Human Factors Aspects of Medical Devices (Chap. 13, pp. 543-593). In M. Weinger, M. Wicklund, & D. J. Gardner-Bonneau (eds.). 2011. Boca Raton, FL: CRC Press.

13 Signs, Symbols, and Markings

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CONTENTS

Recent advances in medicine, science, and technology have led to a considerable and growing number of medical devices. Technical innovations have generally been welcomed by health care providers and the general public. However, technological sophistication does not necessarily mean that such devices can be used effectively and safely by users. Medical device use has been shown to be associated with hazards to patients and clinicians. Virtually all medical devices include labels and markings. Labels can assist users in correctly operating a device and at the same time reduce the likelihood of use error.

Medical device use environments have expanded beyond doctors' offices and hospitals to outpatient, community, and home care. The intended users have broadened from trained medical professionals (e.g., physician, nurse, or other health care provider) to include lay patients and caregivers. A variety of users and use environments require different ways

of presenting information. Designers must consider multiple use-related factors to design appropriate labels.

Medical device labeling consists of directions on how to use and care for medical devices as well as information necessary for ensuring users' understanding and safety, including information about risks, precautions, and potential adverse reactions. This chapter provides guidance to designers for their decisions regarding positioning, formatting, and designing of labels and markings for controls, displays, panels, and associated equipment. The information presented here is derived from legal requirements, human factors research, and existing practices.

The chapter is divided into three sections, organized around key design issues. The first section addresses the critical issue of what should be labeled and focuses on the specific legal requirements and voluntary standards that guide medical device labeling in the United States. The second section is an overview of relevant principles from the human factors literature that designers should consider when making labels for a medical device. This section uses a communication-human information processing (C-HIP) framework as a means of organizing the labeling literature. Designers can use this conceptual model as a developmental tool, and investigators can use it as an analytical tool. The third section provides specific recommendations for developing effective medical device labels. Examples of label designs across a range of medical devices are presented. In general, designers need to consider numerous factors in deciding how to label a device. Label characteristics that should be considered include color, anticipated viewing distances and illumination levels, time constraints of users, and understandability criteria, among many others. Labels on medical devices should appropriately attract and hold attention, be understandable and believable, and motivate users to comply with the directives they present. In addition, designers should take into account local conventions and meanings associated with specific markings as well as the reading abilities, visual acuity, and other relevant characteristics of the user population. For example, older adults and people with disabilities have different medical device labeling needs compared to health care professionals. Controls, displays, and other components of medical devices should be appropriately and clearly labeled to permit rapid and accurate human performance.

The importance of gathering user input—to meet the needs of users—when designing medical device labels is emphasized. The general principles of usability testing as it relates to the evaluation of medical device labeling, including the basic processes involved in iterative design and testing, is detailed in Chapter 6, "Testing and Evaluation."

13.1 WHAT SHOULD BE LABELED?

This section reviews the regulations for medical device labeling.

13.1.1 Who Sets the Rules?

In the United States, medical device labeling is regulated by the Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA), a part of the U.S. Department of Health and Human Services. The regulations for medical device labels are provided in the Code of Federal Regulations (CFR). Title 21 of the

CFR concerns food and drugs, and medical device labeling is discussed in Part 801 (Title 21—Food and Drugs). According to the FDA, a *label* is "a display of written, printed or graphic matter upon the immediate container of any article." *Labeling*, a more inclusive term, is defined as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such an article."

In Europe and some other parts of the world, medical device labeling is governed by regulations established by the European Economic Area (EEA) (Study Group 1 of the Global Harmonization Task Force, 2002 http://www.ghtf.org retrieved 7/3/09). Products that meet these requirements receive a stamp of approval termed the "CE mark" that allows them to be marketed in European Union (EU) countries (refer to Figure 13.1). EU products do not have to be evaluated by a third party to receive the CE mark (see Underwriters Laboratories, Inc., n.d.). Instead, the mark is provided contingent on the manufacturer's word that the device meets the necessary requirements. This chapter focuses primarily on legal requirements for medical devices manufactured, distributed, and sold in the United States, but some of the similarities and differences between the FDA's and EU's regulations for medical device labeling are noted at various points.

In addition to legal requirements, there are also voluntary standards relevant to various aspects of medical device labeling, including those established by the International Organization for Standardization (ISO), the International Electrotechnical Commission (IEC), and the American National Standards Institute (ANSI), particularly the ANSI Z-535 standards relating to the design of product safety warnings.

In 1992, a voluntary group of representatives from national medical device regulatory authorities throughout the world formed the Global Harmonization Task Force (GHTF; see http://www.ghtf.org). Since its inception, the GHTF has worked to enhance the safety, effectiveness, performance, and quality of medical devices; to promote technological innovation; to achieve congruence in regulatory practices; and to facilitate international trade. The GHTF also serves as an information source that countries with medical device regulatory systems under development can use to guide their efforts. The GHTF's principles for labeling include informing the user of the following:

- A device's identity and intended use
- Instructions for use, maintenance, and storage
- Risks and warnings

In addition, the GHTF has a goal of promoting symbols as a way to communicate information to international audiences appropriate to users' technical knowledge, experience, education, and training.

FIGURE 13.1 Products that meet requirements established by the EEA receive a stamp of approval, termed the "CE mark," that allows them to be sold and marketed in EU countries.

13.2 GENERAL LABELING REQUIREMENTS

The guidelines below will help medical device manufacturers follow various regulations and industry standards that govern medical device labeling. The categories for these requirements include the following:

- *Content* of labeling, such as identity statements, instructions of use, and model numbers
- *Form* of this labeling, including completeness, language, and conspicuity
- *Location and size* of the labels on medical devices

Additional labeling requirements apply to nonprescription, also called over-the-counter (OTC), medical devices. Given the rapid proliferation of both prescription and nonprescription medical devices for use at home by laypersons, designers should consider the abilities and limitations of users with respect to label design.

13.2.1 Label Content

The following guidelines pertain to the design of medical device labels.

13.2.1.1 Identity Statement

Guideline 13.1: Identity of Manufacturer

Both the EEA and the FDA require that medical device labels contain the name, or trade name, of the manufacturer, packer, or distributor, including the complete address (21 CFR 801.1) (see Figure 13.2). The FDA allows that if the name and address of the manufacturer are available in a local phone directory, the address may be omitted from the label.

Guideline 13.2: Identity of Other Entity

When a device is not manufactured by the entity whose name appears on the label, the name must be modified by a phrase that reveals the connection the entity has with the device. For example, if one company manufactures the device for another company, the label might read, "Manufactured for X company by Y company."

Guideline 13.3: Identity of Importer

In addition to having information that identifies the manufacturer of the device, the labeling of a device marketed in the EU must include the name and address of the person or party responsible for importing the device into the EU.

Guideline 13.4: Catalog or Model Number

Medical devices must contain a label indicating the device's distinctive catalog or model number.

Guideline 13.5: Electrical Rating

Labeling must include the device's electrical rating.

For nonprescription (OTC) devices, FDA- and CE-marked devices must contain identity statements that include both what the device *is* and what it *does* (refer to Figure 13.3). The

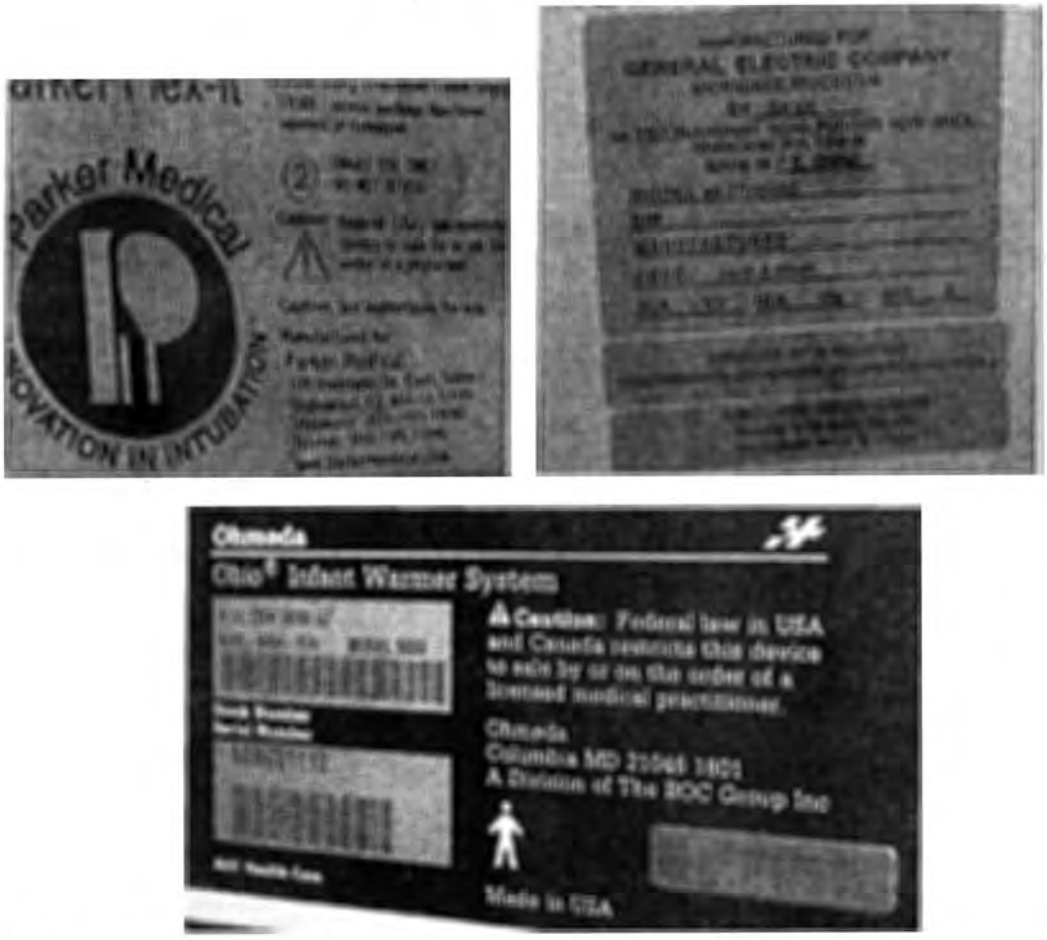


FIGURE 13.2 Both the EEA and the FDA require that medical device labels contain certain information on medical devices, including the name of their manufacturer, including their complete address, and the device's distinctive catalog or model number and electrical rating.

FIGURE 13.3 For nonprescription (OTC) devices, FDA- and CE-marked products must contain identity statements that include what the product is and what the product does.

requirements of a CE-marked device are very similar to those of devices regulated by the FDA (Council Directive 93/42/EEC concerning Medical Devices, 1993). Additional details concerning specifics on nonprescription (OTC) medical device labeling can be found in U.S. 221 CFR 801.

Guideline 13.6: Identity

Labeling on nonprescription (OTC) medical devices and their packaging must include a statement that provides the identity of the device (i.e., what it *is*). The identity statement should be printed in boldface type and should be in text reasonably similar in size in relation to the most prominent text on the panel.

Guideline 13.7: OTC Label Indicates Use

The next part of the identity statement should tell users what the nonprescription (OTC) device does (21 CFR 801.61).

Guideline 13.8: Instructions for Multiple Uses

If a nonprescription (OTC) medical device has multiple uses, instructions for each of the uses must be included with the device.

Guideline 13.9: Device Serial Number

CE-marked nonprescription (OTC) medical devices must be labeled with either the serial number or the word "lot" followed by a batch code of its manufacture. The FDA requires the presence of a control number on each unit, lot, or batch of devices if the device will be used to sustain life or is intended for surgical implantation.

Guideline 13.10: Custom-Made OTC Devices

Custom-made nonprescription (OTC) medical devices must be marked with the phrase "custom-made device."

Guideline 13.11: Quantity of Package Contents

The CFR also requires a declaration of the net quantity of contents of the package by weight (pounds and ounces), numerical count, measure (size), or a combination of the three on labeling of nonprescription (OTC) devices in package form (see 21 CFR 801.62). Metric equivalents should be provided as applicable.

13.2.1.2 Use Statement

While all medical devices should be accompanied by a use statement, the elements of which are described below, this information does not need to appear in on-device labels. Such information more often appears on device packaging or in the instructions for use.

Guideline 13.12: Provide Instructions for Use

Manufacturers are required to provide instructions that allow the device to be used safely for its intended purpose by its intended users (21 CFR 801.4-5).

Guideline 13.13: Foreseeable Alternative Uses

If there is a reasonable probability that a particular medical device will be used for purposes other than those originally intended, then the manufacturer must provide labeling discussing these alternative uses.

Guideline 13.14: Complete List of Uses and Use Conditions

For FDA approval, the directions for use must state all of the device's intended uses as well as all of the conditions under which the device should be used. For devices produced or marketed in the EU, the GHTF recommends that the instructions be sufficiently thorough to allow consumers to use the device safely.

Guideline 13.15: Duration of Use and Manufactured Date

Duration of use should be specified. Devices with a CE mark must include label information that indicates the date after which the device should no longer be used. If an expiration date does not apply to a particular device, then the year the device was manufactured must be provided on the label. FDA-recognized symbols for date of manufacture and expiration date are shown in Figure 13.4.

Guideline 13.16: Timing of Use

If appropriate to device use, the time of administration in relation to other factors (e.g., a meal, another treatment) must be indicated.

Guideline 13.17: Methods of Use

The instructions should include the route and/or method of application and any other preparations that are necessary before the device can be used. Labels on devices marketed in the EEC must also state any special handling instructions.

Guideline 13.18: Frequency of Use

For certain devices, instructions must include the dosing schedule for each use (e.g., "apply to affected area twice per day"), including the usual quantity and frequency for people of different ages and different physical states.

