LivaNova

Health innovation that matters

LivaNova® Neuromodulation

Symbols and Definitions

October 2023

CE 0344

The year of authorization to affix the CE mark:

Model 102	2003	Model 3000	2018
Model 102R	2003	Model 7103	2015
Model 103	2005	Model 7220	2015
Model 104	2005	Model 7250	2015
Model 105	2011	Model 7304	2015
Model 106	2014		
Model 1000	2017		
Model 1000-D	2020		
Model 8103	2019		
Model 302	2003		
Model 303	2006		
Model 304	2009		
Model 220	2002		
Model 402	2005		
Model 502	2003		
Model 2000	2017		

ISO 15223-1:2021

Also registered in ISO 7000 Series if registration number is shown, otherwise ISO 15223-1 symbol number.

ISO 15223-1:2021				
Symbol	Name	Number	Definition	Where Used
 	Caution	7000-0434B 7000-0434A	To indicate caution is necessary when operating the device or control close to where the symbol is placed, or to indicate that 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 Other: • Patient Implant Card
	Temperature limit	7000-0632	Indicates the temperature limits to which the medical device can be safely exposed.	Sales Pack: • All products
	Do not re-use	7000-1051	Indicates a medical device that is intended for one single use only. NOTE: Synonyms for “Do not re-use” are “single use” and “use only once”.	Sales Pack: • All sterile Sterile Pack: • All sterile
	Do not resterilize	7000-2608	Indicates a medical device that is not to be resterilized.	

ISO 15223-1:2021				
Symbol	Name	Number	Definition	Where Used
	Consult instructions for use or consult electronic instructions for use	7000-1641	Indicates the need for the user to consult the instruction for use. NOTE: Synonym for "Consult instructions for use" is "Consult operating instructions".	Sales Pack: • All products Sterile Pack: • All products Device: • Wand (M2000) Other: • Patient Implant Card
	Batch code	7000-2492	Indicates the manufacturer's batch code, so that the batch or lot can be identified. NOTE: Synonyms for "batch code" are "lot number" and "batch number".	Sales Pack: • Tunneler • Accessory Pack • Patient Magnet Sterile Pack: • Tunneler • Accessory Pack

ISO 15223-1:2021				
Symbol	Name	Number	Definition	Where Used
	Serial number	7000-2498	Indicates the manufacturer's serial number, so that a specific medical device can be identified.	**Sales Pack:** • Generator • Lead • Wand • Programmer **Sterile Pack:** • Generator • Lead **Device:** • Generator • Lead • Wand (M2000) • Programmer **Other:** • Patient Implant Card
	Do not use if package is damaged and consult instructions for use	7000-2606	Indicates a medical device that should not be used if the package has been damaged or opened and that the user should consult the Instructions for Use for additional information.	**Sales Pack:** • Generator • Lead • Accessory Pack • Tunneler
	Use by date	7000-2607	Indicates the date after which the medical device is not to be used. **NOTE 1:** For example, June 2002 is expressed as 2002-06. **NOTE 2:** Synonym for “use-by date” is “use by”.	**Sales Pack:** • All sterile **Sterile Pack:** • All sterile

ISO 15223-1:2021				
Symbol	Name	Number	Definition	Where Used
	Patient number	7000-2610	Indicates a unique number associated with an individual patient. NOTE 1: The hash mark (#) is part of the symbol. The patient number appears adjacent to the symbol. NOTE 2: Usage would be to indicate a data entry field or location (e.g., medical device input screen or implant card) or in information provided to the patient.	Other: • Patient Implant Card
	Patient name	7000-3726	Indicates the name of the patient. NOTE: Usage would be to indicate a data entry field or location (e.g., medical device input screen or implant card) or in information provided to the patient.	Other: • Patient Implant Card
	Single patient - multiple use	7000-3706	Indicates a medical device that may be used multiple times (multiple procedures) on a single patient.	Sales Pack: • Patient Magnet
	Patient information website	7000-3705	Indicates a website where a patient may obtain additional information on the medical product. NOTE: Usage would be to indicate location of information provided to the patient.	Other: • Patient Implant Card
	Patient identification	60417-5664	Indicates the identification of the data of the patient. NOTE: Usage would be to indicate a data entry field or location (e.g., medical device input screen or implant card) or in information provided to the patient.	Other: • Patient Implant Card

