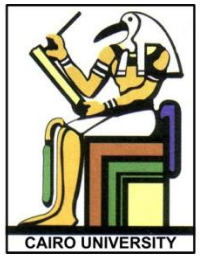

HUMAN FACTORS ENGINEERING: DESIGN OF MEDICAL DEVICES

Lecture 5

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Signs, Symbols, and Markings

- Proper labeling can have an enormous impact on how a user interacts with a device by increasing intuitiveness, minimizing required training, and ensuring accurate performance.
- Properly designed labeling presents users with instructions, identifications, markings, symbols, colors, and commands that they already know or can easily intuit.
- Labeling of medical devices and associated accessories, shipping containers, and wrappings
  - applies to labels, symbols, demarcation lines, shading, positioning, formatting, and markings related to the controls, displays, connectors, and other features of a medical device.
- Labeling should be the absolute last resort for protecting users from potential risks.

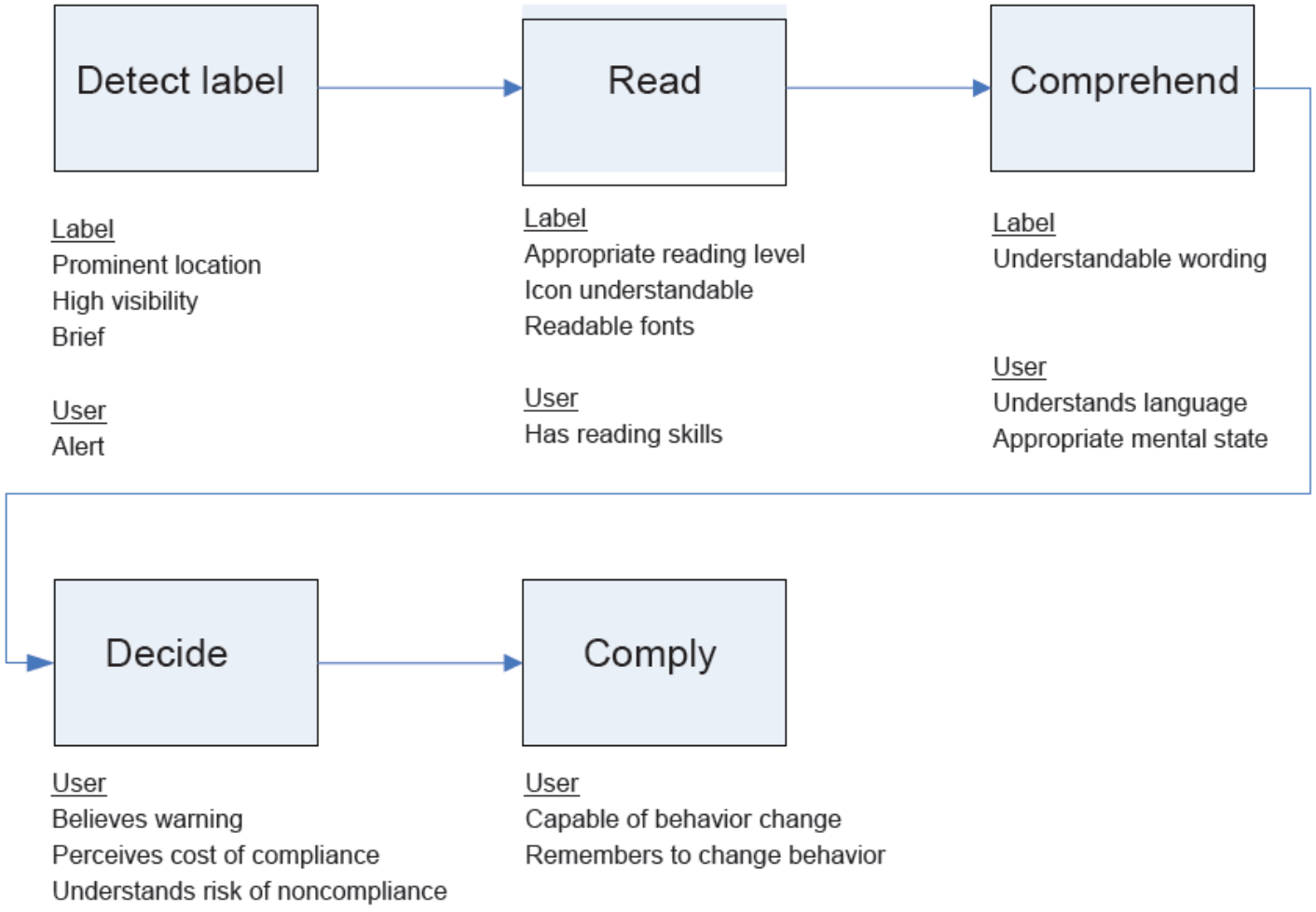
General Considerations

- All equipment elements that are not intuitively obvious, that have some usable functions, or that require identification for other reasons should be labeled or marked.
- Markings should be positioned so that they are clearly associated with the correct equipment feature and not obscured by hand positions or equipment components.
- Appropriate markings can enhance the identification of both individual elements and their functional relationships.
- Labels should be visible at typical viewing distances and angles.

