
CRIT-LINE®
Where Therapy and Diagnostics Meet
Insight for Enhanced FLUID MANAGEMENT

The Importance of Fluid Management

Many dialysis patients are fluid overloaded or hypervolemic, which can lead to hypertension[1], left ventricular hypertrophy[2], and congestive heart failure[3]. Cardiovascular strain can be a consequence of interdialytic weight gain, chronic fluid overload and inappropriate fluid removal during hemodialysis.[4,5]. Fluid overload leads to hemodynamic instability, and most probably higher cardiovascular morbidity[6,7]. As such, fluid management and the achievement of a normal hydration status or euvolemia is important.

One of the goals of dialysis is removal of excess fluid by ultrafiltration. However, if the rate of this fluid removal--or the ultrafiltration rate--is too fast for the patient, hypovolemia can occur, resulting in intradialytic morbid events such as cramping, nausea, dizziness and "crashing".

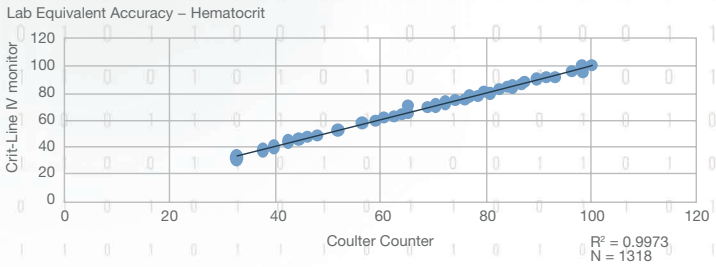
The ability to achieve a proper balance between the Ultrafiltration Rate (UFR) and plasma refill has been an ongoing challenge in the administration of dialysis treatments[8].

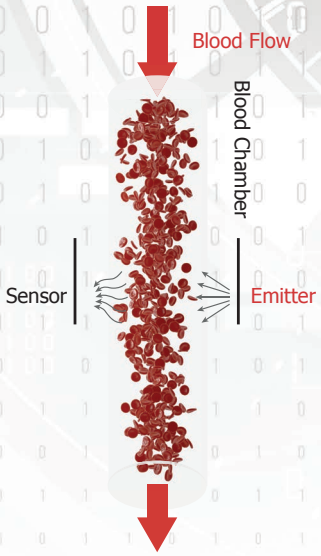
Optical Precision for Real Time Lab-Equivalent Results

Hct Range: 10–60 Hct
Hct Accuracy: ±1 Hct SD

Oxygen Saturation Instrument Range and Accuracy

@ Hct	Accurate within ±3%	Accurate within ±5%
45 – 60	60 – 100	50 – 100
20– 45	50– 100	30– 100
10 – 20	not specified	40 – 100





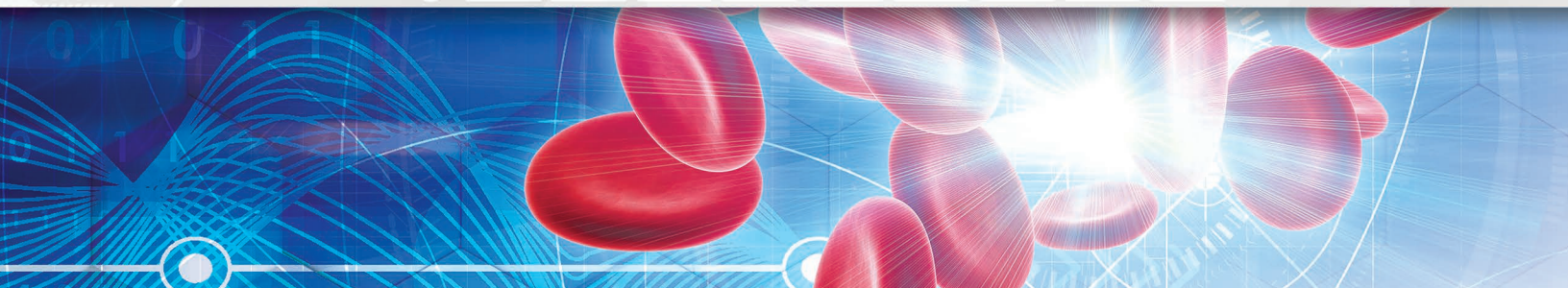
Crit-Line® technology is a non-invasive approach that continuously monitors a patient's relative blood volume (% RBV), which is the percent change in blood volume from the start of a dialysis session to the end of that session. Crit-Line operates by measuring the hematocrit level (which is inversely proportional to blood volume) through optical technology. During dialysis, the extra-corporeal blood flow is trans-illuminated by multiple wavelengths of light. Utilizing the principles of Beer's Law – which relates light absorbance and its transmittance through any given material – the hematocrit level is continuously measured. This continuous non-invasive Hct measurement correlates positively (R = 0.89) with Hct levels determined by centrifugation[9].

