REFERENCE GUIDE

CRIT-LINE IV

CRIT-LINE IV
Where Therapy and Diagnostics Meet

This reference is to be used in conjunction with the Crit-Line® IV Monitor User's Guide (P/N CL80050002). Refer to the User's Guide for a complete description of alerts, warnings, cautions, and advisory messages.

Indications for Use: 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 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 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.
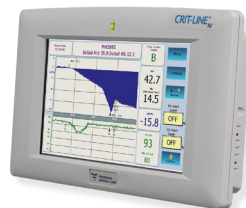
Crit-Line IV System

Sensor Clip

Sensor clip

USB connector

Verification filter
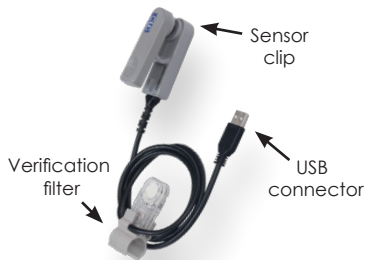
Sensor clip attaches to the Crit-Line blood chamber.

Crit-Line Blood Chamber

Disposable utilized with the sensor clip.

Crit-Line IV Monitor

Displays data from the sensor clip.

Crit-Line IV Monitor Setup Instructions

1. Keep the Crit-Line IV monitor plugged in at all times; power switch **OFF** when not in use.

2. Inspect the blood chamber and its sterile package prior to use. Refer to the blood chamber package label to ensure that the blood chamber sterilization has not expired.

3. Remove the blood chamber from its sterile package and using aseptic technique attach the red connector to the arterial port of the dialyzer. Make certain the connection is tight.

4. Connect the arterial bloodline to the blood chamber. Be careful to not cross-thread the connection. Continue bloodline set-up per manufacturer's instructions.

(Continued on next page)

Connecting the Crit-Line blood chamber

5. Prime the system per unit procedure.

6. Turn power switch **ON**.

7. Inspect the Crit-Line blood chamber to ensure it is fully primed with flowing blood and is absent of leakage and/or air bubbles.

8. Attach sensor clip to the blood chamber.

   Note: Make sure the sensor clip is properly in place PRIOR to initiating the treatment.

Connecting the sensor clip

9. Check for proper blood flow in the extracorporeal circuit, including the Crit-Line blood chamber, before starting the patient treatment with the Crit-Line IV monitor.

10. Select **Patient Run**. Wait 3–5 minutes with the blood pump at ≥150 ml/min to ensure blood is flowing in circuit.

11. Select **Start Run**.

12. If **Auto Run** has been selected, simply attach the sensor clip onto the Crit-Line blood chamber and the monitor will start taking measurements once blood is sensed.

13. If the monitor loses power during treatment, restore power and resume treatment.

Note: Make certain that no air is in the blood chamber after priming. Any air present in the chamber will cause the hematocrit reading to be inaccurate.

Helpful Hints

1. ALWAYS treat the patient first, then utilize the Crit-Line IV monitor.

2. Intervene as necessary to optimize treatment.

3. Use the Markers feature (intervention or symptom) to mark events/ changes in treatment (every ten minutes as needed).

4. Perform a plasma refill check as needed or at treatment end; reduce UF rate to 300 ml/hr for ten minutes and assess plasma refill.

5. If no printing or data retrieval is available, consider charting information from the main screen, such as Hct (initial), Hb (initial), Sat (min), Hct (max), and ending BV Change %.

6. Select **End Run** before saline rinse-back procedure.

Monitoring the Treatment from the Crit-Line IV Monitor Screen

The patient treatment screen is used for monitoring a patient's hematocrit, oxygen saturation and percent change in blood volume in real time during a dialysis treatment. This screen can display either Percent Change Blood Volume (ΔBV%) or Hematocrit (Hct) on the upper graph depending on display selection. The display selection is made from the Patient Run Option menu. On the lower graph, the Oxygen Saturation (O_2 Sat) graph will always display. The ΔBV% and O_2 Sat graphs are displayed by default.
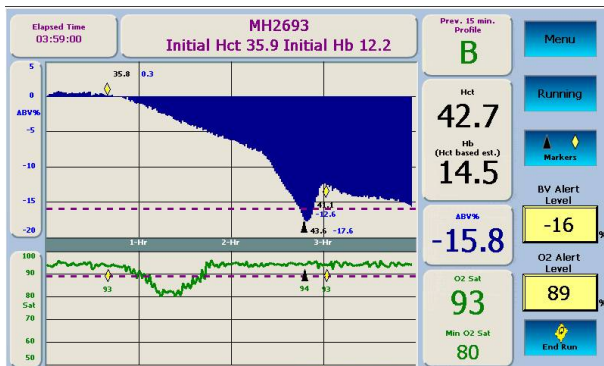

Figure 3:
Crit-Line IV monitor screen showing BV and oxygen saturation graphs

Graphing of the data begins after the sensor clip senses blood and the hematocrit has been stable for 60 seconds. The default graph is for a 4 hour treatment. The graph will rescale to accommodate longer treatments.

