

EXHALO™

SHIELD

Distributed by:

SOVEREIGN MEDICAL, INC.

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Why do I need the EXHALO Shield?

Aerosol-generating medical procedures (AGMPs) are interventions that can produce aerosols as a result of artificial manipulation of a person's airway. Additional precautions over and above baseline precautions are required when providing AGMPs

Precautions when performing the following AGMPs. (SEE BELOW FOR HIGHEST RISK AGMPs that require PROTECTED Droplet-Content-Enhanced). Droplet + Contact + Enhanced PPE (N95 + Full Face Shield, Level 2 gown and gloves) for the following:

- Bag-mask-valve ventilation (with a filter)
- CPAP or Non-Invasive Ventilation (until COVID-19 negative result)
- High flow or humidified oxygen
- Non-humidified oxygen at > 50%
- Tracheostomy insertion/tube change/decannulation
- Use of cough-assist device
- Open suctioning
- Any procedure that may cause a breach in ventilator circuit
- Ventilator circuit change (Flusso when changing circuit or switching from manual to mechanical ventilation)
- Inhaled anaesthetic

What is the EXHALO Shield?

A barrier between patients and staff



EXHALO shield was designed to minimize the release of airborne contaminants and aerosol particles upon patient exhalation

EXHALO Product Highlights:



- Works with many brands of oxygen or aerosol masks that utilize a metal nose clip
- Fits onto Adult and Pediatric aerosol and oxygen masks
- When used in collaboration with hospital vacuum system, helps direct patient exhalation
- Enhanced protection for patients and clinical staff
- Lightweight, transparent
- Single patient use, latex and BPA Free
- Assists hospitals with inventory management
 - Only one sku required to work with existing hospital oxygen masks

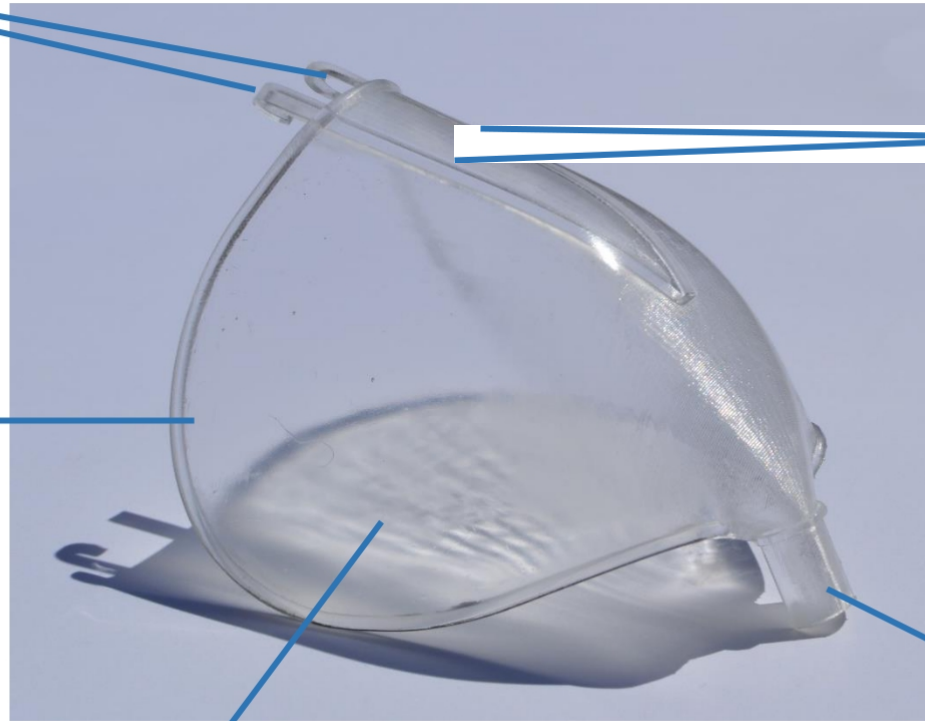
Product Code: 420-1900 cs 50



EXHALO Product Highlights:



Integrated Attachment Clips



Internal Channels to Guide Vacuum Flow

Transparent

Suction Port

Unique Design, cannot block exhalation ports



What masks does EXHALO work with?

Nebulizer, Simple, High-Concentration, Non-Rebreather, Aerosol, Entrainment



Single Securement: Salter, Sunmed **Dual Securement:** Hudson RCI, Hospitak, Airlife, Respan, Flexicare

Oxygen Therapy - Not just nebulizers!

Aerosol Mask



Simple Mask



Non-Rebreather Mask



EXHALO™

SHIELD

Rx Only   **REF** 420-1900
- Non-Sterile
- Not made with
Natural Rubber Latex

Instructions for Use

- Attach the port on the EXHALO Shield to suction tubing, set suction regulator to continuous suction between 80-100 mmHg for Adults and Pediatrics
- Hook the two prongs on the EXHALO shield to the metal nose clip of the mask.
- Single patient use to be disposed of in the same manner as the mask which the device is used with. Should the device become soiled or damaged, discard and replace with a new one.

Caution / Attention:

- Oxygen flow must be delivered when using EXHALO
- EXHALO is not a substitute for clinical staff wearing the appropriate personal protective equipment as per hospital policies.

