

FAQ

Frequently Asked Questions
Regarding Fluid Shift, Relative Blood Volume
and Crit-Line® Technology



1 What is the primary function of Crit-Line technology?

Crit-Line technology is designed to non-invasively measure the patient's hematocrit, oxygen saturation and percent change in intravascular blood volume. In addition, the device provides a calculated hemoglobin. With these real time data points, provided throughout the duration of the hemodialysis treatment, the clinician can visualize relative changes in blood volume.

The technology is available as a stand-alone device (Crit-Line IV Monitor) or as an optional module on the 2008T hemodialysis machine (CLiC™ device).

2 What is plasma refill? Is it the same for every patient?

During hemodialysis, fluid is removed by ultrafiltration using the dialysis membrane. This can cause plasma refill, which is a shift in fluid from tissues into the blood. The speed at which the fluid shifts is called the plasma refill rate (PRR). The PRR is determined by the hydrostatic, oncotic, and osmotic pressure gradients between the capillary and the interstitial space.¹

Plasma refill differs from patient to patient and can differ from treatment to treatment and even during a single treatment. Due to the dynamic and changing nature of plasma refill, it cannot be assumed that pre-set parameters should be consistent throughout the duration of the treatment.

The ability to maintain plasma volume during ultrafiltration requires mobilization of fluid from the interstitial into the intravascular space. Vascular refilling is influenced by both patient-specific and treatment-related factors that dictate the distribution of water between the body fluid compartments.²

3 Why does my patient experience intradialytic hypotension (IDH) during some treatments?

IDH occurs when the dialysis ultrafiltration rate exceeds the rate of plasma refill from normal physiologic compensatory mechanisms. When refill trails behind ultrafiltration, physiologic mechanisms are brought to action to maintain blood pressure, heart rate, myocardial contractility, peripheral vasoconstriction, augmentation of venous return, and release of vasoactive mediators.³

4 Are there specific comorbid conditions that contribute to intradialytic hypotension (IDH)?

Patients with specific co-morbidities such as autonomic dysfunction, diabetes mellitus, coronary artery disease, systolic dysfunction, and left ventricular hypertrophy are at risk for IDH. Evidence shows that there are non-cardiovascular implications that contribute to fluid overload such as inflammation and hypoalbuminemia. Decreased serum albumin level predicts poor survival in end-stage renal failure. Hypoalbuminemia is multifactorial and related to poor nutrition, inflammation, and comorbid disease.^{4,5}

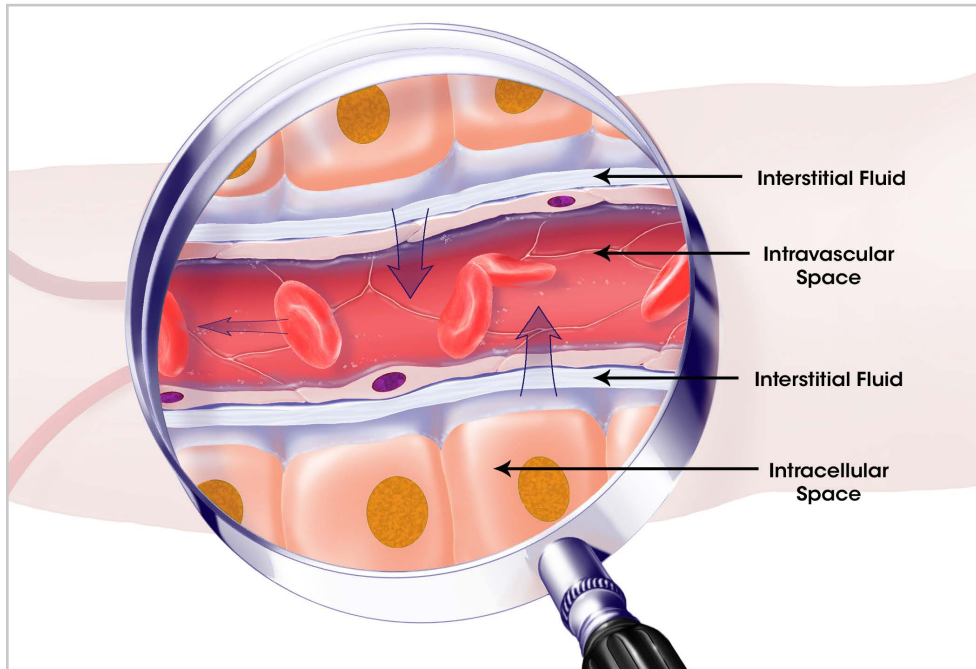
5 How does low albumin affect fluid removal during hemodialysis?

