

Thermofluid
TF251 Manual

IMPORTANT NOTICES

The Thermofluid **MUST** not be returned for repair without a certificate confirming the unit(s) has been decontaminated. **WHEN** this is not possible the nature of the contamination must be specified on the accompanying documentation which must be attached to the outside of the container. Please refer to the DHSS or CSA recommendations.

This manual applies to equipment manufactured after 01.01.2000

The correct fuse rating must be fitted inside the mains plug. This fuse must be 5A. Please note that there are internal fuses fitted to the transformer and printed circuit board inside the unit, which may be damaged if an incorrectly fused mains lead is used.

The Thermofluid must not be mounted except at the vertical. The user must ensure the mounting pole is suitable to carry the unit and will remain stable.

The unit should be inspected to check for any damage prior to use. The unit should not be used if any such damage is found.

The unit should be inspected for electrical safety and compliance to the full calibration procedure annually or immediately if dropped or damaged by a competent engineer.

The equipment should not be used in the presence of mobile phones etc. The equipment complies with IEC 60601-1-2 (EMC.)

The equipment should not be disposed of without due care to the environment. Specialist advice should be sought from JMW Medical Ltd at the time of disposal.

The Thermofluid is manufactured by:

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PLEASE READ ALL SECTIONS CAREFULLY

Symbols used in this manual and on the product

1. Alternating Current



2. Protective Earth (ground)



3. Equipotentiality



4. Attention, consult ACCOMPANYING DOCUMENTS.



5. Off (power: disconnection from the mains)



6. On (power: connection to the mains)



7. Type B Applied Part



8. Conformity to the European Medical Device Directive 93/42/EEC as certified by Notified Body N. 0577



0577

9. Protection against the ingress of fluids IEC60529

IPX0

10. Year of manufacture



11. Serial Number

SN

12. Catalogue number

REF

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1. THERMOFLUID 251 SPECIFICATIONS

Classification:	Class 1, Type B applied part Not suitable for use in the presence of a flammable anaesthetic mixtures with air or nitrous oxide.
Conformity:	EN60601-1: 1990, BS5724 Pt. 1, IEC 60601-1-2 (EMC.)
Protection against ingress of fluids	IPXO
Mode of operation	Continuous
Supply Voltage:	230 ac 50/60Hz. (Can be configured to 110V ac.)
Supply Power:	3 Amps maximum.
Temperature Control Range:	Factory pre-set to 39 degree Celsius (plates at 40 degrees Celsius to allow for the thermal gap between the tube/bag and the plate)
Temperature Control Accuracy:	+/- 0.4 degree Celsius
Mains Input Fusing:	T5A 20mm, Live and Neutral.
Mains plug or lead fuse	5A
Internal low voltage fuses	F2A (inline with transformer output wires)
Internal Supply Fuses:	T2.0A, 20mm
Sensor Resistance	20K Ohms. + or – 1% at 25 degrees celcius
Mounting Clamp:	To suit 10 - 45mm round or square pole. The Thermofluid must not be mounted at more than 10° from the vertical.
Recommended Tubing set	(1500mm) TE1500, for snake: (4mm OD) (2000mm) TE2000 (4000mm) TE4000
Recommended Blood Bag:	(55ml nominal primed volume) TB250
Warm up time:	Approximately 1 minute.
Overall Size:	H-365mm, W-230mm, D-125mm.
Weight:	5.0kg.
Environmental conditions for transport and storage	Temperature range –10 to +30 degrees Celsius Humidity less than 90% non condensing Pressure 500 to 1000 Hectare Pascal

2. Guidance and manufacture's declaration – electromagnetic emissions

<p>The Thermofluid is intended for use in the electromagnetic environment specified below. The customer or user of the Thermofluid should assure that it is used in such an environment.</p>		
Emissions Test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Thermofluid uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Thermofluid is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Complies	
Voltage fluctuations/ flicker emissions	Complies	
RF emissions CISPR 11	Complies	The Thermofluid is not suitable for interconnection with other equipment

3. DESIGN CONCEPT

In modern clinical circumstances such as operating theatres, air conditioning systems produce frequent air changes and low ambient temperatures. Patients, particularly the frail and young are therefore in constant danger of hypothermia. JMW Medical products can be used to alleviate such problems.

The JMW Thermomat heated pads are used in general patient warming.

For Infusions/transfusions JMW have developed fluid heating equipment. The Thermofluid 251 warms fluids up to a rate of 250ml per minute.

Thermal shock can result by rapid infusion of as little as 500-1500ml of fluid at a temperature lower than the patient. The JMW Medical Thermofluid 251 solves this problem by pre-heating the fluid through a standard extension set. (For high rates a disposable blood bag must be used with the Thermofluid 251).

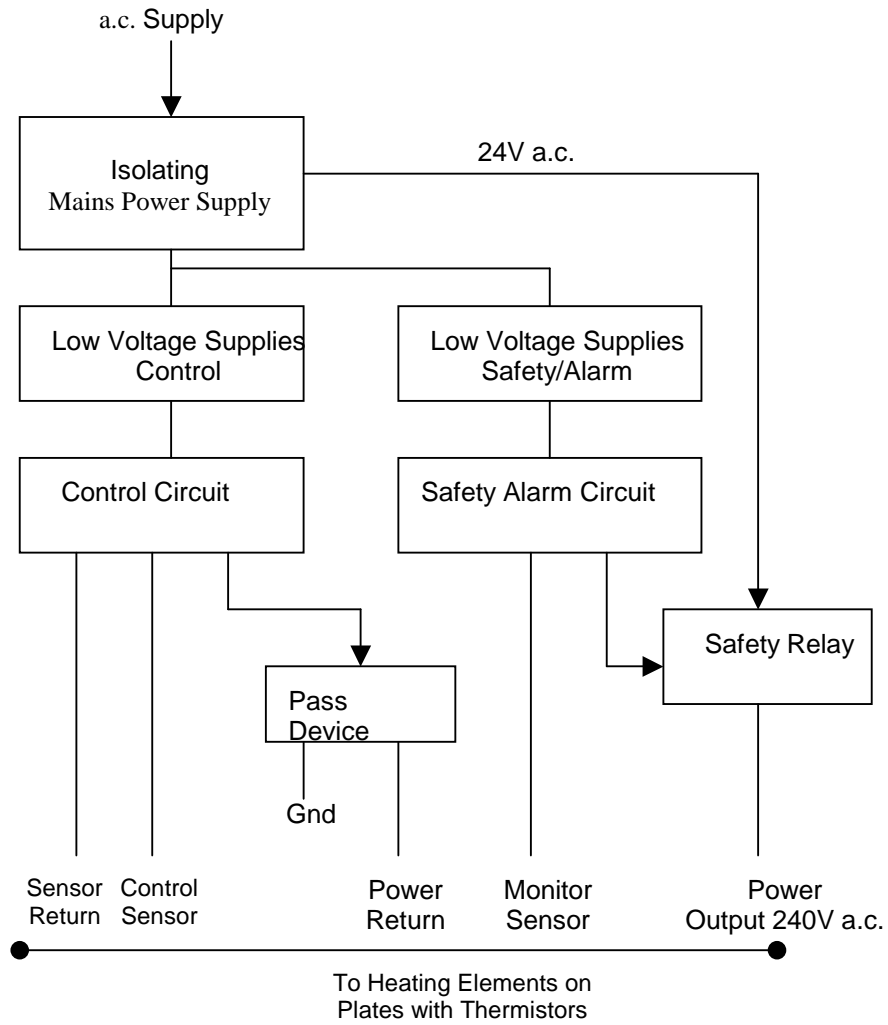
The TF251 has a 'snake' pattern in the doorplate only with the second plate being designed to hold the industry bag.

Blood warmers that use a bath of water are prone to contamination by various bacteria. Medical reports hold the view that contamination with this type of blood warmer leads to septicaemia. Water baths are also considered a general hazard in the theatre if the water is spilled making the floor slimy. The JMW Medical Thermofluid uses a dry heat exchanger, which alleviates all such problems.

The Thermofluid may be positioned very close to the delivery point and maybe mounted directly onto the operating table. Most other systems dissipate the heating provided over the necessarily long delivery line. Safety is of prime concern in this type of electrical/electronic application. Sophisticated control and dual alarm circuitry prevent any failure hazard.

Unlike other products using a bag it is possible to open and close the door during operation.

4. BLOCK DIAGRAM



5. OPERATING INFORMATION

5.1 GENERAL

The Thermofluid 251 can heat fluids in a variety of useful ways:

- 5.1.1 For low infusion rates (up to 100ml/min) a low cost tubing set can be utilised in the snake.
- 5.1.2 For high demand rates a blood bag (as detailed in the specifications) must be used on the plate opposite the snake.
- 5.1.3 For ultimate use, the extra tubing supplied on the exit from the blood bag (for post-heating) or an extension set at the front of the blood bag (for pre-heating) is put through the snake.
- 5.1.4 Another useful combination is to heat blood in the blood bag while simultaneously heating an alternative fluid in the snake. This fluid would typically take the form of saline for "washing-out" debris during operating procedures.

5.2 USING THE SNAKE

- 5.2.1 The tubing is easily placed in the "Snake". Always use 4mm OD tubing.
- 5.2.2 Refer to Figure 1 on next page. E1 to E3 are tube entry points. Select the appropriate entry point for the tubing length utilised. X1 to X5 are tube exit points. The following table gives details to select entry and exit points according to approximate tubing length:

Entry Point	Exit Point	Tubing Length
E1	X1	700mm
E1	X2	1100mm
E1	X3	1900mm
E1	X5	2700mm
E1	X2	700mm
E2	X3	1500mm
E2	X4	2200mm
E2	X5	2300mm
E3	X4	700mm
E3	X5	1100mm

- 5.2.3 Please note that whatever entry and exit combination is used, the blood or fluid can not be overheated providing the equipment is serviced to the correct specification.

