Non-Contact Respiratory Rate Monitoring with raybaby in an NICU: An Observational Study

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ABSTRACT

Objectives: This study aimed at evaluating the reliability of respiratory rate obtained by a non-contact technology with respect to a medically validated monitor among preterm babies. Design: This observational study compared the respiratory rates from raybaby's non-contact technology and FDA approved Earlysense unit for the same instants of time through 760 hours of monitoring. 18 preterm babies in the NICU of a paediatric specialty hospital in India were considered for the study. The raybaby device was installed in front of the incubator and the contact-free FDA approved device was placed below the mattress of the incubator. The Respiratory Rate monitored was displayed on the device's monitoring screen. Respiratory rates from both devices were compared to calculate the agreement between the values. Correlation, Accuracy, Hit Percentage and Fit Curves for the non-contact technology of raybaby with respect to the clinically certified device.

Results: With 760 hours of monitoring, 37404 breathing instances were analysed. This yielded an accuracy of 98%. 95% of the data points fell within the +/- 5 units error range which is usually followed by medical devices.

Conclusions: Raybaby uses a non-contact technology for monitoring Respiratory Rate. The average breathing rate observed was 33 to 43 breaths per minute, which falls within the breathing range of 30-60 breaths per minute. From the 37404 data points analysed, raybaby® establishes further proof for the breathing range and trend found in babies. The accuracy of

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non-contact technology for respiratory monitoring establishes great potential for making health monitoring less intrusive and efficient for use. This renders the technology as a hopeful tool for respiratory monitoring to deploy at observation units during the pandemic.

Keywords: Non-contact technology; Paediatric health monitoring, Breathing Rate; Vitals monitoring; Artificial intelligence; Remote monitoring; Medical technology; Early detection; Respiratory diseases

What this paper adds
Respiratory rate is an early indicator of health deterioration but not documented most of the time. There is a need to record it less intrusively in new-borns. Technology needs to be leveraged to make it more effective and less manual.
This study sheds light on the breathing rate trends in new-borns and compares two non-contact technologies on its effectiveness in monitoring the same. Despite being completely non-contact, the vitals are accurately captured without any manual intervention during monitoring.

Introduction
In the past decade, wearable technology and computer vision-based systems have made significant advancements in the healthcare sector, especially with regards to monitoring vitals such as heart rate, ECG and pulse oximetry. Moving towards an age where healthcare is being envisioned with a personalized approach and people are increasingly looking at their environment to be least intruded, non-invasive approaches like Actigraphy gathers much interest. Already levelling up to its demand, fitness and health trackers are adopting and experimenting with the approach of actigraphy and the accuracy of such disruptive technology. Due to recent advances in AI & computing power, there has been some work done in auto-videosomnography techniques with decent success. However, we find videosomnography as intrusion on privacy, and hence there is a need for an alternate means of monitoring sleep without video.
With the research at RIoT Solutions Inc, we introduce radiosomnography, a method of monitoring health and wellness data using low-power radio waves. raybaby® is the world's first non-contact radar-based health and sleep monitoring system for infants. There is substantial evidence that an abnormal respiratory rate is a predictor of potentially serious clinical event, in general. Current technologies for monitoring respiration rate involve chest belts or sensors that establish contact with the body [3]. These methods are uncomfortable for babies in NICU units. Babies admitted in NICUs are often very small for chest belts. Most vital monitoring equipment used in hospitals requires a physical attachment to the body in one way or the other. Movement of patient is also a common source of error found in the readings from these devices. Further, the presence of wires connected to the body triggers a general fear in the users- the already overwhelmed new parents in case of babies.

Body temperature, heart rate, respiratory (or breathing) rate and blood pressure are four vital signs that can predict the health condition of infants. There is substantial evidence that an abnormal respiratory rate is a predictor of potentially serious clinical event [1][2]. Respiratory Rate is the number of breaths inhaled per minute.

