

Sarns™ TCM II

Technical Support Manual



System Software Version 2.0
Remote Software Version A

Technical Support Manual

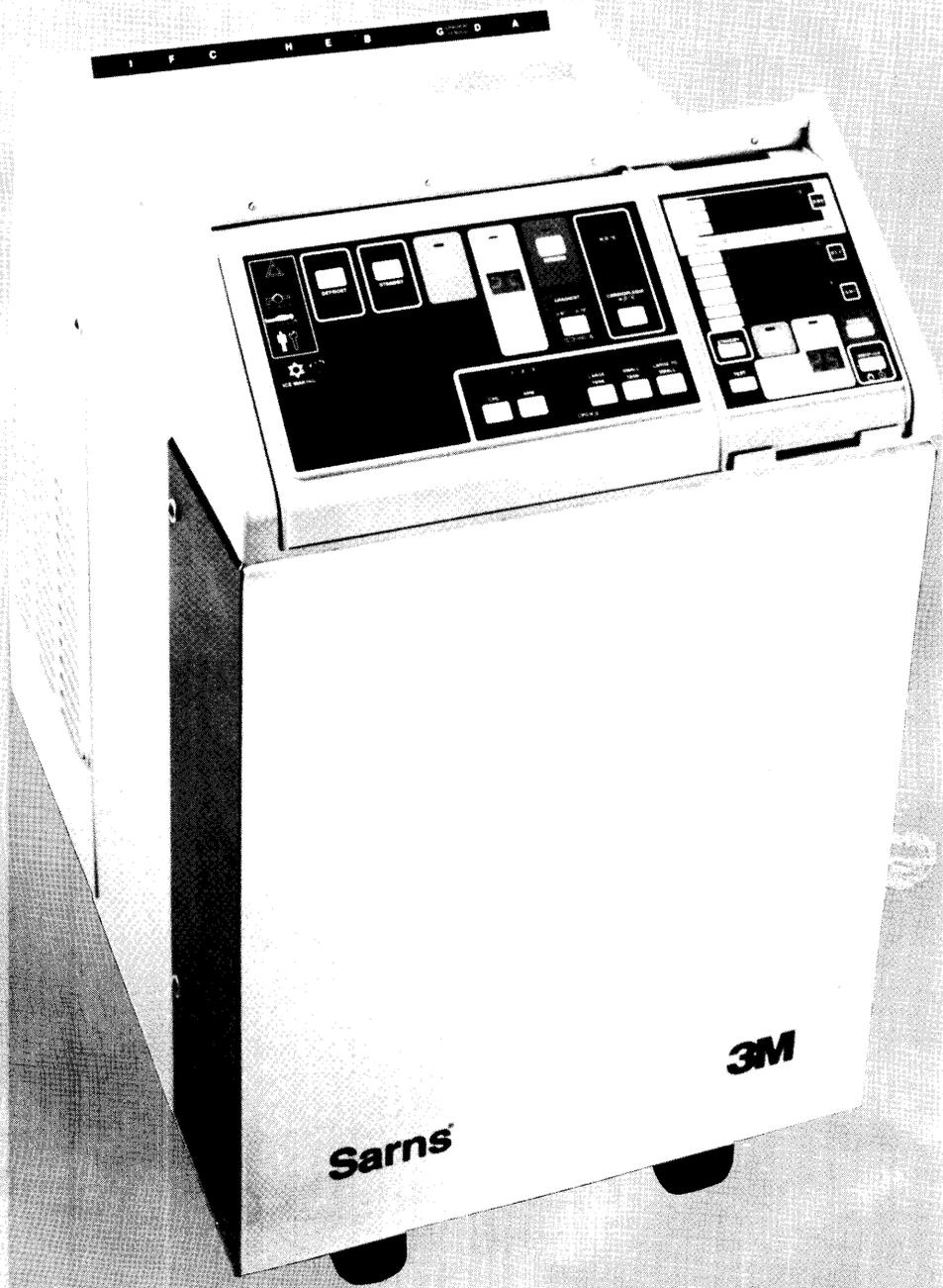
Sarns™ TCM II

4415 115 V/60 Hz w/ Cardioplegia (3M I.D. No. 98-0702-0629-1)

4416 220-240 V/50 Hz w/ Cardioplegia (3M I.D. No. 98-0702-0627-5)

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How To Use This Manual

This manual provides technical information about the Sarns™ TCM II. It is intended for Certified Clinical Engineers, Biomedical Electrical Technicians, and those trained to service Sarns equipment. The information in this manual is specific to this device and should not be used for any other equipment.

Precaution: Those competent in the areas of electrical and mechanical repair, such as hospital technicians, may replace those parts designated in this manual as replaceable. More complex repairs may be made only by persons specifically trained and certified by Sarns to work on the Sarns™ TCM II.

Read the Operators Manual before making any checks or replacements. The manual includes a description of the product, safety warnings, and equipment precautions, preparation, operation and maintenance information, and warranty limits.

Use the Check and Calibration Procedure for preventive maintenance.

Contact Sarns Service, your 3M subsidiary or your authorized Sarns representative when replacing any parts.

Refer to the Performance Specification and Diagrams for basic information on how the system should function.

Fully test the Sarns™ TCM II after each servicing, using the tests included in the Operators Manual.

Warnings

Before servicing the system, disconnect the Sarns™ TCM II from the wall power source.

Always review the Safety Warnings and Equipment Precautions contained in the Operators Manual before servicing the system.

Check and Calibration Procedure

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Preliminary Steps

On the lower right side of the TCM, above the System Power and Ice Maker switches:

- Record TCM part number.
- Record TCM serial number.
- Record TCM run hours.

If TCM has a Remote Temperature Display Module, look on the right side of the module:

- Record the Module part number.
- Record the Module serial number.

Prepare the System

Be aware of the following:

- Unless otherwise specified, the various voltages listed throughout this procedure are based on a nominal line voltage to the unit.
- Whenever a check condition is not met, refer to the appropriate Heater, Pump and Valve sections located in the Troubleshooting Chart.

Before conducting any checks or calibrations, prepare the system as follows:

1. Set-up

a. Connect all water loops.

Note: Include a ball-type valve and drainage line in the following cardioplegia and arterial water circuits. (These connectors are included in the accessory kit: P/N 78-8067-4125-8.) Connecting loops of more than 2 ft. in length may affect the rewarm time specified on the following pages.

- Position the unit near a sink or floor drain.
- Locate In and Out ports at the bottom of the rear of the TCM.
- Connect 2 ft. (0,6 m) tubing to In port labeled ART H2O.
- Connect the other end of the same tube to the ART H2O Out port.
- Connect 2 ft. (0,6 m) tubing to In port labeled CPG H2O.
- Connect other end of same tube to CPG H2O Out port.
- Connect 2 ft. (0,6 m) tubing to In port labeled BKT H2O.
- Connect other end of same tubing to BKT H2O Out port.

b. Add water, filling both tanks to the maximum level indicated.

c. Check that ground impedance is less than .1 ohm.

d. Check the ground leakage current.

2. Verify Power Supply

Note: For AC reference point, use Pin 2 of Plug 50 or 51, located at Heaters 1 and 2. The DC common is the negative (-) lead of the large blue capacitor, located above the heat sink assembly midway up the right front side of the unit.

a. Turn System Power and the Ice Maker OFF.

b. Remove the lower front panel.

- Locate two screws on right side of TCM that connect front panel to TCM and remove them.
- Locate two screws on left side of TCM that connect front panel to TCM and remove them.
- Gently lift and remove the front panel.
- Place front panel away from the TCM.

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- c. Remove the rear panel.
 - Locate two screws at top of the rear panel and remove them.
 - Locate and remove two screws at bottom of the rear panel.
 - Half-way down on both sides of the rear panel, locate and disconnect latches connecting rear panel to side panels.
 - Place panel away from the TCM.
- d. Remove the side panels.
 - Locate and remove three screws connecting right side panel to the TCM.
 - Locate and remove three screws connecting left side panel to the TCM.
 - Place both side panels away from the TCM.
- e. Turn System Power ON and verify the following voltage readings on each side of the fuse. If the correct voltage is not read at each end, replace the fuse and recheck the voltage.

Fuse Nominal Voltage

<u>Fuse</u>	<u>Location</u>	<u>Fuse Rating</u>	<u>Nominal Voltage</u>
F1	Main board	6.25A slo-blo	4.8 to 5.2 VDC
F2	Main board	1 AMP	26 to 31 VDC for 115 VAC, or 23 to 29 VDC for 220 VAC
F3	Main board	100 mA slo-blo	-26 to -31 VDC for 115 VAC, or -23 to -29 for 220 VAC
F4	Not used		
F5	Not used		
F6	Main board	7A slo-blo, 115 V 5A slo-blo, 220 V	115 VAC 220 VAC
F7	Cardioplegia board	100 mA slo-blo	7 to 11 VDC
F8	Cardioplegia board	100 mA slo-blo	26 to 31 VDC for 115 VAC or 23 to 29 for 220 VAC
F9	Compressor board	1/32 AMP	115 VAC or 220 VAC
F10	Midway up the front of machine, left of the blue capacitor	6.25A slo-blo	7 to 11 VDC
F11	Main board	3 AMP	115 VAC
F13	Compressor board	100 mA slo-blo	10-15 VAC
F14	Compressor board	100 mA slo-blo	115 VAC or 220 VAC

- f. Press CPG to start cardioplegia. Make sure the #3 LED above the RPM switch is lit. Check:

F12	Cardioplegia board	2.5 AMP	115 VAC
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- g. Press CPG switch to turn cardioplegia OFF.

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3. Verify Startup Conditions

- a. Turn System Power ON.
 - Self test lasts approximately 6 seconds. Verify that:
 - All front panel LEDs light.
 - All displays show “88.”
 - The sonalert sounds.
 - Displays and LEDs turn off briefly.
 - Software version 2.0.0 is displayed as “02” on the Maintain display, and “00” on the Water Temperature display.
 - Standby LED begins flashing.
 - All valves energize, signaled by audible click.
 - Internal Prime lasts approximately 60 seconds. Afterward, verify:
 - Standby LED stops flashing, but remains lit.
 - Cooldown LED flashes (until next mode is selected).
 - The Maintain display shows 25°.
 - Water Temperature display shows manifold water temperature.

