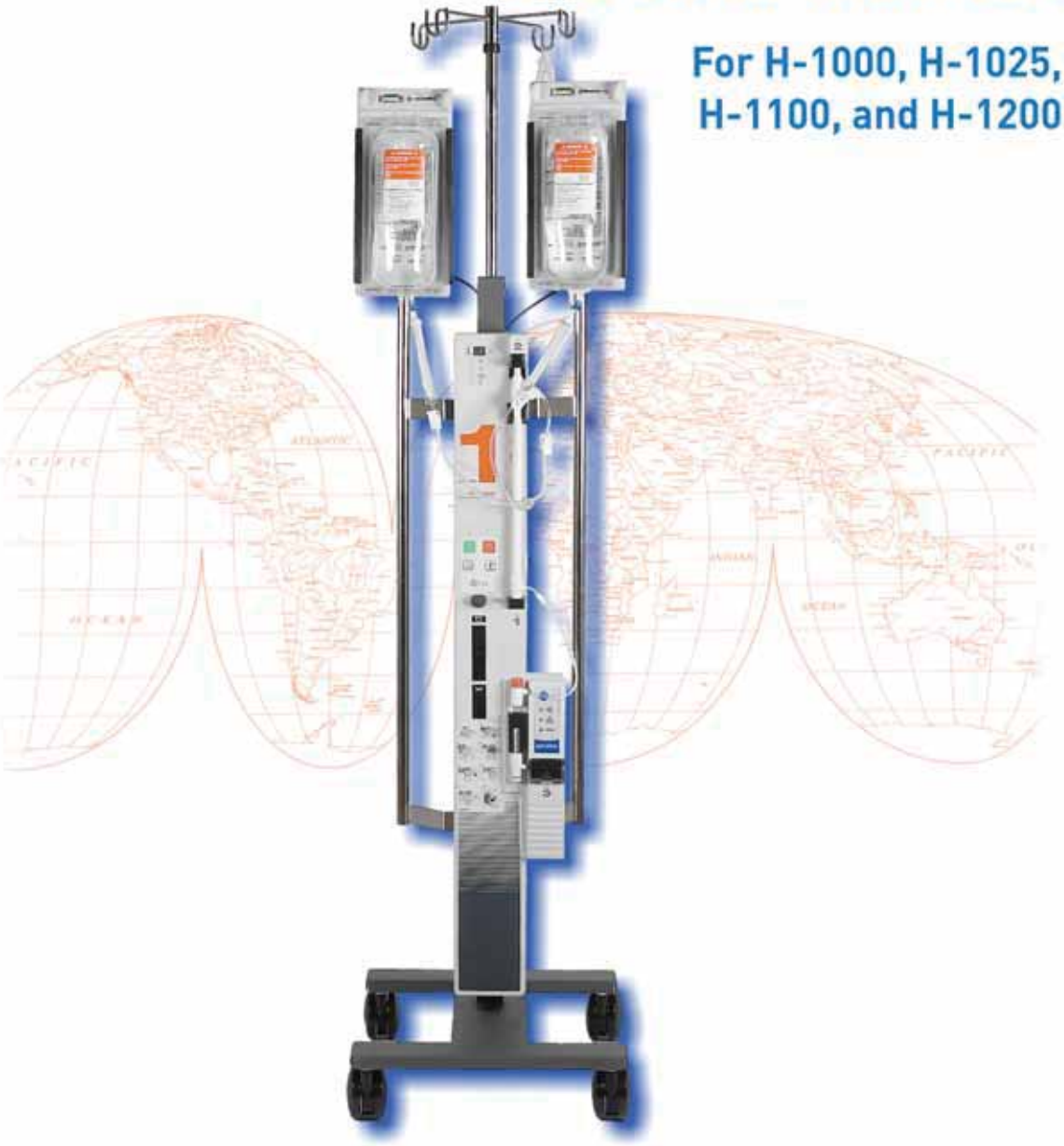
LEVEL 1®

TECHNICAL SERVICE PACK

en

Level 1® Fast Flow Blood and Fluid Warmers

For H-1000, H-1025, H-1100, and H-1200



Part Number 4534011 Rev. 001 (10/11)

smiths medical

Level 1® H-1200

Fast Flow Fluid Warmer

smiths medical

bringing technology to life

Fast Flow Blood and Fluid Warmers

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Welcome...

... to one of

Smiths Medical's

Technical Service Packs

Who are we?

Smiths Medical is a global manufacturer and supplier of medical devices for treating critically ill patients. These devices may be used in high-risk situations, and include ambulatory and hospital infusion pumps, neo-natal and paediatric monitors, blood and fluid warmers, and convective warming systems for patients.

Figure P - 1: A selection of Smiths Products - old and new

Smiths Medical has a long history, bringing many well known brands to the market, such as Portex®, Level 1®, BCI®, Graseby, Wallace®, Bivona®, Pneupac®, Deltec®, DHD® and Medex® . It is part of the Smiths Group, a British engineering consortium founded in 1851.

Smiths Medical is a world leader in the design, manufacture and distribution of medical devices.

What about Level 1®?

The Level 1® range of products is synonymous with a high quality, cost effective range of temperature management products. The range includes blood and fluid warming products for both gravity flow and fast flow intravenous or irrigation applications, and convective (hot air) warming systems. These products help to prevent hypothermia and maintain normothermia in patients undergoing surgery in the operating theatre, recovery ward and in the casualty departments in emergency situations.

Why is Temperature Management important?

Patients undergoing surgical procedures are exposed to a variety of influences that have a effect on their ability to maintain their normal body temperature[h] (Normothermia). If these factors persist for a prolonged period of time[b,d], the patient will become hypothermic, i.e., their body temperature drops below 36°C. Even mild hypothermia (34°-36°C) puts patients at risk. Trauma cases and extensive procedures present well-known temperature management challenges. But so can routine operations. Clinical evidence shows that warming is important in any case lasting more than an hour and/or using more than one litre of fluid.

(References are cited on page xii)

What hypothermia does to the patient

- Cardiovascular instability [a, e, g, h]
  - Vasoconstriction, decreased cardiac output, and changes in electrical conduction can contribute to an increased incidence of cardiac ischemia, arrhythmias, and arrest.
- Increased coagulopathy [f, h, j]
  - Coagulopathy may result in increased bleeding, possibly necessitating blood transfusions.
- Altered action and reduced clearance of anesthetics [h]
  - Hypothermia decreases a patient's metabolism, resulting in a need for higher amounts of anesthetics. It also contributes to delayed emergence from anesthesia and longer recovery room stays.
- Increased risk of wound infection [a, h]
  - Wound infection and delayed wound healing result in longer hospital stays. Wound infection can prolong hospitalization.
- Postoperative discomfort [c, h, j]
  - Thermal discomfort, shivering, and fatigue can occur when core temperature decreases by 1°C .

The Level 1® Fast Flow Blood and Fluid Warmers

The Level 1® H-1200 Fast Flow Blood and Fluid Warmer provides a rapid flow of warmed fluids, such as crystalloid or blood product, including red blood cells, as volume replacement for patients suffering from blood loss due to trauma or surgery.

A Blood and Fluid Warmer provides a flow of warmed fluid to re-warm patients during surgery by trained medical personnel. I.V. fluid and/or blood products are warmed through the use of a sealed heat exchanger through which heated recirculating solution flows.

(References are cited on page xii)

Pressure Infusion Chambers can be used to apply pressure to the bagged infusate and thereby deliver the fluids at a faster flow rate. An Air Detector/Clamp monitors for the presence of air in the disposable Gas Vent/Filter Assembly, and automatically clamps off the patient line and sounds an alarm if a bubble of air is detected.

This manual is appropriate for the servicing and testing of the H-1200 Fast Flow Blood and Fluid Warmer. There are a number of earlier models (such as H-1000), and some still-current models (for example, H-1100), that share technology with the H-1200; this manual will also help in dealing with those and their variants. Pre-tower style models (e.g., H-250, H-500) are not covered.

The models covered, and a comparison of features is shown below.

Model	Application		Features			
	Infusion/ Fluid Replace-ment	Normo-thermic Irrigation	Fluid Warming	Pressure Cham-bers	Powered Elevating I.V. Pole	Air Detect/ Clamp
H-1000 / System 1000	✔	✖	✔	✖	✖	✖
H-1025	✔	✖	✔	✔	✖	✖
H-1100	✖	✔	✔	✖	✔	✖
H-1200	✔	✖	✔	✔	✖	✔

Note that the Pressure Chambers (Part number H-2) and the Air Detector / Clamp (part number H-31B) may be retrofitted to an existing H-1000 or H-1025 to bring it up to the latest specification.

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- *Read the entire Operators Manual for each device before operating any of the Level 1® Fast Flow Blood and Fluid warmers. Failure to follow the instructions and important information contained in these manuals can lead to death or serious injury.*

- *The issue date of this Technical Service Pack is included for your information. If one year or more has elapsed between the issue date of this manual and servicing of the device, the user should contact Smiths Medical to inquire if a more current version of this manual is available.*

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Revision History

Issue No:	Reason for Change	Pages Affected	Date
000	New Revision - First Release	All	September 2007
001	Updated EU Rep address Replace QRG	vii, viii, ix, App 4-3, App 3-5to18	October 2011

Aims

To provide technical engineering support staff with the practical and theoretical knowledge necessary to ...

- ... diagnose,
- maintain,
- repair,
- and update ...

... Smiths Medical products to meet the needs of your healthcare establishment's equipment management protocols.

Objectives

This manual provides the necessary information to enable a qualified Biomedical Engineer or Technician with appropriate experience to successfully repair or replace components, and recalibrate the Level 1® Fast Flow Blood and Fluid Warmers, either routinely or following repair work.

The material covered by this manual is also offered as part of a training course that can be held at Smiths Medical, or at your own establishment. Successful training course attendees are eligible for certification by Smiths Medical. We strongly recommend course attendance for the highest standards of maintenance for your Level 1® Fast Flow Blood and Fluid Warmers. Please contact your local Smiths Medical distributor for more details.

On completion, delegates will have knowledge of the following:

- General functionality and device application.
- Principles of operation of electronic and mechanical systems.
- Access to, and use of, the menu systems as appropriate.
- Appropriate methods of testing and the equipment required.
- Essential safety features and verification of performance.
- Routine maintenance requirements.
- Analysis of faults, fault codes and download software as appropriate.

References

Reference	Source
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(b)	Frank SM, Nguyen JM, Garcia CM, Barnes RA. Temperature monitoring practices during regional anaesthesia. *Anesth Analg. 1999;88:373-377*
(c)	GuiffreM, Finnie J, Lynam DA, Smith D. Rewarming postoperative patients: lights, blankets, or forced warm air. *J Post Anesth Nurs 1991:6:387-393*
(d)	McNeil B. Addressing the problems of inadvertent hypothermia in surgical patients. Part 2: Self Learning Package *Br J Theatre Nurs. 1998;8:25,27-33.*
(e)	Morrison RC. Hypothermia in the elderly. *Int Anesthesiol Clin. 1988;26:124-133.*
(f)	Ouellette RG. Comparison of four intraoperative warming devices. *J Am Assoc Nurse Anesth 1993;61:394-396*
(g)	Sessler DI, Schroeder M, Merrifield B, Matsukawa T, Cheng C. Optimal duration and temperature of prewarming. *Anesthesiology. 1995;82:674-681*
(h)	Sessler DI. Mild perioperative hypothermia. *New Engl J Med. 1997;335:1730-1737.*
(j)	Sobota C, Stewart TP, Payne MM, Mathieu A. Managing perioperative temperature. *New World Health*

Level 1® H-1200

Fast Flow Fluid Warmer

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Fast Flow Blood and Fluid Warmers

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Introduction

The Level 1® Fast Flow Blood and Fluid Warmers are designed for use with Level 1® "D" series disposables, to warm blood and IV fluids and deliver them at high flow rates and normothermic temperatures.

H-1000/ System 1000

Developed from the earlier units H-250 and H-500, the H-1000 was the base model in the current "tower" style. A warmed solution is circulated around the unit, passing upwards through a heat exchanger that transfers the heat to the infusate. The temperature of the recirculating solution is closely monitored by no less than four thermistors and two mechanical thermostat devices.

The infusate passes through the heat exchanger in the opposite direction to the recirculating solution, giving better temperature control. The heat exchanger also features an aluminium core for maximum efficiency. Alarms, both audible and visual, give warning of error conditions, such as excessively high temperatures, low fluid levels, or incorrectly fitted disposables.

Figure 1 - 1: An H-1025, showing pressure chambers.

H-1025

The H-1025 Fast Flow Blood and Fluid Warmer, fitted with pressure chambers, handles the toughest and most unpredictable trauma cases in the operating room and emergency department. Warm fluids can be delivered as fast as 1,100 ml/minute. The pressure chambers accommodate all standard blood and solution bags, applying and maintaining constant 300 mmHg pressure, forcing the infusate through at a greater rate than is achievable by gravity alone.

H-1100

The H-1100, although positioned for a rather different medical function, is essentially the same as a H-1000 base unit, with the additional novel feature of an electrically powered self-elevating IV pole able to lift up to 12 litres of fluid. Widely used for irrigation during urology procedures, this variation allows greater bag height to be achieved, while still making the task of bag changing easier for nurses. Greater bag height means that the available gravity pressure to drive the irrigating fluid towards the patient is increased, resulting in higher maximum flow rates without reliance on pressure chambers which limit bag size.

H-1200

The new H-1200 Fast Flow Blood and Fluid Warmer builds on the benefits of the existing Level 1 Fluid Warmer legacy, and incorporates the features of integrated air detection and automatic clamping capability.

An ultrasonic signal continually passes through the fluid filled gas vent/filter assembly. If a bolus of air displaces the fluid in the gas vent/filter assembly, the ultrasonic signal is broken and the clamp closes, stopping the air before it enters the patient line.

Simultaneously, audible and visual alarms are activated, notifying the user that the fluid flow has stopped. Clearing the bolus of air and restoring the fluid flow are quickly accomplished without disconnecting from the patient.

Figure 1 - 2: The Air Detector/Automatic Clamp, which is a standard fitting for H-1200, can be retrofitted to earlier models. The model shown here is a H-31B, developed from the earlier SA-1000 and H-30 models. (see section 8 for details)

Superior Performance

A series of truly universal machines that handle your toughest and most unpredictable cases, delivering warm fluids as fast as 60,000 ml/hr or as slow as 75 ml/hr. All models feature an aluminium heat exchanger which transfers heat 1000 times faster than plastic and counter-current recirculating solution to provide safe, effective and stable heating.

Features

- Integrated, highly effective design gives unparalleled ease of use.
- Pressure Chambers:
  - *Accommodate all standard blood and solution bags.*
  - *Constant 300 mmHg pressure is applied and maintained.*
  - *On/Off toggle switch automatically pressurizes chamber.*
- Heat Exchanger:
  - *Aluminum heat exchanger transfers heat 1000 times faster than plastic at high flows.*
  - *Counter current 42°C recirculating solution for effective and stable heat.*
- Digital display of Recirculating Solution temperature.
- Electronic circuitry continuously monitors Recirculating Solution temperature.
- Green “Warming” operating LED.
- Coloured fault indicator LEDs identify common fault conditions.
- Audible alarm indication.
- Alarm test facility.

Specifications: H-1025

Weights and Dimensions	H-1025	
Height	170.8 cm	67¼ inches
Depth	50.8cm	20 inches
Width	50.8cm	20 inches
Weight (dry)	30.0 kg	66 lbs

Performance	H-1025
Min Flow Rate*	75 ml/hr*
Max Flow Rate*	66 l/hr*
Temperature Set Point	41.7 °C +/- 0.3 °C
Over Temperature Set Point	43.9 °C +/- 0.1 °C
Warming from Room Temp. (21°C) to 41°C	3 to 7 min
Compressor Source Pressure	300 mmHg
Reservoir Capacity	1.4 litres 0.37 US gallons 0.31 UK gallons

* Depends on disposable administration set used, whether pressurised or not, cannula/catheter size used and fluid type.

WARNING: Anaesthetics: Not Suitable for use in the presence of flammable anaesthetic mixtures with air or oxygen or with nitrous oxide.

Environmental	H-1025
Operating Temperature	10°C - 45°C
Operating Humidity (non-condensing)	30% - 75%
Transport / Storage Temperature	0°C - 70°C
Transport / Storage Humidity (non-condensing)	30% - 75%

Electrical	H-1025	
	US	UK/EUR
Mode of Operation	Continuous	
Electrical Safety Classification	Class 1 Equipment Type BF applied part	
Supply Voltage	115 V AC	230 V AC
Supply Current	12 A	6 A
Supply Frequency	60 Hz	50 Hz
Aux Outlet	1.5 A	0.75 A

Standards Compliance	H-1025
Product Safety	EN 60601-1, UL 2601-1
EMC	EN 60601-1-2, FCC 47 CFR Part 15, Class B
Enclosure Protection	IEC 60529 IP Code: IPX1
Fluid Warmers	ASTM F2172-02
Latex	All Level 1® Fast Flow Disposable Administration sets are latex-free

Specifications: H-1100

Weights and Dimensions	H-1100	
Height (retracted)	183.0 cm	72 inches
Height (extended)	254.0 cm	100 inches
Depth	48.3cm	19 inches
Width	48.3cm	19 inches
Weight (dry)	38.13 kg	84.17 lbs

Performance	H-1100
Min Flow Rate*	42 l/hr*
Max Flow Rate*	60 l/hr*
Temperature Set Point	41.7 °C +/- 0.3 °C
Over Temperature Set Point	43.9 °C +/- 0.1 °C
Warming from Room Temp. (21°C) to 30°C to 41°C	 within 60 seconds 3 to 10 minutes.
Reservoir Capacity	1.4 litres 0.37 US gallons 0.31 UK gallons

* Dependent on laparoscope used and the height of the bags

WARNING: Anaesthetics: Not Suitable for use in the presence of flammable anaesthetic mixtures with air or oxygen or with nitrous oxide.

Environmental	H-1100
Operating Temperature	10°C - 45°C
Operating Humidity (non-condensing)	30% - 75%
Transport / Storage Temperature	0°C - 70°C
Transport / Storage Humidity (non-condensing)	30% - 75%

Electrical	H-1100	
	US	UK/EUR
Mode of Operation	Continuous	
Electrical Safety Classification	Class 1 Equipment Type BF applied part	
Supply Voltage	115 V AC	230 V AC
Supply Current	12 A	6 A
Supply Frequency	60 Hz	50 Hz
Aux Outlet	1.5 A	0.75 A

Standards Compliance	H-1100
Product Safety	EN 60601-1, UL 2601-1
EMC	EN 60601-1-2, FCC 47 CFR Part 15, Class B
Enclosure Protection	IEC 60529 IP Code: IPX1
Fluid Warmers	ASTM F2172-02
Latex	All Level 1® Fast Flow Disposable Administration sets are latex-free

Specifications: H-1200

Weights and Dimensions	H-1200	
Height	170.0 cm	67 inches
Depth	51.0cm	20 inches
Width	51.0cm	20 inches
Weight (dry)	28.5 kg	63 lbs

Performance	H-1200
Min Flow Rate*	75 ml/hr*
Max Flow Rate*	66 l/hr*
Temperature Set Point	41.7 °C +/- 0.3 °C
Over Temperature Set Point	43.9 °C +/- 0.1 °C
Heating from Room Temp. (21°C) to 30°C to 41°C	 within 60 seconds 3 to 10 minutes.
Compressor source pressure	300 mmHg
Reservoir Capacity	1.4 litres 0.37 US gallons 0.31 UK gallons

* Depends on disposable administration set used, if pressurised or not, cannula/catheter size used and fluid type.

WARNING: Anaesthetics: Not Suitable for use in the presence of flammable anaesthetic mixtures with air or oxygen or with nitrous oxide.

Environmental	H-1200
Operating Temperature	10°C to 40°C
Operating Humidity	10 to 95% (non-condensing)
Transport Temperature	-18°C to 60°C
Storage Temperature	5°C to 40°C
Transport / Storage Humidity	5 to 95% (non-condensing)

Electrical	H-1200	
	US	UK/EUR
Mode of Operation	Continuous	
Electrical Safety Classification	Class 1 Equipment Type BF applied part	
Supply Voltage	115 V AC	230 V AC
Supply Current	12 A	6 A
Supply Frequency	60 Hz	50 Hz
Aux Outlet	1.5 A	0.75 A

Standards Compliance	H-1200
Product Safety	EN 60601-1, UL 2601-1
EMC	EN 60601-1-2, FCC 47 CFR Part 15, Class B
Enclosure Protection	IEC 60529 IP Code: IPX1
Fluid Warmers	ASTM F2172-02
Latex	All Level 1® Fast Flow Disposable Administration sets are latex-free

Controls and Displays

Controls

Controls are found on a small membrane button panel at waist level, just above the reservoir filler cap. On H-1100 models fitted with extending poles, an additional panel on the left of the pole housing contains the buttons for raising and lowering the pole.

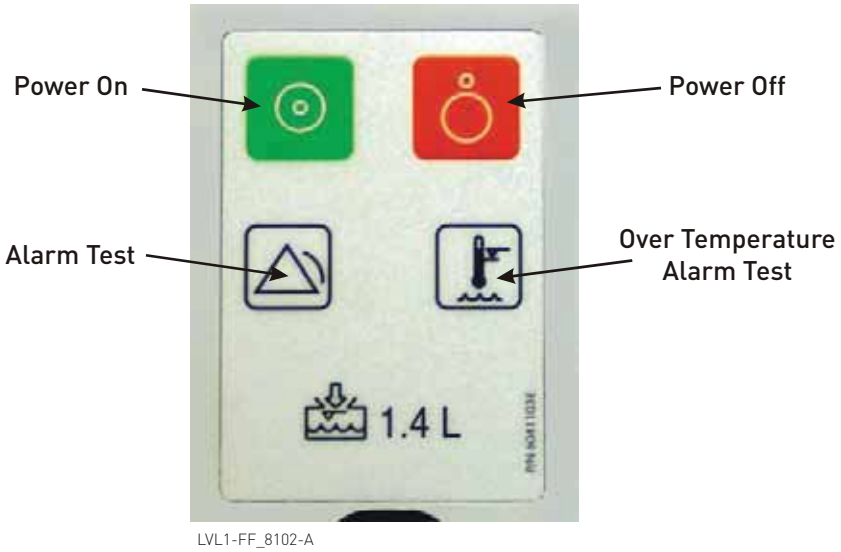

Figure 1 - 3: Control Panel

Figure 1 - 4: Additional Panel for powered I.V. pole
Up / Down buttons (H-1100 only)

Displays

The Temperature Display LCD, and the Status Monitoring LEDs are arranged in a panel near the top of the tower, adjacent to the upper Heat Exchanger socket. When running normally, the display shows green against the “Normal Operation” symbol.

Figure 1 - 5: Display Panel - Running Normally

There are three distinct “Alarm” states each of which is announced by a flashing coloured LED, and an accompanying strident Audible Alarm.

Figure 1 - 6: Alarm - Recirculating Solution Level Low

Figure 1 - 7: Alarm - Over Temperature

Figure 1 - 8: Alarm - Disposable not correctly fitted, possibility of leak!

On early units, as in the picture above, an additional warning LED is fitted adjacent to the #2 socket, to show that the fitting error is at the top of the heat exchanger. This feature was discontinued from serial number 20040418 onwards. Units prior to this would also have a red LED in the Display Panel, not orange as shown here.

Disposables

- High performance disposables are designed for fast, easy set up. All disposables feature a sterile fluid path for the I.V. fluid.

  - *D-Series Disposable Administration Sets are sold for use in the U.S.A. and elsewhere.*

  - *DI-Series Disposable Administration Sets are sold for use in markets in the EU.*

  - *IR-series disposables are for use with the H-1100 unit for procedures requiring irrigation.*

  - *IRI-series disposables are for use with the H-1100 unit in markets outside of the U.S.A. for procedures requiring irrigation.*

  - *All Level 1® disposables are equipped with integral Gas Vent / Filter.*

  - *All disposables are equally suitable for use in older units such as H-1025 and the newer H-1200 incorporating the H-31B automatic Air Detector / Patient Line Clamp. The Air Detector does not need a special disposable to operate.*

The French Scale

Also known as the Charriere scale, devised by Joseph F. B. Charriere, a French instrument maker (1803-1876), this measurement system is widely used to specify I.V. needles, cannulas and catheters.

The scale is particularly convenient for measuring tubular or cylindrical objects, since it is based on the circumference, rather than the diameter. Circumferences are easy to measure with a flexible ruler, or by rolling the item over a flat ruler. Diameters, being generally less accessible, can be more challenging to measure.

1 Fr unit ≈ 1 mm of circumference ≈ 0.3 mm of diameter

French Number	Gauge	Outside Diameter		Inside Diameter*	
		inch	mm	inch	mm
1	27	0.016	0.4	0.007	0.10
2	24	0.025	0.6	0.012	0.30
3	20	0.037	0.9	0.020	0.50
4	18	0.047	1.2	0.025	0.60
5	16	0.065	1.7	0.030	0.70
6	14	0.079	2.0	0.040	1.00
7	13	0.095	2.4	0.050	1.30
8	12	0.106	2.7	0.055	1.40
9	11	0.118	3.0	0.062	1.60
10	-	0.125	3.3	0.098	2.50
-	10	0.134	3.4	0.106	2.70
11	9	0.145	3.7	0.118	3.00
12	-	0.157	4.0	0.120	3.05
13	8	0.169	4.3	0.122	3.10
14	-	0.185	4.7	0.125	3.20
15	-	0.197	5.0	0.127	3.22

NOTE: ** Inside Diameter (Bore) may vary from manufacturer to manufacturer, and also may depend on the wall material (silicone rubber, PU, etc).*

Level 1® H-1200

Fast Flow Fluid Warmer

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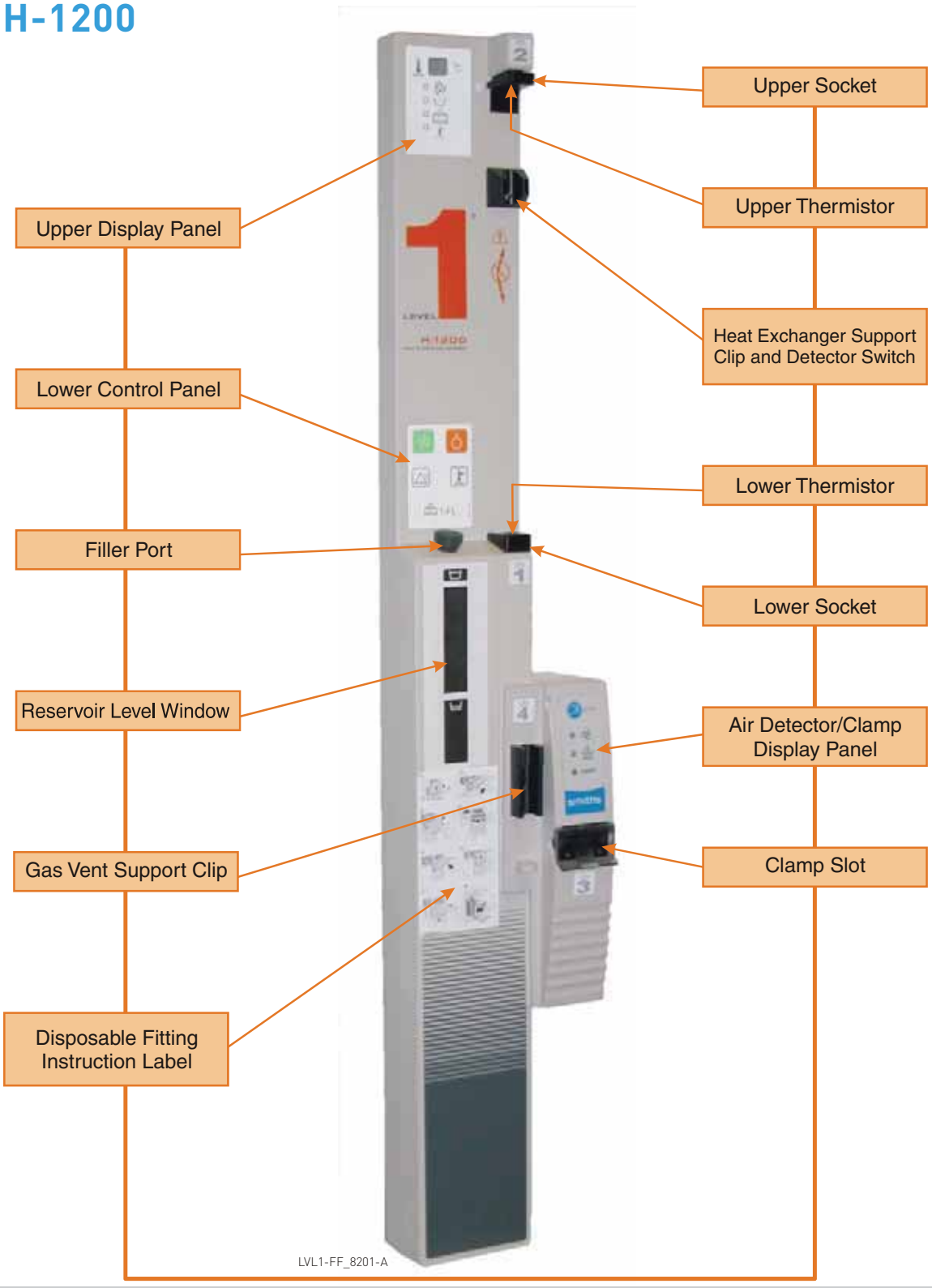
Sub-assemblies

Items covered by this section are as follows:

- External Features
  - *All exterior features as seen from either front, back, or even underneath the Fluid warmer.*
- Mechanical Assembly
  - *How the various modular parts are assembled and fixed together.*
- Recirculating Solution path
  - *Components involved in the recirculating solution flow which carries the heat from the heaters to the infused fluid.*
- Air Components (H-1025, H-1125, H-1200)
  - *Models fitted with pressure chambers have additional components to provide a suitable supply of compressed air to pressurise the chambers.*
- Presssure Chambers (H-1025, H-1125, H-1200)
  - *The interior construction and assembly of both old and new types of the pressure chambers.*
- Air Detector / Clamp (H-1200)
  - *Standard fitment on H-1200, or aftermarket add-on for H-1000 / H-1025*

