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**Vsadki (implantati) za kirurgijo - Aktivni medicinski pripomočki za vsaditev - 2. del:
Srčni spodbujevalniki (ISO/DIS 14708-2:2018)**

Implants for surgery - Active implantable medical devices - Part 2: Cardiac pacemakers
(ISO/DIS 14708-2:2018)

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Implants chirurgicaux - Dispositifs médicaux implantables actifs - Partie 2: Stimulateurs
cardiaques (ISO/DIS 14708-2:2018)

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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 2: Cardiac pacemakers

Implants chirurgicaux — Dispositifs médicaux implantables actifs —
Partie 2: Stimulateurs cardiaques

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71 Foreword

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

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

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85 any patent rights identified during the development of the document will be in the Introduction and/or
86 on the ISO list of patent declarations received. www.iso.org/patents

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

89 ISO 14708-2 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee
90 SC 6, *Active implants*.

91 This third edition cancels and replaces the second edition (ISO 14708-2:2012), which has been
92 technically revised.

93 A list of all parts in the ISO 14708 series can be found on the ISO website.

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.

99 Introduction

100 This document specifies particular requirements for those ACTIVE IMPLANTABLE MEDICAL DEVICES intended
101 to treat bradyarrhythmias (PACEMAKERS), to provide basic assurance of safety to both patients and users.

102 In recent years, other active implantable cardiovascular devices have emerged, most notably devices
103 that perform the function of improving cardiac output by optimizing ventricular synchrony, in addition
104 to performing PACEMAKER functions.

105 Although these devices can deliver an additional therapy with respect to PACEMAKERS, most of their
106 requirements are similar so that, in most cases, the concepts that apply to PACEMAKERS also apply to CRT-
107 P devices, and the appropriate way to test a CRT-P device is similar to the way PACEMAKERS are tested.

108 An implantable cardiac PACEMAKER is essentially a powered electronic device within a sealed,
109 encapsulating enclosure (an IMPLANTABLE PULSE GENERATOR). The device can stimulate heart BEATS by
110 generating electrical impulses which are transmitted to the heart along implanted, insulated conductors
111 with ELECTRODES (LEADS). The PACEMAKER can be adjusted non-invasively by an electronic device, known
112 as a programmer.

113 This document is relevant to all parts of implantable PACEMAKERS, including all ACCESSORIES. Typical
114 examples are IMPLANTABLE PULSE GENERATORS, LEADS, ADAPTORS, programmers and the related software.

115 The requirements of this part of ISO 14708-2 supplement or modify those of ISO 14708-1, referred to as
116 the General Standard. The requirements of this document take priority over those of ISO 14708-1.

117 Figures or tables that are additional to those of ISO 14708-1 are numbered starting from 101;
118 additional annexes are lettered AA, BB, etc.

119 Although both this document and the Directive 90/385/EEC deal with the same products, the structure
120 and purpose of the two documents are different. Annex AA correlates the requirements of the Directive
121 with the subclauses of ISO 14708-1 and this document. Annex BB provides reference in the other
122 direction, from this document to the Directive. Annex CC is a rationale providing further explanation of
123 the subclauses of this document.

124 Annex DD describes a coding system that may be used to designate bradyarrhythmia pacing modes.
125 Annex EE defines reference points for measurements of PULSE AMPLITUDE and PULSE DURATION, and the
126 form of test signal used to determine SENSITIVITY.

127 All annexes except Annex EE are informative.

Implants for surgery — Active implantable medical devices — Part 2: Cardiac PACEMAKERS

1 Scope

This document specifies requirements that are applicable to those ACTIVE IMPLANTABLE MEDICAL DEVICES intended to treat bradyarrhythmias and devices that provide therapies for cardiac resynchronization.

The tests that are specified in this document are type tests, and are to be carried out on samples of a device to show compliance.

This document was designed for Bradyarrhythmia PULSE generators used with endocardial or epicardial LEADS. At the time of this edition, the authors recognized the emergence of leadless technologies for which adaptations of this part will be required. Such adaptations are left to the discretion of MANUFACTURERS incorporating these technologies.

This document is also applicable to some non-implantable parts and ACCESSORIES of the devices (see NOTE 1).

The electrical characteristics of the IMPLANTABLE PULSE GENERATOR or LEAD are determined either by the appropriate method detailed in this particular standard or by any other method demonstrated to have an accuracy equal to, or better than, the method specified. In case of dispute, the method detailed in this particular standard applies.

Any features of an ACTIVE IMPLANTABLE MEDICAL DEVICE intended to treat tachyarrhythmias are covered by ISO 14708-6.

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

NOTE 2 In this document, terms printed in small capital letters are used as defined in Clause 3. Where a defined term is used as a qualifier in another term, it is not printed in small capital letters unless the concept thus qualified is also defined.

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.

