



## Upright Bag-Mask Resuscitator Comprehensive Document

June 2016

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## June Update Summary

There are several updates since the last version of this document.

- Upright DFU now available in Spanish (in addition to English and French).
- Burkina Faso is using Upright nationwide.
- WHO has released technical specifications for Neonatal resuscitation devices.

## The History

The Helping Babies Breathe Alliance started to roll out the Helping Babies Breathe training in 2010. This simplified, hands-on newborn resuscitation training quickly spread across the world. By mid-2015, HBB training has reached over 300,000 birth attendants in over 75 low resource countries<sup>1</sup>. Throughout the implementation of the training, alliance partners and trainers got important insight into how to improve the training program and together they identified several key issues with current resuscitation equipment, particularly related to the design and use of the bag mask resuscitator.

1. **Poor mask seal:** Creating a good mask seal is a difficult skill, even after HBB training. Research has shown that with available bag-masks, facemask leakage varied from 24% to 59%<sup>2</sup> (Schilleman et al, 2013 & [Schmölzer et al, 2011](#)). Although this leakage is always not a problem due to large bag volumes, it may prevent adequate ventilation in cases of fluid filled lungs and newborns with low lung compliance.
2. **Mask design:** The HBB training is teaching the “C-grip” with the thumb and index fingers creating a C on top of the mask. But the existing mask design is not optimal for this grip. It has a very small surface on top with large inviting sides that make users, even after training, incorrectly put their fingers on the side and press the mask together, which creates openings on the sides of the mask and the seal is broken. Also, as the top is soft, even with a correct C-grip, if the weight is not distributed evenly between the two fingers on top, it’s difficult to create a seal.
3. **Masks falling out during a resuscitation:** An existing problem in the market is that masks are difficult to correctly push into the bag’s connector and can easily fall off during a resuscitation, taking away essential time that should be used to help the baby breathe.
4. **Positioning causes leakage:** The traditional design can be counterproductive to ventilations as the weight of one’s hand can tilt the bag-mask downwards, leading to increased leakage.
5. **Inadequate cleaning and decontamination:** Even if a traditional bag-mask can be taken apart to be cleaned, it was clear to the HBB alliance that the cleaning process lacked focus, and that it was difficult for many providers to reassemble them correctly. Reusable bag-masks on the market contain nine to twelve parts. With every added part, users are more likely to made mistakes during disassembly and reassembly procedures. Some of these assembly mistakes can lead to poor patient outcomes.<sup>3</sup>

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<sup>1</sup> Helping Babies Breathe: Lessons learned guiding the way forward. A 5-year report from the HBB Global Development Alliance.

<sup>2</sup> The Schilleman study was conducted in the Netherlands and the Schmölzer study was conducted in Australia

<sup>3</sup> Schmölzer GM: Assessment of tidal volume and gas leakage during mask ventilation of preterm infants in the delivery room. Archives of disease and childhood fetal and neonatal edition 2008, 93(3):F393-7.

This feedback was shared with Laerdal Global Health, who worked very closely with the alliance partners and global experts to address the issues in a new upright version of the bag-mask:

1. **Improving mask sealing, by**

- **The upright design:** The dominant hand holds the bag, and helps the user provide an even, downward pressure onto the mask.
- **The new “Laerdal Newborn Mask”:** The mask<sup>4</sup> has a thicker and broader top surface than most other facemasks, and a more pliable bottom cuff part. This design makes it easier to hold the mask correctly, enabling a better mask seal. The stiffer top distributes the grip more evenly than before, and it’s almost impossible to place fingers incorrectly on the side of the mask, as it’s too small and soft to accommodate the fingers. The Newborn Mask is also designed to give a snap fit with Upright bag and Simplified Resuscitator, to prevent the mask from disconnecting from the bag during use.<sup>5</sup>

2. **Easier to disassemble and reassemble correctly for cleaning and disinfection**

- Upright has fewer parts (total 6) compared to other resuscitators (typically 9 - 12), making Upright significantly easier to disassemble and reassemble correctly. Extensive time has also been spent on developing solutions that will make it easier for the user to take the bag apart and put it back together, for example adding a pull strap to the large soft part of the bag.
- A highly visible label around the neck coupling is a reminder on how the parts are reassembled after cleaning.
- The product comes with a pictorial poster that shows assembly, disassembly, disinfection and testing steps. [See Upright DFU.](#)

3. **Larger bag volume**

- The volume of the bag has been increased to 320 ml (from typically 220-250 ml on other resuscitators), to help compensate for mask leakage and for the air that is released through the pop-off safety valve when the user is ventilating too vigorously.

