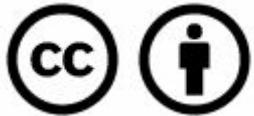


Ineffective Pre-oxygenation with Bag-Valve-Masks

Conflicting Clinical Use, Device Performance &
Regulatory Standards

Kate Kazlovich PhD Candidate
Azad Mashari MD
UHN Anesthesia & Pain Management Grand Rounds - 2021 . 3 . 12

Attribution 4.0 International (CC BY 4.0)



You are free to:

Share - copy and redistribute the material in any medium or format.

Adapt - remix, transform, and build upon the material for any purpose, even commercially.

The licensor cannot revoke these freedoms as long as you follow the license terms.

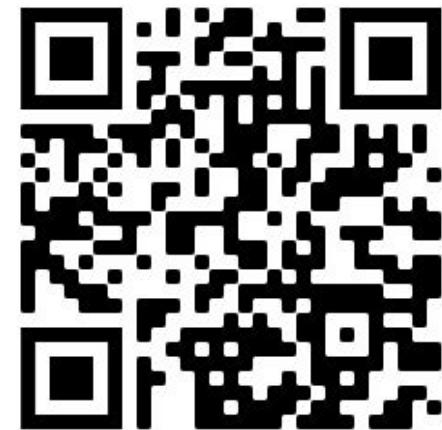
Under the following terms:

Attribution - You must give appropriate credit, provide a link to the license, and indicate if changes were made. You may do so in any reasonable manner, but not in any way that suggests the licensor endorses you or your use.

No additional restrictions - You may not apply legal terms or technological measures that legally restrict others from doing anything the license permits.

Project Data Repository: <https://github.com/tgh-apil/BVM-Evaluation>

Attribute as "Kazlovich & Mashari (2021) Ineffective Pre-oxygenation with Bag-Valve-Masks: Conflicting Clinical Expectations, Device Performance and Regulatory Requirements. UHN Anesthesia & Pain Management Grand Rounds. <https://github.com/tgh-apil/BVM-Evaluation>"



Competing Interests & Funding

The authors have no financial interest or connection with the devices and vendors discussed.

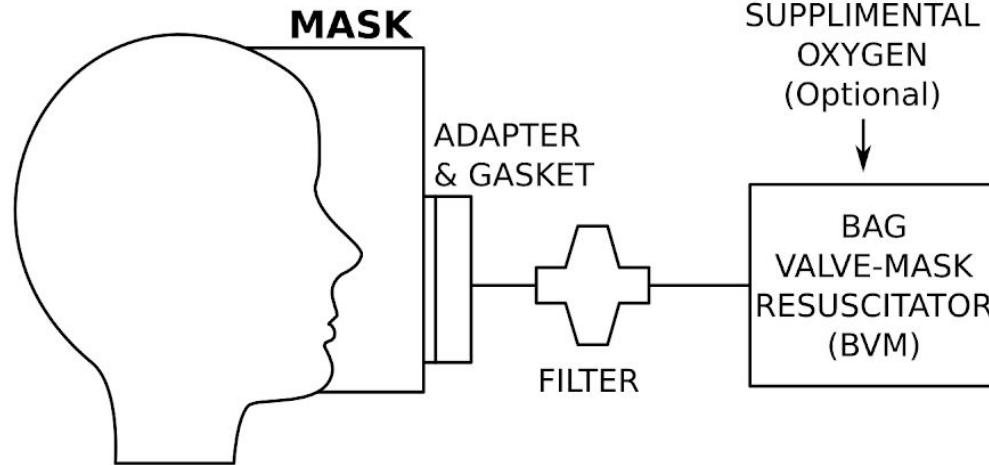
No project specific funding for the work presented here.

Research Funding

1. UHN/SHS Anesthesia Associates
2. Toronto General and Western Hospital Foundation
3. UHN AMO COVID-19 Fund
4. Ontario Centers of Excellence
5. NSERC Alliance Grant

Unexpected Finding:

PEEP valve made it much harder to **Inspire** through some BVMs



Questions

1. Are the BVM valves **entraining air from the expiratory port** during spontaneous inspiration?
2. **Isolated problem or systematic manufacturing defect** affecting tens of thousands of devices in the middle of a respiratory pandemic?

Devices Tested

3 samples each from different lots:

1. **Ambu Spur II** Adult BVM Disposable Resuscitator ([Ambu A/S Copenhagen, Denmark](#))

2. **CAREstream CARE-BVM**
[CS-100-A100-F-Univ Disposable Resuscitator](#)
([CAREstream Medical, Oakville, ON - Eastern Canada](#), [Surrey, BC - Western Canada](#))

3. **Laerdal Silicone Resuscitator (LSR)**
[Laerdal Medical, Toronto, CA](#)



