PROTOCOL: Apr 2014

Study Design: Phase I/II Clinical Trial (single arm)

Study participants: postnatal mothers and early neonates
Inclusion criteria
Postnatal mothers
Newborns with birth weight above 1.8 kg -- not sick and on full feeds

Testing device – RBM device. This is a wearable sensor tag which can monitor temperature and transmit the data wirelessly using Bluetooth Low Energy.
The sensor tag operates off a CR2032 coin cell and can operate for 1 year. The enclosure package takes into account design elements and incorporates hermetic sealing, no sharp corners, no crevices for accumulation of bacteria/dust and is easily sterilizable
(technical details of preliminary pre-clinical testing are available at URL: http://chips.ece.iisc.ernet.in/images/2/25/BIODEVICES_2014_24.pdf).

Fig 1. Neonate in ICU with temperature probe

Fig 2. Neonate mannequin with RBM device

Fig 3. Baby-friendly enclosure

Fig 4. Disassembled prototype

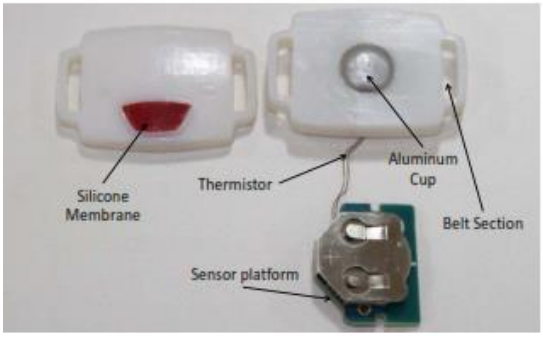


Fig 5. Top and bottom view of the sensor

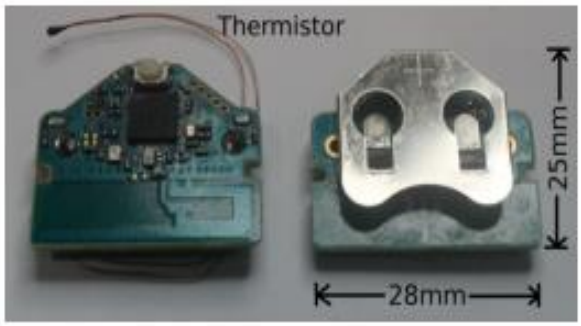
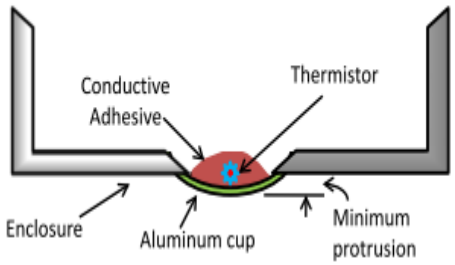


Fig 6. Vertical cross-sectional view of the enclosure



A gateway to bridge the sensor tag and the cellular infrastructure is housed independently or within a cellphone. The cellphone will display the temperature reading from the RBM device.

Location of device & probes

The RBM device will be placed on the abdomen between the xiphisternum and the umbilicus. Both the other probes (radiant warmer and the multichannel) will be placed near the RBM device separately.

Device adhesion

The RBM device will be strapped onto the abdomen using a combination of cotton and micropore adhesive tape.

Sample size and sampling technique

25 mother-baby pairs

250 readings (A sample size of about 250 readings will ensure a power of 80% to detect a 5% difference in measurements between devices with 95% confidence)

[At least 5 readings from mother and 5 readings from a neonate]

Pre-requisites for conduct of experiment

Radiant warmer and multichannel probe – both to be examined and serviced by the biomedical engineering dept; calibration certificate to be obtained from the responsible external agency

Testing comparisons

RBM device *vs* Radiant warmer probe *vs* Multichannel probe *vs* manual thermometer

Duration & frequency of sampling

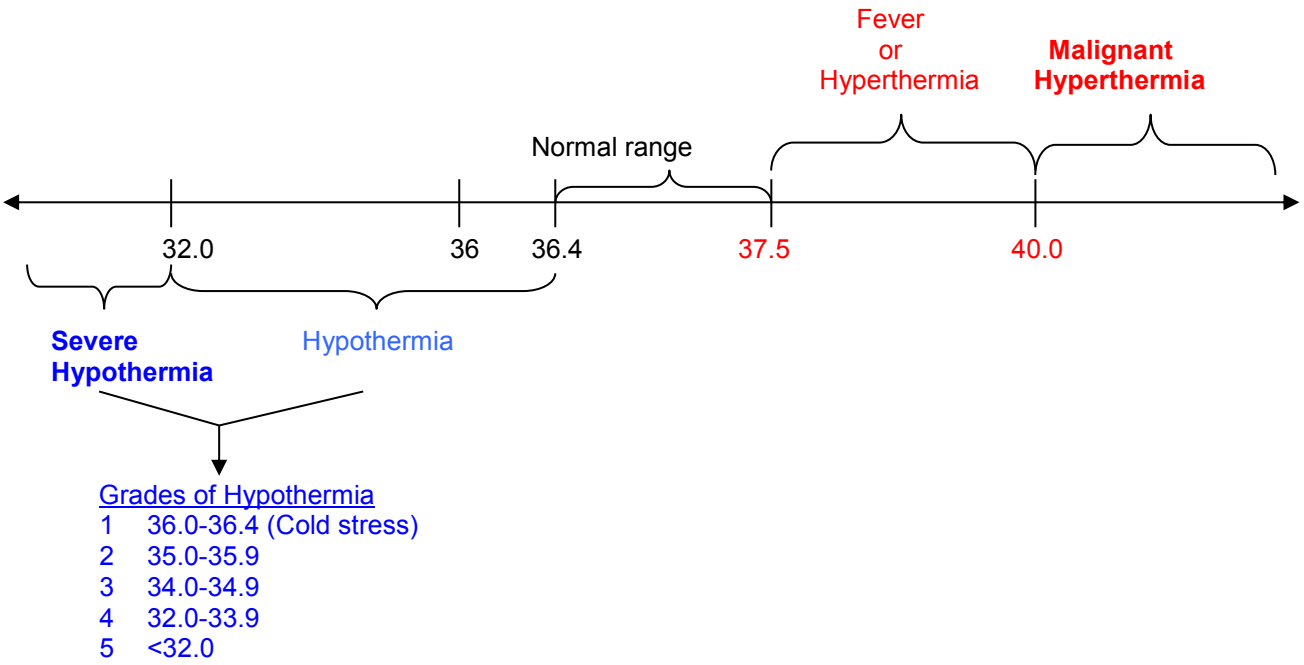
Initially, after strapping on all 3 probes – there will be a waiting period of 10 minutes for temperature stabilization. Then the experiment will be started.

RBM device, multichannel probe & Radiant warmer probe – will automatically obtain readings continuously (every few seconds) and readings will be taken every 5 minutes.

Manual thermometer readings will be taken every 15 minutes at the following 5 timings: 0, 15, 30, 45 and 60 minutes

Participant safety

For newborns – when the temperature on the radiant warmer is beyond the normal range (36.5 to 37.5 deg Celsius), routine appropriate care as per neonatology department protocols will take precedence over the conduct of the experiment



Grades of Hypothermia

1 36.0-36.4 (Cold stress)
2 35.0-35.9
3 34.0-34.9
4 32.0-33.9
5 <32.0