




















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SYMBOLS GLOSSARY

SYMBOL	SYMBOL TITLE	DESCRIPTION	STANDARD TITLE & DESIGNATION NUMBER	REFERENCE NUMBER
	Date of Manufacture	Indicates the date when the medical device was manufactured.	ISO & ANSI/AAMI/ISO 15223-1 Medical devices—Symbols to be used with medical device labels—General requirements.	5.1.3
	Manufacturer	Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.	ISO & ANSI/AAMI/ISO 15223-1 Medical devices—Symbols to be used with medical device labels—General requirements.	5.1.1
	Authorized representative in the European community	Indicates the Authorized Representative in the European Community.	ISO & ANSI/AAMI/ISO 15223-1 Medical devices—Symbols to be used with medical device labels—General requirements.	5.1.2
	Conformité Européene (European Conformity)	CE Marking on a product is a manufacturer's declaration that the product complies with the essential requirements of the relevant European health, safety and environmental protection legislation.	Directive 93/68/EEC.	N/A
	Reorder Number	Indicates the manufacturer's catalogue number so that the medical device can be identified.	ISO & ANSI/AAMI/ISO 15223-1 Medical devices—Symbols to be used with medical device labels—General requirements.	5.1.6
	Serial Number	Indicates the manufacturer's serial number so that a specific medical device can be identified.	ISO & ANSI/AAMI/ISO 15223-1 Medical devices—Symbols to be used with medical device labels—General requirements.	5.1.7
	Batch Code	Indicates the manufacturer's batch code so that the batch or lot can be identified.	ISO & ANSI/AAMI/ISO 15223-1 Medical devices—Symbols to be used with medical device labels—General requirements.	5.1.5
	Refer to instruction manual/booklet	To signify that the instruction manual/booklet must be read.	ISO 7010—Graphical Symbols—Safety Colors and Safety Signs—Registered Safety Signs	ISO 7010-M002
	Consult Instructions for Use	Indicates the need for the user to consult the Instructions for Use.	ISO & ANSI/AAMI/ISO 15223-1 Medical devices—Symbols to be used with medical device labels—General requirements.	5.4.3
	General mandatory action sign	To signify a mandatory action	ISO 7010—Graphical Symbols—Safety Colors and Safety Signs—Registered Safety Signs	ISO 7010-M001

SYMBOL	SYMBOL TITLE	DESCRIPTION	STANDARD TITLE & DESIGNATION NUMBER	REFERENCE NUMBER
	MR Safe	An item that poses no known hazards resulting from exposure to any MR environment. MR Safe items are composed of materials that are electrically non-conductive, nonmetallic and nonmagnetic.	ASTM F2503 – 13 Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment	7.3.1
	MR Conditional	An item with demonstrated safety in the MR environment within defined conditions.	ASTM F2503 – 13 Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment	7.3.2
	MR Unsafe	An item which poses unacceptable risks to the patient, medical staff or other persons within the MR environment.	ASTM F2503 – 13 Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment	7.3.3
	Caution	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.	ISO & ANSI/AAMI/ISO 15223-1 Medical devices—Symbols to be used with medical device labels—General requirements.	5.4.4
	General warning sign	To signify a general warning	ISO 7010—Graphical Symbols—Safety Colors and Safety Signs—Registered Safety Signs	ISO 7010-W001
	Warning; Electricity	To warn of electricity	ISO 7010—Graphical Symbols—Safety Colors and Safety Signs—Registered Safety Signs	ISO 7010-W012
	Do Not Reuse	Indicates a medical device that is intended for one use or for use on a single patient during a single procedure.	ISO & ANSI/AAMI/ISO 15223-1 Medical devices—Symbols to be used with medical device labels—General requirements.	5.4.2
	Protective Insulation: Devices of Protection Class II	To identify equipment meeting the safety requirements specified for Class II equipment.	ISO 7010—Graphical Symbols—Safety Colors and Safety Signs—Registered Safety Signs	IEC 60417-5172
	Waste Electrical and Electronic Equipment Directive (WEEE)	Waste products should not be disposed of with household waste. e.g. at a local authority collection point.	Waste Electrical and Electronic Equipment Directive (WEEE)	RoHS Directive 2002/96/EC
	Type BF Applied Part	On medical equipment. To identify a type BF applied part complying with IEC 60601-1.	IEC 60417 — Graphical Symbols for Use on Equipment	IEC 60417-5333
	Type B Applied Part	On medical equipment. To identify a type B applied part complying with IEC 60601-1.	IEC 60417 — Graphical Symbols for Use on Equipment	IEC 60417-5840

SYMBOL	SYMBOL TITLE	DESCRIPTION	STANDARD TITLE & DESIGNATION NUMBER	REFERENCE NUMBER
	Keep Dry	Indicates a medical device that needs to be protected from moisture.	ISO & ANSI/AAMI/ISO 15223-1 Medical devices—Symbols to be used with medical device labels—General requirements.	5.3.4
	Fragile, handle with care	Indicates a medical device that can be broken or damaged if not handled carefully.	ISO & ANSI/AAMI/ISO 15223-1 Medical devices—Symbols to be used with medical device labels—General requirements.	5.3.1
	This Way Up	To indicate correct upright position of the transport package.	ISO 7000 — Graphical symbols for use on equipment — Registered symbols	ISO 7000-6023
	Temperature Limit	To indicate the maximum and minimum temperature limits at which the item shall be stored, transported or used.	ISO 7000 — Graphical symbols for use on equipment — Registered symbols	ISO 7000-6032
	Quantity	Indicates quantity of medical devices contained within the packaging.	N/A	N/A
	Purchase Order	Indicates the Customer Purchase Order Number for the purchase of the medical device contained within the packaging.	N/A	N/A