

Autopheresis-C Plasmapheresis System

Service Manual

Model A-200 (4R4550)
Model A-201 (4R4560)
Model A-401 (4R4561)
Model A-200 (R4R4585)

APC 6.0x

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GENERAL DESCRIPTION

The Autopheresis-C system is an automated plasmapheresis system comprised of the Autopheresis-C instrument and the Plasmacell-C disposable set. The system achieves a rapid, but gentle separation of whole blood into concentrated cellular components and virtually cell-free *plasma* by means of a rotating membrane filter. The concentrated cellular components are reinfused back to the donor and plasma collected for transfusion is transfused or processed as *Fresh Frozen Plasma* (FFP). Collected plasma may also be processed as *Source Plasma*.

The collection of plasma by the Autopheresis-C system is a fully automated procedure with the donor connected to the disposable set throughout the collection process. Multiple safety systems and alarm functions are incorporated into the plasmapheresis system to ensure donor and operator safety.

The collection procedure requires a single venipuncture, which means that one access site is used to draw whole blood and return concentrated cellular components. Because of this, the procedure involves sequential *cycles* of alternating *phases*, one in which plasma is separated and collected, and the other in which residual cellular components are reinfused. *Venous pressure* is continuously monitored to optimize fluid flow without exceeding the flow capacity of the donor's vein.

Operating panel keys and message displays allow the operator to control the procedure, gather important information on its status and handle error conditions that may arise.

Documentation Conventions Used

Conventions used in this Operator's Manual are as follows:

Formatting

Bold Bold type face is used for emphasis.

Underline Underlining is used to highlight the letters used for forming abbreviations. For example, TransMembrane Pressure (TMP).

SMALL CAPS Small capitals are used in the text when referring to other sections of this manual.

Message The messages displayed on the Autopheresis-C instrument's operating panel are referenced in this manual using this special formatting.

Symbols

The following symbols are used for categorizing information in this manual.



Note: It is used to highlight important information aside from the main text.

PURPOSE OF MANUAL

This manual is to be used by Baxter Certified trained technical personnel only to assemble, set up, check out, configure and service the instrument. Before attempting to assemble or operate this instrument, be sure to read this manual to become thoroughly familiar with the system components and controls.

The instructions and operating procedures presented in this manual are based on established procedures developed by the Fenwal Division through system development and extensive operating experience.

If you need additional information, contact the Service Provider at:
(800) 207-4889 toll free in the U.S.A.

PRECAUTIONARY STATEMENT

As with any equipment used in the processing of human blood, there is the possibility of contamination from equipment with potentially hazardous and infectious substances. It should be assumed that any equipment so used is contaminated and the appropriate precautions observed.

Therefore it is important that the appropriate solutions be selected for disinfecting the equipment surfaces. Users will need to select disinfectants found to inactivate a broad range of microorganisms which include clinically important bacteria, fungi, and viruses. Many of the conventional cleaning solutions will not disinfect the instrument surfaces. Many disinfectants will also not be effective on dirt covered surfaces, so they must be cleaned first.

For cleaning the surfaces of the equipment, a mild detergent should be used. Cleaning solutions that contain abrasives or solvents may damage the instrument and must not be used.

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INTRODUCTION

This section describes unpacking, assembly instructions, instrument test procedure with information on configuring instrument parameters for the Autopheris-C Instrument (See Figure 2.1 Autopheris-C Instrument Model A-200).

- Unpacking the Instrument
- Assembly of Instrument
- Attach Optional Accessories
 1. Bottle, Bag/Bottle Hanger
 2. SpikeSmart Hanger
 3. Alert Light
 4. Hard Cover Door
- Visual Inspection
 1. Inside Upper Console
 2. Outside Upper Console
- Instrument Test Procedure
- Procedural Config/Defaults
- Performance Config/Defaults

The following tools will be required to assemble the instrument:

- Flat Blade Screwdriver, Large
- Flat Blade Screwdriver, Small
- Adjustable Wrench, Small
- Hex Key, 5/32"
- Hex Key, 3/16"
- Diagonal Cutler

Identify correct collection hanger used at the customer site. Both bottle hangers, or dual bag/bottle hangers must be ordered separately.

Identify if customer uses Plasmacell-C separation devices with SpikeSmart hanger.

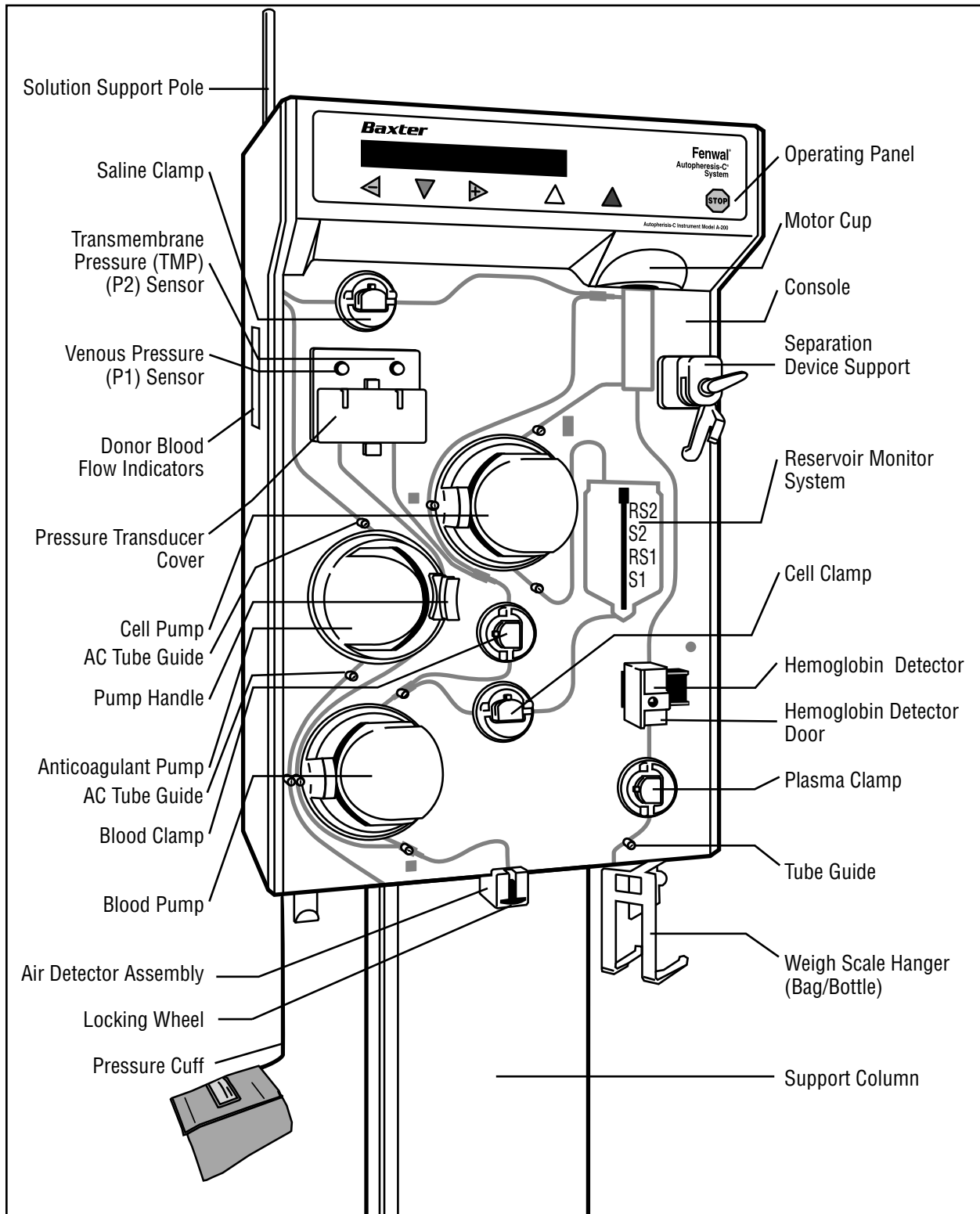


Figure 2.1 Autopheresis-C Instrument Model A-200

UNPACKING

Open shipping container and remove upper console. Take care not to damage weigh scale when removing unit. Set device on its side to prevent damage.

Remove accessory pack and verify completeness:

- 1 each Bag Hanger
- 1 each Pressure Cuff
- 2 each Locking Casters
- 2 each Adjusting Casters
- 2 each 2 Amp and 2 each 4 Amp Slo Blo Fuses
- 1 each Filter and Filter Bracket
- 4 each 3/16" Hex Head Screws with Washers
- 6 each Mounting Screws (black) with Washers
- 1 each Velcro Square

Remove support column from carton. Place support column on front side with the power switch facing up (See Figure 2.2 for Column Support and Base, and Figure 2.3 for Interconnect Diagram - Support Column).

Remove base from shipping container.

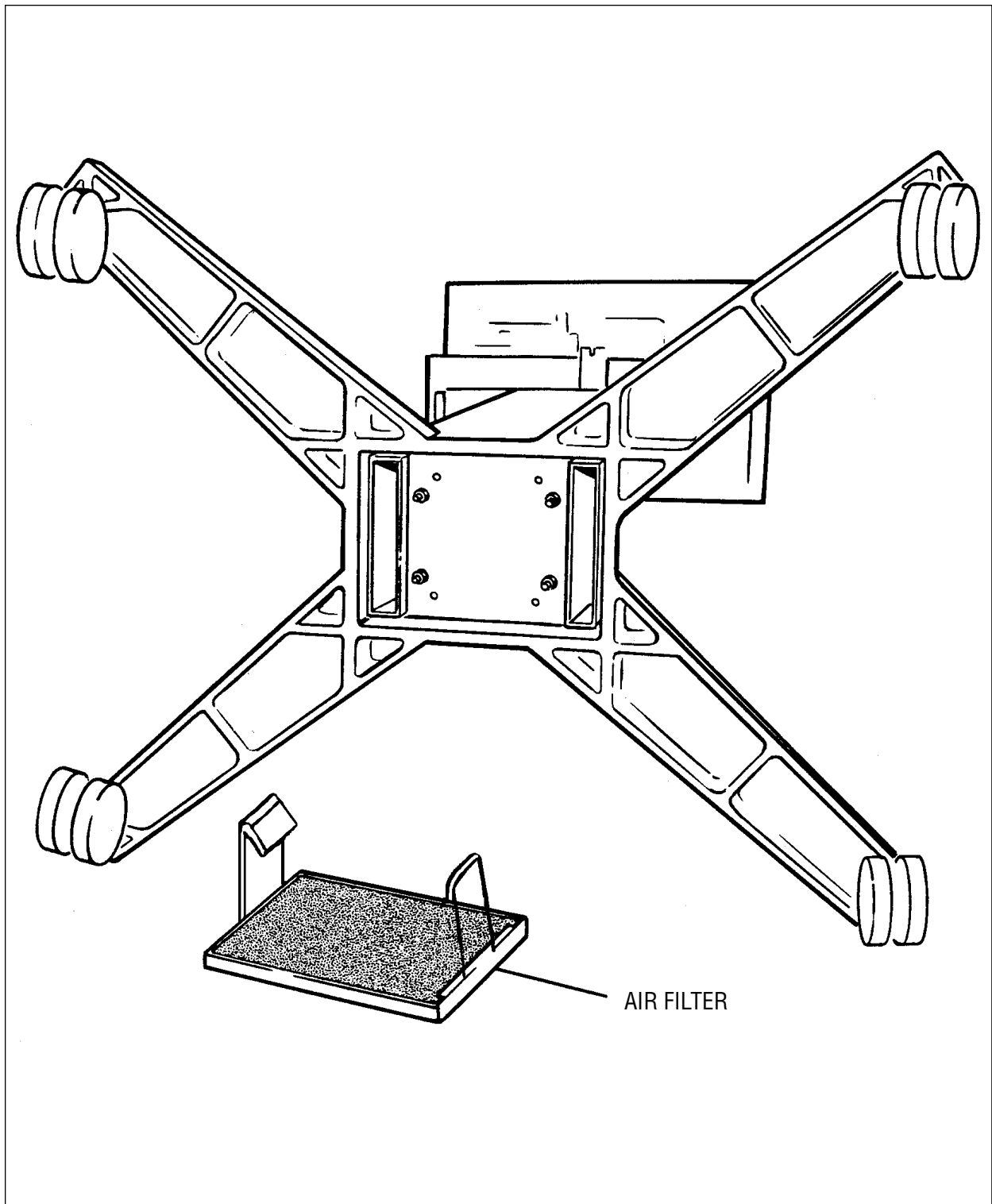
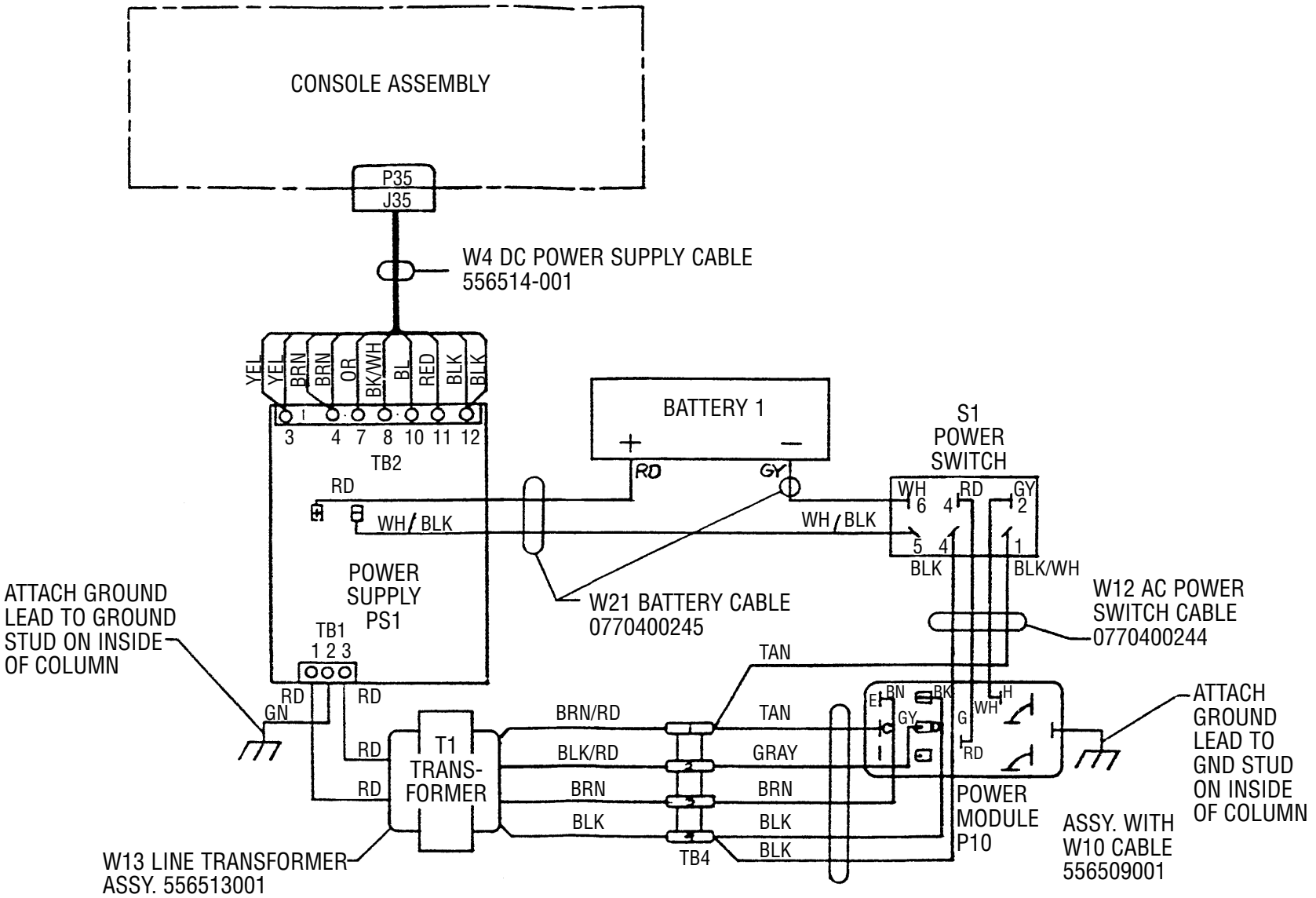


Figure 2.2 Column Support and Base

Figure 2.3 Interconnect Diagram - Support Column



VOLTAGE SELECTION

Position support column on work area (shipping carton) with power switch OFF and facing up.

To open voltage selector and fuse compartment, insert a small flat blade screwdriver under the edge of power module cover and pop cover open.

Remove both fuse holders. Note that the arrows on both fuse holders point down. See Figure 2.4, Fuse Replacement.

Insert appropriate fuse to match voltage rating.

- 4 Amp Slo Blo for 115 VAC
- 2 Amp Slo Blo for 230 VAC

Install fuses in both fuse holders and reinsert holders in power input module.



Note: Arrows on fuse holders must point down.

Locate voltage selector ball, rotate to correct voltage setting (115 or 230 VAC).

Snap power module cover to power input module back in place.

Verify that the proper voltage selection is visible through the power module cover.

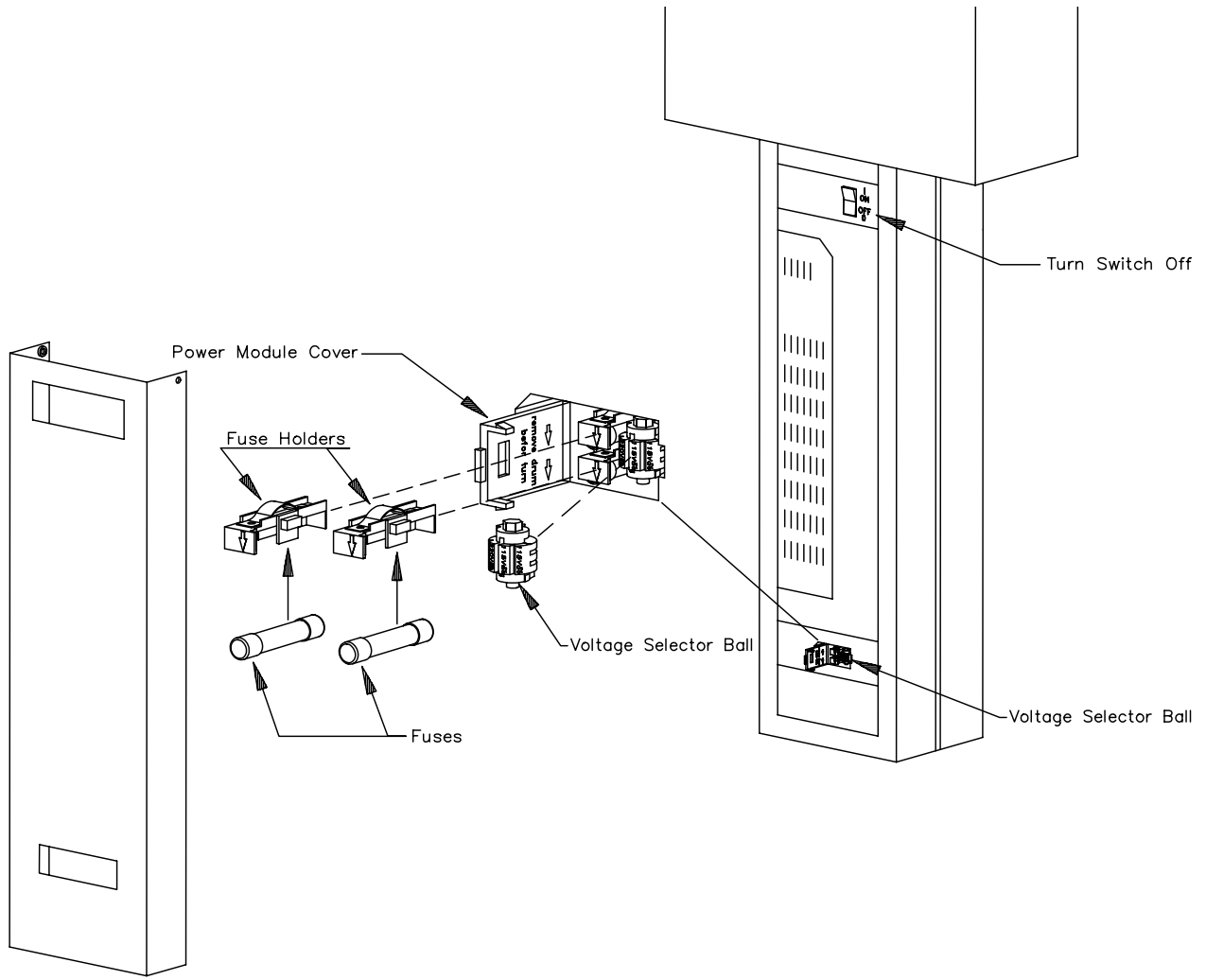


Figure 2.4 Fuse Replacement

ASSEMBLY

Attach base to the support column with 4 each 3/16" hex head screws (See Figure 2.2 Column Support and Base).

Attach casters to the base assembly. Attach casters with the leveling wheels to the side with the power switch (rear of device). Attach braking casters to the front side of base assembly (front of device).

Place the filter into the filter bracket. Press fit the filter bracket into the base assembly. Stand the support column and base assembly in an upright position.

Locate the power connector J35 on the top of the support column. Position the locking tabs in an upright position.

Pick up the upper console from opposite corners. Do not touch the weigh scale, or air detector assembly. Gently place the upper console on the support column. Align the 2 each mounting holes on the upper console to the support column. Ensure the power switch is in the back of the instrument.



Note: Upper console may require two people for installation.

Install the 2 each mounting screws at the rear lower edge of the upper console with a 5/32" hex key.

Gain access to the upper console by turning counterclockwise one-quarter turn two each latch screws on rear door.

Install the 4 each mounting screws near power connector P35 with a 5/32" hex key.

Remove tie wrap and protective material on connector P35 and connect to the support column connector J35. Lock the tabs by pulling upwards in a vertical position.

Caution: Do not cut any wires when removing tie wrap.

Attach pressure cuff on output port under left front corner of instrument.

Set solution support pole to the desired height by rotating pole to rear of instrument, lifting to one of the preset heights and locking into position by rotating pole back to the forward position.

Attach power cord to appliance inlet module and plug other end into power source to be used.

ATTACH OPTIONAL ACCESSORIES

Install bag, bottle or bag/bottle hanger to the weigh scale using 5/32" hex key.

Install SpikeSmart hanger as defined in the Operator's Manual per customer requirements.

An optional alert light providing increased visibility to alert/alarms is available.

A hard cover door providing coverage to the upper console is available.

VISUAL INSPECTION

Inside Upper Console

Verify all data connectors are properly oriented and latched in place.

Verify all power connectors are aligned with the PCB and properly oriented.

Exterior Upper Console

Ensure clamps and pumps are orientated to the disposable set pathway.

Verify the lower separation device support opens and closes smoothly.

Verify the hemoglobin detector door opens and latches shut smoothly.

Verify the transducer door opens and snaps shut in the closed position.

Verify locking wheel on air detector turns freely.

Remove the pressure transducer protectors from both P1 and P2 pressure transducers.

Caution: Do not use metal tools when removing protectors.

AUTOPHERESIS-C INSTRUMENT SOFTWARE INSTALLATION

Required Documents:

- A-20X, A-40X Test Procedure
- A-20X, A-40X Test Procedure Data Sheet (Table 2.1)
- Config/Defaults Data Sheet (Table 2.3)

Required Parts:

- U14 TRAN (EURO/ASIA), optional
- U15 TRAN (EURO/ASIA)
- U16 CORE
- U17 APC
- IC Chip Extractor

Document Current Instrument Statistics

1. While depressing the **F** symbol, turn the system ON. Maintain pressure until "Statistics" is displayed. Record the following items at the top of the A-20X, A-40X Test Procedure Data Sheet.
2. Press ADVANCE ▼ **Record on Data Sheet.**
Press ADVANCE ▼ **Record on Data Sheet.**
Press ADVANCE ▼ **Record on Data Sheet.**

Procedure



Note: Autopheresis-C Instrument must be OFF and have power removed before proceeding with software upgrade. When servicing the instrument, service personnel must observe safety precautions. (i.e., Before touching any PCB, always touch chassis ground first. Do not allow loose clothing or jewelry to touch any PCB when servicing the instrument).

1. Record date of software upgrade, unit serial number, customer name, address, city, state, telephone, contact person on Test Procedure Data Sheet and Serial Number list.

2. Open rear door of instrument by turning both locking latches one-quarter turn counterclockwise.
3. Using the IC EPROM extractor tool, remove current EPROM's located on the CPU Board, chip designators U14, U15, U16, U17 and return to Baxter.
4. Install new software EPROM's in the appropriate IC sockets. Ensure correct orientation of EPROM's. Match the notch at the end of the EPROM's with the corresponding notch on the CPU Board.



Note: U15 MUST CONTAIN A TRANSLATION CHIP!

U14 may contain optional second translation chip.

U16 takes the CORE chip and U17 takes the APC chip.

5. Turn DIP switch S1, SW1 ON, and switch SW2 through SW8 OFF.
6. Turn instrument ON. Autopheresis-C will display **Self Test XXX** (where XXX = Version Number).
7. Autopheresis-C displays **HELP #14** and will sound a continuous tone and activate alert light. Refer to APPENDIX B for additional notes on this topic.
8. Press **F** in Fenwal. Tone and light stop.
9. Autopheresis-C displays **Init EEPROM: 80 sec** and proceeds with EEPROM initialization. Donor Bar Graph LEDs will be randomly illuminated at this time.
10. Autopheresis-C displays **Test (Press STOP)**. Press the **STOP** button. Alert light is activated.
11. Autopheresis-C displays **Config: Defaults**.
12. Press ADVANCE **▼**. Donor Bar Graph LEDs will be randomly illuminated at this time. Alert light activates.
13. Autopheresis-C displays **Plasmapheresis** and waits 5 seconds before proceeding to "AP-C Version XXX (where XXX = Version Number) Copyright 1999 Baxter Healthcare Corporation All Rights Reserved Nylon Membrane Saline Protocol ... Wait". Alert light off.
14. Autopheresis-C displays **Test Menu**.
15. Perform the A-20X, A-40X instrument test procedure.

INSTRUMENT TEST PROCEDURE

This procedure provides testing and configuration instructions for Autopheresis-C Instruments.



Note: The following procedure must be performed by a qualified service personnel.



Note: Any Autopheresis-C Instrument being tested using this procedure must have the A-20X, A-40X Test Procedure Data Sheet Rev. 6.0x Software (TPDS) Part Number 1571256xxx completed. Any values found out of range while performing test procedure must be corrected and documented on the TPDS. If a part replacement is required, a new TPDS must be performed.



Note: Before performing the A-20X, A-40X Rev. 6.0x test procedure, document current instrument statistics by entering the Statistics Menu as defined in the Operator's Manual.



Note: The following symbols are used to reference membrane panel switches: ◀, ADVANCE ▼, ▶ BACK ▲. This is the order found on the membrane panel.



Note: Do not perform a plasmapheresis procedure until a complete TPDS is completed.



Note: Donors cannot be connected to the system at any time during the Autopheresis-C Instrument test procedure.



Note: Power receptacle must be a 3-wire, grounded outlet.















The following tools are required to test the instrument:

- Hemoglobin Detector Calibrator 1571256212
- Calibrated Weights - 500 g and 1,000 g
- 2 each Hemostats
- 2 each 50 cc Syringes
- "Y" section of tubing for the Pressure Transducers
- Trimpot Adjustment Tool
- 1 each Plasmacell-C Disposable Set
- Reservoir Blocking Device
- Parent EEPROM Socket Adapter (optional)

1. Remove power from device being tested. Turn unit **ON**. Front panel display must remain lit for a minimum of three minutes without power. If device fails to remain lit for three minutes, battery is discharged.
Mark box when complete.
2. Open rear door of instrument. Locate DIP switch S1 on the CPU Board. Turn SW1 ON, and SW2 through SW8 OFF. Plug power cord into outlet.








Note: Instrument power switch is still **ON**.

3. Verify fan operation. **Mark box when complete.**
4. Verify [Self Test XXX], [Test (Press STOP)] press  button. Alert light activates when you press  and shuts off at the [Plasmapheresis] display.
Mark box when complete.
5. Verify the message [AP-C Version XXX] (where XXX=Version Number) Copyright "1999" Baxter Healthcare Corporation All Rights Reserved. Instrument will eventually display [Test Menu]. Record software version on data sheet.
6. Press  to [Pump Tests].
7. Press ADVANCE  [Motor Vari Spd/Dir].
8. Press ADVANCE  to [PUMPS].
9. Select forward or reverse using  or .  displays [Pumps FWD].
 displays [Pumps REV].
10. Press ADVANCE  to [Rate: 0 0 OFF].
Press and hold  until [170 17 HIGH] is displayed. Motors must be quiet.
Mark box when complete.
11. Press BACK  to exit the test back to [Motor Vari Spd/Dir].
12. Press  to [M1 Speed Test].
13. Press ADVANCE  to enter the test. The display will read: [1 40 XX 0], (where XX can be between 60 and 64) and the AC pump will be turning. Allow pump speed to stabilize.

















Note: A possible "Stalled Motor 4" alarm can occur if pump motors are not stopped between tests.

14. Press and hold  until you get the <BCK> Over Speed3 message, a beep tone sounds and the alert light flashes. **Mark box (item #16), if "Over Speed3" message occurs for each pump.**
15. Press BACK  to 1 40 XXX Y. Verify if the acceleration value, "Y" is 3 or 4. **Record acceleration value on data sheet (item #16) for each pump tested.** Press BACK  to stop pumps.
16. Press BACK  to M1 Speed Test. Press the  button to continue testing the remaining pumps as defined from Steps 13 through 15.



Note: Motor 4 will not be a functional test in a model A-200 or A-400. Motors must come to a complete stop, if retesting is required.




