COSMIC MEDICAL

Test Reports

"COSMIC BUBBLE HELMET"

Date: June 21, 2020

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Air Flow Leak of COSMIC Bubble Helmet Compared to Intersurgical Starmed CaStar CPAP Hood

Project #: COSMICBH1

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Approved By:
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Date: May 21, 2020

Objective

The objective of this test is to quantify air flow losses in the helmet due to leaks and ensure the helmet is capable of withstanding airflow while pressurized under operating conditions. Air flow losses also determine the air dispersion levels (escaping from the neck gasket) from the helmet. Leaks in the helmet can be characterized by observing the difference between measured inflow and outflow.

Equipment

- Mallinckrodt Puritan-Bennet PTS-2000 Ventilator Tester (x2)
- Air and oxygen source
- Air and oxygen tubing
- Intersurgical Air-Guard Clear HEPA viral filter
- AMBU PEEP valve
- Bubble helmet assembly

Methods

Calibration: characterizing flow sensors

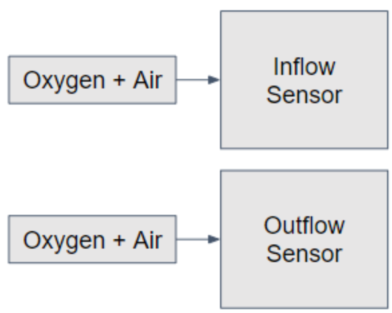

Figure 1. Schematic diagram for calibrating sensors

1. Ensure both sensors are set to the same measurement settings.
2. Set airflow source to 15 L/min.
3. Connect airflow source to inflow sensor input. Record measured flow and disconnect airflow source.
4. Connect airflow source to outflow sensor input. Record measured flow and disconnect airflow source.

Calibration: characterizing circuit losses

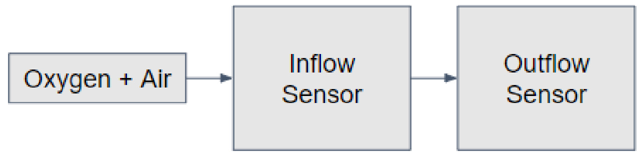

Figure 2. Schematic diagram for calculating circuit losses

1. Ensure both sensors are set to the same measurement settings.
2. Connect inflow sensor output to outflow sensor input.
3. Set airflow source to 15 L/min.
4. Connect airflow source to inflow sensor input. Wait until readings reach stable values. Record measured flow from both sensors and disconnect airflow source.

Each prototype will be tested with airflow varying between 15 L/min to 150 L/min. Three sets of tests for each prototype will be conducted: one with the PEEP valve set to 5 cmH_2O, the second with the PEEP valve set to 10 cmH_2O[1], and the third with the PEEP valve set to 15 cmH_2O. Calibration tests should be conducted before each test.

1. Intersurgical. "StarMed Study Portfolio." *StarMed Study Portfolio*. StarMedStudy, 2015.

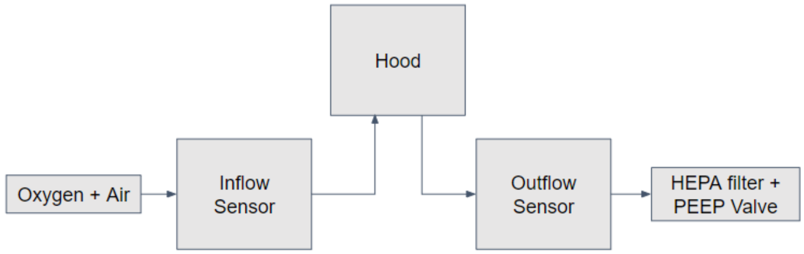

Figure 3. Schematic diagram for airflow test

1. Ensure both sensors are set to the same measurement settings.
2. Connect inflow sensor output to hood inspiratory port. Connect hood expiratory port to outflow sensor input. Connect outflow sensor output to HEPA filter and PEEP valve. Connect airflow source to inflow sensor input.
3. Set PEEP valve to 5 cmH_2O.
4. Set airflow source to 15 L/min.
5. Wait for the system to reach steady state when the helmet becomes fully pressurized and readings from both sensors maintain a steady value.
6. Record flow values from both sensors. Record pressure reading from outflow sensor.
7. Repeat steps 4-6 for increments of airflow up to 150 L/min. This is up to the discretion of the tester based on performance of the helmet. Do not exceed failure mode for helmets.
8. Repeat steps 4-7 for PEEP 10 cmH2O and PEEP 15 cmH_2O

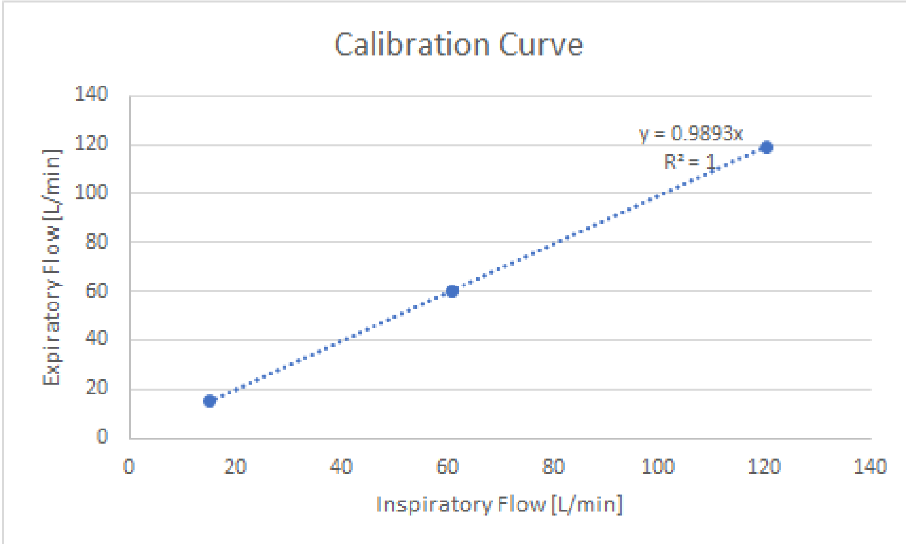

Figure 4. Circuit loss data

Results:

COSMIC Bubble Helmet Test Results -- cont'd on page 6

PEEP (cm H_2O)	Inspiratory flow (L/min)	Measured Inspiratory flow (L/min)	Measures Expiratory flow (L/min)	Calibrated Expiratory flow (L/min)	Proto 4.1 PEEP 5
5	15	14.9	14.1	14.22375	4.54%
5	20	19.9	19	19.16675	3.68%
5	30	30	29.07	29.32513	2.25%
5	45	45.1	43.74	44.12388	2.16%
5	60	60.02	58.22	58.73096	2.15%
5	70	70	68.4	69.0003	1.43%
5	80	80.02	78.5	79.18894	1.04%
5	100	100.2	99	99.86886	0.33%

5	120	120.15	118.1	119.1365	0.84%
5	150	150.03	147.88	149.1778	0.57%
PEEP (cmH_2O)	**Inspiratory flow (L/min)**	**Measured Inspiratory flow (L/min)**	**Measures Expiratory flow (L/min)**	**Calibrated Expiratory flow (L/min)**	**Proto 4.1 PEEP 10**
10	15	15.11	13.98	14.12835	6.50%
10	20	20.05	18.88	19.08034	4.84%
10	30	30.01	28.77	29.07529	3.11%
10	45	45.06	43.38	43.84032	2.71%
10	60	60	58	58.61546	2.31%
10	80	80.15	78.36	79.19151	1.20%
10	100	100.01	98.06	99.10056	0.91%
10	120	120.02	117.65	118.8984	0.93%
10	150	150	147.45	149.0147	0.66%

PEEP (cmH_2O)	Inspiratory flow (L/min)	Measured Inspiratory flow (L/min)	Measures Expiratory flow (L/min)	Calibrated Expiratory flow (L/min)	Proto 4.1 PEEP 15
15	15	15.1	13.61	13.7572	8.89%
15	20	20.03	18.58	18.78096	6.24%

15	30	30	28.46	28.76782	4.11%
15	45	45	43.11	43.57627	3.16%
15	60	60.01	57.88	58.50601	2.51%
15	80	80.03	77.96	78.80319	1.53%
15	100	100.04	97.76	98.81735	1.22%
15	120	120.28	118.06	119.3369	0.78%
15	150	150.14	146.7	148.2867	1.23%

StarMed Hood Test Results (With Manometer hole taped) -- cont'd on pg. 8

PEEP (cmH_2O)	Inspiratory flow (L/min)	Measured Inspiratory flow (L/min)	Measures Expiratory flow (L/min)	Calibrated Expiratory flow (L/min)	StarMed PEEP 5
5	15	15.2	13.6	13.67109	10.06%
5	20	20.1	18.5	18.5967	7.48%
5	30	29.9	27.9	28.04584	6.20%
5	45	45.1	42.8	43.02372	4.60%
5	60	60.3	57.2	57.49899	4.65%
5	70	70.3	67.6	67.95336	3.34%
5	100	100.6	97.2	97.70808	2.87%

5	120	120.3	116.4	117.0084	2.74%
5	150	150.1	146.3	147.0647	2.02%

PEEP (cmH_2O)	Inspiratory flow (L/min)	Measured Inspiratory flow (L/min)	Measures Expiratory flow (L/min)	Calibrated Expiratory flow (L/min)	StarMed PEEP 10
10	15	15.1	13.1	13.15261	12.90%
10	30	30.6	27.4	27.51004	10.10%
10	45	45.2	42.9	43.07229	4.71%
10	60	60.3	56.9	57.12851	5.26%
10	80	80.6	77.2	77.51004	3.83%
10	120	121.5	117.5	117.9719	2.90%
10	150	149.9	146.3	146.8876	2.01%
PEEP (cmH_2O)	**Inspiratory flow (L/min)**	**Measured Inspiratory flow (L/min)**	**Measures Expiratory flow (L/min)**	**Calibrated Expiratory flow (L/min)**	**StarMed PEEP 15**
15	15	15.9	12.7	12.751	19.81%
15	30	30.1	27.1	27.20884	9.61%
15	45	44.9	41.5	41.66667	7.20%
15	60	60.1	56.4	56.62651	5.78%
15	80	80.2	76	76.30522	4.86%

