Electrical safety assessment of a prototype device for electromagnetic stimulation of the ear in patients with tinnitus

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ABSTRACT:

Aim: The aim of the study was to evaluate the results of electrical safety results of a prototype electromagnetic ear stimulation device in patients with tinnitus.

Material and methods: The electrical safety tests of the prototype device for electro- and magnetostimulation of the hearing organ were carried out at the Center for Attestation and Certification Tests in Gliwice. The tests concerned selected parameters including the PN-EN standard.

Results: Safety studies of the prototype electrical stimulation device for the ear in patients with tinnitus were necessary to perform the planned further preclinical studies. Obtained results regarding: identification and labeling of the device; protection against electric shock; checking protective earthing, functional earthing and potential equalization; checking the leakage current and auxiliary currents of the patient; checking the distances through the solid insulation and the use of thin insulating spacers; checking the electrical strength of the device insulation; checking protection against mechanical hazards of the device; checking the risk associated with surfaces, corners and edges, and checking the protection against excessive temperatures and other threats comply with the standard PN-EN.

Conclusions: No risk to the patient and medical staff. Tests of protection against mechanical hazards of the device have shown that the only movable part whose contact with the patient could cause an unacceptable risk is the fan installed inside the housing.

KEYWORDS: ear stimulation, electrical safety, prototype device, tinnitus

ABBREVIATIONS

TMS – transcranial magnetic stimulation
URPL – Office for Registration of Medicinal Products

INTRODUCTION

Implementing electrical stimulation of the ear in the treatment of tinnitus has been studied since the 1970s. Currently, available literature provides various hypotheses explaining the beneficial influence of electrical stimulation of the ear on tinnitus [1, 2].

For example, Portmann et al. [1] focused on the modification of electrical potential in the cochlea, while Watanabe et al. [2] emphasized the role of improved blood flow inside the inner ear or the synchronization of impulse discharge in auditory nerve fibers.

Transcranial magnetic stimulation (TMS) has been known in medicine for several decades as a non-invasive method allowing for modulation of cortical excitability, which is why it has recently drawn more attention. Thanks to its influence on the cerebral cortex, it may serve as a therapeutic tool in the management of a great variety of neuropsychiatric disorders [3–5].

Numerous clinical studies have demonstrated the effectiveness of transcranial magnetic stimulation of the temporal lobe in the treatment of tinnitus [6].

Animal model of tinnitus (involving cochlear damage induced by exposure to noise or administration of ototoxic drugs) allowed for a detailed analysis of the effects that electrical stimulation has on cochlear hair cells and other segments of the auditory pathway. Electrical stimulation proved to have a positive influence both on the ear structures and behavioral manifestations of tinnitus in animals [7–9].

Positron emission tomography has shown that TMS with a double-cone coil can modulate the activity of deeper brain structures, as well as brain areas located more peripherally than the targeted region [10, 11].

**RESULTS**

Identification and marking of the device demonstrated:

- readability of marking from a 1-m distance;
- loss of readability after rubbing the marking with distilled water, ethyl spirit (90%) and isopropyl alcohol;
- the size of the device allows for placing complete markings on it;
- the ISO 7000-1641 symbol is placed on the product nameplate;

This innovative prototype device for electromagnetic stimulation of the ear was designed and constructed specifically for the diagnosis and treatment of subjective tinnitus in our Clinic.

The design of our device is based on many years of the authors’ experience in the field of tinnitus treatment with ear stimulation [12].

Previous studies evaluated the electromagnetic compatibility of a prototype device for ear stimulation in patients suffering from tinnitus [13].

The aim of this study is to assess the electrical safety of a prototype device for electromagnetic stimulation of the ear in patients with tinnitus.

**MATERIALS AND METHODS**

The prototype device for electrical and magnetic stimulation of the ear in clinical setting consists of the following elements: computer program, stimulator, earphone equipped with an electrode for stimulation and magnetic field micro-exciters.