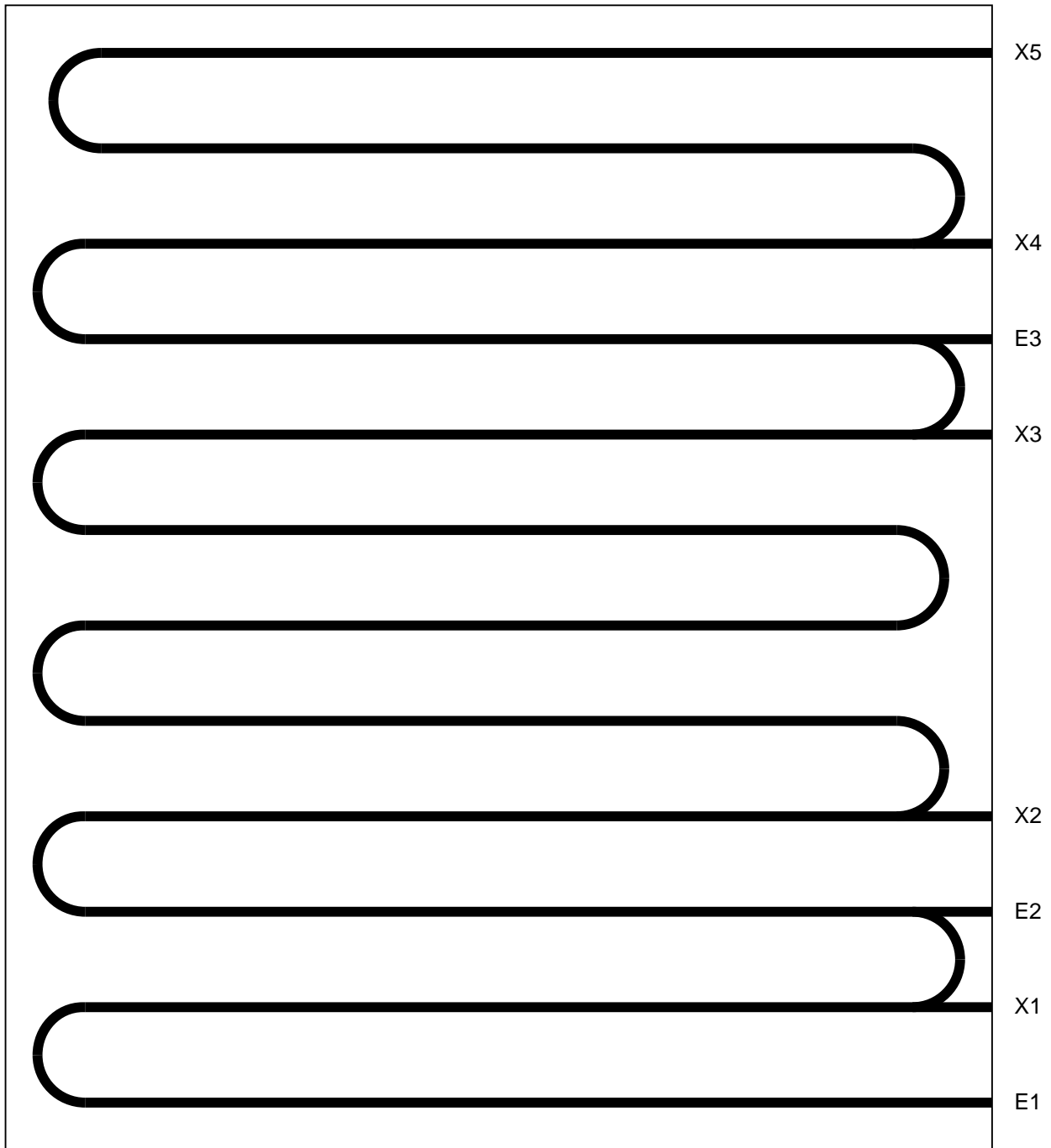


FIGURE 1
En - Entry point. Xn - Exit point.

- 5.2.4 Mount the Thermofluid 251 on an infusion pole or similar such that the fluid reservoir can be suspended above it.
- 5.2.5 Open the Thermofluid 251 by releasing the catch at the side.

- 5.2.6 Having determined the tubing length and appropriate entry and exit points (in 1.2 above) install the tube by laying it in the selected channel.
- 5.2.7 Plug in to the mains and switch on at the rear of the Thermofluid 251. Test the alarm system. The power and heat lamp will illuminate on the top panel of the unit and the 3 digit LED display will show increasing temperature up to the pre-set of 39 degree Celsius. As the operating temperature is reached the heat lamp will begin to flash and the plate temperature display will show 39 degree Celsius +/- 0.4 degree Celsius. The Thermofluid 251 is now ready for use.

5.3 USING THE BLOOD BAG

- 5.3.1 Mount the Thermofluid 251 on an infusion stand such that the fluid reservoir can be suspended above it.
- 5.3.2 Plug in to the mains and switch on at the rear of the Thermofluid 251. Test the alarm system. The power and heat lamp will illuminate at the top of the unit and the 3-digit LED display will show increasing temperature up to the pre-set of 39 degree Celsius. As the operating temperature is reached the heat lamp will begin to flash and the plate temperature display will show 39 degree Celsius +/- 0.4 degree Celsius. The Thermofluid 251 is now ready for use.
- 5.3.3 The Thermofluid 251 may be left switched on but it is recommended that the blood bag should not be fitted until required.
- 5.3.4 Open the Thermofluid 251 by releasing the catch at the side.
- 5.3.5 Attach the blood bag to the four fixing points on the flat plate (opposite the snake).
- 5.3.6 Close and latch the Thermofluid 251 then close the OUTLET roller clamp.

It is possible to open and close the door at any time during it's operation should the need arise. Note that flow will decrease during opening, as the bag expands and increase during closing as the bag is compressed.

- 5.3.7 Connect the blood reservoir using a standard giving set, (a filter may be used if required) to the INLET connection at the bottom of the blood bag.
- 5.3.8 Open the INLET clamp.
- 5.3.9 Prime the complete system as follows:
 - 5.3.9.1 Squeeze the OUTLET bubble trap and open the OUTLET roller clamp. When the system is primed, close the OUTLET clamp.
 - 5.3.9.2 Release the OUTLET bubble trap and confirm that the fluid level is between the "MIN" and "MAX" marks.
 - 5.3.9.3 Connect the blood bag outlet adapter to another giving set. Open the OUTLET clamp and prime the giving set.
- 5.3.10 Connect the giving set to the patient and adjust the flow rate using the OUTLET roller clamp. Note that the level in the bubble trap must be maintained between the "MIN" and "MAX" marks at all times.

6. ALARMS

The Thermofluid 251 alarm circuitry will operate if the factory pre-selected temperature exceeds 41 degree Celsius at the plates. If this occurs an internal audible alarm and visual alarm (red lamp on display panel) operate. Power is also disconnected from the heating elements of the Thermofluid 251. If this should occur, switch off at the rear and allow the Thermofluid 251 to cool. Check that the alarm test switch on the rear panel was not accidentally operated. If not, switch on again. If the Thermofluid should repeatedly alarm refer the complete unit to a qualified technician. The alarm will sound for a short period when the mains power is disconnected. An alarm will sound if the plate temperature is less than 10 degrees Celsius.

7. ALARM TEST

Confidence that the alarm circuitry of the Thermofluid 251 is operational is achieved by using the alarm test button on the rear panel. When pushed, an audible alarm is given and the red alarm indicator on the display panel is illuminated. This alarm test should be performed before each use.

8. SIMPLE TEMPERATURE CHECK

This is only a simple user check and is not a full calibration.

- 8.1.1 Close and latch the Thermofluid 251 plates together.
- 8.1.2 Switch the mains on and allow the temperature to stabilise. This will take approximately 5 minutes and is indicated by the heat lamp (amber) on the top panel flashing at approximately 1-second intervals.
- 8.1.3 Insert a calibrated thermometer that is traceable to national standards into tube entry E1 as shown in figure 1.
- 8.1.4 The thermometer should read the same as the factory selected plate temperature, nominally 39 degree Celsius +/- 0.5 degree Celsius. The unit may be factory pre-set to any temperature required if requested.

9. CLEANING INFORMATION

The Thermofluid 251 should be cleaned with soap and water, a mild detergent, or it may be disinfected and sterilised using Formaldehyde, Chloramine or Cidex. The Thermofluid 251 must not be autoclaved.

10. SERVICE AND REPAIR

After the warranty period expires, only experienced qualified technicians should attempt repair to the Thermofluid 251. Alternatively return the complete equipment to JMW Medical for service. Trained personnel should calibrate the TF251 at not greater than six month intervals or immediately if dropped or damaged. A test jig is required to correctly calibrate the TF251.

11. CIRCUIT DESCRIPTION

11.1 MAIN CONTROL PCB CIRCUIT DESCRIPTION.

Reference should be made to the circuit diagrams J118-70001 sheets 1 to 5. Sheet 1 is the top level showing the main functional blocks of the circuit.

11.1.1 Control Loop (Sheet 2)

The main control loop consists of external thermistors connected to J4 and J5, which are biased by R1 and R2. R1 biases the Control Sensor (CS) and R2 biases the Monitor Sensor (MS). The sensors are 20k ohms at 25 degree Celsius. Each thermistor loop consists of 2 x 10k thermistors.

J118-70001 sheet 2 shows the control circuitry. The Control Sensor (CS) signal is filtered and then buffered by U1A before being used by the proportional temperature controller U2 at pin 6. This IC compares the voltage from the control sensors with the voltage from the temperature set-up potentiometer on pin 9. Out on pin 3 produces pulses to fire the TRIAC Q1. The power to the heating elements is varied from continuous, pulses every half cycle, to low power, one pulse per second giving one half cycle out of every 50 cycles of the mains supply.

