

2018 Vascular Access for Hemodialysis Symposium

May 10-12, 2018
New Orleans, LA



Vascular Access Surveillance Overview

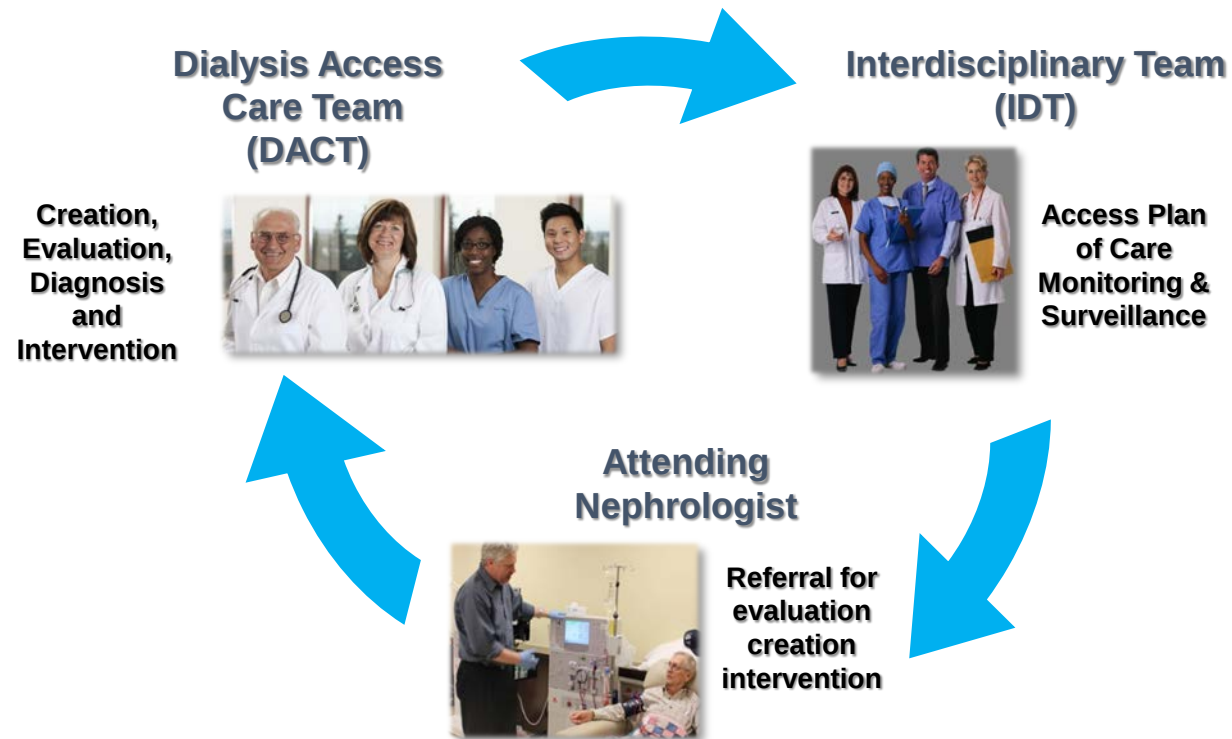
Deborah Brouwer-Maier RN, CNN

Disclosure: Employee Transonic System Inc.

Vascular Access Marketing Manager



Dialysis Access: Nephrologist as Lead



CMS Conditions for Coverage: Vascular Access

V Tag	Regulation	Interpretive Guideline
511	Evaluation of access type	Referrals for access creation
550/551	IDT provide access monitoring and referrals need to create and sustain vascular access	Clinic must have on-going monitoring and surveillance program Plan of Care for the Dialysis Access
456	Patient to be informed and participate in all aspects of their care	Self-cannulation needs to be an option
512	Eval patients desired level of participation in the dialysis care process	Support patients active role in care such as access care
455	Privacy & Confidentiality of Medical Records	HIPAA release is NOT required to share protected health information for continuity of care

U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services (2008), Part 494 Conditions For Coverage for End-Stage Renal Disease Facilities, Interpretive Guidelines

KDOQI Clinical Practice Guidelines and Clinical Practice Recommendations Vascular Access (2006)

- GUIDELINE 4. DETECTION OF ACCESS DYSFUNCTION: MONITORING, SURVEILLANCE, AND DIAGNOSTIC TESTING
- Prospective surveillance of fistulae and grafts for hemodynamically significant stenosis, when combined with correction of the anatomic stenosis, may improve patency rates and may decrease the incidence of thrombosis.
- 4.1 Physical examination (monitoring):
 - Physical examination should be used to detect dysfunction in fistulae and grafts at least monthly by a qualified individual. (B)

KDOQI 4.2 Surveillance of Grafts:

4.2 Surveillance of Grafts:

- Techniques, not mutually exclusive, that may be used in surveillance for stenosis in grafts include:
 - 4.2.1 Preferred:
 - 4.2.1.1 Intra-access flow by using 1 of several methods that are outlined in Table 7 using sequential measurements with trend analysis. (A)
 - 4.2.1.2 Directly measured or derived static venous dialysis pressure by 1 of several methods. (A) (Protocol provided in Table 8 for using transducers on HD machines to measure directly; criteria in Table 9 for derived methods.)
 - 4.2.1.3 Duplex ultrasound. (A)
 - 4.2.2 Acceptable: 4.2.2.1 Physical findings of persistent swelling of the arm, presence of collateral veins, prolonged bleeding after needle withdrawal, or altered characteristics of pulse or thrill in a graft. (B)
 - 4.2.3 Unacceptable: 4.2.3.1 Unstandardized dynamic venous pressures (DVPs) should not be used.

