Republic of the Philippines
Department of Health
METRO MANILA CENTER FOR HEALTH DEVELOPMENT

SUPPLEMENTAL/ BID BULLETIN NO. 1

IB 2022 – 078E
IB 2022-078E PROCUREMENT OF 1 UNIT NEWBORN HEARING SCREENING MACHINE (REBID)

This Supplemental/Bid Bulletin No. 1 is being issued to revise provisions/specifications in the Bidding Documents for a forecited project:

Revision and clarification to provisions/specifications in the Bidding Documents:
*No changes as stipulated in the technical specifications

Bidders are advised to use the following attached forms and submit together with all required documents for the submission of bids on 23rd day of May 2022, 9:00 AM:

This Supplemental/Bid Bulletin No. 1 shall form an integral part of the Bidding Documents. All other provisions indicated in the bidding documents which are not affected by this Supplemental/Bid Bulletin No. 1 shall remain in effect.

For guidance and information of all concerned.

Issued this 30th day of May 2022 in MMCHD

Approved by:

ALELI ANNIE GRACE P. SUDIACAL, MD, MPH
Director III / BAC Chairperson

Republic of the Philippines
Department of Health
METRO MANILA CENTER FOR HEALTH DEVELOPMENT

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TECHNICAL SPECIFICATIONS

Item No. **1**	**NEWBORN HEARING SCREENING MACHINE**	Qty./Unit	**1 Unit**
Name of Manufacturer:			Country of Origin
Brand:			Model: (if applicable)
ABC: **600,000.00**			

PURCHASER'S SPECIFICATION	STATEMENT OF COMPLIANCE
A. Technical Specifications: • Includes: Audiometer, Auto acoustic Emission Machine and Tympanometer a) Audio meter Capable of screening and diagnostic Capable of air and bone conduction and masking Capable of pure tone audiometry Capable of being upgraded to high frequency, speech and play audiometry Capable of storing up to 1000 tests Capable of giving detailed test results and history Must be colored touchscreen operated Must be with interchangeable transducers Frequency range of 125Hz to 16Hz b) Auto Acoustic Emission Machine Capable of screening and diagnostic Capable of storing up to 1000 tests Must be interchangeable OAE probe Must be with distortion Auto acoustic quick and diagnostic emission sets Capable of cartoon mode that can yield more than 12 frequencies Must be with second probe for simultaneous testing of both ears Capable of DP Threshold estimation with label Minimum operating hours of battery must not be less than 10 hours Must be with instrument charger, accessory box and carrying bag c) Tympanometer	

Must be colored touchscreen and menu guided Capable of giving detailed test results and history Capable of storing up to 1000 tests Must be with data and patient management software Must be with USB port for data communication Must be with Interchangeable transducers Must be with TEOAE, DPOAE, automated audiograms based on DP threshold Must be with calibration cavities Must be with at least one (1) tympanic probe Must be with at least one (1) mono headset DD45 Multi-frequency Tympanometry (4 tones or 2 tones at once) 1000 Hz tone Pressure range of -300 to 300 daPa Must be with 5 individually configurable presents Capable of tymp + reflex automatic sequence Must be with automatic reflex threshold Reflex 500, 1000, 2000, 3000, 4000 Hz stimulus up to 100 dB HL Broadband, high and low pass noise stimulus up to 90 dB HL	
B. <u>DOCUMENTARY REQUIREMENTS:</u> 1. Product brochure or technical data sheet(s) of the equipment showing the technical specifications 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 Certificate of Distributorship (as first Tier Distributor) issued by the Manufacturer of each equipment authorizing the bidder to sell/distribute the offered equipment. 4. Proof (such as sales invoice) that the Brand of the equipment has been sold to other health facilities in the Philippines. 5. Notarized Certificate of 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 discontinued models and were not subjected to any product recall.	

6. 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.	
C. REQUIREMENTS IF AWARDED THE CONTRACT: 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 **30** calendar days upon receipt of Notice to Proceed. 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 the proper use and maintenance of the equipment to the end-users and to the hospital maintenance staff within 3 days upon delivery of the equipment 4. **Warranty**: Warranty certificate for two (2) years on parts and service. 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. Notarized undertaking that the supplier shall conduct the necessary corrective maintenance within five (5) calendar days upon notification of the 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 the warranty period. 6. **Manuals**: The supplier must provide the end-user one (1) hard and one (1) soft copy of the following: a) Service manual in English language b) Operation manual in English language 7. With "**DOH-MMCHD HFEP**"(Government Property not for sale) sticker in each unit.	
D. Additional Requirement to be submitted by the Single/Lowest Calculated Bidder (SCB/LCB) as part of post qualification: 1. One (1) original sample of manufacturer's product to be submitted and returned after evaluation. The sample submitted and approved during the evaluation shall be the same item to be delivered upon award of contract. Prototype of the labelling instruction must be part of the sample submitted however, the technical specifications of the labelling instruction of the product must be complied upon delivery	