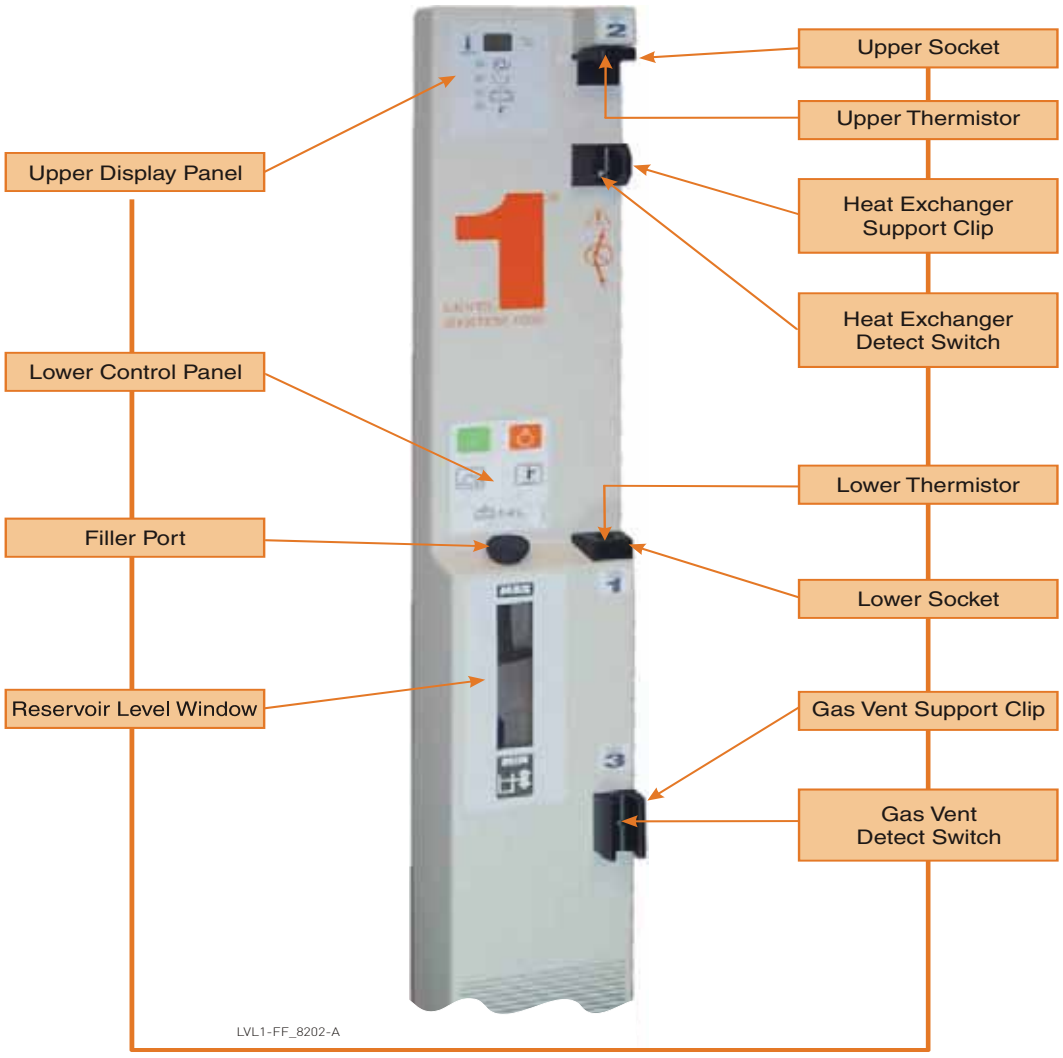
External Features

H-1200



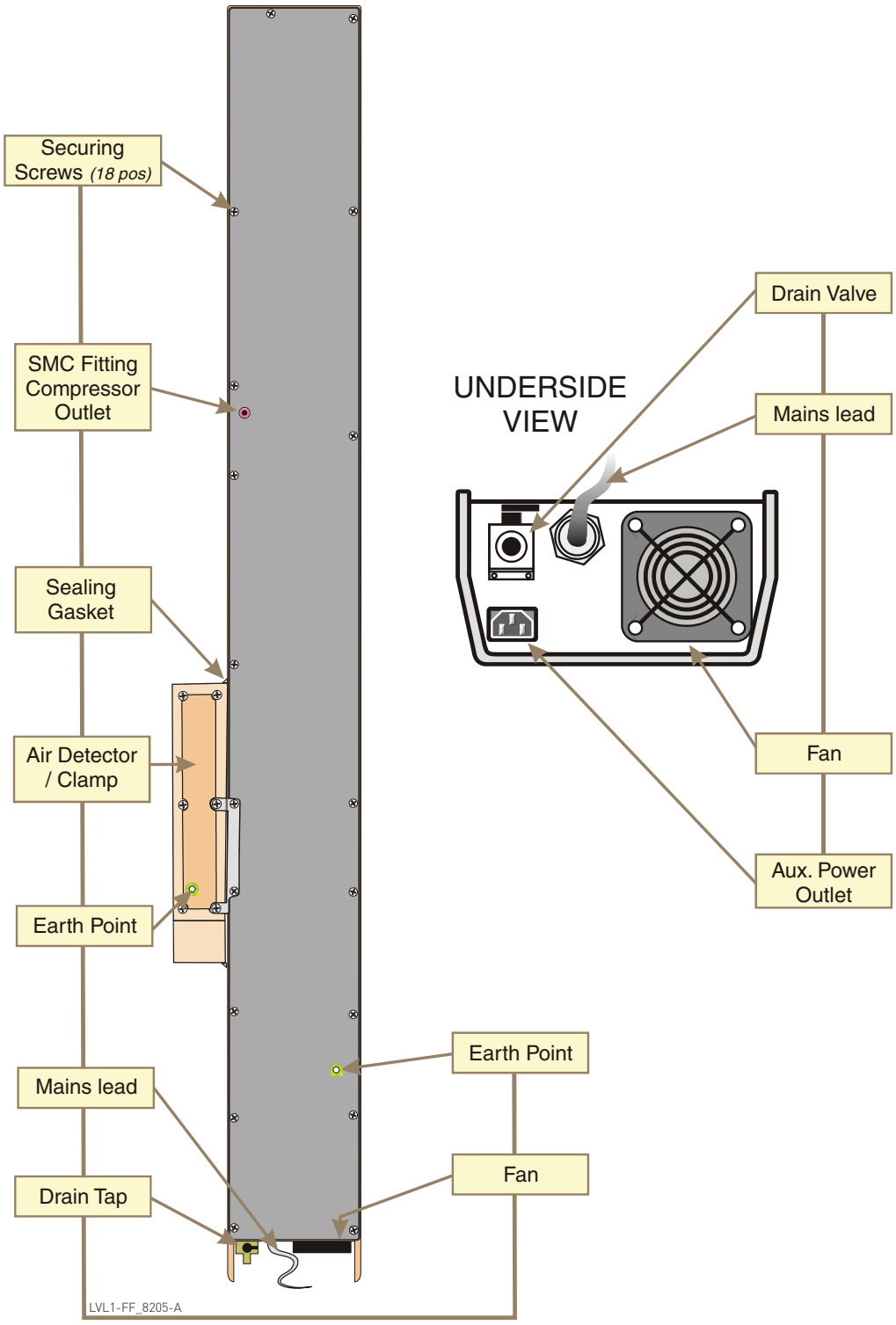
External Features

H-1000 / H-1025 / H-1100

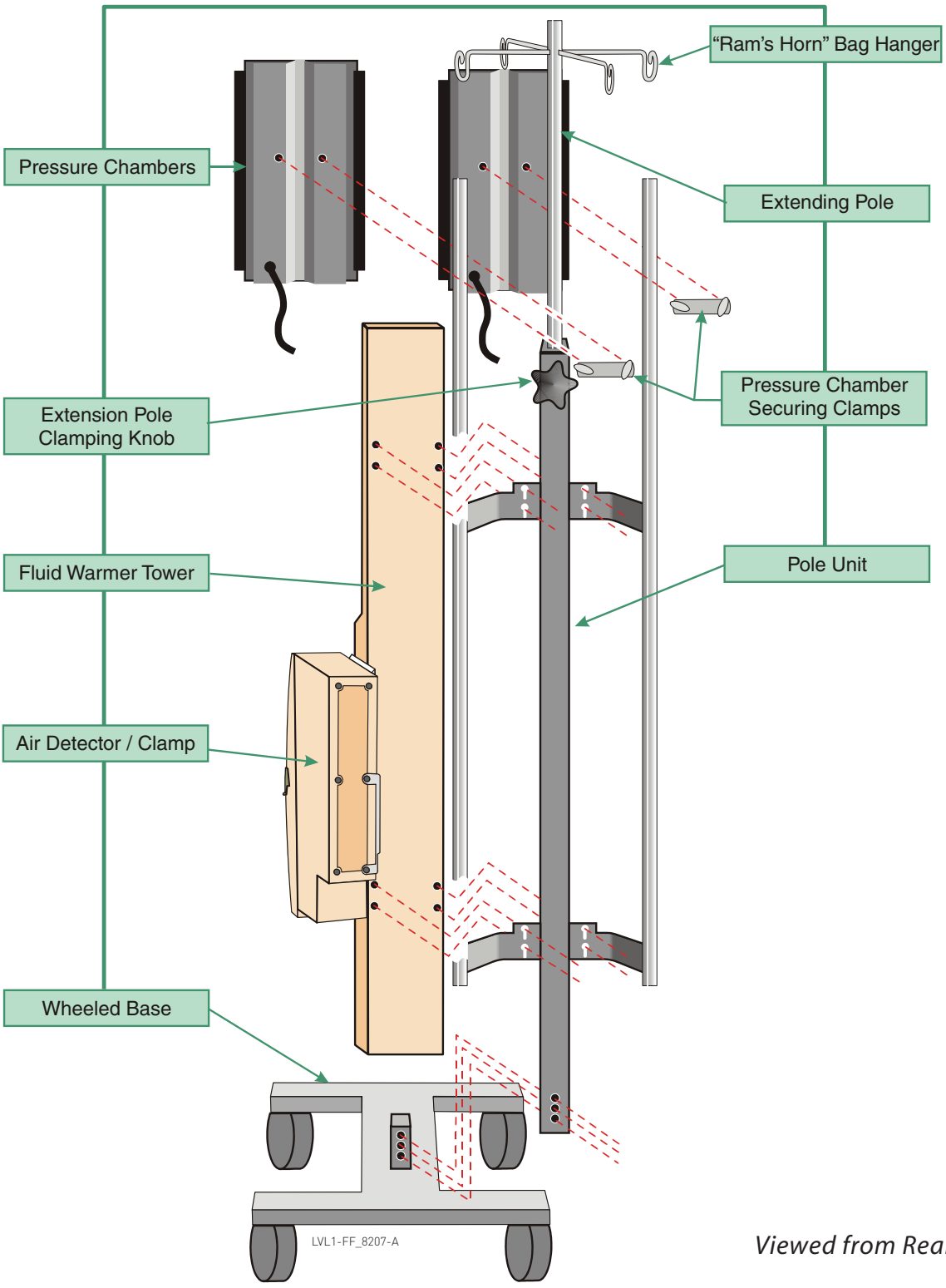


External Features

Rear View

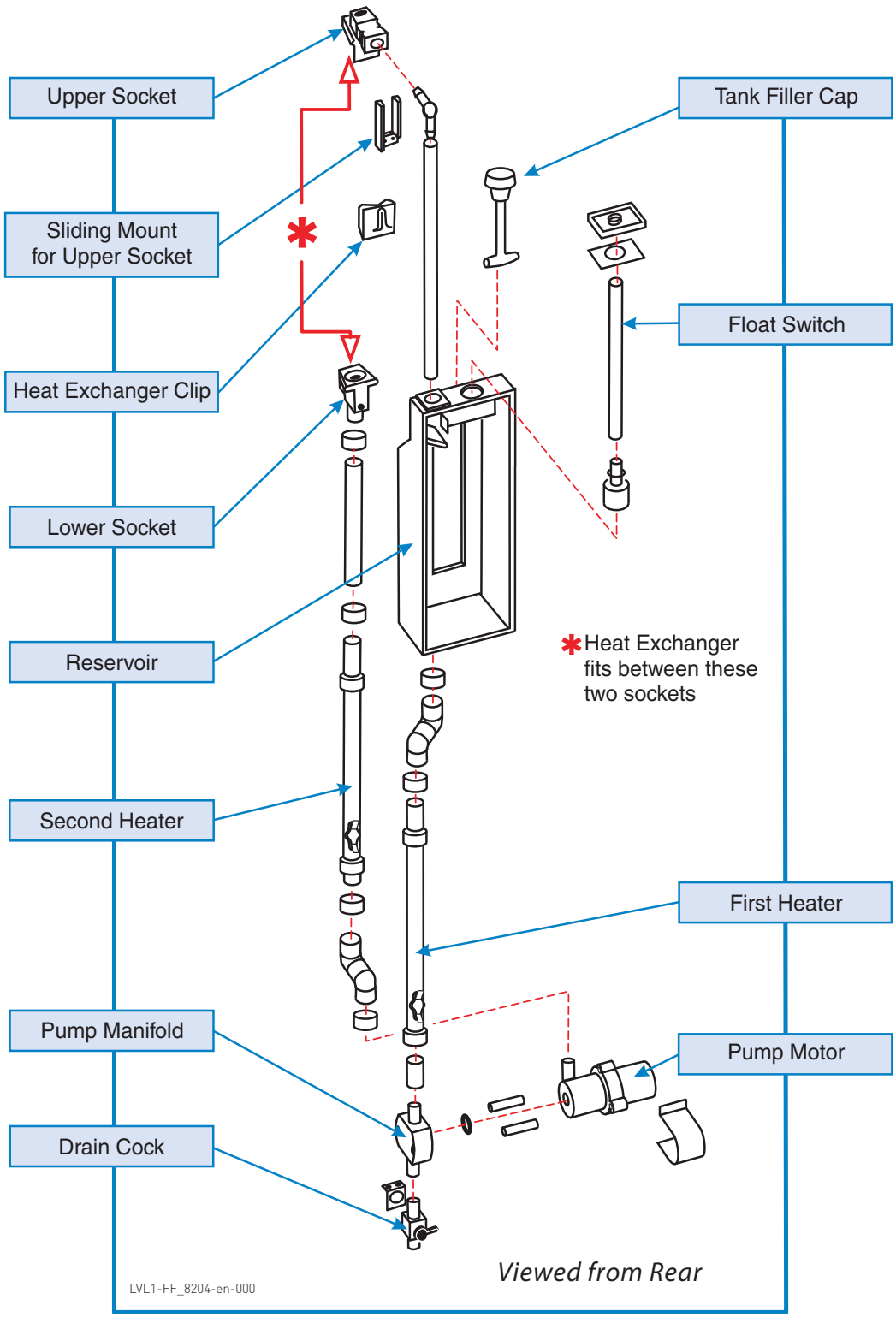


Mechanical Assembly

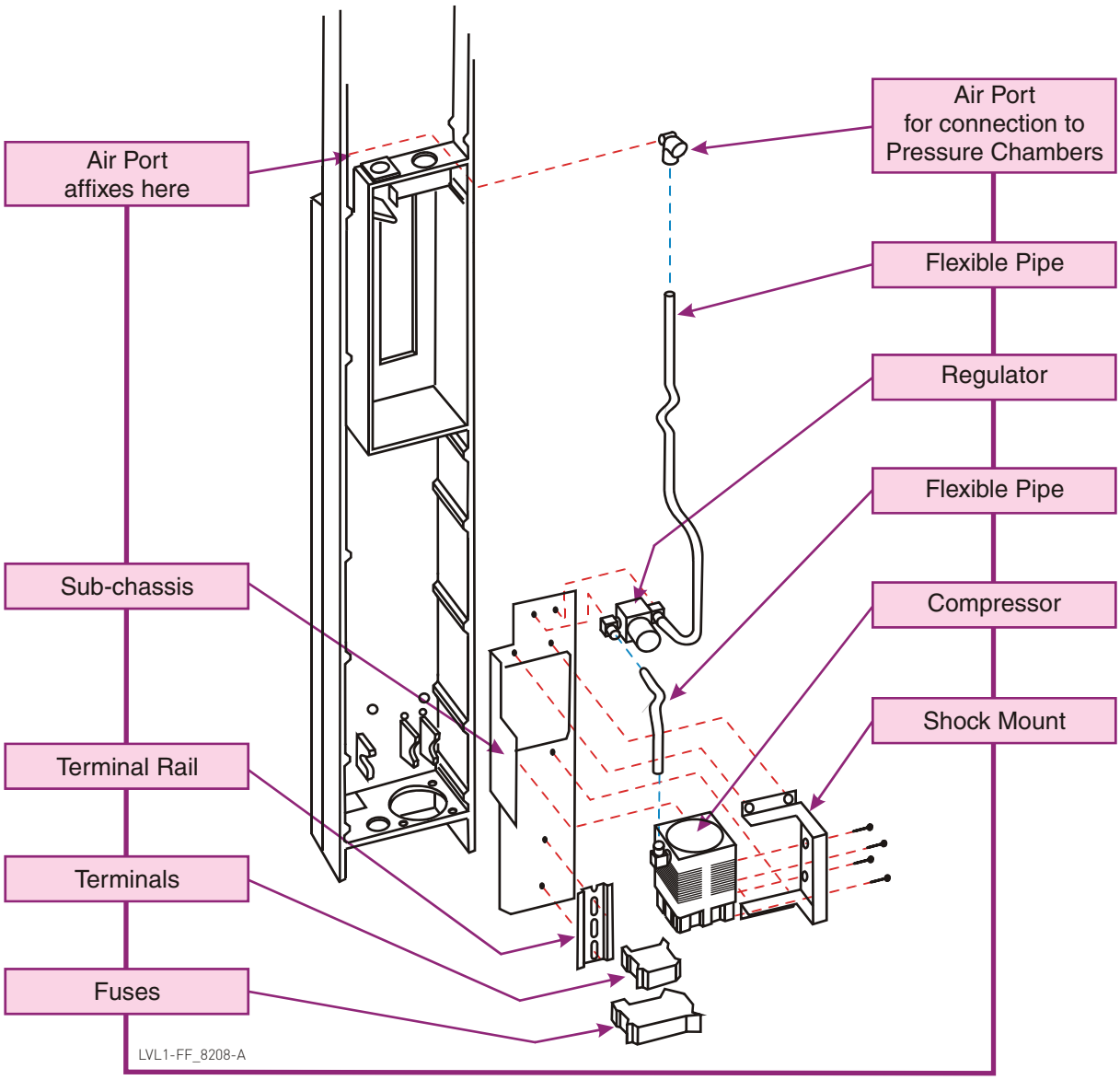


Viewed from Rear

Recirculating Solution Path



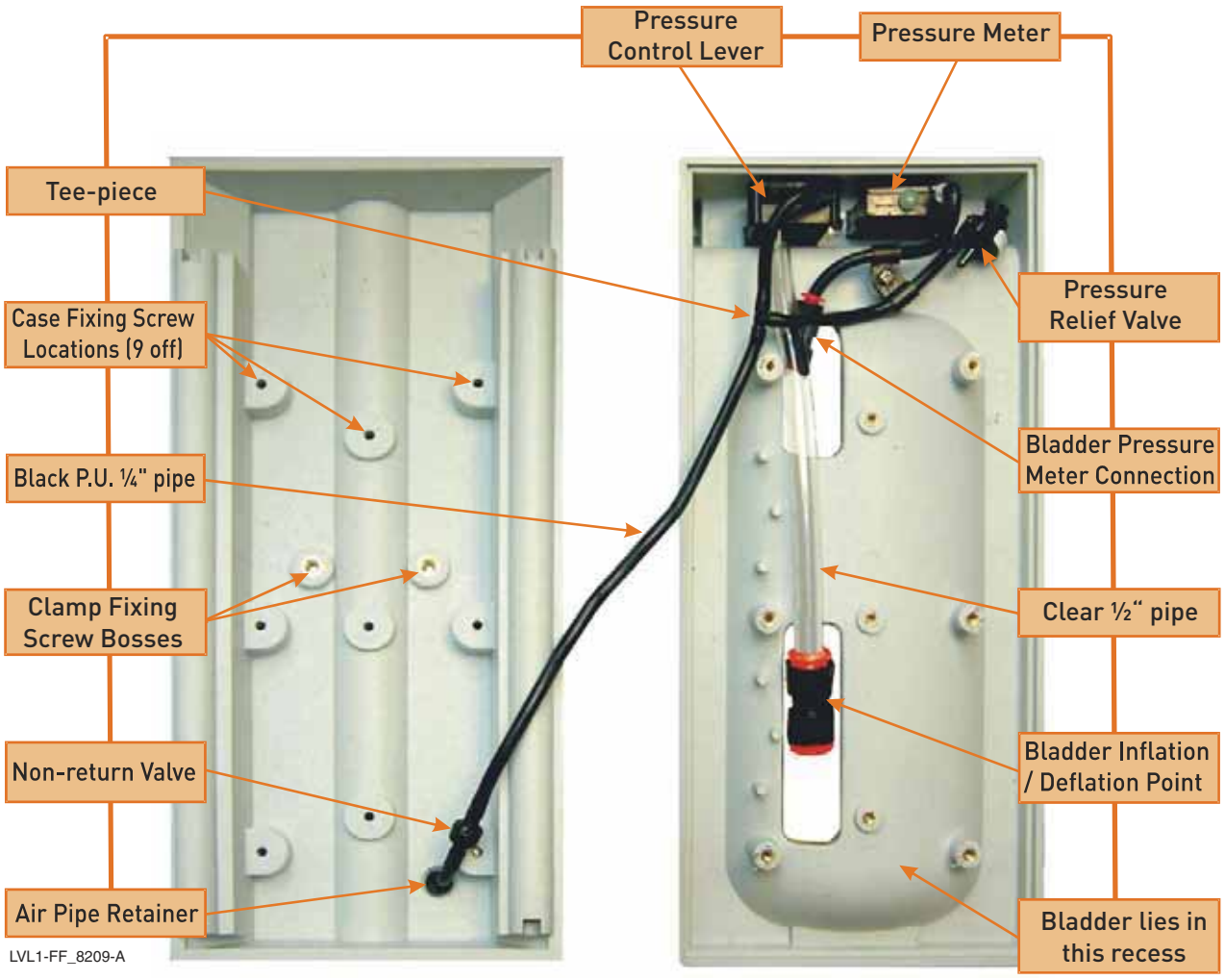
Air Components



Viewed from Rear

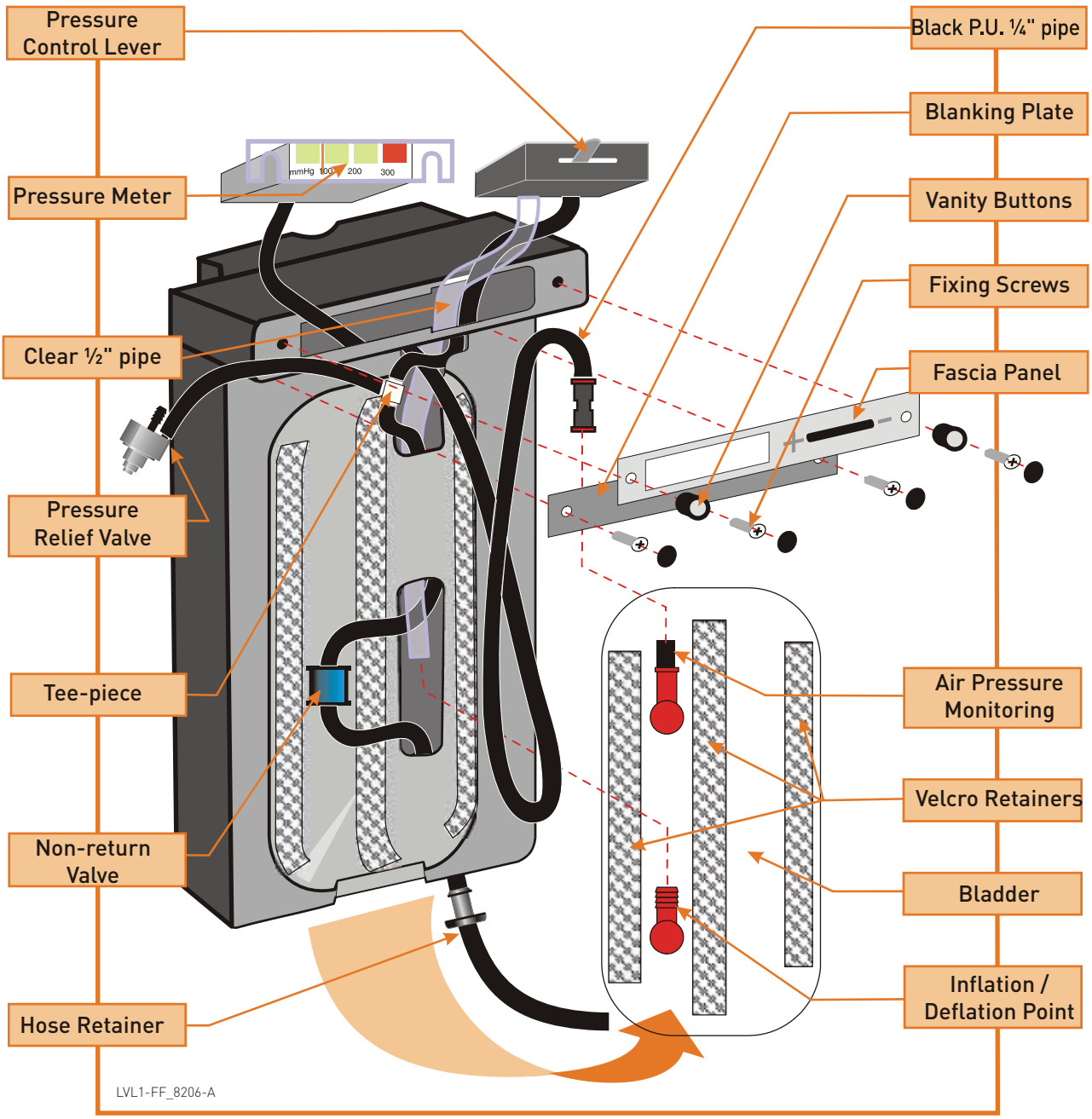
Pressure Chamber

(new style 2-part beige case)

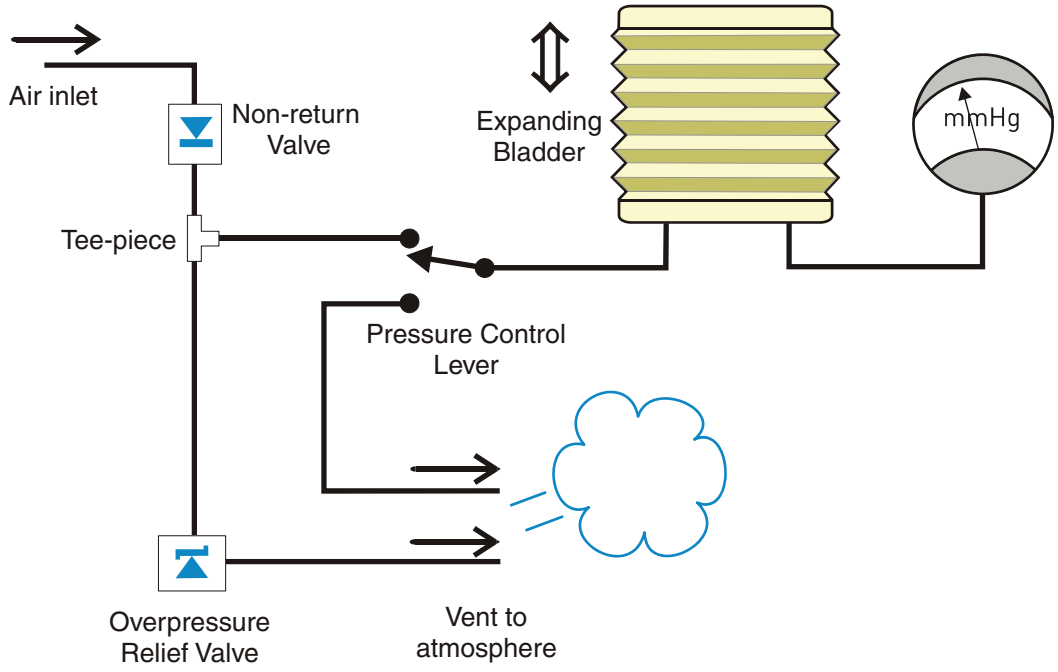


Pressure Chamber

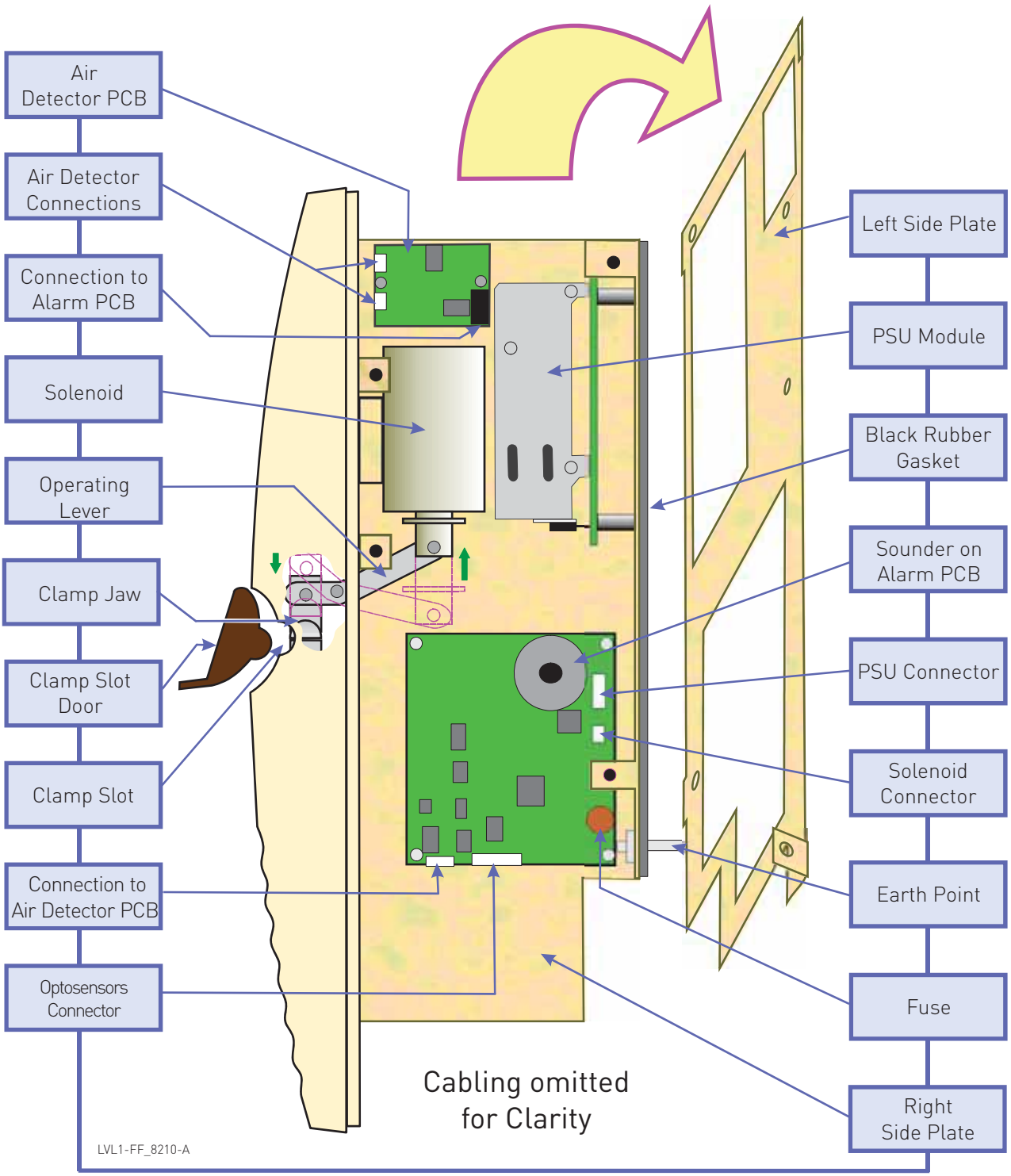
(older style dark grey case)



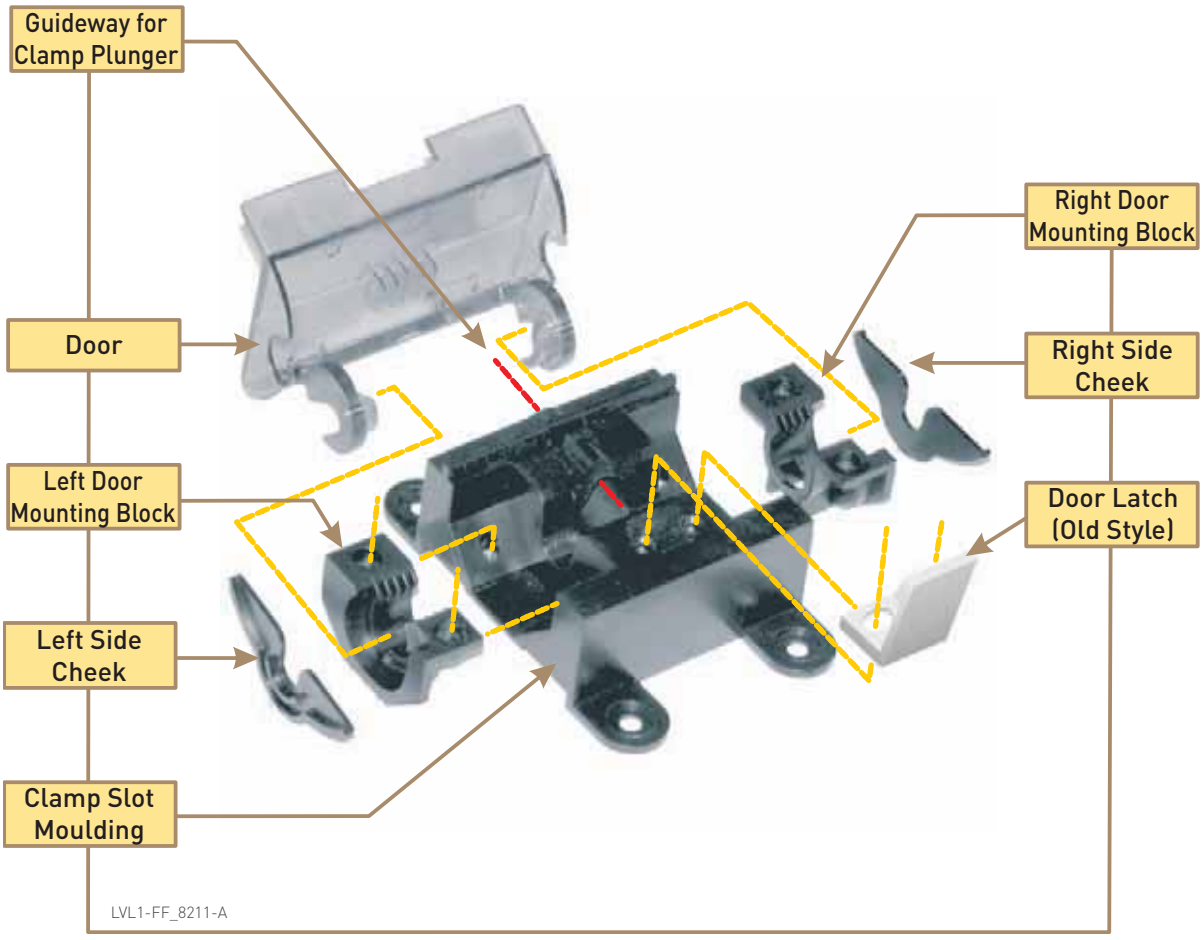
Pressure Chamber "Wiring" Diagram



Air Detector / Clamp



Clamp Slot Door Components



- This picture shows the older style all-plastic door latch. You can see the newer metal latch in Figure 4 - 43 on page 97.

Level 1® H-1200

Fast Flow Fluid Warmer

smiths medical

bringing technology to life

Fast Flow Blood and Fluid Warmers

LEVEL 1®

Technical Description

The essential core of the H-1000 system is the heat exchanger built into the disposable set. The rest of the device exists to provide the heat exchanger either with heat to operate it, or with infusate fluids to pass through it. The heating is indirect, using a recirculating solution of either pure distilled water or dilute hydrogen peroxide as a transfer medium.

Heat is provided by two electrical heaters, totalling about 1000 watts. The heater units are shaped in the form of hollow tubes. The recirculating solution is pumped through these tubular heaters and is heated as it passes through. One of the heaters is active over the whole range of temperatures and demands, while the other is primarily for rapidly bringing the warmer up to its working temperature from a cold start.

The heater output, and thus the temperature of the recirculating solution, is controlled by an electronic Pulse Width Modulation circuit, which takes its feedback from two thermistor assemblies submerged in the recirculating solution where it enters and exits the heat exchanger.

Figure 3 - 1: The spiralling inside the Heat Exchanger can clearly be seen on this aluminium interior component

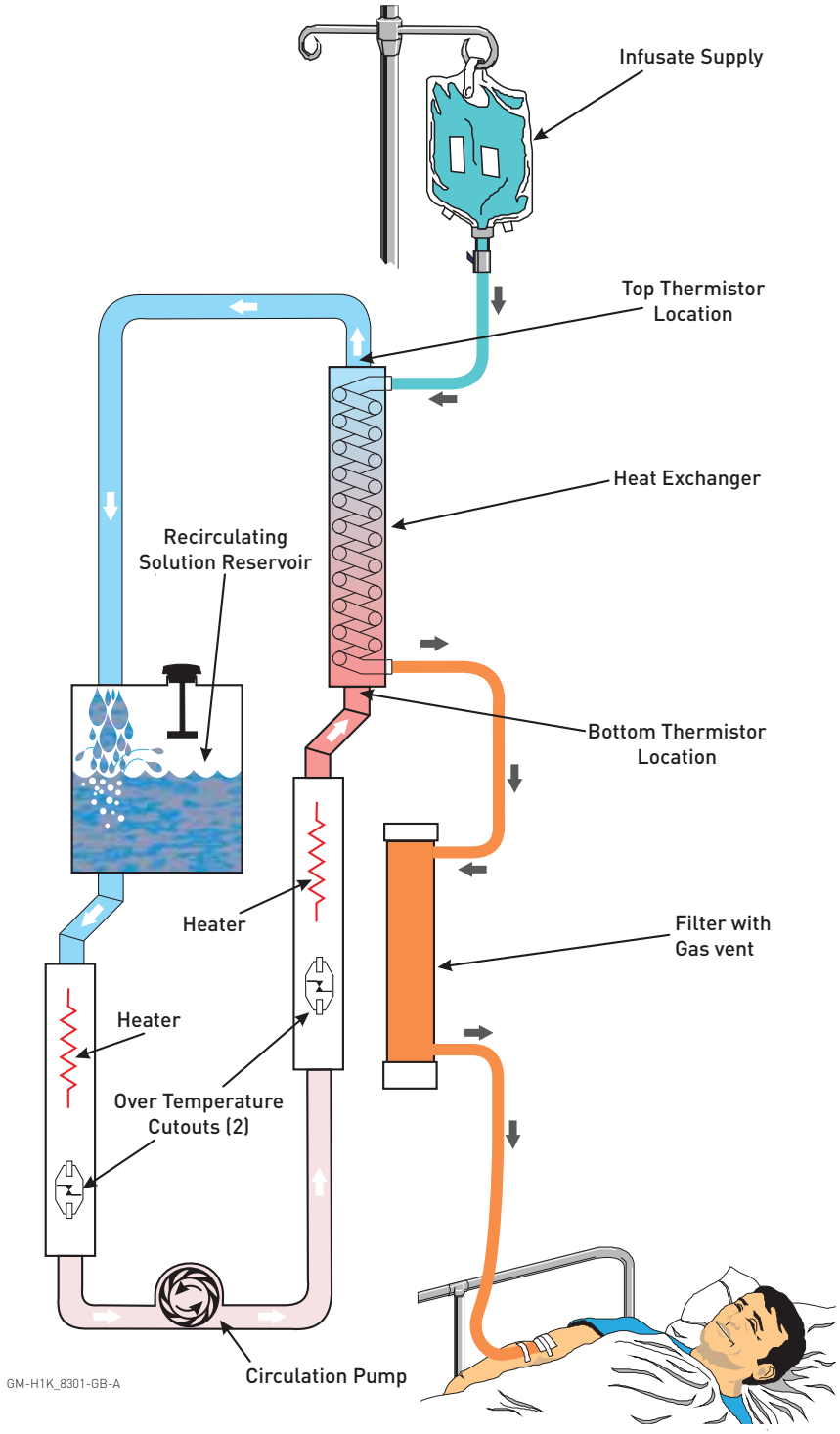


Figure 3 - 2: The general arrangement of components and fluid flows is shown here, with a idea of the temperature changes involved

Each Thermistor assembly contains two independent thermistors, so that no single component failure can cause thermal runaway, which would lead to fluid delivery to the patient at potentially dangerous temperatures.

In normal use, the secondary thermistors' outputs are used to operate a digital temperature display, giving confidence to the clinical team that the unit is working correctly.

The heated recirculating solution is forced upwards through the outermost spiral of the Heat Exchanger, as the infusate fluid passes downwards through the inner spiral. By opposing the two flows in this way, heat transferance is maximised for highest efficiency.

The normal application of these warmers is in situations like theatres, where trauma patients require high flow rates of infused fluid or blood. To this end, some models in the series have additional features to help speed up the flow of infusate. The H-1100 has an electrically powered extending pole so that the I.V.pole can be raised higher, giving a greater head of fluid, and so increased pressure forcing the fluids through the fluid path.

An option available to all models is to use pressure chambers to squeeze the infusate bags, so increasing the pressure and flowrate. All models of recent manufacture are fitted with an on-board compressor to provide a supply of pressurised air for these chambers

Air from the internal compressor is used to inflate a flexible bladder inside a rigid container, which also contains the bagged infusate. As the space in the container is filled, pressure (up to 300 mmHg) is applied to the outside of the infusate bag. A pressure control lever releases the pressure when it is necessary to replace the bag.

The internal compressor has enough output to operate two pressure infusors. The air supplied by the internal compressor is filtered and regulated so that excessive pressure, which could be damaging to the Heat Exchanger, Gas-Vent Filter, or even the patient, is avoided.

Figure 3 - 3: A pressure chamber, showing the partly inflated flexible bladder inside the rigid, clear-fronted enclosure. A Pressure Meter (top left) lets the operator know when the system is pressurised.

Compare this photograph with Figure 4 - 27 on page 79, which shows the more up-to-date design of pressure chamber.

The Way it Works

Heater Control

The part of the circuit based around U6B, C, and D is a free-running low frequency (3.5 Hz) triangle wave oscillator. If C5 happens to be charged to less than 5v, the circuit acts to charge it up via R17. Conversely, if C5 happens to be charged to greater than 5v, then R17 will try to discharge it. This results in a square-wave output from U6B, which is integrated by U6D to give a flat-sided symmetrical triangle of about 150mV pk-pk amplitude, centred about the mid-rail 5v level.

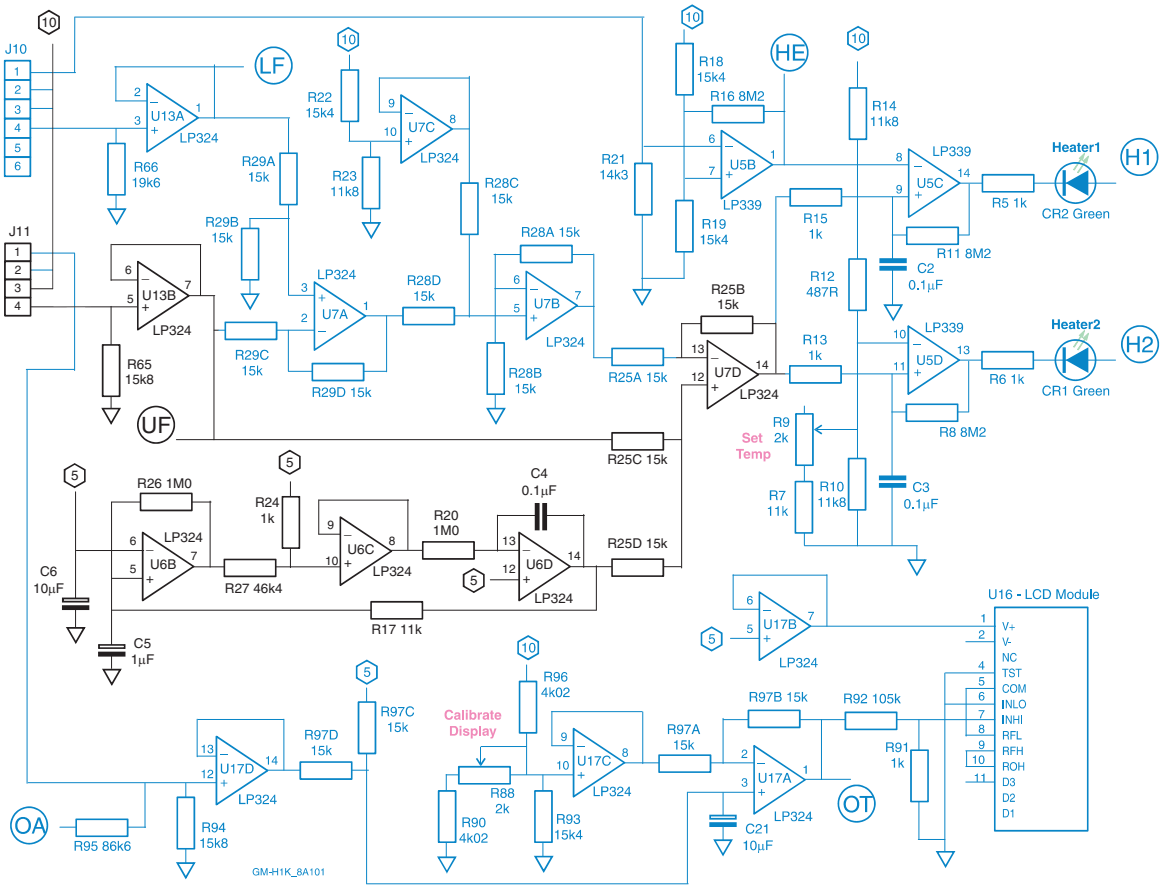


Figure 3 - 4: Making Waves

Before being presented to U7, this triangle wave is summed with the buffered voltage derived from the Upper Thermistor. This has the effect of putting a temperature-related amount of DC offset into the waveform, so that it's single-cycle average can be greater or less than the nominal 5v centre point.

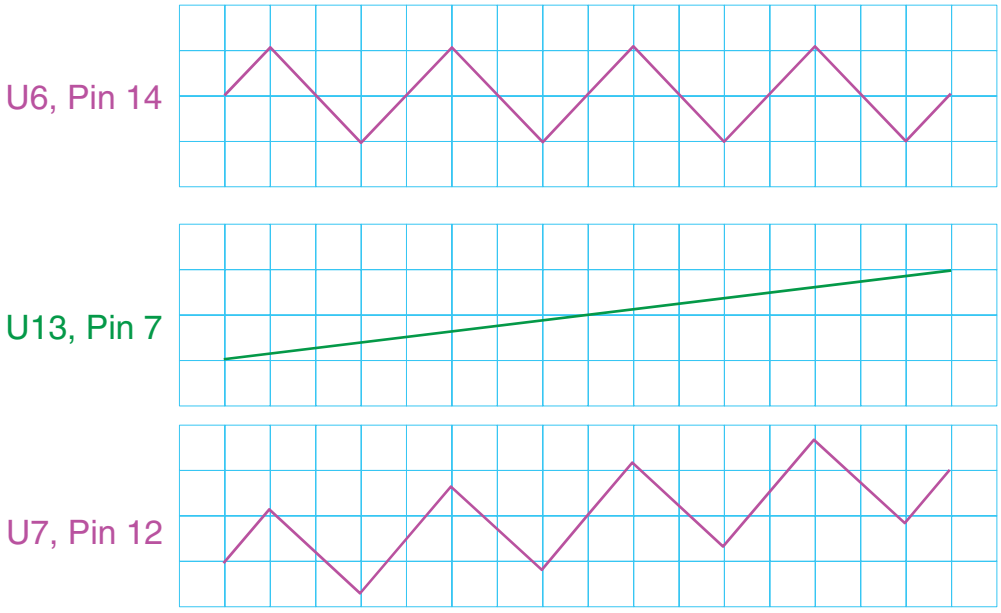


Figure 3 - 5: Summing a wave with a ramp

U7 pin 12 is compared with the signal at pin 13, which is derived from U7A via U7B. U7A has it's positive input provided by the Lower Thermistor, and it's negative input comes from the Upper Thermistor. This means that the output of U7A is proportional to the difference in voltage between the Upper and Lower Thermistor outputs, and therefore, in proportion to any temperature difference across the ends of the Heat Exchanger.

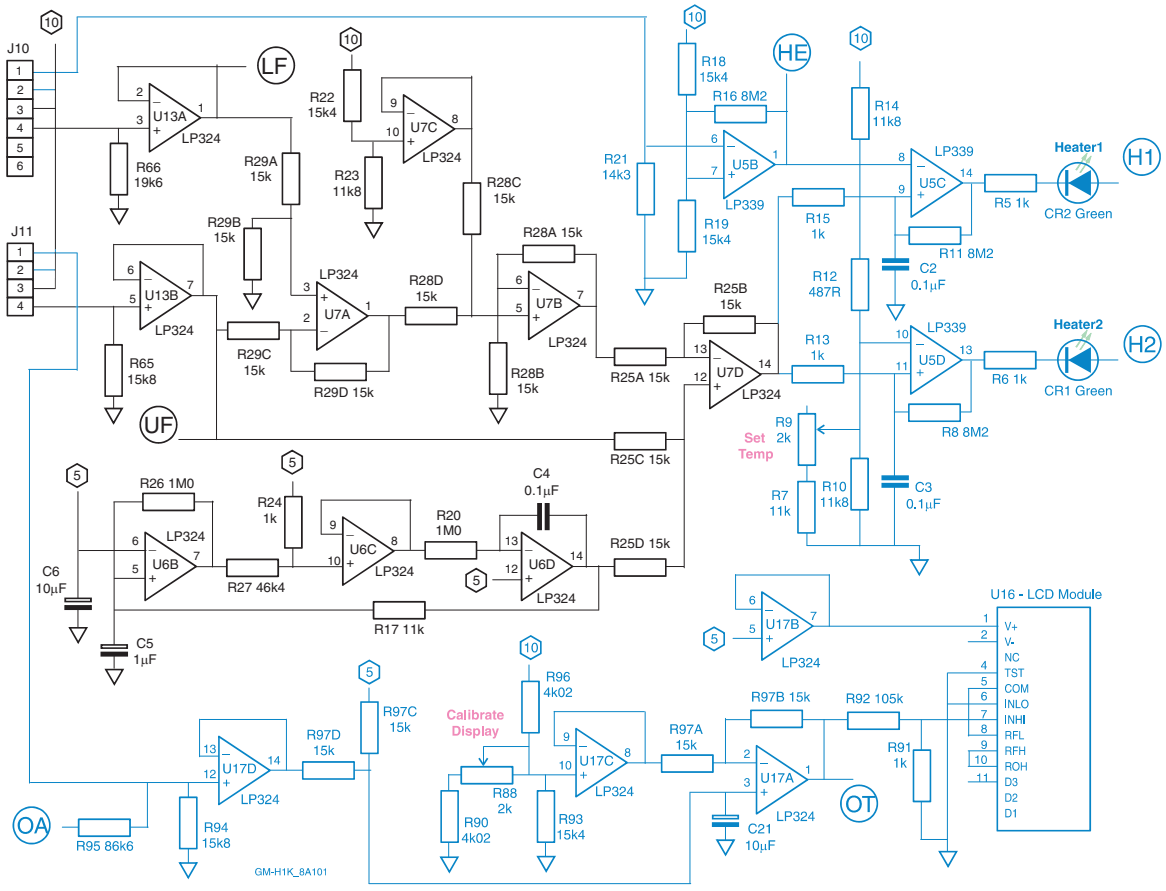


Figure 3 - 6: Comparing the differences

This gives a good degree of control, because there are two factors which have an effect on the heater controller. There is a direct control that heats the water until the circulation past the Upper Thermistor reaches the desired temperature. But the heater is only powered on when there is a demand, since if there is no infused fluid flow taking heat from the circulation, there will be no temperature drop.

This can be seen by considering the following three scenarios.

1) System cold after first switching on

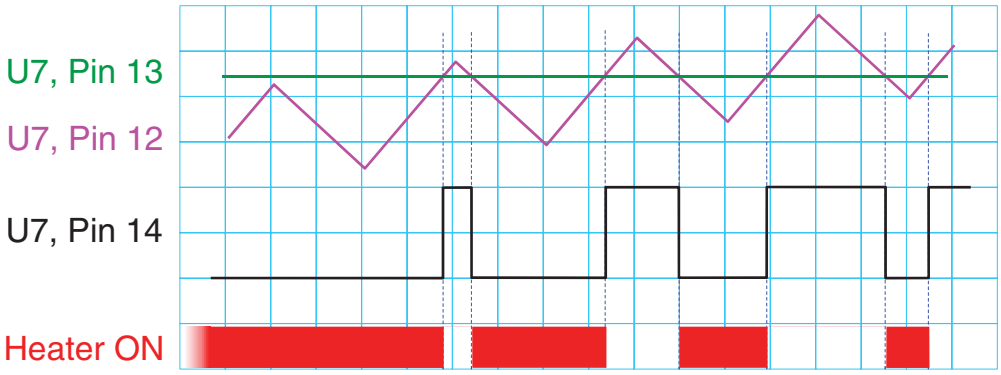


Figure 3 - 7: Getting Warmer

Under the influence of the Upper Thermistor (as discussed on the previous page), our triangle wave gradually creeps upwards as the temperature rises. As it approaches the set point, the heater begins pulsing, initially with quite long pulses, but ultimately with quite short pulses. This gradual approach to the target minimises any risk of overshoot, so that the infusate (and the patient) never get overheated.

Note that, although the system is warming up from cold (15°C - 20°C) to operating tempeature (~40°C), U7 pin 13's voltage remains steady or nearly so. It's because both ends of the Heat Exchanger warm up at just about the same rate, and only *differences* in temperature cause a variation in this signal.

2) System idling at operating temperature.

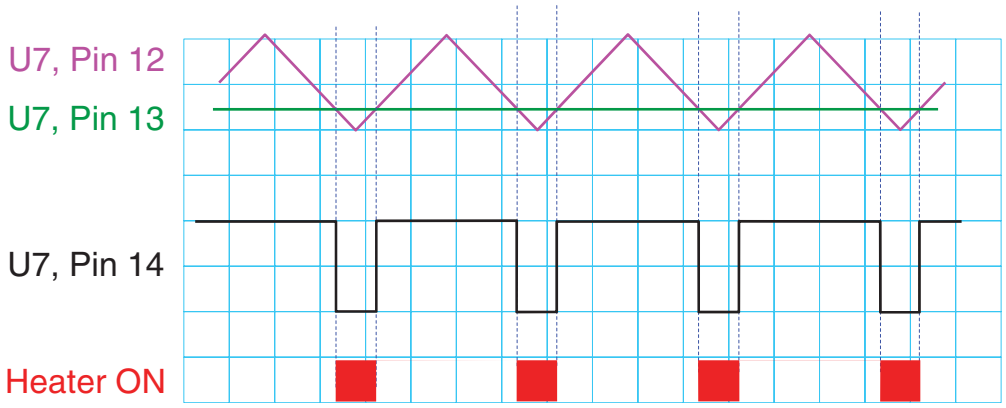


Figure 3 - 8: Ticking Over

The temperature is steady so, while it is still “triangling”, the waveform at pin 12 no longer shows any upward or downward trend. The pin 13 signal is steady, so the output to the heater is a series of short pulses, just sufficient to maintain the working temperature.

3) System operating, infusion in progress.

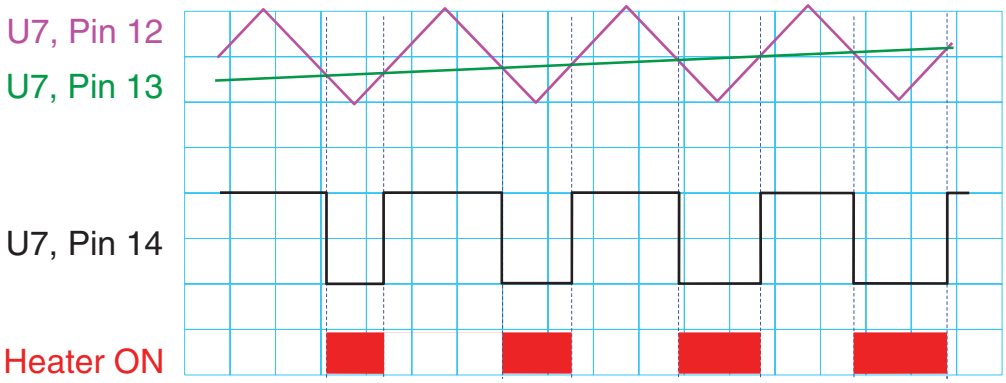


Figure 3 - 9: Demand and Response

The pin 12 waveform, representing the operating temperature, is still stable. Pin 13, on the other hand, is being driven up by the increase in demand.

As cool infusate passes through the Heat Exchanger, heat is extracted from the recirculating solution, so there is now a difference in temperature from bottom to top of the Heat Exchanger. As the voltage at pin 13 rises, the heater pulses become longer, and the interval between them gets shorter, so that more energy is being put into the recirculating solution to maintain its temperature.

The Heater Enable Circuit

In the previous explanation we examined how the H-1200 determines the demand for the heater, but we deliberately ignored the fact that there were in fact two separate heaters. What's more, they don't necessarily work together.

Heater 2 is in fact the more frequently used heater, although both heaters are of the same type. The demand signal from U7 pin 14 is split two ways, reaching the positive inputs of two sections of U5. The corresponding negative inputs are derived from a chain of resistors, such that U5C's input is held at a slightly higher voltage than U5D's input. The exact voltages depend on the setting of the "Set Temp" adjustment, but it's in the area of 3.0 - 3.6 Volts.

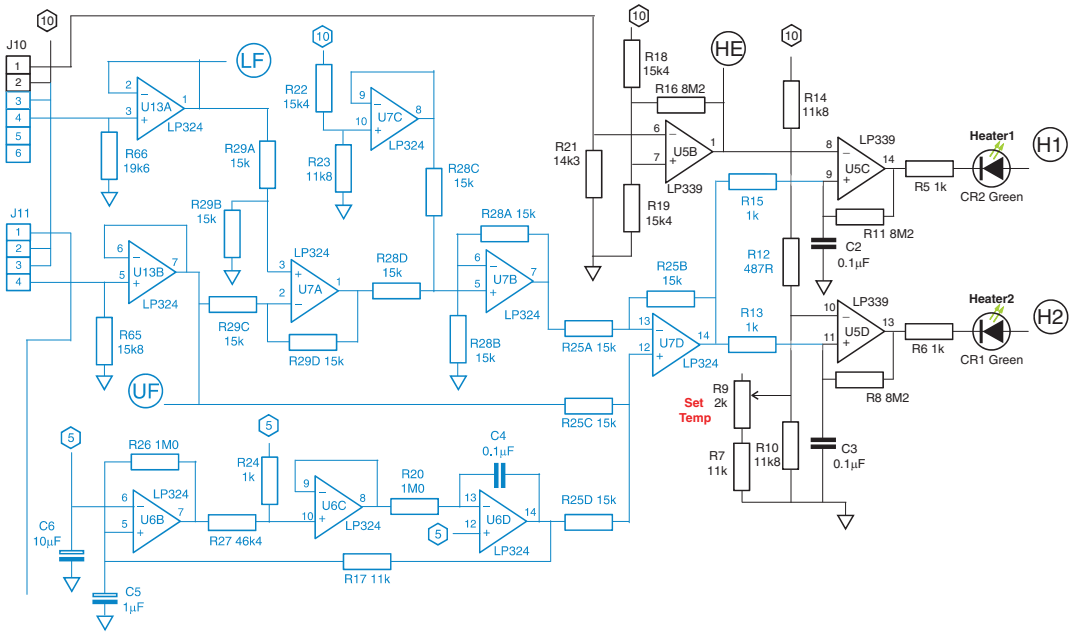


Figure 3 - 10: Setting the temperature

Because the setpoint voltage applied to U5C is slightly higher, the H1 heater is always the last to be turned on, and the first to be turned off. In practice it means that H1 heater will normally only be active when the system is heating up from cold, or if heater H2 goes faulty.

The top end of the resistor chain that creates this behaviour has another trick up its sleeve. The R14/R12 junction, as well as going to the U5C input, is connected to U5B output and U15D output. We will look at the role of U15 later. The U5B comparator takes an input from one of the Lower Thermistor pair (the LS thermistor).

At some temperature set by the resistors R18, R19, and R21, U5B output will go low, thereby removing the reference voltages that allowed U5C and U5D to turn on the heaters. Hence we have an automatic shut-off in the event of excessive temperature.

The Temperature Display

The fourth thermistor - part of the Upper Thermistor pair - is a dual function device. Primarily, it is used to operate the LCD display: its signal is buffered by U17D, a calibrating offset is introduced by U17C, and a smoothing and scaling stage is based around U17A. Finally the signal is fed into the DVM module U16, whose output is read as degrees Centigrade.

The final stage's output is also used to trigger an Over Temperature Alarm, about which we will learn more later. The input can be overriden by the keypad Over Temperature Alarm Test button, via R95, to ensure that the circuitry is functioning correctly. Pressing the button gives a simulated input to the circuit equivalent to a measured temperature of about 45 °C. This should be visible on the display during the test.

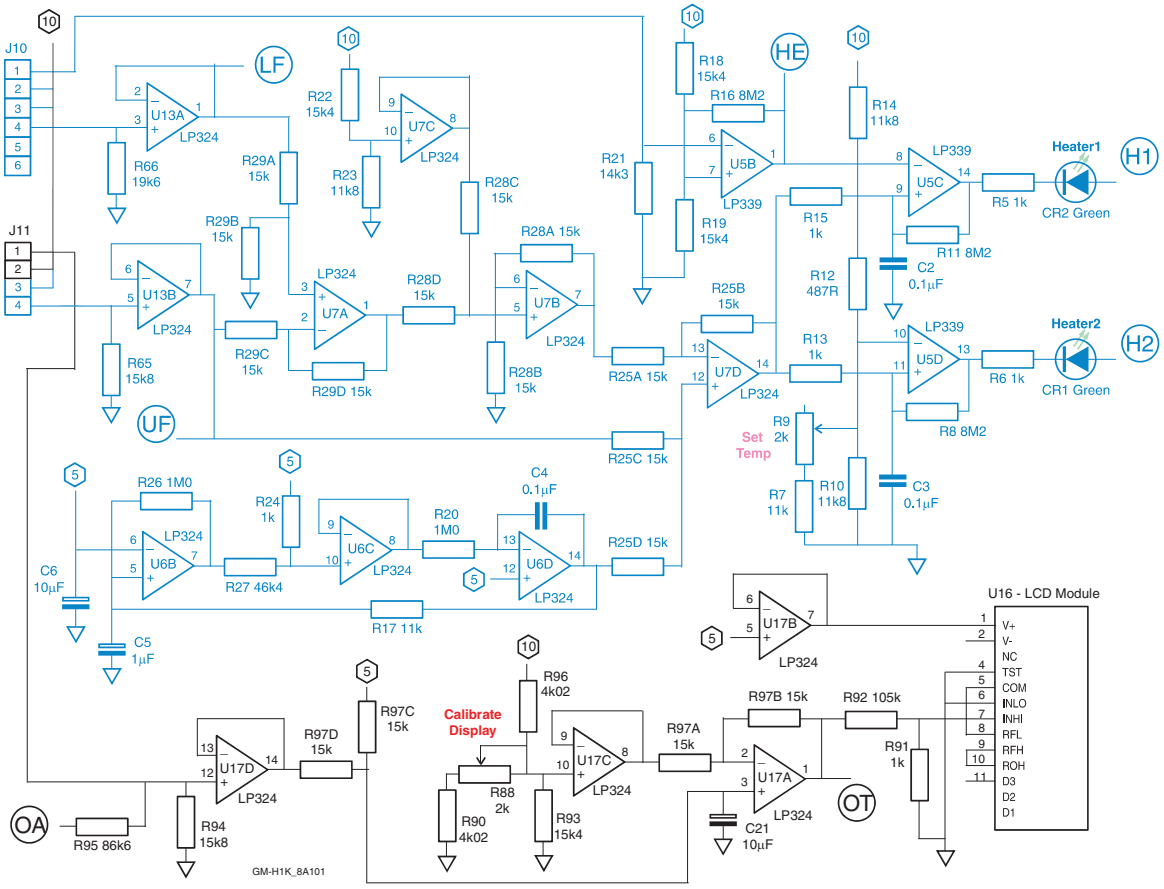


Figure 3 - 11: Show and Tell time

After buffering by U17D, the thermistor's signal is mixed with a DC offset for calibration. Since calibration takes place at the working temperature, and the range of acceptable working temperatures is very small, no provision for adjusting the scaling of the input voltage is required. Again because of the very small spread of acceptable temperatures, no effort is made, or required, to linearise the voltage versus temperature characteristic.

The module is a regular DVM module reading 0 - 199 millivolts, but with decimal points suppressed. This allows the display to be interpreted as degrees Centigrade.

Alarms and Fault Indications

There are three exceptional conditions that may arise in regular use which will lead to an Alarm state being notified both visually and audibly to the user. These are:

- The administration set not being fully engaged in its connection points to the warming system.
- The level in the recirculating solution reservoir falling to below the correct level.
- Detection by the circuitry that the recirculating solution has reached an excessive temperature

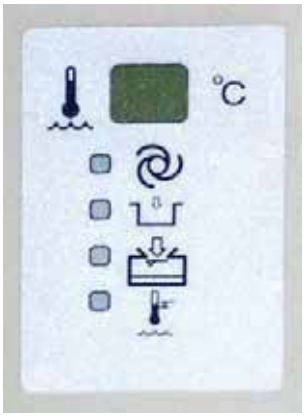


Figure 3 - 12: Four indicators: from top, System OK, Disposable not in place, Recirculating Solution Level Low, Recirculating Solution Over Temperature

In addition to visual and audible alarms, the system will stop circulating and heating the recirculating solution. The infusion in progress, if there is one, will continue, although without the benefit of being warmed.

In addition there are a number of fault conditions which will lead to the H-1200 refusing to operate, and which are indicated to a service technician only after the unit is removed from active service and partially stripped down in the workshop.

There are ten such indications in all, based around U10, U9, and half of U8. Each is functionally similar, typified by the highlighted parts of Figure 3 - 13, “Internal Indicators for troubleshooting.,” on page 48.

