SUPPLEMENTAL BID BULLETIN

ADDENDUM NO. 1

PUBLIC BIDDING FOR THE SUPPLY, DELIVERY, INSTALLATION, TESTING AND COMMISSIONING OF BRAND-NEW REPETITIVE TRANSCRANIAL MAGNETIC STIMULATOR WITH 2 CHANNEL EMG FOR AUTOMATIC MOTOR THRESHOLD DETERMINATION FOR THE USE OF AGED AND WELLNESS UNIT

This Supplemental Bid Bulletin No. **1** dated **May 22, 2024** is issued to clarify, modify or amend items in the Bid Documents. This shall form an integral part of the Bid Documents.

A. Amendments / Clarifications:

FROM	TO
Under Section VI: Schedule of Requirements / Section VII: Technical Specifications / List of Items **On Delivery Period:** a. One time delivery within **30 calendar days upon receipt of Notice to Deliver.**	**Under Section VI: Schedule of Requirements / Section VII: Technical Specifications / List of Items** **On Delivery Period:** a. One time delivery within ***90 calendar days upon receipt of Notice to Deliver.***
ON LIST OF ITEMS / TECHNICAL SPECIFICATIONS **Under Item No 1. Supply, Delivery, Installation, Testing and Commissioning of a Brand-New Repetitive Transcranial Magnetic Stimulator with 2 Channel EMG for Automatic Motor Threshold Determination for the use of Aged and Wellness Unit CY 2024** **SPECIFICATIONS:** **D. Cooled Coils** Stimulation mode: • single pulse • train • burst • ramp • sweep frequency ***Request to amend to:*** ➢ *"Stimulation mode: single pulse / train / burst / ramp / sweep frequency"*	**ON LIST OF ITEMS / TECHNICAL SPECIFICATIONS** **Under Item No 1. Supply, Delivery, Installation, Testing and Commissioning of a Brand-New Repetitive Transcranial Magnetic Stimulator with 2 Channel EMG for Automatic Motor Threshold Determination for the use of Aged and Wellness Unit CY 2024** **SPECIFICATIONS:** **D. Cooled Coils** Stimulation mode: • single pulse • train • burst • ramp • sweep frequency ***Answer:*** ➢ *"Retain the original specification."*

"There is no Health without Mental Health"

Maximum Frequency: 100 Hz ***Request to be amended to:*** ➢ *"Maximum Frequency: 30-60 HZ"* *Justification:* *"The latest protocol approved by the US FDA is Thetaburst with frequency of 50 Hz. Incorporating more than 60Hz in the system may cause human error to select more than what is approved by International Approving bodies."*	Maximum Frequency: 100 Hz ***Answer:*** ➢ *"Retain the original specification since there are other protocols which need a higher level of frequency such as stroke patients, schizophrenia, Late Stage Demenia, and among others ."*
a. Stimulator units – IP20 ***Request to be amended to:*** ➢ *"a. Stimulator Units: IP20, IPX0 or according to manufacturer's specifications."* *Justification:* ➢ *"Magventure's Stimulator Units are US FDA cleared with CE Mark. They passed majority of regulatory bodies worldwide. IP grade is not pat of any evaluation process."*	a. Stimulator units – IP20, ***IPX0 or according to manufacturer's specifications.***
Cooling Agent Pressure limit in coil while operating: ≤ 0.35 MPa (Megapascal) ***Request to be amended to:*** ➢ *"Cooling Agent Pressure limit in coil while operating:* *≤ 0.35 MPa (Megapascal)* ***or According to Manufacturer's Specification"*** *Justification:* ➢ *"Our system does not measure the pressure limit of its cooling agent. It works by determining the actual coil temperature for a more comprehensive and safer working condition."*	Cooling Agent Pressure limit in coil while operating: ≤ 0.35 MPa (Megapascal) ***Answer:*** ➢ *"Retain the original specification. Providing a pressure limit will ensure safety and efficiency of the cooling units to be used in stimulating patients. This is a relevant safety feature of the system to enable the use of the system to multiple patients per day."*
Type of cooling agent: Silicone oil ***Request to be amended to:*** ➢ *"Type of cooling agent: Silicone oil* ***or unique liquid-based oil"***	Type of cooling agent: Silicone oil ***or unique liquid-based oil***

