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HemoFlow Model 300 Training Plan

Introduction

This outline provides guidance to the trainer for introducing the HemoFlow™ 300 Blood Draw Monitor / Mixer to new users. It corresponds with pages in the HemoFlow™ 300 Operator's Guide. Training using this format will emphasize the important steps and central features of the device. The trainer should understand the basic HemoFlow operation and be familiar with the Operator's Guide.

For more effective learning, it is recommended that the learners look through the Operator's Guide during the training session. After the initial training, each user should perform several calibrations and simulated draws to become familiar with device operation. We recommend the use of training bag sets that are made from two bags filled with water. One bag simulates the "donor" and the other is used for the collection bag. The water is then slowly drained back and forth for each simulated draw. Hold the "donor" source bag a few inches above the collection bag that is on the HemoFlow tray.

Lesson 1: HemoFlow Overview

The HemoFlow 300 is an electronic device designed to assist in blood donations. It measures the volume of blood collected, provides automatic mixing, and clamps off the tubing automatically at the end of the draw. If the flow is slow, the HemoFlow alarms the phlebotomist so a correction can be made before the bag is lost. Other monitor features can help assure that the draw will complete successfully in the allotted time.

By using the HemoFlow, more bags can be completed successfully with less phlebotomist attendance. It is intended to improve efficiency and make the blood collection process operate more smoothly. The HemoFlow operates by constantly weighing the collection bag on its tray. For convenience, the HemoFlow converts the weight of the donation to volume of blood. Displays are shown in total collected volume, not weight. The volume to be collected is programmed in milliliters, and the weight and type of bag is automatically accounted for.

HemoFlow Layout Descriptions (page 2)

Digital Display: Shows volume, flow rate, time, and various alarm messages.

Keys: There are five keys for simple operation. The only essential key for performing a draw is the START key.

Dual Function of Keys. Most keys have two functions. The "Short Press" activates the primary function. A "short press" is a momentary press of the key. The second function is activated by a "Long Press" (Hold the key down for about 3 seconds, until the display changes).

Tubing Clamp. Located on the right side of the control panel. The release button opens the clamp when the draw is complete. The tubing inserts from the side.

Bag Tray. The tray is used to hold and rock the bag during the mixing process. The bag is continuously weighed on the tray, allowing the HemoFlow to determine the progress of the blood draw by weighing the bag as it fills.

Lesson 2: Preparing the HemoFlow for Use

1. **Setup** *(page 5*
    a. Take HemoFlow out of transport case and allow to sit in the donation room for 20 to 30 minutes. This allows the HemoFlow temperature to adjust to the room to improve the calibration accuracy.
    b. Slide the HemoFlow pole clamp over mounting pole.
    c. Position the bottom of the HemoFlow about 9 inches above the floor and tighten the thumbscrew.
    d. To attach the tray, tip the tray back and slide the bag tray support arm onto the two small ball chains on the underside of the HemoFlow.
    e. No precise leveling is required.

2. **Daily Calibration (Daily QC)** *(pages 6-7).*
    a. Make sure that there is no weight on the tray.
    b. Long press the SCALE key until "CAL -0-" is displayed.
    c. When "CAL 500" is displayed, hang the 500 gram calibration weight by hanging it between the holes on the tray.
    d. Calibration is complete when "SCL 500" is displayed.

3. **Volume Programming** *(page 8).*
    a. To check the collection volume setting, press the VOLUME key when not in a draw. The volume will be shown in milliliters.
    b. To change the collection volume setting, long press the VOLUME key until the display starts to flash.
    c. Change the volume by repeated pressing the VOLUME key or pressing and holding it to auto-step the volume.
    d. The volume can be set to 250 to 550 milliliters in 10ml steps.
    e. If the target collection volume is observed to be incorrect at the start, press the ALARM / OFF key to power off, press the VOL key to set the correct volume, then press START again to restart the draw. *(NOTE: This feature is not available in Version 10 software).*

4. **Placing the Bag and Inserting the Tubing** *(page 9-10).*
    a. Place the bag on the tray. NOTE: The bag and anticoagulant must weigh at least 25 grams before starting a draw.
    b. Insert tubing into clamp. Hold the tubing in both hands and stretch a little to ease insertion. Press release button on clamp if not open. Clamp will stay open after the release button is pressed.
    c. Check that tubing loops loosely below the bag with no tension – about 2 - 3 inches. Tubing should not be tight. *This is very important!*

PRACTICE - Before moving on to the next lesson, guide each learner as they practice each of the following skills until they feel confident.

1. Mount the HemoFlow to the floor stand or other mounting system, such as a bed mount.
2. Calibrate the HemoFlow.
3. Check the programmed volume setting.
4. Change the programmed volume setting.
5. Place the bag on the tray and insert the tubing.

Lesson 3: Using the HemoFlow for a Draw

Starting the Draw *(page 9).*

a. With bag and tubing in place, press START. HemoFlow will wait for flow to begin.
b. Perform venepuncture and begin draw.
c. Always press START *before* performing venepuncture. *This is very important!*
d. The display will flash the target collection volume. *(NOTE: For Version 10 software, a "-0-" is flashed).*
e. Release the hemostat or open the HemoFlow clamp to start flow.
f. When flow starts, mixing will begin automatically and draw volume will be displayed.

End of Draw *(page 16).*

a. Towards the end of the collection, the HemoFlow will beep every few seconds alerting that the end is near. For the best accuracy, do not disturb the bag during this time.
b. When the collection volume is reached, the HemoFlow will automatically clamp the tubing, display "End", and give three distinct ring sounds. The red LED light will flash slowly.
c. At the end, before the bag is removed, the user may press the VOL key to display volume, the SCALE key to display the final total weight, or the START key to display the final draw time.

