

1.5 Reusable neonatal suction system

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BACKGROUND

Actual need

WHO estimates that nearly 1 million newborns in low and middle income countries die from birth asphyxia each year. A similar number are disabled due to inadequate breathing at birth.¹ To stimulate spontaneous breathing, or perform bag-mask ventilation effectively, an open airway is mandatory. Often this requires clearing the mouth and nose of mucous and meconium using vacuum.^{2,3}

Current situation

Whereas available neonatal suction devices available cannot be cleaned for reuse, budgets generally prevent single patient use.⁴

Meeting a challenge

UN's Millennium Development Goal No 4 (MDG 4) aims at reducing the mortality of children, including newborns, by 2/3 by 2015. To help reach the MDG 4 we have developed a new neonatal suction device which is clinically effective, easy and safe to use, available at a low price and can be reused for multiple patients over a very long period of time. This device is also suitable for large scale training of birth attendants.



PRODUCT QUALITIES



Design

- Ergonomic shape allows convenient one hand operation
- Inviting non-clinical look as represented by a friendly penguin
- Easy opening and closure in connection with emptying and cleaning
- One-part design requires no disassembly/reassembly

Material

- See-through silicone rubber permits immediate visual inspection of any suctioned matter
- Can be cleaned in high temperatures by methods including boiling and autoclaving
- Soft beak shaped nozzle will not hurt baby's mouth and nostrils
- Withstands aging and discoloring during storage over extended periods of time

Cleaning

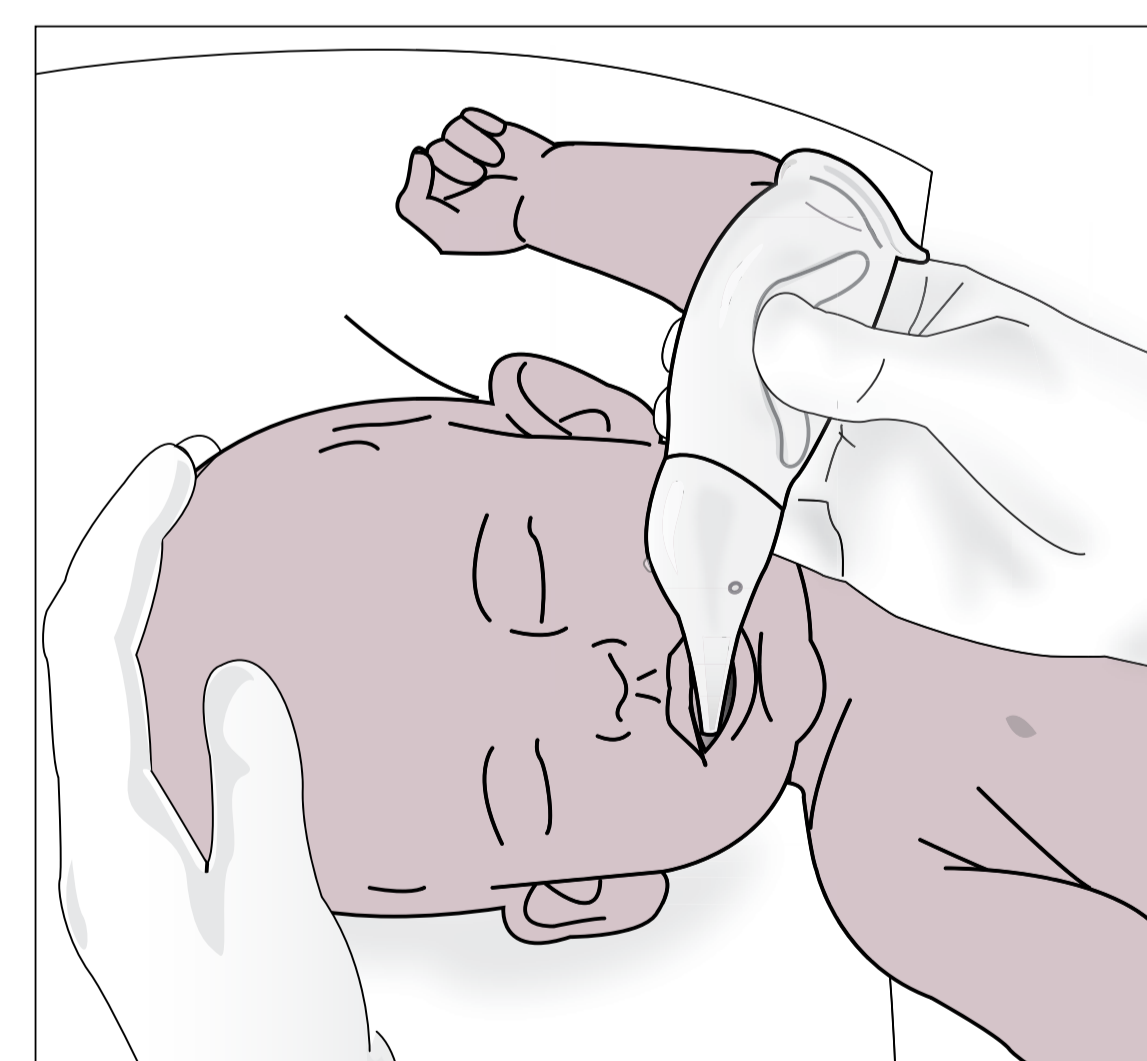
- Penguin head can easily be flipped to the side to allow easy emptying of suctioned matter during use, and can as easily and quickly be flipped back for continued suction
- After mechanical removal of debris boiling in water for 10 min. has been documented to provide effective decontamination to be safely ready for reuse⁵

