]

A theoretical model (Fig. 3.3) demonstrates that at a blood flow of 400 mL/min, access recirculation is likely to begin appearing. When access flow is 300 mL/min and blood flow is 400 mL/min, 100 mL/min must be drawn from the venous return to make up the deficit at the arterial needle. Recirculation then equals 100/400 mL/min or 25%. If repeat measurements confirm the presence of recirculation, two possibilities exist:

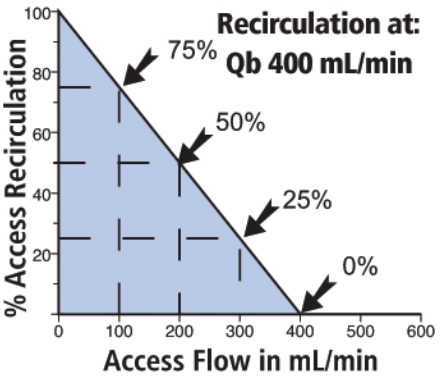


Fig. 3.3: Recirculation (theoretical): When delivered blood flow (Qb) is 400 mL/min, access recirculation theoretically appears at an access flow of 399 mL/min or anything below the delivered blood flow. If measured access flow is 300 mL/min, there is theoretically 25% recirculation; at 200 mL/min measured access flow, 50% recirculation; at 100 mL/min measured access flow, 75% recirculation.

Zero Percent Recirculation (0% Access Recirculation (AR))

As a late indicator of a failing access, recirculation generally occurs when access flow (AF) is less than dialysis pump flow (Qb). Because Transonic ultrasound dilution technology is able to separate actual peripheral vascular access recirculation from cardiopulmonary recirculation, measurement of zero percent access recirculation has become the new recirculation standard.[7-9] Modalities which cannot separate cardiopulmonary recirculation from access recirculation will indicate false positive recirculation.

2. Access Recirculation cont.

To measure vascular access recirculation, Flow/dilution Sensors monitor the blood's ultrasound velocity (1560 - 1590 m/sec). The greater the protein concentration in the blood, the faster ultrasound will travel. When a bolus of isotonic saline (velocity in blood is 1533 m/sec) is injected into the blood, the blood protein concentration is diluted. Flow/dilution Sensors detect the reduced ultrasound velocity.[9]

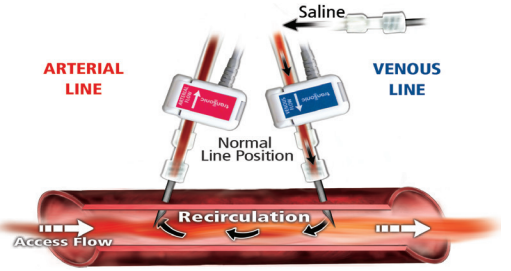


Fig. 3.4: Recirculation Measurement. Saline is introduced into the venous sensor with the dialysis lines in normal position. Access recirculation (back flow) through the vascular access into the arterial needle is measured.

When recirculation occurs, the saline indicator returns immediately to the arterial line (Fig. 3.4) where the diluted blood is detected by the arterial sensor. The Monitor's software converts the data into conventional dilution curves (Fig. 3.5). The first blue curve indicates the saline dilution as blood flows through the venous sensor. The second red curve represents saline dilution as flow passes through the arterial sensor. Recirculation is calculated as a ratio of the area under the arterial curve to the area under the venous curve.

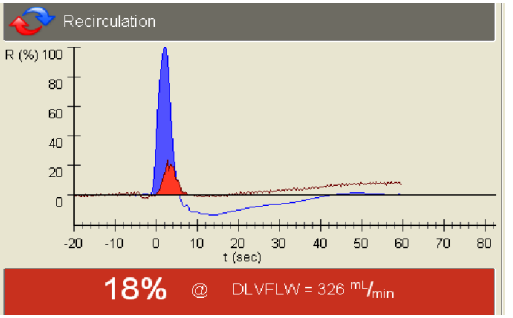


Fig. 3.5: A blue venous (upper) dilution curve followed by a red (lower)arterial curve. The ratio of the areas under the curves indicates 18% recirculation.

True Recirculation — Access at Risk

When recirculation is not accounted for by blood line reversal, the patient's access may be at risk for thrombosis because recirculation is a late predictor of access dysfunction.

