

Merge Healthcare

Symbols Glossary

© Copyright Merge Healthcare Solutions Inc. 2022.

Licensed materials – Property of Merge Healthcare Solutions Inc.

The content of this document is confidential information of Merge Healthcare Solutions Inc. and its use and disclosure is subject to the terms of the agreement pursuant to which you obtained the software that accompanies the documentation.

Merge Healthcare and the Merge Healthcare logo are trademarks of Merge Healthcare Inc.

Microsoft, Windows, and the Windows logo are trademarks of Microsoft Corporation in the United States, other countries, or both.

All other names are trademarks or registered trademarks of their respective companies.

U.S. GOVERNMENT RESTRICTED RIGHTS:

This product is a “Commercial Item” offered with “Restricted Rights.” The Government’s rights to use, modify, reproduce, release, perform, display or disclose this documentation are subject to the restrictions set forth in Federal Acquisition Regulation (“FAR”) 12.211 and 12.212 for civilian agencies and in DFARS 227.7202-3 for military agencies. Contractor is Merge Healthcare Solutions Inc.



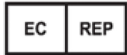






For application support or to report issues with user documentation, contact Customer Support:

- ☎ 1-877-741-5369 (North America)
- +31.20.514.5073 (Europe, the Middle East and Africa)
- 1800 316 746 (Australia)









✉ mergesupport@merative.com







Part	Date	Revision	Description
QS-123940	09/2016	1	Initial release of document
	12/2016	2	Addition of hardware symbols for the GEO expansion project.
	08/2016	3	Update for symbols changed
	05/2019	4	Update for symbols changed
	03/2021	5	Update for symbols changed, converted to PDF of website version.
	09/2022	6	Update for symbols changed, converted back to standalone document







The following symbols may be found on the labeling and packaging of Merge Healthcare medical devices:


Symbol	Symbol Title	Reference Number	Description	Standard Title and Designation Number
	Manufacturer	5.1.1	Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC and EU MDR 2017/745.	ISO 15223-1 Medical devices - Symbols to be used with medical device labels - General Requirements
	Date of Manufacture	5.1.3	Indicates the date when the medical device was manufactured.	ISO 15223-1 Medical devices - Symbols to be used with medical device labels - General Requirements
	Authorized Representative in the European Community / European Union	5.1.2	Indicates the Authorized Representative in the European Community.	ISO 15223-1 Medical devices - Symbols to be used with medical device labels - General Requirements
	Authorized Representative in Switzerland	5.1.2	Indicates the Authorized Representative in Switzerland.	ISO 15223-1 Medical devices - Symbols to be used with medical device labels - General Requirements
	Part or Catalog Number	5.1.6	Indicates the manufacturer's catalog number so that the medical device can be identified.	ISO 15223-1 Medical devices - Symbols to be used with medical device labels - General Requirements
	Batch Code	5.1.5	Indicates the manufacturer's batch code so that the batch or lot can be identified.	ISO 15223-1 Medical devices - Symbols to be used with medical device labels - General Requirements
	Serial Number	5.1.7	Indicates the manufacturer's serial number so that the medical device can be identified.	ISO 15223-1 Medical devices - Symbols to be used with medical device labels - General Requirements
	Medical Device	5.7.7	Indicates the labeled product is a medical device.	MDR 2017/745 – Art. 18 - §1d
	Country of Manufacture	6049	Identifies the country of manufacture of products.	ISO 7000 / IEC 60417 Graphical symbols for use on equipment

Symbol	Symbol Title	Reference Number	Description	Standard Title and Designation Number
	WEEE Waste of Electrical and Electronic Equipment	N/A	Indicates that when end user wishes to discard this product it must be sent to separate sent to separate collection facilities for recovery and recycling in the EU.	BS EN 50419:2006 Marking of Electrical Equipment in accordance with Article 11(2) of Directive 2002/96/EC (WEEE)
	United Kingdom Conformity	N/A	Equivalent to the EU CE marking. CE marking on a product is a manufacturer's declaration that the product complies with essential requirements of the relevant European health, safety and environmental protection legislation.	Directive 93/68/EEC CE Marking Directive EU Medical Device Regulation 2017/745
	CE Marking	N/A	CE marking on a product is a manufacturer's declaration that the product complies with essential requirements of the relevant European health, safety and environmental protection legislation.	Directive 93/68/EEC CE Marking Directive EU Medical Device Regulation 2017/745.
	CE Marking with Notified Body	N/A	CE marking on a product is a manufacturer's declaration that the product complies with essential requirements of the relevant European health, safety and environmental protection legislation.	Directive 93/68/EEC CE Marking Directive EU Medical Device Regulation 2017/745.
	US Symbol for Prescription Only Medical Devices	N/A	The symbol for Prescription Device. Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.	21 CFR 801.109

