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13. ABSTRACT (Maximum 200 Words)

A disposable blood heat exchanger was developed and tested to the requirements necessary to cool the blood at a flow rate of 500ml/min from 38 deg C to 10 deg C. This exchanger is incorporated into the Mild to Moderate Hypothermia induction device.

A prototype of a mild to moderate Hypothermia induction Device was designed, fabricated, Laboratory tested and delivered to The Safar Center for Resuscitation Research. The device will be used in the animal studies that are being performed at the Safar Center. The data from these studies will be used in future work to improve the device design and to make design changes as requested by the researchers at the Safar Center.
A second prototype for the induction of profound Hypothermia via a cold flush through the aorta was designed and is being fabricated.

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FINAL REPORT

AWARD NO: DAMD17-01-2-0051

PRINCIPAL INVESTIGATOR: Ralph Gill, BSME

INSTITUTION: Ardiem Medical, Inc.

TITLE: Devices for Emergency Hypothermia and Military Applications

Introduction:

Recent work that indicates benefits of induced hypothermia has brought about renewed interest in this technique as well as expanded studies.[1,2,3,4] Out of these studies had arisen the need for two devices for the induction of therapeutic hypothermia.

A device is desired for rapid induction of mild hypothermia under spontaneous circulation via venous or arterial shunts. The second device is for use in transport vehicles, helicopters or field hospitals; will maintain a large volume reservoir (20 liters) of fluid at approximately -5°C; for the induction of profound hypothermia. Cooling devices and blood heat exchangers that are available do not have the capacities required to rapidly induce hypothermia nor are they compact enough to be portable. This work is intended to research methodologies and develop prototypes for these devices.

Body:

1. Mild to Moderate Hypothermia Induction Device Development

1.1. Description

The mild hypothermia procedure is intended to lower the core body temperature under spontaneous circulation, (shunt blood flow with or without use of a pump)—after cardiac arrest, during surgical procedures, after traumatic brain injury, in acute stroke, after spinal cord injury, etc. with spontaneous blood flow. The induction of mild hypothermia has been shown to decrease the damage to organs specifically the brain during low blood flow. Several access techniques for inducing mild hypothermia are available depending upon the specific situation and are discussed by SCRR, the variations do not materially affect the device design or configuration.

1.2.Blood heat exchanger development

Existing heat exchangers intended for the cooling of blood are not capable of cooling to the extent required for the induction of mild hypothermia within the time frame desired. The heat exchanger is required to lower the temperature of the blood that passes through it approximately 28°C at a flow rate of 500ml/min.

1.2.1 Heat exchanger requirements

The heat exchanger secondary side must be disposable and be heparin bonded. In conjunction with the primary side of the exchanger, the heat exchanger must cool blood from 38°C to approximately 10°C, at a flow rate of 500ml/min or approximately 10% of the adult cardiac output.

1.2.2 Design of disposable Blood heat exchanger

The concept for the secondary side of the blood heat exchanger is shown in the following figure.

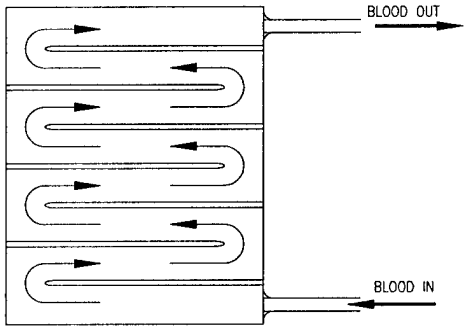


Fig 1
Secondary Heat Exchanger Concept

Calculations to determine the secondary heat exchanger dimensions:

Density	$\rho_{blood} = 1060$ kg/m^3
Specific Heat	$c_{blood} = 3.8$ kJ/kg °C
Viscosity	$\mu_{blood} = .004$ kg/m sec
Process Flow Rate	500 mL/min (blood)

- **Mass flow rate**

$\dot{m}$= (volumetric flow rate)(ρ)

$$\dot{m} = \left[\frac{0.5L}{\min}\right]\left(\frac{\min}{60\sec}\right)\left(\frac{1000cm^3}{L}\right)\left(\frac{m^3}{10^6 cm^3}\right)\left[1060\frac{kg}{m^3}\right]$$

$\dot{m} = 8.833 * 10^{-3}\ kg/\text{sec}$

- **Heat to be removed from blood**

Worst case: $T_1 = 40°C$
$T_2 = 0°C$

$\mathbf{Q} = \dot{m} c \Delta T$

$$Q = \left(8.833 * 10^{-3}\ \frac{kg}{\text{sec}}\right)\left(3800 \frac{J}{kg°C}\right)(40°C)$$

$$Q = 1342.616\ \frac{J}{\text{sec}} = 1342.616\ \text{W} \sim 1300\ \text{watts}$$

- **Type of flow**

Reynolds Number: $\mathbf{R_e} = \dfrac{\rho \bar{V} D}{\mu}$ For circular shape: D = pipe diameter

For turbulent flow: $\mathbf{R_e} > 2300$

For non-circular shapes: $D = D_h$

Hydraulic Diameter: $\mathbf{D_h} = \dfrac{4A}{P_w}$ A = cross-sectional area of duct

P_w = wetted perimeter of duct

For rectangular duct: width = b $A = bh$
height = h $P_w = 2(b+h)$

Aspect ratio: ar = h/b $D_h = \dfrac{4A}{P_w} = \dfrac{2h}{1+ar}$

Hydraulic diameter concept can be applied in the approximate range of $\frac{1}{3} < ar < 3$

$$\dot{m} = \bar{V} \rho A \qquad \bar{V} = \frac{\dot{m}}{\rho A}$$

$$\mathbf{R_e} = \frac{\rho \bar{V} D}{\mu} = \frac{(\rho)\left(\frac{\dot{m}}{\rho A}\right)\left(\frac{4A}{P_w}\right)}{\mu} = \frac{(\dot{m})(4)}{(P_w)(\mu)} \geq 2300 \text{ for turbulent flow}$$

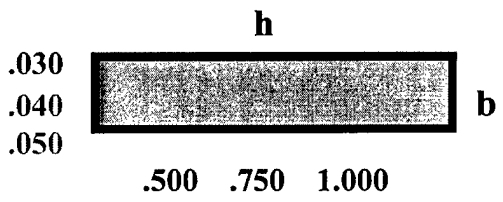
$$R_e = 2300 = \frac{\left(8.833 * 10^{-3} \frac{kg}{\sec}\right)(4)}{(P_w)\left(.004 \frac{kg}{m * \sec}\right)}$$

$P_w = .00384m = 3.84mm$

Fig 2
Typical blood flow channel cross section

R_e	P_w (m)	h (mm)	b (mm)	h (in)	b (in)	ar (h/b)
3000	.00294	.470	1.000	.0185	.0394	.4695
2500	.00353	.515	1.250	.0203	.0492	.4126
2300	.00384	.520	1.400	.0205	.0551	.3721
2000	.00442	.610	1.610	.0240	.0630	.3810
1000	.00883	1.000	3.415	.0394	.1344	.2932
500	.01767	1.250	7.585	.0492	.2986	.1648
186.97	47.244	1.270	22.352	.0500	.8800	.0568

R_e	P_w (m)	h (mm)	b (mm)	h (in)	b (in)	ar (h/b)
328.12	.02692	.762	12.700	.030	.500	.0600
222.94	.03962	.762	19.050	.030	.750	.0400
168.83	.05232	.762	25.400	.030	1.000	.0300
322.02	.02743	1.016	12.700	.040	.500	.0800
220.11	.04013	1.016	19.050	.040	.750	.0533
167.20	.05283	1.016	25.400	.040	1.000	.0400
31.14	.02794	1.270	12.700	.050	.500	.1000
217.35	.04064	1.270	19.050	.050	.750	.0667
165.60	.05334	1.270	25.400	.050	1.000	.0500



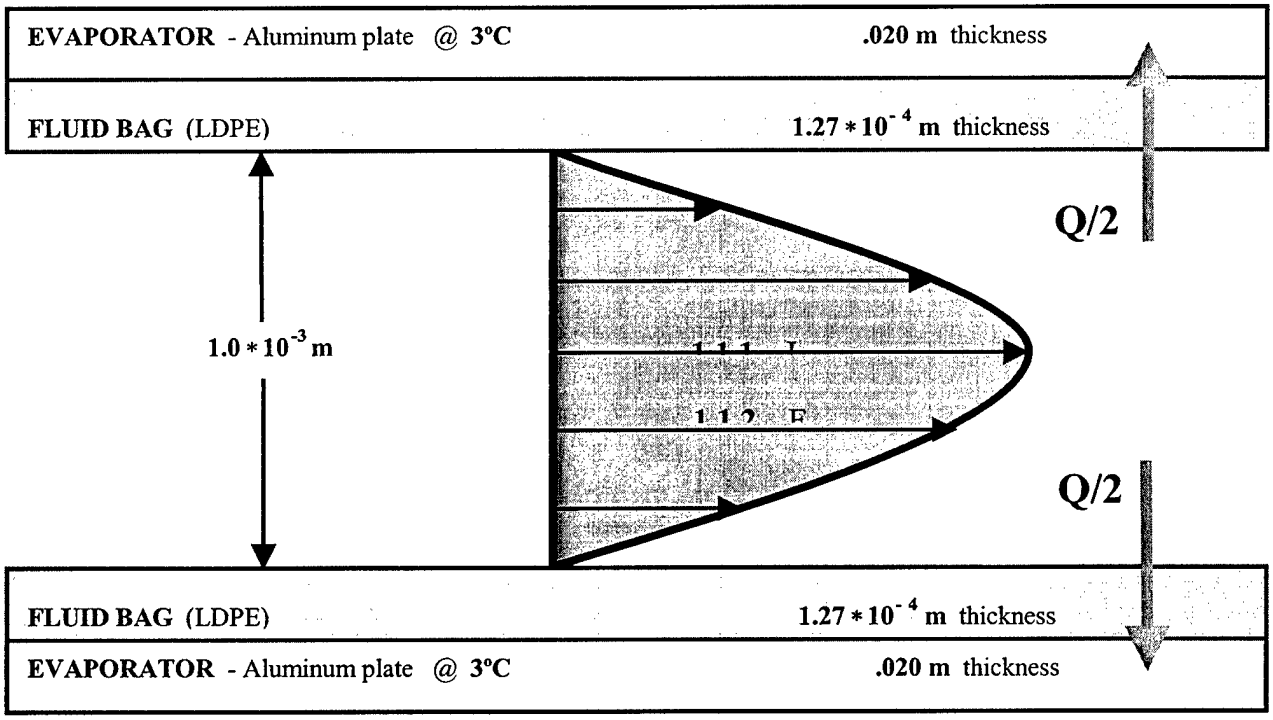
- **Heat Transfer through fluid bag to evaporator**

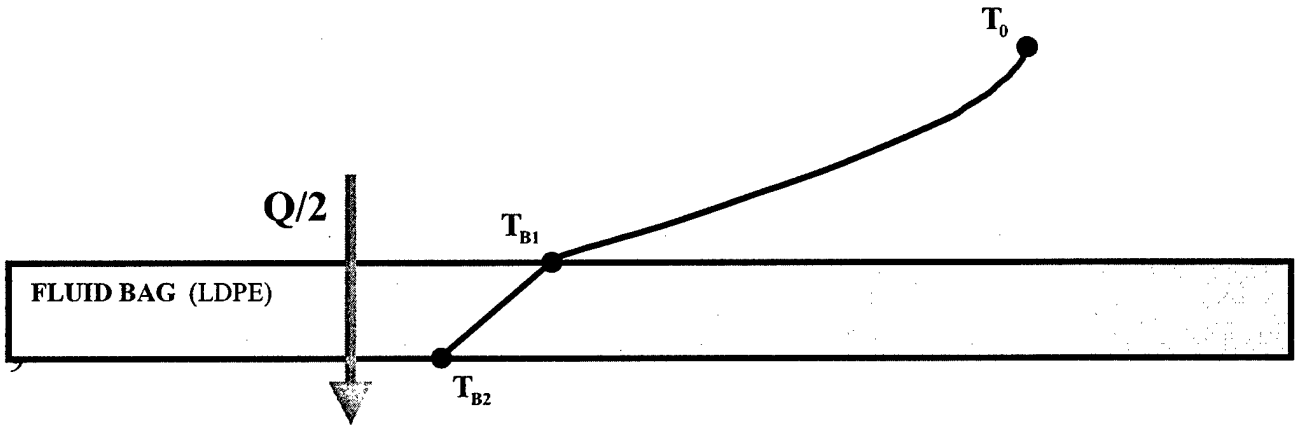
Fluid Bag (assume LDPE) thickness: $x = 1.27 * 10^{-4} m$
Thermal conductivity of LDPE: $k = .33 W/m K$

Thermal conductivity of blood: $k = .49 W/m K$

Blood Temperature (inlet): $T_0 = T_{B1} = 40°C$
(outlet): $T_{B2} = 3°C$

Total heat transfer from blood: $Q_{Blood} = 1300 W$





- **Computing hydraulic diameter**

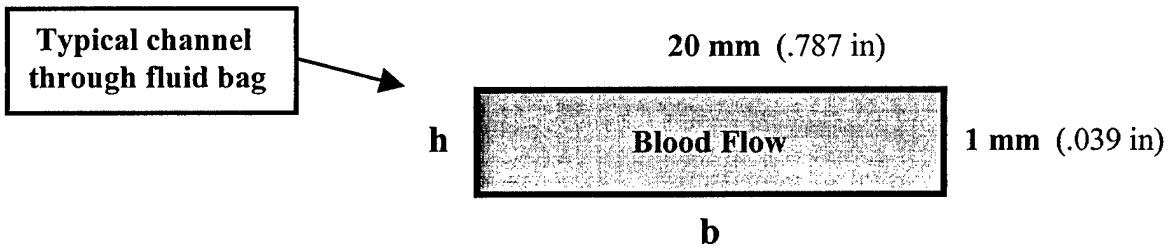


Fig 3
Typical secondary heat exchanger channel

Area

$$A = h \times b$$

$$A = (1\,\text{mm})(20\,\text{mm}) = 20 * 10^{-6}\,\text{m}^2$$

Perimeter – wetted

$$P_w = 2(h + b)$$

$$P_w = 2(20\,\text{mm} + 1\,\text{mm}) = 42 * 10^{-3}\,\text{m}$$

Hydraulic diameter

$$D_h = \frac{4A}{P_w} = \frac{(4)(20 * 10^{-6}\,\text{m}^2)}{42 * 10^{-3}\,\text{m}} = 1.905 * 10^{-3}\,\text{m}$$

- **Computing convection heat-transfer coefficient (h) for blood**

Computing Nusselt number

For heat transfer in a laminar flow tube (using hydraulic diameter)

For blood: $$Nu_d = \frac{h_{Blood} D_h}{k_{Blood}} = 4.364$$

$$Nu_d = \frac{(h_{Blood})(1.905*10^{-3}\,m)}{.49\frac{W}{m\,k}} = 4.364 \qquad h_{Blood} = \frac{(4.364)\left(.49\frac{W}{m\,K}\right)}{1.905*10^{-3}\,m}$$

$$h_{Blood} = 1.22*10^{3}\ W/m^2K$$

- **Computing area required for heat transfer**

U = overall heat-transfer coefficient

$$Q' = UA\Delta T = \frac{T_{B1} - T_{B2}}{\frac{1}{h_{Blood}A} + \frac{\Delta x}{k_{LDPE}A}} \qquad U = \frac{1}{\frac{1}{h_{Blood}} + \frac{\Delta x}{k_{LDPE}}}$$

$$U = \frac{1}{\frac{1}{h_{Blood}} + \frac{\Delta x}{k_{LDPE}}} = \left[\left(1.22*10^{3}\ W/m^2K\right)^{-1} + \left(\frac{1.27*10^{-4}\,m}{.33\ W/m\,K}\right)\right]^{-1}$$

$$U = 830.21\ W/m^2{}^{\circ}K$$

$$Q' = UA\Delta T \qquad Q' = Q/2 = \frac{1300\,W}{2} = 650\,W$$

$$A = \frac{Q'}{U\Delta T} = \frac{650W}{(830.21\ W/m^2K)(40^{\circ}C - 3^{\circ}C)}$$

$$A = 2.116*10^{-2}\,m^2$$

Assumption: 75% of bag surface area will make contact with evaporator plates

$$A' = A + 25\%A = (21.16*10^{-3}\,m^2 + 0.25(21.16*10^{-3}\,m^2))$$

$$A' = 2.645*10^{-2}\,m^2$$

Bag size required approximately: 100mm x 265mm **(3.94 in x 10.43 in)**

1.2.3 Test Results of the Heat exchanger Characterization (Appendix_E)

1.2.4 The Mild-Moderate Hypothermia Induction device prototype, while in operation, has the capability of outputting temperature data to a computer in real time. Such data was collected, processed, and plotted in order to determine the precision and accuracy of the temperature controls. The result was that temperature control is better than specification (±0.5°C) with accuracy ±0.3°C from 0°C to 60°C but ±0.2°C in the 32°C to 42°C band. The average cooling/warming rate of the heat exchanger is ~1°C/min with no load and of the outflow is ~0.5°C/min @ 500 mL/min. Cooling of the device by Cooling Means Development

1.2.5 Requirements

The capacity of the heat exchanger is (from the above heat exchanger calculations) 1300 Watts (4440 Btu/hr). T he cooling unit must allow for inefficiencies in the system and heat gain at the evaporator plates. The unit chosen is capable of pumping 6050 Btu/hr at 90°F ambient and 30°F evaporating temperature.

The temperature of the blood leaving the heat exchanger must be controlled to +/- .5°C therefore on off switching of the compressor for temperature control is not an option. The following paragraph describes the control method.

1.2.6 Design

There are three major methods of controlling the evaporator temperature, of a vapor compression refrigeration system.

(1) The first method is the switching on and off of the compressor. This method causes large swings in the evaporator temperature. The temperature swings are a result of the differential between the on and off limits.
This method also requires frequent cycling of the compressor and creates severe mechanical wear.

• An excessively high switching frequency causes excessive **motor heating**

• During the startup phase, the **oil pressure** is low; bearing lubrication is not optimal; high switching frequencies reduce the life of the respective parts

• **Oil return** in intermittent mode: More oil enters the refrigerant cycle during startup than during continuous operation; frequent switching does not provide sufficient oil return

(2) The second method is the addition of heat to the evaporator. This method is very inefficient to say the least, since we are driving the compressor at max cooling and the adding heat from another source in order to control the temperature. Not only is it inefficient but also requires additional power for the heating circuit.

(3) The third method of controlling the evaporator temperature is through modulation of the system cooling capacity. The modulation of the cooling capacity can be accomplished in several ways. The compressor operates full time with these capacity control methods.

A. Simple suction-throttle control

The simple suction control method consists of adding a throttling valve in the low-pressure (suction) line between the evaporator and the compressor. The valve throttles the gas flow depending on the evaporator temperature. This throttling increases the pressure gradient between the evaporator and the compressor. The pressure and vaporization temperature rises in the evaporator and it falls between the valve and the compressor.

Simple suction control provides for continuous throttling of the refrigeration capacity down to approximately 50% capacity. This limit is determined by the minimum refrigerant throughput that must be guaranteed for the cooling of the compressor. In the suction-throttle control method a bypass assures the minimum throughput across the suction-throttle control valve (not shown in fig 4).

The following figure is a representation of a suction control circuit.

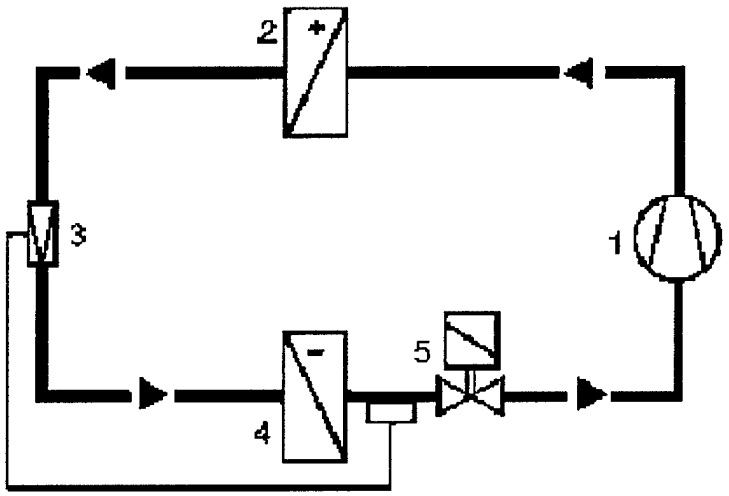


Fig 4

Simple suction control

1. compressor
2. condenser
3. expansion valve
4. evaporator
5. suction-throttle valve

B. Suction-throttle control with hot gas bypass

This method of control consists of adding hot gas bypass, in addition to the suction-control valve, compressor cooling is provided by a portion of the gas that does not pass through the evaporator. This method provides 0 to 100% capacity control. The following figure (fig 5) shows the suction-control with the addition of the gas by-pass circuit.

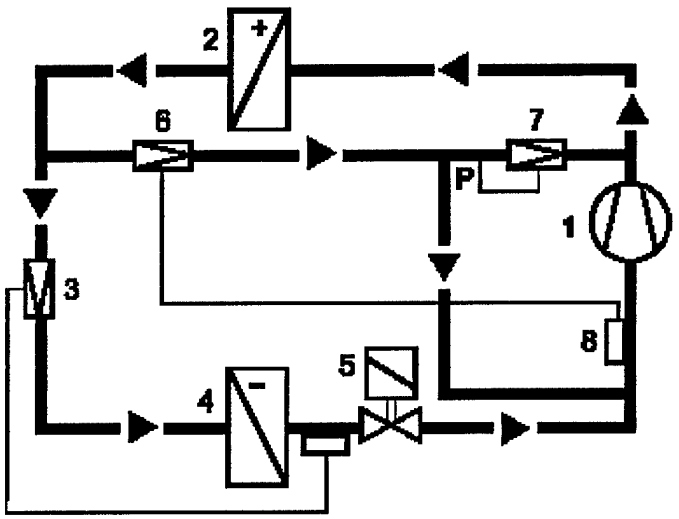


Fig. 5
Suction-throttle control with hot-gas bypass

1. compressor
2. condenser
3. expansion valve
4. evaporator
5. suction-throttle valve
6. post injection valve
7. automatic hot gas bypass valve
8. sensor

The throttling valve (5) reduces the pressure in the intake pipe below the value set on the automatic capacity control valve (7). The bypass valve opens, supplying a given quantity of hot gas to the compressor. The hot gas causes the temperature in the intake pipe to rise. In order to avoid excessive heating of the suction gas and, therefor, of the compressor, the suction gas is cooled via a post-injection valve (6). The sensor (8) acquires the temperature in the intake pipe and opens the post injection valve (6) as the suction gas temperature rises. Due to the

evaporation of the liquid refrigerant, the temperature in the intake pipe falls to the desired operating temperature.

C. Direct hot-gas bypass control

Dividing and diverting the hot gas flow can also control the refrigeration cycle. In the direct bypass method the hot gas is diverted from the discharge to the intake side of the compressor. A modulating valve (fig 3, no. 5) in the bypass pipe varies the amount of gas flowing through the evaporator. The smaller volume reduces the refrigeration capacity because the increased vaporization temperature causes a rising pressure in the evaporator. Figure 6 depicts schematically the direct hot-gas bypass control circuit.

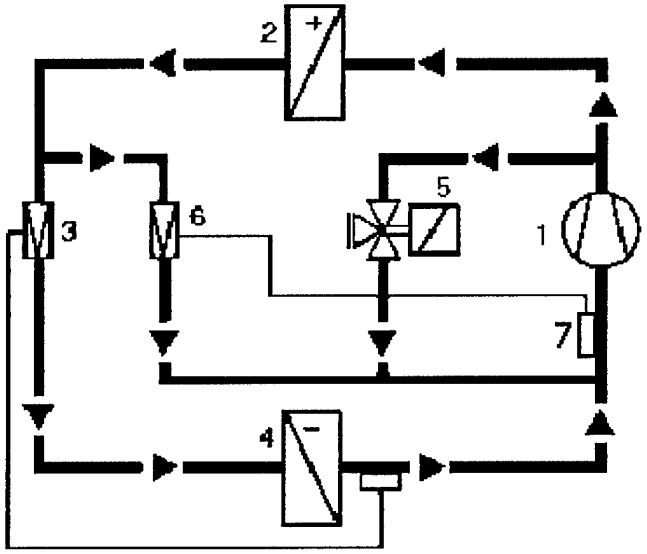


Fig. 6
Direct hot-gas bypass

1. compressor
2. condenser
3. expansion valve
4. evaporator
5. bypass control valve
6. post injection valve
7. sensor

If full cooling capacity is required, the hot gas-bypass control valve (5) and the automatic, thermostatic post injection valve (6) are closed. The operation of the bypass valve and the post injection is similar to that described in the suction-control with hot-gas bypass above.

D. Indirect hot-gas bypass control

This control method uses a controllable bypass from the high-pressure side with the injection occurring between the expansion valve and the evaporator. In the high demand mode the bypass remains closed and the system supplies its full output. If the demand falls, the controller continuously opens the hot-gas bypass valve. Hot-gas now flows through the bypass to the evaporator inlet where it mixes with the liquid refrigerant and is cooled. As the liquid evaporates the vaporization temperature rises thus lowering the system output. This concept is depicted in figure 7.

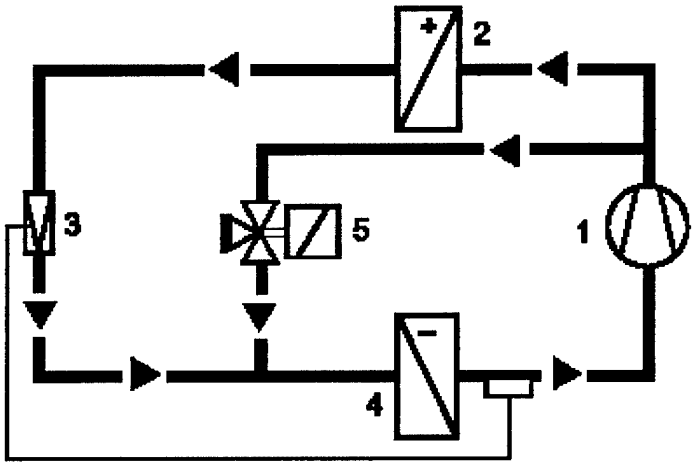


Fig. 7
Indirect hot-gas bypass control

1. compressor
2. condenser
3. expansion valve
4. evaporator
5. bypass control valve

To use this method the expansion valve must be capable of controlling the refrigerant supply between 100% and the minimum load.
Based on the discussion above the indirect hot-gas bypass method was chosen for the control of the mild to moderate system.
The hot-gas bypass valve (5) is stepper motor actuated, the control is a closed loop that uses temperature as the feed back.
The system control circuitry is discussed further in the following paragraph.

1.2.7 Electronic design and controls (APPENDIX_K)

The electronics consist of three PCBs (Main, Display, and Temp Connector) and four subassemblies (User Input, Indicators, Pump Motor, and Compressor/Valve.
The electronics are used to input operator selections, drive indicators and display, monitor temperatures, and control temperature and flow rate. A block diagram of the Hypothermia Main board is shown in Fig.1. It consist of eight basic sections:

1. Power section: An external 12 VDC switching power supply is used to power up the electronics and electromechanical components. An on board switching voltage regulator converts the input dc voltage to 5 V with 80% efficiency and a linear voltage regulator regulates the 5 V down to 3.3 V. The 3.3 V is used for biasing the embedded microcontroller module, which is mounted on board. The 5 V biases all other circuits.
2. The Controller Connectors section: This section provides means for mounting and connecting the embedded microcontroller (Rabbit RCM3400) to the main board. It also includes a serial RS232 port, and a programming port.
3. User Inputs section: This includes inputs from two front panel rotary switches, one for setting temperature and one for setting flow, a toggle switch for selecting displaying body temperature 1 or body temperature 2, and two push-button switches for setting body temperature (one switch to increase the other to decrease).
4. User Outputs section: The Display interfaces are included here. Provision is made to enable serial or parallel interfacing of LEDs or parallel interfacing of LCD. Also included are drivers for seven indicator LEDs for POWER ON, FLOW OK (within set-point), TEMPERATURE OK (within set-point), SYSTEM OK (self diagnostics return no problems), and the three operational states MODE 1, MODE 2, MODE 3.
5. Patient Temperature Read section: In this section two body temperatures plus inflow and outflow temperatures are sensed via thermistors connected to isolated circuits, then multiplexed and converted to digital and outputted in serial sequential format by a 12-bit A/D.
6. Heat Exchanger Temperature Read section: This section provides thermistor interfaces for the heat exchanger and ambient temperatures by a 12-bit A/D.
7. Temperature Control section: Two power drivers are included one for a vapor compressor and one for a valve. Provisions for monitoring current draw are included.
8. Flow Control section: A power driver for a pump motor is included plus electronics for driving an optocoupler used as a tachometer to enable motor speed readout and feedback.

1.3.System test results (Appendix_E)

The testing setup consisted of a large (30 liter) lab container filled with water at an initial temperature of approximately 37 °C. The water was pumped through the heat exchanger at a rate of 500 mL/min and the temperature into and out of the heat exchanger was monitored and recorded. The temperature set point was varied step wise to determine the time response and the temperature accuracy leaving the heat exchanger. Further details and plotted graphs can be found in Appendix E.

2. Profound Hypothermia Induction Device

2.1. Description

Profound hypothermia is intended for use primarily in cases of trauma-induced exsanguination cardiac arrest. In these cases, which are considered unresuscitable by

standard methods, the profound hypothermia (suspended animation), with or without drugs, is intended to preserve the organs for delayed resuscitation, organ repair, or organ harvesting.
The induction of profound hypothermia is accomplished by a rapid one way flush with a large volume of cold fluid via the thoracic aorta toward the heart and brain, with drainage from the right atrium.

2.2.Device requirements (Appendix_J)

a) Maintain a large volume (20 liters) of pre-cooled sterile fluid at a temperature of -10°C to 4°C. (isotonic saline solution is presently used, other fluids to be researched and or developed by SCCR or others)

b) Deliver the fluid by means of a pump @1-2 liters/min via a disposable, sterile tubing set and a catheter with a bore diameter of 3mm. (the delivery catheter is not part of the device, the tubing and connecting means are part of a disposable set and will be included as part of the device)

c) Device is for use in the hospital trauma emergency room setting and the power requirements are to be consistent with that available in the hospital.

2.2.1 Heat pumping capacity required for maintaining 20 liters of pre-cooled fluid at -5°C
The cold box portion of the device consists of an inner and outer shell separated by 2 inches of polyurethane foam. The total heat gain and thus the heat that is required to be pumped from the cold box is calculated to be 20 W. Based upon this value the Danfoss BD compressor was chosen for the prototype it will give us a 2:1 safety factor. (Appendix F)

Key Research Accomplishments:

- Designed and tested a disposable blood cooling heat exchanger for cooling blood in an extra-corporeal circuit.
- Designed, constructed, and tested a Mild-Moderate Hypothermia Induction device prototype to the specification requirements that were established in the previous phase. The device was delivered to Safar Center for Resuscitation Research in Pittsburgh, PA in August to be used for tests in animals.
- Tested the temperature control of the device.
- Designed and presently constructing a prototype of the Profound Hypothermia Induction device.
- Developed a spreadsheet for simulating the hypothermia induction process to enable quick calculation of the cooling power and procedure time based on desired flow rate, fluid temperature, body weight, and hypothermic body temperature.
- Estimated realistic power requirements for Mild-Moderate and Profound Hypothermia Induction devices that utilize existing and established cooling technologies. (Appendix C)

- Researched commercially available battery, fuel cell, and supercapacitor technologies for possible deployment in a portable field-use device. (Appendix D)
- Researched maximum weight and size limitations of a portable field-use device by the military. (Appendix B)
- Estimated minimum weight and size attainable of a portable filed-use device that utilizes existing and established cooling technologies.

Reportable Outcomes:

See the body of this report.

There were no publications, patents or licenses, etc. applied for or issued in connection with this work.

Conclusions:

The conclusions that resulted from this work are that the fabrication of a mild-moderate and profound hypothermia induction devices that use existing and proven technology is feasible. However, the devices are larger and heavier than desired. After acquiring feed back data from the lab use of the devices by the Safar Center the devices will require refinement including size and weight reduction.

Personnel

Personnel Participating and Receiving Pay From This Research Effort

Alsippi, Richard	Jr. Engineer
Cupp, James	Research Engineer
Felton, Dave	Mgr. Test Engineering
Garland, Brian	Machine Shop Supervisor
Gill, Ralph	Mgr. Mechanical Engineering
Grata, Jeremy	Mgr. Research
Gresko, Brian	Mechanical Engineer
McMurry, Dave	President
Myers, Larry	Jr. Electronics Engineer
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References:

[1]Plattner O, et al. Efficacy of intra-operative cooling methods. Anesthesiology 1997; 87:1089-95.

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APPENDICES

Appendix A: Hypothermia Induction Engineering Considerations
Appendix B: Military Load Limits for Individual Soldiers
Appendix C: Hypothermia Induction Devices Electrical Power Requirements
Appendix D: Energy Storage Devices for Possible Use in Portable Hypothermia Device
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Appendix F: Profound Hypothermia Device Cold Box Calculations
Appendix G: Profound Hypothermia Induction Prototype Device Weight Analysis
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APPENDIX A
TECHNICAL REPORT

Technical Report x.dot, Rev. A, Effective 01-06-03

RECORD NO.

AM-00001

TITLE OF TECHNICAL REPORT		REVISION
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ASSOCIATED REPORTS

Review_Hypothermia Project.doc

Abstract

Thermodynamic equations for hypothermia induction are derived and are solved for mild and profound case. Results are tabulated and plotted for various parameters.

For mild hypothermia induction, the procedure time decreases with increasing flow rate and increases with body weight. Procedure time also increases as the desired hypothermic body temperature decreases and decreases as the fluid temperature becomes colder. The cooling system thermal power requirements and by extension the electrical power requirements increase with increasing flow rate but is independent of body temperature.

For profound hypothermia induction, the procedure time again decreases with increasing flow rate and body weight. The procedure time heavily depends on the temperature of the pre-chilled fluid and the degree the body will be chilled. A large volume of fluid is required that increases dramatically with body weight and fluid temperature but is independent of flow rate.

APPENDIX A

Background

The objective of the hypothermia project is to develop devices for enabling two different states of hypothermia:

- **A)** Mild to Moderate Hypothermia where the body core temperature is dropped to 30 - 34°C and maintain that temperature for at least 30 minutes.
- **B)** Profound hypothermia where the core body temperature is dropped to the range of 10 - 20°C.

Introduction

The mild hypothermia procedure is intended to lower the core body temperature under spontaneous circulation, (shunt blood flow with or without use of a pump) after cardiac arrest, during surgical procedures, after traumatic brain injury, in acute stroke, after spinal cord injury, etc. with spontaneous blood flow.

Profound hypothermia is intended for use primarily in cases of trauma-induced exsanguinations cardiac arrest. In these cases, which are considered unresuscitable by standard methods, the profound hypothermia (suspended animation), with or without drugs, is intended to preserve the organs for delayed resuscitation, organ repair, or organ harvesting.
The induction of profound hypothermia is accomplished by a rapid one way flush with a large volume of cold fluid via the thoracic aorta toward the heart and brain, with drainage from the right atrium.

Purpose

This work was done in order to provide insight, answer questions, and facilitate engineering decisions designing the hypothermia induction system. The calculations in this work were done using an EXCEL spreadsheet (Calc_Hth.xls).

Description of Apparatus and Setup

General Hypothermia Induction Relationships[1]

We assume that during procedure the atmospheric pressure and ambient temperature remain unchanged.

On the patient's body side, the heat contained for a mass m_b at the beginning of the procedure at time t_i is equal to

$$Q_{bi} = c_b m_b T_{bi}$$

Where c_b is the specific heat of the human body and T_{bi} is the normal body temperature at t_i. At the end of the procedure at time t_f, the heat contained in the body will be equal to

$$Q_{bf} = c_b m_b T_{bf}$$

Where T_{bf} is the hypothermic body temperature at t_f. The body metabolism, during the procedure will produce heat at a rate P_m, therefore the total heat produced that we need to remove from the body will be equal to

$$Q_{bt} = Q_{bi} - Q_{bf} + P_m (t_f - t_i) \text{ or}$$

$$Q_{bt} = c_b m_b \Delta T_b + P_m \Delta t_p \qquad 1.$$

Where $\Delta T_b = T_{bi} - T_{bf}$ and $\Delta t_p = t_f - t_i$ is the procedure time.

The metabolic rate P_m varies from individual to individual, varies with food intake, varies with level of activity, and varies with time. A constant rate is assumed considering that the patient is resting during the procedure and thus his/her metabolic rate should not change much during the short time of the procedure. However minimum and maximum rates should be considered to account for patient size and age.

On the chiller side, the same equations apply. Therefore

$$Q_{fi} = c_f m_f T_{fi} \text{ and } Q_{ff} = c_f m_f T_{ff} \text{ and } Q_{ft} = c_f m_f T_{fi} - c_f m_f T_{ff} \text{ and}$$

$$Q_{ft} = c_f m_f \Delta T_f \qquad 2.$$

Where c_f is the specific heat of the fluid, m_f is the mass of the fluid that needs to be pumped during the procedure, and T_{fi} and T_{ff} are the initial and final circulating fluid temperatures respectively.

The mass of the fluid is related to its density ρ_f and its volume V_f as follows

$$m_f = k \rho_f V_f. \qquad 3.$$

Where k is a conversion constant $k = 10^{-3}$ m^3/l

The pumped volume of fluid is related to flow rate of the pump and procedure time as follows

$$V_f = R_f \Delta t_p. \qquad 4.$$

Hence by substitution, we relate mass to flow rate and procedure time as follows

$$m_f = k \rho_f R_f \Delta t_p. \qquad 5.$$

Substituting in Eq. 2, we obtain the total heat pumped during the procedure time. Procedure time is the time it takes to reduce body temperature to T_{bf} only and not the time that it maintains it at this temperature.

$$Q_{ft} = c_f\, k\, \rho_f\, R_f\, \Delta T_f\, \Delta t_p \qquad 6.$$

Equating the total heat produced by the body Q_{bt} (Eq.1) and total heat pumped Q_{ft} (Eq. 6) and then solving for procedure time Δt_p we get

$$\Delta t_p = (c_b\, m_b\, \Delta T_b) / (c_f\, k\, \rho_f\, R_f\, \Delta T_f - P_m) \qquad 7.$$

Eq. 7 shows that the procedure time, for a given flow rate, depends on the body mass, the initial and desired final body temperature, the initial and final fluid temperature, and the metabolic rate.

Eq. 7 can be solved for flow rate as a function of procedure time. Therefore

$$R_f = (c_b\, m_b\, \Delta T_b + P_m\, \Delta t_p) / (c_f\, k\, \rho_f\, R_f\, \Delta T_f\, \Delta t_p) \qquad 8.$$

Eq. 7 can also be solved for ΔT_b to show the reduction of body temperature versus procedure time as follows

$$\Delta T_b = (c_f\, k\, \rho_f\, R_f\, \Delta T_f - P_m)\, \Delta t_p / (c_b\, m_b) \qquad 9.$$

Eq. 7 can also be solved for T_{ff} to show how this parameter, which coincides with the chiller outflow temperature set point, is related to desired flow rate and procedure time as follows

$$T_{ff} = T_{fi} - (c_b\, m_b\, \Delta T_b + P_m\, \Delta t_p) / (c_f\, k\, \rho_f\, R_f\, \Delta t_p\, R_f) \qquad 10.$$

The required thermal power of the cooling unit $P_c = Q_{tf}/\Delta t_p$ can be determined from Eq. 6 as follows

$$P_c = c_f\, k\, \rho_f\, R_f\, \Delta T_f \qquad 11.$$

The time Δt_f that will take the chiller to cool volume V_f of saline from t_{if} to t_{ff} is given by Q_f/P_c. Therefore by substituting Eq. 3 into Eq. 2 and dividing by the chiller thermal power P_c, we get

$$\Delta t_f = c_f\, k\, \rho_f\, V_f\, \Delta T_f / P_c \qquad 12.$$

Defining $Q_f = c_b\, m_b\, \Delta T_b$ we can write Eq. 7 simply as $\Delta t_p = Q_f / (P_c - P_m)$

Typical values for pertinent specific heat and density are shown in the table of Fig. 1.

	Specific heat (kJ/kg-K)	Density (kg/m3)
Body	2.946	1257
Blood	3.894	1060
Heart-Brain	3.732	1047
Saline 8% NaCl	4.195	1055
Saline 12% NaCl	4.195	1079
Saline 16% NaCl	4.195	1137

FIGURE 1. SPECIFIC HEAT AND DENSITY DATA[2].