U2 provides an external reference voltage VZ that is set to 7.5V by R16 and then buffered by U1D before being used to provide the bias for the thermistors through R1 and R2. This reference is also used to bias the temperature set-up potentiometer R12. U2 has a zero crossing detector using pin 10 as input and a 1 second ramp generator set by C3.

The voltage from the temperature set-up potentiometer arrives at U2 pin 9. This signal is linear to temperature setting, but to enable the internal control system U2 to function with NTC thermistors this signal is made non-linear and compatible with the NTC thermistors. The modified control signal QR is available at U2 pin 8 and is used by the Alarm circuitry.

11.1.2 Alarm Circuit (Sheet 3)

There are 9 possible sources of alarm, which will cause the sounder to activate followed 15 seconds later by disconnection of the power to the mattress. They are divided into the following groups. All signals are buffered before being used. The CS signal is buffered by U7A, the MS by U7B and QR by U7D. The CS and MS signals are also filtered to stop any noise from the heating elements causing damage to the buffer IC's. The 9 alarm signals are displayed on the PCB using LED's.

LED	Description	Diode
1	CS-MS > 3 degree Celsius	D21
2	MS-CS > 3 degree Celsius	D14
3	CS > T max	D15
4	MS > T max	D16
5	QR > T max	D17
6	CS < 10 degree Celsius	D18
7	MS < 10 degree Celsius	D19
8	V ref. < 7.5V	D20
9	Changed Temperature	D13 not used.

> Means greater than

< Means less than

11.1.2.1 Control and Monitor >3 degree difference

The buffered CS and MS signals are subtracted from each other and amplified by 10 by U10C to produce a +/-2.5V signal if the difference is greater than 3 degree Celsius. Comparator U9B and U9C generate an alarm at TP8 and TP9 should the difference in temperature be greater than 3 degree Celsius in either direction.

11.1.2.2 Control, Monitor and QR >41 degree Celsius

The buffered CS, MS and QR signals are compared with a voltage equivalent to 41 degree Celsius by U5D, U6A and U5C to produce alarm signals on TP9, TP10 and TP11 should any of them be greater than 41 degree Celsius.

11.1.2.3 Control and Monitor < 10 degree Celsius

The buffered CS and MS signals are compared with a voltage equivalent to 10 degree Celsius by U5B and U3D to produce an alarm signal on TP12 and TP13 should either be less than 10 degree Celsius.

11.1.2.4 V Reference < 7.5V

The +VZ reference voltage used in the control loop is compared with a secondary reference voltage and should it be less than 7.5V an alarm is generated at TP6.

11.1.2.5 Temperature Changed

This is NOT used in this product.

11.1.3 Alarm Sounder

All the 9 alarm outputs are OR'ed together using D13 to 21. Should any of the 9 alarms be active the output of the associated comparator will be low -12V and will pull down the gate of T1 so switching it off. This in turn switches T2 ON so enabling U4 to pulse the sounder On/Off. Should power be removed from the unit C12 stores enough power to keep the sounder going for up to 10 seconds. When any of the alarms has been active for more than 15 seconds, the signal is delayed by U3A and B, the relay controlling power to the heating elements is removed.

11.1.4 Display Buffer and References (Sheet 4)

11.1.4.1 Signal Conditioning

This is performed by U8A which linearises, inverts and conditions the signal from CS-B. R58 pre-sets the offset and R61 sets the gain of this circuit. Typical values are 0.678V offset and 0.135 gain.

11.1.4.2 References

U8B and U8C generate the +7.5V and -7.5V references. The alarm circuits use these. The -5V required by the ADC is generated by U8D.

11.1.5 Power Supplies (Sheet 5)

There are two separate sets of power supplies. One for the control loop circuitry and the second for the alarm circuitry. This is to ensure that one cannot interfere with the other and so produce faults, which do not exist, and more importantly the system will not fail to report faults should they exist. The same component is not shared between the control and safety circuits for the same reason.

11.1.5.1 Control Supplies

Two regulators U11 and U10 produce plus and minus 12 volts for the control circuitry.

11.1.5.2 Alarm Supplies

Three regulators U9, U12 and U13 produce +5V and +/-12V for the alarm and display circuitry.

11.2 Display PCB Circuit Description

The circuit is contained on J118-70002.

11.2.1 ADC

U1 contains a 3 digit ADC and LED drivers. The ADC requires a 1V reference provided by D1 and set-up using R4. This is set to 1.000V between TP1 and TP2. The three 7 segment green LED displays, LED1, 2 and 3, are directly driven by U1.

11.2.2 Status LED's

There are three LED's, Fault, Heat and Power. The Green Power LED is driven by the +12VC supply and as such is illuminated whenever the unit is connected to the mains a.c. supply and switched ON. The Amber Heat LED is connected across the heating element output and as such is illuminated whenever power is being supplied to the heating elements, pulsed or continuous. The Red Fault LED is only illuminated when the internal relay RLY1 is NOT actuated i.e. when power has been removed from the heating elements due to an alarm condition.

POWER, green LED D2, is activated from the +5V supply. The HEAT, amber LED D3, is activated when power is being applied to the heating elements. The ALARM, red LED D4, is activated when the relay has been de-energised due to one of the alarm signals.

11.3 Mains and internal wiring.

The a.c. supply 230/110V enters the unit via a connector and filter. The live and neutral are then independently fused, F1 & F2 at T5A, before entering the ON/OFF switch, which controls the power to the transformer. The transformer produces 24V a.c. and 12V a.c. The Transformer has primary taps allowing it to be set for 230V a.c. or 110V a.c. The standard setting is 230V a.c. The transformer output windings are fused by F3 & F4 at F2A.

The output of the transformer fuses F3 & F4 connect to the Main PCB using a 4 way 5mm terminal block J1.

All connections between the two PCB's are via J6 on the Main PCB and J1 on the display PCB

12. Test and Calibration Procedure.

As calibration is not possible without a Simcal5 instructions are not included in the manual and come with the Simcal5. If you have a Simcal5 check the revision of the instructions and the revision of the Simcal5 before commencing calibration. The work instructions for calibration procedure are WI 006 and the results sheet is CT 003. (On the 01.03.2000 these were revision C and B respectively)

TF251 Test and Calibration – WI 006.C

1 PURPOSE

1.1 The purpose of this Work Instruction is to detail the steps, which must be taken to complete the TF251 calibration and test.

2 REFERENCES

2.1 QP 031 - Non Conforming items
CT 003 - Test results sheet

3 INSTRUCTIONS

3.1 Non-conforming items are to be handled as detailed in QP 031 - Non-conforming item procedure.

3.2 The technical drawings give all details of construction, including wire lengths and colours and should be followed closely.

3.3 The results from the following tests should be recorded on test results sheet CT 003.

4 TEST EQUIPMENT

Test jig SIMCAL5
Digital Voltmeter
Test Adapter to SIMCAL5
Sound Meter

5 CALIBRATION OF MAIN PCB

Record Test equipment used and serial number on the test sheet.

Connect the Main PCB Assembly to the rear panel assembly. Test Jig SIMCAL5 should be connected to the Main PCB using Adaptor. Set SIMCAL5 to 33 deg C. Measure the voltage at the following points with reference to TP22 or TP23.

	Location	Result	Tolerance
5.1	TP25	+12Volts	11.40 to 12.60
5.2	TP24	-12Volts	11.40 to 12.60
5.3	TP26	+12Volts	11.40 to 12.60
5.4	TP27	-12Volts	11.40 to 12.60
5.5	TP20	+5.0Volts	4.75 to 5.25
5.6	TP21	+1.23Volts	1.20 to 1.30
5.7	TP19	+7.50Volts	Set R63 for 7.50 + or - 0.01
5.8	TP18	-7.50Volts	7.49 to 7.51
5.9	TP1	+7.50Volts	Set R16 for 7.50 + or - 0.01
5.10	Set Test Jig to 39 deg C then adjust R12 for flashing HEAT LED. The ON time should be set for 10 to 15% using meter on test jig.		
5.11	TP5	Set R29 for alarm on 41 deg C. Take reading of TP5.	2.71 to 2.73 volts
5.12	U8 Pin 14	-5.0Volts	4.75 to 5.25

6 CALIBRATION OF DISPLAY PCB

Connect the Display PCB using cable.

6.1 On Display PCB TP1 to TP2. 1.000V Set R38 for 0.999 to 1.001 Volts.

6.2 On Main PCB

TP17 0.687Volts Set R58 for 0.686 to 0.688.

6.3 Set Test Jig to 33 degree C then adjust R61 for 32.9 to 33.1 displayed on front panel display.

6.4 Set Test Jig to 40 degree C and check that display now shows 40.0.

7 ALARMS

The unit is now checked for all Alarm conditions. The PCB has 9 LED's that provide indication as to which alarm has been activated. As each test is performed the alarm condition should be left for 15 seconds at which time the ALARM LED on the front panel should illuminate and the relay should disconnect power from the Test Jig.

Alarm LED	Description	Diode
1	CS-MS > 3 degree C	D21
2	MS-CS > 3 degree C	D14
3	CS > T Max	D15
4	MS > T Max	D16
5	QR > T Max	D17
6	CS < 10 degree C	D18
7	MS < 10 degree C	D19
8	V ref < 7.5V	D20
9	Changed Temperature	D13 not used

Set Test Jig to CS-MS > 3 degrees	LED 1
Set Test Jig to MS-CS > 3 degrees	LED 2
Set Test Jig to CS 41.	LED 3.
Set Test Jig to MS 41.	LED 4.
Set Test Jig to CS o.c.	LED 6.
Set Test Jig to MS o.c.	LED 7.

8. Check for correct operation (section 7) with mains set to 199v AC
9. Check the alarm noise level is greater than 65 dB at 1 metre.
10. Ensure all paperwork is present, complete and accurate.

