AFFORDABLE DEVICE FOR THERAPEUTIC HYPOTHERMIA FOR NEONATES

USER MANUAL
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ABOUT THE COMPANY

Pluss Polymers Pvt. Ltd. is a materials research and manufacturing organization specializing in the field of specialty polymers and phase change materials. Pluss has been a pioneer in its field with many firsts to its name. Pluss has worked with industries in India and across the globe on use of Phase Change Materials (PCMs) for maintaining precise temperatures in a variety of applications. MiraCradle™ – Neonate Cooler is one such endeavor for the healthcare industry.

For more information, please visit
www.miracradle.com and www.pluss.co.in

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HOW TO READ THIS MANUAL

This manual describes the features and operations of the MiraCradle™- Neonate Cooler. Read it carefully before use to avoid any possible risk to the newborn or the doctor.

Illustrations in this manual indicate the key features of the product and are not an exact graphical reproduction.

Read all safety precautions and warnings before using the device.

Common signs seen in this manual are explained in the table below.

<table>
<thead>
<tr>
<th>REFER</th>
<th>CAUTION</th>
<th>WARNING</th>
</tr>
</thead>
<tbody>
<tr>
<td>Instructs the user to read specific sections within this User Manual that contain additional relevant information</td>
<td>Is a cautionary that user must check before continuing the use of the product</td>
<td>Is a critical warning which instructs the user to stop using the product until the conditions mentioned are fulfilled</td>
</tr>
</tbody>
</table>

CONTRAINDICATIONS

No general contraindications are known. For possible adverse effects study the relevant treatment and therapy protocols

Avoid skin contact of the PCMs with the infant

Avoid skin contact of Conduction Mattress with the infant

Do not use the PCMs if it is not charged or not in the desired temperature range

Refer: Section 6.2.2 Page 12
PRODUCT RELATED

MiraCradle™ - Neonate Cooler is an affordable passive cooling device for neonates or newborns suffering from Hypoxic Ischemic Encephalopathy (HIE). It uses the advanced savE® Phase Change Material (PCM) technology to induce therapeutic hypothermia. It has been researched, designed and developed by Pluss Polymers Pvt. Ltd. in collaboration with the Department of Neonatology, Christian Medical College, Vellore, India.

4.1 When to use

MiraCradle™- Neonate Cooler serves as a more viable and easy-to-use alternative to existing solutions for inducing and sustaining mild hypothermia in newborns for treatment of asphyxia related complications. Use the device in a Neonatal ICU which is equipped with all other necessary treatment and data acquisition devices for assessing the health and well-being of the newborn under treatment.

4.2 Who should use

The device intends to make whole-body cooling and sustenance of hypothermal temperatures in newborns an easy and supervision-free process. It is strictly a medical device, and should be operated by or under the supervision of a medically trained person who is well versed in the concept of neonatal care and understands the sensitivities for treatment of such newborns.

4.3 Declaration of substances

MiraCradle™ - Neonate Cooler is a non-invasive device in which only the bed sheet on top comes in contact with the newborn. The product does not include any toxic substances. The Phase Change Materials (PCM) are made using non-toxic fatty acids and are completely safe for use near a newborn. The phase change materials are form stable, ensuring that they retain form and shape while changing phase from solid to liquid, thus avoiding any risk of the phase change material leaking and coming in contact with the human body.

4.4 Minimal requirements to use

Use this product only in a Neonatal ICU with facilities greater than level 2 (Level 2+). Most newborns suffering from HIE need a multisystem support in addition to cooling such as radiant warmer, multi-parameter monitor, ventilator, neonatal rectal probe, neuro-imaging devices, etc. The hospital must make all necessary arrangements for treatment before using MiraCradle™ - Neonate Cooler for cooling the newborn.

Refer: Section 5.2 Page 8.

4.5 User responsibility

Do not alter this product or use for any purpose other than as described in this manual. Check this product before use. Do not use a defective product. Replace parts that are broken, missing, plainly worn, distorted, or contaminated immediately by contacting customer care immediately.

The user of this product will bear the sole responsibility for any malfunction that results from improper use, faulty maintenance, improper repair, damage, or alteration by anyone other than authorized personnel.
5.1 Introduction

Birth asphyxia is a major cause of Hypoxic Ischemic Encephalopathy (HIE) and consequential brain damage or even death. Therapeutic hypothermia induced by cooling a newborn to around 33 °C for three days after birth has been proven to be the only effective medical intervention which reduces brain damage, and improves a newborn’s chance of normal survival.

MiraCradle™-Neonate Cooler is an affordable passive cooling device for newborns. It uses advanced save® phase change material technology to induce therapeutic hypothermia among newborns suffering from HIE.

THE MIRACRADLE™ - NEONATE COOLER CONSISTS OF THE FOLLOWING COMPONENTS

Conduction Mattress: This is a gel based bed which improves heat transfer between the newborn and the PCM. It also provides a comfortable surface for the newborn to lie on.

PCM save® FS-21: This is the middle layer of the device. save® FS-21 is used in conjunction with save® FS-29 to quickly bring the temperature of the newborn down to 33°C. It is subsequently removed and save® FS-29 takes over to sustain the temperature for longer hours.

