


















GLOSSARY OF SYMBOLS






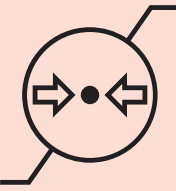

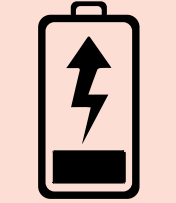
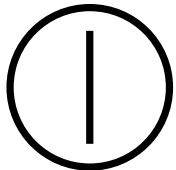
GLOSSARY OF SYMBOLS

SYMBOL	STANDARD REFERENCE	STANDARD TITLE	SYMBOL TITLE	EXPLANATORY TEXT
	EN 980, Clause 5.12	Symbols for use in the labelling of medical devices.	Manufacturer	Indicates the medical device manufacturer.
	ISO 15223-1, Clause 5.1.1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.		
	ISO 7000-3082	Graphical symbols for use on equipment.		
	ISO 15223-1, Clause 5.1.8	Medical devices — Symbols to be used with information to be supplied by the manufacturer.	Importer	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	ISO 7000-3725	Graphical symbols for use on equipment.		
	EN 980, Clause 5.10	Symbols for use in the labelling of medical devices.	Catalogue or model number	Indicates the date when the medical device was manufactured.
	ISO 15223-1, Clause 5.1.6	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.		
	ISO 7000- 2493	Graphical symbols for use on equipment.		
	EN 980, Clause 5.6	Symbols for use in the labelling of medical devices.	Date of manufacture	Indicates the date when the medical device was manufactured.
	ISO 15223-1, Clause 5.1.3	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.		
	ISO 7000-2497	Graphical symbols for use on equipment.		
	EN 60417-6049	Graphical symbols for use on equipment.	Country of origin	To identify the country of manufacture of products.
	ISO 3166-1	Codes for the representation of names of countries and their subdivisions — Part 1:Country codes.		
	EN 980, Clause 5.13	Symbols for use in the labelling of medical devices.	Authorized European representative	Indicates the Authorized representative in the European Community/ European Union.
	ISO 15223-1, Clause 5.1.2	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.		
	ISO 15223-1, Clause 5.1.9	Medical devices — Symbols to be used with information to be supplied by the manufacturer.	Distributor	Indicates the entity distributing the medical device into the locale.
	ISO 7000-3724	Graphical symbols for use on equipment.		
	ISO 15223-1, Clause 5.1.10	Medical devices — Symbols to be used with information to be supplied by the manufacturer.	Model Number	Indicates the model number or type number of a product.
	IEC 60417-6050	Graphical symbols for use on equipment.		

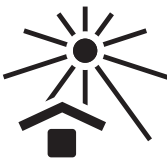




GLOSSARY OF SYMBOLS

SYMBOL	STANDARD REFERENCE	STANDARD TITLE	SYMBOL TITLE	EXPLANATORY TEXT
	EN 980, Clause 5.5	Symbols for use in the labelling of medical devices.	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified.
	ISO 15223-1, Clause 5.1.7	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.		
	ISO 7000-2498	Graphical symbols for use on equipment.		
	EN 980, Clause 5.4	Symbols for use in the labelling of medical devices.	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	ISO 15223-1, Clause 5.1.5	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.		
	ISO 7000-2492	Graphical symbols for use on equipment.		
	EN 980, Clause 5.3	Symbols for use in the labelling of medical devices.	Use by	Indicates the date after which the medical device is not to be used.
	ISO 15223-1, Clause 5.1.4	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.		
	ISO 7000-2607	Graphical symbols for use on equipment.		
	EN 980, Clause 5.16	Symbols for use in the labelling of medical devices.	In vitro diagnostic medical device	Indicates a medical device that is intended to be used as an in vitro diagnostic medical device.
	ISO 15223-1, Clause 5.5.1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.		
	ISO 7010-M002, IEC 60601-1, Table D.2, Symbol 10	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance.	Follow instructions for use or follow electronic instructions for use.	Follow instructions for use.
	EN 980, Clause 5.18	Symbols for use in the labelling of medical devices.	Consult instructions for use or consult electronic instructions for use.	Indicates the need for the user to consult the instructions for use.
	ISO 15223-1, Clause 5.4.3	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.		
	IEC 60601-1, Table D.1, Symbol 11	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance.		
	ISO 7000-1641	Graphical symbols for use on equipment.		
	EN 980, Clause 5.11	Symbols for use in the labelling of medical devices.	Caution: Read all warnings and precautions in instructions for use	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 15223-1, Clause 5.4.4	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.		
	IEC 60601-1, Table D.1, Symbol 10	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance.		
	ISO 7000-0434	Graphical symbols for use on equipment.		





