ElectroTherm

'ThermaCon'

Infusion Fluid Heater

Energy efficient technology!

GENERAL DESCRIPTION

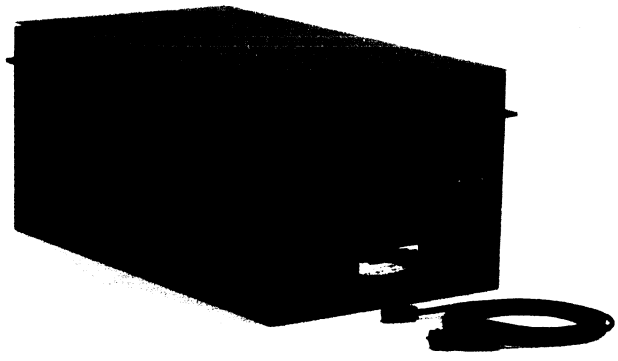
The ***ThermaCon*** is a quality Australian made product manufactured from high-grade materials meeting Australian electrical safety Standards. If used according to the following instructions, it will safely and reliably meet your specific heating requirements.

The ***ThermaCon*** is designed to provide a convenient heating/insulation system for raising and maintaining the temperature of liquid infusion fluid bags at a base depot ready for transfer into the portable *ThermaBag* for transport in Ambulance vehicles.

Development of the ***ThermaCon*** is made possible by using new carbon-graphite radiant electric heating elements that have unique advantages over conventional metal elements.

The electric heating elements gently radiate energy into the fluid through the floor and walls of the ***ThermaCon***. Efficient, multi-layer insulation materials inside the container panels and lid minimize energy loss and form a stand-alone 'warm room' suitable for operation in low ambient temperatures.

Normal temperature regulation in the ***ThermaCon*** is provided by a micro-processor based digital Controller with sensor located in one end wall sensing air temperature inside the container. Abnormal temperature limiting is provided by a thermal Cutoff located against the heating element surface and connected in series with the supply wiring.



OPERATING INSTRUCTIONS

'ThermaCon'

Date: June 2009

Before operating your ***ThermaCon, PLEASE READ THESE INSTRUCTIONS!***

GENERAL CARE

Your *ThermaCon* is constructed to give years of safe, trouble free service, but normal care in handling, operating and storage is required.

Your *ThermaCon* is designed and warranted for specific use *only* - raising and maintaining the temperature of up to twenty-four 1 litre bags of infusion fluid while powered by a 240V a.c. to 12V d.c Power Supply. **DO NOT** use it for any other purpose.

DO NOT use the *ThermaCon* where liquid spillage may occur, in wet areas, or outdoors unprotected from weather!

HANDLING

Care must be taken to avoid physical damage to the *ThermaCon* that could result in damage to the power socket. Care must also be taken to keep the *ThermaCon* dry.

CAUTION

Electrical appliance - Handle with care!

TESTING

Periodically, your *ThermaCon* should be tested for electrical safety by a qualified person in accordance with AS/NZS3760:2003 'In service safety inspection and testing of electrical equipment', or an equivalent safety standard for country of operation.

OPERATING

Your *ThermaCon* is easy to use!

Load up to twenty-four 1 litre bags of infusion fluid into the *ThermaCon.* Ensure the lid is replaced and fitting flush. To maintain optimum heating performance and temperature regulation, the lid should be closed except when removing or replacing liquid bags.

Connect the Power Supply cord bayonet plug into the power socket of the ThermaCon. Engage the connection with a clockwise quarter-turn twist. Do not over-stress the connectors.

Connect the Power Supply flexible mains cord into a power outlet and turn 'ON' to commence heating.

Correct temperature is maintained by a sensor connected to a digital electronic temperature Controller fitted to the end wall of the *ThermaCon.*

The Red LED indicator next to the power socket of the *ThermaCon* will light constantly to indicate power, and heating, 'ON'.

A flashing Red/Green LED indicates that the Controller is regulating internal temperature by cycling power to the heating elements.

The *ThermaCon* is designed to be safely operated continuously with power connected.

CLEANING

If your *ThermaCon* becomes soiled, clean inside and outside with a damp cloth and mild detergent.

NEVER IMMERSE IN WATER OR HOSE DOWN! - DO NOT USE SOLVENTS!

WARNING!

The *ThermaCon* is not intended for use by persons (including children) with reduced physical, sensory or mental capabilities, or lack of experience and knowledge.

The *ThermaCon* is to be handled, installed and operated by trained personnel only.

The *ThermaCon* is to be tested by qualified personnel only.

Operate the *ThermaCon* indoors only.

Do not operate the *ThermaCon* if the power connectors are damaged.

SPECIFICATION

ThermaCon
12V d.c. 75W
Normal Temperature Regulation (by electronic Controller): 40℃ +/- 2℃
Abnormal Element Temperature Limiting (by Cutoff): 144℃ +0℃ -4℃

Power Supply
Input: 90-264V a.c. 47–63Hz Output: 12V d.c. 6.66A, 80W
Ambient operating conditions: 0-40℃

Manufactured in accordance with AS/NZS 60335.1 and 60335.2.15

Proper care and use of your ***ThermaCon*** and ancillary equipment in accordance with these Operating Instructions is the responsibility of the purchaser. The manufacturer and its suppliers and agents do not accept responsibility for any injury, loss or damages caused through misuse of these products.

Your ***ThermaCon*** is guaranteed against defects in materials or workmanship for twelve months from date of purchase. Guarantee is limited to repair or replacement of unserviceable parts or replacement of Heater.

Manufactured in Australia by:
ELECTROTHERM PTY LTD
ABN 12 055 597 058
10 Keppler Circuit, Seaford, Victoria 3198, Australia
Tel: 61 3 9775 1575 Fax: 61 3 9775 1595
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16 July 2009

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Mr M Bell
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Seaford Vic 3198

Dear Michael

ELECTRICAL SAFETY INSPECTION REPORT: THERMACON MODEL 920-851 INFUSION FLUID HEATER

The following is a report of an inspection carried out on a sample of the above appliance to determine if the above appliance complied with the principal safety aspects of AS/NZS 60335.2.15 : 2002 + A1, A2, A3, & A4 [Part 2] and AS/NZS 60335.1: 2002 + A1, A2, & A3 [Part 1].

This report comprises of 7 pages including 1 page with 6 photographs. It is an inspection report covering the principal safety clauses and limited testing to the above standards relevant to the Thermacon appliance. It is not purported to be a full test report to the above safety standards.

MARKINGS.

The markings of the components are as follows:

Thermacon: Model 920-851 12V dc 72W Manufactured in Australia by Electrotherm Pty Ltd. Tel. +61 3 9775 1575. Complies with AS/NZS 60335.1 and AS/NZS 60335.2.15.

Power Supply Unit: Amtex Model LFZVC90NS12E AC Adaptor 220-240V, 90-100VA, 50-60Hz; Output 12V 6.6A dc, ⧈ ✔ N820.

DESCRIPTION:

The above electrical equipment comprises of the Thermacon and a 240/12V Extra Low Voltage Power Supply Unit. The equipment is intended for use at an ambulance station to warm and store up to 24 one litre sealed plastic bags of infusion fluid for medical purposes.

The Thermacon is a rectangular shaped open box with a lid and is made from aluminium sheet. The approximate dimensions of the Thermacon are: 640 mm long, 345 mm wide and 275 mm high. The inner metal liner of the Thermacon is wrapped with a 12V 72W thin sheet flexible heating element with a series connected 144° "Microtemp" thermal fuse attached to it on one side. Thermal insulation is provided between the outer enclosure and the inner metal liner which is fixed inside the outer enclosure. An electronic thermostat is located behind the small metal panel which incorporates the 12V supply inlet socket. It is intended to maintain the temperature of the infusion fluid in the enclosure at approximately 40°. The power supply unit is connected to the Thermacon via a plastic "in line" two pole ELV connector.

Note: The information contained in this report is based on inspection of a sample with limited testing being performed. Full examination and testing to the relevant safety standard may reveal additional points of non-compliance. Health aspects related to the medical use of the appliance are not addressed in this report.

INSPECTION REPORT DETAILS.

The details of the compliance of the Thermacon equipment with the relevant clauses of the above safety standards are provided in the following table. All relevant safety clauses are noted as complying, assessed as being safe or not applicable in the decision column of the table.

CONCLUSION.

It is noted that the temperature rise of the electrical insulation during normal operation and abnormal operation with the thermostat rendered inoperative, are well within the continuous temperature rating of the insulation. The heater operates at a safe voltage of 12V dc and presents no electrical or fire hazards because all electrical components are located within the metal enclosure. Also the Amtex Model LFZVC90NS12E ELV power supply unit is an Australian safety approved type [Approval No: NSW23963] which is protected against overload and short circuit.

Accordingly in my opinion the Thermacon Model 920-851 Infusion Fluid Heater and its associated ELV power supply unit comply with the essential safety aspects of AS/NZS 60335.2.15 and AS/NZS 60335.1 and are safe products when used in accordance with the instructions for use provided by the manufacturer.

If you have any queries about this report, please do not hesitate to contact me.

Best regards

W S Curry

William Curry

Note: The information contained in this report is based on inspection of a sample with limited testing being performed. Full examination and testing to the relevant safety standard may reveal additional points of non-compliance. Health aspects related to the medical use of the appliance are not addressed in this report.

SAFETY COMPLIANCE INSPECTION REPORT: MODEL 920 851 THERMABAG.
Assessment of compliance with AS/NZS 60335.2.15: 2002 + A1, A2, A3, & A4 [Part 2] and AS/NZS 60335.1: 2002 + A1, A2, & A3 [Part 1].

