Hussam Eid

From: Google Forms <forms-receipts-noreply@google.com>
Sent: April 2, 2020 12:12 AM
To: info@hussameid.com
Subject: Basic Requirements - Evaluation

Google Forms

Thanks for filling out Basic Requirements - Evaluation

Here's what we got from you:

Basic Requirements - Evaluation

This form is for the evaluation of the design to meet the basic challenge requirements that were outlined at the start.

You will be asked to evaluate the design's ability to meet each requirement according to the following scale:

0 = Does not meet the requirement,
1 = Somewhat meets the requirement,
2 = Absolutely meets the requirement

A score for each requirement must be given.

I addition you will be asked to identify the reference documents which show compliance to the requirement (i.e where in your prepared documentation does it show that you meet the requirement)

Email address *

info@hussameid.com

General Information

Please enter the name of the team under evaluation along with your name and email. This information will be kept confidential. Email is just for assurance of fair judging.

Name of the team being evaluated *

Pneumvent

Name of Evaluator *

Hussam Eid

Ventilation Features and Specifications

Please select the choice which best represents your evaluation of the design's capability to meet the following requirements.

Pressure controlled; inspiratory pressure up to 40cmH2O, expiratory pressure up to 25cm H2O *

- ( ) 0 - Does not meet
- ( ) 1 - Somewhat meets
- (X) 2 - Absolutely meets
- ( ) N/A

Please list the reference document where it can be shown the design meets this requirement. Please specific exact sections if helpful

Section: "User guide" Document: "PNEUMVENT_USER_GUIDE.pdf" Page: "3" Points:"6 and 7" Section: "Circuit diagrams" Document: "Pneumvent.pdf" Page: "2 of 7 & 4 of 7" Section:Code Software Document:"PneumVent_Frimware.zip"

Respiratory rate 6-40 breaths/ minute *

- ( ) 0 - Does not meet
- ( ) 1 - Somewhat meets
- (X) 2 - Absolutely meets
- ( ) N/A

Please list the reference document where it can be shown the design meets this requirement. Please specific exact sections if helpful

Section: "User guide" Document: "PNEUMVENT_USER_GUIDE.pdf" Page: "3" Point: 9 Section: Code Software Document: "PneumVent_Frimware.zip" Section: "Circuit diagrams" Document: "Pneumvent.pdf" Page: "2 of 7 & 4 of 7"

Adjustable inspiratory time or I:E ratio *

- ( ) 0 - Does not meet
- ( ) 1 - Somewhat meets
- (X) 2 - Absolutely meets
- ( ) N/A

Please list the reference document where it can be shown the design meets this requirement. Please specific exact sections if helpful

Section: "User guide" Document: "PNEUMVENT_USER_GUIDE.pdf" Page: "3" Points: 8 Section: Code Software Document: "PneumVent_Frimware.zip"

Tidal volume measurement (Y piece/other, considering aerosolization risk vs. ease, cost of flow/VT circuit location) *

- ( ) 0 - Does not meet
- ( ) 1 - Somewhat meets
- (X) 2 - Absolutely meets
- ( ) N/A

Please list the reference document where it can be shown the design meets this requirement. Please specific exact sections if helpful

Section: "Block diagram" Document: "PneumVent, Pneumatic Block Diagram" Section: "User guide" Document: "PNEUMVENT_USER_GUIDE.pdf" Page: "3" Points: 5,6,7,8 Section: "Circuit diagrams" Document: "Pneumvent.pdf" Page: "2 of 7 & 3 of 7 & 4 of 7" Section: Code Software Document: "PneumVent_Frimware.zip"

Capacity to control circuit humidity and temperature (HME, inline or combination) *

- ( ) 0 - Does not meet
- (X) 1 - Somewhat meets
- ( ) 2 - Absolutely meets
- ( ) N/A

Please list the reference document where it can be shown the design meets this requirement. Please specific exact sections if helpful

Section: "Assembly" Document: "Pneumvent Tubing.pdf"

FiO2 from 21% to 100% in 10% increments; vs./ or room air, 30, 40, 60 and 100% *

- ( ) 0 - Does not meet
- ( ) 1 - Somewhat meets
- (X) 2 - Absolutely meets
- ( ) N/A

Please list the reference document where it can be shown the design meets this requirement. Please specific exact sections if helpful