ISO 15223-1:2021				
Symbol	Name	Number	Definition	Where Used
	Healthcare center or doctor	7001- Pi PF 044	To indicate the address of the health care center or doctor where medical information about the patient may be found. NOTE 1: The embedded cross can be deleted or replaced with another element appropriate with cultural requirements. NOTE 2: Usage would be to indicate a data entry field or location (e.g., medical device input screen or implant card) or in information provided to the patient.	Other: • Patient Implant Card
	Medical device	5.7.7	Indicates the item is a medical device.	Sales Pack: • All products Sterile Pack: • All products
	Unique device identifier	5.7.10	Indicates a carrier that contains Unique Device Identifier information.	Sales Pack: • All products Sterile Pack: • All products
	Date	7000- 5662	To identify the date that information was entered or a medical procedure took place. NOTE: Usage would be to indicate a data entry field or location (e.g., medical device input screen or implant card) or in information provided to the patient.	Other: • Patient Implant Card

ISO 15223-1:2021				
Symbol	Name	Number	Definition	Where Used
	Model number	7000-6050	To identify the model number or type of product.	**Sales Pack:** • All products **Sterile Pack:** • All sterile **Other:** • Patient Implant Card
	Date of manufacture and Country of manufacture	7000-6049 Note: one combined symbol is used as permitted in IEC 60417.	To identify the country of manufacture of products. In the application of this symbol, the two letter country code defined in ISO 3166-1 is shown. In the application of this symbol, the "CC" shall be replaced by either the two letter country code or the three letter country code defined in ISO 3166-1. The date of manufacture may be added adjacent to this symbol. **NOTE:** Not all authorities with jurisdiction recognize the two letter or three letter country codes found in ISO 3166-1.	**Sales Pack:** • All products **Sterile Pack:** • All sterile
	Catalogue number	7000-2493	Indicates the manufacturer's catalogue number so that the medical device can be identified. **NOTE:** Synonyms for "catalogue number" are "reference number" and "reorder number".	

ISO 15223-1:2021				
Symbol	Name	Number	Definition	Where Used
	Sterile	7000-2499	The device is provided sterile.	Sales Pack: • All sterile Sterile Pack: • All sterile
	Sterilized using vaporized hydrogen peroxide	5.2.10	Indicates a medical device that has been sterilized using vaporized hydrogen peroxide. NOTE 1: This symbol can be used to indicate that the product has been subjected to vapour phase hydrogen peroxide processes. NOTE 2: The use of this symbol in Europe is explained in EN 556-1, clause 4.1 and the associated note.	Sales Pack: • All products if sterilized by hydrogen peroxide Sterile Pack: • All products if sterilized by hydrogen peroxide
	Sterilized using ethylene oxide	7000-2501	Indicates a medical device that has been sterilized using ethylene oxide.	Sales Pack: • All products if sterilized by ethylene oxide Sterile Pack: • All products if sterilized by ethylene oxide

ISO 15223-1:2021				
Symbol	Name	Number	Definition	Where Used
	Single sterile barrier system with protective package inside	7000-3708	Indicates a single sterile barrier system with protective packaging inside. NOTE 1: The protective packaging located inside the sterile barrier system is designed to prevent damage to the contents or to help with aseptic presentation. It does not provide a microbial barrier to maintain sterility. NOTE 2: Additional information on sterile barrier systems can be found in ISO 11607-1 and ISO 11607-2.	Sterile Pack: • All sterile
	Importer	7000-3725	Indicates the entity importing the medical device into the locale.	Sales Pack: • All products IFU: • All products
	Authorized Representative in the European Community / European Union	5.1.2	Indicates the authorized representative in the European Community / European Union. NOTE 1: This symbol is used to indicate information that is required in the European Community / European Union. NOTE 2: Additional guidance can be found in EN 1041, ISO 18113-1, ISO 18113-2, ISO 18113-3, ISO 1811-4 and ISO 18113-5. NOTE 3: If multiple symbols (i.e., Authorized Representative, Importer, Distributor, Translation, or Repackaging) identify the same responsible entity, the name and address need not be duplicated.	Sales Pack: • All products IFU: • All products

