PROJECT COMPLETION REPORT

1. **Project Number** : 8225

2. **Title of the Project** : Smart Assistive Breathing Device
3. **Funding Agency Name** : SCTIMST, TDF

4. **Project Reference Number provided by the Funding Agency**: 8225

5. **Principal Investigator (Name & Address): Sarath S Nair**

   Dept of Medical Devices Engineering, BMT Wing, SCTIMST

6. **Co-Investigators (Name & Address):**
   i. Mr. Vinodkumar V, Dept of Medical Devices Engineering, BMT Wing
   Mr. Nagesh D S, Dept of Medical Devices Engineering, BMT Wing
   Dr Thimas Koshy, Dept of Anaesthesiology, SCTIMST
   Dr Manikandan, Dept of Anaesthesiology, SCTIMST
   Mr Manoj S, Dept of Clinical Engineering, SCTIMST

7. **Implementing Institution** : SCTIMST

8. **Collaborating Institutions** : Nil

9. **Date of Commencement** : 01/04/2020

10. **Duration** : 2 Years

11. **Date of Completion** : 31/05/2020

12. **Objectives as approved :**
    This project aims to develop a A low cost Battery-operated Assistive Breathing Unit with digital controls for respiration will be the deliverable of the project. Hence the emergency ventilation to patients suffering from breathing trouble can be provided thus reducing mortality due to COVID-19 to a large extent.

13. **Deviation made from original objectives if any, while implementing the project and reasons thereof :**

    Nil

14. **Field/Experimental work giving full details of summary of methods adopted, data collected**

supported by necessary tables, charts, diagrams and photographs :

1. Introduction

Millions of people worldwide are affected by the new pandemic COVID-19, and the numbers are increasing at a very faster rate calling for immediate development of necessary ventilators for emergency use. However, the number of ventilators available in hospitals is very limited especially in India.

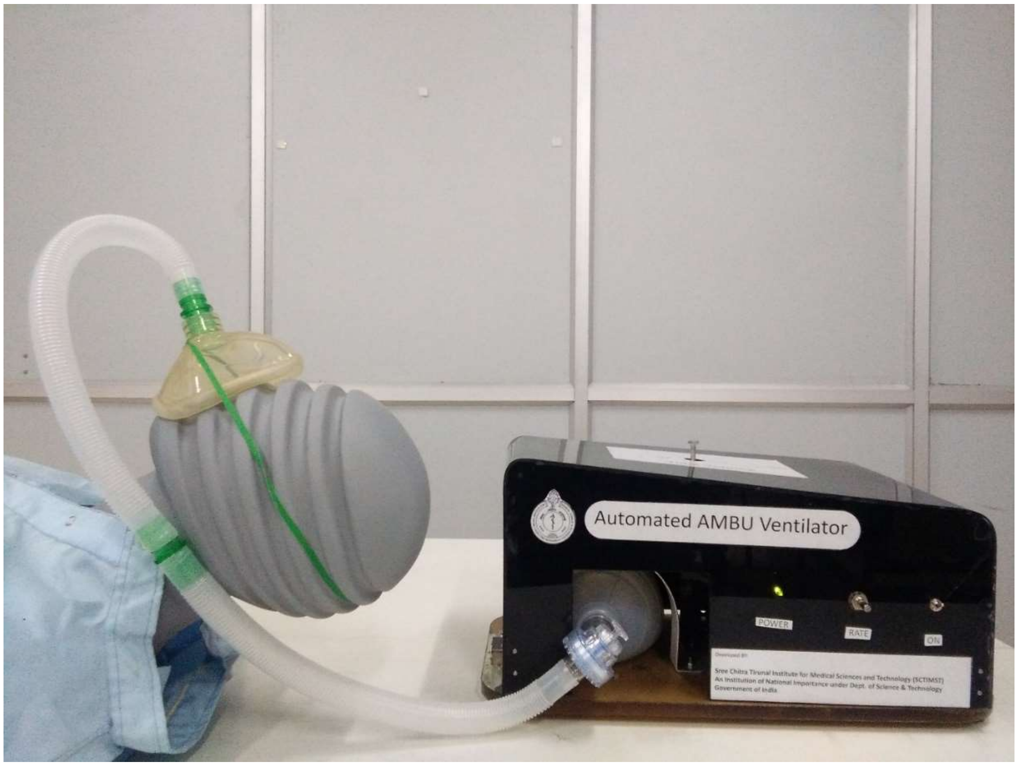
To tackle the situation, Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST), an institute of national importance under Department of Science and Technology, Govt. of India, with its long tradition of developing and commercializing challenging and needy medical devices, has introduced an Emergency Breathing Assist System which will be of very beneficial to assist the breathing of the critical patients who is not accessible to ICU ventilators.

For enabling rapid production, the device is designed with readily available components so that it becomes an alternative solution for ventilator shortages by providing ventilation support to the needy as advised by the clinicians.

This portable and light weight device enables positive pressure ventilation with controlled rate of expiration, I:E Ratio (Inspiratory to Expiratory Ratio), Tidal Volume, etc., Also A PEEP (Positive End Expiratory Pressure) Valve is added as an extra component to maintain pressure on the lower airways at the end of the breathing cycle which prevents the alveoli from collapsing during expiration. The compressed gas source can also be attached to the system. The device measures, pressure, breath per minute, tidal volume and informs the operator about any malfunction through different visual and audible alarms. The automatic device will minimize the need of support personnel in the isolation room as well as in ambulatory environment thereby enabling safer, effective and lung protective operation to COVID patients.

As we are gearing up the emergency preparedness to reduce mortality, this device can be manufactured in a low resource setting with minimum cost.

The technology of the device is transferred to M/s Wipro 3D, for scale up and commercialised in the brand name AirBridge EBAS.



The device is further jointly developed into an industrial grade model with a brand name **AirBridge** for commercial production as shown in Figure below.

AirBridge - Wipro Chitra EBAS

1. Principle of Operation

The EBAS works by sucking in air and oxygen connected to the inlet ports of a Ball Valve Mask reservoir or BVM bag and gives to the lungs of the person when it squeezes

The consumables required to operate the device are

1.BVM resuscitator adult (1.5 to 2L) with pressure relief valve
at 40 cm H2O with reservoir bag attachment. Silicone preferred
2. PEEP valve (adjustable range 0-20 cm H2O)
3. Unidirectional valve (Non rebreathing Valve)
4. Corrugated tube 22 mm, 1-1.5 m length
5. HME-Bacterial-Viral filter
6. Tubing for oxygen supply

For regulating the FiO2 as per clinical requirements, the clinical setup should have an oxygen regulator to the oxygen inlet line.

Ventilation Method: The device has time triggered positive pressure, volume-controlled mode, which has controls of

1. Tidal Volume
2. Breath per Minutes
3. I:E Ratio
4. Battery Operation
5. Alarms
6. Monitoring of out of limit operation

The inlet air passes through a Heat & Moisture exchanger/bacterial and viral filter
The exhaled air is expelled to the environment through an outlet valve in the reservoir
The rate of respiration is adjusted by providing delay between the squeezing of the bag. The delay is provided non electronically by toggling between two voltage levels. The motor is supplied with two voltage levels during inhalation and exhalation cycle
During inhalation cycle the voltage is set to press the bag for a set time as required clinically for inhalation
During exhalation cycle the voltage is set to release the bag for a set time as required clinically for exhalation. Combined effect of slowing down the motor along with a spring recoiling is used to achieve this. Thus a clinically relevant inhalation: exhalation (I:E) ratio can be achieved. Usually this has to vary between (1:1 to 1:5)
The rate of respiration is changed by slowing down the motor after complete deflation of the bag. For identifying this, a limit switch is used on the lever. The limit switch is wired such that, the motor gets a different voltage which allows it to run a slower rate than the inhalation exhalation duration. Thus, a clinically relevant rate between 10 to 30 bpm can be achieved.
In case of emergency, when the electrical power is absent or machine fails, an SOS lever can be operated with very less effort to maintain the ventilation.

2.

3. <u>Scope</u>

Ventilators are non-notified device in India and hence no regulatory requirements have been laid down so far. A regulatory strategy for getting the manufacturing permission is to ensure compliance with the major specifications/performance requirements. specifications of predicate devices, ICU ventilators as per different national and international standard has been used as a guidance to frame the minimum performance requirements.
These are the minimally acceptable performance requirements for a ventilator which can be used in emergency purposes as an interim life saver. A ventilator with lower specifications than this is likely to

provide no clinical benefit and might lead to increased harm, which would be unacceptable for clinicians.

As per the guidelines laid down by MHRA[5] for rapidly manufactured ventilator system (RMVS), the following statements are clearly stated.

1. It is accepted that full demonstration of compliance to ISO 80601-2-12:2020 is unrealistic in the time frame required for development. Nevertheless, compliance with the essential safety standards must be demonstrated for patient safety.
2. It is not anticipated that devices will be CE marked and approval by the MHRA will be through the "Exceptional use of non-CE marked medical devices" route (https://www.gov.uk/guidance/exceptional-use-of-non-ce-marked-medical-devices).
3. When the current emergency has passed these devices will NOT be usable for routine care unless they have been CE marked through the Medical Device Regulations. The device must display a prominent indelible label to this effect.

Considering the above aspects from different regulatory agencies across the world, the specification of SCTIMST BVM ventilator shall be developed after testing referring to various guidelines provided in Indian standard and ISO standard for an ICU ventilator. Also, the specifications developed may be compared with a standard ICU ventilator in use and also with a rapidly manufactured BVM based ventilator to tackle the covid situation.

4.

