Newborn ventilation trainer*

Country of origin China

Primary use Healthcare provider

education and training

Category Training manikin

Commercial information _

List price (USD): 285*

Year of commercialization: 2023 Number of units distributed: 400 Currently marketed in: Globally

Model: NeoNatalie Live - Newborn Ventilation

Trainer

* Not-for-profit price for SDG3 qualifying countries

https://tinyurl.com/ycx62jp5



Product description _

NeoNatalie Live is a smart manikin that enables short and flexible training in newborn ventilation.

Together with a complementary app, NeoNatalie Live allows health workers to practice ventilation skills on their own. The manikin and app also enable newborn resuscitation team training and scenarios aligned with WHO's Essential Newborn Care Course and the Helping Babies Breathe program.

Product details.

Accessories: NeoNatalie Live includes the manikin itself (with user guide, baby cap, blanket, USB charger and cable), and the accompanying app to be downloaded from AppStore/GooglePlay. Products like Upright (with/without PEEP - 25 USD/30 USD), NeoBeat (190 USD) and mobile devices may be purchased separately to be used together with NeoNatalie Live.

Consumables: None Warranty duration: 1 year

Lifetime: Shelf life is 3 years (if properly stored and maintained). It is advised to charge the device

occasionally during long time storage.

Energy requirements: 110-240 VAC, 50/60Hz input power wall socket.

Facility requirements: Wifi is required when downloading the NeoNatalie Live app for first use.

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* Information reported by manufacturer, October 2023

WHO assessment**

Clinical



Clinical



This technology is intended to train healthcare professionals on newborn ventilation. The manikin simulates four different patient cases and provides real-time training performance feedback through a complementary app that debriefs on each training

session. The app also enables newborn resuscitation team training.

Overall, this technology is very useful in effectively training healthcare professionals, particularly in LMICs, where simulation-based education can be limited or absent.

Comparison with WHO technical specifications

Compliant.

The manufacturer provided the necessary detailed technical specifications, also supporting their declarations with the requested technical documentation (user guide or manual). In particular, WHO has a recent publication ("WHO neonatal resuscitation manikin: technical specifications. Geneva: World Health Organization; 2021 (WHO medical device technical series")) that can be used to compare the technical requirements provided. Following the release of the WHO technical specifications, WHO has issued additional guidelines regarding new born resuscitation, which eliminate the necessity for chest compressions in neonates. Consequently, the technology can be considered "compliant" with the existing WHO technical criteria and practical guidelines based solely on the stimulation and positive-pressure ventilation actions.

Regulatory



Pre-market assessment

Post-market

assessment



Not applicable



Not applicable



Quality system assessment



Not applicable



Security



Not applicable

This product is not a medical device, and hence it is not applicable to assess it based on medical devices regulatoy requirements. .

Health technology assessment

Indicators

Evidence assessment

Innovation

































NeoNatalie Live is a smart manikin that enables short and flexible training on newborn ventilation. Some early results of the provided evidence show promising outcomes from the implementation of the technology. It simulates various patient cases and provides objective performance feedback to help build competence and confidence in health workers. NeoNatalie Live system increased training frequency, staff participation, and ventilation quality. This device serves as a critical learning experience and opportunity to practice clinical assessment, decision-making and the execution of interventions.

Repeated practice may also improve provider comfort in managing such high-pressure scenarios independently. However, advantages compared to other solutions that could be employed in the same task should be discussed in detail. Although it is sold for a not-for-profit price for eligible LMICs, only preliminary cost-effectiveness studies exist, showing its cost effectiveness is largely dependent on the scaling and region of its implementation.

Technology 9 readiness level

Technology evidence Recommended assessment with caution

Health technology management



Durability



Health-care delivery platform









maintenance





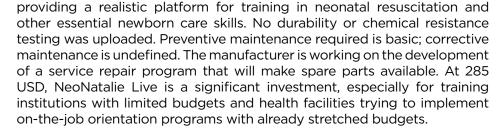






Affordability



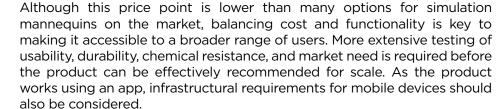


The NeoNatalie Live is designed to mimic the real-life responses of a newborn, such as variable heart rates, respiratory rates, and crying,



Local access to technical support







Ease of cleaning





Intellectual property and local production



Technology transferability



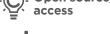
Intellectual property: The product is protected by copyright, trade secrets, and trademarks. A clearance is required to use this technology.



Open source/



Local production: The business case is weak if this product alone is considered for local manufacturing: volumes are low, required materials are import-dependent, the skill required is high, added manufacturing and technology are already in an optimal cost environment, and the final





Local production



WHO guidance

WHO Essential Newborn Care Modular Course. (2022). https://cdn.who.int/media/docs/defaultsource/mca-documents/nbh/enc-course/modules/11-facilitator-notes-kangaroo-mother-care-16.03.22. pdf?sfvrsn=ab181d02 5

product is in the form of a semi-knocked-down kit.

- Managing Complications in Pregnancy and Childbirth: A guide for midwives and doctors. (2017). https://iris.who.int/bitstream/handle/10665/255760/9789241565493-eng.pdf?sequence=1
- WHO neonatal resuscitation manikin technical specifications (2021). https://www.who.int/publications/i/item/9789240031333
- WHO Technical specifications of Neonatal Resuscitation Devices (2016). https://www.who.int/publications/i/item/9789241510264