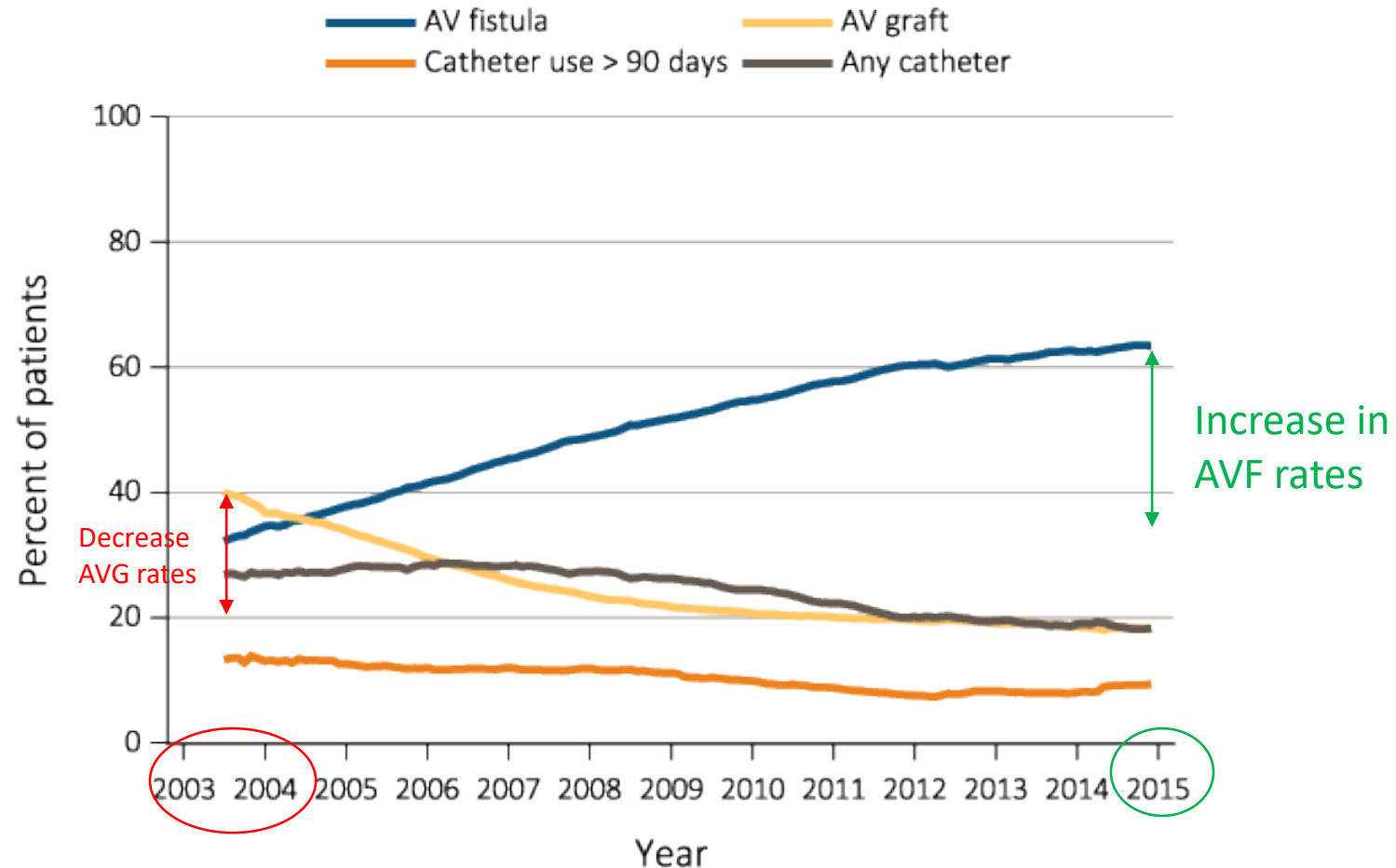
4.3 Surveillance in Fistulae:

- Techniques, not mutually exclusive, that may be used in surveillance for stenosis in AVFs include:
 - 4.3.1 Preferred: 4.3.1.1 Direct flow measurements. (A)
 - 4.3.1.2 Physical findings of persistent swelling of the arm, presence of collateral veins, prolonged bleeding after needle withdrawal, or altered characteristics of pulse or thrill in the outflow vein. (B)
 - 4.3.1.3 Duplex ultrasound. (A)
- 4.3.2 Acceptable: 4.3.2.1 Recirculation using a non-urea-based dilutional method. (B)
- 4.3.2.2 Static pressures (B), direct or derived. (B)

KDOQI Flow Methods in Dialysis Access

Method	Still Available Method
Duplex Doppler Ultrasound (DDU)	Yes- but not available in the dialysis unit
Magnetic Resonance Angiography (MRA)	Yes- but not available in the dialysis unit
Variable Flow Doppler Ultrasound (VFDU)	Yes- but not available in the dialysis unit
Ultrasound Dilution (UDT) Transonic	Yes
Crit-line (optodilution) (OABF) HemaMetrics/FMC	Feature Off the Market
Crit-line (direct transcutaneous) (TQA) HemaMetrics/FMC	Feature Off the Market
Glucose pump infusion technique (GPT)	Used in research only
Urea Dilution (UreaD)	Used in research only
Differential Conductivity (HDM) Gambro	Feature Off the Market
In Line Dialysance (DD) Fresenius	Yes- intergraded with Fresenius HD machine as On-Line Clearance feature

Trends in vascular access type use among ESRD prevalent patients, 2003-2014



Data Source: Special analyses, USRDS ESRD Database, and Fistula First data. Fistula First data reported from July 2003 through April 2012, CROWNWeb data are reported from June 2012 through December 2014. Abbreviations: AV, arteriovenous; ESRD, end-stage renal disease.

