



# A HealthTech Report

## An Investigation into the Context of Use and Functionality of Neonatal Resuscitator Devices

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# **An Investigation into the Context of Use and Functionality of Neonatal Resuscitator Devices**

**Submitted to:  
United States Agency for International Development (USAID)**

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## List of Abbreviations

ASTM	American Society of Testing and Materials
PEEP	Positive End-Expiratory Pressure
TBA	Traditional Birthing Attendant
WHO	World Health Organization

## Executive Summary

### Introduction

Birth asphyxia, which refers to the condition when a baby does not breathe at birth, is estimated to account for one-third of the approximate 4 million neonatal deaths that occur annually.<sup>1</sup> Appropriate care for birth asphyxia requires that neonatal resuscitation skills and appropriate technology be made available to all skilled birth attendants<sup>2</sup> and to community-level workers where skilled attendants are not available. According to the World Health Organization (WHO), basic newborn resuscitation requires a bag and a mask for ventilation, a mucus extractor for suctioning, a source of warmth for thermal protection, and a clock.<sup>3</sup> Neonatal resuscitation devices are also available in a tube and mask design.

From October 2004 through July 2005, PATH implemented a multifaceted investigation into the context of use and functionality of neonatal resuscitators currently available for use in developing countries. The goal of the project was to increase our understanding of these dimensions of neonatal resuscitator use and make the results of these findings available to health care workers in low-resource settings.

### Methods and Materials

The investigation consisted of three parts: (1) an opinion survey of neonatal experts about the context of use of different resuscitator designs (i.e., bag and mask and tube/mouth and mask), (2) bench testing of 14 different models of devices, and (3) evaluation of the same models of devices by both inexperienced and experienced users.

In order to obtain devices for both the user and bench evaluation, the PATH procurement team contacted individual resuscitator manufacturers or resuscitator distributors. Based on their responses, resuscitators were procured either through simple purchasing or via donation for the purposes of this evaluation. In total, 11 devices were procured for the evaluation. Additionally, three devices from a previous evaluation (conducted in 2003–2004) were included in portions of this evaluation.<sup>4</sup>

Resuscitators are listed as follows: manufacturer with model name and number:

1. Portex 1<sup>st</sup> Response (8527 MPB)
2. Blue Cross (IBW-01)
3. Laerdal Silicone (860056)
4. Laerdal The Bag (84002903)
5. Kay and Company (Silicone Infant Resuscitator)
6. CPR-Pro Rescuer (4000IN Rescuer Infant)
7. BLS Systems (Manual resuscitator)
8. PJ Dahlhausen (CH436-51.5000.00.100)
9. Topster (SR-003)
10. Tekno Design
11. Hospitak/Unomedical (1054-E Neonate mask)
12. Laerdal Pocket Mask (Paediatric Pocket Mask)
13. Portex Safe Response Mouth-to-Mask Resuscitator [long tube]
14. Portex Safe Response Mouth-to-Mask Resuscitator [short tube]

## Conclusions

In general, the bag and mask devices were used by more practitioners and in more places than the tube and mask design. The bag and mask device was preferred by skilled and unskilled users as well as by neonatal experts. In general, the tube and mask device was not well known; when the tube and mask device was evaluated by users it was considered less functional than the bag and mask design. Disposable devices were not recommended by either neonatal experts or skilled users.

Results from the expert opinion survey indicated that the device features that mattered most for the bag and mask device were ease of use, size of the mask, and overall device function. Features of most concern with the tube and mask device were ease of use and availability. Also, a need for frequent refresher training and practice using resuscitation devices among all groups of health care workers was identified. Device readiness at births and use of devices that have not been used for a long period of time were issues of concern among many; such issues could be addressed in refresher trainings. Appropriately sized devices, especially those that could be used with preterm and low-birth-weight infants, was identified as an additional need. Concern about potential HIV transmission with the use of the tube and mask device was noted by several respondents and is an issue that warrants further exploration.

Several specific design recommendations for neonatal resuscitators were identified. We believe that these features will help ensure safe and proper operation among the greatest variety of users. They include:

- Standard connections in order to permit procurement of masks of different sizes and from different manufacturers.
- Pressure relief valve to limit the possibility of lung trauma in the neonate.
- Properly sized and form-fitting mask in order to increase the likelihood of quickly establishing a good facial seal on the neonate.
- Properly sized bag that can deliver an appropriate volume without excessive attention by the user and that fits the target users' hands.
- Design features (e.g., ridged surfaces, large screw threads) that assist with disassembly and reassembly of device for proper cleaning and disinfecting.
- Complete instructions, including a diagram for assembly or disassembly, that are written at a reading level appropriate for the target audience. Instructions on how to establish an optimal breathing pattern for use with tube and mask designs was also suggested.

It is important to note that this device evaluation was not exhaustive; in other words, it did not include all neonatal resuscitator devices currently available on the global market. The devices that were evaluated were included in the evaluation because the manufacturer responded to our inquiries about device procurement and because they were representative of a specific design type (i.e., bag and mask or tube and mask). Thus, it would be prudent not to use this device evaluation as the basis for recommendations relating to global best practices

for neonatal resuscitation device use. Rather, further research could be undertaken to strengthen the evidence base by assessing feedback from users in a variety of developing countries.

The outcomes of this research will be used to develop a “Practical Selection of Neonatal Resuscitators—A Field Guide.” It is anticipated that this guide will be helpful for policymakers and program implementers when making a decision about what type of resuscitation device is most appropriate for their neonatal health program. The field guide contains reviews of 11 currently available resuscitators and provides information and ratings for each of them in a concise and easy-to-read format. Information about important device features, resuscitation parameters, laboratory evaluations, user feedback and usability are included for each device.

## References

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<sup>1</sup> World Health Organization (WHO), Department of Reproductive Health and Research. *Perinatal and Neonatal Mortality: Global, Regional, and Country Estimates*. Second Edition, Draft 5 ed. 2001.

<sup>2</sup> Saving Newborn Lives. *Birth Asphyxia: Report of a Meeting, Cape Town, South Africa 29<sup>th</sup> November to 2<sup>nd</sup> December*. 12-1-2002.

<sup>3</sup> World Health Organization (WHO). *Basic Newborn Resuscitations: A Practical Guide (WHO/RHT/MSM/98.1)*. Geneva: WHO; 1998.

<sup>4</sup> Seamans Y. *Neonatal Resuscitator Evaluation*. 2004.

## Introduction

Birth asphyxia, which refers to the condition when a baby does not breathe at birth, is estimated to account for one-third of the approximate 4 million neonatal deaths that occur annually.<sup>1</sup> This results in over 1 million neonatal deaths and an unknown number with long-term neurological disability. Over two-thirds of neonatal deaths and about 40% of infant deaths occur in the first week of life; birth asphyxia is a major cause of death in the same time period. Limited data suggest that deaths due to birth asphyxia have remained relatively unchanged in developing countries.<sup>2</sup>

The key to reducing death due to birth asphyxia is the provision of appropriate care to underserved populations during delivery. Approximately 61 million women deliver babies each year without skilled care. Appropriate care for birth asphyxia requires that neonatal resuscitation skills and appropriate technology be made available to all skilled birth attendants and to community-level workers where skilled attendants are not available.<sup>2</sup> According to the World Health Organization (WHO), basic newborn resuscitation requires a bag and a mask for ventilation, a mucus extractor for suctioning, a source of warmth for thermal protection, and a clock.<sup>3</sup> Neonatal resuscitation devices are also available in a tube and mask design.

From October 2004 through July 2005, PATH implemented a multifaceted investigation into the context of use and functionality of neonatal resuscitators currently available for use in developing countries. The goal of the project was to increase our understanding of these dimensions of neonatal resuscitator use and make the results of these findings available to health care workers in low-resource settings.

## Methods and Materials

The investigation consisted of three parts: (1) an opinion survey of neonatal experts about the context of use of different resuscitator designs (i.e., bag and mask and tube/mouth and mask), (2) procurement and bench testing of 14 different models of devices, and (3) evaluation of the same models of devices by both inexperienced and experienced users.

### Context of Use Expert Opinion Survey

The areas of inquiry for the expert opinion survey related to resuscitator use scenarios, context of training, device readiness, the use and features of both bag and mask and tube/mouth and mask designs, and design preferences including multiuse versus single use. An electronic survey was created using SurveyMonkey (<http://www.surveymonkey.com/>), an online survey tool. A list of 80 experts in the field of international neonatal health was compiled through personal contacts and referrals. These individuals were invited to complete the electronic survey following the principles outlined in Dillman.<sup>4</sup> The survey was available online and was collected from February through June 2005. The PATH Human Subjects Protection Committee reviewed the study protocol and granted research approval.

## **Procurement of Neonatal Resuscitator Devices**

In order to obtain devices for both the user and bench evaluation, the PATH procurement team contacted individual resuscitator manufacturers or resuscitator distributors. Based on their responses, resuscitators were procured either through simple purchasing or via donation for the purposes of this evaluation. In total, 11 devices were procured for the evaluation. Additionally, three devices from a previous evaluation (conducted in 2003–2004) were included in portions of this evaluation.<sup>4</sup>

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- |   |  |
|---|--|
| 1. Portex 1 <sup>st</sup> Response (8527 MPB)     | 8. PJ Dahlhausen (CH436-51.5000.00.100)                          |
| 2. Blue Cross (IBW-01)                            | 9. Topster (SR-003)  |
| 3. Laerdal Silicone (860056)                      | 10. Tekno Design   |
| 4. Laerdal The Bag (84002903)                     | 11. Hospitak/Unomedical (1054-E Neonate mask)                    |
| 5. Kay and Company (Silicone Infant Resuscitator) | 12. Laerdal Pocket Mask (Paediatric Pocket Mask)                 |
| 6. CPR-Pro Rescuer (4000IN Rescuer Infant)        | 13. Portex Safe Response Mouth-to-Mask Resuscitator [long tube]  |
| 7. BLS Systems (Manual resuscitator)              | 14. Portex Safe Response Mouth-to-Mask Resuscitator [short tube] |

Numbers 1 through 9 are self inflating, bag and mask resuscitators and numbers 10 through 14 are mouth to mask resuscitators. No flow inflating bag and mask resuscitators were procured due to the necessity of compressed oxygen for use.

Not all resuscitators were used for all parts of the evaluation due to availability at different times, time constraints of the evaluation, and dismissal of three devices due to inappropriately sized masks (Portex Safe Response Mouth-to-Mask resuscitators and Laerdal Pocket Mask).

## **Bench Evaluation of Neonatal Resuscitator Devices**

Laboratory evaluations were developed based partially on the American Society of Testing and Materials (ASTM) standard for resuscitators<sup>5</sup> as well as previously published evaluations of neonatal or adult resuscitators<sup>6,7,8</sup> and their functional components (e.g., masks).<sup>9,10,11</sup>

These evaluations were conducted at PATH in order to:

- Identify the features of the resuscitators (including safety features, instructions, packaging).
- Characterize the operation of the resuscitators.
- Identify differences between the resuscitators that could lead to different performance characteristics.
- Identify positive and negative features of the resuscitator design.

The following evaluations were conducted:

## 1. Resuscitator Features

- *General characteristics*: General characteristics of resuscitator (e.g., dimensions, weight).
- *Components*: Standard components included with resuscitator and their characteristics (e.g., type and size of mask, packaging) and extra components included with the resuscitator (e.g., oxygen connection tubes).
- *Features*: Additional features of the resuscitator that are not required for basic operation (e.g., pressure relief valve).
- *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., full-term neonate, low-birth-weight infant).
- *Instruction-completeness and ease of reading*: Instructions included with the resuscitators were evaluated for completeness based on complete and correct information, accompanying diagrams, technical information, and reuse instructions. Instructions were additionally evaluated using a Flesch Reading Ease score, a method used to classify the ease of reading based on the length of words and sentences.