Notation applied in Decision Column: P (Pass); F (Fail); N.A. (Not applicable): A (Assessed as being safe)

CLAUSE	REQUIREMENT	REMARKS	DECISION
3	DEFINITIONS		
3.4.2	Safety Extra Low Voltage: Voltage not exceeding 42 V between conductors and between conductors and earth, the no-load voltage not exceeding 50 V. When derived from the mains supply the voltage must be obtained from a safety isolating transformer.	Voltage output from Australian approved safety isolating transformer is 12Vd.c.	P
5	GENERAL CONDITIONS FOR TESTS	Noted	
6	CLASSIFICATION	Appliance is Class III operating at 12V DC	P
7	MARKING & INSTRUCTIONS		
7.1	Marking to include rated voltage, rated input, nature of supply, manufacturer's name & model number. [Part 1]	Marking: Thermacon Model 920-851 12V dc 75W Manufactured by Electrotherm Pty Ltd	P
7.12	Instructions for safe use to be provided. [Part 1]	Suitable instructions provided. Appliance not likely to be used by children.	P
7.13	Instructions required in English	Instructions are in English	P
7.14	Instructions and marking to be legible	Marking complies with Test of Marking	P
7.15	Markings placed on the part of the appliance & clearly discernable.[Part 1]	Marking is on side of appliance	P
8	PROTECTION AGAINST ACCESS TO LIVE PARTS	Appliance has no live parts exceeding Extra Low Voltage	P
9	STARTING OF MOTOR OPERATED APPLIANCES		N.A.
10	POWER INPUT & CURRENT		
10.1	For heating appliances rated above 25W to 200W, the measured power input not to deviate from marked input by ±10%	Marked input 72W Measured input @ 12.0V = 66.0W (- 8.3%)	P
11	HEATING		
11.4	Heating appliances are operated at 1.15 times rated input. The output voltage of Power Supply Unit does not change from 12V d.c. when supply voltage varied from 0.94 -1.06 times supply voltage [240V]	Test conducted at 240V	P
11.8	Temperature rise values not to exceed limits of Table 3 and protective devices shall not operate.	Temperature rise of centre of Thermacon [without saline bags] = 25K in ambient of 15°. Temperature rise of inside wall = 28K. Limit for insulation= 215K	P
12	VOID		
13	LEAKAGE CURRENT & ELECTRIC STRENGTH		
13.1	Leakage current	Not relevant	N.A.
13.2	Electric strength test	Test of insulation @ 500V dc between 12V wiring and metal enclosure OK.	P
14	TRANSIENT OVERVOLTAGES	Appliance not connected directly to mains voltage	N.A.
15	MOISTURE RESISTANCE		
15.1	Test for IP rated appliances	Appliance has no specific Degree of Protection	N.A.

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15.2	Spillage test	Appliance has no liquid container as such. Saline bags are sealed, the inner enclosure is sealed & there are no live parts that could be affected by spillage.	N.A.
15.3	Humidity test	Appliance has no live parts that could be affected by humidity.	N.A
16	LEAKAGE CURRENT & ELECTRIC STRENGTH		
16.1	Leakage current	Not relevant	N.A.
16.2	Electric strength test	Test of insulation @ 500V dc between 12V wiring and enclosure OK	P
17	OVERLOAD PROTECTION OF TRANSFORMERS & CIRCUITS	No component transformers incorporated. Power supply unit complies with its own safety standard.	N.A.
18	ENDURANCE	This clause not applicable [Part 2]	N.A.
19	ABNORMAL OPERATION		
19.1	Appliances shall be constructed so that as a result of abnormal or careless operation, the risk of fire, mechanical damage impairing safety or protection against electric shock is obviated as far as is practicable. Electronic circuits shall be designed and applied so that a fault condition will not render the appliance unsafe with regard to electric shock, fire hazard, mechanical hazard or dangerous malfunction. [Part 1]	Electronic temperature controller operates at 12V dc. With any component short circuited or open circuited, no dangerous malfunction or hazard occurs. Short circuiting of the switched mode Power Supply Unit results in shut down of the output.	P
19.4	The appliance is tested under the conditions specified in clause 11. Any control that limits the temperature during the test of clause 11 is short-circuited	Manufacturer's tests with thermostat rendered inoperative indicate a maximum temperature on insulation at base of appliance of 61° in an ambient of 15°. This equates to a temperature of 71° referred to the standard ambient of 25°. Note the 144°C thermal fuse [microtemp] located on the heating element does not operate.	P
19.11.1	Fault conditions (a) to (f) are applied to electronic circuits	Deemed to comply by inspection of construction of appliance, circuitry and overload protection device.	P
19.11.2	Fault conditions (a) to (g) are applied to electronic circuits	Deemed to comply by inspection of construction of appliance, circuitry and overload protection device	P
19.13	During the tests the appliance shall not emit flames, molten metal, or poisonous or ignitable gas in hazardous amounts and temperature rises shall not exceed the values shown in table 9. After the tests compliance with Clause 8 shall not be impaired and the appliance shall comply with 20.2 if it can still be operated.	Temperature rise does not exceed the limits of Table 9.	P
20	STABILITY & MECHANICAL HAZARDS	Appliance is portable and stable. No moving parts or mechanical hazards observed.	P
21	MECHANICAL STRENGTH	Appliance has robust metal enclosure and does not incorporate any live parts. Deemed to comply.	P
22	CONSTRUCTION		
22.3	Appliances with pins for insertion into socket outlets tested as assembled. [Part 1 annex B]	No such plug pins on appliance.	N.A.

Note: The information contained in this report is based on inspection of a sample with limited testing being performed. Full examination and testing to the relevant safety standard may reveal additional points of non-compliance. Health aspects related to the medical use of the appliance are not addressed in this report.

22.6	Appliances shall be constructed so that their electrical insulation cannot be affected by water that could condense on cold surfaces or by liquid that could leak from containers etc. After this test, inspection shall show that there is no trace of liquid on windings or insulation that could result in a reduction of creepage distances below the values specified in 29.2.	Insulation is functional insulation operating at 12V dc. In accordance with 29.2.4 these creepage distances may be reduced if the appliance complies with clause 19 with the functional insulation short-circuited. No hazard will arise if the heating element is subjected to spillage. Deemed to comply.	P
22.8	For appliances having compartments to which access can be gained without the aid of a tool and that are likely to be cleaned in normal use, the electrical connections shall be arranged so that they are not subject to pulling during cleaning	No such wiring.	P
22.21	Wood, cotton, silk, ordinary paper and similar fibrous or hygroscopic material shall not be used as insulation, unless impregnated.	No such insulation	P
22.22	Appliances shall not contain asbestos	No asbestos in appliance	P
22.26	Appliances having parts of class III construction shall be constructed so that the insulation between parts operating at safety extra-low voltage and other live parts complies with the requirements for double insulation or reinforced insulation.	No live parts in appliance	P
22.41	Appliances shall not incorporate components, other than lamps, containing mercury.	No mercury in appliance.	P
23	INTERNAL WIRING		
23.1	Wireways shall be smooth and free from sharp edges.	Complies	P
23.8	Aluminium wires shall not be used for internal wiring.	No aluminium wires used	P
23.9	Stranded conductors shall not be consolidated by lead-tin soldering where they are subjected to contact pressure, unless the clamping means is constructed so that there is no risk of bad contact due to cold flow of the solder.	No such consolidation of conductors	P
24	COMPONENTS		
24.1	Components shall comply with the safety requirements specified in the relevant IEC standard as far as they reasonably apply.	Microtemp thermal cut out is UL Listed however it is not relied upon for safety in respect of AS/NZS 60335.1.	P
25	SUPPLY CONNECTION & EXTERNAL FLEXIBLE CORDS		
25.1	Appliances shall be provided with means of connection to supply mains.	No supply mains connection. Flexible cord connects to 12V PSU via 2 pole connector.	N.A.
25.8	Conductors of supply cords to have adequate cross sectional area per Table 11	Rated input current 6.0A Conductors of ELVPSU are 18AWG (0.82 mm^2) rated at 7.5A	P
25.17	Cord anchorage to be adequate	Appliance inlet device fitted.	N.A
26	TERMINALS FOR EXTERNAL CONDUCTORS		
26.11	For appliances having type Y attachment or type Z attachment, soldered, welded, crimped or similar connections may be used for the connection of external conductors.		N.A
27	PROVISION FOR EARTHING	Appliance is Class III; no earthing required	N.A.

Note: The information contained in this report is based on inspection of a sample with limited testing being performed. Full examination and testing to the relevant safety standard may reveal additional points of non-compliance. Health aspects related to the medical use of the appliance are not addressed in this report.

