BS ISO 27185:2012

BSI Standards Publication

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

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National foreword

This British Standard is the UK implementation of ISO 27185:2012.

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A list of organizations represented on this committee can be obtained on request to its secretary.

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INTERNATIONAL STANDARD

ISO 27185

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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

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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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*.

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.

INTERNATIONAL STANDARD **ISO 27185:2012(E)**

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

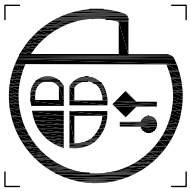
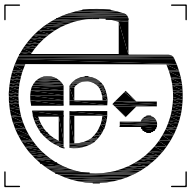
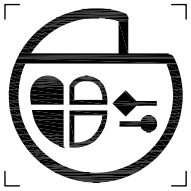
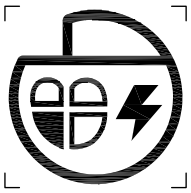
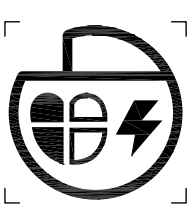
No.	Graphical symbol	Title	Description of symbol	Informative notes	Related subclause in AIMD product standards	ISO 7000 registration number
6.1		Pacemaker, single chamber, right ventricular	To indicate implantable pacemakers that are intended to stimulate and sense in the right ventricle of the heart	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*)

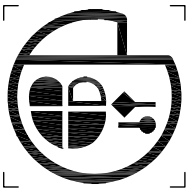
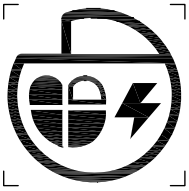
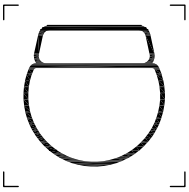
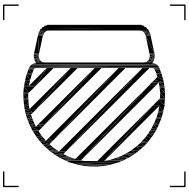
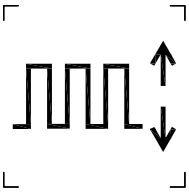
No.	Graphical symbol	Title	Description of symbol	Informative notes	Related subclause in AIMD product standards	ISO 7000 registration number
6.6		Cardiac resynchronization therapy pacemaker, right atrial, right ventricular, left ventricular	To indicate an implantable pacemaker that is intended to stimulate 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*)

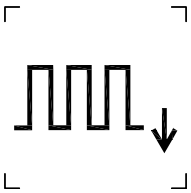
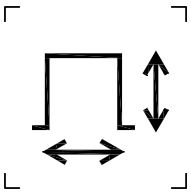
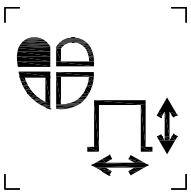
No.	Graphical symbol	Title	Description of symbol	Informative notes	Related subclause in AIMD product standards	ISO 7000 registration number
6.11		Minimum rate	To indicate the shipping parameters for minimum rate	NOTE Synonyms for “Minimum rate” are “Lower rate” or “Rest rate”.	9.4.1 (ISO 14708-2:2005, 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*)

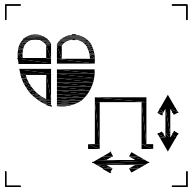
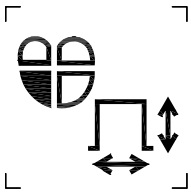
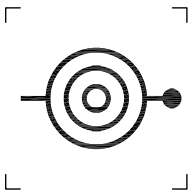
No.	Graphical symbol	Title	Description of symbol	Informative notes	Related subclause in AIMD product standards	ISO 7000 registration number
6.14		Amplitude and pulse width, left ventricular	To indicate the shipping parameters for left-ventricular amplitude and pulse width	NOTE Synonyms for “Amplitude 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*)