15	120	120.27	116.2	116.6667	3.00%
15	150	149.4	145.5	146.0843	2.22%

Graphs

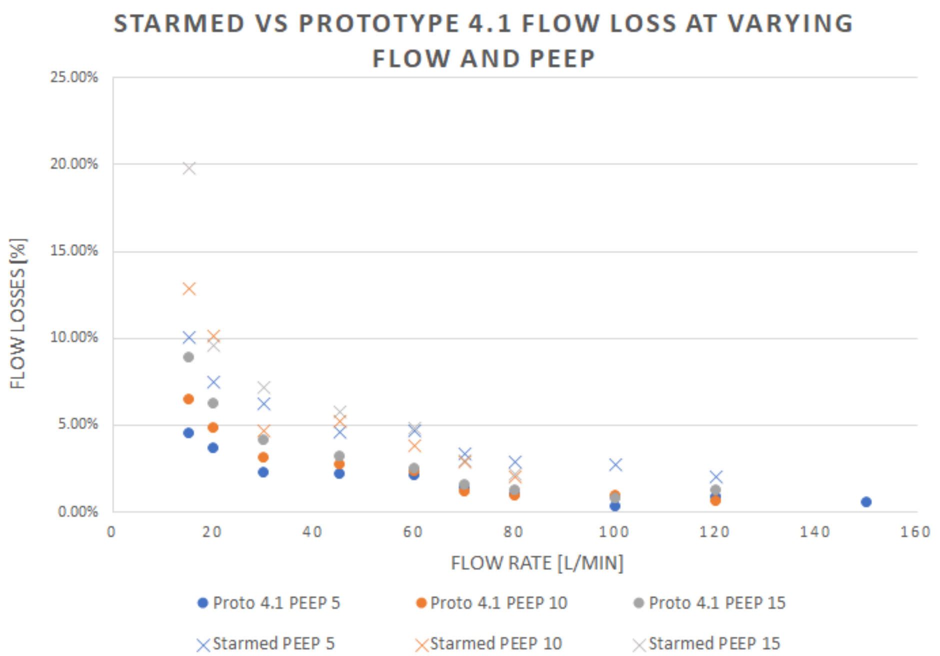

Figure 5: Air flow leak of the COSMIC Bubble Helmet (referred as prototype 4.1) to the CaStar CPAP hood with the manometer port sealed

Discussion

The COSMIC Bubble helmet consistently has fewer occurrences of air leakage than the StarMed hood at PEEP valve settings of 5, 10, and 15 cmH_2O. In a recent study performed by Feriolin, the StarMed helmet (with the neck cushion well inflated) has a negligible air dispersion radius compared to the one meter air dispersion radius of high-flow nasal cannula[1]. The tests provide evidence that the COSMIC Bubble Helmet has smaller air dispersion rates compared to the StarMed hood -with the described test setup- and can reduce virus aerosolization compared to high-flow nasal cannula. Note that the StarMed hood's manometer used a flow passthrough method to calculate internal pressure and contributed to leakage, so the top of the manometer was taped for a good comparison of neck gasket air leakage.

1. Ferioli, Martina, et al. "Protecting Healthcare Workers from SARS-CoV-2 Infection: Practical Indications." *European Respiratory Review*, vol. 29, no. 155, 2020, p. 200068., doi:10.1183/16000617.0068-2020.

Static Flow CO_2 Dilution in COSMIC Bubble Helmet

Project #: COSMICBH1

Results reported by:
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Vionarica Gusti, BSc., M.D.

Approved By:
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Wan Jun Wu, BASc. candidate (Co-lead of COSMIC Bubble Helmet) on June 4th, 2020

Date: May 21, 2020

Background

There is a potential for CO_2 accumulation and rebreathing in the helmet. Taccone's study on the effects of helmet ventilation on carbon dioxide rebreathing was carried out in healthy volunteers (n=8) and provides evidence that CO_2 levels are not related to the applied PEEP or hood volume[1]. Taccone's research builds upon investigations that showed the hood's CO_2 concentration is independent of the PEEP and dependent on the gas flow[2]. The authors found that the inspired CO_2 of helmet-based CPAP delivery through a ventilator was high (1.7 ± 0.4 kPa $PiCO_2$) while delivery of CPAP with a continuous high flow was low (0.3 ± 0.2 kPa $PiCO_2$ at a flow of 60L/min). The authors concluded the helmet should only be used with continuous high flow devices and the hood CO_2 level is independent of the applied PEEP or hood volume. The CO_2 level's independence on hood volume and PEEP is further supported by Fodil et al. 's study of the simulated dead space. The computer simulations show that the effective dead space for face masks (which has a volume comparable to tidal volume) while larger volumes such as a helmet have an effective dead space of approximately 4% of the hood's volume with a maximum of half the patient's tidal volume[3]. The paper suggests that patients with smaller tidal volumes are protected from CO_2 rebreathing by a larger internal volume. The existing research will be used to find the high, continuous flow required for the COSMIC helmet to minimize CO_2 rebreathing and CO_2 accumulation. Additionally, it provides evidence that CO_2 effects are independent of PEEP and volume.

1. Taccone, Paolo, et al. "Continuous Positive Airway Pressure Delivered with a 'Helmet': Effects on Carbon Dioxide Rebreathing." *Critical Care Medicine*, vol. 32, no. 10, 30 Sept. 2004, pp. 2090–2096., doi:10.1097/01.ccm.0000142577.63316.c0.
2. Patroniti, Nicole, et al. "Head Helmet versus Face Mask for Non-Invasive Continuous Positive Airway Pressure: a Physiological Study." *Intensive Care Medicine*, vol. 29, no. 10, 2003, pp. 1680–1687., doi:10.1007/s00134-003-1931-8.
3. Fodil, R., et al. "Comparison of Patient–Ventilator Interfaces Based on Their Computerized Effective Dead Space." *Intensive Care Medicine*, vol. 37, no. 2, 2010, pp. 257–262., doi:10.1007/s00134-010-2066-3.

Objective

The objective of this test is to ensure that the bubble helmet design does not allow for dangerous increases in CO_2 levels. CO_2 levels should not exceed a 20% relative increase[4] (International Organization for Standardization [17510], 2015), therefore this test will determine if the airflow characteristics adequately prevent rebreathing of CO_2. The maximum recommended time-weighted average for inspired CO_2 in industry is 1 %, 7.6 mmHg[4].