Crit-Line Technology: A Window into the Patient's Bloodstream

Crit-Line non-invasive optical technology provides continuous monitoring of Hct and O_2 Sat levels throughout the dialysis session. Key measurements are then used to provide accurate calculations of Hgb and Relative Blood Volume Change (%RBV). Crit-Line technology also allows the user to set a patient-specific critical RBV level below which an alarm will alert the user.

Immediate Access to Key Data Points:

Initial Hct - Initial Hgb - O_2 Sat Level - %RBVΔ

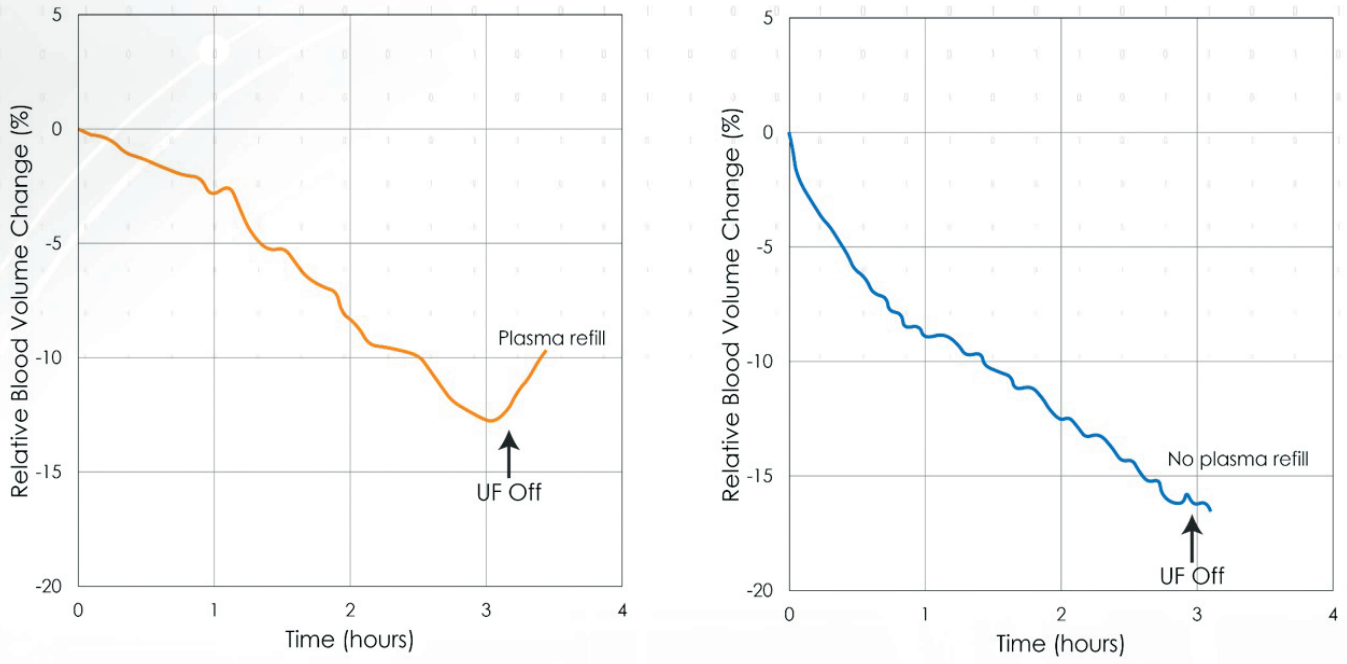


Providing Insight into Fluid Shifts and Plasma Refill During HD

Knowledge of plasma refill and compartment shifts can help in understanding intradialytic events and may improve fluid removal. Jabarra et. al, assessed the relationship between blood volume changes and plasma refill. They demonstrated that in the absence of ultrafiltration, RBV monitoring could detect whether fluid was shifting from extracellular to the intravascular space.[10]

By performing a refill check, clinicians can assess whether plasma refill is occurring.

