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Indications for 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 uid is removed from the blood) 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 technology is available as a stand-alone device (Crit-Line III Monitor, Crit-Line IV Monitor) or as an optional module on the 2008T hemodialysis machine (CLiC™ device).

Caution: Federal (U.S.) 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 fmcna.com.

CRIT-LINE®
Where Therapy and Diagnostics Meet

FRESENIUS MEDICAL CARE
RENAL TECHNOLOGIES

Standing Order Considerations: Use of Crit-Line® Monitor (CLM) for Outpatient Dialysis

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.

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:[1]

S_vO_2	*60-80%.*
$S_{cv}O_2$	*60-80%.*
S_aO_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.

*Note: If Physician/NP/PA orders increase dialysis frequency greater than 3x per week, then follow appropriate medical justification (ICD coding) policy.

FRESENIUS MEDICAL CARE
RENAL TECHNOLOGIES

Standing Order Considerations: Use of Crit-Line® Monitor (CLM) for Outpatient Dialysis

HCP Considerations for Monitoring Blood Volume Changes*

e.g., Thirty (30) minutes after the initiation of the dialysis treatment, begin to monitor the blood volume (BV) change as indicated by the profiles below, and observe patient for signs and symptoms of hypovolemia.

e.g., Repeat the evaluation every ____ minutes, per clinic policy and procedure.
- e.g., ____ minutes to be consistent with routine BP monitoring protocol

e.g., Set Blood Volume (BV) Alert at the beginning of the treatment to (-) ____, per clinic policy and procedure, or based on individual patient's known response.
- e.g., Set one BV alert level max per treatment, or
- e.g., Set two BV alert level recommendations per treatments, or
- e.g., Set hourly BV alert level recommendations.[3]

  HR 1: Between -4 and -7%
  HR 2: Between -6 and -11%
  HR 3: Between -8 and -14%

e.g., Each time the Crit-Line %BVΔ reaches the BV alert level, review Crit-Line profile trend, evaluate the patient for hypovolemia, and adjust the BV alert based on the patient evaluation and CLM profile data.
- e.g., Increase BV alert level by ____.
- e.g., Adjust hourly BV alert level recommendations, within following range:[2]

  HR 1: Between -4 and -7%
  HR 2: Between -6 and -11%
  HR 3: Between -8 and -14%

***Please consult with Physician/NP/PA if patient is diagnosed with acute kidney injury (AKI) for goal-directed therapy as blood volume monitoring guidelines differ for this population.**

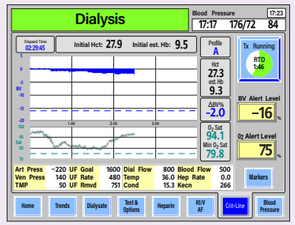
Standing Order Considerations: Use of Crit-Line® Monitor (CLM) for Outpatient Dialysis

HCP Considerations for Monitoring Blood Volume Changes (continued)

e.g., For patients experiencing blood volume change associated with profile A.

Profile A: A flat or upward slope reduction of blood volume is not achieving 3% per hour.

2008T with CLiC screen



Crit-Line IV screen

- Based on RN Assessment:
  - If no change in UF goal, continue to evaluate patient every 30 minutes, **or**
  - If increase in the UF goal is needed, increase by ____ ml every thirty (30) minutes until patient converts to Profile B (BV reduction between 3-6.5% per hour), **or**
  - If the treatment duration is greater than 6 hours, increase the UF goal every hour until patient converts to Profile B (BV reduction between 3-6.5% per hour).

  Medical literature has suggested that UF goal increases between 100 and 200 ml may be associated with improving patient outcomes. [3,4,5,6]
  (Note: Do not exceed clinic policy on maximum UFR.)

- Monitor the patient for signs or symptoms of hypovolemia and treat according to "Assessment and Treatment of Hypovolemia" section.

- If the UF goal is increased greater than ____ ml over the course of the treatment (____ upward adjustments of ____ ml each) or would exceed the recommended/ prescribed volume, call Physician/NP/PA to evaluate target weight Rx.

- If patient has a history of cramping, follow RN assessment, increasing UF goal by ____ ml every ____ minutes until patient converts to Profile B (BV reduction between 3-6.5% per hour).

  Medical literature has suggested that UF goal increases between 25 and 50 ml every 30 minutes may be associated with improving patient outcomes.[3,4,5,6]
  (Note: Do not exceed clinic policy on maximum UFR.)

