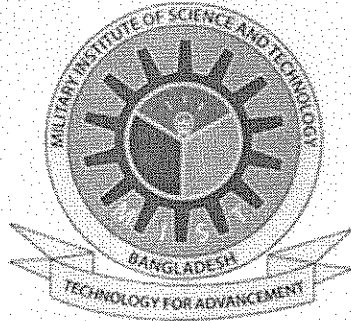


# Technical Evaluation & Validation of Locally Manufactured Ventilator (LMV)

## Ventilator Type: Emergency

Applicant Organization/Team Name: .....

Conducted by

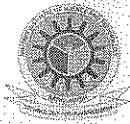
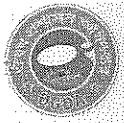


**Military Institute of Science and Technology (MIST)**

**Mirpur Cantonment, Dhaka-1216**

Version: MIST\_Ventilator\_TV\_E\_1.0

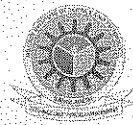
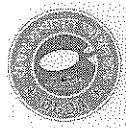
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## Summary of Technical Evaluation & Validation

Clause Ser.	Events	Remarks
A	Ventilation Characteristics	
B	Gas and Electricity Supply	
C	Infection Control	
D	Monitoring and Alarm	
E	Biological Safety	
F	Software Safety	
G	Additional Observations	

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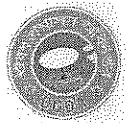


## Overall Recommendation

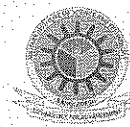
### Signatures of the Technical Evaluation & Validation Committee

<p>..... Maj Md. Ashrafuzzaman, PhD, EME Dated.....</p>	<p>..... Lt Col Muhmmad Nazrul Islam, PhD, Sigs Dated.....</p>	<p>..... Assistant Professor Golam Mostafa Dated.....</p>
<p>..... Name Dated.....</p>	<p>..... Name Dated.....</p>	<p>..... Name Dated.....</p>

*[Handwritten Signature]*

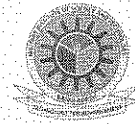
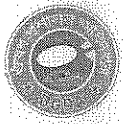


## Glossary



Before we proceed to the testing queries, this paper work would like to present elaborated introduction of some important abbreviated keywords:

Serial No	Abbreviated Form	Elaboration
1	ARDS	Acute Respiratory Distress Syndrome: a life-threatening form of respiratory failure where the lungs become severely inflamed due to an infection or injury and can't provide the body's vital organs with enough oxygen.
2	SIMV-PC	Synchronized Intermittent Mandatory Ventilation – Pressure Controlled: a mode of ventilation where the patient is allowed to take spontaneous breaths, the machine will assist the patients breathing when a spontaneous breath is taken. If the patient does not make a pre-set number of breaths a minute (i.e. 10) the machine provides mechanical ventilation to provide the set number.
3	CMV	Continuous Mandatory Ventilation
4	PCV	Pressure Controlled Ventilation
5	VCV	Volume Controlled Ventilation
6	PRVC	Pressure Regulated Volume Controlled: A mode of ventilation where a set tidal volume is delivered to the patient while maintain the lowest pressure possible in the airway, to avoid trauma.
7	CPAP	Continuous Positive Airway Pressure a non-invasive ventilation mode that provides a constant steady pressure to keep the lungs expanded.
8	BIPAP	Bi-level Positive Airway Pressure: a non-invasive ventilation mode that provides different levels of pressure when the patient inhales and exhales.
9	IPPV	Intermittent Positive Pressure Ventilation: a mandatory invasive ventilation mode used to replace a patient's breathing when they cannot for themselves. Can be either volume controlled or pressure controlled. It does not synchronize any patient breathing efforts.
10	PEEP	Positive End-Expiratory Pressure: The lower pressure applied to the patient's airway to allow them to breathe out, but not too much.
11	EPAP	Expiratory Positive Airway Pressure: Similar to PEEP, pressure applied to the airway on patient expiration to prevent collapse of the airway.
12	HMEF	Heat and Moisture Exchange Filter: device fitted to the patient end of the breathing system, contains hydrophobic medium that absorbs heat and moisture from the patients exhaled breath and uses absorbed moisture to humidify inhaled gases. Can also filter bacteria and viruses, this will be used on all patients. WARNING can affect delivered pressure.
13	RF	Radio Frequency: Many medical devices are sensitive to RF interference. Care should be taken to ensure that this is kept to a minimum.
14	EM	Electro Magnetic Emissions: Many medical devices are sensitive to EM interference. Care should be taken to ensure that this is kept to a minimum.
15	FiO2	Fraction of inspired oxygen: concentration of oxygen in the gas mixture that the patient inhales
16	AGSS	Anaesthetic gas scavenging system: where anaesthetic agents have been included in the gas mixture, this system is used to collect and remove exhaled gas to avoid exposure to health care professionals.
17	LMV	Locally Manufactured Ventilator



