



2008T Hemodialysis Machine with CLiC™ Device



Participant Workbook



RENAL TECHNOLOGIES

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 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.

Introduction

The *2008T Hemodialysis Machine with CLiC Device Participant Workbook* (Workbook) is solely for training skilled healthcare professionals in the use of the 2008T hemodialysis machine with CLiC device. This Workbook is intended to be used as a companion to the *2008T Hemodialysis Machine with CLiC User's Guide* (User's Guide, P/N 490206), which contains detailed instructions for all machine functions.

This Workbook is designed to be flexible, taking into account the various experience and skill level of the participants, the number of participants, and the amount of time available for training purposes. Similarly, this Workbook recommends that participants have the opportunity to use the 2008T hemodialysis machine with CLiC device during a patient dialysis session to enhance the training experience. This hands-on experience may occur at the time of training or over several days depending on the facility, shift schedules, etc., and should be tailored to each facility, participant and situation.

Each facility determines who will participate in the In-Service Training. It is anticipated that participants will include nurses, patient care technicians (PCT), and physicians, with nurses being the primary focus of the In-Service Training.

Training Prework:

In order to ensure that participants have the clinical background needed to interpret the data, all nurses must complete the following online 2008T Hemodialysis Machine with CLiC Device course prior to attending the In-Service Training:

www.Crit-lineTrainingCourse.com

Completion of the prework by other participants (e.g., PCTs) is at the discretion of each facility.

Training Resources:

In addition to this Workbook, the following materials are incorporated into the 2008T hemodialysis machine with CLiC device In-Service Training:

- *2008T Hemodialysis Machine with CLiC User's Guide (P/N 490206)*
- *2008T Hemodialysis Machine with CLiC Device Reference Guide (P/N 102111-01)*
- *CLiC QuickStart Guide (P/N 102445-01)*

Icons and Descriptions:

The following icons are used in this Workbook to provide direction and clarity:

Icons and Descriptions	
	Instructor explanation and demonstration
	Facilitation tips and supplemental comments
	Warning or caution

Training Topics

Welcome/getting started

- 2008T Hemodialysis Machine with CLiC Device Participant Workbook Introduction
- 2008T Hemodialysis Machine with CLiC User's Guide Introduction

2008T hemodialysis machine with CLiC device overview

- Crit-Line screen features
- Setup
- Blood chamber placement
- Sensor clip

Preparation for treatment

- Verify accuracy routine

Initiation and termination of treatment

- Sensor clip attachment
- Start run
- BV alert level
- O₂ alert level
- Markers
- Ending a treatment
- Printing/downloading treatment results
- Cleaning

Troubleshooting

- Alarms
- Review Profiles A, B, and C

Hands-on demonstration

- Facility patient treatment area

Getting Started



Register your Attendance by Signing the In-Service Training Sign-In Sheet

Review the Participant Workbook

Note: The **CLiC QuickStart Guide**, which will be used during the In-Service Training, is an excellent troubleshooting resource.

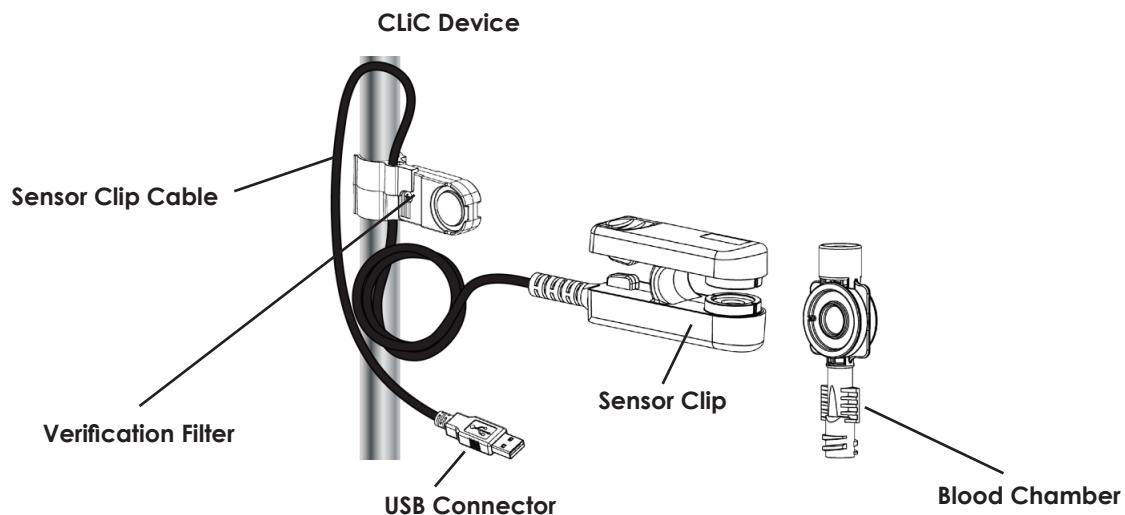
Introduction of the 2008T Hemodialysis Machine with CLiC User's Guide

- Have the User's Guide available for reference during the training.

