

**ALL INDIA INSTITUTE OF MEDICAL SCIENCES
ANSARI NAGAR, NEW DELHI-29
STORES SECTION(CNC)**

T. No. 218/CNC/Neuro/2023-24/St.

Dated: 24.12.2024

Sub:- Purchase of "Electro Physiology (EP) System-01No." for department of Neurology, CNC, AIIMS, New Delhi-29 on proprietary basis-Inviting comments thereof.

The CNC (AIIMS) is in the process to purchase of **Electro Physiology (EP) System-01No."** for department of Neurology, CNC, AIIMS, New Delhi-29 on proprietary basis from M/s. NEXSTIM, Helsinki, Finland through their Indian supplier M/s. Indian Surgical Solutions, New Delhi. The proposal submitted by M/s. Indian Surgical Solutions and PAC Certifications are attached.

The above documents are being uploaded for open information to submit Suggestion/objections/comments, if any, by any manufacturer/Supplier firm regarding proprietary nature of the equipment/item, within 15 days of issue of this document on AIIMS website by giving Tender No. **218/CNC/Neuro/2023-24/St.** The comments/objections should be submitted in the office of Stores Officer (CNC), Room No. 3, 1st Floor, New Pvt. Ward, CNC at AIIMS, New Delhi-29 on or before **09.01.2025 upto 12.00 noon.**, failing which it will be presumed that any other vendor is having no comment to offer and purchase process will be initiated further for purchase of item as per procedure. No suggestions/objections will be considered after 09.01.2025.

Encl: Related documents enclosed.

Yatuh
24/12/24
STORES OFFICER
(CNC, AIIMS, N.DELHI-29)


 **भंडार अधिकारी**
Store Officer
हृद तंत्रिका केन्द्र / C.N. Centre
अ. मा. आ. सं., नई दिल्ली/A.I.I.M.S., New Delhi-110029

Electro Physiology (EP) System- 01No)

Item No. 342 (OM No. 12/17/2019-PPD)

(Approx. Cost 05 Crores)

TECHNICAL SPECIFICATION (Revised Dated- 19/01/2024)

1. Non –invasive mapping of the primary motor cortex, speech area and vision of the brain to its Exact anatomical cortical gyrus.
2. Should indicate MRI-guided and electric field (E-field) navigated, noninvasive, repetitive TMS stimulation of the motor cortex.
3. The integrated e-field navigated TMS system should have intended use to provide information that may be used in the assessment of the primary motor cortex and speech and vision cortex for pre-procedural planning.
4. with CE /FDA marking.
5. The integrated e-field navigated TMS system enabling targeting and delivering noninvasive repetitive TMS stimulation with electric field targeting to the patient's dorsolateral prefrontal, vision, bocas area and other language areas cortex.
6. System Features:
 - 1) Creation of 3D rendering from MRI
 - 2) Tool for marking the desired therapy target on MRI
 - 3) Software tool to get cortical grid to assist in systematic brain mapping
 - 4) Guided co-registration
 - 5) E-field modeling showing reallocation of maximal stimulation
 - 6) The orientation of the TMS induced E-field shown on cortical anatomy for individually tailored stimulation and a personalized therapy
 - 7) Real-time stimulating electric-field visualization
 - 8) E-field navigation, TMS control and EMG measurement integrated into one user interface
 - 9) TMS stimulator, EMG system and Navigator designed by one company and clinical trial

Gang

and

Parveen

Anu

Dr. MANJARI TRIPATHI
Professor & Head
Dept. of Neurology
Neurosciences Centre
All India Institute of Medical Sciences, New Delhi-20

Dr. DEEPTI VIBHA
Professor
Dept. of Neurology
Neurosciences Centre
All India Institute of Medical Sciences, New Delhi-20

Dr. Neera Chaudhary
Prof. Neurology
All India Institute of Medical Sciences, New Delhi-20

Dr. Prof. Neurology
All India Institute of Medical Sciences, New Delhi-20

validated as one integrated system

10) Computer-aided motor threshold-finding, single operator, integrated on-line EMG monitoring and response control

11) Single-pulse stimulation for location of motor cortex

12) Pre-programmed rTMS sequences for therapy

13) Stimulation coil with coil tracker having 360 degree visibility of the coil, coil can be rotated during the mapping without recalibrating the coil tracker to follow the sulcuses

14) Automatic recording of stimulation and response data, documentation of session workflow for later replication and analysis.

