
**Cardiac rhythm management devices —
Symbols to be used with cardiac rhythm
management device labels, and
information to be supplied — General
requirements**

*Dispositifs de gestion du rythme cardiaque — Symboles à utiliser avec
les marquages de dispositif de rythme cardiaque et informations à
fournir — Exigences générales*



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ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

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Foreword

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

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 27185 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 6, *Active implants*.

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Introduction

This International Standard addresses the presentation of certain items of information that are considered by regulatory authorities to be essential for the safe and proper use of cardiac rhythm management medical devices. As such, the items are required to be presented with the device in most regulatory domains. The information can be required on the device itself, as part of the label, or provided with the device.

Many countries require the use of their own language to present textual information with medical devices. This presents problems to device manufacturers and users.

Manufacturers seek to take costs out of labelling by reducing or rationalizing variants. This presents a major problem of translation, design and logistics when multiple languages are included on a single label or piece of documentation.

Users, presented with devices labelled in a number of different languages, can experience confusion and delay in locating the appropriate language.

This International Standard proposes solutions to these problems through the use of internationally recognized symbols, with precisely defined meanings, that are independent of language.

This International Standard is primarily intended to be used by:

- manufacturers of cardiac rhythm management medical devices who market identical products in countries having different language requirements for labelling;
- users of cardiac rhythm management medical devices who draw their supplies from a number of sources and can have varied language capabilities.

This International Standard can also be of assistance to

- distributors of cardiac rhythm management medical devices or other representatives of manufacturers;
- health care providers responsible for training as well as those being trained;
- those responsible for post-market vigilance;
- health care regulatory authorities, testing organizations, certification bodies and other organizations responsible for implementing regulations affecting medical devices and having responsibility for post-market surveillance.

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Cardiac rhythm management devices — Symbols to be used with cardiac rhythm management device labels, and information to be supplied — General requirements

1 Scope

This International Standard specifies requirements for the use of symbols conveying information on the safe and effective use of cardiac rhythm management medical devices. Table 1 gives a list of existing symbols that comply with the requirements of this International Standard.

This International Standard is applicable to, and limited to, symbols for cardiac rhythm management medical devices that can be marketed globally. These symbols can be used on the devices themselves or their labelling.

NOTE Other standards specify additional symbols that are applicable to particular kinds or groups of devices or to particular situations. Examples of such sources are identified in the Bibliography. This listing is not exhaustive.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 15223-2, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Symbol development, selection and validation*

ISO 80416-2, *Basic principles for graphical symbols for use on equipment — Part 2: Form and use of arrows*

IEC 80416-1:2008, *Basic principles for graphical symbols for use on equipment — Part 1: Creation of graphical symbols for registration*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1

characteristic information

mental representation of a property or properties of an object or set of objects

3.2

compound symbol

series of individual symbols linked together to form a piece of information that it is intended to read as a single unit

3.3

description

normative text that defines the purpose, the application, and the use of the symbol

[IEC 80416-1:2008, 3.2]

3.4

graphical symbol

graphical object that communicates **characteristic information** (3.1) without relying on language to communicate the information

3.5

graphical symbol element

graphical object that has a particular meaning and that is used in combination with other graphical symbol elements to create a **graphical symbol** (3.4) which communicates more complete meaning

3.6

iconic presentation

pictorial or graphical representation using familiar objects including alphanumeric characters

3.7

non-programmable

device parameter that cannot be modified by the physician

3.8

programmable

device parameter that can be modified by the physician

3.9

symbol original

drawing of a symbol, prepared in accordance with IEC 80416-1, used for reference or reproduction purposes

[IEC 80416-1:2008, 3.3]

3.10

symbol used in medical device labelling

object presented on the label and/or associated documentation of a medical device that communicates **characteristic information** (3.1) without relying on knowledge of the language of a particular nation or people by the supplier or receiver of the information

NOTE The symbol can utilize symbolic or iconic presentation.

3.11

title

unique name by which a symbol is identified and spoken of

[IEC 80416-1:2008, 3.5]

4 Abbreviated terms

ATP	Anti-tachycardia pacing
A-V	Atrial-ventricular
CRT-D	Cardiac resynchronization therapy — defibrillation
CRT-P	Cardiac resynchronization therapy — pacing
ICD	Implantable cardioverter defibrillator

IPG	Implantable pulse generator
LV	Left ventricular
PVARP	Post-ventricular atrial refractory period
RA	Right atrial
RV	Right ventricular

NOTE The definitions for these terms are provided in the respective standards for the product. See the Bibliography for a list of these standards.

5 General requirements

5.1 Proposal of symbols for adoption

Proposals for symbols for adoption into ISO 27185 shall be submitted to the secretariat of ISO/TC 150/SC 6.

Symbols being proposed shall be presented following the dimensional criteria and design principles set out in IEC 80416-1 and ISO 80416-2. Where the presentation is symbolic, alphanumeric characters shall not be part of the symbol. Alphanumeric characters may be used when appropriate and relevant in a symbol with iconic presentation.

Symbols presented for advice on acceptability or procedural details may be presented as symbol concepts. Symbols presented for formal adoption shall be symbol originals (see 3.9).

Any symbol proposed for adoption into this International Standard shall be applicable to cardiac rhythm management devices and have global applicability.

5.2 Requirements for usage

When risk management shows that it is appropriate to use symbols to convey information essential for proper use on the cardiac rhythm management medical devices, on its package, or in associated documentation, the symbols provided in Table 1 should be used.

NOTE 1 Other symbols can be used to convey different information. Many other standards specify symbols for particular purposes and/or for particular kinds of devices. The Bibliography lists some of these standards.

In use, the graphical representation of symbols shall comply with that shown in this International Standard, especially with respect to relative dimensions including line thickness, orientation and the absence or presence of filled or shaded areas.

As part of risk management and taking account of the specifics and size of the product and its packaging, the manufacturer shall determine the appropriate size necessary for the symbol to be legible for its intended function. Symbols are designed as specified in the requirements of IEC 80416-1 and ISO 80416-2 in order to maximize the clarity of the symbol in a reduced form.

NOTE 2 Colours and minimum dimensions are not specified in this International Standard.

The manufacturer shall ensure that no additional risk is incurred before using symbols. Alternatively, appropriate strategies shall be adopted to negate the risk.

NOTE 3 Additional information regarding risk is available in ISO 14971.

