

# HEALTH BIZ INDIA

India's 1st Online Healthcare Business Magazine

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A good 'leader-administrator' can move various stakeholders into action with ease

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The standard cooling equipment available in the market costs about ₹10-15 lakh, while MiraCradle™ is priced just below ₹2 lakh





# MIRACRADLE™ SAVING LIVES, SAVING MONEY

Although therapeutic hypothermia has proven to be the only medical intervention beneficial for perinatal asphyxia; it is not practiced widely. The standard cooling equipment available in the market are very expensive, costing approximately ₹10-15 lakh (\$15,000-\$25,000). It cannot be afforded by most of the hospitals in India or other low and middle income countries.

This is where MiraCradle™ (a neonate cooler) steps in. MiraCradle™ is an affordable passive cooling device, which uses the advanced saveE® phase change material (PCM) technology to induce therapeutic hypothermia among newborns suffering from birth asphyxia. It has been developed by Pluss Polymers in collaboration with CMC Vellore.

The quality and the value for money it offers makes MiraCradle™ an ideal candidate for our Inspire Series

By: Jayara Sharma

**P**erinatal asphyxia, neonatal asphyxia, or birth asphyxia is the medical condition resulting from deprivation of oxygen to the newborn that lasts long enough to cause physical damage especially to the brain. Hypoxic ischemic encephalopathy (HIE) associated with acute perinatal asphyxia in the term or near term newborns causes a neurological syndrome, which can develop in a newborn after a period of birth asphyxia. HIE is one of the most common causes of neurological complications.





resulting in chronic handicapping conditions, the most common of which is cerebral palsy. Therapeutic hypothermia induced by cooling the newborn's internal body temperature to 33.5°C and maintaining the temperature between 33°C and 34°C for 72 hours reduces the risk of death or major disability and increases the rate of normal survival at the age of 18 months among newborns with moderate or severe HIE.

Although therapeutic hypothermia has proven to be the only medical intervention beneficial for perinatal asphyxia; it is not practiced widely. The standard cooling equipments available in the market are very expensive costing approximately ₹10-15 lakh (\$15,000-\$25,000). It cannot be afforded by most of the hospitals in India or other low and middle income countries. Several low cost methods have been tried, most popular being the use of ice packs to cool the baby. Ice packs have the disadvantage

of having to be changed quite often, leading to very high amount of manual supervision and due to the very low surface temperature (0°C), induce a lot of shivering, wider swings in temperature and an increased risk of subcutaneous fat necrosis.

Because of the unavailability of an affordable and efficient device to cool babies, the therapeutic hypothermia treatment is not being practiced in India. According to the recent WHO Global Health Survey in 2013, approximately 1,50,000 infants died in one year because of birth asphyxia in India. It is the second-largest cause of newborn deaths in India and it is nowhere close to coming down. India has a tough target to meet for the MDG-4 goal of reducing neonatal mortality by December 2015 and we are nowhere close to it!

#### The idea for MiraCradle

It all started with CMC Vellore scouting for an affordable

and efficient solution to do the therapeutic hypothermia treatment in late 2011. They were earlier using ice packs and were unhappy with it. They were looking for possible alternatives to ice packs, which will be less labour intensive, effective and affordable. With their research, CMC Vellore came across Phase Change Materials (PCMs) as one of the possible solutions and contacted Pluss, the pioneer and the only manufacturer of PCMs in India. Pluss was initially unaware of the solution being sought by CMC and just supplied PCMs. After 6-8 months when CMC Vellore had some success with PCMs, they presented their research at the National Neonatology Conference in 2012 in Delhi. This is when leading doctors from CMC Vellore visited Pluss to describe in detail the extent of the problem and the solution required. Pluss joined hands with CMC in December 2012 to take the project forward to design an affordable and

#### The reach

- JIPMER, Puducherry
- SRMC Chennai
- St. John's Medical College, Bangalore
- The Cradle, Gurgaon (Apollo Hospitals Initiative)
- Paramitha Hospital, Hyderabad
- Fernandez Hospital, Hyderabad
- Jubilee Mission Hospital, Thrissur
- AMRI Hospital, Kolkata
- Kasturba Hospital, Manipal

efficient device for cooling babies.

The project was further supported under the Design Clinic Scheme for MSME's jointly run by the Government of India and the National Institute of Design. Over two years, extensive research and trials were done on the type and quantity of PCM, the design of the product and other intricacies before the final prototype was tested at CMC in March 2014. The product was commercially launched in August 2014. The standard cost of similar technology in the market is about ₹10-15 lakh (\$15,000-\$25,000), while MiraCradle costs under ₹2 lakh including all taxes!

In an exclusive joint chat with Dr. Niranjana Thomas, Professor and Head, Department of Neonatology, CMC Vellore and Samit Jain, Managing Director, PLUSS Polymers, Health Biz India explores more into this remarkable indigenous solution.