4. Association for the Advancement of Medical Instrumentation. (2015). sleep apnoea therapy equipment. (17510) Retrieved from https://www.iso.org/obp/ui#iso:std:iso:17510:ed-1:v1:en

Test background: Static Flow CO_2 Accumulation in COSMIC Bubble helmet

We performed a CO_2 accumulation test using a static flow set up, an in-house $EtCO_2$ testing developed in-house in Vancouver General Hospital Biomedical Engineering Department. We determine the amount of fresh gas flow required to dilute the titrated $EtCO_2$ flow from static flow 10L/min CO_2 at $EtCO_2$ 39mmHg. We use 10L/min as an estimation of minute ventilation of a normal adult with tidal volume of 500mL and respiratory rate of 20 breaths per minute, set at physiological level of 39mmHg. CO_2 sampling at the exhaust port intermittently.

Equipment

- Air and oxygen source
- CO_2 monitor
- CO_2 source (>99%)
- Test lung simulator (in house solenoid valves mixing chamber for fresh oxygen gas flow and CO_2 titrated to 39mmHg at 10L/min.
- Respiratory tubings and connectors
- COSMIC Bubble helmet
- A glass head mannequin

Methods

1. Connect the CO_2 and fresh air flow source to the helmet's inspiratory port
2. Connect a HEPA filter and peep valve to the expiratory port, set PEEP valve to 5 cmH2O
3. Connect the CO_2 sensor at the outflow port of the helmet
4. Adjust the flow of fresh air from 0 to 60 L/min in increments of five (5) and observe the CO_2 output (refer to CO_2 out in results below) at each step after the system equilibrates
5. Record $ETCO_2$ as CO_2 in (mmHg) and $FiCO_2$ as CO_2 Out (mmHg) from the CO_2 monitor

Results

Calculate the relative CO_2 concentration with the following formula:

$$Relative\ [CO_2]\ change\ = \frac{(step\ 9\ value) - (step\ 7\ value)}{(step\ 7\ value)} \text{x } 100\%$$

Remember, **the maximum CO_2 should be no more than a 20% increase** relative to ambient conditions.

CO_2 Accumulation at various flow rates

Flow CO_2 in (L/min)	PEEP (cmH_2O)	Flow of fresh gas (L/min)	CO_2 in (mm Hg)	CO_2 out (mm Hg)	CO_2 remaining (%)
10	5	0	39	37	94.9%
10	5	5	39	27	69.2%
10	5	10	39	20	51.3%
10	5	15	39	16	41.0%
10	5	20	39	14	35.9%
10	5	25	39	12	30.8%
10	5	30	39	10	25.6%
10	5	40	39	8	20.5%
10	5	50	39	7	17.9%
10	5	60	39	5	12.8%

10	5	80	39	5	12.8%

Graphs

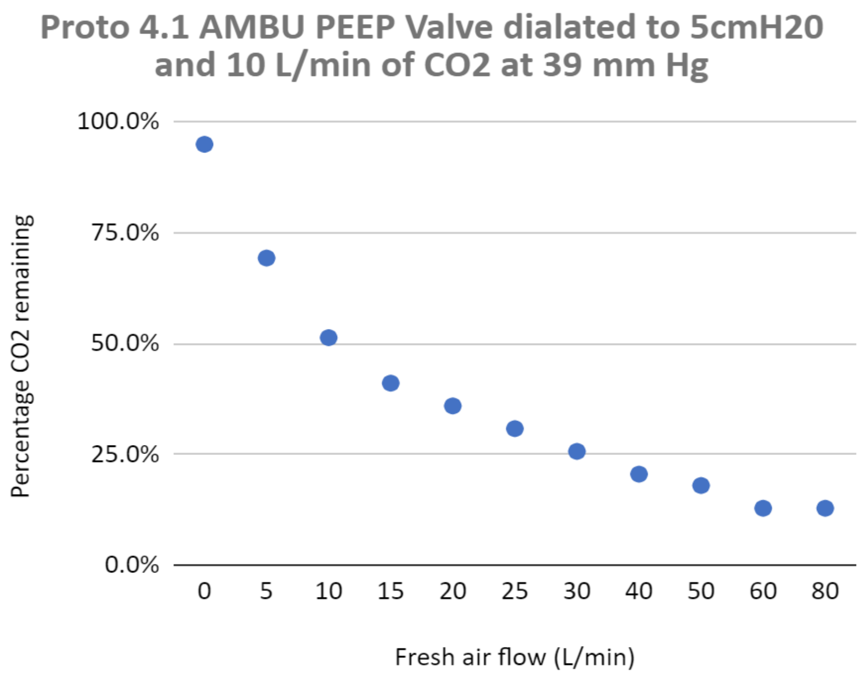

Figure 6. CO2 accumulation within the COSMIC Bubble Helmet

Discussion

The static CO_2 dilution experiment showed that at the upper limit of simulated CO_2 production in normal breathing, a minimum 40L/min is required to prevent accumulation of CO_2 over 7.6mmHg inside the helmet[4]. This test result does not estimate rebreathing of CO2 in a human subject, however, it shows fresh air flow and CO_2 mixing and clearance from the helmet. This finding supports the common therapeutic flow rate for commercial helmet non-invasive ventilation set at a recommended minimum of 30L/min in hyperbaric oxygen therapy usage and therapeutic level of 50-120L/min in hemet CPAP therapy in literature.