Symbols may be used without accompanying text. When this is not permitted by statute or regulation, the minimum text in all required languages associated with the symbol should be the referent of this International

Standard. Refer to the “Title” column in Table 1 for the minimum text to accompany the symbol. The information under “Informative notes” provides synonyms for titles.

When one or more values are associated with a particular symbol, they should be placed immediately adjacent to the primary graphical element in the symbol most closely related to the value. Examples of associating values with particular symbols are provided in Annex A.

6 Symbols

When appropriate, certain information essential for proper use, as required in the appropriate standard, shall be indicated on the medical device, on its package, or in the associated documentation by using the corresponding symbols given in Table 1. Examples are provided in Annex A.

Table 1 — Symbols to convey information essential for proper use

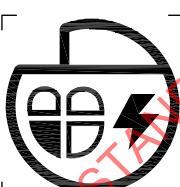
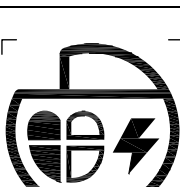
No.	Graphical symbol	Title	Description of symbol	Informative notes	Related subclause in AIMD product standards	ISO 7000 registration number
6.1		Pacemaker, single chamber, right ventricular	To indicate implantable pacemakers that are intended to stimulate and sense in the right ventricle of the heart	NOTE A synonym for “Pacemaker, single chamber, right ventricular” is “Pacemaker (single chamber, RV)”.	9.3 (ISO 14708-1:2000, EN 45502-1:1998) Description of the device	ISO 7000-3038
6.2		Pacemaker, single chamber, right atrial	To indicate an implantable pacemaker that is intended to stimulate and sense in the right atrium of the heart	NOTE A synonym for “Pacemaker, single chamber, right atrial” is “Pacemaker (single chamber, RA)”.	9.3 (ISO 14708-1:2000, EN 45502-1:1998) Description of the device	ISO 7000-3039
6.3		Pacemaker, dual chamber, right atrial, right ventricular	To indicate an implantable pacemaker that is intended to stimulate and sense in both the right atrium and right ventricle of the heart	NOTE Synonyms for “Pacemaker, dual chamber, right atrial, right ventricular” are “Pacemaker (dual chamber, RA, RV)” or “Pacemaker (dual chamber)”.	9.3 (ISO 14708-1:2000, EN 45502-1:1998) Description of the device	ISO 7000-3040
6.4		Implantable cardioverter defibrillator, single chamber, right ventricular	To indicate an implantable cardioverter defibrillator that is intended to stimulate and sense in the right ventricle and to shock the heart	NOTE A synonym for “Implantable cardioverter defibrillator, single chamber, right ventricular” is “ICD (single chamber, RV)”.	9.3 (ISO 14708-1:2000, EN 45502-1:1998) Description of the device	ISO 7000-3041
6.5		Implantable cardioverter defibrillator, dual chamber, right atrial, right ventricular	To indicate an implantable cardioverter defibrillator that is intended to stimulate and sense in the right atrium and right ventricle and to shock the heart	NOTE Synonyms for “Implantable cardioverter defibrillator, dual chamber, right atrial, right ventricular” are “ICD (dual chamber, RA, RV)” or “ICD (dual chamber)”.	9.3 (ISO 14708-1:2000, EN 45502-1:1998) Description of the device	ISO 7000-3042

Table 1 (continued)

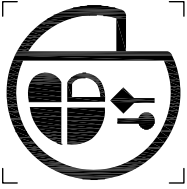
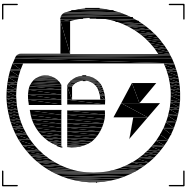
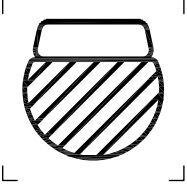
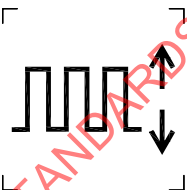
No.	Graphical symbol	Title	Description of symbol	Informative notes	Related subclause in AIMD product standards	ISO 7000 registration number
6.6		Cardiac resynchronization therapy pacemaker, right atrial, right ventricular, left ventricular	To indicate an implantable pacemaker that is intended to stimulate and sense in the right atrium, right ventricle and left ventricle of the heart	NOTE Synonyms for "Cardiac resynchronization therapy pacemaker, right atrial, right ventricular, left ventricular" are "CRT-P, RA, RV, LV" or "CRT-P".	9.3 (ISO 14708-1:2000, EN 45502-1:1998) Description of the device	ISO 7000-3043
6.7		Cardiac resynchronization therapy defibrillator, right atrial, right ventricular, left ventricular	To indicate an implantable cardioverter defibrillator that is intended to stimulate and sense in the right atrium, right ventricle and left ventricle; and to shock the heart	NOTE Synonyms for "Cardiac resynchronization therapy defibrillator, right atrial, right ventricular, left ventricular" are "CRT-D, RA, RV, LV" or "CRT-D".	9.3 (ISO 14708-1:2000, EN 45502-1:1998) Description of the device	ISO 7000-3044
6.8		Implantable device	To indicate an implantable device		9.3 (ISO 14708-1:2000, EN 45502-1:1998) Description of the device	ISO 7000-3045
6.9		Implantable device (coated)	To indicate an implantable device with coating for allergies or to prevent unintended muscle stimulation		9.3 (ISO 14708-1:2000, EN 45502-1:1998) Description of the device	ISO 7000-3046
6.10		Maximum tracking rate and minimum rate	To indicate the shipping parameters for maximum tracking rate and minimum rate	NOTE Synonyms for "Maximum tracking rate and minimum rate" are "Upper tracking rate/lower rate", "Max tracking rate/minimum rate", or "Max track rate/minimum rate".	9.4.1 (ISO 14708-2:2005, EN 45502-2-1:2003) The IPGs non-programmable ¹ characteristics for each input/output terminal, as applicable: the basic rate in reciprocal minutes ¹ This symbol may be used for programmable as well as non-programmable parameters.	ISO 7000-3047

Table 1 (continued)