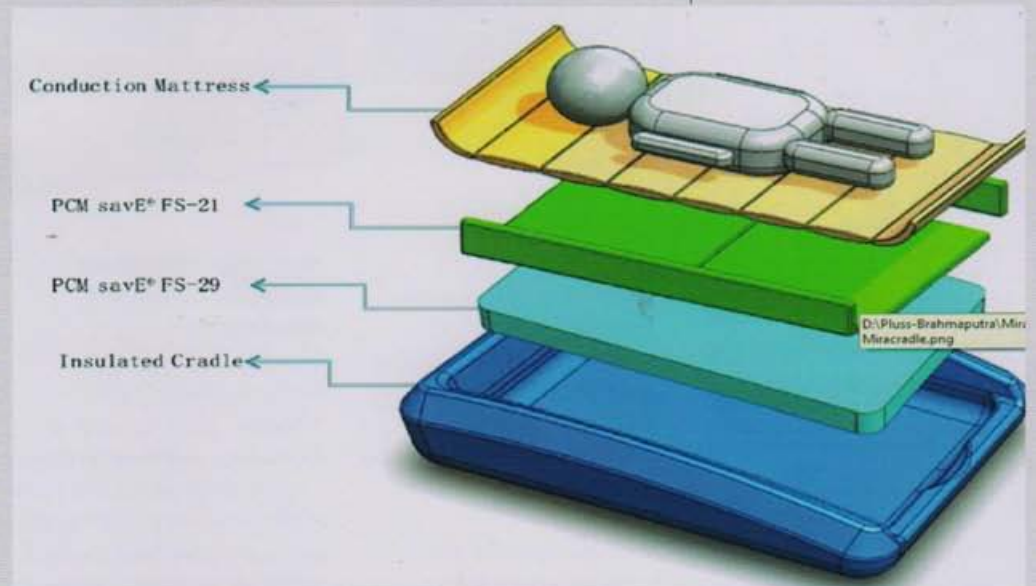
the feedback. Post product development, CMC played the key role of developing the right protocols for using the product including all the dos and don'ts.

#### Explain in detail about the save® phase change material technology.

save® phase change materials (PCMs) are special thermal energy storage materials being

extensively used as a reliable source of energy to maintain required temperatures in various industries. They use chemical bonds to store and release heat. The thermal energy transfer occurs at a particular temperature when a material changes from a solid to a liquid or from a liquid to a solid. This is called a change in state or 'phase'.

There are three major factors



#### What roles did Pluss and CMC Vellore play in designing the solution?

The initial success of CMC, Vellore in cooling babies using PCM supplied by Pluss led Pluss to translate it into an efficient system by developing the right technology for the device and CMC assisted in extensive trials and feedback of the technology developed by Pluss. Both worked hand in hand to develop the final product. Over a period of two years, several prototypes were developed by Pluss. Feedbacks on prototypes were given by CMC, based on the actual usage and the product was further modified based on





CMC Vellore has used MiraCradle™ to treat 45 babies until now, and the product has its presence in 16 hospitals across 9 states in India

What qualify a PCM:

- High latent energy storage capacity
- Consistency in performance over substantial number of cycles
- Constant temperature during release and absorption of energy
- Best example of a phase change material is ice.

#### How much investment went into developing MiraCradle?

The complete cost of developing MiraCradle™ - Neonate Cooler in terms of technology was done by Pluss. CMC Vellore played a key role in the trials and evaluating the product to give Pluss feedback on the improvements required in phase change material or the design of the product. The total investment by PLUS is of the order of a few crores over the last two years. The project at CMC Vellore was funded through the institutional (CMC) research grants.

#### What is the technological difference between MiraCradle™ and other expensive neonate coolers?

The expensive solutions use sophisticated electronics to cool babies, whereas MiraCradle™ is a non-electronic solution based on advanced safe® phase change material technology.

MiraCradle™ uses the first-of-its-kind form stable PCMs. PCMs have been incorporated in a polymer matrix to ensure that when changing phase from solid to liquid PCMs retain the shape and form avoiding any risk of the PCM leaking from its encapsulation, thus making it completely safe for the user as well as the patient.

To ensure precise temperature control, MiraCradle™ uses a cascaded system of PCMs. Cascaded system is a patented technology that employs use of two or more form of stabilised PCM mattresses with melt/freeze at different temperatures. By engineering the melting points, thicknesses, conductivities and placement of the involved layers, a "quasi-automated" cooling system is created, which, while being completely passive, behaves like a servo-automated cooling device.

Components of MiraCradle™ include:

- Insulated Cradle: It is





a remolded plastic structure, which serves as a framework for placing all the other components of MiraCradle™ neonate cooler and also provides insulation to the PCM helping it last for longer hours.

