A new resuscitator and facemask for newborns has been designed specifically to make newborn ventilation easier and more effective. It is designed for sustainability in low-resource settings, by being reusable and by achieving high-level disinfection with locally available methods. With fewer parts, reprocessing is easier. One version includes a novel PEEP valve.

**EXECUTIVE SUMMARY**

**Need**
- One in 10 newborns need assistance to initiate breathing after birth.¹
- Mortality increases by 16% for every 30-second delay in achieving effective ventilation of the baby.²
- Creating a good mask seal is a difficult skill.²

**More effective ventilations**
In a randomized clinical study, the new design was compared to a traditional horizontal-oriented resuscitator. The facemask was kept the new design for both resuscitator types. The new design showed higher mean tidal volume and gas leak during mask ventilation of preterm infants at birth of 29% (1.6-33%) and 40% (0-92%).²

**Improved usability**
A study from Seattle compared the new device with a traditional design. Thirty-eight participants ranging from neonatologists to midwifery students used the two designs with a mask and test lung, and afterwards performed disassembly and reassembly steps. Users then rated the devices on a Likert-scale, and results were calculated with a paired-sample t-test. The new design was rated significantly better (p=0.05). The participants on apparent durability ease of holding mask, ease of use (general), ease of disassembly and ease of assembly, but significantly less on ability to observe chemical disinfection.²

**Sustainable for low-resource settings**
**Disinfection**
- Steam-autoclavable, but is also validated for high-level disinfection with methods which may be the only available methods in low-resource settings. Boiling in clean water, or immersion in activated glutaraldehyde.

**Durability**
- Constricted with only durable materials (silicone rubber, polyvinylplastics, stainless steel), and is tested for 100 cycles of each reprocessing method.
- Spare parts of valve components and masks are available.

**Usability in reprocessing**
- Designed with a few components as possible, so as to reduce complexity in reprocessing (New device: 7 components for the user to handle, Traditional devices: 8 to 13 components).
- Complete reprocessing instructions are designed as an A3-size poster that can be hung on the wall.

**PRODUCT QUALITIES**

**Peek Valve**
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 helps prevent repeated lung alveolar collapse during ventilation. The help recruit lung volume more efficiently, clear congestion, and has snap connection to accessory oxygen kit.

**Better mask sealing**
A manikin study with inexperienced nursing and medical students found that the new resuscitator and facemask provided significantly less mask leakage (16% vs 60%, p<0.001) than the traditional design.³

**FACEMASK DESIGN**

**Ease of assembly and function testing**
It has been reported from rural hospitals in Kenya that even trained staff fail to consistently disassemble devices before disinfection, and devices frequently were overexposed to chemical disinfection.³

**False End Expiratory Pressure (PEEP)** is recommended for prerebirth babies.⁴

**Disinfection and reassembly**
- Disassemble and wipe with disinfectant
- Wipe off all debris
- Reassemble

**References**

**Imperfect mask seal**
- A good mask seal is a difficult skill. Two studies found median facemask leak with preterm infants at birth of 29% (1.6-33%) and 40% (0-92%).²
- In low-resource settings, manual bag-mask valves are typically used. These need to be reusable, low-cost, and easy to use and reprocess (disassembly, cleaning and disinfection, re-assembly and function testing).³
- It has been reported from rural hospitals in Kenya that even trained staff fail to consistently disassemble devices before disinfection, and devices frequently were overexposed to chemical disinfection.³
- Positive End-Expiratory Pressure (PEEP) is recommended for prerebirth babies.⁴

**PRODUCT QUALITIES**

**Reusable Peek Valve**
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**Improved ergonomic position**
with the vertical-oriented resuscitator with mass of device centered directly over facemask.

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