## 2. Resuscitator Operation

- *Pressure-limiting valve*: The pressure recorded at the patient connection port when air at a flow rate of 15 L/min was passed through the resuscitator (per ASTM standards).<sup>5</sup> This test evaluates the proper function of the pressure-limiting valve in relation to the manufacturer's designation.
- *Pressure-limiting valve (during simulated use)*: The maximum pressure recorded at the patient connection port when the resuscitator was connected to an artificial lung and the resuscitator was operated with rapid compressions.
- *Maximum tidal volume*: The maximum tidal volume achieved by the resuscitator attached to a test lung when a user fully squeezed the bag using all four fingers. In some cases, two volumes were recorded if tidal volumes were higher if the pressure relief valve was overridden (i.e., pressed in).
- *Inspiratory resistance*: The pressure recorded at the patient connector when air at a flow rate of 5 L/min was drawn (vacuum) at the patient connector. ASTM standards limit inspiratory resistance to 5 cm H<sub>2</sub>O. Low inspiratory resistance ensures that the neonate can breathe spontaneously if the resuscitator is applied to the face but not in use.
- *Expiratory resistance*: The pressure recorded at the patient connector when air at a flow rate of 5 L/min was passed through the patient connector. ASTM standards limit expiratory resistance to 5 cm H<sub>2</sub>O. Low expiratory resistance ensures that the neonate can exhale without resistance.
- *Maximum compressions per minute*: The average number of compressions possible for a user to complete in one minute while maintaining a peak pressure of 15–25 cm H<sub>2</sub>O.

### 3. Laboratory Evaluations

This section provides information from bench testing on:

- *Cleaning after use:* Evaluated by introducing simulated vomit into the device via the facemask, 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 simulated vomit remaining on the device after one minute of cleaning.
- *Disinfection:* Disassembled resuscitators were submerged in a 0.5% chlorine solution for 24 hours and evaluated for damage. Immersion for an extended period was performed to represent multiple disinfection cycles.
- *Cleaning during use:* Evaluated by introducing simulated vomit into the device via the facemask, disassembling the resuscitator (separating mask, bag, and non-rebreathing valve), and rinsing in a basin of water.
- *Operation after immersion:* Resuscitators were submerged in a basin of water for 10 seconds, removed, shaken for 20 seconds, and proper operation was verified.
- *Effect of vomit on operation:* Evaluated by introducing simulated vomit into the device via the facemask and observing the effect on operation and degree of penetration into the resuscitator. The resuscitator was then rinsed, agitated for 10 seconds in a basin of water, and then proper operation was reevaluated.
- *High temperature operation:* Resuscitators were stored at 55°C for seven days and then evaluated for functionality.
- *Low temperature operation:* Resuscitators were stored at -25°C for seven days and then evaluated for functionality.

#### **User Evaluation of Neonatal Resuscitator Devices**

Midwives and midwifery students currently enrolled at the Seattle Midwifery School participated as the skilled cadre of user evaluators, and PATH employees who were not currently working in the area of neonatal health participated as the unskilled cadre of user evaluators. Skilled users (i.e., midwives and midwifery students) participated in a one-day user evaluation session held in March 2005. These experienced users each used two or three different resuscitation devices with a mannequin for time intervals of two and five minutes. They also used two resuscitators during a two-minute resuscitation of a mannequin attached to a computerized test lung, and disassembled and reassembled at least two devices each. Feedback was provided via written evaluations by users; observation of users by research staff; measurements of proximal pressure, tidal volume and breaths per minute collected via a computerized test lung apparatus;\* and participation by users in a focus group discussion.

Unskilled users participated in a similar evaluation during which they were first briefly trained in the proper operation of the resuscitator by PATH staff. They then used two resuscitators during a two-minute resuscitation of a mannequin attached to a computerized test lung. Additionally, they disassembled and reassembled one device (if sufficient time).

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\* Michigan Instruments Inc. (Grand Rapids, MI) Training and test lung model 5601i. Available at: <http://www.michiganinstruments.com/resp-ttl-adultinfant.htm>. Accessed September 6, 2005.

Data were gathered via observation of users by the evaluators; measurements of proximal pressure, tidal volume, and breaths per minute; and brief discussions with research staff.

The PATH Human Subjects Protection Committee reviewed the study protocols and granted research approval.

Data from the user evaluations were analyzed and reported in the User Feedback and Usability sections of the field guide as follows:

- *Appropriate rate* as measured during a two-minute simulated resuscitation using a test lung.
- *Ease of use* describes the ability of the user to intuitively adopt correct and consistent use of the resuscitator. This was evaluated based on both user comments and through observation by evaluators.
- *Perceived comfort* indicates the perceived comfort during use of the resuscitator based on comments by the users.
- *Use consistency* indicates the number and significance of problems observed or noted by the evaluator during use.
- *Disassembly/reassembly* describes the ease and completeness of disassembly and reassembly by users without written instructions. Users disassembled the device independently and then with additional coaching by the evaluator if needed for complete disassembly. They then reassembled the device independently and/or with coaching.
- *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.

## Results

### Context of Use Expert Opinion Survey

The electronic survey was sent to 83 neonatal experts. Three of the e-mail addresses bounced back and we were unable to access corrected addresses for those individuals. This resulted in a total sample size of 80 experts. 22 individuals completed the survey, resulting in a response rate of 28%.

#### *Respondent Characteristics*

A total of 52.6% of the respondents (10/19) conduct the majority of their work in sub-Saharan Africa, 21.1% (4/19) in South and Southeast Asia, 10.5% (2/19) in North America/Europe, and another 10.5% (2/19) conduct work globally. A total of 73.7% (14/19) currently work as medical doctors, 10.5% (2/19) as nurses, and 15.8% (3/19) as midwives. In addition 36.8% (7/19) were in the public health field. In terms of primary job classifications, 52.6% (10/19) were program planners and/or implementers, 42.1% (8/19) were in health care delivery and research, and 15.8% (3/19) were in policy.

### Scenarios of Use

Of the respondents 85.7% (18/21) reported that they had used a neonatal resuscitator device in a developing country. The most frequent scenario of use for resuscitator devices reported among this group was use in a tertiary care facility (17/19), followed by secondary care facilities (14/19), primary care facilities (8/19), and at home births (1/19).<sup>†</sup> A total of 80% of respondents (16/20) said that they had observed medical doctors in a secondary care facility using a device. Respondents reported other scenarios of device use including (from most commonly observed to least commonly observed): medical doctors in tertiary care facilities (75%; 15/20), nurses in tertiary, secondary, and primary care facilities (65%; 13/20), midwives in secondary care facilities (55%; 11/20) and midwives in primary (50%; 10/20) care facilities.

Respondents reported that the most common scenario of use (at least once a month) occurred with medical doctors in tertiary care facilities (81%). In contrast, the most common scenario of use never observed by respondents was use by traditional birth attendants (TBAs) in primary care facilities (87%), followed by use by TBAs in secondary care facilities (86%) and during home births (71%). It should be noted that low rates of observation may not necessarily be due to the fact that health care workers were not using resuscitator devices in these settings, but because observation in these situations was not occurring. Table 1 further illustrates the findings about the frequency of scenarios of use for neonatal resuscitator devices.

**Table 1. Frequency of Use of Neonatal Resuscitator Devices in Developing Countries, as Observed by Respondents**

Respondents	Never	Rarely (less than 1 time/year)	Somewhat Common (1-3 times/year)	Common (at least 1 time/quarter)	Very Common (at least 1 time/month)
Medical doctors in tertiary care facility	0% (0)	0% (0)	10% (2/21)	10% (2/21)	81% (17/21)
Nurses in tertiary care facility	0% (0)	5% (1/21)	10% (2/21)	19% (4/21)	67% (14/21)
Medical doctors in secondary care facility	0% (0)	5% (1/20)	5% (1/20)	40% (8/20)	50% (10/20)
Nurses in secondary care facility	5% (1/20)	15% (3/20)	5% (1/20)	30% (6/20)	45% (9/20)
Midwives in secondary care facility	11% (2/18)	6% (1/18)	11% (2/18)	22% (4/18)	50% (9/18)
TBAs in secondary care facility	86% (12/14)	14% (2/14)	0% (0)	0% (0)	0% (0)
Medical doctors in primary care facility	24% (4/17)	35% (6/17)	6% (1/17)	6% (1/17)	29% (5/17)
Nurses in primary care facility	28% (5/18)	22% (4/18)	17% (3/18)	0% (0)	33% (6/18)

<sup>†</sup> Tertiary care facility = provincial or national referral hospital; Secondary care facility = first referral level facility such as district hospital or other facility that has access to a minimal amount of neonatal technologies and at least intermittent electricity; Primary Care facility = health centers or village-level care facilities.

<b>Respondents</b>	<b>Never</b>	<b>Rarely (less than 1 time/year)</b>	<b>Somewhat Common (1-3 times/year)</b>	<b>Common (at least 1 time/quarter)</b>	<b>Very Common (at least 1 time/month)</b>
Midwives in primary care facility	28% (5/18)	11% (2/18)	17% (3/18)	17% (3/18)	28% (5/18)
TBAs in primary care facility	87% (13/15)	7% (1/15)	0% (0)	0% (0)	7% (1/15)
Midwives at home birth	47% (7/15)	13% (2/15)	27% (4/15)	7% (1/15)	7% (1/15)
TBAs at home birth	71% (12/17)	18% (3/17)	6% (1/17)	6% (1/17)	0% (0)

### *Context of Training*

Approximately 91% (20/22) of respondents had trained other health care workers in the use neonatal resuscitators. Of those who had trained others, training with nurses in a tertiary care facility was the most frequently reported (80%; 16/20). A total of 75% of respondents (15/20) had trained midwives in secondary care facilities, and 70% of respondents (14/20), reported having trained medical doctors in tertiary and secondary care facilities, and nurses in secondary care facilities. While some respondents reported having trained TBAs about resuscitator devices, the numbers were much lower. For example, only 4 respondents of 20 (20%) noted they had trained TBAs to use the devices at home births.

Respondents answered positively in all cases, except for traditional birth attendants, to questions related to whether or not health care workers trained to use the devices had confidence in their abilities to use it accurately and safely. Respondents believed that 91% (19/21) of medical doctors, 75% (15/20) of nurses, and 85% (17/20) of midwives had confidence in their abilities to use the device accurately and safely. About one-half of respondents, 53% (10/19), stated that they believed TBAs lacked the confidence to use the device accurately and safely.

When asked to explain the reasoning why they felt medical doctors had confidence in their abilities to use these devices accurately and safely, respondents overwhelmingly noted that it was because use of the device is included in their medical training, and because doctors must gain certification in the use of devices through observation and practice. Additionally, respondents noted that correct use of these devices requires opportunities to refresh skills either through training or regular use of the device in real life situations. Without this, skills rapidly decline. Respondents noted these same issues with nurses and midwives, but said that in certain settings, resuscitation is thought of as doctor's work, and therefore nurses do not recognize it as something they should perform. Moreover, some respondents noted that nurses do not perform or assist in deliveries and therefore are not given opportunities to train with these devices.

When asked their reasoning regarding their responses on the use of neonatal resuscitators by TBAs, most respondents felt that it would be possible to train them adequately to use the devices safely and accurately but that this was not currently happening, and therefore they did not have confidence in this group of health care worker's abilities to resuscitate infants.

Those with experience training TBAs through research and pilot projects noted that because of their lack of clinical background, training in use of resuscitator devices must be very selective and applied more extensively with adequate and regular supervision. One respondent felt that it would be better to encourage and promote skilled attendance at home births rather than train TBAs in the use of these devices.

Given the importance of training noted in these responses, it seems clear that there is a need for frequent refresher training and practice using the devices among all groups of health care workers. Despite this need, 62% (13/21) of respondents reported that refresher training happens rarely if at all. A total of 29% (6/21) said that it happens approximately once a year, while only 10% (2/21) said that it happens two to three times a year.

### *Device Readiness*

Respondents cited the bag and mask device most frequently when asked to describe the types of resuscitators currently being used by health care workers attending births. A total of 95% of respondents noted that this device was currently used in secondary care facilities, 90% said it was currently used in tertiary care facilities, and 62% said it was used in primary care facilities. The tube and mask device was used less frequently, although 55% of respondents who mentioned it said it was currently used in primary care facilities. Table 2 outlines these responses more fully.

