Bone Marrow Processing (BMP) Procedure

The bone marrow processing (BMP) procedure is used with a WBC disposable tubing set to remove mononuclear cells (MNCs) from bone marrow.

"Stem cells" for transfusion is not a biological product licensed by the U.S. Food and Drug Administration. Gambro BCT makes no claims for the efficacy of this product. Stem cell collections should be done in accordance with Investigational Device Exemptions.

This procedure uses the single-stage filler. Anticoagulated bone marrow enters the inlet chamber through the inlet tube. As it flows through the channel, it is separated into three layers: the red blood cells on the outside, the buffy coat containing the selected white blood cells in the center, and the platelet-rich plasma on the inside. The red blood cell/plasma interface is established during Quick Start. After Quick Start, the plasma pump flow rate is adjusted by the operator to hold the interface in a constant position. The white blood cells are drawn from the channel through the WBC collect tube, while the platelet-rich plasma exits through the plasma tube.

Anticoagulant must be added to the bone marrow before you start, but neither anticoagulant nor the AC pump is used during the procedure.
Equipment and Supplies

- COBE Spectra Apheresis System
- Single-stage filler
- Collect flow path overlay
- Bone Marrow Processing Set
- WBC disposable tubing set
- COBE Spectra WBC Colorgram™ (Reorder Number 700744-000)
- 1000 mL 0.9% sodium chloride (NaCl) for injection.
- Forceps or hemostats
- One 600-mL transfer bag with a needle adapter for plasma collection. If the bone marrow has an RBC volume greater than 215 mL, you will be prompted to connect a plasma collection bag during the procedure.
- 170-micron filter administration set (if bone marrow is not pre-filtered or if additional filtering is needed)

Before You Start

The following sections address items you should consider before beginning a Bone Marrow Processing (BMP) procedure.

Filtering the Bone Marrow

The bone marrow should be filtered with a 170-micron filter to remove bone chips, debris, and clots before transferring the bone marrow to the BMP set. If the bone marrow is not pre-filtered, you need to connect a 170-micron filter administration set to the bone marrow bag, then connect the filter administration set to the luer connectors on the BMP Set (see page 5-12).

Adding Anticoagulant

Before processing the bone marrow, you must add ACD-A to the bone marrow at a ratio of 1:10.

1. Weigh the bags of bone marrow.
2. Calculate the volume:
   \[
   \frac{\text{bone marrow weight} - \text{bag tare weight(s)}}{1.058} = \text{Volume (mL)}
   \]
3. Calculate the volume of ACD-A to add:
   \[
   \frac{\text{Volume (mL)}}{10} = \text{ACD-A Volume}
   \]
4. Measure the hematocrit of the bone marrow after the ACD-A has been added. This is the hematocrit you will enter during Entering Bone Marrow Data.
Interface Problems

If the interface is difficult to maintain and recoveries are low, it may be due to over-heparinization. Bone marrow processing literature supports using 8–10 units of heparin per mL to avoid clumping problems.

Counting Cell Recoveries

Because this is an MNC procedure, it is important to know what type of cells you are counting: Total Nucleated Cells (TNC) or Mononuclear Cells (MNC). You will be counting MNC recoveries, not TNC recoveries. The percentage recoveries on TNC counts will be lower because granulocytes are being removed.

BMP Fluid Volumes

For a complete explanation of fluid volumes, see Chapter 9, Fluid Volumes, in the COBE Spectra Essentials.

The following table shows the fluid volumes for the BMP procedure:

<table>
<thead>
<tr>
<th>Fluid Volume</th>
<th>Volume</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disposable Tubing Set Volume</td>
<td>285 mL</td>
</tr>
<tr>
<td>Total Equivalent Whole Blood Volume</td>
<td>285 mL</td>
</tr>
<tr>
<td>Total RBC Volume</td>
<td>114 mL</td>
</tr>
<tr>
<td>Residual RBC Volume</td>
<td>24 mL</td>
</tr>
</tbody>
</table>

Volumes Processed During Rinseback

The following table shows the volume of blood and saline returned to the collection bag at each stage of Rinseback:

<table>
<thead>
<tr>
<th>Fluid Volume</th>
<th>Volume</th>
</tr>
</thead>
<tbody>
<tr>
<td>Collect</td>
<td>60 mL</td>
</tr>
<tr>
<td>Returning RBCs</td>
<td>120 mL</td>
</tr>
<tr>
<td>Evacuating Channel</td>
<td>125 mL</td>
</tr>
<tr>
<td>Rinsing Channel</td>
<td>108 mL</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>413 mL</strong></td>
</tr>
</tbody>
</table>
Starting Values for Procedure