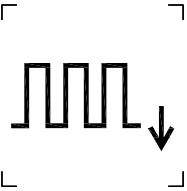
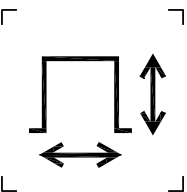
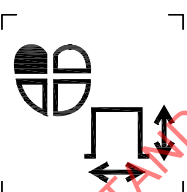
No.	Graphical symbol	Title	Description of symbol	Informative notes	Related subclause in AIMD product standards	ISO 7000 registration number
6.11		Minimum rate	To indicate the shipping parameters for minimum rate	NOTE Synonyms for "Minimum rate" are "Lower rate" or "Rest rate".	9.4.1 (ISO 14708-2:2005, EN 45502-2-1:2003) The IPGs non-programmable ¹ characteristics for each input/output terminal, as applicable: the basic rate in reciprocal minutes ¹ This symbol may be used for programmable as well as non-programmable parameters.	ISO 7000-3048
6.12		Amplitude and pulse width, general	To indicate the general shipping parameters for amplitude and pulse width	NOTE Synonyms for "Amplitude and pulse width, general" are "Amplitude and pulse width" or "Amplitude/pulse width".	9.4.1 (ISO 14708-2:2005, EN 45502-2-1:2003) The IPGs non-programmable ¹ characteristics for each input/output terminal, as applicable: the pulse amplitude (in volts or milliamperes) ¹ This symbol may be used for programmable as well as non-programmable parameters.	ISO 7000-3049
6.13		Amplitude and pulse width, right atrial	To indicate the shipping parameters for atrial amplitude and pulse width	NOTE Synonyms for "Amplitude and pulse width, right atrial" are "Atrial amplitude/pulse width" or "Amplitude and pulse width, RA" or "Amplitude/pulse width, RA" or "Amplitude/pulse width, right atrial".	9.4.1 (ISO 14708-2:2005, EN 45502-2-1:2003) The IPGs non-programmable ¹ characteristics for each input/output terminal, as applicable: the pulse amplitude (in volts or milliamperes) ¹ This symbol may be used for programmable as well as non-programmable parameters.	ISO 7000-3050

Table 1 (continued)

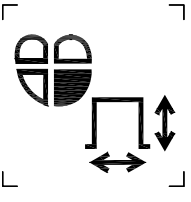
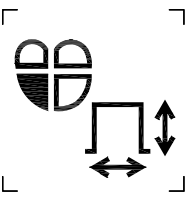
No.	Graphical symbol	Title	Description of symbol	Informative notes	Related subclause in AIMD product standards	ISO 7000 registration number
6.14		Amplitude and pulse width, left ventricular	To indicate the shipping parameters for left-ventricular amplitude and pulse width	NOTE Synonyms for "Amplitude and pulse width, left ventricular" are "LV amplitude/pulse width" or "Amplitude/pulse width, LV" or "Amplitude and pulse width, LV" or "Amplitude/pulse width, left ventricular".	9.4.1 (ISO 14708-2:2005, EN 45502-2-1:2003) The IPGs non-programmable ¹ characteristics for each input/output terminal, as applicable: the pulse amplitude (in volts or milliamperes) ¹ This symbol may be used for programmable as well as non-programmable parameters.	ISO 7000-3051
6.15		Amplitude and pulse width, right ventricular	To indicate the shipping parameters for right-ventricular amplitude and pulse width	NOTE Synonyms for "Amplitude and pulse width, right ventricular" are "RV amplitude/pulse width" or "Amplitude/pulse width, RV" or "Amplitude and pulse width, RV" or "Amplitude/pulse width, right ventricular".	9.4.1 (ISO 14708-2:2005, EN 45502-2-1:2003) The IPGs non-programmable ¹ characteristics for each input/output terminal, as applicable: the pulse amplitude (in volts or milliamperes) ¹ This symbol may be used for programmable as well as non-programmable parameters.	ISO 7000-3052
6.16		Sensitivity	To indicate the shipping parameter for sensitivity (defined as the size of the signal to which the pacemaker ought to respond).		9.4.1 (ISO 14708-2:2005, EN 45502-2-1:2003) The IPGs non-programmable ¹ characteristics for each input/output terminal, as applicable: the sensitivity (in millivolts) ¹ This symbol may be used for programmable as well as non-programmable parameters.	ISO 7000-3053

Table 1 (continued)

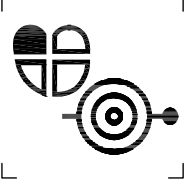
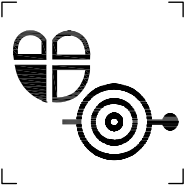
No.	Graphical symbol	Title	Description of symbol	Informative notes	Related subclause in AIMD product standards	ISO 7000 registration number
6.17		Sensitivity, right atrial	To indicate the shipping parameters for right-atrial sensitivity	NOTE Synonyms for "Sensitivity, right atrial" are "Atrial sensitivity" or "Sensitivity, RA" or "Right atrial sensitivity".	9.4.1 (ISO 14708-2:2005, EN 45502-2-1:2003) The IPGs non-programmable ¹ characteristics for each input/output terminal, as applicable: the sensitivity (in millivolts) ¹ This symbol may be used for programmable as well as non-programmable parameters.	ISO 7000-3054
6.18		Sensitivity, right ventricular	To indicate the shipping parameters for right-ventricular sensitivity	NOTE Synonyms for "Sensitivity, right ventricular" are "Sensitivity, RV" or "Right ventricular sensitivity" or "Ventricular sensitivity".	9.4.1 (ISO 14708-2:2005, EN 45502-2-1:2003) The IPGs non-programmable ¹ characteristics for each input/output terminal, as applicable: the sensitivity (in millivolts) ¹ This symbol may be used for programmable as well as non-programmable parameters.	ISO 7000-3055
6.19		Refractory period, right atrial	To indicate the shipping parameters for atrial refractory period	NOTE Synonyms for "Refractory period, right atrial" are "Refractory period, RA" or "Right atrial refractory period" or "RA, refractory period" or "Atrial refractory period".	9.4.1 (ISO 14708-2:2005, EN 45502-2-1:2003) The IPGs non-programmable ¹ characteristics for each input/output terminal, as applicable: the refractory period (in milliseconds) ¹ This symbol may be used for programmable as well as non-programmable parameters.	ISO 7000-3056

Table 1 (continued)

