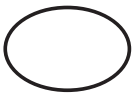
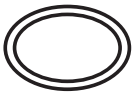
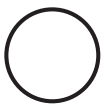
DIGITAL SYMBOLS GLOSSARY

This document contains symbols that may appear on product labeling. The symbols referenced were not created by Applied Medical Resources. Please refer to the Instructions for Use for the indications, contraindications, warnings, precautions, instructions and other information.

Symbol	Symbol Title	Title & Designation Number of Standard	Symbol Reference Number
	Medical Device	ISO 15223-1:2021 Medical devices-Symbols to be used with information to be supplied by the manufacturer-Part 1: General requirements	5.7.7
	CE mark	Directive 93/42/EEC Regulation (EU) 2017-745;Amd5;2024	Annex V
	Catalogue number	ISO 15223-1:2021 Medical devices-Symbols to be used with information to be supplied by the manufacturer-Part 1: General requirements	5.1.6
	Batch code	ISO 15223-1:2021 Medical devices-Symbols to be used with information to be supplied by the manufacturer-Part 1: General requirements	5.1.5
	Sterilized using irradiation	ISO 15223-1:2021 Medical devices-Symbols to be used with information to be supplied by the manufacturer-Part 1: General requirements	5.2.4
	Sterilized using ethylene oxide	ISO 15223-1:2021 Medical devices-Symbols to be used with information to be supplied by the manufacturer-Part 1: General requirements	5.2.3
	Sterile	ISO 15223-1:2021 Medical devices-Symbols to be used with information to be supplied by the manufacturer-Part 1: General requirements	5.2.1
	Single sterile barrier system	ISO 15223-1:2021 Medical devices-Symbols to be used with information to be supplied by the manufacturer-Part 1: General requirements	5.2.11
	Single sterile barrier system with protective packaging inside	ISO 15223-1:2021 Medical devices-Symbols to be used with information to be supplied by the manufacturer-Part 1: General requirements	5.2.13
	Single sterile barrier system with protective packaging outside	ISO 15223-1:2021 Medical devices-Symbols to be used with information to be supplied by the manufacturer-Part 1: General requirements	5.2.14
	Double sterile barrier system	ISO 15223-1:2021 Medical devices-Symbols to be used with information to be supplied by the manufacturer-Part 1: General requirements	5.2.12

Symbol	Symbol Title	Title & Designation Number of Standard	Symbol Reference Number
	Use by date	ISO 15223-1:2021 Medical devices-Symbols to be used with information to be supplied by the manufacturer-Part 1: General requirements	5.1.4
	Serial number	ISO 15223-1:2021 Medical devices-Symbols to be used with information to be supplied by the manufacturer-Part 1: General requirements	5.1.7
	CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.	21CFR Part 801;2022	801.109(b)(1)
	Caution	ISO 15223-1:2021 Medical devices-Symbols to be used with information to be supplied by the manufacturer-Part 1: General requirements	5.4.4
		IEC 60601-1;ed3;am2;2020 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance	Annex D, Table D.1, No. 10
	Do not reuse	ISO 15223-1:2021 Medical devices-Symbols to be used with information to be supplied by the manufacturer-Part 1: General requirements	5.4.2
	Do not resterilize	ISO 15223-1:2021 Medical devices-Symbols to be used with information to be supplied by the manufacturer-Part 1: General requirements	5.2.6
	Do not use if package is damaged and consult instructions for use	ISO 15223-1:2021 Medical devices-Symbols to be used with information to be supplied by the manufacturer-Part 1: General requirements	5.2.8
	Consult instructions for use or consult electronic instructions for use	ISO 15223-1:2021 Medical devices-Symbols to be used with information to be supplied by the manufacturer-Part 1: General requirements	5.4.3
	Follow operating instructions	IEC 60601-1;ed3;am2;2020 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance	Annex D, Table D.1, No.11
	Consult instructions for use / This safety sign is blue in color per ISO 7010-M002.	ISO 20417;2021;Corr1;2021: Information to be supplied by the manufacturer. Symbol derived from ISO 7010 M002	6.1.5
	Follow instructions for use	IEC 60601-1;ed3;am2;2020 Medical Electrical Equipment - Part 1: General requirements for basic safety and essential performance	7.2.3 7.2.5
	Non-pyrogenic	ISO 15223-1:2021 Medical devices-Symbols to be used with information to be supplied by the manufacturer-Part 1: General requirements	5.6.3

Symbol	Symbol Title	Title & Designation Number of Standard	Symbol Reference Number
	Contains or presence of phthalate	BS EN 15986:2011 Symbol for use in the labelling of medical devices – Requirements for labelling of medical devices containing phthalates	4.2 Figure 1
	Non-ionizing radiation	IEC 60601-1-2;ed4;am1;2020 - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests	N/A
	Contains hazardous substances	ISO 15223-1:2021 Medical devices-Symbols to be used with information to be supplied by the manufacturer-Part 1: General requirements	5.4.10
	Temperature limitation	ISO 15223-1:2021 Medical devices-Symbols to be used with information to be supplied by the manufacturer-Part 1: General requirements IEC 60601-1;ed3;am2;2020 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance	5.3.7
	Upper limit of temperature	ISO 15223-1:2021 Medical devices-Symbols to be used with information to be supplied by the manufacturer-Part 1: General requirements IEC 60601-1;ed3;am2;2020 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance	5.3.6
	Lower limit of temperature	ISO 15223-1:2021 Medical devices-Symbols to be used with information to be supplied by the manufacturer-Part 1: General requirements IEC 60601-1;ed3;am2;2020 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance	5.3.5
	Humidity limitation	ISO 15223-1:2021 Medical devices-Symbols to be used with information to be supplied by the manufacturer-Part 1: General requirements IEC 60601-1;ed3;am2;2020 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance	5.3.8
	Atmospheric pressure limitation	ISO 15223-1:2021 Medical devices-Symbols to be used with information to be supplied by the manufacturer-Part 1: General requirements IEC 60601-1;ed3;am2;2020 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance	5.3.9
	Separate collection for all batteries and accumulators	DIRECTIVE 2006/66/EC of the European Parliament and of the Council	Annex II

