Evaluation the results of electromagnetic compatibility of a prototype device for ear stimulation in patients with tinnitus

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ABSTRACT:

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

Material and methods: The electromagnetic compatibility tests of the prototype device for electro- and magnetostimulation of the hearing organ were carried out at the Center for Attestation and Certification Tests OBAC Sp. z o. o. in Gliwice in 2020. The following product standards were used: PN-EN 60601-1-2:2015-11 – medical electrical equipment (general requirements for basic safety and essential functioning; PN-EN 55011:2012 - industrial, scientific and medical equipment [characteristics of radio frequency disturbances] ) PN-EN 61000-3-2:2014-10 – electromagnetic compatibility (EMC), permissible levels of harmonic current emissions (phase load current ≤ 16 A).

Results: The level of expanded uncertainty in the measurement of conducted disturbances in the range of 0.150–30MHz does not exceed the level specified in the PN-EN-55016-4-2:2011 standard. In the study of the emission of radiated disturbances up to 1GHz in the frequency range of 30–1000MHz (PN-EN 55011:2012 standard), it was found that the setting of the EUT during the tests was in accordance with the requirements of the standard. The level of expanded uncertainty in the measurement of radiated disturbances in the 30–1000MHz range does not exceed the level specified in the PN-EN 55016–4-2:2011 standard. The measured current harmonic levels (phase power supply current ≤16A) with a frequency range of 50Hz–2kHz do not exceed the permissible levels specified in the PN-EN 61000-3-2:2014-10 standard. The test of resistance to the magnetic field at the frequency of the power grid (PN-EN 61000-4-8: 2010 standard also showed that the setting of the EUT during the tests was in accordance with the requirements of the standard and the result was positive.

Conclusions: Testing of immunity to radiated radio frequency electromagnetic field (PN-EN 61000-4-3:2007 +A1:2008+A2:2011 standard) and testing of resistance to magnetic field at power frequency (PN-EN 61000-4-8 standard: 2010) did not exceed the level specified in the standard and showed a positive result. The measured harmonic levels of the network current (phase supply current ≤16A) with the frequency range 50Hz–2kHz do not exceed the permissible levels specified in the PN-EN 61000-3-2:2014-10 standard for a class A device.

KEYWORDS: ear stimulation, electromagnetic compatibility, prototype device, tinnitus

ABBREVIATIONS

EMC – Electromagnetic compatibility
EPO – European Patent Office
RF – radiofrequency
TMS – Transcranial magnetic stimulation

INTRODUCTION

Transcranial magnetic stimulation (TMS) has been used in medicine as a non-invasive method affecting the excitability of the cerebral cortex for several decades, gaining increasing attention as a therapeutic tool in a wide range of neuropsychiatric disorders [1–3]. Repetitive transcranial magnetic stimulation at low frequencies, such as 1 Hz, effectively reduces cortical activity, particularly within the areas of increased excitability.

Numerous clinical studies have demonstrated the efficacy of transcranial magnetic stimulation of the temporal lobe as the method for the treatment of tinnitus [4–7]. Typically, TMS is applied using a figure-eight-shaped coil placed in the temporal region. The method directly affects the activity of superficial cortical areas while also exerting indirect effects on areas in functional connection with the areas subject to stimulation, such as the thalamus. As shown by positron emission tomography scans, TMS using a dual conical coil is also capable...
of modulating the activity of deeper brain structures as well as those located more peripherally from the stimulated areas [8–9].

Electric and magnetic stimulation of the ear targets the structures responsible for the development of tinnitus, most frequently found within the inner ear (cochlea).

The prototype device is designed for electro- and magnetostimulation of the auditory organ in patients with tinnitus as well as for expanding the range of available options for the diagnostics of the auditory organ and tinnitus in this group of patients. The device facilitates extensive control of the parameters of stimulation allowing for individualized selection of stimulation conditions. The stimulator is a battery-powered device which generates user-defined electrical signals.

