



European
Diagnostic
Manufacturers
Association

Place Saint Lambert 14
1200 Woluwé St Lambert
Brussels, Belgium
+32 2 772 2225 tel
+32 2 772 2329 fax
edma@edma-ivd.be
www.edma-ivd.be

“IVD Symbols” for reagents and instruments

14th March 2005

◆ Introduction

The purpose of this EDMA Guidance Document is to list all the relevant symbols to be used with IVD products (reagents and instruments).

These symbols are developed in parallel at both European levels (by CEN/CENELEC) and International level (by ISO/IEC) in the following documents:

	Medical Devices (including IVDs)	General
CEN	<p><u>CEN/TC 257/WG2</u></p> <p>EN 980:2003 “Graphical symbols for use in the labelling of MDs” (Harmonised: Ref. OJEC C83/2 Apr 04)</p>	
ISO	<p><u>ISO/TC 210/WG3</u></p> <p>ISO 15223:2000 “Symbols to be used with Medical Devices labels, labelling and information to be supplied”</p> <p>- 1st amendment AM1:2002 - 2nd amendment AM2:2003</p>	<p><u>ISO/TC 145</u></p> <p>ISO 7000:2004 “Graphical symbols for use on equipment – Index and synopsis”</p> <p>ISO 3864-1:2002 “Graphical symbols: Safety colours and safety signs”</p>
IEC/ CENELEC	<p><u>IEC/TC 62 A</u></p> <p>IEC / TR 60878 Ed.2.0:2003 “Graphical symbols for electrical equipment in medical practice”</p>	<p><u>IEC/TC 3 SC 3</u></p> <p>IEC 60417:2000 “Graphical symbols for use on equipment” (Harmonised: Ref. OJEC Oct 2002)</p>
EU Directives		<p>Directive 2002/96/EC (WEEE) on Waste Electrical and Electronic Equipment</p> <p>Directive 2001/59/EC adapting to technical progress for the 28th time Council Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (Text with EEA relevance.)</p>
EDMA Guidance	<p><u>“EDMA Symbols” for IVD reagents/components</u></p>	

◆ CEN symbols

◆ EN 980: “Graphical symbols for use in the labelling of MDs”.

This Standard was mandated by the European Commission to support essential requirements of EU Directive(s) on Medical Devices (including the IVD Directive).

This Standard was:

- ratified by CEN in 1996 (references published in OJEC C293 14 Oct 00)
- amended a 1st time in 1999: EN 980: 1996 / A1:1999 (references published in OJEC C293 14 Oct 00)
- amended a 2nd time in 2001: EN 980:1996 / A2:2001 (references published in OJEC C182 31 Jul 02).
- revised in 2003 to introduce 10 new symbols - 4 were specifically requested by EDMA – (references published in OJEC C83/02 Apr 04)

◆ ISO symbols

◆ ISO 15223 “Medical Devices - Symbols to be used with medical device labels, labelling and information to be supplied”

This Standard was:

- published in April 2000.
- It is to be noted that this document replaces the ISO Technical Report published in October 1998 because it was urgently needed, but simultaneously circulated for adoption as International Standard.
- amended a 1st time in 1999: ISO 15223 /AM1, to introduce 7 additional symbols (published in August 2002).
 - amended a 2nd time in 2000: ISO 15223: /AM2 to introduce 2 new symbols (published in August 2003).
 - Revision started in 2004 to introduce 3 new symbols:
 1. “Contains sufficient for <n> tests”
 2. “For IVD performance evaluation only”
 3. “Authorised representative in the EC”

◆ ISO 7000 “Graphical symbols for use on equipment – Index and synopsis”

The 2nd edition was published in November 1989. A proposal for revision dated December 2000 has been circulated.

◆ ISO 3864 “Graphical Symbols – Safety colours and safety signs”

This standard consists of three parts,

- First part “Graphical symbols -- Safety colours and safety signs -- Part 1: Design principles for safety signs in workplaces and public areas” was published in June 2002.
- Second part “Graphical symbols -- Safety colours and safety signs -- Part 2: Design principles for product safety labels” was published in October 2004
- Third part “Graphical symbols -- Safety colours and safety signs -- Part 3: Design criteria for graphical symbols used in safety signs” is still under development.

◆ IEC/ CENELEC Symbols

◆ IEC 60417 “Graphical symbols for use on equipment”

This Standard was ratified in 2000 (references published in OJEC in Oct 02).

◆ IEC / TR 60878 Ed.2.0 “Graphical symbols for electrical equipment in medical practice”.

This Technical Report was ratified in July 2003.

It lists all the relevant symbols published in IEC 60417 or in ISO 7000 to be used with electrical equipment in medical practice.

