Sign, Sign Everywhere a Sign
Making Sense of Graphic Symbols on Medical Device Labeling

Learning Objectives
• Explain the need for various signs and symbols used in medical device labeling.
• Describe the meaning behind symbols found on medical device packaging, instruments and equipment.
• List resources available that help identify the requirements and definition for commonly used symbols.

Objective 1
Explain the need for various signs and symbols used in medical device labeling.

Why So Many Symbols?
World wide marketing
• Communicate important information globally
  • Internationally recognized symbols
    • Graphics, Pictograms, or Icons
Many Languages

So Many Symbols

- Applicable to a broad spectrum of devices
- Can be found
  - On the device itself,
  - On the package, or
  - In the associated documentation (IFU)

Easily Defined?

What's That Sign?
What’s That Sign?

ANSI/AAMI/ISO 15223-1:2012

Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied –

Part 1: General requirements

Who is ANSI?

• American National Standard Institute
  • Organization
  • Officially represents the US in international standards-setting
  • Coordinates the development and promotion of all US standards
  • Approves AAMI standards as American National Standards
  • Sit on International Standards Committees (ISO)

WHO IS AAMI

Association for the Advancement of Medical Instrumentation
Purpose of AAMI

- Assist health care professionals and industry in US and abroad with the:
  - Use
  - Acceptance, and
  - Advancement of medical technology

- Includes developing sterilization practices for healthcare facilities as well as industrial sterilization practices

AAMI Organization

- Nonprofit organization
- Founded in 1967
- Nearly 6,000 members around the world
- Common goal of members
  - Increase understanding and beneficial use of medical instrumentation

AAMI Organization

- Recognized as the foremost voluntary standards-setting organizations in the US
- AAMI Standards and Recommended Practices represent a national consensus

International Organization for Standardization (ISO)

- Founded in 1947
- Develop and publish international standards through global consensus
  - Help to break down barriers to international trade
- Publish more than 19,500 International Standards in aspects of technology and business
  - Food safety,
  - Computers,
  - Agriculture, and
  - Healthcare

http://www.iso.org/iso/home.htm
Harmonized Standards

• So far, only a few AAMI medical device manufacturer standards have been harmonized with ISO

• Why?
  ✓ Health care facilities standards have not been harmonized because of major differences in sterilization practices between the US and parts of Europe

Harmonized Standard Example

ANSI/AAMI/ISO 11140-1:2005 (R) 2010

• Sterilization of health care products—Chemical Indicators—Part 1: General requirements

• Specifies performance requirements for indicators that show exposure to sterilization processes by means of physical and/or chemical change of substances

Harmonized Standard Example

ANSI/AAMI/ISO 15223-1:2012 Medical devices—Symbols to be used with medical device labels, labeling, and information to be supplied—Part 1: General requirements.

• Identifies requirements for the development and use of symbols that may be used to convey information on the safe and effective use of medical devices.
  • It also lists symbols that satisfy the requirements of this part of ANSI/AAMI/ISO 15223.

Terms and Definitions

Section 3

3.2 description
normative text which defines the purpose, application and use of the symbol

3.3 label
written, printed, or graphic information provided upon the medical device itself

3.5 symbol used in medical device labeling
  graphical representation appearing on the label and/or associated documentation of a medical device that communicates characteristic information without the need for the supplier or receiver of the information to have knowledge of the language of a particular nation or people

ANSI/AAMI/ISO 15223-1:2012 Medical devices—Symbols to be used with medical device labels, labeling, and information to be supplied—Part 1: General requirements.
Section 4.2
Requirements for usage

- Symbols shall comply with graphical ISO 7000 with respect to dimensions, line thickness, orientation and shaded areas. (Table 1 symbol graphics)

- Important that symbols are used properly. (Annex B: guidance on usage)

- Manufacturer shall ensure that no additional risk is incurred by using symbol.

ANSI/AAMI/ISO 15223-1:2012 Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied – Part 1: General requirements.