TF251 - CALIBRATION AND TEST RECORD – CT 003

Unit Serial Number: _____ Tested By: _____ Date _____

PCB Serial No. _____ Transformer No. _____

Date _____ Test Equipment _____

Test No.	Range	Result	OK?
5.1	TP 25	+11.40 to +12.60	
5.2	TP 24	-11.40 to -12.60	
5.3	TP 26	+11.40 to +12.60	
5.4	TP 27	-11.40 to -12.60	
5.5	TP 20	+4.75 to +5.25	
5.6	TP 21	+1.20 to +1.30	
5.7	TP19 set R63	+7.50 + or – 0.01	
5.8	TP18	-7.49 to -7.51	
5.9	TP 1 Set R16		
5.10	Set R12 for flashing @ 39°C	On time 10-15%	
5.11	TP5 Set R29 for 41°C Alarm.	Record TP5 value	
5.12	U8 Pin 14	-4.75 to -5.25	
6.1	TP1 to TP2 Set R38	0.998 to 1.002	
6.2	TP17 Set R58	0.686 to 0.688	
6.3	At 33°C Set R61 for	32.9 to 33.1 on Display	
6.4	At 40°C check for	40.0 on Display	
7.1	Jig Set 36/39	LED 1	
7.2	Jig Set 39/36	LED 2	
7.3	Jig Set CS 41 MS 39	LED 3	
7.4	Jig Set CS 39 MS 41	LED 4	
7.5	Jig Set CS o.c.	LED 6 & LED 1	
7.6	Jig Set MS o.c.	LED 7 & LED 2	
8.1	240Va.c. down at 199Va.c.	Retest as above	
9.1	Alarm noise	>65Db @ 1 M	

Blood warmer Soak Test and Verification – WI 013.A

1 PURPOSE

1.1 The purpose of this Work Instruction is to detail the steps which must be taken to complete the Blood warmer Soak Test.

2 REFERENCES

- 2.1 QP 031 - Non Conforming items
- CT 003 - Test results sheet
- CT 007 - Test and Calibration Results Sheet (Blood warmer)
- CT 008 - Acceptance Criteria (Blood warmer)

3 INSTRUCTIONS

3.1 Non-conforming items are to be handled as detailed in QP 031 - Non-conforming item procedure.

3.2 The results from the following work instructions should be recorded on test results sheet CT 007. For limits to values refer to CT008 acceptance criteria.

a. Place the blood warmer in the test area and switch it on with the plates dry. After a short while the Heat LED should start to flash on and off; once this happens record the temperature at which Heat LED goes off. After the Heat LED goes off the temperature will continue to rise on the display, when this happens, record the highest (overshoot) value. Then record the temperature when the heat LED starts to flash again. After about 5 minutes record the stabilised temperature. Whilst waiting to check the stabilised temperature, ensure the alarm works by pressing the alarm button; the alarm should sound and the fault light should illuminate after 15 to 20 seconds.

b. Insert a fluid bag and allow water to circulate for several minutes at flow # 4, to allow the blood warmer to cool down, and then switch blood warmer on. Record the temperature at which Heat LED goes off. Record highest (overshoot) value and record the temperature when the heat LED starts to flash again. After 5 minutes record the stabilised temperature and ensure that the alarm functions when alarm button is pressed. Record the water temperature entering the blood warmer and also record temperature of the water exiting. Refer to CT008 acceptance criteria to ensure that the temperatures recorded are within the limits set.

c. Allow the blood warmer to cool and then select flow # 8. The previous steps should be repeated however it should be noted that it may be unnecessary to record the overshoot temperature. Remember to refer to CT008 acceptance criteria to ensure that the temperatures recorded are within the limits set.

Having completed and recorded the tests described above the fluid bag should be removed and the machine should be left switched on for a minimum of 24 hours. For the first 2 hours the temperature on the display should be checked every 30 minutes. For the remaining 22 hours it should be checked on an occasional basis (a minimum of 4 checks). The temperature should remain at 39°C +0.3 / - 0.1.

TEST EQUIPMENT

Digital Thermometer
Watson AR flow inducer
Fluid bag

BLOODWARMER TEST RESULTS SHEET

SERIAL No _____ TYPE _____ RC No _____

WORKS ORDER No _____ T/FORMER No _____

Step	Operation	Value
1a	Switch machine on with plates dry	
1b	Record temperature at which Heat LED goes off 38.9-39.5	
1c	Record highest (overshoot) value. 39.6 to 40.5	
1d	Record temperature at which Heat LED starts flashing 38.9 to 39.6	
1e	After 5 minutes record the stabilised temperature 38.7 to 39.5	
1f	Alarm functions when alarm button is pressed	
2a	Insert fluid bag and allow water to circulate for several minutes (at flow # 4), and then switch fluid warmer on.	
2b	Record temperature at which Heat LED goes off 38.9 to 39.5	
2c	Record highest (overshoot) value. 39.6 to 40.5	
2d	Record temperature at which Heat LED starts flashing 38.9 to 39.5	
2e	After 5 minutes record the stabilised temperature 38.7 to 39.5	
2f	Record water temperature entering the fluid warmer	
2g	Record water temperature exiting the fluid warmer	
2h	Do these temperature meet CT008 acceptance criteria	
3a	Allow fluid warmer to cool then select flow # 8	
3b	Record temperature at which Heat LED goes off 38.9 to 39.5	
3c	Record highest (overshoot) value. 39.6 to 40.5	
3d	Record temperature at which Heat LED starts flashing 38.9 to 39.5	
3e	After 5 minutes record the stabilised temperature 38.7 to 39.5	
3f	Record water temperature entering the fluid warmer	
3g	Record water temperature exiting the fluid warmer	
3h	Do these temperatures meet CT008 acceptance criteria	

Test equipment used _____

Test completed by _____

Date _____

Blood warmer test acceptance criteria – CT 008A

Inlet Temperature (°C) _____ Outlet Temperature (°C) _____
 Flow # 4 Flow # 8

	Flow #4	Flow #8
10.0 – 10.9	28 - 36	24 – 30
11.0 – 11.9	29 - 37	25 – 31
12.0 – 12.9	30 - 38	26 – 32
13.0 – 13.9	31 – 39	27 – 33
14.0 – 14.9	32 – 39	28 – 34
15.0 – 15.9	33 – 39	29 – 35
16.0 – 16.9	33 – 39	30 – 36
17.0 – 17.9	33 – 39	31 – 37
18.0 – 18.9	34 – 39	32 – 38
19.0 – 19.9	34 – 39	33 – 39
20.0 – 20.9	35 – 39	34 – 39
Dry test	Stabilised temperature	39°C ±0.5°C

Test completed by _____

Date _____

13. MATERIALS LIST

(The suppliers may change from time to time)

J118-00001 Thermofluid General Assembly 1						
ITEM	DESCRIPTION	JMW Part No	QTY	Manufacturer	Supplier	Part No.
	Case Assembly	J118-60001	1			
	Rear Panel Assembly	J118-60002	1			
	Main PCB Assy	J118-70001	1			
	Display PCB Assy	J118-70002	1			

J118-60001 Case Assembly 1						
ITEM	DESCRIPTION	JMW Part No.	QTY	Manufacturer	Supplier	Part No.
	Front Cover	J118-20001	1			
	Warmer Plate 'A'	J118-20002	1			
	Warmer Plate 'B'	J118-20003	1			
	Back Insulator	J118-20004	1			
	Hinge To Bracket	J118-20007	1			
	Hinge Middle Bracket	J118-20008	1			
	Hinge Bottom Bracket	J118-20009	1			
	Overlay Thermofluid	J118-40001	1			
	Heating Elements	J118-40006	2			
	10k Thermistors	108-0001	4			
	Conn. 4 way Housing	356-0014	2	Molex 22-01-2045	Farnell	143-128
	Insert 0.1"	356-0024	8	Molex 08-50-0032	Farnell	143-201
	Wire 7/0.2 Purple	322-0043	a/r	Farnell		140-311
	Wire 7/0.2 Grey	322-0037	a/r	Farnell		149-319
	M4x16 SS CSK Hex Head	310-0033	10	Serco Ryan	RS	171-837
	M3x16 SS CSK Hex Head	310-0020	10		RS	171-809
	M6x16 SS Btn Hex Head	310-0038	7		RS	183-8727
	M4x10 Pozi Pan Head	310-0024	4	Serco Ryan	Farnell	149-517
	Wire 32/0.2mm Grn/Yel	322-0019	a/r		Farnell	150-134
	Wire 16/0.2 Black	322-0004	a/r		Farnell	140-339
	Conn 4 way 0.156	356-0021	2	Molex	Farnell	143-159
	Insert 0.156	356-0025	8	Molex	Farnell	143-193
	Protex Clamp 18-613	317-0001	1	Protex 18-613		18613
	Protex Catchplate 01-613	317-0000	1	Protex 01-613		01613
	Ring M4 Blue	359-0014	1	Davico	Farnell	150-275
	Ring M6 Blue	359-0015	1	Davico	Farnell	150-277
	Earth CAble Assembly	J118-75002	1			
	M4 Nut Nyloc	311-0008	2	Serco Ryan		

J118-60002 Rear Panel Assembly 1						
ITEM	DESCRIPTION	JMW Part No	QTY	Manufacturer	Supplier	Part No
	Back Cover Plate	J118-20005	1	JMW		
	Clamp Frame	J118-20010	1	Duneill		
	Clamp Cam	J118-20011	1	Duneill		
	Clamp Support	J118-10001	1	Phoenix Precision		
	Tube Support	J118-20012	1	Duneill		
	Wing Knob M6 Female	337-0007	1	J G Coates		1032
	Mains Trans/fmr 12-0-12	131-0007	1			
Q1.	Triac	254-0003	1	SGS	Farnell	BTA40-400B
	RLY1	Relay 1PCO 24V 30A			331-0003	1 Farnell
	176-590					
	Fuseholder	300-0001	1	Bulgin	Farnell	F357
	Fuseholder	301-0001	1	Bulgin	Farnell	F357
	Switch DPST Green 0/1	344-0000	1	RS		664-553
	Inlet Filter	354-0001	1	Farnell		L12135C/L