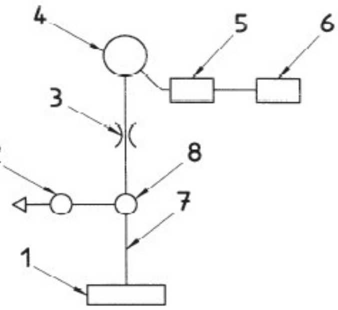
5. **Benchmark performance evaluation for Chitra EBAS**

Based on various requirements specified in IS/ISO, Govt. agencies across the world, a benchmark performance criteria requirement is given below. The Chitra EBAS is tested adhering to the standards and the performances are given below. **This document will be updated as on when the results of various tests conducted are finished.**

Test Procedure

To establish the safety and effectiveness of the EBAS, experiments are conducted as per the guidelines and procedures described in International Standard ISO 10651-3 Lung ventilators for medical use - Part 3: Particular requirements for emergency and transport ventilators.

As per the standard, a test set up is prepared to conduct experiments on EBAS and measure the various ventilator parameters to establish its effectiveness as shown in Figure below.



Key

1 Ventilator

2 Volume measurement device to be tested

3 Resistance to flow

4 Test lung

5 Pressure sensor

6 Recorder (pressure as a function of time) with an accuracy ± 2 % of actual reading for verification of accuracy of volume measurement device

7 Breathing system

8 Expiratory valve

NOTE — Location of the volume measurement device (2) is arbitrary; it may be located elsewhere in the breathing system.

Figure 1 — Typical configuration of test apparatus for measurement of expiratory volume

Table 1 — Conditions for expiratory volume measurements

Adjustable parameter	Test conditions		
	Adult use	Paediatric use	Neonatal use
Tidal volume, V_T (ml) as measured by a pressure sensor on the test lung ($V_T = C \times p_W$ max.)	500	300	30
Respiratory cycle frequency, f (min^{-1})	10	20	30
I/E ratio	1/2 or nearest	1/2 or nearest	1/2 or nearest
Resistance to flow, R (kPa·l^{-1}·s^{-1})	0,5 ± 10 %	2 ± 10 %	5 ± 10 %
Isothermal compliance, C (ml/kPa)	500 ± 5 %	200 ± 5 %	10 ± 5 %
NOTE — The accuracies for C and R apply over the entire range of measurements.			

Test Setup

For conducting the test, an adult test lung is fitted on to the output of a standard adult BVM bag and inserted into the EBAS. A side port is fitted on to the test lung inlet port and connected to a manometer. The test lung is inserted into a beaker having 10 liters of water and a scale attached to measure the variation of water column in liters. The test lung is arrested to avoid in movement during its operation. The machine is turned on and operated at different bpm, tidal volume I:E ratio to measure the minimum and maximum values of each parameter. For Test Set Up refer MHRA Guideline.

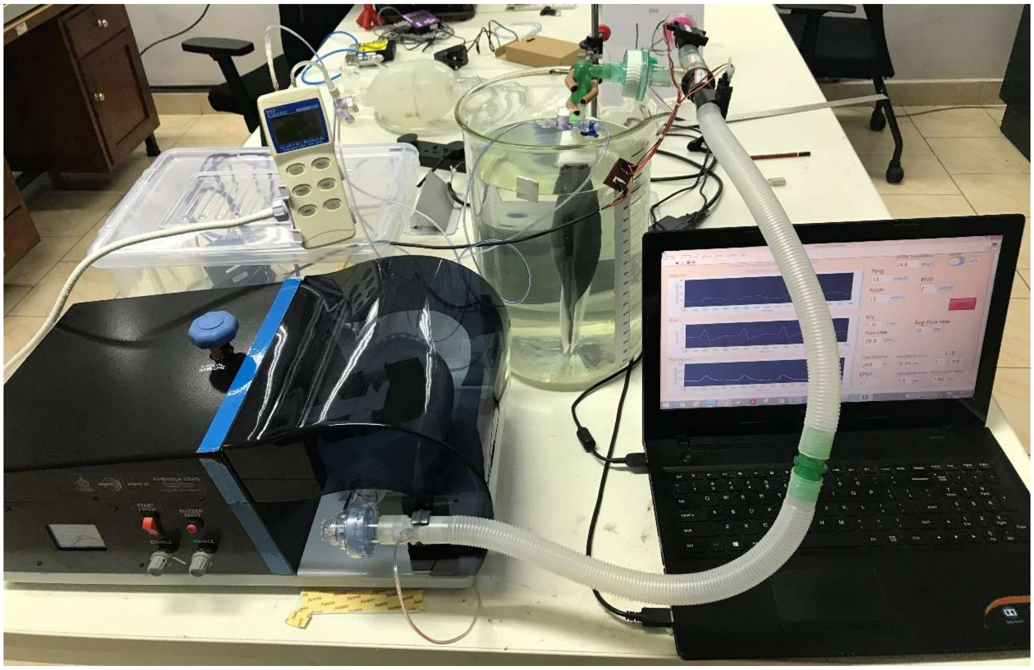


Fig 1. The Performance evaluation test set up

Various tests are conducted as given below to establish the performance of the EBAS such as

1. Range of Tidal Volume
2. Tidal Volume Accuracy
3. Range of Respiratory Rate Test
4. Range of operation of I:E Ratio
5. Leakage Test
6. Peak Pressure Test
7. Pressure drop in Airway Circuit Test

The details of each tests, its observations and results are provided below.

Test 1: Range of Tidal Volume: This test is meant to measure the minimum and maximum tidal volume, which can be obtained from the machine as per the procedure given below. For the same, a respiration rate of 10 and I:E ratio of 1:2 or nearer is set on the DUT.
Procedure for determining the maximum and minimum range of tidal volume in the EBAS.

Test 1.a To determine maximum tidal volume

1. Place the device under test on the worktable and place an BVM bag on the slot provided on the DUT.
2. Immerse the test lung on a graduated beaker filled with water (water column).
3. Connect the outlet of BVM bag to the test lung via a flow sensor.
4. On the exhalation side, connect another flow sensor and peep control valve.
5. Connect a pressure sensor on the common pathway to monitor the pressure inside the lung.
6. Adjust the tidal volume knob to its maximum in the safe region.
7. Power on the DUT and observe the tidal volume indicated on the device, actual tidal volume in the water column as well as tidal volume measured in the instrumentation panel.
8. Tabulate the observations.

As per the procedure the device under test DUT is connected with the airway circuit and ten observations are made with two different bags. The tidal volume obtained in the water column as well as in the instrumentation panel are noted down as shown below. The average of the tidal volume displayed in the instrumentation panel and its standard deviation are calculated.

EBAS - Maximum Tidal Volume						
Sl No	Bag No	EBAS No	Respiration Rate	Water Column (ml)	Instrumentation Panel(ml)	Accuracy (%)
1	1	EBAS V1 002	10	500	499	0.2
2	1	EBAS V1 002	10	500	492	1.6
	1	EBAS V1 002	10	500	496	0.8
3	1	EBAS V1 002	10	500	470	6.0
	1	EBAS V1 002	10	500	477	4.6
4	1	EBAS V1 002	10	500	490	2.0
	1	EBAS V1 002	10	500	506	-1.2
5	1	EBAS V1 002	10	500	502	-0.4
9	2	EBAS V1 002	10	500	474	5.2
10	2	EBAS V1 002	10	500	479	4.2
11	2	EBAS V1 002	15	500	519	-3.8
12	2	EBAS V1 002	15	500	492	1.6
13	2	EBAS V1 002	15	500	511	-2.2
14	2	EBAS V1 002	15	500	490	2.0
15	2	EBAS V1 002	15	500	498	0.4
16	2	EBAS V1 002	15	500	489	2.2
17	2	EBAS V1 002	15	500	490	2.0
18	2	EBAS V1 002	15	500	488	2.4
19	2	EBAS V1 002	15	500	487	2.6
20	2	EBAS V1 002	15	500	488	2.4
		Avg		500	492	
		SD			12	

From the tests, it can be observed that the maximum tidal volume which can b obtained from the device is 491+/-12 ml as per the instrumentation panel and 500ml as per the water column readings.

Test 1.b - To determine minimum tidal volume

9. Place the device under test on the worktable and place an BVM bag on the slot provided on the DUT.
10. Immerse the test lung on a graduated beaker filled with water (water column).
11. Connect the outlet of BVM bag to the test lung via a flow sensor.
12. On the exhalation side, connect another flow sensor and peep control valve.
13. Connect a pressure sensor on the common pathway to monitor the pressure inside the lung.
14. Adjust the tidal volume knob to its minimum in the safe region.
15. Power on the DUT and observe the tidal volume indicated on the device, actual tidal volume in the water column as well as tidal volume measured in the instrumentation panel.
16. Tabulate the observations.

As per the procedure the device under test DUT is connected with the airway circuit and ten observations are made with two different bags with 30 Breaths per minute and 16 breaths per minute. The tidal volume obtained in the water column as well as in the instrumentation panel are noted down as shown below. The average of the tidal volume displayed in the instrumentation panel and its standard deviation are calculated.

EBAS - Minimum Tidal Volume						
Sl No	Bag No	EBAS No	Respiration Rate	Water Column (ml)	Instrumentation Panel(ml)	Accuracy (%)
1	1	EBAS V1 002	34	200	208	-4.0
2	1	EBAS V1 002	34	200	232	-16.0
	1	EBAS V1 002	34	200	209	-4.5
3	1	EBAS V1 002	34	200	207	-3.5
	1	EBAS V1 002	34	200	228	-14.0
4	1	EBAS V1 002	34	200	210	-5.0
	1	EBAS V1 002	34	200	237	-18.5
5	1	EBAS V1 002	34	200	219	-9.5
9	2	EBAS V1 002	34	200	209	-4.5
10	2	EBAS V1 002	34	200	227	-13.5
11	2	EBAS V1 002	16	200	222	-11.0
12	2	EBAS V1 002	16	200	258	-29.0
13	2	EBAS V1 002	16	200	247	-23.5
14	2	EBAS V1 002	16	200	237	-18.5
15	2	EBAS V1 002	16	200	268	-34.0
16	2	EBAS V1 002	16	200	255	-27.5
17	2	EBAS V1 002	16	200	238	-19.0
18	2	EBAS V1	16	200	237	-18.5

		002				
19	2	EBAS V1 002	16	200	260	-30.0
20	2	EBAS V1 002	16	200	244	-22.0
		Avg		200	233	
		SD			19	

From the tests, it can be observed that the minimum tidal volume which can be obtained from the device is 233+/-19 ml as per the instrumentation panel and 200ml as per the water column readings.