4. **Even more convenient to store and transport**

- The silicone bag can be folded for reduced volume during transportation. The length of the bag is shortened by 73 mm when folded.
- The product can stand upright or hang from an integrated strap, to help reduce risk of soiling of the product before use.

5. **Can be high-level disinfected in low-resource settings**

- Upright has been independently validated to achieve high-level disinfection with boiling in clean water, when specified reprocessing procedures are followed. It can be high level disinfected with glutaraldehyde (following manufacturer’s recommendation). It can also be sterilized by autoclaving.

The process of developing Upright took over 3 years. Global newborn resuscitation experts within the Helping Babies Breathe Global Alliance worked closely with Laerdal Global Health to create an affordable improved newborn bag mask of quality and standard. This design resulted in a product

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<sup>4</sup> The Laerdal Newborn Mask comes in two sizes: 1 and 0.

<sup>5</sup> The Laerdal Newborn Mask is also compatible with Simplified Resuscitator and other Laerdal resuscitators

that is durable, CE marked (hence tested and approved to be used in Western hospital settings) and long-lasting but costs customers under twenty dollars.

### **Purchasing Options**

Upright can be purchased either as a stand-alone model or as part of the NeoNatalie kit at [www.laerdalglobalhealth.com](http://www.laerdalglobalhealth.com).

<b>Product</b>	<b>Cost* 1 Oct 2014 to 1 Oct 2015</b>	<b>Cost* 1 Oct 2015 to 31 Dec 2016</b>
Upright bag-mask	\$19	\$20
Upright bag-mask with oxygen kit	\$22	\$24
Upright bag-mask with NeoNatalie and accessories	\$58	\$60

\* This does not include shipping and custom clearance etc.

Upright's Oxygen Kit can be easily attached or detached for settings that require oxygen.



## Awards and Recognition

- WHO 2014 Compendium*  
Upright was selected to be in the WHO’s Compendium of Innovative Health Technologies for Low-Resource Settings. See more at [http://www.who.int/medical\\_devices/innovation/en/](http://www.who.int/medical_devices/innovation/en/).
- PATH’s Innovation Countdown 2030 Report<sup>6</sup>*  
In June 2015, Upright was chosen as one of 30 high-impact innovations to save lives. Read the report at <http://ic2030.org/>.
- Norsk Design - Award of Design Excellence*  
Norway Design awarded Upright the award of design excellence in April 2015. In its verdict, the Award of Design Excellence Jury wrote: “The bag has clear functional advantages thanks to its vertical product architecture. The changed angle makes it easier to use and gives close contact with the child. The mask is intuitive and has a design that minimizes the mask leak. Upright can be folded, so that is small and compact. It is easy to assemble and disassemble and facilitates good cleaning practices. With only seven mechanical components, this cost-effective bag will save lives. The product has a robust and credible expression with clear universal qualities. In a remarkable way, Laerdal Global Health have solved the challenges they have been facing. Upright is a textbook example of successful use of design.” Read about the award of design excellence [here](#).
- Core 77 Design Awards*  
Upright was selected by the Core77 Design Awards, an internationally recognized design competition, as a notable submission in the design for social impact competition in June 2015. Read more about this competition [here](#).
- NPR features Upright as Top 5 Innovations*  
In July 2015, NPR and PATH narrowed down their countdown 2030 report and featured five top innovations that are already in use and show great promise. Read the entire article [here](#).

## Locations where Upright is being used in HBB Training

Since Upright was launched, over 5,000 Uprights are now in use in over 40 countries. An up-to-date list of current users is available on request. Partners such as UNFPA, Save the Children, ICM, and Red Cross are using Upright in HBB training.

