



SLOVENSKI STANDARD
oSIST prEN ISO 14708-6:2018
01-julij-2018

**Vsadki (implantati) za kirurgijo - Aktivni medicinski pripomočki za vsaditev - 6. del:
Posebne zahteve za aktivne vsadljive medicinske pripomočke, namenjene za
zdravljenje tahiaritmije (vključuje vsadljive defibrilatorje) (ISO/DIS 14708-6:2018)**

Implants for surgery - Active implantable medical devices - Part 6: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (including implantable defibrillators) (ISO/DIS 14708-6:2018)

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Implants chirurgicaux - Dispositifs médicaux implantables actifs - Partie 6: Exigences particulières pour les dispositifs médicaux implantables actifs destinés à traiter la tachyarythmie (y compris les défibrillateurs implantables) (ISO/DIS 14708-6:2018)

Ta slovenski standard je istoveten z: prEN ISO 14708-6

ICS:

11.040.40	Implantanti za kirurgijo, protetiko in ortetiko	Implants for surgery, prosthetics and orthotics
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DRAFT INTERNATIONAL STANDARD

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Implants for surgery — Active implantable medical devices —

Part 6:

Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (including implantable defibrillators)

*Implants chirurgicaux — Dispositifs médicaux implantables actifs —**Partie 6: Exigences particulières pour les dispositifs médicaux implantables actifs destinés à traiter la tachyarythmie (y compris les défibrillateurs implantables)*

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73 Foreword

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

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

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

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

91 ISO 14708-6 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee
92 SC 6, *Active implants*.

93 A list of all parts in the ISO 14708 series can be found on the ISO website.
<https://standards.iteh.ai/catalog/standards/sist/5bf1ed5b-c5d0-4709-b322-87438c21088d/ksist-fpren-iso-14708-6-2019>

94 NOTE The attention of Member Bodies is drawn to the fact that equipment MANUFACTURERS and testing
95 organizations might need a transitional period following publication of a new, amended, or revised ISO
96 publication in which to make products in accordance with the new requirements and to equip them for
97 conducting new or revised tests. It is the recommendation of the committee that the content of this publication
98 not be adopted for mandatory implementation nationally earlier than three years from the date of publication.

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99 **Introduction**

100 This document specifies particular requirements for IMPLANTABLE CARDIOVERTER DEFIBRILLATORS and the
101 functions of ACTIVE IMPLANTABLE MEDICAL DEVICES intended to treat tachyarrhythmia, to provide basic
102 assurance of safety for both patients and users.

103 An external defibrillator is a MEDICAL DEVICE used, in the emergency setting, to deliver a high-energy
104 shock to the heart, by means of ELECTRODES applied to the external chest wall, in patients suffering
105 ventricular fibrillation (a rapid, disorganized and potentially lethal heart rhythm abnormality), to
106 restore normal heart action. External defibrillators can also be used, in emergency or elective settings,
107 to terminate other ventricular or atrial tachyarrhythmias by delivery of a high-energy shock,
108 synchronized to the intrinsic cardiac rhythm, a procedure known as CARディオVERSION. In patients known
109 to be at RISK of such arrhythmias, due to the occurrence of previous episodes or the presence of specific
110 predisposing cardiac conditions, an IMPLANTABLE CARDIOVERTER DEFIBRILLATOR might be implanted to
111 perform similar functions. The implantable device, which is much smaller than an external defibrillator,
112 is contained within a sealed, encapsulating enclosure. It generates high voltage PULSES from an enclosed,
113 miniature, electrical battery. The PULSES are transmitted to the heart by means of implanted, insulated
114 conductors with ELECTRODES (LEADS). The IMPLANTABLE CARDIOVERTER DEFIBRILLATOR can also incorporate
115 other sensing and pacing functions, such as rate support for bradycardia and ANTITACHYCARDIA PACING
116 (ATP) to terminate certain tachyarrhythmias without the need of a high-energy shock. The defibrillator
117 can be adjusted non-invasively by means of an electronic device, known as a programmer.

118 In recent years, other active implantable cardiovascular devices have emerged, most notably devices
119 that perform the function of improving cardiac output by optimizing ventricular synchrony, in addition
120 to performing ICD functions.

121 Although these devices can deliver an additional therapy with respect to ICD devices, most of their
122 requirements are similar so that, in most cases, the concepts that apply to ICDs also apply to CRT-D
123 devices, and the appropriate way to test a CRT-D device is similar to the way ICDs are tested.

