

NOW AVAILABLE

OLYMPIC COOL-CAP®



The only FDA approved device for treating HIE



Direct Head Cooling

- Safe
- Effective
- Proven

Introduction

OLYMPIC COOL-CAP®

A major clinical trial has shown that direct brain cooling can be effective in reducing the severity of newborn HIE.

The Olympic Cool-Cap is the only FDA approved device for administering brain cooling for HIE. Both the hardware and software conform to the clinical trial protocol and are designed to help the clinician safely administer treatment.

The object of the trial protocol was to cool the brain for 72 hours while assuring the infant's core (rectal) temperature did not drop below the safe limit of $34.5^{\circ}\text{C}\pm 0.5^{\circ}\text{C}$. Head cooling proved efficacious and there were no serious adverse results.

To control core temperature, the clinician adjusts the cap temperature while the infant is under the radiant warmer. The Olympic Cool-Cap gives the clinician precise control so as to avoid unsafe temperature excursion during the initial cool-down, the 72 hour cooling period, and the warm-up. It monitors all critical temperature parameters, displays a continuous tracing of core temperature, computes rate of change, and as well as providing sensitive temperature adjustment.

In addition, the Olympic Cool-Cap helps solve two problems that can impede the administration of this treatment:

- Because some time may elapse between HIE babies, even the physician and staff that are fully trained on cooling may need to be refreshed on the protocol when an HIE baby presents. The Cool-Cap has a special software program that helps guide the clinician through the protocol step by step.
- The sooner cooling starts after birth, the better the outcome. This puts time pressure on the staff to gather and assemble all the equipment and supplies. The Cool-Cap is always ready for immediate use. All supplies (caps, tubes, etc.) are organized and stored with the cooling unit, and a software Wizards leads the staff through the setup of equipment and the patient.

The Olympic Cool-Cap has been designed to make treatment as easy as possible for the clinical staff and to assure safe and efficacious treatment.

A Complete System for treating HIE

FDA Approved – Equipment – Supplies – Protocol and Software

The Control System and Cooling Unit

Touch Screen



Solid-state Cooler

Control System

All operator controls and displays are on the touch screen. This eliminates mechanical buttons and a separate keyboard, and it enables the clinician to enter commands and notes while viewing patient data. Critical patient data is displayed in larger, color coded numbers for easy reading.

The software program guides the physician and staff through the cooling protocol from start to finish. The program includes an initial setup wizard, prompts, alarms, and a Help window. The patient's rectal temperature is plotted on a 74 hour graph. A second temperature graph allows the clinician to zoom and scroll for a closer look at the core temperature, which helps in adjusting cooling.

The clinician can enter real-time clinical notes (e.g., drugs administered) directly on the screen during treatment for review during and after treatment.

Cooling Unit

A solid-state water cooler (not a refrigerator compressor) is used for more rapid and precise temperature control. Temperature response is 0.1° C. The solid-state cooler is also very reliable and quiet. Water flow rate and pressure are accurately maintained for all size caps.

Filling and draining the cooling unit is simple and fast. The cooling unit is fill by connecting it to any readily available one-litre bag of sterile water. At the end of the treatment, the water is drained back into the bag for disposal. No internal cleaning of the cooling unit is required after use, except for periodic maintenance.

The Cooling Cap

The cooling cap itself was designed for the clinical trial and incorporates refinements based on experience during the trial. It consists of a water recirculating cap next to the infant's skin which is covered by an insulated outer cap. The cap provides uniform and controlled cooling of the critical region of the head.

The inner cap has a network of channels that recirculate water from the cooling unit for efficient and controlled heat transfer. The pattern of the water channels provides maximum and uniform cooling contact with the head and prevents pressure points.

To help maintain the desired cap cooling temperature, the outer cap is insulated and is covered with reflective metal foil to minimize heating caused by the radiant warmer.

The disposable cooling cap is furnished in three sizes.



Water cap Efficient design for cooling the brain directly.



Outer cap Insulated to help maintain temperature. Reflects heat.

Supplies Storage

To make sure that all necessary supplies (thermistors, etc.) and separate parts, like tubing, are always available so treatment can begin immediately, two clearly identified storage containers with labeled compartments and inventory re-order lists are provided as accessories to the Olympic Cool Cap. (See list of supplies on back page.)

