BWI Symbols Glossary

This document contains symbols that may appear on the product packaging or labeling. It provides information on the symbol including the standards title, reference, and description, where available. This document does not contain company created symbols, pictograms or graphical images. Refer to Labeling when using company specific symbols or images.

Please read the full Instructions For Use (IFU) or User Manual (UM) for detailed information on proper use, indications, contraindications, warnings, precautions and adverse events. Use the approved source files when using images for Desk Top Publishing (DTP). This document does not replace the Instructions For Use or User Manual.

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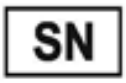
Index

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

Image	Accompanying Text	Reference	Description
	Catalogue Number	5.1.6	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	Batch code	5.1.5	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Serial Number	5.1.7	Indicates the manufacturer's serial number so that a specific medical device can be identified.
	Caution	5.4.4	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	Consult Instructions for use or consult electronic instructions for use	5.4.3	Indicates the need for the user to consult the instructions for use. When used to indicate an instruction to consult an electronic instructions for use (e-IFU), this symbol is accompanied by an e-IFU indicator. This indicator may represent the manufacturer's e-IFU website or any other appropriate indication on the use of e-IFU. The indicator may be placed either alongside, beneath or surrounding the symbol.
 www.e-ifu.com	Consult Instructions for use or e-IFU indicator	5.4.3	Indicates the need for the user to consult the instructions for use. When used to indicate an instruction to consult an electronic instructions for use (e-IFU), this symbol is accompanied by an e-IFU indicator. This indicator may represent the manufacturer's e-IFU website or any other appropriate indication on the use of e-IFU. The indicator may be placed either alongside, beneath or surrounding the symbol.
	Manufacturer	5.1.1	Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.
	Date of Manufacture	5.1.3	Indicates the date when the medical device was manufactured.

	Use-by date	5.1.4	Indicates the date after which the medical device is not to be used.
	Do not re-use	5.4.2	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure
	Authorized Representative in the European Community	5.1.2	Indicates the Authorized representative in the European Community.
	Fragile	5.3.1	Indicates a medical device that can be broken or damaged if not handled carefully.
	Humidity limitation	5.3.8	Indicates the range of humidity to which the medical device can be safely exposed.
	Keep away from sunlight	5.3.2	Indicates a medical device that needs protection from light sources.
	Keep dry	5.3.4	Indicates a medical device that needs to be protected from moisture.
	Sterilized using ethylene oxide	5.2.3	Indicates a medical device that has been sterilized using ethylene oxide.
	Sterilized using irradiation	5.2.4	Indicates a medical device that has been sterilized using irradiation.
	Do not resterilize	5.2.6	Indicates a medical device that is not to be resterilized
	Non-sterile	5.2.7	Indicates a medical device that has not been subjected to a sterilization process.
	Temperature limit	5.37	Indicates the temperature limits to which the medical device can be safely exposed.
	Do not use if package is damaged	5.2.8	Indicates a medical device that should not be used if the package has been damaged or opened.

	Atmospheric pressure limitation	5.3.9	Indicates the range of atmospheric pressure to which the medical device can be safely exposed.
	The device is latex-free	5.4.5	Indicates NEGATION of 5.4.5 Contains Latex*
	Unique Device Identifier	5.7.10	Indicates the Unique Device Identifier Information
	Non-pyrogenic	5.6.3	Indicates a medical device that is non-pyrogenic.
	Medical Device	5.7.7	Indicates the item is a medical device

* Refer to ISO 15223-1:2021 Annex B.2 Negation Symbol

ISO 7000 Graphical symbols for use on equipment – Index and synopsis

Image	Accompanying Text	Reference
	Packaging Unit	2794
	Single sterile barrier system	3707
	Double sterile barrier system	3704
	Single sterile barrier system with protective packaging inside	3708

	Single sterile barrier system with protective packaging outside	3709
	Single patient multiple use	3706
	Patient information website	3705
	Contains hazardous substances	3723

ISO 7001 — Graphical symbols -- Public information symbols

Image	Accompanying Text	Reference
	Health care centre or doctor	PI PF 044

IEC 60601-1 Medical electrical equipment Part 1: General requirements for basic safety and essential performance

Image	Accompanying Text	Reference
	Potential Equalization Port	Annex D, 8

IEC TR 60878 Graphical symbols for electrical equipment in medical practice

Image	Accompanying Text	Reference
	Foot switch	5114
	Non-ionizing electromagnetic radiation	5140
	Fuse	5016
	Alarm	5307

