



NATIONAL INSTITUTE OF MENTAL HEALTH & NEURO SCIENCES
(Institute of National Importance), P.B. No. 2900, Hosur Road, Bengaluru – 560 029
Ph: 26995023 to 25 / 5090 E-mail: aaos@nimhans.ac.in
Fax: 080-26571563/26564830/2121/6811 Website: www.nimhans.ac.in/tender


STRD4/VENKAT/PSY/2020-21

20 February 2021

Subject: Purchase of Soterix transcranial Electrical Stimulation (tES) Device for Dr. Venkatasubramanian, Dept. of Psychiatry, NIMHANS (Project)

A request letter has been received from Dr. G. Venkatasubramanian from Dept. of Psychiatry for procurement of "Soterix transcranial Electrical Stimulation (tES) Device" on proprietary basis from Soterix Medical, Inc, USA.

The proprietary certificate, specification and authorization certificate of above-mentioned equipment/consumable is being uploaded on NIMHANS website for open information to invite objection, comments, if any, from any manufacturer regarding proprietary nature of the item within 14 days from the date of issue/uploading of the notification giving reference STRD4/VENKAT/PSY/2020-21. The comments should be sent to **Shri D.P. Nagaraj, Administrative Officer (Purchase) on or before 05 March 2021 up to 03:30 p.m.** failing which it will be presumed that any other vendor/company is having no comment to officer and case will be decided purely on merits.


Shri D.P. Nagaraj
Administrative Officer (Purchase)
Administrative Officer (S)

प्रशासनिक अधिकारी (एस)
National Institute of Mental Health & Neuro Sciences
Bengaluru - 560 029.

राष्ट्रीय मानसिक स्वास्थ्य एवं स्नायु विज्ञान संस्थान
Enclosures:
बंगलूरु- ५६० ०२९

1. Proprietary Certificate from Soterix Medical Inc, USA.
2. Proprietary Certificate from Dr. Venkatasubramanian, Dept. of Psychiatry.
3. Specification Sheet of the Equipment/consumable that is to be procured on proprietary basis.



SOTERIX MEDICAL, INC
ASPEN CORPORATE PARK
1480 US HIGHWAY 9 NORTH, 204
WOODBRIDGE, NJ 07095
TEL: 888-990-8327
FAX: 212-315-3232
CONTACT@SOTERIXMEDICAL.COM

February 17th, 2021

TO WHOMSOEVER IT MAY CONCERN

This letter is to confirm that High-Definition tDCS (HD-tDCS/HD-tES) is an exclusive Neuromodulation technology developed by Soterix Medical Inc. Invented at The City College of New York, it is the only technology platform that allows tolerated non-invasive delivery of therapeutic current to desired brain regions. HD-tDCS/HD-tES is currently offered via exclusive hardware: MxN (5, 9, and 32 channel active devices) and the 4x1 (4 channel passive) systems and exclusive software: HD-Targets and HD-Explore. HD-tDCS/HD-tES is made possible through innovations in electrode design allowing safe and tolerated passage of current through proprietary "High-Definition" electrodes, individualized brain current flow modeling and through patented targeting algorithms indicating how to place and energize HD-electrodes on the head.

Furthermore, HD-tDCS/HD-tES systems provided by Soterix Medical are the only tDCS/tES devices that allow complete integration options for research-grade EEG and fNIRS systems

If you require any additional information, please feel free to contact me directly.

Sincerely,

Kamran Nazim

Chief Product Officer

Soterix Medical, Inc.

Dr. G. Venkatasubramanian, MD, PhD,
डॉ. जी. वेंकटसुब्रमण्यन, एमडी, पीएचडी,
Professor & Head / प्राध्यापक और मुख्य
Department of Clinical Neurosciences
द्वितीय तंत्रिका विज्ञान विभाग
NIMHANS, बंगलूरु,
Bangalore-560029 / बंगलूरु - ५६००२९

Administrative Officer (S)

प्रशासनिक अधिकारी (एस)
National Institute of Mental Health & Neuro Sciences
Bengaluru - 560 029.

राष्ट्रीय मानसिक स्वास्थ्य एवं तंत्रिका विज्ञान संस्थान
बंगलूरु - ५६० ०२९



SOTERIX MEDICAL, INC
ASPEN CORPORATE PARK
1480 US HIGHWAY 9 NORTH, 204
WOODBIDGE, NJ 07095
TEL:888-990-8327
FAX:212-315-3232
CONTACT@SOTERIXMEDICAL.COM

TO WHOMSOEVER IT MAY CONCERN

This letter is to confirm that Soterix Medical Inc. is the worldwide exclusive provider for the sale and distribution of 1x1 tES system incorporating features like RELAX, TICKLE, and TRUECURRENT™. These features ensure subject safety, comfort and operator ease-of-use.

