Attention ⚠ ISO 15223-1 4th Edition is almost here: How to update your medical device labeling to comply with the new requirements

July 8, 2021

Eisner Safety Consultants

Presented by Leo the "IEC 60601 Guy" Eisner

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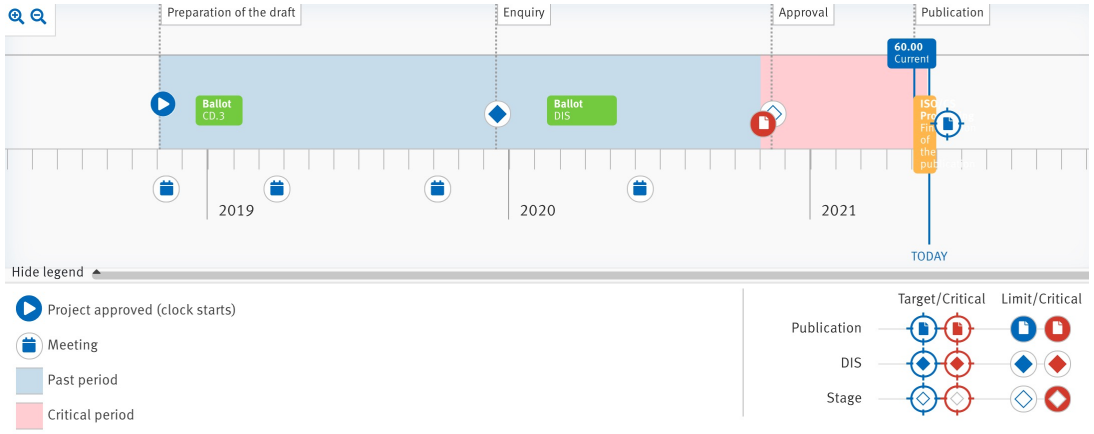
Topics

- Timing of ISO 15223-1, 4th edition
- Summary of Changes 3rd to 4th ed.
  - Revised Introduction & Scope
  - Title Change
  - Addition & Deletion of Defined Terms
  - Addition of Symbols
  - Expansion of Annex A containing examples & new guidance
  - Other Changes
- What's in the Future?

Timeline of ISO 15223-1 4th Edition



Stage	Version	Description	Target date	Limit date	Started	Status
10.99	1	New project approved			2018-11-05	Closed
20.00	1	New project registered in TC/SC work programme			2018-11-05	Closed
30.00	1	Committee draft (CD) registered			2018-11-22	Closed
30.20	1	CD study/ballot initiated			2018-12-19	Closed
30.60	1	Close of voting/comment period			2019-02-14	Closed
30.99	1	CD approved for registration as DIS			2019-12-05	Closed
40.00	1	DIS registered	2019-11-03	2019-11-05	2019-12-18	Closed
40.20	1	DIS ballot initiated	2020-02-19		2020-02-19	Closed
40.60	1	Close of voting	2020-05-13		2020-05-14	Closed
40.99	1	Full report circulated: DIS approved for registration as FDIS			2020-06-28	Closed
50.00	1	Final text received or FDIS registered for formal approval	2020-09-02		2020-11-17	Closed
50.20	1	Proof sent to Secretariat or FDIS ballot initiated: 2 months	2021-03-07		2021-03-07	Closed
50.60	1	Close of voting -- Proof returned by Secretariat	2021-05-02		2021-05-03	Closed
60.00	**1**	**International Standard under publication**			**2021-05-09**	**Current**
60.60		International Standard published	2021-07-04	2020-11-05		Awaiting

ISO 15223-1 4th Edition is ~~almost~~ here!!! FINALLY PUBLISHED!!

Schedule as of 12 June '21 – Above International Std Published on 6 Jul '21

POLL

Has your company started to plan for the ISO 15223-1:2021 changes?