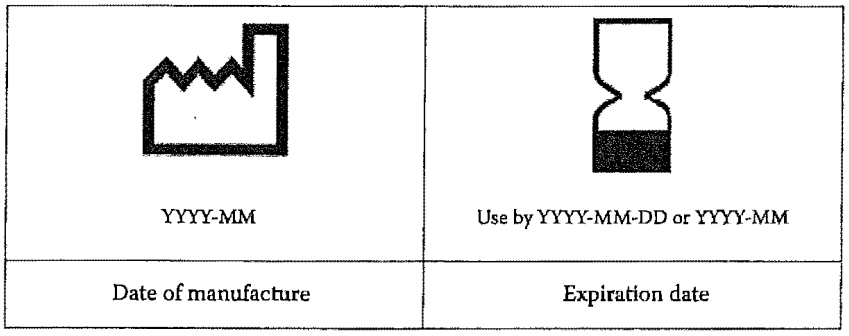


FIGURE 13.4 The symbol on the left is used by the ISO to depict "date of manufacture," while the one on the right is used to list a device's expiration date.

13.2.1.3 Handling Statement

GUIDELINE 13.19: STORAGE

Devices that have a CE mark must have a label that indicates any special storage instructions (see Council Directive 93/42/EEC concerning Medical Devices, 1993).

GUIDELINE 13.20: STERILIZATION INSTRUCTION LABELING

Medical device labels in the EU must include the appropriate method of sterilization, if necessary. Nonprescription (OTC) medical devices that must remain sterile to be used for their intended purpose must include information specifying the part of the device that must remain sterile prior to use (21 CFR 801.10). The EU counterpart for medical devices that must be used under sterile conditions requires that labeling include the word "sterile" and the appropriate method of sterilization directly on the CE mark label (see Figure 13.5).

13.2.1.4 Warning/Precaution Statements

GUIDELINE 13.21: WARNINGS FOR SAFE USE

Warnings or precautions required to ensure safe use must be included on a device or its accompanying labeling (Council Directive 93/42/EEC concerning Medical Devices, 1993; 21 CFR 801.5).

GUIDELINE 13.22: FORESEEABLE RISKS

The GHTF recommends that manufacturers warn intended users of any risks that are reasonably foreseeable. For example, labeling would indicate that radiation may be emitted from a device or that there is the potential for electromagnetic interference from other equipment.

It is noteworthy that the EEA and the FDA have adopted similar positions concerning the use of warnings on nonprescription (OTC) medical device labeling.

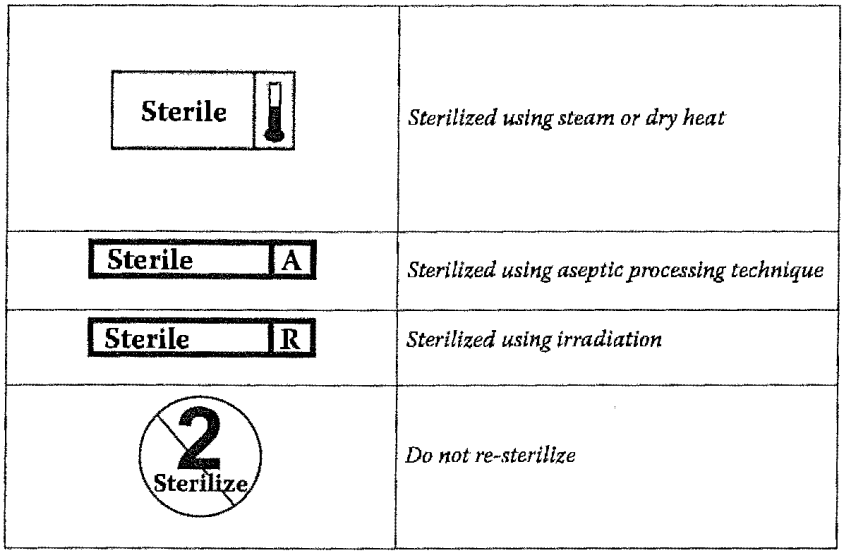


FIGURE 13.5 These labels show examples of FDA-recognized symbols used to specify the medical devices that must remain sterile for their intended use as well as the appropriate methods of sterilization, such as steam or dry heat, aseptic processing, radiation, or a chemical process.

FIGURE 13.6 Clear labeling with text about specific hazards can help reduce the likelihood of user error and injury.

13.2.1.5 Specific Hazards Statements

Guideline 13.23: Specific Hazards

According to the FDA (2000), device labeling must identify specific hazards associated with OTC medical devices and warn users of these hazards (refer to Figure 13.6). Additional considerations for dealing with specific hazards are described below.

Guideline 13.24: Additional Hazard Information

There is no prohibition against providing additional hazard-related information and warnings on labels when it is warranted. The information provided will depend on the particular medical device and the nature of the hazard. Optimal label content would be revealed by analytic methods described later in this chapter.

Guideline 13.25: Warnings for Specific Risks, Including Latex

The FDA requires specific warnings for some risks. For example, labeling on devices that contain natural rubber latex must contain one of four variants of the following statement (in bold print): "Caution: This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions" (see 21 CFR 801.437 for all four statements). This labeling requirement derives from reports documenting instances in which people have had serious allergic reactions from natural latex proteins in a wide range of medical devices (e.g., Brehler and Kutting, 2001; Dyck, 2000; Zak, Kaste, and Schwarzenberger, 2000).

The importance of specific warnings is further illustrated in injuries from magnetic resonance imaging (MRI) systems, which operate using an intense static magnetic field to generate images. The machine's magnetic field strength, about 100,000 times that of the earth's, has a serious downside—it can pull metal items into its interior. In one instance, a hospital reported expensive damages when a floor buffer left nearby by the janitorial staff was drawn into the machine. Patients can be seriously injured if they happen to be in the path of metal objects, such as scissors and IV poles, under the influence of the magnetic field. Patients have been killed after being struck by oxygen tanks that were magnetically pulled into the opening of MRI machines. In addition, the presence of metallic or magnetized items can adversely affect the proper function of the scanner, resulting in poor-quality images. Warning labels need to be placed not only on the machine itself but also elsewhere in the use environment to warn users and other individuals of the risks before they get too close to the magnet.

13.2.1.6 Investigational Use Statement

Guideline 13.26: Indication of Investigational Situations Device

Labeling for medical devices that are only to be used in investigational situations must contain the statement: "CAUTION: Investigational device. Limited by Federal (or United States) law to investigational use" (see 21 CFR 812.5). In the EEA, devices made for investigational use must include the phrase "exclusively for clinical investigations" on the label to receive the CE mark (Council Directive 93/42/EEC concerning Medical Devices, 1993).

13.2.2 Label Form

Guideline 13.27: Accessibility of Label Information

Label information should be readily accessible but should not interfere with use of the device. This information can be included in the context of labeling claims, advertising, or separate written statements.

Guideline 13.28: Avoid Misleading Statements

Labeling should be worded carefully to minimize the risk of misunderstandings that could lead to misuse of a device and/or injury (refer to 21 CFR 801.6).

Guideline 13.29: Primary User Languages

Labels should be in the primary language of the intended user population (see Figure 13.7). If the medical device is intended for sole use in places where the predominant language is

FIGURE 13.7 When it can be reasonably anticipated that non-English-speaking people will also be exposed to a hazard, text should be duplicated in the secondary language. Symbols and pictorials can also help ensure that people will understand the intended message.

not English (e.g., Spanish), designers may use this language on labeling (see 21 CFR 801.16). Manufacturers, distributors, or other entities are allowed to substitute the predominant language for English when developing the device's labeling.

13.2.3 Location and Size

13.2.3.1 Prominence

The FDA has established requirements that address the issue of prominence of labels on medical devices (21 CFR 801.15). These regulations describe the size and location of labels both on the medical devices themselves and in device packaging.

Guideline 13.30: Conspicuity of Labels

Labels on medical devices must be prominently displayed so that users are likely to notice and read them (21 CFR 801.15). Factors that tend to increase the likelihood that users will notice and read labeling include print size, color, contrast, and sufficient label space. These and other factors are discussed in greater detail in the third section of this chapter.

Guideline 13.31: Avoid Mixing Essential and Unessential Information

Designers should avoid embedding required information within other less important textual or graphic materials. For example, required information should not be placed within a label containing marketing-type information.

13.2.3.2 Principal Display Panel

All mandatory label information on an OTC medical device and its packaging must be placed on the *principal display panel* (CFR 801.60). The term "principal display panel" refers to the part of a device or its packaging that is most likely to be seen by consumers when the device is displayed for retail sale. Frequently, this is the largest available surface area. Regardless of shape (e.g., rectangular, cylindrical, other shapes), the principal display panel must be large enough to accommodate all the required label information without reducing conspicuity or legibility of the information contained therein. Designers should consult 21 CFR 801.60 for specific guidance on how to determine the location and area of the principal display panel. Designers should also follow this guideline for nonprescription (OTC) medical device labels.

Guideline 13.32: Label Text Orientation

In general, label text should be located parallel to the base of the package or to the base of the device during normal use.

13.3 LABELS FOR DEVICE IDENTIFICATION, INSTRUCTIONS, AND HAZARDS

Labels and markings are used on a wide variety of medical device components, including controls, keyboards, keypads, legend switches, displays, and access openings. In this section, the rationale for and general characteristics of such labels and markings are described. Labels and markings on medical devices are frequently used to identify, locate,

and functionally group user display and control components. Markings are also important to users when reading mechanical displays and adjusting mechanical controls. Legends list and/or explain symbols included in labeling. Labels for equipment components need to include certain information in particular formats. The sections that follow describe the design attributes of labels, including markings and legends.

Guideline 13.33: Label Shouldn't Impede Device Use

Labels should facilitate device use. Label size, location, and design should not interfere with device use.

Guideline 13.34: Identification Statement

Medical devices should provide identification information that is readily accessible (refer to Figure 13.2). The identification statement should include the following:

- Name of manufacturer
- Catalog or model number
- Electrical rating (if electromechanical device)

Guideline 13.35: Label Legibility

Labels should be legible to users under expected use conditions.

Guideline 13.36: Label Illumination

Generally, except for devices used routinely under low-ambient-light conditions, labels should be legible without internal illumination.

Guideline 13.37: Hazard Warning Statement

Users and maintenance personnel should be warned of hazards that could be encountered during the use, handling, storage, maintenance, or repair of the device. Examples of key-words for hazard statements are "fire," "radiation explosion," "shock," and "infection."

Guideline 13.38: Statement of Flammability

Electrical medical devices should be labeled to indicate whether they should or should not be used in the presence of flammable substances or oxygen-rich atmospheres.

Guideline 13.39: Label Formatting

Labels should communicate effectively and quickly.

Guidance on label formatting (e.g., Lehto and Miller, 1986; Wogalter, DeJoy, and Laughery, 1999; Wogalter and Vigilante, 2006) can generally be obtained by considering the following:

- Existing law/regulations concerning labels, which have recently been more specific about label format.
- Voluntary standards, such as the most current version of ANSI Z535.4, titled "American National Standard for Product Safety Signs and Labels," which has reasonably good label format specifications.

- Many formatting factors can enhance the effectiveness of labeling, including size, list format, "chunking" through bulleted points, and white space. More information can be found in the literature (e.g., Laughery, Wogalter, and Young, 1994; Wogalter, Young, and Laughery, 2001).

13.3.1 Labels for Electromechanical Components

The specific labeling requirements for electromechanical components of medical devices are derived from standards developed by the IEC. The IEC is an international organization that promotes international standardization in electronics. IEC requirements are widely recognized throughout the world. IEC 60601-1 (XXXX) addresses the general requirements for electromedical devices (see IEC 60601-1, subclause 2.2.15). Examples of devices fitting the definition of electromechanical devices include battery-operated thermometers. MRI and gamma imaging systems, endoscopic cameras, and infusion pumps. Accessories to this equipment can also fall under this standard.

13.3.1.1 Electrical Receptacle and Connector Labels

Guideline 13.40: Functionality

Receptacles and connectors should be labeled with their intended function or connecting cable.

Warning labels that identify specific hazards are particularly important when similar design and compatible receptacles and connectors offer the possibility of misconnecting them. For example, deaths have occurred from the incorrect connection of portable blood pressure monitors to patient IV lines. Manufacturers have issued warning letters describing the hazard, but such after-market notifications are known to be a weak risk mitigation strategy. When possible, the use of specific-shaped connectors that cannot be misconnected is advisable (see Figure 13.8).

Guideline 13.41: Electrical Load Information

Convenience receptacles should be labeled with their maximum allowable load presented in amperes or watts, as shown in Figure 13.9 (see IEC 60601-1).

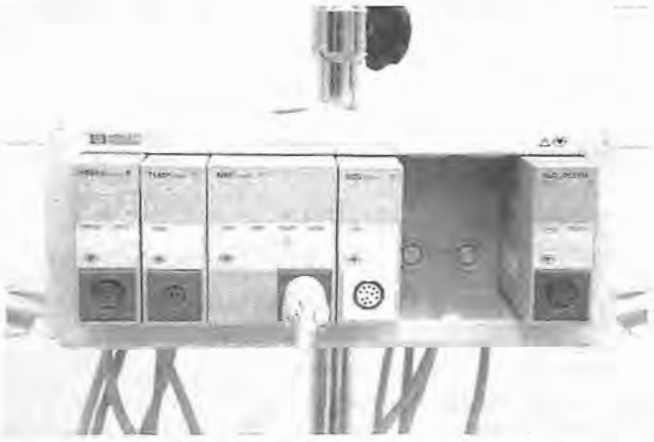


FIGURE 13.8 **(See color insert following page 564.)** The use of specific-shape connectors and color coding can help reduce user error.

FIGURE 13.9 Labels listing voltage load help decrease the likelihood of equipment damage or injury to the people who use or come into contact with medical devices.

Guideline 13.42: Color Coding of Connectors

Distinguishing connectors and having connectors, colors match their respective receptacles can help to avoid misconnections (see Figure 13.10). See Chapter 9, Connections and Connectors.

13.3.1.2 Fuse and Circuit-Breaker Labels

Guideline 13.43: Fuse Rating

The type and current amperage rating of fuses accessible from the outside of the equipment should be permanently marked adjacent to the fuse holder. Fuse ratings should be indicated either in whole number, common fractions, or whole number plus common fractions (see IEC 60601-1).

Guideline 13.44: Spare Fuse Holders

The term "SPARE," printed in all uppercase letters, should be marked adjacent to each spare fuse holder (see IEC 60601-1).

Guideline 13.45: Fuse/Circuit Breaker Legibility

Labeling of fuses and circuit breakers should be legible under ambient lighting conditions expected in the likely environments in which these devices will be used (see IEC 60601-1).