**Table 2. Neonatal Resuscitators Currently in Use by Health Workers Attending Births in Developing Countries**

<b>Resuscitators</b>	<b>Tertiary care facility</b>	<b>Secondary care facility</b>	<b>Primary care facility</b>	<b>In the home</b>
Bag and mask	90% (19/21)	95% (20/21)	62% (13/21)	19% (4/21)
Tube and mask	36% (4/11)	18% (2/11)	55% (6/11)	45% (5/11)
Other	38% (3/8)	25% (2/8)	88% (7/8)	63% (5/8)

When asked to further define the category of “other,” respondents said that in some places nasal continuous positive airway pressure was used, as well as Vapotherm<sup>‡</sup> and Neopuff<sup>§</sup> devices in Latin America. Some respondents noted that medical and nursing staff were also trained in endotracheal intubation. Most, however, noted that mouth-to-mouth resuscitation with a gauze barrier was the most common type of resuscitation used when no resuscitator device was available.

When asked whether or not the device was available and ready when needed, 42% (8/19) said that it was ready and available for all deliveries, while 16% (3/19) said it was ready only when a complication was anticipated. Of those who said “other” in response to this question, most said that it varied depending on the facility, and that it was usually available for births in tertiary and secondary hospitals but not in primary care facilities.

<sup>‡</sup> Vapotherm 2000i (Vapotherm. Stevensville, MD). Available at: <http://www.vtherm.com/products/2000i.asp> Accessed September 6, 2005.

<sup>§</sup> Neopuff Infant Resuscitator (Fisher and Paykel Healthcare. Laguna Hills, CA). Available at: [http://www.fphcare.com/neonatal/resuscitation\\_products1.asp](http://www.fphcare.com/neonatal/resuscitation_products1.asp). Accessed September 6, 2005.

All respondents said that use of resuscitator devices in homes or primary care facilities is acceptable to community members. Respondents noted that because the device is used to save the life of the baby it will be acceptable to many and noted that it is critical to explain the importance and usefulness of the device to family and community members to increase their understanding and acceptance of its use. Some respondents noted that those health care practitioners working in primary facilities or in homes have asked to be trained with the device so that they can use it to help save lives. Several respondents noted that acceptance of these devices will really depend on the culture and traditional beliefs in a country. They felt strongly that remote cultures which have less contact with modern technologies would have a much more difficult time accepting the use of the devices.

**Table 3. Questions and Answers on Survey Regarding Bag and Mask vs. Tube and Mask\*\***

Questions	Bag and Mask	Tube and Mask
Number of respondents with experience using the device	20/21 (95.2%)	4/19 (21.1%)
How many newborns have you effectively resuscitated with each device?		
None	0	1/4 (25%)
1-4 newborns	0	2/4 (50%)
5-20 newborns	3/19 (16%)	0
21 or more newborns	13/19 (68.4%)	0
Other	4/19 (21.1%) <sup>††</sup>	1/4 (25%) <sup>††</sup>
How many newborns have you seen other health care workers resuscitate effectively with each device?		
None	0	1/4 (25%)
1-4 newborns	0	1/4 (25%)
5-20 newborns	2/19 (10.5%)	1/4 (25%)
21 or more newborns	13/19 (68.4%)	0
Other	4/19 (21.1%)	1/4 (25%)
Overall is the device easy to use for newborn resuscitation?		
Yes	20/20 (100%)	2/4 (50%)
No	0	2/4 (50%)
Is the device easy to assemble and disassemble for cleaning without written instructions?		
Yes	14/18 (77.8%)	3/3 (100%)
No	4/18 (22.2%)	0
What features make it easy to use?		
Clear instructions/easy to read	10/19 (52.6%)	2/4 (50%)

\*\* Because not all respondents answered each question, the percentages and number of respondents indicated are not consistent from question to question. Percentages are based on the number of respondents answering each question.

†† Answers included: “hundreds” and “30 years experience with thousands of infants”.

<b>Questions</b>	<b>Bag and Mask</b>	<b>Tube and Mask</b>
Pictures for nonliterate populations	8/19 (42.1%)	3/4 (75%)
Few parts to assemble	15/19 (78.9%)	4/4 (100%)
Easy to clean	11/19 (57.9%)	2/4 (50%)
Other:	4/19 (21.1%)	2/4 (50%)
What features make it difficult to use?		
Instructions are difficult to read	5/14 (35.7%)	1/5 (20%)
No instructions for nonliterate populations	6/14 (42.9%)	1/5 (20%)
Too many parts to assemble	6/14 (42.9%)	0
Difficult to clean	8/14 (57.1%)	0
Tiring to use for more than a few minutes	5/14 (35.7%)	3/5 (60%)
Other	2/14 (14.3%)	3/5 (60%)
Is it easy to train someone how to use this device?		
Yes	17/19 (89.5%)	3/4 (75%)
No	2/19 (10.5%)	1/4 (25%)
Is the face mask provided usually the appropriate size for most newborns?		
Yes	9/19 (47.4%)	2/4 (50%)
No	10/19 (52.6%)	2/4 (50%)
Is the device easy to clean?		
Yes	12/18 (66.7%)	3/3 (100%)
No	6/18 (33.3%)	0
After cleaning the device are you confident that any/all bacteria and microbes have been removed and that it has not been damaged due to the cleaning process?		
Yes	7/18 (38.9%)	1/3 (33.3%)
No	11/18 (61.1%)	2/3 (66.1%)
Is the device easy to store?		
Yes	18/18 (100%)	3/3 (100%)
No	0	0
How long are these devices able to remain in good working condition?		
Less than 1 year	3/17 (17.6%)	0
1-5 years	12/17 (70.6%)	4/4 (100%)
More than 5 years	2/17 (11.8%)	0
Is the device easily accessible/easy to find when needed?		
Yes	14/17 (82.4%)	3/3 (100%)
No	3/17 (17.6%)	0
Do you have confidence that after long periods of nonuse, a previously used, cleaned, and stored device will work adequately?		
Yes	11/18 (61.1%)	2/3 (66.7%)
No	7/18 (38.9%)	1/3 (33.3%)
Do you have confidence that after long periods of		

Questions	Bag and Mask	Tube and Mask
nonuse, a previously used, cleaned, and stored device is safe during use? Yes No	10/18 (55.6%) 8/18 (44.4%)	3/3 (100%) 0
In your opinion, can health workers use the device easily and safely, without any refresher training, after long periods of nonuse? Yes No	7/17 (41.2%) 10/17 (58.8%)	1/2 (50%) 1/2 (50%)
Which features matter most to you when forming your overall opinion about the device?	Bag: 10/18 (55.6%) Mask: 12/18 (66.7%) Valve: 7/18 (38.9%) Other: 3/18 (16.7%)	Tube: 3/5 (60%) Mouthpiece: 2/5 (40%) Mask: 2/5 (40%) Valve: 2/5 (40%)
In general, which device do you prefer	17/19 (89.5%)	0 (0%)

As can be seen in Table 3 above, there is a clear preference for the bag and mask device over the tube and mask device. In fact, when asked which device they preferred, 89.5% (17/19) of respondents said they preferred the bag and mask. Overwhelmingly, the reasons given for preferring the bag and mask related to its ease of use and the fact that it does not physically burden the user. Respondents stated that the bag and mask was easier to use because it did not require bending forward for long periods of time, and that it was not too heavy. They also felt that the bag and mask device was a more effective method and safer for both the baby and the user. This was because respondents felt that there was little fear of contracting HIV with the bag and mask design.

The tube and mask design was liked for its simplicity and because it was small and portable. Respondents reported being fearful of contracting HIV with the tube and mask device. They also said that the tube and mask device was difficult to use because it requires the user to constantly bend forward and blow 30 to 40 times per minute, the infant is not visible during resuscitation, and because it is difficult to tell if the pressure being used is appropriate.

Respondents noted that it is difficult to use old bag and mask devices. They also noted that the bag and mask device requires skills to know how to place the mask over the infant's face properly, determine if they are using it correctly, and whether the bag is functioning correctly.

Several reasons about why the bag and mask device was not considered easy to clean were mentioned. First, respondents said that it was difficult to really get inside of the device to remove all of the bacteria and microbes, especially when cleaning supplies were unavailable at sites such as primary- and community-level health centers. Additionally, respondents noted complacency with cleaning techniques as a reason that residue builds up inside of the device as well as a misinterpretation of the importance of cleaning the device. This occurs because it is a noninvasive device, and many health care workers "forget" the importance of cleaning the device despite its use from baby to baby. In contrast, one respondent noted that

it was difficult to properly clean out the tube of the tube and mask design, and that the design allows some residue to remain inside the tube, even after cleaning.

Respondents mentioned a range of places for storing the bag and mask device. Two respondents mentioned that it was stored on the emergency cart or tray, covered by a clean cloth. Three respondents said it was stored either beside or on the resuscitation table in the delivery room, while nine respondents said it was stored either on a clean surface or in a cupboard in the delivery or emergency rooms. The same was largely true for the tube and mask device. When asked whether the devices were easily accessible or easy to find when needed, most respondents said that it depended heavily on where it is stored. One respondent noted that when the device was not readily available, (i.e., stored in a cabinet and not on a table or tray available at the time of need) precious moments were lost while health care workers found the device, fumbled with it, and prepared it for use. Another respondent noted that it depended heavily on the facility and whether or not it was prepared for emergencies. In low-resource settings, however, where several units may need to share devices, it could be difficult to find a device in a labor room as it is often stored in a nursery or emergency room.

After long periods of nonuse, previously used, cleaned, and stored devices may not be entirely ready for use. According to respondents, the deterioration of rubber in the bag and mask device may not allow the device to close correctly over the nose and mouth of the newborn, and the valve may get stuck or the bag may not inflate properly. The majority of respondents highly recommended checking the device before using it or entering into a delivery to ensure safety. They also suggested cleaning the device if it had not been used for long periods of time. Additionally, they recommended conducting practice sessions with either type of device prior to deliveries so health care workers can maintain proper techniques and skills for using the devices. The need for frequent refresher trainings was stressed in terms of ensuring safe and effective use of either device type.

Several improvements were suggested for both designs of resuscitators. One respondent said that the importance of having appropriate bag and mask sizes available for newborn and premature/low-birth-weight babies cannot be overemphasized as they are the ones that are not available when most needed. Several respondents noted that it would be good to have these different mask and bag sizes with the same device, sized for both newborns and premature babies. Automatic pop-off and auto-reinflatable devices for use with or without oxygen were also suggested. One respondent suggested designing a device that could be disinfected in the autoclave. Making masks out of materials that are more flexible and malleable that could be shaped to fit over newborn's nose and mouth was also suggested. Additionally, one respondent noted the need for a device that was manufactured in a developing country was very important, as it is very expensive to purchase devices that are manufactured in developed countries. These issues should be examined more closely in order to develop plans and modifications to improve resuscitator devices for use in developing-country settings.

Ease of use, size of the mask, and overall device function were the features that mattered most to those who had experience using bag and mask devices. Ease of use and availability

were the features that most mattered to those with experience using the tube and mask device.

### *Device Features: Disposability*

A total of 77.8% of respondents (14/18) did not think that a disposable resuscitator was feasible for developing countries, while 22.2% (4/18) thought it was feasible. The main two reasons why this was not considered feasible, according to respondents, were cost and supply issues. While most people felt that a disposable resuscitator might be a good idea in theory, they felt that the high cost associated with disposable goods would make it prohibitive for developing-country use. Given the competing priorities in health care budgets, many felt that it would be difficult to convince hospitals and other centers to purchase these devices. Additionally, most people were concerned with shortages and being “out of stock” when the device was needed. Some were also concerned about reuse issues, and that because many things are reused in developing countries, disposable resuscitators would be as well, making them dangerous and ineffective. Respondents felt that making a reusable device from easy to clean and higher quality materials and ensuring adequate training might overcome these barriers. The training should include information not only on how to use the device, but also how to care for it during and after use.

When asked to describe any advantages that might be attributable to disposable resuscitators, two issues rose to the top. First, because these resuscitators will be disposed of, there is no need to clean them, which is a major advantage in primary- or community-level health centers where there are often very few supplies to adequately clean or sterilize equipment. In turn, this would make them safer to use in terms of guaranteeing cleanliness and reducing the risk of cross-contamination between uses. Some respondents felt that a disposable device might actually be cheaper, thus reducing the costs for health centers and making it more affordable to primary and community health centers.

