FeNO (Fractional Exhaled Nitric Oxide) Device

Technical Specification

S.N.	Purchaser's Specifications	Bidder's Compliance Sheet		
	FeNO Device (Fractional Exhaled Nitric Oxide)			
	Manufacturer			
	Brand			
	Type / Model			
	Country of Origin			
1	**Description of Function**	**Yes/No**	**Page No in Catalogue**	**Remarks**
1.1	Fractional exhaled Nitric Oxide (FeNO) is a good marker for eosinophilic airway inflammation and is considered to be a good indicator of corticosteroid response. The production of nitric oxide is often found to be higher in inflammatory conditions such as asthma; therefore FeNO monitoring can be used for the detection and management of such conditions, but also to differentiate between COPD, ACOS and other interstitial lung diseases that are not assessed by other means, such as lung function. FeNO measurement is a simple, rapid, highly reproducible, and non-invasive method of airway inflammation assessment.			
2	**Operational Requirements**			
2.1	Non-invasive, quick and easy to perform. An ergonomic design, fully-portable and incorporated with antimicrobial technology for optimum infection control.			
3	**System Configuration**			
3.1	FeNO device, complete unit with all standard accessories.			
4	**Technical Specifications**			
4.1	Detection principle must have electrochemical sensor.			
4.2	Display must be full colour touchscreen.			
4.3	Case must have polycarbonate/ABS blend with antimicrobial technology.			

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4.4	Should have concentration range 5 - 500 ppb.			
4.5	Should have accuracy ± 5 ppb of measured value ≤ 50 ppb and ± 10% of measured value > 50 ppb			
4.6	Should have T90 response time ≤ 10 second			
4.7	Should have operating temperature 15 - 30°C			
4.8	Should have storage/transport temperature 0 - 50°C			
4.9	Should have sensor operating life 5 years (Subject to servicing).			
4.10	Should have warm up time ≤ 60 seconds			
4.11	FeNO device should have power of 1 × main rechargeable Li-ion battery - Approx. 100 uses on fully charged battery or more.			
4.12	Should have a free patient management software, available with the device which enables us to track patients' progress, view live readings, and download results plus much more.			
4.13	Mouthpiece should have dimension compatible to the device.			
5	**Accessories, spares and consumables**			
5.1	All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials, to be included in the offer. Bidders must specify the quantity of every item included in their offer (including items not specified above).			
6	**Operating Environment**			
6.1	The product offered shall be designed to be stored and to operate normally under the conditions of the purchaser's country. The conditions include Power Supply, Climate, Temperature, Humidity, etc.			
7	**Standards and Safety Requirements**			
7.1	Must submit ISO13485:2003/AC: 2007 for Medical Devices.			

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7.2	Manufacturer's declaration of compliance to all relevant European Medical Device Regulations CE (93/42/ EEC Directives) and must be cleared by FDA.			
8	**User Training**			
8.1	Must provide user training (including how to use and maintain the equipment).			
9	**Warranty**			
9.1	Comprehensive warranty for 1 year after acceptance including standard accessories and parts.			
10	**Maintenance Service During Warranty Period**			
10.1	During warranty period supplier must ensure corrective/breakdown maintenance whenever required.			
11	**Installation and Commissioning**			
11.1	Supplier must accomplish proper commissioning of equipment onsite.			
12.	**Documentation**			
12.1	User (Operating) manual in English			
12.2	Certificate of calibration and inspection from factory.