“Simplicity is the Ultimate Sophistication”

Leonardo da Vinci

PLUSSTAINABLE /plʌsˈsteɪnəb(ə)l/

able to maintain the optimal rate or level to meet the needs of the present without compromising the needs of future generations, the **PLUSS way**.

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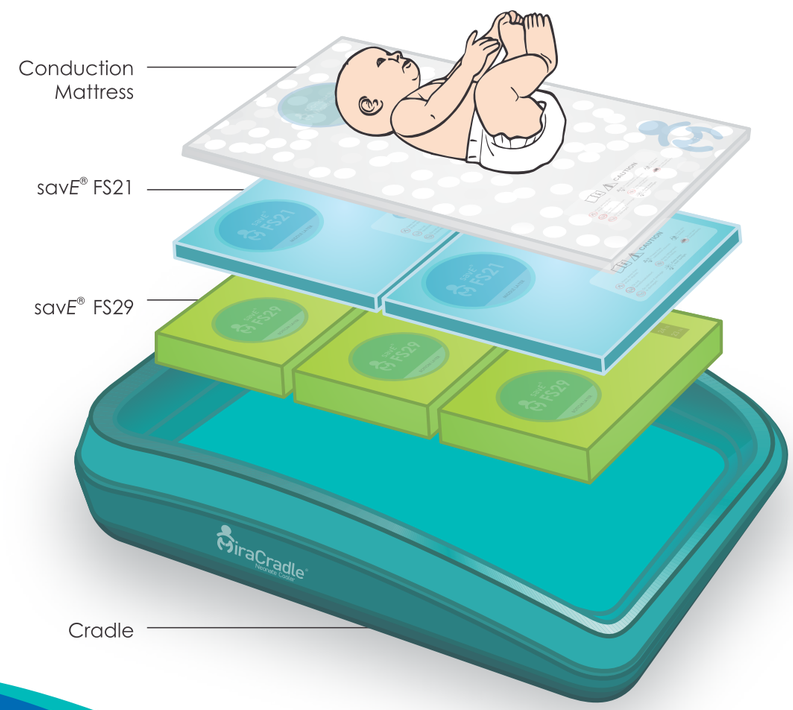
Version No. 10, May 2021 / MiraCradle UM

MiraCradle®
Neonate Cooler

AFFORDABLE DEVICE FOR THERAPEUTIC HYPOTHERMIA FOR NEONATES



USER MANUAL

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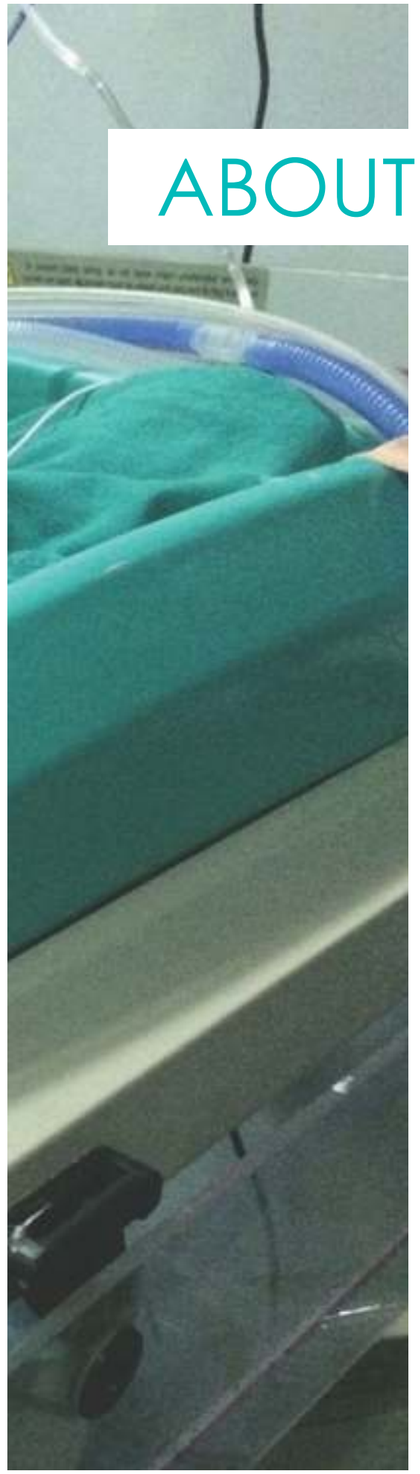