Experimental set-up

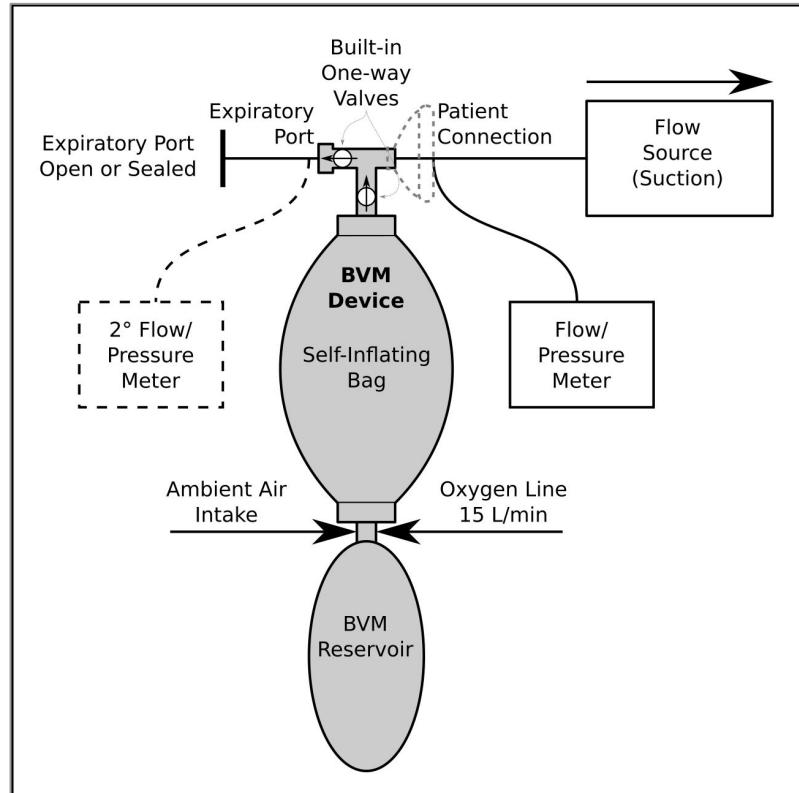
3 models; 3 samples/model

To evaluate valve competence measured inspiratory flow-pressure relationship with expiratory port open vs. blocked.

If patient valve is competent blockage of the expiratory port should not impact inspiratory flow.

Procedure followed CSA-Z10651-4-08 (R2018) with addition of testing under blocked expiratory port condition

Flow and pressure measured using FluxMed® GrH Respiratory mechanics monitors.



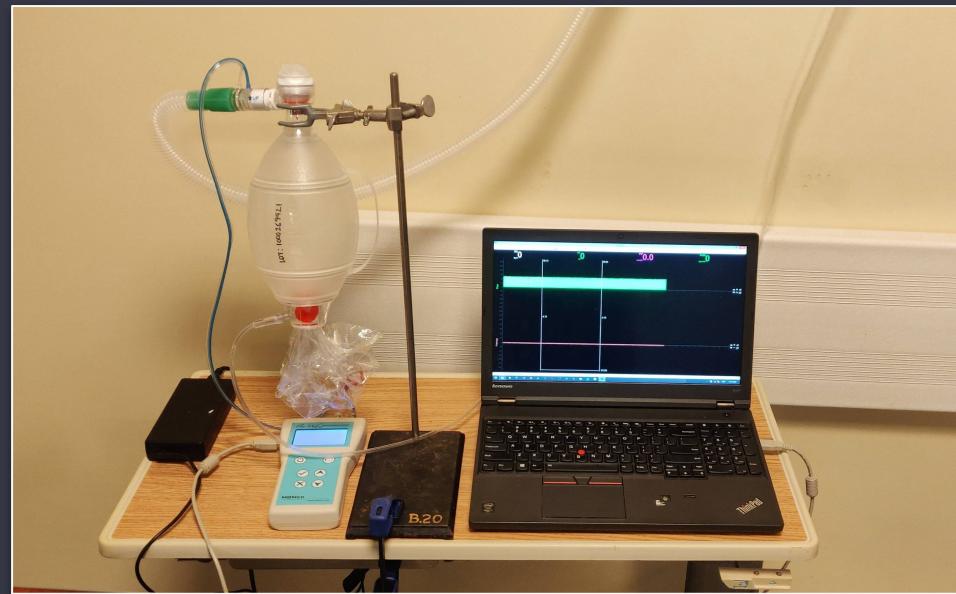
Experimental set-up

Inspiratory port of BVM connected to in-line respiratory monitor which was then connected to **wall suction**.

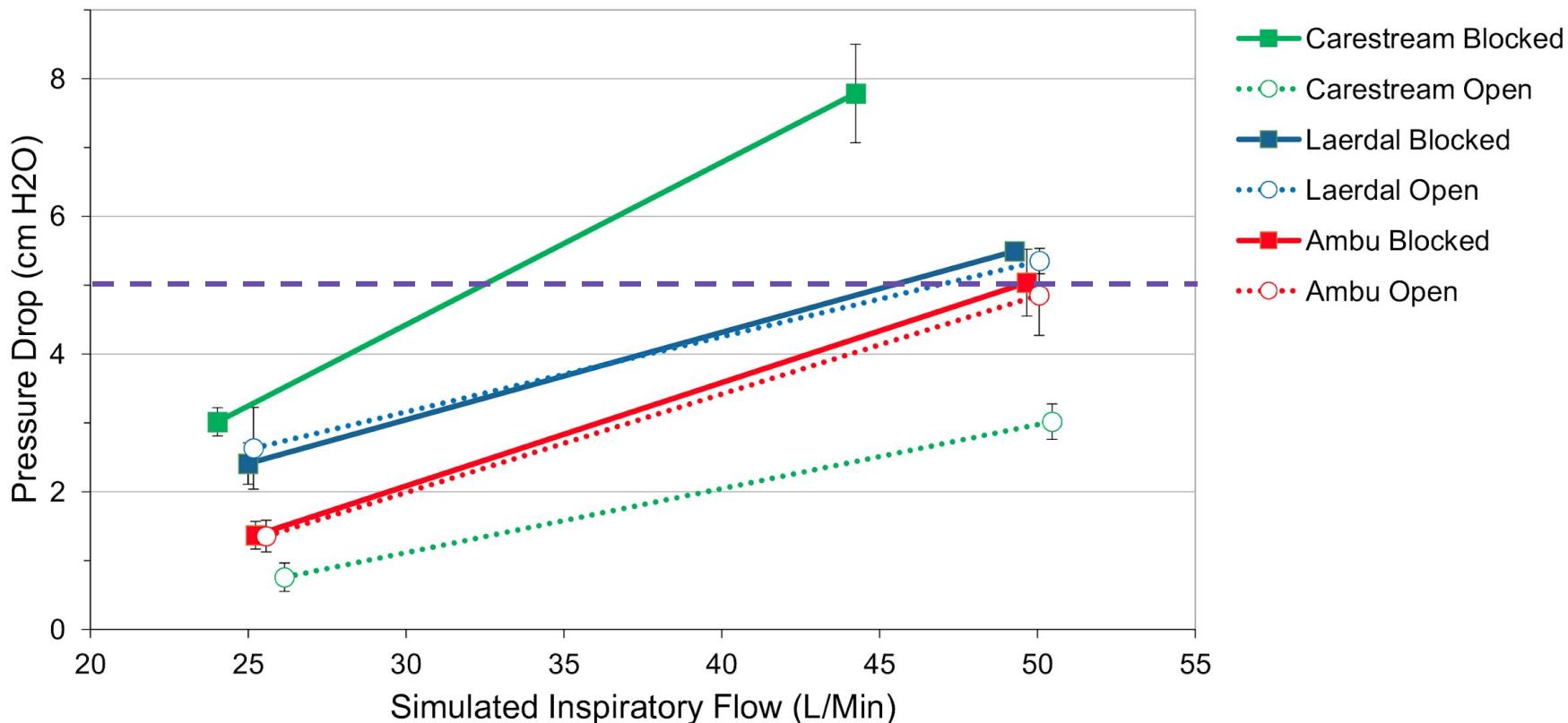
Oxygen at 15 L/min.

