

Heart rate meter, for newborn

Country of origin | Norway
 Primary function | Monitoring
 Category | Medical device

Commercial information

List price (USD): \$150¹

Year of commercialization: 2018

Number of units distributed: 101-1,000

Currently marketed in: Europe, Australia, New Zealand, and Tanzania²

Brand: Laerdal Medical AS¹

Model: NeoBeat Newborn Heart Rate Meter



Health problem addressed

An estimated 10 million newborns are born every year that are not breathing and require resuscitation. Due to insufficient oxygenation of the newborn, 0.7 million newborns died and 1.15 million newborns suffered permanent brain injury. To address this issue, there is a need for immediate provision of newborn's heart rate to support health care workers in performing effective ventilations, by application of a reusable ECG heart rate meter onto the wet newborn's chest and quick continuous display of the newborn's ECG heartrate.²

Product description

ECG signals from newborn's wet chest are picked up by dry stainless-steel electrodes that are embedded in one spring-elastic plastic buckle. A housing includes a rechargeable battery, signals processor, and a bright-LED display.¹

Product details

Accessories: USB 5V power supply (charger), AC plug kit to fit various global electrical systems³

Warranty duration: 1 year¹

Lifetime: 2-5 years¹

Energy requirements: Continuous power supply (AC powered, 110V/220V, 5W)¹

Facility requirements: Disinfection with 70% ethanols¹

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¹ Reported by manufacturer on 26 November 2020

² Reported by manufacturer on 11 January 2021

³ Reported by manufacturer on 16 December 2020

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

Some WHO requested information and documentation for all three Regulatory and Quality Assessment categories is absent. Therefore, a thorough review of this product was not possible at this time. Laerdal has obtained an EU MDD CE Mark for the AS NeoBeat Newborn Heart Rate Meter. The regulatory status for the various accessories is currently unclear. Laerdal has obtained an ISO 13485:2016 certificate. Laerdal must also ensure they comply with local country import and pre-market regulations.

Technology evidence assessment

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

This portable device is clinically useful for timely monitoring of critical newborns that require resuscitation. There is no need for extra workers other than the health care personnel resuscitating the newborn. The device is battery-powered, simple, and easy to use. Decontamination is necessary after each use. The manufacturer provides the device to low-resource settings at a subsidized cost. Spare parts can be procured through the manufacturer's website. Additional safety and regulation documentation is needed and further clarity is required for labeling.

Summary

Transferability		Technology readiness level	8
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: Neonatal ICU

This product is a heart monitor for newborns. It is applied to the newborn's chest with an elastic spring and buckle and dry stainless-steel electrodes make contact with the skin. A housing with a rechargeable battery, signal processor, and LED display is on the center of the buckle. The device includes a charging stand. The device must be attached to the newborn skin up to two minutes in order for the heart rate readings to appear. Although the product is easy to apply, there are concerns about pressure and skin irritation on the fragile newborn chest due to the long duration of use. The manufacturer suggests that the product can assist during emergencies, however, it would obstruct a chest x-ray or cardiac resuscitation if urgently needed. The product requires minimal maintenance, is easy to clean, and seems to be well supported by sales and technical staff.