◆ CEN, ISO & IEC symbols available in electronic format

◆ EN 980 Standard

Symbols are available on floppy disk, as TIF and EPS files (encapsulated post script) at the Finnish Standards Association:

<http://www.sfs.fi/luettelo/sfs.php>

P.O. Box 116, 00241 Helsinki, FINLAND

The order must be sent to: sales@sfs.fi

Prices: € 42.51 (paper version), € 68 (CD Rom or E-mail)

◆ ISO 15223 Standard

This Standard can also be provided in electronic format (PDF only) for the price of CHF 56 (about €36.19) and Amendments 1 & 2 for the price of CHF 16 (€10.34) each. The order can be done directly on the ISO Website: www.iso.ch

- ⇒ Click on ISO CATALOGUE
- ⇒ Choose International Standards
- ⇒ Select ISO number
- ⇒ Type in Search criteria: 15223

◆ ISO 3864 Standard

The first two parts of this standard (ISO 3864-1:2002 and ISO 3864-2:2004) are completed, and available for 99 CHF (64 €) each.

More information on availability and relevant prices of ISO Standards can be obtained at the ISO Central Secretariat, sales department:

E-mail: sales@iso.ch

◆ IEC 60417 & IEC / TR 60878

These documents can be provided in electronic format (PDF files).

The order can be done directly on the IEC Website <http://www.iec.ch/> from

- IEC 60417

CHF 500 (~323€) for access to the online symbols database, including all symbols from IEC 60417 and ISO 7000 (12 months).

- TR 60878 (2003-07) Ed.2.0

CHF 252 (€ 163)

◆ [EDMA Guidance on "EDMA symbols" for IVD reagents / components](#)

The use of symbols as an alternative to language is recommended in the IVD Directive.

Annex I.8.2 of the IVD Directive states that *"Where appropriate, the information to be supplied should take the form of symbols. Any symbol and identification colour used must conform to the harmonised standards. In areas for which no standards exist, the symbols and colour used must be described in the documentation supplied with the device."*

Even if a number of symbols have been developed (or are under development) in standards, all the needs of IVD manufacturers to use symbols on the small size labels cannot be met.

The EDMA Labelling Task Force has then decided to develop this Guidance Document

proposing to the European IVD manufacturers a number of "symbols", useful for our industry, in order to avoid translation of commonly used wording related to reagent/component names. For the purpose of this guidance, they will be referred to as "EDMA symbols".

It is felt that these "EDMA symbols" will be very useful for IVD labelling, if widely adopted by IVD manufacturers. Such guidance should help to prevent the use by different manufacturers of different "symbols" for the same concept or vice-versa.

◆ [Other EDMA documents pertaining to symbols:](#)

If you have more questions about Symbols or Labelling in general, the following EDMA documents will help you.

◆ [EDMA Guidance "User Awareness of Symbols"](#)

◆ [EDMA Guidance "Labels of IVD Reagents"](#)

◆ [EDMA Questions & Answers cards](#)

- [Q&A N° 41:](#)

Harmonised European Standards

"What are harmonised standards and what is the advantage to a manufacturer in using them?"

- [Q&A N° 42:](#)

Symbols for IVD Labelling






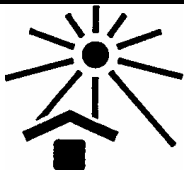



"The IVD Directive Annex I, Part B, Paragraph 8.2 states: *Where appropriate, the information to be supplied should take the form of symbols. Any symbol and identification colour used must conform to the harmonised standards. In areas for which no standards exist, the symbols and colour used must be described in the documentation supplied with the device.*


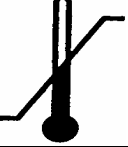









Which symbols can IVD manufacturers use now?"









- [Q&A N° 53:](#)


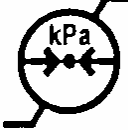


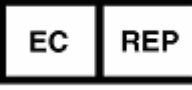






Dimension and colour of symbols













"When a manufacturer uses a symbol on a label, must he respect some rules regarding the dimension or the colour of that symbol? Must that symbol have a minimum dimension as specified in Annex X of the IVD Directive for CE mark?"









