List of Titles

AAMI Standard

AAMI HE48:1993

Human factors engineering guidelines and preferred practices for the design of medical devices

AAMI
Association for the Advancement of Medical Instrumentation

AAMI HE48:1993
(Revision of AAMI HE:1988)

Human factors engineering guidelines and preferred practices for the design of medical devices

NOTE: In the course of the AAMI Human Factors Engineering Committee's most recent review of HE48:1993, *Human factors engineering guidelines and preferred practices for the design of medical devices*, the committee decided that standards users would be better served if the document was divided into separate standards covering: (1) human factors *design process*, and (2) human factors *design principles*. The human factors design process (previously addressed in section 5 of the 1993 standard) is now addressed in the new American National Standard, *Human factors design process for medical devices*, and is designated ANSI/AAMI HE74:2001. Human factors design principles are being addressed in a new standard under development by the AAMI Human Factors Engineering Committee. The new design principles standard will carry the designation HE75. Until that document is published, standards users can refer to HE48 for recommendations concerning human factors design principles. ANSI/AAMI HE74:2001, *Human factors design process for medical devices,* was originally designated ANSI/AAMI HE48:2001. It was later redesignated ANSI/AAMI HE74:2001. HE74 is a partial revision of HE48.

ANSI/AAMI HE48:1993 has been withdrawn administratively as an American National Standard. However, the AAMI Human Factors Engineering Committee requested that copies of HE48 remain available while the committee develops HE75. Therefore, HE48 remains available to the public as AAMI HE48:1993 and any reference to it as an American National Standard is no longer appropriate.

— November 2001

Developed by
Association for the Advancement of Medical Instrumentation

Abstract: The purpose of this recommended practice is to provide ergonomic information and human factors engineering guidance so that optimum user and patient safety, system safety and performance, and operator effectiveness will be reflected in medical device design.

Association for the Advancement of Medical Instrumentation

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Human factors engineering guidelines and preferred practices for the design of medical devices

American National Standard

AAMI HE48—1993
(Revision of AAMI HE—1988)

Developed by
Association for the Advancement of Medical Instrumentation

Approved 16 September 1993 by
American National Standards Institute, Inc.

Abstract:

The purpose of this recommended practice is to provide ergonomic information and human factors engineering guidance so that optimum user and patient safety, system safety and performance, and operator effectiveness will be reflected in medical device design.

Association for the Advancement of Medical Instrumentation

Human Engineering Committee

This recommended practice was developed by the AAMI Human Engineering Committee. Committee approval of the recommended practice does not necessarily imply that all committee members voted for its approval.

The AAMI **Human Engineering Committee** has the following members:

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Christopher R. Goodrich

Members: M. Lee Bancroft, Beth Israel Hospital
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NOTE—Participation by federal agency representatives in the development of this recommended practice does not constitute endorsement by the federal government or any of its agencies.

Foreword

This recommended practice was developed by the Human Engineering Committee of the Association for the Advancement of Medical Instrumentation.

Major changes from the previous (first) edition of the guidelines are the addition of sections on user-computer interfaces and the human factors engineering process and elaboration of the anthropometric data that were available when the guidelines were originally approved in 1988. While this new material has significantly expanded the second edition of *Human factors engineering guidelines and preferred practices for the design of medical devices* in important areas, the committee has already identified areas for future development during the next review/revision cycle. Specifically, the committee believes that devices which represent new approaches to human-machine interface design should be addressed in a future edition and seeks more anthropometric data specific to the medical community upon which to base the recommendations contained in this document. Comments and/or information from readers of the document in these two areas are particularly sought by the committee.

Another area for future development is harmonization of the AAMI document with relevant international standards. Much work is taking place internationally in the human factors engineering or "ergonomics" area, and this revision reflects early efforts to harmonize. The international documents specific to medical devices are still at the draft stage and subject to change. Thus, complete harmonization was not possible at the time this document was prepared.

The recommended practice reflects the conscientious efforts of health care professionals, in cooperation with medical device manufacturers and human factors professionals, to provide ergonomic information and human factors engineering (HFE) guidance so that optimum user and patient safety, system safety and performance, and operator effectiveness will be reflected in medical device design.

The title of the recommended practice includes the phrase, "guidelines and preferred practices," underscoring the committee's view that most design decisions, including those recommended here, should be made within the overall context of specific product applications and therefore cannot emanate from hard, inflexible design requirements for all medical devices.

As used within the context of this document, "shall" indicates requirements strictly to be followed in order to conform to the recommended practice; "should" indicates that among several possibilities one is recommended as particularly suitable, without mentioning or excluding others, or that a certain course of action is preferred but not necessarily required, or that (in the negative form) a certain possibility or course of action should be avoided but is not prohibited; "may" is used to indicate a course of action is permissible within the limits of the recommended practice; and "can" is used as a statement of possibility and capability. "Must" is used only to describe "unavoidable" situations, including those mandated by government regulation.

The concepts incorporated in this recommended practice should not be considered static. Recommendations must be reviewed and updated periodically to assimilate new data and technological developments.

Use of trade names and citation of proprietary devices does not constitute endorsement.

Suggestions for improving this recommended practice are invited. Comments and suggested revisions should be sent to AAMI, 3330 Washington Boulevard, Suite 400, Arlington, Virginia 22201.

NOTE—This foreword does not contain provisions of the American National Standard, *Human factors engineering guidelines and preferred practices for the design of medical devices* (ANSI/AAMI HE48—1993), but does provide important information about its development and use.

Human factors engineering guidelines and preferred practices for the design of medical devices

1 Scope

This recommended practice deals with the controls, displays, consoles, size, weight, and general user interface design of medical devices. User instructions, manuals, software, and algorithms associated with medical devices are only briefly discussed and the reader should refer to additional appropriate materials and sources for further information.

NOTE—Recommendations concerning documentation to be provided by medical device manufacturers are given in the AAMI *Guideline for establishing and administering medical instrumentation maintenance programs* (AAMI MIR2, 1992).

The provisions of this recommended practice are not intended to be inflexible design requirements nor to limit advancement, but to encourage the development of new technology provided that it meets or exceeds the intent of the general human factors engineering (HFE) design recommendations contained within.

2 Normative references

The following documents contain provisions that through reference herein, constitute provisions of this recommended practice. At the time of publication, the editions indicated were current.

AMERICAN NATIONAL STANDARDS INSTITUTE. *Breathing machines for medical use*. ANSI Z79.6. New York: ANSI, 1975.

AMERICAN NATIONAL STANDARDS INSTITUTE. *Components and systems of continuous-flow anesthesia machines for human use, Minimum performance and safety requirements for*. ANSI Z79.8. New York: ANSI, 1979.

AMERICAN NATIONAL STANDARDS INSTITUTE. *Criteria for safety symbols*. ANSI Z535.3. New York: ANSI, 1991.

AMERICAN NATIONAL STANDARDS INSTITUTE. *Environmental and facility safety signs*. ANSI Z535.1. New York: ANSI, 1991.

AMERICAN NATIONAL STANDARDS INSTITUTE. *Measurement and designation of noise emitted by*

computer and business equipment, Methods for (ASA 61). ANSI S12.10. New York: ANSI, 1990

AMERICAN NATIONAL STANDARDS INSTITUTE. *Product safety signs and labels*. ANSI Z535.4. New York: ANSI, 1991.

AMERICAN NATIONAL STANDARDS INSTITUTE. *Safety color code*. ANSI Z535.1. New York: ANSI, 1991.

ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION. *Cardiac defibrillator devices*. AAMI DF2. Arlington (Vir.): AAMI, 1989.

ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION. *Guideline for establishing and administering medical instrumentation maintenance programs*. AAMI MIR2. Arlington (Vir.): AAMI, 1992.

ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION. *Interchangeability and performance of resistive bridge type blood pressure transducers*. AAMI BP23. Arlington (Vir.): AAMI, 1986.

ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION. *Standard for ECG connectors*. AAMI ECGC. Arlington (Vir.): AAMI, 1983.

COMPRESSED GAS ASSOCIATION. *Diameter-index safety system (non-interchangeable low pressure connections for medical gas applications)*. CGA V5. Arlington (Vir.): CGA, 1989.

FAIR PACKAGING AND LABELING ACT (Public Law 89-755). 89th Congress, S.985.3, November 1966.

FAIR PACKAGING AND LABELING ACT (Public Law 89-755). Medical Device Amendments. 28 May 1976.

HUMAN FACTORS AND ERGONOMICS SOCIETY. *American national standard for human factors engineering of visual display terminal workstations*. ANSI/HFS 100. Santa Monica (Calif.): Human Factors and Ergonomics Society, 1988.

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION. *Acoustics: determination of sound power levels of noise sources—engineering methods for free-field conditions over a reflecting plane*. ISO 37.44. Geneva (Switzerland): ISO, 1981.

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION. *ISO general purpose screw threads—basic profile*. ISO 68. Geneva (Switzerland): ISO, 1973.

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION. *ISO inch screw threads—basic dimensions*. ISO 725. Geneva (Switzerland): ISO, 1978.

3 Definitions

For the purposes of this recommended practice, the following definitions apply.

3.1 Human factors: An applied science concerned with the characteristics of people that need to be considered in designing and arranging things that they use in order that people and things will interact most effectively and safely. The design issues addressed by human factors professionals are broad (e.g., the design of hardware, software, facilities, procedures, training and organizations). A common synonym for human factors is ergonomics.

3.2 Human factors engineering (HFE): Within the broader discipline of human factors, human factors engineering is the application of knowledge about human characteristics and limitations to the design of the physical (i.e., hardware, software, and architectural) aspects of systems and equipment.

NOTE—The goal of human factors engineering is to achieve optimal system performance by assuring that the design and development of the system or equipment, the human tasks required to operate, maintain, control, and support the system or the equipment, and the work environment are compatible with the sensory, perceptual, mental, and physical attributes of personnel involved in the above human tasks.

4 Purpose

The purpose of this recommended practice is to provide ergonomics information and HFE guidelines so that optimum user and patient safety, system safety and performance, and operator effectiveness will be reflected in medical device design. These guidelines are intended to promote effective work patterns, ensure personnel health and safety, and eliminate or minimize environmental stress, design-induced human errors, distractions, and complexities associated with the use of modern medical technology. These guidelines are an important foundation for good HFE design of medical devices and equipment. However, adherence to these guidelines alone does NOT guarantee a successful HFE design; appropriate testing and evaluation are essential.

Because users of medical devices may be either male or female, this recommended practice attempts to set guidelines that will help ensure compatibility of design for both male and female users. Allowances have also been made for the likelihood that a significant number of device operators will be smaller, for example less than 152 cm (5 feet) tall, than female members of the U.S. Armed Forces (e.g., see DOD-HDBK-743A and Clauser et al., 1972) and other populations on which anthropometric data is currently available and on which many current HFE guidelines and standards are based.

Users frequently deal with highly complex medical devices from numerous manufacturers, often under conditions of extreme psychophysiological stress. Often they are neither highly trained nor experienced in medical device operation. The environment is often noisy, and critical decisions must be made as quickly as possible. This recommended practice is intended to encourage designers of medical devices to take into account these and other characteristics of the medical device environment, including how the user actually behaves, not how he or she is supposed to behave.

Although these guidelines are intended to expose the designer to relevant topics that may have an impact on the design of the device, they are not intended to serve as a substitute for the involvement of qualified human factors experts.

5 Human factors engineering process [NOTE: Effective 2 May 2001, section 5 of this standard is superseded by ANSI/AAMI HE74:2001.]

HFE is not blind adherence to a set of guidelines. Rather, HFE is the sum of several processes. The most important of these are the analytic process that directs the user of guidelines, the design and development process that tailors those guidelines for the specific application, and the test and evaluation process, which verifies that the design and development process has resolved issues identified in the analytic process.

HFE should be integrated into the design and improvement of medical devices. HFE integration begins with early planning and may continue throughout the life cycle of the device. As a minimum, HFE should continue until the device is introduced commercially. HFE efforts following commercial introduction are important to improvement of the device and development of future devices.

5.1 Planning

An HFE plan should be developed as an integral part of the overall plan for device development. The plan should guide HFE efforts in the interrelated processes of analysis, design and development, and test and evaluation. The plan should describe HFE tasks necessary to complete each process, the expected results of those tasks, the resources needed to accomplish those tasks, the means of coordinating those tasks with the overall process for device development, and the schedule for that coordination.

5.1.1 Tasks and products

The plan should identify the HFE tasks to be accomplished during analysis, design and development, and test and evaluation. Expected results of those tasks and the relationship of those products to the overall project should be described.

5.1.2 Resources

The plan should address the resources necessary for its accomplishment.

5.1.2.1 Personnel resources

The plan should identify the personnel resources, including levels of effort, necessary for its management and coordination as well as for accomplishment of its individual tasks. Personnel needs may be satisfied by in-house resources, but use of contractors, consultants and even volunteers may, in many cases, be necessary.

Use of a multidisciplinary team is often the best way to assure full value from the HFE effort. Personnel from a broad spectrum of specialties (e.g., Human-Machine Interface Specialists, Procedures Specialists, Training Specialists, Biomedical Engineers, Physicians, Life Scientists, Physical Scientists, Industrial Designers, Fabricators, Photographers, and representative users and maintainers) may assist the performance of a given task. Typical end users of the device should be active participants at each stage of development. This is often essential for successful design.

The structure of the team may vary based on a number of factors (e.g., purpose of the device), but personnel who are broadly versed in HFE and experienced in integrating its tasks and products into design projects should be integral members of the team.

The plan should include an orientation program for the multidisciplinary team. The goal is to develop a shared, basic understanding of the overall project, the spectrum of technical issues to be addressed, and the process and products of HFE in relation to the overall project.

5.1.2.2 Other resources

The plan should also identify other resource needs consistent with the planned HFE tasks. A broad spectrum of resources ranging from office space and equipment through data collection forms, scientific equipment, cameras, video recorders, and computers to device mock-ups and prototypes may be appropriate.

5.1.3 Coordination

The plan should identify how those involved in the HFE effort will interact with others. This includes access to the facilities, personnel, and information necessary to perform HFE tasks and to the decision makers who should make use of the results of those tasks.

5.1.4 Schedules

The plan should assure that results of HFE tasks are available in time to influence the design of the proposed device as well as the conduct of the overall project. Analysis tasks should begin very early. Iterations of analysis tasks that refine earlier products may continue throughout the project. Design and development build on the products of early analysis, and iterations may also continue throughout the project. Test and evaluation should begin with the earliest products of design and development (e.g., drawings and specifications). The results of test and evaluation should influence subsequent iterations of analysis, design and development, and test and evaluation tasks.

5.2 Analysis

Successful human factors engineering is predicated on careful analyses. Early analyses should focus on the objectives of the proposed device and the functions that should be performed to meet those objectives. Later analyses should focus on the critical human performance required of specific personnel as a means of establishing the HFE parameters for design of the device and associated job aids, procedures, and training and for establishing HFE test and evaluation criteria for the device. Analyses should be updated as required to remain current with the design effort.

Analyses from outside sources should be used if available. Others may have performed function and task analyses, critical incident studies, or incident investigations that provide insight about human roles in the system of which the proposed device will be a part. Despite their potential value, others' data and results should be used with care. Information crucial to design of the proposed device should be subjected to confirmatory analysis.

5.2.1 Definition of objectives

Analysis should begin with a clear understanding of the proposed device's objectives within the system of which the device and associated personnel are a part, or within the marketplace where the consumer is the user of the device as a "stand-alone" or in conjunction with other devices.

Important objectives include effectiveness, safety, efficiency, reliability, availability, operability, maintainability, durability, initial cost, and life cycle costs. Successful analysis, design and development, and test and evaluation depend upon explicit, complete, and up-to-date descriptions of the proposed device's objectives.

5.2.2 Function analysis

The functions that must be performed to meet each of the proposed device's objectives should be identified. Analyses should determine the performance required to satisfy each function. Analyses should also be used to identify and characterize human, equipment and, if applicable, software resources that might reasonably perform the functions necessary to accomplish the various objectives and to allocate those functions to humans, equipment, software, or a combination of these.

5.2.2.1 Performance requirement estimates

The operations and decisions necessary to meet the proposed device's objectives should be described without reference to specific machine implementation or level of human involvement. Essential performance parameters should be established for operations and decisions. Where possible, required performance should be quantified (e.g., maximum allowable response times, tolerance bands for controlled variables).

5.2.2.2 Performance capability estimates

Plausible human roles (e.g., operator, maintainer, programmer, decision maker, communicator, monitor) consistent with the functions that must be performed to meet the proposed device's objectives should be identified. User population capabilities should be estimated in terms of the parameters associated with estimated performance requirements for each potential human role. Comparable estimates of equipment should be made. The possibility of enhancing human or equipment capabilities (e.g., through more stringent selection and training of personnel or through advanced equipment design) should be considered, and the costs of such enhancement should be considered in trade-off and cost-benefit studies before functions are allocated.

5.2.2.3 Function allocation

Performance requirement estimates should be compared with performance capability estimates to make initial determination as to which functions necessary to meet the device's objectives should be accomplished by equipment, which should be reserved for the humans, and which should be accomplished by a combination of the two.

5.2.3 Equipment selection

HFE guidelines should be applied, along with all other design requirements, in the selection of equipment used by humans.

5.2.4 Task analysis

The individual tasks necessary to accomplish the functions allocated to humans and the functions allocated to a combination of humans and equipment should be analyzed.

5.2.4.1 Gross analysis of tasks

Gross analysis of tasks should provide one basis for making HFE design decisions (e.g., verifying, to the extent practicable before hardware fabrication, whether the objectives of the proposed device can be satisfied by equipment, humans, and combinations of the two per the initial function allocation). Gross analysis of tasks should also be used as basic information for developing preliminary staffing levels, equipment procedures, and skill, training, and communication requirements. Finally, tasks involving critical human performance should be identified. Critical human performance consists of necessary human actions which—if not accomplished in accordance with functional requirements—will most likely have an adverse effect on satisfaction of the device's objectives.

5.2.4.2 Analysis of critical tasks

Analysis of critical tasks (i.e., tasks involving critical human performance) should identify the following:

a) information required by persons performing the task, including cues for task initiation;

b) information available;

c) appropriate evaluation processes;

d) decisions to be reached after evaluation;

e) actions to be taken;

f) work space available;

g) location and condition of the work environment(s);

h) frequency and tolerances of action;

i) time base;

j) feedback on the adequacy of actions taken;

k) tools and equipment required;

l) number of personnel required, their specialties, experience, and capabilities;

m) job aids or references required;

n) any required communications;

o) special hazards involved;

p) required interactions if more than one person is involved;

q) performance limits of personnel;

r) performance limits of equipment;

s) potential performance anomalies and error conditions.

The analysis should be performed for all affected objectives of the proposed device.

5.2.4.3 Workload analysis

Individual and crew workload analysis should be performed and compared with performance criteria. Task and workload analysis should be performed with actual users in the actual user environment (or a realistic simulation of it) to validate design goals and device performance.

5.3 Design and development

During design and development of the proposed device, the results of early HFE analyses along with other appropriate HFE inputs (e.g., the guidelines provided by this document) should be converted into detailed equipment design features. HFE of the device should be evaluated continuously for adequacy (see 5.4). Test and evaluation results should be considered in the ongoing design and development process.

5.3.1 Preliminary design

HFE guidelines should be reflected in design criteria documents, performance specifications, drawings, functional flow diagrams, system and subsystem schematic block diagrams, interface control drawings, overall layout drawings and so forth. Preliminary configuration and arrangement should reflect the initial allocation of functions and should be consistent with HFE guidelines. Work flow and task flow diagrams for use of the device in the actual environment should be developed.

5.3.2 Studies, experiments, and laboratory tests

Design and development should include HFE studies, experiments, and laboratory tests to resolve concerns related to critical human performance. Results of studies, experiments, and tests should be used to revise initial function allocations and device designs in a way that assures satisfaction of the device's objectives.

5.3.3 Mock-ups and models

At the earliest practical time and well before fabrication of device prototypes, full-scale three-dimensional mock-ups of device components associated with critical human performance should be constructed. Materials and workmanship need be no more sophisticated than necessary to allow the mock-ups to be used in determining whether the size, shape, arrangement, and panel content of the components are adequate for human use. Static or functional mock-ups should be used to solve access, work space, and related HFE problems and to incorporate solutions into the design. Functional mock-ups should be provided for components associated with critical tasks where human performance measurements are necessary. In some cases scale models may be substituted for mock-ups.

5.3.4 Dynamic simulation

Dynamic simulation techniques should be used as an HFE design tool when necessary for the detailed design of equipment associated with critical human performance.

5.3.5 Detailed design drawings

Detailed design drawings should reflect HFE guidelines selected to assure that the device satisfies its objectives. The following drawings are included:

a) panel layout drawings;

b) communication system drawings;

c) overall layout drawings;

d) control drawings and other drawings depicting components important to operation and maintenance by human operators.

5.3.6 Performance and design specifications

Performance and design specifications should reflect the application of HFE guidelines that are necessary to satisfy the device's objectives.

5.3.7 Equipment procedure development

Procedures for operating, maintaining, or otherwise using the device should reflect HFE principles. For computerized systems where operating and maintenance procedures are largely determined by software programs, HFE should be applied throughout the software program planning and development. This effort should be accomplished to assure that the human functions and tasks identified through HFE analysis are organized and sequenced for efficiency, safety and reliability, and to assure that the results of this effort are reflected in the development of operational, training, and technical publications.

5.4 Test and evaluation

HFE test and evaluation should be directed toward verifying that the system can be operated, maintained, supported, and controlled appropriately by user personnel in the intended operational environment. The process is intended to determine whether performance of all tasks, including critical tasks, by personnel selected, trained, and equipped as defined by the system and working under realistic conditions and intended operation and maintenance tasks by the consumer will be adequate to meet the design objectives of the proposed device. Test and evaluation also determine whether features that increase the probability of human error have been introduced into the device or larger system and whether the proposed device conforms to appropriately tailored HFE guidelines.

5.4.1 Planning

HFE test and evaluation plans should be incorporated into the normal test and evaluation program for medical devices. Planning should be integrated into engineering design and development tests, capability demonstrations, and other development tests. Test and evaluation plans should include methods of testing (e.g., use of checklists, data sheets, test participant descriptors, questionnaires, operating procedures, and test procedures), schedules, quantitative measures, test criteria, and reporting processes.

5.4.2 Scheduling

HFE test and evaluation should begin as early as possible. Results of early design reviews, mock-up inspections, demonstrations and the like should be used in planning and conducting later tests as well as in redefining the human factors issues applicable to the device.

5.4.3 Implementation

Test documentation (e.g., checklists, data sheets, test participant descriptors, questionnaires, operating procedures, test procedures) sufficient to implement the HFE test and evaluation plan should be available at each test site.

HFE test and evaluation should include:

a) simulation (or, if possible, actual conduct) of a work cycle;

b) tests of tasks for which human performance is critical to success;

c) tests of a representative sample of noncritical, scheduled and unscheduled maintenance tasks in addition to any tasks selected for maintainability demonstrations;

d) evaluation of proposed job aids, new equipment training programs, training equipment, and special support equipment;

e) use of personnel who are representative of the range of intended user populations in terms of skills, knowledge, abilities, size, strength, etc. Testing should include garments and equipment commonly in use during the actual task;

f) collection of task performance data in simulated or, preferably, actual operational environments;

g) identification of discrepancies between required and obtained task performance;

h) criteria for acceptable performance of the test.

5.4.4 Failure analysis

All failures occurring during test and evaluation should be reviewed to differentiate between failures that are due to equipment alone, failures due to personnel-equipment incompatibilities, and failures due to human error. Design conditions that may contribute substantially to human error should be identified and referred to design and development for appropriate resolution.

6 General recommendations for human factors engineering design

The design of medical devices should reflect HFE design features that increase the potential for successful performance of tasks and for satisfaction of design objectives.

6.1 Consistency

Where common functions are involved, consistency is encouraged in controls, displays, markings, codings, and arrangement schemes for consoles and instrument panels.

6.2 Simplicity

Simplicity in all designs is encouraged. Equipment should be designed to be operated, maintained, and repaired in its operational environment by personnel with appropriate but minimal training. Unnecessary or cumbersome operations should be avoided when simpler, more efficient alternatives are available.

