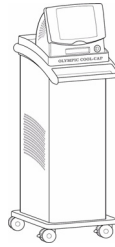


Specification



OLYMPIC COOL-CAP® SYSTEM

Intended Use

The Olympic Cool-Cap® system is intended to provide selective head cooling with mild systemic hypothermia in critical care treatment areas.

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: The above dimensions and weight are for the Olympic Cool-Cap system, which includes the control unit mounted on the cooling unit.

Electrical

Power Requirements

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

Ground

Does not exceed 0.13Ω

Fuses

Two internal: 8A, 250V, Slo-Blo
One internal: 10A, 250V, Slo-Blo ceramic

Environmental

Temperature

- | | | |
|----------------------|-----------|-----------|
| ■ Operating: | 70–78°F | 21–25.5°C |
| ■ Shipping: | 40–158°F | -40–70°C |
| ■ Storage: | | |
| Cooling Unit and TSM | -40–158°F | -40–70°C |
| Control Unit | -4–113°F | -20–45°C |

Relative Humidity (RH)

- Operating: 0–95%
- Non-Operating: 10–100%

Operating Altitude

Up to 6560 ft Up to 2000 m

Operating and Non-Operating Pressure

500–1060 hPa 14.7–31.3 inHg

Controls

- **Mains power** switch, located on back of cooling unit, changes device state **ON (I)** or **OFF (O)**; the operating system loads and the start screen displays on the control unit
- **Touch controls** for starting and monitoring treatment (cooling-rewarm), entering and reviewing infant data.

Computer

User Interface

- Color liquid crystal display (LCD) touch-screen
- 800 x 600 pixel resolution, 32-bit color

External Connections

Electrical

Hospital-grade power cord

Water

- Bag of sterile water, 1 liter
- IN/OUT, FILL, and DRAIN connectors

Product and Consumables

Item

Catalog No.

| | |
|--|-------|
| Olympic Cool-Cap system | 60010 |
| Control unit, cooling unit, and heat shield. Power cord, software, and instructions. | |
| Accessory case A — Cooling cap sets (2 small, 4 medium, 2 large), 4 temperature sensor sets. Accessory case B — reusable accessories (main hose support, main hose, cap tube support, cap connector tubes, spiked fill tube, temperature sensor module, module clips, test kit, cleaning kit). | |
| Complete Cap Set, Size Small | 60020 |
| Complete Cap Set, Size Medium | 60021 |
| Complete Cap Set, Size Large | 60022 |
| Each cap set is complete with water cap, water cap retainer, and insulating cap. | |
| Temperature Sensor Adapter | 60060 |
| Temperature Sensor Set | 60040 |
| Complete with rectal temperature sensor, skin/scalp temperature sensors, and TempHeart® shields. | |
| Temperature Sensor Module Clips, bag of 5 | 60061 |

Note: For reorder numbers for parts and accessories, refer to the *Olympic Cool-Cap Operator's and Service Manuals*.

Regulatory, Electrical Safety, and Classifications

Applicable Standards

- Canadian Standards Association (CSA) 60601:1-M90
- International Electrotechnical Commission (IEC) 60601-1-1: Amendments I and II and 60601-1-2 (2000)
- Underwriters Laboratory (UL) 60601-1

Regulatory Classifications

- United States Food and Drug Administration (FDA) Class III
- Health Canada, Therapeutic Products Directorate, Class II
- European Union (EU) Medical Device Directive (MDD), Class IIb

Operation / Enclosure

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

Maintenance and Service

Routine maintenance, such as annual and bi-monthly inspection and cleaning, can be performed by biomedical technicians. The Olympic Cool-Cap unit must be returned to the factory for servicing.

For maintenance and service information, consult the *Olympic Cool-Cap Service Manual*. Wiring diagrams and schematics are available upon request.

Warranty

Standard one-year warranty, with a no-charge loaner unit.

Electromagnetic Compatibility

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

Product Disposal

Disposal of the Olympic Cool-Cap system does not require any special precautions. Dispose of according to your local disposal regulations.

The fluorescent light in the LCD display contains a small amount of mercury; consult your local requirements.