2. Access Recirculation cont.

Venous Stenosis

When a venous stenosis occurs, and access flow does not meet pump demands, some newly dialyzed blood from the venous line recirculates immediately back into the arterial line to compensate for a flow deficit at the arterial needle (Fig. 3.6).

Stenosis Between Needles

Although access recirculation generally occurs when access flow is less than dialysis pump flow, an important exception exists when a stenosis occurs between the dialysis needles (Fig. 3.7). Because the stenosis limits flow through the access, the pump simply bypasses the stenosis (the area of greatest hemodynamic resistance) altogether and zero recirculation is reported.

Inadvertent Reversal of Blood Lines

If hemodialysis measurements detects vascular access recirculation but the recirculation disappears after the blood lines are reversed, the hemodialysis lines have been inadvertently reversed. At times blood lines are inadvertently reversed with respect to conventional dialysis line orientation. To determine if this is the case, examine whether the venous needle is placed upstream from the arterial needle with respect to the direction of the access flow. Then repeat the recirculation measurement after intentionally cross-connecting the arterial line to the venous needle and vice-versa. If the result is zero percent recirculation, or if the recirculation measurement is less than the first for the same delivered blood flow, the lines have been inadvertently reversed and the second blood line orientation is correct. Document this correct orientation on the patient's record to prevent recurrence of inadvertent blood line reversal.

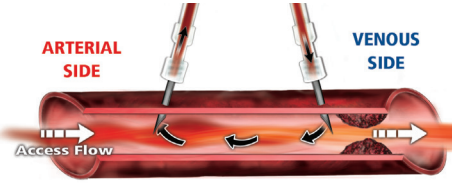


Fig. 3.6: Access recirculation caused by venous stenosis. Some dialyzed blood recirculates back from the venous needle to the arterial needle.

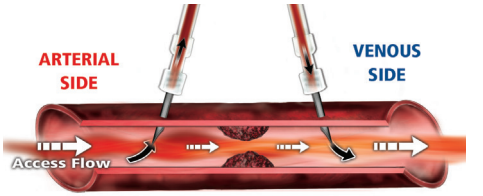


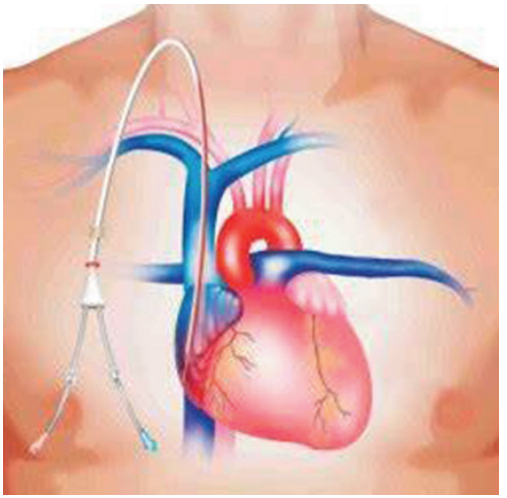
Fig. 3.7: When 0% recirculation occurs although access flow is less than delivered blood flow, a mid-graft stenosis limits access flow. Pump flow (Qb) bypasses the stenosis.

B. Hemodialysis Adequacy in Central Venous Catheters (CVCs)

Even though central venous catheters (CVCs) are prone to thrombosis and infection, 80.9% of patients use a catheter at initiation of HD, and 21.1% of prevalent patients continue that use.[1] (Note the 2019 KDOQI updated definition of CVC dysfunction: failure to maintain the prescribed extracorporeal blood flow required for adequate hemodialysis without lengthening the prescribed HD treatment.) Yet, catheter dysfunction remains a serious cause for concern for hemodialysis providers. Two potential pitfalls to achieving adequate catheter dose delivery include:

- A fibrin sheath can block the catheter's lumen, thus impeding flow and causing a severe drop in dialysis dose delivery.
- The close proximity of the catheter's arterial entry and venous return ports make recirculation and underdialysis likely.

