Commercially available

Patient monitoring system*

Country of origin | United States of America
Primary use | Diagnosis/measurement/monitoring
Category | Medical device (including in vitro diagnostics)

Commercial information

List price (USD): 275
Year of commercialization: 2021
Number of units distributed: 214
Currently marketed in: Ghana, Kenya and Uganda
Model: 1

Product description

The Neopenda neoGuardTM is a patient monitoring system consisting of the following components: wireless sensor devices, reusable wearable bands, and a software application that receives, displays, and stores data from the sensor devices. The sensor devices use a reflectance pulse oximeter and temperature sensors to measure the pulse rate, blood oxygen saturation (SpO2), respiration rate, and temperature of the patient. The neoGuard devices are attached to the patient's body by reusable wearable bands and are battery-powered. The devices transmit data using low-energy Bluetooth® in a localized communication architecture. Data is received by a software application installed on a tablet.

Product details

Accessories: Sensor device charging cable: GlobTek microUSB GTM96060-0606-1.0, or equivalent, Tablet charging cable: Samsung Galaxy Tab A 10.1" 32GB SM-T510NZKAXAR, or equivalent, Wall plug adapter for tablet charging cable: Ceptics IG-7, or equivalent, Tablet case: Poetic Samsung Galaxy Tab A 10.1 case, or equivalent, Security cable: Ruiwor RW0202 locking cable, or equivalent, Instructions for use, Quick guide

Consumables: 70-90% isopropyl alcohol cotton

Warranty duration: 2 years

Lifetime: 2 years - equivalent to maximum 17 110 hours of monitoring, approximately 292 cycles of battery recharging, and approximately 1460 cycles of stretching the band (twice per day)

Energy requirements: Medical grade (2 x MOPP from input to output according to EN 60601-1:2006), Input (AC): 100–240 V, 50–60 Hz, Output (DC): 5 V, 1.5 A

Facility requirements: Electricity supply for charging and recharging the neoGuard device

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

WHO assessment**

Clinical

Clinical → Recommended

This product is for non-invasive continuous monitoring of blood oxygen saturation (SpO2), pulse rate (PR), respiration rate (RR), and temperature. It is composed of a wearable band to put around the head where the sensor device is connected, and measurements are taken on the forehead. It is designed for low-resource settings, and it works without the internet as the devices transmit the information to the central interface via Bluetooth.

This technology improves patient monitoring, especially in low-resource settings. It is easy to operate and allows centralized monitoring of many patients at the same time.

** This assessment was initiated November 2023

Comparison with WHO technical specifications

Cannot be verified.

The manufacturer provides the necessary detailed technical specifications, along with technical documentation (that is instructions and user manual) supporting their declarations. Since even the most basic WHO available technical specifications document related to patient vital signs monitors will include the NIBP (Non-Invasive Blood Pressure) measurement and this parameter is not monitored by the proposed technology, at the time of this report creation, WHO similar device technical specifications are not available to compare this type of technology which is an equipment specifically dedicated to monitoring just only the patient SPO2, temperature, respiratory and pulse rates.

Regulatory

Pre-market assessment	Proceed
Post-market assessment	Proceed with caution
Quality system assessment	Proceed
Security	Proceed

Pre-market: The product has obtained market approval in Kenya. The manufacturer has shared the design verification and validation test report list and the reports. Based on the certification and standards for the performance of this device, the documentation submitted is adequate to demonstrate that the product is safe and effective.

Post-market: The manufacturer declared that they have some of the post-market documentation but did not submit the post-market surveillance and vigilance documentation. According to the submission, there have been no recalls or adverse events reported. Nevertheless, it is considered good regulatory practice to establish the complete PM system before introducing the product to the market.

Quality management system (QMS): The manufacturer site has valid ISO13485:2016 certification for the manufacturing of the product. Based on the certification and standards, the manufacturing of the product conforms to ISO13485:2016 and the performance of the product is safe and effective.

Security: The manufacturer has declared conformance to IEC62304 software validation for the lifecycle of the device and hence addressed the cybersecurity risk. The manufacturer has submitted risk management documentation, including the risk analysis, risk management plan, risk control, post-production information, and other hazard reports.

Health technology assessment

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

This wearable monitoring device, utilizing two non-invasive sensors, offers advantages for both patients, especially newborns, and healthcare providers in resource-limited settings. It allows real-time monitoring and visualization of four vital signs for up to 15 patients, potentially reducing the detection time for deteriorating patients, enabling faster treatment initiation, and decreasing mortality rates, particularly in neonatal care. The device has undergone rigorous validation in phases 1, 2, and 3 clinical trials, demonstrating safety, feasibility, and effectiveness without reported adverse events. Developed with robust risk management protocols, it conforms to EN ISO 14971:2019 standards.

While compact and cost-effective, further research is ongoing to optimize its performance and assess its cost-effectiveness in comparison to standard care equipment. Feasibility studies indicate general patient acceptance, with minimal withdrawal of consent by parents of monitored newborns. Its reduced size and efficiency in monitoring multiple vital signs suggest increased sustainability by minimizing equipment idle time.

Technology readiness level 9

Technology evidence assessment Recommended

Health technology management

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

Health-care delivery platform

The neoGuard system is a multiparameter neonatal monitoring device with a patient-specific sensor and a tablet-based central monitoring server. 15 NeoGuard sensors can be used with a single monitoring server. Operationally, the sensor is placed on the forehead of each newborn patient requiring monitoring. While this non-traditional placement might offer certain technical advantages, practical challenges related to skin sensitivity, movement, access, interference with other equipment, and infant comfort make it a less favorable option in neonatal care. The tablet-based user interface is underdeveloped and would benefit from further UX improvement.

The manufacturer also advises against opening or repairing the device, emphasizing the need for manufacturer-only maintenance and software updates; as a tablet-based system, the maintenance and durability elements of any tablet will also contribute to the longevity of the product. Cleaning the device is straightforward; the manufacturer has provided clear guidelines for cleaning using isopropyl alcohol. Although the initial unit cost for the sensors is reasonable for a multiparameter device, the cost for long-term maintenance of the software, server, and tablet is not clear. NeoGuard presents a solution for a much-needed centralized neonatal monitoring system but faces challenges with usability and maintenance.

Intellectual property and local production

- Technology transferability
- Open source/ access
- Local production

Intellectual property: This technology uses proprietary software. The technology is protected by patents, trademarks and copyrights, however, there are pending patents. The use of all intellectual property will require clearance.

Local production: The product has a compliant manufacturing process. The technology has a moderate business case in end-to-end production as the technology is highly import-dependent, key manufacturing know-how is likely to be with the contract or licensed manufacturers, and a comparatively high level of technical and quality control expertise and related infrastructure is required. However, the SKD approach can be considered for local production with an anticipation of low volumes until the technology is widely accepted in the region.