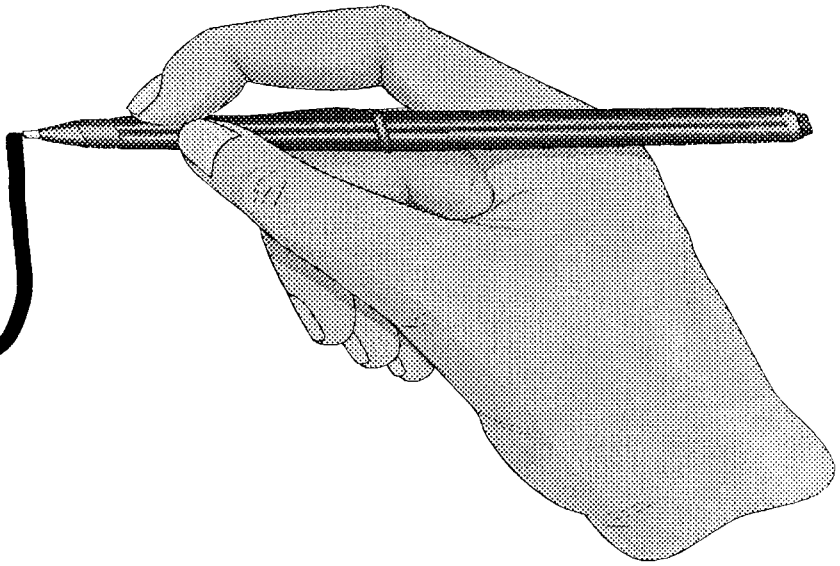
This guidance was written prior to the February 27, 1997 implementation of FDA's Good Guidance Practices, GGP's. It does not create or confer rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both. This guidance will be updated in the next revision to include the standard elements of GGP's.

Write It Right



Recommendations for Developing User Instruction Manuals for Medical Devices Used in Home Health Care

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration
Center for Devices and Radiological Health

PLEASE
Read this entire booklet before writing user instructions

If you have any questions, please call:

Division of Small Manufacturers Assistance
Office of Training and Assistance
Center for Devices and Radiological Health
Food and Drug Administration

phone **301-443-6597**
FAX **301-443-8818**

HHS Publication FDA 93-4236

Write It Right

Recommendations for Developing User Instruction Manuals for Medical Devices Used in Home Health Care

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August 1993

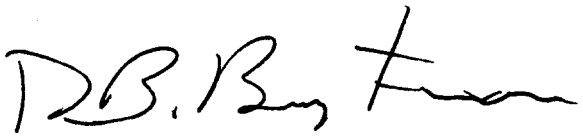
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration
Center for Devices and Radiological Health

FOREWORD

The Center for Devices and Radiological Health, FDA, develops and implements national programs to protect the public health in the fields of medical devices and radiological health. These programs are intended to assure the safety, effectiveness, and proper labeling of medical devices, to control unnecessary human exposure to potentially hazardous ionizing and nonionizing radiation, and to ensure the safe, efficacious use of such radiation.

The Center publishes the results of its work in scientific journals and in its own technical reports. These reports provide a mechanism for disseminating results of CDRH and contractor projects. They are sold by the Government Printing Office and/or the National Technical Information Service.

We welcome your comments and requests for further information.



D. Bruce Burlington, M.D.
Director
Center for Devices
and Radiological Health

PREFACE

The Food and Drug Administration's Center for Devices and Radiological Health (CDRH) is aware that the use of medical devices in the home is increasing dramatically.

User error is a growing problem with home care devices. One factor that contributes to the increase in these errors is the difficulty that lay users have understanding the instruction manuals provided with devices. Most current user instruction manuals are written for health care professionals. When the device is dispensed for home use, lay users may not receive adequate instructions on its use or have the appropriate education and experience that the professional users of medical devices have. Therefore, it is essential that home use device instruction manuals be developed for lay users. This booklet is designed to assist manufacturers of home use devices to plan and write their manuals for lay users.

Caution

In preparing home use instruction manuals, in addition to focusing on the needs of the lay user, manufacturers must comply with all applicable device regulations, including labeling and marketing clearance requirements. The following market clearance guidance provides a basic framework for that compliance. Manufacturers may contact the appropriate division of the Office of Device Evaluation (ODE), CDRH, for a specific determination of whether or not a PMA supplement or 510(k) submission is required when a labeling change is made.

For a device marketed through the
Premarket Approval (PMA) Process
(21 CFR 814)

Manufacturers can develop and distribute a home use instruction manual for the device only if that manual has been approved by FDA as part of the original PMA or as part of an approved PMA supplement.

For a device marketed through the
Premarket Notification Process (510k)
(21 CFR 807)

- A manufacturer of a 510(k)ed device that is a **prescription device** (as described in 21 CFR 801.109) or a **restricted device** (as described in 520(e) of the Food, Drug, and Cosmetic Act) and/or a **preamendments prescription device** can develop and distribute a home use instruction manual for that device without further FDA clearance if all of the following conditions are met:

    a) The device is a legally marketed prescription device,
    b) A licensed practitioner prescribes the device for home use,
    c) The home use instruction manual is provided with the device when the device is supplied to the home,
    d) Home use of the device is considered as acceptable medical practice in the U.S., and
    e) The device has not been changed or modified in any way, including intended use, that would require submission of a new 510(k). [See CFR 807.81(a) (3)].

- A manufacturer of a 510(k)ed device that is a **prescription or restricted device and/or preamendments prescription device,** who would like to market that device over-the-counter, must submit a new 510(k) to FDA.

This booklet addresses only certain aspects of the device labeling regulations. The Office of Device Evaluation, CDRH, has prepared a General Program Memorandum (#G91-1), Device Labeling Guidance to assist manufacturers in complying with the regulations. This memorandum and other publications covering device labeling requirements are available from the *Division of Small Manufacturers Assistance, CDRH, by calling 1-800-638-2041; in Maryland, call 301-443-6597.*

James L. Morrison
Acting Director
Office of Training and Assistance

ABSTRACT

Backinger, C.L., Kingsley, P.A. Write It Right: Recommendations for Developing User Instructions for Medical Devices Used in Home Health Care. HHS Publication FDA 93-4258 (August 1993) (64 pp.).

With home health care patients and their care givers using an increasing number of medical devices of varying complexity, the Center for Devices and Radiological Health, FDA, has concerns about the safe and effective use of these medical devices in the home. Current instruction manuals may be inadequate for the average lay user, exacerbating the problem of device user error.

This booklet was developed to assist manufacturers as they write lay user instructions for medical devices used in home health care. The goal of the booklet is to help assure that all users of medical devices used in home health care have readable and understandable instructions in order to operate these devices safely and effectively. It includes, and is intended to be a model of, principles of writing and design. These recommendations cover both content and format. They include: planning a user instruction manual, writing instructions, writing warnings, and designing and testing the manual.

The recommendations in *Write It Right* are meant to be used as an adjunct to the labeling regulations, which apply to all medical device labeling.

CONTENTS

INTRODUCTION

This booklet contains recommendations to help manufacturers develop high quality instruction manuals for lay (non-professional) users of medical devices used in the home. Instruction manuals provide directions to help users operate devices safely and effectively. Lay users, and professionals who help them, have asked for device instruction manuals that are easy to read, understand and follow.