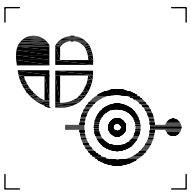
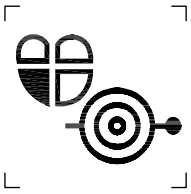
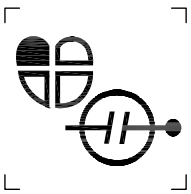
No.	Graphical symbol	Title	Description of symbol	Informative notes	Related subclause in AIMD product standards	ISO 7000 registration number
6.17		Sensitivity, right atrial	To indicate the shipping parameters for right-atrial sensitivity	NOTE Synonyms for “Sensitivity, right atrial” are “Atrial sensitivity” 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*)

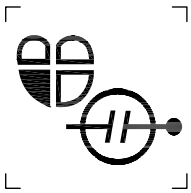
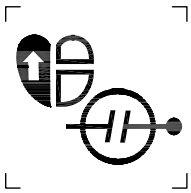
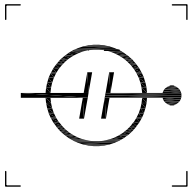
No.	Graphical symbol	Title	Description of symbol	Informative notes	Related subclause in AIMD product standards	ISO 7000 registration number
6.20		Refractory period, right ventricular	To indicate the shipping parameters for ventricular refractory period	NOTE Synonyms for “Refractory period, right ventricular” 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*)

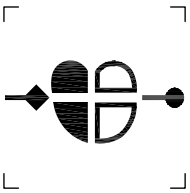
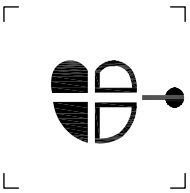
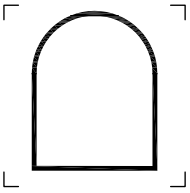
No.	Graphical symbol	Title	Description of symbol	Informative notes	Related subclause in AIMD product standards	ISO 7000 registration number
6.23		Atrial to ventricular interval, paced and sensed	To indicate the shipping parameters for paced and sensed atrial to ventricular interval	NOTE Synonyms for “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*)

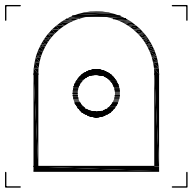
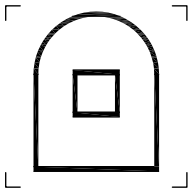
No.	Graphical symbol	Title	Description of symbol	Informative notes	Related subclause in AIMD product standards	ISO 7000 registration number
6.26		Single pole high voltage connector cavity for defibrillator	To indicate the shape to be used for identifying single pole high voltage (DF-1) connector cavity 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*)

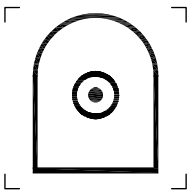
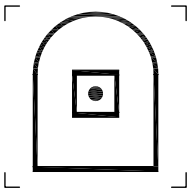
No.	Graphical symbol	Title	Description of symbol	Informative notes	Related subclause in AIMD product standards	ISO 7000 registration number
6.28		Single pole low voltage connector cavity for pacemaker and defibrillator	To indicate the shape to be used for identifying single pole low voltage (IS-1) connector 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*)

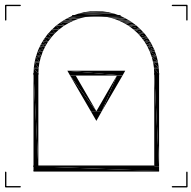
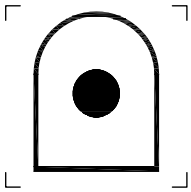
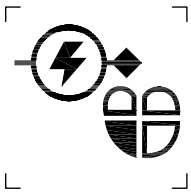
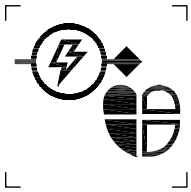
No.	Graphical symbol	Title	Description of symbol	Informative notes	Related subclause in AIMD product standards	ISO 7000 registration number
6.30		Non-standard connector cavity	To indicate the shape to be used for identifying non-standard connector cavity locations	NOTE 1 A synonym for “Non-standard connector 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*)