Test 2. Breaths per Minute: To measure the minimum and maximum value of bpm; the knob on the front side of the machine is turned to its full left position and full right position. The device is operated and the time of one respiration cycle is measured using a stopwatch as per the procedure given below.

Procedure for determining the range of variation of BPM in the EBAS at different tidal volumes.

Place the device under test on the worktable and place an BVM bag on the slot provided on the DUT.

1. Immerse the test lung on a graduated beaker filled with water (water column).
2. Connect the outlet of BVM bag to the test lung via a flow sensor.
3. On the exhalation side, connect another flow sensor and peep control valve.
4. Connect a pressure sensor on the common pathway to monitor the pressure inside the lung.
5. Set BPM as 10 and tidal volume as 500mL for first reading.
6. Power on the DUT and observe the BPM and tidal volume indicated on the device (set value), BPM counted manually using a stopwatch, tidal volume in the water column as well as both measured in the instrumentation panel.
7. Tabulate the observations.
8. Repeat the procedure for different values of tidal volume at intervals of 100mL, with same BPM.
9. Repeat the entire procedure for different values of BPM up to 30.

Test 3. Range of Inhalation: Exhalation Ratio (I:E): To measure the I:E ratio; the knob on the front side of the machine is turned to its full left position and full right position. The device is operated, and the time of one inhalation and exhalation is measured using a stopwatch. The I:E ratio is computed based on the values obtained. Procedure for determining the maximum and minimum range of I:E ratio in the EBAS is given below.

1. Place the device under test on the worktable and place an BVM bag on the slot provided on the DUT.
2. Immerse the test lung on a graduated beaker filled with water (water column).
3. Connect the outlet of BVM bag to the test lung via a flow sensor.
4. On the exhalation side, connect another flow sensor and peep control valve.
5. Connect a pressure sensor on the common pathway to monitor the pressure inside the lung.
6. Set inhalation time and exhalation time as 1sec for the first reading.
7. Adjust the tidal volume knob to a suitable value (say 400ml).
8. Power on the DUT and observe the inhalation and exhalation time indicated on the device (set value), both measured using a stopwatch as well as both measured in the instrumentation panel.
9. Tabulate the observations.
10. Repeat the procedure from different values of inhalation and exhalation time.

As per the procedure of test 2 and test 3, both the DUT is connected to the airway circuit and operated for various BPM, inhalation time and exhalation time. The I:E ratio for each operating condition is computed. The minimum, maximum values of BPM, inhalation time, exhalation time and corresponding I:E ratio is calculated. The results of various tests conducted are given in the table below.

Test for determination of range of BPM and I:E Ratio								
Sl No	Bag No	EBAS No	Respiration Rate	Water Column (ml)	Instrumentation Panel(ml)	Inhalation Time (s)	Exhalation Time(s)	I:E Ratio
1	1	EBAS V1 002	12	500	504	2.3	2.5	01:01:03
2	1	EBAS V1 002	12	500	515	1.97	2.9	01:01:05
	1	EBAS V1 002	11	500	520	2.02	3.5	01:01:08
3	1	EBAS V1 002	10	500	524	2.01	4	01:02
	1	EBAS V1 002	9	500	552	1.97	4.4	01:02:02
4	1	EBAS V1 002	15	500	552	1.41	3.5	01:02:05
	1	EBAS V1 002	14	500	572	1.44	4	01:02:08
5	1	EBAS V1 002	14	500	569	1.42	4.2	01:03
9	1	EBAS V1 002	13	500	558	1.41	4.5	01:03:02
10	1	EBAS V1 002	11	500	548	1.2	4.2	01:03:05
11	1	EBAS V1 002	11	500	553	1.12	3.9	01:03:05
12	1	EBAS V1 002	12	500	521	1.07	4	01:03:07
13	1	EBAS V1 002	13	500	554	0.94	3.8	01:04
14	1	EBAS V1 002	12	500	562	0.96	4.2	01:04:03
15	1	EBAS V1 002	11	500	552	0.96	4.7	01:04:09
16	1	EBAS V1 002	10	500	522	0.97	4.8	01:05
17	1	EBAS V1 002	15	500	526	2.07	1.9	01:01:01
18	1	EBAS V1 002	13	500	510	2.59	2.1	01:03:01
19	1	EBAS V1 002	10	500	551	3.55	2.1	01:07:01
20	2	EBAS V1 003	34	200	208			
21	1	EBAS V1 002	19	200	262	0.63	2.5	01:03:09
22	1	EBAS V1 002	10	200	251	0.68	2.7	01:07
23	1	EBAS V1 002	13	200	239	0.93	3.8	01:04:01
24	1	EBAS V1 002	12	200	230	1.34	3.6	01:02:07
25	1	EBAS V1 002	11	200	226	1.35	4.3	01:03:02
26	1	EBAS V1 002	10	200	245	1.36	5.6	01:03:06
27	1	EBAS V1 002	10	200	242	1.36	4	01:03
28	1	EBAS V1 002	10	200	230	1.36	4.8	01:03:05
29	1	EBAS V1 002	9	200	236	1.93	5.1	01:02:06
30	1	EBAS V1 002	16	400	407	1.81	2	01:01:01
31	1	EBAS V1 002	19	400	465	1.32	1.9	01:01:04
32	1	EBAS V1 002	21	400	499	1.08	1.6	01:01:06
33	1	EBAS V1 002	21	400	476	1.02	2	01:02
34	1	EBAS V1 002	17	400	461	1.02	2.5	01:02:04
35	1	EBAS V1 002	15	400	481	1.03	2.9	01:02:08
36	1	EBAS V1 002	14	400	456	1.04	3.1	01:03
37	1	EBAS V1 002	12	400	440	1.05	3.8	01:03:06
38	1	EBAS V1 002	11	400	477	1.06	4.2	01:03:09
39	1	EBAS V1 002	10	400	461	1.09	5.2	01:04:08
40	1	EBAS V1 002	10	400	479	1.07	4.8	01:04:04
41	1	EBAS V1 002	11	400	447	1.06	4.2	01:04
42	1	EBAS V1 002	10	400	472	0.98	4.9	01:05
43	1	EBAS V1 002	18	300	300	1.49	1.8	01:01:02
44	1	EBAS V1 002	24	300	358	1	1.5	01:01:05
45	1	EBAS V1 002	22	300	349	0.93	1.7	01:01:09
46	1	EBAS V1 002	22	300	349	0.86	1.8	01:02
47	1	EBAS V1 002	23	300	347	0.83	1.8	01:02:02
48	1	EBAS V1 002	22	300	353	0.8	1.9	01:02:04
49	1	EBAS V1 002	19	300	369	0.82	2.4	01:03
50	1	EBAS V1 002	16	300	376	0.83	3	01:03:06
51	1	EBAS V1 002	14	300	336	0.83	3.2	01:03:08
52	1	EBAS V1 002	14	300	352	0.85	3.5	01:04:01
53	1	EBAS V1 002	14	300	350	0.8	3.5	01:04:04
54	1	EBAS V1 002	14	300	367	0.73	3.5	01:04:08
55	2	EBAS V1 003	34	200				
	1	EBAS V1 002	14	300	344	0.69	3.5	01:05
		Min	9	200	208	0.63	1.5	
		Max	34	500	572	3.55	5.6	

Test 4. Determination of Pressure drop in Airway Circuit Test

This test is conducted to determine the Inspiratory and Expiratory resistances during normal operation of the EBAS. For the same, the DUT is subjected to the following test procedure and the observations are noted down.

1. Place the device under test on the worktable and place an BVM bag on the slot provided on the DUT.
2. Immerse the test lung on a graduated beaker filled with water (water column).
3. Connect the outlet of BVM bag to the test lung via a flow sensor.
4. Connect a pressure sensor (P1) at the near end of the BVM bag outlet connected to the test lung and another pressure sensor (P2) on the same pathway nearer to the test lung.

5. On the exhalation side, connect another flow sensor and peep control valve.
6. Connect a pressure sensor (P3) on the expiration side at the farther end from test lung.
7. Adjust the tidal volume and inhalation time to get a flowrate of 60LPM (for adult).
8. Power on the DUT and observe the readings of P1, P2 and P3.
9. Tabulate the observations.
10. Repeat the procedure six times.

As per the procedure of test 4 the DUT is connected to the airway circuit and operated for various BPM and tidal volume. The difference in pressure obtained from the entry point of the patient connection to the exit point of the BVM is calculated as given in the table below. The average pressure drop is calculated.

Determination of Pressure drop across the line between Ambu Bag and Test Lung						
	Tidal Volume(ml)		Presure drop(cmH20)			
Sl No	BPM	Instrumentation panel		Type of Bag		
1	15	500	5	Bag 1		
2	15	200	5			
3	15	200	5	Bag 2		
4	16	500	5			
5	15	250	5			
6	15	300	5			
7	15	350	5			
8	15	415	5			
9	15	454	5			
	Avg		5			

From the tests, it can be observed that the pressure drop in the airway circuit is approximately 5cm H2O.

Test 5. Test for determination of Tidal Volume variation with different BVM bag

This test is conducted to determine the percentage variation from true reading when BVM bags of different make are used. To conduct the test, the DUT is subjected to the test set up as per the ISO 10651-3 standard with multiple BVM bags. The airway circuit is connected with each BVM bag and different tidal volumes are set on the machine. For each set tidal volume, water column reading and reading on the **LabVIEW** instrumentation panel are noted down. The results of the test are given below.

