CLiC

Powerfully Simple

Frequently Asked Questions

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

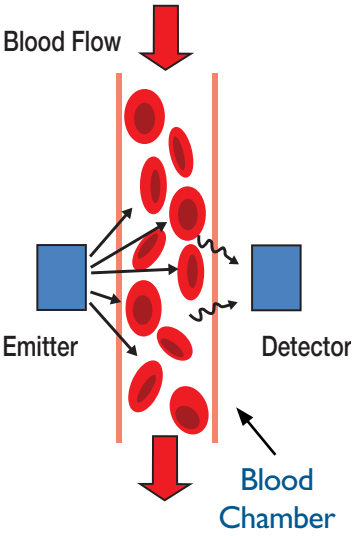
Note: Read the Instructions for Use for safe and proper use of these devices. For a complete description of hazards, contraindications, side effects and precautions, see full package labeling at www.fmcna.com.

What is the indication for use of the CLiC device?

The CLiC device is used with the 2008T hemodialysis machine to non-invasively measure hematocrit, oxygen saturation and percent change in intravascular 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 CLiC device 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 the use with the CLiC device sensor clip during acute and chronic hemodialysis therapy to non-invasively measure hematocrit, percentage change in blood volume and oxygen saturation. The blood chamber connects 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.

2 How does the CLiC device make its measurements?

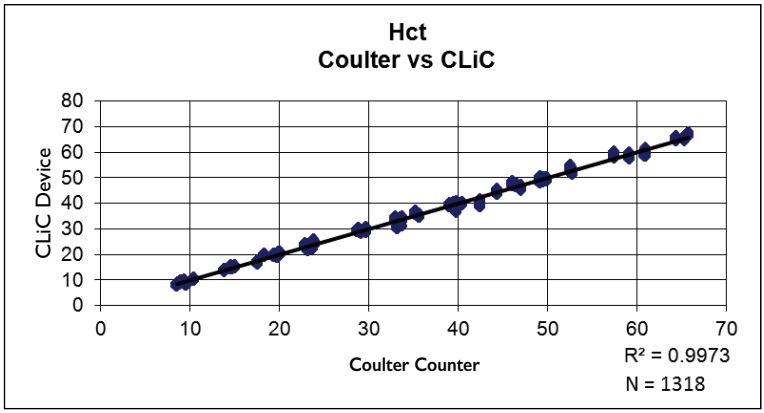
The CLiC device sensor clip emits multiple wavelengths of light through a disposable viewing window that is called a blood chamber. The blood chamber is indicated for use with the CLiC device. The blood is trans-illuminated by multiple wavelengths of light and the differences in blood absorption between blood constituents allow for identification and measurement of hematocrit and oxygen saturation.

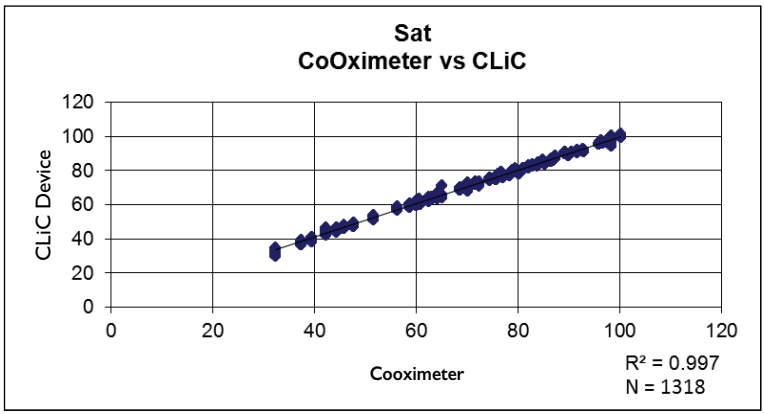


3 What is the range and accuracy of CLiC technology?

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

Oxygen Saturation Instrument Range & 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