13.3.2 Section Summary

There are numerous legal requirements that manufacturers and other entities must meet with respect to the design of medical device labeling. Manufacturers, distributors, and other

(a)

(b)

FIGURE 13.10 **(See color insert following page 564.)** Color coding can be a useful technique for improving labeling on (a) receptacles and (b) connectors.

persons involved with the design or implementation of medical device labeling should consult these requirements directly for complete, up-to-date regulations and standards. The designer may also need to seek advice from experts who know the current state of the art and science of labeling design.

The FDA, EEA, and other organizations set regulations and standards that shape medical device label design and encourage manufacturers to make labels that are conspicuous, legible, understandable, and durable, among other aspects. Labels meeting the regulations and standards, however, do not ensure that the labels are, in fact, effective. Given the importance of enabling the proper safe use of the device, human factors engineering must be incorporated into the label design process. The effectiveness of label design can be assessed using human factors techniques, including particularly usability testing with representative users under realistic use situations. The next section is an overview of human factors principles that are applicable to the design of medical device labeling.

13.4 HUMAN FACTORS PRINCIPLES FOR DESIGNING MEDICAL DEVICE LABELS

There is a considerable body of human factors research on warnings that has been conducted across various products and domains, yielding principles that can be generalized to labeling practices. Nevertheless, the most effective labeling for a particular device is likely to be different in form from one device to another. This chapter concerns labels across all medical devices without a focus on a particular medical device or even a class of devices. The general principles provided should be considered during label design even though all of them may not be applicable to a specific device. The right mix of design attributes is dependent on the device and other factors, and it is beyond the scope of this chapter to particularize the factors for a given medical device.

Because of the substantial differences in users and settings, a device that may be useful in one situation (e.g., by physicians in a clinic) may introduce considerable risk during use in another situation (e.g., by lay users in their homes). Indeed, even experienced, highly trained individuals can make mistakes under time-constrained, heavy-mental-workload conditions (e.g., Weinger, Slagle, Kim, and Gonzales, 2001; Weinger et al., 1994). Under some emergency conditions, medical device users may have little or no time to refer to device labels, instructions, or warnings. Even under the best of conditions, users may extract little or nothing from poorly designed labels. Human factors research provides not only a database of information on label design but also methods that can be used to test label efficacy.

13.4.1 Safety-Related Goals of Labels

When designing device labels that have safety implications, the principles associated with warning label design apply even if the warning is not explicit. There are three goals of medical device labels with respect to safety: informing, changing behavior, and reminding.

Guideline 13.46: Inform Users

Labeling should inform users about the consequences (e.g., potential hazards) of the use of a medical device or its applicable component(s).

Guideline 13.47: Affect User Behavior

Labeling should encourage or promote appropriate user behavior. For example, users should be discouraged from performing unsafe acts that they might otherwise do without the benefit of exposure to the device's labeling.

Guideline 13.48: Remind Users

On-device labels should serve to remind users about conditions or hazards even if they may already know some or all about. Thus, one of the functions of labeling is to cue recall of pertinent information.

13.4.2 Hazard Control Hierarchy

Although this chapter focuses on device labels as an aid for proper device use and injury prevention, it is important to note that engineering design solutions are usually preferred over warning labels to guide proper use and reduce hazards.

Device hazards need to be discovered and, to some extent, managed by manufacturers. Manufacturers need to conduct a systematic use hazard analysis to discover the hazards of the device. Once the use hazards are discovered and analyzed, manufacturers should reduce or eliminate them when possible and practical. The basic *hazard-control hierarchy* (Sanders and McCormick, 1993) offers a useful framework to guide decisions concerning limiting potential injury from use and foreseeable misuse. The levels of the hierarchy are presented below in order of priority based on their likely effectiveness in preventing user injury:

1. *Design to remove the hazard.* The best method of hazard control is to remove the hazard. If the hazard is eliminated, then the likelihood of injury is greatly reduced. But hazards cannot always be eliminated by design and still yield a functional, usable device. For example, one cannot eliminate all the hazards associated with the use of electricity or radiation in medical devices that require energy sources.
2. *Design to guard against contact with the hazard.* For hazards that cannot be eliminated, the next best hazard control strategy is to guard against contact with the hazard. An example of built-in guarding is the "dead-man" switch that shuts off the power when a portable fluoroscope handle is released.
3. *Ensure prior training and/or experience.* This is a form of process guarding. For example, users may be required to train as or work with experts before they can use a device. Alternatively, users may need to obtain a prescription for certain medical devices. Because it depends to a greater extent on the user, this is a less effective form of risk mitigation.
4. *Use warning labeling.* Not all hazards can be eliminated or guarded against. In such cases, warnings in the device's labeling are necessary. However, this is the weakest form of risk mitigation, and success requires careful label design and use testing.

Thus, good device design procedures attempt initially to design out or eliminate hazards. It is far better to design a control switch so as to reduce the likelihood of inadvertent

activation than to give easy access to a control with a warning label being the only method to prevent inappropriate use. Labels should be considered as a supplement to good design as opposed to a substitute for proper design (Lehto and Salvendy, 1995). Moreover, training can vary in quantity and quality, and labeling can aid or supplement training.

13.4.3 Medical Device Liability and Warning Labels

Previously, manufacturers could reasonably assume that the use of most complex medical devices would be restricted to highly trained health care personnel. Until recently in the United States, if manufacturers provided adequate warning to qualified health care professionals, they were shielded from liability. This is called the "learned intermediary doctrine" (LID). LID is based on the notion that the well-trained prescriber is in the best position to communicate all the relevant warning information to end users (*Sterling Drug v. Cornish*, 370 F.2d 82, 85, 8th Cir. 1966). However, a growing body of case law has weakened this legal protection. Increasingly, manufacturers of poorly designed medical devices have been found responsible in liability cases if their devices were shown to have caused patient or user injury. Now that more devices are being used at home, frequently with little or no health care practitioner involvement, whatever liability protection is still afforded by the LID is being further weakened. In the legal arena, defective device design can include defective labeling. More specifically, if instructions and warnings are necessary to operate the device properly and safely and if that information is inadequate, then the device can be rendered defective.

13.4.4 Communication-Human Information Processing (C-HIP) Model

The C-HIP model (Wogalter, DeJoy, et al., 1999) combines elements of two simple models from communication theory and human information processing to describe warning and other related processing. In the basic model, people's mental activities are described as a sequence of stages that begin with a source of that information that uses one or more channels to convey the information to a receiver. The receiver must then notice and attend to the information. The attended-to information must be understood, and for it to be believed, it must be consistent with the person's belief system so as to motivate (energize) behavioral compliance. Usually the goal of a warning label is to produce behavioral compliance to the directive (although sometimes the goal of a warning is to convey information or remind the user of existing information). Newer conceptions of the C-HIP model are provided in Wogalter (2006) and include the aspects of other environmental stimuli, receiver characteristics, and delivery.

At each stage of the model, information may be processed by "flowing through" to the next stage, or it can produce a stoppage or bottleneck to information flow before the process yields behavioral compliance. Depending on the circumstances, processing might not attain the goal of behavioral compliance, but the labels might still be somewhat effective in the role of providing understandable information and reminding the user about a previously known hazard. For example, information can positively influence comprehension about the hazard but still be discrepant with the person's beliefs and attitudes. If so, this could block any effect on motivation and behavior; that is, the individual might disregard the warning and not comply. While a warning could produce better understanding and lead to

somewhat more informed decision making, it may be considered ineffective according to a strict behavioral criterion in that it does not necessarily produce the desired safe behavior.

The C-HIP model not only decomposes processing into basic stages to better understand the process but can also assist in understanding why a warning might not be effective. Suppose that a warning label is not meeting the goal of high levels of behavioral compliance. One possible solution might be to increase the size of the warning label so that more people will likely see it. But noticing the warning might not be the problem. User testing might reveal that most users see, read, and understand the warning and believe the message but are still not complying with the directed behavior. According to the C-HIP model, the problem then is likely to be at the motivation stage. Users may not be complying because it is difficult to carry out the directed behavior (e.g., because of time, effort, money, or physical disability), or the warning does not adequately indicate the severity of the consequences. In these cases, a more explicit description of the consequences and a way to facilitate performance of the behavior should be considered. Thus, the C-HIP model can be used to determine the specific causes of failure, thereby redirecting limited resources toward correcting the critical aspects of the label's design.

Processing of a label may be nonlinear. The most current version of the C-HIP model contains feedback loops, as illustrated in Figure 13.11 (see Wogalter, 2006). As a result of repeated exposures, users could become habituated to a label. As a consequence, they will be less likely to attend to it on subsequent occasions. Here, memory, as part of the comprehension stage, affects the attention stage. Another example of how a later stage of processing can affect initial label perception is that some people might not believe that a medical device is hazardous. A third example is that the person may not understand the information contained in the labeling the first time they read it. As a result, they may return to an earlier stage (attention) and read it again.

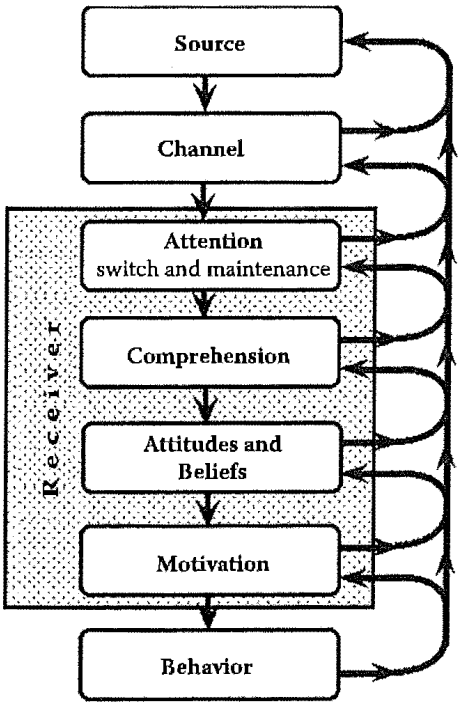


FIGURE 13.11 The C-HIP model. (Adapted from Wogalter, M.S., DeJoy, D.M., and Laughery, K.R., *Warnings and Risk Communication*, Taylor & Francis, London, 1999.)

13.5 COMPONENTS OF THE C-HIP MODEL

In the following sections, a short description of the each of the main stages of the C-HIP model are described.

13.5.1 Source

The *source* is the originator or initial transmitter of the risk information and can be a person(s) or an organization (e.g., the manufacturer, the FDA). Research shows that the source of a warning can affect people's perceptions about the material presented. Information perceived coming from a reliable, expert source (e.g., the Surgeon General, the FDA) adds credibility to the message being considered (Cohen, Cohen, Mendat and Wogalter, 2006; Cox and Wogalter, 2006; Morris and Mazis, 1999; Wogalter, Kalsher, and Rashid, 1999).

13.5.2 Channel

The *channel* is the way in which information is transmitted from the source to one or more users. There are two basic dimensions of the channel. The first dimension is the media in which the information is embedded. Device use information, including warnings, can be presented in various ways, such as on-device labels, supplemental labeling information (e.g., operator manuals), live and audiovisual training, Web sites, and so on. The second dimension is the sensory modality. Product safety information is most commonly presented visually (e.g., device use instructions and warnings, pictorials and symbols) or auditorily (e.g., alert/alarm tones, voice). Potentially valuable warning information could also be presented via tactual (e.g., vibration) and olfactory (e.g., odor) modalities.

13.5.3 Delivery

This *delivery* process considers the interface between channel and the receiver. Safety information that never actually reaches the user has no practical utility (Wogalter, 2006). It needs to be "delivered" to the receiver to have any chance of being perceived. A label that cannot be seen at the device user's position will obviously be less influential compared to another that the user can see. Although location and placement are key aspects of the delivery process, label designers need to also consider users' knowledge, abilities, and skills. For example, some users will be novices to the task or may have perceptual difficulties (e.g., sound insensitivity, color blindness). Also, some users may not receive device use training, may not seek out safety information beyond the device itself (i.e., on-device label), or may not have access to the user's manual (Wogalter, Vigilante, and Baneth, 1998). Thus, particularly for lay use devices, on-device labels should be well designed and be effective without need for supplemental materials.

13.5.4 Receiver

The next main aspect of the model, the *receiver*, encompasses a set of human information processing stages. First, the user must attend to the label content for sufficient duration to ensure that the information is perceived. In subsequent stages, the label must be easily

understood and fit with the user's existing beliefs and attitudes. If it does not fit, then the information must persuade the user to change his or her beliefs and attitudes. Finally, the information must motivate the user to perform the desired actions (or avoid unsafe actions).

The following sections describe stages within the *receiver* portion of the C-HIP model.

13.5.4.1 Attract Attention

Generally, use of medical devices occurs in environments that have many stimuli competing for people's attention. The label must initially attract attention. The more noticeable the labeling, the more likely attention will be switched to it. Several characteristics affect noticeability. "Salience" is a broad term that refers to aspects that aid in making the label more conspicuous or prominent.

GUIDELINE 13.49: SALIENCE

Labeling should stand out from background and other competing information.

Some users will not be actively seeking information about potential hazards because they are focused on the tasks they are trying to accomplish. New users may take longer to extract the relevant information from labeling than experienced users. This is also true of users who are under stressful, distracting, or high-workload conditions. Some features that increase salience include the following (see also Figure 13.12):

- Large print (Wogalter et al., 1987)
- High color contrast and brightness contrast (Sanders and McCormick, 1993)
- Use of distinguishable colors (Braun and Silver, 1995; Sanders and McCormick, 1993)
- Pictorial symbols (Kalsher, Wogalter, and Racicot, 1996; Young, Wogalter, Laughery, Magurno, and Lovvoll, 1995)
- Prominent and appropriate label placement (Wogalter and Young, 1994; Wogalter et al., 1987)

FIGURE 13.12 **(See color insert following page 564.)** Salience refers to aspects that aid in making the label more conspicuous or prominent. In this example, the labeling is made more conspicuous through the use of color, placement, and coherent information grouping.

