
صنایع پزشکی
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دانش بنیان
knowledge Enterprise

# Model : SBNeo

Total body cooling device for treatment of neonates suffering hypoxic ischemic encephalopathy (HIE)

The first and sole licensed manufacturer in Iran

Sarma Behboud Sepanta Medical Industries
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## Treatment Mechanism

By placing the neonate on a cold mattress, the core temperature decreases to 33.5 degrees Celsius

The core temperature is maintained within this range for 72 hours

Decrease in temperature slows down the metabolic rate

Brain cells are able to recover, which ultimately reduces or stops further brain damage

## Total Body Cooling Timeline

The critical 6-hour window after onset of asphyxiation

Evaluating the admission criteria for neonates cooling protocol

Cooling with maximum power

Stabilizing temperature around 33.5 °C with minimum temperature deviations

Slow rewarming at a rate of 0.5°C/hour

## Functional Features

- Two main Modes of Operation include:

a) Single-point temperature control mode

In this mode, the clinician can set the rectal target temperature and the device will automatically perform cooling or heating operations at the tuned rate or at maximum power, depending on user's choice. Then the device will maintain the target temperature without interruption and with minimum fluctuations. This operation mode effectively transforms the device into a temperature management system that can be used for hypothermia, hyperthermia, or normothermia treatments.

b) Multi-point temperature control mode

This operation mode is based on the standard protocol of asphyxia treatment. The user determines the target rectal temperature (by default 33.5 degrees Celsius), and the device cools the infant in the shortest possible time. The core temperature is then maintained during the requested period, which is 72 hours in the standard protocol. Finally, the device gradually rewarms the neonate at a set rate (maximally, 0.5°C/hour) until reaching the normal temperature of 37 degrees or any other desired temperature.

- Simultaneous reading and display of surface and core body temperature using skin and rectal sensors
- The temperature display accuracy is 0.1°C, the maximum temperature stabilization error is 0.5°C , and temperature sampling is done every 1 second
- The possibility of viewing changes in rectal temperature during the entire treatment period as a graph with various graphic capabilities
- Easy and safe use of machine due to design of the device's accessories storage space inside the
- Advanced and adaptive temperature control algorithm with self-tuning capability
- The possibility of immediate fast rewarming during treatment at the discretion of the treatment staff
- Multilayer hardware and software temperature protection systems

## Technical Specifications

**Dimensions**
50*40* 98 CM

**Weight** 52 Kg

**Coolant Temp**
16-42 °C

**Power supply**
220 Volt 50 Hz

**Noise intensity**
53db at 1 meter

**Power consume**
520 Watt

**Filling Jar volume**
0.5 Lit

**Coolant tank volume**
3.5 Lit



### Sensors

- Reusable paediatric rectal probe
- Disposable paediatric rectal probe
- Reusable paediatric skin probe
- Disposable paediatric skin probe

### Connecting pipes

- Silicone hoses with flex insulation
- Protected with fabric cover

### User interface

- 7–inch touch LCD

### Controller

- PID Dual mode

### Cooling System

- Thermoelectric modules

### Heating system

- Electric element heaters

### Coolant

- Pure water

### Structure

- Metal structure with electrostatic heat treated paint

### Connectors

- Non-spill quick couplings

### Mattress

- Biocompatible
- Washable
- Uniform heat treatment

MANA Neonate Cooling
مانا سردکننده نوزادان

# Approvals and Certificates


پروانه تولید وسیله پزشکی ( مشروط - یک ساله )


CERTIFICATE

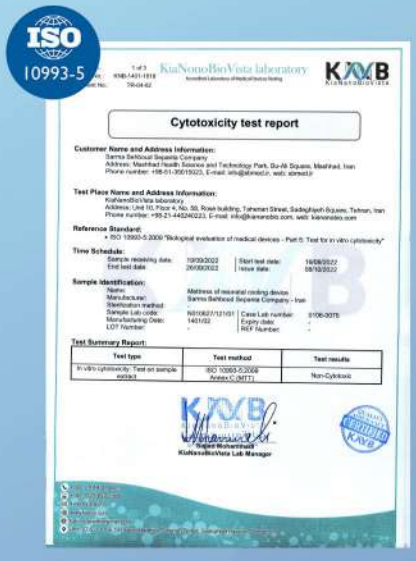
No. 23-B-1654 Rev. 0

Sarma Behboud Sepanta Medical Industries

ISO 13485:2016

Medical Devices Quality Management System


EMC COMPLIANCE REPORT


Cytotoxicity test report


Irritation test report


Sensitization test report