PCM save® FS-29: This forms the bottom layer of the MiraCradle™-Neonate cooler. Three units of save® FS-29 PCM are placed at the bottom of the Cradle. save® FS-29 in solid state passively extracts heat from the newborn’s body which is at 37°C thereby inducing and sustaining hypothermia.

Cradle: This is a roto-moulded plastic structure which serves as a framework for placing all the other components of MiraCradle™-Neonate Cooler. It is especially designed to provide insulation to the PCM helping it last for longer hours.

A charged PCM (Refer: Section 5.1.2 Page 6) save® FS-29 and save® FS-21 maintain the temperature between 33-34°C for a period of 72 hours as per the recommended treatment procedure.

5.1.1 Cradle

This is the exoskeleton of the device. The cradle holds all the cooling components of MiraCradle™ - Neonate Cooler as well as the newborn. It provides requisite insulation to the PCM mattresses from ambient heat. It is a roto-moulded hollow polyethylene structure and the hollow part is injected with polyurethane foam for insulation.
The cradle is designed to fit in almost all the commonly used baby bassinets available in the market. It is light-weight, portable and easy to clean.

5.1.2 Phase Change Materials (PCMs)

Phase Change Materials (PCMs) are special thermal energy storage materials being extensively used to maintain required temperatures in different applications in various industries. PCMs store and release heat in the form of latent heat. The thermal energy transfer occurs when a material changes phase from solid to a liquid or from liquid to a solid. To learn more, visit: www.pluss.co.in

MiraCradle™ - Neonate Cooler consists of two PCMs:
1. savE® FS-29
2. savE® FS-21

savE® FS-29
savE® FS-29 has a phase change temperature of 29°C. It freezes below 29°C and melts above 29°C. It is a form stable PCM i.e., while it changes phase from solid to liquid or liquid to solid, it retains its form and shape. The only visible change is that the PCM is flexible in liquid state as compared to a “rock” in solid state.

Quantity: 6 units of savE® FS-29 are supplied with one MiraCradle™ - Neonate Cooler. Each unit weighs approximately 1.03 kgs and measures approximately 180mm x 330mm.

Charging Time: savE® FS-29 generally takes 8-10 hours to get charged when stored in the bottom part of a refrigerator.

Caution: Store at a temperature between 6-15°C in the bottom part of the refrigerator.

Do not store in the freezer section of a refrigerator.

Note: Charged savE® FS-29 means that it is in solid state and the material is hard and rigid.

Usage: The savE® FS-29 PCM is used for maintaining and sustaining hypothermia. At a time, only three units of savE® FS-29 are used for cooling the newborn. They are not required to be replaced during the 72 hour treatment process. However it may vary depending on the weight of the newborn, surrounding temperature and method of use. The other three units of savE® FS-29 are standby units and should be kept in the refrigerator at all times, charged and ready for use. If the temperature of the newborn is shooting above 34°C, these standby PCMs can be used as replacement to bring the temperature down and continue treatment.

Shelf Life: Because of the constant wear and tear of the outer covering, replace the savE® FS-29 PCM units two years from the date of first use.

Refer: Section 6.2 Page 11; Section 6.4 Page 13; Section 7.1 Page 18; Section 7.2 Page 20.
savE® FS-21

savE® FS-21 has a phase change temperature of 21°C. It freezes below 21°C and melts above 21°C. It is a form stable PCM i.e. while it changes phase from solid to liquid or liquid to solid, it retains its form and shape. The only visible change is that the PCM is flexible in liquid state as compared to a “rock” in solid state.

**Quantity:** 2 units of savE® FS-21 is supplied with one MiraCradle™ - Neonate Cooler. Each unit weighs approximately 0.4 kgs and measures approximately 270mm x 330mm.

**Charging Time:** savE® FS-21 when stored in the bottom part of a refrigerator, generally takes 6-8 hours to get charged.

![Caution: Store at a temperature between 6-15°C in the bottom part of the refrigerator. Do not store in the freezer section of a refrigerator.]

**Note:** Charged savE® FS-21 means that it is in solid state and the material is hard and rigid.

**Usage:** savE® FS-21 PCM is used in conjunction with savE® FS-29 PCM. savE® FS-21 PCM is used to control the temperature of the newborn during the treatment process when the temperature of the newborn starts drifting above 33.8°C. When the temperature starts drifting above 33.8°C, savE® FS-21 PCM is introduced between the savE® FS-29 PCM and the conduction mattress for a few minutes until the temperature reaches 33.6°C. Once the temperature reaches 33.6°C, the savE® FS-21 PCM is removed and placed in the storage (refrigerator) again.

savE® FS-21 PCM is also used to induce hypothermia at the start of cooling the newborn. If the temperature of the newborn does not drop below 34°C even half an hour after the cooling process is initiated, introduce the savE® FS-21 PCM between the savE® FS-29 PCM and the conduction mattress for a few minutes until the temperature reaches 33.8°C. Once the temperature reaches 33.8°C, remove the savE® FS-21 PCM and place in the storage (refrigerator) again.

![Caution: Ensure that the savE® FS-21 PCM is hard and rigid before use. If not, place it back in the refrigerator for charging.]

**Note:** If not in use, the savE® FS-21 PCM should always be kept in the storage.

**Shelf Life:** Because of the constant wear and tear of the outer covering, replace the savE® FS-21 PCM units two years from the date of first use.