### Tab. I. Results from testing of the patient leakage current and patient auxiliary current

<table>
<thead>
<tr>
<th>TYPE OF MEASURED CURRENT AND CONFIGURATION OF SWITCHES</th>
<th>LEAKAGE CURRENT - ELECTRICAL STIMULATION</th>
<th>VOLTAGE [V]</th>
<th>FREQUENCY [HZ]</th>
<th>CURRENT MEASUREMENT BEFORE MOISTURIZING [µA]</th>
<th>CURRENT MEASUREMENT AFTER MOISTURISING [µA]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contact current</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(S1 = 1, S5 = 1, S7 = 1, S12 = 1)</td>
<td></td>
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<td></td>
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<tr>
<td>(S1 = 1, S5 = 0, S7 = 0, S12 = 1)</td>
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</tbody>
</table>

**Tab. II. Results of distance through solid insulation testing and the use of thin insulation spacers (requirements in accordance with Table 11 of the applicable standard).**

<table>
<thead>
<tr>
<th>MEASUREMENT SITE ACCORDING TO THE ELECTRIC SHOCK PROTECTION DIAGRAM</th>
<th>VOLTAGE</th>
<th>SUPERFICIAL REQUIRED VALUE</th>
<th>MEASURED VALUE</th>
</tr>
</thead>
<tbody>
<tr>
<td>AC power socket</td>
<td>13 V DC</td>
<td>0.8</td>
<td>3.65</td>
</tr>
<tr>
<td>AC plug</td>
<td>13 V DC</td>
<td>0.8</td>
<td>4.15</td>
</tr>
</tbody>
</table>

**Tab. III. Results of distance through solid insulation testing and the use of thin insulation spacers (requirements in accordance with Table 16 of the applicable standard).**

<table>
<thead>
<tr>
<th>MEASUREMENT SITE ACCORDING TO THE ELECTRIC SHOCK PROTECTION DIAGRAM</th>
<th>VOLTAGE</th>
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<th>MEASURED VALUE</th>
</tr>
</thead>
<tbody>
<tr>
<td>AC power socket</td>
<td>13 V DC</td>
<td>1.9</td>
<td>3.65</td>
</tr>
<tr>
<td>AC plug</td>
<td>13 V DC</td>
<td>1.9</td>
<td>4.15</td>
</tr>
</tbody>
</table>

Electrical safety tests of the prototype device for electromagnetic stimulation of the ear were conducted at the Attestation and Certification Research Center in Gliwice as part of the concluded agreement.

Testing of hazards associated with surfaces, corners, and edges found that:

- the examined device has no sharp edges;
- the device maintains balance when placed on a surface tilted from the horizontal plane by a 10-degree angle, when tested in its transport position;
- the device is labeled with the ISO 7010-PO18 “do not sit down on the device” marking placed on its side wall.

The results of testing for protection against high temperatures and other hazards comply with the PN-EN standard.

DISCUSSION

Owing to the Authors’ own clinical experience, the device is able to meet even the most individualized needs of patients in terms of treatment, providing them with the ability to precisely adjust the therapeutic stimulus. Stimulation of the ear allows us to act on the very cause of tinnitus. Moreover, our previous research has demonstrated that when the stimulus is delivered in the described way, it can also modulate the bioelectrical activity of the brain which undergoes secondary abnormal changes in patients suffering from tinnitus [14].

Testing the electrical safety of a prototype device for electromagnetic stimulation of the ear in patients with tinnitus was a necessary step in order to commence preclinical studies which have already been planned.

Protection against electric shock testing showed that: the AKM65US15 power supply provided by the XP Power meets the IEC 60601-1 standard; the device housing is made of plastic; separation from the power supply is achieved with the use of an AC adapter compliant with the applicable standard; the maximum voltage for the device part separated from the power supply is 13V DC; a Lemo connector from the Redel P series was used (the connector design the applicable standard).

Testing of the patient leakage current and patient auxiliary current are presented in Tab. I.

