



# IBM Watson Health Imaging

## **SYMBOLS GLOSSARY**

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The symbols glossary is provided electronically at <http://www.merge.com/Customers/Statements-and-Patches.aspx>.



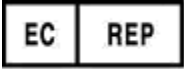



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Part	Date	Version	Description
QS-123940	May/2019	4.0	Update to symbols.
	Aug/2017	3.0	Update for symbols changed.
	Dec/2016	2.0	Addition of hardware symbols for the GEO expansion project.
	Sept/2016	1.0	Initial release of document.













The following symbols may be found on the labeling and packaging of Watson Health Imaging medical devices:

<b>Symbol</b>	<b>Symbol Title</b>	<b>Reference Number</b>	<b>Description</b>	<b>Standard Title and Designation Number</b>
	Manufacturer	5.1.1	Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC	ISO 15233-1 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 15233-1 Medical devices - Symbols to be used with medical device labels - General Requirements
	Authorized Representative in the European Community	5.1.2	Indicates the Authorized Representative in the European Community	ISO 15233-1 Medical devices - Symbols to be used with medical device labels - General Requirements
	Catalogue number	5.1.6	Indicates the manufacturer's catalogue number so that the medical device can be identified	ISO 15233-1 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 15233-1 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 a specific medical device can be identified	ISO 15233-1 Medical devices - Symbols to be used with medical device labels - General Requirements

Symbol	Symbol Title	Reference Number	Description	Standard Title and Designation Number
 or 	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 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)
	European Conformity	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, in practice by many of the so-called Product Directives	Directive 93/68/EEC CE Marking Directive
	Temperature Limit	5.3.7	Indicates the temperature limits to which the medical device can be safely exposed	ISO 15233-1 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 15233-1 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 safely exposed	ISO 15233-1 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 15233-1 Medical devices - Symbols to be used with medical device labels - General Requirements

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  If the symbol is for electronic indications for use (eIFU), a URL address is indicated below the symbol to indicate the instructions for use are available in electronic form	ISO 15233-1 Medical devices - Symbols to be used with medical device labels - General Requirements
Rx ONLY	Prescription Use	N/A	Indicates that the product is a medical device and Federal Law (USA) restricts this device to sale by or on the order of a physician	21 CFR 801.109
	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
	Caution	5.4.4	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 15233-1 Medical devices - Symbols to be used with medical device labels - General Requirements
	Warning; Electricity	ISO 7010-W012	To warn of electricity	IEC/TR 60878 Graphical Symbols for Electrical Equipment in Medical Practice
	Equipotentiality	5021	To identify 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	IEC/TR 60878 Graphical symbols for electrical equipment in medical practice

Symbol	Symbol Title	Reference Number	Description	Standard Title and Designation Number
	Alternating current	5032	To indicate on the rating plate that the equipment is suitable for alternating current only; to identify relevant terminals	IEC/TR 60878 Graphical symbols for electrical equipment in medical practice
	Fuse	5016	Identifies fuse boxes or their locations	IEC 60417 / Graphical symbols for use on equipment
	Stand-by	5009	To identify the switch or switch position by of which part of the equipment is switched on in order to bring it into the stand-by condition	IEC/TR 60878 Graphical symbols for electrical equipment in medical practice
	ON/OFF (push/push)	5010	To indicate disconnection form 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	IEC 60417 Graphical Symbols for use on equipment
	Type CF defibrillation - proof patient applied part	5021	To identify a defibrillation-proof CF applied part complying with IEC 60601-1	IEC 60417 Graphical symbols for use on equipment
	Battery	5001B	To identify a device related to the power supply by primary or secondary battery, for instance a cover for the battery compartment, or the connector terminals	IEC 60417 – Graphical Symbols for Use on Equipment
	Protective earth, protective ground	5032	To identify 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	IEC 60417 Graphical symbols for use on equipment

<b>Symbol</b>	<b>Symbol Title</b>	<b>Reference Number</b>	<b>Description</b>	<b>Standard Title and Designation Number</b>
	Electrostatic sensitive devices	5134	To indicate packages containing electrostatic sensitive devices, or to identify a device or a connector that has not been tested for immunity to electrostatic discharge	IEC 60417 – Graphical Symbols for Use on Equipment
	Type B applied part	5840	Identifies a type B applied part complying with IEC 60601-1	IEC 60417 Graphical symbols for use on equipment
	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	IEC 60417 / Graphical symbols for use on equipment