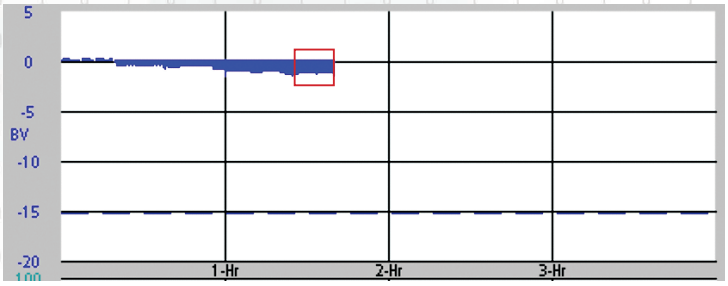
Plasma refill can be assessed with Crit-Line.



Relative blood volume monitoring can be used to assess the presence or absence of plasma refill when ultrafiltration is turned off or to mininum depending upon clinic policy.

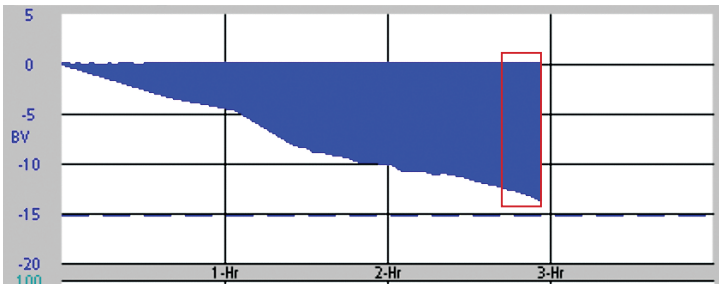
Crit-Line Technology Profiles

The Crit-Line technology offers easy-to-interpret patient profiles that can help the clinician with treatment assessment and intervention during hemodialysis. By monitoring relative blood volume percent changes, clinicians can adjust treatment as necessary to maximize fluid removal and prevent common symptoms of dialysis, such as nausea, vomiting and cramping.



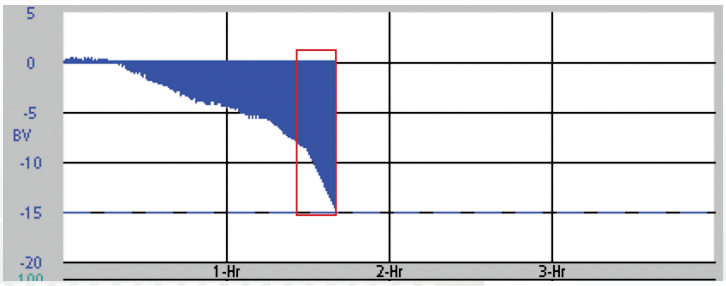
Profile A:

Profile A, represented with a flat or slightly positive, slope, is displayed when the measurements taken over the previous 15 minutes result in a profile that is ≤ -3% per hour.



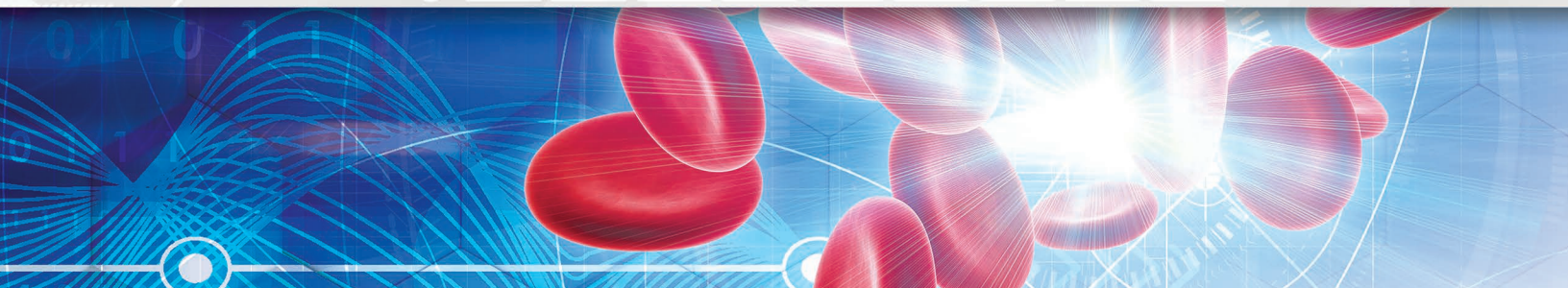
Profile B:

Profile B is displayed when the measurements taken over the previous 15 minutes result in a profile that is > -3% per hour and ≤ -6.5 % per hour. The ideal slope is not a fixed percentage of change in BV, and will vary from patient to patient.