Of the four vital signs, respiratory rate, in particular, is often not recorded, even when the child's primary problem is a respiratory condition. For example, respiratory distress syndrome (RDS), a breathing disorder found in prematurely born babies and among the most common causes of death in the first month of life. It affects about 1 percent of new-born infants and is the leading cause of death in babies who are born prematurely. With preterm birth being world's no.1 cause for new-born deaths, it becomes crucial to monitor the new-born's health continuously over the period of preterm. Global estimates show

that in 2014, approximately 10.6% of all live births globally were preterm [5]. As depicted in Willaims Obstetrics, 25th Edition, distribution of babies born in different stages of preterm with 7.1% in less than 27 weeks, 12.1% in 32-33 weeks and 71.3% in 34-36 weeks [6].

Further there is substantial evidence that an abnormal respiratory rate is a predictor of potentially serious clinical event, in general. Abnormal respiratory rate also predicts babies with pneumonia, the biggest killer of children in developing countries especially in Africa and Asia. Current technologies for monitoring respiration rate involve chest belts or sensors that establish contact with the body [3]. These methods are uncomfortable for babies in NICU units. Babies admitted in NICUs are often very small for chest belts. Most vital monitoring equipment used in hospitals requires a physical attachment to the body in one way or the other. Movement of patient is also a common source of error found in the readings from these devices. Further, the presence of wires connected to the body triggers a general fear in the users- the already overwhelmed new parents in case of babies.


Figure 1. NICU setting at Cloudnine Hospital, Jayanagar

Methods

This observational study was conducted at the NICU (**Figure 1**) of CloudNine Hospital, Jayanagar, Bengaluru, India. The study aimed at finding agreement and thereby, accuracy of respiratory rate derived from RIoT's non-contact technology w.r.t the medically validated device, commenced with approval from the Ethical Committee of the hospital. The data being discussed in this work were collected through multiple sessions from 30th April 2019 to 4th March 2020. 18 different volunteers from age groups varying from 30 weeks to 41 weeks were enrolled on consent of the concerned.
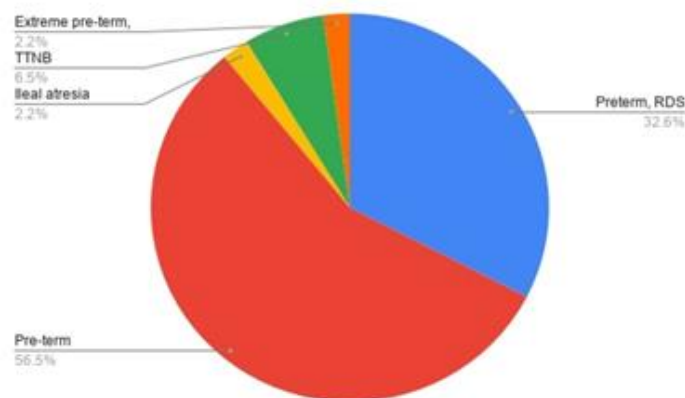

Figure 2. Distribution of diagnosis in the study population

The participants were diagnosed with preterm, including conditions of RDS, Ileal atresia and TTNB (**Figure 2**). Infants with known cases of sleep apnea were excluded.The sensor embedded in the raybaby® device uses the pattern of chest movement to derive breathing rate as well as movement data with signal processing algorithms. AI algorithms works on the same data along with baby's details such as weight, age, preterm or not and provides information such as - awake, rollover, walking around, crying etc. The data reflects on the mobile app that comes with raybaby®.

