

## Monivent has signed an agreement with Stanford for usability study in the US

**Monivent AB announces that the company has signed an agreement with Stanford on behalf of the simulation center CAPE, Center for Advanced Pediatric and Perinatal Education, for the implementation of the planned usability study in the US. The usability study, which is a necessary part of the application for market approval in the US, will be conducted in October to enable finalizing the 510(k) submission to the FDA shortly after that.**

Conducting a usability study, analyzing how US healthcare professionals interact with the Neo100 system during use in a simulated setting, is what remains before Monivent can complete and submit its application to the FDA regarding market approval for Neo100 in the US. Monivent can now announce that an agreement has been signed for the implementation of this usability study together with CAPE. CAPE is a unique simulation center for training and research in neonatology and pediatrics with the aim of leading innovation and dissemination of new methods to improve human machine interaction and performance in the delivery of healthcare. CAPE is located at Packard Children's Hospital Stanford, which provides access to several clinical disciplines for participation in usability studies.

CAPE was founded and is led by Dr. Louis P. Halamek, who is a professor in the Division of Neonatal and Developmental Medicine at Stanford University and holds a clinical position at Lucile Packard Children's Hospital at Stanford. Dr. Halamek is also Associate Director of Education and Training in Neonatal-Perinatal Medicine at Stanford University School of Medicine. Through collaboration with NASA, Dr. Halamek has recognized the benefits of a cross-industry approach to risk assessment, safety, and effectiveness, which is applied to the work at CAPE to optimize performance in high-risk activities such as neonatal resuscitation.

With this background, the team at CAPE has great knowledge and experience in the care process itself and the unique environment that Neo100 will be used in. They also have the best opportunity to simulate the clinical environment to create a user scenario that is as realistic as possible, which is important for the quality of the study and its results.

"The US is a very important market for us, and we see great interest in the product from American doctors. Continuing the work to obtain market approval and be able to initiate sales in the USA as soon as possible is also important for the ongoing dialogue with an industry leading player regarding a global distribution agreement for the Neo100," says Maria Lindqvist, CEO of Monivent.

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*Monivent AB ("Monivent") develops, manufactures and sells medical devices in order to improve the emergency care provided to newborns in need of respiratory support at birth. About three to six percent of all newborns end up in this critical situation and healthcare professionals today lack good tools to determine how effective this manual ventilation is. Monivent has developed equipment that measure the airflow to the child directly in the face mask via a sensor module that sends data wirelessly to an external monitor. The caregiver thereby receives immediate feedback, which enables necessary adjustments to support an effective but at the same time gentle treatment. The company is also marketing a product for simulation-based training on manikins, building on the same technology as the clinical product. The clinical product, Monivent Neo100, is not available for sale in the United States.*