2016 Annual Data Report, Vol 2,

ESRD, CH 4

Access Flow By Type and Location

AVG Lower Arm	AVF Lower Arm	AVF Upper Arm
400-1000 mL/min	300-800 mL/min	300->3000 mL/min

Methods to be Reviewed

- In Line Dialysance (DD) Fresenius - now On-Line Clearance (OLC) is a Surrogate for flow
- Ultrasound Dilution (UDT) Transonic actual flow measurement

Fresenius OLC Steps

Run Access Flow? Blood Pressure 10:04
9:00 100/70 53

Enable OLC ☒ On ☐ Off OLC Calculator OLC Data Manual OLC Test Access Flow ☒ On ☐ Off

Volume **30.0** L Target Kt/V **1.40** Single Pool
of Tests **6** Delivered Kt/V **0.00** Single Pool
Blood Vol. Processed **0.2** L

Access Flow

- * Press CONFIRM to start the Access Flow Test
- * Press Escape to delay the Access Flow Test to the next OLC test
- * To cancel the Access Flow test, turn off the test with the Access Flow button

Home Trends Dialysate Test & Options Heparin Kt/V AF BTM BVM Blood Pressure

Reverse bloodlines Blood Pressure 10:05
9:00 100/70 53

Enable OLC ☒ On ☐ Off OLC Calculator OLC Data Manual OLC Test Access Flow ☒ On ☐ Off

Volume **30.0** L Target Kt/V **1.40** Single Pool
of Tests **6** Delivered Kt/V **0.00** Single Pool
Blood Vol. Processed **0.2** L

Access Flow

- * Stop the blood pump and clamp the lines
- * Reverse the Arterial and Venous blood lines
- * Unclamp the lines and start the blood pump at the same speed
- * Press CONFIRM

Home Trends Dialysate Test & Options Heparin Kt/V AF BTM BVM Blood Pressure



10-12 minutes for 1st KECN



Source <http://fmcna-bloodlines.com/twister.html>

Fresenius OLC Steps

Switch bloodlines back Press CONFIRM.

Enable OLC ☒ On ☐ Off

OLC Calculator OLC Data Manual OLC Test Access Flow ☒ On ☐ Off

Volume **30.0** L

Target Kt/V **1.40** Single Pool

of Tests **6**

Delivered Kt/V **0.00** Single Pool

Blood Vol. Processed **0.6** L

Access Flow

- * Stop the blood pump and clamp the lines
- * Return the Arterial and Venous lines to their normal positions
- * Unclass the lines and start the blood pump at the prescribed rate
- * Press CONFIRM

Access Flow **850** ml/min

Home Trends Dialysate Test & Options Heparin Kt/V AF BTM BVM Blood Pressure



10-12 minutes 2nd KECN with
Blood Flow Reduced

Access Flow complete Blood Pressure **10:19**
9:00 100/70 53

Enable OLC ☒ On ☐ Off

OLC Calculator OLC Data Manual OLC Test Access Flow ☒ On ☐ Off

Volume **30.0** L

Target Kt/V **1.40** Single Pool

of Tests **6**

Delivered Kt/V **0.00** Single Pool

Blood Vol. Processed **0.5** L

Access Flow

- * Press CONFIRM

Access Flow **850** ml/min

Home Trends Dialysate Test & Options Heparin Kt/V AF BTM BVM Blood Pressure

Source <http://fmcna-bloodlines.com/twister.html>

Fresenius OCT Steps

Dialysis

Blood Pressure

10:51

10:45 120/90 100

Enable OLC

On

Off

Kt/V Calculator

OLC/AF Data

Manual OLC Test

Access Flow

On

Off

Volume

34.9 L

Actual Time

3:20 H:M in

Plasma Na+

137.6 mEq/L

Blood Vol P_{rocessed}

60.4 L

Target Kt/V

1.40 Single Pool

Delivered Kt/V

1.35 Single Pool

Delivered Kt/V

1.15 Equilibrated

Delivered Kt

47.1 L

Access Flow

986 ml/min

Time

Kec_n

0:15 240

AF 0:22 193

1:15 235

1:45 235

2:15 235

2:45 236

3:15 232

Mean 235

Home

Trends

Dialysate

Test, Options

Heparin

Kt/V AF

BTM BVM

Blood Pressure

KECN MATH	
1 st KECN	240
AF KECN	193
Delta of the difference	47

Delta of 1st KECN to AF KECN Math

- **Recirculation within the access**
 - A difference of approximately less than ($<$) 20 points between K Access Flow 1 to K Access Flow 2
 - Can also be “negative error value” on the machine
- **High flow access**
 - A significant difference of greater than ($>$)20 points between K Access Flow 1 to K Access Flow 2

Fresenius On-line Clearance: One Main Publication

Comparison of Hemodialysis Blood Access Flow Rates Using Online Measurement of Conductivity Dialysance and Ultrasound Dilution

Eduardo Lacson, Jr, MD, MPH, FASN,¹ J. Michael Lazarus, MD,¹ Roy Panlilio, MD,¹ and Frank Gotch, MD^{1,2}

Background: Routine access flow (AF) surveillance is recommended by the Kidney Disease Outcomes Quality Initiative as one of several components for an arteriovenous vascular access maintenance program. A reliable, but affordable, measurement tool is needed for outpatient hemodialysis facilities.

