













## GLOSSARY OF SYMBOLS








The present document lists and explains the symbols that can be found on Stago reagents, analyzers and IVD accessories.

Symbol	Meaning
General IVD symbols	
	<p>Indicates the conformity of the medical device with the provisions of this Directive to enable it to move freely within the Community and to be put into service in accordance with its intended purpose.</p> <p>Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices</p>
	<p><i>In vitro</i> diagnostic medical device</p> <p>Indicates a medical device that is intended to be used as an <i>in vitro</i> diagnostic medical device.</p> <p>NF EN ISO 15223-1, symbol #5.5.1</p>
	<p>Caution: Federal law restricts this device to sale by or on the order of a physician.</p> <p>21 CFR PART 809 - In vitro diagnostic products for human use</p>
	<p>Manufacturer</p> <p>Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.</p> <p>NF EN ISO 15223-1, symbol #5.1.1</p>
	<p>Date of manufacture</p> <p>Indicates the date when the medical device was manufactured.</p> <p>NF EN ISO 15223-1, symbol #5.1.3</p>
	<p>Use-by date</p> <p>Indicates the date after which the medical device is not to be used.</p> <p>NF EN ISO 15223-1, symbol #5.1.4</p>
	<p>Batch code</p> <p>Indicates the manufacturer's batch code so that the batch or lot can be identified.</p> <p>NF EN ISO 15223-1, symbol #5.1.5</p>













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Symbol	Meaning
General IVD symbols	
	<p>Catalogue number</p> <p>Indicates the manufacturer's catalogue number so that the medical device can be identified.</p> <p>NF EN ISO 15223-1, symbol #5.1.6</p>
	<p>Serial number</p> <p>Indicates the manufacturer's serial number so that a specific medical device can be identified.</p> <p>NF EN ISO 15223-1, symbol #5.1.7</p>
	<p>Consult instructions for use</p> <p>Indicates the need for the user to consult the instructions for use.</p> <p>NF EN ISO 15223-1, symbol #5.4.3</p>
	<p>Contains sufficient for &lt;n&gt; tests</p> <p>Indicates the total number of IVD tests that can be performed with the IVD.</p> <p>NF EN ISO 15223-1, symbol #5.5.5</p>
	<p>For IVD performance evaluation only</p> <p>Indicates an IVD medical device that is intended to be used only for evaluating its performance characteristics before it is placed on the market for medical diagnostic use.</p> <p>NF EN ISO 15223-1, symbol #5.5.6</p>







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Symbol	Meaning
Safety	
	<p>Biological risks</p> <p>Indicates that there are potential biological risks associated with the medical device.</p> <p>NF EN ISO 15223-1, symbol #5.4.1</p>
	<p>Biological risks (used on analyzers)</p> <p>Indicates that there are potential biological risks.</p> <p>IEC 61010-2-081</p>
	<p>Caution</p> <p>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.</p> <p><i>Sometimes used with a yellow background.</i></p> <p>NF EN ISO 15223-1, symbol #5.4.4</p>
	<p>Keep away from magnetic fields</p>
	<p>Warning; Magnetic field</p> <p>ISO 7000 DB, symbol #W006</p>
	<p>Do not re-use</p> <p>Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.</p> <p>NF EN ISO 15223-1, symbol #5.4.2</p>
	<p>Caution, possibility of electric shock</p> <p><i>Sometimes used with a yellow background.</i></p> <p>IEC 61010-1, symbol #12</p>

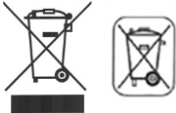



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Symbol	Meaning
Safety	
	<p>PROTECTIVE CONDUCTOR TERMINAL</p> <p><i>Sometimes used with a yellow background.</i></p> <p>IEC 61010-1, symbol #6</p>
	<p>Earth (ground) TERMINAL</p> <p>IEC 61010-1, symbol #5</p>
	<p>Caution, hot surface</p> <p><i>Sometimes used with a yellow background.</i></p> <p>IEC 61010-1, symbol #13</p>
	<p>On (Power)</p> <p>IEC 61010-1, symbol #9</p>
	<p>Off (Power)</p> <p>IEC 61010-1, symbol #10</p>
	<p>On/Off</p>
	<p>Direct current</p> <p>IEC 61010-1, symbol #1</p>
	<p>Alternating current</p> <p>IEC 61010-1, symbol #2</p>
	<p>Do not introduce hands</p>
	<p>Compliance to UL safety certification.</p>
	<p>Compliance to CSA safety certification.</p>
	<p>Warning; Laser beam</p> <p>ISO 7000 DB, symbol #W004</p>



