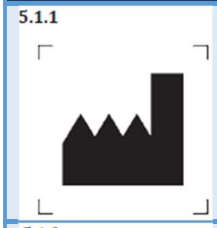
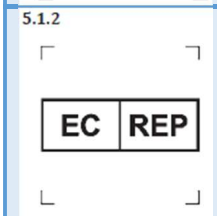
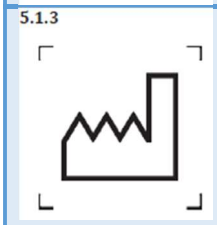
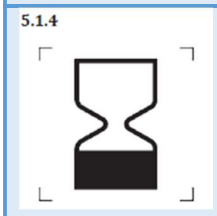
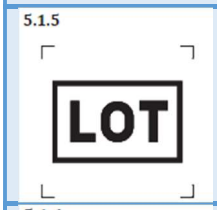
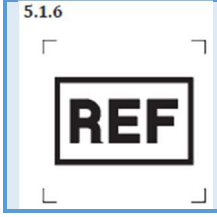
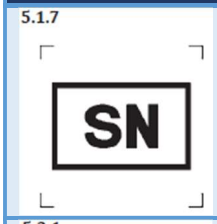
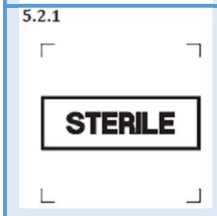
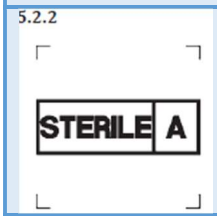
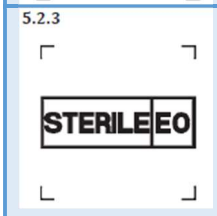
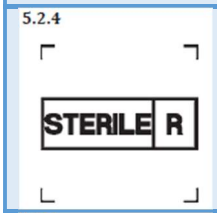
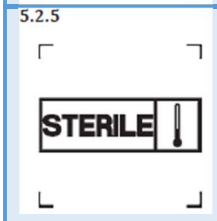
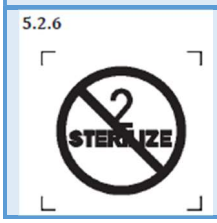
Commonly Used Symbols by Busse Hospital Disposables
As per ISO 15223-1 and FDA Requirements

SYMBOL AND REFERENCE SYMBOL NUMBER	Title of Symbol	DESCRIPTION OF SYMBOL	REQUIEREMENTS/NOTES
5.1.1 	Manufacturer	Indicates the medical device manufacturer	This symbol shall be accompanied by the name and address of the manufacturer (i.e. the person placing the medical device on the market), adjacent to the symbol.
5.1.2 	Authorized representative in the European Community	Indicates the authorized representative in the European Community.	This symbol shall be accompanied by the name and address of the authorized representative in the European Community, adjacent to the symbol.
5.1.3 	Date of manufacture	Indicates the date when the medical device was manufactured.	This symbol shall be accompanied by a date to indicate the date of manufacture. This shall be expressed as in ISO 8601 as four digits for the year and, where appropriate, two digits for the month and two digits for the day. The date shall be located adjacent to the symbol.
5.1.4 	Use-by date	Indicates the date after which the medical device is not to be used.	This symbol shall be accompanied by a date to indicate that the medical device should not be used after the end of the year, month or day shown. The date shall be expressed as in ISO 8601 as four digits for the year and, where appropriate, two digits for the month and two digits for the day. The date shall be located adjacent to the symbol.
5.1.5 	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.	This symbol shall be accompanied by the manufacturer's batch code. The batch code shall be adjacent to the symbol.
5.1.6 	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.	The manufacturer's catalogue number shall be adjacent to the symbol.