Notes:
The body specific heat and density depend on body fat percentage[2]. An average value is used here.
The blood specific heat and density depend on hematocrit[3]. An average value is used here.
Adult cardiac output is about 5 l/min and blood volume is 7 - 9% of body weight (4 - 6 l).

References:
1. Review_Hypothermia Project.doc
2. http://www-ibt.etec.uni-karlsruhe.de/people/mag/frames/papers/EMC99-MD/node3.html
3. http://engr.smu.edu/~cd/EE5340/lect21/sld010.htm

Summary of Data and Results

Mild Hypothermia Induction Calculations

In the Mild Hypothermia induction case, the fluid (patient's blood) is cooled to T_{if} (6 – 12°C) and is circulated at a flow rate of 0.1 to 0.5 l/m in order to reduce and maintain the body temperature to T_{bf} (10 – 20°C). The initial fluid temperature can be safely assumed equal to the initial body temperature. Therefore $T_{fi} = T_{bi}$.

APPENDIX A

For the calculations, a metabolic heat rate at rest of 6.3 kJ/min for an 80 kg and 10% lower of this value for a 40 kg, and 10% higher of this value for a 120 kg body weight were used. The initial body temperature is assumed 37°C. Based on these assumptions and using Eq. 7 and 11 and the data shown in the table of Fig. 1, the data shown in the tables of Fig. 2 to Fig. 7 was calculated for procedure time in minutes and cooling power in watts versus flow rate for a 40 kg, 80 kg, and 120 kg body weights and for various settings of final body temperature and final fluid temperature.

Rf (l/min)	40 kg	80 kg	120 kg	Pc (W)
0.1	43.9	95.3	156.2	229
0.2	16.2	33.4	51.7	457
0.3	10.0	20.3	31.0	686
0.4	7.2	14.6	22.1	915
0.5	5.6	11.3	17.2	1143
0.6	4.6	9.3	14.1	1372
0.7	3.9	7.9	11.9	1601
0.8	3.4	6.8	10.3	1829
0.9	3.0	6.0	9.1	2058
1	2.7	5.4	8.1	2287

FIGURE 2, COOLING POWER AND PROCEDURE TIME IN MINUTES FOR A 40 KG, A 80 KG, AND A 120 KG PERSON (T_{BF} = 34°C AND T_{FF} = 6°C).

Rf (l/min)	40 kg	80 kg	120 kg	Pc (W)
0.1	49.3	108.2	179.6	214
0.2	17.7	36.5	56.6	428
0.3	10.8	22.0	33.6	642
0.4	7.7	15.7	23.9	856
0.5	6.0	12.2	18.5	1070
0.6	5.0	10.0	15.1	1283
0.7	4.2	8.5	12.8	1497
0.8	3.6	7.3	11.1	1711
0.9	3.2	6.5	9.8	1925
1	2.9	5.8	8.7	2139

FIGURE 3, COOLING POWER AND PROCEDURE TIME IN MINUTES FOR A 40 KG, A 80 KG, AND A 120 KG PERSON (T_{BF} = 34°C AND T_{FF} = 8°C).

Rf (l/min)	40 kg	80 kg	120 kg	Pc (W)
0.1	56.3	125.2	211.3	199
0.2	19.4	40.2	62.5	398
0.3	11.7	23.9	36.7	597
0.4	8.4	17.0	26.0	797
0.5	6.5	13.2	20.1	996
0.6	5.4	10.8	16.4	1195
0.7	4.5	9.1	13.8	1394
0.8	3.9	7.9	12.0	1593
0.9	3.5	7.0	10.5	1792
1	3.1	6.2	9.4	1992

FIGURE 4, COOLING POWER AND PROCEDURE TIME IN MINUTES FOR A 40 KG, A 80 KG, AND A 120 KG PERSON (T_{BF} = 34°C AND T_{FF} = 10°C).

Rf (l/min)	40 kg	80 kg	120 kg	Pc (W)
0.1	29.3	63.5	104.1	229
0.2	10.8	22.3	34.5	457
0.3	6.6	13.5	20.7	686
0.4	4.8	9.7	14.7	915
0.5	3.7	7.6	11.5	1143
0.6	3.1	6.2	9.4	1372
0.7	2.6	5.3	7.9	1601
0.8	2.3	4.6	6.9	1829
0.9	2.0	4.0	6.1	2058
1	1.8	3.6	5.4	2287

FIGURE 5, COOLING POWER AND PROCEDURE TIME IN MINUTES FOR A 40 KG, A 80 KG, AND A 120 KG PERSON (T_{BF} = 35°C AND T_{FF} = 6°C).

APPENDIX A

Rf (l/min)	40 kg	80 kg	120 kg	Pc (W)
0.1	32.9	72.1	119.7	214
0.2	11.8	24.3	37.7	428
0.3	7.2	14.6	22.4	642
0.4	5.2	10.5	15.9	856
0.5	4.0	8.1	12.4	1070
0.6	3.3	6.7	10.1	1283
0.7	2.8	5.6	8.5	1497
0.8	2.4	4.9	7.4	1711
0.9	2.1	4.3	6.5	1925
1	1.9	3.9	5.8	2139

FIGURE 6, COOLING POWER AND PROCEDURE TIME IN MINUTES FOR A 40 KG, A 80 KG, AND A 120 KG PERSON (T_{BF} = 35°C AND T_{FF} = 8°C).

Rf (l/min)	40 kg	80 kg	120 kg	Pc (W)
0.1	37.5	83.4	140.9	199
0.2	12.9	26.8	41.7	398
0.3	7.8	16.0	24.4	597
0.4	5.6	11.4	17.3	797
0.5	4.4	8.8	13.4	996
0.6	3.6	7.2	10.9	1195
0.7	3.0	6.1	9.2	1394
0.8	2.6	5.3	8.0	1593
0.9	2.3	4.7	7.0	1792
1	2.1	4.2	6.3	1992

FIGURE 7, COOLING POWER AND PROCEDURE TIME IN MINUTES FOR A 40 KG, A 80 KG, AND A 120 KG PERSON (T_{BF} = 35°C AND T_{FF} = 10°C).

Using time data from the tables shown in Fig. 2, Fig. 3, and Fig. 4 at 0.5 l/min only we form the table shown in Fig. 8 and plot it in Fig. 9.

m (kg)	6 °C	8 °C	10 °C
40	5.6	6	6.5
80	11.3	12.2	13.2
120	17.2	18.5	20.1

FIGURE 8, PROCEDURE TIME VERSUS BODY MASS FOR VARIOUS FLUID TEMPERATURES

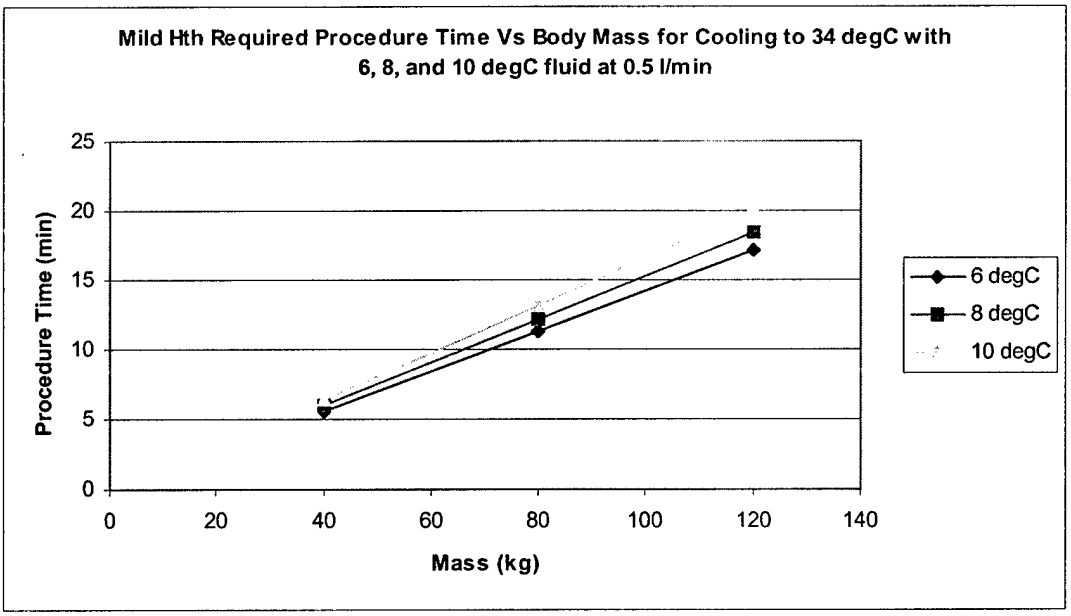


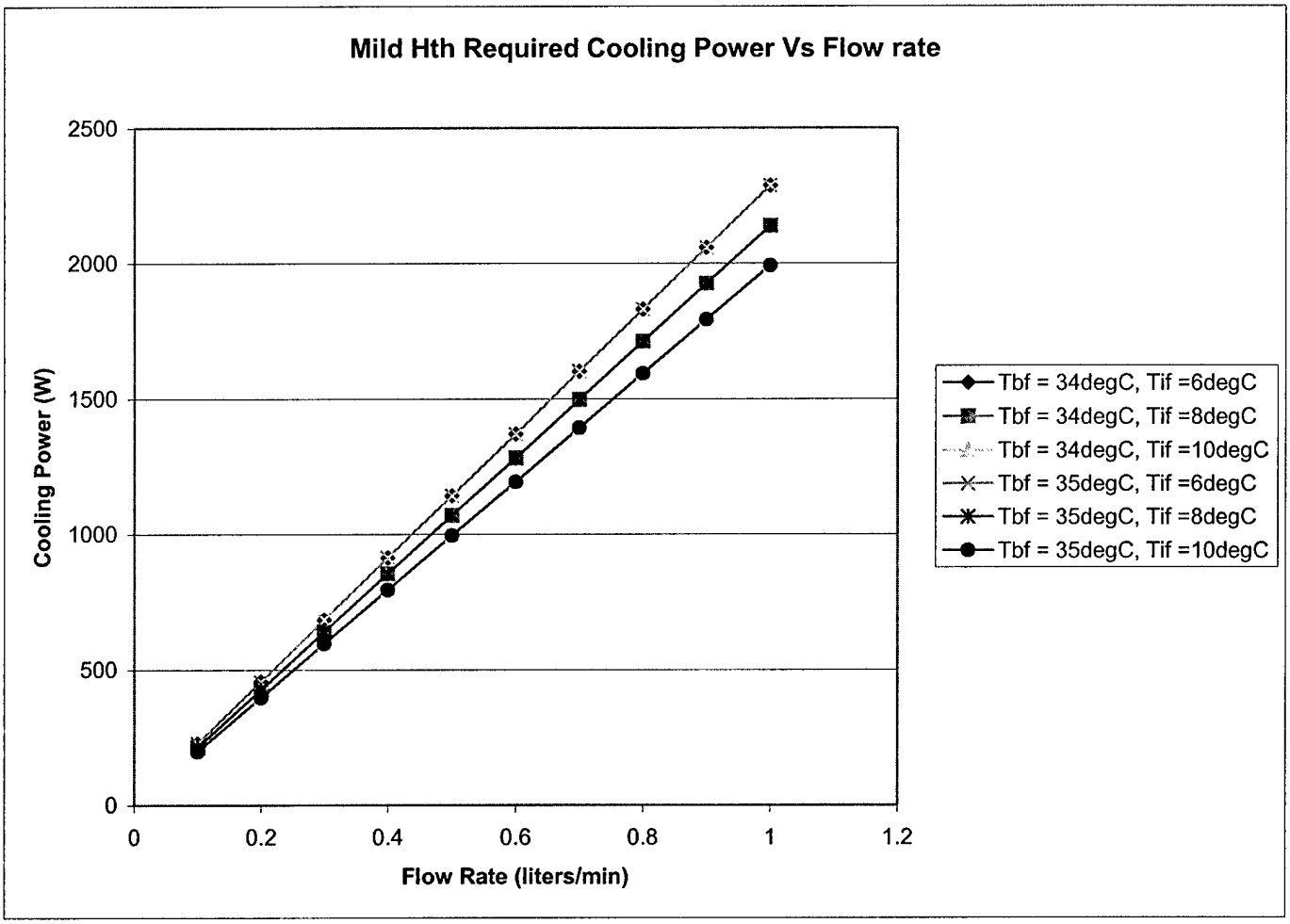
FIGURE 9, PROCEDURE TIME VERSUS BODY MASS FOR VARIOUS FLUID TEMPERATURES

The table shown in Fig, 10 and the graph shown in Fig. 11 summarize the cooling power requirements in watts versus flow rate at various combinations of final body temperature and final fluid temperature.

APPENDIX A

Rf (l/min)	Tbf = 34degC, Tif =6degC	Tbf = 34degC, Tif =8degC	Tbf = 34degC, Tif =10degC	Tbf = 35degC, Tif =6degC	Tbf = 35degC, Tif =8degC	Tbf = 35degC, Tif =10degC
0.1	229	214	199	229	214	199
0.2	457	428	398	457	428	398
0.3	686	642	597	686	642	597
0.4	915	856	797	915	856	797
0.5	1143	1070	996	1143	1070	996
0.6	1372	1283	1195	1372	1283	1195
0.7	1601	1497	1394	1601	1497	1394
0.8	1829	1711	1593	1829	1711	1593
0.9	2058	1925	1792	2058	1925	1792
1	2287	2139	1992	2287	2139	1992

FIGURE 10, MILD HTH REQUIRED COOLING POWER VERSUS FLUID FLOW RATE FOR VARIOUS TEMPERATURE SETTINGS.



VARIOUS FIGURE 11, MILD HTH REQUIRED COOLING POWER VERSUS FLUID FLOW RATE FOR TEMPERATURE SETTINGS.

Profound Hypothermia Induction Calculations

In Profound Hypothermia induction case, a volume, probably in 20 l bags, of pre-chilled fluid (saline 8% solution used in the calculations) to T_{fi} is used to flush the body or part of the body (Heart-Brain) at preset flow rate (1 – 2 l/min) in order to reduce and maintain the body or Heart-Brain temperature to T_{bf}. The procedure will be performed to patients that are clinically dead to extend animation or preserve organs. Therefore there is no metabolic activity and so $P_m = 0$. Also after the body is flushed and profound hypothermia has been achieved, the fluid temperature exiting the body and the body temperature will be in equilibrium so $T_{ff} = T_{bf}$. The initial body temperature is assumed 37°C.

APPENDIX A

The table[4] shown in Fig. 12 is included for reference.

Temperature (°C)	Symptoms
28	Muscle failure
30	Loss of body temperature control
33	Loss of consciousness
37	Normal
42	Central nervous system breakdown
44	Death

FIGURE 12, BODY TEMPERATURE AND ASSOCIATED SYMPTOMS.

Based on these assumptions and using Eq. 4 and 7 and the data shown in the table of Fig. 1, the data shown in the tables of Fig. 13 to Fig. 21 was calculated for procedure time and cooling power versus flow rate for 40 kg, 80 kg, and 120 kg body weights, for Heart-Brain cooling only (heart = 0.4 kg, brain = 1.4 kg, other = 0.3 kg, total mass = 21 kg)[1] and for various settings of final body temperature and final fluid temperature.

Rf (l/min)	40 kg	80 kg	120 kg	Heart-Brain
0.5	95.9	191.7	287.6	5.0
1	47.9	95.9	143.8	2.5
1.5	32.0	63.9	95.9	1.7
2	24.0	47.9	71.9	1.3
2.5	19.2	38.3	57.5	1.0
3	16.0	32.0	47.9	0.8
3.5	13.7	27.4	41.1	0.7
4	12.0	24.0	35.9	0.6
4.5	10.7	21.3	32.0	0.6
5	9.6	19.2	28.8	0.5
V (liters)	47.9	95.9	143.8	2.5

FIGURE 13, VOLUME OF FLUID REQUIRED AND PROCEDURE TIME IN MINUTES FOR A 40 KG, A 80 KG, AND A 120 KG PERSON (T_{BF} = 10°C AND T_{IF} = -5°C).

Rf (l/min)	40 kg	80 kg	120 kg	Heart-Brain
0.5	58.6	117.2	175.7	3.1
1	29.3	58.6	87.9	1.5
1.5	19.5	39.1	58.6	1.0
2	14.6	29.3	43.9	0.8
2.5	11.7	23.4	35.1	0.6
3	9.8	19.5	29.3	0.5
3.5	8.4	16.7	25.1	0.4
4	7.3	14.6	22.0	0.4
4.5	6.5	13.0	19.5	0.3
5	5.9	11.7	17.6	0.3
V (liters)	29.3	58.6	87.9	1.5

FIGURE 14, VOLUME OF FLUID REQUIRED AND PROCEDURE TIME IN MINUTES FOR A 40 KG, A 80 KG, AND A 120 KG PERSON (T_{BF} = 15°C AND T_{IF} = -5°C).

Rf (l/min)	40 kg	80 kg	120 kg	Heart-Brain
0.5	36.2	72.4	108.6	1.9
1	18.1	36.2	54.3	1.0
1.5	12.1	24.1	36.2	0.6
2	9.1	18.1	27.2	0.5
2.5	7.2	14.5	21.7	0.4
3	6.0	12.1	18.1	0.3
3.5	5.2	10.3	15.5	0.3
4	4.5	9.1	13.6	0.2
4.5	4.0	8.0	12.1	0.2
5	3.6	7.2	10.9	0.2
V (liters)	18.1	36.2	54.3	1.0

FIGURE 15, VOLUME OF FLUID REQUIRED AND PROCEDURE TIME IN MINUTES FOR A 40 KG, A 80 KG, AND A 120 KG PERSON (T_{BF} = 20°C AND T_{IF} = -5°C).

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Rf (l/min)	40 kg	80 kg	120 kg	Heart-Brain
0.5	143.8	287.6	431.3	7.5
1	71.9	143.8	215.7	3.8
1.5	47.9	95.9	143.8	2.5
2	35.9	71.9	107.8	1.9
2.5	28.8	57.5	86.3	1.5
3	24.0	47.9	71.9	1.3
3.5	20.5	41.1	61.6	1.1
4	18.0	35.9	53.9	0.9
4.5	16.0	32.0	47.9	0.8
5	14.4	28.8	43.1	0.8
V (liters)	71.9	143.8	215.7	3.8

FIGURE 16, VOLUME OF FLUID REQUIRED AND PROCEDURE TIME IN MINUTES FOR A 40 KG, A 80 KG, AND A 120 KG PERSON (T_{BF} = 10°C AND T_{IF} = 0°C).

Rf (l/min)	40 kg	80 kg	120 kg	Heart-Brain
0.5	78.1	156.2	234.3	4.1
1	39.1	78.1	117.2	2.1
1.5	26.0	52.1	78.1	1.4
2	19.5	39.1	58.6	1.0
2.5	15.6	31.2	46.9	0.8
3	13.0	26.0	39.1	0.7
3.5	11.2	22.3	33.5	0.6
4	9.8	19.5	29.3	0.5
4.5	8.7	17.4	26.0	0.5
5	7.8	15.6	23.4	0.4
V (liters)	39.1	78.1	117.2	2.1

FIGURE 17, VOLUME OF FLUID REQUIRED AND PROCEDURE TIME IN MINUTES FOR A 40 KG, A 80 KG, AND A 120 KG PERSON (T_{BF} = 15°C AND T_{IF} = 0°C).

Rf (l/min)	40 kg	80 kg	120 kg	Heart-Brain
0.5	45.3	90.5	135.8	2.4
1	22.6	45.3	67.9	1.2
1.5	15.1	30.2	45.3	0.8
2	11.3	22.6	33.9	0.6
2.5	9.1	18.1	27.2	0.5
3	7.5	15.1	22.6	0.4
3.5	6.5	12.9	19.4	0.3
4	5.7	11.3	17.0	0.3
4.5	5.0	10.1	15.1	0.3
5	4.5	9.1	13.6	0.2
V (liters)	22.6	45.3	67.9	1.2

FIGURE 18, VOLUME OF FLUID REQUIRED AND PROCEDURE TIME IN MINUTES FOR A 40 KG, A 80 KG, AND A 120 KG PERSON (T_{BF} = 20°C AND T_{IF} = 0°C).

Rf (l/min)	40 kg	80 kg	120 kg	Heart-Brain
0.5	287.6	575.1	862.7	15.1
1	143.8	287.6	431.3	7.5
1.5	95.9	191.7	287.6	5.0
2	71.9	143.8	215.7	3.8
2.5	57.5	115.0	172.5	3.0
3	47.9	95.9	143.8	2.5
3.5	41.1	82.2	123.2	2.2
4	35.9	71.9	107.8	1.9
4.5	32.0	63.9	95.9	1.7
5	28.8	57.5	86.3	1.5

V (liters)	143.8	287.6	431.3	7.5

FIGURE 19, VOLUME OF FLUID REQUIRED AND PROCEDURE TIME IN MINUTES FOR A 40 KG, A 80 KG, AND A 120 KG PERSON (T_{BF} = 10°C AND T_{IF} = 5°C).

Rf (l/min)	40 kg	80 kg	120 kg	Heart-Brain
0.5	117.2	234.3	351.5	6.2
1	58.6	117.2	175.7	3.1
1.5	39.1	78.1	117.2	2.1
2	29.3	58.6	87.9	1.5
2.5	23.4	46.9	70.3	1.2
3	19.5	39.1	58.6	1.0
3.5	16.7	33.5	50.2	0.9
4	14.6	29.3	43.9	0.8
4.5	13.0	26.0	39.1	0.7
5	11.7	23.4	35.1	0.6
V (liters)	58.6	117.2	175.7	3.1

FIGURE 20, VOLUME OF FLUID REQUIRED AND PROCEDURE TIME IN MINUTES FOR A 40 KG, A 80 KG, AND A 120 KG PERSON (T_{BF} = 15°C AND T_{IF} = 5°C).

Rf (l/min)	40 kg	80 kg	120 kg	Heart-Brain
0.5	60.4	120.7	181.1	3.2
1	30.2	60.4	90.5	1.6
1.5	20.1	40.2	60.4	1.1
2	15.1	30.2	45.3	0.8
2.5	12.1	24.1	36.2	0.6
3	10.1	20.1	30.2	0.5
3.5	8.6	17.2	25.9	0.5
4	7.5	15.1	22.6	0.4
4.5	6.7	13.4	20.1	0.4
5	6.0	12.1	18.1	0.3
V (liters)	30.2	60.4	90.5	1.6

FIGURE 21, VOLUME OF FLUID REQUIRED (L) AND PROCEDURE TIME (MINUTES) FOR A 40 KG, A 80 KG, AND A 120 KG PERSON (T_{BF} = 20°C AND T_{IF} = 5°C).

Using time data from the tables shown in Fig. 16, Fig. 17, and Fig. 18 at 2 l/min only we form the table shown in Fig. 22 and plot it in Fig. 23.

m (kg)	10 °C	15 °C	20 °C
40	35.9	19.5	11.3
80	71.9	39.1	22.6
120	107.8	58.6	33.9

FIGURE 22, PROCEDURE TIME VERSUS BODY MASS FOR 10 DEGC, 15 DEGC. AND 20 DEGC BODY COOLING

APPENDIX A

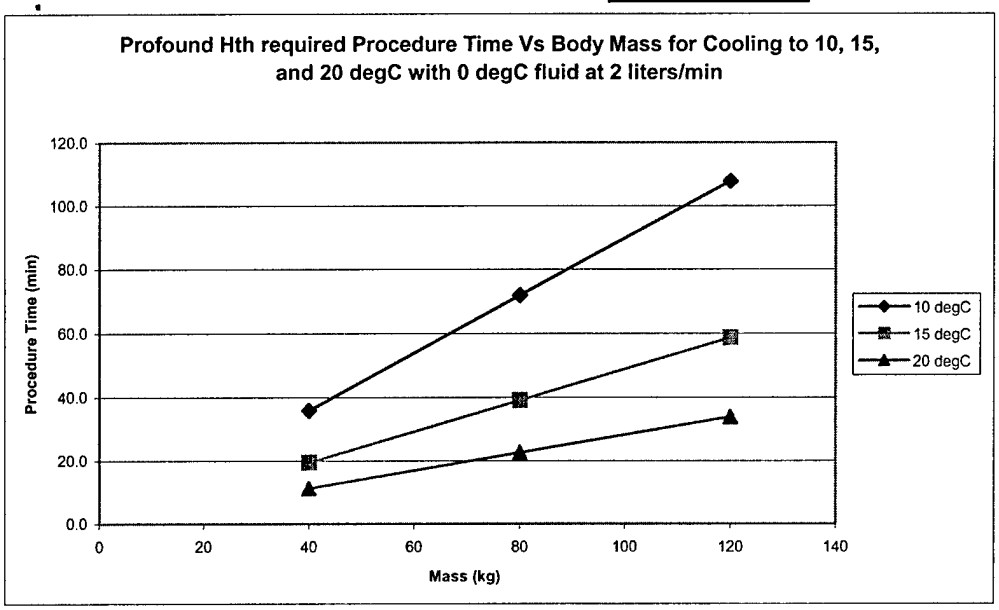

FIGURE 23, PROCEDURE TIME VERSUS BODY MASS FOR 10 DEGC, 15 DEGC. AND 20 DEGC BODY COOLING

The table shown in Fig. 24 and the graph shown in Fig. 25 summarize the volume of fluid required to achieve profound hypothermia for 40 kg, 80 kg, and 120 kg of body weight and for Heart-Brain cooling and for various combinations of final body temperature and initial fluid temperature (outflow temperature set point).

Conditions	40 kg	80 kg	120 kg	Heart-Brain
Tbf = 10degC, Tif = -5degC	47.9	95.9	143.8	2.5
Tbf = 15degC, Tif = -5degC	29.3	58.6	87.9	1.5
Tbf = 20degC, Tif = -5degC	18.1	36.2	54.3	1.0
Tbf = 10degC, Tif = 0degC	71.9	143.8	215.7	3.8
Tbf = 15degC, Tif = 0degC	39.1	78.1	117.2	2.1
Tbf = 20degC, Tif = 0degC	22.6	45.3	67.9	1.2
Tbf = 10degC, Tif = 5degC	143.8	287.6	431.3	7.5
Tbf = 15degC, Tif = 5degC	58.6	117.2	175.7	3.1
Tbf = 20degC, Tif = 5degC	30.2	60.4	90.5	1.6

FIGURE 24, REQUIRED FLUID VOLUME (LITERS) FOR PROFOUND INDUCTION FOR DIFFERENT BODY WEIGHTS AND FOR HEART-BRAIN AT VARIOUS TEMPERATURE SETTINGS.

APPENDIX A

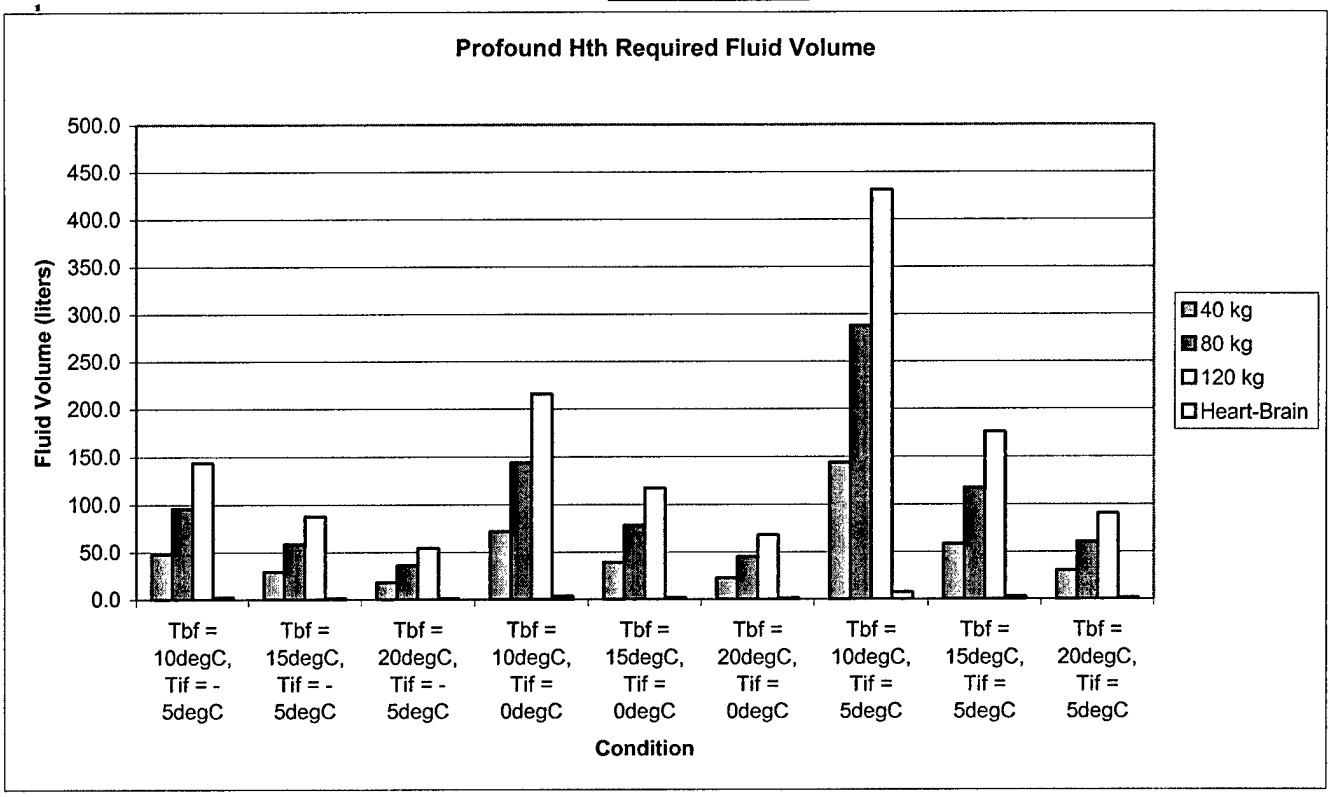

FIGURE 25, REQUIRED FLUID VOLUME (LITERS) FOR PROFOUND INDUCTION FOR DIFFERENT BODY WEIGHTS AND FOR HEART-BRAIN AT VARIOUS TEMPERATURE SETTINGS.

Utilizing Eq. 12, we determine the time in hours it will take to chill a 10 l, 20 l, 40 l, 60 l, and 80 l bag of saline (8% solution) from 27°C to 5°C, 0°C, and –5°C versus cooling thermal power. The results are shown in the tables of Fig. 26, Fig. 27, and Fig. 28.

Pc (W)	5 liters	10 liters	20 liters	40 liters
50	3.9	7.9	15.7	31.5
100	2.0	3.9	7.9	15.7
200	1.0	2.0	3.9	7.9
300	0.7	1.3	2.6	5.2
400	0.5	1.0	2.0	3.9
500	0.4	0.8	1.6	3.1
600	0.3	0.7	1.3	2.6
700	0.3	0.6	1.1	2.2
800	0.2	0.5	1.0	2.0
900	0.2	0.4	0.9	1.7
1000	0.2	0.4	0.8	1.6
1100	0.2	0.4	0.7	1.4
1200	0.2	0.3	0.7	1.3
1300	0.2	0.3	0.6	1.2
1400	0.1	0.3	0.6	1.1
1500	0.1	0.3	0.5	1.0

FIGURE 26, TIME IN HOURS REQUIRED FOR COOLING A BAG OF 8% SALINE AND OF INDICATED VOLUME FROM 27°C TO 5°C VERSUS COOLING SYSTEM THERMAL POWER.

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Pc (W)	5 liters	10 liters	20 liters	40 liters
50	3.3	6.6	13.3	26.6
100	1.7	3.3	6.6	13.3
200	0.8	1.7	3.3	6.6
300	0.6	1.1	2.2	4.4
400	0.4	0.8	1.7	3.3
500	0.3	0.7	1.3	2.7
600	0.3	0.6	1.1	2.2
700	0.2	0.5	0.9	1.9
800	0.2	0.4	0.8	1.7
900	0.2	0.4	0.7	1.5
1000	0.2	0.3	0.7	1.3
1100	0.2	0.3	0.6	1.2
1200	0.1	0.3	0.6	1.1
1300	0.1	0.3	0.5	1.0
1400	0.1	0.2	0.5	0.9
1500	0.1	0.2	0.4	0.9

FIGURE 27, TIME IN HOURS REQUIRED FOR COOLING A BAG OF 8% SALINE AND OF INDICATED VOLUME FROM 27°C TO 0°C VERSUS COOLING SYSTEM THERMAL POWER.

Pc (W)	5 liters	10 liters	20 liters	40 liters
50	2.7	5.4	10.8	21.6
100	1.4	2.7	5.4	10.8
200	0.7	1.4	2.7	5.4
300	0.5	0.9	1.8	3.6
400	0.3	0.7	1.4	2.7
500	0.3	0.5	1.1	2.2
600	0.2	0.5	0.9	1.8
700	0.2	0.4	0.8	1.5
800	0.2	0.3	0.7	1.4
900	0.2	0.3	0.6	1.2
1000	0.1	0.3	0.5	1.1
1100	0.1	0.2	0.5	1.0
1200	0.1	0.2	0.5	0.9
1300	0.1	0.2	0.4	0.8
1400	0.1	0.2	0.4	0.8
1500	0.1	0.2	0.4	0.7

FIGURE 28, TIME IN HOURS REQUIRED FOR COOLING A BAG OF 8% SALINE AND OF INDICATED VOLUME FROM 27°C TO -5°C VERSUS COOLING SYSTEM THERMAL POWER.

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Conclusions

The procedure time, for mild hypothermia induction, decreases with increasing flow rate and increases with increasing body mass. Procedure time also increases as the desired hypothermic body temperature decreases and decreases as the fluid becomes colder. The cooling system thermal power requirements and by extension the electrical power requirements increase with increasing flow rate and increasing fluid temperature. Therefore there are limitations and trade offs. For example the lowest blood temperature allowable in order to avoid damage is 6°C while circulating at 10% of cardiac output (0.5 l/min). This rate requires about 1150 W and results to 5 - 20 minutes procedure time for hypothermic body temperature of 34°C and blood temperature (entering the body) between 6°C and 10°C for a person weighing 40 - 120 kg. It will be the operator's decision to use 6°C versus 10°C depending on the size of the patient and the risks involved.

In profound hypothermia induction, the procedure time again decreases with increasing flow rate and body weight. The procedure time heavily depends on the temperature of the pre-chilled fluid and to the degree the body will be chilled. The large volume of fluid that is required which also increases dramatically with body weight but is independent of flow rate. For example, it will take 23 minutes and about 45 liters of pre-chilled 0°C saline at 2 liters/min to flush an 80 kg person and drop the body temperature to 20°C.

APPENDIX A

Suggestions for Further Work

All the results derived in this work are based on parameters that may be too optimistic. They should be treated as such in the practical design. The results presented are also for a certain range of values that I believe to be pertinent. You can recalculate for any value if necessary by using the spread Calc_Hth 0.xls.

APPENDIX B

ARDIEM

TECHNICAL REPORT

Technical Report x.dot, Rev. A, Effective 01-06-03

RECORD NO.

AM-00005

TITLE OF TECHNICAL REPORT		REVISION
Military Load Limits for Individual Soldiers		0
PROJECT OR PROGRAM NAME	**PROGRAM NUMBER**	**DATE**
Emergency Hypothermia	2003-01	07-02-03
DESCRIPTION OF TASK PROMPTING TECHNICAL REPORT	**NAME OF AUTHOR**	
What is the weight limit of an individually portable emergency hypothermia device	Dave McMurry	

TECHNICAL AREA

Mechanical, System Engineering

SUBJECT AND KEY TECHNICAL WORDS

Hypothermia, Weight, Battlefield, Load Limit, Portable

DOCUMENTATION TYPE

☐ Validation	☐ Error Budget	☐ Reliability	☐ Sensitivity
☐ Verification	☐ Product Support	☐ Risk Analysis	☒ Other

ASSOCIATED REPORTS

None

Abstract

The final objective of the emergency hypothermia program for the U. S. Military is a portable device capable of rapidly inducing suspended animation in a wounded soldier. A state of suspended animation provides time for transportation to a facility where a physician can repair the wounds and resuscitate the soldier.

The ultimate mode of portability for such a device is that an individual soldier (medical technician) can transport the device to its point of use. To determine a weight allowance for an emergency hypothermia device, it is first necessary and essential to research the load limit standards set forth by the U. S. Army.

The governing document military planners use in the execution of load management for U.S. soldiers is FM 21-18, a field manual. FM 21-18 specifies load limits in a comprehensive set of combat situations and conditions ranging from a fighting load of 48 pounds up to an emergency load of 150 pounds. In use, the frontline medic would carry and employ an emergency hypothermia device to save a severely wounded soldier. In most envisioned scenarios, this would occur in a combat situation where load limits for combat would apply.

With the information provided in FM 21-18 and the projected use conditions, an emergency hypothermia device should weigh no more than 72 pounds in total for a single soldier to carry to the point of application. It is preferable to keep the device weight less than the recommended fighting load of 48 pounds but since, in application, it would only be carried a short distance, the higher load is feasible.

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Background

- World War I, II, the Korean Conflict, and the Vietnam War all provided strong evidence that improving rapid access of combat casualties to specialized medical care led to a reduction in mortality rates. In World War II, the time from injury to definitive surgical care ranged from 6 to 12 hours with an associated mortality rate of 5.8%. In the Vietnam War, the average time from injury to emergency care was 65-80 minutes, with a mortality rate below 2.0%. In the United States, the development of major civilian trauma services, over the past several decades, has led to reductions in preventable deaths from 73% to 9% when patients were treated within these specialized trauma systems. For patients who were inappropriately treated within non-trauma specialized systems, the preventable mortality rate remained high, at 67%. Similarly, critically injured combat personnel located at remote locations without immediate access to specialized trauma care remain at risk of high mortality rates. Severe peripheral injuries can lead to traumatic hemorrhage and death, although most vital organs often remain intact, but at risk from shock and ischemia. Pioneering studies in the 1950s and 1960s demonstrated the impact of combined airway control and mouth-to-mouth breathing with external cardiac massage for basic cardiopulmonary resuscitation (CPR) life support, followed by advanced and extended life support procedures for cardiopulmonary-cerebral resuscitation (CPCR), including cardiopulmonary bypass (CPB). Now, immediate and targeted therapeutic hypothermia interventions may be able to isolate vital organs such as the heart, brain, spinal cord and associated vasculatures, and impose a state of clinical preservation until transport can be provided to an arena of more specialized acute surgical care and delayed resuscitation. Animal studies have demonstrated that hypothermia could help to preserve brain function by reducing oxygen requirements and injurious biochemical, metabolic, and inflammatory cascades.

Rapid massive hemorrhage and exsanguination in combat casualties and trauma victims resulting in cardiac arrest has remained an unrecoverable event because the required surgery for quickly controlling the bleeding cannot be performed in the field. Bellamy and Safar suggested innovative concepts that would focus on preservation of viability for the victim who rapidly succumbs to exsanguination and/or cardiac arrest instead of immediate definitive resuscitation, until hemostasis and subsequent delayed resuscitation could be achieved. For this novel approach, targeted brain and heart hypothermia as well as pharmacologic interventions have been pursued at the Safar Center for Resuscitation Research. For the past several years, the Safar Center has pursued the use of direct aortic cold flush with isotonic saline solutions to cool the brain and heart as rapidly as possible.

The development of devices and methods to address immediate and targeted interventional logistics, vital organ isolation, physiologic preservative administration, and monitoring for emergency hypothermia would uniquely enable preservation and delayed resuscitation at specialty care centers, thereby reducing civilian and combat casualty mortality rates. These devices will ultimately provide the necessary means for inducing suspended animation or preservative-resuscitative hypothermia, initially for use in hospital emergency rooms, then mobile ICU ambulances or helicopters, and eventually for field combat paramedics.

Introduction

Historically, 45% of casualties dying in combat succumb to blood loss without adequate emergency medical interventions. The ability to delay resuscitation and provide hypothermic suspended animation would protect the injured's brain and other vital organs from oxygen deprivation while awaiting evacuation to an appropriate medical facility. Such intervention would effectively extend the "golden hour" window--increasing the time for transport and the necessary surgery and resuscitation. "Delayed resuscitation techniques" meet the military medical requirement to provide effective, life-saving care for severely injured and hemorrhaging casualties.

Preservation of the patient who cannot be resuscitated by standard means during cardiac arrest requires the rapid induction of profound hypothermia to extend the time for delayed resuscitation to 1-2 hours or longer. This induction of suspended animation requires an aortic flush of large volumes of cold (- 5 to +5 °C) fluid. The enabling compact and mobile devices required for the application of emergency hypothermia do not presently exist.