A total of 33.3% (6/18) thought a package containing a disposable resuscitator and a cloth for the infant’s shoulders would be very useful in developing countries, and 38.9% (7/18) thought it would be somewhat useful. In addition 27.8% (5/18) thought that it would not be useful whatsoever. Some felt that a cloth was not very useful as it is not used in most cases, while others felt that packaging them together would reduce panic and rushing to find one when needed. Most respondents were again concerned about the cost and felt that a disposable cloth would be wasteful and not very feasible. If such a package could be developed and made cost effective, it may have some advantages for developing-country use. In order to remain affordable to programs in developing countries, respondents noted that this type of package would need to cost between US\$0.50 and US\$5. Many people pointed out that because the cost will likely be passed on to the family, it should be as low as possible, even free.

Sixty percent (9/15) of respondents noted that the most likely user for this type of package would be TBAs at home births, followed by 53.3% (8/15) who felt that both nurses and midwives in primary care facilities and at home births would be the most likely to use this

package. Medical doctors in primary and tertiary care facilities were noted by 40% (6/15) of respondents as being the most likely to use this package.

### **Bench Testing of Neonatal Resuscitation Devices**

While specific bench testing results can be found in Appendices 2 through 6 and in the field guide, general results are presented here. In many cases, we did not find substantial differences between different resuscitators of one type (bag and mask or mouth-to-mask). However, specific problems with certain resuscitators were consistent amongst multiple users and can highlight both problems with these models as well as general problems that can exist with resuscitation devices.

- *Mask size:* In general, one mask was included with each resuscitator. Resuscitators that came designated for neonatal use included either a mask suitable for full term infants or for low-birth-weight infants (or both).
- *Mask type:* Two mask types were included with the evaluated resuscitators, (1) a round, silicone, one-piece mask with a soft flange to seal against the neonate's face or (2) a teardrop shaped "anatomical" mask with an air filled bladder as the interface. Both these mask types are used extensively and can provide a proper seal. Because of the materials and design, the silicone mask may be better for long-term use that includes disinfection (all resuscitators evaluated that are designed for multiple uses came equipped with a one-piece silicone mask).
- *Pressure relief valve:* All bag and mask resuscitators except the Blue Cross resuscitator came equipped with a pressure relief valve designed to open at 35–40 cm H<sub>2</sub>O pressure. Of the resuscitators equipped with a pressure relief valve, two were tested outside the normal recommended pressures (23 cm H<sub>2</sub>O and 50 cm H<sub>2</sub>O) which could create unsafe conditions or inadequate pressure during resuscitation.
- *Mask connections:* All resuscitators came with standard-sized mask connection ports that would permit exchange of masks of different sizes or from different suppliers.
- *Instructions:* Among the different manufacturers, instructions for use varied greatly in completeness and ease of reading. While some manufacturers included detailed instructions complete with performance specifications and guidelines for reuse, other manufacturers limited their instructions to a few simple instructional sentences printed on the packaging bag. Ease of reading scores also varied widely, typically more difficult levels were associated with the more detailed instructional inserts.
- *Maximum tidal volume:* Maximum tidal volumes, as measured by the instrumented test lung, ranged from 61 ml to 188 ml (without overriding the pressure relief valve). Because the average resuscitation volume is a fraction of these tidal volumes, all tested resuscitators are capable of delivering an appropriate volume of air for neonatal resuscitation.
- *Inspiratory and expiratory resistance:* All resuscitators evaluated met the ASTM standards for both inspiratory and expiratory resistance.
- *Maximum compressions per minute:* All resuscitators evaluated were capable of providing more than 200 compressions per minute; far above the desired breath rate

for resuscitation. Maximum resuscitation rate was not limited by the device but by the physical duration of the operator.

- *Cleaning after use:* In general, resuscitators were easily cleaned with simple rinsing and brushing. Vomit tends to stay on the mask side of the non-rebreathing (duckbill) valve located in the front portion of the resuscitator. This greatly limits the penetration into the main bag and limits the necessity of complete disassembly and cleaning.
- *Disinfection:* In general, disinfection with bleach did not seriously damage the resuscitators. The majority of damage that did occur was corrosion of the spring in the pressure relief valve. It is unknown if this could compromise the function of the valve over extended use.
- *Cleaning during use:* All resuscitators could be partially disassembled, rinsed, and reassembled in less than 30 seconds by a user who was familiar with the device.
- *Operation after immersion:* All resuscitators evaluated were operable after immersion in water.
- *Effect of vomit on operation:* All resuscitators evaluated were operable after contamination with simulated vomit and a simple rinsing.
- *High and low temperature operation:* Resuscitators designed for multiple uses demonstrated proper operation after both high and low temperature storage. Because of the use of silicone as the bag material, these resuscitators did not display any short- or long-term loss of operation. However, bag and mask devices designed for single use were fabricated with less expensive bag materials and demonstrated poor operation after cold storage due to a stiff bag. After thawing, proper operation of these resuscitators was restored.
- *Pressure and volume delivered during simulated use:* Both pressure and volume measurement varied significantly between different devices as well as between different users. While a test lung was used to help simulate the resistance and compliance of a “normal” resuscitation, users lacked typical visual cues to appropriate pressure and volume (chest rise). Both volumes and pressures varied greatly between users of one device—indicating that users could strongly influence the operation of the resuscitators. Unskilled users who were encouraged to observe a manometer during use were able to achieve consistent pressures despite their lack of experience. However, volumes delivered varied amongst both users and devices.
- *Breath rate:* Breath rate varied significantly between users based on the device, their training, and the duration of the resuscitation period. Breath rate during the evaluation of the mouth-to-mask devices was generally lower (in comparison to bag and mask devices) and users did not typically maintain the recommended 40–60 breaths per minute.
- *Ease of use and comfort:* Both ease of use and user comfort varied depending on both the type of device as well as the manufacturer. Both parameters are influenced by users’ previous experience, hand size, and stamina. In general, no resuscitators were judged as very difficult to use or uncomfortable.

- *Use consistency:* Most devices operated in a consistent fashion during the entire resuscitation period. Two devices that had noted problems were the Blue Cross resuscitator that did not provide an inspiration every time the bag was compressed and the PJ Dahlhausen resuscitator that required a rapid bag compression in order to achieve the desired pressure.
- *Disassembly and reassembly:* Ease of disassembly and reassembly varied depending on users' experience, manual dexterity, and the design of the resuscitator. Some resuscitators were better designed for disassembly with ridged surfaces to facilitate unscrewing, colored components to distinguish different parts, and properly sized components to limit excessive effort. Users often needed coaching in order to completely and correctly assemble or disassemble the resuscitators.

### **User Evaluation of Neonatal Resuscitation Devices**

A total of 10 skilled and 23 unskilled users participated in the user evaluation of devices. Skilled participants were either senior midwifery students (5/10) or practicing midwives (5/10), and were females ranging from 23 to 55 years of age with up to 30 years of midwifery experience. All participants had been trained in neonatal resuscitation using bag and mask equipment. Six of ten (60%) had used resuscitation equipment during a birth. Seven of ten (70%) had assisted during a resuscitation attempt. No demographic data were collected for unskilled users.

Overall device impressions were derived from a combined data set that incorporated qualitative feedback from both skilled and unskilled users during user evaluations. Summary impressions are reported below:

*Portex 1<sup>st</sup> Response:* In general, users felt that the bag was comfortable to use and easy to hold. The plastic was soft and responsive which limited fatigue and gave feedback on the amount of pressure applied.

Because it is designed as a single-use resuscitator, disassembly and reassembly is limited to removing and replacing the mask

*Blue Cross Resuscitator:* The resuscitator did not provide consistent respirations and participants frequently modified their resuscitation technique to accommodate and improve the performance of the resuscitator (i.e., rapid squeezing helped to ensure the operation). Users were aware of device malfunction, as there was no resistance felt in compressing the bag when the device was malfunctioning.

Participants commented that instructions would be needed to ensure complete disassembly and reassembly. During reassembly and disassembly, participants had difficulty reassembling the plastic ends into the bag and many did not remove the o-rings during disassembly.

*Laerdal Silicone Resuscitator:* Users' perceptions were variable on the usability—some found that the larger bag permitted more control while others indicated that the bag was too large and soft to get a good estimate of volume and pressure. With the mannequin used,

establishing a seal with the mask was more difficult than for other resuscitators and led to hand fatigue. The mask sometimes came out of the connector if the bag dropped below horizontal.

Some users commented that disassembly and assembly were difficult due to the device's complexity, while others indicated that the resuscitator was logically constructed, making the operations self-evident.

*Laerdal The Bag:* Users' perceptions were variable on the use of this resuscitator due to its large bag with a strap—some found the size and strap to be comfortable and give a sense of confidence, while others found the bag to be too large for their hands. Because it is designed as a single-use resuscitator, disassembly and assembly is limited to the mask and the pressure relief valve connector (two parts). However, for some participants, there was some confusion during reassembly.

*Kay and Company:* In general, participants indicated that the device was comfortable during use, but there was minimal feedback during use, and the bag required a full squeeze to achieve the desired resuscitation pressures. Fully squeezing the bag led to increased fatigue over longer periods of resuscitation.

Participants found that certain disassembly and assembly steps were difficult (removing and replacing back end of bag), and not all users completed disassembling the device without coaching.

*CPR-Pro Rescuer:* (Not evaluated by midwives.) Participants found that the resuscitator performed better than other similar resuscitators due to better bag resistance and greater responsiveness.

Because it is designed as a single-use resuscitator, disassembly and assembly are limited to removing and replacing the mask.

*BLS Systems:* Participants found this resuscitator to be relatively easy to use and comfortable. Several participants that resuscitated in a sitting position noted arm fatigue after two minutes of use.

Disassembly and assembly was straightforward for most participants. However, reassembling the back end was noted as difficult and removal of the pressure relief valve was not always evident.

*PJ Dahlhausen:* Participant's responses were variable—some found the bag to be comfortable and providing good feedback. Other participants felt the bag material was too firm and that rapid, short squeezes were necessary to generate the desired pressure.

Disassembly required coaching and some participants found the back end difficult to remove and reassemble. One participant found that the front valve threads also fit in the back end—potentially leading to confusion or misassembly.

*Topster:* (Not evaluated by midwives.) Participants found use straightforward and comments were limited. One trained user indicated that there was not a good sense of resistance during use.

Disassembly and reassembly required a little coaching and participants found that the back end was difficult to reassemble.

*Tekno tube and mask design:* Participants found use straightforward and easy to learn—potentially easier than bag and mask resuscitators. However, maintenance of the proper rate was difficult due to fatigue and accumulation of saliva. Some users clamped mouthpiece in mouth while others used their hand to hold it up to their lips.

Disassembly and assembly was straightforward and required minimal instruction.

*Hospitak/Unomedical Mouth to Mask:* Participants found use straightforward but fatiguing. While some found it was easier to control the pressure than with a bag and mask, others found the quantity of air to be more subjective and the rate to be inconsistent. Participants noted that use of the tube and mask requires full attention, and it is difficult to give instructions or monitor other activities while resuscitating.

Disassembly and assembly are limited to removal and replacement of the mask.

*Skilled User Feedback*

A nominal group ranking exercise was conducted with skilled users only. The device rankings from most to least preferred device are presented below:

**Table 4. Device Ranking and Comments From Skilled Users Only**

Device Ranking <sup>††</sup>	Name of Device	User Comments
1	Kay and Company	Liked texture and size of device; bad shape to fit hand
2	Laerdal The Bag	Bag too big; liked feel of bag material, hard to hold mask on face to get good seal
3	CPR-Pro Rescuer	A favorite one, good shape to fit hand but nobody actually used device
4	P.J. Dahlhausen	Liked it but hard to give enough pressure
5	BLS Systems Portex 1 <sup>st</sup> Response (bag and mask)	Bad shape to fit hand (Portex)
6	Tekno Hospitak/Unomedical Laerdal Silicone Resuscitator	Best of tube and mask design; like flat mouth piece (Hospitak) Hard to hold mask on face to get good seal; round mouth piece not ergonomic (Tekno)

<sup>††</sup> Listed in order of selection by more people as the preferred options. Device #2 “Blue Cross” was not selected by any participant. One participant said the device seemed “scary.”

