


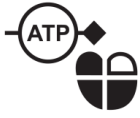




















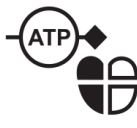

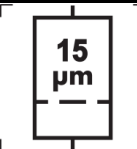


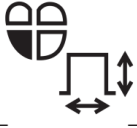












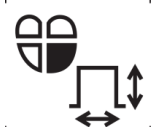


Glossary of Symbols Used in Device Labeling












ISO 15223-1 (www.iso.org)




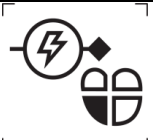

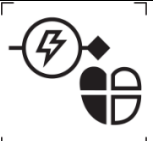





SYMBOL	TITLE/MEANING	Function/Description	REG DATE
	Anti-tachycardia pacing, right ventricular	To indicate the availability of right ventricular anti-tachycardia pacing.	5/9/2011
	Biological risks	To indicate a reference to substances that may be hazardous to men, animals, plants, or the environment based on biological activity (for example, holding a virus).	1/15/2004
	Temperature limit	To indicate the maximum and minimum temperature limits at which the item shall be stored, transported or used.	6/4/2014
	Anti-tachycardia pacing (right atrial, right ventricular, left ventricular)	To indicate the availability of right atrial and ventricular and left ventricular anti-tachycardia pacing.	5/9/2011
	Protect from heat and radioactive sources	On packaging. To indicate that the contents of the package may deteriorate or be rendered totally unusable by heat or ionizing radiation and must be protected from these.	1/15/2004
	Operator's manual; operating instructions	To identify the location where the operator's manual is stored or to identify information that relates to the operating instructions. To indicate that the operating instructions should be considered when operating the device or control close to where the symbol is placed.	1/15/2004
	Refractory period, post ventricular	To indicate the shipping parameters for post ventricular atrial refractory period.	5/9/2011
	Atmospheric pressure limitation	To indicate the acceptable upper and lower limits of atmospheric pressure for transport and storage.	1/15/2004
	Single pole high voltage connector cavity for defibrillator	To identify a single pole high voltage (DF-1) connector cavity on the defibrillator.	5/9/2011
	Negative control	To identify material that is used as a negative control to be part of the quality control procedure, for example on an in vitro diagnostic device or the corresponding packaging.	1/15/2004












SYMBOL	TITLE/MEANING	Function/Description	REG DATE
	Non-standard connector cavity	To identify a non-standard connector cavity on the defibrillator.	5/9/2011
	Drops per milliliter	On medical devices: to indicate the number of drops per milliliter. That means the design of the drip tube in the drip chamber of the system.	9/8/2005
	Do not use if package is damaged	To indicate that the device must not be used if the package holding the device is damaged, for example on packaging of medical devices.	1/15/2004
	Defibrillation	To indicate the availability of the tachyarrhythmia therapy defibrillation.	5/9/2011
	One-way valve	On medical devices: to indicate a product with check valve in the fluid path (one way only). For the user it is important to know that the administration is only possible one way. No possibility in aspiration or withdrawal of solution.	9/8/2005
	Vein lifter	To identify the vein lifter instrument used in medical device implantation.	5/9/2011
	Non-pyrogenic	On medical devices: to indicate that the product is non-pyrogenic.	9/8/2005
	Patient number	To identify 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.	1/15/2004
	Humidity limitation	To indicate the acceptable upper and lower limits of relative humidity for transport and storage.	1/15/2004
	Four pole high voltage connector cavity for defibrillator	To identify a four pole high voltage (DF-4) connector cavity on the defibrillator.	5/9/2011
	In vitro diagnostic (IVD) device for performance evaluation	To identify an IVD device that is intended to be used only for evaluating its performance characteristics before it is placed on the market for medical diagnostic use.	10/2/2011