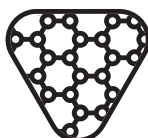


GLOSSARY OF SYMBOLS

SYMBOL	STANDARD REFERENCE	STANDARD TITLE	SYMBOL TITLE	EXPLANATORY TEXT
	IEC 60601-1-2: 2007, Clause 5.1.1	Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral standard: Electromagnetic compatibility — Requirements and tests	Non-ionizing electromagnetic radiation	To indicate generally elevated, potentially hazardous, levels of nonionizing radiation, or to indicate equipment or systems e.g. in the medical electrical area that include RF transmitters or that intentionally apply RF electromagnetic energy for diagnosis or treatment.
	IEC 60417-5140	Graphical symbols for use on equipment.		
	IEC 60878-5140	Graphical symbols for electrical equipment in medical practice.		
	ISO 15223-1, Clause 5.3.8	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	Storage humidity range	Indicates the range of humidity to which the medical device can be safely exposed.
	ISO 7000-2620	Graphical symbols for use on equipment.		
	EN 980, Clause 5.17.3	Symbols for use in the labelling of medical devices.	Storage temperature range	Indicates the temperature limits to which the medical device can be safely exposed.
	ISO 15223-1, Clause 5.3.7	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.		
	ISO 7000-0632	Graphical symbols for use on equipment.		
	ISO 15223-1, Clause 5.3.9	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	Atmospheric Pressure	Indicates the range of atmospheric pressure to which the medical device can be safely exposed.
	ISO 7000-2621	Graphical symbols on equipment.		
	ASTM F2503	Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment.	Magnetic Resonance (MR) unsafe	Keep away from magnetic resonance imaging (MRI) equipment.
	IEC 60417-5639	Graphical Symbols for Use on Equipment (derivative symbol and meaning)	Rechargeable battery	Recharge by date
	ISO 7000-5639			
	IEC 60417-5546		Battery check	
	ISO 7000-5546			
	ISO 7000-5007	Graphical Symbols for Use on Equipment (derivative meaning)	ON (power)	Activate by date
	ISO 7000-5008		OFF (power)	
	ISO 7000-5010		OFF (power)	
	IEC 60417-5007			
	IEC 60417-5008			
	IEC 60417-5010			



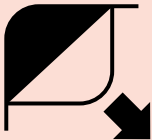





GLOSSARY OF SYMBOLS

SYMBOL	STANDARD REFERENCE	STANDARD TITLE	SYMBOL TITLE	EXPLANATORY TEXT
	ISO 15223-1, Clause 5.3.2	Medical devices — Symbols to be used with information to be supplied by the manufacturer.	Keep away from sunlight	Indicates a medical device that needs protection from light sources.
	ISO 7000-0624	Graphical symbols for use on equipment.		
	EN 980, Clause 5.21	Symbols for use in the labelling of medical devices.	Keep dry	Indicates a medical device that needs to be protected from moisture.
	ISO 15223-1, Clause 5.3.4	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.		
	ISO 7000-0626	Graphical symbols for use on equipment.		
	ISO 15223-1, Clause 5.3.1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	Fragile, handle with care	Indicates a medical device that can be broken or damaged if not handled carefully.
	ISO 7000-0621	Graphical symbols for use on equipment.		
	IEC 60601-1, Table D.1, Symbol 20	Medical electrical equipment —	Type BF applied part	To identify a type BF applied part complying with IEC 60601-1.
	IEC 60417- 5333	Part 1: General requirements for basic safety and essential performance.		
	IEC 60601-1, Table D.1, Symbol 19	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance.	Type B applied part	To identify a type B applied part complying with IEC 60601-1.
	IEC 60417-5840	Graphical symbols for use on equipment.		
IPN ₁ N ₂	IEC 60601-1, Table D.3, Symbol 2	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance.	Degree of Ingress Protection Provided by Enclosure	Manufacturer-determined degree of particle and water ingress protection, where...
	IEC 60529	Degrees of Protection Provided by Enclosures (IP Code).		N ₁ = degree of protection from particulates (scale of 0-6); and N ₂ = degree of protection from water (scale of 0-8) NOTE When a characteristic numeral is not required to be specified, it is replaced by the letter "X".
				Protection against insertion of large objects and dripping water.
				Protected against solid foreign objects of 12.5 mm and greater, and against the effects of continuous immersion in water.
				Protected against the effects of continuous immersion in water.
1P22				
1P28				
1PX8				