- **PCM save® FS-29:** This forms the bottom layer of MiraCradle™. Three units of FS-29 PCM are placed at the bottom of insulated cradle. FS-29 in solid state passively extracts heat from the neonate's body which is at 37°C thereby inducing and sustaining hypothermia.
- **PCM save® FS-21:** This is the second layer of the device. FS-21 is used in conjunction with FS - 29 to quickly bring the temperature of the neonate down to 33°C. It is subsequently removed and FS - 29 takes over to sustain the temperature for longer hours.
- **Conduction Mattress:** The conduction mattress is a gel bed, which provides a smooth surface for the baby to lie on and improves heat transfer between the baby and the PCM.

**What marketing initiatives are being taken to ensure**

**the technology also reaches the rural areas of India?**

Plus has a dedicated team of personnel and distributors who are handling the marketing of MiraCradle™. Plus also has a distributor network with VNG Medical Innovation Systems handling North and South India, AVI Healthcare handling Western region and Phoenix Neomed for South Africa and the Sub Saharan region.

Plus has been conducting a series of regional workshops across India to create awareness and educate the doctors on how to use the product as well as the treatment methods. These workshops are being conducted in collaboration with the hospitals that started using the technology first and are well versed with it. Plus has already conducted workshops in Vellore, Pune, Mumbai, Hyderabad, Jaipur and Bangalore. Further workshops are being planned in Kolkata, Guwahati, Varanasi, Puducherry, Lucknow, Chandigarh and Ahmedabad. These will help us reach to even the remotest areas in the country.

Further, Plus is in talks with the Indian Academy of

### The MiraCradle™ Team

**Apoorva Bahwari, Associate R&D:** A graduate in Polymer Science and Technology from IIT, Roorkee, Apoorva is a walking encyclopaedia on anything related to science or otherwise. With a sharp bent of mind for anything analytical or new, he led the team for the development and design of the product. Working day and night, he ensured finding the right PCM to meet all the conditions, which included maintaining the temperature of the baby for 72 hours without any external source. He is currently working with his team on further enhancing the product.

**Dr. Niranjan Thomas, Professor and head-Neonatology, Christian Medical College, Vellore:** Pioneered the research in cooling babies in India. He published the first trial of cooling babies in India using cool gel packs and developed the PCM cooling device from India. He led all the trials at CMC Vellore and provided feedbacks on the improvements required. He has presented his results with the CMC PCM based cooling device and the MiraCradle™ at all the relevant medical forums and is currently assisting on spreading awareness and educating doctors on how to practice therapeutic hypothermia treatment. This is being done along with other leading neonatologists in India from premier medical institutions.

**Ankit Jhanwar, Manager - Corporate Planning:** Ankit is a graduate in Polymer Science and Engineering from IIT, Roorkee (2011). He completed a certificate course in Entrepreneurship, Management and Global Leadership from the prestigious London School of Economics and Political Science and additionally qualified the Level 2 from the CFA Institute.

Passionate about entrepreneurship, Ankit led the product development and marketing initiative for MiraCradle™ as an 'entrepreneur' over the last one year right from concept selling and working along with Dr. Niranjan Thomas in identifying the 15 nodal hospitals to take the technology for cooling birth asphyxiated babies (HIE) to a commercial scale. He is currently working on expanding the product reach not only in India but internationally in countries like Bangladesh, Sri Lanka, Philippines, Malaysia, South Africa and Nigeria.



Paediatrics, World Health Organization and UNICEF on adopting this on a large scale across the country. A Health Technology Assessment is being done by the National Health Systems and Resource Centre under the Ministry of Health and Family Welfare; this will enlist MiraCradle™ under the innovative technology section and open up for purchases by the government organisations.

Advertisements are being given at relevant magazines such as Indian Paediatrics, which has subscription of over 18,000 and is read by almost every paediatrician in the country. The product is also being showcased at all the relevant exhibitions and conferences across India. With such concerted efforts, we are sure that within a year's time, the product shall reach



“According to the recent WHO Global Health Survey in 2013, approximately 1,50,000 infants died in one year because of birth asphyxia in India

every nook and corner of the country.

**Is this a US FDA approved product?**

No, it is not approved by the US FDA. Plus is going for CE marking with the help of UL India and shall have the same by the end of May 2015.

**What kind of after-sales services are being provided with the product?**

The best part of MiraCradle™ - Neonate Cooler is the zero maintenance cost. PCMs have been designed to last as long as two years. All the components of the product can be easily cleaned using a normal disinfectant. The product comes with a detailed user manual, which not only lists details of how to use the product but also has guidelines on the complete treatment process. Plus gives specially-designed instruction boards along with the product, which can be stuck on the wall close to the device making it easier for nurses to use the device.

Plus shall be coming up with a training video and a resources page on the website, which will include the research data, treatment protocols, etc. to further enhance the user experience with MiraCradle™ - Neonate Cooler. We already have a distribution network across India whose sales representatives have been extensively trained to service the product if required. And last but not the least, we are just a phone call away. We are not giant multinationals and have a lean cross functional team and are proud of it. [www.plusindia.com](#)