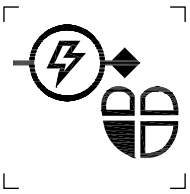
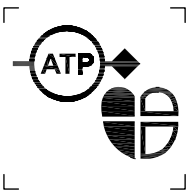
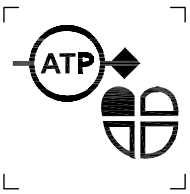
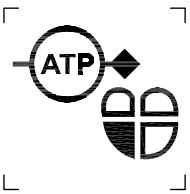
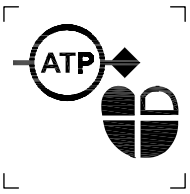
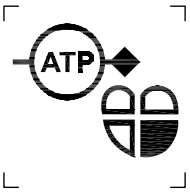
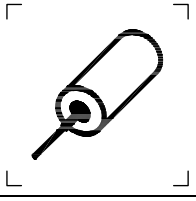
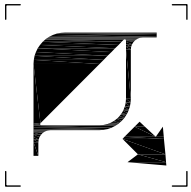
No.	Graphical symbol	Title	Description of symbol	Informative notes	Related subclause in AIMD product standards	ISO 7000 registration number
6.34		Ventricular cardioversion	To indicate the availability of the tachyarrhythmia therapy ventricular cardioversion	NOTE A synonym for "Ventricular cardioversion" 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)

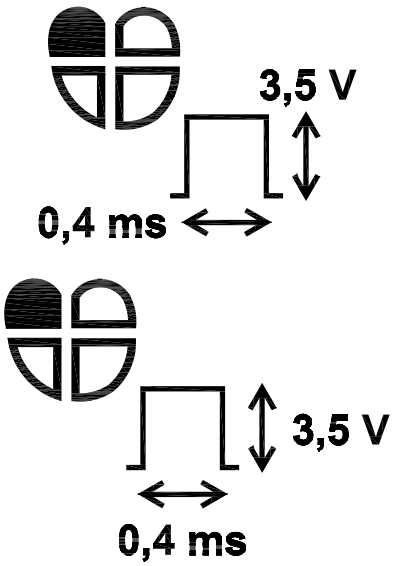
Examples of use of symbols

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.

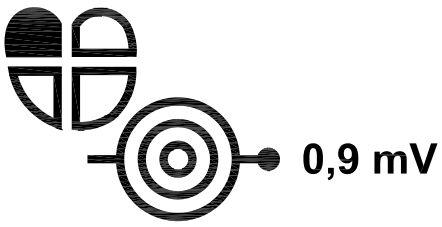
A.2 Amplitude and pulse width, right atrial

