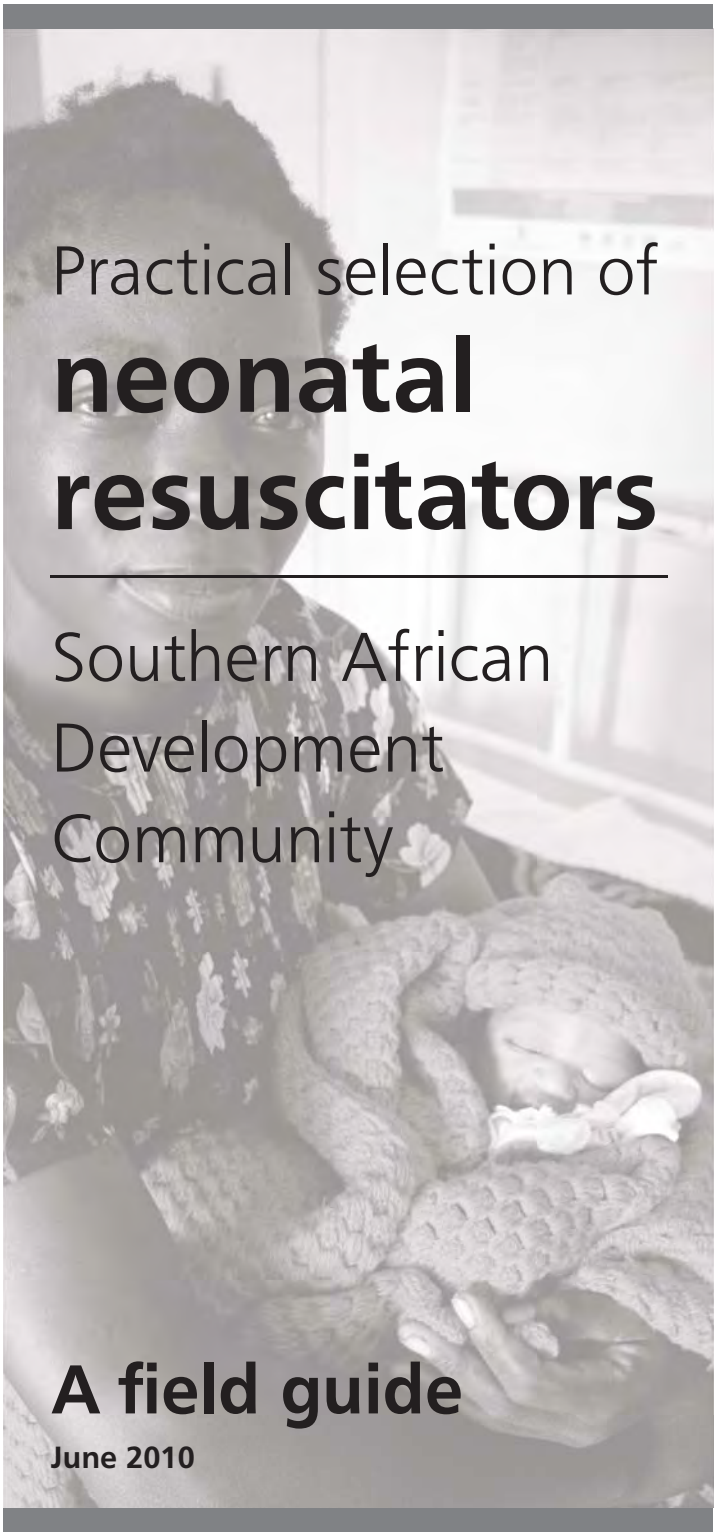

Practical selection of **neonatal resuscitators**

Southern African Development Community

A field guide

June 2010

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Notes

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Notes

Neonatal Resuscitators

PATH conducted a market study in 2008 to identify neonatal resuscitators available in the Southern African Development Community (SADC) region.* These resuscitators are included in this region-specific version of the *Practical Selection of Neonatal Resuscitators: A Field Guide*. All resuscitators identified were bag-and-mask designs. We have also included two devices that offer a tube-and-mask design. This guide presents about the criteria used during the device evaluation, evaluation results for each device, and suggestions for choosing a resuscitator.