CO_2 Accumulation in the COSMIC Bubble Helmet

Project #: COSMICBH1

Results reported by:
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Wan Jun Wu, BASc. candidate (Co-lead of COSMIC Bubble Helmet) on June 4th, 2020

Date: May 21, 2020

Objective

To quantify flow rate required to operate the COSMIC bubble helmet to prevent CO_2 accumulation.

Equipment

1. CO_2 Monitor
2. Smart CapnoLine Plus™ oral and nasal cannula CO_2 monitoring probe
3. COSMIC Bubble Helmet
4. Flow meters
5. Respiratory tubings and connectors

Methods

1. Provide healthy subjects with CO_2 monitoring nasal cannula connected to a CO2 monitor or attached a CO_2 sensor at the outflow port.
2. Donned COSMIC Bubble Helmet into the subject as per instruction provided
3. Attach a HEPA filter and peep valve to the expiratory port, set PEEP valve to 5 cmH2O
4. Adjust the flow of fresh air from 0 to 60L/min in increments of 10L/min and observe the CO_2 output (refer to CO_2 out in results below) at each step after the system equilibrates
5. Record $ETCO_2$ as CO_2 in (mmHg) and $FiCO_2$ as (mmHg) from the CO_2 monitor

Results

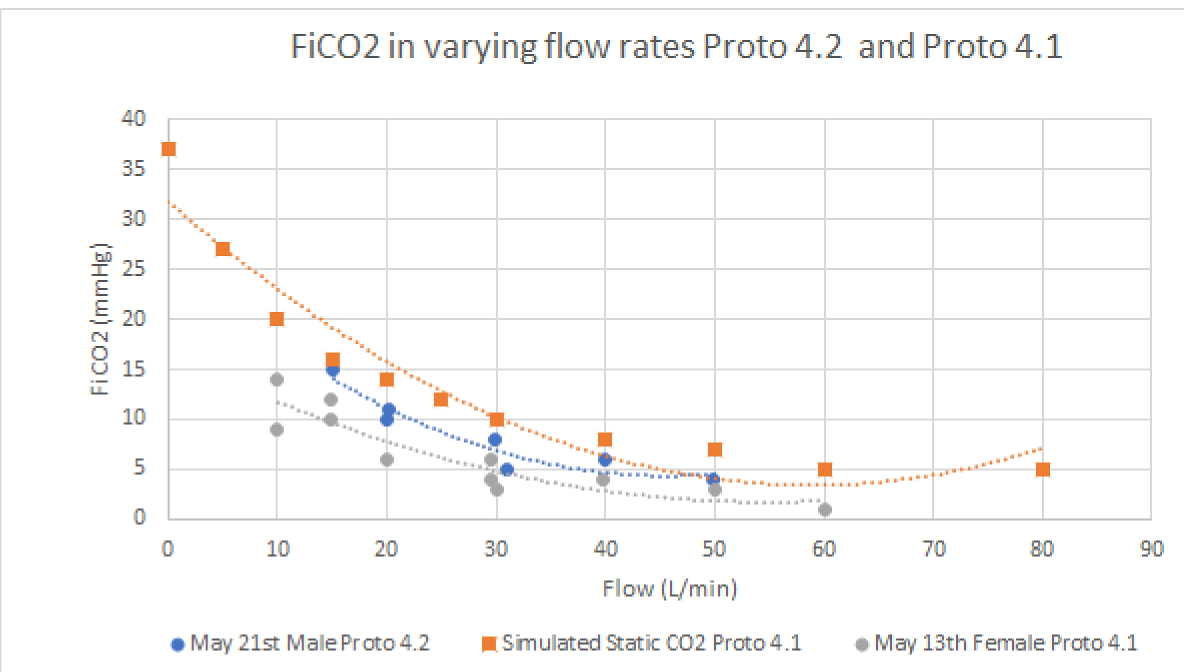

Figure 7: Level of $FiCO_2$ (mmHg) vs fresh air flow rate (L/min) inside the COSMIC bubble helmets on healthy volunteers as compared to the static flow CO_2 level experiment (Fig. 6).

Average $FiCO_2$ n=2 (15L/min: 12.3 mmHg, 20L/min: 8.5 mmHg, 30L/min: 5.25mmHg, 40L/min: 5mmHg, 50L/min: 3.5mmHg).

Discussion

We demonstrated that with two human subjects, one male and one female, a minimum flow rate of 30L/min is required to prevent increase in $FiCO_2$ above 7.6mmHg. The subjects in these experiments were healthy young adults in a sitting resting position. The recommended level for therapeutic patient use will be determined in future clinical trial feasibility study of the COSMIC bubble helmet and beyond the scope of this experiment. We demonstrated that the COSMIC bubble helmet is safe and comfortable to use for the duration of the experiment (approx. 60 minutes). Subject reported no clinical signs of CO_2 rebreathing during the experiment. Future experiments will be conducted to evaluate CO_2 accumulation in prolonged wear over several hours.

PEEP Range of COSMIC Bubble Helmet Compared to the Intersurgical Starmed CaStar CPAP Hood

Project #: COSMICBH1

Results reported by:
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Approved By:
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Wan Jun Wu, BASc. candidate (Co-lead of COSMIC Bubble Helmet) on June 4th, 2020

Date: May 21, 2020

Objective

The objective of this test is to determine whether the bubble helmet can withstand the operating pressures in the range of 5-to-25 cmH_2O, with a safety margin up to 60cmH_2O.