- **Yes**
- **No**

Planning for ISO 15223-1, 4th ed. Changes

INTERNATIONAL STANDARD

ISO 15223-1

Fourth edition
2021-07

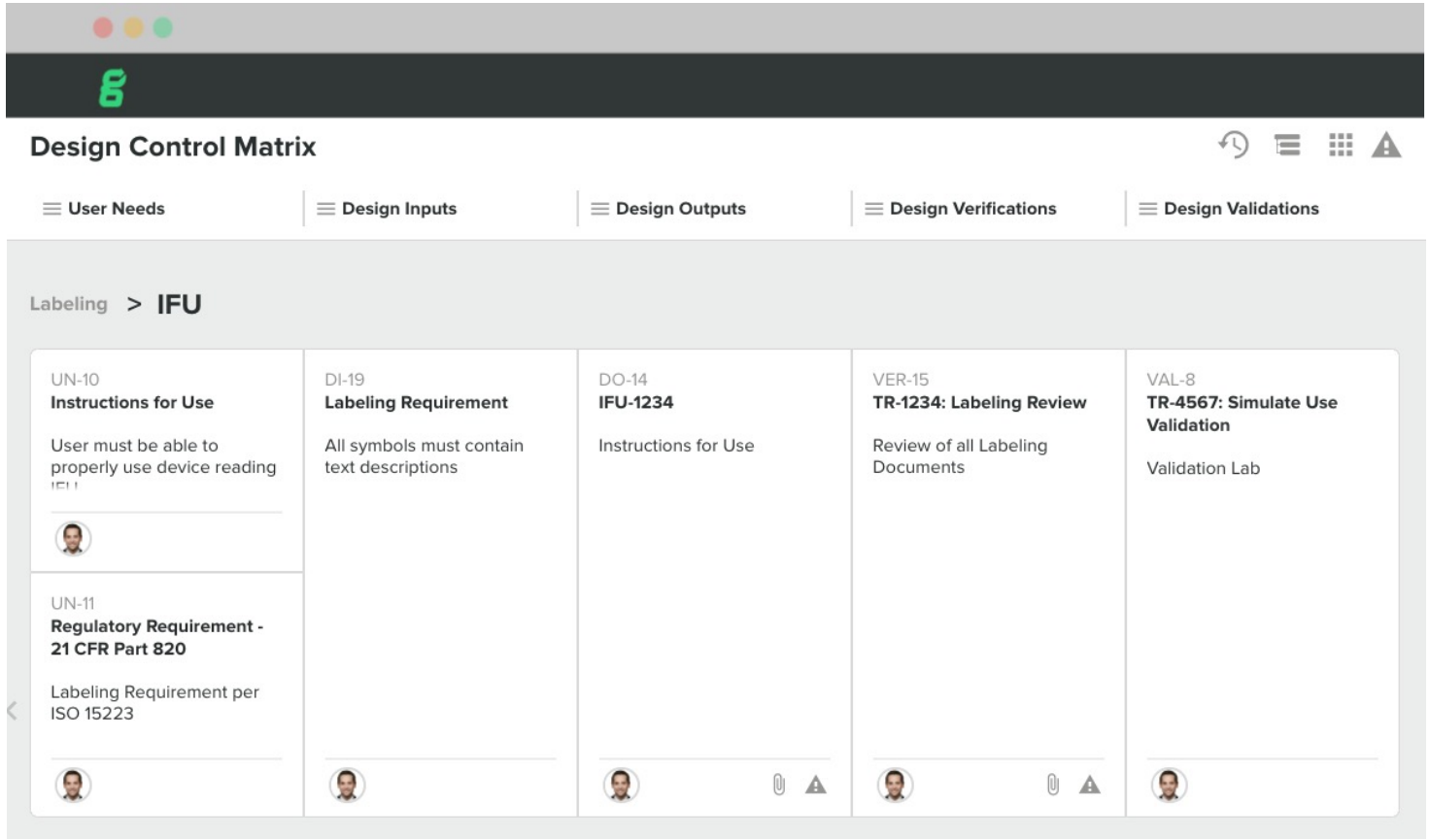
Medical devices — Symbols to be used with information to be supplied by the manufacturer —

Part 1:
General requirements

Dispositifs médicaux — Symboles à utiliser avec les informations à fournir par le fabricant —

Partie 1: Exigences générales

Reference number
ISO 15223-1:2021(E)



Summary of Changes 3rd to 4th Edition

- Revised Introduction & Scope
- Title of Standard Changed
- Deleted defined terms
- Added defined terms from ISO 20417, ISO 13485 & ISO 14971;
- Added 20 new symbols validated per ISO 15223-2;
- Added 5 existing symbols from ISO 7000, ISO 7010 & IEC 60417;
- Expansion of Annex A containing examples & new guidance;
- Moved information about European Regulations to informative notes;
- Other changes.