Importance of Resuscitation

Birth asphyxia refers to the condition when a baby does not breathe at birth. Asphyxia is estimated to account for one-third of the estimated 4 million neonatal deaths that occur annually. This results in over 1 million neonatal deaths and an unknown number of infants with long-term neurological disability. Reducing birth asphyxia and neonatal death requires appropriate care including a resuscitator available at every birth.

Neonatal resuscitators, when properly used, can lower the incidence of mortality associated with neonatal asphyxia. In order to achieve this, resuscitators need to be made available to all birth attendants in conjunction with adequate training.

Mechanics of Resuscitation

Newborn resuscitation should begin as soon as asphyxia is identified. After clearing the airway and correctly positioning the newborn's head and neck, the health worker positions the mask over the mouth and nose and holds it with light pressure to form an airtight seal. Breaths should then be delivered at a rate of 40–60 breaths per minute. While it may be

* As of June 2010, SADC member states include Angola, Botswana, the Democratic Republic of Congo, Lesotho, Madagascar, Malawi, Mauritius, Mozambique, Namibia, Seychelles, South Africa, Swaziland, United Republic of Tanzania, Zambia, and Zimbabwe.

uncommon to have an in-line manometer (pressure gauge), caregivers should observe the infant's chest to ensure chest rise with each breath. Typical pressures may exceed 30 cm H_2O for the initial breath and then typically diminish to 15–20 cm H_2O. Tidal volumes are small, typically 5–8 ml/kg of newborn weight.[†]

How to Choose a Resuscitator[‡]

☑ Choose desired features

Features on most resuscitator models are similar, but variation exists. Depending on your program, features such as oxygen ports and reservoirs, high-quality packaging, or a compact profile may be important.

☑ Choose bag and mask or tube and mask

Both types of resuscitators can reduce the incidence of neonatal mortality, but each has distinct advantages and disadvantages. The Republic of South Africa does not include the use of tube-and-mask devices in their current guidelines.

☑ Decide between disposable and reusable

Depending on the nature of your program and the rate of neonatal asphyxia, single-use or multiuse resuscitators may be more cost-effective. If the environment of use indicates that resuscitators will always be reused, it may be advisable to invest in a multiuse resuscitator to permit correct cleaning and disinfection after use.

Notes

[†] This section provides a brief overview of a resuscitation procedure but is not meant to be a substitute for proper training. More information can be found online at www.helpingbabiesbreathe.org, www.aap.org/nrp/, and www.ilcor.org.

[‡] The Adcock Ingram resuscitator is a single-use device available in South Africa, but it was not included in this guide because does not meet international standards for resuscitators. Additionally, its mode of operation is different from other resuscitators and therefore does not contain standard components (e.g., valve to prevent rebreathing of exhaled carbon dioxide). Special training should accompany this resuscitator if integrated into resuscitation programs.

Notes

☑ Decide on a price range.

Resuscitators are now available from a wide variety of manufacturers and can vary widely in price despite having many of the same features. Resuscitators manufactured in the United States or Europe are often higher priced than similar resuscitators manufactured in other countries. The resuscitators in this field guide are divided into resuscitators costing under US$30 and over US$30.

Single-Use vs. Multiuse Resuscitators

Single-use (disposable) resuscitators can be lower priced than similar reusable models. However, single-use resuscitators are often manufactured with lower cost materials that cannot be reprocessed and are often sealed to prevent disassembly. Single-use models are not included in this guide.

Multiuse (reusable) resuscitators are often higher priced than similar disposable models. Reusable resuscitators are typically designed for both disassembly and reprocessing (including autoclaving). Due to the possibility of reuse, the cost per use of multiuse resuscitators may be lower than similar single-use resuscitators.

