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# APHERESIS PROCEDURE BY FRESENIUS MACHINE (DEPARTMENT OF TRANSFUSION MEDICINE)

Transfusion Medicine

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## ABSTRACT

Collection of platelets by apheresis has been a major advancement in transfusion medicine. It has allowed the supply of a therapeutically beneficial component to grow with medical needs. Donors find fulfillment in more frequent donations than are possible with whole blood and know that their donation fills a special need. New technology allows leukocyte reduction in the collection of the component with or without the use of filtration. Matching for refractory patients is possible. However, platelets collected by apheresis have not been shown to be hemostatically different from platelets separated from whole blood donations, and thus, do not represent an advance in therapeutic efficacy. The use of apheresis platelets does reduce donor exposure, but this has not been shown to be a safety advance, although it seems intuitively obvious that transfusion risk is statistically reduced in some patients requiring only a few platelet transfusions. Support of patients by apheresis platelets may or may not reduce the risk of alloimmunization. Apheresis platelets from some equipment have less white blood cell contamination even in the absence of filtration, which may be an advantage. Apheresis platelets could be a major step in the ultimate customization of blood collection, in which some donors would preferentially donate red blood cells, whereas others would donate platelets or plasma depending on their blood type and ability to donate frequently, and the current medical need of their donation. Perhaps this would be the most significant advance from the medical progress initiated by Cohn almost 50 years ago.[1]

The role of platelets (PLTs) in the control and prevention of thrombocytopenic hemorrhage was noted in 1910, and since then there has been continuous progress toward understanding the physiologic characteristics of PLTs and how to prepare them for therapeutic use. PLTs can be isolated from whole blood or by apheresis. The procedure of collecting PLTs from a donor with the help of an automated cell separator is known as plateletpheresis. In this procedure, blood is withdrawn from the donor and separated into various components; then, the desired component is retained and the remaining constituents are returned to the donor. PLTs collected using this method are known as single-donor PLTs (SDPs) [2]

- **PURPOSE**
- To prepare single donor platelet concentrate in the Department of Transfusion medicine with the help of Fresenius Cell Separator for the use in patient suffering from thrombocytopenia
- **SCOPE**
- The single unit of platelet apheresis of high dose minimizes the exposure of multiple donors & maximize the benefits of the particular blood component to the patient.

**RESPONSIBILITY**

- The procedure is performed by trained technical / medical personnel under the supervision of consultant who is responsible for the smooth conduction of procedure
- Make sure that all pre requisites have been completed [3]

## KEYWORDS

Separation, Apheresis, Platelets, Blood, Procedure, Fresenius.

**INTRODUCTION**

- The apheresis procedure is based on the principle of dual step centrifugation based on the specific gravity of blood component
- Single needle platelet pheresis on Fresenius Cell Separator is a single arm procedure where in blood is drawn and returned back through the same venous access. In spite of single arm procedure, the separation is continuous flow.
- The procedure takes place in the form of cycles, the inlet cycle and the return cycle.
- During the inlet cycle, whole blood is drawn from the donor and separated in the centrifuge compartment. 40% of the drawn blood goes into the reservoir bag. During the Return cycle, red cell and plasma are returned back to the donor and the blood in the reservoir bag enters the centrifuge compartment for separation, thus maintaining continuous flow separation.
- Platelets are retained inside the collection container of the machine and the remaining blood is return back to the donor.[4]

**Prerequisites:**

- Selection of donor
- Properly screened healthy donor is selected for donation. Donor selection follows the standard blood donation criteria.