Two focus group discussions about device preferences and features were also conducted with skilled users. Participants were able to provide generalized impressions about the usefulness of each type of resuscitator design, as follows:

*Bag and mask design:* All focus group discussion participants preferred this design over the tube and mask design. Specific comments related to the importance of how the mask attaches to the bag and the size of the bag itself.

“I think how the mask attaches to the bag is really important. Some of them are just \_\_\_ with no little ridges or anything. And other ones have ridges like this to make it a more secure connection.” [FGD #2]

“Just the size of the bag makes a huge difference. The one that had a huge bag on it just gave you more pressure than you want.” [FGD #2]

[The size of the bag should be] “Not too big but you need it big enough to get the pressure.” [FGD #1]

Several participants also noted that the arm holding the bag got tired when performing the five minute user test.

*Tube and mask design:* Focus group participants discussed many aspects of the tube and mask design. For the most part, participants felt that the tube and mask design would be less preferable than the bag and mask design for the following reasons:

- Having to stop and swallow and wipe your mouth when using the device or blow some small amount of saliva into the tube at the same time as breathing into it.
- Difficult to keep your body in position (i.e., hunched over) while conducting resuscitation for a long period of time.
- Not being able to verbalize during resuscitation and not being able to stop and communicate information with someone.
- Not being able to keep a fast enough rate of breaths per minute.
- Not being able to monitor the mother.
- Not being in an optimal position to see the chest rise on the baby.
- Not being able to maintain a consistent rate without getting more exhausted than seems necessary.

The inability to verbalize while using the tube and mask design was identified as a major challenge when using the device by several participants. For example:

“Especially if you’re the only attendant and his mother has just given birth, who knows what is happening with her you know. You need to be able to talk to someone else or talk to her. You need to tell her what is going on or tell her what to do. I feel like using your voice is really important to them.” [FGD #2]

Focus group participants identified one feature that they particularly liked about the tube and mask design. They liked the flexibility of being able to adjust their breath as needed which is more akin to mouth-to-mouth resuscitation.

“You are actually using your own body to breathe the baby, you can feel the resistance. You know, you are really having to push in a way that you don’t with the bag and mask so maybe they are more intuitive in a certain way since you have a more direct connection to the baby and what is actually going on. Are they getting air or not?” [FGD #1]

“But I just feel the tubes are more intuitive as you are literally putting your own breath into the baby, like you would do if you were doing CPR. . . . [With a bag and mask] if you are not good at looking at chest rise, you can not get the sense that there is air going in.” [FGD #1]

Other positive aspects of the tube and mask design were also mentioned. One participant stated that she thought it would not be difficult to learn how to use the tube and mask design as there “is no learning curve.” Several participants noted that the ease of assembly and disassembly and cleaning was much greater for tube and mask devices than for bag and mask devices. Participants suggested that it might be helpful to include the following in device instructions: (1) a diagram of all the parts of the tube and mask device and (2) instruction on how to regulate your breathing pattern without hyperventilating (e.g., one participant used a nose breathing pattern very successfully).

Since none of the focus group discussion participants had used a tube and mask device before, they hypothesized about how it would be to conduct a resuscitation using a tube and mask design. In addition to the challenges mentioned above, they identified other possible pitfalls as described below:

“But on the other hand, I could take one hand off the device and feel the cord stump. So that would be good information. The other thing I was just thinking about just now, is that, if you were to need chest compressions, I don’t know if it would be harder or easier with one of those long tubes. I would just throw it down and pick up the baby and do mouth to mouth if I needed to do chest compressions. Because I have done that before.” [FGD #1]

A couple of participants also stated that the tubes appeared flimsy as if they would get holes in them and that they did not think that they would be durable.

## **Discussion**

We believe that this investigation into neonatal resuscitator devices yielded important information regarding how devices are used in low-resource settings and the positive and negative aspects of device designs and models. A limitation to these investigations is that they were not designed to be representative and are subject, therefore, to selection bias. For example, a minority of participants in the expert opinion survey was composed of nurses (11%) or midwives (16%). A further limitation of the expert opinion survey was that it did not reach an adequate number of practitioners who had experience using the tube and mask

design. The overwhelming preference for the bag and mask design may be due to a lack of familiarity with other types of designs such as the tube and mask.

Nevertheless, the preference for bag and mask design was echoed by participants in the user evaluation. Skilled user impressions could be influenced by the fact that all had been trained and certified in resuscitation techniques using a bag and mask design. In addition, skilled and unskilled users who participated in the study may not be representative of developing-country practitioners or those thoroughly familiar with the context of use of resuscitator devices in low-resource settings.

Although the bench evaluation of various devices was not hampered by these types of limitations, other limitations to the bench evaluation are important to note. For instance, PATH technical staff with a working knowledge of standard cleaning and disinfection methods and with experience in disassembling and reassembly of complex devices performed the cleaning evaluations. This staff experience may not reflect the usual experience of the typical resuscitator user. The test lung used in the bench evaluation was set with specific compliance and resistance parameters based on current literature and after technical discussions with persons experienced in neonatal resuscitation. However, the test lung parameters may not have accurately reflected “realistic” resuscitation conditions. Further, the bench evaluation was conducted by technicians without actual resuscitation experience.

## **Conclusions**

In general, the bag and mask devices were used by more practitioners and in more places than the tube and mask design. The bag and mask device was preferred by skilled and unskilled users as well as by neonatal experts. In general, the tube and mask device was not well known; when the tube and mask device was evaluated by users it was considered less functional than the bag and mask design. Disposable devices were not recommended by either neonatal experts or skilled users.

Results from the expert opinion survey indicated that the device features that mattered most for the bag and mask device were ease of use, size of the mask, and overall device function. Features of most concern with the tube and mask device were ease of use and availability. Also, a need for frequent refresher training and practice using resuscitation devices among all groups of health care workers was identified. Device readiness at births and use of devices that have not been used for a long period of time were issues of concern among many; such issues could be addressed in refresher trainings. Appropriately sized devices, especially those that could be used with preterm and low-birth-weight infants, was identified as an additional need. Concern about potential HIV transmission with the use of the tube and mask device was noted by several respondents and is an issue that warrants further exploration.

Several specific design recommendations for neonatal resuscitators were identified. We believe that these features will help ensure safe and proper operation among the greatest variety of users. They include:

- Standard connections in order to permit procurement of masks of different sizes and from different manufacturers.
- Pressure relief valve to limit the possibility of lung trauma in the neonate.
- Properly sized and form-fitting mask in order to increase the likelihood of quickly establishing a good facial seal on the neonate.
- Properly sized bag that can deliver an appropriate volume without excessive attention by the user and that fits the target users' hands.
- Design features (e.g., ridged surfaces, large screw threads) that assist with disassembly and reassembly of device for proper cleaning and disinfection.
- Complete instructions, including a diagram for assembly or disassembly, that are written at a reading level appropriate for the target audience. Instructions on how to establish an optimal breathing pattern for use with tube and mask designs was also suggested.

It is important to note that this device evaluation was not exhaustive; in other words, it did not include all neonatal resuscitator devices available currently on the global market. The devices that were evaluated were included in the evaluation because the manufacturer responded to our inquiries about device procurement and because they were representative of a specific design type (i.e., bag and mask or tube and mask). Thus, it would not be prudent to use this device evaluation as the basis for recommendations relating to global best practices for neonatal resuscitation device use. Rather, further research could be undertaken to strengthen the evidence base by assessing feedback from users in a variety of developing countries.

The outcomes of this research will be used to develop a “Practical Selection of Neonatal Resuscitators—A Field Guide.” It is anticipated that this guide will be helpful for policymakers and program implementers when making a decision about what type of resuscitation device is most appropriate for their neonatal health program. The field guide contains reviews of 11 currently available resuscitators and provides information and ratings for each of them in a concise and easy-to-read format. Information about the device features that count, resuscitation parameters, laboratory evaluations, user feedback and usability are included for each device.

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## Appendix 1: Expert Opinion Survey Instrument

### Neonatal Resuscitator Device Expert Group Survey Questionnaire

Welcome! We appreciate that you are taking time to complete our survey on neonatal resuscitators in developing countries. Please note that all questions in this survey refer to non-invasive resuscitation devices such as bag and mask or tube and mask designs (see pictures below) and *not* to endotracheal intubation or oropharyngeal suction. Your answers to these questions are anonymous; we are not able to link your name to your e-mail address. We expect that it will take about 30-60 minutes to complete this questionnaire.

#### Context of Use

1. Have you used a neonatal resuscitator device in a developing country?

Yes

No

If YES, please tick all scenarios of use that you have experienced:

In tertiary care facility (provincial or national referral hospital)

In secondary care facility (i.e., first referral level facility such as District Hospital or other facility that has access to minimal amount of neonatal technologies and at least intermittent electricity)

In primary care facilities such as health centers or village-level care facilities

At home birth

Other, please specify \_\_\_\_\_.

2. Have you observed other health care workers using a neonatal resuscitator in a developing country?

Yes

No

If YES, please tick all scenarios of use that you have observed:

By medical doctors in tertiary care facility

By nurses in tertiary care facility

By medical doctors in secondary care facility

By nurses in secondary care facility

By midwives in secondary care facility

- \_\_\_ By medical doctors in primary care facility
- \_\_\_ By nurses in primary care facility
- \_\_\_ By midwives in primary care facility
- \_\_\_ By traditional birth attendants in primary care facility

- \_\_\_ By midwives at home birth
- \_\_\_ By traditional birth attendants at home birth

\_\_\_ Other, please specify \_\_\_\_\_.

3. In your opinion, how often are neonatal resuscitators used in the following scenarios (please tick one box for each row)?

	Never	Rarely (less than 1 time/year)	Somewhat Common (1-3 times/year)	Common (at least 1 time/quarter)	Very Common (at least 1 time/month)
By medical doctors in tertiary care facility					
By nurses in tertiary care facility					
By medical doctors in secondary care facility					
By nurses in secondary care facility					
By midwives in secondary care facility					
By traditional birth attendants in secondary care facility					
By medical doctors in primary care facility					
By nurses in primary care facility					
By midwives in primary care facility					
By traditional birth attendants in primary care facility					
By midwives at home birth					
By traditional birth attendants at home birth					

**Context of Training**

4. Have you trained others in the use of a neonatal resuscitator device in a developing country?

Yes

No

If YES, please tick all that apply:

With medical doctors in tertiary care facility

With nurses in tertiary care facility

With medical doctors in secondary care facility

With nurses in secondary care facility

With midwives in secondary care facility

With medical doctors in primary care facility

With nurses in primary care facility

With midwives in primary care facility

With traditional birth attendants in primary care facility

With midwives at home birth

With traditional birth attendants at home birth

Other, please specify\_\_\_\_\_.

5. Do you believe that **medical doctors** who are trained to use the device have confidence in their abilities to use the device accurately and safely?

Yes

No

Why or why not?\_\_\_\_\_.

6. Do you believe that **nurses** who are trained to use the device have confidence in their abilities to use the device accurately and safely?

Yes

No

Why or why not?\_\_\_\_\_.

7. Do you believe that **trained midwives** who are trained to use the device have confidence in their abilities to use the device accurately and safely?

Yes

No

Why or why not? \_\_\_\_\_.

8. Do you believe that **traditional birth attendants** who are trained to use the device have confidence in their abilities to use the device accurately and safely?

Yes

No

Why or why not? \_\_\_\_\_.

9. In your experience, how often is refresher training about safe and correct use of neonatal resuscitators conducted with health care providers?

Once per year

2-3 times per year

4 or more times per year

Monthly

Other \_\_\_\_\_.

**Device Readiness**

10. In your experience, what types of neonatal resuscitators are currently being used by health care workers who attend births (please tick all that apply)?

	Tertiary care facility	Secondary care facility	Primary care facility	In the home
Bag and mask				
Tube and mask				
Other, specify _____				

11. In general, is the neonatal resuscitator available and ready (i.e., prepped and available with the other equipment that will be needed at delivery) for all deliveries or only when needed?

It is available and ready for all deliveries

It is available and ready for deliveries when a complication is anticipated

Other \_\_\_\_\_.

12. Do you believe that use of neonatal resuscitators in the home or in a primary care facility setting is acceptable to community members?

Yes

No

Why or why not? \_\_\_\_\_.

