

**Elektroakustika. Kuuldeaparaadid. Osa 13:
Elektromagnetiline ühilduvus (EMC)**

Electroacoustics – Hearing aids Part 13: Electromagnetic compatibility (EMC)

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN 60118-13:2011 sisaldab Euroopa standardi EN 60118-13:2011 ingliskeelset teksti.

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English version

**Electroacoustics -
Hearing aids -
Part 13: Electromagnetic compatibility (EMC)
(IEC 60118-13:2011)**

Electroacoustique -
Appareils de correction auditive -
Partie 13: Compatibilité électromagnétique
(CEM)
(CEI 60118-13:2011)

Akustik -
Hörgeräte -
Teil 13: Elektromagnetische
Verträglichkeit (EMV)
(IEC 60118-13:2011)

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Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CENELEC member.

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CENELEC

European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

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Foreword

The text of document 29/737/FDIS, future edition 3 of IEC 60118-13, prepared by IEC TC 29, Electroacoustics, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 60118-13 on 2011-05-16.

This European Standard supersedes EN 60118-13:2005.

EN 60118-13:2011 introduces a new set of requirements for use of hearing aids with mobile phones.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN and CENELEC shall not be held responsible for identifying any or all such patent rights.

The following dates were fixed:

- | | | |
|--|-------|------------|
| – latest date by which the EN has to be implemented at national level by publication of an identical national standard or by endorsement | (dop) | 2012-02-16 |
| – latest date by which the national standards conflicting with the EN have to be withdrawn | (dow) | 2014-05-16 |

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and covers essential requirements of EC Directive MDD (93/42/EEC). See Annex ZZ.

Annexes ZA and ZZ have been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 60118-13:2011 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following note has to be added for the standard indicated:

| | |
|-------------|--------------------------------|
| IEC 60118-4 | NOTE Harmonized as EN 60118-4. |
|-------------|--------------------------------|

Annex ZA (normative)

Normative references to international publications with their corresponding European publications

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE When an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

| <u>Publication</u> | <u>Year</u> | <u>Title</u> | <u>EN/HD</u> | <u>Year</u> |
|--------------------|-------------|---|---------------|-------------|
| IEC 60118-0 | - | Hearing aids - Part 0: Measurement of electroacoustical characteristics | EN 60118-0 | - |
| IEC 60118-2 | - | Hearing aids - Part 2: Hearing aids with automatic gain control circuits | EN 60118-2 | - |
| IEC 60118-7 | - | Electroacoustics - Hearing aids - Part 7: Measurement of the performance characteristics of hearing aids for production, supply and delivery quality assurance purposes | EN 60118-7 | - |
| IEC 60318-4 | - | Electroacoustics - Simulators of human head and ear - Part 4: Occluded-ear simulator for the measurement of earphones coupled to the ear by means of ear inserts | EN 60318-4 | - |
| IEC 60318-5 | - | Electroacoustics - Simulators of human head and ear - Part 5: 2 cm ³ coupler for the measurement of hearing aids and earphones coupled to the ear by means of ear inserts | EN 60318-5 | - |
| IEC 61000-4-3 | - | Electromagnetic compatibility (EMC) - Part 4-3: Testing and measurement techniques - Radiated, radio-frequency, electromagnetic field immunity test | EN 61000-4-3 | - |
| IEC 61000-4-20 | - | Electromagnetic compatibility (EMC) - Part 4-20: Testing and measurement techniques - Emission and immunity testing in transverse electromagnetic (TEM) waveguides | EN 61000-4-20 | - |

Annex ZZ (informative)

Coverage of Essential Requirements of EC Directives

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and within its scope the standard covers only the following essential requirements out of those given in Annex I of the EC Directive 93/42/EEC:

- ER 3, only for the aspect of electromagnetic compatibility for performance.

Compliance with this standard provides one means of conformity with the specified essential requirements of the Directive concerned.

WARNING: Other requirements and other EC Directives may be applicable to the products falling within the scope of this standard.

CONTENTS

| | |
|--|----|
| FOREWORD..... | 3 |
| INTRODUCTION..... | 5 |
| 1 Scope..... | 7 |
| 2 Normative references | 7 |
| 3 Terms and definitions | 8 |
| 4 Requirements for immunity | 9 |
| 5 Immunity test procedures | 10 |
| 6 Measurement uncertainty | 13 |
| Annex A (informative) Background for establishing test methods, performance criteria and test levels | 15 |
| Bibliography..... | 20 |
| Figure 1 – Example of a test arrangement for hearing aid immunity measurements using a one-port TEM cell (asymmetric septum)..... | 11 |
| Figure 2 – Examples of input-output response curves at 1 000 Hz and the determination of gain at an input level of 55 dB..... | 12 |
| Figure 3 – Positioning of hearing aid during RF exposure | 12 |
| Figure 4 – Examples of determination of IRIL by electromagnetic immunity (EMI) testing | 13 |
| Figure A.1 – Ratio of 1:2 between field strength and interference level in dB | 16 |
| Figure A.2 – Example of test arrangement for hearing aid immunity measurements using dipole antenna..... | 18 |
| Figure A.3 – Digital wireless devices antenna designs | 19 |
| Table 1 – Field strengths of RF test signals to be used to establish immunity for bystander compatible and user compatible hearing aids | 9 |

INTRODUCTION

This standard introduces specifications for EMC requirements for hearing aids.

Hearing aids basically consist of a microphone, an amplifier, a induction pick-up coil and a small earphone (receiver). For behind the ear (BTE) hearing aids the sound is often fed to the ear canal by means of an individually made ear mould (ear insert). In the ear (ITE) hearing aids have the active circuitry located in the auditory canal.

