Photo: Amy McIver

A HealthTech Report

Testing of an Operator-Powered Neonatal Resuscitator, Conducted December 2012

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Contents

Introduction

Purpose

The purpose of this bench testing was to evaluate and compare the performance of a new prototype resuscitator (the Upright) with an existing, commercially available resuscitator (the NeoNatalie). The Upright resuscitator is intended to be easier to use, and less expensive to produce than the NeoNatalie. Both devices are manufactured by Laerdal Global Health (Stavanger, Norway).

Scope

The emphasis of this bench testing was to compare two resuscitators for operational and human factors considerations and to evaluate ventilatory performance in the prototype resuscitator as compared with the commercially available resuscitator. The results of these tests are intended to provide a baseline for further testing involving users, both on the bench and in the field. It is assumed that tests specified by the International Organization for Standardization (ISO) 10651-4:2002[1] have been—or will be—performed by the manufacturer as part of their quality management system and therefore were not repeated in full as part of this evaluation. Additionally, analyses of dead space in the resuscitator and performance at environmental extremes were not performed, largely due to a lack of suitable test apparatus.

Prior evaluations

This is the third round of testing that has been performed with these two resuscitators. The first round of testing was performed in March 2011 and compared the performance of the Upright resuscitator with the NeoNatalie resuscitator and a "simplified" resuscitator incorporating some features of both. The second round of testing was performed in December 2011 in order to evaluate the simplified and Upright resuscitators after modifications in their designs that resulted from information gleaned during the first round. Subsequent to the second round of testing, Laerdal decided to discontinue development of the simplified resuscitator. This report details the results and conclusions from a third round of testing of the Upright and NeoNatalie resuscitators only. It has been formatted in a similar fashion to the prior reports to facilitate comparative review where the reader is interested in doing so.

Informative references

ISO 10651-4:2002(E) Lung ventilators—Part 4: Particular requirements for operator-powered resuscitators.

[1] The International Organization for Standardization (ISO) website. ISO standards catalog. Available at: http://www.iso.org/iso/iso_catalogue/catalogue_ics/catalogue_detail_ics.htm?ics1=11&ics2=40&ics3=10&csnumber=30712. Accessed November 28, 2011.

Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 10651-4:2002(E) apply.

Background

In addition to the 60 million newborn births occurring at home, there are large gaps in the availability and use of neonatal resuscitation at many facilities in developing countries. With the recent introduction and scale-up of the simplified algorithm and health worker education program, Helping Babies Breathe™, neonatal resuscitation is being rapidly expanded to first-level and first-referral facilities and in some community settings. However, cadres of community and facility health providers—such as skilled birth attendants—may see relatively few newborns each year that require resuscitation with positive-pressure ventilation. There is increasing awareness that current neonatal resuscitation devices designed for hospital settings may not be the most appropriate, feasible, effective, or cost-effective devices for health care providers with relatively few opportunities to perform or practice resuscitation. Infrequent users have rapid skill decay—especially regarding such vital functions as maintaining a good mask seal over the newborn's nose and mouth. Most currently available bag-and-mask devices have a complex design with 11 parts upon disassembly. This is not a concern in hospital settings in developed countries where devices used for a given patient are disposed after use. In developing-country settings, however, where device reuse for different patients is essential, the complexity of the currently available devices impedes disassembly, cleansing (with microbicide), and reassembly. Moreover, retention of critical resuscitation skills (e.g., maintaining an adequate seal)—especially for cadres who perform neonatal resuscitation infrequently—is impeded by design complexities and functional challenges of current standard devices.

Laerdal has conducted extensive research and development to simplify neonatal resuscitation devices to address these design problems and to reduce the cost of devices for low-resource settings. A simplified prototype version of Laerdal's existing NeoNatalie resuscitator—the Upright resuscitator—has been developed. This resuscitator features fewer user-assembled parts, and these parts have been redesigned to reduce the hazard associated with incorrect reassembly after cleaning. In addition to having fewer parts, the device features a larger self-inflating ventilation bag that is vertically in-line with the mask as opposed to being aligned horizontally and perpendicular to the mask as is the case with the NeoNatalie. These features result in several advantages:

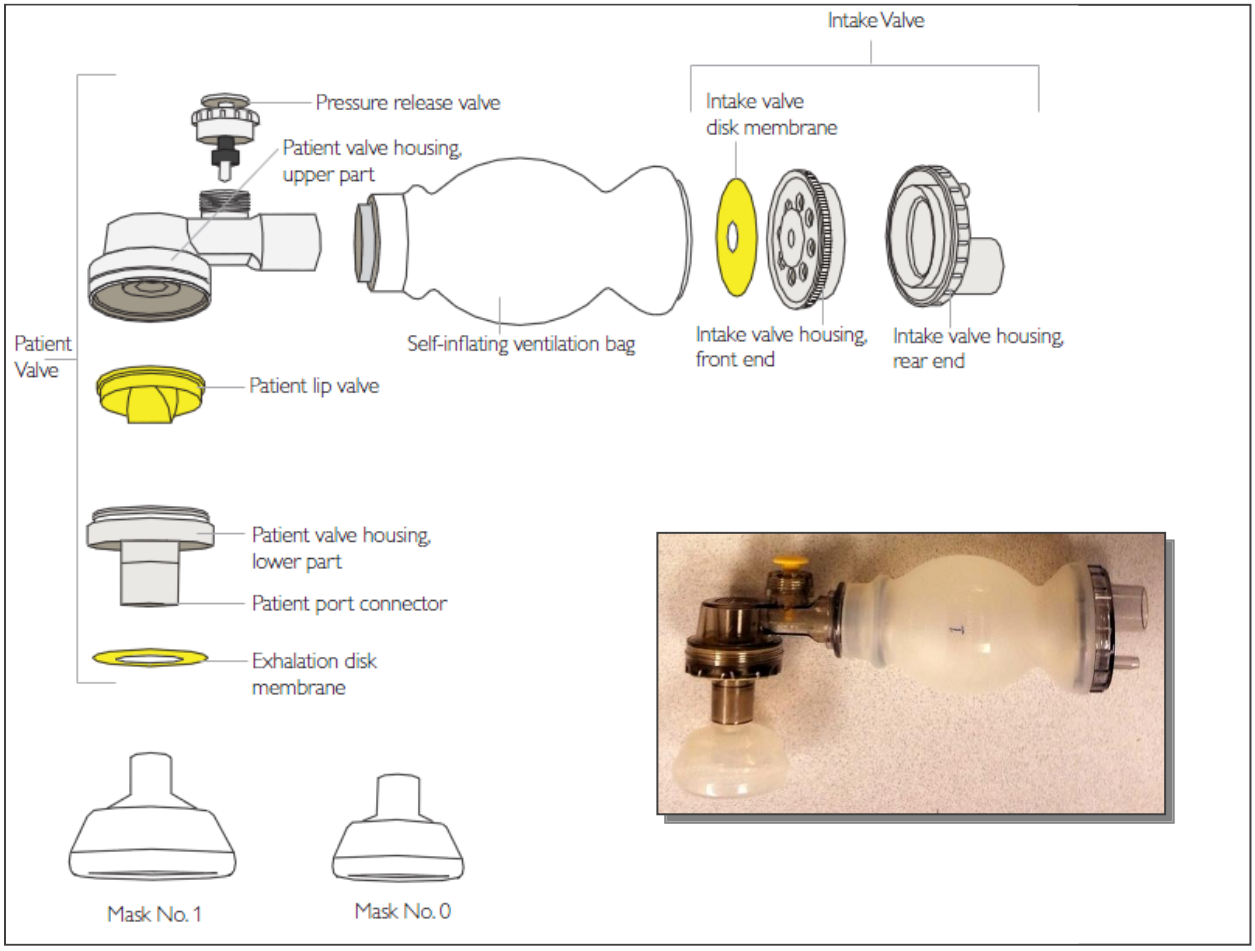
- 45 percent increased volume (320 ml vs. 220 ml) to help overcome inadequate volume of ventilated breaths due to leakage.
- Improved mask and vertically oriented bag intended to reduce leak at the mask/face interface.
- A relocated pop-off valve, now integrated with the intake valve.
- Ease of disassembly and reassembly for cleaning (7 parts vs. 10 parts).
- An estimated 33 percent lower cost (US$10).

Description of the devices

NeoNatalie

The NeoNatalie resuscitator (shown in Figure 1) is one of Laerdal's existing commercially available resuscitators and has been used in the field for some time. It consists of 10 parts (11 if two mask sizes are included) that can be dismantled and reassembled by the user. The nominal volume of the self-inflating ventilation bag is 220 ml. The proximal end of the device consists of a relatively complex assembly that performs several functions: it contains a patient port connector (a standard interface for connecting to the face mask), a patient lip valve that prevents rebreathing into the device, and a pressure release valve that can be overridden if necessary. The bag itself is made from silicone and self-inflates after squeezing in preparation for the next ventilation cycle. The rear of the device consists of the intake valve, which includes a thread for attachment to an external oxygen supply. This device is designed to be held horizontally by the user.

Figure 1. A diagram showing the disassembled NeoNatalie resuscitator and a photograph (inset) of the assembled device.