13.5.4.2 Hold Attention

Labeling that is noticed but fails to maintain attention long enough for its content to be encoded may not be useful (unless it serves as a reminder). People may notice device labels but not stop to examine them. For adequate processing of label content to occur, attention must be maintained on the message for a sufficient duration of time (Wogalter and Leonard, 1999; Wogalter and Vigilante, 2006). Some of the same design features that capture attention (Section 13.5.4.1) can also be used to *maintain* attention (e.g., Barlow and Wogalter, 1991; Wogalter, Forbes, and Barlow, 1993). Some additional design features to hold attention include the following (see also Figure 13.12):

- Aesthetically pleasing;
- Easy-to-read print (large enough to be read easily) (Wogalter, Magurno, Dietrich, and Scott, 1999)
- White space (Wogalter and Vigilante, 2003)
- Coherent information groupings (Hartley, 1994)
- Bulleted lists as opposed to long, continuous paragraphs (Desaulniers, 1987; Wogalter and Post, 1989)
- Ragged-right justification (i.e., only the left margin justified)

Guideline 13.50: Optimal Quantity of Label Information

Users are more likely to rapidly acquire the meaning of labeling that is brief rather than lengthy. Labels containing greater amounts of information may, however, be needed for completeness. Because such labels need to be examined for longer periods of time, they should incorporate qualities that both attract and hold attention as well as reduce the effort required to acquire the label's information content.

13.5.4.3 Label Comprehension

Labeling that is attended to and examined may have little or no value if the user does not understand (comprehend) the intended message.

Guideline 13.51: Informative Labels

The label should give the user an appreciation of hazards and their consequences, provide useful instructions (dos and don'ts), and enable informed judgment.

Guideline 13.52: Explicit Information

The information presented should be explicit. The information should be specific rather than general (Laughery and Paige-Smith, 2006; Laughery, Vaubel, Young, Brelsford, and Rowe, 1993). Vague statements can more easily be misinterpreted. For example, the statement "Hazardous to your health" does not provide an appreciation of potential consequences in a situation where the specific hazard is poisonous vapor that, if inhaled, can cause heart failure and brain damage. When possible and practical, labels should explicitly describe the risks, what actions users should take (or avoid taking) to avoid injury, and the consequences of not complying with the recommended behaviors.

Guideline 13.53: Target Lowest-Level Abilities

Whether labeling information will be understood depends on characteristics of both the label and the user. To maximize comprehension, label information should be written to take into account the lower-level abilities and skills of the target population.

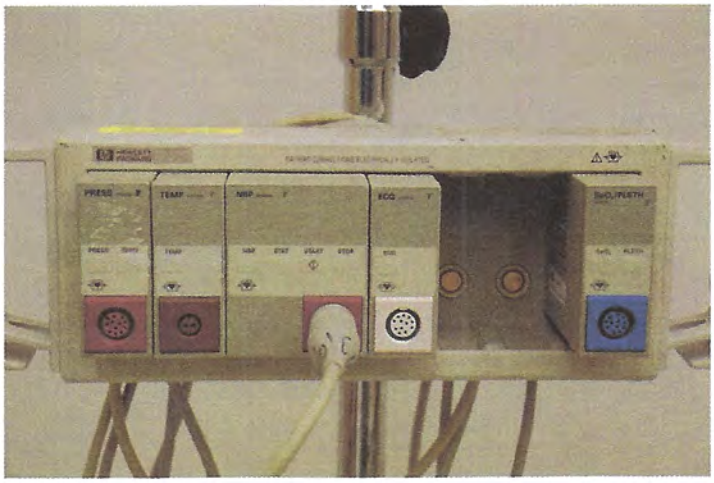
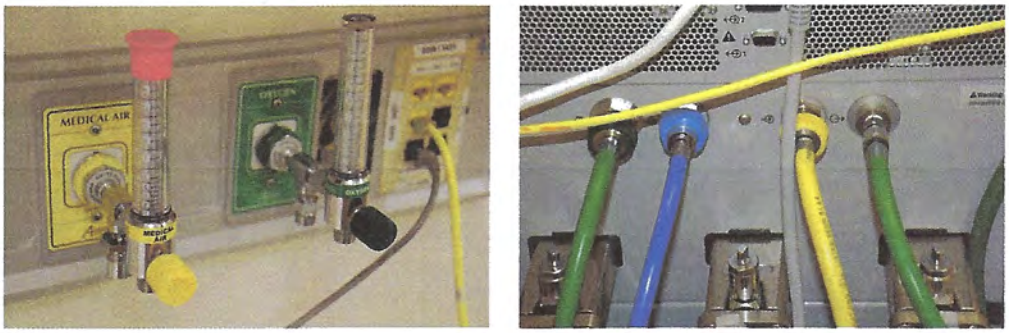


FIGURE 13.8 The use of specific-shape connectors and color coding can help reduce user error.



(a) (b)

FIGURE 13.10 Color coding can be a useful technique for improving labeling on (a) receptacles and (b) connectors.

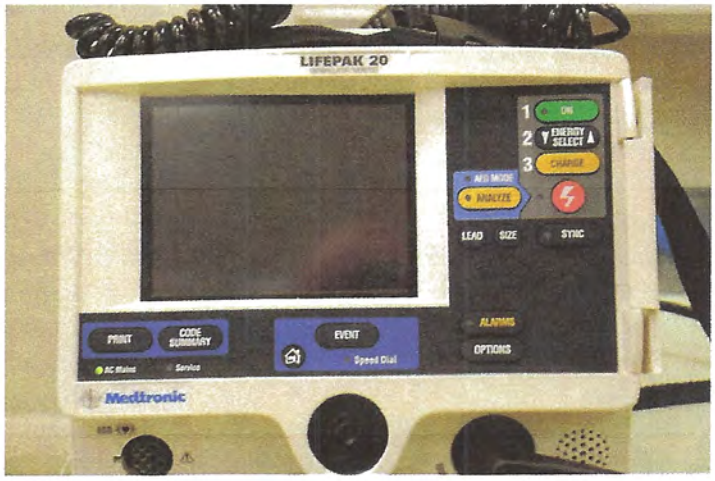


FIGURE 13.12 Salience refers to aspects that aid in making the label more conspicuous or prominent. In this example, the labeling is made more conspicuous through the use of color, placement, and coherent information grouping.

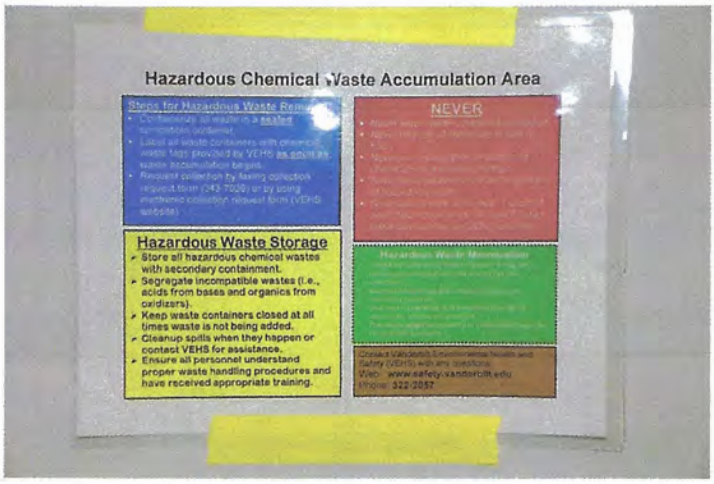


FIGURE 13.20 The use of different background colors can help differentiate various portions of labeling.

FIGURE 13.23 Redundant coding can help ensure that users receive the information they need to operate medical devices safely.

Do not design for the average user because this will miss about half the users. User groups include the following:

- *Professional users.* If the labeling is intended only for trained health professionals such as surgeons and operating room nurses, then designers reasonably can assume some level of user knowledge and skill when making decisions concerning labeling content and format. Even so, there is a broad range of training of health care professionals. Assumptions about background knowledge should be verified with a random sample of representative users.
- *Lay users.* If the medical device is being designed for use by laypersons (i.e., a broad spectrum of the general population), designers cannot assume the same level of knowledge and skills as that of trained health care professionals. A much wider range of education, experience, and skills should be expected. Labels should be designed to accommodate persons with a seventh-grade reading ability if practical or possible.
- *Non-English speakers.* Not everyone in the United States using medical devices reads English, and many devices are designed to be marketed outside the country. Potential solutions to the language problem include the use of simple terminology, increasing label size to accommodate translations, and the use of readily understood pictorial symbols (refer to Figure 13.7)
- *Disabled or impaired users.* Particularly for medical devices designed for patients, labels must be designed to accommodate users with cognitive, perceptual, or other impairments (see Chapter 18, "Home Health Care"). Some of these considerations with respect to older adults are described in Mayhorn and Podany (2006).

13.5.4.3.1 Habituation to Label Message

Repeated and long-term exposure to device labeling—even if well designed—may produce habituation, diminishing the labels' ability to attract and hold attention (Wogalter and Laughery, 1996). One way to reduce habituation is through a periodic change of labeling. This may not be possible for a variety of reasons, including regulations that mandate labeling on medical devices be relatively permanent under ordinary conditions of use. Moreover, periodic changes to a medical device user interface could affect use and requires validation testing.

13.5.4.4 Fit with User Beliefs and Attitudes

According to the C-HIP model, even if device labeling successfully captures and maintains attention and is understood, it still might fail to elicit the desired safety behavior because of discrepant beliefs or attitudes held by the receiver relative to the label's message. According to the C-HIP model, labeling will be successfully processed at this stage if the information concurs with the user's current beliefs and attitudes (see DeJoy, 1999; Riley, 2006). A message that is in accordance with the user's beliefs/attitudes will tend to activate and reinforce what the user already knows and expects, thereby increasing compliance with label instructions. Conversely, if device information conflicts with the user's existing beliefs and attitudes, the labeling message may not be processed further, and compliance will likely be decreased (Wogalter and Laughery, 2006). To overcome this, added salience and other changes to the device may be needed.

Two important beliefs and attitudes related to labels are *perceived familiarity* and *perceived hazard*. In general, when people believe that they are familiar with a device, task, or environment, they are less likely to look for or read safety-related information (e.g., Godfrey, Allender, Laughery, and Smith, 1983; Wogalter, Brelsford, Desaulniers, and Laughery, 1991; Wright, 1982). Familiarity beliefs are formed from past similar experience where relevant information has been acquired and remembered. Familiarity produces the belief that nearly everything of relevance is already adequately known (Wogalter et al., 1991). A person who is familiar with a device might assume that a similar device operates the same way. If these expectations and reality do not match, use errors can occur. Familiar devices tend to be perceived as less hazardous than less familiar ones. Perceived hazard is also closely associated with beliefs about the expected injury severity level and is less closely tied with injury probability beliefs (Wogalter et al., 1991). People who do not perceive a device as hazardous are less likely to notice or read its label (Wogalter, Brems, and Martin, 1993; Wogalter et al., 1991).

Guideline 13.54: Alter User's Beliefs and Attitudes

Labels should be designed to alter user's existing beliefs and attitudes when they are not concordant with the realities of device use (e.g., actual use hazards). This difficult task is facilitated if the information is presented in a form that will be noticed, read, and understood.

Design elements that facilitate persuasion include the following:

- *Salience.* Labeling that is salient is more likely to capture the attention of a person who is not looking for warnings or other important device information either because of familiarity effects or low hazard perception. Salience may also enhance a user's belief that the label information is important.
- *Credible source.* A credible source (e.g., expert authority such as the FDA) can favorably affect beliefs concerning label importance and relevance.
- *Severity of the consequences.* Explicit information about the severity of potential consequences increases perceived hazard and intentions to comply.

13.5.4.5 Motivation

Once device labeling is noticed, read, and understood and is consistent with a person's beliefs and attitudes (or brings about a change in discrepant beliefs and attitudes), the next stage of C-HIP is motivation. The label must sufficiently energize the user to carry out the desired behavior. When the label is asking a person to do something that he or she would otherwise not do, a considerable amount of motivation may be needed. Motivation is affected by the relative trade-offs between the competing costs of compliance and noncompliance.

The costs of compliance include money, time, and convenience. One way to reduce the costs of compliance is to make the behavior requested in the label easier to perform. For example, if personal protective equipment (PPE) is necessary when using a medical device, the device manufacturer might consider making the PPE more available to users, perhaps by providing the PPE with the device and including a convenient storage place for it in the device.

In addition, the costs of noncompliance (i.e., consequences), such as severe injury and monetary loss, should be clearly and conspicuously presented (Wogalter, Allison, and

McKenna, 1989; Wogalter et al., 1987). This is another reason that giving explicit statements with specific negative outcomes rather than general ones is preferable (Laughery et al., 1993).

13.5.4.6 Label Must Produce Compliance

If the user is sufficiently motivated, then he or she is likely to carry out the desired behavior. Behavioral compliance research shows that warnings and other safety-related materials are usually effective if properly designed and implemented (e.g., Cox, Wogalter, Stokes, and Murff, 1997; Kalsher and Williams, 2006; Laughery et al., 1994).

13.5.4.7 Labeling May Influence Users Indirectly

Information from labels may reach users indirectly. Indirect methods of communication include user-to-user transmission and changes in use environment culture or norms. An example is an experienced user orally telling a new user pertinent safety information based on information that he or she acquired at an earlier time. That person, in turn, may change his or her behavior accordingly. To the extent that labeling information alters the behavior of a sufficient number of users, the behavior may become a norm of the use environment (i.e., part of "Culture"), thereby propagating and reinforcing the behavior even in the absence of future direct contact with labeling (see also **13.5.5.1**).

13.5.5 Other Human Factors Issues

Other factors that influence motivation to comply are external to the labeling but nevertheless may affect labeling effectiveness. A medical device manufacturer cannot control the local situation in which a device is used. Thus, it is foreseeable that devices will not always be used under optimal conditions. For example, a device might be used in low lighting. Other factors that affect motivation to comply include social influence (Wogalter et al., 1989), time stress (Wogalter, Magurno, Rashid, and Klein, 1998), and mental workload (Wogalter and Usher, 1999).

13.5.5.1 Social Influence

Observation of how other users behave can affect an individual users' behavior with respect to a device. If people observe others not complying with a label's directive to wear protective equipment while using a particular medical device and further observe them not being harmed, they may conclude that it is unnecessary to wear protective equipment themselves (Wogalter et al., 1989). By contrast, observing others complying with a label's directive can have a positive influence. Device manufacturers should try to positively influence use behaviors through effective device design, labeling, and training.