Revised Introduction & Scope

- Revised introduction & scope to make clearer
- Intro: "…specific information on the *medical device* itself, as part of the packaging, or in the *accompanying information*….this information can be provided as *symbols* that have a specific meaning…" (small part of intro)
- Scope: "This document specifies *symbols* used to express information supplied for a *medical device* ~~labelling that convey information on the safe and effective use of medical devices. It also lists symbols that satisfy the requirements of this document~~."
  (~~deleted from prev ed.~~, next 2 para's cleaned up)

Title of Standard Changed

3rd ed. (2016) Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements

4th ed. (2021) Medical devices - Symbols to be used with ~~medical device labels, labelling and~~ information to be supplied by the manufacturer - Part 1: General requirements

Deletion of Defined Terms

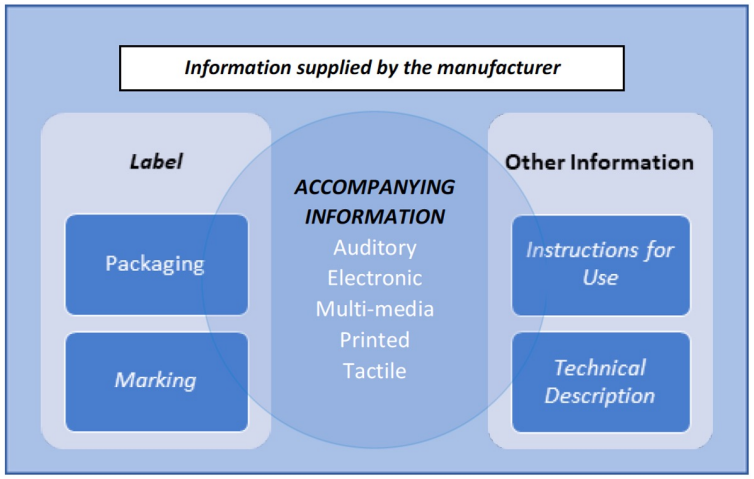
- Deletion of defined terms
  - labelling – deleted title & definition
    - NOTE: *Label* updated definition – previous just on device **but now** also on packaging
  - characteristic information

Addition of Defined Terms ISO 20417:2021

- ISO 20417:2021 Medical devices — Information to be supplied by the manufacturer – Normative referenced std
  - Intro: "…standard provides the requirements for the identification and *labels* on a *medical device* or *accessory*, their packaging, *marking* of a *medical device* or *accessory* and *accompanying information*."

Modified fig from ISO 20417:2021 modified

Figure 1 from ISO 15223-1, 4th ed.



Addition of Defined Terms Source ISO 20417:2021

- *accompanying information*
- *catalogue number*
- *distributor*
- *importer*
- *information supplied by the manufacturer*
- *instructions for use, IFU*
- *Label**
- *lot number, batch code, batch number, lot code*
- *marking*
- *model number*
- *serial number*
- *single patient multiple use*
- *single use, do not re-use, use only once*
- *sterile*

Reason ISO 20417 def's added so don't need to purchase std -- <u>but still need to meet 20417 labeling requirements</u>

Addition of Defined Terms ISO 13485:2016 & ISO 14971:2019

- ISO 13485:2016 – Bibliographic std (Informative)
  - ***medical device***
- ISO 14971:2019 –Bibliographic std (Informative)
  - ***manufacturer***
  - ***risk***
  - ***risk assessment***

Note: Informative → Not a requirement → Guidance

ADDED SYMBOLS

Table 1 formatting changes

Table 1 — *Symbols* to convey ~~information essential for proper use~~*medical device* information

