SPECIFICATIONS FOR

TENDER # 0171-0819

SUPPLY OF ONE COMBINATION EMG/NCS/EP AND EEG SYSTEM FOR WESTERN HEALTH

CLOSING DATE: **25 February 2008**

CLOSING TIME: **11:00 AM (Newfoundland Time)**

Invitation to Tender for One Combination EMG/NCS/EP and EEG System

1.0 General Provisions

1.1 Intent

This invitation to Tender is intended to obtain One Combination EMG/NCS/EP and EEG System for the Western Regional Integrated Health Authority (Western Health) at the Western Memorial Regional Hospital.

This Tender is concerned with the acquisition of One Combination EMG/NCS/EP and EEG System for the Western Memorial Regional Hospital with consideration of the following:

- Ongoing service and maintenance support.
- All manuals, documents and initial supplies.
- The right to reproduce any printed materials supplied with the product for the purpose of using the product.
- Training and training manuals.
- Future enhancement availability.

1.1.1 Western Health reserves the right to order additional units at the same price for a period up to and including 31 December 2008.

1.2 Client Background

Western Health was established in 2005 and is responsible for the delivery of Health and Community Services in the Western Region.

1.3 Vendor Response

1.3.1 Vendor's tender must contain an Executive Summary which shall contain:

a. A brief description of the product being quoted.

b. The name, title and address of the Vendor's representative responsible for the preparation of the Tender.

1.3.2 All prices quoted for goods and services must be specified in Canadian dollars, FOB Western Memorial Regional Hospital. All Tenders will be held to be valid for ninety (90) days following the Tender closing date.

1.3.3 Tenders must be received in full on or before the exact closing time and date indicated. **TENDERS RECEIVED AFTER THAT TIME WILL NOT BE CONSIDERED.**

1.3.4 All costs relating to the work and materials supplied by the Vendor in responding to this Invitation to Tender must be borne by the Vendor.

1.4 Release of Information

1.4.1 While Tender is Open:

The names of individuals or companies who have picked up the tender documents will **not** be released.

1.4.2 At Tender Opening:

Only the names of the bidders will be read out.

1.4.3 After Tender Opening:

1. No further information will be released until after the contract is awarded.
2. After award, only the name and bid price of the successful bidder will be made available.
3. Information will be made available for a 90 day period only.

1.4.4 FYI, Statements that are included as part of our Tender calls:

While bidders are welcome to attend the public opening, please be advised that it is not our policy to release bid information. Only the names of the bidders will be released.

1.5 **Communication During Tendering**

1.5.1 All communications with Western Health with respect to this invitation to Tender must be directed in writing to the attention of:

Mr. John Piercey
Regional Director, Materiels Management
Western Health
P.O. Box 2005
Corner Brook, Newfoundland
A2H 6J7
Tel: (709) 637-5511
Fax: (709) 634-2649
Email: johnpiercey@westernhealth.nl.ca

1.5.2 Western Health may, during the assessment period, request meetings with the Vendors to clarify points in the Tender. No changes by the Vendor will be permitted after the Tender closing date.

1.5.3 Faxed Tender responses will be accepted with the condition that the original Tender documents are received at Western Health's Materiels Management Department no later than **Five** working days following the Tender closing date.

1.5.4 All bids must be sent in a sealed envelope clearly marked with Tender Name and Number to: Materiels Management Department, Western Health, Western Memorial Regional Hospital, Lower Level, P.O. Box 2005, Corner Brook, NL A2H 6J7.

1.5.5 Bids submitted by electronic transmission (e-mail) <u>will not be accepted.</u>

1.5.6 Companies submitting fax Tenders are doing so at their own risk and the fax Tender must be at the public opening as specified in the Tender information. This Authority will not be responsible for in-house courier services if companies submit quotations by fax machine. The time stated on the fax Tender will become null and void since it is the responsibility of the company placing the Tender to have their Tender at the public opening, therefore, this Authority will not be responsible for any damages or liabilities.