Study Design: Diagnostic test study.

Setting & Participants: 50 adult patients with 27 grafts and 23 fistulas from a single center who consented to sequential AF measurements, all performed within the first 90 minutes of the hemodialysis treatment.

Index Test: AF measured by using online conductivity dialysance (OLC-AF).

Reference Test: AF measured by using ultrasound dilution (UD-AF).

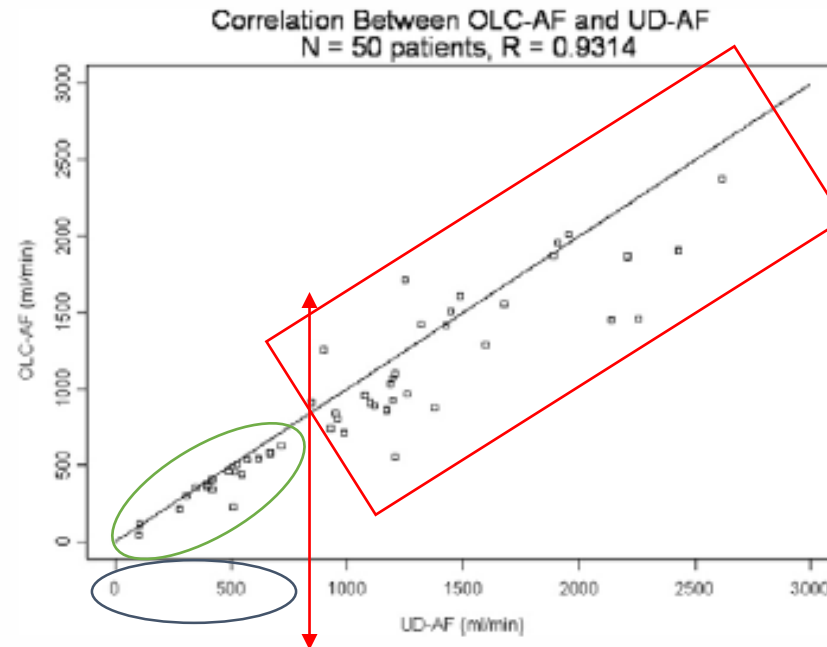
Results: Mean UD-AF was $1,086 \pm 629$ mL/min, and mean OLC-AF was 951 ± 575 mL/min, with a mean difference of 135 ± 229 mL/min. OLC-AF correlated significantly with UD-AF (0.93 ; $P < 0.0001$), becoming tighter for flows less than 1,000 mL/min (0.95 ; $P < 0.0001$). The coefficient of variation for sequential measurement by using UD was 6.4%, and for OLC, 11.5%, with the difference becoming insignificant (7.6% versus 8.8%; $P = 0.5$) for flows less than 1,000 mL/min. The average of 2 sequential UD-AF measurements correlated tightly with that of OLC-AF (0.99 ; $P < 0.0001$).

Limitations: Tests were performed by 2 highly trained coordinators in a single clinic with a small sample size, and clinical outcomes were not evaluated.

Conclusion: The OLC method is a reasonable alternative to UD for flow surveillance of arteriovenous hemodialysis accesses and provides an option for widespread implementation of a vascular access surveillance program. Additional studies are needed to determine whether routine use impacts on clinical outcomes.

Am J Kidney Dis 51:99-106. © 2007 by the National Kidney Foundation, Inc.

Comparison of Access Flow Rates OCL-AF vs. Transonic AF



Green AF less than
800 mL/min close
correlation

Red AF >800 mL/min
not good correlation

Figure 3. Paired correlation between access flow (AF) measured by means of online clearance (OLC-AF) and ultrasound dilution (UD-AF). There is tight correlation, especially at values less than 1,000 mL/min. The solid line illustrates unity.

Comparison of Hemodialysis Blood Access Flow Rates Using Online Measurement of Conductivity
Dialysance and Ultrasound Dilution by Lacson, Eduardo et al. in American Journal of Kidney Diseases ,
Volume 51, Issue 1, 99-106, 2007