Reference number ~~of *symbol*~~ and ~~*symbol*~~ graphic	Title ~~of *symbol*~~	~~*Description of symbol*~~	Requirements	~~Informative notes~~Notes	Restrictions of use	Additional requirements	ISO/IEC *symbol* number ~~/~~and registration date [a]

- Changes include:
  - New and existing symbol changes & details within table
  - MDR, GHTF, & IMDRF impacts show up in Notes as can't be requirements – an ISO requirement
  - *Italics* for defined terms (not normal format for ISO standards)
  - Clarifications and changes to existing symbols

ADDED 20 NEW SYMBOLS (VALIDATED PER ISO 15223-2)

Background

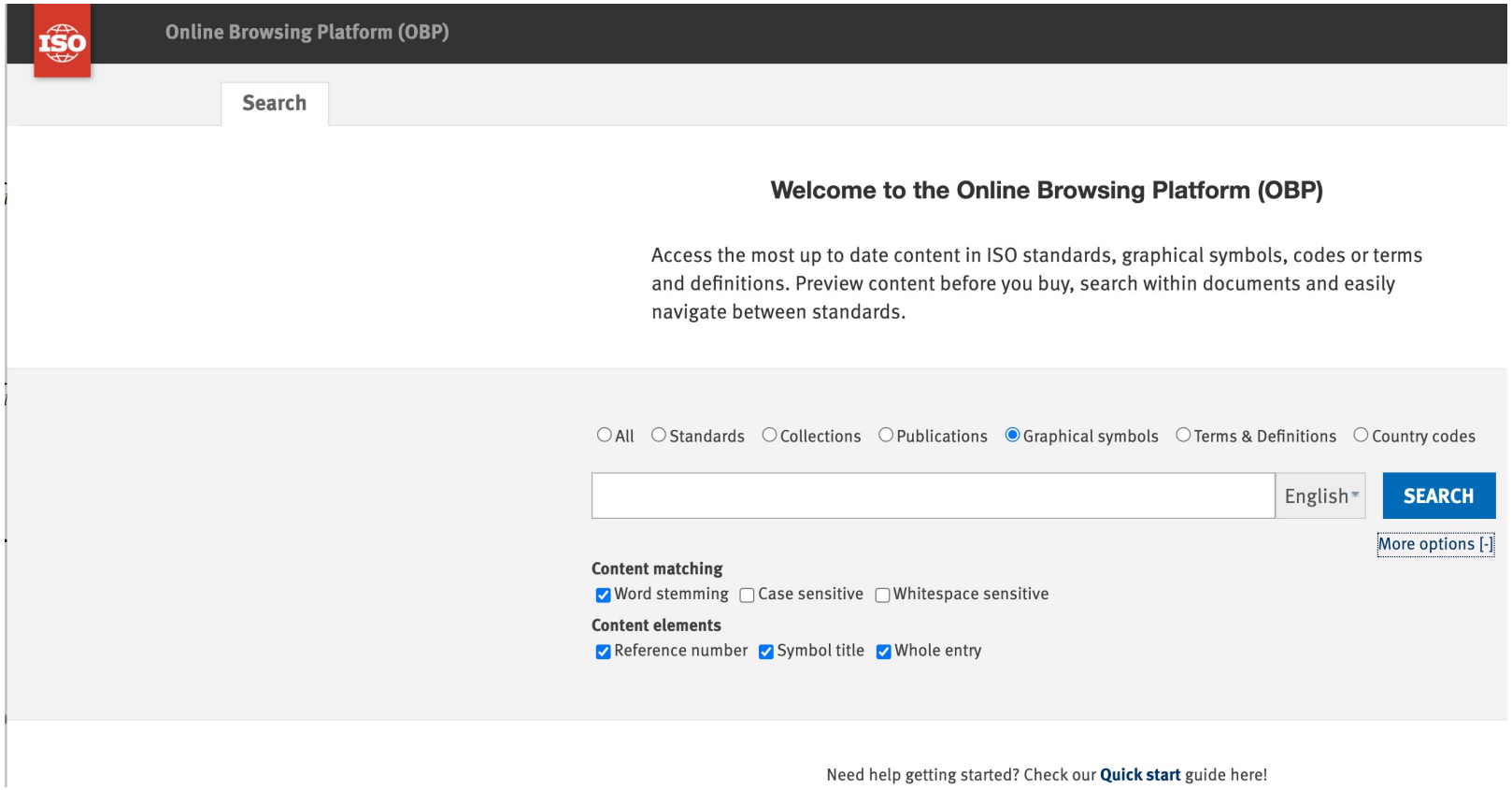
- Jun ‘17 N197 - proposed 21 new symbols potential candidates for inclusion in 15223-1 via 15223-2 validation process – None adopted as proposed
- Nov ’17 N204 - Feedback on symbols proposed from N197
  - 12 symbols no persuasive justification or existing IEC/ISO symbol
  - 9 symbols further development recommended
  - 8 add’l candidates (3 rejected, 1 considered as an ISO 7000 symbol and 4 were potential candidates via 15223-2 val process)

