Department of Health
Central Luzon Center for Health Development
MARIVELES MENTAL WELLNESS AND GENERAL HOSPITAL
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ITEM NO. 270

TERMS OF REFERENCE

Unit Cost: P132,000.00

Name of Project

Supply, Delivery, Testing and Commissioning of Brand New
ELECTROCARDIOGRAM MACHINE
(Public Bidding)

Technical Specification

Features:

- Ultra- Compact and lightweight design, high- resolution color touch screen, comprehensive filters and anti-noise technology
- Provide reliable signal quality
- 12-lead simultaneous acquisition and display, 3 channels with analyzer-signal quality identification
- long time sampling

Minimum Specifications:

ECG Sampling Rate: at least 1000 samples/sec/channel
Pacer detection sampling rate: at least 16,000 samples/second/channel
ECG amplifier: DC-coupled
Acquisition mode: Pre- or post-acquisition, provide 10 seconds of instantaneous ECG acquisition
Dynamic range: AC differential ±10 mV, DC offset ±600 mV
Resolution: at least 1 µV/LSB
Frequency response: –3 dB @ 0.05 to 150 Hz
Baseline drift filter: 0.05 Hz, with Baseline Drift Removal (BDR)
Artifact filter: at least 20 Hz, 35 Hz
AC filter: 50/60 Hz
Common mode rejection ratio: ≥110 dB (with AC filter switched off)
ADC: 24 bits
Input impedance: >50 MΩ @ 10 Hz, and must be defibrillator protected
Time Constant ≥3.2 s
Noise Level ≤15 µV
Patient leakage: <10 µA
Heart rate meter: 30 to 300 BPM ±10% or ±5 BPM, whichever is greater
Sensitivity/gain: at least 2.5, 5, 10, 20, L=10 C=5, L=20 C=10 mm/mV, and Auto

Display Type: TFT LCD with LED graphics and must be touchscreen
Display Data: at least with Patient ID, Patient name, gender, age, heart rate, clock, battery power indicator, waveforms, lead labels, speed, gain, filter settings, warning messages, information messages, network, USB status

Can be powered by AC and/or Battery
Battery must be at least Li-ion with 4500mAh
Charging time must be at least less than or equal to 6 hours or 7 hours
Battery capacity of more than 3hrs of continuous operation

Printer
Thermal dot array or better
Writer speed: at least 5, 12.5, 25, 50 mm/s
Number of traces: 12 leads
Writer speed accuracy: +-5%
Writer amplitude accuracy: +-5%

Writer resolution: Horizontal 40 dots/mm @ 25 mm/s, Vertical 8 dots/mm

Measurement and interpretation: Automated 12-lead ECG analysis program for adults and pediatrics
Resting ECG mode: Records and prints 12-lead resting ECG with 10-second duration as a standard feature
Internal storage: 800 ECGs in internal memory

Equipped with Wifi
Equipped with Barcode Scanner
With USB flash drive storage

Standard Accessories:

- ECG Cable (Anatomical Design)
- Adult Precordial suction electrodes (6 pcs/ set, match to 4mm ECG cable)
- Adult Limb Clamp electrodes (4 pcs/ set, match to 4mm ECG cable)
- Recording Paper (Roll, 80mm x 20mm at least)
- Power Cord (at least Philippine Standard)
- Charger

Documentary Requirements

1. Product brochure or technical data sheet(s) of the equipment showing the technical specification in English language.

2. Valid and current Certificate of Compliance of manufacturer of the equipment with the latest version of ISO 13485: Quality Management System – Requirements for regulatory purposes in the name of the **manufacturer.** The Certificates must be issued by an independent Certifying Body/Agency.

3. Valid and current Certificate of Compliance and/or Test Report on the latest version of IEC 60101-2-27. The Certificate and/or Test Report must be issued by an independent Certifying Agency

4. Valid Certificate of Distribution (as Authorized Distributor) issued by the Manufacturer of each equipment authorizing the bidder to sell/distribute the offered equipment.

5. Proof (such as sales invoice) that the Brand of the equipment has been sold to other health facilities in the Philippines.

6. Notarized Certificate from the bidder:
   a) That the brand of the equipment has been in the local and/or international market for at least five (5) years.

   b) That the equipment and its accessories are brand new, unused, not discontinued models and were not subjected to any product recall.

   c) Bidder's valid and current License to Operate (LTO) as medical device distributor issued by the Philippine Food and Drug Administration. In case of expired LTO, the following must be submitted:
   i. Copy of expired LTO
   ii. Application for renewal
   iii. Official Receipt as proof of payment for the renewal of LTO

7. Calibration certificate of the equipment from the manufacturer.

Requirements if awarded the Contract

1. **Completion period:** The delivery, testing and commissioning of the equipment and its accessories, including the training of end-user and maintenance staff must be completed within **45 calendar days** upon receipt of the Purchase order.

2. **Testing:** Prior to acceptance, the end user shall conduct a physical inspection and functionality test. The equipment must be functioning and must have no physical damage and defect.

3. **Training:** The supplier shall provide a training on proper use and maintenance of the equipment to the end-users and to the hospital maintenance staff.

4. **Warranty:** Warranty certificate for two (2) years on parts and on services. The supplier shall either repair or replace any item or part in the equipment that is found to be defective in material or in workmanship under normal use. The warranty period shall commence from the date of acceptance by the end-user after testing and commissioning.

5. The supplier must be amenable to customize the required power supply of the equipment to the necessary electrical requirements needed for the operation of the equipment in the hospital

6. Notarized undertaking that the supplier shall conduct the necessary corrective maintenance within five (5) calendar days upon notification of equipment breakdown from the end-user. The undertaking shall include a statement that the number of days where the equipment is unusable due to defective material or workmanship, shall be added to warranty period.

7. Notarized undertaking that the supplier shall provide free quarterly preventive maintenance and calibration service of the equipment for at least one (1) year.

8. **Manuals:** The supplier provide the end-user one (1) hard and one (1) soft copy of the following:
   a. Service manual in English language
   b. Operations manual in English language

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