1.5.7 In order to contribute to waste reduction and promote environmental protection, the Western Health will endeavour to acquire goods and services that support these principles, therefore, product(s) quoted should include:

- maximum level of post-consumer waste and/or recyclable content
- minimal packaging
- minimal environmental hazards
- maximum energy efficiency
- potential for recycling
- disposal costs
- must not reduce the quality of the product required or affect the intended use of the product
- must not significantly impact the acquisition cost

1.5.8 Are the quoted price(s) on this tender (where applicable) available to our employees?

Yes ☐ No ☐ N/A ☐

Administratively the Western Integrated Health Authority will not be involved in ordering, servicing, warranty and payment; the employee(s) would deal directly with the company.

1.6 Tender Acceptance

1.6.1 Any acquisitions resultant from this invitation to Tender shall be subject to the Public Tendering Act.

1.6.2 The Tenders shall be opened in the Private Dining Room at The Western Memorial Regional Hospital on the scheduled date and time.

1.6.3 Any Tender may be accepted in whole or in part. The lowest Tender may not necessarily be accepted and Western Health reserves the right to cancel the Tender call. Western Health shall not be held responsible or liable for the payment of any costs that are incurred by the bidder in preparing a Tender in response to this invitation to Tender.

1.7 Warranty

The Vendor shall warrant that the product supplied to Western Health shall equal the published specifications.

The Vendor shall provide no less than a 1-year warranty on the system. The Vendor agrees to provide free of charge all parts and labour necessary to repair the system during the first year of operation.

2.0 **Product Specifications**

Medical Device License Number for the product tendered _____

Must be able to record EMG, Nerve Conduction studies, Evoked Potentials and EEG, all in the same unit, with one PC and one cart.

EEG – Minimum of 32 channels

- EEG Amplifier must be IP addressable
- EEG amplifier must be connected via CAT5 networking cable
- Must be able to initiate impedance check from amplifier
- EEG amplifier must have built-in electrode connections
- Must have a passive headbox with cable (min. 32 inputs)
- Amplifier noise in the recording must be less than 2 uV (microvolts) peak to peak, at any frequency 0.1 to 100 Hz.
- Amplifier sampling rates must be software controlled and adjustable from 125 to 2000 Hz.
- Programmable and adjustable montages, recording parameters and recording notations.
- Programming must be fully Windows XP Professional compatible.
- Filing system and database management software
- Must be capable of archiving patient files to CD, DVD, or Network server.
- Must be USB 2.0 compatible.
- Must be network ready.
- Must provide user in-service for Neurology Technologists.
- Must have LED photic strobe capable of 60Hz stimulation
- Must be capable of displaying EEG trends such as amplitude integrated EEG (aEEG), Envelope, Absolute Band Power, Total Power, Burst Suppression Monitoring, Spectral Edge, Peak frequency, and Sprectrogram, during acquisition and review

EMG, NCS, & Evoked Potentials – Minimum of 4 channels

- Must be fully programmable and adjustable software
- Must be capable of recording Brainstem Auditory Evoked Potentials, hand-held flash VEPs, Pattern Reversal VEPs, SSEPs
- The system shall be able to perform routine and multi-channel motor nerve conduction studies, in the assessment of the integrity of the peripheral large-fiber motor nerves.
- The system shall be able to perform routine and multi-channel sensory nerve conduction studies, in the assessment of the integrity of the peripheral large-fiber sensory nerves.
- The system shall be able to perform F-Wave studies, in the assessment of the integrity of the peripheral large-fiber sensory and motor nerves.
- The system shall be able to perform H-Reflex studies, in the assessment of the integrity of the peripheral large-fiber motor nerves.
- The system shall be able to perform Blink Reflex studies, in the assessment of the integrity of facial and trigeminal nerves and the investigation of brainstem function.

- The system shall be able to perform routine and Motor Unit Number Estimation studies, using the Statistical, Incremental, F-wave, Spike Triggered Averaging, and Multi-Point Stimulation methods.
- The system shall be able to perform routine and multi-channel motor nerve conduction studies, in the assessment of neuromuscular transmission disorders.
- The system shall be able to perform routine and autonomic nerve studies, in the assessment of the integrity of the small-fiber nervous system.

