CLiC
Powerfully Simple

2008T Hemodialysis Machine with CLiC™ Device
REFERENCE GUIDE

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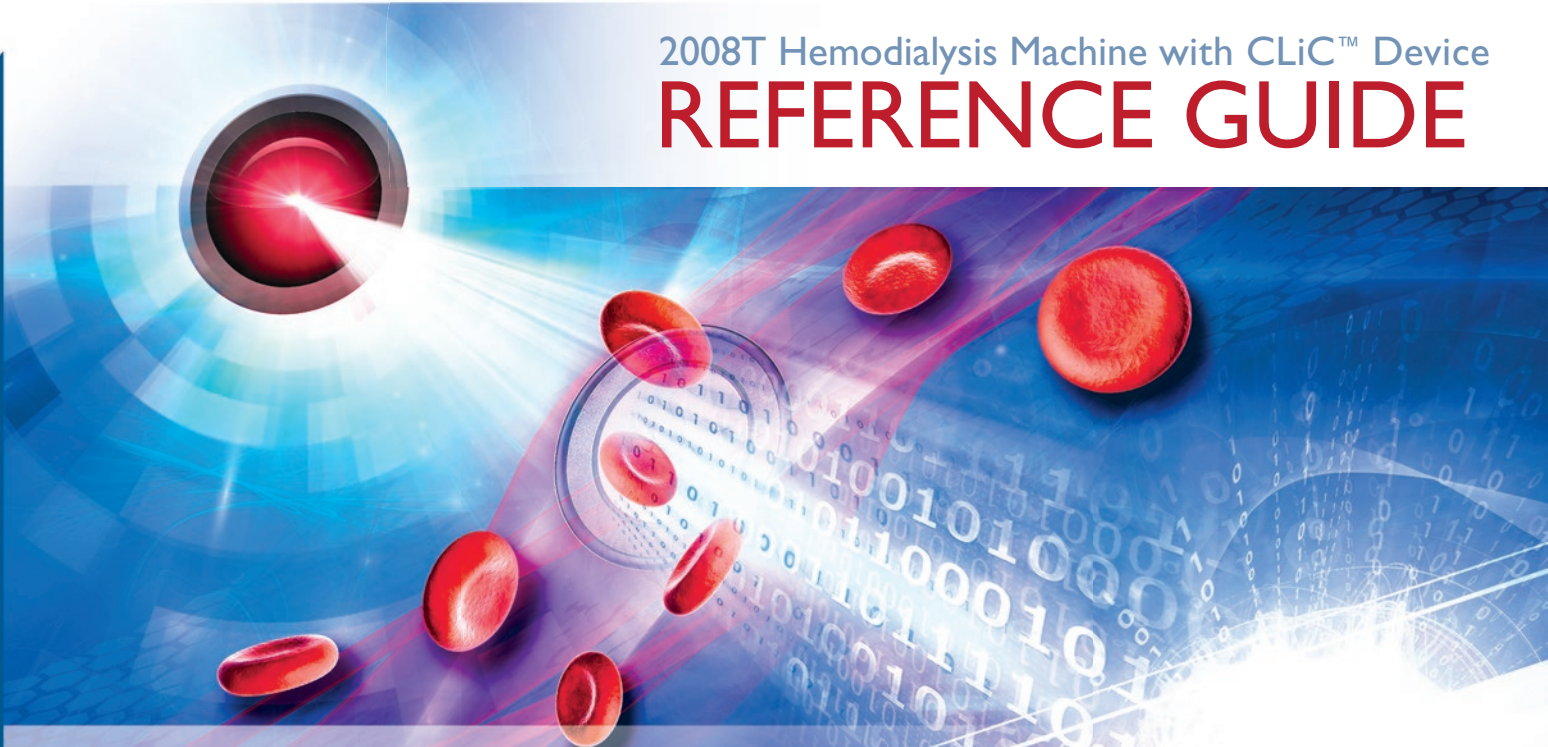
This reference is to be used in conjunction with the CLiC Device User's Guide (P/N 102111-01).
Refer to the User's Guide for a complete description of alerts, warnings, cautions, and advisory messages.

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.

Caution: Federal (US) law restricts these devices to sale only 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.