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Female 0.187 Faston	359-0020	4		RS	433-107
Fuse Link T5A	301-0004	2	Beswick TDS506		Farnell 151-525
Ring 6mm Blue	359-0015	1	Davico	Farnell	150-277
Heatshrink Tubing	323-0006	a/r		Farnell	107-468
Wire 7/0.2 Brown UL1015	322-0018	a/r		Farnell	140312
Wire 7/0.2 Blue UL1015	322-0038	a/r		Farnell	140-317
Wire 32/0.2 Grn/Ylw DEF61-12		322-0019		a/r	Farnell 150-134
Retainer Kit	354-0004	1	Bulgin Kt0006	Farnell	KIT6
M6x40	310-0040	1		RS	553-712
M4 Nyloc Nuts	311-0008	2	Serco Ryan		
M5x10 SS Button Head	310-0034	2	Serco Ryan		
M5 Nylon Washers	312-0015	2		Farnell	
M6x50 stud	310-0041	1		RS	280-391
5x24mm SS Spring Pin	313-0000	1			
M4x12 Pozi Pan Head	310-0042	2	Serco Ryan		
M4 Shk Prf Washer	312-0004	2	Serco Ryan	Farnell	149-696
M4 Full Nut	311-0003	2		Farnell	149-682
Switch Assembly	J118-750011				
Earth Pin	356-0030	1	Multicontact		04.0057
M6 Washer	356-0033	2	Multicontact		08.0704
M6 Nut	356-0032	2	Multicontact		
Earth Label	356-0029	1	Multicontact		14.5010
M4 Plain Washer	312-0012	4	Serco Ryan	Farnell	149-689
M6 Plain Washer	312-0014	1	Serco Ryan		
Sounder Assembly	J118-75003	1			

J118-70001 Main PCB Assy		1				
ITEM	DESCRIPTION	JMW Part No.	QTY	Manufacturer	Supplier	Part No.
	Bare PCB	J118-30001	1			
D1,2,3,4,5,6,7,8,9,10,11,12,13,14,15,16,17,18,19,20,21.	Diode 1N4148	250-0001	21		Farnell	1N4148
D32,33,34,36,37	Diode 1N4007			251-0000	5	Farnell
D36A	Diode Zener 7V5	25x-xxxx	1		Farnell	368-210
R1,2.	Resistor 18k 0.25W 1%	100-0042	2	Philips MRS25	Farnell	MRS25-18k
R3.	Resistor 100R 0.25W 1%	100-0006	1	Philips MRS25	Farnell	MRS25-100R
R5,10,17,18,23,24,47,69.	Resistor 100k 0.25W 1%			100-0049	8	Philips
R6,31,33,36,37,40,44.	Resistor 1M0 0.25W 1%			100-0054	7	Philips
R7,8,21,25,26,27,39,42,45,48,49,50,51,53,54,55,60,65,66,67,68,71,72,73,74,75,76,70.	Resistor 10k 0.25W 1%			100-0038	27	Philips
R9.	Resistor 2k0 0.25W 1%	100-0024	1	Philips MRS25	Farnell	MRS25-2k0
R11.	Resistor 30k 0.25W 1%		100-0046		1	Philips MRS25
R13.	Resistor 5k6 0.25W 1%	100-0032				Farnell MRS25-5k6
R14.	Resistor 390R 0.25W 1%	100-0015	1	Philips MRS25	Farnell	MRS25-390R
R15.	Resistor 150k 0.25W 1%	100-0050	1	Philips MRS25	Farnell	MRS25-150k
R19,20.	Resistor 27k 0.25W 1%	100-0045	2	Philips MRS25	Farnell	MRS25-27k
R22,43.	Resistor 22R 0.25W 1%	100-0001	2	Philips MRS25	Farnell	MRS25-22R
R28.	Resistor 6k8 0.25W 1%	100-0028	1	Philips MRS25	Farnell	MRS25-3k9

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R30.	Resistor 7k5 0.25W 1%	100-0035	1	Philips MRS25	Farnell	MRS25-7K5
R32,34,35,41, 46,4,77.	Resistor 1k0 0.25W 1%	100-0020	7	Philips MRS25	Farnell	MRS25-1k0
R38.	Resistor 20k 0.25W 1%	100-0043	1	Philips MRS25	Farnell	MRS25-20k
R52,64.	Resistor 8k2 0.25W 1%	100-0036	2	Philips MRS25	Farnell	MRS25-8k2
R56.	Resistor 4k3 0.25W 1%	100-0029	1	Philips MRS25	Farnell	MRS25-2k4
R57.	Resistor 6k8 0.25W 1%	100-0033	1	Philips MRS25	Farnell	MRS25-6k8
R59.	Resistor 1k2 0.25W 1%	100-0021	1	Philips MRS25	Farnell	MRS25-1k2
R62.	Resistor 15k 0.25W 1%	100-0040	1	Philips MRS25	Farnell	MRS25-15k
D35,38,39.	Zener 9V1	255-0009	3	Philips	Farnell	BZT03 C9V1
(U2)	DIL Skt 16 way	357-0001	1	Harwin D2816-01	Farnell	178-829
(U1),(U3),(U5), (U6),(U7),(U8).	DIL Skt 14 way	357-0000	6	Harwin D2814-01	Farnell	178-828
(U4).	DIL Skt 8 way	357-0006	1	Harwin D2808-0	Farnell	178-827
RN1.	Resnet 9x10k SIL	106-0000	1	Bourns 4610x-101	Farnell	148-995
C1,2,4,6,7,11, 15,16,17,18, 19,20,21,22, 23,24,27,28, 29,34,35,40,8.	Cap Ceramic 0.1uF	120-0002	23	JPR Electronics		130-037
C3.	Cap Crmc 0.047uF 100V	120-0001	1	Philips CW20A 473M	Farnell	143-734
C5,9,25,32,33, 38,39.	Cap Elec. 10uF 50V		7	Philips 035 90008	Farnell	107-406
C8,13.	Cap Elec. 1uF 63V	122-0001	2	Philips 035 58108	Farnell	107-411
C10.	Cap Elec. 220uF 25V	122-0011	1	Philips 035 56221		107-392
C12.	Cap Elec. 1000uF 16V	122-0003	1	Waycom WHT	Farnell	148-847
C14.	Cap Elec. 68uF 40V	122-0006	1	Philips	Farnell	286-485
C30,31,36,37	Cap Elec.100uF 50V		4		Farnell	320- 1703
T1,3.	N-FET ZVN2106A	264-0001	2	Zetex	Farnell	ZVN2106A
T2.	NPN 2N3904	260-0001	1		Farnell	2N3904
U10,13.	Regulator -12V 100mA	234-0007	2	NS	Farnell	LM79L12ACZ
U11,12.	Regulator +12V 100mA	234-0002	2	NS	Farnell	LM78L12ACZ
D31.	Reference 1.2V	256-0000	1	AMS	Farnell	AMS9491BN
J1.	Conn. SIL 4 way term block		355-0005		1	Wieland 8191/4
	Farnell	151-796				
J2,3.	Conn. SIL 4x0.156 Plug		356-0010		2	Molex 26-48-1242
	Farnell	151-899				
J4,5.	Conn. SIL 4x0.1 Plug	356-0006	2	Molex 22-27-2041	Farnell	143-141
J6.	Conn. SIL 8x0.1 Plug	356-0009	1	Molex 22-27-2081	Farnell	143-143
J7.	Conn. SIL 2x0.1 PLug	356-0004	1	Molex 22-27-2021	Farnell	143-139
J8.	Conn. SIL 3x0.1 Plug	356-0003	1	Molex 22-27-2031	Farnell	143-140
LK1,2	Conn SIL 2x0.1 Header		356-0036		2	Harwin M20-
9993606	Farnell	148-533				
(F1),(F2).	Fuseholder PCB	300-0002	2	Belling 5229	Farnell	146-123
F1,F2.	Fuse Link T2A	301-	2	Bussman	Farnell	534-195
R16.	R Var 20k	105-0002	1	Bourns 3296Y	Farnell	348-132
R12.	R Var 10k	105-0000	1	Bourns 3296Y	Farnell	348-
R29,58,63.	R Var 2k0	105-0001	3	Bourns 3296Y	Farnell	348-107
R61.	R Var 500R	105-0005	1	Bourns 3296Y	Farnell	348-089
TP3,4,5,6,7, 8,9,10,11,12, 13,14,15,16, 17,18,19,20,21	Test Point	356-0035	19	William Hughes		200-201
(U9).	TO220 Heatsink	309-0002	1	Redpoint SW25-4	Farnell	175-650
U9.	Regulator 5V 1A	234-0004	1	NS	Farnell	LM7805CT
D22,23,24,25 26,27,28,29,30	RED LED	240-0010	9	QT	Farnell	MV57123-17
U2.	Temperature Cont	TDA1023	239-0001		1	Philips TDA1023/N3
	ESD	027397C				
U1,7,8.	Quad Op-amp 324	231-0000	3	NS	Farnell	LM324N
U3,5,6.	Quad Comp. 339.	230-0000	3	NS	Farnell	LM339N