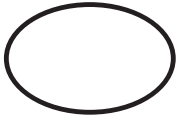




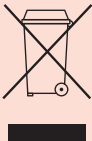



GLOSSARY OF SYMBOLS

SYMBOL	STANDARD REFERENCE	STANDARD TITLE	SYMBOL TITLE	EXPLANATORY TEXT
1P48				Protected against solid foreign objects of 1.0 mm and greater, and against the effects of continuous immersion in water.
1PX7				Protected against the effects of temporary immersion in water.
	ISO 15223-1, Clause 5.4.7	Medical devices — Symbols to be used with information to be supplied by the manufacturer.	Contains a medicinal substance	Indicates a medical device that contains or incorporates a medicinal substance.
	ISO 7000-3701	Graphical symbols for use on equipment.		
	ISO 15223-1, Clause 5.4.6	Medical devices — Symbols to be used with information to be supplied by the manufacturer.	Contains human blood or plasma derivatives	Indicates a medical device that contains or incorporates human blood or plasma derivatives.
	ISO 7000-3701	Graphical symbols for use on equipment.		
	ISO 15223-1, Clause 5.4.9	Medical devices — Symbols to be used with information to be supplied by the manufacturer.	Contains biological material of human origin	Indicates a medical device that contains biological tissue, cells, or their derivatives, of human origin.
	ISO 7000-3701	Graphical symbols for use on equipment.		
	ISO 15223-1, Clause 5.4.10	Medical devices — Symbols to be used with information to be supplied by the manufacturer.	Contains hazardous substances	Indicates a medical device that contains substances that can be carcinogenic, mutagenic, reprotoxic (CMR), or substances with endocrine disrupting properties.
	ISO 7000-3723	Graphical symbols for use on equipment.		
	ISO 15223-1, Clause 5.4.11	Medical devices — Symbols to be used with information to be supplied by the manufacturer.	Contains nano materials	Indicates a medical device that contains nano materials.
	ISO 7000-3703	Graphical symbols for use on equipment.		
	ISO 15223-1, Clause 5.4.12	Medical devices — Symbols to be used with information to be supplied by the manufacturer.	Single patient, multiple use	Indicates a medical device that may be used multiple times (multiple procedures) on a single patient.
	ISO 7000-3706	Graphical symbols for use on equipment.		
	ISO 15223-1, Clause 5.4.1	Medical devices — Symbols to be used with information to be supplied by the manufacturer.	Biological risks	Indicates that there are potential biological risks associated with the medical device.
	ISO 7000-0659	Graphical symbols for use on equipment.		






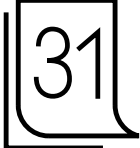


GLOSSARY OF SYMBOLS

SYMBOL	STANDARD REFERENCE	STANDARD TITLE	SYMBOL TITLE	EXPLANATORY TEXT
	EN 980, Clause 5.2	Symbols for use in the labelling of medical devices.	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 15223-1, Clause 5.4.2	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.		
	ISO 7000-1051	Graphical symbols for use on equipment.		
	EN 980, Clause 5.22	Symbols for use in the labelling of medical devices.	Do not resterilize	Indicates a medical device that is not to be resterilized.
	ISO 15223-1, Clause 5.2.6	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.		
	ISO 7000-2608	Graphical symbols for use on equipment.		
	ISO 7000-3079	Graphical symbols for use on equipment.	Open here	To identify the location where the package can be opened and to indicate the method of opening it.
	EN 980, Clause 6.2	Symbols for use in the labelling of medical devices.	Contains natural rubber or latex	Indicates the presence of natural rubber or dry natural rubber latex as a material of construction within the medical device or the packaging of a medical device.
	ISO 15223-1, Clause 5.4.5	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.		
	EN 980, Clause 5.23	Symbols for use in the labelling of medical devices.	Non sterile	Indicates a medical device that has not been subjected to a sterilization process.
	ISO 15223-1, Clause 5.2.7	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.		
	ISO 7000-2609	Graphical symbols for use on equipment.		
	EN 980, Clause 5.7	Symbols for use in the labelling of medical devices.	Product subjected to a sterilization process	Indicates a medical device that has been subjected to a sterilization process.
	ISO 15223-1, Clause 5.2.1	Medical devices — Symbols to be used with medical device labels, labelling and information...		
	ISO 7000-2499	Graphical symbols for use on Equipment.		
	EN 980, Clause 5.8.2	Symbols for use in the labelling of medical devices.	Sterilized by ethylene oxide treatment	Indicates a medical device that has been sterilized using ethylene oxide.
	ISO 15223-1, Clause 5.2.3	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.		
	ISO 7000-2501	Graphical symbols for use on equipment.		
	EN 980, Clause 5.8.3	Symbols for use in the labelling of medical devices.	Sterilized using irradiation	Indicates a medical device that has been sterilized using irradiation.
	ISO 15223-1, Clause 5.2.4	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.		
	ISO 7000-2502	Graphical symbols for use on equipment.		

