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HUMAN FACTORS PRINCIPLES FOR MEDICAL DEVICE LABELING

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INTRODUCTION

By government regulation and industry practice, instructions accompanying distribution of medical devices to the public are termed "labeling". Medical device labeling consists of directions on how to use and care for medical devices. It also includes supplementary information necessary for understanding and safety, such as information about risks, precautions, warnings, potential adverse reactions, etc. This report presents principles for medical device labeling for use by labeling developers and designers. These principles are just as applicable to supplementary information and labels on medical devices as they are to the instructional booklets that accompany devices.

Clinical and laboratory details of value to professionals who prescribe or sell medical devices also are included under labeling. Many of these details are further subsumed under the title "package insert". Labeling and package inserts are regulated by the federal government under the requirements for labeling drugs and medical devices. Federal regulations require that labeling for medical devices be provided in a specific format. These regulations are contained in 21 CFR Part 801. Complete and accurate labeling is important to the safe, reliable operation of medical devices, whether used by the consumer in the home or by the professional in the hospital.

This report describes and extends the findings of an FDA project that examined the effectiveness of labeling for soft contact lenses, a widely used medical device (Callan, Gwynne, Cardinal, & Kelly, 1990; Gwynne, Cardinal, Easterly, & Callan, 1991; Gwynne, Provo, & Callan, 1992). One outcome of that project was a set of recommendations for making contact lens labeling more useful to the consumer. Many of those recommendations are valuable for labeling medical devices in general, not just contact lenses. The recommendations are presented here as principles for developing labeling for all medical devices.

This report may be viewed as a companion document to the FDA booklet, ***Write It*** Right: ***Recommendations for Developing User Instruction Manuals for Medical Devices Used in Home Health Care.*** That booklet provided guidance for the entire process of producing an instruction manual, from initial planning to dissemination of the final product. This report focuses on a more general aspect of that process, the underlying principles of instruction, human factors, and cognitive psychology that are involved in designing effective labeling for medical devices.

This project viewed medical device labeling in terms of content and presentation / format. Content refers to the types of information that should be included in instructional material.

Presentation / format refers to the manner and style in which that information is conveyed. When used together, they contribute greatly to the development of effective Labeling for medical devices. Content and presentation / format are discussed in this report in terms of the following areas:

Content	Presentation / Format
Organization	Language and Readability
Background Information	Illustrations and Graphics
Procedures	Highlighting
Risk Communication	Typography and Legibility
Supplementary Information	Physical Characteristics

Research in document design, human factors, and cognitive psychology in each of these areas has been summarized and integrated to provide principles of effective medical device labeling. A reference list of articles and books is provided after the discussion of each area. The bibliography at the end of this report contains a complete set of references for each area. A third section of this report discusses topics that are related to medical device labeling, although not central to the main concerns of this report. These topics include instructional theory, methods for evaluating medical device labeling, alternative instructional media, and regulations, standards, and guidelines for medical device labeling.

CONTENT

Organization

Organization refers to how topics in labeling are arranged in relation to each other. Organization is a major determinant of how well labeling can be understood and followed. In general, the first section should contain background information about the purpose of a medical device. Mention any significant hazards associated with device use here. Ensuing sections should describe procedures for operating and maintaining the device. Sections discussing possible health risks and device troubleshooting are often needed, too.

Titles, headings, subheadings, and summaries are examples of organization elements. They aid rapid location of information, improve retention of device operation, motivate users to use to labeling regularly, and emphasize the order in which procedures are performed. Organization

elements such as tables of contents and margin index tabs help readers locate specific topics. They also promote an understanding of how procedures are related to each other.

The table of contents from the model lens care booklet, displayed below, shows how descriptive titles for headings and subheadings communicate the content of each section. These titles correspond word-for-word with the headings and subheadings in the booklet text.

Organization Example

TABLE OF CONTENTS

Lens Care Chart 2

Introduction 3

General Precautions 4

Putting On Lenses 9

Taking Off Lenses 17

Cleaning and Disinfection 21

Cold (Chemical) Disinfection 26

Heat (Thermal) Disinfection 28

Emergency Heat Disinfection 30

Enzyme Cleaning 32

Lens Case Cleaning and Disinfection 33

What To Do When You Have Problems While Wearing Lenses 35

Organization References

Asubel, D.P. (1960). The use of advance organizers in the learning and retention of meaningful verbal material. *Journal* of Educational Psychology, *51*, 267-272.

