



SLOVENSKI STANDARD
oSIST prEN ISO 14708-7:2018
01-junij-2018

**Vsadki (implantati) za kirurgijo - Aktivni medicinski pripomočki za vsaditev - 7. del:
Posebne zahteve za sisteme s polžkovim vsadkom (ISO/DIS 14708-7:2018)**

Implants for surgery - Active implantable medical devices - Part 7: Particular requirements for cochlear implant systems (ISO/DIS 14708-7:2018)

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Implants chirurgicaux - Dispositifs médicaux implantables actifs - Partie 7: Exigences particulières pour les systèmes d'implant cochléaire (ISO/DIS 14708-7:2018)

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ICS:

11.040.40	Implantanti za kirurgijo, protetiko in ortetiko	Implants for surgery, prosthetics and orthotics
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Implants for surgery — Active implantable medical devices —

Part 7: Particular requirements for cochlear implant systems

*Implants chirurgicaux — Dispositifs médicaux implantables actifs —**Partie 7: Exigences particulières pour les systèmes d'implant cochléaire*

ICS: 11.040.40

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75 Foreword

76 ISO (the International Organization for Standardization) is a worldwide federation of national
77 standards bodies (ISO member bodies). The work of preparing International Standards is normally
78 carried out through ISO technical committees. Each member body interested in a subject for which a
79 technical committee has been established has the right to be represented on that committee.
80 International organizations, governmental and non-governmental, in liaison with ISO, also take part in
81 the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all
82 matters of electrotechnical standardization.

83 The procedures used to develop this document and those intended for its further maintenance are
84 described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the
85 different types of ISO documents should be noted. This document was drafted in accordance with the
86 editorial rules of the ISO/IEC Directives, Part 2. www.iso.org/directives

87 Attention is drawn to the possibility that some of the elements of this document may be the subject of
88 patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of
89 any patent rights identified during the development of the document will be in the Introduction and/or
90 on the ISO list of patent declarations received. www.iso.org/patents

91 Any trade name used in this document is information given for the convenience of users and does not
92 constitute an endorsement.

93 For an explanation on the meaning of ISO specific terms and expressions related to conformity
94 assessment, as well as information about ISO's adherence to the World Trade Organization (WTO)
95 principles in the Technical Barriers to Trade (TBT) see the following URL:
96 www.iso.org/iso/foreword.html.

97 This document was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee
98 SC 6, *Active implants*.

99 This second edition cancels and replaces the first edition (ISO 14708-7:2013), which has been
100 technically revised.

101 The main changes compared to the previous edition are:

- 102 — alignment to the updated ISO 14708-1:2014
- 103 — significant changes to clauses 17, 22, 27
- 104 — many clauses have been replaced by references to the ANSI/AAMI CI86:2017 standard

105 A list of all part in the ISO 14708 series can be found on the ISO website.

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106 **Introduction**

107 This document specifies particular requirements for ACTIVE IMPLANTABLE MEDICAL DEVICES used to treat
108 hearing impairment via electrical stimulation (for example cochlear implant systems or auditory
109 brainstem implant systems), to provide basic assurance of safety for both patients and users.

110 A COCHLEAR IMPLANT SYSTEM or AUDITORY BRAINSTEM IMPLANT SYSTEM is an ACTIVE IMPLANTABLE MEDICAL
111 DEVICE comprising implantable and NON-IMPLANTABLE PARTS (external parts). The power source may be
112 externally derived or from an internal battery. The IMPLANT SYSTEM is designed to restore hearing via
113 electrical stimulation of the auditory pathways. Externally or internally processed acoustic information
114 is converted to electrical stimulation signals which are delivered via one or more electrodes. The
115 working parameters of the device may be adjusted via a non-implantable accessory.

116 This document is relevant to all parts of IMPLANT SYSTEMS, including accessories.

117 The requirements of this document supplement or modify those of ISO 14708-1, *Implants for surgery —*
118 *Active implantable medical devices — Part 1: General requirements for safety, marking and for*
119 *information to be provided by the manufacturer.*

120 Figures or tables that are additional to those of Part 1 are numbered starting from 101; additional
121 annexes are lettered AA, BB, etc.

122 In this part of ISO 14708, terms printed in small capital letters are used as defined in Clause 3. Where a
123 defined term is used as a qualifier in another term, it is not printed in small capital letters unless the
124 concept thus qualified is also defined.

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125 **Implants for surgery — Active implantable medical devices —** 126 **Part 7: Particular requirements for cochlear implant systems**

127 **1 Scope**

128 This part of ISO 14708 specifies requirements that are applicable to those ACTIVE IMPLANTABLE MEDICAL
 129 DEVICES that are intended to treat hearing impairment via electrical stimulation of the auditory
 130 pathways. Devices which treat hearing impairment via means other than electrical stimulation are not
 131 covered by this part of ISO 14708.