Albumin accounts for roughly 80% of the total oncotic pressure exerted by blood plasma on interstitial fluid. Reduced oncotic pressure, typically due to hypoalbuminemia, occurs in several diseases such as renal disease where the loss of albumin occurs across the glomerulus (nephrotic syndrome), and common causes may include diabetic nephropathy, lupus nephropathy, amyloidosis).^{6,7}

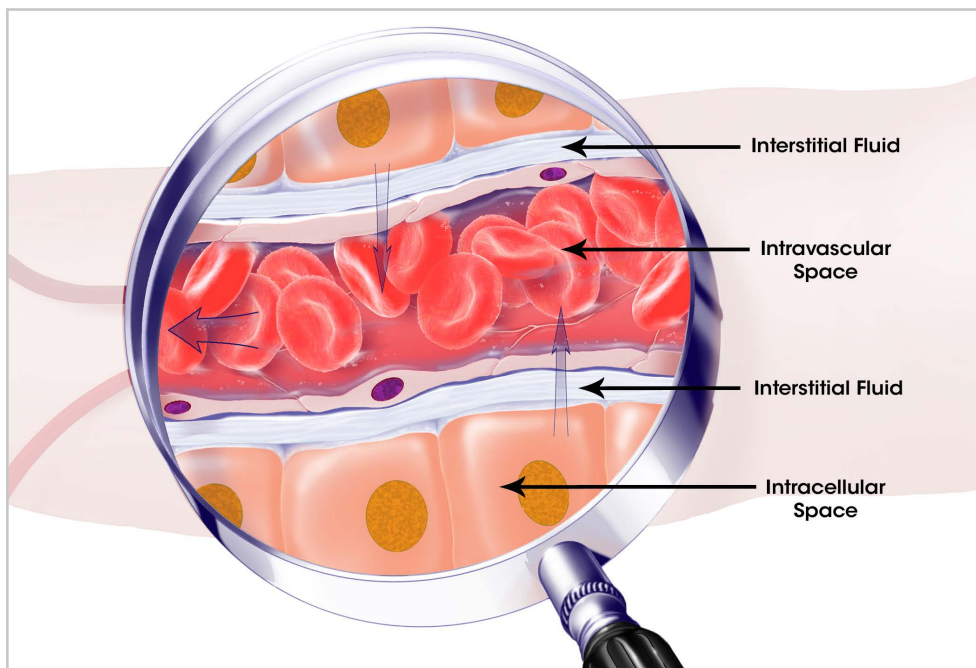


6 Why is Crit-Line valuable during ultrafiltration?

Having a window into the patient's intravascular space during ultrafiltration, the clinician, under physician direction, can increase or decrease the patient's ultrafiltration rate to optimize the rate of fluid removal while avoiding common symptoms of dialysis.