Transonic Hemodialysis Monitor

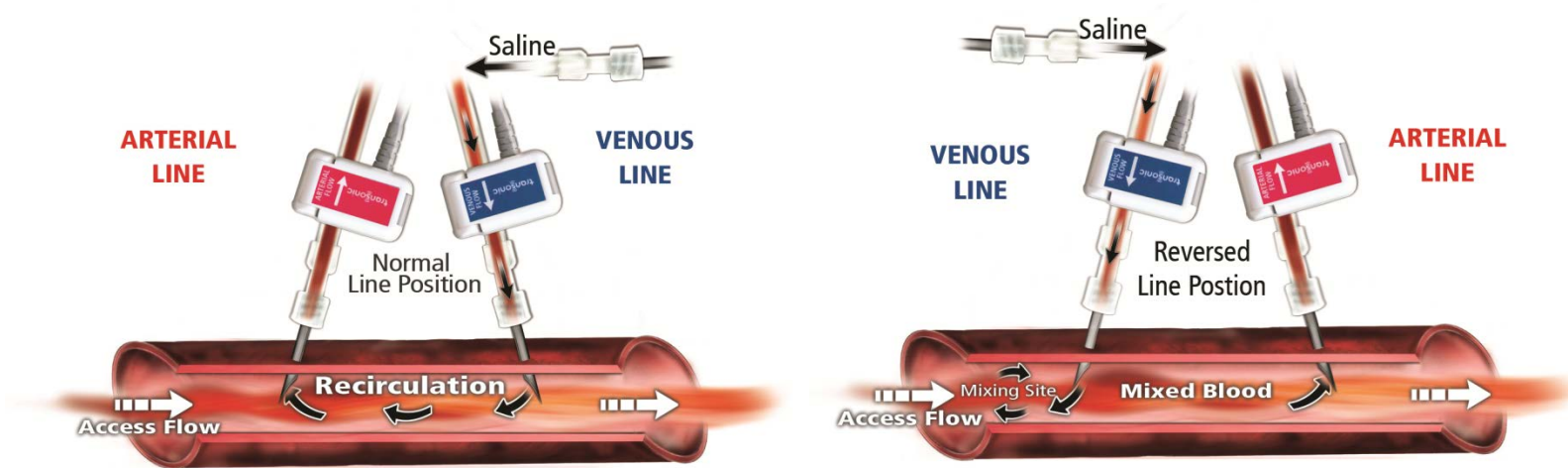


Ease of Use

- Portable (rechargeable battery)
- Easy to clean
- Touch screen operated
- Short measurement period (<10 min)
- Sensors easily attach to outside of existing dialysis tubing