Background

- Nov ’17 N204 Feedback on symbols proposed from N197 (Cont’ed)
  - Contains or Incorporates Blood Products
  - Contains a Medicinal Substance
  - Device contains CMR substances
  - Device contains Nano Material
  - Device Contains Cells of Human Origin
  - Device Contains Animal (Non Human) Tissue
  - Sterilization by Vapour-Phase Hydrogen Peroxide
  - Breaching compromises sterility (Single, double barriers, etc.)
- 4th ed. project officially opened Nov ’18

ISO Online Browsing Platform

https://www.iso.org/obp/ui/#home



Manufacturer Symbols (5.1)

- Reference #: **5.1.8** Title: ***Importer***
- Description: entity importing *med dvc* into locale
- Requirement: *symbol* shall include name & address of importing entity, near *symbol*.
- Note: If multiple *symbols* (i.e., AR, *Importer*, *Distributor*, Translation, or Repackaging) identify same responsible entity, don't duplicate name & address. ***(ISO 7000-3725)***

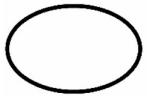
- Reference #: **5.1.9** Title: **Distributor**
- Description: entity distributing *med dvc* into locale
- Requirement: *symbol* shall include name & address of distributor near *symbol*.
- Note: Same as 5.1.8 ***(ISO 7000-3724)***

Sterilization Symbol (5.2)

- Reference #: **5.2.10** Title: **Sterilized using vaporized hydrogen peroxide**
- Description: *med dvc* sterilized using vaporized hydrogen peroxide
- Note: use of *symbol* in Europe explained in EN 556-1, clause 4.1.
- Restriction of use: Use of *symbol* precludes use of 5.2.1 STERILE
- ISO/IEC #: ***N/A***

Four Sterile Barrier Symbols (5.2)

- Section 5.2 - Sterility



- Ref #: **5.2.11** Title: **Single *sterile* barrier system (sbs)** ***(ISO 7000-3707)***

- Ref #: **5.2.12** Title: **Double sbs** ***(ISO 7000-3704)***

- Ref #: **5.2.13** Title: **Single sbs with protective packaging inside** ***(ISO 7000-3708)***

- Ref #: **5.2.14** Title: **Single sbs with protective packaging outside** ***(ISO 7000-3709)***

Four Sterile Barrier Symbols (5.2) (Cont'ed)

- "Requirement" same for all 4: Any of 4 symbols shall be placed near or in combo with symbol
  - 5.2.1 STERILE 5.2.2 STERILE A 5.2.3 STERILE EO 5.2.4 STERILE R
    5.2.5 STERILE 5.2.9 STERILE or 5.2.10 STERILE VH2O2

- Note 1 – Explains what the lines & dashes mean for the barriers
- Note 2 same for all 4: Additional info on sbs systems → ISO 11607-1 & ISO 11607-2

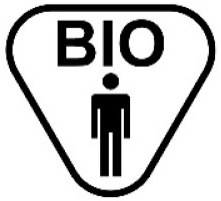
Seven Safe Use Symbols (5.4)