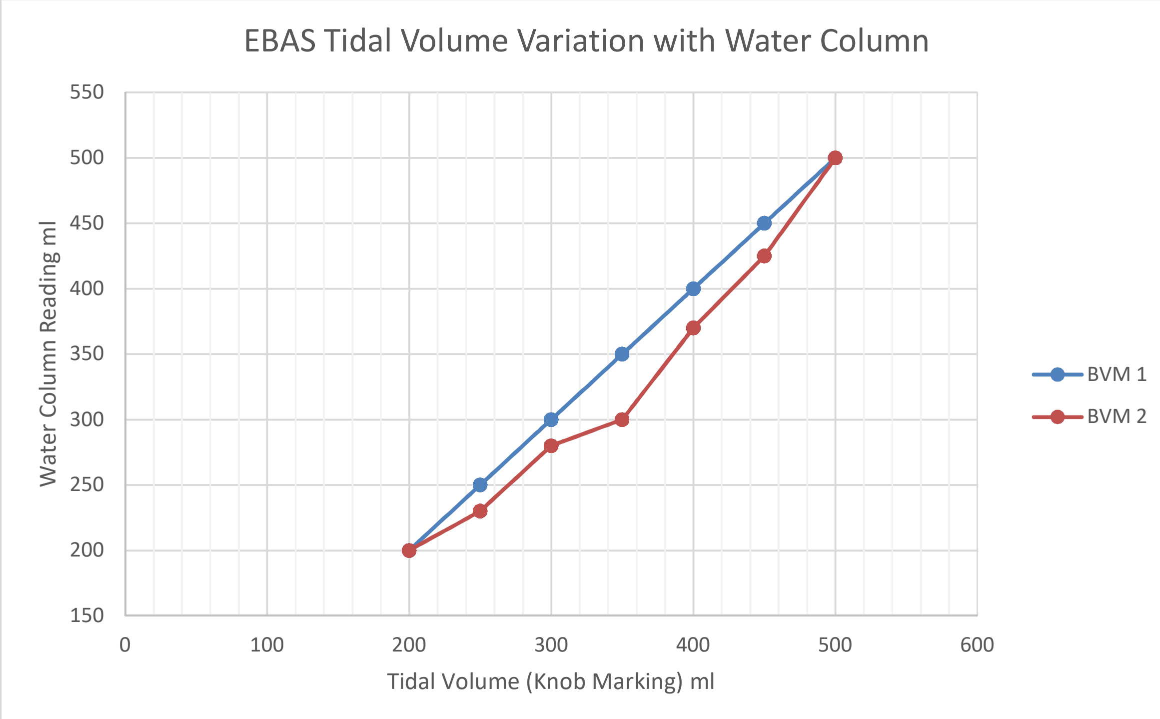
Sl No	BVM	BPM	I:E Ratio	Marking on Knob	Water column (ml)	Lab view	% Accuracy with water column	% Accuracy with LabVIEW
1	Bag 1	13	01:02	500	500	540	0	7
2	Bag 1	13	01:02	500	500	538	0	7
3	Bag 1	13	01:02	500	500	485	0	-3
4	Bag 1	13	01:02	500	500	492	0	-2
5	Bag 1	13	01:02	500	500	578	0	13
6	Bag 1	13	01:02	500	500	526	0	5
7	Bag 1	13	01:02	500	500	534	0	6
8	Bag 1	13	01:02	500	500	538	0	7

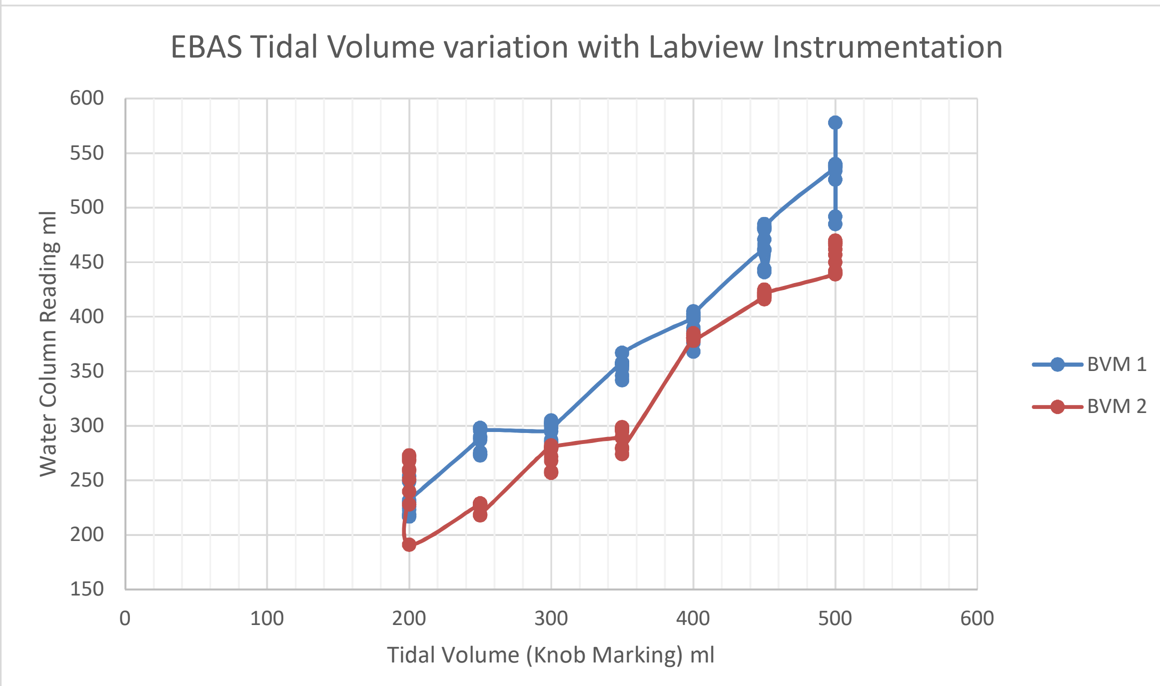
9	Bag 1	13	01:02	500	500	540	0	7
10	Bag 1	13	01:02	500	500	537	0	7
1	Bag 1	13	01:02:05	450	450	482	0	7
2	Bag 1	13	01:02:05	450	450	444	0	-1
3	Bag 1	13	01:02:05	450	450	461	0	2
4	Bag 1	13	01:02:05	450	450	471	0	4
5	Bag 1	13	01:02:05	450	450	481	0	6
6	Bag 1	13	01:02:05	450	450	480	0	6
7	Bag 1	13	01:02:05	450	450	485	0	7
8	Bag 1	13	01:02:05	450	450	482	0	7
9	Bag 1	13	01:02:05	450	450	441	0	-2
10	Bag 1	13	01:02:05	450	450	462	0	3
1	Bag 1	13	01:02:00	400	400	403	0	1
2	Bag 1	13	01:02:00	400	400	398	0	-1
3	Bag 1	13	01:02:00	400	400	402	0	0
4	Bag 1	13	01:02:00	400	400	376	0	-6
5	Bag 1	13	01:02:00	400	400	390	0	-3
6	Bag 1	13	01:02:00	400	400	400	0	0
7	Bag 1	13	01:02:00	400	400	405	0	1
8	Bag 1	13	01:02:00	400	400	368	0	-9
9	Bag 1	13	01:02:00	400	400	387	0	-3
10	Bag 1	13	01:02:00	400	400	398	0	-1
1	Bag 1	14	01:02:04	350	350	367	0	5
2	Bag 1	14	01:02:04	350	350	353	0	1
3	Bag 1	14	01:02:04	350	350	358	0	2
4	Bag 1	14	01:02:04	350	350	357	0	2
5	Bag 1	14	01:02:04	350	350	342	0	-2
6	Bag 1	14	01:02:04	350	350	357	0	2
7	Bag 1	14	01:02:04	350	350	356	0	2
8	Bag 1	14	01:02:04	350	350	357	0	2
9	Bag 1	14	01:02:04	350	350	346	0	-1
10	Bag 1	14	01:02:04	350	350	358	0	2
1	Bag 1	14	01:02:05	300	300	298	0	-1
2	Bag 1	14	01:02:05	300	300	305	0	2
3	Bag 1	14	01:02:05	300	300	285	0	-5
4	Bag 1	14	01:02:05	300	300	301	0	0
5	Bag 1	14	01:02:05	300	300	302	0	1
6	Bag 1	14	01:02:05	300	300	287	0	-5
7	Bag 1	14	01:02:05	300	300	303	0	1
8	Bag 1	14	01:02:05	300	300	304	0	1
9	Bag 1	14	01:02:05	300	300	301	0	0
10	Bag 1	14	01:02:05	300	300	295	0	-2
1	Bag 1	19	01:02	250	250	296	0	16
2	Bag 1	19	01:02	250	250	290	0	14
3	Bag 1	19	01:02	250	250	274	0	9
4	Bag 1	19	01:02	250	250	276	0	9
5	Bag 1	19	01:02	250	250	298	0	16