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



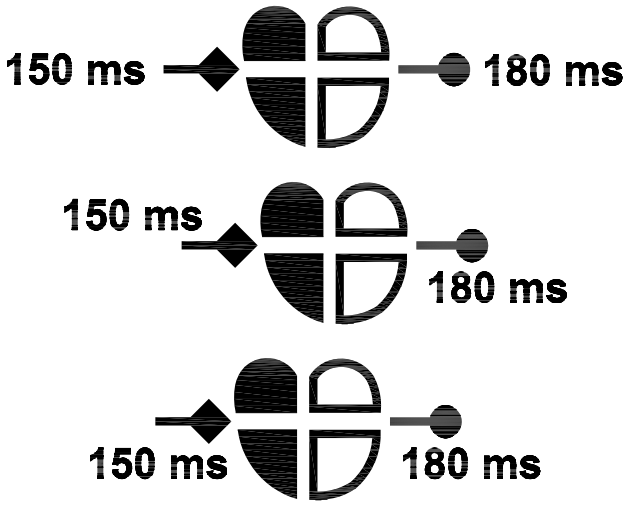
A.3 Sensitivity, right atrial

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



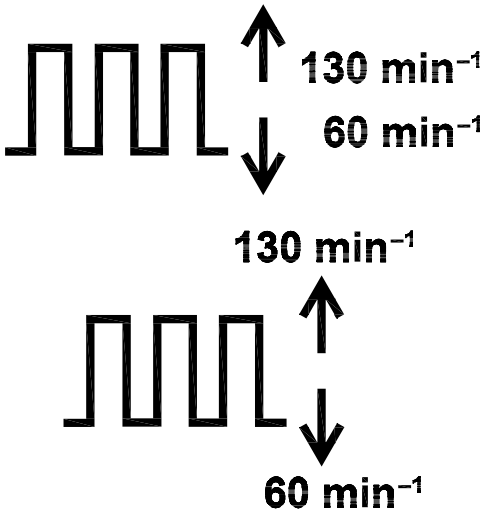
A.4 Atrial to ventricular interval, paced and sensed

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:

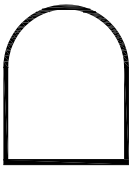


NOTE There is the option to place “bpm” or “ppm” in parentheses following “min^{-1}” when developing labelling for international applications.

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):

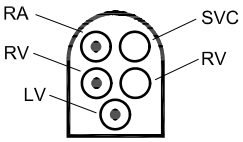
HEADER SHAPE



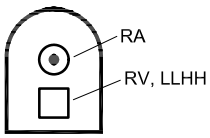
BORE OPTIONS

IS1 DF1 IS4 DF4 NON-STANDARD LEGACY

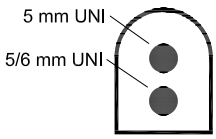
CONNECTOR EXAMPLES:



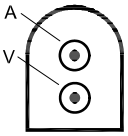
CRT CONNECTOR



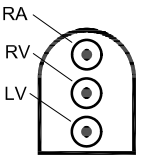
ICD WITH DF4 CONNECTOR



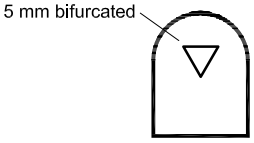
PACEMAKER WITH LEGACY CONNECTOR



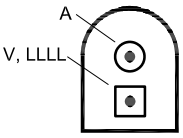
PACEMAKER WITH IS-1 CONNECTORS



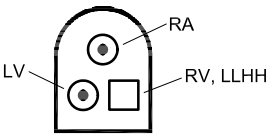
CRT (PACING) CONNECTOR



PACEMAKER WITH NON-STANDARD CONNECTOR



PACEMAKER WITH IS4 CONNECTOR



CRT WITH DF4 CONNECTOR

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.

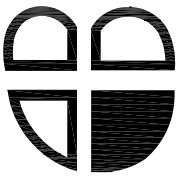


Figure B.1 — Example of a left-ventricle parameter

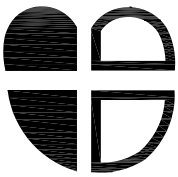


Figure B.2 — Example of a right-atrium and right-ventricle parameter

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.

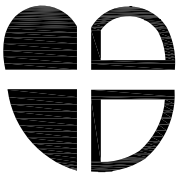


Figure B.3 — Example of an indication of an interval or delay

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

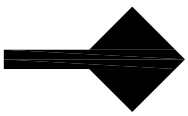


Figure B.5 — Example of a symbol representing therapy delivery

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.

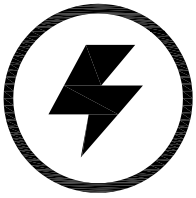


Figure B.8 — Example of a defibrillation symbol

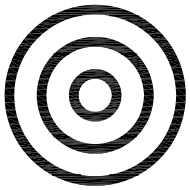


Figure B.9 — Example of a sensitivity symbol

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.

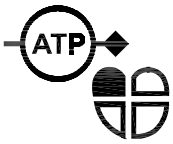


Figure B.12 — Example of an atrial ATP symbol

Figure B.13 represents the ventricular refractory period.