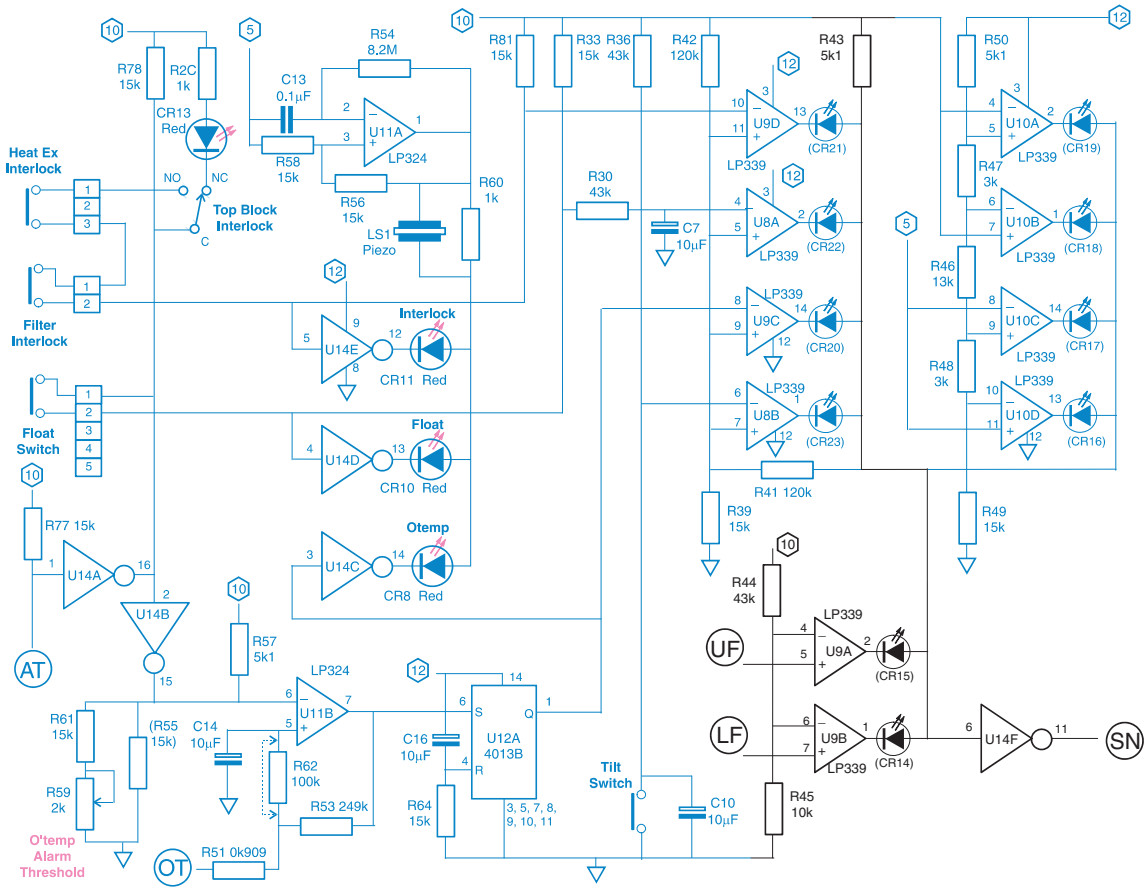


Figure 3 - 13: Internal Indicators for troubleshooting.

A voltage divider keeps pins 4 and 6 of U9 at a steady voltage just below 2 volts. U9 compares this voltage with the voltages being received from the thermistors UF and LF. If either UF or LF were to output a voltage less than 2 volts, it would indicate that either an implausibly low temperature had been experienced, or more likely, the wiring to the thermistor had become damaged or disconnected, and needed closer inspection.

U9, either at pin 1 or 2, will go to a logical zero, thus lighting the LED CR14 or CR15. Because U8, U9 and U10 are all open collector types, any one of the ten fault warning channels going low is sufficient to turn off inverter U14F, inhibiting the power circuits.

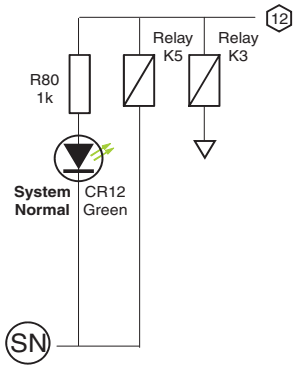


Figure 3 - 14: Signal SN (System Normal) switches Relay K5, which in turn controls the system pump motor and, via relays K1 and K2, the heater elements.

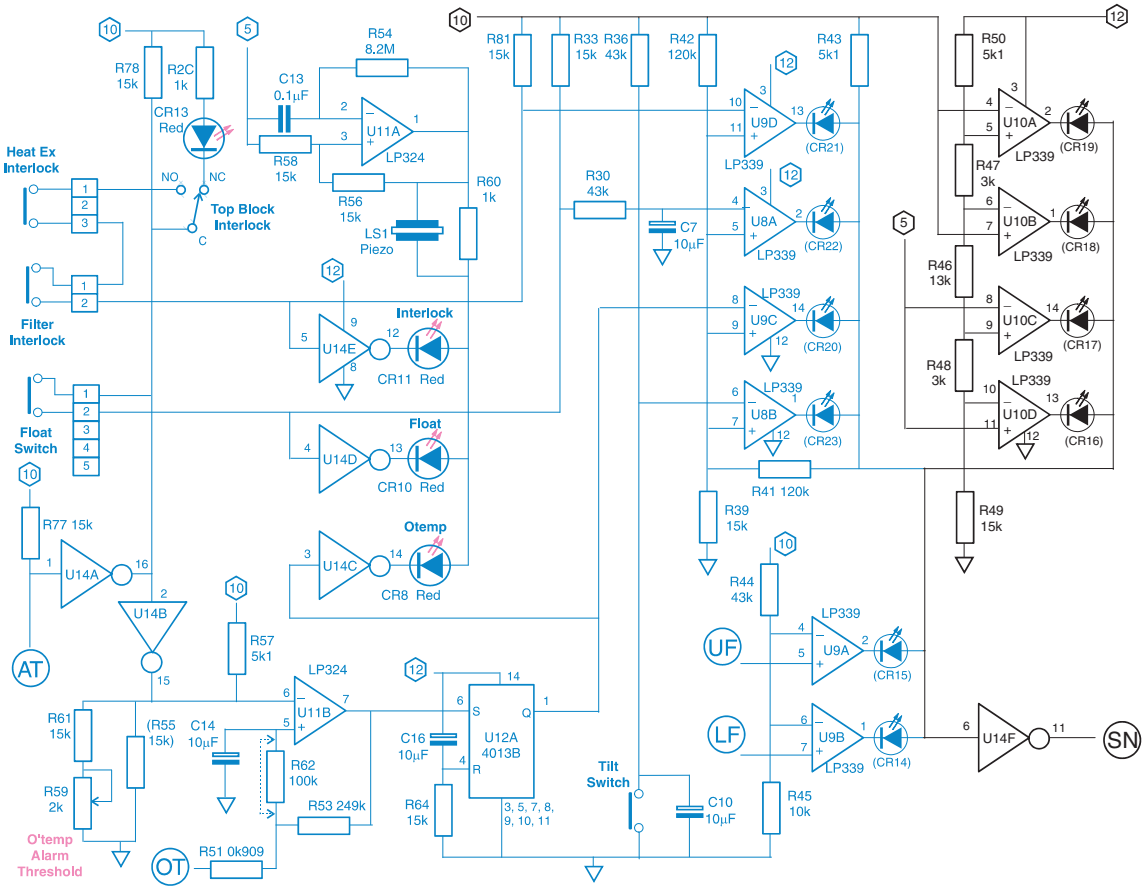


Figure 3 - 15: Keeping the Power Supplies on the Rails

These four fault reporting channels continuously monitor the 5 and 10 volt supply rails for over- or under-voltage. The string of resistors R46 - R50 set the upper and lower thresholds for triggering the shutdown response.

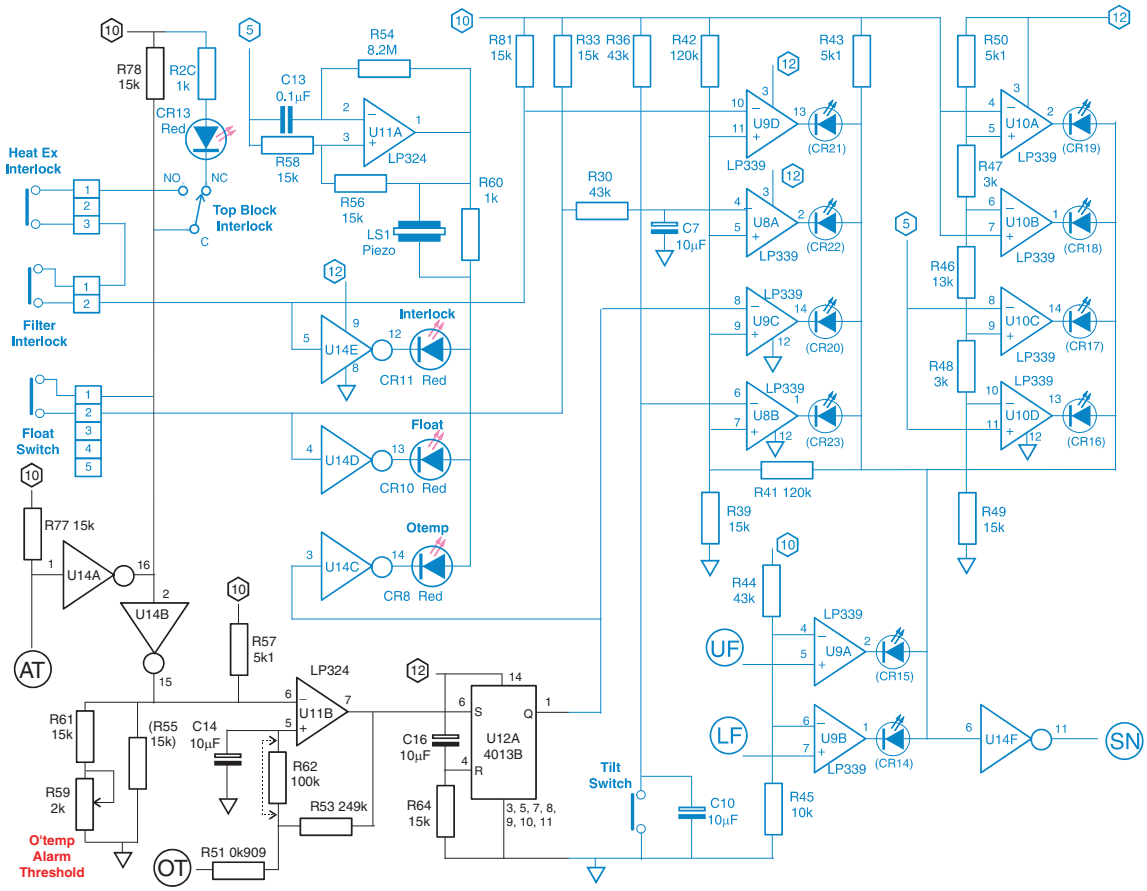


Figure 3 - 16: Sticky Heat

Some of the inputs to this array of fault indicators have interesting characteristics. In this figure we have picked out the Over Temperature Alarm, triggered by signal OT which comes from the temperature display circuit described earlier on page 46.

Figure 3 - 17: The "Alarm Test" button has this symbol

You can also see that another input - AT - is present. This is the general Alarm Test signal which originates at this pushbutton (illustration, left) on the keypad. As well as simulating an Over Temperature condition, this button should set off the "Disposable not fitted" interlock, and the "Recirculating Solution Level Low" warnings.

The current temperature is compared with an adjustable set point by the op-amp U11B, rigged as a comparator. If it exceeds the set point, or the set point is artificially reduced by the Alarm Test button, U11B's output SETS a flipflop, U12A, so that the alarm cannot be cleared except by cycling the mains power to the unit. This is the only fault condition that is latched. Other faults may affect the warming system's ability to function, or may tend to reduce its life expectancy, but overheating the recirculating solution may have a direct and detrimental effect on a patient.

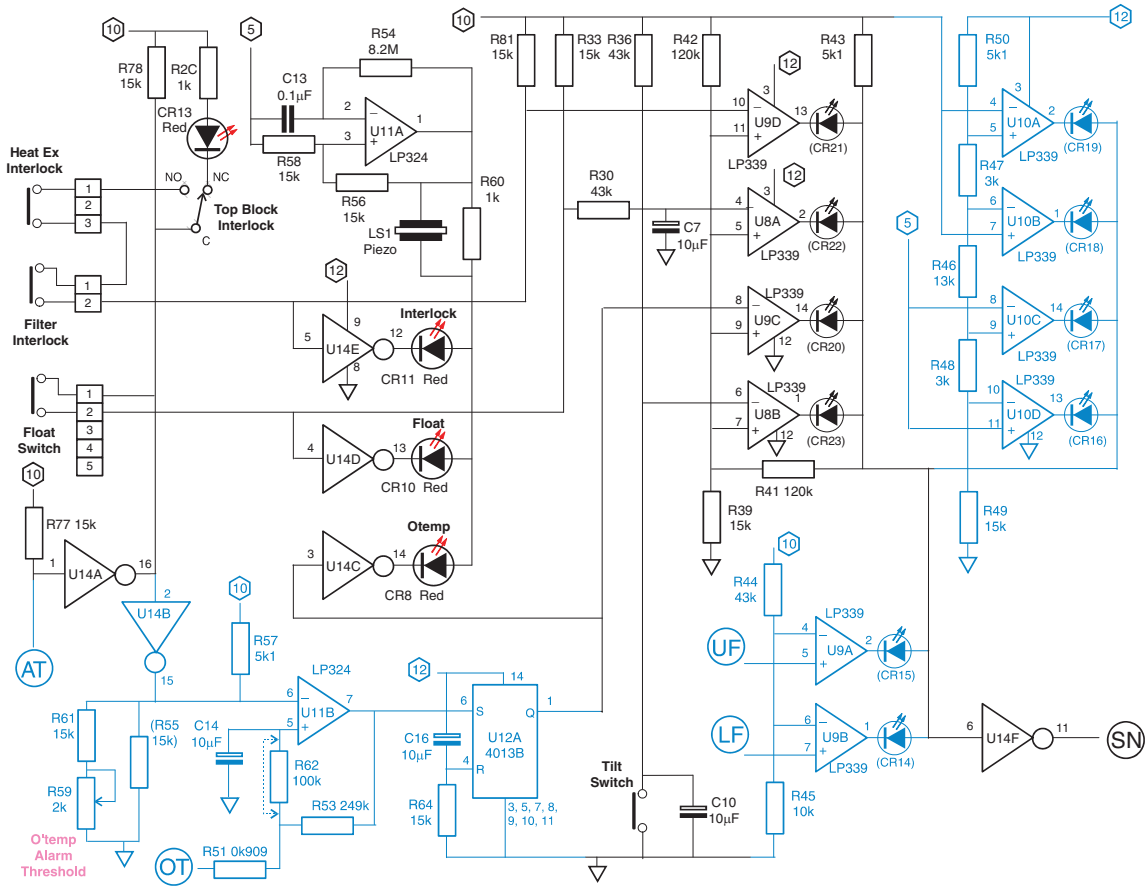


Figure 3 - 18: Final Warnings

The final point of interest in this area is the circuitry surrounding U11A (see over). This functions as a slow speed squarewave oscillator, whose output is coupled to the inverters U14C, D, and E via the display panel mounted LEDs CR8, CR10 and CR11. If one of the inverter outputs is driven low by any one of the three alarm conditions (Over Temperature, Disposable Interlock, Recirculating Solution Level Low) occurring, then the corresponding LED will flash on and off. While on, the volts dropped across R60 will activate the piezo sounder LS1, thus giving synchronised audible and visible alarms to the user.

Power Circuitry

The 12v rail used here is a completely separate supply, derived from a separate secondary on the mains transformer so that the higher current devices (relays, pump motor, etc) do not create any interference to the control electronics' 12v, 10v and 5v supplies .

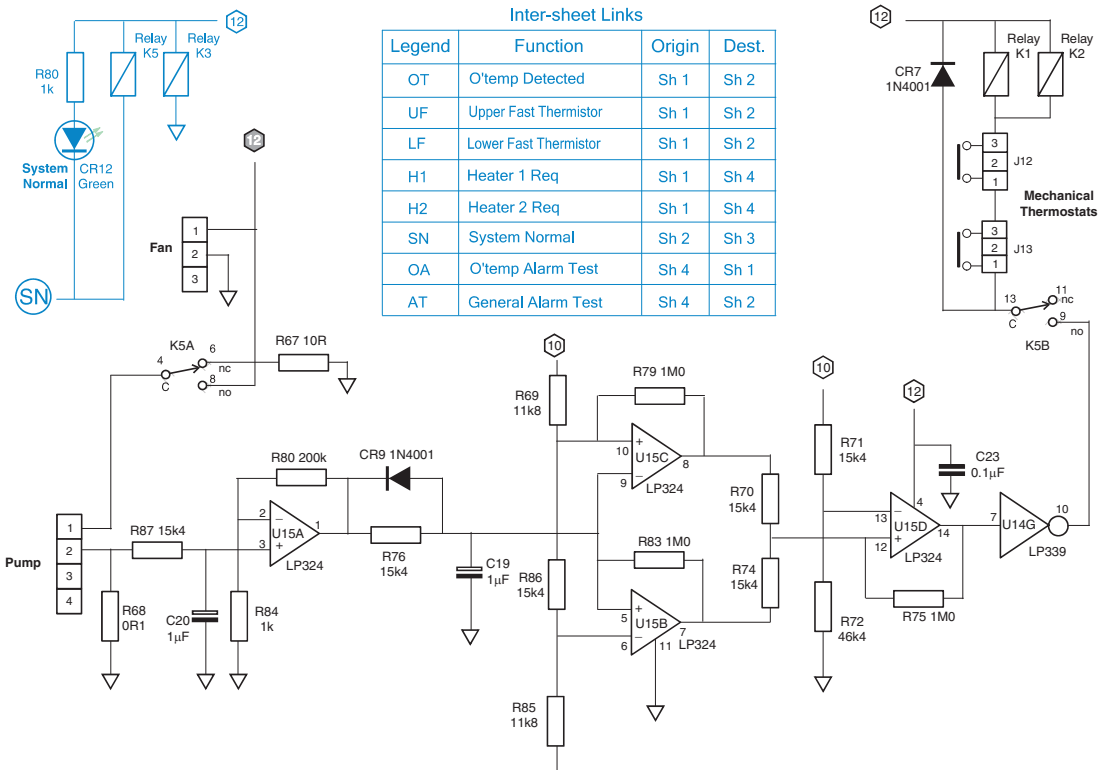


Figure 3 - 19: Motor Current Monitoring

The fan is energised whenever the unit is switched on, regardless of any fault conditions. If there are no fault conditions, K5 will be made, so the pump motor power supply is completed. The return is via R68, allowing the current drain of the motor to be monitored by U15A. After amplification and rectification, the signal enters the window detector U15B and C. Assuming that the pump motor current is "normal", i.e. neither too great or too little, U14G will allow the heater control relays K1 and K2 to energise.

Exercise

It's obvious that if the motor current is too great that there must be a problem that must be attended to, but why would the motor current being less than expected be a concern? What circumstances would cause this symptom, and potentially be such a problem that the heaters must be inhibited?

Is it that....

- *Excessive frothing in the recirculating solution means the motor is not experiencing the normal resistance to turning, and at the same time the frothing may lead to localised dry running and thus overheating of the heater elements.*

- *Insulation breakdown may have occurred in the heater elements, allowing excessive leakage current into the recirculating solution flow. This partly negates the normal motor current flow, alternately increasing and reducing the monitored values.*

- *A leak of recirculating solution is conducting some of the motor current directly to ground so that the current in the return path, i.e. the current that is being monitored, is less than the supply current.*

- *Seepage through the shaft seals has filled the motor case with recirculating solution, so the motor is running much cooler than is normal, so reducing its current requirement.*

Or is it something completely different?

Level 1® H-1200

Fast Flow Fluid Warmer

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Fast Flow Blood and Fluid Warmers

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Tower Unit Disassembly Procedure

Tools you will need

- Small and Medium (#1 and #2) Phillips screwdrivers.
- Small straight head screwdriver.
- Oetiker Pliers.
- Imperial size Allen Keys ($^{1}/_{8}$, $^{5}/_{64}$, and $^{3}/_{32}$).

Before Starting

- Ensure Unit is unplugged.
- Unplug any powered accessories from the auxiliary power outlet on the bottom of the unit.
- Apply Castor Brakes.
- Drain Recirculating Solution from Unit. You may need to agitate the unit to get the last of the solution out.
- Remove the Administration Set.
- Move the pressure control(s) to the “deflate” position (-).
- Disconnect airline from pressure chambers.
- Release 8 screws that hold the tower to the pole unit.
- Place tower face down on a suitable work surface. Support it on suitable blocks (the transit packing pieces are ideal) so that it is level and steady and not resting on the disposable sockets or the air detector / clamp. Protect the unit from being scratched.

Accessing the PCB

Remove the18 screws that retain the back cover panel. Current production models have an earth bonding point on the back cover, and the wiring to this will need releasing to fully remove the cover. Put the panel and screws in a safe place.

If an Air Detector / Clamp is fitted, make sure its weight is supported when you remove the screws holding its bracket. Fitting a scrap Gas Vent to the #4 clip will help.

Start by releasing the control panel ribbon cable from the PCB socket, to prevent damage. Disconnect the return pipe from the Upper Socket with a sharp upward tug. There may be a small escape of recirculating solution at this point, so have an absorbant cloth or tissue handy.

Figure 4 - 1: A sharp upward tug will usually disconnect the Return Pipe.

Figure 4 - 2: Once the elbow is released, the tube can be withdrawn gently from the reservoir tank.

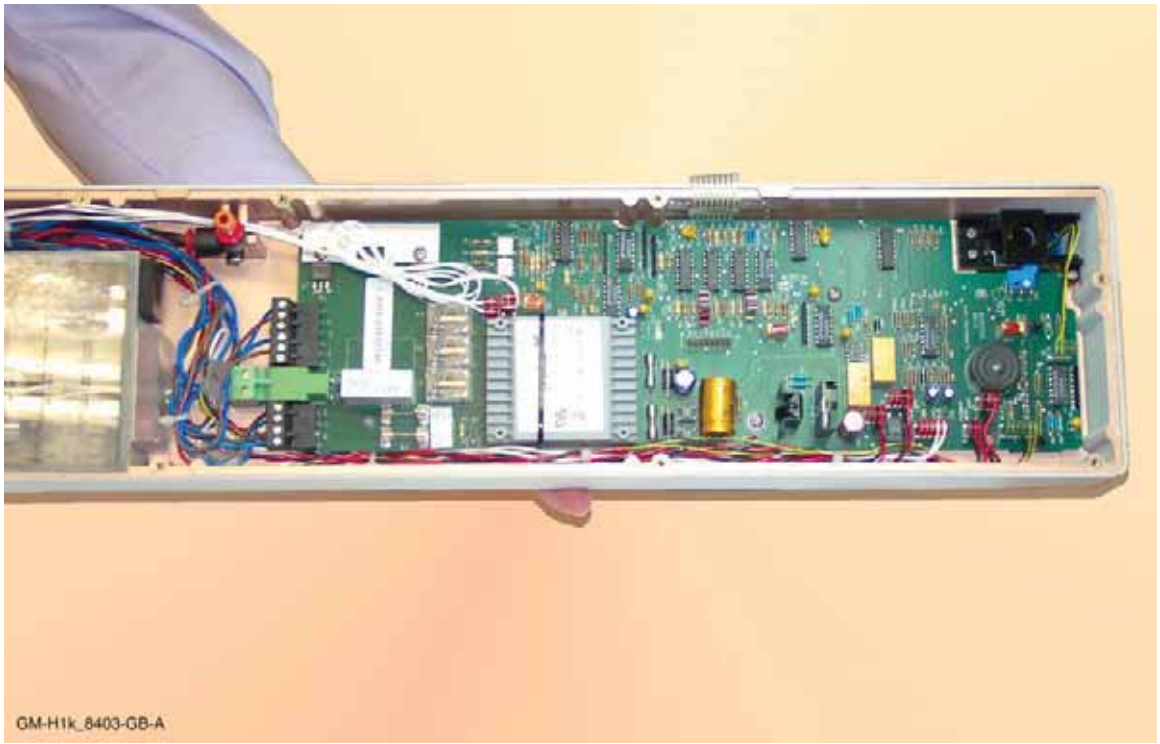


Figure 4 - 3: This would be a good time to take careful note of the routing and colour codes of the cables around the PCB. The picture on the next page will help you.

PCB Connections

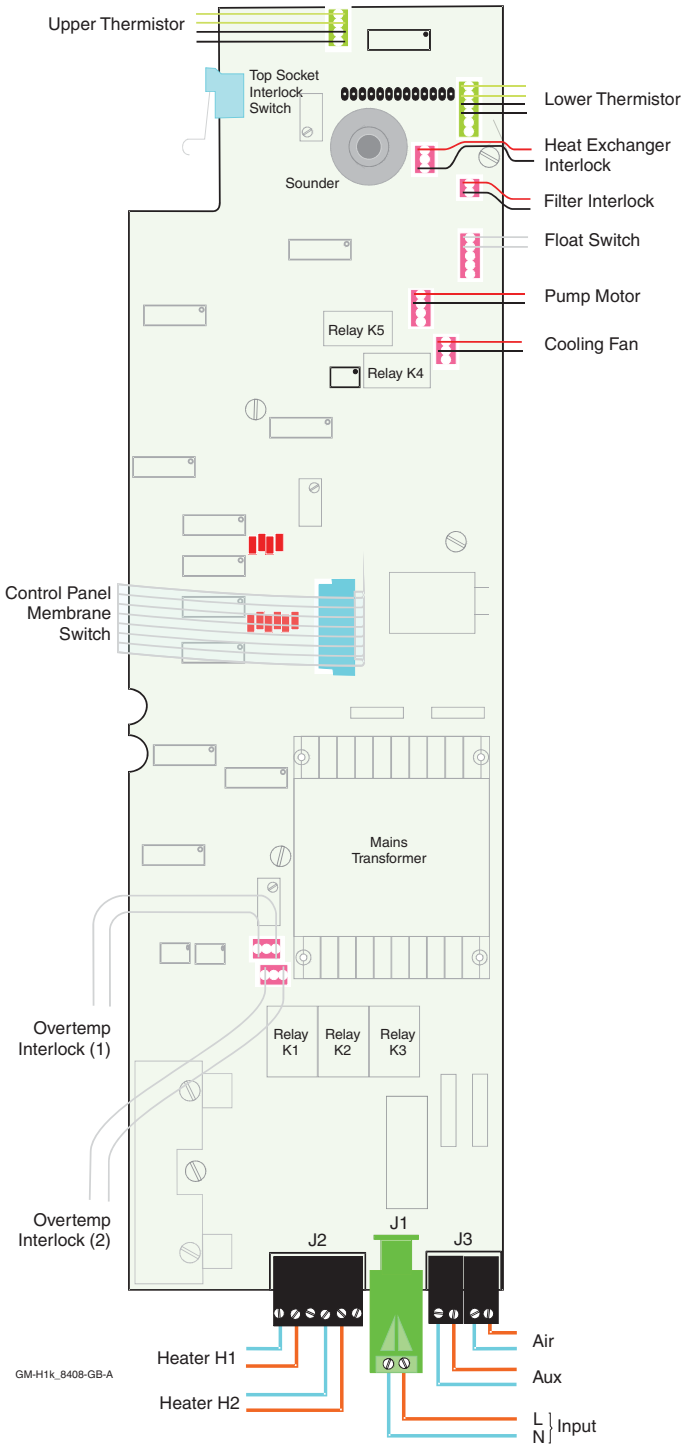


Figure 4 - 4: Plug-in connectors on the PCB

Removing the PCB

To remove the PCB, disconnect all plug-in connectors. Undo and remove the five screws indicated in Figure 4 - 5 on page 61. Lift the upper socket to its fully extended position, so that it does not catch on the microswitch operating lever, and gently lift out the PCB.

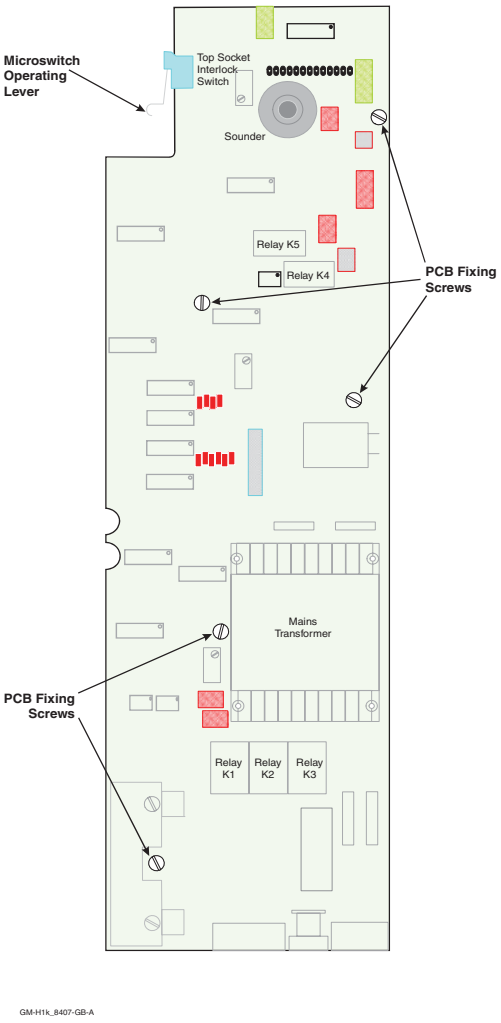


Figure 4 - 5: PCB Mounting Screws

! WARNING: STATIC-SENSITIVE COMPONENTS.
Ensure that proper antistatic precautions are taken before attempting any procedure that requires handling the PCB.

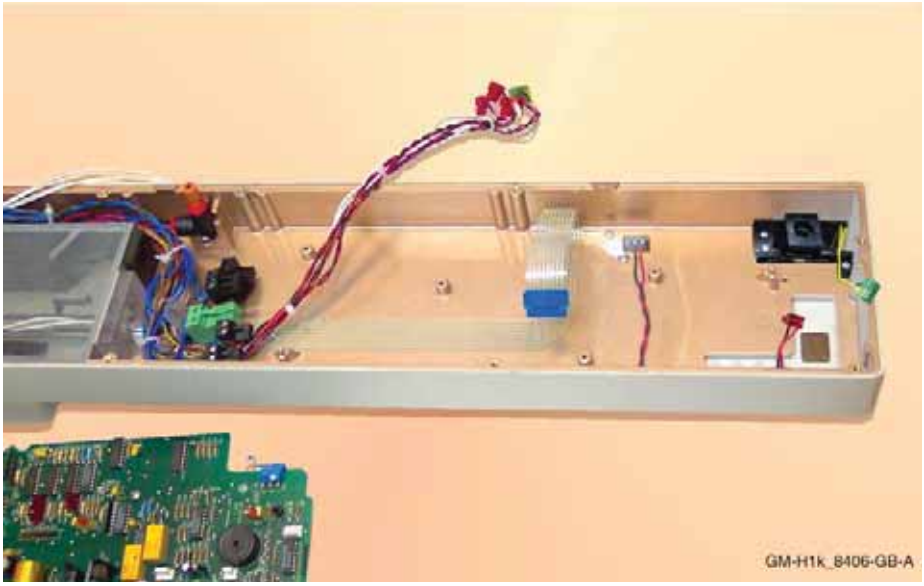


Figure 4 - 6: The PCB can be gently removed.

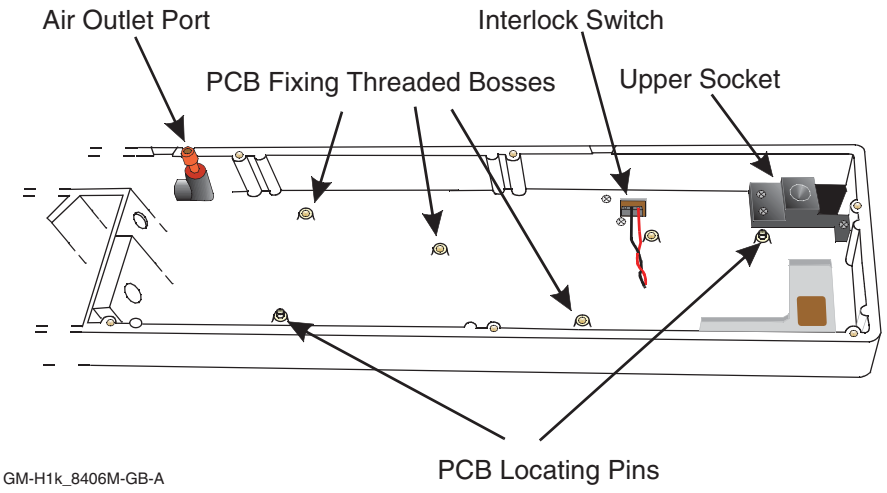


Figure 4 - 7: Noteworthy features normally hidden until the PCB is removed

Removing the Top Socket

Remove the PCB as shown previously.

With a $^{3}/_{32}$nds inch Allen key, remove the three fixing screws.

Slide the moving part of the socket mechanism as far as it will go in the direction of the YELLOW arrow.

Slide the lower static part of the mechanism in the direction of the RED arrow until it comes free.

Pull the moving part in the direction of the BLUE arrow. Some manipulation may be required to completely free it.

Re-fitting is the reverse of dismantling. Use a little silicone grease on the sliding tracks when re-assembling. Take care with the thermistor wiring.

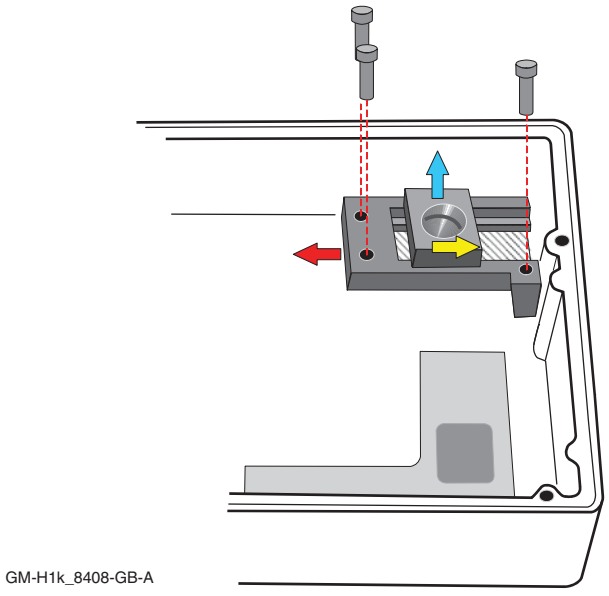


Figure 4 - 8: Removal of the Top Socket

Air Compressor and Heaters

The compressor attaches to an acoustically isolated sub-chassis, fastened to the main system chassis. In most cases it will be easier to remove the compressor and sub-chassis while leaving the main chassis in place. If it is expected that further work will be required, on the water pump for example, you may choose to remove the entire chassis from the cabinet for dismantling, and then dismantle individual parts from it.

If you intend to remove the entire chassis, or just the pump or either heater, this will involve opening the Recirculating Solution path. To reseal the hose connections you will need a set of Oetiker pliers, and the appropriate clips - in both sizes - to clamp onto the hoses.

Figure 4 - 9: Oetiker Pliers are specially shaped to close the Oetiker clips without damage

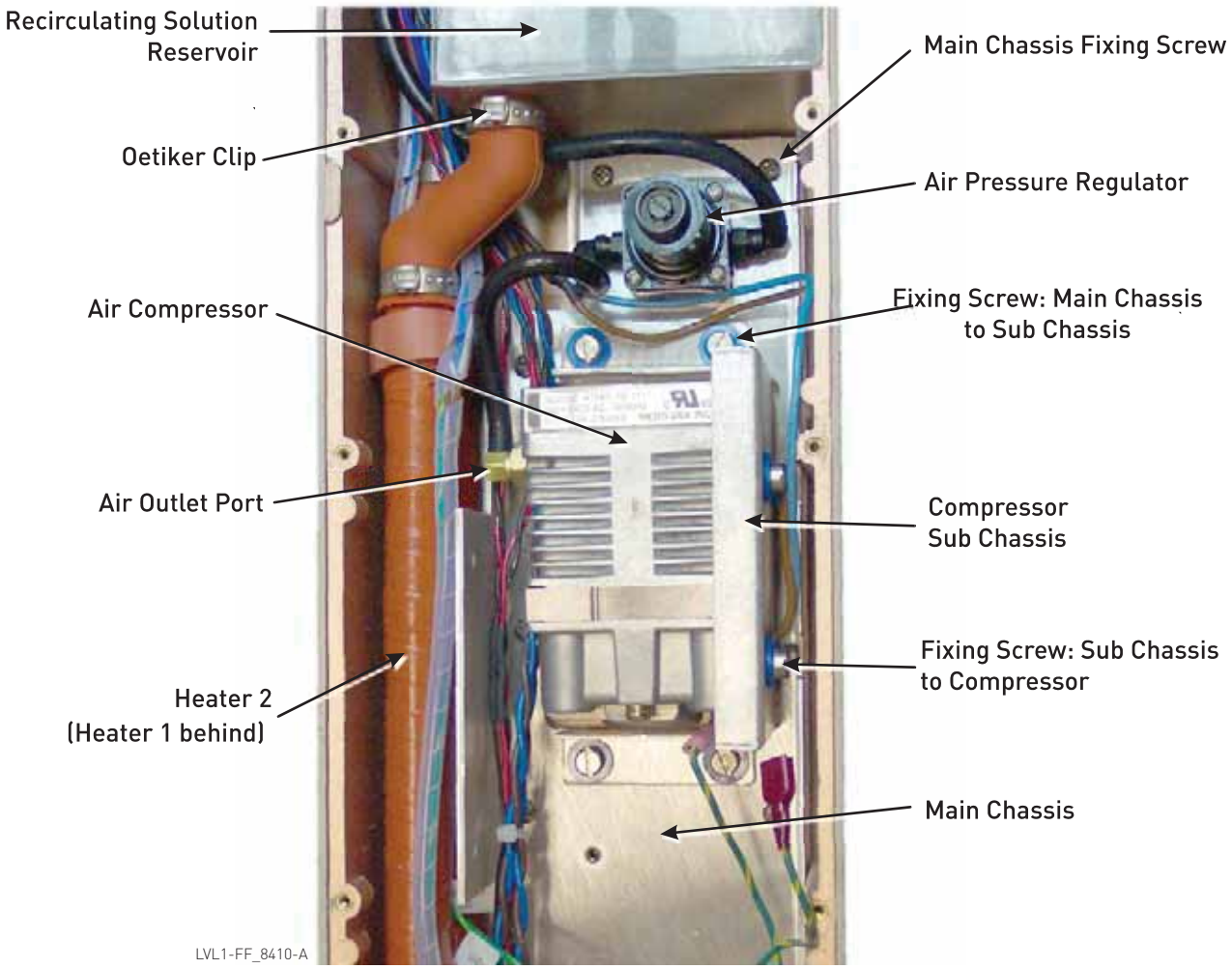


Figure 4 - 10: Parts in the vicinity of the Compressor

Replaceable parts in this area are:

- *Compressor*
- *Regulator*
- *1/4 inch Black tube*
- *Heater Assembly*

Part numbers for these (and other) spares will be found in Section 7.

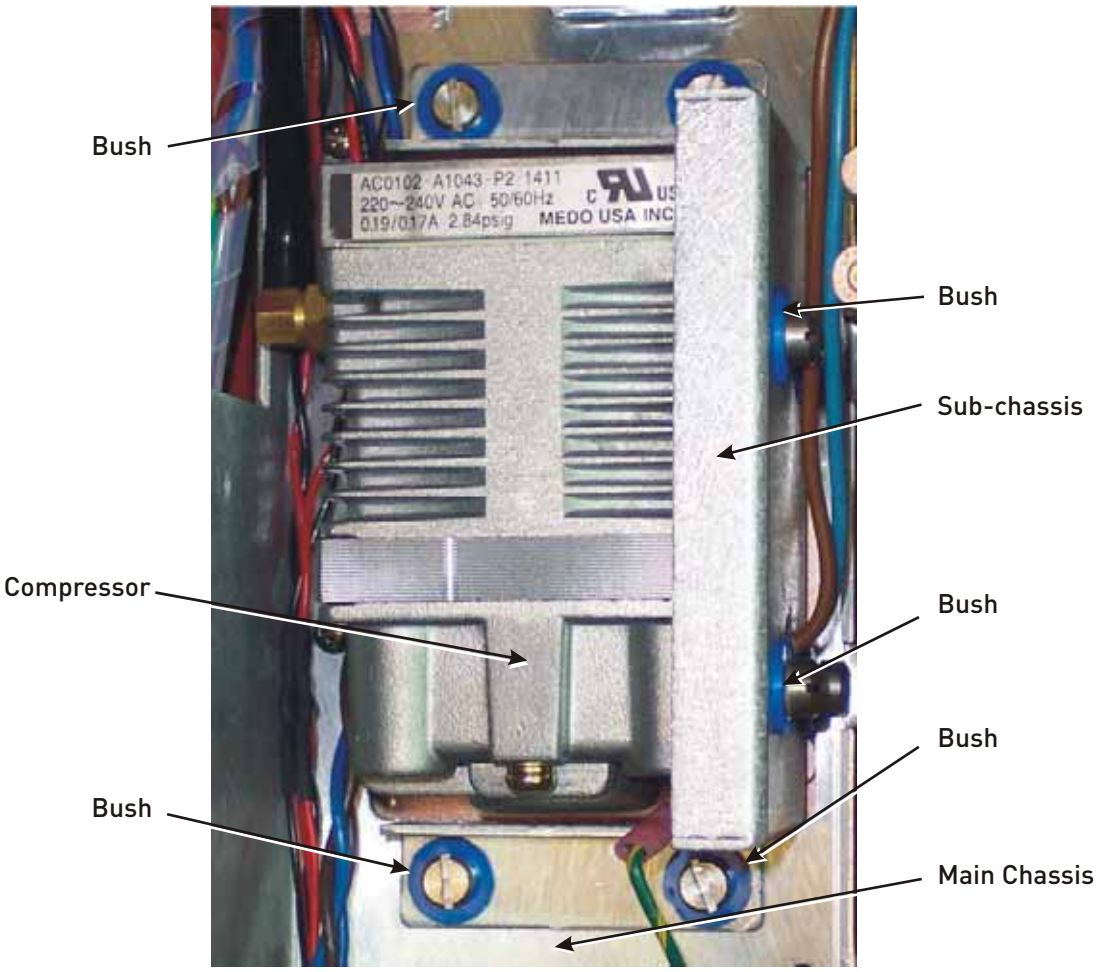


Figure 4 - 11: Acoustic decoupling between the compressor and it's sub-chassis, and also between the sub-chassis and the main chassis, to reduce the nuisance of the compressor's buzzing noise.

Be careful to get the Regulator input and output air ports correctly identified: although no lasting damage will be done, the system will not function correctly if they are reversed.

The following parts are replaceable if necessary:

- *Acoustic Shock Mount Sub-Chassis,*
- *Blue Bushes and M4 Shoulder Screws*

Around the Pump

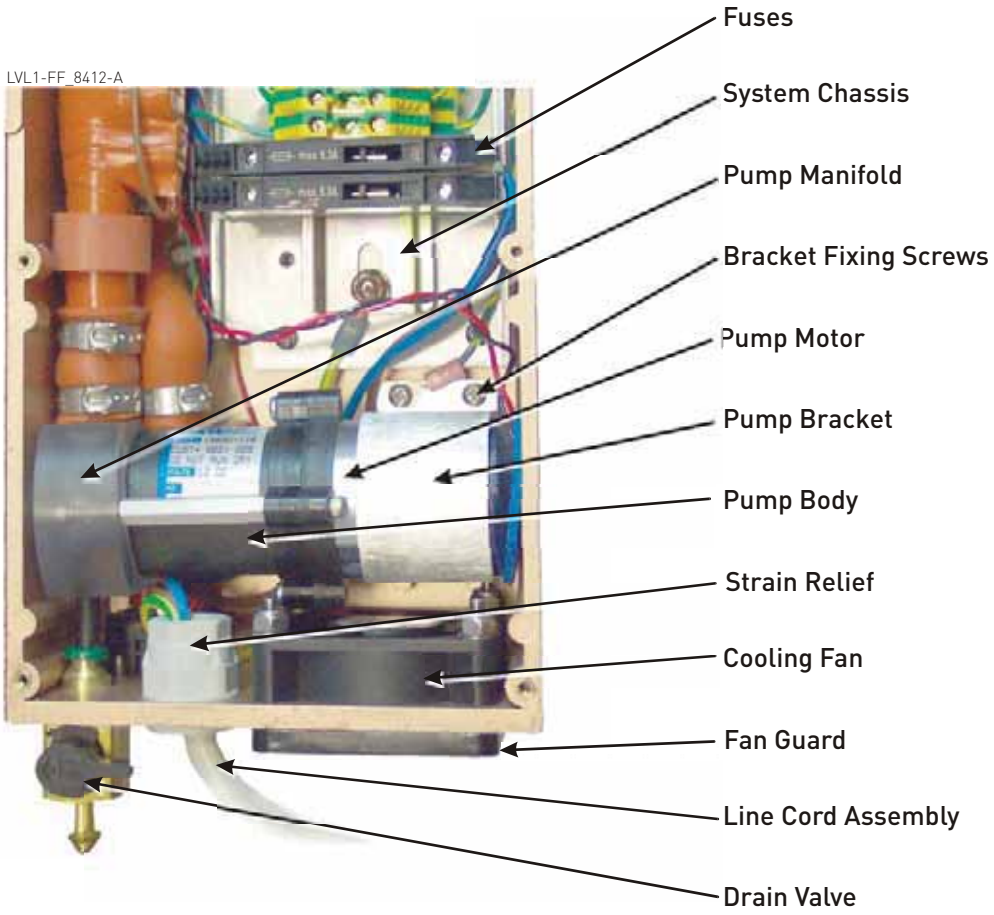


Figure 4 - 12: The Pump and it's surroundings

Useful Parts:

- *Pump*
- *Drain Valve*
- *Fan 12v DC*
- *Fan Guard*
- *Strain Relief*
- *Strain Relief Nut*
- *Line Cord Assembly*

Replacing the Upper Thermistor

The Upper Thermistor is easily visible after removal of the top socket from the unit (See Figure 4 - 8, “Removal of the Top Socket,” on page 63)

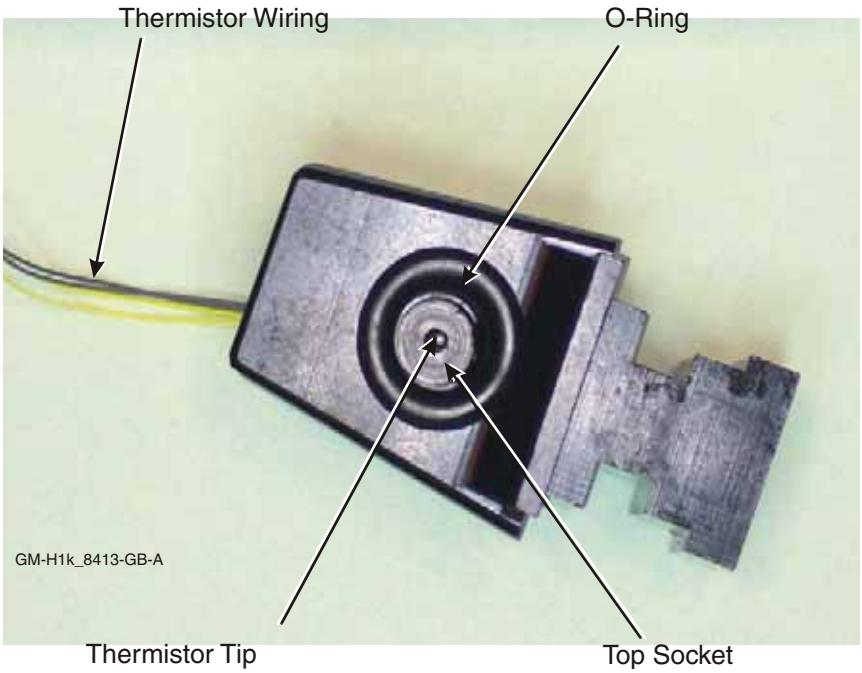


Figure 4 - 13: The upper thermistor package is seen “end-on” in this view.