Electromyography (EMG) Acquisition Software

- The system shall be able to perform EMG studies using multiple display modes for acquisition, Spontaneous, Motor Unit, Maximal Volitional, and Interference Pattern Analysis (IPA).
- The system shall be able to store which display mode is the default for the user and would be the first display mode observed upon entry into data acquisition.
- The system shall be able to record and display both triggered and free run EMG data. These two types of data shall be displayed in independent windows during acquisition and have independent timebases.
- The software shall allow for display parameters to be modified by using a pointing device or control panel, including timebase, sensitivity, trigger level, markers, filters, and trace delay.
- The display sensitivities shall be locked and change in unison between the free run and triggered data.
- The system shall allow the selection of muscle and side being examined from the acquisition screen.
- The system shall be able to display triggered data in both a raster and superimposed format. The number of traces displayed in the raster mode shall be user controlled. This ability shall be controlled in the acquisition screen and have the possibility of this value being stored permanently, if desired by the user.
- The system shall have the ability to store up to 120 seconds of free run EMG data. The system shall have the ability to replay this data with complete synchronization of audio and video during the entire 120 seconds.
- The system shall be able to reply stored EMG data and acquire additional triggered motor unit potentials during reanalysis.
- The system shall allow the ability to store the free run EMG data manually or have the system store the data automatically. This ability shall be controlled in the acquisition screen and have the possibility of this value being stored permanently, if desired by the user.
- The system shall allow the ability to change amount of free run data that is being stored. This shall be done, in the acquisition screen, through a menu of time durations for the user to select and have the possibility of being this value being stored permanently, if desired by the user.
- The system shall have the ability to select a free run data segment to review while in the acquisition screen.
- The software shall play back the free run data using a multi-media control bar. This will allow for play and pause of the data, and the ability to manual scan through the data using the icon in the media bar.

- The software shall display the amount of EMG data that is currently available for permanent storage and indicate when the system is collecting data for storage with a flashing green light in the acquisition screen.
- The software shall have the ability have unlimited playback of EMG data, immediately after acquisition, without having to permanently store the data.
- The system shall display the trigger rate of the data being recorded. This information will have the option of not being displayed in the settings.
- The system shall display the criteria of the trigger, positive or negative, in the acquisition screen. This setting shall be changed using the pointing device.
- The system shall be able to store and/or acquire data in any of the display modes and play it back in any of the other display modes.
- The system shall have the ability to quantify triggered EMG data, in the motor unit display mode, for duration, amplitude, phases, spike duration, risetime, area, size index, and number of polyphasic units.
- The system shall display the quantified information in a table. The table shall indicate the motor unit being examined, the mean and standard deviation of all motor units studied, and the mean and standard deviation of all non-polyphasic units examined. All of this information shall be able to be transferred to a final exam report.
- The system shall be able to display the number of motor units examined in the acquisition screen.
- The system shall have the ability to display an averaged motor unit potential. This potential shall be comprised of a number of the triggered waveforms being collected.
- The system shall have a review mode to display up to 40 recorded motor units. These shall be displayed 20 per page. The motor units shall be numbered and indicate if there is any associated free run data stored from which the motor unit was extracted.
- The review mode shall allow the ability to edit any of the markers set on the individual motor units. Selection of the motor unit and changing of the markers shall be controlled with the pointing device.
- All display parameters and page selection, in the review mode, shall be controlled with the pointing device.
- The system shall display the data tables from any analysis done in the motor unit display mode or maximum volitional display mode.
- The system shall be able to analyze data during maximum contraction of the muscle. This shall be done in a separate display mode with appropriate timebase and display sensitivity.
- The system shall quantify EMG data and display values for this data in the maximum volitional display mode. The values examined shall be peak-to-peak amplitude, root mean square, mean root voltage, and turns per second.
- The trigger level in any of the display modes shall be controlled by the pointing device or the cursor wheel on the system control panel.
- The system shall have the ability to hide the trigger line with the pointing device.
- The system shall allow a trigger window to be created using the pointing device. The size of the window shall be set by the user and allow for motor units with a certain criteria to be examined.

