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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)

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FOREWORD

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

This third edition cancels and replaces the second edition published in 2004 and constitutes a technical revision. It introduces a new set of requirements for use of hearing aids with mobile phones.

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

FDIS	Report on voting
29/737/FDIS	29/745/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 publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

A list of all parts of the IEC 60118 series, 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 web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

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- withdrawn,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

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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.

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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 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*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60118-0, IEC 60118-7, and IEC 61000-4-3 as well as the following apply.

3.1
hearing aid
wearable instrument, containing a variety of individual adjustment facilities, intended to aid a person with impaired hearing. Consisting of a microphone, amplifier, an induction pick-up coil (optional) and earphone, powered by a battery

NOTE Hearing aids can be placed on the body (BW), behind the ear (BTE) or in the ear (ITE).

3.2
bystander compatibility
immunity of a hearing aid that ensures it is usable in environments where digital wireless devices are in operation in the proximity of the hearing aid wearer (2 m, see A.4)

3.3
user compatibility
immunity of a hearing aid that ensures it is usable when the wearer is using a digital wireless device at the wearer´s own aided ear

3.4
reference orientation (of a hearing aid)
orientation of the hearing aid with respect to the RF emitting source which corresponds to the orientation of the hearing aid under actual use on a person facing or using an RF emitting source

3.5
input related interference level
IRIL
level used to characterise the immunity of the hearing aid

NOTE Acoustic IRIL is expressed relative to 20 μPa in decibels, and is calculated by subtracting the gain of the hearing aid from the level of a 1 kHz signal measured at the output of the hearing aid during exposure to a 1 kHz modulated RF field in microphone mode. The gain of the hearing aid is determined at 1 kHz using an input sound pressure level of 55 dB.

If the hearing aid provides an additional directional microphone, the gain determined with the omnidirectional microphone is used for determination of IRIL.

If the hearing aid provides an induction pick-up coil, the control settings used for acoustic measurement are used. Induction pick-up coil IRIL is expressed as the equivalent acoustic input r.m.s levels re 20 μPa in decibels, based on the assumption that the magnetic field strength level re 1A/m of –20 dB is practically equivalent to the acoustic sound pressure level of 70 dB.

The induction pick-up coil IRIL is calculated by subtracting the output of the hearing aid[2)] in dB minus 55 dB, from the level of 1 kHz signal measured at the output of the hearing aid during exposure to a 1 kHz 80% modulated RF field in induction pick-up coil mode.

Decreasing values of IRIL indicate increasing immunity.

Further details are given in Annex A.

3.6
GSM
global system for mobile communication

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2 Determined at –35 dB input level re 1A/m at 1 kHz.

3.7
TEM cell
closed measuring device in which a voltage difference creates a TEM-mode electromagnetic field

3.8
radio frequency
RF
frequency of electromagnetic radiation within the range of 30 kHz to 30 GHz

4 Requirements for immunity

Table 1 states the field strengths of RF test signals to establish immunity for bystander compatible and user compatible hearing aids. Bystander compatibility shall be fulfilled as a minimum specification, whereas user compatibility is an additional feature, which can be claimed if the specifications are met by the hearing aid.

Table 1 – Field strengths of RF test signals to be used to establish immunity for bystander compatible and user compatible hearing aids

	Bystander compatibility IRIL ≤ 55 dB for field strengths, *E* in V/m						**User compatibility IRIL ≤ 55 dB for field strengths, *E* in V/m**					
Frequency range GHz	<0,8	0,8-0,96	0,96-1,4	1,4-2,0	2,0-2,48	>2,48	<0,8	0,8-0,96	0,96-1,4	1,4-2,0	2,0-2,48	>2,48
Microphone mode	Unnecessary	3,5	Unnecessary	2	1,5	Unnecessary	Unnecessary	90	Unnecessary	50	35	Unnecessary
Induction pick-up coil mode[a]	Unnecessary	3,5	Unnecessary	2	1,5	Unnecessary	Unnecessary	90	Unnecessary	50	35	Unnecessary
Directional microphone mode[a]	Unnecessary	3,5	Unnecessary	2	1,5	Unnecessary	Unnecessary	Unnecessary	Unnecessary	Unnecessary	Unnecessary	Unnecessary
Test field strengths are given as unmodulated carrier levels.												
[a] If provided by the hearing aid.												

NOTE 1 Table 1 has been updated for frequencies above 2,0 GHz. Wireless services like Bluetooth operate in the 2,0 GHz to 2,48 GHz range. Services in this frequency range are typically running at lower power levels compared to services below 1 GHz. TDMA modulation (eg. used in GSM mobile phones and DECT wireless phones) has been shown to generate the most aggressive interference in hearing aids to date, while CDMA and other modulations schemes are less aggressive. The test levels used since the first edition of IEC 60118-13 in 1996 have through testing of more than 1 000 hearing aid models demonstrated to be sufficiently high to ensure well-functioning hearing aids in daily life, with only a few complaints from hearing aid users who are annoyed by interference from digital wireless devices. A test field strength 3 dB below the 1,4 GHz to 2,0 GHz range is considered sufficient to sustain well-functioning hearing aids in daily life regarding interference in the 2,0 GHz to 2,48 GHz range because services in the latter frequency range are typically running at lower power levels compared to services below 1 GHz. Additional national standards may supplement ranges in Table 1.