The thermistor package itself is retained purely by friction and a small O-Ring (not visible in this picture). It can be pushed out in the direction of the wires, and a replacement re-inserted from the same side. Don’t pull on the wires unnecessarily.

O-Rings can be lubricated while “in situ” with a smear of silicone grease on a cotton bud. Always lubricate new O-Rings.

Replaceable Parts:

- *O-Ring (set)*
- *Upper Thermistor package*

Replacing the Lower Thermistor

The Lower Thermistor package is accessible from inside the unit, adjacent to the reservoir.

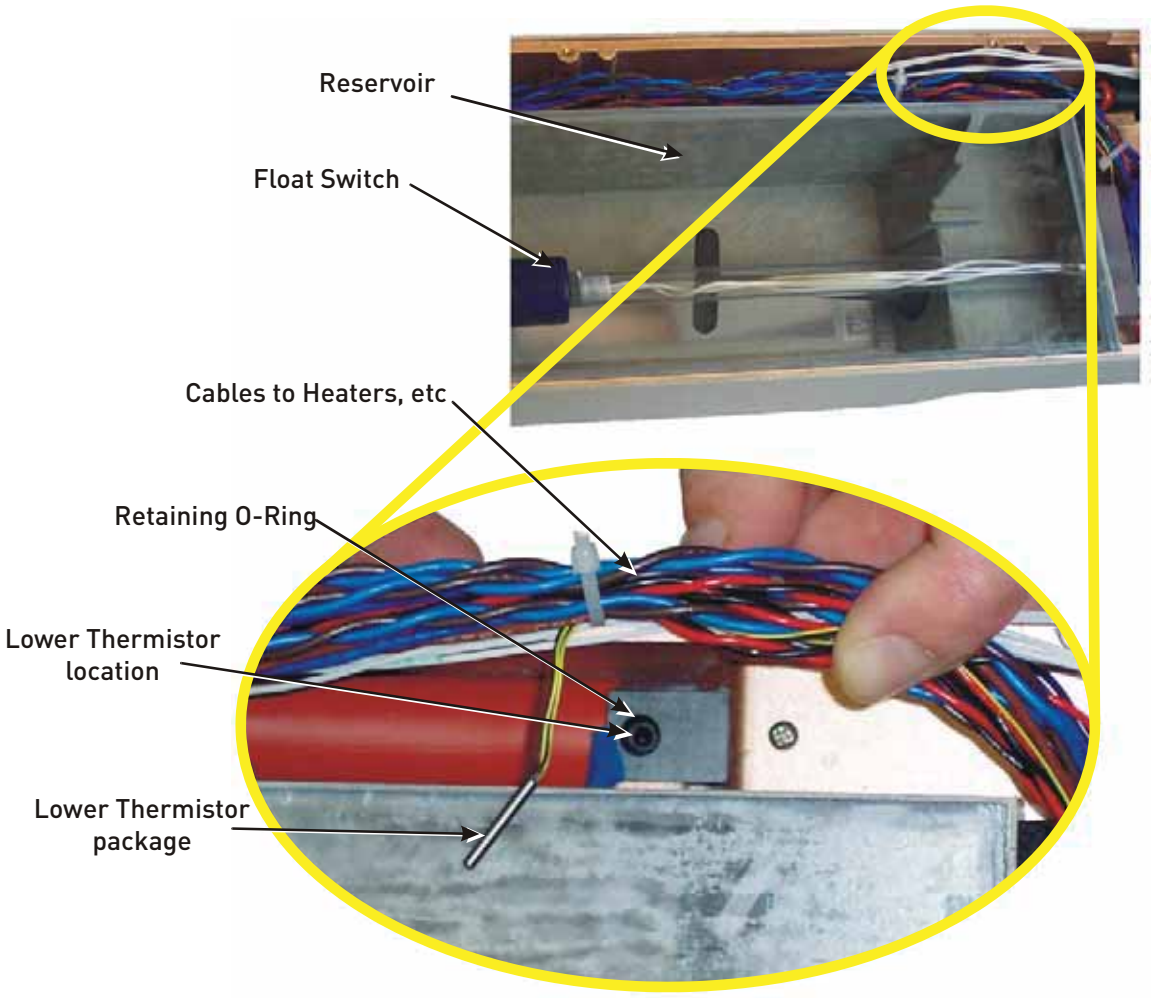


Figure 4 - 14: Lower Thermistor Location

Replaceables:

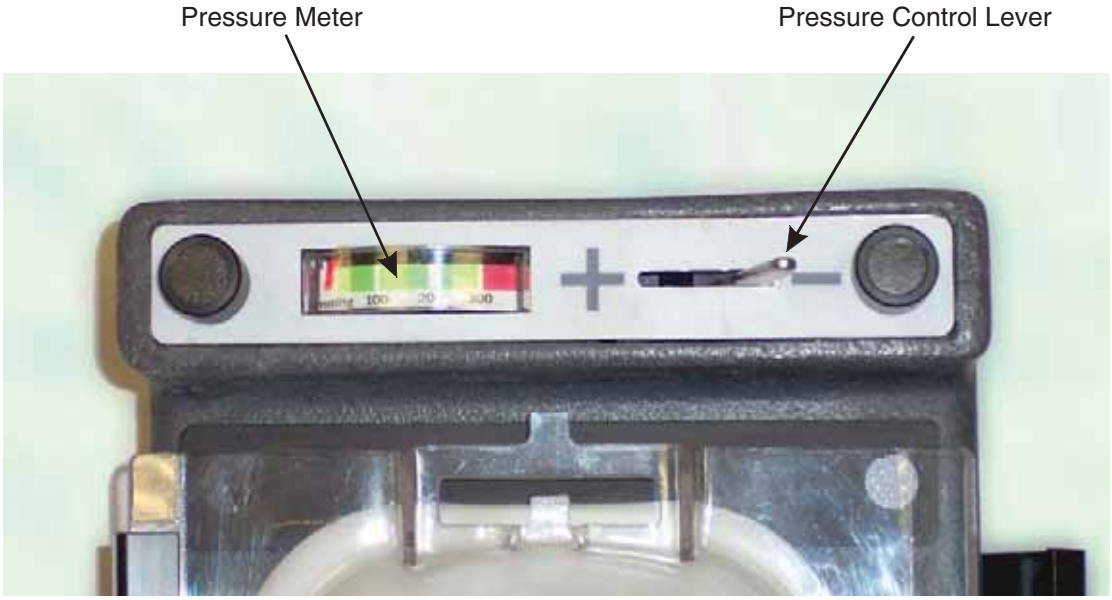
- *Lower Thermistor package*
- *Small O-Ring*

The Pressure Chambers

NOTE: Before starting work on the pressure chambers, disconnect the air hose from the system unit, and vent any residual pressure to atmosphere by moving the control lever to the deflate position, indicated by the "-" sign. Double check with the pressure meter that the pressure has dissipated before opening the pressure chamber.

NOTE: If your pressure chambers are made from a beige-coloured plastic, see the section on the newer-style chambers on page 79

Original Design.



GM-H1k_8415-GB-A

Figure 4 - 15: Original design Pressure Control Lever and Pressure Meter

Remove the pressure chamber from the pole by completely undoing the two screws at the back of the unit that retain the poleclamp.

To Remove the Clear Plastic Front

Hold the pressure chamber face down as shown, with the door held firmly in the open position by the right hand.

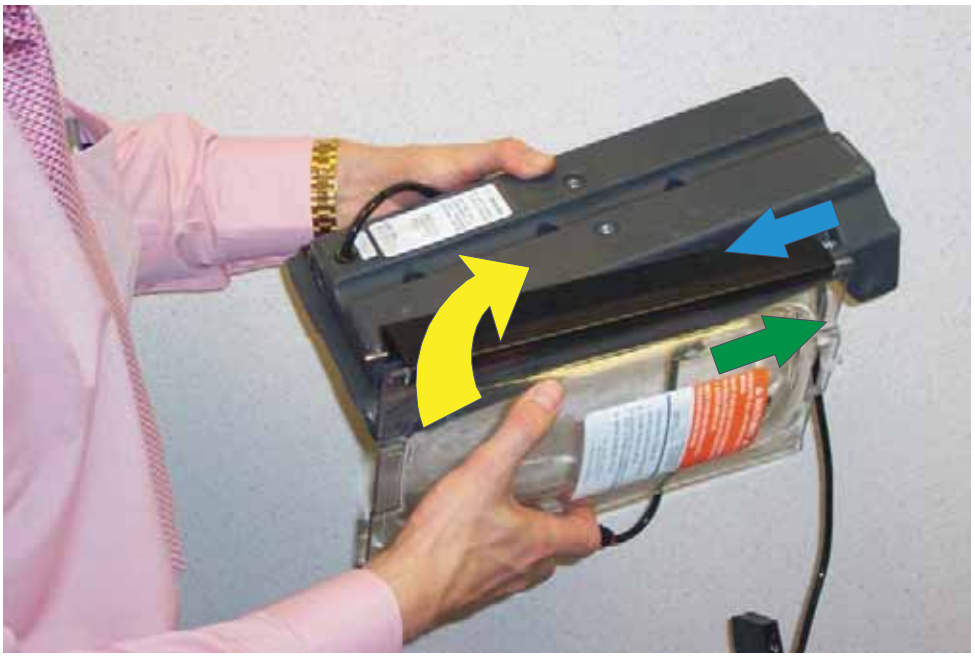


Figure 4 - 16: Removing the front door

Push the door in the direction of the GREEN arrow until the spring-loaded bottom pin is freed.

Twist the door in the direction of the YELLOW arrow to disengage it.

Finally release the spring tension by allowing it to move back in the direction of the BLUE arrow.

Removing the Bladder

Figure 4 - 17: Removing the Bladder - 1

Carefully peel away the Velcro® tape that holds the bladder in place. Underneath the bladder you will find two air hose connectors. These have a retaining action that requires you to push the ring that surrounds the connection *into* the connecting piece to release the grip on the hosepipe. *(See picture below)*

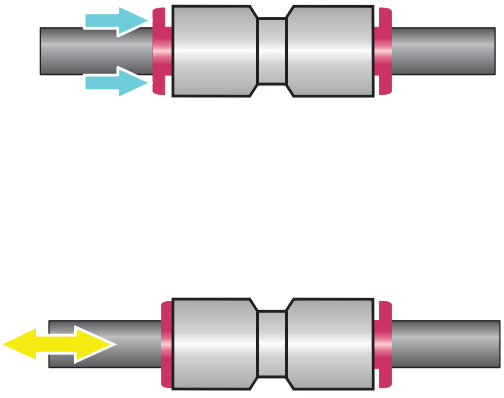


Figure 4 - 18: Removing the Bladder - 2

The two connections to the bladder are different sizes, so they cannot be incorrectly refitted. The larger of the two supplies and removes air for inflation and deflation purposes. The smaller connector takes the air pressure to the pressure meter for monitoring.

Figure 4 - 19: Removing the Bladder - 3

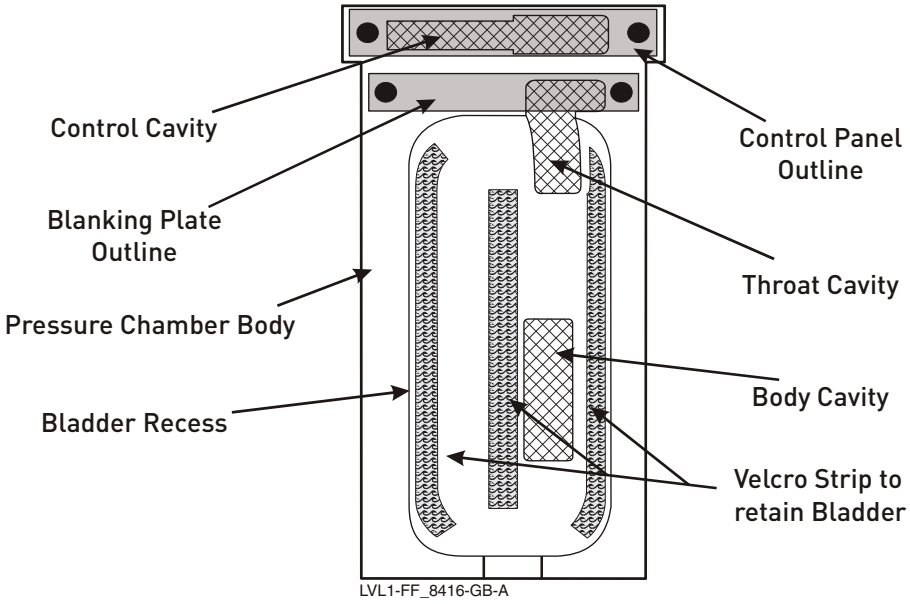


Figure 4 - 20: What's behind the bladder.

Figure 4 - 21: The pipe from the Bladder to the Pressure Meter can be eased out of the throat cavity: there's more of it than you would expect!

Internal Pressure Chamber Components

The next step is to open up the access panels or cover plates that camouflage the cavities. They are secured with concealed screws, covered with black self-adhesive "buttons" which can be gently lifted off and retained for re-use.

Figure 4 - 22: Removing the Cover Plates - 1

Figure 4 - 23: Removing the Cover Plates - 2

Any further dismantling required, to replace faulty components, for example, can be tackled with confidence, by inspection and copying of the existing arrangement of parts.

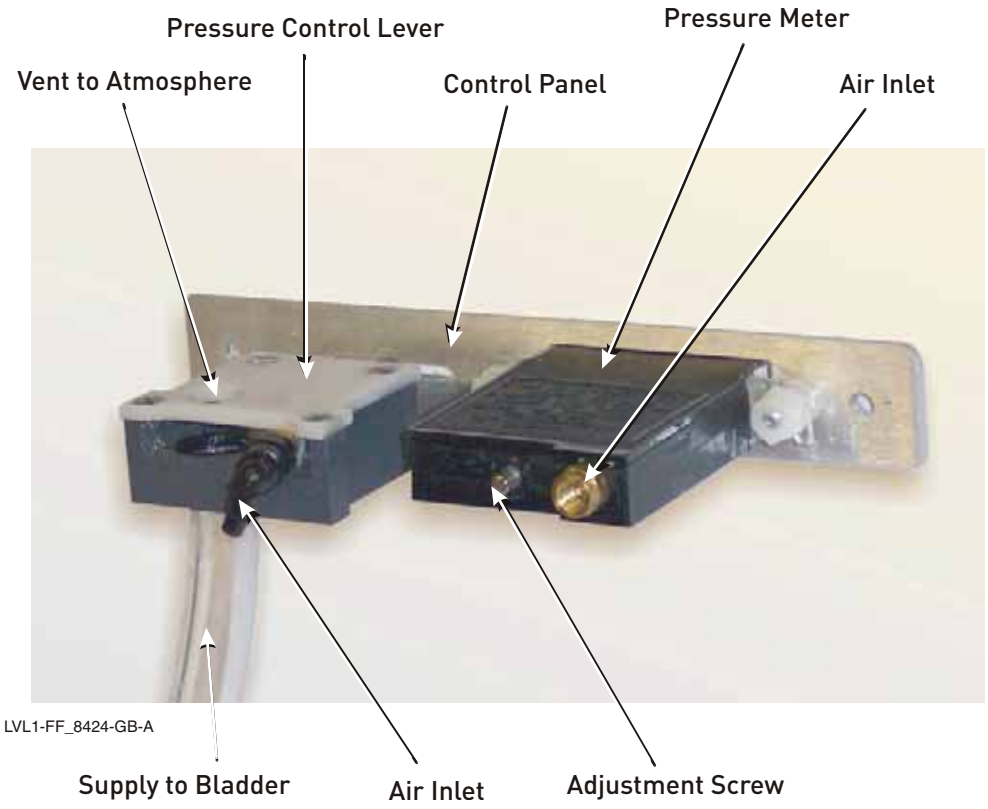


Figure 4 - 24: Pressure Chamber Control Panel - Rear View

Flexible ¼ inch pipe-work connects the various active elements together. There is a tee-piece that forms a branch to an overpressure valve which limits the maximum force that can be applied to the infusate bags.

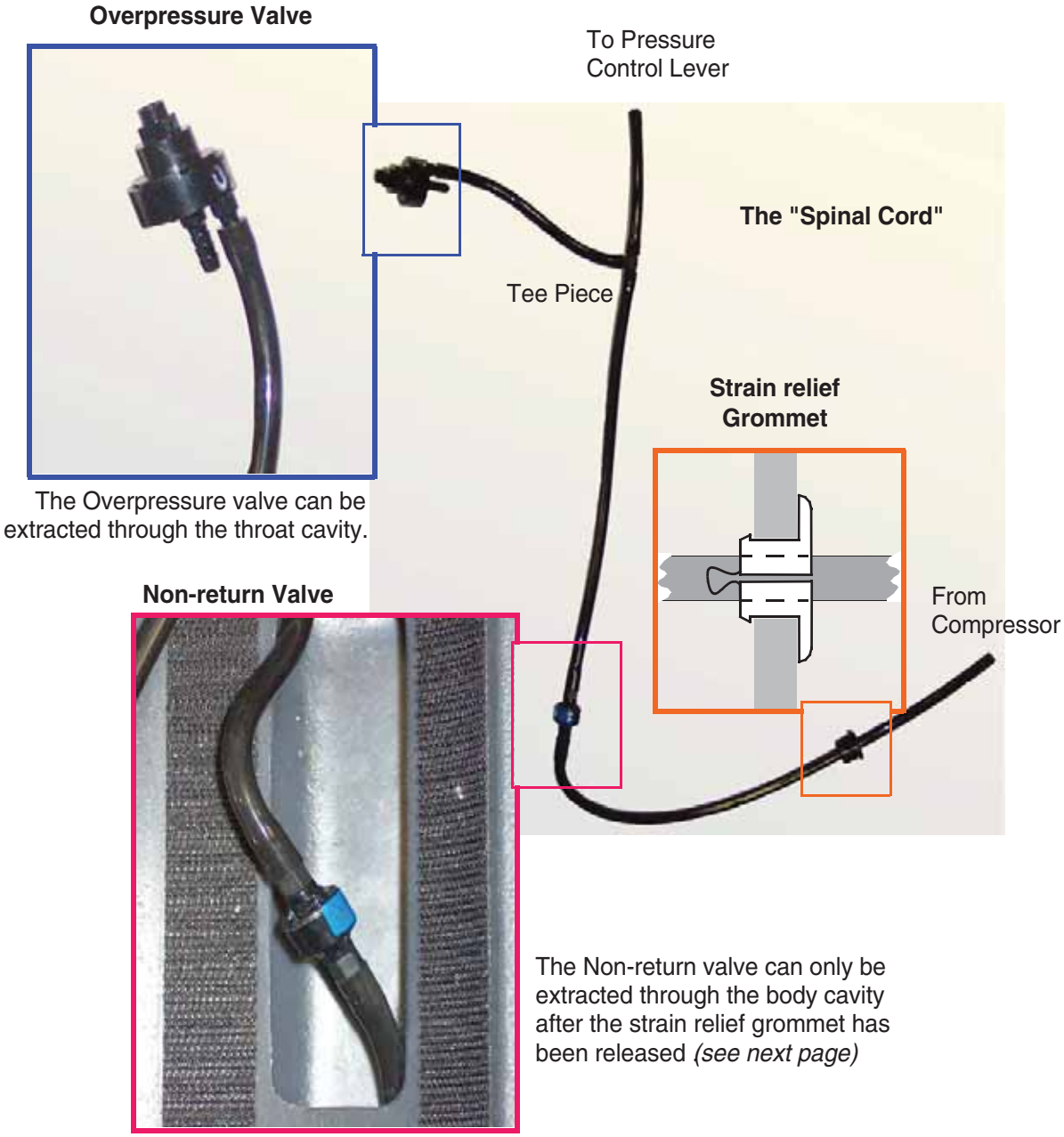


Figure 4 - 25: These parts are normally hidden within the body of the pressure chamber

The non-return valve maintains the current pressure on the infusate, even if the supply hose is accidentally disconnected. If the pressure in the infusate bag were suddenly reduced, backflow could result.

Releasing the Strain Relief Grommet is a matter of squeezing the two halves together so that the tangs can be eased out through the hole towards the outside of the chamber body.

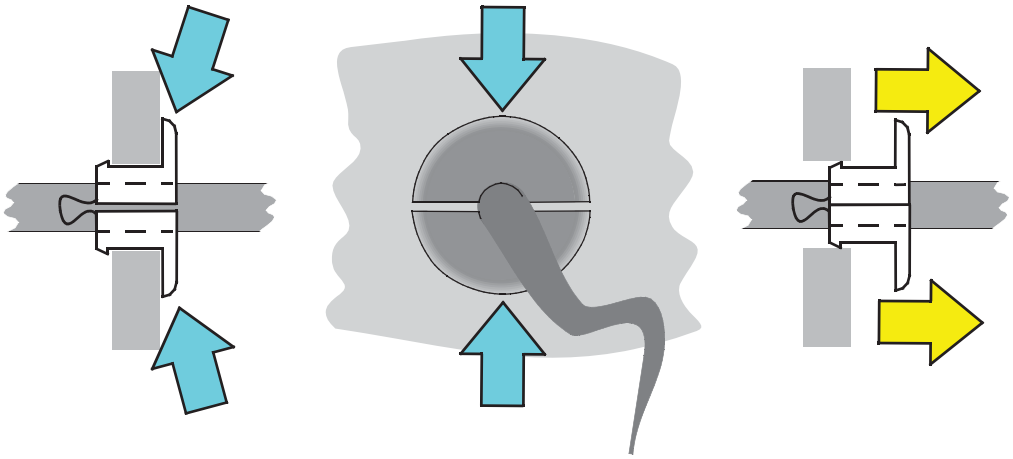


Figure 4 - 26: Dealing with the Strain Relief Grommet

Refitting is the reverse process.

New Style Pressure Chambers

The newer style of pressure chamber can be identified by the off-white plastic material used for the main body mouldings. Early models were charcoal grey. Further differences can be observed at the control panel: new style models have moulded cheeks to protect the meter and operating lever against knocks and damage.

Figure 4 - 27: New- style H-2 Pressure Chamber, front view

Removing the Door and Bladder

Unclip the black retaining clip on the left hand front edge to open the moulded transparent door. By pushing gently upwards against the spring, the door hinge can be disconnected from the body of the pressure chamber.

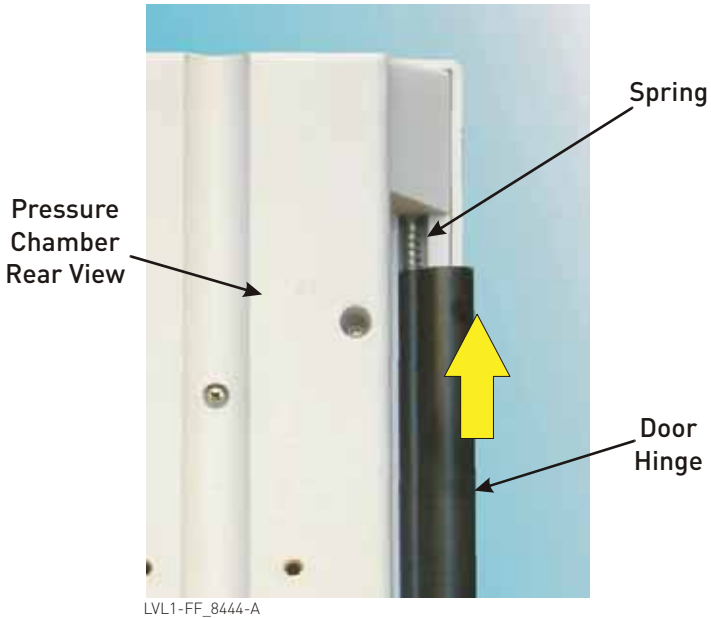


Figure 4 - 28: Unhitching the door hinge

At this stage the bladder can be removed from the front cavity and replaced if necessary. It is retained by three Velcro strips. See the previous section “Removing the Bladder” on page 72 for disconnection information if needed.

The bladder can be removed by working entirely from the front, but if you are planning on doing other work that requires access to the insides of the pressure chamber, you will find it a bit easier to wait until the back is off before disconnecting the bladder.

Internal Parts

Replacing any of the internal parts means undoing the back of the unit. Place the pressure chamber, minus the door, face down on a suitable firm surface and undo the nine retaining screws. The back of the case can be lifted off and placed to the side. Remember it is still attached to the front section by an air hose.

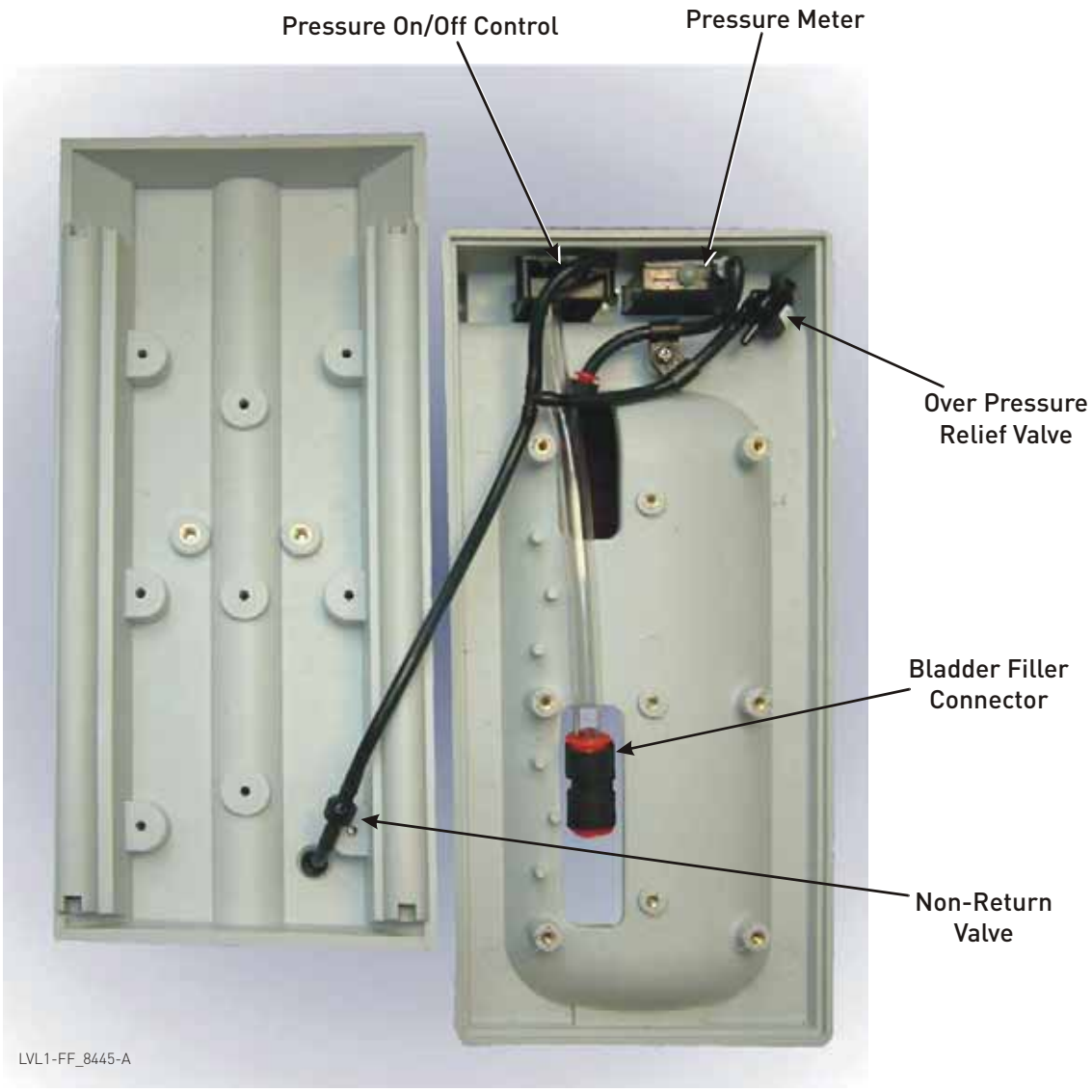


Figure 4 - 29: New style Pressure Chambers - internal view

All internal components are now accessible, and may be replaced as necessary.

When re-assembling, ensure that the black air hose is routed to the inner side of the case screw boss as shown in Figure 4-31, to avoid it becoming trapped and damaged.

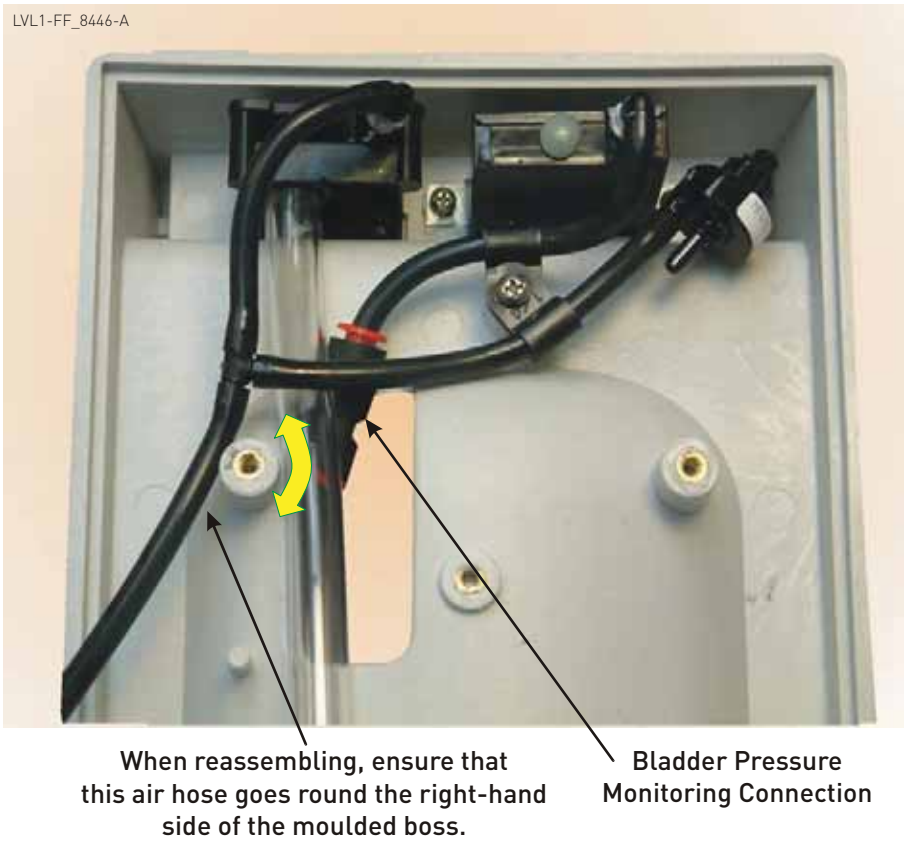


Figure 4 - 30: Reassembly: caution needed here

H-31B Air Detector / Clamp

You will need:

- Small and medium (#1 and #2) Phillips screwdrivers.
- Imperial size Allen Keys ($^{1}/_{8}$, $^{5}/_{64}$, and $^{3}/_{32}$).

NOTE: Note: For some of the 5/64 Allen headed screws, you will find it very much easier to use a ball ended hex driver rather than the regular "L" shaped key.

NOTE: Note: Unless specifically noted otherwise, references to H-1200 will be taken to include H-1000 or H-1025 Fast Flow Blood and Fluid Warmers.

Separating the H-31B from the Tower

Make sure the tower unit has been drained down, and separate it from the wheeled base / pole assembly. Lay the tower face down using two suitable support blocks, one at each end to allow it to lie flat and steady, keeping the weight off the socket connectors. The foam transit packaging pieces are ideal for this. Having a scrap Gas Vent inserted into the #4 clip position is a good idea, as it will help prevent the weight of the H-31B from straining the mains wiring.

(H-1000, H-1025) Unplug the mains supply to the H-31B from the socket on the bottom of the tower, and release any cable clips tidying the cable run.

Remove the screws that secure the back panel, making sure to support the weight of the air detector / clamp as you release the two screws that also hold the H-31B's retaining bracket.

(H-1200 only) With the back of the tower removed, locate the mains wiring that supplies the H-31B. You will find an earth wire going down to the bottom of the tower unit to the terminal rail there, and a live/neutral pair going up past the reservoir and linking to the "Aux" output of the PCB. Release these wires (making a note of where they were attached), and disentangle them sufficiently to allow the H-31B to lie comfortably alongside the tower without straining the wiring.

Opening the H-31B

(Refer to photo, overleaf) Undo the two Phillips screws (1), (2) on the back of the H-31B and remove the retaining bracket.

Using the 5/64ths Allen key, undo the four remaining screws (3), (4), (5), and (6) that hold the Rear Enclosure Cover of the H-31B to the internal chassis. There is an additional screw at the bottom of the enclosure (7) that must be removed.

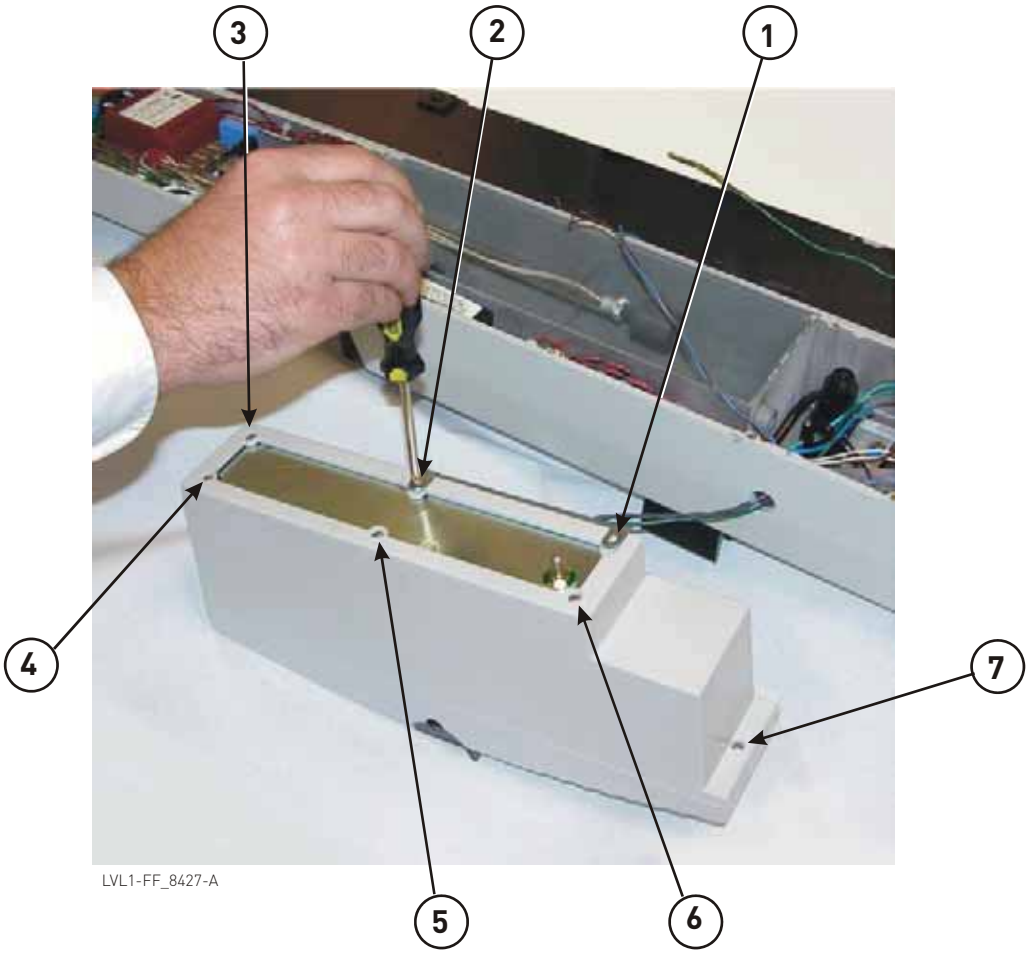


Figure 4 - 31: Removing the rear casing of the H-31B

With a small craft knife, make a cut through the sealing gasket at the point where it turns the corner between the Rear Enclosure Cover and the flange of the Front Panel Moulding. At this stage the Rear Enclosure Cover can be slid up over the chassis and put to one side. It is usually a snug fit and may need patience, persistance and some manipulation to remove. If it is on an H-1200, take care not to overstress the mains wires of the H-31B where they exit through the hole in the side.

Accessing the PCBs

The internal chassis is made up of a Baseplate fixed to the inside of the Front Panel Moulding, on which are mounted the mechanical components that make up the solenoid-operated tubing clamp. The left hand Side Support Plate (as viewed from the front of the unit) supports the PCBs and power supply electronics. The right hand Side Support Plate serves to provide mechanical strength and rigidity.

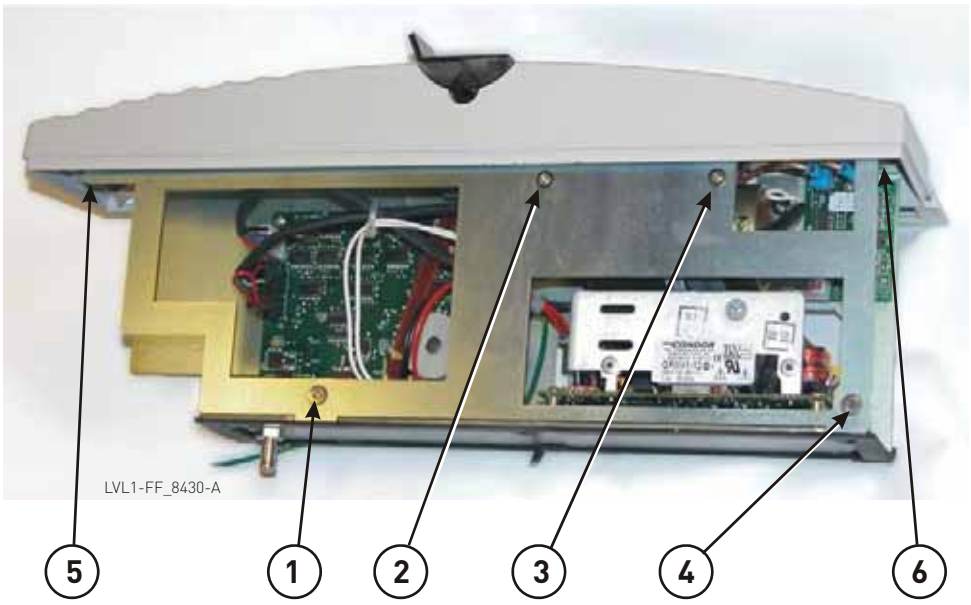


Figure 4 - 32: Removing the right -hand Side Support Plate

Lay the H-31B on its left side (the side nearest to the tower when fully assembled) and remove the right Side Support Plate.

There are four screws facing you (1), (2), (3), and (4) and two more (5) and (6) attaching the Side Support Plate to the Front Panel Moulding. Note the sizes of these screws, as they are not all identical.

With the support plate removed, you have access to the two PCBs.

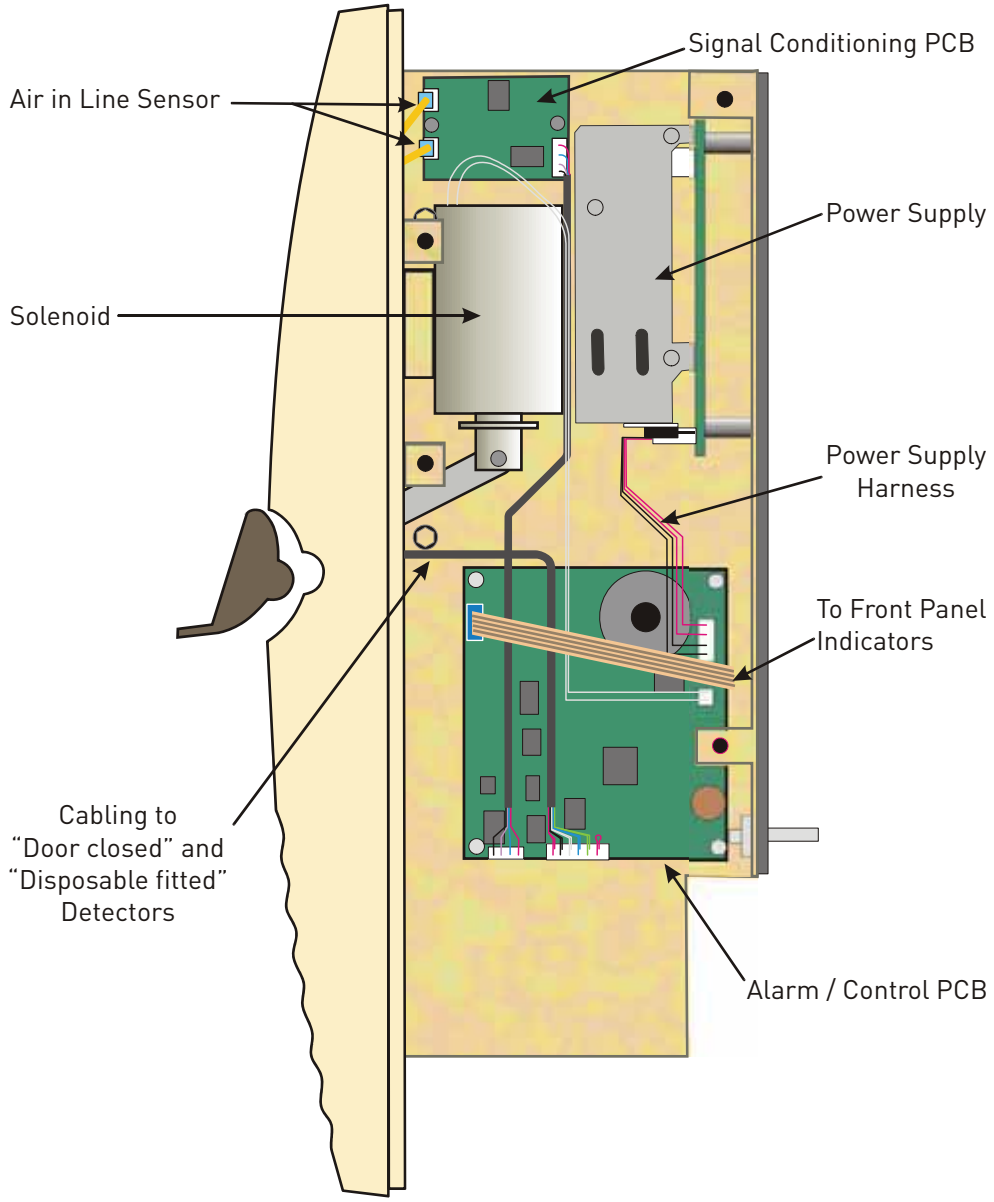


Figure 4 - 33: H-31B internal electronic components

Power Supply Module

To fully access the Power Supply Module, it is necessary to remove the left Side Support Plate. Before separating the left Side Support Plate from the Baseplate, unplug the twin blue connectors for the Air-in-Line Sensor wiring, the Indicators' ribbon cable, the Solenoid connector, and the "Door Closed" / "Disposable Fitted" Sensors' connector, so as not to overstrain them.

Two screws (1) and (2) attach the left Side Support Plate to the Baseplate. These are a little tricky, as they undo from the inner side of the plate, rather than from the outside. This makes one of them - (1) in the picture, below - particularly awkward to access. This is where having a ball ended hex driver really comes in handy.

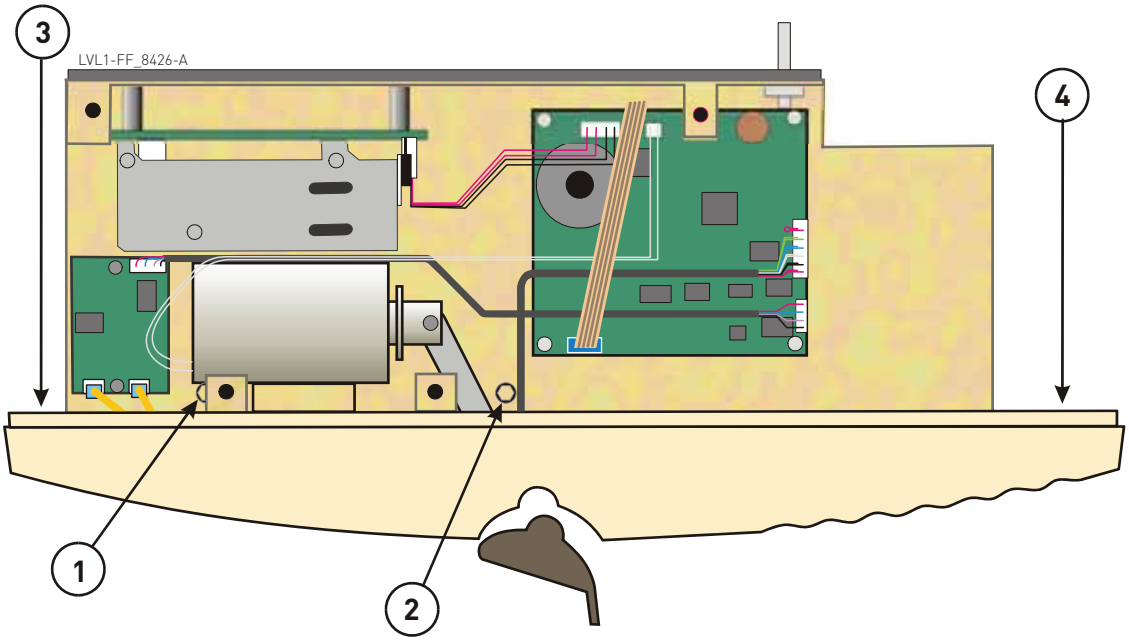


Figure 4 - 34: Dismantling the left Side Support Plate

Two more screws (3), (4) attach the left Side Support Plate to the Front Panel Moulding. In early models (before November 2005), the bottom-most screw (4) also secured an earth strap,

This earth connection subsequently proved redundant and it was eliminated from production. If your unit has a *sound* earth strap, take note of the routing so you can replace it as you found it. However, if the earth strap on your unit is damaged, then it's not necessary to replace it. Instead, just trim the loose end back to where it passes through the slot in the front panel moulding, so that it cannot foul on any part of the moving mechanism. Take care not to damage the flexi-ribbon cable feeding the front panel LEDs

Figure 4 - 35: Left Side Support Plate - Earth Strap Close-up

With the left Side Support Plate detached, it is a simple task to disconnect and remove the Power Supply Module if it is to be replaced.

"Door Closed" and "Disposable Fitted" Sensors

These two related sensors can be found attached to the Baseplate, just below and to the left of the Solenoid. They share a common wiring harness, so should only be removed and replaced as a pair.

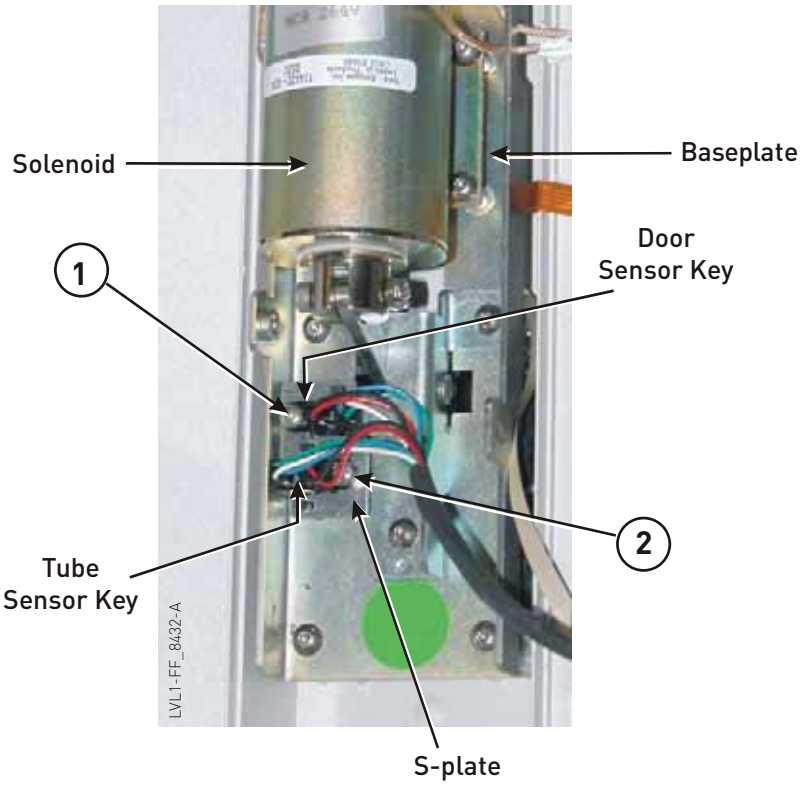


Figure 4 - 36: Location of the Optosensors for “Door Closed” and “Disposable Fitted”

Loosen the two Phillips screws (1) and (2), but prior to removing them, apply light pressure to the S-Plate with thumb and finger, so as to prevent the Key Return Springs escaping. With the screws removed, and maintaining the pressure on the S-Plate, the sensors and their harness can be extricated. Once the Optosensors are clear, you can gently release the pressure on the S-plate. The S-Plate and Key Return Springs will normally remain in place unless you invert or severely tilt the Front Panel Moulding.

