LivaNova® Neuromodulation

Symbols and Definitions

May 2020

ISO 7000 Graphical Symbols for use on equipment — Registered Symbols				
Symbol	**Name**	**Number**	**Definition**	**Where Used**
	Caution	0434B	Caution is necessary when operating the device or control close to where the symbol is placed, or the current situation needs operator awareness or operator action in order to avoid undesirable consequences.	**Sales Pack:** ■ All Products **IFU:** ■ All Products **Software Screen:** ■ Programmer
	Temperature limit	0632	Maximum and minimum temperature limits at which the item shall be stored, transported or used.	**Sales Pack:** ■ All Products
	Do not re-use	1051	The item is for single use only and must not be used more than once, for example on packages of medical disposables.	**Sales Pack:** ■ All Sterile **Sterile Pack:** ■ All Sterile
	Operator's manual; operating instructions	1641	The location where the operator's manual is stored or to identify information that relates to the operating instructions.	**Sales Pack:** ■ All Products **Sterile Pack:** ■ All Products **Device:** ■ Wand
	Tie down point	2069	The location on the machine or equipment that is used to tie down or secure the machine or equipment to prevent movement during transport.	**Sales Pack:** ■ Lead ■ Accessory Pack **Sterile Pack:** ■ Lead ■ Accessory Pack
	Batch code	2492	The manufacturer's batch or lot code	**Sales Pack:** ■ Tunneler ■ Accessory Pack ■ Patient Kit **Sterile Pack:** ■ Tunneler ■ Accessory Pack
	Date of manufacture	2497	The date on which a product was manufactured. [2017: Replaced by IEC 60417-6049 on Cyberonics/LivaNova Neuromodulation products.]	**Sales Pack:** ■ All Products **Sterile Pack:** ■ All Sterile

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Symbol	Name	Number	Definition	Where Used
SN	Serial number	2498	The manufacturer's serial number.	**Sales Pack:** ■ Generator ■ Lead ■ Wand ■ SW + Computer **Sterile Pack:** ■ Generator ■ Lead **Device:** ■ Generator ■ Lead ■ Wand ■ SW + Computer
STERILE	Sterile	2499	The device is provided sterile.	**Sales Pack:** ■ All Sterile **Sterile Pack:** ■ All Sterile
	Do not use if package is damaged	2606	The device must not be used if the package holding the device is damaged, for example on packaging of medical devices.	**Sales Pack:** ■ All Products
	Use by date	2607	The device should not be used after the date accompanying the symbol, for example on a medical device or its packaging.	**Sales Pack:** ■ All Sterile **Sterile Pack:** ■ All Sterile
	Patient number	2610	The control or the indicator for the patient number, for example to identify the place where the patient number or identification code is found or can be entered.	**Other:** ■ Implant Card
	Humidity limitation	2620	The acceptable upper and lower limits of relative humidity for transport and storage.	**Sales Pack:** ■ All Products **Sterile Pack:** ■ All Sterile
	Non-pyrogenic	2724	The product is non-pyrogenic.	**Sales Pack:** ■ All implantable **Sterile Pack:** ■ All implantable
	Packaging unit	2794	The number of pieces in the package.	**Sales Pack:** ■ All Products
	Implantable device	3045	Implantable device.	**Sales Pack:** ■ Generator **Sterile Pack:** ■ Generator
	Non-standard connector cavity	3067	A non-standard connector cavity on the [device].	**Sales Pack:** ■ Generator ■ Lead **Sterile Pack:** ■ Generator ■ Lead

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Symbol	Name	Number	Definition	Where Used
	Torque wrench for implantable pulse generator	3077	The torque limiting wrench used to connect a lead to the implantable pulse generator.	**Sales Pack:** ■ Generator ■ Accessory Pack **Sterile Pack:** ■ Generator ■ Accessory Pack
	Manufacturer	3082	The manufacturer of a product. This symbol shall be used filled in all applications to differentiate if from ISO 7000-2497.	**Sales Pack:** ■ All Products **Sterile Pack:** ■ All Products **IFU:** ■ All Products

