Design of a Cold-Weather Mask for Asthmatics

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Executive Summary

Asthma is a chronic inflammatory lung disease that inflames and narrows the airways, causing less air to flow to the lungs. Asthma is a serious condition that causes more than 10,000 deaths in the United States each year. It is therefore important to take preventative measures to protect against asthma attacks and symptoms.

To address this issue, a heating mask/respirator hybrid has been developed. Included in the design, there will be a passive, copper mesh heat exchanger to moderate the temperature fluctuation in respired air while maintaining breathability and comfort for the user. To prevent moisture buildup that may irritate the user, wicking fabric is used at the face-mask interface. As external particulates can cause an onset of an asthma attack, a N95 filter is incorporated in the mouthpiece of the design. A port has also been implemented in the mask to provide quick access to the inhaler without removing the mask during an asthma attack.

After several experiments varying path length, copper density and heat exchanger size, a prototype based on pressure differentials and temperature fluctuations was chosen. The heat exchanger, which includes a 8" heat exchanger path length, 0.8g of copper mesh per square inch of mask space, and a volume of 122 in^3, has comparable temperature fluctuations to the PolarWrap, a commonly used passive heat exchanger mask using the same copper based heat exchanger technology, and has a pressure gradient across the mask most similar to that of the ideal case – a simple scarf.

This cold weather mask was found to be as successful as PolarWrap in terms of heating the inhaled air and breathability. The inclusion of port and filter provides a fast access to medication during an asthma attack and protects the user from asthma triggers such as particulates. These additions make the cold weather mask a novel and useful prevention device for asthmatics.

Clinical Need: Preventative Treatment for Asthma

What is asthma?
- Disease of lungs; muscles of bronchial tubes tighten and thicken; air passageways become mucous filled

Who is affected by asthma?
- 34.1 million Americans diagnosed with asthma; 9 million of those diagnosed are under18
- It is the most common chronic condition among children; is 3rd leading cause of hospitalization for children
- Accounts for 2 million emergency visits and 10,000 deaths in the U.S. per year

What causes asthma and what can we do to prevent it?
- Varies from person to person: pollen, dust, and exercise are common causes
- Studies have found that **sudden drops in temperature and humidity can trigger bronchial spasms**
- Heating masks exist, but they have a number of problems:
  - Temperature fluctuations can occur within the mask- could be enough to trigger an attack
  - No way to easily deliver medication in the event of an asthma attack while wearing the mask
  - Moisture accumulates against face- can be uncomfortable

Market Description

- Asthma market worth $15 billion worldwide
- Major players in the asthma market: GlaxoSmithKline, AstraZeneca, and Merck.
- Insurance does not cover any accessories for asthma treatment.
- Product Advantages
  - Acts as an immediate preventative measure against asthma attacks
  - One-time purchase helps prevent asthma attacks for entire lifespan of individual
  - May reduce amount of inhaler medicine that needs to be purchased by reducing frequency of attacks
  - Increased lung strength of child by filtering the inhaled air

Design

- Fleece used as outer covering
  - Flap cut in exterior of fleece directly in front of mouth to allow for port access
  - 1/8" thick rubber cap glued to inside of flap; acts as stopper to port
- Polycarbonate port cut using the mill
  - 1 ¾" OD, 1 ½" ID, ½" thick on the bottom half, ¼" thick on the top half
  - 1/8" thick, slitted memory foam was glued into port to act as a pass-through
  - 1/8" thick rubber stopper fits into outermost section of the port when the port is not in use
- Pleather pouch filled with copper mesh serves as heat exchanger. Centered, circular hole in the pouch allows for port access. A small piece of N95 filter covers the opening in the pouch hole and allows warmed air to flow into the wearer's mouth. A pathlength for airflow was sewn into the heat exchanger.
- Port was sewn into the hole within the heat exchanger and the heat exchanger was sewn into the outer fleece pouch.
- Wicking layer sewn directly onto the side of the fleece that was to be adjacent to the face
- Velcro fasteners attached to fleece to allow wearer to easily take on/off the mask

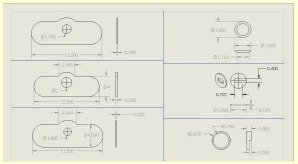

Figure 1. Schematic of heat exchanger components. Starting from the top left and going clockwise: the outer diameter of the port within the heat exchanger, the rubber stopper, the foam pass-through, the plastic port, the inner diameter of the port within the heat exchanger, and the copper mesh within the heat exchanger