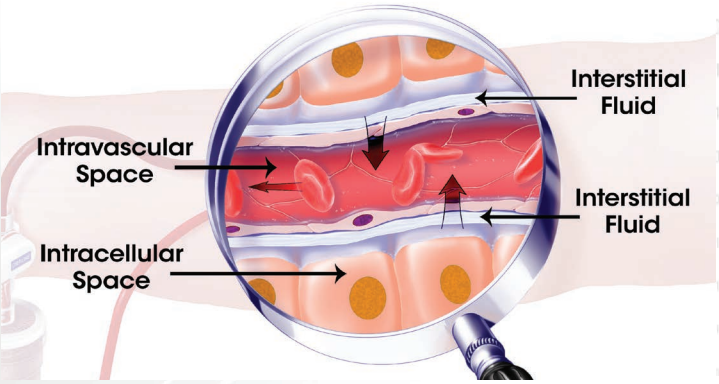
Profile C:

Profile C, represented with a steep declining slope, is displayed when the measurements taken over the previous 15 minutes result in a profile that is > -6.5% per hour.



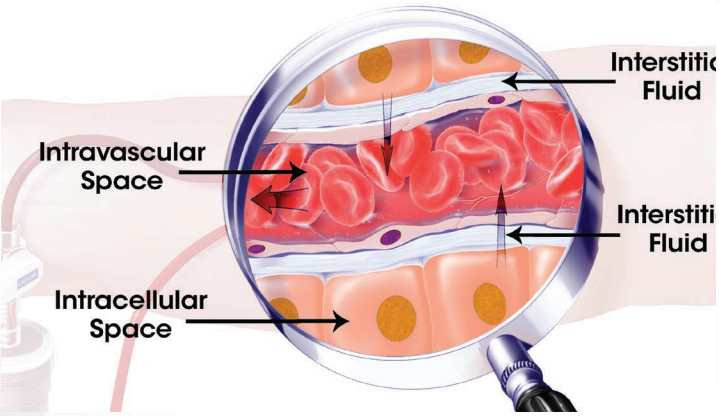
Curves Matter

The patient profiles provided by Crit-Line gives the clinician a continuous real-time visual of how the patient is tolerating the UFR. The profiles are classified by the Crit-Line monitor as A (flat or slightly positive curve), B (gradually declining curve), or C (steep declining curve). While a B curve represents the best compromise between UFR and avoidance of intradialytic symptoms, both A and C curves may indicate situations that could warrant clinician intervention.



Profile A:

This profile indicates that the patient's plasma refill rate is occurring at the same or greater rate than the ultrafiltration. Profile A suggests that the ultrafiltration rate might be increased without immediate risk of intradialytic symptoms.

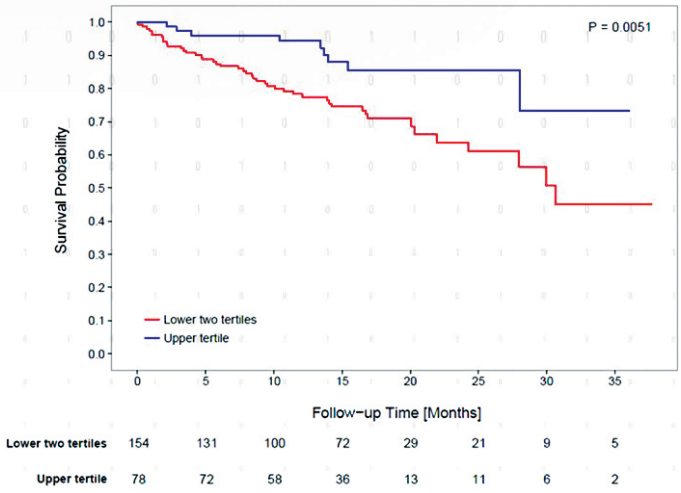


Profile C:

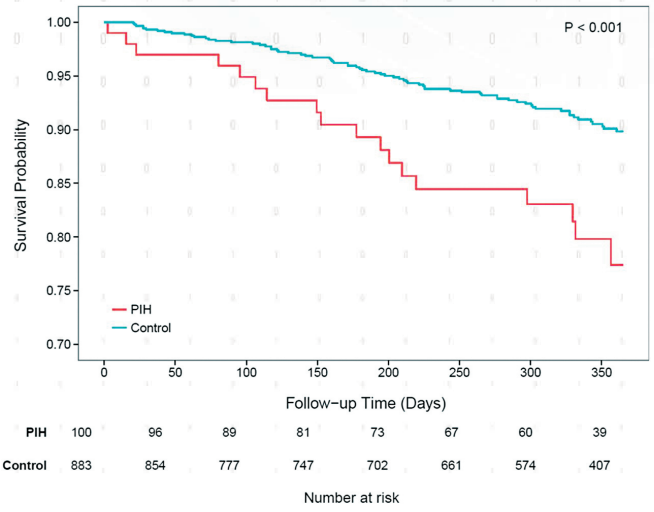
Represented as a steep slope, Profile C indicates a rapid decrease in blood volume and bears a higher risk for intradialytic symptoms.

Continuous Monitoring of O_2 Saturation Because Hypoxia Matters

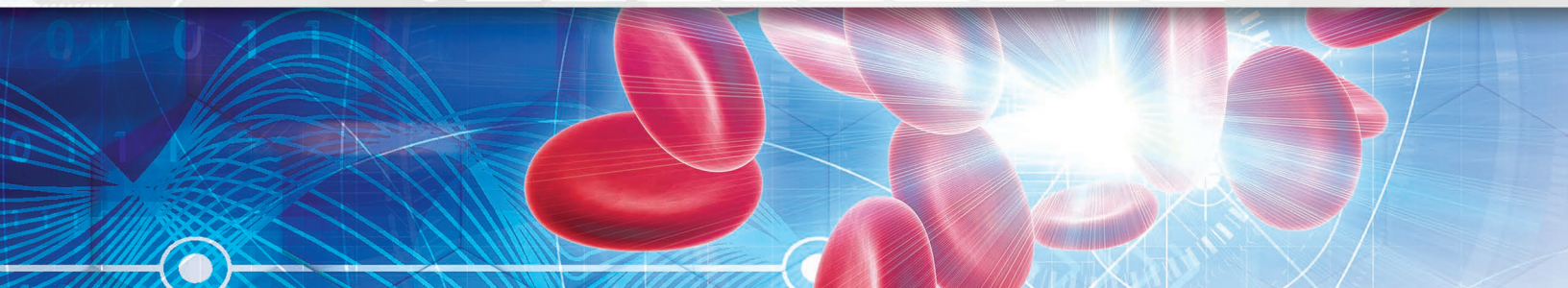
Crit-Line technology also provides clinicians with the ability to continuously monitor SaO_2 and $ScvO_2$ (derived) during dialysis therapy. Several recent studies have demonstrated an association between lower intradialytic SaO_2 or $ScvO_2$ levels and poor outcomes. Chan et al[1] demonstrated an association between lower intradialytic $ScvO_2$ and shorter survival time while Meyring-Wosten et al[2] demonstrated an association between Prolonged Intradialytic Hypoxia (SaO_2 < 90% for at least one-third of the treatment time) and lower survival probability.



Chan et. al, suggest a 1% decrease in mean $ScvO_2$ was associated with a 4% increase in mortality.



Meyring-Wösten et al suggest a relationship between Prolonged Intradialytic Hypoxemia (PIH) and lower probability of survival vs. non-PIH patients.