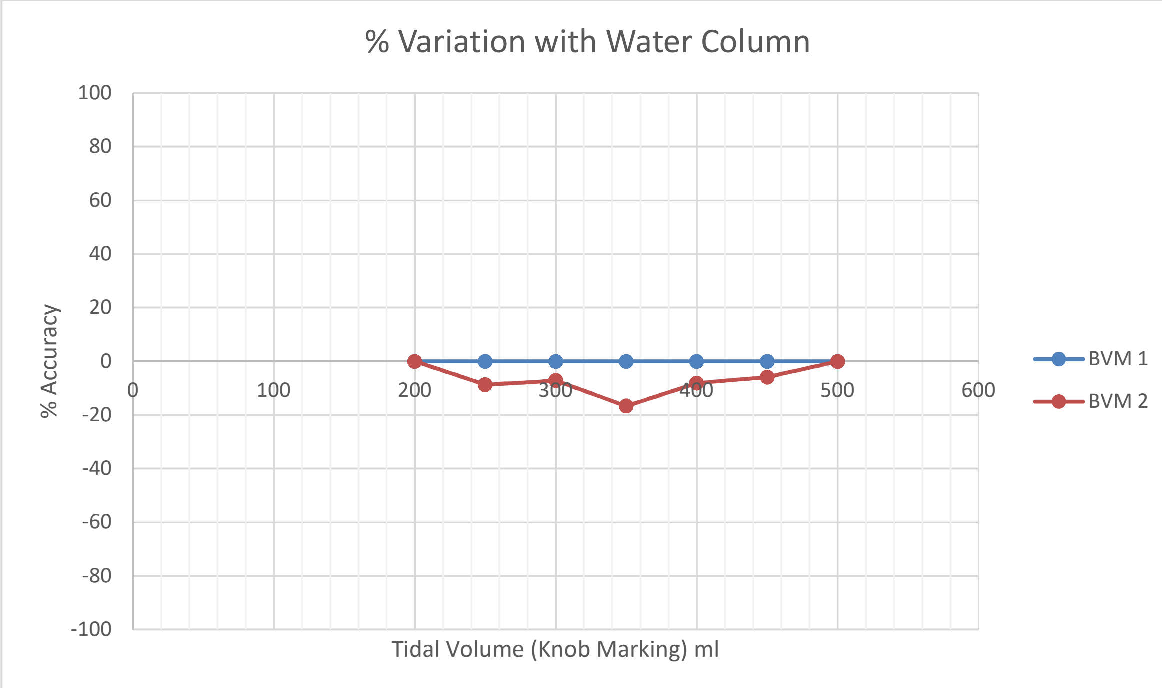
6	Bag 1	19	01:02	250	250	287	0	13
7	Bag 1	19	01:02	250	250	273	0	8
8	Bag 1	19	01:02	250	250	274	0	9
9	Bag 1	19	01:02	250	250	298	0	16
10	Bag 1	19	01:02	250	250	289	0	13
1	Bag 1	12	01:04	200	200	232	0	14
2	Bag 1	12	01:04	200	200	230	0	13
3	Bag 1	12	01:04	200	200	226	0	12
4	Bag 1	12	01:04	200	200	223	0	10
5	Bag 1	12	01:04	200	200	219	0	9
6	Bag 1	12	01:04	200	200	217	0	8
7	Bag 1	12	01:04	200	200	218	0	8
8	Bag 1	12	01:04	200	200	217	0	8
9	Bag 1	12	01:04	200	200	254	0	21
10	Bag 1	12	01:04	200	200	249	0	20
1	Bag 2	13	01:02	500	500	468	0	-7
2	Bag 2	13	01:02	500	500	470	0	-6
3	Bag 2	13	01:02	500	500	468	0	-7
4	Bag 2	13	01:02	500	500	466	0	-7
5	Bag 2	13	01:02	500	500	462	0	-8
6	Bag 2	13	01:02	500	500	457	0	-9
7	Bag 2	13	01:02	500	500	450	0	-11
8	Bag 2	13	01:02	500	500	440	0	-14
9	Bag 2	13	01:02	500	500	442	0	-13
10	Bag 2	13	01:02	500	500	439	0	-14
1	Bag 2	12	01:02.5	450	425	422	-6	-7
2	Bag 2	12	01:02.5	450	425	423	-6	-6
3	Bag 2	12	01:02.5	450	425	425	-6	-6
4	Bag 2	12	01:02.5	450	425	422	-6	-7
5	Bag 2	12	01:02.5	450	425	419	-6	-7
6	Bag 2	12	01:02.5	450	425	421	-6	-7
7	Bag 2	12	01:02.5	450	425	420	-6	-7
8	Bag 2	12	01:02.5	450	425	419	-6	-7
9	Bag 2	12	01:02.5	450	425	416	-6	-8
10	Bag 2	12	01:02.5	450	425	418	-6	-8
1	Bag 2	12	01:03	400	370	378	-8	-6
2	Bag 2	12	01:03	400	370	380	-8	-5
3	Bag 2	12	01:03	400	370	381	-8	-5
4	Bag 2	12	01:03	400	370	383	-8	-4
5	Bag 2	12	01:03	400	370	380	-8	-5
6	Bag 2	12	01:03	400	370	385	-8	-4
7	Bag 2	12	01:03	400	370	383	-8	-4
8	Bag 2	12	01:03	400	370	381	-8	-5
9	Bag 2	12	01:03	400	370	384	-8	-4
10	Bag 2	12	01:03	400	370	381	-8	-5
1	Bag 2	13	01:02	350	300	279	-17	-25
2	Bag 2	13	01:02	350	300	290	-17	-21

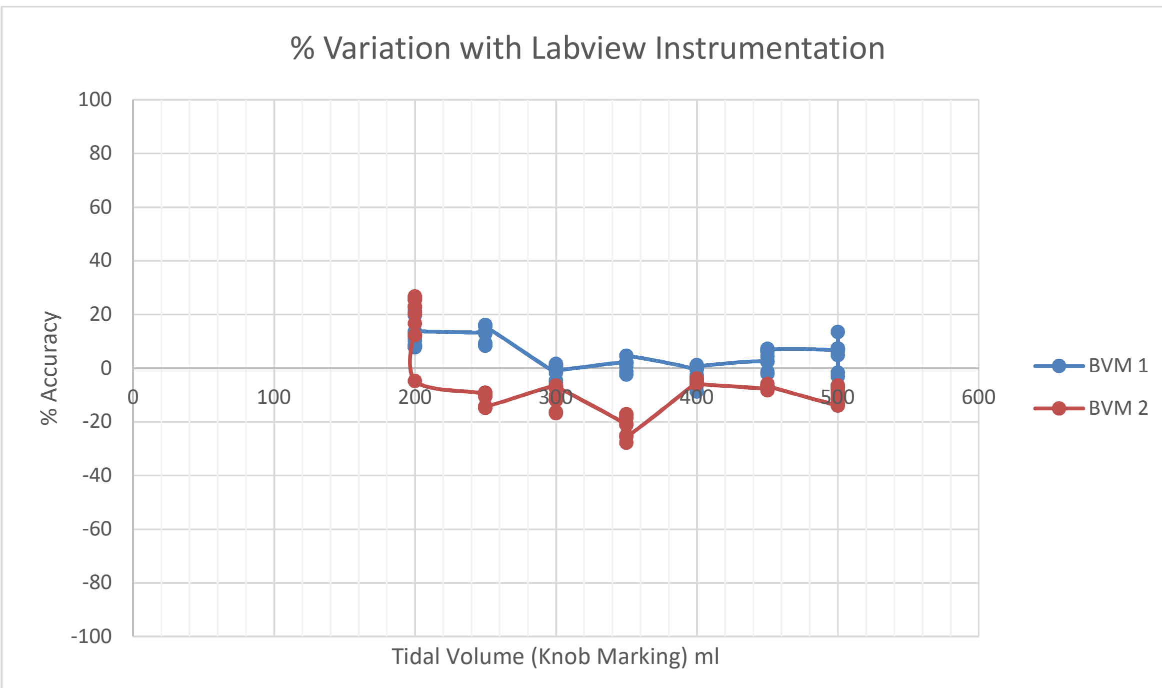
3	Bag 2	13	01:02	350	300	295	-17	-19
4	Bag 2	13	01:02	350	300	298	-17	-17
5	Bag 2	13	01:02	350	300	299	-17	-17
6	Bag 2	13	01:02	350	300	297	-17	-18
7	Bag 2	13	01:02	350	300	296	-17	-18
8	Bag 2	13	01:02	350	300	274	-17	-28
9	Bag 2	13	01:02	350	300	280	-17	-25
10	Bag 2	13	01:02	350	300	289	-17	-21
1	Bag 2	13	01:02.3	300	280	281	-7	-7
2	Bag 2	13	01:02.3	300	280	280	-7	-7
3	Bag 2	13	01:02.3	300	280	257	-7	-17
4	Bag 2	13	01:02.3	300	280	268	-7	-12
5	Bag 2	13	01:02.3	300	280	279	-7	-8
6	Bag 2	13	01:02.3	300	280	280	-7	-7
7	Bag 2	13	01:02.3	300	280	281	-7	-7
8	Bag 2	13	01:02.3	300	280	258	-7	-16
9	Bag 2	13	01:02.3	300	280	272	-7	-10
10	Bag 2	13	01:02.3	300	280	282	-7	-6
1	Bag 2	13	01:02	250	230	219	-9	-14
2	Bag 2	13	01:02	250	230	226	-9	-11
3	Bag 2	13	01:02	250	230	229	-9	-9
4	Bag 2	13	01:02	250	230	228	-9	-10
5	Bag 2	13	01:02	250	230	218	-9	-15
6	Bag 2	13	01:02	250	230	229	-9	-9
7	Bag 2	13	01:02	250	230	228	-9	-10
8	Bag 2	13	01:02	250	230	229	-9	-9
9	Bag 2	13	01:02	250	230	218	-9	-15
10	Bag 2	13	01:02	250	230	228	-9	-10
1	Bag 2	30	01:04	200	200	191	0	-5
2	Bag 2	30	01:04	200	200	240	0	17
3	Bag 2	30	01:04	200	200	228	0	12
4	Bag 2	30	01:04	200	200	251	0	20
5	Bag 2	30	01:04	200	200	260	0	23
6	Bag 2	30	01:04	200	200	269	0	26
7	Bag 2	30	01:04	200	200	273	0	27
8	Bag 2	30	01:04	200	200	259	0	23
9	Bag 2	30	01:04	200	200	268	0	25
10	Bag 2	30	01:04	200	200	272	0	26

As per the test observations, the relationships between the Tidal volume in the knob to the tidal volume given by water column as well tidal volume measured in instrumentation panel are plotted as given in figures below. Also, the percentage accuracy of each reading is also plotted.