Protection against mechanical hazards testing conducted for our device revealed that:

- the only moving part which could cause an unacceptable risk when coming in contact with the patient or the operator, is the fan installed inside the device housing. However, access to the fan is protected by the device housing, as well as the protective mesh secured with screws;
- the metal fan case is characterized by a solid construction (therefore this part does not create any additional unacceptable risk).

Testing of hazards associated with surfaces, corners, and edges, as well as testing for protection against high temperatures, were all found to comply with the PN-EN standard.

The obtained results regarding: identification and labeling of the device; protection against electric shock; verifying protective and functional grounding, as well as potential equalization; identifying the patient leakage current and patient auxiliary current; looking for gaps within the device solid insulation; checking the electrical resistance of the device insulation; examining protection against mechanical hazards; identifying hazards associated with surfaces, corners and edges, as well as testing for protection against high temperatures, were all found to comply with the PN-EN standard.

Positive results of electrical safety assessment of a prototype device for electromagnetic stimulation of the ear in patients with tinnitus found that:

- the device is equipped with an AC power adapter, electrodes for both magnetic and electrical conduction (described in the device documentation);
- the AC power adapter uses the AKM65US15 power supply produced by Power, which meets the IEC 60601-1 standard and is used to charge the internal battery;
- lithium-ion battery type RRC2140 produced by RRC Power meets the IEC 61133 standard;
- the on “I”/off “O” switch is located on the side wall of the device (the switch marking is clearly defined);
- parameters may be adjusted on the device;
- the ISO 7000-0434A symbol is placed on the device;
- the appliance is protected by Class III insulation – while operating, it is powered by an internal source (during battery charging, the device is separated from the power grid with the use of an AC adapter which fulfills the requirements of this standard).

Protection against electric shock testing showed that: the AKM65US1565 power supply provided by the XP Power meets the IEC 60601-1 standard; the device housing is made of plastic; separation from the power supply is achieved with the use of an AC adapter compliant with the applicable standard; the maximum voltage for the device part separated from the power supply is 13V DC; a Lemo connector from the Redel P series was used (the connector design the applicable standard).

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<table>
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<tr>
<th>MEASUREMENT SITE</th>
<th>INSULATION TYPE</th>
<th>RATED VOLTAGE</th>
<th>TESTING VOLTAGE</th>
<th>MEASUREMENT</th>
<th>MEASUREMENT RESULT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device housing – one MOOP protection from the 5V power supply</td>
<td>Basic</td>
<td>13 V</td>
<td>500 V</td>
<td>BW</td>
<td>BW</td>
</tr>
<tr>
<td>Device housing – one MOOP protection from the power grid</td>
<td>Double</td>
<td>230 V</td>
<td>4000 V</td>
<td>BW</td>
<td>BW</td>
</tr>
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Tinnitus have enabled us to perform preclinical studies which were then published [14, 15].

The innovative prototype device responds to a major clinical demand and thanks to the European patent it was granted (January 27, 2021, European Patent Office, No. 3498166), it also presents a very promising potential for commercialization.

The prototype device for electrical and magnetic stimulation of the ear is classified as class IIA medical device in accordance with classification rule 9 of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017.

Having obtained consent from the Office for Registration of Medicinal Products (URPL) of the Republic of Poland, we designed randomized double-blind clinical trials involving a large population of 300 patients with subjective tinnitus.

Conducting these studies is a necessary step in order to register the prototype device as a medicinal product.

CONCLUSIONS

1. The results of electrical safety assessment of a prototype device for electromagnetic stimulation of the ear in patients with tinnitus were found to comply with the PN-EN standard and no unacceptable risk for the patient and medical staff was identified.

2. Protection against mechanical hazards testing has demonstrated that the only moving part which could cause an unacceptable risk when coming in contact with the patient or the operator, is the fan installed inside the device housing. However, access to the fan is protected by the device housing, as well as the protective mesh secured with screws.

REFERENCES


