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Urgent Field Safety Notice

Neuro Omega system,
DATE 04-Sep-2018
Field Advisory Note [FAN]

Attention: //////////////////////////////////

Details on affected devices:

Neuro Omega system with:

Catalogue number: (Neuro Omega) NOM-000000-00 + (Drive) 750-000020-00 + (EMG) 750-000010-00 + (EEG) 750-000010-12

Software version number: Any

Description of the problem:

In case Neuro Omega EMG/ECOG “Global stimulation return” connector of the Headbox is not properly connected, stimulation current may return through the Microelectrodes’ contacts (Micro and Macro). Current can reach high charge density which may cause tissue harm.

Advise on action to be taken by the user:

Do not perform cortical stimulation (by ECOG Headbox) or peripheral nerves stimulation (by EMG Headbox) while deep electrode is connected. Disconnect MER cable from drive while stimulating from EMG/ECOG Headbox.

Alpha Omega is working to provide proper solution that will allow safe use of MER and cortical/ peripheral nerves stimulation simultaneously, and will advise about the solution as soon as it's available

Transmission of this Field Safety Notice:

1. Alpha Omega's distributors, product managers, field applications and service engineers
2. Alpha Omega's Authorized Representative and agents
3. Relevant competent authorities
4. EU notified Body

Contact reference person:

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The undersigned confirms that this notice has been notified the appropriate Regulatory Agencies:
FDA, Health Canada, Europe

Please confirm receiving this Field Advisory Note, in writing or by Return Email to the above reference person.

Questions or clarification thru your contact person for Alpha Omega North America, Alpha Omega Europe or one Alpha Omega distributors.

Signature

Maysana Mousa

QA RA Manager