124 This document is relevant to all parts of ACTIVE IMPLANTABLE MEDICAL DEVICES intended to treat
125 tachyarrhythmia other than pacing functions to control bradyarrhythmia or provide cardiac
126 resynchronization. Typical examples are IMPLANTABLE PULSE GENERATORS, LEADS, ADAPTORS, ACCESSORIES,
127 programmers and the related software (bradyarrhythmia and cardiac resynchronization pacing
128 functions are dealt with in ISO 14708-2).

129 The requirements of this document supplement or modify those of ISO 14708-1, *Implants for surgery —*
130 *Active implantable medical devices — Part 1: General requirements for safety, marking and for*
131 *information to be provided by the manufacturer*, hereinafter referred to as ISO 14708-1. The
132 requirements of this document take priority over those of ISO 14708-1.

133 Figures or tables that are additional to those of ISO 14708-1 are numbered starting from 101.

134 Annex D describes a coding system that may be used to designate tachyarrhythmia therapy modes. All
135 annexes are informative.

136 **Implants for surgery — Active implantable medical devices —**
137 **Part 6: Particular requirements for active implantable medical**
138 **devices intended to treat tachyarrhythmia (including implantable**
139 **defibrillators)**

140 **1 Scope**

141 This document specifies requirements that are applicable to IMPLANTABLE CARDIOVERTER DEFIBRILLATORS
142 AND CRT-Ds and the functions of ACTIVE IMPLANTABLE MEDICAL DEVICES intended to treat tachyarrhythmia.

143 The tests that are specified in ISO 14708 are type tests and are to be carried out on samples of a device to
144 show compliance.

145 This document was designed for tachyarrhythmia PULSE generators used with either endocardial or
146 epicardial LEADS. At the time of this edition, the authors recognized the emergence of technologies that
147 do not use ENDOCARDIAL or EPICARDIAL LEADS for which adaptations of this part will be required. Such
148 adaptations are left to the discretion of MANUFACTURERS incorporating these technologies.

149 This document is also applicable to some non-implantable parts and accessories of the devices (see
150 Note 1).

151 The characteristics of the IMPLANTABLE PULSE GENERATOR or LEAD shall be determined by either the
152 appropriate method detailed in this document or by any other method demonstrated to have accuracy
153 equal to, or better than, the method specified. In the case of dispute, the method detailed in this
154 document shall apply. <https://standards.iteh.ai/catalog/standards/sist/5bfl ed5b-c5d0-4709-b322-87438c21088d/ksist-fpr-en-iso-14708-6-2019>

155 Any aspect of an ACTIVE IMPLANTABLE MEDICAL DEVICE intended to treat bradyarrhythmias or cardiac
156 resynchronization is covered by ISO 14708-2.

157 NOTE 1 The device that is commonly referred to as an ACTIVE IMPLANTABLE MEDICAL DEVICE might in fact be a single
158 device, a combination of devices, or a combination of a device or devices and one or more accessories. Not all of
159 these parts are required to be either partially or totally implantable, but there is a need to specify some
160 requirements of non-implantable parts and accessories if they could affect the safety or performance of the
161 implantable device.

162 NOTE 2 The terminology used in this European Standard is intended to be consistent with the terminology of
163 Directive 90/385/EEC.

164 NOTE 3 In this document, terms printed in small capital letters are used as defined in Clause 3. Where a defined
165 term is used as a qualifier in another term, it is not printed in small capital letters unless the concept thus qualified
166 is also defined.

167 NOTE 4 Particular requirements for congestive heart failure devices are under consideration. These types of
168 devices are not covered by this document.

169 **2 Normative references**

170 The following documents, in whole or in part, are normatively referenced in this document and are
171 indispensable for its application. For dated references, only the edition cited applies. For undated
172 references, the latest edition of the referenced document (including any amendments) applies.