EBAS Tidal Volume Variation with Water Column
Water Column Reading ml
Tidal Volume (Knob Marking) ml
550
500
450
400
350
300
250
200
150
0
100
200
300
400
500
600
BVM 1
BVM 2


EBAS Tidal Volume variation with Labview Instrumentation
Water Column Reading ml
Tidal Volume (Knob Marking) ml
600
550
500
450
400
350
300
250
200
150
0
100
200
300
400
500
600
BVM 1
BVM 2





As per the above observations, it can be seen that, the maximum % BVM to BVM variation falls under 20% for all the observations. For the tidal volume, 350 and 200, there were a few instances of %variation of 30%. However, with actual observations with water column, the % variations retains to less than 20% of the displayed value.

Test 6. Test for determination of Tidal Volume Accuracy

This test is conducted to determine the accuracy of the tidal volume indicator present in the EBAS. To conduct the test, the DUT is subjected to the test set up as per the ISO 10651-3 standard with multiple BVM bags. The airway circuit is connected with each BVM bag and different tidal volumes are set on the machine. For each set tidal volume, water column reading and reading on the **LabVIEW** instrumentation panel are noted down. The results of the test are given below.

As per the ISO 10651-3 standard, the tidal volume, BPM and the I:E ratio to be setup in the machine to establish its accuracy is given below.

Figure 1 — Typical configuration of test apparatus for measurement of expiratory volume

Table 1 — Conditions for expiratory volume measurements

Adjustable parameter	Test conditions Adult use	Paediatric use	Neonatal use
Tidal volume, V_T (ml) as measured by a pressure sensor on the test lung ($V_T = C \times p_W$ max.)	500	300	30
Respiratory cycle frequency, f (min^{-1})	10	20	30
I/E ratio	1/2 or nearest	1/2 or nearest	1/2 or nearest
Resistance to flow, R (kPa·l^{-1}·s^{-1})	0,5 ± 10 %	2 ± 10 %	5 ± 10 %
Isothermal compliance, C (ml/kPa)	500 ± 5 %	200 ± 5 %	10 ± 5 %
NOTE — The accuracies for C and R apply over the entire range of measurements.			

The DUT is subjected to the above test conditions and the following observations are made.

Determination of accuracy of Tidal volume measurement as per ISO 10651-3									
Sl.No	**BVM**	**BPM**	**I:E Ratio**	**Marking on knob**	**Water coloumn (ml)**	**Lab View**	**% Accuracy with water column**	**% Accuracy with LabView**	**Avg % Accuracy**
1	BVM 1	20	01:01.9	300	275	292	-9.1	-2.7	
2	BVM 1	20	01:01.9	300	292	284	-2.7	-5.6	
3	BVM 1	20	01:01.9	300	275	289	-9.1	-3.8	
4	BVM 1	20	01:01.9	300	275	292	-9.1	-2.7	
5	BVM 1	20	01:01.9	300	275	280	-9.1	-7.1	
6	BVM 1	20	01:01.9	300	275	290	-9.1	-3.4	-3.6
7	BVM 1	20	01:01.9	300	275	295	-9.1	-1.7	
8	BVM 1	20	01:01.9	300	275	292	-9.1	-2.7	
9	BVM 1	20	01:01.9	300	275	291	-9.1	-3.1	
10	BVM 1	20	01:01.9	300	275	290	-9.1	-3.4	
11	BVM 1	10	02:00.0	500	450	430	-11.1	-16.3	
12	BVM 1	10	01:02	500	450	444	-11.1	-12.6	
13	BVM 1	10	01:02	500	450	432	-11.1	-15.7	
14	BVM 1	10	01:02	500	450	450	-11.1	-11.1	
15	BVM 1	10	01:02	500	450	429	-11.1	-16.6	
16	BVM 1	10	01:02	500	450	454	-11.1	-10.1	-14.2
17	BVM 1	10	01:02	500	450	431	-11.1	-16.0	
18	BVM 1	10	01:02	500	450	430	-11.1	-16.3	
19	BVM 1	10	01:02	500	450	451	-11.1	-10.9	
20	BVM 1	10	01:02	500	450	428	-11.1	-16.8	
21	BVM 2	10	01:02	500	500	500	0.0	0.0	
22	BVM 2	10	01:02	500	500	500	0.0	0.0	1.6
23	BVM 2	10	01:02	500	500	532	0.0	6.0	

24	BVM 2	10	01:02	500	500	499	0.0	-0.2	
25	BVM 2	10	01:02	500	500	498	0.0	-0.4	
26	BVM 2	10	01:02	500	500	530	0.0	5.7	
27	BVM 2	10	01:02	500	500	499	0.0	-0.2	
28	BVM 2	10	01:02	500	500	500	0.0	0.0	
29	BVM 2	10	01:02	500	500	528	0.0	5.3	
30	BVM 2	10	01:02	500	500	498	0.0	-0.4	

From the above table it can be inferred that, the maximum % accuracy of the measured tidal volume lies within 20% of the actual tidal volume for different BPM as well as different BVM.

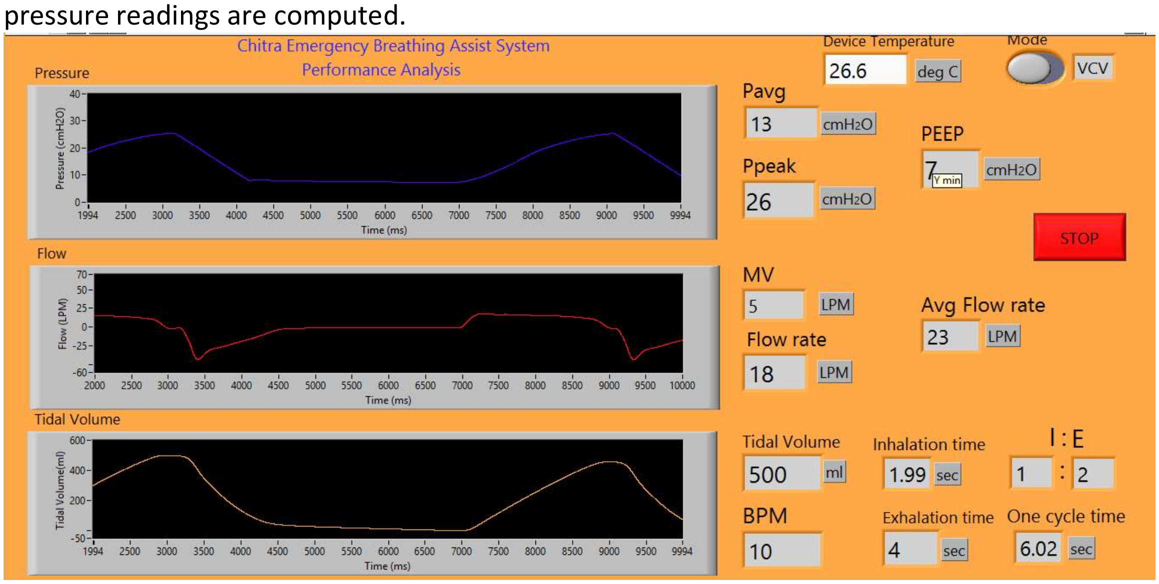
Test 7. PEEP Test

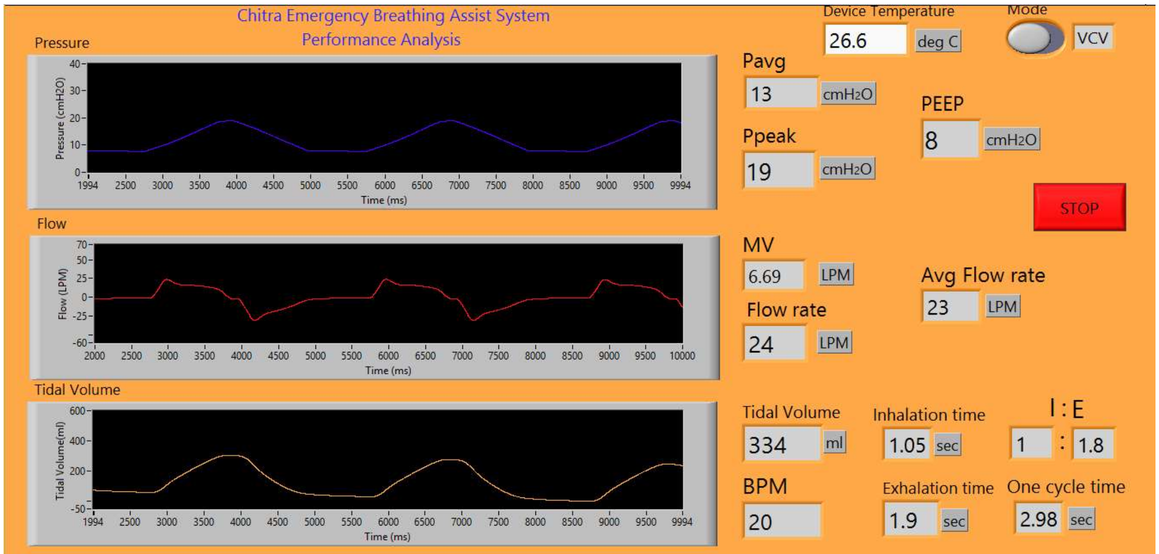
This test is conducted to evaluate the performance of the device under different PEEP conditions. In which, the DUT is subjected to different set value of PEEP by physically adjusting the PEEP valve put in the airway circuit. The device is operated at 500ml tidal volume and at a respiration rate of 10 bpm with an I:E ratio of 1:2. The minimum value of pressure exhibited after the inspiration cycle is measured from the waveform displayed in the instrumentation panel.

From the above table it can be inferred that, the EBAS can provide different PEEP set by the valve precisely.