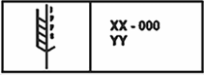






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Symbol	Meaning
Safety	
	Do not stare into beam
	Wear protective gloves. ISO 7000 DB, symbol #M009
	Protective gloves mandatory
	Goggles mandatory
	Maximum altitude. ISO 7000 DB, symbol #6343
	Do not use in tropical climate areas.




**NOTE:** CLP/GHS hazardous pictograms are presented in reagent labeling and safety data sheet.

Symbol	Meaning
Packages and boxes	
	Separate collection: do not discard with other waste.  For additional information about the disposal procedure, see Warnings chapter of the Reference Manual.  Directive 2012/19/EU (WEEE recast)
	Compliance with Chinese standard SJ/T 11364
	Stacking limit number. NF EN ISO 780, symbol #16
	Do not stack NF EN ISO 780, symbol #17




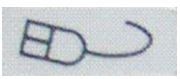


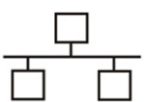
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Symbol	Meaning
Packages and boxes	
	This way up NF EN ISO 780, symbol #13
	Natural wood
	Compliance to International Standards for Phytosanitary Measures 15 – Regulation of wood packaging material in international trade
	Recyclable corrugated cardboard.
	Recycling ISO 7000 DB, symbol #1135
	Keep away from sunlight Indicates a medical device that needs protection from light sources. NF EN ISO 15223-1, symbol #5.3.2
	Keep dry Indicates a medical device that needs to be protected from moisture. NF EN ISO 15223-1, symbol #5.3.4
	Humidity limitation Indicates the range of humidity to which the medical device can be safely exposed. NF EN ISO 15223-1, symbol #5.3.8
	Fragile, handle with care Indicates a medical device that can be broken or damaged if not handled carefully. NF EN ISO 15223-1, symbol #5.3.1

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Symbol	Meaning
Packages and boxes	
	<p>Temperature limit</p> <p>Indicates the temperature limits to which the medical device can be safely exposed.</p> <p>NF EN ISO 15223-1, symbol #5.3.7</p>
	<p>Atmospheric pressure limitation</p> <p>Indicates the range of atmospheric pressure to which the medical device can be safely exposed.</p> <p>NF EN ISO 15223-1, symbol #5.3.9</p>
	<p>Direction of rotation of the cuvette roll reel</p>

## Other symbols

Symbol	Meaning
Connection pictograms	
	<p>Touchscreen connection</p>
	<p>Monitor connection</p>
	<p>Keyboard connection</p>
	<p>Mouse connection</p>
	<p>Server (host computer) connection</p>
	<p>USB port</p>
	<p>Network connection</p>

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Symbol	Meaning
Fluidic pictograms	
	Cooling liquid
	Cleaning solution
	Used liquid container



### **Bibliography**

- NF EN ISO 15223-1 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: general requirements
- ISO 7000 DB (ex: ISO 7000) Graphical symbols for use on equipment – Registered symbols
- IEC 61010-1 Safety requirements for electrical equipment for measurement, control and laboratory use - Part 1: General Requirements
- IEC 61010-2-081 Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2- 081: particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes
- NF EN ISO 780 Packaging - Distribution packaging - Graphical symbols for handling and storage of packages
- ISPM 15 - International Standards for Phytosanitary Measures 15 – Regulation of wood packaging material in international trade
- Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices
- Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE)
- 21 CFR PART 809 - In vitro diagnostic products for human use
- SJ/T 11364 People's Republic of China Electronic Industry Standard - Marking for the restricted use of hazardous substances In electronic and electrical products

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Date*	Reference	Version	Modifications
2021-02-19	520233	/	Creation.
2021-11-16	520233-A	/	Title "Environment, packages and boxes pictograms" changed to "Packages and boxes"  Addition of symbols "Protective gloves mandatory", "Goggles mandatory", "Atmospheric pressure limitation", "Direction of rotation of the cuvette roll reel".

\* YYYY-MM-DD