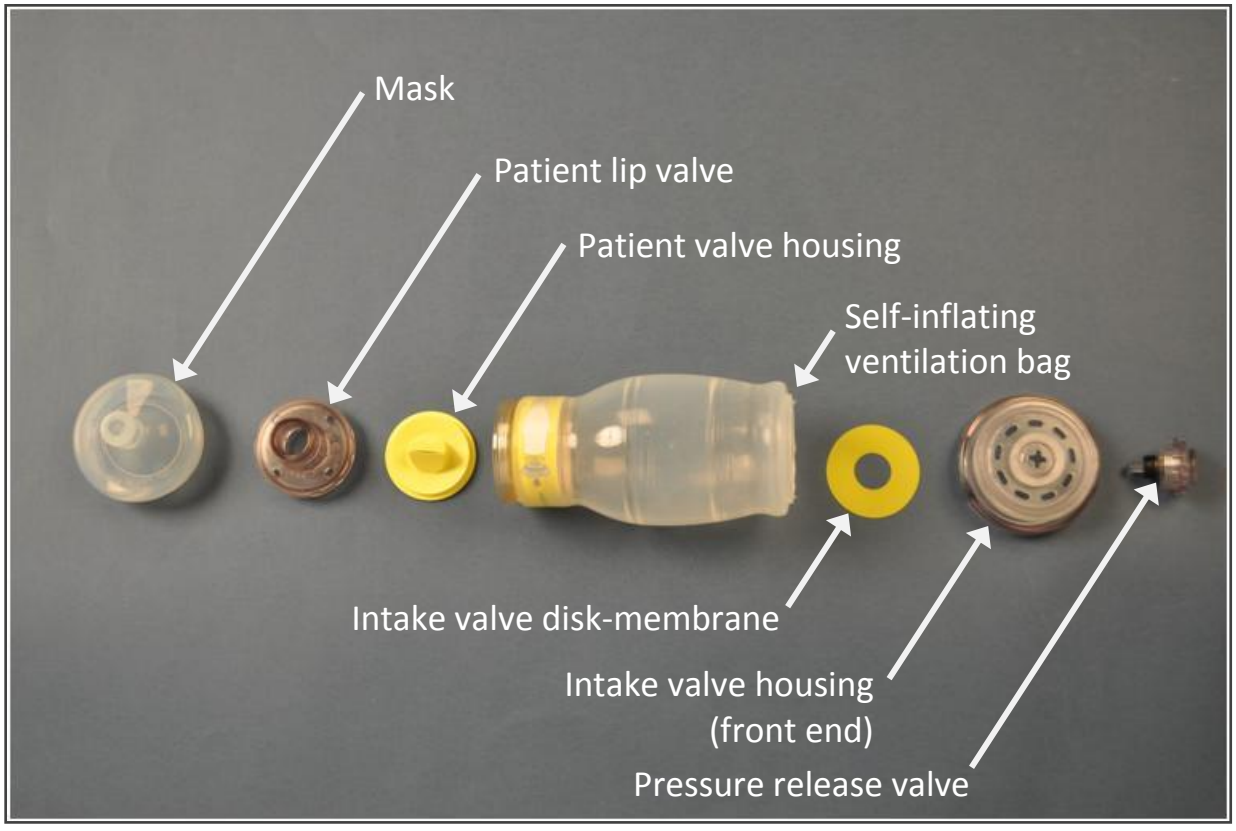


Upright

The Upright resuscitator (shown in Figure 2) has been redesigned to be less complex to assemble and disassemble and easier to use than the NeoNatalie resuscitator. The Upright resuscitator features a 45 percent increase in the nominal volume (320 ml) of the self-inflating ventilation bag, which is also more elongated in shape than the NeoNatalie. This is intended to facilitate delivery of the appropriate tidal volumes to the neonate. Another important feature is the relocation and integration of the pressure release (pop-off) valve, which was moved from the patient valve housing proximal to the mask to the intake valve housing at the distal end of the device. Finally, there is no exhalation disk membrane (used during administration of anesthesia).

The mask has also been significantly redesigned. The body of the mask has been made much thicker in order to minimize distortion during application to the neonate's airway and encourage correct hand placement. The rim that contacts the patient has been made thinner and molded into a cushion shape much like a hovercraft cushion. This change is intended to result in a mask that better conforms to the contours of the face, thereby reducing leak.

Figure 2. A photograph showing the disassembled Upright resuscitator. Note that the rear end of the intake valve housing (see Figure 1) is planned to be supplied as part of an optional oxygen accessory kit (not shown).



Operational evaluation

Overview

The two resuscitators were qualitatively evaluated to identify key differences that do not necessarily pertain to ventilatory performance (ventilatory performance is addressed in the next section of this report).

The NeoNatalie resuscitator includes ten components (including mask) that must be disassembled by the user for cleaning. The Upright resuscitator has seven components (including mask) that must be disassembled by the user. The Upright resuscitator also has fewer production parts (12 vs. 15) and, as a result, is likely to be much less expensive to produce. Finally, the rear end of the intake valve housing (see Figures 1 and 2) for the Upright resuscitator is not included as part of the basic kit, but is planned to be supplied as part of an oxygen accessory kit.

Mask

The mask design has been significantly modified, with a substantial thickening of the mask body to minimize distortion during application to the patient airway, which in turn should reduce leakage. The patient-contacting portion of the mask has also been made more compliant by means of a thin, concave, cushioning seal. These modifications are intended to improve the mask seal and reduce leakage of air during use.

In addition, the mask stem features a small raised rim designed to ensure a positive and reliable fit with the patient port connector. This rim helps to prevent the mask from coming loose during use.

Assembly and disassembly

There are two ways in which the NeoNatalie resuscitator can be reassembled incorrectly after disassembly and cleaning: (1) the intake valve can be reassembled backwards into the ventilation bag, and (2) the intake valve and exhalation valve disk membranes can be interchanged. The Upright resuscitator obviates this hazard with a redesigned intake valve housing (making it difficult to assemble incorrectly) and by eliminating the exhalation valve disk membrane.

The intake valve housing was found to be challenging to both insert and remove from the self-inflating bag during assembly and disassembly. A feature such as a thumb tab on the side of the ventilation bag (next to the intake valve) would facilitate removal of the intake valve housing and prevent the resuscitator from rolling off the table if it were placed on its side.

It was noted that the assembly instructions were oriented so that they could be read while the device was placed on the table with the mask uppermost (i.e., resting on the intake valve). This was thought to be a helpful visual cue in encouraging the user to set down the device in a way that minimizes contamination of the mask through surface contact.

During disassembly, it was found that the pressure-limiting valve can be quite challenging to unscrew for cleaning. Our testers noted that fingers and thumbs were pinched in the gap between the valve and housing on more than one occasion. We suggest that relatively minor modifications to this area of the device be considered to alleviate the potential for injury.

Ventilatory performance tests

Overview

All resuscitator testing was performed at Seattle Children's Hospital in March 2013 in the respiratory research laboratory with the aid of Robert DiBlasi, a practicing respiratory therapist and researcher. Each of the resuscitators was allowed two hours to reach equilibrium with ambient conditions in the laboratory.

Three of each resuscitator type was used during the testing and each individual device was labeled as test article 1, 2, or 3 using a permanent marker. In total, six test articles were used. For each test, testing order was randomized among all six articles. The test setup was dismantled for each repetition, although the resuscitators themselves were left intact.

Test apparatus

The test apparatus was as follows:

- ASL 5000™ Active Servo Lung (Ingmar Medical).
- Pressure transducer (CheckMate™ 600, Transmation, Rochester, NY).
- Standard plastic respiratory connectors.
- Air source (50 psig, wall) and back-pressure compensated 15 standard liters per minute (SLPM) flowmeter (Timeter®).
- Vacuum source (wall) and regulator (Precision Medical).
- Avea™ ventilator model 16184 (Viasys Healthcare, Palm Springs, CA)—for measurement of vacuum flow rate.
- Ratcheting bar clamp (Quick-Grip®).
- Stopwatch.