An innovative prototype device for electro- and magnetostimulation of the ear had been specially designed and constructed for the diagnosis and treatment of subjective tinnitus at the Department of Otolaryngology, Laryngological Oncology, Audiology and Phoniatrics of the Medical University of Lodz (with contribution from the Technical University of Lodz). A computer program working with the device, facilitated individualized design of therapeutic stimuli (electric or magnetic pulse waveforms) as tailored to the patient’s tinnitus. Thanks to the non-invasive nature of the procedure, stimulations can be repeated to create a cycle of treatments for a cumulative effect involving neuroplastic and neuromodulatory changes.

The development of the device design was preceded by many years of experience in ear stimulation being used to treat tinnitus [10]. Owing to this experience, the device answers the highly individualized therapeutic needs of patients by providing the opportunity to customize the therapeutic stimulus. Ear stimulation affects the factors responsible for tinnitus, with our studies to date showing that when administering a stimulus through this route, we are also able to modulate the bioelectric activity of the brain, which is usually subject to secondary pathological alterations in tinnitus patients.

The aim of the study was to evaluate the results of electromagnetic compatibility of a prototype ear stimulation device for use in patients with tinnitus.

**MATERIAL AND METHODS**

Electromagnetic compatibility tests of a prototype device for electro- and magnetostimulation of the hearing organ (Fig. 1.–2.) were carried out in 2020 at the Institute for Research, Attestation, and Certification OBAC Ltd. in Gliwice.

The following product standards were used:

• PN-EN 55011:2012 – Industrial, scientific and medical equipment – Radio-frequency disturbance characteristics – Limits and methods of measurement;

The following tests were carried out as per the primary standards:

• PN-EN 61000-4-8:2010 – Electromagnetic compatibility (EMC) – Part 4–8: Testing and measurement techniques – Power frequency magnetic field immunity test.

Additional commissioned examinations included:

• measurement of electromagnetic disturbance voltage at the AC power supply connection – as per the PN-EN 55011:2012 standard;
• measurement of radiated electromagnetic disturbances [30–1000 MHz] – as per the PN-EN 55011:2012 standard;
• measurement of mains harmonic current emissions – as per the PN-EN 61000-3-2:2014 standard;
• immunity to radiofrequency (RF) radiated disturbances – as per the PN-EN 61000-4-3:2007+A1:2008+A2:2011 standard;
• immunity to power frequency magnetic field – as per the PN-EN 61000-4-8:2010 (Fig. 3.).

RESULTS

Examination of conducted disturbances within the frequency range of 0,15–30MHz (as per the PN-EN 55011:2012 standard) revealed that the EUT setting during the tests was in accordance with the requirements of the standard. The surveillance of the EUT was carried out visually by constant observation. The device was operating in the battery charging mode.

The measurement uncertainty for the measurement range of 0.15–30 MHz at the measurement lab was established as $U_{\text{lab}} = 3.44$ dB. Extension coefficient = 2. Uncertainty level: approximately 95%. The level of expanded uncertainty in relation to the measurement of conducted disturbances within the range of 0.150–30MHz does not exceed the level specified in the PN-EN-55016-4-2:2011 standard (Fig. 4.). The level of disturbances as emitted by the EUT did not exceed the maximum permissible level which means that a positive result was obtained.

Examination of radiated disturbances up to 1GHz within the frequency range of 30–1000MHz (as per the PN-EN 55011:2012 standard) revealed that the EUT setting during the tests was in accordance with the requirements of the standard. The measurement was made with a receiver complete with a peak detector (initial scan) and a quasi-peak detector (final scan). The results of the measurement correspond to the maximum emission during the test, taking into account the changes in:

- the height of the antenna above the reference ground (range of 1–4 m);
- azimuth (0–360° rotation of the measuring table);
- polarization of the antenna (horizontal vs vertical).

During the tests, the device was operating in the electrostimulation and magnetostimulation mode.