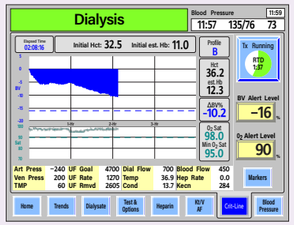
Standing Order Considerations: Use of Crit-Line® Monitor (CLM) for Outpatient Dialysis

HCP Considerations for Monitoring Blood Volume Changes (continued)

e.g., For patients experiencing blood volume change associated with profile B.

Profile B: A gradual downward slope BV reduction between 3% and 6.5% per hour.

2008T with CLiC screen



Crit-Line IV screen

- Maintain UFR based on patient evaluation.
- Note the total treatment BV reduction.
- At any time during the course of treatment if the reduction in blood volume is greater than ____%, increase observation of the patient with vital signs to every ____ minutes.

  Medical literature has suggested that increased observation frequency of vital signs may be associated with improving patient outcomes.[3,4,5,6]

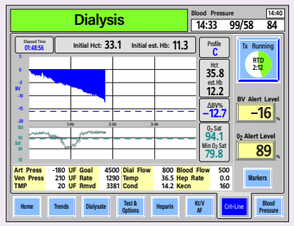
  Medical literature has suggested that a blood volume reduction of greater that 8% per hour, may be associated with higher risk of intradialytic symptoms.[7,8,9]

- Monitor the patient for signs and symptoms of hypovolemia.
- If Profile B flattens out and becomes Profile A (BV reduction does not achieve 3% per hour), then based on RN assessment, proceed with Profile A treatment procedures as outlined above.

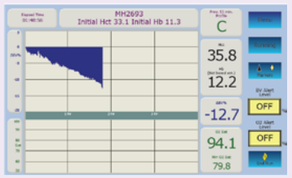
e.g., For patients experiencing blood volume change associated with profile C.

Profile C: A steep slope BV reduction exceeds 6.5% per hour.

2008T with CLiC screen



Crit-Line IV screen



- Check BP.
- Monitor patient for signs and symptoms of hypovolemia:
- If symptomatic (symptoms as defined in "Assessment and Treatment of Hypovolemia" section):
  Treat according to "Assessment and Treatment of Hypovolemia" section.
- If not symptomatic (no symptoms and no hypotension as defined in "Assessment and Treatment of Hypovolemia" section):
  - Decrease UF goal by ____ ml and recheck BV profile every ____ minutes after UF goal is decreased, as determined by clinic policy and procedure or for individual patient.
  - Continue to decrease UF goal by ____ ml every ____ minutes, as determined by clinic policy and procedure or for individual patient until curve converts to Profile B (BV reduction between 3% and 6.5%).

  Medical literature has suggested that UF goal decreases between 25 and 50 ml every 15 to 30 minutes, pending clinical assessment, may be associated with improving patient outcomes.[3,4,5,6]

  - Follow Profile B procedures as noted above.

Standing Order Considerations: Use of Crit-Line® Monitor (CLM) for Outpatient Dialysis

HCP Considerations for Assessment and Treatment of Hypovolemia

e.g., Assess patient for hypovolemia, including hypotension.

Definitions: [10,11,12]

Sitting Pre-TX Systolic Blood Pressure (BP)	Hypotension is defined as follows
Less than 100 mmHg	Drop in systolic BP of 20 mmHg or more
100-150 mmHg	Systolic BP less than 100 mmHg or a drop in systolic of 20 mmHg
Greater than 150 mmHg	Systolic BP less than 100 mmHg

- Symptomatic Hypotension—a decrease in either systolic BP (SBP) ≥20 mmHg or mean arterial pressure ≥10 mmHg as well as associated symptoms
- IDH definitions are based exclusively on SBP measurements, such as SBP reduction by some requisite amount during treatment (20, 30, and 40 mmHg)
- An intradialytic SBP below a threshold value (90, 95, and 100 mmHg)

- Refer to the clinic policy regarding management and prevention of hypotension.
  - Monitor patient for any of the following signs and symptoms, including but not limited to tachycardia, weakness, dizziness, nausea, vomiting, cramping, change in mentation, and diaphoresis.

