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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 — Symbols 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.

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

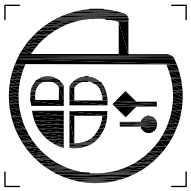
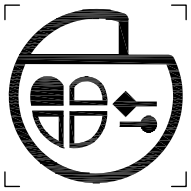
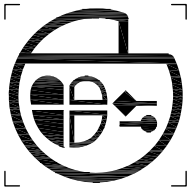
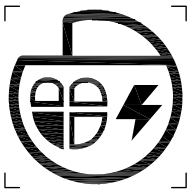
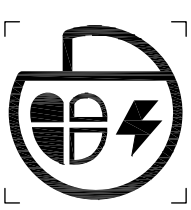
No.	Graphical symbol	Title	Description of symbol	Informative notes	Related subclause in AIMD product standards	ISO 7000 registration number
6.1		Pacemaker, single chamber, right ventricular	To indicate implantable pacemakers that are intended to stimulate and sense in the right ventricle of the heart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

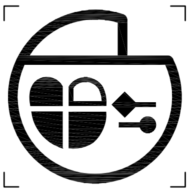
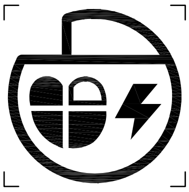
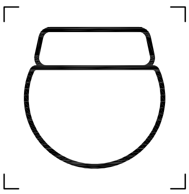
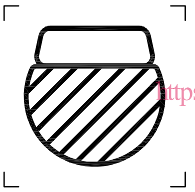
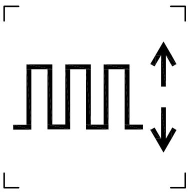
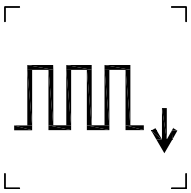
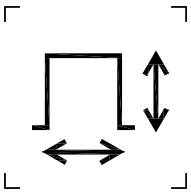
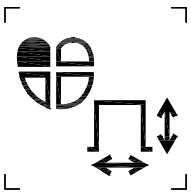
No.	Graphical symbol	Title	Description of symbol	Informative notes	Related subclause in AIMD product standards	ISO 7000 registration number
6.6		Cardiac resynchronization therapy pacemaker, right atrial, right ventricular, left ventricular	To indicate an implantable pacemaker that is intended to stimulate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