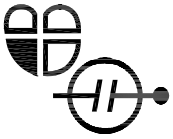


Figure B.13 — Example of a ventricular refractory period symbol

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.

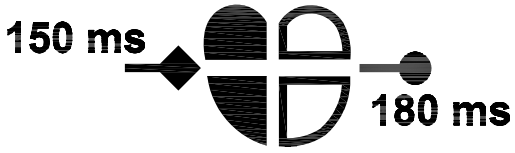


Figure B.14 — Example of an A-V interval symbol

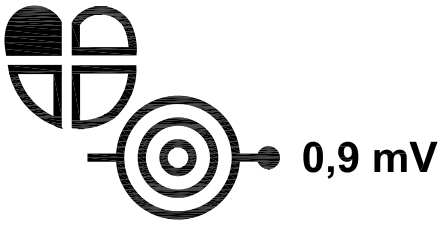


Figure B.15 — Example of an atrial sensitivity symbol

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.

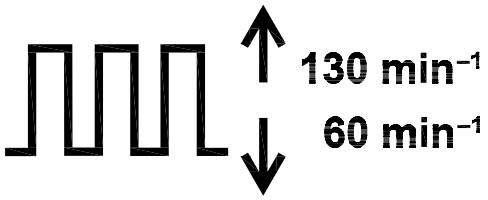


Figure B.16 — Example of an upper tracking rate/lower rate symbol

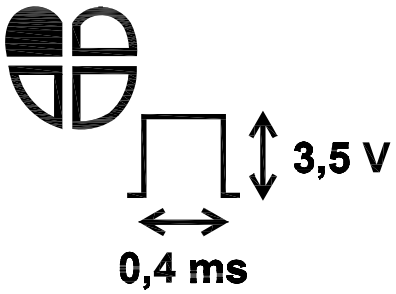


Figure B.17 — Example of an atrial amplitude/pulse width symbol

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.)

C.4 Pass/fail criteria

Given that the data represent the responses from a survey group that is seeing the symbols for the first time, it is expected that not all symbols would be intuitively understood. The meaning of some symbols is complicated, so while users find some symbols easy to understand, others are harder to understand. Prior to administering the survey, it was decided that the acceptability of the symbol should be expressed on a sliding scale:

a) 66 % to 100 % correct: validated as easily understandable by the survey group;

b) 50 % to 65 % correct: validated as somewhat understandable by the survey group;

c) below 50 % correct: poor understanding; requires re-evaluation of design for better understanding by the user group, or indicates a necessity to learn a symbol's meaning.

C.5 Survey test examples

The surveys were divided into different groupings to create a random, counter-balanced presentation of symbols. Twenty-six different survey sheets were created and divided into seven different surveys.

C.6 Data

The data gathered during the testing was scored and is summarized in Table C.1.