Note: With Temperature Display Module installed, remote control LEDs respond like their counterpart on the main control panel. For temperature, the A, D, and G LEDs light. With no probes installed, the temperature displays show —.—.—.

- b. Prime External Loops.
 - Press Cooldown switch. Leave system in Cooldown mode until all air bubbles are purged from external tubing.
- c. Press Standby.

4. Check Maintain Mode

The Maintain mode begins warming water or adding cold water to attain and maintain an operator-selected temperature.

Note: When the Maintain switch is pressed, one or two heaters may turn on, or water may flow over the cold plate to maintain the selected temperature.

- a. Press and hold the Maintain DOWN arrow to observe Maintain display decrease in 1° increments from 25° until stopping at 00°.
- b. Press and hold the Maintain UP arrow to observe Maintain display increase in 1° increments to 25°.
- c. Press Maintain. Observe:
 - The Maintain LED lights.
 - The main pump starts.
 - Valve 2 energizes. (Valve 1 may energize if water temperature exceeds set Maintain temperature.)
 - The water temperature increases or decreases in 1° increments to 25 ± 1°C and maintains that temperature.
 - Wait one minute for water temperature to stabilize.
- d. Press Standby; the Standby LED lights. Main pump stops.
- e. Press Maintain UP arrow until Maintain display shows 30°.
 - Simultaneously Press Maintain and start external timer. Observe:
 - Maintain LED lights.
 - Main pump starts.

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- Record the time it takes for water temperature to reach 30°C. It should take 3 minutes or less. If it takes longer than 3 minutes to maintain 30°C and there is evidence of cold water trickling over the cold plate, Valve 1 may be malfunctioning.
 - f. Press Standby.
 - g. Press and hold Maintain UP arrow until Maintain display shows 42°C.
 - h. Press Maintain. Observe:
Water temperature increases to and maintains $42 \pm 1^\circ\text{C}$.
 - i. Press Standby; Standby LED lights.
 - j. Press Maintain DOWN arrow until Maintain display shows 25°C.
 - k. Press Maintain. Observe:
Water flows at high rate over cold plate until water temperature is 32°C (with adequate ice supply).
Water flow then decreases by one-half until 25°C is reached.
- Note:** Water temperature may overshoot 5-7°C. Before proceeding, allow water temperature to stabilize at 25°C.
- l. Press Standby: Standby LED lights. Main pump stops.

5. Check Cooldown Mode

Cooldown mode opens the valves to circulate cold water from the large tank through the main hose circuitry and blanket circuitry if appropriate.

- a. Check that there is an adequate supply of ice for this procedure.
- b. Check that water temperature is 25°C. If is not, press Maintain UP or DOWN arrow to 25°C and press Maintain switch. Wait until temperature stabilizes at 25°C.
- c. Press Cooldown switch. Observe:
Cooldown LED lights.
Heaters go off.
Water flows full-force over the cold plate.
Water temperature decreases to below 10°C in less than 20 seconds.
- d. Press Standby.

Note: If the water temperature takes longer than 1 minute to decrease below 10°C, check that ice supply is adequate. Verify that main pump has started. Verify that Valve 1 only is energized.

6. Check Rewarm Mode

Rewarm mode activates the heaters to warm water at maximum speed up to 42°C.

- a. Press Rewarm switch. Observe:
Rewarm LED lights.
Pump starts.
Both heaters come on.
Heater #1 turns off immediately after water temperature passes 41°C.
Valve 2 only energizes.
Water temperature should increase 10°C in 3 minutes or less.
Water temperature display shows 42°C and maintains 41° to 42°C.
Heater #2 cycles on and off to maintain 41° to 42°C.

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7. Check Pump Not Primed Alarm

The Pump Not Primed LED lights to warn that outlet pressure has dropped because the main pump has lost its prime and shut off. This alarm does not apply to the cardioplegia pump.

- a. Make sure System Power is OFF.
- b. Disconnect Plug 21 from the main board.
- c. Turn System Power ON. Allow for Startup procedure to finish.
- d. Press Cooldown switch. Observe:
Within 5 to 10 seconds, the unit will simultaneously beep, light the Pump Not Primed LED, and automatically change to Standby mode.

Note: On the TCM I, the Pump Not Primed LED does not remain lit.

- e. Turn System Power OFF.
- f. Reconnect Plug 21.

Note: If alarm does not function properly, refer to Troubleshooting section.

8. Check H2O > 42°C Alarm and Thermostat

The H2O > 42°C alarm LED lights to warn that the water temperature is at or above 42.5°C. When this occurs, the alarm sounds and the heaters automatically turn off.

- a. Turn System Power and Ice Maker switches OFF.
- b. Locate main board.
 - Remove P12 from J12 on main board.
 - Install P/J 12 Over-Temperature Fixture between J12 and P 12 cable harness.

Note: The above procedure will allow the temperature to increase above what the software allows; the software is bypassed in order to check the thermostat.

- c. Turn System Power ON.
- d. Press Rewarm. Observe:
Water temperature continues to increase through 42°C, but not exceed 44°C. (This may take some time depending on the original water temperature.)
The sonalert sounds.
The H2O > 42°C LED lights.

Note: If the water temperature exceeds 44°C, check to make sure there are no kinks in the external water lines, and that the thermostat is properly connected.

- e. Turn System Power OFF.
- f. Remove P/J 12 Over-Temperature Fixture and reconnect P12 with J12.

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9. Check the Compressor

Note: The Ice Maker switch starts and stops the compressor. However, when returning from OFF to ON position, there will be a delay of up to 6 minutes before the compressor starts again.

- a. Make sure System Power and Ice Maker switches are OFF.
- b. Simultaneously turn Ice Maker switch ON and start an external timer.
Observe:
The green Ice Maker lamp (located on the left side of the main panel) lights within 6 minutes.

Note: With a substantial amount of ice already present in the large tank, compressor might not start, but green Ice Maker lamp will light.

- c. Make sure fan runs quietly. Listen for excessive rattling. (A dirty unit or mechanical failure can prevent the fan from functioning properly.)

Note: The compressor will often rattle when System Power is turned ON.

- d. Turn the Ice Maker switch OFF.

Note: Clean the condenser coils at least once every 3 months. Unplug the system from its wall power supply. Remove the back and left rear panel. Use a soft brush or vacuum to remove lint from coils. Replace the panels and plug system back into wall power.

Precaution: Remove any lint from the refrigeration coils to prevent damage to the ice maker. When cleaning coils, beware of sharp edges.

10. Check the Service Alarm.

The Service LED lights to warn that the water temperature is not changing as expected, that the 2 internal temperature probes are not in agreement, or that there are problems within the A to D board. This alarm is labelled as System Malfunction on models prior to TCM II.

- a. Make sure System Power and Ice Maker are OFF.
- b. Locate connectors P1 and P2 on the main board.
- c. Remove either connector P1 or P2 from the main board.
- d. Turn System Power ON. Observe:
Sonalert sounds for 3 seconds.
Service Alarm/System Malfunction LED lights.
- e. Reconnect P1 or P2. Service Alarm/System Malfunction LED goes off.
- f. Press Standby.

11. Check the Cardioplegia Water Supply

Note: The large tank mode and the small tank mode are both dependent on an external closed loop for water flow. The large to small tank mode is not dependent on an external closed loop.

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- a. Press the CPG (cardioplegia) pump switch. Observe:
The pump LED lights and the pump starts.
Valves 4 and 6 energize.
The #3 LED above the RPM switch is lit, indicating that water flows full force from the small tank to the large tank.
- b. Vary the pump speeds and check the flow rate changes accordingly.
 - Press the RPM switch once. The #1 (low speed) LED lights and water flows from the small tank into the large tank at a greatly reduced rate.
 - Press the RPM switch again. The #2 (medium speed) LED lights. The water flow rate increases.
 - Press the RPM switch again. The #3 LED lights. The water flow rate increases to an even greater speed.
- c. Press the large tank switch. Observe:
The large tank LED lights.
Valve 4 only energizes.
Water continues flowing from the small tank into the large tank, and through the CPG ports.
 - Using a clamp or hands, momentarily restrict the water flowing through the external loop leading to the CPG ports. Observe:
Water stops flowing from the small tank into the large tank.
- d. Place an external thermometer into the small tank.
 - Press and hold the CPG water display switch. Observe:
The temperature in the small tank is the same as the CPG water display $\pm 1^{\circ}\text{C}$.
- e. Press Standby.

12. Check the Low Flow to Blanket Alarm.

The Low Flow to Blanket LED warns that water flow for the blanket is low.

- a. Verify that the blanket hose or closed loop is connected to the blanket ports.
- b. Press Cooldown.
- c. Remove one (1) side of the blanket loop from its port. Observe:
The Low Flow to Blanket LED lights.
- d. Reconnect the dislodged side of the blanket loop. Observe:
The Low Flow to Blanket LED goes out.
- e. Press Standby.

13. Check Defrost Mode.

Defrost mode turns the compressor off and the heaters on. It circulates warm water throughout the large tank until the water temperature reaches 20°C .

Note: Standby mode must be selected before Defrost can be initiated.

Note: On TCM I, Low Flow to Blanket LED lights during Defrost mode.

- a. If not in Standby mode, press Standby. Observe:
The Standby LED lights.

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- b. Press Defrost. Observe:
 - The Defrost LED lights.
 - The heaters and main pump turn on until the water temperature reaches 20°C.
 - Water runs full force over the cold plate.
 - Valves 1 and 3 only energize.

- c. Press Standby.

Note: If the water temperature display shows 20°C or above, the system will automatically revert to Standby mode. After the water temperature reaches 20°C, the Ice Maker (if turned on) will start.