Inspiratory-resistance test

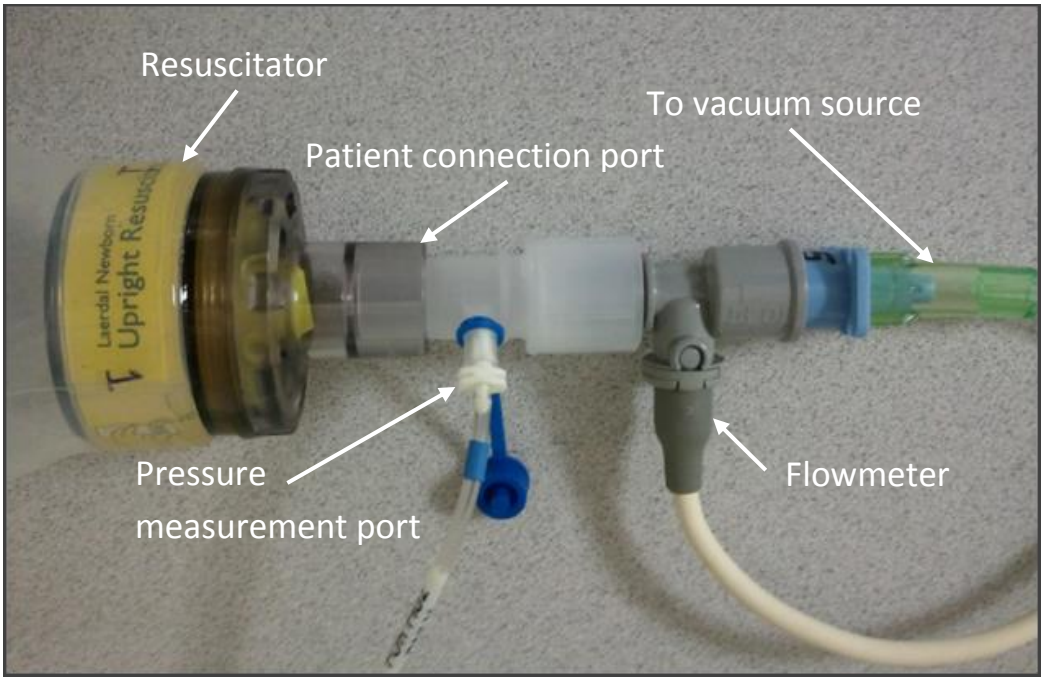
Overview

The design of a resuscitator should be such that it is possible for the patient to breathe spontaneously without excessive effort when the resuscitator is applied to the patient's airway but is not activated by the operator. ISO 10651-4:2002(E) requires the pressure generated at the patient connection port to be less than or equal to 0.5 kPa (≈ 5 cmH_2O) under standard test conditions.

Method

As illustrated in Figure 3, the patient-connection port was connected to a wall vacuum source producing an air flow of 5 SLPM as recorded by the Avea ventilator. The pressure generated at the patient connection port was recorded.

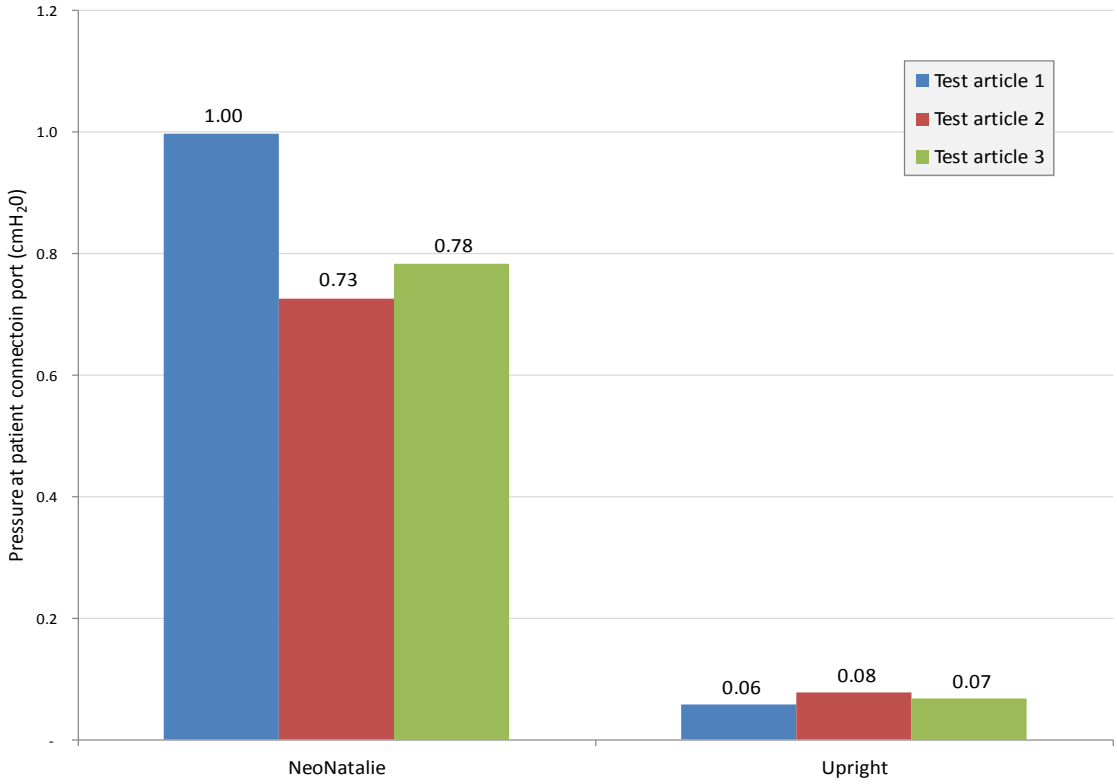
Figure 3. Inspiratory-resistance testing setup for one of the Upright resuscitator test articles. The photograph shows the Upright resuscitator connected to the pressure measurement port, flowmeter, and vacuum source (left to right).



