

Template for comments and secretariat observations

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IN 01	662	201.3.76		te	<p>In this standard, the word 'Replacement' has been used to signify the replacement of entire clause (see line 571),</p> <p>The replacement doesn't contain a definition. Its not clear replacement is only for note to entry of definition as well.</p> <p>Add a definition based on 4.1 of general standard as applicable for hearing aids.</p>	<p>Replace with text:</p> <p>201.3.76 PATIENT <i>Replacement:</i> living being (person or animal) undergoing a medical, surgical or dental procedure or person for whom the HEARING AID or HEARING AID SYSTEM is intended.</p> <p>Note 1 to entry: In this particular standard and in applying the requirements of the general standard, the term 665 PATIENT has the meaning explained in the second paragraph of 4.1 of the general standard. The PATIENT is also usually the OPERATOR.</p> <p>The term PATIENT is being used in this document in line with the general terminology in the medical product field. It is, however, understood that the user of a HEARING AIDS is typically not an ill person but someone healthy with a hearing impairment in a HOME HEALTHCARE ENVIRONMENT.</p>	
IN 02	668	201.3.76		ed	Add line as Note 2 for clarity.	<p>Add text:</p> <p>Note 2 to entry: The term PATIENT is being used in this document in line [...]</p>	
IN 03	703	201.3.204		te	<p>Error in definition needs to be corrected.</p> <p>SPL is $10 * \log$ of ratio of square of p_{rms} to square of reference value p_0</p>	<p>Replace definition with text:</p> <p>Ten times the logarithm to the base 10 of the ratio of the square of the root-mean-square of the sound pressure in the time domain, p, to the square of the reference value, p_0, expressed in decibels.</p>	

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Date: 10-01-2024	Document: 29/1163/CD	Project: IEC 60601-2-66 ED4
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IN 04	729	201.3.206		ed	Update “US-OSSPL” to “UC-OSSPL”	Replace with: If an increase of input sound pressure level by 3 dB results in an increase of output sound pressure level by less than 1 dB, the UC-OSSPL is reached.	
IN 05	737	201.3.208		te	The definition is not grammatically clear. It is the condition of hearing aid after ‘fitting’ (for non-DTC hearing aids). Correct spelling of risk management.	201.3.208 USE-CONDITION the setting of the HEARING AID characterized by the acoustic parameters UC-GAIN80 and UC-OSSPL which is derived either from the HEARING AID FITTING process, or, in case of DIRECT-TO-CONSUMER HEARING AIDS, from the procedures in accordance with the RISK MANAGEMENT of the manufacturer	
IN 06	740	201.3.208		ed	“See Figure 201.101” is not part of definition. Include as Note 1 and renumber subsequent notes.	Add note 1 to entry as: “Note 1 to entry : See Figure 201.101” Renumber subsequent notes	
IN 07	741	201.3.208	Note 1	te	As a result of the FITTING process, the hearing aid user volume is not usually at its maximum position. The note should be updated to reflect that this setting is needed for recording/verification measurements.	Update note as: Note 2 to entry: For recording and verification measurements, user-controlled volume control is set to maximum position.	
IN 08	742	201.3.208	Note 2	ed	Update “US-GAIN80” to “UC-GAIN80”	Replace with: Note 3 to entry: In case of multiple user-selectable hearing-programs, UC-GAIN80 and UC-OSSPL apply to each program.	