173 ISO 5841-3:2013, *Implants for surgery — Cardiac pacemakers — Part 3: Low-profile connectors (IS-1) for*
174 *implantable pacemakers*

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175 ISO 8601:2004, *Data elements and interchange formats — Information interchange — Representation of*
176 *dates and times*

177 ISO 11318:2002, *Cardiac defibrillators — Connector assembly DF-1 for implantable defibrillators —*
178 *Dimensions and test requirements*

179 ISO 14117:2018, *Active implantable medical devices — Electromagnetic compatibility — EMC test*
180 *protocols for implantable cardiac pacemakers and implantable cardioverter defibrillators*

181 ISO 14708-1:2014, *Implants for surgery — Active implantable medical devices — Part 1: General*
182 *requirements for safety, marking and for information to be provided by the manufacturer*

183 ISO 14708-2:2018, *Implants for surgery — Active implantable medical devices — Part 2: Cardiac*
184 *pacemakers*

185 ISO 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information*
186 *to be supplied — Part 1: General requirements*

187 IEC 60878, *Graphical symbols for electrical equipment in medical practice*

188 3 Terms and definitions

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

191 — ISO Online browsing platform: available at <http://www.iso.org/obp>

192 — IEC Electropedia: available at <http://www.electropedia.org/>
<https://standards.iteh.ai/catalog/standards/sist/5bf1ed5b-c5d0-4709-b322-87438c21088d/ksist-fpren-iso-14708-6-2019>

193 3.101**194 adaptor**

195 special connector used between an otherwise incompatible IMPLANTABLE PULSE GENERATOR and a LEAD

196 [SOURCE: ISO 14708-2:2018, 3.102]

197 3.102**198 implantable cardioverter defibrillator****199 ICD**

200 ACTIVE IMPLANTABLE MEDICAL DEVICE comprising an IMPLANTABLE PULSE GENERATOR and LEAD(S) that is
201 intended to detect and correct tachycardias and fibrillation by application of
202 CARDIOVERSION/DEFIBRILLATION PULSE(S) to the heart

203 3.103**204 implantable pulse generator****205 IPG**

206 part of the ACTIVE IMPLANTABLE MEDICAL DEVICE, including the power supply and electronic circuit that
207 produces an electrical output

208 NOTE 1 to entry: For purposes of this document, the term IMPLANTABLE PULSE GENERATOR describes any ACTIVE
209 IMPLANTABLE MEDICAL DEVICE that incorporates functions intended to treat tachyarrhythmias.

210 [SOURCE: ISO 14708-2:2018, 3.104, modified – “ACTIVE IMPLANTABLE MEDICAL DEVICE” substituted for
211 “PACEMAKER”, NOTE 1 to entry added]

- 212 **3.104**
213 **sensitivity**
214 **sensing threshold**
215 minimum signal required to consistently control the function of the IMPLANTABLE PULSE GENERATOR
- 216 [SOURCE: ISO 14708-2:2018, 3.108]
- 217 **3.106**
218 **electrode**
219 electrically conducting part (usually the termination of a LEAD), which is designed to form an interface
220 with body tissue or body fluid
- 221 [SOURCE: ISO 14708-2:2018, 3.109]
- 222 **3.107**
223 **endocardial lead**
224 LEAD with an ELECTRODE designed to make a contact with the endocardium, or inner surface of the heart
- 225 [SOURCE: ISO 14708-2:2018, 3.112]
- 226 **3.108**
227 **epicardial lead**
228 LEAD with an ELECTRODE designed to make a contact with the epicardium, or outer surface of the heart
- 229 [SOURCE: ISO 14708-2:2018, 3.113]
- 230 **3.109**
231 **transvenous**
232 approach to the heart through the venous system
- 233 [SOURCE: ISO 14708-2:2018, 3.114]
- 234 **3.110**
235 **insertion diameter**
236 ⟨lead⟩
237 minimum bore of a rigid cylindrical tube into which the LEAD (not including the connector) can be
238 inserted
- 239 [SOURCE: ISO 14708-2:2018, 3.115]
- 240 **3.112**
241 **lead pacing impedance**
242 Z_p
243 impedance that is formed by the ratio of a voltage PULSE to the resulting current
- 244 [SOURCE: ISO 14708-2:2018, 3.117].
- 245 **3.114**
246 **model designation**
247 name and/or a combination of letters and numbers used by a MANUFACTURER to distinguish, by function
248 or type, one device from another
- 249 [SOURCE: ISO 14708-2:2018, 3.119]

