ICS 17.140.50 SLOVENSKÁ TECHNICKÁ NORMA August 2024

STN	**Elektroakustika Sluchové protézy Časť 0: Meranie prevádzkových charakteristík sluchových protéz**	**STN EN IEC 60118-0 36 8860**

Electroacoustics - Hearing aids - Part 0: Measurement of the performance characteristics of hearing aids

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. 07/24

Obsahuje: EN IEC 60118-0:2024, IEC 60118-0:2022

Oznámením tejto normy sa od 10.05.2027 ruší
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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN IEC 60118-0

May 2024

ICS 17.140.50

Supersedes EN 60118-0:2015

English Version

Electroacoustics - Hearing aids - Part 0: Measurement of the performance characteristics of hearing aids (IEC 60118-0:2022)

Électroacoustique - Appareils de correction auditive - Partie 0: Mesure des caractéristiques fonctionnelles des appareils de correction auditive (IEC 60118-0:2022)

Akustik - Hörgeräte - Teil 0: Messung der Leistungsmerkmale von Hörgeräten (IEC 60118-0:2022)

This European Standard was approved by CENELEC on 2022-10-04. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

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

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.

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

Ref. No. EN IEC 60118-0:2024 E

European foreword

The text of document 29/1126/FDIS, future edition 4 of IEC 60118-0, prepared by IEC/TC 29 "Electroacoustics" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN IEC 60118-0:2024.

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) 2024-11-10
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2027-05-10

This document supersedes EN 60118-0:2015 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 standardization request addressed to CENELEC by the European Commission. The Standing Committee of the EFTA States subsequently approves these requests for its Member States.

For the relationship with EU Legislation, see informative Annex ZZ, which is an integral part of this document.

Any feedback and questions on this document should be directed to the users' national committee. A complete listing of these bodies can be found on the CENELEC website.

Endorsement notice

The text of the International Standard IEC 60118-0:2022 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 standard indicated:

IEC 60068 (series)	NOTE	Approved as EN 60068 (series)
IEC 60118-7:2005	NOTE	Approved as EN 60118-7:2005 (not modified)
IEC 60118-8:2005	NOTE	Approved as EN 60118-8:2005 (not modified)
IEC 60118-15	NOTE	Approved as EN 60118-15
IEC 61094-8:2012	NOTE	Approved as EN 61094-8:2012 (not modified)

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.cencenelec.eu.

Publication	Year	Title	EN/HD	Year
IEC 60118-12	-	Hearing aids – Part 12: Dimensions of electrical connector systems	EN 60118-12	1996
IEC 60318-4	2010	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	2010
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	EN 60318-5	2006
IEC 60318-8	-	Electroacoustics – Simulators of human head and ear – Part 8: Acoustic coupler for high-frequency measurements of hearing aids and earphones coupled to the ear by means of ear inserts	EN 60318-8	2022
IEC 60268-2	1987	Sound system equipment – Part 2: Explanation of general terms and calculation methods	-	-
+ AMD 1	1991		-	-
IEC 60263	-	Scales and sizes for plotting frequency characteristics and polar diagrams	EN IEC 60263	2020
IEC 61094-4	-	Measurement microphones – Part 4: Specifications for working standard microphones	EN 61094-4	1995
ISO 3	1973	Preferred numbers – Series of preferred numbers		

Annex ZZ
(informative)

Relationship between this European standard and the General Safety and Performance Requirements of Regulation (EU) 2017/745 aimed to be covered

This European standard has been prepared under M/575 to provide one voluntary means of conforming to the General Safety and Performance Requirements of Regulation (EU) 2017/745 of 5 April 2017 concerning medical devices [OJ L 117] and to system or process requirements including those relating to quality management systems, risk management, post-market surveillance systems, clinical investigations, clinical evaluation or post-market clinical follow-up.

Once this standard is cited in the Official Journal of the European Union under that Regulation, compliance with the normative clauses of this standard given in Table ZZ.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding General Safety and Performance Requirements of that Regulation, and associated EFTA Regulations.

Where a definition in this standard differs from a definition of the same term set out in Regulation (EU) 2017/745, the differences shall be indicated in this Annex Z. For the purpose of using this standard in support of the requirements set out in Regulation (EU) 2017/745, the definitions set out in this Regulation prevail.

Where the European standard is an adoption of an International Standard, the scope of this standard can differ from the scope of the European Regulation that it supports. As the scope of the applicable regulatory requirements differ from nation to nation and region to region, the standard can only support European regulatory requirements to the extent of the scope of the European Regulation for medical devices (EU) 2017/745).

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 Regulation (EU) 2017/745. This means that risks have to be ‘reduced as far as possible’, ‘reduced to the lowest possible level’, ‘reduced as far as possible and appropriate’, ‘removed or reduced as far as possible’, ‘eliminated or reduced as far as possible’, ’removed or minimized as far as possible’, or ‘minimized’, according to the wording of the corresponding General Safety and Performance Requirement.

NOTE 2 The manufacturer’s policy for determining **acceptable risk** must be in compliance with General Safety and Performance Requirements 1, 2, 3, 4, 5, 8, 9, 10, 11, 14, 16, 17, 18, 19, 20, 21 and 22 of the Regulation.