Country	Amount
Bangladesh	170
Burkina Faso	75
Ethiopia	1292
India	16
Malawi	250
Mali	190
Senegal	50
Sierra Leone	30
Tanzania	35
Zambia	250
<b>Total in HBB programs</b>	<b>2358</b>

<sup>6</sup> PATH. Reimagining Global Health, The 2030 Countdown Report: <http://ic2030.org/report/>

### Other Locations using Upright<sup>7</sup>

Country	Amount	Country	Amount
Australia	55	Kenya	52
Belgium	26	Liberia	10
Benin	12	Madagascar	560
Burkina Faso	918	Mali	180
Burundi	19	Niger	60
Cambodia	53	Nigeria	231
Canada	1	Norway	1
Cuba	25	Papua New Guinea	42
DRC	45	Rwanda	12
Gambia	4	Switzerland	13
Greece	3	Tanzania	97
Guatemala	100	Thailand	25
Guinea	300	Uganda	89
Haiti	64	United Kingdom	63
Hong Kong	2	United States <sup>8</sup>	2
India	257	Vietnam	152
Israel	8	Zambia	16
Japan	1	<b>TOTAL</b>	<b>3498</b>

#### *Additional information:*

The Govt. of India is discussing with IAP, NNF, AAP and partners to introduce Upright in the Helping 100,000 Babies Survive & Thrive program in India in 5 districts where HBB and ECEB will be tested.

The Ministry of Health in Ethiopia with the Ethiopian Pediatrics Society has decided to use Upright for the Helping 100,000 Babies Survive & Thrive project, which is currently rolling out in all 180 hospitals in Ethiopia.

#### **International Regulatory Approval for Clinical Use**

Upright is CE marked, and therefore is approved for clinical use and sale in all countries that accept CE marking. Currently a limited number of languages are provided (EN, N, NL, F, D).

<sup>7</sup> Please note that some of these organizations may use Upright in HBB training.

<sup>8</sup> Not for clinical use.

Laerdal has not applied for US FDA approval of Upright, as the US is not an intended market for Upright at this time.

Proper CE-marking indicates that ISO 10651-4 has been met. ISO 10651-4 is the recognized standard for manual self-expanding resuscitators. Regulatory bodies of Europe (CE-marking), USA (FDA), Canada, Australia, Japan, etc, all require that ISO 10651-4 is met for sales in their countries. Upright has been rigorously tested both internally and through external labs for safety and efficacy.

Therefore, only countries that require specific regulatory approval separate from CE marking (like the US) are not using Upright for clinical use in their countries. This does not apply to most developing countries. Therefore, since our current focus is the 75 MDG countries, which do not require FDA approved devices, 510(k) approval is not necessarily required for Upright to be adopted. In addition, it took over 2 years to get Simplified resuscitator FDA approved and the process was very costly. Going through a similar process for Upright will just add an unnecessary cost to the product that has already gone through an extensive testing and quality approval process to be CE marked.

Regarding cleaning, disinfection and sterilization of reusable medical devices, the AAMI TIR12 and TIR30 standards are to our experience equally acceptable for both FDA 510(k) approval and CE-marking. Regarding sterilization by steam autoclaving, there are some different standards and expectations between Europe and the US.

### **Upright Validation & Verification**

Upright meets ISO 10651-4:2002/EN ISO 10651-4:2009, Lung ventilators – Particular requirements for operator-powered resuscitators, for newborns and infants with up to 10 kg body mass. Upright underwent extensive testing to verify values for tidal volume, expiratory and inspiratory resistance, patient valve malfunction, pressure limitation (pop off) and dead space. The accessory oxygen kit complies with requirements for oxygen concentration. Upright also underwent environmental challenges, such as extreme operating (-18 °C to 50 °C) and storage (-40 °C to 60 °C) temperatures, contamination with simulated vomitus, immersion in water, and 1 meter high drop testing, to ensure that it operates safely under all conditions.