ABOUT THE COMPANY

Established in 1994, Pluss Advanced Technologies Pvt. Ltd. (formerly Pluss Polymers Pvt. Ltd.) is a materials research and manufacturing company involved in the field of speciality polymeric additives and phase change materials. Research and innovation has been the focus of the company since inception. The company bears the distinction of pioneering and creating cost effective and innovative products and applications that provide impacting solutions. Experience, interdisciplinary thinking and practical skills form the growth guidelines for PLUSS®. The company has an equity infusion from Tata Capital Innovations Fund.

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

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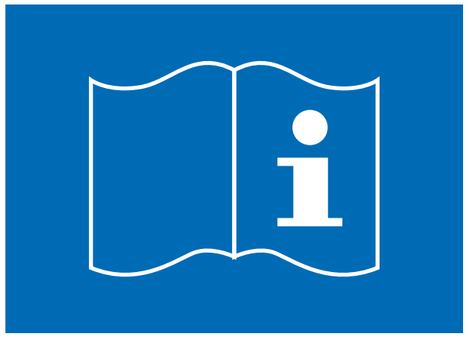
HOW TO READ THIS MANUAL

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.



REFER
Instructs the user to read specific sections within this user manual that contain additional relevant information.

CAUTION
Is a cautionary that user must check before continuing the use of the product.

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 they are not charged or not in the desired temperature range.
Refer: Section 6.2.2 Page 12.

PRODUCT RELATED

MiraCradle® - Neonate Cooler is an affordable cooling device for neonates or newborns suffering from Hypoxic Ischemic Encephalopathy (HIE). It uses the advanced sav*E*® Phase Change Material (PCM) technology to induce Therapeutic Hypothermia. It has been researched, designed and developed by Pluss Advanced Technologies 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 PCMs are made using non-toxic fatty acids and are completely safe for use near a newborn. The PCMs are form stable, ensuring that they retain form and shape while changing phase from solid to liquid, thus avoiding any risk of the PCM 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 multi-system 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 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.

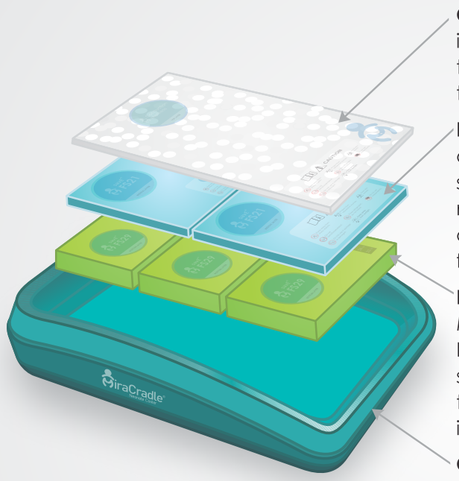
PRODUCT DESCRIPTION

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 cooling device for newborns. It uses advanced sav*E*® PCM 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 sav*E*® FS21: This is the middle layer of the device. sav*E*® FS21 is used in conjunction with sav*E*® FS29 to quickly bring the temperature of the newborn down to 33°C. It is subsequently removed and sav*E*® FS29 takes over to sustain the temperature for longer hours.

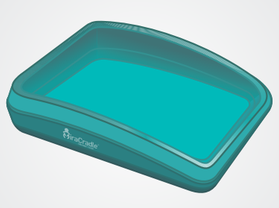
PCM sav*E*® FS29: This forms the bottom layer of the MiraCradle®- Neonate cooler. Three units of sav*E*® FS29 PCM are placed at the bottom of the Cradle. sav*E*® FS29 in solid state passively extracts heat from the newborn's body which is at 37°C thereby inducing and sustaining hypothermia.

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) sav*E*® FS29 and sav*E*® FS21 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)

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. sav*E*® FS29
2. sav*E*® FS21

sav*E*® FS29

sav*E*® FS29 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: Six units of sav*E*® FS29 are supplied with one MiraCradle® - Neonate Cooler. Each unit weighs approximately 1.03 kgs and measures approximately 180mm x 330mm.