Equipment

- Air and oxygen source
- Air and oxygen tubing
- Pressure meter
- Simulated patient neck
- Intersurgical Air-Guard Clear HEPA viral filter
- AMBU PEEP valve
- Bubble helmet assembly

Methods

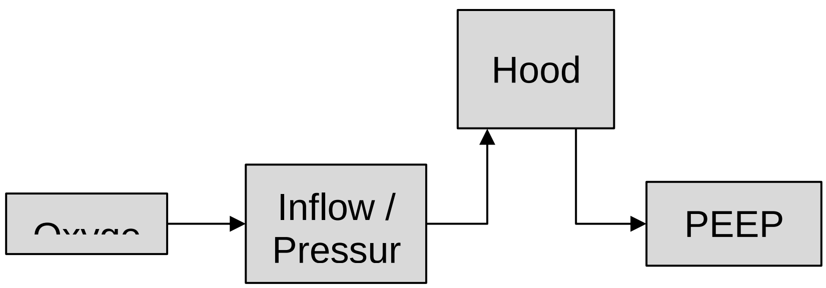

Figure 8. Schematic Diagram for PEEP test

1. Connect the pressure source to the helmet inflow port, the expiratory assembly to the helmet outflow port, and the silicone plug in the unused port. In this test, exclude the HEPA filter from the expiratory assembly to prevent it from influencing pressure readings.
2. Connect the pressure gauge to the expiratory port in series with the PEEP valve without a HEPA filter.
3. Place the helmet over the simulated patient neck, ensuring the neck ring creates a seal.
4. Pressurize the helmet at 5 cmH_2O, and observe the readings of the pressure meter.
5. Increase flow from 15 -120 L/min and record
6. Increase the pressure threshold of the PEEP valve by increments of 5 cmH_2O until 15 cmH_2O and record the pressure reading.

Results

COSMIC Bubble Helmet test results

Measured Inspiratory flow (L/min)	Pressure meter reading (cm H_2O) [PEEP @ 5 cmH_2O]	Pressure meter reading (cm H_2O) [PEEP @ 10 cmH_2O]	Pressure meter reading (cm H_2O) [PEEP @ 15 cmH_2O]
15	5	9.95	14.94
30	5.88	10.79	15.98
45	6.79	11.45	16.54
60	7.95	12.67	17.59
80	10.1	14.24	18.93
100	14.7	16.05	20.63
120	21.2	20.3	22.6
150	31.3	30.71	30.12

StarMed CPAP Hood test results (Manometer hole taped)

Measured Inspiratory flow (L/min)	Pressure meter reading (cmH_2O) [@ PEEP 5 cmH_2O]	Pressure meter reading (cm H_2O) [@ PEEP 10 cmH_2O]	Pressure meter reading (cm H_2O) [@ PEEP 15 cmH_2O]
15	5.6	10.5	14.7
30	6.4	11.5	15.7
45	7.3	12.01	16.2
60	8.43	13.1	16.9
80	9.39	14.6	18.3
100	14.2	N/A	N/A
120	21	20.2	22
150	30.91	30.4	29.6

Discussion

The results for pressure containment were nearly identical for both the COSMIC Bubble helmet and the StarMed hood. The pressure inside the helmet is dependent on the flow rate in addition to the PEEP valve setting. This proves that the helmet is able to withstand high pressures of 30 cmH2O without observed failure of the components: hood, neck seal, and straps. It was further observed that the pressure in the hood is highly dependent on the flow at higher flow rates (>120 L/min).