Test 7. Peak Pressure Test

This test is conducted to evaluate the maximum pressure developed by the device during its operation. The device is operated at 500ml tidal volume, 300ml tidal volume and at a respiration rate of 10 bpm and 20 bpm with an I:E ratio of 1:2. The maximum value of pressure exhibited during the inspiration cycle is measured from the waveform displayed in the instrumentation panel as shown below for various set conditions. The observations are noted down and the average of all peak pressure readings are computed.





Tidal Volume	BPM	I:E Ratio	Peak Pressure	Avg Pressure
500	10	1:2	26	13
300	20	1:2	24	13
Avg			25	13

From the above table it can be inferred that, the peak pressure produced by EBAS is 25 cm H2O.

Test 8: Durability/Reliability Analysis

Unlike ICU ventilators, the BVM based ventilators are used only for short term operations to mitigate the COVID situation. The reliability of the device must be established by providing sufficient documentary evidence of the selection of all internal components with satisfactory reliability and meeting performance criteria as per various international standards.

For establishing the reliability, the device is operated at different ventilator parameters continuously as long as failure modes are observed. During the test, the device operated for more than 12 days and exhibits no variation in performance data and no signs of failure. The device is in operation for more than 3 months meeting all necessary conditions of the MHRA guidelines. All components are selected having life of more than 6 months even in continuous operation as shown below. The device is also tested with multiple BVM bags.

Comparison of technical Specification with benchmark devices

The table below shows the comparison of specification of different emergency/transport ventilators

Parameters	**MIT E-Vent[1]**	**Medtronic PB 560[2]**	**IS 10796[3]**	**ISO 10651[4]**	**MHRA Guidelines for RMVS**	**EBAS Specification***
Respiratory Rate	8-40 breaths/ min	1-60 breaths/ min	20 breaths/ min	10 breaths/ min	10-30 breaths/ min	10- 30 breaths/min
Tidal Volume	200-800 ml	50-2000ml	500 ml	500 ml	400 ml	200-500ml
I/E Ratio	1:1 – 1:4	1:4 to 1:1	1:2	1:1 – 1:4	1:1-1:3	1:1 to 1:5
Voltage	110-230V	100-240	As per IS	As per IEC	As per IEC	110-240V

		VAC	8607 (Part 1-3)	60601 standard	60601 & IEC 62353	
Reliability	Not conducted	Not mentioned	The specified standards don't mention about reliability testing.	The specified standards don't mention about reliability testing.	Performance tests conducted Refer Appendix B	The device is operated to more than 12 days continuously without any failure modes. The Device is also operated with multiple BVM bags
Emergency stop	Yes	Yes	Yes	Yes	Yes	Yes
Manual Operation	Yes. The reservoir is kept open allowing manual operation	Yes	Yes	Yes	Yes	Dedicated SOS lever is provided which gives an effortless actuation of the reservoir. Also, tidal volume adjustment is provided as a manual set value.

*Specifications are developed as per standard test procedure mentioned in the ISO 10651-3 standard

Compliance with MHRA guideline for Rapidly Manufactured Ventilator System

Medicines & Healthcare products Regulatory Agency

MHRA

Introduction

This is a specification of the minimally (and some preferred options) clinically acceptable ventilator to be used in UK hospitals during the current COVID-19 pandemic caused by SARS-CoV-2 virus. It sets out the clinical requirements based on the consensus of what is 'minimally acceptable' performance in the opinion of the anesthesia and intensive care medicine professionals and medical device regulators given the emergency situation. It is for devices, which are most likely to confer therapeutic benefit on a patient requiring invasive ventilation because of respiratory failure caused by SARS-CoV-2, used in the initial care of patients requiring urgent ventilation. A ventilator with lower specifications than this is likely to provide no clinical benefit and might lead to increased harm, which would be unacceptable for clinicians. Intensive care medicine is a whole system of care and ventilators cannot be safely used on any patient without trained staff and other equipment and medicines. Where these impinge on the specification they are mentioned below. It is proposed these ventilators would be for short-term stabilization for a few hours, but this may be extended up to 1-day use for a patient in extremis as the bare minimum function. Ideally it would also be able to function as a broader function ventilator which could support a patient through a number of days, when more advanced ventilatory support becomes necessary.

Must: Defines the minimum viable product clinically acceptable by clinicians

Should: Highly desirable features of considerable benefit for therapeutic use. As time is of the essence if omitting one of these features significantly accelerates development and production it should be considered

Could: Features or options often found in respirators, but are of significantly lower priority in terms of the current need and should not be considered if they delay production and development or the provision of more important features

Requirement by MHRA guidelines for RMVS	Compliance of Chitra EBAS
It is proposed these ventilators would be for short-term stabilization for a few hours, but this may be extended up to 1-day use for a patient in extremis as the bare minimum function. Ideally it would also be able to function as a broader function ventilator which could support a patient through a number of days, when more advanced ventilatory support becomes necessary.	The device operated more than one day continuously as part of laboratory testing. Will be put for stringent multi days testing after scale up to more prototypes.
Ventilation 1. Must have at least 1, optionally 2 modes of ventilation a. Must have CMV. b. The CMV mode must be either i. (ideally) Pressure Regulated Volume Control, or ii. pressure controlled ventilation (PCV) or iii. minimally a volumecontrolled ventilation (VCV)	The device operates in Volume controlled ventilation
If volume control ventilation is used, the user must be able to set inspiratory airway pressure limit in the range at least 15 – 40 cmH2O in at least increments of 5 cmH2O	Volume control ventilation mode is present with adjustment in tidal volume set by the user. The inlet airway pressure need to be manually adjusted and set by using a pressure regulator which is a part of the clinical facility.
Inspiratory: Expiratory ratio (I:E). The proportion of each breathing cycle that is spent breathing in compared to breathing out. a. RMVS must provide 1:2.0 (i.e. expiration lasts twice as long as inspiration) as the default setting. b. RMVS could provide adjustable I:E in the	The ventilator can achieve I:E ratio in the range of 1:1 to 1:5

range 1:1 – 1:3.	
Respiratory Rate. The number of breathing cycles every minute. a. RMVS must provide a range 10 – 30 breaths per minute in increments of 2 (only in mandatory mode) that can be set by the user	Respiratory rate in the range of 10-30 can be achieved
Tidal Volume (Vt) setting, if provided. The volume of gas flowing into the lungs during one inspiratory cycle a. Must have at least one setting of 400ml +/- 10 ml. b. Should have 350ml and 450 ml options. c. Could have a range 250 – 600 ml in steps of 50ml. d. Could have a range up to 800 ml	Tidal volume can be adjusted in the range of 200ml to 500ml.
Incoming Gas Supply. a. All gas connectors and hoses must comply with BS EN ISO 5359:2014+A1:2017, ISO 5359:2014/AMD 1:2017 and BS 2050: 1978 Electrical Conductivity	This is not part of the machine but the specification of the BVM bag which is a consumable. Part of BVM bag consumable- comply to standards. Air inlet diameter 22mm Oxygen inlet diameter = 5.4mm
Must connect to wall pipeline oxygen supply via BS 5682:2015 compatible probes (Schrader). If hose not permanently fixed to machine, then must connect with NIST (Non-Interchangeable Screw Thread to ISO 18082:2014/AMD 1:2017). Oxygen pipeline pressure is approximately 3.7 – 4.5 bar.	As standard BVM is used, the inlet airway ports are standard dimensions suitable for wall pipeline oxygen supply.
If RMVS connects to wall pipeline Medical Air (MA4, NOT SA7) it must be via BS 5682:2015 compatible probes.	As standard BVM is used, the inlet airway ports are standard dimensions suitable for wall pipeline oxygen supply.
Electricity Supply a. If mains powered RMVS must connect to 240V mains via standard UK 3pin plug. b. Must be PAT tested to the adapted IEC 60601, IEC 62353 standards c. If electricity is required for functioning, RMVS must have a battery backup of at least 20 minutes in case of mains electricity failure. d. Could utilise hot swappable batteries so that it can be run on battery supply for	Available The machine is capable to take AC voltage using standard 3 pin plug with a range of 110V to 240V. The device is provided with a battery back of approximately 30 minutes by design. In house testing conducted for Hipot Test Insulation Resistance Earth Bond Tests

an extended period, e.g. 2 hours for within hospital transfer. e. Must avoid harmful RF or EM emissions that could interfere with other critical care equipment.	As per IEC 60601-1 standard
Gas supply to patient.	Standard hospital gas specifications to be used.
All elements in the gas pathway must meet biological safety and low-pressure oxygen safety standards, especially to minimise risk of fire or contamination of the patient's airway.	Yes, as part of the standard hospital guidelines
Infection control For clinical guidelines on infection control for ventilator equipment see Appendix A 1. All parts coming into contact with the patient's breath must be either disposable or designed to be reusable 2. All working components of the device must be contained within an impermeable casing. 3. All external surfaces must be cleanable in the likely event that they get respiratory secretions or blood splatter on them. Cleaning would be by healthcare workers manually wiping using an approved surface wipe with disinfectant or cloths and approved surface cleaning liquid There will be a separately sourced HMEF-bacterial-viral filter between the machine and patient which may impact on resistance within the system, which may need to be accounted for with some designs. The pressure being delivered to the patient is the specified pressure. If the filter has a resistance of, say 2 cmH2O at 30 lpm, the ventilator needs to output 37 cmH2O to achieve a set 35 cmH2O at the patient. This will need further detailed consideration. Viral filtering filters may have much higher resistance that may be clinically relevant.	Disposable BVM bag USED The bag can be sterilized and disinfected All external surfaces are made smooth with no sharp edges and no depths such that, the device can be cleaned easily by operator with clinically used cleaning agents. Bacterial and viral filters are used in the airways. The pressure requirements and ventilator functions are checked with the filters in the line.
Could include facility for hot water humidifier to be included in breathing system.	May be provided by the clinical team if deemed necessary as a separate item.
Monitoring and Alarms IEC60601-1-8:2006 is the one relevant standard for alarms for RMVS. Alarms, alarm	Various alarms have been provided Some alarms are to indicate normal functioning of the device such as