17. After testing the last pump, press  to Spinner Test.
 18. Press ADVANCE  to enter the test. Display will read 0 0 0 FWD.
 19. Press  once and the display will read 25 1 Z FWD.
-  **Note:** Z indicates that the motor will not regulate at this speed so this number will flash, showing either a 0 or 4. If the display indicates a constant 0 at this location, that is an indication that the spinner has locked-up and repair should be called.
20. Press and hold  until the spinner has attained a speed of 3600 RPM.
 21. Verify commanded and actual speed if Hall count is 144. **Mark box when complete.**
 22. Press BACK  twice to exit the pump tests.
 23. Press  to Clamp/Sensor Tests.
 24. Press ADVANCE  to Clamp Test.
 25. Press ADVANCE  to Clamps.
 26. Toggle the clamps using  to open all clamps and  to close all clamps. Verify all clamps open and close. **Mark box when complete.**
 27. Press ADVANCE  to Saline Clamp CLOSED and verify its operation by pressing  and  buttons. Allow the clamp to remain in the open position for 30 seconds to verify that the hold in circuit, as well as the pull-in circuit, is functioning.

28. Press ADVANCE ▼ and sequence through all the clamps in a similar fashion. **Mark box when complete.**














Note: The Blood Clamp is a normally open clamp so the hold in circuit must be checked with the clamp in the closed position. The Divert Clamp is not installed in the A-200 or A-400 device.

29. Press BACK ▲ until you reach `Clamp Test` then press ▶ to `Sensor Display`.
30. Press ADVANCE ▼ to `AAAAAAAA`. **Mark box when complete.**
31. Using an opaque, non-metallic object, sequentially block the sensors in the reservoir slot. The display will change from "A" to "B" as each sensor is blocked. Reading from the bottom of slot, you will have sensors **S1, RS1, S2, and RS2**. These will correspond with the first four "A's", from left to right. At this time, verify the four green LED's on donor bar graph are ON. They will be illuminated while the sensors are not blocked and will extinguish, from bottom to top, as sensors are blocked from S1 through RS2. Remove reservoir blocking tool. **Mark box when complete.**
32. Place a fluid-filled length of tubing in the air detector sensor and the "A", fifth from the left, should change to "B." **Mark box when complete.**
33. Install a length of tubing behind the pressure transducer door in the region of each blood detector sensors and close the door. The "A's" located in the (from the left) 6th and 7th position change to "B's." These represent **S4 and S5**. **Mark box when complete.**
34. Remove the tubing from the air detector sensor and pressure transducer.
35. Press BACK ▲ to `Sensor Display`.
36. Press ▶ to `A/D Converters`.
37. Press ADVANCE ▼ to `AD03: aaa bbb ccc ddd`.
- "a's" represent P1
- "b's" represent P3
- "c's" represent the weigh scale
- "d's" represent Hb Signal. This number will be flashing.

38. Press  to AD47 . These values are not used.
39. Press BACK  twice to .
40. Press  to .



Note: Before performing HbDet tests, ensure rear door and Hb Detector doors are closed and tubing is removed from the Hb Detector.

41. Press ADVANCE  to . Press ADVANCE  to with x= RAW RED REF, y= RAW GREEN REF, and z= RAW REF **Background**. The **background** value (z) will be between 20-60 units. **Mark box when complete.**
42. Press BACK , then  to .
43. Press ADVANCE  to with x= RAWRED SIG, y= RAWGREEN SIG, and z= RAW SIG **Background**. The **background** value (z) will be between 20-60 units. **Mark box when complete.**
44. Press BACK , then  to .
45. Press ADVANCE  to , with:
- | | |
|--------------------------------|------------------|
| "a" being Corrected Red Ref | (between 60-180) |
| "b" being Corrected Green Ref. | (between 60-180) |
| "c" being Corrected Red Sig, | (between 60-145) |
| "d" being Corrected Green Sig | (between 60-145) |
- Mark boxes when complete.**
46. Press BACK  then  to . Press  to .

- 47. Press ADVANCE ▼. The display indications are as follows:
RELSPT ACT POINT RELSPT AVED % ABSORP. CAL TRIP
 The value of actual and average RELSPT must be 220 or greater.
Mark box when complete.
- 48. The Hb Detector can not be calibrated with a RELSPT value of 256.
- 49. Press ◀, RELSPT AVED and % ABSORP must go to "0." **Mark box when complete.**
- 50. Open Hb Detector door and insert Hb Calibrator (P/N 1571256212) in the Hb Detector and allow the numbers to stabilize. **Mark box when complete.**



Note: Hb Calibrator must be free of physical defects.

- 51. Press ▶ to calibrate the Hb Detector. You should get one of the following messages. **Mark box if Hb Detector calibrates in range 71% - 89%. Ideal range 76 - 80%.**

EEPROM Burn Good

The system program has not detected an error during calibration.

EEPROM Burn Error

The system has detected an error during calibration. Error should be corrected and calibration performed.



HbDet Cal Verified








The new calibration trip point is within three points of the previous value and the system has not recalibrated.

HbDet Cal Error

Calibration has been attempted with new trip point out of range.

- 52. Press BACK ▲ and **record the new Hb Calibration Trip Point (farthest to right) on the data sheet.** Remove Hb Calibrator.
- 53. To verify new Hb Calibration, the system must be turned OFF, then turned back ON, go to Hb RELSPT Act/Avg and check to see that the new trip point is the value shown in the calibrated trip point location of the display.
- 54. Press BACK ▲ twice to HbDet Tests, press ▶ to P/Wt/Cuff/Air Tests.

55. Press ADVANCE ▼ to P1 P2 P3 Display.
56. Press ADVANCE ▼ to xxx yyy zzz pp. You should have a continuous tone.
57. Press BACK ▲ to P1 P2 P3 Display. The tone will cease.
58. Install “Y” tubing behind the pressure transducer door in the area of the blood detectors and close the door.
59. Press ADVANCE ▼ to xxx yyy zzz pp. You should not hear a tone.
60. The display indicates as follows:
 - xxx = P1 pressure
 - yyy = P2 pressure
 - zzz = P3 pressure
 - pp = cycle counts of cuff compressor
61. Position “Y” section of blood tubing behind transducer door with a 50cc syringe attached to the common end. Draw a negative pressure on the transducers and verify that you can reach at least **-310 mmHg**. Hemostat the common line. Verify maximum difference between both pressure transducers is 25 mmHg and pressure does not decrease by more than 4 mmHg for two minutes. **Mark box when complete.**
 **Note:** P1 and P2 Luer fittings must have connectors found on disposable.
Remove the hemostat and push a positive pressure on the transducers. The transducers must reach at least **465 mmHg**. Hemostat the common line. Pressure can not decrease by more than 4 mmHg for two minutes. Remove the hemostat. **Mark box when complete.**
 **Note:** P1 and P2 Luer fittings must have connectors found on disposable.
62. Pinch the cuff line with your fingers at the instrument output port.
 - a. While monitoring the display, press and **hold** ▶, P3 must reach at least **171 mmHg** and the cycle count must not exceed **25**. **Mark on data sheet.** If the system fails either portion of this check, a simple adjustment may resolve the problem. To make the adjustment, follow Steps c through f.

- b. Locate the compressor frequency adjustment potentiometer, [R123] on the upper left section of the Driver Board. Pinch the cuff line with your fingers at the instrument output port.
 - c. While monitoring the third number, press and hold the  button while adjusting the [R123] potentiometer for the maximum reading of cuff pressure (Third number). Then turn [R123] counterclockwise one half turn.
 - d. Release pressure by pressing . Also release line at output port after each R123 adjustment to allow pressure to equalize between adjustments.
 - e. Perform pressure test as defined in Step 61.
63. Release the cuff line output port and press BACK  to P1 P2 P3 Display.
 64. Press  to Weigh Scale #1.
 65. Press ADVANCE  to Weight: xx OFF.
 66. You will see some value that indicates the untared weight on the scale. Verify that ADVANCE  toggles the tare of the scale to zero.
 67. Press  to Weight: 0 LOW. This indicates that the spinner is running at LOW speed.
 68. Using calibrated weights, verify correct operation of the weight scale between 0 and 1000 grams. The acceptable variation is as follows:

Scale # 1



$$0 = 0 \pm 1 \text{ gram}$$

$$500 = 500 \pm 2 \text{ grams}$$

$$1000 = 1000 \pm 3 \text{ grams}$$



Note: If necessary, adjust the weight scale using R16 on the Analog Board. Recheck all weights and readjust R16 as necessary. Readjustment should not be required more than three times. **Mark box when complete.**

69. Press BACK  to Weigh Scale #1.
70. Press  to Pressure Cuff.

71. Press ADVANCE ▼ to [Cuff: xxx yyy].



Note: x = Commanded cuff pressure in mmHg.
y = Actual cuff pressure in mmHg.

72. Roll up the cuff and hold it in your hand. Press ▶ to increase cuff pressure. Verify that actual cuff pressure will track commanded cuff pressure. Cuff pressure will increment in 4 mmHg steps to a maximum of 120 mmHg. **Mark box when complete.**

73. At 120 mmHg, release some pressure on your hand and verify that actual pressure will increase to compensate.

74. Now increase manual pressure. Verify that the dump valve will compensate and reduce actual pressure, and then reinflate to the commanded pressure. **Mark box when complete.**

75. Using ◀ button, decrease cuff pressure down to zero.

76. Press BACK ▲ to [Pressure Cuff].

77. Press ▶ to [Air Detector Test].

78. Press ADVANCE ▼. You will get the alert light and continuous tone. **Mark box when complete.**

79. Insert tubing with a fluid-filled syringe attached in the air detector sensor. Push fluid up into the region of the sensor. The tone should go off and the alert light should extinguish. **Mark box when complete.**

80. Press ▶ and tug on fluid filled tubing. The alert light will flash and the tone will be beeping. The message [Check Air, Purge (-)] is displayed. **Mark box when complete.**





81. Press ◀ and the display should show [...Wait] and then [Purging Air P1 Cuff] accompanied by M1 and M2 turning. **Mark box when complete.**

82. When the blood pump simulates it has pumped 9 mL of blood into the reservoir, the display will indicate [Check Air (BCK), Purge (-)].

83. If air is reintroduced into the air detector sensor, the sequence will repeat. Press BACK ▲ twice to [Air Detector Test].

84. Press BACK ▲ to [P/Wt/Cuff/Air Tests].

85. Press ▶ three times to [Field Tests]. Press ADVANCE ▼ to [Memory Display]. Press the ▶ three times to [Calibrate Rsv LEDs].

86. Press ADVANCE ▼. Display will read 1 1 1 1 (+2). If display reads anything else above three, something is interfering with the light path of that particular sensor. Resolve the problem by cleaning the reservoir channel. **Mark box when complete.**
 87. Block the reservoir slot with something opaque that will not scratch the lens. Press ADVANCE ▼, the display will read 3000 3000 3000 3000. **Mark box when complete.**
 88. Press BACK ▲ to Calibrate Rsv LEDs.
 89. Press BACK ▲ twice to Test Menu.
 90. Turn the system OFF. Open rear door by turning two latch screws. Turn switch S1 position SW1 through SW8 OFF.
 91. Turn instrument ON. Once the display reads Test (Press STOP) turn switch, S1 on the CPU Board, position SW2 ON to edit procedure menu items. Turn position SW3 and SW4 ON to Edit remaining Config/Default items.
-  **Note:** Indicate on Config/Default Data Sheet what switch positions are used. All data associated with switch positions (column SW1) require data.
92. Press the  button. Once the instrument displays Plasmapheresis, press the BACK ▲ button. The display will read: Edit AC: YES when in the Config/Default Menu.
-  **Note:** Plasmapheresis is displayed for approximately 15 seconds.
93. Set Config/Default values per customer requirements. There are two options available for setting the Config/Default values:
 - a. Edit/store each item on the Config/Default Data Sheet enclosed within this manual for each instrument.
 - b. Perform the EEPROM Config Parameter Cloning Procedure identified within this manual. One Config/Default Data Sheet must be filled out to document the correct checksum value for customer. Record Checksum value on top of Config/Defaults Data Sheet.
 94. Exit Config/Default by pressing the  button at the (-)Top, (+) Exit Menu display. Open rear door of instrument and turn S1, SW2, SW3, SW4, OFF.
 95. Enter "Statistics" Menu by pressing the BACK ▲ when Plasmapheresis is displayed.


96. Press ADVANCE ▼ Run hours: xxxxxx
Record on Data Sheet.
- Press ADVANCE ▼ VP hours: xxxxxx
Record on Data Sheet.
- Press ADVANCE ▼ Procedures: xxxxxx
Record on Data Sheet.
- Press ADVANCE ▼ Config: Defaults
Record on Data Sheet.
- Press ADVANCE ▼ (-)Top, (+)Exit Menu



Note: “Defaults” is displayed next to “Config”: when Config Default values remain unchanged. A check sum value is displayed if any of the default values have been changed. **Record “Check sum” value or “Defaults” on Test Procedure Data Sheet and the Config/Defaults Data Sheet.**



Note: If “Defaults” is identified as the “Config” value, the Config/Default Data Sheet is NOT required.

97. Exit statistics by pressing the  button at the (-)Top, (+) Exit Menu display. Press ADVANCE ▼, and go to Install Set.
98. Install a Plasmacell-C disposable set and perform Install Ck. Record information in Steps 99-101. **Perform the next three steps and mark box when complete.**
99. Identify the maximum negative P1 pressure achieved at the start of the Install Ck sequence. Maximum negative pressure is achieved after M1 stops and pressure begins to go positive. This value must be less than -20 mmHg.
100. Identify both the P1 and P2 pressures at the leak test, when both M2 and M3 pumps stop. Pressures will remain constant and must be greater than 200 mmHg.

101. Follow recommended action for pumps that are unable to meet pressure limits identified in the following table.

| Pump Tested | Test | Limit | Recommended Action |
|-------------------------|---|--------------------|------------------------------------|
| Anticoagulant Pump (M1) | Maximum negative P1 pressure (after M1 stops) | $P1 \leq -20$ mmHg | Replace Pump Head parts on M1 Pump |
| Blood Pump (M2) | P1 pressure at the leak test (after M2 stops) | $P1 \geq 200$ mmHg | Replace Pump Head parts on M2 Pump |
| Cell Pump (M3) | P2 pressure at the leak test (after M3 stops) | $P2 \geq 200$ mmHg | Replace Pump Head parts on M3 Pump |

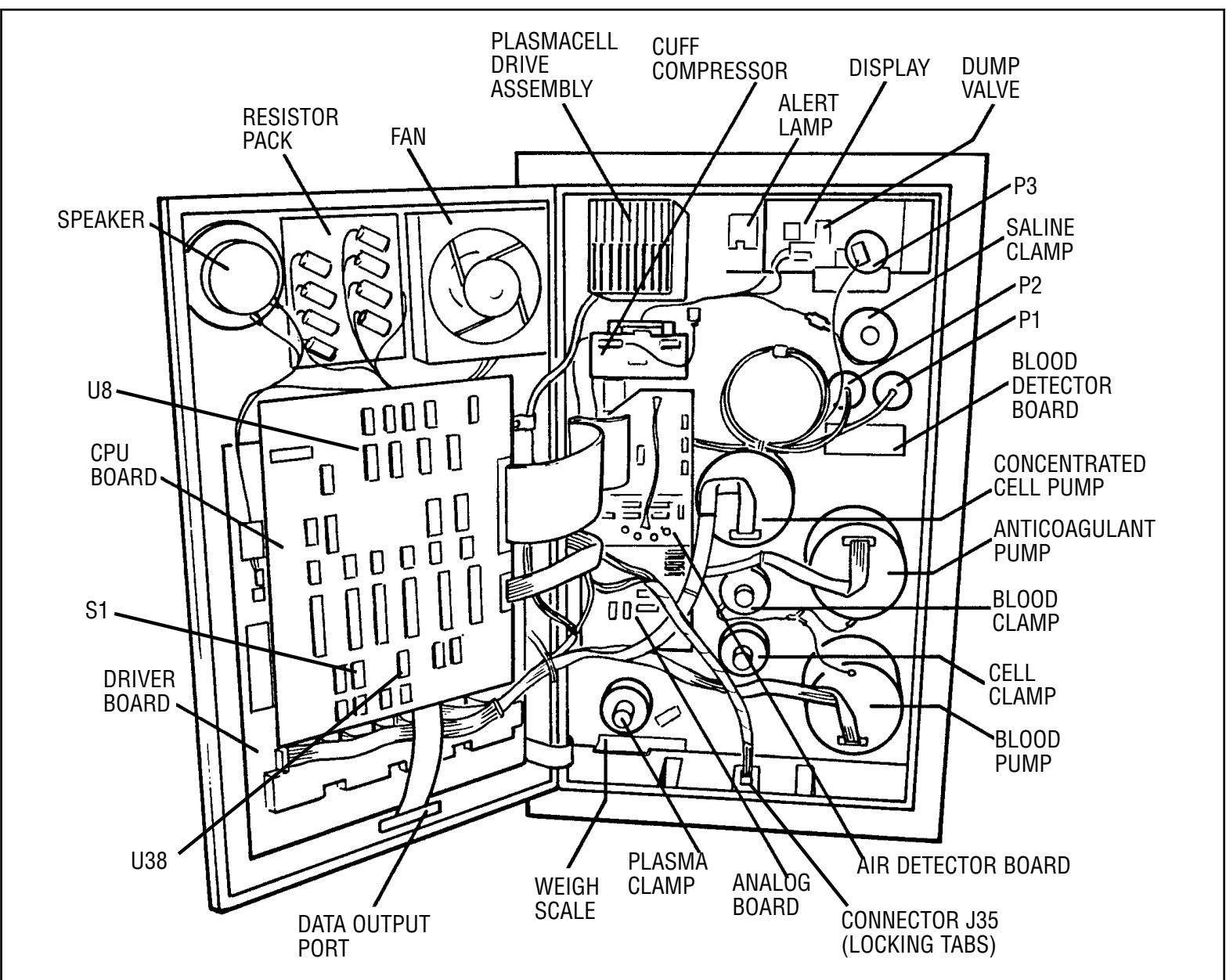


Figure 2.5 Rear View of Internal Console

A-20X, A-40X Test Procedure Data Sheet, Rev 6.0

Config/Default Data Sheet included: Yes No Service Provider: BIS PBU Self Service

Indicate document being used:

INSTALL SOFTWARE UPGRADE PM PART REMOVAL FSR








For software upgrade: Run Hours: VP Hours: Procedures:

BIS FSE's must complete the shaded areas only, the Service Report contains the remaining information.


| | | | | | |
|---------------------------------------|---|----------------------------|--|--------------------|--------------------------|
| Account Name: | | Unit Serial Number: | | Date: | |
| Address: | | | Model#: | | Product Code: |
| City: | | State: | Zip: | | Telephone: |
| Qty | Part #/ Description | | | Removed SN# | Installed SN# |
| | | | | | |
| Instrument Repair Information: | | | | | |
| 1 | Battery | <input type="checkbox"/> | Maximum Positive Pressure P1 P2 | | |
| 3 | Fan Operation | <input type="checkbox"/> | 2 min leak test (4 mmHg) | | <input type="checkbox"/> |
| 4 | Press STOP (Alert Light ON) | <input type="checkbox"/> | 61 Compressor Test | | <input type="checkbox"/> |
| | | | min 171 mmHg max 25 counts | | <input type="checkbox"/> |
| 5 | Software Version _____ | | 67 Weight scale verification | | |
| | | | 0, 500 (+/-2 gms), 1000 (+/- 3 gms) | | <input type="checkbox"/> |
| 10 | Pumps reach 170 17 and quiet | <input type="checkbox"/> | 71 Cuff pressure tracks command | | <input type="checkbox"/> |
| 16 | MTR speed tests: | | 73 Cuff re-inflates to command pressure | | <input type="checkbox"/> |
| | MTR1 Accel Value _____ Overspeed3 | <input type="checkbox"/> | 77 Air detector tone & light | | <input type="checkbox"/> |
| | MTR2 Accel Value _____ Overspeed3 | <input type="checkbox"/> | 78 Air detector fluid tests | | <input type="checkbox"/> |
| | MTR3 Accel Value _____ Overspeed3 | <input type="checkbox"/> | 79 Press [+], Check Air, Purge (-) # | | <input type="checkbox"/> |
| | MTR4 Accel Value _____ Overspeed3 | <input type="checkbox"/> | 80 "Purging Air" and pumps turn | | <input type="checkbox"/> |
| 21 | Spinner at 3600 rpm, count stable at 144 | <input type="checkbox"/> | 85 Cal Rsv LEDs slot open | | <input type="checkbox"/> |
| 26 | Clamps all open and close | <input type="checkbox"/> | 86 Cal Rsv LEDs slot blocked | | <input type="checkbox"/> |
| 28 | Clamps hold | <input type="checkbox"/> | 92 Matrix complete | | <input type="checkbox"/> |
| 30 | Sensor Tests All "A"s | <input type="checkbox"/> | 95 Run Hours: _____ | | |
| 31 | Reservoir Sensor change from "A" to "B" | <input type="checkbox"/> | VP Hours: _____ | | |
| 32 | Air detector to "B" | <input type="checkbox"/> | Procedures: _____ | | |
| 33 | Blood Detector Sensors S4 and S5 change to "B" | <input type="checkbox"/> | Config.: _____ | | |
| 40 | Hb RAWREF Background Red, Green, Raw (20-60) | <input type="checkbox"/> | 97. Instrument passes disposable test | | <input type="checkbox"/> |
| | | | P1 < -20 mmHg <input type="checkbox"/> P1 > 200 mmHg <input type="checkbox"/> P1 > 200 mmHg <input type="checkbox"/> | | |
| 42 | Hb RAWSIG Background Red, Green, Raw (20-60) | <input type="checkbox"/> | | | |
| 44 | Corr Red and Green Ref (60-180) Corr Red and Green Sig (60-145) | <input type="checkbox"/> | | | |
| 46 | RELSPT Greater than 220 | <input type="checkbox"/> | Service Provider | | |
| 48 | RELSPT goes to zero | <input type="checkbox"/> | Print Name | | |
| 49 | Insert Filter, displayed numbers stabilize | <input type="checkbox"/> | Signature | | |
| 50 | EPROM Burn Good | <input type="checkbox"/> | Customer Signature | | |
| 51 | Calibration Trip Point _____ | | Customer Printed Name/Title | | |
| 60 | Maximum Negative Pressure P1 P2 2 min leak test (4 mmHg) | <input type="checkbox"/> | | | |

Table 2.1 Test Procedure Data Sheet

LANGUAGE SELECTION

- | | |
|--------------------------|---|
| 1. From the Test Menu... | Press  four times |
| P/Wt/Cuff/Air Tests | Press  |
| DIP/Volume/Time | Press  three times |
| Message Test | Press  to enter menu item. Display will read Language Selection . Press  and the display will indicate the default language English. Press  until the desired language is displayed. Press  to select. |



Note: You can be sure you have selected the language when you press the  button and the display switches between language selection and the language you selected (See Figure 2.6 Language Selection).



Note: The actual languages which will be displayed will depend on which TRAN chip (or both) you have installed.

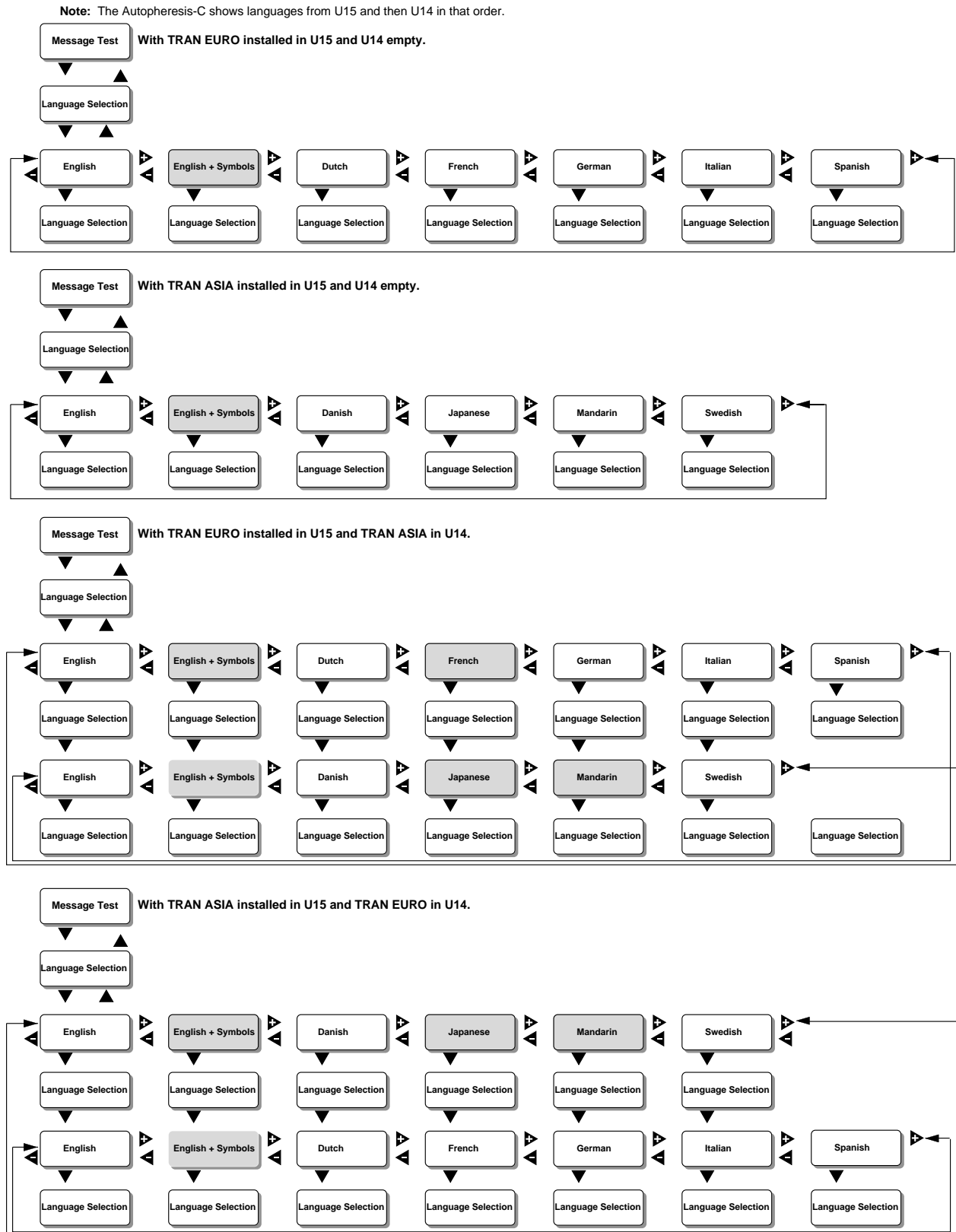


Figure 2.6 Language Selection

CONFIGURATION/DEFAULTS MENU

The Configuration/Defaults Menu shall be where the default values and functions of the instrument are set by the Self-Service personnel, Field Service staff, or Engineering.

1. The Configuration/Defaults Menu shall not be readily accessible to the operator.
 - a. This menu is entered by pressing BACK ▲ while Plasmapheresis is displayed and SW2 and/or SW3 on the DIP switch S1 is closed.
 - b. Original defaults can be reset by closing SW2, SW3 and SW4 on the DIP switch S1, and entering the appropriate menu item.



Note: Items set by closing SW2 and SW3 of DIP switch S1 are designated for Baxter Engineering R&D only.