- Reference #: **5.4.6** Title: **Contains human blood or plasma derivatives**
- Description: *med dvc contains* / incorporates human blood / plasma derivatives
- Requirement: embedded cross may be deleted / replaced with another element appropriate with cultural requirements. ***(ISO 7000-3701)***

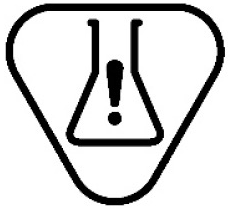
- Reference #: **5.4.7** Title: **Contains a medicinal substance**
- Description: *med dvc contains* / incorporates medicinal substance
- Requirement: same text as 5.4.6 ***(ISO 7000-3702)***

Seven Safe Use Symbols (5.4)

- Reference #: **5.4.8** Title: **Contains biological material of animal origin**
- Description: *med dvc* contains biological tissue, cells, or their derivatives, of animal origin ***(ISO 7000-3699)***

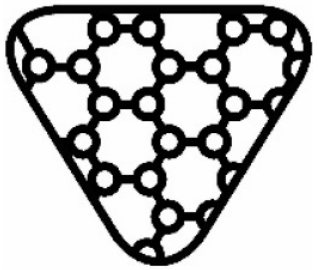


- Reference #: **5.4.9** Title: **Contains biological material of human origin**
- Description: *med dvc* contains biological tissue, cells, or their derivatives, of human origin ***(ISO 7000-3700)***



- Reference #: **5.4.10** Title: **Contains hazardous substances**
- Description: *med dvc* contains substances can be carcinogenic, mutagenic, reprotoxic (CMR), / substances with endocrine disrupting properties
- Note: term "substances" used → single / multiple substances ***(ISO 7000-3723)***

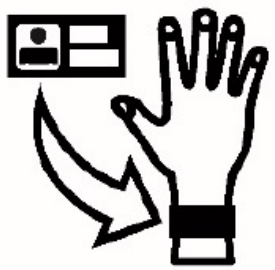
Seven Safe Use Symbols (5.4)



- Reference #: **5.4.11** Title: **Contains nano materials**
- Description: *med dvc contains* nano materials ***(ISO 7000-3703)***

- Reference #: **5.4.12** Title: **Single patient multiple use**
- Description: *med dvc* may be used multiple times (multiple procedures) on single patient ***(ISO 7000-3706)***

Six "Others" Symbols (5.7)

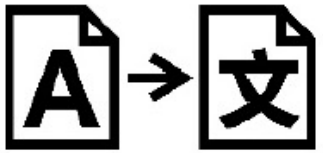


- Reference #: **5.7.2** Title: **Patient name**
- Description: name of patient
- Requirement: If used, *symbol* shall appear next to patient name or space provided to record it. ***(ISO 7000-3726)***

- Reference #: **5.7.4** Title: **Patient information website**
- Description: website where patient obtain add'l info on medical product
- Requirement: web address shall be next to *symbol*
- Note: indicate location of info avail to patient ***(ISO 7000-3705)***

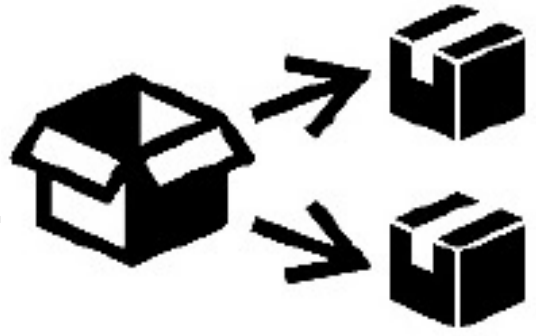
Six "Others" Symbols (5.7)

- Reference #: **5.7.7** Title: ***Medical device***
- Description: *med dvc*
- Note: in Europe - full def of "*medical device*" in 2017/745 MDR. Other jurisdictions may have different def's. ***(ISO/IEC #: N/A)***