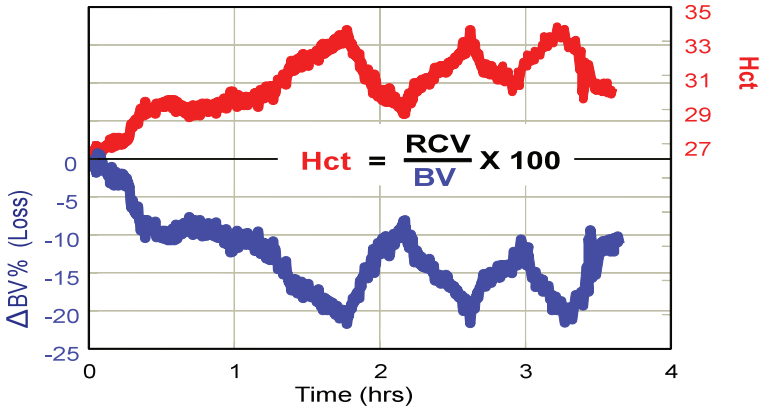
4 Where is the CLiC device blood chamber placed?

The blood chamber is attached between the arterial bloodline and the arterial side of the dialyzer.

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

There is an inverse relationship between hematocrit and blood volume change. As hematocrit goes up, blood volume goes down and vice versa. Blood volume is calculated using the following formula:

$\Delta BV\% = \{(H_2/H_1)-1\} \times 100$
H_2 = initial Hct
H_1 = current Hct

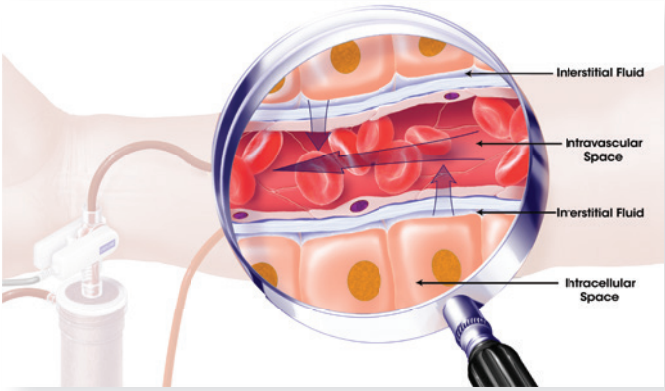


6 Why is measuring intravascular blood volume helpful?

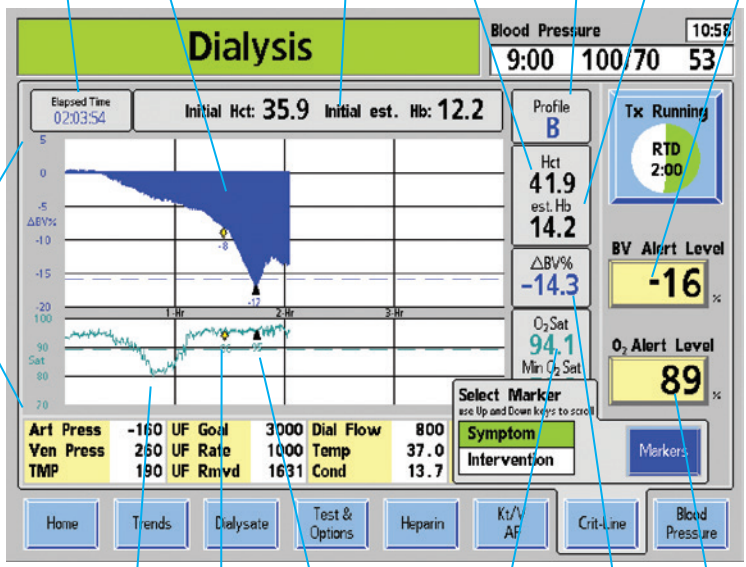
Measuring intravascular blood volume is helpful because it assists the caregiver in determining the net difference between the total amount of fluid removed from the patient and the vascular refill rate. Achieving the right balance between ultrafiltration rate and vascular refill rate is important to optimize fluid removal without causing intradialytic symptoms:

- A low UF rate combined with a high refill rate potentially misses the opportunity for more effective fluid removal.
- A high UF rate combined with a slow refill rate can lead to symptoms like dizziness, nausea and hypotension.