ISO 7001
Graphical Symbols - Public Information Symbols

Symbol	Name	Number	Definition	Where Used
	Direction arrow	PI PF 030	To indicate direction of movement of people.	**Sales Pack:** ■ All Products
	Healthcare center or doctor	PI PF 044	To indicate the location of a facility where healthcare is offered.	**Other:** ■ Implant card
	Do not throw away	ISO 7001 PI PF 027 + ISO 7010 P001	To indicate a receptacle for the acceptance of trash or litter or rubbish being thrown away. General prohibition sign A combined symbol to signify that user should not throw away the material.	**Other:** ■ Implant card

IEC 60417
Graphical Symbols for Use on Equipment

Symbol	Name	Number	Definition	Where Used
	Battery, general	5001B	The power supply by primary or secondary battery.	**Sales Pack:** ■ Wand (M201)
	Positioning of cell	5002	The battery holder itself and to identify the positioning of the cell(s) inside the battery holder [added text also shows negative and battery type].	**Device:** ■ Wand (M2000), battery compartment
	Stand-by	5009	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, and to identify the control to shift to or to indicate the state of low power consumption. Each of different states of power consumption may be indicated using a corresponding color.	**Device:** ■ Wand
	Type BF applied part	5333	A type BF applied part complying with IEC 60601-1	**Device:** ■ Wand

IEC 60417
Graphical Symbols for Use on Equipment

Symbol	Name	Number	Definition	Where Used
	Battery Check	5546	A control to check the condition of a primary or secondary battery or to identify the battery condition indicator.	**Device:** ■ Wand (M2000)
	Date	5662	The control which sets and indicates the date.	**Other:** ■ Implant card
	Memory Disk	5884	Cartridge type memory disks [additional memory storage provided]	**Sales Pack:** ■ SW+Computer
	Disc media	5986	Disc media	**Sales Pack:** ■ SW+Media (alone)
	Country of Manufacture + Date of Manufacture	6049	Country of manufacture. Also used to indicate date of manufacture, as permitted in ISO 60417, when placed next to manufacture date.	**Sales Pack:** ■ All Products **Sterile Pack:** ■ All Sterile
	Model Number	6050	To identify the model number or type number of a product. In the application of this symbol, the model number or type number of the product should be accompanied with this symbol.	**Sales Pack:** ■ All Products **Sterile Pack:** ■ All Sterile
	PC	6234	Personal computer	**Sales Pack:** ■ SW+Computer
	Permanent-magnet moving-coil instrument	6267	The instrument which operates by the interaction of the magnetic field due to a current in a movable coil with the field of a fixed permanent magnet.	**Sales Pack:** ■ Patient Kit

Other Sources

Symbol	Name	Source	Number	Definition	Where Used
℞Only	Prescription Statement	21 CFR 801.109(c)	N/A	U.S. federal law restricts this device to sale by or on the order of a physician.	**Sales Pack:** ■ All Products except investigational products **IFU:** ■ All Products except M220
	European Authorized Representative	ISO 15223-1	5.1.2	Authorized Representative in the European Community – a natural or legal person established in the European Economic Area (EEA, including EU & EFTA) who, explicitly designated by a non-European manufacturer, acts on his behalf in carrying out certain tasks required in the applicable directives.	**Sales Pack:** ■ All Products **IFU:** ■ All Products
	WEEE	EN 50419	N/A	Do not dispose to unsorted municipal waste	**Sales Pack:** ■ Wand ■ SW+Computer

CE	CE Mark	90/385/EEC	N/A	Indicates conformity with the essential health and safety requirements set out in European Directives	**Sales Pack:** ■ All Products except investigational products **IFU:** ■ All Products
	MR Conditional	ASTM F2503–08	N/A	ASTM Recommended Icon Associated with an item that has been demonstrated to pose no known hazards in a specified MRI environment with specified conditions of use.	**Sales Pack:** ■ Generator ■ IGP **Other:** ■ Implant Card
	MR Unsafe	ASTM F2503–08	N/A	ASTM Recommended Icon Associated with the MR UNSAFE ASTM Term	**Sales Pack:** ■ Wand ■ SW+Computer **Device:** ■ Wand
	China RoHS	SJ/T 11364-2014	N/A	Indicates that this electronic and electrical product contains certain hazardous substances and can be used safely during its Environmental Protection Use Period (EPUP) as defined in SJ/T 11364-2014 and should enter into the recycling system after its environmental protection use period. A circled 10 indicates an EPUP of 10 years.	**Sales Pack:** Wand

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