- Reference #: **5.7.8** Title: Translation
- Description: original *med dvc* info undergone translation supplements / replaces original info
- Requirement: *symbol* shall be accompanied by name & address of entity responsible for translation activity, near *symbol*
- Note: Same note as Importer (5.1.8), Distributor (5.1.9), etc. ***(ISO 7000-3728)***

Six "Others" Symbols (5.7)



- Reference #: **5.7.9** Title: Repackaging
- Description: modification to original *med dvc* packaging configuration occurred
- Requirement: *symbol* shall be accompanied by name & address of entity responsible for repackaging activity, near *symbol*
- Note 1: depending on AHJ additional info such as date of repackaging may be required
- Note 2: Same note as Importer (5.1.8), Distributor (5.1.9), etc.
- Restrictions of use: *symbol* use only when repackaging other than mfr ***(ISO 7000-3727)***

Six "Others" Symbols (5.7)

- Reference #: **5.7.10** Title: Unique device identifier
- Description: carrier contains UDI info
- Requirement: *symbol* may be used when multiple data carriers present on label. If used, *symbol* shall be placed near UDI carrier
- Note: *symbol* identifies UDI carrier (ISO/IEC #: ***N/A)***

ADDED EXISTING 5 SYMBOLS FROM ISO 7000, ISO 7010 & IEC 60417

Added Existing 5 Symbols – Manufacture (5.1)

- Reference #: **5.1.10** Title: ***Model number***
- Description: *model / type number* of product
- Requirement: *model number* placed shall be near *symbol* ***(IEC 60417-6050)***

- Reference #: **5.1.11** Title: **Country of manufacture**
- Description: country of manufacture of products
- Requirement: "CC" replaces by either 2 or 3 letter country code defined in ISO 3166-1. Date of manufacture allowed near symbol.
- Note: Not all AHJs recognize 2 or 3 letter country codes.
- Restrictions of use: use of symbol with a date of manufacture precludes use of symbol 5.1.3  ***(IEC 60417-6049)***

Added Existing 5 Symbols – "Others" (5.7)

- Reference #: **5.7.3** Title: **Patient identification**
- Description: identification data of patient
- Requirement: If used, *symbol* appear near patient id / space provided to record it
- Note: **?** part of symbol ***(ISO 7000-5664)***

- Reference #: **5.7.5** Title: **Health care centre or doctor**
- Description: address of health care centre / doctor where medical info about patient found
- Requirement: If used, *symbol* shall appear near address of health care facility / doctor or space provided to record it
- Note: cross can be deleted / replaced with another item appropriate with cultural requirements ***(ISO 7001-PI PF 044)***

Added Existing 5 Symbols – "Others" (5.7)

- Reference #: **5.7.6** Title: **Date**
- Description: date info entered or med procedure took place
- Requirement: If used, *symbol* appear near date appropriate for use of *symbol* or space provided to record it. ***(IEC 60417-5662)***

ANNEX A CHANGES

Annex A - Changes

- Title Change
  - "Guidance and examples of *symbols* use, including multiple *symbols"*
- New Note: Requested info such as Name, address, date, etc. shown in example *symbols* on the right or below may be located elsewhere if info is unambiguous
- A.1 Guidance: Defined terms *accompanying information (3.1)* & *information supplied by the manufacturer (3.6)* are very similar & their application may vary by AHJs.

Annex A - Changes

- A.2 – A.4, A.7 – A.9, A.19 New Examples: Text next to symbol on right or below *symbol* vs Old Examples A.1 – A.3, A.6 – A.8, A.14 different for same *symbols*
- Examples of use *symbol* w/ name & address
  - A.10 *Importer,* A.11 *Distributor,* A.19 Translation, A.20 Repacking
- A.12 Country of manufacturer examples of use *symbol* w/ or w/o date of manufacture
- A.21 Examples of use of *symbol* 5.7.10, "Unique Device Identifier"

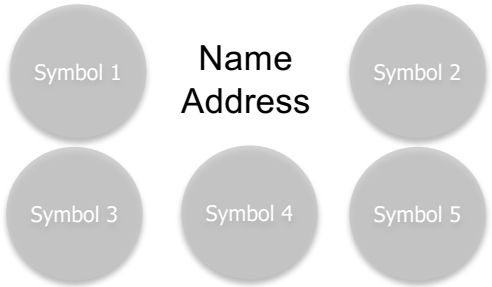
(01)01234567891011
(11)200622
(17)240622
(21)88888888