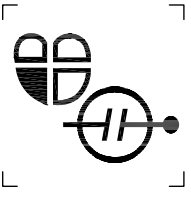
No.	Graphical symbol	Title	Description of symbol	Informative notes	Related subclause in AIMD product standards	ISO 7000 registration number
6.20		Refractory period, right ventricular	To indicate the shipping parameters for ventricular refractory period	NOTE Synonyms for "Refractory period, right ventricular" are "Refractory period, RV" or "Right ventricular refractory period" or "RV, refractory period" or "Ventricular refractory period".	9.4.1 (ISO 14708-2:2005, EN 45502-2-1:2003) The IPGs non-programmable ¹ characteristics for each input/output terminal, as applicable: the refractory period (in milliseconds) ¹ This symbol may be used for programmable as well as non-programmable parameters.	ISO 7000-3057
6.21		Atrial refractory period, post ventricular	To indicate the shipping parameters for post ventricular atrial refractory period	NOTE Synonyms for "Atrial refractory period, post ventricular" are "Post ventricular atrial refractory period" or "PVARP".	9.4.1 (ISO 14708-2:2005, EN 45502-2-1:2003) The IPGs non-programmable ¹ characteristics for each input/output terminal, as applicable: the refractory period (in milliseconds) ¹ This symbol may be used for programmable as well as non-programmable parameters.	ISO 7000-3058
6.22		Refractory period	To indicate the shipping parameters for refractory period		9.4.1 (ISO 14708-2:2005, EN 45502-2-1:2003) The IPGs non-programmable ¹ characteristics for each input/output terminal, as applicable: the refractory period (in milliseconds) ¹ This symbol may be used for programmable as well as non-programmable parameters.	ISO 7000-3059

Table 1 (continued)

No.	Graphical symbol	Title	Description of symbol	Informative notes	Related subclause in AIMD product standards	ISO 7000 registration number
6.23		Atrial to ventricular interval, paced and sensed	To indicate the shipping parameters for paced and sensed atrial to ventricular interval	NOTE Synonyms for "Atrial to ventricular interval, paced and sensed" are "A-V interval (paced/sensed)" or "AV interval (paced/sensed)".	9.4.1 (ISO 14708-2:2005, EN 45502-2-1:2003) The IPGs non-programmable ¹ characteristics for each input/output terminal, as applicable: the A/V interval, if applicable (in milliseconds) ¹ This symbol may be used for programmable as well as non-programmable parameters.	ISO 7000-3060
6.24		Sensed atrial to ventricular interval	To indicate the shipping parameters for sensed atrial to ventricular interval	NOTE Synonyms for "Sensed atrial to ventricular interval" are "Sensed A-V interval" or "Sensed AV interval".	9.4.1 (ISO 14708-2:2005, EN 45502-2-1:2003) The IPGs non-programmable ¹ characteristics for each input/output terminal, as applicable: the A/V interval, if applicable (in milliseconds) ¹ This symbol may be used for programmable as well as non-programmable parameters.	ISO 7000-3061
6.25		Header face	To indicate the header face to be used for identifying connector bore locations		9.4.1 (ISO 14708-2:2005, EN 45502-2-1:2003) The connector geometry, or provide a reference by symbols defined in published connector standards	ISO 7000-3062

Table 1 (continued)

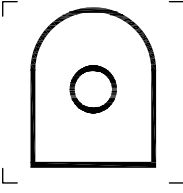
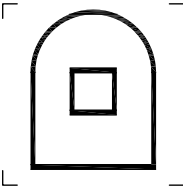
No.	Graphical symbol	Title	Description of symbol	Informative notes	Related subclause in AIMD product standards	ISO 7000 registration number
6.26		Single pole high voltage connector cavity for defibrillator	To indicate the shape to be used for identifying single pole high voltage (DF-1) connector cavity locations for defibrillators	NOTE 1 Synonyms for "Single pole high voltage connector cavity for defibrillator" are "DF-1" or "DF-1 connector cavity" employing terms familiar to the discipline. NOTE 2 The header shape is included in this symbol to show perspective. See Annex A for examples of this symbol's usage. NOTE 3 Unipolar or bipolar may be identified using text. See Annex A for an example of how this identification is accomplished.	9.4.1 (ISO 14708-2:2005, EN 45502-2-1:2003) The connector geometry, or provide a reference by symbols defined in published connector standards	ISO 7000-3063
6.27		Four pole high voltage connector cavity for defibrillator	To indicate the shape to be used for identifying four pole high voltage (DF4) connector cavity locations for defibrillators	NOTE 1 Synonyms for "Four pole high voltage connector cavity for defibrillator" are "DF4" or "DF4 connector cavity". NOTE 2 The header shape is included in this symbol to show perspective. See Annex A for examples of this symbol's usage. NOTE 3 Unipolar or bipolar may be identified using text. See Annex A for an example of how this identification is accomplished.	9.4.1 (ISO 14708-2:2005, EN 45502-2-1:2003) The connector geometry, or provide a reference by symbols defined in published connector standards	ISO 7000-3064

Table 1 (continued)

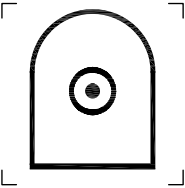
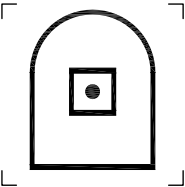
No.	Graphical symbol	Title	Description of symbol	Informative notes	Related subclause in AIMD product standards	ISO 7000 registration number
6.28		Single pole low voltage connector cavity for pacemaker and defibrillator	To indicate the shape to be used for identifying single pole low voltage (IS-1) connector cavity locations	NOTE 1 Synonyms for "Single pole low voltage connector cavity for pacemaker and defibrillator" are "IS-1" or "IS-1 connector cavity". NOTE 2 The header shape is included in this symbol to show perspective. See Annex A for examples of this symbol's usage. NOTE 3 Unipolar or bipolar may be identified using text. See Annex A for an example of how this identification is accomplished.	9.4.1 (ISO 14708-2:2005, EN 45502-2-1:2003) The connector geometry, or provide a reference by symbols defined in published connector standards	ISO 7000-3065
6.29		Four pole low voltage connector cavity for pacemaker and defibrillator	To indicate the shape to be used for identifying four pole low voltage (IS4) connector cavity locations	NOTE 1 Synonyms for "Four pole low voltage connector cavity for pacemaker and defibrillator" are "IS4" or "IS4 connector cavity". NOTE 2 The header shape is included in this symbol to show perspective. See Annex A for examples of this symbol's usage. NOTE 3 Unipolar or bipolar may be identified using text. See Annex A for an example of how this identification is accomplished.	9.4.1 (ISO 14708-2:2005, EN 45502-2-1:2003) The connector geometry, or provide a reference by symbols defined in published connector standards	ISO 7000-3066

Table 1 (continued)