Instruction manuals are just one part of the total labeling that you must prepare for your products. "***Labeling*** includes all written, printed or graphic matter (1) on the article itself or any of its containers or wrappers, or (2) accompanying the article" [Section 201(m) of the Food, Drug, and Cosmetic Act, As Amended].

It is essential to remember that all labeling must comply with applicable labeling requirements under 21 CFR Parts 801 and 809.

The Office of Device Evaluation, Center for Devices and Radiological Health (CDRH), has prepared a General Program Memorandum (#G91-1), Device Labeling Guidance, to help you in complying with the regulations. While complying with these regulations, you can use the recommendations in this booklet to refine your instructions to assure that any user of the device can understand and use them to operate the device safely and effectively.

Some technical information required by the labeling regulations for professional use may not be appropriate for lay user instructions. Health care professionals need information, such as some indications for use as well as some setup and troubleshooting information, that lay users do not need. Include such information in other labeling for your device.

In this booklet, we present some concepts essential to the process of developing good user instructions. Some tasks will follow one another while other activities may be done at the same time. The process that you use will depend on your organization and the device you are writing about. However, that process should address each of these concepts. The concepts that we will cover are:

- user research
- task analysis
- instruction content and organization
- writing procedures
- writing warnings
- format design
- testing and revision, and
- distribution.

The recommendations in this booklet are meant to help you develop and write an instruction manual that lay users can easily read and understand. This booklet is written and formatted as an example of these recommendations.

There is no one right way to write an instruction manual. These recommendations are flexible. The format and content of your manual will depend on your device and the people who use it.

Your goal should be to provide the ***least competent user*** with the information necessary to use your device in the most safe and effective manner possible. No recommendations can guarantee that users will not make errors. But, with instructions that are easy to read and understand, the user is more comfortable with the device and is likely to make fewer errors. Good instructions promote the safe and effective use of your device by ***any*** user.

PLANNING

What Do You Do First?

User Research

Before writing your instruction manual, determine who the users of your device will be. Tailor your manual to typical user characteristics, if possible.

The primary users of your device may be:

- patients,
- family members, or
- others, such as friends, volunteers, and hired care givers.

These people want to learn to use medical devices so the patient can stay home rather than remain in a health care institution. Lay users may or may not have device training and help. While the best situation is for users to be trained in using the device, your manual may be the only instructions which users receive. For others, the manual will be a reference when a professional is not easily available.

Lay users differ in education, literacy, primary language and life experience from professionals who use medical devices. With most devices, the range of users is too broad to establish a specific user profile. Talk to people who use your device or devices like it to pinpoint general characteristics that could determine your approach to writing instructions. For example, do users have:

- serious illnesses or disabilities?
- sensory problems, such as poor vision or hearing?
- hand coordination problems?

Are they:

- elderly?
- on medication that may interfere with memory, understanding, or ability to carry out procedures?
- literate?
- able to read and understand English?

Study the environment in which your device is likely to be used. The environment often affects the device and the user. Consider user characteristics and the environment in the design and the content of your instruction manual.

Coordinated Approach

The development of the instructions should be part of the overall plan for the design of the device. If you design your device with human factors in mind, it will be safer and easier to operate. As a result, you can write less complex instructions. Don't let your instruction manual be an afterthought as you prepare to market your device. Designing the device and preparing instructions for its use should be a coordinated effort.

The designers of the device should not have sole responsibility for writing the instructions. When you know a device well, it is often hard to put yourself in the place of the new users and to imagine problems that they might face. Set up a team that includes the device designer, a skilled writer and a graphic designer. Ideally, at least one member of your team should have some background in writing instructions. Members may be from your own organization or consultants. In addition, consult health care professionals and lay users for ideas. Pretesting may be helpful in gathering important information from these groups. Pretesting is discussed in the section, "Testing."

Task Analysis

Start with a **task analysis.** To do a task analysis, identify and organize in order all the steps necessary for performing the entire process required to use the device. Walk through the steps using the actual equipment. The information that you gather from this process will be developed into your instructions. The information for each step might include materials and equipment to be used, actions, results of actions, possible errors with results, and corrections.

What Information Should You Include in the Manual?

At the beginning of the manual, advise your user to read the entire instruction manual before trying to operate the device. Let the user know that it is unsafe to start using the device before reading the whole manual. This advice can be presented in various ways to catch the reader's attention. For example, you could have a separate page with this message on it before the Table of Contents or a highlighted sentence at the top of the Table of Contents page.

Content Areas

Include the following 16 content areas in the following order. If you choose to change the order of the content areas, test your planned order with users to make sure that it meets their needs.

1. User assistance information

Design a page or a clearly marked section at the beginning of the manual that tells users how to get help for problems with the device. This section should be very easy for the user to find. It may be as simple as adding your customer assistance number to the front cover where you already have your company name, device name and model number. Or you may wish to include a page in the manual with your 800 number or the number that your organization has designated for customer assistance. On that page, provide space for phone numbers of the home medical equipment supplier, the home health care agency, and the doctor.

Note: *Ideally, your 800 number should be on the device.*

2. Table of Contents

Provide a complete list of content areas with page numbers. Use the same headings you use in the text.

Although glossaries are occasionally included in manuals, they are ***not recommended*** *because their use requires cross referencing by the reader. If you decide to use a glossary, place it after the Table of Contents to alert readers that it is there to help them. Whether or not a glossary is used, definitions should appear in the text.*

3. General warnings and cautions

General warnings and cautions are those that provide critical information needed before the device is used. Place these warnings and cautions at the beginning of the manual where the user will see them right away. General warnings and cautions can be listed in separate sections with the headings **"Warnings"** and **"Precautions"**.

A **warning** is a statement that alerts the user to the possibility of injury, death, or other serious adverse reactions associated with the use or misuse of the device.

A **caution** is a statement that alerts the user to the possibility of a problem with the device associated with its use or misuse. Such problems include device malfunction, device failure, damage to the device or damage to other property. The caution statement includes the **precaution** that should be taken to avoid the hazard.

There may be conditions under which a device should **not** be used **(contraindications)**. These situations generally exist when the risks associated with the use of the device are greater than the benefits. Some may be the result of the environment and are discussed later. Others may be changes in health or other conditions that occur after the patient has begun using the device. These conditions should be listed with other general warnings and cautions.

If the device is a prescription or restricted device, tell the user to use it only for the person for whom it was ordered and only for the use for which it was intended.

A common general warning would alert the user to stop using the device if certain symptoms or operating problems occur. An important general warning for users of life-supporting devices may be information about the need for a back-up device in case significant problems occur. In the case when a backup is not possible, your warning could contain emergency instructions. You may need to write a general caution about infection control as well as specific procedural steps for infection control in each content area where they apply.

Place **specific** *warnings and cautions that relate to steps in a procedure right before the task or instruction that they refer to. Research has shown that this placement helps users remember and pay attention to warnings and cautions better than any other placement. Specific warnings and cautions should have special formats or graphics that draw attention to them. Later in this booklet is a discussion of the proper way to write warnings and cautions.*

Note: *Overwarning has the effect of not warning at all. The reader stops paying attention to excess warnings.*

4. Purpose of the device (Indications for use)

Briefly describe the indications for which home use is appropriate. These should be consistent with FDA marketing clearance for the device.