The measurement uncertainty for the measurement range of 30–200 MHz at horizontal polarization was established as $U_{\text{lab}} = 5.06$ dB. The measurement uncertainty for the measurement range of 30–200 MHz at vertical polarization was established as $U_{\text{lab}} = 5.17$ dB. The measurement uncertainty for the measurement range of 200–1000 MHz at horizontal polarization was established as $U_{\text{lab}} = 5.34$ dB. The measurement uncertainty for the measurement range of 200–1000 MHz at vertical polarization was established as $U_{\text{lab}} = 6.29$ dB. Extension coefficient = 2. Uncertainty level: approximately 95%. The level of expanded uncertainty in relation to the measurement of radiated disturbances within the range of 30–1000MHz does not exceed the level specified in the PN-EN 55016-4-2:2011 standard (Fig. 5.).
The following results were obtained:

- the level of expanded uncertainty in relation to the measurement of conducted disturbances within the range of 0.150–30MHz does not exceed the level specified in the PN-EN-55016-4-2:2011 standard;
- examination of radiated disturbances up to 1 GHz within the frequency range of 30–1000 MHz (as per the PN-EN 55011:2012 standard) revealed that the EUT setting during the tests was in accordance with the requirements of the standard;
- the level of expanded uncertainty in relation to the measurement of radiated disturbances within the range of 30–1000 MHz does not exceed the level specified in the PN-EN 55016-4-2:2011 standard;
- the measured levels of harmonic current (phase supply current ≤16 A) with a frequency range of 50 Hz–2 kHz were positive as they did not exceed the permissible levels as specified in PN-EN 61000-3-2:2014-10 for a class IIA device;
- examination of immunity to power frequency magnetic field (as per the PN-EN 61000-4-8:2010 standard) also revealed that the EUT setting during the test was in accordance with the requirements of the standard, translating to a positive test result.

The obtained positive results of electromagnetic compatibility studies for the prototype ear stimulation device for use in patients with tinnitus have facilitated the conduct of preclinical studies as presented in the other publications [11, 12].

The preliminary results of these studies are suggestive of the high effectiveness of magnetostimulation as delivered using the prototype ear electrostimulation device in the treatment of tinnitus. No negative effect of stimulation on the hearing and tinnitus could be observed.

The innovative prototype device responds to huge clinical demand while also having great marketing potential owing to the European patent no. 3498166 as granted on 27 January 2021 by the European Patent Office (EPO).

The patent has been validated in the following European countries: Germany, France, United Kingdom, Italy, and Poland.

The prototype device for electro- and magnetostimulation of the ear has been classified as a Class IIA medical device in accordance with Rule 9 of the classification according to Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017.

After obtaining the relevant approval from the Office for Registration of Medicinal Products (URPL) of the Republic of Poland, a randomized, double-blind and placebo-controlled clinical trial to be carried out in a large population of 300 patients with subjective tinnitus was scheduled for the period of 01.12.2021 through 28.02.2026.

This trial is necessary for the registration of the prototype device as a medicinal product.
CONCLUSIONS

1. The results of the radiated radiofrequency electromagnetic field immunity test (as per the PN-EN 61000-4-3:2007+A1:2008+A2:2011 standard) and the power frequency magnetic field immunity test (as per the PN-EN 61000-4-8:2010 standard) were positive as they did not exceed the levels specified in the standards.

2. The measured levels of mains harmonic current (phase supply current ≤16 A) with a frequency range of 50 Hz–2 kHz were positive as they did not exceed the permissible levels as specified in PN-EN 61000-3-2:2014-10 for a class IIA device.

3. On the basis of the conducted electromagnetic compatibility studies, the prototype device for electro- and magnetostimulation of the ear has been classified as a Class IIA medical device in accordance with Rule 9 of the classification according to Regulation (EU) 2017/745 of the European Parliament and of the Council.

REFERENCES