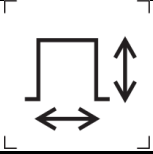


SYMBOL	TITLE/MEANING	Function/Description	REG DATE
	Sterile fluid path	To identify the presence of a sterile fluid path within the medical device when other parts of the medical device are not necessarily supplied sterile.	10/5/2011
	Non-sterile	To indicate that the device that is normally provided sterile in the same or similar packaging has not been sterilized.	1/15/2004
	Open here	To identify the location where the package can be opened and to indicate the method of opening it.	5/9/2011
	Anti-tachycardia pacing, right atrial and right ventricular	To indicate the availability of right atrial and ventricular anti-tachycardia pacing.	5/9/2011
	Anti-tachycardia pacing, left ventricular	To indicate the availability of left ventricular anti-tachycardia pacing.	5/9/2011
	Liquid filter with pore size	On medical devices: to indicate that the infusion or transfusion system contains a liquid filter in various sizes.	9/8/2005
	Sterilized using steam or dry heat	To indicate that the device is provided sterile and has been sterilized using steam or dry heat.	1/15/2004
	Catalogue number	To identify the manufacturer's catalogue number, for example on a medical device or the corresponding packaging. The catalogue number shall be placed adjacent to the symbol.	1/15/2004
	Amplitude and pulse width, right ventricular	To indicate the shipping parameters for right ventricular amplitude and pulse width.	5/9/2011
	Lower limit of temperature	To identify the minimum temperature limit. The temperature value may be shown adjacent to the symbol.	1/15/2004
	Minimum tracking rate	To indicate the shipping parameters for minimum tracking rate.	5/9/2011

SYMBOL	TITLE/MEANING	Function/Description	REG DATE
	Sterilized using ethylene oxide	To indicate that the device is provided sterile and has been sterilized using ethylene oxide.	1/15/2004
	Keep away from sunlight	To indicate that transport package shall not be exposed to sunlight.	6/4/2014
	Sensitivity	To indicate the shipping parameter for sensitivity.	5/9/2011
	Refractory period, right atrial	To indicate the shipping parameters for atrial refractory period.	5/9/2011
	Implantable device, coated	To indicate a reference to an active coated implantable device.	5/9/2011
	Cardiac resynchronization therapy pacemaker, right atrial, right ventricular, left ventricular	To identify an implantable pacemaker that is intended to stimulate and sense in the right atrium, right ventricle and the left ventricle of the heart.	5/9/2011
	Sensitivity, right ventricular	To indicate the shipping parameters for right ventricular sensitivity.	5/9/2011
	Header face	To identify the header face for connector bore locations on the implantable pulse generator.	5/9/2011
	Amplitude and pulse width, left ventricular	To indicate the shipping parameters for left ventricular amplitude and pulse width.	5/9/2011
	Refractory period	To indicate the shipping parameters for refractory period.	5/9/2011
	Atrial to ventricular interval, paced and sensed	To indicate the shipping parameters for paced and sensed atrial to ventricular interval.	5/9/2011

SYMBOL	TITLE/MEANING	Function/Description	REG DATE
	Sensed atrial to ventricular interval	To indicate the shipping parameters for sensed atrial to ventricular interval.	5/9/2011
	Caution	To indicate that caution is necessary when operating the device or control close to where the symbol is placed. To indicate that the current situation needs operator awareness or operator action in order to avoid undesirable consequences. On the health app quality label: to indicate that the health app requires approval from a health professional for	1/15/2004
	Fluid path	On medical devices: to indicate the flow path for fluids.	9/8/2005
	Implantable cardioverter defibrillator, single chamber, right ventricular	To identify an implantable cardioverter defibrillator that is intended to stimulate and sense in the right ventricle and to shock the heart.	5/9/2011
	Amplitude and pulse width, right atrial	To indicate the shipping parameters for right atrial amplitude and pulse width.	5/9/2011
	Upper limit of temperature	To identify the maximum temperature limit. The temperature value may be shown adjacent to the symbol.	1/15/2004
	Implantable device	To identify the implantable device.	5/9/2011
	Do not resterilize	To indicate that the device should not be re-sterilized after it once has been sterilized.	1/15/2004
	Refractory period, right ventricular	To indicate the shipping parameters for ventricular refractory period.	5/9/2011
	Pacemaker, dual chamber, right atrial, right ventricular	To identify an implantable pacemaker that is intended to stimulate and sense in both the right atrium and right ventricle of the heart.	5/9/2011
	Manufacturer	To identify the manufacturer of a product. On the health app quality label: to identify the manufacturer of the health app.	10/2/2011