Blaiwes, A.S. (1974). Formats for presenting procedural instructions. *Journal* of Applied Psychology, 59, 683-686.

Hartley, J., & Jonassen, D.H. (1985). The role of headings in printed and electronic text. In D.H. Jonassen (Ed.), *The* technology of text, Vol. 2. Englewood Cliffs, NJ: Educational Technology Publications.

Hartley, J., & Trueman, M. (1981). The effects of changes in layout and changes in wording on preferences for instructional text. Visible Language, *XV*, 13-31.

Hartley, J., & Trueman, M. (1985). A research strategy for text designers: The role of headings. Instructional Science, *14*, 99-155.

Mayer, R.E. (1979). Can advance organizers influence meaningful learning? *Review of Educational* Research, 37.37 1-383.

Tips on Organization

- Organize labeling topics according to device operation and maintenance requirements
- Separate different sections by titles, headings, and subheadings
- Advance organizers, such as tables of contents, aid user understanding by delimiting major sections of labeling

---

Background Information

Background information consists of information that device users should know before operating a medical device. Present background information early in labeling, before the procedures on how to operate and maintain the device, and keep it in a separate section. This prevents background information from distracting users while they operate a device. Background information includes the following elements:

- Intended Purpose of the Device
- General Warnings
- Supplies and Materials
- Device Components
- Conditions of Device Use
- User Preparation

Intended Purpose of the Device

Describe the purpose of the device, the medical need of persons who use it, and indications for using it. Explain how the information supplied by the device should be used under the direction of a health care professional to monitor or treat medical conditions.

Device Components

Describe each device component and its function in enough detail so the device user can understand how the device operates. Furnish a device illustration with each component clearly labeled along with the text description. Stress the need for users to familiarize themselves with device components before using the device.

If the device is electronic or mechanical, provide explanations for all major device features and operations, such as:

- Operating modes
- Display messages
- Control actuation
- Battery loading and testing
- Cleaning and maintenance
- Calibration

General Warnings

A warning is a statement that makes a device user aware of the fact that a severe adverse health consequence can arise from device use. General warnings consist of crucial information needed before operating a device. An example of a general warning is the need to stop using a device if certain symptoms arise. State general warnings about device use at an early point in the labeling. (In contrast, state specific warnings in the appropriate procedure sections, just before the step to which they apply.) Discuss hazards associated with noncompliant device use and pitfalls in interpreting test results. Avoid technical jargon so that the lay user can understand the warning. Present warnings in special formats that draw attention to them. The Presentation / Format section of this report discusses several possible formats for warnings.

Conditions of Device Use

State the conditions required to operate a medical device safely and reliably. Discuss any conditions that can impair device operation, such as excessive temperature or humidity. Otherwise, users may operate a device under coriditions that produce faulty device operation or inaccurate test results. State the consequences of operating a device under unacceptable conditions. Discuss storage conditions, emphasizing those conditions that could damage the device. Provide information about special handling of the device or its supplies as appropriate.

Supplies and Materials

Describe and illustrate all supplies and materials needed to operate or maintain a device. Specify quantity, size, and type for all supplies needed, whether or not they accompany the device.

User Preparation

Tests performed by some medical devices require that certain items either be ingested or not be ingested prior to or during the test. Make sure the labeling makes this requirement clear.

Background Information References

Bailey, R.W. (1989). *Human performance engineering* (2nd ed.). Chapter 20: Documentation. Englewood Cliffs, NJ: Prentice Hall.

Savol, R.M., Charles, H.C., Daniel, A., Kafka, M.T., Romano, R.M., Thilman, D., Tomaszewski, J.P., & Vetter, C. (1989). *Labeling of* home-use *in vitro testing products. Proposed* Guideline. National Committee for Clinical Laboratory Standards (NCCLS) Document GP 14-P, Vol. 9, No. 8. Draft version.

Tips on Background Information

- Provide basic information about the purpose of device
- Provide general information about how to use the device
- State general warnings and precautions
- List and illustrate supplies needed to use the device

Procedures

A procedure is a set of steps that tells the user how to operate or maintain a medical device. State procedures in short sentences and familiar words; otherwise, user error is likely to occur. A procedure may be accompanied by a rationale or further explanation that directs user performance. For example, tips about potential pitfalls in device operation can help the user avoid mistakes. Make this information brief and locate it next to the relevant step.

Preinstruction Statement

Provide a statement emphasizing the need to carefully read all instructions before using a device at the beginning of labeling. A reference source such as a customer assistance telephone number is also useful at this point.

