

Optical screening jaundice device, neonatal

Country of origin	Norway
Primary function	Monitoring
Category	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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¹ Reported by manufacturer on 26 November 2020

² Reported by manufacturer on 5 February 2021

³ 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		Innovation
	Risk/benefit ratio	Impact	
Medical			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.
Safety			
Economy			
Organizational			
Legal			
Social			
Ethical			
Green environment			

Summary			
Transferability		Technology readiness level	5
Evidence (according to GRADE)		Technology evidence assessment	Recommended with caution

Health technology and engineering management

Domains	Appropriateness	Domains	Appropriateness	Target setting: Neonatal care
Durability		Ease of maintenance		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 Use		Infrastructure requirements		
Positive impact on clinical outcomes		Local access to sales support		
Affordability		Local access to technical support		
Engineering resources minimization		Local access to training		
Cultural and social acceptability		Local access to spare parts		
Environmental conditions		Local production		
Aesthetics		Locations of use within target setting		
Ease of cleaning				