Note: As it may take 2-3 hours to reach 20°C in Defrost mode if previous steps followed in sequence, during which time existing ice will melt, simply confirming that the Defrost mode is operational may suffice.

Note: If TCM does not have the optional Remote Temperature Module, proceed to Step 19 Calibrating the Main System.

14. Check the Remote Temperature Display Module.

- a. Verify the high and low alarm limits.
 - Set a high limit on channel A.
 - Press the black ABC switch until channel A LED lights.
 - Press and quickly release the High switch. Observe:
 - The top display shows 42°C.
 - Press and hold the High switch until the display shows 24°C.
 - Set a low limit on channel A.
 - Press and quickly release the Low switch. Observe:
 - The top display shows 00.0°C.
 - Press and hold the Low switch until the display shows 05°C.
- b. Verify that each alarm limit will display properly without changing the setting.
 - Press the ABC switch until the channel A LED lights.
 - Press and quickly release the High switch. Observe:
 - The top display shows 24°C for approximately 3 seconds.
 - Press and quickly release the Low switch. Observe:
 - The top display shows 05.0°C for approximately 3 seconds.
- c. Verify that alarms function properly.
 - Insert a 47° probe for the Temperature Probe Module into channel A on the first module. Observe:
 - The sonalert sounds for approximately 3 seconds.

Note: If your TCM II has more than one (1) Temperature Probe Module installed, repeat the above steps for each module.

Note: If the alarm limits for two (2) probes are exceeded, both probe LEDs will flash. If one of these probes is also selected for display, its LED will flash at a higher rate.

- d. Verify the temperature display accuracy.
 - Insert a 25° probe for Temperature Probe Modules into channel A. Observe:
 - The channel A LED lights.
 - The display shows 25°C ± .2 degrees. If not, refer to Step 20. Calibrate the Temperature Display Module (Remote Controls).

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- Replace the 25° probe with a 47° probe. Observe:
The display should show 47°C ± .2 degrees. If not, refer to Step 20.
Calibrate the Temperature Display Module (Remote Controls).
- e. Repeat steps a through d for each temperature probe installed.

15. Check the Cooldown Mode. (Remote Controls)

- a. Press the Cooldown switch (remote). Observe:
Remote Cooldown LED lights.
Cooldown mode begins.
- b. Press Standby (remote).

16. Check the Maintain Mode. (Remote Controls)

- a. Press Maintain UP or DOWN arrow until display shows 25°C.
- b. Press Maintain switch (remote). Observe:
Remote Maintain LED lights.
Water temperature displayed increases/decreases toward temperature
displayed on Maintain display on panel.
Water Temperature Display stabilizes at 25°C.
- c. Press Standby (remote).

17. Check the Rewarm Mode. (Remote Controls)

- a. Press the Rewarm switch (remote). Observe:
Remote Rewarm LED lights.
Water temperature display indicates water temperature is increasing.
- b. Press Standby (remote).

18. Check the Gradient Maintain Mode and the Gradient Rewarm Mode.

- a. Insert a 25° probe for Gradient Temperature into channel G on the
Temperature Module. Observe:
Channel G on the display should read 25°C ± .2 degrees.
Display will stay the same throughout this test.
- b. Press the remote Maintain arrow UP until reaching 40°C.
- c. Press the Gradient switch on the main panel one time. Observe:
The gradient 6° LED lights.
- d. Press remote Maintain switch. Observe:
The water temperature display increases to 31°C (25 plus 6) and holds.
- e. Press the Gradient switch again. Observe:
The gradient 6° LED goes out.
The gradient 10° lights.
Water temperature increases to 35°C.
- f. Press the Gradient switch again. Observe:
The 10° LED goes out.
Note increasing temperature.
- g. Repeat Step 18 to this point, but select Rewarm mode instead of Maintain.
- h. Remove the 25°C probe.
- i. Press Standby.

Check and Calibration Procedure

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19. Calibrate the Main System.

Note: Proper static precautions should be observed.

- a. Turn the System Power and Ice maker switches OFF.
 - Locate the card cage (upper right side on front of the unit).
 - Unplug ribbon cable on the A to D Board (center board in the card cage).
 - Remove the Main Computer Board (front board in the card cage).
 - Remove the Communications Board (back board in the card cage).
- b. Install the 5-Pin-Connector A to D fixture to the A to D board. (The red wire should be up and on pin 5.)
- c. Connect a voltmeter to the A to D board.
 - Connect the common lead of the meter to the black wire.
 - Connect the positive lead of the voltmeter to the blue wire.
- d. Turn the System Power ON.
 - Use a nonconductive screwdriver or equivalent to adjust R18 Ref Cal (bottom pot) to show 2.500 volts \pm .001 volts DC.
 - Disconnect meter from the blue wire (reference).
 - Connect meter to red wire on the test fixture.
 - Disconnect J3.
 - Install a 0° A to D Fixture to connector P3 on the main board.
 - Turn R23 Zero (middle pot) clockwise until a positive reading is indicated on the voltmeter.
 - Adjust R23 for .005 \pm .005 volts DC.
 - Disconnect the 0° A to D Fixture from connector P3.
 - Install the 40° A to D Fixture to connector P3.
 - Adjust R29 Gain (top pot) to show 4.000 \pm .002 volts DC.
 - Remove the 40° A to D Fixture from Connector P3.
- e. Insert connector J1 (main temperature sensor) into connector P3. Observe:
 - The voltmeter should indicate the manifold temperature (1 volt = 10°C)
 - Record reading on voltmeter.
- f. Disconnect connector J1.
 - Insert connector J1 into P1 position.
 - Insert connector J2 (back-up temperature sensor) into connector P3 position. Observe:
 - The voltmeter should show the same as in Step 19-e \pm .015 volts.
 - If readings do not agree, replace the dual temperature sensor and repeat Steps 19-a through 19-f.
- g. Remove connector J2.
 - Insert connector J2 into connector P2 position.
 - Insert connector J3 (cardioplegia temperature sensor) into connector P3 position. Observe:
 - The voltmeter indicates the cardioplegia water temperature (1 volt = 10°C).
- h. Short the purple wires of the 5-Pin-Connector. Observe:
 - The voltmeter shows 2.82 \pm .02 V. If not, repeat the A to D calibration.
- i. Turn the System Power OFF.

Note: If the A to D board fails this calibration, replace it with a new A to D board and repeat the A to D calibration.

- j. Remove the 5-Pin-Connector Fixture.

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- k. Install the main computer board and communications board and their associated connectors.

20. Calibrate the Temperature Display Module (Remote Controls)

- a. Turn System Power OFF.
 - Remove the rear panel.
- b. Turn System Power ON.
 - Adjust R2 for each Temperature Module until the associated display shows $25.0 \pm .1^{\circ}\text{C}$.
- d. Turn the System Power OFF.

21. Reattach front, rear and side panels.

TCM II System Product Performance Specification

16579701 R/F

I. Product Description

A. Physical Description

The cabinet is constructed of finished structural foam, stainless steel, and aluminum with a baked enamel finish. Six outer side panels are fixed to a steel inner frame which provides support and stability. The top is made of structural foam with EMI protective inner finish.

The main unit houses the rotomolded ice reservoir, the heaters, the control computer and other major electronic components, the plumbing circuitry, the Ice Maker and the Blanket Supply.

The Cardioplegia Water Supply mounts in the main unit and consists of the pump, plumbing, and circuitry that controls delivery of water to cardioplegia heat exchangers.

The Temperature Display Module mounts in a pocket on the main unit or elsewhere in the operating room (up to 7.5' away from the main unit). In order to use the Display Module, one to three Temperature Probe Modules must be installed in the main unit.

	TCM II Cabinet	Temperature Display Module
Height:	34.5" (87.6 cm)	8-3/4" (22.2 cm)
Width:	20" (50.8 cm)	5-1/2" (14 cm)
Depth:	29.5" (74.9 cm)	2-1/2" (6.4 cm)
	Large Tank	Small Tank
Length:	18.5" (47 cm)	9.5" (24.1 cm)
Width:	8.7" (22.1 cm)	5.5" (14 cm)
Depth:	21.5" (54.6 cm)	9.3" (23.6 cm)
Capacity:		
Water	9 gal (34 L)	1.2 gal (4.5 L)
or		
Crushed Ice	40 lbs (18.1 kg)	7.5 lbs (3.4 kg)

Weight of unit with all options installed:

- Approximately 294 lbs. (133.4 kg) with tanks empty.
- Approximately 386 lbs. (175.1 kg) with tanks full of water.

B. Electrical Description

1. Power Requirements

115 Volt (nominal) System	220 Volt (nominal) System
108-122V~, 60 Hz	210-250V~, 50 Hz
16 Amperes, max.	12 Amperes, max.

Temperature Display Module

5 volt power supply
2.2 Amperes, max.

2. High Potential Specifications per ES10210.

3. Current Leakage:

- 1) Enclosure current leakage = 100µA MAX for 115 volt system, 500µA max for 220 volt system.
- 2) Current leakage to patient = 10µA MAX

4. Ground Impedance: .1 ohm maximum.

TCM II System Product Performance Specification

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5. EMI/RFI Compliance: TCM II will comply with:
FDA susceptibility and emissions requirements under MDS 201-0004
and FCC rules part 15 subpart J CLASS A equipment.

6. Maximum Compressor Current (measured 15 min. after compressor
turns on)
115V system 9.2A
220/240V system 4.3A

C. Hydraulic Description

Water pumps (2) used are 1/8 hp. Heaters (2) are 700 and 850 watt each
for 115V unit and 1000 watt each for the 220V unit.

D. Calibrations

Check and Calibration procedures per Technical Service Manual.

