ICS 17.140.50, 33.100.20 SLOVENSKÁ TECHNICKÁ NORMA Júl 2020

STN	**Elektroakustika Sluchové protézy Časť 13: Požiadavky a metódy merania odolnosti voči elektromagnetickému rušeniu digitálnych mobilných bezdrôtových prístrojov**	**STN EN IEC 60118-13 36 8860**

Electroacoustics - Hearing aids - Part 13: Requirements and methods of measurement for electromagnetic immunity to mobile digital wireless devices

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 06/20

Obsahuje: EN IEC 60118-13:2020, IEC 60118-13:2019

Oznámením tejto normy sa od 19.02.2023 ruší
STN EN 60118-13 (36 8860) z decembra 2011

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN IEC 60118-13

April 2020

ICS 17.140.50; 33.100.20

Supersedes EN 60118-13:2011 and all of its amendments and corrigenda (if any)

English Version

Electroacoustics - Hearing aids - Part 13: Requirements and methods of measurement for electromagnetic immunity to mobile digital wireless devices (IEC 60118-13:2019)

Électroacoustique - Appareils de correction auditive - Partie 13: Exigences et méthodes de mesure de l'immunité électromagnétique aux appareils numériques mobiles sans fil (IEC 60118-13:2019)

Elektroakustik - Hörgeräte - Teil 13: Elektromagnetische Verträglichkeit (EMV), Störfestigkeit gegen digitale Mobilfunkgeräte (IEC 60118-13:2019)

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

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

EN IEC 60118-13:2020 (E)

European foreword

The text of document 29/1024/FDIS, future edition 5 of IEC 60118-13, prepared by IEC/TC 29 "Electroacoustics" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN IEC 60118-13:2020.

The following dates are fixed:

- latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2020-11-19
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2023-02-19

This document supersedes EN 60118-13:2011 and all of its amendments and corrigenda (if any).

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

This document has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For the relationship with EU Directive(s) see informative Annex ZZ, which is an integral part of this document.

Endorsement notice

The text of the International Standard IEC 60118-13:2019 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following notes have to be added for the standards indicated:

IEC 60118-4	NOTE	Harmonized as EN 60118-4
IEC 60118-7	NOTE	Harmonized as EN 60118-7
IEC 60118-15	NOTE	Harmonized as EN 60118-15
IEC 60601-1-2	NOTE	Harmonized as EN 60601-1-2
IEC 61000-4-2	NOTE	Harmonized as EN 61000-4-2
IEC 61000-4-8	NOTE	Harmonized as EN 61000-4-8
IEC 60601-2-66	NOTE	Harmonized as EN 60601-2-66
CISPR 11	NOTE	Harmonized as EN 55011

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 1 Where an International Publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

NOTE 2 Up-to-date information on the latest versions of the European Standards listed in this annex is available here: www.cenelec.eu.

Publication	Year	Title	EN/HD	Year
IEC 60118-0	2015	Electroacoustics - Hearing aids - Part 0: Measurement of the performance characteristics of hearing aids	EN 60118-0	2015
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	2006
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 + A1 + A2	2006 2008 2010
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	2010

Annex ZZ
(informative)

Relationship between this European Standard and the essential requirements of Directive 93/42/EEC [1993 OJ L 169] aimed to be covered

This European Standard has been prepared under a Commission's standardization request M/023 concerning the development of European Standards related to medical devices to provide one voluntary means of conforming to essential requirements of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices [1993 OJ L 160].

Once this standard is cited in the Official Journal of the European Union under that Directive, compliance with the normative clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding essential requirements of that Directive and associated EFTA regulations.

NOTE 1 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with Directive 93/42/EEC as amended by 2007/47/EC. This means that risks have to be reduced 'as far as possible', 'to a minimum', 'to the lowest possible level', 'minimized' or 'removed', according to the wording of the corresponding essential requirement.

NOTE 2 The manufacturer's policy for determining acceptable risk must be in compliance with Essential Requirements 1, 2, 5, 6, 7, 8, 9, 11 and 12 of the Directive.

NOTE 3 This Annex ZZ is based on normative references according to the table of references in the European foreword, replacing the references in the core text.

NOTE 4 When an Essential Requirement does not appear in Table ZZ.1, it means that it is not addressed by this European Standard.

Table ZZ.1 — Correspondence between this European Standard and Annex I of Directive 93/42/EEC [1993 OJ L 169]

Essential Requirements of Directive 93/42/EEC	Clause(s)/sub-clause(s) of this EN	Remarks/Notes
3	5, 6	These clauses specify requirements and test methods to verify the immunity of the device to radiated electromagnetic fields from mobile phones. Design manufacturing and packaging are not covered.
9.1, first sentence only	5	Covered for the use of a hearing aid in combination with a mobile phone with regards to radiated electromagnetic fields.
9.2, second indent	5	Covered with regards to immunity to radiated electromagnetic fields from mobile phones.