## 1. Introduction

COVID-19 pandemic caused by SARS-CoV-2 has recently increased the need of ventilators in hospitals throughout the world. Sudden increase in the demand of ventilators has created a crisis in the international market and many countries are now taking initiatives to produce locally designed ventilators. The whole world including Bangladesh is going through a critical period. Many individuals, independent researchers, research facilities, software firms, educational institutes and industries in Bangladesh have developed different categories of ventilators to save the life of the patient during the transition period. In order to cope with the limited resources, it is imperative to determine whether these ventilators are suitable for human use at all.

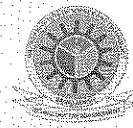
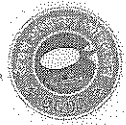
This protocol aims at classifying locally made different types of ventilators based on their technical capabilities, efficiency, vulnerability and potential for application to humans. It follows the guidelines of intensive care medical professionals and anaesthetists to set a minimum criteria and performance of a ventilator to be called either as a Locally Manufactured Ventilator for Emergency use (LMV (E)) and Locally Manufactured Ventilator for Conventional ICU (LMV(C)). It is for alternative and conventional ventilators designed in an emergency situation in order to save life of a patient requiring urgent or long-term ventilation for respiratory failure caused by SARS-CoV-2 or any accident. Devices not meeting the standards of the protocol are likely to provide no benefit to the patient in need of emergency or long-term ventilation and might lead to increased harm. This technical evaluation is performed to meet the present COVID-19 crisis where the minimum required parameters has been considered. When the current emergency has passed these devices should require further testing and validation for further regular healthcare use.

## 2. Objectives

The objectives of the report is as follows-

1. Functionality testing of a locally made ventilator.
2. Evaluation of safety of a locally made ventilator.
3. Evaluation of viability for clinical testing.





### 3. Technical Evaluation & Validation

Although there is a number of factors to be monitored for the practicability of a Conventional ventilator, for the pandemic of COVID-19 only the following (minimal) specifications will be considered for its viability. This is to confer therapeutic benefit (urgent ventilation at acute condition) for a COVID-19 affected patient requiring invasive ventilation due to respiratory failure

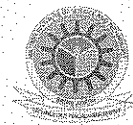
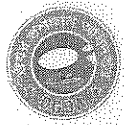
Furthermore in the testing questionnaires' three words- 'Must', 'Should', and 'Could' have special definition as-

**Must** : Defines the minimum viable product clinically acceptable by clinicians

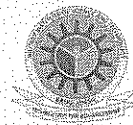
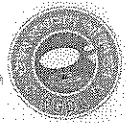
**Should** : Defines highly desirable features of considerable benefit for therapeutic use. As time is of the essence if omitting one of these features significantly accelerates development and production it should be considered

**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

Clause No	Items for Checking	Meets the Minimum Requirements (Yes/No)	Remarks
<b>A. Ventilation</b>			
1	1.1	Must have at least 1 modes of ventilation	
	1.2	Must have the CMV mode as- a. (Ideally) Volume controlled ventilation (VCV) with pressure limit control and pressure release valve or b. (Minimum) Volume controlled ventilation (VCV) with pressure release valve?	
		1.3	For the VCV test, the user sets a tidal volume and respiratory rate. The tidal volume is delivered during the inspiratory period. Acceptable only if additional pressure limiting controls are available.
2	Inspiratory airway pressure, the higher pressure should not exceed 40 cm H <sub>2</sub> O for normal lung and 60 cm H <sub>2</sub> O for tight lung.		
3	Must have PEEP: The pressure maintained in the breathing system during expiration. must provide a range 5-20 cm H <sub>2</sub> O adjustable in 5 cm H <sub>2</sub> O increments.		