No.	Graphical symbol	Title	Description of symbol	Informative notes	Related subclause in AIMD product standards	ISO 7000 registration number
6.30		Non-standard connector cavity	To indicate the shape to be used for identifying non-standard connector cavity locations	NOTE 1 A synonym for "Non-standard connector cavity" is "Non-standard". NOTE 2 The header shape is included in this symbol to show perspective. See Annex A for examples of this symbol's usage. NOTE 3 Unipolar or bipolar may be identified using text. See Annex A for an example of how this identification is accomplished.	9.4.1 (ISO 14708-2:2005, EN 45502-2-1:2003) The connector geometry, or provide a reference by symbols defined in published connector standards	ISO 7000-3067
6.31		Legacy connector cavity	To indicate the shape to be used for identifying legacy connector cavity locations	NOTE 1 A synonym for "Legacy connector cavity" is "Legacy cavity". NOTE 2 The header shape is included in this symbol to show perspective. See Annex A for examples of this symbol's usage. NOTE 3 Unipolar or bipolar may be identified using text. See Annex A for an example of how this identification is accomplished.	9.4.1 (ISO 14708-2:2005, EN 45502-2-1:2003) The connector geometry, or provide a reference by symbols defined in published connector standards	ISO 7000-3068
6.32		Defibrillation	To indicate the availability of the tachyarrhythmia therapy defibrillation	NOTE Synonyms for "Defibrillation" are "Shock" or "Shocking".	9.4.1 (ISO 14708-6:2010, EN 45502-2-2:2008) The sales packaging containing an IPG shall bear a list of the tachyarrhythmia therapies available.	ISO 7000-3069
6.33		Atrial or ventricular cardioversion	To indicate the availability of the tachyarrhythmia therapy atrial or ventricular cardioversion	NOTE Synonyms for "Atrial or ventricular cardioversion" are "AV cardioversion" or "A-V cardioversion".	9.4.1 (ISO 14708-6:2010, EN 45502-2-2:2008) The sales packaging containing an IPG shall bear a list of the tachyarrhythmia therapies available.	ISO 7000-3070

Table 1 (continued)

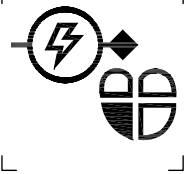
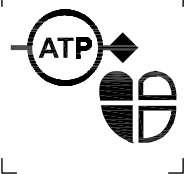
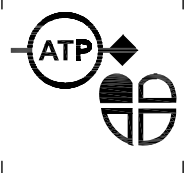
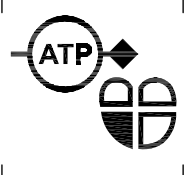
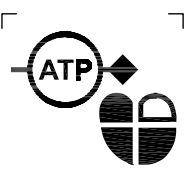
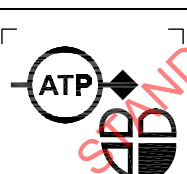
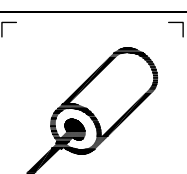
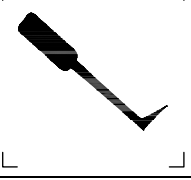
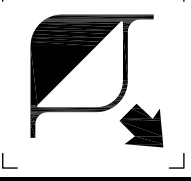
No.	Graphical symbol	Title	Description of symbol	Informative notes	Related subclause in AIMD product standards	ISO 7000 registration number
6.34		Ventricular cardioversion	To indicate the availability of the tachyarrhythmia therapy ventricular cardioversion	NOTE A synonym for "Ventricular cardioversion" is "V cardioversion".	9.4.1 (ISO 14708-6:2010, EN 45502-2-2:2008) The sales packaging containing an IPG shall bear a list of the tachyarrhythmia therapies available.	ISO 7000-3071
6.35		Anti-tachycardia pacing, right atrial and right ventricular	To indicate the availability of right-atrial and ventricular anti-tachycardia pacing	NOTE Synonyms for "Anti-tachycardia pacing, right atrial and right ventricular" are "Anti-tachycardia pacing (RA, RV)" or "Anti-tachycardia pacing, RA, RV".	9.4.1 (ISO 14708-6:2010, EN 45502-2-2:2008) The sales packaging containing an IPG shall bear a list of the tachyarrhythmia therapies available.	ISO 7000-3072
6.36		Anti-tachycardia pacing, right atrial	To indicate the availability of right-atrial anti-tachycardia pacing	NOTE Synonyms for "Anti-tachycardia pacing, right atrial" are "Anti-tachycardia pacing (RA)" or "Anti-tachycardia pacing, RA".	9.4.1 (ISO 14708-6:2010, EN 45502-2-2:2008) The sales packaging containing an IPG shall bear a list of the tachyarrhythmia therapies available.	ISO 7000-3073
6.37		Anti-tachycardia pacing, right ventricular	To indicate the availability of right-ventricular anti-tachycardia pacing	NOTE Synonyms for "Anti-tachycardia pacing, right ventricular" are "Anti-tachycardia pacing (RV)" or "Anti-tachycardia pacing, RV".	9.4.1 (ISO 14708-6:2010, EN 45502-2-2:2008) The sales packaging containing an IPG shall bear a list of the tachyarrhythmia therapies available.	ISO 7000-3074
6.38		Anti-tachycardia pacing (right atrial, right ventricular, left ventricular)	To indicate the availability of right-atrial and ventricular and left-ventricular anti-tachycardia pacing	NOTE Synonyms for "Anti-tachycardia pacing (right atrial, right ventricular, left ventricular)" are "Anti-tachycardia pacing (RA, RV, LV)" or "Anti-tachycardia pacing, RA/RV/LV".	9.4.1 (ISO 14708-6:2010, EN 45502-2-2:2008) The sales packaging containing an IPG shall bear a list of the tachyarrhythmia therapies available.	ISO 7000-3075
6.39		Anti-tachycardia pacing, left ventricular	To indicate the availability of left-ventricular anti-tachycardia pacing	NOTE Synonyms for "Anti-tachycardia pacing, left ventricular" are "Anti-tachycardia pacing (LV)" or "Anti-tachycardia pacing, LV".	9.4.1 (ISO 14708-6:2010, EN 45502-2-2:2008) The sales packaging containing an IPG shall bear a list of the tachyarrhythmia therapies available.	ISO 7000-3076
6.40		Torque wrench, implantable pulse generator	Torque-limiting wrench used to connect a lead to an implantable pulse generator	NOTE A synonym for "Torque wrench, implantable pulse generator" is "Torque wrench".	9.8 (ISO 14708-1:2000, EN 45502-2-1:2003) Identify the accessories in the package	ISO 7000-3077

