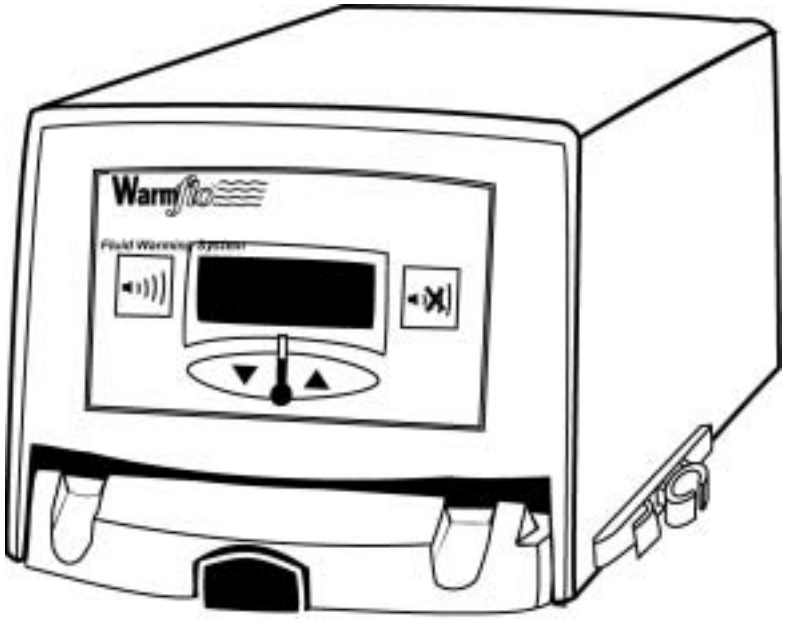
Warm*flo* Fluid Warming System

Model FW-538

SERVICE MANUAL



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Warnings and Cautions

Warnings in this manual are identified by the WARNING symbol shown above.

A warning alerts you to potentially serious outcomes (death, injury, or adverse events) to the user or the patient.

Warnings

WARNING: Possible electrical shock hazard. The warming unit should only by serviced by a qualified technician. If a qualified technician is not available, please notify your sales/service center.

WARNING: The fluid warmer must be plugged into a properly grounded 115 volt AC power source.

WARNING: Grounding reliability can only be achieved when the fluid warmer is connected to an equivalent receptacle marked "HOSPITAL ONLY" or "HOSPITAL GRADE."

WARNING: If a malfunction occurs in the fluid warmer, discontinue use. Notify your sales/service center of the malfunction. The unit must be serviced by an authorized service technician.

WARNING: Cassette pressures above 300 mmHg may cause hemolysis. Excessive pressures may burst the cassette.

Cautions

Cautions are identified by the CAUTION symbol shown above.

A caution alerts you to exercise care necessary for the safe and effective use of the FW-538.

Caution: Do not store liquids on top of the fluid warmer.

Caution: Use only Warm*flo*® disposable fluid warming sets with the fluid warmer.

Caution: Do not use the fluid warmer with preheated fluids. Fluids preheated above 44ºC may activate the heater safety mechanism, causing the high temperature alarm to activate.

Notes

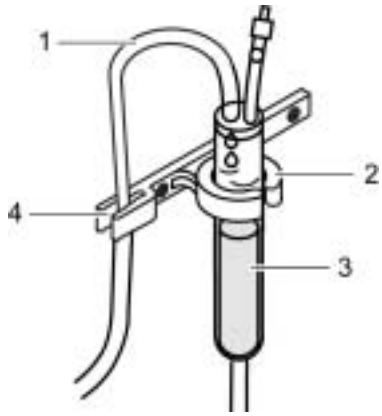
Notes are identified by the Note symbol shown above.

Notes provide additional helpful information.

Disposable Fluid Warming Set Warnings & Cautions

WARNING: Refer to the instructions for use provided with all disposable fluid warming sets prior to use.

Caution: To avoid potential kinks in the fluid line at point 1 (Figure 1 below), route the fluid line through the channel in the filter mounting bracket as shown:



1 — Potential kink area	2 — Filter mounting bracket
3 — Filter	4 — Slide tubing through channel

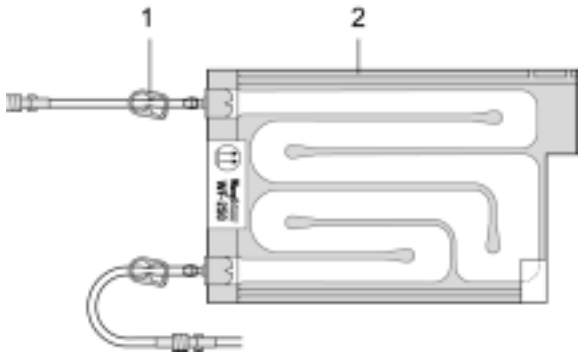
Figure 1: Filter and Filter Mount

Caution: Do not attempt to prime the disposable fluid set while the heat exchanger cassette is outside the fluid warmer or while the door is not latched.

Caution: If the fluid set has primed before the heat exchanger cassette is inserted into the fluid warmer, open all clamps distal to the heat exchanger cassette and allow the cassette to relax before attempting to insert the cassette.

Caution: After use, turn off the automated pressure infusor or release pressure cuffs, if used. Always close the red pinch clamp (Figure 2) prior to removing the heat exchanger cassette from the fluid

warmer. Failure to do so could result in rupturing the heat exchanger cassette.



1 — Red clamp	2 — Heat exchanger cassette

Figure 2: WF-250 Heat Exchanger Cassette

Indications for Use

The FW-538 fluid warming system is used to provide safe and effective warming of fluids, such as blood, blood products, physiologic fluids, and irrigation fluids. The FW-538 can be used for all types of surgical procedures and operations that require warmed fluids administered to patients.

Contra-Indications

There are no known contra-indications for use of this device.

Description

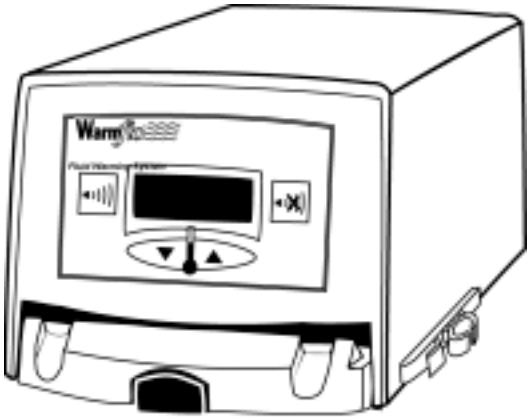


Figure 3: Warm*flo* FW-538

The FW-538 fluid warming system is designed for use in medical environments under the direction of a physician to warm blood, intravenous (IV), and irrigation fluids.

The FW-538 fluid warming system uses a heat exchanger cassette that is inserted between microprocessor-controlled heater plates located within the warmer housing. The dry heat process is safe, reliable, and requires little warm up time.

There are a variety of disposable blood and fluid administration sets available for use in routine surgery, standard intravenous warming, and irrigation applications.

The FW-538 fluid warming system may be used as a gravity flow device or in conjunction with automatic and manual pressure infusors and irrigation pumps to deliver fluids.

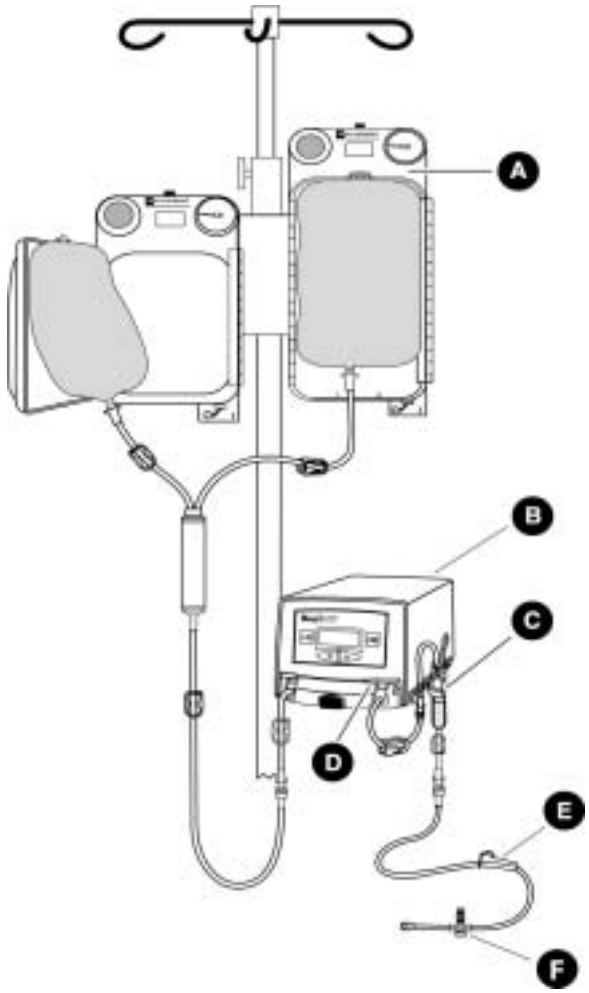


Figure 4: Warm*flo* Model FW-538 with WF-250 Surgery Set

A	*Warmflo*® pressure infusor or irrigation pump (optional)	**D**	WF-250 heat exchanger cassette
B	*Warmflo*® model FW-538	**E**	Roller clamp
C	Air eliminator chamber with filter	**F**	Dual injection port

System Symbols

The following symbols are used on the FW-538 unit.

	On
	Off
	Alarm Test
	Alarm Silence
	Underwriters Laboratories Inc.
	Canadian Standards Association
	Shock Hazard BF Classification
IPX2	Drip Proof
	Refer to Instructions for Use
	Equipotential Terminal (ground)

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Introduction

The Warm*flo* FW-538 software provides three internal test modes. After pressing the Increase and Decrease temperature buttons simultaneously for five seconds, the unit enters the internal test mode. A series of test modes are accessible in a round-robin fashion by pressing the increase button. When a test is initially entered, its test number is displayed in the first LED, while the other LEDs are blank. The test number is displayed for one second.

Pressing the alarm silence button during any test will cause the program to return to normal operating mode.

Tests

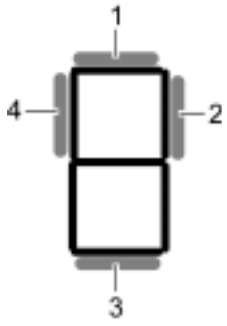
All temperatures displayed in the internal test modes are actual temperatures without rounding.

Test #1: Zone Heating Monitoring

The first LED indicates which zones are heating. The remaining three LEDs display the output temperature.

Test #2: Individual Thermistor Monitoring

The first LED indicates the currently selected zone (1, 2, 3, lower plate). The selected zone is displayed as an illuminated segment in the first LED. These segments are mapped in the following way:



1 — Zone 2

2 — Zone 3

3 — Lower plate

4 — Zone 1

The remaining three LEDs display the temperature of currently monitored zone. Pressing the decrease button cycles the selected zone round-robin from zone 1 to the lower plate.

Test #3: Automatic Thermistor Zone Monitoring

The first LED indicates the currently selected zone (1, 2, 3, or lower plate), using the same method as in test #2 above. The remaining three LEDs display the temperature of that zone. The zone number cycles automatically at a 1 Hz rate round-robin from zones 1 to the lower plate.

System Testing

There are two system performance checks for the FW-538 fluid warmer. The first check verifies the output temperature of fluid passing through a WF-8860 test cassette. The second check confirms that the over-temperature alarm is functioning properly.

Output Temperature Test

Equipment Required for Output Temperature Check

This procedure checks the output temperature of fluid passing through a test cassette installed in the FW-538. In addition to the FW-538 fluid warming system, the following equipment will be required.

- WF-8860 test kit (part number 8860), which contains:
  - Cassette and tubing
  - Myocardial thermocouple temperature probe
  - WI-48 high flow wound irrigator
- Reusable TAB instrument cable (part number 502-0065)
- Mon-a-therm® temperature monitor, model 6510 or equivalent (type T thermocouple temperature monitor)
- Saline IV bag

The following equipment is optional:

- Warm*flo* pressure infusor or Warm*flo* irrigation pump
- Graduated cylinder

Test Procedure

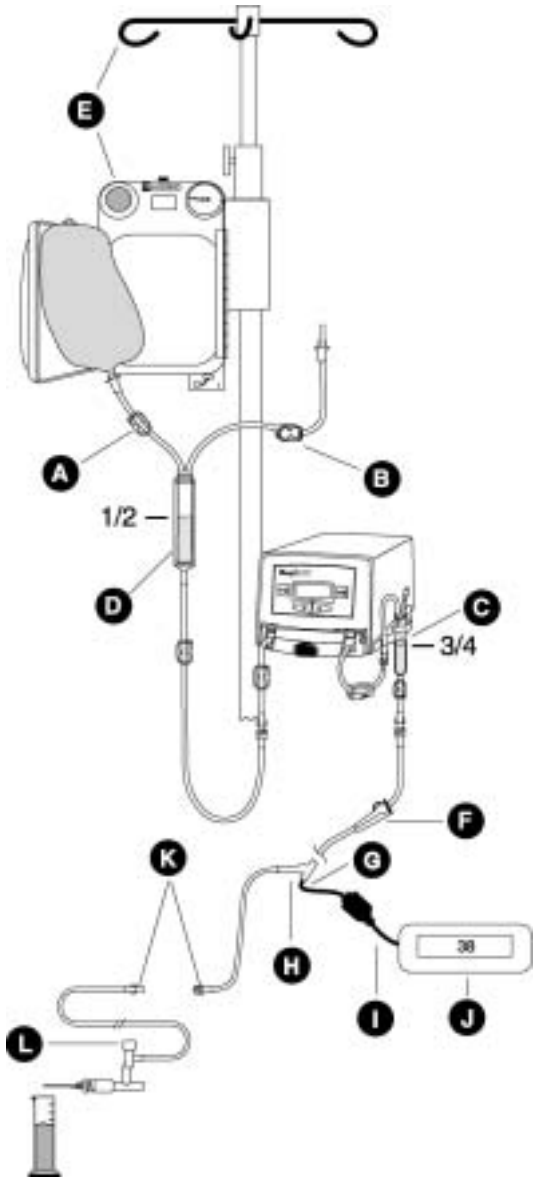


Figure 5: Setup for Output Temperature Check

Referring to Figure 5, check the output temperature of the FW-538 system:

1. Turn the Warm*flo* fluid warming system power switch located at the rear of the unit to the ON position. The control panel will display the start-up test mode, followed by the software revision number. When the temperature set point is displayed (38°C default), the unit is ready for operation.

2. Push the door latch button on the fluid warming system to open the cassette door. The door will open approximately 1/2 inch (1.27 cm).

3. Slide a clean WF-8860 test cassette into the door opening until it is fully inserted.

4. Close the door by firmly lifting up on the door until it clicks into position. This is indicated by the appearance of a green band on the top edge of the door latch button.

Note: To ensure that the door is closed, pull out on the door latch button until the green band is visible.

5. Close the clamp indicated Ⓑ.

6. Mount the air elimination chamber Ⓒ into the holder on the side of the FW-538.

7. Open the clamp indicated Ⓐ and use this line to spike the saline IV bag.

8. Hold both the saline bag and the drip chamber Ⓓ upside down. Squeeze the saline bag to push air from the bag into the drip chamber. Continue to squeeze until the drip chamber is half full of fluid.

9. Turn the saline bag right side up and hang the bag from the IV pole hook or install it in the Warm*flo* pressure infusor or irrigation pump Ⓔ.

10. Close the roller clamp Ⓕ on the cassette outlet tube.

11. Open the clamp Ⓐ below the saline bag.

12. Pinch the ball in the air vent tube on the air elimination chamber Ⓒ. Saline solution will begin to flow from the bag into the WF-8860 test cassette set. Allow the chamber to fill 3/4 to the top with saline solution. Do not allow solution to rise into the air vent tube.