Section: "User guide" Document: "PNEUMVENT_USER_GUIDE.pdf" Page: "3" Points: 10 Section: "Circuit diagrams" Document: "Pneumvent.pdf" Page: "2 of 7 & 4 of 7"

Optional Requirement: O2 concentration readout *

- ( ) 0 - Does not meet
- ( ) 1 - Somewhat meets
- (X) 2 - Absolutely meets
- ( ) N/A

Please list the reference document where it can be shown the design meets this requirement. Please specific exact sections if helpful

Section: "User guide" Document: "PNEUMVENT_USER_GUIDE.pdf" Page: "3" Points: 10

Triggering—timed and/or patient-triggered *

- ( ) 0 - Does not meet
- ( ) 1 - Somewhat meets
- (X) 2 - Absolutely meets
- ( ) N/A

Please list the reference document where it can be shown the design meets this requirement. Please specific exact sections if helpful

Section: "User guide" Document: "PNEUMVENT_USER_GUIDE.pdf" Page: "2 & 3" Section: CONFIGURE BUTTON & Breathing Controller Section: "Circuit diagrams" Document: "Pneumvent.pdf" Page: "2 of 7 & 3 of 7" Section: Code Software Document: "PneumVent_Frimware.zip"

Can be connected to standard masks, tubes and standard oxygen connectors *

- ( ) 0 - Does not meet
- ( ) 1 - Somewhat meets
- (X) 2 - Absolutely meets
- ( ) N/A

Please list the reference document where it can be shown the design meets this requirement. Please specific exact sections if helpful

Section: "Assembly" Document: "Pneumvent Tubing.pdf" Section: "Block diagram" Document: "PneumVent, Pneumatic Block Diagram"

Accuracy (within <10% for volume/pressure, 1 breath a minute for rate) *

- ( ) 0 - Does not meet
- ( ) 1 - Somewhat meets
- (X) 2 - Absolutely meets
- ( ) N/A

Please list the reference document where it can be shown the design meets this requirement. Please specific exact sections if helpful

Section: "Circuit diagrams" Document: "Pneumvent.pdf" Page: "4 of 7" Section: "User guide" Document: "PNEUMVENT_USER_GUIDE.pdf" Page: "2 & 3"

Dual circuit with non-rebreathing valve *

- ( ) 0 - Does not meet
- ( ) 1 - Somewhat meets
- (X) 2 - Absolutely meets
- ( ) N/A

Please list the reference document where it can be shown the design meets this requirement. Please specific exact sections if helpful

Section: "Assembly" Document: "Pneumvent Tubing.pdf" Section: "Block diagram" Document: "PneumVent, Pneumatic Block Diagram"

Patient Safety

Minute Ventilation (low/high) alarm, peak and low expiratory pressure (or peak + other disconnection alarm). *

- ( ) 0 - Does not meet
- ( ) 1 - Somewhat meets
- (X) 2 - Absolutely meets
- ( ) N/A

Please list the reference document where it can be shown the design meets this requirement. Please specific exact sections if helpful

Section: "Circuit diagrams" Document: "Pneumvent.pdf" Page: "5 of 7" Section: "2D drawings" Document: "Assembly_Pneumvent.pdf" Page:2

Optional Requirement: Oxygen concentration high and low threshold alarms *

- ( ) 0 - Does not meet
- ( ) 1 - Somewhat meets
- (X) 2 - Absolutely meets
- ( ) N/A

Please list the reference document where it can be shown the design meets this requirement. Please specific exact sections if helpful

Section: "Circuit diagrams" Document: "Pneumvent.pdf" Page: "5 of 7" Section: "Code Software" Document: "PneumVent_Frimware.zip"

40cm H20 mechanical failsafe value to limit maximum airway pressure *

- ( ) 0 - Does not meet
- ( ) 1 - Somewhat meets
- (X) 2 - Absolutely meets
- ( ) N/A

Please list the reference document where it can be shown the design meets this requirement. Please specific exact sections if helpful

Section: "Circuit diagrams" Document: "Pneumvent.pdf" Page: "7 of 7"

Preliminary considerations for patient safety, operator safety, and device efficacy *

- ( ) 0 - Does not meet
- ( ) 1 - Somewhat meets
- (X) 2 - Absolutely meets
- ( ) N/A

Please list the reference document where it can be shown the design meets this requirement. Please specific exact sections if helpful