- The system shall have a notepad available for entering the findings of the examination. This notepad shall be available in all display modes, with entries being made using the pointing device or buttons on the system control panel.
- The system shall allow the notepad to be entirely customized by the user with 12 columns and 10 rows available to fill with values. The font size and width of the notepad shall be set by the user.
- The system shall have the ability to open the notepad with the user indicated normal values pre-selected. This shall be controlled by the user and permanently stored in the settings.
- The system shall allow the user to select the values using the pointing device or buttons on the system control panel.
- The system shall allow the user to select all of the designated normal values with a single icon in the notepad. The system shall also allow the user to deselect all of the values with a single icon in the notepad.
- The system shall allow a designated general comments field to be available and active when the notepad is opened. Individual comments shall also be allowed in designated cells within the notepad.
- The system shall allow for the notepad to be used during acquisition or post acquisition, depending on the user preference.
- The system shall allow all entries, in the notepad, to be edited post acquisition.
- The entries made in the notepad shall be stored upon leaving the acquisition screen. There shall also be an indication of when the notepad has been used during acquisition on a muscle.
- The system shall be able to transfer all entries made in the notepad to the final report. The notepad shall have the ability to be stored in several formats in the final report templates.
- The system shall have a customizing window, in the EMG setting, for the notepad. The user shall have the ability to reorganize the order of the grouped columns, individual columns under the group header, and rows within a column.
- The system shall allow the user the ability to rename or create new group headers, column headers, or values. These shall be stored permanently in the settings.

Evoked Potential (EP) Acquisition Software

- The system shall be able to provide Somatosensory Evoked Potentials (SSEPs) from the upper and lower limbs, in the investigation of the large-fiber sensory system.
- The system shall be able to provide Pattern-reversal and Flash Visual Evoked Potentials (VEPs)
- The system shall provide Auditory Evoked Potentials (AEPs).
- The system shall provide testing for Vestibular Myogenic Evoked Response.

Multi-Modality Programs (MMP) Acquisition Software

- The system shall be able to provide Sympathetic Skin Response (SSR) from the upper and lower limbs, in the investigation of the small-fiber sensory system.
- The system shall be able to provide R-R Interval testing from the QRS complex, in the investigation of the small-fiber sensory system.

- The system shall be able to provide Valsalva Maneuver testing from the QRS complex, in the investigation of the small-fiber sensory system.
- The system shall be able to provide Spike Trigger Averaging testing.
- The system shall be able to provide multiple channels of free run EMG testing.

Error Handling & Diagnostics

- The system software shall provide a comprehensive set of messages for identified errors and a suggestion to the user for possible corrective action, in each error case. The error messages shall be available in the same language as the main system software.
- The system shall retain a log of all error messages identified by the system software.
- The system shall have a diagnostics software package accessible that will provide detailed information on the function of all of the hardware pieces.

• Must provide user in-service for Neurology Technologists.

EMG/NCS/EP Amplifier

- The amplifier system shall provide 4 to 8 electrode inputs which are optically isolated and certified to at least type BF European classification.
- The amplifier system shall provide 2 to 4 recording channels in the differential mode.
- The amplifier unit shall include DIN 42802 electrode connections for the 8 electrode inputs, plus two isolated ground connections.
- It shall be possible to check electrode impedance through software
- The amplifier system shall be available with a fully compatible pattern-reversal photic stimulator, but shall also be capable of providing a TTL active high trigger pulse (controlled by the host system software) for control of an alternative Photic stimulator.
- The amplifier shall be equipped with a 16 bit Analog-to-Digital Converter (ADC) with a 100 KHz sampling rate.
- The amplifier system shall offer a sensitivity range from 1μV per division to 10mV division in 13 steps. 2 Volts peak to peak maximum full scale output.
- The Common Mode Rejection Ratio of the amplifier shall be 110dB, typical. Also, >105dB with 50 to 60 Hz notch filtering, typical.
- The system low filter (-3dB) settings shall be of 1 or 2 pole type with 6 or 12 dB per octave roll-off. The filter settings shall be software selectable of 1, 2, 5, 10, 20, 30, 150, and 500 Hz.
- The system high filter (-3dB) settings shall be 2 pole type with 12 dB per octave roll-off. The filter settings shall be software selectable of 15, 30, 100, 250, 1.5K, 2K, 3K, 10K (Hz).
- Input Noise shall be <= 1 μV RMS from 1 Hz – 10KHz with the input shorted.
- Amplifier Input Impedance shall be at least 100 MOhm.
- The system shall have a notch filter that is selectable between 50 Hz and 60 Hz and can be selectively turned on and off.