CLiC System

CLiC Device

Sensor clip

USB connector

Verification filter
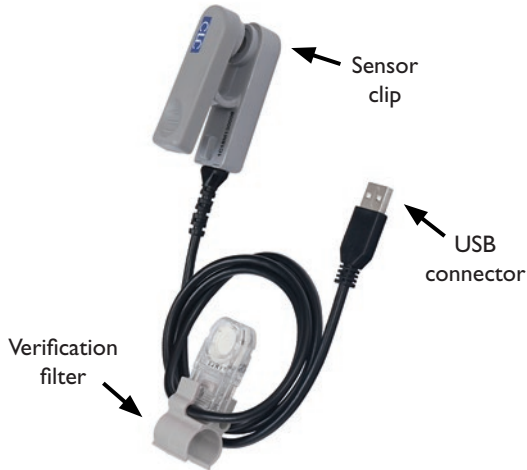
Sensor clip attaches to the CLiC device blood chamber.

CLiC Device Blood Chamber

Disposable utilized with the sensor clip.

Crit-Line Screen on 2008T Machine

Display data from the sensor clip.

CLiC Device Setup Instructions

1. 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.

2. 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.

3. 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 blood chamber

4. Prime the system per unit procedure.

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

6. 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

7. Check for proper blood flow in the extracorporeal circuit, including the blood chamber, before starting the patient treatment with the CLiC device.

8. Graphing of the data begins once the CLiC device senses blood and the hematocrit has been stable for 60 seconds with the Tx clock and blood pump running.

   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 CLiC device.

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. Patient monitoring with the CLiC device will end once RTD is zero.

Monitoring the Treatment from the CLiC 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 the service mode setting. The lower graph can display either oxygen saturation or blood pressure. To switch between oxygen saturation and blood pressure, touch the graph on the screen and press **CONFIRM**. The ΔBV% and O_2 Sat graphs are displayed by default.
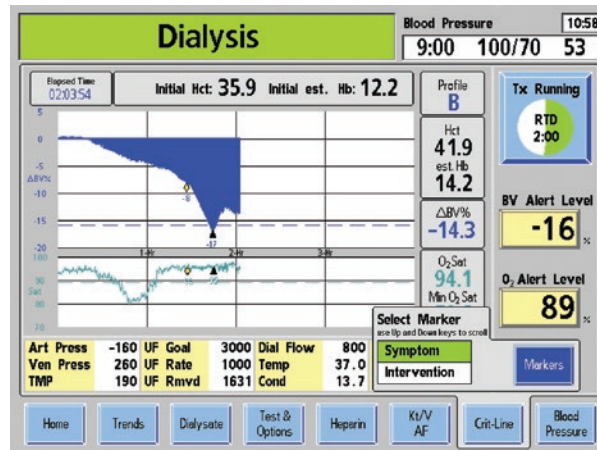
Figure 3:
Crit-Line screen showing BV and oxygen saturation graphs

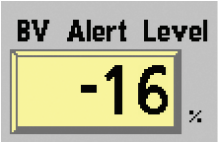# Listed are features common to all graph displays:

Graphing of the data begins after the CLiC device reads blood sensed and the hematocrit has been stable for sixty seconds with the Tx Clock and blood pump running. Graphs are displayed for a minimum of four hour (default) and maximum of ten hours.

Feature	Function
Elapsed Time 02:03:54	**Elapsed Time** – The treatment time while the Tx Clock is running. If the Tx Clock is paused or an event pauses the treatment (such as an alarm), then the Elapsed Time is paused along with CLiC device data collection.
Initial Hct: 35.9	**Initial Hct** – The initial hematocrit (Hct) value is recorded along with the first data point when graphing begins.
Initial est. 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.