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

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

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

165 ISO 14117:—¹, *Active implantable medical devices — Electromagnetic compatibility — EMC test*
 166 *protocols for implantable cardiac pacemakers, implantable cardioverter defibrillators and cardiac*
 167 *resynchronization devices, Second Edition*

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

170 ISO 27186:2010, *Active implantable medical devices - Four-pole connector system for implantable cardiac*
 171 *rhythm management devices - Dimensional and test requirements*

172 3 Terms and definitions

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

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

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

177 — IEC Electropedia: available at <http://www.electropedia.org/>

178 3.101

179 accessories

180 articles which, while not being a device, are intended specifically by the MANUFACTURER to be used
 181 together with a device in accordance with the use of the device intended by the device MANUFACTURER

182 3.102

183 adaptor

184 special connector used between an otherwise incompatible active IMPLANTABLE PULSE GENERATOR and a
 185 LEAD

186 3.103

187 pacemaker

188 ACTIVE IMPLANTABLE MEDICAL DEVICE intended to treat bradyarrhythmias, comprising an IMPLANTABLE
 189 PULSE GENERATOR and LEAD(S)

190 3.104

191 implantable pulse generator

192 part of the PACEMAKER, including the power supply and electronic circuit that produces an electrical
 193 output

194 3.105

195 sensor

196 part of a PACEMAKER that is designed to detect signals for the purpose of RATE MODULATION or other
 197 control purposes

¹ In development.

- 198 **3.106**
 199 **dual-chamber**
 200 condition of relating both to the atrium and ventricle
- 201 **3.107**
 202 **implantable cardiac resynchronization therapy pacing device**
 203 **CRT-P**
 204 ACTIVE IMPLANTABLE MEDICAL DEVICE intended to provide improved ventricular activation to optimize
 205 cardiac output, comprising an IMPLANTABLE PULSE GENERATOR and LEADS
- 206 [SOURCE: ISO 14117:201x, 3.3, modified – PULSE GENERATOR substituted for “DUT”]
- 207 **3.108**
 208 **sensitivity**
 209 minimum signal required to control consistently the function of the IMPLANTABLE PULSE GENERATOR
- 210 **3.109**
 211 **electrode**
 212 electrically conducting part (usually the termination of a LEAD), which is designed to form an interface
 213 with body tissue or body fluid
- 214 **3.110**
 215 **bipolar lead**
 216 LEAD with two ELECTRODES, electrically isolated from each other
- 217 **3.111**
 218 **unipolar lead**
 219 LEAD with one ELECTRODE
- 220 **3.112**
 221 **endocardial lead**
 222 LEAD with an ELECTRODE designed to make contact with the endocardium, or inner surface of the heart
- 223 **3.113**
 224 **epicardial lead**
 225 LEAD with an ELECTRODE designed to make contact with the epicardium, or outer surface of the heart
- 226 **3.114**
 227 **transvenous**
 228 approach to the heart through the venous system
- 229 **3.115**
 230 **insertion diameter**
 231 ⟨LEAD⟩ minimum bore of a rigid cylindrical tube into which the LEAD (not including the connector) can be
 232 inserted
- 233 **3.117**
 234 **lead pacing impedance**
 235 Z_p
 236 impedance that is formed by the ratio of a voltage PULSE to the resulting current

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237 Note 1 to entry: The impedance is composed of the ELECTRODE to tissue interface and the LEAD impedance.

238 **3.119**

239 **model designation**

240 name and/or a combination of letters and numbers used by a MANUFACTURER to distinguish, by function
241 or type, one device from another

242 **3.120**

243 **serial number**

244 unique combination of letters and/or numbers, selected by the MANUFACTURER, intended to distinguish a
245 device from other devices with the same MODEL DESIGNATION

246 **3.121**

247 **beat**

248 ordered spontaneous or paced activity of the heart

249 **3.122**

250 **pulse**

251 electrical output of an IMPLANTABLE PULSE GENERATOR intended to stimulate the myocardium

252 **3.123**

253 **pulse amplitude**

254 amplitude of the PULSE

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255 Note 1 to entry: The PULSE AMPLITUDE is measured according to the procedure in 6.1.2

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256 **3.124**

257 **pulse duration**

258 duration of the PULSE

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259 Note 1 to entry: The PULSE DURATION is measured according to the procedure in 6.1.2

260 **3.125**

261 **pulse interval**

262 interval between equivalent points of two consecutive PULSES

263 Note 1 to entry: The PULSE INTERVAL is measured according to the procedure in 6.1.2

264

265 **3.126**

266 **basic pulse interval**

267 PULSE INTERVAL in absence of sensed cardiac or other electrical influence

268 **3.127**

269 **pulse rate**

270 number of PULSES per minute

271 Note 1 to entry: The PULSE RATE is measured according to the procedure in 6.1.2

272

273 **3.128**

274 **basic rate**

275 PULSE RATE of an IMPLANTABLE PULSE GENERATOR, either atrial or ventricular, unmodified by sensed cardiac
276 or other electrical influence

277 **3.129**

278 **atrioventricular interval**

279 **AV interval**

280 delay between an atrial PULSE or the sensing of an atrial depolarization and the subsequent ventricular
281 PULSE or the sensing of a ventricular depolarization

282 Note 1 to entry: The AV INTERVAL is measured according to the procedure in 6.1.8

283

284 **3.130**

285 **escape interval**

286 time elapsing between the sensing of a spontaneous BEAT and the succeeding non-triggered PULSE of an
287 IMPLANTABLE PULSE GENERATOR

288 Note 1 to entry: The ESCAPE INTERVAL is measured according to the procedure in 6.1.5

289

290 **3.131**

291 **hysteresis**

292 characteristic of an IMPLANTABLE PULSE GENERATOR defined by the difference between the ESCAPE INTERVAL
293 and the BASIC PULSE INTERVAL

294 Note 1 to entry: The ESCAPE INTERVAL is normally longer than the BASIC PULSE INTERVAL; this is "positive" HYSTERESIS.