2. The Configuration/Defaults Menu shall not be accessible when a procedure is running or when a donor is connected to the instrument.
3. The Configuration/Defaults Menu items are shown in the first column of Table 2.2 Config/Default Matrix (Underline represents flashing display in Edit mode).
4. To select edited Config/Default values and to exit the menu, press the ► key at the (-) Top, (+) Exit Menu display.
5. Key presses during select mode in the Configuration/Defaults Menu follow the general rules previously discussed except for the following:
 - a. In the bottom menu item, (-) Top, (+) Exit Menu, the ◀ key moves from current selection to the first menu item, Edit AC: nn.
 - b. The **F** key displays the factory defaults value of the menu item.
6. Key presses during Edit mode follow the general rules previously discussed except for the following:
 - a. In Reset Defaults, if YES is accepted, the system shall reset all selections in the Configuration/Defaults Menu to their original default selection, exits the menu and restarts the system.
 - b. The **F** key shall reset the menu item to its factory default value.
7. Exit from the Configuration/Defaults Menu shall restart the system.

| Config/Default Matrix | | | | | |
|-------------------------------|-----------------------------|-----------------------------|-----------------------------|-----------------------------|--|
| Menu Item/ Display | Action for [+] | Action for [-] | Action for [BCK] | Action for [ADV] | Comments Other Dependencies |
| Edit AC:Y/N | Edit AC: <u>aa</u> | Edit AC: <u>aa</u> | Edit AC: <u>aa</u> | AC Ratio: n% | aa is YES or NO, SW2 closed |
| AC Ratio: nn% | AC Ratio: <u>nn%</u> | AC Ratio: <u>nn%</u> | none | AC Volume: nnn mL | SW2 closed |
| AC Volume = nnn mL | AC Volume = <u>nnn</u> mL | AC Volume = <u>nnn</u> mL | AC Ratio: nn% | Plasma Max: nnn mL | SW2 closed |
| Plasma Max: nnnn mL | Plasma Max: <u>nnnn</u> mL | Plasma Max: <u>nnnn</u> mL | AC Volume = nnn mL | Plasma Vol1: nnnn mL | SW2+SW3 closed |
| Plasma Vol1: nnnn mL | Plasma Vol1: <u>nnnn</u> mL | Plasma Vol1: <u>nnnn</u> mL | Plasma Max: nnnn mL | Plasma Vol2: nnnn mL | SW2 closed |
| Plasma Vol2: nnnn mL | Plasma Vol2: <u>nnnn</u> mL | Plasma Vol2: <u>nnnn</u> mL | Plasma Vol1: nnnn mL | Plasma Vol3: nnnn mL | SW2 closed |
| Plasma Vol3: nnnn mL | Plasma Vol3: <u>nnnn</u> mL | Plasma Vol3: <u>nnnn</u> mL | Plasma Vol2: nnnn mL | Remove Plasma: Y/N | SW2 closed |
| Remove Plasma: Y/N | Remove Plasma: <u>aaa</u> | Remove Plasma: <u>aaa</u> | Plasma Vol3: nnnn mL | Saline Protocol: Y/N | SW2 closed, allows "Remove Container" prompt before saline infusion for a saline protocol procedure. |
| Saline Protocol: Y/N | Saline Protocol: <u>aaa</u> | Saline Protocol: <u>aaa</u> | Remove Plasma: aaa | Saline Vol1: nnn mL | SW2 closed |
| Saline Vol1: nnn mL | Saline Vol1: <u>nnnn</u> mL | Saline Vol1: <u>nnnn</u> mL | Saline Protocol: Y/N | Saline Vol2: nnn mL | SW2 closed |
| Saline Vol2: nnn mL | Saline Vol2: <u>nnnn</u> mL | Saline Vol2: <u>nnnn</u> mL | Saline Vol1: nnn mL | Saline Vol3: nnn mL | SW2 closed |
| Saline Vol3: nnn mL | Saline Vol3: <u>nnnn</u> mL | Saline Vol3: <u>nnnn</u> mL | Saline Vol2: nnn mL | Parameter View: Y/N | SW2 closed |
| Parameter View: Y/N | Parameter View: <u>aaa</u> | Parameter View: <u>aaa</u> | Saline Vol3: nnn mL | Adaptive Cuff: nn | SW2 closed |
| Adaptive Cuff: nn | Adaptive Cuff: <u>nn</u> | Adaptive Cuff: <u>nn</u> | Parameter View: aaa | Cuff: nn | in mmHg, SW2 closed |
| Cuff: nn | Cuff: <u>nn</u> | Cuff: <u>nn</u> | Adaptive Cuff: nn | Prompt Grip: aaa | in number of cycles, SW2+SW3 closed |
| Prompt Grip: Y/N | Prompt Grip: <u>aaa</u> | Prompt Grip: <u>aaa</u> | Cuff: nn | Squeeze Alert: nn | SW2+SW3 closed |
| Squeeze Alert: nn | Squeeze Alert: <u>nn</u> | Squeeze Alert: <u>nn</u> | Prompt Grip: Y/N | Draw Max: nnn | in mmHg, SW2 closed |
| Draw Max: nnn | Draw Max: <u>nnn</u> | Draw Max: <u>nnn</u> | Squeeze Alert: nn | Return Max: nnn | in mL/min, SW2+SW3 closed |
| Return Max: nnn | Return Max: <u>nnn</u> | Return Max: <u>nnn</u> | Draw Max: nnn | Blood Flow: <u>aaaa</u> | in mL/min, SW2+SW3 closed |
| Blood Flow: aaaa | Blood Flow: <u>aaaa</u> | Blood Flow: <u>aaaa</u> | Return Max: nnn | Max Time: nn.nn | SW2 closed, HIGH or LOW to enable extended flow (less than 60 mL/min draw rate) |
| Max Time: nn.nn | Max Time: <u>nn.nn</u> | Max Time: <u>nn.nn</u> | Blood Flow: <u>High/Low</u> | Occlusion: Y/N | in min, SW2 closed |

Table 2.2 Config/Default Matrix

| Config/Default Matrix | | | | | |
|-------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|--|
| Menu Item/ Display | Action for [+] | Action for [-] | Action for [BCK] | Action for [ADV] | Comments Other Dependencies |
| Occlusion: | Occlusion: YES | Occlusion: NO | Max Time: nn:nn | Occlusion Time: nn | SW2+SW3 closed |
| Occlusion Time: nn | Occlusion Time: <u>nn</u> | Occlusion Time: <u>nn</u> | Occlusion: Y/N | Vein Slope mmHg: <u>nn</u> | SW2+SW3 closed |
| Vein Slope mmHg: <u>nn</u> | Vein Slope mmHg: <u>nn</u> | Vein Slope mmHg: <u>nn</u> | Occlusion time:nn | Vein Settle Time: <u>nn</u> | SW2+SW3 closed |
| Vein Settle Time: <u>nn</u> | Vein Settle Time: <u>nn</u> | Vein Settle Time: <u>nn</u> | Vein Slope mmHg: <u>nn</u> | Membrane: <u>aaaa</u> | in cycles, SW2+SW3 closed |
| Membrane: <u>aaaa</u> | Membrane: <u>aaaa</u> | Membrane: <u>aaaa</u> | Vein Settle Time: nn | TMP Slope: <u>n.nnn</u> | SW2+SW3 closed |
| TMP Slope: <u>n.nnn</u> | TMP Slope: <u>n.nnn</u> | TMP Slope: <u>n.nnn</u> | Membrane: <u>aaaa</u> | TMP PQFudge: <u>nn</u> | SW2+SW3 closed |
| TMP PQFudge: <u>nn</u> | TMP PQFudge: <u>nn</u> | TMP PQFudge: <u>nn</u> | TMP Slope: <u>n.nnn</u> | TMP PQDecrease: nn | in mmHg, SW2+SW3 closed |
| TMP PQDecrease: <u>nn</u> | TMP PQDecrease: <u>nn</u> | TMP PQDecrease: <u>nn</u> | TMP PQFudge: <u>nn</u> | TMP M2 Offset: <u>nn</u> | in mmHg, SW2+SW3 closed, first cycle decrease in operating pressure |
| TMP M2 Offset: <u>nn</u> | TMP M2 Offset: <u>nn</u> | TMP M2 Offset: <u>nn</u> | TMP PQDecrease: <u>nn</u> | TMP Gain: <u>n.nnn</u> | SW2+SW3 closed, effect of M2 flow rate on P2 pressure |
| TMP Gain: n.nnn | TMP Gain: <u>n.nnn</u> | TMP Gain: <u>n.nnn</u> | TMP M2 Offset: <u>nn</u> | TMP Ctrl: <u>nn</u> | SW2+SW3 closed |
| TMP Ctrl: <u>nn</u> | TMP Ctrl: <u>nn</u> | TMP Ctrl: <u>nn</u> | TMP Gain: <u>n.nnn</u> | TMP Gamma: <u>n.nnn</u> | in mmHg, SW2+SW3 closed, maximum offset for determining operating pressure |
| TMP Gamma: <u>n.nnn</u> | TMP Gamma: <u>n.nnn</u> | TMP Gamma: <u>n.nnn</u> | TMP Ctrl: <u>nn</u> | TMP Stable Time: <u>nn</u> | SW2+SW3 closed |
| TMP Stable Time: <u>nn</u> | TMP Stable Time: <u>nn</u> | TMP Stable Time: <u>nn</u> | TMP Gamma: <u>n.nnn</u> | TMP Kickdown: <u>nn</u> | in cycles, SW2+SW3 closed, time M2 has to be stable to exit from TMP calibration |
| TMP Kickdown: <u>nn</u> | TMP Kickdown: <u>nn</u> | TMP Kickdown: <u>nn</u> | TMP Stable Time: <u>nn</u> | TMP Damping: <u>n.nnn</u> | in mmHg, SW2+SW3 closed, offset before TMP calibration reduces plasma flow rate |
| TMP Damping: <u>n.nnn</u> | TMP Damping: <u>n.nnn</u> | TMP Damping: <u>n.nnn</u> | TMP Kickdown: <u>nn</u> | Spin0: nnnn RPM | SW2+SW3 closed |
| Spin0: <u>nnnn</u> RPM | Spin0: <u>nnnn</u> RPM | Spin0: <u>nnnn</u> RPM | TMP Damping: <u>n.nnn</u> | Spin0High: <u>nnnn</u> RPM | SW2+SW3 closed |
| Spin0High: <u>nnnn</u> RPM | Spin0High: <u>nnnn</u> RPM | Spin0High: <u>nnnn</u> RPM | Spin0: <u>nnnn</u> RPM | Spin100: <u>nnnn</u> RPM | SW2+SW3 closed |
| Spin 100: <u>nnnn</u> RPM | Spin 100: <u>nnnn</u> RPM | Spin 100: <u>nnnn</u> RPM | Spin0High: <u>nnnn</u> RPM | Reset Defaults: <u>Y/N</u> | SW2+SW3 closed |
| Reset Defaults: <u>Y/N</u> | Reset Defaults: <u>aaa</u> | Reset Defaults: <u>aaa</u> | Spin100: nnnn RPM | (-) Top, (+) Exit Menu | SW2+SW3+SW4 closed |
| (-) Top, (+) Exit Menu | exit menu | Edit AC: <u>Y/N</u> | Reset Defaults: NO | none | |

Table 2.2 Config/Default Matrix (continued)

Serial Number: _____

Name/Signature: _____ Date: _____

Config/Defaults Data Sheet SW2 ___ SW3 ___ SW4 ___

Config: _____

| | Menu Item/Display | DIP Switch S1 | Default | Data |
|-----|------------------------|--|---------|------|
| 1. | Edit AC:Y/N | SW2 | YES | |
| 2. | AC Ratio: nn% | SW2 closed | 6 | |
| 3. | AC Volume = nnn mL | SW2 closed | 230 | |
| 4. | Plasma Max: nnnn mL | SW2+SW3 closed | 880 | |
| 5. | Plasma Vol1: nnnn mL | SW2 closed | 690 | |
| 6. | Plasma Vol2: nnnn mL | SW2 closed | 825 | |
| 7. | Plasma Vol3: nnnn mL | SW2 closed | 880 | |
| 8. | Remove Plasma : Y/N | SW2 closed, allows "Remove Container" prompt before saline infusion for a saline protocol procedure. | YES | |
| 9. | Saline Protocol: Y/N | SW2 closed | YES | |
| 10. | Saline Vol1: nnn mL | SW2 closed | 300 | |
| 11. | Saline Vol2: nnn mL | SW2 closed | 400 | |
| 12. | Saline Vol3: nnn mL | SW2 closed | 500 | |
| 13. | Parameter View: Y/N | SW2 closed | YES | |
| 14. | Adaptive Cuff: nn | in mmHg, SW2 closed | 36 | |
| 15. | Cuff: nn | in number of cycles, SW2+SW3 closed | 80 | |
| 16. | Prompt Grip: Y/N | SW2+SW3 closed | NO | |
| 17. | Squeeze Alert: nn | in mmHg, SW2 closed | 50 | |
| 18. | Draw Max: nnn | in mL/min, SW2+SW3 closed | 100 | |
| 19. | Return Max: nnn | in mL/min, SW2+SW3 closed, | 130 | |
| 20. | Blood Flow: aaaa | SW2 closed, HIGH or LOW to enable extended flow (less than 60 mL/min draw rate) | HIGH | |
| 21. | Max Time: nn : nn | in min, SW2 closed | OFF | |
| 22. | Occlusion: | SW2+SW3 closed | NO | |
| 23. | Occlusion Time:nn | SW2+SW3 closed | 20 | |
| 24. | Vein Slope mmHg:nn | SW2+SW3 closed | 24 | |
| 25. | Vein Settle Time: nn | in cycles, SW2+SW3 closed | 40 | |
| 26. | Membrane: aaaa | SW2+SW3 closed | NYLON | |
| 27. | TMP Slope: n.nnn | SW2+SW3 closed | 0.813 | |
| 28. | TMP PQFudge: nn | in mmHg, SW2+SW3 closed | 30 | |
| 29. | TMP PQDecrease: nn | in mmHg, SW2+SW3 closed, first cycle decrease in operating pressure | 4 | |
| 30. | TMP M2 Offset: nn | SW2+SW3 closed, effect of M2 flow rate on P2 pressure | 69 | |
| 31. | TMP Gain: n.nnn | SW2+SW3 closed | 0.602 | |
| 32. | TMP Ctrl: nn | in mmHg, SW2+SW3 closed, maximum offset for determining operating pressure | 30 | |
| 33. | TMP Gamma: n.nnn | SW2+SW3 closed | 0.996 | |
| 34. | TMP Stable Time: nn | in cycles, SW2+SW3 closed, time M2 has to be stable to exit from TMP calibration. | 0 | |
| 35. | TMP Kickdown: nn | in mmHg, SW2+SW3 closed, offset before TMP calibration reduces plasma flow rate | 12 | |
| 36. | TMP Damping: n.nnn | SW2+SW3 closed | 0.301 | |
| 37. | Spin0: nnnn RPM | SW2+SW3 closed | 1500 | |
| 38. | Spin0High: nnnn RPM | SW2+SW3 closed | 2200 | |
| 39. | Spin100: nnnn RPM | SW2+SW3 closed | 3600 | |
| 40. | Reset Defaults: Y/N | SW2+SW3+SW4 closed | NO | |
| 41. | (-) Top, (+) Exit Menu | | | |

Table 2.3 Config/Default Data Sheet

EEPROM CONFIG PARAMETER CLONING PROCEDURE

For Autopheresis-C Software Rev. 5.90B00 and Above

This procedure describes how to create an EEPROM (U38) containing master configuration data to be used in the cloning of other instruments at a center or an organization.



Note: The master EEPROM has Config/Default values, and the selected language. Instrument specific data, such as run hours and number of procedures are not cloned or changed.

Cloning Prerequisites

1. A "parent EEPROM" socket adapter. The adapter allows the EEPROM to be inserted into the EPROM socket. This adapter isolates pins 1 and 26, and connects pin 27 of the EEPROM to pin 28, or 5VDC.



Note: Never insert an EEPROM into an EPROM socket without an adapter socket.



Note: The Run hours, VP hours and the number of procedures may be initialized when a master is created. It is recommended that a blank EEPROM be used for creating the master EEPROM.

2. One each Autopheresis-C Instrument for programming the Config/Default data into the master EEPROM.
3. Anti-static foam for carrying the EEPROM part between machines.
4. A blank dedicated EEPROM to be used for creating the master.
5. Document procedure using an A-20X, A-40X Test Procedure Data Sheet and a Config/Default Data Sheet.

Procedure

Create Master EEPROM

1. Remove the original EEPROM chip from socket U38 on the CPU Board.
Place the chip in anti-static foam and label with instrument serial number.



Note: An EEPROM (U38) is device specific and must be returned to the original instrument from which it was removed.

2. Insert the EEPROM chip from item 4 (cloning prerequisites) into socket U38 to be programmed as the master.
3. Turn ON the Autopheresis-C Instrument. `Init EEPROM: xx Sec` (where xx= seconds counting down) is displayed while the master chip is initialized.



Note: If a Help #14 message occurs, press the `F` in Fenwal to continue.

4. Once the display reads `Test (Press STOP)` turn DIP switch S1 on the CPU Board:

SW2 ON

Edit Procedure Menu items.

SW3 and SW4 ON

Edit remaining Config/Default items.



Note: Indicate on Config/Default Data Sheet what switches are used. Data associated with switch identified positions require data entry.

5. Press the `STOP` button, the display will read `Config/Default`. Press the ADVANCE `▼` button, the alert light will turn ON and the Config/Default values become selected.
6. Once the instrument displays `Plasmapheresis`, press the BACK `▲` button. The display will read: `Edit AC: YES` when in the Config/Defaults Menu.



Note: Plasmapheresis is displayed for approximately 15 seconds.

7. When the Autopheresis-C Instrument is in the Config/Default Menu, program in the desired Config values per customer requirements.
8. At the end of the Config/Default Menu the display will read `(-) Top, (+) Exit Menu`. Press the `▶` button to select edited Config/Default values and to exit the menu.
9. The language default is English. To select another language, enter the Test Menu and go to `Message Test` and ADVANCE `▼` to `Language Selection`.

10. After programming and verifying all parameters, turn OFF all switch positions on DIP switch S1. Then turn the instrument OFF, and then ON.
11. Verify the Autopheresis-C Instrument performs calibration and self test sequence. This indicates successful programming of the master.
12. Turn the Autopheresis-C Instrument OFF.
13. Remove the master EEPROM from socket U38 and restore the original EEPROM to socket U38.

Program an Instrument Using the Master EEPROM

14. Insert the master EEPROM into the parent EEPROM socket adapter.
15. Insert the socket adapter with the master EEPROM into socket U8 on the CPU Board of an instrument to be programmed. [**Not in U38**]
16. Turn ON the Autopheresis-C Instrument and press the Stop key when prompted.
17. Observe that the alternating display shows:
CloneEE Done then Config: nn-xxxx-yyyy and the alert light is ON.
18. Document the alphanumeric sequence nn-xxxx-yyyy or Config: Defaults on the Test Procedure Data Sheet and the Config/Default Data Sheet.
19. Turn OFF the Autopheresis-C Instrument and remove the parent EEPROM socket adapter with the master EEPROM.
20. Turn ON the Autopheresis-C Instrument and verify the Autopheresis-C Instrument performs the calibration and self test sequence.
21. Repeat Steps 13 - 21 for each instrument to receive the master EEPROM Config/Default data.

POST INSTALLATION

It is important to monitor one complete donation to ensure the correct operation of all donor features.

MENU DIAGRAMS

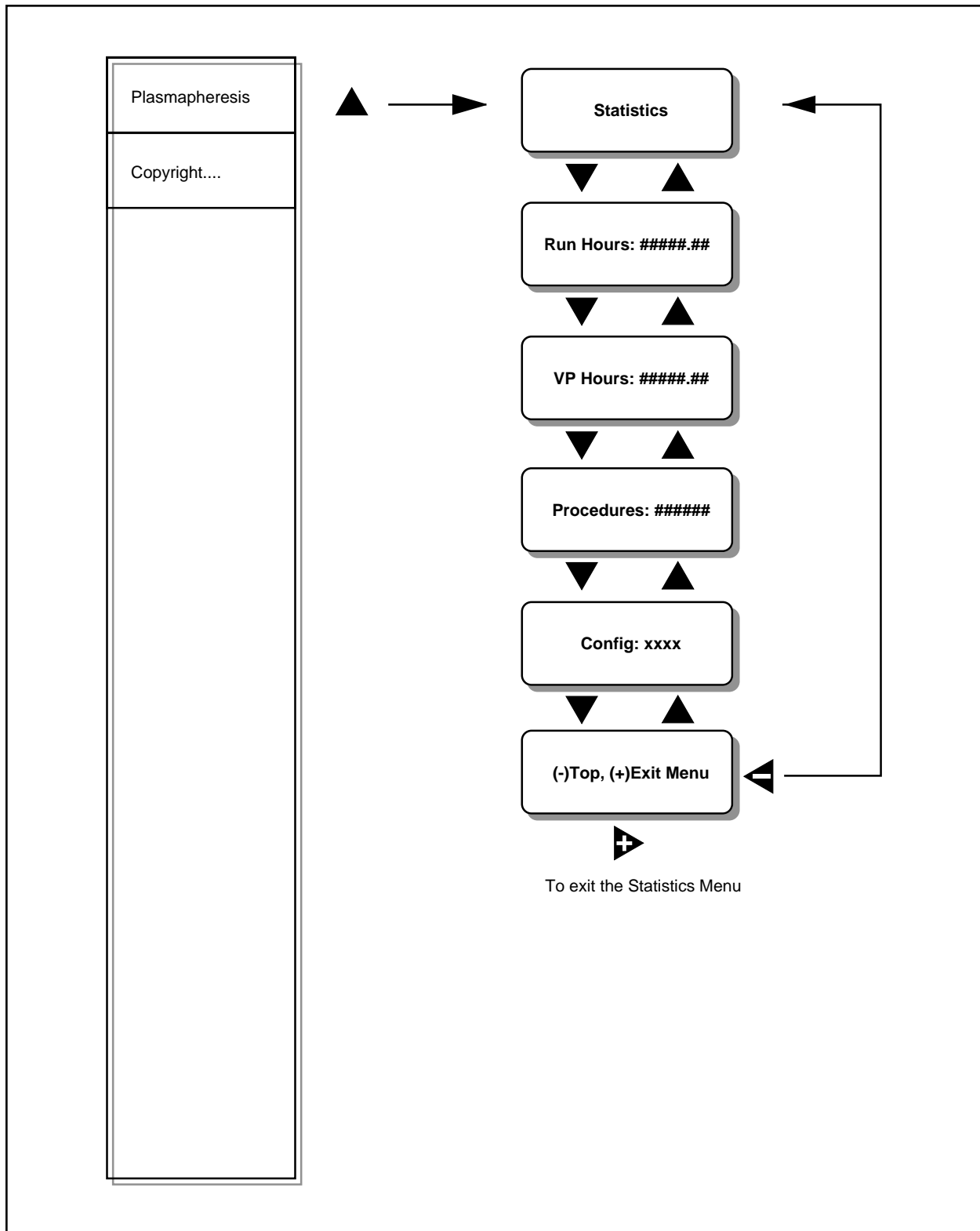


Figure 2.7 APC Statistic Menu

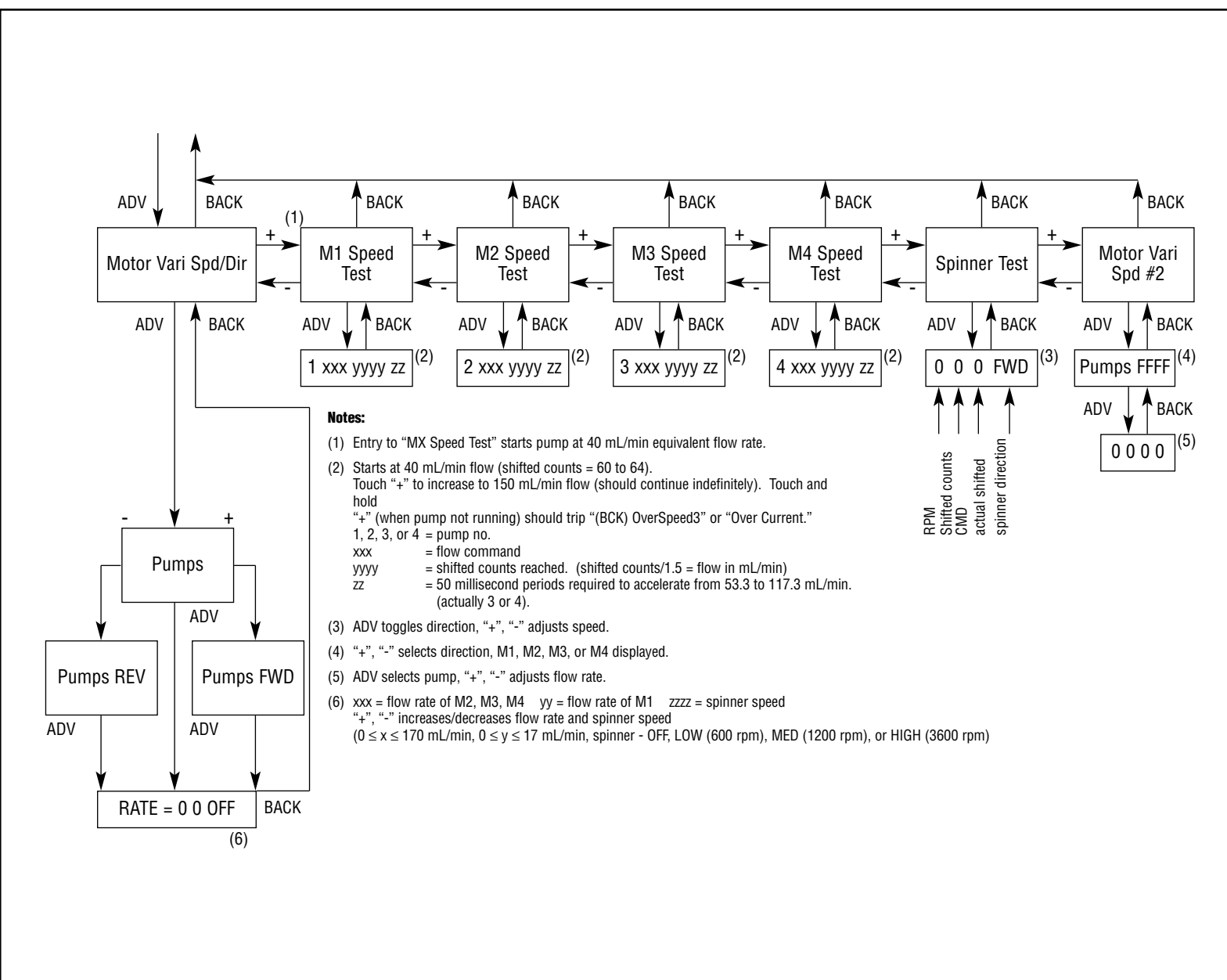
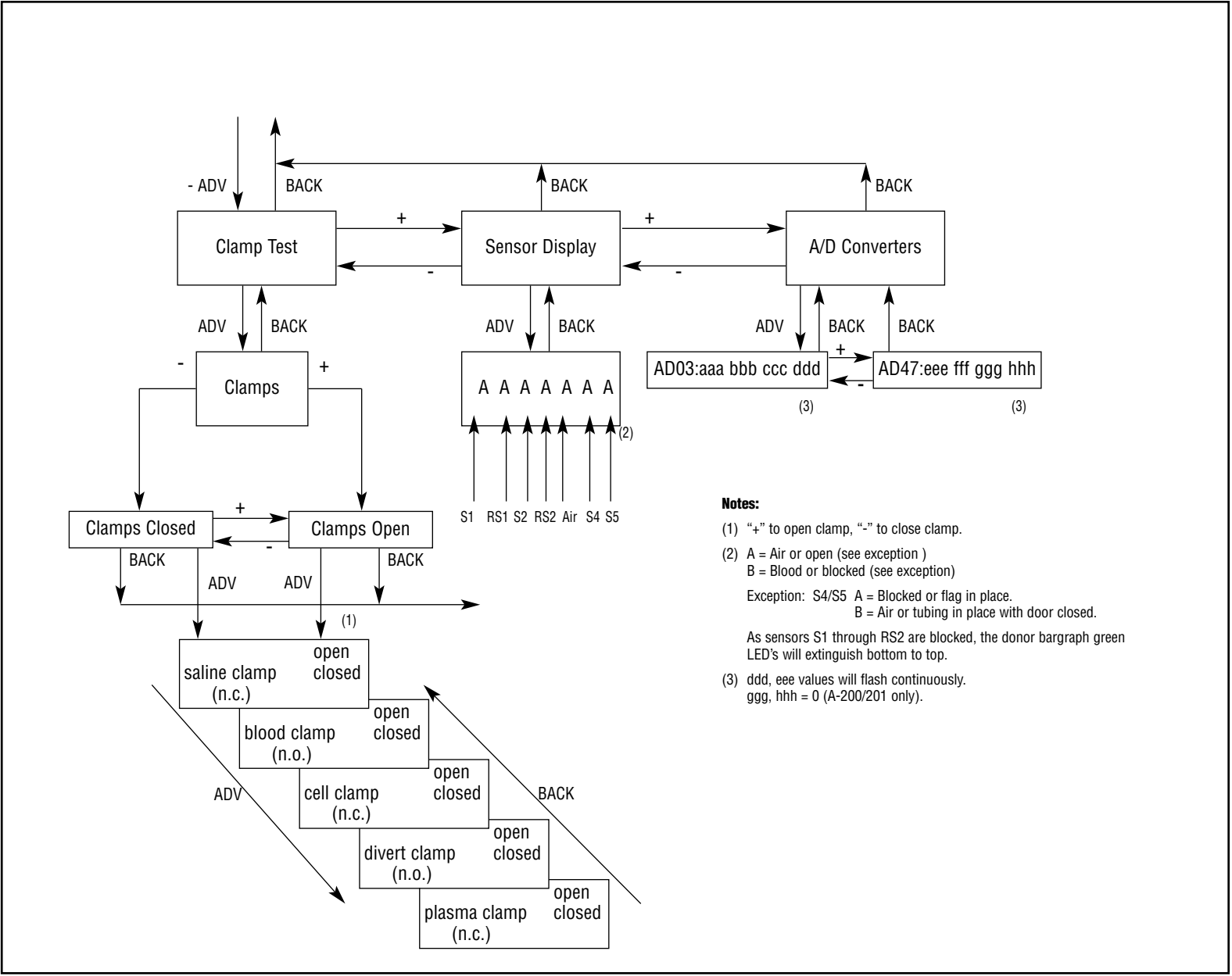


Figure 2.8 Pump Tests Menu



Notes:

- (1) "+" to open clamp, "-" to close clamp.
- (2) A = Air or open (see exception)
B = Blood or blocked (see exception)
Exception: S4/S5 A = Blocked or flag in place.
B = Air or tubing in place with door closed.
- As sensors S1 through RS2 are blocked, the donor bargraph green LED's will extinguish bottom to top.
- (3) ddd, eee values will flash continuously.
ggg, hhh = 0 (A-200/201 only).