Test conditions: **expiratory port open vs. blocked**

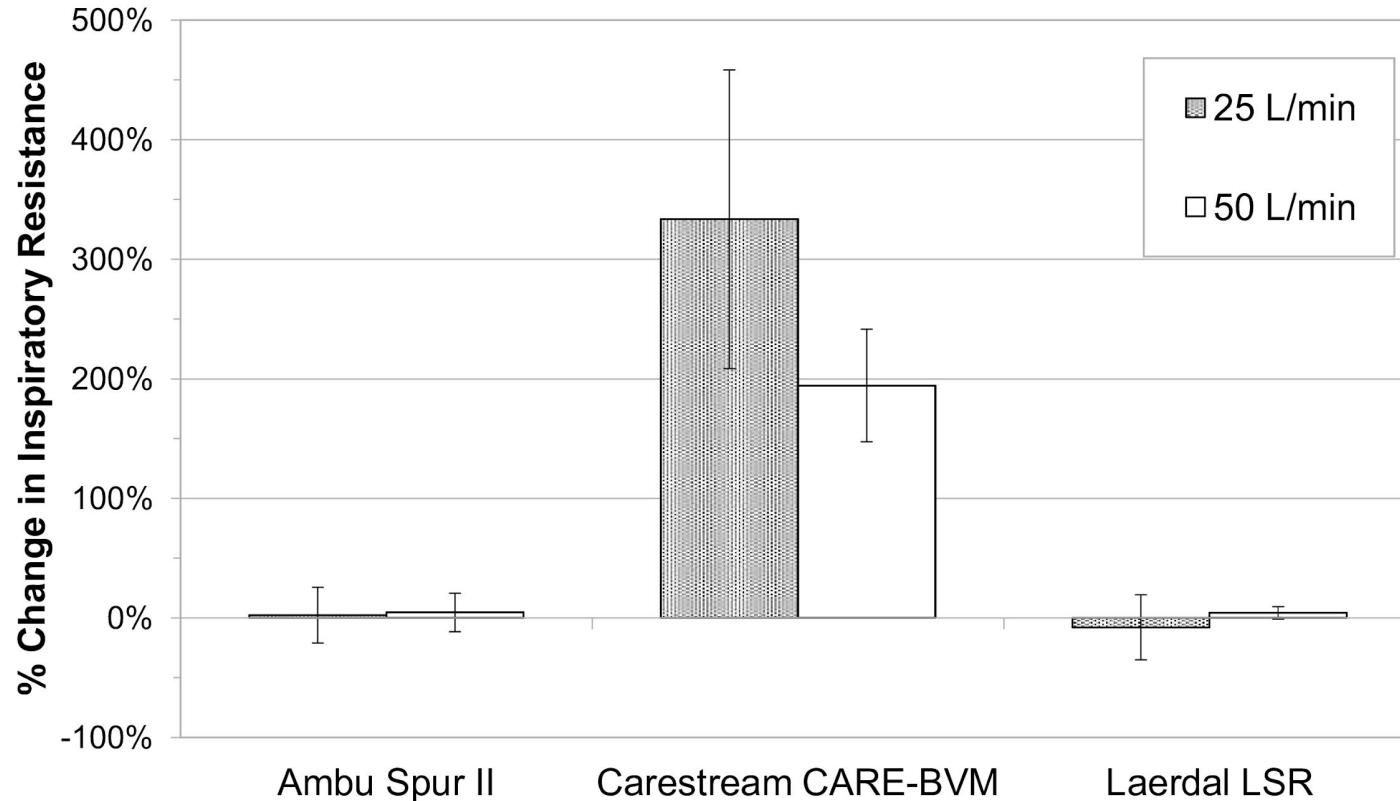
1. Suction titrated to flows of **~25 & 50 L/min.**
2. **Pressure** and **flow** recorded at 256 Hz and averaged over 120 seconds.
3. For blocked measurements expiratory port was fully sealed with polyethylene plastic food wrapping.



