1. HOLTER RECORDER UNIT	
S.N.	**Technical Specifications**
	Manufacturer:
	Brand:
	Type/Model:
	Country of origin
1	**DESCRIPTION OF FUNCTION**
1.1	It is used to evaluate the presence of "erratic heart beats" or arrhythmias in patients with or without symptoms. Also to evaluate the effect of medications, to evaluate pacemaker function. It is also used to assist in the detection of narrowed arteries in the heart, which may result in inadequate blood supply to the heart muscles.
2	**OPERATIONAL REQUIREMENTS**
2.1	Holter Monitor with three channel digital recorder with removable or inbuilt storage media such CF Card and operating with rechargeable battery.
3	**SYSTEM REQUIREMENTS**
3.1	Holter Monitor unit with recording and analysis software, complete with accessories
4	**TECHNICAL SPECIFICATIONS**
4.1	Shall be PC based Holter monitoring and analysis software capable of working with latest windows configuration (windows 10 or above)
4.2	Shall be 12 lead Holter recorder with simultaneous acquisition of data from all leads (10 or 12 ECG lead cable) and recorded for upto 48 hours or more.
4.3	Shall have full disclosure of ECG waveforms with different colour coding for different clinical events.
4.4	Shall have feature to highlight arrhythmia segment in different colors to be distinguishable.
4.5	Shall have multiple templates for editing to analyse VE, SVE, V-RUN, SV-RUN, PAUSE, ST.
4.6	Shall detect and analyze Atrial fibrillation/ Atrial Flutter.
4.7	Shall have Pace Maker auto detection and analysis.
4.8	Shall have ST scan and analysis.
4.9	Shall have QT analysis with validation.
4.10	Shall provide tachycardia, bradycardia and pause detection.
4.11	Shall have artifact detection and deduction feature to provide noise free waveforms.
4.12	Shall have removable SD card with adapter for data transferring or inbuilt memory.
4.13	Shall have rechargeable battery with long life. Shall support the entire recording without the need for battery replacement.
4.14	Shall have rechargeable battery with long life.

4.15	Shall have storage of each leads data for 24 hours for upto 2 days with no data compression needed for patients with irregular arrthymias.
4.18	Shall be light weight (preferable less than 140gms), heavy duty, durable and with water ingres protection.
4.19	Digital recorder shall have sampling frequency of 32000 samples/sec/channel or better for pacemaker spike detection, 180samples/sec/channel for standard recording and storage.
4.20.1	Shall have facility to entry patients name and ID.
4.20.2	Shall have facility to review, edit and exports reports.
4.20.3	Shall have fast processing with availability to download ECG data within 5 minutes or less.
4.20.4	Shall be capable of exporting ECG reports in HL7 format or PDF for secure email transfer.
4.20.5	Shall accept multiple number of recorder (if needed later). So, hospital can only purchase the separate Holter unit.
4.20.6	Shall have facility to color print ECG waveforms.
4.20.7	Shall have tools for clinical diagnosis, waveform noise corrections.
4.20.8	Shall have facility to magnify any segment of the waveform and measure it on screen.
4.20.9	Shall have lead quality check feature.
5	**ACCESSORIES, SPARES, CONSUMABLES**
5.1	Shall provide ECG cable - 2 sets
5.2	PC of latest configuration with 24" LCD or LED monitor, CPU of i5 processor, 4 GB RAM, 256 GB SSD-01 no.
5.3	HP Colour laser printer- 01 no.
5.4	Rechargeable battery - 2 sets
5.5	Battery charger - 1 sets
5.6	Holter analysis software - 1 pc
5.7	Holter belt - 2 pcs
5.8	Holter carrying pouch - 1pc
5.9	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 (from EU Notified Body) for Medical Devices OR
7.2	CE (93/42 EEC Directives) (from EU Notified Body) and USFDA approved (510K) product certificate.
7.3	Shall meet IEC-60601-2-47 General Requirements of Safety for Electromagnetic Compatibility or must comply with 89/366/EEC; EMC directive
8	**TRAINING**
8.1	Must provide user application training (including how to use and maintain the equipment) until complete familiarity to the concerned department and bio maintenance staff by authorized trained company engineer. ((Mandatory, unable to perform shall result in disqualification)
8.2	Must provide service training (installation, assembling, disassembling, routine check, preventive maintenance, first level trouble shooting) to Bio medical staffs by trained company engineer onsite with certificate of training completion. (Mandatory, unable to perform shall result in disqualification)
9	**WARRANTY**
9.1	Comprehensive warranty for 3 years on the system and followed by 2 years of free servicing.
9.2	The warranty starts from the day of complete satisfactory of installation of equipment.
10	**MAINTENANCE DURING SERVICE PERIOD**
10.1	During warranty period supplier must ensure corrective/breakdown maintenance whenever required.
10.2	Four preventive maintenances shall be performed annually through out warranty period.
10.3	95% uptime shall be guaranteed.
11	**GUARANTEE**
11.1	The bidder must ensure the service and complete spare parts support for 10 years of the system, including accessories.
12	**MAINTENANCE CONTRACT PROPOSAL**
12.1	A written document for AMC (Annual Maintenance Contract) and CMC (Comprehensive Maintenance Contract) to be submitted separately. (Mandatory)
13	**INSTALLATION, INSPECTION, COMMISSIONING**
13.1	The bidder must arrange for the equipment to be installed and commissioned by certified or qualified personnel; any prerequisites for installation to be communicated to the purchaser in advance, in detail
13.2	Inspections to verify the compliance of the offered equipment as per specifications will be conducted by the technical team appointed by the Hospital.

13.3	The job description of Hospital technical team and Company Service Engineer shall be clearly spelt out. Shall provide routine check manufacturer checklist. (Mandatory)
14	**DOCUMENTATION**
14.1	User manual in English both printed form and CD. (mandatory)
14.2	Service (Technician/Maintenance) manual in English both printed form and CD. (mandatory)
14.3	Certificate of calibration and inspection from the factory. (mandatory)
14.4	Please provide a complete list of Spare parts and Accessories, along with cost and part numbers to be used with the system applicable for 2 years after expiration of comprehensive warranty. (mandatory)
14.5	Bidders shall mention model number and provide availability chart or Yes/No chart and highlight mentioning page no. with original catalogue having specification as provided by the manufacturing company. Photocopy, Scan copy or self-made specification will not be accepted.
14.6	Company must mandatorily (compulsorily) provide Authorization letter from parent (Origin) company to prove that they have been legally authorized for dealership (Sales/ Service) of that particular equipment in Nepal.
NOTE: Bidder must completely fill the Technical Specification Form (TSF). Only Yes/no/all complies should not be written. Page number in the catalogue of all the required parameters must be clearly mentioned and highlighted. Failure in doing so shall lead to rejection of bid from technical committee.	

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