

**THE ONLY FDA-
APPROVED
DEVICE FOR
TREATING
HIE**

OLYMPIC COOL-CAP[®] System

Selective Head Cooling

- Proven safe & effective
- Easy to use — built-in protocols



***Changing the
standard of care
in the NICU***

OLYMPIC COOL-CAP® SYSTEM

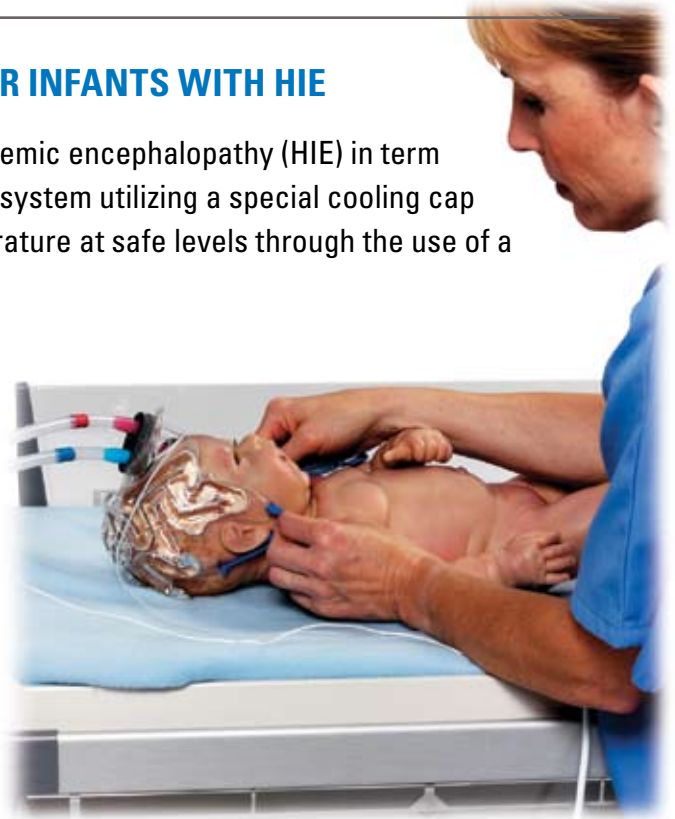
CHANGING THE STANDARD OF CARE IN THE NICU FOR INFANTS WITH HIE

The only FDA approved device for the treatment of hypoxic-ischemic encephalopathy (HIE) in term infants, the Olympic Cool-Cap System is a unique and complete system utilizing a special cooling cap to provide selective brain cooling while maintaining core temperature at safe levels through the use of a radiant warmer.

Administered to newborns within the first six hours of life, treatment with the Olympic Cool-Cap System can prevent or significantly reduce the severity of neurologic injury associated with HIE.

CLINICAL BENEFITS

- Provides neuroprotection while minimizing the side effects due to hypothermia
- Allows infant brain cooling while maintaining infant core temperature at safe levels
- Results in meaningful improvements in neurodevelopmental outcome and survival rates at 18 months of age
- Improved outcome for babies with early intervention



BETTER TREATMENT THROUGH BETTER DIAGNOSIS

- The Olympic CFM 6000 cerebral function monitor helps assess extent of HIE to determine if cooling is indicated



- When used in conjunction with the Cool-Cap System, the CFM 6000 provides greater confidence in diagnosing & treating babies in the first few hours of life

PROVEN SAFE & EFFECTIVE

In a randomized-controlled, multi-center, international clinical trial, the Olympic Cool-Cap was shown to reduce or prevent neurological damage associated with HIE in some infants¹.

¹References available upon request.

OLYMPIC COOL-CAP® SYSTEM COMPONENTS



Control Unit

- Easy-to-use touch screen design
- Built-in protocols with wizard instructions helps guide user through treatment

Cooling Unit

- Solid-state water cooler with precise temperature control
- Very reliable & quiet
- Simple, fast and safe filling & draining
- Temperature displays: cooling cap, rectal, scalp, skin & optional sensors

Cooling Cap

Three-piece set in three sizes (small, medium, large)



Insulated outer cap

- Helps maintain cooling temperature by reflecting external heat from radiant warmer