The following table shows the default run parameters this procedure begins with:

<table>
<thead>
<tr>
<th>Run Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Volume processed for bone marrows of greater than 215 mL RBC volume</td>
<td>3X bone marrow volume, counted from time the collect valve is opened</td>
</tr>
<tr>
<td>Volume processed for bone marrows between 170 and 215 mL RBC volume</td>
<td>4X bone marrow volume, counted from time the collect valve is opened</td>
</tr>
<tr>
<td>Volume processed for bone marrows of between 100 and 170 mL RBC volume</td>
<td>5X bone marrow volume, counted from time the collect valve is opened</td>
</tr>
<tr>
<td>Inlet:AC Ratio (the AC pump is not used, so this value is inconsequential)</td>
<td>99.9:1</td>
</tr>
<tr>
<td>Collect Pump Flow Rate</td>
<td>1.5 mL/min</td>
</tr>
<tr>
<td>Inlet Pump Flow Rate (bone marrow volume &gt; 1 liter)</td>
<td>90 mL/min</td>
</tr>
<tr>
<td>Inlet Pump Flow Rate (bone marrow volume &lt; 1 liter)</td>
<td>70 mL/min</td>
</tr>
</tbody>
</table>

Clinical trials demonstrate that processing the bone marrow more than the default of three times the bone marrow volume in adult bone marrow did not increase the MNC yield but did increase the granulocyte contamination.

Caution: Clinical data have indicated that bone marrows of less than 125 mL RBC volume will be processed less efficiently.

Ranges for Bone Marrow Data

The following table shows the allowed and validated ranges for the data you enter during this procedure:

<table>
<thead>
<tr>
<th>Entered Data</th>
<th>Allowed Range</th>
<th>Validated Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Bag Volume</td>
<td>100–6000 mL</td>
<td>300–6000 mL</td>
</tr>
<tr>
<td>Bone Marrow Hct</td>
<td>10–80%</td>
<td>15–45%</td>
</tr>
</tbody>
</table>

Ranges for Run Results

When changing the BMP run results, the following value ranges are allowed for changed values:

<table>
<thead>
<tr>
<th>Value</th>
<th>Allowed Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Run Time</td>
<td>10–999 min</td>
</tr>
<tr>
<td>Inlet Pump Flow Rate</td>
<td>up to 150 mL/min</td>
</tr>
<tr>
<td>Collect Volume</td>
<td>10–9999 mL</td>
</tr>
<tr>
<td>Inlet Volume</td>
<td>100–32,000 mL</td>
</tr>
</tbody>
</table>
Setting Up the Spectra System

Turn on the COBE Spectra Apheresis System. For details, see Setting up the Spectra System on page 4-1 of the COBE Spectra Essentials.

Installing the Filler

For a picture of the single-stage filler, see Figure 2-1 on page 2-6.

Loading the Disposable Tubing Set

Placing Tubing on the Front Panel

The following instructions are a condensed version of the detailed instructions found on page 4-4 of the COBE Spectra Essentials. If you are unfamiliar with loading the disposable tubing set, follow the detailed instructions. If you are an experienced operator, use the following steps only as a guideline.

1. Install the Collect flow path overlay on the front panel.
2. Remove the inlet line coil and remove the paper tapes.
3. Hang the access connection on the hook on the left side of the IV pole. (The three lines attached to this connection are taped together.)
4. Place the green-striped access saline line over the top of the system.
5. Remove the return line coil and remove the paper tapes.
6. Hang the return connection on the hook on the left side of the IV pole. (The two lines attached to this connection are taped together.)
7. Place the return saline line over the top of the system.
8. Hang the saline, waste and collection bags on the IV pole.
9. Snap the pump cartridges into the cartridge clamps.
10. Press CONTINUE to load the tubing into the pumps.

Note: ACD-A is not needed during this procedure.
Make sure all four pumps are loaded. After pumps are loaded, valves automatically open to the Load position. You cannot load the tubing until the valves open.