**Refer:** Section 6.2 Page 11; Section 6.4 Page 13; Section 7.1 Page 18; Section 7.2 Page 20.
5.1.3 Conduction Mattress

Conduction Mattress is a gel based mattress which is placed over the PCM layers. It weighs approximately 1.2 kg and measures approximately 540mm x 300mm.

It enhances the heat transfer between the newborn and the PCM layers, and also provides a smooth surface for the newborn to lie on.

⚠️ Caution: Ensure that the conduction mattress is flat and uniform before use, if not please distribute the gel uniformly using your hands.

Note: Store the conduction mattress at room temperature. Do not store in a refrigerator.

Refer: Section 6.2 Page 11; Section 6.4 Page 13; Section 7.1 Page 18; Section 7.2 Page 20.

5.2 Associated equipment required

MiraCradle™ - Neonate Cooler induces and sustains hypothermia for 72 hours and provides precise temperature control. However, the equipment mentioned below are essential for effective treatment of the newborn:

1. Warmer: An infant radiant warmer is essential for using MiraCradle™ - Neonate Cooler. The warming source is required to keep a check on temperature dropping below 33°C. The warmer should be used in manual mode, it is turned off when cooling is initiated and used when the temperature drops below the desired range.

2. Neonatal Rectal Probe: Required to monitor the core temperature of the newborn.

3. Multi-parameter monitor: Required for constant monitoring of the temperature and setting alarms for the desired temperature range of the newborn.

4. The treatment of HIE may also require other devices such as ventilator, neuro-imaging devices, etc. The hospital and the doctor should have the required understanding and arrangements before starting the therapeutic hypothermia treatment.
5.3 Selection of patient

Selection of newborn for the therapeutic hypothermia treatment is as important as the treatment process. The NICHD criteria for cooling newborns have been modified for Indian conditions and the following guidelines are used by Department of Neonatology, Christian Medical College, Vellore, India. Practicing neonatologists may adopt or modify these guidelines.

Inborn

1. GA >35 wks / Birth weight > 1800 g/ < 6 hours of age
2. Physiological Criteria - Any 1 of the following
   i. ABG (UC/1st postnatal hr) pH < 7.0 or ABE > - 12
   ii. Apgar score < 5 at 5’
   iii. Ventilation required for at least 10’
3. Neurological Criteria - Seizures OR Evidence of moderate or severe encephalopathy (3 of 6 criteria in modified Sarnat)

Modified Sarnat:

| Criteria for defining moderate/severe encephalopathy – 3/6 areas should be present |
| Category                        | Moderate Encephalopathy | Severe Encephalopathy |
| Level of consciousness         | Lethargic               | Stupor or Coma         |
| Spontaneous activity           | Decreased activity      | No activity            |
| Posture                        | Distal Flexion          | Decerebrate            |
| Complete extension             |                          |                        |
| Tone                           | Hypotonia               | Flaccid                |
| (focal or generalized)         |                          |                        |
| Primitive reflexes             |                          |                        |
| Suck                           | Weak                    | Absent                 |
| Moro                           | Incomplete              | Absent                 |
| Autonomic system               |                          |                        |
| Pupils                         | Constricted             | Deviated, dilated or non-reactive to light |
| Heart rate                     | Bradycardia             | Variable               |
| Respiration                    | Periodic Breathing      | Apnea                  |
1. GA > 35 wks / Birth weight > 1800 g / < 6 hours of age
2. Physiological Criteria - Newborns who did not cry immediately after birth/required resuscitation/APGAR score < 5 at 5’ (if available)
3. Neurological Criteria – Seizures OR Evidence of encephalopathy

**Warning:** The newborn should fulfill criteria 1, 2 and 3. If not, do not use the product.

**Note:** These are guidelines and final decision for the therapeutic hypothermia treatment lies with the attending qualified doctor.

# HOW TO USE THE MIRACRADLE™ - NEONATE COOLER

This section contains step-by-step instructions on using the MiraCradle™ - Neonate Cooler for the therapeutic hypothermia treatment. It is advisable to go through this section thoroughly and clarify any doubts with the company before using the product.

## 6.1 Contents

MiraCradle™ - Neonate Cooler consists of the components listed below. Check the contents on unpacking and report any missing components to the company within 48 hours of receiving the product.

<table>
<thead>
<tr>
<th>Product</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cradle</td>
<td>1 unit</td>
</tr>
<tr>
<td>savE® FS-29</td>
<td>6 units</td>
</tr>
<tr>
<td>savE® FS-21</td>
<td>2 units</td>
</tr>
<tr>
<td>Conduction Mattress</td>
<td>1 unit</td>
</tr>
</tbody>
</table>

Check for any damages that may have occurred during shipping and report to the distributor with a copy to the company.
6.2 Before use

6.2.1 Checking the components

Ensure that the cradle is clean and sanitized with any hospital approved disinfectant. Soap water mixture or Isopropyl Alcohol are suggested sanitizing solutions. Refer: Section 7.2.1 Page 20.

Ensure that savE© FS-29 PCM, savE© FS-21 PCM and the Conduction Mattress are also cleaned and sanitized with a hospital approved disinfectant. Refer: Section 7.2.1 Page 20.

Ensure that the savE© FS-29 PCM and savE© FS-21 PCM feel hard and rigid.

