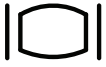
BS EN ISO 15223-1: 2012 Medical devices—Symbols to be used with medical device labels, labeling and information to be supplied. Part 1: General requirements				
Symbol	**Symbol Ref. No.**	**Symbol Title**	**Additional Information**	**ISO 7000 Reg. No.**
	5.1.1	Manufacturer	The date of manufacture, as well as the name and address of the manufacturer, can be combined in one symbol.	3082
	5.1.2	Authorized representative in the European Community		
	5.1.3	Date of manufacture	This symbol can be filled or unfilled. If filled, the date of manufacture as well as the name and address of the manufacturer can be combined in one symbol.	2497
	5.1.4	Use-by date	Synonym for "use-by date" is "use by."	2507
	5.1.5	Batch code	Synonyms for "batch code" are "lot number" and "batch number."	2492
	5.1.6	Catalogue number	Synonyms for "catalogue number" are "reference number" and "reorder number."	2493
	5.1.7	Serial number		2498
	5.2.3	Sterilized using ethylene oxide		2501
	5.2.4	Sterilized using irradiation		2502
	5.2.6	Do not resterilize		2508
	5.2.8	Do not use if package is damaged	This symbol may also mean "Do not use if the product sterile barrier system or its packaging is compromised."	2506
	5.3.1	Fragile, handle with care		0621
	5.3.4	Keep dry		0626

BS EN ISO 15223-1: 2012 Medical devices—Symbols to be used with medical device labels, labeling and information to be supplied. Part 1: General requirements				
Symbol	**Symbol Ref. No.**	**Symbol Title**	**Additional Information**	**ISO 7000 Reg. No.**
	5.3.7	Temperature limit		0632
	5.3.8	Humidity limitation		2620
	5.3.9	Atmospheric pressure limitation		2621
	5.4.2	Do not re-use	Synonyms for "Do not re-use" are "single use" and "use only once."	1051
	5.4.3	Consult instructions for use	Synonym for "Consult instructions for use" is "Consult operating instructions."	1641
	5.4.4	Caution	This symbol is essentially a cautionary symbol and should be used to highlight the fact that there are specific warnings or precautions associated with the medical device, which are not otherwise found on the label.	0434A
	5.4.5	Contains or presence of natural rubber latex		
	5.6.3	Non-pyrogenic		2724

IEC TR 60878 Ed. 3.0 b:2015 Graphical symbols for electrical equipment in medical practice				
Symbol	**Symbol Ref. No.**	**Symbol Title**	**Additional Information**	**Additional References**
	5007	"ON" (power)	To indicate connection to the mains, at least for mains switches, or their positions, and all those cases where safety is involved.	IEC 60417-5007 (2002-10)
	5008	"OFF" (power)	To indicate disconnection from the mains, at least for main switches, or their positions, and all those cases where safety is involved.	IEC 60417-5008 (2002-10)
	5010	"ON"/"OFF" (push-push)	To indicate connection to or disconnection from the mains, at least for mains switches or their positions, and all those cases where safety is involved. Each position, "ON" or "OFF", is a stable position	IEC 60417-5010 (2002-10)
	5032	Alternating current	To indicate on the rating plate that the equipment is suitable for alternating current only; to identify relevant terminals.	IEC 60417-5032 (2002-10)
	5019	Protective earth; protective ground	To identify any terminal which is intended for connection to an external conductor for protection against electric shock in case of fault, or the terminal of a protective earth (ground) electrode.	IEC 60417-5019 (2006-08)
	5021	Equipotentiality	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 60417-5021 (2002-10)
	5031	Direct current	To indicate on the rating plate that the equipment is suitable for direct current only; to identify relevant terminals.	IEC 60417-5031 (2002-10)
	5051	Television monitor	To identify the terminals and controls for a television monitor.	IEC 60417-5051 (2002-10)
	5140	Non-ionizing electromagnetic radiation	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 60417-5140 (2003-04)
	2794	Packaging unit	To indicate the number of pieces in the package. *Note – A number is inserted in the symbol to indicate the number of parts in the package.*	ISO 7000-2794 (2009-02)
	5172	Class II equipment	To identify equipment meetings the safety requirements specified for Class II equipment according to IEC 61140.	IEC 60417-5172 (2003-02)
	5335	Type CF applied part	To identify a type CF part complying with IEC 60601-1. *Note 1 – C = Cardial.* *Note 2 – F = Floating applied part.*	IEC 60417-5335 (2002-10)