11 Install the following:
- The lines in the collect/replace and plasma valves
- The return pressure sensor in its housing
- The RBC line in the RBC valve and detector
- The return and inlet air chambers in the air detectors
- The waste divert lines in the waste divert valve assembly
- The line in the centrifuge pressure sensor housing
- The access pressure sensor in its housing
- The return line in the return valve

The Single-Stage WBC Channel

Inlet Tube (red plastic) – where anticoagulated bone marrow enters the inlet chamber.
Inlet Chamber – where anticoagulated bone marrow enters the channel.

Channel – where centrifugal force and the differences among the specific gravities of the blood components cause the bone marrow to separate into its components.

Collection Chamber – contains the exit tubes.

WBC Collect Tube – where white blood cells exit the channel for the collection bag.

RBC Tube (clear plastic, larger diameter) – where red blood cells exit the channel.

Control Tube (clear plastic, smaller diameter) – helps maintain the interface in the channel. The RBC and control tubes are joined into one tube near the centrifuge collar.

Plasma Tube (yellow plastic) – where platelet-rich plasma exits the channel and is mixed with red blood cells before return to the collection bag.

Installing the Channel in the Filler

1. Press UNLOCK COVER. Slide back the centrifuge cover and lower the centrifuge door.

2. Rotate the centrifuge so the loading port is open to the front. Make sure the centrifuge collar holder is resting on the outer rim of the filler.

3. Fold the channel in half, insert it through the lower loading port, and pull it out the top.

4. Load the centrifuge collar into the centrifuge collar holder, and snap the cover over the collar. Push the filler latch down into the locked position.

5. Press the channel into position, then press the tubes into the appropriate filler slots, as shown in the following table.

<table>
<thead>
<tr>
<th>Far Left Slot</th>
<th>Left Slot</th>
<th>Right Slot</th>
<th>Far Right Slot</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clear tube</td>
<td>Clear tube</td>
<td>Clear tube with stripe on top</td>
<td>Red tube</td>
</tr>
<tr>
<td>Yellow tube on bottom</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Figure 5-2: Single-stage WBC channel
6 Place the lower bearing in the lower bearing holder and the upper bearing in the upper bearing holder.

7 Place the upper collar in the upper collar holder.

8 Press the multi-lumen tubing into the exit slot on the right side of the centrifuge compartment.

**Caution:** Before you begin Prime, inspect all tubing, especially in the centrifuge and on the front panel, to make sure it is not severely kinked. Lines that are partially or completely occluded may interfere with the correct procedure operation. Do not use the disposable tubing set if it is severely kinked.

9 Rotate the centrifuge clockwise several times to make sure the tubing does not twist and the upper bearing remains in place, then close the centrifuge door and cover.

Continue with *Priming the Disposable Tubing Set* on the next page.
Priming the Disposable Tubing Set

**Note:** Bone marrow data is normally entered after Prime is complete, but it can be entered during Prime. To do this, press **MENU ON/OFF** any time after Step 1 below, then press 1 to select “Data Entry.” See *Entering Bone Marrow Data* on page 5-13 for specific instructions.

**Select set:**
1 = ELP, 2 = TPE, 3 = WBC, 4 = RBCX

1 Press 3 to select “WBC.”
If you make a mistake and enter the wrong number, see *Correcting Incorrectly Entered Disposable Tubing Set* on page 11-3 in the COBE Spectra Essentials. This screen is different for the different Spectra system versions.

2 Press 3 to select “BMP.”

3 Close the white pinch clamps on the access and return lines near the luer connections. Close the roller clamps on the access and return saline lines.

4 Place a hemostat on the AC line (the middle, clear tubing on the access lines) at the access manifold (see Figure 5-4).

5 Press **CONTINUE**.

6 Connect the access and return saline lines to the saline container. Place the plastic spike in the spike port (after removing cap).
Clean the injection port with alcohol before inserting the metal spike.
Fill the drip chambers half full.

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Bone Marrow Processing (BMP) Procedure

7 Press CONTINUE.

Caution: Make sure the white spike on the access saline line and the purple needle on the return saline line are attached to the normal saline container.

Make sure fluid is flowing into the drip chambers.

8 Open the access and return saline lines.

Press CONTINUE to prime.

Caution: Once fluid has entered the disposable tubing set, do not disturb sensors in pressure sensor housings (or the centrifuge pressure sensor) because this prevents transducers from accurately monitoring pressures.

