



REPUBLIC OF THE PHILIPPINES  
Department of Health  
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**Section VI**

**Schedule of Requirements**

PUBLIC BIDDING FOR THE SUPPLY, DELIVERY, INSTALLATION, TESTING AND  
COMMISSIONING OF BRAND-NEW POLYSOMNOGRAPHY MACHINE FOR SLEEP  
CLINIC CY 2024

IB No. E-009-2024-PB

The delivery schedule expressed as weeks/months stipulates hereafter a delivery date which is the date of delivery to the project site.

Item No.	Description	Qty	Delivery Site			Delivery Period and Terms of Payment
			OFFICE	FACILITY	ADDRESS	
1	<p><b>Supply, Delivery, Installation, Testing and Commissioning of a Brand-New Polysomnography Machine for Sleep Clinic CY 2024</b></p> <p><b>GENERAL SPECIFICATIONS:</b></p> <p>1) Designed for the acquisition of EEG and Polysomnography (PSG) data</p> <p>2) Software allows recording, displaying, analysis, printing, and storage of physiological signals to assists in the diagnosis of various sleep disorders and sleep related respiratory disorders.</p> <p>3) Automated analysis of physiological signals.</p> <p>4) Audio/visual alert for user-defined threshold on calibrated DC input.</p> <p>5) Sleep report templates are provided that summarize the recorded and scored sleep data</p>	1	Sleep Clinic	Neurological Room, Pavilion 11	National Center for Mental Health	<p>a. One-time delivery within <b>thirty (30) calendar days</b> upon receipt of Notice to Deliver</p> <p>b. Terms of payment at least 30 days from receipt of Sales invoice</p>

	<p>ranges for trended values.</p> <p><b>AMPLIFIER SPECIFICATIONS:</b></p>									
	<ol style="list-style-type: none"> <li>1) AC Channels: 64 AC Channels</li> <li>2) Referential Inputs: 40 referential (additional 24 referential channels programmable to differential channels)</li> <li>3) Programmable up to 12 Differential inputs</li> <li>4) With 6 Sensor Inputs dedicated for chest effort, abdominal effort, snore, airflow, pressure, and position sensors</li> <li>5) With up to 11 derived traces</li> <li>6) DC Channels up to 16 channels</li> <li>7) With 8-bit TTL digital timer</li> <li>8) Pulse Oximetry monitoring includes SpO2, Pulse Rate, Photoplethysmogram (PPG), and Pulse Quality</li> <li>9) Input Impedance - Common Mode <math>\geq 1\text{ G}\Omega</math></li> <li>10) Input Impedance - Differential Mode: <math>40\text{ M}\Omega / 280\text{pF} \pm 20\%</math></li> <li>11) Input Noise - <math>\leq 2\text{ uV}</math> pk-to-pk (0.1Hz to 70 Hz), <math>\leq 40\text{nV}\sqrt{\text{Hz}}</math> wideband</li> <li>12) Common Mode Rejection Ratio (CMMR) <math>\geq 106\text{ dB}</math> min</li> <li>13) Sampling Rates - 256, 512, 1024, 2048, 4096</li> <li>14) Bandwidth - DC to <math>\sim 1/3</math> of sample rate selected or 1600 Hz max. programmable (default 0.08Hz)</li> <li>15) Input Signal Range - 20mV pk-to-pk, <math>\pm 0.3\text{VDC}</math></li> </ol> <p><b>HOST INTERFACE</b></p> <ol style="list-style-type: none"> <li>1) With network connection of Gigabit Ethernet DHCP</li> </ol>									