The goals of delayed resuscitation and hypothermic suspended animation will be achieved through the techniques of metabolic down-regulation, hypothermia, hibernation induction, and suspended metabolism and will include studies that: (1) help save combat casualties from uncontrollable, internal organ or vascular, traumatic exsanguinations, by enabling delayed resuscitation, hypothermic suspended animation, and evacuation, followed by definitive surgical care and full resuscitation; (2) help save non-traumatic cases of sudden death, previously unrecoverable before definitive surgical repair; and (3) enable selected surgical procedures to be performed which are only possible during a state of no blood flow. To meet these goals, we must research and develop cooling devices capable of providing profound hypothermia in emergency rooms, mobile advanced life support ambulances, field hospitals, forward military echelons of combat casualty care, and rural or other remote locations. A critical element in this endeavor is to determine limits of size and weight for the device that will satisfy operational criteria.

APPENDIX B

Purpose

Determine the weight limits of an emergency hypothermia device for suspended animation that is portable by a single individual.

Description of Apparatus and Setup

Experimental work is not required at this time.

Summary of Data and Results

FM 21-18, Foot Marches, states that the "Fighting Load" for a conditioned soldier should not exceed 48 pounds. A Fighting Load is the necessities a soldier must carry during combat or when combat is imminent. It is important to recognize that load weights consists of all clothing and equipment that are worn and carried. A Fighting Load includes bayonet, weapon, clothing, Load Bearing Equipment (LBE), reduced amount of ammunition, environmental protection, plus some amount of food and water.

The "Approach March Load," or movement to the battle area, should not exceed 72 pounds. Again, this is all clothing and equipment worn and carried by the soldier. An Approach March load consists of clothing, weapon, basic load of ammunition, LBE, small assault pack, or lightly loaded rucksack or poncho roll.

Often in combat operations, soldiers are required to navigate through terrain impassable to vehicles or where ground/air transportation resources are not available. In these circumstances, a conditioned soldier may be required to carry loads much larger than the 72 pound Approach March load. FM 21-18 categorizes these circumstances as "Emergency Approach March" loads. Loads up to 120 pounds can be carried for several days over distances of 20 kilometers per day. With proper equipment, loads up to 150 pounds are feasible though fatigue is certain and injuries more likely to occur.

These load limits are the average capability of a typical foot soldier. The actual load carrying capacity of an individual soldier for a specific situation is based on numerous factors including weather, conditioning, strength, and size. Soldiers who are physically fit to Army Physical Fitness Test standards can carry loads that are 45 percent of their body weight (average 72 pounds) at four (4) kilometers per hour for eight-hour approach marches.

In actual combat operations, it is common for soldiers to carry significantly more than the prescribed 48 pounds (Fighting Load) or 72 pounds (Approach March Load). During the landings at Normandy on D-Day, 1944, American soldiers carried more than 80 pounds of equipment. In 1982, during the Falkland Islands conflict, British marines marched across the East Falkland Island carrying an average of 120 pounds, some carrying up to 145 pounds. Even more extreme, when the United States invaded Grenada in 1983, U. S. rangers parachuting onto the Salinas Airfield carried an average load of 167 pounds, though much of the weight was carried in a separate ruck. A more recent example is during Operation Desert Storm in 1992, the average soldier in one infantry brigade carried more than 100 pounds. Though these are extreme examples, it can be shown historically, going back several hundred years, that the infantry soldier in combat operations is commonly overloaded.

It is not just the necessities of war that force soldiers to carry larger loads than dictated by common sense or military doctrine. Overloading often occurs in training during peacetime and can even be considered the norm. The Army's Joint Readiness Training Center (JRTC) observed over the course of several rotations that the average rifle platoon soldier's warm weather load is 88.3 pounds and the average cold weather load is 101.5 pounds. This average does not include the soldier's uniform and boots.

It is apparent American soldiers consistently carry loads greater than specified by military doctrine (FM 21-18) even though the detrimental effects of overloading have been demonstrated and noted by military planners and technicians time and again over many years of military operations. However this should not be viewed as a license to intentionally design an emergency hypothermia device with a weight greater than that prescribed by doctrine if it is meant to be portable by an individual soldier.

In general terms, the emergency hypothermia unit designed for the current cold flush protocol consists of three articles: (1) the apparatus for delivering the cold solution; (2) the cooling device and its power supply for cooling the solution to the prescribe temperature and maintaining it at that temperature during transportation and storage; and, (3) the cold solution which is flushed through the patient's body to induce suspended animation. Under the best of circumstances, it will be an extremely difficult task to reduce the delivery apparatus, cooling device, and flush solution to a combined weight of 72 pounds. Because of weight and power requirements, it is logical to assume that for the first units fielded, the cooling device will have to be transported by vehicle. If correct, then only the weight of the delivery apparatus and cooling solution should be considered transportable by an individual soldier under the current protocol.

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The current protocol for inducing suspended animation requires a minimum of twenty (20) liters of solution, which alone weighs approximately 44 pounds, just four (4) pounds short of the 48 pound Fighting Load. If a 72 pound Approach March Load is the standard, then a 28 pound margin remains for the delivery apparatus, again assuming the cooling device is transported by vehicle and not by a soldier. The 20 liter requirement for flushing a human is an estimate based on animal studies. Future work may demonstrate a need for more, perhaps significantly more, cooled solution (and subsequent weight) to induce profound hypothermia temperatures. If more solution is required for a single event or if the capability to treat more than one soldier is required at this level of deployment, then additional soldiers will be required to transport the delivery apparatus and associated cooling solution to avoid exceeding the 72 pound limit. Using a cold flush to induce suspended animation in a single soldier makes it difficult to reduce the weight much beyond 72 pounds (44 pounds of fluid and 28 pounds for the delivery apparatus), even without considering the weight of the cooling device. While the weight of the delivery apparatus and solution may be designed within acceptable limits for a single soldier, enough fluid and disposables to treat more than a single casualty will still exceed the individual load limit. Obviously, there is a need to reduce the solution requirement or find a transportation method that does not require a soldier.

Using a vehicle to deploy the hypothermia unit to the front lines is the most viable approach for treating combat casualties on site with the flush protocol. The cooling device requires significant power and time to cool the solution to temperatures below 10°C. Once cooled, the solution must be stored and transported in a manner that maintains the cooled temperature. In essence, this means a cooling device is required during transportation to its point of use. This could be a single device that both cools and maintains the solution at required temperatures or the solution could be cooled in a centralized location and then moved to the combat area in a separate device that is just maintains the proper temperature. In either case, a device to cool the solution or to just maintain the solution's temperature will require electrical power. Battery power is possibility but the power requirements and battery life with current technology impose severe limits on its application. Power cells are another possibility but the technology has not yet progressed far enough to make applications in this area practical. They are heavy and operate at high temperatures. Batteries and fuel cells will be investigated further in later studies. As a result, during transportation of the solution from one location to another, the power source will most likely have to be provided by or carried on a vehicle. It follows then that, excluding a change in the suspended animation protocol, it may be necessary to use a vehicle (or mule) to transport the emergency hypothermia unit and solution as close as possible to the combat area. From this point the delivery apparatus and required solutions would be carried by a soldier or soldiers to the location of the casualty, or the casualty could be carried to the emergency hypothermia unit. A mule may allow deployment of the hypothermia unit and fluid sufficient to treat multiple casualties in the combat area. Since Army planners are considering development of new types of mules to carry more of the soldier's equipment, it may be possible to incorporate hypothermia devices and other medical equipment into this concept.

Conclusions

The Army's intended deployment of the hypothermia unit has a major bearing on design weight and on the question of whether a medic carries the unit into combat operations. Designers are working with the supposition that at some point a soldier will have to transport the hypothermia unit on the battlefield. The question then becomes how much can it weigh. To determine the answer to this question, designers will need answers to many other questions. How far will a soldier be expected to transport the device? Will it be necessary for a soldier to carry all the hypothermia components or will some of them be transported by vehicle? Should designers use Combat Load or Approach March Load conditions? Will it be transported to the combat area by vehicle, carried in by soldiers, or a combination of both? Will it deployed at platoon, company, or battalion level (or even higher)? Answers to most of these questions are not yet available, but for current design work, we will assume a weight limit imposed by Approach March Load conditions. This assumption is acceptable because it is logical that an individual solder may transport such a device to the combat area if necessary, but very unlikely, considering the weight of essential equipment already carried, a soldier would intentionally carry such a device into combat on a routine basis. With this assumption, the design weight limit for the emergency hypothermia unit is 72 pounds. This weight is somewhat excessive because it does not take into consideration other essential equipment carried by a medic or soldier. In a brief, one time, emergency situation and over a short distance, 72 pounds is reasonable, but if carried longer distances, the hypothermia unit will need to weigh 15 to 20 pounds less. The load must be of a configuration and size such that it is compatible with a soldier's LBE.

Under the constraint of the current protocol for inducing suspended animation using a cold flush, the size and weight of the cooling device and its power supply dictates transportation by vehicle. The weight of sufficient solution for multiple treatments exceeds the 72 pound limit and should also be transported by vehicle. Additionally, the solution must be maintained in the cooling device until needed for a suspended animation flush. Considering these limitations, the emergency hypothermia unit should be transported to the combat area by vehicle. When a situation commands its use, a soldier (medic) would carry the delivery apparatus and appropriate solution from the vehicle to the casualty or carry the casualty to the vehicle.

Until the suspended animation protocol is revised to require less solution or a new technology is developed for cooling the solution, it will be extremely difficult to reduce the weight of the complete hypothermia unit to acceptable limits.

Suggestions for Further Work

It will be beneficial to conduct additional research into alternate power sources and cooling methodologies. Research and testing is ongoing and necessary to establish a suspended animation protocol that is both effective and compatible with existing technologies.

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Appendix 1

ARMY FIELD MANUAL 21-18

CHAPTER 5

Soldier's Load Management and Training for FOOT MARCHES

The ability of a soldier to march and fight is directly related to his load. The maximum individual load limit cannot be exceeded as an infantry soldier will not accomplish his mission. Soldiers fight light with only the equipment required for the immediate mission. They receive additional weapon systems and materiel when required. Effective individual fighting load's and minimum approach march loads can only be achieved through safeguarding and transporting portions of the load--commanders must decide to tailor loads that result from risk analysis. Transportation resources must be used to avoid excessive loads on soldiers such as CLOHE at company level and SLOHE at battalion level.

"No soldier should be compelled to walk until he actually enters battle. From that point forward he should carry nothing but what he wears, his ammunition, his rations and his toilet articles. When battle is concluded he should get new uniforms, new everything."

General George Patton, Jr.

Section I

TRANSPORT RESPONSIBILITY

The soldier load concept transfers responsibility for transporting part of the load from the individual soldier to battalion and division staff, and transfers the load from men to CLOHE. The soldier load problem can be reduced by reorganizing existing transport resources, which entails dedicating resources to the roles of CLOHE and SLOHE.

5-1. SIZE OF COMPANY LOADS

Table 5-1 shows planning figures for the required load-handling lift for each infantry company.

Table 5-1. Soldiers loads requiring transportation.

a. **Transportation Resources.** The provision of CLOHE at company level and SLOHE at battalion level is the responsibility of the command level that has control of transportation resources for ongoing operations.

b. **Resupply.** Company commanders will more readily make risk judgments if they have operational control of transportation. They can reduce the weight of ammunition, food, and water carried by their men to carry an immediate resupply, which consists of part of their basic load.

5-2. EXPEDIENTS FOR EXTRA TRANSPORTATION

If extra transportation resources are not given to battalions, greater reliance must be placed on--

a. **Extensive use of helicopters to free unit HMMWVs for use as CLOHE and SLOHE.** This might entail allocating one dedicated helicopter to each infantry brigade for logistical support to release three HMMWVs and trailers required for each company for load handling.

b. **Deployment of corps plug transportation assets.** Corps assets could be placed under the operational control of battalions for use as load-handling equipment. Forward deployment of corps transportation assets in the division can release existing HMMWVs and can improve the soldier load-carrying capacity of units, as will direct resupply of forward units by airdrop or steerable parachutes.

c. **Host nation support.** Units should be prepared to use local resources to include conventional vehicles, agricultural tractors, beasts of burden and their handlers, and human porters, which are obtained through host nation support, renting, and capture. Leaders must know the legal parameters of commandeering equipment and animals. The required funding must be provided for renting equipment. Possible host nation resources should be identified in contingency plans. At least one man in each platoon should be designated as a general-purpose driver.

Section II

FACTORS AFFECTING THE SOLDIER'S LOAD

Commanders at all levels must understand the factors affecting the soldier's load and the subsequent capabilities or limitations produced in the unit. The physical limitations of individual soldiers, stress, and the weight of equipment and munitions all affect the soldier's ability to carry his required load. These factors must be carefully analyzed by the commander or leader in the load determination process.

5-3. PHYSICAL LIMITATIONS

The fighting load for a conditioned soldier should not exceed 48 pounds and the approach march load should not exceed 72 pounds. These load weights include all clothing and equipment that are worn and carried.

a. A soldier's ability to react to the enemy is reduced by the burden of his load. Load carrying causes fatigue and lack of agility, placing soldiers at a disadvantage when rapid reaction to the enemy is required. For example, the time a soldier needs to complete an obstacle course is increased from 10 to 15 percent, depending on the configuration of the load, for every 10 pounds of equipment carried. It is likely that a soldier's agility in the assault will be degraded similarly.

b. Speed of movement is as important a factor in causing exhaustion as the weight of the load carried. The chart at Figure 5-1 shows the length of time that work rates can be sustained before soldiers become exhausted and energy expenditure rates for march speeds and loads. A burst rate of energy expenditure of 900 to 1,000 calories per hour can only be sustained for 6 to 10 minutes. Fighting loads must be light so that the bursts of energy available to a soldier are used to move and to fight, rather than to carry more than the minimum fighting equipment.

c. When carrying loads during approach marches, a soldier's speed can cause a rate-of-energy expenditure of over 300 calories per hour and can erode the reserves of energy needed upon enemy contact. March speeds must be reduced when loads are heavier to stay within reasonable energy expenditure rates. Carrying awkward loads and heavy handheld items causes further degradation of march speed and agility. The distance marched in six hours decreases by about 2 km for every 10 pounds carried over 40 pounds. Figure 5-2 shows speeds that are sustainable with given loads, which results in an energy expenditure of 300 calories per hour.

Figure 5-1. Work rate and energy expenditure.

Figure 5-2. March speeds.

5-4. STRESS

Battlefield stress decreases the ability of soldiers to carry their loads. Fear burns up the glycogen in the muscles required to perform physical tasks. This wartime factor is often overlooked in peacetime, but the commander must consider such a factor when establishing the load for each soldier. However, applying strong leadership to produce well-trained, highly motivated soldiers can lessen some of the effects of stress.

5-5. MUNITIONS AND EQUIPMENT

As the modern battlefield becomes more sophisticated, potential enemies develop better protected equipment, which could be presented as fleeting targets. Unless technological breakthroughs occur, increasingly heavy munitions and new types of target acquisition and communications equipment will be required by frontline soldiers to defeat the enemy.

a. In the future, the foot soldier's load can be decreased only by sending him into battle inadequately equipped or by providing some means of load-handling equipment to help him carry required equipment. Weights of selected items are provided in Table 5-2.

Table 5-2. Weights of selected items.

Table 5-2a. Weights of selected items.

b. Unless part of the load is removed from the soldier's back and carried elsewhere, all individual load weights are too heavy. Even if rucksacks are removed, key teams on the battlefield cannot fulfill their roles unless they carry excessively heavy loads. Soldiers who must carry heavy loads restrict the mobility of their units.

c. Overloaded soldiers include the antiarmor teams (individuals carry weights of 111, 101, and 90 pounds), mortar teams (individuals carrying 83 pounds, even after distributing 100 mortar rounds of 3.5 pounds each), fire support teams (carry 92 to 95 pounds), and M60 machine gun teams (carry 78 to 87 pounds). All radio operators equipped with the AN/PRC-77 and KY57 VINSON secure device are also loaded above the maximum recommended combat load (84 pounds). AT4 gunners and low-level voice intercept teams are overloaded as well as Stinger and engineer breaching teams.

Section III

ECHELONING AND LOAD TAILORING

A diagram showing the concept of dividing the total soldier load into combat, sustainment, and contingency loads and the different levels of combat loads (fighting and approach march) is at Figure 5-3.

Figure 5-3. Load echelon diagram.

5-6. COMBAT LOAD

The definition of a combat load that is carried by soldiers is as follows: The minimum mission-essential equipment, as determined by the commander responsible for carrying out the mission, required for soldiers to fight and survive immediate combat operations. The combat load is the essential load carried by soldiers in forward subunits or the load that accompanies soldiers other than fighting loads.

a. **Fighting Load.** The fighting load includes bayonet, weapon, clothing, helmet, and LBE, and a reduced amount of ammunition.

(1) For hand-to-hand combat and operations requiring stealth, carrying any load is a disadvantage. Soldiers designated for any mission should carry no more than the weapons and ammunition required to achieve their task; loads carried by assaulting troops should be the minimum.

(2) Unless some form of CLOHE is available, cross-loading machine gun ammunition, mortar rounds, antitank weapons, and radio operator's equipment causes assault loads to be more than the limit of 48 pounds. This weight restricts an individual's ability to move in dynamic operations. Extremely heavy fighting loads must be rearranged so that the excess weight can be redistributed to supporting weapons or can be shed by assaulting troops before contact with the enemy.

b. **Approach March Load.** The approach march load includes clothing, weapon, basic load of ammunition, LBE, small assault pack, or lightly loaded rucksack or poncho roll.

(1) On prolonged dynamic operations, the soldier must carry enough equipment and munitions for fighting and existing until resupply. In offensive operations, soldiers designated as assault troops need equipment to survive during the consolidation phase, in addition to carrying munitions for the assault. A limit of 72 pounds for a soldier load should be enforced.

(2) Normally, the soldier's large rucksack is not part of the approach march load. If the field pack internal frame is issued, only the small assault pack section is carried--the large section should be kept at battalion level. If the ALICE system is used, either a partly loaded small ALICE should be carried individually with a duffle bag or one large ALICE for each man should be kept at battalion level.

c. **Emergency Approach March Loads.** Circumstances could require soldiers to carry loads heavier than 72 pounds such as approach marches through terrain impassable to vehicles or where ground/air transportation resources are not available. Therefore, larger rucksacks must be carried. These emergency approach march loads can be carried easily by well-conditioned soldiers. When the mission demands that soldiers be employed as porters, loads of up to 120 pounds can be carried for several days over distances of 20 km a day. Although loads of up to 150 pounds are feasible, the soldier could become fatigued or even injured. If possible, contact with the enemy should be avoided since march speeds will be slow.

d. **Shedding Items on Contact.** Rucksacks, assault packs, and other items of the approach march load should be placed in caches before combat, and contact and antiambush drills must include shedding most of the approach march load. However, this procedure makes it difficult for the soldier to retrieve his equipment later in the battle, and it should only be used when transport is unavailable.

5-7. TAILORING COMBAT LOAD TO METT-T>

When confronted with the unacceptable loads that soldiers may be required to carry, senior commanders would like to establish firm limits. However, when realistically applying such guidelines, the soldier may not survive and win on the modern battlefield if his munitions and survival items are less effective than his enemy's.

a. Senior leaders must resist the temptation to prescribe the soldier's load. Only the subunit commander, who is assigned a specific mission, has information on all the factors that must be considered to decide the equipment needed for his mission. He must also have the authority to decide what load his soldiers must carry. The subunit commander receives guidance from his superiors, but any standard load imposed on him only inhibits his ability to make the correct judgment.

b. Consideration of risk judgments that must routinely be taken by subunit commanders are at Table 5-3. To use the table, the commander prioritizes the factors in column 1 based on an estimate of the situation. This estimate includes a complete analysis of the unit's mission at the end of the march, the enemy situation, the terrain to be marched on or through, the expected weather, and the physical condition of the troops. After prioritization, the commander decides what items to include in the soldier's load and what items to leave with the sustainment load in the unit trains area.

c. Considerations for this decision-making are included in columns 2, 3 and 4. This prioritization allows the commander to tailor the soldier's load based on the mission and to decide what items are to be transported or stored in the sustainment load. The mission analysis also identifies requirements for additional transportation assets.

Table 5-3. Risk judgments in load planning.

Table 5-3. (Continued.)

Table 5-3. (Continued.)

Table 5-3. (Continued.)

Table 5-3. (Continued.)

5-8. ECHELONING THE SOLDIER'S LOAD

When the size of the combat load has been established, needs can be determined for echeloning at battalion-, division-, or force-level trains for other equipment assigned to foot soldiers. Given the approved load limits for individual soldiers (fighting load of 48 pounds; approach march load of 72 pounds), commanders can use the following as a guide for tailoring the equipment and supplies into three echelons. (See Appendix D.)

a. **Combat Load.** Company commanders are responsible for all the equipment included in combat loads.

b. **Sustainment Load.** Battalion S4s are responsible for the safe custody and movement of sustainment loads. This responsibility may be delegated to company supply sergeants. The definition of sustainment load is as follows: equipment that is determined by the commander to be required for sustained operations, which will be brought forward to the soldiers under unit arrangements as required by the commander.

(1) The sustainment load includes individual large rucksacks or A-bags that contain spare clothing and equipment: sleeping bags when not required for survival, limited personal effects, protective items for specific threats (armored vests and chemical protective suits), and a mobile store of unit equipment.

(2) This equipment should be stored in a forward operations base--such as the battalion combat trains area--and pushed forward to front-line soldiers as arranged by the S4. Resupply of ammunition, food, and water is not included in this definition of sustainment load; however, the sustainment load could be pushed forward at the same time as normal resupply.

c. **Resupply.** Combat and sustainment loads contain ammunition, water, and food to enable units to operate until resupplied, but the amounts carried directly reflect the front-line soldier's confidence in the reliability and frequency of resupply. This concept assumes the normal operation of the battalion resupply system, but transport carrying an immediate company resupply should normally be under the operational control of the company commander.

d. **Contingency Load.** The contingency load is stored under divisional or corps arrangements until required. It consists of all other items of individual and unit equipment not required for ongoing operations such as the soldier's B-bag for extra clothing and TOW missiles in theatres where there is no armored threat.

(1) B-bags should be palletized in company loads, and contingency TO&E equipment should be centralized in battalion packs. Contingency loads are not flown into deployment areas as part of the initial sorties. When contingency loads arrive in theater, plans should be made at or above division level to store unit contingency equipment. Items of equipment can then be returned to units if the operational situation changes, if the unit is deployed into an area where items of the contingency load are needed, or if the unit is staged through a rear assembly area.

(2) The key to this process it that instructions are issued to soldiers before deployment, listing the items of individual and TO&E equipment that should not accompany them on the initial deployment. Contingency equipment could remain in CONUS, or be stored at a base area in unit packs, or be used as a pool of equipment to be issued as required by the G4.

(3) Provision must also be made for some items of equipment to be back-loaded from battalion to division control upon arrival in theater. This allows units to deploy heavy for maximum flexibility and to add to contingency loads when in theater to fight light.

NOTE: In addition to the LBE, rucksack, A-bags, and B-bags, soldiers leave a C-box of personal equipment at their home station before deployment.

e. **Load Planning.** Units should develop packing lists to include specific deployment options, based on guidance from the chain of command. Once deployment has taken place, authority should be delegated to battalion commanders to send items back to division for inclusion in contingency loads. Company commanders should be authorized to vary the composition of combat and sustainment loads.

5-9. MINIMUM-LOAD CONCEPT

All soldiers, regardless of the threat environment and mission, always carry certain items common to the any mission. These items are the minimum-load configuration (MLC) along with the soldier's assigned weapon system and minimum amount of ammunition. Additions or deletions to the MLC will be based on the unit commander's estimate of the situation.

Section IV

TRAINING

Training in foot marches develops a unit's ability to march to its destination in a condition to accomplish its mission.

5-10. UNIT CHARACTERISTICS

Whether a force is mounted or dismounted, success in combat depends upon troops who can move dismounted cross-country, covering a great distance in the shortest time. The following unit traits are important in achieving this goal: unit discipline, good leadership, teamwork, high morale, endurance, and mental and physical stamina.

5-11. PHYSICAL CONDITIONING

An essential element of training foot soldiers is proper physical and mental conditioning, which develops stamina and endurance to perform required tasks. The best results are obtained from cross-country marches, although physical training and negotiating obstacle courses are also useful. Loads should be light and distances short at the beginning of training, becoming more difficult as training continues. By the end of training, troops should be accustomed to rigorous conditions that are most likely encountered in subsequent operations.

a. Soldiers who are physically fit to APFT standards can carry loads that are 45 percent of their body weight (average 72 pounds) at 4 kph for eight-hour approach marches. The amount of energy expended and discomfort experienced in carrying these loads can be reduced if soldiers have participated in a specialized program of physical conditioning. As a result, much heavier emergency loads can be carried at reduced speeds. Soldiers whose mission is to operate on foot for long periods without resupply can benefit from such training and conditioning.

b. After a 30-day preparatory training period, soldiers can march 12 miles in less than 3 hours loaded to about 60 pounds, when energy expenditure at that rate would cause exhaustion in 2.5 hours for soldiers who have not received special training. A number of considerations should be examined when developing a program for march conditioning.

(1) Aerobic conditioning (running) should not exceed 3 to 5 sessions each week (30 to 45 minutes each session). Excessive aerobic conditioning could be counterproductive to meeting other physical fitness objectives.

(2) Extended marching with loads is the most demanding physical requirement for infantry soldiers. Training programs should include specific progressive load-bearing marches. Progressions should be developed for increasing a load or distance marched but not at the same time. This training meets the requirement for both aerobic and muscular (legs and back) endurance. Progressive extended marches of 5, 10, 15, and 20 miles should be mandatory training and be scheduled regularly.

(3) Infantry physical training programs should include scheduled (two or three times each week) progressive resistance (strength) training to sustain or improve muscular strength. Also, muscular endurance training should be included. This training should include both upper and lower body muscle groups with emphasis on the upper body. Intensive progressive resistance training (three sessions each week in 48-hour intervals) should be mandatory for soldiers who lack adequate muscle mass (lean tissue) of the upper body.

(4) Mandatory elements of any fitness program should be: load-bearing progressive marches; resistance strength training; aerobic training; and anaerobic (speed and agility) training to include negotiating obstacles and confidence courses.

c. The following is a suggested program for physical conditioning.

(1) Train-up program for six weeks consisting of four one-hour daily workouts and one-half day each week to include:

(a) Two upper body exercise periods (push-ups, dips, sit-ups, and chin-ups or pull-ups).

(b) Two lower body exercise periods (sprints, relays, fireman carry, boot dusters, step-ups on benches).

(c) Two marches: one with heavy load and a short distance, one with light load and a longer distance, or both combined with tactical missions.

(d) Two slow-paced distance runs of 3 to 5 miles at 80 percent maximum heart rate *(FM 21-20)*.

(e) One light run of two miles at 60 to 80 percent maximum heart rate.

(2) Sustainment program as determined by the commander based upon the seven physical training principles *(FM 21-20)*.

(a) Regularity (three to five times each week).

(b) Progression (slow, steady increase of load or distance).

(c) Overload (work until muscles are fatigued)

(d) Variety (circuit training, free weights, calisthenics/ isometrics, confidence and obstacles courses).

(e) Balance (flexibility and muscular balance).

(f) Recovery (stress different muscle groups each day).

(g) Specificity (body adapts to a specific demands).

5-12. NUTRITION

Proper nutrition planning can improve soldier performance and reduce exertion required for a given work load. A preload-bearing diet that is high in carbohydrates can add to a soldier's ability to carry his load. It increases muscle glycogen levels as a "buffer" or reserve against exhaustion. Soldiers with high glycogen levels could require less rations for short load-bearing missions than soldiers low in muscle glycogen.

5-13. TACTICAL TRAINING

Units should train regularly with their dummy basic load of ammunition. The execution of a platoon load-carrying test should be included in the ARTEP-- for example, carrying an average load of 70 pounds for 12 miles followed by a tactical exercise, followed by an additional 12 miles and tactical exercise to be completed in a period of 24 hours.

5-14. LEADER TRAINING

Improved use of aimed fire and fire discipline decreases the risk of depleting ammunition, allowing commanders to carry reduced loads of ammunition when foot mobility is paramount.

a. **Commanders.** Potential commanders and staff officers must understand the following points:

(1) The composition of loads depends on METT-T factors. Load planning involves the subunit commander, acting under guidance from his superior, in a series of risk judgments that require balancing the physical ability of his soldiers against the risks of not carrying items of clothing, equipment, food, water, or munitions.

(2) Levels of command above company must support the front-line soldier by arranging for items of individual and subunit equipment to be kept in trains or base areas and by providing resources to fulfill the role of CLOHE and SLOHE. Echeloning of loads must be planned so that combat loads, sustainment loads (battalion level), contingency loads (divisional level), and equipment at home base are properly accounted for, safeguarded, and available to the soldier.

b. **Junior Leaders.** Junior leaders should be taught to make risk judgments involved in load planning and movement as well as load discipline.

5-15. SUSTAINMENT (INTEGRATED) TRAINING

Previously learned subjects should be integrate with foot marches to maintain overall proficiency and to inject realism into training. The subjects to be integrated and their required emphasis depend on the area of operations in which the training is conducted. A list of subjects that apply to most disciplines includes:

- Camouflage.
- Reconnaissance and security.
- Map reading.
- Use of the compass and other navigational aids.
- Fire support planning.
- Air defense planning.
- NBC defense planning.
- First aid and personal hygiene.
- Field sanitation.
- Occupation of bivouac and assembly areas.

- Tent pitching/field craft.
- Preparation of individual and small-group rations.
- Evacuation of casualties.
- Care of clothing and equipment.
- React to ambushes.
- Use of arm-and-hand signals.
- Request for indirect fire.

5-16. ENVIRONMENTAL TRAINING

Training should consider the terrain and climate of the area in which the unit will subsequently conduct operations. The training program must include familiarization with special equipment and the application of specialized techniques to tactical principles. Specialized training procedures for desert, jungle, arctic, and mountain areas are found in manuals dealing with those areas of operations.

5-17. MARCH DISCIPLINE

March discipline must be stressed throughout training. Aspects requiring special consideration are maintaining the rate of march and distances between men and units, and ensuring proper timing and use of halts and rest periods. Troops must not drop MRE wrappers or other refuse along the trail, and they must observe prescribed sanitation procedures. At halts any material that could attract the attention of the enemy or could identify a force should be removed or buried. When contact with the enemy is imminent, noise discipline must be observed for required security.

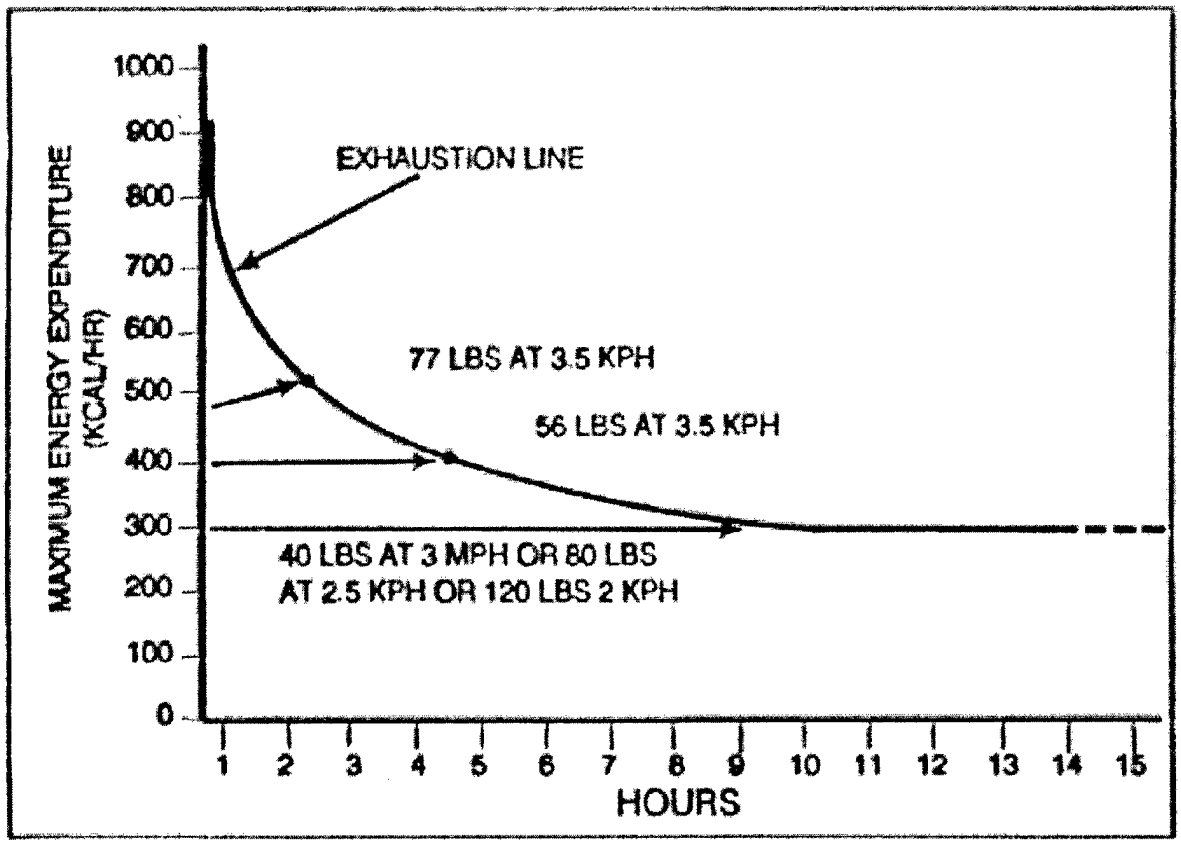
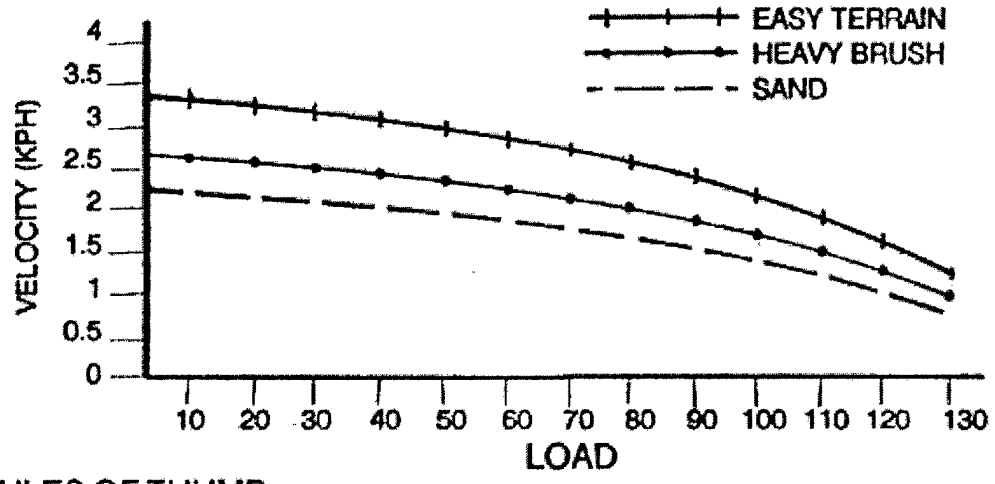


Figure 5-1. Work rate and energy expenditure.



RULES OF THUMB:

1. DISTANCE MARCHED IN 6 HOURS DECREASES BY 2 KILOMETERS FOR EVERY 10 POUNDS CARRIED OVER 40 POUNDS.
2. TIME OVER ASSAULT COURSE INCREASES BY 15 PERCENT FOR EVERY 10 POUNDS CARRIED OVER 40 POUNDS.
3. DISTANCES TRAVELED REDUCED BY HALF OVER AVERAGE GRADIENTS OF 10 PERCENT.

Figure 5-2. March speeds.

SCARF, WOOL	.4
SLEEPING BAG	7.1
BELT, TROUSERS	.2
HELMET, BALLISTIC	3.4
BELT, PISTOL, w/SUSPENDERS AND FIRST-AID POUCH	1.6
TOILET ARTICLES	2.0
WEAPONS:	
M16	1.6
M203	10.0
M60 MG	23.3
M249 SAW	15.2
AMMUNITION:	
5.56 w/MAG (30 rds)	.9
7.62 LKD (100 rds)	7.0
40-mm (ALL TYPES)	.5
5.56 LKD (200 rds)	7.6
GRENADE, FRAGMENTATION	1.0
GRENADE, SMOKE	1.0
RD, 60-mm MORTAR, HE	3.5
RD, 81-mm MORTAR, HE	9.3
LAW	5.2
MINE, M21	18.0
CLAYMORE, M18	5.0
DRAGON, MSL	25.3
AT4	14.0
FLARE, TRIP	1.0
BAYONET, w/SCABBARD	1.3
CASE, SMALL-ARMS	.9
TELEPHONE, TA-1	1.5
E-TOOL, w/CARRIER	2.5
ALICE, MEDIUM, w/FRAME	6.3
ALICE, LARGE, w/FRAME	6.6
AN/PRC-77, w/BATTERY	20.8
M60 SPARE BARREL w/BAG	8.0
60-mm MORTAR, M225	14.4
60-mm SIGHT, M64	2.5
60-mm BASEPLATE, M-7	14.4
60-mm BIPOD	13.2
81-mm MORTAR, M29	30.0
81-mm SIGHT, M53	6.0
81-mm NIGHTLIGHT	2.0
81-mm BASEPLATE	25.0
81-mm BIPOD	40.0
BINOCULARS	3.2
FLASHLIGHT, w/BATTERY	.8
COMPASS, M2	.3
DRAGON TRACKER	8.1
DRAGON NIGHTSIGHT	34.0
AN/PVS-5 NVG	1.9
AN/PVS-4 NVD	3.9
PISTOL, CAL .45	2.5
PROTECTIVE MASK, w/DECON KIT	3.0

Table 5-2. Weights of selected items.

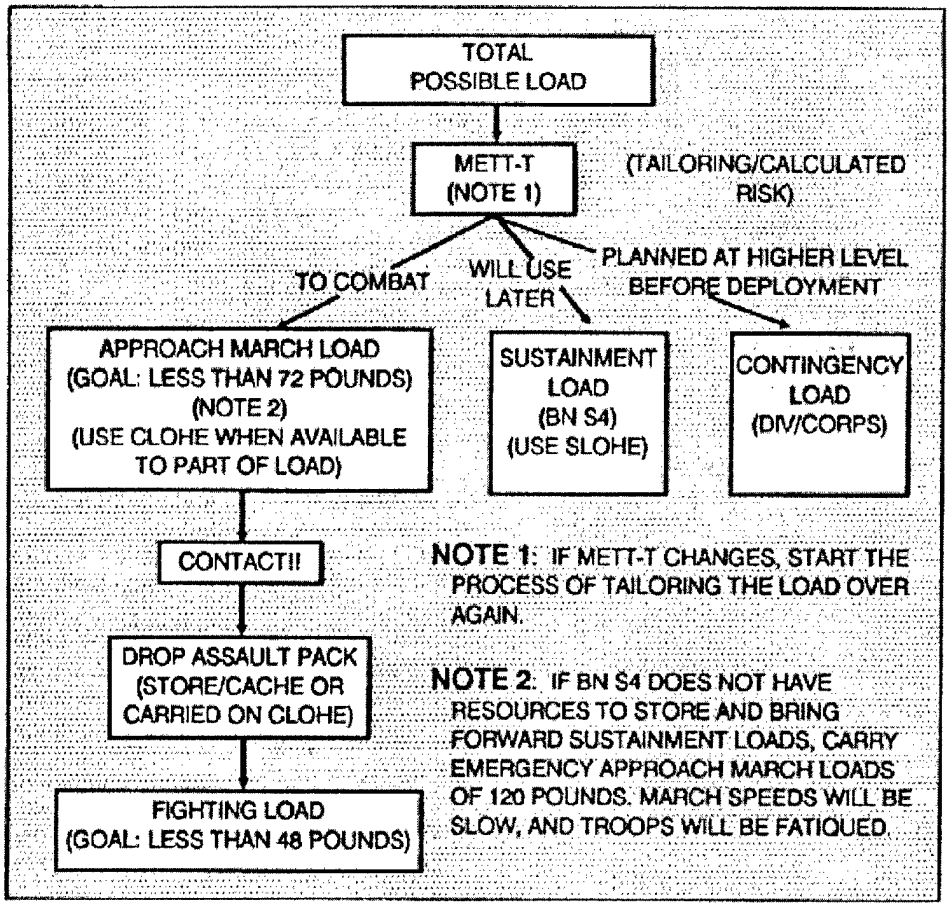


Figure 5-3. Load echelon diagram.

	RISK ASSESSMENT		
1 FACTOR/QUESTION	2 TAKE	3 LEAVE	4 REMARKS
MISSION			
a. To defeat the enemy in close battle.	Reduced munitions Water	Food Threat protection Environmental protection	Mobility is paramount with 40-pound loads
b. To get there quickly.		Reserve munitions	

Table 5-3. Risk judgments in load planning.