13. Tap the air elimination chamber Ⓒ to release micro bubbles from the enclosed filter screen.

14. Attach the female Luer end of the high flow wound irrigator WI-48 Ⓚ to the male luer end of the WF-8860 test cassette.

Caution: Use of the WF-8860 test cassette without the high flow wound irrigator WI-48 attached may lead to higher-than-expected temperatures of the output fluid while running the output temperature check.

15. Open the roller clamp Ⓕ and press the button on the WI-48 Ⓛ to open the line. Allow solution to flow until air is purged from the high flow wound irrigator tubing.

16. Release the WI-48 button and close the roller clamp.

17. Insert the myocardial thermocouple temperature probe G into the distal Y-injection port H of the cassette set. The probe should be carefully positioned inside the port so that fluid is flowing around the surface of the probe at its distal end.

18. Connect the temperature probe to the reusable TAB instrument cable I, which in turn should be connected to a type T thermocouple temperature monitor J, such as a Mon-a-therm model 6510.

19. Turn on the thermocouple temperature monitor.

20. Use the roller clamp F on the cassette outlet tube to adjust the fluid flow to 100 ± 25 ml per minute while the button on the WI-48 L is depressed.

Note: This flow may be measured by timing fluid collection in a small graduated cylinder.

21. Allow the fluid to flow for 1 minute before taking readings. The average fluid output temperature should be 38° C ± 2°C at 100 ± 25 ml per minute, as measured by the temperature probe.

22. If the above performance cannot be met, refer to *Troubleshooting* on page 19.

Over-Temperature Alarm Check

This procedure verifies the operation of the alarm system when an over-temperature condition is detected during operation of the FW-538. In addition to the FW-538 fluid warming system, the following equipment is required.

WARNING: Liquid at 55-65°C is a burn hazard. Use care in handling the IV bag and its heated contents.

- WF-8860 test kit (part number 8860), which contains:
  - Cassette and tubing
  - WI-48 high flow wound irrigator
- Saline IV bags (2): Cool one bag to 8-10°C; heat second bag to 55-65°C
- IV pole

The following equipment is optional:

- Warm*flo* pressure infusor(s) or Warm*flo* irrigation pump(s)
- Graduated cylinder
- Mon-a-therm® temperature monitor, model 6510 or equivalent (type T thermocouple temperature monitor) and reusable TAB instrument cable (part number 502-0065)

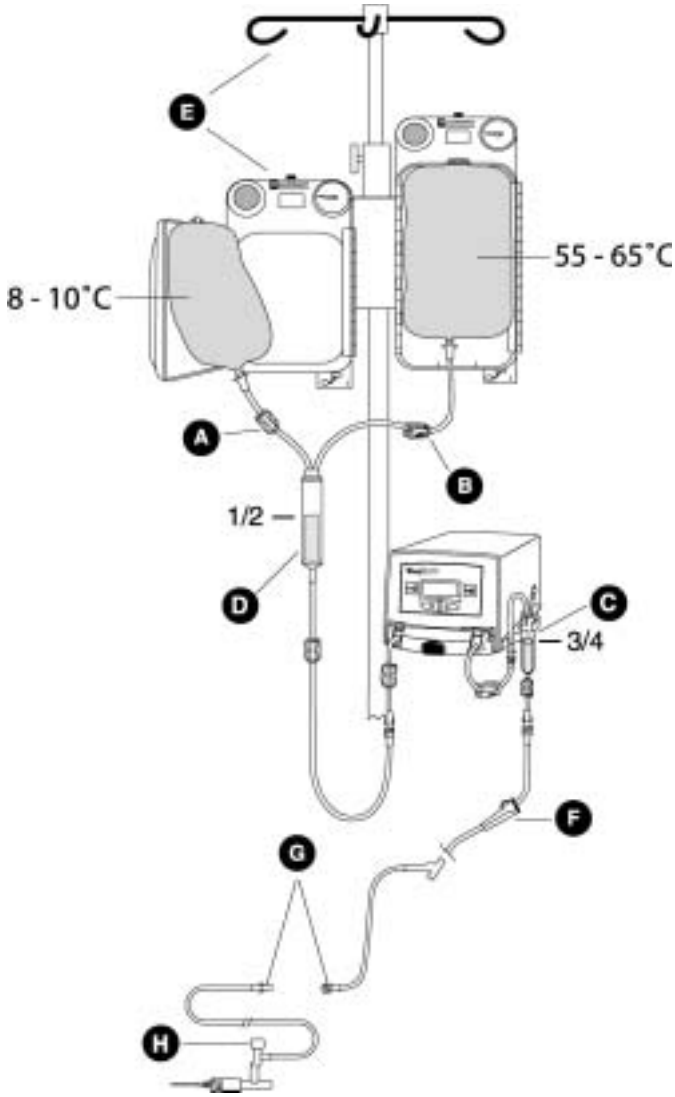


Figure 6: Setup for Over-Temperature Alarm Function Check

Referring to Figure 6, set up the FW-538 to verify the operation of the over-temperature alarm:

1. Turn the Warm*flo* fluid warming system power switch located at the rear of the unit to the ON position. The control panel will display the start-up test mode, followed by the software revision number. When the temperature set point is displayed (38°C default), the unit is ready for operation.

2. Push the door latch button on the fluid warming system to open the cassette door. The door will open approximately 1/2 inch (1.27 cm).

3. Slide a clean WF-8860 test cassette into the door opening until it is fully inserted.

4. Close the door by firmly lifting up on the door until it clicks into position. This is indicated by the appearance of a green band on the top edge of the door latch button.

Note: To ensure that the door is closed, pull out on the door latch button until the green band is visible.

5. Close the pinch clamp Ⓑ.

6. Mount the air elimination chamber into the holder Ⓒ on the side of the FW-538.

7. Open the pinch clamp Ⓐ and use this line to spike the 8-10° saline IV bag. Install the 8-10°C saline IV bag as follows:

   a. Hold both the saline bag and the drip chamber upside down. Squeeze the saline bag to push air from the bag into the drip chamber. Continue to squeeze until the drip chamber is half full of fluid Ⓓ.

   b. Close the pinch clamp Ⓐ.

   c. Turn the saline bag right side up and hang the bag from the IV pole hook at least one (1) meter from the warming unit or install it in a Warm*flo* pressure infusor or irrigation pump Ⓔ.

8. Open the pinch clamp Ⓑ and use this line to spike the 55-65°C saline IV bag. Install the 55-65°C saline IV bag as follows:

Note: The Mon-a-therm monitor and temperature probe may be used to determine the temperature of the pre-warmed IV solution.

   a. Hold both the saline bag and the drip chamber Ⓓ upside down. Squeeze the saline bag to push air from the bag into the drip chamber. Continue to squeeze until the drip chamber is half full of fluid.

   b. Close the indicated pinch clamp Ⓑ.

   c. Turn the saline bag right side up and hang the bag from the IV pole hook at least one (1) meter above the warming unit, or install it in a Warm*flo* pressure infusor or irrigation pump Ⓔ.

9. Close the roller clamp Ⓕ on the cassette outlet tube.

10. Pinch the ball in the air vent tube on the air elimination chamber Ⓒ. Saline solution will begin to flow from the bag into the 8860 test cassette set. Allow the chamber to fill 3/4 to the top with saline solution. Do not allow solution to rise into the air vent tube.

11. Tap the air elimination chamber Ⓒ to release micro bubbles from the enclosed filter screen.

12. Attach the female Luer end of the high flow wound irrigator WI-48 to the male Luer end of a clean WF-8860 test cassette Ⓖ.

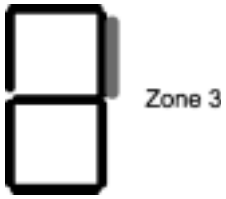
13. Open the roller clamp Ⓕ and depress the button on the WI-48 Ⓗ to purge the air from the high flow wound irrigator tubing.

14. Close the roller clamp Ⓕ after air has been fully purged.

15. Activate the internal test mode of the fluid warming system by simultaneously pressing the Increase and Decrease temperature buttons for five seconds.

16. Select Test Mode #2 (individual thermistor monitoring) by pressing the Increase temperature button until the number “2” is briefly displayed in the first LED of the fluid warmer display.

17. Press the Decrease temperature button to select Zone 3 monitoring. When the segment on the right side of the first LED is illuminated, Zone 3 monitoring is active.



18. Open the pinch clamp Ⓐ below the 8-10°C bag.

19. Use the roller clamp Ⓕ on the cassette outlet tube to adjust the fluid flow to 100 ±25 ml per minute while the button Ⓗ on the WI-48 is depressed.

Note: This flow rate may be measured by timing fluid collection in a small graduated cylinder.

20. Allow the 8-10°C fluid to flow for one minute.

21. Close the pinch clamp Ⓐ, stopping the flow of 8-10°C fluid through the system.

22. Open the pinch clamp (B) below the 50-65°C saline bag and depress the button (H) on the WI-48 to allow the pre-warmed fluid to flow through the system.

23. Observe the temperature at the Zone 3 thermistor on the display of the fluid warming system.

    As the 55-65°C fluid flows through the test cassette, the FW-538 heater plates absorb the excess heat, driving their temperature above the set point of 38°C.

    Two seconds after the temperature reaches 44.5°C ±1°C, the first over-temperature alarm activates. The heater plates are immediately disabled, and an intermittent tone sounds at one-second intervals.

    If the temperature subsequently falls below 44.5°C, and there is no system fault code reported, the unit will resume normal operation.

Note: If the unit is in the normal operating display mode when the first over-temperature alarm sounds, the display will read **H44.5** (±1.0°C).

24. Two seconds after the temperature exceeds 45°C ±1°C, the second over-temperature alarm is activated. This condition is indicated by a repetitive tone at one-second intervals.

Note: If the unit is in the normal operating display mode when the second over-temperature alarm sounds, the display will read **H45.0** (±1.0°C), and will alternate with the display of a fault code, if appropriate.

Note: If the temperature of the heater plates rises too quickly, the first temperature alarm may not sound the intermittent beep. Rather, the first audible alarm may be a continuous tone, signaling the second over-temperature alarm that occurs above 45°C. The procedure may be repeated using a slower flow rate or using pre-warmed saline solution of slightly lower temperature.

25. If the fluid warming system fails to properly enter the over-temperature alarm condition, and/or fails to demonstrate both audible and visual over-temperature alarms, immediately remove the unit from service. Notify your sales/service center of the malfunction. The unit must be serviced by an authorized service technician.

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If the solutions in this section fail to correct the problem, contact Nellcor's Technical Service Department (1.800.635.5267) or your local representative.

Problems

Table 1: System Problems and Solutions

Symptom	Observe	Solution
The LED display is dark.	AC power cord is not plugged in.	• Plug in the power cord.
	Power switch is not turned on.	• Turn the power switch on rear panel to ON (I).
	Fuse is blown.	• Open enclosure and replace fuse. See *Fuse Replacement* on page 34.
	LED connector is loose.	• Push down LED connector into the J10 receptacle on the main circuit board. See *Display PCB Assembly Replacement* on page 38.
Cassette door will not engage latch.	The cassette is full of fluid and the tubing clamps are closed.	• Close the red clamp at the heat exchanger to release pressure on the cassette. Release the fluid downstream. • If transferring a cassette from one warmer to another, be sure the red and white clamps are open.
Cassette door will not open.	The cassette is full of fluid and/or under pressure.	• Close the red clamp at the heat exchanger to release pressure on the cassette. Release the fluid downstream.
	Spring mechanism inside door is broken.	• The Warm*flo* unit provides an emergency technique to remove the cassette if normal procedures do not open the door. Locate the hole in the middle part of the bottom of the door. (It can be felt with a finger.) Insert a #2 Phillips screwdriver. Push until door opens. See Figure 31 on page 48.

Table 1: System Problems and Solutions (Continued)

Symptom	Observe	Solution
Fluid output temperature is too low.	The temperature set point is too low.	• Adjust the temperature set point to the desired setting.
	The fluid flow is being restricted above the heat exchanger.	• Ensure all clamps above the heat exchanger for the spike in use are open.
	Excessive high flow rate.	• Reducing the flow rate will increase warming efficiency.
	Heater plates are dirty.	• Open the cassette door and clean the heater plates according to instructions in *Preventive Maintenance* on page 27.
Over-Temperature Alarm	Pre-warmed fluids were used.	• Do not use pre-warmed fluids.
	High flow rate stopped suddenly.	• Unit will cool and alarm will reset automatically.
Low Temperature Alarm	Excessive high flow rate	• Reduce the flow rate.

Table 2: System Fault Codes

Fault Code	Problem	Solution
FAULT CODE F_01	Defective or wrong EPROM	• Replace main PCB assembly. See *Main PCB Assembly Replacement* on page 36.
FAULT CODE F_02	Defective RAM	• Replace main PCB assembly. See *Main PCB Assembly Replacement* on page 36.
FAULT CODE F_04	Defective NVRAM	• Replace main PCB assembly. See *Main PCB Assembly Replacement* on page 36.
FAULT CODE F_05	Membrane panel switch is stuck.	• Push the button again. Restart the unit. • Replace cover assembly if problem persists. See *Cover Assembly Replacement* on page 30.
FAULT CODE F_08	Microprocessor failure	• Replace main PCB assembly. See *Main PCB Assembly Replacement* on page 36.

Table 2: System Fault Codes (Continued)

Fault Code	Problem	Solution
FAULT CODE F_09	OT_REF offset out of range Voltage Reference error	• Replace main PCB assembly. See *Main PCB Assembly Replacement* on page 36.
FAULT CODE F_10	EXT_OT failure	• Replace main PCB assembly. See *Main PCB Assembly Replacement* on page 36.
FAULT CODE F_11	Heater Zone 1 thermistor failure	• Thermistor in Zone 1 is open or shorted, possibly caused by a loose connector, J6, on main board. Push J6 connector all the way down. See *Main PCB Assembly Replacement* on page 36. • Defective thermistor. Replace chassis assembly. See *Chassis Assembly Replacement* on page 50. • If the previous two steps don't resolve problem, replace main PCB assembly. See *Main PCB Assembly Replacement* on page 36.
FAULT CODE F_12	Heat Zone 2 thermistor failure	• Thermistor in Zone 2 is open or shorted, possibly caused by a loose connector, J6, on main board. Push J6 connector all the way down. See *Main PCB Assembly Replacement* on page 36. • Defective thermistor. Replace chassis assembly. See *Chassis Assembly Replacement* on page 50. • If previous two steps don't resolve problem, replace main PCB assembly. See *Main PCB Assembly Replacement* on page 36.

Table 2: System Fault Codes (Continued)

Fault Code	Problem	Solution
FAULT CODE F_13	Heater Zone 3 thermistor failure.	• Thermistor in Zone 3 is open or shorted, possibly caused by a loose connector, J6, on main board. Push J6 connector all the way down. See *Main PCB Assembly Replacement* on page 36. • Defective thermistor. Replace chassis assembly. See *Chassis Assembly Replacement* on page 50. • If previous two steps don't resolve problem, replace main PCB assembly. See *Main PCB Assembly Replacement* on page 36.
FAULT CODE F_17	Heater lower plate thermistor failure.	• Thermistor in lower plate is open or shorted, possibly caused by a loose connector, J6, on main board. Push J6 connector all the way down. See *Main PCB Assembly Replacement* on page 36. • Defective thermistor. Replace door assembly. See *Door Assembly Replacement* on page 46. • If previous two steps don't resolve problem, replace main PCB assembly. See *Main PCB Assembly Replacement* on page 36.
FAULT CODE F_20	Heater Enable failure.	• Temperature higher than 44.5°C is sensed. Shut down the unit. Wait for 5 minutes. Restart the unit. If problem persists, replace the main PCB assembly. See *Main PCB Assembly Replacement* on page 36.

