

Technical Specifications	
<b>Sr.No</b>	<b>Controller System</b>
<b>A</b>	
1	The system should have a micro-processor-based controller to aerosolize the drug in two modes (Intermittent modes and continuous mode) through the nebulization unit.
2	It should be operated with adaptor (input 100-240 VAC50-60 Hz, output 9V) and internal rechargeable nickel metal hydride (NiMH) battery for minimum 45 mins for portable applications.
3	The controller automatically switches to battery operation in case of AC power failure
4	The AC/DC adaptor should be warranted against defects in manufacturing for a period of two years from the date of purchase.
5	Should have built in controller system in all the leading ventilators (GE, Maquet, etc) and that should be mentioned in the IFU of the ventilator OEM Company
<b>B</b>	<b>Nebulization Unit</b>
1	Nebulisation unit should work on vibrating mesh technology capable to generate uniform particle size between 1-5 microns and should be operated through wired controller system to power the nebulizer chamber. The mesh should be made up of palladium metal
2	The Nebulisation unit should be validated for single patient use for up to 28 days intermittent use based upon a typical usage profile of 4 treatments per day or 7 days continuous use with the continuous nebulization tube set having 6 ml drug loading capacity
3	Should deliver all clinically certified aerosol drugs for all age groups and should be a fast and silent operating system and easy to set up
4	Noise level: $\leq 35$ dB measured at 0.3 m distance; Flow rate: $> 0.2$ mL/min (Average $\sim >0.30$ mL/min)
5	Nebulization unit should be compatible to be used inline with T-piece on multiple modalities like mechanical ventilator, non invasive ventilator, high flow nasal cannula, high frequency oscillator ventilator or as a stand-alone nebulisation unit.
6	The standalone nebulization unit should be used with or without O2 via mouthpiece or mask.
7	The residual volume of drug in medication chamber is $\leq 0.1$ ml for 3 ml dose.
<b>C</b>	<b>Product Quality and Safety Standard Certification</b>
1	Should be ISO and 4 Digit Notifies Body CE certified/BIS/USFDA.
2	Should have installation report or supply order from government institutions in last 2 years in India (SO to be submitted) with satisfactory performance certificate.
3	The quoting company should have direct office in India with a dedicated sales and clinical team to provide on site demonstration and user training and service.
4	The quoted medical device must be registered under CDSCO and submit the license for manufacture to sale or distribute the medical device.
5.	Should have market standing certificate for last 3 years
6.	In case the product is from countries sharing land border with India the bidder should provide evidence of registration with DPIIT Competent Authority,
7.	Demonstration of product before the technical committee is needed to be given at AIIMS Jammu during technical evaluation of the bid.
8.	Warranty 1 year and CMC for nest 4 years to be quoted separately.

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