A low UF rate combined with a high refill rate potentially misses the opportunity for more effective fluid removal.^{8,9}



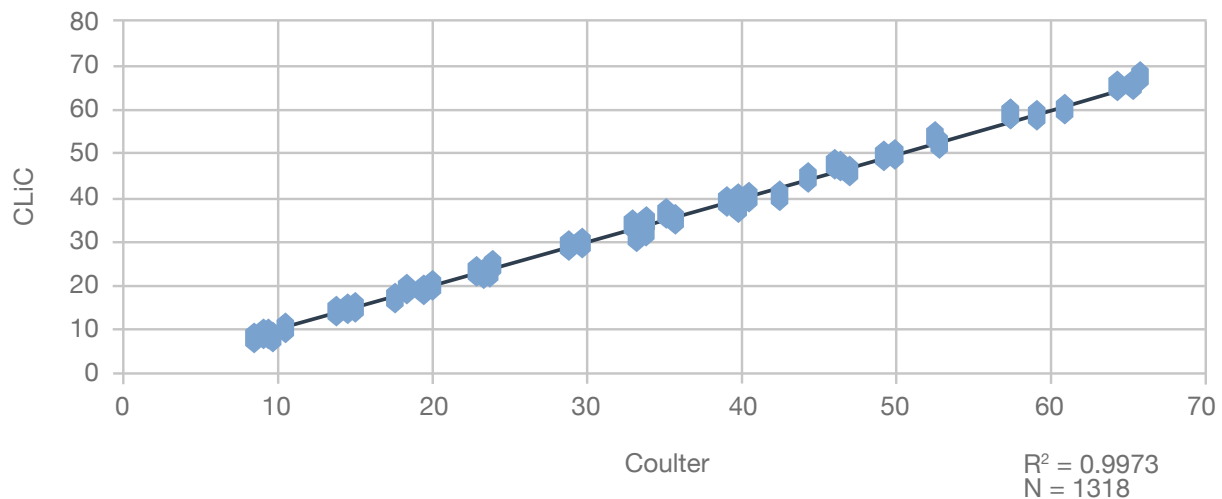
A high UF rate combined with a slow refill rate can lead to symptoms like dizziness, nausea and hypotension.^{9,10}

7 How does the Crit-Line device conduct measurements?

The Crit-Line sensor clip (CLiC™ device) emits multiple wavelengths of light through a disposable viewing window called a blood chamber attached to the hemodialysis bloodline. The blood is trans-illuminated by multiple wavelengths of light and the differences in light absorption between blood constituents allow for identification and measurement of hematocrit and oxygen saturation.

8 Does the Crit-Line provide a lab equivalent HCT? What is the range and accuracy of CLiC technology?

Yes, the Crit-Line device provides lab equivalent hematocrit. Each device is calibrated through comparison to lab-based Coulter equipment for HCT and a Co-Oximeter for oxygen saturation accuracy.



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

Oxygen Saturation Instrument Range and Accuracy

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

9 Why does the O₂ Saturation on the Crit-Line device read much lower than the pulse oximeter reading used in the facility?

The Crit-Line device reads the oxygen saturation of blood from the patient's access site. If the patient has a central venous catheter, the tip of the catheter sits in the right atrium. Therefore, it is reading S_{CV}O₂.

S_{CV}O₂ measures venous blood returning from the upper half of the body. It is the best evidence-based parameter to manage oxygen delivery and oxygen consumptions of the organs. S_{CV}O₂ can help the clinician understand how well the heart is working to deliver necessary oxygen to the organ tissues. The normal ranges for S_{CV}O₂ vary from 60% to 80%.^{11,12,13,14,15}

S_aO₂ measures the percentage of arterial oxygen bound to hemoglobin. Because this point of access is an arteriovenous fistula or graft, it provides an accurate assessment of arterial blood oxygenation status. This S_aO₂ can help the clinician to understand the oxygen saturation of the arterial blood and to assess the patient's respiratory function. Normal ranges vary from 90% to 100%.^{12,13,14,15}

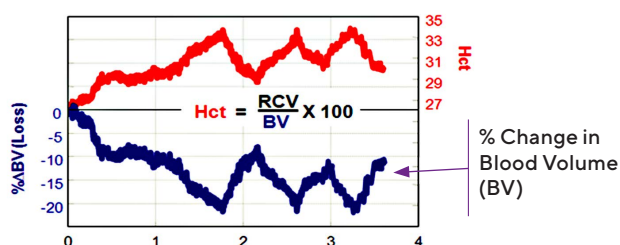
10 Where is the CLiC device blood chamber placed?