Table 2: System Fault Codes (Continued)

Fault Code	Problem	Solution
FAULT CODE F_21	Triac Zone 1 failure. Heater Zone 1 does not turn on during initialization.	• Shut down the unit. Wait for 5 minutes. Restart the unit. • Defective Triac Q6 or Optoisolator U4. Replace main PCB assembly. See *Main PCB Assembly Replacement* on page 36.
FAULT CODE F_22	Triac Zone 2 failure. Heater Zone 2 does not turn on during initialization.	• Shut down the unit. Wait for 5 minutes. Restart the unit. • Defective Triac Q4 or Optoisolator U2. Replace main PCB assembly. See *Main PCB Assembly Replacement* on page 36.
FAULT CODE F_23	Triac Zone 3 failure. Heater Zone 3 does not turn on during initialization.	• Shut down the unit. Wait for 5 minutes. Restart the unit. • Defective Triac Q2 or Optoisolator U1. Replace main PCB assembly. See *Main PCB Assembly Replacement* on page 36.
FAULT CODE F_30	Heater Zone 1 failed preheat test. A/D channel 1 failed preheat warmer test. Temperature higher than 42°C is sensed during preheat test.	• Cassette with preheated fluid is used. Shut down the unit. Wait for 5 minutes. Restart the unit. • Defective thermistor in Zone 1. Replace main PCB assembly. See *Main PCB Assembly Replacement* on page 36.
FAULT CODE F_31	Heater Zone 2 failed preheat test. A/D channel 2 failed preheat warmer test. Temperature higher than 42°C is sensed during preheat test.	• Cassette with preheated fluid is used. Shut down the unit. Wait for 5 minutes. Restart the unit. • Defective thermistor in Zone 2. Replace main PCB assembly. See *Main PCB Assembly Replacement* on page 36.
FAULT CODE F_32	Heater Zone 3 failed preheat test. A/D channel 3 failed preheat warmer test. Temperature higher than 42°C is sensed during preheat test.	• Cassette with preheated fluid is used. Shut down the unit. Wait for 5 minutes. Restart the unit. • Defective thermistor in Zone 3. Replace main PCB assembly. See *Main PCB Assembly Replacement* on page 36.

Table 2: System Fault Codes (Continued)

Fault Code	Problem	Solution
FAULT CODE F_41	Heater control failure. Heater is stuck on.	• Shut down the unit. Wait for 5 minutes. Restart the unit. • Defective Triac. Replace main PCB assembly. See *Main PCB Assembly Replacement* on page 36.
FAULT CODE F_42	Heater Zone 1 turn on failure. Heater Zone 1 does not turn on during run time.	• Shut down the unit. Wait for 5 minutes. Restart the unit. • Defective Triac Q6 or Optoisolator U4. Replace main PCB assembly.
FAULT CODE F_43	Heater Zone 2 turn on failure	• Shut down the unit. Wait for 5 minutes. Restart the unit. • Defective Triac Q4 or Optoisolator U2. Replace main PCB assembly.
FAULT CODE F_44	Heater Zone 3 turn on failure	• Shut down the unit. Wait for 5 minutes. Restart the unit. • Defective Triac Q2 or Optoisolator U1. Replace main PCB assembly. See *Main PCB Assembly Replacement* on page 36.
FAULT CODE F_45	External RAM test failure	• Replace main PCB board. See *Main PCB Assembly Replacement* on page 36.
FAULT CODE F_46	Thermistor test failure	• Shut down the unit. Wait for 5 minutes. Restart the unit. • Replace main PCB board. See *Main PCB Assembly Replacement* on page 36.

NVRAM Mode

The system uses an NVRAM (nonvolatile random access memory) U19 chip for permanent storage of fault codes. The microprocessor enters the NVRAM mode if the test pin (J14 pin 1) is connected to ground (J14 pin 2). If the jumper is installed between J14 pin 1 and pin 2 when the unit is powered on, the last fault code stored in NVRAM is displayed.

Note: Normal operation mode requires the jumper to be removed or to be installed on one pin only.

The unit is supplied with a jumper only on one pin of the J14 connector. If the test pin is not installed, the program will bypass the NVRAM mode and display a fault code only when one is detected.

The NVRAM storage holds the most recent 16 fault codes. With the jumper connecting pin 1 to pin 2, the display shows the most recent fault code in the format F_##. Press the increase button to cycle through all the stored fault codes in a round-robin fashion.

After reviewing the fault codes, remove the jumper while the unit is on, clearing all of the fault codes. Install the jumper on only one pin. Turn off the unit. When the unit is restarted, it will return to normal operation mode and will display a fault code only when one is detected.

Electromagnetic Interference

This device has been tested and found to comply with the limits for medical devices to the IEC 60601-1-2:1993. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation.

However, because of the proliferation of radio-frequency transmitting equipment and other sources of electrical noise in the healthcare environment, it is possible that high levels of such interference, due to close proximity or strength of a source, may result in disruption of performance of this device.

This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with these instructions, may cause harmful interference with other devices in the vicinity. Disruption or interference may be evidenced by cessation of operation or incorrect functioning. If this occurs, the site of use should be surveyed to determine the source of this disruption, and actions taken to eliminate the source.

The user is encouraged to try to correct the interference by one or more of the following measures:

- Turn equipment in the vicinity off and on to isolate the offending equipment.
- Reorient or relocate the other receiving device.
- Increase the separation between the interfering equipment and this equipment.
- If assistance is required, contact Nellcor’s Technical Service Department or your local representative.

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WARNING: Electrical shock hazard. Disconnect the unit from AC power prior to cleaning. Thoroughly dry before returning to service.

Caution: Do not scratch the heater plates. Do not use abrasive materials or treated polishing cloth.

Caution: To prevent equipment damage, do not autoclave or immerse in liquids.

Note: For easy access to the heater plates, with cassette door in open position, push the release button on the bottom of the unit. The door will swing open approximately 3 inches (7.62 cm). (See Figure 7 below.)

Figure 7: Accessing Heater Plates

The following preventive maintenance procedures are recommended.

Table 3: System Preventative Maintenance

Action	Frequency	Method
Clean exterior surfaces	As required with use.	Use warm, mild soap water and soft cloth. Heater plates must be smooth, clean and free of surface imperfections to assure proper warming performance.
Clean heater plates	As required if contaminated with blood or other fluids or debris.	Use soft cloth moistened with mild soapy water. Wipe dry with clean, soft cloth.

Table 3: System Preventative Maintenance (Continued)

Action	Frequency	Method
Electrical safety check	Prior to patient use and annually thereafter.	Refer to hospital standards.
Output temperature performance check	Annually	Refer to *Performance Verification* on page 9.
Alarm test	Annually. May be tested prior to each use or at any time during use.	Press the Alarm Test button on the front control panel. Anytime the unit is turned on, audible and visual high and low temperature alarms will cycle for approximately 10 seconds, then the unit will automatically return to normal operation.

WARNING: Possible electrical shock hazard. The warming unit should only by serviced by a qualified technician. If a qualified technician is not available, please notify your sales/service center.

Information

To obtain information about a warranty, if any, for this product, contact Nellcor's Customer Services Department or your local Nellcor representative.

For technical support, or to obtain service, contact Nellcor's Customer Service Department at:

Tyco Healthcare Group LP
Nellcor Puritan Bennett Division
4280 Hacienda Drive
Pleasanton, CA 94588

1.800.635.5267

Introduction

The FW-538 can be disassembled down to all major component parts, including:

- Chassis assembly
- Cover assembly
- Door assembly
- Fuse
- PCBs

WARNING: Before attempting to open or disassemble the FW-538, disconnect the FW-538 from AC power.

Caution: Observe ESD (electrostatic discharge) precautions when working within the unit.

Replacement Level Support

The replacement level supported for this product is to the printed circuit board (PCB) and major subassembly level. Once you isolate a suspected PCB, follow the procedures below to replace the PCB with a known good PCB. Check to see if the trouble symptom disappears and that the FW-538 passes all performance tests. If the trouble symptom persists, swap back the replacement PCB with the suspected malfunctioning PCB (the original PCB that was installed when you started troubleshooting) and continue troubleshooting as directed in *Troubleshooting* on page 19.

Cover Assembly Replacement

The replacement cover assembly comes assembled with:

- 1 — molded cover
- 1 — key pad
- 1 — warning label

The tools required for this procedure are:

Tool	Parameters/Use
Hex driver	9/64 inch
Phillips screwdriver	#1
Torque driver/wrench	6 inch/lbs (15 cm/kg)
	5 inch/lbs (13 cm/kg)

Use the following procedure to replace the cover assembly.

1. Turn the FW-538 off by pressing the power switch, located at the back of the unit, to “0”.
2. Unplug the FW-538 from AC power.
3. Disconnect the power cord from the rear of the FW-538.

4. Remove the filter mounting bracket from the cover assembly, using a 1/4 inch hex driver. See Figure 8.

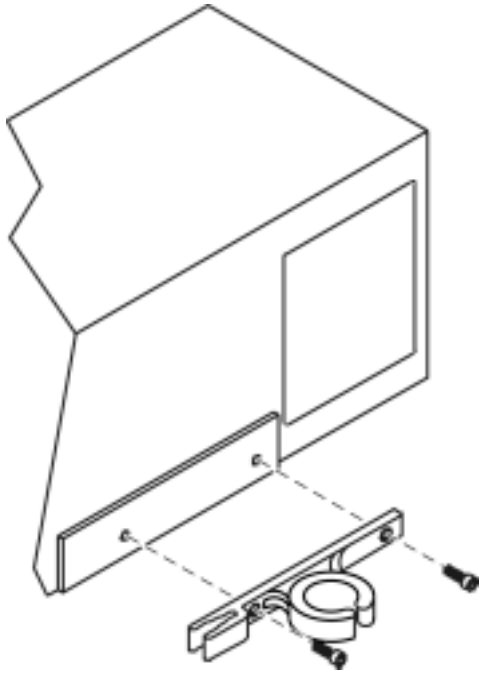


Figure 8: Filter Mounting Bracket Removal

5. Remove the IV pole mounting bracket, using a 1/4 inch allen wrench. See Figure 9.

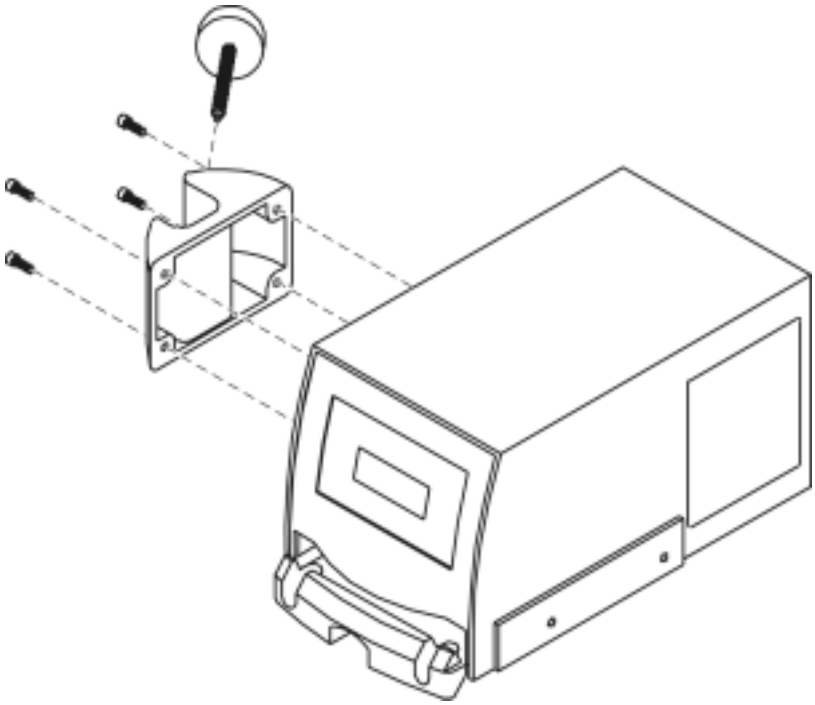


Figure 9: IV Mounting Bracket Removal

Caution: The cover is attached to the main pcb by two cables. Use care when lifting the cover off of the unit. Do not put excessive pressure on the connecting cables.

6. Lift the cover assembly off of the FW-538.

7. Disconnect the keypad cable from the main PCB assembly. See Figure 10, item 1.

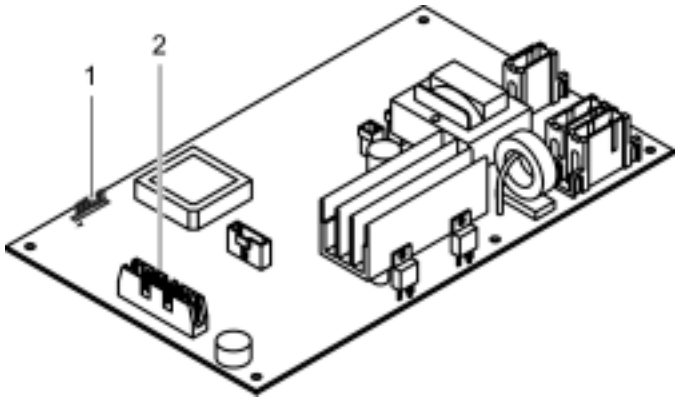
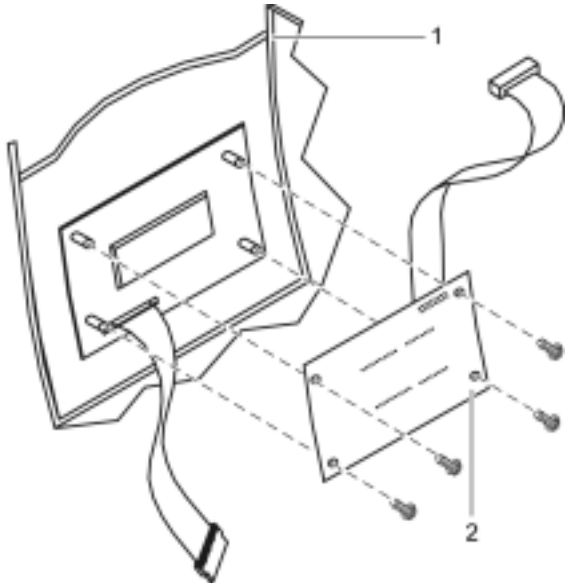


Figure 10: Cover Assembly Cable Connections

8. Disconnect the display PCB assembly cable from the main PCB assembly. See Figure 10. item 2.

9. Remove the display PCB assembly from the cover assembly. See Figure 11.



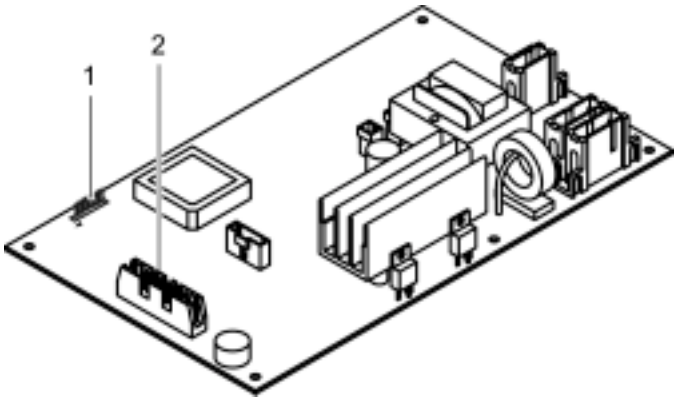
1 — Cover assembly	2 — Display PCB assembly

Figure 11: Display PCB Assembly Removal

10. Discard the old cover assembly in accordance with local regulations.

11. Install the display PCB assembly into the new cover assembly. The screws should be torqued to 5 inch/lbs (13 cm/kg). See Figure 11.