Figure 2.9 Clamp/Sensor Tests Menu

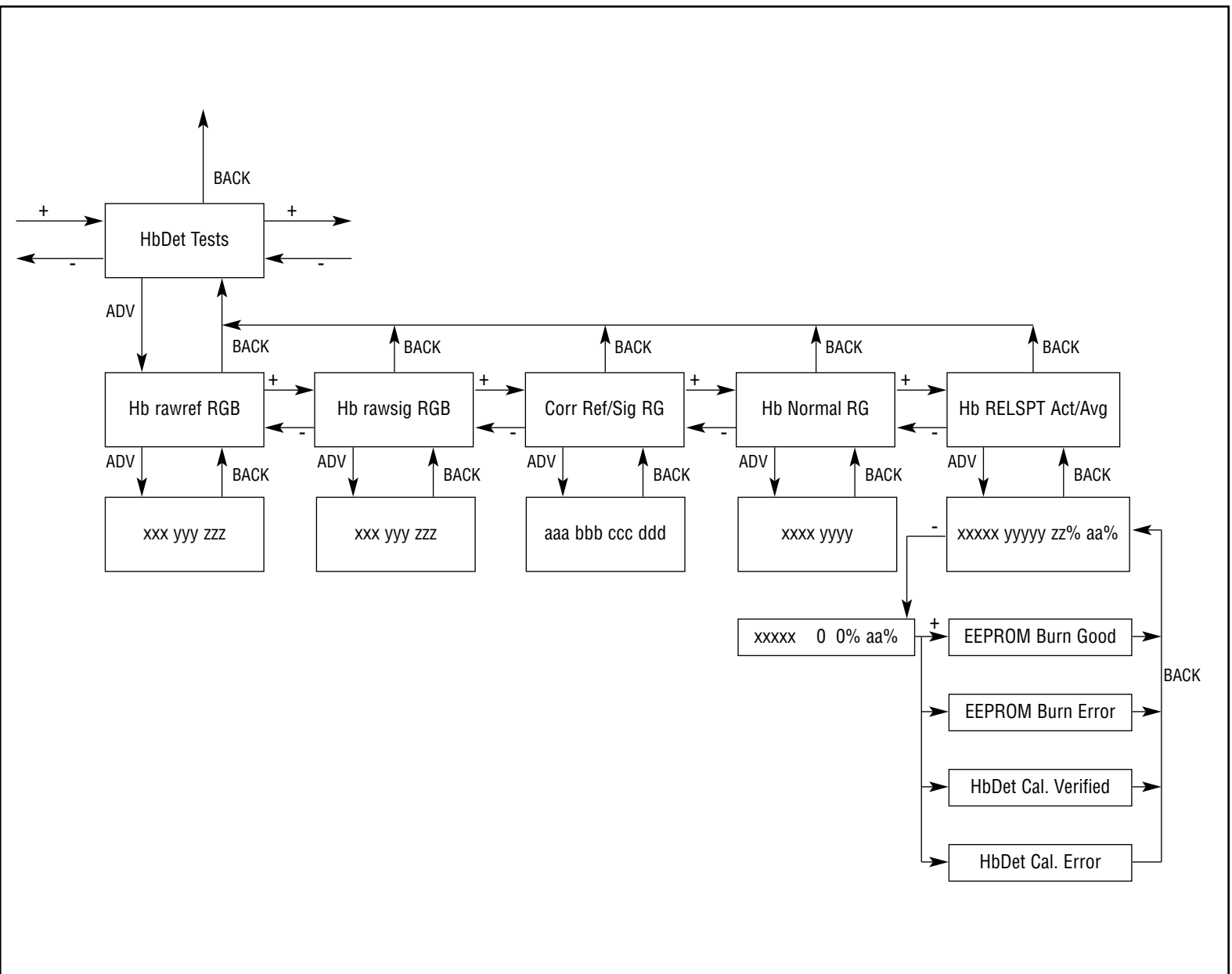
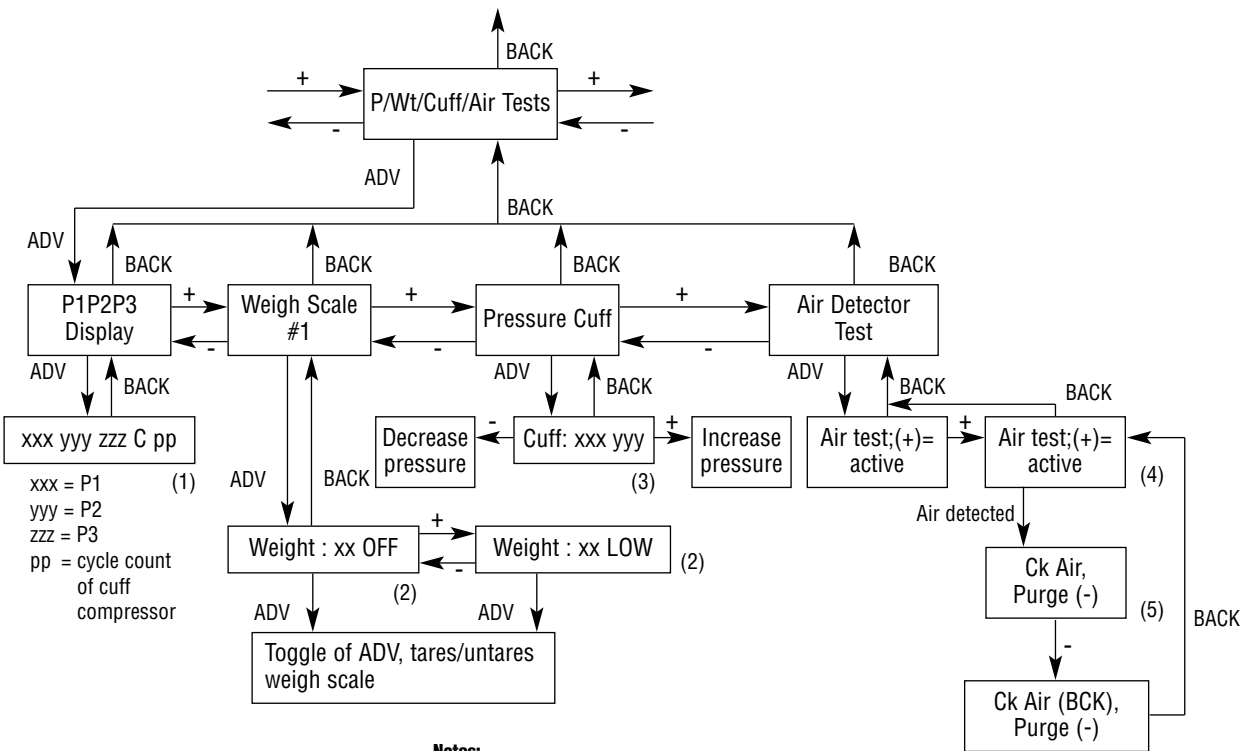


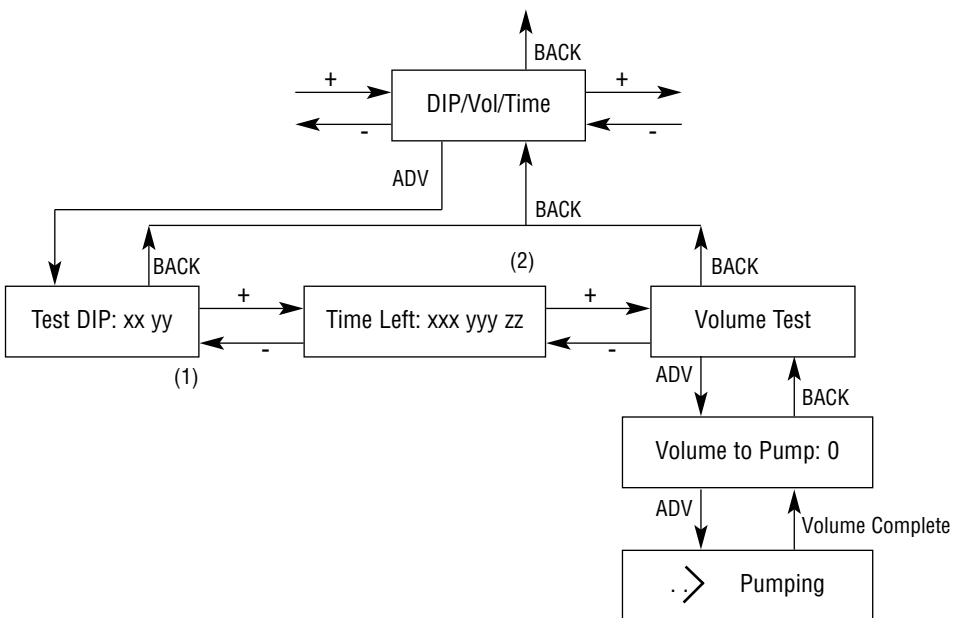
Figure 2.10 HbDet Tests Menu



Notes:

- (1) If tubing is not in place and door closed, continuous tone will sound.
 To test cuff compressor:
 (a) Hemostat cuff line at output port.
 (b) Press and hold "+"
 $P3 \geq 171$ mmHg
 $C \leq 25$ counts
- (2) OFF/LOW relates to spinner.
 OFF = spinner OFF, LOW = spinner at 600 RPM
- (3) xxx = commanded pressure, mmHg
 yyy = actual pressure, mmHg
- (4) Air = continuous tone and alert light,
 Fluid = no tone/alert light
- (5) Air detected, duplicates normal system air purge cycle.

Figure 2.11 Pressure/Weight/Cuff/Air Tests Menu



Notes:

- (1) xx = Switch state (hexadecimal)
yy = # of times switches set since power on (hexadecimal)
- (2) programmer use only

Figure 2.12 DIP/Vol/Time Tests Menu

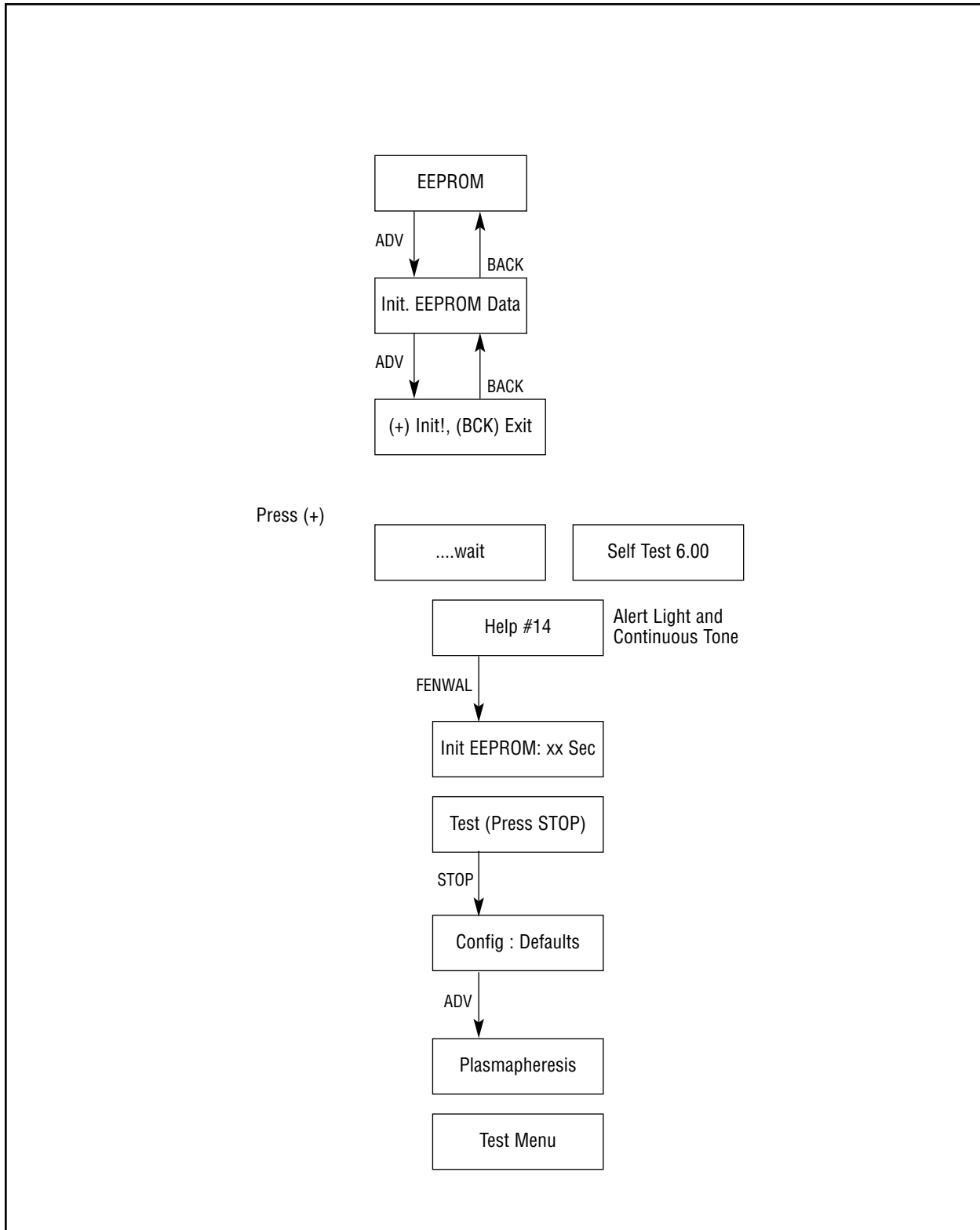


Figure 2.13 EEPROM

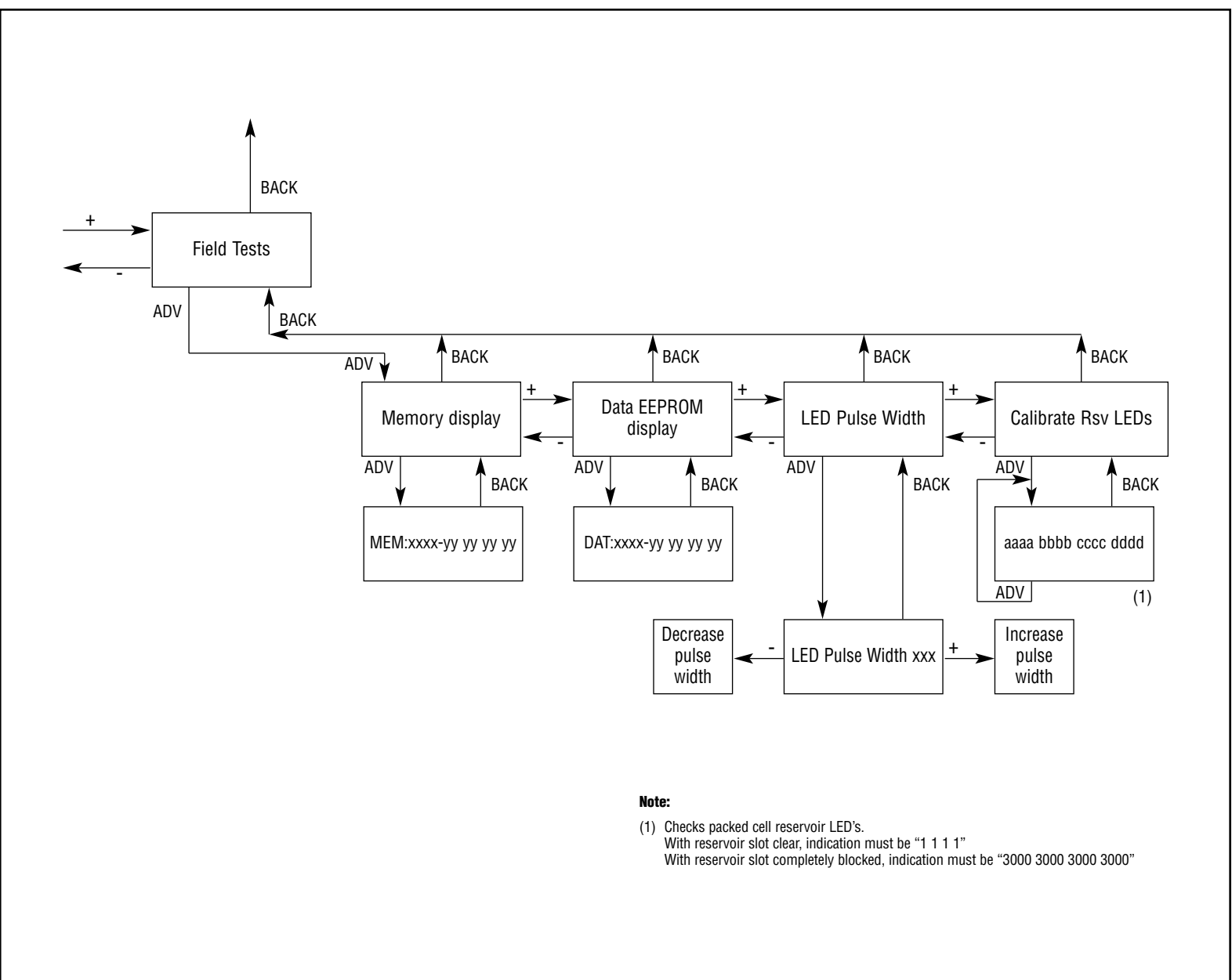


Figure 2.14 Field Tests Menu

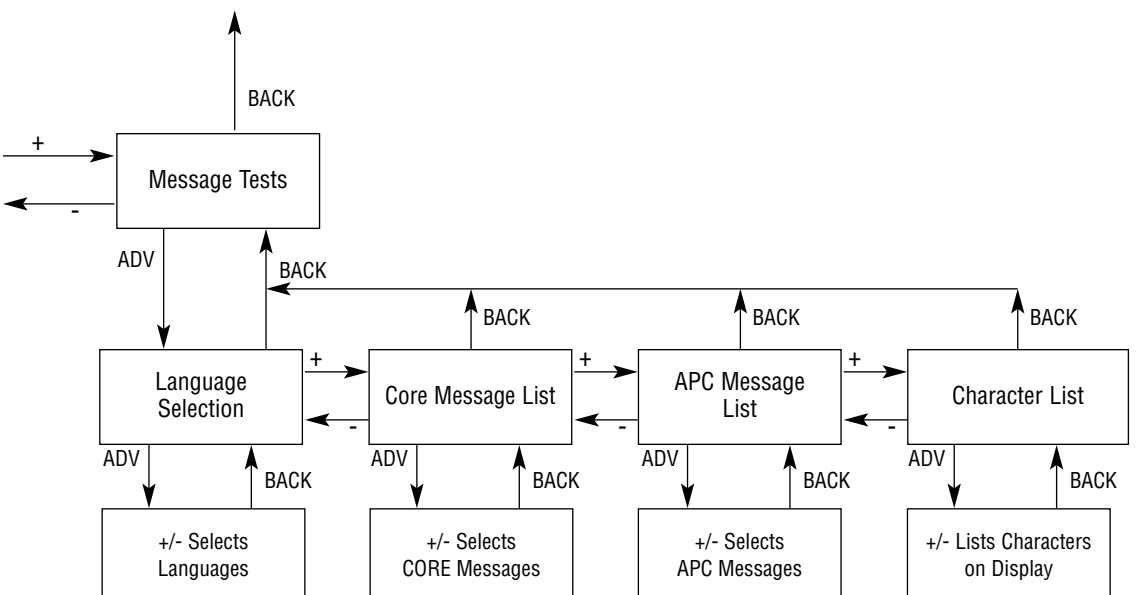
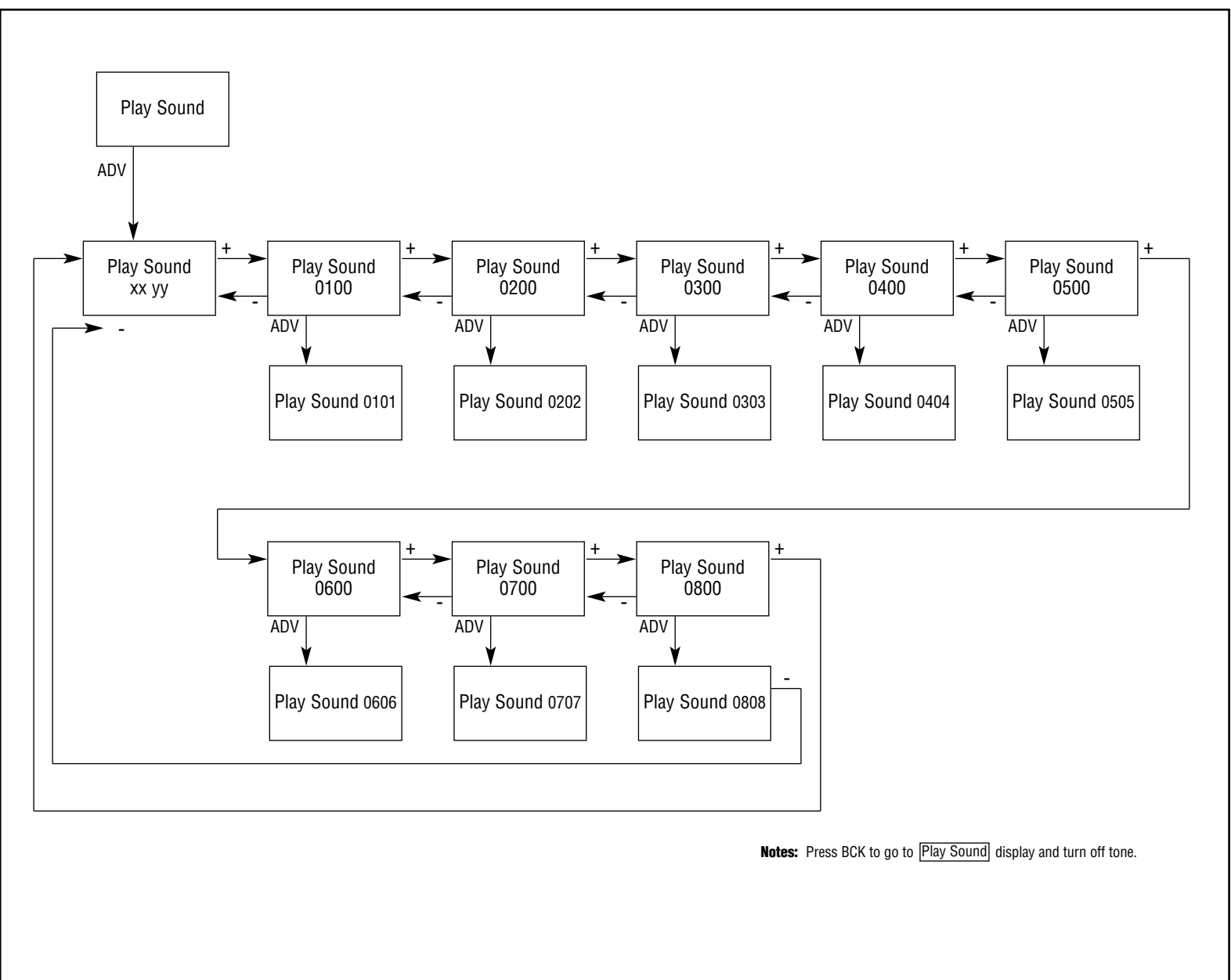


Figure 2.15 Message Tests Menu



Notes: Press BCK to go to Play Sound display and turn off tone.

Figure 2.16 Play Sound

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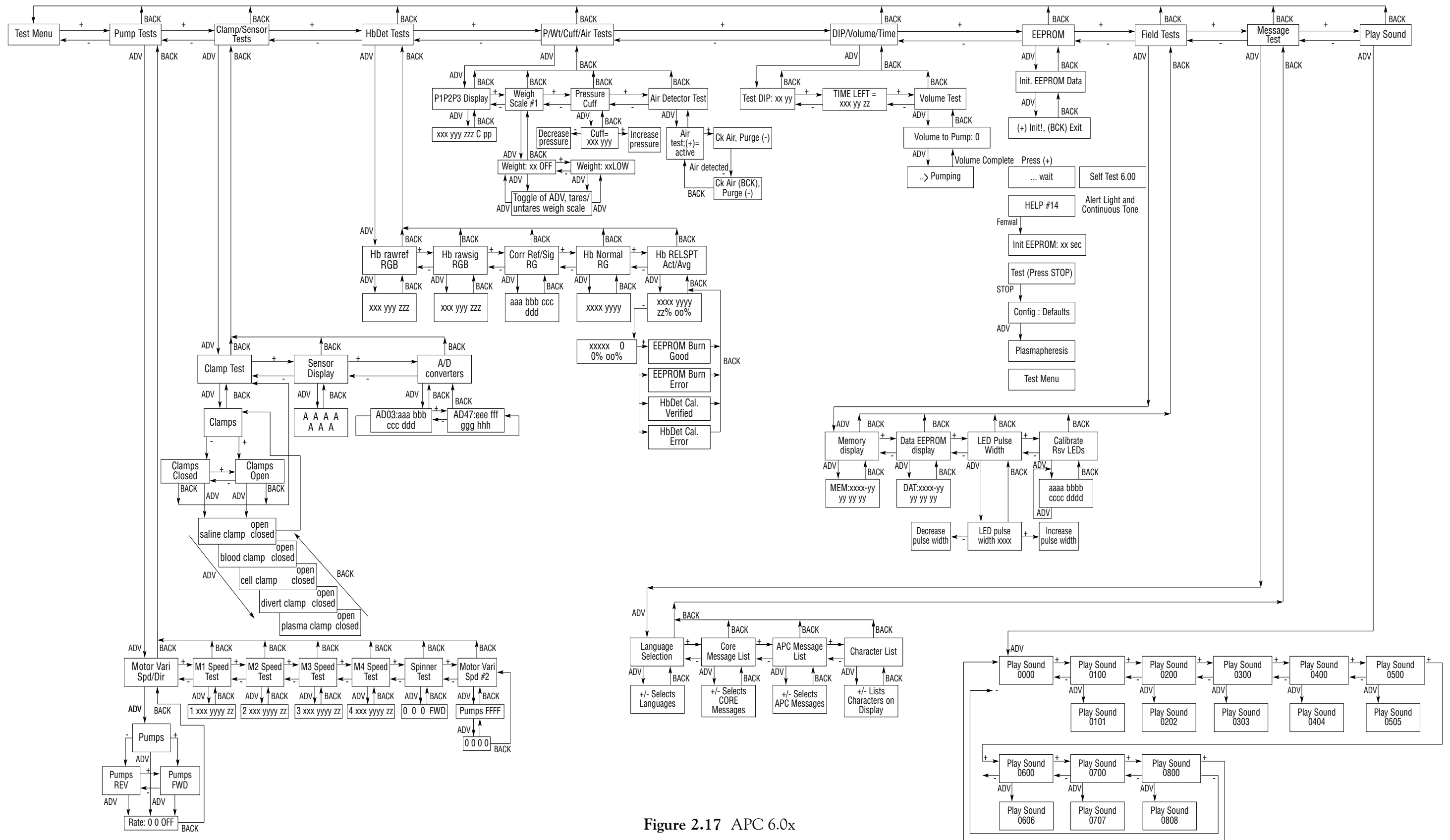


Figure 2.17 APC 6.0x

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INTRODUCTION

In this section, we discuss the following items:

SUBSYSTEM DESCRIPTIONS

- Pumps
- Clamps and Valves
- Spinner
- Air Detector
- Blood Detector
- Weigh Scale
- Pressure Sensors
- Cuff Compressor
- Display
- Membrane Panel and Donor Bar Graph
- Low Voltage Power Distribution

UPPER CONSOLE

- Electronics Circuit Description
- System Interconnection - An Overview
- Electronic Circuit Description
 - CPU Board
 - Driver Board
 - Analog Board
 - Spinner Board
 - Display Board
- Support Column
- Support Column Electronics
- Low Voltage Power Supply
- Backup Battery
- Isolation Transformer
- Power Input Module

SUBSYSTEM DESCRIPTIONS

Pumps

The pump motors are directly cabled (W16) to the Driver Board. Control for the Driver Board comes from the CPU by means of the W2 cable.

Each of the pump functions has a dedicated VIA counter on the CPU Board connected to count the tachometer pulses generated by the motor driver circuitry on the Driver Board. Control of motor direction is also accomplished using a VIA output line. The CPU test strips provide convenient access to these lines.

The Driver Board receives the pump speed command from the CPU and attempts to operate the motor at the desired speed. Due to mechanical load variations, circuit tolerances, etc. the actual pump speed will be somewhat in error. The tachometer pulses generated by the motor control circuit are then counted by the VIA associated with that particular pump giving the processor a measurement of how much the pump has rotated in the last 100 millisecond cycle. The CPU then adjusts the controller speed command to obtain the desired operating speed. The net result is a wideband analog feedback loop (the controller circuitry on the Driver Board) which is inside a lower bandwidth digital feedback loop.

The motor and its associated circuitry generate 12 tachometer pulses per revolution. Most of the display messages associated with the pumps express speed as an equivalent flow rate in milliliters per minute, assuming the tubing which is normally installed in that particular pump.

The pump driver circuitry is protected against overload conditions by a hardware circuit which will remove drive power if a current larger than about 2.5 amperes is supplied to any one of the motors. A circuit delay of one second or so is provided to allow for startup or dynamic braking which result in larger currents for short periods of time. (Please note: MTR 2 has a longer delay to enable "Fast Stops.") Additional protection is provided in the system firmware which will command motor speed to zero if tachometer pulses are not received within a reasonable time after a non-zero speed command has been sent.

The system also has protection against a pump runaway condition through an overspeed detection circuit and through firmware speed verification logic.

Clamps and Valves

The clamps and valves are connected to the Driver Board by means of the W7 cable. The clamp and valve control signals come to the Driver Board from the CPU VIAs where they originate by means of the W2 cable. The hold current limiting resistors mounted on the resistor pack are connected to the Driver Board at J37.

The clamps and valves are driven at a high current level for approximately 0.5 seconds after they are actuated by the CPU to assure that the plungers have been drawn into the solenoids. After the initial high current level, the pull in circuit turns off and the hold circuit which passes current through the current limiting resistor on the resistor pack, supplies a lower current to minimize heating.

Spinner

The spinner assembly is connected to the CPU by means of the Spinner Cable W11.

The spinner receives direction and speed commands from the CPU in terms of equivalent tachometer counts per 100 millisecond period. An internal controller maintains constant speed in spite of load changes. The spinner controller reports actual equivalent counts back to the CPU which are displayed in the spinner test menu. The relation between command and speed is 25 revolutions per minute per command bit.

At very low commanded speeds (below about 75 RPM) the operation of the spinner may appear to be intermittent as the driven device stops and starts.

Operation near maximum speed (> 5900 RPM) or under heavy loading or with direction changes without first stopping rotation may result in an audible "singing" sound as the drive circuitry goes into current limiting.



Note: There is no overspeed protection for the spinner.

Air Detector

The air detector subsystem consists of the sensor assembly which is located at the bottom center of the upper console and an electronics assembly which is piggy-backed on top of the analog processor. Connection to the CPU and Driver Board is by means of the W17 cable to the analog processor, the W1 cable to the CPU, and W2 cable to the Driver Board.

The air detector has two output lines which go to VIA inputs on the CPU. Each of these lines indicate the presence of fluid or air in the sensor head. The CPU tests each of these lines every 100 milliseconds to verify no hardware fault and the proper operating condition, i.e., air or fluid. A transition to "air" on one of the lines will cause a processor interrupt request (IRQ) and result in immediate response to the condition. One of the air detector outputs also continues on the Driver Board where it is one of the inputs to the power control and fault latch circuit. If a transition to "air" occurs while the air detector is enabled, the power to the donor connected motors is removed and the tubing clamps revert to their safe state.

The air detector input to the fault latch can be disabled (RED AIR DSBL*) by the CPU to allow normal system operation when it is known that there will be air in the detector line, during priming of the set, for example.

The fault latch and the air detector circuitry are extensively tested during system power-up and "install set" to ensure that hardware faults do not exist undetected. The circuitry in the detector electronics and the monitoring by the CPU is designed so that any single point failure will be detected by a mismatch in the condition indicated by the two output lines, or will falsely indicate "air" which is a donor safe condition.

Blood Detector

The blood detectors outputs are connected through a buffer to the CPU VIA inputs by means of the W9 cable to the analog processor and the W1 cable to the CPU. The CPU checks the logic state of these inputs on each 100 millisecond cycle.

The purpose of these detectors is to make certain the set tubing is firmly seated on the pressure transducers and not leaking. This is essential to proper system operation as the pressure measurements are used by the processor to develop the pump flow commands. Wetting of the transducer sterility protectors – caused by an air leak allowing fluid to move up the tubing set toward the pressure sensors – would result in pressure measurement errors.