The blood chamber is attached between the arterial bloodline and the arterial side of the dialyzer. For customers purchasing the CombiSet SMARTECH[®] bloodlines, the blood chamber is integrated into the arterial bloodline.

11 How does the CLiC device calculate percent change in relative blood volume?

There is an inverse relationship between hematocrit and relative blood volume change.

This inverse relationship is shown in the picture below.



Relative blood volume is calculated using the following formula:

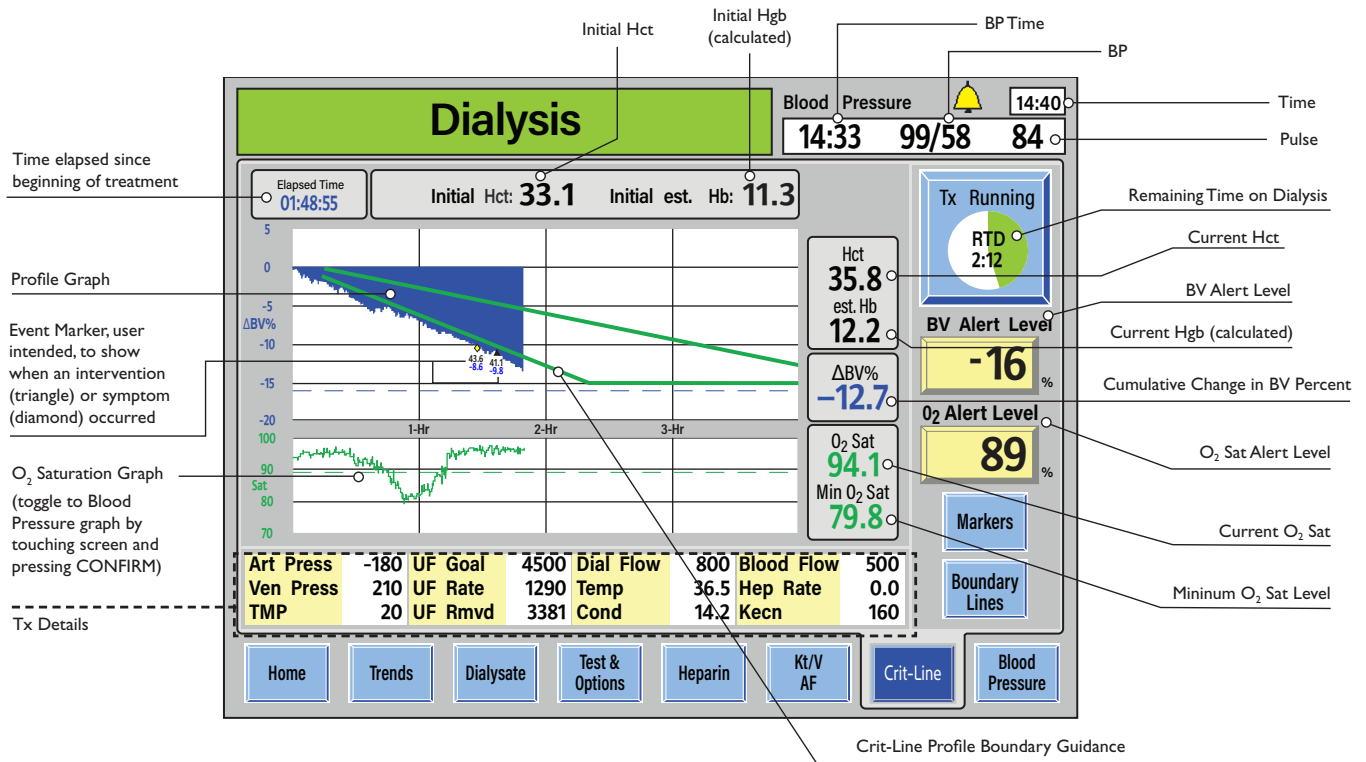
$$1 \text{ BV}\% \Delta = \{(H1/H2)-1\} \times 100$$