Example

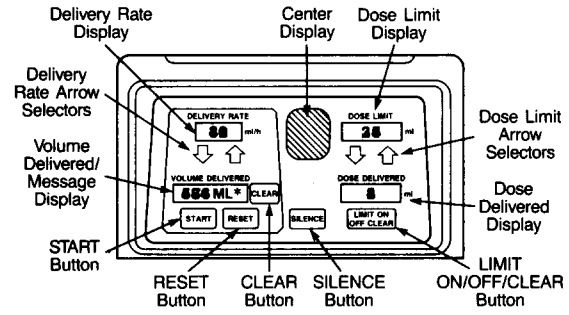
Blood sugar (serum glucose) monitors are for people with diabetes who need to check the level of sugar in their blood. The amount of insulin they will use depends on the reading this monitor gives them. By taking a sample of blood from a finger and placing it on a special strip, diabetics can tell what their current blood sugar level is. They can use this information to follow the doctor's advice for insulin dosage or other medications.

5. Description of the device

Give a brief physical description of the device, its parts and accessories. A graphic may be the simplest and clearest way to describe a device. Graphics are described later in this booklet in the section, "Designing."

All parts of the device shown in the graphic, such as switches, dials, and meters, should be labeled with numbers, letters, or words. The function or purpose of each labeled item should be briefly described in the text of this section.

Example



6. Environmental conditions that affect use

Explain any conditions under which the device should **not** be used. The user must be aware of these situations. For example, an electrical device should not be used in a wet environment. Some of this information may need to be included in the general warnings and cautions section if the user needs this information before using the device.

Make sure your user knows what conditions **are** necessary for the device to operate safely and effectively. For example, if the user needs electricity or water to operate the device, clearly state that. Also, explain what the patient needs to use the device in alternative situations such as while traveling, shopping, or going to school. Tell the user what must done to prepare for a potential problem. For example, a generator or battery back-up may be needed for an electrical device in case of a power outage.

Discuss all conditions that may affect the operation of the device such as changes in temperature, or movement of the patient. These conditions would not necessarily make the use of the device dangerous or inappropriate. However, the user may need instructions on how to adapt the device to the condition.

Describe special actions the user must take to transport a device that is not usually moved from the user's home.

7. Setup instructions

If the home user should never be responsible for the setup of the device, tell the user. Omit these instructions from the lay user manual.

Include in setup instructions for the lay user:

- a parts list, if appropriate.
- list of materials and tools needed for setup.
- unpacking instructions, if appropriate.
- directions for device placement in the home, if appropriate, such as a table top or floor. Also state if the device should remain in one place after setup.
- any warnings or safety instructions specifically related to setup, placed right before the corresponding task or instruction.
- results of incorrect setup.
- numbered setup instruction steps in logical order.
- any special preparation before first use of the device, such as cleaning or disinfection.
- space to write in user-specific instructions.
- who to call if there is a problem. You may refer users to the assistance section in your manual. This topic is discussed in "Assistance" on page 5.

8. Check-out

If your device requires any type of check-out procedure for safety and effectiveness, explain this process completely. The check-out task may be as simple as a visual inspection of the device. Another example of a check-out procedure is calibration.

Include:

- when the check-out should be done, such as at the time of setup or before each use.
- step-by-step procedures of checking proper function of necessary parts of the device.
- what to do if the check-out shows that the device is not working properly.
- who to call if there is a problem. You may refer users to the assistance section in your manual.

A clock or calendar graphic may be useful to show the user correct times or days to check the device.

9. Operating instructions

Include:

- special preparation the user needs before operation, such as handwashing or device warm-up procedures.
- any warnings or safety instructions specifically related to operation, placed immediately before the corresponding task or instruction.
- results of incorrect operation.
- operating steps in logical order, with the expected results.
- space for user-specific instructions.
- who to call if there is a problem. You may refer users to the assistance section in your manual.

10. Cleaning

If appropriate, provide complete instructions for cleaning the device.

- List the supplies needed and give step-by-step procedures.
- State how often the device should be cleaned.
- Tell the user what cleaning accomplishes.
- Tell the user what the results of failure to clean will be.
- Include appropriate warnings or cautions for cleaning agents.
- Describe the results of using improper cleaning solutions or methods.

11. Maintenance

Clearly describe the maintenance actions that are the responsibility of the user. If the user is not responsible for maintenance, briefly outline proper maintenance actions, who is responsible, and how often the action should be done. The user will then know what to expect and can act if proper maintenance is not provided. If your device has some maintenance procedures to be done by the user and some done by others, you may wish to write this section in two parts. Two sections will help make clear to users what they should and should not be doing to maintain the device.

12. Storage

Clearly describe proper preparation for storage and storage conditions. State the results of improper storage conditions.

Example

CAUTION

Do not store in a damp area. Dampness may affect device and cause rust.

If extended storage may affect the device, inform the user. You may also need to include information in the sections on setup, check-out, operation and maintenance that address extended storage.

13. Troubleshooting

When a problem occurs, troubleshooting helps determine if the problem is with the device or with the patient's condition. Anticipate any problems your user may have with setup, operation or maintenance. Provide solutions for these problems in the troubleshooting section. Group similar problems, such as problems with alarms, and highlight each group heading. Highlighting makes it easy to find each group of problems and the specific problems in it. Put the most life-threatening problems first in each section.

Format this section so the user can locate specific problems quickly. The troubleshooting section could be a table with a column for signs of trouble and a column for actions.

Clearly describe the symptom of each problem in as few words as possible so the user can easily match the description to the problem observed. If your device displays error messages, list them and what they mean. Explain the steps necessary to correct the problem. Do not confuse the reader with technical reasons for problems unless the reasons are important to the corrective action.

If there are problems that users cannot or should not try to solve themselves, include warnings or cautions and tell them how to get help.

Instruct users to call their health care professionals for emergency assistance if troubleshooting reveals a patient health problem rather than a device problem.

Tell the user how to report adverse incidents to you.

Examples

If X occurs, do not try to fix or operate the device. Call your health care professional.

If Y occurs, do not try to fix or operate the device. Call your home medical equipment supplier at xxx-xxxx.

If Z occurs, do not try to fix or operate the device. Call the manufacturer at 1-800-xxx-xxxx.

Note: *Putting assistance information in this section does not eliminate the need for the separate assistance section described earlier.*

14. Summary

Include a brief summary, preferably one page, of essential information. Be aware that "basic steps of operation" for a complex device may be lengthy. To avoid creating a multiple page summary, find out what your users really need on a summary card. Limit your summary to this essential information. Place the summary at the end of the user instructions so users will first read the full instructions.

Include in the summary:

- a statement that this summary is not intended to replace complete user instructions and that the entire manual should be read before the device is operated.
- general warnings and cautions that apply to the use of the information in the summary.
- basic steps of operation, including specific warnings and cautions.
- phone numbers (or space to write in phone numbers) for help.

You could provide the summary on a removable laminated card or heavy paper if it is likely to be used frequently. If your device is portable, a separate card will be very useful. Consider providing some method for the user to attach the summary card permanently to the device, for example a chain.

Professionals may be dealing with a number of similar devices for other patients. A separate summary page may be useful for these users to highlight specific information about your device. Include this summary with other technical information for the professional as discussed in the section, "Technical Information".

15. Index

Alphabetize all the important subjects that are included in the manual and assign corresponding page numbers so users can easily find them.

16. Date

Put the date that your user instruction manual is issued or revised on the manual where it can be easily found. You are required to date labeling for prescription devices and it is recommended for all other devices.