Contraindications:

- Patients who cannot tolerate a face mask

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US and Int'l Pat. Pending.
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IFU0272C

How does EXHALO Against Current Therapy?

Pediatric Use

Current Therapy



EXHALO Solution



It does not remove all medication, if it did patient would not get treatment!

How does EXHALO Against Current Therapy?

Adult Use

Current Therapy



EXHALO Solution



It does not remove all medication, if it did patient would not get treatment!

Oxygen Delivery Concentrations in Simulated Spontaneously Breathing Patients using the EXHALO™ Shield

F.Florenza BHSc, RRT, FCSRT, M.Eberley RRT
McArthur Medical Sales Inc.

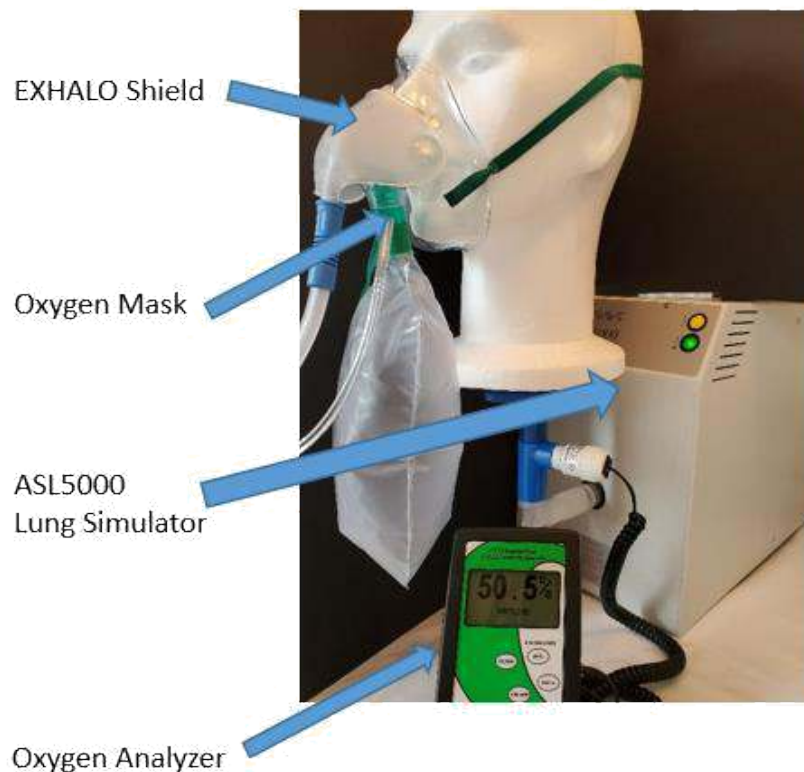
Introduction

The EXHALO Shield is a new innovative device designed to minimize the release of airborne contaminants and aerosol particles upon patient exhalation

Methods

- Spontaneously breathing COPD lung profile set up on ASL5000 (IngMar Medical):
 - Spont. Tidal Volume (V_t) = 565 ml
 - 18 breaths per minute
 - Inspiratory Muscle Pressure – 24 cmH₂O
 - Inspiratory Rise Time - 35%
- An Aerosol mask with Nebulizer, Simple Mask and Non-Rebreather mask (Salter Labs, USA) on the manikin head attached to the ASL5000
- An ASL lung simulator was set with 21 ml/cmH₂O compliance and 53 cmH₂O/litre/sec resistance
- Oxygen driving flow set as follows:
 - Aerosol mask with nebulizer - 6 L/min and allowed to nebulize for 5 min.
 - Simple mask - 6 L/min for 5 min.
 - Non-Rebreather mask - 8 L/min for 5 min.
- The EXHALO Shield was connected to a portable suction unit set at 100 mmHg (DeVilbiss Healthcare)
- Oxygen monitored with Analytical Industries All 2000 A oxygen analyzer

Experimental Set Up



Study Purpose

- To assess the use of the EXHALO Shield in collaboration with oxygen delivery devices.

Results

	Without EXHALO Shield		
	Simple Mask Average ± SD	Aerosol Mask Average ± SD	Non-Rebreather Mask Average ± SD
Average FIO ₂ Measured	35.55 ± 1.35	39.85 ± 2.45	51.75 ± 0.95
Minimum FIO ₂ Measured	34.2	37.4	50.8

	With EXHALO Shield		
	Simple Mask Average ± SD	Aerosol Mask Average ± SD	Non-Rebreather Mask Average ± SD
Average FIO ₂ Measured	36.3 ± 0.5	41.2 ± 1.7	50.9 ± 0.2
Minimum FIO ₂ Measured	35.8	39.5	50.7

Conclusion

- The use of the EXHALO Shield with Aerosol mask, simple mask and non-rebreather masks did not affect oxygen delivery.

Videos of EXHALO Shield in Use:

Current Therapy

EXHALO Solution

<https://youtu.be/-Xr7ae4h2h0>

What patient/where should it be used?

- Every nebulizer treatment
- With any infectious patient receiving oxygen therapy
- With any oxygen mask delivering more than 6 lpm of oxygen flow
- In all patient areas (ICU, PICU, ER, Wards)
- Patient transport



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