	<p>2) Direct Connection: USB 2.0 Hi-Speed, Gigabit Ethernet</p>								
	<p><b>ENVIRONMENTAL CONDITIONS</b></p> <p>Operating Environmental Limits</p> <ol style="list-style-type: none"> <li>1) Temperature: 10°C to 30°C (50°F to 86°F)</li> <li>2) Relative Humidity: 30%–75%</li> <li>3) Atmospheric Pressure: 70 kPa–106 kPa</li> </ol> <p><b>TRANSPORT AND STORAGE</b></p> <ol style="list-style-type: none"> <li>1) Temperature: -25°C to 60°C (-13°F to 140°F)</li> <li>2) Relative Humidity: 10%–95%</li> <li>3) Atmospheric Pressure - 50 kPa to 106 kPa</li> </ol> <p><b>AMPLIFIER AND BASE UNIT FEATURES AND USAGE</b></p> <ol style="list-style-type: none"> <li>1) Amplifier use a proprietary 3-dimensional body position pod to gather and generate position and activity data from the patient.</li> <li>2) The base unit provides a potential equalization conductor</li> <li>3) The amplifier has luer lock allows the connection of a cannula to allow recording of airflow via pressure sensor.</li> </ol> <p><b>SOFTWARE FEATURES</b></p> <ol style="list-style-type: none"> <li>1) Capable to determine which toolbars appear on screen</li> <li>2) Acquisition Mode must include the following (Montage, Note, Protocol, Video, Camera, Workflow, Stopwatch, Sleep Summary, Flow</li> </ol>								

	Volume Loop, Status Bar, Dock toolbars). Review mode must include the following (Montage, Note, Video, Review, Staging, Study, Sleep Summary, Flow Volume Loop, Status Bar, Dock Toolbars)					
	3) With Flow-Volume Loop Toolbar which displays exhaled flow plotted upwards and exhaled volume to the right.					
	4) With Stopwatch Toolbar which measures and displays elapsed time or event duration.					
	5) With Heads Up Display Toolbar used to display parameters recorded during collection or in review					
	6) With Frequency Tool used to display FFT information and data statistics in the frequency domain during review. The Spectrum graph and detail options are configurable and can be saved as an event for later review or copied to the clipboard as an image for insertion into another application.					
	7) Capable to create and/or edit montage (Montage Creation Tool)					
	8) With Montage Conversion Tool used to convert a montage originally created for one headbox to work with a different one (Import / Export).					
	9) With Sleep event analyzers designed to help medical professionals and technologists with the identification of events of interest in study recordings. These analyzers are set to					

	<p>factory default settings and can be customized.</p> <p>10) The following analyzers are available: aEEG, Amplitude,</p>									
	<p>Apnea, Arousal, Auto-Staging, Bradycardia, Breath Rate, Central Apnea, DSA, Data Trends, Heart Rate, Hypopnea, Limb Movement, Obstructive Apnea, Oxygen Desaturation, QEEG, Snoring, Stellate ICTA-D, Stellate ICTA-S, Tachycardia</p> <p><b>SAFETY STANDARD OF COMPLIANCE AND NORMATIVE REFERENCES (Certified True Copy)</b></p> <p>IEC 60601-1:2012 - General Safety Third Edition</p> <p>CAN / CSA-C22.2 No. 60601-1: 08(R2013) +C2:2011</p> <p>IEC 60601-1-6:2010 – Usability Third Edition</p> <p>IEC 62366:2007, Edition 1.0</p> <p>IEC 60601-2-26:2012 – Electroencephalographs Third Edition</p> <p>IEC60601-2-61:2011 - Pulse Oximeters</p> <p>EN ISO 80601-2-61:2011, Edition 1</p> <p><b>EMC STANDARD OF COMPLIANCE AND NORMATIVE REFERENCES (Certified True Copy)</b></p> <p>IEC 60601-1-2:2014 – EMC Fourth Edition</p> <p>IEC 61000-3-2:2014, Fourth Edition</p>									