13.5.5.2 Stress and Workload

In high-stress and high-workload situations, competing activities limit the cognitive capacity or resources available for processing label information and complying with desired use behavior. Under these conditions, considerable emphases on safety and reduced cost of compliance may be required to overcome the barriers. Efforts that reduce stress and workload should also facilitate compliance.

13.6 USING HUMAN FACTORS PRINCIPLES TO ENHANCE COMPONENTS OF MEDICAL DEVICE LABELING

This section provides specific guidance on how to apply human factors principles to the design of medical device labels

13.6.1 Label Content

One of the most important, if not *the* most important, aspects of labels is the message content. Clarity, consistency, completeness, and brevity of label information are critical. As simple as these criteria may seem, achieving them requires systematic effort during the development process.

Designers should consider the following guidelines when developing label content.

Guideline 13.55: Understand Label Users

Designers should understand the device's intended user population. Lay users are likely to have little or no medical or technical education.

Guideline 13.56: Identify Essential Label Information

Designers should determine what information is needed on the label. This may entail review of the literature, observation of users, and interviews with experts and representatives of potential users. Prioritize label content on the basis of input from subject domain experts, human factors experts, and especially potential users.

Guideline 13.57: Choose Words Carefully

Words should be chosen to express exactly the idea or action intended. The wording should be clear, direct, accurate, complete, and succinct.

Guideline 13.58: Nontechnical content

The use of unusual or technical terms should be avoided, particularly for device labels intended for lay users.

Guideline 13.59: Understandable to All Label Users

Labels should be understood by those users with the lowest expected level of cognitive abilities. For example, information for lay users should be written at or below the seventh-grade reading comprehension level (age 13) (see 21 CFR 801.5).

Guideline 13.60: Be Consistent with User Expectations

Recognized practices, expectations, and conventions of the target users (e.g., laypersons vs. health care workers) should be considered.

Guideline 13.61: Testing of Label Content

Test label content using a representative sample of users to ensure that the intended message is being conveyed and to identify any incorrect or misleading information.

Guideline 13.62: Comprehension of Label Language

If it is determined that non-English users will be unable to comprehend the on-device text, then supplemental labeling should be developed that accurately transmits the relevant hazard information to those users (see Figure 13.7). The specific implementation will depend on a number of constraints:

- Simplicity of the English text or the number of languages required to meet the needs of expected device users
- Availability of acceptably comprehensible symbolic representations (i.e., ones that meet established criteria; see Guideline 13.64)
- The amount of space available to present label information in alternative languages and/or to include pictorials that are language independent
- Current regulations and standards

13.6.1.1 Abbreviations, Initials, and Symbols

Graphical symbols or text abbreviations may be used on labels, for example, when space is limited or they are expected to be more effective than the represented text. If symbols or abbreviations are used due to space constraints, understandability should be at least equivalent to full text labeling.

Guideline 13.63: Sparing Use of Abbreviations and Initials

Abbreviations and initials should be designations or names that are well known to the population of intended users. If there is any question, then a formal evaluation with a representative sample of device users should be conducted.

Guideline 13.64: Understandable Symbols

Symbols should have a meaning commonly understood by most users. According to safety symbol standards, 85% or more of a representative sample of 50 potential users should understand a symbol's intended meaning, with less than 5% critical confusions (ANSI Z535.3, 2002). Critical confusions are errors of understanding in which people report the opposite of the intended meaning or answer in a way that is potentially dangerous. These performance criteria and guidelines can be reasonably extended to the assessment of the understandability of textual notations, such as abbreviations and initials. However, if use errors due to symbol confusion can have safety implications, 100% of users tested must not make use errors or other effective risk mitigations must be employed.

Designers should also familiarize themselves with other organizations that offer guidance on symbol selection for medical device labels, such as the IEC and the ISO. Some of the more relevant specific standards on the use of symbols include EN 1041, EN 1658, ISO 780, ISO 7000, ISO/TR 15223, IEC 601-1, IEC 601-2, IEC 60417-1, IEC 60417-2, IEC 878, and EN 980. More than 7,000 symbols are described in these standards, many of which are applicable to medical devices, diagnostic kits, and associated equipment and instrumentation. They also include specifications for position, size, and unit measurements. In the EU, manufacturers are allowed to devise their own symbols and use them on labels or instructions for use if they are fully explained and their safety is evaluated. The ANSI Z535.3 (2002) symbol standard contains appendices on how to develop and test safety symbols. Topics such as iterative design and testing, user feedback, and cost-saving methods in assessing comprehension from concept to symbol are also discussed (see also

Deppa, 2006; Goldsworthy and Kaplan, 2006; Miller and Parent, 2006; Sojourner and Wogalter, 1998; Wogalter, Silver, Leonard, and Zaikina, 2006).

13.6.2 Location Aids and Functional Relationships

Location aids such as demarcation (e.g., boundaries or borders), color coding, shading, mimics (physical representations of medical device components and their relationship to one another), and flashing lights may be used to indicate the positions of and relationships among related controls and displays.

Guideline 13.65: Redundant Location Coding

Redundant location aids should be used particularly when a single method of presenting label information cannot be expected to be adequate, such as for devices that are expected to be used under degraded environmental conditions (e.g., low-light or changing light conditions).

Guideline 13.66: Demarcation and Shading

Designers should use some form of demarcation or shading to group together related items such as controls and displays as illustrated in Figure 13.13.

Guideline 13.67: Mimics

Mimics should be used to enhance users understanding of device function or system relationships. Mimics are displays that help users simultaneously monitor multiple components that compromise a medical device or system (Wiegmann et al., 2002). Mimic displays can help operators detect and diagnose problems as they arise. Mimics differ from other location aids in that they reflect functional and/or spatial relationships among components of the medical device. Mimics integrate representations of displays and controls into a composite graphic or pictorial. Properly designed mimics enhance a user's ability to identify, monitor, and/or manipulate medical device displays and controls in real time. Additional factors that can further enhance the utility of mimic displays include color contrast and consistency.

Guideline 13.68: Consistent Mimic Colors

Lines depicting flow of the same contents (e.g., blood, oxygen) should be colored the same.

Guideline 13.69: Minimize Parallel Mimic Lines

Designers should minimize the number of similarly colored lines, termed "sensor" lines, running parallel to one another so that users can quickly identify any one of the lines if needed (see Chapanis and Yoblick, 2001).

FIGURE 13.13 Use of demarcation to group related information displayed on a medical device.

13.6.3 Position and Placement

One of the most important factors contributing to label effectiveness is the positioning of labels and other markings on medical devices and their packaging. Designers must take into account the aspects of visibility, spatial orientation, proximity, and shape.

13.6.3.1 Visibility

Guideline 13.70: Viewing Angles

Labels should be positioned to ensure visibility and legibility from expected vertical or horizontal viewing angles as well as from angles above or below eye level.

Guideline 13.71: Flat, Nonglossy Surface

The use of a flat, nonglossy surface will prevent veiling glare from obscuring the display.

13.6.3.2 Orientation

Improperly oriented labels can lead to confusion and cause delays in locating and identifying important controls and/or displays.

Guideline 13.72: User Orientation vs. Label Orientation

The orientation of labels should be consistent with the user's likely physical orientation while operating the device (see Figure 13.14).

FIGURE 13.14 The orientation of labeling should make it easy for users to read and should be consistent with the user's likely orientation while operating the device.

Guideline 13.73: Horizontal Orientation

Orient labels horizontally so that they may be read quickly from left to right. In most languages, including English, people read from top to bottom and left to right. However, a different orientation may be appropriate for users of other languages (e.g., Hebrew, Arabic, Chinese).

13.6.3.3 Shape

Guideline 13.74: Shape of Labels and Controls

The shape of controls and their labels should strengthen the association between the control and its function (Sanders and McCormick, 1993).

Guideline 13.75: Curved Labels

Do not use curved text on labels, except for setting delimiters for rotary controls and displays (see Figure 13.15).

13.6.3.4 Location

Guideline 13.76: Proximity of Labels and Controls

Labels and other markings should be placed near the controls that they describe—either on the control itself or immediately adjacent to it—so that it is easy for the user to make the desired association between the two objects (see Figure 13.16).

Guideline 13.77: Graphics Adjacent to Text

Graphics should be placed adjacent or as close as possible to its associated text so that it is easy to make the connection between the two.

Guideline 13.78: No Obstructions to Label Viewing

Labels and other markings should not be blocked from view by hand positions or other equipment components. Labels should remain visible and legible once the user's hand is placed on the control.

FIGURE 13.15 Avoid using curved text on labels, except as setting delimiters for rotary controls and display.

FIGURE 13.16 Example of a device on which the labels and markings are placed on or near the controls they describe.

13.6.4 Gestalt Principles

A well-established set of perceptual guidelines, termed *Gestalt principles*, may facilitate design decisions concerning medical device labeling (and device components) (e.g., Wolfe et al., 2006). Gestalt principles describe people's tendency to see separate, isolated parts as organized wholes (e.g., Baron and Kalsher, 2005). The focal point of Gestalt theory is the idea of "grouping," or how we tend to interpret visual patterns in certain ways. The main factors that determine grouping are the "laws" of similarity, proximity, and good continuation. A description and representation of each of these principles is provided in Figure 13.17.

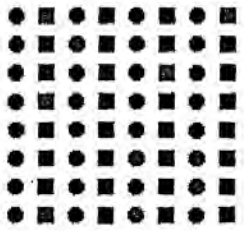
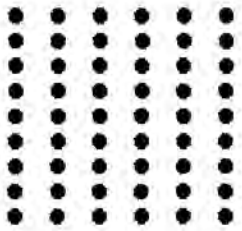
		
The **law of similarity** states that objects which share visual characteristics such as shape, size, color, texture, value or orientation tend to be perceived as a group or pattern	The **law of proximity** states that objects near each other tend to be seen as a unit.	The **law of good continuation** states that objects arranged in either a straight line or a smooth curve tend to be seen as a unit. People tend to see two lines: one from "a" to "b" and another from "c" to "d", even though this graphic could represent another set of lines, one from"a" to "d" and another from "c" to "b".

FIGURE 13.17 Examples of Gestalt principles of grouping: similarity, proximity, and good continuation.

FIGURE 13.18 Labels should be placed close to the related controls, displays, ports, and so on to which they refer. These photos of medical devices show how the use of Gestalt principles can enhance the effectiveness of medical labeling.

GUIDELINE 13.79: GROUPING LABELS OR LABEL ELEMENTS

Related label elements or labels should be grouped together. Labels should be placed with the controls and displays with which they are associated (see Figure 13.18).

GUIDELINE 13.80: SEPARATE ADJACENT DEVICE ELEMENTS

Adjacent controls and displays and their labeling should be separated by sufficient space or other design elements so that they are viewed as separate.

13.6.5 POPULATION STEREOTYPES AND EXPECTATIONS

Population stereotypes are social and cultural norms affecting people's expectations on how a device works. Different parts of the world may have different expectations about how some things work or should work. Furthermore, people are likely to generalize from one device (e.g., light switch) to something similar (e.g., the power switch on a medical device). In North America, most people expect that to turn on the light, one moves the switch to an up position. Thus, the population stereotype for "on" is up and for "off" is down. In Europe, the expected movement to turn on a light switch is opposite ("on" is down). When device function is consistent with the user population stereotypes, use errors decrease. However, stereotypes are based on learning and experience, which may differ to some degree between individuals in a population. In general, label designs that make use of knowledge about people's tendencies will facilitate performance in terms of faster time and fewer errors.

Guideline 13.81: Best Labels Will Not Compensate for Poor Interface Design

When device design is not compatible with users' expectations, labeling must, in a sense, work harder to control users' behavior. However, labeling should not be used as a substitute for good user interface design.

13.6.6 Durable Materials

Guideline 13.82: Durability

Labels should be resistant to wear and tear over the expected life span of the device (Glasscock and Dorris, 2006). To accomplish this goal, designers should take into account the environments in which the device will likely be used, user characteristics, materials, inks, coatings, and so on. Examples of worn labeling on medical devices are presented in Figure 13.19.

Guideline 13.83: Difficult to Detach

The label should not be easily removed or be severely abraded when the device is subjected to ordinary wear and use. In most instances, labels should be difficult to detach.

Guideline 13.84: Adhesive Residue from Labels

Nonsterilizable labels on devices such as surgical tools should be removable to permit sterilization. In such cases, there should be no adhesive residue.

Guideline 13.85: Replaceable Labels

Removable labels must be readily replaceable. In general, the labels should be printed redundantly in other places, such as device manuals or on the Internet. Assigning part numbers to the labels is advisable to facilitate reordering.

FIGURE 13.19 Examples of worn medical device labels.

Guideline 13.86: Device Manufacturer Label

A durable label containing manufacturer contact information (along with device identification and serial number) should be placed where it is accessible.

Guideline 13.87: Static Electricity

A buildup of static electricity can pose a safety hazard when medical devices are used in certain environments. In these instances, labels should be constructed of polyester, polyamide, or other materials known to reduce the buildup of static electricity.

13.6.7 Legibility

Legibility is the ease with which the details of displayed material can be accurately discriminated. Poor legibility can reduce people's ability to read and comprehend medical device labels. Labels should be easy to read so that users are able to extract and encode the information; otherwise, attention will not be held, and the user may attend to something else. As described earlier, legibility is part of the attention maintenance or holding stage of the C-HIP model, thus affecting whether a warning is understood, affects beliefs, and so on. Poor legibility may stem from label design, labeling material, choice of font and font size, or other factors, such as aspects of the environment (e.g., illumination levels) or user characteristics (e.g., visual acuity). In particular, older adults with age-related perceptual or cognitive limitations may not have the ability to read small print in dimmer lighting conditions. Given the increasing percentage of older adults, designers should attempt to design labels that compensate for age-related perceptual and cognitive decrements.

Guideline 13.88: Environmental Effects on Label Legibility

To attain adequate label legibility, designers should consider the following environmental influences that can degrade legibility (Sawyer, 1993): low levels of ambient light, glare-producing surfaces, damage from heat, use of improper cleaning products, humidity, and moisture.