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- 250 **3.115**
251 **serial number**
252 unique combination of letters and/or numbers, selected by the MANUFACTURER, intended to distinguish a
253 device from other devices with the same MODEL DESIGNATION
- 254 [SOURCE: ISO 14708-2:2018, 3.120]
- 255 **3.117**
256 **pulse**
257 electrical output of an IMPLANTABLE PULSE GENERATOR other than CD PULSE intended to stimulate the
258 myocardium
- 259 [SOURCE: ISO 14708-2:2018, 3.122, modified – added “other than CD PULSE”.]
- 260 **3.118**
261 **pulse amplitude**
262 amplitude of the PULSE
- 263 [SOURCE: ISO 14708-2:2018, 3.123]
- 264 **3.119**
265 **pulse duration**
266 duration of the PULSE
- 267 [SOURCE: ISO 14708-2:2018, 3.124]
- 268 **3.120**
269 **pulse interval**
270 interval between equivalent points of two consecutive PULSES
- 271 [SOURCE: ISO 14708-2:2018, 3.125]
- 272 **3.122**
273 **automatic sensitivity control**
274 automatic adjustment of the SENSITIVITY in response to available physiological signals
- 275 **3.123**
276 **beginning of service**
277 **BOS**
278 time at which an individual IMPLANTABLE PULSE GENERATOR is first released by the MANUFACTURER as fit for
279 being placed on the market
- 280 [SOURCE: ISO 14708-2:2018, 3.138]
- 281 **3.124**
282 **end of service**
283 **EOS**
284 time at which the PROLONGED SERVICE PERIOD has elapsed and no further pacing function is specified nor
285 can be expected
- 286 [SOURCE: ISO 14708-2: 2018, 3.139]

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- 287 **3.125**
 288 **prolonged service period**
 289 **PSP**
 290 period beyond the RECOMMENDED REPLACEMENT TIME during which the IMPLANTABLE PULSE GENERATOR
 291 continues to function as specified by the MANUFACTURER
- 292 [SOURCE: ISO 14708-2, 3.141, modified – deleted “to prolong basic Bradyarrhythmia pacing”]
- 293 **3.126**
 294 **power source indicator**
 295 means of indicating the electrical status of the power source during the IMPLANTABLE PULSE GENERATOR'S
 296 service life
- 297 [SOURCE: ISO 14708-2:2018, 3.142]
- 298 **3.127**
 299 **recommended replacement time**
 300 **RRT**
 301 time at which the POWER SOURCE INDICATOR reaches the value set by the MANUFACTURER of the IMPLANTABLE
 302 PULSE GENERATOR for its recommended replacement.
- 303 [SOURCE: ISO 14708-2:2018, 3.143]
- 304 Note 1 to entry: This indicates entry into the PROLONGED SERVICE PERIOD
- 305 **3.128**
 306 **antitachycardia pacing**
 307 **ATP**
 308 cardiac pacing sequences intended to terminate re-entry tachycardias
- 309 **3.130**
 310 **ATP only device**
 311 IMPLANTABLE PULSE GENERATOR capable of delivering rapid sequences of pacing PULSES to terminate
 312 ventricular (VT) and atrial (AT) tachycardia and atrial fibrillation (AF)
- 313 **3.131**
 314 **cardioversion**
 315 termination of atrial tachyarrhythmia or ventricular tachycardia by PULSE(S) synchronized to cardiac
 316 events
- 317 **3.132**
 318 **cardioversion/defibrillation pulse**
 319 **CD pulse**
 320 high-energy monophasic, biphasic, or multiphasic PULSE intended to restore normal rhythm by shocking
 321 the heart
- 322 **3.133**
 323 **capacitor formation**
 324 any charge to maximum-programmed energy that dissipates off the capacitors (is not dumped) for at
 325 least 10 min
- 326 **3.134**
 327 **cardioversion/defibrillation lead**
 328 **CD lead**
 329 LEAD used to conduct a CD PULSE from the IMPLANTABLE PULSE GENERATOR to the heart

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330 **3.135**331 **charge time**

332 the time required to charge the high-voltage capacitors to a specified CD PULSE ENERGY

333 **3.136**334 **delivered cardioversion/defibrillation pulse energy**335 **delivered CD pulse energy**

336 total energy delivered to a standard load (50 Ω) by all phases of a CD PULSE, measured according to 6.1.3

337 **3.137**338 **defibrillation**

339 termination of fibrillation

340 **3.138**341 **ICD output voltage**

342 peak voltage of the CARDIOVERSION/DEFIBRILLATION PULSES, measured according to 6.1.2

343 **3.139**344 **terminal**

345 electrically separate conductive device connection

346 **3.140**347 **implantable cardiac resynchronization therapy/defibrillator device**348 **CRT-D**

349 ACTIVE IMPLANTABLE MEDICAL DEVICE intended to detect and correct tachycardias and fibrillation by
 350 application of CARDIOVERSION/DEFIBRILLATION PULSES to the heart, and to provide improved ventricular
 351 activation to optimize cardiac output, comprising an IMPLANTABLE PULSE GENERATOR and LEADS

352 **4 Symbols and abbreviated terms**

353 *This clause of ISO 14708-1 applies.*

354 NOTE See ISO 27185 for symbols to use when expressing information so as to reduce the need for multiple
 355 languages on packaging and in manuals.