E. Compatibility with Other Equipment

1. Heat Exchangers. The TCM II is designed for use with all heat
exchangers that will withstand 11 psi (568 mmHg) pressure and
temperatures of 0-42°C.
2. Thermal Blankets. The TCM II is designed for use with thermal blankets
that will withstand pressures of 10 psi (517 mmHg) and temperatures of
0-42°C.
3. Cardioplegia Heat Exchangers. TCM II is designed for use with “drop-
in” heat exchangers which fit into the small tank along with the neces-
sary ice, and with water manifold heat exchangers that will withstand
pressures of up to 11 psi (568 mmHg).
4. Temperature Probes. The TCM II is designed for use with (Yellow
Springs Instruments) YSI Series 400 temperature probes.

II. Product Performance Statements

A. Pressure Performance

Pressure performance figures below are applicable when the TCM II is
connected to only that specific piece of external equipment, i.e., blanket
performance is applicable with only a blanket connected to the unit. As the
blanket and heat exchanger draw from a common water supply and the
ports are internally connected, different pressure performance figures will
result when the TCM II is connected to both an oxygenator and a blanket or
when extensive lengths of tubing are connected.

To obtain the pressure performance, the TCM II was tested by connecting a
set of in and out ports with a 4' loop of tubing. A flow rate meter was
inserted into this loop of tubing to obtain the flow rate with no restrictions.
A pressure meter tapped into the tubing at a point close to the out port to
obtain the maximum pressure.

The TCM II was operated in Rewarm mode to test the blanket and heat
exchanger pressure performance; it was operated in External Small Tank
mode with the pump at high speed to determine the cardioplegia pressure
performance.

Water Out Port	Flow Rate (no restriction)	Pressure (maximum)
Heat Exchanger	5.5 gal/min 21.0 L/Min	15.0 psi (700 mmHg)
Blanket Supply	.8 gal/min 3.3 L/Min	11.8 psi (610 mmHg)
Cardioplegia Supply	2.1 gal/min 5.1 L/Min	7.5 psi (386 mmHg)

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B. Temperature Performance

Temperature performance figures represent nominal design figures.

1. Temperature Limits

Heating

Maximum heaters (2) output	1550 watts @ 115V 2000 watts @ 220V
Maximum water temperature	42°C
Temperature gradient control	6° or 10°C
Defrost cycle maximum temperature	20°C

Cooling using an Ice Maker

Power requirement	1200 watts
Ice making capability starting with 25°C water:	50 lbs (22.7 kg) in 8 hours 19 lbs (8.6 kg) in 3 hours
Water temperature selection range:	0-42°C

2. Temperature Control

- General. A redundant (2) thermistor system signals "system failure" if a significant discrepancy between thermistors ($>5.1^{\circ}\text{C}$) is sensed. Plus an overtemperature thermostat cuts off power to the heaters if water temperature reaches 43°C .
- Maintain Mode. The main computer controls the temperature of the output water according to the maintain temperature which has been set by the operator; a setting range of $0-42^{\circ}\text{C}$ is available.
- Rewarm mode. The main computer limits the maximum rewarm temperature of the output water to 42.2°C or to 6°C or 10°C venous blood — water temperature gradient.
- Cooling mode. Water is supplied at the temperature of the water in the ice reservoir.

3. Temperature Monitoring

- Output water temperature is monitored and is displayed on the front panel in a range of $0-50^{\circ}\text{C}$.
- Patient or extracorporeal circuit temperature sensing and display accuracy is $\pm 0.3^{\circ}\text{C}$. The Temperature Probe Modules allow a sensing range of $0-50^{\circ}\text{C}$.

III. Operating Systems

A. Hydraulic System

The Hydraulic System includes the plumbing, valves, Hansen fittings, tanks, pump, manifold, and two heaters (see Hydraulic Block Diagram, part number 16095001, for details). The Cardioplegia Water Supply adds a second pump, additional plumbing, valves, and use of the smaller tank. The hydraulic system also includes:

- Flow switch, on the blanket outlet line, to detect low flow for the blanket.
- Pressure switch, on the heat exchanger outlet line, to sense inadequate water pressure in the main plumbing in order to protect the pump.
- Thermistor T1, in the manifold, to monitor water output temperature and to monitor manifold water temperature.
- Thermistor T2, in the manifold, to serve as a check on T1.
- Thermistor T3, on the Cardioplegia output line, to measure cardioplegia water output temperature.
- Thermistor OT1 switch, in the manifold, set to activate at 43°C .

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B. Ice Maker System

The Ice Maker System includes a compressor, ice thickness sensor, cold plate, refrigerant plumbing, refrigerant plumbing switch, filter dryer in the refrigerant line, and its own circuitry (see Compressor Block Diagram, part number 16388000, and Compressor Delay Performance Specification, part number 78-8067-3893-2, for details).

C. Electronic System

The electronic system includes the circuit breakers, the PC boards, and the software. It is the communication center for the unit. The operator inputs information through the external controls and displays. The microprocessors on the PC boards receive the input and control the internal systems according to the software program.

1. Power

- a. 115 or 220 VAC unit has two circuit breakers: one for Ice making and one for the main TCM.
- b. The AC power for the main TCM supplies energy for the heaters, the Cardioplegia subsystem, the pumps, and the transformers; the transformer supplies 115 VAC power to solenoid valves and other voltages to the DC power supplies for the PC boards.

2. PC Boards

The TCM II system may have up to a total of 14 PC boards; these are listed below with their basic purpose; for further details see the specific PC board specification.

- a. The Main Board is a mother board for the main unit; it is a central terminus for cables and holds fuses; it also contains some driver electronics and some power supply components.
- b. The A/D-Timer Board expands the computer I/O ports; it receives the thermistor input which measures internal water temperature and converts this input for computer use; it contains the watchdog circuitry; it also contains the interrupt timer for the main computer.
- c. The Main Display Board contains displays for the main unit and connects the panel switches to the computer.
- d. The Main Computer Board performs most of the logic for the main unit; it communicates, processes information and directs functions. It also communicates to the user via the panel controls and displays.
- e. The Compressor Delay Board gives protection for the compressor by controlling power to the compressor used in the Ice Making System.
- f. The Cardioplegia Display Board extends the functions of the main board.
- g. The Cardioplegia Relay Board contains relays for cardioplegia valves and pumps.
- h. The Remote Mother Board electronically interconnects all parts of the Temperature Display Module.
- i. The Remote Display Board contains displays and related electronics for the Temperature Display Module.

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- j. The Remote Computer Board performs most of the logic for the Temperature Display Module. This remote computer stores information from the main microprocessor; it determines which probe information is selected for display and which digital display to use; it relays remote control information to the main unit microprocessor; it controls the alarm limit functions; it tests the functioning of the Temperature Probe Module.
 - k. The Temperature Probe Module Board has a microprocessor which analyzes and determines the probe temperature and sends the information to the TCM II Main Computer. This board is electrically isolated for patient safety.
 - l. The Communications Board is located in the main unit; it assists the main computer in communicating with the Temperature Probe Modules and the Temperature Display Module.
3. Software
- There are three different software programs in the complete system: one in the main computer in the TCM II, one in the remote computer in the Temperature Display Module, and one in each Temperature Probe Module. See the PC board selection above or refer to the component specifications for details.

IV. Controls

A. Main Unit

System Circuit Breaker Switch (CBS) ON: the main computer conducts a 6 second initialization which turns all LEDs on and off and displays software version on the Maintain and water temperature displays. Next, the main computer conducts an internal prime of approximately 1 minute duration with all valves open so that water fills the plumbing and the internal air is released; the valves remain open and the pumps and heaters may not be turned on from the panel during this period. Finally, the main computer allows full panel selection. Note: The System CBS must remain off for about 2 seconds to repeat this startup procedure completely or the Temperature Display Module may not initialize properly. The default startup setting is Maintain 25°C

Standby Mode: the main computer displays the water temperature sensed by Thermistor T1; it does not activate heaters or pump.

Cooldown Mode: the main computer opens Valve 1 to allow water from the large reservoir to flow to the pump, activates the pump to circulate water through plumbing, and displays the water temperature sensed by Thermistor T1.

Rewarm Mode: the main computer opens Valve 2 to bypass the large reservoir and direct water through the heater manifold, activates the pump to circulate warm water through the plumbing, and displays water temperature as sensed by Thermistor T1. The target temperature for rewarm is 42°C OR the value determined by the gradient selection. Using the water temperature as sensed by Thermistor T1, the main computer turns off one heater when the water temperature is approximately 0.8°C below the target temperature, and turns off the second heater if the water temperature is approximately 0.4°C below the target temperature. It cycles the heaters on and off to maintain water temperature equal to the target temperature.

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Maintain Mode: the main computer compares the output water temperature as sensed by Thermistor T1 to the maintain temperature set by the operator. The computer also displays the output water temperature and controls Valves 1 and 2 and Heaters 1 and 2 as follows to maintain the set temperature.

Condition	Valve 1	Valve 2	Heater 1	Heater 2
$T(\text{water}) - T(\text{set}) > 7.8^{\circ}\text{C}$	Open	Closed	Off	Off
$0.8^{\circ}\text{C} < T(\text{water}) - T(\text{set}) < 7.8^{\circ}\text{C}$	Open	Open	Off	Off
$-0.4^{\circ}\text{C} < T(\text{water}) - T(\text{set}) < 0.8^{\circ}\text{C}$	Closed	Open	Off	Off
$-2^{\circ}\text{C} < T(\text{water}) - T(\text{set}) < -0.4^{\circ}\text{C}$	Closed	Open	Off	On
$T(\text{water}) - T(\text{set}) < -2^{\circ}\text{C}$	Closed	Open	On	On

NOTE that, when cooling, valve 2 is opened when the temperature is within 7.8°C of the maintain setting to partially bypass the large reservoir and reduce the cooling rate.

Gradient Selection: the main computer monitors the information from the Temperature Probe Module microprocessor and compares venous blood temperature (measured by probe G) to the water output temperature as sensed by Thermistor T1; it limits the water temperature to no more than 6° or 10° (according to gradient selected) above the venous blood temperature reading and controls the valves and the heaters accordingly. Gradient selection requires installation of a Temperature Display Module and at least one Temperature Probe Module, with Temperature Probe G monitoring the patient's venous blood temperature. It is active in both Maintain and Rewarm Modes. It is disabled if no probe is connected in position G.

