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INTERNATIONAL STANDARD

NORME INTERNATIONALE

colour inside

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

Électroacoustique – Appareils de correction auditive – Partie 13: Compatibilité électromagnétique (CEM)

IEC 60118-13:2016-01(en-fr)

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FOREWORD

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International Standard IEC 60118-13 has been prepared by IEC technical committee 29: Electroacoustics.

This fourth edition cancels and replaces the third edition published in 2011 and constitutes a technical revision. This edition includes the following significant technical changes with respect to the previous edition:

a) introduction of a new set of general EMC requirements for hearing aids.

It has the status of a product EMC standard in accordance with IEC Guide 107, *Electromagnetic compatibility – Guide to the drafting of electromagnetic compatibility publications*.

The text of this standard is based on the following documents:

FDIS	Report on voting
29/889/FDIS	29/896/RVD

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

This publication 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 publication will remain unchanged until the stability date indicated on the IEC website under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

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- withdrawn,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

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INTRODUCTION

This international standard specifies EMC requirements of hearing aids. Most hearing aids contain digital signal processors and some can contain wireless transceivers.

As the generic IEC 60601-1-2 EMC standard does not apply to hearing aids (ref. IEC 60601-2-66:2015, 201.17), this revision of IEC 60118-13:2011 introduces additional specifications for EMC requirements for hearing aids. 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 standard will not totally ensure hearing aid user's 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 that 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 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 provide valuable information during design and development of hearing aids.

In addition the standard now contains ESD radiated and immunity requirements to address the EMC compliance, because manufacturers of hearing aids have faced questions of compliance by agencies that require compliance to applicable standards. The lack of an applicable standard can allow for misinterpretations and/or lack of agreement of applicable standards. Without this revision other EMC standards may be applied which contain requirements that are not relevant to hearing aids. This revision will now provide manufacturers and test agencies a compliance standard that specifically addresses those requirements.

Hearing aids are battery powered. Therefore, disturbances related to a.c. or d.c. power inputs are not relevant and are identified as not applicable within this document. Hearing aids are not normally connected to other equipment through cables, and therefore common mode transients and common mode surges are not relevant and also identified as not applicable.

Hearing aids can now contain RF transceivers used for wireless communication, which comply with existing standards addressed by entities such as the FCC, R&TTE or other wireless directives. This revision is not intended to replace those standards but rather points the user to those standards. National authorities on wireless and medical devices should be contacted for advice. The users of this standard should consult the publications by those entities for further knowledge to test communications of wireless hearing aids and use this standard to supplement those needs.

It is recognized that the introduction of new wireless products coexists with existing spectra, potential networks and other wireless products (medical as well as non-medical). This revision does not address coexistence and the user of this standard should consult applicable entities for guidance.

Hearing aids, where the outputs are non-acoustic, e.g. bone conduction hearing aids, are not described directly in this standard, but the standard can be used if precise descriptions of measurement setup for these types of hearing aids are given by the manufacturer.

ELECTROACOUSTICS – HEARING AIDS –

Part 13: Electromagnetic compatibility (EMC)

1 Scope

This part of IEC 60118 covers relevant EMC phenomena for hearing aids. Hearing aid immunity to high frequency fields originating from digital wireless devices such as mobile phones was originally identified as the most relevant EMC phenomena impacting hearing aids. Since the inclusion of RF generating components within hearing aids, such as digital signal processors or wireless transceivers, additional EMC compliance requirements apply. The EMC requirements now included are radiated emissions and immunity to electrostatic discharge, power frequency magnetic fields, and radiated RF electromagnetic fields. Requirements associated with connected power and signal lines are not included.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. 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, *Electroacoustics – Hearing aids – Part 0: Measurement of the performance characteristics of hearing aids*

IEC 60118-7:2005, *Electroacoustics – Hearing aids – Part 7: Measurement of the performance characteristics of hearing aids for production, supply and delivery quality assurance purposes*

IEC 60118-15, *Electroacoustics – Hearing aids – Part 15: Methods for characterising signal processing in hearing aids with a speech-like signal*

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 61000-4-2, *Electromagnetic compatibility (EMC) – Part 4-2: Testing and measurement techniques – Electrostatic discharge immunity test*

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

IEC 61000-4-8, *Electromagnetic compatibility (EMC) – Part 4-8: Testing and measurement techniques – Power frequency magnetic 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*

CISPR 11:2015, *Industrial, scientific and medical equipment – Radio-frequency disturbance characteristics – Limits and methods of measurement*