H1 = initial HCT

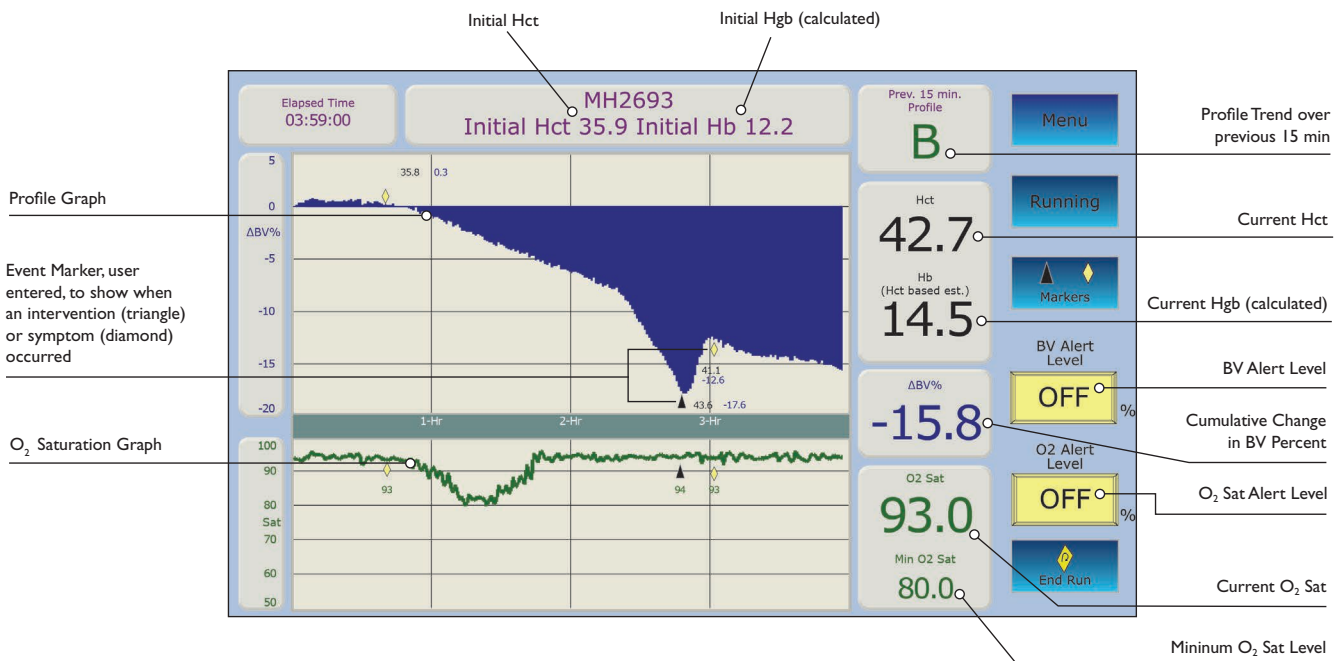
H2 = current HCT

12 What information is displayed on the Crit-Line screen?

2008T with CLIC™



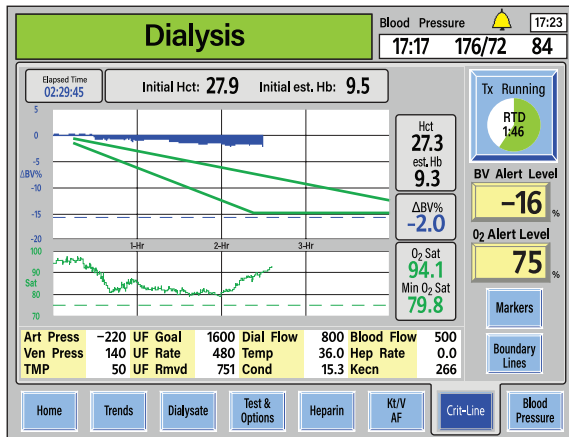
Crit-Line IV Monitor



13 What is a Crit-Line Profile and how do I interpret the data?

Crit-Line provides a graphic display of the percent change in relative blood volume throughout the treatment. This is referred to as the Crit-Line profile.

