

## **Type Size**

Use a large enough type size for the labeling to be legible to the intended user audience. Because many medical device users are older people, type size is an especially important feature of medical device labeling.

9-point and smaller type makes it likely that readers will skip the material or develop eyestrain.

10-point type is an acceptable minimum size for general audiences, but not for the elderly.

12-point type is an excellent compromise between the need to conserve space and to present legible instructions. Twelve-point type is also the best overall size for visually impaired persons and the elderly.

14-point type is good for visually impaired readers and the elderly.

18-point type should be used sparingly, if at all.

## **Type Font**

Most type fonts in common use are about equally legible, although Times Roman is perhaps the least fatiguing (Simpson & Casey, 1988). Serif type is easier to read than sans-serif type. (A serif is a fine horizontal line finishing off the main stroke of a letter.) Use serif type whenever possible. Labeling printed in several different fonts retards reading speed. Use a common font consistently throughout a document. Minimize the use of multiple fonts.

## **Line Length**

Long line lengths are the norm for non-instructional, narrative writing printed on standard letter-size paper, such as this report.

The best line length for an instruction booklet printed in 12-point type is  $4.0 \pm 1.25$  inches. Longer lines may strain the eye as it scans across their entire length, making it easier to jump to the wrong next line. This is an especially crucial consideration for medical devices, where the steps of each operating procedure must be performed in their correct sequence.

Shorter lines (less than 2.5 inches)  
slow reading due to the large  
number of back-and-forth eye  
movements required while reading

even a single sentence. Curtail or eliminate the use of shorter lines.

### All Capitals and Italics

TEXT PRINTED IN ALL CAPITAL LETTERS INTERFERES WITH LEGIBILITY AND TAKES UP MORE SPACE. IT ALSO SLOWS READING SPEED (BY AS MUCH AS 20%, TINKER, 1963) BECAUSE THE SHAPES OF THE LETTERS DO NOT VARY GREATLY. *Similarly, use italicized type sparingly because it also retards reading speed.*

If used judiciously, however, ALL-CAPITALS and *italics* can highlight important text.

The following example of the proper use of all-capitals is from the model lens care booklet:

<p style="text-align: center;"><b>ALL-CAPITALS Example</b></p> <p>This booklet explains how to take care of your soft contact lenses.</p> <p>READ THIS BOOKLET CAREFULLY from beginning to end. KEEP IT to help answer questions about your lens care.</p> <p>If you have more questions about care and wear of soft contact lenses after reading this book, call or visit your eye care practitioner.</p>
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Ragged right margins make labeling easier to read than right-justified text. Readers can keep track of their place because the right profile helps distinguish one line from another. The eye does not have to adjust to variable spacing between words as it does with right-justified lines. Proportional spacing produces uniform spacing between letters within a word.

Black print on a white background is a universal standard for print contrast. Minimize the use of hyphenation; it requires the reader to remember the last syllable on the previous line. Persons with limited vision or poor memory often find this to be difficult.

### Typography and Legibility References

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### Tips on Typography and Legibility

- Use adequate type size (12 pt. is the best all-around type size)
- Use serif type for text and sans serif for titles and headlines
- Proportional spacing is important for ease of reading
- Maintain high print to background contrast ratio
- Keep line length short enough for reading ease
- Ragged right margins are preferred
- Minimize hyphenations, especially in short words
- Use words in all-capitals and italics judiciously

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### Physical Characteristics

Physical characteristics of labeling influence its ease of use and subjective appeal. Documents should be compact, accessible, and easily used under actual device operating conditions. These factors contribute to the extent to which labeling is read, comprehended, followed, and retained. Desirable physical characteristics for medical device labeling stem from two factors: (a) how the document will be used and (b) the updating requirement.

Documents such as technical manuals are typically used when a device is not being operated. These documents are often book length and should be sized accordingly. Other documents, such as operator's booklets and quick reference guides, are used while operating a medical device. They must be designed for ease of access and use, which necessitates a smaller format.

Updating a document involves adding or deleting pages. Ring binding is ideal for meeting this requirement. Spiral binding is preferable for documents that will not be modified (Simpson & Casey, 1988). All documents should lay flat without assistance so that users can have both hands free to operate the device.

Paper with a dull finish is better than glossy paper, which can produce a distracting reflection into the eye. Paper should be heavy enough to prevent show-through.

### **Physical Characteristics References**

Hartley, J. (1978). *Designing instructional text* (pp. 9-12). London: Kogan Page.

Simpson, H., & Casey, S.M. (1988). *Designing effective user documentation: A human-factors approach* (Ch. 8). New York: McGraw-Hill.

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### **Tips on Physical Characteristics**

- Use an orientation that allows text and graphics to be displayed together
  - Make size appropriate to purpose
  - Use binding type appropriate to updating requirement
  - Ensure that document will lay flat
  - Paper should have a dull finish and not show through
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### **RELATED TOPICS**

#### **Instructional Theory**

Much research has been conducted on the theoretical bases of teaching people to operate devices. Specific details of these theories lie beyond the scope of this report. It is appropriate to mention instructional theory, however, because it has influenced the principles of medical device labeling presented in this report. The references listed below are most relevant to medical device labeling. The bibliography contains papers related to more theoretical topics which are nonetheless applicable to labeling design, development, and evaluation.

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## **Evaluation of Medical Device Labeling**

Labeling for a medical device that has been approved by FDA should undergo premarket testing and evaluation. Pretesting involves the systematic collection of data from members of the intended user group on various characteristics of the labeling. Pretesting can identify specific strengths and weaknesses of labeling. Use the findings from pretesting to improve labeling before the device is brought to market.

Pretests of labeling should focus on one or more of the following areas: user comprehension, user performance, acceptability, and credibility. Focus on the characteristics of the intended user group to make the labeling most effective for them. A major shortcoming of much medical device labeling is that it has not been written with the target users in mind. Consequently, users have often misunderstood or been unable to comprehend labeling.

Several methods can be used to pretest medical device labeling, including focus group interviews, in-depth individual interviews, questionnaires, and readability testing. Most often, some combination of these methods must be used to develop the most effective labeling

possible. The accompanying reference list contains representative articles and monographs that illustrate how these methods are used to assess, evaluate, and improve medical device labeling.

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### Alternative Instructional Media

This report has been concerned exclusively with printed labeling as the means of instructing persons to operate medical devices. The instructional value of media other than printed labeling has received little research attention to date. Yet preliminary findings are noteworthy. For example, participants in the user observation studies of this project preferred individual demonstrations and videotapes over printed labeling. And multimedia instructional packages produce more compliant performance than any single instructional medium. Thus, although printed materials play an important role in teaching people how to operate medical devices, alternative media merit investigation. The following reference list provides a sampling of research on media other than printed labeling.

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### **Regulations, Standards, and Guidelines**

Regulations, standards, and guidelines help ensure that medical devices are designed, manufactured, and used in a safe and effective manner. Regulations are rules, restrictions, or controls prescribed by a constituted authority. Standards identify specific, essential requirements for materials, methods, or practices. Like regulations, standards are applied without modification. Guidelines are developed through consensus and describe criteria for general operating practice, procedure, or material. Guidelines are the least binding of the three categories of prescription, and may be used as written or modified to fit particular needs.

### **Regulations, Standards, and Guidelines References**

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- United States, Code of Federal Regulations, Title 21 Food and Drug Administration, DHHS, *Part 809*, *In vitro* diagnostic products for human use, Subpart B, Labeling for *in vitro* diagnostic products.
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