Optical screeing jaundice device, neonatal

Country of origin Primary function Category

Norway Monitoring eHealth/mHealth solution

Commercial information _

List price (USD): \$1001

Development Stage: Prototype is tested and waiting

regulatory approval.2 Brand: Picterus¹ **Model:** 1.03

Health problem addressed.

A global estimation reported that extreme neonatal jaundice (NNJ) affected 481,000 late-preterm and term newborns during 2010. Failure to detect and manage it resulted in 114,100 avoidable neonatal deaths and 63,000 infants with severe disabilities. The global burden was extremely higher for the poorest countries and 75% of mortality occurred in Sub-Saharan Africa and South Asia, attributing this outcome to lack of preventive services and effective treatment.1

Product description.

The technology is based on biomedical optics and photonics further complemented with machine learning algorithms that facilitates accurate remote diagnostics by taking a simple picture with a Smartphone. A medical worker or parents puts the color calibration card on the newborn's chest, the Smartphone recognizes the card, and the App automatically takes a few pictures. The pictures are analyzed through algorithms and provide a bilirubin estimate.¹

Product details

Consumables: Color calibration card¹ Other Required Products: Smart phone¹

Lifetime: 0-2 years¹

Energy Requirements: Energy to charge the smart phone¹

Facility Requirements: Access to internet (offline version will be available at a later stage)¹

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- Reported by manufacturer on 26 November 2020
- Reported by manufacturer on 5 February 2021
- Reported by manufacturer on 9 February 2021

WHO ASSESSMENT

WHO specification comparison

At the time of report creation, WHO technical specifications are not available to compare against for this type of technology.

Regulatory assessment



Pre-market assessment



Proceed with caution



Post-market assessment



Proceed with caution



Quality system assessment



Proceed with caution

Significant work is needed on developing robust pre-market regulatory, post-market regulatory, and quality system plans to ensure this prototype will be able to be successfully brought to market. Picterus should develop their medical device support documentation and data.

Technology evidence assessment

Domains

Evidence assessment Risk/benefit Impact Innovation



Medical









Safety























Legal







Social











Green environ-

Ethical







This technology is not connected to COVID-19 requirements. As a prototype, there might be some impact on diagnostic tools for the future, but there are many open issues such as different skin colors, potential outcome related evidence. There are also some discrepancies between printed and presented description (based on the actual development phases). Also the diagnostic cards are quite expensive and not feasible for areas with higher humidity. The clinical effect is to be proven by relevant evidence.

Summary

Transferability



Technology readiness level



Evidence (according to **GRADE)**



Technology evidence assessment

Recommended with caution

Health technology and engineering management

Domains

Appropri-

Domains

Appropriateness

Target setting: Neonatal care



Durability







Infrastructure





Ease of Use

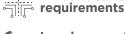
Affordability

Engineering

resources minimization

acceptability























Local access to spare parts





Cultural

and social









Locations of use within target setting



This product is based on software App that uses SmartPhone to measure the yellowness of subcutaneous tissue in neonates by pointing the camera at the neonate chest and contrasting it with a color-coded calibration card. The software according to the submitter can estimate bilirubin concentrations in newborns in a few minutes. The submitter stated the equipment is intended to support a healthcare provider assessment of neonatal bilirubin but not as a stand-alone diagnostic device. The measurement is dependent upon the quality of the SmartPhone camera, the retention of the colors on the card, and the accuracy of the software application. An important comment is made that this App can be used only with the Samsung Galaxy S7 SmartPhone. Overall, this product is highly mobile and easy to use, but lacks evidence for availability of technical support, training, spare parts, and appropriate operation under various environmental conditions.



Ease of cleaning

Aesthetics