### **Reprocessing & Disinfection Testing**

Manual Cleaning Effectiveness Study, performed by NAMSA\*:

- Requirements: Based on guidelines in AAMI TIR12 and TIR30. The cleaning process ensures that disinfection/sterilization process can be effective.
- Testing: Device is soiled with worst-case contaminants regarding cleaning (i.e. blood and proteins), allowed to dry for 1 hour, and then cleaned in accordance with the User Guide. This is repeated 5 times. The cleaned products are extracted for remaining contaminants, and the extract is subjected to a protein analysis and hemoglobin analysis, with positive and negative controls.
- Results: The acceptance criteria are < 6.4 µg/cm<sup>2</sup> of protein and < 2.2 µg/cm<sup>2</sup> of hemoglobin. These criteria were met and Upright passed the test.



Steam Sterilization Efficacy Study, performed by NAMSA:

- Requirements: In accordance with ANSI/AAMI/ISO 17665, AAMI TIR12, and ANSI/AAMI ST79.
- Specification: Sterilization procedure in the User Guide: Steam autoclaving at 132 °C, 10 minutes, unwrapped, gravity cycle configuration.
- Testing: The study was done as a half-cycle (5 minutes), which is worst case to 10 minutes.
- Results: Sterilization of biological indicators (*Geobacillus stearothermophilus* spores), which Upright passed.

High-level disinfection; Cleaning and Boiling validation, performed by NAMSA: Standard was updated in 2010.

- Requirements: In accordance with AAMI TIR12
- Specification: Boiling at 100 °C for 10 minutes
- Testing: Contaminated with a bacteria. Devices soiled internally into the patient port and externally from soiled gloved hands.
- Results: Acceptance criteria is > 6 log reduction, which Upright passed.

High-level disinfection; Cleaning and Glutaraldehyde validation, performed by NAMSA: Standard was updated in 2010.

- Requirements: Specified for immersion in activated glutaraldehyde solution for 60 minutes
- Testing: Contaminated with bacteria. Devices soiled internally into the patient port and externally from soiled gloved hands.
- Results: Acceptance criteria is > 6 log reduction, which Upright passed.

In addition, material compatibility tests are performed for each specified disinfection process. Typically 100 complete reprocessing cycles are performed. No significant performance change or visual degradation has been seen.

\*NAMSA is a well-known medical device contract research organization with several decades of experience with medical device product testing. They follow the standards set by the device industry and conduct tests for regulatory bodies (i.e. CE and FDA testing).

### **Completed Studies**

**Location:** Seattle

**Collaborator:** PATH

- Research done between March 2011 through December 2012
- Published March 2013 (User Evaluation of Simplified Neonatal Resuscitators)
- Research Question:
  - Is Upright easier to use/more acceptable than Simplified Resuscitator?
  - Is Upright easier to assemble and disassemble compared with Simplified Resuscitator?
  - Does Upright have decreased mask leak?
- Methods: Each of the devices was tested for user ventilatory performance with newborn simulator and an Ingmar Medical ASL-5000 test lung, for two newborn patient-condition scenarios:

- Low-compliance lung expansion (0.5 ml/cmH<sub>2</sub>O), simulating newborns with fluid-filled lungs.
- Normal-compliance lung expansion (2.0 ml/cmH<sub>2</sub>O), simulating infants with fully developed lungs.
- **Results:**
  - Improved ventilation: The percentage of inadequate ventilations is significantly lower for Upright device than for Simplified Resuscitator (8.31% vs. 19.01%, respectively;  $p < 0.001$ ) on the low-compliance setting and (1.05% vs. 8.64%, respectively;  $p < 0.001$ ) on the normal-compliance setting.
  - The majority (68%) of participants stated that they preferred Upright resuscitator.
  - Disassembly of Simplified Resuscitator took longer (87.94 +/- 44.22 seconds) as compared to Upright device (64.27 +/- 39.05 seconds) ( $p = 0.0245$ ). Participants were able to correctly assemble all component parts of Simplified Resuscitator less often than those of Upright device (summary index score of 13% vs. 53%, respectively).
  - Decreased mask leak: In low-compliance settings, the leak through the mask-face interface was significantly less for Upright device than for Simplified Resuscitator (8.83 vs. 12.41 ml/s)
- [Publication](#)