132 The tests that are specified in this part of ISO 14708 are type tests and are to be carried out on samples
 133 of a device to show compliance.

134 This part of ISO 14708 is also applicable to NON-IMPLANTABLE PARTS and accessories of the devices (see
 135 NOTE).

136 The electrical characteristics of the IMPLANTABLE PART are determined by either the appropriate method
 137 detailed in this part of ISO 14708 or by any other method demonstrated to have an accuracy equal to, or
 138 better than, the method specified. In the case of dispute, the method detailed in this part of ISO 14708
 139 applies.

140 NOTE A device that is commonly referred to as an active implantable medical device can in fact be a single
 141 device, a combination of devices, or a combination of a device or devices and one or more accessories. Not all of
 142 these parts are required to be either partially or totally implantable, this standard specifies those requirements of
 143 NON-IMPLANTABLE PARTS and accessories which could affect the safety or performance of the implantable part.

144 **2 Normative references**

<https://standards.iteh.ai/catalog/standards/sist/15cf6367-2b30-4eb2-960a-390ed40810/iso-14708-7:2018>

145 The following documents are referred to in the text in such a way that some or all of their content
 146 constitutes requirements of this document. For dated references, only the edition cited applies. For
 147 undated references, the latest edition of the referenced document (including any amendments) applies.

148 This clause of ISO 14708-1 applies except as follows:

149 Additional references:

150 ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk*
 151 *management process*

152 ISO 11607-1, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials,*
 153 *sterile barrier systems and packaging systems*

154 ISO 14155, *Clinical investigation of medical devices for human subjects — Good clinical practice*

155 ISO 14971, *Medical devices — Application of risk management to medical devices*

156 IEC 60068-2-27, *Environmental testing — Part 2-27: Tests — Test Ea and guidance: Shock*

157 IEC 60068-2-31, *Environmental testing — Part 2-31: Tests — Test Ec: Rough handling shocks, primarily*
 158 *for equipment-type specimens*

159 IEC 60068-2-47, *Environmental testing — Part 2-47: Test — Mounting of specimens for vibration, impact*
 160 *and similar dynamic tests*

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- 161 IEC 60068-2-64, *Environmental testing — Part 2-64: Tests — Test Fh: Vibration, broadband random and*
 162 *guidance*
- 163 IEC 60068-2-75, *Environmental testing — Part 2-75: Tests — Test Eh: Hammer tests*
- 164 IEC 60118-6, *Hearing aids — Part 6: Characteristics of electrical input circuits for hearing aids*
- 165 IEC 60601-1:2012, *Medical electrical equipment — Part 1: General requirements for basic safety and*
 166 *essential performance*
- 167 IEC 60601-1-2, *Medical electrical equipment — Part 1-2: General requirements for basic safety and*
 168 *essential performance — Collateral standard: Electromagnetic compatibility — Requirements and tests*
- 169 IEC 61000-4-2, *Electromagnetic compatibility (EMC) — Part 4-2: Testing and measurement techniques —*
 170 *Electrostatic discharge immunity test*
- 171 IEC 62304, *Medical device software — Software life cycle processes*
- 172 EN 1593, *Non-destructive testing — Leak testing — Bubble emission techniques*
- 173 EN 13185, *Non-destructive testing — Leak testing — Tracer gas method*
- 174 ANSI/AAMI CI86:2017, *Cochlear implant systems: Requirements for safety, functional verification,*
 175 *labeling and reliability reporting*

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176 3 Terms and definitions (standards.iteh.ai)

177 For the purposes of this document, the terms and definitions given in ISO 14708-1 and the following
 178 apply.

179 ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- 180 — ISO Online browsing platform: available at <http://www.iso.org/obp>
- 181 — IEC Electropedia: available at <http://www.electropedia.org/>

182 3.101

183 cochlear implant system

184 CIS

185 active implantable medical device, comprising implantable and NON-IMPLANTABLE PARTS, intended to
 186 treat hearing impairment via electrical stimulation of the cochlea

187 3.102

188 auditory brainstem implant system

189 ABIS

190 ACTIVE IMPLANTABLE MEDICAL DEVICE, comprising implantable and NON-IMPLANTABLE PARTS, intended to
 191 treat hearing impairment via electrical stimulation of the auditory brainstem

