

Clinical Background of The Bempu Hypothermia Alert Device "BEMPU Bracelet"

ID	Study Name	Sample Size	Description	Results
1	Catching and Reducing Hypothermia in Newborns in Clinical and Home Settings in India: Utility Study of a New Medical Device* PI: Mona Sharma BEMPU & Dr. Archana, St. Philomena's	27 Doctors, 24 Families, 93 Neonates	The purpose of this study was to show the utility of a new temperature-monitoring device for hypothermia in neonates in clinical and home settings in India. Quantitative and Qualitative user feedback was gathered from doctors and parents on device accuracy and acceptability. Doctors were asked to confirm incidences of hypothermia and to present feedback on hospital utility; parents were asked to provide feedback on satisfaction. Data was collected through semi-structured surveys, allowing participants to provide additional feedback.	In the Doctor Feedback Study, 89% of doctors who used the device observed at least one case of hypothermia in the home or clinical setting; 89% of doctors who used the device recommend it to be used in their practice. In the Parent Feedback Study, 86% of families complied with regular use of the device in the NICU or postnatal wards and 84% of families continued use in their home. 100% of the mothers who used the device used corrective care when the alarm sounded – care included kangaroo care, swaddling, and seeking medical intervention 1 case of sepsis was detected in home use
2	Sensitivity Specificity Study of BEMPU Bracelet in Detecting Hypothermia in Low Birth Weight Neonates PI: Dr. Vishnu Bhat, JIPMER Pondicherry	460 Neonates ≤ 2kgs	The purpose of this study was to evaluate the BEMPU Bracelet in diagnosing hypothermia in LBW neonates. The subjects were given the BEMPU Bracelet to wear for 24 hours during their stay in the postnatal ward. Standard temperature monitoring was performed every 6 hours; additionally, temperature was taken after every bracelet alarm. Data was collected by nurses and doctors on temperature monitoring forms and then uploaded to excel for analysis.	484 true positive cases, 96 false positive cases, 7 false negative cases, and 1,837 true negative cases resulting in: Sensitivity of 98.57% Specificity of 95.03% Positive Predictive Value of 83.45% Negative Predictive Value of 99.62% All false positives axilla values measured between 36.5 C and 36.8 C, which is close to the threshold definition for hypothermia (< 36.5). The 4 false negatives were above 36.3 C, which is borderline.
3	Accuracy and Utility in Ward Use: Independent Study PI: Dr. Bharat Parmar, BJ Medical College, Ahmedabad *	45 Neonates	The purpose of this study was to evaluate the accuracy and utility of the BEMPU Bracelet in various clinical situations. Study was conducted in delivery room, postnatal ward, and NICU. Temperatures were recorded as per the standard of care and data was collected by nurses and doctors on temperature monitoring forms and then uploaded to excel for analysis.	120 true positive cases, 12 false positive cases resulting in: Positive Predictive Value of 90.91% Principal Investigator found the BEMPU Bracelet to be a simple, easy, and accurate method for early detection hypothermia in newborns. PI observed the promotion of Kangaroo Care and breastfeeding.
4	Randomized Double Blinded Control Study of Effect of Bempu Hypothermia Alert Device on Weight Gain in Low Birth Weight Babies at Home PI: Dr. Jagadish Somanna, Indira Gandhi Institute of Child Health	50 Neonates < 2.5 kgs	The purpose of this study is to determine the relationship between the BEMPU Bracelet and uptake of Kangaroo Care. The study will use patient diaries and weekly follow up appointments to gather data on weight, length, head circumference, and hours of KC per day. The study will place the BEMPU Bracelet on the wrist of ½ of neonates; the other half of neonates will be part of the control group and receive a placebo BEMPU Bracelet, which will not alarm, but will log temperature data. Sample size was calculated by weight gain data collected from a sample pilot of the study which showed the average weight gain for BEMPU Group and the Control Group as 31.54 and 17.36 grams per day over a 4 week period.	44 neonates completed the 4-week trial; 23 in the control group and 21 in the BEMPU group; of these, 19 control and 19 BEMPU participants completed KMC diaries. The results of the clinical trial reveal parents of neonates in the BEMPU group demonstrated better compliance to KMC. In the BEMPU group, the average daily time spent doing KMC was significantly higher in first (3.02 v 1.96 h, p= 0.016) and fourth (3.04 v 2.38 h, p= 0.094) week of discharge. There was an increase of weight gain in the BEMPU group on the fourth (28.3 v 22.9 g, p= 0.057) week of discharge. The BEMPU Bracelet was found to be an effective intervention to promote newborn weight gain and parent adherence to Kangaroo Care, and it should be considered an effective intervention for LBW neonates discharged in the home.