28	SCREWS AND CONNECTIONS		
28.1	Fixings, electrical connections and connections providing earthing continuity shall withstand the mechanical stresses occurring in normal use. Screws used for these purposes shall not be of metal which is soft or liable to creep, such as zinc or aluminium.	Connections comply.	P
29	CLEARANCES, CREEPAGE DISTANCES AND SOLID INSULATION		
29.1	Clearances shall not be less than the values specified in Table 16, taking into account the rated impulse voltage for the overvoltage categories of Table 15.	Clearances adequate for 12V circuits	P
29.2	Appliances shall be constructed so that creepage distances are not less than those appropriate for the working voltage, taking into account the material group and the pollution degree.	Creepage distances on PCB adequate for 12V circuits	P
30	RESISTANCE TO HEAT AND FIRE		
30.1	Ball Pressure Test on insulation supporting live parts etc.	No live parts in appliance	N.A.
30.2.1	550°C Glow Wire test on non metallic parts	Test not conducted. All electrical insulation [PTFE impregnated fiberglass] & Silicon rubber insulated wiring fully within metal enclosure; deemed to comply.	P
30.2.2	750° GW test on insulation supporting parts that carry a current > 0.5A.	Test not conducted. 12V circuitry considered to be unable to cause an arcing fault. All electrical insulation [PTFE impregnated fiberglass] fully within metal enclosure. Provision of 144° thermal fuse considered to be satisfactory protection against ignition. Deemed to comply.	P
30.2.4	Needle Flame Test on PCBs unless base material is classified V-0 to IEC 60695-11-10. [Part 1]	Base material of thermostat PCB [fiberglass] is classified UL94 V-0 which is considered to be equivalent. Also located within full metal enclosure. Deemed to comply	P
31	RESISTANCE TO RUSTING	No metallic parts subject to rusting.	P
32	RADIATION, TOXICITY & SIMILAR HAZARDS	No radiation or toxic hazards.	P

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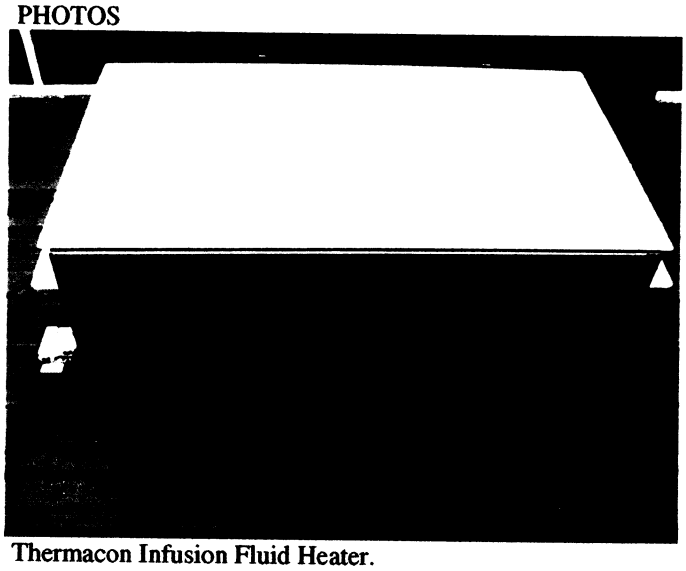
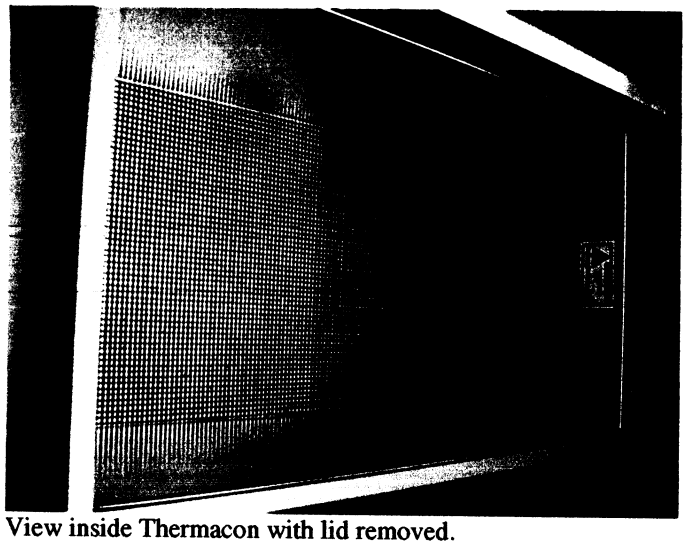
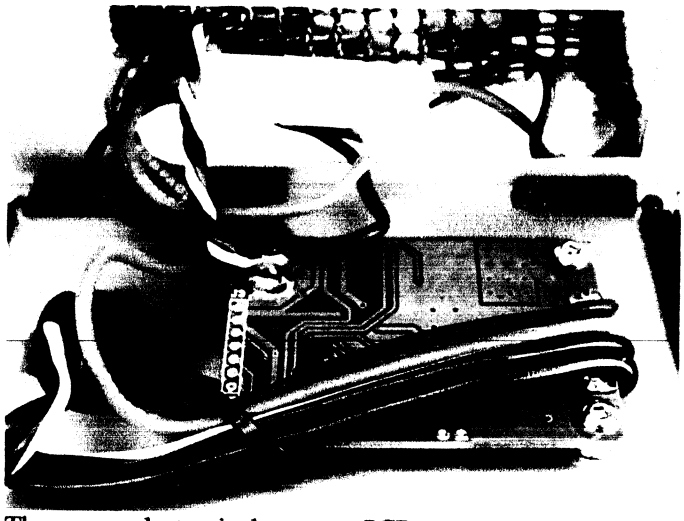
PHOTOS



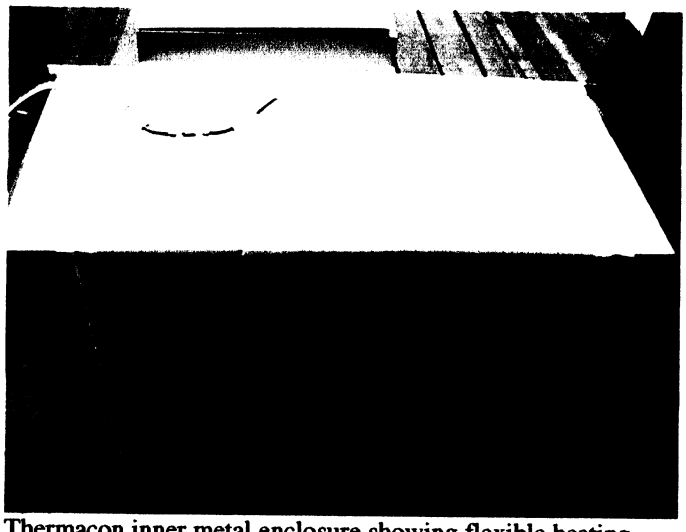
Thermacon Infusion Fluid Heater.



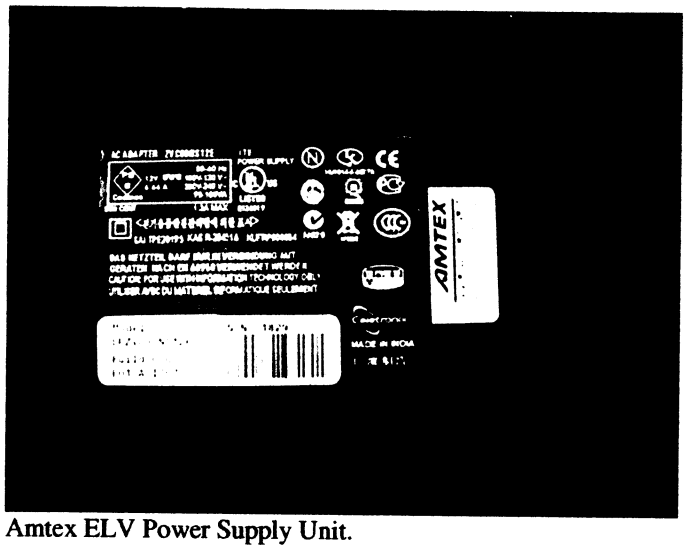
View inside Thermacon with lid removed.



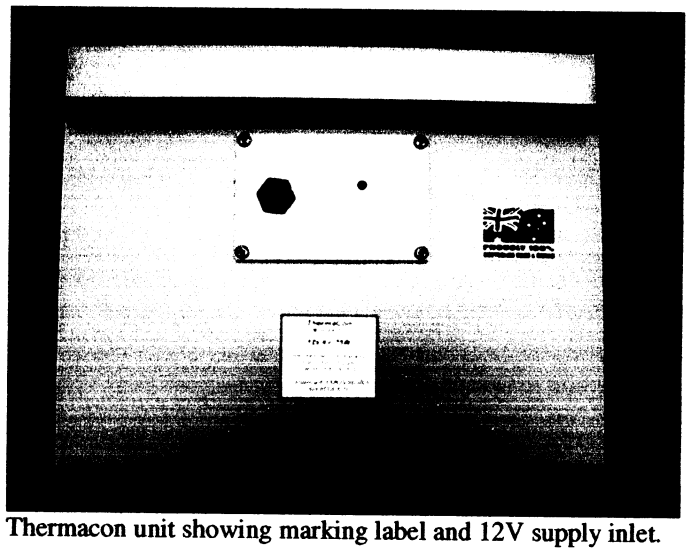
Thermacon electronic thermostat PCB.



Thermacon inner metal enclosure showing flexible heating element with thermal fuse on side of inner liner.



Amtex ELV Power Supply Unit.



Thermacon unit showing marking label and 12V supply inlet.

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ElectroTherm

'ThermaBag'

Infusion Fluid Portable Heater

Energy efficient technology!

GENERAL DESCRIPTION

The ***ThermaBag*** is a quality Australian made product manufactured from high-grade materials meeting Australian electrical safety Standards. If used according to the following instructions, it will safely and reliably meet your specific heating requirements.

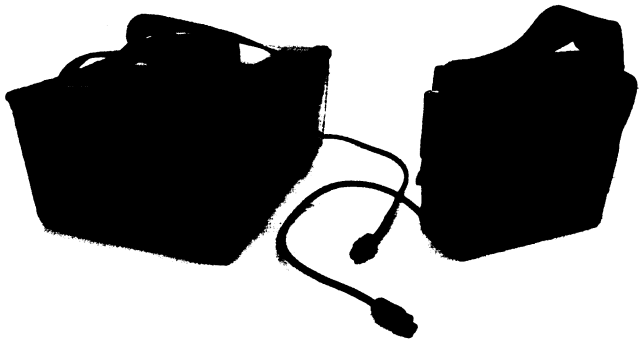
The ***ThermaBag*** is designed to provide a convenient heating/insulation system for maintaining the temperature of liquid infusion fluid transported in Ambulance vehicles.