General Considerations

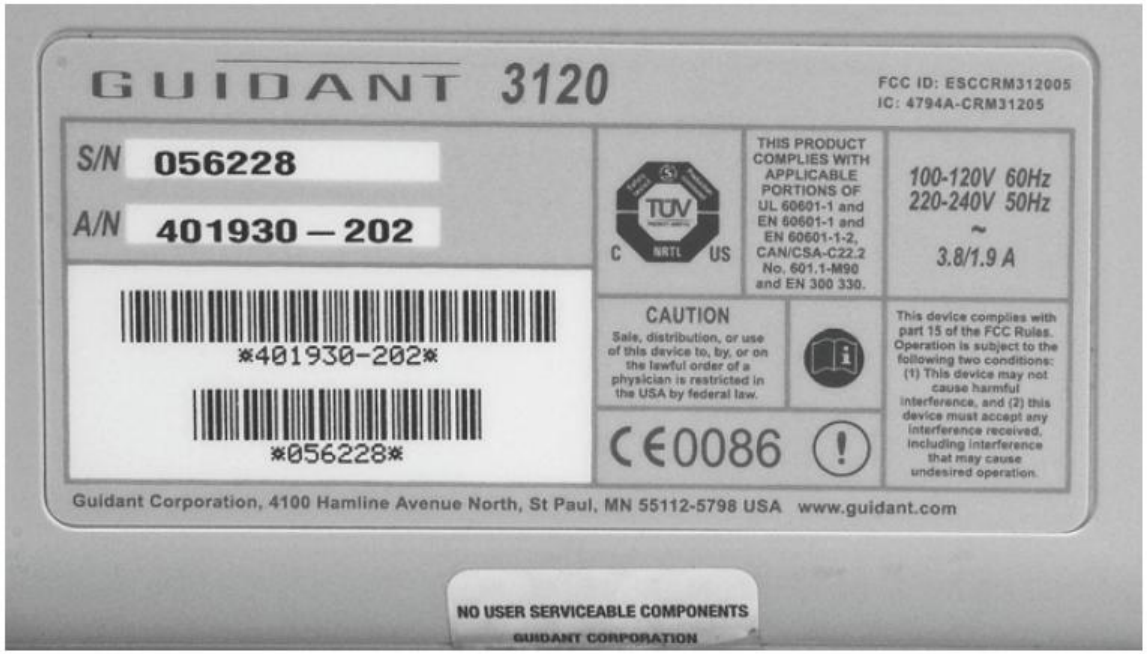
- Labels should be resistant to wear and tear.
- Ambiguous symbols, codes, or terminology should be avoided.
- Designing for legibility requires careful analysis of ambient illumination in typical use environments.
- Consistency of placement, terminology, and coding is critical.
- All markings should be tested with typical users. Users can be clinicians, caregivers, patients, or maintenance personnel and can vary by age, disability, and other characteristics.

Label Design Model



Design Guidelines

- Labels for equipment identification
  - At a minimum, provide the name or trade name of the manufacturer, a distinctive catalog or model number, and the electrical rating
  - Positioning of nonfunctional markings (e.g., logo) should not distract from or compromise the clear presentation of other information

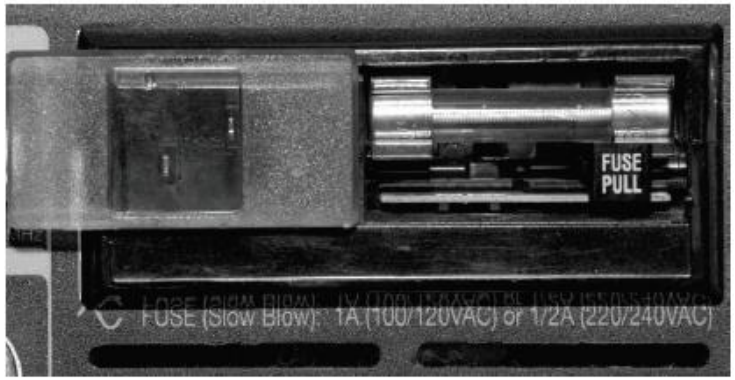


Design Guidelines

- Descriptions of equipment functions
  - Should be located outside the primary display area.
- Hazard labels
  - Hazards categorized as (a) death or irreversible injury, (b) reversible injury, and (c) minor injury or discomfort.
  - Used to alert personnel to possible hazards that could be encountered during the use, handling, storage, or repair of a device.