295 **3.132**

296 **interference pulse rate**

297 PULSE RATE with which the IMPLANTABLE PULSE GENERATOR responds when it senses electrical activity that
298 it recognizes as interference

299 **3.133**

300 **maximum tracking rate**

301 maximum PULSE RATE at which the IMPLANTABLE PULSE GENERATOR will respond on a 1:1 basis to a
302 triggering signal

303 **3.134**

304 **rate modulation**

305 altering of the PULSE INTERVAL as a function of a control parameter other than a sensed BEAT

306 **3.135**

307 **refractory period**

308 period of time during which atrial or ventricular PACEMAKER timing is unaffected by sensed spontaneous
309 depolarizations, although sensing is not completely disabled

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310 **3.136**311 **test pulse interval**

312 PULSE INTERVAL of an IMPLANTABLE PULSE GENERATOR when directly influenced by a testing device

313 **3.137**314 **test pulse rate**

315 PULSE RATE of an IMPLANTABLE PULSE GENERATOR when directly influenced by a testing device

316 **3.138**317 **beginning of service**318 **BOS**

319 time at which an individual IMPLANTABLE PULSE GENERATOR is first released by the MANUFACTURER as fit for
320 being placed on the market

321 **3.139**322 **end of service**323 **EOS**

324 time at which the PROLONGED SERVICE PERIOD has elapsed and no further pacing function is specified nor
325 can be expected

326 **3.140**327 **projected service life**

328 period from the implantation of the IMPLANTABLE PULSE GENERATOR to the RECOMMENDED REPLACEMENT
329 TIME under defined conditions

330 **3.141**331 **prolonged service period**332 **PSP**

333 period beyond the RECOMMENDED REPLACEMENT TIME during which the IMPLANTABLE PULSE GENERATOR
334 continues to function as specified by the MANUFACTURER to prolong basic bradyarrhythmia pacing

335 **3.142**336 **power source indicator**

337 means of indicating the electrical status of the power source during the IMPLANTABLE PULSE GENERATOR's
338 service life

339 **3.143**340 **recommended replacement time**341 **RRT**

342 time at which the POWER SOURCE INDICATOR reaches the value set by the MANUFACTURER of the IMPLANTABLE
343 PULSE GENERATOR for its recommended replacement

344 Note 1 to entry: This indicates entry into the PROLONGED SERVICE PERIOD.

345 **3.144**346 **stoichiometric capacity**

347 capacity as defined by the active materials contents in the power source

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348 **3.145**

349 **usable capacity**

350 portion of the STOICHIOMETRIC CAPACITY of the power source that can be utilized by the IMPLANTABLE PULSE
351 GENERATOR until END OF SERVICE is reached

352 **4 Symbols and abbreviated terms**

353 *This clause of the General Standard applies.*

354 Additional NOTE.

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

357 **5 General requirements for non-implantable parts**

358 *This clause of the General Standard applies.*

359 **6 Measurements of IMPLANTABLE PULSE GENERATOR and LEAD characteristics**

360 **6.1 Measurement of IMPLANTABLE PULSE GENERATOR characteristics**

361 **6.1.1 General considerations**

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

365 The values of the IMPLANTABLE PULSE GENERATOR characteristics measured in accordance with the
366 methods described in this clause shall be within the range of values stated by the MANUFACTURER in the
367 accompanying documentation [see 28.8].

368 The procedures shall be performed with the IMPLANTABLE PULSE GENERATOR at a temperature of
369 $37\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$, connected to a load of $500\text{ }\Omega \pm 1\%$ and set to the nominal settings recommended by the
370 MANUFACTURER (the factory recommended settings), unless otherwise stated.

371 If the IMPLANTABLE PULSE GENERATOR has multichannel functionality, each channel's characteristics shall
372 be determined separately. For simplicity, all the measurement procedures provided show bipolar
373 IMPLANTABLE PULSE GENERATORS. For unipolar IMPLANTABLE PULSE GENERATORS, the case is properly
374 incorporated in the set-up as the indifferent terminal.

375 In this document, the term "oscilloscope" may also be interpreted as including data acquisition systems
376 capable of performing similar measurements.

377 **6.1.2 Measurement of PULSE AMPLITUDE, PULSE DURATION, PULSE INTERVAL, and PULSE RATE**

378 *Procedure:* Use an interval counter and an oscilloscope.

379 The IMPLANTABLE PULSE GENERATOR shall be connected to a $500\text{ }\Omega \pm 1\%$ load resistor (R_L), and the test
380 equipment as shown in Figure 101. The oscilloscope shall be adjusted to display one PULSE in full.