Ultrasound Dilution Technology

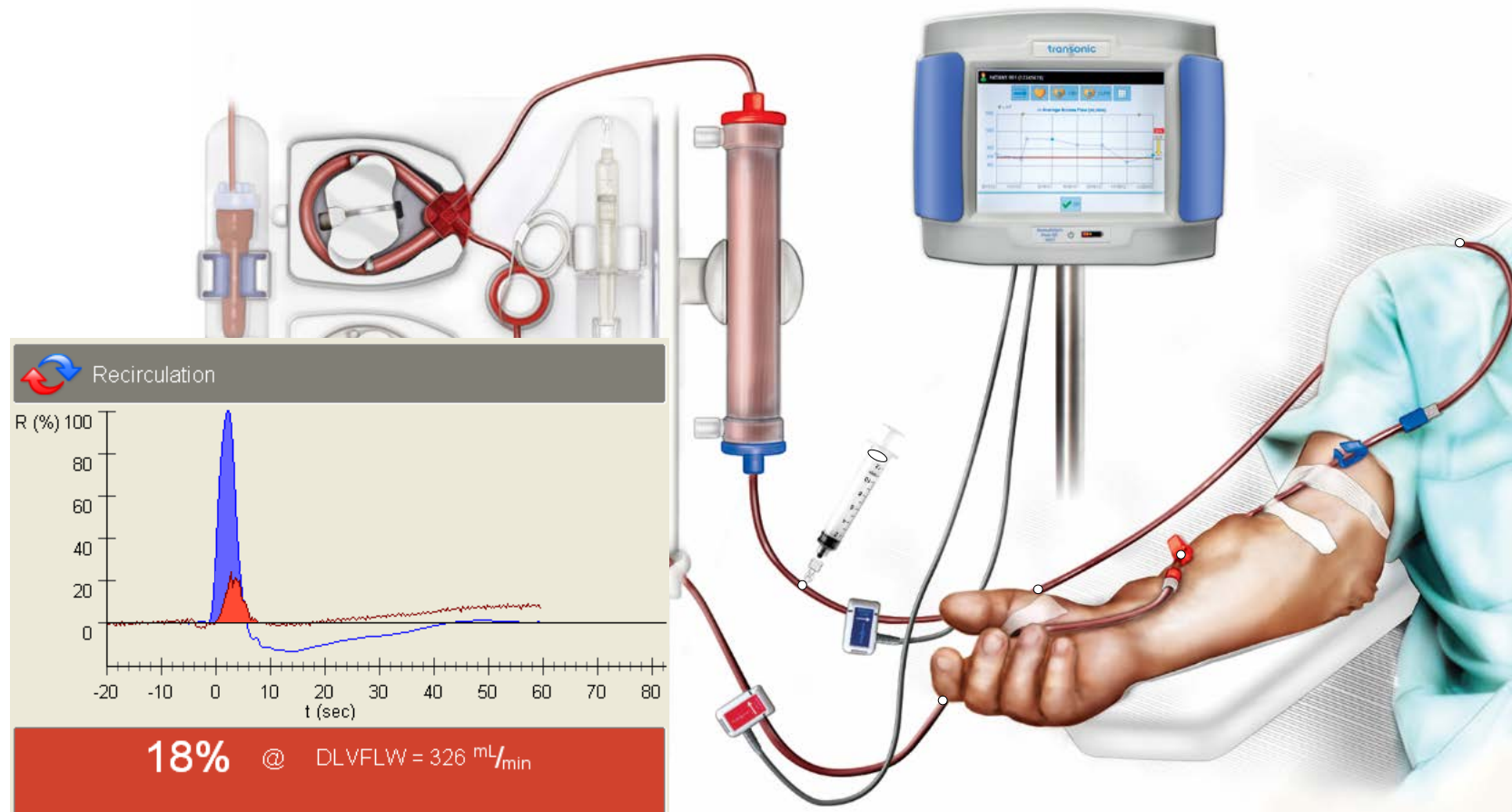


- Recirculation

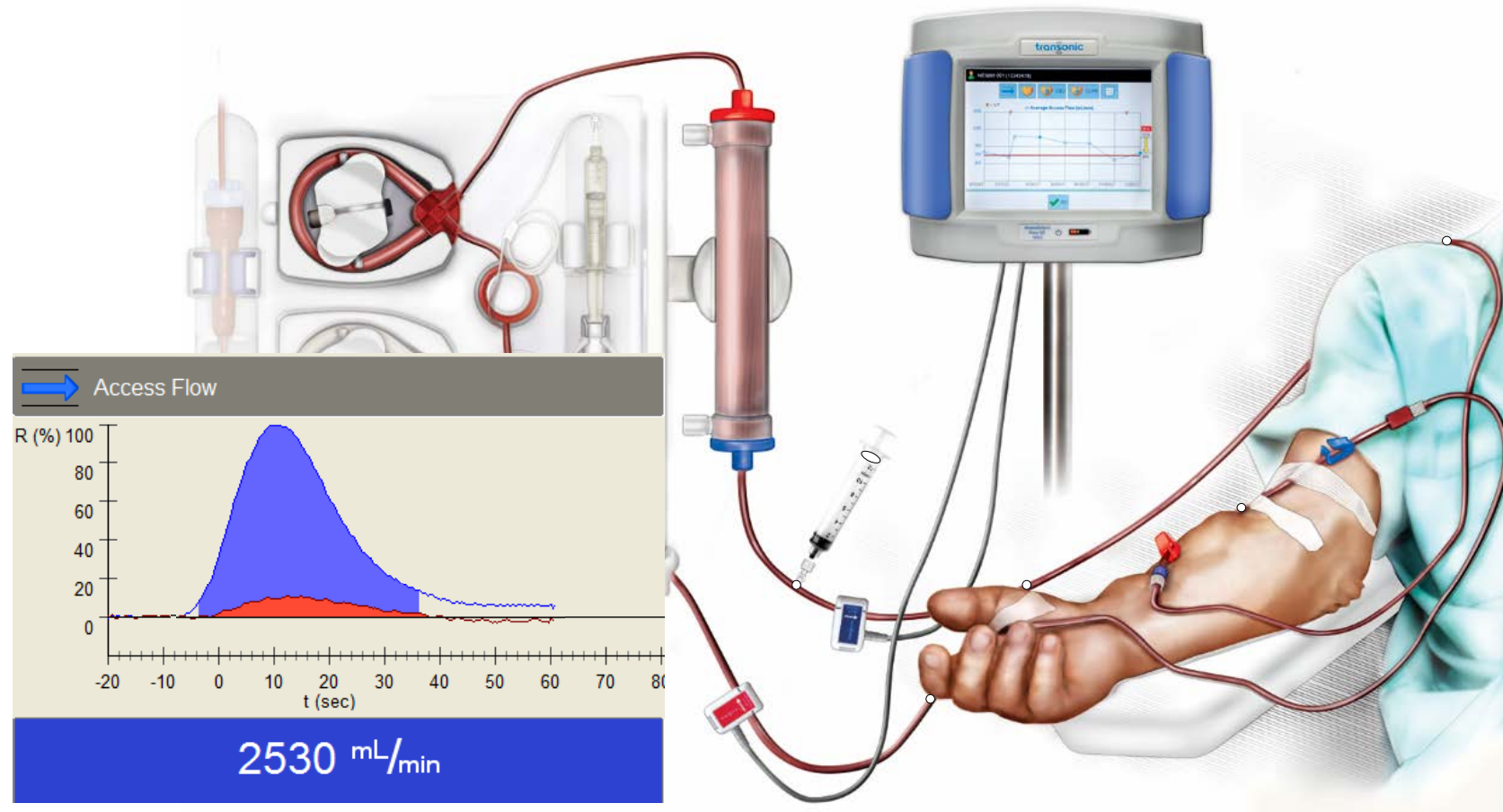
- Access Flow

- with line reversal
Krivitski Method[®]