Objective 2
Describe the meaning behind symbols found on medical device packaging, instruments and equipment.

Table 1
Symbols convey information essential for proper use

Symbols categorized in sections
- 5.1 Manufacturer
- 5.2 Sterility
- 5.3 Storage
- 5.4 Safe Use
- 5.5 IVD (in-vitro-diagnostic)
- 5.6 Transfusion
- 5.7 Other

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### Table 1
Symbols to convey information essential for proper use

<table>
<thead>
<tr>
<th>Reference number or symbol</th>
<th>Title of symbol</th>
<th>Description of symbol</th>
<th>Requirements</th>
<th>Note</th>
<th>Restrictions for use</th>
<th>Additional requirements</th>
<th>ISO/IEC Reg. no</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.2 Sterility</td>
<td>Sterile</td>
<td>Indicates a medical device that has been subjected to a sterilization process.</td>
<td>date of manufacture, lot number</td>
<td>In Europe, this symbol is restricted to use on terminally sterilized medical devices (14 of EN 556-1:2001 applies, including its associated note).</td>
<td>2499</td>
<td>2469</td>
<td></td>
</tr>
</tbody>
</table>

ANSI/AAMI/ISO 15223-1:2012 Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied – Part 1: General requirements.

### Manufacturer Symbol Examples

**Date of Manufacturer**
- Accompanied the date of manufacture
  - Expressed as:
    - four digits for the year, and where appropriate,
    - two digits for the month, and
    - two digits for the day.

**Manufacturer Symbols**
- Use by date
  - Accompanied by a date devices should be used by

**Batch code (lot number)**
- LOT ABC123
  - Accompanied by the manufacturers batch code

**Catalog number**
- REF ABC123
  - Accompanied by the catalog number

**Serial number (specific identification for medical device)**
- SN
  - Accompanied by the serial number

### Storage Environment Limitations Examples

**Keep away from sunlight (or heat)**
- Indicates a medical device that needs protection from light sources.

**Protect from heat and radioactive sources**
- (or sunlight and radioactive sources)
Storage Environment Limitations

Keep dry (or away from rain)
• Indicates a medical device that needs to be protected from moisture.

Humidity limitations
• Limits of humidity are indicated adjacent to the horizontal lines.

Storage Limitations

Atmospheric pressure limitations
• Indicates the range of atmospheric pressure to which the medical device can be safely exposed.

- kPa - Kilopascals. A metric unit used to measure pressure. 1 Kilopascal equals 1000 pascals, and approximately 0.1450 psi.
Safe Use Examples

• 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:  
    • Single use
    • Use only once

• Do not re-sterilize
  • Indicates a medical device that is not to be re-sterilized.

Safe Use Examples

• Single patient use
  ✔ Use indicated for one patient only
  ✔ No multiple patient use

Sterility Examples Package Cautions

Do not use if package is damaged
  • Device should not be used if the package has been damaged or opened.

Sterility Examples Package Cautions

Non-sterile
  • Device has not subjected to a sterilization process.
    • Used to distinguish between devices sold in sterile and non-sterile conditions.
Sterility Examples

- Sterilized using aseptic processing techniques
- Sterilized using ethylene oxide
- Sterilized using irradiation
- Sterilized using steam or dry heat

Safety Signs

- No Pushing
- No sitting
- No stepping on surface

Product must be collected separately. Do not dispose of as unsorted municipal waste. Contact local distributor for disposal information.
Safety Signs
- Warning electricity
- Dangerous voltage
- Emergency stop

Dentistry equipment
- Dental turbine air motor with illumination
- Dental turbine low voltage electric motor with illumination

Dentistry equipment
- Water-cooling
- Air-cooling

Biological and Biohazard
Biological Risk
- 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.
- Use eye protection.
Storage, Cautions, and IFU Examples

- Caution, consult accompanying documents
  - Information needed for the proper use of the device

- Consult instructions for use (operating instructions)
  - Information needed for the proper use of the device

Fragile, handle with care
- Indicates a medical device that can be broken or damaged if not handled carefully.