For more information, see the following sections in the COBE Spectra Essentials:

- Repositioning the Access Pressure Sensor Diaphragm on page 12-6
- Repositioning the Return Pressure Sensor Diaphragm on page 12-7

9 Press CONTINUE.

10 Make sure the screen says “BMP” in the lower right-hand corner.

The Spectra system finishes Prime automatically. A number of different screens appear. Pumps start and stop, valves open and close, the centrifuge starts and stops, and tubing fills with fluid during Prime.

11 Open the white pinch clamps on the access and return lines. Allow saline to fill the luer lock connections by gravity. Close the white pinch clamps.

12 Press CONTINUE.

13 Close the green-striped access saline line roller clamp. Close the white access line pinch clamp.

14 Press CONTINUE.

Power up tests in progress.

15 Priming inlet line and air chamber.

Prime BMP

The AC and inlet pumps start and stop as the system does a series of self-checks.

Open access saline line.

Press CONTINUE
15 Open the access saline line.
16 Press CONTINUE.

Perform alarm tests (YES/NO)?

17 Press YES to run alarm tests, then follow the instructions on the screen. See Chapter 7, Alarm Tests, in the COBE Spectra Essentials.

– or –

Press NO to bypass the alarm tests.

Continue with Transferring Bone Marrow to the BMP Set on the next page.
Transferring Bone Marrow to the BMP Set

During the BMP procedure, you must place hemostats at various clamp points on the BMP set. The following instructions tell you when to place and remove the hemostats; Figure 5-6 illustrates the clamp points (0 through 4) as they are referred to in the instructions.

Figure 5-5: BMP Set

Figure 5-6: BMP Set clamp points 0 through 4
Follow these steps to transfer the bone marrow into the BMP set.

1. Clamp the BMP set at clamp point 0 (see Figure 5-6).
2. Close all white pinch clamps on the administration lines of the BMP set. These include four spike lines and two luer connection lines.
3. Add ACD-A to the bone marrow if you have not already done so (see Adding Anticoagulant on page 5-2).
4. If the bone marrow has been prefiltered, use the spikes on the administration lines to connect the bone marrow bag(s) to the BMP set.
   
   – or –

   If filtering is required:
   
   a. Connect a 170-micron filter administration set to the bone marrow bag.

   b. Connect the filter administration set to the luer connector on the BMP Set.

   Note: The air chamber below the spikes is not intended to filter the bone marrow. If the chamber clogs, additional filtering may be required.

5. Open the clamps on the spike line or luer line (whichever you are using) on the BMP Set.
6. Open the clamps on the administration lines.
7. Hang or hold the bone marrow bag above bag A to transfer the bone marrow into bag A.
8. Once the bone marrow has been transferred, seal and remove the administration line of the BMP Set. Continue with Entering Bone Marrow Data.

### Entering Bone Marrow Data

The Spectra system uses entered bone marrow data to customize BMP procedures.

- **Total bag volume** = {____} mL
- **Bone Marrow hematocrit** = {__} %

1. Enter the total bag volume for the bone marrow (bone marrow + AC) in milliliters, then press ENTER.
2. Enter the hematocrit of the bone marrow (after ACD-A has been added) as a whole number, then press ENTER.

The Spectra control program uses the hematocrit to calculate the plasma pump flow rate.

Note: The minimum RBC volume in the bone marrow is 100 mL. The Spectra system will check the total bag volume times the hematocrit to prevent you from entering a combination resulting in fewer RBCs.

If the RBC volume of the bone marrow is < 100 mL, you can add patient-compatible, leukoreduced, irradiated, CMV-negative, packed RBCs to the bone marrow before processing.
The Spectra system uses entered data and microprocessor algorithms to calculate and display the following information on the screen:

- **Inlet volume** (in milliliters)
- **Inlet pump flow rate** (in milliliters per minute)
- **Run time** (in minutes)
- **Collect volume** (in milliliters)

These are not the target run results but rather the inlet volume and run time adequate for:

- Quick Start to be completed,
- You to monitor and more accurately establish the interface, and
- You to open the collect valve.

*Do not change these values; they will be updated when the collect valve is opened.*

Press YES to accept the run results, then continue with *Connecting the BMP Set to the WBC Disposable Tubing Set* on the next page.
Connecting the BMP Set to the WBC Disposable Tubing Set

See figures 5-5 and 5-6 on page 5-12 for illustration of the BMP set and the hemostat clamp points.