1. Pre procedure platelet count should be above 150,000 / µl
2. A platelet count is not required if four weeks or more have elapsed since the last procedure
3. If the donation interval is less than 4 weeks, the donor platelet count should be above 150,000/µl before subsequent plateletpheresis occurs
4. Interval between donations should be at least 48 hours and donors should not undergo platelet pheresis more than twice in a week or more than 24 times in a year.
5. If the donor donates a unit of whole blood or if it becomes impossible to return the donor's red cells during previous platelet apheresis, at least three months should elapse before a subsequent plateletpheresis procedure unless the extracorporeal volume is less than 100 ml.
6. Donors who have taken aspirin containing medications within 72 hours of donation should not be accepted as a plateletpheresis donor
7. He should not be fasting prior to the procedure, however, should refrain from oily/fatty food

- A prominent and easily accessible antecubital vein on one of the arms is selected for the pheresis.
- For routine platelet apheresis the donor is tested for the Transfusion transmitted disease a day prior to the procedure by ELISA
- For urgent apheresis a signed consent form from treating doctor and patient for rapid screening must be taken
- Other donor parameters such as Hematocrit, Height, and Weight are required to be entered into the machine
- Informed written consent is taken from the donor [5]

**MATERIAL**

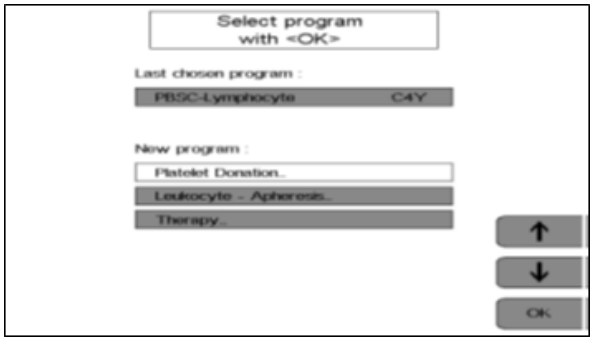
- Single needle closed system amicus kit
- Material for phlebotomy. Please refer to the procedure No 3 & 4
- EDTA (lavender top) vacutainer for product sampling
- Tube sealer

- Oral calcium tablets
- Emergency medicine tray

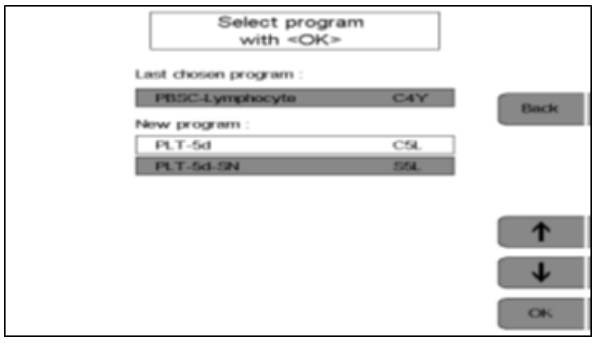
**Procedure**

- 1.Press Power On through I switch in front panel.
- 2.Screen will display, showing software version. PRESS CONTINUE.


- 3.Following screen will display. Use up/down arrow key to select PLATELET DONATION and PRESS OK.

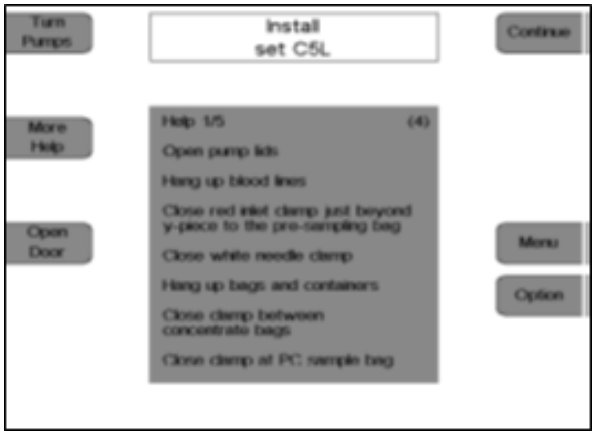



- 4.Select PLT-5D program by using up/down keys and PRESS OK.




**KIT INSTALLATION:**

- 5. INSTALL SET will display. Follow the Help instructions on the screen on total 5 screen pages as below.