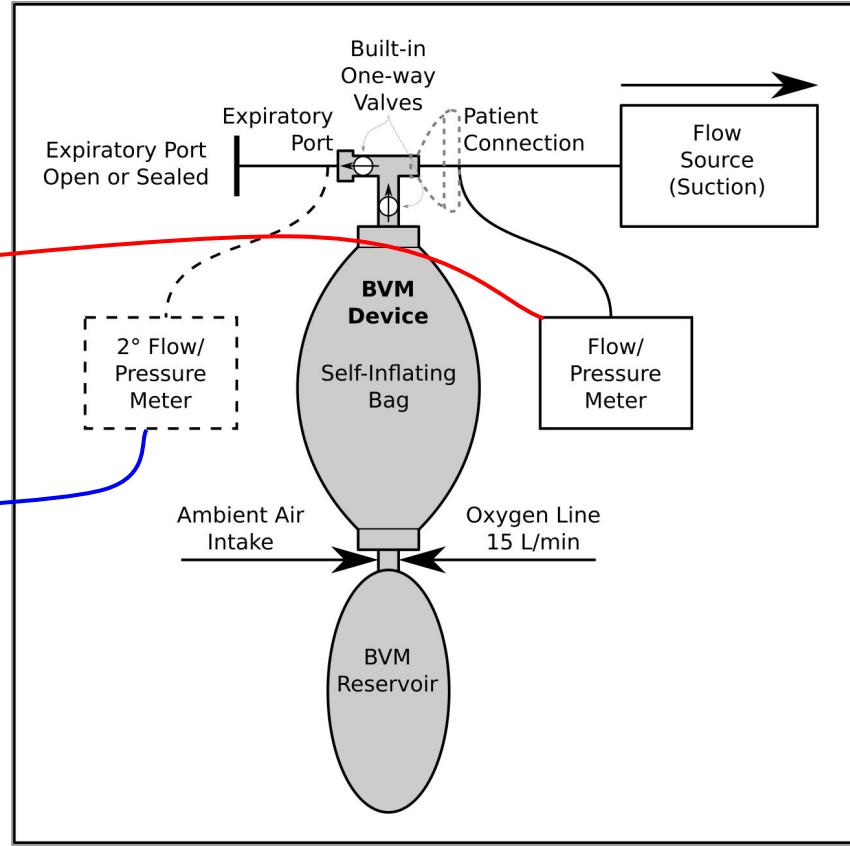
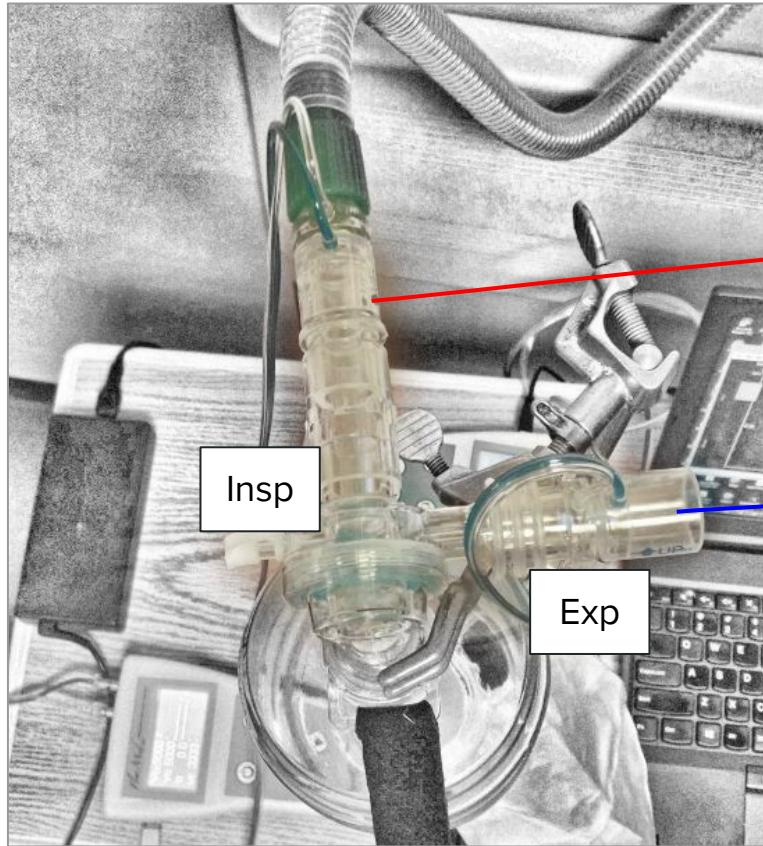
Pressure Drop vs. Inspiratory Flow With Expiratory Ports Open or Blocked in 3 Models of Bag-Valve-Mask Devices



% Change in Inspiratory Resistance with Blockage of Expiratory Port in 3 Models of Bag-Valve-Mask Devices



Experiment set-up: Measuring Inspiratory Leak Through Expiratory Port



Experiment set-up: Measuring Inspiratory Leak Through Expiratory Port



Sample	Target Inspiratory Flow (L/min)	Inspiratory Port Flow (L/min)	Expiratory Port Flow (L/min)	% Inspiratory Flow from Expiratory Port Leak
CARE-BVM (LOT: 230070)	25	25.3	14.7	58.0%
	50	49.7	36.6	73.6%
CARE-BVM (LOT: 220070)	25	25.3	11.9	47.0%
	50	49.9	25.3	50.7%
CARE-BVM (LOT: 140059)	25	25.8	11.2	43.3%
	50	51.2	29.6	57.8%

https://drive.google.com/file/d/1_ppU5NFp3fZgbe4sZXqNGGjswEY7Ntem/view?usp=sharing

Video showing the reservoir bag on BVM not collapsing despite 50 L/min suction flow at the inspiratory port and 15 L/min of oxygen flowing into the reservoir.

Immediate Bottom Line for Clinical Practice

Carestream BVMs are **not suitable for pre-oxygenation of awake breathing patients**

- Without PEEP valve: **maximum delivered oxygen ~ 35-60%**
- With PEEP valve: **high inspiratory resistance**
 - **Large mask leaks** with minor seal defects >> **Low FiO₂**
 - Increased work of breathing, potential **hypoventilation** especially in patients with respiratory compromise
 - **Anxiety, claustrophobia, feeling of suffocation** (independent of psychiatric history)

Carestream BVMs are suitable only for manual positive pressure ventilation

Immediate Bottom Line for Clinical Practice

Ambu Spur II (disposable) & Laerdal LSR (reusable) do not entrain air from expiratory port and **can be used** for pre-oxygenation of awake patients.

However ...

- Moderate inspiratory resistance (5 - 5.5 cm H₂O at 50 L/min)
 - **Good seal essential** for effective pre-oxygenation
 - Increased WOB with potential **hypoventilation, anxiety, claustrophobia**
 - Consider alternatives as appropriate (NRB, High flow NP)

The plot thickens ...



What is a BVM without a V?