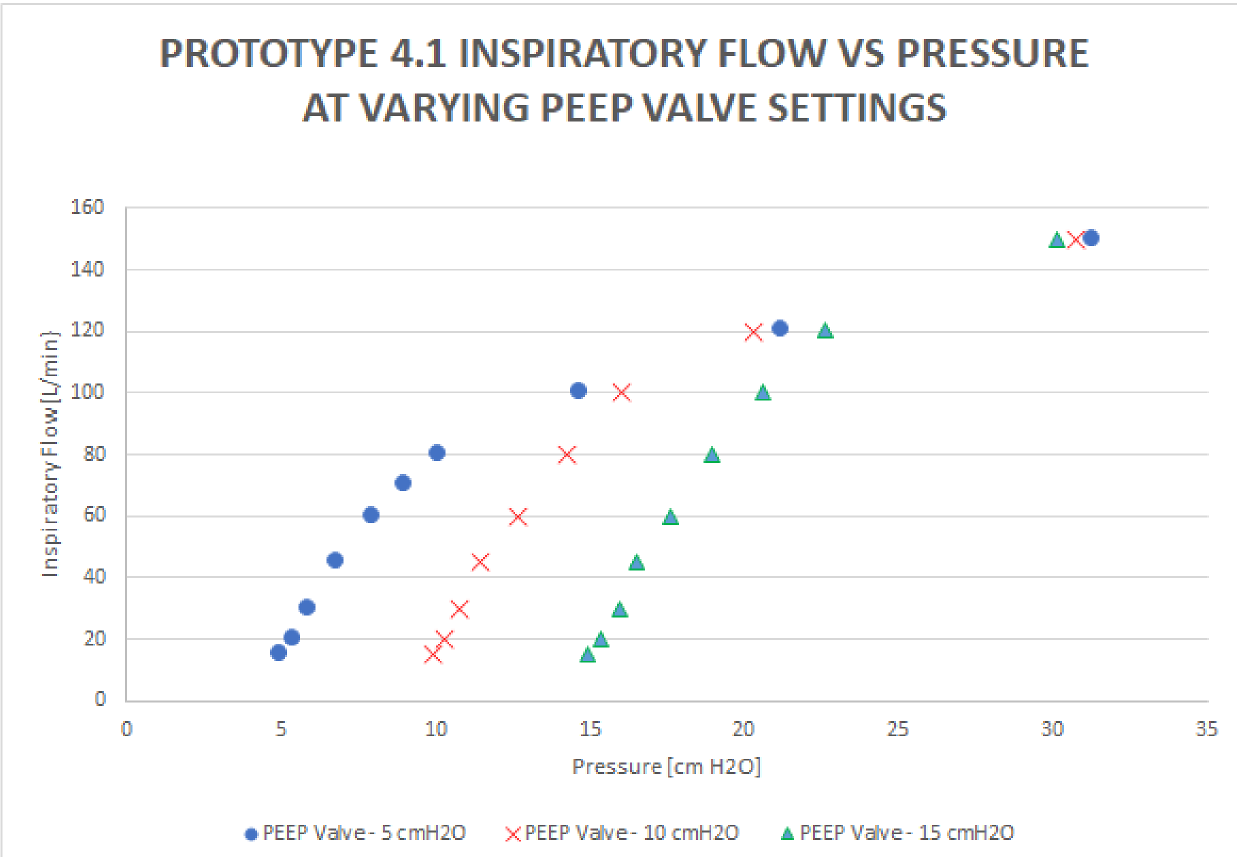

Figure 9. Pressure vs inspiratory flow at varying PEEP valve settings

Operating Noise Level of COSMIC Bubble Helmet "CPAP Hood" Compared to Similar NIV Helmet Ventilation Systems

Project #: COSMICBH1

Results reported by:
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Approved By:
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Wan Jun Wu, BASc. candidate (Co-lead of COSMIC Bubble Helmet) on June 4th, 2020

Objective

Noise is expected due to turbulent airflow in the helmet. The objective of this test is to determine if the noise level within the helmet is within acceptable values at various flows. Acceptable values are determined by existing helmets by Intersurgical and Dimar (referenced in discussions).

Equipment

- Quest electronic permissible sound level meter 211A/FS.
- COSMIC Bubble Helmet Proto 4.1
- Respiratory circuit attachments and connectors
- Intersurgical Air-Guard Clear breathing filter (HEPA)
- Ambu® PEEP Valves
- Wall oxygen
- Flowmeter PTS 2000
- Digital pressure gauge PTS 2000
- Head and neck mannequin

Method

Sound pressure will be measured using a sound meter at different gas flow levels between 15 - 120 L/min to quantify the sound levels in the helmet.

Results

The COSMIC Bubble Helmet performed similarly to the CaStar CPAP Hood in the lab as well as to the helmets tested in the study referenced below.

Table 1. Noise at Various Flow Rates for COSMIC Bubble Helmet

Inspiratory flow (L/min)	Sound Pressure (dB) Test 1	Sound Pressure (dB) Test 2
15	50	<70
30	69	<70
45	80	76
60	87	81
80	88	83
100	83	85
120	87	87

Table 2. Noise at Various Flow Rates for CaStar CPAP Hood

Inspiratory flow (L/min)	Sound Pressure (dB) Test 1	Sound Pressure (dB) Test 2
15	N/A	<70
30	65	65
45	N/A	70
60	77	75

80	N/A	75
100	N/A	80
120	N/A	87

Discussion

Note that ambient noise was not accounted for in our experiment and that actual sound pressure values would be lower. Additionally, our head and neck mannequin is aerodynamically smooth but we assumed the laminarizaing effects of the mannequin are negligible. PEEP also had negligible effects on sound pressure.

StarMed and Dimar hoods perform similarly in noise levels, and there is a 38% increase in sound pressure level at a gas flow of 40 L/min compared to a 20 L/min (74 dBA vs. 52 dBA respectively)[1]. The authors of the study suggest a diffuser filter should not be used with gas flows over 30 L/min because the filter will amplify the sound pressure. However, we found that a diffuser HEPA filter placed before the inflow port attenuates sound at all flow rates by approximately 7 dB. Our results found that our helmet performs similarly to the existing Intersurgical CaStar CPAP Hood and Dimar hood. Earplug is advisable for patients who experience discomfort with the noise level.

[1]Benavente-Fernández, Isabel, et al. "Effect of Filters on the Noise Generated by Continuous Positive Airway Pressure Delivered via a Helmet." *Noise and Health*, vol. 19, no. 86, Jan. 2017, pp. 20–23., doi:10.4103/1463-1741.199237.

CO2 Accumulation of Starmed CaStar CPAP Hood

Project #: COSMICBH1

Results reported by:
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Approved By:
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Wan Jun Wu, BASc. candidate (Co-lead of COSMIC Bubble Helmet) on June 21, 2020

Date: June 4, 2020

Objective

To get a benchmark of CO2 accumulation within a Health Canada and FDA approved NIV helmet ventilation device.

Equipment

1. CO_2 Monitor

2. Smart CapnoLine Plus™ oral and nasal cannula CO_2 monitoring probe
3. Starmed CPAP Hood
4. Flow meters
5. Respiratory tubings and connectors

Methods

1. Provide healthy subjects with CO_2 monitoring nasal cannula connected to a CO2 monitor or attached a CO_2 sensor at the outflow port.
2. Donned Starmed CPAP Hood into the subject as per instruction provided
3. Attach a HEPA filter and peep valve to the expiratory port, set PEEP valve to 5 cmH2O
4. Adjust the flow of fresh air from 0 to 60L/min in increments of 10L/min and observe the CO_2 output (refer to CO_2 out in results below) at each step after the system equilibrates
5. Record $ETCO_2$ as CO_2 in (mmHg) and $FiCO_2$ as (mmHg) from the CO_2 monitor