Air-in-Line Sensor

The Air-in-Line Sensor assembly is held by the two Phillips screws behind the flange section of the Front Panel Moulding. Removal is greatly simplified if the Solenoid / Baseplate assembly is loosened from the Front Panel Moulding, to allow the connectors to more easily pass through the hole in the chassis. Lift off the S-Plate covering the door and tube Sensor Keys, being wary not to lose any of the tiny Key Return Springs. Lift out both Keys, noting the difference in sizes and shapes, and the orientation of the Door Sensor Key.

To release the Baseplate, undo the screws (1) through (4) shown in Figure 4-38. Note that screw (1) is slightly longer than the others. Screw (5), although it appears to require removing, can, and should, be left in situ during this operation.

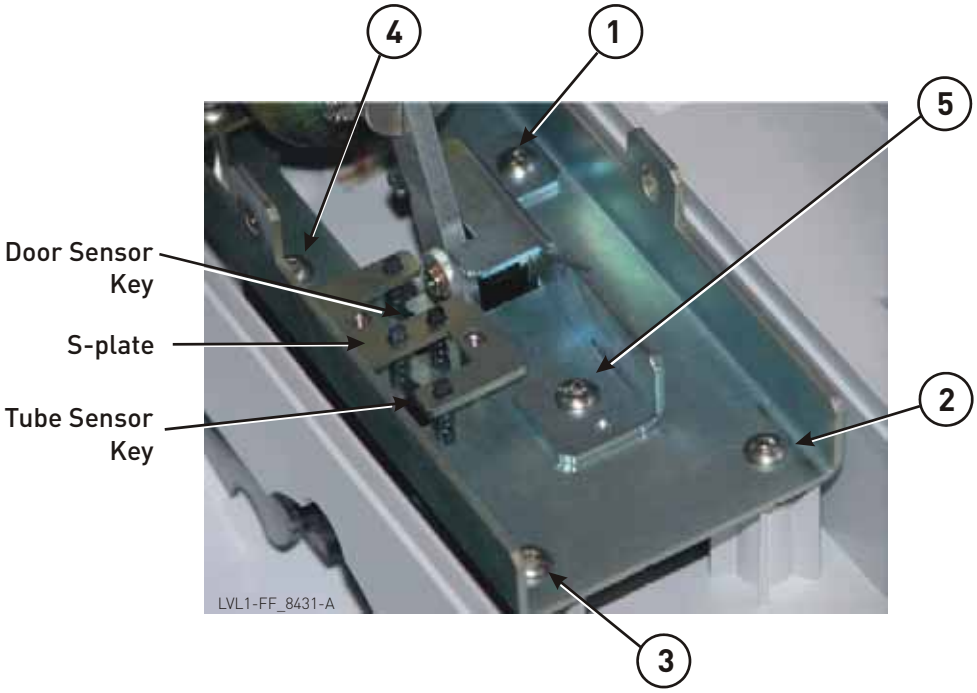


Figure 4 - 37: Releasing the Baseplate

It is not necessary to completely remove the Solenoid and Baseplate assembly for this procedure. All we need is enough clearance to facilitate threading the Air-in-Line Sensor cables and their connectors through the chassis opening.

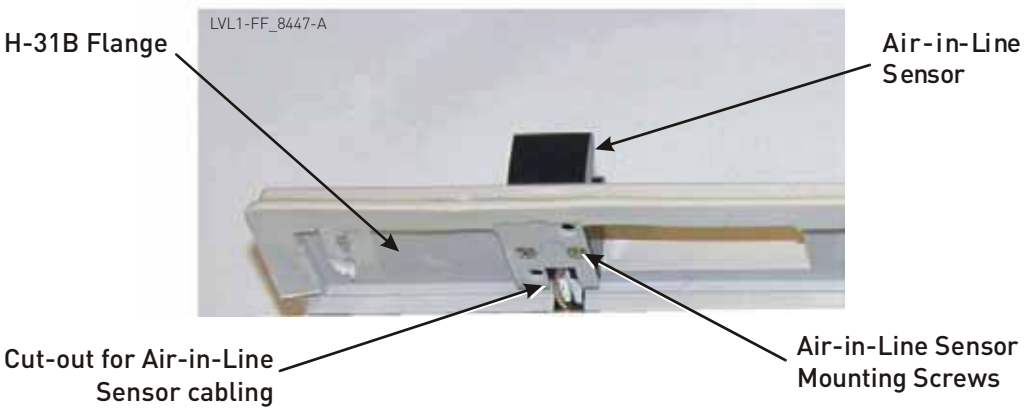


Figure 4 - 38: Air-in-Line Sensor Location

Solenoid Assembly

To completely remove the Solenoid and Baseplate from the Front Panel Moulding, slide the assembly towards the top of the Front Panel Moulding ("top" in this context means the uppermost end when the H-31B is mounted on a vertical tower unit in the normal way). The Clamp Plunger will slide out of its guideway in the moulded Clamp Slot Block, and the Solenoid assembly is now free.

Reassembly

To reassemble the H-31B, start by offering up the Solenoid and its attached components to the Front Panel Moulding. Holding the Front Panel vertically, top end upwards, manoeuvre the Clamp Plunger so that it drops back into its guideway. Notice the routing of the Indicators' ribbon cable and the earth strap, if present, and ensure they are not trapped or strained.

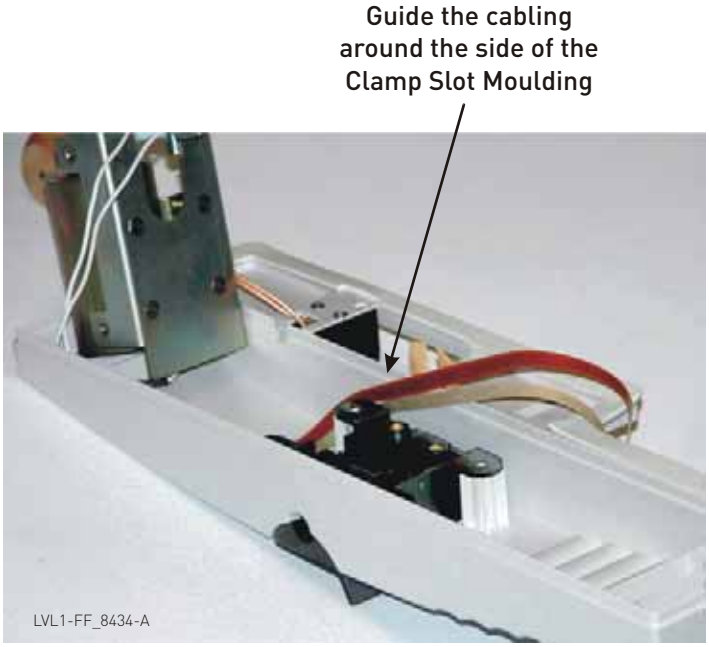


Figure 4 - 39: Ribbon Routing

Make sure the Air-in-Line Sensor wiring is threaded through the hole in the chassis side, then line up the screw holes with the threaded inserts and replace the screws, putting the longer screw in the #1 location (Figure 4-38). Reattach the Air-in-Line Sensor if it has been removed. You will see a small cutout in the Air-in-Line Detector base to clear the wiring: the sensor unit must be oriented so that this cutout is aligned with the wiring cutout in the Front Panel Moulding.

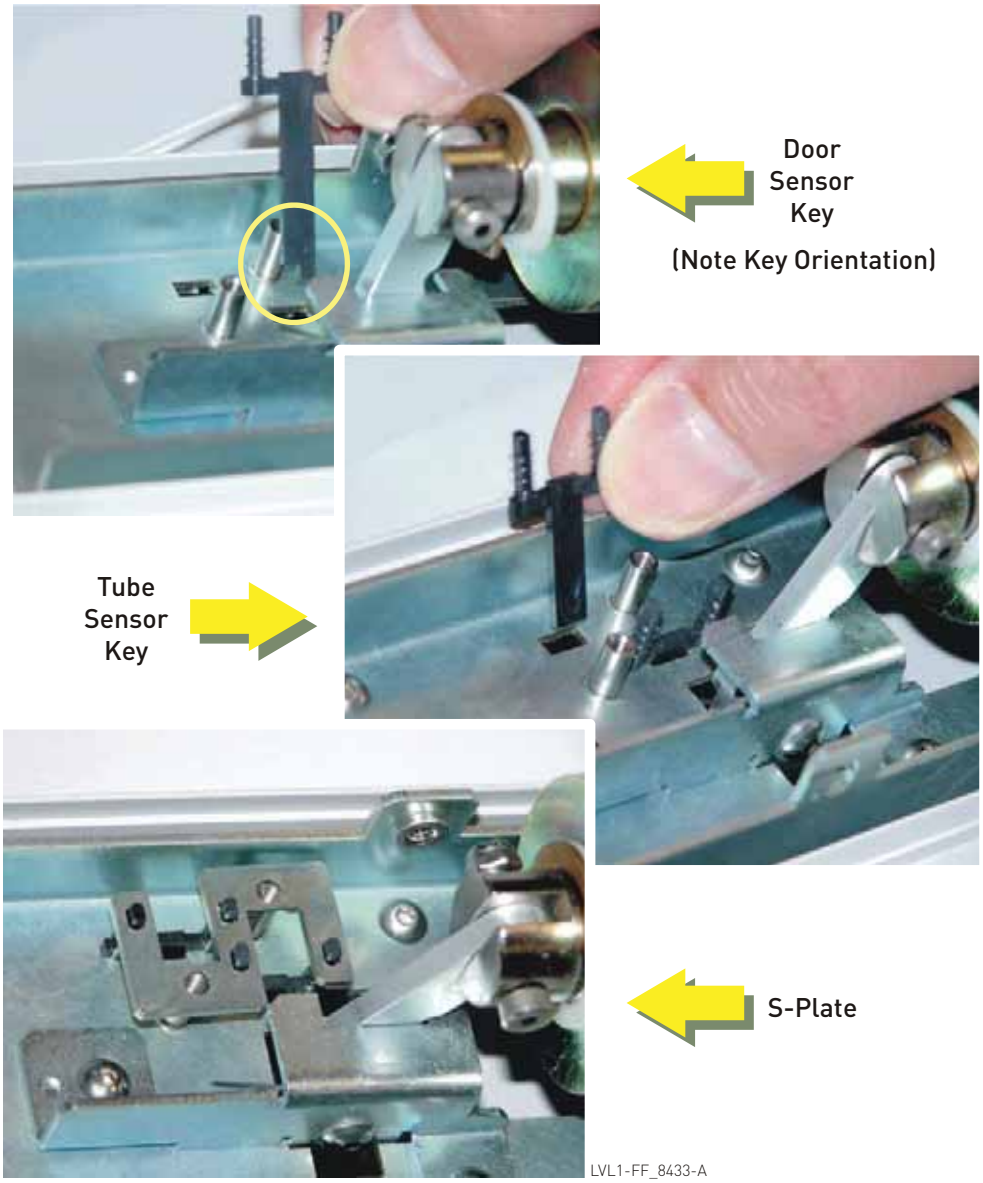


Figure 4 - 40: Reassembling the Optosensors and their actuating keys

Insert the Door Sensor Key and the Tube Sensor Key into their respective slots. The Door Sensor Key must be inserted as shown, with the protruding flag nearer to the Solenoid. Ensure that each of the plastic pegs on the back of each key has a Key Return Spring in place. Drop the S-Plate into position over the springs, noting the orientation. Refit the "Door Closed" and "Disposable Fitted" Optosensor pair.

Re-attach the left Side Support Plate. You may find it helpful to use a long 5mm diameter screwdriver (A) behind the Side Support Plate. By resting the screwdriver in the lip of the Front Panel Moulding (B), it lifts the Side Support Plate roughly into place so you can get the screws (C) started in their threaded inserts.

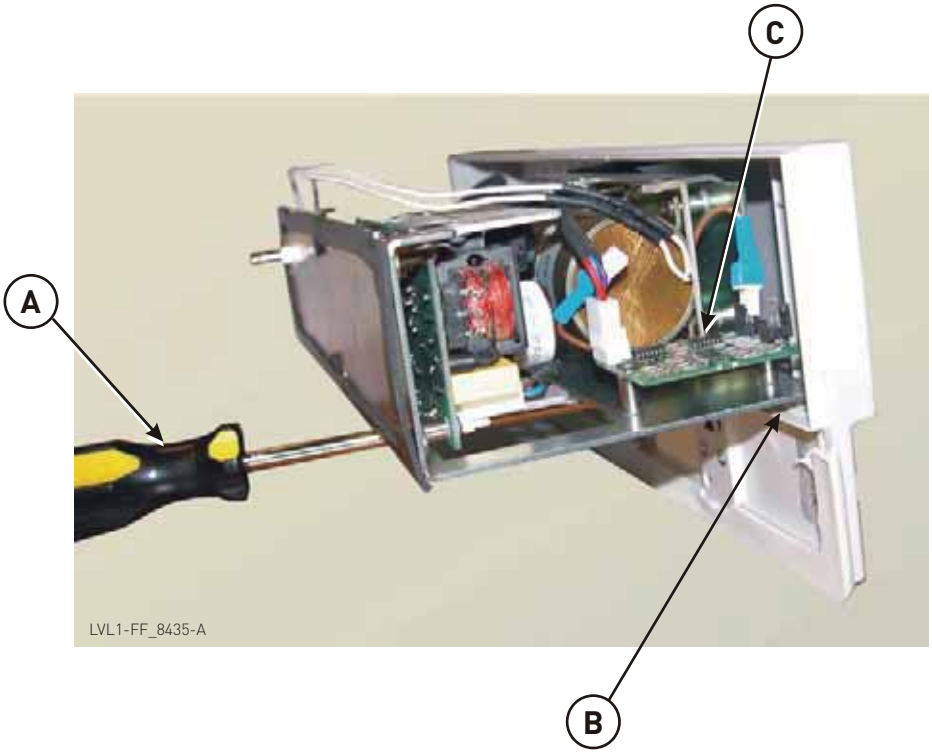


Figure 4 - 41: Re-attaching the left-hand Side Support Plate

Don't forget the earth strap (if fitted) when you refit the screw at the bottom of the Front Panel. Route the Indicators' ribbon cable through the large hole under the control / alarm PCB, around the edge and over the top of the PCB. Secure the ribbon to the left Side Support Plate with a small piece of adhesive tape, so that it will not be able to chafe against the rear enclosure cover when that is refitted.

Plug in any other wiring connectors that have been disconnected. Notice that one of the Air-in-Line detector cables is marked with an adhesive label. This cable goes to the pin connector nearer to the top edge of the H-31B (i.e., the pin connector furthest from the solenoid).

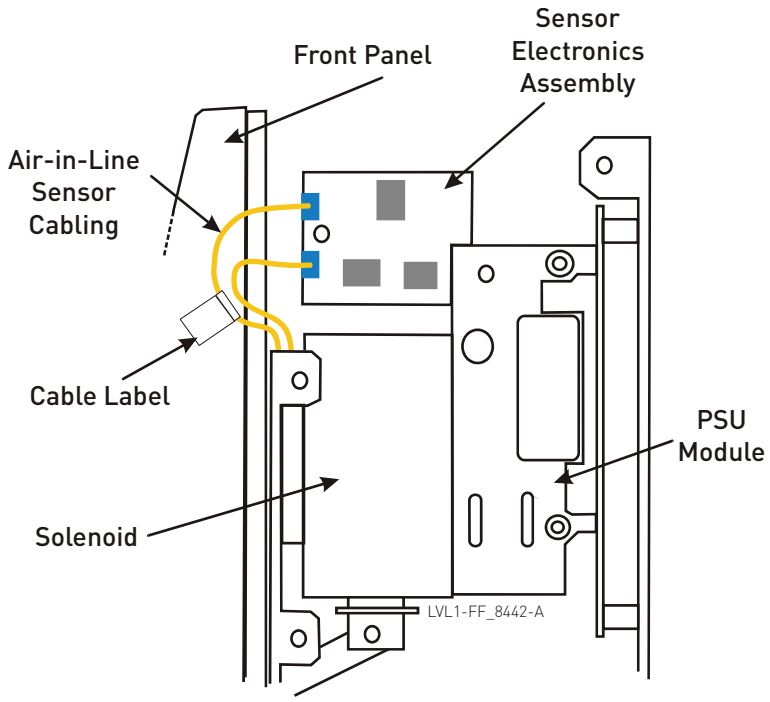


Figure 4 - 42: Air-in-Line Sensor Wiring Diagram

Tidy the wiring with a plastic cable tie. Refit the right Side Support Plate. Check that the Solenoid armature and its attached lever mechanism moves freely and that it "drops" into the Clamp Open state when held upright.

Thread the mains wiring through the side hole in the Rear Enclosure Cover and gently ease the cover into place. Refit the case screws and the mounting bracket.

Perform the Functional Tests (page 116) and the Operational Tests (page 145) before returning this unit to active service.

To replace the Door

You will need:

- $^{3}/_{32}$ *Imperial size Allen key*

NOTE: To replace the Door it is not necessary to remove the Door Latch (unless that also is to be replaced) nor to open the H-31B case.

Open the door to expose the four silver headed Allen screws marked (1) to (4) in Figure 4 - 43. Undo and completely remove these screws. The door and the two Door Mounting Blocks can now be pulled away from the Clamp Slot moulding as a unit.

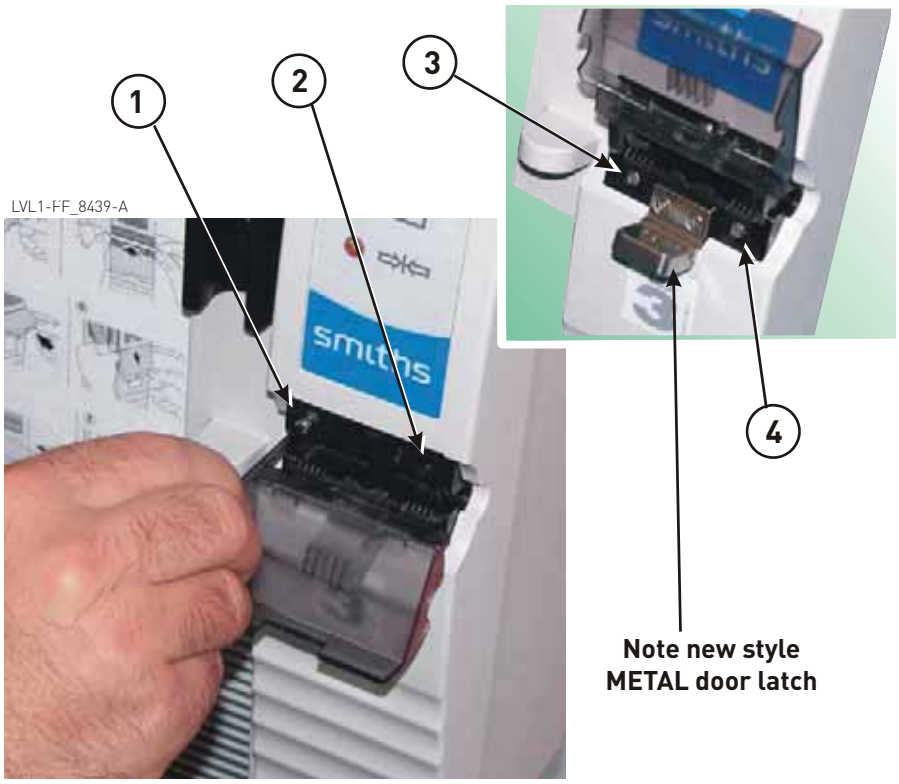


Figure 4 - 43: Door Removal

Do not interchange the Door Mounting Blocks, they are left- and right- handed parts. Examine the Mounting Blocks for signs of wear or damage, and if necessary clean and / or replace them.

Discard the old door, and assemble the Mounting Blocks to the hinges of the new door, making sure that they are fitted to the correct ends of the door. Be careful of the tiny limit pins which must engage in their guide slots.

Figure 4 - 44: The curved guide slot for the limit pin can be seen in this view of the Mounting Block

You will need to apply gentle outward pressure to the Mounting Blocks to hold the assembly together until it can be offered up to the recesses in the Clamp Slot Moulding.

Replace the assembly in its recesses and refit the Allen screws. Remember that the screws are threaded into plastic, so be sure not to overtighten them. Check that the door moves freely in its travel and it can be fully opened and fully closed. Check also that the latch secures the door in the closed position.

Perform the Functional Tests shown on page 116 before returning this unit to active service.

To replace the Door Latch

You will need:

- *Medium (#2) Phillips screwdriver,*
- *2 - 3 inch length of 4-40 threaded rod.*

NOTE: To change the Door Latch it is not necessary to remove the Door (unless that also is to be replaced) nor to open the H-31B case.

The door latch is secured by two small Philips screws to a plastic "double nut" behind the lower part of the Clamp Slot moulding. Take Care! If you completely remove these screws to replace a broken latch, the double nut will fall away from its location making it impossible to refit the screws! To avoid this, follow one of the techniques described here.

Figure 4 - 45: The “Threaded Rod” technique - Part one

Threaded Rod Technique

Unscrew the left hand Phillips screw and remove it. Insert the length of 4-40 threaded rod through the hole in the Clamp Slot moulding, and start screwing it into the double nut, winding it in sufficiently to hold the double nut, but still leaving enough length protruding out of the hole to act as a handle.

Now you can remove the other Phillips screw. The old latch can now be removed by sliding it carefully over the threaded rod. Place the replacement latch over the end of the threaded rod, and offer it up to the H-31B. Fit the right-hand fixing screw and partly tighten, making sure it has started to bite into the double nut. Now it is safe to remove the threaded rod.

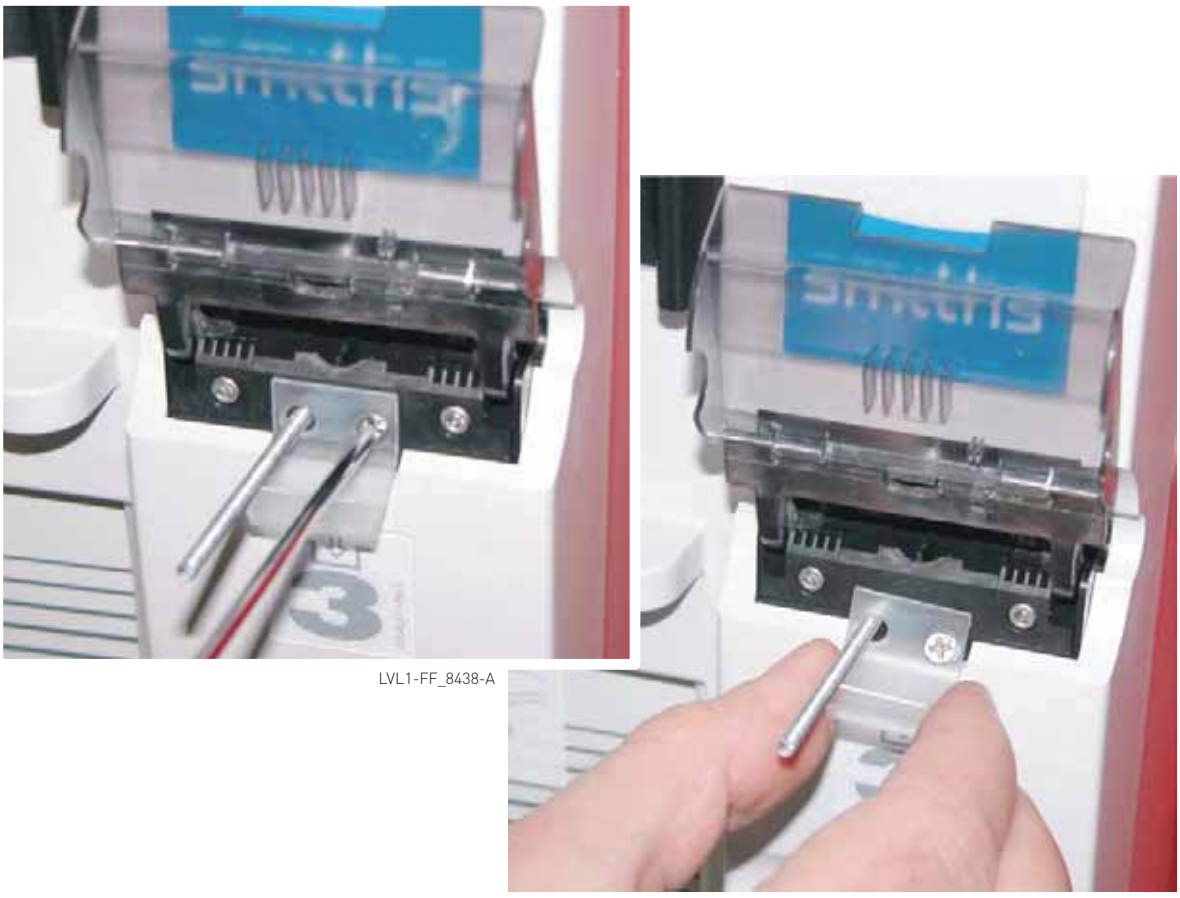


Figure 4 - 46: The threaded rod prevents loss of the double nut inside the panel.

Refit the left hand screw, and tighten them both evenly. Bear in mind you are screwing into a threaded plastic block, so take great care not to over-tighten as the double nut's thread could strip.

Notice that this picture sequence shows the original style plastic door latch. If you are replacing a latch, the likelihood is that you will be replacing it with one of the later style metal latches as shown in Figure 4 - 43 on page 97. Both latch types are interchangeable, but only metal style latches are available as spares.

Side by Side Technique

This can be used if you don't have a length of threaded rod. Undo and completely remove the right hand screw. Do not discard the screw.

Loosen BUT DO NOT REMOVE the left hand screw. Three turns should be about right. Rotate the old latch through 180° so that it is sticking out to the left.

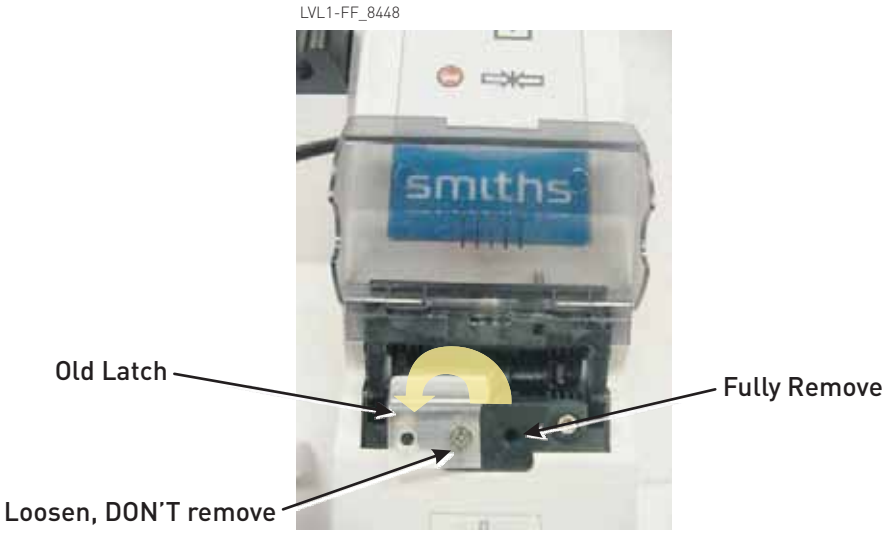


Figure 4 - 47: Side by side Technique - First Step

Using the screw removed earlier, loosely attach the new latch by its *right hand* screw hole to the vacant screw hole in the clamp slot moulding. Make sure the screw has begun to "bite" into the hidden double nut.

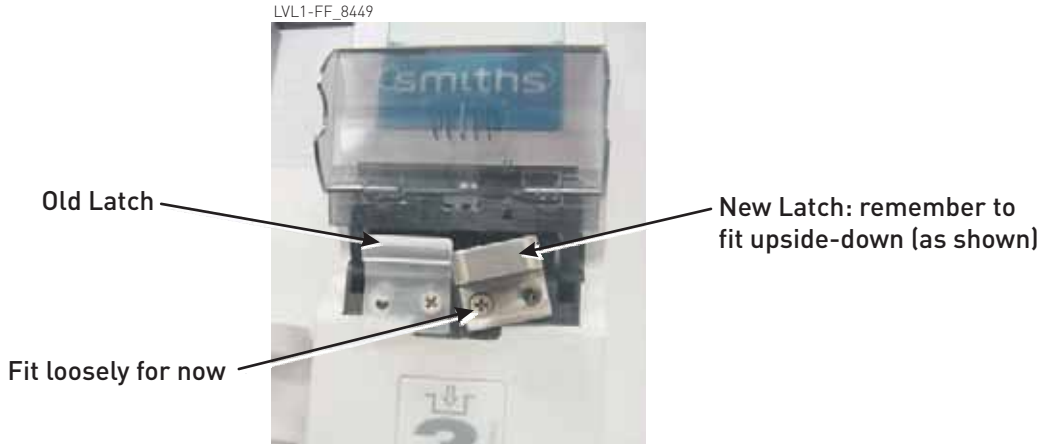


Figure 4 - 48: Side by side Technique - Step two

Now fully remove the left hand screw, and discard the old latch in accordance with your establishment's procedures. Swivel the new latch into position and refit the left hand screw. Align the new latch and carefully tighten - but not overtighten - both screws.

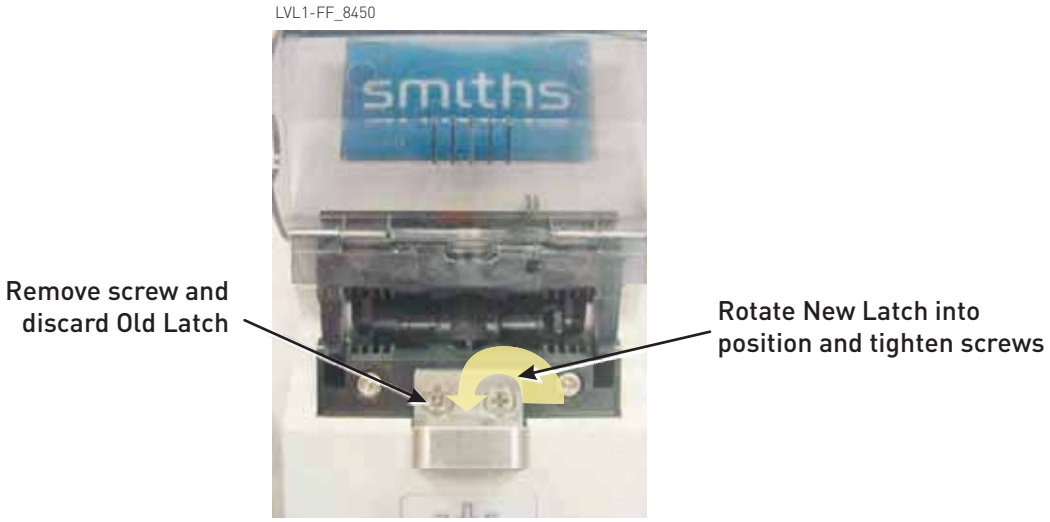


Figure 4 - 49: Side by side Technique - Completion

Checking the new Door Latch Assembly

If this procedure has been done as part of a larger repair then you must perform the Functional Tests shown on page 116 before returning this unit to active service.

Otherwise, perform these specific Door Latch Functional Tests:

Action	Response	Pass /Fail
Close the H-31B's door	■ *Ensure that the Latch locks the door in place.*	
Press the Latch.	■ *Make sure that the Latch releases the door when pressed.*	
Check that the door is able to move freely through its full range of travel.		
Take an F-10 Filter and fill it with water. Load it into the Gas Vent Holder (#4) on the H-31B / H-1200. Do not yet thread the patient line through the Clamp Slot (#3), but ensure the door is closed and latched. Switch ON the unit.	■ *The H-31B should enter the tubing alarm mode, with Yellow LED and audible alarm sounding.*	
Swith OFF the unit. Thread the patient line through the Clamp Slot (#3). Close and latch the door. Switch the unit ON again.	■ *Verify that no alarms sound and the green "OK" LED is illuminated.*	

Level 1® H-1200

Fast Flow Fluid Warmer

smiths medical

bringing technology to life

Fast Flow Blood and Fluid Warmers

LEVEL 1®

Maintenance

Before each use

Carefully inspect the Fast Flow Blood and Fluid Warmer for signs of damage, cracked or split case, insecure castors, loose fittings, damaged mains cable, etc.

Lubricating the O-Ring Seals

If the Disposable Set does not install easily, lubricate the O-Ring Seals. Using a cotton swab, apply a small amount of silicone grease (Smiths Medical Part Number 8004002) to the O-Rings in the lower and upper Heat Exchanger sockets (identified as **1** and **2** respectively on the front face). It is not necessary to remove the O-Rings or dismantle the sockets.

If this does not solve the problem, reject the unit.

After each use

Ensure there is no visible damage, and that a disposable can be mounted and dismounted without difficulty. Wipe all external surfaces with a soft cloth, using an aqueous solution of mild detergent. If necessary, the external surfaces may be disinfected using a solution of 10% bleach in distilled water.

- *Do not autoclave.*
- *Do not use alcohol or solvents.*
- *Do not use abrasive cleaning agents.*
- *Do not use cold sterilants.*
- *Do not immerse any part of the unit in liquids.*

Routine Maintenance Tasks

Smiths Medical recommends that preventative maintenance be carried out at specified intervals. Some maintenance tasks need to be repeated at 30-day intervals and others at annual intervals, depending on your choice of recirculating solution.

The approved recirculating solutions and their associated maintenance protocols are:

Recirculating Solution	At 30-day Intervals	At 12-month Intervals
Sterile Distilled Water	Visual Inspection Lubricate O-Ring Seals Replace Recirculating Solution	Test All Alarms Replace O-Ring Seals Replace Recirculating Solution Verify Temperature Calibration Electrical Safety Test
Hydrogen Peroxide Solution	Visual Inspection Lubricate O-Ring Seals	Test All Alarms Replace O-Ring Seals Replace Recirculating Solution Verify Temperature Calibration Electrical Safety Test

Precise directions for mixing recirculating solution to the correct strength are given on page 127.

Exceptionally, if the unit has had any non-routine servicing or repair work, it will need to undergo a more thorough test and recalibration sequence. This is detailed on page 130 and onward.

Every 30 days

- Perform a Visual Inspection looking for damage, cracked or split case, insecure castors, loose fittings, damaged mains cable, etc.

- Lubricate O-Ring Seals at sockets **1** and **2** with a cotton swab, applying a small amount of silicone grease to the O-Rings. Refer to page 107 for further details.

If using DISTILLED WATER as the recirculating solution:

- Drain and replace the recirculating solution as described on page 127.

Finally

- Fill in, sign, and date the maintenance log record.

Every 12 Months

Your establishment's policies may mandate that these routine maintenance procedures be followed more frequently.

Either, if using DISTILLED WATER as the recirculating solution:

- Drain and replace the recirculating solution as described on page 127.

or, if using HYDROGEN PEROXIDE as the recirculating solution:

- Drain and replace the recirculating solution as described on page 129.

O-Rings

- Replace the O-Rings by prising them carefully out of their sockets. Remember to lubricate the replacements before putting them into their locations.

Fan Filter

- Remove the fan guard / filter assembly from the underside of the system unit. Depending on the age of the unit, it may be a snap-in fitting or a fitting attached by screws.
- Rinse the filter element in warm soapy water, and allow to dry before re-assembly.
- If there is any damage to the guard or filter, then replace it.

Alarm Testing

- Visually check that the recirculating solution level in the reservoir is above the MIN mark. Attach a Disposable Set, ensuring that it is free from kinks and twists.

- Plug the unit into the electricity supply and switch on. Verify that the unit is working normally (recirculating solution circulating, temperature display gradually rising towards 41°C).

Alarm Test Button

- Press and hold the Alarm Test Button. Observe:
  - the GREEN LED extinguishes.
  - the THREE ALARM LEDs light up.
  - the AUDIBLE ALARM commences beeping.

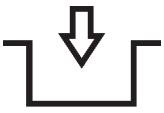
- Release the Alarm Test Button: all alarms should clear except for the Over Temperature alarm. The Audible Alarm will continue sounding.

- Cycle the mains power OFF and ON again to clear the Over Temperature alarm.

Recirculating Solution Level Alarm Test

- While the unit is running, open the Reservoir Filler port, and insert a long thin non-magnetic implement (a clean discarded chopstick would be ideal) through the filler into the reservoir.
- Viewing through the window on the front of the unit, gently depress the floating part of the Level Sensor. The Alarm should activate as shown in Figure 1 - 6 on page 14 and stop the unit.
- Removing your implement should clear the alarm condition. The unit will restart.

Interlock Alarm Test



- While running, test the Interlock Alarm by easing the disposable away from the following three interlock switch locations:
  - *Heat Exchanger holder above socket #1,*
  - *Inside Socket #2*
  - *Gas-vent / Filter holder*
- On each occasion, the unit should halt with the Interlock Alarm illuminated and sounding as shown in Figure 1 - 8 on page 15
- Reseating the disposable should clear the alarm and allow the unit to restart.

Over Temperature Test

- Test the Over Temperature Alarm by pressing the Over Temperature Alarm Test button.
- The alarm shown in Figure 1 - 7 on page 15 will be activated, with audible accompaniment.
- You will have to cycle the mains OFF and ON again to reset this alarm.

Cold Start Test

- Test the unit from an ambient temperature of 21°C. If necessary, switch off and allow the unit to cool.
- Switch ON the unit and note the time, or start a stopwatch. With no flow through the patient side of the disposable, the unit should reach its target temperature in the time specified here.

Model	Target Temperature	Max. Time from 21°C
System 1000 or H-1000	41°C	7 minutes
H-1025, H-1028	41°C	7 minutes
H-1100	30°C 41°C	60 seconds 10 minutes
H-1200	30°C 41°C	60 seconds 10 minutes

Temperature Display Calibration Test

- Install a TEMPCHECK DSTA-40 in place of the Heat exchanger. Install a fully primed Gas Vent / Filter into its holder.

- As an alternative to the TEMPCHECK, you can use a Thermal Calibration Well (part number 80-03-002) in conjunction with a NIST traceable digital thermometer accurate to within 0.1°C fitted with a probe of 0.099 inch max O.D. and a length of between 0.50 and 1.50 inches.

- If using a TEMPCHECK to test an upgraded H-1025 with externally powered H-31B, you will need to unplug the Air Detector for the duration of the next test. Plug the TEMPCHECK 's Mains cable into the Auxiliary Outlet socket. You may need to carefully unpeel the black sticker covering the Auxiliary Outlet on the bottom of the Warmer, and loosely attach it in a safe place ready for re-use.

NOTE: **The Auxiliary Outlet is for use only with approved accessories supplied by your Smiths Medical distributor for that purpose.**

- Run the unit for 15 minutes to allow the temperature to stabilise. Verify that:

  - *the TEMPCHECK shows a temperature between 41°C and 42°C*

  - *The display on the unit under test indicates the same temperature ± 0.3°C.*

- If either of these conditions is not met, the unit will require either recalibration or repairing and recalibration before it can be returned to active service.

Pressure Chamber Check / Calibration Verification

NOTE: **If there is any failure in any section of this test sequence, then after repairs are completed you should use the more stringent "After Repair or Incident" testing sequence (see "Testing Pressure Chambers" on page 141) before returning the unit to active duty.**

- If the unit you are testing is not equipped with pressure chambers, mark the tick box with "N/A" and move on to the next item.

- Visually inspect all external pipework and fittings. If there is any damage, put the unit to one side for repairs.

- Disconnect the pressure chamber's supply hose, and attach a calibrated pressure gauge to the air outlet on the back of the tower. Verify that the air supply pressure is 5.6 PSI +0.0/-0.2.

For each Pressure Chamber:

- Inspect the pressure chamber for damage. In particular pay attention to hinges and door latches. Make sure the pressure gauge is still securely located as these can be dislodged by a drop or severe knock.

- Install a 1000ml I.V. bag into the pressure chamber, then close the cover and secure the latch. Reconnect the pressure chamber to the air supply fitting on the back of the tower unit.

- Pressurize the bladder by switching the toggle lever to the "+" position.

- Ensure that the gauge on the pressure chamber reads in the range 280 to 290 mmHg and is not in the red.

- Disconnect the pressure chamber from the air supply and ensure the unit holds its pressure at 290 mmHg (+0/ -10mmHg) for a minimum of 15 seconds.

- Switch the toggle lever to the "-" position, and verify that the bladder deflates.

- Remove the I.V. bag and fill in the Service History record. Clean the Pressure Chambers and stick service labels as appropriate.

Air Detector / Clamp Routine Functional Testing

To perform the routine functional verification tests, you will need the H-31B attached to a H-1200 or H-1025 tower unit. Install a primed F-10 Gas Vent/Filter Assembly into Block #4 of the tower, and fit a length of patient line into the Clamp Slot #3 of the device. Close and latch the Clamp Slot Door.

Power-on Test

This test verifies that the visual and audible indicators function correctly. This self-test is performed by the device's electronic controller when power is first applied. The following are the visual and audible observations to be made right after powering up the unit.

- *The GREEN LED should light.*
- *The YELLOW LED should illuminate for approximately 2 seconds and then extinguish.*
- *The RED LED should illuminate for approximately 2 seconds and then extinguish.*
- *Audible alarm should be heard for approximately 2 seconds.*

Automatic Operation Mode Test

Automatic Operation mode should occur immediately after the power-on test is completed. The following are the visual and audible observations.

- *The GREEN LED shall illuminate.*
- *No audible alarm shall be heard.*

Door Interlock Test

This test is to verify that the interlocks for "Tubing in Place" and "Door Open" function properly.

Open the Clamp Slot Door.

- *Verify the door freely moves through its entire range of travel.*
- *The Disposable Interlock YELLOW LED shall illuminate.*
- *The audible alarm shall beep approximately every 5 seconds.*

Remove the Patient Line from the Clamp Slot, and re-close the Clamp Slot Door.

- *The Disposable Interlock YELLOW LED shall stay illuminated.*
- *The audible alarm shall continue to beep approximately every 5 seconds.*

Replace the Patient Line, and re-close the Clamp Slot Door.

- *Verify that the door closes and latches.*
- *Verify the Yellow LED and the Audible Alarm are off and the Green LED is illuminated.*

Air Detector Test

This test is to verify that the Air Detector/Clamp functions correctly. Install a disposable set, spiked into a saline I.V. bag in the pressure chamber. Ensure the disposable is fully primed. Place the outlet of the patient line into a suitable container to collect the outflow.

Switch on the Unit, and pressurise the pressure chamber by sliding the lever on the chamber to the plus (+) position. Release any tubing clamps, and observe saline exiting from the distal end of the patient line.

Move the top of the Gas Vent/Filter Assembly away from the Air Detector sensor as shown.

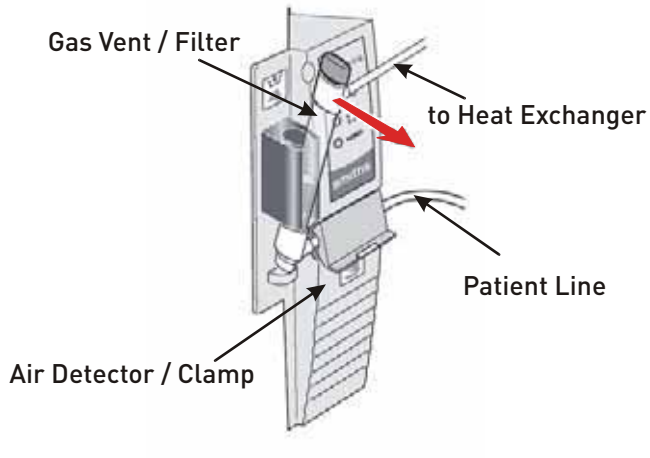


Figure 5 - 1: Air Detector Functional Test

Observe that:

- *The clamped RED LED shall flash on for 1 second then off 1 second (repeating).*
- *The audible alarm shall sound for approximately 1 second and then off for approximately 1 second (repeating).*

- *The clamp shall activate and pinch the tubing closed. No further saline should exit the patient line.*
- *The Tower Unit's "disposable" alarm should also activate.*

Re-install the Gas Vent / Filter Assembly into Block #4.

- *The clamp must release the tubing after approximately 4 seconds.*
- *The green Automatic Operation LED on the Air Detector/ Clamp Control Panel illuminates.*
- *The RED LED should extinguish, and all alarms are silenced.*

If any of the above responses are not observed, this unit must not be returned to active duty until it has been repaired and re-tested.

NOTE: **After any remedial work, re-test the unit in accordance with the more stringent "After Repair or Incident" test sequence (see "Air Detector / Clamp Testing" on page 145 and onwards).**

Electrical Safety Test

- Dismantle the TEMP CHECK test assembly and Gas Vent, and replace with a normal disposable. If the unit is a standard H-1025, H-1100 or H-1200, replace the black sticker over the Aux socket. If the unit being tested is an upgraded H-1025, with externally powered H-31B, plug this back into the Aux socket.
- If your establishment mandates an Annual Electrical Safety Test, then perform this now.

Finally ...

- Document the date and results of your tests and return the unit to active service.

Routine Maintenance Checklists

- You may freely photocopy the checklists on page 122, page 123, page 124 and page 125 to act as a continuing record of your routine maintenance.

- You may also copy the various Service Checklists which you will find later in this chapter, on page 139, page 140, page 144, and page 152, as required.

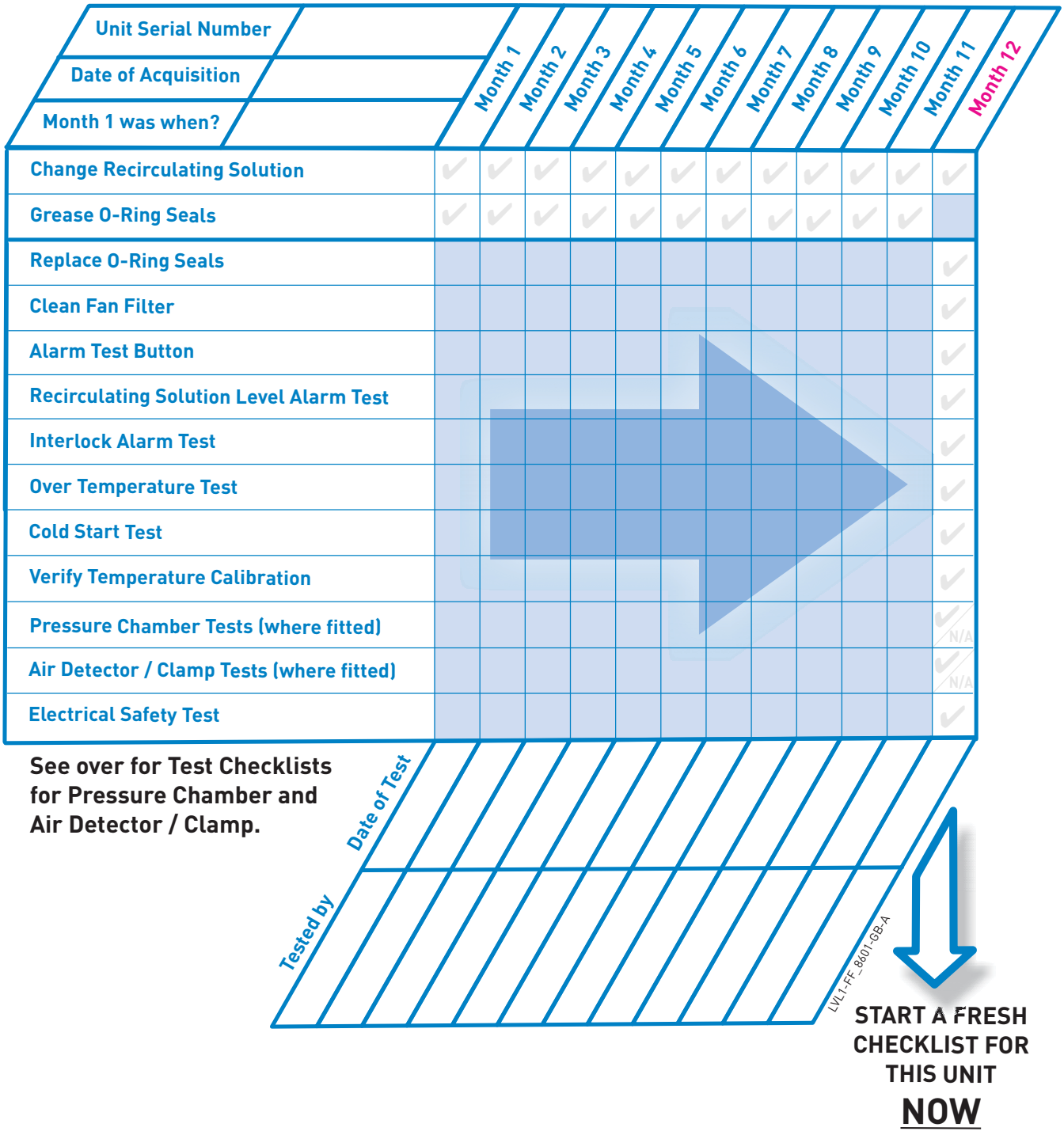
  - *Alternatively use these pages as templates to create your own checklists, to ensure that all service and maintenance activity is completed correctly, and adequately documented.*

- The correct Routine Maintenance checklist to use is dependent on the choice of protocol used for maintenance on the Fast Flow Blood and Fluid Warmers in your care.