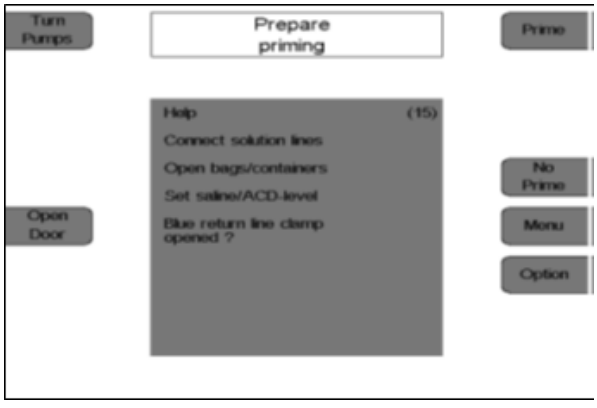

1. Open All 4 pump lids.
2. Hang up blood inlet/return lines on right side IV rack hooks of cell separator.
3. Close RED inlet clamp just beyond Y piece to the pre sampling bag.
4. Close WHITE needle clamp.
5. Hang up storage Platelet Bags at left side of device, Close clamp between 2 platelets concentrate storage bags.
6. Close Clamp at Platelet concentrate sample bag.
7. Hang empty bag at hook above return drip chamber.
8. Hang Plasma bag at hook above clamp 4.
9. Install all 4 pump segments by inserting the top pump adapters to color coded pumps, hold with fingers and PRESS TURN PUMPS. PUMPS will be loaded automatically. Close PUMP LIDS to all 4 PUMPS.
10. Install the RETURN DRIP CHAMBER at the AIR DETECTOR in such a way that DRIP CHAMBER is equally outside the DETECTOR on both TOP/BOTTOM side of DETECTOR.

- Install the plasma line in clamp 4 between the Y-piece and drip chamber.
- Install the plasma line section marked by the yellow tabs into the Hb/Hct detector.
- Insert the line leading to the empty bag in clamp 5.
- Insert the return line in clamp 1.
- Insert the inlet line of the cell pump into the cell detector.
- Install the drip chamber of the ACD line, which is identified by a green clamp, in the ACD detector and pull the drip chamber completely down.
- Install the pump adapter for the ACD pump. The threading pin for the ACD pump must be in the 5 o'clock position. If this is not the case prior to installing the adapter, press the Turn Pumps key. Pump will be automatically loaded
- Install the two saline lines in clamp 2 and clamp 3. Make sure that the lines are installed so that their color matches the color coding of the covering foil and the color of the roller clamp (red line clamp 2, blue line Clamp 3.
- Screw the filters of the red-coded pressure measuring lines for the inlet pressure onto the red-coded pressure measurement port for the inlet pressure.
- Screw the blue-coded pressure measuring line for the return pressure onto the blue-coded pressure measurement port for the return pressure.
- Hold the separation chamber at the upper centrifuge adapter and let it hang down freely beside the device to avoid twisting of the line.
- Open the hinged door of the chamber holder. Push the circular adapter of the separation chamber into the groove in the central funnel. Close the hinged door until it locks into place. The locking pin on the flat side of the chamber holder must no longer be visible.

Remove the empty packaging from the centrifuge door. Press the Open-Door key. Slide the centrifuge door open. If Open Door is not displayed, the door cannot be opened.