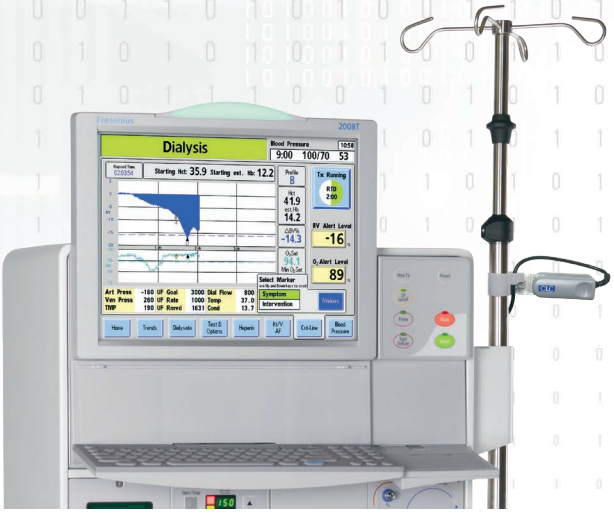


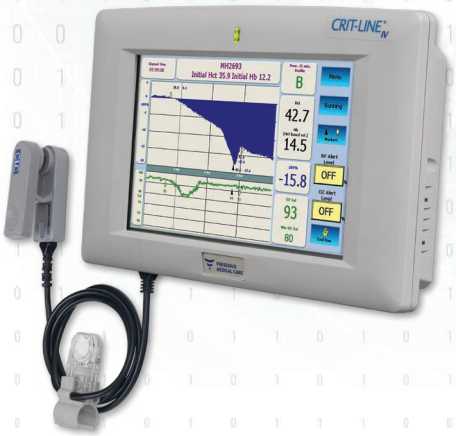
Why Crit-Line Technology is Important

- Provides insight as to how a patient is tolerating dialysis.
- Provides data to help the clinician remove the maximum amount of fluid while preventing common complications of dialysis.
- Provides data to help identify patients that may be at risk for intradialytic complications.
- Helps the healthcare professional visualize the patient's plasma refill rate in real-time.
- Provides a more effective dialysis treatment.

Crit-Line Technology Offerings

Crit-Line technology can be integrated into dialysis therapy:



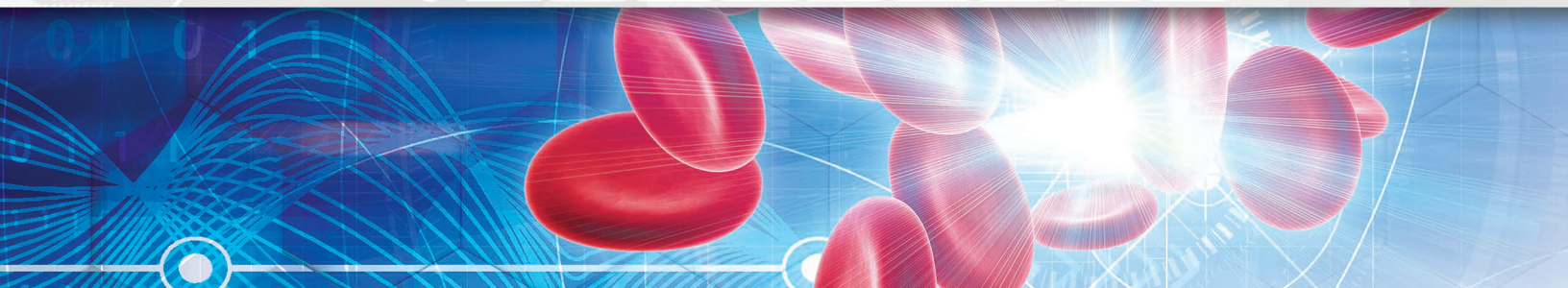


CLiC™ is Crit-Line technology integrated directly into the Fresenius Medical Care 2008T HD machine, allowing for all key dialysis and Crit-Line metrics to be displayed on one screen. Clinicians have access to data for immediate intervention though the touch screen functionality of the 2008T interface.

With Clinical Data eXchange™ (CDX), the 2008T machine becomes an integrated component of the Medical Information System (MIS) utilized in the dialysis clinic. Clinicians use the CDX toggle key to navigate between dialysis screens and the MIS system. All intervention and observations entered are immediately recorded and uploaded to the electronic medical record.

Crit-Line IV Monitor is a stand-alone device which can be used in conjunction with all Fresenius Medical Care 2008® series HD machines as well as other HD delivery systems.

The stand-alone device allows for continuous real-time RBV monitoring and access to key data points during dialysis therapy.



Crit-Line technology is a cost-effective method to continuously monitor key blood parameters during therapy allowing the clinician to determine appropriate intervention, if needed, during treatment.