### **Bag and Mask: Device Features**

13. Do you have experience using **bag and mask devices**?

Yes

No

If NO, skip to Question 33.

14. How many newborns have you resuscitated effectively with **bag and mask devices**?

None

1-4

5-20

21 or more

Other \_\_\_\_\_.

15. How many newborns have you seen other health care workers resuscitate effectively with **bag and mask devices**?

None

1-4

5-20

21 or more

Other \_\_\_\_\_.

16. Overall, is a **bag and mask device** easy to use for newborn resuscitation?

Yes

No

17. Is the **bag and mask device** easy to assemble and disassemble for cleaning without written instructions?

Yes

No

18. What features of the **bag and mask device** make it easy to use?

Clear instructions that are easy to read

Pictorial instructions for non-literate populations

Few parts to assemble

Easy to clean

Other \_\_\_\_\_.

19. What features of the **bag and mask device** make it difficult to use?

Instructions are difficult to read

No instructions for non-literate populations

Too many parts to assemble

Difficult to clean

Physically tiring to use for more than a few minutes

Other \_\_\_\_\_.

20. Is it easy to train someone how to use a **bag and mask device**?

Yes

No

21. Is the face mask usually provided the appropriate size for most newborns?

Yes

No

22. Is the **bag and mask device** easy to clean?

Yes

No, why not? \_\_\_\_\_.

23. After cleaning the **bag and mask device**, are you confident that any/all bacteria and microbes have been removed and that it has not been damaged due to the cleaning process?

Yes

No, why not? \_\_\_\_\_.

24. Is the **bag and mask device** easy to store?

Yes

No, why not? \_\_\_\_\_.

25. Where is the **bag and mask device** normally stored?\_\_\_\_\_.

26. How long are these **bag and mask devices** able to remain in good working condition?

\_\_\_ Less than 1 year

\_\_\_ 1-5 years

\_\_\_ More than 5 years

27. Is the **bag and mask device** easily accessible/easy to find in case it is needed?

\_\_\_ Yes

\_\_\_ No, why not?\_\_\_\_\_.

28 Do you have confidence that, after long periods of non-use, a previously used, cleaned and stored **bag and mask device** will work adequately?

\_\_\_ Yes

\_\_\_ No, why not?\_\_\_\_\_.

29. Do you have confidence that, after long periods of non-use, a previously used, cleaned and stored **bag and mask device** is safe during use?

\_\_\_ Yes

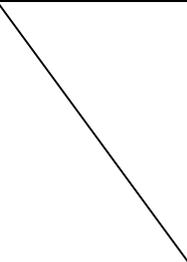
\_\_\_ No, why not?\_\_\_\_\_.

30. In your opinion, can health workers use the **bag and mask device** easily and safely, without any refresher training, after long periods of non-use?

\_\_\_ Yes

\_\_\_ No, why not?\_\_\_\_\_.

31. Please comment on the following device features (put the number that corresponds to your opinion in each box):

	Please rate how well you LIKE this feature (explain why) 1 =Dislike a lot 2=Dislike somewhat 3=Neither like nor dislike 4=Like somewhat 5=Like very much	Please rate how IMPORTANT this feature is to successful resuscitation (explain why) 1 =Not important at all 2=Somewhat important 3= Very important 4=No opinion	Suggested IMPROVEMENTS to feature (please specify)
Bag			
Mask			
Valve			
Overall device			
Other, specify: _____			

32. Which features noted above matter most to you when forming your overall opinion about the bag and mask device?

- \_\_\_ Bag
- \_\_\_ Mask
- \_\_\_ Valve
- \_\_\_ Other, specify: \_\_\_\_\_.

**Tube and Mask (or Mouth and Mask): Device Features**

33. Do you have experience using tube and mask devices?

- \_\_\_ Yes
- \_\_\_ No

If NO, skip to Question 53.

34. How many newborns have you resuscitated effectively with **tube and mask devices**?

- None
- 1-4
- 5-20
- 21 or more
- Other \_\_\_\_\_.

35. How many newborns have you seen other health care workers resuscitate effectively with this **tube and mask device**?

- None
- 1-4
- 5-20
- 21 or more
- Other \_\_\_\_\_.

36. Overall, is this **tube and mask device** easy to use for newborn resuscitation?

- Yes
- No

37. Is the **tube and mask device** easy to assemble and disassemble for cleaning without written instructions?

- Yes
- No

38. What features of the **tube and mask device** make it easy to use?

- Clear instructions that are easy to read
- Pictorial instructions for non-literate populations
- Few parts to assemble
- Easy to clean
- Other \_\_\_\_\_.

39. What features of the **tube and mask device** make it difficult to use?

- Instructions are difficult to read
- No instructions for non-literate populations
- Too many parts to assemble
- Difficult to clean

Physically tiring to use for more than a few minutes  
 Other \_\_\_\_\_.

40. Is it easy to train someone how to use this **tube and mask device**?

Yes  
 No

41. Is the face mask the appropriate size for most newborns?

Yes  
 No

42. Is the **tube and mask device** easy to clean?

Yes  
 No, why not? \_\_\_\_\_.

43. After cleaning the **tube and mask device**, are you confident that any/all bacteria and microbes have been removed and that it has not been damaged due to the cleaning process?

Yes  
 No, why not? \_\_\_\_\_.

44. Is the **tube and mask device** easy to store?

Yes  
 No, why not? \_\_\_\_\_.

45. Where is the **tube and mask device** normally stored?

\_\_\_\_\_.

46. How long are these **tube and mask devices** able to remain in good working condition?

Less than 1 year  
 1-5 years  
 More than 5 years

47. Is the **tube and mask device** easily accessible/easy to find in case it is needed?

Yes  
 No, why not? \_\_\_\_\_.

48. Do you have confidence that, after long periods of non-use, a previously used, cleaned and stored **tube and mask device** will work adequately?

\_\_\_ Yes

\_\_\_ No, why not? \_\_\_\_\_.

49. Do you have confidence that, after long periods of non-use, a previously used, cleaned and stored **tube and mask device** is safe during use?

\_\_\_ Yes

\_\_\_ No, why not? \_\_\_\_\_.

50. In your opinion, can the **tube and mask device** be used easily and safely, without any refresher training, after long periods of non-use?

\_\_\_ Yes

\_\_\_ No, why not? \_\_\_\_\_.

51. Please comment on the following device features (put the number that corresponds to your opinion in each box):

	Please rate how well you LIKE this feature (explain why) 1 =Dislike a lot 2=Dislike somewhat 3=Neither like nor dislike 4=Like somewhat 5=Like very much	Please rate how IMPORTANT this feature is to successful resuscitation (explain why) 1 =Not important at all 2=Somewhat important 3= Very important 4=No opinion	Suggested IMPROVEMENTS to feature (please specify)
Tube			
Mouthpiece			
Mask			
Valve			
Overall device			
Other, specify: _____			

52. Which features noted above matter most to you when forming your overall opinion about the tube and mask type of device?

- Tube
- Mouthpiece
- Mask
- Valve
- Other, specify: \_\_\_\_\_.

53. In general, which type of device do you prefer to use?

- Bag and mask
- Tube and mask or mouth and mask
- Other, specify: \_\_\_\_\_.

**Device Features: Disposability**

54. Do you think that a disposable resuscitator is feasible for use in developing countries?

- Yes
- No, why not? \_\_\_\_\_.

55. What are the main advantages of a disposable resuscitator for developing country use?

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56. What are the main disadvantages of a disposable resuscitator for developing country use?

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57. How useful do you think a package containing a disposable resuscitator and a cloth to put under the infant's shoulders would be for developing country use?

- Very useful
- Somewhat useful
- Not useful at all

Why? \_\_\_\_\_.

58. What would be the most such a package could cost and still be affordable to the programs where you work?

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59. What would be the most likely scenario of use for such a package?

By medical doctors in tertiary care facility

By nurses in tertiary care facility

By medical doctors in secondary care facility

By nurses in secondary care facility

By midwives in secondary care facility

By medical doctors in primary care facility

By nurses in primary care facility

By midwives in primary care facility

By traditional birth attendants in primary care facility

By midwives at home birth

By traditional birth attendants at home birth

All of the above

Other, please specify \_\_\_\_\_.

**Respondent Background**

Now, please tell us a bit about yourself:

60. Where do you conduct the majority of your work related to neonatal health?

North America/Europe

Latin America and the Caribbean

South Asia

Southeast Asia

Sub-Saharan Africa

North Africa/Middle East

Global

61. What is your professional status (check all that apply)?

Medical doctor

Nurse

Midwife

Public health (MPH or other relevant degree)

Other \_\_\_\_\_.

62. What is your primary job classification?

Health care delivery

Research

Program planning or implementation

Policy

Other \_\_\_\_\_.

63. Please share any other comments or thoughts you have about neonatal resuscitator devices and/or their use in developing countries:

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THANK YOU VERY MUCH for your participation!

## Appendix 2: Technical Review Summary by PATH Design Staff

### Portex 1<sup>st</sup> Response

- Anatomical mask may provide for better sealing.
- Flexible connection between bag and valve body requires two hands to resuscitate (cannot provide mask pressure using bag).
- Molded instructions will not wear off, but they are hard to see.
- Device cannot be disassembled but may permit rinsing without disassembly.

### Blue Cross

- Device does not incorporate a pressure relief valve to limit the pressure provided to the infant.
- Simple design without extra components is good for novice user.
- Size of bag may be difficult for users with small hands.
- Lanyard ring may tear bag with use.
- Two-piece mask can be difficult to assemble—especially if wet.
- Spring (that controls valve operation) may rust with extended use.
- Mask pieces may be differently affected by chemical disinfection and affect reassembly.
- Two-piece mask may hold contaminants more than one-piece masks.

### Laerdal Silicone Resuscitator

- Interface between mask and valve body is too tight—mask cannot seat fully and can easily become dislodged during use.
- Visualization of duckbill valve through the top of the valve body may help the user confirm proper operation.
- Size of bag may be difficult for users with small hands.
- Clear bag can help user confirm cleanliness before use.

### Laerdal The Bag

- Strap may help user hold bag during long periods of resuscitation.
- Size of bag may be difficult for users with small hands. In inexperienced users, large bag may lead to higher tidal volumes.

### Kay and Company

- Mask can slip from valve body during use.
- Flexible connection between bag and valve body requires two hands to resuscitate (cannot provide mask pressure using bag).
- Smaller bag may be appropriate for users with smaller hands.
- Can lock pressure relief valve—valve position is not clear to user.

### CPR-Pro

- May be able to use the device with one hand due to increased rigidity between the valve body and bag.

### BLS Systems

- Can lock pressure relief valve—valve position is not clear to user.
- Yellow tint of hard plastic components makes the device look aged or reprocessed.

### PJ Dahlhausen

- Ridges on mask stem allow it to seat fully in the valve body and help prevent the mask from dislodging during use.
- Visualization of duckbill valve through the top of the valve body may help the user confirm proper operation.
- Pressure relief valve cannot be locked.
- Bag size and shape may allow user to use all four fingers and limit fatigue.

### Topster

- Ridges on mask stem allow it to seat fully in the valve body and help prevent the mask from dislodging during use.
- Visualization of duckbill valve through the top of the valve body may help the user confirm proper operation.
- No indication on pressure relief valve.

### Appendix 3: Technical Characteristics of the Resuscitator Devices

Manufacturer/Name	Tidal Volume	Max Compressions per minute	Pressure Limiter (absolute max and range)	Pressure Limiter @ 15 L/min	Inspiratory Resistance @ 5L/min	Expiratory Resistance @ 5L/min
Portex 1 <sup>st</sup> Response Infant Manual Resuscitator Ref: 8527MPB	105 ml	258	44–49	36	0	0
Blue Cross Resuscitator	182 ml	222	83–120	N/A	0	0
Laerdal Silicone Resuscitator	125 ml (304 ml with pressure relief valve in)	246	36–40	32	0	0
Laerdal The Bag, Infant	188 ml (708 ml)	259	42–46	§§	0	0
Kay and Company Artificial Resuscitator	109 ml (122 ml)	251	45–46	50	0	1
CPR-Pro	185 ml (203 ml)	268	49–54	38	0	0
BLS Systems Manual Resuscitator	153 ml	263	42–46	36	0	0
P.J. Dahlhausen & Co. Infant Resuscitator Set	61 ml (135 ml)	266	31–42	23	0	0
Topster SR-003	94 ml (132 ml)	278	41.0–62.69	42	0	1
AMBU Infant Resuscitator				40	1	1
Portex Safe Response Mouth-to-Mask Resuscitator						
Portex Safe Response Pocket Mask						
Tekno						
Hospitak/Unomedical						

§§ Leak around back seal caused air leakage and prevented the pressure-relief valve from activating at the standard flow rate.