Effectiveness

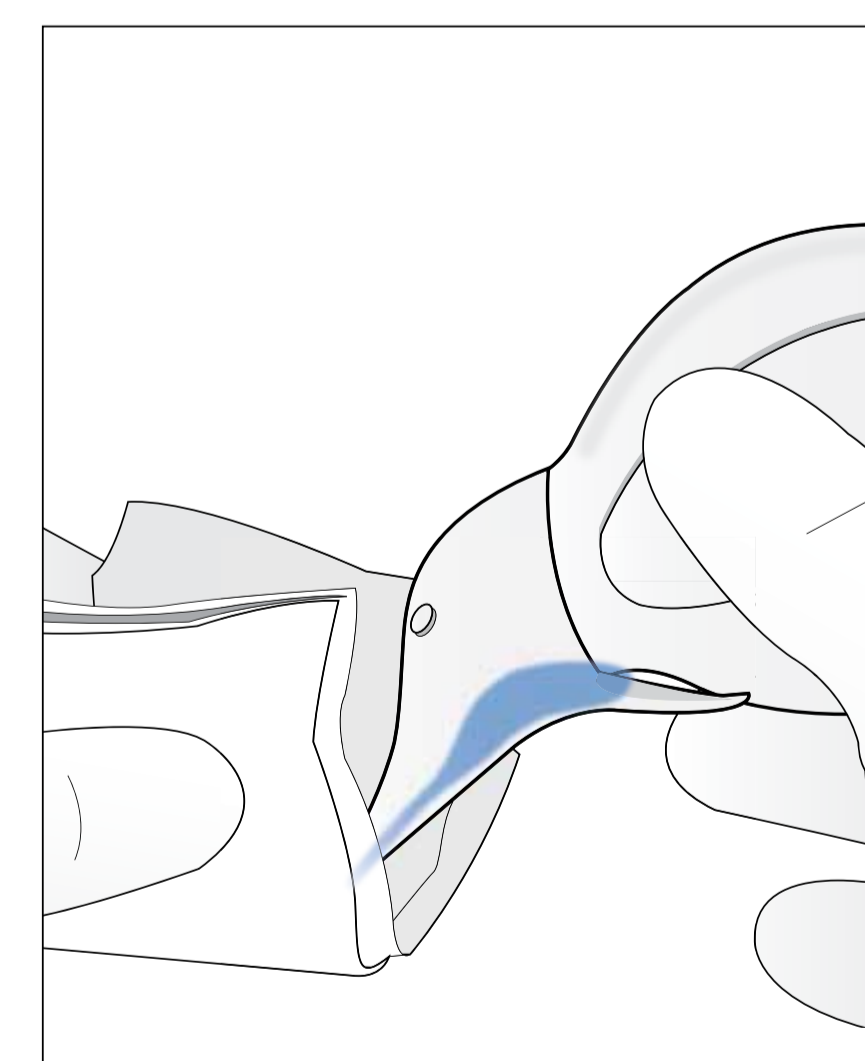
- Meets recommendations of providing vacuum of up to 100 mmHG (136 cmH2O)