The pressure transducer housing in which the Detector Circuit Board is mounted, also contains safety interlocks so that the absence of properly installed tubing will indicate the “blocked” condition.

Weigh Scale

The weigh scale consists of the load cell assembly and its adaptive hardware (bag/bottle hanger) and a portion of the Analog Board containing the associated amplifier and D/A and A/D convertors which communicate with the CPU Internal I/O bus by means of the W1 cable.

The analog processor test strip provides access to the weigh scale preamplifier output (TP3) as well as the scale error input to the A/D (TP2). In normal operation, TP2 should remain within the 0.46 to 4.6 volt linear A/D range. The load cell is powered from the analog processor 8.2 volt reference circuit. This reference is available on the test strip TP11.

Caution: Do not short TP11 to adjacent test pins.

The CPU reads the weight error signal on A/D channel number 2 and computes a weight value to write to the D/A. The A/D measurement represents the difference between the actual scale load and the value of the word written to the D/A. Each weigh scale A/D bit corresponds to 0.5 grams (-64 to +64 grams range) and weigh scale D/A bit corresponds to 5.0 grams (0 to 1275 grams range) load on the scale assembly.

When the value written to the D/A is close to the load on the scale, the error signal becomes small and an accurate weight can be computed. The weight measurement is performed every 100 milliseconds. Eight consecutive measurements are averaged to reduce the noise in the final weight value.

To determine the actual weight of plasma collected, it is necessary to take an initial reading of the hanger and empty bag. This initial reading is called a tare value and is recorded by the CPU during the "install set" sequence as a reference for later readings. When testing the scale, the test menu provides a means to obtain new tare value or to set the tare value to zero if desired.

Pressure Sensors

The pressure sensors are connected directly to the analog processor. The analog processor provides signal conditioning and A/D conversion. The resulting digital data is communicated to the CPU Internal I/O bus over the W1 cable.

The pressure sensor outputs are DC voltages proportional to the applied pressure. The nominal output with no pressure is 3.0 volts at J30, J31, or J32 pin 2. The pressure sensors are powered from the analog processor 8.2 volt reference output. This voltage is available on the test strip TP11.

Pressure measurements are taken each 100 milliseconds by the CPU. The displayed pressure values are the result of averaging 11 consecutive measurements to minimize the measurement noise due to pump pressure surges. The pressure measurements have a range of -6 to +9 PSI (-310 to +465 mmHg).

At system power up, the CPU records a set of initial values which is assumed to correspond to atmospheric pressure. The firmware specifies a window of acceptable atmospheric pressure values and will present a "Help #21" message for values outside the window. All subsequent measurements are referenced to these initial values and reflect pressure changes from atmospheric. A sensor with no pressure applied should indicate no more than 4 mmHg pressure drift due to machine warm-up.

Cuff Compressor

The cuff compressor assembly is connected to the Driver Board by the W7 cable. The compressor drive circuits are commanded from the CPU over the W2 cable from the VIA outputs.

The compressor drive circuit applies a switched 24 volt drive signal to the cuff compressor coil and a series resistor that resides on the resistor pack. The drive frequency is adjusted to achieve approximate maximum flow rate from the compressor rather than peak operating pressure. The compressor performance can be evaluated using the test menu.

Display

There are two display modules available on the Autopheresis-C Instrument. There is a text display module that has a row of 5 x 7 characters, and a graphics display module that provides 192 x 16 dots across the entire display.

The display module is connected to the CPU by means of the W1 cable. This cable contains an extension of the Internal I/O data bus as well as the decoded address control lines necessary for the peripheral controller interface.

Operation of the display requires that both the power cable W3 and data cable W1 be in place to avoid overloading the internal display tube power supply.

The system messages are supplied from the CPU using the standard ASCII character set and control characters along with a few added special characters to describe the control panel buttons and enhance the presentation of messages in some of the European languages. For the graphics display module, the Unicode character set, a two-byte character set that allows display of non-Latin characters such as Chinese or Japanese, can be enabled by placing a shorting block across the JF jumper on the Display Board. Unicode requires software version 6.0 or later, and a translation EPROM in U15 or U14 that supports the desired language. The Autopheresis-C software automatically detects the type of Display Board on the instrument, and for the case of the graphics display module, determines if Unicode mode is enabled or not.

The text display module has a self-test mode which can be entered by connecting test point TP1 to ground at TP2. In this mode, the display will slowly present the character set to confirm that it is operating properly. The graphics display module has a similar self-test mode which is entered by shorting the headers marked JT on the Display Board. The character sets can also be checked by entering the test menu and selecting Character List under the Message Test selection.

Membrane Panel and Donor Bar Graph

The membrane panel is connected to the CPU through one of the two bar graph modules by means of the W5 cable. The push button inputs and LED outputs go to VIA pins on the CPU.

All of the membrane panel switches are normally open and connected to the associated VIA line to ground when pushed. The bar graphs provide pullup resistors for the switches.

Low Voltage Power Distribution

The low voltage output from the column power supply is distributed as follows:

| | | |
|--------|---|---|
| +5 VDC | Analog Board (W3) Driver Board (W3) CPU Board (W3) Display Board (W3 and W1) | Spinner Board (W3) Bar Graph Boards (W5) Alert Light (W7) |
|--------|---|---|



Note: The actual power rating could be +5 to +5.1 VDC, depending on the power supply needed.

| | |
|---------|--|
| +15 VDC | Analog Board (W3) Driver Board (W3) CPU Board (W3) Air Detector Electronics (W17) |
|---------|--|



Note: The actual power rating could be +15 to +15.4 VDC, depending on the power supply needed.

| | |
|---------|--|
| -15 VDC | Analog Board (W3) Driver Board (W3) CPU Board (W3) |
| +24 VDC | Driver Board (W3) Spinner Assembly (W3) CPU Board (W2) |



Note: The actual power rating could be +24 to +26 VDC, depending on the power supply needed.

The system common ground point (Unipoint Ground) is made on the Driver Board in the vicinity of the J14 and J16 connectors. There is also a strap (W48) to the console back door at this point. The console back door is grounded to the console frame by means of two flexible foil ground strips at top and bottom of the door hinged side. For proper protection against electro-static discharge (ESD), the door latches must also make contact to the frame when the door is closed.

Each of the system components which protrude through the front panel has a grounding wire to meet the low frequency and DC ground conductivity requirements. In addition, each component is intimately mounted (either conductive surface to conductive surface or conductive gasket to conductive surface) to assure a high frequency ground for protection against ESD.

UPPER CONSOLE

This section of the manual discusses each of the major electronic components of the Autopheresis-C Instrument, their interface with each other, and how they control the mechanical components of the system.

The upper console of the system houses the basic electronic circuitry and interface responsible for the microprocessor control of system pumps, clamps, valves and sensors, as well as the appropriate safety and alarm functions.

Electronics Circuit Description

The five major circuit boards making up the system are:

- CPU Board
- Driver Board
- Analog Board
- Spinner Board
- Display Board

System Interconnection - An Overview

System interconnection is best demonstrated using the System Layout and Functional Block Diagram given as Figure 3-1.

In this diagram the CPU Board is shown connected to the Driver, Analog, Display, and Spinner Boards. It is also shown connected to some minor Circuit Board assemblies such as the donor bar graph and control panel (panel display). The low voltage power and remote interface cabling is illustrated as well.

The CPU Board is the primary controlling element in the system. This control will be detailed as we proceed with the discussion of the principles of operation.

The Driver Board provides the power circuitry required for locally controlling the blood, cell, and anticoagulant (AC) pumps, the reinfusion, blood, saline, and plasma line clamps, the cuff compressor and cuff dump valve, the prompt valve, the fault latch, the speaker and the fan.

The Analog Board converts the outputs of the venous (P1), transmbrane (P2), cuff (P3) pressure sensors, the hemoglobin (Hb) detection subsystem, and the weigh scale into data used by the CPU Board. It also provides an interface for the reservoir level sensors (S1, RS1) and (S2, RS2), the air detection subsystem, and the blood detectors (S4, S5).

The Spinner Board controls the spinner motor.

The Display Board displays the system messages indicating mode and system state.

Electronic Circuit Description

CPU Board

The CPU Board contains the system microprocessor - a 65C02 general -purpose 8-bit processor. It addresses 64 Kbytes of memory using 16 address lines (PRAD0-PRAD15) and 8 data lines (PROD0-PROD7).

The processor address lines are fed through a buffer and become address bus lines AB0 through AB15 which are distributed to the memory devices, the major address decoder, the I/O address decoders, the Versatile Interface Adaptors (VIAs), all of which are located on the CPU Board, and off board to the Analog and Display Boards (J2), the Driver Board (J6), and Spinner Board (J27).

To better understand the overall operation of the CPU Board it is necessary to view the system memory map. Figure 3-2 shows the memory and I/O devices as viewed from the processor's 64K address space. As mentioned before, the CPU can address 64 Kbytes which may be represented as hexadecimal addresses 0000 through FFFF. Each of the read only memory (ROM) devices contain 32 Kbytes of memory. Therefore you would expect the system to use only two ROMs, a low order ROM addressed from 0000 through 7FFF, and a high order ROM with addresses 8000 through FFFF. However, in order to provide additional program memory capability, four additional ROMs are added to the low order address portion of memory. Only one of these five 32 Kbyte sections are active at any time. Effectively then, the system can utilize up to six ROMs, one high order (fixed) ROM and five low order (switched) ROMs providing a total of nearly 168 Kbytes of program memory.

The selection of the low order ROMs is controlled by bank switch circuitry associated with the major address decoder.

Within the 64 Kbyte memory map small blocks are reserved for read/write memory (RAM) and system I/O. There are two 2-Kbyte RAMs, a low order RAM with addresses 0000 through 07FF and a high order RAM with addresses 0800 through 0FFF. Addresses in the range C000 through CFFF are reserved for the system I/O. Here the low order addresses C000 through C7FF are designated Internal I/O and addresses C800 through CFFF relate to External I/O.

The major address decode logic provides the signals that select between the high and low order ROMs, high and low RAM, and Internal or External I/O, by examining a few of the high order address lines.

The I/O address decoders provide further decoding sufficient to allocate small blocks of 16 addresses to each of the I/O functions.

The bidirectional processor data lines (PROD0 - PROD7) are buffered to create three separate data buses for the system. The memory devices (RAM and ROM) are connected to the Memory Data Bus (MED0 - MED7). All I/O devices on the CPU, Analog, and Driver Boards, are connected to the Internal I/O Data Bus (0D0 - 0D7). The External I/O Data Bus (8D0 - 8D7) is connected to the Spinner Board.

Internal I/O consists mainly of the VIAs, a data EEPROM, and the dip switches. The four VIAs provide the major portion of the processor's I/O capability. Each VIA can be programmed to provide two 8 bit parallel ports, an 8 bit serial port, and various combinations of 16 bit timers and counters. These interface lines allow the CPU to control clamps, motor direction, sequence the hemoglobin detector, pulse the cell reservoir circuitry, sense the control panel switches, count the motor tachometer pulses, and perform various other tasks which proceed far slower than CPU speed. Each VIA also provides an interrupt function (IRQ) for the CPU. Each of the VIAs has an adjacent test strip (TP1 - 4) which makes the VIA pins readily available for easy trouble-shooting. This is very helpful in checking signals from the Analog and Driver Boards which aren't conveniently accessed.

Notice on the block diagram that there is also an 8 bit data bus and 13 bit address bus from the VIAs to the data EEPROM. The EEPROM contains constants, such as the Hb detector calibration values, which are needed each time system power is restored.

The system interface with the control panel and donor bar graph is also accomplished with VIA ports. The J9 connector provides this access.

Another CPU I/O function provided from the VIAs, the data port, is accessible at the rear of the assembled console. This port has been used extensively in system firmware development. It provides an 8 bit parallel output port and a bidirectional serial port for data transfer. This port is under CPU firmware control.



Note: Connection to this port in an operating instrument must only be made using the approved optically isolated data cable.

The CPU dip switches are located in the lower left corner of the CPU Board and permit the service technician to select the proper message language for the installation and various other firmware customization features.

The CPU also contains the power monitor circuit. This circuit monitors, in a global fashion, the 24 VDC, the ± 15 VDC and 8.2 VDC. If any of these voltages are missing, the instrument will display the **Plug in Power Cord** message.

Driver Board

The function of the Driver Board is to support the operation of the mechanical components of the system such as the pump motor drives, valves and clamps, cuff compressor, speaker and fan in accordance with instructions from the CPU. This board provides control for four pump motors, however only three are used in the Model A-200. Drivers are also provided for eight clamps or valves, only six of which are used in the Model A-200.

The Driver Board may be divided into the following functional areas:

- Power Control and Fault Latch
- Pump Motor Controllers
- Clamp Drivers
- Miscellaneous Functions (cuff compressor, alert light, tone generator, and fan)

Incoming power is provided through two connectors: The +15 VDC, -15 VDC, +5 VDC, and 15 RTN, 5 RTN are used for general board power and are supplied through J14. The 24 VDC and 24 RTN power is used for the pump controllers, compressor driver, fan and clamp drivers and is input through J16.

The power control and fault latch circuits are designed to protect against faulty system operation should a hardware malfunction occur. Since many of the fault detection mechanisms are duplicated by similar protection mechanisms in the operating firmware, the hardware protection circuits are thoroughly checked during system self test each time power is applied and during "install set".

Inputs to the fault latch come from the operator's control panel stop button, the air detector, and from the CPU, as well as overspeed and overcurrent detection circuits on the Driver Board. The fault latch is designed so that if any abnormal indication is received, the 24 volt power to the AC and blood pumps is removed by deactivating the power relay RL1. If the fault is due to a watchdog timeout, each of the motor controllers is disabled by holding the tach pulse line high. The fault latch also provides outputs to the CPU to permit self test and appropriate fault diagnostic messages if required.

The fault latch input from the CPU consists of a train of pulses (MTRENSTB) which the watchdog timer (U36 and U37) requires to occur within specific intervals. The CPU normally generates this output twice each 100 millisecond cycle. CPU malfunction will result in the watchdog timing out and is indicated by the DEADCMPTR line. An attempt is made to recover the CPU by means of the non-maskable interrupt line (NMI), but the power control and fault latch circuits will have independently put the system into a safe state.

The pump motor drive circuits for the AC, blood, and cell pumps are essentially identical, so the following description will reference only the motor 1 drive (AC pump). The differences will be detailed later in this discussion.

The pump motors are a 3-phase, brushless design which requires commutation by the drive electronics. The rotor position information required to perform commutation is determined by three Hall sensors and supplied to the drive electronics as a three bit binary code. The commutation pattern is coded into a PROM (U40) and accessed using the Hall code plus a direction control bit from the CPU as an address. Two different patterns are coded to accomplish motor reversal. The PROM outputs control the Half-Bridge drivers (DR15 - DR20) which connect one of the motor phases to 24RTN, allow a second to float open, and pulse the third to +24 volts under control of the pulse width modulator (U11).

The PROM also generates a square wave output with six cycles per motor revolution. The square wave is processed by U16 and associated circuitry to develop a pulse train called MTR1TACH whose pulse rate is 12 pulses per motor revolution. This pulse train is counted by one of the VIAs on the CPU and gives a measure of motor speed.

The current in the motor is sensed by R16 and compared (U27) to a fixed reference voltage to develop the overcurrent fault signal. This signal will protect the motor drive circuit against a sustained overload.

The motor voltage, which is partially due to the drive output pulses and partially due to back EMF which results from generator action, is also compared to a reference in U33 to develop the overspeed fault signal. This signal verifies that the motor speed is within normal operating limits.

The motor controller receives a speed command from the CPU by means of the Internal I/O Data bus. The command results in an output voltage from the digital to analog convertor (DAC) circuit (U7 and AR1). This voltage is compared to the averaged value of the tachometer pulse train in the pulse width modulator (U11) to provide a pulse whose width will increase if actual motor speed is lower than the commanded speed.

The primary difference between the pump motor drivers is that the 24 volt power is only available to the AC and blood pumps when the fault latch indicates "no fault", whereas 24 volt is always available to the cell pump. A second difference relates to the circuit delay in sensing an overcurrent fault. The overcurrent circuit for the blood pump has an approximate 3-second delay to permit the motor to be "fast stopped" by commanding a motor reversal without tripping the overcurrent fault detection circuit. Note also the blood pump is provided with a hardware direction indication (U23) which can be monitored by the CPU.

The eight Clamp Drivers provide on/off control of the tubing clamps and cuff dump and squeeze (prompt) valves. The eight circuits are nearly identical so only the saline clamp driver will be discussed. Two drive transistors are used so that the large current required for solenoid-pull-in can be reduced to a smaller hold current to minimize power consumption. The pull-in current is held for approximately one-half second after the driver is commanded on. The resistors that limit the hold current are located off board on the resistor pack.

The differences between hold resistor values relate to the design differences between normally open (N/O) and normally closed (N/C) clamps. The N/O clamps require a 30 ohm value while the N/C clamps use a 40 ohm resistor. The valves require less current and, therefore, have a 75 ohm resistor.

The miscellaneous functions include the compressor driver circuit, the alert lamp driver, the tone generator, and the fan.

The compressor drive circuit consists of an oscillator (U3), some wave shaping logic (U1 and U2) and two half-bridge drivers (DR1 and DR2). The frequency can be adjusted by means of R123 to match the mechanical resonance of the compressor assembly and get maximum flow rate.

The alert light buffer (Q15) provides the relatively large current drive required by the alert light.

The tone generator (U32 and Q1) develops the tone frequencies used to attract the operators attention.

The fan is connected to the 24 volt input power through a series resistor.

Analog Board

The function of the Analog Board is to collect information from the various system sensors/detectors, and convert the analog signals into digital form such that further processing by the CPU is possible. The circuits involved in the process are:

- Analog-to-Digital (A/D) Converter
- Analog Reference Regulator
- Pressure Sensors Inputs (P1 Venous, P2 Transmembrane, P3 Cuff)
- Weigh Scale Electronics
- Hemoglobin (Hb) Detector
- Cell Reservoir Sensors
- Air Detector and Blood Detector Interfaces

The A/D converter contains an 8-channel multiplexer (U1), which receives analog signals from the various sensing devices. The 8 channels provide for three pressure measurements, two Hb detector measurements, and one weigh scale measurement. (There are two spare channels.) Each of the analog input signals is first passed through an RC network to eliminate noise. The digital output of the A/D converter is sent back to the CPU on the Internal I/O data lines (J3).

The analog reference regulator (VR1), takes the +15 VDC supply as an input and outputs the 8.2 volt precision reference voltage for the pressure transducers and load cell. This 8.2 reference is further divided by a resistor/amplifier network to establish upper and lower reference voltages for the A/D converter (U1). The A/D references span approximately 4 V, with the lower reference roughly .46 V (TP19) and the upper reference 4.56 V (TP20).

The pressure sensors (P1/J30, P2/J31, P3/J32) operate from the 8.2 V. Each sensor provides an output voltage, which is related to the applied pressure.

The load cell (J29) for the weigh scale is also powered by the 8.2 volts. It contains a bridge circuit, which returns a differential error voltage proportional to the weight applied, that is, the amount of plasma collected. This voltage, which is typically only a few microvolts, is amplified by U3 whose gain may be adjusted to correct for load cell and amplifier tolerances. The output of U3 is combined with the output from U1, a digital-to-analog

convertor (DAC) which is commanded from the CPU, to form an error signal measured by the A/D convertor. The computer firmware adjusts the value of the DAC output and combines it with the A/D measurement to determine the scale reading.

The Hb detector electronics consists of a two color (red and green) LED driven under CPU control and two photodiode/amplifier circuits which provide inputs to the A/D.

The emitter LED and photodiodes are installed on the back side of the Analog Board where they are enclosed in the Hb Detector optics assembly that projects through the system front panel. The plasma line is placed in a transparent tube guide that is part of the optics assembly.

The Hb Detector optics also contain three mirrors which are arranged to allow measurement of two light paths. A small percentage of light emitted by the LED is routed directly to the reference channel detector. This direct light output measurement permits computer normalization of the raw hemoglobin signal by compensating for variations in LED output. The remaining portion of light is concentrated on the tube guide where it passes through the fluid in the tubing and then is directed to the signal channel detector.

The CPU controls the drive to the red/green LED in a three phase cycle: red on, green on, both off with each phase lasting for 1/10th sec. Two ADC values are measured at the end of each phase, representing the amount of light present at the signal and reference photodetectors. These numbers are the "raw" measurements referred to in the firmware documentation and display messages. In particular "Hb rawsigR" is the signal channel measurement made for the red phase, "Hb rawsigG" is the signal channel measurement made for the green phase, and "Hb rawsigB" is the signal channel with red and green LEDs off phase (or background) measurement.

The CPU processes these six values to determine four "corrected" measurements ("Cor Ref R" and "Cor Ref G" for example), that is, the red and green measurements with the background light subtracted for each of the two channels. This data is further processed by dividing each of the corrected signal measurements by the corresponding corrected reference and multiplying by 256 to derive the "normalized" red and green measurements, that is, those corrected for LED variations. Finally, the relative spectral transmission "RELSPT" of the fluid is calculated by dividing the normalized green measurement by the normalized red measurement and again multiplying by 256.

During **INSTALL SET Ø Ø**, a reading is taken by the Hb detector with an empty tube in the guide. This empty RELSPT is stored by the CPU and used to determine the percent change in RELSPT when the tube is filled with product during normal system operation.

A calibration constant for each system is determined at the time of installation by inserting a colored reference filter in the Hb tube guide in place of the tube. The color filter sets the threshold percent change in RELSPT allowed for the most sensitive Hb detector operation. The resulting calibration constant is stored in the CPU data EEPROM so that it can be retrieved each time the system is powered on.

The cell reservoir level sensor circuitry consists of four infrared LED/sensor pairs and a transistor that operate as a unit under software control. The infrared LED/sensor pairs are mounted in the support housing as part of the Analog Board. This assembly is positioned on the rear of the front panel behind the reservoir slot. Under CPU control, the drive transistor pulses the LEDs. As the level of blood in the cell reservoir changes LED/sensor pairs will become blocked or unblocked providing level information to the CPU for control of system sequencing.

The air detector (J45) and blood detector (J44) interfaces are directly connected to the CPU Board through connector (J3) without intervening circuitry.

Spinner Board

The basic function of the Spinner Board is to control the spinner motor, which operates the separation device. The inputs to the board are +5 VDC, +24 VDC power and the External I/O data bus, which provides the CPU commands. The 24 VDC power is directly transferred to the spinner motor for its operation while the 5 VDC provides the necessary power for the Control Logic. The board can be divided into three functional groups: Bias Supply, Power Bridge, and Control Logic.

The Bias Supply provides operating voltages for the Power Bridge isolation and drive circuitry.

The Power Bridge connects each of the three motor phases to either the 24 volt input power, the 24 volt return, or allows them to float as determined by the state of the six logic inputs to the optoisolators. The isolators prevent the high frequency voltages and currents present in the bridge from interfering with the logic signals in the system. The bridge also contains a current sensing resistor for circuit protection and local power filtering for the 24 volt lines.

The Control Logic consists of the same 8741 peripheral controller that is used in the display module (different internal firmware of course) and a few logic devices to interface with the power bridge, the External I/O bus and the motor Hall devices. The controller firmware communicates with the system CPU and accepts speed commands while reporting back actual motor speed every 100 milliseconds. The controller reads the Hall inputs and supplies logic outputs to commutate the spinner motor and maintain constant operating speed in spite of load changes.

Display Board

The Display Board receives the messages to be displayed from the CPU. The display controller has two major tasks to accomplish: communications with the host processor and providing the refresh cycle for the display tube.

The primary component of the text display module is the 8741 peripheral controller. The controller is a complete 8 bit microprocessor containing its own firmware and RAM. The controller has a direct interface with the host processor through the internal I/O bus.

The power for the display module controller and support logic is taken from the +5 volt supply. The +5 volts is also converted to provide the AC filament voltage and low power +45 volt output for the display tube.

A useful test point on the text display module is labeled DISPTTEST (TP1) (display test). With this pin low and system power applied, the display module goes into an automatic self test mode whereby the entire character set will be displayed. This feature can be used to determine whether the CPU or display has failed if no messages occur at system power-on.

The graphics display module has the same operating principles as the text display module. It uses the M37451 microcontroller as its primary component. The graphics display has a similar test feature where the entire character set can be displayed, one character at a time. This test can be invoked by placing a shorting block on the headers marked JT.

Support Column

The support column provides structural support for the upper console as well as housing the system, power switch and input power functions.

The support column electronics house the following:

- Low Voltage Power Supply
- Backup Battery
- Isolation Transformer
- Power Input Module

The support column supplies +5 VDC, ± 15 VDC and +24 VDC to the upper console.

Support Column Electronics

The support column contains the main power supply, the battery which supplies partial system power if the input power line is interrupted, the line isolation transformer, and the power input module.

Low Voltage Power Supply

The main power supply accepts a nominal 115 VAC or 230 VAC input from the isolation transformer and outputs +24 VDC, and the +15 VDC and -15 VDC. These supply outputs are not backed up by the battery. An intermediate output supplies an internal battery charging circuit which is connected to the 12 volt lead-acid battery used for backup system operation. The +5 VDC power supply output convertor operates directly from the battery.

With a Cherokee power supply, outputs may be individually adjusted and are protected from accidental overload by current limiting circuitry.

With a Converter Concept power supply, the only outputs that may be adjusted are the 24 VDC and the 5 VDC.

Cooling for the power supply is provided by mounting it against the side of one of the two system air intake ducts. The base of the column contains mounting provisions for an air filter assembly.

Backup Battery

The backup battery is mounted inside the column assembly. The battery holder bears a label with information relating to the battery age. Normal lifetime for a battery of this type is approximately five years. Care should be taken not to accidentally short circuit the battery.

Isolation Transformer

The line isolation transformer provides the very low line leakage currents demanded of patient connected equipment. It also permits operation of the system from either a nominal 115 VAC or 230 VAC power line and over a wide range of line frequencies. The operating voltage selection is made on the power input module.

Power Input Module

The power input module integrates a line cord connector, line voltage selector, fuse holders, and line noise filter into a compact assembly.

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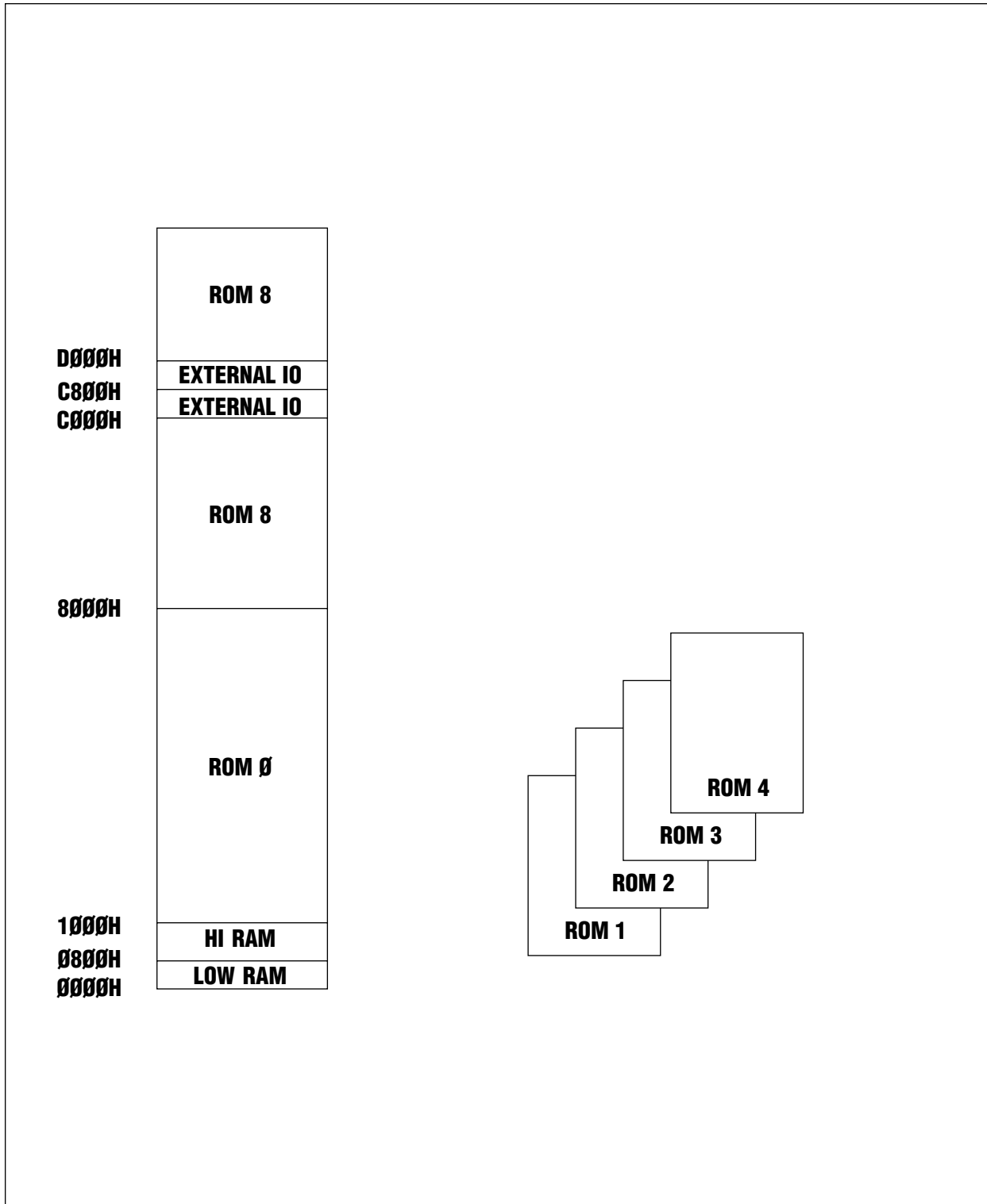


Figure 3-2 - System Memory Map

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INTRODUCTION

This section describes how to make adjustments on the Autopheresis-C Instrument.

All tools used for calibration(s) must be calibrated according to approved procedures.