6.3 Safety

Medical device design should reflect system and personnel safety factors, including the elimination or minimization of the potential for human error during operation and maintenance under both routine and nonroutine or emergency conditions. Machines should be designed to minimize consequence of human error.

6.3.1 Redundancy

Design should incorporate redundant, diverse elements arranged in a manner that increases overall reliability (e.g., parallel, totally independent devices) when failure can result in inability to perform a critical function.

6.3.2 Connectors

Connectors for medical devices should conform to applicable standards (see Huang et al., 1992) and connectors should be designed to ensure that the appropriate equipment is connected correctly and that hazardous connections are prevented.

6.3.3 Device failure

Any medical device failure should immediately be displayed to the operator and should not adversely affect safe operation. Where failures can affect safe operation, simple means and procedures for averting adverse effects should be provided. This recommendation is particularly important when failure of the device is life-threatening (e.g., failure of life support equipment or devices controlling patient exposure to hazardous materials). When the device failure is life-threatening or could mask a life-threatening condition, an audible alarm and a visual display should be provided to indicate the device failure (see also 11.15). It may be necessary to use battery power for such an alarm. Wherever possible, explicit notification of the source of failure should be provided to the user. Concise instructions on how to return to operation or how to invoke alternate backup methods should be provided.

6.4 Environmental and organizational considerations

The design of medical devices should consider the following:

a) the levels of noise, vibration, humidity, and heat that will be generated by the device and the levels of noise, vibration, humidity, and heat to which the device and its operators and maintainers will be exposed in the anticipated operational environment;

b) the need for protecting operators and patients from electrical shock, thermal, infectious, toxicologic, radiologic, electromagnetic, visual, and explosion risks, as well as from potential design hazards, such as sharp edges and corners, and the danger of the device falling on the patient or operator;

c) the adequacy of the physical, visual, auditory, and other communication links among personnel and between personnel and equipment;

d) the importance of minimizing psychophysiological stress and fatigue in the clinical environment in which the medical device will be used;

e) the impact on operator effectiveness of the arrangement of controls, displays, and markings on consoles and panels;

f) the potential effects of natural or artificial illumination used in the operation, control, and maintenance of the device;

g) the need for rapid, safe, simple, and economical maintenance and repair;

h) the possible positions of the device in relation to the users (e.g., operators, monitors, maintainers) as a function of the user's location and mobility;

i) the electromagnetic environment(s) in which the device is intended to be used.

6.4.1 Noise

Consideration should be given to the effects of noise on device users, other workers, and the patient. Steady-state noise generated by the device during normal operation should be minimized and should not exceed 50 decibels (dBA) at each operator or patient location when measured in accordance with ISO standard 3744. Noise generated within the 600 – 4,800 Hz frequency range should be minimized to reduce auditory interference with normal speech (see ANSI S12.10, 1990). Consideration should be given to the acoustical attributes and the other sources of noise in the environments in which the device will be used.

6.4.2 Ambient illumination

Sufficient contrast should be provided between all displayed information and the display background to ensure that the operator will be able to perceive the required information under all expected lighting conditions. When multiple displays are grouped together, their brightness should be uniform so that all will appear of equal brightness throughout the range from full ON to full OFF. Displays should be constructed, arranged, and mounted to prevent any reduction in readability caused by the reflection of ambient illumination from surrounding surfaces. Reflections from instruments and consoles in protective shields and other enclosures should be avoided. If necessary, shields or other enclosures should be employed to ensure that system performance will not be compromised. Medical devices may be used under a wide range of ambient lighting conditions, from floodlighting for videotaping procedures to near darkness for endoscopic procedures. Protective eye-wear use (e.g., laser goggles) and its effects on the readability and distinguishability of displayed information should be considered, where applicable.

6.4.3 Surface temperature and vibration

6.4.3.1 Surface temperature

During normal use, medical device surfaces and components that can come into contact with operators or patients should not exceed the temperature limits indicated in table 1 (see next page).

6.4.3.2 Vibration

Vibration of visual displays should not compromise user performance enough to lower it below the required level.

Table 1—Maximum allowable temperature

	Continuous contact	Momentary contact
Metallic	55°C	60°C
Glass	65°C	70°C
Plastic or Wood	75°C	85°C

(IEC 601-1, 1988 and UL 544)

6.4.4 Maintainability

6.4.4.1 Cleaning

Device surfaces should be smooth and free of pockets and crevices. The surface finish should withstand commonly used cleaning and disinfecting agents. The outer casing should prevent cleaning solutions and solvents from penetrating mechanical and electrical components, which might result in operator hazard or mechanical failure. Devices should withstand the effects of commonly used bactericidal, fungicidal, and virucidal disinfectants even when applied after each patient use for an extended period.

NOTE—The manufacturer should advise the user about suitable cleaning, disinfection, radiological decontamination, and sterilization agents, methods, and intervals and about any special precautions to be observed. AAMI MIR2-1992 specifies the information to be provided by device manufacturers with respect to cleaning, sterilization, and intervals.

6.4.4.2 Lamp testing/removal

Means should be provided to ensure that lamps in indicators are operable. Where possible, provision should be made for rapid, convenient removal of the lamp from the front of the display panel or for other means of verifying operation without compromising the lamp's resistance to fluid penetration. Display circuits should be designed so that externally accessible bulbs may be removed and replaced when power is applied without causing indicator circuit components to fail and without imposing personnel safety hazards.

6.4.5 Damage prevention and stability

Systems and equipment should be sufficiently rugged to withstand handling during operation, maintenance, supply, and transport within the environment in which they are used.

6.4.5.1 Component protection

Controls, connectors, and other device components susceptible to damage should be recessed or otherwise protected.

6.4.5.2 Mobile devices

Free-standing mobile devices should be stable and designed to eliminate tipping in normal use and servicing. Casters should be used to help move equipment in and out of elevators or across uneven sections of the floor. Casters may be provided with braking capabilities which assist in stabilizing the device to which they are attached. Mobile devices should be surrounded by protective, shock-absorbent guardrails, preferably at a height that will enable personnel to use the rails as handgrips for moving the equipment.

6.4.5.3 Portable devices

Portable devices should be easy to hold securely by hand; for large portable devices, one or more handles should be provided. A device with a single handle should not be considered portable if it weighs more than 10 kg (22 lb) or if its size exceeds 63 x 51 x 22 cm, (25 x 20 x 8-1/2 inches). Protective guardrails, such as those recommended for mobile devices, are useful not only for transporting small, portable devices but also for avoiding equipment damage. Small, portable devices are likely to be dropped or placed on the floor; thus the use of shock-absorbing design and impact-resistant materials is especially important. Device-specific standards such as Cardiac Defibrillator Devices (AAMI DF2, 1989) should be used to determine specific drop-test requirements.

6.4.5.4 Mounted devices

If a device is intended for mounting, means should be provided to attach the device securely to the equipment or to the surface on which it will be used. Bolt and nut threads should conform to the provisions of ISO 68, 1973 and ISO 725, 1978. The device should have a threaded socket to receive an attachment bolt. For devices weighing up to 2 kg (4.4 lbs), an M6 socket and bolt may prove satisfactory, while for larger and heavier devices an M10 bolt and socket may be preferred. Alternatively, slots or handles may be provided on the sides of the devices through which Velcro™ or similar retaining straps may be passed to secure the device to its support.

6.5 Console and panel layout

The layout of consoles and panels is a compromise among a number of considerations. In some instances, various HFE guidelines will conflict, not only with each other, but also with other design requirements. Because it is difficult to rate the conflicting considerations for importance, final decisions should be based on careful evaluation and sound judgment.

6.5.1 Organizing principles

Controls and displays should be placed to promote effective and efficient procedures, safe operation, and maximum awareness of current conditions. Three organizing principles for achieving this condition are grouping by task sequence, grouping by function, and grouping by importance and frequency of use.

6.5.1.1 Grouping by task sequence

Controls and displays should be assigned to consoles and panels so as to minimize user movement, and controls and displays which are used together during a normal task sequence should be grouped together. To the extent practical, assignment and grouping of console and panel components should consider both normal and emergency procedures. It should be practical to perform all frequently occurring routine tasks, and time-sensitive emergency tasks, with a minimum of human movement from one console or panel to another console or panel. In particular:

a) Displays which are observed in a specified sequence should be grouped together. It is desirable that they be positioned so that they are normally used in a left-to-right, top-to-bottom, or other natural sequence.

b) Controls which are operated in sequence should be grouped together. It is desirable that they be positioned so that they are normally used in a left-to-right, top-to-bottom, or other natural sequence.

c) When there is a set of related controls and displays, the layout of displays should be symmetrical with the controls they represent.

6.5.1.2 Grouping by system function

Within the constraints of grouping by task sequence, controls and displays should be assigned to consoles and panels in functional groups related to system structure. This grouping should promote easy understanding of the relationship between controls and displays and the system, and it should assist in graphic or pictorial display of system relationships (i.e., use of "mimics"—see 8.2.2). In particular, functionally related controls and displays should be grouped together when they are

a) used together to perform tasks related to a specific function;

b) identical in purpose (e.g., controls for multiple identical components).

6.5.1.3 Grouping by importance and frequency of use

Within the constraints of grouping by task sequence and by system function, controls and displays should be assigned to consoles and panels depending on their priority.

6.5.2 Priority of control and display location

The location of controls and displays on consoles and panels should be consistent with their priority. Priority of location refers to the optimum placement of the most important controls and displays in the visual and manual workspaces on the panel or console. The relative priority of location of controls and displays is a function of

a) frequency and duration of use;

b) accuracy and speed required for reading a display or operating a control;

c) possible results of an error or delay in using the control or display (e.g., degradation of system performance, safety hazards to personnel, or equipment damage);

d) ease of manipulating a control in various possible locations in terms of force, precision, and speed required;

e) the sequence of use of system components.

6.5.3 Arranging controls and displays on the console

Controls and displays on the console should be arranged as follows (in addition see section 7):

a) Primary controls should be located at a level between (applicable seated or standing) waist height for the tall user and shoulder height for the short user (see figures 1 and 2, pages 9 and 10).

b) Two controls intended for simultaneous use by a seated operator should not require crossing or interchanging hands.

c) Frequently used controls should be located to the left front or right front of the operator and should be grouped together unless there are overriding reasons for separating them. For purposes of control placement, it should be assumed that the operator will be right-handed.

d) Controls should be located so that they can be checked visually from the user's normal operating position.

e) All controls should be within the maximum reach of the seated operator (see figure 1, next page).

f) Controls requiring fine adjustments should be located closer to the operator's line of vision than controls needing only gross positioning.

g) Controls that have to be manipulated while the operator is monitoring a display should be placed close to and directly below that display.

h) Controls used infrequently (other than immediate action controls) should be placed to one side, or even covered, to prevent accidental activation.

i) Controls used occasionally may be mounted behind hinged doors or recessed into the panel to reduce distraction and to prevent accidental activation.

j) If controls have to be placed where operators cannot see them, they should be located and arranged to account for operators' tendency to reach too low for controls placed above shoulder level, too high for controls placed below shoulder level, and too far to the rear when controls are on either side of them.

k) The displays used most frequently should be grouped together and placed in the preferred viewing area (see figure 2a, page 11).

l) Whenever feasible, display faces should be perpendicular to the user's normal line of sight. In no case should the angle of the display plane to the normal line of sight be less than 45° (see figure 2b, page 12). Parallax should be minimized.

6.5.4 Separation of controls

Recommended minimum control separation distances are shown in figure 3 (see page 13) and table 2 (see pages 14–15). In many cases separation should be greater. The functional requirements that should be considered are access, accidental activation, and simultaneous activation.

6.5.4.1 Access

Control access should not be impeded by any position of an adjacent control.

6.5.4.2 Inadvertent activation

Control activation should not result in accidental activation of an adjacent control.

6.5.4.3 Simultaneous activation

Simultaneous activation of adjacent controls (where required) should be possible.

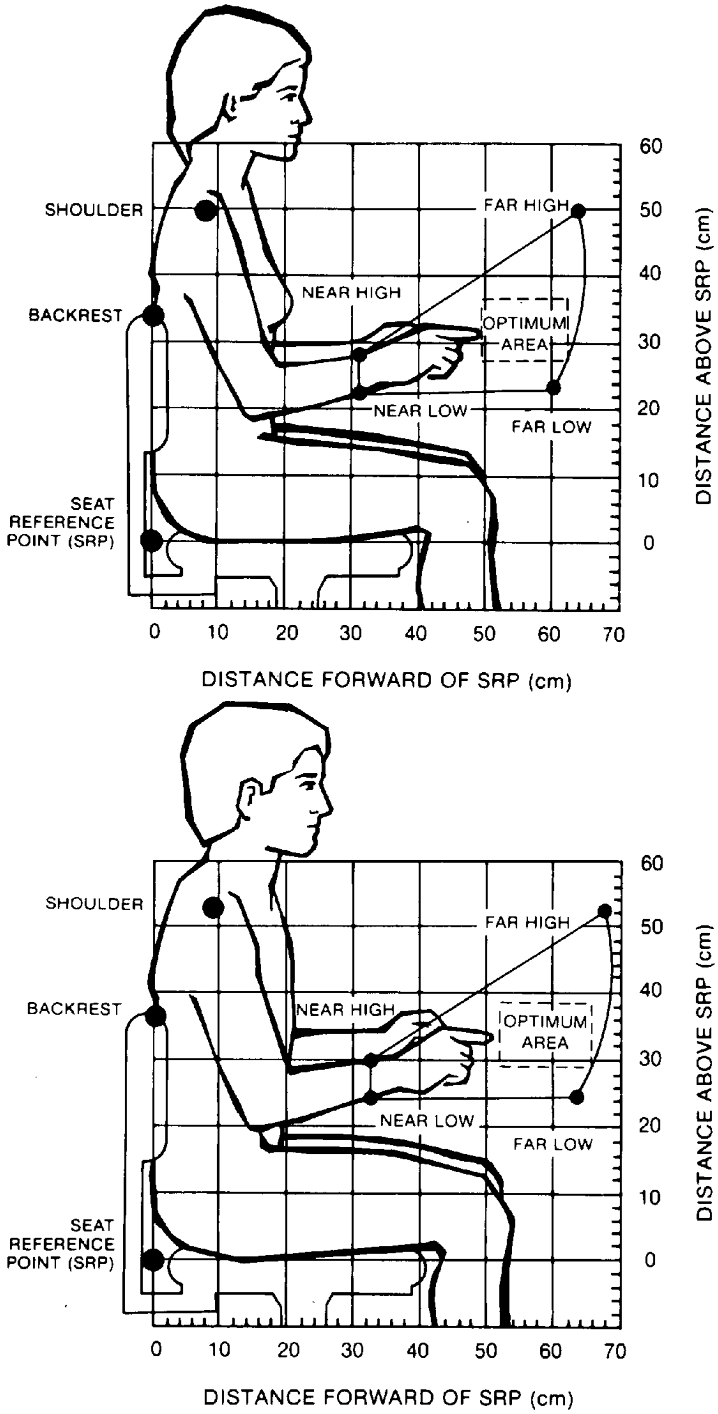


Figure 1—Optimum manual control space: seated operator

(Adapted from MIL-HDBK-759)

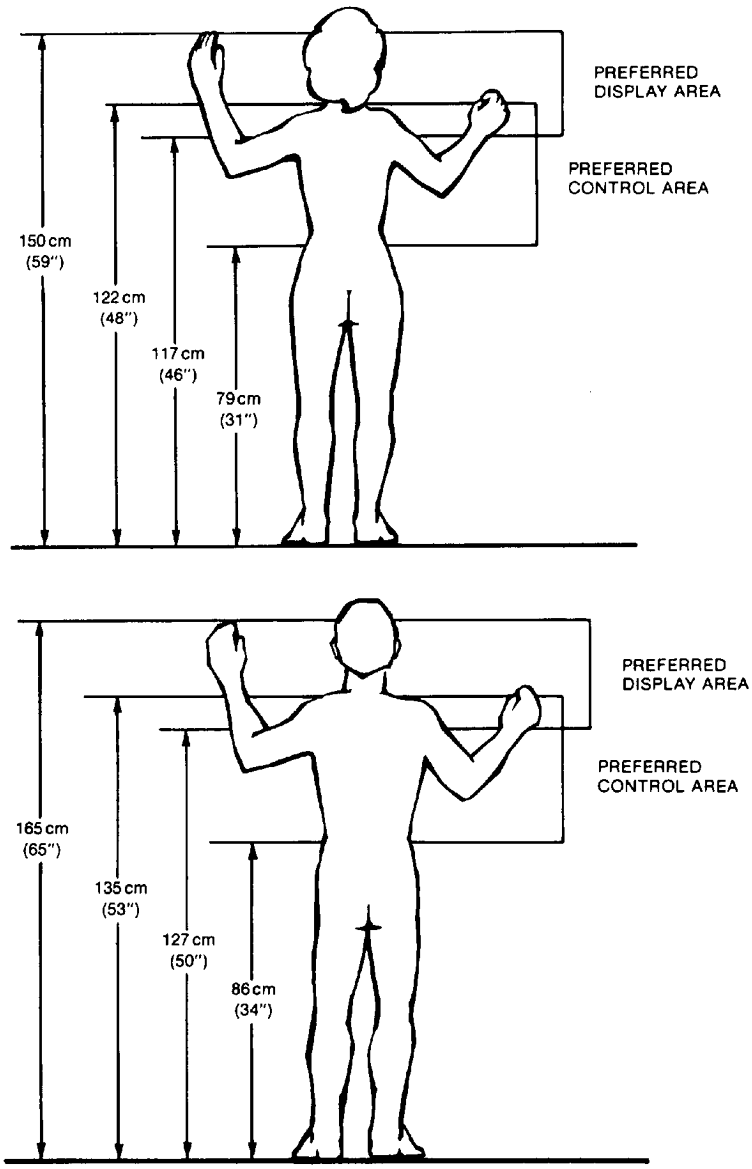
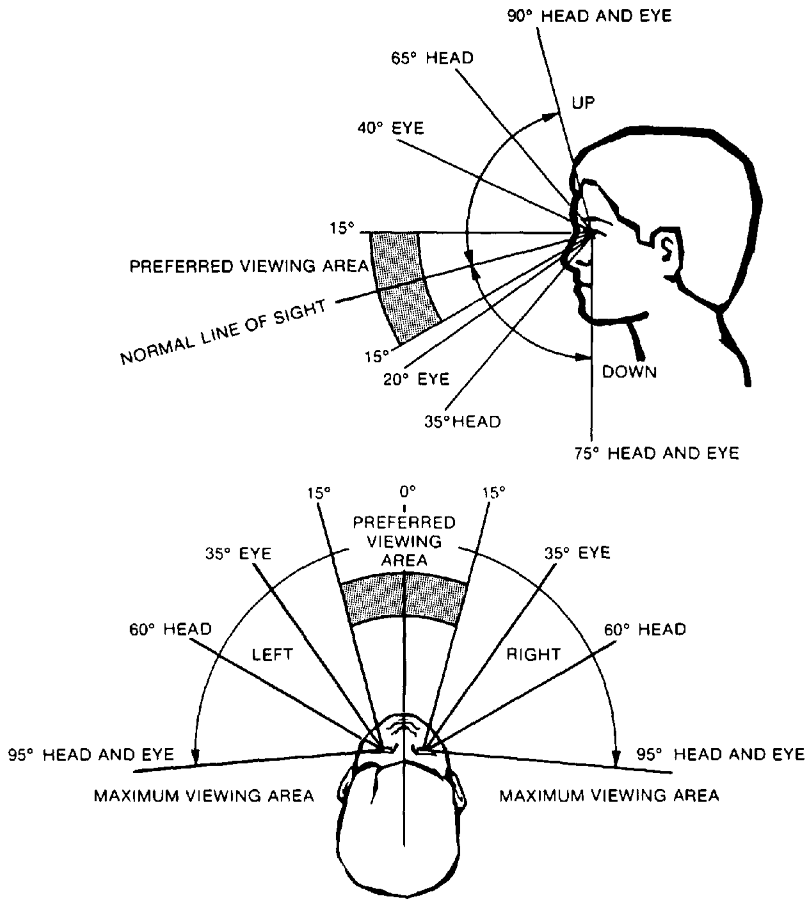


Figure 2—Preferred control and display areas, flat panel: standing operator

(Adapted from MIL-HDBK-759)



		MAXIMUM*		
	PREFERRED	EYE ROTATION	HEAD ROTATION	HEAD AND EYE ROTATION
UP	15°	40°	65°	90°
DOWN	15°	20°	35°	75°
RIGHT	15°	35°	60°	95°
LEFT	15°	35°	60°	95°

* Display area on the console defined by the angles measured from the normal line of sight.