## Appendix 4: Resuscitator Components

Manufacturer/Name	Mask	Included Components	Features	Packaging
Portex 1 <sup>st</sup> Response Infant Manual Resuscitator Ref: 8527MPB	Anatomical air-filled. Clear hard plastic top.	Infant and neonatal masks, Positive end-expiratory pressure (PEEP) valve, oxygen reservoir bag and oxygen tubing connector	Pressure-limiting valve covers Single use—cannot be disassembled	Plastic zip-lock bag with printed instructions (printed on bag)
Blue Cross Resuscitator	Round two-piece. Opaque silicone face piece, clear hard plastic top.	Open end oxygen reservoir (tube)		Plastic zip-lock bag inside cardboard box
Laerdal Silicone Resuscitator	Round one-piece silicone.	Oxygen reservoir bag	Pressure-limiting valve (35 cm H <sub>2</sub> O)	Plastic zip-lock bag inside cardboard box
Laerdal The Bag, Infant	Anatomical air-filled with refillable bladder. Clear plastic hard top.	Oxygen reservoir bag and tubing connector	Pressure-limiting valve (40 cm H <sub>2</sub> O) Single use—cannot be disassembled	Disposable plastic bag
Kay and Company Artificial Resuscitator	Round one-piece silicone. Light green.	Oxygen reservoir bag and tubing connector	Pressure-limiting valve	Nylon bag with drawstring and instructions (printed on bag) inside cardboard box
CPR-Pro	Anatomical air-filled. Clear hard plastic top.	Oxygen reservoir bag and tubing connector	Pressure-limiting valve	Plastic drawstring bag inside cardboard box
BLS Systems Manual Resuscitator	Round one-piece silicone.	Oxygen reservoir bag and tubing connector	Pressure-limiting valve	Plastic drawstring bag
P.J. Dahlhausen & Co. Infant Resuscitator Set	Round one-piece silicone. Two silicone face masks included (sizes 0 & 1).		Pressure-limiting valve	Disposable box inside cardboard box
AMBU Infant Resuscitator				
Portex Safe Response Mouth-to-Mask Resuscitator	Child-sized anatomical mask		In-line filter	Disposable plastic bag
Portex Safe Response	Adult sized anatomical mask		In-line filter	

<b>Manufacturer/Name</b>	<b>Mask</b>	<b>Included Components</b>	<b>Features</b>	<b>Packaging</b>
Pocket Mask				
Tekno	Round two-piece. Opaque silicone face piece, clear hard plastic top.			Disposable plastic bag
Hospitak/Unomedical	Anatomical air-filled with refillable bladder.		In-line filter	Disposable plastic bag
Topster SR-003	Round one-piece mask	Oxygen reservoir bag, tubing connector, and 40, 50, 60 mm airways	Pressure-limiting valve	Plastic hard case with handle

## Appendix 5: Functional Evaluation Data Summary

### Neonatal Resuscitator Functionality During Simulated Use Situations

#### Effect of vomit on device function

Device	Effect of Vomit	Operation After Immersion	Cleaning After Use	Cleaning During Use	Disinfection	Operation After Exposure to and Storage at High and Low Temperatures
Portex 1 <sup>st</sup> Response	Functional, no penetration past rebreathing valve. Rinsed clean with agitation.	Yes, water in bag.	Clean with minimal effort. Brushing not applicable since device cannot be disassembled.	< 30 seconds	Some rust on spring. Device and relief valve operational.	Cold: not functional until bag warmed. Hot: fully functional.
Blue Cross	Functional, no penetration past rebreathing valve. Rinsing eliminated vomit except in mask; further rinsing cleared mask.	Yes, no water in bag.	Clean with minimal brushing required. Difficult to open valve body. Difficult to reassemble mask.	< 30 seconds (did not disassemble mask)	Significant rust on spring and discolored pink valve component. Device still operational.	Cold: fully functional. Hot: fully functional.
Laerdal Silicone	Functional, no penetration past rebreathing valve. Rinsing eliminated vomit except in mask flange.	Yes, water in bag that could be cleared with shaking.	Clean with minimal effort. Mask requires extra attention to ensure cleanliness. Serrations assist with disassembly but can trap contaminants.	< 30 seconds	No damage to spring. Device operational.	Cold: fully functional. Hot: fully functional.
Laerdal The Bag	Functional, no penetration past rebreathing valve. Rinsing eliminated vomit except some remaining on rebreathing valve.	Yes, water in bag.	Clean except for rebreathing valve. Difficult to access valve, some residual still present after cleaning.	< 30 seconds	Run on spring. Device and relief valve operational.	Cold: bag not functional. Mask fitting loose. Hot: fully functional.
Kay and Company	Functional, no penetration past rebreathing valve. Rinsing eliminated vomit except in mask flange.	Yes, water in bag.	Clean with minimal effort. Easy to disassemble. Clear body permits easy visualization of interior.	< 30 seconds	No damage to spring. Device operational.	Cold: fully functional. Hot: fully functional.

<b>Device</b>	<b>Effect of Vomit</b>	<b>Operation After Immersion</b>	<b>Cleaning After Use</b>	<b>Cleaning During Use</b>	<b>Disinfection</b>	<b>Operation After Exposure to and Storage at High and Low Temperatures</b>
CPR- Pro	Functional, no penetration past rebreathing valve. Could not disassemble.	Yes, water in bag.	Clean but cannot disassemble. Water removed from bag and valve through shaking and squeezing the bag.	< 30 seconds	No damage to spring. Device operational.	Cold: not functional until bag warmed. Hot: fully functional.
BLS Systems	Functional, no penetration past rebreathing valve. Rinsing eliminated vomit except in valve flange.	Yes, water in bag.	Clean with minimal effort. Clear body permits easy visualization of interior.	< 30 seconds	No damage to spring. Device operational.	Cold: fully functional. Hot: fully functional.
PJ Dahlhausen	Functional, no penetration past rebreathing valve. Rinsing eliminated vomit.	Yes, water in bag.	Clean with minimal effort.	< 30 seconds	No damage to spring. Device operational.	Cold: fully functional. Hot: fully functional.
Tekno	Vomit limited to mask side—fully functional. Rinsing eliminated vomit.		Clean with minimal effort. Disassembly is minimal.	< 30 seconds (did not disassemble mask)	Operational. No apparent damage to valve.	Cold: fully functional. Hot: fully functional.
Hospitak/Unomedical	Vomit limited to mask side—fully functional. Rinsing eliminated vomit. Filter appears dry after rinsing.		Clean with minimal effort. Disassembly is minimal.	< 30 seconds	Operational. Filter is soaked; functionality unknown.	Cold: not functional due to frozen filter (wet from reprocessing). Hot: fully functional.
Laerdal Pocket Mask	Vomit pours out of valve. Rinsing eliminated vomit.		Clean with minimal effort.	< 30 seconds		Cold: fully functional. Hot: fully functional.
Topster	Functional, no penetration past rebreathing valve. Rinsing worked very well to eliminate vomit.	Yes, water in bag.	Clean with minimal effort. Smoke colored plastic is difficult to see through.	< 30 seconds		Cold: fully functional. Hot: fully functional.

## Appendix 6: Neonatal Resuscitator Instructions

### **Portex 1<sup>st</sup> Response**

Complete instructions printed on plastic, zip-lock bag. The Portex 1<sup>st</sup> Response is intended for use with patient with a body mass up to 10 kg. The Portex 1<sup>st</sup> Response is labeled for single use and does not include instructions for reprocessing or reuse. Separate instructions are included with the PEEP valve. The instructions also include a section on technical specifications that gives specifications such as dead space, maximum stroke volume, operating environmental limits, and attainable delivery pressures. Instructions include a line drawing with part callouts. Instructions include information about the pressure-limiting valve and include instructions to verify operation.

Flesch Reading Ease for use instructions only):

Words: 360

Syllables: 600

Sentences: 28

Ave word length: 1.67

Ave sentence length: 12.86

Score: 52.5 (Fairly difficult—High School)

### **Blue Cross Silicone Infant Resuscitator**

Instructions accompany resuscitator in a separate nine-page paper manual. Manual incorporates instructions for both adult and infant resuscitators. Instructions include written and pictorial (line drawings) guides to disassembly and assembly (with special emphasis placed on correct assembly of the spring valve), general resuscitator functioning, testing before use, and recommendations for cleaning and sterilizing. Included is a parts list with material specification and part numbers. Instructions indicate that the infant resuscitator should generate pressures of 50 cm H<sub>2</sub>O.

Flesch Reading Ease (for use instructions only):

Words: 74

Syllables: 102

Sentences: 3

Ave word length: 1.38

Ave sentence length: 24.67

Score: 65 (Standard—8<sup>th</sup>–9<sup>th</sup> grade)

### **Laerdal Silicone Resuscitator**

Instructions accompany resuscitator on a large fold-out sheet. Written instructions are accompanied by black and white photos and illustrations. Manual incorporates instructions for three resuscitators (preterm, pediatric, and adult) and includes information and illustrations of additional components that are available for the different models (including multiple facemasks). Instructions include a guide to accessories; functional testing of the resuscitator and pressure-

limiting valve; explicit cleaning, disinfection, and sterilization procedures; assembly, and storage. Included are technical specifications and a parts list with material specifications.

Flesch Reading Ease (for use instructions only):

Words: 246

Syllables: 408

Sentences: 13

Ave word length: 1.66

Ave sentence length: 18.92

Score: 47 (Difficult—College)

### **Laerdal The Bag–Infant**

Instructions accompany resuscitator on a single-folded sheet (8.5” x 11”). Instructions are limited to written instructions and do not include illustrations. Instructions are generic for the The Bag series, including three resuscitator sizes. Instructions indicate that the resuscitator is designed for single use and, consequently, the instructions do not include cleaning or reuse information. Instructions include preoperative functional tests, cautions, specifications for use, and available accessories.

Flesch Reading Ease (for use instructions only):

Words: 219

Syllables: 392

Sentences: 13

Ave word length: 1.79

Ave sentence length: 16.85

Score: 38 (Difficult—college)

### **Kay and Company Artificial Resuscitator**

Instructions are printed on the side of the cardboard box and on the nylon storage bag. Instructions are not specific for neonatal resuscitation, and the accompanying four illustrations show an adult resuscitation. No specifications or additional information accompany the resuscitator. Instructions contain grammar and spelling errors.

Flesch Reading Ease (for use instructions only):

Words: 78

Syllables: 103

Sentences: 11

Ave word length: 1.32

Ave sentence length: 7.09

Score: 88 (Easy—5<sup>th</sup>–6<sup>th</sup> grade)

**CPR-Pro**

Instructions are printed on a small sheet of paper. Instructions seem to be generic resuscitator instructions and no illustrations are included. Instructions include basic precautions and reminders on assembly and testing (without explicit instructions). Instructions indicate that the resuscitator is for single use only.

Flesch Reading Ease (for use instructions only):

Words: 72

Syllables: 130

Sentences: 7

Ave word length: 1.81

Ave sentence length: 10.29

Score: 43 (Difficult—College)

**BLS Systems Manual Resuscitator**

Instructions are printed on a large sheet of paper folded into quarters. Written instructions are accompanied by a poorly reproduced product photo and clearer line drawings of components and operation. Instructions are generic for three sizes of resuscitator (adult, child, and infant) and operation illustrations show an adult resuscitation. Instructions include precautions, exploded view drawing and parts description, assembly instructions, performance specifications, and recommendations for confirming proper operation.

Flesch Reading Ease (for use instructions only):

Words: 125

Syllables: 218

Sentences: 10

Ave word length: 1.74

Ave sentence length: 12.5

Score: 47 (Difficult—College)

**PJ Dahlhausen & Co. Infant Resuscitator Set**

Instructions are printed on a glossy, paper booklet that is in English and German. Written instructions are accompanied by clear line drawings of components and resuscitation procedures. Instructions are generic for three sizes of resuscitator (adult, child, and infant). Instructions include precautions, exploded view drawings, extensive performance and material specifications, methods to confirm proper operation, and cleaning and sterilization guidelines.