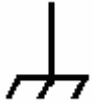



SYMBOLS	FOR	ISO		CEN	IEC	Others
		ISO 7000	ISO 15223	EN 980	IEC 60417	
	ISO 7000: Biological hazards (ISO 15223:Biological risks)	✓ 0659	✓ 3.1	✓ 4.18		(See also ISO 3864)
	Do not reuse	✓ 1051	✓ 3.2	✓ 4.1		
	Consult instructions for use	✓ 1641	✓ 3.3	✓ 4.17		
	ISO 15223 & EN 980: Caution, consult accompanying documents EN 980 synonym for: Attention, see instructions for use (ISO 7000: Caution)	✓ 0434	✓ 3.4	✓ 4.9		IEC 60878 Note: In case of application as a safety sign the rules according to ISO 3864 shall be <u>adhered to</u> . (See also ISO 3864)
	Fragile, handle with care	✓ 0621	✓ 3.5			
	ISO 15223 : Keep away from sunlight (ISO 7000 : Keep away from heat)	✓ 0624	✓ 3.6			
	Protect from heat and radioactive sources	✓ 0615	✓ 3.7			
	Keep dry	✓ 0626	✓ 3.8			
	Lower limit of temperature	✓ 0534	✓ 3.9	✓ 4.16.2		












SYMBOLS	FOR	ISO		CEN	IEC	Others
		ISO 7000	ISO 15223	EN 980	IEC 60417	
	Upper limit of temperature	✓ 0533	✓ 3.10	✓ 4.16.1		
	Temperature limitation	✓ 0632	✓ 3.11	✓ 4.16.3		
	Use by		✓ 3.12	✓ 4.2		
	Date of manufacture	✓ 2497	✓ 3.13	✓ 4.5		
	Batch code		✓ 3.14	✓ 4.3		
	Catalogue number N.B. EN 980: REF (box is an option)		✓ 3.15	✓ 4.8		
	Serial number N.B. EN 980: SN (box is an option)		✓ 3.16	✓ 4.4		
	Control		✓ 3.17			
	Negative control		✓ 3.18			
	Positive control		✓ 3.19			
	Sterile Def. "sterile" given in EN 556 (for terminally-sterilized MD only)		✓ 3.20	✓ 4.6		












SYMBOLS	FOR	ISO		CEN	IEC	Others
		ISO 7000	ISO 15223	EN 980	IEC 60417	
	Sterilized using aseptic processing techniques		✓ 3.21	✓ 4.10		
	ISO: Sterilized using ethylene oxide (for terminally-sterilized MD only) CEN: Method of sterilization using ethylene oxide		✓ 3.22	✓ 4.7.1		
	ISO: Sterilized using irradiation (for terminally-sterilized MD only) CEN: Method of sterilization using irradiation		✓ 3.23	✓ 4.7.2		
	ISO: Sterilized using steam or dry heat (for terminally-sterilized MD only) CEN: Method of sterilization using steam or dry heat		✓ 3.24	✓ 4.7.3		
	Do not re-sterilize		✓ In AM1 1			
	Non-sterile		✓ In AM1 2			
	Do not use if package damaged		✓ In AM1 3			
	ISO: <i>In vitro</i> diagnostic device CEN: <i>In vitro</i> diagnostic medical device		✓ In AM1 4	✓ 4.15		










SYMBOLS	FOR	ISO		CEN EN 980	IEC IEC 60417	Others
		ISO 7000	ISO 15223			
	Humidity limitation		✓ In AM1 5			
	Atmospheric pressure limitation		✓ In AM1 6			
	ISO 7000: Person number ISO 15223: Patient number	✓ 2610	✓ In AM1 7			
	Manufacturer			✓ 4.11		
	Authorised representative in the European Community.			✓ 4.12		
	Contains sufficient for <n> tests	✓ 0518		✓ 4.13		
	For IVD Performance Evaluation only			✓ 4.14		
	Earth (Ground)				✓ 5017	
	Protective Earth (Ground)				✓ 5019	
	Direct current				✓ 5031	
	Alternating current				✓ 5032	










SYMBOLS	FOR	ISO		CEN EN 980	IEC IEC 60417	Others
		ISO 7000	ISO 15223			
	Both direct and alternating current				✓ 5033	
	Dangerous voltage				✓ 5036	(See also ISO 3864)
	Radiation of laser apparatus				✓ 5152	(See also IEC 60601-2-22:101)
	Door open				✓ 5624	
	Contrast				✓ 5057	
	Printer				✓ 5193	
	„On“ (Power)				✓ 5007	
	„Off“ (Power)				✓ 5008	
	Stand By				✓ 5009	
	"ON"/"OFF" (push-push)				✓ 5010	
	Fast Stop				✓ 5178	
	Start (of action)				✓ 5104	









SYMBOLS	FOR	ISO		CEN EN 980	IEC IEC 60417	Others
		ISO 7000	ISO 15223			
	Stop (of action)				✓ 5110	
	Emergency stop				✓ 5638	
	"IN" position of a bi-stable push control				✓ 5268	
	"OUT" position of a bi-stable push control				✓ 5269	
	Positioning of cell				✓ 5002	
	Battery check				✓ 5546	
	Fuse				✓ 5016	
	Noiseless (clean) earth (ground)				✓ 5018	
	Frame or chassis				✓ 5020	
	Equipotentiality				✓ 5021	
	Television monitor				✓ 5051	
	Not to be used in residential areas				✓ 5109	(See also ISO 3864)