Step-by-step Instructions

Procedures should be broken down into a series of short, discrete steps instead of a single long paragraph. This makes it easier for device users to perform the correct actions while refemng to the labeling. Each procedure may include the following information:

- Conditions under which the procedure should be performed
- Supplies and equipment needed

- Timing requirements for time-critical steps
- Factors that influence device use or test results

  Examples to clarify text and illustrations, as needed

The following example of a procedure comes from the model lens care booklet:

> Instructions Example
>
> STEP 5 - Place Lens on Your Eye
>
> Place your lens on the tip of your index finger.
>
> Hold down the lower eyelid with the middle finger of the same hand and look up.
>
> Place the lens on the lower portion of the white part of the eye.
>
> **Look** down and remove your finger from the lens. The lens should then center itself.

Reading and Interpreting Test Results

Include a description of how test results should be read and interpreted. The following elements are essential to this description.

Cautionary Notes on Reading Results. Explicitly state any conditions that can influence the reading of test results. Examples of these conditions include timing of reactions, and temperature and lighting conditions under which results are read.

Reading Results. Describe fully the procedure for obtaining test results. If a mathematical computation is required, furnish an example.

Interpreting Results. Interpret the meaning of all possible test results. The proper treatment of ambiguous results as well as the limitations of the test are important to consider when interpreting results. State the range of acceptable results so that invalid results can be detected.

Acting on Results. Describe the action to follow for a given result. Examples include seeking advice from a health care professional or retesting to confirm a test result. Make the user aware of the possibility of obtaining invalid results, the hazards associated with acting on them, and ways to detect them.

Procedures References

Carroll, J.M. Smith-Kerker, P.L., Ford, J.R., & Mazur-Rimetz, S.A. (1987-1988). The minimal manual. ***Human–Computer Interaction,*** 3, 123-153.

Charney, D.H., Reder, L.M., & Wells, G.W. (1988). Studies of elaboration in instructional texts. In S. Doheny-Farina (Ed.), ***Effective documentation: What we have learned from research.*** Cambridge, ***MA:*** MIT Press.

Hartley, J. (1978). ***Designing instructional text*** (pp. 101-111). London: Kogan Page.

Hartley, J. (1990). Is this text any use? Methods for evaluating text. In J.R. Wilson and E. N. Corlett (Eds.), ***Evaluation*** of human ***work: A practical ergonomics methodology*** (pp. 248-270). London: Taylor & Francis.

Wieringa, D., Moore, C., & Barnes, V. (1993) Procedure Writing, Principles and Practices. Columbus: Battelle Press.

Tips on Procedures

- Emphasize actions and skills involved in medical device use.
- Specify required steps and necessary testing conditions.
- Specify necessary supplies and materials.
- Do not dilute procedures with excessive justifications and rationales.

Risk Communication

Risk communication tells the device user about the potential hazards of operating a device and how to minimize them The National Research Council (1989) identified several risk communication content areas that are especially important to medical device labeling. They include harmful effects that can occur as a result of using a device, the incidence of harmful effects, and environmental factors that influence device use. These areas take many factors into account, including device operational features and requirements, user group characteristics, conditions under which a device is used, and the type and incidence of harmful effects associated with device use.

Risk Communication References

National Research Council (1989). ***Improving risk communication.*** Washington, ***D.C.:*** National Academy Press.

Ryan, J.P. (1991). ***Design of warning labels and instructions.*** New York: ***Van*** Nostrand Reinhold.

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

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

Young, S.L., & Wogalter, M.S. (1988). Memory of instruction manual warnings: Effects of pictorial icons and conspicuous print. In Proceedings of the *Human* Factors Society, *32nd* Annual Meeting (pp. 905-909). Santa Monica, CA: Human Factors Society.

Tips on Risk Communication

- Do not minimize harmful effects associated with device use.
- Include incidence of harmful effects if known.
- Provide remedies for harmful effects or refer to appropriate authority.
- Describe environmental factors that influence operators and devices.

Supplementary Information

Supplementary information consists of information that the device user will find helpful over the course of time of using a device. It can include information about the device, a means for recording test results, and a description of the treatment or monitoring regimen that the device user is following. Supplementary information is often best presented in a table rather than as text. This helps the device user to rapidly and easily locate specific items of information.

Device Information

List the complete brand name, model number, and date of manufacture of the device. Include the name, address, and telephone number of the device manufacturer and distributor so that the device user can obtain more detailed information about the device.