Important Features for Safe and Proper Resuscitation

Properly Sized and Form-Fitting Mask

Proper resuscitation depends on a good seal between the resuscitator and the neonate. Resuscitators are equipped with a variety of mask types including air-filled anatomically shaped masks or round, one- or two-piece masks (with a silicone flange). Resuscitators generally include one mask size for normal birthweight neonates. Purchasers will want to procure an additional mask for low-birthweight neonates for each resuscitator.

Pressure-Relief Valve

Preventing lung damage is a paramount concern for anyone performing resuscitations. A pressure-relief

valve is designed to limit the pressure that the resuscitator can deliver. All bag-and-mask resuscitator models tested had a relief valve except the Blue Cross resuscitator. *Note: Many of the models evaluated lacked any indication regarding the position of the valve—enabling the user to disable the relief valve without their knowledge.*

Minimal Dead Airspace

Resuscitators that minimize dead airspace between the neonate's face and the non-rebreathing valve prevent the neonate from rebreathing expelled air with a higher concentration of CO_2. **Note: Dead airspace volume was not determined during this evaluation**.

Critical decision

Bag and Mask

Pros

- Pressure-limiting valve on most models reduces risk of lung rupture.
- More familiarity on part of providers.
- Wider variety on the market.

Cons

- Higher cost.
- More parts.

VBM

Device Information	**Model Number**	**VBM 80-10-300**
	Supplier	VBM Medical Inc. 524 Herriman Court Noblesville, IN 46060 United States
	Website	www.vbm-medical.com
	Cost (as purchased)	**US$30**
Features That Count	Mask size	Normal birthweight neonate
	Mask type	Round one-piece silicone
	Properly sized bag	Yes
	Pressure-relief valve/position indication	Yes/yes
	Designed for assembly/ disassembly	Yes
	Standard mask connections	Yes
Device Features	Components	No additional components
	Features	Pressure-relief valve
	Packaging	Plastic bag
	Single-use/multiuse	Multiuse
Laboratory Evaluations	Pressure-limiting valve (@ 15 L/min air flow)	33 cm H_2O
	Cleaning—effectiveness	❷
	Disinfection—device durability	❷
	Instructions—completeness	❷
	Instructions—ease of reading	Standard
Usability	Ease of use/comfort	❷
	Dissassembly/reassembly	❷
	Device ergonomics	❷

❶ Very good ❷ Good ❸ OK ❹ Fair ❺ Poor

Unomedical

Device Information	**Model Number**	**Hospitak 735-E**
	Supplier	Unomedical (USA) 5701-1 S. Ware Rd McAllen, Texas 78503 United States
	Website	www.unomedical.net
	Cost (as purchased)	**US$30**
Features That Count	Mask size	Normal birthweight neonate
	Mask type	Anatomical two-piece plastic with air-filled bladder
	Properly sized bag	Yes
	Pressure-relief valve/position indication	Yes/no
	Designed for assembly/ disassembly	No (designed for single use)
	Standard mask connections	Yes
Device Features	Components	Oxygen reservoir tube (attached); oxygen tubing connector
	Features	Pressure-limiting valve Note: cannot lock down
	Packaging	Plastic bag
	Single-use/multiuse	Single-use
Laboratory Evaluations	Pressure-limiting valve (@ 15 L/min air flow)	Not applicable
	Cleaning—effectiveness	❹ (designed for single use)
	Disinfection—device durability	Not applicable (designed for single use)
	Instructions—completeness	❷
	Instructions—ease of reading	Very difficult
Usability	Ease of use/comfort	❷
	Dissassembly/reassembly	❹ (designed for single use)
	Device ergonomics	❸

Note: The Hospitak resuscitator is designated as a single-use device. The Hospitak is not designed for disassembly or constructed of materials that would remain functional after multiple disinfections.