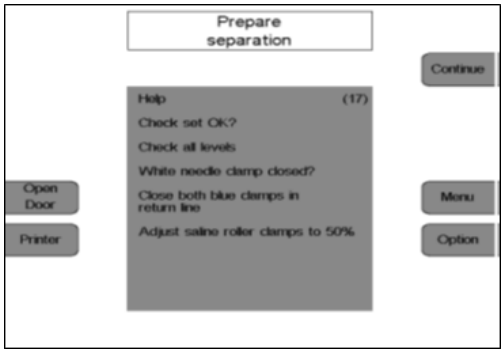
- Turn the centrifuge rotor until one of the two-line guides is on the right of the rotor. Push the chamber holder with the installed separation chamber under the rotor with the lines pointing down.
- Push the chamber holder onto the guide rail until it is felt to be locked. Swing the locking flap down until it clicks into place. Pass the centrifuge tubing through the line guide.
- Push the upper centrifuge adapter narrow side first into the upper adapter holder. Should it be necessary to slightly turn the adapter, then turn it in the direction in which the individual lines are twisted around one another.
- After a test revolution and another visual check, close the centrifuge door. The door is properly locked, when the Open-Door key is displayed. Place the Air Protect in the holder.
- Caution Ensure that the centrifuge tubing is not trapped between chamber holder and rotor.
- Note Manually turn the rotor one full revolution counter-clockwise to verify correct installation.
- After a test revolution and another visual check, close the centrifuge door. The door is properly locked, when the Open-Door key is displayed. Place the Air Protect in the holder.
- Checks After Apheresis Set and Separation Chamber Installation
- Visually verify the following:
- The red clamp on the inlet line below the branch to the pre-sampling bag, the white needle clamp, the clamp between the concentrate bags and the clamp on the concentrate sampling bag

must be closed.
- All other stop clamps on the set must be open.
- The separation chamber must be correctly installed.
- The drip chamber in the air detector and the ACD-A drip chamber must be correctly installed in their holders.
- The ACD-A pump adapter and the ACD-A line must be correctly installed in the ACD-A pump below the drip counter.
- The return line is installed in clamp 1. The saline lines must be inserted in clamp 2 and clamp 3.
- The plasma line must be installed in clamp 4.
- The line leading to the empty bag must installed in clamp 5.
- Preparing for Priming: PRESS CONTINUE; Following screen will display.

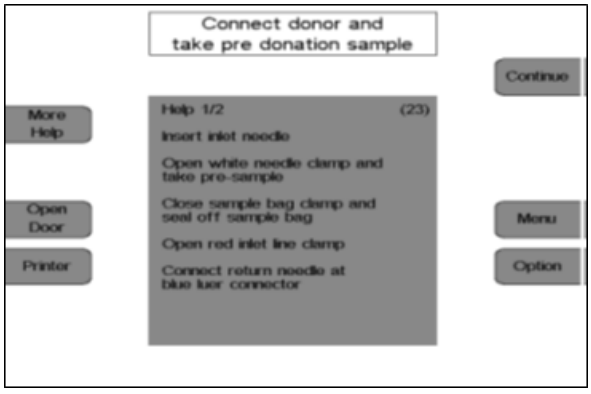



- 6. Prior to priming the set, a user guide is available to assist with the connection of the saline and ACD-A solutions. Connect the ACD-A bag to the green connector and hang it from the upper left hook on the front of the device. Break the cone of the ACD-A bag. Deaerate the ACD-A drip chamber by pressing it and set the level to approximately 1 cm, so that the fluid level is approximately 1 cm below the optical sensor. Connect the saline bag to the two transparent connectors. Hang the saline bag from the front left hook. Break the cones and set the fluid level in the two drip chambers.
- START PRIME by PRESSING PRIME KEY. During priming saline and ACD-A will be pumped into the set to displace the air and check as follows automatically. In case of any error in loading an alarm will be displayed with help screen available for the same error.
- First ALARM test will be performed by the machine automatically. After the alarm test, PRESS CONTINUE to start PRIME.
- RE PRIME can be done by selecting the PRIME key again after the completion of AUTOMATIC PRIME. PRIME takes around 6 minutes to complete.
- At the end of PRIME, PRIME SALINE DIVERSION can be selected by using UP/DOWN keys to DONOR or to WASTE BAG.