Record of Test Results

Many devices measure some physiological or biochemical process in a series of tests over an extended time period. In these cases, include a form for recording the date, time, and results of each test. This record can be used by a health care professional in diagnosis and treatment.

The following example comes from the model lens care booklet. It illustrates the type of supplementary information that device users often find to be valuable.

Supplementary Information Example

LENS OWNER

Name _____

Street _____

City / State / Zip _____

Phone _____

Lens Prescription _____

LENS CARE PRACTITIONER

Name _____

Street _____

City / State / Zip _____

Phone _____

Prescription Date _____

LENS	TYPE	POWER	DIAMETER	BASE	CURVE
RIGHT					
LEFT					

APPOINTMENT SCHEDULE

Date _____ Time _____

Date _____ Time _____

Date _____ Time _____

Date _____ Time _____

LENS MANUFACTURER'S PHONE NUMBER

_____

Type of Disinfection System (check one)

Cold (Chemical) ☐

Heat (Thermal) ■

Tips on Supplementary Information

- Provide specific, complete identification information about the device
- Include name, address, and telephone number of the device manufacturer
- Provide adequate space for recording information specific to the patient and his or her health care regimen such as visits to a health care professional.

Language and Readability

Language is the correct, succinct, and clear use of words in order to convey information. Readability is the relative ease with which text can be understood. In terms of medical device labeling, good language and readability amount to stating instructions simply, directly, and unambiguously. They minimize reading effort and make labeling understandable to as many readers as possible.

Each procedure should consist of short, concise sentences written in simple, familiar words. Split procedures into several short paragraphs instead of using a smaller number of longer paragraphs; this improves comprehension and reading speed. Use the active voice rather than the passive voice. Do not dilute procedures with lengthy justifications and rationales; they draw the reader's attention from the procedural steps. Minimize technical terminology, polysyllabic words, and complicated expressions.

Readability, often neglected by authors of medical device labeling, assesses how hard instructions are to read. Readability measures depend on writing style (word use, sentence characteristics) rather than on content. Write labeling so that its readability lies below the user group's reading grade level. The sixth grade level is a good target for readability. Labeling written at this level can be understood by most device users.

Language and Readability References

Bailey, R.W. (1989). ***Human performance engineering*** (2nd ed.). Chapter 20: Documentation. Englewood Cliffs, NJ: Prentice Hall.

Coke, E. U. (1976). Reading rate, readability and variations in task-induced processing. ***Journal of Educational Psychology, 68,*** 167-173.

Coleman, E.B. (1962). Improving comprehensibility by shortening sentences. ***Journal of Applied Psychology, 46,*** 131-134.

Gunning, R. (1968). The technique of clear writing (rev. ed.). New York: McGraw-Hill.

Kincaid, J. P., Fishburne, R. P., Rogers, R. L., & Chissom B. S. (1975). ***Derivation of new readability formulas for Navy establishment personnel.*** Naval Training Command, Research Branch Report 8-75.

Klare, G.R. (1979). Writing to inform: Making it readable. ***Information Design Journal, 1,*** 98-105.

Mills, G.H., & Walter, J.A. (1986). ***Technical writing*** (5th ed.). New York: Holt, Rinehart, and Winston.

Monteith, M. K. (February, 1980). How well does the average American read? Some facts, figures, and opinions. *Journal* of Reading, ERIC/RCS, 460-464.

Strunk, W., & White, E.B. (1979). The elements of style. (3rd ed.). New York: Macmillan.

Wright, P., & Threlfall, M.S. (1980). Reader's expectations about format influence the usability of an index. Journal of Research Communication *Studies, 2*, 99-106.

Tips on Language and Readability

- Write short, direct sentences
- Use the positive, active voice
- Use short, simple, familiar, non-technical words
- Keep readability at or below sixth grade level

Illustrations and Graphics

Illustrations and graphics consist of photographs, drawings, cartoons, tables, and graphs. They should simplify medical device operation by augmenting text descriptions. Illustrations and graphics are usually remembered better than words. They also reduce readers' reliance on text, a decided advantage for poor readers.

In most cases, do not include illustrations if they simply repeat the text. Instead, use them to show aspects of device operation that are hard to express verbally. Locate illustrations and graphics next to the relevant text. This keeps the reader's eyes from jumping around the page from the text to the accompanying illustration. Take particular care to ensure that illustrations accurately correspond to the related text description.