12. Connect the display PCB assembly cable and the keypad cable to the main PCB assembly. See Figure 12.



1 — Keypad cable connection	2 — Display cable connection

Figure 12: Cover Assembly Cable Connections

13. Place the cover assembly on the FW-538 unit.

14. Install the IV pole mount bracket on the FW-538. The screws should be torqued to 6 inch/lbs (15 cm/kg). See Figure 13.

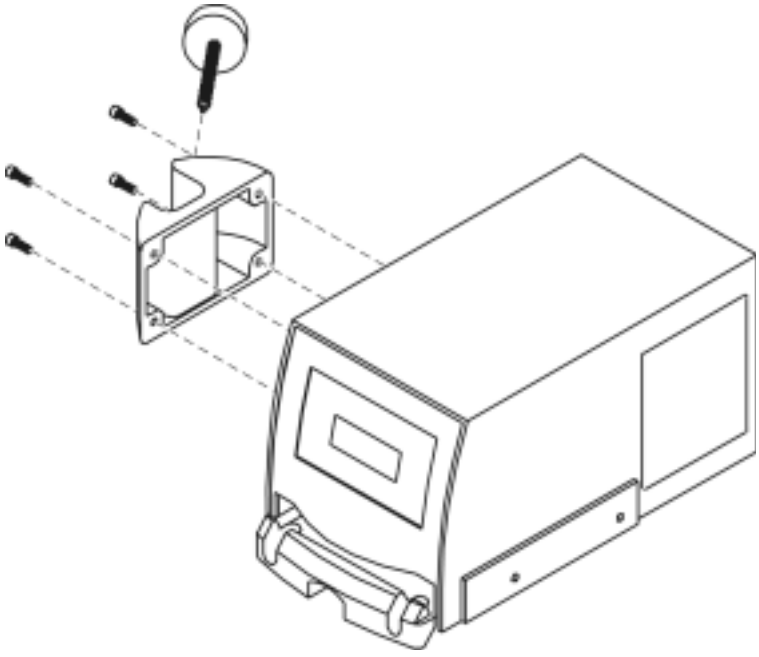


Figure 13: IV Mounting Bracket Removal

15. Install the filter mounting bracket from the cover assembly. The screws should be torqued to 6 inch/lbs (15 cm/kg). See Figure 14.

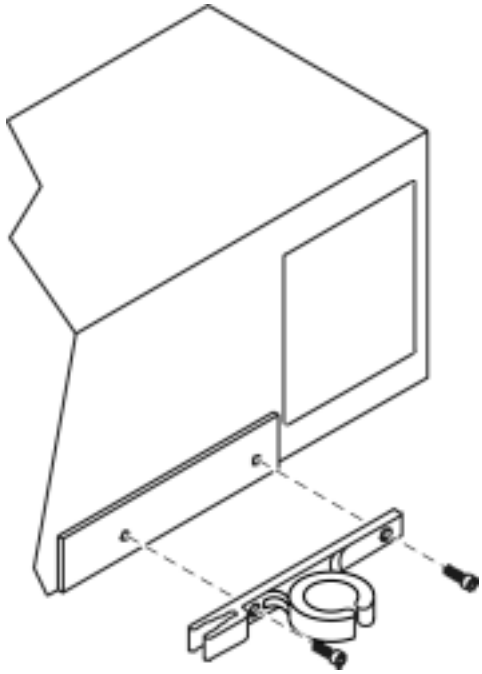


Figure 14: Filter Mounting Bracket Removal

16. Perform the following checks/test to verify proper operation of the FW-538 prior to returning the unit into service:

    - *Test #1: Zone Heating Monitoring* on page 9
    - *Test #2: Individual Thermistor Monitoring* on page 9
    - *Test #3: Automatic Thermistor Zone Monitoring* on page 10
    - *Output Temperature Test* on page 10
    - *Over-Temperature Alarm Check* on page 13

Fuse Replacement

The tools required for this procedure are:

Tool	Parameters/Use
Hex driver	9/64 inch
Torque driver/wrench	6 inch/lbs (15 cm/kg)

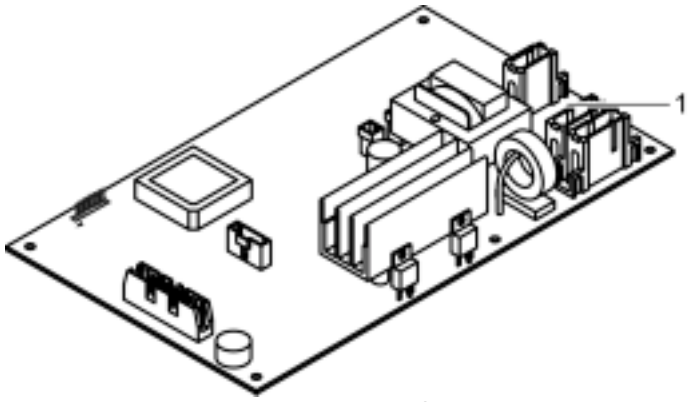
Use the following procedure to replace the FW-538 fuse.

1. Turn the FW-538 off by pressing the power switch, located at the back of the unit, to “0”.

2. Unplug the FW-538 from AC power.

3. Remove the FW-538 cover. See *Cover Assembly Replacement* on page 30.

4. Remove the fuse and insert a new fuse. See Figure 15.



1 — Fuse Location

Figure 15: Fuse Location

5. Replace cover assembly. See *Cover Assembly Replacement* on page 30.

6. Perform the following checks/test to verify proper operation of the FW-538 prior to returning the unit into service:

   - *Test #1: Zone Heating Monitoring* on page 9
   - *Test #2: Individual Thermistor Monitoring* on page 9
   - *Test #3: Automatic Thermistor Zone Monitoring* on page 10
   - *Output Temperature Test* on page 10
   - *Over-Temperature Alarm Check* on page 13

IV Pole Mount Replacement

Use the following procedure to replace the IV pole mounting bracket.

1. Remove the IV pole mounting bracket. See *Cover Assembly Replacement*, step 5 on page 31.

2. Install the new IV pole mounting bracket. See *Cover Assembly Replacement*, step 14 on page 33.

Main PCB Assembly Replacement

The main PCB assembly comes assembled with:

- 1 — universal control PCB
- 1 — 0.032A fuse
- 2 — jumpers JMP2 and JMP3

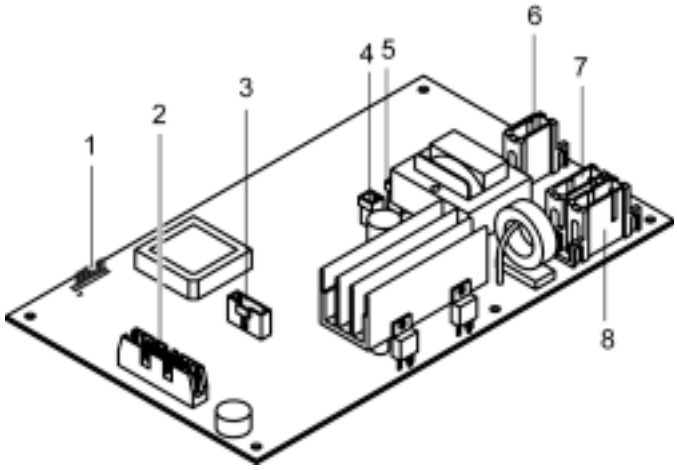
The tools required for this procedure are:

Tool	Parameters/Use
Hex driver	9/64 inch
Phillips screwdriver	#1
Torque driver/wrench	6 inch/lbs (15 cm/kg)
	3 inch/lbs (8 cm/kg)

Use the following procedure to replace the main PCB assembly.

1. Turn the FW-538 off by pressing the power switch, located at the back of the unit, to “0”.
2. Unplug the FW-538 from AC power.
3. Remove the power cord from the FW-538.
4. Remove the FW-538 cover. See *Cover Assembly Replacement* on page 30.

5. Disconnect all cables from the main PCB assembly. See Figure 16.



1 — J12	2 — J10	3 — J14	4 — J9
5 — J4	6 — J3	7 — J1	8 — J2

Figure 16: Main PCB Cable Connections

6. Remove the screws holding the main PCB assembly to the chassis assembly. See Figure 17.

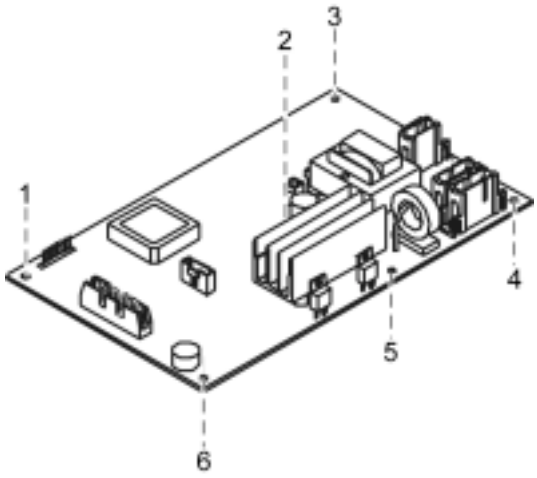


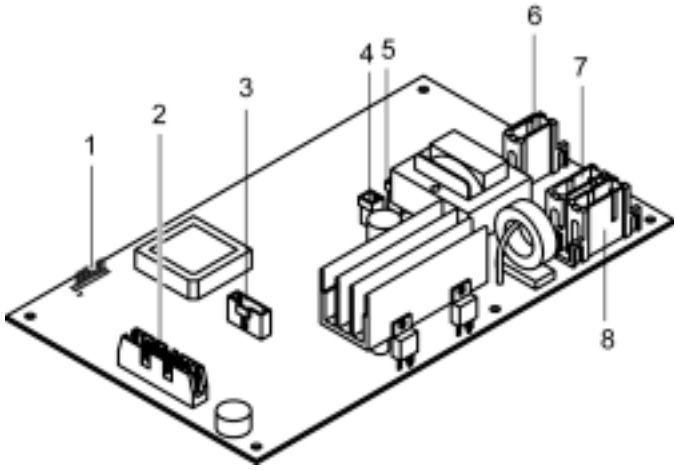
Figure 17: Main PCB Screws

7. Carefully lift the main PCB assembly from the chassis assembly.

8. Discard the removed main PCB assembly in accordance with local regulations.

9. Install the new main PCB assembly in the FW-538. The screws should be torqued to 3 inch/lbs (8 cm/kg). See Figure 17.

10. Connect all cables to the main PCB assembly. See Figure 18.



1 — J12	2 — J14	3 — J10	4 — J9
5 — J4	6 — J3	7 — J1	8 — J2

Figure 18: Main PCB Cable Connections

11. Replace the cover assembly on the FW-538. See *Cover Assembly Replacement*, step 12 on page 33.

12. Perform the following checks/test to verify proper operation of the FW-538 prior to returning the unit into service:

    - *Test #1: Zone Heating Monitoring* on page 9
    - *Test #2: Individual Thermistor Monitoring* on page 9
    - *Test #3: Automatic Thermistor Zone Monitoring* on page 10
    - *Output Temperature Test* on page 10
    - *Over-Temperature Alarm Check* on page 13

Display PCB Assembly Replacement

The replacement display PCB assembly comes assembled with:

- 1 — display PCB
- 1 — 16 pin connector
- 1 — 16 conductor ribbon cable

The tools required for this procedure are:

Tool	Parameters/Use
Hex driver	9/64 inch
Phillips screwdriver	#1
Torque driver/wrench	6 inch/lbs (15 cm/kg)
	5 inch/lbs (13 cm/kg)

Use the following procedure to replace the display PCB assembly.

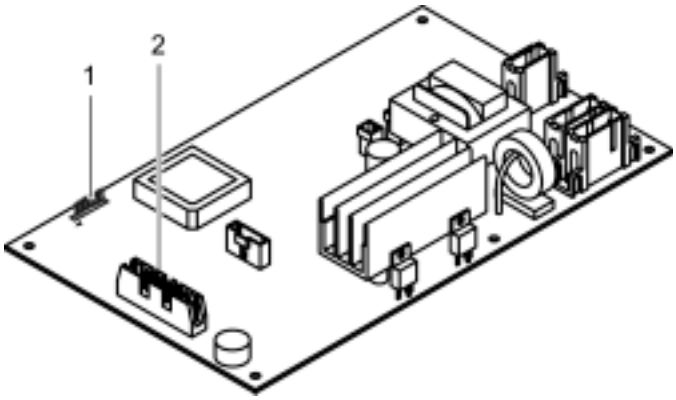
1. Turn the FW-538 off by pressing the power switch, located at the back of the unit, to “0”.

2. Unplug the FW-538 from AC power.

3. Disconnect the power cord from the FW-538.

4. Remove the FW-538 cover. See *Cover Assembly Replacement* on page 30.

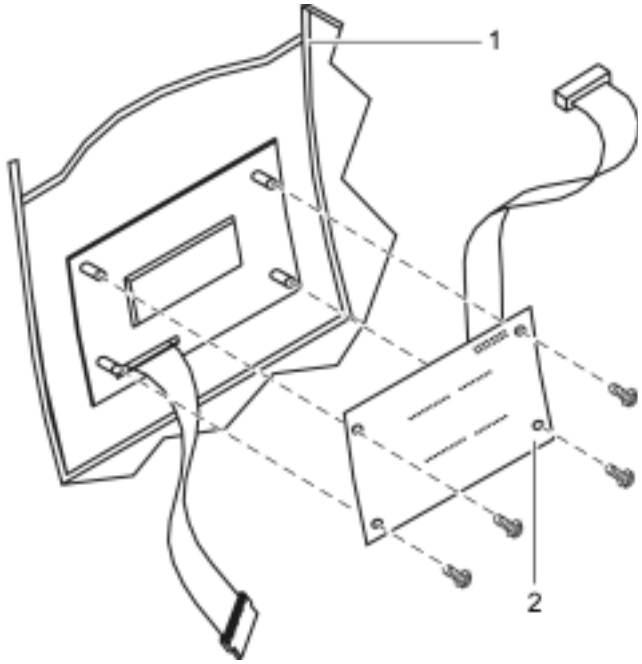
5. Disconnect the cover assembly cables from the main pcb. See Figure 19.



1 — Keypad cable connection	2 — Display cable connection

Figure 19: Cover Assembly Cable Connections

6. Remove the screws holding the display assembly to the cover. See Figure 20.



1 — Cover assembly	2 — Display PCB assembly

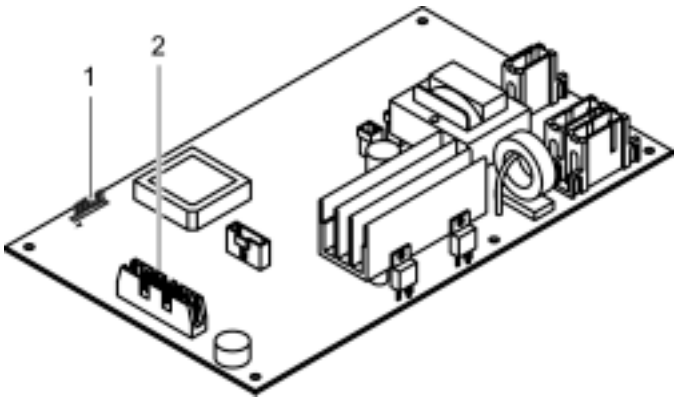
Figure 20: Display Assembly Screws

7. Remove the display PCB assembly.

8. Discard the removed display PCB in accordance with local regulations.

9. Install the new display assembly in the cover assembly. The screws should be torqued to 5 inch/lbs (13 cm/kg). See Figure 20.