Water-cap retainer

- Holds water cap securely in place



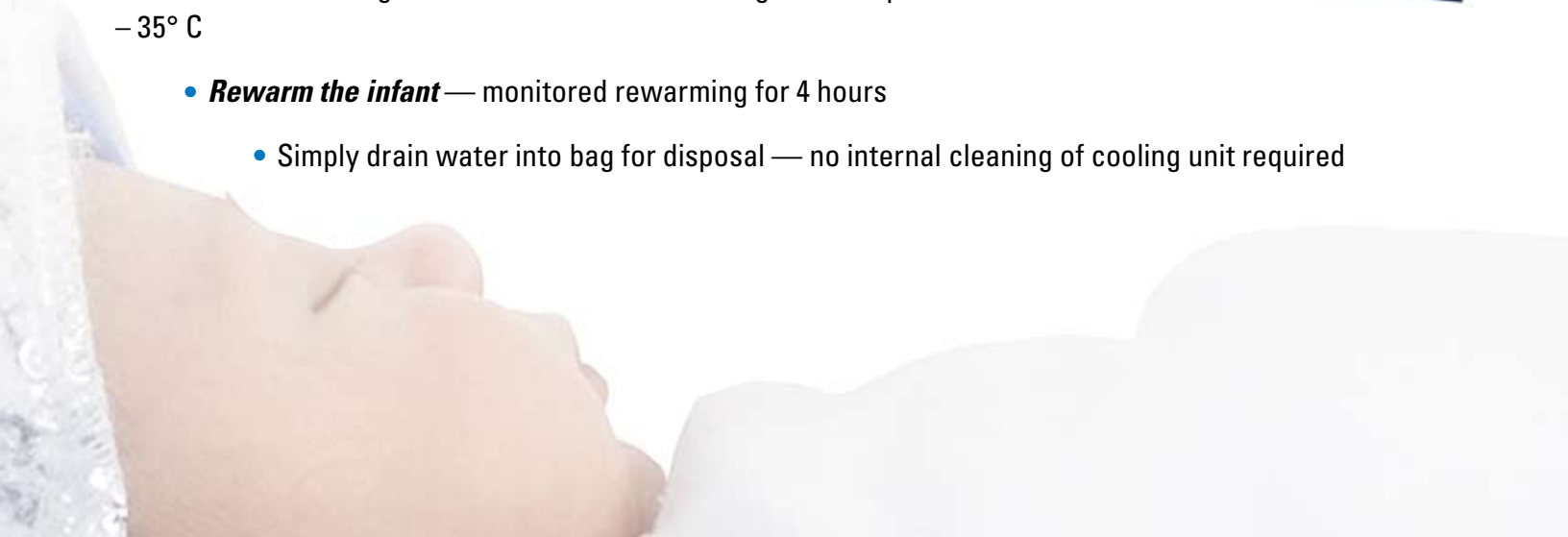
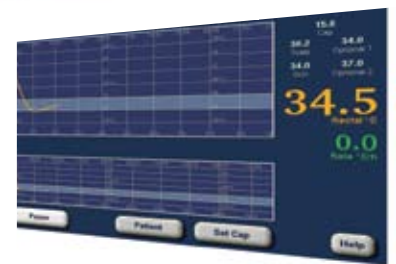
Water cap

- Soft water-circulating channels provide efficient, controlled and uniform cooling contact without pressure points

TREATING INFANTS

Simple Operation with Sophisticated Results

- **Wizards & Prompts** — simply follow the built-in protocol to administer treatment
- **Initiate Treatment Quickly** — enter only weight & gestational age to start cooling
- **Lower Infant's Temperature** — ensure safety with continuous temperature displays & trend data, while alarms assure safe cooling technique
- During cooling, enter real-time clinical notes directly on screen for review
- Maintain brain cooling for 72 hours while maintaining core temperature of 34 – 35° C
 - **Rewarm the infant** — monitored rewarming for 4 hours
 - Simply drain water into bag for disposal — no internal cleaning of cooling unit required



ORDERING & SPECIFICATIONS



ORDERING INFORMATION

Catalog No.

OLYMPIC COOL-CAP SYSTEM 60010

Control unit, cooling unit and heat shield. Accessory case A — Cooling cap sets (2 Sm, 4 Med, 2 Lg), 4 Temperature sensor sets. Accessory case B — Reusable items.

Cooling cap set, small size 60020

Fits most infants with head circumference < 32 cm and weight < 2.5kg. Includes water cap, water cap retainer, and insulating cap.

Cooling cap set, medium size 60021

Fits most infants with head circumference 32-37 cm and weight 2.5-4.0 kg. Includes water cap, water cap retainer, and insulating cap.

Cooling cap set, large size 60022

Fits most infants with head circumference > 37 cm and weight > 4.0 kg. Includes water cap, water cap retainer, and insulating cap.

Temperature sensor set 60040

Includes one rectal sensor, two skin/scalp sensors, and 12 single-adhesive Tempheart® shields for scalp and skin sensors.

Temperature sensor adapter 60060

Allows reusable YSI 400 and equivalent temperature sensors to be used with the temperature sensor module.

Temperature sensor module clips 60061

Bag of five; secures temperature sensor module to infant's bedding to help keep sensors in place.

TECHNICAL SPECIFICATIONS

Power Requirements

- Voltage: 100–240V~, single phase
- Consumption: 5.5A
- Frequency (current): 50/60 ±1 Hz
- Control unit voltage from cooling unit: 12Vdc, 3A

Dimensions

52.0-in. high × 17.1-in. wide × 22.3-in. deep
132.1-cm high × 43.4-cm wide × 56.6-cm deep

Weight

115 lb 52 kg

Note: Includes the control unit mounted on the cooling unit.

Electrical

Hospital-grade power cord

Applicable Standards

International Electrotechnical Commission (IEC) 60601-1-1: Amendments I and II and 60601-1-2 (2000)

Regulatory Classifications

European Union (EU) Medical Device Directive (MDD), Class IIb

US Class 3

Health Canada Class 2

Operation / Enclosure

IEC Class I shock protection. Continuous. Ordinary equipment IXPØ. Installation/overvoltage category II. Pollution degree 2. Indoor use only.

Electromagnetic Compatibility

The Cool-Cap system complies with the requirements of IEC 60601-1-2 (2001).

Product Disposal

No special precautions. Dispose of according to your local regulations.

Cool-Cap® is a registered trademark of Tiara Medical Systems, Inc.

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