

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

# **OLYMPIC COOL-CAP<sup>®</sup> 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 infants<sup>1</sup>.

<sup>1</sup>References 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



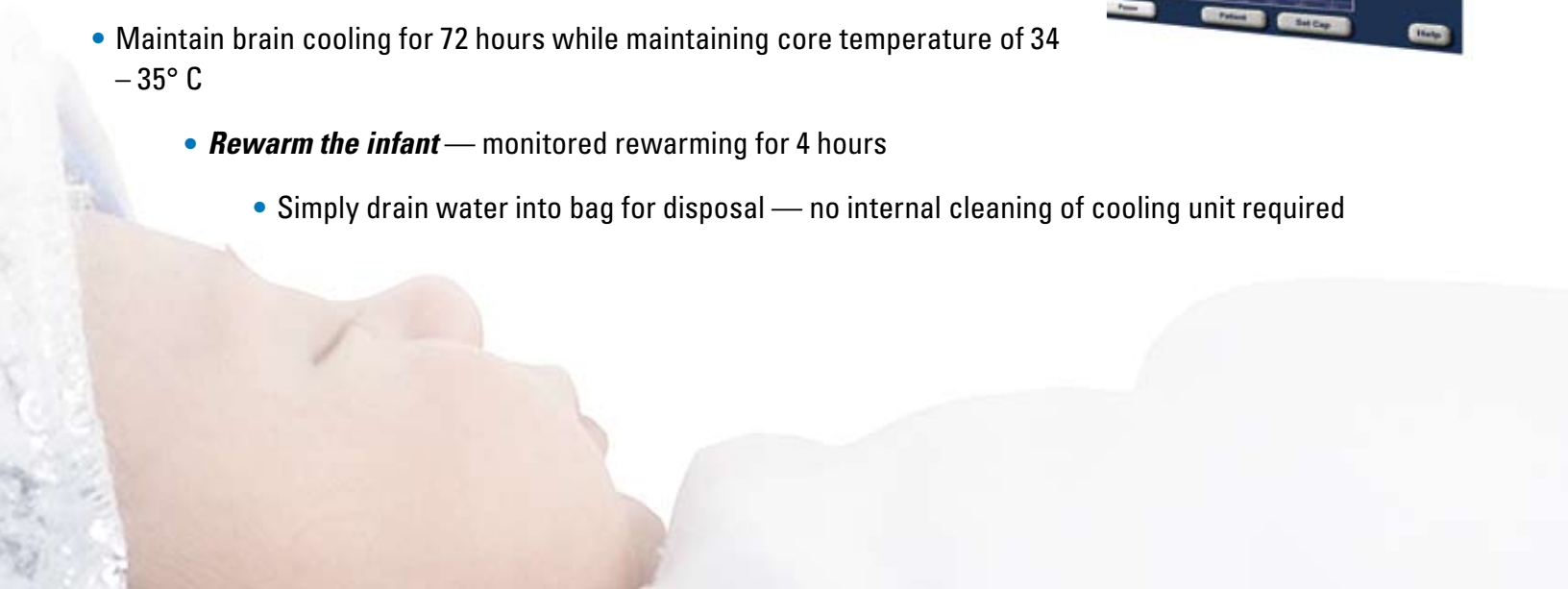
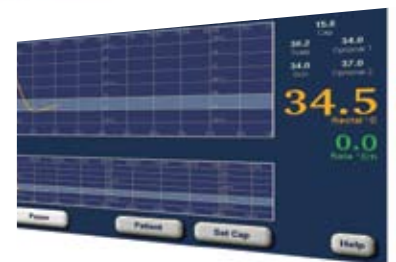
### Water cap

- 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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