10. Connect the cover assembly cables to the main PCB assembly. See Figure 21.



1 — Keypad cable connection	2 — Display cable connection

Figure 21: Cover Assembly Cable Connections

11. Install the cover assembly on the FW-538. See *Cover Assembly Replacement*. step 13 on page 33.

12. Perform the following checks/test to verify proper operation of the FW-538 prior to returning the unit into service:

    - *Test #1: Zone Heating Monitoring* on page 9
    - *Test #2: Individual Thermistor Monitoring* on page 9
    - *Test #3: Automatic Thermistor Zone Monitoring* on page 10
    - *Output Temperature Test* on page 10
    - *Over-Temperature Alarm Check* on page 13

Rear Panel Assembly Replacement

The replacement rear panel assembly comes assembled with:

- 1 — rear panel
- 1 — fan assembly
- 1 — equipment label
- 1 — equipment serial number label
- 1 — 3-position connector
- 1 — 6 Amp circuit breaker
- 1 — 6 Amp input filter
- 1 — equipotential pin
- 2 — 6 mm thin nuts
- 2 — 6 mm lock washers
- 1 — color code washer
- 1 — ground label
- 1 — 3 inch (7.6 cm) brown wire assembly
- 1 — 3 inch (7.6 cm) blue wire assembly
- 1 — 5.25 inch (13.34 cm) brown wire assembly

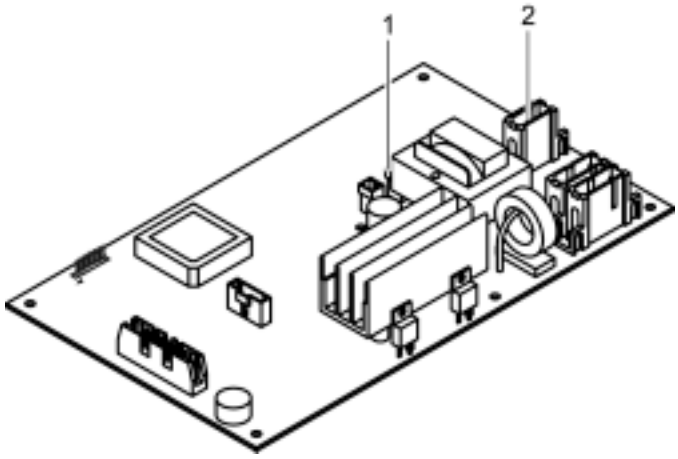
- 1 — 5.25 inch (13.34 cm) blue wire assembly
- 2 — 4.5 inch (11.4 cm) green/yellow wire assemblies

The tools required for this procedure are:

Tool	Parameters/Use
Hex driver	9/64 inch
Phillips screwdriver	#1
Socket	10 mm
Torque driver/wrench	3 inch/lbs (8 cm/kg)
	40 inch/lbs (102 cm/kg)

Use the following procedure to replace the rear panel assembly.

1. Turn the FW-538 off by pressing the power switch, located at the back of the unit, to “0”.
2. Unplug the FW-538 from AC power.
3. Disconnect the power cord from the FW-538.
4. Remove the FW-538 cover assembly. See *Cover Assembly Replacement* on page 30.
5. Place the cover assembly in a safe place.
6. Disconnect the rear panel assembly cables from the main PCB assembly. See Figure 22.



1 — J4	2 — J3

Figure 22: Rear Panel Cable Connections

Note: On some of the FW-538 units, the equipment label covers the rear panel assembly screws.

7. Remove the rear panel assembly equipment label. See Figure 23, item 1.

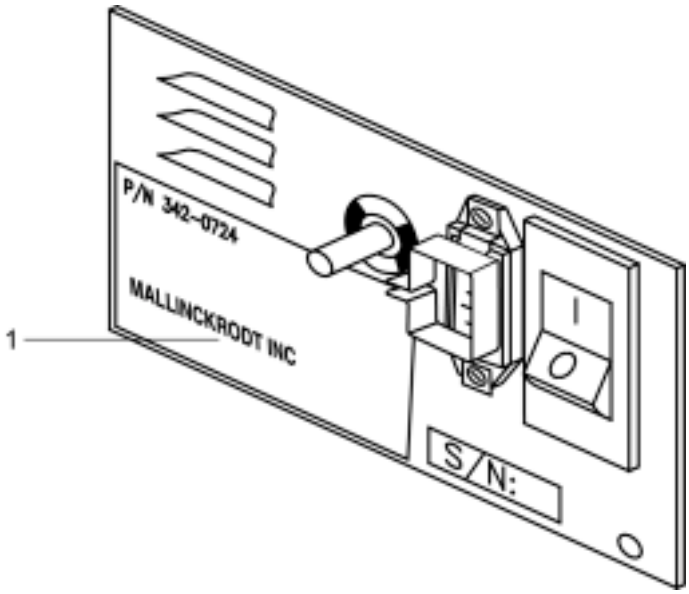


Figure 23: Rear Panel

Caution: When the rear panel assembly is unscrewed from the chassis assembly, there will still be two green/yellow wires attached to the chassis. Do not place undue stress on these wires.

8. Remove the rear panel assembly from the chassis assembly. See Figure 24.

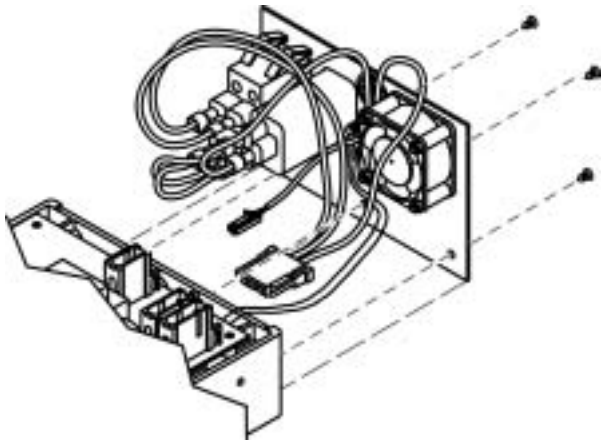
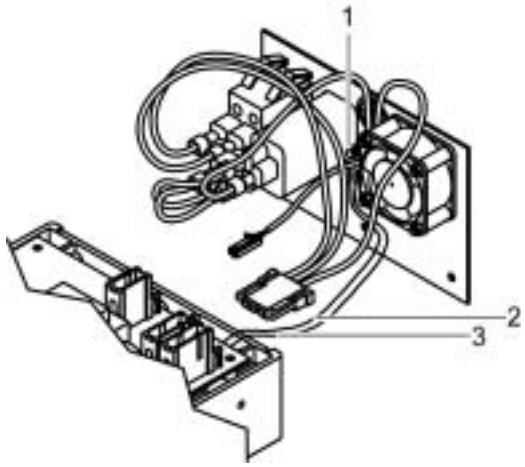


Figure 24: Rear Panel Screws

9. Disconnect the two small green/yellow wires attached to the chassis assembly from the rear panel assembly equipotential terminal. See Figure 25.

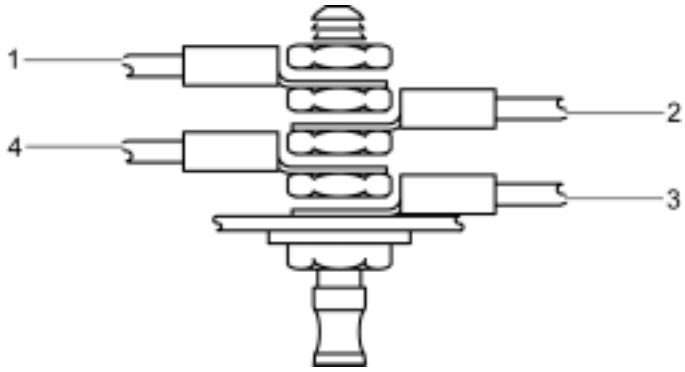


1 — Equipotential terminal	2 — Green/yellow wire
3 — Green/yellow wire	

Figure 25: Rear Panel Ground

10. Discard the removed rear panel assembly in accordance with local regulations.

11. Install the two green/yellow wires on the replacement rear panel equipotential terminal. The nuts should be torqued to 40 inch/lbs (102 cm/kg). See Figure 25 and Figure 26.



1 — Green/yellow wire to chassis	2 — Green/yellow wire to chassis
3 — Green/yellow wire to J3	4 — Green/yellow wire to filter

Figure 26: Equipotential Terminal Wiring

12. Connect the replacement rear panel assembly to the chassis assembly. The screws should be torqued to 3 inch/lbs (8 cm/kg). See Figure 27.

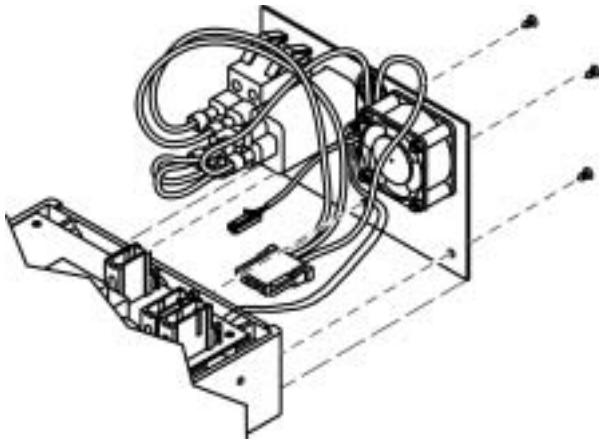


Figure 27: Rear Panel Assembly Connection

13. Connect the rear panel assembly cables to the main PCB assembly. See Figure 28.

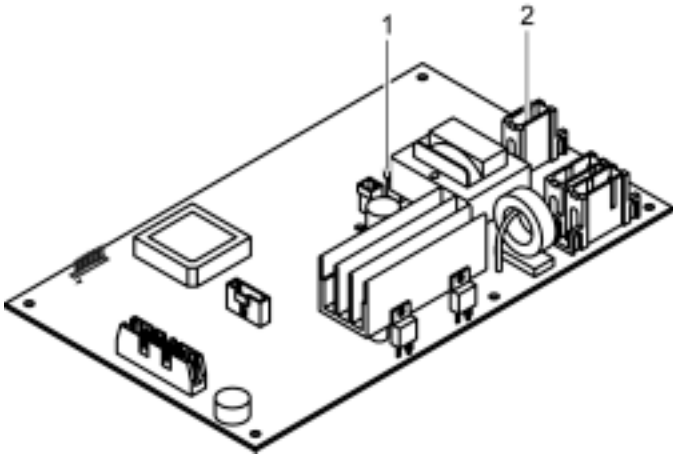


Figure 28: Rear Panel Assembly Cable Connections

14. Install the cover assembly on the FW-538. See *Cover Assembly Replacement*. step 13 on page 33.

15. Perform the following checks/test to verify proper operation of the FW-538 prior to returning the unit into service:

    - *Test #1: Zone Heating Monitoring* on page 9
    - *Test #2: Individual Thermistor Monitoring* on page 9
    - *Test #3: Automatic Thermistor Zone Monitoring* on page 10
    - *Output Temperature Test* on page 10

- *Over-Temperature Alarm Check* on page 13

Door Assembly Replacement

The replacement door assembly comes assembled with:

- 1 — molded door
- 13 — #4 x 38 flat head self tapping screws
- 1 — lower heat plate assembly
- 1 — spring latch assembly
- 1 — push bottom spring
- 1 — door limiter spring
- 1 — bottom molded door
- 1 — molded door limiter
- 1 — molded right latch
- 1 — molded button
- 1 — molded left latch

The tools required for this procedure are:

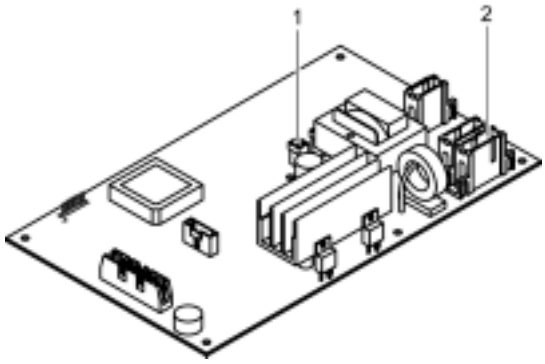
Tool	Parameters/Use
Hex driver	9/64 inch
Phillips screwdriver	#1

Use the following procedure to replace the door assembly.

1. Turn the FW-538 off by pressing the power switch, located at the back of the unit, to “0”.
2. Unplug the FW-538 from AC power.
3. Remove the power cord from the FW-538.
4. Remove the FW-538 cover assembly. See *Cover Assembly Replacement* on page 30.

5. Remove the rear panel from the chassis. See *Rear Panel Assembly Replacement* on page 41.

6. Disconnect door assembly cables from the chassis assembly. See Figure 29.



1 — J9	2 — J2

Figure 29: Door Assembly Cable Connections

7. Remove the door assembly pin from the chassis assembly. See Figure 30.

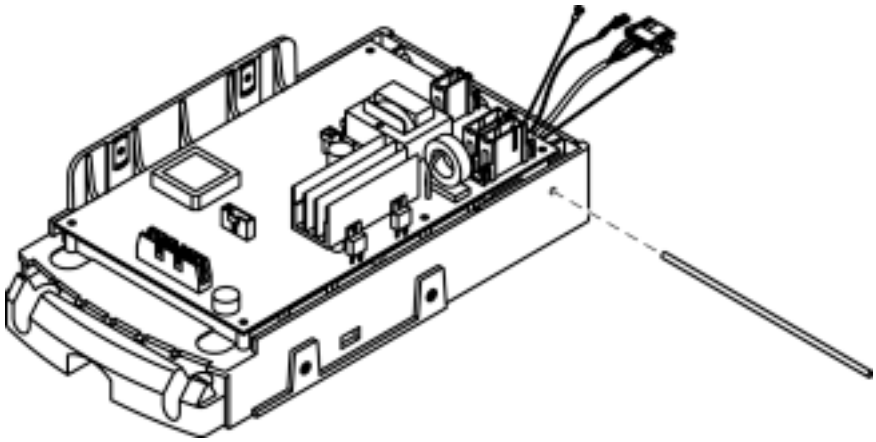
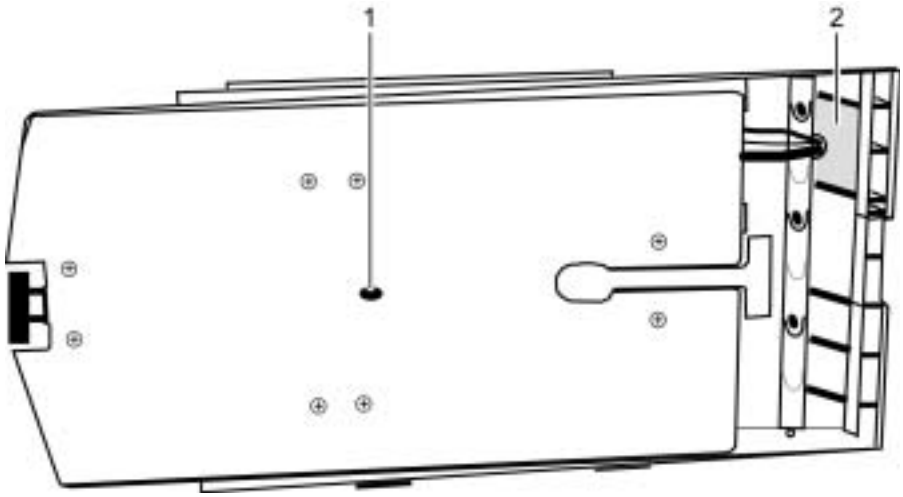


Figure 30: Door Assembly Pin

Note: It is not necessary to remove the main pcb from the chassis assembly.

8. Remove the cable retainer from the chassis assembly. See Figure 31. The cable retainer should be pushed from the top of the chassis assembly.



