Newly commercialized

Passive, contact-free, continuous vital sign monitoring*

Country of origin | Republic of Korea

Primary use | Diagnosis/measurement/monitoring

Category | Medical device (including in vitro diagnostics)

Commercial information

List price (USD): 285

Year of commercialization: 2021

Number of units distributed: 7800

Currently marketed in: Australia, Republic of Korea, Singapore, USA

Model: XK300

Product description

Xandar Kardian's XK300 utilizes UWB radars to automatically obtain resting heart rate, resting respiratory rate, body motion index and presence (in bed/room) detection. Since it uses radar, it is 100% contact-free and collects vital signs continuously. On average, the sensors pick up 6000 or more data per patient, every 24 h. It is being deployed in the USA at various skilled nursing facilities, which has resulted in an average of 2 days early detection of health deterioration - before the onset of symptoms of COVID-19, heart attacks, sepsis, and even urinary tract infection without the need for any staff to monitor or relying on patient compliance.

Product details

Accessories: Gateway is required if the health data are to be sent to a cloud based dashboard connected to an EMR system. The system is designed to run on-premise so that no Internet connection is necessary to use the device. Data transmission is optimized, so multiple devices can use a single LTE gateway to stream data continuously to remote clinicians.

Consumables: This is a non-contact, ambient, passive monitoring device. Therefore, it does not have any consumables and is designed to run for more than 10 years in the field.

Warranty duration: 2 years full warranty + 3 years conditional (based on application and field environment).

Lifetime: 10 years

Energy requirements: 700 mW power ~ less than 1W. It is not designed for battery power, but can run 10 days with a 20 000 mAh battery pack.

Facility requirements: AC/DC power source. It can work on power over ethernet or even solar power that charges the battery which can sustain continuous 700 mW of power usage when turned on. Wi-Fi is preferred, but it can run on Lorawan, narrow band Internet of Things, Long-term Evolution or even on-premise (no connection). XK300 has been field tested in various countries and facility environments.

Contact: Sam Yang | Phone: + 41 633 38170 | Web: https://bit.ly/4cNF4Fd

*** Information reported by manufacturer, October 2023**

WHO assessment**

Clinical

Clinical — Recommended with caution

Vital signs remain at the centre of the monitoring of any patient, in health or disease states, in all settings. Equally, detection of early deterioration is essential during patient monitoring, to ensure timely reassessment and transfer. Traditional vital sign monitoring can involve multiple contacts between a patient and health-care providers, which can be problematic during an infectious disease outbreak. Likewise, adequate cleaning and disinfection of equipment between two patients can sometimes be problematic, so contactless remote monitoring systems can be advantageous in this context.

This solution provides a contactless remote monitoring system for heart and respiratory rate, with preclinical and clinical use in neonates and adults, with promising results. Blood pressure and body temperature would require separate assessment. As the device is designed to monitor only one patient, its use may be limited in settings when adequate patient distancing cannot be assured.

**** This assessment was initiated November 2023**

Comparison with WHO technical specifications

Cannot be verified.

The manufacturer does not provide the user manual (just an installation manual). Moreover, the specifications described in the submission form are missing many important details such as the respiratory rate and the resting heart rate measurement ranges and their related accuracies. At the time of this report creation, WHO/UNICEF technical specifications were not available to compare this type of technology with a radar-based technology that measures only "resting" vital signs (respiratory rate and resting heart rate) and body motion/detection, as no vital signs monitoring system/unit technical specification documentations were available at WHO/UNICEF.

Regulatory

Pre-market assessment	Proceed
Post-market assessment	Proceed with caution
Quality system assessment	Proceed with caution
Security	Not acceptable

Pre-market: This product is a class II medical device in the USA and class IIa in the EU and Australia and has obtained market approval in Australia, the Republic of Korea, Singapore, and the USA.

Reports were not submitted to demonstrate compliance with the relevant standards.

Post-market: The manufacturer did not submit the post-market surveillance and vigilance documentation. The complaint handling, recall, and adverse event reporting documents were not declared.

Quality management system (QMS): The manufacturer did not submit documents on ISO13485:2016 or e-QMS USFDA standard to demonstrate that manufacture of the product conforms to these standards and hence it is not possible to verify.

Security: Security assessment was not declared and therefore could not be verified.

Health technology assessment

Indicators	Evidence assessment	Innovation
Medical	Proceed	
Safety	Proceed	
Economy	Proceed with caution	
Organizational	Proceed with caution	
Legal	Proceed	
Social	Proceed	
Ethical	Proceed	
Green environment	Proceed	

Adoption of this radar sensor technology in low-resource settings (LRS) could represent a step forward in health-care services, tailored to the unique challenges of those regions. With its cost-effective pricing model, particularly the one-time cost option in LRS, this technology is an accessible solution for advanced patient monitoring. Its effectiveness in non-invasively tracking of multiple patients' vital signs simultaneously while reducing the burden of continuously checking all patients could facilitate health-care delivery, potentially leading to improved health outcomes through early detection and intervention. The installation procedure should be considered prior to adoption. The ease of use by end users further enhances its appeal, ensuring that health-care facilities with limited technical resources can adopt it without substantial infrastructural or personnel changes. Moreover, the technology's environmental benefits, such as reduced energy consumption and waste, align with the growing need for sustainable health-care solutions. Ethically, it upholds patient dignity and privacy while offering equitable access to state-of-the-art health-care monitoring.

Technology readiness level 9

Technology evidence assessment Recommended

Health technology management

- Durability: N/A
- Ease of Use
- Ease of maintenance
- Environmental conditions
- Affordability
- Local access to technical support
- Ease of cleaning
- Infrastructure requirements

Health-care delivery platform

The product provides distant monitoring of vital signs through radars in rooms. Patients who are not restricted to a bed can move around while being monitored. The durability will need testing in harsh conditions. No testing has been done so far and no data have been collected in hot, humid, dusty, and above all non-climatized environments. The technology does not require preventive maintenance, resists high and low temperatures, and can technically function with solar-powered battery packs. The affordability depends on the number of spaces and people the system is monitoring. It is not clear whether one system can identify and simultaneously monitor several patients. It is therefore less affordable than centralized care but offers a different, more preventive service. Recurrent subscription is a risk in public health settings in low-resource settings. The usability is not clear (platform or app to read data, who is in charge, how are alarms sent to health workers, will they move to see the patient, will the patient go to the health facility), nor is it maintenance. The product is not primarily developed for low-resource settings, and adapted information and evidence will be necessary to assess it use in such settings.

Intellectual property and local production

- Technology transferability
- Open source/ access
- Local production

Intellectual property: The software is proprietary. Some of the critical technologies in the device are third-party dependent. The software is under trade secret and copyright protection. Evidence of a registered trademark is not available for the product. This technology is copyright and patent-protected, the use of all intellectual property will require clearance. Some of the patents are pending.

Local production: There is a weak business case for local production. Manufacturing know-how is with contract manufacturers. Highly import dependent, and requires high-level technical expertise and technology infrastructure.