CONTACT YOUR LOCAL FRESENIUS RENAL THERAPIES SALES REPRESENTATIVE TO LEARN MORE ABOUT CRIT-LINE TECHNOLOGY OR ANY OTHER FRESENIUS RENAL THERAPIES PRODUCT OFFERING.

FOOTNOTES

1. Dionisio P, et al. Influence of the hydration state on blood pressure values in a group of patients on regular maintenance hemodialysis Blood Purif. 1997; 15:25-33

2. Stegmayr BG. Ultrafiltation and dry weight – what are the cardiovascular effects? Artif Organs 2003; 27:227-229

3. Harnett JD, et al. Congestive heart failure in dialysis patients: Prevalence, incidence, prognosis and risk factors Kidney Int. 1995; 47:884-890

4. Kalantar-Zadeh K, et al. Fluid retention is associated with cardiovascular mortality in patients undergoing long-term hemodialysis. Circulation. 2009; 119(5):671–679

5. Wizemann V, et al. The mortality risk of overhydration in haemodialysis patients. Nephrol Dial Transplant. 2009; 24(5):1574–1579

6. Jacobs LH, et al. Inflammation, overhydration and cardiac biomarkers in haemodialysis patients: a longitudinal study. Nephrol Dial Transplant. 2010; 25(1):243–248.

7. David S, et al. Diagnostic value of N-terminal pro-B-type natriuretic peptide (NT-proBNP) for left ventricular dysfunction in patients with chronic kidney disease stage 5 on haemodialysis. Nephrol Dial Transplant. 2008; 23(4):1370–1377

8. Levin NW, et al. Eds. Clinical Dialysis 2nd Ed Norwalk: Appleton & Lange; 1990:172-201

9. Leypoldt J, Cheung A, et al. Determination of Circulating Blood Volume by Continuously Monitoring Hematocrit during Hemodialysis Journal of the American Society of Nephrology 1995; 6:214-219

10. Jabara AE, et al. Determination of fluid shifts during chronic hemodialysis using bioimpedance spectroscopy and in-line hematocrit monitor. ASAIO J. 1995 Jul-Sep; 41(3):M682-7.

11. Chan L, Zhang H, et al. Intradialytic Central Venous Oxygen Saturation is Associated with Clinical Outcomes in Hemodialysis Patients Scientific Reports 7:8581

12. Meyring-Wosten A, et al. Intradialytic Hypoxemia and Clinical Outcomes in Patients on Hemodialysis Clin J Am Soc Nephrol 11: 616–625, April, 2016

DISCLOSURE STATEMENTS:

Chan et al.
Fresenius Medical Care Renal Therapies Group (FMCRTG) is the manufacturer of the Crit-Line technology that is the subject of this journal article. In this study, the Crit-Line technology is used according to the FDA-approved indications for use (see below); however, the study discusses the use of the Crit-Line technology as a diagnostic tool in assessment of mortality rates and blood pressure, which is not part of the FDA-approved indications for use. The significant risks or safety concerns known to FMCRTG concerning the unapproved use of the Crit-Line technology are as follows: The authors note that lower $ScvO_2$ levels, obtained with Crit-Line technology, are associated with poorer survival. They also noted that patient with lower $ScvO_2$ had lower pre-HD and lower post-HD SBP, but correlation scores between $ScvO_2$ were very low. However, as they noted their study was observational in nature and cannot determine definitive associations between use of Crit-Line and lower mortality, or provide insight into cardiovascular effects or potential for adverse events. At the time of publication, the authors had a financial interest in the product and company; all authors were employees of FMCRTG and/or affiliated Fresenius Medical Care North America entities. Funding for the study discussed in the article was provided by FMCRTG.

Jabarra et al.
Fresenius Medical Care Renal Therapies Group (FMCRTG) is the manufacturer of the Crit-Line technology that is the subject of this journal article. In this study, the Crit-Line technology is used according to the FDA-approved indications for use (see below), however, the study discusses the use of the Crit-Line technology as a diagnostic tool in assessment in conjunction with a bioimpedance spectroscopy device for measuring the plasma refill rate and weight changes; the combined use is not part of the FDA-approved indications for use. The significant risks or safety concerns known to FMCRTG concerning the unapproved use of the Crit-Line technology are as follows: Some data provided in the article cannot be solely obtained with the Crit-Line technology. The authors also state that in-line hematocrit monitoring provided absolute blood volume and the plasma refill rate (PRR). The Crit-Line technology does not measure absolute blood volume, only relative blood volume. The authors calculated the PRR from computed plasma volumes, which were determined with the bioimpedance device. Misunderstanding of the use of Crit-line technology or the measurements provided by Crit-Line technology may lead to inaccurate patient assessments and inappropriate fluid management.