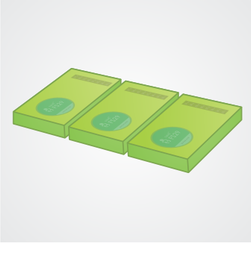
Charging Time: sav*E*® FS29 generally takes 8-10 hours to get charged when stored in the bottom part of a refrigerator.

Caution: Remove the cloth bag and 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 sav*E*® FS29 means that it is in solid state and the material is hard and rigid.

Usage: The sav*E*® FS29 PCM is used for maintaining and sustaining hypothermia. At a time, only three units of sav*E*® FS29 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 sav*E*® FS29 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.



Note: For replacement of sav*E*® FS29 PCM, ☞ **Refer:** Section 7.2.4.

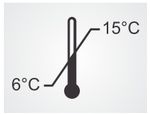
☞ **Refer:** Section 6.2 Page 11; Section 6.4 Page 13; Section 7.1 Page 18; Section 7.2 Page 20.

savE® FS21

savE® FS21 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® FS21 is supplied with one MiraCradle® - Neonate Cooler. Each unit weighs approximately 0.4 kgs and measures approximately 270mm x 330mm.

Charging Time: savE® FS21 when stored in the bottom part of a refrigerator, generally takes 6-8 hours to get charged.



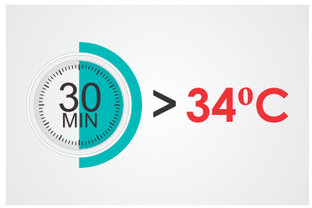
Caution: Remove the cloth bag and store at a temperature between 6°-15°C in the bottom part of the refrigerator.

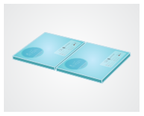
Do not store in the freezer section of a refrigerator.

Note: Charged savE® FS21 means that it is in solid state and the material is hard and rigid.

Usage: savE® FS21 PCM is used in conjunction with savE® FS29 PCM. savE® FS21 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® FS21 PCM is introduced between the savE® FS29 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® FS21 PCM is removed and placed in the storage (refrigerator) again.

savE® FS21 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® FS21 PCM between the savE® FS29 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® FS21 PCM and place in the storage (refrigerator) again.





Caution: Ensure that the savE® FS21 PCM is hard and rigid before use. If not, place it back in the refrigerator for charging.

Note: If not in use, the savE® FS21 PCM should always be kept in the storage with the cloth bag removed.

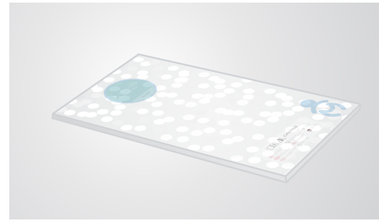
Note: For replacement of savE® FS21 PCM, **Refer:** Section 7.2.4

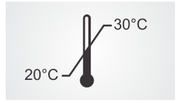
Refer: Section 6.2 Page 11; Section 6.4 Page 13; Section 7.1 Page 18; Section 7.2 Page 20.

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.





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

- For replacement of conduction mattress, refer to section 7.2.4

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

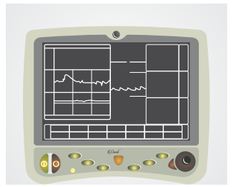
5.2 Associated equipment required

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.

Caution:

- Cradle should be placed on level surface all the time.
- Placing the Miracradle® in the bassinet of the warmer would reduce the distance between the patient and the radiant warming source and may cause a change in heating performance of the warmer. This change may alter the duration of therapy and could result in patient injury.

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 Complete extension	Decerebrate
Tone	Hypotonia (focal or generalized)	Flaccid
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

Outborn

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

⚠ **Caution:** 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.

Product	Quantity
Cradle	1 unit
savE® FS29	6 units
savE® FS21	2 units
Conduction Mattress	1 unit

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

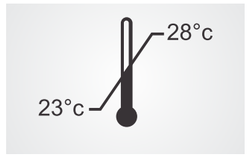
6.2.1 Checking the components

Ensure that the cradle is clean and sanitized with any hospital approved disinfectant. Soap water, IPA and Dismozon are suggested sanitizing solutions. **Refer:** Section 7.2.1 Page 20.

