Neonatal bag-mask

Country of origin | Norway

Health problem addressed

Around 10 million babies born annually need assistance to breathe, and for approximately 6 million of these babies basic resuscitation such as bag-mask ventilation is sufficient, without need for more advanced measures. Low-income countries account for over two-thirds of the world's neonatal deaths, and a large number of birth attendants need to be trained and have access to effective, affordable and therapeutic tools.

Product description

The proposed solution is a reusable bag-mask for use in developing countries. It can ventilate newborns and babies up to 10 kg who need help breathing. It makes it easier to obtain mask seal and provide effective ventilations, with a new mask design and an upright stance of the bag. The bag volume is 330 ml and includes a pop-off valve, which limits the applied airway pressure to 30 to 45 cmH2O.

Developer's claims of products benefits

The product has 7 parts including the mask (compared to 9 to 12 parts for current manual reusable bag-masks), which makes reprocessing faster, easier, and less prone to errors. The loop tab on the bag makes it easier to remove from the valve during disassembly compared to current bag-masks. Other technological improvements include improved mask sealing, larger bag volume, added convenience to storage and transport, and high-level disinfection in low-resource setting

Suitability for low-resource settings

The product can be used in any setting, and does not require any electricity or automated equipment. The product can be high-level disinfected by boiling with clean water, chemical disinfection, or steam autoclaving. The product was designed with 7 parts including the mask to improve speed and ease of reprocessing between uses.

Operating steps

The Directions for Use (DFU) explains disassembly and reassembly, cleaning and disinfection, and testing before use. The bag-mask disassembles into 7 parts, reducing room for error with reassembly compared to other available products with more parts. After disassembly and cleaning, boiling, chemical solution, or autoclaving can disinfect the bag-mask. Before the bag-mask is ready for use, 4 steps must be performed to ensure that components are functioning correctly.

Regulatory status

Meets ISO 10651-4:2002/EN ISO 10651-4:2009, Lung ventilators – Particular requirements for operator–powered resuscitators, for babies up to 10 kg. Newborn Mask - Snap design, fits connectors in accordance with ISO 5356-1:2004 - Anesthetic and respiratory equipment.

Future work and challenges

This year, the CE marked product will be field tested in India by PATH (www.path.org) as well as in Tanzania at Haydom Lutheran Hospital. The product will be offered on a not-for-profit basis for use in 75 focus countries relative to the UN Millennium Development goals. In order to achieve sufficient implementation every user should be trained or re-trained and receive follow-up support in newborn resuscitation.

Use and maintenance

User: Intended for use by a physician, nurse or midwife.

Training: The product should only be used by persons who have received sufficient training in newborn resuscitation. This could be a one-day training program such as Helping Babies Breathe

Maintenance: The product must be disinfected between patients

Environment of use

Setting: Designed for use in indoor urban and rural settings at all levels of health care facilities.

Facility requirements: The technology requires a clean water supply, temperature range of between -18 to 50 °C, and availability of some sterilization method, either boiling, chemical glutaraldehyde solution or steam autoclaving can be used.

Product specifications

Weight (kg): 0.19

Dimensions: 72mm x 85mm x 217mm

Consumables: none required, reusable system

Lifetime: 5 years

Shelf life: 5 years

Retail price (USD): 20

Other features: reusable

Year of commercialization: 2014

Currently sold in: offered on not for profit basis to the 75 countries listed as focus countries relative to the UN MDGs.

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