**Location:** Tanzania & Norway

**Collaborator:** Safer Births, Dr. Monica Thallinger

**Details:**

- Research Question: Is Upright or the standard bag-mask easier to use and which do students prefer?
- Method:
  - 41 nursing and medical students without any knowledge of newborn resuscitation were trained in basic bag-mask ventilation and ventilated with the two devices; a new Upright resuscitator and a standard newborn resuscitator (Laerdal Medical, Stavanger) on a NeoNatalie manikin in random order. Ventilation data was collected with the Newborn Resuscitation Monitor. The students answered questions grading mask seal (1) and ease of air entry (2) from 1 (difficult) to 4 (easy) and finally which device they preferred.
- Results:
  - Less mask leak: Mean mask leakage for Upright was 46% and standard 60% (paired sample test  $p < 0.001$ , which indicates a significant difference in mask leakage between the products)
  - Easier to ventilate: Mean score of 3.5 for Upright and 3.2 for standard (where 4 is easy and 1 is difficult)
  - 31 of 41 (76%) students preferred Upright resuscitator
  - Mean expired lung volume was 15.5 ml for Upright and 13.8 for standard resuscitator with mean difference 1.7 ml (one sample t-test for paired observations  $p = 0.03$ , which indicates a significant difference in the amount of air delivered into the lungs of the manikin).

- [Abstract](#)

**Location:** Tanzania & Norway

**Collaborator:** Safer Births, Dr. Monica Thallinger

**Details:**

- Research Question: Is Upright or the standard bag-mask easier to use and which do students prefer?
- Method:
  - 83 nursing and medical students from Tanzania and Norway without any knowledge of newborn resuscitation were trained in basic bag-mask ventilation. They ventilated with two new devices, Upright resuscitator and a standard newborn resuscitator, on a NeoNatalie manikin in a random order. Ventilation data was collected with the Newborn Resuscitation Monitor and analyzed for all students. The students answered questions grading mask seal (1) and ease of air entry (2) from 1 (difficult) to 4 (easy) and finally which device they preferred.
- Results:
  - Less mask leak: Mean mask leakage for standard was 57% and Upright 48%.
  - 68% of the students preferred Upright resuscitator.
  - Mean expired lung volume was 15.9 ml for Upright and 14.6 for standard resuscitator with mean difference 1.4 ml. This indicates that Upright's improved mask seal led to a higher amount of air delivered.
  - For "mask seal" mean score was 2.7 for standard and 3.2 for Upright (one sample binomial test  $p < 0.01$ , indicating significantly better perception of mask seal), and for "ease of air entry" 3.0 for standard and 3.4 for Upright ( $p < 0.01$ , indicating a significantly better perception of ease of air entry for the students)
  - [Abstract](#), [Published Paper](#)

**Location:** Uttar Pradesh, India

**Collaborator:** PATH, Save the Children, Aligarh Muslim University (AMU)

**Details:**

- Study was approved by PATH and AMU
- IRBs and data collection was conducted in late August 2015.
- Tests were conducted using NeoNatalie manikin, Laerdal Silicone 500ml bag and mask resuscitator and Upright resuscitator
- Research Question: Is Upright when compared with the Laerdal 500 ml resuscitator more effective in delivering adequate ventilation, and is it easier to use?
- Will complete quantitative and qualitative user evaluation:
  - Quantitative: simulation using the manikin connected to a test lung; will measure proportion of adequate ventilations achieved when using each resuscitator
  - Qualitative: evaluating preference and ergonomics.
- Publication anticipated summer 2016.

**Location:** Haydom, Tanzania

**Collaborator:** Safer Births, Dr. Monica Thallinger

**Details:**

- Randomized control trial on resuscitated newborns (n=300)
- Research Question: Are the clinical outcomes of babies resuscitated with Upright resuscitator and standard equipment equivalent?
- Publication anticipated summer 2016

**Ongoing Studies**

**Location:** India

**Collaborator:** URC USAID Applying Science to Strengthen and Improve Systems (ASSIST) Project

**Details:**

- This testing with sample size between 40-60 health workers from 15 facilities.
- Bag selection (between Upright and Simplified resuscitator) will be randomized. Test will be done on NeoNatalie Newborn Simulator.
- This study aims to answer several questions:
  - If you were trained on resuscitation during your pre-service education or with NSSK, do you need to be retrained to use Upright or can you use it without additional training?
  - Will providers trained on simplified resuscitators need additional training for using Upright?
  - After trying both- Upright and simplified resuscitators, which one do providers find more comfortable and perceive as more effective?
  - Compare how long does it take in seconds to get chest rise with two sample bag-masks.
  - The study is also contemplating looking into comparing the time it takes to take the two sample masks apart and put the them back together again.