  Important: Hypotension symptoms may differ for individual patients.
- If BP is low or has dropped by more than 20 mmHg, and patient is asymptomatic following RN assessment:
  - Increase BP monitoring frequency to ____ minutes and evaluate current BV% change and UFR, and reassess in ____ minutes.
    - e.g., Increase BP monitoring frequency to 15 minutes, evaluate, and reassess in 5 minutes.
  - Place in Trendelenburg position and continue to monitor BP and BV% change every ____ minutes.
    - e.g., Continue to monitor BP and BV% change every 15 minutes.
- If BP is low or dropped by more than 20 mmHg, and patient is symptomatic following RN assessment, place into Trendelenburg position; reduce UF rate to minimum, reassess in 1-2 minutes.
  - If still symptomatic, administer ____ ml normal saline bolus per Physician/NP/PA order and reassess in 5 minutes.
  - If symptoms persist, continue to leave UF rate at minimum, and administer ____ ml normal saline per physician/NP/PA order **and**
    e.g., Consider reduction in dialysate temperature by ____ degrees.

  Medical literature has suggested that lowering the dialysate temperature by 0.5 to 1 degree, but not below 35 degrees, may be associated with improving patient outcomes.[3, 4,5,6,]
- If symptoms are resolved, perform refill check (see Intravascular (Plasma) Refill Test Following Hypotensive Episode or Cramping section), and monitor BP and BV% change every ____ minutes for remainder of treatment, per clinic policy and procedure.
  - e.g., Monitor BP and BV% change every 15 minutes for remainder of treatment.

Standing Order Considerations: Use of Crit-Line® Monitor (CLM) for Outpatient Dialysis

HCP Considerations for Intravascular (Plasma) Refill Test Following Hypotensive Episode or Cramping

e.g., Perform the intravascular (plasma) refill test (see Intravascular Refill Test Procedure section) and evaluate the blood volume BV% change and Crit-Line data following a hypotensive episode.

Note: Following any normal saline or fluid administration, wait 10 minutes following completion of administration to begin refill test.[7]

- If refill is present, increase UF goal by ____ ml, but ____ ml lower than original goal prior to hypotensive episode, consistent with clinic policy and procedure or Physician/NP/PA order.
- If no refill is present, then:
  - Continue minimum UF rate (____ ml/hr), per clinic policy and procedures or manufacturer's recommendations.
  - Replace fluid based on BP, symptoms, and Physician/NP/PA order.

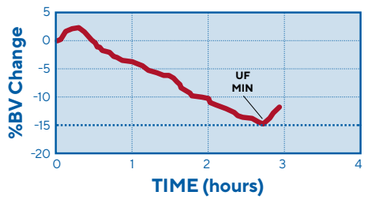
e.g., If patient experiences cramping without hypotension:

- Decrease UF rate to HD delivery system UF minimum setting (300 ml/hr for 2008T HD delivery system) and reassess in ____ minutes, per clinic policy and procedure or Physician/NP/PA order.
  - e.g., Reassess in 1 to 2 minutes.[3]
- If patient continues to cramp, administer normal saline per clinic policy and Physician/NP/PA order.
- Consider reduction in dialysate temperature.
  Medical literature has suggested that lowering dialysate temperature by 0.5 to 1 degree, but not below 35 degrees, may be associated with improving patient outcomes.[3,4,5,6]
- Check for plasma refill.
  Note: Following normal saline administration, wait 10 minutes to begin refill test.[7]
  - If refill is present, increase UF goal by ____ ml, but ____ ml, as outlined in clinic policy and procedure or Physician/NP/PA order, lower than original goal prior to cramping episode.
- Consider discussion of longer treatment time or an extra treatment with Physician/NP/PA
  - If no refill, then continue minimum UF rate based on HD delivery system UF minimum setting (300 ml/hr for 2008T HD delivery system). Continue with normal saline administration based on symptoms and Physician/NP/PA order.

Standing Order Considerations: Use of Crit-Line® Monitor (CLM) for Outpatient Dialysis

Intravascular Refill Test Procedure with Crit-Line*

1. Reduce UF rate to HD delivery system UF minimum setting (300 ml/hr for 2008T HD delivery system).
2. Record HCT value (H1), wait 10 minutes.
3. Record HCT value (H2).



Refill is present when a hematocrit (HCT) decreases greater than or equal to 0.5 when the UF Rate (UFR) is reduced to the minimum for ten (10) minutes.[7]

**Intravascular Refill Test Procedure can be completed any time during the treatment, following clinic policy and procedure and manufacturer's IFU.*

Notes