A current profile is the cumulative change in blood volume divided by the total elapsed time of the treatment.

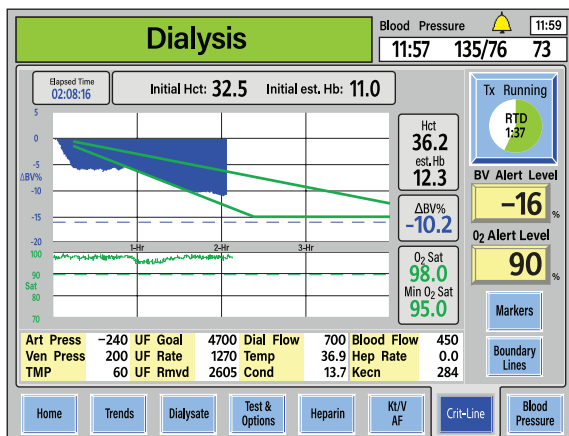


Flat or Positive Slope

RBV Reduction less than 3% per hour

This profile indicates that the patient's plasma refill rate is occurring at the same or a greater rate than ultrafiltration. This type of profile would suggest that the clinician might be able to increase the ultrafiltration rate slightly without immediate risk of intradialytic symptoms.

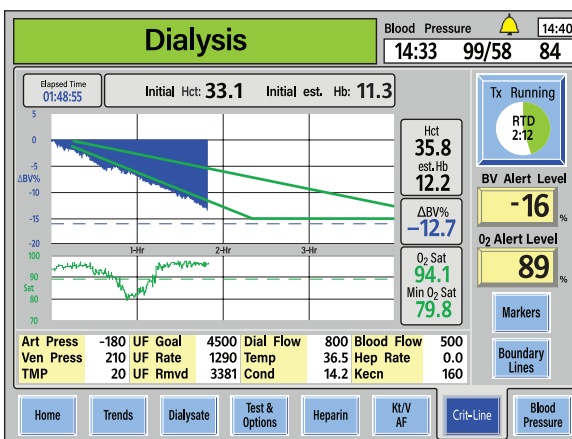
Please note that this profile may be acceptable in some patients but not others. Thus the clinician should always assess the patient's condition before making any interventions.



Gradual Slope

RBV reduction Between 3% per hour 6.5% per hour

This profile has been targeted to find the best compromise between a high ultrafiltration rate and the prevention of intradialytic symptoms. The ideal slope is not a fixed percentage of change in blood volume and will vary from patient to patient based on their individual characteristics.



