SPECIFICATIONS FOR HOLTER MONITORING WITH RECORDING SYSTEM

A. SOFTWARE:

The system should have the following software and capabilities as standard

- 1. The system should work on Licensed Windows software.
- 2. More than 72 hours of Ambulatory ECG Recording & Analysis Software.
- 3. ST Measurement software with an ST trend and measurement values.
- 4. Heart Rate Variability Software with HRV differential histogram, HRV histogram, HRV scatterplot.
- 5. Colour-coded HRV Power Spectrogram in terms of low power, middle range power, and high-power values.
- 6. HRV tabular summary should be available.
- 7. The values of the HRV histogram and HRV differential histogram should be exported to a CSV file.
- 8. HRV Analysis in time & frequency domain.
- 9. Pacemaker Analysis should be there with PM-PM histogram, and PM-R histogram and the values of this histogram should be exported to a CSV file.
- 10. Pacemaker analysis tabular summary should be there with Undefined paced, Fusion, Atrial paced, Ventricular paced Dual-chamber paced, PM FailedToCapture, PM FailedTo Sense, PM Failed To Pace and Total paced data.
- 11. ECG Template matching software
- 12. Should detect P wave accurately for atrial fibrillation screening
- 13. Should have specialized Graphical software for detection of the onset of Atrial Fibrillation
- 14. Should have Artifact Detection Software and automatic exclusion of artifacts.
- 15. Should have atrial analysis
- 16. Should have QT analysis
- 17. Should have RR Interval measurement Beat by Beat
- 18. Should have calipers for measurements of time in msec and heart rate and preferably amplitude measurement.

19. Should have apnoea analysis

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Page 1 of 5

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- 20. Should have specialized Graphical representation software to provide information on sleep quality and level of stress
- 21. Should have an easy view of ECG of all leads
- 22. Should have colored Graphical Representation of QT intervals, PR Intervals, Tachogram (R-R interval) & ST Alteration
- 23. Should be able to save the complete test report in PDF format
- 24. Should be able to send the data via e-mail.
- 25. System should allow the user to reclassify the complex as well as ECG templates.
- 26. Should allow the user to make different workflow patterns.
- 27. Should give the Tabular Summary showing all recorded ECG details.
- 28. Should have strip marking and strip directory.

B. HARDWARE:

- 1. Recorder should be compact and lightweight.
- 2. Weight should not be more than 130gms without abattery.
- 3. Should have a sampling frequency of at least30000 Hz
- 4. Should record 3 Channels with 5/7 lead patient cable
- 5. The same recorder should have the capability of measuring derived 12 Lead from 3 channels
- 6. Should have 16 GB removable Compact flash card & capable of storing 24/48/72 hours and moreof ECG.
- 7. Data should be transferred/analyzed via an SD card reader.
- 8. Should have displayed to check pre-hook-up ECG quality.
- 9. Should have an option of selecting the resolution of the recording. The maximum resolution of the recording should be 1024 Hz with a storage rate of 1000Hz: 12bit.
- 10. Should detect Apnea, QRS, P Wave.
- 11. Should have Event Marker / Patient Marker button on the recorder.
- 12. Should record for more than 7 days of Holter recording.
- 13. Should use a singleAAA battery to record 48/24 hrsof ECG

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- 14. Should also have an internal rechargeable battery so that if in case the AAA battery depletes internal battery takes over the recording without any break
- 15. System should print all the Holter Test Report on Laser Printer on ordinary paper & not on Thermal Chart Paper.

C. STORAGE SYSTEM:

The system with data storage facility with the following configuration

Windows Licensed Software

- 1. i 7 Processor
- 2. 1 TB HDD
- 3. RM: 4 GB
- 4. DVD Writer
- 5. Cabinet with SMPS
- 6. 24-inch LCD Touchscreen monitor
- 7. Black & White Laser Printer
- 8. Suitable Table for placing data storage system
- 9. No. OF Recorders: 02 nos.
- 10. No. Of Analyser: 1 nos.

Conditions for tenderers:

- 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 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

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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.
- 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.

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- 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. 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.

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