Ensure that the savE© FS-29 PCM, savE© FS-21 PCM and Conduction Mattress are not punctured or leaking.

Ensure that the temperature indicator on the savE© FS-29 PCM is in the desired range. Refer: Section 6.3 Page 13.

Ensure that the Conduction Mattress is flat and uniform before use. If not, distribute the gel uniformly using your hands.
6.2.2 Checking the savE\textsuperscript{®} FS-29 PCM

The savE\textsuperscript{®} FS-29 and savE\textsuperscript{®} FS-21 PCM units should feel hard and rigid. If flexible, do not use and charge completely in the refrigerator.

\(\text{Refer: Section 5.1.2 Page 6.}\)

Temperature indicator: If the savE\textsuperscript{®} FS-29 PCM is hard and rigid, then check the temperature on the indicator placed on the right side.

\(\text{Refer: Section 6.3 Page 13.}\)

While placing the savE\textsuperscript{®} FS-29 PCM in the cradle, ensure that the temperature indicator faces upwards.

Take three units of savE\textsuperscript{®} FS-29 PCM and place it at the bottom of the cradle. savE\textsuperscript{®} FS-29 forms the bottom layer of the MiraCradle\textsuperscript{TM} - Neonate Cooler.

\(\text{Warning: Ensure that the PCMs and the Conduction Mattress are not leaking from the pouch. If leaking, report to the company immediately for replacement.}\)

\(\text{Caution: Keep the PCMs and the Conduction Mattress away from sharp objects.}\)

\(\text{Caution: The contents of PCMs and the Conduction Mattress are non-toxic in nature. They are not fit for human consumption and should be kept away from children.}\)

6.2.3 Preparing the associated equipment

\(\text{STEP 1 \ Get a thin clean bed sheet to cover all the components of the MiraCradle\textsuperscript{TM} - Neonate Cooler.}\)

\(\text{STEP 2 \ Turn off the warmer. The warmer should be used in manual mode.}\)

\(\text{STEP 3 \ Insert a rectal probe 3-5 cm within the rectum to monitor the core temperature of the newborn.}\)
6.3 Reading the temperature indicator

**ALL BLACK**

- savE® FS-29 is **NOT OK for use.**
- Place it under the warmer or in ambient room conditions until the temperature indicator shows 23°C. Once it shows 23°C, switch off the warmer and start using savE® FS-29 PCM.

**23°C -28°C**

- savE® FS-29 is **OK for use.**
- Above 28°C savE® FS-29 is **NOT OK for use** and should be replaced with a charged unit.

6.4 Assembling the MiraCradle™ - Neonate Cooler

**STEP 1** Place the cradle in the bassinet of the warmer.

**STEP 2** Place three units of charged savE® FS-29 in the cradle.

**STEP 3** Place the Conduction Mattress on top of savE® FS-29.

**STEP 4** Place a thin clean bed sheet on top of the conduction mattress.

⚠️ Caution: The bassinet of the warmer should be of size greater than 66 x 47 cm

⚠️ Caution: The NICU temperature should be between 24-30°C
6.5 Operating the MiraCradle™ - Neonate Cooler

6.5.1 Inducing Hypothermia

**STEP 1**
Place the newborn on top of the bed sheet.

**STEP 2**
Set temperature alarm limits as 33.2°C and 33.8°C on the multi-parameter monitor.

**STEP 3**
Insert rectal probe and start monitoring the temperature of the newborn in the multi-parameter monitor on a continuous basis.

**STEP 4**
Observe the temperature of newborn every five minutes during induction phase.

**STEP 5**
If the temperature of the newborn does not fall below 34°C for half an hour after initiating the cooling process, introduce savE® FS-21 PCM between the savE® FS-29 PCM and the conduction mattress for few minutes until the temperature reaches 33.8°C.

**STEP 6**
Once the temperature reaches 33.8°C, remove the savE® FS-21 PCM and place it in the refrigerator again.

**STEP 7**
savE® FS-29 PCM and the conduction mattress will sustain hypothermia for the next 72 hours.

Note: Usually savE® FS-29 PCM is sufficient to induce hypothermia but when the environment temperature is greater than 27°C or the newborn’s metabolic rate or weight is high, savE® FS-21 PCM may be additionally required to induce hypothermia.
6.5.2 Sustaining Hypothermia

**STEP 1**
The target temperature of the newborn is 33.5°C with upper and lower limits of 34°C and 33°C respectively.

**STEP 2**
The temperature of the newborn should be monitored continuously and recorded every 15 minutes for the first one hour and every one hour post the initial one hour.

**If temperature goes over 33.8°C**

Guard: save® FS-21

**STEP 3**
If the rectal temperature of the newborn rises to 33.8°C (upper alarm limit), introduce save® FS-21 PCM between save® FS-29 and Conduction Mattress.

Caution: save® FS-21 PCM should feel hard and rigid before it is introduced.

**STEP 4**
save® FS-21 PCM should be subsequently removed when the temperature reaches 33.6°C. This process can be as short as a few minutes.

**Warning:** save® FS-21 PCM should not come in direct contact with the newborn.

**If the rectal temperature of the newborn decreases to 33.2°C (lower alarm limit)**

1. Place a folded piece of cloth under the newborn and cover the newborn with a sheet.

2. If the temperature still continues to drop, switch on the warmer in manual mode at 10-20% output until the temperature increases to 33.5°C.