Coil surface temperature enabling automatic stimulation stop at (39+/-2) °C ***Request to be amended to:***	Coil surface temperature enabling automatic stimulation stop at (39+/-2) °C ***Answer:***
➢ *"Coil surface temperature enabling automatic stimulation stop according to manufacturer's specification"* *Justification:* ➢ *"To ensure better and safer working environment, our system has better coil design with a better temperature threshold which will automatically be disabled when the temperature exceeds 43°C (109°F) or between 44°C (111°F) for more than 10 minutes. Other system's coil melt down at 40°C or higher. Furthermore, as an extra precaution, there is implemented an ITP algorithm (ITP -Intelligent Temperature Prediction) that predicts the temperature of the coil even faster than the temperature sensor placed in the coil."*	➢ *"Retain the original specification. This specification is important to avoid overheating and causing unsafe stimulation to patients. The limit is around 39-41 Celsius, since it is suitable here in the Philippines."*
Intensity in % of MT: 0-150% ***Request to be amended to:*** ➢ *"Intensity in % of MT: 0-150%* ***or manufacturer's specifications"*** ➢ *"Intensity in % of MT: 0-120%"* *Justification:* ➢ *"As per US FDA Clearance and CE approval, 120% of MT is recommended. More than that may risk safety of the patient undergoing the approved protocol."*	Intensity in % of MT: 0-150% ***Answer:*** ➢ *"Retain the original specification. The MT percentage limit differs for other patients. Since some threshold can be around 20-50% only allowing around 130% intensity of MT %. This will help us accommodate other patients with smaller cortical excitability."*
Without extra power unit: At least 5Hz ***Request to be amended to:*** ➢ "Extra power unit is mandatory" *Justification:* ➢ *"The Isolation Transformer reduces leakage current and is able to distribute power for stimulators and auxiliary devices such as the Coil Cooler unit, Treatment Chair and Vacuum Pump. This is a mandatory requirement to*	Without extra power unit: At least 5Hz ***Answer:*** ➢ *"Retain the original specification. "Extra power unit" may be interpreted differently as a power supply similar to UPS which is a different type of hardware. The extra power supply mentioned in the specification is required for achieving 100 Hz of stimulation rate that allows us to maximize the machine for other protocols."*

comply with the leakage current requirements according to IEC 60601-1."	
With extra power supply unit: At least 20Hz ***Request to be amended to:*** ➢ *"With extra power supply unit: complies with 60601-1"* *Justification:* ➢ *"The Isolation Transformer reduces leakage current and is able to distribute power for stimulators and auxiliary devices such as the Coil Cooler unit, Treatment Chair and Vacuum Pump. This is a mandatory requirement to comply with the leakage current requirements according to IEC 60601-1."*	With extra power supply unit: At least 20Hz ***Answer:*** ➢ *"Retain the original specification. "Extra power unit" may be interpreted differently as a power supply similar to UPS which is a different type of hardware. The extra power supply mentioned in the specification is required for achieving 100 Hz of stimulation rate that allows us to maximize the machine for other protocols."*
Number of Pulses: At least 10,000 ***Request to be amended to:*** ➢ *"Number of Pulses: At least 3,000 to 10,000 per session or manufacturer's specifications"* ➢ *"Number of Pulses: According to Protocol"* *Justification:* ➢ *"As per US FDA clearance for the standard depression protocol (19-37.5 min), the approved number of pulses per session is 3000, for the Theta Burst Stimulation (3 min and 9 sec), the approved number of pulses per session is only 600 while for the treatment of OCD, the number of pulses is 2000."*	Number of Pulses: At least 10,000 ***Answer:*** ➢ *"Retain the original specification. This shouldn't be changed to ensure that the TMS equipment can accommodate a higher volume of patients with numerous sessions per day which will be beneficial to the institution.* *The range includes all the capacity of most TMS machines with good quality and updated systems."*
Temperature: +5 till +40°C ***Request to be amended to:*** ➢ *"Temperature: +5 till +35°C or manufacturer's specifications"*	Temperature: +5 till +40°C ***Answer:*** ➢ *"Retain the original specification. Be specific on the manufacturer's specifications."*
Humidity: 30-85% ***Request to be amended to:*** ➢ *"Humidity: from 10 to 80% or manufacturer's specifications"*	Humidity: **20**-85%