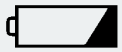
ISO 15223-1:2021				
Symbol	Name	Number	Definition	Where Used
	Swiss Authorized Representative	5.1.2	Indicates the authorized representative in Switzerland.	Sales Pack: • All products IFU: • All products
	Humidity limitation	7000-2620	Indicates the range of humidity to which the medical device can safely be exposed.	Sales Pack: • Programmer • Wand
	Non-pyrogenic	7000-2724	Indicates a medical device that is non-pyrogenic.	Sales Pack: • All implantable Sterile Pack: • All implantable
	Manufacturer	7000-3082	Indicates the medical device manufacturer. NOTE 1: This symbol is used to indicate information that is required in Europe and can be required in other authorities having jurisdiction. NOTE 2: For use in Europe the full definition of "manufacturer" is given in EU Regulations 2017/745 and 2017/746. Other jurisdictions can have unique definitions. NOTE 3: The date of manufacture, as well as the name and address of the manufacturer, can be combined in one symbol.	Sales Pack: • All products Sterile Pack: • All products IFU: • All products Other: • Patient Implant Card

ISO 7000 and IEC 60417

Includes symbols registered in ISO 7000 or IEC 60417 series and associated standards that are not also included in ISO 15223-1.

ISO 7000 and IEC 60417				
Symbol	Name	Number	Definition	Where Used
	Trash box or litter bin or rubbish bin + General prohibition sign = Do not throw away	7000-PI PF 027 + 7010-P001	To indicate a receptacle for the acceptance of trash or litter or rubbish being thrown away. + To signify a prohibited action. Not doing an action specified by the supplementary sign. = As combined per ISO 7000, a symbol to signify that user should not throw away the material.	Other: • Patient Implant Card
	Tie down point	7000-2069	To identify the location on the machine or equipment that is used to tie down or secure the machine or equipment to prevent movement during transport. [As applied, to identify the component used to tie down the lead during the implant procedure.]	Sales Pack: • Lead • Accessory Pack
	Non-standard connector cavity	7000-3067	To identify a non-standard connector cavity on the defibrillator. [As applied, to identify that the lead pin and the pulse generator cavity do not fit any connector standard.]	Sales Pack: • Generator • Lead

ISO 7000 and IEC 60417				
Symbol	Name	Number	Definition	Where Used
	Implantable device	7000-3045	To identify the implantable device. [As applied on the sales package, to identify the implantable pulse generator.] [As applied on the patient implant card to identify the implantable pulse generator or lead.]	Sales Pack: • Generator Other: • Patient Implant Card
	Packaging unit + Direction arrow = Packaging unit items follow	7000-2794 7001-PI PF 030	To indicate the number of pieces in the package. + To indicate the direction of movement of people. Only to be used in conjunction with other symbols. = As combined per ISO 7000, a symbol to signify the packaging unit items follow the symbol.	Sales Pack: • All opaque packages
	Torque wrench for implantable pulse generator	7000-3077	To identify the torque limiting wrench used to connect a lead to the implantable pulse generator.	Sales Pack: • Generator • Accessory Pack
	Open here	7000-3079	To identify the location where the package can be opened and to indicate the method of opening it.	Sterile Pack: • All sterile
	Battery, general	60417-5001B	The power supply by primary or secondary battery.	Sales Pack: • Wand (M201)
	Positioning of cell	60417-5002	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