Development of the ***ThermaBag*** is made possible by using new carbon-graphite radiant electric heating element that has unique advantages over conventional metal elements.

The electric heating element gently radiates energy into the fluid through the floor of the flexible fabric Bag. Efficient, multi-layer insulation materials inside the jacket panels minimize energy loss and form a stand-alone miniature 'warm room' suitable for heating in low ambient temperatures.

The Velcro® panels of your ***ThermaBag*** are made from heavy duty PVC coated warp knit polyester which is flexible, durable, washable and flame retardant. It is resistant to most acids, alkalis and most solvents.

Normal temperature regulation in the ***ThermaBag*** is provided by a micro-processor based digital Controller with sensor located in one end wall sensing air temperature inside the bag. Abnormal temperature limiting is provided by a thermal Cutoff located against the heating element surface and connected in series with the supply wiring.



OPERATING INSTRUCTIONS

'ThermaBag'

Date: June 2009

Before operating your ***ThermaBag, PLEASE READ THESE INSTRUCTIONS!***

GENERAL CARE

Your *ThermaBag* is constructed to give years of safe, trouble free service, but normal care in handling, operating and storage is required.

Your *ThermaBag* is designed and warranted for specific use *only* - maintaining the temperature of four 1 litre bags of saline infusion fluid while powered by a 12V sealed rechargeable battery. **DO NOT** use it for any other purpose.

DO NOT use the *ThermaBag* where liquid spillage may occur, in wet areas, or outdoors unprotected from weather!

HANDLING

Care must be taken to avoid physical damage to the *ThermaBag* that could result in rips and tears of the jacket surfaces and/or stress to the power cord or socket. Care must also be taken to keep the *ThermaBag* dry.

CAUTION

Electrical appliance - Handle with care!

TESTING

Periodically, your *ThermaBag* should be tested for electrical safety by a qualified person in accordance with AS/NZS3760:2003 'In service safety inspection and testing of electrical equipment', or an equivalent safety standard for country of operation.

OPERATING

Your *ThermaBag* is easy to use!

Load four 1 litre bags of pre-heated infusion fluid into the *ThermaBag*. Ensure the lid fits squarely to allow the Velcro® seals to engage. To maintain optimum heating performance and temperature regulation, the lid should be closed except when removing or replacing liquid bags.

Correct temperature is maintained by a sensor connected to a digital electronic temperature controller fitted to the end wall of the ThermaBag.

With a fully charged Battery, connect the Battery power cord plug into the *ThermaBag* power cord socket to commence heating.

The LED indicator in the lid of the *ThermaBag* will light constantly to indicate power 'ON'.

A flashing LED indicates a low Battery voltage condition. In this case, the Battery is electronically isolated from the ThermaBag and no heating takes place. To restore heating, replace the discharged Battery with a fully charged one as soon as possible.

Fit the ThermaBag and Battery inside the Ambulance drawer for transportation.

Your Deep-Cycle Battery is easy to recharge and maintain!

At any time, your rechargeable Battery can be connected to the 3-step plug-pack Battery Charger.

Before placing the Battery on charge, inspect the Battery for any damage or loose wires or connections. Ensure the white button of the Circuit Breaker is flush. If the white button has 'popped' up, indicating a short circuit, the Battery should not be recharged or used before the cause has been investigated.

No matter what state of discharge a serviceable Battery is in, it will be automatically recharged and held at optimum voltage ready for use whenever the Green LED indicator is 'ON'. A Red or Yellow LED means the Battery is in recharge cycle mode and should not be disconnected from the Charger until the Green LED indicates.

Whenever the Green LED is visible, the Battery is ready for use.

CLEANING

If your *ThermaBag* becomes soiled, clean the jacket with a damp cloth and mild detergent.

NEVER IMMERSE IN WATER OR HOSE DOWN! - DO NOT USE SOLVENTS!

WARNING!

The *ThermaBag* is not intended for use by persons (including children) with reduced physical, sensory or mental capabilities, or lack of experience and knowledge.

The *ThermaBag* is to be handled, installed and operated by trained personnel only.

The *ThermaBag* is to be tested by qualified personnel only.

If the supply cord is damaged, it must be replaced by Electrotherm or similarly qualified persons in order to avoid a hazard.

Operate the *ThermaBag* indoors or in-vehicle only.

Do not operate the *ThermaBag* if the inside surface or power cord is damaged.

SPECIFICATION

ThermaBag
12V d.c. 15W
Normal Temperature Regulation (by electronic Controller): 40℃ +/- 2℃
Abnormal Element Temperature Limiting (by Cutoff): 144℃ +0℃ -4℃

Battery
12V d.c. 20Ah
Circuit Breaker rating: 5A

Manufactured in accordance with AS/NZS 60335.1 and 60335.2.15

Proper care and use of your ***ThermaBag*** and ancillary equipment in accordance with these Operating Instructions is the responsibility of the purchaser. The manufacturer and its suppliers and agents do not accept responsibility for any injury, loss or damages caused through misuse of these products.

Your ***ThermaBag*** is guaranteed against defects in materials or workmanship for twelve months from date of purchase. Guarantee is limited to repair or replacement of unserviceable parts or replacement of Heater.

Manufactured in Australia by:
ELECTROTHERM PTY LTD
ABN 12 055 597 058
10 Keppler Circuit, Seaford, Victoria 3198, Australia
Tel: 61 3 9775 1575 Fax: 61 3 9775 1595
Email: sales@electrotherm.com.au

15 July 2009

W S Curry P. Eng.
Electrical Consultant
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Mr M Bell
Electrotherm Ltd
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Dear Michael

ELECTRICAL SAFETY INSPECTION REPORT: THERMABAG MODEL 920-851 INFUSION FLUID HEATER

The following is a report of an inspection carried out on a sample of the above appliance to determine if the above appliance complied with the principal safety aspects of AS/NZS 60335.2.15 : 2002 + A1, A2, A3, & A4 [Part 2] and AS/NZS 60335.1: 2002 + A1, A2, & A3 [Part 1].

This report comprises of 7 pages including 1 page of 6 photographs. It is an inspection report covering the principal safety clauses and limited testing to the above standards relevant to the Thermabag appliance. It is not purported to be a full test report to the above safety standards.

MARKINGS.

The markings of the components are as follows:

Thermabag: Model 920-851 12V dc 15W Manufactured in Australia by Electrotherm Pty Ltd. Tel. +61 3 9775 1575. Complies with AS/NZS 60335.1 and AS/NZS 60335.2.15.

Battery Charger: Amtex Type 9640 3 step charger 230V ac 50-60 Hz 0.5A, ⧈ Output 14.7V 2.7A, Standby 13.8V Made in Norway. Australian safety approval number N15923.

Battery: CSB Sealed Lead Acid Type Model EVX 12200, 12V 20 AH. Attached manual resetting over current device; Heinemann PUSH RE-CIRK-IT, 32-50V dc 5A.

DESCRIPTION:

The above electrical equipment comprises of the Thermabag, a 12V 20 Ampere Hour sealed lead acid battery and a "Plug Pack" type of 230V constant voltage battery charger. The charger is only used to maintain the charge the battery at an ambulance station and is not connected do the battery during use. The 12V battery has a 5A overload manually reset over current circuit breaker attached to the polyester webbing used as a carrying handle.

The Thermabag is a rectangular shaped flexible carrying bag made of PVC impregnated woven polyester with "Velcro" fasteners on the lid and has nylon webbing carrying handles. It is intended for use in ambulance transportation of up to four one litre infusion fluid sealed plastic bags for medical purposes. During transportation the battery is connected to the Thermabag which maintains the pre heated infusion fluid at a temperature of approximately 40°.

Note: The information contained in this report is based on inspection of a sample with limited testing being performed. Full examination and testing to the relevant safety standard may reveal additional points of non-compliance. Health aspects related to the medical use of the appliance are not addressed in this report.

A LED indicator on the top of the unit indicates operation of the heating element and flashes when the battery voltage has dropped to a level at which re-charging is required. A 12V15W flexible thin sheet heating element with a series connected 144° "Microtemp" thermal fuse attached to it is incorporated in the base of the Thermabag. A small fiberglass PCB mounted electronic thermostat is incorporated in the side of the bag adjacent to the supply cord entry. Connection to the battery is effected via a plastic "in line" two pole ELV connector. The battery charger can also be connected to the battery via the same connector when the battery is disconnected from the Thermabag. The approximate dimensions of the Thermabag are: 290mm long, 235mm wide and 130 mm high.

INSPECTION REPORT DETAILS.

The details of the compliance of the Thermabag equipment with the relevant clauses of the above safety standards are provided in the following table. All relevant safety clauses are noted as complying, assessed as being safe or not applicable in the decision column of the table.

CONCLUSION.

The Amtex battery charger is an Australian safety approved type which is protected against overload, short circuit and reversed polarity and it is designed to keep the battery fully charged without overcharging it. The construction of the appliance and the normal and abnormal operating temperatures of the electrical insulation are well within the limits specified for the materials.

Accordingly in my opinion the Thermabag Model 920-851 12V battery operated Portable Infusion Fluid Heater complies with the essential safety aspects of AS/NZS 60335.2.15 and AS/NZS 60335.1 and is a safe appliance when used in accordance with the instructions for use provided by the manufacturer.

