Scientific Reports publishes a paper covering an early version of Calmark's technology

Findings from Calmark's clinical study from 2015/2016, conducted in collaboration with Södersjukhuset in Stockholm, Sweden, and Vietnam National Children's Hospital (VNCH) in Hanoi, Vietnam, will be published in the scientific journal Scientific Reports, part of the Nature Research family. The paper is titled "A rapid smartphone-based lactate dehydrogenase test for neonatal diagnostics at the point of care" and concludes that the point-of-care (POC) method for analysis provided reliable results within four minutes. The paper is published online on June 26.

"This research study was conducted 4 years ago, on an early prototype of Calmark's technology. Although the product doesn't look the same today, the underlying principle remains the same and the results are highly important", says Mathias Karlsson, Chairman of the Board and co-founder of Calmark. "We wanted to test our patent, which is based on camera technology, in an early stage, and obtain input from clinical ward settings. We set out to demonstrate proof of concept for our idea."

The risk of erroneous decisions can be drastically reduced by identifying the smallest possible testable product, and quickly build and test it. This approach to very early-stage testing is referred to as "minimum viable product", MVP, and means that everything but the essential features is left out. The feedback, comments and reactions provided by the test users then form the basis for the choice of direction from there on. The focus and design is determined by actual needs.

"During the study, both clinics and distributors remarked that a smartphone would not work in a clinical setting, it would never be as good as a fixed instrument", says Mathias Karlsson. "I am proud that we conducted this study both abroad and in Sweden at the very early prototype stage, and we learnt a lot for the future production."

The study was conducted on an early, manually manufactured prototype of a filter-based POC assay that requires minute amounts of blood and delivers colorimetric-based measurement of the LDH concentration in less than four minutes using a smartphone camera. LDH is a well-known marker of cellular damage in research settings, but still remains under-utilized as a marker for severe disease in newborns. LDH concentrations measured with the POC test, as well as the reference method, were obtained from 88 infants (62 from Stockholm and 26 from Hanoi).

The conditions of the study differed greatly between Sweden and Vietnam, regarding climate conditions and patient base. Most importantly, the Vietnamese infants had generally been ill longer than the Swedish. The reason for this is that VNCH is a university hospital, without a local maternity ward but with regional responsibility for neonatal intensive care in Northern Vietnam. The infants had been transported to the hospital following the suspicion of disease. In spite of these substantial differences, the sensitivity of the study was 75 percent.

"In retrospect, the results we achieved were amazing even in a clinical sense, even though the goal rather was to describe a possible method for a future diagnostic tool that could meet all the clinical criteria. The fact that Scientific Reports now acknowledges our work and our findings proves that we are on the right track", Mathias Karlsson says.

The full article "***A rapid smartphone-based lactate dehydrogenase test for neonatal diagnostics at the point of care***" is freely available online at www.nature.com/articles/s41598-019-45606-0

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This information is information that Calmark Sweden AB is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact person set out above, on 26 June 2019.

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Calmark Sweden AB is a medical technology company developing a point-of-care (POC) analyzis method with easier and faster sampling of medical conditions in newborns. The unique test platform, which consists of a reader and single-use products, is expected to be ready for launch in 2020 when three important POC tests are introduced. The WHO estimates that 1.5 billion children will be born worldwide by 2030. In the Western world, the introduction of POC diagnostics is resulting in huge savings and shorter healthcare chains. In less developed healthcare systems, the product helps save lives. Calmark aims to become the global leader and ultimately to offer all relevant POC tests for the first period of life, regardless of where in the world a baby is born. Read more about Calmark www.calmark.se/eng/home.