75 Arkay Drive, Hauppauge NY 11788
www.busseinc.com

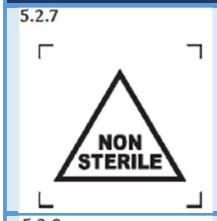
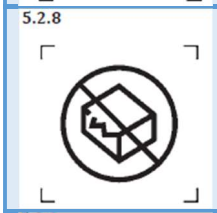
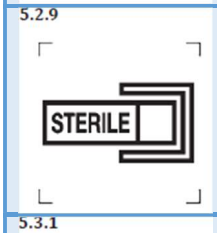
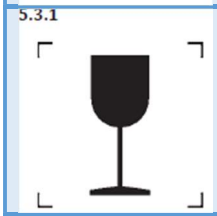
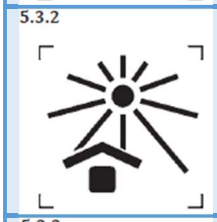
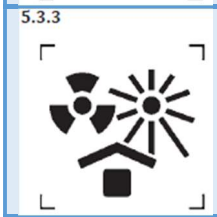
Commonly Used Symbols by Busse Hospital Disposables
As per ISO 15223-1 and FDA Requirements

SYMBOL AND REFERENCE SYMBOL NUMBER	Title of Symbol	DESCRIPTION OF SYMBOL	REQUIEREMENTS/NOTES
5.1.7 	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified.	This symbol shall be accompanied by the manufacturer's serial number. The serial number shall be adjacent to the symbol.
5.2.1 	Sterile	Indicates a medical device that has been subjected to a sterilization process	
5.2.2 	Sterilized using aseptic processing techniques	Indicates a medical device that has been manufactured using accepted aseptic techniques.	
5.2.3 	Sterilized using ethylene oxide	Indicates a medical device that has been sterilized using ethylene oxide.	
5.2.4 	Sterilized using irradiation	Indicates a medical device that has been sterilized using irradiation.	
5.2.5 	Sterilized using steam or dry heat	Indicates a medical device that has been sterilized using steam or dry heat.	
5.2.6 	Do not reserialize	Indicates a medical device that is not to be reserialized.	

75 Arkay Drive, Hauppauge NY 11788
www.busseinc.com

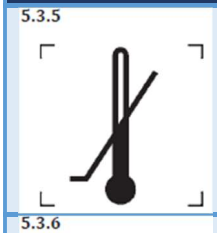
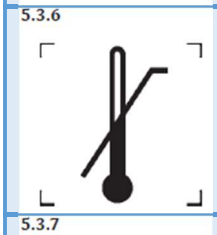
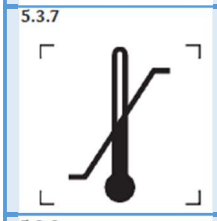
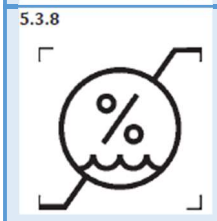
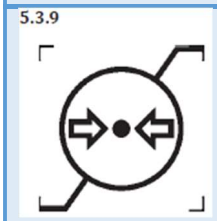
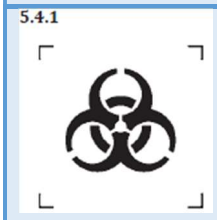
Hospital Disposables

Commonly Used Symbols by Busse Hospital Disposables
As per ISO 15223-1 and FDA Requirements

SYMBOL AND REFERENCE SYMBOL NUMBER	Title of Symbol	DESCRIPTION OF SYMBOL	REQUIEREMENTS/NOTES
5.2.7 	Non-sterile	Indicates a medical device that has not been subjected to a sterilization process.	
5.2.8 	Do not use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened.	This symbol may also mean "Do not use if the product sterile barrier system or its packaging is compromised".
5.2.9 	Sterile fluid path	Indicates the presence of a sterile fluid path within the medical device in cases when other parts of the medical device, including the exterior, might not be supplied sterile.	The method of sterilization shall be indicated in the empty box, as appropriate. The part of the medical device that is sterile shall be identified in the information supplied by the manufacturer.
5.3.1 	Fragile, handle with care	Indicates a medical device that can be broken or damaged if not handled carefully.	
5.3.2 	Keep away from sunlight	Indicates a medical device that needs protection from light sources.	This symbol can also mean "Keep away from heat", as referenced in ISO 7000.
5.3.3 	Protect from heat and radioactive sources	Indicates a medical device that needs protection from heat and radioactive sources.	This symbol can also mean "Keep away from sunlight and radioactive sources".
5.3.4 	Keep dry	Indicates a medical device that needs to be protected from moisture.	This symbol can also mean "Keep away from rain" as referenced in ISO 7000.