Design Guidelines

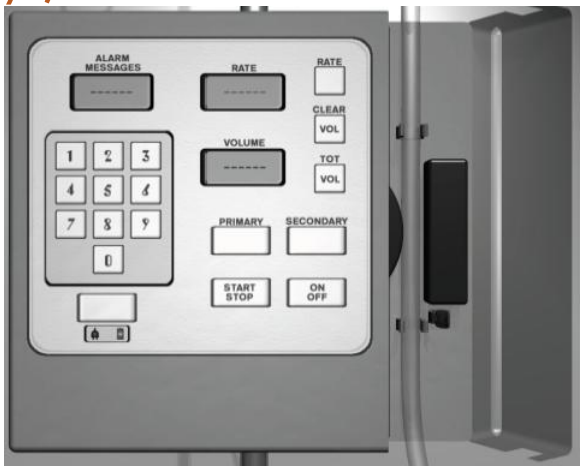
- Electrical receptacle and connector labels
  - Receptacles and connectors should be marked with their power rating and the intended function or connecting cable
  - Convenience receptacles should be labeled with the maximum allowable load in amperes or watts
- Fuse and circuit-breaker labels
  - permanently marked adjacent to the fuse holder
  - legible in the ambient illumination anticipated



Design Guidelines

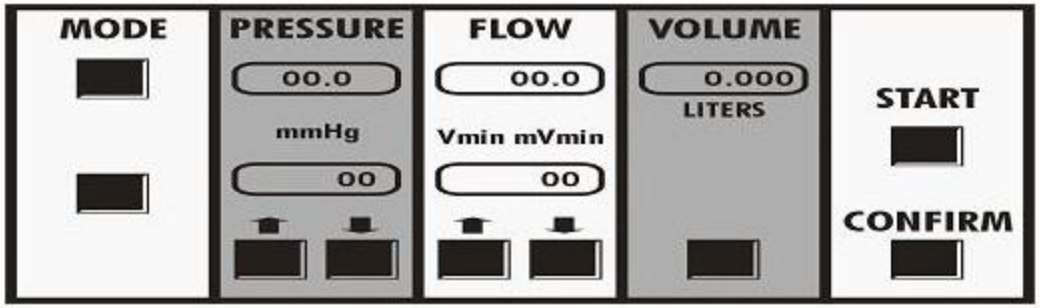
- Labels on controls, keyboards, and keypads
  - Intended to facilitate identifying, locating, and functionally grouping user display and control components.
  - Markings of control positions are also important to users when they adjust mechanical controls and read mechanical displays
- Positioning and mounting of labels
  - Placed near above panel elements, panel displays, or flow lines that users grasp, press, follow, or otherwise handle
  - positioned for visibility and readability

    from typical viewing angles
  - separated by sufficient space



Design Guidelines

- Label orientation
  - Labels should be oriented horizontally so that they can be read quickly
- Indications of functional relationships
  - "Location aids" such as demarcation, color coding, background shading, mimics, and flashing lights can be used to indicate the positions of, and relationships between, functionally related controls, displays, and other features.
  - Redundant if necessary to ensure reliability

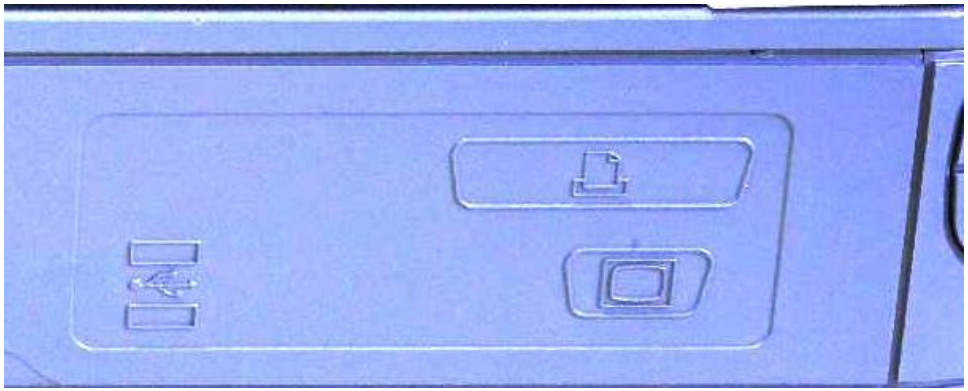


Design Guidelines

- Permanence and durability of labels
  - Markings should be permanent and should remain legible throughout the intended life of the equipment under anticipated use and maintenance conditions.
  - Durability is of special concern for controls like keypads and pushbuttons because constant use can lead to wear.
  - Etched molding