Feature	Function
Markers	**Markers button** – Selecting this button displays a menu to insert an event marker on the BV and O_2 Saturation graphs. Use the ▲ or ▼ (up or down) keys on the keyboard to select either 'Symptom' or 'Intervention'. Pressing the **CONFIRM** key places the **marker** and the value on the latest point on the graph; pressing the **ESCAPE** key exits the menu without placing a marker. • The Symptom marker is displayed as a yellow diamond • The Intervention marker is displayed as a black triangle • Markers on the BV graph display the BV% change value at that data point in blue • Markers on the Hct graph display the Hematocrit value at that data point in black • Markers on the O_2 Sat graph display the Oxygen Saturation value at that data point in green NOTE: Markers can only be set when the Tx Clock is running and the CLiC device is not disabled. Resizing the graph may cause markers to rotate in order to better fit the space depending on the limits. If there is not enough space between markers, the machine will not place a marker in order to prevent overlap.

Feature	Function
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 first 15 minutes of treatment. The profile can be: **Profile A** BV change is less than or equal to -3% per hour (default) **Profile B** BV change is more than -3% and less than or equal to -6.5% per hour **Profile C** BV change exceeds -6.5% per hour
Hct **41.9**	**Current Hematocrit Value**

Feature	Function
est. Hb 14.2	**Current Estimated Hemoglobin Value** – Calculated from the hematocrit using the following equation: Hb = Hct/2.94
O₂ Sat 94.1	**Current Oxygen Saturation Value**
94.1 Min O₂ Sat	**Minimum Oxygen Saturation Value** – The minimum oxygen saturation value over all data points.
△BV% -14.3	**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 (Blood Volume) Alert Level (under physician direction). When the current BV% change drops below the set BV alert level, the 2008T hemodialysis machine stops the UF pump and displays the alert message "Rel. Blood Volume Low". This message will occur until the user changes the level or sets the BV Alert Level to OFF. To set the BV Alert Level, select the **BV Alert Level** button and enter the desired value using the ▲ or ▼ (up or down) keys or the numbers on the keyboard and press the **CONFIRM** key. To turn the BV Alert level OFF, enter "0" (zero) on the keyboard and press the **CONFIRM** key. The BV Alert Level can be set from -1 to -20 or 0 for OFF. The default setting is -15. The BV alert level is drawn as a blue dotted line across the BV graph.

| Feature	Function
O₂ Alert Level **89** %	**O₂ 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. The alert can be cleared by setting the O_2 Alert Level to OFF. To set the O_2 Alert Level, select the O_2 Alert Level button and enter the desired value using the ▲ or ▼ (up or down) keys or the numbers on the keyboard and press the **CONFIRM** key. To turn the O_2 Alert level OFF, enter "0" (zero) on the keyboard and press the **CONFIRM** key. The O_2 Alert Level defaults to 89 and can be set from 45 to 95. Setting the O_2 Alert Level to any value 44 or lower turns the O_2 Alert Level OFF. The O_2 alert level is drawn as a green dotted line across the Oxygen Saturation graph.

Blood Volume Profiles

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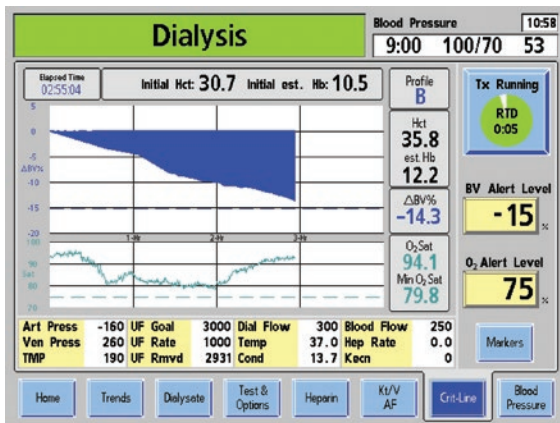
Profile A
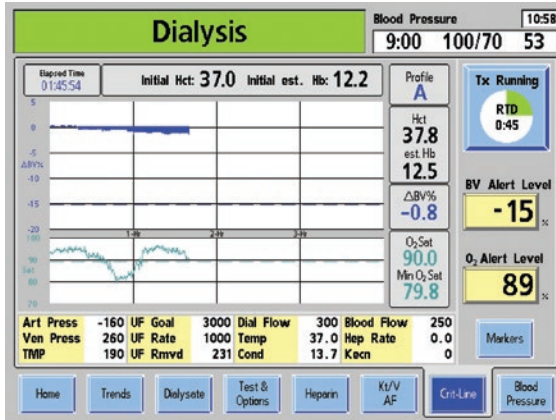
Profile A will be displayed when the measurements taken over the previous 15 minutes result in a profile that is ≤-3% per hour.
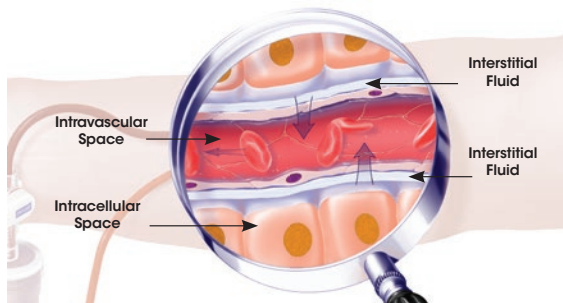