Ensure that savE® FS29 PCM, savE® FS21 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 cloth bag is removed and the savE® FS29 PCM and savE® FS21 PCM feel hard and rigid.

Ensure that the savE® FS29 PCM, savE® FS21 PCM and conduction mattress are not punctured or leaking.

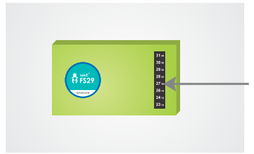


Ensure that the temperature indicator on the savE® FS29 PCM is in the desired range. **Refer:** Section 6.3 Page 13.

Ensure that the conduction mattress is flat and uniform before use. If not, distribute the gel uniformly using your hands.

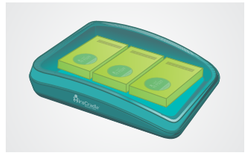
6.2.2 Checking the savE® FS29 PCM

The savE® FS29 and savE® FS21 PCM units should feel hard and rigid. If flexible, do not use and charge completely in the refrigerator. **Refer:** Section 5.1.2 Page 6.



Temperature indicator: If the savE® FS29 PCM is hard and rigid, then check the temperature on the indicator placed on the right side. **Refer:** Section 6.3 Page 13.

While placing the savE® FS29 PCM in the cradle, ensure that the temperature indicator faces upwards.

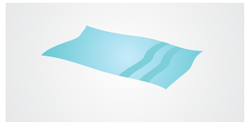


Take three units of savE® FS29 PCM and place it at the bottom of the cradle. savE® FS29 forms the bottom layer of the MiraCradle® - Neonate Cooler.

Caution:

- Ensure that the PCMs and the conduction mattress are not leaking from the pouch. If leaking, report to the company immediately for replacement.
- Keep the PCMs and the conduction mattress away from sharp objects.
- 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.

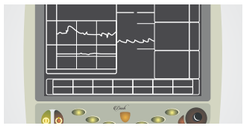
6.2.3 Preparing the associated equipment



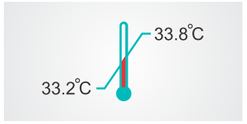
STEP 1 Get a thin clean bed sheet to cover all the components of the MiraCradle® - Neonate Cooler.

STEP 2 Turn off the warmer. The warmer should be used in manual mode.

STEP 3 Insert a rectal probe 3-5 cm within the rectum to monitor the core temperature of the newborn.

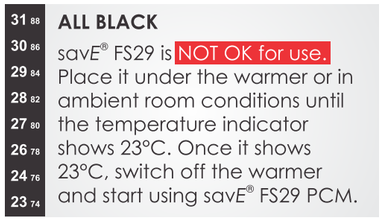


STEP 4 The rectal probe should be connected to a multi-parameter monitor.

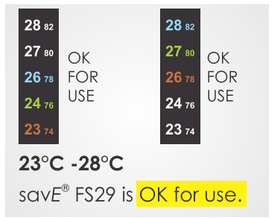


STEP 5 Set temperature alarm limits of 33.2°C and 33.8°C on the multi-parameter monitor.

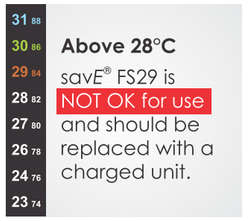
6.3 Reading the temperature indicator



ALL BLACK
savE® FS29 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® FS29 PCM.

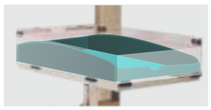


23°C -28°C
savE® FS29 is OK for use.

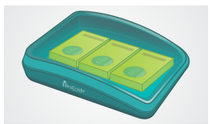


Above 28°C
savE® FS29 is NOT OK for use and should be replaced with a charged unit.

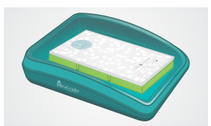
6.4 Assembling the MiraCradle® - Neonate Cooler



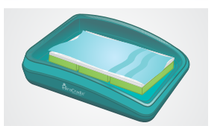
STEP 1 Place the cradle in the bassinet of the warmer. It should be placed on level surface all the time.



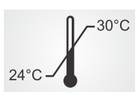
STEP 2 Place three units of charged savE® FS29 in the cradle with the cloth bag removed.