Are CARE-BVM devices **officially defective? No!**

CARE-BVM conforms with the international technical standard ISO 10651-4-08 that is accepted by FDA, Health Canada and most other health regulators

The Official & Somewhat Secret Definition of BVM

CSA-Z10651-4-08 (reaffirmed 2018): Lung ventilators – Part 4: Particular requirements for operator-powered resuscitators ISO 10651-4:2002

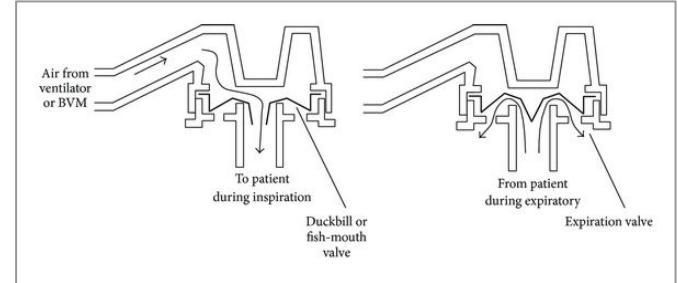
- Deliver $\geq 35\%$ oxygen with no more than 15 L/min line supply
 - Deliver $\geq 85\%$ oxygen with “additional accessory” (i.e. reservoir)
 - Not explicitly required in spontaneous ventilation
- Inspiratory pressure drop $\leq 5 \text{ cm H}_2\text{O}$ at 50 L/min peak flow
 - Not explicitly required with PEEP valve in place
- No requirement against entrainment of air via expiratory port during spontaneous breathing

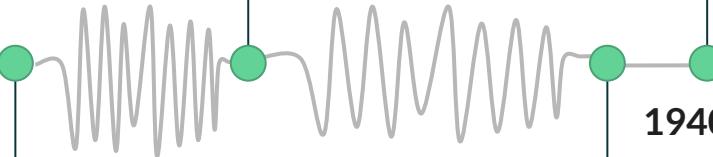


Does not require BVMs to provide effective pre-oxygenation

Everything you have ever wanted to know about **Bag-Valve-Mask Manual Resuscitators**

but were afraid to ask





50-19 million y.a platypus
and echidna lines split

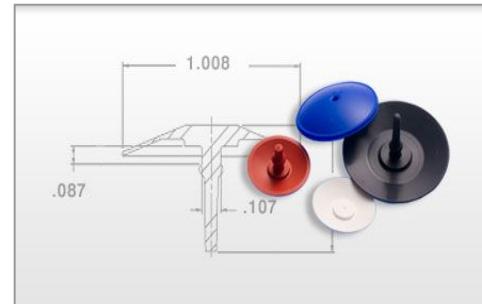
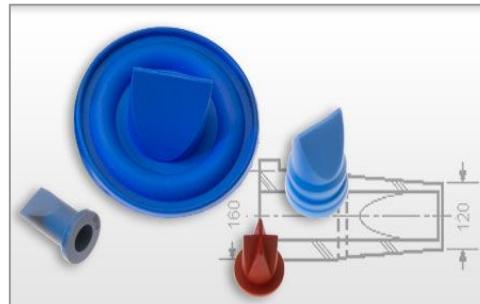


129-200 CE
Galen writes about
lungs & ventilation

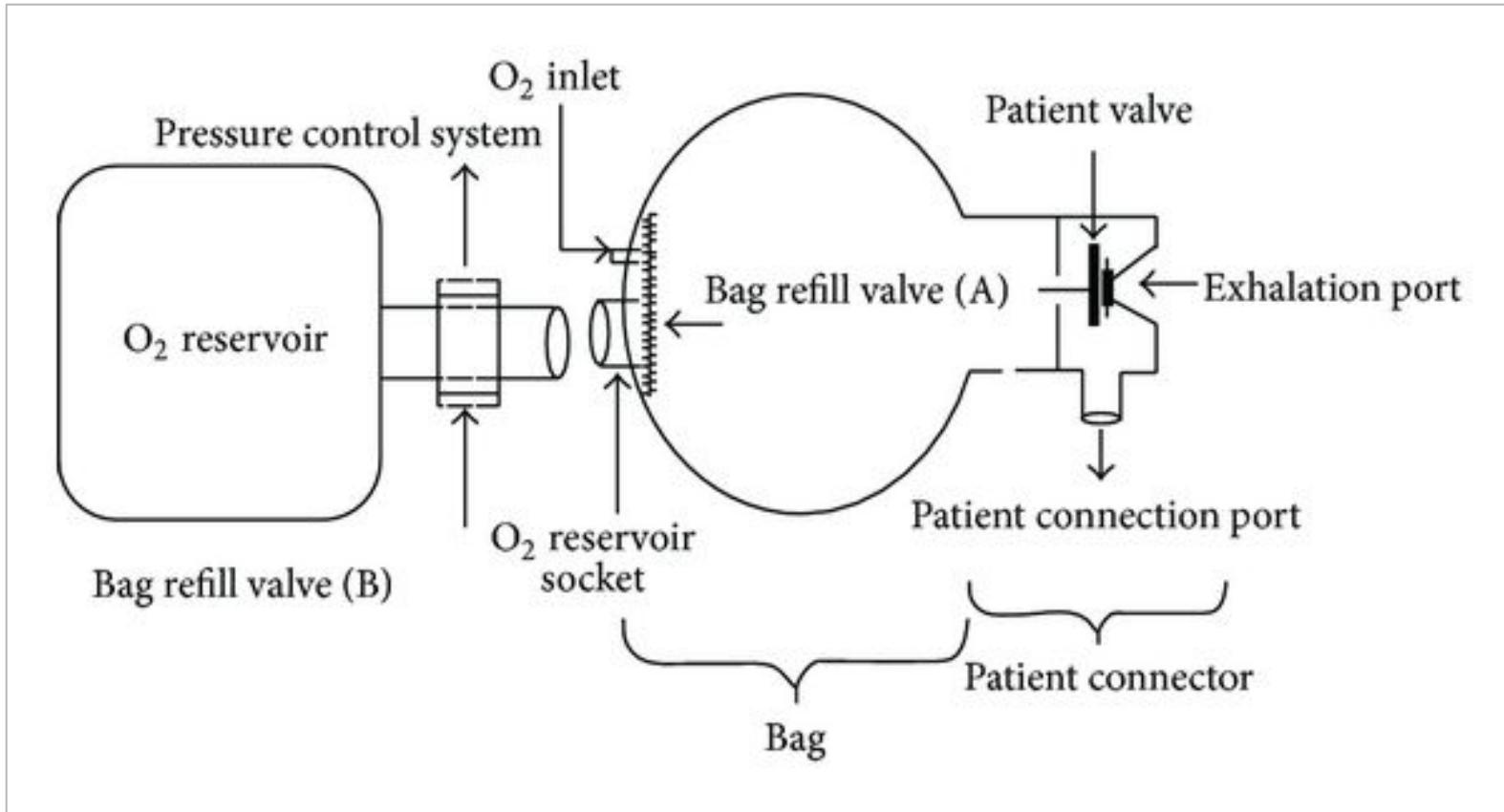
1953 German engineer Holger Hesse & Danish anesthetist Henning Ruben invent the **Artificial Manual Breathing Unit** ("Ambu"). Marketed in 1956