Notes:

2008T Hemodialysis Machine with CLiC Device Overview

	<p>Review the physical features and setup of the CLiC device.</p> <p>Features</p> <ul style="list-style-type: none">• Sensor Clip• USB Connector• Sensor Clip Cable• Verification Filter• Blood Chamber <p>Setup</p> <ul style="list-style-type: none">• Attach blood chamber and check position• Prime (per unit procedure)
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Notes:

Preparation for Treatment



Review the steps required to prepare for a patient treatment using the CLiC device.

Verification Filter

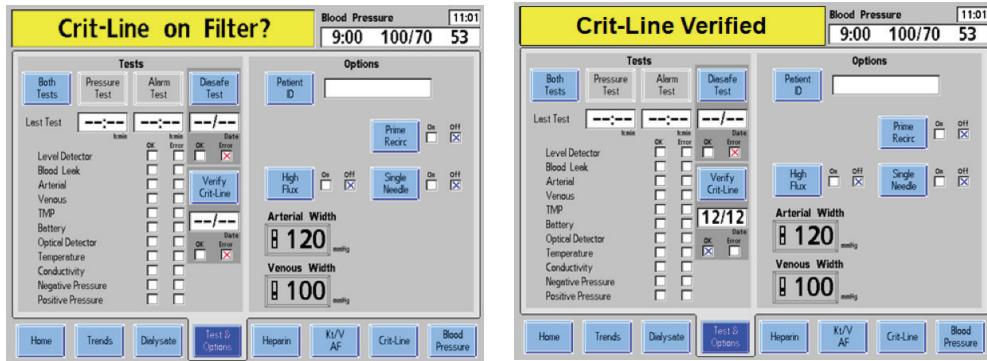
The CLiC device features a unique verification filter that is used to periodically verify the device's accuracy. The verification filter is attached to the CLiC device's USB cable. The sensor clip should be securely clipped to the verification filter when it is not in use.

When the sensor clip is stored on the verification filter, the 2008T hemodialysis machine automatically verifies the accuracy of the CLiC device when entering Dialysis Mode.

If the sensor clip is not stored on the verification filter, the device must be manually verified at least once per month.

Verify Accuracy Routine

- Place sensor clip on verification filter
- Test options screen: select **Verify Crit-Line**
- Follow directions on screen if verify accuracy routine is not successful



Verifying the CLiC Device

	<p>Manually Verify Accuracy</p> <p>Selecting the Test and Options tab screen allows the user to perform a manual verification on accuracy of the CLiC device.</p> <p> Note: In most cases, it is not necessary to perform a manual verification. If the sensor clip is placed onto the verification filter, the 2008T hemodialysis machine with CLiC device will automatically perform a verification test once per day, and the date of the most recent successful verification will be displayed below the Test and Option Screen.</p> <p>Follow these basic steps to manually verify accuracy:</p> <ol style="list-style-type: none">1. Place sensor clip on verification filter.<ol style="list-style-type: none">1. Hold the sensor clip such that one side is held by the index finger and the other side held by the thumb. Squeeze the sensor clip to spread the sensor elements apart.2. Place the sensor clip over the verification filter such that the sensor elements cover the middle portion of the verification filter.3. Release the sensor clip to allow the sensor elements to seat on the verification filter.4. Make certain that the sensor clip has locked securely into place on the verification filter by noting the audible and tactile click.2. Test options screen: Select Verify Crit-Line and Confirm.3. If verification test fails: The CLiC device is not ready to use during treatment.
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Verifying the CLiC Device

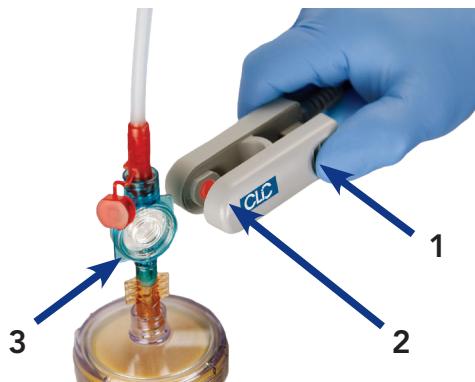
Action Steps
<p>Verify the CLiC device:</p> <ul style="list-style-type: none">• Place the sensor clip on the verification filter, which is attached to its USB cable.• Wait up to one minute for the message to clear. If the message clears, the CLiC device is verified. <p>If the message is not cleared:</p> <ul style="list-style-type: none">• Select the Test & Options screen-button then select the Verify Crit-Line button. This will start the verification process manually.• Wait up to one minute for the message to clear. If the message is still not cleared, the CLiC device cannot be used for the dialysis treatment.• Disconnect the CLiC device cable from the USB port.• Press the RESET key to disable the CLiC device.• Contact a qualified service technician.