The monitor provides the caregiver with information about the patient´s relative blood volume and vascular refill rate during dialysis in order to make timely interventions.



7 What information is on the Crit-Line touchscreen?



Time elapsed since beginning of treatment

BV% change graph

initial Hct and initial Hb

Current HCT Value

Current blood volume profile (based on previous 15 minutes)

Current Hb Value (estimated)

Blood volume alert level

BV % Change displayed in increments of 5 %

Oxygen saturation graph

Symptom marker

Intervention marker

Current O_2 Sat Value

Current BV% change cumulative since beginning of treatment

Oxygen saturation alert level

8 How are the various blood volume profiles interpreted?

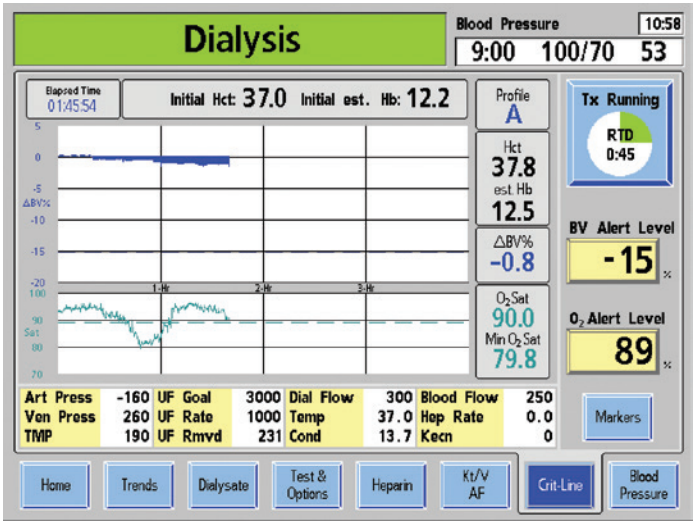
Note: Always assess the patient's condition before making any interventions.

Profile A:

With the ultrafiltration rate above minimum, a flat or positive profile indicates that the patient's plasma refill rate is occurring at the same or a greater rate than ultrafiltration. A blood volume Profile A suggests that the ultrafiltration rate might be increased without immediate risk of intradialytic symptoms.

When using the CLiC device, a Profile A will be displayed when the measurements taken over the previous 15 minutes result in a profile that is ≤-3% per hour.

Please note that a Profile A might be acceptable in some patients but not others. Thus, the clinician should always assess the patient's condition before making any interventions.

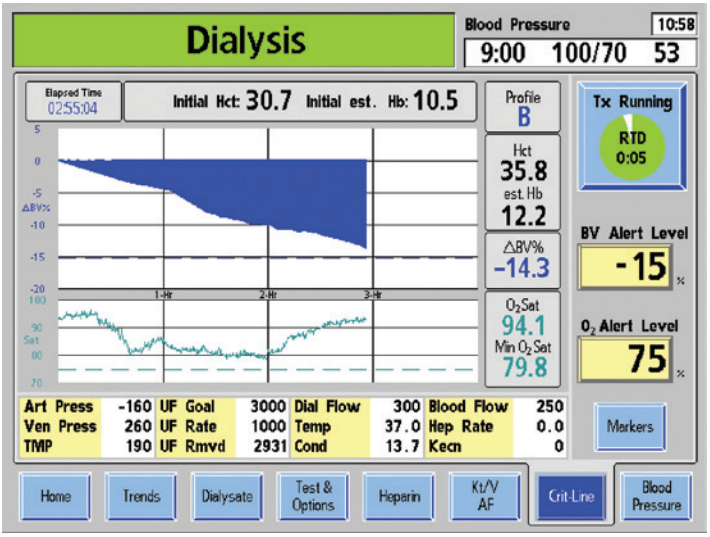


Profile B:

A Profile B, or gradual slope, 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 BV, and will vary from patient to patient. Typical published values range from -3% per hour to -8% per hour depending on patient characteristics and treatment algorithm.[1,2,3,4,5,6]

Published algorithms in chronic hemodialysis patients suggest a BV change of up to -8% per hour in the first hour, with an additional BV change of <-4% per hour in the following hour, up to a maximum total BV change of -16% at end of a 3-4 hour dialysis session.[1,2,3]

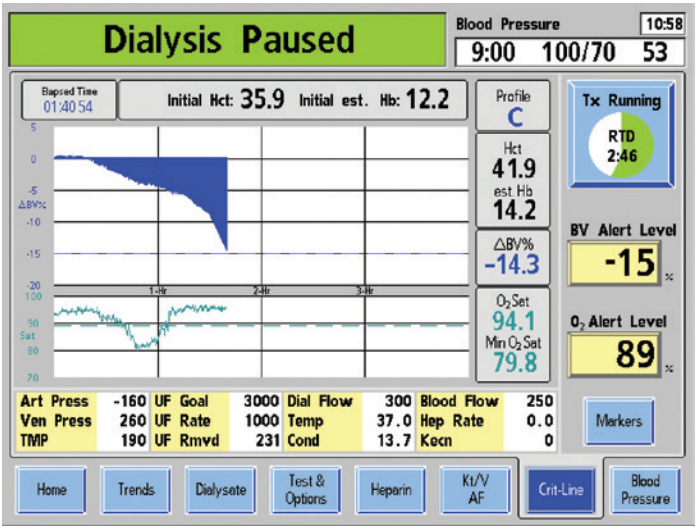
Closer monitoring should be considered once the BV% change approaches or exceeds -6.5% per hour. When using the CLiC device, a Profile B will be displayed when the measurements taken over the previous 15 minutes result in a profile that is >-3% per hour and ≤-6.5% per hour.



Profile C:

A steep slope represents a rapid decrease in blood volume and bears a higher risk for intradialytic symptoms. Literature indicates that this might occur at a BV change of >-8% per hour.[1, 3, 5, 6] or at a total BV change of >-16% at the end of a 3-4 hour dialysis session.[1, 2, 3]

However, some patients may have a lower or higher tolerance depending on cardiovascular status and other comorbidities. When using the CLiC device, Profile C will be displayed when the measurements taken over the previous 15 result in a profile that is >-6.5 % per hour.



9 What happens if the treatment goes longer than four hours?

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

10 Does the CLiC device tell the user what intervention should be made?

The CLiC device does not tell the user what to do, but provides information on how the patient is tolerating the UF rate. The CLiC device is not intended to replace the judgment or experience of the attending physician or other medical professional. The hemodialysis treatment prescription is the responsibility of the attending physician.

11 How can the CLiC device help the caregiver to prevent common dialysis-related symptoms?

If the CLiC device is showing a Profile C indicating that the fluid is being removed too quickly, the caregiver can reduce the UF rate to help prevent a hypovolemic event from occurring. Sometimes a patient has a lot of fluid to remove but the fluid has simply not shifted yet into the intravascular space. Fluid can only be removed from the intravascular space and the CLiC device can indicate when there is fluid to remove and when there is no fluid to remove. Knowing when to remove and when not to remove fluid can help the caregiver prevent hypovolemic symptoms from occurring.

12 Does the CLiC device have to be verified before each use?

The CLiC device does not need to be verified before each use. The CLiC device must pass verification once every 30 days. If the sensor clip is docked onto its verification filter, it will automatically verify accuracy once per day. This verification process takes about 10 seconds to complete.