Results

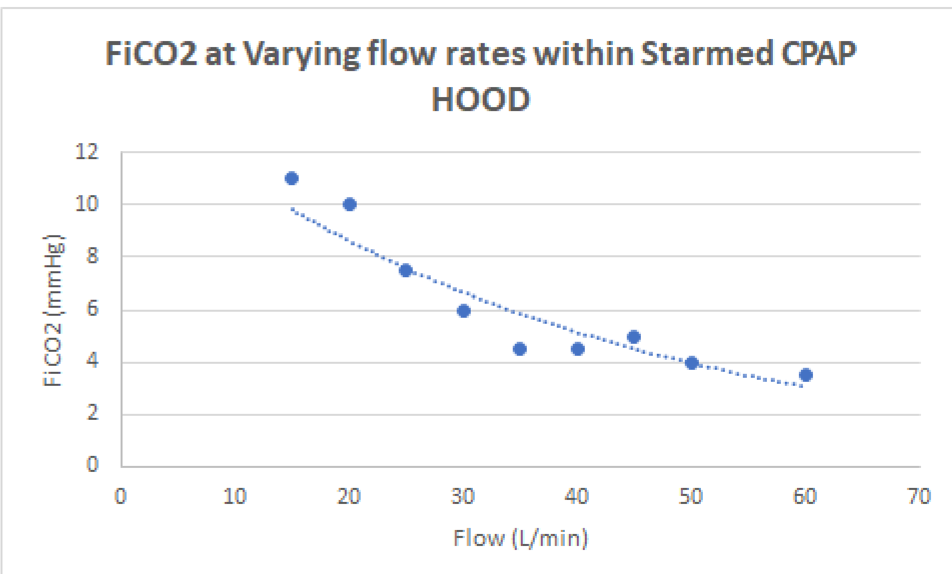

Figure 10. Level of $FiCO_2$ (mmHg) vs fresh air flow rate (L/min) inside the Starmed CPAP Hood on healthy volunteers

Discussion

Using these results, we can set a benchmark to compare results obtained from testing the COSMIC Bubble Helmet. Obtaining similar or superior results will set reasonable grounds for Health Canada approval.

CO2 Accumulation within the COSMIC Bubble Helmet running on BiPAP

Project #: COSMICBH1

Results reported by:
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Date: June 4, 2020

Objective

To test the COSMIC Bubble Helmet using a BiPAP machine to ensure there are no harmful levels of CO2 buildup.

Equipment

1. CO_2 Monitor
2. BiPAP Machine
3. Smart CapnoLine Plus™ oral and nasal cannula CO_2 monitoring probe
4. COSMIC Bubble Helmet
5. Respiratory tubings and connectors

Methods

1. Provide healthy subjects with CO_2 monitoring nasal cannula connected to a CO2 monitor or attached a CO_2 sensor at the outflow port.
2. Donned COSMIC Bubble Helmet on to the subject as per instruction provided
3. Attach a HEPA filter to the expiratory port
4. Connect the BiPAP machine to the inspiratory port
5. Set the ramp speed to maximum on the BiPAP machine
6. Record $EtCO_2$ in (mmHg) and $FiCO_2$ as (mmHg) from the CO_2 monitor for 30min in 1 min increments

Results

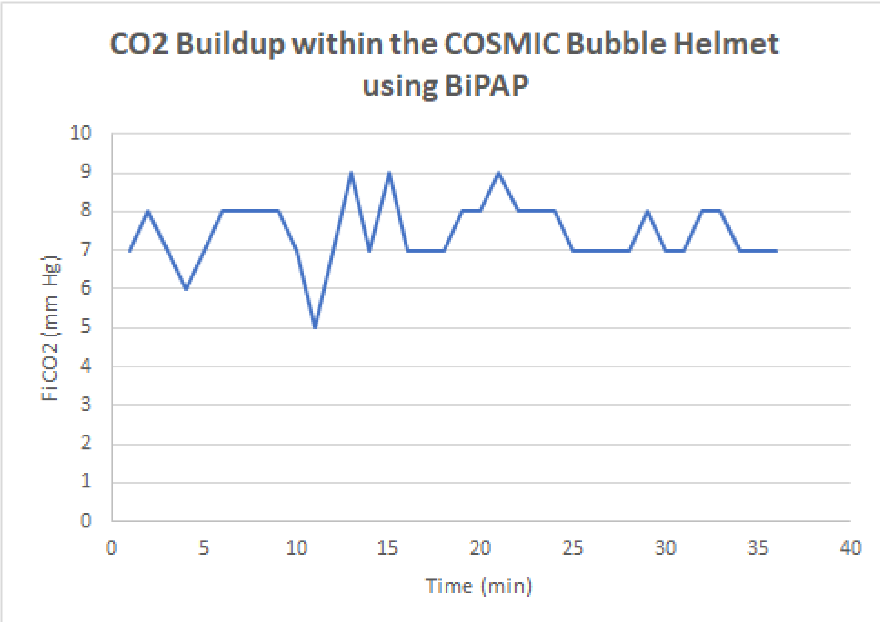

Figure 11. CO2 buildup within COSMIC Bubble Helmet using BiPAP

Discussion

Here we show that, over a period of 30 min using a BiPAP machine for air flow, the FiCO2 does not exceed 9 mm Hg with a mean of 7.44 mm Hg. These results meet the accordance of ISO 17510, where it states that the mean FiCO2 should not exceed 7.6 mmHg. Although the test was conducted with a sample size of one, these results pose significant evidence that the COSMIC Bubble Helmet is suitable for use with a BiPAP machine. Further testing with a larger sample size will strengthen this claim.