Specific Design Guidance

- Consistency
  - Wording, symbology, coding, and all other aspects of labeling should be consistent within devices and systems.
- Label content
  - Clarity, consistency, and brevity of label information are critical
- Use of symbols
  - ANSI/AAMI/IEC TIR 60878

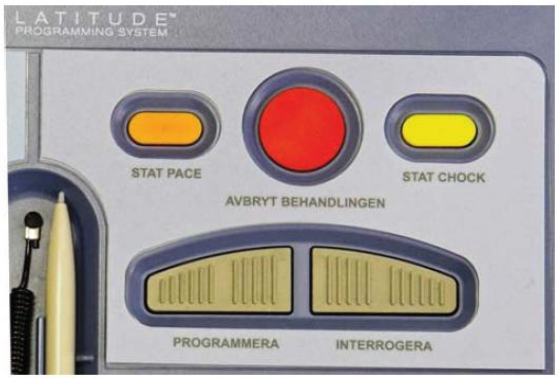


Specific Design Guidance

- Legibility
  - Contrast, lettering, character height (refer to Ch. 6)
  - Assessed under worst-case viewing conditions (i.e., max intended viewing distance and angle, worst-case lighting, and min exposure time)
- Coding
  - Refers to use of shapes, colors, symbols, or other attributes that have established meanings or associations for a given user population.
  - Facilitates quick, accurate identification of controls, displays, connector ports, and other features.
- Application of color to mimics and flow lines
  - Different colors with sufficient contrast
  - Lines depicting the flow of the same contents (e.g., blood, oxygen) should have the same color throughout the system

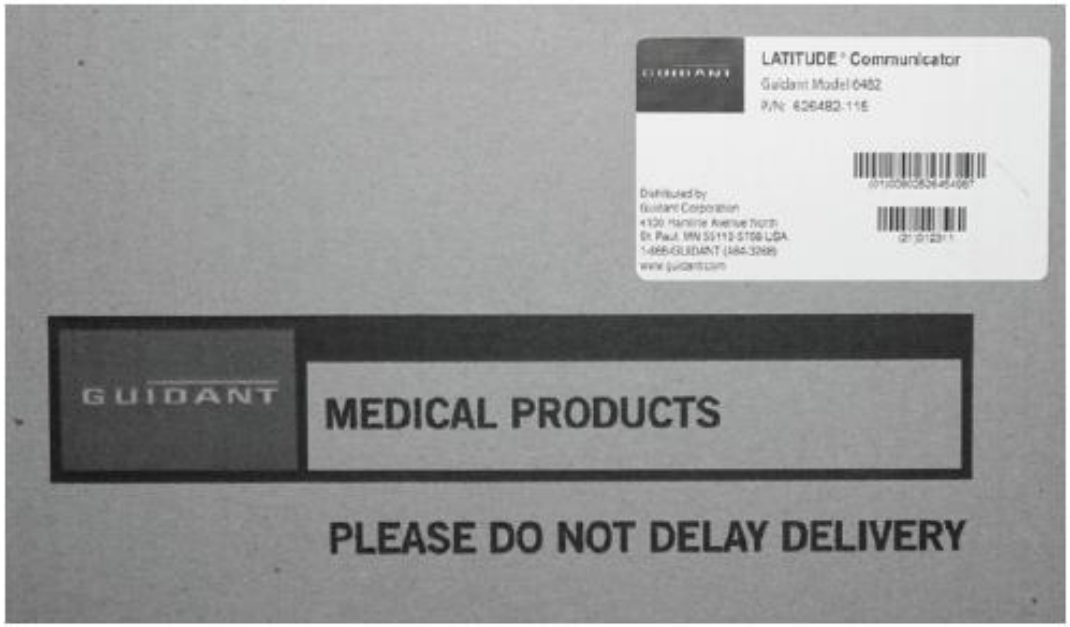
Specific Design Guidance

- Flow lines
  - Symbols for equipment integrated into flow paths (e.g., pumps, filters, valves) should be used consistently.
  - Different line widths can be used to code flow paths (e.g., significance, volume, level) and should not overlap.
  - Distinctive arrowheads should clearly identify flow directions.
  - Origin and destination (or terminal) points should be labeled
  - Component representations (e.g., graphics) on flow lines should be identified with words or abbreviations as well.
- Language
  - Intended user language



Specific Design Guidance

- Package labels
  - Should provide the product and model names and the name and business address of the manufacturer, packer, or distributor.
  - Should also describe shipping and storage requirements.



Specific Design Guidance

- Hierarchical schemes
  - Largest labels identify major systems or workstations, whereas smaller, subordinate labels identify subsystems or functional groups.
  - System or workstation labels are about 25% larger than subsystem or functional-group labels.
  - Subsystem or functional-group labels are about 25% larger than component labels.
  - Component labels are about 25% larger than control-movement information or position identifiers.

Covered Material

- Chapter 10