

Technical Bulletin

Ref: **TB-16015-ENG**

Issue date: **September 2016**

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

Priority: Low

INOmax DS_{IR}® Plus MRI / and accessories








Classification: Information for Distribution


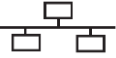









Affected parts: Operation Manuals / Accessory package labels











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 Européenne (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. |
|  | 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 |

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|---|---|------------------|---|---|
| | | | | 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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