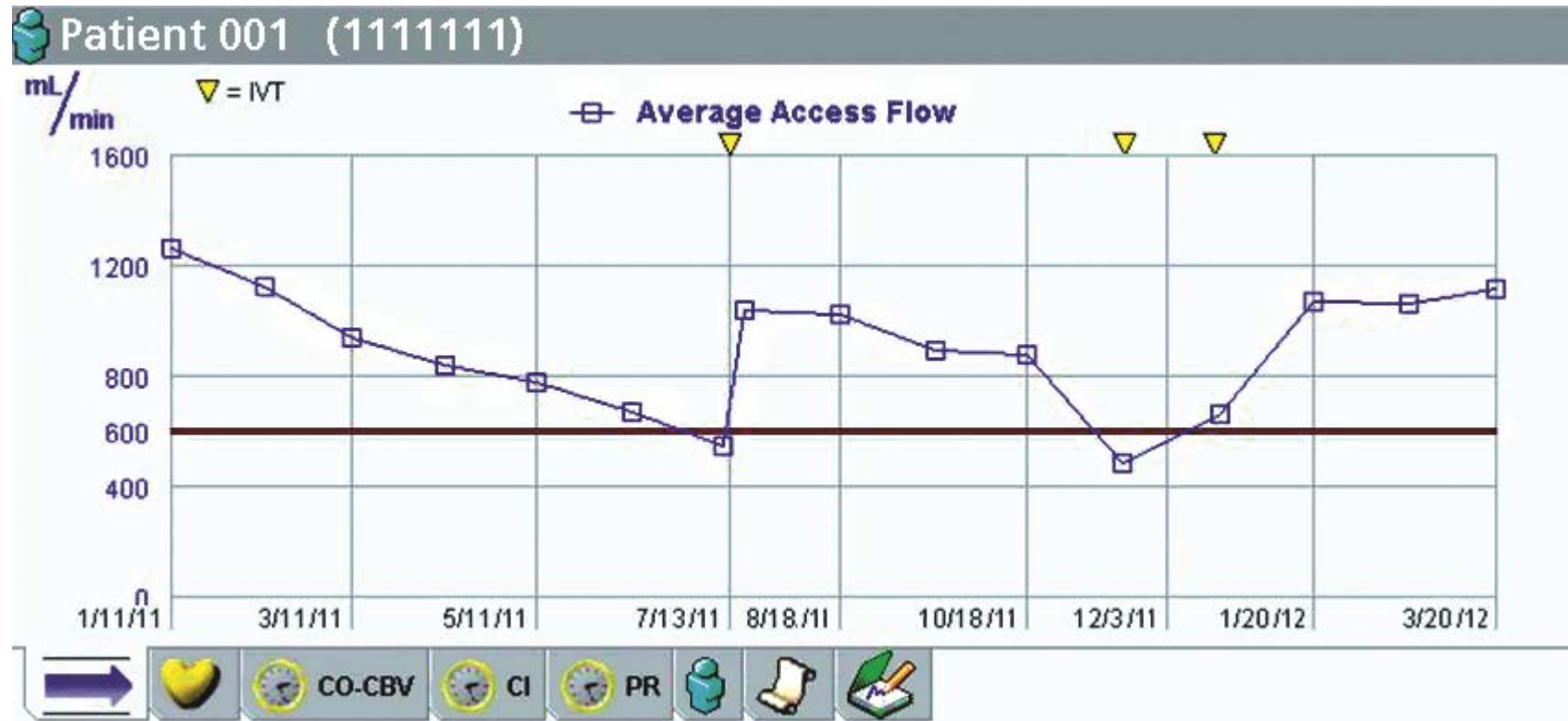
Recirculation



Access Flow



Advanced Software Capability



Fresenius OLC vs. Transonic Ultrasound Dilution

Clinical Measurement	Access Type	Fresenius OLC	Transonic Ultrasound Dilution
Access Flow	AVF, AVG	✓ Range ends at 2000 mL/min	✓ Range ends at 4000 mL/min
Access Recirculation	AVF, AVG, Catheters	No	✓ True 0%
Delivered Flow	AVF, AVG, Catheters	No	✓
Cardiac Output including AF/CO ratio	AVF/AVG	No	✓
Data Trending	AVF, AVG, Catheter	No	✓
Time for Measurement	Catheter	No	DFR and Recirculation 5 mins
	AVF, AVG	20-22 mins	10 mins for all measurements, documentation and infection control between patients
Time of Reduced Blood Flow Rates		20-24 mins per test at 200-300	2 mins for line reversal and measurement

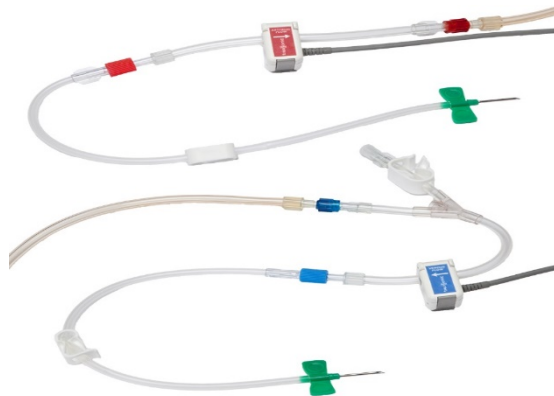
Transonic Cardiac Output Parameters

Transonic proprietary ultrasound indicator dilution technology measures Cardiac Output and reports the following derived cardiac function parameters:

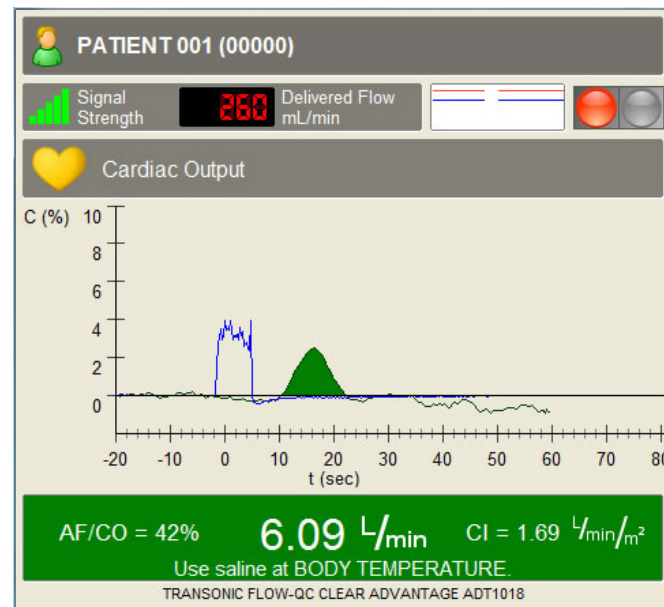
- Cardiac Output (CO);
- Cardiac Index (CI);
- Peripheral Resistance (PR);
- Central Blood Volume (CBV);
- Central Blood Volume Index (CBVI);
- Ratio of Access Flow to Cardiac Output (AF/CO).

