SPECIFICATIONS FOR WHOLE BODY PLETHYSMOGRAPH+DIFFUSION STUDY+ IMPULSE OSCILLOMETRY/FORCED OSCILLOMETRY (FOT)

COMPLETE SPIROMETRY SYSTEM

Pulmonary Function Test for analysis and enhanced spirometry with the latest, advanced technology for the measurement of static lung volumes through whole body plethysmography (Thoracic Gas volume) and airway resistance with minimal patient effort &real-time display of curves using the latest Ultrasonic Flow Sensor technology, which is easy to disassemble & clean with following specifications:

A. **Standard measurements:**
   1. Dynamic lung volumes and flow rates: FVC, IVC, VC, MVV, VT, FEV1, FEV6, FEV1/FEV6, PEF, PIF, FEF 25-75, FEV1/VC%, MEF25%, MEF50%, MEF75%, MVV
   2. Static lung volume measurements: FRC Plethysmography, ERV, RV, TLC, VC, IC
   3. Airway Resistance and compliance: the real-time display of curves and full editing capabilities for s_{Reff}, s_{Rtot}, $s_{R0.5}$and determination of R_{eff}, R_{tot}, $R_{0.5}$etc.
   4. CO-Diffusion SB Real-time: with continuous, high-speed gas analysis for calculation of DLCO, VA, KCO, TLC, FRC, RV and trapped gas evaluation.
   5. CO Diffusion Intra-breath or equivalent alternative diffusion method with a non-breath hold manoeuvres with continuous, high-speed gas analysis for calculation of DLCO, VA, KCO, TLC, FRC, RV.
   6. Pre and Post medication testing for therapy control.
   7. MIP/MEP Maximum Inspiratory and Expiratory pressures for measuring respiratory muscle strength.
   8. SNIP to easily measure nasal inspiratory pressure.
   9. R_{occ} for easy and fast determination of occlusion resistance with just one single shutter manoeuvre during door opened.

B. Must have integrated automated, software-controlled nebulizer for accurate and safe bronchial provocation testing also inside the cabin through an inbuilt dosimeter.

C. Must have facility for spirometry with airway resistance/reactance analysis during tidal breathing including differentiation between central and peripheral airway

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resistance, with portable Impulse Oscillometry/FOT device outside the cabin for use in paediatric and elderly patients with less compliance.

D. Technical Requirements:

- Flow measurement- Ultrasonic
- Range ±16 L/s Accuracy 2 ±%
- Resistance <0.05 Kpa/(Ls) at 16L/s
- Resolution 0.01 l/s
- Volume determination digital integration Range ±20L
- Frequency range 0-100 Hz
- Fully computerized calibration procedure for flow sensors and gas analyzers
- System should be free from any Volume Calibration.
- Ultrasonic sensor using double shot technology

E. **Body Cabin:**

- A wide cabin with an internal volume range of 800-1200 litres to provide ease of accessibility and comfort to the patient without affecting volume changes.
- Comfortable height with low entry step adjustable height of the chair with swivel arm/ fixed bench) with a maximal load of 150 kg or above
- Patient door handle inside — to support patients with claustrophobia
- Built-in compensation chamber for quick artefact reduction
- 3D-adjustable Ultrasonic sensor inside the cabin for excellent patient fitting
- Inbuilt small diffusion unit inside the cabin for an ultra-fast accurate multigas analyzer for CO and Methane or Helium
- Gas sampling close to the mouth via a thin sample line.
- Inhalation of the gas via built-in demand valve for minimum gas consumption.
- Airway pressure monitoring during the complete manoeuvre for full quality control
- Integrated loudspeaker or equivalent

F. **The Bodyplethysmography Measurement:**

- Full test procedures should be able to complete in less than 3 minutes
- Should be able to view the last 5-6 s Raw loops with automatic slope (BTPS) compensation
- Guidance and patient animation for stable sRaw and tidal breathing including a view of breathing frequency (BF)

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- Should be able to perform combined slow/forced spirometry maneuver or separated maneuver
- Different animation incentives to perform Forced Spirometry
- Should be able to review comprehensive results with clear, easy-to-read, logical screens, assisting technician and clinician with a variety of tools like Z-score, ULN-LLN, classification bar for obstruction and restriction, automated interpretation to improve clinical outcome
- Should have Single-click overlay functionality of all trials for resistance and FRC plethysmography curves to check reproducibility and quality
- Resistance/Volume loop for the quick diagnosis
- Comprehensive setting possibilities (axis scaling, resting/painting mode, number of loops, tangents for sReff, sRtot, ERV or IRV manoeuvre etc.

