

INTERNATIONAL STANDARD

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

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

IEC 60118-13:2016

<https://standards.iteh.ai/standards/iec/d6c29890-aa32-40a7-9471-441592911dcb/iec-60118-13-2016>



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INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

COMMISSION
ELECTROTECHNIQUE
INTERNATIONALE

ICS 17.140.50; 33.100.20

ISBN 978-2-8322-3098-5

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CONTENTS

FOREWORD.....	4
INTRODUCTION.....	6
1 Scope.....	7
2 Normative references	7
3 Terms and definitions	8
4 Operation and function of the hearing aid	10
5 Specification of EMC environment	10
6 Requirements for electromagnetic emissions	10
6.1 Requirements for radiated emissions	10
6.2 Limits of radiated emissions.....	10
6.3 Procedure for radiated emissions.....	10
7 Requirements for electromagnetic immunity	10
7.1 General.....	10
7.2 Compliance criteria.....	10
7.3 Radiated RF electromagnetic fields.....	11
7.3.1 General	11
7.3.2 Requirements	11
7.3.3 Procedure.....	13
7.4 Electrostatic Discharge (ESD).....	13
7.4.1 Requirements	13
7.4.2 Procedure.....	13
7.5 Power frequency magnetic fields.....	13
7.5.1 Requirements	13
7.5.2 Procedure.....	13
8 Test procedures for immunity to radiated RF electromagnetic fields	13
8.1 General.....	13
8.2 Test equipment and RF signal.....	13
8.3 Hearing aid test setting	13
8.4 Determination of gain.....	14
8.5 Hearing aid output coupling during immunity test	14
8.6 Position of the hearing aid during immunity test	15
8.7 Measurement of the input related ambient noise (<i>IRAN</i>)	17
8.8 Measurement of the output related interference level (<i>ORIL</i>).....	17
8.9 Calculation of the input related interference level (<i>IRIL</i>)	18
8.10 Report	18
9 Measurement uncertainty for immunity to radiated RF electromagnetic fields	18
Annex A (informative) Background for establishing test methods, performance criteria and test levels	19
A.1 General.....	19
A.2 Radiated RF electromagnetic fields, history of the test method	19
A.3 Performance criteria	21
A.4 Test field strengths – Bystander compatibility	21
A.5 Field strengths – User compatibility	21
Annex B (informative) Rationale for particular clauses and subclauses	24
B.1 Rationale for Clause 6 Requirements for electromagnetic emissions.....	24

B.2	Rationale for 6.1 Radiated emissions	24
B.3	Rationale for Clause 6 Requirements for RF emissions and Clause 7 Requirements for electromagnetic immunity	24
B.4	Rationale for 7.2 Compliance criteria	24
B.5	Rationale for 7.3 Radiated RF electromagnetic fields	24
B.6	Rationale for 7.4 Electrostatic discharge (ESD).....	24
B.7	Rationale for 7.5 Power frequency magnetic fields	25
	Bibliography.....	26

Figure 1	– Examples of input-output response curves at 1 000 Hz and the determination of gain at an input level of 55 dB.....	14
Figure 2	– Example of a test arrangement for hearing aid immunity measurements using a GTEM cell	15
Figure 3	– Positioning of BTE, during RF exposure	16
Figure 4	– Positioning of BTE with receiver, during RF exposure	16
Figure 5	– Positioning of ITE with receiver, during RF exposure	17
Figure A.1	– Ratio of 1:2 between field strength and interference level in dB	20
Figure A.2	– Example of test arrangement for hearing aid immunity measurements using dipole antenna.....	22
Table 1	– Field strengths of RF test signals to be used to establish immunity for bystander compatible and user compatible hearing aids	12

INTERNATIONAL ELECTROTECHNICAL COMMISSION

ELECTROACOUSTICS – HEARING AIDS –**Part 13: Electromagnetic compatibility (EMC)**

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

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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 cm³ 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*

3 Terms and definitions

For the purposes of this document, the definitions given in IEC 60118-0, IEC 60118-7, IEC 60118-15 and IEC 61000-4-3 as well as the following apply.

3.1

hearing aid

wearable instrument intended to aid a person with impaired hearing, usually consisting of a microphone, amplifier, signal processor and earphone, powered by a low-voltage battery and possibly also containing an induction pick-up coil and which is fitted using audiometric and prescriptive methods

Note 1 to entry: Hearing aids can be placed on the body (BW), behind the ear (BTE), in the ear (ITE) or in the canal (ITC).

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

3.3

user compatibility

immunity of hearing aid that ensures that 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 an RF emitting source

3.5

gain

G

difference between the acoustic or the magnetic equivalent input level (L_{in}) and the respective acoustic output level ($L_{p,out}$).

Note 1 to entry: The gain is determined at an Acoustic Input Sound Pressure Level of 55 dB (SPL) or (for induction pick-up coils) at a magnetic field strength level re 1 A/m of -35 dB which is the Magnetic Equivalent of 55 dB (SPL).

Note 2 to entry: $G/dB = L_{p,out} - L_{in} - 55$.

Note 3 to entry: If not stated otherwise in this document gain is determined at a frequency of 1 kHz.

