







































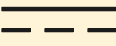

Symbols Glossary




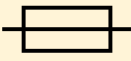








Our labelling is designed to meet all applicable international regulations/directives and standards. A compiled listing of symbols that may appear on our product labelling and the meaning of the symbol is provided here:











Symbol	Symbol Title	Explanatory Text	Reference	Title
	Manufacturer	Indicates the medical device manufacturer.	ISO 15223-1, Clause 5.1.1	Medical devices – Symbols to be used with information to be supplied by the manufacturer, Part 1: General requirements.
			ISO 7000-3082	Graphical symbols for use on equipment.
	EC Representative	Indicates the authorized representative in the European Community.	ISO 15223-1, Clause 5.1.2	Medical devices – Symbols to be used with information to be supplied by the manufacturer, Part 1: General requirements.
	EU Representative	Indicates the authorized representative in the European Community.	ISO 15223-1, Clause 5.1.2	Medical devices – Symbols to be used with information to be supplied by the manufacturer, Part 1: General requirements.
	Importer	Indicates the entity importing the medical device into the locale.	ISO 15223-1, Clause 5.1.8	Medical devices – Symbols to be used with information to be supplied by the manufacturer, Part 1: General requirements.
			ISO 7000-3725 IEC 60417-3725	Graphical symbols for use on equipment.
	Distributor	Indicates the entity distributing the medical device into the locale.	ISO 15223-1, Clause 5.1.9	Medical devices – Symbols to be used with information to be supplied by the manufacturer, Part 1: General requirements.
			ISO 7000-3724 IEC 60417-3724	Graphical symbols for use on equipment.
	Use-by-date	Indicates the date after which that the device should not be used.	ISO 15223-1, Clause 5.1.4	Medical devices – Symbols to be used with information to be supplied by the manufacturer, Part 1: General requirements.
			ISO 7000-2607	Graphical symbols for use on equipment.
	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 information to be supplied by the manufacturer, Part 1: General requirements.
			ISO 7000-2497	Graphical symbols for use on equipment.
	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 information to be supplied by the manufacturer, Part 1: General requirements.
			ISO 7000-2492	Graphical symbols for use on equipment.

Symbol	Symbol Title	Explanatory Text	Reference	Title
	Catalogue number	Indicates the manufacturer's catalogue # so that the medical device can be identified.	ISO 15223-1, Clause 5.1.6	Medical devices – Symbols to be used with information to be supplied by the manufacturer, Part 1: General requirements.
			ISO 7000-2493	Graphical symbols for use on equipment.
	Serial number	Indicates the manufacturer's serial # so that a specific medical device can be identified.	ISO 15223-1, Clause 5.1.7	Medical devices – Symbols to be used with information to be supplied by the manufacturer, Part 1: General requirements.
			ISO 7000-2498	Graphical symbols for use on equipment.
	Country of manufacture	Indicates the country where the medical device was manufactured.	ISO 15223-1, Clause 5.1.11	Medical devices – Symbols to be used with information to be supplied by the manufacturer, Part 1: General requirements.
			ISO 7000-6049 IEC 60417-6049	Graphical symbols for use on equipment.
	Medical Device	Indicates a medical device.	ISO 15223-1, Clause 5.7.7	Medical devices – Symbols to be used with information to be supplied by the manufacturer, Part 1: General requirements.
	TÜV Symbol	Indicates compliance with additional USA and Canada safety requirements for medical electrical equipment.	ANSI/AAMI ES60601-1:2005/A2:2021 CSA C22.2 No.60601-1:2014/A2:2022-03	TÜV (Technical Inspection Association) mark indicates that the product is manufactured in compliance with NRTL Deviations USA/Canada.
	Conformité Européenne	Indicates compliance with the product specific EU requirements.	EU MDR 2017/745 Annex V EU MDD 93/42 Annex XII	This symbol indicates compliance with the General Safety and Performance Requirements of the European Medical Device Regulation 2017/745 and compliance with the essential requirements of the Council Directive 93/42/ EEC of 14 June 1993 concerning medical devices.
	Consult 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 information to be supplied by the manufacturer, Part 1: General requirements.
			ISO 7000-1641	Graphical symbols for use on equipment.
	Refer to instruction manual/booklet. NOTE ON ME EQUIPMENT: Follow Instructions for Use	Signifies that the manual/booklet must be read.	IEC 60601-1, Table D.2, No 10	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.
			ISO 7010-M002	Graphical symbols – Safety colours and safety signs – Registered safety signs.
	Crossed-out wheeled bin	Do not dispose of electric/electronic devices together with unsorted municipal waste.	ISO 7000-6414 EN 50419	Marking of Electrical and Electronic Equipment.
	Audio paused	To identify the control for AUDIO PAUSED or to indicate that the ALARM SYSTEM is in the AUDIO PAUSED state.	IEC 60601-1-8, Table C.1	Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems. Alternative use as Medela internal symbol.
			IEC 60417-5576-2	Graphical symbols for use on equipment