Defrost Mode: the main computer switches on both heaters, shuts off the ice maker, starts the pump, and opens Valves 1 and 3 to circulate warm water through main reservoir; then, after a one minute delay, it shuts off the pump and heaters when the water temperature reaches 20°C (sensed by Thermistor T1), reverts to Standby mode, and starts the compressor if the Ice Maker controls are On; it continuously displays the water temperature as sensed by Thermistor T1.

Ice Making Circuit Breaker On:

- The compressor starts and the Ice Making indicator lights. The cold plate in the main reservoir builds an ice bank. An ice bank sensor shuts the compressor off when the ice bank is full.
- If the system CB is On, the compressor will run only if the Compressor CB is On and no more than one heater is operating. The main computer operates relays to shut off the ice maker when both heaters are on in order to limit the current draw of the TCM II: use of the CPG pump will not be affected. The ice maker is also disabled in Standby Mode if this mode was entered due to an error condition. When turning on the Compressor CBS switch, a compressor delay prevents restart of the compressor for 2 to 6 minutes (see Compressor Delay Performance Specification, part number 78-8067-3893-2).

Water Output Temperature Display: The main computer digitizes and displays the thermistor probe output signals; thermistor 1 monitors the main output water temperature and thermistor 3 measures the cardioplegia water output temperature.

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Maintain Set switches: The main computer relays 25 to the display until this number is changed by the set switches. The setting reverts to 25 whenever startup is repeated.

B. Cardioplegia Supply

Pump On-Off: the main computer activates the cardioplegia pump and opens valves according to the External or Internal mode selection.

Pump Speeds: the main computer lights the high, medium, or low LED according to the switch position.

External-Internal modes: the main computer lights the appropriate LED for the mode selected.

Large Tank External: with the pump On, the main computer opens Valve 4 to allow water from the large tank to be pumped to the cardioplegia water outlet port; water returns to the small tank and overflows into the large tank.

Small Tank External: with the pump On, the main computer opens Valve 5 to allow water from the small reservoir to be pumped to the cardioplegia outlet port; water returns to the small tank.

Large to Small Tank Internal: with the pump On, the main computer opens Valves 4 and 6 to allow water to recirculate from the large tank to the small tank; the water returns to the large tank by overflow.

C. Temperature Display Module

Probe Displays: the remote computer receives probe information in the form of binary coded decimal signals from the main computer. This information is translated into logic signals appropriate for LED number displays and indicators. Each display is updated and powered many times per second. The probe display switch directs the remote computer as to which probe information to display; the remote computer lights the appropriate probe LED.

Remote Controls: the remote computer sends selected information to the main computer which lights the corresponding LED on the main panel and directs the proper mode function; the main computer returns the information to the remote computer which in turn lights the corresponding remote LED.

Test switch: the remote computer, via the main computer, requests a set resistance for the probe input. If the Temperature Probe Module is functioning correctly, the appropriate display will show 25 ± 4 ; the top display pertains to the first Temperature Probe Module, the middle display pertains to the second module, and the bottom display pertains to the third module. If the corresponding module is not connected, the display will be blank.

High and Low alarm limits: the alarm switches are used to display and establish high and low values in the remote computer for probes A, B, and C. If the alarm limit value is exceeded, the remote computer triggers the probe LED to flash and a buzzer to sound. The flashrate is faster if the particular probe is also being displayed. The default alarm limits on startup are 42°C and 0°C.

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V. Safety Features

A. Internal System Safety Features (No External Indicators)

1. Startup is a two part process: (1) A 3 second initialization which turns all LEDs on and then off to verify their function, followed by a 3 second display of the software version and then the display of specific startup conditions; (2) An internal priming procedure lasting approximately 1 minute during which all valves are open and the pumps and heaters remain off. Panel selections relating to the valves, pumps, and heaters are inactive during startup. Startup ends with the unit in a Standby mode with the Cooldown LED flashing to indicate modes are completely available but that external priming is still required.
2. System Monitor circuitry ensures that the main computer operates properly. It consists of a watchdog circuit which includes a timer that must be reset by the main computer at specified intervals. If the timer is not reset when specified, due to the main computer getting caught in a loop or otherwise failing, the System Monitor circuitry shuts off the pump and heaters and forces the computer to repeat the startup routine; the software will attempt to repeat the watchdog test, the priming procedure, and the display of startup conditions.
3. Compressor Delay circuitry protects the ice making compressor by preventing early restarting. There is a 2 to 6 minute restart delay which prevents the motor from overload by allowing pressures in the system to equalize (see Compressor Delay Component specification, part number 78-8067-3893-2, for details). The compressor is disabled by the main software when more than one heater is on to prevent excessive current draw.
4. Communications Errors: The computer software screens all data transmissions and rejects any that do not conform to data format requirements. This prevents electrical interference which could alter command signals or generate false command signals.
5. Overtemperature Protection: A separate thermostat OT1 switches off the heaters if the output water temperature is over 42.5°C. Also, a selection range of only 0-42 is available.

B. Safety Features with Panel Warning Indicators

1. Low Flow To Blanket: within 15 seconds of the flow switch detecting a flow of less than 1 ± 1 L/Min on the blanket inlet, the main computer lights the warning indicator LED. This warning is not active when the unit is in Standby mode, during the startup procedure, or in Defrost Mode.
2. Pump Not Primed: within 5 seconds of the pressure switch sensing inadequate water pressure in the main plumbing, the main computer lights the warning indicator LED, sounds an alarm, stops the pump, and goes into STANDBY mode. This warning is not active when the unit is in Standby mode or during the startup procedure. The audible alarm will sound for 2 seconds at 60 second intervals until Cooldown, Maintain, Rewarm or Defrost Mode is selected by the user.

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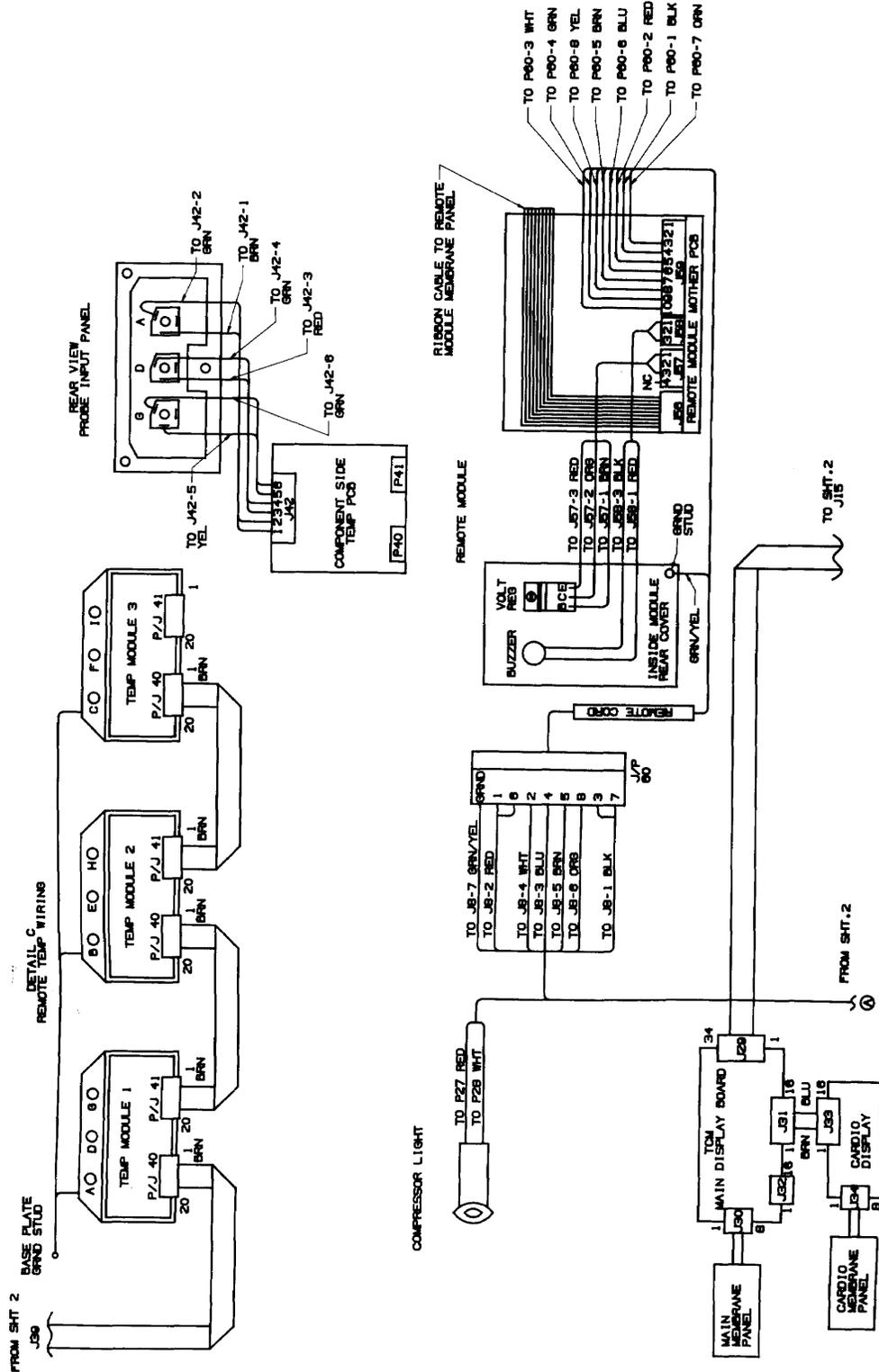
3. **System Malfunction:** the main computer compares the inputs from Thermistor T1 and the redundant Thermistor T2; if the inputs from T1 and T2 differ by $>5.1^{\circ}\text{C}$ when in a mode other than cooldown, it lights the warning indicator LED and sounds an alarm. System malfunction is also activated if the internal reference temperature does not read within specs ($26.5\text{-}29.4^{\circ}\text{C}$).
4. **Over 42°C :** if Thermistor T1 or T2 senses 43° or if the thermostat OT1 senses 43° , the main computer lights the warning indicator LED, sounds an alarm, and shuts off the heaters. Note: With a minimal load, such as only a blanket attached, the unit could go to 43° ; to operate correctly with only a minimal load, the unit may be set in Maintain mode at 40° until additional equipment is attached.