IEC TR 60878 Ed. 3.0 b:2015 Graphical symbols for electrical equipment in medical practice				
Symbol	**Symbol Ref. No.**	**Symbol Title**	**Additional Information**	**Additional References**
	5336	Defibrillation-proof type CF applied part	To identify a defibrillation-proof CF applied part complying with IEC 60601-1. *Note 1 – C = Cardial.* *Note 2 – F = Floating applied part.*	IEC 60417-5336 (2002-10)
	5569	Locking, general	To identify on a control that a function is locked or to show the locked status.	IEC 60417-5569 (2005-05)
	5570	Unlocking	To identify on a control that is a function is not locked or to show the unlocked status.	IEC 60417-5570 (2002-10)
	5998	Computer network	To identify the computer network itself or to indicate the connecting terminals of the computer network.	IEC 60417-5988 (2006-09)
	ISO 7010-M002 (2011-06)	Refer to instruction manual/booklet	To signify that the instruction manual/booklet must be read.	IEC 60601-1 (2005+A1:2012
	ISO 7010-P001 (2011-06)	General prohibition sign	Template for constructing a prohibition sign. *Note - This safety sign cannot be used on its own and requires a supplementary sign to give further information about the action which is prohibited.*	ISO 3864-1 Fig. 1
	ISO-7010-P010 (2011-06)	Do not touch	To prohibit touching objects/parts of an object.	
	ISO 7010-P017 (2011-06)	No pushing	To prohibit pushing on an object.	
	ISO 7010-W001 (2011-06)	General warning sign	To signify a general warning. *Note - This safety sign cannot be used on its own and requires a supplementary sign to give further information about the hazard.* *IEC TR 60878 note: On medical equipment, this safety sign shall only be used if there is no other safety sign for the corresponding hazard. If possible, the hazard or the appropriate precaution should be indicated.*	
	ISO 7010-W005 (2011-06)	Warning: Non-ionizing radiation	To warn of non-ionizing radiation.	
	ISO 7010-W012 (2011-06)	Warning: electricity	To warn of electricity.	

IEC TR 60878 Ed. 3.0 b:2015 Graphical symbols for electrical equipment in medical practice				
Symbol	**Symbol Ref. No.**	**Symbol Title**	**Additional Information**	**Additional References**
	ISO 7010-W024 (2011-06)	Warning: crushing of hands	To warn of a closing motion of mechanical parts of equipment.	

IS EN 15986: 2011 Symbol for use in the labeling of medical devices – Requirements for labeling of medical devices containing phthalates		
Symbol	**Symbol Title**	**Additional Information**
	Contains or presence of phthalate: bis (2-ethylhexyl) phthalate (DEHP)	This symbol is derived from ISO 7000-2725 (“Contains or presence of”).

IS EN 50419:2006 Marking of electrical and electronic equipment in accordance with Article 11(2) of Directive 2002/96/EC (WEEE)		
Symbol	**Symbol Title**	**Additional Information**
	WEEE wheeled bin	This product contains electrical and electronic components that may contain materials which, if disposed with general waste, could be damaging to the environment. Residents of the European Union must follow specific disposal or recycling instructions for this product. Residents outside the European Union must dispose or recycle this product in accordance with local laws or regulations that apply.

IEC 60529:1989+A1:1999 Degrees of protection provided by enclosures (IP Code)	
Symbol	**Additional Information**
IPX0	No protection of equipment against ingress of water with harmful side effects (non-protected).
IP21	Protection of equipment against ingress of solid foreign objects ≥ 12.5 mm diameter. Protection against access to hazardous parts with a finger. Protection against vertically falling water drops when equipment is tilted up to 15°.