If you have any queries about this report, please do not hesitate to contact me.

Best regards

W S Curry

William Curry

Note: The information contained in this report is based on inspection of a sample with limited testing being performed. Full examination and testing to the relevant safety standard may reveal additional points of non-compliance. Health aspects related to the medical use of the appliance are not addressed in this report.

SAFETY COMPLIANCE INSPECTION REPORT: MODEL 920 851 THERMABAG.
Assessment of compliance with AS/NZS 60335.2.15: 2002 + A1, A2, A3, & A4 [Part 2] and AS/NZS 60335.1: 2002 + A1, A2, & A3 [Part 1].

Notation applied in Decision Column: P (Pass); F (Fail); N.A. (Not applicable): A (Assessed as being safe)

CLAUSE	REQUIREMENT	REMARKS	DECISION
3	DEFINITIONS		
3.1.9	Operating conditions for battery operated appliances [Part 1 Annex B]	Appliance operated with a fully charged battery.	P
	If possible the equipment is supplied from the supply mains through the battery charger with the battery initially discharged. [Part 1 Annex B]	Appliance is not intended for connection of the battery charger during use.	N.A.
3.6.2	Part to be removed in order to discard the battery is not considered to be detachable. [Part 1 Annex B]	Battery is a separate component	N.A.
5	GENERAL CONDITIONS FOR TESTS	Noted	
6	CLASSIFICATION	Appliance is Class III operating at 12V DC	P
7	MARKING & INSTRUCTIONS		
7.1	Battery compartment for batteries intended to be replaced by the user to be marked with the battery voltage and terminal polarity. [Part 1 Annex B]	Appliance has no battery compartment & battery is not intended to be replaced by the user.	N.A.
	Marking to include rated voltage, rated input, nature of supply, manufacturer's name & model number. [Part 1]	Marking: Thermabag Model 920-851 12V dc 15W Manufactured by Electrotherm Pty Ltd	P
7.12	Instructions for safe use to be provided. [Part 1]	Suitable instructions provided for Type Y attachment & use by children. Appliance not likely to be used by children.	P
	The instructions for appliances incorporating batteries intended to be replaced by the user includes required information.[Part 1 Annex B	Appliance does not incorporate batteries & battery is not intended to be replaced by the user.	N.A.
	Details how to remove batteries containing materials hazardous to the environment given. [Part 1 Annex B]	Sealed Lead acid battery is a separate item and is marked with information regarding disposal.	N.A.
7.13	Instructions required in English	Instructions are in English	P
7.14	Instructions and marking to be legible	Marking complies with Test of Marking	P
7.15	Markings placed on the part of the appliance connected to the supply mains. [Annex B]	Appliance not connected to supply mains. Marking is on side of appliance	N.A.
8	PROTECTION AGAINST ACCESS TO LIVE PARTS	Appliance has no live parts exceeding Extra Low Voltage	P
9	STARTING OF MOTOR OPERATED APPLIANCES		N.A.
10	POWER INPUT & CURRENT		
10.1	For appliances rated up to 25W, the measured power input not to deviate from marked input by ±20%	Marked input 15W Measured input @ 12.43V = 17.77W +18.46% Note when battery voltage =12V calculated input would be 16.6W = +10.7%	P
11	HEATING		
11.7	The battery is fully charged for the test.		P
11.8	Temperature rise not to exceed values in Table 3 and protective devices not to operate.	Temperature rise of centre of Thermabag [without saline bags] = 21K in ambient of 19°. Temperature rise of centre of Thermabag base = 59K. Limit for insulation= 215K	P
12	VOID		

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13	LEAKAGE CURRENT & ELECTRIC STRENGTH		
13.1	Leakage current	Not relevant	N.A.
13.2	Electric strength test	Test of insulation @ 500V dc OK.	P
14	TRANSIENT OVERVOLTAGES	Appliance not connected to mains voltage	N.A.
15	MOISTURE RESISTANCE		
15.1	Test for IP rated appliances	Appliance has no specific Degree of Protection	N.A.
15.2	Spillage test	Appliance has no liquid container as such. Saline bags are sealed and there are no live parts that could be affected by spillage. Any spillage can drain out of the bag.	N.A.
15.3	Humidity test	Appliance has no live parts that could be affected by humidity.	N.A
16	LEAKAGE CURRENT & ELECTRIC STRENGTH		
16.1	Leakage current	Not relevant	N.A.
16.2	Electric strength test	Test of insulation @ 500V dc OK.	P
17	OVERLOAD PROTECTION OF TRANSFORMERS & CIRCUITS	No transformers incorporated.	N.A.
18	ENDURANCE	This clause not applicable [Part 2]	N.A.
19	ABNORMAL OPERATION		
19.1	Appliances shall be constructed so that as a result of abnormal or careless operation, the risk of fire, mechanical damage impairing safety or protection against electric shock is obviated as far as is practicable. Electronic circuits shall be such that a fault condition will not render the appliance unsafe with regard to electric shock, fire, or mechanical hazard or dangerous malfunction. [Part 1] Appliances subjected to 19.101,19.102 & 19.103 [Part 1 Annex B]	Electronic temperature controller operates at 12V dc. With any component short circuited or open circuited, no dangerous malfunction or hazard occurs. Short circuiting of the battery supply to the appliance results in operation of the 5A manually resetting protection device attached to the battery.	P
19.101	Appliances supplied at rated voltage for 168 hours the battery being continually charged	Not relevant. Appliance is not connected to battery charger during normal use.	N.A.
19.102	Short circuiting of battery terminals for appliances having batteries that can be removed without the aid of a tool and having terminals that can be short-circuited by a thin straight bar.	Thin straight bar cannot short circuit battery terminals.	P
19.103	Appliances having batteries that are replaceable by the user are supplied at rated voltage and operated under normal operation but with the battery removed or in any position allowed by the construction.	Not relevant	N.A.
19.4	The appliance is tested under the conditions specified in clause 11. Any control that limits the temperature during the test of clause 11 is short-circuited	Manufacturer's tests with thermostat rendered inoperative indicate a maximum temperature on insulation at base of appliance of 79° in an ambient of 44°. This equates to a temperature of 60° referred to the standard ambient of 25°. Note the 144°C thermal fuse [microtemp] located on the heating element does not operate.	P
19.11.1	Fault conditions (a) to (f) are applied to electronic circuits	Deemed to comply by inspection of construction of appliance, circuitry and overload protection device.	P
19.11.2	Fault conditions (a) to (g) are applied to electronic circuits	Deemed to comply by inspection of construction of appliance, circuitry and overload protection device	P

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19.13	During the tests the appliance shall not emit flames, molten metal, or poisonous or ignitable gas in hazardous amounts and temperature rises shall not exceed the values shown in table 9. After the tests compliance with Clause 8 shall not be impaired and the appliance shall comply with 20.2 if it can still be operated.	Temperature rise does not exceed the limits of Table 9	P
20	STABILITY & MECHANICAL HAZARDS	Appliance is portable and stable. No moving parts or mechanical hazards observed.	P
21	MECHANICAL STRENGTH	Appliance has flexible enclosure and does not incorporate any live parts. Deemed to comply.	P
22	CONSTRUCTION		
22.3	Appliances with pins for insertion into socket outlets tested as assembled. [Part 1 annex B]	No such plug pins on appliance.	N.A.
22.6	Appliances shall be constructed so that their electrical insulation cannot be affected by water that could condense on cold surfaces or by liquid that could leak from containers, hoses, couplings etc. After this test, inspection shall show that there is no trace of liquid on windings or insulation that could result in a reduction of creepage distances below the values specified in 29.2.	Insulation is functional insulation operating at 12V dc. In accordance with 29.2.4 these creepage distances may be reduced if the appliance complies with clause 19 with the functional insulation short-circuited. No hazard will arise if the heating element is subjected to spillage. Deemed to comply.	P
22.8	For appliances having compartments to which access can be gained without the aid of a tool and that are likely to be cleaned in normal use, the electrical connections shall be arranged so that they are not subject to pulling during cleaning	No such wiring.	P
22.21	Wood, cotton, silk, ordinary paper and similar fibrous or hygroscopic material shall not be used as insulation, unless impregnated.	No such insulation	P
22.22	Appliances shall not contain asbestos	No asbestos in appliance	P
22.26	Appliances having parts of class III construction shall be constructed so that the insulation between parts operating at safety extra-low voltage and other live parts complies with the requirements for double insulation or reinforced insulation.	No live parts in appliance	P
22.41	Appliances shall not incorporate components, other than lamps, containing mercury.	No mercury in appliance.	P
23	INTERNAL WIRING		
23.1	Wireways shall be smooth and free from sharp edges.		P
23.8	Aluminium wires shall not be used for internal wiring.	No aluminium wires used	P
23.9	Stranded conductors shall not be consolidated by lead-tin soldering where they are subjected to contact pressure, unless the clamping means is constructed so that there is no risk of bad contact due to cold flow of the solder.	No such consolidation of conductors	P
24	COMPONENTS		
24.1	Components shall comply with the safety requirements specified in the relevant IEC standard as far as they reasonably apply.	Microtemp thermal cut out is UL Listed however it is not relied upon for safety in respect of AS/NZS 60335.1.	P