This profile is represented as a flat or positive slope. This indicates that the patient's plasma refill rate is occurring at the same or greater rate than the ultrafiltration rate. Profile A suggests that the ultrafiltration rate might be increased without immediate intradialytic symptoms.
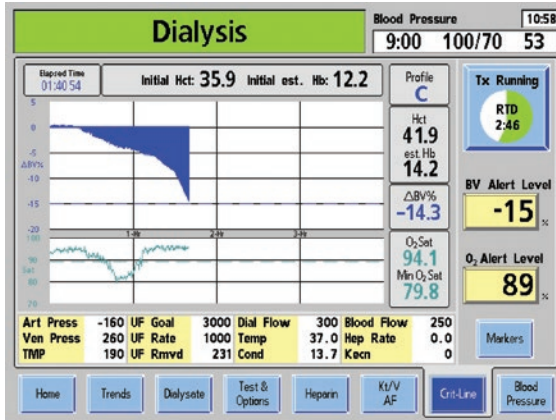
17

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.
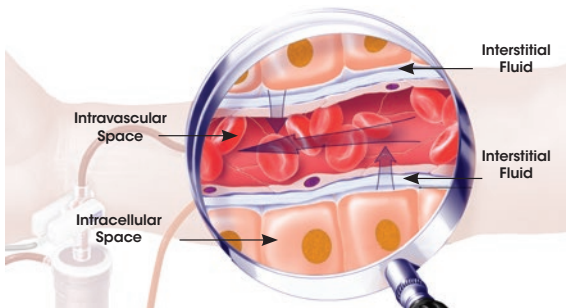

A Profile B, or gradual slope, has been targeted to find the best compromise between a high ultrafiltration rate and the prevention of intradialytic symptoms. The ideal slope is not a fixed percentage of change in BV, and will vary from patient to patient.

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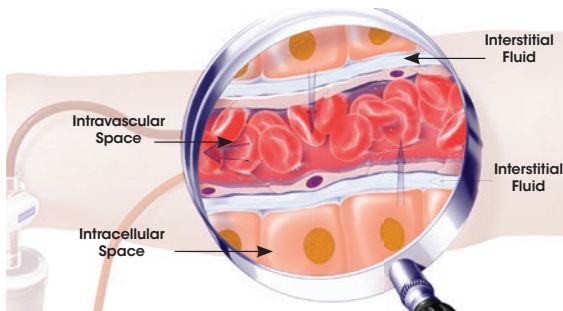
Represented as a steep slope, this profile indicates a rapid decrease in blood volume and bears a higher risk for intradialytic symptoms.

Performing a Plasma Refill Check

1. Reduce UF rate to minimum (300 ml/hr).

2. Record Hct (H1), wait 10 minutes.

3. Record Hct value (H2).

4. If H1-H2 ≥0.5, patient has refill, indicating that additional fluid may be available for removal.

5. If H1-H2 is <0.5, no vascular refill is present.

Ending a Treatment/Printing a Treatment Report

When RTD is zero and the Tx clock is paused, a print button will appear in place of the markers button. To clear the data without printing, press the New Tx button. Printing patient treatment profiles requires additional hardware and software. Please refer to the 2008T Hemodialysis Machine with CLiC Device User's Guide.

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 2008T machine with CLiC device 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 Screen will display an alert message informing the user that the sensor clip needs to be verified. To verify accuracy, press the Test & Options tab then 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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