192 3.103

193 implant system

194 either COCHLEAR IMPLANT SYSTEM or AUDITORY BRAINSTEM IMPLANT SYSTEM

195 3.104

196 non-implantable part

197 external part of the IMPLANT SYSTEM

- 198 Note 1 to entry Examples would include, but are not limited to, sound processor, microphone, coil or power
199 source.
- 200 **3.105**
201 **stimulator**
202 implantable part of the IMPLANT SYSTEM containing electronic circuitry required to produce electrical
203 stimulation
- 204 **3.106**
205 **body-worn**
206 NON-IMPLANTABLE PART of the IMPLANT SYSTEM and worn on the body (e.g. belt or ear level)
- 207 **3.107**
208 **electrode contact**
209 electrically conducting part which is designed to form an interface with body tissue or body fluid
- 210 **3.108**
211 **electrode array**
212 DISTAL part of a LEAD containing more than one ELECTRODE CONTACT
- 213 **3.109**
214 **reference electrode**
215 electrically conducting part designed as return path for electrical stimulation current
- 216 **3.110**
217 **distal**
218 located away from the point of attachment to the STIMULATOR
- 219 **3.111**
220 **proximal**
221 located closest to the point of attachment to the STIMULATOR
- 222 **3.112**
223 **model designation**
224 name and/or a combination of letters and numbers used by a manufacturer to distinguish, by function
225 or type, one device from another
- 226 **3.113**
227 **serial number**
228 unique combination of letters and/or numbers, selected by the manufacturer, intended to distinguish a
229 device from other devices with the same MODEL DESIGNATION
- 230 **3.114**
231 **output signal**
232 electrical output, either pulsatile or analogue, of an IMPLANT SYSTEM intended to stimulate the auditory
233 pathways
- 234 **3.115**
235 **pulse**
236 specified electrical OUTPUT SIGNAL (voltage or current) of a specified amplitude and duration
- 237 **3.116**
238 **biphasic pulse**
239 PULSE which has both negative and positive going phases
- 240 **3.117**

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241 **use-before-date**
 242 date after which the manufacturer recommends that the IMPLANT SYSTEM should not be implanted

243 **3.118**
 244 **magnet**
 245 component producing an external magnetic flux

246 **3.119**
 247 **SAR value**
 248 SAR = Specific Absorption Rate

249 **3.120**
 250 **RF**
 251 Radio Frequency

4 Symbols and abbreviations

253 There are no requirements specified in this part of ISO 14708. However this does not preclude the use
 254 of symbols defined in other standards nor special symbols defined in the accompanying documentation.

5 General requirements for non-implantable parts

256 **5.1** This subclause of ISO 14708-1 applies.

257 **5.2** This subclause of ISO 14708-1 applies.

258 **5.3** This subclause of ISO 14708-1 applies.

259 **5.4** This subclause of ISO 14708-1 applies.

260 **5.5** This subclause of ISO 14708-1 applies.

261 **5.6** This subclause of ISO 14708-1 applies.

262 *Additional subclauses:*

5.7 Protection against external electrical hazards for fully implantable systems

264 Clause 6.5 of ANSI/AAMI CI86:2017 applies.

6 Inspection and measurement

266 If this part of ISO 14708 refers to inspection of design analysis documentation provided by the
 267 manufacturer, it shall include an inspection of the risk management file as required by ISO 14971.

6.1 Measurement of output signal characteristics

269 Clause 8.1 of ANSI/AAMI CI86:2017 applies.

6.2 Measurement of the output SIGNAL amplitude and pulse width

271 Clause 8.2 of ANSI/AAMI CI86:2017 applies

272 **6.3 Impedance measurement accuracy**

273 Clause 8.3 of ANSI/AAMI CI86:2017 applies.

274 **6.4 Inductive link characterization**

275 Clause 8.4 of ANSI/AAMI CI86:2017 applies.

276 **6.5 Sound processor battery testing**

277 Clause 8.5 of ANSI/AAMI CI86:2017 applies.

278 **7 General arrangement of the packaging**

279 **7.1** This subclause of ISO 14708-1 applies.

280 **7.2** This subclause of ISO 14708-1 applies.

281 **8 General markings for active implantable medical devices**

282 **8.1** This subclause of ISO 14708-1 applies.

283 **8.2** This subclause of ISO 14708-1 applies.

284 **9 Markings on the SALES PACKAGING**

285 **9.1** This subclause of ISO 14708-1 applies.

286 **9.2** This subclause of ISO 14708-1 applies except as follows:

287 *Replacement:*

288 The sales packaging shall bear the name and full address of the manufacturer.

289 The SALES PACKAGING shall also bear the name and address of the authorized representative, if the
290 manufacturer does not have a registered place of business in the European Community.

291 Compliance is checked by inspection.

292 **9.3** *Replacement*

293 Where an IMPLANT SYSTEM is supplied in separate sub-assembly packaging, each individual SALES
294 PACKAGING shall bear a description of the contents of the packaging, the model designation or part
295 number and, if applicable the batch number or the serial number.