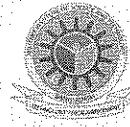
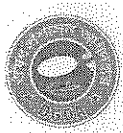
Clause No	Items for Checking	Meets the Minimum Requirements (Yes/No)	Remarks
4	Inspiratory: Expiratory ratio (I:E). The proportion of each breathing cycle that is spent breathing in compared to breathing out. a. Must provide 1:2 (i.e. expiration lasts twice as long as inspiration) as the default setting. b. Could provide adjustable I:E in the range 1:1 – 1:3.		
5	Respiratory Rate: The number of breathing cycles every minute. Must provide range 10 – 30 breaths per minute in increments of 2 or less that can be set by the user.		
6	Tidal Volume (V <sub>T</sub> ) 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.		
<b>B. Gas and Electricity</b>			
1	Incoming Gas Supply-		
	1.1	All gas connectors and hoses must be medical grade.	
	1.2	Oxygen supply system should be robust.	
1.3	Average oxygen consumption must be no more than 8 lpm. This may be allowed to increase as greater certainty is gained over oxygen supply.		
2	Electricity Supply-		
	2.1	If mains powered, must connect to 220 V mains via standard 3pin plug.	
	2.2	If electricity is required for functioning, must have a battery backup of at least 20 minutes in case of mains electricity failure.	
	2.3	Could utilize hot swappable batteries so that it can be run on battery supply for an extended period, e.g. 2 hours for within hospital transfer.	
2.4	Must avoid harmful RF or EM emissions that could interfere with other critical care equipment.		
3	Gas supply to patient- The patient breathing system valve arrangement must avoid detrimental rebreathing.		
4	All elements in the gas pathway must meet biological safety and low-pressure oxygen safety standards, especially to minimize risk of fire or contamination of the patient's airway.		



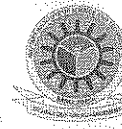
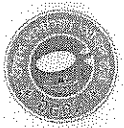
Clause No	Items for Checking	Meets the Minimum Requirements (Yes/No)	Remarks
<b>C. Infection control</b>			
1	All parts coming into contact with the patient's breath must be both disposable and reusable.		
2	All working components of the device must be contained within an impermeable casing.		
3	All 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.		
4	There must be a separately sourced HMEF-bacterial-viral filter between the machine and patient.		
5	Could include facility for hot water humidifier to be included in breathing system		
<b>D. Monitoring and Alarms</b>			
Alarms, alarm limits, and priorities are complex areas to optimize 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. To check the following points need some attentions-			
1	Must have alarm at:		
	1.1 Electricity supply failure.		
	1.2 Machine switched off while in mandatory ventilation mode.		
	1.3 Mechanical failure.		
	Should have alarm at:		
	1.4 Inspiratory airway pressure exceeded.		
1.5 Patient Disconnecting Alarm.			
2	Monitoring displayed continuously so the user can verify.		
	2.1 Must show the current settings of tidal volume, respiratory rate and I:E ratio.		
	2.2 Should show the actual current airway pressure		

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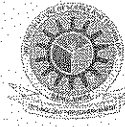
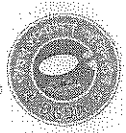




Clause No	Items for Checking	Meets the Minimum Requirements (Yes/No)	Remarks
<b>E. Biological Safety</b>			
1	Materials of Construction (raw materials) a. The materials of construction must be medical grade and biocompatible. b. Polyvinyl chloride (PVC) must be avoided in the patient gas pathway c. PVC should be avoided elsewhere		
2	Hazard Mitigation		
	2.1 Leachable substances (in condensate): chemical removed from the medical device by the action of water, other liquids or other gases related to the use of the medical device- insure a HME filter is used between the ventilator and breathing system.		
	2.2 If any glue or adhesive is used, it must be medical grade and should not emit Volatile Organic Compounds (VOC) or leach chemicals during operation.		
<b>F. Software Safety</b>			
	The software features will be discussed with the technical development team. The following documents should be provided.		
1	Are the features claimed in the software requirement specification (SRS) implemented into the software developed?		
2	Are the ways of exception handling clearly addressed in the software architecture and software design?		
3	Is the verification and validation process planned, conducted (inhouse testing) and reported?		
4	Is the user interface of the software user-friendly?		
	a. Visual Alarm Signals as well as audible alarm signals b. Labels clearly visible from at least 4ft distance c. Access distance to set up the RR, TV and I:E ratio is not more than 2 clicks.		
<b>G. Miscellaneous</b>			
1	Must be reliable. LMV(E) must be capable of continuous operation (100% duty cycle) for 8 Hours minimum.		
2	Could be floor standing and light enough to mount on patient bed with orientation independent functioning.		
3	Should be as robust as possible.		