Initiation and Termination of Treatment

  	<h3>Connecting the Blood Chamber</h3> <p>Follow these steps to attach the disposable blood chamber to the dialyzer during the extracorporeal bloodline setup before priming the bloodlines.</p> <p>Note: The Crit-Line blood chamber is tinted blue in color and must be used with the CLiC device.</p> <p>Note: The Crit-Line blood chamber is intended for single-use only. A new sterile blood chamber must be used for each monitoring session.</p> <ol style="list-style-type: none">1. Inspect Crit-Line blood chamber and packaging. Inspect the Crit-Line 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. Connect Crit-Line blood chamber to dialyzer. Remove the blood chamber from its sterile package and aseptically attach the red connector to the arterial port of the dialyzer. Make sure the connection is tight.3. Continue setting up the bloodlines. Continue to set up the bloodlines as described in Chapter 2, "Connecting the Extracorporeal Blood Circuit" in the <i>2008T Hemodialysis Machine Operator's Manual (P/N 490122)</i>. <p>Note: When connecting the arterial bloodline to the Crit-Line blood chamber (not the dialyzer), hold the Crit-Line blood chamber securely in one hand and aseptically attach the dialyzer end of the arterial bloodline with the other hand. Be careful that you do not cross-thread the connection. The connection of the Crit-Line blood chamber to the arterial bloodline must not leak.</p> <p>Note: Make sure no air is in the Crit-Line blood chamber after priming. The accuracy of the hematocrit and oxygen saturation readings may be adversely affected if there is any air present in the Crit-Line blood chamber.</p>
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Initiation and Termination of Treatment

Connecting the CLiC Device to the Blood Chamber



Follow the steps below to attach the sensor clip to the Crit-Line blood chamber:

1. Pinch open the sensor clip.

Hold the sensor clip such that one side is held by the index finger and the other by the thumb. Squeeze the sensor clip to spread the sensor elements apart.

2. Attach the sensor clip onto the blood chamber.

Caution: Before attaching the sensor clip, check carefully for leaks at the connections between the blood chamber and the dialyzer, and the blood chamber and the arterial bloodline. Improper attachment of the arterial bloodline to the Crit-Line blood chamber can cause blood or saline to leak onto and into the sensor clip. This can damage the CLiC device.

Note: Make sure that the CLiC device is plugged into the USB port located on the right side of the 2008T hemodialysis machine display screen.

- Place the sensor clip over the Crit-Line Blood Chamber so that the optical sensor covers the lens of the Crit-Line Blood Chamber.
- Release the sensor clip to allow the optical sensor to seat on the viewing area of the Crit-Line Blood Chamber.
- Make certain that the sensor clip has locked securely into place on the Crit-Line Blood Chamber by noting the audible and tactile click.
- Ensure that the sensor clip is perpendicular to the top of the dialyzer and cannot be easily rotated up or down while attached to the blood chamber to ensure its proper placement.

Note: Make sure that the sensor clip is properly in place before treatment initiation. If the sensor clip is not properly seated on the Crit-Line blood chamber, the accuracy of the hematocrit and oxygen saturation readings may be adversely affected.

Initiation and Termination of Treatment

3. Check for proper blood flow before selecting Tx Clock.

When starting the blood pump at the beginning of treatment, visually verify prescribed blood flow in the extracorporeal circuit, including the Crit-Line blood chamber, before starting the Tx Clock.

Note: Graphing of the data begins after the CLiC device reads blood sensed, the hematocrit has been stable for sixty seconds, and the Tx Clock and blood pump are running.

Start Run

Explain blood volume (BV) alert level and O₂ alert level function

- Set initial BV alert level limit

BV Alert Level button

Sets the BV alert level. When the current $\Delta BV\%$ 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**.

Navigate Screens

Reading Graphs on the Crit-Line screen

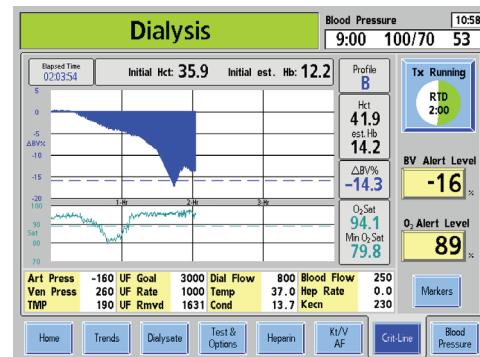
The Crit-Line screen can display either Blood Volume (BV) or Hematocrit (Hct) on the upper graph depending on the Service Mode setting.