(01)01234567891011(11)200622(17)240622(21)88888888

Annex A - Changes

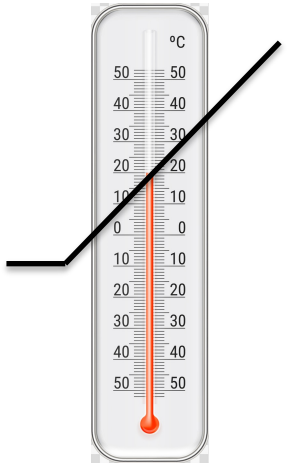
- A.22 Examples of use of *symbols* 5.2.11 – 5.2.14 in conjunction with *symbols* 5.2.1 – 5.2.5, 5.2.9 or 5.2.10

- A.23 how deal with multiple *symbols* used together
  - *symbols* AR (EC REP), *Importer*, *Distributor*, Translation, or Repackaging all have notes indicating the same responsible entity doesn't need to duplicate their name & address. So, A.23 shows many ways to lay out in groups of 2, 3, 4, & 5 symbols with 1 name & address



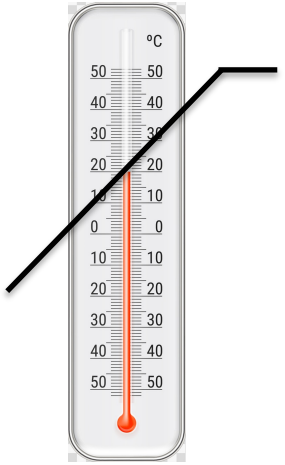
Annex A - Changes

- Deleted the temperature limit examples out of Annex A for Symbols from Table 1 - Representations only below



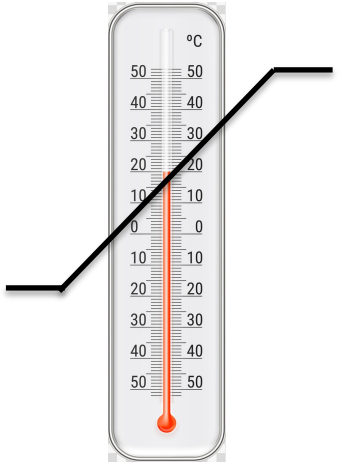
5.3.5

ISO 7000-0534



5.3.6

ISO 7000-0533



5.3.7

ISO 7000-0632

OTHER CHANGES

Changes in Consult instructions for use & Caution – Existing Symbols (15223-1)

- If use consult IFU as primary risk control measure for a specific risk control measure (e.g., IFU has safety info) per ISO 20417:21 either (ISO 7010-M002) or text of mandatory action to read IFU.
  OR use [ISO 20417:21, Cl. 6.1.5; ISO 15223-1:21 for 5.4.3 Note 2 refers to ISO 20417 & ISO 7010-M002; IEC 60601-1:05+A1:12+A2:20, Cl 7.2.3 except no text option]
- Caution – (5.4.4)

  - Not to be used solely for Consult IFU. Use an option above
  - Always has been a safety caution not for consult IFU but was used incorrectly

Other Change

- New (Informative) Annex C → Terminology Alphabetized index of defined terms

WHAT'S IN THE FUTURE?

Potential for next revision

- Would need to be validated per ISO 15223-2
  - # of cycles reprocessed
  - Low temp steam & formaldehyde sterilization
  - QTY for quantity
  - 5.7 *Symbols* that look male make gender neutral or ½ male / ½ female
  - 5.7.3 ? → not clear about data to enter. Change *symbol* to make clearer
  - Symbol to identify a system, procedure pack or convenience kit producer
- Consider adding to symbols list for ISO 15223-1 for next revision
  - ISO 7000-1640 – Technical manual; manual for service
  - ISO 7000 registered exempts ISO 15223-2 validation (4.1 a)

Contact Us

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