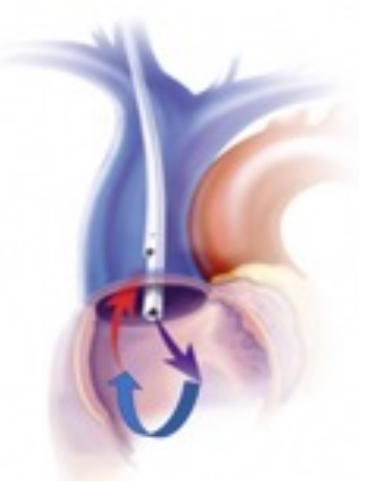
Note: if any intervention occurs, such as the use of a thrombotic agent, the Delivered Flow and Recirculation measurements can be repeated to determine the effectiveness of the intervention.



Central venous catheter inserted via the jugular vein into the right atrium of the heart to serve as a vascular access for hemodialysis.

B. Hemodialysis Adequacy in Catheters cont.

Delivered Blood Flow and Recirculation to Optimize Catheter Dialysis Measurements



Compare Transonic Delivered Blood Flow reading with the hemodialysis machine's pump setting. If the disparity is more than 10%, check for kinked tubing. A fibrin sheath might be restricting inflow and reducing dose delivery. The optimization of hemodialysis for catheter connection configuration with the Transonic Hemodialysis Monitor can be used to then check for recirculation. If the connection is then reversed, the Delivered Flow and Recirculation measurements should then be repeated to determine the best catheter configuration.

- The nurse can adjust the dialysis delivery parameters (time, pump setting etc.) to compensate for recirculation and deliver the prescribed dose of dialysis to the patient.
- Dialysis lines may be reversed. Reversing the lines might also correct high recirculation.

The nurse should report unusual delivered blood flow and recirculation readings to the Patient Care Team and/or nephrologist to ensure optimum short- and long-term management of the patient's hemodialysis treatment.

Optimizing HD Adequacy in Catheters
Catheter Configurations with the Transonic HD Monitor: Step 1

MEASURE DELIVERED BLOOD FLOW RATE

With the bloodlines configured as normally used (document configuration), measure flow.

Transonic Delivered blood Flow rate (Qb) is within 0-10% of the hemodialysis machine's set blood pump speed or delivery flow rate.*

YES

TRANSONIC DELIVERED BLOOD FLOW RATE (QB) IS WITHIN 0-10% OF HEMODIALYSIS MACHINE'S SET

Current blood pump setting is maximizing the Delivered blood Flow with the current catheter to bloodline configuration.

PROCEED TO RECIRCULATION MEASUREMENT

TRANSONIC DELIVERED BLOOD FLOW RATE (QB) IS WITHIN 0-10% OF HEMODIALYSIS MACHINE'S SET OR DELIVERY FLOW READING*

Current blood pump setting is maximizing the Delivered Blood Flow with the current catheter to bloodline configuration.

PROCEED TO RECIRCULATION MEASUREMENT

NO

TRANSONIC DELIVERED BLOOD FLOW RATE (QB) IS >10% LOWER THAN THE HEMODIALYSIS MACHINE'S SET BLOOD PUMP SPEED OR DELIVERY FLOW READING*

Only proceed if both catheter lumens had blood return with treatment initiation.

Using aseptic technique, reverse the catheter configuration by reversing the blood lines to the opposite lumens of the catheter than used for the initial measurement. Document configuration.

Repeat the blood flow measurement.

YES

NO

TRANSONIC DELIVERED BLOOD FLOW RATE (QB) IS 10% LOWER THAN THE HEMODIALYSIS MACHINE'S SET BLOOD PUMP SPEED

Carefully document measurement and catheter configurations.

Proceed to recirculation measurements with both catheter configurations.

Escalate the results of the findings to the nephrologist for possible catheter evaluation or prescription adjustment to address catheter dysfunction.