Accessories

Although these 16 content areas will be enough for most manuals, there may be more information to include. For example, if your device comes with accessories, discuss all appropriate content areas for each accessory, as you did for the main device. You could have a separate accessories section or include information on the accessories in the content areas that apply.

You may need to include a general warning at the beginning of your manual advising users of problems that may occur if they use accessories other than those recommended by the manufacturer.

Example

WARNING

Use only xxx tubing with this pump.
If other tubing is used, incorrect doses may result.

Technical Information

Some detailed and very technical information may not be appropriate for lay user instructions. For instance, it may not be safe for lay users to adjust settings or try certain functions. This information, as well as indications not approved for home use, adverse reactions only associated with uses of the device other than in home care, and some setup and troubleshooting information not meant for lay users, may, and, in some cases, must be omitted from lay user instructions.

You can provide required technical information, not appropriate for home lay user instructions, to the professional in several different ways. For example, you could use:

- separate manuals for the lay user and the professional,
- a tabbed manual with separate sections for lay users and health care professionals and others who may use, dispense, or service the device, or
- technical supplements or appendices to the user instructions. Examples include sections describing how the device operates or giving technical specifications for any user who wants more detailed information.

Using one of these approaches would help keep the basic instructions as simple as possible and still provide complete information to the professional. You may devise a unique approach based on the users of your device.

WRITING

What Does the User Need?

Once the task analysis is complete, refine the instructions using appropriate language and graphics. As you refine the instructions, consider what you found in your user population research. Take into account limitations of typical users that you found.

The user needs to know what to do, how to do it, and when to do it. Don't bury this important information in a lot of text. In general, your instructions should:

- focus on **how to** operate the device. It is usually not necessary to provide a detailed explanation for lay users of how the device works or why it does what it does. That approach could lead to information overload.
- assume that your user does not have device or medical knowledge or ability.
- provide logically ordered steps for the task and make the user aware of the importance of doing the steps in order.
- state the purpose and the expected outcome of each task.
- tell the user what steps are essential and which ones are optional.
- be written at a sixth to seventh grade reading level to reach most of the population.
- be clear the first time they are read. Many people will not reread something they do not understand.

How Do You Write Instructions?

Format Your Instructions

Organize your instructions using any of a number of formats such as text, a flowchart, or a list. Your choice of format will depend on the complexity of the instructions and what that you learned about your users. For any format you choose:

- Use headings that describe the information that follows. Make sure that short headings tell the reader enough about what is in that section.
- Highlight headings so that they are easily distinguished from the text.
- Include only one topic in each heading.

Example

Poor: Maintenance and Storage

Better: Two separate sections titled "Maintenance" and "Storage"

- Begin each section under a heading with a topic sentence to let the reader know what to expect.
- Number steps that must be completed in order as this booklet does in the section, "What Information Should You Include in the Manual?"
- Bullet lists that have no specific order of importance such as this section you are reading.
- Avoid mixing formats **within sections** of procedural instructions. Mixed formats can be confusing when you are trying to follow step-by-step instructions. However, mixed formats can be useful in the overall manual if used carefully. An example of a mixed format is a checklist for supplies used before starting text of procedural steps.

Text

Text uses words in complete sentences that form paragraphs. Text is useful for simple instructions, to accompany graphics and to help the user when few decisions are required. Your text should anticipate and answer user questions. Use a question and answer format, when appropriate. This approach encourages the reader to look for information.

Text has the following advantages:

- It is familiar to users because it is like spoken language.
- It is easy to develop, update, and handle.
- It can be single or double column. You may use the second column for graphics or for more detailed information for use by professionals or more experienced users. This is effective if the manual will be used by different types of users. Make sure the columns are distinct. For example, use different size type or a line between the columns. Label each column on every page. The reader should be able to follow each column without interference from the other.
- It can be constructed to tell the user that other steps are necessary if the user must do more than one procedure at a time.

Example

At the same time, insert the test strip and press the button marked, "Timer".

Text has the following disadvantages:

- It is more likely to contain excess information.
- It usually requires more space than flowcharts and lists.
- It is more difficult for a reader to find specific items in text than in flowcharts and lists.
- It is more difficult for the user to picture the whole procedure quickly.

Flowchart

A flowchart is a diagram using symbols or brief verbal cues to represent an order of operations. It is useful when users must make numerous decisions or when there are complex sequences of actions or parallel tasks.

A flowchart has the following advantages:

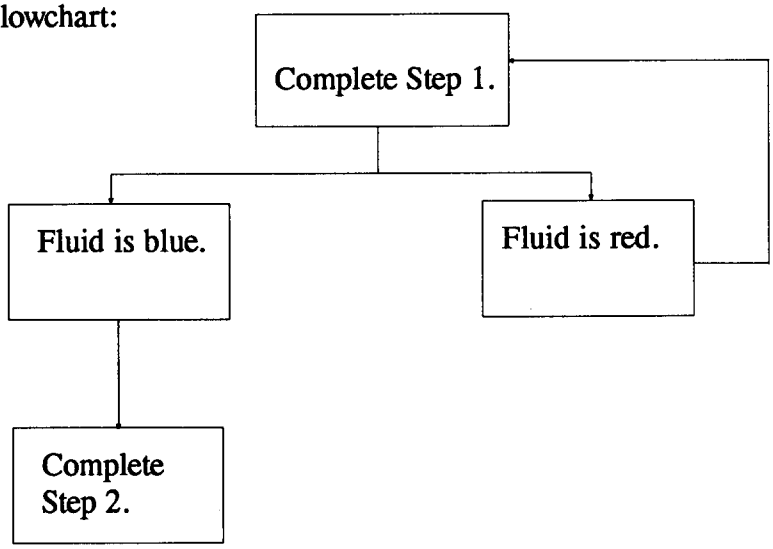
- It uses symbols in a logical order rather than detailed explanations.
- It guides users through a series of sequential, simple decisions.
- It simplifies conditional actions. In the text, these are written as "if ___, then ___" statements that may be difficult for some readers to understand. In a flowchart, they are represented graphically and may be easier to follow.

Example

Text: If, after Step 1 is completed, the fluid is blue, then proceed to Step 2.

If the fluid is red, then repeat Step 1.

Flowchart:



A flowchart has the following disadvantages:

- It may be difficult for some users to understand without training because less detailed information is included in flowchart than in text.
- It may require more research to develop than text.
- It may be difficult to depict complex procedures accurately and simply.
- It should be contained entirely on one page, which may be difficult for long tasks.

Flowcharts should be as simple as possible. Each flowchart should be labeled and contained on one page. Doing more than one procedure at a time may make using two flowcharts on separate pages difficult. Consider other formats in this case.

List

A list is an item-by-item series of words, phrases, or sentences. Lists may be useful for informing readers of such things as accessories included with device or supplies needed to clean the device. You may use a list along with other formats in the overall instruction manual, but avoid mixing formats within procedural instructions. Mixed formats can make the procedural instructions confusing.

A list may also be a checklist. A checklist provides a space before each item to mark when an action is completed or an item identified. The space may also be used to record the result of an action or identification such as the reading of a dial. A checklist is useful when the user is first learning how to operate the device, when failure to follow every step may be hazardous or when the device requires a safety check-out before use. When using a checklist for a task, list the items on the checklist in the order in which they should be performed. If your checklist is to be used more than once and is to be written on, consider providing copies to get the user started. Advise the user to make additional copies.

A checklist has the following advantages:

- It is useful for lengthy tasks.
- Checking off each action or item when the step is completed may help to improve user compliance.
- It is helpful when learning to use an unfamiliar device.