EarlySense monitor is an FDA approved contact-less continuous measurement system for heart and breathing rates. This system, also addressed as Medically Validated Under the Mattress (MVUM) Sensor in the findings, is based on a piezo-electric sensor that is placed under the patient's mattress and automatically starts measuring with no need for activation, involvement or contact with the device by patient or nurse. In this body of work, we show that we have been able to achieve 98% accuracy of breathing rate monitoring in babies born preterm.The study comprised of continuous monitoring of babies born pre-term simultaneously using raybaby® & EarlySense. raybaby® hardware and EarlySense Monitoring System were placed close to the subject for collecting respiratory data. The placement of the devices is shown in **Figure 3**. raybaby® unit was placed at a distance of 1 meter from the subject while EarlySense unit was placed under the mattress.
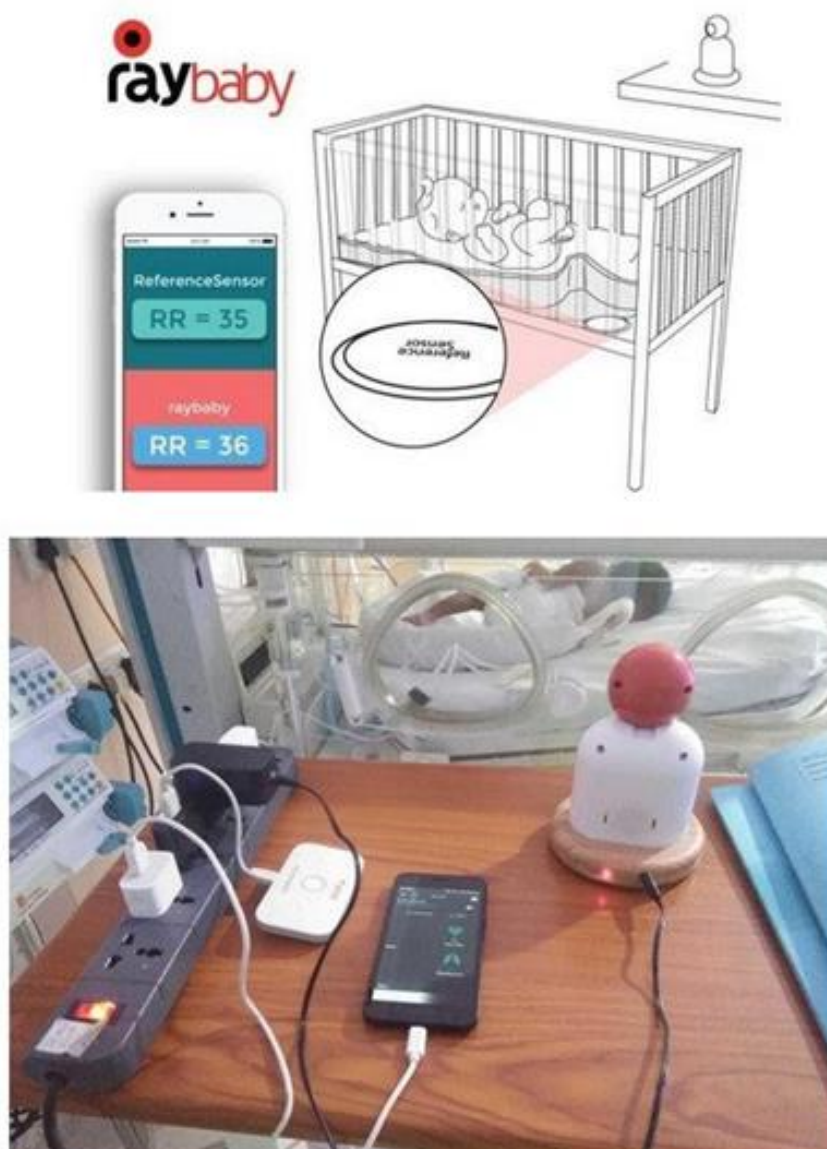
Figure 3. Placement of raybaby® and Earlysense Under the Mattress unit for monitoring

Prior to monitoring, the age, sex and weight of every baby were recorded. The breathing rates at every 30 second interval were considered for evaluation from a monitoring duration that varied from 1 to 267 hours. The data from both devices was investigated to analyze the amount of data that falls under the defined limits for percentage deviation. Mean and standard deviation was considered for each dataset from both devices. Any data point within the upper and lower limit defined with a tolerance of 5 units was taken into consideration for the analysis, the rest are considered outliers. This range-based correlation was adopted as the data corrupted from the external environment was found to fall outside the defined limits.