1940s unidirectional breathing valves developed
(Duckbill, Mushroom etc).

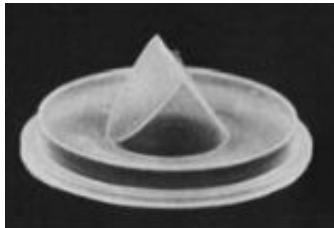


BVM: General Design



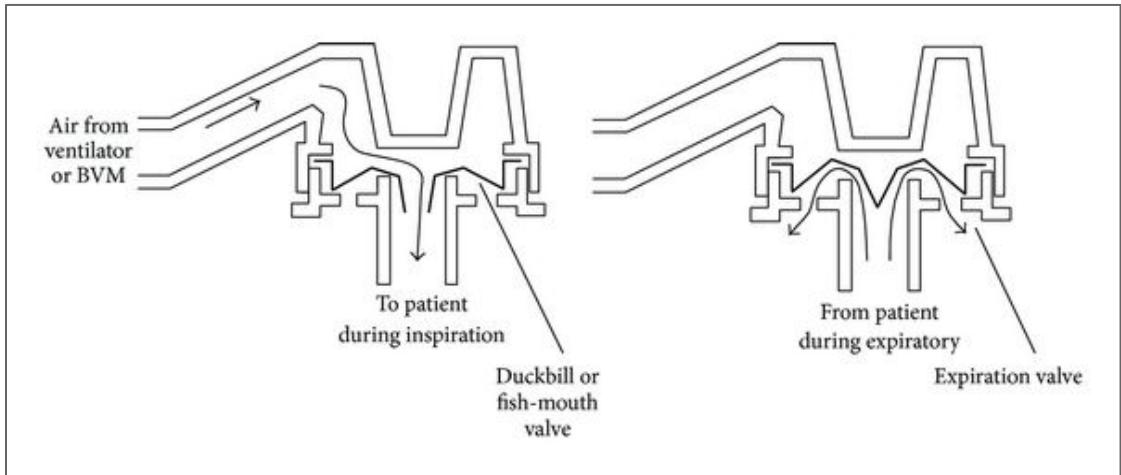
Duckbill (Fishmouth) Valve (e.g. CARE-BVM)

Positive pressure **upstream** of valve forces bills **open** & pushed flange against seat to **block expiratory path.**



Positive pressure **downstream** pushes bills **closed** & pushes flange away from seat to **opens expiratory path.**

But ...



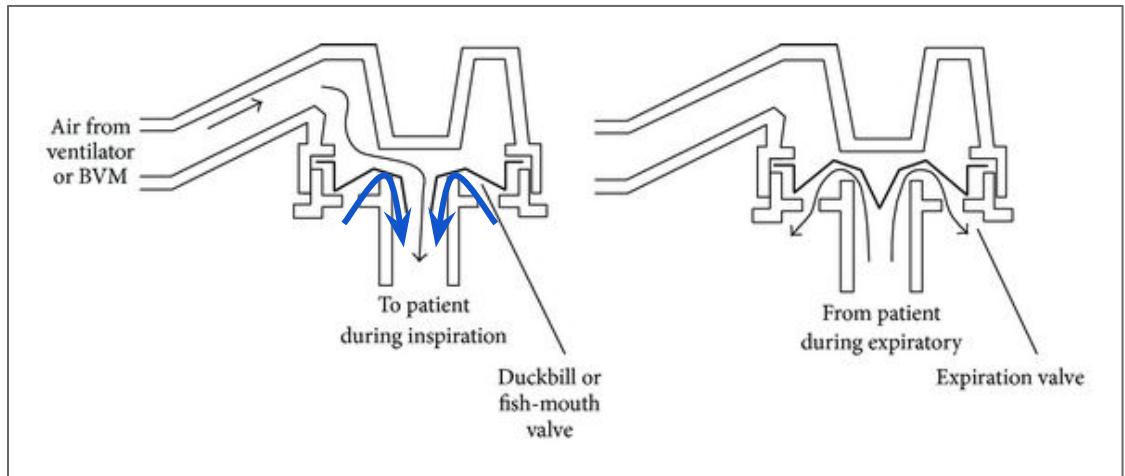
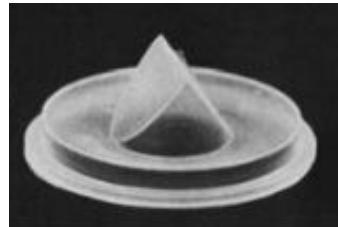
Duckbill (Fishmouth) Valve (e.g. CARE-BVM)

Positive pressure **upstream** of valve forces bills **open** & pushed flange against seat to **block expiratory path**.

Positive pressure **downstream** pushes bills **closed** & pushes flange away from seat to **opens expiratory path**.

But ...

Negative pressure downstream may open the valve without fully blocking expiratory path
→ **entainment of air**



Manual resuscitators and spontaneous ventilation— An evaluation

PETER J. MILLS, FFARCS; JUSTINA BAPTISTE, BSC; JON PRESTON, MD; GEORGE M. BARNAS, PhD

“... the most important determinant of percent-delivered oxygen was valve design. Valves incorporating a “disc” element to prevent air entrainment from the expiratory port gave the most efficient oxygen delivery, while ‘duck-bill’ valves did not reliably prevent air entrainment.”