CO Measurements Require IV Push

- The CO measurement requires the rapid injection of 30cc's of body temperature normal saline into the special bloodline tubing inserted between the standard bloodlines and the AV fistula needles



Transonic Screen Display of Cardiac Output



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

Clinical Relevance

NORMAL CARDIAC FUNCTION VALUES (Hemodialysis Population)

Cardiac function depends on age, gender, and medical history (diabetes or cardiac disease). Cardiac parameters may fluctuate dramatically during a hemodialysis treatment. Flow-QC Surveillance measures:

CO	Cardiac Output	5 to 8 L/min (wgt & hgt dependent)
CI	Cardiac Index	2.2 to 4.5 L/min/m ²
CBV	Central Blood Volume	0.8 to 1.6 L (weight dependent)
CBVI	Central Blood Volume Index	11 - 17 ml/kg
PR	Peripheral Resistance	9.6 - 18.8 mmHg/L/min

Clinical Relevance Fluid Volume Related

Parameter*	Typical Range	Abnormal Range	Clinical Relevance	Interpretation & Recommendations
Cardiac Output (CO)	5 - 8 L/min	< 2 L/min > 10 L/min	Increased risk for cardiovascular complications and failure.	Assess AF, CI & AF/CO to determine AV access impact. Refer to cardiologist for further testing.
Cardiac Index (CI)	2.2 - 4.5 L/min/m ²	< 2.0 L/min/m ²	If observed at the start of the session: indicates potential deterioration of cardiac function. If observed as a drop in CI during the session: indicates potential cardiac condition, inadequate dry weight estimation and/or effects of medication.	Inadequate dry weight estimation. The dry weight and medications should be examined by a doctor and changed if needed and CHP measurements repeated.
		> 5 L/min/m ²	May indicate: heart overload due to high access flow, significant volume of accumulated liquid between dialysis sessions and/or low hematocrit levels.	Determine reason for increased CI and implement proper treatment: • AV access intervention • Change in dialysis prescription • Change of erythropoietin prescription
Access Flow (AF)	500 - 1600 mL/min for fistulas	< 500 mL/min for fistulas < 600 mL/min for grafts	Indicates potential stenosis and/or thrombosis risk.	Significant volume of accumulated liquid between dialysis sessions
	600 - 2000 mL/min for grafts	> 1600 mL/min for fistulas > 2000 mL/min for grafts	Cardiac function compromised resulting in cardiomegaly of heart failure.	
AF/CO	< 20%	> 30%	Increased risk for cardiovascular complications and failure.	Consider reducing AF by banding or other surgical procedure. Refer to cardiologist for further testing.

What About the Cardiovascular Effects of an AV Fistula?

Immediate hemodynamic effects of AVF creation	Increase in Cardiac Output (10-20%). Increase in Sympathetic nervous system activity (increasing contractility). Increase in Stroke volume and heart rate. Decrease in Peripheral Resistance.
Hemodynamic changes within one week of AVF creation	• Increase in Circulating Blood Volume resulting in increased left atrial, inferior vena cava, and left ventricle end-diastolic volume (LVEDV). • Increase in Neuro-hormones: atrial natriuretic peptide (ANP) and brain natriuretic peptide (BNP) implying atrial and ventricular filling pressure are increased. (ANP is a powerful vasodilator and BNP is correlated with echocardiographic features). Decrease in Plasma renin and aldosterone levels. Decrease in Systemic vascular resistance and systolic/diastolic blood pressure.

MacRae JM et al, "The Cardiovascular Effects of Arteriovenous Fistulas in Chronic Kidney disease: A Cause for Concern?" Seminar in Dialysis 2006; 19:349-352

Cardiovascular Effects of an AV Fistula

Consequences of long-term AVF creation	Left Ventricular Hypertrophy (LVH): An adaptive response to increased cardiac workload caused by volume or pressure overload.
	High-Output Cardiac Failure • Patients with high-flow AVFs are most likely have a greater risk of developing CHF and greater increase in LVEDV. • AVFs in HD patients may contribute to the development of heart failure. • Left ventricle enlargement at the start of HD is very common and progressive left ventricle dilation with hypertrophy continues over time. Most of the left ventricle growth occurs during the first year of dialysis.
	Exacerbation of Coronary Ischemia • AVF placement is associated with increased myocardial O₂ demand that may not be met, especially in patients with established coronary artery disease (CAD) or left ventricle hypertrophy (LVH). • Increased O₂ consumption may have clinical manifestations in dialysis patients who have had CABG. A decrease in coronary perfusion that occurred with the onset of HD was demonstrated by the reduction in graft flow and reversible hypokinesis of the anterior left ventricle wall. • High-flow AVFs with an associated high cardiac output may increase O₂ demand and reduce supply more than a smaller AVF.
	Central Vein Stenosis • The endothelium plays an active role in vascular remodeling by secreting vasoactive substances and growth factors in response to alterations in flow and shear stress. • Increased blood flow due to AVF creation alters the shear stress on the endothelium and promotes production of substances like transforming growth factor (TGF)-β and NO which dilate the vessel lumen. • A majority of central vein stenosis occurs at the junction of the cephalic and subclavian veins. There was a high correlation between the location of a central vein stenosis and ipsilateral AVF. It suggests that altered flow hemodynamics due to a fistula may result in endothelial damage and vascular remodeling, leading to stenosis.

MaeRee JM et al. "The Cardiovascular Effects of Arteriovenous Fistulas in Chronic Kidney disease: A Cause for Concern?" Seminar in Dialysis 2006; 19:349-352

AF/CO Ratio

- The AF/CO ratio is the percentage ratio of the patient's access flow to the patient's cardiac output.
- If too much cardiac output is being diverted to the AV fistula, the patient is at risk of High Output Cardiac Failure
- AF/CO ratio should be less than 25%
- AV/CO ratio greater than 30% should be evaluated
- VA fistula banding to reduce the arterial inflow can be used to alter the AF/CO ratio

MacRae JM et al, "The Cardiovascular Effects of Arteriovenous Fistulas in Chronic Kidney disease: A Cause for Concern?" Seminar in Dialysis 2006; 19:349-352

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