	RISK ASSESSMENT		
1 FACTOR/QUESTION	2 TAKE	3 LEAVE	4 REMARKS
c. To sustain stealth operations independent of resupply.	Water Food Environmental protection Reduced munitions Camouflage	Reserve munitions Threat protection	Maximum loads depend on speed/distance for dynamic operations.
d. To carry maximum combat power.	Munitions Water Threat protection Limited environmental protection	Food	Maximum loads depend on speed/distance for dynamic operations.
e. For static operations.	Basic load and reserve of ammunition Barrier materiel Maximum threat protection Some comfort items to achieve quality rest periods Water Food		
RESUPPLY			
a. Reliability.	Less amounts of all classes of supply		Best solution is for the commander to control his own immediate resupply transport resources.
b. On call.		Reserve munitions	

Table 5-3. (Continued.)

	RISK ASSESSMENT		
1 FACTOR/QUESTION	2 TAKE	3 LEAVE	4 REMARKS
c. Planned.		Food Environmental protection Quality rest Equipment	
DEFEAT THE THREAT			Basic load must be tailored to meet the threat.
Antipersonnel	Small-arms/ grenades/ Claymores		
Antiemplacement Antisoft vehicle Antimateriel Antitank Antiair	Grenades/66-mm Rocket/ demolitions AT4/machine gun ammunition Demolition/ grenades Dragon/AT4 Machine gun ammunition		
SURVIVE THE THREAT			Soldiers take the minimum of threat protection.
Ballistic PASGT vest protection			PAGST vest reduces casualties by 50 percent during bombardment.
NBC protection	Protective mask	MOPP suit if enemy use of chemical weapons is low	

Table 5-3. (Continued.)

	RISK ASSESSMENT		
1 FACTOR/QUESTION	2 TAKE	3 LEAVE	4 REMARKS
Electronic Warfare	VINSON		Secure communications probably not viable below bde/bn level in light units unless COMSEC is of high priority to achieve mission.
TERRAIN			
Flat, improved road			Terrain may cause an increase of time required to conduct march; resupply cross country may be difficult.
Cross country	Water consumption increased		
Hills, improved road			
WEATHER			Energy must be maintained to fight by control of loads/march speeds.
a.Environmental Survival:			

Table 5-3. (Continued.)

	RISK ASSESSMENT		
1 FACTOR/QUESTION	2 TAKE	3 LEAVE	4 REMARKS
Exposure	Poncho Extra clothing Limited number of sleeping bags		Work rates should be reduced.
Heat exhaustion	Water	Threat protection	
Disease	Water purification tablets Mosquito nets		When in combat, men with excess fat can survive off natural reserves.
b. Sustenance	High-caloric food		Average of four hours quality sleep each day.
c. Quality rest	Sleeping bags/ pads		

Table 5-3. (Continued.)

APPENDIX D

ASSEMBLY AREAS

The battalion occupies an assembly area for security while preparing for future operations. Preparations include reorganizing, issuing orders, receiving and issuing supplies, and maintaining vehicles and equipment. Occupation of an assembly area can be directed by a higher commander or by the battalion commander. (See FM 7-20 for a detailed discussion on the occupation of assembly areas.)

D-1. CHARACTERISTICS

A force in an assembly area is given some security by being behind friendly lines, and by having another friendly element between it and the enemy. Regardless, the battalion must defend itself should the enemy break through, bypass forward defenses, drop airborne or air assault forces, or be seen from the air. It normally uses the same techniques used in the perimeter defense. The assembly area should provide--

- Concealment from air and ground observation.
- Cover from direct fire.
- Space for dispersion against massed chemical or nuclear fires.
- Adequate entrances, exits, and internal routes.
- Good drainage and soil conditions that support battalion or attached vehicles.

D-2. QUARTERING PARTY

Before the main body leaves the assembly area, the march commander sends a quartering party (or advance party) to the forward assembly area. The reconnaissance and the quartering parties do not travel as part of the march column. They precede the main body and move by infiltration.

a. A quartering party normally comprises an OIC (HHC commander, XO of the HHC, or battalion S1), security element, communications and medical personnel, and required staff section and subordinate unit personnel. Its mission is to reconnoiter the new area and to guide march elements to the assembly area. The commander of the quartering party must be told the route, order of march, and estimated time of arrival of the main body. A battalion quartering party consists of the quartering parties from each subordinate company. A company quartering party consists of one element from each platoon.

b. The quartering party should have enough guides, markers, and pioneer tools to improve the new area. As march elements clear the RP, quartering party members waiting in covered and concealed positions move out to guide elements to selected areas without halt.

c. To reduce being seen by the enemy during occupation, the quartering party reconnoiters. Then, it organizes the assembly area before the battalion arrives. The party ensures the area has the required features. It selects areas for each company, CP, and CS and CSS element. The party then guides arriving elements into position. This avoids stopping moving units on an exposed route of march.

D-3. ORGANIZATION

The assembly area is organized by assigning companies sectors of the battalion perimeter or dispersed company assembly areas (Figure D-1). It must allow for good dispersion of all elements of the battalion.

a. Security can be augmented by visual observation, sensors, and surveillance devices. Road security is the duty of the company in whose sector the units pass through. Contact points for units can also be named to help in coordinating security. All exits and entrances to the assembly area are strictly controlled. OPs cover key terrain features and avenues of approach.

b. The scout platoon maybe tasked to reconnoiter routes of movement to counterattack positions, defensive positions, or passage lanes. It may also provide security by setting up OPs, roadblocks, or traffic control points.

c. CS elements are positioned with units they are to support. They are located to provide support to all elements of the battalion.

d. The battalion CP and trains are centrally located for security, which helps to plan, issue orders, distribute supplies, and so on.

e. Communication between elements is by wire or by messenger. Radio is used only in an emergency.

Figure D-1. Assembly areas.

f. Company assembly areas should be large enough to allow for dispersion and for cover and concealment from observation and enemy direct fires. Company positions within the battalion assembly area should aid movement for future operations.

g. Placement of mortars should consider minimum employment distance. This may result in mortars positioned in adjacent company sectors where emplacement must be coordinated. Mortars are normally employed with two-thirds of their range forward. This covers the center of the company sector as the main direction of fire.

h. The quartering party must prepare for occupation of an assembly area during limited visibility. The vital handoff occurs at the RP. Coordination allows for a smooth passage of the march unit through the RP without halts. Guides meet the march unit at the RP. They lead the unit along a marked route to the assembly area. Subunit guides, using planned colored lights or flash recognition signals, link up with platoons/sections and lead them to prepared sectors. Individual, vehicle, crew, or squad positions are marked with stakes, chemical lights, engineer tape, or prelaid communication wire.

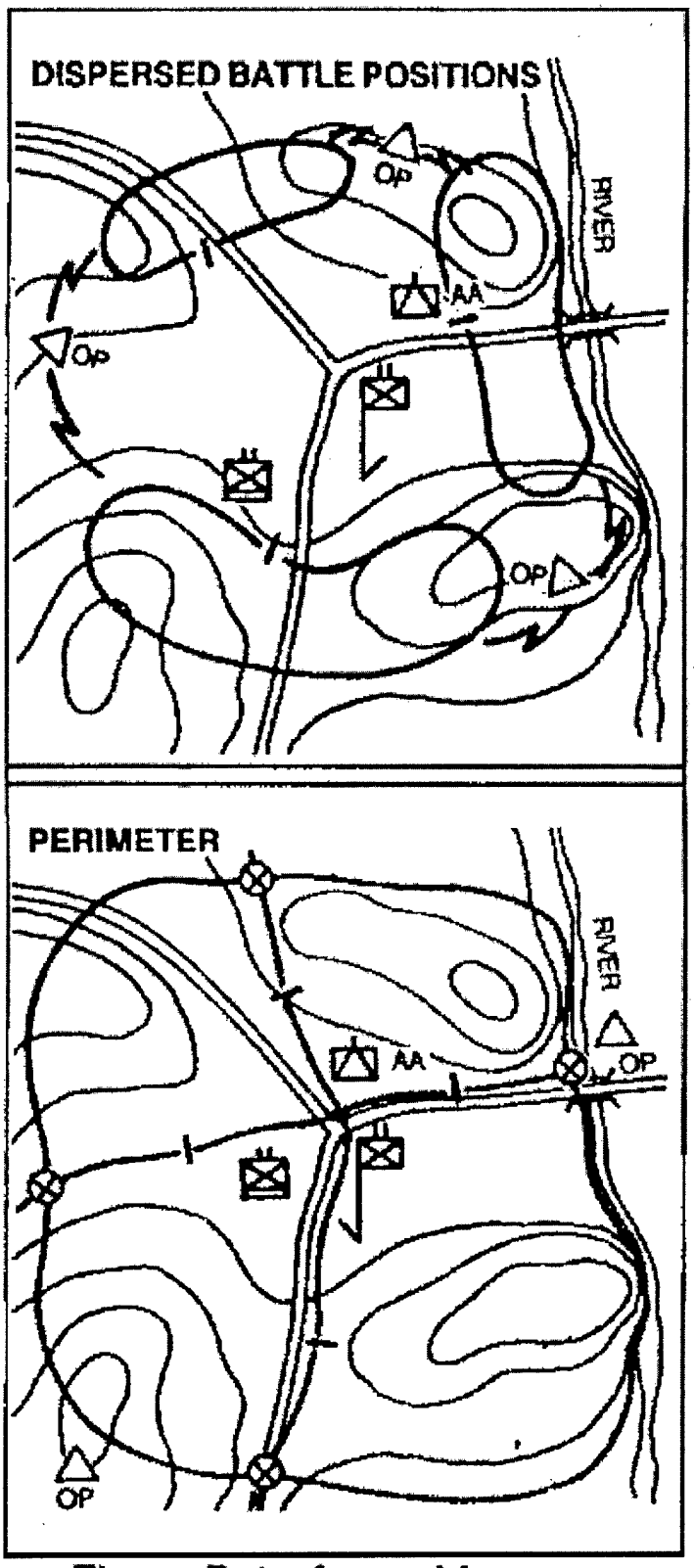


Figure D-1. Assembly areas.

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APPENDIX C
TECHNICAL REPORT

Technical Report x.dot, Rev. A, Effective 01-06-03

RECORD NO.

AM-00002

TITLE OF TECHNICAL REPORT		REVISION
Hypothermia Induction Devices Electrical Power Requirements		0
PROJECT OR PROGRAM NAME	PROGRAM NUMBER	DATE
Hypothermia	2003-01	
DESCRIPTION OF TASK PROMPTING TECHNICAL REPORT	NAME OF AUTHOR	
System Design	Mike Pitsakis	

TECHNICAL AREA

SUBJECT AND KEY TECHNICAL WORDS

Power, amperage

DOCUMENTATION TYPE

☐ Validation	☐ Error Budget	☐ Reliability	☐ Sensitivity
☐ Verification	☐ Product Support	☐ Risk Analysis	☒ Other

ASSOCIATED REPORTS

TR_Hypo020727 CR.doc

Abstract

Power requirements for the Mild-Moderate and Profound Hypothermia Induction Devices are estimated. The Mild-Mod device power requirements are excessive making field use impossible. Even vehicle operation will be challenging. In the Profound device case, up to 6 A of current is required if the pumping system and the cooling systems do not need to be on at the same time. The energy storage device for 1-hr operation (6 Ah) will be much smaller and lighter than and for 6-hour operation (36 Ah).

APPENDIX C

Background

Either Mild-Mod or Profound Hypothermia Induction device employs a cooling and a pumping system. While similar pumping systems (that operate at 12 VDC) are used for either case, the thermal power capability and electrical power requirements of the Mild-Mod cooling system are much larger. Therefore the Mild-Mod operates at 120 VAC while the Profound cooling system operates at 12 VDC. The design a scheme that accommodates powering of these devices by an energy storage device and determining power requirements, necessitates a block diagram of the devices and of the power distribution for each case.

Introduction

A block diagram of the Mild-Mod system for line operation is shown in Fig. 1. The Cooling, Pumping, as well as the electronics systems are shown. Because the system is powered from the line EMC filtering, inrush current protection, and line isolation are required by medical device regulation. An AC/DC converter (power supply) is also required for powering the electronics and pump motor. The electronics include a DC/DC converter for powering up the controllable valve of the refrigeration system. The compressor of the refrigeration system operates at 120VAC.

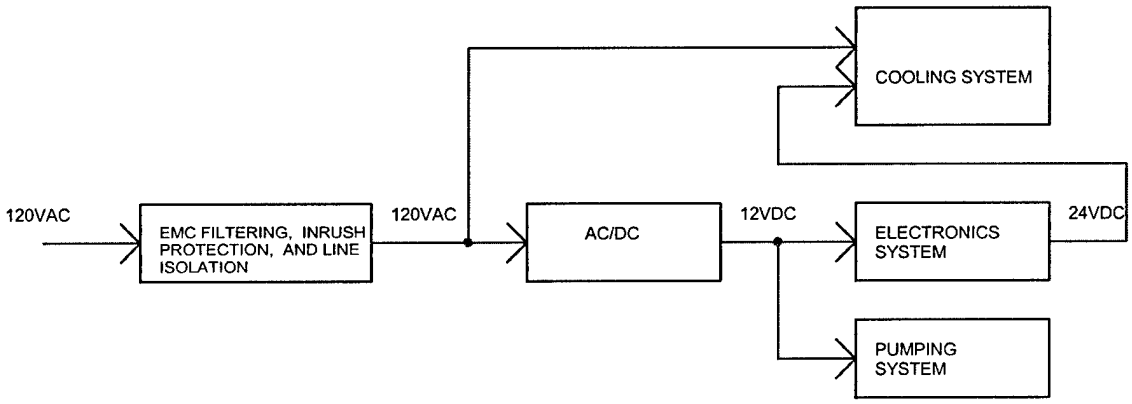

FIGURE 1, BLOCK DIAGRAM SHOWING POWER CONNECTIONS FOR LINE OPERATION SYS 1 (MIXED AC AND DC COMPONENTS)

If the same system is to operate from an energy storage device with 12 VDC output, the connections shown in the block diagram of Fig 2, will be necessary. Here a DC/AC converter (inverter) is needed to provide 120VAC for the compressor of the cooling system.

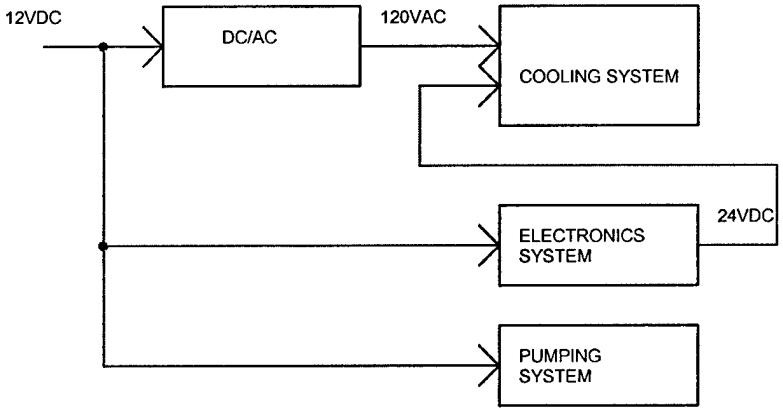

FIGURE 2, BLOCK DIAGRAM SHOWING POWER CONNECTIONS FOR BATTERY OPERATION SYS 2 (MIXED AC AND DC COMPONENTS)

The Profound system can operate entirely at 12VDC as shown in Fig. 3. Line operation is accomplished with the addition of an AC/DC converter (power supply).

APPENDIX C

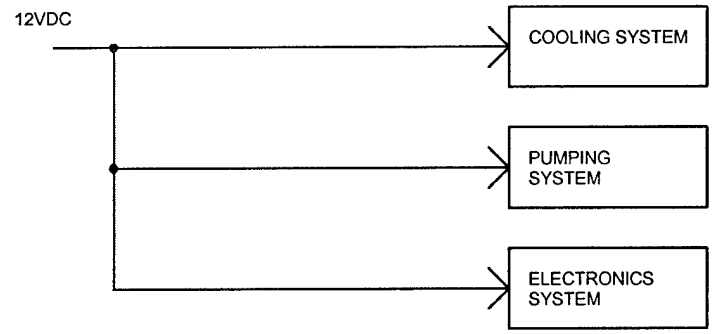

FIGURE 3, BLOCK DIAGRAM SHOWING POWER CONNECTIONS FOR BATTERY OPERATION SYS 3 (ALL DC COMPONENTS)

Purpose

In this work the electrical power requirements of the Mild-Mod and Profound Hypothermia Induction devices are determined with extension to possible portable operation.

Description of Apparatus and Setup

Not Applicable.

Summary of Data and Results

For the three systems shown in Fig. 1, Fig. 2, and Fig. 3, the power requirements and current draw for each subsystem are summarized in the table shown in Fig. 4. The DC/AC and AC/DC converters are included because they dissipate power as well (efficiency 70 – 90%). The last column has values of the fraction of the total power dissipated by each component.

SYS 1	Power (W) @ 12VDC	Draw (A) @ 12VDC	Power (VA) @ 115VAC	Draw (A) @ 115VAC	% power
Electronics System	4.0	0.3	5.0	0.0	0.00
Pumping System	68.0	5.7	85.0	0.7	0.04
Cooling System 1	0.0	0.0	2200.0	19.1	0.92
Cooling System 2	48.0	4.0	60.0	0.5	0.03
AC/DC Converter	24.0	2.0	30.0	0.3	0.01
Total	144.0	12.0	2380.0	20.7	1.00

SYS 2	Power (W) @ 12VDC	Draw (A) @ 12VDC	Power (VA) @ 115VAC	Draw (A) @ 115VAC	% power
Electronics System	4.0	0.3	5.0	0.0	0.00
Pumping System	68.0	5.7	85.0	0.7	0.03
Cooling System 1	0.0	0.0	2200.0	19.1	0.89
Cooling System 2	48.0	4.0	60.0	0.5	0.02
DC/AC Converter	0.0	0.0	115.0	1.0	0.05
Total	120.0	10.0	2465.0	21.4	1.00

SYS 3	Power (W) @ 12VDC	Draw (A) @ 12VDC	Power (VA) @ 115VAC	Draw (A) @ 115VAC	% power
Electronics System	4.0	0.3	0.0	0.0	0.03
Pumping System	68.0	5.7	0.0	0.0	0.49
Cooling System	67.2	5.6	0.0	0.0	0.48
Total	139.2	11.6	0.0	0.0	1.00

FIGURE 4

Conclusions

The requirements for an energy storage device that powers the Profound or the Mild-Mod system are summarized in the table of Fig. 5.

APPENDIX C

To relax the current draw, in the Profound device case, to 6 A and the power to 72 W, I assume that there is no need for the pump and for the refrigerator to be on at the same time. The energy storage device for 1-hr operation will be much smaller and lighter than and for 6-hour operation.

The Mild-Mod device poses excessive power requirements making field use impossible. Even vehicle use for 1-hour operation will be challenging.

	Voltage (V)	Current (A)	Power (W)	Capacity 1 (A h)	Capacity 2 (A h)	Energy 1 (W h)	Energy 2 (W h)
Profound	12	6	72	6	36	72	432
Mild-Mod	12	220	2640	220	1320	2640	15840

1 For 1 hour operation **2** For 6 hour operation

FIGURE 5

Suggestions for Further Work

The results and conclusions need be re-evaluated if the cooling requirement specifications change.

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APPENDIX D
TECHNICAL REPORT

Technical Report x.dot, Rev. A, Effective 01-06-03

RECORD NO.

AM-00003

TITLE OF TECHNICAL REPORT		REVISION
Energy Storage Devices for Possible Use in Portable Hypothermia Device		0
PROJECT OR PROGRAM NAME	PROGRAM NUMBER	DATE
Hypothermia	2003-01	7/8/03
DESCRIPTION OF TASK PROMPTING TECHNICAL REPORT		NAME OF AUTHOR
Selection of an electrical power source for a portable Hypothermia Induction device		Mike Pitsakis
TECHNICAL AREA		
Electrical Energy Storage		
SUBJECT AND KEY TECHNICAL WORDS		
Energy Storage Device, Battery, Fuel Cell, Supercapacitor		

DOCUMENTATION TYPE

☐ Validation	☐ Error Budget	☐ Reliability	☐ Sensitivity
☐ Verification	☐ Product Support	☐ Risk Analysis	☒ Other

ASSOCIATED REPORTS

TR_Hypo 030708 MP, TR_Hypo 020727 CR.doc

Abstract

Battery, Fuel Cell, and Supercapacitor technologies are described, compared, and evaluated for the purpose of determining possible use in a portable Hypothermia Induction Device. Fuel Cell and Supercapacitor technologies are still evolving or not applicable yet. Batteries are the only alternative with Lithium Ion the first choice, Nickel Metal Hydride the second, and Lead Acid the third.

APPENDIX D

Background

The portable hypothermia induction device will be powered by a rechargeable or reusable energy storage device. The energy storage device apart from providing the required voltage and current for the required period of time (see Fig. 1 for requirements[1]) must be as small in size and as lightweight as possible. In addition it will have to operate over a wide temperature range for large number of cycles, have a long service life, low self-discharge rate, be safe to the operator and patient and also be environmentally friendly.

Such a device, however, is only ideal, and trade offs are in order. Hence insight in this field is necessary in order to reach sound decisions. We will therefore define the terminology used in the field and then discuss several of the technologies currently in use or in development. Then decide which technology is most suitable for use in the portable hypothermia induction device.

	Voltage (V)	Current (A)	Power (W)	Capacity 1 (A h)	Capacity 2 (A h)	Energy 1 (W h)	Energy 2 (W h)
Profound	12	6	72	6	36	72	432
Mild-Mod	12	220	2640	220	1320	2640	15840

1 For 1 hour operation **2** For 6 hour operation

FIGURE 1

Battery: An energy storage device that converts chemical energy into electrical energy on demand by use of redox (reduction/oxidation) reactions. Batteries are divided into primary (single use) and secondary cells (rechargeable).

Fuel Cell: An energy storage device similar to a battery except that reactants are supplied to it from an external source.

Supercapacitor: A capacitor of enormous capacitance capable of storing a large amount of energy.

Cathode: The positive electrode of a galvanic cell where reduction occurs during discharge.

Anode: The negative electrode of a galvanic cell where oxidation occurs during discharge.

Discharge curve: A plot of cell voltage Vs time for fast and slow discharge rates. See Fig. 2

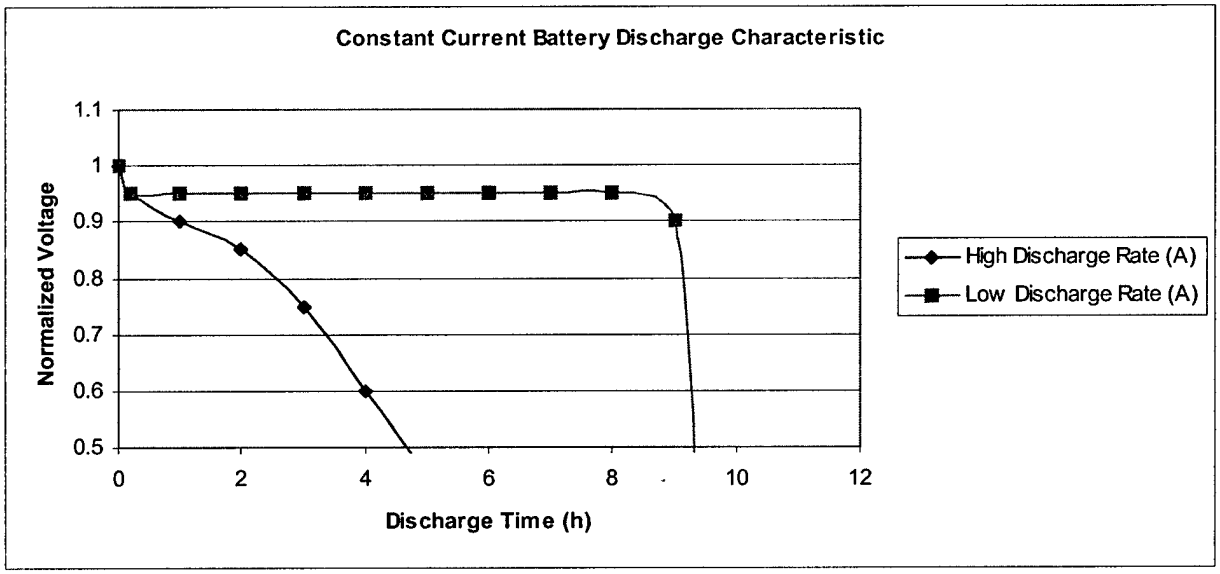

FIGURE 2

Power: P = V I, in units of Watts. Where V is cell voltage in Volts and I is cell current in Amperes.

[1] See TR_Hypo 030708 MP.doc

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Energy: E = P t in units of Watt Hours (W h).
Energy Density (or specific energy): ρ_e = E / m in units of W h / kg. Where m is mass. This is a measure of the energy stored per unit mass. Sometimes it is expressed in terms of volume rather that mass.

Power Density (or specific power): ρ_p = P / m in units of W / kg. This is a measure of how fast energy can be delivered from the device per unit mass. Sometimes it is expressed in terms of volume rather that mass.

Ragone Plot: A plot of energy density Vs power density.

Efficiency: The ratio of the maximum energy that may be stored in a battery to the energy required for charging it. It's less than 1 because some energy is lost as heat.

Effective Internal Resistance: The lumped source resistance of the cell in Ω.

Capacity (A h): The current available from a fully charged battery over a period of time in units of A h. Capacity is specified by manufacturers at different discharge time intervals. The accepted capacity rating time period is the "20-hour rate" but sometimes ratings at the 10, 6, or 5-hour rate and 1-hour rates are also given for comparison and for different applications. Amp-hours are specified at particular rates because of the Peukert Effect. The Peukert value is directly related to the internal resistance of the battery. The larger the internal resistance, the higher the losses while charging and discharging, especially at higher currents. This also means that the faster a battery is used (discharged), the lower the AH capacity. In other words if a battery is rated 100 Ah at 20 h its 1-hour rating will a lot less.

CA, CCA, and MCA: Starting batteries are usually rated as CCA (Cold Cranking Amps) or MCA (Marine Cranking Amps), which is the same as CA. CA and MCA ratings are referenced at 32°F, while CCA is referenced at 0°F.

Trickle Charge: A low overcharge current continuously applied to a battery in order to keep it at full charge.

DOD: Depth of Discharge refers to how low a battery can be discharged. It varies among battery types. Note that a discharged battery can register 50 - 80% of its fully charged voltage and still be 100% out of charge.

Number of cycles: Charge/discharge cycles that can be obtained for secondary cells.

Self-Discharge Rate: Reflects how rapidly the cell loses potential while unused in the charged state.

Temperature effects: Batteries operate best at room temperature. At higher temperature provide more energy but with reduced number of cycles. They are best preserved at low temperatures but most loose their energy until returned to normal temperatures.

Safety: Relating to failure modes and rates, toxicity of materials, reactive components, short-circuit, or puncture behavior.

Environmental concerns: Relating to disposability and recyclability.

Introduction

Batteries

Na S – Secondary

Sodium Sulfur batteries use a molten sodium metal anode, molten sulfur cathode, and a solid alumina electrolyte. Some obvious advantages of these materials are the low potential of the Na anode and low cost of the active materials. An operating temperature of 300 - 400 °C is necessary to keep the sulfur electrode molten. The electrolyte used here is Na-beta-alumina, which is an oxide structure. Although long studied for use in electric vehicles, these cells have not been commercialized. A major disadvantage of these cells is the inherent danger of separating molten Na and S with a brittle ceramic electrolyte, as failure of this separator can lead to a highly exothermic chemical reaction.

Recently, some research efforts have focused on replacing the molten sulfur cathode with a polydisulfide such as polyethylenedisulfide, $(SSCH_2CH_2)_n$. These cells can be discharged just above the melting temperature of Na (90°C). The

discharge reaction involves scission of the S-S disulfide linkage in the polymer backbone, and charge involves repolymerization of the resulting dithiolate salt.

Ni Cd - Secondary

Nickel Cadmium batteries contain a $Ni(OH)_2$ cathode, Cd anode and aqueous KOH electrolyte. $Ni(OH)_2$ has a layered CdI_2 structure, and NiOOH is apparently a complex, multiphase material. The memory effect is an interesting phenomenon where the unused capacity of a cell cannot be utilized if the cell is not fully discharged. This is apparently related to the formation of a passive surface on the electrodes that forms a barrier to further cell reaction.

Ni MH – Secondary

The Nickel Metal Hydride cell was an adaptation of the NiCd cell that used the NiOOH electrode coupled to a H_2 fuel-cell electrode in a pressurized, sealed battery. This configuration, with cell pressures of approx. 40 atm, was only practical in selected applications, such as the aerospace industry, and was not safe for use by typical consumers. In the NiMH cell, however, the anode is a metal hydride electrode that serves as a solid source of reduced hydrogen that can be oxidized to form protons. The anodes are comprised of hydrogen storage metals: classic examples of these include Pd and $LaNi_5$, but these are not used in NiMH cells for a variety of reasons (for example the cost of Pd). The anodes used in these cells are complex alloys containing many metals, such as an alloy of V, Ti, Zr, Ni, Cr, Co, and surprisingly Fe. The underlying chemistry of these alloys and reasons for superior performance are not clearly understood, and the compositions are determined by empirical testing methods.

Li Ion – Secondary

Lithium-ion batteries are lightweight, rechargeable batteries that were developed in the early 1990s. At the core of these batteries is a lithium compound that acts as the anode, the negatively charged terminal where an electric current exits a battery to charge a device. Traditionally, lithium-ion batteries have used toxic-salts as the electrolyte for the chemical fluid that forms the internal, electrical connection between the anode and the cathode -- the cathode being the positively charged terminal where the electrical current returns to the battery.

There are two types of lithium ion rechargeable batteries available on the market: one uses a cathode material of lithium cobaltite and the other uses that of lithium manganate. Although a battery using lithium cobaltite has a high discharge energy density, this type of battery has some problems. For example, the material cost is high because cobalt, a rare metal, is used and a protection circuit is required to prevent overcharging. NEC TOKIN Corporation has solved these problems. The group is the first company in the world to succeed in putting stable spinel type lithium manganate technology to practical use. This success has lead to existence lithium manganate lithium ion rechargeable batteries using spinel type lithium manganate as the cathode material.

More recently Lithium Ion Polymer batteries have become available. In these batteries Li Ion is shuttled from Li metal electrode to metal oxide with a solid polymer as electrolyte. This electrolyte resembles a plastic-like film that does not conduct electricity but allows an exchange of ions (electrically charged atoms or groups of atoms). The polymer electrolyte replaces the traditional porous separator, which is soaked with electrolyte. The dry polymer design offers simplifications with respect to fabrication, ruggedness, safety and thin profile geometry. There is no danger of flammability because no liquid or gelled electrolyte is used. With a cell thickness measuring as little as one millimeter, equipment designers are left to their own imagination in terms of form, shape and size.

On going research promises to improve Lithium Ion batteries. A new type of electrolyte for lithium-ion batteries, developed by scientists at Brookhaven National Laboratory, is expected to produce batteries that are less expensive and more environmentally friendly. By raising the capacity of these new boron-based electrolyte batteries, researchers believe they can develop a more efficient power source for hybrid electric vehicles (HEVs) while work at Sandia is promising:

"LIVERMORE, Calif., March 6, 2003. Researchers at the Department of Energy's Sandia National Laboratories in Livermore, Calif., have developed a new class of composite anode materials composed of silicon and graphite that may double the energy storage capacities currently possessed by graphite anodes, potentially leading to rechargeable lithium-ion batteries with more power, longer life, and smaller sizes"

Note that lithium will ignite or explode on contact with water.

Pb Acid – Secondary

APPENDIX D

With the exception of some very expensive NiCd batteries, all large rechargeable batteries are Lead-Acid type. The cells are constructed from a PbO_2 cathode, Pb anode, and sulfuric acid electrolyte. Both electrodes dissolve into the electrolyte during the discharge reaction. When charged the reverse reactions occur, although overcharge will lead to the electrolysis of water and consequent production of (hazardous) $H_2(g)$ at the cathode. The electrolyte solution is typically 30% Sulfuric acid and 70% water at full charge. The plate thickness (positive plate) matters because of a factor called "positive grid corrosion". This ranks among the top three reasons for battery failure. The positive (+) plate is what gets eaten away gradually over time, so eventually there is nothing left - it all falls to the bottom as sediment. Thicker plates are directly related to longer life, so other things being equal, the battery with the thickest plates will last the longest.

Pb Acid Types

Lead acid batteries are classified by application and construction. The major applications are starting, deep-cycle, and marine. The major construction types are flooded (wet), gelled, and AGM (Absorbed Glass Mat). Flooded may be standard, with removable caps, or the so-called "maintenance free. Gelled batteries are sealed and a few are "valve regulated", which means that a tiny valve keeps a slight positive pressure. Nearly all AGM batteries are sealed valve regulated commonly referred to as VRLA, (Valve Regulated Lead-Acid). Most valve regulated are under some pressure (1 - 4 psi at sea level).

Starting Batteries

Starting (sometimes called SLI, for starting, lighting, ignition) batteries are commonly used to start and run engines. Engine starters need a very large starting current for a very short time. Starting batteries have a large number of thin plates (0.040") thick for maximum surface area. The plates are composed of a lead "sponge", similar in appearance to a very fine foam sponge. This gives a very large surface area, but if deep cycled, this sponge will quickly be consumed and fall to the bottom of the cells. Automotive batteries will generally fail after 30-150 deep cycles if deep cycled, while they may last for thousands of cycles in normal starting use (2-5% discharge).

Deep-Cycle Batteries

Deep-cycle batteries are used in solar electric (PV), backup power, and RV and boat "house" batteries. Deep cycle batteries are designed to be discharged down as much as 80% time after time, and have much thicker plates. The major difference between a true deep cycle battery and others is that the plates are solid lead plates not sponge. The popular golf cart battery is generally a "semi" deep cycle - better than any starting battery, better than most marine, but not as good as a true deep cycle solid lead plate, such the L-16 or industrial type. However, because the golf cart (T-105, US-2200, GC-4 etc) batteries are so common, they are usually quite economical for small to medium systems.

Industrial deep cycle batteries sometimes called "fork lift", "traction" or "stationary" batteries, are used where power is needed over a longer period of time, and are designed to be "deep cycled", or discharged down as low as 20% of full charge (80% DOD, or Depth of Discharge). These are often called traction batteries because of their widespread use in forklifts, golf carts, and floor sweepers (from which we get the "GC" and "FS" series of battery sizes). Deep cycle batteries have much thicker plates than automotive batteries while forklift batteries may have plates more than 1/4" thick (0.265" for example in the Rolls-Surrette) almost 7 times as thick as starting batteries. The Lead-Antimony types have a very long lifespan, but higher self discharge rates.

A deep cycle battery may be used as a starting battery, providing that allowance is made for the lower cranking amps compared to a similar size starting battery. As a general rule, if you are going to use a true deep cycle battery (such as the Concorde) also as a starting battery, it should be oversized about 20% compared to the existing or recommended starting battery group size to get the same cranking amps.

Marine Batteries

Marine batteries are hybrid starting and deep-cycle batteries, while a few (Rolls-Surrette and Concorde, for example) are true deep cycle. In the hybrid, the plates may be composed of Lead sponge, but it is coarser and heavier than that used in starting batteries. It is often hard to tell what you are getting in a "marine" battery, but most are a hybrid. "Hybrid" types should not be discharged more than 50%.

Gell Cells

Gelled batteries, or "Gel Cells" contain acid that has been "gelled" by the addition of Silica, turning the solution into a solid mass. The advantage of these batteries is that it is impossible to spill acid even if they are broken. However, there are

several disadvantages. One is that they must be charged at a slower rate (C/20) to prevent excess gas from damaging the cells. They cannot be fast charged on a conventional automotive charger or they may be permanently damaged. This is not usually a problem with solar electric systems, but if an auxiliary generator or inverter bulk charger is used, current must be limited to the manufacturers specifications.

AGM

This is a newer type of sealed Pb Acid battery having all the advantages of the gelled battery and none of the disadvantages at the same cost. They are also called "starved electrolyte", as the mat is about 95% saturated rather than fully soaked. Since the electrolyte is contained in the glass mats, it cannot spill, even if broken. In addition, since there is no liquid to freeze and expand, they are practically immune from freezing damage.

Nearly all AGM batteries are "recombinant" - that means that the Oxygen and Hydrogen recombine inside the battery. These use gas phase transfer of oxygen to the negative plates to recombine them back into water while charging and prevent the loss of water through electrolysis. The recombining is typically 99+% efficient, so almost no water is lost.

A new AGM typically self-discharges at about 1-2% per month, while an old one may be as much as 2% per week.

VRLA

The Valve Regulated Lead Acid (VRLA) battery is an AGM battery that is hermetically sealed and operate under pressure in order to recombine the oxygen and hydrogen produced during the charge process back into water. While flooded cells lose up to 1% per day due to self-discharge, VRLA batteries lose 1-3% per month. There is virtually no gassing under normal operating conditions.

Lead Acid Battery Size Codes

Batteries come in all different sizes. Many have "group" sizes, which is based upon the physical size and terminal placement. Typical BCI codes are group U1, 24, 27, and 31. Industrial batteries are usually designated by a part number such as "FS" for floor sweeper, or "GC" for golf cart. Many batteries follow no particular code, and are just manufacturers part numbers. Other standard size codes are 4D & 8D, large industrial batteries, commonly used in solar electric systems. Some common battery size codes used are listed in the table of Fig. 3 (ratings are approximate).

Size Codes	Ratings
U1	34 - 40 Ah @ 12 V
Group 24	70 - 85 Ah @12 V
Group 27	85 -105 Ah @ 12 V
Group 31	95 -125 Ah @ 12 V
4-D	180 - 215 Ah @ 12 V
8-D	225 - 255 Ah @ 12 V
T-105	180 - 220 Ah @ 6 V
L-36	340 - 415 Ah @ 6 V

FIGURE 3

Fuel Cells

All fuel cells have the same basic operating principle. An input fuel is catalytically reacted (electrons removed from the fuel elements) in the fuel cell to create an electric current. Fuel cells consist of an electrolyte material, which is sandwiched in between two thin electrodes (porous anode and cathode). The input fuel passes over the anode (and oxygen over the cathode) where it catalytically splits into ions and electrons. The electrons go through an external circuit to serve an electric load while the ions move through the electrolyte toward the oppositely charged electrode. At the electrode, ions combine to create by-products, primarily water and CO_2. Depending on the input fuel and electrolyte, different chemical reactions will occur.

Phosphoric Acid

APPENDIX D

The Phosphoric Acid Fuel Cell (PAFC) is the most mature fuel cell technology in terms of system development and commercialization activities. It has been under development for more than 20 years and has received a total worldwide investment in the development and demonstration of the technology in excess of $500 million. The PAFC was selected for substantial development a number of years ago because of the belief that, among the low temperature fuel cells, it was the only technology, which showed relative tolerance for reformed hydrocarbon fuels and thus could have widespread applicability in the near term.

Molten Carbonate

The Molten Carbonate Fuel Cell (MCFC) evolved from work in the 1960's aimed at producing a fuel cell which would operate directly on coal. While direct operation on coal seems less likely today, operation on coal-derived fuel gases or natural gas is viable.

Solid Oxide

The Solid Oxide Fuel Cell (SOFC) uses a ceramic, solid-phase electrolyte which reduces corrosion considerations and eliminates the electrolyte management problems associated with the liquid electrolyte fuel cells. To achieve adequate ionic conductivity in such a ceramic, however, the system must operate at about 1830°F (1000°C). At that temperature, internal reforming of carbonaceous fuels should be possible, and the waste heat from such a device would be easily utilized by conventional thermal electricity generating plants to yield excellent fuel efficiency.

Proton Exchange Membrane

The Proton Exchange Membrane Fuel Cell (PEFC) offers an order of magnitude higher power density than any other fuel cell system, with the exception of the advanced aerospace AFC, which has comparable performance. The PEFC can operate on reformed hydrocarbon fuels, with pretreatment, and on air. The use of a solid polymer electrolyte eliminates the corrosion and safety concerns associated with liquid electrolyte fuel cells. Its low operating temperature provides instant start-up and requires no thermal shielding to protect personnel. Recent advances in performance and design offer the possibility of lower cost than any other fuel cell system. A comparison of the fuel cell types is summarized in Fig. 4.

	PAFC	MCFC	SOFC	PEMFC
ELECTROLYTE	Phosphoric Acid	Molten Carbonate Salt	Ceramic	Polymer
OPERATING TEMPERATURE	375°F (190°C)	1200°F (650°C)	1830°F (1000°C)	175°F (80°C)
FUELS	Hydrogen(H_2) Reformate	H_2/CO/ Reformate	H_2/CO_2/CH4 Reformate	H_2 Reformate
REFORMING	External	External/Internal	External/Internal	External
OXIDANT	O_2/Air	CO_2/O_2/Air	O_2/Air	O_2/Air
EFFICIENCY (HHV)	40-50%	50-60%	45-55%	40-50%

FIGURE 4

Hydrogen gas is not a very energy-dense fuel, meaning it contains little energy per unit volume compared to a liquid fuel like gasoline or methanol. So it is difficult to fit enough hydrogen gas into a fuel cell powered car to give it a reasonable driving range. Liquid hydrogen has good energy density, but it must be stored at extremely low temperatures and high pressures; this makes storing and transporting it rather difficult. Common fuels like natural gas, propane and gasoline, and less common ones like methanol and ethanol, all have hydrogen in their molecular structure. If there were a technology that could remove the hydrogen from these fuels and use it to power the fuel cell, the hydrogen storage and distribution problem would be eliminated almost entirely. A device that performs this function is called a fuel processor, or a reformer an is in development There are a two types of reformers, one reforming methanol and the other reforming natural gas.