On the lower graph, the Oxygen Saturation (O₂ Sat) graph can be changed to display blood pressure—select the graph and press the **CONFIRM** key.

The Blood Volume (BV) and Oxygen Saturation (O₂ Sat) graphs are displayed by default.

Graphing the data begins after the CLiC device reads blood sensed and the hematocrit has been stable for sixty seconds with the Tx Clock and the blood pump running. Graphs are displayed for a minimum of four (default) and maximum of ten hours. Graphs are resized larger during the treatment depending on the min/max values, RTD, and alert levels.

- Assess Data Points
 - Hematocrit (Hct)
 - Blood Volume (BV) Change (%)
 - Minimum Oxygen Saturation (Min O₂ Sat)
- Adjust BV Alert Level (if necessary)
- Change Profile Display



Initiation and Termination of Treatment

Setting an Event Marker

Marker button – Selecting this button displays a menu to insert an event marker on the blood volume and oxygen 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.

Marker Display Symbols

- The **Symptom** marker is a yellow diamond. ♦
- The **Intervention** marker is a black triangle. ▲
- The **Blood Volume graph** displays the BV% change value at that data point in blue.
- The **Hct graph** displays the Hematocrit value at that data point in black.
- The **Oxygen Saturation graph** displays the Oxygen Saturation value at that data point in green.

End Treatment

When the treatment is complete and the Tx Clock is paused, pinch the sensor clip to spread the sensor elements apart and gently remove the sensor clip from the Crit-Line blood chamber. Store the CLiC device by attaching the sensor clip to the verification filter, which is attached to its USB cable. Discard the disposable Crit-Line blood chamber with the rest of the bloodlines.

Print Treatment Results

Printing a CLiC Device Treatment Report

When RTD is zero and the Tx Clock is paused, a **Print** button will appear on the Crit-Line screen in place of the **Marker** button.

Note: To clear the data on the Crit-Line screen without printing, press the **New Tx** key.

- Select **printer method**
- Marker button becomes print button when treatment completed

Note: Printing is an optional feature which requires additional hardware on the 2008T hemodialysis machine.

Initiation and Termination of Treatment

Cleaning

- Sensor Clip
- Verification Filter

Cleaning and Disinfecting the CLiC Device

The CLiC device is a sensitive electro-optical device. Use care when cleaning the sensor clip and verification filter to prevent damage. The exterior of the sensor clip, and the verification filter, must be cleaned at the end of every treatment with dilute bleach solution (1:100) or other suitable hospital disinfectant.

Freshly prepared dilute bleach solution (1:100) is currently recommended by the Center for Disease Control as a suitable disinfectant for the hepatitis virus. Because surface contamination is the general mode of transmission for this type of virus, thorough cleaning of the exterior is essential.



Caution: Wipe the CLiC device with a cloth dampened with the cleaning solution. Do not spray the solution on the CLiC device. Do not immerse the CLiC device in any type of liquid. If liquids infiltrate the sensor clip, they will damage it.

Caution: Do not use abrasive materials or solvents to clean the CLiC device. Doing so may cause damage to the sensor clip.

Caution: Be careful not to scratch or damage the verification filter. If the verification filter is scratched or damaged, it may cause the CLiC device to fail verification of accuracy.

Caution: If the CLiC device becomes contaminated with blood, it must be thoroughly disinfected before the next treatment. Freshly prepared dilute bleach solution (1:100) or surface disinfectants such as Cavicide or Envirocide are recommended.

Notes:

CLiC Device In-Service Training Evaluation

Facility Name: _____

Date: _____

Instructor: _____

Thank you for participating in training for the CLiC device. We value your feedback and will appreciate your completing the following evaluation in order to help us provide the best possible training experience.

Please indicate your response to each of the following statements by circling the appropriate number on the right	Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
The Program:					
1. Adequate time was allowed to cover the program content	1	2	3	4	5
2. The pace of the training was appropriate	1	2	3	4	5
3. The material was presented in a way that made it easy to learn	1	2	3	4	5
4. The support material was adequate and well-organized	1	2	3	4	5
5. There was adequate time for questions and follow-up	1	2	3	4	5
The Instructor:					
6. ...created an environment conducive to learning	1	2	3	4	5
7. ...was knowledgeable about the clinical setting	1	2	3	4	5
8. ...effectively communicated the key concepts	1	2	3	4	5
9. ...encouraged application of theoretical knowledge	1	2	3	4	5
10. ...helped develop problem-solving skills	1	2	3	4	5
11. ...was available for questions and individualized instruction	1	2	3	4	5
12. ...overall, was an effective clinical instructor	1	2	3	4	5
The Overall Experience:					
13. The training met my expectations and goals	1	2	3	4	5
14. I feel better-informed regarding the CLiC device	1	2	3	4	5

What did you like most about the training experience?