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25	SUPPLY CONNECTION & EXTERNAL FLEXIBLE CORDS		
25.1	Appliances shall be provided with means of connection to supply mains.	No supply mains connection. Flexible cord connects to 12V battery via in line 2 pole connector.	N.A.
25.8	Conductors of supply cords to have adequate cross sectional area per Table 11	Rated input current 1.43A Supply conductors are 0.5 mm^2	P
25.17	Cord anchorage to be adequate	Mass of appliance with 4 saline bags >4 kg. 100N pull force applied as per 25.15.	P
26	TERMINALS FOR EXTERNAL CONDUCTORS		
26.11	For appliances having type Y attachment or type Z attachment, soldered, welded, crimped or similar connections may be used for the connection of external conductors.	Means of attachment of 12V supply cord considered to be Type Y. Soldered connections on PCB OK.	P
27	PROVISION FOR EARTHING	Appliance is Class III; no earthing required	N.A.
28	SCREWS AND CONNECTIONS		
28.1	Fixings, electrical connections and connections providing earthing continuity shall withstand the mechanical stresses occurring in normal use. Screws used for these purposes shall not be of metal which is soft or liable to creep, such as zinc or aluminium.	Battery terminal screws are M5 plated steel. They are not intended to be tightened during installation or by the user.	P
29	CLEARANCES, CREEPAGE DISTANCES AND SOLID INSULATION		
29.1	Clearances shall not be less than the values specified in Table 16, taking into account the rated impulse voltage for the overvoltage categories of Table 15.	Clearances adequate for 12V circuits	P
29.2	Appliances shall be constructed so that creepage distances are not less than those appropriate for the working voltage, taking into account the material group and the pollution degree.	Creepage distances on PCB adequate for 12V circuits	P
30	RESISTANCE TO HEAT AND FIRE		
30.1	Ball Pressure Test on insulation supporting live parts etc.	No live parts in appliance	N.A.
30.2.1	550°C Glow Wire test on non metallic parts	Test not conducted. PTFE impregnated fiberglass insulation deemed to comply.	A
30.2.2	750° GW test on insulation supporting parts that carry a current > 0.5A. [Part 1 Annex B] Note: No parts of appliance connected to supply mains during charging]	Test not conducted. 12V circuitry considered to be unable to cause an arcing fault. PTFE impregnated fiberglass insulation of heating element and PVC coated knitted polyester enclosure, plus provision of 144° thermal fuse considered to be satisfactory protection against ignition.	A
30.2.4	Needle Flame Test on PCBs unless base material is classified V-0 to IEC 60695-11-10. [Part 1]	Base material of thermostat PCB is Micarta Type H-22033 Grade FR-4 [glass epoxy laminate] is classified UL94 V-0 which is considered to be equivalent. Deemed to comply	P
31	RESISTANCE TO RUSTING	No metallic parts subject to rusting.	P
32	RADIATION, TOXICITY & SIMILAR HAZARDS	No radiation or toxic hazards.	P

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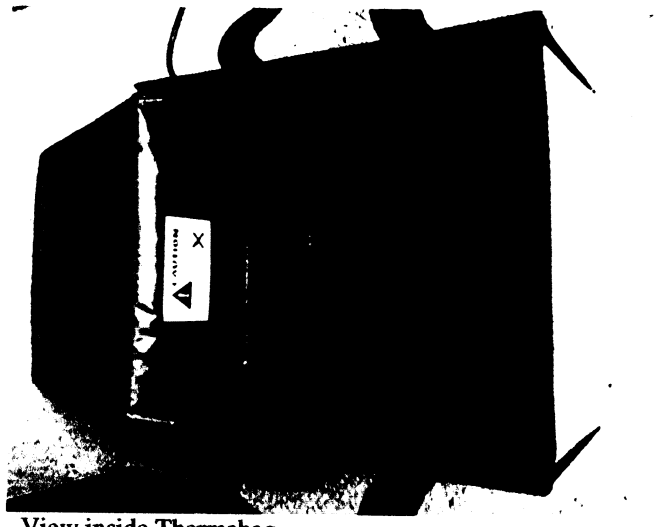
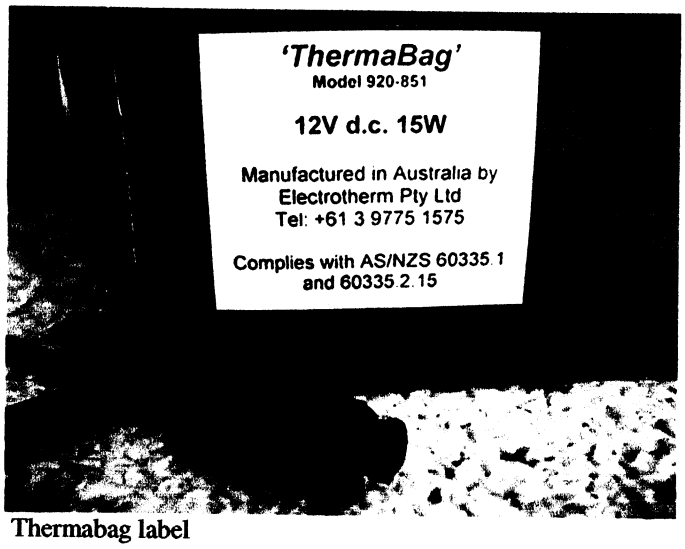
PHOTOS

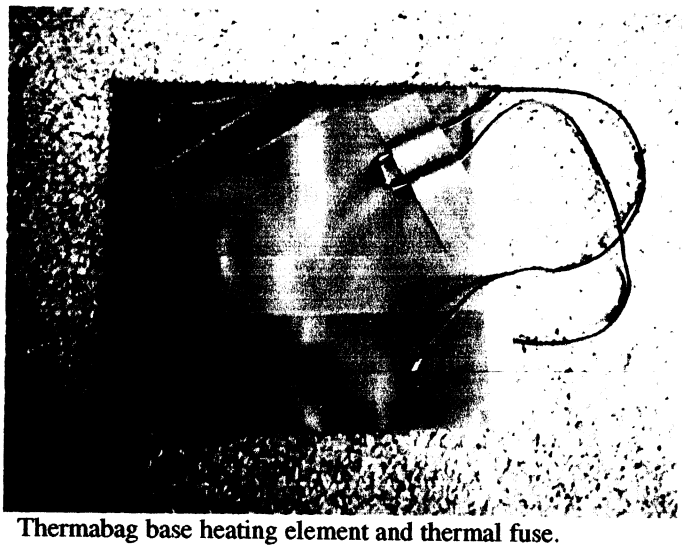
Thermabag 12V battery and charger.



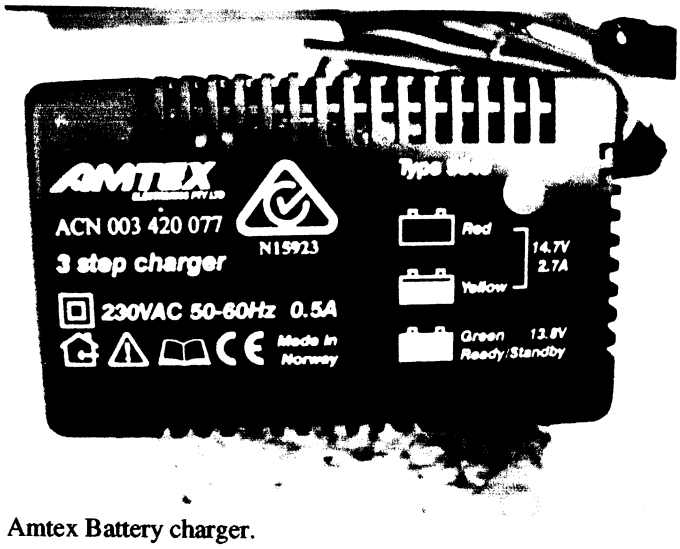
View inside Thermabag



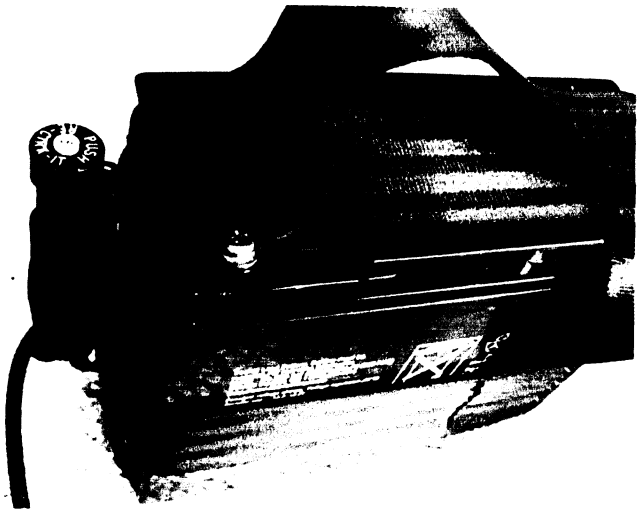
Thermabag label



Thermabag base heating element and thermal fuse.



Amtex Battery charger.



12V battery showing 5A over current circuit breaker

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FLUID WARMING SYSTEM

Updated - 20/07/2009

It has been recognised for a long time that there is an increase in morbidity and mortality in the hypothermic trauma patient. Pre-hospital care should attempt to prevent heat loss and maintain a body core temperature of 37 degrees Celsius. The administration of normothermic fluid, in conjunction with other non-invasive techniques, is to assist in the prevention of heat loss. It is not used to rewarm a hypothermic patient.

All patients, with the exception of those that benefit from active cooling and those that are hyperthermic from environmental causes, that require fluid administration in accordance to Ambulance Victoria guidelines, should receive fluid that is normal body temperature.