Clause No	Items for Checking	Meets the Minimum Requirements (Yes/No)	Remarks
4	It must be intuitive to use for qualified medical personnel, but these may not be specialists in ventilator use. a. Must include Instructions for Use. b. Instructions for use should be built into the labeling of the ventilator, e.g. with 'connect this to wall' etc. Must include clear labeling of all critical functions and controls using standard terms, pictograms and colors that will be readily recognized by healthcare staff.		
5	Must Provide User manual		
6	Service Manual should provide and is highly recommended. For end user delivery it is a must.		
<b>H. Additional Observation</b>			
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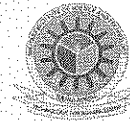
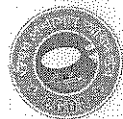


## 4. Ventilation Test

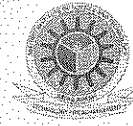
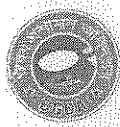
### 4.1 Volume Controlled Ventilation Test (Compliance)

Test No	Test Lung Compliance ml/cmH <sub>2</sub> O ± 10%	Test Lung Resistance cmH <sub>2</sub> O/l/s ± 10%	Tidal Volume ml	Rate Min <sup>-1</sup>	I:E	O <sub>2</sub> %	PEEP	Findings	Remarks
1	50	5	400	20	1:2	50-60	5		
2	50	5	400	20	1:2	90-100	5		
3	50	5	400	12	1:2	50-60	5		
4	50	5	400	12	1:2	90-100	5		
5	50	5	400	20	1:2	50-60	10		
6	50	5	400	20	1:2	90-100	10		
7	50	5	400	12	1:2	50-60	10		
8	50	5	400	12	1:2	90-100	10		
9	50	5	400	20	1:2	50-60	15		
10	50	5	400	20	1:2	90-100	15		
11	50	5	400	12	1:2	50-60	15		
12	50	5	400	12	1:2	90-100	15		
13	20	5	400	20	1:2	50-60	5		
14	20	5	400	20	1:2	90-100	5		
15	20	5	400	12	1:2	50-60	5		
16	20	5	400	12	1:2	90-100	5		
17	20	5	400	20	1:2	50-60	10		
18	20	5	400	20	1:2	90-100	10		
19	20	5	400	12	1:2	50-60	10		
20	20	5	400	20	1:2	50-60	10		
21	20	5	400	20	1:2	50-60	15		
22	20	5	400	20	1:2	90-100	15		
23	20	5	400	12	1:2	50-60	15		
24	20	5	400	20	1:2	50-60	15		

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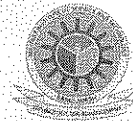
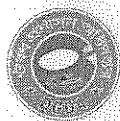
25	10	5	400	20	1:2	50-60	5		
26	10	5	400	20	1:2	90-100	5		
27	10	5	400	12	1:2	50-60	5		
28	10	5	400	12	1:2	90-100	5		
29	10	5	400	20	1:2	50-60	10		
30	10	5	400	20	1:2	90-100	10		
31	10	5	400	12	1:2	50-60	10		
32	10	5	400	20	1:2	50-60	10		
33	10	5	400	20	1:2	50-60	15		
34	10	5	400	20	1:2	90-100	15		
35	10	5	400	12	1:2	50-60	15		
36	10	5	400	20	1:2	50-60	15		



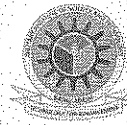
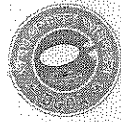
## 4.2 Volume Controlled Ventilation Test (Resistance)

