

Technical Bulletin

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Issue date: **November 2016**

Product: INOmax DS_{IR}[®] / INOmax DS_{IR}[®] Plus /

Priority: Low

INOmax DS_{IR}[®] Plus MRI / and accessories








Classification: Information for Distribution


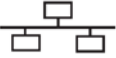









Affected parts: Operation Manuals / Accessory package labels











Subject: **Symbols Glossary for Devices and Associated Accessories Labeling and Packaging**












The symbols glossary is provided electronically at www.inomax.com.




The following symbols may be found on the labeling and packaging for INOmax DS_{IR} / INOmax DS_{IR} Plus / INOmax DS_{IR} Plus MRI devices and associated accessories:

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.
	Atmospheric pressure limitation	5.3.9	Indicates the range of atmospheric pressure to which the medical device can be safely exposed.	ISO & ANSI/AAMI/ ISO 15223-1 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 & ANSI/AAMI/ 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 & ANSI/AAMI/ ISO 15223-1 Medical devices – Symbols to be used with medical device labels – General requirements.
	Battery check (running on battery)	5546	To identify a control to check the condition of a primary or secondary battery or to identify the battery condition indicator.	IEC/TR 60878 Graphical symbols for electrical equipment in medical practice.
	Bell cancel (alarm silence)	5576	To identify the control whereby a bell may be switched off or to indicate the operating status of the bell.	IEC/TR 60878 Graphical symbols for electrical equipment in medical practice.
	Catalogue number	5.1.6	Indicates the manufacturer's catalogue number so that the medical device can be identified.	ISO & ANSI/AAMI/ 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	5.4.4	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.	ISO & ANSI/AAMI/ ISO 15223-1 Medical devices – Symbols to be used with medical device labels – General requirements.
	Computer Network	5988	To identify the computer network itself or to indicate the connecting terminal of the computer network.	IEC/TR 60878 Graphical symbols for electrical equipment in medical practice.
	Conformité Européene (European Conformity)	N/A	CE Marking on a product is a manufacturer's declaration that the product complies with the 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
	Contain or presence of	2725	To indicate that the equipment contains the identified product or substance.	IEC/TR 60878 Graphical symbols for electrical equipment in medical practice.
	Corrosive	GHS05	Corrosive to skin. Corrosive to metal.	Regulation (EC) No 1272/2008 Classification, labelling and packaging of substances and mixtures
	Date of manufacture	5.1.3	Indicates the date when the medical device was manufactured.	ISO & ANSI/AAMI/ ISO 15223-1 Medical devices – Symbols to be used with medical device labels – General requirements.
	Do not reuse	5.4.2	Indicates a medical device that is intended for one use or for use on a single patient during a single procedure.	ISO & ANSI/AAMI/ ISO 15223-1 Medical devices – Symbols to be used with medical device labels – General requirements.
	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, not necessarily being the earth (ground) potential, e.g. for local bonding.	IEC/TR 60878 Graphical symbols for electrical equipment in medical practice.
	Fragile, handle with care	5.3.1	Indicates a medical device that can be broken or damaged if not handled carefully.	ISO & ANSI/AAMI/ ISO 15223-1 Medical devices – Symbols to be used with medical device labels – General requirements.
	Fuse	5016	To identify fuse boxes or their location.	IEC/TR 60878 Graphical symbols for electrical equipment in medical practice.
	General symbol for recovery/recyclable	1135	To indicate that a material is part of a recovery/recycling Process.	IEC/TR 60878 Graphical symbols for electrical equipment in medical practice.