C. Temperature Display Module Safety Features

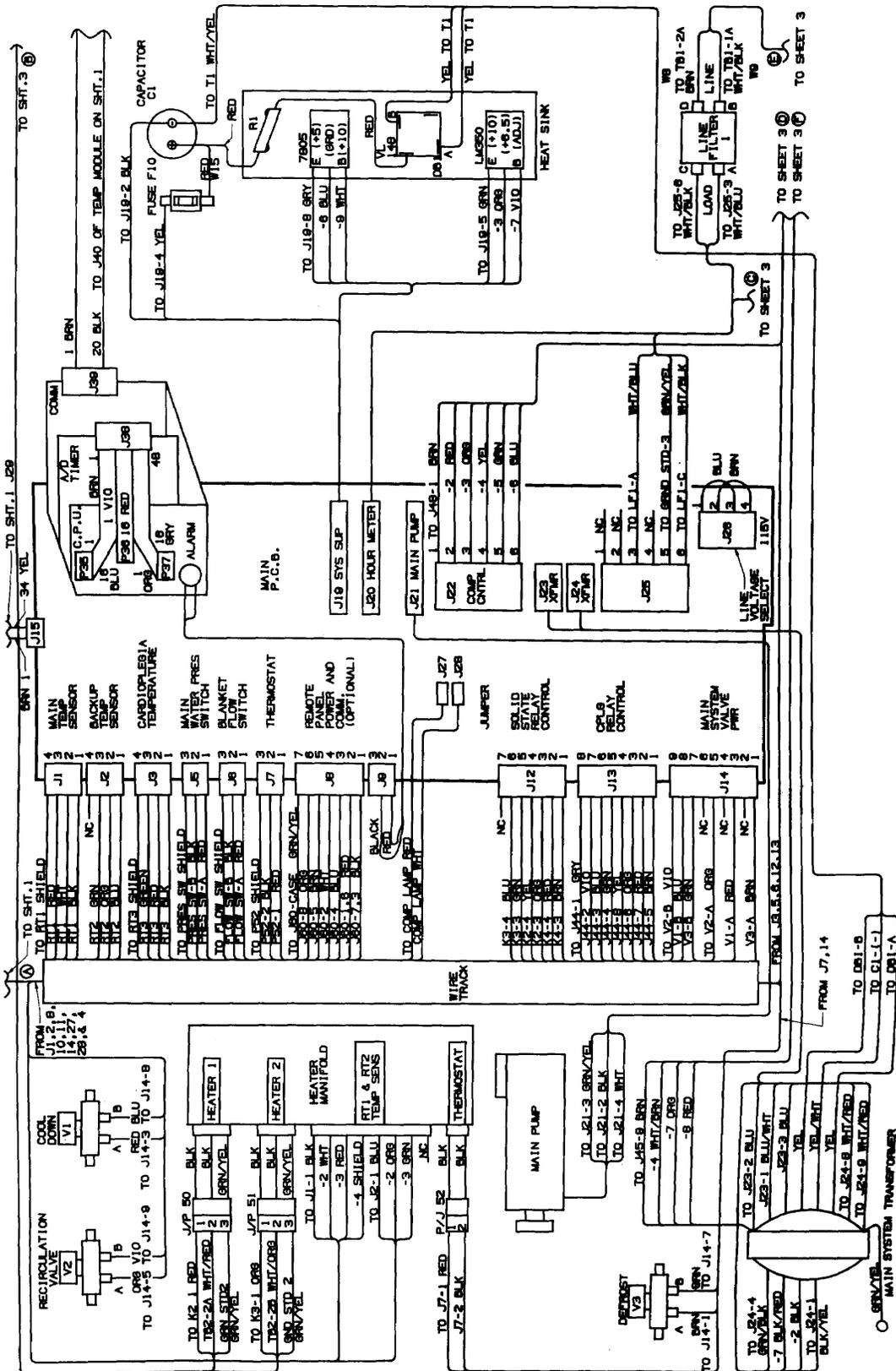
1. **Watchdog circuitry:** each display is powered serially many times per second. If the displays are powered continuously they will burn out. The watchdog circuit detects if the displays are being powered improperly and turns off the displays and LEDs on the Temperature Display Module.
2. **Startup routine:** the remote computer does a 3 second initialization which completes shortly before the main computer finishes its initialization. Correct startup conditions appear on the Temperature Display Module but all valves will remain open and the pumps and heaters will remain off for approximately 1 minute while the main unit is completing the internal priming procedure.
3. **Error information on probe displays:** the remote computer causes the display to go blank if there is a bad temperature probe module or no module installed. The remote computer directs the display of “—” if the temperature a probe senses is below -4°C or if no probe is attached; it directs the display to show 99.9 if the temperature a probes senses is over 50°C .