What could we do to improve the training experience?

Other Suggestions/Comments:

Name (optional): _____

Please return this evaluation to your unit supervisor or fax to _____ . Thank you for your feedback!

2008T Machine with CLiC Device In-Service Training Sign-In Sheet



(Signature indicates attendance only, not competence or expertise)

Presented by: _____, RN, Clinical In-Service Specialist

Facility: _____ **Date:** _____

2008T Machine with CLiC™ Device In-Service Training Checklist



Facility: _____ **Date of In-Service Training:** _____

Address: _____ **Nurse Manager:** _____

City: _____ **State:** _____ **Zip:** _____ **Phone:** _____

Presented by: _____, RN

Training Topics

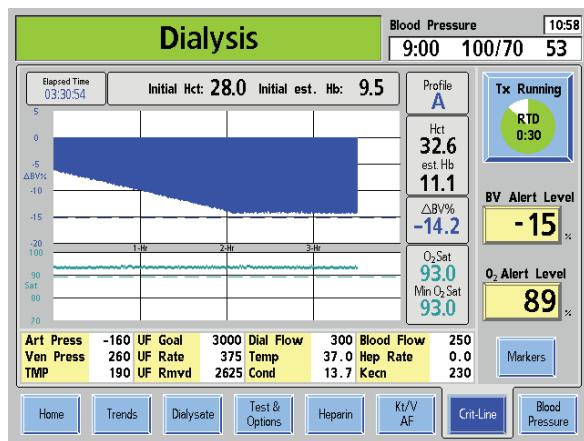
Checkmarks indicate topics reviewed during the in-service training; no representation is made regarding the participant competence or expertise.

Training Topics	✓
1. Sensor Overview:	
• Turn on 2008T machine and select Crit-Line screen	
2. Preparing Treatment:	
• Place sensor clip on verification filter	
• Select and verify accuracy from Test and Options screen	
3. Initiating Treatment:	
• Enter patient identification	
• Connect the sensor clip to the sensor blood chamber	
• Select Tx running from Crit-Line screen and confirm	
• Locate and verbalize the following parameters on the Crit-Line screen	
a. Elapsed Time	
b. Start Hct & Hgb	
c. ΔBV%	
d. O ₂ Sat	
e. Min O ₂ Sat	
f. Current Profile	
g. Current Hct	
h. Current Hgb	
• Locate and set BV Alert Level	
• Locate and set O ₂ Alert Level	
• Locate and describe graphs on 2008T Crit-Line screen	
• Demonstrate how to change O ₂ Sat graph to B/P graph	
• Demonstrate use of Marker	
a. Symptom	
b. Intervention	
4. Ending Treatment:	
• Pause Tx Options (Pause and Terminate Crit-Line Monitoring)	
• Print results	
• Cleaning and Disinfection of CLiC device	
5. Alarms and Troubleshooting	
• Identify and verbalize Profile A, B and C	
• Review error messages	

Appendix

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| | <ul style="list-style-type: none">1. Case Studies2. Fluid Distribution Model3. Frequently Asked Questions |
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Case Study: Patient #1



Patient History:

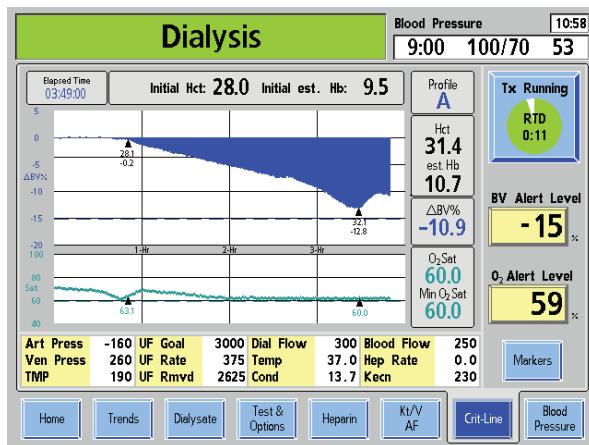
Patient #1 is a 43-year-old male with an AV fistula; he dialyzes M/W/F for three hours and thirty minutes. The patient has gained 2.3 Kg since his last treatment. BP 130/70, pulse 70, respirations 18 and regular. He has no edema noted, lungs clear to auscultation. Renal failure is secondary to application of IV contrast media.