IEC 60417 Graphical Symbols for Use on Equipment

Image	Accompanying Text	Reference
	Alternating Current	5032
	On/Off	5010
	The device may be damaged by electrostatic discharge (ESD) if a person without ESD protection touches a COMM receptacle. Do not touch without appropriate ESD protection.	5134
	Defibrillation-proof type CF applied part.	5336
	Foot pedal {OEM}, Pedal {BWI}	6378

	Person identification	5664
	Date – to indicate date of implantation	5662

IEC 60529 Degrees of protection provided by enclosures (IP Code)

Image	Accompanying Text	Reference
IPX0	Not protected against ingress of liquids (water)	4.1
IPX1	Can resist water that drips vertically onto the product	4.1
IPX8	Liquid-tight The [foot] pedal is water resistant	4.1
IP21	The device is protected against solid foreign objects of 12.5 mm diameter and greater and is protected against vertically falling water drops.	4.1
IP23	Protected against solid objects over 12 mm (for example, fingers). Protected against direct sprays of water up to 60 degrees from vertical.	4.1
IP54	The device is protected against dust and is protected against splashing water	4.1

ISO 7010 Graphical Symbols- Safety colors and safety signs- Registered safety signs

Image	Accompanying Text	Reference
	Refer to instruction manual/booklet	M002

ISO 3864-2 Graphical Symbols - Safety

Image	Accompanying Text
	Object is heavy. Be careful when lifting. Two people are required to lift the generator console to prevent injury.

ASTM F2503-13 Standard Practice for Marking Medical Devices and Other Items for Safety and in the Magnetic Resonance Environment

Image	Accompanying Text	Reference
	MR Conditional	Table 2, Figure 6
	MR Unsafe	Table 2 Figure 9

Title 21 Code of Federal Regulations Parts 801.109

Image	Accompanying Text
	Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

DIRECTIVE 2012/19/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 4 July 2012 on waste electrical and electronic equipment (WEEE)

Image	Accompanying Text
	• IFU - Waste Electrical and Electronic Equipment Directive (WEEE)—Dispose of in a manner consistent with required EU Directives in your local jurisdiction. {This symbol is for cables and not catheters; Cables must use.} • BWI UM -Separate collection for electrical and electronic equipment, in compliance with Waste Electrical and Electronic Equipment Directive (WEEE) • OEM UM - Separate collection for electrical and electronic equipment
	• Waste Electrical and Electronic Equipment Directive (WEEE)—Dispose of in a manner consistent with required EU Directives in your local jurisdiction. {This symbol is for cables and not catheters; Cables must use.} • Separate collection for electrical and electronic equipment, in compliance with Waste Electrical and Electronic Equipment Directive (WEEE) • Separate collection for electrical and electronic equipment *

EN 15986:2011 Symbols for use in the labelling of medical devices — Requirements for labelling of medical devices containing Phthalates

Image	Accompanying Text	Reference
	Contains or presence of phthalate	A.2, Figure A.2
	The device does not contain phthalates	A.2, Figure A.2 with NEGATION
	Contains or presence of phthalate	A.5, Figure A.7

* Per EN 50419, the manufacturer may use either the black bar or Design of Marking to indicate the device is placed on the market after 13 Aug 2005.

Standard of the Electronics Industry of the People's Republic of China SJ/T 11364-2014

Image	Accompanying Text
	The electrical and electronic product contains some hazardous substances which can be safely used during their environment-friendly use period; after their environment-friendly use period expires, they shall be put into the recycling system. (applicable to China only per SJ/T 11364-2014) 2
	Indicates that the Electrical and Electronic Product (EEP) contains toxic and hazardous substances or elements over the defined maximum concentration values. The names and content of the toxic and hazardous substances or elements shall be provided in the Chinese product instruction manual. The number "50" in the symbol refers to the environment-friendly use period; after their environment-friendly use period expires, they shall be put into the recycling system (People's Republic of China symbol for Restriction of Hazardous Substances (RoHS) in electrical and electronic products).
	The electrical and electronic product contains no hazardous substance; they are green and environment-friendly products; can be recycled after being discarded and shall not be abandoned at discretion. (applicable to China only per SJ/T 11364-2014) 2

Medical- General Medical equipment as to electrical shock, fire and mechanical hazards only in accordance with UL 60601-1 / CAN/CSA C22.2 NO. 601-1 / ANSI/AAMI ES60601-1 (2005) / CAN/CSA C22.2 NO. 60601-1 (2008) 40GF

	Certification

EU 2017/745 MDR, Annex V

CE 2797	BSI
CE 0344	DEKRA
CE	Class 1 Non-Registered
CE	OEM Include NB#

Other Non Standards - Symbols

UK CA	UK Conformity Assessed
GB REP	Authorized Representative in Great Britain
CH REP	Authorized Representative in Switzerland