The power source normally used is a small battery. On some hearing aids, the user can perform some adjustments of the controls of the hearing aid, which in some cases is by means of a remote control.

The standard only deals with hearing aid immunity, as experience has shown that hearing aids do not emit electromagnetic signals to an extent that can disturb other equipment. Other EMC phenomena, such as RF emission and electrostatic discharge, are not currently known to be a significant problem in connection with hearing aids. Based on new knowledge, they could be considered in connection with future revisions or extensions of this standard. Hearing aids containing RF transmitting equipment are covered by this standard regarding immunity, however the RF transmitting equipment is not covered. Experience in connection with the use of hearing aids in recent times has identified digital wireless devices, such as DECT wireless phones and GSM mobile phones as potential sources of disturbance for hearing aids. Interference in hearing aids depends on the emitted power from the wireless telephone as well as the immunity of the hearing aid. The performance criteria in this standard will not totally ensure hearing aid users interference- and noise-free use of wireless telephones but will establish useable conditions in most situations. In practice a hearing aid user, when using a digital wireless device, will seek, if possible, to find a position on the ear which gives a minimum or no interference in the hearing aid.

Hearing aids are battery powered devices, and therefore disturbances related to a.c. or d.c. power inputs are not relevant and are therefore not considered in this standard.

Hearing aids whose outputs are non-acoustic, e.g. cochlear implants and bone conduction hearing aids, are not covered by this standard.

In some cases, hearing aids are connected to other equipment by cable, but this standard does not cover common mode transients and common mode surges on such cable connections.

Based on experience in connection with the use of hearing aids, relevant sources of disturbance for hearing aids include low frequency radiated magnetic fields, which may interact with the induction pick-up coil input included in some hearing aids. As the induction pick-up coil input is an intended feature of some hearing aids, and the hearing aid therefore must have a certain sensitivity to low frequency magnetic fields, it is not relevant to specify immunity against disturbing low frequency magnetic fields. To avoid unintended interference from low frequency magnetic noise fields, the recommendations specified in IEC 60118-4 [1]¹, regarding specifications for induction loop systems, should be followed.

With regard to high frequency radiated electromagnetic fields originating from RF wireless devices such as digital mobile telephone systems, only sources of disturbance which are currently known to be a problem in connection with hearing aids are covered. Reference is made to IEC 61000-4-3, which identifies digital radio telephone systems operating in the frequency ranges 0,8 GHz to 0,96 GHz and 1,4 GHz to 2,48 GHz to be potential sources of interference. Future versions may add tests for other frequency bands, as they come into more common use. Hearing aids are used in all environments as outlined in IEC 61000-4-3.

¹ Figures in square brackets refer to the bibliography.

Various test methods have been considered for determining the immunity of hearing aids. When a wireless telephone is used close to a hearing aid, there is an RF near-field illumination of the hearing aid. However, validation investigations in preparing this standard have shown that it is possible to establish a correlation between the measured far-field immunity level and the immunity level experienced by an actual hearing aid used in conjunction with a digital wireless device. The use of a far-field test has shown high reproducibility, and is considered sufficient to verify and express the immunity of hearing aids. Near-field illumination of the hearing aid (i.e. by generating an RF field using a dipole antenna) could however bring valuable information during design and development of hearing aids.

ELECTROACOUSTICS – HEARING AIDS –

Part 13: Electromagnetic compatibility (EMC)

1 Scope

This part of IEC 60118 in principle covers all relevant EMC phenomena for hearing aids. EMC phenomena, such as RF emission and electrostatic discharge, are not currently known to be a significant problem in connection with hearing aids and are therefore not dealt with. Based on new knowledge, they could be considered in connection with future revisions or extensions of this standard. Hearing aid immunity to high frequency electromagnetic fields originating from digital wireless devices operating in the frequency ranges 0,8 GHz to 0,96 GHz and 1,4 GHz to 2,48 GHz is currently identified as the only relevant EMC phenomenon regarding hearing aids. Future editions of this part of IEC 60118 may add tests for other frequency bands, as they come into more common use. IEC 61000-4-3 is the basis for relevant EMC tests to be conducted on hearing aids. Measurement methods and acceptance levels are described in this part of IEC 60118.

For the purpose of this part of IEC 60118, two immunity classes of hearing aids are defined (see 3.1) related to their use. "Bystander compatible" ensures that a hearing aid is usable in environments where digital wireless devices are in operation in the proximity of the hearing aid wearer. "User compatible" hearing aids ensures that a hearing aid is usable when the wearer is using a digital wireless device at the wearer's own aided ear.

Measurement methods for hearing aids with non-acoustic outputs and for hearing aids connected to other equipment by cables are not given in this standard.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

IEC 60118-0, *Hearing aids – Part 0: Measurement of electroacoustical characteristics*

IEC 60118-2, *Hearing aids – Part 2: Hearing aids with automatic gain control circuits*

IEC 60118-7, *Electroacoustics – Hearing aids – Part 7: Measurement of the performance characteristics of hearing aids for production, supply and delivery quality assurance purposes*

IEC 60318-4, *Electroacoustics – Simulators of human head and ear – Part 4: Occluded-ear simulator for the measurement of earphones coupled to the ear by means of ear inserts*

IEC 60318-5, *Electroacoustics – Simulators of human head and ear – Part 5: 2 cm³ coupler for the measurement of hearing aids and earphones coupled to the ear by means of ear inserts*

IEC 61000-4-3, *Electromagnetic compatibility (EMC) – Part 4-3: Testing and measurement techniques – Radiated, radio-frequency, electromagnetic field immunity test*

IEC 61000-4-20, *Electromagnetic compatibility (EMC) – Part 4-20: Testing and measurement techniques – Emission and immunity testing in transverse electromagnetic (TEM) waveguides*