15) The orientation of the TMS induced E-field shown on cortical anatomy for individually tailored stimulation and a personalized therapy.

16) Should be able to fuse ESI and MSI from VEEG and MEG systems already at AIIMS.

17) Cost of all software and hardware to be given, software updates to be there, disposable parts to be quoted and fixed for 10 years.

18) Stimulator specs and types available all to be stated.

7. Each system should comprise the following components as integrated system:

1) Mobile cart with PC and 24" display incl. mouse, keyboard, licence key, DVD-R/RW drive.

2) TMS II+ Stimulator & Cooling Unit.

3) Polaris Tracking System (arm-mounted)

4) EMG Amplifier and EMG power unit.

5) Foot Switch

6) RFID Reader Set

7) Medical grade isolation transformer and power cables

8) Digitizer Pen

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id. Singh



Dr. Neera Chaudhary
Dir. of Neurology
GIPMER, New Delhi

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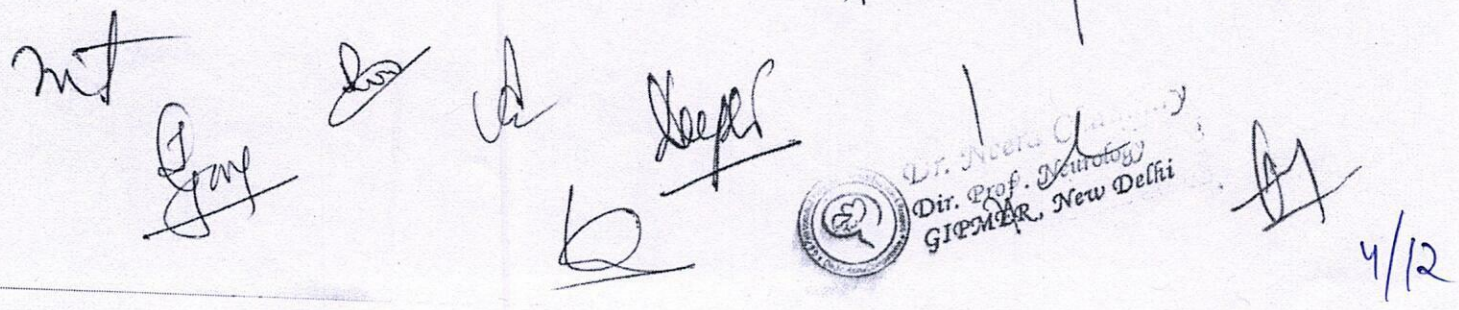
- 9) Patient Chair with Coil Positioning Holder
- 10) Software, enabling navigated rTMS up to 50 Hz
- 11) Cooled Coil for Coil Positioning Holder
- 12) Start-up kit:
 - a. EMG electrodes (1000 pcs)
 - b. EMG electrode cables (20+4 pcs 24 pieces)
 - c. EMG GND electrode cables (12+12 pcs total 24)
 - d. Reflective sphere markers for tracking tools (50 pcs)
 - e. Demo head
 - f. User Manual

13) Head Trackers white-200 pcs.

8. The real-time stimulating electric field navigated system should be USDFA & CE Certified for major depressive disorder (MDD)/equivalent to Indian Standard.

9. The vendor must quoted rates of the following accessories/consumables separately which will be considered for ranking (L-1)/life cycle cost purpose. The rates of these items will remain valid for 10 years (during warranty & CAMC period) for the date of Installation of equipment for future purchases also, if required, as and when required basis.

- 1) Operator Chair -01 No.
- 2) Patient Chair Cushion Set -01 No.
- 3) Focal Coil with Tracker* - 1 No.
- 4) Cooled Coil - 1 No.
- 5) Report Maker Software - 1 No.
- 6) Planning Station - 1 No.
- 7) SFTP Data Transfer Module - 1 No.
- 8) EMG electrodes (240 pcs/box) - 10000 Nos.


 The bottom section of the document contains several handwritten signatures in various colors (black, blue, red) and a circular official stamp. The stamp is from the Department of Neurology, GIPMER, New Delhi, and is signed by Dr. Neeta Chandra. There are also some handwritten initials and a date '4/12' in the bottom right corner.

9) EMG electrode cable – 12 Nos.

10) EMG GND electrode cable – 12 Nos.

11) White Head Trackers (20 pcs) – 26000 Nos.

12) Passive Marker Spheres - 25 pcs

13) Head Trackers white per box of 20pcs – 26000 Nos.

14) Holder for stimulator – 5 Nos.