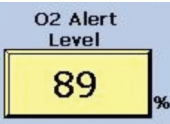**Listed below are features common to all graph displays:**

Feature	Function
Elapsed Time 03:59:00	**Elapsed Time**—The elapsed time from the beginning of the treatment. The elapsed time does not include any time during which the treatment is paused.
Initial Hct 35.9	**Initial Hct**—The initial hematocrit value is recorded along with the first data point when graphing begins.
Initial Hb 12.2	**Initial Hb**—The initial hemoglobin (Hb) value is recorded along with the first data point when graphing begins. It is calculated based on the hematocrit reading.
MH2693	**Patient ID**—Refers to the Patient ID assigned to the patient treatment monitoring session. The Patient ID will only display if it has been entered.

10

Feature	Function
Markers	**Markers button**—Selecting this button displays a menu to insert an event marker on the Blood Volume and Oxygen Saturation graphs. Once the Markers button is pressed, the event marker selection screen will appear: • The Symptom marker is displayed as a yellow diamond. • The Intervention marker is displayed as a black triangle. • Both BV% change and hematocrit marker values are displayed in the Hct and BV% change screens. • The BV graph marker displays the BV% change value at that data point in blue. • The Hct graph marker displays the Hematocrit value at that data point in black. • The Oxygen Sat graph marker displays the Oxygen Saturation value at that data point in green. **Note:** Markers can only be set when treatment monitoring is active (i.e., not paused). To prevent clutter on the graphs, the time between entering markers must be at least ten minutes.

Feature	Function
Prev. 15 min. Profile **B**	**Current Blood Volume Change Profile**—The profile starts calculating after the first two blood volume measurements and is computed over the previous 15 minutes of data. As a result, no profile is displayed during the first 15 minutes of treatment. The profiles can be as follows: **Profile A** BV change is ≤-3% per hour. This is a flat or positive slope. **Profile B** BV change is >-3% and ≤-6.5% per hour. This is a gradual slope. **Profile C** BV change >-6.5% per hour. This is a steep slope representing a rapid decrease in blood volume. No profile is shown while a treatment is paused. Once resumed, a new profile will be established.
Hct **42.7**	**Current Hematocrit Value**

| Feature	Function
Hb (Hct based est.) **14.5**	**Current Estimated Hemoglobin Value**—Calculated from the hematocrit using the following equation: Hb = Hct/2.94
O2 Sat **93**	**Current Oxygen Saturation Value**
Min O2 Sat **80**	**Minimum Oxygen Saturation Value**—The minimum oxygen saturation value over all data points.
ΔBV% **-15.8**	**Blood Volume Change**—The percent change in blood volume since the start of the treatment. The BV change value is calculated from the following equation: $\Delta BV\% = [(H_2/H_1) - 1] \times 100$ H_2=initial Hct H_1=current Hct

Feature	Function
BV Alert Level **-16** %	**BV Alert Level button**—Sets the BV Alert Level. When the current BV% change drops below the set BV alert level, the Crit-Line IV monitor displays the alert message "Rel. Blood Volume Low". This message will be displayed until the BV% change increases above the set BV alert level or until the BV Alert Level is set to OFF. Selecting the BV Alert Level Button displays a menu to set the BV Alert Level. Once the BV Alert Level button is pressed, the BV Alert Level selection screen will appear to the left of the BV Alert Level button. Set the BV Alert Level by pressing the yellow up or down button until the desired value is displayed in the in the BV Alert Level box to the right of the select screen. The dotted line on the BV% graphs moves to the set BV Alert Level. The default value is OFF. Once the BV alert option has been selected press the **Confirm** button to confirm the entry. Press the **Cancel** button to return the original setting. Press the **Disable** button to set the BV Alert Level to OFF.

| Feature	Function
O2 Alert Level **89** %	**O$_2$ Alert Level button**—This button sets the oxygen saturation alert level. When the current O$_2$ Sat drops below the O$_2$ Alert Level, the alert message "Oxygen Saturation Low" is displayed in the Status Box. This message will occur until the O$_2$ level rises above the O$_2$ Alert Level or until the user changes the level or sets the O$_2$ Alert Level to OFF. Set the O$_2$ Alert Level by pressing the yellow up and down button until the desired level is displayed in the O$_2$ Alert Level box to the right of the selection screen. The dotted line on the O$_2$ graph moves to the set O$_2$ Alert Level. The default value is OFF. Once the O$_2$ alert level has been selected press the **Confirm** button to confirm the entry. Press the **Cancel** button to return the original setting. Press the **Disable** button to set the O$_2$ Alert Level to OFF.