Results

As illustrated in Figure 4, the mean inspiratory resistance of the Upright resuscitator (0.06 cmH_2O) was significantly lower than that of the NeoNatalie (0.73 cmH_2O).

Figure 4. Inspiratory-resistance testing results. Vacuum pressure at the patient connection port is shown for each test article of each resuscitator type. Test articles 1, 2, and 3 are shown in blue, red, and green, respectively. Pressures are shown for a test flow rate of 5 SLPM.



Discussion

The inspiratory resistance observed for the Upright resuscitators represents a significant reduction compared to the NeoNatalie, although all resuscitators meet the ISO standard requirement.

Expiratory-resistance test

Overview

To facilitate exhalation, expiratory resistance should be minimized unless there are special clinical indications to impose such resistance. ISO 10651-4:2002(E) requires the pressure generated at the patient connection port to be less than or equal to 0.5 kPa (≈ 5 cmH_2O) under standard test conditions.

Method

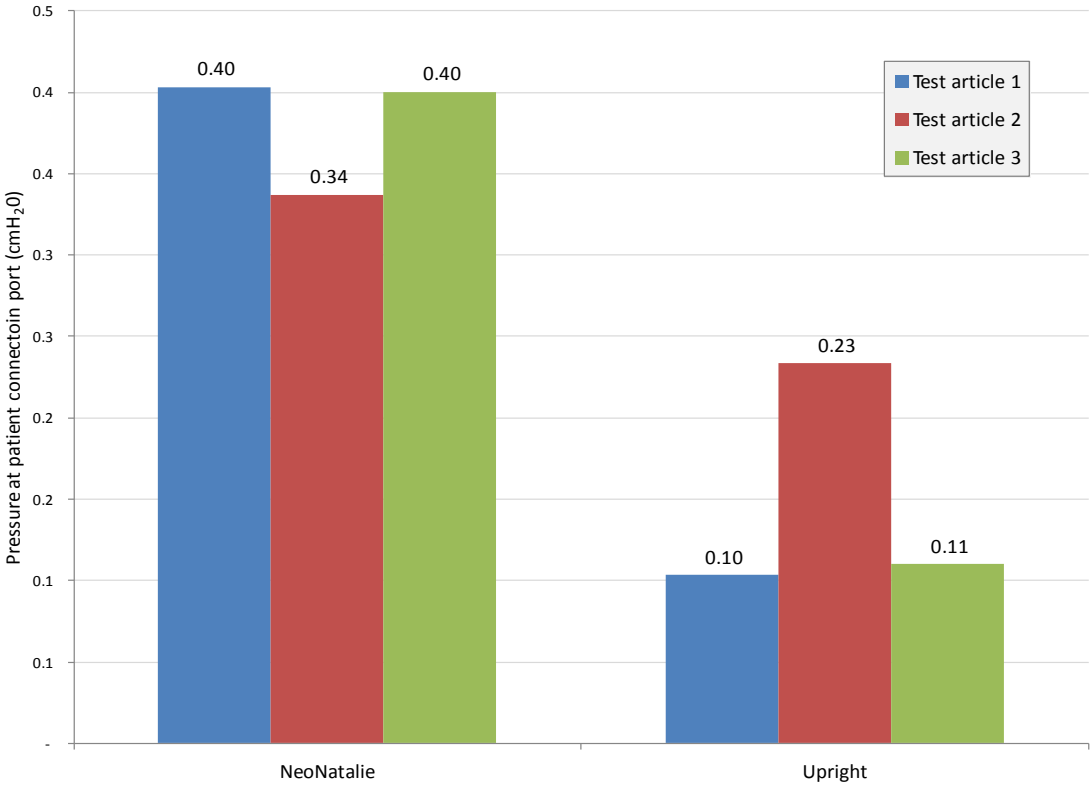
The patient connection port was connected to a wall air source producing an air flow of 5 SLPM as recorded by the ball flowmeter attached at the wall. The pressure generated at the patient connection port was recorded.

The setup is similar to that shown in Figure 3, except that gas flow is recorded directly at the air source by a back-pressure compensated flowmeter instead of the inline flowmeter that records flow from the vacuum source as shown.

Results

Mean expiratory resistances (pressure recorded at 5 SLPM) for the two types of resuscitators were as follows: NeoNatalie resuscitator was 0.38 cmH_2O, and the Upright resuscitator was 0.15 cmH_2O. See Figure 5 below.

Figure 5. Expiratory-resistance test results. Pressure at the patient connection port is plotted for each test article of each resuscitator type. Test articles 1, 2, and 3 are shown in blue, red, and green, respectively. Pressures shown are for a test flow rate of 5 SLPM.



Discussion

There appears to be an improved (i.e., lower) expiratory resistance observed with the Upright resuscitator compared with the NeoNatalie resuscitator, although both resuscitators meet the ISO standard requirement.

Minimum delivered volume test

Overview

For neonatal ventilation, a typical tidal volume is approximately 4 ml/kg to 8 ml/kg. The tidal volume requirements of 15 ml/kg used by ISO 10651-4:2002 are higher in order to compensate for mask leakage. Experience shows that, due to leaks and changing compliance during resuscitation of neonates, delivered volumes of the order of 20 ml to 30 ml are needed to achieve a tidal volume of 20 ml or less.