**Upcoming Studies**

**Location:** Kathmandu, Nepal

**Collaborator:** Dr. Ashish KC (UNICEF Nepal)

**Details:**

- Dr. Ashish conducted a large study on Helping Babies Breathe implementation in Nepal (*Implementing a simplified neonatal resuscitation protocol-helping babies breathe at birth (HBB)* - at a tertiary level hospital in Nepal for an increased perinatal survival. BMC Pediatr. 2012 Oct 5;12:159. doi: 10.1186/1471-2431-12-159.)
- This study is a follow-up study using Upright
- Dr. Ashish's team will film resuscitations using cameras in newborn care corners
- The team is looking into comparing simplified resuscitator to Upright resuscitator

**Location:** Uganda

**Collaborator:** Mbarara University, MIT, Massachusetts General Hospital, Harvard

**Details:**

- The Augmented Infant Resuscitator (AIR) project will be using Upright bag-mask in their tests
- This project has received two SLAB grants

### Upright in India

**Location:** India, Maharashtra. Two high delivery load facilities in the Pune district of Maharashtra

**Collaborator:** Center of Excellence, Laerdal Global Health in collaboration with Govt. of Maharashtra.

**Details:**

- Providers trained in NSSK (updated HBB) got a refresher on HBB with Upright and then have continuous training with Upright using NeoNatalie placed in the delivery room.
- A baseline data collection was completed in July 2015 prior to the training started.
- The facilities are planning to setup cameras to monitor that people are practicing with the models. The aim is to observe whether people are practicing resuscitations regularly and whether they are performing them correctly.
- Almost all providers in the labor rooms in these facilities have been trained in using Upright. Uprights have also been placed in the labor rooms.

### Upright with Newborn PEEP



Positive End-Expiratory Pressure (PEEP) retains a volume of air in the lungs between each ventilation. For newborns with fluid-filled or immature lungs, PEEP during first and subsequent ventilations helps clear fluid from the lungs, reduces airways resistance, recruits lung volume and reduces damage to the newborn's lung tissue from repeated lung alveolar collapse.

Newborn PEEP is an accessory being developed for Upright and is anticipated to be available late 2016. Newborn PEEP is a PEEP valve intended for preterm and term newborns and infants up to 10 kg body mass who require respiratory support. Newborn PEEP replaces Upright's patient port connector. Upright is used as normal when Newborn PEEP is attached.

Research conducted by Dr. Monica Thallinger also show that students were able to provide acceptable levels of PEEP using Upright with Newborn PEEP even with high rates of mask leakage ([link to abstract](#)).

### **WHO Technical Specifications for NeoNatal Resuscitation Devices**

WHO, as part of the United Nations Commission on Life-Saving Commodities for Women and Children, published technical specifications on basic newborn resuscitation in 2016, which provides a guideline for procuring neonatal resuscitation equipment in low resource settings to decrease infant mortality rate. This document can be download at this [link](#).

These specifications are the result of a collaboration of experts from different backgrounds and organizations, including WHO, UNICEF, CHAI, PATH and Save the Children, and Upright is accepted under their specifications for a self-inflating neonatal resuscitation bag with mask.

### **Interesting Research Questions Currently Not Addressed in Any Ongoing Studies**

- What is the cause of low tidal volumes during newborn resuscitation?
- Is there a better seal with Upright when you are working in a clinical environment (not just with manikins)?
- Can people who have been trained with an Upright use a traditional bag-mask safely/correctly?
- Can Upright be used as a transition product for practitioners who are using the 500 mL bags?
- Can you have a conventional bag-mask and an Upright bag present in a facility or do you only need to have an Upright present?
- Is there a difference in outcomes between preterm and term babies?
- If a provider who has experience only with "traditional" bag-mask resuscitators on children or adults is given Upright, will they be able to use the skills they have on adults/children with Upright on newborns?

### **Contact Information**

In case of further questions or concerns, please contact:

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