15) Training workshop (1) and maintenance manpower.

10. The system quoted should be warranted for 05 comprehensive (including all spares, accessories, all third party items and labour) + Quote rates for 05 years Comprehensive AMC (including all spares, accessories, all third party items and labour) from the date of satisfactory installation of equipment.

Note: The cost of equipment, CAMC (NPV value) + Accessory/consumables mentioned in point No.09 above, will be considered for ranking (L-1) purpose.

11. The cost of all consumables/accessories/spares/parts (In segregated/separate list of each component) should be quoted/uploaded (in PDF) with price bid and the same should be valid for 10 years for future purchases as and when required basis. In case, firm did not quote any consumables/accessories/spares/parts price alongwith original price bid and the same required in future to run the system, bidder must provide the same to the user department at free of cost without any additional condition.

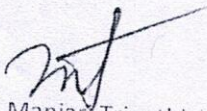
12. If desired by the TSEC, Demonstration of quoted product would be mandatory at AIIMS, New Delhi premises. Only seven days' period will be given for preparation of demo unit and not further extension will be provided. All bidders are advised to keep ready their quoted product for demonstration. None attending demo meeting/non-demonstration of quoted product, the bid will be summarily rejected.


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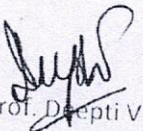
Dr. KARAN MADAN
MD (Medicine), DM (Pulmonary & Critical Care Medicine)
Additional Professor
Department of Pulmonary, Critical Care & Sleep Medicine
All India Institute of Medical Sciences, New Delhi-110029


Dr. Neera C.
Dir. Prof. Neurology
GIEMER, New Delhi

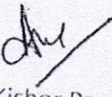
LIFE CYCLE COST PER YEAR			Quantity required per year	Unit price	Total cost per Year
8)	EMG electrodes	3 pcs per patient for initial session to determine motor threshold	780	835.00	651300.00
9)	EMG electrode cables	10 Nos.	10	95000.00	950000.00
10)	EMG GND electrode cables	10 Nos.	10	95000.00	950000.00
11)	White Head Trackers	1 head tracker per session (one patient requires minimum 10 sessions, so you need 10 head trackers per patient)	2600	40800.00	106080000.00
12)	Reflective sphere markers for tracking tools	25 pcs	25	8000.00	200000.00
13)	Head Trackers white	1 head tracker per session (one patient requires minimum 10 sessions, so you need 10 head trackers per patient)	2600	40800.00	106080000.00

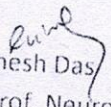

Prof. Manjari Tripathi
H.O.D. Neurology



Prof. Achal Kr. Srivastava
Chairman TSEC (Neurology)

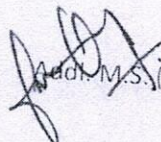

Prof. Deepti Vibha
Department of Neurology

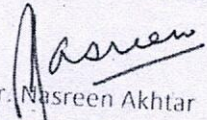

Dr. Robpa Rajan
Addl. Prof. Neurology

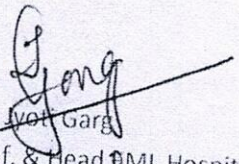

Dr. Awadh Kishor Pandit
Addl. Prof Neurology

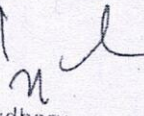

Dr. Animesh Das
Assoc. Prof. Neurology



Dr. Elavarasi A.
Assoc. Prof. Neurology


Addl. M.S. (CNC)


Dr. Nasreen Akhtar
Addl. Prof. Physiology Deptt.
Dr. NASREEN AKHTAR, MD, MCh
Additional Professor
अपर-अधिपति/Additional Profes
स्वीर क्रिया विज्ञान विभाग/Deptt. of Phys
अ. भा. आ. सं., आई दिल्ली-110
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Dr. Jyoti Garg
Prof. & Head RML Hospital
External Expert and
DGHS Nominee.