Symbol	Symbol Title	Explanatory Text	Reference	Title
	Caution	Indicates that caution is necessary when operating the device or control close to where the symbol is placed or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.	ISO 15223-1, Clause 5.4.4.	Medical devices – Symbols to be used with information to be supplied by the manufacturer, Part 1: General requirements.
			ISO 7000-0434A	Graphical symbols for use on equipment.
	General Warning	Indicates general warning.	IEC 60601-1 Table D.2 Symbol 2	Medical electrical equipment – Part 1: General Requirements for basic safety and essential performance.
			ISO 7010-W001	Graphical symbols – Safety colours and safety signs – Registered safety signs.
	Sterilized using ethylene oxide	Indicates that the device is provided sterile and has been sterilized using ethylene oxide.	ISO 15223-1, Clause 5.2.3	Medical devices – Symbols to be used with information to be supplied by the manufacturer, Part 1: General requirements.
			ISO 7000-2501	Graphical symbols for use on equipment.
	Sterilized using irradiation	Indicates that the device is provided sterile and has been sterilized using irradiation.	ISO 15223-1, Clause 5.2.4	Medical devices – Symbols to be used with information to be supplied by the manufacturer, Part 1: General requirements.
			ISO 7000-2502	Graphical symbols for use on equipment.
	Non-sterile	Indicates that the device that is normally provided sterile in the same or similar packaging has not been sterilized.	ISO 15223-1, Clause 5.2.7	Medical devices – Symbols to be used with information to be supplied by the manufacturer, Part 1: General requirements.
			ISO 7000-2609	Graphical symbols for use on equipment.
	Sterile single barrier system	Indicates that there is 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, Part 1: General requirements.
			ISO 7000-3707	Graphical symbols for use on equipment.
	Single sterile barrier system with protective packaging inside	Indicates that there is a single sterile barrier system with protective packaging inside.	ISO 15223-1, Clause 5.2.13	Medical devices – Symbols to be used with information to be supplied by the manufacturer, Part 1: General requirements.
			ISO 7000-3708	Graphical symbols for use on equipment.
	Single sterile barrier system with protective packaging outside	Indicates that there is a single sterile barrier system with protective packaging outside.	ISO 15223-1, Clause 5.2.14	Medical devices – Symbols to be used with information to be supplied by the manufacturer, Part 1: General requirements.
			ISO 7000-3709	Graphical symbols for use on equipment.
	Do not use if package is damaged	Indicates that the device must not be used if the package holding the device is damaged.	ISO 15223-1, Clause 5.2.8	Medical devices – Symbols to be used with information to be supplied by the manufacturer, Part 1: General requirements.
			ISO 7000-2606	Graphical symbols for use on equipment.
	Open here (Sterile Barrier System (SBS))	Identifies the location where the sterile packaged medical device can be opened and to indicate the method of opening it.	ISO 7000-3079	Graphical symbols for use on equipment.
	Do not re-use	Indicates that the item is for single use only and must not be used more than once, for example on packages of medical disposables.	ISO 15223-1, Clause 5.4.2	Medical devices – Symbols to be used with information to be supplied by the manufacturer, Part 1: General requirements.
			ISO 7000-1051	Graphical symbols for use on equipment.
	Fragile, handle with care	Indicates that the contents of the transport package are fragile and the package shall be handled with care.	ISO 15223-1, Clause 5.3.1	Medical devices – Symbols to be used with information to be supplied by the manufacturer, Part 1: General requirements.
			ISO 7000-0621	Graphical symbols for use on equipment.