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U4.	Timer 555.	233-0000	1	TI	Farnell	TLC555CP
(U11).	M3x10 Pozi Pan Head	310-0006	1		Farnell	149-556
(U11).	M3 Full Nut	311-0002	1	Serco Ryan		
(U11).	M3 Plain Washer	312-0010	1	Serco Ryan		
(U11).	M3 Shk Prf Washer	312-0003	1	Serco Ryan		
	Faston 6.35mm Blue	359-0007	2	Davico	Farnell	150-307
	Faston 4.8mm Red	359-0010	1	Davico	Farnell	150-304
	Wire 32/0.2 Grn/Yel	322-0019	a/r		Farnell	150-134
	Wire 32/0.2 Orange	322-0032	a/r		Farnell	296-491
	Wire 16/0.2 Red	322-0006	a/r		Farnell	140-341

J118-70002		Display PCB Assembly			1		
ITEM	DESCRIPTION	JMW Part No.	QTY	Manufacturer	Supplier	Part No.	
	Bare PCB	J118-30002	1	Strathclyde Circuits			
R1.	Resistor 680R 0.25W	100-0019	1	Philips MRS25	Farnell	MRS25-680R	
R2,6.	Resistor 100k 0.25W 1%	100-0049	2	Philips MRS25	Farnell	MRS25-100k	
R3.	Resistor 15k 0.25W 1%	100-0040	1	Philips MRS25	Farnell	MRS25-15k	
R5.	Resistor 10k 0.25W 1%	100-0038	1	Philips MRS25	Farnell	MRS25-10k	
R7.	Resistor 470k 0.25W 1%	100-0053	1	Philips MRS25	Farnell	MRS25-470k	
R8.	Resistor 270R 0.25W 1%	100-0011	1	Philips MRS25	Farnell	MRS25-270R	
C1.	Cap Ceramic 330pF	120-0004	1	Philips 683 58331	Farnell	683 58331	
C2,3,6,8,9.	Cap Ceramic 0.1uF	120-0002	5	JPR Electronics	130-037		
C5.	Cap. Polyester 0.22uF	121-0001	1	Wima MKS2	Farnell	143-682	
C4.	Cap Cm 0.047uF 100V	120-0001	1	Philips CW20A 473M	Farnell	143-734	
C7.	Cap Elec. 220uF 10V	122-0005	1	Philips 030 34221	Farnell	305-388	
LED1,2,3.	7 Segment Green LED	241-0000	3	HP HDSP5601	Farnell	HDSP5601	
R4.	R Var 5k0	105-0004	1	Spectrol 64Y	Farnell	64Y 5k0	
D1.	Reference 1.2V	256-0000	1	AMS	Farnell	AMS9491BN	
D2.	LED Green	240-0004	1	HP HLMP-M500	Farnell	HLMP-M500	
D3.	LED Amber	240-0000	1	HP HLMP-M300	Farnell	HLMP-M300	
D4.	LED Red	240-0009	1	HP HLMP-M200	Farnell	HLMP-M200	
TP1,2.	Test Point	356-0035	2	William Hughes		200-201	
U1.	Display Driver/ADC	232-0000	1	UMC	Farnell	UM7107A	

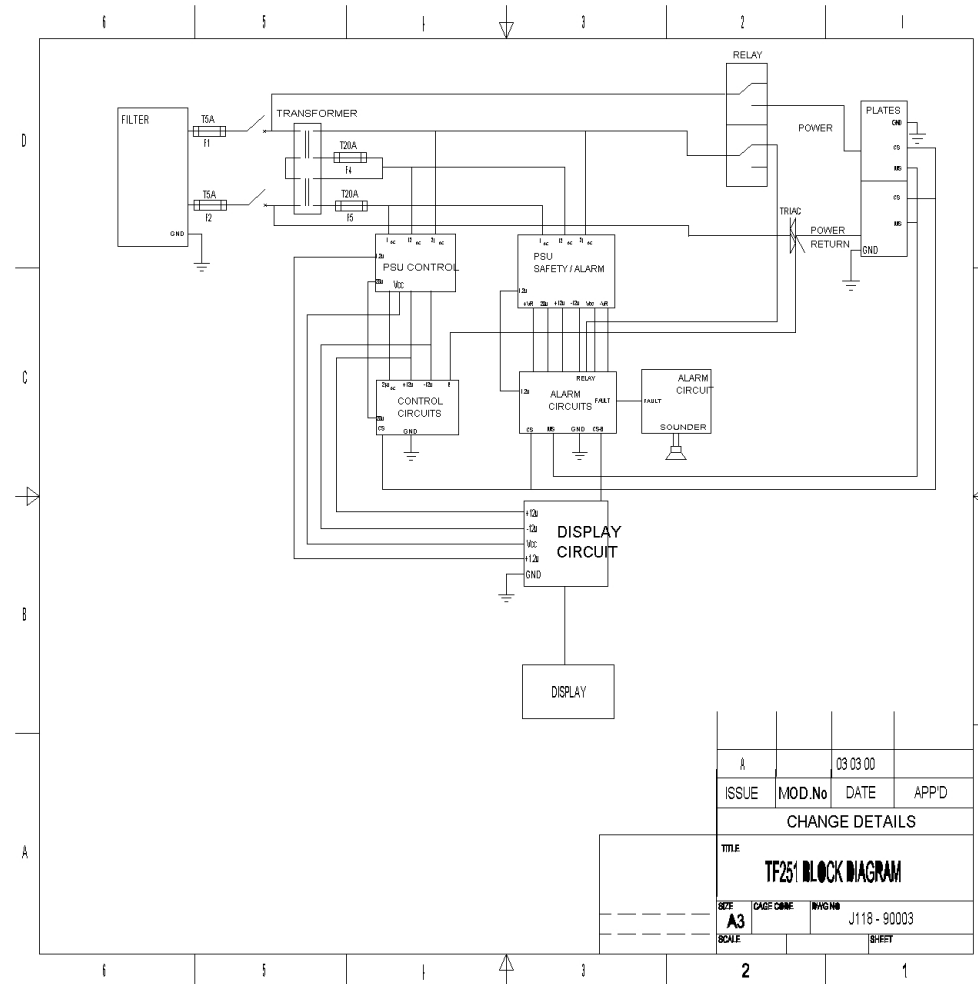
J118-75001		Switch Assembly			1		
ITEM	DESCRIPTION	JMW Part No.	QTY	Manufacturer	Supplier	Part No.	
	Switch mom 1PCO	341-0008	1	C and K	Phoenix Electronics	8121-SHZ	
	Dress nut and cap	341-0006	1	C and K	Phoenix Electronics	8125	
	Conn. 3way Header 0.1"	356-0013	1	Molex 22-01-2035	Farnell	143-127	
	Inserts 0.1"	356-0024	3	Molex 08-50-0032	Farnell	143-201	
	Wire 7/0.2 Brown	322-0018	a/r		Farnell	140-312	
	Wire 7/0.2 Red	322-0017	a/r		Farnell	140-313	
	Wire 7/0.2 Orange	322-0016	a/r		Farnell	140-341	

J118-75002 Earth Cable Assembly 1						
ITEM	DESCRIPTION	JMW Part No.	QTY	Manufacturer	Supplier	Part No.
	Ring M6 Blue	359-0015	1		Davico	Farnell 150-277
	Ring M4 Blue	359-0014	1		Davico	Farnell 150-275
	Wire 32/0.2mm Grn/Yel	322-0019	a/r			Farnell 150-134

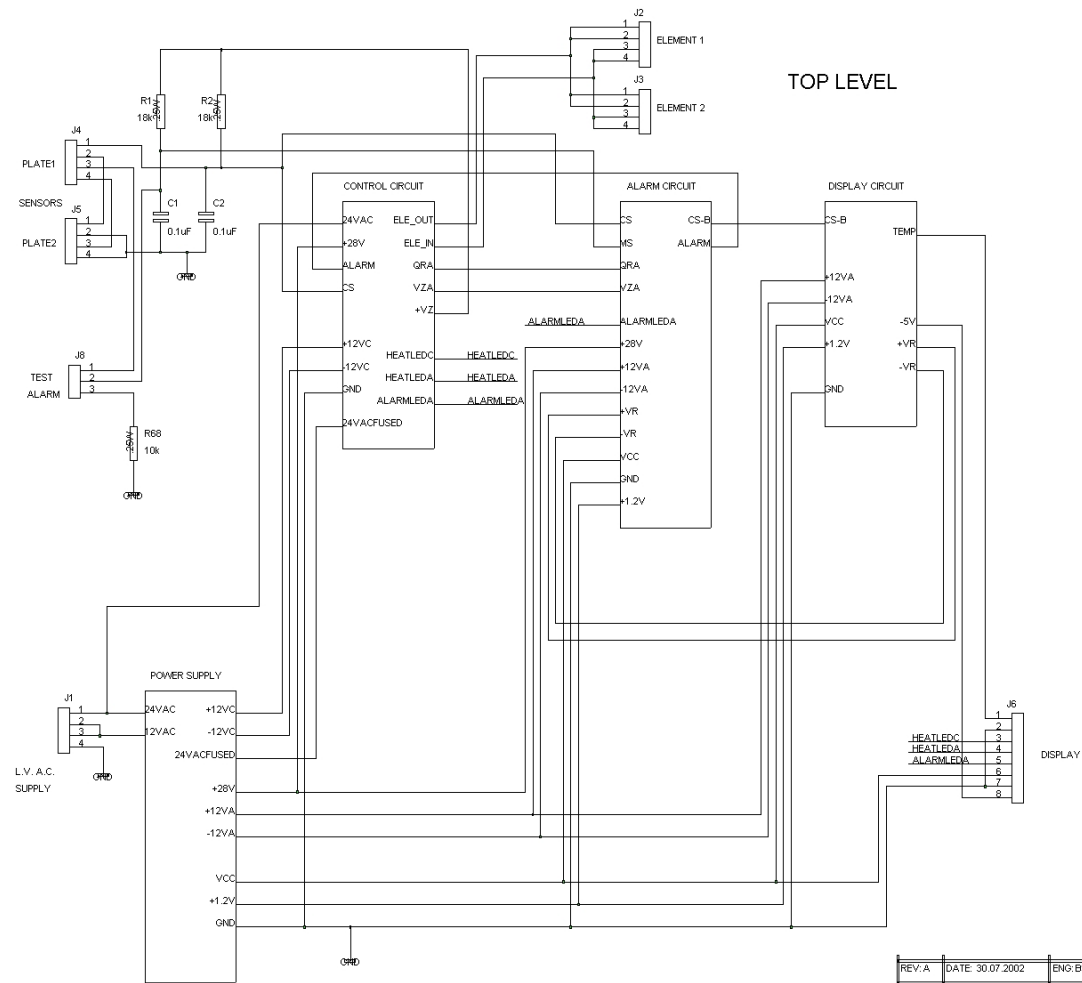
J118-75003 Sounder Assembly 1						
ITEM	DESCRIPTION	JMW Part No.	QTY	Manufacturer	Supplier	Part No.
	Sounder	336-0003	1			Farnell 223-920
	Conn. 3way Header 0.1"	356-0012	1	Molex 22-01-2025		Farnell 143-126
	Inserts 0.1"	356-0024	3	Molex 08-50-0032		Farnell 143-201

14. Circuit Diagrams.

The next pages detail the circuit diagrams for the TF251.