1 — Door Release	2 — Cable Retainer

Figure 31: Door Assembly Cable Retainer

9. Slide the door assembly cables through the bottom of the chassis assembly. See Figure 32.

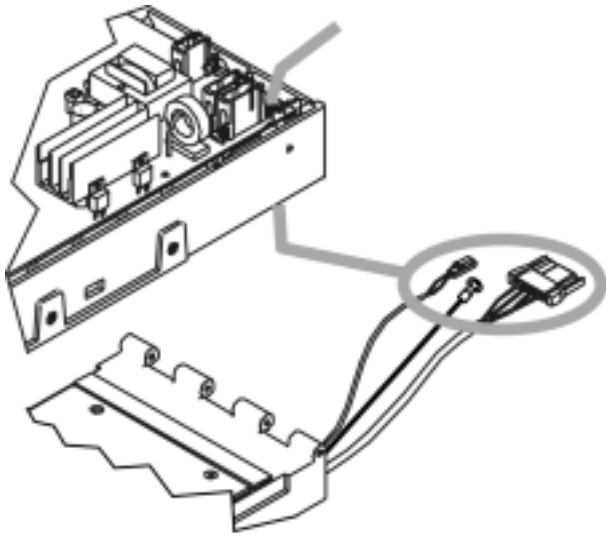


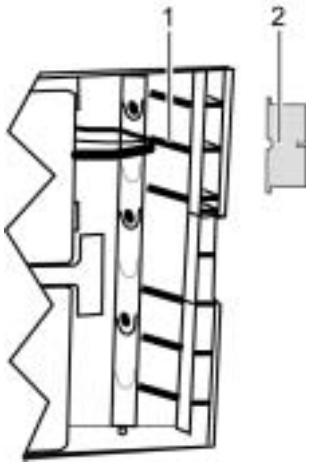
Figure 32: Door Assembly Cable Routing

10. Discard the removed door assembly in accordance with local regulations.

11. Route replacement door assembly cables through the bottom of the chassis assembly. See Figure 32.

12. Place the new door assembly into the chassis assembly and position it as shown in Figure 33.

13. Install the cable retainer into the chassis assembly. See Figure 33. The cable retainer slot should be placed on the chassis assembly support and the cable retainer pressed into place.



1 — Chassis assembly support	2 — Cable retainer

Figure 33: Cable Retainer Placement

14. Slide the door assembly into position with the door assembly pin holes aligned and insert the pin. See Figure 34.

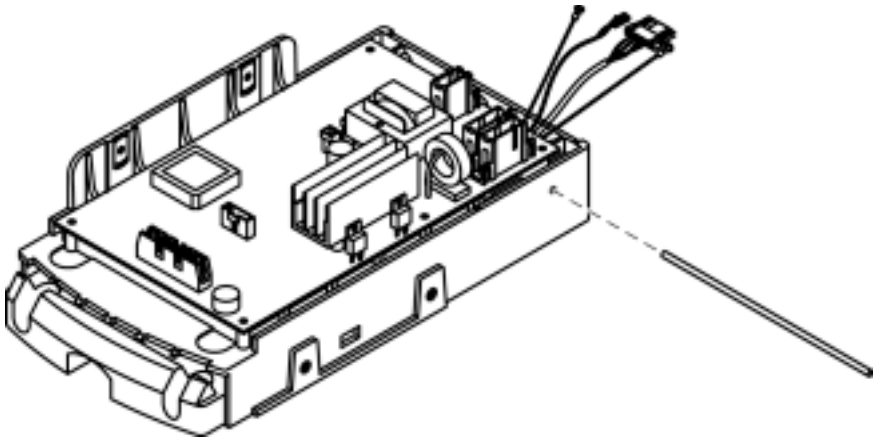


Figure 34: Door Assembly Pin Installation

15. Reconnect the door assembly cables to the main pcb. See Figure 35.

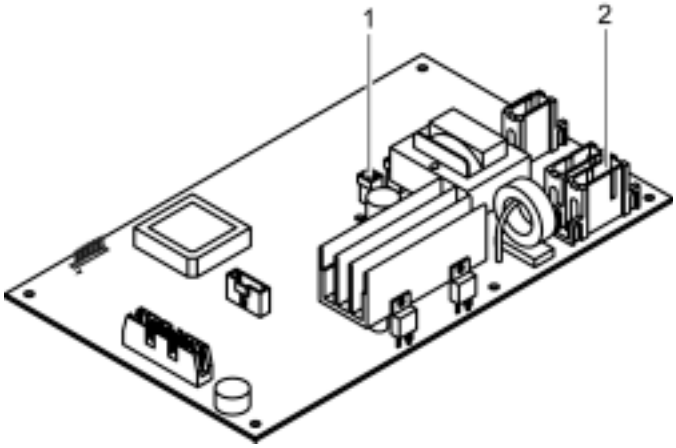


Figure 35: Door Assembly Cable Connections

16. Install the rear panel assembly. See *Rear Panel Assembly Replacement*, step 11 on page 44.

17. Install the cover assembly on the FW-538. See *Cover Assembly Replacement*. step 13 on page 33.

18. Perform the following checks/test to verify proper operation of the FW-538 prior to returning the unit into service:

    - *Test #1: Zone Heating Monitoring* on page 9
    - *Test #2: Individual Thermistor Monitoring* on page 9
    - *Test #3: Automatic Thermistor Zone Monitoring* on page 10
    - *Output Temperature Test* on page 10
    - *Over-Temperature Alarm Check* on page 13

Chassis Assembly Replacement

The replacement chassis assembly comes assembled with:

- 1 — molded chassis
- 6 — threaded inserts
- 5 — #4 x 3/8 flat head self tapping screws
- 1 — upper heater plate assembly

The tools required for this procedure are:

Tool	Parameters/Use
Hex driver	9/64 inch
Phillips screwdriver	#1

Use the following procedure to replace the chassis assembly.

1. Turn the FW-538 off by pressing the power switch, located at the back of the unit, to “0”.

2. Unplug the FW-538 from AC power.

3. Remove the power cord from the FW-538.

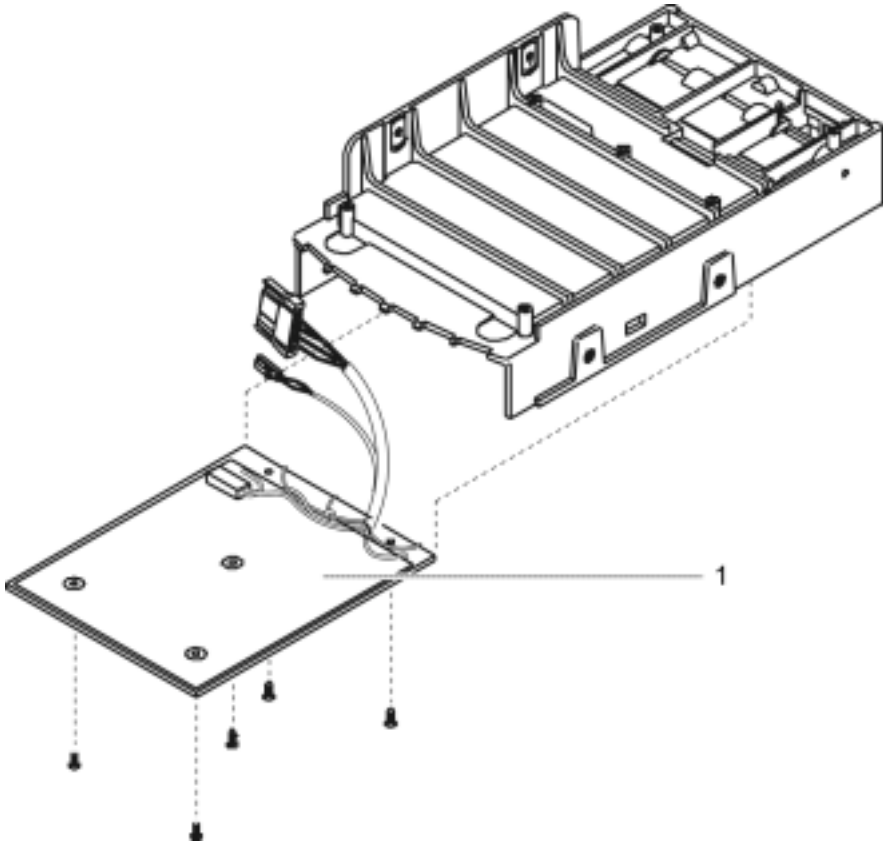
4. Remove the FW-538 cover assembly. See *Cover Assembly Replacement* on page 30.

5. Remove the rear panel assembly from the chassis. See *Rear Panel Assembly Replacement* on page 41.

6. Remove the main PCB assembly. See *Main PCB Assembly Replacement* on page 36.

7. Remove the door assembly. See *Door Assembly Replacement* on page 46.

8. Remove the upper heater plate from the main chassis. See Figure 36.



1 — Upper Heater Plate

Figure 36: Upper Heater Assembly

9. Discard the old chassis assembly in accordance with local regulations.

10. Install upper heater plate in the new chassis assembly. See Figure 36.

11. Install the door assembly on the new chassis assembly. See *Door Assembly Replacement* step 11 on page 48.

12. Install the main PCB assembly on the chassis assembly. See *Main PCB Assembly Replacement* step 9 on page 37.

13. Install the rear panel on the chassis. See See *Rear Panel Assembly Replacement*.step 11 on page 44.

14. Install the cover assembly. See See *Cover Assembly Replacement* step 11 on page 33.

15. Perform the following checks/test to verify proper operation of the FW-538 prior to returning the unit into service:

    - *Test #1: Zone Heating Monitoring* on page 9

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Dimensions

Height	4.75 inches (12 cm)
Width	5.75 inches (14.5 cm)
Depth	11 inches (28 cm)

Weight

8 pounds (3.63 kg)

Technical Specifications

Complies with Standards: IEC 601.1, UL 2601, C22.2 No 601.1-M90

Supply voltage	115 Volts AC
Operating frequency	50 to 60 Hz
Maximum operating current	12 Amperes
Maximum heating power	1,440 Watts
Warmer circuit breaker rating	12 Amperes
Electrical equipment class	Class 1 equipment
Patient applied part	Type BF equipment
Heat transfer method	Dry Heat
Temperature control range	28.0 ° C to 42.0° C
Default set point temperature	38.0° C
Low temperature alarm	3.0° C below set point
High temperature alarm	44.5° C
Secondary heater disable	45.0° C
Display screen	Four-digit green LED
Fluid ingress protection	Drip Proof (IPX2)

Operating temperature range	50° F to 86° F (10° C to 30° C)
Operating relative humidity	10% to 95% non-condensing
Operating elevation	0 to 10,000 feet (0 to 3,048 meters)
Mode of operation	Continuous

Transportation and Storage

Ambient temperature	-13º F to 131º F (-25° C to 55° C)
Relative humidity	10% to 95% non-condensing
Elevation	0 to 10,000 feet (0 to 3,048 meters)

Performance Requirements

1. 10°C fluid at the input of the cassette must be warmed to a minimum of 35 °C at four feet (1.2 meters) past the air trap with a 38°C temperature set point. This applies to a flow rate range of 15 to 250 ml/minute.

2. 20°C fluid at the input of the cassette must be warmed to a minimum of 35°C at four feet (1.2 meters) past the air trap with a 38°C temperature set point. This applies to a flow rate range of 15 to 250 ml/minute.

Compliance

Table 4: Model FW-538 Compliance

Item	Compliant With
Equipment classification	Safety Standards: EN 60601-1 (same as EN60601-1), CSA 601.1, UL 2601-1, EN 60601-2-35, EN 60601-1-2 (second edition)
Type of protection	Class I (on AC power)
Degree of protection	Type BF - Applied part
Mode of operation	Continuous
Resistant to liquid ingress	EN 60601-1, sub-clause 44.6 for class IPX0, ordinary

Table 4: Model FW-538 Compliance

Item	Compliant With
Degree of Safety in presence of a flammable anaesthetic	UL 2601-1, sub-clause 5.5, Not suitable
Applied label to indicate Type BF applied part	EN 60601-1 Symbol 2 of Table DII of Appendix D
Equipotential lug symbol to indicate a potential equalization conductor	EN 60601-1 Symbol 9 of Table DI of Appendix D
Attention symbol, consult accompanying documentation	EN 60601-1 Symbols 14 of Table DI of Appendix D
External case made with non-conductive plastic	EN 60601-1, sub-clause 16(a)
No holes in case top	EN 60601-1, sub-clause 16(b)
Rigid case	EN 60601-1, sub-clause 21(a)
Case mechanically strong	EN 60601-1, sub-clause 21(b)
Case handle	EN 60601-1, sub-clause 21(c)
Resistant to rough handling	EN 60601-1, sub-clause 21.6
Tip/tilt test	EN 60601-1, sub-clause 24.1
Resistant to liquid ingress due to spills	EN 60601-1, sub-clause 44.3 as modified by EN 865, clause 4
Environmental	EN 60601-1, sub-clause 44.5
Cleaning	EN 60601-1, sub-clause 44.7
Case surface made of non-toxic materials	EN 60601-1, sub-clause 48
Case resistant to heat and fire	EN 60601-1, sub-clause 59.2(b)
Fuse holder	EN 60601-1, sub-clause 59.3
Exterior markings	EN 60601-1, sub-clause 6.1, 6.3, and 6.4
Front panel and case labeling	EN 60878, EN 980, ISO 7000, EN 60417-1, EN 60417-2
Button spacing	ISO 7250
Year of manufacture symbol	EN 980
Conductive coating and polymeric materials	UL 2601-1, clause 55
Operation during physical shock	EN 60068-2-27 at 100 g
Operation during vibration	EN 60068-2-6 and EN 60068-2-34

Table 4: Model FW-538 Compliance

Item	Compliant With
Electromagnetic Compatibility	EN 60601-1, sub clause 36, EN 60601-1-2 (second edition)
Radiated and conducted emissions	EN 55011, Group 1, Class B
Harmonic emissions	EN 61000-3-2
Electrostatic discharge immunity	EN 61000-4-2, level 3 table top equipment
Radiated radio-frequency electromagnetic field immunity	EN 61000-4-3 at 3V/m
Electrical fast transient/burst immunity	EN 61000-4-4, level 3, Table 10
Surge immunity	EN 61000-4-5, level 3; FDA Reviewer's Guide
Conducted EMI susceptibility	EN 61000-4-6 at 3 Vrms
Power frequency magnetic fields	EN 61000-4-8 at 3 Vrms
Operation with line voltage variations	EN 61000-4-11, Table 7
Operation with electrical line voltage variations	FDA Reviewer's Guide
Radiated magnetic field emissions	RE 101/Army/7cm of MIL-STD-461E
Magnetic field susceptibility	RS 101 in MIL-STD-461E
Quasi-static electric field susceptibility	FDA Reviewer's Guide

Manufacturer's Declaration

WARNING: The use of accessories and cables other than those specified may result in increased emission and/or decreased immunity of the FW-538.

Table 5: Electromagnetic Emissions

The FW-538 is suitable for use in the specified electromagnetic environment. The customer and/or user of the FW-538 should assure that it is used in an electromagnetic environment as described below:

Emissions Test	Compliance	Electromagnetic Environment Guidance
RF emission CISPR 11	Group 1	The FW-538 must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions CISPR 11	Class B	The FW-538 is suitable for use in all establishments.
Harmonic emissions EN 61000-3-2	Complies	

Table 6: Electromagnetic Immunity

The FW-538 is suitable for use in the specified electromagnetic environment. The customer and/or user of the FW-538 should assure that it is used in an electromagnetic environment as described below.

Immunity Test	EN 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment Guidance
Electrostatic discharge (ESD) EN 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floor should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electric fast transient/ burst EN 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial and/or hospital environment

Note: UT is the AC mains voltage prior to application of the test level.

Table 6: Electromagnetic Immunity

The FW-538 is suitable for use in the specified electromagnetic environment. The customer and/or user of the FW-538 should assure that it is used in an electromagnetic environment as described below.