Table C.1 — Summary validation data

Symbol number from Table 1	Symbol title	Total survey answers	Total correct answers	Total incorrect answers	Percentage correct
6.1	IPG (single chamber, RV)	67	61	6	91,0
6.2	IPG (single chamber, RA)	53	45	8	84,9
6.3	IPG (dual chamber)	65	60	5	92,3
6.4	ICD (single chamber)	66	61	5	92,4
6.5	ICD (dual chamber)	53	51	2	96,2
6.6	CRT-P	65	56	9	86,2
6.7	CRT-D	92	78	14	84,8
—	Rate	51	47	4	92,2
6.10	Upper tracking rate	51	45	6	88,2
6.10	Lower rate	46	44	2	95,7
6.11	Lower rate	50	50	0	100,0
6.12	Amplitude	45	35	10	77,8
6.12	Pulse width	46	37	9	80,4
6.13	Atrial amplitude	49	41	8	83,7
6.13	Atrial pulse width	52	42	10	80,8
6.14	LV amplitude	48	40	8	83,3
6.14	LV pulse width	55	51	4	92,7
6.15	RV amplitude	47	41	6	87,2
6.15	RV pulse width	50	40	10	80,0
6.16	Sensitivity	49	42	7	85,7
6.17	Atrial sensitivity	71	65	6	91,5
6.18	Ventricular sensitivity	70	61	9	87,1
6.19	Atrial refractory period	51	41	10	80,4
6.20	Ventricular refractory period	46	34	12	73,9
6.21	PVARP	46	36	10	78,3
6.22	Refractory period	50	38	12	76,0
6.23	Paced A-V interval	51	32	19	62,7
6.23	Sensed A-V interval	50	33	17	66,0
6.24	Sensed A-V interval	50	40	10	80,0
6.32	Defibrillation	92	60	32	65,2
6.33	AV cardioversion	92	84	8	91,3
6.34	V cardioversion	92	60	32	65,2
6.35	Anti-tachycardia pacing (RA, RV)	67	65	2	97,0
6.36	Anti-tachycardia pacing (RA)	66	61	5	92,4
6.37	Anti-tachycardia pacing (RV)	90	79	11	87,8
6.38	Anti-tachycardia pacing (RA, RV, LV)	65	59	6	90,8
6.39	Anti-tachycardia pacing (LV)	78	72	6	92,3
	Totals:	**2 227**	**1 887**	**340**	**84,7**

C.7 Interpretation of data

Based on the test scores for individual symbols, each proposed symbol can be evaluated for its expected performance in the field: intuitively understood by most, generally understood by many, and not understood by a significant minority. Symbols falling in the latter category can be well designed, but they will, nevertheless, require learning on the part of some users.

Applying the pass/fail criteria, all symbols except for three tested as “easily understandable” by the survey group. The three symbols that were less understandable (symbol 6.23, Paced A-V interval; symbol 6.32, Defibrillation; and symbol 6.34, V cardioversion) scored in the 50 % to 65 % grouping, just below the 66 % threshold.

The Defibrillation and V cardioversion symbols were frequently mistaken for each other. The respondents knew they had the correct two symbols but they failed to distinguish correctly between the two. They sometimes hedged their “bets” by flipping responses. Learning the meaning of the solid lightning bolt and the meaning of the outline lightning bolt will bring respondents' understanding up to the level of the other symbols. In other words, these two symbols would be more effective with an instruction indicating that a solid bolt equals high energy and an outline bolt equals less energy than is used during cardioversion.

The Paced A-V interval symbol might be singled out as a very difficult symbol to understand, but the Sensed A-V interval performed well, and respondents scored high on the pace and sense graphical symbols. It is expected that, with time and exposure, the symbol and its meaning will be learned.

C.8 Handling of outliers

The responses gathered in this validation testing were collected by an independent survey company for the benefit of the ISO 27185 working group. Some surveys, and parts of surveys, were eliminated from data analysis due to being “outliers”. Outliers included surveys not fully completed, and surveys where it was clear that the respondent was making random choices.

Respondents were recruited between seminar sessions, discussions and other events. Consequently, some surveys showed signs that the respondent had run out of time and randomly filled in the last one or two sheets of the survey as quickly as possible, without regard for diligence and accuracy. Some survey sheets were completed in the front section and left blank for the last few sheets of the survey.

C.9 Rationale for no re-validation of symbols following recommended changes from ISO/TC 145/SC 3

C.9.1 Symbol grouping 6.1, 6.2, 6.3, 6.4, 6.5, 6.6, 6.7, 6.9

C.9.1.1 Modifications since validation include the following:

— thicker line weight for device shape to help discriminate between the shape associated with implant direction and heart symbol/arrows/lightning bolt associated with the application of therapy to a directed heart chamber;

— change to “pace” arrow to present a unique therapy not to be confused with other ISO 80416-2 associated actions;

— enlargement of lightning bolt image for clarity when reduced;

— modification of heart shape to make the line thickness of the white lines between heart chambers meet the IEC 80416-1 requirements;

— change for 6.9 image to replace fully filled (black) space with hatching.