Meyring-Wosten et al.
Fresenius Medical Care Renal Therapies Group (FMCRTG) is the manufacturer of the Crit-Line technology that is the subject of this journal article. In this study, the Crit-Line technology is used according to the FDA-approved indications for use (see below), however, the study discusses hospitalization, mortality and erythropoietin requirements with use of the Crit-Line technology, which is not part of the FDA-approved indications for use. The significant risks or safety concerns known to FMCRTG concerning the unapproved use of the Crit-Line technology are as follows: (1) use of Crit-Line technology in assessing outcomes with prolonged intradialytic hypoxemia (PIH); (2) study may not be generalizable; (3) PIH, determined by Crit-Line measurements of O_2 saturation, was shown in this study to be associated with known markers of inflammation, higher erythropoietin requirements, and higher all-cause hospitalization and mortality; (4) the study was observational and retrospective in nature and cannot determine definitive associations between use of Crit-Line and the outcomes discussed. Further studies are needed to properly assess hypotheses and study limitations. At the time of publication, the authors had a financial interest in the product and company; all authors were employees of FMCRTG and/or affiliated Fresenius Medical Care North America entities. Funding for the study discussed in the article was provided by FMCRTG.

Indications for Use: The CLiC device is used with the 2008T hemodialysis machine to non-invasively measure hematocrit, oxygen saturation and percent change in blood volume. The CLiC device measures hematocrit, percent change in blood volume and oxygen saturation in real time for application in the treatment of dialysis patients with the intended purpose of providing a more effective treatment for both the dialysis patient and the clinician. Based on the data that the monitor provides, the clinician/nurse, under physician direction, intervenes (i.e., increases or decreases the rate at which fluid is removed from the blood) in order to remove the maximum amount of fluid from the dialysis patient without the patient experiencing the common complications of dialysis which include nausea, cramping and vomiting. The CLiC blood chamber is a sterile, single use, disposable, optical cuvette designed for use with the CLiC monitor's sensor clip during acute and chronic hemodialysis therapy to non-invasively measure hematocrit, percent change in blood volume and oxygen saturation. The blood chamber is connected between the arterial bloodline and the dialyzer within the extracorporeal circuit during the hemodialysis treatment. The 2008T hemodialysis machine is indicated for acute and chronic dialysis therapy. The Crit-Line III monitor is a non-invasive hematocrit, oxygen saturation and percent change in blood volume monitor used in the treatment of hemodialysis patients. In addition, the Crit-Line III monitor estimates access recirculation and access blood flow in hemodialysis patients. The Crit-Line IV monitor is used to non-invasively measure hematocrit, oxygen saturation and percent change in blood volume. The sensor clip measures hematocrit, percent change in blood volume and oxygen saturation in real time for application in the treatment of dialysis patients with the intended purpose of providing a more effective treatment for both the dialysis patient and the clinician. Based on the data that the monitor provides, the clinician/nurse, under physician direction, intervenes (i.e. increases or decreases the rate at which uid is removed from the blood) in order to remove the maximum amount of uid from the dialysis patient without the patient experiencing the common complications of dialysis which include nausea, cramping and vomiting. The Crit-Line blood chamber is a sterile, single-use, disposable, optical cuvette designed for use with the Crit-Line sensor clip during acute and chronic hemodialysis therapy to non-invasively measure hematocrit, percent change in blood volume and oxygen saturation. The blood chamber is connected between the arterial bloodline and the dialyzer within the extracorporeal circuit during the hemodialysis treatment.

Caution: Federal (US) law restricts these devices to sale by or on the order of a physician.

Note: Read the Instructions for Use for safe and proper use of these devices. For a complete description of hazards, contraindications, side effects and precautions, see full package labeling at www.fmcna.com.

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RENAL TECHNOLOGIES

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