*Some Hemodialysis Machine's display both a Set Blood Pump Speed and Delivery Flow Reading. If both readings are displayed on your Hemodialysis machine use the Delivery Flow Reading

Catheter Configurations:

- Normal Configuration: Arterial Catheter Hub to Arterial Bloodline + Venous Catheter Hub to Venous Bloodline
- Reverse Configuration: Arterial Catheter Hub to Venous Bloodline + Venous Catheter Hub to Arterial Catheter Hub

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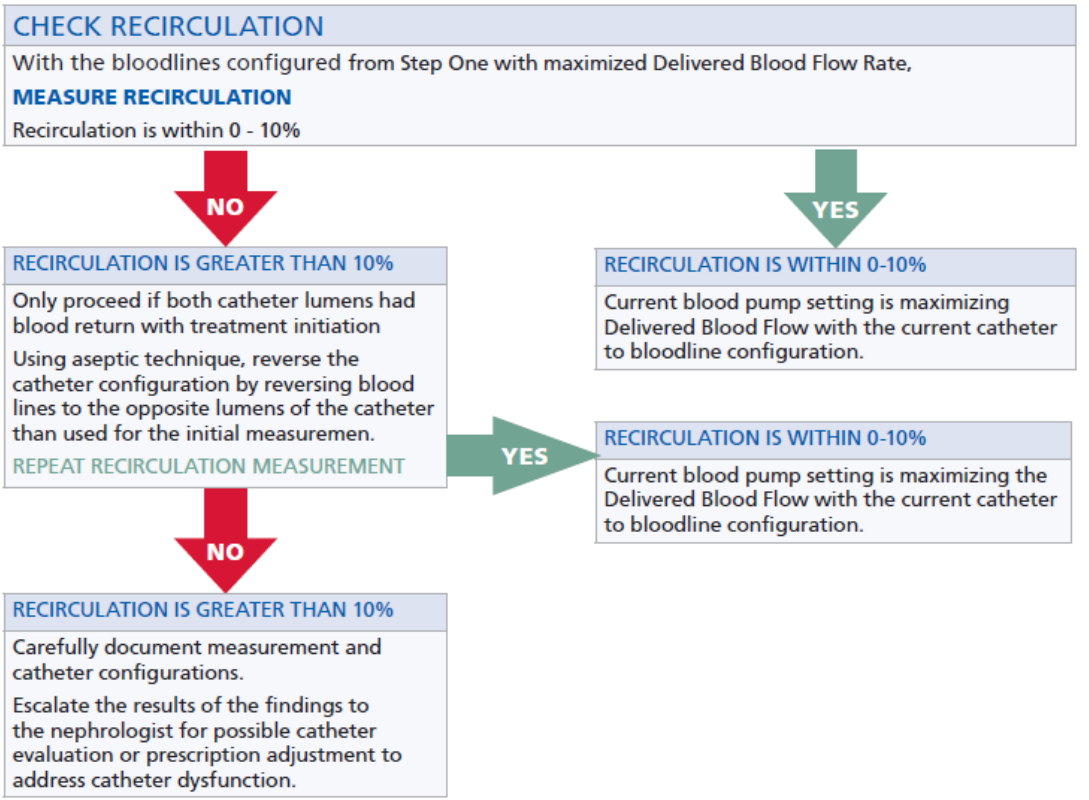
Optimizing HD Adequacy in Catheters cont.
Catheter Configurations with the Transonic HD Monitor: Step 2



Optimizing HD Adequacy in Catheters cont.
Catheter Configurations with the Transonic HD Monitor for use with Fresenius 5008 or other Hemodialysis Machines that have Compensated Blood flow Rates: Step 1

MEASURE DELIVERED BLOOD FLOW RATE

With the bloodlines configured as normally used (document configuration), measure flow.

Transonic delivered blood flow rate (Qb) is higher than the Fresenius 5008 set blood pump speed or within 0-10% lower than the set blood pump speed.

NOTE: Both higher and lower differences are displayed in RED on the Transonic screen.

YES

TRANSONIC DELIVERED BLOOD FLOW RATE (QB) IS HIGHER THAN THE FRESENIUS 5008 SET BLOOD PUMP SPEED OR IS WITHIN 0-10% LOWER THAN THE SET BLOOD PUMP SPEED.

Current blood pump setting is maximizing the Delivered Blood Flow with the current catheter to bloodline configuration.

PROCEED TO RECIRCULATION MEASUREMENT

NO

TRANSONIC DELIVERED BLOOD FLOW RATE (QB) IS >10% LOWER THAN THE FRESENIUS 5008 SET BLOOD PUMP SPEED

Only proceed if both catheter lumens had blood return with treatment initiation.

Using aseptic technique, reverse the catheter configuration by reversing blood lines to the opposite lumens of the catheter than used for the initial measurement. Document configuration.

Repeat the blood flow measurement.