ELECTRICAL ADJUSTMENTS

- Pump Overspeed Threshold (9.35 VDC)
- Reference Voltage for Pressure Transducers and Weigh Scale (8.196 VDC)
- Cuff Compressor Frequency Adjustment
- Weigh Scale Adjustment
- Speaker Volume

MECHANICAL ADJUSTMENTS

- Pressure Transducer
- Hb Detector

SPINNER SEAL FORCE CALIBRATION PROCEDURE

ELECTRICAL ADJUSTMENTS

Pump Overspeed Threshold (9.35 VDC)

The pump threshold voltage should be verified before replacing the Pump or Driver Board for an overspeed alarm.

Monitor overspeed threshold voltage on the lower right hand side of the Driver Board at TP 19 with a voltmeter. Use TP5 for ground.

Adjust R116 until TP 19 measures 9.35 VDC.

Analog Reference Voltage for Pressure Transducers and Weigh Scale (8.196 VDC)

The 8.196 VDC analog reference voltage should be verified when the instrument displays pressure transducer or weigh scale problems.

Monitor analog reference voltage on the 22 pin test connector, pin 11 on the Analog Board with a voltmeter. Use TP 23 as ground.

Adjust R26 until pin 11 measures 8.196 VDC.

Cuff Compressor Frequency Adjustment

If the cuff compressor is slow to inflate the cuff compressor driver may need adjustment.

Go to **P/Wt/Cuff/Air Tests** and press ADVANCE ▼ to **P1 P2 P3 Display** within the test menu.

Install "Y" tubing behind the pressure transducer door in the area of the blood detectors and close the door.

Press ADVANCE ▼ to **xxx yyy zzz pp**. The display indicates as follows:


xxx = P1 pressure



yyy = P2 pressure

zzz = P3 pressure

pp = cycle counts of cuff compressor

Pinch the cuff line with your fingers at the instrument output port.

While monitoring the display, press and **hold**  , P3 must reach at least **171 mmHg** and the cycle count must not exceed **25**. If the system fails either portion of this check, a simple adjustment may resolve the problem. To make the adjustment, do the following:


1. Locate the compressor frequency adjustment potentiometer [R 123] on the upper left section of the Driver Board. Pinch the cuff line with your fingers at the instrument output port.
2. While monitoring the third number, press and hold the  button. Adjust [R 123] potentiometer for the maximum reading of cuff pressure (Third number). Then turn [R 123] counterclockwise one half turn.
3. Release pressure by pressing  . Also release line at output port after each [R 123] adjustment to allow pressure to equalize between adjustments.
4. Perform pressure test.


Weigh Scale Adjustment

When an instrument is unable to pass daily weigh scale verification an adjustment may be required.

Go to the Weigh Scale #1 test display within the test menu.

Press ADVANCE  to Wt. gms = xx OFF.

You will see some value that indicates the untared weight on the scale. Verify that ADVANCE  toggles the tare of the scale to zero.

Press  to Wt. gms = xx LOW. This indicates that the spinner is running at LOW speed.

Adjust R16 until each weight tolerance is within specification. Perform weight test until no adjustment is necessary between weights.

Scale #1

0 = 0 ± 1 gram

500 = 500 ± 2 grams

1000 = 1000 ± 3 grams



Note: The weigh scale adjustment should not require an excess of three attempts to complete.

Speaker Volume

Go to P/Wt/Cuff/Air Tests and Press ADVANCE ▼ to P1 P2 P3 Display.

Press ADVANCE ▼ to xxx yyy zzz pp. You should have a continuous tone.

Adjust the volume potentiometer located on the Driver Board until the desired speaker volume is achieved.

MECHANICAL ADJUSTMENTS AND REPAIRS

Pressure Transducer Assembly

The pressure transducer assembly “houses” the following:

Two (2) optical blood level detectors covered by a card reader

One (1) venous pressure transducer (P1)

One (1) device pressure transducer (P2)

In the event of a fluid spill/contamination, the assembly components should be cleaned to remove debris and to ensure proper functioning of the optical detectors and pressure transducers.

1. Remove pressure transducer cover as defined in the PARTS REMOVAL section (See Figure 4-1).

Tools required: 5/32" Hex Key.

- a. Pull the transducer cover plate out. Locate the socket head screw on top of the transducer cover plate. Using a 5/32" hex key, remove the screw by turning counterclockwise. Support transducer cover plate as it will be loose.
- b. Remove the transducer cover plate and clean.
- c. Observe the black “flags” between each optical detector. Verify each flag spring is in place by pressing down on each flag and then releasing. The flags should return to their original position.
- d. Observe windows of the assembly holder, card reader. Make sure they are not scratched or missing. Otherwise replace card reader assembly.



Note: Flags must be vertical and centered before reassembly.

2. Installing the pressure transducer cover.

Tools Required: 5/32" Hex Key.

- a. Place the pressure transducer cover plate over the two (2) optical detectors.
 - b. Insert a socket head screw into the screw hole on the cover plate. Using a 5/32" hex key, securely fasten the screw by turning it clockwise.
 - c. Press to close the transducer cover plate.
3. Adjust the pressure transducer cover movement if pressure transducer door is "loose," and does not "snap" closed.
- a. Open rear door of instrument and gain access to the transducer cover adjustment on the right side of the pressure transducer.
 - b. Adjust the spring tension using a small 1/8" hex key (1-1/2" long) until the transducer cover snaps shut.

Hb Detector Door Adjustment

Locate adjustment screw on right hand side of Hb Detector door. Turn adjustment screw using a small flat blade screw driver. Adjustment screw has a nylon insert on screw ensuring adjustment remains constant.

Evaluate Hb detector door latching force by pushing closed Hb Detector door (See Figure 4-2).

SPINNER SEAL FORCE CALIBRATION PROCEDURE

Required Tools:

Seal Force Adjustment Tool (T221C)

Calibrated weight inclusive in T221C

Non-Ferrous adjustment tool for potentiometers

Digital MultiMeter (DMM)

TF22PC 22 pin Test Connector

Calibrated weight 500, 1000 grams


1. Verify reference voltage 8.196 VDC on the Analog Board by measuring voltage across TP11 (plus) and TP23 (ground) with a DMM. Adjust the voltage if necessary using R26 on the Analog Board.
2. Enter the test menu by opening the rear door of device and switching SW1 of S1 on the CPU Board **ON**. Plug power cord into outlet, and turn unit **ON**.
3. Using the following calibrated weights, verify correct operation of the weigh scale. The acceptable variation is as follows:








0 = 0 ± 1 gram

500 = 500 ± 2 grams

1000 = 1000 ± 3 grams

If necessary, adjust weigh scale using R16 on the Analog Board. Re-check both weights and re-adjust if necessary.

4. Turn instrument power OFF. Unplug weigh scale cable (J 29 on the Analog Board) and plug the seal force adjustment tool (T221C) into J 29.
5. Turn S1 switch SW1 on the CPU Board to the ON position. Turn instrument ON.
6. After self test routine, display will read Test (Press STOP). Press the  button and wait for Test Menu.

7. Press the  button until [P/W/Cuff/Air Tests] is displayed. Press the ADVANCE  button. The display will read [P123 display]. Press the  button. The display will read [Weigh Scale #1]. Press the ADVANCE  button. The display will read [Wt gms = ## OFF].
8. Hold the seal force adjustment tool on top of the instrument. Place the 380 gram weight on the seal force adjustment tool. Gently spin the weight on tool. Press the ADVANCE  button to tare the weight. The display will read [Wt gms =0 OFF] (± 1).
9. Remove the 380 gram weight from the seal force adjustment tool. Display will indicate a negative number. Place the seal force adjustment tool into the plasma cell drive.
10. Close the lower device support slowly. Move the seal force adjustment tool until the tool is flush with the lower device support.
11. Press the  button to start the spinner motor. The display will change from [Wt gms = ## OFF] to [Wt gms = ## LOW].
12. Turn the knurled housing on the seal force adjustment tool until the display goes to zero as defined in Step 7.
13. Press the  button to stop the spinner. Open the lower device support and remove the seal force adjustment tool.
14. Turn instrument power OFF. Unplug seal force adjustment tool from connector J 29. Reconnect weigh scale to J 29.
15. Using the following calibrated weights, verify correct operation of the weigh scale. The acceptable variation is as follows:

| | | | |
|------|---|------|---------------|
| 0 | = | 0 | ± 1 gram |
| 500 | = | 500 | ± 2 grams |
| 1000 | = | 1000 | ± 3 grams |
16. Turn S1 switch SW1 on the CPU Board to the OFF position. Turn instrument OFF. Test plasma cell drive by performing a complete test procedure data sheet.

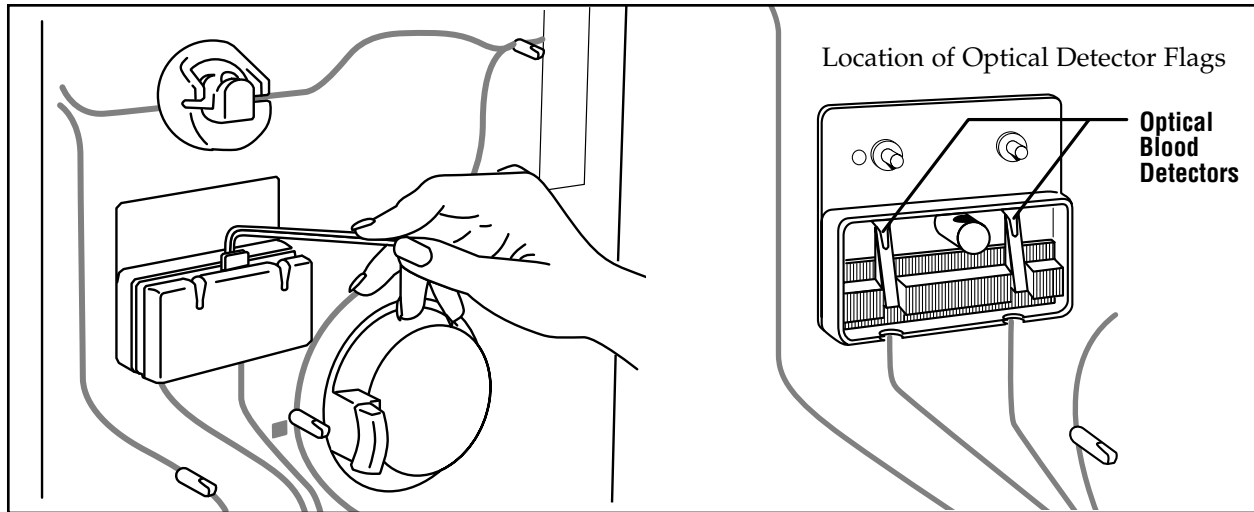


Figure 4.1 Removing the Pressure Transducer Cover

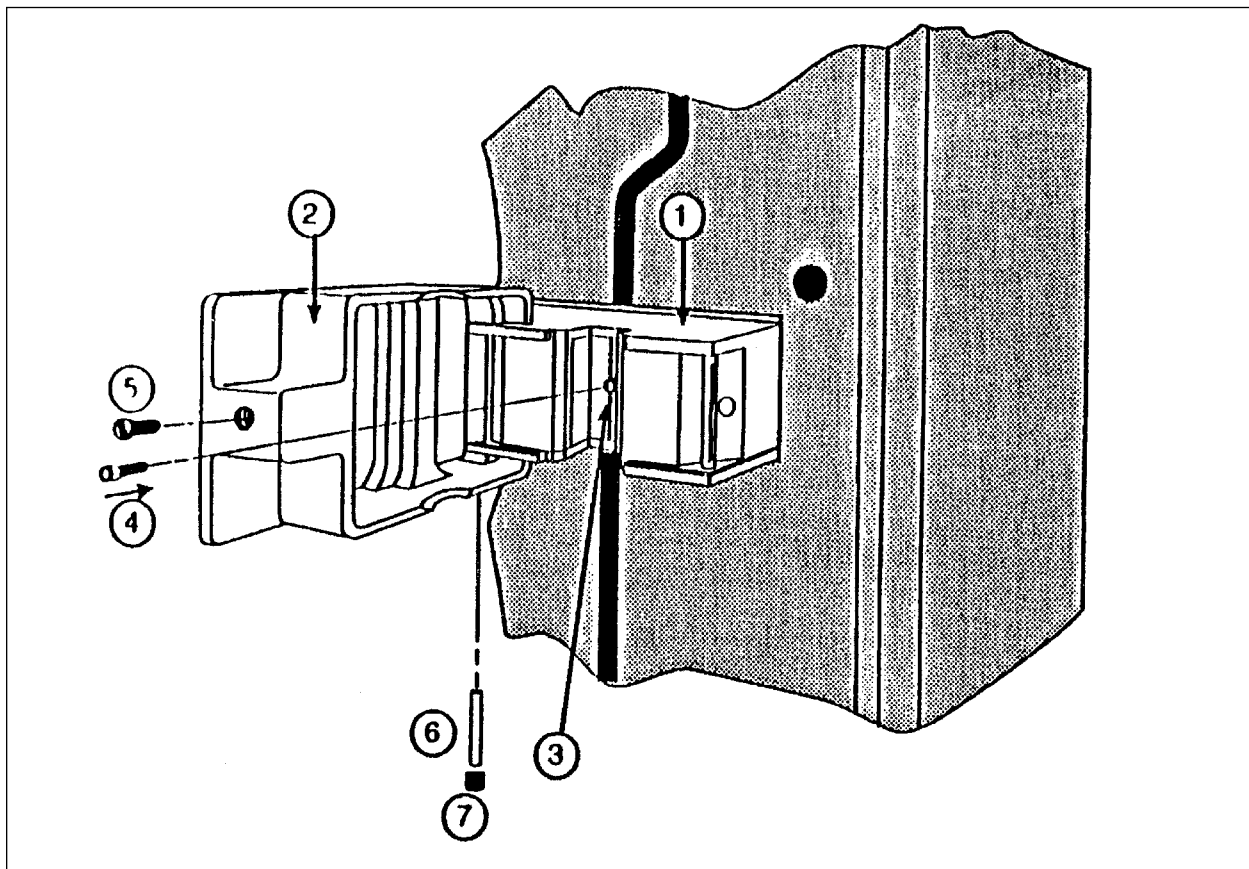


Figure 4.2 Hb Detector Door Assembly

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INTRODUCTION

The preventive maintenance section describes what must occur to optimize system performance. The following cleaning, and scheduled maintenance will be reviewed:

EXTERNAL CLEANING

- Exterior
- Air Detector
- Reservoir Channel and Hemoglobin Detector
- Membrane Panel Switch
- Air Filter
- Motor Cup

INTERNAL CLEANING

- Inside the Upper Console
- Card Reader Window
- Pump Assemblies

SCHEDULED MAINTENANCE

- Daily
- Monthly
- Annually

Use a mild soap or approved cleaner applied to a lint-free swab, cloth or brush when cleaning the instrument. Do not use solvents or abrasive cleaners on the instrument.

EXTERNAL CLEANING

Exterior

Clean the exterior of the instrument. Once the instrument is clean remove any excess cleaners.

Caution: Do not use solvents or abrasive cleaners on the exterior of the instrument.

Air Detector

Clean the air detector to provide optimal transmission and reception of the ultrasonic air sensor. The air detector channel must be dry before using.

Reservoir Channel and Hemoglobin Detector

Clean the clear plastic protecting the reservoir and hemoglobin optical detectors.

Caution: Do not use solvents or abrasive cleaners that will cloud lenses. Dry lenses thoroughly with a lint-free swab.

Membrane Panel Switch

The membrane panel switch with display window must be cleaned to ensure visibility of display. Clean membrane panel switches.

Caution: Solvents or abrasive cleaners will damage the plastic exterior surface on the membrane switch.

Air Filter

The air filter is located on the bottom of the support column. Push down on the tabs on the air filter tray located at the base. Replace air filter if damaged. Wash air filter in soapy water. Rinse well and air dry. Insert the dry foam pad at the bottom of the support column.

Caution: Do not operate the Autopheresis-C Instrument unless the air filter is installed.

Motor Cup

Clean the motor cup if a leak has occurred in the separation device.



Note: Use extreme care when cleaning motor cup to prevent misalignment.

Caution: Misalignment of the motor cup may result in a malfunction. Do not insert a tightly wadded cloth or a sharp instrument into the motor cup.

INTERNAL CLEANING

Upper Console

Internal Cleaning Using Compressed Air

Isolate instrument from other instruments. This is to ensure dust removed from the instrument will not be reintroduced into production area.

Gain access to the upper console by turning counterclockwise one-quarter turn both latch screws on rear door.

Using compressed air, remove all dust from the following areas (Start from the top and work downward):

- Fan

- All Flat Surfaces

- Weigh Scale

- Printed Circuit Boards

Once cleaning is complete, verify all connectors are firmly locked in place.

Internal Cleaning Using Vacuum Cleaner

Gain access to the upper console by turning counterclockwise one-quarter turn both latch screws on rear door.

Using a natural hair (non-conductive) brush, remove all dust from the following areas while vacuuming (start from the top and work downward):

- Fan

- Printed Circuit Boards

- All Flat Surfaces

- Weigh Scale

Once cleaning is complete, verify all connectors are firmly locked in place.

Card Reader Window

Card reader windows behind the transducer cover. Replace card reader windows if scratched or missing.



Note: Clean card reader window by removing transducer cover.

Caution: Do not use any solvents or abrasive cleaners that can scratch or cloud the card reader window. Do not allow liquid to enter transducer ports.

Allow assembly to dry before installing the disposable set. Never attempt to clean foreign debris from pressure transducer orifices. Invasive type probing will damage the pressure transducers.

Pump Assemblies

If blood or solutions have gotten inside pump assemblies, remove pump cover, roller cage assembly, and mandrel per parts removal procedure and clean. Rinse and dry the components before assembling.



Note: Do not soak roller cage for more than two minutes. Dry roller cage immediately after cleaning.

SCHEDULED MAINTENANCE

The following scheduled maintenance is recommended for the Autopheresis-C Instrument.

Daily Tasks

Verify weigh scale operation per Operator's Manual.

Review recorded system messages that interfered with normal system operation that may indicate need for service.

Clean any fluid spills from instrument.

During installation check, inspect for noisy/clicking pumps. Replace any mandrels making clicking noises.

During install check, monitor install check messages **Leak at P1** and **Leak at P2** identifying possible P1 or P2 Luer damage. Replace defective Luers per PARTS REMOVAL section.

Inspect the lower device support for smooth operation.

Open and close all pumps, checking for smooth operation with no loose components.

Verify hemoglobin detector door opens and closes smoothly. Adjust as defined in MAKING ADJUSTMENTS section. Hemoglobin detector door must latch securely.

Check pressure transducer door for proper operation. Push and pull on door. Door must slide in and out freely. If pressure transducer door does not snap shut, adjust as defined in the MAKING ADJUSTMENTS section.

Verify collection hanger is free from damage and securely fastened to the weigh scale.

Verify power switch is securely attached to support column.

Verify instrument is level, balanced and stable.

Verify power cord is free from rips and tears. Replace if frayed or damaged.

Verify pressure cuff sleeve and tubing is free from rips and tears. Replace if damaged.

Monthly Tasks

Clean the reservoir channel hemoglobin detector.

Clean the air detector channel.

Verify casters can lock, and roll freely. Replace if needed.

Remove pump roller cage per PARTS REMOVAL section, and verify pump rollers turn freely. Repair or replace any worn or loose components.

Inspect transducer Luers for blockage or damage to the outside surface.

Remove and clean lower air filter.

Annual Tasks

Follow cleaning instructions identified within this PREVENTIVE MAINTENANCE section.

Clean interior of instrument.

Perform Autopheresis-C test procedure annually to ensure instrument is functioning to specification.

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INTRODUCTION

This section describes how to replace service parts and service parts requiring advanced training for the Autopheresis-C Instrument.



Note: Once the instrument is repaired, the Autopheresis-C Test Procedure Data Sheet must be performed unless otherwise noted.



Note: Gain access to the upper console by turning counterclockwise one-quarter turn both latch screws on rear door.

SERVICE PART DESCRIPTION

- Active Pressure Cuff
- Air Detector
- Blood Detector Assembly
- Button, USA (Bag Hanger)
- Cuff Compressor
- Clamp Assembly
- Fan, Cooling
- Filter Frame, Replacement Filter
- Lens, Reservoir Molded
- Luer Adapters, Pressure Transducer
- Membrane Panel
- PCB, Analog
- PCB, CPU
- PCB, Bar Graph
- PCB, Display
- PCB, Driver
- PCB, Spinner
- PCB, Air Sensor

- Pressure Transducer (P1 and P2)
- Pump Assemblies
- Pump, Cover, Rotor and Mandrel
- Speaker
- Support Column
- Tube Guide
- Weigh Scale Assembly
- Resistor Pack Board

ADVANCED TRAINING SERVICE PARTS

- Lower Device Support
- Plasma Cell Drive
- Power Supply
- Battery
- Power Switch Module



The following tools are required to perform service parts removal:

| | |
|--------------------------------|--------------------------------|
| EPROM Removal Tool | Screw Driver, Flat Blade #1 |
| Calibrated Weight 500, 1000 gm | Screw Driver, Flat Blade #2 |
| Channel Locks | Screw Driver, Flat Blade large |
| Hex Key, Ball Tip; 1/8" | Screw #256 |
| Hex Key, 3/32" | Nut Driver, 11/32" |
| Hex Key, 5/64" | Nut Driver, 5/16" |
| Hex Key, 3/16" | Volt Meter |
| Hex Key, 5/32" | Wrench, 3/8" |
| Hb Calibrator Tool | Wrench, 1/2" |
| Screw Driver, Phillips #1 | 50 cc Syringes |
| Screw Driver, Phillips #2 | "Y" Section of Pump Tubing |



Note: Before performing any of the following repairs, power must be removed from the device and anti static precautions must be observed. All repairable parts removed from a device must be repackaged utilizing packaging from the replacement part.



Note: To enter the "Test Menu", SW1 of S1 on the CPU, PCB must be ON. After display scrolls through a start up sequence, the display will prompt you to press . Once  is pressed, Test Menu will be displayed.

SERVICE PART DESCRIPTION

Active Pressure Cuff

Active pressure cuff (P3) is located inside the upper console, next to the Display PCB.

1. Loosen 2 each 11/32" poly lock nuts holding P3 active pressure cuff assembly in place. Lift active pressure cuff off mounting posts.
2. Remove tubing at compressor and base of upper console.
3. Install replacement active pressure cuff onto mounting posts. Tighten 2 each poly lock nuts.
4. Install tubing at compressor and base of upper console.

Air Detector

The air detector is located at the bottom/front/center of the device.

1. From the rear of the device, locate two each cables from air detector assembly. Follow cables from air detector to the Air Detector PCB. Remove two each cables by pulling straight away from the Air Detector PCB. (**Note:** You may have to twist connector when removing cable. Do not pull on wire.)
2. Locate ground wire attached to air detector. Remove 5/16" nut holding ground wire to chassis of device. (Leave ground wire with air detector assembly.)
3. Face front of device and look up at the air sensor assembly. Remove two each Phillips screws and lock washers attaching air detector to upper console assembly.
4. Remove defective Air Detector by carefully pulling ground wire, and air detector cables through access hole in front of upper console.
5. Install replacement air detector by feeding air detector cables, and ground wire through access hole in front of upper console. Install Phillips screws and lock washers removed in Step 4.

6. Attach ground wire on replacement air detector to ground lug with 5/16" nut removed in Step 3. Ensure there are three each ground wires attached to ground lug.
7. Thoroughly push both air detector cable connectors into receptacles marked "T" and "R" on the Air Detector PCB. These cables can go into either receptacle.

Blood Detector Assembly

The blood detector is located on the P1 P2 pressure transducer assembly.

1. Locate Blood Detector PCB under the P1 P2 pressure transducers. Remove connector P 18 observing orientation to J 18.
2. Using a 3/32" hex key, remove 4 each cap screws holding the Blood Detector PCB to the P1 P2 pressure transducer.
3. Gently pull Blood Detector PCB toward you by placing fingers on each end of the PCB. Remove PCB from the device.
4. Install replacement Blood Detector PCB with J 18 on top side of the PCB. Install 4 each 3/32" cap screws removed in Step 3. Do not over tighten cap screws.
5. Reconnect connector P 18 onto Blood Detector PCB J 18.

Button, USA (Bag Hanger)

A modification to bag hanger buttons has been made. New buttons have a hook preventing bags from slipping off bag hangers.

1. Remove the bag hanger from the weigh scale assembly by removing mounting hardware with a 5/32" hex key.
2. Grasp each bag hanger button with channel locks. Gently twist the buttons back and forth while pulling out button.
3. Attach new pressure buttons (P/N 9185000015) with pan head screws (P/N 4059979022). Before tightening into place, ensure button hooks are pointing toward weigh scale mounting hole (up).
4. Re-attach bag hanger to weigh scale with a 5/32" hex key.
5. Perform daily weigh scale verification per Operator's Manual.

Cuff Compressor

The cuff compressor is located under the plasma cell drive on the upper left hand corner of the device (as seen from the rear).

1. Using 1/8" ball tipped hex key, loosen two each mounting screws on each side of compressor assembly.
2. Disconnect wire connector by pulling back on tab. Lift compressor cuff up and away from front housing.
3. Disconnect tubing at center of compressor leaving tubing between two outlet ports on compressor.
4. Install replacement compressor cuff by positioning compressor on two mounting screws loosened in Step 2, then tighten screws.
5. Re-connect wire connector. Re-attach compressor tubing removed in Step 4 to compressor assembly.
6. Test compressor cuff by performing a complete Test Procedure Data Sheet (TPDS).

Clamp Assembly



Note: All clamps on the Autopheresis-C device are removed in a similar fashion. The following part removal sequence can be applied to all 4 clamps on the Autopheresis-C device. An exact part location can be made using the enclosed drawings.

1. Using a 1/4" nut driver, remove the ground screw from the clamp assembly.



Note: For plasma clamp, remove ground wire from instrument first. Ground wire must be routed above clamp to ensure ground wire does not interfere with weigh scale.

2. Using a 5/16" nut driver, remove the 2 each poly lock nuts holding the clamp assembly to the front panel assembly.
3. Squeezing the connector lock on the two wire connector, pull connector apart.
4. Pull defective clamp assembly from rear of device.

5. Install replacement clamp assembly on front panel assembly. Ensure correct orientation of clamp assembly by using fluid path drawings on upper console. Ensure O-ring is seated on clamp head.
6. Tighten 2 each 5/16" poly lock nuts using nut driver.
7. Re-attach ground screw to new clamp assembly.

Fan, Cooling



Note: The cooling fan is located on the rear door assembly. Whenever the device is ON, the fan must be on. The fan is a DC motor, therefore polarity must be observed when installing replacement fan.

1. Locate red and black wires powering fan. Observe polarity, red = (+) and black = (-). Pull connectors at end of red and black wires by pulling away from fan.
2. Remove 4 each 5/16" poly lock nuts holding fan in place. Remove fan from rear door assembly.
3. Install replacement fan onto 4 each bolts. Ensure power connectors are facing down. Replace 4 each 5/16" nuts removed in Step 3, and tighten.
4. Re-attach connectors from red (+) and black (-) wires on new fan.
5. Test cooling fan by observing air flow out of rear door vent.

Filter Frame, Replacement Filter



Note: The filter and frame are located underneath the support column.

1. To remove the filter frame, or replace the filter, locate the frame grill underneath support column and pull straight down.
2. Replace the filter or the frame as required.
3. Place the filter in the frame and push frame with tabs pointing up into support column. The frame tabs must lock over top of base assembly.

Lens, Reservoir Molded



Note: The reservoir lens is designed to prevent fluid spills from contacting the reservoir sensors on the Analog Board while allowing S1, RS1, S2, and RS2 signals to pass through the lens.

1. Remove the Analog Board as defined within this section.
2. Remove the 8 each poly lock nuts holding the lens in place with a 1/4" nut driver.
3. Clean any residue from the reservoir lens opening.
4. Install replacement lens on the 8 each standoffs and press the lens on to front panel.



Note: Lens spring must be mounted on the top of the reservoir channel.

5. Re-install the Analog Board as defined within this section.

Luer Adapters, Pressure Transducer



Note: Luer adapters found on P1 and P2 pressure transducer are responsible for the interface between the disposable kit and the instrument pressure monitoring system. When the Luer adapters are identified as leaking, the following procedure can be performed.

1. Using channel locks, twist the Luer adapter off of the adapter transducer.
2. Remove all residual Lock tite from the adapter transducer.
3. Apply one drop of Lock tite 609 to adapter transducer.



Note: Do not allow Lock tite to enter transducer port.

4. Push and twist Luer adapter to adapter transducer.



Note: Luer adapter can not be touched for 24 hours.

Membrane Panel



Note: The membrane panel is located on the upper console. To determine if the membrane panel is defective, connect a replacement membrane panel (i.e., not installed) with J8 on Bar Graph PCB and exercise switches. If replacement membrane panel corrects the reported problem, replace the membrane panel (Power must be off before removing connectors on Bar Graph PCB.)

1. Once the membrane panel is found to be defective, remove membrane panel connector, P8 from Bar Graph PCB. Gently pry ribbon cable holder open using a flat blade screwdriver, and free cable from cable holder.
2. Remove the alert lamp connector P26 from the membrane panel.
3. Remove compressor as defined in this section.
4. Remove plasma cell drive as defined in this section.
5. Remove active pressure cuff as defined in this section.
6. Remove 2 each ground screws from each side of membrane panel.
7. Push membrane panel out from inside of instrument (by plasma cell drive). Once membrane is lifted from front panel, peel entire membrane panel from instrument. Remove all remaining adhesive from upper console using adhesive remover.
8. Ensure surface area is clean and free of debris. Remove adhesive backing from membrane panel. Carefully feed connector J8 through access hole on upper console. Align membrane panel with relief on upper console and press membrane panel into place.
9. Re-connect connector P8 on membrane panel with J8 on Bar Graph PCB. Re-attach cable holder from Step 2.
10. Re-connect the alert lamp connector J26 to the membrane panel.
11. Re-attach ground screws removed in Step 5.
12. Install plasma cell drive, active pressure cuff and compressor as defined in this section.

PCB, Analog



Note: The Analog PCB must be removed as a whole assembly. The hemoglobin detector can not be removed separately. The Analog PCB is located in the lower left side of the device (from rear).

1. From the rear of the device, locate and disconnect J45 connector from Analog PCB. Remove two each screws holding the Air Sensor PCB and place Air Sensor PCB to the side.
2. Remove all connectors P12, P3, P29, P44, P45, P32, P31, P30 from the Analog PCB.