“... high percent-delivered oxygen to spontaneously ventilating patients... is best achieved by a manual resuscitator unit with a valve of low resistance, incorporating a disc to prevent air entrainment. We recommend that manufacturers indicate... the degree to which their manual resuscitator unit presents resistance and delivers oxygen to a spontaneously ventilating subject.”

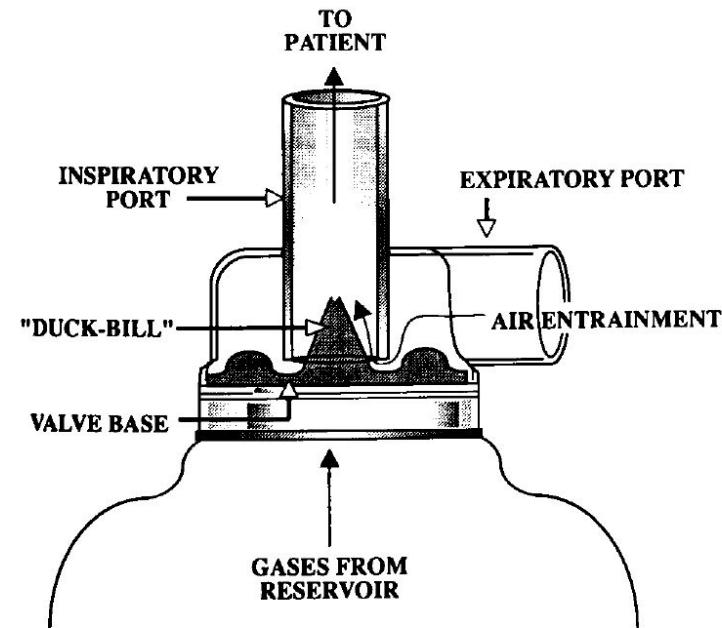


Figure 2. Diagram of a typical “duck-bill” valve (no “discs” to prevent air entrainment from expiratory port).

Air Entrainment in BVMs During Spontaneous Ventilation

1. Nimmagadda et al (2000) Efficacy of preoxygenation with tidal volume breathing. Comparison of breathing systems. *Anesthesiology*. 2000 Sep;93(3):693–8.
2. Driver et al. (2017) Flush Rate Oxygen for Emergency Airway Preoxygenation. *Ann Emerg Med* 69(1):1–6.
3. Driver et al. (2018) Preoxygenation With Flush Rate Oxygen: Comparing the Nonrebreather Mask With the Bag-Valve Mask. *Ann Emerg Med*. 71(3):381–6.

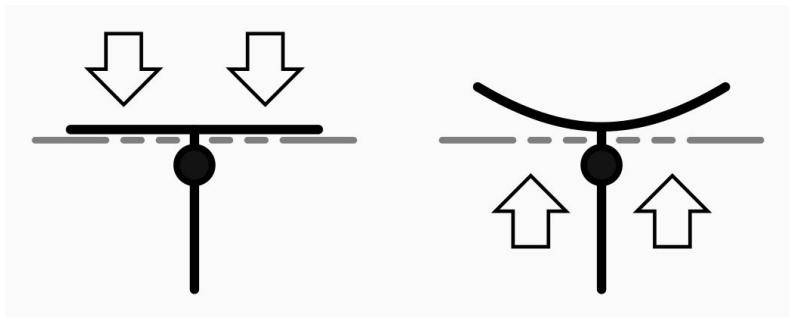
The “mushroom” valve (e.g. Ambu Spur II)



The oldest and simplest design.

Depending on housing design & quality may allow air entrainment from expiratory port.

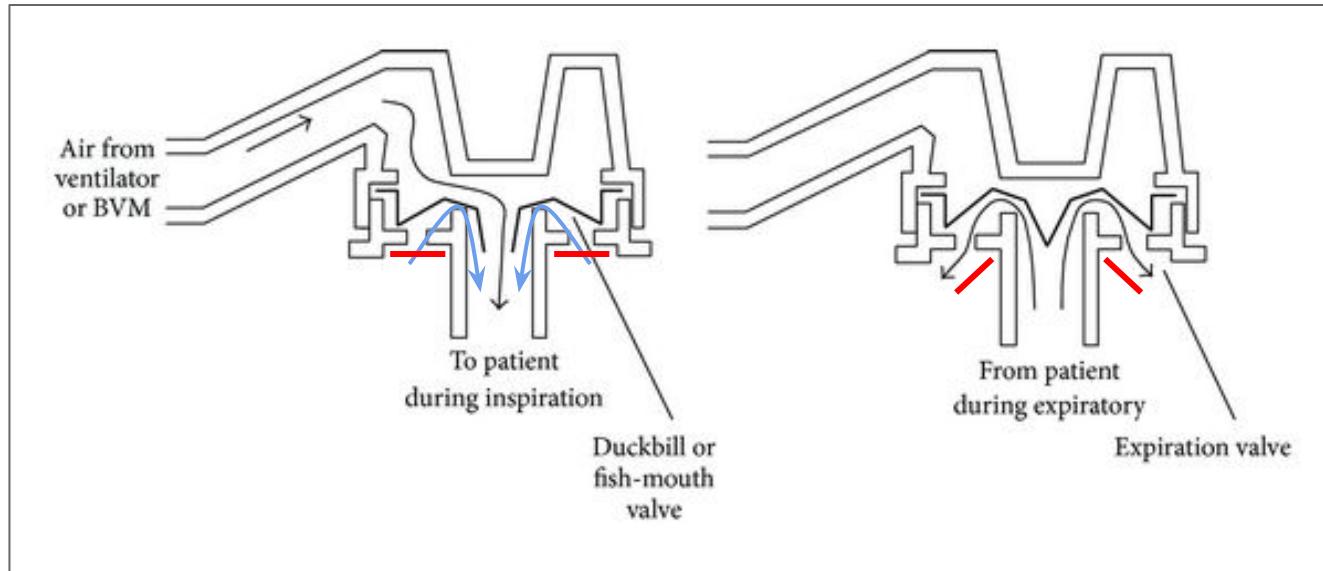
The particular model we tested (Ambu) did not allow detectible air entrainment.