Section: "Circuit diagrams" Document: "Pneumvent.pdf" Page: "1 of 7" (Total isolation from mains power supply and battery)

Device incorporates expiratory flow contamination to environment (HEPA or another filter, other device). *

- ( ) 0 - Does not meet
- ( ) 1 - Somewhat meets
- (X) 2 - Absolutely meets
- ( ) N/A

Please list the reference document where it can be shown the design meets this requirement. Please specific exact sections if helpful

Section: "Assembly" Document: "Pneumvent Tubing.pdf"

Controlled 'stand-by' or on/off function to stop flow during disconnection of ETT from vent without aerosolization. *

- ( ) 0 - Does not meet
- ( ) 1 - Somewhat meets
- (X) 2 - Absolutely meets
- ( ) N/A

Please list the reference document where it can be shown the design meets this requirement. Please specific exact sections if helpful

Section: "User guide" Document: "PNEUMVENT_USER_GUIDE.pdf" Section: Code Software Document: "PneumVent_Frimware.zip"

Total disinfection capacity (surface-all models-and consider circuit disinfection time/safety vs. disposable ventilator) *

- ( ) 0 - Does not meet
- ( ) 1 - Somewhat meets
- (X) 2 - Absolutely meets

- ( ) N/A

Please list the reference document where it can be shown the design meets this requirement. Please specific exact sections if helpful

Section: "Assembly" Document: "Pneumvent Tubing.pdf"

Design Requirements

Simple, intuitive user interface *

- ( ) 0 - Does not meet
- ( ) 1 - Somewhat meets
- (X) 2 - Absolutely meets
- ( ) N/A

Please list the reference document where it can be shown the design meets this requirement. Please specific exact sections if helpful

Section: "User guide" Document: "PNEUMVENT_USER_GUIDE.pdf"

Optional Requirement: Configuration wizard to guide a first-time user through the settings. *

- ( ) 0 - Does not meet
- (X) 1 - Somewhat meets
- ( ) 2 - Absolutely meets
- ( ) N/A

Please list the reference document where it can be shown the design meets this requirement. Please specific exact sections if helpful

Section: Code Software Document: "PneumVent_Frimware.zip"

Optional Requirement: Sequential screen instructions to allow an inexperienced operator to use the ventilator, with a 'go directly to settings' bypass for ventilator-trained carers) *

- ( ) 0 - Does not meet
- (X) 1 - Somewhat meets
- ( ) 2 - Absolutely meets
- ( ) N/A

Please list the reference document where it can be shown the design meets this requirement. Please specific exact sections if helpful

Section: Code Software Document: "PneumVent_Frimware.zip"

Preferably modular, with known failure potential (modular component/other) *

- ( ) 0 - Does not meet
- ( ) 1 - Somewhat meets
- (X) 2 - Absolutely meets
- ( ) N/A

Please list the reference document where it can be shown the design meets this requirement. Please specific exact sections if helpful

Section: "2D drawings" Document: "Assembly_Pneumvent.pdf"

Easy to service (per module if modular) *

- ( ) 0 - Does not meet
- ( ) 1 - Somewhat meets
- (X) 2 - Absolutely meets
- ( ) N/A

Please list the reference document where it can be shown the design meets this requirement. Please specific exact sections if helpful

Section: "2D drawings" Document: "Assembly_Pneumvent.pdf"

Settings legible (at 1m or as per relevant standard), clear markings with standard pictograms especially for critical functions *

- ( ) 0 - Does not meet
- ( ) 1 - Somewhat meets
- (X) 2 - Absolutely meets
- ( ) N/A

Please list the reference document where it can be shown the design meets this requirement. Please specific exact sections if helpful

Section: "2D drawings" Document: "Assembly_Pneumvent.pdf"

Available Material *

- ( ) 0 - Does not meet
- ( ) 1 - Somewhat meets
- (X) 2 - Absolutely meets
- ( ) N/A

Please list the reference document where it can be shown the design meets this requirement. Please specific exact sections if helpful

Section: Bill materials Document: "Pneumvent_BOM.pdf"

120V and 240V operation *

- ( ) 0 - Does not meet
- ( ) 1 - Somewhat meets
- (X) 2 - Absolutely meets
- ( ) N/A

Please list the reference document where it can be shown the design meets this requirement. Please specific exact sections if helpful