NOTE 3 When a General Safety and Performance 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 Regulation (EU) 2017/745 [OJ L 117] and to system or process requirements including those relating to quality management systems, risk management, post-market surveillance systems, clinical investigations, clinical evaluation or post-market clinical follow-up

General Safety and Performance Requirements of Regulation (EU) 2017/745	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
1	Clauses 7, 8, 9, 10	Coverage is limited to electro-acoustic performance measurements and measurement of the safety relevant maximum acoustic output of hearing aids. It should be noted, the measurement results obtained by the methods specified in this document will express the performance under conditions of the measurement and can deviate substantially from the performance of the hearing aid under actual conditions of use.
10.1. (h)	Clause 10	Covers measurement procedures for the electro-acoustical parameters of hearing aids
14.2. (a)	Clause 10.4	Covers the measurement and specification of the safety relevant maximum output sound pressure level of a hearing aid; The risk of hearing damage, if measurement exceeds specified measurement uncertainty limits and/or tolerances, is mitigated by process control, such as training, regular maintenance and calibration of equipment.

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 product(s) falling within the scope of this standard.

IEC 60118-0

Edition 4.0 2022-08

INTERNATIONAL STANDARD

NORME INTERNATIONALE

Electroacoustics – Hearing aids – Part 0: Measurement of the performance characteristics of hearing aids

Électroacoustique – Appareils de correction auditive – Partie 0: Mesure des caractéristiques fonctionnelles des appareils de correction auditive

IEC 60118-0:2022-08(en-fr)

IEC 60118-0

Edition 4.0 2022-08

INTERNATIONAL STANDARD

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Electroacoustics – Hearing aids – Part 0: Measurement of the performance characteristics of hearing aids

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

COMMISSION ELECTROTECHNIQUE INTERNATIONALE

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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ELECTROACOUSTICS – HEARING AIDS –

Part 0: Measurement of the performance characteristics of hearing aids

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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8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

IEC 60118-0 has been prepared by technical committee 29: Electroacoustics. It is an International Standard.

This fourth edition merges and updates the methods previously described in IEC 60118-0:2015 and IEC 60118-7:2005. It cancels and replaces the third edition of IEC 60118-0 published in 2015. This edition constitutes a technical revision.

Measurements for quality control as described in IEC 60118-7:2005 can be found in Clause 10 of this document.

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

a) the default use of an acoustic coupler according to IEC 60318-5,
b) addition of the optional use of an occluded ear simulator according to IEC 60318-4,

c) addition of the optional use of an acoustic coupler according to IEC 60318-8 (new standard based on IEC TS 62886) when information about the response above 8 kHz is needed, or the optional use of the acoustic coupler according to IEC 60318-8 for deep insert hearing aids,

d) the addition of measurements of the performance of hearing aids for production, supply and delivery quality assurance purposes,

e) corrected and updated measurement configuration and methods, adding the use of a sequential measurement as preferred configuration,

f) updated and expanded measurement procedures for the non-acoustic inputs of the hearing aid.

NOTE The substitution method described in Annex B has no relation to the substitution method described in IEC 60118-0:2015.

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

Draft	Report on voting
29/1126/FDIS	29/1129/RVD

Full information on the voting for its approval can be found in the report on voting indicated in the above table.

The language used for the development of this International Standard is English.

This document was drafted in accordance with ISO/IEC Directives, Part 2, and developed in accordance with ISO/IEC Directives, Part 1 and ISO/IEC Directives, IEC Supplement, available at www.iec.ch/members_experts/refdocs. The main document types developed by IEC are described in greater detail at www.iec.ch/standardsdev/publications.

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 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.

ELECTROACOUSTICS – HEARING AIDS –

Part 0: Measurement of the performance characteristics of hearing aids

1 Scope

This part of IEC 60118 gives recommendations for the measurement of the performance characteristics of air conduction hearing aids measured with an acoustic coupler or occluded ear simulator.

This document is applicable to the measurement and evaluation of the electroacoustical characteristics of hearing aids, for example for type testing and manufacturer data sheets.

This document is also applicable for the measurement of the performance characteristics of hearing aids for production, supply and delivery quality-assurance purposes.

The measurement results obtained by the methods specified in this document will express the performance under conditions of the measurement and can deviate substantially from the performance of the hearing aid under actual conditions of use.

This document primarily uses an acoustic coupler according to IEC 60318-5 which is only intended for loading a hearing aid with specified acoustic impedance and is not intended to reproduce the sound pressure in a person's ear. For measurements reflecting the output level in the normal human ear the occluded ear simulator according to IEC 60318-4 can be used. For extended high-frequency measurements and for deep insert hearing aids, the acoustic coupler according to IEC 60318-8 can be used.

This document also covers measurement of hearing aids with non-acoustic inputs, such as wireless, inductive or electrical input.

This document does not cover the measurement of hearing aids for simulated in situ working conditions, for which IEC 60118-8 can be applied.

This document does not cover the measurement of hearing aids under typical user settings and using a speech-like signal, for which IEC 60118-15 can be applied.

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 60118-12, *Hearing aids – Part 12: Dimensions of electrical connector systems*

IEC 60318-4:2010, *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 cm^3 coupler for the measurement of hearing aids and earphones coupled to the ear by means of ear inserts*

IEC 60318-8, *Electroacoustics – Simulators of human head and ear – Part 8: Acoustic coupler for high-frequency measurements of hearing aids and earphones coupled to the ear by means of ear inserts*

IEC 60268-2, *Sound system equipment – Part 2: Explanation of general terms and calculation methods*

IEC 60263, *Scales and sizes for plotting frequency characteristics and polar diagrams*

IEC 61094-4, *Measurement microphones – Part 4: Specifications for working standard microphones*

ISO 3, *Preferred numbers – Series of preferred numbers*