<https://shundasealing2018.en.made-in-china.com/product/QNYmdRnuOkWc/China-Fmvq-Mushroom-Valve-Umbrella-Check-Valve.html>

Fishmouth-flap Valve (e.g. Laerdal LSR)

Adds a flap valve to the classic duckbill/fishmouth valve to prevent reverse flow through the expiratory port.



Conclusions

1. Current technical requirements for BVMs do not adequately address use in spontaneously ventilating patients.

- Recognized for **over 3 decades** but the relevant standards have not been modified.
- Extremely **limited access** to technical standards; lack of transparency
- International standards organizations and regulators are critical in making medical technologies effective and safe but they are far from perfect. Increasing engagement from clinicians is required.

Conclusion

2. As a practice group and health care institution we need to understand and assess the tools we use with great vigilance.

In-house capacity for testing and evaluating critical devices can make a significant contribution to patient safety and institutional resilience

References

1. Khoury et al. From mouth-to-mouth to bag-valve-mask ventilation: evolution and characteristics of actual devices--a review of the literature. *Biomed Res Int.* 2014;2014:762053.
2. Dorsch et al. 10 - Manual Resuscitators. In: *Understanding Anesthesia Equipment*. 5th edition. Philadelphia: Lippincott Williams & Wilkins; 2007.
3. International Organization for Standardization. CSA-Z10651-4-08 (reaffirmed 2018): Lung ventilators — Part 4: Particular requirements for operator-powered resuscitators ISO 10651-4:2002. International Organization for Standardization (ISO); 2002.
4. Mills et al. Manual resuscitators and spontaneous ventilation--an evaluation. *Crit Care Med.* 1991 Nov;19(11):1425–31.

Thank You!

Project Team

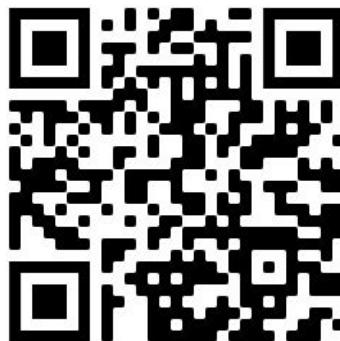
Vahid Anwari

Joe Fisher

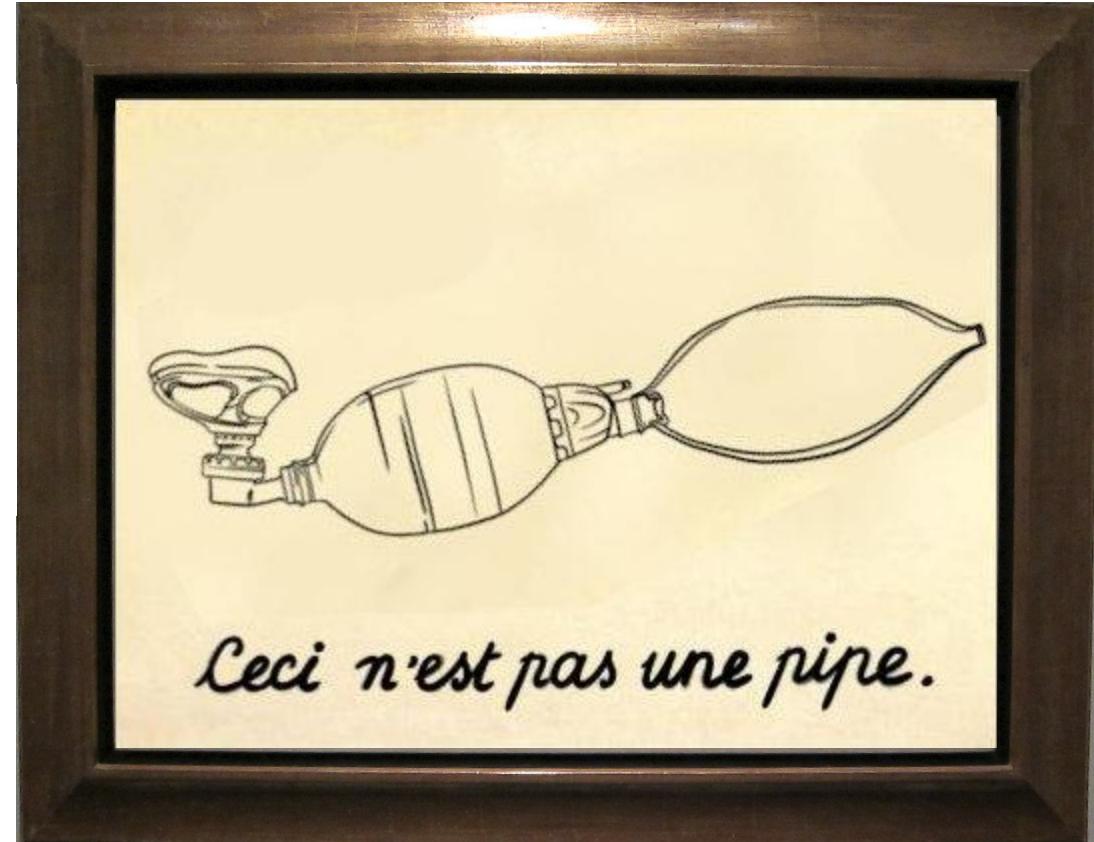
Ilya Lembrikov

Victoria Li

Joshua Hiansen



Thank you to Ana Lopez Filici & Ray Janisse for assistance in navigating the follow-up with product suppliers and vendors.



Modified from 1. BVM image by Nick Smith (CC-BY-NC 2.0) <https://www.flickr.com/photos/157046855@N03/49841437843> and 2. "The Treachery of Images (This Is Not a Pipe) (La Trahison des Images [Ceci N'est Pas une Pipe]), 1929" by [dalylab](#) is licensed under CC BY-NC-SA 2.0