The data collected was assessed to find Fit curve, Hit Percentage, Absolute deviation and Percentage deviation versus Hit percentage between raybaby® and Earlysense.

The participants were monitored by both raybaby® monitor and EarlySense unit simultaneously. During the study, the state of the baby i.e., sleeping, awake or crying were also noted. The timestamps for which movement occurred around within the area of recording was also recorded to understand the impact of external factors on data being recorded. The respiratory rate was also recorded by manually counting the number of breaths by a trained professional while the baby is asleep and whenever the baby is in a calm state. Manual counting of breaths is considered as the industry standard for measurement of respiration rate.

Results

From 760 hours of breathing rate monitoring, 37404 breathing instances analysed, datapoints influenced by external factors like movement around the subject were eliminated from correlation, yielding an accuracy of 98%. Of the thousands of datapoints considered, metrics drawn were based on range-based correlation, mean deviation among other parameters to establish the accuracy of raybaby® w.r.t the clinically approved reference device. A scatter plot was drawn to illustrate a range-based correlation.

The plot in **Figure 4** depicts the relationship between breathing rate data from raybaby® and Earlysense's medically validated under the mattress sensor breathing data with raybaby'®s breathing data(rpm) on x axis and Earlysense's breathing data on y-axis. The mid-line represents the x=y axis and the two lines on either side were plotted at a difference of 5 units from the midline. All the data points lying in between these lines can be considered to be similar with the acceptance of 5 breaths per minute. Certified medical devices follow an industry acceptable error range of +/- 5 units.
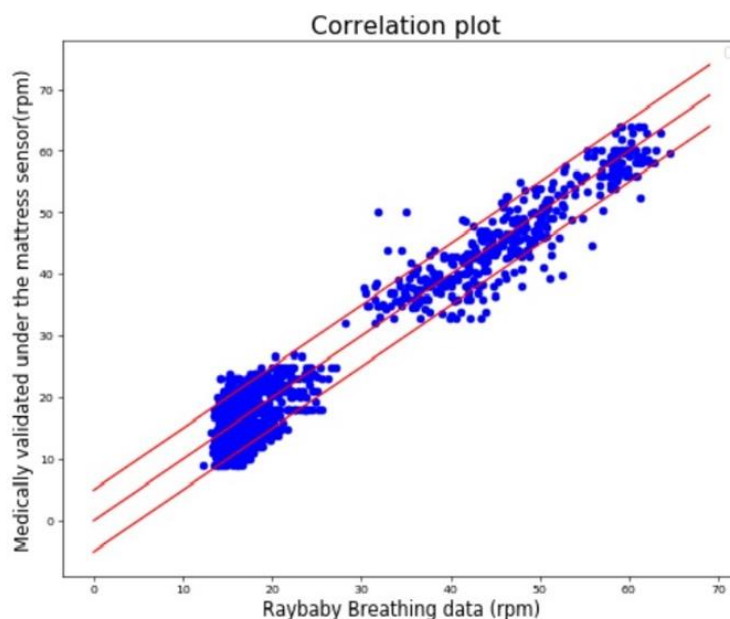