3. If the temperature still does not rise, increase the output of the warmer until the temperature increases to 33.5°C.

4. Then in sequence, switch off the warmer, uncover the newborn and remove the cloth from under the newborn as the temperature rises.
6.5.3 Re-warming phase

1. The target re-warming rate is 0.2°C/hr and the target temperature is 36.5°C in a span of 12 hours.

2. At the end of 72 hours of induced hypothermia, cover the newborn with a sheet and switch on the warmer at 10-30% output levels. The temperature should rise by 0.2°C/hour.

3. Record the temperature and re-warming rate every hour.

4. If the re-warming rate is greater than 0.2°C/hr, switch off the warmer until the re-warming rate comes back to normal.

5. Once the temperature reaches 36.5°C, the newborn is removed from the MiraCradle™ - Neonate Cooler and kept in a normal open care system.

6. Monitor the rectal temperature for further 8 hours to prevent hyperthermia from settling in.

7. Sedation and analgesia may be administered as per the hospital unit policy if newborn is ventilated or there is clinical evidence of pain i.e., heart rate >100, grimacing and inconsolable crying and excessive shivering.

⚠️ Warning: Use the warmer only in manual mode. Automated mode will raise the temperature too quickly.

⚠️ Warning: Do not remove the newborn from the MiraCradle™ - Neonate Cooler during the re-warming phase. It will increase the temperature too quickly.

⚠️ Caution: Ensure that savE® FS-21 PCM is not in use when re-warming is initiated.
**Clinical monitoring**

Continuously monitor heart rate, SPO$_2$, blood pressure, rectal temperature and skin temperature on the multi-parameter monitor.

<table>
<thead>
<tr>
<th>Document readings as shown below:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heart Rate</td>
</tr>
<tr>
<td>Respiratory Rate</td>
</tr>
<tr>
<td>Blood Pressure</td>
</tr>
<tr>
<td>SPO$_2$</td>
</tr>
<tr>
<td>Rectal Temperature</td>
</tr>
<tr>
<td>Skin Temperature</td>
</tr>
<tr>
<td>Neurological Exam</td>
</tr>
<tr>
<td>Urine Output</td>
</tr>
<tr>
<td>Skin Breakdown/Redness</td>
</tr>
</tbody>
</table>

**Note:** These are just guidelines, the final decision of clinical monitoring lies with the attending qualified doctor.

**Lab monitoring**

The following laboratory parameters may need to be monitored at regular intervals

<table>
<thead>
<tr>
<th>Labs</th>
<th>Baseline</th>
<th>24 hours</th>
<th>48 hours</th>
<th>72 hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>S. Electrolytes</td>
<td></td>
<td>✔</td>
<td></td>
<td>✔</td>
</tr>
<tr>
<td>Blood Urea</td>
<td></td>
<td>✔</td>
<td></td>
<td>✔</td>
</tr>
<tr>
<td>S. Creatinine</td>
<td></td>
<td>✔</td>
<td></td>
<td>✔</td>
</tr>
<tr>
<td>Blood Sugar</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PT/PTT</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Hb, TC, DC, Plat</td>
<td>✔</td>
<td></td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>SGOT/SGPT</td>
<td>✔</td>
<td></td>
<td></td>
<td>✔</td>
</tr>
<tr>
<td>ECG</td>
<td>When clinically indicated (drop in heart rate &lt;80/minute)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Note:** These are just guidelines, the final decision of clinical monitoring lies with the attending qualified doctor.

Check blood gases as per the asphyxia protocol. Stop cooling prior to 72 hours if there is

1. Persistent hypoxemia in 100% oxygen.
2. Life threatening coagulopathy.
3. Arrhythmia requiring medical treatment (not sinus bradycardia).

**Note:** These are just guidelines, the final decision of when to stop cooling lies with the attending qualified doctor.
7.1 Safety Instructions

It is critical to understand and follow all safety measures before using the MiraCradle™ - Neonate Cooler. The precautions mentioned below are to prevent possible risk of injury to the newborn or the doctor and ensure correct usage of the device.

Note carefully the warning and caution labels that have been put on savE® FS-29, savE® FS-21 and Conduction Mattress.

7.1.1 General

Cautions

- Read this user manual carefully before using the device.
- Read all the warning and caution labels before use.
- Do not use if any of the contents are damaged. Contact the company immediately for replacement.
- Store savE® FS-29, savE® FS-21 and Conduction Mattress as per instructions.
  
Usage

- Monitor vital signs of the newborn as per the asphyxia treatment protocol used by the hospital.
- Sanitize Cradle, savE® FS-29, savE® FS-21 and Conduction Mattress before and after every use.
  
Expiry dates

- Replace savE® FS-29 and savE® FS-21 two years from the date of first use.
- Replace the temperature indicator on savE® FS-29 one year from the date of manufacturing.
- Replace Conduction Mattress six months after the date of first use.

7.1.2 savE® FS-29

Cautions

- Replace two years from the date of first use.
- Read the caution and warning labels carefully.
- Do not consume the contents of savE® FS-29.
- Contact the company for replacement of temperature indicator if the temperature indicator peels off.
- The contents of savE® FS-29 are non-toxic in nature. It is not fit for human consumption and should be kept away from children.