Symbol	Symbol Title	Explanatory Text	Reference	Title
	Keep away from sunlight	Indicates that transport package shall not be exposed to sunlight.	ISO 15223-1, Clause 5.3.2	Medical devices – Symbols to be used with information to be supplied by the manufacturer, Part 1: General requirements.
			ISO 7000-0624	Graphical symbols for use on equipment.
	Keep away from rain	Indicates that the transport package shall be kept away from rain and in dry conditions.	ISO 15223-1, Clause 5.3.4	Medical devices – Symbols to be used with information to be supplied by the manufacturer, Part 1: General requirements.
			ISO 7000-0626	Graphical symbols for use on equipment.
	This way up	To indicate correct upright position of the transport package.	ISO 7000-0623	Graphical symbols for use on equipment.
	Temperature limit	Indicates the maximum and minimum temperature limits at which the item shall be stored, transported or used.	ISO 15223-1, Clause 5.3.7	Medical devices – Symbols to be used with information to be supplied by the manufacturer, Part 1: General requirements.
			ISO 7000-0632	Graphical symbols for use on equipment.
	Humidity limitation	Indicates the acceptable upper and lower limits of relative humidity for transport and storage.	ISO 15223-1, Clause 5.3.8	Medical devices – Symbols to be used with information to be supplied by the manufacturer, Part 1: General requirements.
			ISO 7000-2620	Graphical symbols for use on equipment.
	Atmospheric pressure limitation	Indicates the acceptable upper and lower limits of atmospheric pressure for transport and storage.	ISO 15223-1, Clause 5.3.9	Medical devices – Symbols to be used with information to be supplied by the manufacturer, Part 1: General requirements.
			ISO 7000-2621	Graphical symbols for use on equipment.
IPN ₁ N ₂	Degree of protection	Degree of protection against ingress of foreign objects and moisture. N ₁ =degree of protection from particles; N ₂ =degree of protection from water.	IEC 60601-1 Table D.3 Symbol 2 IP Code.	Medical electrical equipment – Part 1: General Requirements for basic safety and essential performance.
			IEC 60529	Degrees of protection provided by enclosures (IP Code).
	Class II electrical equipment	Indicates basic protection and fault protection are provided by double insulation or reinforced insulation.	IEC 60601-1 Table D.1 Symbol 9 Class II equipment.	Medical electrical equipment – Part 1: General Requirements for basic safety and essential performance.
			IEC 60417-5172	Graphical symbols for use on equipment.
	Alternating current	Indicates the rating plate that the equipment is suitable for alternating current only; to identify relevant terminals.	IEC 60601-1, Table D.1 Symbol 1, Alternating current	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.
			IEC 60601-1, Table D.1 Symbol 1, Alternating current	Graphical symbols for electrical equipment in medical practice.
			ISO 7000-5032 IEC 60417-5032	Graphical symbols for use on equipment.
	Direct current	Indicates the rating plate that the equipment is suitable for direct current only; to identify relevant terminals.	IEC 60601-1, Table D.1, Symbol 4, Direct current	Medical electrical equipment – Part 1: General Requirements for basic safety and essential performance.
			IEC 60878	Graphical symbols for electrical equipment in medical practice.
			ISO 7000-5031 IEC 60417-5031	Graphical symbols for use on equipment.
	Type BF Applied Part	Identifies a type BF applied part complying with IEC 60601-1.	IEC 60601-1 Table D.1 Symbol 20 Type of BF applied part	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.
			ISO 7000-5333 IEC 60417-5333	Graphical symbols for use on equipment.