Guideline 13.89: User Attributes Affecting Label Legibility

Designers should consider the following user attributes that could affect legibility of labels (Mayhorn and Podony, 2006; Smith-Jackson, 2006b):

- Age
- Literacy and numeracy
- Perceptual limitations (e.g., color blindness, visual acuity)
- Expectations (Vredenburgh and Zackowitz, 2006)
- Cultural differences (Smith-Jackson, 2006a)
- Experience and training

Because medical devices are being used increasingly by laypeople in nonmedical settings (i.e., in the home), the labeling intended for such users should take into account the wide range of sensory and cognitive characteristics in the general population. When designing for the general population, designers should anticipate much higher levels of variability on most relevant user characteristics.

Guideline 13.90: Contextual Factors Affecting Label Legibility

Designers should consider a variety of situational or contextual factors that could adversely affect label legibility, including the following:

- Heavy task load (Wogalter and Usher, 1999)
- Stress (e.g., Vredenburgh and Helmick-Rich, 2006)
- Fatigue (e.g. Vredenburgh and Helmick-Rich, 2006)
- Use of alcohol and other drugs
- Physical health and illness

Guideline 13.91: Typical Label Reading Distances

Relevant text and pictorial components on medical device labels should be legible at expected viewing distances and angles. Advice on size and font characteristics is provided in Section 13.6.7.2.

Guideline 13.92: Use Conditions Affecting Label Legibility

Characters and symbols should be designed to be legible by intended users under the full range of expected use conditions. A medical device user's ability to physically read the warning label is, of course, crucial to compliance. An instrument known as the Lockhart Legibility Instrument has been developed to conduct tests in which the amount of light necessary to read a label is controlled (Bix, Lockhart, Cardoso, and Selke, 2003). The test participant rotates a filter within the instrument until legibility is achieved. A number of factors, including color, font size and other typography, and distance, both alone and in combination, can be varied under different lighting conditions to determine their impact on legibility of labeling.

13.6.7.1 Highlighting and Contrast

Legibility can be enhanced through highlighting and contrast (Frascara, 2006; Wogalter and Vigilante, 2006).

Guideline 13.93: Highlighting for Labels

Designers should use highlighting to call attention to important aspects of medical device operation. The use of highlighting can provide visual relief, emphasize important points, and attract user attention to particularly important sections of text. Highlighting techniques include the use of the following:

- Color
- Bolding
- Underlining
- Italics
- Reverse printing (e.g., white text on black background)
- Varied font styles
- Boxing in of text
- Offsetting borders and backgrounds
- White space

Guideline 13.94: Consistent Use of Label Highlighting

Highlighting techniques should be used consistently throughout all device labels.

Guideline 13.95: Overuse of Label Highlighting

Highlighting should not be overused, as its effectiveness will then be diminished. For example, overuse of italics or all uppercase lettering are known to reduce legibility. Another example of poor use of highlighting is the use of a gray background as a highlight for black print, as this reduces contrast (see Guideline 13.97). Designers must carefully choose which important information to highlight; this should be the most important information and information that might otherwise be missed.

Guideline 13.96: Uppercase Lettering

Uppercase lettering is recommended for signal words and also may be useful for accentuating the salience of a few words of text. An example is the use of uppercase lettering to distinguish different drug names (e.g., DOBUTamine vs. DOPamine).

Guideline 13.97: Contrast of Label Print

Contrast of light/dark or dark/light print is another technique designers can use to enhance legibility (Bix et al., 2003; Sanders and McCormick, 1993). Generally, black and white provides the best contrast, but labeling does not have to be achromatic: Many color combinations may be used as long as there is a large difference in light–dark and color contrast. Designers should generally use dark characters against a light background. The reverse can also be used, but if the labeling is implemented as a projected display (such as LEDs), the potential for "irradiation" should be taken into account. Irradiation is the tendency for white lettering on a black background to "spread out." Thus, when using white print on a black background, designers should compensate by employing fonts with a thinner stroke width.

Guideline 13.98: Color and Ambient Light

Color can be used to differentiate important words or text (e.g., hazard warnings). Choose color combinations that produce adequate contrast. Various color combinations of background to differentiate sections of label text are illustrated in Figure 13.20.

The perception of color can be affected by the label's materials, reflective gloss, and ambient lighting conditions as well as user characteristics (color blindness and tinted eyewear).

FIGURE 13.20 **(See color insert following page 564.)** The use of different background colors can help differentiate various portions of labeling.

The anticipated range of these factors should be considered to determine the colors used and their presentation (e.g., materials, inks, coatings). The impact of anticipated light conditions should also be considered. A related factor with respect to lighting is the angle at which a label is presented relative to the user's position. Although direct, perpendicular viewing is usually best, some lighting conditions may cause veiling glare, whereby the label information is obscured by reflected light, particularly on high-gloss surfaces (see Figure 13.20). In such a case, adjustment of the viewing angle or a change in labeling materials should be considered.

Guideline 13.99: Color Coding of Warnings on Labels

When warnings are used, it is generally advisable to use red, orange, and yellow for hazard-related messages since those colors are associated with hazards as specified in medical device standards, such as IEC60601-1-8 (unless user testing shows other colors to be acceptable).

13.6.7.2 Typography

Typography is the arrangement, style, and general appearance of the component alphanumeric material. It encompasses various characteristics of print, including type fonts, type size, and type styles. Typography affects legibility, information transmission, and search (Frascara, 2006; Simpson and Casey, 1988). Several of the most important factors are described below.

Guideline 13.100: Type Size for Labels

Designers should use a type size large enough for the relevant information to be extracted from the label at eye distances in which the device is being operated by the intended user audience and under the anticipated lighting conditions (Wogalter and Vigilante, 2003). Guidelines such as ANSI Z535.4's appendix provide minimum suggested types sizes based on distances and good/poor viewing conditions.

Guideline 13.101: Type Font on Labels

Many fonts in common use to display text are comparably legible. Fancy fonts like Old English and script should not be used, as they are less familiar and could slow reading speed and, in extreme cases, comprehension. Serif fonts, such as Times Roman, have embellishments on the component parts of the letters that distinguish the letters to a greater extent than sans serif letters (e.g., Helvetica, Arial). Times Roman is one of the most frequently used fonts and thus is highly familiar to most people. Whether to use serif or sans serif fonts can be determined as follows:

- *Serif fonts.* Use serif fonts for smaller-sized print (i.e., 9 to 14 points) because they are easier to read than sans serif fonts.
- *Sans serif fonts.* Use sans serif for larger type, such as signs or posters. Sans serif fonts are generally preferred for electronic labels.

Guideline 13.102: Multiple Fonts on a Level

While the use of a different font can highlight particular text passages, generally avoid the use of multiple font types on the same label. Multiple fonts can be distracting, unattractive, and can reduce the speed at which the information is encoded. Also, if the label is not aesthetically pleasing, it could have less attention-holding power.

FIGURE 13.21 Mixed-case letters should, in general, be used in medical labeling, including warnings. The label also shows the uppercase WARNING after the international symbol for alert or warning.

Guideline 13.103: Sentence Case Is Preferred

Mixed-case (using both upper- and lowercase) letters should, in general, be used (see Figure 13.21). All uppercase (all capital) letters is a poor choice for users with low visual acuity, under low legibility (e.g., small print), and in glare exposure conditions. Lowercase letters are usually more legible than uppercase letters, as their shapes are more distinguishable, even though they are smaller in size. Uppercase letters have more similar components, making them less distinguishable (Backinger and Kingsley, 1993).

Guideline 13.104: Uppercase for Signal Words

Uppercase should be used for signal words, such as "DANGER" and "CAUTION." Warning standards (e.g., ANSI Z535) specify this as part of a panel that also includes an alert symbol (triangle enclosing an exclamation point) and a corresponding color. Together, these components may form a trigger that facilitates recognition and response (Wickens, Lee, Liu, and Gordon-Becker, 2003). In selective instances, uppercase may be used to highlight important text but not for a large grouping of words (refer to Figure 13.21).

Guideline 13.105: Text Emphasis

Italics, underlining, or bolding can be used to highlight important text. Excessive use of any such emphasis coding will diminish its benefit.

Guideline 13.106: Vertical Text Spacing (Leading)

The space between lines—known as leading—should be at least 25% to 30% of the text size (e.g., Hartley, 1994; Misanchuk, 1992; Sanders and McCormick, 1993). This distance helps reduce inadvertent switching between lines of text (see Figure 13.22).

Guideline 13.107: Kerning

Kerning is adjustment of spacing between letters to make large print appear consistently spaced and to fit the text into relatively short columns (e.g., Hartley, 1994; Misanchuk, 1992; Sanders and McCormick, 1993). Kerning should be adjusted to maximize readability.

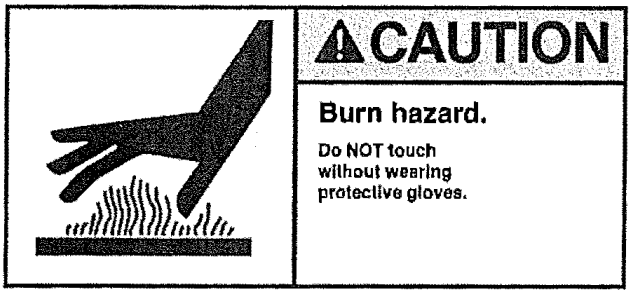


FIGURE 13.22 The leading and spacing of text on this label show an improper proportion, with the type size of some of the message text too small in comparison to the signal word and label size.

GUIDELINE 13.108: HORIZONTAL SPACING BETWEEN LETTERS

The distance between letters (i.e., horizontal spacing) should not be so limited that one character appears to touch the sides of the next. Nor should letters be spread so far apart that additional eye movements are required to read the text (Watanabe, 1994) (see Figure 13.22).

13.6.7.3 Other Strategies

Usually, space for labeling is limited. Rather than make the print too small to satisfy the completeness criterion or making the print so large that some important information is omitted, designers should consider other strategies to display the information, such as increasing the available surface area and prioritizing components of a label.

GUIDELINE 13.109: OVERALL LABEL SIZE

Designers could consider increasing the surface area available for the label (Wogalter and Vigilante, 2003; Wogalter and Young, 1994).

GUIDELINE 13.110: PRIORITIZATION OF LABEL COMPONENTS

Prioritization refers to ordering the components of a label with respect to importance. The most important information should be presented first and/or otherwise enhanced by highlighting (e.g., larger size, color). Decisions can be based on judgments of overall importance, severity and probability of injury, and whether the information is already known by users (Vigilante and Wogalter, 1997). When high-profile space is limited, items of the lowest priority may need to relegated to other labeling (e.g., supplemental presentation materials, such as the user manual).

13.6.8 CODING

Coding refers to the use of physical attributes within a presentation to signify or designate some association, organization, or meaning. Coding methods include color, shape, graphical elements and location. The purpose of coding is to help users distinguish important characteristic features and identify functionally related and/or critical features. For example, code markings on gauges are placed to convey the desirable operating range, dangerous operating levels, status information, or alarm conditions.

13.6.8.1 Redundant Codes

GUIDELINE 13.111: REDUNDANCY OF CODING

Coding used to convey safety-critical information, actions, or device functions should have redundancy. That is, the same information should be presented via two or more modes to ensure that users receive it.

Several types of coding can be used, including color, size, location, shape, and symbols (see Figure 13.23). Color should not be the sole means for identifying and/or distinguishing critical information elements, nor should it be the primary means of doing so. Redundant coding, especially of critical information, should be provided for several reasons. For example, coding only with color can lead to use error for the following reasons:

1. Lighting can vary and 'wash out' some colors (e.g., because of glare), accentuating the need for a "backup" code.
2. Some users are likely to have some form of color blindness. In the United States, approximately 7% of men and 1% of women are red-green color blind and cannot distinguish between these two colors. A smaller percentage of people have a blue-yellow color weakness. For this reason, more than one code in addition to color should be used.

Both the ISO and ANSI recommend the use of redundant coding of warning information to ensure that the level of hazard is accurately conveyed. ANSI guidelines accomplish this goal by pairing each of three colors with one of three specific signal words in a warning's header (refer to Figure 13.24). ISO standards for devices marketed in the EEA tend to incorporate shape coding of the external borders along with color in safety symbols (see Figure 13.25a). Recently, there have been efforts to harmonize ANSI and ISO guidelines for warnings (see Figure 13.25b).

13.6.8.2 Color Coding

Color coding can be used to enhance the transfer of relevant information to device users by making important labeling information stand out (refer to Figures 13.8, 13.10, and 13.20). Color coding of labels facilitates visual identification and reduces the likelihood that users

FIGURE 13.23 **(See color insert following page 564.)** Redundant coding can help ensure that users receive the information they need to operate medical devices safely.

FIGURE 13.24 ANSI Z-535 (2002) recommends the use of three different colors to connote differing levels of hazard.

will inadvertently manipulate the wrong device element. For many people, color is highly effective in drawing attention to and distinguishing important device information (Wiklund and Dolan, 1996).

Color can also be used to communicate varying conditions, such as levels of hazard or other quantity, as illustrated in Figure 13.26. Important considerations when using color coding are consistency, color choice, and number of colors. Despite the potential problems of using color as a method of coding, consumers have a strong preference for the use of color in applications. However, some additional considerations are discussed below.

Guideline 13.112: Consistency of Color Coding

Colors that have a designated meaning or that are expected to elicit a specific user response should be used consistently throughout a device.

Guideline 13.113: Color Coding Consistent with Expectations

Color coding should, whenever possible, be consistent with users' expectations, customs, and prior experience with similar devices.

Guideline 13.114: Most Readily Identified Colors

Red, green, yellow, orange, and blue are the most easily identified (named and recognized) colors.

(a) ISO standards for devices sold in the EEA tend to incorporate shape coding along with color in safety symbols.

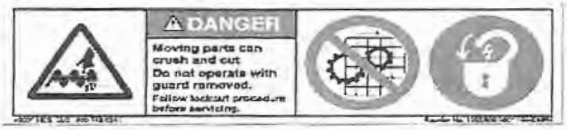
Strong magnetic field warning–yellow triangle with black border (ISO).Graphic must be black.

Pacemaker prohibition–white and red circle with red slash (ISO) and black graphic

(b) Examples of harmonized warnings.