limits, and priorities are complex areas to optimise for human usability. The key is to get enough alarms but not too many and for alarms to be clearly ranked so that more urgent patient safety problems are highlighted more. Early attention to this area is important, and should be built in from the start. 1. Must alarm at: a. Gas or electricity supply failure. b. Machine switched off while in mandatory ventilation mode. c. Inspiratory airway pressure exceeded. d. Inspiratory and PEEP pressure not achieved (equivalent to disconnection alarm). e. Tidal volume not achieved or exceeded. 2. Monitoring displayed continuously so the user can verify. a. Must show the current settings of tidal volume, frequency, PEEP, FiO2, ventilation mode. b. Must show the actual current airway pressure c. Should show the achieved tidal volume, breathing rate, PEEP, andFiO2.	Audio Beep during inspiration as well as Visual green indicator for inhalation and Red indicator for exhalation Many alarms are provided to indicate abnormal functioning of the device Such as High pressure Low pressure High tidal volume Low tidal volume High I:E ratio High respiration rate Tube disconnection BVM misplacement etc
Biological Safety The authoritative standard covering this area is ISO 18562-1:2017 "Biocompatibility evaluation of breathing gas pathways in healthcare applications. Evaluation and testing within a risk management process". 1. Materials of Construction (raw materials) A) The chosen material must be reasonably pure and simple in nature (minimise the use of additives where possible) B) For components requiring flexibility avoid the use of materials requiring plasticisers. Good candidates are those materials that belong to the polyolefin family, examples include polyethylene and polypropylene C) For structural components materials such as polycarbonate or Acrylonitrile butadiene styrene (ABS) should be used without additives, although reinforcement with glass fibre would be acceptable D) Polyvinyl chloride (PVC) must be avoided	The standards ask for the Bio compatibility analysis of the air way. The Automated BVM ventilator has no components which handle the air way by any component of the ventilator inside. But all the components which handles airway are hospital consumables, such as BVM bag, PEEP Valve, HME as well as HEPA filters along with the 22mm air and oxygen tubings. All these are part of hospital supplies which should have bio compatibility tested by the respective manufactures. All the other mechanical parts of the ventilator, which may come in contact with the operator are made with already known bio compatible materials.

in the patient gas pathway E) PVC should be avoided elsewhere	
Software Safety Software in a high-risk device like RMVS will almost certainly have the capability to cause serious injury or death if risk control measures are not adequately implemented.	The device is an electromechanical device with minimal intervention to electronic software for its operation. The device operates even if, the software fails in measurement. The software is a part of add on electronics which performs only diagnosis and not any control operation. In this way reliability of the machine is ensured at worst case operating environment.
Miscellaneous 1. Must be reliable. RMVS must be capable of continuous operation (100% duty cycle) for 14 days	To be conducted after scale up of the prototypes and as part of pilot production.

Specifications for consumables to use along with the machine

1. Bag valve mask complying to the specifications of ISO 10651-4: Requirements for operator powered resuscitators[6].
2. PEEP of **5-20 cm H_2O** required
3. HEPA Filter (if required)
4. Heat & Moisture Exchanger (HME) filter (if required)

Additional Features

a) SOS Operation

Dedicated SOS lever is provided which gives an effortless actuation of the reservoir. Also, tidal volume adjustment is provided.

b) Alarms

The alarms actuate with varying intensity to indicate the inhalation and exhalation cycles. The alarms also actuate at different tones and intensities for various mal functions and low high situations. The major alarms and sensors in the device are
The device contains alarm for the following events

1. Turn on,
2. Battery operation
3. High Tidal Volume
4. Low Tidal Volume
5. High BPM
6. High I:E ratio
7. Low Inhalation time
8. Tube disconnection

Sensors: The following sensors are provided in the device

1. Tidal Volume sensing
2. Voltage Sensing

15. Detailed analysis of results: Detailed specification obtained after performance evaluation is as shown below.

Sr. No.	Parameter	Technical Specification	Remarks
1	Mode of Operation	Positive Pressure, Volume-controlled ventilation	Tidal volume adjusted through manual controls
2	Respiratory Rate	10 – 30 BPM	Motorized operation in steps of 1 BPM
3	Accuracy of Respiration Rate	+/-1 BPM	As per test conditions with standard airway circuit consumables
4	Tidal Volume	200 – 500 ml	Manual setting by turn knob.
5	Tidal Volume Accuracy	Variation less than +/-20%	As per test conditions with standard airway circuit

		of set tidal volume	consumables
6	I:E Ratio	1:1 To 1:5	Digital control
7	Range of Inhalation Time	0.5s to 1.5s	Knob control
8	Range of Exhalation Time	1s to 5s	Knob Control
9	Peak Pressure	<30 cm H2O	As per test conditions with standard airway circuit consumables
10	Airway Pressure Drop	< 6cm H2O	As per test conditions with standard airway circuit consumables
11	Minute Volume	6-15 LPM	Adjustable through tidal volume control and respiratory rate

12	Flow Rate	12-55 LPM	Adjustable through tidal volume control
13	Alarms	Codes F1 to F7	Out of range conditions
14	Maximum operations of the motor	15,00,000 cycles	As per manufacturers data sheet
15	Recommended duration of continuous operation	The device meets the requirements in guidelines for Rapidly manufactured Ventilator System Medicines & Healthcare Products Regulatory Agency (MHRA), United Kingdom.	
16	Maximum Operating Cabin Temperature	Up to 50^0C	
17	Operating Relative Humidity	40% to 80%	
18	Operating Voltage	Adaptor input voltage: 230V AC, 50 – 60 Hz Machine Input Voltage : 12V DC	

19	Dimensions	549 mm X 322 mm X 261 mm (Approx.)
20	Weight	Approx. 10 Kgs
21	Compliance	The functional specifications of the machine are compliant to the requirements of IS 10796, ISO 10651-3 and guidelines for Rapidly manufactured Ventilator System Medicines & Healthcare Products Regulatory Agency (MHRA), United Kingdom as per preclinical laboratory evaluations.
22	Operators	Trained medical personnel only
23	Battery Backup	3 hours
24	Reliability	The device has undergone reliability tests as per Rapidly manufactured Ventilator System Medicines & Healthcare Products Regulatory Agency (MHRA), United Kingdom

16. Summary sheet of not more than 2 pages under the following heads :
(Title, Introduction, Rationale, Objectives, Methodology, Results, Translational Potential)

As provided in Q14.

17. Science and Technology benefits accrued :

a. List of research publications with complete details :

b. Manpower trained on the project :

		i.	**Research Scientists or Research Fellows**	**:**	**0**
		ii.	**No. of PhD's produced**	**:**	**0**
		iii.	**Other Technical Personnel trained**	**:**	**0**
	c.	**Patents taken, if any**		**:**	**1**
	d.	**Products developed, if any**		**:**	**AirBrdige Emergeny Breathing Assist System (Transferred to Wipro 3D and commercialized in the brand name AirBrdidge EBAS)**

20 Abstract: (In 300 words for possible publication in ...... Bulletin)

Millions of people worldwide are affected by the new pandemic COVID-19, and the numbers are increasing at a very faster rate calling for immediate development of necessary ventilators for emergency use. However, the number of ventilators available in hospitals is very limited especially in India.

In this alarming situation, handy artificial manual breathing unit (AMBU) will be highly helpful. AMBU bag or a bag-valve-mask (BVM) is a hand-held device used to provide positive pressure ventilation to a patient who is either not breathing or who is breathing inadequately. However, use of AMBU needs a bystander for its operations who is highly susceptible and non-advisable to be in close contact with the COVID-19 patient.

To tackle the situation, Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST), an institute of national importance under Department of Science and Technology, Govt. of India, with its long tradition of developing and commercializing challenging and needy medical devices, has introduced an Emergency Breathing Assist device which will be of very beneficial to assist the breathing of the critical patients who is not accessible to ICU ventilators.

For enabling rapid production, the device is designed with readily available components so that it becomes an alternative solution for ventilator shortages by providing ventilation support to the needy as advised by the clinicians.

This portable and light weight device enables positive pressure ventilation with controlled rate of expiration, I:E Ratio (Inspiratory to Expiratory Ratio), Tidal Volume, etc., Also A PEEP (Positive End Expiratory Pressure) Valve can be added as an extra component to maintain pressure on the lower airways at the end of the breathing cycle which prevents the alveoli from collapsing during expiration. The compressed gas source can also be attached to the system. The automatic device will minimize the need of support personnel in the isolation room thereby enabling safer, effective and lung protective operation to COVID patients.

As emergency preparedness to reduce mortality, this device can be manufactured in a low resource setting with minimum cost.

Features:

- Control of Rate of expiration, I:E Ratio (Inspiratory to Expiratory Ratio), Tidal Volume, etc.,
- Inhalation time control from 0.5s to 1 seconds
- Exhalation time control from 1 sec to 6 seconds

- Tidal Volume of 500ml
- Minimum Tidal volume adjust by 5ml
- I:E ratio control from 1:1 to 1:5
- A PEEP (Positive End Expiratory Pressure) Valve can be added as an extra component.
- Portable and Rugged design with low cost automated AMBU ventilation support.
- Provision for Battery operation.
- Mobility for intra-hospital transport/Ambulance transport.
- Invasive and non-invasive ventilation support.
- SOS operation in case of electricity or machine failure.

21. Procurement/Usage of Equipment:

a. Details of Equipment: Nil

Sl. No.	Name of Equipment	Make/ Model	Cost (Rs.)	Date of Installation	Utilisation	Remarks regarding maintenance breakdown

b. Suggestions for disposal of equipment(s):

No equipment purchased

Sarath S Nair (30/11/2023)

(Name and Signature of PIs with date)

Routing: *Signed copy of "Project completion Report" by PI → root@sctimst.ac.in, rpc@sctimst.ac.in*