STEP 3 Place the conduction mattress on top of savE® FS29.



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



Caution:
- The cradle should be placed on level surface all the time.
- The bassinet of the warmer should be of size greater than 66 x 47 cm.
- The NICU temperature should be between 24°-30°C.
- Additional heat sources may have an impact on the lasting of the PCMs and therefore the cooling therapy.

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.

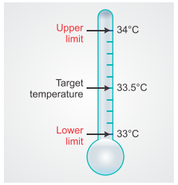
STEP 5
If the temperature of the newborn does not fall below 34°C for half an hour after initiating the cooling process, introduce savE® FS21 PCM between the savE® FS29 PCM and the conduction mattress for few minutes until the temperature reaches 33.8°C.

STEP 6
Once the temperature reaches 33.8°C, remove the savE® FS21 PCM and place it in the refrigerator again.

STEP 7
savE® FS29 PCM and the conduction mattress will sustain hypothermia for the next 72 hours.

Note: Usually savE® FS29 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® FS21 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

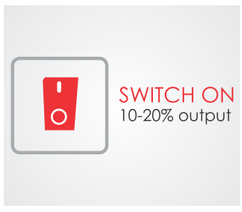
STEP 3
If the rectal temperature of the newborn rises to 33.8°C (upper alarm limit), introduce savE® FS21 PCM between savE® FS29 and conduction mattress.

STEP 4
savE® FS21 PCM should be subsequently removed when the temperature reaches 33.6°C. This process can be as short as a few minutes.

Caution:
- savE® FS21 PCM should feel hard and rigid before it is introduced.
- savE® FS21 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)

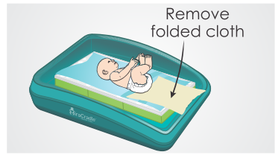
1. Place a folded piece of cloth under the newborn and cover the newborn with a sheet.



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.



Caution:
- Use the warmer only in manual mode. Automated mode will raise the temperature too quickly.

6.5.3 Re-warming phase

0.2°C

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.

SWITCH ON
10-20% output

2. At the end of 72 hours of induced hypothermia, cover the newborn with a sheet and switch on the warmer at 10-20% output levels. The temperature should rise by 0.2°C/hour.

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

>0.2°C
SWITCH
OFF

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.

Caution:
- Use the warmer only in manual mode. Automated mode will raise the temperature too quickly.
- Do not remove the newborn from the MiraCradle® - Neonate Cooler during the re-warming phase. It will increase the temperature too quickly.
- Ensure that savE® FS21 PCM is not in use when re-warming is initiated.
- Placing the Miracradle® in the bassinet of the warmer would reduce the distance between the patient and the radiant warming source and may cause a change in heating performance of the warmer. This change may alter the duration of therapy and could result in patient injury.

Clinical monitoring

Continuously monitor heart rate, SPO_2, blood pressure, rectal temperature and skin temperature on the multi-parameter monitor.

Document readings as shown below:	
Heart Rate	Q1H
Respiratory Rate	Q1H
Blood Pressure	Q1H - more frequently if hypotensive
SPO_2	Q1H
Rectal Temperature	Q15 minutes for first 4 hours then Q1H
Skin Temperature	Q1H
Neurological Exam	At recruitment prior to cooling and Q24H till normal/discharge
Urine Output	Q6H
Skin Breakdown/Redness	Q4H

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

Labs	Baseline	24 hours	48 hours	72 hours
S. Electrolytes		✓		✓
Blood Urea		✓		✓
S. Creatinine		✓		✓
Blood Sugar				
PT/PTT	✓	✓	✓	✓
Hb, TC, DC, Plat	✓		✓	✓
SGOT/SGPT	✓			
ECG	When clinically indicated (drop in heart rate <80/minute)			

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).
4. Decision on withdrawal of care-signs of irreversible brain death.

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

REFERENCE

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 label that has been put on savE® FS29, savE® FS21 and conduction mattress.

7.1.1 General

Cautions

- Read this user manual carefully before using the device.
- Read all the caution labels carefully.
- Do not use if any of the contents are damaged. Contact the company immediately for replacement.
- Store savE® FS29, savE® FS21 and conduction mattress as per instructions.
  ☞ **Refer:** Section 7.2.2 Page 21.