➢ *"Humidity: 20-80% or according to manufacturer's specification"* *Justification:* ➢ *"The machine should be well kept with a controlled temperature and humidity."*	
Dimension & Weight: At least 92 x 167 x 46 mm & not more than 0.35kg ***Request to be amended to:*** ➢ *"Dimension & Weight: At least 49x16x38cm & at least 0.35-15kg or manufacturer's specifications"* ➢ *"Dimension & Weight (EMG): according to manufacturer's specifications"* *Justification:* ➢ *"Functionality of the EMG system does not rely on its amplifier dimensions."*	Dimension & Weight: ***according to manufacturer's specifications***
Inclusions: Number of pulses: - Figure-of-eight coil- up to 10,000 pulses ***Request to be amended to:*** ➢ *"Figure-of-eight coil-up to at least 3,000 to 10,000 pulses or manufacturer's specifications"*	**Inclusions:** Number of pulses: - Figure-of-eight coil- up to 10,000 pulses ***Answer:*** ➢ *"Retain the original specification. Be specific on the manufacturer's specifications."*
STANDARD REQUIREMENTS: 9. Authenticated by the Philippine Consulate from the Country of Origin for Certification from the Manufacturer that the unit warranty should not be affected by change of distributorship. ***Request to be amended to:*** ➢ *"With notarized letter of undertaking from the local distributor that the unit warranty should not be affected by change of distributorship."* ➢ *"Local Notary Public can be applied in replacement for the authentication from the Philippine consulate."*	STANDARD REQUIREMENTS: 9. Authenticated by the Philippine Consulate from the Country of Origin for Certification from the Manufacturer that the unit warranty should not be affected by change of distributorship. ***Answer:*** ➢ *"Accepted. Because of the time frame allotted for procurement of the TMS, a certification from a Local Notary Public may suffice."*

Justification: ➢ *"Since the process will take some time to release and the schedules might not meet the specific time frame for this project. And also, the cost will be high for this."*	
Post-qualification demo ***Request:*** ➢ *"To conduct a virtual demo of the machine"* *Justification:* ➢ *"Since the virtual demo is a real-time demo where the end-users and TWG members can observe the machine virtually. The model required for this project is a more advanced model than what we usually provide that's why some of the features are not part of our demo unit."*	Post-qualification demo ***Answer:*** ➢ *"Accepted since most of the TMS machine will be coming from different countries, a recorded promotional video of the actual machine including, but not limited to its specifications and its essential features can be provided. An actual demo of the machine will be required once the machine is available."*
ON SECTION III: BID DATA SHEET **Under ITB Clause No. 20.2** h. The bidder must provide the current and valid certificate of Authorized of Exclusive or Distributorship i. The bidder must provide the current and valid certificate of Manufacturer's compliance with ISO 13485 j. The bidder/supplier shall secure a certificate from manufacturer stating that the equipment is brand new and unused. k. Bidder's certificate guaranteeing the availability on the supply of spare parts five (5) years from end of production. A certificate must be issued by the manufactured for the bidder. l. Certification that the bidder must be in the business in the local market for a minimum of five (5) years. m. Certification that the system or machine is not a retrofit solution. n. The winning bidder shall provide current and valid calibration certificate for each equipment during delivery.	**ON SECTION III: BID DATA SHEET** **Under ITB Clause No. 20.2** h. ***Notarized*** current and valid certificate of Authorized or Exclusive of Distributorship i. ***Notarized / CTC*** current and valid certificate of Manufacturer's compliance with ISO 13485 j. ***Notarized*** certificate from manufacturer stating that the equipment is brand new and unused. k. ***Notarized*** bidder's certificate guaranteeing the availability on the supply of spare parts five (5) years from end of production. A certificate must be issued by the manufactured for the bidder. l. ***Notarized*** certification that the bidder must be in the business in the local market for a minimum of five (5) years. m. ***Notarized*** certification that the system or machine is not a retrofit solution. n. ***Notarized*** ~~current and valid calibration certificate for each equipment during delivery~~. ***(Note: The document will not be required during post-qualification but will be required during delivery.)***