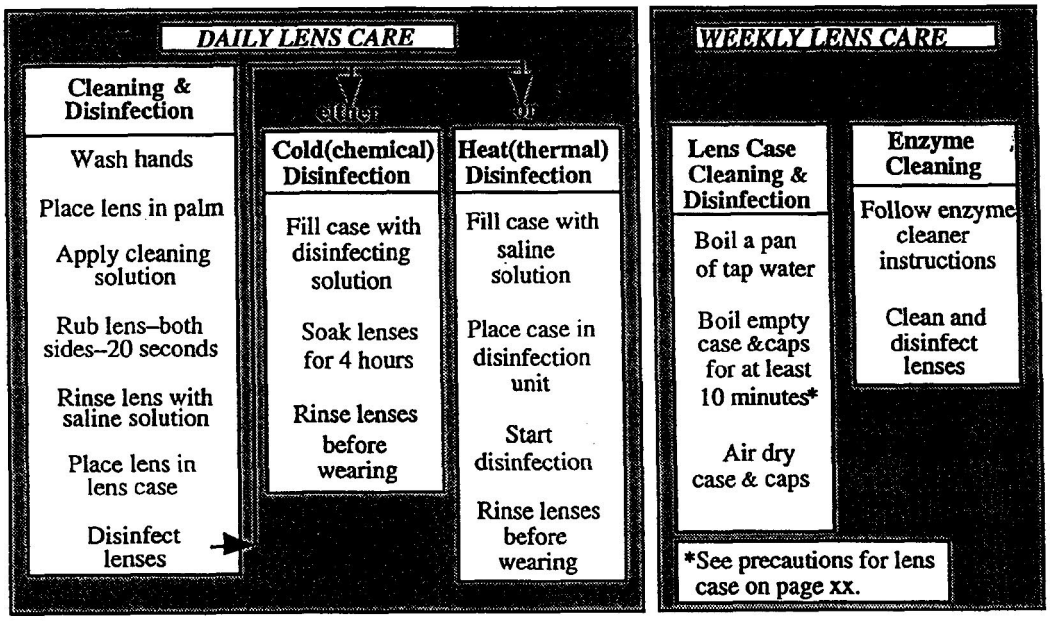
Illustrations should be clear, simple, and uncluttered. Each illustration should convey only one idea; this reduces user error. Photographs convey the exact appearance of objects and show them in three dimensions. Line drawings emphasize specific details and object dimensions (Bailey, 1989).

Color illustrations are generally preferred over black and white illustrations. They attract and hold readers' attention better due to their lifelike character and greater conspicuity (Marcus, 1992). Research conducted as part of this project found a strong subjective preference for color illustrations. This preference resulted in more attention being given to instructions with color illustrations. At the same time, however, no definite link has been established between the use

of color **and** improved task performance, although color used in conjunction with other highlighting techniques does promote improved memory for task features (e.g., Young & Wogalter, 1988).

The flow chart below, developed as part of the model lens care booklet, shows the effectiveness of illustrations in medical device labeling. **A** flow chart is a graphical way to depict procedures. It neatly summarizes the complete set of procedures involved in cleaning and disinfecting soft contact lenses. It is a valuable memory aid for experienced users who are already familiar with lens care procedures.

Graphics Example*



‡Exact wording may differ, depending en lens care system.

Illustrations and Graphics References

Barker, E., & Krebs, M.J. (April 1977). ***Color coding effects on human performance: An annotated bibliography.*** Arlington, ***VA.*** Office of Naval Research.

Birren, F. (1978). ***Color and human response.*** New York: ***Van*** Nostrand Reinhold.

Houghton, H.A., & Willows, D.M. (Eds.) (1987). ***The psychology of illustration,*** Vol. ***2,*** Instructional issues. New York: Springer.

Jonassen, D.H. (1982). ***The technology of text.*** Englewood Cliffs, NJ: Educational Technology Publications.

Lewis, E. (1988). Design principles for pictorial information. In S. Doheny-Farina (Ed.), *Effective documentation: What we have learned from research.* Cambridge, MA: MIT Press.

Marcus, A. (1992). *Graphic design for electronic documents and user interfaces* (Ch. 4, Color, pp. 77-96). New York: ACM Press.

MacDonald-Ross, M. (1977). Graphics in text: A bibliography. In L.S. Shulman (Ed.), *Review of research in education,* vol. 5. Itasca, IL: Peacock

Tufte, E.R. (1983). *The visual display of quantitative information,* Cheshire, CT: Graphics Press.

Twyman, M. (1985). Using pictorial language: A discussion of the dimensions of the problem. In T. M. Duffy & R. Waller (Eds.), *Designing usable texts* (pp. 245-312). New York: Academic Press.