**Warning:** Whenever the RBC volume is greater than 215 mL, the BMP procedure automatically collects plasma during the first volume of bone marrow processed, so you **must** connect a plasma bag to the plasma line luer connection of the WBC set.

1. If the bone marrow RBC volume is greater than 215 mL, this message appears:

   ![Connect plasma bag.](image)

2. If you have not already done so, hang and connect a 600-mL transfer bag to the plasma line.

3. Press ENTER.

   ![Connect Bone Marrow.](image)

4. Hang bag A and bag B next to each other on the IV pole, with bag A on the left as shown in Figure 5-5.

5. Connect the red line on the BMP Set to the WBC disposable tubing set access line.

6. Connect the blue line on the BMP Set to the WBC disposable tubing set return line.

7. Close the roller clamps on the access and return saline lines.

8. Remove the hemostat from clamp point 0 (see Figure 5-6).

9. Allow the bone marrow bag access and return lines to fill.

10. Place a hemostat at clamp point 1 (see Figure 5-6).

11. Open the white pinch clamps on the access and return lines. Continue with *Starting the Run* on the next page.

**Warning:** Whenever the RBC volume is greater than 215 mL, the BMP procedure automatically collects plasma during the first volume of bone marrow processed, so you **must** connect a plasma bag to the plasma line luer connection of the WBC set.
## Starting the Run

**Note:** During the Run, gently mix the bone marrow to help prevent cellular components from settling.

Press CONTINUE to start the Run.

<table>
<thead>
<tr>
<th>AC</th>
<th>Inlet</th>
<th>Plasma</th>
<th>Collect</th>
<th>Inlet/AC</th>
<th>Spin</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Replace</td>
<td>Ratio</td>
<td>RPM</td>
</tr>
</tbody>
</table>

- Diverting prime saline.

**Note:** AC infusion rate is not applicable to BMP. The AC pump is at 0 mL/min (though not restricted to 0 mL/min) throughout the procedure because the bone marrow has been previously anticoagulated.

Several valves change positions and several pumps change flow rates as the system performs a final valve position check once the Run is entered. The return valve remains closed during this test.

### Quick Start

During Quick Start, the Spectra system automatically adjusts the plasma pump flow rate to establish the interface.

Quick Start requires an accurate (within 2–3%) bone marrow hematocrit to properly establish the interface.

**Note:** If you change the plasma pump flow rate or enter the Manual mode during Quick Start, Quick Start ends. You need to establish the interface yourself by following the procedures in *Establishing the Optimum Interface* on page 2-22 of the Mononuclear Cell (MNC) Collection Procedure.

Quick Start completed. Monitor collect line. Press CLEAR.

Press CLEAR. The run results screen appears. The inlet volume displayed is now the volume the Spectra system will process during the Run.

### Monitoring the Interface

When Quick Start is complete, monitor the collect line with the COBE Spectra WBC Colorgram to maintain the optimum interface position.

### Using the COBE Spectra WBC Colorgram

The COBE Spectra WBC Colorgram helps you determine when the hematocrit of the collect line is correct.
1 Insert the Colorgram beneath the smallest clear collect line where it exits the centrifuge chamber, just below the four-lumen connector (see Figure 5-7).

Figure 5-7: Correct position of COBE Spectra WBC Colorgram

2 Compare the colored rectangles on the Colorgram with the color of the collect line.

Note: Observe the Colorgram under cool, white fluorescent light for the most accurate color comparison.

You should collect at close to 5% on the Colorgram.

Note: Pink-based media or hemolysis will affect the color of the collect line. Collecting at 5% compensates for a pink baseline color.

3 If the color of the collect line is too dark for the type of cells being collected, decrease the plasma pump flow rate by 0.3 to 1.0 mL/min, with 3 to 5 minutes between each adjustment.

If the color of the collect line is too light, increase the plasma pump flow rate by the same adjustments.

4 Once the optimum interface is established, continue to use the Colorgram to monitor the collect line and make appropriate adjustments to the plasma pump flow rate.

See also Establishing the Optimum Interface on page 2-22 of the Mononuclear Cell (MNC) Collection Procedure.

Opening the Collect Valve

Once the interface is established, you must open the collect valve.

1 Press VALVE.

2 Press 4 to select “Collect.”

3 Press 1 to select “Collect.”

4 Press ENTER.

If you review the run results now (see Changing the Bone Marrow Data or Reviewing End Results on page 5-22), you will see the predicted end values.