<p>IEC 61000-3-2 Harmonic emissions – Class A</p> <p>IEC 61000-3-3:2013, Third Edition Voltage</p>									
<p>Fluctuations/ Flicker emissions</p> <p>CISPR11, Edition 5.0 A1:2010 RF emissions – Group 1, Class A</p> <p>IEC 61000-4-2:2008, Second Edition</p> <p>IEC 61000-4-2 Electrostatic Discharge (ESD) ±8 kV contact (to the patient lead and exposed metal), ±15 kV air</p> <p>IEC 61000-4-3 Third Edition with A1:2007+A2:2010</p> <p>IEC 61000-4-3, 3 Vrms, 80 MHz to 2.7 GHz</p> <p>IEC 61000-4-4:2012, Third Edition, fast transient/burst ±2 kV power supply ±1 kV</p> <p>IEC 61000-4-5:2014, Third Edition</p>									
<p>IEC 61000-4-5 ±1 kV Surge differential mode ±2 kV common mode</p> <p>IEC 61000-4-6 Second Edition with A1:2004 + A2:2006</p> <p>IEC 61000-4-6, 150 kHz to 80 MHz</p> <p>IEC 61000-4-8:2009, Second Edition</p> <p>IEC 61000-4-8, Power frequency (50/60 Hz) magnetic field, 30 A/m</p> <p><b>INCLUDED ACCESSORIES</b></p> <p>1) Base unit 2) Breakout Box 3) Breakout to Base Cable</p>									

	<p>4) Replacement Fuse for Base Unit</p> <p>5) USB-to-Ethernet Adaptor</p> <p>6) Quantum Nonin Oximeter Adapter Cable</p>							
	<p>7) Nonin Reusable Soft Sensor, Medium, model 8000SM</p> <p>8) Patient Event Button, 5ft (1.5m)</p> <p>9) Isolation Transformer</p> <p>10) Nasal Cannulas 72in (183cm)</p> <p>11) Airflow Thermistor 78in (198cm)</p> <p>12) Snoring Sensor 78in (198cm)</p> <p>13) Gold EEG Cup Electrodes 10MM, 1.5M, TP</p> <p>14) Body Positioning Pod</p> <p>15) Reusable Belt - Small Abdomen 78" cable length</p> <p>16) Reusable Belt - Small Thorax 78" cable length</p> <p>17) Reusable Belt - Medium Abdomen 78" cable length</p> <p>18) Reusable Belt - Medium Thorax 78" cable length</p> <p>19) Large Abdomen 78" cable length</p> <p>20) Large Thorax 78" cable length</p>							
	<p><b>STANDARD REQUIREMENTS</b></p> <p>1) CTC/Notarized certification of current and valid Authorized or Exclusive Distributorship.</p> <p>2) CTC/Notarized certificate of current and valid Manufacturer's compliance with ISO 13485.</p> <p>3) Notarized certification from the manufacturer stating that the equipment is brand new, unused and not a discontinued model or was listed in the market recall.</p>							

	<p>4) Notarized certificate guaranteeing the availability on the supply of spare parts ten</p>					
	<p>(10) years from end of production. A certification must be issued by the manufacturer for the bidder.</p> <p>5) Notarized certification that the bidder must be in the business in the local market for a minimum of five (5) years.</p> <p>6) Notarized certification that the system or machine is not a retrofit solution.</p> <p>7) Notarized Certificate of manufacturer's approved US FDA Premarket Notification (PMN) or CE Mark Approval.</p> <p>8) The winning bidder shall provide current and valid calibration certificate for the equipment during delivery.</p> <p>9) Notarized certification that the supplier has the capability or authority for corrective and preventive maintenance of the unit.</p>					
	<p>10) 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.</p> <p>11) Notarized certificate that the bidder/supplier shall provide a two (2) years warranty for parts and services that include corrective maintenance, preventive maintenance, and/or calibration. The warranty shall commence upon the</p>					



	acceptance of the end user.					
	12) Bidder must provide preventive maintenance and/or calibration schedule within the warranty period.					
	13) Notarized certification that the supplier/bidder shall provide applications training and certification for end users and maintenance personnel of the hospital.					
	14) CTC/Notarized 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.					
<b>CONFORME:</b>						
<i>(Company Name)</i>						
<i>(Name and Signature of Authorized Representative)</i>						