Figure 4. Correlation Plot of Breathing Rate data from raybaby® Vs Earlysense

I The Fit Curve was studied to understand the relation between raybaby® and MVUMS from which a correlation coefficient of 0.97972 was inferred. As depicted in **Figure 5**, the dashed line represents the ideal case, i.e. x=y line. The red line depicts the relation between raybaby® and medically validated under the mattress sensor. This line was plotted using linear regression formula. The correlation coefficient of 0.97972 implies to the slope of the line. This indicates that the MVUMS is 0.97972 times proportional to raybaby® data.
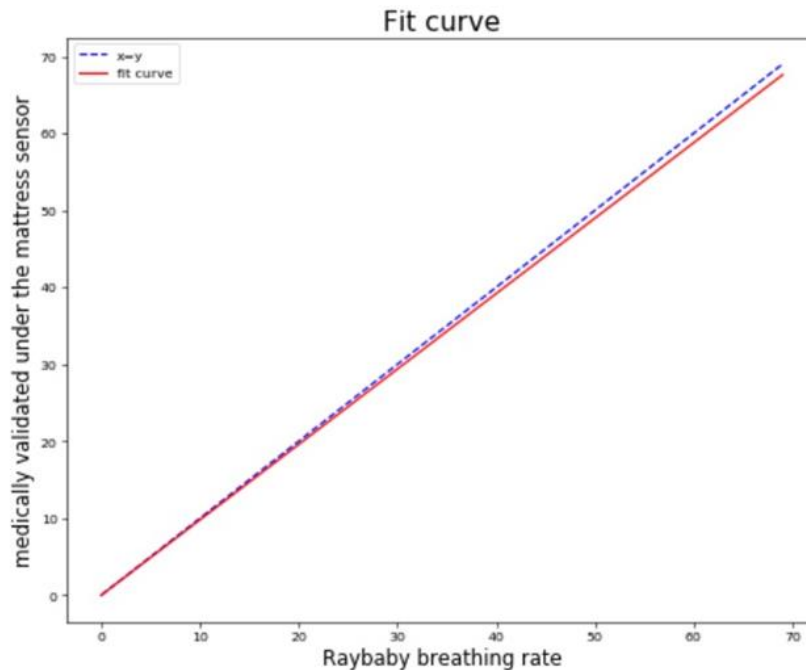
Figure 5. Fit curve showing correlation between raybaby® and Earlysense

Hit percentage was visualized as shown in **Figure 6** for studying the percentage deviation for different data sets. 90% of the data comes under less than 20% deviation in most of the sample population.
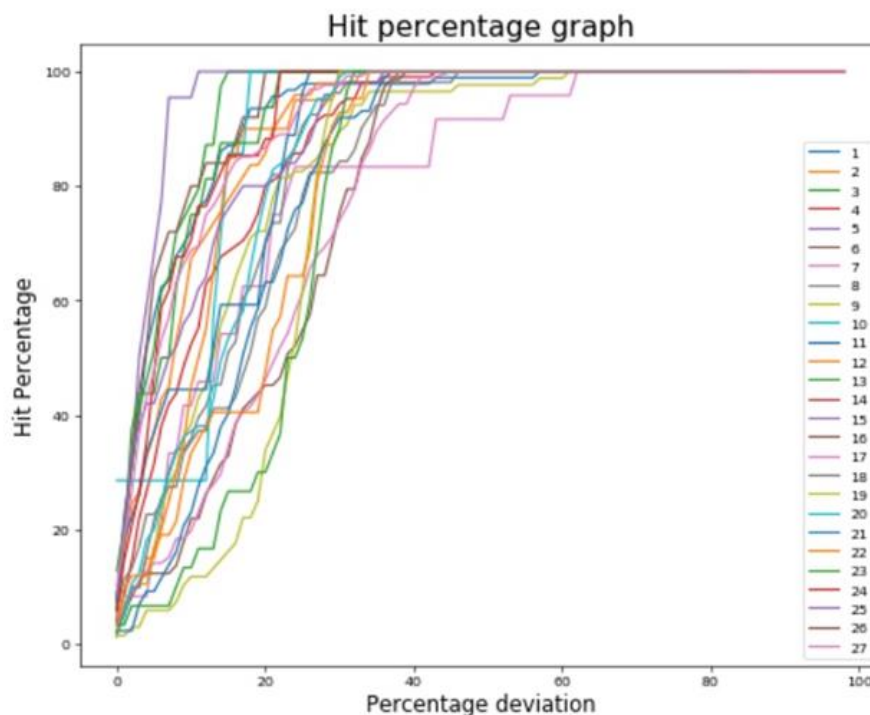
Figure 6. Hit Percentage for different data sets

On correlating Hit Percentage to Absolute Deviation, no data point was found to have absolute deviation more than 10 units as depicted in **Figure 7**. Therefore, data collected from raybaby® and medically validated under the mattress sensor, EarlySense were equiva- lent in practical settings. 95% of the data fell under absolute deviation of less than 5 units.