Test No	Test Lung Compliance ml/cmH <sub>2</sub> O ± 10%	Test Lung Resistance cmH <sub>2</sub> O/l/s ± 10%	Tidal Volume ml	Rate Min <sup>-1</sup>	I:E	O <sub>2</sub> %	PEEP	Findings	Remarks
1	50	5	400	20	1:2	50-60	5		
2	50	5	400	20	1:2	90-100	5		
3	50	5	400	12	1:2	50-60	5		
4	50	5	400	12	1:2	90-100	5		
5	50	5	400	20	1:2	50-60	10		
6	50	5	400	20	1:2	90-100	10		
7	50	5	400	12	1:2	50-60	10		
8	50	5	400	12	1:2	90-100	10		
9	50	5	400	20	1:2	50-60	15		
10	50	5	400	20	1:2	90-100	15		
11	50	5	400	12	1:2	50-60	15		
12	50	5	400	12	1:2	90-100	15		
13	20	20	400	20	1:2	50-60	5		
14	20	20	400	20	1:2	90-100	5		
15	20	20	400	12	1:2	50-60	5		
16	20	20	400	12	1:2	90-100	5		
17	20	20	400	20	1:2	50-60	10		
18	20	20	400	20	1:2	90-100	10		
19	20	20	400	12	1:2	50-60	10		
20	20	20	400	20	1:2	50-60	10		
21	20	20	400	20	1:2	50-60	15		
22	20	20	400	20	1:2	90-100	15		
23	20	20	400	12	1:2	50-60	15		
24	20	20	400	20	1:2	50-60	15		
25	10	50	400	20	1:2	50-60	5		
26	10	50	400	20	1:2	90-100	5		



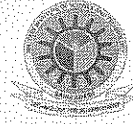
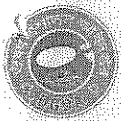


27	10	50	400	12	1:2	50-60	5		
28	10	50	400	12	1:2	90-100	5		
29	10	50	400	20	1:2	50-60	10		
30	10	50	400	20	1:2	90-100	10		
31	10	50	400	12	1:2	50-60	10		
32	10	50	400	20	1:2	50-60	10		
33	10	50	400	20	1:2	50-60	15		
34	10	50	400	20	1:2	90-100	15		
35	10	50	400	12	1:2	50-60	15		
36	10	50	400	20	1:2	50-60	15		



### 4.3 Volume Controlled Ventilation Test (Tidal Volume)

Test No	Test Lung Compliance ml/cmH <sub>2</sub> O ± 10%	Test Lung Resistance cm H <sub>2</sub> O/l/s ± 10%	Tidal Volume ml	Rate Min <sup>-1</sup>	I:E	O <sub>2</sub> %	PEEP	Findings	Remarks
1	50	5	300	20	1:2	50-60	5		
2	50	5	300	20	1:2	90-100	5		
3	50	5	300	12	1:2	50-60	5		
4	50	5	300	12	1:2	90-100	5		
5	50	5	300	20	1:2	50-60	10		
6	50	5	300	20	1:2	90-100	10		
7	50	5	300	12	1:2	50-60	10		
8	50	5	300	12	1:2	90-100	10		
9	50	5	300	20	1:2	50-60	15		
10	50	5	300	20	1:2	90-100	15		
11	50	5	300	12	1:2	50-60	15		
12	50	5	300	12	1:2	90-100	15		
13	20	20	300	20	1:2	50-60	5		
14	20	20	300	20	1:2	90-100	5		
15	20	20	300	12	1:2	50-60	5		
16	20	20	300	12	1:2	90-100	5		
17	20	20	300	20	1:2	50-60	10		
18	20	20	300	20	1:2	90-100	10		
19	20	20	300	12	1:2	50-60	10		
20	20	20	300	20	1:2	50-60	10		
21	20	20	300	20	1:2	50-60	15		
22	20	20	300	20	1:2	90-100	15		
23	20	20	300	12	1:2	50-60	15		
24	20	20	300	20	1:2	50-60	15		
25	10	50	300	20	1:2	50-60	5		
26	10	50	300	20	1:2	90-100	5		



27	10	50	300	12	1:2	50-60	5		
28	10	50	300	12	1:2	90-100	5		
29	10	50	300	20	1:2	50-60	10		
30	10	50	300	20	1:2	90-100	10		
31	10	50	300	12	1:2	50-60	10		
32	10	50	300	20	1:2	50-60	10		
33	10	50	300	20	1:2	50-60	15		
34	10	50	300	20	1:2	90-100	15		
35	10	50	300	12	1:2	50-60	15		
36	10	50	300	20	1:2	50-60	15		

#### 4.4 Documents Attached with this Report

- 1.
- 2.
- 3.
- 4.
- 5.

.....END OF REPORT.....

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*[Handwritten signatures and initials]*