Usage

- Before using, check that it is hard and rigid.
- Before using, check that the temperature indicator is in the desired range.
- Place with the temperature indicator side facing upwards.
• Use only in conjunction with the cradle. Do not use with any other newborn interface. The company will not guarantee the performance of the device when used with a newborn interface other than the provided cradle.

• savE® FS-29 forms the bottom layer of the MiraCradle™ - Neonate Cooler

• Avoid direct contact of PCMs with the newborn.

• Use only for giving the therapeutic hypothermia treatment. Do not use it in any other manners other than as prescribed.

• Replace the temperature indicator one year from the date of manufacturing.

**Expiry dates**

• Store savE® FS-29 as per instructions. Refer: Section 7.2.2 Page 21.

• Do not store in a deep freezer.

• Always store on a clean flat surface. Do not bend/break/distort.

• Keep savE® FS-29 away from sharp and abrasive objects.

• Do not use if the pouch is punctured or leaking. Contact the company immediately for replacement.

• Do not expose to any kind of radiation.

**7.1.3 savE® FS-21**

**Cautions**

• Replace savE® FS-21 two years from the date of first use.

• Read the caution and warning labels carefully.

• Do not consume the contents of savE® FS-21.

• The contents of savE® FS-21 are non-toxic in nature. It is not fit for human consumption and should be kept away from children.

**Usage**

• Do not use if the pouch is punctured or leaking. Contact the company immediately for replacement.

• Use only in conjunction with the provided cradle and as per the instructions mentioned in this user manual. Do not use with any other newborn interface. The company will not guarantee the performance of the device when used with a newborn interface other than the cradle.

• savE® FS-21 forms the middle layer of the MiraCradle™ - Neonate Cooler.

• Avoid direct contact with the newborn.

• Before using, check that it is hard and rigid.

• Use only for giving the therapeutic hypothermia treatment. Do not use it in any other manners other than as prescribed.

**Storage**

• Keep away from sharp and abrasive objects.

• Store savE® FS-21. Refer: Section 7.2.2 Page 21.

• Do not store in a deep freezer.

• Always store on a clean flat surface. Do not bend/break/distort.

• Do not expose to any kind of radiation.
7.1.4 Conduction Mattress

**Cautions**
- Do not use if the pouch is punctured or leaking. Contact the company immediately for replacement.
- Replace Conduction Mattress six months from the date of first use.
- Read the caution and warning labels carefully.
- Do not consume the contents of Conduction Mattress.
- The contents of the Conduction Mattress are non-toxic in nature. It is not fit for human consumption and should be kept away from children.

**Usage**
- Use only in conjunction with the cradle. Do not use with any other newborn interface. The company will not guarantee the performance of the device when used with a newborn interface other than the provided cradle.
- Conduction Mattress forms the top layer of the MiraCradle™ - Neonate Cooler.
- Avoid direct contact with the newborn.
- Before using, check that it is flat, uniform and does not have any lumps. Distribute the gel evenly with your hands.
- Use only for giving the therapeutic hypothermia treatment. Do not use it in any other manners other than as prescribed.

**Storage**
- Keep away from sharp and abrasive objects.
- Store Conduction Mattress. [↩] Refer: Section 7.2.2 Page 22.
- Store in a cool, dry place and at room temperature. Do not store in refrigerator.
- Do not place any heavy objects on the conduction mattress.
- Always store on a clean flat surface. Do not fold or bend.
- Do not expose to any kind of radiation.

7.1.5 Cradle
- Use only for the purpose of therapeutic hypothermia treatment and not for any other use.
- Keep away from sharp objects.
- Store in a cool, dry place.
- Do not expose to any kind of radiation.
- Sanitize before every use. [↩] Refer: Section 7.2.1 Page 21.
- Avoid direct contact with the newborn.

7.2 Maintenance

7.2.1 Cleaning

**Cleaning Liquids**
Use Isopropyl Alcohol solution or soap water or any newborn-friendly cleaning solutions that the hospital normally uses for cleaning plastics and other surfaces that the newborn comes in contact with and to periodically sanitize the various components of the MiraCradle™ - Neonate Cooler.
Cradle

- Sanitize the Cradle every time before and after use with a dampened cloth dipped in one of the cleaning solutions mentioned above.
- Do not use cloth saturated in excess liquid.

savE® FS-29

- Sanitize savE® FS-29 every time before and after use with a dampened cloth dipped in one of the cleaning solutions mentioned above.
- Do not use cloth saturated in excess liquid or immerse savE® FS-29 in water.
- Ensure that the temperature indicator is not damaged and does not peel off during the cleaning process.

savE® FS-21

- Sanitize savE® FS-21 every time before and after use with a dampened cloth dipped in one of the cleaning solutions mentioned above.
- Do not use cloth saturated in excess liquid or immerse savE® FS-21 in water.

Conduction Mattress

- Sanitize the Conduction Mattress every time before and after use with a dampened cloth dipped in one of the cleaning solutions mentioned above.
- Do not use cloth saturated in excess liquid or immerse Conduction Mattress in water.
- Do not use the following cleaning solutions for cleaning:
  - Solutions that contain Methyl Ethyl Ketones, toluene or acetones.
  - Solutions that have been known to injure newborn skin or are toxic to newborns.