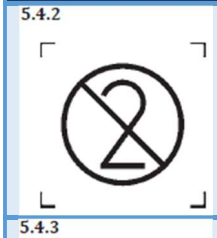
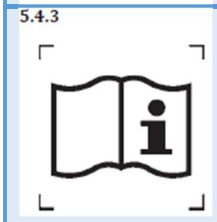
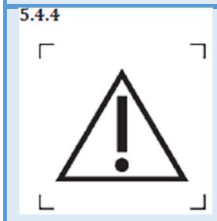
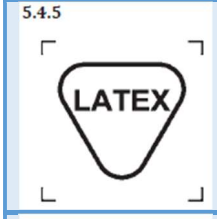
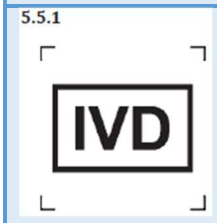
75 Arkay Drive, Hauppauge NY 11788
www.busseinc.com

Commonly Used Symbols by Busse Hospital Disposables
As per ISO 15223-1 and FDA Requirements

SYMBOL AND REFERENCE SYMBOL NUMBER	Title of Symbol	DESCRIPTION OF SYMBOL	REQUIEREMENTS/NOTES
5.3.5 	Lower limit of temperature	Indicates the lower limit of temperature to which the medical device can be safely exposed.	The lower limit of temperature shall be indicated adjacent to the lower horizontal line.
5.3.6 	Upper limit of temperature	Indicates the upper limit of temperature to which the medical device can be safely exposed.	The upper limit of temperature shall be indicated adjacent to the upper horizontal line.
5.3.7 	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed.	The upper and lower limits of temperature shall be indicated adjacent to the upper and lower horizontal lines.
5.3.8 	Humidity limitation	Indicates the range of humidity to which the medical device can be safely exposed.	The humidity limitation shall be indicated adjacent to the upper and lower horizontal lines.
5.3.9 	Atmospheric pressure limitation	Indicates the range of atmospheric pressure to which the medical device can be safely exposed.	The atmospheric pressure limitations shall be indicated adjacent to the upper and lower horizontal lines.
5.4.1 	Biological risks	Indicates that there are potential biological risks associated with the medical device.	This symbol is not to be confused with the “Biohazard” sign intended to be used in the workplace.

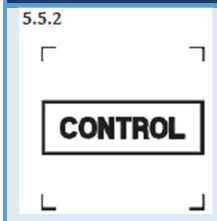
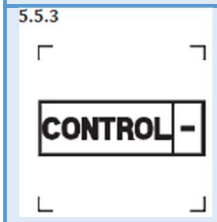
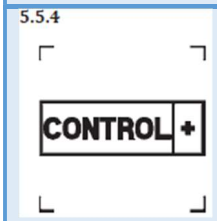
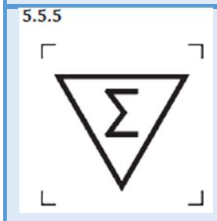
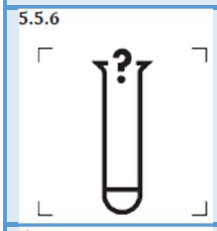
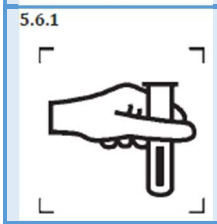
75 Arkay Drive, Hauppauge NY 11788
www.busseinc.com

Commonly Used Symbols by Busse Hospital Disposables
As per ISO 15223-1 and FDA Requirements

SYMBOL AND REFERENCE SYMBOL NUMBER	Title of Symbol	DESCRIPTION OF SYMBOL	REQUIEREMENTS/NOTES
5.4.2 	Do not re-use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.	Synonyms for “Do not reuse” are “single use” and “use only once”.
5.4.3 	Consult instructions for use	Indicates the need for the user to consult the instructions for use.	1 Synonym for “Consult instructions for use” is “Consult operating instructions”. 2 Consider the difference between the description of this symbol and that of symbol 5.4.4.
5.4.4 	Caution	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.	1 Consider the difference between the description of this symbol and that of symbol 5.4.3. 2 This symbol is essentially a cautionary symbol and is 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.
Rx ONLY	Rx Only	The symbol restricts the device to sold by or on the order of a physician, dentist, veterinarian, or with the descriptive designation of any other practitioner licensed by the law of the State in which the practitioner practices to use or order the use of the device; and the method of its application or use.	* Symbol is not required by ISO 15223-1, and it is used by Busse Hospital Disposables due to FDA requirements 21CFR801.109.
5.4.5 	Contains or presence of natural rubber latex	Indicates the presence of natural rubber or dry natural rubber latex as a material of construction within the medical device or the packaging of a medical device.	This symbol is intended to warn those people who may have allergic reactions to certain proteins in latex.
	Not Made with Natural Rubber Latex	Indicates the product does not contain the presence of natural rubber latex as a material of construction within the medical device or the packaging of a medical device.	*Symbol is not required by ISO 15223-1, and it is used by Busse Hospital Disposables due to FDA requirements 79 FR 71436.
5.5.1 	In vitro diagnostic medical device	Indicates a medical device that is intended to be used as an in vitro diagnostic medical device.	This symbol should only be used to identify in vitro diagnostic medical devices and not to specify that the medical device is for “in vitro use”.