Note: Remove 22-pin connector for instruments with optional alert light.

3. Remove Hb detector cover by removing 5/64" socket head screw with a 5/64" ball end Hex Key from underside of Hb detector. Thread #256 screw into hinge pin. Remove hinge pin by pulling #256 screw downward. Save hinge pin and socket head screw for installation of replacement Analog PCB.
4. Remove 4 each 5/16" poly lock nuts and nylon washers holding Analog PCB to front housing.
5. Remove two each 1/4" (long) standoffs that hold the Air Detector PCB and two each 1/4" (short) standoffs holding the Hb detector in place. Remove ground wire from ground stud on instrument with 5/16" nut driver.
6. Remove Analog PCB from instrument.
7. Remove Hb gasket from defective Analog PCB, and install onto replacement Analog PCB.
8. Install replacement Analog PCB by inserting Hb detector into opening on front panel. Re-attach 4 each 5/16" poly lock nuts onto front housing attachment bolts.
9. Re-attach both standoffs for the Hb detector and Air Detector PCB. Re-attach Air Detector PCB to standoffs. Re-attach W17 to P45 on the Analog PCB.
10. Re-attach connectors P12, P3, P29, P44, P32, P31, P30 to Analog PCB. Re-attach both air detector cables to Air Detector PCB.



Note: Replace the 22-pin test connector if instrument has alert light (wire attached to pin 15).

11. Install Hb detector cover on new Hb detector. Slide hinge pin through Hb cover and Hb detector hinge pin holes. Re-attach 5/64" socket head screw using a 5/64" hex key.

PCB, CPU



Note: The CPU PCB is located on the rear door. The CPU PCB is mounted directly on top of the Driver PCB. Replacement CPU PCB Boards will have new U38 EEPROM's.


1. Before changing the CPU PCB for a "computer" related problem, ensure the program PROM's (U16, U17) are not defective by exchanging them with a known good pair (Step 5 below.) If problem persists, remove power from device and follow the CPU PCB replacement procedure.
2. Remove power from device. Next, gain access to the upper console by turning counterclockwise one-quarter turn both latch screws on rear door.
3. Disconnect all data ribbon cables (P2, P9, P28, P6 and P27) by opening the locking arms at the end of each connector. Remove the power connector P13 from the CPU PCB by pulling straight away from PCB.
4. Using a #1 Phillips screwdriver, remove the 5 each screws and insulating washers from the four corners and the center of the PCB. Remove the CPU PCB from the device.
5. Using an EPROM removal tool, remove the program PROM's U16, and U17 from the defective CPU PCB. Install program PROM's in their respective sockets on the CPU PCB. Ensure notches on PROM's match artwork on the PCB surface.
6. Install known good PROM's onto replacement CPU PCB observing orientation of PROM's.
7. Position CPU PCB enabling you to read all connector designators. (i.e., J27, J6, J28, J13, J9 and J2). This will ensure the PCB is positioned correctly. Install 5 each Phillips screws removed in Step 4.
8. Re-attach all connectors removed in Step 3. Ensure all locking arms are firmly seated on connector body.

PCB, Bar Graph



Note: The Bar Graph PCB is located on either side of the device. The first Bar Graph PCB replacement procedure will cover the PCB on the right side, or side with the Hb detector. The second Bar Graph PCB discussed will be on the left side, or side with the cuff compressor.

PCB, Bar Graph on right side of device

1. Remove the saline clamp as outlined in the clamp removal portion of this document. This will enable you to access top left mounting screw on the Bar Graph PCB.
2. Disconnect both connectors, P8 and P7 going to Bar Graph PCB.
3. Remove 4 each #1 Phillips screws holding Bar Graph PCB into place. Remove defective Bar Graph PCB. Ensure standoff washers are present on 4 each mounting holes. Standoff washers must also be present under 4 each Phillips screws removed.
4. Ensure standoff washers are glued to Bar Graph PCB.
5. Install new Bar Graph PCB into position with J7 at the bottom. Re-connect J7, and membrane switch connector J8 to the Bar Graph PCB.
6. Attach 4 each #1 Phillips screws holding Bar Graph PCB in place.
7. Install saline clamp per guidelines defined in this document.
8. Enter "Memory Display" test in the Test Menu. Next, press  to Data EEPROM display.

PCB, Bar Graph on left side of device

1. Locate ribbon cable holder above Bar Graph PCB, and gently pry holder open using a flat blade screwdriver. Free ribbon cables and remove P7 from Bar Graph PCB.
2. Remove connector J3 on the Analog PCB.
3. Remove 4 each #1 Phillips screws holding Bar Graph PCB into place. Remove defective Bar Graph PCB. Ensure standoff washers are present on 4 each mounting holes. Standoff washers must also be present under 4 each Phillips screws removed (4 each washers can be glued to hold in place.)

4. Remove protective cover from J8 on defective PCB, and install on replacement PCB. Install new Bar Graph PCB into position with J7 at the bottom. Re-connect P7 on new Bar Graph PCB.
5. Attach 4 each #1 Phillips screws holding Bar Graph PCB in place.
6. Install cuff compressor per guidelines defined in this section.

PCB, Display



Note: The Display PCB is located on the top upper console.

1. Loosen the two each 11/32" poly lock nuts holding the active pressure cuff in place. Lift the active pressure cuff, and allow assembly to drop below the top shelf of the upper console.
2. Remove connectors P20, and P4 from the Display PCB.
3. Loosen the 4 each standard screws holding the Display PCB in place. The screws will detach the Display PCB from the upper console but will not come off the Display PCB.
4. Put replacement Display PCB in place. Ensure J4 is on bottom of PCB. Re-connect connector P20 and P4 on new Display PCB.
5. While holding Display PCB in place, turn bottom 2 each standard screws by hand until they begin to catch. Turn the top 2 each screws until they begin to catch. Tighten 4 each screws using a # 2 flathead screwdriver.
6. Re-position active pressure cuff into position, and tighten the 2 each poly lock nuts.

PCB, Driver



Note: The Driver PCB is located behind the CPU PCB on the rear door assembly.

1. Remove CPU PCB per guidelines described in this procedure.
2. Remove connectors J10, J5, J37, J25, J14, J16, and motor cables J22, J23, J21. Remove load resistor J24 and install on replacement Driver PCB.
3. Remove 5/16" nut holding ground wire to Driver PCB.
4. Remove two each cable straps on device side of PCB with a #2 Phillips screwdriver.

5. Remove remaining PCB mount Phillips screws holding Driver PCB on to rear door.
6. Remove center standoff attached to rear door. Driver PCB can now be removed from the instrument.
7. Remove 2 each plastic standoffs attached to Driver PCB. Keep plastic nuts with standoff. Install both plastic standoffs and nuts onto replacement Driver PCB. Re-attach load resistor J24 and ground wire to replacement Driver PCB.
8. Install replacement Driver PCB onto rear door of device with heat sinks on the bottom with center standoff. Install Phillips screws removed in Step 6. Re-attach two each cord strap screws removed in Step 5.
9. Remove P5 (W2) from defective Driver PCB, and install on new Driver PCB. Re-attach 5/16" nut removed in Step 4.
10. Re-connect connectors J10, J5, J37, J25, J14, J16, and motor cables J22, J23, and J21.
11. Re-connect CPU PCB as described in guidelines described in this document.

PCB, Spinner



Note: The Spinner PCB is located within the plasma cell drive.

1. Remove plasma cell drive as outlined within this document.
2. With a 3/32" hex key, remove 6 each cap screws holding cover to plasma cell drive.
3. With a 3/16" hex key, remove 2 each cap screws holding Spinners PCB's heat sink to plasma cell drive heat sink.
4. Using a #1 Phillips screwdriver, remove Phillips screw (towards front of PCB) holding Spinner PCB in place.
5. From narrow end, lift Spinner PCB up and away from heat sink portion of plasma cell drive.
6. Remove connector from plasma cell drive. Remove Spinner PCB from plasma cell drive.

7. Re-connect Spinner PCB connector into plasma cell drive. Hook must be nearest connector shield.
8. Position Spinner PCB into plasma cell drive.
9. Install 2 each 3/16" cap screws holding heat sink on Spinner PCB to heat sink on plasma cell drive and tighten.
10. Install Phillips screw holding Spinner PCB onto plasma cell drive assembly.
11. Install cover over Spinner PCB with 6 each hex screws.
12. Install plasma cell drive as outlined in this section.
13. Install compressor as outlined in this section.

PCB, Air Detector



Note: The Air Detector PCB is located on the Analog PCB, and can be accessed from the rear door.

1. From the rear of the device, locate two each cables from air detector assembly. Follow cables from air detector to the Air Detector PCB. Remove two each cables by pulling straight away from the Air Detector PCB.



Note: You may have to twist connector while removing cable.

2. Remove 2 each Phillips screws holding Air Detector PCB to Analog PCB. Disconnect W17 from Air Detector PCB. Remove Air Detector PCB.
3. Re-connect W17, and two each cables from the air detector to Air Detector PCB. Air detector cables are interchangeable.
4. Attach replacement Air Detector PCB to Analog PCB with 2 each Phillips screws removed in Step 3.

Pressure Transducer (P1 and P2)



Note: The P1 P2 pressure transducer can be replaced as an assembly. However, if the failed pressure transducer can be identified, a more cost effective repair can be made by exchanging the specific pressure transducer. The following steps apply to the P1, or the P2 pressure transducer. Both pressure transducers in the P1 P2 assembly are the same part number.



Note: Before replacing P1 P2 pressure transducers for an apparent failure, first clean the P1 P2 transducer assembly per the Preventive Maintenance Procedure.

P1 = Venous Pressure (P30)

P2 = Transmembrane Pressure, TMP (P31)

1. Remove the appropriate connector from the Analog PCB. Remove appropriate cable from any cable ties.



Note: If Luer locks are used, they must be removed before the next step.

2. Using a 5/32" hex key, remove the 2 each mounting hardware from the pressure transducer assembly.



Note: If pressure transducer is difficult to remove, use adjustable wrench to turn transducer back and forth. Then pull transducer toward you.

3. Install replacement pressure transducer into pressure transducer assembly.
4. Install pressure transducer with 2 each 5/32" cap screws.
5. Test pressure transducer by performing a complete Test Procedure Data Sheet.
6. If the pressure transducer cover is found to be loose, the cover can be adjusted per MAKING ADJUSTMENTS section.

Card Reader

1. Open transducer cover and remove cap screw holding cover in place with a 5/32" hex key. Remove transducer cover.
2. Remove P1 and P2 flags by removing cap screws with a 3/32" hex key.



Note: Ensure springs remain screwed in place within their respective mounting holes.

3. Remove 6 each cap screws holding the card reader in place with a 3/32" hex key. Remove card reader.
4. Install replacement card reader on pressure transducer assembly, and attach with the 6 each cap screws using a 3/32" hex key.
5. Install flags and attach using a 3/32" hex key.



Note: Straight edge of flags must be facing the center of the pressure transducer assembly.

6. With the cap screw from Step 1, attach the pressure transducer cover to the pressure transducer assembly using a 5/32" hex key.

Pump Assemblies



Note: There are 3 each pumps in an Autopheresis-C Instrument. The following steps apply to all three pumps. Specific parts within the pump assembly will be covered (see Figure 6-1).

1. Remove ribbon cable from pump assembly.
2. Remove ground nut from pump assembly with a 5/16" nut driver.
3. Remove pump assembly retainers by pushing inward, and away from pump assembly to release.
4. Turn pump assembly each way while pushing forward from back of instrument. Remove pump assembly from device.
5. Verify pump gasket is still in place around mounting hole for pump assembly.
6. Install pump assembly by matching pump cover opening, and tubing path marked on upper console assembly.
7. Push pump assembly into place.



Note: You may have to twist pump assembly to ensure pump gasket does not come loose.

8. Replace pump retainer by pushing inward and towards slots on outer edge of pump assembly.
9. Attach ground wire nut with 5/16" nut driver.
10. Re-attach ribbon cable to pump assembly.



Note: The hook on the connector must face the shield on the pump connector.

Pump Cover, Rotor and Mandrel Assembly



Note: The following steps are for pump cover, rotor, mandrel assembly, extension spring, and the bronze pump link removal. This section is for repair of cracked, rusted or missing parts (see Figure 6-1).

1. To remove the pump cover, push tab in toward the front panel. Slide the pump cover toward the handle and lift off.
2. To remove the mandrel assembly, remove the pump cover as described in the previous step.
3. Remove the roller cage assembly by pulling off pump shaft.
4. To remove the mandrel assembly, close the handle and rotate the mandrel assembly clockwise until the assembly slips out of slot. Pull mandrel assembly from pump.
5. Remove 2 each Phillips screws holding the pump retainer and remove the pump cover retainer.
6. Using a needle nose pliers, grasp the bronze pump link and remove from the pump assembly.
7. Remove the bronze pump link from the spring.
8. Using a small flat blade screwdriver, remove the extension spring.
9. Attach extension spring to the bronze pump link.
10. Place the bronze pump link on the pump assembly. The standoff on the bronze pump link must match up to the ridge stop on the pump assembly.

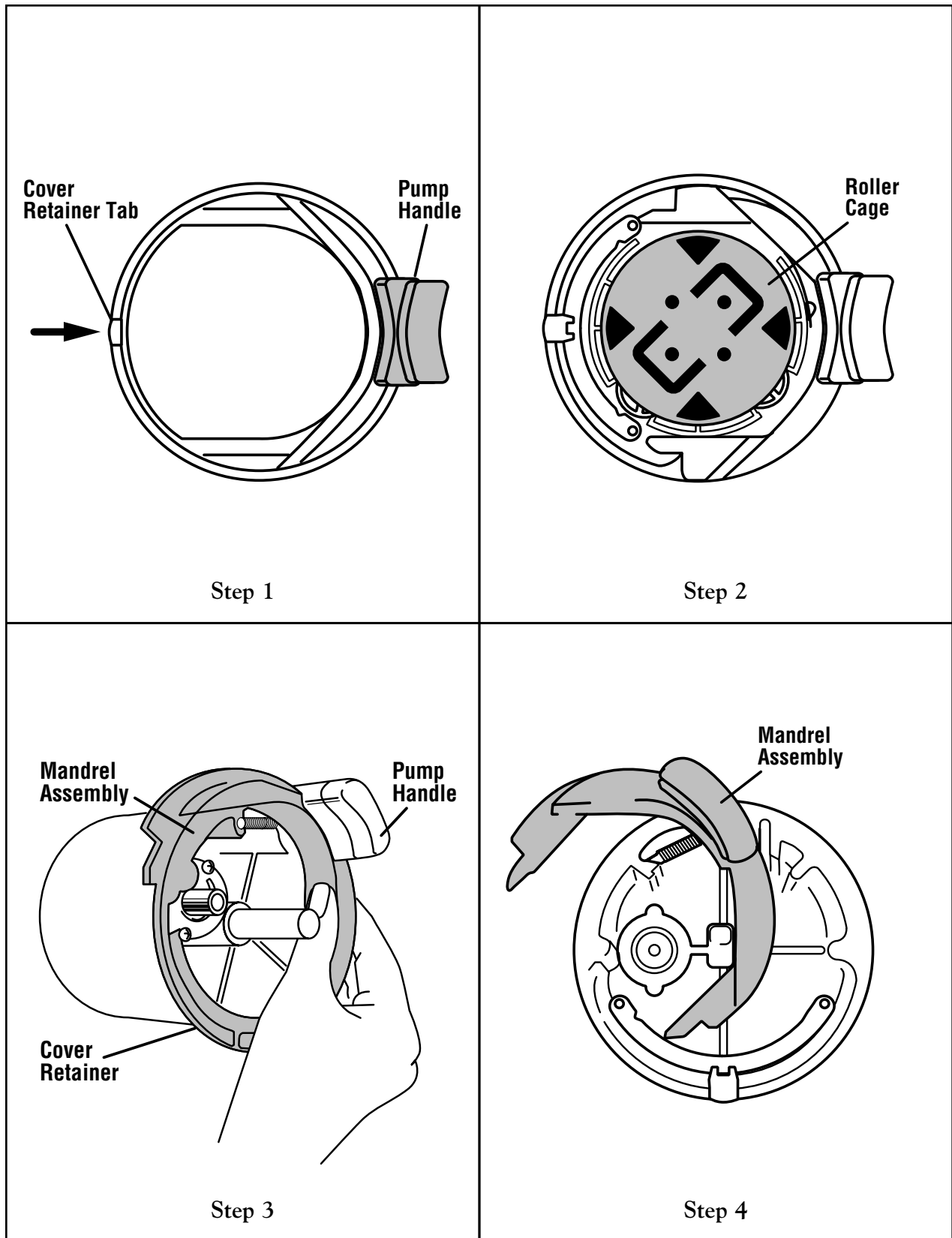


Figure 6.1 Disassembly of Pumps

Speaker



Note: The speaker assembly is located on the rear door assembly in the upper right hand corner.

1. Remove the 2 each 5/16" nuts holding the speaker assembly into place.
2. Disconnect the 2 each leads from the speaker assembly. The positive and ground leads must be connected the same way on the replacement speaker.
3. Install the replacement speaker with the 2 each 5/16" nuts.
4. Re-attach the positive lead to the connector marked with a red dot. The ground lead is attached to the other lead.

Support Column



Note: The support column can be replaced as a whole assembly. The replacement support column utilizes the front and rear shroud from the support column being replaced. A table top or cart will be helpful in performing the following repairs.

For troubleshooting purposes only, verify support column is defective by jumping a known good support column with the RS-232C shielded cable to the upper console under test. If the power supply related problem no longer exists, replace the support column. If the failure persists, further troubleshooting is required.

1. Disconnect power source from upper console assembly by disconnecting power at connector J35 at the center of the support column.
2. Remove the upper console by removing the 6 each 5/32" hex head screws attaching the two assemblies together. 2 longer screws are located on either side of the serial number plate. There are 4 each shorter screws around connector J35.
3. Lift upper console up and place on either side of device.



Note: Do not touch weigh scale, or air detector assemblies while removing upper console.

4. Remove shrouds by removing the 4 each screws at the top of the support column. Pull apart from the bottom both shrouds. There are 2 each detents on the bottom of each shroud holding them in place.

5. Place support column on a table or a cart. Remove the filter and filter tray as described in this procedure.
6. Remove the base assembly with the four casters by removing the 4 each cap screws with a 3/16" hex key.
7. Stage the defective support column for shipment to manufacturer.
8. Place replacement support column on table or cart.
9. Verify power source switch, by appliance inlet, is set to customer requirements (i.e., 115 VAC or 230 VAC.)
10. Using a flat blade screwdriver, open fuse compartment. Verify fuses are correct for power source. If power source is 115 VAC, fuses must be 4 Amp Slo Blo. If power source is 230 VAC, fuses must be 2 Amp Slo Blo.
11. Install base assembly with casters by attaching 4 each cap screws removed in Step 6. The adjustable casters must be mounted on side with fuse holder.
12. Place the filter in the frame and push frame with tabs pointing up into support column. The frame tabs can be inserted into either short side of the support column.
13. Attach front and rear shroud by locking detents on shroud, and aligning plastic channel on each side of chassis.
14. Stand unit upright on base assembly. Stand locking tabs for power connector P35 in the upright position.
15. Place upper console on support column. Re-attach 6 each 5/32" hex head screws removed in Step 2.
16. Re-connect power connector P35. Secure locking tabs holding connector in place.

Tube Guide



Note: Replacement of tubing guides can be performed in the following manner.

1. Locate mounting hardware of the tube guide to be replaced inside the upper console.
2. Using a #2 Phillips screwdriver, remove mounting hardware holding tube guide in place.
3. Before tightening mounting hardware, align tube guide with silk screen. Tighten mounting hardware.

Weigh Scale Assembly



Note: The weigh scale assembly is located at the bottom center of the upper console assembly.

1. Remove plasma clamp as defined in the CLAMP REMOVAL section of this procedure.
2. Disconnect cable P-29 from the Analog PCB. Remove cable from the wire clips. Remove the weigh scale from the device by removing 2 each 3/8" nuts.



Note: You must use a Phillips screwdriver to hold screw from bottom, outside of device.

3. Install replacement weigh scale assembly. Attach weigh scale using 2 each 3/8" poly lock nuts removed in Step 3. Attach ground nut removed in Step 2.
4. Re-attach P-29 to the Analog PCB.



Note: The hook on the connector must face the shield on the pump connector.



Note: Weigh scale cable must be routed under all other wires.

5. Re-attach plasma clamp per guidelines defined in this procedure.



Note: Ground wire must be routed on top of plasma clamp.

6. Re-attach hanger (bag or bottle) to weigh scale assembly.

Resistor Pack Board



Note: The Resistor Pack Board is located on the rear door next to the speaker. This component is responsible for maintaining hold-in current for all clamp assemblies. If an N/C clamp is unable to remain Open, or an N/O clamp is unable to remain closed, replace the resistor pack.

1. Remove the CPU PCB as defined in this section.
2. Disconnect P37 from the Driver PCB.
3. Remove the 4 each nuts holding the Resistor Pack Board with a 3/8" nutdriver. Remove the Resistor Pack Board.
4. Install replacement Resistor Pack Board onto rear door. Re-attach using the 4 each nuts using a 3/8" nutdriver.
5. Re-connect P37 to the CPU PCB.
6. Attach the CPU PCB as defined in this section.

ADVANCED TRAINING SERVICE PARTS

Advanced trained service personnel only should perform the following repairs.



Note: Once the instrument has been repaired, the Autopheresis-C Test Procedure Data Sheet must be performed.



Note: Gain access to the upper console by turning counterclockwise one-quarter turn both latch screws on rear door.



Note: Before performing any of the following repairs, power must be removed from the device, and anti-static precautions must be observed. All repairable parts removed from a device must be re-packaged utilizing packaging from the replacement part.

The following tools are required to perform advanced troubleshooting:

| | |
|---------------------------|------------------------|
| Hex Key, 5/32" | Nut Driver, 11/32" |
| Hex Key, 1/8" ball tipped | Flat Blade Screwdriver |

Lower Device Support

Spinner Seal Force Calibration Procedure



Note: The lower device support is used to support the Plasmacell-C disposable set separation device. If the lower device support were to become loose, or require replacement, the spinner seal force adjustment procedure must be performed after the repair.

1. Locate 2 each cap screws holding the lower device support onto upper console. Remove both cap screws using a 5/32" hex key. Remove ground wire by removing connector.
2. Install replacement lower device support onto upper console. Attach both cap screws holding the lower device support onto upper console. Do not tighten cap screws.
3. Place the seal force adjustment tool into the plasma cell drive. Close the lower device support slowly. Move the seal force adjustment tool until the tool is flush with the lower device support.
4. While pushing up on the lower device support, tighten both cap screws using a 5/32" hex key.
5. Perform spinner seal force calibration as defined in the MAKING ADJUSTMENTS section.

Plasma Cell Drive



Note: The plasma cell drive is located in the upper right corner of the device (from front of instrument.) The compressor must be removed first for the plasma cell drive to be removed. Once plasma cell drive is replaced, perform the spinner seal force adjustment procedure.

1. Using 1/8" ball tipped hex key, loosen both mounting screws on each side of compressor assembly.
2. Lift compressor up and away from front housing. Let compressor hang down away from plasma cell drive.
3. Remove power connector (P42) from plasma cell drive, Spinner PCB.
4. Using an 11/32" nut driver, remove two each poly lock nuts holding plasma cell drive to the upper console (located above compressor.)
5. With a 5/32" hex key, remove the cap screw holding the plasma cell drive to the top of the upper console. Hold plasma cell drive while removing 5/32" cap screw ensuring cell drive does not fall.
6. Remove ribbon cable holder to gain access to connector P41.
7. Gently pull plasma cell drive from inside upper console. Once the plasma cell drive is out far enough, remove ribbon cable P41 from the Spinner PCB. Remove plasma cell drive from the device.
8. Lift replacement plasma cell drive into place. Re-attach ribbon cable P41 to Spinner PCB. Cable connectors are keyed to ensure correct orientation. Ensure P41 is locked into connector.
9. Re-attach plasma cell drive to upper console using the 5/32" cap screw, and 2 each 11/32" nuts.
10. Re-attach power connector P42 to Spinner PCB. Ensure correct orientation. Hook at end of connector must be nearest to the connector shield on Spinner PCB.



Note: Red and black wire must be routed out the bottom of connector.

11. Secure ribbon cable removed in Step 6 under cable holder.
12. Install compressor by positioning compressor on two mounting screws loosened in Step 2, then tightening both screws.
13. Perform **spinner seal force calibration procedure** as defined within the advanced training module. Test plasma cell drive by performing a complete Test Procedure Data Sheet.

Power Supply



Note: The power supply is located near the bottom of the support column. Power supply connectors mentioned are numbered, and have a corresponding number on the power supply connector. Do NOT remove any power supply wires that are not numbered. This is to ensure the new power supply will be wired correctly. All connectors, except the battery can be removed with a #2 Phillips, or a regular screwdriver.

For troubleshooting purposes only:

Verify voltages on Driver Board: TP12, ground, TP6 24 VDC; Analog Board: +5, -15, +15. Then ensure line fuses have continuity. If open, replace. If voltages are not present, verify power cord has continuity to instrument. If power is getting to the instrument, replace the power supply.

Caution: Extreme CAUTION must be taken when reconnecting power supply to ensure all connections are made correctly. Electrical damage may be the result.

1. Remove power cord from the appliance inlet.
2. Loosen 2 each #2 Phillips screws holding the air detector to the upper console.
3. Remove 4 each 5/16" screws holding front and rear shrouds to support column chassis.
4. Remove shrouds one at a time by pulling apart from the bottom. There are 2 each detents on the bottom of each shroud holding them in place.
5. Remove 4 each screws holding EMI shield front with 8/32" hex key. Separate EMI shield from support column. Remove 4 each screws holding EMI shield rear with 8/32" hex key. Separate EMI shield from support column.

6. Locate 6 each power supply mounting screws on the "Weigh Scale" side of the support column and remove. Carefully set power supply on chassis near appliance inlet.
7. Remove power to power supply by disconnecting the hot, neutral, and ground wires at the bottom of the supply. Note the wires and the connector are labeled "1, 2, 3".
8. Locate the Battery Charge PCB at the top of the power supply (facing the battery). Disconnect the two wires marked "+" and "-" from the battery charge circuit.
9. Remove all wire connectors from the top of the power supply. The following list represents what numbers are used on W4.



Note: Do not allow screws to fall into power supply or support column. Loose hardware can cause a short circuit.

- TB2-3 (2 each yellow) - Install from rear of device
 - TB2-4 (2 each brown) - Install from rear of device
 - TB2-7 (1 each orange) - Install from front of device
 - TB2-8 (1 each white) - Install from front of device
 - TB2-9 (1 each white/black strip) - Install from front of device
 - TB2-10 (1 each blue) - Install from front of device
 - TB2-11 (1 each red) - Install from front of device
 - TB2-12 (2 each black) - Install from front of device
10. Install replacement power supply by attaching 3 each power source wires labeled "1, 2, 3".
 11. Position power supply on chassis and re-connect Battery. Connect the "+" on the wire to the "+" on the Battery Charge PCB, and the "-" on the wire to the "-" on the Battery Charge PCB.
 12. Re-connect all power supply wires removed in Step 8. Note the side of device mentioned for easy access to connector locations.
 13. Lift power supply, and align 6 each mounting hardware up with power supply. Start all 6 screws to ensure they line up with power supply. Tighten 6 each screws.

14. Cover 6 each holes utilized in the above step with tape to prevent dust from entering the device.
15. Re-attach EMI shield front and rear with 4 each 8/32" hex keys.
16. Slide front shroud (without access holes) up under air detector assembly. Push bottom of shroud onto support column locking detents onto support column.
17. Attach rear shroud by locking detents on shroud, and aligning gasket on each side of chassis. Install 4 each screws removed in Step 3.
18. Tighten air detector screws using #2 Phillips screwdriver.

Battery



Note: The battery is located in the support column. The battery provides power to the Display PCB, and the CPU PCB when AC power is removed from the instrument. If the display can not remain illuminated for 3 minutes after removing AC power, the battery must be replaced.

1. Remove power cord from the appliance inlet.
2. Loosen 2 each #2 Phillips screws holding the air detector to the upper console.
3. Remove 4 each 5/16" screws holding front and rear shrouds to support column chassis.
4. Remove shrouds one at a time by pulling apart from the bottom. There are 2 each detents on the bottom of each shroud holding them in place.
5. Remove 4 each screws holding EMI shield front with 8/32" hex key. Separate EMI shield from support column. Remove 4 each screws holding EMI shield rear with 8/32" hex key. Separate EMI shield from support column.
6. From the front of the instrument, remove the two connectors from the battery observing orientation of wires.
7. With a #2 Phillips screwdriver loosen 4 each screws holding battery in place. While holding battery against support column, remove 4 each screws holding battery in place.
8. Remove battery from support column. Using a flat blade screwdriver, remove 4 each clips holding battery cover together.

9. Separate battery cover lid and remove defective battery from inside battery cover. Battery terminals must be present through access holes on cover.
10. Install replacement battery inside cover and attach clips around cover and lid. Flat portion of clip must be on lid side of cover.
11. Attach the two wire connectors to the replacement battery.



Note: Red wire must be connected to the red terminal.

12. Attach the battery using the 4 each screws removed in Step 8.



Note: Position clips to line up with screws if necessary.

13. Re-attach EMI shield front and rear with 4 each 8/32" hex keys.
14. Cover 4 each holes utilized in the above step with tape to prevent dust from entering the device.
15. Slide front shroud (without access holes) up under air detector assembly. Push bottom of shroud onto support column locking detents onto support column.
16. Attach rear shroud by locking detents on shroud, and aligning gasket on each side of chassis. Install 4 each screws removed in Step 3.
17. Tighten air detector screws using #2 Phillips screwdriver.

Power Switch Module



Note: The power switch module assembly is present in 2 forms: a rocker style and toggle version. The rocker type switch is no longer available. The following steps identify toggle switch replacement only.

A toggle switch can cause a **Plug in Power Cord** message if the switch throw is inadequate. To test the toggle switch, turn switch ON, and measure the continuity from the top to the bottom of the power module contacts. If the resistance is not 0 +/- 1 ohm, install the 0.040" shim.