Table 1 (continued)

No.	Graphical symbol	Title	Description of symbol	Informative notes	Related subclause in AIMD product standards	ISO 7000 registration number
6.41		Vein lifter	Vein lifter for use in medical device implant		9.8 (ISO 14708-1:2000, EN 45502-2-1:2003) Identify the accessories in the package	ISO 7000-3078
6.42		Open here	To indicate the location and method for opening a sterile package		11.9 (ISO 14708-1:2000, EN 45502-2-1:2003) Instructions for opening the package	ISO 7000-3079

Annex A (informative)

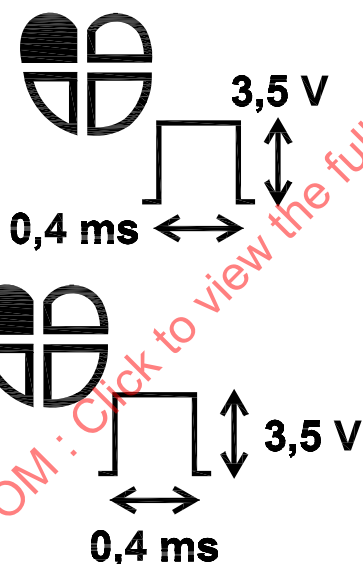
Examples of use of symbols

A.1 General

Clauses A.2 to A.6 illustrate how symbols may be used on package labels to convey required information. These are examples only; additional options may be created at the discretion of the user.

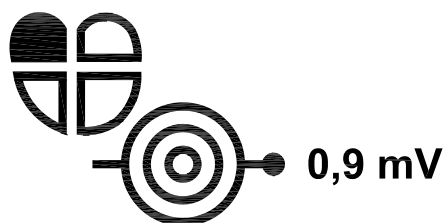
A.2 Amplitude and pulse width, right atrial

The symbol for “amplitude and pulse width, right atrial” used with associated values:



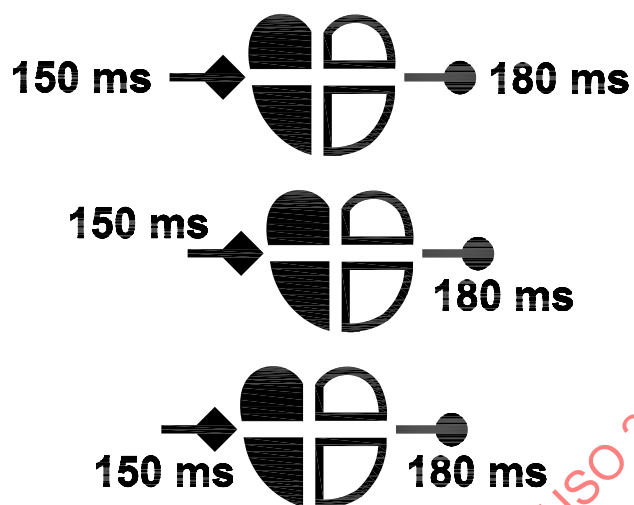
A.3 Sensitivity, right atrial

The symbol for “sensitivity, right atrial” used with associated values:



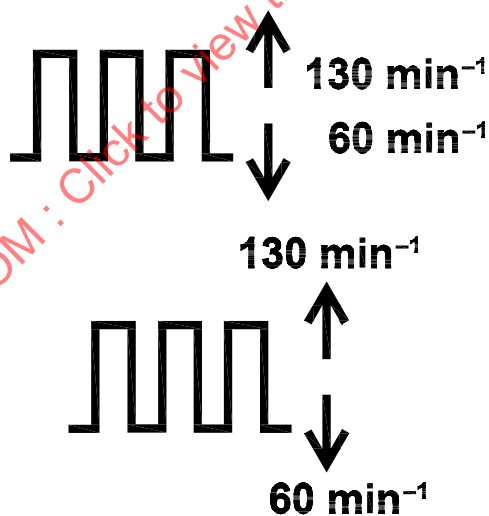
A.4 Atrial to ventricular interval, paced and sensed

The symbol for “atrial to ventricular interval, paced and sensed” used with associated values”:



A.5 Maximum tracking rate and minimum rate

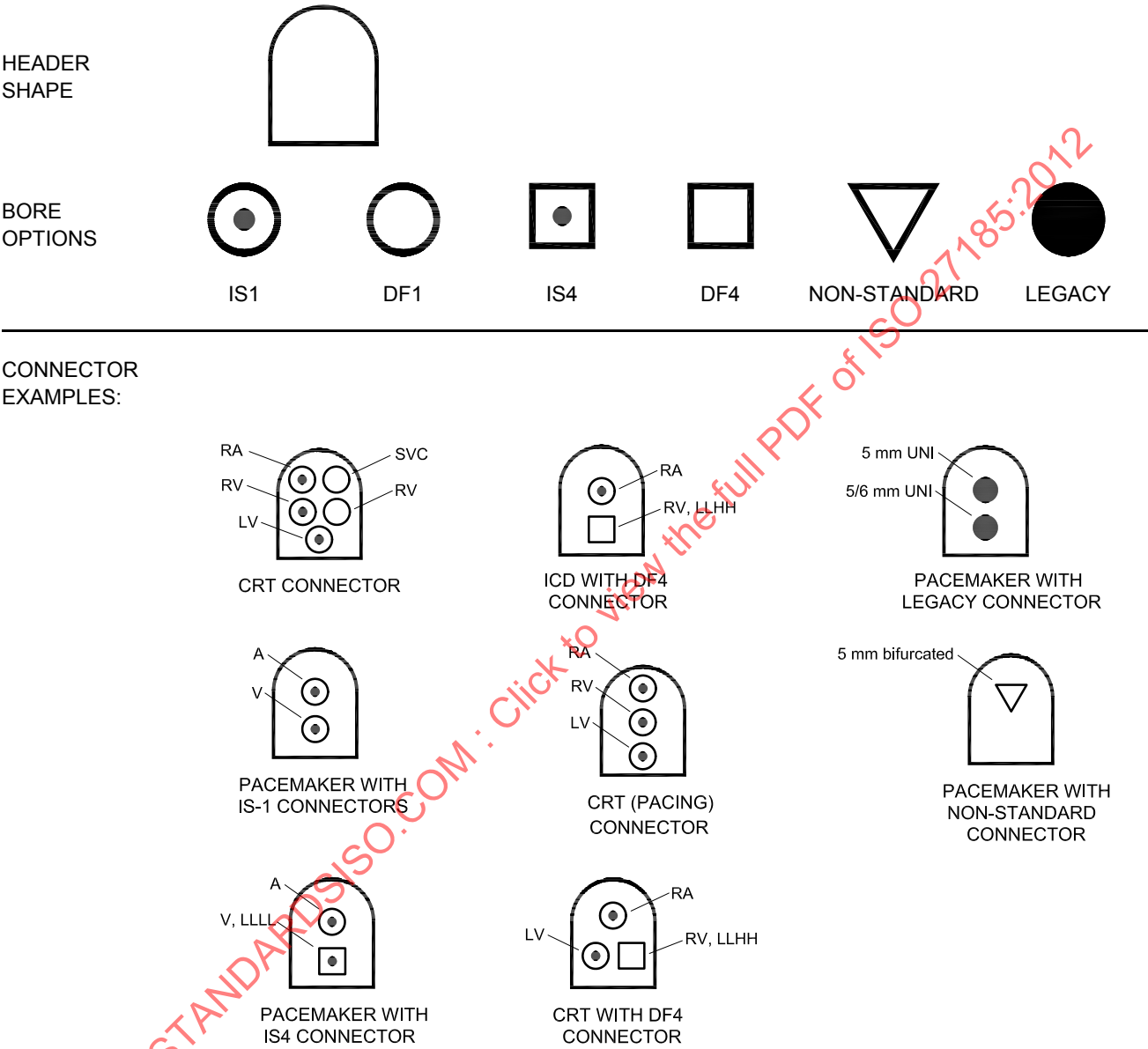
The symbol for “maximum tracking rate and minimum rate” used with associated values:



NOTE There is the option to place “bpm” or “ppm” in parentheses following “min⁻¹” when developing labelling for international applications.

A.6 Header and bore graphics

Header and bore graphics, as individual symbols and combined (conceptually), to represent specific headers (note that connector examples shown include mixtures of bore designations and locations on the header face that are representative of real-world possibilities and are intended to provide perspective on usage for the user):



Annex B (informative)

Graphical symbol system for implantable cardiac devices

Implantable cardiac devices that include pacemakers (IPGs), defibrillators (ICDs) and cardiac resynchronization devices (CRTs) contain adjustable settings for sensing heart rhythms and delivering appropriate therapies. Such devices are shipped from the factory with nominal settings, many of which are listed on the outer label of the device package. This information provides the implanter with quick access to key settings, e.g. knowing whether a feature is turned “On” or “Off”, or the magnitude of a particular setting.

To accommodate different local languages, device labels have traditionally been printed in multiple languages. Some package labels need to accommodate 15 or more languages on a single label. As a consequence, the label becomes hard to read due to shrinking fonts and complex layout designs. Other industries have faced similar multiple-language space constraints and addressed the problem through the use of graphical symbols.

For example, the garment industry provides care instructions on sewn-in garment tags that indicate washing action, water temperature, drying temperature, as well as dry-cleaning instructions. The individual graphical symbols are created from primary graphical symbol elements that are combined in a systematic way to form each graphical symbol's overall meaning. For example, the graphical symbol element for temperature level is represented by one, two or three dots. Applied to the machine-washing graphical symbol element, the dot(s) represent the washing temperature. Applied to the machine-drying graphical symbol element, the dot(s) represent the drying temperature.

NATO military-map graphical symbols are also based on primary graphical symbol elements that are combined to create more complete meanings. One example is to combine the graphical symbol element that represents armour, or infantry, along with another graphical symbol element that represents unit size to convey the size of an armoured, or infantry, unit located on a map. Such graphical symbols are able to communicate across languages since the meaning of a given graphical symbol is the same whether the map reader's native language is Italian, German, French or English.

An important aspect of these graphical symbol systems is that they consist of primary graphical symbol elements, each having a particular meaning, that are combined into one graphical symbol to create a more complete meaning. The graphical symbol's meaning, whether it be “machine wash medium temperature” or “infantry platoon” can be deconstructed in the same way that a sentence can be parsed. Knowing the meanings of the primary graphical symbol elements helps the reader understand a graphical symbol's meaning. Such a graphical symbol system also allows for the creation of new graphical symbols by creating new combinations of the basic graphical symbol elements.

What follows is a graphical symbol system created for implantable cardiac devices that is based on primary graphical symbol elements combined to create a complete meaning.

IPGs, CRTs and ICDs use transvenous or epicardial leads to sense and deliver therapy within or on the heart. Currently, these leads are referred to as the right-ventricular, left-ventricular, and right-atrial leads, regardless of where the lead is fixated within a chamber, or on the heart in the case of a LV lead or epicardial lead. Any sensing and therapy parameters associated with a given lead can, therefore, be graphically represented by indicating the chamber where the lead is fixated and where any sensing and pacing electrodes, or other transducers, are located.

To indicate the chamber involved with a sensing or therapeutic parameter, a pictogram of the heart is used, with the involved chamber darkened in. For parameters that involve signals from two leads, two chambers are darkened. Figure B.1 indicates a parameter that involves the left ventricle, whether it be sensing or pacing. Figure B.2 represents a parameter involving the right atrium and right ventricle.

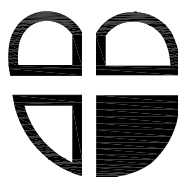


Figure B.1 — Example of a left-ventricle parameter

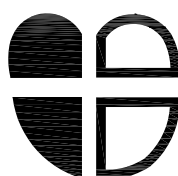


Figure B.2 — Example of a right-atrium and right-ventricle parameter

When an interval or delay is present between two chambers, the image is modified to include a space or gap as shown in Figure B.3.

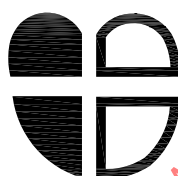


Figure B.3 — Example of an indication of an interval or delay

The parameters associated with implantable cardiac devices can be classified as sensing parameters and therapy parameters. The sensing parameters receive signals from the heart. The therapy parameters deliver energy to the heart. The graphical symbol element that represents sensing is a solid, disk-tipped arrow. The disk-tipped arrow points away from the heart to reinforce the message that a signal is coming from the heart. The graphical symbol element that represents therapy delivery is a diamond-tipped arrow. The diamond-tipped arrow points to the heart to reinforce the message that a signal is being delivered to the heart. Figures B.4 and B.5 were selected based on having high associative strength with their intended meanings.