A checklist has the following disadvantage:

- It only allows basic instructions with little additional information.

The following sections are not procedural steps. They are recommendations, and are not listed in any particular order.

Writing Procedures

* Write procedures in short, identifiable steps. Put the steps in the order that they should be performed.

* Before each set of steps, tell the reader how many steps are in the procedure. This helps the reader avoid missing steps.

* Number each step in Arabic numbers such as 1, 2, 3. Do not use Roman numerals such as I, II, III; letters such as A, B, C; or words such as one, two, three.

* Limit each step to no more than three logically connected actions. If actions are not related, they should be in separate steps.

* Make the instructions for each action clear and definite to prevent misunderstandings. This approach is especially critical for steps that require more than one action.

Example

Poor: Turn the machine on.

Better: To turn the machine on:
1. Plug the power cord into an AC outlet.
2. Facing the front of the machine, find the black power switch on the right side.
3. Turn the power switch to the "ON" position.

* Tell the user what to expect from an action.

Example

Poor: Flip the switch to the "ON" position.

Better: Facing the front of the machine, flip the black switch on the left side, marked "ON/OFF" to the "ON" position.
The green light will go on.

* Discuss common user errors at the point in procedures where they are likely to occur. Provide information to prevent and correct user errors.

* Each step should be contained on one page. If the entire step will not fit on a single page, break the step into smaller substeps, each fitting on a page or less. Put more than one step on a page only if each step and accompanying graphics are complete on that page.

* Avoid referring the user to another place in the manual for other information (cross referencing). It is confusing to the reader and interrupts the flow of the procedures. If cross referencing is absolutely necessary, make sure the reader knows when to return to the original place.

Example

Poor: If the alarm sounds, go back to the beginning of chapter X.

Better: If the alarm sounds:
1. Turn to page X.
2. Repeat steps 1 and 2 on page X.
3. Return to step 1 on page Y.

Sentence Construction

* Use as few words as possible to present an idea or describe an action.

Example

Poor: Find the opaque plastic container that has a blue line on the upper half of it and fill it with any type of water until you reach the blue line.

Better: Fill the plastic container to the blue line with tap water.

* Use no more than one clause in a sentence.

Example

Poor: Check the power cord and do not use it if you find cuts or frays or it is loosely connected to the device.

Better:
1. Look at the power cord for cuts or frays. If it is cut or frayed, do not use the device.
2. Tug lightly on the power cord. If it slips out of the device, do not use the device.
3. Call 1-800-xxx-xxxx if you need help.

* Place phrases that describe or explain at the end of the sentence. Phrases at the beginning or in the middle of a sentence may be confusing.

Example

Poor: Before using this device, you should read the instruction manual.

Better: Read the instruction manual before using this device.

Note: *This recommendation does not apply to "if _____, then _____" statements. These statements need to have the qualifying information first to cue the user that there is an action to perform.*

* Write the way you talk. Avoid formal language.

Example

Poor: Insert the blue cable into the blue socket on the anterior section of the machine to form a completed circuit of the electrical system.

Better: Plug the blue cord into the blue hole on the front of the machine.

* Express ideas of similar content in similar form.

Example

Poor: Twist the large dial clockwise until it stops. Turning the small dial, move it 3 notches counterclockwise.

Better:
1. Turn the large dial marked X clockwise until it stops.
2. Turn the small dial marked Y counterclockwise 3 notches from the "Off" position.

* Users should be able to read the instructions aloud. Do not use parentheses for information that should be read. Parentheses cause the reader to hesitate at part of the sentence making it hard to read. Use parentheses only for extra information such as technical terms.

* Don't promote the product in the manual. Ads or promotions in the text will interfere with the user's ability to follow instructions.

* Use bullets, lists, or more than one sentence instead of a long sentence that requires a lot of punctuation.

Example

Gather the following supplies for parenteral infusion pump therapy:

infusion pump
parenteral fluid
I.V. tubing
in-line filter
extension tubing, if applicable
2 connecting needles or locking connectors
heparin
saline
filtration needle
2 needles
2 syringes
alcohol wipes

Word Choice

* Use the same term to identify the device and its parts throughout the manual. Avoid synonyms or alternate phrases.

Example

If you start with "dial", do not call it a "knob" later.

* Put adjectives and adverbs close to the words they modify.

Example

Poor: The wire that is covered with green plastic.

Better: The green wire...

* Avoid adverbs that are difficult to define or interpret.

Example

Poor: Respond quickly.

Better: Respond within one minute.

* Use active rather than passive verbs.

Example

Poor: The dial should be turned clockwise.

Better: Turn the dial clockwise.

* Use action verbs, not nouns created from verbs.

Example

Poor: Utilization, maintenance, avoidance

Better: Use, maintain, avoid

* Use specific terms. Vague terms may be misinterpreted.

Example

Poor: Device operates poorly in a cool room.

Better: Device will not operate below 60 degrees F.

* Use personal pronouns.

Example

Poor: The user should not operate this device near water.

Better: You should not operate this device near water.

* Avoid abbreviations or acronyms. If you feel that abbreviations or acronyms are necessary, define them the first time you use them. Use them consistently.

Example

Abbreviation: oxygen instead of O_2

Acronym: home medical equipment instead of HME

* Use lay language rather than uncommon jargon or technical terms. If technical terms are necessary, use lay language first with the technical word in parentheses.

Example

Poor: 65 mm is the tolerance level.
Better: 65 mm is the highest level at which this gauge should be set (tolerance level).

* Terms should be defined the first time that they occur in the text. Keep definitions simple and concise.

Readability

Readability is the grade level of reading ability needed to read a piece of writing. Experts recommend not exceeding the sixth to seventh grade reading level to reach most of the population. To do this, limit each sentence to 25 words or fewer. Try to use words of three syllables or fewer.

Test your manual for readability to assure that as many lay users of your device as possible can **read** your instructions. Several methods are available for testing written materials. Consult the reference section of this booklet for further information about these methods. Use the method that fits your needs. Readability testing will alert you to the need to simplify your manual if the reading level is too high.

Be aware, however, that readability testing addresses only the reading level and will not guarantee that the material can be **understood.** The suggestions in this booklet are offered to help you develop instructions that can be both easily read and understood.

How Do You Write Warnings and Cautions?

Use written warnings and cautions only after you have made all possible attempts to design the hazard-related feature out of the device.

Most people think the words often used to alert readers to a hazard (signal words), such as "danger", "warning" and "caution", have little difference in meaning. We recommend the use of "warning' and "caution", since these are the terms used in the labeling regulations The goal is to assure consistency in your manual and across all device manuals.

"Warning" is the term for the words and graphics that alert the user to possible injury, death or other serious adverse reactions associated with the use or misuse of the device.

Example

WARNING

Using this device can cause injury to your unborn baby. Do not use if you are pregnant.

"Caution" is the term for the words and graphics that alert the user to the possibility of a problem with the device associated with its use or misuse. Such problems include device malfunctions, device failure, damage to the device or damage to other property.

Example

CAUTION

Do not store in a damp area. Dampness may affect device performance and materials, and cause rust.

General warnings and cautions provide critical information that the patient needs before using the device. Place all such warnings and cautions at the beginning of the manual where the user will see them right away.

A warning or caution that applies to a **specific** instruction or action should precede the instruction to which it applies. Researchers have found that a separate section combining all of this type of warning does not help the user avoid hazards unless these warnings are also included with the step in the instructions to which they apply. Include only warning information relevant to the upcoming procedural step.