A Percentage deviation versus Hit Percentage graph was plotted, which indicated 95% percentage deviation for all the data collectively came under 30% deviation as shown in **Figure 8**.

$$Deviation(\%) = \frac{breathingrate(raybaby®) - breathingrate(MVUMS)}{breathingrate(raybaby®)} \times 100 \quad (1)$$
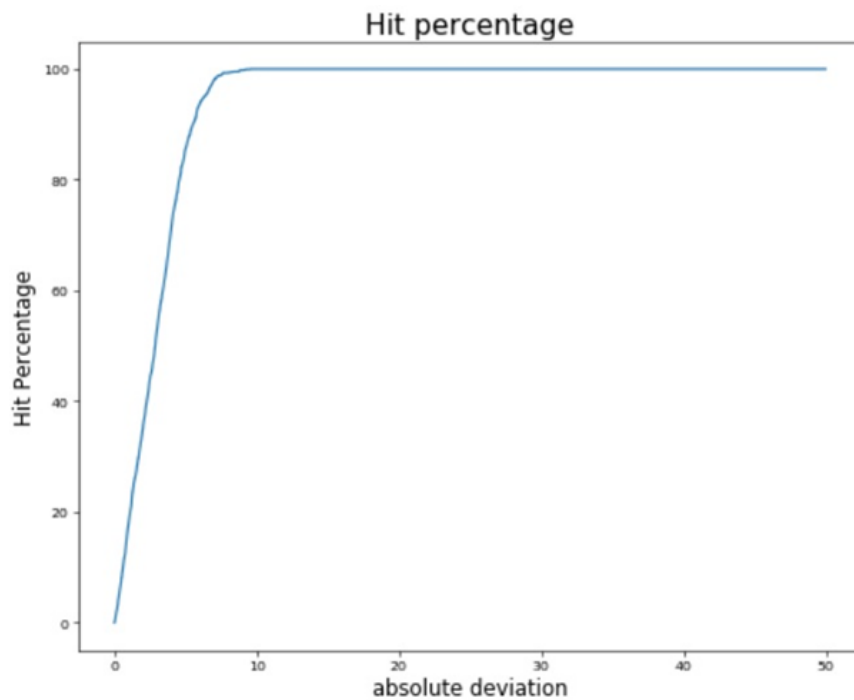
Figure 7. Absolute deviation Vs Hit percentage
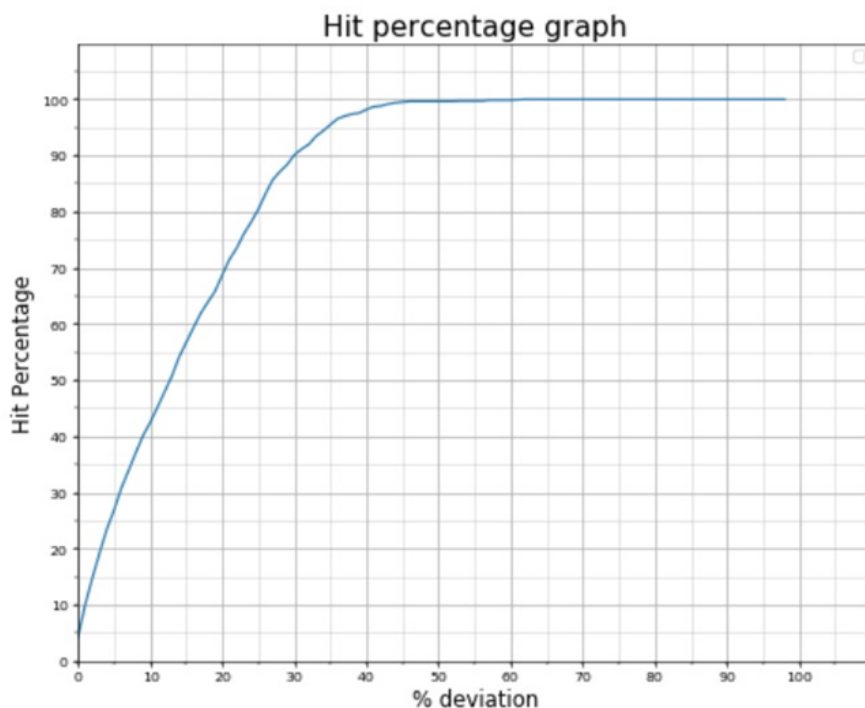
Figure 8. Percentage deviation Vs Hit Percentage