Diagrams

Wiring Diagram 115 Volt

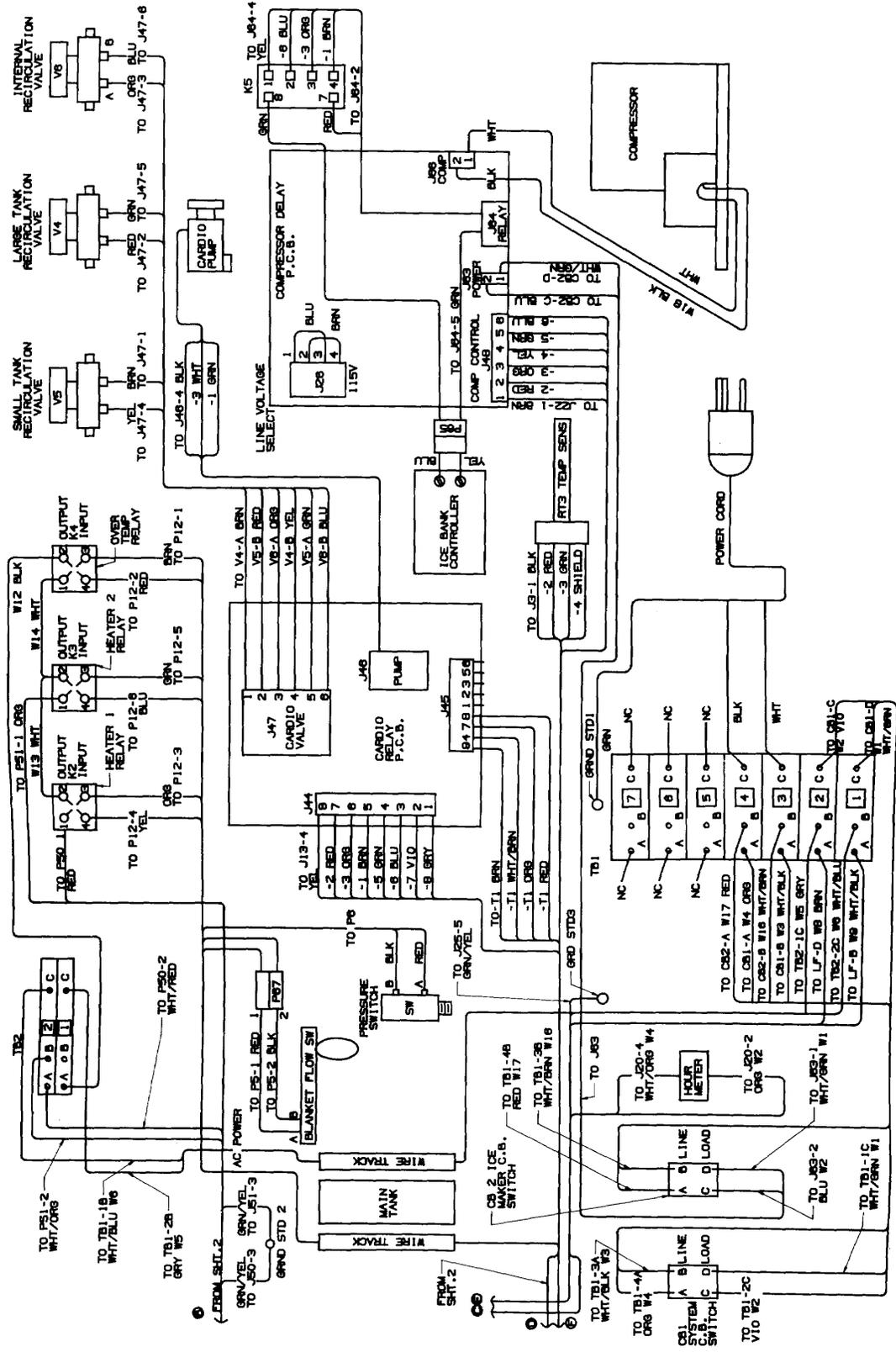


Wiring Diagram 115 Volt

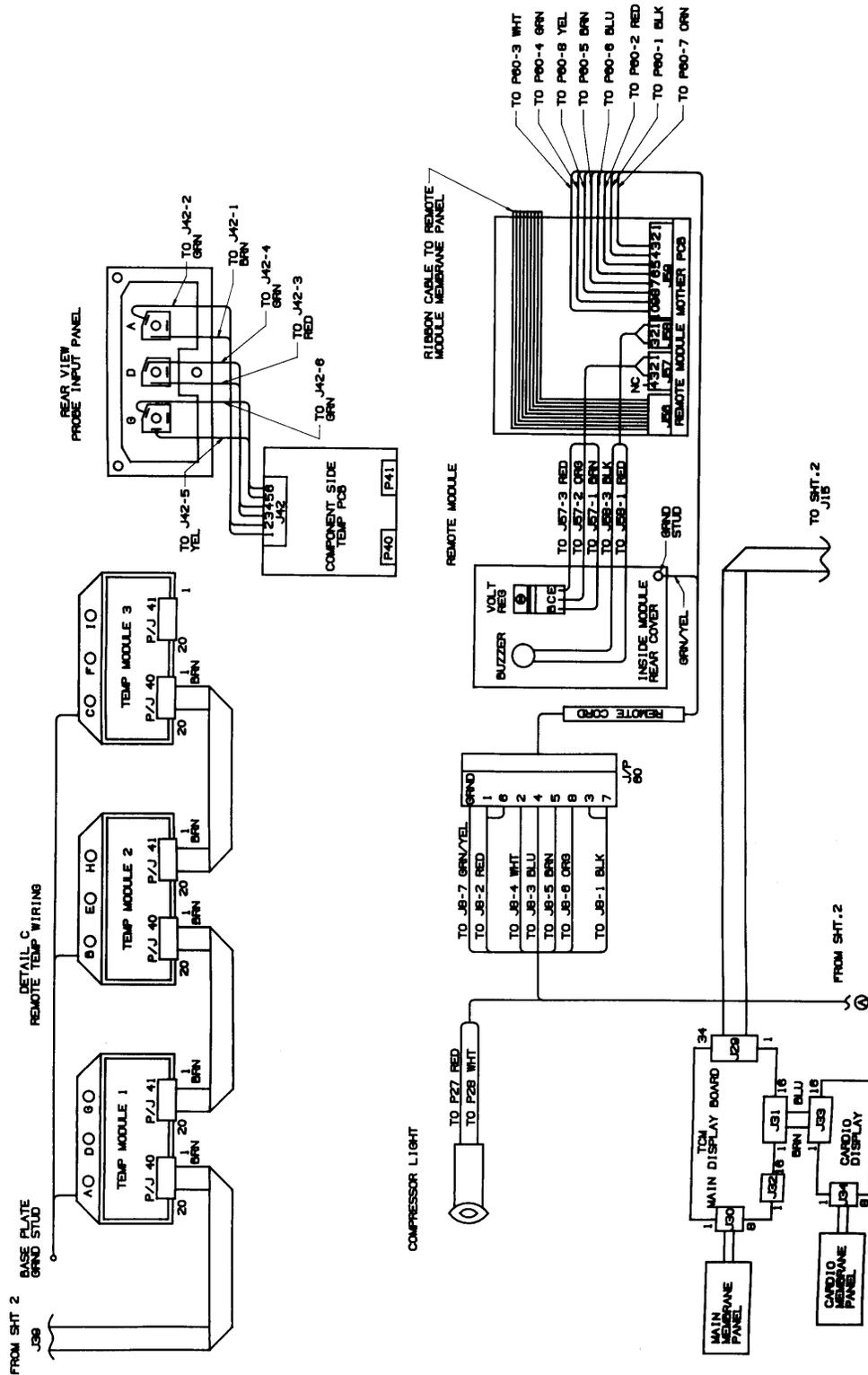


Diagrams

Wiring Diagram 115 Volt

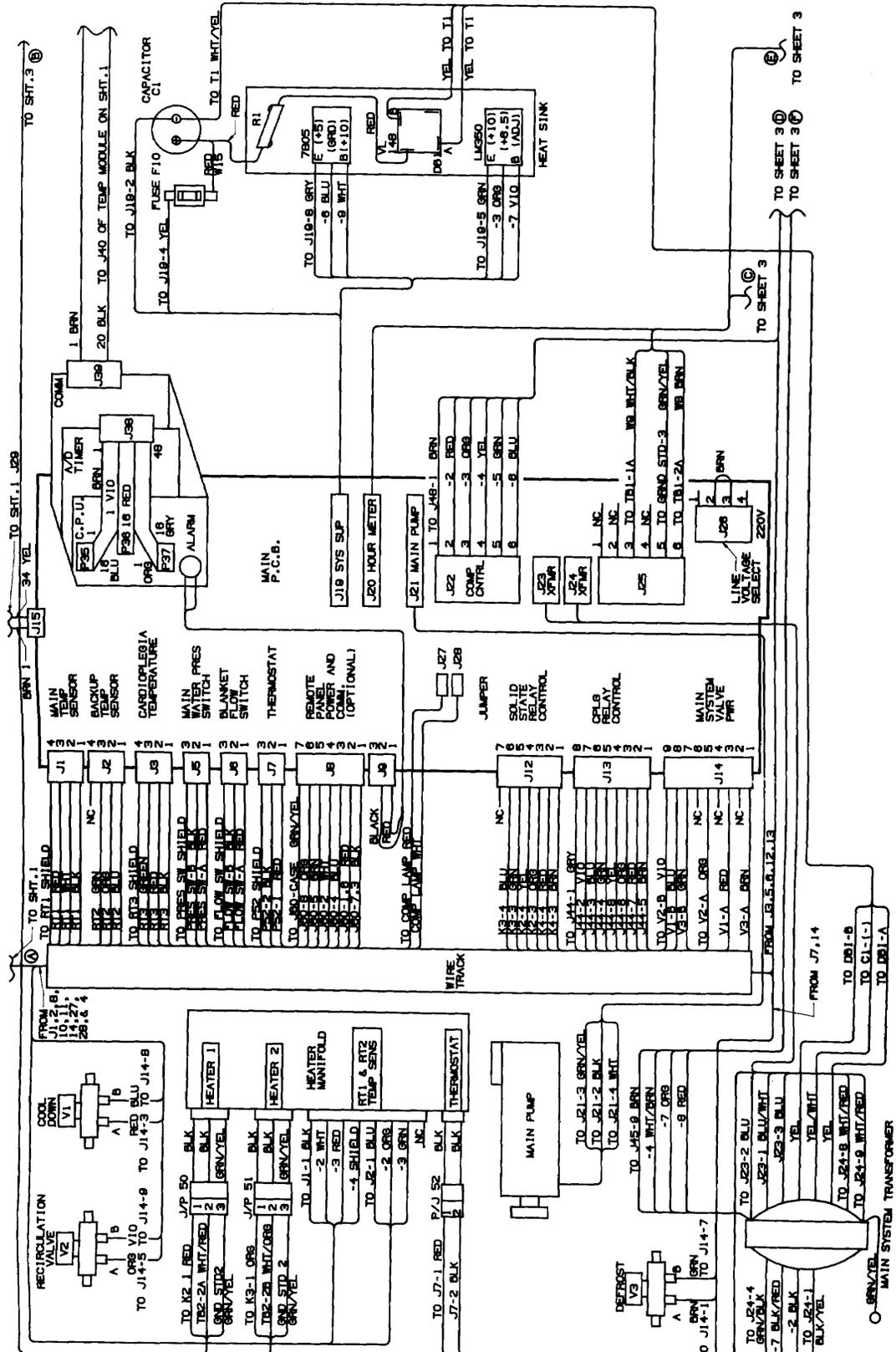


Wiring Diagram 220/240 Volt



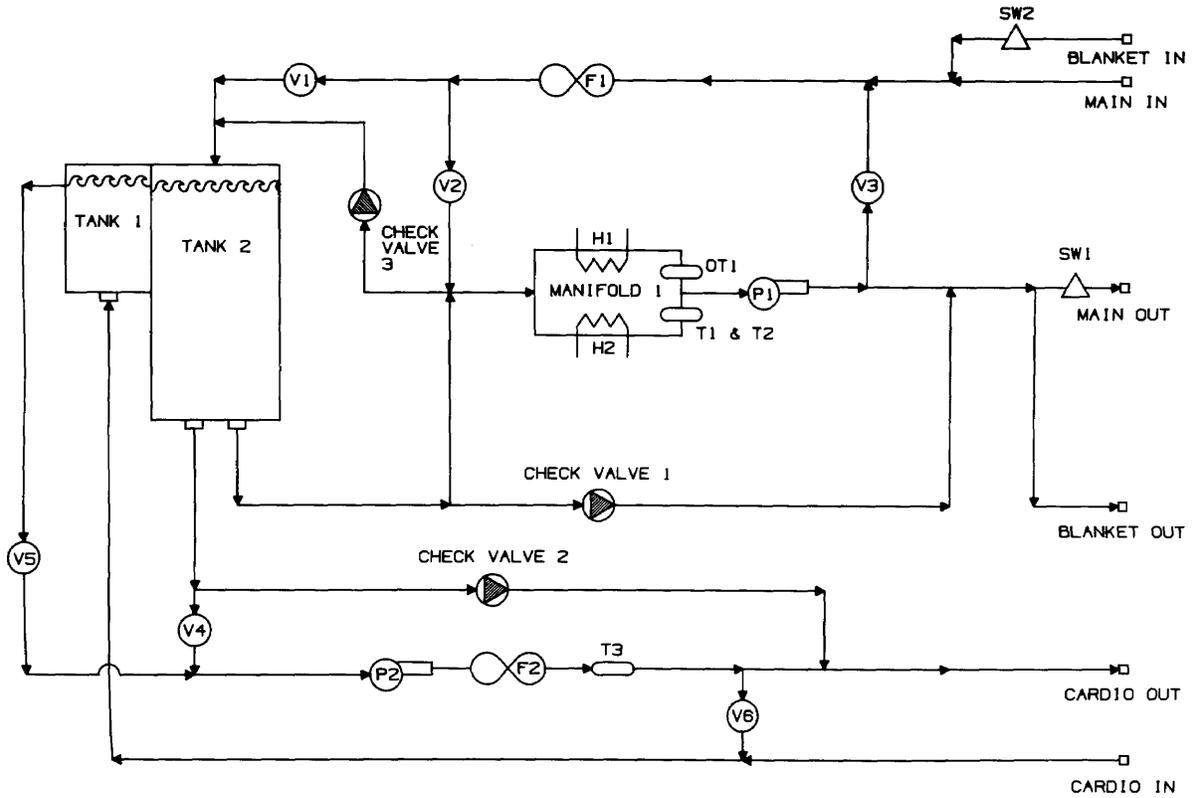
Diagrams

Wiring Diagram 220/240 Volt



Diagrams

Hydraulic Diagram

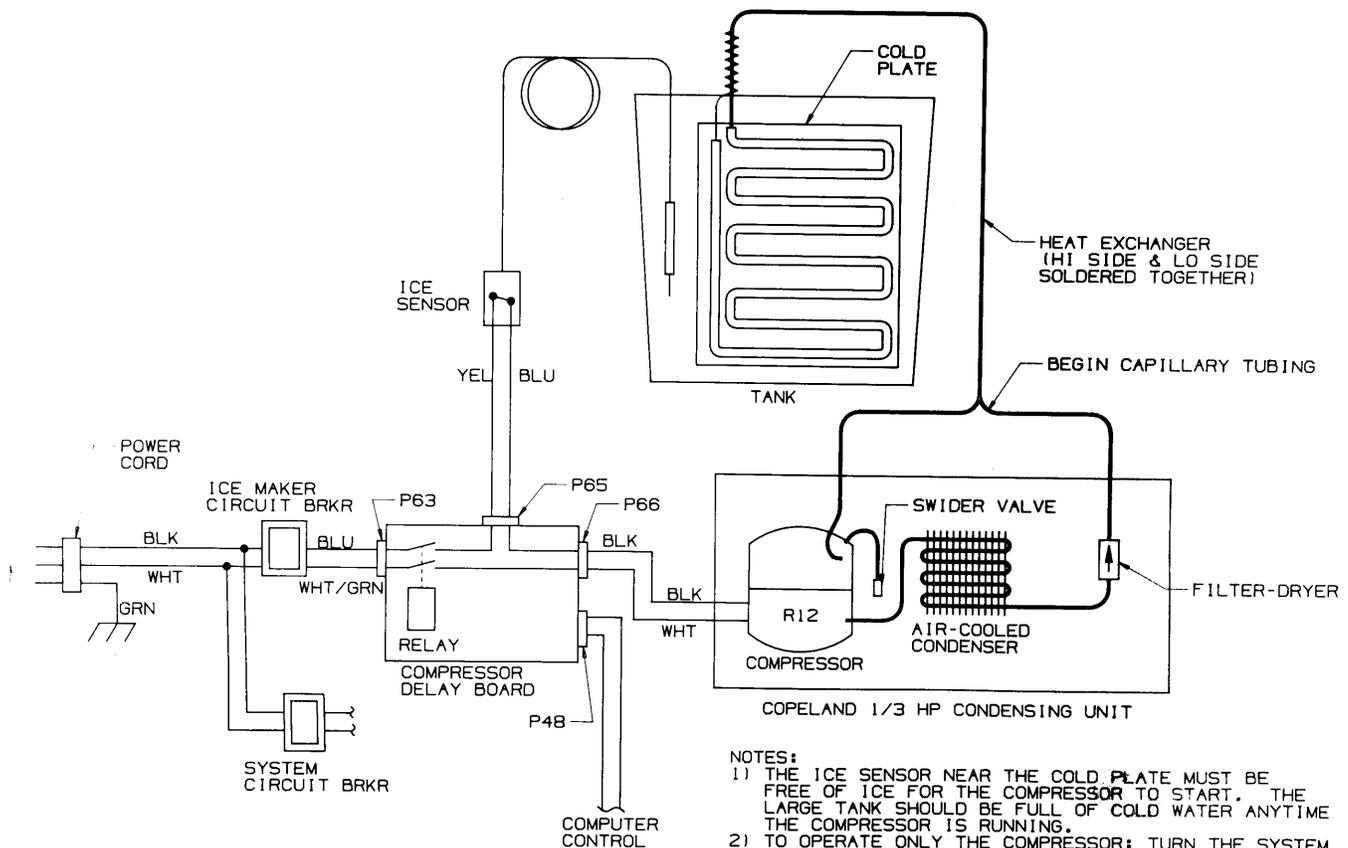


THE COMPLETE HYDRAULIC CIRCUIT, WITH ALL OPTIONS, IS COMPRISED OF THE FOLLOWING:

- TK1 - CARDIOPLEGIA TANK-OVERFLOW INTO MAIN TANK.
- TK2 - MAIN ICE TANK.
- P1 - MAIN OUTPUT PUMP, 20 LPM.
- P2 - CARDIOPLEGIA OUTPUT PUMP.
- F1 - MAIN LINE FILTER.
- F2 - CARDIOPLEGIA LINE FILTER.
- V1 - COOL VALVE N.C.
- V2 - RECIRCULATION VALVE N.C.
- V3 - DEFROST VALVE (ALLOWS INTERNAL RECIRCULATION)N.C.
- V4 - CARDIOPLEGIA TANK 2 DRAW VALVE N.C.
- V5 - CARDIOPLEGIA TANK 1 DRAW VALVE N.C.
- V6 - CARDIOPLEGIA RECIRCULATION VALVE N.C.

- MANI - HEATER MANIFOLD FOR MAIN OUTPUT. ALSO CONTAINS T1, T2, OT1.
- SW1 - SWITCH FOR MAIN OUTPUT.
- SW2 - SWITCH FOR BLANKET OUTPUT.
- H1 - 700W/120V (1000W/220V) FOR FINE CONTROL.
- H2 - 700W/120V (1000W/220V) FOR FULL POWER HEAT.
- T1 - MAIN OUTPUT THERMISTOR.
- T2 - MAIN REDUNDANT THERMISTOR.
- T3 - CARDIOPLEGIA OUTPUT THERMISTOR.
- OT1 - MAIN OUTPUT OVERTEMP THERMOSTAT.

Compressor Block Diagram



NOTES:

- 1) THE ICE SENSOR NEAR THE COLD PLATE MUST BE FREE OF ICE FOR THE COMPRESSOR TO START. THE LARGE TANK SHOULD BE FULL OF COLD WATER ANYTIME THE COMPRESSOR IS RUNNING.
- 2) TO OPERATE ONLY THE COMPRESSOR: TURN THE SYSTEM CIRCUIT BREAKER OFF, TURN THE ICE MAKER CIRCUIT BREAKER ON. AFTER 5 MINUTES DELAY, THE COMPRESSOR SHOULD START.
- 3) VOLTAGE AT P66 ON THE COMPRESSOR DELAY BOARD SHOULD BE THE SAME AS THE AC LINE VOLTAGE.

Parts List

Use the following list when ordering replacement parts.

Replacement Parts	Sarns Part No.	3M I.D. No.
Communications PC Assembly	15708010	78-8066-6255-3
Thermostat Assembly	16069010	78-8066-7428-5
Fuse 6.25 A (Slo Blo 3AG 250V)	23420607	26-1008-2360-3
Main Transformer Assembly	78-8067-3831-2	Same
Solid State Relay (280 VAC, 25A)	23510150	26-1008-1696-1
Main Computer Card	78-8066-7957-3	Same
A/D Timer PC Assembly	15726010	78-8066-6256-1