o. Certification that the supplier has the capability or authority for corrective and preventive maintenance of the unit. The certificate must be affected by the manufacturer to the bidder.	o. ***Notarized*** certification that the supplier has the capability or authority for corrective and preventive maintenance of the unit. The certificate must be affected by the manufacturer to the bidder.
p. Certification from the manufacturer authenticated by the Philippine consulate from the country of origin of the unit that the warranty should not be affected with a change of distributor.	p. ***Notarized*** certification from the manufacturer authenticated by the Philippine consulate from the country of origin of the unit that the warranty should not be affected with a change of distributor. ***(Local Notary Public can be applied in replacement for the authentication from the Philippine consulate.)***
q. Warranty certification; Certification that the bidder/supplier shall provide a five (5) years warranty for parts and services that include corrective maintenance, preventive maintenance, and/or calibration. The warranty shall commence upon the acceptance of the end user. r. Bidder must provide preventive maintenance and/or calibration schedule within warranty period.	q. Warranty certification: ***Notarized*** certification that the bidder/supplier shall provide a five (5) years warranty for parts and services that include corrective maintenance, preventive maintenance, and/or calibration. The warranty shall commence upon the acceptance of the end user. ~~r. Bidder must provide preventive maintenance and/or calibration schedule within warranty period.~~ ***(Note: The document will not be required during post-qualification but will be required during delivery.)***
s. Certification that the supplier/bidder shall provide applications training and certification for end users and maintenance personnel of the hospital. t. Certification to provide Manuals: Two (2) sets of Service Manual in English Language and Two (2) sets of User Manual in English Language upon delivery of the equipment.	s. ***Notarized*** certification that the supplier/bidder shall provide applications training and certification for end users and maintenance personnel of the hospital. t. ***Notarized / CTC*** certification to provide Manuals: Two (2) sets of Service Manual in English Language and Two (2) sets of User Manual in English Language upon delivery of the equipment.

Other Matters:

A. Bid Security shall be 120 calendar days from the date of submission and opening of bids.

B. Section VII: Technical Specifications - Please write "COMPLY" to indicate that requirements are met.

C. Eligibility requirements and technical proposal should be in one folder and financial proposal in a separate folder, with shoelace on top instead of fastener, table of contents and index tabs in words, not numbers.

D. Folder of Eligibility requirements and technical proposal should be placed in one envelope. And folder of Financial proposal should be in another envelope. Both envelopes shall then be placed in one mother envelope marked as **"Original Bid"**

E. For the Lowest Calculated Bidder, as part of Post Qualification process, equipment demonstration or site installation visit is required.

F. Documents should be arranged chronologically according to the checklist issued.

G. Color code for folders and envelope: **GREEN**

H. Typographical error must be counter signed by the authorized representative.

I. All other provisions on the bidding documents which are not affected shall remain in effect.

J. The deadline for **Submission and Opening of Bids** is scheduled on **May 29, 2024, 9:00 AM**, at the **BAC Conference Room**, National Center for Mental Health Compound, Mandaluyong City.

K. Any bid submitted after the deadline for submission shall be declared **"LATE"** and shall NOT be accepted.

L. The BAC shall open the bids immediately after the deadline for submission and receipt of bids.

For the information and guidance of all concerned.

ALDEN C. CUYOS, MD, FPPA, IFAPA
Chairperson, BAC for Equipment CY 2024