






















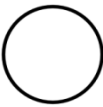
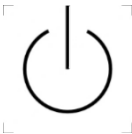










Symbol	Description of symbol	Reference number and title of symbol	Title and designation number of standard
	Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.	5.1.1 Manufacturer	ISO 15223-1:2016(E): Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements
	Indicates the authorized representative in the European Community.	5.1.2 Authorized representative in the European Community	ISO 15223-1:2016(E): Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements
	Indicates the date when the medical device was manufactured.	5.1.3 Date of Manufacture	ISO 15223-1:2016(E): Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements
	Indicates the date after which the medical device is not to be used.	5.1.4 Use-by date	ISO 15223-1:2016(E): Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements
	Indicates the manufacturer's batch code so that the batch or lot can be identified.	5.1.5 Batch code	ISO 15223-1:2016(E): Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements
	Indicates the manufacturer's catalogue number so that the medical device can be identified.	5.1.6 Catalogue number	ISO 15223-1:2016(E): Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements






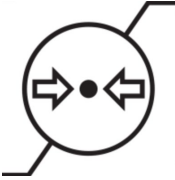
Symbol	Description of symbol	Reference number and title of symbol	Title and designation number of standard
	Indicates a medical device that has been sterilized using ethylene oxide.	5.2.3 Sterilized using ethylene oxide	ISO 15223-1:2016(E): Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements
	Indicates a medical device that has been sterilized using irradiation.	5.2.4 Sterilized using irradiation	ISO 15223-1:2016(E): Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements
	Indicates a medical device that should not be used if the package has been damaged or opened.	5.2.8 Do not use if package is damaged	ISO 15223-1:2016(E): Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements
	Indicates the presence of a sterile fluid path within the medical device in cases when other parts of the medical device, including the exterior, might not be supplied sterile.	5.2.9 Sterile fluid path	ISO 15223-1:2016(E): Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements
	Indicates a medical device that can be broken or damaged if not handled carefully.	5.3.1 Fragile, handle with care	ISO 15223-1:2016(E): Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements
	To indicate that the contents of the transport package are fragile and the package shall be handled with care.	Reference No. 0621 Fragile- handle with care	ISO 7000 Graphical symbols for use on equipment - Registered symbols




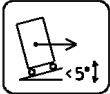



Symbol	Description of symbol	Reference number and title of symbol	Title and designation number of standard
	Indicates a medical device that needs protection from light sources.	5.3.2 Keep away from sunlight	ISO 15223-1:2016(E): Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements
	Indicates the temperature limits to which the medical device can be safely exposed.	5.3.7 Temperature limit	ISO 15223-1:2016(E): Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements
	To indicate the maximum and minimum temperature limits at which the item shall be stored, transported or used.	Reference No. 0632 Temperature limit	ISO 7000 Graphical symbols for use on equipment - Registered symbols
	Indicates the range of humidity to which the medical device can be safely exposed.	5.3.8 Humidity limitation	ISO 15223-1:2016(E): Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements
	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.	5.4.2 Do not re-use	ISO 15223-1:2016(E): Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements
	Indicates the need for the user to consult the instructions for use.	5.4.3 Consult instructions for use	ISO 15223-1:2016(E): Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements


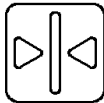


Symbol	Description of symbol	Reference number and title of symbol	Title and designation number of standard
	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.	5.4.4 Caution	ISO 15223-1:2016(E): Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements
	Indicates a medical device that is non-pyrogenic.	5.6.3 Non-pyrogenic	ISO 15223-1:2016(E): Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements
	Indicates the number of drops per millilitre.	5.6.4 Drops per millilitre	ISO 15223-1:2016(E): Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements
	To signify that the instruction manual / booklet must be read.	Reference No. M002 Refer to instruction manual/booklet	ISO 7010 Graphical Symbols – Safety colours and safety signs – Registered safety signs
	To identify a type B applied part complying with IEC 60601-1.	Reference No. 5840 Type B applied part	IEC 60417 Graphical Symbols for Use on Equipment
	To identify a type BF applied part complying with IEC 60601-1.	Reference No. 5333 Type BF applied part	IEC 60417 Graphical Symbols for Use on Equipment
	To indicate connection to the mains, at least for mains switches or their positions, and all those cases where safety is involved.	Reference No. 5007 "ON" (power)	IEC 60417 Graphical Symbols for Use on Equipment