Packaging Examples

- CE mark
  - Product conforms with the essential requirements in the European Medical Devices Directive 93/42/EEC.

- Do not open packaging using a knife/blade

Recyclable
### Safe Use Examples

- Contains or presence of natural rubber (latex)
  - Indicates the presence of natural rubber (not synthetic rubber) or dry natural rubber latex as a material of construction within the medical device or the packaging of a medical device.

- Product does not contain natural rubber (latex)

- Latex Free

- Irritant – May cause inflammation to the skin or other mucous membranes

### IVD–specific Examples

- In vitro diagnostic medical device
  - Intended to be used as an in vitro diagnostic medical device.

In vitro diagnostics are tests that can detect diseases, conditions, or infections. Some tests are used in laboratory or other health professional settings and other tests are for consumers to use at home. FDA

### IVD–specific Examples

- Control material intended to verify the performance characteristics of another medical device.

- Control intended to verify the results in the expected negative range.

- Control intended to verify the results in the expected positive range.

### Transfusion/Infusion Examples

- Sampling site (processing application)
  - Not the site on the patient where samples are taken

- Fluid path
  - Indicates the presence of a fluid path.
Transfusion/Infusion Examples

- Non-pyrogenic
  - Indicates a medical device that is non-pyrogenic.

- Pyrogen - a fever-producing substance.

Transfusion/Infusion Examples

- Drops per milliliter
  - 20 is the example – replaced by appropriate number of drops

- Liquid filter with pore size
  - Contains a filter of a particular nominal pore size
  - 15 is the example used

Transfusion/Infusion Examples

- One-way valve
  - Allows flow in only one direction

Other Example

- Patient number
  - Indicates a unique number associated with an individual patient
Objective 3

List resources available that help identify the requirements and definition for commonly used symbols.

ISO Symbols are Everywhere

ISO graphical symbols help us every day. Find out how!

http://www.iso.org/iso/graphical-symbols_booklet.pdf

Everyday ISO Symbols

- Accessible elevator
- Way out or exit
- Evacuation assembly point

http://www.iso.org/iso/graphical-symbols_booklet.pdf
Everyday ISO Symbols

- Fire alarm
- Emergency exit
- Hospital

http://www.iso.org/iso/graphical-symbols_booklet.pdf

One of my favorite international signs!

http://www.iso.org/iso/graphical-symbols_booklet.pdf

Everyday ISO Symbols

- Slippery surface
- Not drinking water
- No access for persons with pacemakers

http://www.iso.org/iso/graphical-symbols_booklet.pdf

Resources

- ANSI/AAMI/ISO 15223-1:2012 Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied – Part 1: General requirements.
- ANSI/AAMI/IEC TIR60878:2003 Graphical symbols for electrical equipment in medical practice
- ISO 11140-1:2005 Sterilization of health care products - Chemical indicators - Part 1: General requirements
Other Online Resources

- [http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm085604.htm](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm085604.htm)

New AAMI Documents Being Developed

- New Technical Information Reports (TIR) being developed
  - Human Factors for Medical Device Reprocessing
  - Endoscope Reprocessing
  - Standardized Instructions for Use

- TIR is not a recommended practice
  - Review of an important technical issue or health care practice, and
  - Statement of expert opinion released by a technical committee

Other New AAMI Resources

- Sterile Processing Benchmarks (SPB)
  - Web-based tool
  - Partner with IAHCSMM

- Sterile Processing In Healthcare Facilities: Preparing for Accreditation Surveys (Rose Seavey)

- Building for the Future: Construction and renovation of Sterile Processing Facilities (Cyndie Haldeman)

- Leading Practice Integrated Process Flow and Automation in the Modern Central Sterile Supply Department (Mark Duru)

Questions!