Symbol	Symbol Title	Reference Number	Description	Standard Title and Designation Number
	Humidity limitation	5.3.8	Indicates the range of humidity to which the medical device can be safely exposed.	ISO & ANSI/AAMI/ ISO 15223-1 Medical devices – Symbols to be used with medical device labels – General requirements.
	Input/output (infrared)	5448	To identify a combined input/output connector or mode.	IEC/TR 60878, Graphical symbols for electrical equipment in medical practice.
	Input (sample gas or nitric oxide)	5034	To identify an input terminal when it is necessary to distinguish between inputs and outputs.	IEC/TR 60878, Graphical symbols for electrical equipment in medical practice.
	Keep dry	5.3.4	Indicates a medical device that needs to be protected from moisture.	ISO & ANSI/AAMI/ ISO 15223-1 Medical devices – Symbols to be used with medical device labels – General requirements.
	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 & ANSI/AAMI/ ISO 15223-1 Medical devices – Symbols to be used with medical device labels – General requirements.
	MR conditional	7.4.6.1	An item with demonstrated safety in the MR environment within defined conditions.	ASTM F2503-13 Standard Practice for Marking medical devices and other items for safety in the magnetic resonance environment
	Non-ionizing electromagnetic radiation	5140	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.	IEC/TR 60878 Graphical symbols for electrical equipment in medical practice.
	No pushing	ISO7010-P017	To prohibit pushing against an object.	IEC/TR 60878, Graphical symbols for electrical equipment in medical practice.
	On (power)	5007	To indicate connection to the mains, at least for mains switches or their positions, and all those cases where safety is involved.	IEC/TR 60878 Graphical symbols for electrical equipment in medical practice.
	Output (sample gas and nitric oxide)	5035	To identify an output terminal when it is necessary to distinguish between inputs and outputs.	IEC/TR 60878, Graphical symbols for electrical equipment in medical practice.
Rx ONLY	Prescription use	N/A	Caution: Federal law 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
	Protect from heat and radioactive sources	5.3.3	Indicates a medical device that needs protection from heat and radioactive sources.	ISO & ANSI/AAMI/ ISO 15223-1 Medical devices – Symbols to be used with medical device labels – General requirements.
	Refer to instruction manual/booklet	ISO 7010-M002	To signify that the instruction manual/booklet must be read.	IEC/TR 60878 Graphical symbols for electrical equipment in medical practice
	Serial number	5.1.7	Indicates the manufacturer's serial number so that a specific medical device can be identified.	ISO & ANSI/AAMI/ ISO 15223-1 Medical devices – Symbols to be used with medical device labels – General requirements.
	Stacking limit by mass	0630	On transport packaging. To indicate that stacking possibilities are limited because of the nature of the package.	IEC/TR 60878 Graphical symbols for electrical equipment in medical practice
	Stacking limit by number	2403	On transport packaging. To indicate that the items are not to be vertically stacked higher than the specified number of items.	IEC/TR 60878, Graphical symbols for electrical equipment in medical practice.
	Stand-by	5009	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.	IEC/TR 60878, Graphical symbols for electrical equipment in medical practice.
	Temperature	0034	To signify temperature or function associated with temperature. e.g. temperature indication – temperature monitoring points. Units of measurement, e.g. °C, can be added to symbol.	IEC/TR 60878, Graphical symbols for electrical equipment in medical practice.
	Temperature limit	5.3.7	Indicates the temperature limits to which the medical device can be safely exposed.	ISO & ANSI/AAMI/ ISO 15223-1 Medical devices – Symbols to be used with medical device labels – General requirements.
	This way up	0623	On transport packaging. To indicate the correct upright position.	IEC/TR 60878 Graphical symbols for electrical equipment in medical practice.
	Type B applied part	5840	On medical equipment. To identify a type B applied part complying with IEC 60601-1. <i>Note - B = Body.</i>	IEC/TR 60878 Graphical symbols for electrical equipment in medical practice.
	Use by date	5.1.4	Indicates the date after which the medical device is not to be used.	ISO & ANSI/AAMI/ 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
	Use No Oil	0248	Use No Oil.	ISO 7000 Graphical symbols for use on equipment – registered symbols ISO10524-1 Pressure regulators for use with medical gases – Part 1: Pressure regulators and pressure regulators with flow-metering devices
	Universal serial bus (USB)	N/A	USB icon is used to identify USB plugs and receptacles.	IEC 62680-2-1 Universal Serial Bus interfaces for data and power Part 2-1: Universal Serial Bus Specification, Revision 2.0 (TA 14)
	WEEE Waste of Electrical and Electronic Equipment	N/A	Indicates that when end-user wishes to discard this product is 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)

For technical assistance regarding the INOmax DS_{IR}, please contact technical support at 1-877-566-9466 (North America) or your specific country manager.

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