Symbol	Description of symbol	Reference number and title of symbol	Title and designation number of standard
	To indicate disconnection from the mains, at least for mains switches or their positions, and all those cases where safety is involved.	Reference No. 5008 "OFF" (power)	IEC 60417 Graphical Symbols for Use on Equipment
	To identify the switch or switch position by means of which part of the equipment is switched on in order to bring it into the stand-by condition, and to identify the control to shift to or to indicate the state of low power consumption. Each of different states of power consumption may be indicated using a corresponding colour.	Reference No. 5009 Stand-by	IEC 60417 Graphical Symbols for Use on Equipment
	To indicate on the rating plate that the equipment is suitable for alternating current only; to identify relevant terminals.	Reference No. 5032 Alternating current	IEC 60417 Graphical Symbols for Use on Equipment
	To identify any terminal which is intended for connection to an external conductor for protection against electric shock in case of a fault, or the terminal of a protective earth (ground) electrode.	Reference No. 5019 Protective earth; protective ground	IEC 60417 Graphical Symbols for Use on Equipment

Symbol	Description of symbol	Reference number and title of symbol	Title and designation number of standard
	To identify the terminals which, when connected together, bring the various parts of an equipment or of a system to the same potential, not necessarily being the earth (ground) potential, e.g. for local bonding.	Reference No. 5021 Equipotentiality	IEC 60417 Graphical Symbols for Use on Equipment
	To indicate correct upright position of the transport package	Reference No. 0623 This way up	ISO 7000 Graphical symbols for use on equipment - Registered symbols
	To indicate that hooks shall not be used for handling the transport package.	Reference No. 0622 Use no hooks	ISO 7000 Graphical symbols for use on equipment - Registered symbols
	To indicate that the transport package shall be kept away from rain and in dry conditions.	Reference No. 0626 Keep away from rain	ISO 7000 Graphical symbols for use on equipment - Registered symbols
IPX1	To identify category AP equipment complying with IEC 60601-1 which also specifies the way in which this symbol has to be used.	Ingress Protection Against Dripping Water (vertically falling drops)	IEC 60601-1 Medical Electrical Equipment, Part 1: General Requirements for Safety IP degrees in accordance with IEC 60529 / EN 60529
	To indicate that the transport package shall not be rolled or turned over but shall remain in the upright position.	Reference No. 2405 Do not roll	ISO 7000 Graphical symbols for use on equipment - Registered symbols
	To indicate that the items shall not be vertically stacked, either because of the nature of the transport packaging or because of the nature of the items themselves.	Reference No. 2402 Do not stack	ISO 7000 Graphical symbols for use on equipment - Registered symbols

Symbol	Description of symbol	Reference number and title of symbol	Title and designation number of standard
	To indicate mass. To identify a function related to mass.	Reference No. 1321A Mass; weight	ISO 7000 Graphical symbols for use on equipment - Registered symbols
	Indicates the manufacturer's serial number so that a specific medical device can be identified.	Reference 5.1.7 Serial number	ISO 15223-1 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements
	To indicate that the items shall not be vertically stacked beyond the specified number, either because of the nature of the transport packaging or because of the nature of the items themselves.	Reference No. 2403 Stacking limit by number	ISO 7000 Graphical symbols for use on equipment - Registered symbols
	To identify the positive and negative connections (the polarity) of a d.c. power supply, or the positive and negative connections on a piece of equipment to which a d.c. power supply may be connected.	Reference No. 5926 Polarity of d.c. power connector	IEC 60417 — Graphical Symbols for Use on Equipment
	To indicate on the rating plate that the equipment is suitable for direct current only; to identify relevant terminals.	Reference No. 5031 Direct current	IEC 60417 — Graphical Symbols for Use on Equipment
	To indicate the acceptable upper and lower limits of atmospheric pressure for transport and storage	Reference No. 2621 Atmospheric pressure limitation	ISO 7000 — Graphical symbols for use on equipment — Registered symbols

Symbol	Description of symbol	Reference number and title of symbol	Title and designation number of standard
Symbols <u>not</u> from Standards			
Rx Only or Rx ONLY	Caution: Federal law (USA) restricts this device to sale by or on the order of a licensed healthcare practitioner.	21 CFR Part 801.109 Prescription use only	FDA Quality System Regulation – Labeling requirements
	Not made with natural rubber latex	NA	
	Not made with di(2-ethylhexyl) phthalate	NA	
	Not made with Bisphenol-A	NA	
	Keep transport position when moving the device on more than a 5-degree slope.	NA	
	Alarm sounds mute switch	NA	
	Blood pump switch Green – ON Red – OFF	NA	
	Bubble detector	NA	

Symbol	Description of symbol	Reference number and title of symbol	Title and designation number of standard
	Blood sensor	NA	
	Clamp	NA	
	Not for use with Hemodiafiltration	NA	
	This device must be used on dialysis machines with an ultrafiltration controller or accurate fluid balancing system.	NA	