Steep Slope

RBV reduction greater than 6.5 % per hour

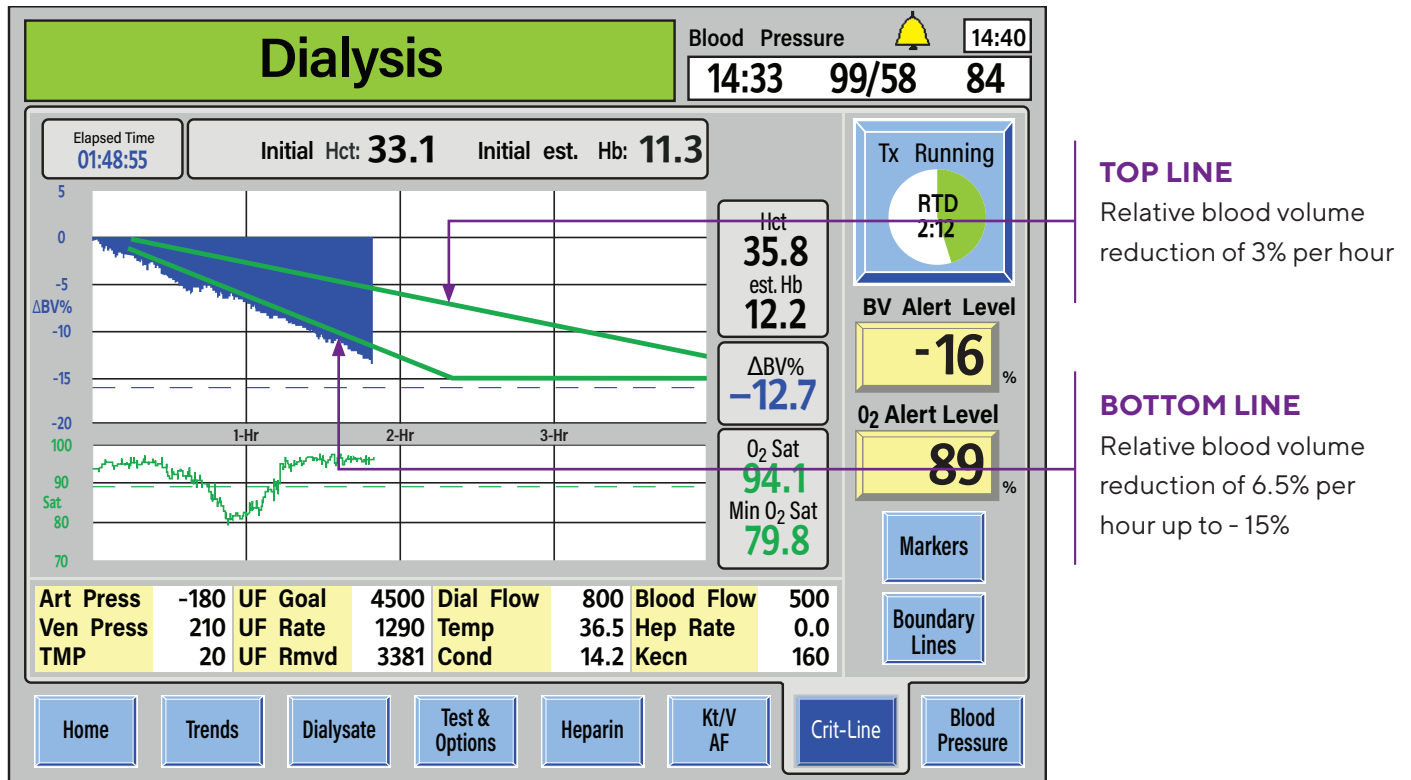
This slope represents a rapid decrease in blood volume. The ultrafiltration rate exceeds the patient's refill rate.

This slope bears a higher risk for intradialytic symptoms during ultrafiltration given the patient's inability to mobilize the excess volume from their tissue compartments into their intravascular compartment.

Some patients may have a lower or higher tolerance depending on their cardiovascular status and other comorbidities (i.e., diabetes, autoimmune disturbances, malnutrition).

14 What are Crit-Line Profile Boundary Lines?

The Crit-Line profile boundary lines are visual lines displayed on the Crit-Line screen of the 2008T BlueStar™ machines, which help to visually represent data related to key threshold rates that have been shown to impact mortality and morbidity outcomes.⁹



What is the purpose of the boundary lines and how can they be helpful?

They are designed to provide an additional visual aid that supports clinical observation of ultrafiltration tolerance during the hemodialysis treatment. When using guidance lines in combination with clinical observation, the blood volume reduction rate zone may help optimize ultrafiltration while reducing risk of intradialytic symptoms.^{9, 16}

Is there data that shows patients do better when their blood volume profile is between the two boundary lines?