7.2.2 Storage

savE® FS-29

1. Store in a cool dry place, at a temperature between 6-15°C, commonly in the bottom part of the refrigerator.
2. Normally, savE® FS-29 is ready for use after 8-10 hours of charging in a refrigerator.
3. Do not store in the freezer section of a refrigerator.
4. Do not place heavy objects on savE® FS-29.
5. Do not fold/bend/distort savE® FS-29. It should always be stored flat on a clean surface.
6. When not in use, ensure that it is stored in the cloth bag provided and kept away from insects, rodents etc.
7. Do not stack one above the other in storage.
8. Ensure that the cloth bag of savE® FS-29 is clean. Wash with regular detergent used for hospital linen.
9. Keep away from any kind of radiation.

savE® FS-21

1. Store in a cool dry place, at a temperature between 6-15°C, commonly in the bottom part of the refrigerator.
2. Normally, savE® FS-21 is ready for use after 6-8 hours of charging in a refrigerator.
3. Do not store in the freezer section of a refrigerator.
4. Do not place heavy objects on savE® FS-21.
5. Do not fold/bend/distort savE® FS-21. It should always be stored flat on a clean surface.
6. When not in use, ensure that it is stored in the cloth bag provided and kept away from insects, rodents, etc.
7. Do not stack one above the other in storage.
8. Do not stack savE® FS-21 above savE® FS-29 in storage or vice versa.
9. Ensure that the cloth bag of savE® FS-21 is clean.
10. Keep away from any kind of radiation.

**Conduction Mattress**

1. Store in a cool dry place at room temperature. Do not store in a refrigerator.
2. Do not place heavy objects on the Conduction Mattress.
3. Do not fold/bend/distort. It should always be stored flat on a clean surface.
4. Ensure that no lumps are formed in the Conduction Mattress. Distribute the gel uniformly using your hands.
5. When not in use, ensure that Conduction Mattress is wrapped in plastic and kept away from insects, rodents, etc.
6. Keep away from any kind of radiation.
7. Discard immediately if any kind of bacterial growth is seen.

**Cradle**

1. Store in a cool dry place.
2. Keep away from any kind of radiation.
3. When not in use the Cradle should be stored wrapped in a plastic sheet in a clean area.

### 7.2.3 Periodic calibration check

1. Once in every three months, cross-check the temperature on the temperature indicator of the charged savE® FS-29 with a standard clinical thermometer to ensure that the temperature indicator is working properly.
2. The temperature difference should not be more than ±0.5°C.
3. If the temperature difference is greater than ±1°C, contact the company immediately for replacement of the temperature indicator.

### 7.2.3 Periodic replacement

1. Replace savE® FS-29 two years from the date of first use. Do not use savE® FS-29 after its expiry date under any circumstances.
2. Replace savE® FS-21 two years from the date of first use. Do not use savE® FS-21 after its expiry date under any circumstances.
3. Replace Conduction Mattress six months from the date of first use. Do not use Conduction Mattress after its expiry date under any circumstances.
4. Replace the temperature indicator on savE® FS-29 units one year from the date of manufacturing.
# Glossary

