

BWI Symbols Glossary



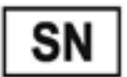








This document contains symbols that may appear on the product packaging or labeling. It provides information on the symbol including the standards title, reference, and description, where available. This document does not contain company created symbols, pictograms, or graphical images.













Please read the full Instructions For Use for detailed information on proper use, indications, contraindications, warnings, precautions and adverse events. This document does not replace the Instructions For Use.

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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 | 5.4.3 | Indicates the need for the user to consult the instructions for use. |
|  | 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* |
|  | Non-pyrogenic | 5.6.3 | Indicates a medical device that is non-pyrogenic. |

* Refer to ISO 15223-1:2016 Annex B.2 Negation Symbol

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

Image **Accompanying Text**

Reference

| | | |
|---|-----------------------|-------------|
|  | <p>Packaging Unit</p> | <p>2794</p> |
|---|-----------------------|-------------|

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

Image

Accompanying Text

Reference




| | | |
|---|------------------------------------|-------------------|
|  | <p>Potential Equalization Port</p> | <p>Annex D, 8</p> |
|---|------------------------------------|-------------------|

IEC TR 60878 Graphical symbols for electrical equipment in medical practice

Image






Accompanying Text

Reference

| | | |
|---|---|-------------|
|  | <p>Foot switch</p> | <p>5114</p> |
|  | <p>Non-ionizing electromagnetic radiation</p> | <p>5140</p> |
|  | <p>Fuse</p> | <p>5016</p> |

| | | |
|---|-------|------|
|  | 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 |

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


| Image | Accompanying Text | Reference |
|-------------|--|-----------|
| IPX0 | Not protected against ingress of liquids (water) | 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 |

| | | |
|-------------|---|-----|
| 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 |



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 |



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 |
|---|--|
|  | <ul style="list-style-type: none"> 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 |
|  | <ul style="list-style-type: none"> 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 |

* 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 |
|---|---|
|  | <p>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</p> |
|  | <p>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).</p> |
|  | <p>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</p> |

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 |
|---|---------------|