Harmonized ISO and ANSI label combining three colors with a specific signal word and ISO standard safety shapes.

Mandatory action–blue circle with white graphics (ISO) (above) and harmonized ISO and ANSI label (right): indicates an action to take to avoid the hazard.



Label format combining a warning, a prohibition, and mandatory action, incorporating ISO standards shapes with ANSI formatting.

FIGURE 13.25 (a) Examples of ISO labels, advocating more shape coding, and (b) harmonized warnings that incorporate both ISO and ANSI formatting features.

The number of colors used for coding should be kept to the minimum needed to provide sufficiently distinctive information. Unfortunately, existing guidelines are inconsistent regarding the maximum number of colors that should be used. Some guidelines recommend using no more than four colors on a label, whereas others are more lenient. For instance, the National Aeronautics and Space Administration (NASA) allows the use of up to six colors on device labels. NASA also recommends no more than three shades of gray if users must either recall the meaning of each color or make identifications on the basis of color or shade. A general recommendation is to use no more than five colors (refer to

FIGURE 13.26 Color can be an effective tool for conveying safety critical information such as the identity of breathing gases. Note that in this case, shape and position coding are also used to reduce the risk of use error.

Figures 13.8, 13.10, 13.12, 13.15, 13.20, and 13.23). If color coding is not self-evident, a legend should be provided in the device labeling to assist the user in determining the meaning of each color code. Users are better able to distinguish colors presented concurrently (e.g., on the same fixed label) than those presented sequentially (e.g., on different screens of an electronic display).

Guideline 13.115: Minimize the Number of Colors

In general, using only two or three colors on a label is better than using eight or nine colors. If more categories are needed, then other methods of coding should be incorporated, such as shape, patterns, and so on.

Guideline 13.116: Meaning of Color Codings

Color conventions and meanings should play influence decisions about the choice of color coding.

Worldwide, there are differences with respect to color conventions, such as color coding of medical gas cylinder contents used in medical procedures. For example, different combinations of green and gray are used to designate oxygen, carbon dioxide, and nitrogen cylinders. Patient deaths have occurred when a mix-up between carbon dioxide (nonflammable) and oxygen (flammable) has taken place and an ignition source was applied (e.g., a surgical laser).

As mentioned earlier, there is a device warning label standard that recommends certain colors for designating hazards (ANSI Z535, 2002). This standard recommends the use of three different colors to indicate differing levels of hazard (in decreasing order): red, orange, and yellow (refer to Figure 13.24). ISO recommendations for the use of color for warning labels are similar. The colors blue and green may be used for safety-related and other important information. See ANSI Z535.1 (2002) for specifications of color in terms of CIE color space and associated Pantone chips.

Guideline 13.117: Use of Red Color

Designers should use red to indicate hazards that, if not avoided, will lead to death (ANSI Z535, 2002). Red is also used for fire safety and emergency stop control. The use of red to indicate other kinds of conditions should be minimized.

Guideline 13.118: Use of Orange Color

According to ANSI Z535 (2002), the color orange should generally be used to indicate hazards that, if not avoided, can lead to serious injury or death. In the signal word panel, the print is black, and the background is orange. Some rendered oranges have insufficient contrast in certain lighting conditions and should be avoided on labels.

Guideline 13.119: Use of Yellow Color

The color yellow should generally be used for advisory messages, including warning of hazards that, if not avoided, could lead to minor injury or property damage (ANSI Z535, 2002). However, people generally tend to view orange and yellow as connoting similar levels of hazard. Black print on a yellow background is much more legible than black print on an orange background.

13.6.8.3 Size Coding

Size coding generally applies to actual controls and connectors but might also be used in labels to provide an additional means of enhancing visual discrimination. However, size coding is generally less effective than most other kinds of coding methods (Sanders and McCormick, 1993).

Guideline 13.120: Consistency of Label Element Size

Similar elements (or elements used for similar functions) could be coded with the same-size labels or labeling elements.

Guideline 13.121: Number of Sizes

Generally, no more than three different sizes should be employed. The ability to make reliable distinctions among different-size elements depends on the magnitude of these differences:

- *Large differences.* Generally, larger differences between the size code components make them more distinguishable.
- *Twenty percent bigger.* In general, the largest device element should be at least 20% bigger than the smallest.

Optimal size coding also depends on viewing distance: Greater expected viewing distances would require larger differences in size between the device elements.

13.6.8.4 Location Coding

Guideline 13.122: Location Coding

Designers can use location coding to relate device elements according to functional groups or sequence of use. Location coding should be applied consistently across devices and, where possible, systems.

13.6.8.5 Shape Coding

Shape coding in labeling can strengthen the association between a control and its function. The ISO advocates the use of shape coding in labeling (Warburton, 2004). However, ANSI is less enthusiastic about shape coding because it may be a weaker coding modality than, for example, color. See Sanders and McCormick (1993) for an overview of various shape and control dimensions.

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Guideline 13.123: Recognizable Shapes

When devising shape-coding systems for control devices, designers should incorporate shapes that are highly recognizable, such as circles, squares, and triangles (Riley, Cochran, and Ballard, 1982).

Guideline 13.124: Tactile Coding

Shape coding can also involve tactile cues, such as raised labels or buttons (e.g., Mendat and Wogalter, 2004). This is a type of texture coding that is otherwise uncommonly used in label design.

13.6.8.6 Graphics and Symbols

Guideline 13.125: Use Recognizable Symbols

Graphics and symbols should be selected or developed that are easily recognizable by the intended user population. In general, graphics and symbols that closely resemble their referents are more easily understood than those used to represent abstract concepts, such as radiation and biological risk (see Figure 13.27). Such abstract symbols and graphics may require training and/or accompanying text to ensure that users will interpret them correctly. When using abstract graphics or symbols for critical information transmission, other forms of coding should be considered.

Guideline 13.126: Consistency and Convention in Symbol Choice

Symbols integrated into graphic depictions of flow paths (e.g., pumps, filters, valves, gain controls) should be based on consistency and convention.

Guideline 13.127: Symbol Testing

The effectiveness of symbols intended to convey critical information should be established through user testing. Testing protocols are described in ANSI Z535.3 (2002) for safety symbols and in several chapters in Wogalter (2006) for warning labels (e.g., see Deppa, 2006).

13.6.9 Section Summary

This section provided specific design guidelines for medical device labels. The guidelines are based on human factors principles and will facilitate label designs that are both effective and meet prevailing legal requirements. The guidelines provided here are intended as general recommendations and should not be applied in a "cookbook" fashion. There is an almost infinite variety of medical device designs and configurations, and exceptions or better alternatives are inevitable.

Indeed, medical device use environments can vary greatly (e.g., operating rooms, emergency rooms, hospital units, ambulances, homes), and many factors contribute to label effectiveness, such as user characteristics (e.g., current knowledge, stress), the expected use environment (e.g., lighting), and the task demands and exigencies (e.g., viewing distances). The effectiveness of any particular label design will depend on how it is used. Testing under the various expected use conditions can help to evaluate label effectiveness and determine the adequacy of the label's design. Existing standards provide some guidance for label development and testing, such as the addendum/appendix of ANSI Z535.3 (2007). Wogalter, Conzola, and Vigilante (2006) outline usability principles that could be used when developing label text. Without testing, the label designer does not know whether

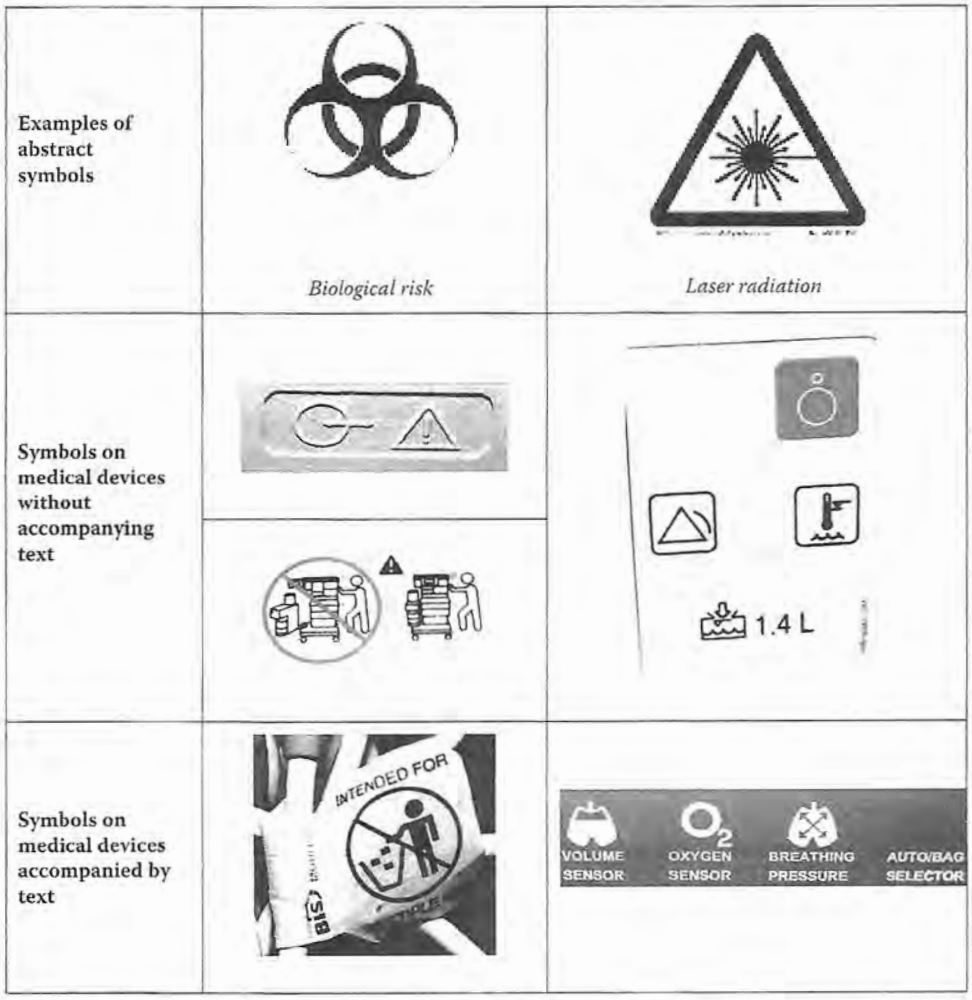

FIGURE 13.27 Users may require training or accompanying text to understand the meaning of symbols and graphics. Iterative testing with a representative sample of likely users can help determine comprehensibility of symbols.

the label will do its job—fulfill its intended mission—to inform, to facilitate compliance, and to remind.

13.7 CONCLUSIONS

This chapter consisted of three sections organized around key design issues. The first section addressed the critical issue of what should be labeled and focused on the specific legal requirements and voluntary standards that guide medical device labeling in the United States. The second section presented an overview of the relevant human factors literature that should be considered when designing labels for a medical device. This section used a C-HIP (Communication-Human Information Processing) framework as a means of organizing and understanding the labeling literature. Designers can use C-HIP as a developmental tool, while investigators can use it as an analytical tool. In the third section, specific guidelines were provided for developing effective medical device labels and their

associated components. Because of the breadth and scope of medical devices, specifics for any given application could not be provided. All the principles will not be applicable to any given device, and usability evaluation (testing) will be required for critical labeling design decisions.

The overall goal of the chapter, of course, is to provide designers with practical guidelines for developing on-device labels for medical devices. It is intended to advance the labeling of medical devices by assisting designers in designing, formatting, and positioning of labels and markings for controls, displays, panels, and associated equipment. Labels should be considered as a supplement to, not a substitute for, good device design. (Lehto and Salvendy, 1995). An exposed switch mounted on the surface of a control panel is more likely than a recessed one to be inadvertently activated despite an effective warning label. The guidance provided for labels in this chapter may apply to other instructional and warning materials besides on-device labeling (see Chapter 5, Documentation).

Legal requirements, standards, and human factors principles specify certain characteristics to ensure that medical device labeling is effective. Labels and markings on medical devices should be attention getting, understandable, believable and motivate compliance. In addition, label designs should take into account local conventions and meanings associated with specific markings as well as the abilities and limitations of the intended user population. Controls, displays, and other components of medical devices should be labeled appropriately and clearly to assure rapid and accurate human performance and to prevent user errors which could cause user or patient injury. Finally, gathering user input during the development process is vital to ensure that labels meet users' needs.

ACKNOWLEDGMENTS

The authors are grateful to Peter B. Carstensen and Charles (Dick) Sawyer from the U.S. Food and Drug Administration for their work in helping to develop a preliminary version of this chapter. The authors are grateful for the assistance in allowing photographs to be taken of various medical devices at Albany Medical Center (Albany, NY) and Duke Medical Center (Durham, NC) hospitals. Thanks are also due to Jennifer A. Cowley, a graduate student in the Department of Psychology at North Carolina State University, and Courtney Ellert, a student in the Electronic Media, Arts, and Communication program at Rensselaer Polytechnic Institute.

REFERENCES

Barlow, T. and Wogalter, M. S. (1991). Increasing the surface area on small product containers to facilitate communication of label information and warnings. In *Proceedings of Interface 91* (pp. 88–93). Santa Monica, CA: Human Factors Society.

Baron, R. A. and Kalsher, M. J. (2005). *Psychology: From Science to Practice.* Needham Heights, MA: Allyn & Bacon.

Bix, L., Lockhart, H., Cardoso, F., and Selke, S. (2003). The effect of color contrast on message legibility. *Journal of Design Communication.* Available: http://scholar.lib.vt.edu/ejournals/JDC/Spring-2003/colorcontrast.html.

Braun, C. C. and Silver, N. C. (1995). Interaction of signal word and colour on warning labels: Differences in perceived hazard and behavioural compliance. *Ergonomics, 38,* 2207–2220.

Brehler, R. and Kutting, B. (2001). Natural rubber latex allergy: A problem of interdisciplinary concern in medicine. *Archives of Internal Medicine, 161,* 1057–1064.

Chapanis, A. and Yoblick, D. A. (2001). Another test of sensor lines on control panels. *Ergonomics, 44,* 1302–1311.