Several publications reference an association between overall reduction of blood volume, improved survivability, and reduction of hospitalizations.^{17, 18} In 2018, Preciado et al, concluded that specific hourly intradialytic RBV ranges were shown to be associated with lower all-cause mortality in chronic HD patients.⁹

15 Does Crit-Line continue to provide data in longer dialysis treatments?

If the treatment goes longer than four hours, the Crit-Line display will rescale to accumulate data up to a maximum of 10 hours.

16 Does the CLiC device tell the user what interventions should be made?

Crit-Line devices do NOT tell the user what interventions should be made. They provide accurate, real-time information on how the patient is tolerating the ultrafiltration rate during the hemodialysis treatment. The Crit-Line devices are not intended to replace the judgment or experience of the attending physician or other medical professionals. The hemodialysis treatment prescription is the sole responsibility of the attending physician.

17 How can the data points provided by the Crit-Line device help caregiver prevent common dialysis related symptoms?

During the hemodialysis treatment, if a patient graph is exhibiting a steep slope, indicating the patient does not have plasma refill, the caregiver can provide immediate intervention under physician direction to help avoid common symptoms of IDH.^{1,19,20}

18 How can one prescribe Crit-Line technology?

Items for HCP Consideration When Establishing General Orders

Frequency of Use

e.g., Crit-Line Monitor should be used as prescribed by Physician/NP/PA order.

Discontinuation/Adjustment in Treatment Parameters

e.g., Do not use Crit-Line when using Sodium modeling or ultrafiltration (UF) profiling during treatment, as no studies support concomitant use.

e.g., Do not use Crit-Line monitor during treatments with hypertonic solutions, as no studies support concomitant use.

e.g., Do not use Crit-Line monitor during any blood product administration, as no studies support concomitant use and is not recommended per manufacturer's IFU.

UF Goal and UF Rate Setting

e.g., Determine UF goal based on assessment and physician target weight order.

e.g., If post-treatment weight is less than the estimated dry weight or patient presents below target weight and is stable by RN assessment, _____

Suggestions for consideration:

- » Call Physician/NP/PA for new EDW order
- » Set UF goal to last post weight if hemodynamics are stable and patient asymptomatic

e.g., If ultrafiltration rate (UFR) will exceed _____ ml/kg/hr (specific to patient) during Crit-Line Monitoring, consult Physician/NP/PA to determine whether Physician/NP/PA wants to order:

Suggestions for consideration:

- » approve UFR
- » increase treatment time
- » schedule extra treatment*

Oxygen Saturation Monitoring

e.g., Oxygen saturation will be monitored during treatment. Supplement oxygen if below the following range _____ - _____%.

Medical literature suggests medical assessment for oxygen levels below of the following ranges: ^{12,13,14,15}

$S_V O_2$ 60-80%.

$S_{CV} O_2$ 60-80%.

$S_a O_2$ 90-100%.

Clinical Observation or Assessment

e.g., Nurse to consult with Physician/NP/PA when nurse believes that, based on assessment of the patient's condition, it may not be appropriate to follow this standing order.

These considerations have been developed by the Fresenius Medical Care Renal Therapies Group. They are intended to provide pertinent data to assist healthcare professionals (HCP) in forming their own conclusions and making decisions. They are not intended to replace the judgment or experience of the attending physician or other medical professionals. The treatment prescription is the sole responsibility of the attending physician.

Please refer to the instructions for use (IFU) for detailed information on device description, instructions, contraindications, warnings, and precautions.

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Use: Crit-Line Technology is designed to non-invasively measure hematocrit, oxygen saturation and percent change in blood volume. The technology employs a sensor clip which emits multiple wavelengths of light to trans-illuminate the blood in the Crit-Line blood chamber. The differences in light absorption between blood constituents allow for the identification and measurement of the hematocrit. The measurement of hematocrit, percent change in blood volume and oxygen saturation in real-time during hemodialysis is intended to provide 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, can intervene (i.e., by increasing or decreasing the rate at which fluid is removed from the blood) 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 technology is available as a stand-alone device (Crit-Line IV Monitor) or as an optional module on the 2008T hemodialysis machine (CLiC™ device).

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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