<table>
<thead>
<tr>
<th>Term</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABE</td>
<td>Acute Bacterial Endocarditis.</td>
</tr>
<tr>
<td>ABG (UC)</td>
<td>Arterial Blood Gas - A test performed using arterial blood used mainly in pulmonology and critical care medicine to determine pH, partial pressure of CO₂ and O₂, and the bicarbonate levels.</td>
</tr>
<tr>
<td>Analgesia</td>
<td>A deadening or absence of sense of pain; relief from pain without loss of consciousness.</td>
</tr>
<tr>
<td>Apgar score</td>
<td>A quick test performed on a baby at 1 and 5 minutes after birth. The 1-minute score determines how well the baby tolerated the birthing process. The 5-minute score tells how well the baby is doing outside the mother’s womb. It is done to determine if the new born needs help with breathing or has heart trouble. The score takes into account breathing effort, heart rate, muscle tone, reflexes and skin colour.</td>
</tr>
<tr>
<td>Apnea</td>
<td>A suspension of external breathing. During apnea, there is no movement of the muscles of inhalation and the volume of the lungs initially remains unchanged. Depending on how blocked the airways are (patency), there may or may not be a flow of gas between the lungs and the environment; gas exchange within the lungs and cellular respiration is not affected.</td>
</tr>
<tr>
<td>Arrhythmia</td>
<td>A group of conditions in which the electrical activity of the heart is irregular, faster, or slower than normal.</td>
</tr>
<tr>
<td>Autonomic system</td>
<td>A part of the nervous system that regulates key involuntary functions of the body, including the activity of the heart muscle; the smooth muscles, including the muscles of the intestinal tract; and the glands</td>
</tr>
<tr>
<td>Baby bassinets</td>
<td>A bed designed specifically for newborn babies</td>
</tr>
<tr>
<td>Birth Asphyxia</td>
<td>A medical condition resulting from lack of oxygen to the newborn</td>
</tr>
<tr>
<td>Blood gases</td>
<td>A measurement of amount of oxygen and carbon dioxide in blood; determines the acidity of the blood</td>
</tr>
<tr>
<td>Blood sugar</td>
<td>A measurement of the amount of glucose or sugar in blood</td>
</tr>
<tr>
<td>Blood urea</td>
<td>A measurement of the amount of urea/nitrogen in blood; indicative of functioning of liver</td>
</tr>
<tr>
<td>Bradycardia</td>
<td>Extremely slow heart rate, that results in insufficient blood flow to the brain.</td>
</tr>
<tr>
<td>Charged PCM</td>
<td>A PCM that is ready to use. In this context, a charged PCM means that the PCM is in the solid state and the material is hard and rigid.</td>
</tr>
<tr>
<td>Coagulopathy</td>
<td>Clotting or bleeding disorder, in which blood’s ability to clot or coagulate is impaired.</td>
</tr>
<tr>
<td>Conduction</td>
<td>Thermal conduction is the transfer of internal energy within a body due to a temperature gradient</td>
</tr>
<tr>
<td>DC</td>
<td>Differential count</td>
</tr>
<tr>
<td>Decerebrate</td>
<td>To eliminate cerebral brain function by removing the cerebrum, cutting across the brain stem, or severing certain arteries in the brain stem.</td>
</tr>
<tr>
<td>Distal Flexion Complete Extension</td>
<td>Interphalangeal articulations are the hinge joints between the phalanges of the hand. Those between the second and third phalanges are called distal phalanges. It refers to the flexion and extension of the distal phalanges.</td>
</tr>
<tr>
<td>ECG</td>
<td>Electrocardiography (ECG). This is the recording of the electrical activity of the heart</td>
</tr>
<tr>
<td>GA</td>
<td>General Anaesthesia</td>
</tr>
<tr>
<td>Hb</td>
<td>Hemoglobin</td>
</tr>
<tr>
<td>Term</td>
<td>Definition</td>
</tr>
<tr>
<td>-----------------------------------------</td>
<td>---------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Hypotonia (focal or generalized)</td>
<td>Hypotonia is diminished muscle tone.</td>
</tr>
<tr>
<td>Hypoxemia</td>
<td>Abnormally low level of oxygen in arterial blood.</td>
</tr>
<tr>
<td>Hypoxic Ischemic</td>
<td>A condition in which the entire brain is deprived of adequate oxygen supply, but deprivation is not total. HIE is associated in most cases with oxygen deprivation in the neonate due to birth asphyxia</td>
</tr>
<tr>
<td>Encephalopathy (HIE)</td>
<td></td>
</tr>
<tr>
<td>ICU</td>
<td>Intensive Care Unit</td>
</tr>
<tr>
<td>Latent heat</td>
<td>The quantity of heat absorbed or released by a substance while changing phase</td>
</tr>
<tr>
<td>Neuro-imaging devices</td>
<td>A device that directly or indirectly provides images of the structure and functioning of the nervous system</td>
</tr>
<tr>
<td>NICHD</td>
<td>Eunice Kennedy Shriver National Institute of Child Health and Human Development</td>
</tr>
<tr>
<td>Phase Change Materials (PCMs)</td>
<td>PCMs are special thermal energy storage materials that store or release heat while changing phase from solid to liquid or liquid to solid at a constant temperature</td>
</tr>
<tr>
<td>Plat.</td>
<td>Platelets are colorless blood cells that play an important role in blood clotting</td>
</tr>
<tr>
<td>PT</td>
<td>Prothrombin Test - A blood test that measures the time it takes for the liquid portion (plasma) of the blood to clot.</td>
</tr>
<tr>
<td>PTT</td>
<td>Partial Thromboplastin Test used to investigate unexplained bleeding or clotting.</td>
</tr>
<tr>
<td>Q1H</td>
<td>Every one hour</td>
</tr>
<tr>
<td>Neonatal rectal probe</td>
<td>Neonatal rectal probes are used to measure the rectal temperature of neonates</td>
</tr>
<tr>
<td>S. Creatinine</td>
<td>Serum (Blood) Creatinine - allows calculation of creatinine level</td>
</tr>
<tr>
<td>S. Electrolytes</td>
<td>Serum (Blood) Electrolytes</td>
</tr>
<tr>
<td>Sarnat</td>
<td>It is a classification scale for HIE among the newborn</td>
</tr>
<tr>
<td>SGOT</td>
<td>Serum Glutamic Oxaloacetic Transaminase - measured to determine liver health</td>
</tr>
<tr>
<td>SGPT</td>
<td>Serum Glutamic Pyruvic Transaminase - measured to determine liver health.</td>
</tr>
<tr>
<td>SPO₂</td>
<td>It stands for Peripheral capillary oxygen saturation. It is an estimation of the oxygen saturation level. Oxygen saturation is a term referring to the concentration of oxygen in the blood. It measures the percentage of hemoglobin binding sites in the bloodstream occupied by oxygen.</td>
</tr>
<tr>
<td>TC</td>
<td>Total count</td>
</tr>
<tr>
<td>Therapeutic hypothermia</td>
<td>It is a treatment method in which a specific body temperature is maintained for a specific duration in order to achieve better health outcomes</td>
</tr>
<tr>
<td>Ventilator</td>
<td>It is a medical device designed to assist breathing for a patient who is unable to breathe</td>
</tr>
</tbody>
</table>
“Simplicity is the Ultimate Sophistication”

Leonardo da Vinci