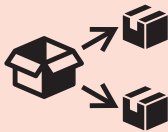

GLOSSARY OF SYMBOLS

SYMBOL	STANDARD REFERENCE	STANDARD TITLE	SYMBOL TITLE	EXPLANATORY TEXT
	EN 980, Clause 5.8.4	Symbols for use in the labelling of medical devices.	Sterilized using steam or dry heat	Indicates a medical device that has been sterilized using steam or dry heat.
	ISO 15223-1, Clause 5.2.5	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.		
	ISO 7000-2503	Graphical symbols for use on equipment.		
	ISO 7000-3707	Graphical symbols for use on equipment	Single sterile barrier system	Indicates a single sterile barrier system
	ISO 15223-1, Clause 5.2.11	Medical devices — Symbols to be used with information to be supplied by the manufacturer.		
	ISO 15223-1, Clause 5.6.3	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied .	Non-pyrogenic	Indicates a medical device that is non-pyrogenic.
	ISO 7000-2724	Graphical symbols for use on equipment.		
	ISO 15223-1:2012 (Annex B, 15223-1:2012)	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Non-pyrogenic	Indicates a medical device that is non-pyrogenic.
	ISO 15223-1:2012 (Annex B, 15223-1:2012)	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Not made with natural rubber latex	Not made with natural rubber latex.
	ISO 15223-1, Clause 5.2.8	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied .	Do not use if package is damaged and consult instructions for use.	Indicates a medical device that should not be used if the package has been damaged or opened.
	ISO 7000-2606	Graphical symbols for use on equipment.		
	EN 50419	Marking of Electrical and Electronic Equipment in accordance with Article 11(2) of Directive 2002/96/EC (WEEE).	Recycle: Electronic Equipment	Do not dispose of this product in unsorted municipal waste stream.
  	EN 15986, Clause 4.2	Symbol for use in the labelling of medical devices. Requirements for labelling of medical devices containing phthalates.	DEHP di(2-ethylexyl) phthalate BBP (Benzyl butyl phthalate) DBP (Dibutyl phthalate)	Contains phthalate

GLOSSARY OF SYMBOLS

SYMBOL	STANDARD REFERENCE	STANDARD TITLE	SYMBOL TITLE	EXPLANATORY TEXT
	ISO 15223 1 Clause 5.7.1	Medical devices — Symbols to be used with information to be supplied by the manufacturer.	Patient number	Indicates a unique number associated with an individual patient.
	ISO 7000-2610	Graphical symbols for use on equipment.		
	ISO 15223 1 Clause 5.7.2	Medical devices — Symbols to be used with information to be supplied by the manufacturer.	Patient name	Indicates the name of the patient.
	ISO 7000-3726	Graphical symbols for use on equipment.		
	ISO 15223 1 Clause 5.7.3	Medical devices — Symbols to be used with information to be supplied by the manufacturer.	Patient identification	Indicates the identification data of the patient.
	IEC 60417-5664	Graphical symbols for use on equipment.		
	ISO 15223 1 Clause 5.7.4	Medical devices — Symbols to be used with information to be supplied by the manufacturer.	Patient information website	Indicates a website where a patient can obtain additional information on the medical product.
	ISO 7000-3705	Graphical symbols for use on equipment.		
	ISO 15223 1 Clause 5.7.5	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied .	Health care centre or doctor	Indicates the address of the health care centre or doctor where medical information about the patient may be found.
	ISO 7001 PI PF 044	Public information symbols.		
	ISO 15223 1 Clause 5.7.6	Medical devices — Symbols to be used with information to be supplied by the manufacturer.	Date	Indicates the date that information was entered or a medical procedure took place.
	IEC 60417-5662	Graphical symbols for use on equipment.		
	ISO/DIS 15223-1:2020(E) DRAFT Reference no. 5.7.7	Medical Devices — Symbols to be used with medical device labels, labeling, and information to be supplied — Part 1: General requirements.	Medical device	Indicates the item is a medical device.
	ISO 15223 1 Clause 5.7.8	Medical devices — Symbols to be used with information to be supplied by the manufacturer.	Translation	Indicates that the original medical device information has undergone a translation which supplements or replaces the original information.
	ISO 7000-3728	Graphical symbols for use on equipment.		

GLOSSARY OF SYMBOLS

SYMBOL	STANDARD REFERENCE	STANDARD TITLE	SYMBOL TITLE	EXPLANATORY TEXT
	ISO 15223 1 Clause 5.7.9	Medical devices — Symbols to be used with information to be supplied by the manufacturer.	Repackaging	Indicates that a modification to the original medical device packaging configuration has occurred.
	ISO 7000-3727	Graphical symbols for use on equipment.		
	ISO 15223 1 Clause 5.7.10	Medical devices — Symbols to be used with information to be supplied by the manufacturer.	Unique device identifier	Indicates a carrier that contains unique device identifier information.