Section: "Circuit diagrams" Document: "Pneumvent.pdf" Page: "1 of 7" Section: "2D drawings" Document: "Assembly_Pneumvent.pdf" Section:"110/220 VAC Power Receptable Input"

Can work without power source for >180 min. *

- ( ) 0 - Does not meet
- ( ) 1 - Somewhat meets
- (X) 2 - Absolutely meets
- ( ) N/A

Please list the reference document where it can be shown the design meets this requirement. Please specific exact sections if helpful

Section: "Circuit diagrams" Document: "Pneumvent.pdf" Page: "1 of 7" Section: "2D drawings" Document: "Assembly_Pneumvent.pdf" Section: "Inside of Enclosure"

Testing, Calibration and Maintenance Requirements

Tests to calibrate and validate volume and pressure settings, verify limits and alarms. *

- ( ) 0 - Does not meet
- ( ) 1 - Somewhat meets
- (X) 2 - Absolutely meets
- ( ) N/A

Please list the reference document where it can be shown the design meets this requirement. Please specific exact sections if helpful

Section: Code Software Document: "PneumVent_Frimware.zip"

Illustrated and clear diagram for taking apart, replacing, and rebuilding the device safely. *

- ( ) 0 - Does not meet
- ( ) 1 - Somewhat meets
- (X) 2 - Absolutely meets
- ( ) N/A

Please list the reference document where it can be shown the design meets this requirement. Please specific exact sections if helpful

Section: "2D drawings" Document: "Assembly_Pneumvent.pdf"

Clearly described and practicable maintenance, diagnostic, and verification test procedures, including routine functional checks. *

- ( ) 0 - Does not meet
- ( ) 1 - Somewhat meets
- (X) 2 - Absolutely meets
- ( ) N/A

Please list the reference document where it can be shown the design meets this requirement. Please specific exact sections if helpful

Section: "2D drawings" Document: "Assembly_Pneumvent.pdf" Section: "User guide" Document: "PNEUMVENT_USER_GUIDE.pdf"

Should be easy to change the battery when necessary. *

- ( ) 0 - Does not meet
- ( ) 1 - Somewhat meets
- (X) 2 - Absolutely meets
- ( ) N/A

Please list the reference document where it can be shown the design meets this requirement. Please specific exact sections if helpful

Section: "2D drawings" Document: "Assembly_Pneumvent.pdf"

Quality Management System Planning

All components must survive a 14-day 100% duty cycle usage, without replacement. *

- ( ) 0 - Does not meet
- ( ) 1 - Somewhat meets
- (X) 2 - Absolutely meets
- ( ) N/A

Please list the reference document where it can be shown the design meets this requirement. Please specific exact sections if helpful

Section: "Circuit diagrams" Document: "Pneumvent.pdf" Section: Code Software Document: "PneumVent_Frimware.zip"

Expected failure rate for all functions (particularly critical ones) shall be estimated using a known methodology. *

- (X) 0 - Does not meet
- ( ) 1 - Somewhat meets
- ( ) 2 - Absolutely meets
- ( ) N/A

Please list the reference document where it can be shown the design meets this requirement. Please specific exact sections if helpful

NA

Alarm related functions shall have an expected failure rate, as per relevant standard *

- ( ) 0 - Does not meet

- (X) 1 - Somewhat meets
- ( ) 2 - Absolutely meets
- ( ) N/A

Please list the reference document where it can be shown the design meets this requirement. Please specific exact sections if helpful

NA

Design shall be modular and time to repair by module replacement shall be quantified. *

- ( ) 0 - Does not meet
- ( ) 1 - Somewhat meets
- (X) 2 - Absolutely meets
- ( ) N/A

Please list the reference document where it can be shown the design meets this requirement. Please specific exact sections if helpful

Section: "2D drawings" Document: "Assembly_Pneumvent.pdf"

Has the team presented a design that you would feel comfortable using on yourself or your family? *

- ( ) 0 - Does not meet
- ( ) 1 - Somewhat meets
- (X) 2 - Absolutely meets
- ( ) N/A

Please list the reference document where it can be shown the design meets this requirement. Please specific exact sections if helpful

NA

Safety

Has the team presented a design that you would feel comfortable using on yourself or your family? *

- (X) Yes
- ( ) No
- ( ) N/A - I don't know