Figure B.4 — Example of a symbol representing sensing

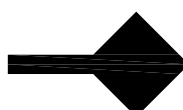


Figure B.5 — Example of a symbol representing therapy delivery

The relationship of the sensing and therapy “arrows” with respect to the heart graphical symbol element is shown in Figures B.6 and B.7.



Figure B.6 — Example of a symbol that represents a signal being delivered to the heart



Figure B.7 — Example of a symbol that represents a signal coming from the heart

Alone, these two graphical symbol elements mean very little in terms of device parameters. There are numerous parameters associated with both sensing and delivering therapies. To add more specific meaning, an additional graphical symbol element is added to the sense or therapy arrows. To emphasize this additional graphical symbol element, it is always presented within a circle. In the following two examples, Figure B.8 represents defibrillation and Figure B.9 represents sensitivity.

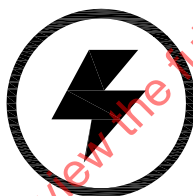


Figure B.8 — Example of a defibrillation symbol

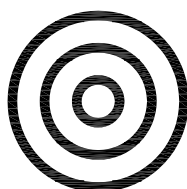


Figure B.9 — Example of a sensitivity symbol

The more specific meaning is applied to the arrow. In the following two examples, Figure B.10 represents a refractory period and Figure B.11 is applied to ATP as shown in Figures B.12 and B.13.



Figure B.10 — Example of a refractory period symbol



Figure B.11 — Example of an ATP symbol

Combining the above with the chambered heart produces the final graphical symbol. Figure B.12 represents the atrial ATP.

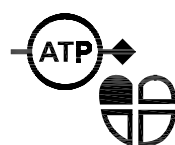


Figure B.12 — Example of an atrial ATP symbol

Figure B.13 represents the ventricular refractory period.



Figure B.13 — Example of a ventricular refractory period symbol

The factory setting, or nominal value, for each parameter is presented to the right of the graphical symbol as shown in the following two examples. For example, the parameter in Figure B.14, A-V interval, is set to 150 ms for pacing and 180 ms for sensing. In Figure B.15, atrial sensitivity, the parameter is set to 0,9 mV.

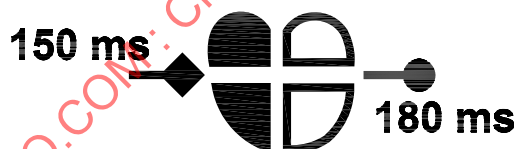


Figure B.14 — Example of an A-V interval symbol

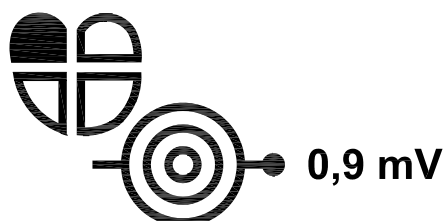


Figure B.15 — Example of an atrial sensitivity symbol

It should be noted that some of the parameters present on device labels require exceptions to the above graphical symbol system. For example, upper tracking rate/lower rate, and atrial amplitude/pulse width are symbolized as follows. Such graphical symbols were selected based on having tested high on associative strength with their intended meanings.

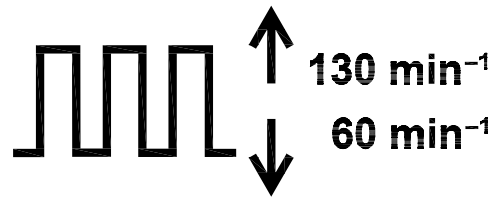


Figure B.16 — Example of an upper tracking rate/lower rate symbol

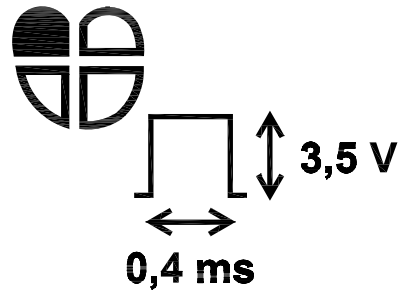


Figure B.17 — Example of an atrial amplitude/pulse width symbol

Annex C (informative)

Validation report for symbols included in this International Standard

C.1 Background

This validation report is provided in conjunction with the requirements of ISO 15223-2.

C.2 Scope

Symbols that are proposed for this International Standard shall convey the intended information to a specific cardiac professional health care group so the device can be used in accordance with its intended purpose.

Validation testing was performed to determine if the proposed symbols successfully convey the intended information to the target group when the symbols were seen for the first time. It was determined that the most effective means of gathering feedback from the primary cardiac health care user group would be by means of surveys administered at the HRS (Heart Rhythm Society) convention in Boston, on May 13th to 15th, 2009. Survey respondents were randomly selected from the attendees of the convention, and fit into one of three categories: physicians, nurses, or industry representatives.

Subsequent to the testing implemented in May 2009 at the HRS convention, TC 145/SC 3 provided feedback on the draft symbols and requested that minor modifications be made to certain symbols. Because these minor modifications did not change the fundamental form of the symbols and, therefore, did not impact interpretation of the symbols, these symbols were not revalidated. Details about the modifications to these symbols and the rationale for not revalidating them following recommended changes from TC 145/SC 3 are supplied in Clause C.9.

Some symbols were not selected to be part of the validation survey because they were considered either too generic and/or literal in nature, or were intended to be included as part of the connector geometry symbol set. These symbols include 6.8 "Implantable device"; 6.9 "Implantable device (coated)"; 6.25 "Header face"; 6.26 "DF-1"; 6.27 "DF4"; 6.28 "IS-1"; 6.29 "IS4"; 6.30 "Non-standard"; 6.31 "Legacy"; 6.40 "Torque wrench"; 6.41 "Vein lifter"; and 6.42 "Open here".

C.3 Sample size

The pre-survey sample size goal was to obtain 55 to 100 survey answers per symbol. After eliminating outlier surveys, the final sample sizes ranged between 45 and 92 answers per symbol. This outcome provided adequate sample sizes to evaluate the understandability of the symbols. (Some symbols were subject to more evaluation because they were used as foils to eliminate the possibility of obvious answers.)