C.9.1.2 Rationale for not re-validating: The changes made to these symbols were cosmetic and very subtle in nature and would be difficult for a surveyor of the original validation to notice, and would, therefore, not likely cause confusion as to the previously understood meaning. The diamond-shape arrowhead was tested within each member company of the STF and proved to be equivalent to the original arrowhead in being strongly associated with the intended meaning. Additional re-validation would provide no value to the current user understanding of these symbols.

C.9.2 Symbol grouping 6.10 to 6.24

C.9.2.1 Modifications since validation include the following:

— removal of “rectangular box” around symbols as it was considered non-functional with respect to the symbol (i.e. it provided no additional information about the symbol, only contained it);

— movement of heart shape to a position 35° diagonally above other therapy aspects of symbol to provide a better visual flow for the viewer;

— change to “pace” arrow to present a unique therapy not to be confused with other ISO 80416-2 associated actions;

— modification of heart shape to make the line thickness of the white lines between heart chambers meet the IEC 80416-1 requirements;

— modification of the location for the two-ended arrows to reflect the respective action for the pulse amplitude and pulse width symbols;

— modification of the 6.21 reversed out arrow to be more in line with ISO standards;

— removal of redundant arrows on 6.23 concurrent with removal of the rectangular box;

— symbol for “Rate” was determined to be redundant to “lower rate” upon completion of validation testing and was removed from registration for this International Standard.

C.9.2.2 Rationale for not re-validating: the basic elements of the originally validated symbols did not change form in such a way as to eliminate the meaning; rather the changes made would help strengthen their meaning. A surveyor of the original validation would still understand the basic meaning of the elements combined to form a symbol. Additional re-validation would provide no value to the current understanding of the symbols.

C.9.3 Symbol grouping 6.28 and 6.29

C.9.3.1 Modifications since validation include the following:

— increased size of the filled-in dot located within the circle to enhance the visual clarity, especially when the symbol is reduced in size.

C.9.3.2 Rationale for not re-validating: the change made to these symbols was cosmetic and very subtle in nature and would be difficult for a surveyor of the original validation to notice, and would therefore not likely cause confusion as to the previously understood meaning. Additional re-validation would provide no value to the current user understanding of these symbols.

C.9.4 Symbol grouping 6.32 to 6.39

C.9.4.1 Modifications since validation include the following:

— removal of “rectangular box” around symbols as it was considered non-functional with respect to the symbol (i.e. it provided no additional information about the symbol, only contained it);

— movement of heart shape to a position 35° diagonally below other therapy aspects of symbol to provide a better visual flow for the viewer;

— change to “pace” arrow to present a unique therapy not to be confused with other ISO 80416-2 associated actions;

— modification of heart shape to make the line thickness of the white lines between heart chambers meet the IEC 80416-1 requirements;

— enlargement of lightning bolt images for clarity when reduced.

C.9.4.2 Rationale for not re-validating: the basic elements of the originally validated symbols did not change form in such a way as to eliminate the meaning; rather the changes made would help strengthen their meaning. A surveyor of the original validation would still understand the basic meaning of the elements combined to form a symbol. Additional re-validation would provide no value to the current understanding of the symbols.

C.9.5 Symbol 6.42

C.9.5.1 Modifications since validation include the following:

— Increased size of the arrow to enhance visual clarity, especially when the symbol is reduced in size.

C.9.5.2 Rationale for not re-validating: The change made to this symbol was cosmetic and very subtle in nature and would be difficult for a surveyor of the original validation to notice, and would, therefore, not likely cause confusion as to the previously understood meaning. Additional re-validation would provide no value to the current user understanding of this symbol.

C.10 Conclusion

The overall percentage of correct answers for the entire symbol group was 84,7 %. The three lowest scoring symbols fell high in the category of “somewhat understandable but learnable over time”. Therefore, it is the conclusion of this team that all of the symbols tested are valid and acceptable for use with medical device labelling.