If you require any additional information, please feel free to contact me directly.

Sincerely,

Kamran Nazim
Chief Product Officer
Soterix Medical, Inc.

Dr. G. Venkatasubramanian, MD, PhD,
डॉ. जी. वेंकटसुब्रमण्यन, एमडी, पीएचडी,
Professor & Head / प्राध्यापक और मुख्य
Department of Clinical Neurosciences
विभाग प्रमुख, क्लिनिकल न्यूरोसाइन्सेस विभाग
NHIA/ANSA, विभाग,
Bangalore-560029 / बंगलूरु - ५६००२९

Administrative Officer (S)
प्रशासनिक अधिकारी (एस)
National Institute of Mental Health & Neuro Sciences
Bengaluru - 560029.
राष्ट्रीय मानसिक स्वास्थ्य एवं रोगों, विज्ञान संस्थान
बंगलूरु - ५६० ०२९

PROPRIETARY CERTIFICATE FORM

1. I hereby certify that the item indented for is proprietary in nature and are manufactured solely by Soterix Medical Inc., New York, USA

2. No other make or model is acceptable for the following reasons:-


Capability of delivering conventional & High-Definition tES protocols (tDCS, tACS, tRNS, tPCS, toDCS) in double-blind, sham controlled mode, Compatible with Neurotargeting Software with subject safety & comfort features (RELAX, TICKLE & TRUECURRENT).

I hereby certify to the best of my knowledge and belief that the items indented for are of proprietary manufacturers being

Soterix Medical Inc., New York, USA

And the requirement of this application will not be met by any substitute stores due to following reason – as detailed above.

Date:


19/2/2021
Signature of the Investigator

Dr. G. Venkatasubramanian

MD, Ph.D.

Professor of Psychiatry

Department of Psychiatry, NIMHANS

KMC Reg. No. : TMN19980001521KTK

Soterix transcranial Electrical Stimulation (tES) Device (Proprietary Item)

1. A Soterix tES device capable of delivering the following types of transcranial Electrical Stimulation (tES) – namely transcranial Direct Current Stimulation (tDCS), transcranial Alternating Current Stimulation (tACS), transcranial Pulsed Current Stimulation (tPCS), transcranial Random Noise Stimulation (tRNS), transcranial oscillating Direct Current Stimulation (toDCS) as per the established protocols.
2. A Soterix tES device capable of all these above-mentioned types of tES in both conventional montage as well as High-Definition (4X1) ring configuration montage.
3. Capability to save at least 5 different clinical trial study settings for any of the above mentioned tES type and deliver double-blind sham or true stimulation through numeric/alpha-numeric undisclosed codes (unique for each one of the studies).
4. User-defined configuration of sham stimulation parameters to ensure utmost optimization as per the study protocol. Feasibility of customized sham setting for each one of the different clinical trial study.
5. SMARTscan-PLUS™ algorithms to provide a simple indication of stimulation conditions that is consistent across real and sham conditions
6. Limited Total Energy (LTE™) to ensure robustness and safety-factors essential for large scale tDCS clinical trial.
7. Ability to deliver electrical current to match with prediction modelled by Neurotargeting Software.
8. Device must possess state-of-the-art in-built quality control features which do not allow the session to start below a certain quality of electrode-contact or above safe voltage limit. It must automatically halt the session whenever optimal stimulation delivery is compromised due to factors like poor quality of electrode contact with scalp, low battery, the sponge pads drying out during the course of session, the voltage exceeding prescribed safety limits, etc. (SMARTscan-PLUS™ algorithms to provide a simple indication of stimulation conditions that is consistent across real and sham stimulation conditions).
9. The device must allow the administrator to pause the on-going session to make adjustments (like adding more solution the sponge pads, repositioning of the electrodes, etc.) without having to abort the session and restart with readjustment of stimulation delivery time as this approach reduces precision and uniformity of stimulation delivery across sessions [Soterix Medical PAUSE™ to allow for controlled interruptions].
10. Compatibility with neurotargeting software to allow customizable electrode placement on case-by-case basis.
11. CE Certification
12. tES Device having been used in multi-centre clinical trials involving patients with psychiatric disorders
13. 5-Year Warranty
14. Compatibility with Indian electrical power supply standards.
15. Soterix Medical Replacement Carbon Rubber Electrode Set
16. Soterix Medical EASYpads (5 cm x 7cm)
17. Soterix Medical EASYstrap
18. High-Definition (HD) Ring Electrodes (12 mm), HD Electrode Holder, HD Gel, HD Cap
19. Minimum 5 Peer-reviewed, PubMed Indexed Publication in Psychiatric Disorders
20. Other mandatory accessories to ensure turnkey operation
21. Availability of technical experts to implement training & continued support during the implementation of clinical trial for the warranty period of 5 years.