Figure 2a—Vertical and horizontal visual field

(Adapted from MIL-STD-1472D)

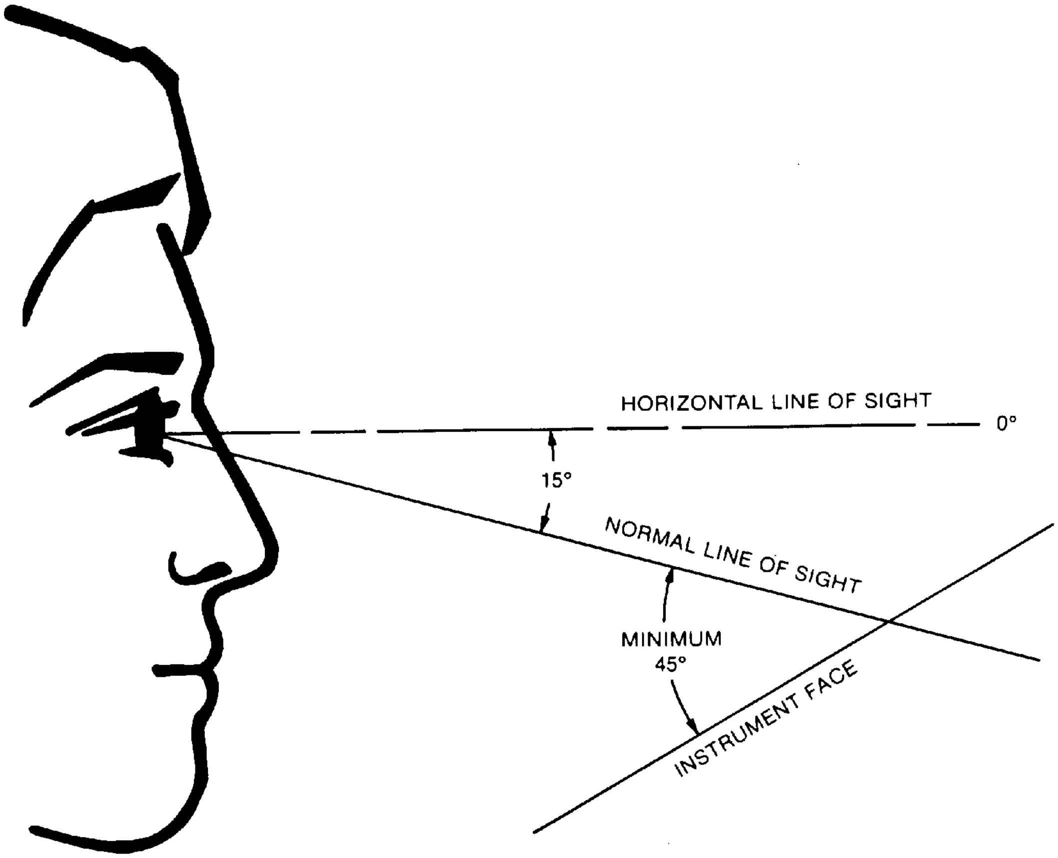


Figure 2b—Lines of sight

(Adapted from MIL-STD-1472D)

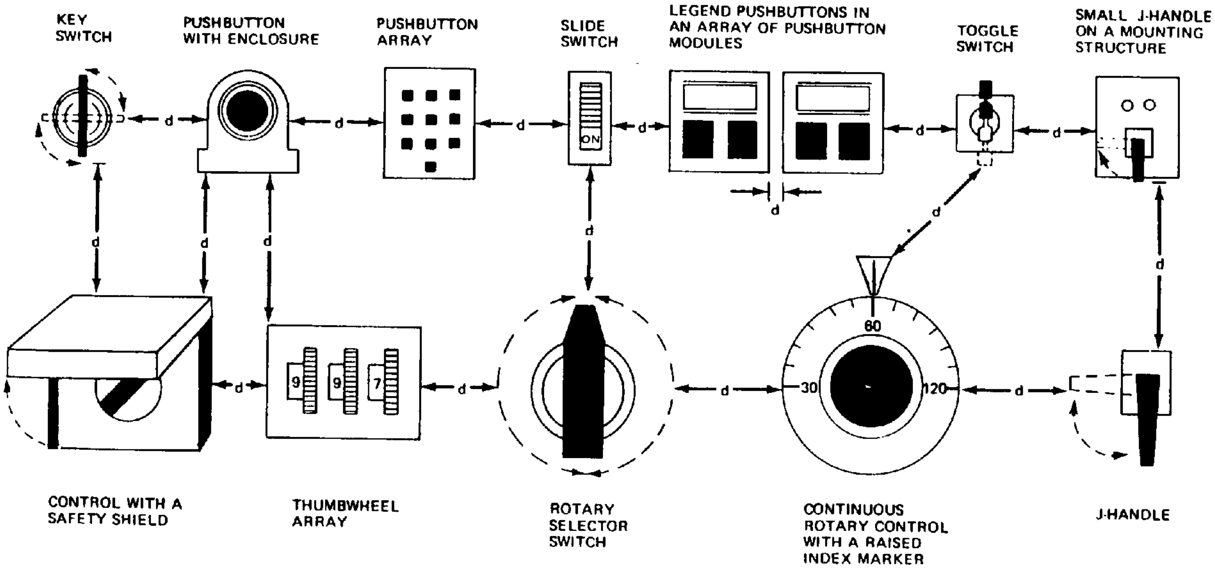


Figure 3—Measurement of minimum separation distance between controls

NOTE—Distances (d) shown in table 2 are measured from edge to edge of the maximum rotation (or movement) envelope of the control. This is the outside dimension of the control in all possible positions, including the body of the control, its supporting structure, and any housing or shield in all positions of the shield. (Adapted from NUREG-0700)

Table 2—Minimum separation distances for controls (inches)

Control	Key-Operated Controls	Push-buttons Not in an Array	Push-button Arrays	Legend Switches, Legend Switch Array	Slide Switches, Rocker Switches	Toggle Switches	Thumb-wheels, Thumb-wheel Arrays	Rotary Selector Switches	Conti-nuous Rotary Controls	J-Handles (Large)	J-Handles (Small)
Key-Operated Controls	1.0	0.5	1.5	1.0	0.75	0.75	0.5	0.75	0.75	5.0	2.0
Push-buttons Not in an Array	0.5	0.5	2.0	2.0	0.5	0.5	0.5	0.5	0.5	6.0	3.0
Push-button Arrays[1]	1.5	2.0	2.0	2.0	1.5	1.5	1.5	2.0	2.0	6.0	3.0
Legend Switches Legend Switch Arrays[2]	1.0	2.0	2.0	2.0	1.5	1.5	1.5	2.0	2.0	6.0	3.0
Slide Switches Rocker Switches	0.75	0.5	1.5	1.5	0.5	0.75	0.5	0.5	0.5	5.0	2.0
Toggle Switches[3]	0.75	0.5	1.5	1.5	0.75	0.75	0.5	0.75	0.75	6.0	3.0

Control	Key-Operated Controls	Push-buttons Not in an Array	Push-button Arrays	Legend Switches, Legend Switch Array	Slide Switches, Rocker Switches	Toggle Switches	Thumb-wheels, Thumb-wheel Arrays	Rotary Selector Switches	Conti-nuous Rotary Controls	J-Handles (Large)	J-Handles (Small)
Thumb-wheels, Thumb-wheel Arrays	0.5	0.5	1.5	1.5	0.5	0.5	0.5	0.75	0.75	5.0	2.0
Rotary Selector Switches	0.75	0.5	2.0	2.0	0.5	0.75	0.75	1.0	1.0	5.0	2.0
Contin-uous Rotary Controls	0.75	0.5	2.0	2.0	0.5	0.75	0.75	1.0	1.0	5.0	2.0
J-Handles (Large)	5.0	6.0	6.0	6.0	5.0	6.0	5.0	5.0	5.0	3.0	5.0
J-Handles (Small)	2.0	3.0	3.0	3.0	2.0	3.0	2.0	2.0	2.0	5.0	1.0

[1] Pushbuttons within an array, 0.75 inches center-to-center.
[2] Legend switches within an array, no minimum distance, but should be separated by a barrier. Barrier should be at least 0.125 inches wide, 0.183 inches high, with rounded edges. Legend switches manufactured as elements of a module array may be mounted as closely as engineering considerations permit.
[3] Toggle switches arrayed in a horizontal line, 0.75 inches center-to-center.
(Adapted from NUREG-0700)

Distances are measured from edge to edge of control rotation envelopes.

6.5.5 Control and display integration

The physical arrangement of controls and displays on consoles and panels (see figure 4, next page) and the relationship of display response to control movement should facilitate recognition of the associations among controls and displays and should facilitate correct operation of the device.

6.5.5.1 Integration of single control and display pairs

When a single control is related to a single display,

a) the control and display should be located close to one another with the control directly below the display;

b) if it is not feasible to mount the control directly below the display, the control should be mounted to the right of the display;

c) the display should be located so that it can be read clearly and without parallax from a normal operating posture during manipulation of the control;

d) the display should be located so that it is not obscured during operation of the control.

6.5.5.2 Integration of multiple controls with a single display

When several interacting controls are associated with a single display,

a) controls should be mounted below the display;

b) controls should be centered on the display;

c) controls should be grouped in a line or matrix;

d) if it is not feasible to mount controls directly below the display, controls should be mounted to the right of the display;

e) where there is a normal order of use, controls should be arranged for use in left-to-right, top-to-bottom, or other natural sequence.

6.5.5.3 Integration of a single control with multiple displays

When more than one display is affected by a single control,

a) displays should be located above the control;

b) displays should be placed as near as possible to the control and centered on the control;

c) displays should be arranged horizontally or in a matrix;

d) if it is not feasible to mount displays above the control, they should be mounted to the left of the control;

e) where there is a normal order of use, displays should read from left-to-right, top-to-bottom, or in some other natural sequence;

f) displays should not be obscured during control manipulation.

6.5.5.4 Integration of controls and displays on a single panel

Groups of related controls and displays should, if possible, be located on a single panel. Appropriate single-panel control-display arrangements, in order of preference, are display above each control, displays and controls in matched rows, and multi-row displays with a single row of controls (see 6.5.5.1–6.5.5.3). Practice should be consistent, so that user expectations are not confused.

6.5.5.4.1 Display above each control

In the preferred configuration of display above each control,

a) each display should be located directly above its associated control;

b) the display/control pairs should be arranged in rows.

6.5.5.4.2 Controls and displays in rows

In the less preferred alternative with displays arrayed in rows as the upper portion of a panel matched to controls arrayed in similar rows below,

a) each control should occupy the same relative position as the display to which it is associated;

b) controls and displays should have corresponding labels.

6.5.5.4.3 Multi-row displays with a single row of controls

In the least preferred alternative in which two or more rows of displays are arrayed above a single row of controls,

a) displays should be ordered left-to-right and top-to-bottom (in normal reading order), and matched to controls ordered left-to-right;

b) controls and displays should have corresponding labels.

6.5.5.5 Integration of controls and displays on separate panels

When controls and related displays have to be placed on separate panels, the displays should be located on a panel above the controls and should otherwise be arranged consistent with 6.5.5.1–6.5.5.4. In no case should related controls and displays be located on separate panels that face each other.

6.5.5.6 Integration of controls and displays on moving parts

The arrangement of controls and/or displays on moving or rotating parts of a device should remain consistent with respect to each other and with respect to the user despite the device's movement or rotation. Satisfaction of this guideline may be difficult for all but the simplest arrangements. If possible, consideration should be given to the location of the controls and/or displays on appropriate stationary elements of the device.

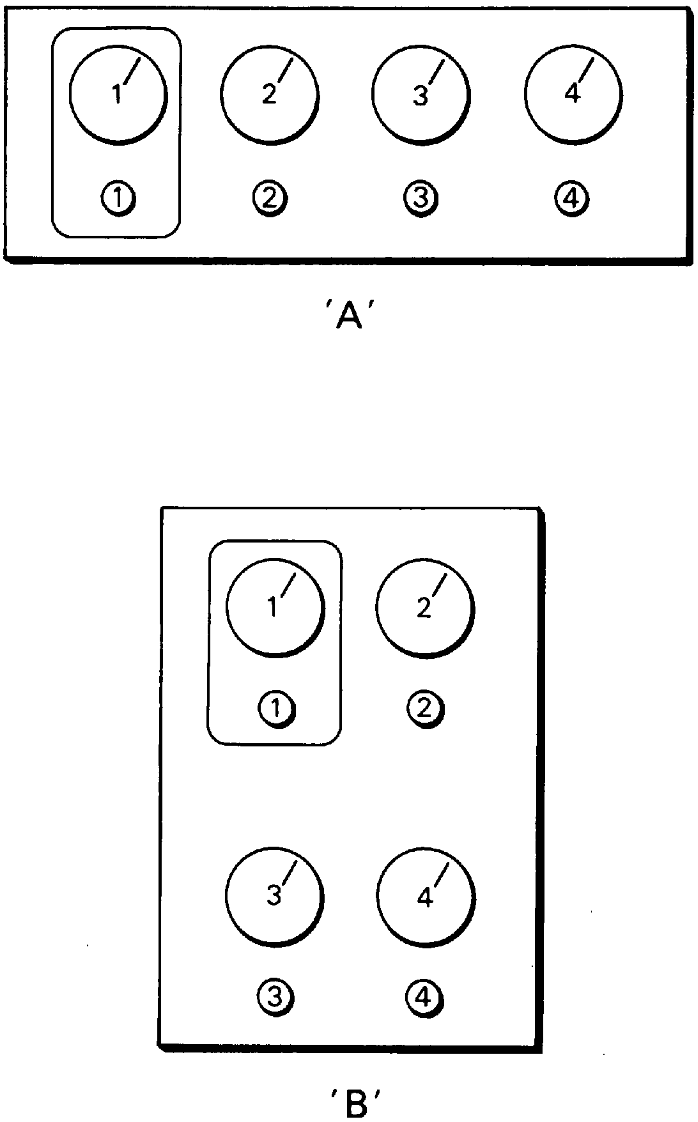


Figure 4—Control display relationship

NOTE—Small circles are controls and large circles are displays.

6.5.5.7 Integration of modular control-display packages

When controls and related displays are assembled in modular packaged units, the design of the packages will limit the location and arrangement which can be achieved. In this case, modules should be selected and arranged to achieve maximum conformity with the principles described above.

6.5.5.8 Display response to control movement

The response of a display to control movement should be consistent, predictable, and compatible with the user's expectations.

6.5.5.8.1 Directional correlation

In general, controls and displays should be chosen to correspond to the control movement stereotypes and preferred display responses shown in tables 3 and 4 (see next page). The direction of a control's movements should be consistent with comparable movements of any related displays or device components. In general, moving a control forward, clockwise, to the right, or upward—or pressing or squeezing it—should turn the device or component on, increase a quantity, or cause the device or component to move forward, clockwise, to the right, or upward, except in the case of mechanical fluid control valves. However, specific device standards, accepted practices, user expectations and/or consistency within a device or system may dictate otherwise. Markings should indicate the correct relationship.

6.5.5.8.1.1 Moving-pointer, fixed circular scale

Clockwise movement of a rotary control or movement of a linear control forward, upward, or to the right should produce a clockwise movement of circular scale pointers and yield an increase in the magnitude of the setting.

6.5.5.8.1.2 Moving-pointer, fixed linear scale

Clockwise movement of a rotary control or movement of a linear control forward, upward, or to the right should produce a movement upward for vertical scale pointers or to the right for horizontal scale pointers and should yield an increase on the magnitude of the setting.

6.5.5.8.1.3 Circular, fixed-pointer, moving scale

Displays with moving scales and fixed pointers or cursors should be avoided. When circular, fixed-pointer, moving-scale indicators are necessary, clockwise movement of a rotary control—or movement of a linear control forward, upward or to the right—should produce a counterclockwise movement of the scale and should yield an increase in the magnitude of the setting.

6.5.5.8.1.4 Linear, fixed-pointer, moving scale

When vertical or horizontal fixed-pointer, moving-scale indicators are necessary, clockwise movement of a related rotary control—or movement of a linear control forward, upward, or to the right—should normally produce a movement of the scale down or to the left and should yield an increase in the magnitude of the setting.

6.5.5.8.1.5 Digital displays

Clockwise movement of a rotary control or movement of a linear control forward, upward, or to the right should produce an increase in the displayed value and yield an increase in the magnitude of the setting (i.e., controlled parameter).

6.5.5.8.1.6 Strings of indicator lights

Clockwise movement of a rotary control or movement of a linear control forward, upward, or to the right should produce a bottom-to-top or left-to-right sequencing in strings of indicator lights.

6.5.5.8.1.7 Display selectors

Where displays are selected for viewing using a rotary selector switch,

a) the control should move clockwise from OFF (if appropriate) through settings 1,2,3...n;

b) the control position sequence should conform to the display sequence;

c) control position indications should correspond with display labels;

d) displays should read off-scale, not zero, when not selected, especially if zero is a possible parameter displayed.

6.5.5.8.1.8 Direct linkage

When a control and a display are directly linked, such as a radio frequency selector and a station pointer, a rotary control should be used if the indicator moves through an arc of more than 180°. Otherwise, a linear control may be used provided that the path of the control movement parallels the average path of the indicator movement and the indicator and the control move in the same relative direction.

6.5.5.8.1.9 Parallel movement

The direction of movement should be the same when the movements of the control and the display are parallel.

6.5.5.8.2 Control/display ratios

Controls should provide a capability to affect the controlled parameter easily and with the required level of precision and displays should provide a capability to distinguish significant values and changes in value of the controlled parameter. The ratio of control movement to display-element movement should facilitate use of the device.

6.5.5.8.2.1 Minimization of time

The control/display ratio (C/D) for continuous adjustment controls should minimize the total time required to make the desired control movement (i.e., slewing time plus fine adjustment time), taking into consideration display size, tolerance requirements, viewing distance, and time delays.

6.5.5.8.2.2 Feedback

Feedback from the display should be apparent for any deliberate movement of a control.

Table 3—Control Movement stereotypes

Function	Direction of control movement
On	Up, right, forward, clockwise, in, pull (push-pull switch)
Off	Down, left, rearward, counterclockwise, out, push (push-pull switch)
Right	Clockwise, right
Left	Counterclockwise, left
Raise	Up
Lower	Down
Retract	Up, rearward, pull
Extend	Down, forward, push
Increase	Forward, up, right, clockwise
Decrease	Rearward, down, left, counterclockwise
Open Valve	Counterclockwise
Close Valve	Clockwise

(Adapted from U.S. Department of Defense [1981b], table 1.3.)

Table 4—Direction of control movement and resulting display responses

			Display plane														
		Type of Movement	Front			Left			Right			Bottom			Overhead		
			Up	Right	Clockwise	Up	Forward	Clockwise	Up	Forward	Clockwise	Forward	Right	Clockwise	Forward	Right	Clockwise
Control Plane	Front	Up	P	A	A	P	A	X	P	A	P	P	A	A	X	A	A
		Right	A	P	A	A	P	A	A	X	A	A	P	P	A	P	X
		Clockwise	A	A	P	P	A	P	X	A	P	A	X	P	A	P	P
	Left	Up	P	A	P	P	A	A	P	A	A	A	X	A	A	P	A
		Forward	A	P	A	A	P	A	A	P	A	P	A	P	P	A	X
		Clockwise	X	A	P	A	A	P	A	A	A	X	A	P	P	A	P
	Right	Up	P	A	X	P	A	A	P	A	A	A	P	A	A	X	A
		Forward	A	X	A	A	P	A	A	P	A	P	A	X	P	A	P
		Clockwise	P	A	P	A	X	A	A	A	P	P	A	P	X	A	P
	Bottom	Forward	P	A	A	A	P	A	A	P	P	P	A	A	P	A	A
		Right	A	P	X	X	A	A	P	A	A	A	P	A	A	P	A
		Clockwise	A	P	P	A	P	P	A	X	P	A	A	P	A	A	A
	Overhead	Forward	X	A	A	A	P	P	A	P	X	P	A	A	P	A	A
		Right	A	P	P	P	A	A	X	A	A	A	P	A	A	P	A
		Clockwise	A	X	P	A	X	P	A	P	P	A	A	A	A	A	P

(Reprinted from U.S. Air Force [1977], Sub-Note [71]).   P = Preferred   A = Acceptable   X = Unacceptable

6.5.5.8.2.3 Range of display-element movement

When a wide range of display-element movement is required, a small movement of the control should generally yield a large movement of the display element (C/D < 1). When a narrow range of display-element movement is required, a large movement of the control should result in a small movement of the display (C/D < 1).

6.5.5.8.2.4 Knob, coarse setting

When a knob is provided for making coarse display-element settings on linear scales with tolerances of 0.4 to 2.5 mm (0.016 to 0.100 inch), one complete turn of the knob should cause the display element to move approximately 150 mm (6 inches).

6.5.5.8.2.5 Knob, fine setting

For fine settings on linear scales with tolerances of 0.18 to 0.38 mm (0.007 to 0.015 inch), one complete turn of the knob should cause the display element to move approximately 25 to 50 mm (1 to 2 inches).

6.5.5.8.2.6 Bracketing

When bracketing is used to locate a maximum or minimum rather than a specific value (e.g., as in tuning a transmitter), the control knob should swing through an arc of not less than 175 mrad (10°) nor more than 525 mrad (30°) on either side of the target value in order to make the peak or dip associated with that value clearly noticeable.

6.5.5.8.2.7 Foot-operated controls

Foot-operated controls should be used only for displays requiring coarse settings.

6.5.5.8.2.8 Lever, coarse setting

When a lever is provided for coarse settings with tolerances of 0.4 to 2.5 mm (0.016 to 0.100 inch), one unit of display-element movement should correspond to three units of lever movement (C/D = 3).

6.5.5.8.2.9 Lever, two-dimensional setting

When a lever is provided to make settings in two dimensions, with a coarse tolerance of 2.5 mm (0.1 inch), one unit of display-element movement should correspond to two and one-half units of lever movement (C/D = 5/2).

6.5.5.8.2.10 Counters

The C/D ratio for counters should be such that one revolution of the knob equals approximately 50 counts (i.e., the rightmost drum makes five complete revolutions and the next to the rightmost drum increases by five counts).

6.5.5.8.3 Display response time lag

There should be no time lag between system condition change and display indication. When there is a time lag between control activation and ultimate system state, there should be an immediate feedback indication of the process and direction of parameter change.

6.5.6 Strings or clusters of similar components

On occasion it may be necessary to have a large group of similar components arranged together in strings, matrices, or other clusters. The HFE guidelines presented in 6.5.1 through 6.5.5 should not be compromised where large clusters of components are concerned. However, if considerations such as search time, discriminability of components, and avoidance of selection errors make a string or matrix the preferred arrangement several issues should be considered.

6.5.6.1 Orientation

Horizontal rows of displays should be used rather than vertical columns.

6.5.6.2 String length

Strings of small displays should not exceed about 500 mm (20 inches) on the console or panel.

6.5.6.3 Number of components

No more than five similar components should be laid out in an unbroken row or column. If more than five similar components need to be laid out together, the string or cluster should be broken up by techniques such as physical spacing, demarcation, or background shading (see 6.5.9 and 8.2).

6.5.6.4 Large matrices

Large matrices of similar components should have the coordinate axes labeled to aid identification of any single component within the grid (e.g., alphabetic rows and numerical columns). The left and top sides of the matrix should be used for labeling. If an appropriate basis exists, large matrices should be subdivided by demarcation or background shading.

6.5.7 Consistency of panel and console layout

When a precedent has been established for the location and arrangement of controls and displays, that standard practice should be followed unless other crucial considerations necessitate a change. For example, the location and arrangement of identical functional groups should be consistent at all locations.

6.5.7.1 Console-to-console and panel-to-panel consistency

Consistent location and arrangement should be maintained where similar functions, consoles, or panels are located at several work stations or units and should be used by the same personnel.

6.5.7.2 Simulator to device consistency

Consistency should be maintained where simulators (including simulators used to obtain the clinical information necessary for treatment planning, e.g., a teletherapy simulator) or procedure trainers are used.

6.5.7.3 Mirror imaging

Mirror imaging should not be used. The layout of any recurring functional groups should be replicated rather than laid out so that one is a complete, or almost complete, symmetrical reversal of the other.

6.5.8 Layout for dual operation

For monitoring system status, if two operators need to use the same control or display, the following criteria should be applied (also see figure 8, page 32):

a) If the controls and displays have a high priority, duplicate sets should be provided whenever space is adequate; otherwise, the controls and displays should be centered between the operators.

b) If secondary controls and displays of equal importance to each operator need to be shared, they should be centered between the operators. Controls and displays more important to one operator than to the other should be placed nearer the operator who is principally responsible for their use.

c) If the primary or secondary controls have to be operated with the user's preferred hand—as in the case of fixed keys, soft keys, keyboards or keypads—duplicate controls should be provided, instead of centering one set between the two operators.

d) If direction-of-movement relationships are important, controls and displays should be located so that both operators face in the same direction.

e) If more than one user need to have simultaneous access to a particular group of controls or displays, the operator with primary responsibility should have physical and visual access to all controls, displays, and communication capabilities necessary to perform assigned tasks adequately.

6.5.9 Enhancing recognition and identification

Once decisions are made about the arrangement of controls and displays on consoles and panels, the user's ability to recognize functional groupings and to identify specific components can be enhanced by use of spacing, labels, location aids (see 8.2), and coding (see 8.3). Distinctive enhancement techniques should be used for emergency controls.

6.5.9.1 Spacing

Spacing consists of physically separating groups of components on a console or panel with enough space between groups so that the boundaries of each group are obvious. Spacing between groups should be at least the width of a typical control or display in the group.

6.5.9.2 Labeling

It is sometimes appropriate to identify controls or displays in alphabetic or numeric sequence. To meet user expectations, displays in a row should be identified sequentially as A, B, C, etc. or 1, 2, 3, etc. Any controls related to those displays should also be identified sequentially as A, B, C, etc. or 1, 2, 3, etc.

6.6 Documentation

Documentation is a general term that includes operator manuals, instruction sheets, online help systems, and maintenance manuals. These materials may be accessed by many types of users; therefore, the documentation should be written to meet the needs of all target populations.

The intent of this section is to provide guidance on developing good documentation and on using the documentation to support the HFE process as well as to furnish instructional material to users. This section is not intended as a complete style guide or a guide to governmental regulation.

NOTE—The U. S. Food and Drug Administration's definition of *labeling* is broad and includes documentation such as operator manuals. Documentation that falls under the definition of *labeling* must comply with the Fair Packaging and Labeling Act (enacted 3 November 1966), with the Medical Device Amendments of 1976 (enacted 28 May 1976), and with applicable regulations on the content of medical device labeling. Reference may also be made to individual device standards.

6.6.1 The process

Preparation of instructional documentation should begin as soon as possible during the specification phase. This assists device designers in identifying critical HFE needs and in producing a consistent human interface. The device and its documentation should be developed together.

6.6.1.1 Initial study

During the planning phase, a study should be made of the capabilities and information needs of the documentation users (e.g., device operators and maintenance personnel). The researcher should learn about

a) the users' mental abilities, including their educational and reading levels;

b) the users' physical abilities. For example, some populations have below-average eyesight or an increased incidence of colorblindness or impaired motor functioning;

c) the users' previous experience with similar technology or devices. This should include an evaluation of any factors that could result in negative educational transfer (i.e., any preconceptions the user may have that could interfere with interpreting the documentation or with learning to use the device);

d) the users' understanding of the general principles of operation and potential hazards associated with the technology;

e) special needs or restrictions of the environment in which the documentation will be used. For example, many nursing areas reduce lighting levels during the night; and emergency medical service personnel often work in environments that are harsh for documents;

f) the approach to documentation taken by manufacturers of similar existing devices. This is useful in identifying terminology and explanatory styles with which the user may already be familiar.