Problem:

Treatment was started and the patient quickly dropped into a negative profile. Use the patient history and the CLiC device data to answer the following questions:

1. Did they initiate the treatment according to operating instructions?
2. What may have been the cause of the immediate drop in blood volume at the beginning of the treatment?
3. What is the O₂ saturation reading and is the reading reasonable based on the access type?
4. What is the patient profile at 20 minutes?
5. Were BV and O₂ Alert Levels set? If yes, what are these limits?
6. Based on your assessment, would you recommend any interventions?

Case Study: Patient #2



Patient History:

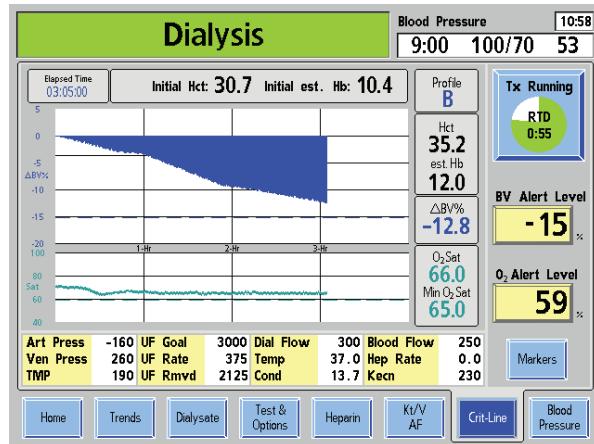
Patient #2 is a 67-year-old female with R subclavian CVC access used for dialysis while her L AV fistula develops. She dialyzes T/Th/S for three hours and forty-five minutes. She has gained 3.0 Kg since her last treatment, but is only 1.2 Kg above her estimated dry weight. She has been complaining that her weight is always different post treatment depending on her caregiver. Looking back through her treatment records, you notice this is true. Her weight fluctuates by 1.5 Kg. She is an insulin-dependent diabetic patient that has CKD 5 secondary to years of not controlling her diabetes. BP 148/90, pulse 100, respirations 24, mild peripheral edema, assessment shows lobes are clear, bases are full.

Problem:

Use the patient history and the CLiC device data to answer the following questions:

- 1. Was the treatment started correctly?**
- 2. What profile is displayed in the first hour and what profile is displayed between the first and the second hour?**
- 3. What intervention likely occurred with the first intervention marker?**
- 4. What does the second intervention marker indicate?**
- 5. What does the directional change at the second arrow represent?**
- 6. What is the O₂ saturation reading and is the reading reasonable based on the access type?**

Case Study: Patient #3



Patient History:

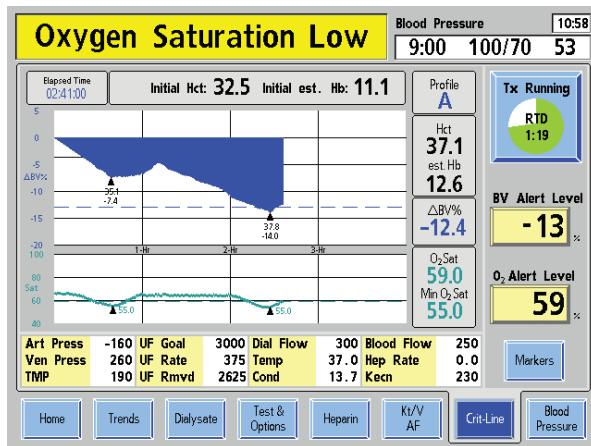
Patient #3 is an 89-year-old male with a L Internal Jugular (IJ) CVC line. He is scheduled for dialysis M/W/F for three hours. He gains 1.5 Kg between treatments and prides himself in his excellent compliance to all recommendations from his dialysis team. BP 120/80, pulse 68, respiration 20, no peripheral edema, clear lungs and no complaints. Patient history only shows very moderate weight gain between treatments and patient usually is at his dry weight post treatment. Only the fluid gained between treatments has to be removed.

Problem:

Use the patient history and the CLiC device data to answer the following questions:

1. Did they initiate treatment according to operating instructions?
2. Based on your assessment, is this a reasonable profile for this patient?
3. What is the O₂ saturation reading and is the reading reasonable based on the access type?
4. Were BV and O₂ Alert Levels set? If yes, what are these limits?