YES

TRANSONIC DELIVERED BLOOD FLOW RATE (QB) IS HIGHER THAN THE FRESENIUS 5008 SET BLOOD PUMP SPEED OR IS WITHIN 0-10% LOWER THAN THE SET BLOOD PUMP SPEED.

Current blood pump setting is maximizing the Delivered Blood Flow with the current catheter to bloodline configuration.

PROCEED TO RECIRCULATION MEASUREMENT

NO

TRANSONIC DELIVERED BLOOD FLOW RATE (QB) IS 10% LOWER THAN THE FRESENIUS 5008 SET BLOOD PUMP SPEED

Carefully document measurement and catheter configurations.

Proceed to recirculation measurements with both catheter configurations.

Escalate the results of the findings to the nephrologist for possible catheter evaluation or prescription adjustment to address catheter dysfunction.

This protocol only applies when using Fresenius 5008 Hemodialysis Machines

Catheter Configurations:

- Normal Configuration: Arterial Catheter Hub to Arterial Bloodline + Venous Catheter Hub to Venous Bloodline
- Reverse Configuration: Arterial Catheter Hub to Venous Bloodline + Venous Catheter Hub to Arterial Catheter Hub

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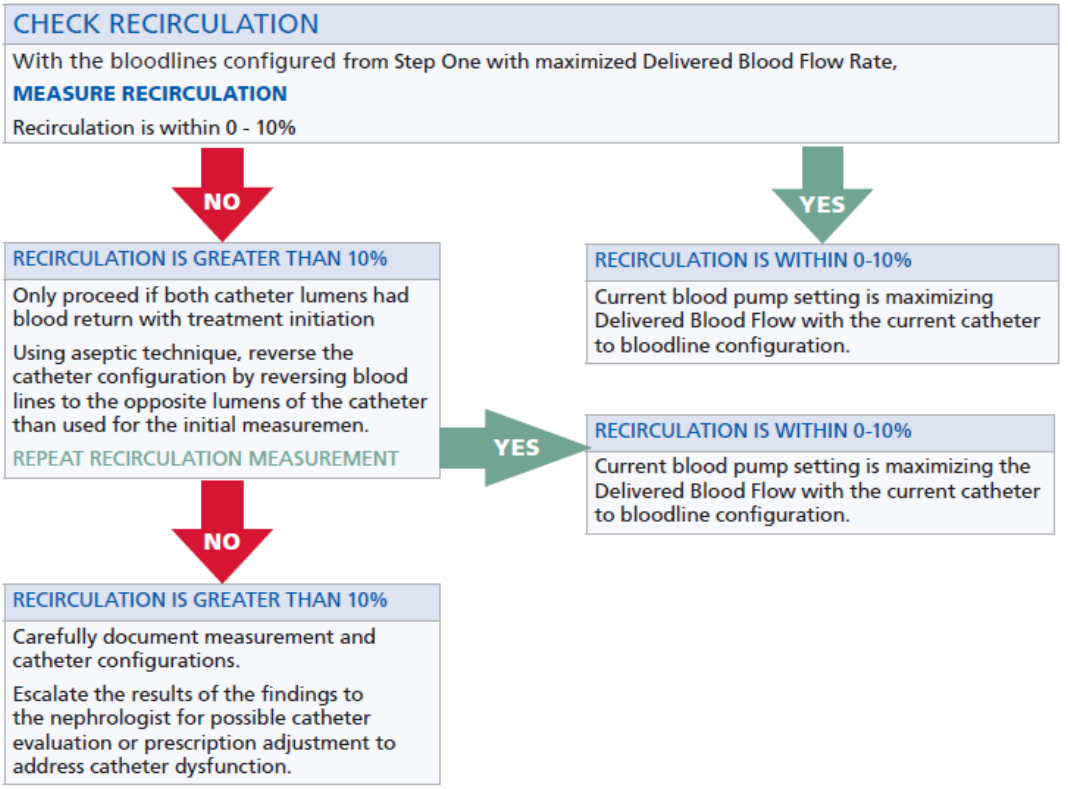
Optimizing HD Adequacy in Catheters cont.
Catheter Configurations with the Transonic HD Monitor for use with Fresenius 5008 or other Hemodialysis Machines that have Compensated Blood flow Rates: Step 2



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