6.6.1.2 Specifications

The specifications should include

a) a list of the types of documentation required, such as operator manuals, maintenance manuals, reminder sheets, and checklists;

b) a specification for readability including the type of index to be used;

c) a list of languages to be used;

d) a list of special needs or restrictions on the documentation, such as limitations on colors, type size, and document size;

e) an outline for each document including a list of expected drawings and illustrations;

f) a schedule for developing the documentation that is linked to the device design schedule.

6.6.1.3 Production of draft documentation

The draft operator's manual should be produced before detailed device design or "prototyping." As a minimum, the operators' manual should include detailed procedures for setup, normal operation, emergency operation, cleaning, and operator troubleshooting. The draft can then serve as a specification for the user interface.

Production of draft maintenance documentation should start at about the same time as the prototype devices begin to resemble production models.

6.6.1.4 Testing and revision

The operator manual should be tested on early prototype devices. Revisions of the manual should precede revisions of the device so that the revised manual can be used as a testing aid.

Later in the development process, the manual should be tested using production models of the device and target populations. It is important that these test populations be truly representative of end-users and that they not have advance knowledge of the device.

Maintenance documentation should be tested on device prototypes that resemble production units as well as on production models.

6.6.2 Writing style

The content should be presented in language free of vague and ambiguous terms. The simplest words and phrases that will convey the intended meaning should be used. Sentences should generally be shorter rather than longer, but not at the risk of lessening comprehension. Terminology within the publication should be consistent. Use of abbreviations should be kept to a minimum. All abbreviations should be defined the first time they are used.

6.6.2.1 Grammatical person and mood

Procedures and instructions should be in the active voice and imperative mood ("Remove paddles from the carrying case"). Imperative mood is always second person and present tense. Descriptive writing should be in the third person, present tense, active voice, and indicative mood ("The discharge buttons send the energy to the electrodes").

6.6.2.2 Procedural steps

Procedural steps presenting step-by-step instructions should be numbered consecutively in arabic numerals.

6.6.2.3 Warnings and cautions

Information included in warnings and cautions should be chosen carefully and with consideration of the skills and training of intended users. It is especially important to inform users about unusual hazards (i.e., those not generally known by intended users) and hazards specific to the device (i.e., those not common to all other devices of the same type). If the text includes too many warnings and cautions about risks known to the user, the technique will lose its effect, i.e., warning about everything warns about nothing.

The statement on hazards should be preceded by a signal word, such as *WARNING* or CAUTION. The signal word should be typographically emphasized so it stands out from the other text.

7 The human factor and the work space

Knowledge of human body measurements and psychological capabilities is a fundamental building block in the design of effective man-machine systems. A small library would be needed to provide all the HFE data required for a full understanding of these topics, but this section is intended to acquaint the reader with selected basic data and with references that designers commonly use to help find their own solutions to human-related design problems. The references cited herein are not intended to be an all-inclusive listing but are carefully chosen sources on topics that have been shown to be related to most design problems.

7.1 Anthropometry

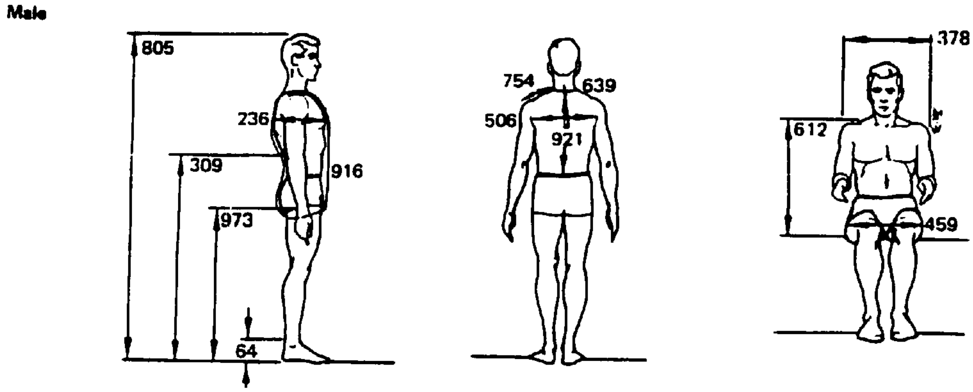
7.1.1 General

Anthropometry is the science of measuring the human body and its parts and functional capacities. The lack of specific data on the population of health care professionals requires the medical device designer to seek out the most appropriate available information.

NOTE—Several commercial software companies produce programs that can assist designers in the anthropometric design of equipment. Designers can turn to both text and software applications that provide the relevant background data.

7.1.2 Physical dimensions

Generally, design limits are based on a range of values from the 5th percentile female to the 95th percentile male for critical body dimensions. The 5th percentile value indicates that five percent of the population will be equal to or smaller than that value and 95 percent will be larger; conversely, the 95th percentile value indicates that 95 percent of the population will be equal to or smaller than that value and five percent will be larger. Therefore, use of a design range from the 5th to the 95th percentile values will theoretically provide coverage for 90 percent of the user population for that dimension. Because many medical devices are used by diverse international populations, the data provided in the figures are based on values for the 40-year-old American male and the 40-year-old Asian female projected to the year 2000 (see figures 5 through 5e, pages 23–28).



Microgravity notes	No.	Dimension	5th percentile	50th percentile	95th percentile
1	805	Stature	169.7 (66.8)	179.9 (70.8)	190.1 (74.8)
1	973	Wrist height			
	64	Ankle height	12.0 (4.7)	13.9 (5.5)	15.8 (6.2)
1	309	Elbow height			
	236	Bust depth	21.8 (8.6)	25.0 (9.8)	28.2 (11.1)
1	916	Vertical trunk circumference	158.7 (62.5)	170.7 (67.2)	182.6 (71.9)
2 1	612	Midshoulder height, sitting	60.8 (23.9)	65.4 (25.7)	70.0 (27.5)
	459	Hip breadth, sitting	34.6 (13.6)	38.4 (15.1)	42.3 (16.6)
1	921	Waist back	43.7 (17.2)	47.6 (18.8)	51.6 (20.3)
	506	Interscye	32.9 (13.0)	39.2 (15.4)	45.4 (17.9)
	639	Neck circumference	35.5 (14.0)	38.7 (15.2)	41.9 (16.5)
	754	Shoulder length	14.8 (5.8)	16.9 (6.7)	19.0 (7.5)
	378	Forearm-forearm breadth	48.8 (19.2)	55.1 (21.7)	61.5 (24.2)

(Note: values in cm with inches in parentheses)

Reference: 274, page 121-128
308
351

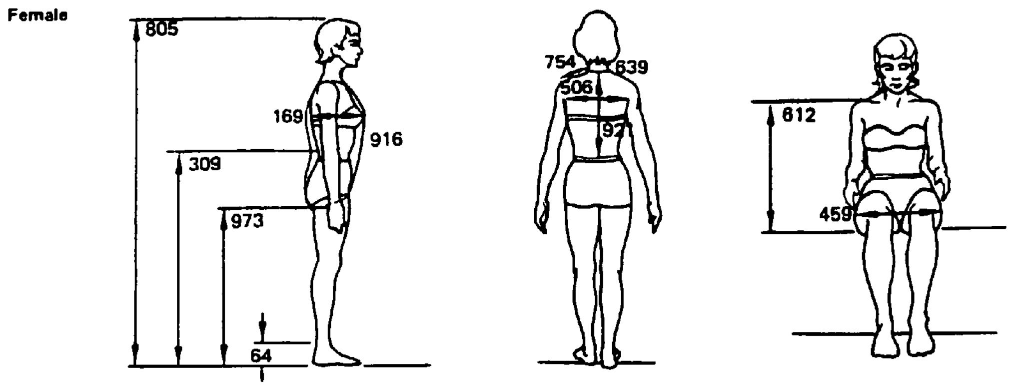
Notes:

a. Gravity conditions — the dimensions apply to a 1-G condition only. Dimensions expected to change significantly due to microgravity are marked. Notations regarding these dimensions are at the end of the Figure.

b. Measurement data — the numbers adjacent to each of the dimensions are reference codes. The same codes are in Volume II of Reference 16. Reference 16, Volume II provides additional data for these measurements plus an explanation of the measurement technique.

Figure 5—Body size of 40-year old American male in Year 2000

(from NASA -STD-3000)



Microgravity notes	No.	Dimension	5th percentile	50th percentile	95th percentile
1	805	Stature	148.9 (58.6)	157.0 (61.8)	165.1 (65.0)
1	973	Wrist height	70.8 (27.9)	76.6 (30.2)	82.4 (32.4)
	64	Ankle height	5.2 (2.0)	6.1 (2.4)	7.0 (2.8)
1	309	Elbow height	92.8 (36.5)	98.4 (38.8)	104.1 (41.0)
	169	Bust depth	17.4 (6.8)	20.5 (8.1)	23.6 (9.3)
1	916	Vertical trunk circumference	136.9 (53.9)	146.0 (57.5)	155.2 (61.1)
2 1	612	Midshoulder height, sitting			
	459	Hip breadth, sitting	30.4 (12.0)	33.7 (13.3)	37.0 (14.6)
1	921	Waist back	35.2 (13.9)	38.1 (15.0)	41.0 (16.1)
	506	Interscye	32.4 (12.8)	35.7 (14.1)	39.0 (15.4)
	639	Neck circumference	34.5 (13.6)	37.1 (14.6)	39.7 (15.6)
	754	Shoulder length	11.3 (4.4)	13.1 (5.1)	14.8 (5.8)

(Note: values in cm with inches in parentheses)

Reference: 274, page 121-128
308
351

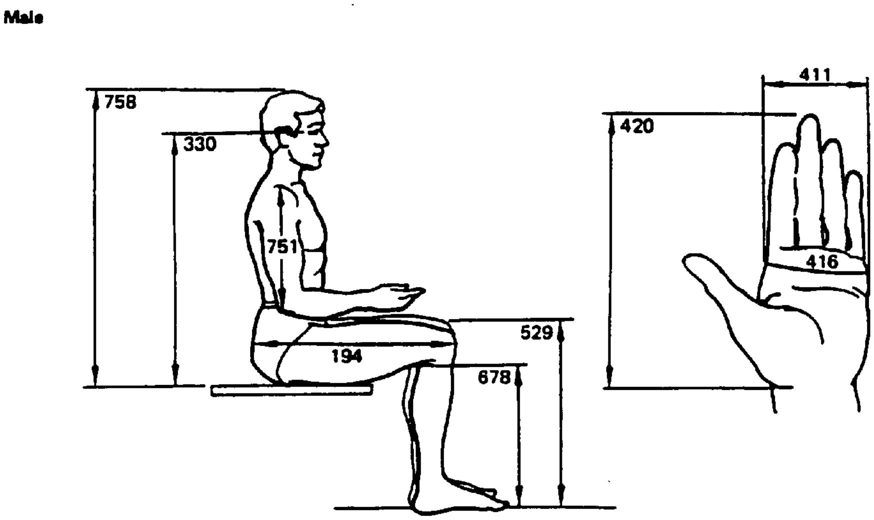
Notes:

a. Gravity conditions — the dimensions apply to a 1-G condition only. Dimension expected to change significantly due to microgravity are marked. Notations regarding these dimensions are at the end of the Figure.

b. Measurement data — the numbers adjacent to each of the dimensions are reference codes. The same codes are in Volume II of Reference 16. Reference 16, Volume II provides additional data for these measurements plus an explanation of the measurement technique.

Figure 5a—Body size of 40-year old Japanese female in Year 2000

(from NASA-STD-3000)



Microgravity notes	No.	Dimension	5th percentile	50th percentile	95th percentile
2 1	758	Sitting height	88.9 (35.0)	94.2 (37.1)	99.5 (39.2)
2 1	330	Eye height, sitting	76.8 (30.3)	81.9 (32.2)	86.9 (34.2)
4	529	Knee height, sitting	52.6 (20.7)	56.7 (22.3)	60.9 (24.0)
	678	Popliteal height	40.6 (16.0)	44.4 (17.5)	48.1 (19.0)
	751	Shoulder-elbow length	33.7 (13.3)	36.6 (14.4)	39.4 (15.5)
	194	Buttock-knee length	56.8 (22.4)	61.3 (24.1)	65.8 (25.9)
	420	Hand length	17.9 (7.0)	19.3 (7.6)	20.6 (8.1)
	411	Hand breadth	8.2 (3.2)	8.9 (3.5)	9.6 (3.8)
	416	Hand circumference	20.3 (8.0)	21.8 (8.6)	23.4 (9.2)

(Note: values in cm with inches in parentheses)

Reference: 274, page 121-128
308
351

Notes:

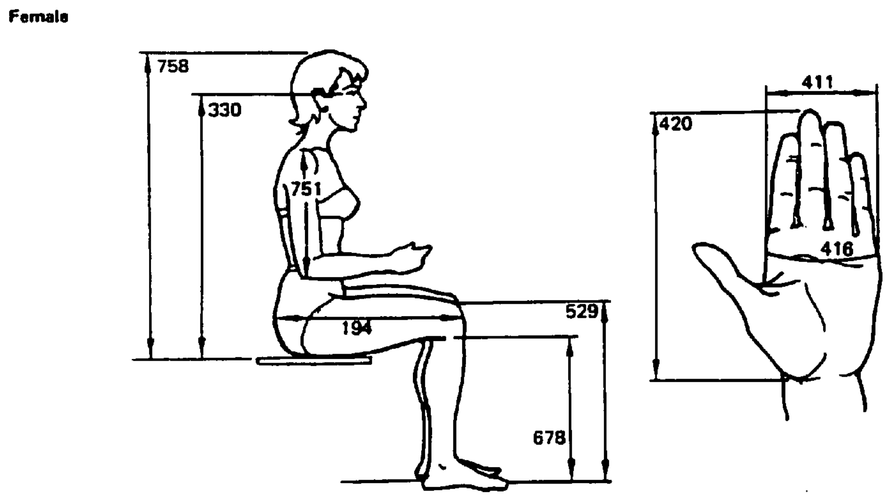
a. Gravity conditions — the dimensions apply to a 1-G condition only. Dimension expected to change significantly due to microgravity are marked. Notations regarding these dimensions are at the end of the Figure.

b. Measurement data — the numbers adjacent to each of the dimensions are reference codes. The same codes are in Volume II of Reference 16. Reference 16, Volume II provides additional data for these measurements plus an explanation of the measurement technique.

Figure 5b—Body size of 40-year old America male in Year 2000

(from NASA-STD-3000)

List of Titles



Microgravity notes	No.	Dimension	5th percentile	50th percentile	95th percentile
2 1	758	Sitting height	78.3 (30.8)	84.8 (33.4)	91.2 (35.9)
2 1	330	Eye height, sitting	68.1 (26.8)	73.8 (29.1)	79.6 (31.4)
4	529	Knee height, sitting	41.6 (16.4)	45.6 (17.9)	49.5 (19.5)
	678	Popliteal height	34.7 (13.6)	38.3 (15.1)	41.9 (16.5)
	751	Shoulder-elbow length	27.2 (10.7)	29.8 (11.7)	32.4 (12.8)
	194	Buttock-knee length	48.9 (19.2)	53.3 (21.0)	57.8 (22.7)
	420	Hand length	15.8 (6.2)	17.2 (6.8)	18.7 (7.3)
	411	Hand breadth	6.9 (2.7)	7.8 (3.1)	8.6 (3.4)
	416	Hand circumference	16.5 (6.5)	17.9 (7.0)	19.3 (7.6)

(Note: values in cm with inches in parentheses)

Reference: 274, page 121-128
308
351

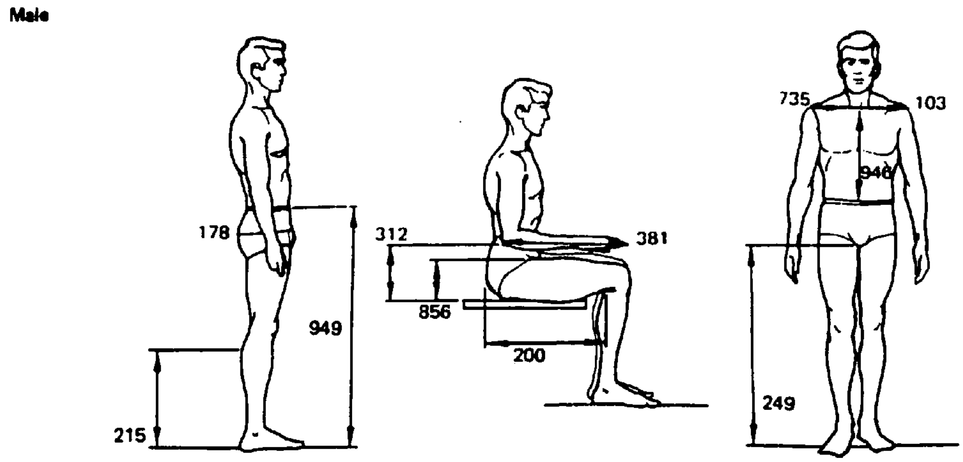
Notes:

a. Gravity conditions — the dimensions apply to a 1-G condition only. Dimension expected to change significantly due to microgravity are marked. Notations regarding these dimensions are at the end of the Figure.

b. Measurement data — the numbers adjacent to each of the dimensions are reference codes. The same codes are in Volume II of Reference 16. Reference 16, Volume II provides additional data for these measurements plus an explanation of the measurement technique.

Figure 5c—Body size of 40-year old Japanese female in Year 2000

(from NASA-STD-3000)



Microgravity notes	No.	Dimension	5th percentile	50th percentile	95th percentile
	949	Waist height	100.4 (39.5)	108.3 (42.6)	116.2 (45.7)
	249	Crotch height	79.4 (31.3)	86.4 (34.0)	93.3 (36.7)
	215	Calf height	32.5 (12.8)	36.2 (14.3)	40.0 (15.7)
	103	Biacromial breadth	37.9 (14.9)	41.1 (16.2)	44.3 (17.5)
1	946	Waist front	37.2 (14.6)	40.9 (16.1)	44.6 (17.5)
	735	Scye circumference	44.4 (17.5)	49.0 (19.3)	53.6 (21.1)
	178	Buttock circumference	91.0 (35.8)	100.2 (39.4)	109.4 (43.1)
1 2	312	Elbow rest height	21.1 (8.3)	25.4 (10.0)	29.7 (11.7)
	856	Thigh clearance	14.5 (5.7)	16.8 (6.6)	19.1 (7.5)
	381	Forearm-hand length			
	200	Buttock-popliteal length	46.9 (18.5)	51.2 (20.2)	55.5 (21.9)

(Note: values in cm with inches in parentheses)

Reference: 274, page 121-128
308
351

Notes:

a. Gravity conditions — the dimensions apply to a 1-G condition only. Dimension expected to change significantly due to microgravity are marked. Notations regarding these dimensions are at the end of the Figure.

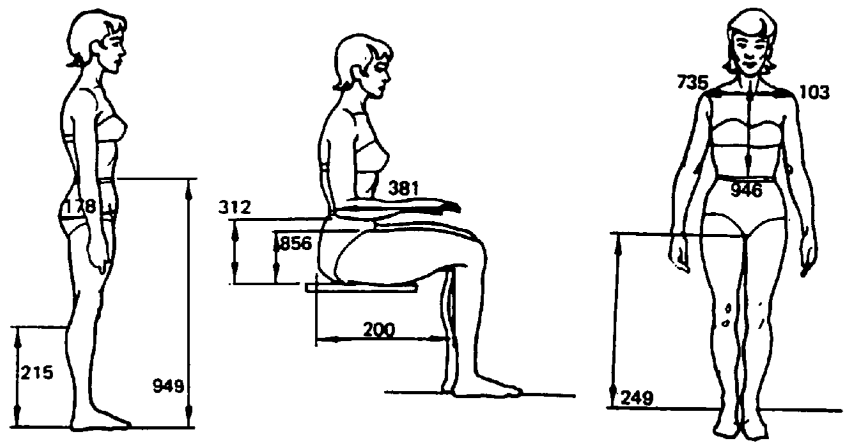
b. Measurement data — the numbers adjacent to each of the dimensions are reference codes. The same codes are in Volume II of Reference 16. Reference 16, Volume II provides additional data for these measurements plus an explanation of the measurement technique.

Figure 5d—Body size of 40-year old American male in Year 2000

(from NASA-STD-3000)

List of Titles

Female



Microgravity notes	No.	Dimension	5th percentile	50th percentile	95th percentile
	949	Waist height	90.1 (35.5)	96.7 (38.1)	103.4 (40.7)
	249	Crotch height	65.2 (25.7)	70.6 (27.8)	76.1 (30.0)
	215	Calf height	25.5 (10.0)	28.9 (11.4)	32.3 (12.7)
	103	Biacromial breadth	32.4 (12.8)	35.7 (14.1)	39.0 (15.4)
1	946	Waist front			
	735	Scye circumference	32.3 (12.7)	36.1 (14.2)	39.8 (15.7)
	178	Buttock circumference	79.9 (31.5)	87.1 (34.3)	94.3 (37.1)
1 2	312	Elbow rest height	20.7 (8.2)	25.0 (9.9)	29.3 (11.5)
	856	Thigh clearance	11.2 (4.4)	12.9 (5.1)	14.5 (5.7)
	381	Forearm-hand length	37.3 (14.7)	41.7 (16.4)	44.6 (17.6)
	200	Buttock-popliteal length	37.9 (14.9)	41.7 (16.4)	45.5 (17.9)

(Note: values in cm with inches in parentheses)

Reference: 274, page 121-128
308
351

Notes:

a. Gravity conditions — the dimensions apply to a 1-G condition only. Dimension expected to change significantly due to microgravity are marked. Notations regarding these dimensions are at the end of the Figure.

b. Measurement data — the numbers adjacent to each of the dimensions are reference codes. The same codes are in Volume II of Reference 16. Reference 16, Volume II provides additional data for these measurements plus an explanation of the measurement technique.

Figure 5e—Body size of 40-year old Japanese female in Year 2000

(from NASA-STD-3000)

7.1.3 Functional dimensions

7.1.3.1 Reach

The reach capabilities of the user population play an important role in the design of the controls and displays of the medical device. The designer should take into consideration both one- and two-handed reaches in the seated and standing positions.

7.1.3.2 Range of motion

Body mobility ranges should be factored into the design process (see Woodson, 1981). Limits of body movement should be considered relative to the age diversity and gender of the target user population(s).

7.1.3.3 Strength

The strength capacities of the device operators may have an impact on the design of the system controls (see figure 6 [next page] and Mathiowetz et al., 1985). The lifting and carrying abilities of the personnel responsible for moving and/or adjusting the device need to be considered to ensure that the device can be transported and adjusted efficiently and safely (see NIOSH, 1981).

7.1.4 Anthropometric data sources

Anthropometric analysis vary widely in their complexity and the type and amount of anthropometric data required. For example, a simple analysis may require a value for the 95th percentile U.S. male stature—data found in many published tables and charts—to determine an overhead clearance. A more involved analysis may involve studying the compatibility between a workstation and a seated 5th percentile U.S. female—an analysis frequently performed using a two-dimensional mannikin. A complex analysis may involve defining reach envelopes and lines of sight in three dimensions—results typically produced using computer models of humans. Accordingly, data tables and charts, two-dimensional mannikins, and computer models can be valuable tools for anthropometric analysis, depending on the application. An extensive number of sources for such tools and data are discussed in the human factors literature.

7.2 Psychological elements

It is crucial to consider human proficiency in perception, cognition, learning, memory, and judgment when designing medical devices to assure that operation of the system is as intuitive, effective, and safe as possible. Much of the information available on the capabilities and limitations of the human mind is not only highly technical, but also difficult to find. One resource (see Boff and Lincoln, 1988) is aimed at the application of basic research findings in human performance to system design, presenting this technical information in a way that will aid its accessibility, interpretability, and applicability by system designers. While this compendium does not extend to all topics of value and cannot replace the participation of qualified human factors experts, it will broaden designers' understanding of psychological considerations.

7.3 Workstation design considerations

Successful workstation design is dependent on considering the nature of the tasks to be completed, the preferred posture(s) of the operator, and the dynamics of the surrounding environment. The design of the workstation needs to take into account the adjustability of the furniture, clearances under work surfaces, keyboard and display support surfaces, seating, footrests, and accessories (input devices, document holders, task lights).