Symbol	Symbol Title	Title & Designation Number of Standard	Symbol Reference Number
	Separate collection for waste of electrical and electronic equipment.	Directive 2002/96/EC Directive 2012/19/EU BS EN 50419:2022	Annex IX 4.1.2(b)
IP2X	Protected against solid foreign objects of 12.5 mm diameter and greater	IEC 60529;ed2.0;2001;am2;2013 CSV/COR2:2015 Degrees of protection provided by enclosures (IP code)	2.1
		IEC 60601-1;ed3;am2;2020 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance	Annex D, Table D.3, No. 2
IPX4	Protected against splashing water	IEC 60529;ed2.0;2001;am2;2013 CSV/COR2:2015 Degrees of protection provided by enclosures (IP code)	4.1
		IEC 60601-1;ed3;am2;2020 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance	Annex D, Table D.3, No. 2
	Stand-by	IEC 60601-1;ed3;am2;2020 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance	Annex D, Table D.1, No. 29
	Alternating current	IEC 60601-1;ed3;am2;2020 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance	Annex D, Table D.1, No. 1
	Type BF Applied Part	IEC 60601-1;ed3;am2;2020 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance	Annex D, Table D.1, No. 20
	Type CF applied part	IEC 60601-1;ed3;am2;2020 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance	Annex D, Table D.1, No. 21
	Defibrillation-proof type CF applied part	IEC 60601-1;ed3;am2;2020 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance	Annex D, Table D.1, No. 27
	On	IEC 60601-1;ed3;am2;2020 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance	Annex D, Table D.1, No. 12
	Off	IEC 60601-1;ed3;am2;2020 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance	Annex D, Table D.1, No. 13
	Equipotentiality	IEC 60601-1;ed3;am2;2020 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance	Annex D, Table D.1, No. 8

Symbol	Symbol Title	Title & Designation Number of Standard	Symbol Reference Number
	Low priority alarm	IEC 60601-1;ed3;am2;2020 Medical electrical equipment: Part 1-8: General requirements for basic safety and essential performance	Annex C, Table C.1
	General markings for a lithium ion battery pack	UL 1642;ed5;2015 UL Standard for Safety – Lithium Batteries UL 2054;ed3;2021UL Standard for Household and Commercial Batteries	N/A
	General warning safety sign	IEC 60601-1;ed3;am2;2020 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance	Annex D, Table D.2, No. 2
	Dangerous Voltage	IEC 60601-1;ed3;am2;2020 – Medical electrical equipment – Part 1: General requirements for basic safety and essential performance	Annex D, Table D.1, No. 24
	HF Isolated Patient Circuit	IEC 60601-1-2;ed4;am1;2020 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests	5.2.2.6
	Class II Equipment	IEC 60601-1;ed3;am2;2020 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance	Annex D, Table D.1, No. 9
	UL Recognized component mark	N/A	N/A
			
			
	UL Listed	N/A	N/A
	UL Classified	N/A	N/A
	Non-sterile	ISO 15223-1:2021 Medical devices-Symbols to be used with information to be supplied by the manufacturer-Part 1: General requirements	5.2.7

Symbol	Symbol Title	Title & Designation Number of Standard	Symbol Reference Number
	Magnetic resonance conditional	ASTM F2503;2023;cor1;2023 Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment	Table 2
	Magnetic resonance safe	ASTM F2503;2023;cor1;2023 Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment	Table 2
	Magnetic resonance unsafe	ASTM F2503;2023;cor1;2023 Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment	Table 2
	Unique device identifier	ISO 15223-1:2021 Medical devices-Symbols to be used with information to be supplied by the manufacturer-Part 1: General requirements	5.7.10
	Authorized Representative in the European Union	ISO 15223-1:2021/Amd 1:2025 Medical devices-Symbols to be used with information to be supplied by the manufacturer-Part 1: General requirements	5.1.2
	Authorized representation in the European Community/European Union	ISO 15223-1:2021 Medical devices-Symbols to be used with information to be supplied by the manufacturer-Part 1: General requirements	5.1.2
	Swiss Authorised Representative	Swissmedic MedDO;2020	Art. 51, para. 1
	UK Conformity Assessment	UK MDR 2002	5.1.2
	Importer	ISO 15223-1:2021 Medical devices-Symbols to be used with information to be supplied by the manufacturer-Part 1: General requirements	5.1.8
	Manufacturer	ISO 15223-1:2021 Medical devices-Symbols to be used with information to be supplied by the manufacturer-Part 1: General requirements	5.1.1
	Manufacturer and date of manufacture		
	Date of manufacture	ISO 15223-1:2021 Medical devices-Symbols to be used with information to be supplied by the manufacturer-Part 1: General requirements	5.1.3

Symbol	Symbol Title	Title & Designation Number of Standard	Symbol Reference Number
	Not made with natural rubber latex	FDA Guidance Rubber Latex;2014 Product or Product Container is not Made with Natural Rubber Latex	4.0
		ISO 15223-1:2021/Amd 1:2025 Medical devices-Symbols to be used with information to be supplied by the manufacturer-Part 1: General requirements	5.4.5 with Annex B, Clause B.2

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