Method

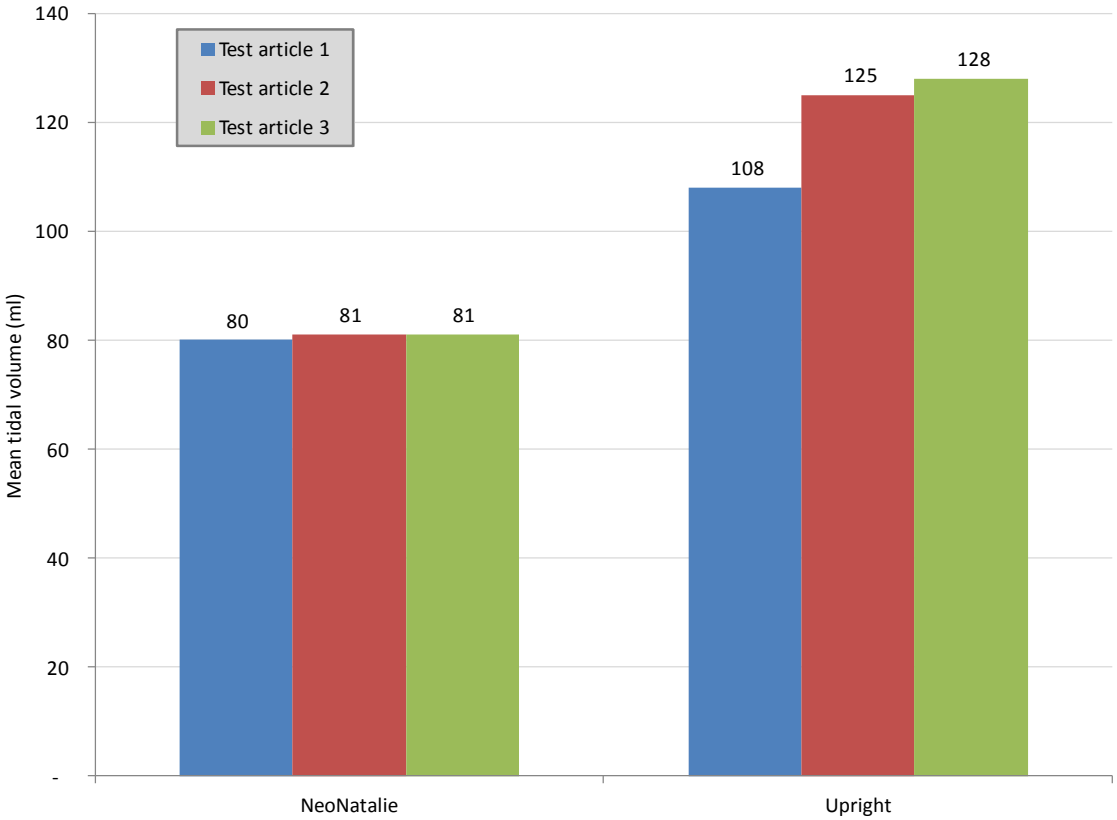
A test lung (ASL 5000) was configured with the following settings: compliance 10 ml/cmH_2O, resistance 20 cmH_2O/l/s, and set to record tidal volume. The resuscitator was connected (without a mask) directly to the test lung, and hand ventilation was performed for 40 cycles at a rate of 25 cycles per minute and an inspiratory to expiratory ratio (I:E) of 1:2. Hand size was conformant to ISO 10651-4:2002(E).

Each resuscitator was squeezed until fingers were touching (i.e., the bag was fully squeezed without being crushed) in order to obtain repeatable tidal volumes deliverable by each device.

Results

The average delivered volume for the NeoNatalie resuscitator was 74 ml, and for the Upright resuscitator it was 121 ml. See Figure 6 below.

Figure 6. Minimum delivered volume test results. Mean tidal volume is shown for each test article of each resuscitator type. Test articles 1, 2, and 3 are shown in blue, red, and green, respectively. The tidal volume was measured for 40 ventilation cycles and averaged.



Discussion

The Upright resuscitator delivered considerably more volume than the NeoNatalie resuscitator. This is largely due to the increased ventilation bag volume, but could also be due in part to more efficient collapsing of the elongated Upright ventilation bag.

Pressure-limitation test

Overview

Resuscitators with pressure-limited systems—those that limit the airway pressure to less than 3 kPa (30 cmH_2O)—may not be able to deliver adequate volume to children with a body weight below 10 kg in cases of high airway resistance and/or reduced lung compliance. This results in the need for a pressure override system; however, this test confirms that the pressure limitation is appropriately set.