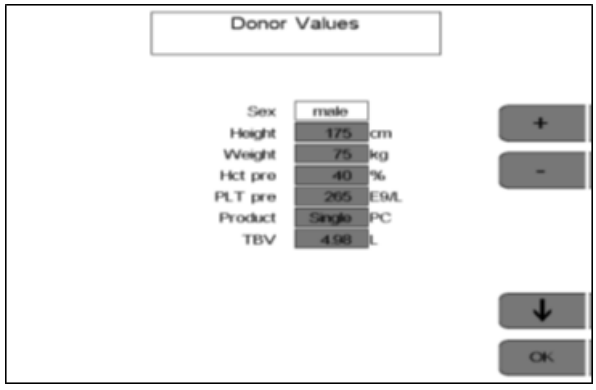
**Preparing for Separation:**
- Visually check the apheresis set. Check and, if necessary, adjust the fluid level of the connected solutions in all drip chambers. Check that the white needle clamp is closed and close, if necessary. Close the two blue return clamps. Set the roller clamps to 50 %. Press the Continue key.




- Connecting the Donor and Collecting a Pre-Donation Sample
- Place the inlet needle. Open the white needle clamp and collect a pre-donation sample of at least 20 ml.Close the clamp on the pre-sampling bag and seal off the pre-sampling bag. Open the red clamp on the inlet line and check that the two red clamps are open. Connect the return needle to the blue Luer lock connector.Deaerate and place the return needle. Open the blue return clamp.
- Press the Continue key.



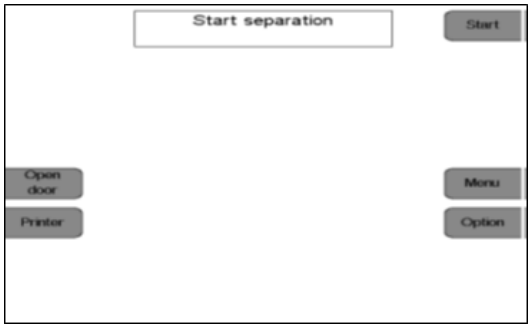

- Menus
- Donor Values: In this screen the donor values (height, weight, etc.) must be entered with the up, down, +and – keys. After entering the data, press the OK key. The software calculates the maximum possible blood flow based on the ACD rate and the donor values set in the Config.sys.
- The calculated values will be displayed in the Procedure Menu screen.




**Procedure Menu:**
- Select the value to be altered with the upand the downkeys.Use the + and – keys to alter the selected value. All values affected by this change will be automatically adapted. A change of the yield will, for example, result in an automatic recalculation of the blood volume to be processed.

- PRESS OK; ALL VALUES WILL BE SAVED.

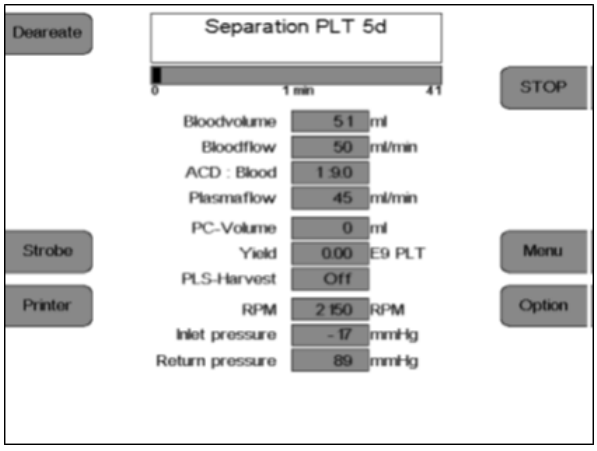
**Separation:**
- All separation parameter changes should be made before starting the program, but can also be made at a later stage.




- **PRESS START:** Press the Start key. The device automatically performs a system pressure test to check the pressure measuring lines for tight connection and to verify correct position of all

clamps at the return drip chamber.