Annex D
(informative)

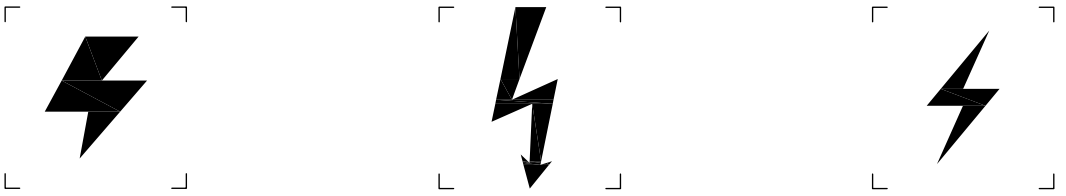
ISO 27185 response to comment in DIS

D.1 Comment

This International Standard received a comment regarding symbols 6.4, 6.6 and 6.7 during DIS balloting as follows: *"If the intent of the symbol element is to convey the 'therapy' rather than electrical or voltage function, it is not appropriate to use the symbol element that might be regarded as high voltage."*

Our response to this comment is provided in the "Template for comments and secretariat observations" and is provided in this annex.

Given the context of use, there should be no confusion of our "therapy" lightning bolt with the "Dangerous voltage" lightning bolt symbol found inside a copy machine or on a high-voltage power line for instance. Our symbol element does convey high power and, in our industry, ICD and CRT-D Active Implantable Medical Devices are thought of as high-power devices versus our low-power pacemaker devices. ICD's and CRT-D's use high-power therapy to defibrillate, so our lightning bolt is accurate and necessary to distinguish such devices from our pacemakers. There was deliberate design intent with our therapy lightning bolt to differentiate it from both the "Dangerous voltage" symbol and the "Electrical power" symbol (See Figure D.1). There was no concern expressed by our industry employees that filled out our surveys in our validation studies as this is the therapy they are familiar with.



a) "Therapy" lightning bolt **b) "Dangerous voltage" lightning bolt** **c) "Electrical power" lightning bolt**

Figure D.1 — Details of different "lightning bolt" symbols

Bibliography

[1] ISO 780, *Packaging — Pictorial marking for handling of goods*

[2] ISO 7000, *Graphical symbols for use on equipment — Index and synopsis*

[3] ISO 14971, *Medical devices — Application of risk management to medical devices*

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

[5] ISO 15225, *Medical devices — Quality management — Medical device nomenclature data structure*

[6] IEC/TR 60878, *Graphical symbols for electrical equipment in medical practice*

[7] IEC 60417-1, *Graphical symbols for use on equipment — Part 1: Overview and application*

[8] EN 980, *Symbols for use in the labelling of medical devices*

[9] EN 45502-1:1998, *Active implantable medical devices — Part 1: General requirements for safety, marking and information to be provided by the manufacturer*

[10] EN 45502-2-1:2003, *Active implantable medical devices — Part 2-1: Particular requirements for active implantable medical devices intended to treat bradyarrhythmia (cardiac pacemakers)*

[11] EN 45502-2-2:2008, *Active implantable medical devices — Part 2-2: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (includes implantable defibrillators)*

[12] ISO 14708-1:2000, *Implants for surgery — Active implantable medical devices — Part 1: General requirements for safety, marking and for information to be provided by the manufacturer*

[13] ISO 14708-2:2005, *Implants for surgery — Active implantable medical devices — Part 2: Cardiac pacemakers*

[14] ISO 14708-6:2010, *Implants for surgery — Active implantable medical devices — Part 6: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (including implantable defibrillators)*

NOTE More information on where to obtain symbols for use on equipment can be obtained by e-mailing symbolsinfo@aami.org or symbols@iso.org.

ICS 01.080.20; 11.040.40
Price based on 31 pages

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