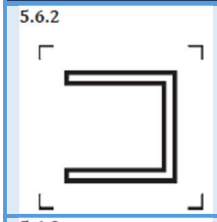
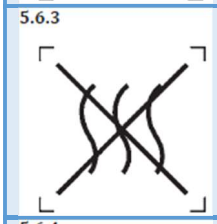
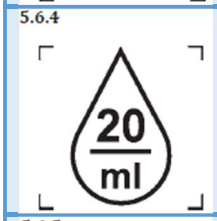
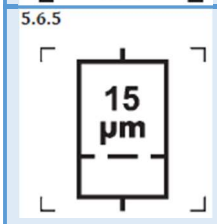
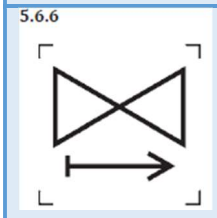
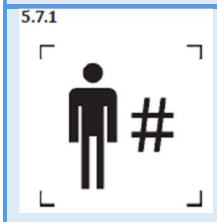
75 Arkay Drive, Hauppauge NY 11788
www.busseinc.com

Commonly Used Symbols by Busse Hospital Disposables
As per ISO 15223-1 and FDA Requirements

SYMBOL AND REFERENCE SYMBOL NUMBER	Title of Symbol	DESCRIPTION OF SYMBOL	REQUIEREMENTS/NOTES
5.5.2 	Control	Indicates a control material that is intended to verify the performance characteristics of another medical device.	
5.5.3 	Negative control	Indicates a control material that is intended to verify the results in the expected negative range.	
5.5.4 	Positive control	Indicates a control material that is intended to verify the results in the expected positive range.	
5.5.5 	Contains sufficient for <n> tests	Indicates the total number of IVD tests that can be performed with the IVD.	The number of tests that can be performed with the IVD shall appear adjacent to the symbol.
5.5.6 	For IVD performance evaluation only	Indicates 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.	A synonym is “IVD for investigational use only”. 2 A medical device that is for IVD performance evaluation only is not intended to be used for an in vitro diagnostic examination for medical purposes (i.e. to yield diagnostic results).
5.6.1 	Sampling site	Indicates a medical device or blood processing application that includes a system dedicated to the collection of samples of a given substance stored in the medical device or blood container.	This is not to be associated with a site on a patient where samples are taken.

Hospital Disposables

Commonly Used Symbols by Busse Hospital Disposables
As per ISO 15223-1 and FDA Requirements

SYMBOL AND REFERENCE SYMBOL NUMBER	Title of Symbol	DESCRIPTION OF SYMBOL	REQUIEREMENTS/NOTES
5.6.2 	Fluid path	Indicates the presence of a fluid path.	
5.6.3 	Non-pyrogenic	Indicates a medical device that is non-pyrogenic.	
5.6.4 	Drops per milliliter	Indicates the number of drops per milliliter.	The number of drops per milliliter is specified; 20 is shown as an example and will be replaced by the appropriate number of drops per milliliter.
5.6.5 	Liquid filter with pore size	Indicates an infusion or transfusion system of the medical device that contains a filter of a particular nominal pore size.	The nominal pore size of the filter is specified; 15 is shown as an example and will be replaced by the appropriate pore size.
5.6.6 	One-way valve	Indicates a medical device with a valve that allows flow in only one direction.	It is important for the user to know that the flow is only possible in one direction and cannot be reversed.
5.7.1 	Patient number	Indicates a unique number associated with an individual patient.	

75 Arkay Drive, Hauppauge NY 11788
www.busseinc.com