HYPOTHERMIA in the TRAUMA PATIENT

Hypothermia in the trauma patient is associated with an increase in morbidity and mortality.
The adverse effects of hypothermia in the trauma patient include:

(1) **Hypercoagulability.** Cold inhibits both platelet function and the enzymatic reaction of the coagulation cascade. Hypothermic patients are prone to "bleeding". DIC (Disseminated Intravascular Coagulation) may occur due to the release of tissue thromboplastins into the blood stream.

(2) **Metabolic Acidosis**. Metabolic thermogenesis occurs with an increase in Adrenaline, Noradrenaline and Thyroxine, with a subsequent rise in the basal metabolic rate and heat production. Acid is the by product, hence the acidosis.

(3) **Oxygen availability decreased.** There is a move to the left of the oxyhaemoglobin dissociation curve, increasing the affinity of haemoglobin for Oxygen and subsequently decreasing the release of Oxygen to the tissues.

(4) **Renal problems.** Impairs renal concentrating abilities and induces a "cold diuresis", leading to significant volume losses. The immobile hypothermic patient is prone to Rhabdomyolysis and acute tubular necrosis may occur due to the myoglobinuria and renal hypoperfusion.

(5) **Hyperglycaemia.** Can be caused by the Catecholamine release. If the body core temperature falls below 30 ° C Insulin secretion decreases and the cells become more resistant to Insulin.

(6) **Negative inotrope.** Hypothermia can cause cardiac depression, myocardial ischaemia and arryythmias.

(7) **Infection.** Hypothermia can promote wound infection through thermoregulatory vasoconstriction, decreased subcutaneous oxygen tension, impaired oxidative killing by neutrophils and decreased collagen deposition.

(8) **Longer in hospital.** Due to the possible complications listed above, if the trauma patients survives, their time spent in hospital is significantly increased. This adds an ongoing cost to the health system.

Research shows that between 60 – 66% of trauma patients arrive to hospital hypothermic!!

"It has been shown that survival, independent of severity of injury, depended on the core temperatures, such that at core temperatures of 34 ° C, 33 °C and 32 ° C, mortality rates were 40%, 69% and 100%, respectively.
The administration of cold intravenous fluid contributed to hypothermia". (Smith 2004)

PREVENTION OF HYPOTHERMIA

To prevent, or minimise the complications of hypothermia it is essential that emergency care providers employ the following strategies, to reduce heat loss from patients:

1. An awareness of heat lost mechanisms.
2. Minimise time spent with skin exposed
3. Minimise time spent in a cold environment.
4. Provide a warm environment (heat ambulance for the patient, not your comfort!)
5. Use a "Thermal Cocoon Blanket Wrap".
6. Put a "Beanie" on the patient.
7. Infuse fluid warmed to 40 ° Celsius, when required, according to AV Guidelines.
8. Education of Paramedics who are not aware of this concept.

It takes 1000 calories of energy, in the form of heat, to raise the temperature of 1 litre of fluid by 1° Celsius.
Therefore, if we administer one litre fluid that is 20° C (often the ambient temperature of ambulance), it will take 17,000 calories of energy for the body to heat it to 37° C. If the traumatised body is unable to do this, we are causing a drop in core temperature - exacerbating the problems associated with hypothermia.
Even if the body has the "energy" to heat the cold fluid, the by product of this energy use is lactic acid.

In April/May the average temperature of the fluid kept inside the MICA 8 vehicle was 20°Celsius. In June the average temperature was between 14 - 15° Celsius, with a temperature of 13.8°Celsius recorded numerous times. This vehicle is kept inside a garage when not in use!!

FLUID ADMINISTRATION

Normothermic fluid can be given to **all** patients that require fluid resuscitation, with the exception of those that benefit from active cooling or are hyperthermic from environmental causes. The amount of fluid given does not change, just the temperature of the fluid!

CONTRAINDICATIONS OF NORMOTHERMIC FLUID

Do **NOT** administer warm fluid to the following patients:

- Cardiac arrest
- Head injury (Trauma and Stroke) that require RSI
- Hyperthermic / heat stress patients from environmental causes.
- * Always check the patient's temperature, prior to the administration of the warm fluid
-

PRECAUTION OF NORMOTHERMIC FLUID

- Symptomatic spinal injuries

WHY ?

Cardiac arrest – Results of the RICH trial indicate these patients have better outcomes when cooled!
Head Injury – Another trial due to start in 2009, thinking that the "traumatic heads" may also do better "cold".
Hyperthermic / Heat stress from environmental causes – obviously already hot.
Spinal Injury – Current thinking is that these patients with an isolated spinal injury may also do better of cold! Requires further research.

RESEARCH

The Consultative Committee on Road Trauma Fatalities, Victoria, in 2005, recommended a trial of warmed fluid for the improved management of the hypothermic trauma patient.

There is a huge amount of literature supporting the fact that hypothermic trauma patients have a higher mortality and morbidity than patients with the same injuries and a core temperature of 37°C.
The "Triad of Death", being Hypothermia, Acidosis and Coagulopathy has been extensively researched and accepted.

Charles Smith, in an article titled "Prevention and Treatment of Hypothermia in Trauma Patients" (2004) showed that delivering 5 litres of fluid IV to an anaesthetised patient, at a flow rate of 290 ml/min, with an outlet temperature of 36 degrees C, caused a drop in mean body temperature of 0.09 degrees C. It took an outlet temperature of 39.4 degrees C with a flow rate of 150 ml/min to show an increase in mean body temperature of 0.21 degrees C.
This article also showed that "conductive heat loss occurs between the patient's circulating blood volume and intravenously administered cold fluids". When 1 litre of crystalloid fluid, at 20 degrees C, is infused into a trauma patient, it corresponds to a 17 kcal loss and a 0.29 degree fall in core temperature.
Results show that a person with a body core temperature of 37°C will decrease with the infusion of cold fluid, but will not increase with fluid that is administered at 37°C

Articles including:
- "Preventing Post-injury Hypothermia During Prolonged Prehospital Evacuation (2002) by H. Husum, T. Olsen, M. Murad, Y.V. Heng, T. Wisborg, M. Gilbert.
- "The Utility of Traditional Prehospital Interventions in Maintaining Thermostasis"(1999) by D. Watts, M. Roche, R. Tricarico, F. Poole, J. Brown, G. Colson, A. Trask, S. Fakhry.

have shown that not only is it safe to administer fluid intravenously at 40 degrees C, it is also what is required to maintain a patients temperature. Anything cooler will actually decrease a patients temperature and will require a great deal more energy production, to raise the body core temperature and acquire a state of homeostasis.

An "International Trauma Care (ITACCS) 2008 article referred to a study by Gore and Beaston in which crystalloid fluid at 54°C was administered safely to hypothermic patients. There was no evidence of intravascular hemolysis, excessive bleeding or hyperkalaemia.
Experiments on dogs have shown that when IV fluids at 65 degrees C have been infused, there has been no thermal injury or hemolysis.

The rapid infuser used in the Alfred Trauma Centre heats the fluid, to be administered intravenously, to 41 ° C.

Research references:

(1) AANC Clinical Issues
- The Trauma Triad of death: Hypothermia, Acidosis and Coagulopathy
- Coagulopathies in Trauma Patients.

(2) Clinical Research Specialist – Katheryn Moore. "Hypotherrmia in Trauma" – Pathophysiology and consequences.
(3) International Trauma Care (ITACCS). Many articles written by Dr Charles Smith related to the principles of fluid warming. I also had email correspondence with Charles. He was very supportive of our warmed fluid developments.
(4) Journal of Trauma
(5) American College of Surgeons.
(6) Annals of Surgery
(7) Society of Critical Care medicine
(8) Harvard Medical School
(9) Department of Surgery, University nof Washington.
(10) Pre-hospital Emergency Care Journal

I also had discussions with Steve Bernard, Mark Fitzgerald and Andrew Davies – Intensive Care and Trauma specialists at the Alfred Hospital, Melbourne.

SYSTEM "SET UP".

1. Normal Saline fluid to be warmed, and maintained at a constant 40 °C, in the "Thermal Box", stored in the branch store room. Runs from 240V.

2. Four one litre bags of fluid to be placed in the "Thermal Bag", located in the lower draw of the ambulance work station.

3. Attached to this "thermal Bag" is a battery, that will provide enough power to maintain the four, one litre bags of fluid, at 40° C. There IS NOT enough power to actually heat the fluid.

4. The 12V 20 Ah battery has been designed to last a 14 hour shift, hence should be changed as part of the car check, at the start of every shift. If the battery is not changed after 14 hours there is an inbuilt battery cut-out switch, to protect the battery being over discharged.

5. Administration of the warm fluid is in accordance with the normal Ambulance Service fluid resuscitation guidelines, (note the listed contraindications).

6. Fluid used from the Thermal bag will be replaced with fluid from the Thermal Box, which in turn will be replaced by fluid from the store room shelf.

7. A bag of fluid must only be warmed to 40 ° Celsius for two weeks. If it has not been used by this date, it can be stored, and used, at room temperature for a further two months. If it has not been used by this time it is to be discarded.

8. Fluid bags MUST be labelled with the date they are to be removed from the warmer and if necessary the "discard date" (3 months after removal from the warmer).

9. If you want to take the "Warming Bag" out of the ambulance, to the patient(s) it has carry handle straps, stored underneath the Bag.

10. The warming "Box" & "Bag" are to be **wiped clean** with an alcohol based cleaner. Never immerse the "Box" or "Bag" in water.

FLUID WARMING INSTRUCTIONS

Baxter, the manufacturer of Normal Saline Intravenous solutions, recommend the following:

1. For normal therapeutic use, these solutions are to be warmed to temperatures between 34 – 40 degrees C

2. Thermostatically controlled warming cabinets, and purpose designed devices, are suitable for warming these solutions.

3. Once warmed, the solution should be stored at the higher temperature until use. Successive warming and cooling cycles may accelerate the rate of degradation of components.