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IN 09	765	201.3.210		te	For consistency in standard, change “hearing data” to “hearing loss data” in definition.	Replace definition with text: A HEARING AID with means and procedures implemented in the HEARING AID and/or its ACCESSORIES (e.g. smartphone app), for performing hearing evaluation or measurements, processing the hearing loss data in an implemented HEARING AID FITTING ALGORITHM and applying the results to the setting of the HEARING AID	
IN 10	779	201.3.214		ed	Update spelling of weighted.	Replace text as: 201.3.214 A-WEIGHTED SOUND EXPOSURE E_{A,T}	
IN 11	788	201.3.214		te	<ol style="list-style-type: none"> IEC 62368-1 doesn't classify 100% CSD in terms of Pa²h, rather, only as 100 % CSD = ≤ 80 dB(A) / 40 h The reference to IEC 62368-1 should be in a note, as it isn't part of the definition. 	Replace text as: NOTE: IEC 62368-1 specifies CSD 100 % as = 80 dB(A) / 40 h which corresponds to sound exposure of 1.6 Pa²h (one week rolling estimate)	
IN 12	791	201.3.215		ed	For consistency, update Notation in term to match formula (L_{Aeq} , Te)	Update notation in term as: EQUIVALENT A-WEIGHTED CONTINUOUS SOUND PRESSURE LEVEL <i>L_{Aeq,Te}</i>	
IN 13	792	201.3.215		te	Proposal to amend definition as proposed, for clarity	Update definition as: Is the constant sound pressure level that would result in the same total sound energy as the fluctuating sound pressure level being produced over a given period of time	

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IN 14	800	201.3.215		te	<ol style="list-style-type: none"> 1. Include reference to definition as per IEC electropedia (IEV ref 801-22-16) as note 2. The reference to IEC 62368-1:2018 should also be in a note. 	<p>NOTE 1: See IEC Electropedia, IEV ref 801-22-16</p> <p>NOTE 2: IEC 62368-1 specifies $L_{Aeq,40} = 80$ dBA as CSD 100 % (rolling 40 h per week)</p>	
IN 15	826	201.4.3		ed	Capitalize “Essential Performance” as per general standard, as it is a defined term.	Replace title as: 201.4.3 ESSENTIAL PERFORMANCE	
IN 16	831	4.5		ed	Spelling of SYSTEMS needs to be corrected.	Replace title as: 4.5 * Alternative RISK CONTROL measures or test methods for ME EQUIPMENT or ME SYSTEMS	
IN 17	834	4.6		te	<p>4.6 of general standard applies to parts that can come into contact with the patient but fall outside of the definition of applied parts.</p> <p>Add note for clarity about hearing aid already being an applied part.</p>	<p>Add note as:</p> <p>201.4.6 ME EQUIPMENT or ME SYSTEM parts that contact the PATIENT [does not apply]</p> <p>Subclause 4.6 of the general standard does not apply.</p> <p>NOTE The HEARING AID itself is classified as a TYPE B APPLIED PART (See 201.5.9.1)</p>	
IN 18	873	201.5.5		te	Since hearing aids are internally powered, connection to power supply is only applicable if HEARING AID is specified for connection to a separate power source (201.8.2.1 and 201.4.10)	<p>Update text as:</p> <p>HEARING AIDS in NORMAL USE are INTERNALLY POWERED.</p> <p>If the instructions for use specify that a HEARING AID or a HEARING AID SYSTEM is intended to receive its power from a separate power supply (external power source), it shall be connected to such a power supply.</p> <p>See also 201.8.2.1</p>	

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IN 19	1023	201.7.2.9		ed	<ol style="list-style-type: none"> Update requirement for clarity Update spelling of ACCOMPANYING DOCUMENTS 	Update line as: Symbol for IP classification may be marked in ACCOMPANYING DOCUMENTS instead of marking on HEARING AID itself.	
IN 20	1059	201.7.4		te	Table C.3 doesn't apply to the particular standard (15.4.2 and 15.4.6 don't apply) Delete the reference.	Update subclause title as: 201.7.4 Marking of controls and instruments (see also Table C.3)	
IN 21	1177	201.7.9.2.4		ed	Change clause text from <i>italic</i> to roman type as per foreword for requirements Change note text from <i>italic</i> to smaller type as per foreword	The instruction for use shall contain the following information: [...] – information on how to proceed if battery exchange is necessary; NOTE In case of primary batteries, [...]	
IN 22	1214	201.7.9.2.9		te	Instructions for battery compartment aren't relevant to all hearing aids (rechargeable) Update requirements for only applicable operations and include requirements for rechargeable hearing aids.	Update text as: This shall include explanation of the functions of controls, battery compartment and signals, instructions for charging as well as connection and disconnection of user detachable parts and ACCESSORIES, as applicable .	
IN 23	1381	201.8.7.3		ed	Figure number needs to be updated (Figure 201.102 is Measuring circuit for LEAKAGE CURRENT)	Update text as: This value applies to current flowing through the network of Figure 12 of the general standard and measured as shown in Figure 201.102 .	