Other Marks and Symbols		
Symbol	**Symbol Description**	**Additional Information**
	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.	USA Code of Federal Regulations 21 CFR Part 801 § 801.109(b)(1)
	European Conformity mark Notified Bodies: BSI Group (0086) SGS SA (0120)	The product conforms to European Medical Directive 93/42/EEC and meets applicable health, safety and environmental requirements. If the mark is accompanied by a number, conformity is verified by the indicated notified body.
	C-UL US Classification mark	Underwriters Laboratories classification mark that indicates compliance with both Canadian and USA requirements. The ACIST CVi® Contrast Delivery System and RXi™ Rapid Exchange FFR System are UL Classified as to electrical shock, fire, mechanical, and other specified hazards, only in accordance with IEC 60601-1, second and third editions.
	UL-BR mark	National Institute of Metrology, Standardization and Industrial Quality (Brazil) and Underwriters Laboratories Brazil classification mark that indicates compliance with Brazilian standards.
	ETL Product Listing mark	Represents compliance to North American product safety standards as determined through independent testing and certification by Intertek Group plc. The ACIST HDi® IVUS System conforms to ANSI/AAMI STD ES60601-1, IEC STDS 60601-2-18 and 60601-2-37. Certified to CSA STD C22.2 No. 60601-1.
	Universal serial bus (USB) port	USB Implementors Forum, Inc. standard icon

Symbols Unique to ACIST Medical, Inc.			
Symbol	**Symbol Description**	**Where Symbol Appears**	**Additional Information**
	Quantity	All products	
	Stock Keeping Unit	CVi® Contrast Delivery System disposables	A product identification code.
	Contact for service	CVi® Contrast Delivery System	Based on ISO 7000:0717 (2004-01)
	Do not tip	CVi® Contrast Delivery System	
	No syringe	CVi® Contrast Delivery System	
	Warning: explosive material	CVi® Contrast Delivery System	Based on ISO 7010-W002 (2011-06).
	On/Off (push/push)	HDi® IVUS System console	Based on IEC 60417-5009 (2002-10)
	PIM port	HDi® IVUS System console	
	LTS port	HDi® IVUS System console	
	Increase brightness	HDi® IVUS System console	Based on symbol 5056 from IS EN 60417-1:2002. Graphical symbols for use on equipment. Part 1: Overview and application (IEC 60417-1:2000) Brightness; brilliance. To identify the brightness control, for example of a light dimmer, a television receiver, a monitor, an oscilloscope.
	Decrease brightness	HDi® IVUS System console	Based on symbol 5056 from IS EN 60417-1:2002. Graphical symbols for use on equipment. Part 1: Overview and application (IEC 60417-1:2000) Brightness; brilliance. To identify the brightness control, for example of a light dimmer, a television receiver, a monitor, an oscilloscope.

Symbols Unique to ACIST Medical, Inc.			
Symbol	**Symbol Description**	**Where Symbol Appears**	**Additional Information**
	Start/Stop imaging	HDi® IVUS System PIM	Based on symbol 5709 from IEC TR 60878 Ed. 3.0 b:2015. Graphical symbols for electrical equipment in medical practice. Probe for sector-shaped sound field. To identify the control or the indicator to activate an ultrasound probe for the generation of a sector-shaped sound field and to identify the corresponding connector. (IEC 60417-5709 [2002-10])
	Start/Stop recording	HDi® IVUS System PIM	
	Telescope anchor orientation	Kodama® Coronary Imaging Catheter sterile bag	
	PIM and LTS orientation	HDi® IVUS System LTS	
	Pull the console forward only when the bed rail mount arm is in the up position.	HDi® IVUS System bed rail mount	
	Do not pull console forward when the bed rail mount arm is in the down position.	HDi® IVUS System bed rail mount	
	Do not insert finger into sterile bag attachment	Kodama® Coronary Imaging Catheter sterile bag	
	Peel off corner	Navvus® Catheter	
	Connector #1 for the BNC connector on the RXi Ao input cable	RXi™ Ao Interface Box	
	Connector #2 for the cath lab invasive blood pressure transducer cable	RXi™ Ao Interface Box	
	Connector #3 for hemo system cable	RXi™ Ao Interface Box	