Processing the Bone Marrow

During processing, the bone marrow is first drawn from bag A and moved to bag B. When the hemostat is moved from clamp point 1 to clamp point 2 (see Figure 5-6 on page 5-12), bone marrow is drawn from bag B and returned to bag A. This transfer between bags continues until the target volume (approximately three times the bone marrow volume) has been processed.

BMP TIMING: Press 1 when Bag A empties, Press 2 to disable beeps.
This screen appears before bag A is empty. The Spectra system beeps when it is time to move the hemostat between clamp points 1 and 2, but you must set the timing of the first beep. If you want to disable the warning beeps for the entire procedure, press 2.

**Note:** While bag A is being processed, the Spectra system will automatically collect plasma. This is to help maintain a stable interface when the procedure switches to processing bag B. The collected plasma can be used for subsequent processing procedures if necessary.

1. Watch the fluid level in bag A. Just before bag A is empty (the fluid level must not fall below the outlet), press 1. Gently mix bag B, then move the hemostat from clamp point 1 to clamp point 2 (see Figure 5-6 on page 5-12). Bone marrow is drawn from bag B.

2. Press CLEAR to remove the BMP Timing message.

3. Monitor the interface and continue to check the collect line hematocrit with the Colorgram.

4. Watch the fluid level in bag B. Just before bag B is empty, when the Spectra system beeps, gently mix bag A, then move the hemostat from clamp point 2 to clamp point 3.

5. Just before bag A is empty the second time, move the hemostat to clamp point 4. (The system beeps to remind you.) Continue collecting until the target volume of bone marrow has been processed.

**Note:** If additional volumes of bone marrow need to be processed to reach the target volume, return the hemostat to clamp point 1 before bag B is empty. Continue the procedure until all bone marrow is processed.

6. When the target volume of bone marrow has been processed, the “End of Run” screen appears.

<table>
<thead>
<tr>
<th>End of Run: 1=Rinseback, 2=Continue Run.</th>
</tr>
</thead>
<tbody>
<tr>
<td>AC  Inlet  Plasma  Collect  Time  Replace  Min  Procedure</td>
</tr>
<tr>
<td>---</td>
</tr>
<tr>
<td>BMP</td>
</tr>
</tbody>
</table>

   **Note:** To view the final run results, see Changing the Bone Marrow Data or Reviewing End Results on page 5-22.

   You may:
   - Continue with Starting Rinseback and Completing the Procedure on page 5-19, or
   - Extend the Run by 10 minutes and take a sample from the collection bag (see Extending the Run Time and Taking a Sample next). Do this if you want to verify the cell counts of the collected product.

**Extending the Run Time and Taking a Sample**
If you want to verify the cell counts of the collected product:

1. Extend the run time by 10 minutes, which is usually long enough to take and count a sample:

   a. At the “End of Run” screen, press 2 to select “Continue Run.”

   b. Press TIME MIN.

   c. Increase the flashing target run time by 10 minutes, then press ENTER.
2 Gently mix the collection bag.
3 Remove a small sample from the collection bag and determine the cell counts.

4 Determine if further processing is needed.

Starting Rinseback and Completing the Procedure

Rinseback is optional but recommended when processing bone marrow. Rinseback evacuates the channel so it is easier to unload and returns the extracorporeal red blood cells to the bone marrow bag if additional processing of the red blood cells is desired.

Caution: The channel contains bone marrow fat as well as RBCs. You may want to wash the RBCs if reinfusion is required.

When you see the “End of Run” screen, follow these steps to complete Rinseback.

1 Press 1 to start Rinseback.

Clamp access. Open access saline.
END OF RUN. Press Continue to Rinseback

2 Press CONTINUE.

3 Close the white pinch clamp on the access line. Open the roller clamp on the green-striped access saline line to allow saline to enter the system.

4 Press CONTINUE.

Clamp and disconnect collection bags.
Press CLEAR

Note: If no key is pressed, the pumps and centrifuge stop after 10 minutes.

Clamp access. Open access saline.
Please wait. PAUSED

The Spectra system delays the start of Rinseback to ensure an adequate pressure drop in the system.

Clamp access. Open access saline.
Press CONTINUE to Rinseback.

Press CONTINUE to continue Rinseback.
5 **IMPORTANT:** Seal the collect line and remove the collection and plasma bags.