You may wish to include information on the likelihood of a hazard. Use care not to understate or overstate this likelihood. Lay users may have difficulty understanding complex statistics, "lifetime risks", and percentages. Consult the **Reference** section for further reading on how to present this type of information.

It is critical that you design warnings and cautions well to effectively alert the user to avoid the hazard.

You may wish to use a graphic to signal your reader that you are about to give them a warning. This may be the one area of the manual in which you can effectively use color. Red or orange is often used for warnings. Yellow is the common color for caution.

Example

A warning or caution should include the following elements:

- the signal word, for example, "WARNING", or "CAUTION",
- a hazard statement briefly explaining what the possible problem is,
- the consequences if instructions are not followed, to give the user a clear idea of the risk, and
- instructions explaining the do's and don'ts necessary to avoid the hazard.

The signal word must come first. The other three elements may be in any order that makes sense. They need not be three separate sentences, bullets or phrases as long as all the information is included.

All warnings and cautions should:

- stand out from the rest of the text. Use highlighting such as centering, bolding, underlining, boxing, icons, color, or any combination.
- use definite terms and graphics commonly associated with that hazard.
- be tested for effectiveness on a representative group of users.

Warnings and cautions should not:

- include instructions that belong with a procedure.
- contain any information not necessary to the warning. Instructions to follow if a hazard occurs should be located in the text that corresponds to the warning. This information should also be included in your troubleshooting section because users may turn to that section when a problem occurs.

Note: *A "note" gives supplemental information to the text and should not be used where a "warning" is needed to call attention to a hazard. A note should be located next to the relevant text and should not be used to direct action.*

DESIGNING

The design should encourage the user to keep and use the manual. If the manual is appealing, users are more likely to consider it valuable and less likely to lose or discard it. Make sure that the instruction manual is the first thing that the user finds when opening the device packaging. If your device has a carrying case, consider designing a pocket for the manual to protect it.

Cover

The cover should be eye catching and easy to identify. Select a simple graphic that symbolizes the device. Your company logo may or may not be the best choice. The graphic could also be used as a sticker on the device to match the manual. Consider using a bright or distinctive color for the cover. The cover should be visually pleasing to the user. Don't put too much on it.

Conditions of Use

Think about the environmental and user conditions under which the device may be used. Design the manual with those conditions in mind. For example:

- if there is likely to be poor lighting, then use large print;
- if any liquid or grease is used with the device, then use waterproof pages;
- if the likely user needs both hands to operate the device, then pages should lay open flat;
- if the manual may be subject to vibrations from the environment, such as ambulance motion, then use large print for easier reading;
- if the likely user has limited hand motion, then use heavy stock paper to make page turning easier; and
- if the likely user may have decreased vision, then use large print.

Consider the effects of use and storage on the manual. The manual should be durable enough to last for the life of the device and tolerate expected use.

Will the user need the manual:

- every time the device is used?
- only while learning to use the device and for troubleshooting after that?

Lamination can preserve the instruction manual if it is used frequently or in a wet environment. If one page, such as a checklist, is used frequently, consider creating a separate laminated page.

A decal or sticker on the device can inform the user that an instruction manual comes with the device. Include a phone number or address in large type on the decal or sticker so the user can contact you to replace a lost manual.

Paper

When possible, manuals should be a standard size, for example, 8 1/2 inches by 11 inches or 5 1/2 inches by 8 1/2 inches. Standard size materials cost less to produce, may be easier to get, avoid waste, and use resources more efficiently than nonstandard sizes. If the page size is too big, the manual will be cumbersome or difficult to store. If the page size is too small, it may restrict print size and graphics and may be difficult to handle. If your device has a carrying case, the manual should fit in the case.

If the size of your manual is restricted by the size of the device, you may need to develop alternative approaches to use the recommendations in this booklet. For example, you may need to fold standard pages. If you use fold-out pages in any size manual, the fold should be slightly inside the right edge of the manual to reduce wear.

The finish of the paper can present a contrast problem. Non-shiny or matte finish pages are easier to read than shiny or glossy pages, especially for the elderly.

Use paper that is thick enough so print and graphics do not show through. Show-through reduces the clarity of the printed words.

Layout

Separate sections of the manual to make them easy to find. One method is to divide sections with different colored paper, colored paper edges or labeled tabs. Consider using heavy paper for these pages.

A loose leaf manual in a ringed binder is appropriate if you anticipate frequent changes. Binders allow the user to remove old pages and insert new ones.

There are different approaches to numbering pages in the manual. You can number the pages consecutively through the manual. You can also number by chapter and page, for example, 2-3 means Chapter 2, page 3. Numbering by chapter and page, rather than by pages only, makes updates easy. Another approach is to number by chapter title, or a short version of the title, and page, for example, Index-5 means page 5 of the Index.

Type

The size of the type should be at least 12 points. This booklet is printed in 12 point type. For elderly or visually impaired users, type should be at least 14 points.

Example

This is 14-point type.

Serif is a style of print that has extra fine lines that finish off the main strokes of a letter. The print in this manual is *serif*. The *sans serif* style has no extra strokes in the letters. (This is sans serif print). The eye uses the extra strokes as anchors to stay on the correct line, making *serif* easier to read than *sans serif* in text. When you write text, use the *serif* style if possible. For individual words, such as headings and signal words, the *sans serif* style may be used.

Use both upper and lower case letters in the body of the text. IT IS DIFFICULT TO READ TEXT WITH ALL CAPITAL LETTERS.

Highlighting

Use highlighting techniques to emphasize important words, thoughts, or phrases. For example, highlight headings, warnings, and/or notes. Highlighting includes:

- **Bolding**
- Underlining
- *Italics*
- CAPITAL LETTERS - good for headings, individual words or phrases, not for general print
- Color - can be used for important words, such as warnings and cautions
- **Background patterns**
- White space - extra white space around something you want to highlight

Use different types of highlighting for different purposes. For example, you may italicize *notes* and bold **warnings**. Don't overdo highlighting. Too much highlighting decreases the impact of your message. Whatever method you choose, BE CONSISTENT.

White space

White space includes margins around the page, the space between lines, the space between sections, and the space around graphics. Careful use of white space will keep your manual from looking too cramped or too spread out. White space is a highlighting method used in this booklet.

Use ragged right margins as in this booklet. They make it easier to keep your place in the text while following instructions than a straight (right justified) margin.

The space between lines of type should be at least 1/16th of an inch. Lines too close together are difficult to read. Too much space between lines is distracting. Be consistent with space between lines throughout the manual.

Increase the amount of white space around important individual words, text, and graphics that you want to emphasize. White space can allow for user notes.

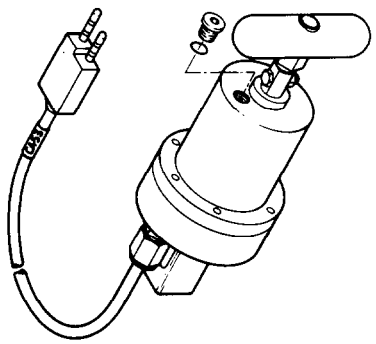
There are no hard and fast rules for the best use of white space in your manual. Use of white space will depend on length of instruction sections, number of graphics, number and placement of warnings, and costs.