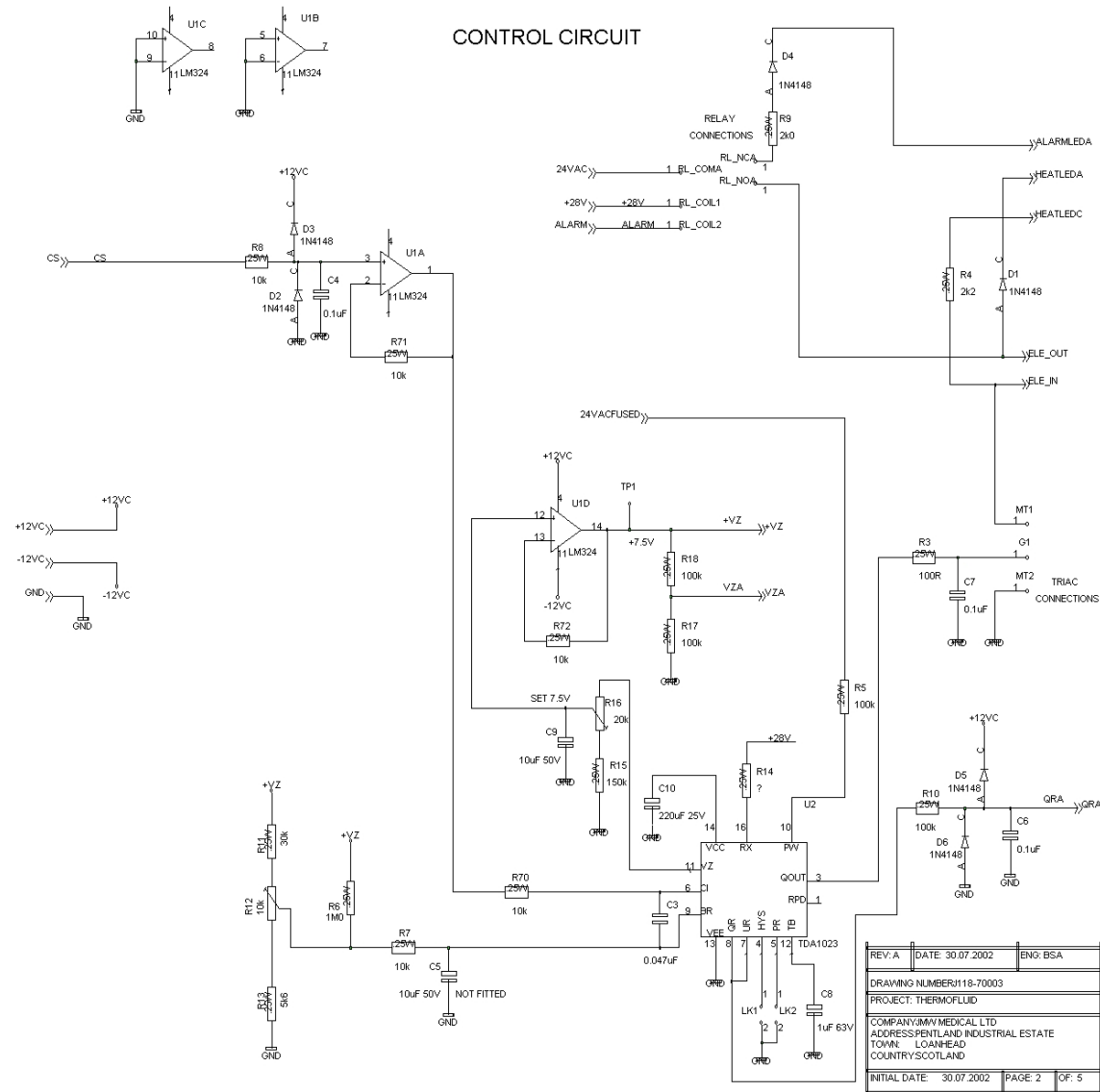
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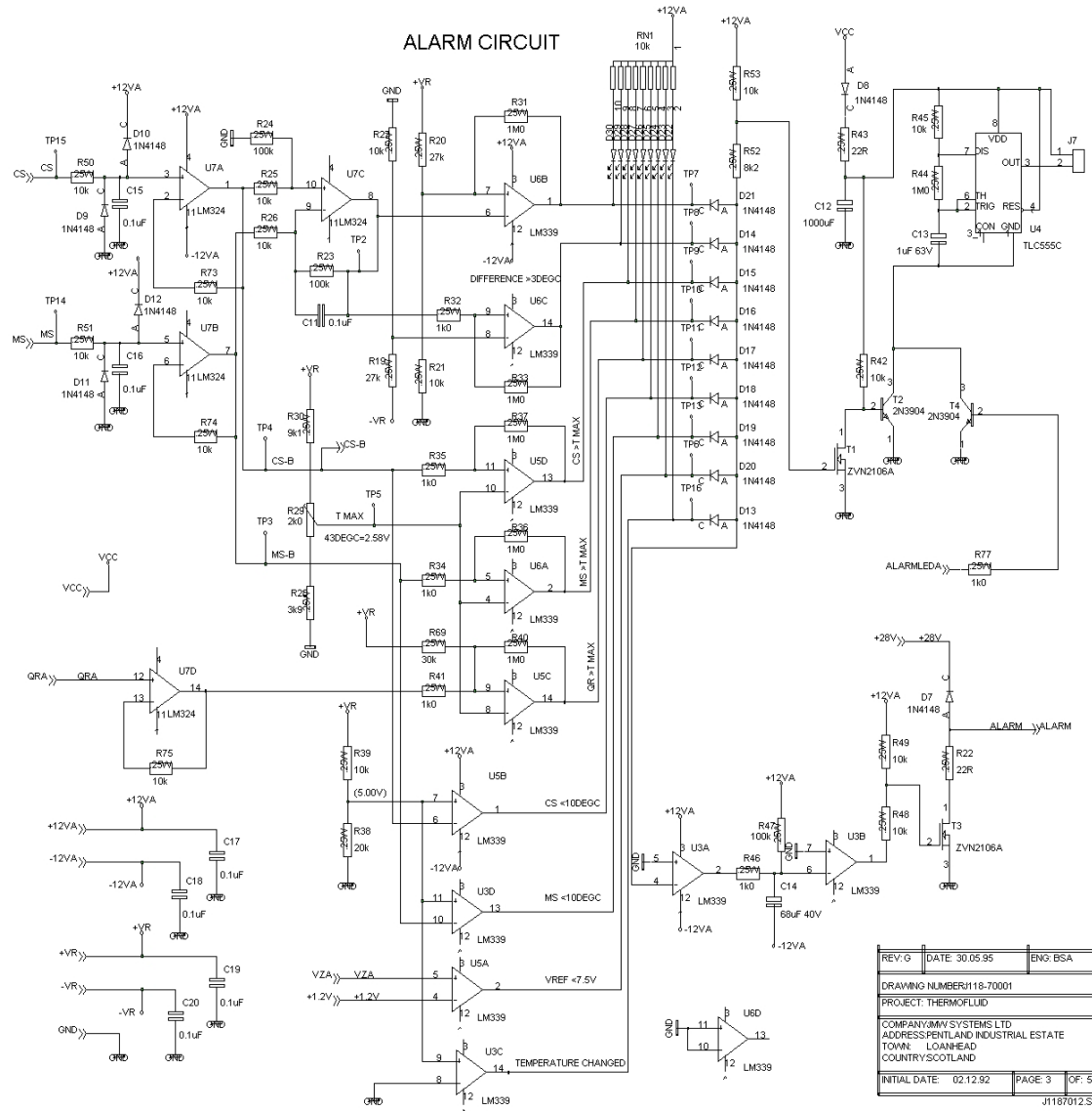
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PROJECT: THERMOFLUID		
COMPANY: JIMMY MEDICAL LTD ADDRESS: PENTLAND INDUSTRIAL ESTATE TOWN: LOANHEAD COUNTRY: SCOTLAND		
INITIAL DATE: 30.07.2002	PAGE: 1	OF: 5