Discussion

Breathing rate monitoring in infants was identified as our first use case to explore our technology's potential as mortality rate reaches as high as 60% even in developed countries. In the U.S., RDS is among the most common causes of death in the first month of life. raybaby® combines the advantages of a video monitor with wellness tracking, without contact. Its technology renders it highly sensitive to even minute variations, and it's AI-powered platform interprets all the data to help new parents form better routines. We were driven by the need to offer a non-contact vitals tracker, and our quest led us to radar technology. We opted for radar-based technology because of its proven success as a highly accurate vitals tracker. We were keen to have a monitor that not only tracked sleep but also respiration – one of the four vital signs in wellness tracking. This brings an assurance of high accuracy to our monitor, tracking breathing even when the baby is swaddled, and even in the dark, noting minute variations.

Figure 2 explains the distribution of diagnosis in the babies who were a part of the study. Ileal atresia is a congenital abnormality where there is significant stenosis or complete absence of a portion of the ileum. There is an increased incidence in those with chromosomal abnormalities. It has been reported that the incidence of jejunal and ileal atresia ranges from one in 1500 to one in 12,000 births. TTNB results from delay in clearance of foetal alveolar fluid after birth. While RDS is prevalent with increasing prematurity, TTNB is found to be the most common cause of respiratory distress in new-born in late-preterm or term infants. As these conditions are found in varying stages of preterm birth, we have tried to cover as many of its occurrences in the NICU, where preterm babies are monitored. From the results we were able to understand that the performance of our technology was in par with the medical grade devices and can be deployed for use in a clinical setting. Although this study would convey the power of non-contact technology, the pilot study was limited to the NICU cases. Including a larger population with multiple respiratory conditions would enable evaluating precision of the technology to a greater extent. The rayIOT technology that powers the device in the study, over 7 billion breathing instances has been studies, covering breathing rate variations during episodes of fever, asthma and sleep apnea in home and consumer settings. With multiple studies for evaluating the rayIOT technology w.r.t clinical and industry standards, the patented non-contact technology is being explored for usage as a reliable tool for clinical and non-clinical settings to make health monitoring easier and less intrusive. With precise breathing rate calculation that falls within the medically acceptable error limits, rayIOT technology has been able to confirm the breathing rate trends for babies with respiratory related illnesses like RDS. Since this respiratory rate is read at a distance on the mobile, it can be used in situations like community diagnosis of pneumonia. Using this non-contact technology would thus help in capturing trends in respiratory pattern, which can be used for predictive analysis and help the medical professionals plan treatments and assess effectiveness of the same in a reliable manner, thus helping with early diagnosis to save lives.

List of abbreviations

Abbreviations: (list and define abbreviations used in the text; [or] Abbreviations: none)
RDS: Respiratory distress syndrome
NICU: Neonatal Intensive Care Unit
TTNB: Transient tachypnea of the new-born
FDA: Food and Drug Administration
MVUMS: Medically Validated under the Mattress Sensor

Competing interest declaration:" *All authors have completed the Unified Competing Interest form at www.icmje.org/coi_disclosure.pdf (available on request from the corresponding author) and declare that (1) Aardra Kannan Ambili, Anjali Palliyil Rajan, Sanchi Poovaya, Adrija*

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