ISO 7000 and IEC 60417				
Symbol	Name	Number	Definition	Where Used
	Stand-by	60417-5009	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 (M2000) • Programmer
	Type BF applied part	60417-5333	A type BF applied part complying with IEC 60601-1.	Device: • Wand (M2000)
	Battery Check	60417-5546	A control to check the condition of a primary or secondary battery or to identify the battery condition indicator.	Device: • Wand (M2000)
	Memory Disk	60417-5884	Cartridge type memory disks [additional memory storage provided]	Sales Pack: • SW + Computer (if separate media)
	Disc media	60417-5986	Disc media	Sales Pack: • SW + Media (alone)
	PC	60417-6234	Personal computer	Sales Pack: • Programmer
	Permanent-magnet moving-coil instrument	60417-6267	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 Magnet

Other Sources

Other Sources				
Symbol	Name	Source	Definition	Where Used
RxOnly ℞	Prescription Statement	21 CFR 801.109(c)	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
	WEEE	EN 50419	Do not dispose to unsorted municipal waste	Sales Pack: • Wand • Programmer Device: • Wand (M2000)
CE	CE Mark	European Directives and Regulations on Medical Devices	Indicates conformity with the essential health and safety requirements set out in European Directives. Depending on classification of product, may be required to be accompanied by Notified Body number. On IFUs, may be used with year unless information provided another way.	Sales Pack: • All commercial products Sterile Pack: • All commercial products IFU: • All commercial products

Other Sources				
Symbol	Name	Source	Definition	Where Used
	MR Conditional	ASTM F2503–20	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 • Lead **Other:** • Patient Implant Card
	MR Unsafe	ASTM F2503–20	ASTM Recommended Icon Associated with the MR UNSAFE ASTM Term	**Sales Pack:** • Wand • Programmer • Patient Magnet **Device:** • Wand (M2000)
	China RoHS	SJ/T 11364-2014	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 (M201)
	China RoHS	SJ/T 11364-2014	Indicates that this electronic and electrical product does not contain any hazardous substances and is a green environmentally friendly product, which can be recycled after being discarded and should not be casually discarded.	**Sales Pack:** • Wand (M2000) **Device:** • Wand (M2000)

Other Sources				
Symbol	Name	Source	Definition	Where Used
GMDN: 34210	Antiseizure / psychiatric-therapy vagus nerve electrical stimulation system	Global Medical Device Nomenclature (GMDN) Database	An assembly of battery-powered sterile devices intended to apply periodic electrical stimuli to the vagus nerve to help control seizures and/or to help treat psychiatric disorder symptoms (e.g., depression). The vagus nerve stimulation (VNS) is provided through a pulse generator, typically implanted in the anterior chest wall, and leads that run subcutaneously to where their electrodes are implanted around the left vagus nerve. The system may be programmed externally following implantation.	Sales Pack: • Generator (VNS Therapy) • Accessory Pack Sterile Pack: • Generator (VNS Therapy) • Accessory Pack
GMDN: 44077	Vagus nerve electrical stimulation system programmer	Global Medical Device Nomenclature (GMDN) Database	A device intended to be used to change, noninvasively, one or more of the operating parameters (the programs) of an implanted stimulator used for vagus nerve stimulation (VNS). It is able to read stored parameters in the implanted device, providing historic and/or current information regarding device performance. The device is typically an electronic wand with a communication antenna that connects to the port of a personal computer (PC) with dedicated software. The PC will then drive the electronics of the wand to communicate with the implanted stimulation system.	Sales Pack: • Programmer • Wand
GMDN: 44041	Vagus nerve electrical stimulation system	Global Medical Device Nomenclature (GMDN) Database	An implantable wire, insulated with non-conductive material except at its electrode(s), intended to be used to make an electrical connection between a pulse generator and the vagus nerve for vagus nerve stimulation (VNS).	Sales Pack: • Lead Sterile Pack: • Lead