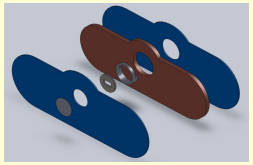

Figure 2. Schematic of layers present in the cold weather mask. From left to right: rubber stopper, outer fleece layer, foam pass-through, plastic port, copper mesh, inner fleece layer + wicking layer

Experimentation

- Tested the following variables:
  - Copper density (0.8g Cu per in^2 of mask vs. 1.09g Cu per in^2 of mask)
  - Pathlength (8 inches vs. 11.5 inches)
  - Size of mask (35 inches squared vs. 48 inches squared)
- Tested the following types of heat exchangers (4 prototypes, 2 controls):
  - Small pleather pouch, high density of copper, short airflow pathlength (S/Sh/H)
  - Big pleather pouch, high density of copper, short airflow pathlength (B/Sh/H)
  - Big pleather pouch, low density of copper, short airflow pathlength (B/Sh/L)
  - Big pleather pouch, high density of copper, long airflow pathlength (B/L/H)
  - Fleece outer pouch containing no heat exchanger (negative control) (scarf)
  - PolarWrap mask (positive control)
- Experiments designed to test:
  - Temperature variation in mask over time and over different activity levels
  - Breathability (pressure drop across mask)
  - Difference in temperature between exhaled and inhaled air

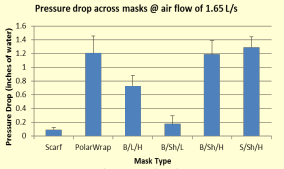

Figure 3. Pressure drop across each mask at room temperature. The lower the drop, the more breathable the mask.

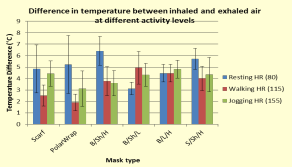

Figure 4. Temperature difference between inhaled air and exhaled air as measured at the face-mask interface. Ambient temperature is 8°C.

Experimentation (Continued)

Results:
- Temp. of exhaled/inhaled air are generally within 5 degrees Celsius of each other
- All masks tend to equilibrate to a constant temperature within 20-40 seconds
- Breathability is greatest for the scarf, second greatest for the large mask with a short pathlength and low copper density, and third greatest for the large mask with the long pathlength and high copper density
- Heavy exercise: max temp reached is lowest for the scarf. The big mask with the short pathlength and low copper density has a slightly lower max temp than the other masks

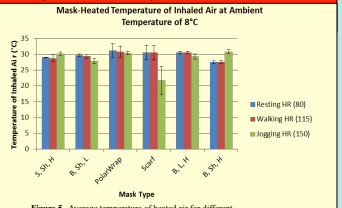

Figure 5. Average temperature of heated air for different mask types. Ambient temperature is 8°C

Novel Innovations

- N95 filter protects against outside air particulates and dust or spore build-up within the mask
- Port in front of mouth allows wearer to rapidly use their inhaler in case of an emergency asthma attack
- Mask's simple, scarf-like appearance is aesthetically pleasing

Estimation of Product Costs

- Manufacturing Cost: $24.47. Retail Price: $35.00. Profit: $10.53
  - Comparable to price of existing PolarWrap mask
- 1470 masks would have to be sold to break even

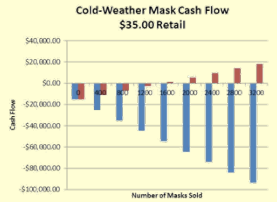

Figure 6. Estimated cash flow from mask sales

Part	Name	Quantity	Manufacturing Method	NRE Cost	Unit Cost
1	Heat Exchanger w/filter	1	Industrial sewing	$3,500	$4.10
2	Port	1	Injection molding	$4,000	$0.26
3	Rubber Cap	1	Lathe	$8,000	$0.16
4	Outer covering	1	Industrial sewing		$4.21
				$15,500	$8.73
			assembly		$6.81
			packaging		$0.20
				Total:	$24.47

Figure 7. Manufacturing costs for cold weather mask

Anticipated Regulatory Pathway and Future Work

- Class II Device:
  - Individual's life does not depend on it; mask is similar to existing heating mask
- 510(K) Pathway:
  - Heat exchanger materials similar to those in PolarWrap mask (patent # 6,196,221))
  - Filters used are N95; already approved by 3M.
    - Tests show that filters do not significantly affect breathability
  - Port is enclosed within mask; provides inhaler access
    - Cannot be removed from mask without sharp instrument; does not present choking hazard
- Future considerations:
  - Test effects of sudden transitions in activity level on temperature of inhaled air
  - Find way to separate port and foam pass-through from mouth; foam can become uncomfortably moist
  - Increase speed and reproducibility of production methods
  - Confirm reproducibility of results