Main PC Assembly	78-8067-1528-6	Same
Dual Temperature Sensor Assembly	15791010	78-8066-6257-9
Socket Hansen (4HK 1/2 NPT)	25332052	26-1008-4153-0
Socket Hansen (4-S25)	11554010	78-8066-7014-3
Solenoid Valve NC (3/4 FNPT 115V)	26-1010-1287-5	Same
Solenoid Valve NC (1/2 FNPT 115V)	26-1010-1288-3	Same
Tank Filter	16001001	78-8066-7411-1
Membrane Switch Card	16568601	78-8066-7604-1
Main Membrane Switch	16568801	78-8066-7605-8
Remote Membrane Switch	16568701	None
Blank Membrane Switch	16588801	78-8066-7670-2
Cardioplegia Display PC Assembly	15730010	78-8066-7355-0
Cardioplegia Membrane Switch	16568601	78-8066-7604-1
Cardioplegia Relay PC Assembly	78-8067-1533-6	Same
Cardioplegia Hansen Socket (3HK 3/8 FNPT)	25332048	26-1008-1833-0
Cardioplegia Pump Assembly	78-8067-4162-1	Same
Blanket Hansen Socket (1JK 1/8 FNPT)	25332054	26-1008-1837-1
Blanket Hansen Plug (1HK 1/8 FNPT)	25332053	26-1008-1836-3
115 Volt Units Only		
Power Cord Lo Leak (20A 125V)	16121001	78-8066-9752-6
Circuit Breaker (18A 250V)	23411805	26-1006-7235-6
Circuit Breaker (15A 250V)	26-1008-6668-5	Same
Corcom 6EHI RFI Filter 6 Amp	26-1010-0856-8	Same
Main Pump Assembly 115 Volt	78-8067-4163-9	Same
Compressor Delay PC Assembly 115 Volt	78-8067-3890-8	Same
Heater Assembly 115 Volt 700 Watt	15997010	78-8066-7409-5
Heater Assembly 115 Volt 850 Watt	16467501	78-8066-7526-6
Square Microswitch Seal	23648144	26-1006-6696-0
220/240 Volt Units Only		
Power Cord Assembly (15A 250V)	78-8067-4008-6	Same
Circuit Breaker (13A 250V)	26-1010-0858-4	Same
Circuit Breaker (6.5A 250V)	26-1010-0859-2	Same
Corcom 20EK1 RFI Filter 20 Amp	26-1007-2910-7	Same
Main Pump Assembly 220/240 Volt	78-8067-4164-7	Same
Compressor Delay PC Assembly 220/240 Volt	78-8067-1523-7	Same
Heater Assembly 220/240 Volt 1000 Watt	16468001	78-8066-7527-4
Square Microswitch Seal	23648144	26-1006-6696-0
Temperature Display Modules Only		
Temperature Module PC Assembly	15703010	78-8066-7352-7
Remote Mother PC Assembly	15734010	78-8066-7356-8
Remote Display PC Assembly	15738010	78-8066-7357-6
Remote Module Retro Kit	78-8066-6198-5	Same
Remote Module Computer Card	15944010	78-8066-7395-6

34-9998-9981-7
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