

Sentec and PyrAmes form partnership to bring noninvasive care to critically ill infants

PyrAmes' novel Boppli™ device enables continuous, noninvasive blood pressure monitoring (cNIBP) for the hospital's most fragile patients

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Blood pressures can be difficult with cuffs in tiny neonates. Arterial lines increase risk of infection. A non-invasive option providing continuous, accurate BP would be an important step forward."

Lamia Soghier, MD, MEd, MBA, NICU Med. Dir. at Children's National Hosp.

and PyrAmes have established a commercial partnership to bring Boppli, PyrAmes' first-of-its-kind continuous noninvasive blood pressure device, to neonatal intensive care teams throughout the United States. Boppli has received Breakthrough Device Designation from the US Food & Drug Administration (FDA) and will be available after FDA 510(k) clearance, which is anticipated in the first half of 2023.

"We are excited to join forces with Sentec to commercialize our Boppli product," said Xina Quan, PhD, Co-Founder and CEO of PyrAmes. "This important step enables us to bring our breakthrough technology to market and transform patient care. We believe Sentec is an ideal partner for us in

the NICU, given our companies' shared mission and focus on noninvasive technologies to enable better healthcare delivery."

In the neonatal intensive care unit (NICU) today, a baby's blood pressure is either monitored continuously through an invasive arterial catheter or intermittently through cuff measurements. Both techniques present certain clinical challenges. The Boppli™ platform offers a new solution to overcome those challenges.

"Blood pressures can be difficult to obtain with a cuff, especially in our tiny neonatal patients where the cuffs are too big which impacts accuracy. Arterial lines are the alternative, but any invasive line increases the risk of infection, so we are always trying to remove them earlier if we can. A non-invasive option that provides continuous, accurate measurements would be an important step forward so we can keep a close eye on our babies without causing them pain or overstimulation," said Lamia Soghier, MD, MEd, MBA, Medical Director and Quality & Safety Officer of the NICU at Children's National Hospital.

Recent clinical research for neonates has highlighted the importance of neuroprotective care for premature infants, providing an optimal sensory environment for babies who should otherwise still be in utero. Everything from sound and light levels to the frequency of painful or stimulating procedures (such as blood draws, cuff measurements, suctioning, or even diapering) can impact proper neurological development. More and more, NICUs are creating quality care bundles with the goal of systematically providing neuroprotective care and improving neurological outcomes for their patients.



Boppli is designed to be a highly-advanced noninvasive blood pressure monitoring device that is ideal for neonatal infants in the NICU

Sentec's flagship transcutaneous CO2

monitoring technology has been adopted by top NICUs around the world looking to keep a close eye on their patients' respiratory status while limiting painful and invasive blood draws. The exclusive distribution partnership between PyrAmes and Sentec will allow Sentec customers to be among the first NICUs to adopt the Boppli solution.

"We are humbled and enthusiastic about offering our healthcare customers yet another option for noninvasive monitoring that advances their goals of providing less invasive, more neuroprotective care in this critical and vulnerable patient population," said Bob Cormier, President of Sentec North America. "We are confident that our partnership with PyrAmes will provide value to our companies, our customers, and most importantly, to patients."

About Boppli™

The Boppli™ is designed to be a highly-advanced noninvasive blood pressure monitoring platform that is ideal for infants in the NICU. It is intended to provide a safer option to arterial lines for patients who require continuous blood pressure measurements and has the potential to revolutionize the standard of care for continuous blood pressure monitoring for neonates. PyrAmes' devices are designed to be noninvasive, wireless, silent, and easier to use than a standard blood pressure cuff. The Boppli™ Band is a single-use, self-powered blood pressure monitor worn on the arm or leg of an infant to wirelessly stream data to a bedside device which continuously displays mean arterial pressure, systolic blood pressure, diastolic blood pressure and heart rate.

Noninvasive transcutaneous monitoring allows physicians in the NICU to monitor carbon dioxide levels continuously and painlessly through patients' skin. Continuously monitoring CO2 levels in real time provides an indication of safe levels of cerebral blood flow as well as the efficacy of ventilatory support for patients' immature or compromised lungs.

Blood draws are the gold standard for accurate CO2 information, but they present issues in the NICU such as blood loss, infection, and pain, with one study revealing NICU patients experiencing up to 17 painful procedures per day, largely due to blood draws driven by the desire for visibility to CO2 levels. Transcutaneous monitoring provides accurate CO2 information without drawing blood and has been shown to result in a decrease in blood draws on ventilated patients in the NICU.

About Sentec

Sentec is a market leader of noninvasive monitoring solutions who develops, manufactures, and markets patient-centric, cost-effective technologies and products that provide clinicians with greater insight to quickly to identify trends, rapidly and more accurately assess patient status, and make well-informed, timely care decisions that can improve patient care. Sentec is driven by the belief that noninvasive monitoring should enable the delivery of less invasive care.

About PyrAmes

PyrAmes is a digital health company focused on fundamentally transforming the delivery of health care through continuous blood pressure monitoring that is accurate, wireless, and noninvasive. The comfort and ease of use of its platform has the potential to provide better blood pressure management for patients ranging from newborns to seniors. The FDA has recognized the company's lead product Boppli™ with Breakthrough Device Designation. Products based on PyrAmes technology are under development and have not yet been cleared by the FDA for distribution.

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