Other Sources				
Symbol	Name	Source	Definition	Where Used
GMDN: 35950	Vascular graft tunneller	Global Medical Device Nomenclature (GMDN) Database	A long, surgical instrument used to tunnel an artificial passageway along vascular tissue planes to create a connecting channel typically for the introduction of a vascular graft or a vascular prosthesis. It can have a variety of designs, but basically it will be a long, round, stiff rod that tapers to a rounded point at the distal tip and have a handle at the proximal end to allow the surgeon to exert the necessary pressure and manipulation to push it through the body tissue. It will typically be made of high-grade stainless steel and possibly other materials for the handle, which may be detachable. This is a reusable device.	Sales Pack: • Tunneler Sterile Pack: • Tunneler
GMDN: 57996	Implantable stimulator control magnet	Global Medical Device Nomenclature (GMDN) Database	A hand-operated, non-sterile, magnetic device designed to be used by a patient to switch an implanted stimulator (e.g., a neurostimulator that can be controlled by a strong external magnetic force) on and off. It typically consists of a small portable magnet (e.g., strontium ferrite) coated with an epoxy that can be carried in the pocket or a handbag (purse) of a patient for convenient access. It is placed by the patient against the skin directly over the site of the implanted stimulator and turned as prescribed by the manufacturer to affect the stimulator. This is a reusable device.	Sales Pack: • Patient Magnet

Other Sources				
Symbol	Name	Source	Definition	Where Used
GMDN: 60824	Cardiac-therapy vagus nerve electrical stimulation system	Global Medical Device Nomenclature (GMDN) Database	An assembly of battery-powered, sterile devices designed to apply periodic stimuli to the vagus nerve as a treatment for cardiac failure. Vagus nerve stimulation (VNS) is provided through a pulse generator, typically implanted in the anterior chest wall, and a lead that runs subcutaneously to an electrode around the right and/or left vagus nerve. It may have an intracardiac sensing electrode implanted into a ventricle of the heart to serve as a heart rate sensor for feedback control of nerve stimulation.	Sales Pack: • Generator (Autonomic Regulation Therapy) Sterile Pack: • Generator (Autonomic Regulation Therapy)
EMDN: J020301	Implantable Pulse Generators	European Medical Device Nomenclature (EMDN) Database	Drug-resistant epilepsy non-surgical therapy implantable neurostimulators	Sales Pack: • Generator (VNS Therapy Epilepsy) Sterile Pack: • Generator (VNS Therapy Epilepsy) Other: • Patient Implant Card

Other Sources				
Symbol	Name	Source	Definition	Where Used
EMDN: J020302	Leads	European Medical Device Nomenclature (EMDN) Database	Vagal neurostimulation leads	Sales Pack: • Lead Sterile Pack: • Lead Other: • Patient Implant Card
EMDN: J020380	Accessory Pack Patient Magnet	European Medical Device Nomenclature (EMDN) Database	Vagal implantable neurostimulators - accessories	Sales Pack: • Accessory Pack • Patient Magnet Sterile Pack: • Accessory Pack
EMDN: J020399	Implantable Pulse Generators - Other	European Medical Device Nomenclature (EMDN) Database	Vagal implantable neurostimulators - other	Sales Pack: • Generator (VNS Therapy Depression) Sterile Pack: • Generator (VNS Therapy Depression) Other: • Patient Implant Card

Other Sources				
Symbol	Name	Source	Definition	Where Used
EMDN: J020701	Wand and Software	European Medical Device Nomenclature (EMDN) Database	Neurostimulator programmers	Sales Pack: • Programmer • Wand
EMDN: N02800208	Tunneler	European Medical Device Nomenclature (EMDN) Database	Tunnelers, single-use	Sales Pack: • Tunneler Sterile Pack: • Tunneler

Contacts and Resources

For information and support in use of the system or any of its accessories, contact LivaNova.

Contacts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Regulatory Authority Websites

Report all adverse events related to the device to LivaNova and to your local regulatory authority.

US	https://www.fda.gov
Australia	https://www.tga.gov.au/
Canada	https://www.canada.ca/en/health-canada.html
UK	https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency
EU	https://ec.europa.eu/growth/sectors/medical-devices/contacts_en