Method

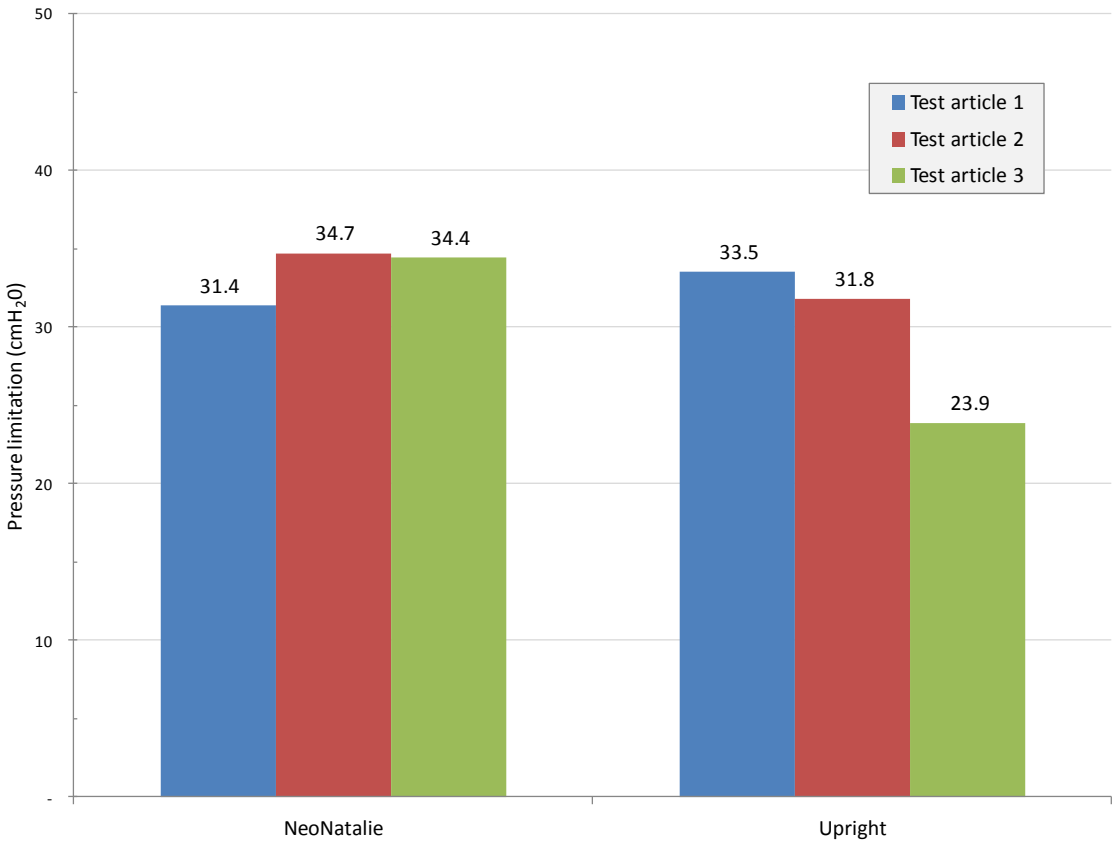
Pressure-limitation testing was performed using both the NeoNatalie and Upright resuscitators.

For the NeoNatalie and Upright resuscitators, a pressure transducer was connected to the patient connection port and the port occluded distal to the pressure sensor using a rubber stopper. The supplied supplemental oxygen kit (intake valve, rear housing, and oxygen tubing) was attached to the intake port of the resuscitator, and the oxygen tubing was connected to a back-pressure compensated flowmeter connected to a wall supply of air. Hot glue was used to occlude the intake valve on the resuscitator's rear housing in order to prevent air escape, and the pressure at the patient intake port was recorded.

Results

The mean pressure limit for each of the resuscitators was as follows: the NeoNatalie resuscitator was 33.5 cmH_2O, and the Upright resuscitator was 29.8 cmH_2O. See Figure 7.

Figure 7. Pressure-limitation test results. Test articles 1, 2, and 3 are shown in blue, red, and green, respectively.



Discussion

The pressure release valve for both devices activated at comparable pressures, although both resuscitators slightly exceeded the ISO limit of 30 cmH_2O.

Leakage test

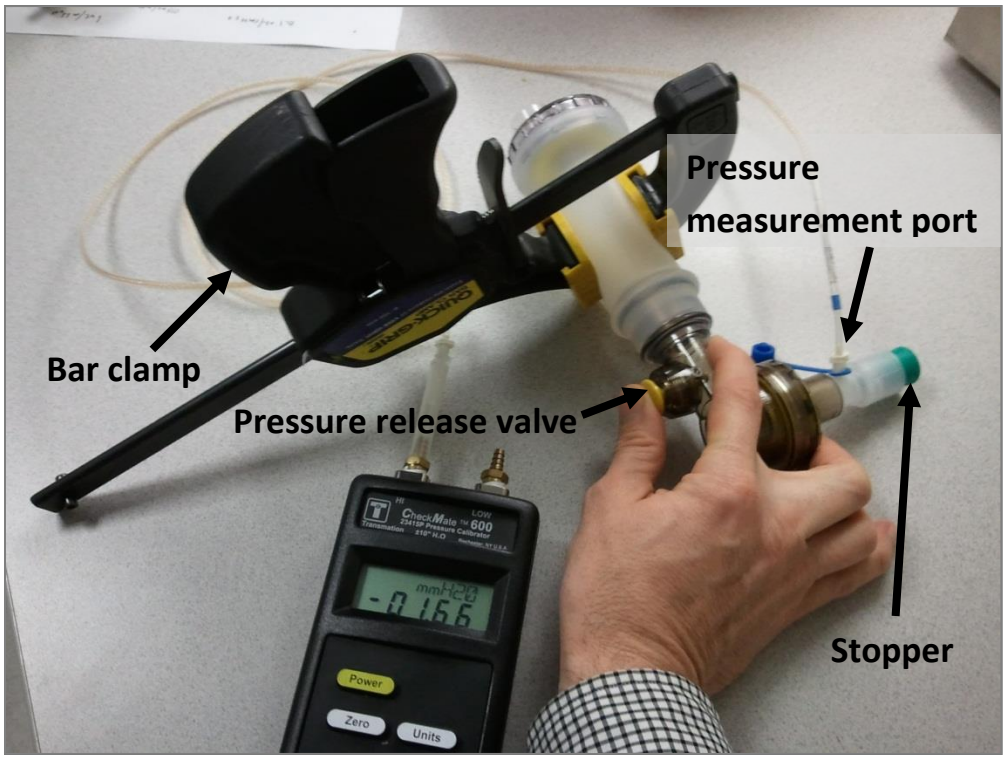
Overview

Resuscitator leakage testing is not a part of the ISO requirement, but it was considered necessary to test in this instance in order to provide a baseline for a subsequent user evaluation designed to assess mask leakage, among other things.