Remove Completed Bag *(page 16).*

a. Clamp or seal the donor tubing with a hemostat, according to standard protocol.
b. Press any key to stop the mixer.
c. Press the HemoFlow clamp release button to open the clamp.
d. Remove the tubing from the clamp. Hold the tubing in both hands and stretch a little to ease removal.
e. Remove the bag from the tray.
f. The HemoFlow will shut down automatically.

PRACTICE - Before moving on to the next lesson, guide each learner as they practice each of the following skills until they feel confident.

1. Check to make sure that the HemoFlow is set up with the bag and tubing in place.
2. Check to make sure that there is no tension in the tube between the bag and the clamp.
2. Practice starting the draw (use 2 water filled bags, as described in the Introduction).
2. Make sure that the learner indicates when flow from the donor should begin. (Remember, flow should begin only **after** pressing the START key, and **after** the display stops flashing).
4. Remove the tubing and bag at the end of the draw.

Lesson 4: Displaying Information During a Draw

VOLUME
The collection volume (in milliliters) is displayed at the beginning of the draw. Press the VOLUME key at any time to return to the volume display.

FLOW RATE
Press the FLOW key to display the flow rate and check for slow flow before it is a problem. 0 to 2 is very slow, 3 to 6 is moderate, 7 to 9 is fast.

TIME
Press the START key to show the draw time in minutes and seconds. The seconds digits flash.

PRACTICE - Before moving on to the next lesson, guide each learner as they practice each of the following skills until they feel confident.

1. Perform another simulated draw using water-filled bags.
2. During the draw, check to see the volume collected.
3. Display the flow rate.
4. Indicate how long the draw has been in progress.
5. At the end of the draw, indicate (1) the total weight collected, (2) the total time of the draw, and (3) the total volume collected.

Lesson 5: Recognizing and Recovering from Common Errors and Alarms

Low Flow Alarm *(page 15).*

If the flow rate drops too low, the HemoFlow will display “Lo Flo” and the red LED light will flash rapidly. If the problem is not corrected within 20 seconds, an audible alarm will sound.To recover from the low flow alarm:

1. Correct the flow problem and the alarm will turn off automatically.
2. If needed, press the ALARM key to silence the alarm. You may also press the ALARM key as soon as “Lo Flo” is displayed to prevent the audio alarm from sounding.

Errors at the Beginning of the Draw *(page 12).*

Bag Err- Indicates that a bag is not on the tray, or a full bag is on the tray. This alarm will also sound if the minimum bag weight is not detected before the START key is pressed.

Job Err- Caused by incorrectly starting the draw before the START key was pressed. To recover, press the SCALE key and complete the draw manually by total weight. Note that the auto-clamp and flow monitor features do not function in this mode.

Errors During a Draw *(page 19).*

14’59 Err- Timeout error has occurred. The draw should be abandoned. The final weight can be checked with the SCALE mode to see if the bag is still useable. (Note: “14’59" is used here as an example. The timeout error will display the actual time limit that has been programmed”).

Errors at the End of a Draw *(page 19).*

Job Err - A job error alarm at the end of the draw is triggered if the draw volume continues after the end of the draw. Usual source of problem is incorrect placement of tubing in the clamp or possible clamp malfunction. IF THIS ERROR OCCURS, IMMEDIATELY CLAMP OFF THE TUBING WITH A HEMOSTAT. Quick action may save the completed bag.

Lo Bat - The low battery alarm indicates that the batteries should be changed or recharged at the end of the day. There is no need to stop the blood drive to change or charge the batteries.

PRACTICE - Before moving on to the next lesson, guide each learner as they practice each of the following skills until they feel confident.

1. Perform another simulated draw using water-filled bags.
2. During the draw, simulate a low flow situation by clamping the tube to prevent flow.
3. Make sure the learner knows how to silence (or prevent) the alarm sound. They should also know that once the low flow problem has been corrected, the alarm will automatically stop.
4. Other alarms (such as the Bag Error and Job Error at the beginning of the draw) can easily be simulated. The depth to which the user is familiar with other alarms can be left to the discretion of the trainer. At the very least, however, the HemoFlow operator should be able to describe the events that would trigger (1) Bag Error and Job Errors at the beginning and end of the draw, and (2) what should be done if the low battery alarm sounds.

Lesson 6: Other HemoFlow Features

Scale Mode *(page 7)*

1) Use the SCALE mode to re-check a bag weight at the end of a draw, or to recover from an operation error.
2) Press the SCALE key to activate the scale mode.
3) The scale mode does not operate during a draw to avoid confusion of total weight versus volume of blood collected.

Time Limit *(page 17).*

1) The HemoFlow has an automatic draw timer.
2) If the time limit is reached, the tubing will be clamped, an alarm will sound, and the draw should be abandoned.
3) The time limit can be set to 10 to 20 minutes.
4) The time limit can also be disabled. (Turned OFF).
5) To change the limit, refer to the User's Guide.

Cleaning *(page 23)*
The HemoFlow can be cleaned with a cloth dampened with an approved disinfectant, mild detergent, or alcohol. The HemoFlow should not be sprayed directly to avoid seepage of the solution into the internal electronics.

If bleach or bleach solutions are used, it is recommended that nothing stronger than a 10% solution be used. Thoroughly remove any bleach solution from the HemoFlow by wiping down with a damp cloth after disinfecting with bleach solution.

CONCLUSION

Once each learner has had a chance to practice and feel comfortable setting up and using the HemoFlow for a draw, and all questions have been asked and answered, follow the training session with the HemoFlow Model 300 Assessment and Sign Off Form. The assessment consists of a multiple choice quiz and a skills demonstration test. Upon successfull completion of the training session and assessment, new HemoFlow users can be awarded the HemoFlow Operator's Certificate, which is located in the Assessment Guide.