296 Compliance is checked by inspection.

297 **9.4** This subclause of ISO 14708-1 applies.

298 **9.5** This subclause of ISO 14708-1 applies.

299 **9.6** This subclause of ISO 14708-1 applies.

300 **9.7** *Replacement*

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301 The SALES PACKAGING of implantable parts of an ACTIVE IMPLANTABLE MEDICAL DEVICE shall bear the USE-
302 BEFORE-DATE, as expressed in 9.6.

303 Compliance shall be checked by inspection.

304 **9.8** This subclause of ISO 14708-1 applies.

305 **9.9** This subclause of ISO 14708-1 applies.

306 **9.10** This subclause of ISO 14708-1 applies.

307 **9.11** This subclause of ISO 14708-1 applies.

308 **9.12** This subclause of ISO 14708-1 applies.

309 **9.13** This subclause of ISO 14708-1 applies.

310 **9.14** This subclause of ISO 14708-1 applies.

311 **10 Construction of the SALES PACKAGING**

312 **10.1** This subclause of ISO 14708-1 applies.

313 **10.2** This subclause of ISO 14708-1 applies.

314 **10.3** This subclause of ISO 14708-1 applies.

315 *Additional note:*

316 NOTE Removable stickers, which provide supplementary information exceeding the information specified in
317 Clause 9 need not to be subjected to the test specified in 10.3.

318 **10.4** This subclause of ISO 14708-1 applies.

319 **11 Markings on the sterile pack**

320 **11.1** This subclause of ISO 14708-1 applies.

321 **11.2** This subclause of ISO 14708-1 applies.

322 **11.3** This subclause of ISO 14708-1 applies.

323 **11.4** This subclause of ISO 14708-1 applies.

324 **11.5** This subclause of ISO 14708-1 applies.

325 **11.6** This subclause of ISO 14708-1 applies.

326 **11.7** This subclause of ISO 14708-1 applies.

327 **11.8** This subclause of ISO 14708-1 applies.

328 **11.9** This subclause of ISO 14708-1 applies.

329 12 Construction of the non-reusable pack

330 12.1 This subclause of ISO 14708-1 applies.

331 12.2 This subclause of ISO 14708-1 applies.

332 12.3 This subclause of ISO 14708-1 applies.

333 13 Markings on the active implantable medical device

334 13.1 This subclause of ISO 14708-1 applies.

335 13.2 This subclause of ISO 14708-1 applies.

336 13.3 Replacement

337 Implantable parts of an IMPLANT SYSTEM shall be unequivocally identifiable (particularly with regard to
338 the model designation of the device), when necessary, without the need for a surgical intervention.

339 Compliance shall be confirmed by inspection of the procedure defined by the manufacturer in the
340 instructions for use (see 28.6).

341 13.4 This subclause of ISO 14708-1 applies.

342 14 Protection from unintentional biological effects being caused by the active 343 implantable medical device (standards.iteh.ai)

344 14.1 This subclause of ISO 14708-1 applies.

345 14.2 Replacement

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346 Any implantable part of the ACTIVE IMPLANTABLE MEDICAL DEVICE, intended in normal use to be in contact
347 with body fluids, shall cause no unacceptable release of particulate matter when the device is used as
348 intended by the manufacturer.

349 Test: The implantable part of the IMPLANT SYSTEM shall be removed aseptically from the NON-REUSABLE
350 PACK. The implantable part shall be immersed in a bath of saline solution, approximately 9 g/l and
351 suitable for injection in a neutral glass container. The volume of the saline in millilitres (ml) shall be
352 $5 \pm 0,5$ times the numerical value of the surface area of the implantable part expressed in cm^2 . The
353 container shall be covered with a glass lid and maintained at (37 ± 2) °C for between 8 h and 18 h, the
354 bath being agitated throughout the period. A reference sample of similar volume shall be prepared from
355 the same batch of saline, maintained and agitated in a similar way to the specimen. A sample of liquid
356 from the specimen bath and from the reference bath shall be compared using apparatus suitable for
357 measurement of particle size, such as apparatus operating on the light blockage principle (see
358 method V.5.7.1 of the European Pharmacopoeia) or the electrical zone sensing principle (the Coulter
359 principle, see Appendix XIII of the British Pharmacopoeia).

360 Compliance shall be confirmed if the excess average count of unintentional particles from the specimen
361 compared to the reference sample does not exceed 100 per ml greater than $5,0 \mu\text{m}$ and does not exceed
362 5 per ml greater than $25 \mu\text{m}$.

363 14.3 This subclause of ISO 14708-1 applies.

364 14.4 This subclause of ISO 14708-1 applies.