7.4 Consoles

The effectiveness with which operators perform their tasks at consoles or instrument panels depends in part on how well the equipment is designed to minimize parallax in viewing displays, allow ready manipulation of controls, and provide adequate space and support for the operator. Although no single console or instrument panel configuration is suitable for all applications, certain configurations are more effective than others. Figures 1 and 2 (pages 9 and 10) and figures 7 through 11 (pages 31–35), which are based on anthropometric data for individuals sitting or standing with erect posture, provide dimensional and other design criteria for various types of consoles. The following sections describe factors that should be considered in the design of console configurations.

7.4.1 Kick space

All cabinets, consoles, and work surfaces requiring the operator to stand or sit close to the front surfaces should contain a kick space at the base (see figure 7, page 31).

7.4.2 Work space

Free floor space, measuring at least 1.2 m (4 feet), should be available in front of each console for accessibility during maintenance (see MIL-STD-1472D).

7.4.3 Storage space

An adequate and suitable storage area on the console or in the immediate work space should be provided for storing materials or accessories used by operators or maintenance personnel.

7.4.4 Panel slope

For normal console operation, the slope of the control-display panel surface should begin at the level of the console work surface.

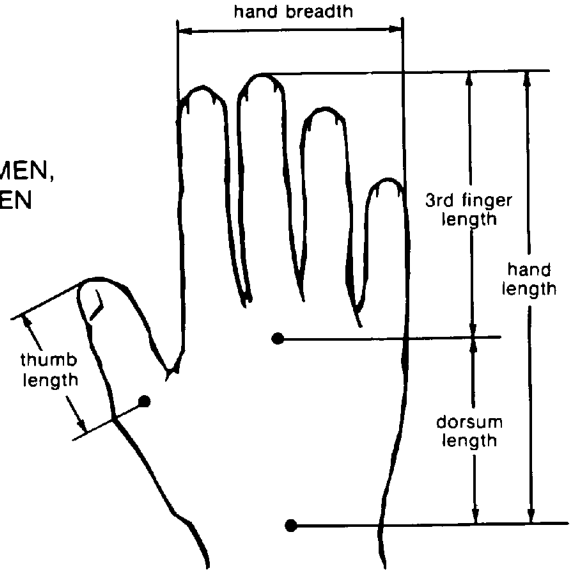
7.4.5 Dimensions

Allowance should be made for the possibility that a significant number of operators may be less than 152 cm (5 feet) tall.

7.4.6 Work surfaces

A horizontal, or nearly horizontal, work surface is recommended, as shown in figures 7 through 10 (pages 31–34). This surface serves primarily as a work or writing surface or as a support for the operator's convenience items, but certain types of controls, such as "joysticks" or tracking controls, can also be part of the surface design. When combining a horizontal work space and a control panel, care should be taken to ensure that operators will have adequate work space—a minimum of 25.0 cm (10 inches) deep, yet still be able to reach the control panel—a maximum of 40.5 cm (16 inches) deep.

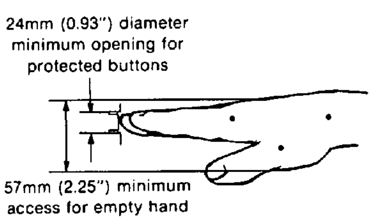
HAND DATA: MEN, WOMEN, & CHILDREN



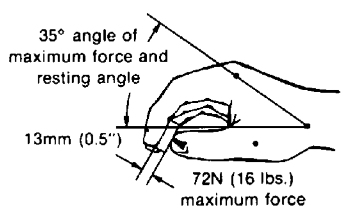
HAND DATA	MEN			WOMEN			CHILDREN			
	2.5% tile	50.% tile	97.5% tile	2.5% tile	50.% tile	97.5% tile	6 yr.	8 yr.	11 yr.	14 yr.
hand length	173mm (6.8")	191mm (7.5")	208mm (8.2")	157mm (6.2")	175mm (6.9")	191mm (7.5")	130mm (5.1")	142mm (5.6")	160mm (6.3")	178mm (7.0")
hand breadth	81mm (3.2")	89mm (3.5")	97mm (3.8")	66mm (2.6")	74mm (2.9")	79mm (3.1")	58mm (2.3")	64mm (2.5")	71mm (2.8")	—
3rd finger lg.	102mm (4.0")	114mm (4.5")	127mm (5.0")	91mm (3.6")	100mm (4.0")	112mm (4.4")	74mm (2.9")	81mm (3.2")	89mm (3.5")	102mm (4.0")
dorsum lg.	71mm (2.8")	75mm (3.0")	81mm (3.2")	66mm (2.6")	74mm (2.9")	79mm (3.1")	56mm (2.2")	61mm (2.4")	71mm (2.8")	75mm (3.0")
thumb length	61mm (2.4")	69mm (2.7")	75mm (3.0")	56mm (2.2")	61mm (2.4")	66mm (2.6")	46mm (1.8")	51mm (2.0")	56mm (2.2")	61mm (2.4")

ADDITIONAL DATA: AVERAGE MAN

ACCESS



FINGER GRIP



HAND GRASP

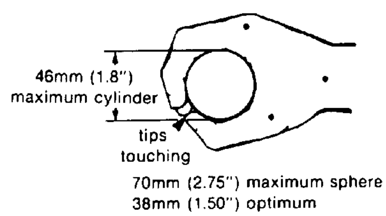


Figure 6—Hand dimensions

(Adapted form Dreyfuss, 1967)

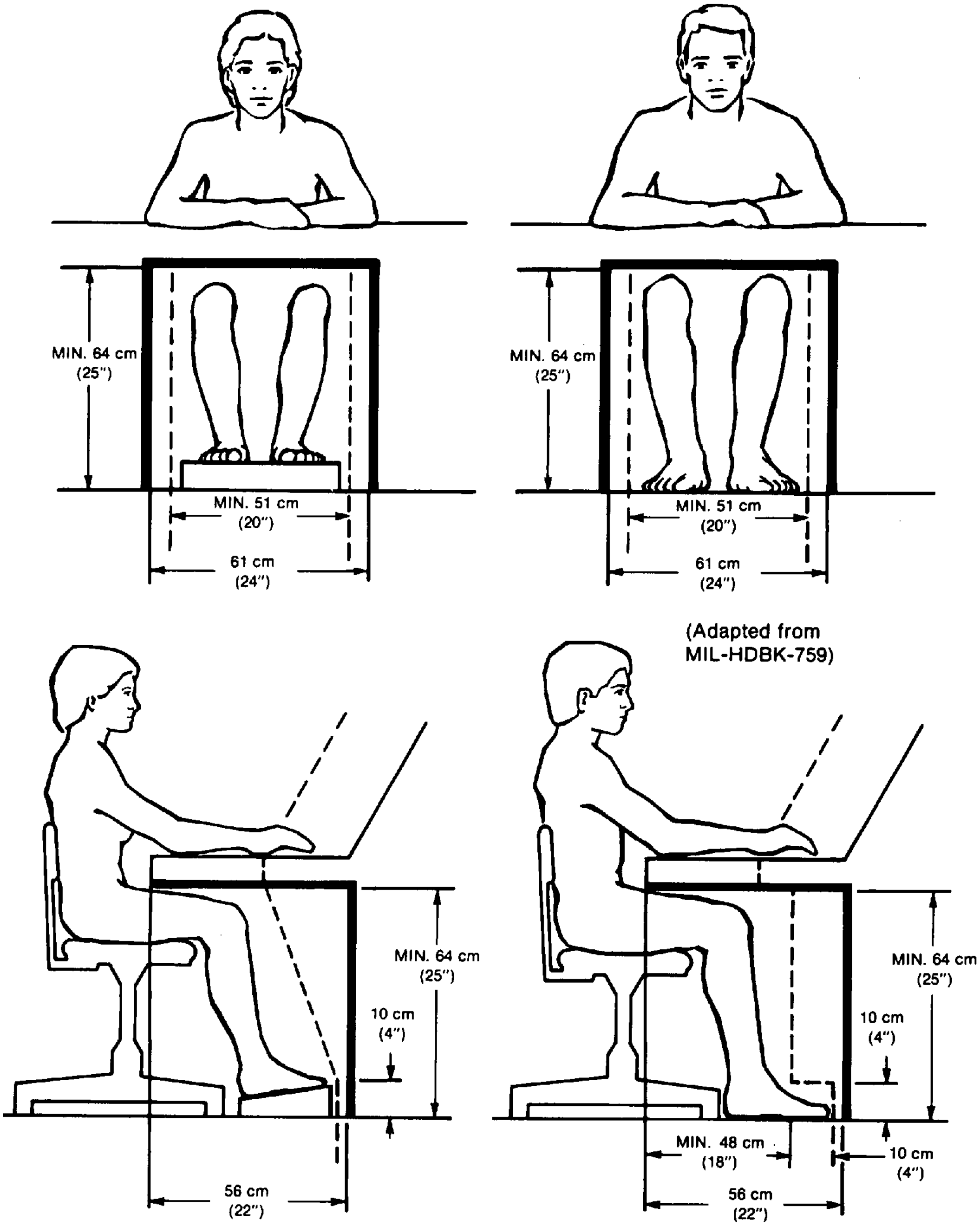


Figure 7—Console leg room dimensions: seated operator

(Adapted from MIL-HDBK-759)

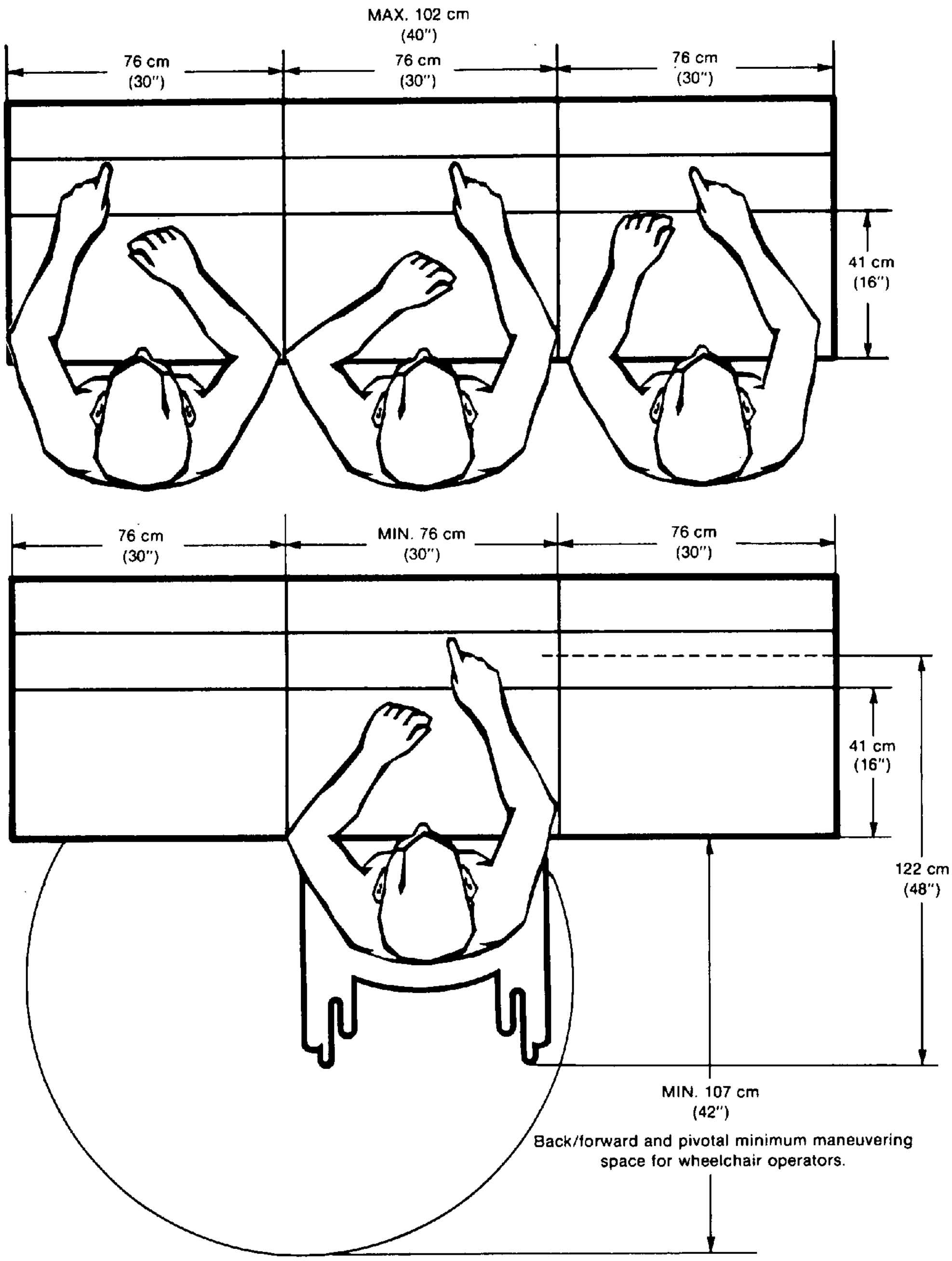


Figure 8—Console dimensions: seated operators

(Adapted from ANSI A 117.1-1986)

NOTE—Operators in wheelchairs will require greater width and clearance.

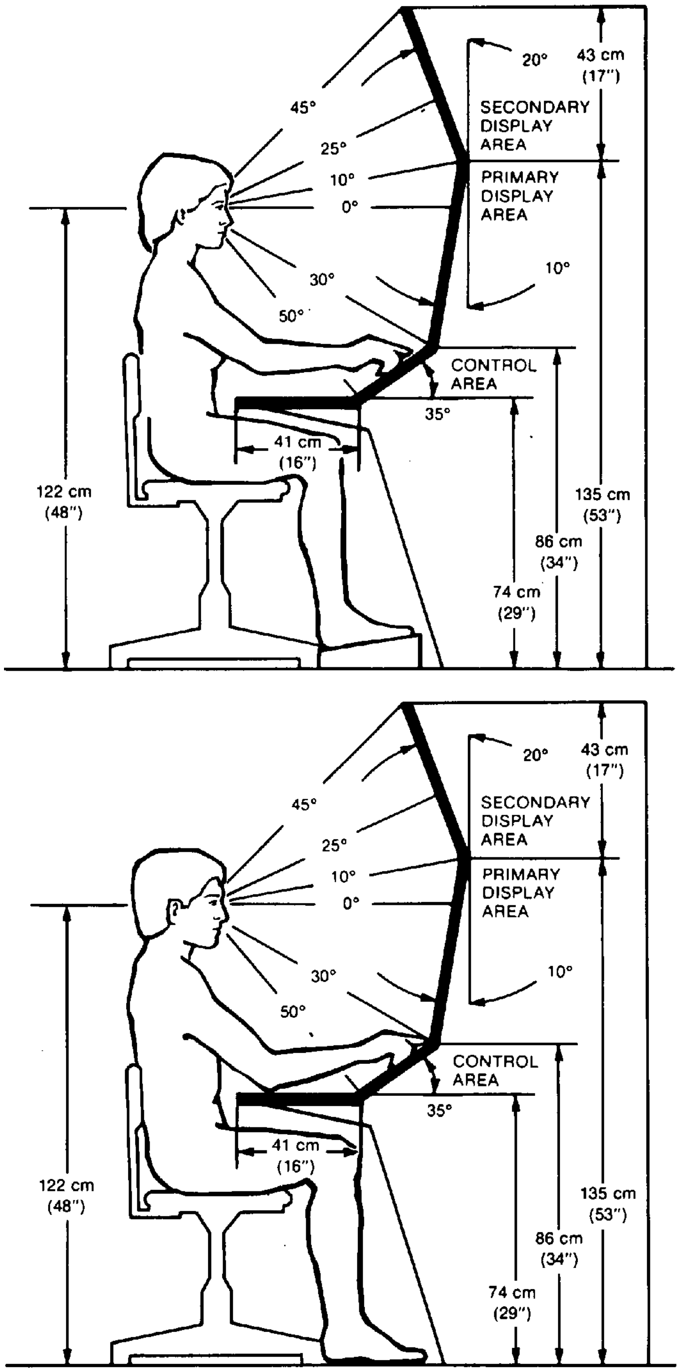


Figure 9—Console dimensions with compound panel: seated operator

(Adapted from MIL-HDBK-759)

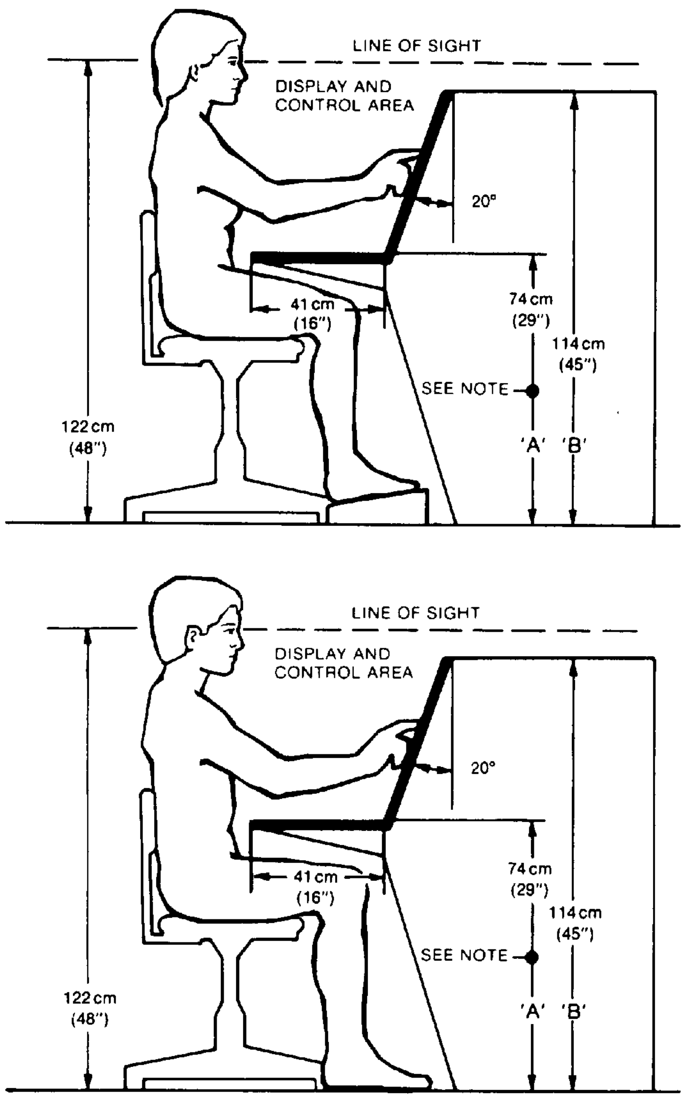
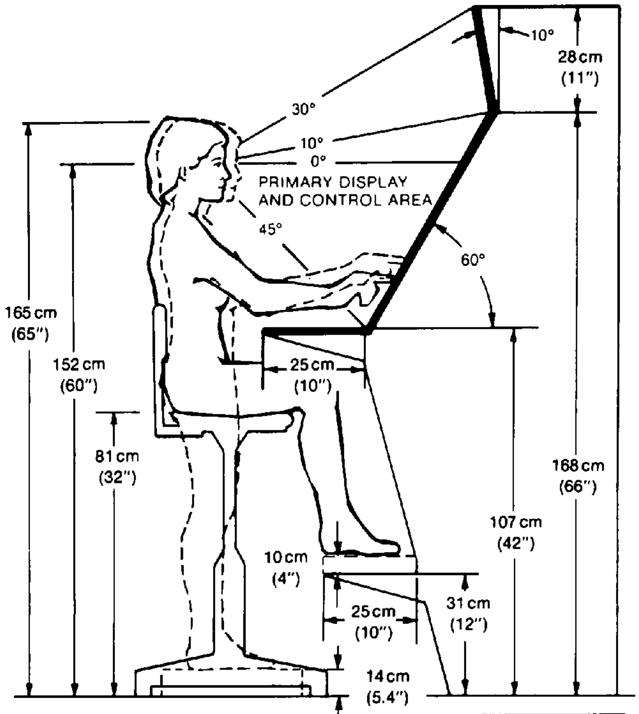


Figure 10—Console dimensions with simple panel: seated operator

(Adapted from MIL-HDBK-759)

NOTE—Increase dimension 'A' to 107 cm (42") and 'B' to 147 cm (58") for standing operation with lookover requirement to maintain the same relationships.



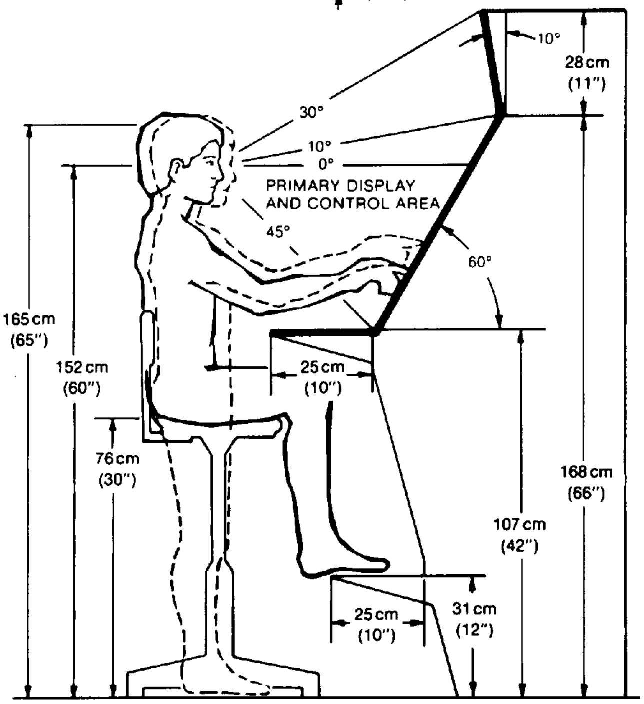


Figure 11—Console dimensions: sit-stand operator

(Adapted from MIL-HDBK-759)

7.4.7 Control and display features

The recommendations of sections 9 and 10 on design and location of controls and displays also apply to console applications.

7.4.8 Visual Display Terminals (VDTs)

Where a VDT is used for text processing, data entry, and data inquiry applications, the VDT, associated furniture, and environments in which the VDT is placed should conform to ANSI/HFS-100; however, where such criteria are not specified by ANSI/ HFS-100, the VDT, associated furniture, and environments should conform to applicable provisions herein.

8 Signs, symbols, and markings

8.1 Markings

Controls, displays, and other equipment items that need to be located, identified, or manipulated should be appropriately and clearly marked to permit rapid and accurate human performance.

NOTE—These recommendations are not all-inclusive. Device markings and other labeling must comply with the Fair Packaging and Labeling Act (enacted 3 November 1966), with the Medical Device Amendments of 1976 (enacted 28 May 1976), and with applicable regulations of the U. S. Food and Drug Administration. For further guidance on the format and content of medical device labeling, reference may also be made to individual device standards.

8.1.1 General characteristics

The characteristics of markings should be determined by such factors as the criticality of the function labeled, the distance from which the labels have to be read, the illumination level, the colors, the time available for reading, the reading accuracy required, and consistency with other markings.

8.1.1.1 Device identification

Device identification markings should, at a minimum, provide the name or trade name of the manufacturer, a distinctive catalog or model number, and the electrical rating. This information should be readily accessible but should not interfere with use of the device.

8.1.1.2 Legend switches

The legend should be legible without internal illumination; the maximum lettering should be three lines of lettering on the legend plate.

8.1.1.3 Electrical receptacles and connectors

Receptacles and connectors should be marked with their intended function or connecting cable. Convenience receptacles should be labeled with maximum allowable load in amperes or watts (refer to appropriate International Electrotechnical Commission, Underwriters Laboratories and Canadian Standards Association standards for specific requirements).

8.1.1.4 Fuses and circuit breakers

The current rating of fuses should be permanently marked adjacent to the fuse holder. "SPARE" should be marked adjacent to each spare fuse holder. Fuse ratings should be indicated either in whole number, common fractions, or whole number plus common fractions. Labeling of fuses and circuit breakers should be legible in the ambient illumination range anticipated for the maintainer's location.