*For more information, please reach out to our clinical team at hello@bempu.com.

ID	Study Name	Sample Size	Description	Results
5	Accuracy of Device and Utility of KMC promotion in the ward: Independent Study from Madurai Medical College PI: Aarushi Manu, Madurai Medical College	1 year study Sample Size TBD (minimum of 300 neonates)	The purpose of this study is to show the utility of a new temperature-monitoring device for hypothermia in neonates in a low-resource government hospital in India. Doctors are recording 6 th hourly temperatures and temperatures during alarm. Data is collected by nurses and doctors on temperature monitoring forms and then uploaded to excel for analysis	The study is currently in progress; projected end date is March 2016 Intermittent data of 46 neonates 368 temperature recordings shows: Sensitivity of 91% Specificity of 98.2% Positive Predictive Value of 78% Negative Predictive Value of 99.4% Feedback from doctors also show an uptake of KMC in the center. Mothers perform KMC whenever the alarm rings and are more consistent in daily KMC practice
6	Study of temperature maintenance during KMC PI: Dr. Neelam Kler, Sir Ganga Ram Hospital	50 neonates monitored for 30 days	The purpose of this study is to determine if babies are truly kept warm during the entirety of KMC. All eligible neonates will be fitted with the BEMPU bracelet on either of the upper limbs during the entire study period. Baseline variables such as heart rate, respiratory rate, temperature and saturation will be recorded in ambient temperature prior to starting KMC. The parameters will also be monitored during KMC with the help of an electronic monitor and saturation probe. Data will be collected by Doctors and Lactation Specialists from Sir Ganga Ram Hospital in New Delhi	The study has recently received ethical approval and will begin October 2016. Study is expected to finish in February 2016.
7	Rajasthan Government Pilot	Open Label Control Trial of 250 BEMPU vs. 125 KMC Promoted Neonates	The purpose of this study is to determine if the BEMPU Bracelet can be integrated into Rajasthan's Facility & Home Based Newborn Care Guidelines. We are working with NHM and WISH to evaluate the feasibility of BEMPU in urban, rural, and tribal government health centers and homes. Data will be collected by nurses and data entry operators from 3 SNCUs and 7 PHCs	This study is currently in progress; projected end date is March 2016 Of the 368 babies enrolled in the study, 218 have been in the study for the 4 full weeks. Intermittent Results as follows: Enrolment & Follow-Up: In the pilot the Bempu group has a follow up rate of 68% and the control group is 42%. Death Rate: Bempu group has a lower death rate of 7% and control group has a rate of 14% KMC Uptake: Feedback from doctors and parents indicated that Bempu was effective in increasing KMC uptake.
8	UNICEF Madhya Pradesh and NHM Madhya Pradesh Feasibility Pilot	Open Label Control Trial of 200 BEMPU vs. 200 KMC Promoted Neonates	The purpose of this study is to determine if the BEMPU Bracelet can be integrated into MP's Facility & Home Based Newborn Care Guidelines. We are working with NHM and UNICEF to evaluate the feasibility of BEMPU in urban, rural, and tribal government health centers and homes. Data will be collected by nurses and data entry operators from 3 SNCUs	The study is waiting for NHM Madhya Pradesh approval.
9	PATH Multi-Country Community Based Study	Open Label Control Trial of 600 BEMPU vs. 600 Stand of Care Neonates in 5 countries	The purpose of this study is evaluate the utility of BEMPU at a community level in India, Nepal, Bangladesh, Nigeria, and Ethiopia. PATH has chosen centers in every country that are leaders in KMC promotion. The study will give information on how BEMPU promotes the uptake of KMC.	The study protocol is currently being finalized

The BEMPU Bracelet has been clinically tested on nearly 1000 babies.

Last updated February 2017