Graphics

Graphics include line drawings, illustrations, symbols, icons, photographs, tables, and graphs. Use of clear, simple, precise graphics helps any user understand instructions. Graphics are useful when referring to controls or parts of the device. Graphics are especially important if the user does not read well, see well or does not read the language used in your manual.

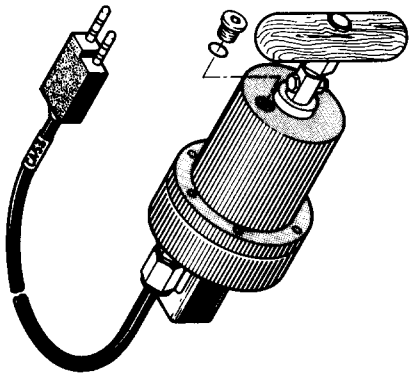
A line drawing is made using solid lines.

Example



An illustration is a shaded or textured drawing.

Example



A symbol is a sign or picture that has been developed to represent an idea. The symbol must be defined or explained because it doesn't mean anything by itself. There are many useful symbols that are already in common use.

Example

$, %, &, #, @

An icon is a drawing that looks like the idea it is meant to represent. Use icons only with text to explain them.

Example

NO SMOKING

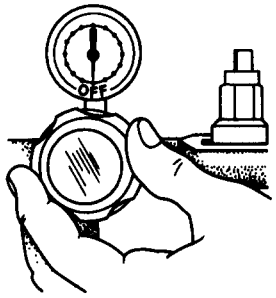
* Good symbols and icons are difficult to design. It is wise to use standardized forms or those already understood by the general population.

  Note: *Standard symbols are published by a number of standards organizations. See "References for Further Reading".*

* Place graphics next to corresponding text. Consider using side-by-side columns of text and graphics to make both easy to follow.

Example

12. Turn the flow control knob counterclockwise until the needle on the dial reads "OFF".



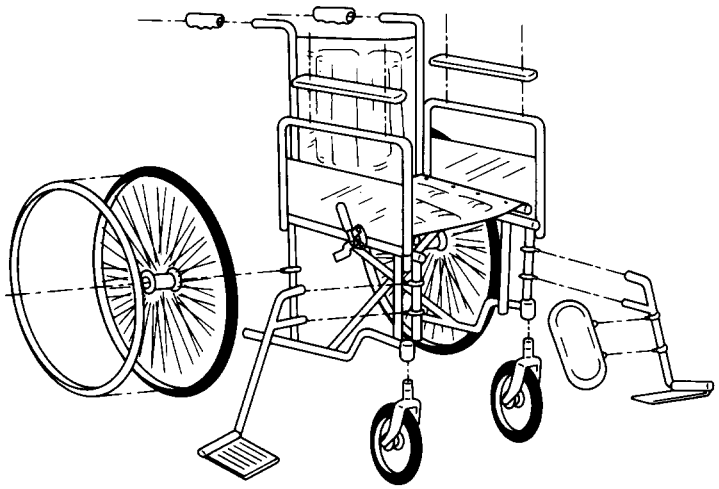
* Set off text and graphics that go together by use of lines, white space, or titles. If a graphic is referred to in the text, it should have a title, for example, Figure 1. The title on the graphic should match the title used in the text.

* Use accurate and precise graphics. Graphics should represent simple concepts, either of actions or of the device and its surroundings. Action graphics should be confined to a single action whenever possible. Use a separate graphic for each distinct idea. Line drawings and illustrations are clearer than photographs. Photos may have distracting extra images and poor contrast.

* Graphics should be large enough to see the focal point and important words clearly. Use as few words as possible. Eliminate detail that is not necessary. The clearest graphics have dark, sharp lines for good contrast. Simple exploded views or cut-away views may be useful. Use exploded views only for devices that the user should put together or take apart.

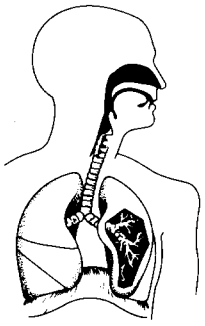
Example

Exploded view



Example

Cut-away view



* In user instruction manuals, tables and graphs are normally not appropriate and their use should be minimized. If a table or graph is necessary, include instructions on its use. Label each table or graph clearly.

Color

Color is not an educational tool. While color on the cover is an excellent way to encourage the user to read and keep your manual, it becomes distracting when overused in the instructions. It can be an effective highlighting technique, if used carefully. If you find it necessary to use color in the text, such as for warnings and cautions, use it consistently.

Black type on a white background is the best contrast and is the easiest to read. If you must use colors other than black and white, consider the contrast of the type color with the background. Some good contrasts are:

Black on yellow
Dark blue on white
Grass green on white

BUT-- remember your user. Blue is difficult for many of the elderly to see. Eight percent of males cannot distinguish pastel colors.

TESTING

Your task is not complete when the manual is written. It is essential that you test what you have written to make sure that **any user** can safely and effectively operate your device following your instructions. While you mainly test your manual on potential users, health care professionals and home medical equipment suppliers can be valuable sources of information in this process.

The first step in testing the manual is to verify that the information is correct. The author must go back over the manual and check it for accuracy. Then the instructions should be given to another person who is familiar with the device and its operation to validate the information. Validation can be done in different ways:

- read the manual through for completeness and accuracy,
- go through the manual using the device as you follow the steps, or
- go through the manual while using a simulator to duplicate various operating conditions.

Choose the approach that best fits your needs. The last two will provide a more realistic setting to check the accuracy of your instructions.

The next essential step is the testing of the manual. We have already discussed readability as an important test for your manual. There are number of additional tests that you should consider. Testing should be done: (1) during planning of the manual, and (2) once the manual is completed. You should test your manual on typical potential users of your device.

This type of testing is called **pretesting**. Pretesting is the systematic gathering of user reactions to the information in your manual before it is produced in final form. You can measure the user's acceptance and comprehension of such things as effectiveness of warnings and cautions, length of material, impact of the cover, clarity of the information, difficulty in reading, and order of activities. Even when your manual is technically correct, these important user factors may be overlooked. Pretesting the manual can uncover problems with user friendliness. Revision or improvement may be made while changes are still possible and

affordable. While pretesting does not guarantee effectiveness, it decreases the risk of producing a manual that could be misunderstood or misinterpreted.

The following are some methods for pretesting. Choose the type that is most useful during planning of the manual or when the manual is in final draft. Pretesting is often conducted by professionals skilled in the various methods. Consult the **Reference** section of this booklet for more information on these methods.

Focus Group Interview

A small group of potential users, usually 6 to 8 people, discusses the best way to present your instructions. The discussion is guided by a skilled moderator toward potential problem areas and possible solutions. The group could develop various formats for drafting the instructions, or work toward a final form from a draft that you have created.

In-Depth Interview

A potential user provides ideas and impressions of possible ways that the instructions could be most effectively written. This person might also review and comment on your draft.

Questionnaire

Potential users respond to a draft of your instructions by answering written questions.

Gatekeeper Review

Health care professionals familiar with your device offer suggestions either during planning or in response to a draft. This review could be done by interview or questionnaire.

Operator Performance Study

Potential users are asked to operate the device while following a draft of the manual. Observers, as well as the users, look for problems with the instructions and differences between the

instructions and operation of the device. This method may also be useful to monitor user problems after the device has been marketed.

Once you have decided on the best test(s) for your users and your manual, make sure that those doing the testing are skilled in the process. Once the testing is complete, use the information that you have gained to revise your manual.