Immunity Test	EN 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment Guidance
Surge EN 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial and/or hospital environment
Voltage dips, short interruptions and voltage variations on power supply EN 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0.5 cycle	<5 % U_T (>95 % dip in $U_{T)}$ for 0.5 cycle	Mains power quality should be that of a typical commercial and/or hospital environment. If the user of the FW-538 requires continued operation during power mains interruption, it is recommended that the FW-538 be powered from an uninterruptible power supply or battery.
	40 % U_T (60 % dip in U_T) for 5 cycles	40 % U_T (60 % dip in $U_{T)}$ for 5 cycles	
	70 % U_T (30 % dip in U_T) for 25 cycles	70 % U_T (30 % dip in $U_{T)}$ for 25 cycles	
	<5 % U_T (95 % dip in U_T) for 5 sec.	<5 % U_T (95 % dip in $U_{T)}$ for 5 sec.	
Power frequency (50/60 Hz) magnetic field EN 61000-4-8	3 A/m	3 A/m	It may be necessary to position the FW-538 further from the sources of power frequency magnetic fields or to install magnetic shielding. The power frequency magnetic field should be measured in the intended installation location to assure that it is sufficiently low.

Note: UT is the AC mains voltage prior to application of the test level.

Table 7: Electromagnetic Immunity, RF Portable Equipment

For portable and mobile communication equipment. The FW-538 is suitable for use in the specified electromagnetic environment. The customer and/or user of the FW-538 should assure that it is used in an electromagnetic environment as described below:

Immunity Test	EN 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment Guidance
Portable and mobile RF communications equipment should be used no closer to any part of the FW-538, including cables, than the recommended separation distance calculated from the equation appropriate for the frequency of the transmitter.			
		Recommended Separation Distance	
Radiated RF EN 61000-4-3	3 V/m 80 MHz 800 MHz	3 V/m	*distance* = 1.2√*Power* 80 MHz to 800 MHz
	3 V/m 800 MHz 2.5 GHz	3 V/m	*distance* = 2.3√*Power* 800 MHz to 2.5 GHz
Conducted RF EN 61000-4-6	3 Vrms 150 kHz 80 MHz	3 Vrms	*distance* = 1.2√*Power* 150 kHz to 80 MHz

Note: Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with survey accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the FW-538 is used exceeds the applicable RF compliance level above, the FW-538 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the FW-538.

Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Interference may occur in the vicinity of equipment marked with the following symbol:

Table 8: Recommended Separation Distances

Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the FW-538 (EN 60601-1-2)

Frequency of Transmitter	26 MHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
Equation	$d = 1.2\sqrt{P}$	$d = 1.2\sqrt{P}$	$d = 2.3\sqrt{P}$
Rated Maximum Output Power of Transmitter in Watts	Separation Distance in Meters	Separation Distance in Meters	Separation Distance in Meters
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the separation distance can be estimated using the equation in the corresponding column, where P is the maximum output [power rating of the transmitter in watts (W)] according to the transmitter manufacturer.

Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Introduction

The following Warm*flo* disposable fluid warming cassettes, pressure infusors, and spare parts are approved for use with the FW-538 fluid warming system. Other fluid cassettes may be available. Contact Nellcor's Technical Service or your local representative, or check the internet at:

http://www.mallinckrodt.com/respiratory/resp/Serv_Supp/Apartweb/main/PartAcceMenu.html

Disposable Fluid Warming Sets

Part Number	Description
SF-150	WF-250 replacement filter
WF-100	Cassette, Fluid Warming
WF-250	Cassette, Surgical Fluid Warming
8860	Test Cassette Kit, WF-8860

Infusors and Irrigators

Part Number	Description
AD 500FW	Infusor, 500 ml
AD 1000FW	Infusor, 1000 ml
AD 1500FW	Infusor, 500 & 1000 ml, Mounted
AD 2000FW	Infusor, Dual 1000 ml, Mounted

If the FW-538 fluid warming system is used with a surgical irrigation pump or an automatic pressure infusor, carefully read the accessory directions for use, and all warnings, precautions, and specifications before using the equipment with the FW-538.

Spare Parts and Accessories

Description	Part Number	Figure 37 Number
Air filter mount bracket	067045	2
Chassis assembly	520-0006SP	5
Cover assembly	128-0017SP	1
Door assembly	520-0010SP	6
Fuse, 0.063A 50 volt	128-5002	
Display PCB assembly,	520-0014SP	7
Main PCB assembly,	520-0017SP12	3
Wire cover plug	128-5018SP	
Power cord, 14 ft.	901-1502SP	
Rear panel assembly	128-0009SP	4
Replacement filter for WF-250 surgical set	SF-150	
IV pole screw	128-2039	8
PCB assembly screws	128-2036	
Rear panel attachment screws	128-2031	
Strain relief	128-2020	

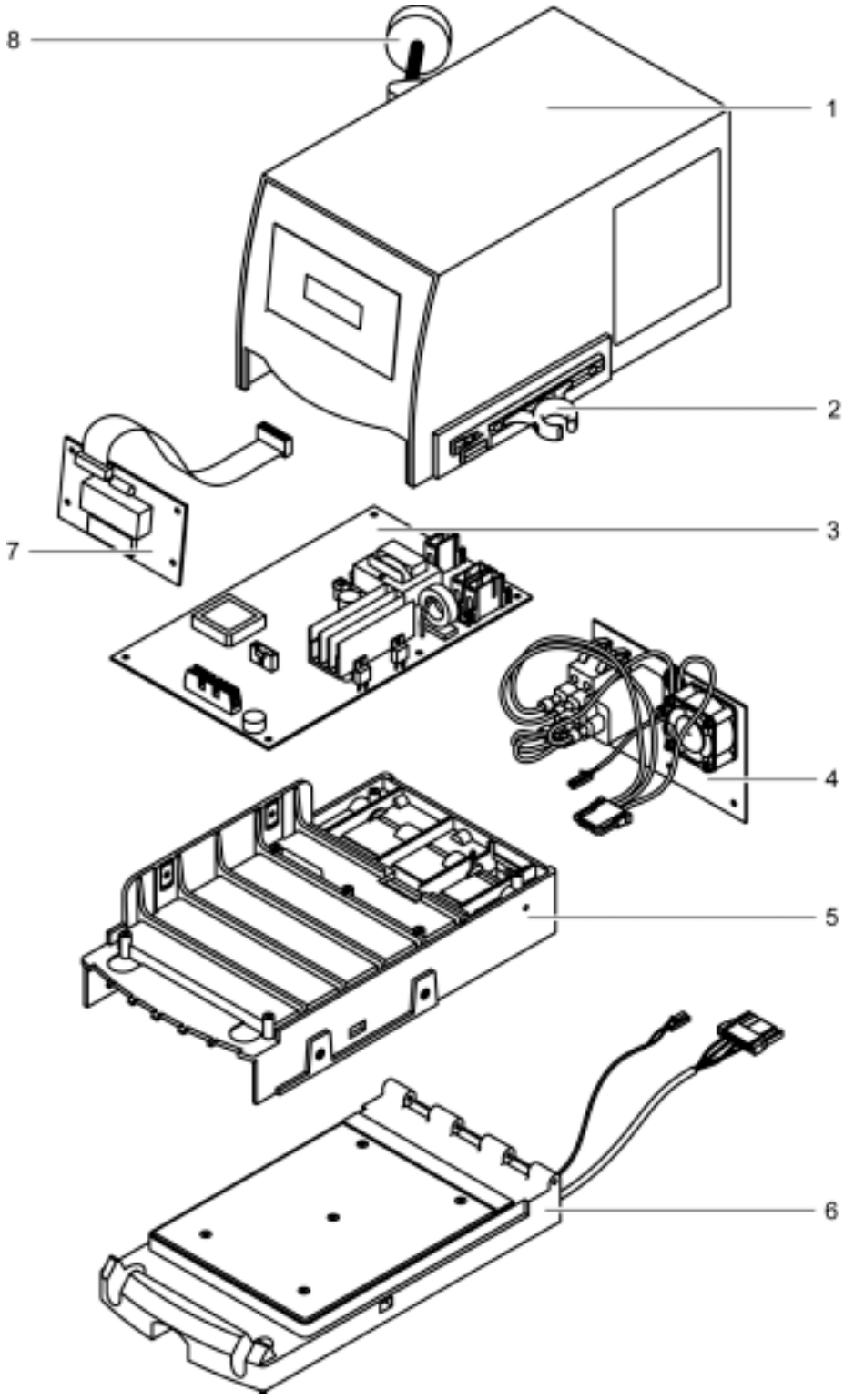


Figure 37: Spare Parts

Disposal of Fluid Sets

Fluid sets should be disposed using the hospital standard procedure for disposing of blood products.

Disposal Of Fluid Warming System

Nellcor recommends that the institution follow local governing ordinances and recycling instructions regarding disposal or recycling of device components. Fluid warming sets cannot be recycled.

The FW-538 fluid warming system contains no toxic materials.

Introduction

To ship the FW-538 for any reason, follow the instructions in this section.

Returning the FW-538

Contact Nellcor's Technical Services Department or your local Nellcor representative for shipping instructions, including a Returned Goods Authorization (RGA) number. Unless otherwise instructed by Nellcor's Technical Services Department, it is not necessary to return accessory items with the FW-538. Pack the FW-538 in its original shipping carton. If the original carton is not available, use a suitable carton with appropriate packing material to protect it during shipping.

Return the FW-538 by any shipping method that provides proof of delivery.

General Instructions

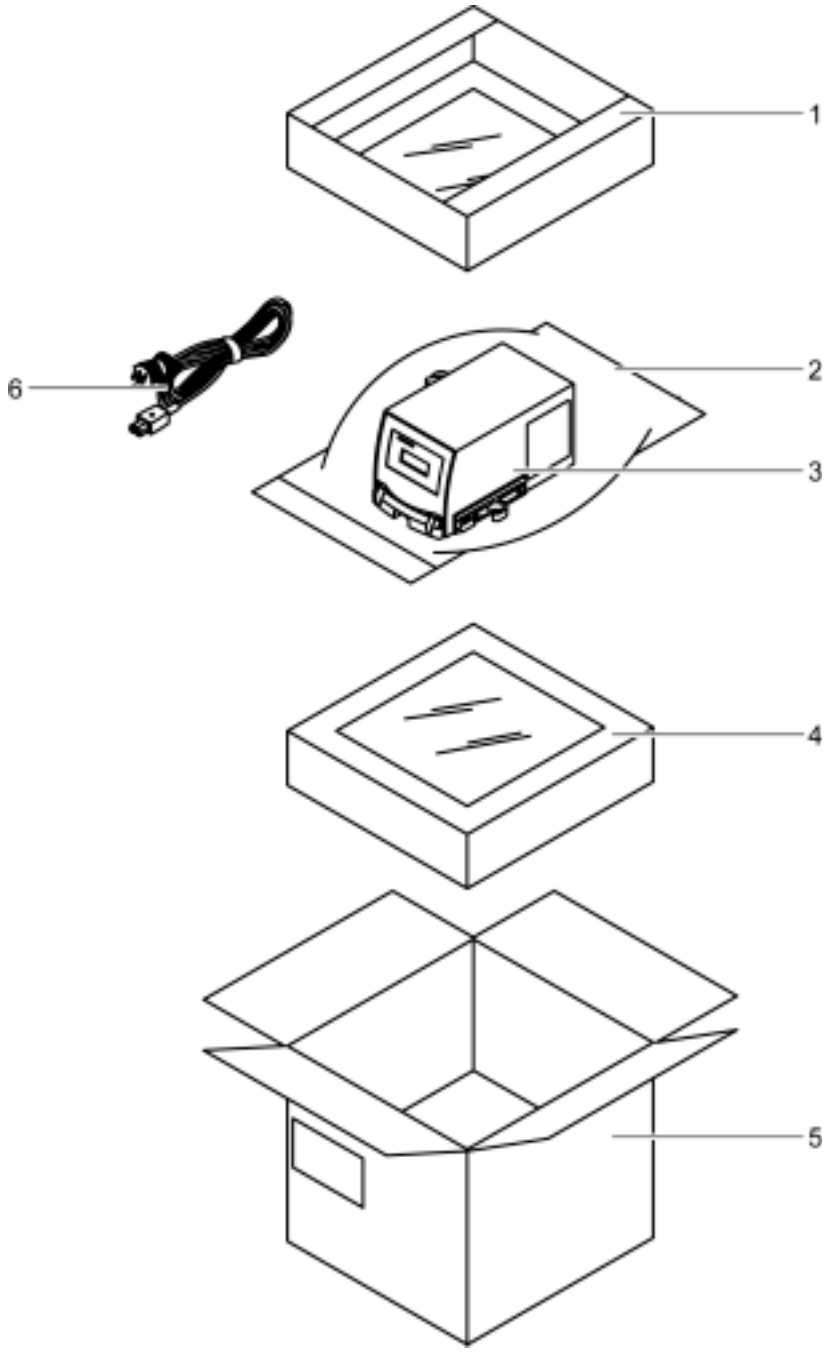
Pack the FW-538 carefully. Failure to follow the instructions in this section may result in loss or damage not covered by any applicable Nellcor warranty. If the original shipping carton is not available, use another suitable carton; North American customers may call Nellcor's Technical Services Department to obtain a shipping carton.

Prior to shipping the FW538, contact your supplier or local Nellcor office (Technical Services Department) for a returned goods authorization number. Mark the shipping carton and any shipping documents with the returned goods authorization (RGA) number. Return the FW-538 by any method that provides proof of delivery.

Repacking in Original Carton

If available, use the original carton and packing materials. See Figure 38. Pack the FW-538 as follows:

1. Place the FW-538 and, if necessary, accessory items in original packaging.



1 — Packing insert	2 — Poly bag
3 — FW-538	4 — Packing insert
5 — Shipping carton	6 — Power cord

Figure 38: Packing

2. Place in shipping carton and seal carton with packing tape.

3. Label carton with shipping address, return address, and RGA number, if applicable.

Repacking in a Different Carton

If the original carton is not available, use the following procedure to pack the FW-538:

1. Place the FW-538 in a poly bag.

2. Locate a corrugated cardboard shipping carton with a bursting strength of at least 200 pounds per square inch (psi).

3. Fill the bottom of the carton with at least 2 inches of packing material.

4. Place the bagged unit on the layer of packing material and fill the box completely with packing material.

5. Seal the carton with packing tape.

6. Label the carton with the shipping address, return address, and RGA number, if applicable.

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Introduction

The schematic diagrams for the *Theory of Operation* are located at the end of this section.

The FW-538 is used to warm fluids that are gravity fed or pressure infusor fed. The fluid warming system heats fluid as it flows through a fluid warming cassette. The cassette is inserted between two heater plates that are Tufram® coated for surface protection. Maximum heat transfer is achieved when the cassette and heater plates are clean, and the cassette expands due to a slight downstream resistance, creating effective surface contact with the heater plates. The top heater plate contains three heater elements and three thermistors (temperature sensors). The bottom heater plate contains three heater elements and one thermistor (temperature sensors).

The fluid warming system software monitors the temperature and duty cycle of the three heater zones, and regulates the fluid temperature by turning the heaters on and off, as needed to maintain the fluid SET POINT temperature. The default SET POINT is 38°C. The temperature control range is from 28°C to 42°C. The preset temperature set point is continuously displayed in the format ##.#, rounded to the nearest 0.5 degree.The reading is updated approximately once every second.

The major components of the FW-538 fluid warming system are:

- two heater plates with four embedded temperature sensors
- keyboard
- main circuit board
- display circuit board

Schematics for the circuit boards are at the back of this section.

