Application form for Technical Evaluation and Validation of Locally Manufactured Ventilator

Version No: MIST_Ventilator_T&V_ V1.0

Release Date: 30 April 2020

1. Applicant's Information

Organization/Team Name:	
Address:	
Telephone/Mobile No:	
Email Address:	
Contact Person's Name:	
Contact Person's Email:	
Contact Person's Mobile No:	
Name of the representative who will remain present during testing:	
Representative's Email Address:	
Representative's Mobile No:	
Name of the Device with version (if applicable)	
Organization/Team Information, experience, and affiliations (Please attach a document separately)	
Please provide a short note about your design	

Initial:_____

2. Technical Specification Form

Ser.	Criteria	Required Parameters	Responses to Parameters (To be specified by applicant)	Remarks
A. Functional Specifications				
1.	Type of Ventilation	Which type of ventilation your device will provide?	☐ Invasive ☐ Non-invasive ☐ Both	
2.	Modes of Ventilation	Mention the modes of ventilation	a. Controlled Modes: ☐ PRVC ☐ PCV ☐ VCV	
			b. Assist Modes: ☐ SIMV-PC ☐ SIMV-VC ☐ AC-PC ☐ AC-VC ☐ None	
			c. Spontaneous Mode ☐ Pressure Support ☐ CPAP ☐ Bi-PAP ☐ None	

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3.	Set Parameters (Parameters to be set/maintained)	**Ventilator Parameters**	**Operating Range (Min- Max)**	**Accuracy (%)**	**Settings** **(Fixed/Controllable/Scale)**	
		Tidal volume (mL)				
		Inspiratory airway pressure/Pressure Control (cm H_2O) 1. Plateau Pressure 2. Peak Pressure				
		Respiratory Rate (bpm)				
		I:E ratio				
		PEEP (cm H_2O)				
		FiO_2 (in %)				
		Peak Inspiratory Flow Rate (lpm)				
		Others				
4.	Sensing/Measured Parameters	The parameters being monitored by your device. Select all that apply.	☐ Exhaled Tidal Volume ☐ Plateau Pressure ☐ Peak airway pressure ☐ PEEP ☐ Breathing rate ☐ FiO_2 ☐ CO2 ☐ Others…….. …….			

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5.	Contents of User Interface	The information presented to the user	a. User Set Values ☐ Tidal Volume ☐ PEEP ☐ FiO2 ☐ Breathing Rate ☐ Ventilation mode ☐ Others…….. …… b. Measured Values ☐ Current Airway Pressure ☐ Exhaled Tidal Volume ☐ Achieved PEEP ☐ Achieved Breathing Rate ☐ Achieved FiO2 ☐ Others…….. …… …….	
6.	Alarms	a. The conditions/situations for triggering an alarm. Select all that apply.	☐ Gas or electricity supply failure ☐ Machine switched off while in mandatory ventilation mode ☐ Peak Inspiratory airway pressure exceeded ☐ Inspiratory and PEEP pressure not achieved (equivalent to disconnection alarm). ☐ Tidal volume not achieved or exceeded ☐ Battery alarms ☐ Circuit Integrity alarm ☐ High and Low Breath Rate alarm ☐ FiO2 alarm ☐ Oxygen failure alarm ☐ Minute volume alarm ☐ Others…….. …….	

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		b. Alarm Type	☐ Audible (Range in dB :……) ☐ Visual	
7.	Safety Valve	Specify the safety valves provided with their position and operating conditions.		
8.	Humidifier	Present or not	☐ Yes ☐ No	
B. Device Specifications (Construction)				
9.	Controlling Hardware Used	What kind of controlling hardware are you using?	☐ PC ☐ SBC/Raspberry Pi ☐ Microcontroller/Arduino ☐ PLC ☐ Others…….. …… ……	
10.	Gas Flow Generator (Pneumatic System)	Please select the pneumatic technology used and then provide the specifications.	☐ AMBU Bag ☐ Turbine/Compressor ☐ Bellow ☐ Others…….. …… …… Specifications:	

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11.	Electrical	a. Main Power Source	☐ AC ☐ DC ☐ Both	
		b. If AC, mention operating voltage, frequency, power consumption and connection type.	• Voltage:……... • Frequency:……... • Power Consumption:…… • Connection Type:…….	
		c. Battery Backup if AC power fails	☐ Yes ☐ No	
		d. Battery Backup (time)		
		e. PAT Testing conducted	☐ Yes ☐ No	
12.	Incoming Gas and Oxygen Supply	a. What are the Gas/Oxygen Sources?		
		b. Oxygen Pipeline Pressure required?		
		c. Is there any Gas Reservoir in your ventilator?	☐ Yes ☐ No	
		d. What is the average Oxygen Consumption?		
		e. What type of Gas connectors, Hoses and probes are you using?		
		f. Is there any Filters at Gas/Oxygen Inlet?	☐ Yes ☐ No	

13.	Physical Dimensions		• Height:…… cm • Length:……..... .cm • Width:…… cm • Weight:…… . cm • Is the device one-man portable? (☐Yes ☐No)	
C. Safety and Usability				
14.	Electromagnetic Compatibility (EMC)	Is your device EMC tested?	☐ Yes ☐ No If yes, attach test reports.	
15.	Biological Safety	a. Materials used in Enclosure		
		b. Materials of the breathing System/Circuit (Pipe, Mask etc.)		
		c. Mention name/model and manufacturer of the breathing system components (if applicable)		
16.	Infection Control	a. Are the parts coming in contact with patient disposable or reusable?	☐ Disposable ☐ Reusable	
		b. External surfaces cleanable or not? (with appropriate surface cleaning agent used in hospitals)	☐ Yes ☐ No	

		c. Are the working components contained within an Impermeable casing/enclosure?	☐ Yes ☐ No	
		d. Are HMEF-bacterial-viral filters / HEPA filter used between machine and patient?	☐ Yes ☐ No	
17.	Reliability	How many hours can it operate continuously (100% duty cycle)?		
18.	Robustness	Is it drop proof from a tolerable height (i.e. drop from Patient bed height to floor)?	☐ Yes ☐ No If yes, mention tolerable height :…… cm	
19.	Operating Environment	Suitable operating environment	☐ Temperature ☐ Pressure ☐ Humidity	
20.	User Interface	Display/Indicator	• Display/Indicator Type:…….. • Display Size:……... • Liquid Protection:……...	
		User Access/Control: Specify (i.e. Button/Touch/Knob)		
21.	User Manual	Provided or Not	☐ Yes ☐ No	
22.	Service Manual	Provided or Not	☐ Yes ☐ No	

Initial:_____

Signature:

Date:

Designation:

Organization:

CHECKLIST FOR SUBMISSION:

1. General information about the organization/team (required)
2. Engineering team information (required)
3. In-house continuous operation test run data (recommended)
4. In-house QC reports and validation (Recommended)
5. User manual (Recommended)
6. Service manual (Recommended)
7. Video Demonstration (Recommended)

*** After successful completion of the application form, please submit it through email to: ventilator.testing@bme.mist.ac.bd

*** For any query please contact: Captain Md Sifatul Muktadir, EME (Mobile: 01769024176)