13 Are there any publications on the use of the CLiC device?

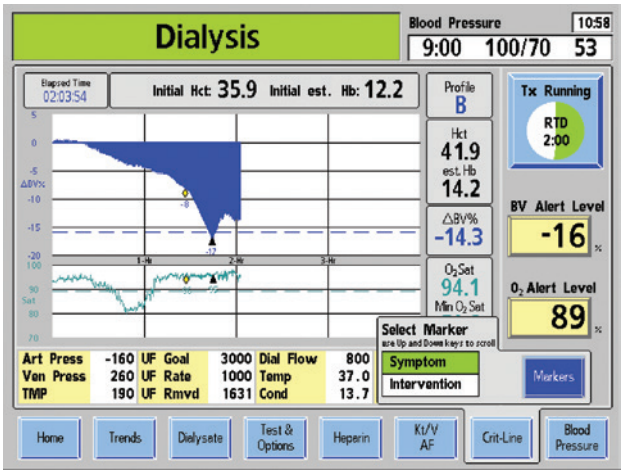
There are numerous publications on the use of Crit-Line technology.

14

How is plasma refill assessed? How does one verify if there is more fluid to remove?

The plasma refill check can be performed at any time during the treatment but is usually performed during the last 10 minutes of treatment. To perform a refill check, the UF is reduced to minimum (300 ml/hr) and the Hct, as displayed on the screen is recorded. After 10 minutes, the hematocrit is recorded again. If the hematocrit value has decreased by ≥ 0.5 or more, then additional fluid may be available for removal.

A positive or negative refill test alone does not necessarily determine whether patients are fluid overloaded or at dry weight. The CLiC device is a tool and does not measure dry weight. Determination of dry weight should always be based on a comprehensive clinical assessment by the physician. Longer dialysis at slower UF rates may be necessary if no refill is present but dry weight is not reached.



15 How can one prescribe Crit-Line technology use?

See below for some examples of how Crit-Line technology use can be prescribed:

Prescribing Fluid Removal by Crit-Line technology:

- Ultra-filter _____ cc as guided by Crit-Line Technology.
- Remove _____ cc by ultra-filtration as tolerated with monitor guidance.
- Ultra-filter _____ cc with monitor guidance. If BP >_____ and Profile B, continue fluid removal.
- Do "refill check" at conclusion of treatment to evaluate plasma refill.

All parameters must be considered in conjunction with a patient's clinical assessment, comorbidities and existing medical history before prescribing or changing a dialysis treatment. Any decision regarding patient treatment is the responsibility of the attending physician.

References:
1. Rodriguez HJ, Domenici R, Diroll A, Goykhman I. "Assessment of Dry Weight by Monitoring Changes in Blood Volume During Hemodialysis using Crit-Line" *Kidney International* 68 (2005): 854–861.
2. Goldstein S, Smith C, Currier H. "Non-invasive Interventions to Decrease Hospitalization and Associated Costs for Pediatric Patients Receiving Hemodialysis" *Journal American Society of Nephrology* 14 (2003): 2127-2131.
3. Michael M, Brewer ED, Goldstein SL. "Blood Volume Monitoring to Achieve Target Weight in Pediatric Hemodialysis Patients" *Pediatric Nephrology* 19 no. 4 (2004): 432-437.
4. Sinha AD, Light RP, Agarwal R. "Relative Plasma Volume Monitoring During Hemodialysis Aids the Assessment of Dry Weight" *Hypertension* 55 (2010): 305–311.
5. Reddan, DN, Szczech, LA et al. "Intradialytic Blood Volume Monitoring in Ambulatory Hemodialysis Patients: A Randomized Trial" *Journal American Society of Nephrology* 16 (2005): 2162-2169.
6. Jain SR, Smith L, Brewer ED, Goldstein SL. "Non-invasive Intravascular Monitoring in the Pediatric Hemodialysis Population" *Pediatric Nephrology* 16 no. 1 (2001):15-8.

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