WARNING 1 — Presumption of conformity stays valid only as long as a reference to this European Standard is maintained in the list published in the Official Journal of the European Union. Users of this standard should consult frequently the latest list published in the Official Journal of the European Union.

WARNING 2 — Other Union legislation may be applicable to the products falling within the scope of this standard.

IEC 60118-13

Edition 5.0 2019-10

INTERNATIONAL STANDARD

NORME INTERNATIONALE

colour inside

Electroacoustics – Hearing aids – Part 13: Requirements and methods of measurement for electromagnetic immunity to mobile digital wireless devices

Électroacoustique – Appareils de correction auditive– Partie 13: Exigences et méthodes de mesure de l'immunité électromagnétique aux appareils numériques mobiles sans fil

IEC 60118-13:2019-10(en-fr)

IEC 60118-13

Edition 5.0 2019-10

INTERNATIONAL STANDARD

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colour inside

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

COMMISSION ELECTROTECHNIQUE INTERNATIONALE

ICS 17.140.50; 33.100.20

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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ELECTROACOUSTICS – HEARING AIDS –

Part 13: Requirements and methods of measurement for electromagnetic immunity to mobile digital wireless devices

FOREWORD

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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International Standard IEC 60118-13 has been prepared by IEC technical committee 29: Electroacoustics.

This fifth edition cancels and replaces the fourth edition published in 2016 and constitutes a technical revision.

This edition includes the following significant technical changes with respect to the previous edition:

a) it introduces a new measurement method and set of EMC requirements for hearing aids immunity to mobile digital wireless devices;
b) generic EMC requirements for hearing aids are no longer included – should be covered by other standards as appropriate.

The text of this International Standard is based on the following documents:

FDIS	Report on voting
29/1024/FDIS	29/1031/RVD

Full information on the voting for the approval of this International Standard can be found in the report on voting indicated in the above table.

This document has been drafted in accordance with the ISO/IEC Directives, Part 2.

A list of all parts in the IEC 60118 series, published under the general title *Electroacoustics – Hearing aids*, can be found on the IEC website.

The committee has decided that the contents of this document will remain unchanged until the stability date indicated on the IEC website under "http://webstore.iec.ch" in the data related to the specific document. At this date, the document will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

IMPORTANT – The 'colour inside' logo on the cover page of this publication indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this document using a colour printer.

INTRODUCTION

This part of IEC 60118 specifies methods of measurement and requirements for hearing aid immunity to digital wireless devices. Most hearing aids contain digital signal processors and some can contain wireless transceivers.

Experience in connection with the use of hearing aids in recent times has identified digital wireless devices, such as wireless telephones and GSM mobile phones, as potential sources of disturbance for hearing aids. Interference in hearing aids depends on the emitted power from the digital wireless device as well as the immunity of the hearing aid. The performance criteria in this document 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 wireless telephone, will seek, if possible, to find a position on the ear, which gives minimum or no interference in the hearing aid. Various test methods have been considered for determining the immunity of hearing aids. When a digital wireless device is used close to a hearing aid, there is an RF near-field illumination of the hearing aid. However, validation investigations in preparing this document 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 provide valuable information during the design and development of hearing aids.

It is recognized that the new wireless products introduced have to coexist with existing spectra, potential networks and other wireless products (medical as well as non-medical). This revision does not address the issue of coexistence, and the user of this document shall consult applicable entities for guidance.

In this fifth edition of IEC 60118-13, the field strengths and hearing aid positioning during measurements have been updated for consistency with IEEE C63.19 [1][1] and ANSI C63.19 [2]. The field strength levels used since the first edition of IEC 60118-13 was published in 1997 have demonstrated, through measurements of more than 1 000 hearing aid models (ref. European Hearing Instrument Manufacturers Association – EHIMA), to be sufficiently high to ensure well-functioning hearing aids in everyday use, with only a small expectation of a few complaints regarding interference from digital wireless devices.

Hearing aids where the outputs are non-acoustic, for example bone conduction hearing aids, are not directly included in this document, but this document can be used if precise descriptions of measurement setups for these types of hearing aids are given by the manufacturer.

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1 Numbers in square brackets refer to the Bibliography

ELECTROACOUSTICS – HEARING AIDS –

Part 13: Requirements and methods of measurement for electromagnetic immunity to mobile digital wireless devices

1 Scope

This part of IEC 60118 covers the relevant EMC phenomena for hearing aids. Hearing aid immunity to high frequency fields originating from digital wireless devices such as mobile phones was identified as one of the most relevant EMC phenomena impacting hearing aids.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 60118-0:2015, *Electroacoustics – Hearing aids – Part 0: Measurement of the performance characteristics of hearing aids*

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*

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*