4. The period for warming solutions in this manner should not exceed 14 days. Solutions that have been warmed for up to 14 days can be returned to room temperature storage, and should be used within 30 – 60 days.

5. Microwave ovens must not be used for warming these products. PVC, from which IV bags are made, is a polar substance, like glucose, sodium chloride and water in the solutions they contain. Polar substances are heated by microwave radiation, and when the bag material or tubing is not in contact with the fluid, it can reach temperatures significantly exceeding that of the fluid. Consequently, melting or charring of the PVC may take place.

The recommendation that the Normal Saline solution can only be heated for a maximum of two weeks, is currently being investigated by the manufacturing company.

SPECIFICATIONS

PORTABLE SOFT "THERMAL BAG"

- Maintains temperature of 4 x 1 litre bags of fluid, at a temperature of 40°C.
- Powered by a 12 volt, 20 Ah sealed acid battery, that lasts for fourteen hours. before requiring recharging. Recommend two batteries in operation for one system. One attached to the soft bag and the other being recharged. Allows for the fluid to be kept at a constant temperature 24 hours a day, 7 days a week.
- Contains state of the art carbon-graphite heating elements.
- Outer layer made with "rip-stop" fabric.
- Sides held together with Velcro seals. Allows for easy, and thorough, cleaning.
- Polyester webbing carry straps.
- Red light on top of the lid. Constant red indicates the battery is warming. A flashing red light indicates the battery needs changing, as it is no longer discharging power. No red light indicated no battery is connected to the circuit.
- 23cm wide x 29.5cm long x 15cm high.
- Liquid Crystal Thermometer. Range 30° - 60°C.

BATTERY CHARGER

- Plug-pack 240V ac/14.1Vdc 3-step

BATTERY

- Sealed lead acid rechargeable "deep cycle" 12Vdc 20Ah
- Power cord link to portable soft bag.
- Circuit breaker
- Discharge limiting device. Cuts off the power when the battery has been used for more than 14 hours. Battery saving mechanism.
- Life of a battery is estimated to be one year of continuous use. Must be factored into ongoing costs.
- 7.5cm wide x 18cm long x 18cm high
- Weight – 6.7 kg
- External webbing with carry handle.

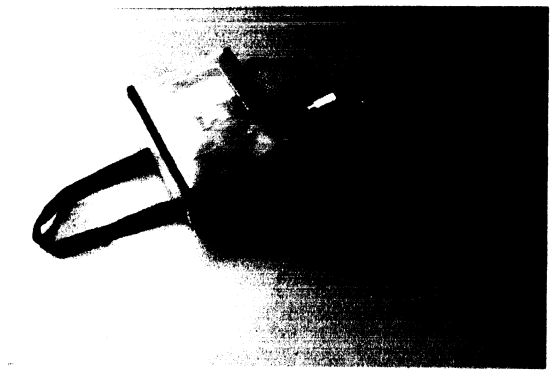
HEATING "THERMAL BOX"

- Insulated 42 litre box that heats the fluid to 40°C.
- Powered from 240 volt mains electricity.
- Power runs through a 240Vac/12Vdc 80 watt converter.
- Liquid Crystal Thermometer. Range 30° - 60°C.
- 64cm wide x 35cm long x 35cm high

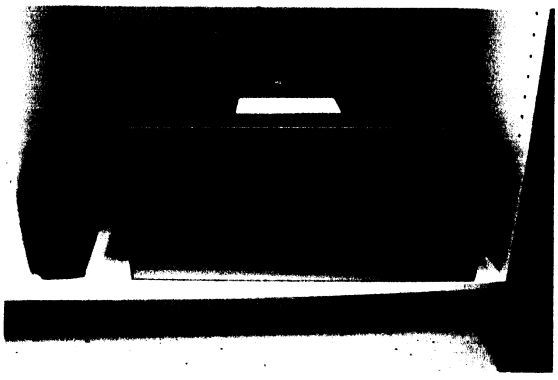
COST – will vary depending on the number ordered.

TOTAL COST = approx $3000.00 (plus postage and handling) – includes GST !!

Heat maintaining bag and 12V 20 Ah battery



Container to heat, then maintain, fluid at 40°C



WARM FLUID

Updated - 20/04/2009

The administration of warm fluid is to "prevent hypothermia". It does not actively warm the patient.

SYSTEM SUMMARY

"HOT BOX"

- "Hot Box" in store room heats fluid to 40°C.
- Fluid can be kept at a constant warm temperature for **2 weeks**. If it has not been used by this time it can be kept at room temperature for a further **2 months**. If it still has not been used, it is to be discarded.
- Fluid to be transferred from the "Hot Box" to the orange "Warm Bag", located on the ambulance. Bottom drawer of work station.

ORANGE "WARM BAG"

- Orange "Warm Bag" will maintain the temperature of the fluid at 40°C. (The battery can only maintain the temperature at 40°C if the ambient temperature is 20°C or greater.) On a cold night, if the temperature in the back of the ambulance is only 10°C, the fluid will only be 30°C!!
- The orange "Warm Bag" will not heat the fluid from room temperature.
- To clean the "Warm Bag": open it out, clean with alcohol wipe, or Virkon, DO NOT immerse in water.
- Is attached to a re-chargeable battery.
- RED LIGHT: located on top of the orange warm bag.
    - Red light on = battery & heater working.
    - Red light flashing = battery power to low, no longer heating. Change battery
    - Red light off = no battery connected.

BATTERY

- Will last 14 hours, hence needs to be changed at the start of every shift.
- If it is left on longer than the 14 hours, the orange warm bag has a battery "cut out" system, to prevent the battery being discharged too far. Preserving the life of the battery.
- The branch has two batteries. One attached to the orange warm bag, the other in the store room, being charged.
- GREEN LIGHT on battery charger indicates the battery is fully charged and ready for use. Red & orange lights indicate the battery is NOT ready for use.

Why do we want to administer warm fluid ??

Hypothermia in the trauma patient is associated with an increase in morbidity and mortality.

"It has been shown that survival, independent of severity of injury, depended on the core temperatures, such that at core temperatures of 34 ° C, 33 °C and 32 ° C, mortality rates were 40%, 69% and 100%, respectively.

The adverse effects of hypothermia in the trauma patient include:

(1) **Hypercoagulability.** Cold inhibits both platelet function and the enzymatic reaction of the coagulation cascade. Hypothermic patients are prone to "bleeding". DIC (Disseminated Intravascular Coagulation) may occur due to the release of tissue thromboplastins into the blood stream.

(2) **Metabolic Acidosis**. Metabolic thermogenesis occurs with an increase in Adrenaline, Noradrenaline and Thyroxine, with a subsequent rise in the basal metabolic rate and heat production. Acid is the by product, hence the acidosis.

(3) **Oxygen availability decreased.** There is a move to the left of the oxyhaemoglobin dissociation curve, increasing the affinity of haemoglobin for Oxygen and subsequently decreasing the release of Oxygen to the tissues.

(4) **Renal problems.** Impairs renal concentrating abilities and induces a "cold diuresis", leading to significant volume losses. The immobile hypothermic patient is prone to Rhabdomyolysis and acute tubular necrosis may occur due to the myoglobinuria and renal hypoperfusion.

(5) **Hyperglycaemia.** Can be caused by the Catecholamine release. If the body core temperature falls below 30 ° C Insulin secretion decreases and the cells become more resistant to Insulin.

It takes 1000 calories of energy, in the form of heat, to raise the temperature of 1 litre of fluid by 1° Celsius.
Therefore, if we administer one litre fluid that is 20° C (often the ambient temperature of ambulance), it will take 17,000 calories of energy for the body to heat it to 37° C. If the traumatised body is unable to do this, we are causing a drop in core temperature. Exacerbating the problems associated with hypothermia.
Even if the body has the "energy" to heat the cold fluid, the by-product of this energy use is lactic acid.

Unless there is a contraindication for its use, all patients can receive the warm fluid. They do not need to "spend energy" warming the fluid up to normal body temperature!!

CONTRAINDICATIONS OF WARM FLUID

Do **NOT** administer warm fluid to the following patients:

- Cardiac arrest
- Head injury (Trauma and Stroke) that require RSI
- Symptomatic spinal injury
- Hyperthermic / heat stress patients (environmental, septic, status epilepticus).

* Always check the patient's temperature, prior to the administration of the warm fluid

WHY ?

Cardiac arrest – Results of the RICH trial indicate these patients do better cold.
Head Injury – Another trial due to start in 2009, thinking that the "traumatic heads" may also do better "cold".
Spinal Injury – Current thinking is that these patients with an isolated spinal injury may also do better of cold! Requires further research.
Status epilepticus – potentially hyperthermic.
Hyperthermic / Heat stress – obviously already hot.
Status epilepticus – potentially hyperthermic.

PREVENTION OF HYPOTHERMIA

Pre-hospital care of the trauma patient should include the following:

1. An awareness of heat lost mechanisms.
2. Minimise time spent with skin exposed
3. Minimise time spent in a cold environment.
4. Provide a warm environment (heat ambulance for the patient, not your comfort!)
5. Use a "Thermal Blanket Wrap".
6. Put a "Beanie" on the patient.
7. Infuse fluid warmed to 40 ° Celsius, when required, according to AV Guidelines.
8. Education of Paramedics who are not aware of this concept.

LITERATURE

Relevant notes and literature can be found in the "Warm Fluid" file in the bottom drawer of the filing cabinet, in the training room.