

In-Flight Patient Cooling Device

Product Design Specifications

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Function: To reduce the risk of brain injury and slow cerebral reperfusion in post-cardiac arrest patients, hypothermia is induced during helicopter or ambulance transport. Hypothermia is induced by infusing saline at 4°C to reach a core body temperature of 32°C to 34°C. To ensure that saline enters the body at 4°C, a method of cooling and maintaining the saline temperature is needed. The method must consider the space constraints of an ambulance or helicopter. Alternative methods, including evaporative cooling, can be used in conjunction with cold saline to induce hypothermia more rapidly. Upon arrival at the hospital, methods are already in place to maintain hypothermia. For effective implementation in Emergency Medical Services nationwide, the method must be cost-effective.

Client Requirements:

- Fit in space available in medical transport vehicle (helicopter or ambulance)
- Easily transported
- Saline temperature maintained at 4°C
- Cool patient to a core body temperature of 32°C to 34°C
- Cost effective

Design Requirements

1. Physical and Operational Characteristics
 - a. *Performance Requirements:* The device must cool the saline to 4°C and maintain this temperature as the saline enters the body. The patient should be cooled to a body temperature of 32°C to 34°C.
 - b. *Safety:* Since the device will be used in transport, there should be no loose pieces. All components of the device must be able to be strapped down in the helicopter. Also, the patient's body temperature should not be cooled below 32°C and the saline should not be cooled to the point of crystallization.
 - c. *Accuracy and Reliability:* The device must be able to maintain the saline at 4°C for up to 35 minutes. The saline should be as close to 4°C as possible as it enters the body.
 - d. *Life in Service:* The device should be reusable and should function for at least 35 minutes without loss of function.
 - e. *Shelf Life:* Not applicable at this time.
 - f. *Operating Environment:* The device should function in ambient temperatures up to 45° C and high heat indices. The device must withstand frequent transport from the storage location to the ambulance or helicopter. It must also function in a moving vehicle. The device should not rely on power from an electrical outlet.
 - g. *Size:* The device must fit in the limited workspace of an ambulance and helicopter.
 - h. *Weight:* The device must be carried by paramedics. It should not weigh more than 30 pounds, but a lighter device would be more desirable as components may be placed on a patient while the stretcher is being loaded into the helicopter/ambulance.
 - i. *Materials:* The materials used should be durable, non-toxic, and easily sterilized.

2. Production Characteristics

- a. *Quantity*: One unit per ambulance and one unit per helicopter for Dane County Emergency Medical Services will need to be produced.
- b. *Target Production Cost*: Cost must be affordable for the Dane County EMS.

3. Miscellaneous

- a. *Standards and Specifications*: All components of the device must be secured in the helicopter or ambulance.
- b. *Subject-Related Concerns*: The device should not cool saline to the point of crystallization to avoid possible patient complications. Hypothermia should be induced as rapidly as possible.
- c. *Competition*: Other devices are currently on the market to induce hypothermia; however, they are not cost effective. The current method for cooling saline in Dane county is ice in a cooler.
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