Willows, D.M., & Houghton, H.A. (Eds.) (1987). *The psychology of illustration,* Vol. 1, Basic research. New York: Springer.

Winn, W.D., & Holliday, W.G. (1982). Design principles for diagrams and charts. In D.H. Jonassen (Ed.), *The technology of text.* Englewood Cliffs, NJ: Educational Technology Publications.

Wright, P. (1982). A user-oriented approach to the design of tables and flow charts. In D.H. Jonassen *(Ed.), The technology of text.* Englewood Cliffs, NJ: Educational Technology Publications.

Young, S.L., & Wogalter, M.S. (1988). Memory of instruction manual warnings: Effects of pictorial icons and conspicuous print. *Proceedings of the Human Factors Society, 33rd Annual Meeting.* Santa Monica, CA: Human Factors Society.

Tips on Illustrations and Graphics

- Use illustrations and graphics to augment and clarify text
- Depict only one step in each illustration
- Place illustrations and graphics next to relevant text
- Ensure that illustrations are clear and clean
- Use photographs for realism
- Use line drawings to capture details

Highlighting

Highlighting emphasizes important aspects of medical device operation by calling attention to them visually. Highlighting techniques include the use of color, bold face, underlining, reverse

printing, varied font styles, boxing-in of text, offsetting borders and backgrounds, and white space. Highlighting provides visual relief, stresses important points, and sets off sections and subsections of text. Highlighting should be applied consistently throughout a given piece of labeling. Take care not to overuse it, or its impact will be lessened.

White Space

Use white space between sections to improve the appearance of a document, make it easier to read, and emphasize divisions between major procedures. Take care to not use excessive white space between lines of text. Too much white space between lines impairs reading speed, comprehension, and legibility. Excessive white space also increases printing costs and makes a set of instructions unnecessarily lengthy. On the other hand, if the amount of space between lines is too small, the lines will blur together for many readers, especially those with poor vision. Labeling with insufficient white space often looks cramped and is hard to read. White space can also be used to delimit different sections in a set of instructions. It can draw the reader's attention to parts of labeling the author wishes to emphasize. For example, white space can lead the reader to specific places in the instructions in this fashion. The eye skips over areas that the author wants the reader to ignore and instead focuses on important information about how to operate or maintain a medical device.

Boxing-in and Bolding

Other highlighting techniques such as boxing-in and bolding can emphasize critical information. The following examples were taken from the model contact lens instruction booklet developed in this project:

> ⚠ WARNING ⚠
>
> Serious injury to the eye and loss of vision may result from problems with contact lenses and Iens care solutions.
>
> Immediately call or visit your eye care practitioner for persistent symptoms of any eye discomfort, watering, vision change, or redness.

Highlighting References

Fowler, R.L., & Barker, A.S. (1974). Effectiveness of highlighting for retention of text material. *Journal of Applied Psychology, 59*, 358-364.

Hartley, J. (1978). ***Designing instructional text*** (pp. 59-66). London: Kogan Page.

Hartley, J. (1980). Space and structure in instructional text. In J. Hartley (Ed.), ***The psychology of written communication*** (pp. 127-144). London: Kogan Page.

Hartley, J., Bartlett, S., & Branthwaite, J.A. (1980). Underlining can make a difference—sometimes. ***Journal of Educational Research,*** 73,218-224.

Marcus, A. (1992). ***Graphic design for electronic documents and user interfaces.*** New York: ACM Press (Ch. 4, Color, pp. 77-96).

Miller, L. (February 1991). Do the white thing. ***Macintosh Magazine,*** 48-50.

Tips on Highlighting

- Leave ample white space between lines and at margins and borders
- Use offsetting borders or backgrounds
- Boldface, italics, color, and reverse printing emphasize important steps
- Section headings and subheadings clarify the organization of labeling
- Boxing-in emphasizes warnings and other critical information

---

Typography and Legibility

Typography is the arrangement, style, and general appearance of material printed from type. It encompasses various characteristics of print, including type fonts, type size, and type styles. Correct typography increases the legibility of a document, minimizes fatigue, maximizes information transmission, and helps the device user locate desired information (Simpson & Casey. 1988).

Legibility determines the ease with which reading material can be accurately perceived under device operating conditions. It is an important factor in medical device labeling, especially when devices are operated by persons who, because of age or physical condition, suffer impaired vision. Legibility is closely related to typographical features. For example, type size, type style, and line width tend to interact to determine the legibility of a document.