TERMS OF REFERENCE

(MEDICAL EQUIPMENT)

ITEM FOR PROCUREMENT: Fetal and Maternal Tocomonitor
QUANTITY: 4 sets
APPROVED BUDGET FOR CONTRACT: 1.4M

SPECIFICATION		REMARKS
PURPOSE OF USE *Indicate the clinical or other purpose of utilization of the device; if relevant indicate area and level of use.*	Provide solutions for all areas of fetal monitoring, ranging from antepartum, intrapartum, and postpartum clinical applications. With integrated monitoring of twins' Fetal heart rate, uterine activity, fetal movement, intrauterine pressure and direct ECG as well as maternal NIBP, SpO2, ECG and Temperature. It offers cost effective and flexible solution for all fetal monitoring needs, without compromising quality, precision, performance and ergonomics.	
TECHNICAL DESCRIPTION *Indicate the detailed characteristics and specific functional requirements* (modules, components, parameters, values, ranges, compatibility), *display parameters and format (*display of pressure, volume, flow, status indicator, digital, trends, etc.) *and user adjustable settings* (parameters, alarm, language that can be adjusted at the discretion of user)	**1.) DISPLAY MONITOR** **Display Mode:** White background, Transmissive The background pane bar supports two standards: 30 ~ 240 (American standard) and 50 ~ 210 (International standard). During monitoring or reviewing, the trace window displays four traces: FHR1 trace, FHR2 trace (dual configuration), AFM trace and TOCO trace. **FHR1/FHR2 trace** The y-axis of the trace indicates the numerics of FHR. The range is 30 bpm ~ 240 bpm (American standard) or 50 bpm ~ 210 bpm (International standard). **AFM trace** The y-axis indicates the scope of fetal movement. **NOTE:**	

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	The AFM trace is only for reference, please take the MFM marks as criterion. **TOCO trace** The y-axis indicates the numeric of TOCO. The range is 0% ~ 100%. **2.) Anti-electric Shock Type** Degree of Protection against Harmful Ingress of Water: Ordinary equipment (sealed equipment without liquid proof) Degree of Safety in Presence of Flammable Gases Main Unit: Ordinary equipment (sealed equipment without liquid proof) US/TOCO Transducers: IPX8 Other Accessories: No liquid ingress protection **3.) Recorder Specifications** Z-fold, thermosensitive; With 1 cm/min, 2 cm/min, 3 cm/min printing speed Up to 25mm/sec; 8 dots/mm **4.) Printer** Print head: at least 128mm thick film Resolution: 8 dots per mm (standard) Printer speeds: 1,2, or 3cm per minute (user selectable) Fast forward: 10 cm/minute FHR scales: 30-240 bpm or 50-210 bpm (user selectable) Annotation: Hospital name, time, date, paper speed, monitoring modes, signal loss High speed: Review and print catch-up at up to 20 cm/minute	
PHYSCIAL DESCRIPTION *Indicate dimension, configuration for complex equipment, mobility, portability,*	**Monitor** Dimensions and Weight	

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weight, handles, wheels, raw material, bio-compatibility, corrosion resistance etc.	At least 12 inches monitor 5.3 kg to 6.1 kg This is intended for use in the electromagnetic environment: **Conducted RF IEC 61000-4-6 with 3 Vrms compliance level,** over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.	
UTILITY REQUIREMENTS *Indicate needed electrical supply (voltage, frequency, permitted fluctuation, battery operation) water and gas supply; quality and flow rate requirements*	**Power Supply** Operating Voltage: 100V-240V~ Operating Frequency: 0Hz/60Hz Input Power : 100- 240VA Battery: 14.8V/4400mAh Rechargeable Lithium-ion The recommended **charge temperature** range is from 0C (+32F) to +40C (+104F).	
ACCESSORIES, CONSUMABLES, SPARE PARTS, OTHER COMPONENT *Indicate needed accessories for full/ proper functioning of device (*quantity, type, number, functional requirements etc), *sterilization, consumables, spare parts, other components* (printer, stands, mounting etc.)	**1. ACCESSORIES** a) Ultrasound (US) Transducers -with sensor, cable and connector -for singleton and multifetal pregnancies b) TOCO Transducers -with sensor, cable and connector c) Belt d) Remote Event Marker e) Fetal Stimulator -hand-held device. In order to reduce the time required for the NST when the fetus is asleep, it can be used to give a mild vibrating stimulation to the fetus through the maternal abdomen. -During NST, the vibrating operation marks can be displayed /printed on CTG trace when	