The molecular formula for methanol is CH_3OH. The goal of the reformer is to remove as much of the hydrogen (H) as possible from this molecule, while minimizing the emission of pollutants such as carbon monoxide (CO). The process starts with the vaporization of liquid methanol and water. Heat produced in the reforming process is used to accomplish this. This mixture of methanol and water vapor is passed through a heated chamber that contains a catalyst. As the methanol molecules hit the catalyst, they split into carbon monoxide (CO) and hydrogen gas (H_2). The water vapor splits into hydrogen gas and oxygen; this oxygen combines with the CO to form CO_2. In this way, very little CO is released, as most of it is converted to CO2.

Natural gas, which is composed mostly of methane (CH_4), is processed using a similar reaction. The methane in the natural gas reacts with water vapor to form carbon monoxide and hydrogen gases. Just as it does when reforming methanol, the water vapor splits into hydrogen gas and oxygen, the oxygen combining with the CO to form CO_2.

Neither of these reactions are perfect; some methanol or natural gas and carbon monoxide make it through without reacting. These are burned in the presence of a catalyst, with a little air to supply oxygen. This converts most of the remaining CO to CO_2, and the remaining methanol to CO_2 and water. Various other devices may be used to clean up any other pollutants, such as sulfur, that may be in the exhaust stream. It is important to eliminate the carbon monoxide from the exhaust stream for two reasons: first, if the CO passes through the fuel cell, the performance and life of the fuel cell are reduced; second, it is a regulated pollutant, so cars are only allowed to produce small amounts of it.

In order to create power, several systems must work together to provide the required electrical output. A typical system would consist of an electrical load (like a house, or an electric motor), a fuel cell and a fuel processor. Let's take the case of a fuel cell powered car. When you step on the gas (hydrogen) pedal, several things happen at about the same time. The electric motor controller starts supplying more current to the electric motor, and the electric motor generates more torque. In the fuel cell, more hydrogen is reacted, producing more electrons, which make their way through the electric motor and controller, keeping up with the increased power demand. The fuel processor starts pumping more methanol though its system, which creates more hydrogen. Another pump increases the flow of hydrogen going to the fuel cell. A similar sequence of events happens in your house when you suddenly increase the electrical demand. For instance, when your air conditioning turns on, the power output of the fuel cell has to increase quickly, or else the lights will dim until the fuel cell can catch up with the demand.

Instead of trying to improve fuel processors to the point where they will emit no regulated pollutants, some companies are working on novel ways to store or produce hydrogen on the vehicle. Ovonic is developing a metal hydride storage device that absorbs hydrogen somewhat like a sponge absorbs water. This eliminates the need for high-pressure storage tanks, and can increase the amount of hydrogen that can be stored on a vehicle.

A downside of the fuel processor is that it decreases the overall efficiency of the fuel-cell. The fuel processor uses heat and pressure to aid the reactions that split out the hydrogen. Depending on the types of fuel used, and the efficiency of the fuel cell and fuel processor, the efficiency improvement over conventional gasoline powered cars can be fairly small.

According to the fuel cell report to congress of February 2003 (http://www.eere.energy.gov/hydrogenandfuelcells/pdfs/fc_report_congress_feb2003.pdf). It is expected that the technology will mature for automotive use by 2015 while several companies partner up for fuel cell development:

"HONOLULU, Jul 3, 2003 /PRNewswire via COMTEX/ -- Hoku Scientific, Inc., announced that it has formed a joint development relationship with SANYO Electric Co., Ltd. The focus of the development effort is a new membrane electrode assembly technology for use in SANYO's Proton Exchange Membrane (PEM) fuel cell. The membrane electrode assembly will incorporate SANYO electrode technology and the Hoku Membrane, a Hoku Scientific product".

"TOKYO, Jul 02, 2003 (United Press International via COMTEX) -- Several Japanese companies are vying to become the first to develop a residential fuel cell unit that would substantially reduce electricity usage".

"SEOUL and HARTFORD, Conn., June 26, 2003 - Hyundai Motor Co. and UTC Fuel Cells, a unit of United Technologies Corp.'s UTC Power unit, have signed an agreement to jointly develop a new automotive fuel cell power plant capable of operating in freezing conditions, one of the remaining hurdles in the development of fuel cells for automobiles".

"TOKYO and South Windsor, Conn., Feb. 5, 2003 - Nissan Motor Co. and UTC Fuel Cells (UTCFC), a part of United Technologies Corporation's (NYSE: UTX) UTC Power unit, today announced the signing of an agreement to jointly develop proton exchange membrane (PEM) fuel cell technology".

"Richland, WA, Sep/2002. InnovaTek demonstrated its InnovaGen™ Fuel Processor technology today for the Army, meeting an important milestone in its development program. The company demonstrated an alpha-stage laboratory prototype that converts diesel fuel to hydrogen using a proprietary catalytic process and an advanced separations membrane. The system produces pure hydrogen at a rate of 12 liters per minute, enough to produce 1 kW electrical energy from a fuel cell".

"DEARBORN, Mich., -Ford Motor Company and Mobil Corporation announced significant progress in developing a smaller, lighter, less expensive on-board gasoline fuel processor for fuel cell vehicles".

Supercapacitors

At one end of the scale, a conventional capacitor has large power density but low energy density. At the other end, batteries have low power density and high energy density. Relative to these established technologies, supercapacitors

- promise a unique combination of high power and high energy density. The energy stored by a capacitor is related to its capacitance, C in Farads, and potential difference, V, between its electrodes as follows:
  $E = \frac{1}{2} C V^2$.
- In contrast to a battery, when a supercapacitor is charged there is no chemical reaction. The energy is stored as a charge or concentration of electrons on the surface of a material. Therefore they are designed to have large surface areas while being very thin such that the capacitance is increased and by extension the energy density. As a result they are very lightweight but tend to have lower energy densities than batteries (certainly not high enough for several applications as of now). Since the charge/discharge reaction is not limited by ionic conduction into the electrode bulk as in batteries but merely by the source and cable current capability. So capacitors can be charged or discharged at high rates and provide high power density. However the energy densities are not high enough for several applications. Also since there is no bulk change in the electrodes, the charge/discharge reactions can typically be cycled many more times than batteries (10^8 cycles per device have been achieved). Like batteries, supercapacitors suffer self-discharge because of leakage current due to finite internal effective series resistance.

Typical supercapacitor specifications are listed below.

Manufacturer: cap-xx (http://www.cap-xx.com/about/default.html)
Product Family: GW1
Capacitance (F): 0.18 to 1.6
ESR (mΩ): 20 to 60
Leakage Current (μA): <2
Short Circuit Current (A): Max. 30
Dimensions (mm x mm): 28.5 x 17
Thickness (mm): 0.81 to 1.9
Voltage (V) Nominal: 2.25
Weight2 (gm): 0.6 to 1.5
Operating Temperature (°C): -30 to +75
Storage Temperature (°C): -40 to +75
Specifications are typical at 20°C.

Maximum capacitance achieved so far is 1 μF and maximum voltage is 4.5 V. However Skeleton Technologies (http://216.239.39.100/search?q=cache:mSsUQB3dzpwJ:www.skeleton-technologies.com/docs/pdf/SuPCaP_web.pdf+supercapacitors&hl=en&ie=UTF-8) claims that they have achieved a major breakthrough in the field of supercapacitors:

"The performance of the latest Skeleton Technologies designs exceeds up to a tenfold that of the best present supercapacitors. Large energy capacity device (290kJ, 48V, 250F) made at Skeleton Technologies (1997).Organic electrolyte research· increasing electrochemical window (up to 3,5 V) creating organic salts with doubly charged ions· optimizing solvents optimizing conductivity (up to 60 millisiemens/cm)· increasing chemical stability· decreasing temperature dependence. Separator· materials research· influence of thickness influence of porosity influence of pore size and shape. Design and packaging of unit cells and stacked cells· organic systems (single cell at 3 V: energy density 9 - 11 Wh/kg, power density 7 000 - 10 000 W/kg). Water-based systems· supercapacitors with large energy capacity (48 V, 250 F) designed in 1997. Skeleton C-nanostructured carbon, a key ingredient in the new high-perfor-mance supercapacitor cell design by Skeleton Technologies. Superimposed is the approximate size of a 50 Farad, 2.5 - 3 V supercapacitor device according to the Skeleton Technologies design. The same cell design principle can be used to make high-power, high-energy supercapacitors of virtually any size, from small memory-backup devices to large units for electric and hybrid vehicles".

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Oerlikan: Specs and data on VRLA batteries (Switzerland) http://www.accuoerlikon.com/

Ultralife: Specs and data on Li Ion, http://www.ulbi.com/techsheets/UBI-5093_UBP563450.pdf

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http://www.panasonic.com/industrial/battery/oem/images/pdf/Panasonic_VRLA_Overview.pdf

Purpose

This work provides insight in energy storage devices, the existing and emerging technologies, specifications, and comparisons for the purpose of selecting the appropriate energy storage device for application in a portable hypothermia induction device.

Description of Apparatus and Setup

Not Applicable.

Summary of Data and Results

To summarize:

Sodium Sulfur (NA S) — These batteries are not very common despite their better than average characteristics but with a possible threat of explosion, it is understandable.

APPENDIX D

Nickel Cadmium (NiCd) — Mature and well understood but relatively low in energy density. The NiCd is used where long life, high discharge rate and economical price are important. Main applications are two-way radios, biomedical equipment, professional video cameras and power tools. The NiCd contains toxic metals and is environmentally unfriendly.

Nickel-Metal Hydride (NiMH) — Has a higher energy density compared to the NiCd at the expense of reduced cycle life. NiMH contains no toxic metals. Applications include mobile phones and laptop computers.

Lithium Ion (Li-Ion) — The fastest growing battery system. Li-ion is used where high-energy density and lightweight is of prime importance. The technology is fragile and a protection circuit is required to assure safety. Applications include notebook computers and cellular phones. The polymer version offers the same attributes in ultra-slim geometry and simplified packaging. Main applications are mobile phones.

Lead Acid (Pb Acid) — Most economical for larger power applications where weight is of little concern. The lead acid battery is the preferred choice for hospital equipment, wheelchairs, emergency lighting and UPS systems.

In Fig. 6, we compare the characteristics of the five rechargeable battery systems we discussed in terms of Nominal Voltage, Energy Density, Power Density, Internal Resistance, Number of Cycles, Temperature Range, and Self-discharge and in Fig. 7 we show a Ragone plot.

Type	Nominal Cell Voltage (V)	Energy Density (W h / Kg	Power Density (W / kg)	Internal Resistance/cell (mW)	Number of Cycles to 80% of initial capacity	Temperature Range (oC)	Self-discharge(%/month)
Na S	2	150	200	No Data	200	No Data	No Data
Ni Cd	1.2	80	150	40	1000	-40 to 60	20
Ni MH	1.2	120	100	60	500	-20 to 60	30
Li Ion	3.6	160	120	125	1000	-20 to 60	10
Pb Acid (AGM)	2	100	100	15	300	-20 to 60	5

FIGURE 5

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DELPHI
Automotive Systems

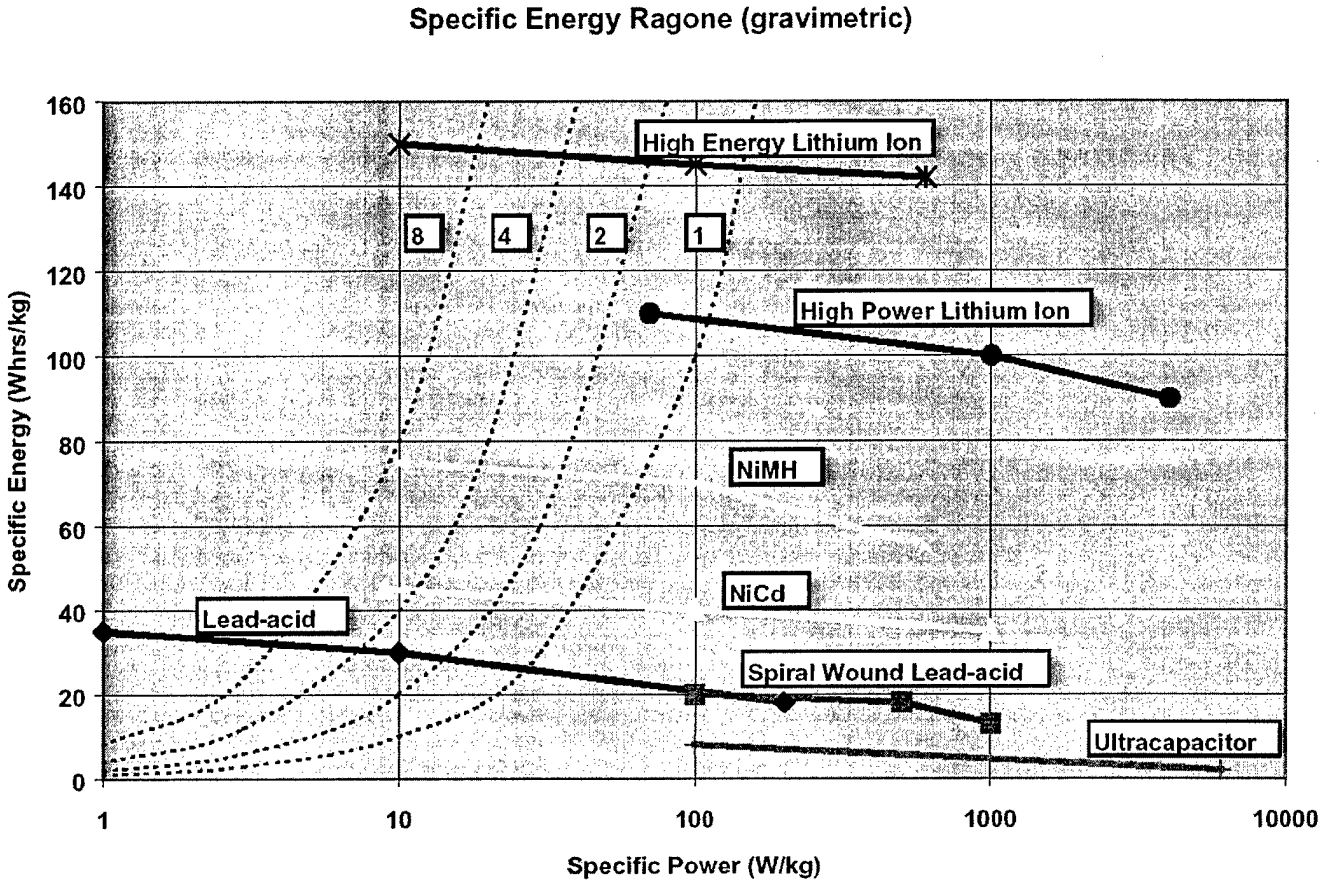

FIGURE 6, COURTESY OF DELPHI AUTOMOTIVE SYSTEMS

Note that none of the technologies have exceeded more than 35% of their theoretical energy densities.

Energy densities and power densities of supercapacitors are compared to those of batteries in the table of Fig. 5

Device	Volumetric Energy Density (W h / L)	Volumetric Power Density (W / L)
Batteries	250	150
Capacitors	5	108

FIGURE 7

Conclusions

It is apparent from the discussion, that fuel cells are not ready for commercialization. Supercapacitors have not reached the level yet to offer the required voltage or energy for use in a portable hypothermia system. Therefore for the time being a battery is the only choice for powering the portable hypothermia induction device.

Among battery types Li-Ion is the first choice with Ni MH a close second if proper sizes are available for either to power the Profound Hypothermia field portable unit or vehicle unit. The well-established deep cycle AGM or VRLA Pb Acid battery is the third choice.

The Mild-Moderate Hypothermia device does not lend to portability due to its enormous power requirements (besides size/weight). However for vehicle use, it may be powered by a 12-volt industrial sealed deep cycle AGM or VRLA Pb Acid battery.

APPENDIX D

Suggestions for Further Work

Developments in supercapacitor and fuel cell technologies as well as in Li Ion batteries need be followed to determine suitability and availability for deployment in a lighter weight portable hypothermia induction device in the future.

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APPENDIX E
TECHNICAL REPORT

Technical Report x.dot

RECORD NO.

AM-00004

TITLE OF TECHNICAL REPORT		REVISION
Temperature Control Testing of The First Mild-Moderate Hypothermia Induction Device Prototype		0
PROJECT OR PROGRAM NAME	PROGRAM NUMBER	DATE
Hypothermia	2003-01	9/3/03
DESCRIPTION OF TASK PROMPTING TECHNICAL REPORT	NAME OF AUTHOR	
Temperature Control Testing	Mike Pitsakis	
TECHNICAL AREA		
Test, Measurement		
SUBJECT AND KEY TECHNICAL WORDS		
Hypothermia, Feedback Control		

DOCUMENTATION TYPE

☐ Validation	☐ Error Budget	☐ Reliability	☐ Sensitivity
☒ Verification	☐ Product Support	☐ Risk Analysis	☐ Other

ASSOCIATED REPORTS

Abstract

The Mild-Moderate Hypothermia Induction device prototype, while in operation, has the capability of outputting temperature data to a computer in real time. Such data was collected, processed, and plotted in order to determine the precision and accuracy of the temperature controls. The result was that temperature control is better than specification (±0.5°C) with accuracy ±0.3°C from 0°C to 60°C but ±0.2°C in the 32°C to 42°C band. The average cooling/warming rate of the heat exchanger is ~1°C/min with no load and of the outflow is ~0.5°C/min @ 500 mL/min. Cooling of the device by a blower fan appears adequate as the internal temperature stayed below 35°C.

APPENDIX E

Background

The mild-to-moderate hypothermia induction device is intended to lower the core body temperature during spontaneous circulation by shunting blood flow after cardiac arrest and defibrillation, after traumatic brain injury, in acute stroke, after spinal cord injury, during surgical procedures, or other interventions.

Introduction

The first prototype of the Mild-to-Moderate hypothermia induction device has been constructed and tested. The device uses vapor-compression refrigeration cycle and a proprietary heat exchanger for cooling the blood. It uses a peristaltic pump for circulating the blood. An electronically controllable hot gas bypass valve accomplishes temperature control.

Purpose

Precise temperature control is extremely important to this device and is one of the requirements listed in the preliminary Design Requirements Document. Temperature control verification testing was performed and the results are reported here.

Description of Apparatus and Setup

The device was designed to monitor internal ambient (inside the device), heat exchanger (primary), inflow (input port of heat exchanger), outflow (output port of heat exchanger), and two patient temperatures and report these at three (3) second intervals to a computer via a serial link using the Hyperlink program. The data in the computer is saved in a text file containing time stamps of when taken. Further the data must be processed by the extract.tcl program to be formatted in columns for importation into a spreadsheet (EXCEL). YSI #44004 (2252 Ω @ 25°C, thermistor Mix "B") temperature sensors were used. These have a ±0.2°C from 0°C to 60°C, ±0.1°C from 32°C to 42°C accuracy (Yellow Spring Instruments data sheet). The Steinhart-Hart model calibrated between –15°C to 45°C is used by software to convert resistance readings to temperature. The 0.1% resistor sensor interface circuit, 12-bit A/D, and the conversion routine add another ±0.1°C to the measurement error (according to the model/simulator spread sheet Mod_Therm YSI.xls).

Summary of Data and Results

Fig.1 shows plots of the heat exchanger primary and ambient (internal) temperatures versus time. The room ambient temperature was 23.2°C (OMEGA 450 AET). The fluid flow was set at 0, for a no load condition. The heat exchanger temperature dropped from 10.0°C to –1.0°C in about eleven (11) minutes as the refrigerator free-ran (no temperature control). Then control was applied at t = 14 minutes with respect to heat exchanger temperature (feedback) with the set point equal to 7.0°C. After about 7 minutes, the temperature settled at the set point. Subsequent set points of 14.0°C, 17.0°C, 19.5°C, and 20.0°C were also reached based on this rate. Finally the refrigerator was allowed to free-run again. The heat exchanger temperature dropped rapidly from 20.0°C to about 10.0°C and then at half the rate to 7.0°C. On average, the cooling or heating rate of the heat exchanger primary is ~1°C/min.

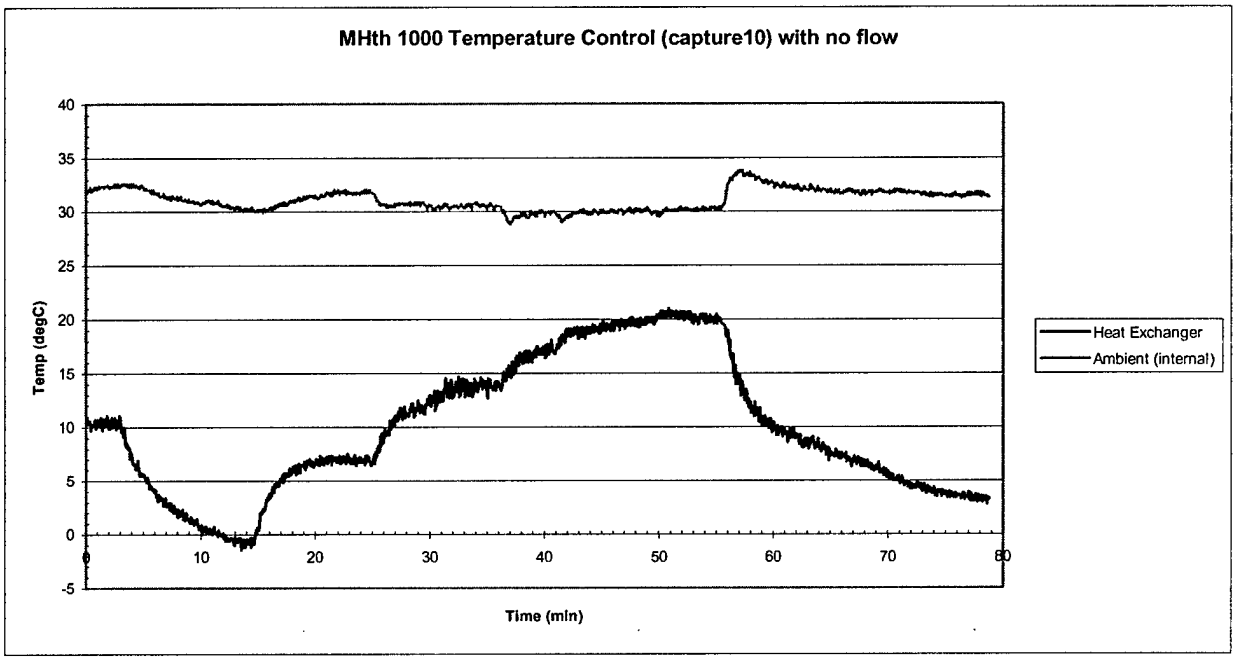

Figure 1.

APPENDIX E

Fig. 2 shows plots of the heat exchanger, ambient (internal), inflow, and outflow temperatures versus time. The room ambient in this case was 24.1°C (OMEGA 450 AET). The fluid flow was set at 500 mL/min. The refrigerator was allowed to free run (no temperature control) then control was applied at t = 22 min with respect to outflow temperature (feedback) with set point equal to 17.0°C. The outflow temperature climbed from 15.0°C to the set point in four (4) minutes just as the heat exchanger did. Similar response was observed at set points of 19.5°C and 21.0°C. The rate of cooling or warming of the outflow temperature is not constant but is equal to ~0.5°C @ 500 mL/min on average. The inflow temperature kept dropping as the outflow increased because the fluid was drawn from and dumped into the same bucket. It appears that the two temperatures are reaching equilibrium asymptotically as expected.

In either case, the internal ambient temperature appears to increase when the heat exchanger temperature decreases (compressor works harder) and vice versa. The temperature in no case however exceeded 35°C.

The heat exchanger temperature data is noisy because of the vibration produced by the compressor (all temperature sensors and readout circuits are similar).

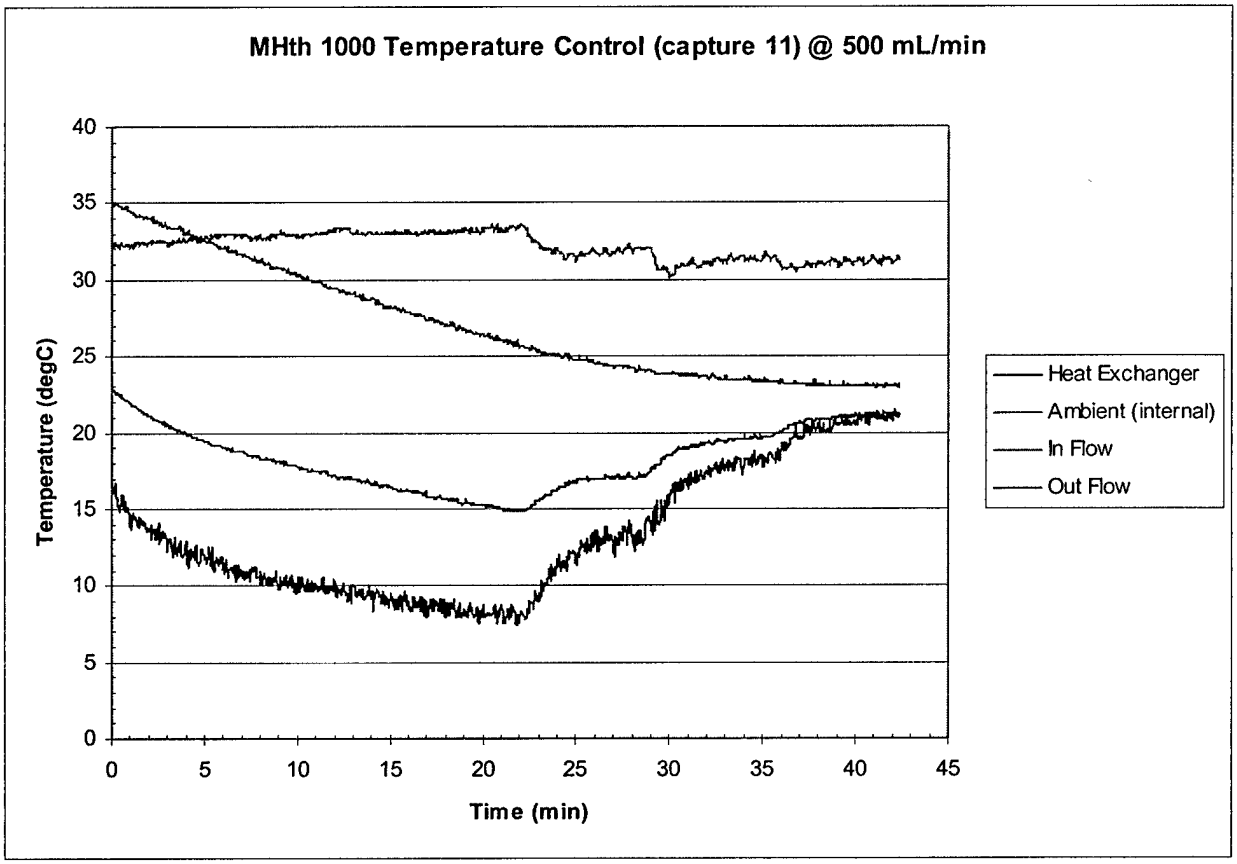

Figure 2.

Conclusions

Temperature control is better than specification (±0.5°C). Accuracy is ±0.3°C from 0 to 60°C but ±0.2°C in the 32 to 42°C band.

The average cooling/warming rate of the heat exchanger is ~1°C/min with no load and of the outflow is ~0.5°C/min @ 500 mL/min. Cooling of the device by a blower fan appears adequate as the internal temperature stayed below 35°C.

Suggestions for Further Work

Temperature tests must be repeated in subsequent prototypes to verify compliance with specification requirements. Also it is important to fine-tune the control to patient temperatures when such data becomes available from the SCRR rather than relying on outflow temperature control.

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APPENDIX F
TECHNICAL REPORT

Technical Report x.dot

RECORD NO.

AM-00006

TITLE OF TECHNICAL REPORT		REVISION
Profound Hypothermia Device Cold Box Calculations		0
PROJECT OR PROGRAM NAME	PROGRAM NUMBER	DATE
Emergency Hypothermia	2003-1	9/11/03
DESCRIPTION OF TASK PROMPTING TECHNICAL REPORT		NAME OF AUTHOR
Design of Prototype Profound Hypothermia Induction Device		Ralph Gill

TECHNICAL AREA

Heat Loss, Thermal Tranmission

SUBJECT AND KEY TECHNICAL WORDS

Thermal,Heat, Cold box, Cooling, Requirements

DOCUMENTATION TYPE

☐ Validation	☐ Error Budget	☐ Reliability	☐ Sensitivity
☐ Verification	☐ Product Support	☐ Risk Analysis	☒ Other

ASSOCIATED REPORTS

TR_Hypo 030606 MP.doc

Abstract

This report presents the heat gain calculations from the profound hypothermia induction device cold box. This heat gain will determine the amount of cooling required and thereby the capacity and size of the cooling means. The results of the calculation indicate that 20 W of power are required to maintain 20 L of fluid at 5°C. Therefore the Danfoss BD50 compressor that we plan to use is sufficient.

APPENDIX F

Background

The profound hypothermia induction device must maintain the temperature of 20 liters of fluid at 5°C in an ambient of 35°C. Refer to technical report TR_Hypo 030606 MP.doc for preceding work.

Introduction

Assuming a cold box of specific dimensions to contain a 20 liter bag of fluid and at the same time allow for access to the pump and tubing and assuming 2" of polyurethane foam insulation, we calculate the heat conduction across the walls.

Purpose

The purpose of this work is to furnish a basis for determining the required heat pumping capacity of the cooling means.

Description of Apparatus and Setup

The following calculations define the heat gain through the walls of the cold box.

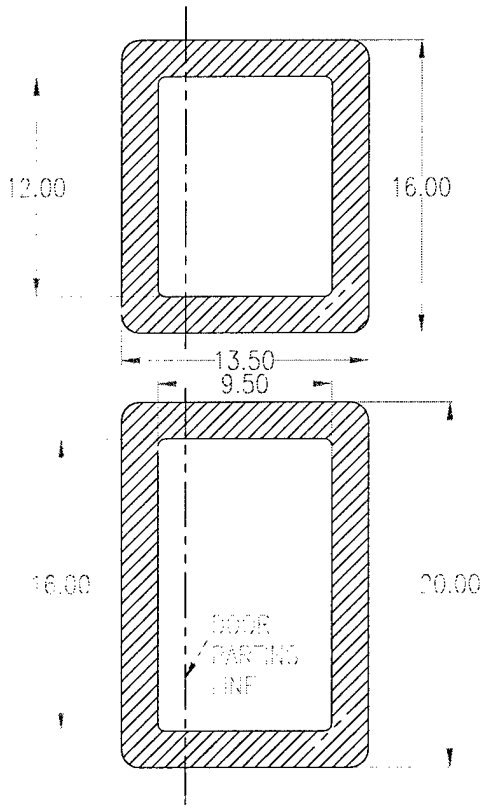

Fig. 1. Cold Box configuration

Box dimensions

1. Outside shell 20"X16"X13.5"
   Surface area =1612 sq in = 11.2 sq ft

Material 3003-0 Aluminum alloy .09 thick

2. Inside shell 16"X12"X9.5"
   Surface area=916 sq in = 6.36 sq ft
   Material 3003-0 Aluminum alloy .09 thick

3. Polyurethane foam insulation 2" thick between shells

The mean surface area for the inner and outer shells is (11.2+6.36)/2 = **8.78 sq ft**
We will use this area in our calculations.

Heat Gain

We will ignore the thermal resistance of .09 thick aluminum; it is very small compared to the foam insulation.

- **Q = K ΔT**
  Where
  Q = heat flow
  K = the thermal conductivity of the material
  ΔT= the temperature differential

No experimental work done.

Summary of Data and Results

Given:

Temperature differential **ΔT** = 72°F
K=.18 BTU-in/sq. ft-hr-°F; for polyurethane closed cell foam

- **Then Q=** (.18 X 8.78 sq. ft x 72 °F)/2 in = 56.89 BTU/hr = **16.7 W**
  This is the heat gain through the foam. Another source of heat gain is through the door seal. The door seal loss can be estimated at .5W/linear foot. From the dimensions above, the linear length of the seal is 6 ft X.5 = **3W**
  Then the total gain is 16.7 + 3 = **20W**

Twenty watts is the total heat gain and thus is the amount of heat that the cooling means is required to pump in order to maintain the temperature difference.

Conclusions

The Danfoss BD50 compressor that we plan to use is sufficient to maintain the box temperature with about 25 watts to spare. This compressor is capable of pumping approximately 45 Watts under these conditions,

Suggestions for Further Work

No further work is required.

ARDIEM MEDICAL

APPENDIX G
TECHNICAL REPORT

Technical Report x.dot, Rev. A, Effective 01-06-03

RECORD #
AM-00007

TITLE OF TECHNICAL REPORT		REVISION
Profound Hypothermia Induction Prototype Device Weight Analysis		0
PROJECT OR PROGRAM NAME	PROGRAM NUMBER	DATE
Emergency Hypothermia	2003-01	9/11/03
DESCRIPTION OF TASK PROMPTING TECHNICAL REPORT	NAME OF AUTHOR	
System Design	Ralph Gill	
TECHNICAL AREA		
System Engineering		
SUBJECT AND KEY TECHNICAL WORDS		
weight, pound, system, reduction		

DOCUMENTATION TYPE

☐ Validation	☐ Error Budget	☐ Reliability	☐ Sensitivity
☐ Verification	☐ Product Support	☐ Risk Analysis	☒ Other

ASSOCIATED REPORTS

Abstract

This report addresses the final weight of the profound hypothermia prototype device, and addresses the possible methods of reducing weight and size. The prototype device weight is estimated from existing part weights and estimates of additional parts. The conclusion from this analysis is that the existing prototype design is heavier than desired and the weight must be reduced in subsequent devices.

APPENDIX G

Background

The Profound Hypothermia Induction Device is ultimately desired to be minimum weight. The first prototype is being constructed from readily obtainable commercial parts and exceeds the desired weight and dimensions.

Introduction

The prototype device weight is estimated from existing part weights and estimates of additional parts.

Purpose

The purpose of this work is to obtain the final weight of the profound Hypothermia Induction prototype device and to consider methods of reducing the weight and dimensions.

Description of Apparatus and Setup

N/A

Summary of Data and Results

The following table itemizes the estimated and measured weights of the system parts and subassemblies.

ITEM	EST. WEIGHT (LB)
compressor/condenser	12.5
evaporator	1.5
coldbox outer shell	10
coldbox inner shell	7
coldbox insulation	1
cold box lid	4
box mounting hardware	1
support frame	40
peristaltic pump and motor	8
controls/readouts	1
panels	4
power supply	3.5
electronics/PCBs	1
Misc. hardware	2
Total	96.5

Conclusions

The conclusion from this analysis is that the existing prototype design is heavier than desired and the weight must be reduced in subsequent devices.

Suggestions for Further Work

Further work is required on the design in order to reduce weight. The areas in which weight can be reduced and possible means of reducing the weight are shown below.

1. Fabricate the cold box and part of the enclosure from thermo-formed or other molded plastic technique. The use of expanded plastic will also reduce the insulation requirements. This use of plastic will remove about 20 pounds from the prototype weight.
2. Replace the pump and motor with a custom design. This change should reduce the weight 3 to 4 pounds.
3. By using the molded plastic for a portion of the enclosure the support frame would be reduced in weight 15 to 20 pounds.

The changes alone would reduce the system weight by 38 to 44 pounds.

ARDIEM

DESIGN REQUIREMENTS DOCUMENT

Design Requirements x.dot

Mild-to-Moderate Hypothermia Induction Device
Program No. 2003-01

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1. Product Functional Requirements

1.1 Maintainability Requirements

1.1.1 Operator Maintenance

1. Operator maintenance will only be cleaning the surfaces of the device in accordance with the operator's guide.
2. Describe operator maintenance in the operator's guide.

1.1.2 Customer Support Maintenance

1. There are no customer support maintenance requirements. The operator performs all preventative and periodic maintenance.

1.1.3 Verification and Validation

1. Perform verification of Maintainability Requirements on Engineering Prototypes. Confirm verification on Manufacturing Prototypes if necessary.
2. Validate the Maintainability Requirements on a Manufacturing Prototype.

1.2 Operational Requirements

1.2.1 Intended Use

1. The device is to be used for the induction of therapeutic hypothermia. The hypothermia is induced through cooling of the blood extra-corporeally by a disposable extra-corporeal circuit and a heat exchanger.
2. The device will be applicable to 95% of the adult population as defined in the AAMI HE 48-1993: Human Factors Engineering Guidelines and Preferred Practices for Design of Medical Devices.

1.2.2 Physical Description

1. The device will be a stand-alone product with a pump system, heat exchanger, custom electronics, inputs and readout for patient temperature sensors and a disposable extra-corporeal circuit.
2. The device will consist of a durable framed enclosure containing a primary heat exchanger, blood pump, custom electronics and operator interface. A disposable extra-corporeal circuit consisting of a secondary heat exchanger, pump head, bubble trap, blood filter, tubing set and connecting means.
3. The device will be movable with wheels and ease of movement such that a single individual can maneuver it.
4. The device weight will be a maximum of 200 kg.
5. The cube dimensions will be a maximum of 22 in X 45 in X 25 in.

1.2.3 Operating Modes

The device will operate in the following modes.

1. Standby Mode, whereby the primary heat exchanger is cooled to a predetermined set point and maintained.
2. Patient Cooling Mode, whereby the blood is pumped through the extra-corporeal circuit and the blood temperature is maintained at a temperature set point determined by the operator input.
3. Maintenance mode, whereby the device will maintain the preset patient sensor temperature.

1.2.3.1 Standby Mode

In this mode, the device will pre-cool the primary heat exchanger to a pre-determined temperature and maintain that temperature.

1. The operator will input the desired blood temperature.
2. From this temperature input, the set point temperature of the primary heat exchanger will be internally calculated. The cooling means will then begin to cool the primary heat exchanger. When it reaches the set point, the device will indicate that the primary heat exchanger has reached the set point temperature and will then maintain that temperature.

1.2.3.2 Patient Cooling Mode

In this mode, the device will pump blood through the disposable extra-corporeal circuit that contains the secondary heat exchanger, and will cool the blood to a preset temperature. The following describes the required steps.

1. The operator will connect the disposable tubing set to the device.
2. The operator will prime the disposable extra corporeal circuit with a sterile solution.
3. The operator will connect the device to the patient via catheters and temperature sensors.
4. The operator will select the desired flow rate from preset values this action will switch the device to the patient cooling mode.
5. After a short stabilizing period (20 minutes), the device will maintain the blood temperature exiting the heat exchanger at the set point.
6. The device will monitor up to four temperatures and display one of them as selected by the operator.
7. The device will alert the operator if a detected fault occurs.

1.2.3.3 Maintenance Mode

In this mode the device will maintain the patient temperature sensor that was selected in 1.3.2.2 at an operator selected set point.

1. The operator will input the desired patient temperature.
2. When the patient temperature monitor detects that the patient temperature has reached the selected temperature the operator will be alerted.
3. The device will switch to the maintenance mode and use the feed back from the patient temperature sensor to maintain the patient temperature at the set point.

1.2.4 Operator Interface

1.2.4.1 The operator input interface will consist of a means of selecting the following parameters:

1. Device power on/off
2. Blood temperature set point
3. Blood flow rate
4. Temperature sensor display selection
5. Patient temperature set point

1.2.4.2 The device output to the operator will consist of the following:

1. Device power on/off indicator
2. Digital set point read out for patient temperature
3. Flow rate selection indicator
4. Blood temperature selection indicator

5. Device operational mode indicators
6. Displayed temperature sensor selection

1.2.5 Training

1. Provide sufficient information in educational materials, labeling, operator's guide.

1.2.6 Verification and Validation

1. Perform verification of Operational Requirements on Engineering Prototypes. Confirm verification on Manufacturing Prototypes if necessary.
2. Validate the Operational Requirements on a Manufacturing Prototype in a clinical trial. Clinical trial results will conform to applicable European Community and Federal Food and Drug Administration Regulations including, but not limited to, the latest revision of EN 540, 21 CFR 812, and applicable standards referenced therein.