Method

As illustrated in Figure 8, a resuscitator was connected to a pressure transducer at the patient connection port and squeezed using a hand clamp until the pressure was observed to increase just in excess of 45 cmH_2O. At this point, squeezing was halted and, when the pressure had decreased (due to leakage) to 45 cmH_2O, a stopwatch was started. Elapsed time was then recorded at intervals of 5 cmH_2O pressure loss. In the case of the Upright resuscitator, pressure loss was too rapid to be able to record elapsed time at 5-cmH_2O intervals and so elapsed time at the endpoint (0 cmH_2O) was the only time point recorded. The pressure-release valve was prevented from opening using finger pressure throughout the duration of the test to exclude this as a source of leak and to purposefully allow the initial pressure in the resuscitator to exceed the pressure limitation. This was intended to simulate a leak during ventilation of a low-compliance lung. Leakage has been specified in terms of pressure loss per unit of time.

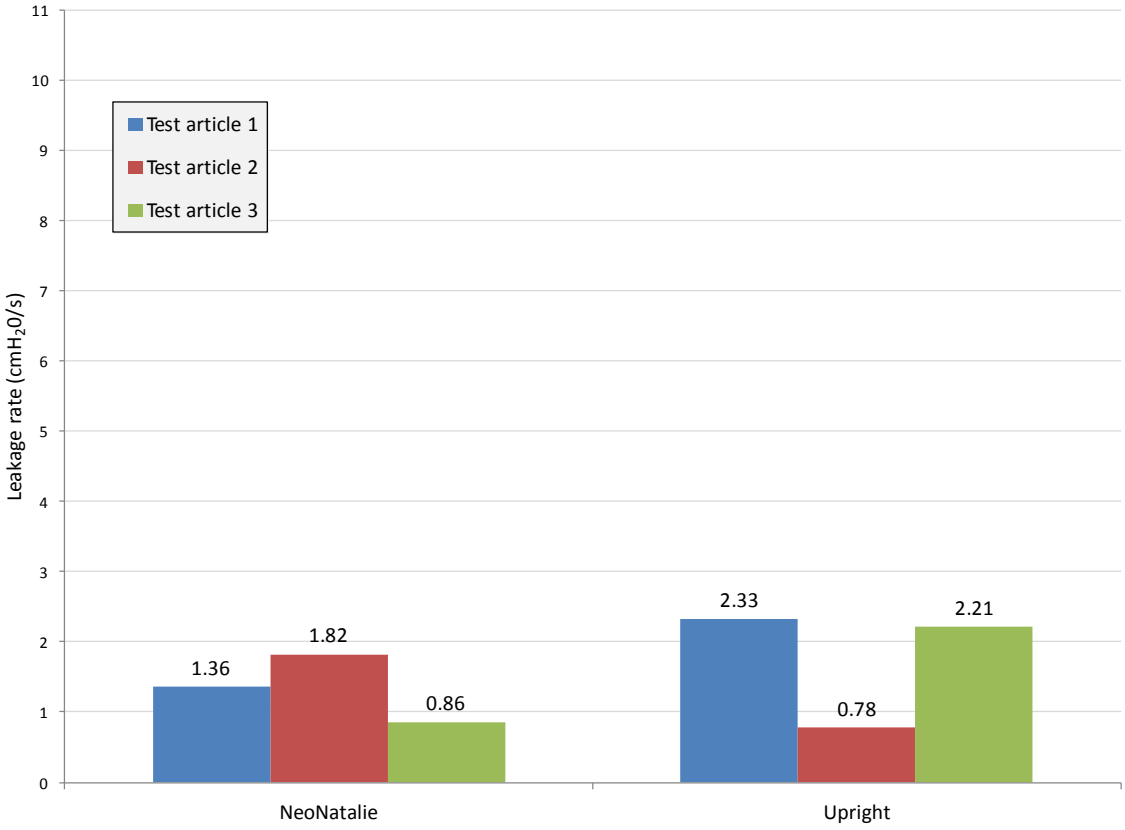
Figure 8. Photograph showing the setup for the leakage test. The pressure release valve was prevented from activating using thumb pressure for the duration of the test.



Results

Leakage rates for each resuscitator are shown in Figure 9. Leakage rates were found to be greatest at pressures below 15 cmH_2O and least at pressures between 15 cmH_2O and 30 cmH_2O for all resuscitators. Average leakage rates were 1.77 cmH_2O/s for the NeoNatalie resuscitator, and 1.35 cmH_2O/s for the Upright resuscitator.

Figure 9. Leakage rates for each resuscitator. Test articles 1, 2, and 3 are shown in blue, red, and green, respectively.



Discussion

It was surprising to observe such variability in leakage rates between test articles and, even more so, between experiments of the same test article. Overall, it was observed that leakage rates were comparable.

Conclusion

In general, the Upright resuscitator performed well when compared with the NeoNatalie resuscitator. The Upright resuscitator has significantly fewer parts and the potential for incorrect assembly has been greatly reduced. The Upright resuscitator has a 45 percent larger ventilation bag that can deliver up to 60 percent more volume (due to the more efficient elongated shape). Together with a mask designed to reduce

leakage, there may in fact be a risk of providing too much volume in the hands of an inexperienced user, and this is a question that should be explored in simulated resuscitation studies.

Assembly and disassembly of the Upright resuscitator is significantly simpler than the NeoNatalie. The instructions printed on the device were found to be helpful. Unscrewing the pressure release valve caused bruised thumbnails on more than one occasion, thus we recommend that this area of the design be reviewed in order to make the removal of this component less prone to causing injury.