Isolated Electrical Stimulator

- The system shall be equipped with a one channel internal electrical stimulator.
- The system shall be available with the option of an additional one channel external electrical stimulator
- The stimulus intensity shall be of a range between 0 to 100 mA or 0 to 400 V. The intensity shall be continuously adjustable with a user selectable maximum range into a 4 kW load
- The stimulus duration shall have a range of 0.01 – 1 ms.
- The stimulus modes shall be single, train (in specific tests), recurrent and non-recurrent operation.
- The stimulus rate shall be 0.1 – 100 per second, depending on the type of test being performed.
- The stimulus shall be activated by a mechanism on the system control panel or remotely from the stimulator probe.
- The stimulus level shall be controlled by using the system control panel or remotely from the stimulator probe.
- The stimulus type shall be selectable and have the option of constant current or constant voltage.
- The stimulator probe shall have the ability to reverse polarity and controls to activate the electrical stimulation and control the intensity of the electrical stimulation.
- The system shall have the ability to display the stimulator level value (current or voltage) in each recording screen.

Auditory Stimulator

- The system shall have click, tone pip or tone burst signal types.
- The stimulus rates shall be 0.1 – 91.1 per second in 20 steps.
- The stimulus intensity shall be 0 to 139 dB pSPL or -31 to 109 dB nHL, depending on the stimulus type, frequency and transducer type.
- The system shall have the ability to control the stimulus intensity with the software. The left and right channels shall be controlled separately, each with a 140 dB dynamic range selectable in a programmable step size.
- The click polarity shall have the selectable options of condensation, rarefaction, and alternating.
- The system shall have a click duration of 100 μsec.
- The system shall have the tone frequencies of 250, 500, 750, 1K, 1.5K, 2K, 3K, 4K, 6K, 8K (Hz).
- The tone frequencies stimulus shall have the following:
  a. Tone Pip Ramp of 2 cycles
  b. Tone Pip Plateau of 0 cycles
  c. Tone Pip Envelope of Blackman
  d. Tone Burst Ramp of 10 ms
  e. Tone Burst Plateau of 200 ms
  f. Tone Burst Envelope of Linear
- The noise masking shall be broadband of 0 to 140 dB in 1 dB steps in a differential mode.

- The systems shall use 300W transducers that in the model of TDH-39 Headphones, TIP 300 Insert Phones, Bone Vibrator.

Signal Averager

- The system shall be able to average data from 1 to 4 channels.
- The system shall have the display modes of normal, odd and even, normal and plus/minus and plus/minus.
- The system shall have a dual buffer averager with the ability to actively change the display modes while recording.
- The system shall have the ability to quickly reject any averages that to not fit the averaging criteria.
- The system shall be able to allow the threshold of the artifact rejection mode to customized. The threshold shall be fixed of variable with the adjustment of the delay of the reject start time or turning the function off, depending on the type of test.
- The signal averager shall have the display sensitivities of 0.001 μV per division to 10 MV per division in 22 steps depending on the test.
- The system shall allow averaging of 2 to 10,000 trials in specific tests.
- The system shall have the averager synchronized with the stimulus production, whether the averager is initiated manually or started with the stimulus.

Waveform Display

- The system shall have a timebase range of 0.2 ms per division to 5 seconds per division in 23 steps, depending on the test being performed.
- The timebase shall have the ability to be displayed as single, dual and individual that are independently selectable in specific tests.
- The waveform trigger shall be computer or manual controlled and selectable for positive and negative slope and input channel.
- The system resolution shall use a 16-Bit A/D converter with a 1 μs effective time resolution.
- The waveforms shall be displayed with a roll and zoom capability in specific tests.