1.3 Quality Requirements

1.3.1 General

1. The manufacturing processes will assure the device is free from defects and meets all product specifications.
2. The manufacturing process and quality system will comply with applicable requirements in the latest revision of the following:
   - The FDA-QSR's as defined in 21CFR, Parts 800 to 1299
   - ISO-13485:2003
   - The Medical Devices Directive, 93/42/ECC and all applicable annexes
   - Any other applicable standard, directive, or regulation.

1.3.2 Verification and Validation

1. Perform verification of Quality Requirements on both the Engineering and Manufacturing Prototypes.
2. Validate the Quality Requirements on a Manufacturing Prototype in a clinical trial. Clinical trial results will conform to applicable European Community and Federal Food and Drug Administration Regulations including, but not limited to, the latest revision of EN 540, 21 CFR 812, and applicable standards referenced therein.

1.4 Repairability Requirements

1.4.1 General

1. Ardiem Medical authorized service centers or factory service personnel will perform all repairs.
2. Design the device to allow easy internal access to perform repairs.
3. Include feature to align/attach optical diagnostic equipment to the probe (control standard, external reference, and/or wavelength standard).
4. Develop a service manual with sufficient detail for a trained service technician to isolate failures.

1.4.2 Verification and Validation

1. Perform verification of Repairability Requirements on Engineering Prototypes. Confirm verification on Manufacturing Prototypes if necessary.
2. Validate the Repairability Requirements on a Manufacturing Prototype.

2. Product Performance Requirements

2.1 Durability Requirements

2.1.1 Shock and Vibration

2.1.1.1 Shipping

1. The device will withstand normal levels of vibration levels as defined in MIL-STD-810E, figure 514.4-1, without incurring functional damage when in the shipping configuration.
2. The device will withstand normal levels of shock as defined in MIL-STD-810E, method 516.4, without incurring functional damage when in the shipping configuration.

2.1.1.2 Handling

1. The device will withstand, in the uncrated configuration, hitting walls and other fixed obstacles at a walking speed and moving in and out of elevators and over thresholds at walking speed.

2.1.1.3 Solvents and Fluids

1. All exposed surfaces will be resistant to damage from commonly used hospital/clinical cleaning fluids (such as alcohol and 10% bleach) and contact with salts, bodily fluids, and glucose solutions.

2.1.1.4 RFI and EMI

1. The device will meet the RFI and EMI immunity requirements listed in 2.2.1 1-4

2.1.1.5 Verification and Validation

1. Perform verification of Durability Requirements on Engineering Prototypes at an external test facility. After each test run, perform a functional test to verify the device performance. Confirm verification on Manufacturing Prototypes if necessary.
2. Validate the Durability Requirements on a Manufacturing Prototype.

2.2 Environmental Requirements

2.2.1 EMC Requirements

1. Electrostatic Discharge Immunity: EN 61000-4-2: 1995
2. Radiated Electromagnetic Field Immunity: EN 61000-4-3: 1995, ENV50140: 1993
3. Electrical Fast Transient / Burst Immunity: EN 61000-4-4: 1995
4. Surge Immunity EN 61000-4-5 1995, A1: 1995
5. Radiated and Conducted Emissions: EN 55011: 1998, FCC Part 15
6. Power Harmonics, EN61000-3-2: 1995, +A1: 1998, +A2: 1998, +A14: 2000
7. Voltage Fluctuation (Flicker): EN61000-3-3: 1995, +A1: 2001
8. Generic Medical EMC: EN 60601-1-2: 1993

2.2.2 Operating Requirements

1. Temperature: 20°C to 25°C
2. Humidity: 30% to 75% max non-condensing relative
3. Pressure: 523mm Hg max 10,000 feet altitude

2.2.3 Storage Requirements

1. Storage Temperature: -40°C to 70°C
2. Humidity: 15°C to 95% max non-condensing relative
3. Pressure: 179mm Hg max 35,000 feet altitude

2.2.4 Verification and Validation

1. Perform verification of EMC Environmental Requirements on a Manufacturing Prototype at a certified test facility.
2. Perform verification of Operating and Storage Environmental Requirements on Engineering Prototypes. Confirm verification on Manufacturing Prototypes if necessary.
3. Validate the Operating and Storage Environmental Requirements on a Manufacturing Prototype.

2.3 Performance Requirements

2.3.1 Electrical Requirements

2.3.1.1 Electrical Safety

1. Design and manufacture the device to comply with product safety requirements of the European Community, US Product Safety Commission, and North American Free Trade Association.
2. Use relevant components that are approved by at least one agency.

2.3.1.2 Power

1. Use a power cord that is tested and certified to meet European Community electrical safety requirements for EU approval.
2. Use a power cord that is tested and certified to meet United States electrical safety requirements for FDA approval.
3. Fuse each side of the mains.
4. Line Voltage: 115 VAC +/-10% or 230 VAC +/-10%.
5. Line Current: 20 A maximum.
6. Line Frequency: 60 Hz +/- 3% or 50 Hz +/-3%.

2.3.1.3 Warm-Up

1. Warm-up period will be 30 minutes to allow the device to stabilize and cool the primary heat exchanger.

2.3.1.4 Verification and Validation

1. Perform verification of Electrical Safety Requirements on a Manufacturing Prototype at an external test facility. Perform verification of all other applicable Electrical Requirements on Engineering Prototypes. Confirm verification on Manufacturing Prototypes if necessary.
2. Validate the Electrical Requirements on a Manufacturing Prototype.

2.3.2 Electronic Requirements

2.3.2.1 Central Processing Unit

1. Use a central processing unit (CPU) to control the overall operation of the device, including data acquisition, electro-mechanical components, operator interfaces, and communications interfaces.
2. Provide capability to reset CPU without cycling power off and on.

2.3.2.2 Real-Time Clock

1. Maintain the device's total operation time over its life.

2. Use a real-time clock (RTC) to associate a specific date and time with each reported measurement.
3. The RTC will continue to operate in the absence of AC line power.

2.3.2.3 PCBAs

1. Design device with no more than three (3) PCBAs.

2.3.2.4 Operator input

The operator will input the following data:

1. Power on/off will be initiated by a switch
2. The desired blood outflow temperature will be entered, by a rotary detent switch, from preset values between 7°C and 17°C in 1° increments.
3. The blood flow rate will be entered, by a rotary detent switch, from preset values between 100 mL/min and 500 mL/min in 100 mL/min increments.
4. Displayed temperature selection will be input by a four (4) position rotary switch
5. Patient temperature set point will be input through two up/down push button switches and read out on a digital display. The set point range will be from 30°C to 38°C in 1°C increments.

2.3.2.5 Operator output

The following data will be output from the device:

1. Power on will be indicated by a light indicator.
2. The blood temperature setting will be indicated by the rotary switch position a light will indicate that it has reached the set point. The device will maintain the temperature set point within ±0.5°C.
3. The blood flow rate will be indicated by the rotary switch position. The device will maintain the pre-set flow rate within ±10% for any selected flow rate.
4. The patient temperature set point will be indicated by a digital readout and a light will indicate that the patient set point has been established. The patient temperature readout accuracy will be ±0.2°C over the range of 32°C to 38°C.
5. The patient temperature control will be maintained to within (TBD).
6. A light will indicate the device mode.
7. An audible alarm and warning light will indicate when a device fault has been detected.

2.3.2.6 Safety limits

1. The electronics will detect and shut down the pump and the refrigerator if the primary heat exchanger temperature drops below 1°C.
2. The electronics will detect and shut down the pump and refrigerator if the secondary heat exchanger temperature (outflow) drops below 5°C.

2.3.2.7 Verification and Validation

1. Perform verification of Electronic Requirements on Engineering Prototypes. Confirm verification on Manufacturing Prototypes if necessary.
2. Validate the Electronic Requirements on a Manufacturing Prototype.

2.3.3 Embedded Software Functional Requirements

2.3.3.1 General

1. Control system operation.
2. Invoke operator input.

3. Provide output.
4. Control temperature.
5. Control flow.

2.3.3.2 Data Collection, Processing, and Relaying

1. Acquire temperature, flow, and other data.
2. Compute averages.
3. Display average temperatures.
4. Report all averages over a serial link.

2.3.3.3 Test and Diagnostics

1. Perform tests to detect faults.
2. Display faults using numeric codes.
3. Alert operator by sounding the buzzer.

2.3.3.4 Safety limits

1. The software will detect and report if the primary heat exchanger temperature drops below 2°C.
2. The software will detect and report if the secondary heat exchanger temperature (outflow) drops below 6°C.

2.3.3.5 Verification and Validation

1. Perform verification of Embedded Software Requirements on Engineering Prototypes. Confirm verification on Manufacturing Prototypes if necessary.
2. Validate the Embedded Software Requirements on a Manufacturing Prototype in a clinical trial. Clinical trial results will conform to applicable European Community and Federal Food and Drug Administration Regulations including, but not limited to, the latest revision of EN 540, 21 CFR 812, and applicable standards referenced therein.

2.3.4 Mechanical Requirements

2.3.4.1 Mechanical Safety

1. Design and manufacture the device to comply with product safety requirements of the European Community, US Product Safety Commission, and North American Free Trade Association.

2.3.4.2 Thermal Requirements

1. Isolate the electrical/electronics compartment from the refrigeration compartment.
2. Limit the internal device temperature to 40°C under normal operating conditions.

2.3.4.3 Verification and Validation

1. Perform verification of Safety Requirements on a Manufacturing Prototype at an external test facility.
2. Perform verification of other Mechanical Requirements on Engineering Prototypes. Confirm verification on Manufacturing Prototypes if necessary.
3. Validate the Mechanical Requirements on a Manufacturing Prototype.

2.4 Reliability Requirements

1. Useful service life is ten (10) years with normal servicing and maintenance.
2. Perform verification of Reliability Requirements on Manufacturing Prototypes by analysis based on MIL STD 217.

2.5 Safety Risk Management Requirements

2.5.1 Safety Modes

For purposes of evaluating risk and determining the proper performance of failure detection and safety in the design, safe operation is defined as one of the following:

1. The ability to detect fault conditions and alert the operator constitutes the primary safety mode of the system.
2. The ability to detect a threatening condition and alert the operator constitutes the secondary safety mode of the system.
3. The tertiary safety mode will be to shut down the pump and refrigeration cycle.

2.5.2 General Risks

1. Identify undesirable system operating conditions with a system risk analysis. The design will anticipate, to the extent possible, the occurrence of failure modes and provide a means of protecting against them. (ISO 10993-1: Biological Evaluation of Medical Devices 1992)
2. General surgical procedural risks, those common to all surgical procedures, are outside the boundaries of the risk assessment for this device.
3. Evaluate risk per ISO 10993-1: Biological Evaluation of Medical Devices 1992.
4. Product safety features, instructions, and labeling must fulfill requirements of: MDD 93/42/ EEC, Annex 1, Essential Requirements; FDA Title 21 CFR 820; and requirements of Ardiem Medical material handling and quality procedures.
5. Include adequate operator safety instructions in manuals and labeling supplied with the device.

2.5.3 Verification and Validation

1. Perform verification of Safety Risk Management Requirements on Engineering Prototypes. Confirm verification on Manufacturing Prototypes if necessary.
2. Validate the Safety Risk Management Requirements on a Manufacturing Prototype in a clinical trial. Clinical trial results will conform to applicable European Community and Federal Food and Drug Administration Regulations including, but not limited to, the latest revision of EN 540, 21 CFR 812, and applicable standards referenced therein.

3. Product Interface Requirements

3.1 Customer Interface Requirements

3.1.1 General

1. Provide appropriate instructional materials (operator's guide, training video, screen prompts, etc.) to allow operator to correctly install and use the device.

3.1.2 Beeper

1. Use an audible beeper to prompt and/or alert the operator when a failure has occurred and/or an action is required.

3.1.3 Display

1. The device will contain a large (0.6-inch or larger) numeric display capable of displaying three (3) digits plus a sign (+/-).
2. The display will be readable under all ambient light conditions.
3. The device will display temperatures, error codes, fault codes, etc. to the operator for communicating to a service technician.

3.1.4 Controls

1. Include a rotary detent switch to allow the operator to select blood temperature (outflow) set point.
2. Include a rotary detent switch to allow the operator to select blood flow set point.
3. Include a rotary detent switch to allow the operator to select displayed temperature.
4. Include two push button switches to allow the operator to select a patient temperature set point.

3.1.5 Language

1. Allow factory configuration to a minimum of one language out of supported languages.
2. Include the following supported languages as a minimum: English (U.S.)
3. Use symbols in accordance with EN 980.

3.1.6 Units of Measure

1. Label controls and display selected and measured values in the following units of measure:
   - Milliliters per minute (mL/min)
   - Degrees centigrade (^{o}C)

3.1.7 Verification and Validation

1. Perform verification of Customer Interface Requirements on Engineering Prototypes. Confirm verification on Manufacturing Prototypes if necessary.
2. Validate the Customer Interface Requirements on a Manufacturing Prototype in a clinical trial. Clinical trial results will conform to applicable European Community and Federal Food and Drug Administration Regulations including, but not limited to, the latest revision of EN 540, 21 CFR 812, and applicable standards referenced therein.

3.2 External Interface Requirements

3.2.1 General

1. The device will contain a serial port capable of communications with a computer (diagnostics only).

2. Use a RS-232 with a DB-9 connector as the serial port electrical interface.
3. Use serial port communications at a minimum baud rate of 19200 baud.

3.2.2 Verification and Validation

1. Perform verification of External Interface Requirements on Engineering Prototypes. Confirm verification on Manufacturing Prototypes if necessary.
2. Validate the External Interface Requirements on a Manufacturing Prototype in a clinical trial. Clinical trial results will conform to applicable European Community and Federal Food and Drug Administration Regulations including, but not limited to, the latest revision of EN 540, 21 CFR 812, and applicable standards referenced therein.

3.3 Labeling Requirements

3.3.1 General

1. Manuals and labels will conform to both European Community and FDA requirements.
2. All labels and manuals will comply with requirements of EN 1041, EN 980, and any other applicable standards.
3. Labeling will also contain the following wording prominently displayed: "CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician."

3.3.2 Safety and Warning Labels

1. Provide adequate safety labels per 93/42 EEC MDD and Title 21 CFR 820.
2. Identify and explain any warnings in the operator's guide.

3.3.3 Shipping Labels

1. TBD

3.3.4 Verification and Validation

1. Perform verification of Labeling Requirements on Engineering Prototypes. Confirm verification on Manufacturing Prototypes if necessary.
2. Validate the Labeling Requirements on a Manufacturing Prototype in a clinical trial. Clinical trial results will conform to applicable European Community and Federal Food and Drug Administration Regulations including, but not limited to, the latest revision of EN 540, 21 CFR 812, and applicable standards referenced therein.

3.4 Service Delivery Requirements

3.4.1 General

1. Deliver all necessary information and support products with the main product delivery.
2. A training program will be available for training of repair and maintenance personnel.
3. Provide a system for supplying spare modules to repair and maintenance personnel.

3.4.2 Verification and Validation

1. Perform verification of Service Delivery Requirements on Engineering Prototypes. Confirm verification on Manufacturing Prototypes if necessary.
2. Validate the Service Delivery Requirements on a Manufacturing Prototype in a clinical trial. Clinical trial results will conform to applicable European Community and Federal Food and Drug Administration Regulations including, but not limited to, the latest revision of EN 540, 21 CFR 812, and applicable standards referenced therein.

4. Product System and Program Requirements

4.1 Business Risk Management Requirements

1. TBD

4.2 Customer Service and Product Support Requirements

1. TBD

4.3 Financial Requirements

1. TBD

4.4 Manufacturability Requirements

4.4.1 Modularity

1. Any assembly of acceptable quality must be interchangeable with any other like assembly.

4.4.2 Test Yields

1. Final assembly test yield will be at least 95% at pilot production.

4.4.3 Components

1. Use industry standards for selection of components.
2. Eliminate fragile, difficult to process components.
3. Where possible, standardized the use of electronic and other components to common types (same connectors, same tolerance resistors, capacitors, etc.)

4.4.4 Custom Components

1. Where possible, use industry standards in design of custom components.
2. Any part of acceptable quality will be interchangeable with any other like part (matched sets as exist for the probe are unacceptable).
3. Where possible, use industry standard finishes.
4. Design hardware to take advantage of castings, stampings, and injection moldings.

4.4.5 Fasteners

1. Where possible, use industry standards in fastener specifications.
2. Where possible, use fasteners types appropriate for auto-feed equipment.

4.4.6 Plastics

1. Design plastics in preparation of future tooling for injection molding.

4.4.7 Verification and Validation

1. Design plastics to meet material handling requirements (packaging, shipping, storage, etc.)
2. Perform verification of Manufacturability Requirements on Engineering Prototypes. Confirm verification on Manufacturing Prototypes.
3. Validate the Manufacturability Requirements during production of Manufacturing Prototypes.

4.5 Manufacturing Requirements

1. TBD

4.6 Marketing Requirements

1. TBD

4.7 Packaging Requirements

4.7.1 General

1. Package to withstand normal customer modes of transportation such as truck cargo space or other expected transportation methods.
2. Package to withstand normal shipping and handling by commercial modes of transport in accordance with ISTA Procedure 1A.
3. Include all other materials and support components in packaging as required.
4. Place visible warnings on the packaging of any shock, vibration, or environmental limitations during shipping and storage.
5. Add Ardiem Medical logo and graphics to the shipping package.
6. Design packaging capabilities for individual or palletized shipment.

4.7.2 Verification and Validation

1. Perform verification of Packaging Requirements on Engineering Prototypes. Confirm verification on Manufacturing Prototypes if necessary.
2. Validate the Packaging Requirements on a Manufacturing Prototype.

4.8 Regulatory Compliance Requirements

4.8.1 General

1. Achieve FDA regulatory compliance.
2. Achieve European Community compliance under Medical Device Directive 93/42/EEC and CE marking authority.

4.8.2 Verification and Validation

1. Perform verification of Regulatory Requirements on Engineering Prototypes. Confirm verification on Manufacturing Prototypes if necessary.
2. Validate the Regulatory Requirements on a Manufacturing Prototype.

4.9 Shipping Requirements

4.9.1 General

1. TBD

4.9.2 Verification and Validation

1. Perform verification of Shipping Requirements on Engineering Prototypes. Confirm verification on Manufacturing Prototypes if necessary.
2. Validate the Shipping Requirements on a Manufacturing Prototype.

4.10 Standards Compliance Requirements

4.10.1 General

1. Use FDA QSRs, IEC standards, EN standards, or others where appropriate.

4.10.2 Verification and Validation

1. Perform verification of Standards Compliance Requirements on Engineering Prototypes. Confirm verification on Manufacturing Prototypes if necessary.

2. Validate the Standards Compliance Requirements on a Manufacturing Prototype.

4.11 Statutory Compliance Requirements

4.11.1 General

1. Satisfy any requirements for compliance with domestic or non-domestic local, state, and/or federal legal edicts or legislation.

4.11.2 Verification and Validation

1. Perform verification of Statutory Compliance Requirements on Engineering Prototypes. Confirm verification on Manufacturing Prototypes if necessary.
2. Validate the Statutory Compliance Requirements on a Manufacturing Prototype.

4.12 Testability Requirements

4.12.1 PCBA Test Requirements

1. Install PCBA test facilities and procedures, either in house or at vendor facility.
2. Production operators and test technicians will run test software.
3. Where possible, write test software with a go/no go output.
4. Upon successful completion of a final test, download the test data to the device history record.
5. If unsuccessful, pass the final test data to the troubleshooting technician or engineer.

4.12.2 Final Test

1. Transmit final test results to a separate computer via the serial link. Upon successful completion of a final test, download the final test data to the device history record.
2. If a final test is unsuccessful, either transmit the raw data collected during the test to an external PC for analysis, or repeat the tests with comparable software on an external PC.
3. In final testing, test all critical specifications to a pass/fail criteria.

4.12.3 Verification and Validation

1. Perform verification of Testability Requirements on Engineering Prototypes. Confirm verification on Manufacturing Prototypes.
2. Validate the Testability Requirements during production of Manufacturing Prototypes.

5. References

5.1 Standards

21 CFR 820	Medical Devices; Current Good Manufacturing Practice Final Rule; Quality System Regulation (1996)
80/181/EEC	Unit Of Measurement
89/336/EEC	On The Approximation Of The Laws Of The Member States Relating To Electromagnetic Compatibility
92/31/EEC	Amending Directive 89/336/EEC On The Approximation Of The Laws Of The Member States Relating To Electromagnetic Compatibility
93/42/EEC	EC Council Directive Concerning Medical Devices (1993)
93/68/EEC	Amending Directives 89/336/EEC (Electromagnetic Compatibility) 90/385/EEC (Active Implantable Medicinal Devices)
EN 1041:1998 E	Terminology, Symbols And Information Provided With Medical Devices - Information Supplied By The Manufacturer With Medical Devices
BS EN 1441	Medical Devices - Risk Analysis
BS EN 30993-1:1994	Biological Evaluation Of Medical Devices - Part 1: Guidance On Selection Of Tests
BS EN 30993-5:1994	Biological Evaluation Of Medical Devices - Part 5: Tests For Cytotoxicity - In Vitro Methods
BS EN 46001:1997	Quality Systems - Medical Devices - Particular Requirements For The Application Of EN ISO 9001
EN 50081-1:1992 E	Electromagnetic Compatibility - Generic Emission Standard Part 1: Residential, Commercial And Light Industry
EN 50103	Guidance On The Application Of EN 29001 And EN 46001 And Of EN 29002 And EN 46002 For The Active (Including Active Implantable) Medical Device Industry
EN 540:1993 E	Clinical Investigation Of Medical Devices For Human Subjects
BS EN 55011:1991	Limits And Methods Of Measurement Of Radio Disturbance Characteristics Of Industrial, Scientific And Medical (ISM) Radio-Frequency Equipment
EN 60601-1-2:1993 E	Medical Electrical Equipment. Part 1. General Requirements For Safety; 2. Collateral Standard: Electromagnetic Compatibility - Requirements And Tests
BS EN 980:1997 (EN 980:1996 E)	Graphical Symbols For Use In The Labeling Of Medical Devices
IEC 127-2	Cartridge Fuse Link, Sheet III Specification For Time Lag Fuses
IEC 601-1-4:1996	Medical Electrical Equipment - Part 1: General Requirements For Safety - 4. Collateral Standard: Programmable Electrical Medical Systems
IEC 60529	Degrees Of Protection Provided By Enclosures
IEC 60601-1:1998	Medical Electrical Equipment. Part 1: General Requirements For Safety
IEC 601-1:1988/A1:1991	Medical Electrical Equipment. Part 1: General Requirements For Safety

IEC 601-1:1988/A2:1995 + Corrigendum Jun 1995	Medical Electrical Equipment. Part 1: General Requirements For Safety
IEC 801-2	Electromagnetic Compatibility For Industrial-Process Measurement And Control Equipment Part 2: Electrostatic Discharge Requirements 1991
ISO 10993-10	Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Sensitization (ISO 10993-10:1995
ISO 10993-12	Biological Evaluation Of Medical Devices - Part 12: Sample Preparation And Reference Materials (ISO 10993-12:1996)
ISO 13485:1996(E)	Quality Systems - Medical Devices - Particular Requirements For The Application Of ISO 9001
ISO 9001:1994(E)	Quality Systems - Model For Quality Assurance In Design, Development, Production, Installation And Servicing
MIL-STD-461D	Electromagnetic Interference Emissions And Susceptibility
UL 2601-1	Standard for Medical Electrical Equipment, Part 1: General Requirements for Safety - Second Edition October 24, 1997

5.2 Acronyms

ADC	Analog-to-Digital Converter
CPU	Central Processing Unit
FIT	Fault Isolation Test
LCD	Liquid Crystal Display
PCBA	Printed Circuit Board Assembly
RTC	Real Time Clock

6. Revisions

Rev.	Description	Author	Effective Date
00	Preliminary Issue	Ralph Gill	9/26/02
01	Completed Requirements	Mike Pitsakis	9/19/03

ARDIEM

DESIGN REQUIREMENTS DOCUMENT

Design Requirements x.dot

Profound Hypothermia Induction Device
Program No. 2003-01

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1. Product Functional Requirements

1.1 Maintainability Requirements

1.1.1 Operator Maintenance

1. Operator maintenance will only be cleaning the surfaces of the device in accordance with the operator's guide.
2. Describe operator maintenance in the operator's guide.

1.1.2 Customer Support Maintenance

1. There are no customer support maintenance requirements. The operator performs all preventative and periodic maintenance.

1.1.3 Verification and Validation

1. Perform verification of Maintainability Requirements on Engineering Prototypes. Confirm verification on Manufacturing Prototypes if necessary.
2. Validate the Maintainability Requirements on a Manufacturing Prototype.

1.2 Operational Requirements

1.2.1 Intended Use

1. The device is to be used for the induction of profound hypothermia (core body temperature at approximately 10°C to 20°C). Profound hypothermia is induced by initiating a rapid one-way flush with a large volume (20 liters) of cold solution via the thoracic aorta.
2. The device will be applicable to 95% of the adult population as defined in the AAMI HE 48-1993: Human Factors Engineering Guidelines and Preferred Practices for Design of Medical Devices.

1.2.2 Physical Description

1. The device will be a stand-alone product with a pump system, heat exchanger, custom electronics, inputs and readout for patient temperature sensors, and a disposable extra-corporeal circuit.
2. The device will consist of a durable framed enclosure containing a primary heat exchanger, a pump, an inner cooling chamber capable of holding a filled 20-liter bag of sterile solution, and custom electronics and operator interface. Also a disposable extra-corporeal circuit consisting of a secondary heat exchanger, pump head, tubing set and connecting means.
3. The device will be movable with wheels and ease of movement such that a single individual can maneuver it.
4. The device weight will be a maximum of 100 kg.
5. The cube dimensions will be a maximum of 28 in X 22 in X 16 in.

1.2.3 Operating Modes

1.2.3.1 Fluid Cooling Mode

1. This is an optional mode for cooling the fluid if pre-chilled fluid is not used. It will take 5 – 6 hours for this depending on initial fluid temperature.
2. The operator inserts a 20-liter bag of fluid in the cold chamber and attaches a temperature probe. Then selects a temperature set point between –5°C to 5°C.
3. The device will turn indicator light MODE 1 on.

4. The device will automatically enter Standby Mode when the fluid reaches the set-point temperature.
5. The device on power on will always start in Fluid Cooling Mode and will return to this mode when it detects warm fluid.

1.2.3.2 Standby Mode

1. In this mode, the device will maintain the 20-liter volume of chilled fluid at the temperature set point –5°C to 5°C.
2. The device will turn indicator light MODE 2 on to alert the operator that it is ready for a procedure.

1.2.3.3 Flush Mode

1. Flush mode: In this mode the device will deliver the fluid through a 3mm bore x 1.5 meter long catheter to the patient at 0.5, 1, 1.5, or 2 L/min selected by the operator. Note that the catheter is not a part of the device.
2. The operator will initiate this mode by selecting a flow rate, after the tubing set has been installed and primed. The action of selecting a flow rate from the three pre-defined flow rates (prime, 1l/min, 1.5l/min, 02 2l/min) will start the pump.
3. The device will turn indicator light MODE 3 on.

1.2.4 Operator Interface

1.2.4.1 The operator input interface will consist of a means of selecting the following parameters:

1. Device power on/off
2. Fluid temperature set point
3. Fluid flow rate
4. A means for connecting the tubing set pump section and connecting to the fluid bag

1.2.4.2 The device output to the operator will consist of the following:

1. Device power on/off indicator
2. Flow rate selection indicator
3. Device operational mode indicators
4. Patient temperature display.

1.2.5 Training

1. Provide sufficient information in educational materials, labeling, operator's guide.

1.2.6 Verification and Validation

1. Perform verification of Operational Requirements on Engineering Prototypes. Confirm verification on Manufacturing Prototypes if necessary.
2. Validate the Operational Requirements on a Manufacturing Prototype in a clinical trial. Clinical trial results will conform to applicable European Community and Federal Food and Drug Administration Regulations including, but not limited to, the latest revision of EN 540, 21 CFR 812, and applicable standards referenced therein.

1.3 Quality Requirements

1.3.1 General

1. The manufacturing processes will assure the device is free from defects and meets all product specifications.

2. The manufacturing process and quality system will comply with applicable requirements in the latest revision of the following:
   - The FDA-QSR's as defined in 21CFR, Parts 800 to 1299
   - ISO-13485:2003
   - The Medical Devices Directive, 93/42/ECC and all applicable annexes
   - Any other applicable standard, directive, or regulation.

1.3.2 Verification and Validation

1. Perform verification of Quality Requirements on both the Engineering and Manufacturing Prototypes.
2. Validate the Quality Requirements on a Manufacturing Prototype in a clinical trial. Clinical trial results will conform to applicable European Community and Federal Food and Drug Administration Regulations including, but not limited to, the latest revision of EN 540, 21 CFR 812, and applicable standards referenced therein.

1.4 Repairability Requirements

1.4.1 General

1. Ardiem Medical authorized service centers or factory service personnel will perform all repairs.
2. Design the device to allow easy internal access to perform repairs.
3. Include feature to align/attach optical diagnostic equipment to the probe (control standard, external reference, and/or wavelength standard).
4. Develop a service manual with sufficient detail for a trained service technician to isolate failures.

1.4.2 Verification and Validation

1. Perform verification of Repairability Requirements on Engineering Prototypes. Confirm verification on Manufacturing Prototypes if necessary.
2. Validate the Repairability Requirements on a Manufacturing Prototype.

2. Product Performance Requirements

2.1 Durability Requirements

2.1.1 Shock and Vibration

2.1.1.1 Shipping

1. The device will withstand normal levels of vibration levels as defined in MIL-STD-810E, figure 514.4-1, without incurring functional damage when in the shipping configuration.
2. The device will withstand normal levels of shock as defined in MIL-STD-810E, method 516.4, without incurring functional damage when in the shipping configuration.

2.1.1.2 Handling

1. The device will withstand, in the uncrated configuration, hitting walls and other fixed obstacles at a walking speed and moving in and out of elevators and over thresholds at walking speed.

2.1.1.3 Solvents and Fluids

1. All exposed surfaces will be resistant to damage from commonly used hospital/clinical cleaning fluids (such as alcohol and 10% bleach) and contact with salts, bodily fluids, and glucose solutions.

2.1.1.4 RFI and EMI

1. The device will meet the RFI and EMI immunity requirements listed in 2.2.1 1-4

2.1.1.5 Verification and Validation

1. Perform verification of Durability Requirements on Engineering Prototypes at an external test facility. After each test run, perform a functional test to verify the device performance. Confirm verification on Manufacturing Prototypes if necessary.
2. Validate the Durability Requirements on a Manufacturing Prototype.

2.2 Environmental Requirements

2.2.1 EMC Requirements

1. Electrostatic Discharge Immunity: EN 61000-4-2: 1995
2. Radiated Electromagnetic Field Immunity: EN 61000-4-3: 1995, ENV50140: 1993
3. Electrical Fast Transient / Burst Immunity: EN 61000-4-4: 1995
4. Surge Immunity EN 61000-4-5 1995, A1: 1995
5. Radiated and Conducted Emissions: EN 55011: 1998, FCC Part 15
6. Power Harmonics, EN61000-3-2: 1995, +A1: 1998, +A2: 1998, +A14: 2000
7. Voltage Fluctuation (Flicker): EN61000-3-3: 1995, +A1: 2001
8. Generic Medical EMC: EN 60601-1-2: 1993

2.2.2 Operating Requirements

1. Temperature: 20°C to 25°C
2. Humidity: 30% to 75% max non-condensing relative
3. Pressure: 523mm Hg max 10,000 feet altitude

2.2.3 Storage Requirements

1. Storage Temperature: -40°C to 70°C
2. Humidity: 15°C to 95% max non-condensing relative
3. Pressure: 179mm Hg max 35,000 feet altitude

2.2.4 Verification and Validation

1. Perform verification of EMC Environmental Requirements on a Manufacturing Prototype at a certified test facility.
2. Perform verification of Operating and Storage Environmental Requirements on Engineering Prototypes. Confirm verification on Manufacturing Prototypes if necessary.
3. Validate the Operating and Storage Environmental Requirements on a Manufacturing Prototype.

2.3 Performance Requirements

2.3.1 Electrical Requirements

2.3.1.1 Electrical Safety

1. Design and manufacture the device to comply with product safety requirements of the European Community, US Product Safety Commission, and North American Free Trade Association.
2. Use relevant components that are approved by at least one agency.

2.3.1.2 Power

1. Use a power cord that is tested and certified to meet European Community electrical safety requirements for EU approval.
2. Use a power cord that is tested and certified to meet United States electrical safety requirements for FDA approval.
3. Fuse each side of the mains.
4. Line Voltage: 115 VAC +/-10% or 230 VAC +/-10%.
5. Line Current: 20 A maximum.
6. Line Frequency: 60 Hz +/- 3% or 50 Hz +/-3%.

2.3.1.3 Warm-Up

1. Warm-up period will be 30 minutes to allow the device to stabilize and cool the primary heat exchanger.

2.3.1.4 Verification and Validation

1. Perform verification of Electrical Safety Requirements on a Manufacturing Prototype at an external test facility. Perform verification of all other applicable Electrical Requirements on Engineering Prototypes. Confirm verification on Manufacturing Prototypes if necessary.
2. Validate the Electrical Requirements on a Manufacturing Prototype.

2.3.2 Electronic Requirements

2.3.2.1 Central Processing Unit

1. Use a central processing unit (CPU) to control the overall operation of the device, including data acquisition, electro-mechanical components, operator interfaces, and communications interfaces.
2. Provide capability to reset CPU without cycling power off and on.

2.3.2.2 Real-Time Clock

1. Maintain the device's total operation time over its life.

2. Use a real-time clock (RTC) to associate a specific date and time with each reported measurement.
3. The RTC will continue to operate in the absence of AC line power.

2.3.2.3 PCBAs

1. Design device with no more than three (3) PCBAs.

2.3.2.4 Operator input

The operator will input the following data:

1. Power on/off will be initiated by a switch
2. The desired fluid temperature will be entered, by a rotary detent switch, from preset values between -5°C and 5°C in 1° increments.
3. The blood flow rate will be entered, by a rotary detent switch, from preset values between 0.5 L/min and 2 L/min in 0.5 L/min increments.

2.3.2.5 Operator output

The following data will be output from the device:

1. Power on will be indicated by a light indicator.
2. The fluid temperature setting will be indicated by the rotary switch position a light will indicate that it has reached the set point. The device will maintain the temperature set point within ±0.5°C.
3. The fluid flow rate will be indicated by the rotary switch position. The device will maintain the pre-set flow rate within ±10% for any selected flow rate.
4. The patient temperature set point will be indicated by a digital readout. The patient temperature readout accuracy will be ±0.3°C over the range of 10°C to 38°C.
5. A light will indicate the device mode.
6. An audible alarm and warning light will indicate when a device fault has been detected.

2.3.2.6 Safety limits

1. The electronics will detect and shut down the pump and the refrigerator if the primary heat exchanger temperature drops below (TBD).
2. The electronics will detect and shut down the pump and refrigerator if the secondary heat exchanger temperature (outflow) drops below -7°C.

2.3.2.7 Verification and Validation

1. Perform verification of Electronic Requirements on Engineering Prototypes. Confirm verification on Manufacturing Prototypes if necessary.
2. Validate the Electronic Requirements on a Manufacturing Prototype.

2.3.3 Embedded Software Functional Requirements

2.3.3.1 General

1. Control system operation.
2. Invoke operator input.
3. Provide output.
4. Control temperature.
5. Control flow.

2.3.3.2 Data Collection, Processing, and Relaying

1. Acquire temperature, flow, and other data.
2. Compute averages.
3. Display average patient temperature.
4. Report all averages over a serial link.

2.3.3.3 Test and Diagnostics

1. Perform tests to detect faults.
2. Display faults using numeric codes.
3. Alert operator by sounding the buzzer.

2.3.3.4 Safety limits

1. The software will detect and report if the primary heat exchanger temperature drops below (TBD).
2. The software will detect and report if the secondary heat exchanger temperature (outflow) drops below -6°C.

2.3.3.5 Verification and Validation

1. Perform verification of Embedded Software Requirements on Engineering Prototypes. Confirm verification on Manufacturing Prototypes if necessary.
2. Validate the Embedded Software Requirements on a Manufacturing Prototype in a clinical trial. Clinical trial results will conform to applicable European Community and Federal Food and Drug Administration Regulations including, but not limited to, the latest revision of EN 540, 21 CFR 812, and applicable standards referenced therein.

2.3.4 Mechanical Requirements

2.3.4.1 Mechanical Safety

1. Design and manufacture the device to comply with product safety requirements of the European Community, US Product Safety Commission, and North American Free Trade Association.

2.3.4.2 Thermal Requirements

1. Isolate the electrical/electronics compartment from the refrigeration compartment.
2. Limit the internal device temperature to 40°C under normal operating conditions.

2.3.4.3 Verification and Validation

1. Perform verification of Safety Requirements on a Manufacturing Prototype at an external test facility.
2. Perform verification of other Mechanical Requirements on Engineering Prototypes. Confirm verification on Manufacturing Prototypes if necessary.
3. Validate the Mechanical Requirements on a Manufacturing Prototype.

2.4 Reliability Requirements

1. Useful service life is ten (10) years with normal servicing and maintenance.
2. Perform verification of Reliability Requirements on Manufacturing Prototypes by analysis based on MIL STD 217.

2.5 Safety Risk Management Requirements

2.5.1 Safety Modes

For purposes of evaluating risk and determining the proper performance of failure detection and safety in the design, safe operation is defined as one of the following:

1. The ability to detect fault conditions and alert the operator constitutes the primary safety mode of the system.
2. The ability to detect a threatening condition and alert the operator constitutes the secondary safety mode of the system.
3. The tertiary safety mode will be to shut down the pump and refrigeration cycle.

2.5.2 General Risks

1. Identify undesirable system operating conditions with a system risk analysis. The design will anticipate, to the extent possible, the occurrence of failure modes and provide a means of protecting against them. (ISO 10993-1: Biological Evaluation of Medical Devices 1992)
2. General surgical procedural risks, those common to all surgical procedures, are outside the boundaries of the risk assessment for this device.
3. Evaluate risk per ISO 10993-1: Biological Evaluation of Medical Devices 1992.
4. Product safety features, instructions, and labeling must fulfill requirements of: MDD 93/42/ EEC, Annex 1, Essential Requirements; FDA Title 21 CFR 820; and requirements of Ardiem Medical material handling and quality procedures.
5. Include adequate operator safety instructions in manuals and labeling supplied with the device.

2.5.3 Verification and Validation

1. Perform verification of Safety Risk Management Requirements on Engineering Prototypes. Confirm verification on Manufacturing Prototypes if necessary.
2. Validate the Safety Risk Management Requirements on a Manufacturing Prototype in a clinical trial. Clinical trial results will conform to applicable European Community and Federal Food and Drug Administration Regulations including, but not limited to, the latest revision of EN 540, 21 CFR 812, and applicable standards referenced therein.

3. Product Interface Requirements

3.1 Customer Interface Requirements

3.1.1 General

1. Provide appropriate instructional materials (operator's guide, training video, screen prompts, etc.) to allow operator to correctly install and use the device.

3.1.2 Beeper

1. Use an audible beeper to prompt and/or alert the operator when a failure has occurred and/or an action is required.

3.1.3 Display

1. The device will contain a large (0.6-inch or larger) numeric display capable of displaying three (3) digits plus a sign (+/-).
2. The display will be readable under all ambient light conditions.
3. The device will display temperature, error codes, fault codes, etc. to the operator for communicating to a service technician.

3.1.4 Controls

1. Include a rotary detent switch to allow the operator to select fluid temperature (outflow) set point.
2. Include a rotary detent switch to allow the operator to select fluid flow set point.

3.1.5 Language

1. Allow factory configuration to a minimum of one language out of supported languages.
2. Include the following supported languages as a minimum: English (U.S.)
3. Use symbols in accordance with EN 980.

3.1.6 Units of Measure

1. Label controls and display selected and measured values in the following units of measure:
   - Liters per minute (L/min)
   - Degrees centigrade (°C)

3.1.7 Verification and Validation

1. Perform verification of Customer Interface Requirements on Engineering Prototypes. Confirm verification on Manufacturing Prototypes if necessary.
2. Validate the Customer Interface Requirements on a Manufacturing Prototype in a clinical trial. Clinical trial results will conform to applicable European Community and Federal Food and Drug Administration Regulations including, but not limited to, the latest revision of EN 540, 21 CFR 812, and applicable standards referenced therein.

3.2 External Interface Requirements

3.2.1 General

1. The device will contain a serial port capable of communications with a computer (diagnostics only).
2. Use a RS-232 with a DB-9 connector as the serial port electrical interface.
3. Use serial port communications at a minimum baud rate of 19200 baud.