Blood Volume Profiles

Note: The Crit-Line IV monitor must always be used in conjunction with clinical assessment and existing medical history before altering a dialysis treatment. The slope of the profile must be monitored and evaluated throughout the patient treatment to determine any necessary intervention.

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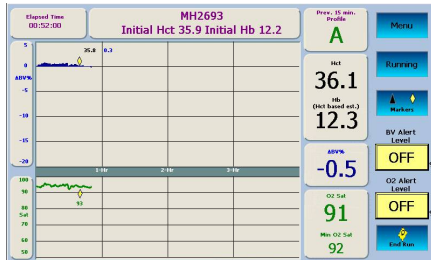
Profile A will be displayed when the measurements taken over the previous 15 minutes result in a profile that is ≤-3% per hour.
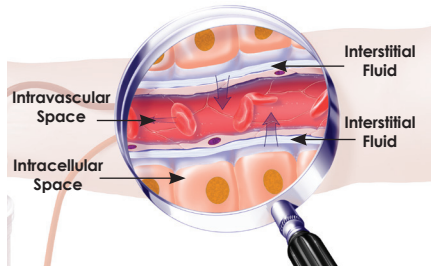

This profile is represented as a flat or positive slope. This indicates that the patient's plasma refill rate is occurring at the same or greater rate than the ultrafiltration rate. Profile A suggests that the ultrafiltration rate might be increased without immediate intradialytic symptoms.

Profile B

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.
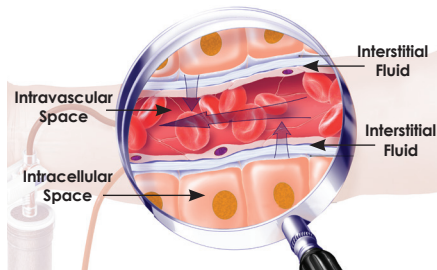

A Profile B, or gradual slope, has been targeted to find the best compromise between a high ultrafiltration rate and the prevention of intradialytic symptoms. The ideal slope is not a fixed percentage of change in BV, and will vary from patient to patient.

Profile C

Profile C will be displayed when the measurements taken over the previous 15 minutes result in a profile that is >-6.5% per hour. If the measurements taken over the previous 15 minutes result in a percent blood volume change greater than -8% per hour, then the message "-ΔBV% greater than 8%/hr" will appear.
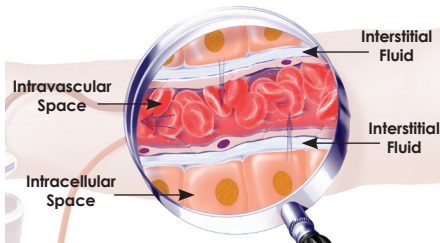
Represented as a steep slope, this profile indicates a rapid decrease in blood volume and bears a higher risk for intradialytic symptoms.

Performing a Plasma Refill Check

1. Reduce UF rate to minimum (300 ml/hr).
2. Record Hct (H_1), wait 10 minutes.
3. Record Hct value (H_2).
4. If H_1-H_2 ≥0.5, patient has refill, indicating that additional fluid may be available for removal.
5. If H_1-H_2 is <0.5, no vascular refill is present.

Ending a Treatment/Printing a Treatment Report

To end a patient treatment, press the **End Run** button. Once the option has been chosen, the End Patient Run option menu will appear. Press the **Print Report** button to terminate the treatment and print the Crit-Line IV monitor patient treatment monitoring session. Press the **Do Not Print** button to terminate the treatment without printing the Crit-Line IV monitor patient treatment monitoring session. Press the **Cancel** button to return to the Crit-Line IV monitor patient treatment monitoring session.

General Tips

The exterior of the sensor clip and verification filter should be cleaned after every treatment with a cloth dampened with 1:100 diluted bleach solution. Do not spray or immerse the sensor clip.

Note: When the sensor clip is stored on its verification filter, the Crit-Line IV monitor will automatically verify the accuracy of the sensor clip on a daily basis. If the sensor clip is not stored on the verification filter, the sensor clip must be verified at least once per month. If it has been more than 30 days since the sensor clip was last verified, the Crit-Line IV monitor will display an alert message informing the user that the sensor clip needs to be verified. To verify accuracy, attach the sensor clip to the verification filter, making sure the sensor clip has locked securely into place. Once the sensor clip has been properly attached to the verification filter, select the **Verify Accuracy** option.

Notes:

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