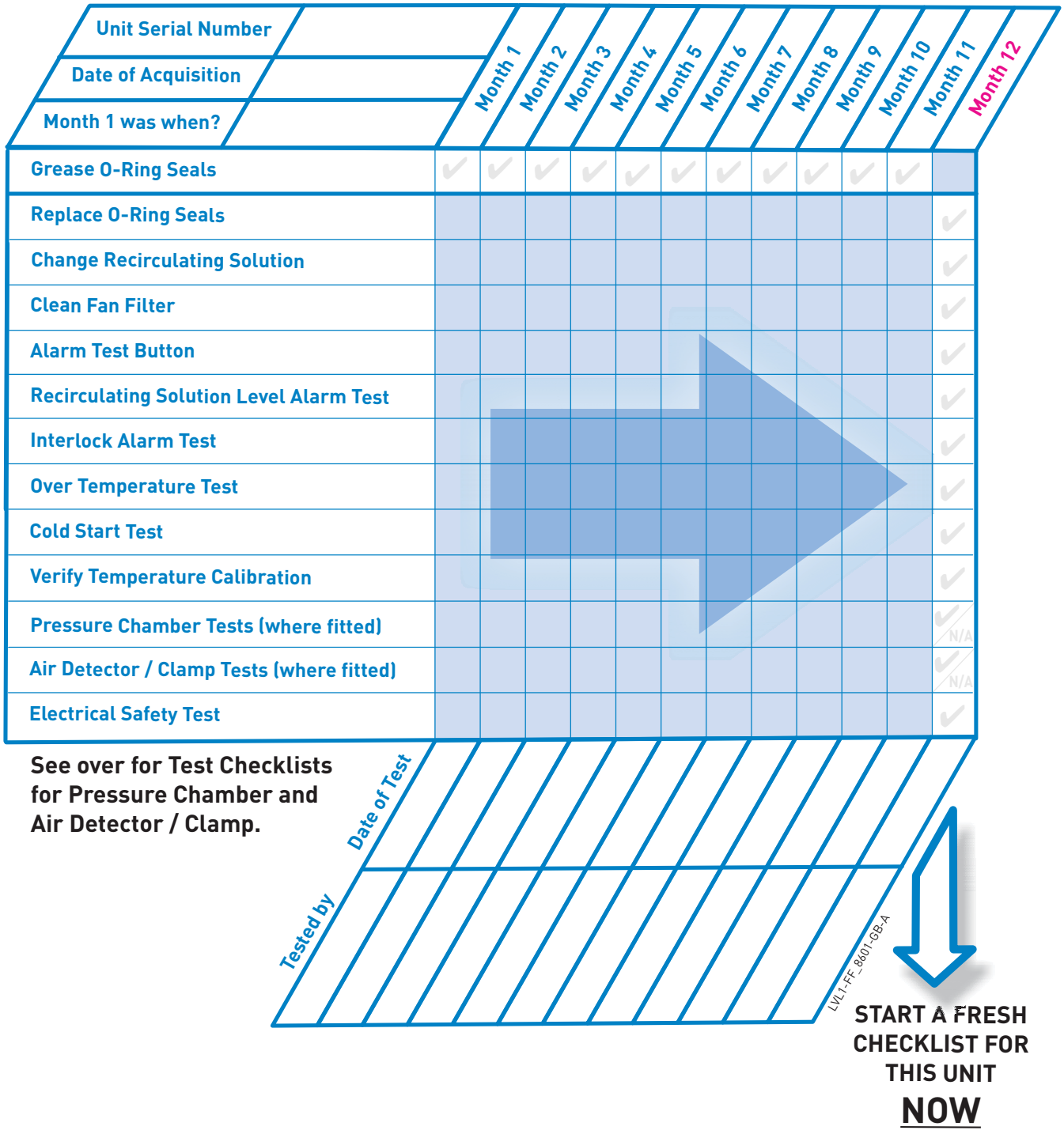
  - *If you choose to stick to the traditional distilled water recirculating solution, you will need the first checklist (page 122). This allows for the changing of the recirculating solution on a monthly cycle.*

  - *Otherwise, the second checklist (page 123) corresponds with Smiths Medical's recommended protocol of having a 12-month interval between solution changes, and using a disinfectant mixture as the recirculating solution on a permanent basis.*

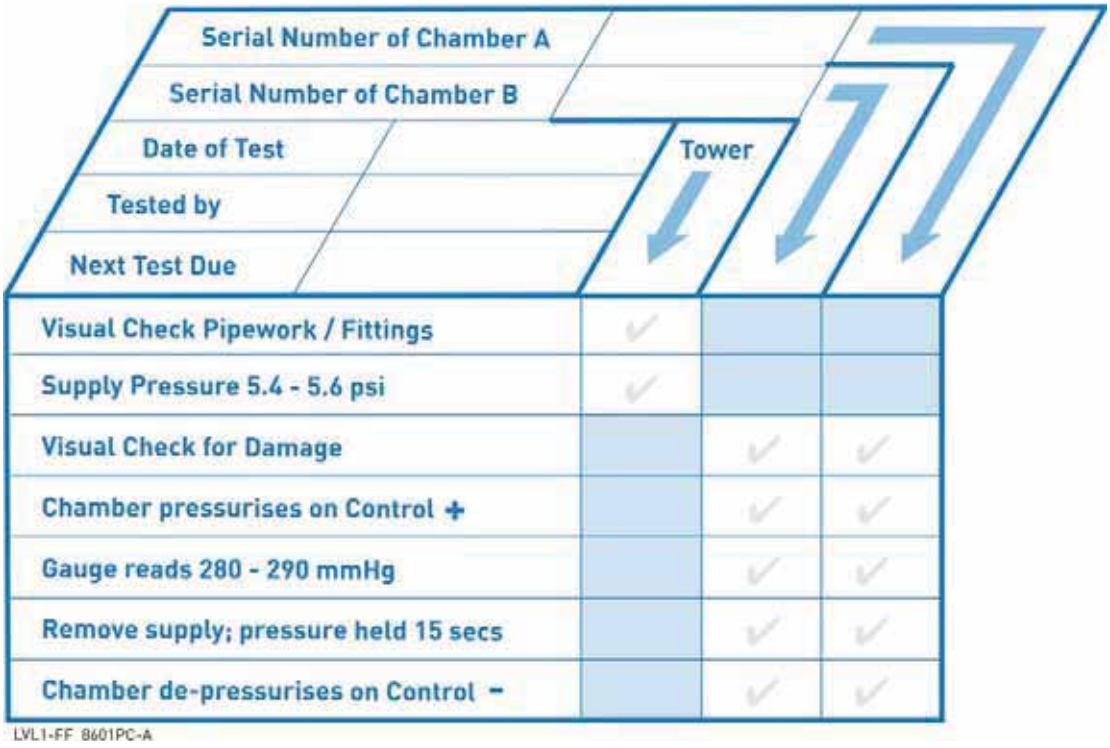
Recirculating Solution is Sterile Distilled Water



Recirculating Solution is 0.3% Hydrogen Peroxide



Pressure Chambers



Air Detector Clamp

Serial Number		General	Clamp SHUT	Green LED	Yellow LED	Red LED	Audible Alarm
Date of Test							
Tested by							
Next Test Due							
Visual Check for Damage		✔					
Power-On Test			✖	✔	✔	✔	✔
After 2 Secs, enters Automatic Mode			✖	✔	✖	✖	✖
Open Door			✖	✖	✔	✖	✔
Unthread tube, close door			✖	✖	✔	✖	✔
Re-thread tube, close door			✖	✔	✖	✖	✖
Dislodge Gas Vent / Filter			✔	✖	✖	✔	✔
Replace Gas Vent / Filter			✖	✔	✖	✖	✖

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Recirculating Solution Renewal

Maintenance Solutions

At service intervals of either 12-months or 30-days, depending on the composition of your recirculating solution, you will need supplies of ready mixed solutions to perform maintenance. To make up a batch (1.4 litres) of solution, you will need:

Formula 1

140ml of 3% Hydrogen Peroxide PLUS 1260ml distilled water

This may be used as a disinfectant fluid for flushing the recirculating solution path during routine maintenance, or as a long-life recirculating solution enabling fluid change intervals to be extended to annually.

Formula 2

700ml of 70% Isopropyl Alcohol PLUS 700ml distilled water

This may be used as a alternative disinfectant fluid for flushing the recirculating solution path during routine maintenance. It is NOT suitable for long-term use as a recirculating solution and should not be used as such.

Distilled Water

Distilled Water Recirculating Solution requires replacing every 30 days. Follow the procedure given here:

[1] Prepare a batch of disinfectant solution as described above for either Formula 1 or Formula 2 (above)

[2] Arrange the Warmer in its normal upright attitude over a suitable water collector or drain. Locate the Drain valve on the underside of the warmer, adjacent to the mains inlet. See External Features (2) on page 24.

[3] Open the Drain valve and completely drain the reservoir.

[4] Close the drain valve, and refill the unit with your prepared batch of disinfectant solution.

[5] Fit a disposable and run the warmer for 30 minutes to circulate the disinfectant solution.

[6] Switch off and drain the reservoir again. Dispose of the used solution and disposable in a manner consistant with usual practice for your establishment.

[7] Close the drain valve, and refill the unit with 1.4 litres of distilled water.

Hydrogen Peroxide

Hydrogen Peroxide (made up as Formula 1) may be used as recirculating fluid for extended periods, but will require replacing at the annual service.

Follow the procedure given here:

[1] Prepare two batches of disinfectant solution as described above for Formula 1, (0.3% Hydrogen Peroxide)

[2] Arrange the Warmer in its normal upright attitude over a suitable water collector. Locate the Drain valve on the underside of the warmer, adjacent to the mains inlet. See External Features (2) on page 24.

[3] Open the Drain valve and completely drain the reservoir.

[4] Close the drain valve, and refill the unit with the first of your prepared batches of Formula 1.

[5] Fit a disposable and run the warmer for 30 minutes to circulate the disinfectant solution.

[6] Switch off and drain the reservoir again. Dispose of the used solution and disposable in a manner consistant with usual practice for your establishment.

[7] Close the drain valve, and refill the unit with your second batch of Formula One.

Full Service Test / Calibration

- A TEMP CHECK

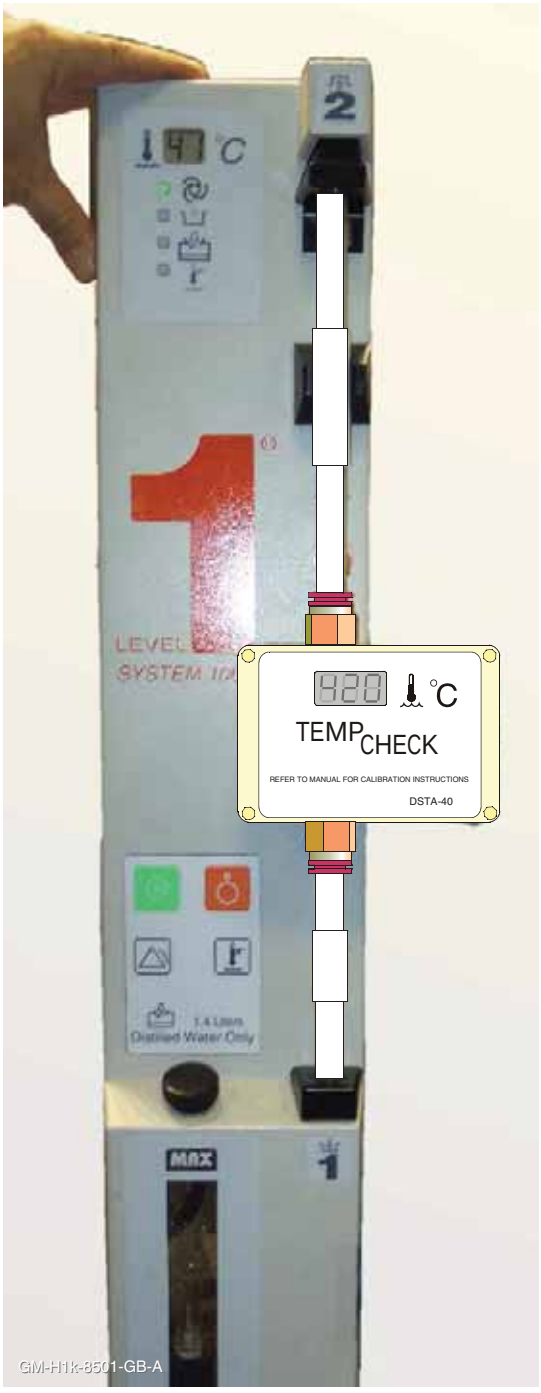


Figure 5 - 2: A TEMP CHECK water temperature gauge.

Things you will need:

DSTA-40 Water Thermometer (see left)

Figure 5 - 3: One type of Flow Meter

- A Flow meter able to measure up to 1 gallon per minute (0 - 5 ltr / min)
- A Float Switch Test Depressor (The clean discarded chopstick?)
- A Calibrated Pressure Meter covering the range 0 - 10 psi (0 - 500 mmHg)

Figure 5 - 4: These are eminently suitable Pressure Meters (with kind permission of Druck Ltd)

Service Test Procedure

for H-1000, H-1025, H-1100, H-1200

1) Setup

[1] Install a Flow Meter into the Heat Exchanger location of the unit.

[2] (H-1200 and upgraded H-1025) Install a fully primed Filter into the filter holder (#4), ensuring that the orange end is uppermost. Thread the patient Line through the Clamp Slot at #3.
(Others) Install a filter into the Filter Holder #3.

[3] Check the Recirculating Solution Level, and if necessary, fill the Unit up to the MAX mark with de-ionised water

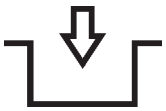
[4] Verify that the ambient temperature is between 20°C and 24°C. If it is outside these limits, do not proceed with the calibration.

2) Check for leaks

[1] Turn unit ON; verify circulation by inspection of the reservoir. Check all fittings and seams for leaks.

[2] Record the flow rate. The rate must be greater than 1 U.S. gallon per minute (3.7 litre/minute). Turn the unit OFF again.

3) Interlock Switch Tests



[1] Remove the Flow Meter and install a TEMP CHECK DSTA-40. With the unit running, gently pull on the piping above the TEMP CHECK to reduce the pressure on the heat exchanger interlock switch. The “Disposable” alarm should activate and the unit should cease pumping.

[2] Allow the TEMP CHECK to return to it’s normal position, and the unit should become operational again.

[3] Stop the Unit. Lift the upper (#2) socket upwards. On attempting a restart, the "Disposable" alarm should activate and, if fitted, the LED to the right of the LCD display should illuminate.

[4] Return the socket to it's normal position, and the unit should become operational again.

[5] Remove the Gas Vent / Filter from the lower interlock block. The "Disposable" alarm should activate and the unit should cease pumping. On the Air Detector (if fitted), the "Clamped" LED and alarm should activate and the "Operational" LED should go out.

[6] Replace the Filter. The Unit should become operational again.

4) Recirculating Solution Level Alarm Test

[1] While the Unit is running, remove the Reservoir Filler port and, using your float switch depressor, depress the float switch inside the reservoir tank. The visual and audible level alarms should activate. The green LED will go out, and the Unit will stop.

[2] Release the Float Switch; the Alarms should clear and the Unit recommence normal running.

5) Alarm Test Switch

[1] Depress and hold the General Alarm Test Switch. The green LED should extinguish, and the unit must cease to pump. All three "Alarm" LEDs should flash, and the audible alarm should sound.

[2] Release the Test Switch: the "Recirculating Solution Level" and "Disposable" alarms should cease, but the "Over Temperature" alarm should still continue. To clear the "Over Temperature" alarm, switch the whole Unit OFF, then ON again.

6) Set Idle Temperature

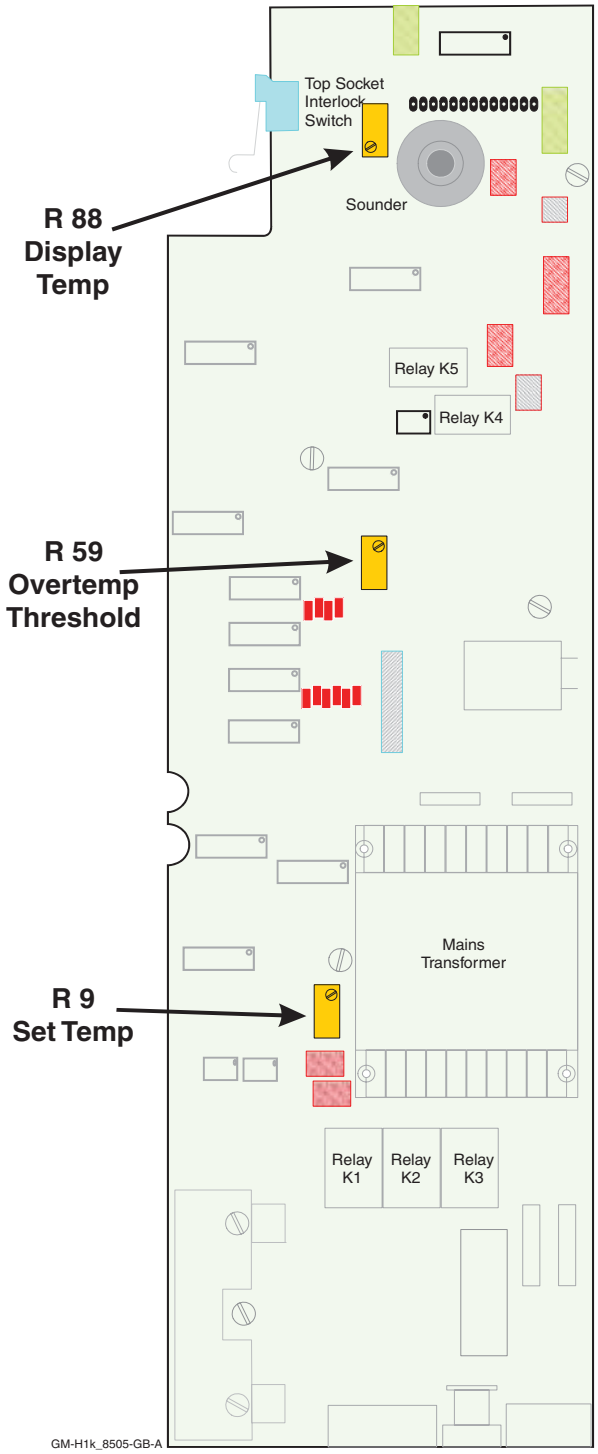


Figure 5 - 5: Location of Adjusters

[1] If the TEMP CHECK thermometer is not yet plugged in, do so now. Allow a few minutes for the TEMP CHECK to stabilise before proceeding.

[2] **USING THE DSTA-40 TEMP CHECK AS A REFERENCE**, adjust R9 so that the water temperature is at 41.7°C ± 0.1°C.

[3] Turn R9 clockwise to raise the temperature, and anti-clockwise to lower it.

[4] Allow time for each adjustment to take effect before making further adjustments.

NOTE: To perform the next series of instructions, you will need to partly remove the self-adhesive fascia from the display panel, to reveal the third digit of the LCD display.

Carefully slide a small flat-bladed screwdriver under the top right-hand corner of the fascia to ease it away from the panel.

If it will not properly adhere after the unit has been calibrated, the fascia should be replaced.

7) Set Over Temperature Alarm Threshold Level

NOTE: **If at any time the Over Temperature alarm is tripped, you will have to cycle the mains switch buttons for the entire Unit OFF then ON again to clear the alarm.** Before starting, peel back the label covering the LCD, so that all three digits are visible.

[1] Ensure that the recirculating solution temperature, as reported by the TEMP CHECK, is at least 41.5°C but no more than 43.5°C before commencing.

[2] Adjust R88 CLOCKWISE so that the LCD display erroneously reports the temperature of the circulating water as being 43.9°C.

[3] If the alarm has come on, adjust R59 ANTI-CLOCKWISE several turns. Cycle the mains, to clear the alarm.

[4] Gradually adjust R59 CLOCKWISE to find the point where the alarm trips.

[5] Turn off the Unit, and adjust R88 several turns ANTI-CLOCKWISE. Turn on the Unit again: gradually adjust R88 CLOCKWISE while watching the LCD temperature display on the Unit. Note the displayed temperature at which the alarm trips. It should be between 43.8°C and 43.9°C.

[6] Repeat twice more, to confirm the activation point.

[7] Turn off the Unit, and adjust R88 several turns ANTI-CLOCKWISE. This will prevent the unit powering back up in an alarm condition.

8) Set Display Calibration

[1] Switch ON and allow the temperature to stabilise. Peel back the label covering the LCD, so that all three digits are visible. Adjust R88 until the LCD temperature display on the Unit matches the display given by the TEMP CHECK ± 0.0°C.

9) Over Temperature Alarm Test Switch

[1] Depress and hold the Over Temperature Alarm Test Switch. The green “Running” LED should extinguish, and the unit must cease to pump. The “Over Temperature Alarm” status LED should flash, and the audible alarm should be sounding.

[2] The LCD reading should have risen to 45.3°C ± 0.4°C.

[3] The alarm state should persist after the Test Switch is released, although the LCD reading will return to normal. The alarm can only be cleared by switching the whole Unit OFF, then ON again.

10) Set Compressor Calibration

[1] Connect a calibrated pressure gauge to the push-fit connector at the rear of the tower unit. (See “External Features” on page 24)

[2] Adjust the pressure regulator until the pressure gauge reads between 5.4 psi and 5.6 psi (280 - 290 mmHg).

11) Idle Check

[1] Check, and if necessary adjust the unit (see paragraph 6-2, page 133) so that the TEMP CHECK reports a temperature of 41.7°C ± 0.1°C. Allow the Unit to run for 30 minutes idling. Ensure that:

[i] the solution continues to recirculate, and there are no leaks.

[ii] the reading on the TEMP-CHECK remains steady at 41.7°C ± 0.1°C.

[iii] the digital display faithfully tracks the TEMP CHECK.

[iv] no alarms are set off.

If either or both heater elements have been renewed, the following test must also be performed:

12) Heater Demand Test

[1] To perform this test you will need a Demand Simulator (see section 6 - Troubleshooting) and an AC Current Meter able to read 0 - 10 Amps at Mains Voltage. A clamp-type meter makes this job much easier.

[2] Turn off the Unit, and replace the TEMP CHECK with a Demand Simulator.

[3] Identify the brown wires on the T-Stat attached to the heater(s) that has been replaced.

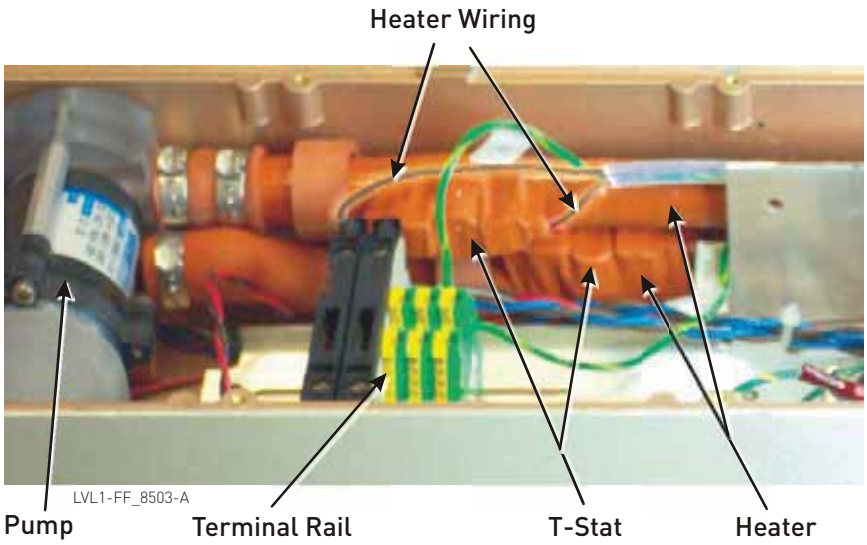


Figure 5 - 6: Connecting the Current Meter

[4] Disconnect one of the brown wires (it doesn't really matter which) from the T-Stat, and re-connect via the AC current meter ***or*** clamp the meter over the chosen wire.

[5] Set the meter to a 5 Amps AC range.

[6] If you have access to a heavy-duty Variac (6 amps minimum):

[i] Unplug the Warmer.

[ii] Locate the compressor fuse F2 (see page 175) and remove it for the duration of the next test.

[iii] Set the Variac Output to 275 V.

[iv] Plug the unit under test into the Variac.

This increases the likelihood that a weak heater will quickly fail, rather than have it fail after the unit has left the workshops and is in active service.

[7] If a suitable Variac is not available, there is an alternative method of applying stress to the heaters to accelerate any potential early-life failure. Switch the Unit ON for 25 - 35 seconds. Switch OFF for 2 minutes. Repeat the switch ON, switch OFF cycle ten times.

[8] Switch ON again, and adjust the flow through the Demand Simulator so that the LCD temperature display reads between 33 °C and 36 °C. If the temperature tends to go too high, then disable the heater not being tested by removing its fuse. You will need to test this heater by itself after the first heater test has been completed.

[9] Maintain this state for 15 minutes, inspecting the heaters for signs of visible damage or other abnormality. Within the **first** five minutes of the burn-in, measure and record the current demand of the new heater(s). Call this value **A**.

[10] Within the **last** five minutes of the burn-in, measure and record the current demand of the new heater(s). Call this value **B**.

[11] Calculate the percentage change in current (**C**) using the following method:

$$C = \frac{(A - B) \times 100}{A}$$

[12] The Heater must be rejected if:

[i] there is any sign of damage or abnormality resulting from the burn-in.

[ii] the percentage change exceeds 10%.

[13] If satisfactory, record the change onto the Service History Record Sheet. Remove the ammeter from the circuit. If you removed the compressor fuse in step [6], refit it now.

In all cases, finish up with these procedures:

13) Safety Testing

[1] Perform the usual electrical safety checks as set down by your establishment's normal procedures.

14) Finally

[1] Verify that the Service History Record is correctly completed.

[2] Clean Unit and affix service label.

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Fast Flow Blood and Fluid Warmer Service Checklist

Hospital Equipment ID No: .....

Serial Number .....

Tested by .....

Date .....

(Numbers in brackets give paragraph reference)	Procedure		Pass?
Install Flowmeter (1.1)	Flow meter s/n:	Calibration Due:	☐
Setup (1.3)	Check Level of Recirculating Solution	Level < MAX Level > MIN	☐
Setup (1.4)	Check Ambient Temperature	Min 20 °C Max 24 °C	Enter Temperature
Leak Check (2.1)	Check for Leaks	No Leaks found	☐
Flow Test (2.2)	Check Flow Rate	Flow > 1 US gall / min (= 3.7 ltr / min)	Enter Flowrate
Install TEMPCHECK, F30 and Patient Line	TEMPCHECK s/n:	Calibration Due:	☐
Interlock Tests (3.2)	Heat Exchanger Interlock	Interlock Alarm Trips	☐
Interlock Tests (3.3)	Upper Socket Interlock	Interlock Alarm Trips	☐
Interlock Tests (3.4)	Filter / Gas Vent Interlock	Interlock Alarm Trips Clamped Alarm Trips*	☐ ☐ * H-1200 only
Recirculating Solution Level Alarm Test (4.1)	Depress Float Switch	Recirculating Solution Level Alarm Trips	☐
Alarm Switch Test (5.1)	Press Test button	All alarm LEDs flashing Audible Alarm pulsing	☐ ☐
Reset Alarm Test (5.2)	Cycle Mains supply	Alarm Resets	☐
Idle Temperature (6.1)	Watch TEMPCHECK Adjust R9	41.6°C minimum 41.8°C maximum	Enter Temperature
Over Temp Set Point (7.6)	Adjust R88 to 43.9°C Repeat twice	Over Temp Alarm Trips Clears when Mains cycled	☐ ☐
Calibrate Display (8.1)	Adjust R88 to match TEMPCHECK	LCD = TEMPCHECK ± 0.0°C	☐
Over Temp Alarm (9.1)	Press and Hold Over Temp Test Switch	Display = 44.9°Cmin 45.7°Cmax Over Temp Alarm Trips	Enter Temperature
	Release Cycle Mains	Alarm Continues Clears when Mains cycled	☐ ☐
Calibrate Air (10.2)	Adjust Regulator	5.4 psi minimum 5.6 psi maximum	Enter Pressure
Idle Check (11.1) Start Time: ..... End Time:	Read TEMPCHECK Adjust R9 if required	41.6°C minimum 41.8°C maximum	Enter Temperature

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Go To Next Page

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Fast Flow Blood and Fluid Warmer Service Checklist

Hospital Equipment ID No: .....

Serial Number .....

Tested by .....

Date .....

Procedure (contd)			Pass?
Was either Heater replaced during Servicing?		NO	DEMAND TEST NOT REQUIRED
		YES	Demand Test must be performed for BOTH heaters
Install Demand Simulator (Adjust Demand Simulator to maintain 38°C or less)		Demand Simulator ID	
Prepare Clamp Ammeter		Clamp Ammeter s/n:	Calibration Due:
Current (12.9)	Initial Current	Enter Current (H1) A1 =	Enter Current (H2) A2 =
	Burn-in 15 minutes	Start of Burn-in Time:	End of Burn-in Time:
Current (12.10)	Final Current	Enter Current (H1) B1 =	Enter Current (H2) B2 =
Heater 1 (12.11)	H1 Current Stability (Ignore any minus signs. Reject if % value is greater than 10)	$C1 = \frac{(A1 - B1) \times 100}{A1}$	Enter Change C1 %
Heater 2 (12.11)	H2 Current Stability (Ignore any minus signs. Reject if % value is greater than 10)	$C2 = \frac{(A2 - B2) \times 100}{A2}$	Enter Change C2 %
Inspection (12.12)	Inspect for signs of damage/abnormality	No visible damage	☐
All Warmers			
Safety Testing (13)	Use your own site's normal electrical test protocol	Perform specified Safety Test	☐
Document your work (14.1)	Complete Service History Record Card	That's THIS document!	☐
Finally... (14.2)	Clean Unit	Affix Labels as required	☐

LVL1-FF_8506-GB-A

Testing Pressure Chambers

After Repair or Incident

NOTE: **This sequence shall be followed after any repair work has been carried out on the pressure chamber that has required opening of the enclosure or replacing any internal parts. Additionally, this sequence is recommended to fully verify the pressure chamber's serviceability after any unusual incident, such as dropping or wetting, has occurred.**

Install a 1000ml I.V. bag into pressure chamber, then close cover and secure latch. Connect the pressure chamber to a regulated air supply and a calibrated pressure gauge using a ¼ 'Y' push-fit hose connector.

1) Calibration Verification

[1] Set the air supply pressure to 5.6 PSI +0.0/-0.2 and pressurize the bladder by switching the toggle lever to the "**+**" position. The pressure chamber must reach 290 mmHg (+0/ -10 mmHg) when it stabilizes.

[2] Ensure that the gauge on pressure chamber reads in the range of 280 to 290 mmHg and is not in the red.

[3] If the Pressure Chamber calibration is within the specified tolerance, proceed to "3) Pressure Test" on page 143. Otherwise recalibrate the unit (see over).

2) Recalibration Procedure

[1] Following the procedures illustrated in Section 4, dismantle the pressure chamber to the extent necessary to access the rear of the pressure meter.

[2] Install a ¼ 'Y' connector in place of the ¼ straight push-fit connector to the tubing which runs to the pressure meter. Connect a calibrated pressure gauge to one of the ports, and an air supply set to 5.6PSI (+0.0/ -0.2) to the remaining port. Compare gauges and adjust the pressure chamber's gauge adjustment screw as needed until readings are equivalent.

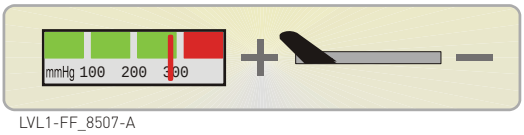

Figure 5 - 7: Meter is reading 290 mmHg (equivalent to 5.6 psi)

[3] Apply hot glue or varnish to the screw when adjustment is complete.

[4] Reassemble the pressure chamber, and repeat the Calibration Verification on the previous page.

3) Pressure Test

[1] Disconnect the pressure chamber from the air supply and ensure the unit holds the pressure of 290 mmHg (+0/ -10mmHg) = 5.6 PSI (+0.0/ -0.2PSI) for a minimum of 15 seconds.

4) Finishing Off

[1] Switch the toggle lever to the "-" position to deflate the pressure chamber, and remove the I.V. bag.

[2] Verify Service Checklist is correctly completed.

[3] Clean Pressure Chamber

[4] Stick service labelling as appropriate.

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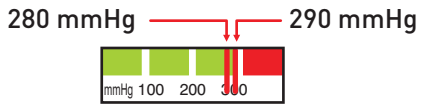
Fast Flow Blood and Fluid Warmer Pressure Chamber Service Checklist

Serial Number .....

Tested by .....

Date .....

Equipment ID No .....



(Numbers in brackets give paragraph reference)		Procedure	Expectation	Pass?
Calibration Verification	**(1.2)**	Pressurise at 5.6 psi Read Gauge	280mmHg MIN 290mmHg MAX	NO YES
Recalibrate	**(2.1)**	Dismantle Unit, apply 5.6psi		☐
	(2.2)	Adjust Gauge	280mmHg MIN 290mmHg MAX	☐
	(2.3)	Seal adjustment screw		☐
	(2.4)	Reassemble pressure chamber		☐
Calibration Re-verification	**(1.2)**	Pressurise at 5.6 psi Read Gauge	280mmHg MIN 290mmHg MAX	☐
Pressure Test	**(3.1)**	Disconnect Supply Watch for 15 secs	Gauge 290mmHg no pressure drop	☐
Finishing Off	**(4.3)** **(4.4)**	Clean Unit Affix Service Label		☐

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Air Detector / Clamp Testing

After Repair or Incident

NOTE: **This sequence shall be followed after any repair work has been carried out on the Air Detector / Clamp that has required opening of the enclosure or replacing any internal parts. Additionally, this sequence is recommended to fully verify the Air Detector / Clamp's serviceability after any unusual incident, such as dropping or wetting, has occurred.**

The Air Detector must be attached to a Tower Unit, either H-1200 or H-1025, to do these tests. In the following paragraphs, any references to H-1200 apply equally to the combination of H-1025 retrofitted with a H-31B.

- You will need:
  - *An Administration Set*
    (D-100/DI-100 is ideal, but others are OK, too)
  - *F-10 Gas Vent / Filter*
  - *F-30 Gas Vent / Filter*
  - *A Saline-filled I.V. Bag*
  - *An empty I.V. bag*

1) Start

[1] Before commencing the tests ensure that there is no visible damage to the exterior of the unit, or any cables attached to it, and that all sealing gaskets are in good condition.

2) Set-up with F-10 Gas Vent Filter

[1] Plug in the H-1200.

[2] Install the D-100 or DI-100 Administration Set into the unit to be tested. Close the clamps of each drip chamber. Remove spike cap off the saline I.V. bag spike port. Insert drip chamber into spike port. Hang the I.V. bag inside one of the pressure chambers. Squeeze the drip chamber until it is half full.

[3] Inflate the empty I.V. bag with air then spike with second drip chamber. Hang the air-filled I.V. bag in the second pressure chamber.

[4] Remove the male luer cap off the end of the patient line. Place patient line into a drain or pail.

[5] Open clamp to saline filled I.V. bag. Saline will flow under gravity pressure to fill the line. Close roller clamp when patient line is primed. The filter will self-prime. Gently tap gas vent filter to release trapped air. Close clamp to saline filled I.V. bag.

[6] Turn on the fast flow fluid warmer and pressurize the pressure chamber containing the air-filled I.V. bag.

[7] The Air Detector will automatically perform a Power-On Test. Verify the following:

- *Green light is illuminated*
- *Yellow light is illuminated*
- *Red light is illuminated*
- *Alarm activates*

[8] Confirm the Air Detector goes into automatic operation. Verify the following:

- *Green light remains illuminated*
- *Yellow light is off*
- *Red light is off*
- *Alarm is off*

3) Tubing Placement Test

[1] Grab the small bore tubing 12 inches from the exit of the door assembly and push the tubing 3 inches closer to the Air Detector. Rotate the tubing in a clockwise motion away from the operator.

- *The unit under test must stay in its automatic operation mode.*

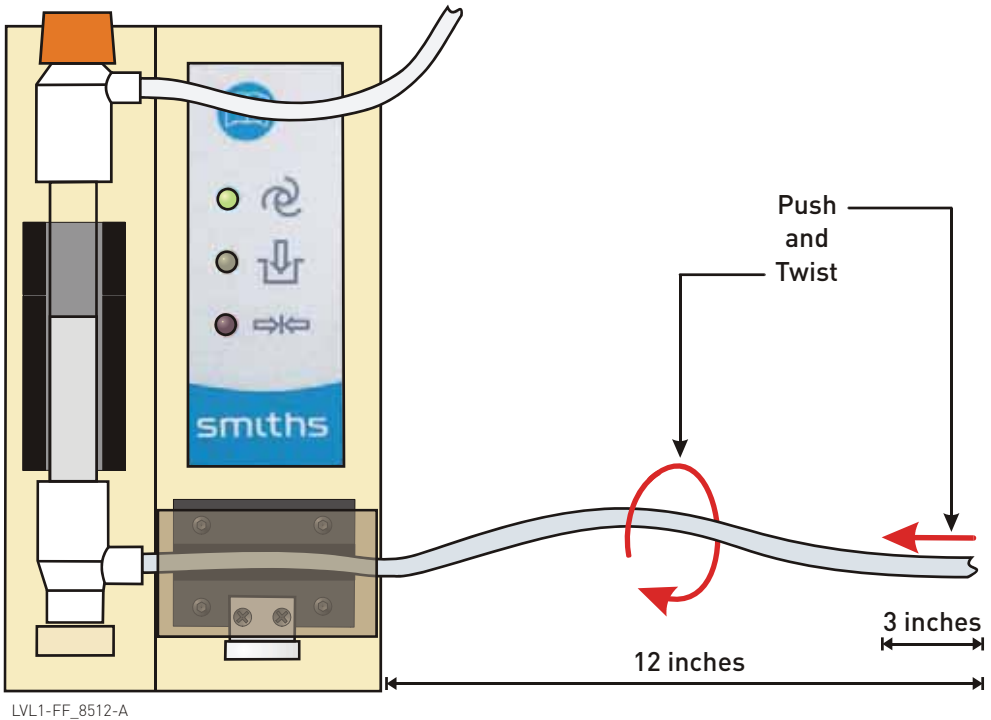

Figure 5 - 8: Tubing Placement Test

4) Clamp Test

[1] Open the clamp to the air-filled I.V. bag. The air will travel through the tubing and into the gas vent filter. The Air Detector shall detect the air and clamp.

[2] Verify that:

- *there is no fluid exiting the distal end of patient line.*

[3] Close clamp to air-filled I.V. bag. Turn off the tower unit. Verify that:

- *clamp disengages tubing.*

5) Set-up with F-30 Gas Vent / Filter

[1] Close roller clamp on patient line. Close clamps above and below F-10 gas vent filter. Remove the F-10 gas vent/ filter.

[2] Install the F-30 gas vent / filter by connecting patient line to the bottom outlet of the F-30 gas vent / filter and the D-100 (DI-100) outlet line to the top inlet of the F-30 gas vent / filter.

[3] Open the patient line roller clamp. Open the clamps above and below the F-30 gas vent filter. Open clamp to saline filled I.V. bag. Saline will flow under gravity pressure to fill the line. Close roller clamp when patient line is primed . The filter will self-prime. Gently tap gas vent filter to release trapped air. Close clamp to saline filled I.V. bag.

[4] Turn on the fast flow fluid warmer and pressurize the pressure chamber containing the air-filled I.V. bag.

[5] The Air Detector will automatically perform a Power On Test. Verify the following Power On Test:

- *GREEN LED is illuminated*
- *YELLOW LED is illuminated*
- *RED LED is illuminated*
- *Alarm activates*

[6] Confirm the Air Detector goes into automatic operation. Verify:

- *GREEN LED remains illuminated*
- *YELLOW LED is off*
- *RED LED is off*
- *Alarm is off*

6) Clamp Test

[1] Open the clamp to the air-filled I.V. bag. The air will travel through the tubing and into the gas vent filter. The Air Detector shall detect the air and clamp.

[2] Verify that:

- *there is no water exiting the distal end of patient line.*

[3] Close clamp to air filled I.V. bag. Turn off the warmer. Verify that:

- *clamp disengages tubing.*

7) Clamp closed dimension

[1] Remove the F-30 Gas Vent/Filter Assembly and unthread the patient line from the Clamp Slot.. Turn the device on, so that the clamp closes its jaws – this is the air detected mode.

[2] Test the clamp closed dimension by attempting to place a 0.030" pin gauge in its jaws. If the pin gauge cannot be inserted beyond the midway point of the jaws then this test is considered a Pass.

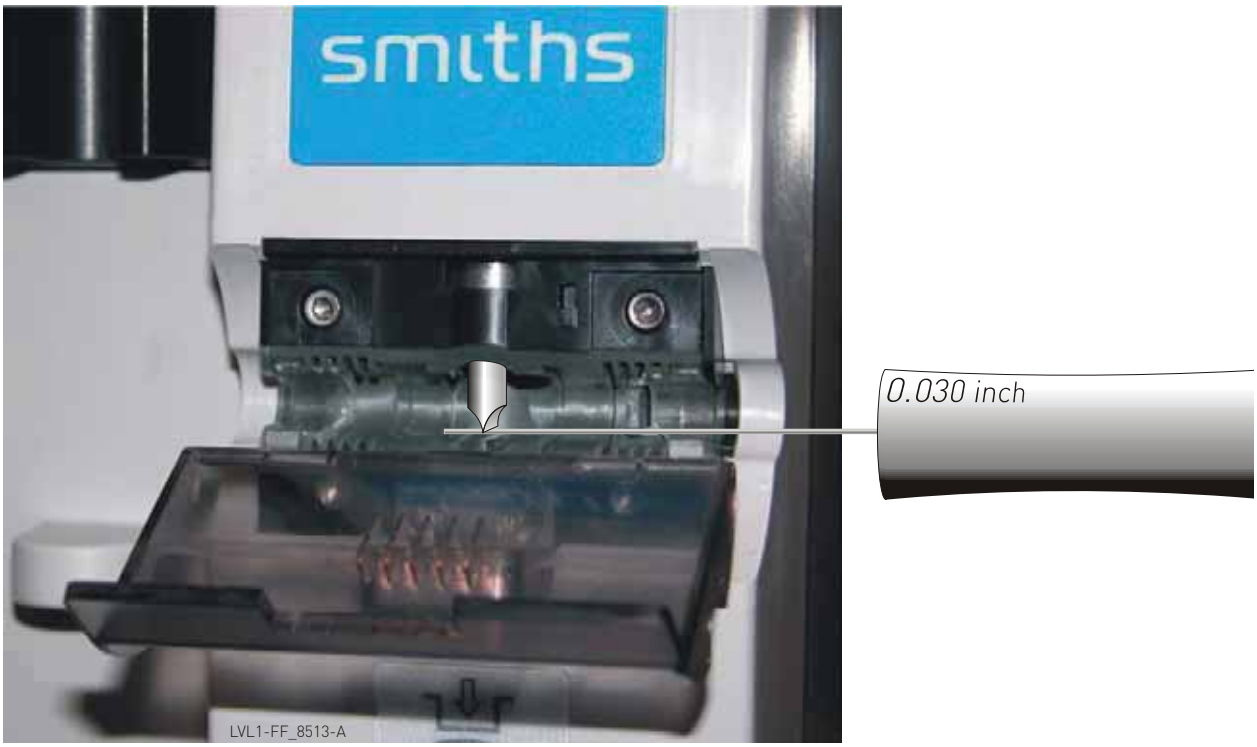

Figure 5 - 9: Testing Clamp Closed spacing with a pin gauge

8) And Finally...

[1] Make sure the unit is clean.

[2] Verify that all labels are properly affixed, in particular that the NTS, CE, and WEEE labels are attached to the H-31B where these are required.

[3] Check also that the Quick Reference Card set is complete and in good condition, and if necessary renew damaged cards. (You will find instructions for making these in Appendix 3).

[4] Check that the service record sheet (see overleaf) has been correctly filled in.

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Fast Flow Blood and Fluid Warmer Air Detector / Clamp Service Checklist

Serial Number .....

Tested by .....

Date .....

Equipment ID No .....

(Numbers in brackets give paragraph reference)	Procedure	Expectation	Pass?
Visual Inspection (1.1)	No sign of damage	Cabling, gaskets in good condition.	☐
Install D-100/F-10: Power-On Test (2.7)	Switch H-1200 ON	Green LED ON Yellow LED ON Red LED ON Alarm SOUNDING	☐
Automatic Mode (2.8)	Wait 5 seconds	Green LED ON Yellow LED OFF Red LED OFF Alarm SILENT	☐
Tubing Placement Test (3.1)	Manipulate tubing where it exits	Unit must stay in Automatic Mode	☐
Clamp Test (4.2)	Open air bag clamp	After air reaches F-10, no saline exits the patient line.	☐
Clamp Release (4.3)	Switch H-1200 OFF	Clamp Disengages Tubing	☐
Remove F-10, Install F-30 Power-On Test (5.5)	Switch H-1200 ON	Green LED ON Yellow LED ON Red LED ON Alarm SOUNDING	☐
Automatic Operation (5.6)	Wait 5 seconds	Green LED ON Yellow LED OFF Red LED OFF Alarm SILENT	☐
Clamp Test (6.2)	Open air bag clamp	After air reaches F-30, no saline exits the patient line.	☐
Clamp Release (6.3)	Switch H-1200 OFF	Clamp Disengages Tubing	☐
Clamp Closed Dimension (7.2)	Remove Disposable, Switch Unit ON	0.030" pin gauge must NOT pass through jaw gap	☐
Clean Unit (8.1)	Use soft cloth	Aqueous detergent or bleach only	☐
Verify Labelling complete (8.2)	Visual Check, Replace where req'd	All labelling to be in good condition	☐
Verify Checklist complete (8.3)	Ensure this sheet is completed	Signed and Dated	☐

Level 1® H-1200

Fast Flow Fluid Warmer

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Fast Flow Blood and Fluid Warmers

LEVEL 1®

A Demand Simulator

The purpose of the Demand Simulator is to apply a thermal drain to the recirculating solution system, so as to load the heaters and exercise them.

After replacement, a new heater needs to be “burned in” to establish that it is completely settled. In normal operation, both heaters are used in the initial stages of warm-up, but only Heater H2 is used to maintain the temperature when it’s already warmed up.