❶ Very good ❷ Good ❸ OK ❹ Fair ❺ Poor

Designed for Assembly/Disassembly

Ridged surfaces on parts that disassemble help identify these parts to the user as well as make the resuscitator easier to disassemble with wet hands. Color coding can help users distinguish different components, and quality design can augment the ease of assembly and disassembly.

Properly Sized Bag
(bag and mask only)

A bag specifically designed for providing appropriate tidal volumes for neonates can help reduce errors during use and simplify training. Most bag-and-mask models had bags that evaluators felt were appropriately sized.

Which is right for your program?

Tube and Mask

Pros

- Often lower cost than bag-and-mask devices.
- Users may feel greater control delivering the pressure and monitoring the neonate's progress.
- Fewer parts.

Cons

- Fatiguing to use.
- Users may need additional training and practice to provide proper and consistent resuscitation.
- Caregiver cannot give instructions or counseling during resuscitation.

Standard Mask Connections

Standard-sized connections are important to ensure compatibility with replacement components and masks from other manufacturers. Standard connections are a 15-mm inner diameter and a 22-mm outer diameter mask connector. Similarly, mask stems should have a 15-mm outer diameter or 22-mm inner diameter.

Guide to the Device Comparison Tables (pp. 9–21)

For each of the devices, the following information is provided in order to assist the reader in making an informed choice when purchasing a neonatal resuscitator. More information about specific resuscitators may also be available from the individual manufacturer or distributor.

The ASTM standard used as the basis for several evaluations is F920-93 Standard Specifications for Minimum Performance and Safety Requirements for Resuscitators Intended for Use with Humans.

Device Information

This section provides basic information on model, supplier, website (for additional information), and cost (as of December 2009).

Features That Count

This section provides information on features that have been identified as particularly important in resuscitator selection.

- **Mask size:** Size of mask(s) included with resuscitator.
- **Mask type:** Type of mask included with resuscitator.
- **Properly sized bag:** Based on user input and international guidelines.

Laerdal

Device Information	**Model Number**	**86005133 Silicone infant resuscitator**
	Supplier	Laerdal 167 Myers Corners Rd Wappingers Falls, NY 12590-8840 United States
	Website	www.laerdal.com
	Cost (as purchased)	**US$225**
Features That Count	Mask size	Neonate (0/1)
	Mask type	Round one-piece silicone
	Properly sized bag	Yes
	Pressure-relief valve/position indication	Yes/cannot disable
	Designed for assembly/ disassembly	Yes
	Standard mask connections	Yes
Device Features	Components	Oxygen reservoir bag
	Features	Pressure-limiting valve
	Packaging	Plastic resealable bag inside cardboard box
	Single-use/multiuse	Multiuse
Laboratory Evaluations	Pressure-limiting valve (@ 15 L/min air flow)	32 cm H_2O
	Cleaning—effectiveness	❸
	Disinfection—device durability	❶
	Instructions—completeness	❶
	Instructions—ease of reading	Difficult
Usability	Ease of use/comfort	❸
	Dissassembly/reassembly	❸
	Device ergonomics	❷

❶ Very good ❷ Good ❸ OK ❹ Fair ❺ Poor

Blue Cross

Device Information	**Model Number**	**BC-2020-RV-CI Neonatal silicone resuscitator**
	Supplier	Blue Cross Emergency Co. 3-12-9, Hongo, Bunkyo-ku Tokyo 131-0033, Japan
	Website	www.bluecross-e.co.jp
	Cost (as purchased)	**US$100**
Features That Count	Mask size	Full-term neonate
	Mask type	Round two-piece. Clear hard plastic top; opaque silicone face seal
	Properly sized bag	Yes
	Pressure-relief valve/position indication	No/not available
	Designed for assembly/ disassembly	Yes
	Standard mask connections	Yes
Device Features	Components	Open-end oxygen reservoir
	Features	Not applicable
	Packaging	Plastic resealable bag inside cardboard box
	Single-use/multiuse	Multiuse
Laboratory Evaluations	Pressure-limiting valve (@ 15 L/min air flow)	Not applicable
	Cleaning—effectiveness	❸
	Disinfection—device durability	❸
	Instructions—completeness	❷ (indicates that 50 cm H_2O pressure should be generated)
	Instructions—ease of reading	Standard
Usability	Ease of use/comfort	❸
	Dissassembly/reassembly	❸
	Device ergonomics	❸