SYMBOLS	FOR	ISO		CEN EN 980	IEC IEC 60417	Others
		ISO 7000	ISO 15223			
	Non-ionizing electromagnetic radiation				✓ 5140	(See also ISO 3864)
	Moisture				✓ 5536	
	Mixing of substances				✓ 5657	
	Manual control	✓ 0096				
	Pressure measurement	✓ 0233				
	Call for maintenance	✓ 0717				
	General symbol for recovery / recyclable	✓ 1135				
	Handbook; manual for operations Note: On medical electrical equipment "Consult service manual".	✓ 1640				
	Sterilizable up to the temperature specified	✓ 1844				
	Print screen; hard copy	✓ 2027				
	Emergency laser off					IEC 60601-2-22:101

SYMBOLS	FOR	ISO		CEN EN 980	IEC IEC 60417	Others
		ISO 7000	ISO 15223			
	Air feeding					IEC 60601-2- 18:102
	Suction					IEC 60601-2- 18:103
	Water bottle					IEC 60601-2- 18:104
	Suction bottle					IEC 60601-2- 18:105
	Caution, hot surface				✓ 5041	(See also ISO 3864)
	Class II equipment				✓ 5172	
	Class III equipment				✓ 5180	
	Type BF applied part				✓ 5333	
	Defibrillation-proof type BF applied part				✓ 5334	
	Person identification				✓ 5664	
	Type B applied part				✓ 5840	

SYMBOLS	FOR	ISO		CEN EN 980	IEC IEC 60417	Others
		ISO 7000	ISO 15223			
	Defibrillation-proof type B applied part				✓ 5841	
	General warning, caution, risk of danger Note: If necessary, this safety sign shall be combined with an additional sign indicating the kind of danger or hazard. Note: colour mandatory					<u>ISO 3864</u> (See Also ISO 15223)
	Caution, risk of electric shock Note: colour mandatory					<u>ISO 3864</u> (See also IEC 60417)
	Warning, biological hazard Note: colour mandatory					<u>ISO 3864</u> (See also ISO 7000)
	Warning, hot surface Note: colour mandatory					<u>ISO 3864</u> (See also IEC 60417)
	Warning, laser beam Note: colour mandatory					<u>ISO 3864</u> (See also IEC 60417)
	Warning, non-ionising electromagnetic radiation Note: colour mandatory					<u>ISO 3864</u> (See also IEC 60417)
	Warning, strong magnetic field Note: colour mandatory					ISO 3864
	Warning, danger of crushing hand Note: colour mandatory					ISO 3864

SYMBOLS	FOR	ISO		CEN EN 980	IEC IEC 60417	Others
		ISO 7000	ISO 15223			
	Not to be used in residential areas Note: colour mandatory					ISO 3864 (See also IEC 60417)
	Do not touch Note: colour mandatory					ISO 3864
	Do not touch, housing energized Note: colour mandatory					ISO 3864
	No seizing in Note: colour mandatory					ISO 3864
	No access for persons with pacemakers Note: colour mandatory					ISO 3864
	Mobile transmitter forbidden Note: colour mandatory					ISO 3864
	Harmful/Irritant Note: This symbol can be accompanied by qualifying letters: Xn for harmful and Xi for irritant					Directive 2001/59/EC
	Toxic Note: This symbol can be accompanied by qualifying letters: T for toxic and T+ very toxic					Directive 2001/59/EC
	Explosive Note: This symbol can be accompanied by qualifying letters: E for explosive E+ for highly explosive					Directive 2001/59/EC

SYMBOLS	FOR	ISO		CEN EN 980	IEC IEC 60417	Others
		ISO 7000	ISO 15223			
	<p>Flammable</p> <p>Note: This symbol can be accompanied by qualifying letters: F for highly flammable, and F+ for extremely flammable:</p>					Directive 2001/59/EC
	<p>Oxidant</p> <p>Note: This symbol can be accompanied by qualifying letter O for oxidizing</p>					Directive 2001/59/EC
	<p>Corrosive</p> <p>Note: This symbol can be accompanied by qualifying letters: C for corrosive</p>					Directive 2001/59/EC
	<p>Environmental Hazard</p> <p>Note: This symbol can be accompanied by qualifying letters: N for Environmental hazard</p>					Directive 2001/59/EC
	<p>"New" waste</p> <p>The bar can be replaced by the date of manufacture.</p>					Directive 2002/96/EC (WEEE) prEN 50419
	<p>Radioactivity</p>					Safety series, IAEA 1960
	<p>This way up</p>					IATA 2004
	<p>Handle with care</p>					ISO 780:1997 Original JIS Z 0150

EDMA Labelling Task Force



14th March 2005