356 **5 General requirements for non-implantable parts**

357 *This clause of ISO 14708-1 applies.*

358 **6 Measurement of IMPLANTABLE PULSE GENERATOR and LEAD characteristics**359 **6.1 Measurement of IMPLANTABLE PULSE GENERATOR characteristics**

360 The MANUFACTURER shall ensure that measurement equipment accuracy is sufficient to support the
 361 stated tolerances for the parameters being measured within this clause and stated by the MANUFACTURER
 362 in the accompanying documentation [see 28.8].

363 The values of the electrical characteristics for the IMPLANTABLE PULSE GENERATOR measured in accordance
 364 with the methods described in this clause shall be within the range of values stated by the
 365 MANUFACTURER in the accompanying documentation [see 28.8.2].

366 **CAUTION** The tests in this subclause can employ the use of high voltage. Failure to use safe
 367 laboratory practices can result in severe electrical shock, resulting in personal injury or death to

368 **the persons handling the equipment or conducting the test. Also damage to electrical equipment**
 369 **is possible.**

370 The measurements shall be made with the IMPLANTABLE PULSE GENERATOR at a temperature of
 371 $37\text{ °C} \pm 2\text{ °C}$.

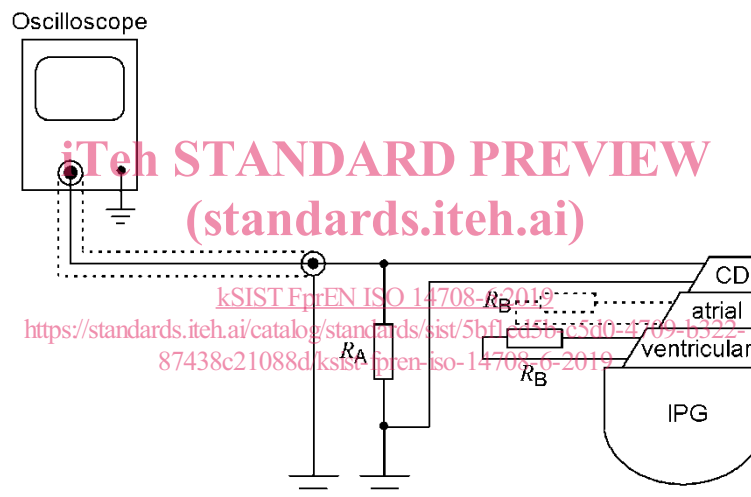
372 6.1.1 Measurement of the bradyarrhythmia characteristics

373 Measurement of the bradyarrhythmia and cardiac resynchronization characteristics of the IMPLANTABLE
 374 PULSE GENERATOR shall be performed using the appropriate methods specified in 6.1 of ISO 14708-2. The
 375 characteristics shall be measured with the tachyarrhythmia therapies inactivated.

376 6.1.2 Measurement of ICD OUTPUT VOLTAGE

377 NOTE This clause does not apply to ATP ONLY DEVICES.

378 Procedure: use an oscilloscope, with input impedance of nominal $1\text{ M}\Omega$, $\leq 30\text{ pF}$.



379

380 **Figure 101 — Measurement of CD PULSE characteristics**

381 The IMPLANTABLE PULSE GENERATOR shall be connected to the oscilloscope as shown in Figure 101.
 382 TERMINALS of the IMPLANTABLE PULSE GENERATOR intended to deliver a CD PULSE shall be connected to a
 383 low-inductance load of $50\ \Omega \pm 1\%$ (R_A). Other inputs/outputs shall be connected to loads of
 384 $500\ \Omega \pm 5\%$ (R_B). The oscilloscope shall be adjusted to display one phase of the CD PULSE.

385 The IMPLANTABLE PULSE GENERATOR shall be programmed to the maximum CD PULSE ENERGY setting.

386 The ICD OUTPUT VOLTAGE (V_{\max}) shall be determined by recording the peak amplitude of the voltage
 387 across the resistor R_A [see Figure 101 and Figure 102].

388 The procedure shall be repeated for each type of CD PULSE (i.e. monophasic, biphasic waveform).

389 The entire procedure shall be repeated for the other required CD PULSE ENERGY settings
 390 [see 28.8.2 d) 2)].