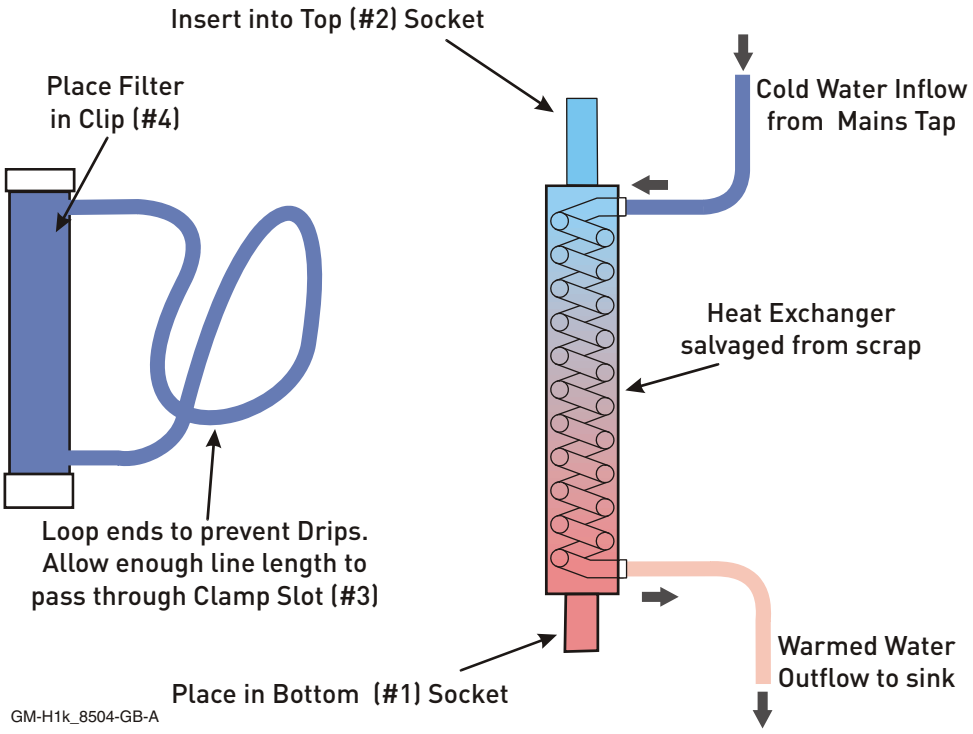

Figure 6 - 1: A Demand Simulator to exercise the Heaters

To ensure that Heater H1 also gets exercised a constant flow of fresh cold water is passed through the heat exchanger, so that equilibrium conditions are never reached. The constantly replenished cold water fools the unit into thinking it's just been turned on, and hasn't yet reached its normal operating conditions.

While the circulating water temperature is less than 36 °C, both heaters should be energised. This ensures that normal operating temperature is reached as rapidly as possible. Above 36 °C, up to working temperature, only one heater is used, to reduce the likelihood of thermal overshoot.

Gather some parts from a scrap disposable set, and scour your "junk-box" for some assorted small hose fittings. You need to arrange things so that you can positively attach the top end of the reclaimed Heat Exchanger to a convenient cold tap, such that it will stay connected without attention.

The outflow from the Heat Exchanger will need to be guided to a waste outlet, such as a sink or convenient drain. You may need to rig a clamp or holder to keep the outflow in place.

Don't forget to salvage a Gas Vent / Filter when you collect the parts to build your Demand Simulator. Although it plays no active part in the simulating of demand, it's presence in its holder is necessary to let the pump circulate the recirculating solution. You will increase its usefulness if you loop a length of patient line between its ends, with enough slack that it can be threaded through the Clamp Slot of the H-31B.

Trouble Shooting - Air Faults

Problem	Check This	Possible Cause
Insufficient or No Pressure	Can you hear the compressor?	If YES: Check that the control lever is fully to the "+" position. Is the air hose damaged, or disconnected at the back of the tower unit or at the "Y" connector? Otherwise, the hose could be damaged or be disconnected internally.
		If NO: Is the Fluid Warmer plugged in and switched on?
Door will not open	Is the bag pressurised?	If YES: Move the control lever fully to the "-" position.
Compressor will not turn off	Is the Fluid Warmer on?	If YES: This is not a fault. The compressor runs whenever the Fluid Warmer is switched on.
		If NO: This is just plain spooky. The compressor should be getting its power from the Warmer.
Compressor seems unduly noisy	Are the pressure chambers in use?	If YES: Ensure that the pneumatic pipework is conected throughout with no open ends. Check that compressor mounting screws are OK.
		If NO: Check that the orange pneumatic plug is in place in compressor outlet port. Check that compressor mounting screws are OK.

Trouble Shooting - Other Faults

Problem	Check This	Possible Cause
Disposable alarm sounding	Is a disposable set fitted?	If YES: Ensure that the disposable set is properly in place at the heat-exchanger holder (#1), the filter/gas-vent holder (#3) and at the (#2) upper socket.
		If NO: Switch off unit until a suitable disposable set is in place.
Recirculating Solution Low Level alarm sounding	Visually check the reservoir. Is the level actually low?	If YES: Top up with replacement recirculating solution. Check for leaks.
		If NO: Check for damaged float switch wiring. Check the float switch by substitution.
Over Temperature alarm sounding	Is the LCD temperature display reading high?	If YES: Turn off the unit, allow to cool before turning on again. If behaviour repeats, remove from service, check thermistors and heater H2's thermostat.
		If NO: Remove with from service, check thermistors, thermostats and PCB power components.
System Unit seems unduly hot	Is the fan inlet obstructed?	If YES: Clear all obstructions.
		If NO: Remove and clean the fan filter. Check the fan is working.
Heat Exchanger difficult to install	Are the O-rings dry?	If YES: Re-lubricate the O-rings with silicone lubricant.
		If NO: Replace the O-rings.

Level 1® H-1200

Fast Flow Fluid Warmer

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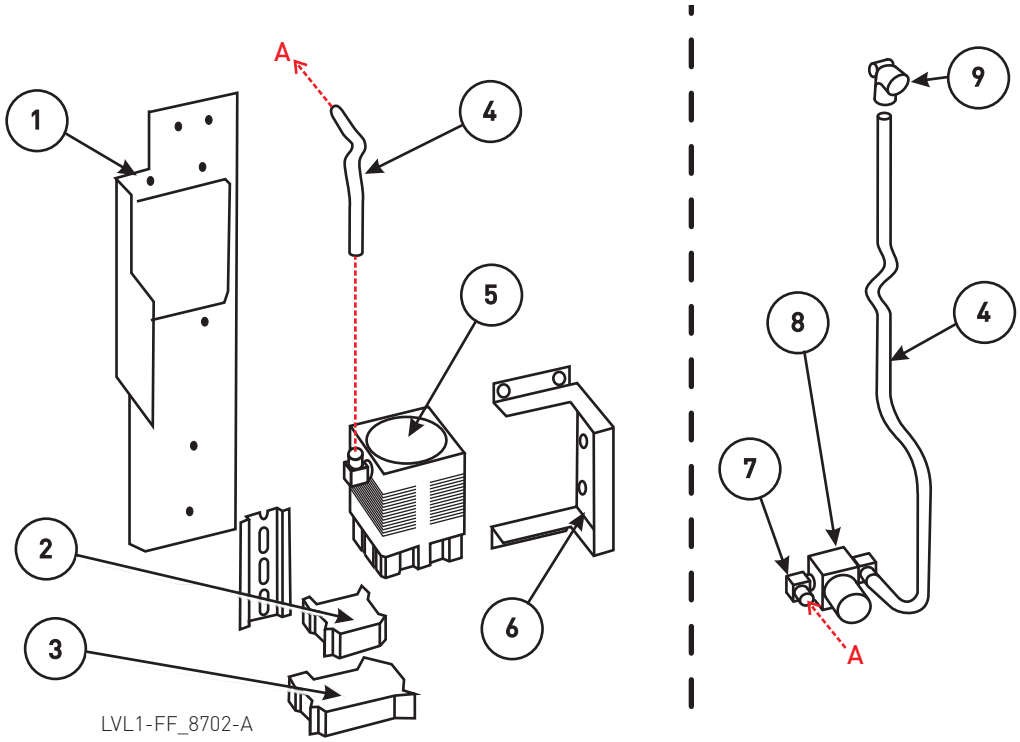
Tower Unit Spare Parts List

Case Exterior - Front

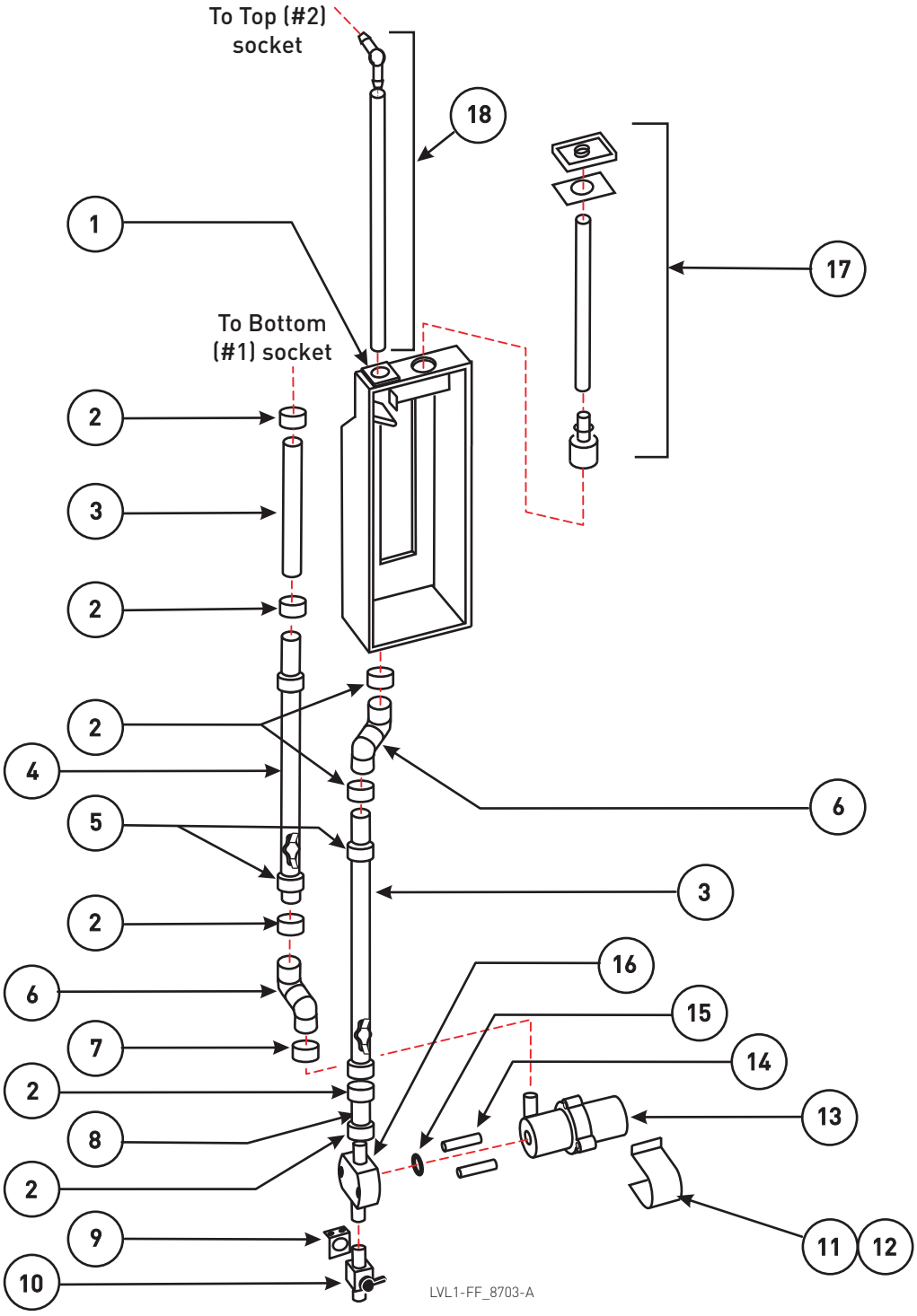
	Case Exterior - Front	Part Numbers
1	Display Panel Adhesive Decal	45-21-720
2	Control Panel Keyboard Membrane / Decal	60-41-103
3	Fillport Cap	62-31-009
4	Enclosure Moulding	64-02-701
5	Top Socket Assembly	72-06-708
6	O-Ring (2 places)	62-40-001
	O-Ring Kit (2 O-rings, Silicone Grease, Allen key)	80-04-003
7	Heat Exchanger Interlock assembly	72-06-706
8	Bottom Socket	64-10-701
9	Gas Vent / Filter Support Assembly	72-06-705
10	Gas Vent / Filter Interlock Switch	60-40-043

Air Components



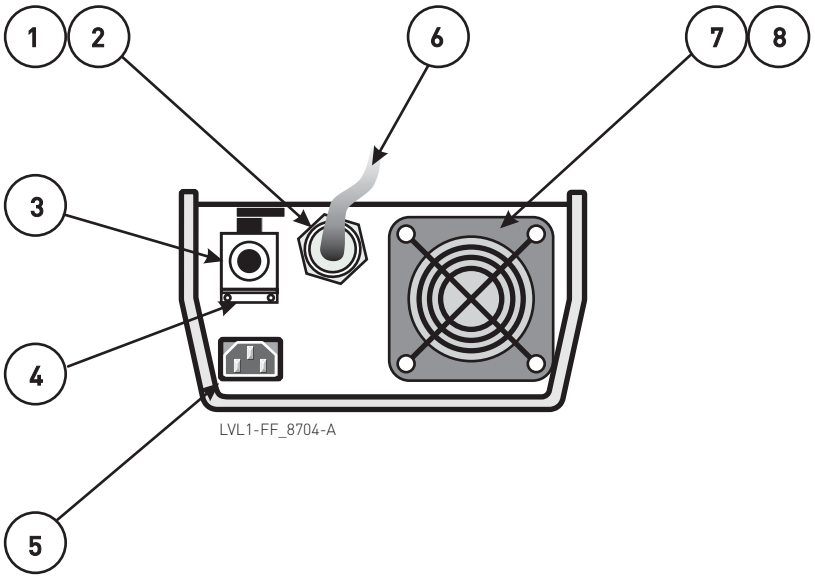
	Air Components	Part Numbers
1	Chassis Assembly, inc. Regulator, 230v Compressor and terminals	72-10-702
1	Chassis Assembly, inc. Regulator, 115v Compressor and terminals	72-10-703
-	Chassis, no compressor, no regulator	64-01-037
2	DIN-rail mounted Terminal	60-47-046
3	DIN-rail mounted Fuseholder (for fuses see Section 8)	60-48-010
4	¼ inch Black PU tubing (per foot)	62-20-010
5	Air Compressor 115v	66-02-001
5	Air Compressor 230v	66-02-002
6	Acoustic Isolation Sub-chassis	64-01-038
-	Blue Acoustic Isolation bushes (8 per set required)	62-03-020
-	Shoulder Screws (8 per set required)	62-01-061
7	Swivel Elbow	62-23-002
8	Regulator	66-06-001
9	SMC fitting	62-22-049
-	Orange plug	62-22-019

Recirculating Solution Path Parts



	Recirculating Solution Path Components	Part Numbers
1	Return Pipe Gasket	62-37-002
2	Oetiker Clip (7 in total)	62-05-042
3	Bottom Socket Tube	62-20-014
4	Heater Unit c/w T-Stat 230 v (2 req'd)	74-02-101
	Heater Unit c/w T-Stat 115 v (2 req'd)	74-02-100
5	Silicone Rubber Spacer (4 in total)	62-20-033
6	S-bend Pipe	62-22-041
7	Oetiker Clip	62-05-025
8	Straight 1" Silicone Tube	62-20-014
9	Drain Tap Bracket	64-01-057
10	Drain Tap	62-27-003
11	Pump Clamp	64-01-701
12	Clamp Retaining Screws (#6 Selftapping x 3/8") 2 in total	62-01-056
13	Pump / Motor	66-01-009
14	Standoffs (2 req'd)	62-05-029
15	O-Ring Seal (use Silicone Lube)	62-40-022
16	Pump Manifold (c/w bonded upper/lower tubing)	74-01-702
-	Pump Assembly (incl. items 13, 14, 15, and 16 above)	74-01-701
17	Float Switch Assembly	72-06-702
18	Return Pipe Assembly	72-06-707

Electrical Parts

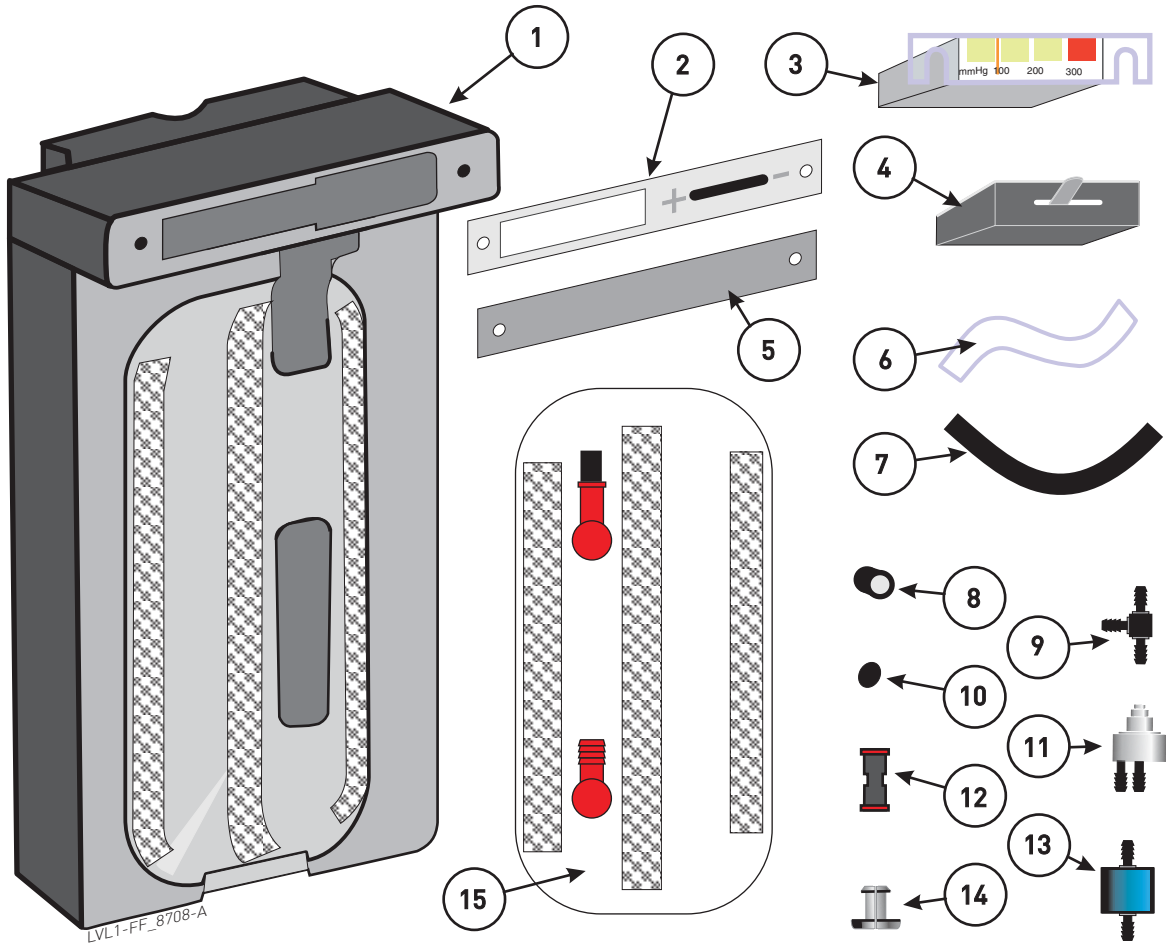


	Electrical Parts	Part Numbers
1	Cable Entry Gland	62-07-013
2	Cable Entry Gland Locknut	62-07-014
3	Drain Tap - see Recirculating Solution Path Parts	-
4	Drain Tap Bracket - see Recirculating Solution Path Parts	-
5	Auxiliary Power Outlet Assembly	72-06-704
6	Mains Inlet Cable - UK	70-01-032
	Mains Inlet Cable - US	70-01-005
7	Cooling Fan	72-06-703
8	Fan Guard	62-32-005
-	In-Line Mains Filter for Heater	60-24-014

Miscellaneous Tower Unit Parts

	Miscellaneous Parts	Part Numbers
-	Thermistor (Top or Bottom)	60-06-700
-	Thermistor mounting O-Ring	62-40-700
-	Label set (U.S.) Old Style	45-21-710
-	Label set (U.S.) New Style	45-21-721
-	H-1025 / H-1100 Label Set (230v)	45-20-016
-	H-1200 Label Set (230v)	45-20-024
-	Hardware Specification Label - H-1000/H-1025 115v	45-21-703
-	Hardware Specification Label - H-1000/H-1025 230v	45-21-704
-	Hardware Specification Label - H-1100 115v	45-21-800
-	Hardware Specification Label - H-1100 230v	45-21-801
-	Hardware Specification Label - H-1200 115v	45-21-705
-	Hardware Specification Label - H-1200 230v	45-21-706
-	Setup label	45-24-089
-	Rear Cover Screws set (16 pcs 4-40 x 1/4 flat head plus 2 pcs 4-40 x 3/8 button head)	62-01-049
-	Old style Main PCB Assembly (115 V)	70-02-700
-	New style Main PCB Assembly (115 V)	70-02-701
-	New style Main PCB Assembly (230 V)	70-02-706
-	Temperature Display Module	60-10-004
-	Power Pole Assembly (H-1100)	72-03-802

Pressure Chamber Spares



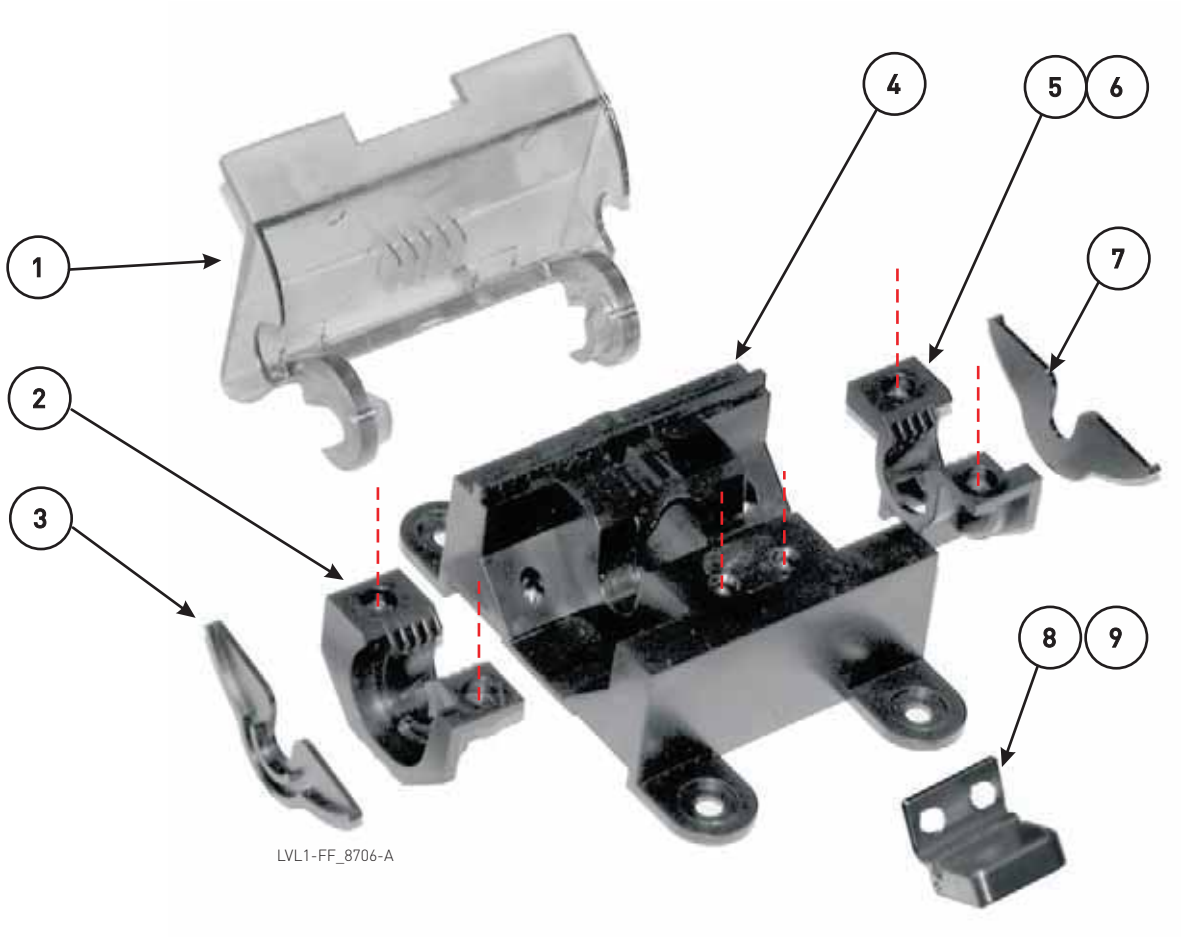
	Original Style Pressure Chamber Parts	Part Numbers
1	Moulded Enclosure - Black (11 inch)	64-02-028
-	11 inch Front Door - Clear c/w Hinge Assembly (US issue)	72-04-026
-	11 inch Front Door - Clear c/w Hinge Assembly (International)	72-04-024
-	Latch for 11 inch door	62-08-006
-	Front Door - Clear c/w Hinge Assembly (10 inch)	72-03-007
-	Latch for 10 inch door	62-08-009
2	Control Panel Fascia Assembly	72-04-027
3	Pressure Gauge Assembly	62-24-003
4	Pressure Control Lever Switch	72-04-008
-	Rubber Toggle cover for Pressure Control Lever Switch	62-31-010
5	Blanking Plate	64-01-034

(cont'd overleaf)

	Original Style Pressure Chamber Parts	Part Numbers
(cont'd from previous page...)		
6	1/2 inch clear PU air hose	62-20-024
7	1/4 inch black PVC air hose	62-20-010
8	Protective knob (2 off)	64-10-030
9	1/4 inch T-piece	62-22-051
10	Self-adhesive screw cover vanity dots (4 off)	45-21-006
11	Pressure relief valve	72-04-023
12	Straight Connector 1/4 inch	62-23-003
-	Straight Connector 1/2 inch	62-23-019
13	Non-Return Valve	62-27-001
14	Strain Relief	62-07-012
15	Bladder (11 inch case)	72-04-021
-	Bladder for 10 inch case	62-21-001
-	Screws set (2 pcs)	62-01-058
-	Poleclamp bracket	64-01-039
-	Poleclamp bracket screws (2 off)	62-05-054

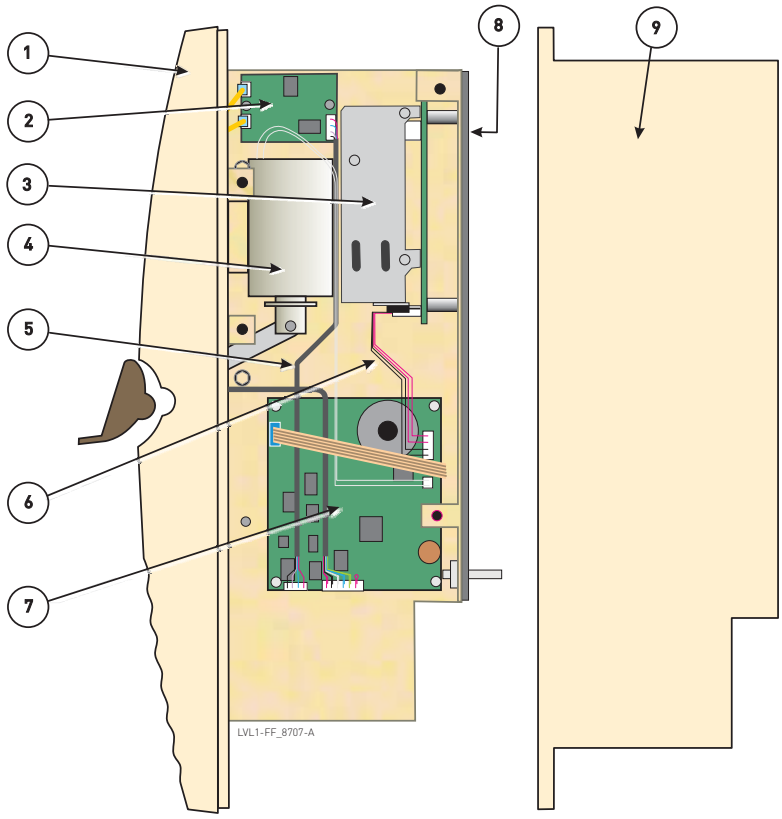
	New Style Pressure Chamber Parts	Part Numbers
-	2-piece Moulded Enclosure Front Half - Beige	64-02-106
-	2-piece Moulded Enclosure Rear Half - Beige	64-02-105
-	Door - Clear c/w Hinge Assembly	72-03-010
-	Door Latch	72-03-011
-	Bladder	62-21-005
-	Front Cover Warning Label (English)	45-21-069
-	Screws set A (6 pcs)	62-01-018
-	Screws set B (3 pcs)	62-01-099
-	Poleclamp bracket	64-01-039
-	Poleclamp bracket screws (2 pcs)	62-05-054

Air Detector / Clamp Spares

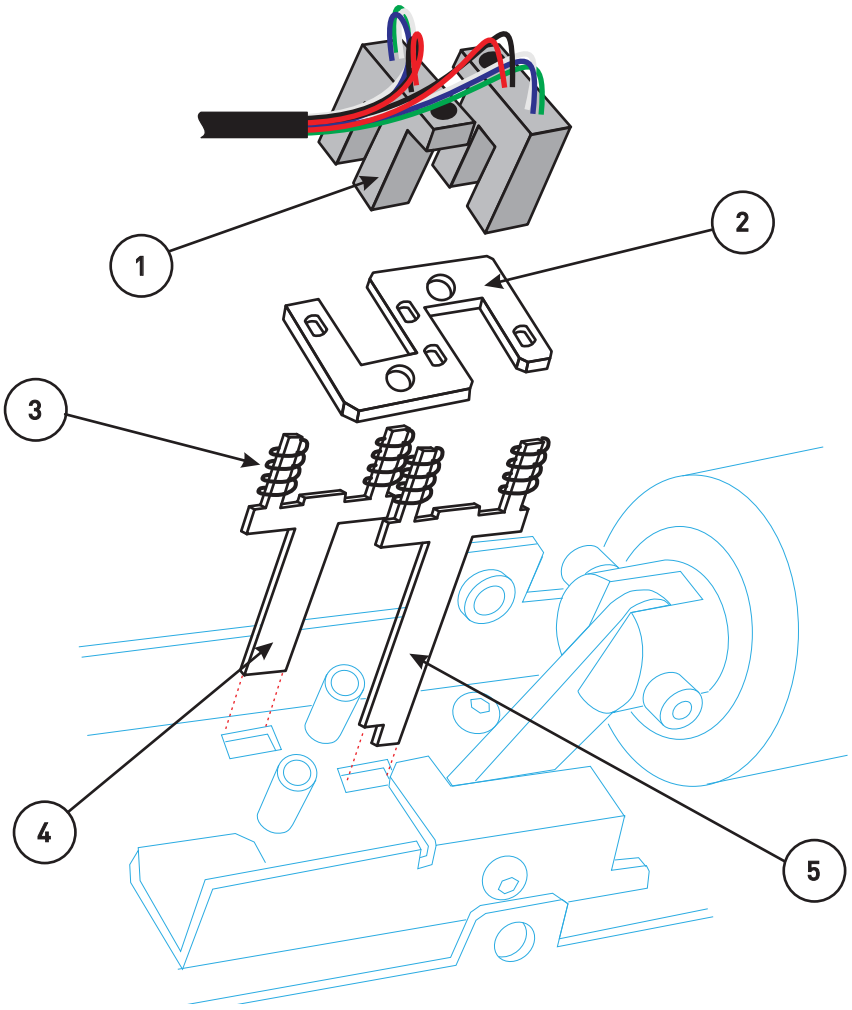


	Air Clamp / Detector External Parts	Part Numbers
1	Articulated Door	64-02-075
2	Left Hand Door Mounting Block	64-02-071
3	Front Cover Rib (L)	64-10-094
4	Clamp Slot Moulding	64-10-104
5	Right Hand Door Mounting Block	64-02-072
6	Door mounting 4-40 x 3/4 Hex Cap Head 18/8ss screws (4 off)	62-01-078
7	Front Cover Rib (R)	64-10-094
8	Door Latch	64-10-099
9	Door Latch 4-40 x 1/2 Phillips Pan Head 18/8ss fixing screws (2 off)	62-01-064
-	Mounting Bracket (Air Detector/Clamp to Tower Unit) *	64-01-079

* may be one of two designs. This part number replaces either type.



	Air Clamp / Detector Major Parts	Part Numbers
1	Front Cover Moulding	64-02-067
2	Air Detector Buffer PCB Assy	60-40-055
3	Power Supply Assembly	60-14-008
4	Solenoid Assembly	66-07-004
5	Wiring Loom (Air Detector PCB - Alarm PCB)	77-00-927
6	Wiring Loom (Alarm PCB - PSU Module)	77-00-928
-	Wiring Loom, Mains - H-1200 for internal routing	70-02-702
-	Wiring Loom, Mains - H-1025 external power cord	77-01-034
7	Alarm PCB Assy	70-02-710
8	Gasket (rear cover)	62-37-008
9	Rear Cover Moulding	64-02-068
-	Pole Gasket (seal between H-31B and Tower)	62-37-013
-	Case Screws (6-32 x 3/8 Phillips head) 2 req'd	62-01-079
-	Case Screws (6-32 x 3/8 hex button head) 5 req'd	62-01-080
-	User Interface Assembly (LED Flexy PCB)	60-41-106



	Air Clamp / Detector Sensor Parts	Part Numbers
1	Optical Switch Assembly	77-00-929
2	S-plate Key Retainer	64-01-080
3	Key Return Spring (4 off)	64-11-043
4	Tube Sensor Key	62-37-011
5	Door Sensor Key	62-37-012
-	Phillips 6-32 x 3/8 inch Pan Head Screws (2 used)	62-01-008
-	Air-in-Line Sensor Assembly	60-40-050
-	Phillips 4-40 x 1/4 inch Flat Head Screws (2 used)	62-01-049

Level 1® H-1200

Fast Flow Fluid Warmer

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Fast Flow Blood and Fluid Warmers

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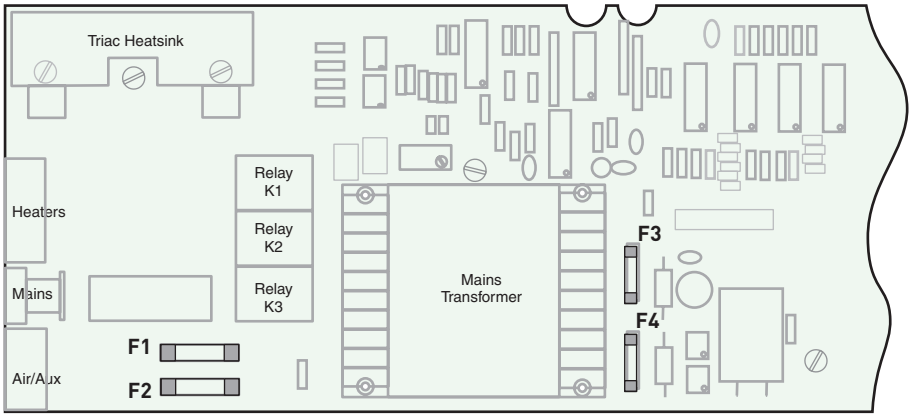
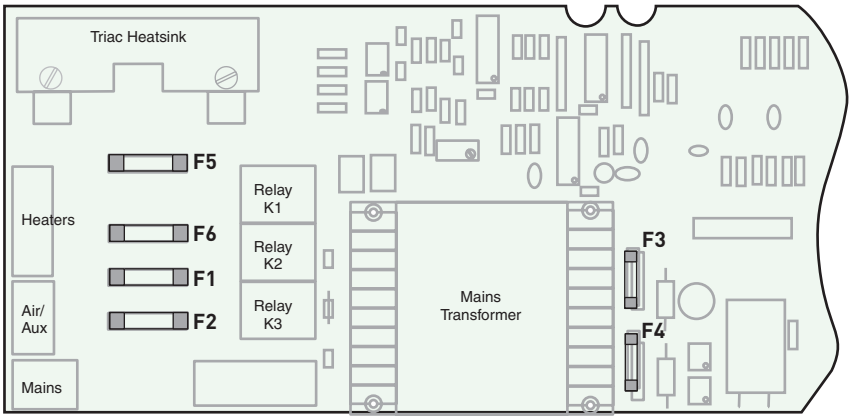
Fusing

Fast Flow Blood and Fluid Warmers are protected by 6 fuses within the tower case. In units fitted with the Air Detector / Clamp, there is a further fuse located inside that part.



Later Models



Early Models

Fuse	Application	Rating	Type	Level 1 Part Number	Function	Location
F1	H-1200 230v	3.15 A	Slow Blow	60-23-033	AUX Output and Air Detector / Clamp	Main PCB
	H-1200 115v	6.3 A	Slow Blow	60-23-030		
F1	others 230v	3.15 A	Slow Blow	60-23-033	AUX Output	Main PCB
	others 115v	6.3 A	Slow Blow	60-23-030		
F2	all types 230v	750 mA	Slow Blow	60-23-023	AIR compressor	Main PCB
	all types 115v	1.6 A	Slow Blow	60-23-028		
F3	all types 230v	1 A	Slow Blow	60-23-017	Low Voltage Logic Supply	Main PCB
	all types 115v	1 A	Slow Blow	60-23-021		
F4	all types 230vv	1 A	Slow Blow	60-23-017	Low Voltage Pump and Fan Supply	Main PCB
	all types 115v	1 A	Slow Blow	60-23-021		
F5*	all types 230v	3.15 A	Slow Blow	60-23-033	Heater 1	DIN Rail
	all types 115v	6.3 A	Slow Blow	60-23-030		
F6*	all types 230v	3.15 A	Slow Blow	60-23-033	Heater 2	DIN Rail
	all types 115v	6.3 A	Slow Blow	60-23-030		

NOTE: ***Some early Units may be fitted with a Main PCB that has additional fuseholders for F5 and F6 installed adjacent to the triacs.**

NOTE: **There is a fuse internal to the H-31B, on the main control / alarm circuit PCB. It is a soldered-in type, and not user replaceable.**

Model Designations

There are several models in the Level 1® Fast Flow Blood and Fluid Warmer range. This list describes various model designations.

H-2

A single pressure chamber, supplied as an accessory to the H-1000 Fast Flow Blood and Fluid warmer, for applying pressure to infusate bags up to 1 litre in capacity. Normally used in pairs.

SA-1000

The original Level 1® air detector and clamp. This was a standalone unit that was hung from an adjacent I.V. stand.

H-30

An air detector and clamp unit designed to integrate with the H-1000 and H-1025 units, and similar in appearance to the current model H-31B air detector and clamp unit. It featured a manual override facility.

H-31B

An automatic air detector and clamp which can be retro-fitted to H-1000 or H-1025 warmers to bring them up to H-1200 specification.

H-1000

All components are now built into the tall, thin, vertical housing. Twin Heaters for quicker warm-up from cold, and higher flowrate capability, while maintaining high efficiency.

H-1025

A version of the H-1000 with dual pressure chambers and integrated compressor / regulator. For new applications, specify H-1200 instead.

H-1028

Same as H-1025 Fast Flow Blood and Fluid Warmer, but packaged with an external SA-1000 air detector / clamp. For new applications specify H-1200.

H-1100

Same as H-1000 but incorporating an electrically powered pole extension mechanism to raise unpressurised irrigation solution bags, thereby gaining pressure and flow rate from gravity power.

H-1125

Same as H-1100 but with dual pressure chambers and integrated compressor regulated to a fixed 300 mmHg pressure. Not a very common configuration.

H-1200

The latest version of the Level 1® Fast Flow Blood and Fluid Warmer is fitted with a built-in air detector / clamp. Using ultrasonic technology, the system automatically shuts down when an air bubble is detected in the I.V. line.

Quick Tests

The following components may be tested by use of a multimeter to measure their DC resistance. These sample figures are approximate and variations of up to 20% should not be a cause for concern. Bear in mind also that some of these components are intended to work in AC circuits, and so the readings you observe are probably not typical of "in-service" conditions.

Item	Typical Resistance
Thermistor (Room Temperature)	40 k Ohms
Thermistor (Warmed between fingers)	25 k Ohms
Heater Element (Room Temperature)	85 Ohms
Thermostat (Room Temperature)	0.5 Ohms
Thermostat (100 °C)	Open Circuit
GRI Pump Motor	11 Ohms
Cooling Fan *	> 1 M Ohm
Compressor Motor *	> 1 M Ohm

* The Cooling Fan and Compressor Motor readings suggest that there is some electronic circuitry internal to these components and simple probing with a resistance meter is not likely to be useful. Instead, check them by substitution, as there is no prospect of repairing either of these parts.

Quick Quiz

NOTE: Some of these questions may have more than one correct answer. Tick ALL those answers you believe are applicable.

[1] A Thermistor is a good choice of temperature control device for this application because:

Its resistance is very stable over a wide range of temperatures. ☐

It is capable of surviving very high temperatures. ☐

Its change-of-resistance characteristic is very predictable. ☐

It is physically very small and robust. ☐

[2] Which of these conditions could possibly prevent an H-1200 from operating? (Tick all those that apply)

Excessively high (40+°C) ambient temperature. ☐

A broken castor on the base unit. ☐

Open circuit Fan motor. ☐

Ambient temperature -20°C. ☐

Overfilled circulating water reservoir. ☐

Heat exchanger fitted upside down. ☐

[3] On an H-1025, an illuminated red L.E.D. to the right of the temperature display indicates that:

Mains power is connected and switched ON. ☐

The top heat exchanger socket IS properly connected. ☐

The top heat exchanger socket is NOT properly connected. ☐

The system is operating normally. ☐

[4] Which of the various alarm tests might not be valid on a H-1200 that has been switched on for less than ten minutes?

General Alarm test button. ☐

Recirculating Solution Level Alarm Test. ☐

Over Temperature Alarm test button. ☐

Disposable Alarm Test. ☐

[5] After storage in an ambient temperature of 21 °C, a fully working H-1100 is switched on. How quickly would you expect it to reach 41 °C ?

under 3 minutes. ☐

over 3 minutes but under 7 minutes. ☐

over 7 minutes but under 11 minutes. ☐

over 11 minutes. ☐

[6] What is indicated by the lighting-up of the LED next to the symbol shown here?

System operating normally. ☐

Cooling fan is faulty. ☐

Recirculating pump is faulty. ☐

Fan filter element needs cleaning. ☐

[7] Which of the following tasks form part of a routine 30-DAY maintenance cycle?

Grease the O-Rings. ☐

Change the O-Rings. ☐

Change the fan filter. ☐

Change the gas vent filter. ☐

[8] Which of these tasks are only required during an ANNUAL maintenance cycle?

General Alarm Test. ☐

Change the O-Rings. ☐

Recirculating Solution Level Alarm Test. ☐

Temperature Display Calibration Check. ☐

[9] Why is the non-return valve so important in the pressure chamber design?

To prevent reverse air flows damaging the regulator if the power fails. ☐

So that infusion flowrate is maintained if the tubing is accidentally disconnected. ☐

The patient can be moved by ambulance without pressure and flowrate dropping. ☐

To mantain the pressure if the bladder is accidentally punctured. ☐

Answer to Exercise on page 53

All of the suggestions we put forward are at least theoretically possible, but none of them are at all likely! There may be several good reasons for the motor current to be unduly low, but the most likely reason is that the tower has lost all its recirculating solution, so the pump is just pushing fresh air around.

The pump bearings were not designed to run dry, so they will be wearing out rapidly, at least until the heater' s T-Stat overheats!