SYMBOL	TITLE/MEANING	Function/Description	REG DATE
	Sterilized using aseptic processing techniques	To indicate that the device is provided sterile and has been sterilized using aseptic processing techniques.	1/15/2004
	Sterile	To indicate that the device is provided sterile.	1/15/2004
	Single pole low voltage connector cavity for pacemaker and defibrillator	To identify a single pole low voltage (IS-1) connector cavity on the defibrillator.	5/9/2011
	Ventricular cardioversion	To indicate the availability of the tachyarrhythmia therapy ventricular cardioversion.	5/9/2011
	Pacemaker, single chamber, right atrial	To identify an implantable pacemaker that is intended to stimulate and sense in the right atrium of the heart	5/9/2011
	Atrial or ventricular cardioversion	To indicate the availability of the tachyarrhythmia therapy atrial or ventricular cardioversion.	5/9/2011
	Batch code	To identify the manufacturer's batch or lot code, for example on a medical device or the corresponding packaging. The code shall be placed adjacent to the symbol.	1/15/2004
	Sensitivity, right atrial	To indicate the shipping parameters for right atrial sensitivity.	5/9/2011
	Keep away from rain	To indicate that the transport package shall be kept away from rain and in dry conditions.	6/4/2014
	Anti-tachycardia pacing, right atrial	To indicate the availability of right atrial anti-tachycardia pacing.	5/9/2011
	Positive control	To identify material that is used as a positive control to be part of the quality control procedure, for example on an in vitro diagnostic device or the corresponding packaging.	1/15/2004

SYMBOL	TITLE/MEANING	Function/Description	REG DATE
	Sampling site	On medical devices or blood process application: to indicate that the device or process application includes a system dedicated to the collection of samples of a given substance stored in this medical device or blood container.	9/8/2005
	Use by date	To indicate that the device should not be used after the date accompanying the symbol, for example on a medical device or its packaging.	1/15/2004
	Legacy connector cavity	To identify a legacy connector cavity on the defibrillator.	5/9/2011
	Contains or presence of	On medical devices: to indicate that the equipment contains the identified product or substance.	9/8/2005
	Torque wrench for implantable pulse generator	To identify the torque limiting wrench used to connect a lead to the implantable pulse generator.	5/9/2011
	Maximum tracking rate and minimum rate	To identify the shipping parameters for maximum tracking rate and minimum rate.	5/9/2011
	Four pole low voltage connector cavity for pacemaker and defibrillator	To identify a four pole low voltage (IS-4) connector cavity on the defibrillator.	5/9/2011
	Do not re-use	To indicate that the item is for single use only and must not be used more than once, for example on packages of medical disposables.	1/15/2004
	Serial number	To identify the manufacturer's serial number, for example on a medical device or its packaging. The serial number shall be placed adjacent to the symbol.	1/15/2004
	Fragile; handle with care	To indicate that the contents of the transport package are fragile and the package shall be handled with care.	6/4/2014
	Counting	To indicate a counter or meter (for example, on operating controls of units).	1/15/2004

SYMBOL	TITLE/MEANING	Function/Description	REG DATE
	Pacemaker, single chamber, right ventricular	To identify the implantable pacemaker that is intended to stimulate and sense in the right ventricle of the heart	5/9/2011
	Date of manufacture	To indicate the date on which a product was manufactured.	1/15/2004
	Sterilized using irradiation	To indicate that the device is provided sterile and has been sterilized using irradiation.	1/15/2004
	Amplitude and pulse width, general	To indicate the general shipping parameters for amplitude and pulse width.	5/9/2011
	Implantable cardioverter defibrillator, dual chamber, right atrial, right ventricular	To identify an implantable cardioverter defibrillator that is intended to stimulate and sense in the right atrium and right ventricle and to shock the heart.	5/9/2011
	Cardiac resynchronization therapy defibrillator, right atrial, right ventricular, left ventricular	To identify an implantable cardioverter defibrillator that is intended to stimulate and sense in the right atrium, right ventricle and left ventricle; and to shock the heart.	1/0/1900