Auxiliary Inputs

- The system shall have an external trigger input that will use the standard TTL logic levels. These TTL logic levels shall be edge triggered and the positive or negative edge selected through the software.
- The system shall have external stimulus output levels that are positive or negative TTL logic levels that are selectable by the software.
- The system shall have a USB 2.0 hub with three USB ports available for external devices.
- The system shall have the ability, with the proper cable, to calibrate the input signal through an auxiliary output, and display using units appropriate to the signals being acquired.
- The system shall be able to continuously monitor skin temperature with a surface sensor and using the internal temperature input.

- The system shall have an input to support a visual stimulator that is a high-efficiency LED goggles.
  - a. Red (635 NM) in a 3x5 array in each eye piece.
  - b. LED flash rate of 0.1 to 100 per second
  - c. LED Flash duration of .01 to 1 msec in .05 steps through software control.
  - d. Interface cable of 15 ft in length control

Biomedical Requirements – CSA or equivalent

• Must provide service manuals.
• Must provide any required test equipment.
▪ Must include descriptive literature with your bid.
▪ Must complete the attached Vendor's Checklist.

3.0 Presentation / Training / Service

3.1 Presentation

A presentation of the Tender and / or a demonstration of the product / system shall be provided, if requested, at the Vendor's expense.

3.2 Training

The Vendor shall provide on-site training to staff in the use of the **Combination EMG/NCS/EP and EEG System**. All costs associated with this training shall be included in the total Tender price. The length of such training shall be what is reasonably required to train the users of the equipment and shall be documented.

3.3 Service

3.3.1 The Vendor shall confirm in writing that Parts and Labour will be available for the quoted system for not less than nine (9) years after the warranty period.

3.3.2 The Vendor shall provide as an option, pricing for a one-year Service Contract including all parts and labour.

3.3.3 The Vendor shall provide all Service and Parts manuals required to service the equipment.

3.3.4 The Vendor shall agree to provide factory training for One in-house Biomedical Technologist and one EEG Technologist as an option, employed by Western Health, for the purpose of maintaining the **Combination EMG/NCS/EP and EEG System**. Such training shall be equal to the training provided to the Vendors own service staff. All costs associated with this training, including travel, accommodations, meals and tuition shall be included in the Tender price.

4.0 Product History and Vendor Reputation

4.1 The Vendor shall provide a list of three (3) organizations where a similar Unit has been installed. Include a contact person for each organization.

5.0 Financial Considerations

5.1 All applicable taxes shall be indicated in the Tender.

5.2 The cost for installation, initial set-up and programming shall be included in the Tender price.

5.3 All costs for training shall be included in the Tender. This includes any travel, meals and accommodation.

5.4 Terms of Payment

The Authority agrees to pay the full invoiced amount within 30 days following acceptance of the installed system by Western Health. Acceptance testing will be completed within 30 days following the complete installation of the system.

6.0 **Vendor Confirmation** (please sign)

I confirm that our Tender meets or exceeds the specifications detailed in this invitation to Tender. I also confirm that all specifications are included in the quoted price. Any items that are optional are noted accordingly.

Signed _____

Title _____

Company Name _____

Address _____
_____

Phone _____

Tender Price $ _____ Tax Extra Yes _____ No _____

TENDER CHECKLIST

TENDER # 0171-0819

DID YOU INCLUDE

HAS TENDER SUBMISSION BEEN SIGNED	Yes ☐	No ☐
COPY OF REQUIRED TENDER DOCUMENTS	Yes ☐	No ☐
COPY OF BROCHURES (IF REQUESTED)	Yes ☐	No ☐
COPY OF WCB LETTER OF GOOD STANDING (IF REQUIRED)	Yes ☐	No ☐
COPY OF PROOF OF INSURANCE (IF REQUIRED)	Yes ☐	No ☐
AMOUNT OF TAX NOTED ON REQUEST FOR QUOTATION FORM	Yes ☐	No ☐
OPTIONAL PRICING FOR TRAINING INCLUDED	Yes ☐	No ☐

NOTE: TENDER RESPONSES MAY BE REJECTED IF YOU ANSWER "NO" TO ANY OF THE ABOVE QUESTIONS.