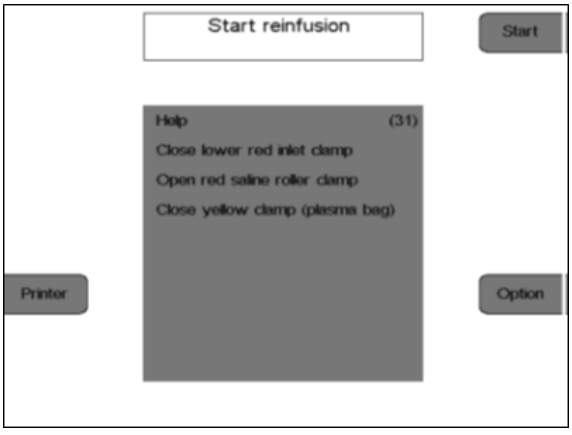
**Automatic operation:**




- Process will be fully automatic till the target volume is processed.
- Separation can be STOP in between; also use DEAREATE for starting donor SALINE to keep the veins patent.
- Additional Plasma can be collected, if desired by selecting Program Menu and Config .sys. Enter desired PLS volume to be collected.
- Separation can be started again by START key. Procedure can be terminated any time in between, by Going to OPTION and Selecting DIRECT REINFUSION Followed by OK at any time.

**Reinfusion:**

- AT the end of processing Target volume Display will show SEPARATION FINISHED. Press CONTINUE, Following Reinfusion start menu will be displayed as following:

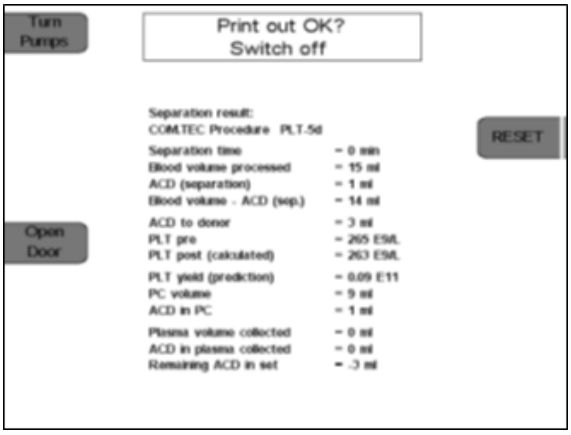



- **Follow the instructions on display as follows:**
- Close the lower red inlet clamp.
- Completely open the red roller clamp of the saline line.
- Close the yellow clamp on the plasma collection bag.
- Disconnect the donor from the inlet line.
- Press the Start key.

- You can terminate Reinfusion pre mature, if desired by selecting OPTION and EXIT REINFUSION followed by OK key.
- END OF REINFUSION:
- Display at the end of reinfusion
- Reinfusion can be continued for another 30 ml by pressing the START key.
- The reinfusion will be terminated by pressing the STOP key.
- Close the stop clamp of the return line.
- Close the yellow stop clamp of the plasma bag.
- Press the Continue key.
- Disconnect the donor from the return line.
- Press the Continue key.

- Deaeration of Concentrate Bags and Collection of Samples:
- The deaerating option is only available if the menu option F
- PC deaerate in the Config.sys has not been deactivated. Display
- Use forceps to clamp both the red blood cell line leading to the drip chamber and the whole blood line below the air separator.
- Remove the cell pump line segment from the pump.

- Remove the concentrate bag, holding its connector up.
- Press the Start key.
- The concentrate bag is being deaerated.
- As soon as the concentrate bag is completely deaerated, press the STOP key.
- If the concentrate bag has not yet been completely deaerated, press the START key to remove another 5 ml of air. On completion of the deaeration, press the STOP key.[6]
- Removing platelet concentrate and set
- Seal off the concentrate bag and remove the set.
- Press the Continue key.
- After the report has been printed, the device can be started for another separation by pressing the RESET key.




- Report will be printed as above on the Printer.
- TURN the device OFF by O key.
- Collection of Concentrate Samples
- On completion of reinfusion thoroughly mix the concentrate in the open concentrate bag.
- Allow the concentrate bag to rest for 1 h.
- Then agitate the bags on a suitable agitator for a minimum of 30 minutes.
- Collect the sample. To obtain a representative sample, the lines must be sufficiently rinsed with platelet concentrate before collecting the sample.[7]

## CONCLUSION:

This procedure is the safest mode of obtaining platelets of good yield. One donor is selected having good platelet count and during the entire procedure one medical technologist is present there to monitor the proceedings. After completing the procedure donor is allowed to rest for minimum 15 minutes and then served with refreshments.

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