Case Study: Patient #4



Patient History:

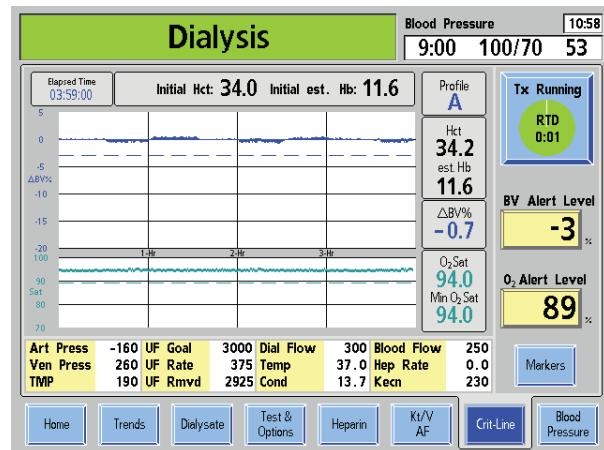
Patient #4 is a 72-year-old male with R IJ CVC access. He dialyzes T/Th/S for three hours. He has an extensive cardiovascular history, including stent placement, previous bypass surgery, and low cardiac output. He is prescribed multiple blood pressure medications, but sometimes forgets to take them at the right time. He arrived for treatment 3.5 Kg over his last post weight and 5.0 Kg away from target weight. BP 90/46, pulse 88 irregular, respirations of 20. His lungs are clear and no edema noted.

Problem:

Use the patient history and the CLiC device data to answer the following questions:

1. Did they initiate treatment according to operating instructions?
2. What profile is being displayed in the first hour of treatment?
3. Is the profile in the first hour reasonable for this patient?
4. What is the O₂ saturation reading and is the reading reasonable based on the access type?
5. In your assessment, do you think the physician needs to consider changes for the next treatment?
6. Was refill present?

Case Study: Patient #5



Patient History:

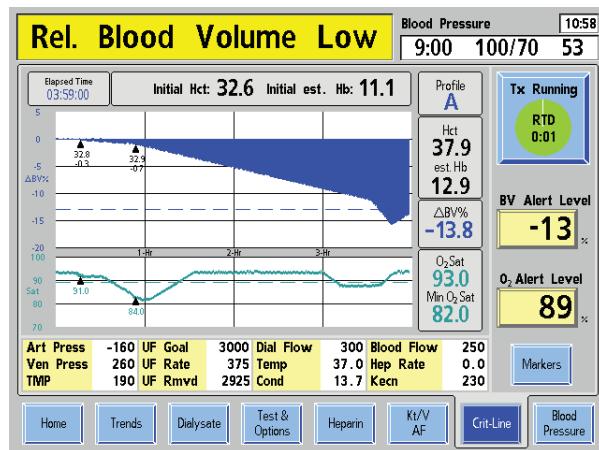
Patient #5 is a 54-year-old female with L AV fistula. She dialyzes M/W/F for four hours after she gets off work. She has 0.5Kg weight gain since her last treatment. As you review her chart you note that she rarely gains much weight between treatments. You notice she brought in 2 jugs for her 24-hour urine collection. Her BP is 110/68, pulse 98, and respirations 16, lungs are clear, no edema noted. She is dialyzed at minimum UF.

Problem:

Use the patient history and the CLiC device to answer the following questions:

1. What profile does this patient graph exhibit?
2. What profile would you expect for this patient given her history and treatment parameters?
3. What is the O₂ saturation reading and is the reading within typical range based on the access type?
4. Were BV and O₂ Alert Levels set? If yes, what are these limits?

Case Study: Patient #6



Patient History:

Patient #6 is a 48-year-old female patient that has L AV fistula. She is scheduled for T/Th/S treatment for four hours. She began dialysis nine months ago and continues to use the same dry weight. Her BP is 158/98, pulse 102, respirations 24, peripheral edema noted before and after treatment, lungs are not clear. Due to clinical signs of over hydration, the physician ordered a reduction in dry weight.

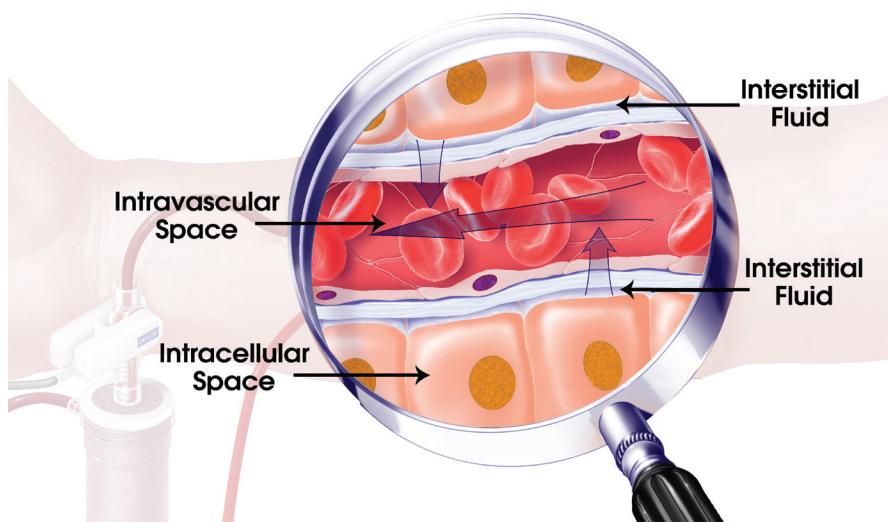
Problem:

Use the patient history and the CLiC device data to answer the following questions:

1. Was the treatment initiated correctly?
2. Does the profile shown seem reasonable for this patient?
3. In your assessment, was the O₂ Saturation for this patient adequate throughout the entire treatment?
4. Did the patient convert to a different profile following the first intervention?
5. What interventions were possibly made at the first intervention marker?
6. Did the patient convert to a different profile following the second intervention?
7. Was refill observed at the end of the treatment?

Fluid Distribution Model

- Intracellular fluid (without blood cell water)
- Interstitial fluid
- Blood
- Circulating BV
- Peripheral BV
 - Ultrafiltration
 - Dialysate osmolarity
 - Dialysate temperature



Frequently Asked Questions

1. What are the three main measurements that are measured by the CLiC device?

Hematocrit, oxygen saturation and percent change in intravascular blood volume.

2. How does the CLiC device make its measurements?

The CLiC 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. How does the CLiC device verify that it is measuring accurately?

Each CLiC device has its own verification filter that is used to periodically verify the accuracy of the CLiC device. This filter is attached to the CLiC device's USB cable.

4. How often should you verify accuracy on the verification filter?

When the sensor clip is stored on the verification filter, it automatically verifies accuracy prior to entering Patient Run Mode. When the sensor clip is not stored on the verification filter, it must be verified once per month.

5. Can the blood chamber be used more than one time?

The blood chamber is intended for single-use only.

6. After priming the circuit, what should I look for before connecting the sensor clip to the blood chamber?

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

7. What are the default CLiC device graphs that are displayed on the 2008T machine?

The blood volume and oxygen saturation graphs are the default screens displayed.

8. What are the other screens that can be displayed?

The blood volume graph can be switched to a hematocrit graph. The oxygen saturation graph can be changed to display blood pressure.

9. When does the CLiC device start to take measurements?

Graphing of the data begins after the user selects Start Run, the CLiC device reads blood sensed, and the hematocrit has been stable for 60 seconds.

10. What is the difference between the intervention markers?

The symptom marker is displayed as a yellow diamond. The intervention marker is displayed as a black triangle.

FAQs (continued)

11. What is the profile that is displayed?

The profile that is displayed is the average percent blood volume change ($\Delta BV\%$) of the previous 15 minutes of data gathered. If the $\Delta BV\%$ is $\leq -3\%$ per hour, the profile will be displayed as an A profile. If the $\Delta BV\%$ is $> -3\%$ per hour and $\leq -6.5\%$ per hour, the profile will be displayed as a B profile. If the $\Delta BV\%$ is $> -6.5\%$ per hour, the profile will be displayed as a C profile.

12. What is the estimated HB value that is displayed?

The hemoglobin value that is displayed is an estimated measurement based on the measured hematocrit.

13. How is percent change in blood volume calculated?

The percent change in blood volume is calculated from the following equation:

$$\Delta BV\% = \{(\bar{H}_2/\bar{H}_1) - 1\} \times 100$$

\bar{H}_2 = Initial Hct

\bar{H}_1 = Current Hct

14. What is the default BV Alert Level?

The default BV Alert Level is -15% and is drawn as a blue dotted line across the BV graph.

15. What is the default O₂ Sat Level?

The O₂ Alert Level defaults to 89 and can be set from 45 to 95.

16. Can you print out the treatment profiles at the end of a treatment?

Yes, treatment profiles can be printed at the end of a treatment. Additional hardware and software are necessary in order to treat patient profiles. Technical Support can be reached at 1-800-227-2572.

17. How do you clean the CLiC device?

The exterior of the sensor clip and the verification filter should be cleaned after every treatment. These can be cleaned with the standard diluted bleach solution (1:100). Wipe the sensor clip clean with a cloth dampened with a cleaning solution; do not spray the solution directly onto the device or immerse the sensor clip into any type of liquid.

18. Can the CLiC device still be used if it continues to fail verification?

No, if the sensor clip continues to fail verification, it is no longer suitable for clinical use. Unless it can be re-calibrated (see User's Guide).

19. What do I do if a sensor clip fails to calibrate?

The sensor clip must be taken out of service. Contact technical support at 1-800-227-2572.

Notes:

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