1. Remove power cord from the appliance inlet.
2. Loosen 2 each #2 Phillips screws holding the air detector to the upper console.
3. Remove 4 each 5/16" screws holding front and rear shrouds to support column chassis.
4. Remove shrouds one at a time by pulling apart from the bottom. There are 2 each detents on the bottom of each shroud holding them in place.
5. Remove 4 each screws holding EMI shield front with 8/32" hex key. Separate EMI shield from support column. Remove 4 each screws holding EMI shield rear with 8/32" hex key. Separate EMI shield from support column.
6. Separate the green switch contacts from the toggle portion of the switch by lifting the black tabs on the switch holder upward and pulling the green switch contact from toggle portion switch.
7. Peel adhesive back from the 0.040" shim P/N and insert shim between green contacts and switch actuator.
8. Re-attach green switch contacts to the toggle portion of the switch by pushing switch contact.

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INTRODUCTION

This section provides troubleshooting guidelines for service personnel. Perform troubleshooting steps identified in the Operator's Manual before proceeding with Service Troubleshooting.

MESSAGE DISPLAYS/SYMPTOMS

(BCK) Overspeed1

(BCK) Overspeed2

(BCK) Overspeed3

- Possible Cause**
1. Missing motor 4 load resistor.
 2. Connection between Driver Board and any pump assemblies has been made incorrectly.
 3. Open circuit on Driver Board.
 4. Pump has failed.

-
- Action**
- Step 1** Install load resistor.
- Step 2** Verify correct power distribution to pumps from Driver Board.
- Step 3** Replace Driver Board.
- Step 4** To identify failed pump assembly, substitute good pump assembly with suspect pump. Perform pump tests within the Menu.

Ck AC Flow/Path

- Possible Cause** The air detector has not detected fluid after a pre-determined volume of AC has been pumped during solutions prime. It also indicates too many bubbles detected during first cycle blood prime.

-
- Action** Perform air detector test in the test menu. If unable to pass test:
- Step 1** Replace the air detector.
- Step 2** Replace the Air Detector PCB.

Ck for Plasmaline Hb

Possible Cause Color change not detected by the Hb detector, or no color change but air bubbles or lipids present at the Hb detector.

Action **Step 1** Perform HbDET tests in the test menu. Perform Hb calibrate.

Step 2 If unable to calibrate, replace the Analog Board.

Cuff pressure slow to respond

Possible Cause 1. Driver Board cuff frequency out of adjustment.
2. Leaky air way system.

Action **Step 1** Adjust cuff frequency as defined in the making adjustments section.

Step 2 Perform leak test.

- a. Enter the "P1/Wt/Cuff/Air Test" within the test menu. Press ADVANCE ▼ until the display reads 0 0 0C 0, press and hold the ▶ key. Allow the pressure cuff to fully inflate.
- b. Squeeze the pressure cuff with your hand. There will be very little leakage.
- c. This checks all the fittings back to the check valve. The check valve is immediately after the compressor.
- d. If a leak has been detected, the cause can be isolated by clamping the tubing paths with a hemostat while applying pressure. Pinch off tubing after connectors to verify their individual integrity.

Frozen Display

Possible Cause Computer locked up.

Action **Step 1** Turn instrument OFF/ON. Re-seat all data connectors J2, J3, J27, J9 and J6.

Step 2 Replace the CPU Board.

Step 3 Replace the program EPROM's.

Leak at P1

Possible Cause For repetitive "Leak at P1" messages with the connection at P1 secure.

Action **Step 1** Place soapy water on Luer fittings. Perform leak test as defined in the test procedure and identify source of leak.

Step 2 If Luer fitting leaks, replace pressure transducer.

Leak at P2

Possible Cause For repetitive "Leak at P2" messages with the connection at P2 secure.

Action **Step 1** Place soapy water on Luer fittings. Perform leak test as defined in the test procedure and identify source of leak.

Step 2 If Luer fitting leaks, replace pressure transducer.

Open Transducer Cvr

Possible Cause During calibration S4 or S5 should read blocked but are not.

Action **Step 1** Verify S4 and S5 flags are present and have free movement within the pressure transducer.

Step 2 Enter the sensor tests within the test menu and verify sensor S4 and S5 are functional. If sensors are unable to pass the sensor test, replace the Blood Detector Board.

Over Current

Possible Cause The hardware overcurrent latch has been tripped, possibly by tubing being caught in the rollers.

Action **Step 1** Enter motor acceleration test within the test menu.
Perform acceleration test on each pump until failed pump is identified.

Step 2 Replace failed pump.

Plug in Power Cord

Possible Cause Interrupted line voltage to the instrument.

Action **Step 1** Verify voltages on Driver Board: TP12, ground, TP6, 24 VDC; Analog Board: +5, -15, +15.

Step 2 Ensure line fuses have continuity. If open, replace.

Step 3 To test toggle switch, turn switch ON, and measure the continuity from the top to the bottom of the power module contacts. If the resistance is not 0 ± 1 ohm, install the 0.040" shim as per parts removal procedure.

Step 4 Verify power cord has continuity to instrument. If power is getting to the instrument, replace the power supply.

Press (BCK) M2dir1**Press (BCK) M2dir2**

Possible Cause The pump is rotating opposite to the pre-programmed direction.

Action **Step 1** Check ability of Motor 2 to operate in both directions.

Step 2 Replace Driver Board.

Press (BCK) SpStall

Possible Cause The plasma cell drive (spinner) speed is slower than the commanded speed.

Action Replace the plasma cell drive.

Press (BCK) SpTO

Possible Cause Communication from the plasma cell drive (spinner) to the CPU Board has failed.

Action **Step 1** Verify the spinner bus cable W11 is securely attached to the CPU Board and the Spinner Board.

Step 2 Replace the W11 cable.

Step 3 Replace the Spinner Board.

Step 4 Replace the CPU Board.

Press (BCK) Stall #

Possible Cause A pump is drawing maximum current and is not speeding up.

Action **Step 1** Replace affected pump.

Step 2 Replace W-16 cable.

Step 3 Replace Driver Board.

Remove Container

Possible Cause At the install set display the untared weigh scale value is greater than 200.

Action Perform weigh scale #1 test in the test menu. If untared value is greater than 200, replace the weigh scale.

RS1 Blocked

Possible Cause Reservoir sensor RS1 is defective.

Action Enter the sensor tests within the test menu and verify sensor RS1 is functional. If sensor is unable to pass the sensor test, replace the Analog Board.

RS2 Blocked

Possible Cause Reservoir sensor RS2 is defective.

Action Enter the sensor tests within the test menu and verify sensor RS2 is functional. If sensor is unable to pass the sensor test, replace the Analog Board.

S1 Blocked

Possible Cause Reservoir sensor S1 is defective.

Action Enter the sensor tests within the test menu and verify sensor S1 is functional. If sensor is unable to pass the sensor test, replace the Analog Board.

S2 Blocked

Possible Cause Reservoir sensor S2 is defective.

Action Enter the sensor tests within the test menu and verify sensor S2 is functional. If sensor is unable to pass the sensor test, replace the Analog Board.

HELP CODES

Help #01

Possible Cause Check reveals that timing is wrong for the 65C02 chip (maybe a 6502 is used) clock cycles counted for execution of ADC in decimal mode. Cycles should be 3 for 65C02, 2 for 6502.

Action Replace CPU Board.

Help #02

Possible Cause Bad CORE chip.
Bent pin.
Bad socket.

Action Replace CORE chip. If problem persists, replace CPU Board.

Help #03

Possible Cause Bad or missing translation chip.
Bent pin.
Bad socket.

Action Install or replace translation chip. If problem persists, replace CPU Board.

Help #04

Possible Cause Bad translation chip.
Bent pin.
Bad socket.

Action Replace translation chip. If problem persists, replace CPU Board.

Help #05

Possible Cause Incompatible translation chip version.

Action Replace translation chip.

Help #06

Possible Cause Bad APC chip.
Bent pin.
Bad socket.

Action Replace APC chip. If problem persists, replace CPU Board.

Help #07

Possible Cause Address xxxx in the RAM (address \$0000...\$0FFF) failed the pattern test. RAM test writes out \$55's and tests, then \$AA's, the \$00's again, and tests for \$00.

Action Replace CPU Board.

Help #08

Possible Cause Interrupt received, but cannot be attributed to any VIA. The VIA chips are the only legal sources for IRQ's. The IRQ was possibly caused by static.

Action Replace CPU Board.

Help #09

Possible Cause Incompatible chip set.

Action Verify version and checksums on TRAN, CORE and APC.
Replace all chips if necessary.

Help #10

Possible Cause An internal error occurred when writing to the EEPROM long term memory storage device (i.e., Seq 2864).

Action Cycle power and monitor for repeated failures.

Help #11

Possible Cause The EEPROM write queue has overflowed. Displayed with one 4 hex digit diagnostic which indicates the address of the code which attempted to overfill the EEPROM write queue.

Action Record the diagnostic information and report to Baxter.

Help #12

Possible Cause Read lock was active when attempting EEPROM deferred verify.

Action Do not replace parts. DO REPORT to Baxter.

Help #13

Possible Cause An internal error occurred when writing to the EEPROM long term memory storage device (i.e., Seq 2864). Perhaps the 2864 needs to be replaced.

Action Replace EEPROM 2864.

Help #14

Possible Cause EEPROM signature is not recognized by the installed software version. Proceeding will cause the EEPROM to be completely initialized. Expected after installation of a software field update.

Action Press the **F** in Fenwal to proceed with initialization of the EEPROM.

Help #15

Possible Cause Self test found unrecoverable corrupt data in the EEPROM. The address of the corrupt data, and the data found in each of the 3 mirror images is printed following the help code. Corrupted data requires re-initialization of part of the EEPROM. The EEPROM partition which requires initialization is one of:

- entire EEPROM (corrupt signature)
- run time hours
- venipuncture hours
- number of donors
- config menu settings
- atmosphere
- reserved.

No initialization will occur until the **F** in Fenwal is pressed to approve the change to EEPROM data. Repeated occurrences of this help code at the same EEPROM address(es) may indicate a faulty EEPROM part.

Action Press the **F** in Fenwal to approve the re-initialization of an EEPROM data partition. The name of the corrupt data partition will be identified on the display as it is re-initialized. Self test will then be restarted at the beginning of the EEPROM test. Verify configuration and calibration settings.

Help #16

Possible Cause Self test found correctable data errors in a partition of the EEPROM. The address of the first data error in the partition, and the total number of errors found in each of the 3 mirror images for that partition is printed following the help code. All correctable data errors for a given partition are serviced by one help code instance. The errors are corrected for the entire block after approval is indicated by pressing the **F** in Fenwal at the help code screen. Repeated occurrences of this help code at the same EEPROM address(es) may indicate a faulty EEPROM part.

Action Press the **F** in Fenwal to approve the correction of recoverable data errors in an EEPROM data partition. After the partition is corrected, self test will be restarted at the beginning of the EEPROM test. Verify configuration and calibration settings.

Help #17

Possible Cause Unrecoverable corrupt data was found in the EEPROM at run time. The address of the corrupt data, and the data found in each of the 3 mirror images is printed following the help code. Corrupted data requires re-initialization of all or part of the EEPROM. The EEPROM partition which requires initialization is one of:

- entire EEPROM (corrupt signature)
- run time hours
- venipuncture hours
- number of donors
- config menu settings
- atmosphere
- reserved

No initialization will occur until the Autopheresis-C has entered the self test following being power cycled. Repeated occurrences of this help code at the same EEPROM address(es) may indicate a faulty EEPROM part.

Action Power cycle the Autopheresis-C. A help code 15 should then occur during self test as a result of the problem detected by help code 17. Proceed with the help code 15 response.

Help #18

Possible Cause A correctable data error was found in the EEPROM at run time. The address of the data in error, and the data found in each of the 3 mirror images is printed following the help code. No correction will occur until the Autopheresis-C has entered the self test following being power cycled. Repeated occurrences of this help code at the same EEPROM address(es) may indicate a faulty EEPROM part.

Action Power cycle the Autopheresis-C. A help code 16 should then occur during self test as a result of the problem detected by help code 18. Proceed with the help code 16 response.

Help #19

Possible Cause Faults were detected during every pass of multiple EEPROM self test scan. During the EEPROM self test, if correctable faults were corrected, or non-correctable faults were formatted, then another pass is made through the self test in an attempt to make a complete pass without detecting any faults. Only 3 total passes are allowed. If every pass finds faults, then the soft test is stopped by help code 19.

Action Replace the EEPROM at U38. If problem persists, replace CPU Board.

Help #20

Possible Cause The redundant ground return line from the air detector is high (should be low), indicating broken cable (or, on A100, missing A-board jumper). Also could be a bad W-17 cable to Air Detector Board. If new air detector assembly is not present (852009-001) this message will be displayed indicating that the fourth lead on the air detector is open or that there has been a fault detection.

Action Verify Air Detector Board version.
Replace Air Detector Board.
Replace W-17.
Replace W-1.
Replace CPU Board.

Help #21

Possible Cause Check reveals a pressure sensor is out of allowable range for atmospheric pressure. Either the sensor is bad or a tube set was left on when the instrument recorded atmospheric pressure. The allowable range for atmospheric pressure is $83 \leq P_n \leq 115$ mach units (default = 99 machine units, 1 mach unit = 4 mmHg).

Action If a tube set is left on the pressure sensors, remove the tube set and cycle power.

Check that the transducers are properly connected.

Replace EEPROM 2864.

Replace Analog Board.

Replace W-1.

Replace CPU Board.

Help #22

Possible Cause The named sensor was read as CLEAR before the reservoir strobe light was turned ON. All sensors must read blocked before the light source is turned ON. Light from external source probably shining directly on the sensor, or the sensor is bad.

Action Enter test menu, sensor test and calibrate reservoir LEDs.

Replace Analog Board.

Help #23

Possible Cause AIR/STOP latch on Driver Board worked but no latch air on CPU Board was detected.

Action Replace CPU Board.

Help #24

Possible Cause Latched AIR signal worked on CPU Board but no AIR/STOP latch on Driver Board was detected.

Action Replace W-2 cable, CPU Board and/or Driver Board.

Help #25

Possible Cause The AIR/STOP latch was triggered, indicating either a STOP or AIR DETECT, but neither STOP or AIR was received by the processor. There is either a problem with the connections to the main CPU Board for AIR or STOP, or a problem with the AIR/STOP latch. These signals may have been falsely triggered by static.

Action Restart and monitor for repetitive failures.

If problem persists, replace CPU Board, Driver Board and/or W-2 cable.

Help #26

Possible Cause An NMI interrupt was received, indicating that the watchdog timer has timed-out. The watchdog timer is not receiving any reset pulses for > 100 ms (i.e., 10 Hz loop has frozen some place; perhaps in an infinite loop or a bad data fetch).

Action Cycle power and monitor for repeated failures.

If problem persists, replace CPU Board, Driver Board and/or W-2 cable.

Help #27

Possible Cause A 65C02 BRK instruction was processed, causing the program to stop and display the BRK message. A BRK instruction is never legally executed in the program.

Action Check that program PROMs are installed correctly.
Replace CPU Board.
Report repetitive failures to Baxter.

Help #28

Possible Cause APC tasks took more than 100 ms to execute.

Action Cycle power and monitor for repeated failures.
Replace CPU Board.
Report repetitive failures to Baxter.

Help #29

Possible Cause CORE test menu tasks took more than 100 ms to execute.

Action Cycle power and monitor for repeated failures.
Replace CPU Board.
Report repetitive failures to Baxter.

Help #30

Possible Cause VIA1 failed on the STOP circuit.

Action Replace CPU Board.

Help #31

Possible Cause VIA3 failed on the STOP circuit.

Action Replace CPU Board.

Help #32

Possible Cause Relay failed on the STOP circuit.

Action Replace CPU Board.

Help #33

Possible Cause 6 ms not remaining after APC task run.

Action Replace APC.

Replace CPU Board.

Report repetitive failures to Baxter.

Help #34

Possible Cause Bad CPU Board

Action Replace CPU Board.

Help #35

Possible Cause Divide by 0 was encountered, or Divide Overflow resulted. The letter after the help code will be "2" or "0", for zero, or overflow.

Action Report to Baxter.

Help #36

Possible Cause Data port was in receive mode when setting EEPROM address.
Possible short on PORTRCV signal at VIA2.

Action Check CPU hardware.
Replace CPU Board.

Help #37

Possible Cause ADC conversion failed.

Action Replace Analog Board.

Help #40

Possible Cause An internal APC error occurred when trying to handle the pump volumes. The resource is no longer available (i.e., the same resource is being deleted twice, the second delete failed).

Action Report to Baxter.

Help #41

Possible Cause The APC tried to allocate memory used to pump a volume of fluid and there are no more internal resources to allocate this memory.

Action Report to Baxter.

Help #51

Possible Cause The atmospheric values for P1 or P2 differ from atmospheric values stored in EEPROM by greater than 16 mmHg. Pressure sensors may be malfunctioning, or the stored EEPROM values may be wrong.

Action Reset the EEPROM values for atmospheric by closing DIP switch 2, then pressing the **F** and ADVANCE **▼** keys when the error is displayed. Power needs to be cycled.

If problem persists, replace pressure transducer, and/or Analog Board.

Replace EEPROM 2864, if necessary.



Note: If machine has been running at least for 1 hour, then the warm atmospheric readings need to be updated.

Help #52

Possible Cause The test for fluid to air transition has failed to generate an interrupt on the VIA. This indicates a VIA failure or the IRQ line is compromised. This message is generated if there is DC AIR and no AIR interrupt.

Action Cycle power and monitor for repeated failures.

Replace CPU Board if problem persists.

Help #53

Possible Cause Hb detector door is closed and the red and green signals are out of range (i.e., red signal, REDSIG, or green signal, GRNSIG, is less than 20 mach units).

Action Check Hb detector in test menu.

Recalibrate Hb detector.

Replace Analog Board.

Help #54

Possible Cause Check reveals no HbDET calibration value in EEPROM.

Action Recalibrate the Hb detector.
Cycle power and check that the system has accepted the new calibration value.
If message returns, replace the EEPROM.

Replace the CPU Board.

Help #57

Possible Cause Value is held in memory in 2 different locations such as the AC ratio air trigger flag and stop trigger flag and the 2 values don't match. Most likely cause is a bad RAM.

Action Replace RAM chip or chips.

Replace CPU Board.

Help #58

Possible Cause The commanded direction of the blood pump, given by the software, is counterclockwise (towards the donor), but without the air detector being enabled.

Action Error exception for development.
No recovery.
Report to Baxter immediately.

Help #59

Possible Cause During machine calibration and before venipuncture, a check reveals a problem with the 24 V relay, either not opening or not closing. Either M1 turned with relay open or M1 did not turn when commanded with relay closed.

Action If message is "Help #59 24," replace Driver Board.

If message is "Help #59 45," replace motor 1, cable to motor 1 and/or Driver Board.

Inspect the relay. Replace Driver Board if necessary.

Replace RAM chip or chips.

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PARTS LIST FOR AUTOPHERESIS-C INSTRUMENT

| Description | Part # |
|-----------------------------------|------------|
| 22 Pin Test Connector | TF22PC |
| Active Pressure Cuff | 556541001 |
| Air Detector Sensor | 851916001 |
| Battery, 12 VDC | 851743001 |
| Blood Pressure Cuff | 556524002T |
| Button, USA | 9185000015 |
| Caster, Leveling | 556511001 |
| Caster, w/brake | 250603002 |
| Clamp "0" Ring | 156515001 |
| Clamp, N/C Quiet | 556581001 |
| Clamp, N/O Quiet | 556580001 |
| Compressor, Cuff | 556543001 |
| Cuff Sleeve | 4994000260 |
| Device Support, Lower | 556570001 |
| Filter Tray (Plastic) | 158126001 |
| Filter Foam | 158127001 |
| Filter Tray, Assy (Tray & Filter) | 558046001 |
| Fuse 2 Amp | 200159023 |
| Fuse 4 Amp | 200159029 |
| Hanger, Bag | 6001256220 |
| Hanger, Bottle | 656504001 |
| Hanger, Dual Bag/Bottle | 1571256219 |

| Description | Part # |
|----------------------------------|---------------|
| Hb Calibrator | 1571256212 |
| Hb Detector Gasket | 6001256110 |
| Hb Calibrator Replacement Filter | TF4702 |
| Luer, Plastic (P1, P2) | 770300212 |
| M4 Load Resistor | 556574001 |
| Membrane Switch | 9165001251 |
| Molded Lens Detector | 770300379 |
| P1, P2 or P3 Pressure Transducer | 851995001T |
| Plasma Cell Drive Assembly | 556588001 |
| Power Supply, Cherokee | 851731002 |
| Power Supply, Converter Concepts | 258087002 |
| Precision Scale with Dust Bag | 558035001 |
| Precision Scale, Screw | 250764101 |
| Precision Scale, Washer | 200516009 |
| Prompt Valve Assembly | 556540001 |
| Pump Assembly | 556519001 |
| Pump Mandrel | 556554001 |
| Pump Cover Retainer | 158104001 |
| Pump Extension Spring | 250711002 |
| Pump Gasket | 156516001 |
| Pump, Bronze Pump Link | 156728001 |
| PCB, Display | 556517001 |
| PCB, Spinner | 556518002 |
| PCB, Air Detector | 852009001 |

| Description | Part # |
|------------------------------|------------|
| PCB, Analog | 556521001 |
| PCB, Bar Graph | 556503001 |
| PCB, Blood Detector | 556501001 |
| PCB, CPU | 556505001 |
| PCB, Driver | 556520001 |
| Resistor Pack | 556571001 |
| Roller, Cage | 556568001 |
| Shim 0.040" | 9025005088 |
| Shroud, Front | 156508001 |
| Shroud, Rear | 156509001 |
| Support Column (Cherokee) | 1571256210 |
| SpikeSmart Hanger | 9075005007 |
| Tube Guide; AC | 156815001 |
| U15 6.0 PROM | |
| U16 6.0 PROM | |
| U17 6.0 PROM | |
| U 38 | 851784001 |
| W-1: Main Bus Cable | 556533001 |
| W-2: A/BI/O Cable | 556532001 |
| W-3: Low Voltage Power Cable | 1571256206 |
| W-4: Power Supply Cable | 556514001 |
| W-5: Donor Bar Graph Cable | 556534001 |
| W-6: Remote Interface Cable | 556531001 |
| W-7: Clamp Cable | 556536001 |

| Description | Part # |
|--|---------------|
| W-8: Fan Cable | 556539001 |
| W-9: Blood Detector Cable | 556538001 |
| W-10: AC Power Supply Cable | 556509001 |
| W-11: Spinner Bus Cable | 556530001 |
| W-12: AC Power Switch Cable | 556512001 |
| W-16: M1, M2, M3 Motor Cable | 556573001 |
| W-17: Air Detector Cable | 556546001 |
| W-19: Motor Ground Wires | 556549001 |
| W-21: Battery Cable | 556513001 |
| W-47: Ground Wire Pressure Transducer, Divert, Reinfusion | 556549002 |
| W-48: Clamp Ground Wire (Plasma, Saline, Blood, Hb Det, Weigh Scale, Air Detector) | 556549003 |
| W-49: Ground Wire Lower Device Support | 556548001 |
| Weigh Scale Bag | 158080001 |

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SCOPE

This procedure is intended to test the air detector in the Autopheresis-C Instrument model A-200. Two Autopheresis-C Instruments are needed in order to perform the test.

Required Equipment:

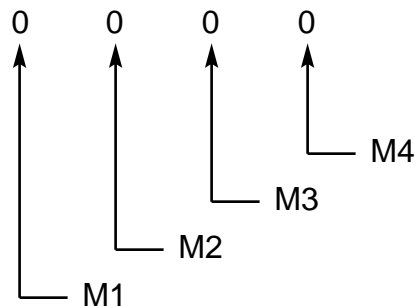
- Air Bubble Test Tube Set Made From Special Tube Set. See Figure A.1 (4R2252), P/N 921-5001-680.
- Water at Room Temperature.
- Hamilton Microliter Syringes (25 μ l) P/N 921-5001-679 or equivalent.
- Autopheresis-C Service Test Fixture, P/N 921-5003-425 or equivalent Autopheresis-C Instrument.



Note: Ensure every measurement instrument used is calibrated before performing this procedure.

TEST PROCEDURE

1. Install the special tube set into M2 of the subordinate AP-C according to Figure A.2.
2. On the subordinate AP-C select **Motor Varispd #2** test program in system test menu. Verify forward (counterclockwise) direction of pumps. Press ADVANCE ▼ and the command flow rates are displayed as:



3. Press ▶ to set the M2 command flow rate to 170 mL/min, let the water run through the tube to remove all the air in the tube. Stop the subordinate AP-C.
4. Install the special tube set into the air sensor housing of the AP-C under test according to Figure A.2.
5. On the AP-C under test, select **Air Detector Test** test program in system test menu. Press ▶ to activate the air purge sequence.
6. Inject the air bubble of determine size into the tube (refer to Table A.1). Verify that the AP-C under test response according to Table A.1.

| Air Bubble Size | Flow Rate | AP-C Response |
|-----------------|------------|--|
| 2 microliters | 30 mL/min | System does not trigger (no tone) Air Purge not required. |
| 17 microliters | 150 mL/min | System trigger (get tone) Air Purge Required. |

Table A.1 Air Bubble Size



Note: Any one failure of these tests shall be considered a failure, and the technician is not allowed to repeat tests until passing.

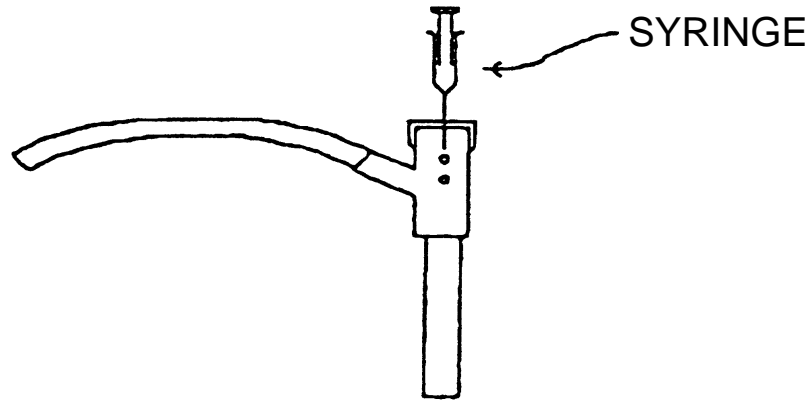


Figure A.1 Special Tube Set

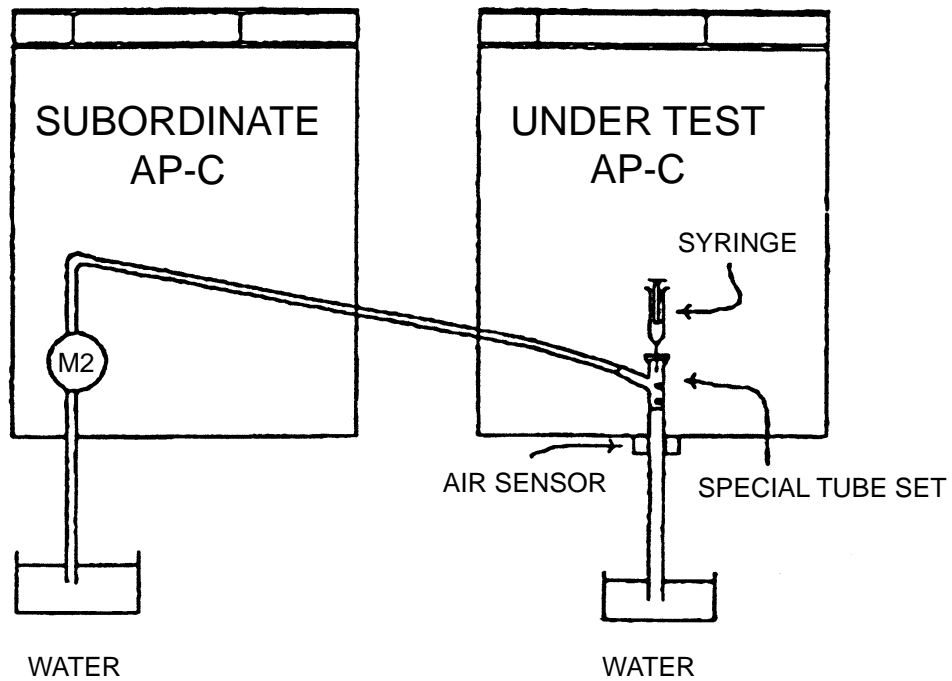


Figure A.2 Air Bubble Test Tube Routing

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AUTOPHERESIS-C VERSION 6.0x SOFTWARE RELEASE NOTES

Autopheresis-C software version 6.0x and above detects, in certain instances, that changes must be made to non-volatile data stored in the EEPROM. In these instances, *operator intervention is required before the data is changed.*

Help code 14 occurs when the EEPROM must be initialized and is expected to occur after a software field upgrade. Help codes 15 - 19 are related to corrupt or correctable data as detected by the EEPROM data mirroring functions, and result in a required keypress before changes to EEPROM data are made. Help codes 14, 15 and 16 require the operator to press the **F** in Fenwal before proceeding to change EEPROM data. Help codes 17 thru 19 do not accept a keypress: They require that power be cycled so that the EEPROM data changes can be handled by help codes 15 and 16 during self test.

In addition to these help codes there are two other instances of messages which require operator intervention in order to proceed with a change to EEPROM data. These are:

- "Config: Defaults"
- "Setting To English"

In both cases the message is displayed and then the Autopheresis-C waits until the operator presses the ADVANCE ▼ key before proceeding to change the data.

*To summarize, help codes which change EEPROM data will wait for the **F** in Fenwal key to be pressed. Non-help code messages which change EEPROM data will wait for the ADVANCE ▼ key to be pressed.*

The field update procedure below shows an example of both types of operator interventions.



Note: The "Config: Defaults" message will be seen

- after the EEPROM is initialized ("Init EEPROM: 80 sec"), and
- after "Reset Defaults: Yes" from the Config Menu.

The "Setting To English" message will be seen after

- changing U15 to a different translation EPROM chip,
- selected translation out of range caused by removing a translation chip (non-U15) on which a translation was selected.