Level 1® H-1200

Fast Flow Fluid Warmer

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Fast Flow Blood and Fluid Warmers

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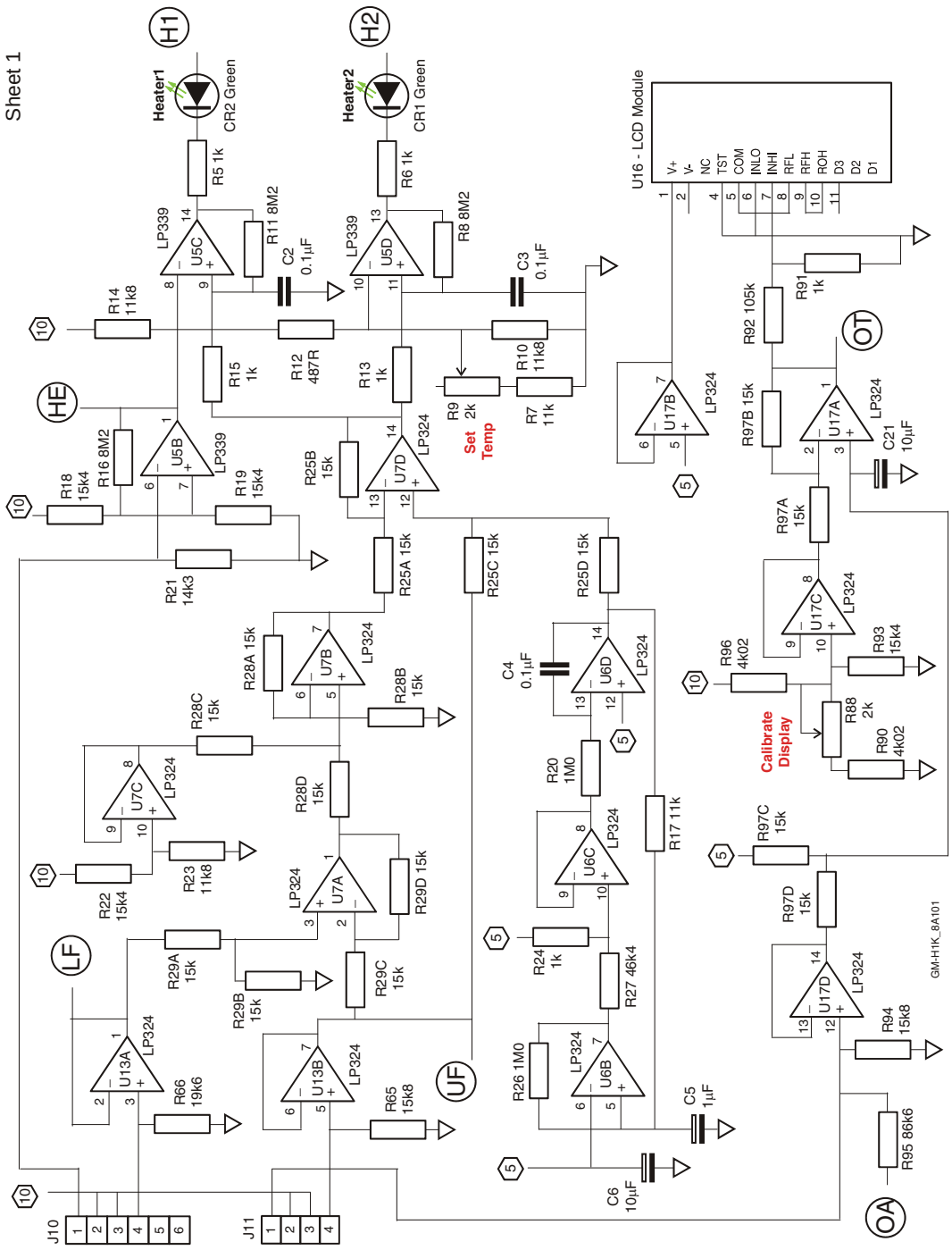
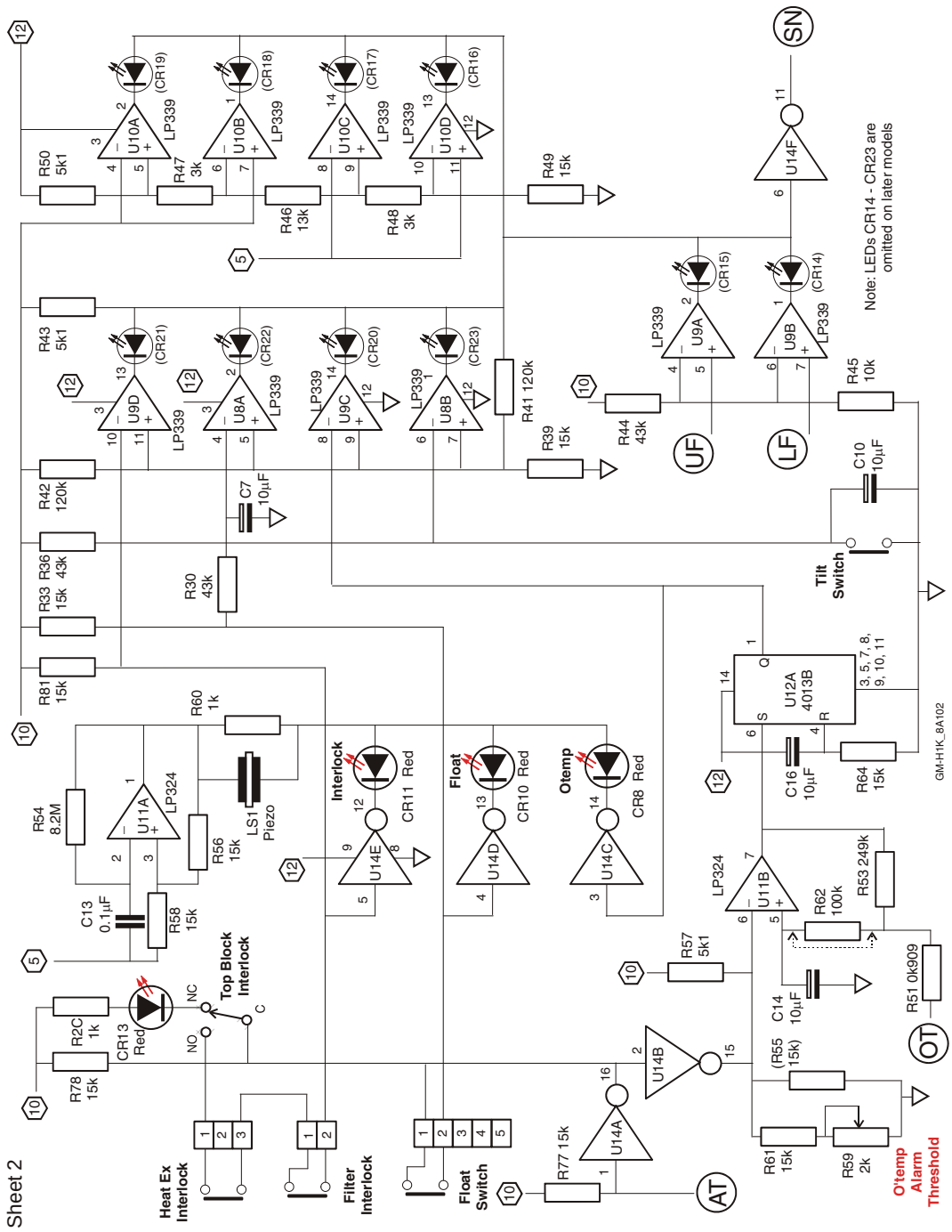
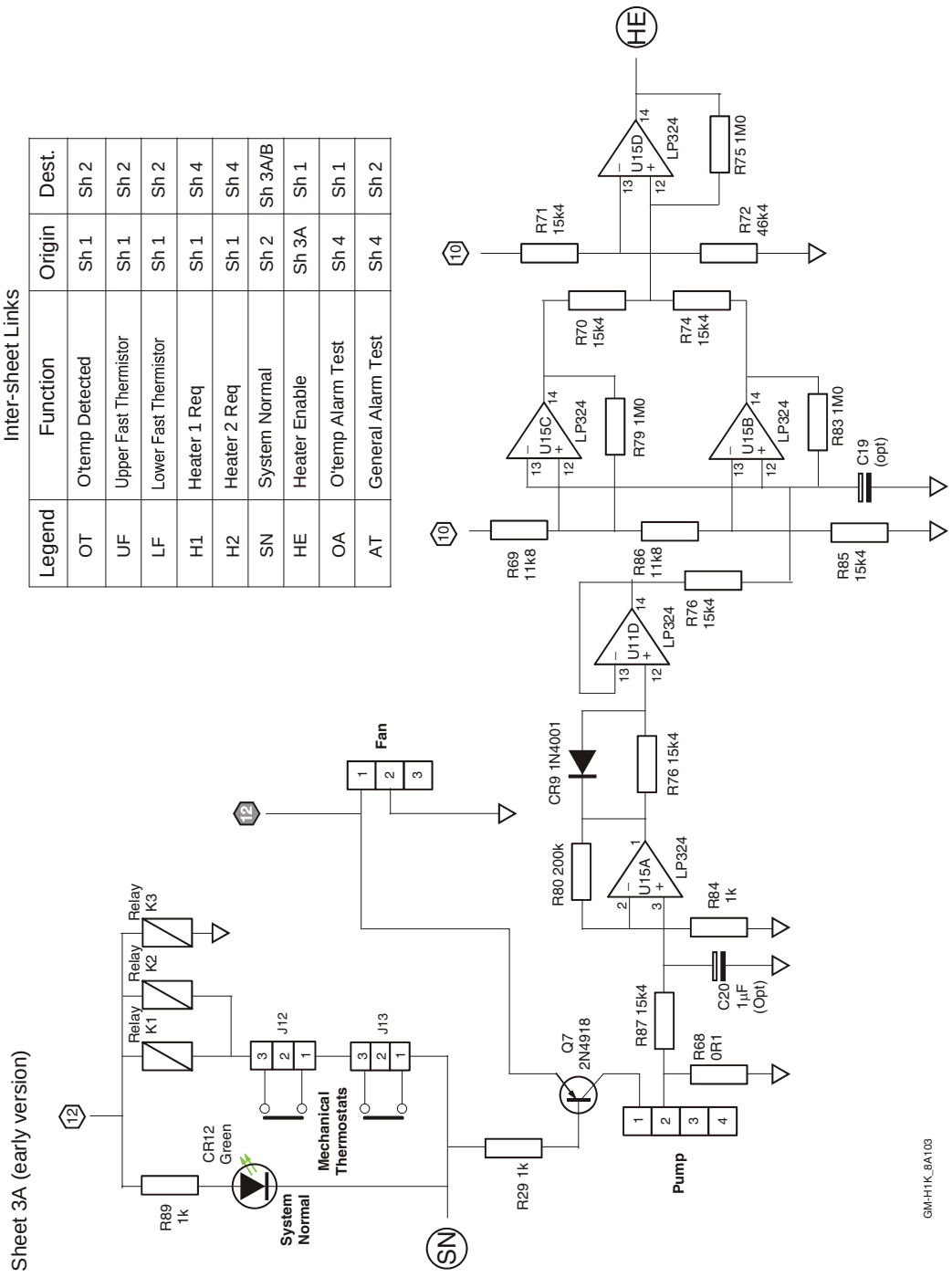
Circuits - 1


Sheet 1
H1
H2
Heater1
CR2 Green
Heater2
CR1 Green
R5 1k
R6 1k
LP339
U5C
U5D
R11 8M2
R8 8M2
C2 0.1µF
C3 0.1µF
R14 11k8
R15 1k
R12 487R
R13 1k
R10 11k8
R9 2k
R7 11k
Set Temp
HE
U5B
R16 8M2
R18 15k4
R19 15k4
R21 14k3
U7D
LP324
R25B 15k
R25A 15k
R25C 15k
R25D 15k
U7B
R28A 15k
R28B 15k
R28C 15k
U7C
R28D 15k
R23 11k8
R22 15k4
U7A
R29D 15k
LF
R29A 15k
R29B 15k
R29C 15k
U13A
R66 19k6
U13B
R65 15k8
UF
U6D
C4 0.1µF
R20 1M0
U6C
R17 11k
R24 1k
R27 46k4
U6B
R26 1M0
C5 1µF
C6 10µF
U16 - LCD Module
V+
V-
NC
TST
COM
INLO
INHI
RFL
RFH
ROH
D3
D2
D1
U17B
R91 1k
R92 105k
R97B 15k
OT
U17A
C21 10µF
R97A 15k
U17C
R96 4k02
R93 15k4
Calibrate Display
R88 2k
R90 4k02
R97C 15k
R97D 15k
U17D
R94 15k8
R95 86k6
OA
J10
J11
GM-H1K_8A101

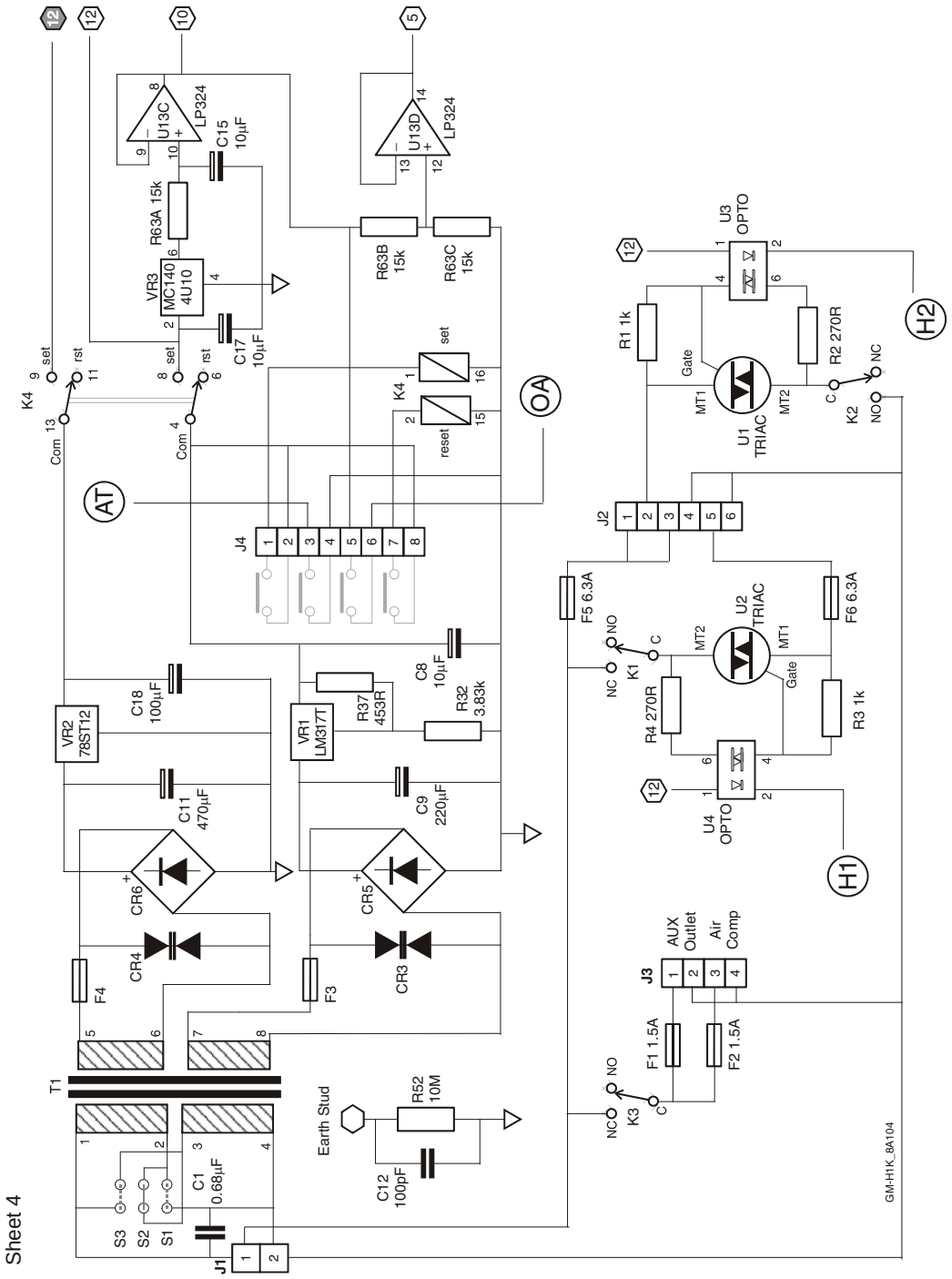
Circuits - 2


Sheet 2
Note: LEDs CR14 - CR23 are omitted on later models
Tilt Switch
Top Block Interlock
Heat Ex Interlock
Filter Interlock
Float Switch
O'temp Alarm Threshold
Interlock
Float
Otemp
GM-H1K_8A102

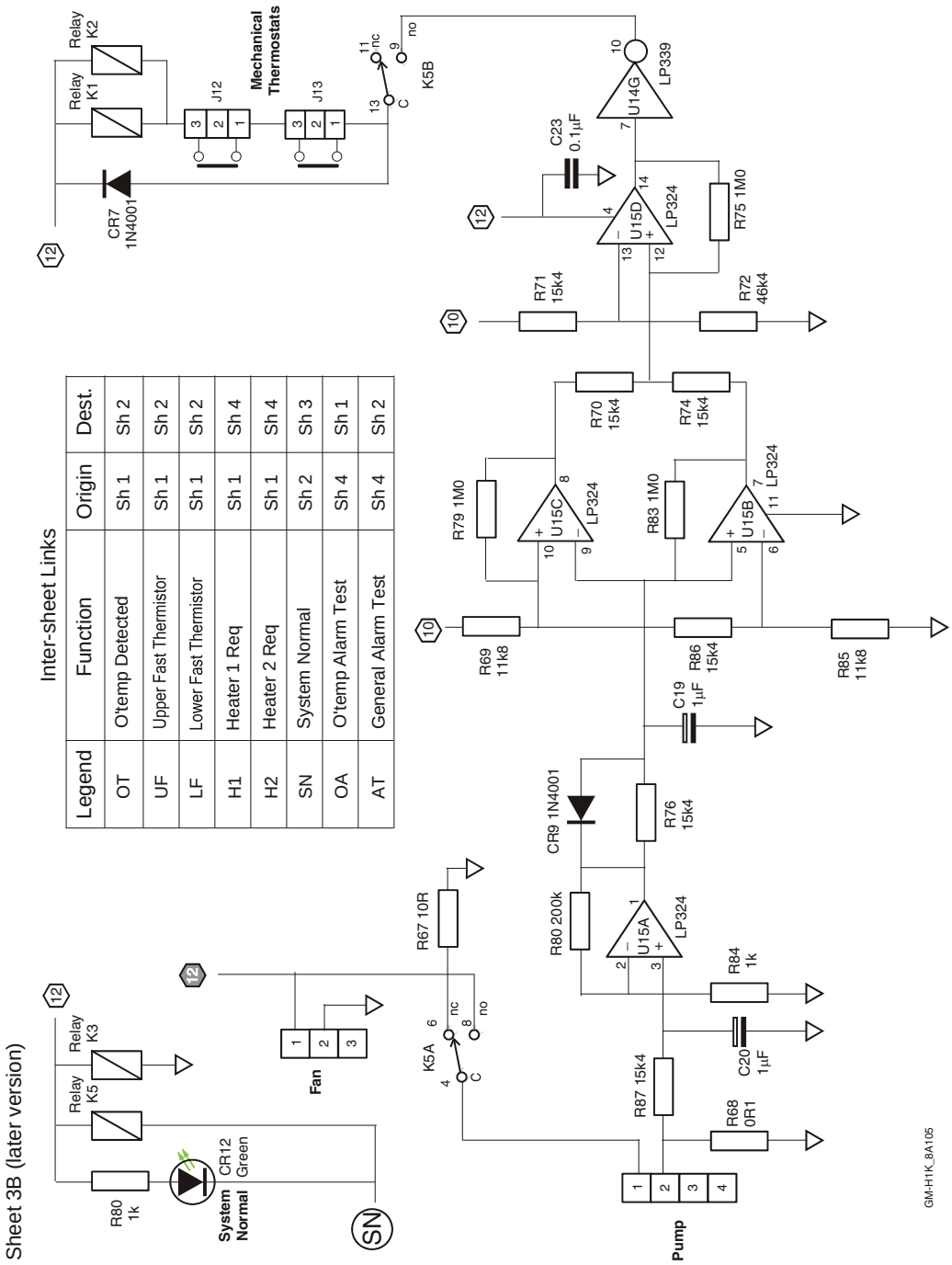
Circuits - 3


Inter-sheet Links
Legend | Function | Origin | Dest.
OT | O'temp Detected | Sh 1 | Sh 2
UF | Upper Fast Thermistor | Sh 1 | Sh 2
LF | Lower Fast Thermistor | Sh 1 | Sh 2
H1 | Heater 1 Req | Sh 1 | Sh 4
H2 | Heater 2 Req | Sh 1 | Sh 4
SN | System Normal | Sh 2 | Sh 3A/B
HE | Heater Enable | Sh 3A | Sh 1
OA | O'temp Alarm Test | Sh 4 | Sh 1
AT | General Alarm Test | Sh 4 | Sh 2
Sheet 3A (early version)
HE
SN
10
12
R71 15k4
R72 46k4
R75 1M0
U15D
LP324
R70 15k4
R74 15k4
U15C
U15B
R79 1M0
R83 1M0
C19 (opt)
R69 11k8
R86 11k8
R85 15k4
U11D
R76 15k4
CR9 1N4001
R80 200k
U15A
R84 1k
C20 1µF (Opt)
R87 15k4
R68 0R1
Q7 2N4918
Fan
Pump
Relay K3
Relay K2
Relay K1
J12
J13
Mechanical Thermostats
CR12 Green
System Normal
R89 1k
R29 1k
GM-H1K_8A103

Circuits - 4


Sheet 4
GM-H1K_8A104
AT
OA
H1
H2
J1
J2
J3
J4
T1
VR1 LM317T
VR2 78ST12
VR3 MC1404U10
U13C LP324
U13D LP324
U1 TRIAC
U2 TRIAC
U3 OPTO
U4 OPTO
K1
K2
K3
K4
F1 1.5A
F2 1.5A
F3
F4
F5 6.3A
F6 6.3A
CR3
CR4
CR5
CR6
C1 0.68µF
C8 10µF
C9 220µF
C11 470µF
C12 100pF
C15 10µF
C17 10µF
C18 100µF
R1 1k
R2 270R
R3 1k
R4 270R
R32 3.83k
R37 453R
R52 10M
R63A 15k
R63B 15k
R63C 15k
S1
S2
S3
Earth Stud
AUX Outlet
Air Comp
Gate
MT1
MT2
Com
set
rst
reset
NO
NC
C

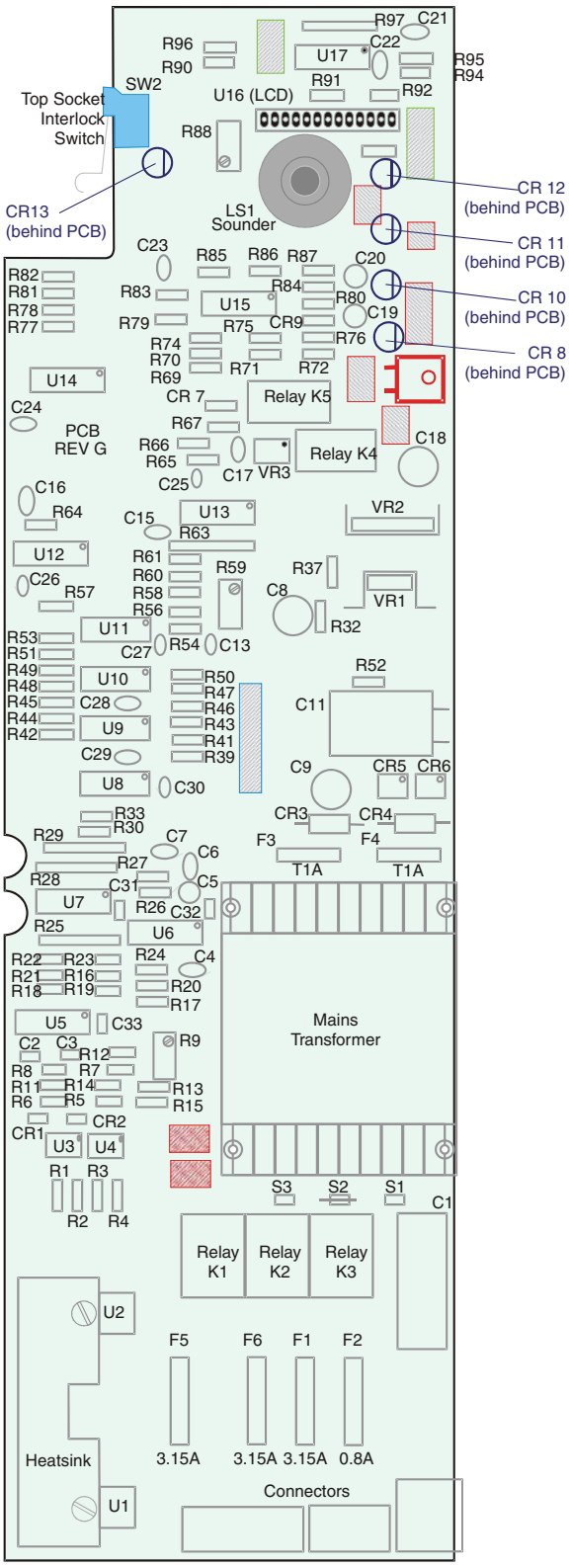
Circuits - 5


Sheet 3B (later version)
Inter-sheet Links
Legend | Function | Origin | Dest.
OT | O'temp Detected | Sh 1 | Sh 2
UF | Upper Fast Thermistor | Sh 1 | Sh 2
LF | Lower Fast Thermistor | Sh 1 | Sh 2
H1 | Heater 1 Req | Sh 1 | Sh 4
H2 | Heater 2 Req | Sh 1 | Sh 4
SN | System Normal | Sh 2 | Sh 3
OA | O'temp Alarm Test | Sh 4 | Sh 1
AT | General Alarm Test | Sh 4 | Sh 2
Mechanical Thermostats
Relay K1
Relay K2
Relay K3
Relay K5
J12
J13
K5B
K5A
CR7 1N4001
CR9 1N4001
CR12 Green
System Normal
Fan
Pump
R67 10R
R68 0R1
R69 11k8
R70 15k4
R71 15k4
R72 46k4
R74 15k4
R75 1M0
R76 15k4
R79 1M0
R80 1k
R80 200k
R83 1M0
R84 1k
R85 11k8
R86 15k4
R87 15k4
C19 1µF
C20 1µF
C23 0.1µF
U14G LP339
U15D LP324
U15C LP324
U15B LP324
U15A LP324
GM-H1K_8A105

PCB Layout

NOTE: Board shown is Revision G.

Other Revision levels may also be found, with detail diferences.



Level 1® H-1200

Fast Flow Fluid Warmer

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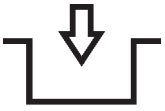
Symbols Glossary

Symbol	Meaning
 GM-H1K_8A301	ATTENTION: Read the accompanying instructions
 GM-H1K_8A303	Recirculating Solution Temperature (°C)
 GM-H1K_8A304	Automatic Operation
 LVL1-FF_8A305	Add Recirculating Solution
 GM-H1K_8A306	Recirculating Solution Over Temperature
 GM-H1K_8A307	Check Disposables

Symbol	Meaning
 GM-H1K_8A309	DO NOT BEND the Heat Exchanger. This could damage the internal aluminium tube, potentially leading to contamination of infusate with the circulating water
 GM-H1K_8A310	POWER ON
 GM-H1K_8A311	POWER OFF
 GM-H1K_8A312	Alarm Test
 GM-H1K_8A313	Over Temperature Test

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Quick Reference Guide Cards

These are reproduced here full size so that the Biomed or EBME can confirm that there is a complete and undamaged set of cards attached to the warmer before returning it to active service.

If any of the cards are damaged or missing, new QRG card sets are available from your usual dealer or distributor.

For H-1200 equipped with H-30 Air Detector/Clamp:

Language	Part Number
English	4533709 EN
French	4533709 FR

For H-1200 equipped with H-31B Air Detector/Clamp:

Language	Part Number
English	4533710 EN
Danish	4533710 DA
German	4533710 DE
Greek	4533710 EL
Spanish	4533710 ES
Finnish	4533710 FI
French	4533710 FR
Italian	4533710 IT
Dutch	4533710 NL
Norwegian	4533710 NO
Portuguese	4533710 PT
Swedish	4533710 SV

LEVEL 1®

LEVEL 1® H-1200 FAST FLOW FLUID WARMER WITH H-31B AIR DETECTOR/CLAMP

QUICK REFERENCE GUIDE

SET UP

This Quick Reference Guide is intended to provide abbreviated instructions and warnings for reference by users familiar with the Level 1® H-1200 Fast Flow Fluid Warmer with H-31B Air Detector/Clamp.

Complete instructions including warnings, cautions and other important information for the safe and proper use of this product are provided in the Operator's Manual supplied with each device.

READ AND FOLLOW ALL INSTRUCTIONS, LABELING AND ACCOMPANYING DOCUMENTS SUPPLIED WITH THIS MEDICAL DEVICE. FAILURE TO FOLLOW INSTRUCTIONS, INCLUDING ALL WARNINGS AND CAUTIONS, COULD RESULT IN DEATH OR SERIOUS INJURY TO THE PATIENT OR USER.

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SET UP

INSTALL THE DISPOSABLE ADMINISTRATION SET

The installation sequence for the Disposable Administration Set corresponds to the numbered Blocks marked 1-2-3-4 on the Fluid Warmer.

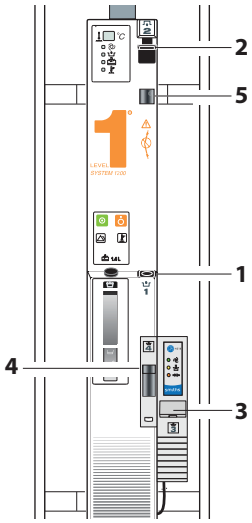
Note: Inspect the disposable set prior to use and confirm Luer connections are secure. D/DI-60HL and D/DI-65HL Disposable Sets require the Heat Exchanger to be placed with the Patient Line extending to the left.

1 Push the bottom end of the Heat Exchanger [the end near the Gas Vent/Filter Assembly] into **1** Block. Press the Heat Exchanger down firmly to properly seat in the block.

2 Slide **2** Block up. Snap Heat Exchanger into guide **5**. Press firmly into place to ensure it is properly seated. Slide **2** Block down, push down firmly to secure.

3 Move the pinch clamp on the Patient Line of the Gas Vent/Filter Assembly next to the Luer connector. Close the pinch clamp.

Note: Disposable Sets use two types of Gas Vent/Filter Assemblies. Step **4**, which describes how to install the Gas Vent/Filter Assembly, is different for each type of Disposable Set. Continue with the appropriate step **4** that applies for your specific Disposable Set.



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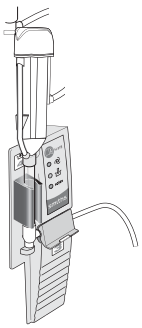
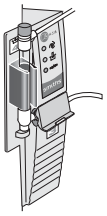
INSTALL THE DISPOSABLE ADMINISTRATION SET (CONT'D)

4 Install the Gas Vent/Filter Assembly for D/DI-65HL, D/DI-75, D/DI-150, and D/DI-350 Disposable Sets.



- **a** Open the **3** Clamp Slot door.
- **b** Align the Gas Vent/Filter Assembly to the **4** Block, and press it into place.
- **c** Press the clip at the top of the Gas Vent Vent/Filter Assembly to the bottom of the Heat Exchanger.
- **d** Insert the Patient Line in the Clamp Slot and push it back into the slot.
- **e** Hold the Patient Line in the Clamp Slot and push the door up to engage the top hinge. Then push the front of the door down to close it.

4 Install the Gas Vent/Filter Assembly for DI-50, D/DI-60HL, D/DI-70, D/DI-100, and D/DI-300 Disposable Sets.



- **a** Open the **3** Clamp Slot door.
- **b** Insert the Patient Line in the Clamp Slot and push it back into the slot.
- **c** Hold the Patient Line in the Clamp Slot and push the door up to engage the top hinge. Then push the front of the door down to close it.
- **d** Pull the Patient Line to the right to align it in the Clamp Slot without kinking.
- **e** Align the Gas Vent/Filter Assembly to the **4** Block, and press it into place.

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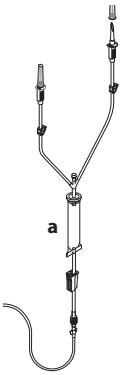
PRIME THE DISPOSABLE ADMINISTRATION SET

1 Close the Disposable Set clamps above the Heat Exchanger.

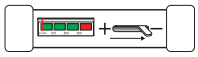
- For DI-50, D/DI-60HL, D/DI-65HL, D/DI-70, and D/DI-75 Disposable Sets,
  - – close pinch clamps below the bag spikes, and
  - – close roller clamp below the drip chamber (**a**).
- For D/DI-100, D/DI-150, D/DI-300, and D/DI-350 Disposable Sets,
  - – close pinch clamps below the drip chambers.



2 Remove all air from the fluid bag:

- **a** Invert fluid bag.
- **b** Use aseptic technique. Pierce membrane of bag port with spike of Disposable Set. Then withdraw spike.
- **c** Squeeze bag to exhaust ALL air.
- **d** Place spike in bag port. Do not allow air to re-enter bag. Repeat this step for each fluid line to be used.

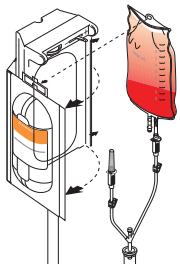
3 Slide lever on H-2 Pressure Chamber to the minus (–) unpressurized position.



4 Hang spiked fluid bag/s in Pressure Chamber:

- **a** Release hinged latch, open door and hang fluid bag inside on tab appropriate for bag size.
- **b** Close the door and secure latch.
- **c** Injection and Spike ports on the fluid bag should extend from opening at the bottom of the Pressure Chambers without being obstructed.

Note: When installing Level 1® D/DI-300 and D/DI-350 Disposable Sets, hang the third fluid bag from the I.V. pole.



READ AND FOLLOW ALL INSTRUCTIONS, LABELING AND ACCOMPANYING DOCUMENTS SUPPLIED WITH THIS MEDICAL DEVICE. FAILURE TO FOLLOW INSTRUCTIONS, INCLUDING ALL WARNINGS AND CAUTIONS, COULD RESULT IN DEATH OR SERIOUS INJURY TO THE PATIENT OR USER.

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PRIME THE DISPOSABLE ADMINISTRATION SET (CONT'D)

5 Open clamps above Drip Chamber(s) – (not necessary with D/DI-100, D/DI-150, D/DI-300, and D/DI-350).

6 Squeeze the Drip Chamber until one-half to three-quarters full of fluid.

7 Open remaining clamps above Heat Exchanger. Fluid flows into the Gas Vent/Filter Assembly.

8 For DI-50, D/DI-60HL, D/DI-70, D/DI-100, and D/DI-300 vigorously tap the Gas/Vent Filter Assembly to dislodge any air bubbles from the filter screen.

9 Turn power ON.

- Air Detector/Clamp enters a Power ON test. All indicators illuminate and the audible warning beeps. If not, remove from service.
- Upon completion of the Power ON test, the green Automatic Operation LED illuminates.

10 Remove male Luer cap from distal end of Patient Line.

Note: With D/DI-60HL and D/DI-65HL Disposable Sets, verify that no recirculating solution comes out of the distal end of the Patient Line.

11 Open pinch clamp just below the Gas Vent/Filter Assembly and complete priming of Patient Line.

12 Allow fluid to flow until no air is observed in the Patient Line and the line is primed with fluid. Then, close the roller clamp on the Patient Line.

Note: On D/DI-60HL and D/DI-65HL Disposable Sets, close the roller clamp below the drip chamber.

READ AND FOLLOW ALL INSTRUCTIONS, LABELING AND ACCOMPANYING DOCUMENTS SUPPLIED WITH THIS MEDICAL DEVICE. FAILURE TO FOLLOW INSTRUCTIONS, INCLUDING ALL WARNINGS AND CAUTIONS, COULD RESULT IN DEATH OR SERIOUS INJURY TO THE PATIENT OR USER.

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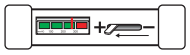
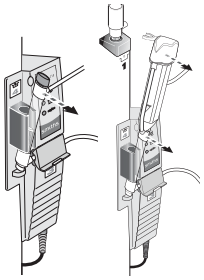
TEST THE AIR DETECTOR/CLAMP

This step is to be performed with the H-1200 in Automatic Operation mode with a primed Disposable Set in place.



1 Slide the lever on the Pressure Chambers to the plus (+) position.

2 Move the Gas Vent/Filter Assembly away from the Air Detector sensor as shown.



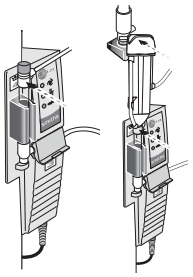
3 The following occurs:

- The Air Detector clamp closes.
- The red Clamped LED illuminates.
- The audible warning signal beeps.
- Fluid Warmer disposable alarm activates.

If any of the above does not occur, remove the device from service.

4 Open the roller clamp on the Patient Line to verify that fluid does not flow. After verifying that no fluid is flowing, close the roller clamp completely.

If fluid flow is observed, remove the device from service.



5 Return to normal operation by placing the Gas Vent/Filter Assembly back into the #**4** block as shown.

The green Automatic Operation LED on the Fluid Warmer Display Panel and on the Air Detector/Clamp Control Panel illuminate.

6 Establish patient connection and begin infusion.

READ AND FOLLOW ALL INSTRUCTIONS, LABELING AND ACCOMPANYING DOCUMENTS SUPPLIED WITH THIS MEDICAL DEVICE. FAILURE TO FOLLOW INSTRUCTIONS, INCLUDING ALL WARNINGS AND CAUTIONS, COULD RESULT IN DEATH OR SERIOUS INJURY TO THE PATIENT OR USER.

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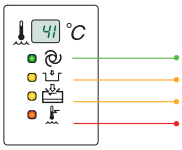
ALARMS: FLUID WARMER

For complete information regarding all alarms, please consult Operator's Manual.

ALARMS

FLUID WARMER DISPLAY PANEL



- Automatic Operation
- Check Disposables, Check Tubing
- Add Recirculating Solution
- Recirculating Solution Over Temperature

HIGH PRIORITY ALARM

Recirculating Solution Over Temperature

Alarm Condition: Recirculating solution temperature has exceeded acceptable temperature for safe use.

Action Required:

- If connected to patient, close all clamps.
- Turn Fluid Warmer OFF.
- Turn Fluid Warmer back ON.
- If alarm condition clears, open all clamps.
- If alarm persists, remove device from service.

MEDIUM PRIORITY ALARMS

Check Disposable, Check Tubing

Alarm Condition: Disposable Set is missing or not fully seated in the Fluid Warmer.

Action Required:

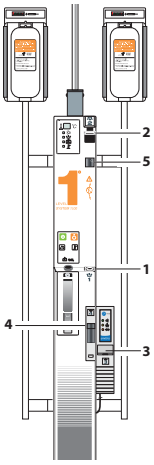
- Verify disposable is secured in:
  - **1** Block.
  - **2** Block - Press Interlock down firmly to engage. (O-Rings may require lubrication. Refer to Maintenance section of Operator's Manual).
  - Heat Exchanger Guide (**5**). Firmly press into Guide **5**.
  - **4** Block - Firmly press Gas/Vent Filter Assembly into Block **4**.

Add Recirculating Solution

Alarm Condition: Recirculating Solution level is below minimum level.

Action Required:

- Fill reservoir to maximum level with either:
  - Distilled water; or
  - 0.3% Hydrogen Peroxide/distilled water solution.



Sequential Block Locations

READ AND FOLLOW ALL INSTRUCTIONS, LABELING AND ACCOMPANYING DOCUMENTS SUPPLIED WITH THIS MEDICAL DEVICE. FAILURE TO FOLLOW INSTRUCTIONS, INCLUDING ALL WARNINGS AND CAUTIONS, COULD RESULT IN DEATH OR SERIOUS INJURY TO THE PATIENT OR USER.

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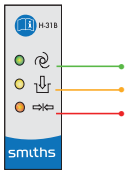
ALARMS

ALARMS: AIR DETECTION

For complete information regarding all alarms, please consult Operator's Manual.

AIR DETECTOR/CLAMP CONTROL PANEL

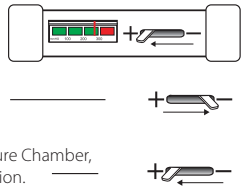


Automatic Operation
Check Disposables, Check Tubing
Air Detected/Clamped

HIGH PRIORITY ALARM

Clamped

Alarm Condition: Air detected in Gas Vent/Filter Assembly.
Action Required:



- Immediately Close ALL clamps on Disposable Set.
- Release pressure: Move lever to minus (-) position.
- Find and remove source of air.
- Spike an air-free bag of I.V. solution, place bag in Pressure Chamber, close and secure door and move lever to plus (+) position.
- Prime drip chamber and open clamps above Gas Vent/Filter Assembly. Fluid should freely flow as air is vented out Gas Vent/Filter Assembly.

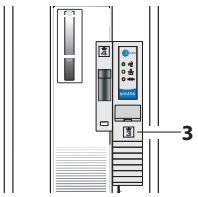
- If fluid does not freely flow, replace Gas Vent/Filter Assembly.

- When air is not present in the Gas Vent/Filter Assembly, the clamp will open and resume Automatic Operation mode.
- If no warning signals are active, the Fluid Warmer is ready for use.
- Open remaining clamp(s) and resume infusion.

MEDIUM PRIORITY ALARM

Check Disposables, Check Tubing

Alarm Condition: Tubing is not fully in Clamp Slot or clamp door not fully closed.
Action Required:



- Open Air Detector door located in **3** Block.
- Check Tubing is fully seated in Clamp Slot.
- Close door (**3**). Ensure the tab on top of the door is fully inserted.

READ AND FOLLOW ALL INSTRUCTIONS, LABELING AND ACCOMPANYING DOCUMENTS SUPPLIED WITH THIS MEDICAL DEVICE. FAILURE TO FOLLOW INSTRUCTIONS, INCLUDING ALL WARNINGS AND CAUTIONS, COULD RESULT IN DEATH OR SERIOUS INJURY TO THE PATIENT OR USER.

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CONTRAINDICATIONS, WARNINGS & CAUTIONS

For a complete list of Contraindications, Warnings & Cautions, please consult Operator's Manual.

CONTRAINDICATIONS ⚠

- Not for use in warming platelets, cryo-precipitates, or granulocyte suspensions.

WARNINGS ⚠

Death or serious injury may occur to the patient or user if these warnings are not followed:

Setup

- Remove all air from the fluid bags before spiking and fluid lines before connecting to the patient. Failure to do so can result in infusion of air into the patient.
- Do not bend the heat exchanger. Bending may damage the heat exchanger allowing communication between the recirculating solution and I.V. fluid path, resulting in the I.V. delivery of inappropriate fluids.
- When injecting medications into the fluid path, do not inject through the triple lumen tubing of the D/DI-60HL and D/DI-65HL Disposable Set. This may allow communication between the recirculating solution and I.V. fluid path.
- Do not re-use partially full fluid bags. Fluid bags that have been partially drained, un-spiked, and then reinstalled may contain air, which if used can result in infusion of air into the patient. Use only new fluid bags from which the air has been removed.
- Disposable Sets are supplied with a sterile fluid path which may be compromised if the caps are not in place. Do not use Disposable Sets if Luer and spike caps are not securely in place, or if Luer connections are not secure as the fluid path may not be sterile and may cause death or serious injury to the patient.

READ AND FOLLOW ALL INSTRUCTIONS, LABELING AND ACCOMPANYING DOCUMENTS SUPPLIED WITH THIS MEDICAL DEVICE. FAILURE TO FOLLOW INSTRUCTIONS, INCLUDING ALL WARNINGS AND CAUTIONS, COULD RESULT IN DEATH OR SERIOUS INJURY TO THE PATIENT OR USER.

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CONTRAINDICATIONS, WARNINGS & CAUTIONS

CONTRAINDICATIONS, WARNINGS & CAUTIONS

CONTRAINDICATIONS, WARNINGS & CAUTIONS (CONT'D)

For a complete list of Contraindications, Warnings & Cautions, please consult Operator's Manual.

- Blood and blood products could contain pathogenic organisms. Failure to follow institutional policy and procedures for biomedical-hazardous materials could lead to exposure to harmful pathogens
- Use of a bedside leukocyte reduction filter may cause a sudden precipitous drop in blood pressure resulting in respitory distress, facial flushing, abdominal pain and nausea, and loss of consciousness. Immediately stop transfusion, and follow institution's protocol for treatment of transfusion reactions.
- Disposable Sets are for single use only. To reduce the risk of cross contamination, do not reuse Disposable Sets.
- Do not use the Fluid Warmer if equipment or Disposable Set malfunction is evident.

Air Detector

- The functional test for the Air Detector/Clamp accessory must be performed before each use. If the device does not function correctly, air in the I.V. line may not be detected, and the patient line may not be clamped. Remove the device from service immediately.
- The tubing must be properly placed in the Clamp Slot of the Air Detector/Clamp. Failure to ensure that the tubing is correctly positioned in the Clamp Slot may result in failure to stop air infusion.
- Do not turn OFF the Fluid Warmer when the Air Detector alarm is active. If the Fluid Warmer is powered OFF in an active alarm state, the Air Detector/Clamp will open and the Air Detector will become disabled. This could allow any air within the Patient Line to be delivered to the patient resulting in serious injury or death.

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CONTRAINDICATIONS, WARNINGS & CAUTIONS (CONT'D)

For a complete list of Contraindications, Warnings & Cautions, please consult Operator's Manual.

- Activation of the Air Detector/Clamp alarm during infusion indicates that fluid flow has stopped and that immediate operator intervention is required to restore fluid flow. Failure to reinstate flow (after purging any air or foam) may result in death or serious injury to the patient.

Alarms

- The functional test for the Air Detector/Clamp accessory must be performed before each use. If any visual indicator does not illuminate or the audible signal does not sound, do not use the Fluid Warmer. Remove the device from service immediately. Fully functional visual and audible alarm systems are essential for the safe use of the Air Detector/Clamp.

Over Temperature

- Activation of the Over Temperature warning signal indicates that warming has stopped and immediate operator intervention is required. Failure to clear the over temperature condition or to take the device out of service may result in death or serious injury to the patient.

Gas/Vent Filter Assembly

- Replace Gas Vent/Filter Assembly every three hours, or when the filter becomes clogged, or when air is slowly vented. Failure to do so will result in a reduction of flow rate. This may result in inadequate patient treatment.
- The replacement Gas Vent/Filter Assembly must be fully primed before continuing infusion. Failure to do so may allow air to be infused into the patient.

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CONTRAINDICATIONS, WARNINGS & CAUTIONS (CONT'D)

For a complete list of Contraindications, Warnings & Cautions, please consult Operator's Manual.

CAUTIONS ⚠

- Malfunction, failure, or damage to the device may occur if these cautions are not followed.

Setup

- When loading fluid bags into Pressure Chambers, choose a hanging hook that allows the bag port to hang freely in the indented slot at the bottom of the chamber door. If bag ports are positioned above this slot, diminished flow could occur.

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KEY SYMBOLS

For a complete list of all symbols, please consult Operator's Manual.

	**Caution**
	Do not bend heat exchanger
	Alarm Test
	ON - Only for a part of the equipment. MAINS are connected
	OFF - Only for a part of the equipment. The MAINS are still connected
	Automatic Operation
	Over Temperature Test (Recirculating Solution Over Temperature)
	Add Recirculating Solution
	Check Disposables, Check Tubing
	Clamped
	Maximum Reservoir Level

READ AND FOLLOW ALL INSTRUCTIONS, LABELING AND ACCOMPANYING DOCUMENTS SUPPLIED WITH THIS MEDICAL DEVICE. FAILURE TO FOLLOW INSTRUCTIONS, INCLUDING ALL WARNINGS AND CAUTIONS, COULD RESULT IN DEATH OR SERIOUS INJURY TO THE PATIENT OR USER.

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KEY SYMBOLS

KEY SYMBOLS

Service Contacts

Contact your Smiths Medical ASD, Inc., Technical Service Department or Smiths Medical ASD, Inc., distributor at:

USA/Canada
Smiths Medical ASD, Inc.
Rockland, MA 02370 USA
USA/Canada 1-800-258-5361
International +1-781-878-8011
Fax +1-781-878-8201

European Representative
Smiths Medical International Ltd.
Ashford, Kent, TN25 4BF, UK
Tel +44 (0) 1233 722100

Australian Representative
Smiths Medical Australasia Pty. Ltd.
Eight Mile Plains, QLD 4113, Australia
Tel +61 (0) 7 3340 1300
Tel NZ (0) 800 444 200
Fax +61 (0) 7 3340 1399

Smiths Medical ASD, Inc.
Rockland, MA 02370 USA
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Fax +1-781-878-8201
www.smiths-medical.com

P/N 4533710 Rev 005 (05/11)

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CE 0473

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LEVEL 1®

General Advisement

These Customer Information Bulletins and Technical Worksheets are included for historical completeness. They relate to subjects that were significant *at the time of issue*. Please be aware that the information contained in them may have been superseded by later issued bulletins or worksheets. Due to continuous evaluation and improvements, changes in specification may also have rendered information in these sheets obsolete.

Both Customer Information Bulletins and Technical Worksheets are issued to address specific topics as they arise. Therefore, these lists are likely to be incomplete and out of date within a fairly short time. If your department does not currently receive updates, you can ensure that you keep this collection complete and maximise its usefulness, by contacting (in the U.S.) your local distributor, or (in the U.K. and Europe) the QA department at the Ashford offices of Smiths Medical International Ltd. (+44 (0)1233 722100), who will arrange for you to receive future releases either by email or post.

At the time of publication, Smiths Medical have only issued two Customer Information Bulletins and no Technical Worksheets pertinent to the Level 1® range of Fast Flow Blood and Fluid Warmers. These are reproduced overleaf.

Information Bulletins Index

Customer Information Bulletin

Bulletin B 1129 Date: June 2003

Level 1® Air Detector/ Clamp Model SA-1000

For use with Level 1® Fast Flow Fluid Warmers
Provides designed-based air detection for Level 1® Fast Flow Fluid Warmers

Dear Level 1 User,

Today's Theatres, A&E Departments and Trauma Units provide a more challenging environment than ever before. Rapid Infusion of fluids involves certain risks. Among those risks is the potential to accidentally infuse air into a patient's venous system. The new Level 1® Air Detector / Clamp is designed to be used with the Level 1® Fast Flow Fluid Warmers to reduce the possibility of human error by providing a design-based air detection device with alarms to alert the user of situations where air is detected within the fluid line. It is important to note that the Level 1® Fast Flow Fluid Warmers are safe and effective when used in accordance with the labelling and instructions for use.

To guard against the introduction of air into a patient's venous system, the Level 1® Air Detector / Clamp Model SA-1000 for use with the Level 1® Fast Flow Fluid Warmers provides the following benefits;

- Detects the presence of air in the Level 1® administration sets.
- If air is detected, fluid flow is shut off, preventing the infusion of air.
- Both visual and audible alarms alert the user to the presence of air.
- Compatible with all existing Level 1® Fast Flow Fluid Warmers.

The Level 1® Air Detector / Clamp Model SA-1000 is compatible with all Level 1® Fast Flow Fluid Warmers and can be quickly and easily installed by your own personnel by following the simple installation instructions provided with the device. The Level 1® Air Detector / Clamp Model SA-1000 also comes with a new Operators Manual which provides clear instructions to enable your staff to use the Level 1® Fast Flow Fluid Warmers with the Model SA-1000. Graseby Medical can provide installation assistance, if necessary, and will provide in-service training on the use of Level 1® Air Detector / Clamp Model SA-1000 for your clinical staff.

For more information on this exciting new product, contact

Graseby Medical, Customer Care
Colonial Way,
Watford, WD24 4LG
01923 246434

Level 1®, Inc.
160 Weymouth Street Rockland
MA 02370
USA/Canada: 1-800-553-8351

NOTE: Please note that both these contact details have ben superceded by your normal Smiths Medical contacts, as shown at the front of this manual.

Customer Information Bulletin

Bulletin B 1135 Date: January 2004

DISCONTINUATION ANNOUNCEMENT

Level 1® H-250, H-275, H-500 and H-525
Fast Flow Fluid Warmer Spare Parts and Service

Dear Customer

In the late 1980's, Smiths Medical (Level 1®), revolutionised rapid infusion practices with the introduction of the H-500 Fast Flow Fluid Warmer. In the following years with the release of automated pressure infusion and the next generation models H-250, H-275 and H-525, literally thousands of patients benefited from these advanced technologies.

Although many of these devices are still in service they have not been manufactured since 1995, when they were replaced by the current H1025 Model and it has become increasingly difficult for Smiths Medical to provide components and spare parts to properly service these units.

As a result, Smiths Medical has determined that it can no longer support the H-250, H-275, H-500 and H-525 Fast Flow Fluid Warmers. Therefore, as of 31 March, 2004, we will discontinue offering spare parts and service for these models.

Air detection capability can be added to existing H-1025 Fast Flow Fluid Warmers by purchasing an H-30 Air Detector / Clamp. Also, if you decide to retain any of the older model units (H-275/H-525), air detection can be added to them by purchasing the SA-1000 Air Detector / Clamp.

Kind regards,

Elaine Whittaker, Marketing Manager , Smiths Medical

LEVEL 1®

THE DETAILS GIVEN IN THIS MANUAL ARE CORRECT AT THE TIME OF GOING TO PRESS. THE COMPANY, HOWEVER, RESERVES THE RIGHT TO IMPROVE THE EQUIPMENT SHOWN.

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