Main Circuit Board: Start-Up

When the unit is turned on, it enters a start-up test mode. The software executes a test of the following microprocessor components:

- RAM (U5)
- ROM (U25)

- CPU registers
- watchdog (U30)
- NVRAM (Non-Volatile RAM, U19)

If one of these tests fails, an appropriate fault code, in the format “F_##”, indicates the condition, and an alarm will sound. For fault code values, refer to Table 2 on page 20. If a fault code is displayed, the unit must be turned off and then restarted. If the fault has been resolved, the unit will then proceed through the sequence of startup tests:

As start-up proceeds, the following events occur:

- Each thermistor is checked for “open”, “short”, and “within range” conditions.
- Each heater is tested to ensure that current flow is under software control and that the power triacs operate correctly.
- If all test results are normal, the unit conducts an LED display test. All segments for each digit are displayed and held for 2 – 3 seconds.
- The software version number is then displayed. The user should verify that all segments are displayed during this time.
- The unit then enters the preheat mode, during which a running dash line is displayed.
- When the default temperature set point is reached, 38°C is displayed.

At this point, the unit enters normal operational mode.

Heater Control Circuitry

The power for the heaters is supplied through power triacs whose drivers are isolated from the microprocessor by zero-crossing type opto-couplers U1, U2, and U4. The microprocessor senses when current is being drawn through the heaters. Heater current-detect circuitry includes transformer T1, diodes D7 and D8, and comparator U15B. The voltage induced in the secondary of the transformer T1 is clamped by D7 and D8. This circuit limits the output “swing” to one diode drop voltage. This voltage is applied to the inputs of the comparator LM393, which in turn sends a CURRENT_SENS signal to U21 (80C5552 microcontroller with an 11.0592 MHz crystal).

The microcontroller initiates a HEATER_SET signal, which is applied to the EXTERNAL_OT U10. Output from U10 is the HEATER_EN signal, which reflects the status of the master triac. This signal may be set HIGH (triac disabled) by the EXT_OT signal provided by hardware. The HEATER_EN (master enable) signal controls the U3 (optoisolator), which in turn powers the HEATER DRIVERS and HEATER CURRENT SENSOR circuit. After heater current is

detected, the microcontrollor initiates an on/off test of each triac through signals DRV_ZN1-DRV_ZN3 (Port 1 of U21), which are applied to the octal buffer U13 in sequence. The HEATER_OC from U21 enables or disables the buffer U13.

Temperature Sensing Circuitry

Four thermistors (SENS_ZN1, SENS_ZN2, SENS_ZN3, and Lower Plate) are embedded in the heater plates using a highly heat-conductive eclectic alloy which allows rapid sensing of zone temperature. Thermistors 1, 2, and 3 are connected to the Main Circuit board through connector J6. The lower plate thermistor is connected to the Main Circuit board through connector J9.

Each sensor is located in the voltage divider circuitry, which comprises a precision resistor (5760 ohms, 0.1%) and the corresponding temperature sensor. The output signal from each voltage divider circuit is monitored by the microprocessor's analog-to-digital converter (P5.0-2, P5.6)

All four thermistors monitor the temperature of the heater plates. The output fluid temperature is affected by both the rate of fluid flow through the cassette and the length of the tubing between the fluid warming system and the patient.

Over-Temperature Operation

If an output temperature of 44.5°C ± 1°C is detected for greater than two seconds, the heater plates will be disabled, an intermittent, audible alarm will sound, and a display of temperature preceded by the letter "H" will indicate over-temperature condition. At this point, all heaters are disabled, and the master triac is turned off.

All of the heater triacs are then tested. If any heaters are still producing current, the program will enter the FAULT mode, an audible alarm will sound, and the appropriate fault code will indicate the condition.

Secondary Over-Temperature Protection

The fluid warming system provides a secondary over-temperature shutdown, separate from the microcontroller, if the temperature exceeds 45°C ± 1°C. A continuous audible alarm and display of temperature preceded by the letter "H" (HXX.X), indicate this condition. If a fault code is reported, the display will alternate between the temperature and the reported fault code.

The secondary over-temperature protection is hardware-implemented. The over-temperature reference signal (OT_REF_HI) is formed by the voltage divider circuit, which consists of R23 (5760 ohms, 1%) and R21 (4530 ohms, 0.1%) the output of which is applied to the comparator U15 pin 13, which disables the heaters. If current to the heaters is detected, this condition is not recoverable without turning off the unit. If the condition is due to preheated fluid or overshoot

due to an abrupt stoppage of flow, the unit will resume operation when the fluid temperature falls below the temperature setting.

Under-Temperature Operation

When the output temperature is 3°C or more below set point for ten seconds, a short beep will sound every five seconds and the display will flash with the first digit displaying “L” to indicate an under-temperature condition, but the warmers will continue operation.

Display Board

The display board is connected by a ribbon cable to J10 of the main circuit board.

The display consists of a four-digit green LED. Each segment of the leading digit is addressable by the microprocessor. In normal operating mode, the first LED segment is blank, and the remaining three digits display only numbers 0 – 9. The display is continuously on and updated at one second intervals.

The display will flash when the heater set point is being increased or decreased. After no change for three seconds, the display will stop blinking and display the set point.

Keyboard

The keyboard is attached to the main circuit board through connector J12. The user interface buttons are monitored at a rate of 10 Hz or greater. The On, Off, Alarm Test, and Alarm Silence buttons on the keyboard are used to control temperature set point and to check or silence the audible alarm.

Temperature Adjustment

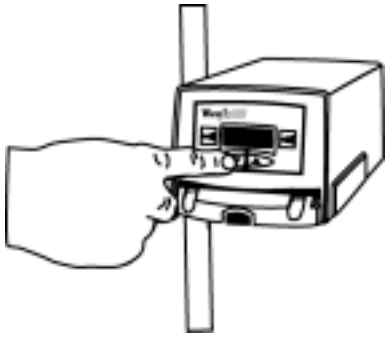

Figure 39: Increasing/Decreasing Temperature

The temperature set point can be adjusted by pressing the increase or decrease button on the front panel, located below the temperature set point display. Pressing the increase button (up arrow) or decrease button (down arrow) will alter the set point in 0.5 degree increments, to a maximum of 42°C or a minimum of 28°C. An error tone is sounded if the set point is already at a limit value. While the user is increasing or decreasing the temperature set point, the display flashes. After no change to the set point is made for three seconds, the display stops flashing and displays the set point.

Alarm Control Buttons

The alarm test buttons are located on either side of the set point display. Pressing the alarm test causes a simulation of an over-temperature alarm, followed by a low temperature alarm. Normal operation automatically resumes within ten seconds after the test.

The alarm silence button silences any alarm (except the secondary over-temperature alarm) for a two-minute period. If the condition persists after the timeout has elapsed, the audible alarm will sound again.

Note: The secondary over-temperature alarm cannot be silenced with this button. The unit must be turned off and allowed to cool.

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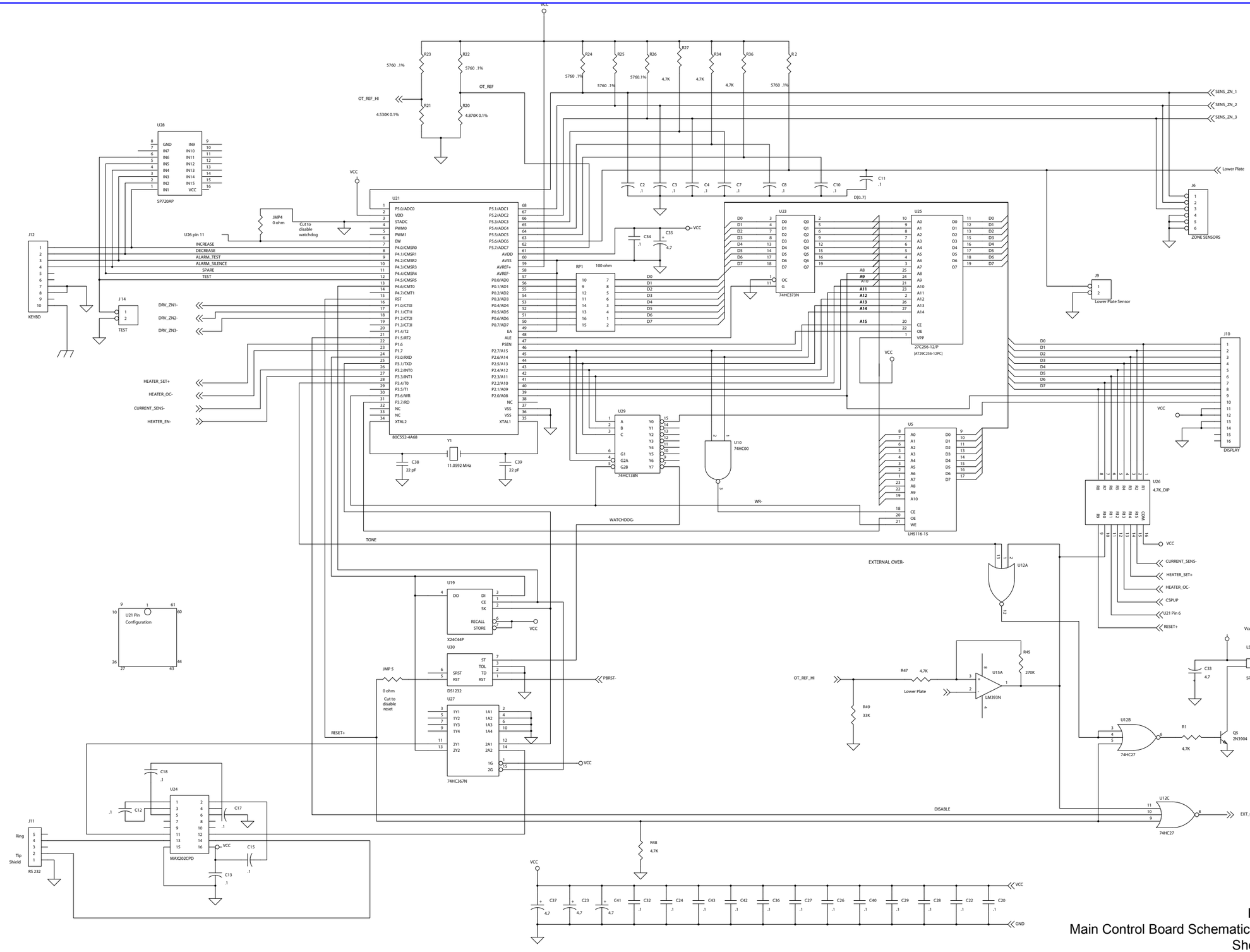

Figure 39
Main Control Board Schematic Diagram
Sheet 1 of 2

DC POWER SUPPLY

FOR 220-240 VAC INPUT CUT J2 AND J3

FOR 100-120 VAC INPUT CUT J1

J3
1 LINE
2 NEUTRAL
3
Power Input

F1
1/16 A_240_VAC Slo Blo

MOV1
275 V

T2
J3 0 Ohms
J1 0 ohm
Z2 0 Ohms
Prem SPW 1100

F3
RXE90

D1
DF04
BRIDGE

U9 LM340T-5
IN OUT GND
Vcc
+5V

C5 470
C6 .1
C1 10

J4
1
2
FAN

T1
TRANSFORMER

VCC
C14 4.7
C25 .1
C16 .1

R33 680

1N4148 D8
D7 1N4148

HEATER ENABLE

VCC
R10 510
U3 ZERO CROSS CIRCUIT MOC3063-T
R8 100
Q1 Q6015L5

HEATER DRIVERS

VCC
R32 510
U4 ZERO CROSS CIRCUIT MOC3063-T
R19 100
Q6 Q6015L5

VCC
R11 510
U2 ZERO CROSS CIRCUIT MOC3063-T
R14 100
Q4 Q6015L5

VCC
R9 510
U1 ZERO CROSS CIRCUIT MOC3063-T
R13 100
Q2 Q6015L5

HEATER CURRENT DETECT

VCC
R44 10K
C19 .1
U15B LM393N
R41 100K
CSPUP
R40 4.7K
R37 680
CURRENT_SENS-

HEATER_SET+

EXTERNAL OVER-TEMPERATURE

U10 74HC00
EXT_OT-

HEATER_EN-

DRV_ZN1-
DRV_ZN2-
DRV_ZN3-

U13 74HC244N
1A1 1A2 1A3 1A4 2A1 2A2 2A3 2A4
1Y1 1Y2 1Y3 1Y4 2Y1 2Y2 2Y3 2Y4
1G 2G

HEATER_OC-

HEATER_OC

J13 TEST
TEST
Vcc +5V
OT_REF HI
OT_REF
CURRENT_SENS-
HEATER_SET-
PBRST-
EXT_OT-

U10 74HC00
U10 74HC00

UPPER HEATER

J1 Burndy HEADER
Zone 1
Zone 2
Zone 3
Heater Common

LOWER HEATER

J2 Burndy HEADER

Power Connections

PART ID	+5V	Ground	
U5		24	12
U9		3	2
U10		14	7
U12		14	7
U13		20	10
U15		8	4
U19		8	5
U21		2	36&37
U23		20	10
U24		16	15
U25		28	14
U26		16	NA
U27		16	8
U28		16	8
U29		16	8
U30		8	4

Figure 40
Main Control Board Schematic Diagram
Sheet 2 of 2

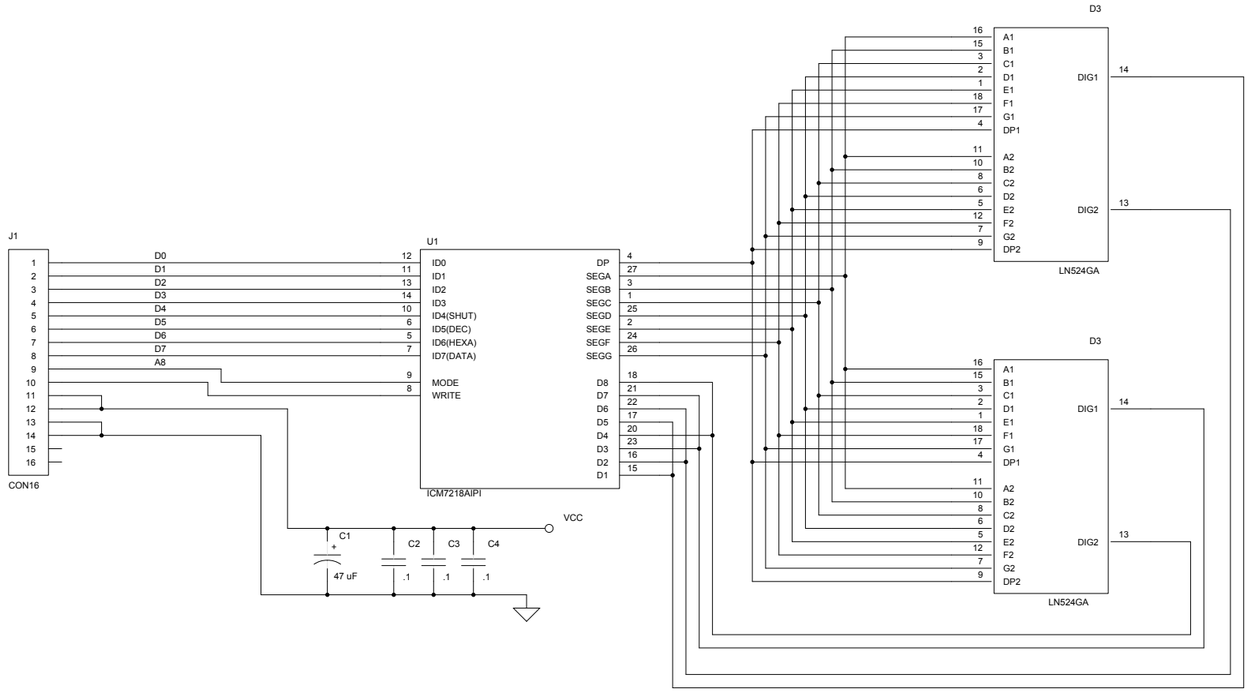

Figure 41
Display Printed Circuit Board
Schematic Diagram

Index

R

S

T

U

W

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