❶ Very good ❷ Good ❸ OK ❹ Fair ❺ Poor

- **Pressure-relief valve/position indication:** More information on proper valve operation can be found in the Laboratory Evaluations section (see pg. 7).
- **Designed for assembly/disassembly:** Whether the resuscitator was designed to facilitate assembly and disassembly.
- **Standard mask connections:** Whether the resuscitator has standard mask connections that will permit it to be used with masks from other manufacturers or differently sized masks (e.g., normal neonate, low-birthweight neonate).

Device Features

This section provides information on:

- **Components:** Extra components included with the resuscitator.
- **Features:** Additional features of the resuscitator that are not required for basic operation.
- **Packaging:** Description of resuscitator packaging.
- **Single-use/multiuse:** Whether the resuscitator is designated by the manufacturer for single or multiple uses.

Laboratory Evaluations

This section provides information from laboratory testing on:

- **Pressure-limiting valve:** The pressure recorded at the patient connection port when air at a flow rate of 15 L per minute was passed through the resuscitator (per American Society for Testing and Materials standards). This test evaluates the proper function of the pressure-limiting valve in relation to the manufacturer's designation.
- **Cleaning–effectiveness:** Evaluated by introducing blood into the device via the face mask, allowing the resuscitator to dry for one hour, and cleaning the resuscitator in a detergent solution using a soft-bristled brush. Score is based on the amount of blood remaining on the device after one minute of cleaning.

- **Disinfection–device durability:** Disassembled resuscitators were submerged in a 0.5% chlorine solution for 48 hours and evaluated for damage. No microbiological evaluation was conducted to determine the degree of disinfection.
- **Instructions–completeness:** Instructions included with the resuscitators were evaluated for completeness based on complete and correct information, accompanying diagrams, technical information, and reuse instructions.
- **Instructions–ease of reading:** Instructions were evaluated using a Flesch Reading Ease score, a method based on the length of words and sentences. Flesch scores are assigned a grade level as follows: Very difficult–post graduate; Difficult–college; fairly difficult–high school; Standard–8th to 9th grade; Fairly easy–7th grade; Easy–5th to 6th grade; Very easy–4th to 5th grade.

Usability

- **Ease of use/comfort:** Describes the ability of the user to intuitively adopt correct and consistent use of the resuscitator.
- **Disassembly/reassembly:** Describes the ease and completeness of disassembly and reassembly by users without written instructions.
- **Device ergonomics:** Describes an ergonomic analysis of the resuscitators as performed by the evaluation team. This includes size of device in relation to hand size, features to improve comfort or usability, and interaction of users with the device.

Ambu

Device Information	**Model Number**	**AMB-288001000 Neonatal resusciatator**
	Supplier	Ambu Inc. 6740 Baymeadow Drive Glen Burnie, MD 21060 United States
	Website	www.ambu.com
	Cost (as purchased)	**US$185**
Features That Count	Mask size	Normal birthweight neonate
	Mask type	Round one-piece silicone
	Properly sized bag	Yes
	Pressure-relief valve/position indication	Yes/not available
	Designed for assembly/ disassembly	Yes
	Standard mask connections	Yes
Device Features	Components	Oxygen reservoir tube
	Features	Pressure-limiting valve Note: cannot lock down
	Packaging	Resealable plastic bag
	Single-use/multiuse	Multiuse
Laboratory Evaluations	Pressure-limiting valve (@ 15 L/min air flow)	40 cm H_2O
	Cleaning—effectiveness	❷
	Disinfection—device durability	❷
	Instructions—completeness	❶
	Instructions—ease of reading	Fairly difficult
Usability	Ease of use/comfort	❶
	Dissassembly/reassembly	❷
	Device ergonomics	❶