8.1.1.5 Hazard warnings

Operators and maintenance personnel should be warned of possible fire, radiation, explosion, shock, infection or other hazards that may be encountered during the use, handling, storage, or repair of the device.

Electromedical instruments should be labeled to show whether they may be used in the presence of flammable gases or oxygen-rich atmospheres (see ANSI Z535.3, 1991 and ANSI Z535.1, 1991). Hazard warnings should be prominent and understandable.

8.1.1.6 Hierarchical scheme

Use of some medical devices may require large arrays of controls and displays. The layout of those controls and displays should be consistent with guidelines in 6.5, Console and panel layout. To further reduce confusion, search time, and redundancy in such cases, a hierarchical labeling scheme should also be used (see figure 12, next page). Even further reductions of confusion and search time can be achieved by combining a hierarchical labeling scheme with guidelines in 8.2.

8.1.1.6.1 Ranking

In a hierarchical labeling scheme, major labels should be used to identify major systems or operator workstations. Subordinate labels should be used to identify subsystems or functional groups. Component labels should be used to identify each discrete panel or console element. Labels should not repeat information contained in higher-level labels.

8.1.1.6.2 Letter graduations

In a hierarchical labeling scheme, labels should be graduated in letter size such that

a) system/workstation labels are about 25 percent larger than subsystem/functional group labels;

b) subsystem/functional group labels are about 25 percent larger than component labels;

c) component labels are about 25 percent larger than control movement information/ position identifiers.

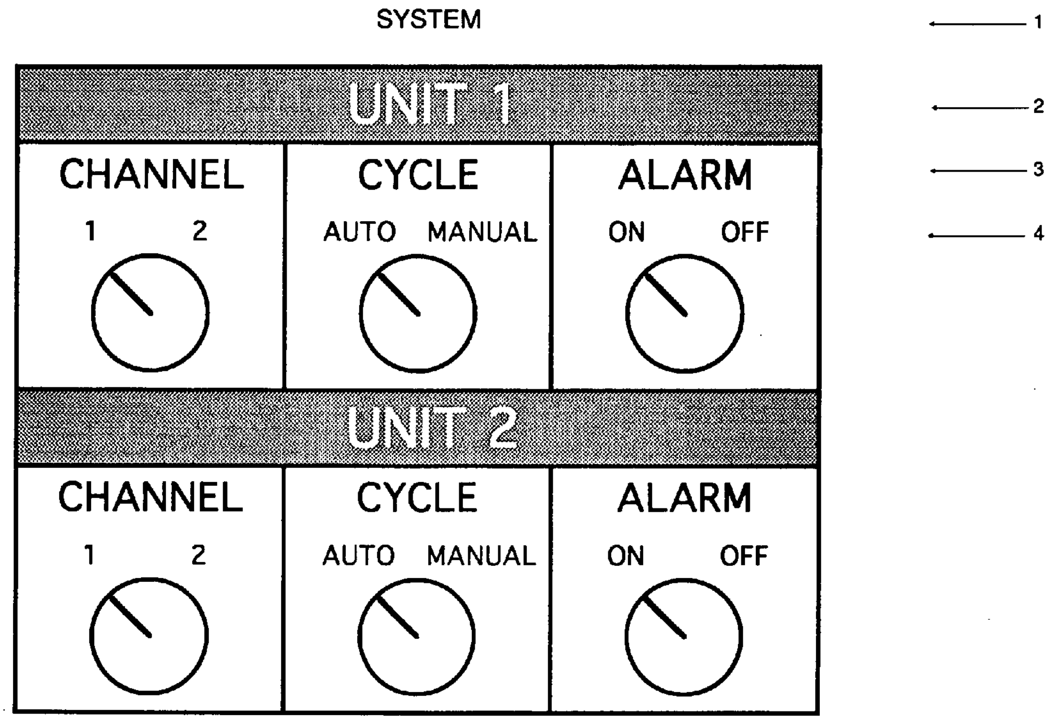
8.1.2 Location

8.1.2.1 Panel labeling

The placement of labels on control panels should follow a hierarchical scheme. An example of such a scheme is shown in figure 12.

8.1.2.2 Normal placement

Normally, labels should be placed above panel elements that users grasp, press or otherwise handle so the label is not obscured by the hand. However, certain panel element positions, user postures, and handling methods may dictate other label placements. Therefore, candidate label positions should be assessed to assure users can see the label while using the associated panel element.



Label Designation	Location
1. System/workstation	Centered near top edge of panel
2. Subsystem/functional group	Centered near top of subsection
3. Component labels	Above component display or control
4. Control position identifiers	Near control

Figure 12—Example of a hierarchical labelling scheme

8.1.2.3 Proximity

Labels should be placed close to the panel element.

8.1.2.4 Adjacent labels

Adjacent labels should be separated by sufficient space so that they are not read as one continuous label.

8.1.2.5 Visibility and readability enhancement

Labels should be positioned to ensure visibility and readability from the position in which they should be read. (Labels for elements located above or below eye level should not be exempt from this guideline.)

8.1.2.6 Functional descriptions

Functional descriptions should be located outside the primary display area.

8.1.2.7 Nonfunctional markings

The positioning of nonfunctional markings (e.g., manufacturer identification or decoration) should not obstruct the goal of clear information presentation.

8.1.2.8 Labels on controls

Labels should not appear on the control itself when an adjustment or manipulation is required that causes the operator's hand to obscure the label during usage.

8.1.3 Mounting

Labels should be mounted in such a way as to preclude accidental removal. Labels should be mounted on a flat surface.

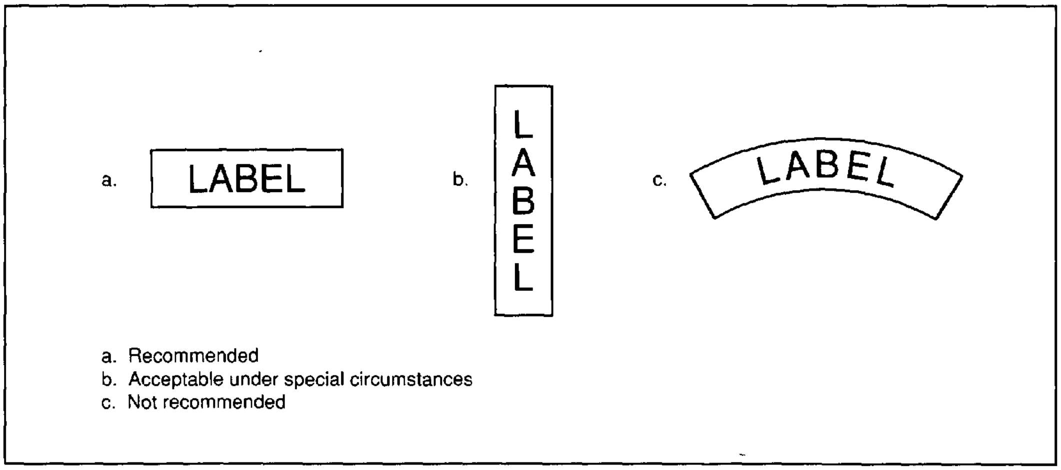


Figure 13—Example label orientations

8.1.4 Spatial orientation

Labels should be oriented horizontally so that they may be read quickly and easily from left to right. Although not normally recommended, vertical orientation may be used but only where its use is justified in providing a better understanding of intended function. Vertical labels should be read from top to bottom. Curved labels should be avoided, except when they provide setting delimiters for rotary controls (see figure 13). Improperly oriented labels can lead to confusion and cause delays in locating and identifying important controls and/or displays.

8.1.5 Visibility

Labels should not cover any other information source. They should not detract from or obscure figures or scales that should be read by the operator. Labels should not be covered or obscured by other units in the equipment assembly. Labels should be visible to the operator during control activation. Labels for elements located above or below eye level should be positioned to ensure their visibility.

8.1.5.1 Durability

All markings should be permanent and should remain legible throughout the life of the equipment under anticipated use and maintenance conditions. Decals, paper labels, and pressure-sensitive labels normally do not provide the degree of permanence needed for most applications.

8.1.6 Content

Labels should describe the function of equipment items. If needed for clarity, engineering characteristics or nomenclature may also be described.

8.1.6.1 Word selection

The words employed in the label should express exactly what action is intended. Instructions should be clear and direct. Words that have a commonly accepted meaning for all intended users should be utilized. Unusual technical terms should be avoided. Words and symbols should be chosen on the basis of operator familiarity provided that the words express the meaning intended.

8.1.6.2 Consistency

Labels should be consistent within and across pieces of equipment in their use of words, acronyms, abbreviations, and part/system numbers. No mismatch should exist between the nomenclature used in documentation and that printed on the labels.

8.1.6.3 Symbols

Symbols should be used only if they have a commonly accepted meaning for all intended users (e.g., %). Symbols should be unique and distinguishable from one another. A commonly accepted standard configuration should be used.

Symbols should be used consistently within and across panels. Use of Roman numerals should be avoided.

8.1.6.4 Brevity

Wording on labels should be brief while still conveying the intended meaning. However, brevity should not be stressed if the results will be unfamiliar to the user.

8.1.6.5 Similarity

Words and abbreviations of similar appearance should be avoided where an error in interpretation could result. When labels containing similar words, abbreviations, or acronyms are located in close proximity to each other, different words should be used to reduce the probability of selecting the wrong display or control.

8.1.6.6 Functional groups

Labels should be used to identify functionally grouped controls and displays. Labels should be located above the functional groups they identify.

8.1.6.7 Control position labeling

All discrete functional control positions should be identified. Direction of motion (increase, decrease) should be identified for continuous-motion rotary controls. Control position information should be visible to the operator during operation of the control.

8.1.6.8 Access opening labels

Access openings should be labeled to identify the function of items accessible through them.

8.1.6.9 Danger, warning, and safety instruction labeling

Any hazard warnings should be prominent and understandable. All danger, warning, and safety instruction labels should be in accordance with appropriate safety standards.

8.1.7 Lettering

The speed and accuracy of human performance in identifying controls and displays are influenced by the size and style of characters used for label lettering.

8.1.7.1 Character height

Height of characters for labels and other markings depends on viewing distance and luminance level. At a viewing distance of 710 mm (28 inches), the height of letters and numerals should be within the range of values given in table 5. For a distance (D) other than 710 mm (28 inches), multiply the values in table 5 by D/710 mm (D/28 inches) to obtain the appropriate character height.

8.1.7.2 Contrast

To ensure adequate contrast and to prevent loss of readability from accumulated dirt, dark characters should be provided on a light background. Colored print may be used for coding purposes under white light or where compatible with anticipated illumination characteristics; and it should conform to the established color coding scheme for the device or the environment in which the device is intended to be used. Colors should be chosen for maximum contrast against the label background. Table 6 (see next page) rates various color combinations in terms of relative legibility.

8.1.7.3 Legibility test criteria

Alphanumeric character legibility should be assessed under worst case viewing conditions (i.e., minimum contrast color combinations, maximum intended viewing distance and angle, worst case lighting, and minimum exposure time). The following test criteria, originally developed for military applications, may be considered strict and best suited for evaluating the characters used in critical information displays.

Accuracy of responses: 98 percent or more of the total identifications should be correct.

Distribution of responses: Confusions involving a single pair of symbols (e.g., B and 8) cannot exceed 20 percent of the permissible error.

Speed of response: Alphanumerics should be identified with a speed of 50 correct identifications per minute or better.

Additional useful information may be found in Shurtleff, DA., 1980.

Table 5—Character height versus luminance

Labels and markings	**Character height**	
	3.5 cd/m^2 (1 foot. - L) or below	**above 3.5 cd/m 2 (1 foot. - L)**
For critical markings, with position variable (e.g., numerals on counters and settable or moving scales)	5 - 8 mm (0.20 - 0.31 inch)	3 - 5 mm (0.12 - 0.20 inch)
For critical markings, with position fixed (e.g., numerals on fixed scales, controls, and switch markings or emergency instructions)	4 - 8 mm (0.16 - 0.31 inch)	2.5 - 5 mm (0.10 - 0.20 inch)
For noncritical markings (e.g., identification labels, routine instructions, or markings required only for familiarization)	1.3 - 5 mm (0.05 - 0.20 inch)	1.3 - 5 mm (0.05 - 0.20 inch)

(Adapted from MIL-STD-1472D)

Table 6—Relative legibility of color combinations under white light

Legibility rating	Color combination
Very good	Black letters on white background
Good	Black on yellow Dark blue on white Dark green on white
Fair	Red on white Red on yellow White on black
Poor	Green on red Red on green Orange on black Orange on white

(Adapted from Woodson and Conover, 1964)

8.2 Location aids

Location aids such as demarcation, color coding, mimics, and flashing lights may be used to enhance operator performance. Several location aid techniques may be used where appropriate.

8.2.1 Demarcation and background shading

To improve the user's ability to correlate related elements, demarcation or background shading techniques (e.g., enclosing related controls and displays within contrasting lines or shaded areas on the console or panel) may be used (see figure 12, page 37 for an example of demarcation techniques integrated with hierarchical labeling).

8.2.1.1 Use

Demarcation or shading can be used to enclose functionally related displays, to enclose functionally related controls, and to group related controls and displays (see figure 3, page 13).

8.2.1.2 Contrast

Demarcation lines and background shading should be visually distinctive from the panel or display background.

8.2.1.3 Permanence

Materials used for demarcation or shading should be permanently attached.

8.2.1.4 Durability

Materials used for demarcation lines and background shading should remain visually distinctive from the panel background throughout the life of the equipment under anticipated use and maintenance conditions. Decals and drafting transfers normally do not provide the degree of permanence needed for most applications.

8.2.2 Mimics (Metaphors)

Mimics (also known as metaphors) integrate the displays and controls of process control systems into graphic or pictorial representations of those systems in a way that reflects functional and/or spatial relationships. Properly designed mimics should enhance the ability to find critical displays and controls and should reduce the potential for human error.

8.2.2.1 Flow lines

Differential line widths may be used to code flow paths (e.g., significance, volume, level). Overlapping of flow lines should be avoided. Flow directions should be clearly indicated by distinctive arrowheads. All origin points should be labeled or flow lines should begin at labeled components. All destination or terminal points should be labeled or flow lines should end at labeled components. Component representations on flow lines should be identified.

8.2.2.2 Color

Flow paths should follow the basic principles outlined in 8.3.2. Mimic colors should be discriminably different from each other. The contrast between the colors and the panel or display background should be adequate. Lines depicting flow of the same contents (e.g., blood, oxygen) should be colored the same throughout the system. No more than four lines of the same color should run parallel to one another if the operator needs to quickly identify any one of the lines.

8.2.2.3 Symbols

Graphic symbols should be readily understood and commonly used. Symbols for equipment integrated into flow paths (e.g., pumps, filters, valves, gain controls) should be used consistently.

8.2.2.3.1 Symbol comprehension

The effectiveness of symbols intended to convey critical information, such as a symbol for a silenced alarm, should be validated through user testing. Tests of less critical symbols may also be warranted to avoid confusions. Testing procedures are defined in ANSI Standard Z535.3, 1991. According to one recommended procedure, a 50-person sample of potential users is shown the candidate symbol, devoid of labeling, and asked to define its meaning. These definitions are judged as correct, incorrect, or indicative of a critical confusion that may be hazardous. The ANSI criterion for symbol acceptance is 85 percent correct responses and no more than 5 percent critical confusions.

8.3 Coding

Device elements may be coded using various sensory stimuli to represent specific information. Coding refers to the use of a system of symbols, shapes, colors, or other variable coding characteristics that are readily identifiable attributes commonly associated with a symbol by means of which such symbols are differentiated (e.g., size, shape, color, location, texture).

8.3.1 General

Coding techniques should be used to help discriminate among individual device elements and to identify functionally related individual elements and critical elements within the device. For example, coding on the face of scale indicators may be used to convey such information as desirable operating range, dangerous operating level, caution, undesirable conditions or inefficient conditions.

8.3.2 Color coding

Color coding should be used cautiously to enhance the transfer of information to the user. The use of colors expected to elicit a specific operator response should be consistent throughout a device and a facility.

8.3.2.1 Redundancy

In all applications of color coding, color should provide redundant information; i.e., the pertinent information should be available from some other cue in addition to color.

8.3.2.2 Number of colors

The number of colors used for coding should be kept to the minimum needed for providing sufficient information (i.e., 2 or 3 colors is much better than 8 or 9 colors).

8.3.2.3 Meaning of colors

Red is used for "warning"-level alarms and its use for other conditions should be minimized. By convention, however, red may be used to mean "stop" or "off," or it may be used to color code a waveform, such as an arterial pressure waveform (see table 7).

Yellow is used for "caution"-level alarms and for "advisory" messages and its use for other conditions should be minimized. By convention, however, yellow may be used to color code a waveform, such as a pulmonary artery waveform.

8.3.2.4 Consistency of meaning

The meaning of a particular color should remain the same across all applications (e.g., whether applied to panel surfaces or projected in signal lights or on CRTs) within and across devices.

8.3.2.5 Contrast among colors used for coding

Colors selected for use in coding should be recognizably different from any other. Table 8 (see next page) lists 22 colors of maximum contrast. Each successive color has been selected to contrast maximally with the color just preceding it and satisfactorily with colors earlier in the list. The first nine colors have been selected to yield satisfactory contrast for red-green-deficient observers as well as color-normal observers. The remaining 13 colors are useful only for color-normal observers.

Table 7—Suggested uses of color coding for medical devices

Color	Meaning
Red	• High priority level (warning) alarm • Emergency • Stop • Off • May be coded to physiological variables, (e.g., arterial blood pressure) • May be coded to other standards such as anesthetic agent colors (e.g., red for halothane)
Yellow	• Medium priority level (caution) alarm (flashing yellow) • Low priority level (advisory) alarm (steady yellow) • Potential hazard • May be coded to physiological variables • May be coded to other standards such as compressed gas cylinders (e.g., yellow for air in the United States)
Green	• Start • On • Normal or ready • May be coded to physiological variables • May be coded to other standards such as compressed gas cylinders (e.g., green for oxygen in the United States)
Other Colors	• Any meaning except the above • May be coded to physiological variables, (e.g., blue for central venous pressure) • May be coded to other standards such as anesthetic agent colors and compressed gas cylinders
NOTE—In some applications, specific standards may dictate other color coding requirements. For example, by convention, some devices use red to indicate ON and green to indicate OFF.	

8.3.2.6 Contrast with backgrounds

Colors selected for coding should contrast well with the background on which the coding appears.

8.3.2.7 Impact of ambient lighting

Ambient lighting in the area in which color coding is used will influence the apparent color of the coded element (especially for surface colors). Each color selected for coding should be evaluated under all illumination conditions under which the coding will be used.

Table 8—Twenty-two colors of maximum contrast

Color serial or selection number	General color name	ISCC-NBS centroid number	ISCC-NBS color-name (abbreviation)	Munsell renotation of ISCC-NBS centroid color
1	white	263	white	2.5 PB 9.5/0.2
2	black	267	black	N 0.8/
3	yellow	82	v.Y	3.3 Y 8.0/14.3
4	purple	218	s.P	6.5 P 4.3/9.2
5	orange	48	v.O	4.1 YR 6.5/15.0
6	light blue	180	v.I.B.	2.7 PB 7.9/6.0
7	red	11	v.R	5.0 R 3.9/15.4
8	buff	90	gy.Y	4.4 Y 7.2/3.8
9	gray	265	med.Gy	3.3 GY 5.4/0.1
10	green	139	v.G	3.2 G 4.9/11.1
11	purplish pink	247	s.pPk	5.6 RP 6.8/9.0
12	blue	178	s.B	2.9 PB 4.1/10.4
13	yellowish pink	26	s.yPk	8.4 R 7.0/9.5
14	violet	207	s.V	0.2 P 3.7/10.1
15	orange yellow	66	v.OY	8.6 YR 7.3/15.2
16	purplish red	256	s.pR	7.3 RP 4.4/11.4
17	greenish yellow	97	v.gY	9.1 Y 8.2/12.0
18	reddish brown	40	s.rBr	0.3 YR 3.1/9.9
19	yellow green	115	v.YG	5.4 GY 6.8/11.2
20	yellowish brown	75	deep yBr	8.8 YR 3.1/5.0
21	reddish orange	34	v.rO	9.8 R 5.4/14.5
22	olive green	126	d.OIG	8.0 BY 2.2/3.6

NOTE—Each color in the list will maximally contrast with those colors listed above and below it (Kelly, 1965).

8.3.3 Size coding

Size coding generally applies to controls and connectors. If size coding is used, discrimination between device elements will be optimized if no more than three different sizes are employed. Similar device elements or elements used for similar functions should be the same size. In general, size discrimination will be unreliable if the size differences do not exceed 1.25 cm (1/2 inch).

8.3.4 Location coding

Location coding may be used to relate device elements according to functional groups. Especially for critical device elements, location should be the same from subsystem to subsystem and from device to device.

8.3.5 Shape coding

Device elements that may be manipulated in a "blind" fashion should be shape coded. Shapes should be visually as well as tactilely identifiable.

9 Controls

In general, controls are of two types: displacement and nondisplacement. Examples of displacement-type controls are rotary knobs, pedals, rotary selector switches, pushbuttons, and toggle switches. Nondisplacement-type controls are exemplified by thermosensitive, capacitive, and force-sensitive devices. Design of controls should allow for the fact that personnel often wear gloves for personal protection. Thermosensitive capacitors and some other controls may not operate correctly when their operator wears gloves.

9.1 Selection

Controls should have characteristics appropriate for their intended functions, environments, and user orientations, and their movements should be consistent with the movements of any related displays or equipment components (see 6.5.5.8.1). Table 9 (see pages 44–45) summarizes selection criteria.

9.2 Shape

The shape of a control should be dictated by its specific functional requirements. In a bank of controls, those controls affecting critical or life-supporting functions should have a special shape and if possible, a standard location. For example, in the United States, the fluted oxygen-flow control knob on anesthesia gas machines is distinguishable by touch from the control knobs for nitrous oxide and other gases (ASTM F1161, 1988).

9.3 Size

The size of a control should be compatible with the human hand and should ensure ease of use. Section 9.7 provides specific design criteria. Some operational situations will require control sizes that do not conform to these dimensional recommendations.

9.4 Feedback

Feedback on control response adequacy should be provided as rapidly as possible. Critical control functions, such as those entered by keyboard, should provide adequate feedback to the operator prior to system acceptance to ensure that the keyed entry is, in fact, errorless and the one that the operator wishes to enter. For feedback and the user-computer interface, see 12.1.2 and 12.6.

9.5 Prevention of accidental activation

Controls should be designed and located to avoid accidental activation. Particular attention should be given to critical controls whose accidental activation might injure patients or personnel or might compromise device performance. One or more of the following methods of preventing accidental control activation should be considered:

a) Locate and orient the controls so that the operator is not likely to strike or move them accidentally in the normal sequence of control movements.

b) Recess, shield, or otherwise surround the controls with physical barriers. The control should be entirely contained within the space created by the recess or barrier (e.g., the "discharge" button on some defibrillators and the "O_2 flush" on anesthesia gas machines).

c) Cover or guard the controls. Neither locks nor safety or lock wire should be used.

d) Provide the controls with interlocks so that an extra manipulation or the prior operation of a related or locking control is needed to activate them. (This approach has been suggested for the "inject" control of angiographic injectors.)

e) Provide the controls with resistance (e.g., viscous or coulomb friction or spring-loading) so that definite or sustained effort is required for activation.

f) When strict sequential activation is needed, include a lock to prevent the control from passing through a position without a delay.

g) Provide detents intermittent static friction resistance corresponding to discrete control settings.

h) Provide a pushbutton with an activation feature that requires (holding) the pushbutton in its depressed position for 2 to 5 seconds before activation occurs.

9.6 "Dead man" controls

"Dead man" controls are controls that, when force is removed, reduce the device to a noncritical operating state. "Dead man" controls should be used whenever incapacitation of the operator could cause a critical condition.

9.7 Specific control designs

9.7.1 Rotary selector switches

Design criteria for rotary selector switches are provided in figure 14 (see page 46).

9.7.1.1 Application

Rotary selector switches are recommended for discrete functions when three or more positions that need a detent are required.

9.7.1.2 Moving pointer, fixed scale

A movable pointer with a fixed scale is preferred over a moving scale with a fixed index that is not readable during rapid motion.