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	the fetal stimulator is connected to the monitor by an audio cable. f) DECG Cable g) Fetal Spiral Electrode h) IUP Cable and catheter i) ECG Cable j) SpO2 and Temperature Transducer k) NIBP Cuff **2. CONSUMABLES** - Paper: GSM 80- 120 Paper thickness: 2- 4mm Length: at least 45m	
ENVIRONMENTAL REQUIREMENTS *Indicate storage and operating temperature, resistance to humidity etc.*	**WORKING** Temperature: +5C ~ + 40C (+41F ~ +104F) Relative Humidity: 25% ~ 80% (non-condensing) Atmospheric Pressure: 860hPa ~ 1060hPa **TRANSPORT AND STORAGE** Temperature: -20C ~ +55C (-4F ~ +131F) Relative Humidity: 25% ~ 93% (non-condensing) Atmospheric Pressure: 700hPa ~ 1060hPa	
DELIVERY *Indicate the when equipment is needed.*	30 – 60 days upon receipt of P.O.	
TRAINING, INSTALLATION & UTILIZATION *Indicate pre installation requirements is any (construction, structural changes, utility, etc.), safety & operation check before handover, end user's training in operation, basic maintenance, user care*	1. **Completion period:** The delivery, installation, testing and commissioning of the equipment and its accessories, including the training of end-users and maintenance staff must be completed within 15 **calendar days** upon delivery. 2. **Testing:** Prior to acceptance, the end user shall conduct a physical inspection and functionality test. The	

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	equipment must be functioning and must have no physical damage and defect. 3. Training: The supplier shall provide a training on the proper use and maintenance of the equipment to the end-users and to the hospital maintenance staff.	
WARRANTY *Indicate warranty period, exclusion, inclusions and other conditions of warranty, preventive maintenance and calibration schedule, software & hardware upgrade availability, spare parts availability post warranty*	1. **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 the date of acceptance by the end-user after testing and commissioning. *Preventive Maintenance/Calibration schedule within the warranty period. 2. Supplier shall conduct the necessary corrective maintenance within five (5) calendar days upon notification of equipment breakdown from the end-user. A service unit will be provided during corrective maintenance. 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 the warranty period.	
DOCUMENTATION *Indicate manuals, brochures, and certifications needed*	**DOCUMENTARY REQUIREMENTS** 1. Product brochure or technical data sheet(s) of the equipment showing the technical specifications in English language 2. Valid Marketing Authorization, Registration Approval or Free Sale Certificate for each equipment issued by the Health Authority in the country country of origin. 3. Valid Certificate of Distributorship (as first Tier Distributor) issued by the Manufacturer of each equipment authorizing the bidder to sell/distribute the offered equipment.	

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	4. List and address of the equipment Manufacturer's branch office, sales office and/or distributor's office. 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 ten (10) years. b. That the equipment and its accessories are brand new, unused, not discounted models and were not subjected to any product recall. 7. Bidder's valid and current License to Operate (LTO) as a 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. 8. **Manuals:** The supplier must provide the end-user ne (1) hard and one (1) soft copy of the following: a. Service manual in English language b. Operations manual in English language	
SAFETY & STANDARD *Indicate international standard & regulatory approval needed*	9. Valid and current Certificate of Compliance of manufacturer of the equipment with the latest version of the 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. 10. Valid and current Certificate of Compliance and/or Test Report on the latest version of IEC 60601-2-	

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	27 Particular requirements for the basic safety and essential performance of electrocardiographic Monitoring equipment. The Certificate and/or Test Report must be issued by an independent Certifying Agency.	

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