❶ Very good ❷ Good ❸ OK ❹ Fair ❺ Poor

Devices Over US$30

Devices Under US$30

Besmed

Device Information	**Model Number**	**BE2303 Infant resuscitator**
	Supplier	East Coast Medical Equipment 80 Clark Road Glenwood Durban 4001 South Africa
	Website	www.besmed.com
	Cost (as purchased)	**US$20**
Features That Count	Mask size	Neonate (0/1)
	Mask type	Round one-piece silicone
	Properly sized bag	Yes
	Pressure-relief valve/position indication	Yes/no
	Designed for assembly/ disassembly	Yes
	Standard mask connections	Yes
Device Features	Components	Oxygen reservoir bag; Oxygen tubing connector
	Features	Pressure-limiting valve
	Packaging	Plastic bag. Optional plastic box.
	Single-use/multiuse	Multiuse
Laboratory Evaluations	Pressure-limiting valve (@ 15 L/min air flow)	40 cm H_2O
	Cleaning—effectiveness	❶
	Disinfection—device durability	❶
	Instructions—completeness	❷
	Instructions—ease of reading	Difficult
Usability	Ease of use/comfort	❶
	Dissassembly/reassembly	❷
	Device ergonomics	❷

❶ Very good ❷ Good ❸ OK ❹ Fair ❺ Poor

Zeal

Device Information	**Model Number**	**MTM1001 BlowSafe mouth to mask resusciator**
	Supplier	Zeal Medical 4/19-A, Piramal Indl Estate, S.V. Road, Goregoan (W) Mumbai-400062 India
	Website	www.zealmedical.com
	Approximate cost	**US$15.00**
Features That Count	Mask size	Neonate (0/1)
	Mask type	Round one-piece silicone
	Properly sized bag	Not applicable
	Pressure-relief valve/position indication	Yes/no
	Designed for assembly/ disassembly	Yes
	Standard mask connections	Yes
Device Features	Components	No additional components
	Features	Pressure-limiting valve Note: cannot lock down.
	Packaging	Zippered bag
	Single-use/multiuse	Multiuse
Laboratory Evaluations	Pressure-limiting valve (@ 15 L/min air flow)	20 cm H_2O
	Cleaning—effectiveness	❶
	Disinfection—device durability	❶
	Instructions—completeness	No instructions
	Instructions—ease of reading	No instructions
Usability	Ease of use/comfort	❸
	Dissassembly/reassembly	❷
	Device ergonomics	❸

Note: The Republic of South Africa does not include the use of tube-and-mask devices in their current guidelines.

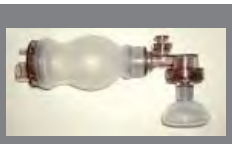
❶ Very good ❷ Good ❸ OK ❹ Fair ❺ Poor

Zeal

Device Information	**Model Number**	**RSB1001 Infant resusciator**
	Supplier	Zeal Medical 4/19-A, Piramal Indl Estate, S.V. Road, Goregoan (W) Mumbai-400062 India
	Website	www.zealmedical.com
	Cost (as purchased)	**US$15**
Features That Count	Mask size	Low-birthweight neonate
	Mask type	Round one-piece silicone
	Properly sized bag	Yes
	Pressure-relief valve/position indication	Yes/no
	Designed for assembly/ disassembly	Yes
	Standard mask connections	Yes
Device Features	Components	Oxygen reservoir bag and tube; oxygen tubing connector
	Features	Pressure-relief valve
	Packaging	Reusable vinyl bag
	Single-use/multiuse	Multiuse
Laboratory Evaluations	Pressure-limiting valve (@ 15 L/min air flow)	40–60 cm H_2O
	Cleaning—effectiveness	❷
	Disinfection—device durability	❷
	Instructions—completeness	No instructions
	Instructions—ease of reading	Fairly easy
Usability	Ease of use/comfort	❷
	Dissassembly/reassembly	❷
	Device ergonomics	❷