3.2.2 Verification and Validation

1. Perform verification of External Interface Requirements on Engineering Prototypes. Confirm verification on Manufacturing Prototypes if necessary.
2. Validate the External Interface Requirements on a Manufacturing Prototype in a clinical trial. Clinical trial results will conform to applicable European Community and Federal Food and Drug Administration Regulations including, but not limited to, the latest revision of EN 540, 21 CFR 812, and applicable standards referenced therein.

3.3 Labeling Requirements

3.3.1 General

1. Manuals and labels will conform to both European Community and FDA requirements.
2. All labels and manuals will comply with requirements of EN 1041, EN 980, and any other applicable standards.
3. Labeling will also contain the following wording prominently displayed: "CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician."

3.3.2 Safety and Warning Labels

1. Provide adequate safety labels per 93/42 EEC MDD and Title 21 CFR 820.
2. Identify and explain any warnings in the operator's guide.

3.3.3 Shipping Labels

1. TBD

3.3.4 Verification and Validation

1. Perform verification of Labeling Requirements on Engineering Prototypes. Confirm verification on Manufacturing Prototypes if necessary.
2. Validate the Labeling Requirements on a Manufacturing Prototype in a clinical trial. Clinical trial results will conform to applicable European Community and Federal Food and Drug Administration Regulations including, but not limited to, the latest revision of EN 540, 21 CFR 812, and applicable standards referenced therein.

3.4 Service Delivery Requirements

3.4.1 General

1. Deliver all necessary information and support products with the main product delivery.
2. A training program will be available for training of repair and maintenance personnel.
3. Provide a system for supplying spare modules to repair and maintenance personnel.

3.4.2 Verification and Validation

1. Perform verification of Service Delivery Requirements on Engineering Prototypes. Confirm verification on Manufacturing Prototypes if necessary.
2. Validate the Service Delivery Requirements on a Manufacturing Prototype in a clinical trial. Clinical trial results will conform to applicable European Community and Federal Food and Drug Administration Regulations including, but not limited to, the latest revision of EN 540, 21 CFR 812, and applicable standards referenced therein.

4. Product System and Program Requirements

4.1 Business Risk Management Requirements

1. TBD

4.2 Customer Service and Product Support Requirements

1. TBD

4.3 Financial Requirements

1. TBD

4.4 Manufacturability Requirements

4.4.1 Modularity

1. Any assembly of acceptable quality must be interchangeable with any other like assembly.

4.4.2 Test Yields

1. Final assembly test yield will be at least 95% at pilot production.

4.4.3 Components

1. Use industry standards for selection of components.
2. Eliminate fragile, difficult to process components.
3. Where possible, standardized the use of electronic and other components to common types (same connectors, same tolerance resistors, capacitors, etc.)

4.4.4 Custom Components

1. Where possible, use industry standards in design of custom components.
2. Any part of acceptable quality will be interchangeable with any other like part (matched sets as exist for the probe are unacceptable).
3. Where possible, use industry standard finishes.
4. Design hardware to take advantage of castings, stampings, and injection moldings.

4.4.5 Fasteners

1. Where possible, use industry standards in fastener specifications.
2. Where possible, use fasteners types appropriate for auto-feed equipment.

4.4.6 Plastics

1. Design plastics in preparation of future tooling for injection molding.

4.4.7 Verification and Validation

1. Design plastics to meet material handling requirements (packaging, shipping, storage, etc.)
2. Perform verification of Manufacturability Requirements on Engineering Prototypes. Confirm verification on Manufacturing Prototypes.
3. Validate the Manufacturability Requirements during production of Manufacturing Prototypes.

4.5 Manufacturing Requirements

1. TBD

4.6 Marketing Requirements

1. TBD

4.7 Packaging Requirements

4.7.1 General

1. Package to withstand normal customer modes of transportation such as truck cargo space or other expected transportation methods.
2. Package to withstand normal shipping and handling by commercial modes of transport in accordance with ISTA Procedure 1A.
3. Include all other materials and support components in packaging as required.
4. Place visible warnings on the packaging of any shock, vibration, or environmental limitations during shipping and storage.
5. Add Ardiem Medical logo and graphics to the shipping package.
6. Design packaging capabilities for individual or palletized shipment.

4.7.2 Verification and Validation

1. Perform verification of Packaging Requirements on Engineering Prototypes. Confirm verification on Manufacturing Prototypes if necessary.
2. Validate the Packaging Requirements on a Manufacturing Prototype.

4.8 Regulatory Compliance Requirements

4.8.1 General

1. Achieve FDA regulatory compliance.
2. Achieve European Community compliance under Medical Device Directive 93/42/EEC and CE marking authority.

4.8.2 Verification and Validation

1. Perform verification of Regulatory Requirements on Engineering Prototypes. Confirm verification on Manufacturing Prototypes if necessary.
2. Validate the Regulatory Requirements on a Manufacturing Prototype.

4.9 Shipping Requirements

4.9.1 General

1. TBD

4.9.2 Verification and Validation

1. Perform verification of Shipping Requirements on Engineering Prototypes. Confirm verification on Manufacturing Prototypes if necessary.
2. Validate the Shipping Requirements on a Manufacturing Prototype.

4.10 Standards Compliance Requirements

4.10.1 General

1. Use FDA QSRs, IEC standards, EN standards, or others where appropriate.

4.10.2 Verification and Validation

1. Perform verification of Standards Compliance Requirements on Engineering Prototypes. Confirm verification on Manufacturing Prototypes if necessary.

2. Validate the Standards Compliance Requirements on a Manufacturing Prototype.

4.11 Statutory Compliance Requirements

4.11.1 General

1. Satisfy any requirements for compliance with domestic or non-domestic local, state, and/or federal legal edicts or legislation.

4.11.2 Verification and Validation

1. Perform verification of Statutory Compliance Requirements on Engineering Prototypes. Confirm verification on Manufacturing Prototypes if necessary.
2. Validate the Statutory Compliance Requirements on a Manufacturing Prototype.

4.12 Testability Requirements

4.12.1 PCBA Test Requirements

1. Install PCBA test facilities and procedures, either in house or at vendor facility.
2. Production operators and test technicians will run test software.
3. Where possible, write test software with a go/no go output.
4. Upon successful completion of a final test, download the test data to the device history record.
5. If unsuccessful, pass the final test data to the troubleshooting technician or engineer.

4.12.2 Final Test

1. Transmit final test results to a separate computer via the serial link. Upon successful completion of a final test, download the final test data to the device history record.
2. If a final test is unsuccessful, either transmit the raw data collected during the test to an external PC for analysis, or repeat the tests with comparable software on an external PC.
3. In final testing, test all critical specifications to a pass/fail criteria.

4.12.3 Verification and Validation

1. Perform verification of Testability Requirements on Engineering Prototypes. Confirm verification on Manufacturing Prototypes.
2. Validate the Testability Requirements during production of Manufacturing Prototypes.

5. References

5.1 Standards

21 CFR 820	Medical Devices; Current Good Manufacturing Practice Final Rule; Quality System Regulation (1996)
80/181/EEC	Unit Of Measurement
89/336/EEC	On The Approximation Of The Laws Of The Member States Relating To Electromagnetic Compatibility
92/31/EEC	Amending Directive 89/336/EEC On The Approximation Of The Laws Of The Member States Relating To Electromagnetic Compatibility
93/42/EEC	EC Council Directive Concerning Medical Devices (1993)
93/68/EEC	Amending Directives 89/336/EEC (Electromagnetic Compatibility) 90/385/EEC (Active Implantable Medicinal Devices)
EN 1041:1998 E	Terminology, Symbols And Information Provided With Medical Devices - Information Supplied By The Manufacturer With Medical Devices
BS EN 1441	Medical Devices - Risk Analysis
BS EN 30993-1:1994	Biological Evaluation Of Medical Devices - Part 1: Guidance On Selection Of Tests
BS EN 30993-5:1994	Biological Evaluation Of Medical Devices - Part 5: Tests For Cytotoxicity - In Vitro Methods
BS EN 46001:1997	Quality Systems - Medical Devices - Particular Requirements For The Application Of EN ISO 9001
EN 50081-1:1992 E	Electromagnetic Compatibility - Generic Emission Standard Part 1: Residential, Commercial And Light Industry
EN 50103	Guidance On The Application Of EN 29001 And EN 46001 And Of EN 29002 And EN 46002 For The Active (Including Active Implantable) Medical Device Industry
EN 540:1993 E	Clinical Investigation Of Medical Devices For Human Subjects
BS EN 55011:1991	Limits And Methods Of Measurement Of Radio Disturbance Characteristics Of Industrial, Scientific And Medical (ISM) Radio-Frequency Equipment
EN 60601-1-2:1993 E	Medical Electrical Equipment. Part 1. General Requirements For Safety; 2. Collateral Standard: Electromagnetic Compatibility - Requirements And Tests
BS EN 980:1997 (EN 980:1996 E)	Graphical Symbols For Use In The Labeling Of Medical Devices
IEC 127-2	Cartridge Fuse Link, Sheet III Specification For Time Lag Fuses
IEC 601-1-4:1996	Medical Electrical Equipment - Part 1: General Requirements For Safety - 4. Collateral Standard: Programmable Electrical Medical Systems
IEC 60529	Degrees Of Protection Provided By Enclosures
IEC 60601-1:1998	Medical Electrical Equipment. Part 1: General Requirements For Safety
IEC 601-1:1988/A1:1991	Medical Electrical Equipment. Part 1: General Requirements For Safety

IEC 601-1:1988/A2:1995 + Corrigendum Jun 1995	Medical Electrical Equipment. Part 1: General Requirements For Safety
IEC 801-2	Electromagnetic Compatibility For Industrial-Process Measurement And Control Equipment Part 2: Electrostatic Discharge Requirements 1991
ISO 10993-10	Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Sensitization (ISO 10993-10:1995
ISO 10993-12	Biological Evaluation Of Medical Devices - Part 12: Sample Preparation And Reference Materials (ISO 10993-12:1996)
ISO 13485:1996(E)	Quality Systems - Medical Devices - Particular Requirements For The Application Of ISO 9001
ISO 9001:1994(E)	Quality Systems - Model For Quality Assurance In Design, Development, Production, Installation And Servicing
MIL-STD-461D	Electromagnetic Interference Emissions And Susceptibility
UL 2601-1	Standard for Medical Electrical Equipment, Part 1: General Requirements for Safety - Second Edition October 24, 1997

5.2 Acronyms

ADC	Analog-to-Digital Converter
CPU	Central Processing Unit
FIT	Fault Isolation Test
LCD	Liquid Crystal Display
PCBA	Printed Circuit Board Assembly
RTC	Real Time Clock

6. Revisions

Rev.	Description	Author	Effective Date
00	Preliminary Issue	Ralph Gill	9/26/02
01	Completed Requirements	Mike Pitsakis	9/24/03

APPENDIX K

ARDIEM MEDICAL, INC. **78000-HD**
Rev. X1

Hypothermia Induction Device
Hardware Description

1. General Description

This document provides information on the operation of the electronics of the Mild-Moderate Hypothermia Induction Device electronics.

2. References

78300-SC	Wiring Diagram
78310-SC	PCB Assembly, Hypothermia Main, Schematic
78320-SC	PCB Assembly, Hypothermia Display, Schematic
78330-SC	PCB Assembly, Hypothermia Temp Connector, Schematic
78340-SC	Subassembly, User Input, Wiring
78350-SC	Subassembly, Pump Motor, Wiring
78360-SC	Subassembly, Compressor/Valve, Wiring
78380-SC	Subassembly, Indicators, Wiring
RC3000UM.pdf	Rabbit Core User Manual
RC3000DH.pdf	Rabbit Core Designer's Handbook
RC3400UM.pdf	Rabbit Core Module User Manual
RC3400 Core Schem 090-0157.pdf	Rabbit Core Module Schematic
RC3400 Proto Schem 090-0162.pdf	Rabbit Core Prototype Schematic

3. Functional Description

3.1 Introduction

The electronics consist of three PCBs (Main, Display, and Temp Connector) and four subassemblies (User Input, Indicators, Pump Motor, and Compressor/Valve.

The electronics are used to input operator selections, drive indicators and display, monitor temperatures, and control temperature and flow rate. A block diagram of the Hypothermia Main board is shown in Fig.1. It consist of eight basic sections:

1. Power section: An external 12 VDC switching power supply is used to power up the electronics and electromechanical components. An on board switching voltage regulator converts the input dc voltage to 5 V with 80% efficiency and a linear voltage regulator regulates the 5 V down to 3.3 V. The 3.3 V is used for biasing the embedded microcontroller module, which is mounted on board. The 5 V biases all other circuits.
2. The Controller Connectors section: This section provides means for mounting and connecting the embedded microcontroller (Rabbit RCM3400) to the main board. It also includes a serial RS232 port, and a programming port.
3. User Inputs section: This includes inputs from two front panel rotary switches, one for setting temperature and one for setting flow, a toggle switch for selecting displaying body temperature 1 or body temperature 2, and two push-button switches for setting body temperature (one switch to increase the other to decrease).

4. User Outputs section: The Display interfaces are included here. Provision is made to enable serial or parallel interfacing of LEDs or parallel interfacing of LCD. Also included are drivers for seven indicator LEDs for POWER ON, FLOW OK (within set-point), TEMPERATURE OK (within set-point), SYSTEM OK (self diagnostics return no problems), and the three operational states STATE 1, STATE 2, STATE 3.
5. PT Temperature Read section: In this section two body temperatures plus inflow and outflow temperatures are sensed via thermistors connected to isolated circuits, then multiplexed and converted to digital and outputted in serial sequential format by a 12-bit A/D.
6. HE Temperature Read section: This section provides thermistor interfaces for the heat exchanger and ambient temperatures by a 12-bit A/D.
7. Temperature Control section: Two power drivers are included one for a vapor compressor and one for a valve. Provisions for monitoring current draw are included.
8. Flow Control section: A power driver for a pump motor is included plus electronics for driving an optocoupler used as a tachometer to enable motor speed readout and feedback.

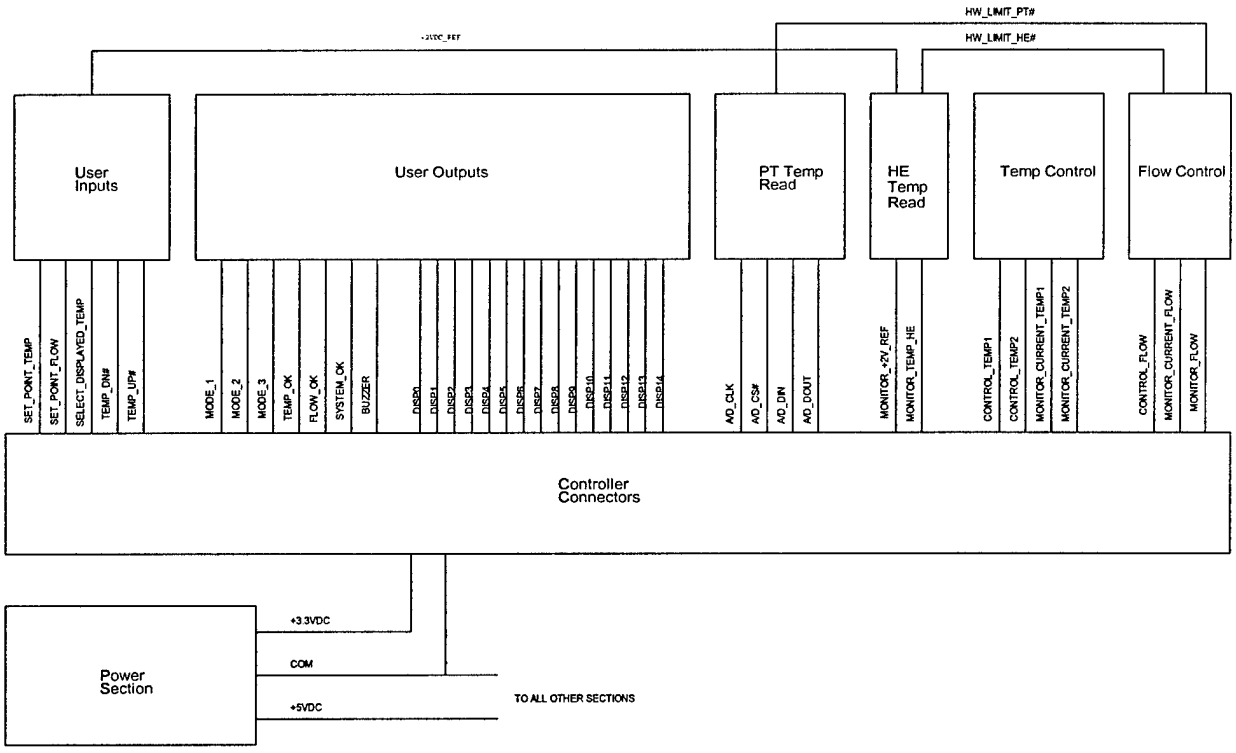

Figure 1

3.2 The Controller Connections/Embedded Microcontroller

The microcontroller module (Rabbit RCM3400) is a separate board (see Fig. 2) that hooks on the Main board via connectors J11 and J12. It features:

- The Rabbit 3000 8-bit microprocessor running at 29.4 MHz
- 47 parallel 5 V tolerant I/O lines: 41 configurable for I/O, 3 fixed inputs, 3 fixed outputs
- Two additional digital inputs, one additional digital output

- Eight single-ended or four differential analog inputs
- One additional analog input
- External reset input
- Alternate I/O bus can be configured for 8 data lines and 6 address lines (shared with parallel I/O lines), I/O read/write
- Ten 8-bit timers (six cascadable) and one 10-bit timer with two match registers
- 512K flash memory and 512K SRAM
- Real-time clock with battery backup
- Watchdog supervisor
- 10-bit free-running PWM counter and four width registers
- Two-channel Input Capture can be used to time input signals from various port pins
- Two-channel Quadrature Decoder accepts inputs from external incremental encoder modules
- Five CMOS-compatible serial ports: maximum asynchronous baud rate of 5.5 Mbps.
- Four ports are configurable as a clocked serial port (SPI), and two ports are configurable as SDLC/HDLC serial ports.
- Supports 1.15 Mbps IrDA transceiver.

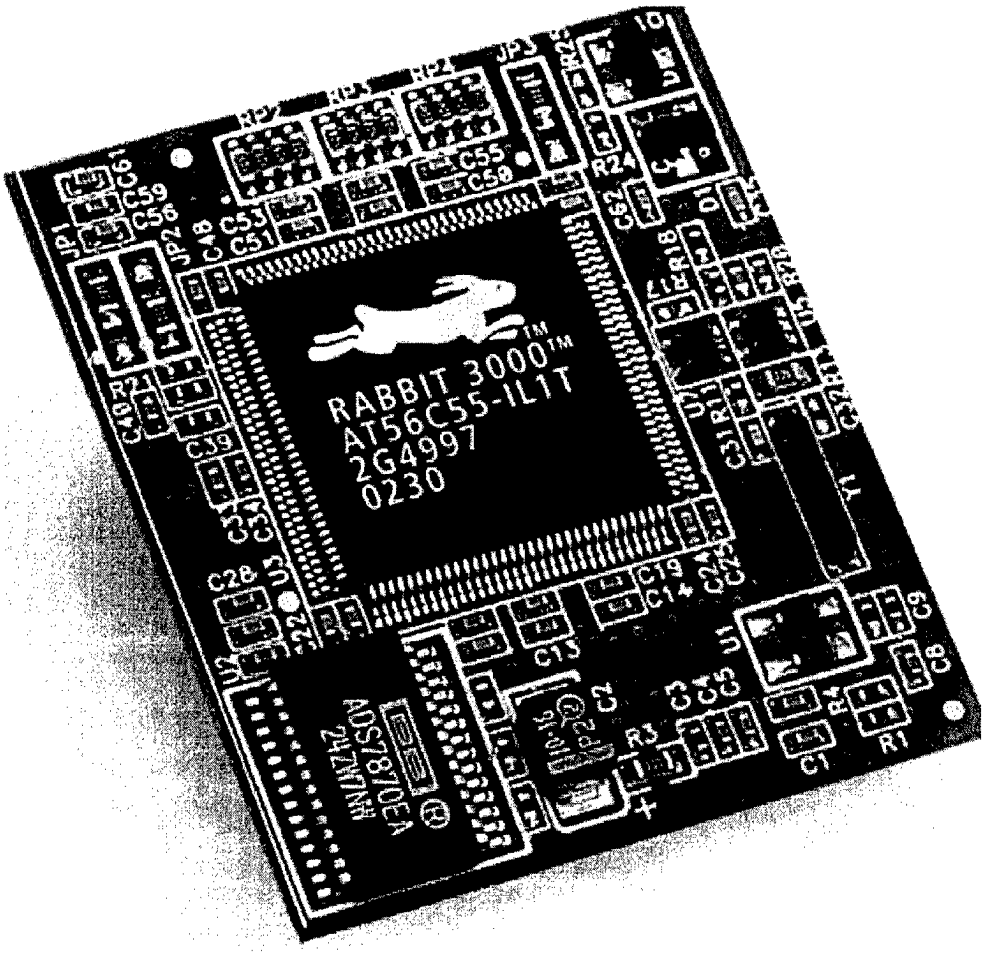

Figure 2

The microcontroller apart from temperature and flow control assignments has some more functions to perform. Those include reading inputs periodically and providing outputs as listed below.

User affected inputs (from front panel) are:

- Outflow Temperature Set-Point (Heat exchanger outflow blood temperature)
- Patient Temperature Set-Point (Up & Down)
- Displayed Temperature Select
- Flow Set-Point

Control Feedback inputs are:

- Process Temperature (analog continuous)
- Process Flow (pulses)

There are some more inputs for the purpose of monitoring. Those are:

- Five temperatures
- Two power supply voltages and two reference voltages
- Three control element currents (pump motor, compressor, and valve)

Indicator outputs are:

- Three operational mode indicators
- Temperature OK
- Flow OK
- Circuit OK

The microcontroller also drives the display.

An audible alert is included via a buzzer that the operator may turn off. The buzzer will activate if there is circuit failure as determined by self diagnostics.

A 12-bit, 8-channel multiplexed A/D is contained on the RCM3400. Set point voltages, process currents, and ambient and heat exchanger temperature signals are routed to the A/D.

The connections to the microcontroller are shown in Fig. 3 and Fig. 4.

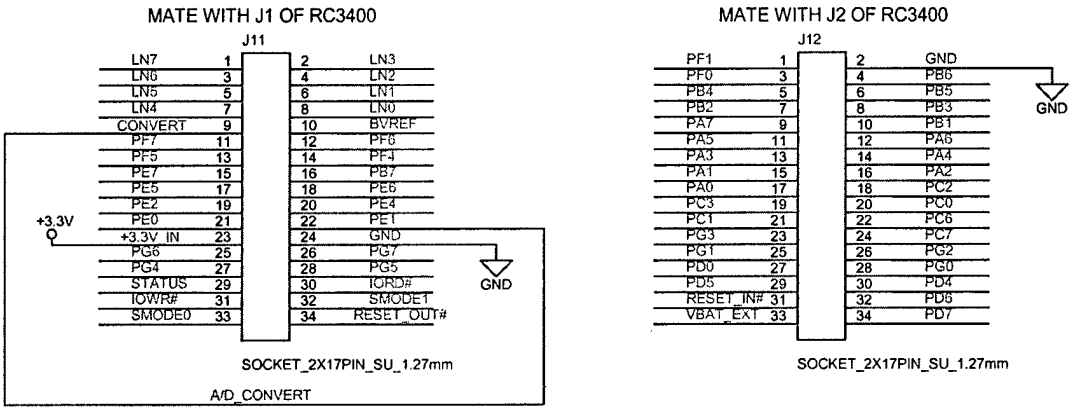

Figure 3

J1 PIN #	PIN NAME	SIGNAL NAME	J2 PIN #	PIN NAME	SIGNAL NAME
1	LN3	MONITOR_CURRENT_TEMP1	1	GND	GND
2	LN7	SELECT_DISPLAYED_TEMP	2	PF1	A/D_CLK
3	LN2	MONITOR_CURRENT_FLOW	3	PB6	TEMP_OK
4	LN6	MONITOR_TEMP_AMB	4	PF0	Not Used
5	LN1	SET_POINT_TEMP 1	5	PB5	FLOW_OK
6	LN5	MONITOR_TEMP_HE	6	PB4	STATE_3
7	LN0	SET_POINT_FLOW	7	PB3	STAET_2
8	LN4	MONITOR_CURRENT_TEMP2	8	PB2	STATE_1
9	BVREF	Not Used	9	PB1	Programer/DSP12
10	CONVERT	A/D_CONVERT	10	PA7	Not Used
11	PF6/PWM2	CONTROL_TEMP1	11	PA6	Not Used
12	PF7/PWM3	CONTROL_TEMP2	12	PA5	Not Used
13	PF4/PWM0	CONTROL_FLOW	13	PA4	Not Used
14	PF5/PWM1	MONITOR_FLOW	14	PA3	Spare In
15	PB7	SYSTEM_OK	15	PA2	Spare In
16	PE7	DISP14/Spare Out	16	PA1	TEMP_DN#
17	PE6	Spare Out	17	PC2	A/D_DIN
18	PE5	INT1B/Spare Interrupt	18	PA0	TEMP_UP#
19	PE4	INT0B/Spare Interrupt	19	PC0/TXD	Serial Out
20	PE2	DISP14/Spare Out	20	PC3	A/D_DOUT
21	PE1	A/D_CS#	21	PC6/TXA	Programer/DSP13
22	PE0	A/D_CONVERT	22	PC1/RXD	Serial In
23	GND	GND	23	PC7/RXA	Programer
24	+3.3V_IN	+3.3V_IN	24	PG3	DISP3
25	PG7	DISP7	25	PG2	DISP2
26	PG6	DISP6	26	PG1	DISP1
27	PG5	DISP5	27	PG0	DISP0
28	PG4	DISP4	28	PD0	BUZZER
29	IORD#	Not Used	29	PD4	DISP8
30	STATUS	Used by programmer	30	PD5	DISP9
31	SMODE1	Used by programmer	31	PD6	DISP10
32	IOWR#	Not Used	32	RESET_IN#	Used by programmer
33	RESET_OUT#	Not Used	33	PD7	DISP11
34	SMODE0	Used by programmer	34	VBAT_EXT	VBAT_EXT

Figure 4

3.2.1 Programming Port

The microcontroller may be programmed via connector J14, shown in Fig. 5. Port lines PC1, PC7, and PB1 with some other lines are dedicated to this purpose. Data transfer from the programming computer is in serial format. A special cable is provided by the manufacturer for programming purposes.

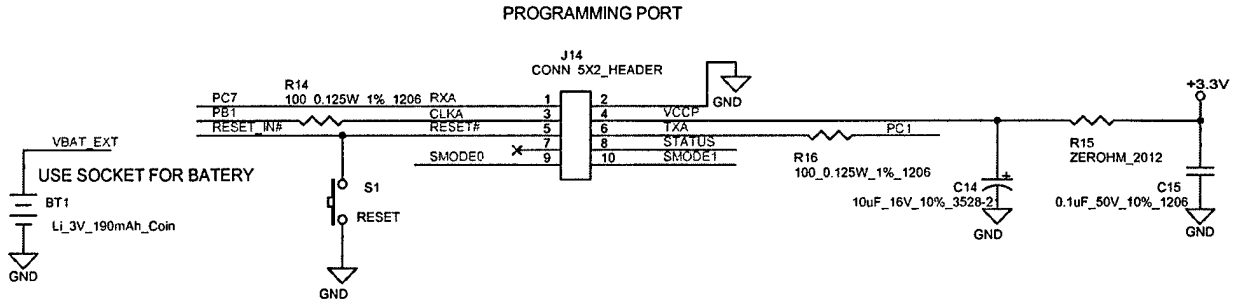

Figure 5

3.2.2 Display Interface

A four-digit seven-segment LCD and associated driving circuits are located on the Display board (see 3.2.2). Connection to it is via connector J7. Four data lines (DISP0-3) and four control lines (DISP8-11) are used (see Fig. 6a). An interface that supports serial LCD is included and is shown in Fig. 6b. Also an interface that supports 8-bit parallel LCD is included (see Fig. 6c).

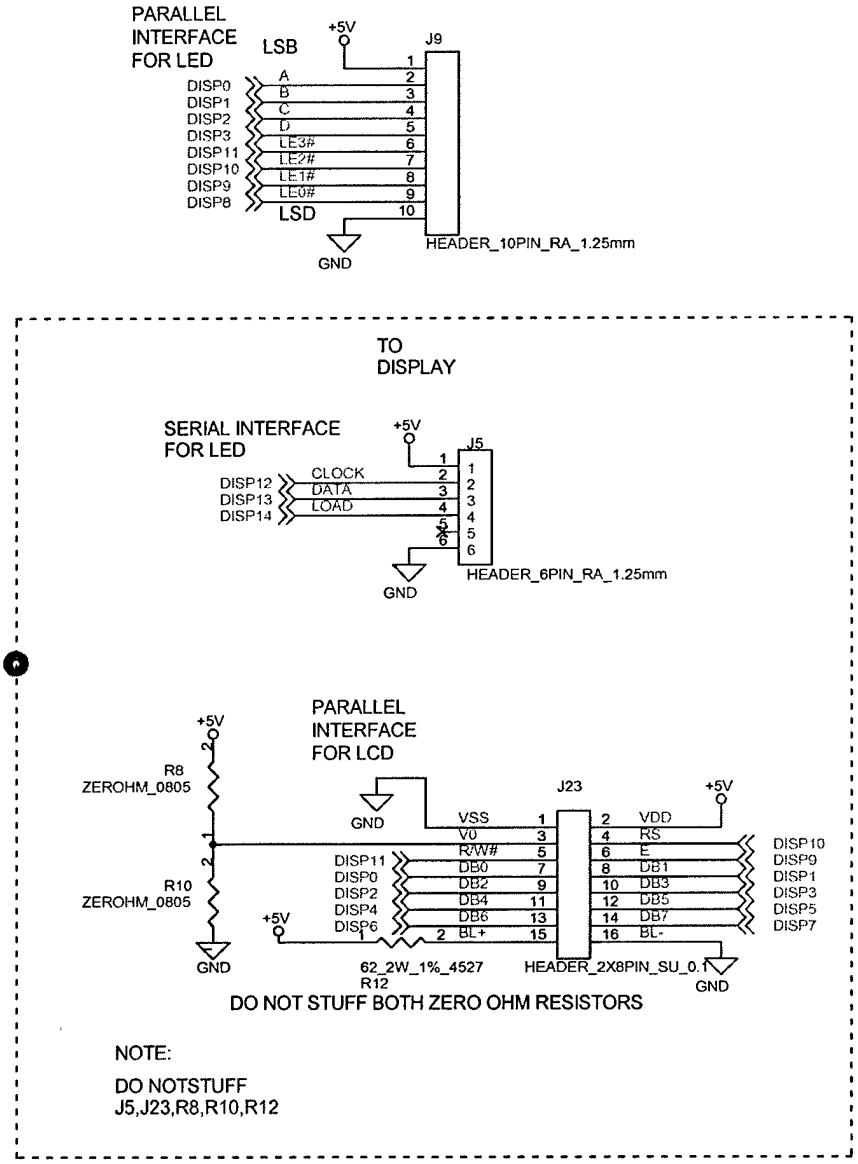

Figure 6

3.2.3 Serial Communications Interface

This interface offers communications between the microcontroller and a PC. It uses a standard RS-232 asynchronous serial interface (NRZ format with one start bit, eight data bits, and one stop bit) at a high baud rate. U3 converts CMOS to RS-232 levels and J13 hooks to the rear panel DB-9 connector (see Fig. 7). The purpose of this interface is to output real time data (flow, temperature, etc) to a PC that can be displayed, plotted, printed, and saved.

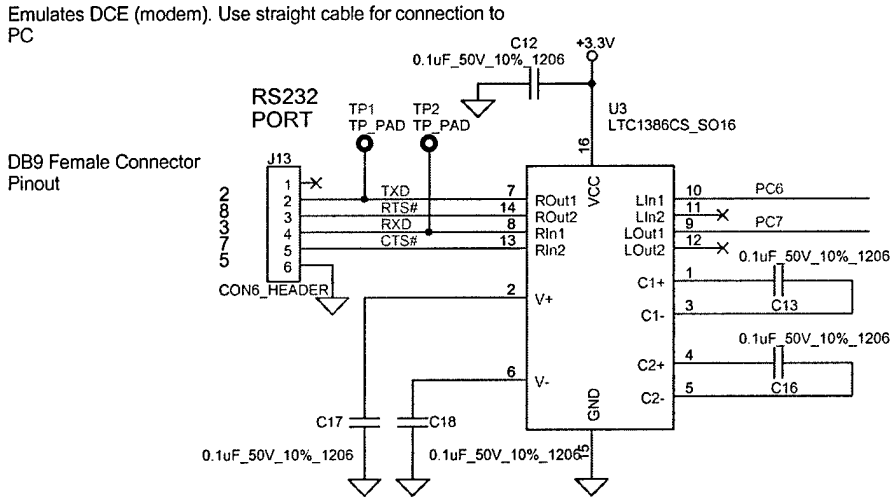

Figure 7

3.3 User Inputs

User input circuits are shown in Fig. 8 (on Main board) and Fig. 9 (front panel assemblies). The outflow (blood) temperature set point and flow rate set point are selected by the operator via rotary switches mounted on the front panel. Each selection provides a distinct voltage by dividing the supply voltage. The selected voltage is then routed to the microcontroller A/D.

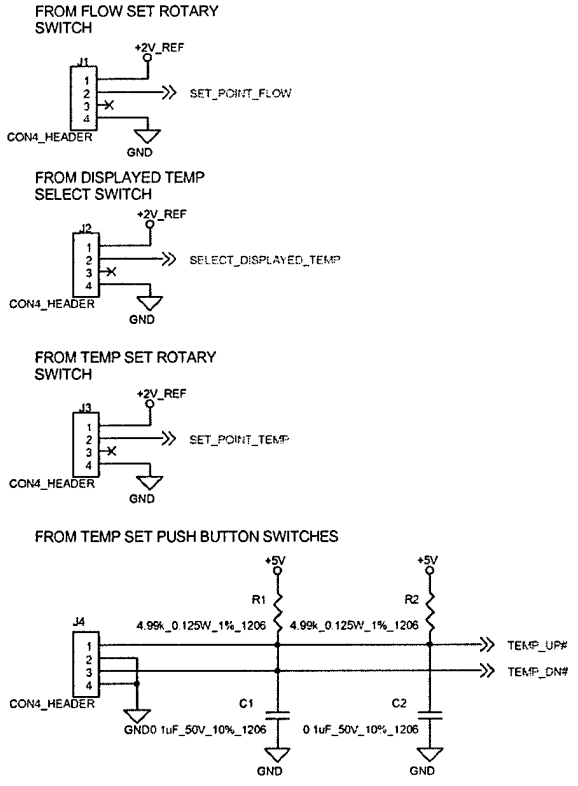

Figure 8

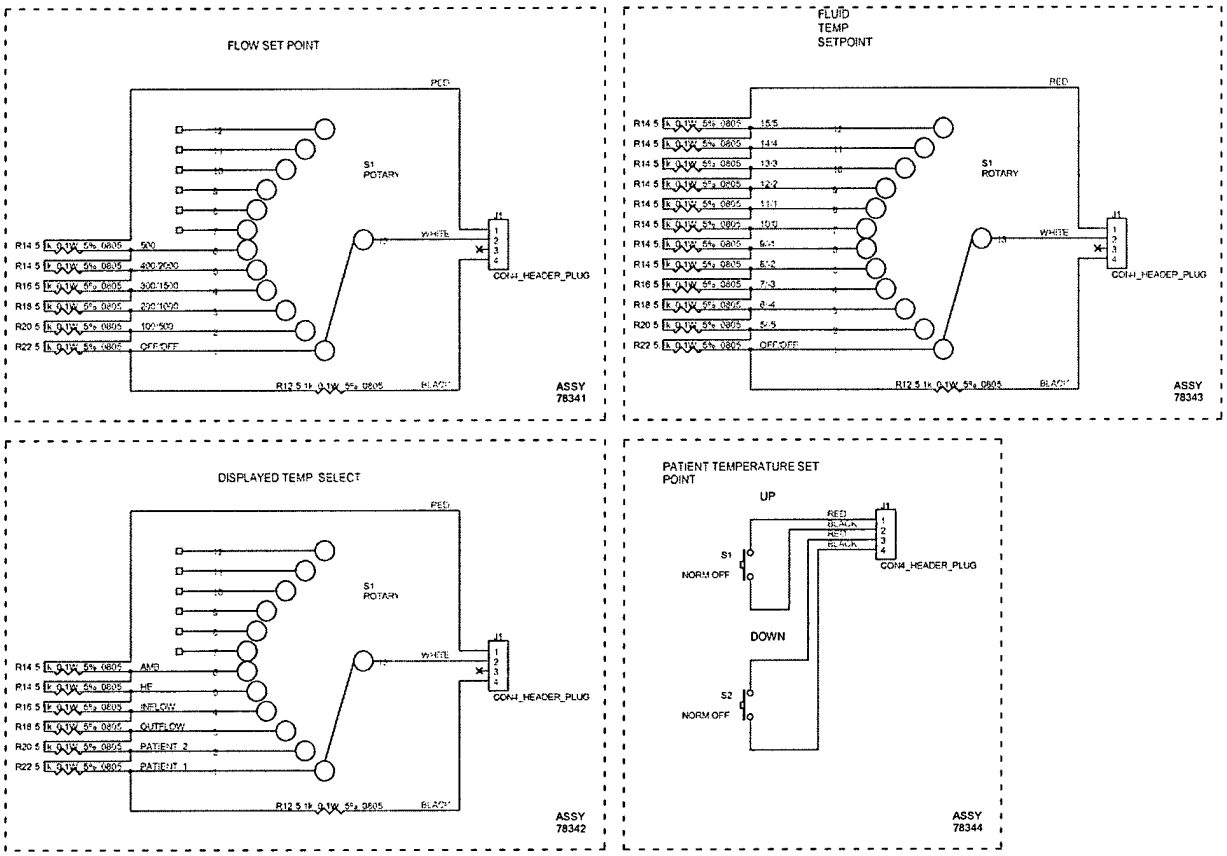

Figure 9

The operator may select patient temperature set point by the use of one up (direction) and one down (direction) push-button switch. The active low outputs of these switches are monitored by the microcontroller and when a low state is sensed the microcontroller displays the present patient set-point selection (or default) and increments/decrements while the operator keeps the push-button depressed.

3.4 User Outputs

3.4.1 Indicator Outputs

Those front panel LEDs and are controlled by the microcontroller via drivers. They include:

STATE_1	Indicates that the device is in the STAND BY operating mode
STATE_2	Indicates that the device is in the patient COOLING mode
STATE_3	Indicates that the device is in the MAINTENANCE mode
FLOW_OK	Indicates targeted flow rate is within set-point range
TEMP_OK	Indicates targeted temperature is within set-point range
SYSTEM_OK	Indicates system is trouble free

There is also an audible alert in case of circuit malfunction, BUZZER_ON. The operator may turn the audible off via a switch on the front panel. The drivers and connector for the LEDs are shown in Fig. 10.