Affordability

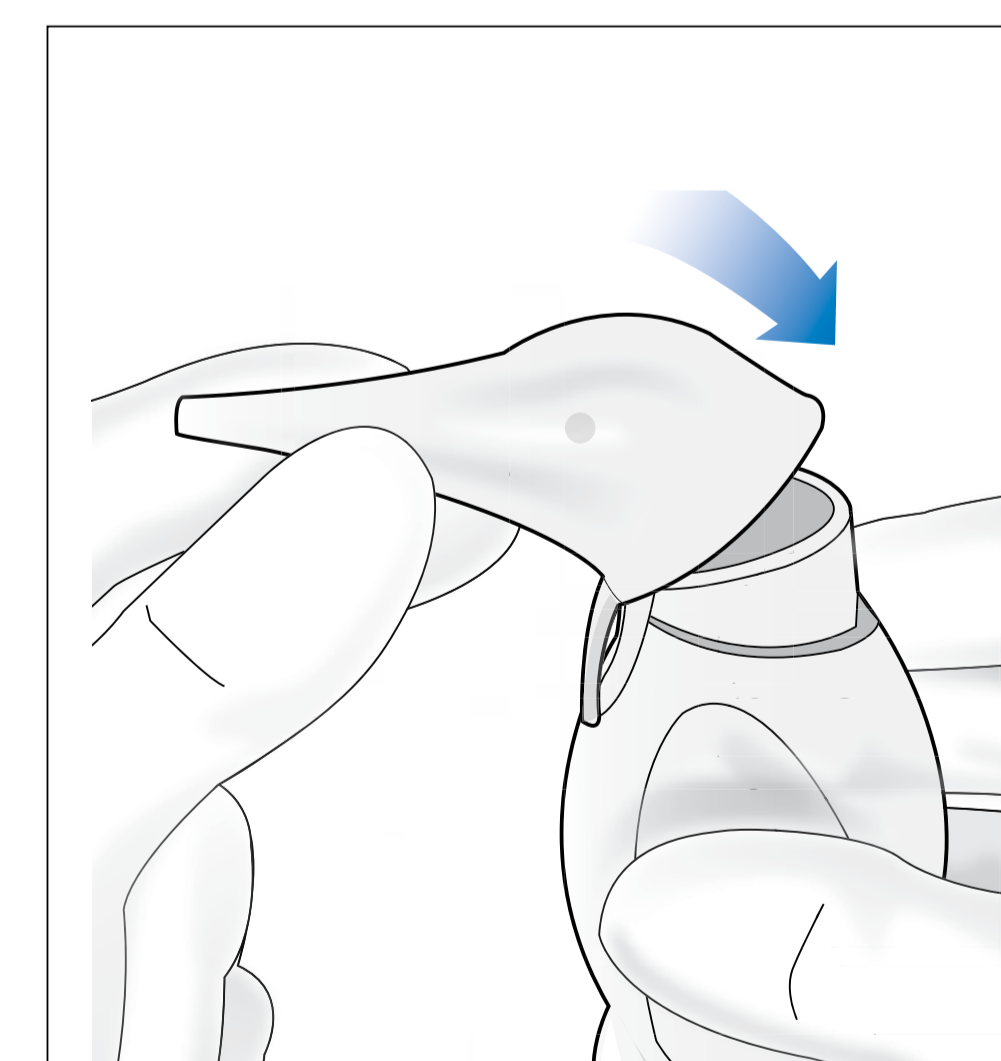
- Low purchase price and use for high numbers of patients over years make this suction device most suitable for general use in low income countries.
- Also ideal for large scale sponsor facilitated distribution on a not-for-profit basis.



To suction



To empty during suction



To clean after suction

References;

1. Lawn, J.E, Lee, A.C, Kinney, M., Sibley, L., Carlo, W.A., Paul, V.K., Pattinson, R., Darmstadt, G.L. Two million intrapartum-related stillbirths and neonatal deaths: Where, why, and what can be done? IJGO 2009; 107: s5-19.
2. WHO, Managing Newborn Problems: A guide for doctors, nurses, and midwives. WHO, Geneva, 2003.
3. American Heart Association, American Academy of Pediatrics. American Heart Association (AHA) Guidelines for Cardiopulmonary Resuscitation (CPR) and Emergency Cardiovascular Care (ECC) of Pediatric and Neonatal Patients: Neonatal Resuscitation Guidelines (2005)
4. Stephen N. Wall , Anne CC Lee, Susan Niermeyer, Mike English , William J. Keenan , Wally Carlo, Zulfiqar A. Bhutta , Abhay Bang , Indira Narayanan, Iwan Ariawan, Joy E. Lawn. (2009). Neonatal resuscitation in low-resource settings: What, who, and how to overcome challenges to scale up? IJGO 2009; 107: s47-64
5. Biomatech. Final Report; Cleaning and disinfection procedure validation according to the AAMI TIR technical report and NF EN ISO 17664 standard on the Silicone Suction Unit, reference part number 986000, batch 5/2010. July 01, 2010. France.

Technical specifications

Nozzle dimensions at tip:	Inner diameter (ID): 3.0 mm Outer diameter (OD): 4.5 mm
Suction strength (typical):	100 mmHg [136 cmH2O]
Operating temperature:	0 °C (32 °F) to 50 °C (122 °F)
Storage temperature:	-20 °C (-4 °F) to 60 °C (160 °F)
Material:	Silicone