3.6

output related interference level

ORIL

sound pressure level at the output of the hearing aid during exposure to a 1 kHz 80 % amplitude modulated RF signal

Note 1 to entry: $ORIL = L_{p,out}$ at 1 kHz, 80 % AM RF.

3.7

input related interference level

IRIL

ORIL with subtraction of gain:

$$IRIL = ORIL - G$$

Note 1 to entry: *IRIL* is used to characterize the immunity of the hearing aid.

3.8

input related ambient noise

IRAN

equivalent acoustic input sound pressure level that would lead to the acoustic noise output produced by a hearing aid:

$$IRAN = ORIL_{RF\ off} - G$$

and

$$ORIL_{RF\ off} = L_{p,out} \text{ at (1 kHz, 80 \% AM), RF switched off}$$

Note 1 to entry: *IRAN* is determined in the same way as *IRIL* but with the RF signal switched off.

3.9

GSM

global system for mobile communication

3.10

TEM cell

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

3.11

GTEM cell

TEM cell that has been altered to extend the usable frequency range

3.12

TDMA

time division multiple access

modulation technique used in digital wireless devices

3.13

code division multiple access

CDMA

modulation technique used in digital wireless devices

3.14

radio frequency

RF

frequency of electromagnetic radiation within the range of 30 kHz to 30 GHz

3.15

Input modes

3.15.1

microphone mode

hearing aid omnidirectional microphone active

3.15.2

induction pick-up coil mode

hearing aid induction pick-up coil active

3.15.3

directional mode

hearing aid directional microphones active

4 Operation and function of the hearing aid

Hearing aids basically consist of a microphone, an amplifier, an optional 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), or with the receiver in the auditory canal (RITE). 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.

5 Specification of EMC environment

Hearing aids are used in all environments as outlined in IEC 61000-4-3.

6 Requirements for electromagnetic emissions

6.1 Requirements for radiated emissions

Hearing aids shall comply with CISPR 11 requirements, based upon their classification. Hearing aids are classified as group 1, class B equipment according to CISPR 11.

6.2 Limits of radiated emissions

Hearing aids shall comply with the limits of group 1, class B equipment as specified by CISPR 11.

6.3 Procedure for radiated emissions

To ensure normal operating conditions the hearing aid's wireless link shall be active (if provided) and monitored. The hearing aid shall be exposed to an acoustic input. ISTS at 65 dB SPL \pm 5 dB as defined in IEC 60118-15 should be used. The exclusion frequency band (if needed) shall be documented in the test results.

The measurement can be carried out using a TEM waveguide in accordance with IEC 61000-4-20.

7 Requirements for electromagnetic immunity

7.1 General

This clause specifies the EMC immunity requirements that are appropriate for hearing aids covered by this standard. During all immunity tests the hearing instrument shall comply with the immunity compliance criteria described in 7.2.

7.2 Compliance criteria

Under the immunity test conditions specified in Clause 8, the hearing aid shall be able to provide basic safety and maintain performance. The following degradations, if associated with basic safety, shall not be allowed:

- component failure;
- changes in programmable parameters;
- reset to factory defaults;
- change of operation mode;

- false alarms (battery and “loss of hearing aid at other side” alarms);
- errors in a calculated, stored or displayed numerical value sufficiently large to affect diagnosis or treatment;
- output above the intended (programmed) maximum power output.

Loss of function during test is allowed, but the hearing aid shall return to normal state with no loss of data (e.g. by switching instrument off and on again).

In addition during exposure to radiated RF electromagnetic fields:

- *IRIL* SPL shall not exceed 55 dB SPL.

7.3 Radiated RF electromagnetic fields

7.3.1 General

For the purpose of the radiated RF electromagnetic fields immunity test, two immunity classes of hearing aids are defined (see 3.2 and 3.3) related to their use.

7.3.2 Requirements

Hearing aids shall comply with the criteria of 7.2 at immunity test levels as specified in Table 1.

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

As sources of disturbance in the frequency range 0,96 GHz to 1,4 GHz below 0,7 GHz and beyond 2,7 GHz are actually not known to affect hearing aids, testing for user compatibility in these frequency ranges is not necessary, but may be considered in future. If the hearing aid provides an additional microphone input mode – directional microphone – 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.

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

	Bystander compatibility <i>I/R/L ≤ 55 dB SPL for field strengths, E in V/m</i>										User compatibility <i>I/R/L ≤ 55 dB SPL for field strengths, E in V/m</i>								
	0,08 to 0,7	0,7 to 96	0,96 to 1,4	1,4 to 2,0	2,0 to 2,7	2,7 to 6,0	0,08 to 0,7	0,7 to 0,96	0,96 to 1,4	1,4 to 2,0	2,0 to 2,7	2,7 to 6,0	0,08 to 0,7	0,7 to 0,96	0,96 to 1,4	1,4 to 2,0	2,0 to 2,7	2,7 to 6,0	
Frequency range GHz	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
Microphone mode	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
Induction pick-up coil mode ^a	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
Directional microphone mode ^a	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
Test field strengths are given as unmodulated carrier levels.																			
^a If provided by hearing aid.																			

NOTE In this fourth edition of IEC 60118-13, Table 1 has been updated for compliance to generic standards regarding bystander test levels. Additional national standards can supplement ranges in Table 1.