Pediatric automated ultrasound

Origin | China, Hong Kong SAR
Primary function | Diagnosis
Category | Medical device

Commercial information

List Price (USD): $600[1]

Price of Consumables Per Use (USD): Less than $0.02 USD for ultrasonic gel or $0.08 USD for ultrasound gel patches.[1]

Development Stage: The automated ultrasound technology is in the rapid prototyping phase of design and development. Imaging trials commenced in Q2 of 2020 and are ongoing during 2021, with bench top lab testing and field MVP testing slated for Q2 2021.[2]

Brand: Bloom Standard limited Kaaria[1]

Model: 1111[1]

Health problem addressed

Despite progress in reducing the size and cost of pediatric ultrasound and echocardiography, the lack of trained sonographers contributes to poor access – often resulting in delayed diagnosis and referral of children with serious medical conditions. The technology being developed automates ultrasound image acquisition and interpretation, eliminating the need for medically-trained sonographers to screen + diagnose infants/children at the point of care to support: (i) early diagnosis of heart and lung conditions, (ii) appropriate, timely referrals and treatment pathways, (iii) lower device and associated skill costs, expanded access to essential non-radiating imaging for young patients with pneumonia/lung conditions (including COVID-19) and cardiac conditions.[2]

Product description

The Automated Ultrasound device is composed of a constellation of CMUT (chip-based) sensors embedded onto a wearable, reusable device and positioned over preset ultrasonic windows on the body to provide relevant images within the thoracic cavity. With an onboard SDK-connected processor the device leverages machine-learning algorithms to map, rank and compare images, sifting through image artifact to interpret physical markers associated with cardiac conditions and lung A/B and pleural lines. Operators are provided simple decision/referral support based on normal vs abnormal findings, requiring no additional knowledge or skill in guided acquisition or interpretation.[2]

Product details

Accessories: Charging port, charging appliance, ultrasonic gel or gel patch, cleaning spirits/supplies.[1]

Consumables: Ultrasound gel or gel patches (working on a design solution that might eliminate this).[1]

Other Required Products: None[1]

Lifetime: 2-5 years[1]

Energy Requirements: Rechargeable battery (DC powered, USB 5V, 4W, 24-hour battery life, 3-hour battery recharge cycle)[1]

Facility requirements: Mobile phone/tablet for running accompanying app. Access to internet only required for firmware updates and special operations such as saving data to the cloud.[1]

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1 Reported by manufacturer on 4 December 2020
2 Reported by manufacturer on 28 January 2021

WHO ASSESSMENT

WHO specification comparison

At the time of report creation, WHO technical specifications are not available to compare 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. Bloom Standard should develop their medical device support documentation and data.

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Technology evidence assessment

Domains	Evidence assessment: Risk/benefit ratio	Evidence assessment: Impact	Innovation
Medical	⚠	⚠	
Safety	✗	⚠	
Economy	⚠	✗	
Organizational	✗	✗	
Legal	⚠	✗	
Social	⚠	✗	✓
Ethical	✗	✗	
Green environment	⚠	⚠	

The device is in need of internet access to cloud solution for artificial intelligence (AI) based advice. The general development is still a prototype. The technology is not COVID specific. There is missing evidence regarding safety (diagnostic support), data protection and any kind of evidence regarding patient related outcome.

Summary

Transferability	✗	Technology readiness level	6
Evidence (according to GRADE)	⚠	Technology evidence assessment	Recommended with caution

Health technology and engineering management

Domains	Appropriateness	Domains	Appropriateness
Durability	⚠	Ease of maintenance	→
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	→		

Target setting: Healthcare facilities

This product provides an innovative approach to accommodate cardiac screening for low resource countries. While evidence from clinical studies is limited, the incorporation of AI-driven application allows this screening to be conducted by locally trained clinical personnel. The images can be transmitted remotely through the internet for specialist confirmation of findings. We could not find evidence for support of both probe replacement as well as technical issues in the intended locations of use.