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IN 24	1397	201.8.7.4.2		ed	Figure number needs to be updated (Figure 201.102 is Measuring circuit for LEAKAGE CURRENT)	Update text as: NOTE 3 See Figure 201.102 for Measuring supply circuit for LEAKAGE CURRENT	
IN 25	1497	201.9.101		te	The pull force isn't defined. Proposed change was also suggested by experts at WG meeting.	Update requirement as: <i>Compliance shall be checked by applying a pulling force.</i>	
IN 26	1512	201.9.103		te	The pull force isn't defined. Proposed change was also suggested by experts at WG meeting.	Update requirement as: <i>Compliance shall be checked by applying a pulling force.</i>	
IN 27	1524	201.11.1.1		ed	Capitalize "Normal use" as per general standard, as it is a defined term.	Replace title as: 201.11.1.1 Maximum temperature during NORMAL USE	
IN 28	1530	201.11.1.1		ed	Update text for clarity that temperature values of Table 23 don't apply to Intended use.	The HEARING AID surface temperature shall not exceed the values given in Table 23 (of the general standard) while operating in NORMAL USE, <i>other than</i> INTENDED USE (e.g. during charging)	
IN 29	1537	201.11.1.2		ed	Capitalize "applied parts" as per general standard, as it is a defined term.	Replace title as: 201.11.1.2 Temperature of APPLIED PARTS	
IN 30	1538	201.11.1.2.1		ed	Update subclause title name to match general standard.	Replace title as: 201.11.1.2.1 APPLIED PARTS intended to supply heat to a PATIENT	
IN 31	1540	201.11.1.2.2		ed	Update subclause title name to match general standard.	Replace title as:	

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						201.11.1.2.2 * APPLIED PARTS not intended to supply heat to a PATIENT	
IN 32	1571	201.11.6		ed	Capitalize “me equipment” as per general standard, as it is a defined term.	Replace title as: 201.11.6 Overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection, sterilization and compatibility with substances used with the ME EQUIPMENT	
IN 33	1574	201.11.6.1		te	Overflow, spillage, and sterilization and compatibility with substances don't apply to hearing aids as mentioned in subclauses of 201.11.6. Update text accordingly.	Update text as: The construction of HEARING AID and HEARING AID SYSTEM shall ensure a sufficient degree of protection against overflow, spillage , leakage, ingress of water or particulate matter, cleaning and disinfection, as applicable . and sterilization as well as compatibility with substances used with the HEARING AID	
IN 34	1589	201.11.6.5		te	As stated in the clause, requirement for ingress protection is determined as per risk assessment. Tests should be performed as per IEC 60529 if appropriate.	Update text as: Compliance shall be checked by inspection and where applicable , by the tests of IEC 60529 with the HEARING AIDS placed in the least favourable position of NORMAL USE.	
IN 35	1685	201.13.1.2		te	Is the inspection of thermal cut-outs and over-current releases by heating and vibration relevant to hearing aids?	Please clarify or Delete the text: After the tests of this subclause, thermal cut-outs and over-current releases shall be inspected to determine that their setting has not changed (by heating, vibration or other causes) sufficiently to affect their safety function.	