Dr. Neera Chaudhary
Prof. & Head G.B. Pant Hospital
(External Expert)


Dr. Karan Madan
Addl. Prof. Pulmonary Medicine
(External Expert)

डॉ. ज्योति गर्ग / Dr. Jyoti Garg
आचार्य एवं विभागाध्यक्ष / Professor & Head
तंत्रिका विज्ञान विभाग / Department of Neurology
अविवास एवं डॉ. रा.म.लो. अस्पताल - 110001
ABVIMS & Dr. RML Hospital New Delhi-110001
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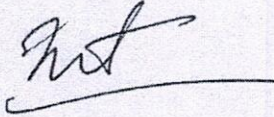
Dr. Neera Chaudhary
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GIPMER, New Delhi


DR. KARAN MADAN
MD (Medicine) & Pulmonary & Critical Care (Medicine)
Additional Professor
Department of Pulmonary, Critical Care & Sleep Medicine
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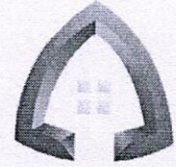
Proprietary Points of Nexstim Navigated Brain Stimulation (NBS) System

1. Stimulating electric field modeling and visualization patent. Method and system for displaying the electric field generated on the brain by transcranial magnetic stimulation. (Patent no.- US 11/853,232 , US 11/853,232, CN ZL200780034028.5, JP 5363321)
2. Method & Apparatus for Dose Computation of Magnetic Stimulation (Patent no.- US 6849040B2 , US 6,849,040; FI 114613, GB 2382780, JP 4313559, CA 2,408,775, DE 10248316.7, (ILM6)
3. Transcranial magnetic stimulation induction coil device and method of manufacture with a high degree of accuracy fused to patients MRI which is uploaded onto the NEXSTIM (Patent no. US7998053B2 , US 7,998,053, US 13/187,582 (D1)
4. Transcranial magnetic stimulation induction coil device with attachment portion for receiving tracking device (Patent no. -US 7,854,232, US 7,854,232, US CIP 12/944,768)
5. Coil holder, device support apparatus (Patent no.- US 14/093073 , US 14/093073)
6. Position-finding apparatus; Enhanced electric field arrow to guide operator to get maximal induced electric field at precise location area of cortex (Patent no- US 14/740,299, JP 2015-133191, RU 2015126354)

Manjari Tripathi



 डॉ. मंजरी त्रिपाठी / Dr. MANJARI TRIPATHI.
आचार्य एवं अध्यक्ष / Professor & Head
तंत्रिका विज्ञान विभाग / Deptt. of Neurology
तंत्रिका विज्ञान केंद्र / Neurosciences Centre
अ.भा.आ.सं., नई दिल्ली / A.I.I.M.S., New Delhi-29



INDIAN SURGICAL SOLUTIONS

Ref.: SOL/431/2023-24

Dated: 22.01.2024

To,
The Director,
All India Institute of medical Sciences
New Delhi

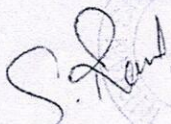
SUB.: SUBMISSION OF NEXSTIM PROPRIETARY ARTICLE CERTIFICATE FOR BRAIN SPEECH & TMS system
REF.: TENDER NO. 218/CNC/Neuro/2023-24/St. For Electro Physiology (EP) System

Dear Sir,

With reference to the above mentioned subject, Please find enclosed the Proprietary Article certificate of NEXSTIM BRAIN SPEECH & TMS system for your kind consideration.

Thanking you,

FOR INDIAN SURGICAL SOLUTIONS


AUTH. SIGNATORY

SR. Radley Bryan

Fateh
mhm

- 901, Vishwadeep Tower, District Centre, Janakpuri New Delhi-110058
- 011-40592105
- indiansurgicalsolutions@gmail.com
- www.indiansurgicalsolutions.com

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Date: August 21, 2023

TO: ALL INDIA INSTITUTE OF MEDICAL SCIENCES (AIIMS), NEW DELHI, INDIA

PROPRIETARY ARTICLE CERTIFICATE

Ladies and Gentlemen,

We, **Nexstim Plc**, a limited liability company who are established proven and reputable manufacturers of **Navigated Transcranial Magnetic Stimulation Systems, Nexstim Navigated Brain Stimulation (NBS) system and Nexstim Navigated Brain Therapy (NBT) system** having registered address at Elimäenkatu 9b, 00510 Helsinki, Finland hereby certify that:

Navigated Transcranial Magnetic Stimulation Systems, Nexstim NBS system and Nexstim NBT systems are a proprietary item of **Nexstim Plc**. It is having the following patented features:

- 1) Stimulating electric field modeling and visualization patent. Method and system for displaying the electric field generated on the brain by transcranial magnetic stimulation.
US 11/853,232
A display shows the visualization surface overlaid on a volumetric image of the brain, the electric field induced on a region of the visualization surface by a transcranial magnetic stimulation ("TMS") induction coil device positioned above the head surface and the TMS coil device. By viewing the display, a user of the TMS coil device can interactively position the TMS coil device in relation to the head surface and, for a target site on the brain at a selected depth, determine the position at which the TMS coil device induces a maximum E-field on a visualization surface corresponding to the selected depth.
US 11/853,232, CN ZL200780034028.5, JP 5363321, (NEX15)
- 2) Method & Apparatus for Dose Computation of Magnetic Stimulation US 6849040B2:
Patent is covering the NBS/NBT systems and key features for E-field dose calculation, visualization that are needed for targeting the stimulation for the brain mapping and diagnostic. The patent defines also the dose of magnetic stimulation as the cumulative sum of the electric field induced in the cortex for a train of pulses given to the subject. The dose depends on the exact location of the coil and the electrical characteristics and shaped of the individual head. The dose can also be extended to determine the effective dose, e.g., stimulation frequency dependent biological or therapeutic response of the brain.
US 6,849,040; FI 114613, GB 2382780, JP 4313559, CA 2,408,775, DE 10248316.7, (ILM6)
- 3) Transcranial magnetic stimulation induction coil device and method of manufacture with a high degree of accuracy
US7998053B2

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Nexstim

A transcranial magnetic stimulation induction coil device ("TMS coil device") is manufactured to contain coil windings of a predetermined size and shape and fixedly positioned at a predetermined location within and orientation in relation to a casing of the TMS coil device. In one embodiment, the coil windings are encased in a casting at a predetermined location within and orientation in relation to the casting, and the casting is fixedly positioned at a predetermined location within and orientation in relation to the casing. The size and shape of the coil windings and the casing within, and the location and orientation of the coil windings in relation to each other and the casing of, the TMS coil device are known with a high level of precision, such that navigated brain stimulation can be performed with the TMS coil device with a high degree of accuracy.

US 7,998,053, US 13/187,582 (D1), (Nex14)

- 4) Transcranial magnetic stimulation induction coil device with attachment portion for receiving tracking device

US 7,854,232,

A transcranial magnetic stimulation ("TMS") induction coil device includes an attachment portion for attachment to a tracking device and providing that the tracking device, when attached to the TMS coil device, is at a predetermined location and orientation in relation to a casing of the TMS coil device. The casing of the TMS coil device also includes a reference point for confirming the accuracy of the attachment of the tracking device to the TMS coil device at the predetermined location and orientation in relation to the casing.

US 7,854,232, US CIP 12/944,768, (NEX13)

- 5) Coil holder, device support apparatus

US 14/093073

According to an example embodiment of the present invention, there is provided an apparatus, comprising a first arm configured to accept a device, the first arm comprising a first counterweight arrangement, a second arm supporting the first arm by a coupling, and a base defining a curve and having the second arm mounted thereon, wherein the second arm is movable along the curve, the base configured to be mounted on a chair. The second arm may be furnished with a second counterweight arrangement.

Using TMS as an example, a patient may be instructed to maintain his head immobile while a stimulating coil is moved along the outer surface of his head. If the coil is held accurately and reliably at the correct location, the stimulating effect can be aimed at a desired location inside the brain. On the other hand if the coil is inaccurately placed or accidentally moves, results of TMS are expected to be adversely affected.

US 14/093073, (NEX28)

- 6) Position-finding apparatus; Enhanced electric field arrow to guide operator to get maximal induced electric field (NEX29)

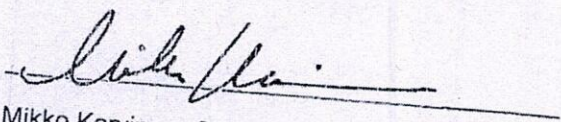
According to an example embodiment of the present invention, there is provided an apparatus comprising at least one receiver configured to receive signals relating to a position of a device

relative to a head, at least one processing core configured to determine, at least in part based on the received signals, the position of the device relative to the head, to compare the position of the device relative to the head to information concerning a position corresponding to a maximal induced electric field, and to cause signals to be transmitted, and wherein the transmitted signals are configured to cause a display to indicate a deviation of the position of the device from the position corresponding to the maximal induced electric field.
US 14/740,299, JP 2015-133191, RU 2015126354

No other manufacturer, other than **Nexstim Plc** is manufacturing the above-mentioned products having those features with clinical validation for pre-procedural planning with accuracy and reproducibility in Neurosurgery.

Yours faithfully,

on August 21, 2023



Mikko Karvinen, CEO
Nexstim Plc
Elimäenkatu 9 B, 00510 Helsinki, Finland