Council Directive 93/42/EEC concerning Medical Devices. (1993, June 14). Retrieved May 5, 2005, from http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=en&numdoc=31993L0042&model=guichett

Cohen, H. H., Cohen, J., Mendat, C. C., and Wogalter, M. S. (2006). Warning channel: Modality and media. In M. S. Wogalter (Ed.) *Handbook of Warnings* (pp. 123–134). Mahwah, NJ: Lawrence Erlbaum Associates.

Cox, E. P. III, and Wogalter, M. S. (2006). Warning source. In M. S. Wogalter (Ed.) *Handbook of Warnings* (pp. 111–122). Mahwah, NJ: Lawrence Erlbaum Associates.

Cox, E. P., III, Wogalter, M. S., Stokes, S. L., and Murff, E. J. T. (1997). Do product warnings increase safe behavior? A meta-analysis. *Journal of Public Policy and Marketing, 16,* 195–204.

DeJoy, D. M. (1999). Attitudes and beliefs. In M. S. Wogalter, D.M. DeJoy, & K.R. Laughery (Eds.) *Warnings and Risk Communication* (pp. 189–219). London: Taylor & Francis.

Deppa, S. W. (2006). U.S. and international standards. In M. S. Wogalter (Ed.), *Handbook of Warnings* (pp. 477–486). Mahwah, NJ: Lawrence Erlbaum Associates.

Desaulniers, D. R. (1987). Layout, organization, and the effectiveness of consumer product warnings. In *Proceedings of the Human Factors Society 31st Annual Meeting* (pp. 56–60). Santa Monica, CA: Human Factors Society.

Dyck, R. (2000). Historical development of latex allergy. *AORN Journal, 72*(1), 27.

Glasscock, N. F. and Dorris, N. T. (2006). Warning degradation and durability. In M. S. Wogalter (Ed.), *Handbook of Warnings* (pp. 499–511). Mahwah, NJ: Lawrence Erlbaum Associates.

Godfrey, S. S., Allender, L., Laughery, K. R. and Smith, V. L. (1983) Warning messages: Will the consumer bother to look? In *Proceedings of the Human Factors Society 27th Annual Meeting* (pp. 950–954). Santa Monica, CA: Human Factors Society.

Goldsworthy, R. and Kaplan, B. (2006). Warning symbol development: A case study on teratogen symbol design and evaluation. In M. S. Wogalter (Ed.), *Handbook of Warnings* (pp. 739–755). Mahwah, NJ: Lawrence Erlbaum Associates.

Frascara, J. (2006). Typography and the visual design of warnings. In M. S. Wogalter (Ed.), *Handbook of Warnings* (pp. 385–406). Mahwah, NJ: Lawrence Erlbaum Associates.

Hartley, J. (1994). *Designing Instructional Text* (3rd ed.). London: Kogan Page; East Brunswick, NJ: Nichols.

International Electrotechnical Commission. (2007). IEC 60601-1 Standard, Medical Electrical Equipment—Part 1: General Requirements for Safety. Geneva: International Electrotechnical Commission.

Kalsher, M. J., Wogalter, M. S., and Racicot, B. M. (1996). Pharmaceutical container labels and warnings: Preference and perceived readability of alternative designs and pictorials, *International Journal of Industrial Ergonomics, 18,* 83–90.

Laughery, K. R. and Paige-Smith, D. (2006). Explicit information in warnings. In M. S. Wogalter (Ed.), *Handbook of Warnings* (pp. 419–428). Mahwah, NJ: Lawrence Erlbaum Associates.

Laughery, K. R., Vaubel, K. P., Young, S. L., Brelsford, J. W., and Rowe, A. L. (1993). Explicitness of consequence information in warning. *Safety Science, 16,* 597–613.

Laughery, K. R., Wogalter, M. S., and Young, S. L. (Eds.). (1994). *Human Factors Perspectives on Warnings: Selections from Human Factors and Ergonomics Society Annual Meetings 1980–1993.* Santa Monica, CA: Human Factors and Ergonomics Society.

Lehto, M. R., and Miller, J. M., (1986). *Warnings, Volume 1: Fundamentals, Design and Evaluation Methodologies.* Fuller Technical, Ann Arbor, MI.

Lehto, M., and Salvendy, G. (1995). Warnings: A supplement not a substitute for other approaches to safety. *Ergonomics, 38,* 2155–2163.

Mayhorn, C. B. and Podony, K. (2006). Warnings and aging: Describing the receiver characteristics of older adults. In M. S. Wogalter (Ed.), *Handbook of Warnings* (pp. 355–362). Mahwah, NJ: Lawrence Erlbaum Associates.

Mazis, M. B. and Morris, L. A. (1999). Channel. In M. S. Wogalter, D. M. DeJoy, & K. R. Laughery (Eds.) *Warnings and risk communication* (pp. 99–121). London: Taylor & Francis.

Mendat, C. C. and Wogalter, M. S. (2004). The effectiveness of tactile cues in cellular phones. *Proceedings of the Human Factors and Ergonomics Society, 48,* 717–720.

Miller, J. M. and Parent, C. (2006). Appendix: Bibliography of standards. In M. S. Wogalter (Ed.), *Handbook of Warnings* (pp. 795–804). Mahwah, NJ: Lawrence Erlbaum Associates.

Misanchuk, E. R. (1992). *Preparing Instructional Text: Document Design Using Desktop Publishing.* Englewood Cliffs, NJ: Educational Technology.

Riley, D. M. (2006). Beliefs, attitudes, and motivation. In M. S. Wogalter (Ed.) *Handbook of Warnings* (pp. 289–300). Mahwah, NJ: Lawrence Erlbaum Associates.

Riley, M. W., Cochran, D. J., and Ballard, J. L., 1982. An investigation of preferred shapes for warning labels. *Human Factors, 24,* 737–742.

Sanders, M. and McCormick, E. (1993). *Human Factors in Engineering and Design.* New York: McGraw-Hill.

Sawyer, D. (1993, June 14). *Do it by design: An Introduction to Human Factors in Medical Devices.* Retrieved May 5, 2005, from http://www.fda.gov/cdrh/humfac/doit.html

Simpson, H. and Casey, S. M. (1988). *Designing Effective User Documentation: A Human-factors Approach.* New York: McGraw-Hill.

Smith-Jackson, T. L. (2006a). Culture and warnings. In M. S. Wogalter (Ed.), *Handbook of Warnings* (pp. 363–372). Mahwah, NJ: Lawrence Erlbaum Associates.

Smith-Jackson, T. L. (2006b). Receiver characteristics. In M. S. Wogalter (Ed.), *Handbook of Warnings* (pp. 335–344). Mahwah, NJ: Lawrence Erlbaum Associates.

Sojourner, R. J. and Wogalter, M. S. (1997). The influence of pictorials on evaluations of prescription medication instructions. *Drug Information Journal, 31,* 963–972.

Study Group 1 of the Global Harmonization Task Force. (2002, March 1). *Labelling for Medical Devices (including in vitro diagnostic devices).* Retrieved May 3, 2004, from www.ghtf.org/sg1/inventorysg1/sg1pd-n043r3.pdf

Underwriters Laboratories, Inc. (n.d.). *CE Mark Info.* Retrieved May 5, 2004, from http://www.ul.com/regulators/CEmarkinfo.html

U.S. Food and Drug Administration. (2000, July 18). *Guidance for Industry and FDA Premarket and Design Control Reviewers—Medical Device Use-safety: Incorporating Human Factors Engineering into Risk Management.* Retrieved May 5, 2004, from http://www.fda.gov/cdrh/humfac/1497.html#_Toc486653483

Vigilante, W. J., Jr., and Wogalter, M. S. (1997). The preferred order of over-the-counter (OTC) pharmaceutical label components. *Drug Information Journal, 31,* 973–988.

Vredenburgh, A. G. and Helmick-Rich, J. (2006). Extrinsic nonwarning factors. In M. S. Wogalter (Ed.), *Handbook of Warnings* (pp. 373–381). Mahwah, NJ: Lawrence Erlbaum Associates.

Vredenburgh, A. G. and Zackowitz, I. B. (2006). Expectations. In M. S. Wogalter (Ed.), *Handbook of Warnings* (pp. 345–354). Mahwah, NJ: Lawrence Erlbaum Associates.

Warburton, D. (2004, April). Are your product safety labels state-of-the-art? *Medical Device and Diagnostic Industry.* Retrieved May 4, 2004, from http://www.devicelink.com/mddi/archive/04/04/001.html

Watanabe, R. K. (1994). The ability of the geriatric population to read labels on over-the-counter medication containers. *Journal of the American Optometric Association, 65,* 32–37.

Weinger, M. B., Herndon, O. W., Paulus, M. P., Gaba, D., Zornow, M. H., and Dallen, L. D. (1994). Objective task analysis and workload assessment of anesthesia providers. *Anesthesiology, 80,* 77–92.

Weinger, M. B., Slagle, J. M., Kim, R. S., and Gonzales, D. C. (2001). A task analysis of the first weeks of training of novice anethesiologists. *Proceedings of the Human Factors and Ergonomics Society, 45,* 404–408.

Wickens, C. D., Lee, J., Liu, Y. D., and Gordon-Becker, S. (2003). *Introduction to Human Factors Engineering* (2nd ed.). Englewood Cliffs, NJ Prentice Hall.

Wiklund, M. and Dolan, W. (1996, October). Why choose color displays? *Medical Device and Diagnostic Industry Magazine*. Retrieved May 4, 2004, from http://www.devicelink.com/mddi/archive/96/10/015.html

Wogalter, M. S. (2006). *Handbook of Warnings*. Mahwah, NJ: Lawrence Erlbaum Associates.

Wogalter, M. S., Allison, S. T., and McKenna, N. A. (1989). The effects of cost and social influence on warning compliance. *Human Factors, 31,* 133–140.

Wogalter, M. S., Brelsford, J. W., Desaulniers, D. R., and Laughery, K. R. (1991). Consumer product warnings: The role of hazard perception. *Journal of Safety Research, 22,* 71–82.

Wogalter, M. S., Brems, D. J., and Martin, E. G. (1993). Risk perception of common consumer products: Judgments of accident frequency and precautionary intent. *Journal of Safety Research, 24,* 97–106.

Wogalter, M. S., Conzola, V. C., and Vigilante, W. J., Jr. (2006). Applying usability engineering principles to the design and testing of warning text. In M. S. Wogalter (Ed.), *Handbook of Warnings* (pp. 487–498). Mahwah, NJ: Lawrence Erlbaum Associates.

Wogalter, M. S., DeJoy, D. M., and Laughery, K. R. (1999). *Warnings and Risk Communication*. London: Taylor & Francis.

Wogalter, M. S., Forbes, R. M., and Barlow, T. (1993). Alternative product label designs: Increasing the surface area and print size. In *Proceedings of Interface 93* (pp. 181–186). Santa Monica, CA: Human Factors Society.

Wogalter, M. S., Godfrey, S. S., Fontenelle, G. A., Desaulniers, D. R., Rothstein, P. R., and Laughery, K. R. (1987). Effectiveness of warnings. *Human Factors, 29,* 599–612.

Wogalter, M. S., Kalsher, M. J., and Rashid. R. (1999). Effect of signal word and source attribution on judgments of warning credibility and compliance likelihood. *International Journal of Industrial Ergonomics, 24,* 185–192.

Wogalter, M. S. and Laughery, K. R. (1996). WARNING: Sign and label effectiveness. *Current Directions in Psychology, 5,* 33–37.

Wogalter, M. S. and Leonard, S. D. (1999). Attention capture and maintenance. In M. S. Wogalter, D. M. DeJoy, and K. R. Laughery (Eds.), *Warnings and Risk Communication* (pp. 123–148). London: Taylor & Francis.

Wogalter, M. S., Magurno, A. B., Dietrich, D., and Scott, K. (1999). Enhancing information acquisition for over-the-counter medications by making better use of container surface space. *Experimental Aging Research, 25,* 27–48.

Wogalter, M. S. and Post, M. P. (1989). Printed computer instructions: The effects of screen pictographs and text format on task performance. In *Proceedings of Interface 89* (pp. 133–138). Santa Monica, CA: Human Factors Society.

Wogalter, M. S., Silver, N. C., Leonard, S. D., and Zaikina, H. (2006). Warning symbols. In M. S. Wogalter (Ed.), *Handbook of Warnings* (pp. 159–176). Mahwah, NJ: Lawrence Erlbaum Associates.

Wogalter, M. S. and Usher, M. (1999). Effects of concurrent cognitive task loading on warning compliance behavior. *Proceedings of the Human Factors and Ergonomics Society, 43,* 106–110.

Wogalter, M. S. and Vigilante, W. J., Jr. (2003). Effects of label format on knowledge acquisition and perceived readability by younger and older adults. *Ergonomics, 46,* 327–344.

Wogalter, M. S. and Vigilante, W. J., Jr. (2006). Attention switch and maintenance. In M. S. Wogalter (Ed.), *Handbook of Warnings* (pp. 245–265). Mahwah, NJ: Lawrence Erlbaum Associates.

Wogalter, M. S., Vigilante, W. J., and Baneth, R. C. (1998). Availability of operator manuals for used consumer products. *Applied Ergonomics, 29,* 193–200.

Wogalter, M. S. and Young, S. L. (1994). Enhancing warning compliance through alternative product label designs. *Applied Ergonomics, 25,* 53–57.

Wogalter, M. S., Young, S. L., and Laughery, K. R., Eds. (2001). *Human Factors Perspectives on Warnings, Volume 2: Selections from Human Factors and Ergonomics Society Annual Meetings 1994–2000*. Santa Monica: Human Factors and Ergonomics Society, in press.

Wolfe, J. M., Kluender, K. R., Levi, D. M., Bartoshuk, L. M., Herz, R. S., Klatzky, R. L., et al. (2006). *Sensation and Perception.* Sunderland, MA: Sinauer Associates.

Wright, P. (1982). Some factors determining when instructions will be read. *Ergonomics, 25,* 225–237.

Young, S. L., Wogalter, M. S., Laughery, K. R., Magurno, A., and Lovvoll, D. (1995). Relative order and space allocation of message components in hazard warning signs. *Proceedings of the Human Factors and Ergonomics Society, 39,* 969–973.

Zak, H. N., Kaste, L. M., and Schwarzenberger, K. (2000, September/October). Health-care workers and latex allergy. *Archives of Environmental Health, 55,* 336–346.