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IN 36	1729	201.14.1		te	IEC 62304, and clause 12.2 adequately cover relevant usability intended for patient safety. As is the case in the general standard.	Update text as: Compliance with IEC 60601-1-6 usability , the IEC 62304 software design and the RISK MANAGEMENT PROCESS by inspection of external or internal audit reports or certificates.	
IN 37	1693	201.13.1.4		ed	The line is not a test specification. Remove <i>italics</i> . (As per foreword)	Remove <i>italics</i> for: For other MECHANICAL HAZARDS See Table 201.102	.
IN 38	1958	Annex E to Annex L		ed	For consistency, include “[does not apply]” to titles of annexes from the general standard that don’t apply in the particular standard. (Annex E, G, H, I, J, K, L)	Include “[does not apply]” to titles of annexes - Annex E, G, H, I, J, K, L.	.
IN 39	2002	Annex M		te	Annex M doesn’t apply to hearing aids (201.8.9 Creepage Distances and air clearances, and 8.9.1.8 of general standard are not applicable.	Add Annex M of general standard as: Annex M (normative) [does not apply] Reduction of pollution degrees (see 8.9.1.8) Annex M of the general standard does not apply.	Member Secretary’s Observations: Agree, we can suggest this change.
IN 40	2045	Annex AA	Table AA.102	te	As Annex AA is informative, update text to remove requirement terms like “shall”, “should” or “may”.	Under ‘ <u>Acoustical</u> ’ heading, update text as: DIRECT-TO-CONSUMER HEARING AIDS are to be safe for all users even for normal hearing users. Under ‘ <u>ACCESSORY</u> ’ heading, update text as: Programming interfaces comply with IEC 60601-1. Alternative wireless programming interfaces are covered by IEC 62368-1 or other applicable IEC safety standards.	.

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IN 41	2173	Annex AA		ed	Include the word 'of' in "Figure AA.102 illustrates the ATS as a function exposure level."	Update text as: Figure AA.102 illustrates the ATS as a function of exposure level.	
IN 42	2199	Annex AA		ed	Update "US-OSSPL" to "UC-OSSPL"	Replace with: d) UC-GAIN80 and UC-OSSPL	
IN 43	2217	Annex AA	Figure AA.104	te	As the graph is displaying output, not gain - Update key 'e' for UC-GAIN80 to reflect this.	Update Key 'e' in Figure AA.104 as: e Output at UC-GAIN80	
IN 44	2239	Annex AA		ed	1. Include equal to 80 dB (A) (IEC 62368-1 specifies 100% CSD as = ≤ 80 dB(A) / 40h) 2. Update notation of sound dose as per formula in definition (201.3.215)	Update text as: By SOUND DOSE monitoring as defined in IEC 62368-1 (LAeq,40 = 80 dBA , rolling 40 h per week)	
IN 45	2333	Annex BB		ge	"NSH" is an unused abbreviation and can be deleted.	Delete Line: NSH Nordic cooperation on disability	
IN 46	2335	Annex BB		ge	"OSHA" is an unused abbreviation and can be deleted.	Delete Line: OSHA Occupational Safety and Health Administration (USA)	
IN 47	2386	Annex EE		ge	50332-3:2017 is a European Standard (EN).	Update text as: The test is performed according to the logic of EN 50332-3:2017	
IN 48	2393	Annex EE		ge	IEC 60118-2:1983 with latest version as Amendment 2 is withdrawn. Add a footnote to that effect.	Update text as: The noise signal of table EE.101 (from Table 1 IEC 60118-2:1983/Amendment 2 *) is preferred.	

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						<p>x The IEC 60118-2:1983 and its Amendment 2:1997 have been withdrawn. (Replace x with footnote number)</p>	
IN 49	2608	Index of defined terms		ed	<p>Update "US-GAIN80" to "UC-GAIN80" Update "US-OSSPL" to "UC-OSSPL"</p>	<p>Replace with: USE-CONDITION GAIN AT 80 DB SPL (UC-GAIN80) USE-CONDITION OSSPL (UC-OSSPL)</p>	

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