Flesch Reading Ease (for use instructions only):

Words: 257

Syllables: 408

Sentences: 15

Ave word length: 1.6

Ave sentence length: 17.13

Score: 54 (Fairly difficult—High School)

### **Portex Safe Response Mouth-to-Mask Resuscitator**

Instructions are printed on a narrow folded paper sheet. Written instructions are accompanied by two line drawings depicting airflow and the proper way to position the device on the patient. Instructions indicate that the device is for single use only. The SAFE RESPONSE is designed for use with an adult or child and includes appropriate face masks. Instructions include precautions and contraindications (including use with infants).

Flesch Reading Ease (for use instructions only):

Words: 238

Syllables: 392

Sentences: 16

Ave word length: 1.65

Ave sentence length: 14.88

Score: 52 (Fairly difficult—High School)

### **Tekno**

Instructions are on a tri-folded sheet of paper. Instructions are exclusively in Indonesian. Written instructions are accompanied by line drawings that illustrate resuscitator components, training with a water column, and resuscitation of an infant (body and facemask positioning). Flesch reading ease was not evaluated due to the language of instruction.

### **Hospitak/Unomedical Mouth to Mask**

No instructions were included with the Hospitak. Product leaflet included with the resuscitator indicates that it is for single use only.

### **Topster SR-003**

Instructions are printed on a glossy booklet in green ink on white paper. Written instructions are accompanied by line drawings of components and resuscitation procedures. Instructions are generic for three sizes of resuscitator (adult, child, and infant). Instructions include precautions, exploded view drawings, extensive performance and material specifications, methods to confirm proper operation, and cleaning and sterilization guidelines. Much of the manual appears to be a replicate of the Dahlhausen manual including some of the specifications and illustrations.

Flesch Reading Ease (for use instructions only):

Words: 153

Syllables: 250

Sentences: 12

Ave word length: 1.63

Ave sentence length: 12.75

Score: 56 (Fairly difficult—High School)

## Appendix 7: Neonatal Resuscitator Use Statistics

### Midwife Neonatal Resuscitator Use Statistics

Device (# of users)	Tidal Volume			Proximal Pressure			BPM
	Minimum	Average	Maximum	Minimum	Average	Maximum	
Portex (1)	33	40	58	22	25	30	25–28
Blue Cross (2)	1	33–42	56	4	24–40	51	18–27
Laerdal Silicone (2)	25	48–66	73	15	25	27	24–35
Laerdal The Bag (2)	5 (46)	62–66	88	6 (23)	27–30	32	20–29
Kay and Company (2)	5	33–41	48	7	20–23	33	27–33
CPR-Pro							
BLS Systems (2)	18	22–41	53	22	25–27	28	25–37
PJ Dahlhausen (1)	9	24	31	7	13	23	25–27
Hospitak/Unomedical (6)	15	37–102	123	11	20–28	39	18–30
Tekno (2)	44	61–68	90	18	24–26	35	22–24
Laerdal Pocket Mask (1)	32	41	53	13	16	20	24–27

### Untrained User Neonatal Resuscitator Use Statistics

Device (# of users)	Tidal Volume			Proximal Pressure			BPM
	Minimum	Average	Maximum	Minimum	Average	Maximum	
Portex (3)	10	23–38	44	10	22–27	31	30–41
Blue Cross (3)	1	24–38	67	4	19–31	44	30–39
Laerdal Silicone (5)	5	31–47	56	9	21–25	28	25–47
Laerdal The Bag (3)	26	32–49	62	17	21–24	27	27–36
Kay and Company (3)	14	20–42	54	15	20–25	28	25–49
CPR-Pro (4)	27	33–60	73	18	20–24	29	20–43
BLS Systems (5)	19	29–55	63	16	21–24	29	23–56
PJ Dahlhausen (5)	3	9–24	27	6	11–22	27	26–60
Tekno (2)	23	46–48	48	20	23	26	32–33
Hospitak/Unomedical(5)	4	24–57	67	6	17–26	30	20–42
Topster(6)	10	21–52	62	11	19–26	26	22–61
Laerdal Pocket Mask (1)	2	38	55	4	21	27	36

## Appendix 8: Skilled Users (Midwives and Midwifery Students) Device Impressions During Use

### **Portex 1<sup>st</sup> Response:**

Limited to mask removal—mask noted as having a poor connection which could loosen with time and use.

Comfortable to use and easy to hold. Plastic was soft and limited fatigue. Inside of bag was noted as “feeling sticky to itself.” One commented that she did not like the mask.

### **Blue Cross Resuscitator**

Both volunteers did not remove o-ring nor disassemble the valve section with the spring. Device had operational difficulty in providing every breath—device would regularly skip breaths. Both participants commented that instruction was necessary to ensure complete disassembly. Difficult to disassemble or assemble in an emergency situation. No five-minute data.

### **Laerdal Silicone Resuscitator**

Difficult for first participant to disassemble and easier for the second since she was able to observe the first. Bottom piece was the most difficult during both disassembly and reassembly. Both were able to reassemble correctly. Participants noted that both operations were complex and difficult to do in a time-critical situation.

Participants thought the bag was big and soft and therefore made estimation of volume and pressure difficult. Learning to use the resuscitator was easy. Difficult to get good seal with mask, and hand holding mask became fatigued.

### **Laerdal The Bag**

Each participant forgot one part—either one at the bottom or pop-off valve. Both thought disassembly was easy but needed some instruction. Assembly was either thought to be easy or more complicated. Familiarity with basic bag and mask design made disassembly and reassembly operations easier.

One participant found the bag easy to use and comfortable while the other found it too large for her hands. Large bag made participants concerned about over inflation. Since both hands were used to operate the resuscitator, participants could not monitor heart tones. Both thought it was easy to learn correct operation.

### **Kay and Company**

Neither participant completed disassembly—did not remove bottom from the bag. One did not remove the pop-off valve. Reassembled correctly to the extent that it was disassembled. Participants thought that the resuscitator was fairly easy to assemble and disassemble—components fit together properly. Participants were not sure whether to leave pop-off valve open or shut. Thought it would be easy to get to main valve to clean if it became stuck during a resuscitation.

Both participants thought that the resuscitator was comfortable. Both commented that it was necessary to squeeze harder than originally thought in order to get proper pressure. Both became fatigued during five minutes of resuscitation and switched hands or commented on fatigue. One participant thought the bag may be too small for users with big hands.

### **CPR-Pro**

Not evaluated.

### **BLS Systems**

Neither participant removed the back end out of the bag, and one did not remove the pop-off valve. One indicated she was unsure how much could be disassembled. One indicated that threaded parts made disassembly easier to figure out. Reassembly was acceptable.

One participant who resuscitated with the mannequin on the table while she sat in a chair commented that, while she preferred this position, she found it fatiguing after two and one-half minutes. Both thought it was relatively easy to use and comfortable.

### **PJ Dahlhausen**

Neither participant removed the pop-off valve, and one did not remove the bottom piece from the bag. Participants needed more instruction to complete disassembly. One felt anxious about reassembly and crooked threads. One felt that the mask attachment was secure.

One thought that the bag was too firm (thumb began to hurt) and the bag did not generate adequate pressure (per the test lung). Both felt the bag was comfortable to hold and one found the bag material to be secure. One felt like she got good feedback and could gauge the amount of air. One commented that the most fatiguing aspect is the hand sealing the mask to the face.

### **Hospitak/Unomedical**

One participant tried to disassemble the valve (which is sealed). Most commented that disassembly and reassembly was easy and straightforward. One commented that reinserting the mouthpiece did not feel immediately secure. One commented that it would be difficult to clean inside the tube.

Difficult to hold on baby on the floor since it requires bending over the baby. Difficult to use consistently for five minutes and give the desired number of BPM.

One put tube into S-shape half way through the resuscitation. One felt faint after using and had to stop part of the way through the resuscitation to regain breath. One commented it was easier to use on table than on floor. Most thought it was easy to learn to use and could tell that air was entering the mannequin. Difficult to look around and impossible to give other instruction was resuscitating. One felt the mouthpiece was well shaped for the mouth. Overall, participants found it fatiguing to use for five minutes and felt that a proper rate was difficult to maintain.

Readjustment of mask for a better seal required participant to stop resuscitating. Some used with one hand on mask and some used with both (perhaps to ensure better seal).

**Tekno**

Thought disassembly and reassembly was easy and not much needed for instructions.

Easy to learn or to train someone. Difficult to maintain over extended period of use. Lots of saliva which was distracting. Could use one handed and monitor vital signs with the other hand but sometimes the tube would slip out of mouth. Difficult to count breaths while using.

**Laerdal Pocket Mask**

Very low and uncomfortable looking position when participant was using on the floor. A lot of spittle was generated. User could get good sense of pressure and chest rise due to proximity.

## Appendix 9: Unskilled Users (PATH staff) Device Impressions During Use

Device	Number of Users	Use Impressions	Disassembly/Reassembly
Portex	3	Good pressure feedback. Difficult to get facial seal. Full hand on bag—fully squeezing the bag each time to achieve desired pressure. Delivering rapid pulses of air.	
Blue Cross	3	Not as good pressure feedback as #1. Forced adaptation to device to achieve proper pressure. Faster squeeze seems to provide more air to neonate. Over-pressuring and need to modify use to limit pressure—harder to moderate pressure. When device malfunctioned, user could determine that there was no pressure in the chamber.	Minimal coaching required for disassembly. Difficulty in reassembling plastic ends into bag. O-rings difficult to see. Assembled front valve assembly backwards onto body.
Laerdal Silicone	5	Seal on face requires significant pressure. Mostly used middle finger to compress bag. Liked feedback from release valve. Bag diameter large for some users' hands. Mask can pull out of the joint if the user lets the bag fall past horizontal. Bag preferred to Topster since user could squeeze more gradually.	Minimal coaching required for disassembly. Reassembly—"logical and well made"—self corrected after incorrect assembly. Color coding would help with reassembly. Easy to disassemble back end.
Laerdal The Bag	3	Can rest fingers on face mask vent to help stabilize mask. User likes the strap but not ridges. Bag gave sense of confidence. Large size influenced comfort.	
Kay and Company	3	Excess volume made user feel less in control. Needed full squeeze to achieve proper pressure. Minimal feedback from device during use.	Sharply curved back end prevents the user from easily pushing in back end in order to remove. Reassembly of back end difficult. "Need additional indications for proper reassembly".
CPR-Pro	4	Preferred to #5 because it was less tiring—more bag resistance. More responsive than #3—could control operation better.	
BLS Systems	5	Bag seems stiffer and more tiring (than 5 or 6) but rebounds quicker than others. Forearm became tired after two minutes of use (while sitting). Larger bag is easier to use than #8.	Complete disassembly. Difficult to reassemble back end.
PJ Dahlhausen	5	Rapid, short squeezes to achieve desired pressure – creating a sharper pressure curve. In some users, rapid squeezes led to higher overall rate. Some users found use more fatiguing than other bag and masks while some found it less tiring. Using entire hand to squeeze in order to achieve pressure.	Complete but difficult to remove back end. Front valve threads fit in back end—possible misassembly.

Topster	6	Trained user thought that was not a good sense of resistance during use.	Minimal coaching for complete disassembly. Confusing front and back end during reassembly.
Tekno	2	Did not clamp mouthpiece in mask—used hand to hold it up to mouth. Easier to use than bag and mask. User thought she could control timing better since it was linked to breath. One user tried to use with pursed lips—difficult to achieve pressure.	
Hospitak/Unomedical	5	Two-handed grip—one on mouthpiece and one on mask. Slow rate—difficult to maintain correct BPM. With use, the mouthpiece loosened and air began to escape. Easier to control pressure than with bag and mask. Harder to maintain consistency during resuscitation. Most reliable performance came from a flute player with good breath control. Users thought that the quantity of air was more subjective than with the bag and mask.	
Laerdal Pocket Mask	1	Spit breaks were necessary. Tired after 1.5 minutes.	

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