Symbol	Symbol Title	Reference Number	Description	Standard Title and Designation Number
	Consult Instructions for Use	5.4.3	Indicates the need for the user to consult the instructions for use.	ISO 15223-1 Medical devices - Symbols to be used with medical device labels - General Requirements
	Consult Electronic Instructions for Use	5.4.3	Indicates the need for the user to consult the electronic instructions for use (eIFU) at the specified website location.	ISO 15223-1 Medical devices - Symbols to be used with medical device labels - General Requirements
	Refer to Instruction Manual/Booklet	ISO 7010-M002	Indicates that the instruction manual / booklet must be read.	IEC/TR 60878 Graphical symbols for electrical equipment in medical practice
	Local Importer	3725	Indicates the entity importing the medical device into the locale.	ISO 7000 / IEC 60417 Graphical symbols for use on equipment
	Temperature Limit	5.3.7	Indicates the temperature limits to which the medical device can be safely exposed.	ISO 15223-1 Medical devices - Symbols to be used with medical device labels - General Requirements
	Humidity Limitation	5.3.8	Indicates the range of the humidity to which the medical device can be safely exposed	ISO 15223-1 Medical devices - Symbols to be used with medical device labels - General Requirements
	Atmospheric Pressure limitation	5.3.9	Indicates the range of atmospheric pressure to which the medical device can be safety exposed.	ISO 15223-1 Medical devices - Symbols to be used with medical device labels - General Requirements
	Keep Dry	5.3.4	Indicates a medical device that needs to be protected from moisture.	ISO 15223-1 Medical devices - Symbols to be used with medical device labels - General Requirements

Symbol	Symbol Title	Reference Number	Description	Standard Title and Designation Number
	Caution	5032	Indicates that 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 Medical devices - Symbols to be used with medical device labels - General Requirements
	Warning: Electricity	5016	Warns of electricity.	ISO 7000 / IEC 60417 Graphical symbols for use on equipment
	Equipotentiality	5021	Identifies the terminals which, when connected together, bring the various parts of an equipment or of a system to the same potential, no necessarily being the earth (ground) potential, e.g., for local bonding.	ISO 7000 / IEC 60417 Graphical symbols for use on equipment
	Current	5032	Indicates on the rating plate that the equipment is suitable for alternating current only; to identify relevant terminals.	ISO 7000 / IEC 60417 Graphical symbols for use on equipment
	Fuse	5016	Identifies fuse boxes or their locations.	ISO 7000 / IEC 60417 Graphical symbols for use on equipment
	Standby	5009	Identifies 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.	ISO 7000 / IEC 60417 Graphical symbols for use on equipment

Symbol	Symbol Title	Reference Number	Description	Standard Title and Designation Number
	ON/OFF (push/push)	5010	Indicates disconnection from the mains, at least for main switches, or their positions, and all those cases where safety is involved. Each position, "ON" or "OFF" is a stable position.	ISO 7000 / IEC 60417 Graphical symbols for use on equipment
	Defibrillation-Proof Type CF Applied Part	5021	To identify a defibrillation-proof type CF applied part complying with IEC 60601-1.	ISO 7000 / IEC 60417 Graphical symbols for use on equipment
	Battery Pack	5001B	Identifies a device related to the power supply by primary or secondary battery, for instance a cover for the battery compartment, or the connector terminals.	ISO 7000 / IEC 60417 Graphical symbols for use on equipment
	Protective Earth, Protective Ground	5032	Identifies any terminal which is intended for connection to an external conductor for protection against electrical shock in case of fault, or the terminal of a protective earth (ground) electrode.	ISO 7000 / IEC 60417 Graphical symbols for use on equipment
	Electrostatic Sensitive Device	5134	Identifies packages containing electrostatic sensitive devices, or to identify a device or a connector that has not been tested for immunity to electrostatic discharge.	ISO 7000 / IEC 60417 Graphical symbols for use on equipment
	Type B Applied Part	5840	Identifies a type B applied part complying with IEC 60601-1.	ISO 7000 / IEC 60417 Graphical symbols for use on equipment

Symbol	Symbol Title	Reference Number	Description	Standard Title and Designation Number
	Non-ionizing Electromagnetic Radiation	5140	Indicates generally elevated, potentially hazardous, levels of non- ionizing radiation, or to indicate equipment or systems e.g., that intentionally apply RF electromagnetic for diagnosis or treatment.	ISO 7000 / IEC 60417 Graphical symbols for use on equipment