6 Press CLEAR.

7 Make sure the return line pinch clamp is open.

A number of different Rinseback screens appear, indicating what the Spectra system is doing while it completes Rinseback. During Rinseback, the Spectra system allows saline to enter the channel to flush final red blood cells back to the bone marrow bag.

8 When Rinseback is completed, close the white pinch clamp on the return line. Close the roller clamp on the green-striped access saline line.

9 Make sure the clamps on all the fluid lines are closed so that fluids do not leak when the disposable tubing set is removed.

10 Press CONTINUE. The Spectra system runs the inlet pump to make sure the bone marrow bag(s) has been disconnected.

11 Record the final volumes processed during the procedure.

   *Note:* Before removing the tubing, make sure the BMP and plasma bags are clamped or sealed and removed.
Removing the Disposable Tubing Set

The following instructions are a condensed version of the detailed instructions found on page 4-14 of the COBE Spectra Essentials. If you are unfamiliar with removing the disposable tubing set, follow the detailed instructions. If you are an experienced operator, use the following steps only as a guideline.

1. Place the ends of the access and return lines in an appropriate biohazard disposal container.
2. Press UNLOCK COVER. Open the centrifuge door and cover.
3. Remove the multi-lumen tubing from the slot on the right side of the centrifuge compartment.
4. Remove the upper collar and the upper and lower bearings.
5. Open the filler latch and pull the tubes and the channel from the filler.
6. Remove the centrifuge collar and remove the channel from the centrifuge compartment.
7. Close the centrifuge door and cover.
8. Press CONTINUE to unload the pumps.
9. Remove the lines from the valves and sensors, then remove the cartridges from the clamps.
10. Remove any needles still attached.
11. Remove the fluid containers and waste bag.
Helpful Hints and Recovery Procedures

This section contains instructions that can be useful during BMP procedures. For more information, see Chapter 11, *Helpful Hints and Recovery Procedures*, in the COBE Spectra Essentials.

### Changing the Bone Marrow Data or Reviewing End Results

Use the following steps to change the entered bone marrow data or view the run results:

1. Press MENU ON/OFF.
2. Press 1 to select “Data Entry.”

To view or change the entered bone marrow data, press 1.

- Total bag volume = \( ___ \) mL
- Bone Marrow hematocrit = \( ___ \) %

To view the run results, press 2.

- Inlet volume = \( ___ \) mL, inlet flow = \( ___ \),
  time = \( ___ \) min. collect = \( ___ \). OK (YES/NO)?

### Recovering and Concentrating RBCs After Bone Marrow Processing

Use these steps to recover donor RBCs after the bone marrow processing has been completed and the MNCs have been collected.

RBCs are concentrated by processing the bone marrow one additional time, during which the plasma removed from the bone marrow is diverted to the plasma bag. The concentrated RBCs flow into the BMP bag.

To do this, you will need a 1-liter transfer bag.

1. Follow the BMP procedure.
2. When the “End of Run” screen appears, press 2 to select “Continue Run,” then increase the run time by 60 minutes.

**Tip:** To increase the run time:

1. Press TIME MIN.
2. Increase the flashing target run time by 60 minutes, then press ENTER.

3. Close the collect valve to stop collecting product. The collection bag can now be sealed and removed.

**Tip:** To close the collect valve:

1. Press VALVE.
2. Press 4 to select “Collect.”
3. Press 2 to select “Return,” then press ENTER.
4 Finish processing the current bag, then press PAUSE.
5 Move the hemostat to the next numbered clamp position.
6 Hang a 1-liter transfer bag and connect it to the plasma line.
7 Set a plasma collect target of 9999.

**Tip:** To change the target plasma collect value:
1 Press TARGET VALUES.
2 Press PLASMA.
3 Enter 9999.
4 Press TARGET VALUES again.

8 Press CONTINUE.
   The Spectra system opens the plasma valve and diverts plasma to the transfer bag, sending concentrated RBCs through the return line to the BMP bag.
9 Once this is complete, press PAUSE. Do not move the hemostat.
10 Press CHANGE MODE, then press 4 to select “Rinseback.”
11 You can now disconnect the BMP bag. A blue insulation sleeve for Seal Safe sealing has been provided just below the bag.

**Caution:** The residual RBCs may contain some fat and other contaminants from the bone marrow harvesting. You should consider washing the RBCs.

**Caution:** Policies on reinfusion of perioperative blood should be followed.