Usage

- Monitor vital signs of the newborn as per the asphyxia treatment protocol used by the hospital.
- Sanitize cradle, savE® FS29, savE® FS21 and conduction mattress before and after every use.
  ☞ **Refer:** Section 7.2.1 Page 20.
- Only trained nurses and doctors who are thorough about the therapeutic hypothermia treatment should use this device.

Notes

- For replacement of savE® FS29 PCM and savE® FS21 PCM, refer to section 7.2.4
- For replacement of conduction mattress, ☞ **Refer:** Section 7.2.4

7.1.2 savE® FS29

Cautions

- For replacement of savE® FS29 PCM, ☞ **Refer:** Section 7.2.4
- Read all the caution labels carefully.
- Do not consume the contents of savE® Fs29.
- Contact the company for replacement of temperature indicator if the temperature indicator peels off.
- The contents of savE® FS29 are non-toxic in nature. It is not fit for human consumption and should be kept away from children.

Usage

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

- 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® FS29 forms the bottom layer of the MiraCradle® - Neonate Cooler.
- Before using, check that the temperature indicator is in the desired range.
- Ensure that it is outside the cloth bag and hard and rigid before use.
- Place with the temperature indicator facing upwards.
- Avoid direct contact with the newborn.
- Do not use if the pouch is punctured or leaking. Contact the company immediately for replacement.

Storage

- Store savE® FS29 as per instructions. ☞ **Refer:** Section 7.2.2 Page 21.
- Do not store in a deep freezer.
- Always keep on a clean flat surface with the cloth bag removed. Do not bend or distort it.
- Keep savE® FS29 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® FS21

Cautions

- For replacement of savE® FS21 PCM, ☞ **Refer:** Section 7.2.4
- Do not consume the contents of savE® FS21.
- The contents of savE® FS21 are non-toxic in nature. It is not fit for human consumption and should be kept away from children.

Usage

- Use only for giving the therapeutic hypothermia treatment. Do not use it in any other manner other than as prescribed.
- 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® FS21 forms the middle layer of the MiraCradle® - Neonate Cooler.
- Ensure that it is outside the cloth bag, and hard and rigid before use.
- Avoid direct contact with the newborn.
- Do not use if the pouch is punctured or leaking. Contact the company immediately for replacement.

Storage

- Keep away from sharp and abrasive objects.
- Store savE® FS21. ☞ **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.
- For replacement of conduction mattress, ☞ **Refer:** 7.2.4
- Read all the caution 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 it 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.
- Cradle should be placed on level surface all the time.

7.2 Maintenance

7.2.1 Cleaning

Cleaning Liquids

Before every use, soap water, Iso-Propyl Alcohol (IPA), Dismozon or any other newborn friendly cleaning solution should be used to sanitize all the surfaces of MiraCradle® that the newborn comes in contact with.

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® FS29

- Sanitize savE® FS29 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® FS29 in water.
- Ensure that the temperature indicator is not damaged and does not peel off during the cleaning process.

savE® FS21

- Sanitize savE® FS21 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® FS21 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 acetone.
  - Solutions that have been known to injure newborn skin or are toxic to newborns.

7.2.2 Storage

savE® FS29

- Remove the cloth bag and store it in a cool place at a temperature between 6°-15°C, preferably in the bottom part of the refrigerator.
- Normally, savE® FS29 is ready for use after 8-10 hours of charging in a refrigerator.
- Do not store in the freezer section of a refrigerator.
- Do not place heavy objects on savE® FS29.
- Do not fold/bend/distort savE® FS29. It should always be stored flat on a clean surface.
- When not in use, ensure that it is stored in the cloth bag provided and kept away from insects, rodents etc.
- Do not stack one above the other in storage.
- Ensure that the cloth bag of savE® FS29 is clean. Wash with regular detergent used for hospital linen.
- Keep away from any kind of radiation.

savE® FS21

- Store in a cool dry place at a temperature between 6°-15°C, commonly in the bottom part of the refrigerator and with the cloth bag removed.
- Normally, savE® FS21 is ready for use after 6-8 hours of charging in a refrigerator.