❶ Very good ❷ Good ❸ OK ❹ Fair ❺ Poor

Headstar



Device Information	**Model Number**	**HS92111I-OC infant resuscitator**
	Supplier	Palmed Medical and Surgical Supplies 4 Clubhouse Place Westnead, South Africa
	Website	www.headstarmedical.com
	Cost (as purchased)	**US$20**
Features That Count	Mask size	Normal birth weight neonate
	Mask type	Round one-piece silicone
	Properly sized bag	Yes
	Pressure-relief valve/position indication	Yes/yes
	Designed for assembly/ disassembly	Yes
	Standard mask connections	Yes
Device Features	Components	Oxygen reservoir bag
	Features	Pressure-relief valve
	Packaging	Cardboard box
	Single-use/multiuse	Multiuse
Laboratory Evaluations	Pressure-limiting valve (@ 15 L/min air flow)	40 cm H_2O
	Cleaning—effectiveness	❷
	Disinfection—device durability	❷
	Instructions—completeness	❸
	Instructions—ease of reading	Very difficult
Usability	Ease of use/comfort	❷
	Dissassembly/reassembly	❷
	Device ergonomics	❷

❶ Very good ❷ Good ❸ OK ❹ Fair ❺ Poor

Laerdal

Device Information	**Model Number**	**820050 Paediatric pocket mask**
	Supplier	Laerdal Medical AS PO Box 377 4002 Stavanger Noroway
	Website	www.laerdal.com
	Cost (as purchased)	**US$14.60** (One-way valve can be purchased separately for use with other masks for US$5.95)
Features That Count	Mask size	Infant/child
	Mask type	Round one-piece silicone
	Properly sized bag	Not applicable
	Pressure-relief valve/position indication	No
	Designed for assembly/ disassembly	Yes
	Standard mask connections	Yes
Device Features	Components	Nitrile gloves; antimicrobial hand wipe
	Features	Not applicable
	Packaging	Zippered nylon bag
	Single-use/multiuse	Labeled as single-use
Laboratory Evaluations	Pressure-limiting valve (@ 15 L/min air flow)	Not applicable
	Cleaning—effectiveness	❶
	Disinfection—device durability	❶
	Instructions—completeness	❷
	Instructions—ease of reading	Fairly easy
Usability	Ease of use/comfort	❹
	Dissassembly/reassembly	❶
	Device ergonomics	❹

❶ Very good ❷ Good ❸ OK ❹ Fair ❺ Poor

Laerdal

Device Information	**Model Number**	**846030 NeoNatalie infant resuscitator**
	Supplier	Laerdal Medical AS PO Box 377 4002 Stavanger Noroway
	Website	www.laerdal.com
	Cost (as purchased)	**US$15** (additional US$2.30 for a supplemental oxygen attachment)
Features That Count	Mask size	Normal and low-birthweight neonate (0/1)
	Mask type	Round one-piece silicone
	Properly sized bag	Yes
	Pressure-relief valve/position indication	Yes/yes
	Designed for assembly/ disassembly	Yes
	Standard mask connections	Yes
Device Features	Components	No additional components
	Features	Pressure-limiting valve
	Packaging	Resealable plastic bag inside cardboard box
	Single-use/multiuse	Multiuse
Laboratory Evaluations	Pressure-limiting valve (@ 15 L/min air flow)	38 cm H_2O
	Cleaning—effectiveness	❷
	Disinfection—device durability	❷
	Instructions—completeness	❶
	Instructions—ease of reading	Fairly easy
Usability	Ease of use/comfort	❶
	Dissassembly/reassembly	❷
	Device ergonomics	❶

❶ Very good ❷ Good ❸ OK ❹ Fair ❺ Poor