9.7.1.3 Positions

Rotary switch positions should not be placed directly opposite each other if confusion could result concerning which end of a double-bar control knob is the pointer.

9.7.1.4 Stops

Stops should be provided at the beginning and end of the range of control positions if switch operation is not required beyond the end positions or specified limits.

9.7.1.5 Resistance

Switch resistance should be elastic—building up, then decreasing, as each position is approached so that the control snaps into position without stopping between adjacent positions.

List of Titles

Table 9—Control selection criteria

Function	Control									
	Toggle switch	Push-button	Bar knob	Round knob	Thumb-wheel (discrete)	Thumb-wheel (cont.)	Crank	Rocker switch	Lever	Joystick/ ball
Select system power state ON-OFF	1	1	3					1	1#	
3-State (OFF-STBY-ON)	1		1							
Select between OFF/Prime Mode/ Secondary Mode(s)	3	2	1						1	
Select one or more of N-related functions	2	1					2			
Select one of N mutually exclusive functions—any order		1								
Select one of 3-24 discrete alterna-tives—sequential order			1							
Select digit—discrete		1 KEYBD	2##		2##					
Set value on—continuous scale				1		2	3		3	
Set value on—discrete steps		1	1		1					
Select operating condition	1	1	2					1	1	
Enter alphanumeric data		1 KEYBD								
Initiate test subfunc-tion (momentary)	1	1	3					1		
Initiate directional function	1	2 Multiple	3			3		1	1 Multiple	
Generate stepping impulse (momentary hold)	1	1								
Slew counters or other numeric readout	1	1		1 Rate Control			1 Manual Only			
Reset mechanical counter, manual				1	3	1				
Interrupt countdown sequence—"hold"	2	1						2		
Engage—disengage mechanical function									1	
Adjust light level continued				1		1			3	
Adjust sound level continued				1		1			3	
Coarse adjustment				1 Small Diam.		2	2 Few Turns		2 Short Throw	
Fine adjustment				1		2	2		3	

	Large Diam.	Large Motion	Many Turns	Long Throw
Adjust to null position	1	2	3	3
Single-coordinate tracking	3		2	1
Two-coordinate tracking			3	1

(1 = Most preferred, 3 = Least preferred) # Lever for heavy duty power circuits ## Only if sequential selection is acceptable
(Adapted from Addendum to Final Report, U.S. Army Missile Command Report RS-CR-80-2

9.7.1.6 Knob style

Pointer, single-bar, and double-bar knob styles are desirable for discrete adjustment, rotary selector switches.

9.7.1.7 Reference line

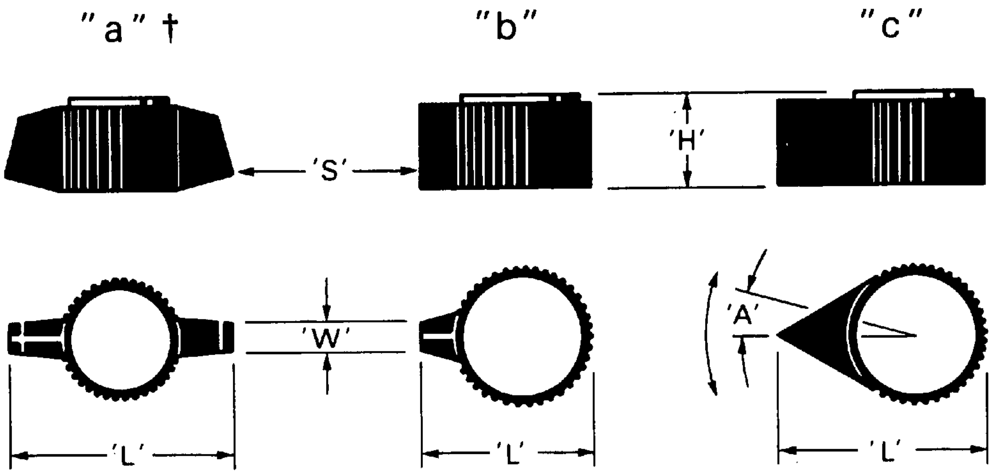
The reference line on rotary switch control knobs should contrast sufficiently with the knob body to ensure legibility under anticipated lighting conditions.

9.7.1.8 Parallax

Rotary switch control knobs should be mounted close enough to their scales to minimize the parallax between the part of the bar or pointer farthest from the scale and the scale markings. When viewed from the operator's normal position, the parallax error should not exceed 25 percent of the distance between scale markings.

9.7.2 Thumbwheel controls

Design criteria for thumbwheels are given in figure 15 (see page 47).



	DIMENSIONS				
	'L' Length			'W' Width	'H' Depth
	"a"	"b"	"c"		
Minimum	25mm (1.0")	16mm (.625")	16mm (.625")	—	13mm (.50")
Maximum	75mm (3.0")	50mm (2.0")	50mm (2.0")	25mm (1.0")	75mm (3.0")

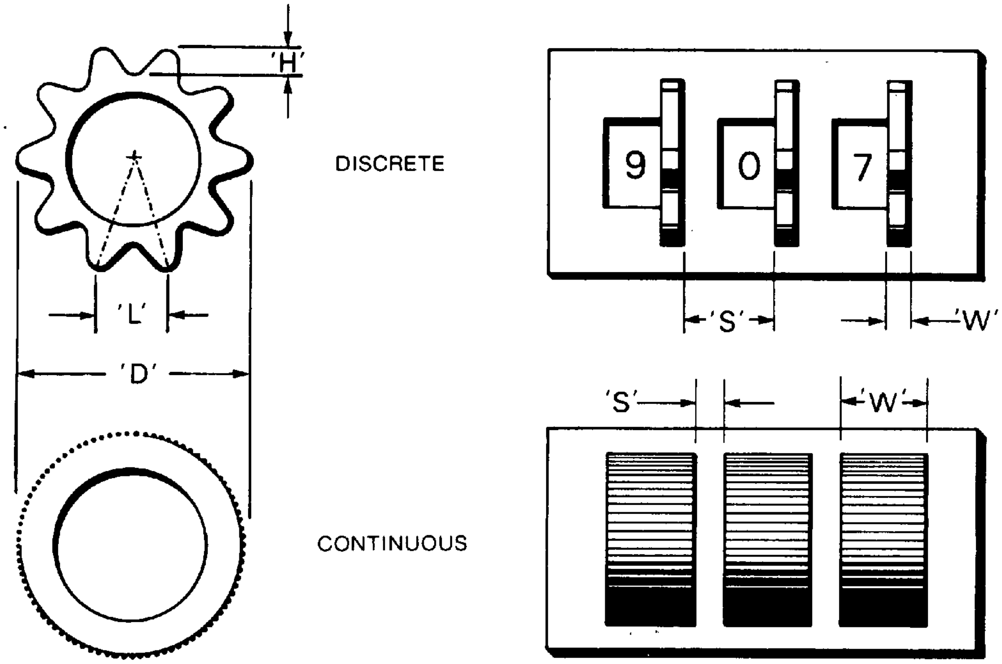
	TORQUE	POSITION DISPLACEMENT		SEPARATION	
		'A'		'S'	
		*	**	One-Hand Random	Two-Hand Operation
Minimum	113mN-m (1.0 in.-lb.)	15 deg.	30 deg.	25mm (1.0")	75mm (3.0")
Maximum	678mN-m (6.0 in.-lb.)	40 deg.	90 deg.	—	—
Preferred		—	—	50mm (2.0")	125mm (5.0")

† Only suitable when knob positions are in 160° of rotation in upper semi-circle.

* For facilitating performance.

** When special engineering requirements demand large separation.

Figure 14—Design and separation: rotary selector switches

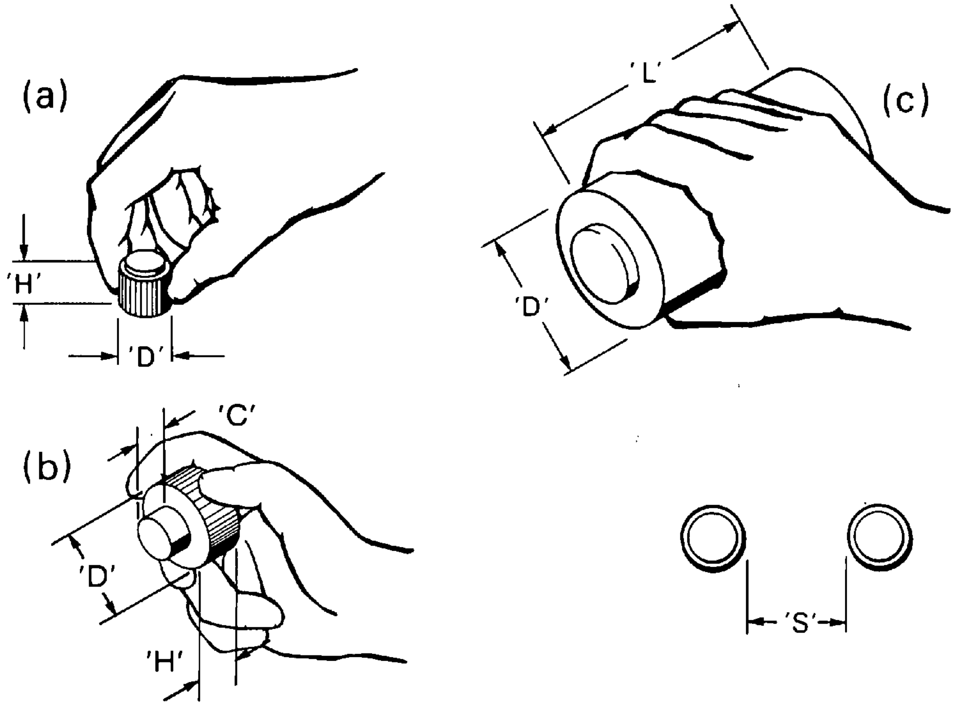


	'D' Diameter	'L' Trough Distance	'W' Width	'H' Depth	'S' Separation	Resistance
DISCRETE THUMBWHEEL						
Minimum	30 mm (1.125")	11mm (0.45")	3 mm (0.125")	3mm (0.125")	10mm (0.4")	165 mN (6 oz.)
Maximum	75 mm (3")	19mm (0.75")		13mm (0.5")	—	560 mN (20 oz.)
CONTINUOUS THUMBWHEEL						
Minimum	20mm (0.8")	—	3 mm (0.125")	—	25 mm (1")	—
Maximum	65mm (2.5")	—	23 mm (0.875")	—	—	330 mN * (12 oz.)

* Continuous resistance in both directions.

Figure 15—Design and separation: thumbwheel controls

(Adapted from MIL-STD-1472D)



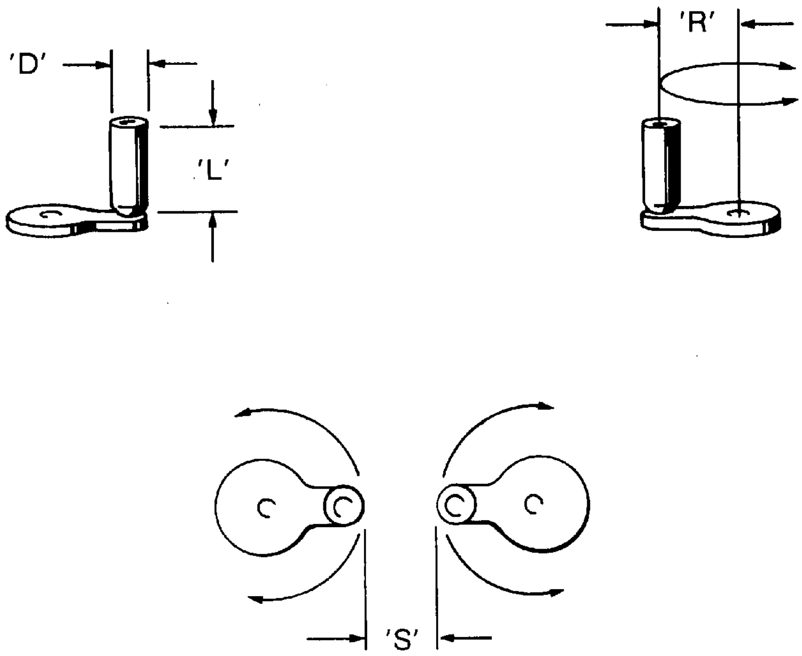
	DIMENSIONS						
	(a) Finger Grasp		(b) Thumb and Fingers Encircled			(c) Palm/Hand Grasp	
	'H' Height	'D' Diameter	'H' Height	'D' Diameter	'C' Clearance	'D' Diameter	'L' Length
Minimum	13 mm (0.5")	10 mm (0.375")	13 mm (0.50")	25 mm (1.0")	16 mm (.625")	38 mm (1.5")	75 mm (3.0")
Maximum	25 mm (1.0")	100 mm (4")	25 mm (1.0")	75 mm (3.0")	—	75 mm (3")	—

	TORQUE		'S' SEPARATION
	*	**	One Hand Individually
Minimum	—	—	25 mm (1.0")
Preferred	—	—	50 mm (2.0")
Maximum	32 mN-m (4.5 in.-oz.)	42 mN-m (6.0 in.-oz.)	—

* To and including 25 mm (1.0") diameter knobs.
** Greater than 25 mm (1.0") diameter knobs.

Figure 16—Design and separation: knobs

(Adapted from MIL-STD-1472D)

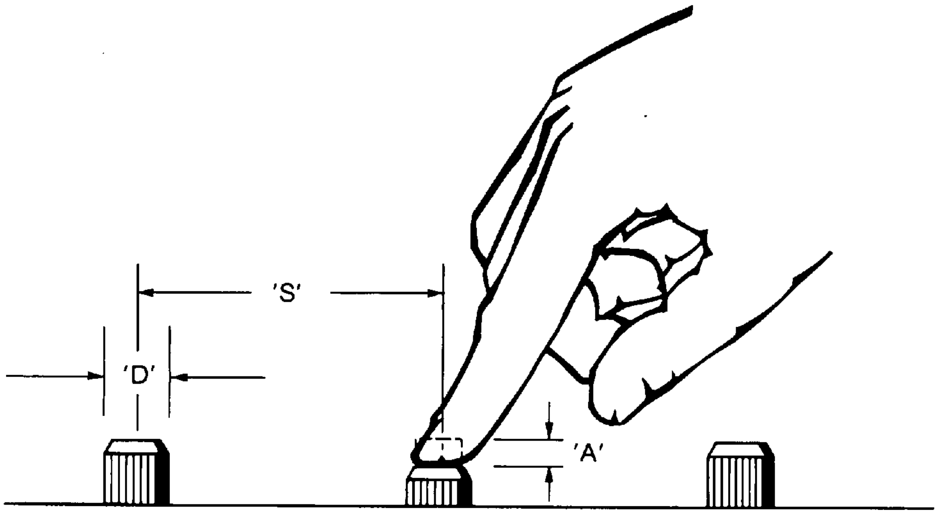


LOAD	SPECIFICATION	HANDLE				R, TURNING RADIUS			
		L, LENGTH		D, DIAMETER		RATE BELOW 100 RPM		RATE ABOVE 100 RPM	
		mm	in.	mm	in.	mm	in.	mm	in.
LIGHT LOADS: Less than 22 N (5 lb). (Wrist and finger movement)	MINIMUM	25	1	10	.375	38	1.5	13	.5
	PREFERRED	38	1.5	13	.5	75	3	65	2.5
	MAXIMUM	75	3	16	.625	125	5	115	4.5
HEAVY LOADS: More than 22 N (5 lb). (Arm movement)	MINIMUM	75	3	25	1	190	7.5	125	5
	PREFERRED	95	3.75	25	1	--	--	--	--
	MAXIMUM	--	--	38	1.5	510	20	230	9

S, Separation between adjacent controls: 75 mm (3") minimum.

Figure 17—Design and separation: cranks

(Adapted from MIL-STD-1472D)



	DIMENSIONS: DIAMETER* D		RESISTANCE		
	Fingertip	Thumb or Palm	Single Finger	Different Fingers	Thumb or Palm
Minimum	9.5 mm (0.375")	19 mm (0.75")	2.8 N (10 oz.)	1.4 N (5 oz.)	2.8 N (10 oz.)
Maximum	25 mm (1")		11 N (40 oz.)	5.6 N (20 oz.)	23 N (80 oz.)

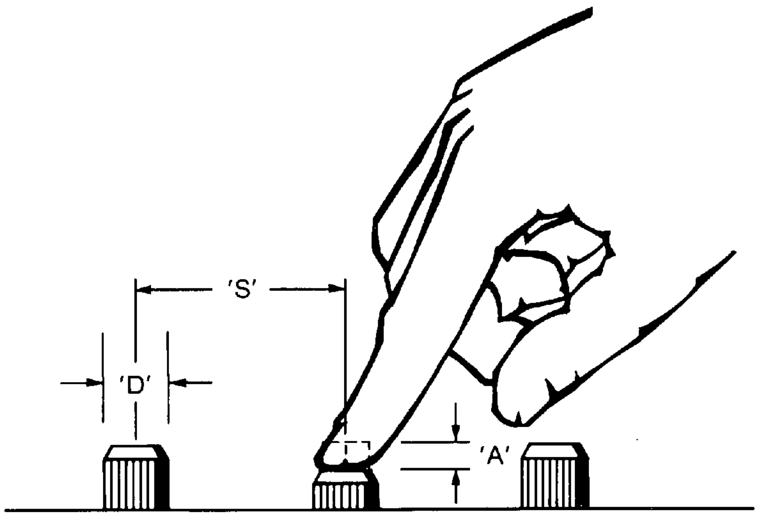
	DISPLACEMENT A	
	Fingertip	Thumb or Palm
Minimum	2 mm (0.078")	3 mm (0.125")
Maximum	6 mm (0.25")	38 mm (1.5")

	SEPARATION S			
	Single Finger	Single Finger Sequential	Different Fingers	Thumb or Palm
Minimum	13 mm (0.5")	6 mm (0.25")	6 mm (0.25")	25 mm (1")
Preferred	50 mm (2")	13 mm (0.5")	13 mm (0.5")	150 mm (6")

*Table applies to square/rectangular buttons also.

Figure 18—Design and separation: pushbuttons (finger- or hand-operated)

(Adapted form MIL-STD-1472D)



	DIMENSIONS	RESISTANCE		
	'D' Diameter *	Numeric	Alpha-numeric	Dual Function
Minimum	10 mm (0.385")	1N (3.5 oz.)	250 mN (0.9 oz.)	250 mN (0.9 oz.)
Maximum	19 mm (0.75")	4N (14.0 oz.)	1.5N (5.3 oz.)	1.5N (5.3 oz.)
Preferred	13 mm (0.5")	—	—	—

	'A' DISPLACEMENT			SEPARATION
	Numeric	Alpha-numeric	Dual Function	'S' (between adjacent key tops)
Minimum	0.8 mm (0.03")	1.3 mm (0.05")	0.8 mm (0.03")	6.4 mm (0.25")
Maximum	4.8 mm (0.19")	6.3 mm (0.25")	4.8 mm (0.19")	—
Preferred	—	—	—	6.4 mm (0.25")

*Table applies to square/rectangular buttons also.

Figure 19—Design and separation: keyboards (pushbutton/finger-operated)

(Adapted from MIL-STD-1472D)

9.7.2.1 Application

Thumbwheels may be either discrete or continuous controls. A discrete thumbwheel may be used if the function requires a compact digital control input device (for a series of numbers) and a readout of these manual inputs for verification. Detent indexing units should provide 10 positions (0 to 9) in digital outputs. For binary detent indexing, there should be 3 or 4 bits and complement outputs. A continuous thumbwheel may be used for applications requiring continuous adjustment.

9.7.2.2 Shape

Each position around the outside edge of a discrete thumbwheel should have a slightly concave surface or should be separated by a raised, high-friction area around the thumbwheel's periphery. Continuous thumbwheels should employ high-friction raised areas to facilitate movement. The thumbwheels should not obstruct the operator's sight of digits within a 30° viewing angle to the left and right of a perpendicular to the thumbwheel digits.

9.7.3 Knobs

Knobs should be used when little force is required and when precise adjustments of a continuous variable are needed. For most tasks, a moving knob with a fixed scale is preferred to a moving scale with a fixed index. If positions or controls that do not involve repeated revolutions need to be distinguishable, a pointer or marker should be available on the knob. Design criteria for knob controls are given in figure 16 (see page 49).

9.7.3.1 Size discrimination

When knob diameter is used as a coding parameter, differences should be at least 0.5 inches. When knob thickness is a coding parameter, differences between thicknesses should measure at least 0.4 inches.

9.7.3.2 Shape discrimination

Knobs or other controls that may be adjusted while the user visually attends to other tasks should be shape coded and separated by an appropriate distance. Rotating knob controls for different types of control actions should be distinguishable by sight and touch and should not be easily confused with one another.

9.7.4 Cranks

Cranks should be used primarily for tasks requiring many rotations of a control, particularly where high rates or large forces are involved. For tasks involving large slewing movements plus small adjustments, a crank handle may be mounted on a knob or handwheel. The crank is for slewing, and the knob or handwheel is for fine adjustments. The crank grip handle should be designed so that it turns freely around its shaft. When cranks are used for fine tuning or other processes involving numerical selection, each rotation should correspond to a multiple of 1, 10, 100, and so on. Design criteria for crank controls are given in figure 17 (see page 50).

9.7.5 Finger- and hand-operated pushbuttons

Pushbuttons should be used when a control or an array of controls is needed for momentary contact or for activating a locking circuit, particularly when they are used frequently (see figures 18 and 19, pages 51 and 52).

9.7.5.1 Shape

The pushbutton surface should be indented to fit the finger. When such design is impractical, the surface should provide frictional resistance to prevent slipping.

9.7.5.2 Positive indication

A positive indication that the control has been activated should be provided (e.g., a snap feel, an audible click, or an integral light). The possibility of an unintended push should be taken into account so that an irreversible function is not activated.

9.7.5.3 Sequence control pushbuttons

A pushbutton that performs more than one function (i.e., cycling through a series of functions by a second touch or continued pressure) should be carefully designed to avoid unintended activation of an irreversible function (e.g., resetting of the device). A confirmation of the step attained should be provided. The possibility of a second push should be taken into account so that an irreversible function is not activated.

9.7.5.4 Interlocks and barriers

Properly designed mechanical interlocks or barriers may be used instead of separating the pushbuttons according to the recommendations in figure 18 (see page 51).

9.7.5.5 Electrical power switches

When the power is ON, electrical power switches of the pushbutton type should be illuminated, the button should stay depressed, or some other positive indication should be provided to signify the energized condition.

9.7.6 Keyboards and keypads

When alphabetical entry is required, the keyboard should use a QWERTY arrangement. When numerical data are to be entered via keypad, a telephone layout is recommended unless the specific user population for which the device is being designed is likely to be more familiar with the calculator layout. Pushbuttons for entry of special function information should also be arranged in a convenient keyboard or keypad format. Whenever practical, the standard ANSI arrangement should be used (see ANSI/HFS 100, 1988). However, there may be instances when the standard size is not practical.

9.7.6.1 Configuration

The keyboard configuration should be one that is familiar to the intended user. Alphabetic keyboards are not recommended as routine input devices.

9.7.6.2 Numeric keypads

Keyboards used in systems requiring substantial numeric input should be equipped with a numeric keypad.

9.7.6.3 Fixed-function (dedicated) keys

9.7.6.3.1 Use

Fixed-function keys (for example, ENTER) should be used for time-critical, error-critical, or frequently used control inputs.

9.7.6.3.2 Standardization

Fixed-function keys should be common throughout a system.

9.7.6.3.3 Availability

Fixed-function keys should be selected to control functions that are continuously available; that is, lockout of fixed-function keys should be minimized. At any step in a transaction sequence, however, function keys that are not used for current inputs should be temporarily disabled under computer control. Mechanical overlays should not be used to indicate nonactive keys.

9.7.6.3.4 Nonactive keys

A keyboard should not include anything other than active keys unless the application calls for a stock keyboard.

9.7.6.3.5 Activation

Except when used to toggle between two opposing states, a fixed-function key should require only a single activation to accomplish its function.

9.7.6.3.6 Feedback

When fixed-function key activation does not result in an immediately observable natural response, some form of system acknowledgment should be provided to the user.