- Do not store in the freezer section of a refrigerator.
- Do not place heavy objects on savE® FS21.
- Do not fold/bend/distort savE® FS21. It should always be stored flat on a clean surface.
- When not in use, ensure that it is stored in the cloth bag provided and kept away from insects, rodents, etc.
- Do not stack one above the other in storage.
- Do not stack savE® FS21 above savE® FS29 in storage or vice versa.
- Ensure that the cloth bag of savE® FS21 is clean.
- Keep away from any kind of radiation.

Conduction mattress

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

Cradle

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

7.2.3 Periodic calibration check

- Once in every month, cross-check the temperature on the temperature indicator of the charged savE® FS29 with a standard clinical thermometer to ensure that the temperature indicator is working properly.
- The temperature difference should not be more than ±1°C.
- If the temperature difference is greater than ±1°C, contact the company immediately for replacement of the temperature indicator.

7.2.4 Periodic replacement

- Replace savE® FS29 PCM after three years from the date of first use or when found damaged.
- Replace savE® FS21 PCM after three years from the date of first use or when found damaged.
- Replace conduction mattress after three years from the date of first use or when found damaged.

GLOSSARY

Term	Description
ABE	Acute Bacterial Endocarditis.
ABG (UC)	Arterial Blood Gas - A test performed using arterial blood used mainly in pulmonology and critical care medicine to determine pH, partial pressure of CO_2 and O_2 and the bicarbonate levels.
Analgesia	A deadening or absence of sense of pain; relief from pain without loss of consciousness.
Apgar score	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.
Apnea	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.
Arrhythmia	A group of conditions in which the electrical activity of the heart is irregular, faster, or slower than normal.
Autonomic system	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.
Baby bassinets	A bed designed specifically for newborn babies.
Birth Asphyxia	A medical condition resulting from lack of oxygen to the newborn.
Blood gases	A measurement of amount of oxygen and carbon dioxide in blood; determines the acidity of the blood.
Blood sugar	A measurement of the amount of glucose or sugar in blood.
Blood urea	A measurement of the amount of urea/nitrogen in blood; indicative of functioning of liver.
Bradycardia	Extremely slow heart rate, that results in insufficient blood flow to the brain.
Charged PCM	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.
Coagulopathy	Clotting or bleeding disorder, in which blood's ability to clot or coagulate is impaired.
Conduction	Thermal conduction is the transfer of internal energy within a body due to a temperature gradient.
DC	Differential count.
Decerebrate	To eliminate cerebral brain function by removing the cerebrum, cutting across the brain stem, or severing certain arteries in the brain stem.
Distal Flexion Complete Extension	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.
ECG	Electrocardiography (ECG). This is the recording of the electrical activity of the heart.
GA	General Anaesthesia.
Hb	Hemoglobin.
Hypotonia (focal or generalized)	Hypotonia is diminished muscle tone.
Hypoxemia	Abnormally low level of oxygen in arterial blood.
Hypoxic Ischemic Encephalopathy (HIE)	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.
ICU	Intensive Care Unit.
Latent heat	The quantity of heat absorbed or released by a substance while changing phase.
Neuro-imaging devices	A device that directly or indirectly provides images of the structure and functioning of the nervous system.
NICHD	Eunice Kennedy Shriver National Institute of Child Health and Human Development.
Phase Change Materials (PCMs)	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.
Plat.	Platelets are colorless blood cells that play an important role in blood clotting.
PT	Prothrombin Test - A blood test that measures the time it takes for the liquid portion (plasma) of the blood to clot.
PTT	Partial Thromboplastin Test used to investigate unexplained bleeding or clotting.
Q1H	Every one hour.
Neonatal rectal probe	Neonatal rectal probes are used to measure the rectal temperature of neonates.
S. Creatinine	Serum (Blood) Creatinine - allows calculation of creatinine level.
S. Electrolytes	Serum (Blood) Electrolytes.
Sarnat	It is a classification scale for HIE among the newborn.
SGOT	Serum Glutamic Oxaloacetic Transaminase - measured to determine liver health.
SGPT	Serum Glutamic Pyruvic Transaminase - measured to determine liver health.
SPO_2	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.
TC	Total count.
Therapeutic hypothermia	It is a treatment method in which a specific body temperature is maintained for a specific duration in order to achieve better health outcomes.
Ventilator	It is a medical device designed to assist breathing for a patient who is unable to breathe.