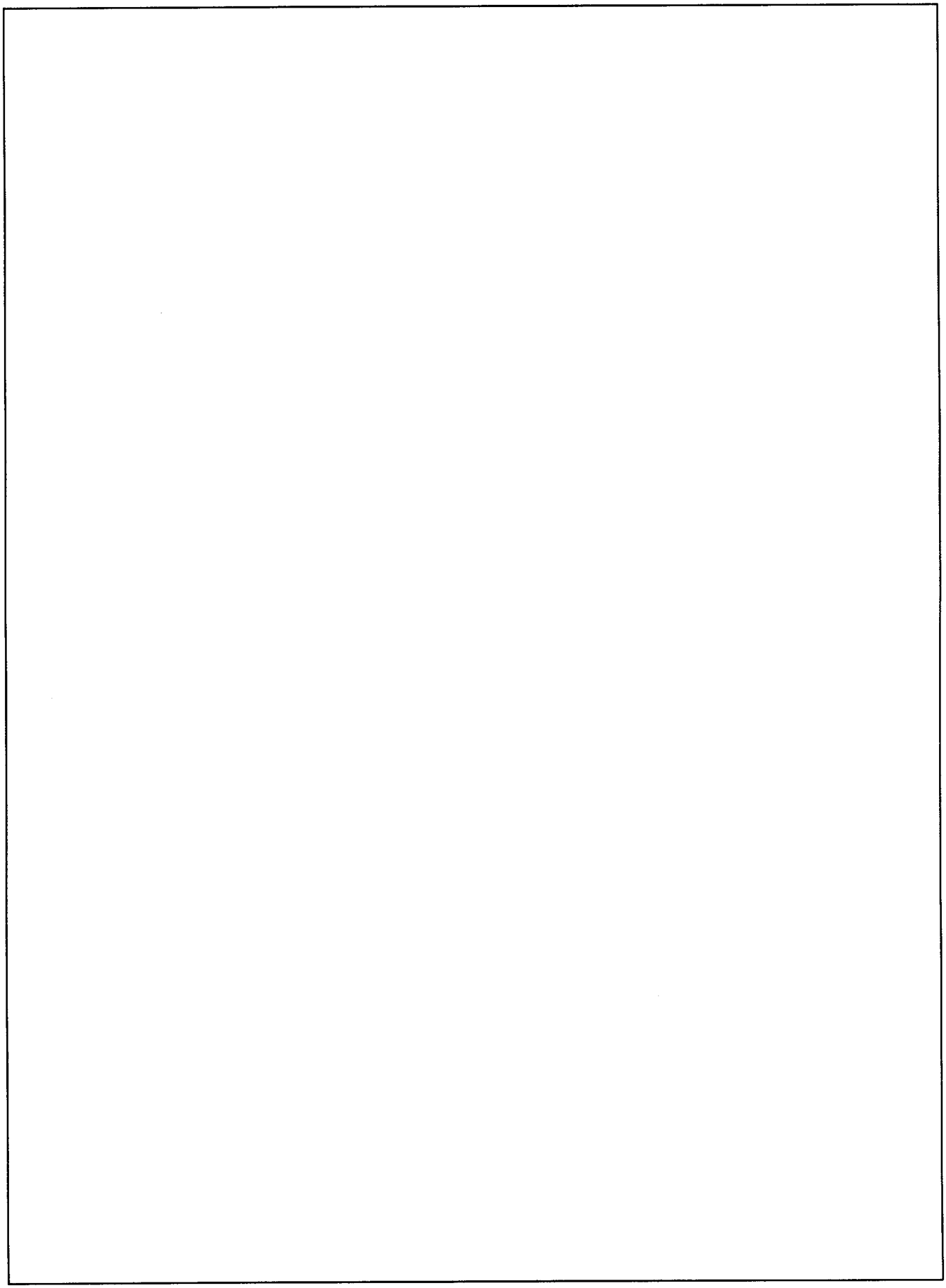
DISTRIBUTING

Once you have developed a manual that is easy to read, understand and follow, **make sure that it gets to the people who need it most – the lay users of your medical device.**

Enlist the aid of health care professionals and home medical equipment suppliers to stress the importance of your manual to the lay users. The professionals and suppliers are the ones who place devices into the hands of lay users. Work with them to make sure that the manuals and any updates get to the user.

Your user needs up-to-date information. When you make changes in your device, be sure to revise the manual. Some manufacturers print a limited number of manuals to avoid having a surplus of old manuals after an update. For instance, if you usually change your device every six months, print only enough manuals to supply users for that time.

Some devices require an effective tracking system to find users. Make use of tracking to update users on changes in the instruction manuals. Consider tracking other devices for this same reason. You may wish to develop a product registration card. Encourage your users to return it to you so you can set up an effective tracking system or registry.



CHECKLIST SUMMARY

Use this checklist to make sure that you have considered all the recommendations in this booklet when developing your manual.

Our manual:

_____ complies with all labeling regulations.
_____ is written for the type of people who use your device.
_____ tells the user how to get help from you.
_____ includes a table of contents.
_____ has general warnings and precautions at the beginning.
_____ briefly describes the purpose of the device.
_____ gives a physical description of the device with a graphic.
_____ explains conditions under which the device should and should not be used.
_____ gives clear setup instructions.
_____ gives clear check-out procedures.
_____ gives clear and easy to follow operating instructions.
_____ provides cleaning instructions.
_____ describes maintenance that the lay user should do.
_____ explains storage.
_____ has a clear, easy to use and find troubleshooting section.
_____ has a summary page with all the critical information on it.
_____ has an alphabetized index.
_____ has an easy to find date of printing.
_____ includes instructions on any accessories.

We have:

_____ done a task analysis for the procedures in our manual.
_____ selected a suitable format (text, flowchart, list).
_____ written and formatted procedures correctly.
_____ used appropriate sentence construction and word choice.
_____ tested our manual to assure sixth to seventh grade reading level.
_____ properly written and placed specific warnings and cautions.

Summary

Our manual:

_____ has a durable distinctive cover.
_____ will stand up to the conditions in which it will be used.
_____ is constructed of non-shiny durable paper.
_____ is laid out to make sections easy to find and update (tabs, binding, page numbering).
_____ uses white space and other highlighting techniques to focus user attention on important information.
_____ is printed in at least 12 point type.
_____ has clear, well-labeled graphics in key places to help user understand text.
_____ is printed in proper contrast.

We have:

_____ tested the manual to make sure that our users can read, understand and follow it.
_____ have taken steps to make sure that our manual gets to our users.

INDEX

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ACKNOWLEDGMENTS

We gratefully acknowledge the contributions of expertise and support of the following individuals. Their ideas and comments helped to ensure the accuracy, completeness and utility of this document.

Diane Baker, CRNI, Intravenous Nurses Society
Donna Biere, Associate Director, Department of Standards, Joint Commission on Accreditation of Healthcare Organizations (JCAHO)
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Bob Demers, RRT, President, American Association for Respiratory Care
A. Joanne Gates, MD, MBA, Associate Medical Director, Children's Hospital, New Orleans
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Additional representatives of health professional organizations and individual experts in the fields of risk communication, technical writing, warning presentation, health care, education, medical device manufacturing, engineering, human factors, law and consumer advocacy preferred not to be individually acknowledged. We are equally grateful for their assistance.

U.S. DEPARTMENT OF
HEALTH AND HUMAN SERVICES

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