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CONTROL CIRCUIT

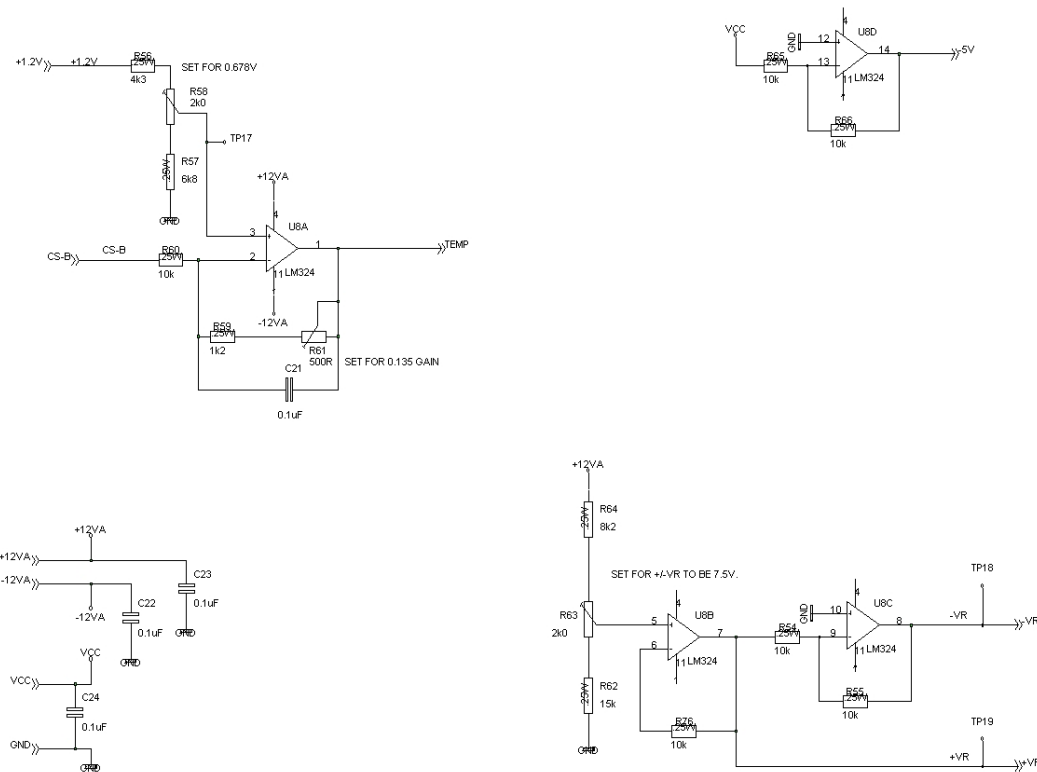


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TOWN: LOANHEAD		
COUNTRY: SCOTLAND		
INITIAL DATE: 30.07.2002	PAGE: 2	OF: 5



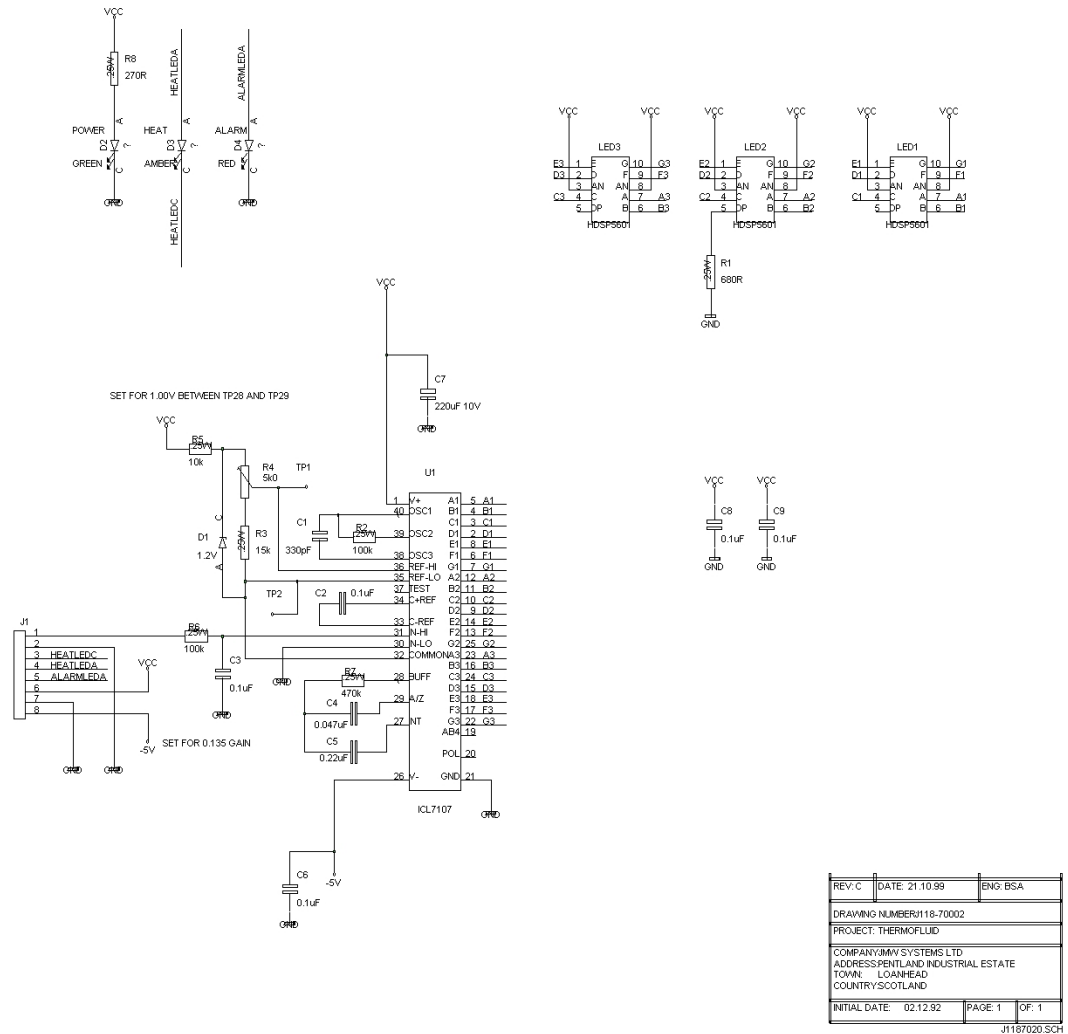
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PROJECT: THERMOFLUID		
COMPANY: VMV SYSTEMS LTD		
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TOWN: LOANHEAD		
COUNTRY: SCOTLAND		
INITIAL DATE: 02.12.92	PAGE: 3	OF: 5
J1187012.SCH		

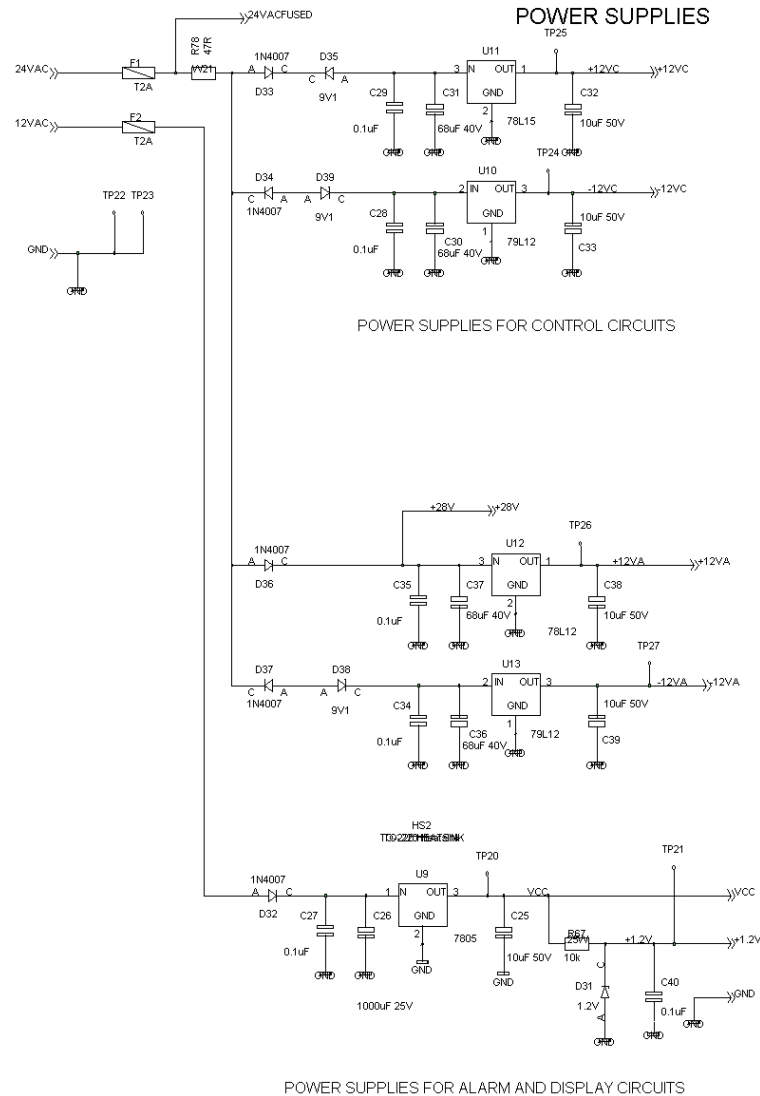
DISPLAY CIRCUIT



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DRAWING NUMBER: J118-70001		
PROJECT: THERMOFLUID		
COMPANY: JMW SYSTEMS LTD ADDRESS: FENLAND INDUSTRIAL ESTATE TOWN: LOANHEAD COUNTRY: SCOTLAND		
INITIAL DATE: 02.12.92	PAGE: 4	OF: 5
J1187013.SCH		

DISPLAY CIRCUIT





REV: G	DATE: 22.06.95	ENG: BSA
DRAWING NUMBER: J118-70001		
PROJECT: THERMOFLUID		
COMPANY: JMW SYSTEMS LTD		
ADDRESS: PENTLAND INDUSTRIAL ESTATE		
TOWN: LOANHEAD		
COUNTRY: SCOTLAND		
INITIAL DATE: 02.12.92	PAGE: 5	OF: 5

J1187014.SCH