G. **The CO-Diffusion SB Realtime Test:**

- Standard breath-holding manoeuvre with all test gases sampled at the mouth, from the start to the end of the test.
- Discard and sample volumes should be able to modify to test even the smallest vital capacity subjects and any volume of dead space.
- Should have Intra- breath/OR equivalent test facility for less cooperative, elderly patients when breath holding is not easy to obtain, with just a slow inhalation and exhalation.
- Should have a training mode so that the patient, coached by the operator, can practice a test with room air and therefore get faster qualitative results on the diffusion manoeuvre without waste of test gas.

H. Forced Oscillometry (FOT)

- Forced Oscillometry (FOT) suitable for measurement of lung dysfunction in paediatrics (4 years onwards), Adults & Geriatric patients.
- Should be able to do the diagnosis in young children, advanced lung disease, geriatric, and neuromuscular patients.
- Should be able to do spontaneous resting breathing with the passive co-operation of the patient and routine spirometry.
- The unit must Sensitive and differentiated determination of PROXIMAL & DISTAL Pulmonary obstruction.
- Must be able to diagnose bronchial instabilities in patients with COPD/Asthma

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14. Should be able to predict reversibility conditions using Tidal breath analysis (Tidal flow-volume)

(IOS – Impulse Spectrum = 5 – 35 simultaneous & continuous measurement where)

I. Other requirements:

- Report Designer for modification of an existing report or generate a new one, i.e. layout, graphs, parameters, style, font size and colour are free configurable.
- System should have all the latest reference values including GLI 2017 as well as India reference values for Spirometry, Diffusion and Body plethysmography. The system should have Ostween reference values for Oscillometry.
- Determination of important parameters of lung diffusion e.g.CO diffusion capacity, Krogh factor and alveolar volume, as well as other absolute volumes.
- Complete test according to ATS/ERS standards incl. ATS/ERS repeatability criteria

J. **Scope of Delivery:**

- Comfortable-sized body cabin with Ultrasonic sensor and shutter
- Built-in fast diffusion multigas analyzer CO/CH4-Helium and demand valve
- Impulse Oscillometry (I0S)/Forced Oscillometry (FOT) outside the cabin
- Compact trolley with height adjustable work surface, preferably from the same manufacturer (local trolley not acceptable)
- Calibration syringe if required, as recommended by the company
- Small microphone
- System box with integrated isolation transformer
- Standard Accessories Kit Including 10 Nose Clips& Pads and 100 Disposable Bacteria Filters must be provided
- Two cylinders each of helium and diffusion gas mixtures
- High Flow pressure reducer for diffusion gas: 1no
- Desktop computer with adequate storage and 23" LED monitor, 64-bit- OS – Original Windows 10, 11th Gen i7 Processor, 16GB RAM with original MS Office and Adobe Reader and DVD writer at least 06 USB ports with **Color-Laser duplex printer**.
- Instruction for Use (English).

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Conditions for tenderer:

1. All accessories should be from the same Original Equipment Manufacturer for the main unit.
2. Instruments must be ISO certified and a copy should be enclosed. (The ISO Certificate must be issued by any organization accredited by the Bureau of Indian Standard or accredited by the international accrediting forum "IAF" (Certificate to be attached).
3. Should be USA FDA and/ or European CE be approved by 4 digits notified body.
4. Other necessary certifications if any required will be provided by the bidder for the smooth functioning of the machine.
5. Installation process should be performed by O.E.M trained service engineers/ service representatives on OEM letterhead or Service Report within 15 days of supply, with the mandatory provision of providing preventive services visit of OEM trained Service Engineer/ Service Representative quarterly per year till the completion of warranty period (i.e., 20 visits for the first 05 years) & further quarterly visits (04 visits/year) year till the completion of CMC period.
6. The equipment should have a Brand name/ Model Number embossed/etched on the equipment.
7. All the technical specifications in the compliance statement must be supported by Original Literature from the firm/ O.E.M with highlighting Numbering & flagging of all technical certificates.
8. Offered Equipment should have a strong Government Installation base.
9. Offered Equipment should have a Regional Sales Service Centre of the Original Equipment Manufacturer in the region for a 95 % uptime guarantee.
10. For the offered main unit, the essential, optional required consumables'/accessories' shelf life should be declared on the Original Equipment Manufacturer's letterhead.
11. In case of technical snag/failure/breakdown the response time for the inspection should be within 24 hours and repair within 05 days otherwise provide a service machine/ alternate arrangement to be made till the period of recovery of the breakdown of the unit, failing which attracts penal action as per the decision of institute/ hospital.

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12. For offered equipment the Training of technical staff and users should be performed by Original Equipment Manufacturer trained Service Engineers at the proper designated place- at bidders' cost.
13. Company should quote their latest model and need to provide an affidavit for the same.
14. As a tendering process the Demonstration of the offered Equipment is Mandatory at hospital/institute premises or other designated places at the bidder's cost.
15. The bidder must comply with the General Financial Rules and their modifications if any issued by the Government of India- 2017.
16. Any bidder from a country that shares a land border with India will be eligible to bid in the tender only if the bidder is registered with the Competent Authority (i.e., Registration certificate issued by the Ministry of Commerce and Industry (Department for Promotion of Industry and Internal Trade- DPIIT after October 2020). If any such bidder is not registered with DPIIT they will be liable for technical disqualification.
17. Principal (OEM) must authorize only one agent to be quoted in the bid otherwise multiple quotes through different agents in the same bid will be canceled.
18. The Bidder and its OEM both have to submit a notarized affidavit on the Indian Non-Judicial Stamp Paper of Rs.100/- that the bidder has not quoted the price higher than the current financial year and last financial year supplied to any government Institute/ Organization/ reputed Private Organization. OEM also has to submit that the price quoted by the bidder in the bid is on its behalf and the lowest in the current and last financial year in the country. Therefore, if at any stage it has been found that the supplier and its OEM have quoted lower rates than those quoted in this bid; the Institute (the purchaser) would be given the benefit of lower rates by the Supplier and any excess payment if any, will become immediately payable to the Institute (the purchaser). If such an affidavit is not submitted, the bid will be outrightly rejected. (Part of technical bid).
19. Guarantee / Warranty Period: Separate offers of Comprehensive Maintenance Contract (CMC on main equipment) and Annual Maintenance Contract (AMC on main equipment) for further 5 years after expiry of 5 years of warranty (i.e., 6th, 7th, 8th, 9th and 10th years) in rupees only (and on basis of percentage of price) should be included in a financial bid in the absence of which the offer is liable to be rejected. Payment for CMC/AMC shall be made only after the expiry of the warranty of 5 years, in case the Institute (the purchaser) decides for availing of CMC/AMC services.

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Contract for CMC/AMC shall be decided on expiry of warranty but rates (not more than 5% inclusive of all taxes for 6th to 10th year) will be frozen at the price of an issued purchase order before the release of payment by the Institute (the purchaser). However, the Institute (the purchaser) may decide not to enter into any CMC/AMC contract without assigning any reason for the same, which shall be binding upon the bid.

20. Should provide 5-year CMC. CMC cannot be more than 5% of the contract value.
21. System configured application-specific educational video tutorials shall be provided as standard with the system.
22. Details of service outlet in India to render services during 5 years warranty period.
23. The principals must give a certificate if the supplier/vendor is changed during the course of the guarantee/warranty period, the principals would be responsible for the upkeep/maintenance of the quote/supplied equipment, besides honouring all the terms and conditions of CMC/AMC in letter and spirit.

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