NOTE 2 As sources of disturbance in the frequency range 0,96 GHz to 1,4 GHz, below 0,8 GHz and beyond 2,48 GHz are not known to affect hearing aids, testing in this frequency range is not considered necessary. If the hearing aid provides an additional microphone input option – directional microphone intended for distant listening in noisy environments – user compatibility is not considered relevant in this position. Compatibility in induction pick-up coil mode is considered important to establish interference free conditions in induction loop environments, and to ensure the ability to use the induction pick-up coil as an input transducer for assistive listening devices for digital wireless devices, e.g. portable hands free kits.

NOTE 3 The requirements to generate high field strengths might drive the RF power amplifier to generate distortion. Care should be taken to ensure that distortion does not affect the measurement results.

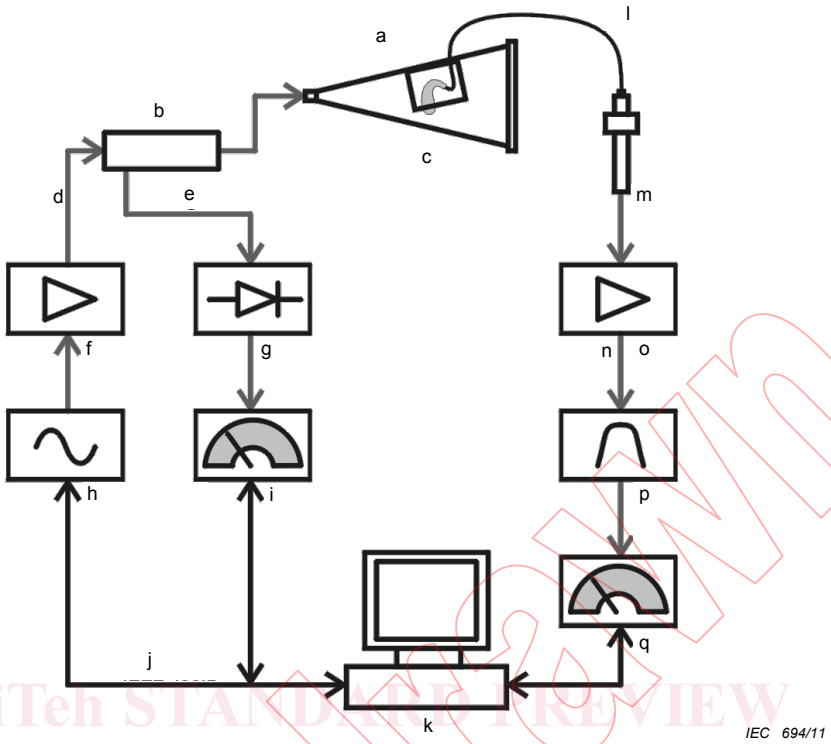
5 Immunity test procedures

5.1 A typical RF-test equipment, test configuration and test procedures, e.g. as specified in IEC 61000-4-20 shall apply. This requires that a 1 kHz 80% sine modulation of the carrier wave is used. As described in A.2, this is a suitable signal for immunity test of hearing aids.

NOTE For small systems without wires (such as hearing aids) suitable GTEM cells and striplines may be used as indicated in IEC 61000-4-20.

5.2 No objects, other than the hearing aid, which could distort the RF-field, shall be present in the test volume.

In order to remove the metallic ear simulator or coupler as specified in IEC 60318-4 and IEC 60318-5 from the test volume, the normal tubing between the hearing aid and the coupler shall be replaced by tubing of 2 mm bore and with a length between 50 mm and 1 000 mm. The choice of ear simulator or coupler and the length of the tubing are not critical, but identical setup should be used for measurement of hearing aid gain and IRIL. For in-the-ear instruments, the outlet from the receiver shall be coupled to the tubing by a suitable adapter. This adapter and the length of the tubing are not critical, as the hearing aid gain is determined in each individual test configuration. An example of a suitable test arrangement is given in Figure 1.



NOTE Measurements should be made to ensure that the background noise level of the test configuration is at least 10 dB lower than the lowest measured acoustic output from the hearing aid.

Key

a hearing aid
b directional coupler
c TEM cell
d RF signal
e RF signal
f power amplifier
g power sensor
h RF generator
i power meter
j measurement instrument interface
k measuring programme
l 500 mm Ø2 mm tubing
m coupler or ear simulator
n audio signal
o microphone power supply
p BP filter, 1 kHz, one-third-octave
q multimeter

Figure 1 – Example of a test arrangement for hearing aid immunity measurements using a one-port TEM cell (asymmetric septum)

5.3 The hearing aid gain control shall be adjusted to the reference test setting and the other controls shall be set to the basic settings as described in IEC 60118-7.

5.4 With the acoustical coupling described in 5.2 and the test conditions described in 5.3, the input-output response of the hearing aid shall be measured at 1 000 Hz as described in IEC 60118-2. This test applies for all hearing aids. From the input-output response curve, determine the gain obtained at 55 dB SPL input level. If the hearing aid provides an induction