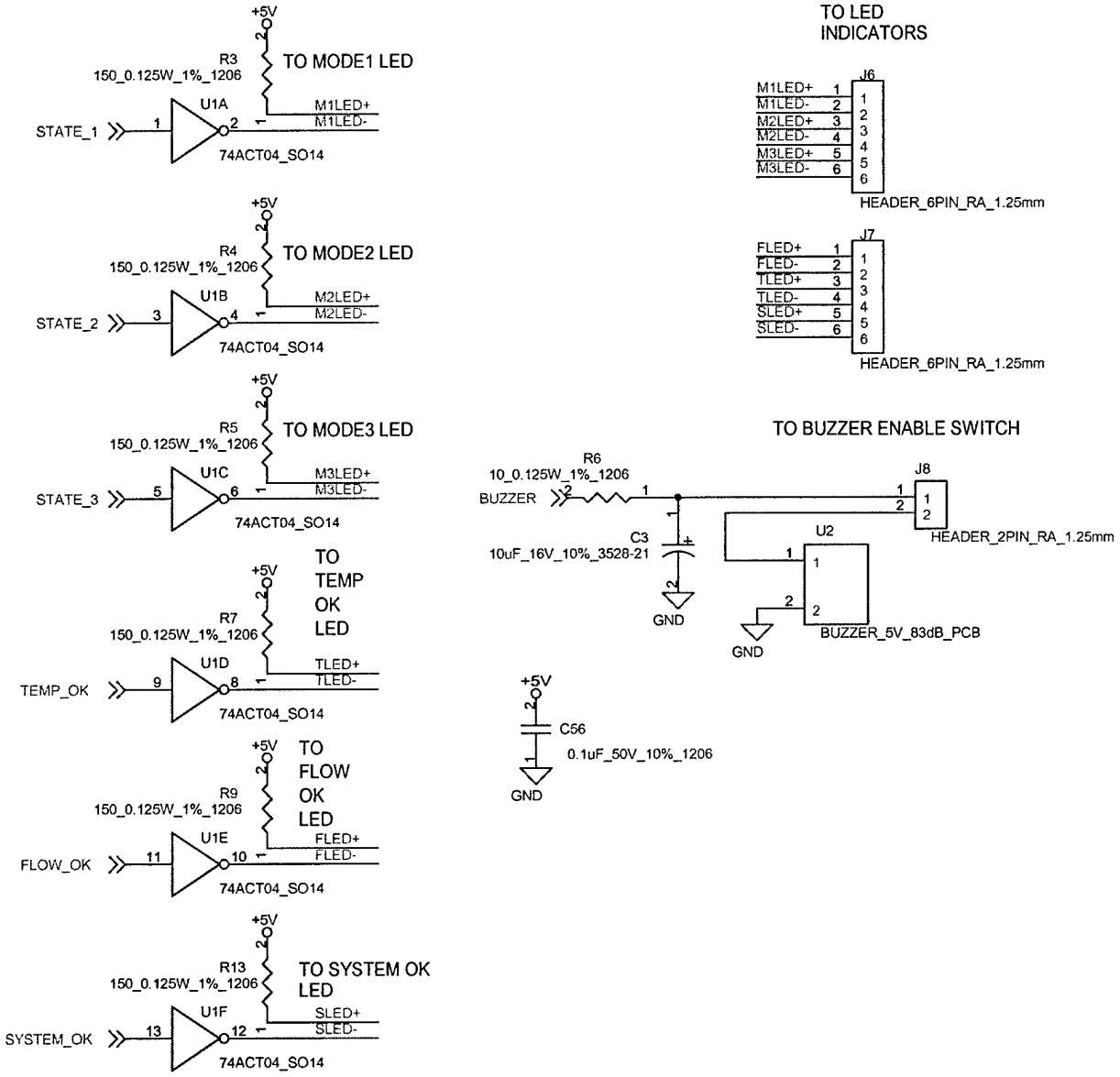

Figure 10

3.4.2 Display Board

The display circuits are shown in Fig.11 along with the four 7-segment LEDs. The 4511 ICs (U1-U4) decode the 4-bit BCD parallel input (A, B, C, D) from the controller to 7-segments. There are also 4 control lines coming form the microcontroller. Those latch the data intended for each digit and therefore multiplex the data lines. The LEDs (U8-U11) are common cathode and are connected to the decoders through resistors networks (U4-U7). Only one segment of the sign LED is driven on to display the negative sign.

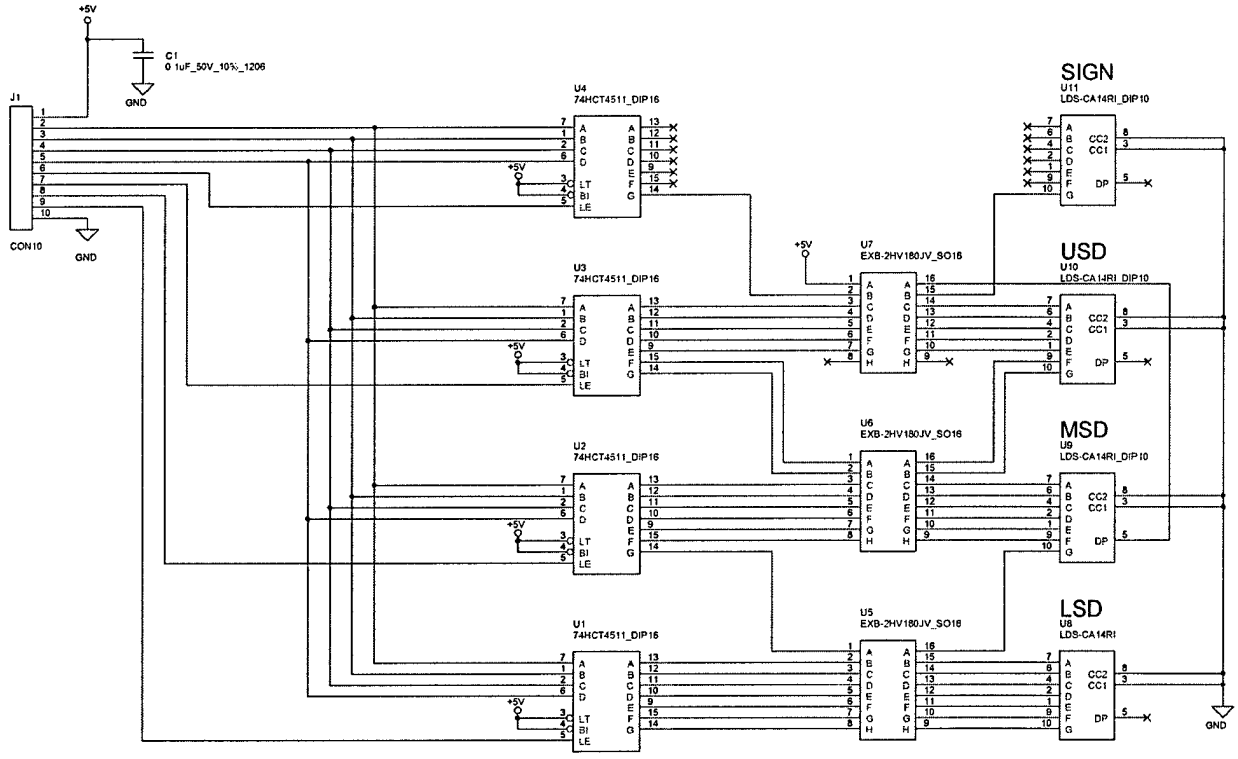

Figure 11

3.5 PT Temperature Read Section

Temperatures are sensed by thermistors (YSI #44004 - Mix "B", 2252 Ω @ 25 °C) that are part of the circuit shown in Fig. 12 (only one of four circuits is shown). A stable 5V voltage, derived from a voltage reference IC and a 3.57 k are used as reference. Amplifier U11 and resistors R42, R43, and R44 scale the voltage developed across the thermistor to match the input range of the A/D (0 to 5V). The amplifier input voltage depends on thermistor resistance as follows:

$$Vin = Vref\ Rth / (Rth + Rref)$$

The amplifier output voltage will be:

$$Vo = Vin\ [(Rf / Ri) + (Rf / Rh) + 1] - Vref\ (Rf / Rh)$$

The resistors can be calculated as follows:

$$Ri = 10k$$

$$Rf = \{[Vout(T1) + Vo] / Vin(T1)\}\ R_i$$

$$Rh = R_f\ Vref / Vo$$

Where $Vo = \{[Vin(T2)\ Vout(T1)] - [Vin(T1)\ Vout(T2)]\} / [Vin(T1) - Vin(T2)]$. Vin and Vout are voltages at the extremes of the desired temperature range. U9 contains internal diodes tied to +5V_ISO and GND_ISO for over voltage protection. Therefore Vref = 5 V, Rref = 3570 Ω, Ri = 10000 Ω, Rh = 8250 Ω, and Rf = 2940 Ω.

The thermistor cable assemblies are connected to the front panel PT Connectors board (see Fig. 14), which connects to the Main board.

The thermistors are calibrated to the range -15 to +45 °C. The Steinhart-Hart coefficients are:

$$a = 1.467140056809390E\text{-}03$$

b = 2.384088270851750E-04

c = 1.009987514947380E-07

See spread sheet Mod_Therm YSI.xls for all the above calculations.

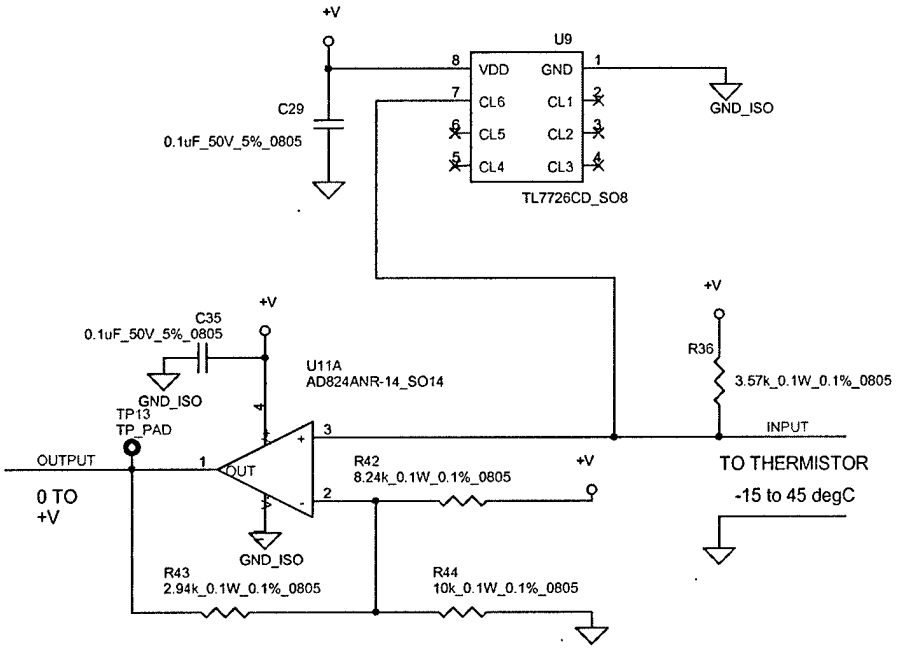

Figure 12

All these temperature circuits are electrically isolated from all other circuits via opto-couplers and the supply voltages by a dc/dc converter as required by safety regulation.

These scaled thermistor voltages plus some supply voltages are multiplexed and converted to digital levels then outputted in a synchronous serial format by a 8-channel multiplexed 12-bit A/D with serial output (U11 Linear Technology LTC1294, see Fig. 13) that is controlled by SW. Refer to the data sheet for handling the control signals (A/D_CS#, A/D_CLK, AND A/D_IN), controlling the multiplexer and the conversion. The serial data from the A/D is on the A/D_OUT line.

Data transfer is initiated by a falling chip select (CS#) signal. When that occurs, the device looks for a start bit on DIN. After the start bit is received a 7-bit input word is shifted into the DIN input, which configures the device and starts the conversion. After one null bit, data is output on the DOUT line. The clock (CLK) synchronizes the data transfer with each bit being transmitted on the falling CLK edge and captured on the rising CLK edge in both transmitting and receiving. Refer to the A/D manufacturer data sheet for more information.

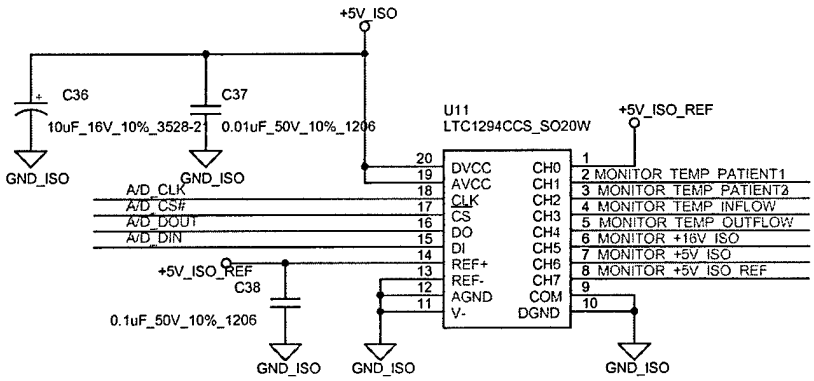
+5V_ISO
C36
10uF_16V_10%_3528-21
C37
0.01uF_50V_10%_1206
GND_ISO
GND_ISO
U11
LTC1294CCS_SO20W
+5V_ISO_REF
20
19
18
17
16
15
14
13
12
11
DVCC
AVCC
CLK
CS
DO
DI
REF+
REF-
AGND
V-
CH0
CH1
CH2
CH3
CH4
CH5
CH6
CH7
COM
DGND
1
2 MONITOR_TEMP_PATIENT1
3 MONITOR_TEMP_PATIENT2
4 MONITOR_TEMP_INFLOW
5 MONITOR_TEMP_OUTFLOW
6 MONITOR_+16V_ISO
7 MONITOR_+5V_ISO
8 MONITOR_+5V_ISO_REF
9
10
A/D_CLK
A/D_CS#
A/D_DOUT
A/D_DIN
+5V_ISO_REF
C38
0.1uF_50V_10%_1206
GND_ISO
GND_ISO
GND_ISO

Figure 13

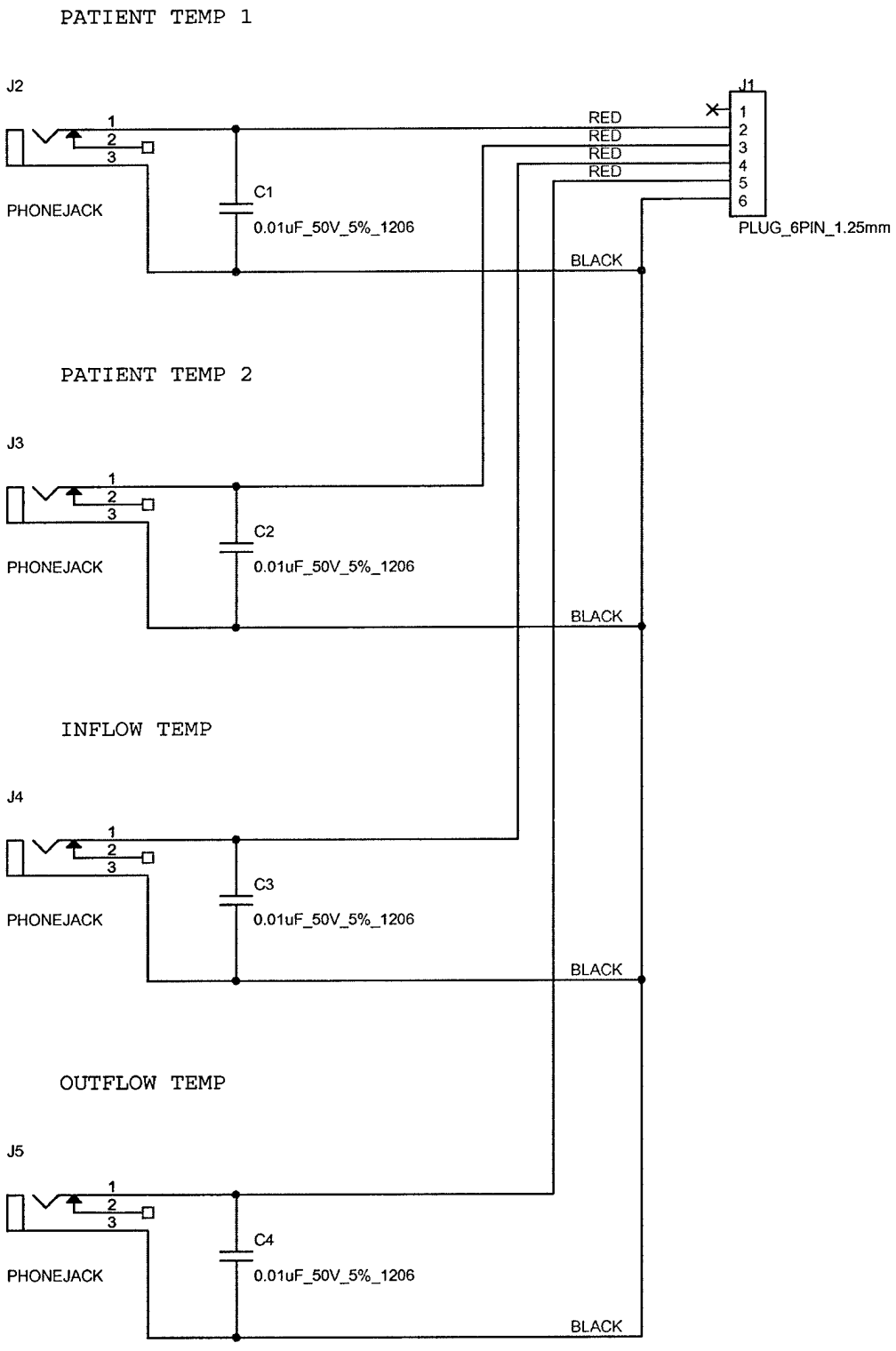
PATIENT TEMP 1
J2
1
2
3
PHONEJACK
C1
0.01uF_50V_5%_1206
RED
RED
RED
RED
BLACK
J1
1
2
3
4
5
6
PLUG_6PIN_1.25mm
PATIENT TEMP 2
J3
1
2
3
PHONEJACK
C2
0.01uF_50V_5%_1206
BLACK
INFLOW TEMP
J4
1
2
3
PHONEJACK
C3
0.01uF_50V_5%_1206
BLACK
OUTFLOW TEMP
J5
1
2
3
PHONEJACK
C4
0.01uF_50V_5%_1206
BLACK

Figure 14

3.6 HE Temperature Read Section

Similar thermistors, thermistor circuits, and scaling amplifiers (see Fig. 15) are used for the heat exchanger and ambient temperature monitoring. A 2V reference voltage is used here because these signals do not need to be isolated from the rest circuits and are routed to 8-channel 12-bit A/D converter with parallel output that has a 0 to 2V input range (Burr Brown ADS7870). This A/D is located on the Controller module.

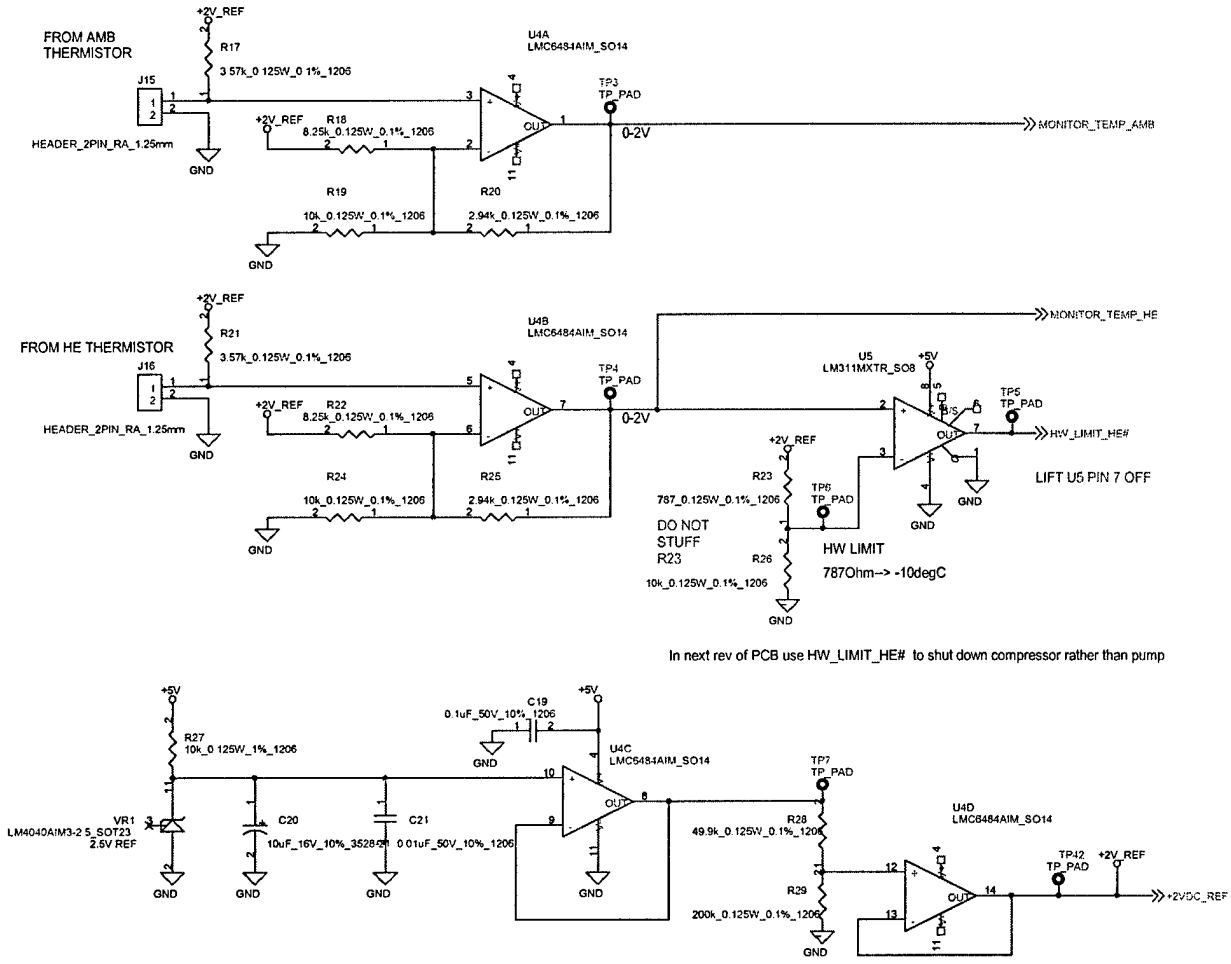

Figure 15

3.7 Temperature Control Section

3.7.1 Control Temperature Input

There are three temperature inputs involved in control. Namely Patient Temp 1, outflow temperature, or heat exchanger temperature. Ultimately is the patient temperature that needs to be stabilized. However this temperature depends on the outflow temperature that in turn depends on the heat exchanger temperature (primary). The latter is the only temperature that is directly controlled by the device. Therefore for control purposes, the heat exchanger temperature will serve as continuously adjustable set point with the patient temperature as an indicator of what that should be.

3.7.2 Control Temperature Output

Since the cooling means elements (vapor compressor and expansion valve) require switching of large currents, the driving circuit shown in Fig 16 is used (similar circuit is used for the expansion vale but not shown). IC U22 drives the switching transistor Q3 and guarantees brake before make switching.

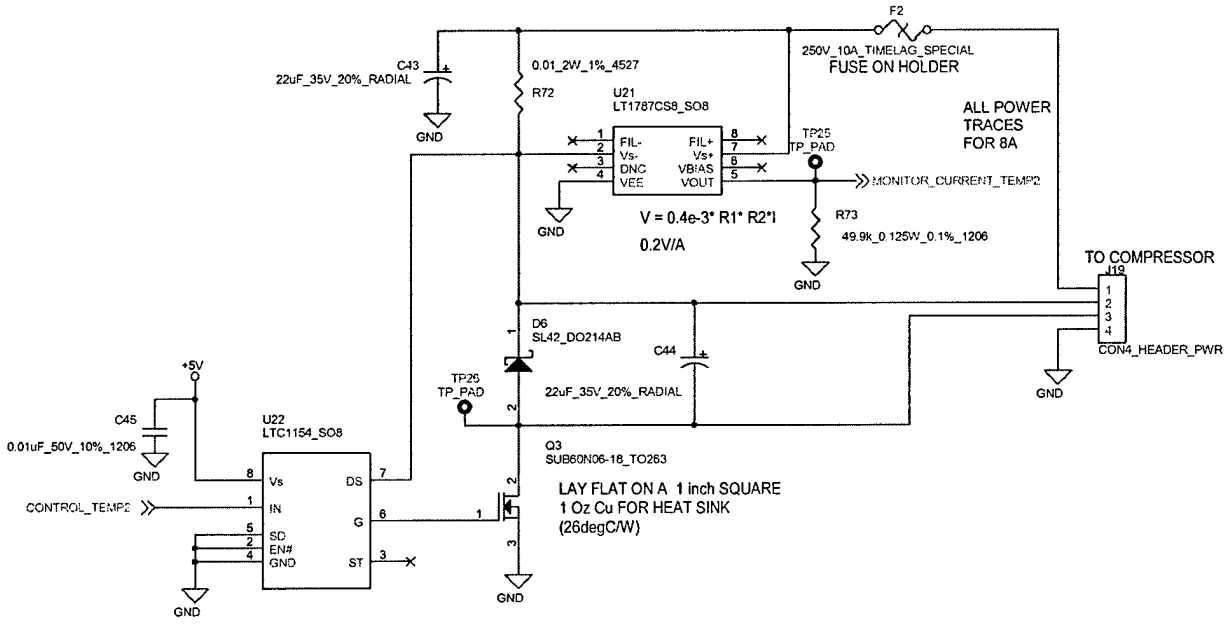

Figure 16

In Mild-Moderate Hypothermia an AC compressor is used. This compressor stays on all the time. Temperature control is accomplished by adjusting refrigerant flow by opening/closing a valve. This valve has a built in stepper motor for controlling valve closure. The stepper motor is driven by two TTL level lines. One line sets the direction (open/close) while the other merely steps the motor with each pulse (5 ms min). Therefore the power drive is not needed and the cable assembly connecting to the valve adapts to TTL as shown in Fig, 17. Use 50 mA fast blow fuses.

In Profound Hypothermia, a 12 VDC compressor is used. Temperature control is accomplished by turning the compressor on/off via a relay closure as shown in Fig. 17. LED D1 reveals the compressor status, R1 sets the compressor speed, and R2 sets the cut out thresholds for battery operation. See Danfoss BD35F datasheet for details. Use a 6.3 A fast acting fuse or preferably a 3.15A slow blow.

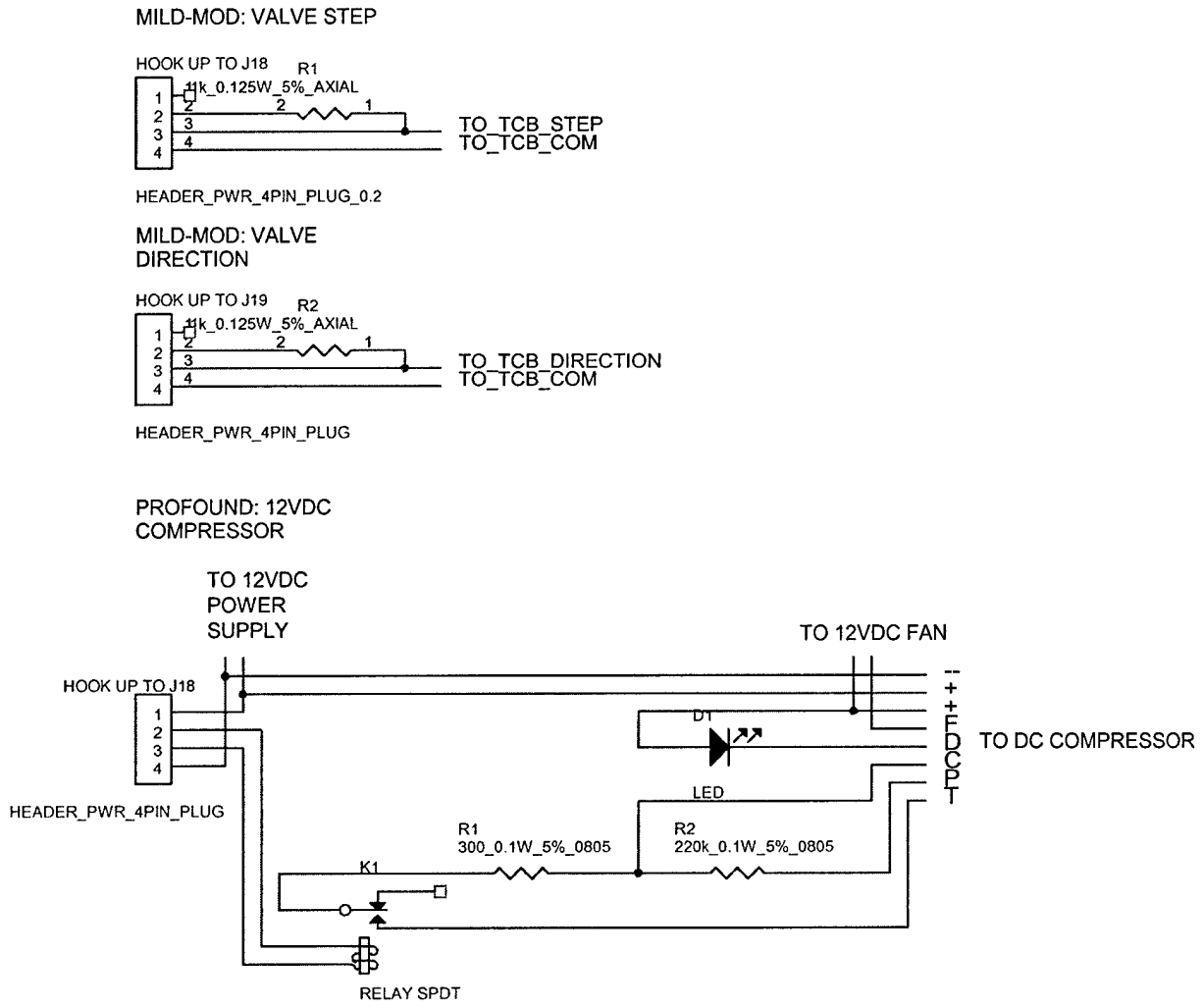

Figure 17

3.7.3 Control Temperature Processing

PID control will be attempted at a low rate of PWM because of the slow response of the cooling means elements. See the HW/SW Interface Design Description for algorithm implementation.

3.8 Flow Control Section

3.8.1 Control Flow Rate Input

Fluid flow is detected indirectly by an optocoupler that is produces a number of pulses for each full rotation of the pump motor. The optocoupler is connected to the Main board via connector J21 (see Fig. 18). IC 74ACT14 reduces jitter and squares off the optocoupler pulses. The pulse stream is routed to special capture input of the microcontroller. The pulses positive edge start and stop the count of special register in the microcontroller with content related to period, T. The frequency, f is given by:

$f = \omega N / 60$ in pulses per second or $T = 60 / \omega N$

Where N is the number of pulses per revolution because of an N window chopper and ω represents the rotational speed of the pump in rev/min.

The relationships below show how flow rate, R_f in ml/min is related to rotational speed ω in rpm and volume V (volume in arc of tubing around pump) in ml/rev

$R_f = \omega V$ ml/min

Solving the previous relationship for ω and substituting in above, we get

$R_f = 60 V / N T$ ml/min

For the Masterflex 7533-60 motor drive with Masterflex 77200-60 pump head, N = 128 ppr, and maximum speed 540 rpm, we can expect f equal to 1152 pps. Masterflex specifies 920 ml/min for L/S 15 tubing (see table below) and 2050 ml/min for L/S 18 at maximum speed. Therefore, V is equal to 1.7038 ml/rev for L/S 15 and 3.7963 ml/rev for L/S 18. The flow rate for these tubing sizes is given by:

$R_f = k / T$ in ml/min T in seconds, k = 0.798 for L/S 15 and k = 1.779 for L/S 18.

Masterflex also specifies 600 rpm maximum speed for pump. If this is true slightly higher flow rate may be achieved than indicated.

Flow rates for Masterflex L/S drive HV-07533-60 L/S tubing compatible pump heads flow rates at 540 rpm.

L/S Tubing	Rf (ml/min)	
L/S 13	32	
L/S 14	113	
L/S 16	430	
L/S 25	920	
L/S 17	1500	
L/S 18	2050	Use for Profound
L/S 15	920	Use for Mild-Mod
L/S 24	1500	
L/S 35	2050	
L/S 36	2600	

For the Masterflex 7533-60, N = 128 and maximum speed is 540 rpm. At the maximum speed we can expect M = (540 x 128) / 60 = 1152 pps. Masterflex specifies 2050 ml/min for L/S 18 tubing at maximum speed. Therefore, V = 102.223 ml and $R_f = V / (60 N T) = 75.130434 / T$. V = Volume in ARC of tubing around pump of length S in ml. Where T is the period in seconds between pulses (T = 1/M).

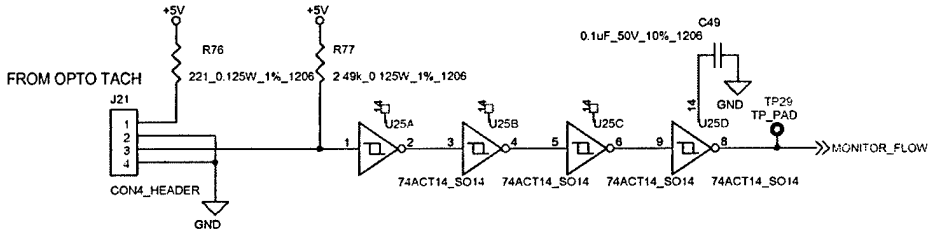

Figure 18

3.8.2 Control Flow Rate Output

The Microcontroller after PID processing the off the flow data, outputs control data that is 10 bits long to the PWM register adjusting the modulation in attempt to bring or maintain the flow within set point range. Note that the motor cannot turn on/off fast enough and therefore

averages the PWM stream as if it was driven by an analog voltage. The drive circuit is shown in Fig. 19 while the cable connection to the pump motor is shown in Fig. 20.

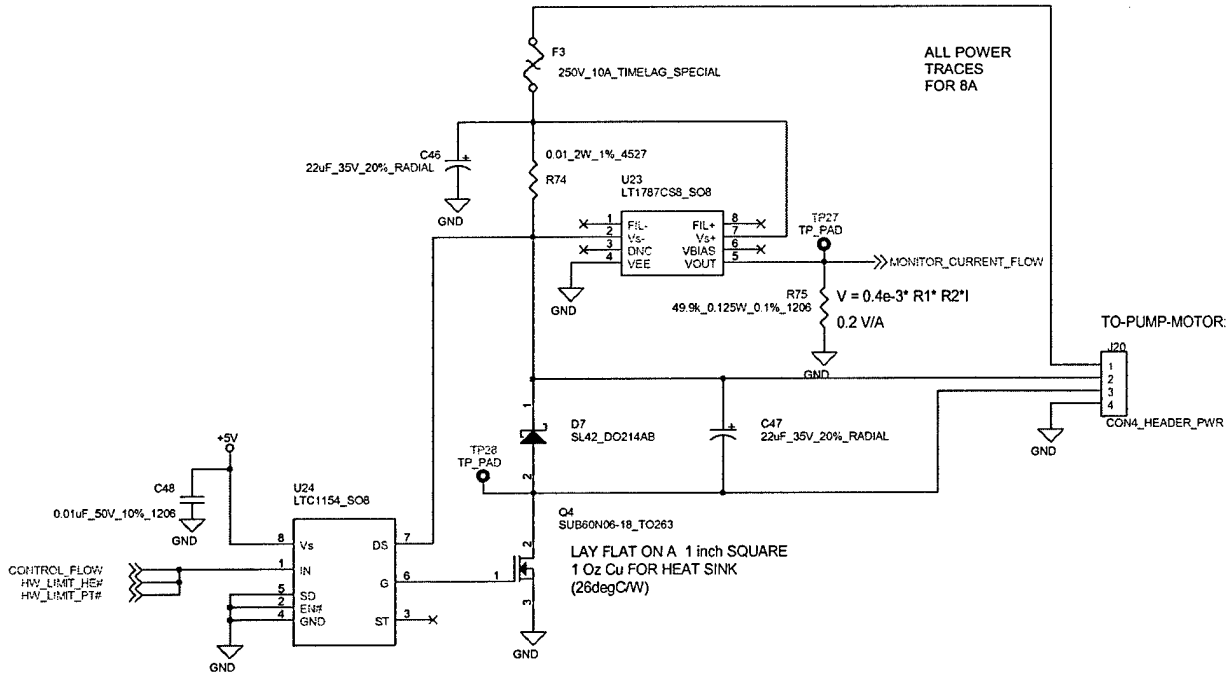

Figure 19

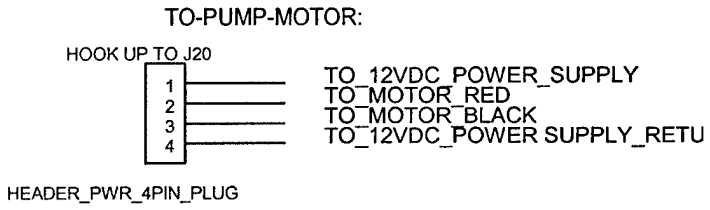

Figure 20

3.8.3 Control Flow Rate Processing

PID control will be attempted with PWM. See the HW/SW Interface Design Description for algorithm implementation.

4. Appendix

In Fig. 21, the temperature/flow ranges are summarized together with required accuracy/resolution.

Mild to Moderate Hypothermia Induction Device Specifications

	Setpoint		Measurement		Control	
Parameter	**Range**	**Resolution**	**Range**	**Accuracy**	**Range**	**Accuracy**
Ambient Temp			-15 to 45 degC	+/-0.1 degC		
HE Temperature	Tfluid - DeltaT	1 degC	-5 to 45 degC	+/-0.1 degC		
Fluid Temperature	5 to 15 degC	1 degC	-5 to 45 degC	+/-0.1 degC	same as meas	+/-0.5 degC
Patient Temperature	30 to 38 degC	0.1 degC	25 to 45 degC	+/-0.1 degC	same as meas	+/-0.5 degC
Blood Flow	100-500 ml/min	100 ml/min	0-1000 ml/min	+/-10 %	same as meas	+/-10 %

Mild to Moderate Hypothermia Induction Device Specifications

	Setpoint		Measurement		Control	
Parameter	**Range**	**Resolution**	**Range**	**Accuracy**	**Range**	**Accuracy**
Ambient Temp			-15 to 45 degC	+/-0.1 degC		
HE Temperature	Tfluid - DeltaT	1 degC	-5 to 45 degC	+/-0.1 degC		
Fluid Temperature	-5 to 5 degC	1 degC	-5 to 45 degC	+/-0.1 degC	same as meas	+/-0.5 degC
Patient Temperature	10 to 20 degC	0.1 degC	10 to 45 degC	+/-0.1 degC	same as meas	+/-0.5 degC
Blood Flow	100-2000 ml/min	100 ml/min	0-1000 ml/min	+/-10 %	same as meas	+/-10 %

Figure 21

In Fig. 22 below, the microcontroller I/O port assignments are summarized.

BIT/PORT	A	B	C	D
0	TEMP_UP# (IN)	Not Available (X)	Serial Out (OUT)	BUZZER (OUT)
1	TEMP_DN# (IN)	Programer/DISP12 (X)	Serial In (IN)	Not Available (X)
2	Spare In (IN)	STATE_1 (OUT)	A/D_DIN (OUT)	Not Available (X)
3	Spare In (IN)	STATE_2 (OUT)	A/D_DOUT (IN)	Not Available (X)
4	Not Used (IN)	STATE_3 (OUT)	Not Available (X)	DISP8 (OUT)
5	Not Used (IN)	FLOW_OK (OUT)	Not Available (X)	DISP9 (OUT)
6	Not Used (IN)	TEMP_OK (OUT)	Programer/DISP13 (X)	DISP10 (OUT)
7	Not Used (IN)	SYSTEM_OK (OUT)	Programer (X)	DISP11 (OUT)
BIT/PORT	**E**	**F**	**G**	**LN (ANALOG)**
0	A/D_CONVERT (OUT)	Not Used (X)	DISP0 (OUT)	SET_POINT_FLOW (IN)
1	A/D_CS# (OUT)	A/D_CLK (OUT)	DISP1 (OUT)	SET_POINT_TEMP1 (IN)
2	DISP12 (OUT)	Not Available (X)	DISP2 (OUT)	MONITOR_CURRENT_FLOW (IN)
3	Not Available (X)	Not Available (X)	DISP3 (OUT)	MONITOR_CURRENT_TEMP1 (IN)
4	INT0 (IN)	CONTROL_FLOW (OUT)	DISP4 (OUT)	MONITOR_CURRENT_TEMP2 (IN)
5	INT1 (IN)	MONITOR_FLOW (OUT)	DISP5 (OUT)	MONITOR_TEMP_HE (IN)
6	Spare Out (OUT)	CONTROL_TEMP1 (OUT)	DISP6 (OUT)	MONITOR_TEMP_AMB (IN)
7	DISP14/Spare Out (OUT)	CONTROL_TEMP2 (OUT)	DISP7 (OUT)	SELECT_DISPLAYED_TEMP (IN)

Figure 22

PCB connectors and jumpers are identified in Fig. 23 below.

CONNECTOR REFERENCE	DISCRIPTION
J1	FLOW SET ROTARY SWITCH
J2	DISPLAYED TEMP SELECT SWITCH
J3	TEMP SET ROTARY SWITCH
J4	TEMP SET PUSH-BUTTON SWITCHES
J5	DISPLAY SERIAL
J6	LED INDICATORS
J7	LED INDICATORS
J8	BUZER ENABLE SWITCH
J9	DISPLAY PARALLEL LED
J10	POWER ON LED
J11	RC3400 CONNECTOR
J12	RC3400 CONNECTOR
J13	SERIAL PORT
J14	PROGRAMMING PORT
J15	AMB THERMISTOR
J16	HE THERMISTOR
J17	PT TEMP CONN
J18	VALVE
J19	COMPRESSOR
J20	PUMP MOTOR
J21	OPTO TACH
J22	POWER IN
J23	DISPLAY PARALLEL LCD
JP1	+5V JUMPER
JP2	+3.3V JUMPER

Figure 23

5. Revisions

Rev.	Description	Author	Effective Date
X1	Initial Issue of Document	Mike Pitsakis	3-21-03
X2	Added flow rate info	Mike Pitsakis	7-15-03