Symbol	Symbol Title	Explanatory Text	Reference	Title
	Type CF Applied Part	Identifies a type CF applied part complying with IEC 60601-1.	IEC 60601-1 Table D.1 Symbol 21 Type CF applied part ISO 7000-5335 IEC 60417-5335	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance. Graphical symbols for use on equipment.
	MR unsafe	Indicates the device or implant is MR unsafe, the device should never be brought to an MRI environment.	ASTM F2503	Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment.
	Unique Device Identifier	Indicates a carrier that contains unique device identifier information.	ISO 15223-1, Clause 5.7.10	Medical devices – Symbols to be used with information to be supplied by the manufacturer.
	Fuse	Identifies the fuse.	IEC 60335-1 ISO 7000-5016 IEC 60417-1 Clause 5016	Household and similar electrical appliances – Safety – Part 1: General requirements. Graphical symbols for use on equipment.
	Prescription only	Indicates that the device requires a prescription in the US.	21 CFR 801.109	Code of Federal Regulations Title 21, Part 801.109.
	Federal Communications Commission	Indicates compliance with the requirements of the Federal Communications Commission.	47 CFR 15	Code of Federal Regulations Title 47, Part 15.
	General symbol for recovery/recyclable	Indicates that the package is capable of being recycled.	ISO 14021-2016	Environmental labels and declarations – Self-declared environmental claims (Type II environmental labelling).
			ISO 7000-1135	Graphical symbols for use on equipment.
	Bluetooth	Trademarks of Bluetooth SIG.	Brand Guide for Bluetooth Trade-marks	N/A
	Recycling code	Indicates the material of which an item is made, for example PAP22.	97/129/EC (alphanumeric codes).	Commission Decision of 28 January 1997 establishing the identification system for packaging materials pursuant to European Parliament and Council Directive 94/62/EC on packaging and packaging waste.
	Lithium ion battery	Indicates lithium ion battery contained or packed with the equipment.	IEC 60086 ANSI C18.1	Primary batteries, Part 1: General.
	Non-ionizing electro-magnetic radiation	To indicate generally elevated, potentially hazardous, levels of non-ionizing 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.	ISO 7000-5140 IEC 60417-5140	Graphical symbols for use on equipment.

Symbol	Symbol Title	Explanatory Text	Reference	Title
	Model Number	Indicates the model number or type number of a product.	ISO 15223-1, Clause 5.1.10 IEC 60417-6050	Medical devices – Symbols to be used with information to be supplied by the manufacturer, Part 1: General requirements. Graphical symbols for use on equipment.
pcs	Pieces	Indicates the quantity of pieces of items in the package.	N/A	N/A Medela internal symbology used in IFU.
	Quantity	Indicates the quantity of items in the package.	N/A	N/A Medela internal symbology used in IFU.
	Legal specification	Indicates the legal specifications of the system.	N/A	N/A Medela internal symbology used in IFU.
	Safety tip	Indicates safety related tip.	N/A	N/A Medela internal symbology used in IFU.
	Class of the system	Indicates the class of the system related to electrical safety.	N/A	N/A Medela internal symbology used in IFU.
	Vacuum level	Indicates the maximum vacuum level of the system.	N/A	N/A Medela internal symbology used in IFU.
	Flow level	Indicates the flow levels of the system.	N/A	N/A Medela internal symbology used in IFU.
	Electrical specification	Indicates the electrical specifications of the system.	N/A	N/A Medela internal symbology used in IFU.
	Weight	Indicates the weight of the system.	N/A	N/A Medela internal symbology used in IFU.
	Dimensions	Indicates the dimensions (h x w x d) of the system.	N/A	N/A Medela internal symbology used in IFU.