9.7.6.4 Variable function ("soft") keys

9.7.6.4.1 Use

Variable function keys may be used for programmable menu selection and entry of control functions.

9.7.6.4.2 Status display

When the effect of a function key varies, the status of the key should be displayed.

9.7.6.4.3 Reprogrammable or inactive default functions

When keys with labeled default functions are reprogrammed or turned off, a visual warning should alert the user that the standard function is not currently accessible via that key.

9.7.6.4.4 Relabeling

Provision should be made for easily relabeling variable function keys. Labels for variable function keys, located along the perimeter of a display, may be generated on the display face. Such labels should closely correspond to the position of the control.

9.7.6.4.5 Easy return to base-level functions

Where the functions assigned to a set of function keys change as a result of user selection, the user should be given an easy means of returning to the initial, base-level functions.

9.7.7 Toggle switches

Design criteria for toggle switches are given in figure 20 (see next page).

9.7.7.1 Application

Toggle switches should be used for functions requiring two discrete positions or where space limitations are severe. Toggle switches with three or more positions should be used only if the use of a rotary control or legend switch control is not feasible or if the toggle switch is of the spring-loaded, center-position-off type. (Toggle switches are considered here to be discrete position controls; small controls that are the same size and shape as toggle switches and that are used for making continuous adjustments are called levers.)

9.7.7.2 Resistance

Resistance should increase gradually, then drop when the switch snaps into position. The operator should not be able to stop the switch between positions.

9.7.7.3 Orientation

Two-position toggle switches should be vertically oriented with OFF in the down position. Horizontal orientation and activation of toggle switches should be employed only for compatibility with the controlled function or the equipment location.

9.7.8 Legend switches

Design criteria for legend (touch or pushbutton) switches are given in figure 21 (see page 55). In addition, the following design considerations should be observed:

a) For positive indication of switch activation, the pushbutton switch should be provided with a detent or lock. For nonmechanical, touch-sensitive switches, a positive indication of activation may be an integral light within or above the switch being activated.

b) The legend should be legible with or without internal illumination.

c) A lamp test or dual lamp/filament arrangement should be provided.

d) All lamps should be easily replaceable.

e) Legend caps should be designed to prevent their accidental interchange, or a means should be provided for checking the caps after installation to ensure that they are properly installed. If the interchangeability of legend caps can compromise the patient's well-being, the former design approach should be taken.

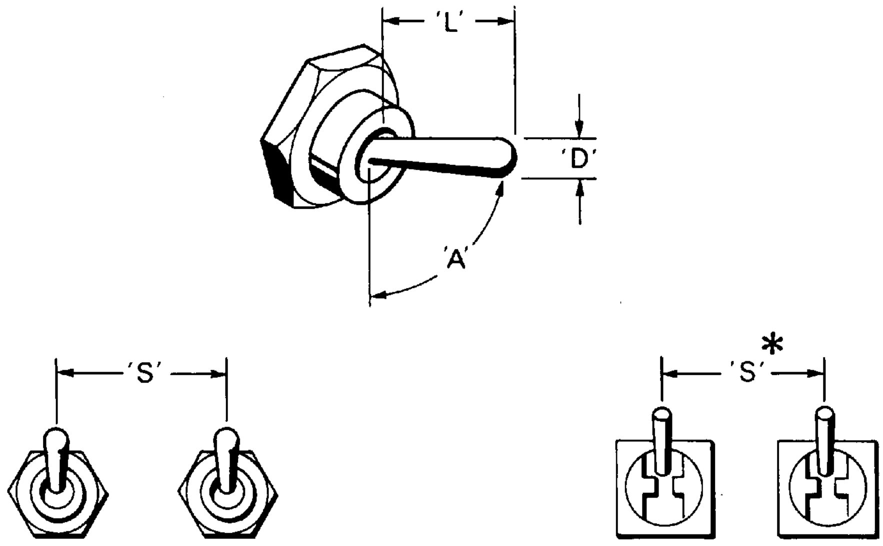
f) For readability, there should be a maximum of three lines of lettering on the legend plate.

9.7.9 Levers, continuous adjustment

Design criteria for continuous adjustment levers are given in figure 22 (see page 56). In addition, the following design considerations should be observed:

a) Levers may be used when large amounts of force or movement are involved or when multidimensional movement of the controls is required.

b) When several levers are grouped close together, the lever handles should be coded and labeled.



	DIMENSIONS		RESISTANCE		ANGULAR DISPLACEMENT BETWEEN POSITIONS 'A'	
	'L' Arm Length	'D' Control Tip	Small Switch	Large Switch	2 Position	3 Position
Minimum	13 mm (0.5")	3 mm (0.125")	2.8 N (10 oz.)	2.8 N (10 oz.)	30 deg.	18 deg.
Maximum	50 mm (2.0")	25 mm (1.0")	4.5 N (16 oz.)	11 N (40 oz.)	80 deg.	40 deg.
Desired					—	25 deg.

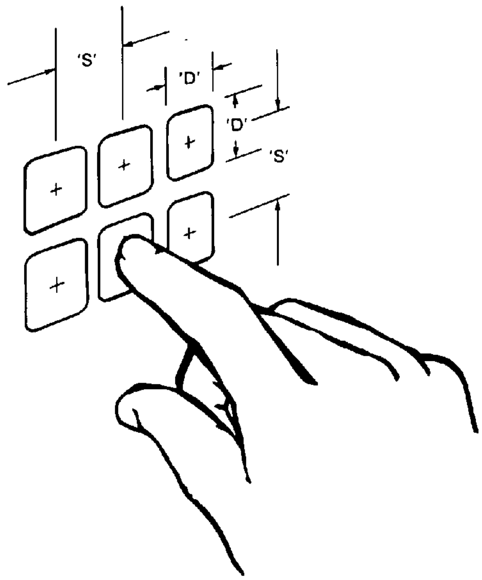
	'S' SEPARATION			
	Single Finger Operation	Single Finger Operation *	Single Finger Sequential Op.	Simultaneous Op. by Different Fingers
Minimum	19mm (0.75")	25mm (1.0")	13mm (0.5")	16mm (0.625")
Preferred	50mm (2.0")	50mm (2.0")	25mm (1.0")	19mm (0.75")

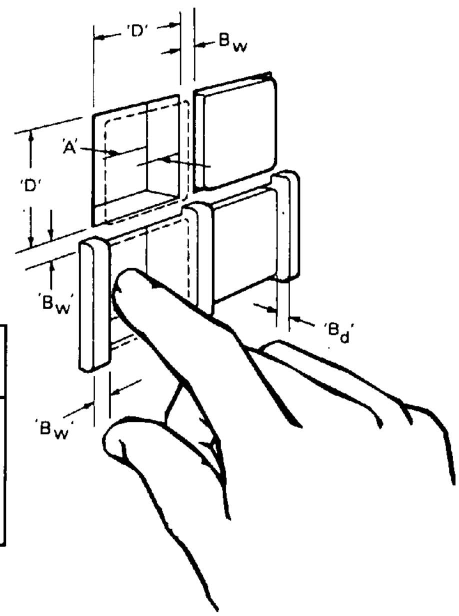
* Using a lever lock toggle switch.

Figure 20—Design and separation: toggle switches

(Adapted from MIL-STD-1472D)

List of Titles





TOUCH SWITCHES

	'D' DIMENSION	'S' SPACING
Minimum	13 mm (0.50")	19 mm (0.75")
Maximum	38 mm (1.5")	—

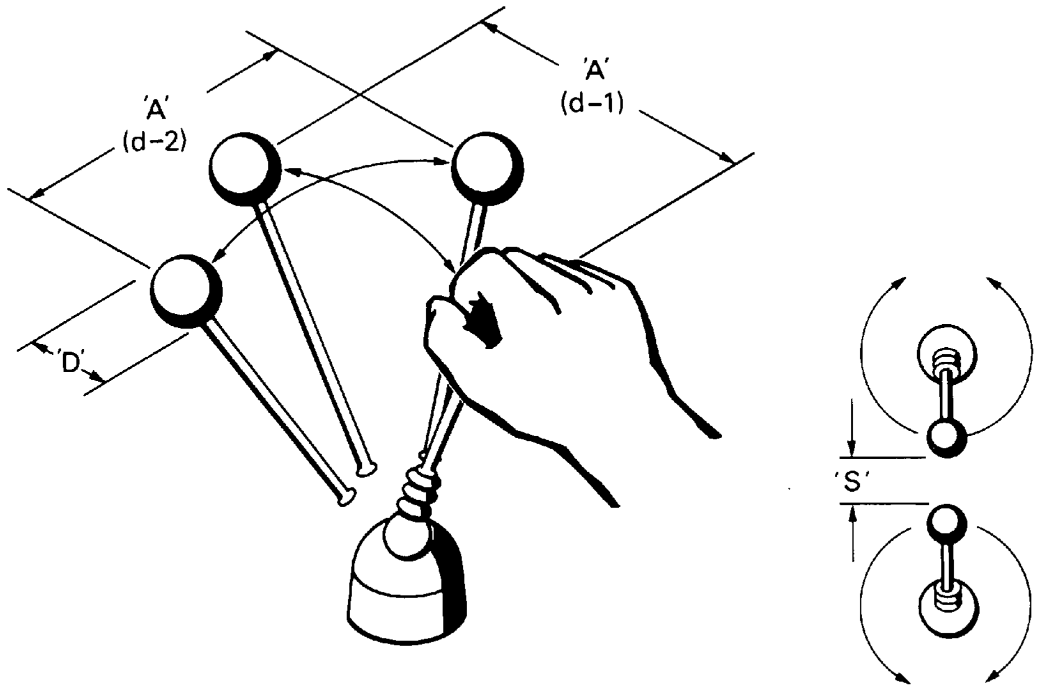
PUSHBUTTON SWITCHES

	'D' DIMENSION	'A' Displacement	SEPARATION/BARRIERS*		RESISTANCE
			'B_w'	'B_d'	
Minimum	19 mm (0.75")	3 mm** (0.125")	3 mm (0.125")	5 mm (0.187")	280 mN (10 oz.)
Maximum	38 mm (1.5")	6 mm (0.250")	6 mm (0.250")	6 mm (0.250")	16.6 N (60 oz.)

* Barriers shall have rounded edges
** 5 mm (.188") for positive position switches.

Figure 21—Design and separation: legend (touch/pushbutton) switches

(Adapted from MIL-STD-1472D)



	'D' DIAMETER		d-1 RESISTANCE	d-2 RESISTANCE
	Finger Grasp	Hand Grasp	One Hand	One Hand
Minimum	13mm (0.5")	38mm (1.5")	9N (2 lb.)	9N (2 lb.)
Maximum	38mm (1.5")	75mm (3.0")	135N (30 lb.)	90N (20 lb.)

	'A' DISPLACEMENT		'S' SEPARATION
	Forward (d-1)	Lateral (d-2)	One Hand Random
Minimum	—	—	50mm (2.0")
Preferred	—	—	100mm (4.0")
Maximum	360mm (14.0")	970mm (38.0")	—

Figure 22—Design and separation: levers

9.7.10 Lightpen

9.7.10.1 Application

A lightpen may be used as an input device when noncritical, imprecise input functions are required. Such direct-pointing controls should be used when item selection is the primary type of data entry. In one design, the lightpen may be positioned on the display screen to detect the presence of a computer-generated track by sensing its refresh pattern; the display system will then present a follower (hook) on the designated track. In another design, the lightpen serves the same function merely by pointing at the screen from a distance. With suitable additional circuitry, a follower can be made to track the movement of the lightpen across the surface of the display, thus allowing it to function as a two-axis controller capable of serving the same purposes as the grid-and-stylus devices (see 9.7.14).

9.7.10.2 Dynamic characteristics

When a direct-touch lightpen is used as a two-axis controller, its dynamic characteristics should conform to 9.7.14.2.

9.7.10.3 Activation

Lightpens should be equipped with a discrete activating-deactivating mechanism. For direct-touch lightpen applications, a push-tip switch requiring 0.5N to 1.4N (2 to 5 oz) of force for activation is usually preferred.

9.7.10.4 Dimensions and mounting

A direct-touch lightpen should be 120 to 180 mm (4.7 to 7.1 inches) long with a diameter of 7 to 20 mm (0.3 to 0.8 inch). A remote-control lightpen may be of similar size and shape or different size and shape, as required. A convenient mounting or storage device (clip, holder, etc.) for the lightpen should be provided.

9.7.10.5 Feedback

Two forms of feedback should be provided to anyone using a lightpen:

a) feedback concerning the position of the lightpen, preferably in the form of a displayed cursor such as a circle or cross hairs or highlighting that informs the user that the system is recognizing the presence of the lightpen. For direct-touch lightpens, the feedback should be great enough to be seen under the point of the lightpen;

b) feedback that the lightpen has activated and the input has been received by the system.

9.7.11 Touch-screen controls for displays

9.7.11.1 Use

Touch-screen control may be used to provide an overlaying control function to data display devices such as CRTs, dot matrix/segmented displays, electroluminescent displays, programmable indicators, or other display devices where direct visual reference access and optimum direct control access are desired.

9.7.11.2 Luminance transmission

Touch-screen displays should have sufficient luminance transmission to allow the display with touch-screen installed to be clearly readable in the intended environment and to meet the display luminance requirements herein.

9.7.11.3 Positive indication

A positive indication of touch-screen activation should be provided to acknowledge the system response to the control action.

9.7.11.4 Dimensions and separation

The dimensions and separation of responsive areas of the touch-screen should conform to figure 21 (see page 55). Force requirements should not be more than 1.5 N (5.3 oz) or less than 250 mN (0.9 oz).

9.7.11.5 Control-display relationships

Touch-screen controls should be designed so that required input actions will not obstruct or distract from the operator's view of time-critical data being displayed simultaneously.

9.7.11.6 Operation by gloved operators

In selecting the touch-screen technology (e.g., infrared, capacitive) recognition that the operator may be wearing protective gloves, and the effects of such gloves on touch-screen operation, should be considered.

9.7.12 Hand-operated joysticks

The term *joystick* refers primarily to hand or finger controls used for cursor placement or precise adjustment. Joystick controls may be used when the task requires precise or continuous control in two or more related dimensions.

9.7.12.1 Hand-operated displacement joysticks (also known as isotonic joysticks)

9.7.12.1.1 Applications

In addition to general uses, the displacement joystick may also be used for various display functions, such as data pickoff from a CRT and generation of free-drawn graphics. In applications which allow the follower (cursor or tracking symbol) to transit beyond the edge of the display, indicators should be provided to aid the operator in bringing the follower back onto the display.

Displacement joysticks that are used for rate control should be spring-loaded for return to center when the operator's hand is removed. (Displacement joysticks usually have a spring resistance to movement away from the center [null] position, although some have no spring.) Using displacement joysticks usually requires less force than using isometric joysticks and is less fatiguing for long periods of operation. When positioning accuracy is more critical than positioning speed, displacement joysticks should be selected over isometric joysticks.

9.7.12.1.1.1 Automatic sequencing

Displacement joysticks that have a deadband near the center or hysteresis should not be used with automatic sequencing of a CRT follower (cursor or tracking symbol) unless they are instrumented for null return or zero-set to the instantaneous position of the stick at the time of sequencing. Upon termination of the automatic sequencing routine, joystick center should again be registered to display center.

9.7.12.1.1.2 Secondary controls

Hand-operated displacement joysticks may be used as mounting platforms for secondary controls, such as thumb- and finger-operated switches. Operation of secondary controls has less induced error when the controls are mounted on the displacement type of handgrip than when they are mounted on an isometric handgrip. Secondary controls should operate perpendicularly to the movement of primary positioning controls when mounted on the handgrip to prevent accidental changes in primary control positioning.

9.7.12.1.2 Dynamic characteristics

Handgrip movement should not exceed 45° from the center position. Movement should be smooth in all directions, and positioning of a follower should be attainable without noticeable backlash, cross-coupling or the need for multiple corrective movements. Control ratios, friction and inertia should meet the dual requirements of rapid gross positioning and precise fine positioning. When the follower is used for generation of free-drawn graphics, its refresher rate on the CRT should be high enough to give the appearance of continuous tracking. Delay between control movement and the confirmation of display response should be minimized and should not exceed 0.1 second.

9.7.12.1.3 Dimensions, resistance, and clearance

The handgrip length should be in the range of 110 to 180 mm (4.3 to 7.1 inches). The grip diameter should not exceed 50 mm (2 inches). Clearances of 100 mm (4 inches) to the side and 50 mm (2 inches) to the rear should be provided to allow for hand movement. Joysticks should be mounted to provide forearm support. Displacement joysticks may require greater clearance than isometric joysticks. Modular devices should be mounted to allow activation of the joystick without slippage, movement, or tilting of the mounting base.

9.7.12.2 Finger-operated displacement joysticks

9.7.12.2.1 Application

In addition to the general uses, finger-operated displacement joysticks are useful for free-drawn graphics. In this application, there is usually no spring return to center, and the resistance should be sufficient to maintain the handle position when the operator's hand is removed.

9.7.12.2.2 Dynamic characteristics

Movement should conform to 9.7.12.1.2.

9.7.12.2.3 Dimensions, resistance, and clearance

The joystick should be mounted on a desk or shelf surface to provide forearm or wrist support. Modular devices should be mounted to allow activation of the joystick without slippage, movement, or tilting of the mounting base.

9.7.12.3 Hand-operated isometric joystick (two axis controllers) (also known as a stiff stick, force stick, or pressure stick)

The hand-operated isometric joystick has no perceptible movement, but its output is a function of the force applied.

9.7.12.3.1 Application

Joystick controls may be used when the task requires precise or continuous control in two or more related dimensions. Isometric joysticks are particularly appropriate for applications

a) that require precise return to center after each use;

b) in which operator feedback is primarily visual rather than tactile feedback from the control itself;

c) in which delay is minimal and coupling is tight between control and input and system reaction.

Isometric sticks should not ordinarily be used in applications where it would be necessary for the operator to maintain a constant force on the control for a long period of time or where there is no definitive feedback when maximum control inputs have been exceeded. Joystick controls may be used when the task requires precise or continuous control in two or more related dimensions. When positioning speed is more critical than positioning accuracy, isometric joysticks should be selected over displacement joysticks. Isometric joysticks may also be used for various display functions such as data pickoff from a CRT. In rate control applications, which may allow the follower (cursor or tracking symbol) to transit beyond the edge of the display, indicators should be provided to aid the operator in bringing the follower back onto the display.

9.7.12.3.2 Dynamic characteristics

Maximum force for full output should not exceed 118 N (26.7 lb).

9.7.12.3.3 Dimensions, resistance, and clearance

The handgrip length should be in the range of 110 to 180 mm (4.3 to 7.1 inches). The grip diameter should not exceed 50 mm (2 inches). Clearances of 100 mm (4 inches) to the side and 50 mm (2 inches) to the rear should be provided to allow for hand movement. Joysticks should be mounted to provide forearm support. Modular devices should be mounted to allow activation of the joystick without slippage, movement, or tilting of the mounting base.

9.7.13 Trackball controllers

9.7.13.1 Application

A ball suspended on low-friction bearings may be used for various control functions such as data pickoff on a display. The ball control cannot provide an automatic return to point of origin; hence, if a ball control is used in applications requiring automatic return to origin following an entry or readout, the interfacing system should provide that return function. Because the ball can be rotated without limit in any direction, it is well suited for applications where there may be accumulative travel in a given direction. In any application that would allow the ball to drive the follower on the display off the edge of the display, indicators should be provided to advise the operator how to bring the follower back onto the display. Ball controls should be used only as position controls (i.e., a given movement of a ball yields a proportional movement of the follower on the display).

9.7.13.2 Dynamic characteristics

The ball control should be capable of rotation in any direction in order to generate any combination of *x* and *y* output values. When the control is moved in either the *x* or *y* directions alone, no cross-coupling (follower movement in the orthogonal direction) should be apparent. For an operator manipulating the control, neither backlash nor cross-coupling should be apparent. Control ratios and dynamic features should meet the dual requirement of rapid gross positioning and smooth, precise fine positioning. When trackball controls are used to make precise or continuous adjustments, wrist support or arm support or both should be provided.

9.7.14 Grid-and-stylus devices

These provisions cover various techniques that utilize some means of establishing an *x* and *y* grid and a stylus for designating specific points on that grid for control purposes (e.g., timeshared *x* and *y* potential grids and a voltage-sensitive stylus). Such devices include finger-pointing grid devices.

9.7.14.1 Application

Grid-and-stylus devices may be used for data pickoff from a CRT, entry of points on a display, generation of free-drawn graphics and similar control applications. The grid may be on a transparent medium allowing placement of the stylus directly over corresponding points on the display or it may be displaced from the display in a convenient position for stylus manipulation. In either case a follower (bug, mark, hook, etc.) should be presented on the display at the coordinate values selected by the stylus. Devices of this type should be used only for zero-order control functions (displacement of the stylus from the reference position causes a proportional displacement of the follower).

9.7.14.2 Dynamic characteristics

Movement of the stylus in any direction on the grid surface should result in smooth movement of the follower in the same direction. Discrete placement of the stylus at any point on the grid should cause the follower to appear at the corresponding coordinates and to remain steady in position as long as the stylus is not moved. Refresh rate for the follower should be high enough to ensure the appearance of a continuous track whenever the stylus is used for generation of free-drawn graphics.

9.7.14.3 Dimensions and mounting

Transparent grids that are used as display overlays should conform to the size of the display. Grids that are displaced from the display should approximate the display size and should be mounted below the display in an orientation that will help preserve directional relationships to the maximum extent possible (i.e., a vertical plane passing through the north/south axis on the grid should pass through or be parallel to the north/south axis on the display).

9.7.15 Free-moving *xy* controller (mouse)

9.7.15.1 Application

On any flat surface where contamination from fluid or particulate matter is improbable to generate *x* and *y* coordinate values that control the position of the follower on the associated display, a free-moving *xy* controller (or mouse) may be used. Such a controller may be used for data pickoff or for entry of coordinate values. It should be used for zero-order control only (i.e., generation of *x* and *y* outputs by the controller results in proportional displacement of the follower). It should not normally be used for generation of free-drawn graphics.

9.7.15.2 Dynamic characteristics

The design of the controller and placement of the maneuvering surface should be such as to allow the operator to orient the controller consistently to within ± 175 mrad (10°) of the correct orientation without visual reference to the controller. For example, when the operator grasps the controller in what seems to be the correct orientation and moves it rectilinearly along what is assumed to be straight up the *y* axis, the follower's direction of movement on the CRT should be between 6,110 and 175 mrad (350° and 10°). The controller should be easily movable in any direction without a change of hand grasp. Movement of the controller should result in smooth movement of the follower in the same direction ± 175 mrad (10°). The controller should be operable using either the left or right hand. A complete excursion of the controller from side to side of the maneuvering area should move the follower from side to side on the display regardless of scale setting or offset unless expanded movement is selected for an automatic sequencing mode of operation. In any application that would allow the controller to drive the follower off the edge of the display, indicators should be provided to assist the operator in bringing the follower back onto the display.

9.7.15.3 Dimensions and shape

The free-moving *xy* controller should have no sharp edges, with limiting dimensions as shown in table 10.

Table 10—Minimum and maximum dimensions suggested for free-moving *xy* controller

	Minimum	Maximum
Width (spanned by thumb to finger grasp)	40 mm (1.6 inches)	70 mm (2.8 inches)
Length	70 mm (2.8 inches)	120 mm (4.7 inches)
Thickness	25 mm (1.0 inches)	40 mm (1.6 inches)

9.7.16 Basic foot controls

Design criteria for foot controls are given in figure 23 (see page 61).

9.7.16.1 Application

Foot-operated controls should be used only when the operator is likely to have both hands occupied when the control is activated or when load sharing among limbs is required. Because foot-operated controls are extremely susceptible to accidental activation, their use should be limited to noncritical operations such as press-to-talk switches. If it is necessary to use foot controls for critical operations because the operator's hands will be occupied (such as with electrosurgical unit foot controls), the control should be caged or somehow protected from accidental activation.

9.7.16.2 Operation

Foot controls should be designed for operation by the toe and ball of the foot rather than the heel. Space permitting, foot-operated pushbuttons should be replaced by or supplemented with a pedal to help locate the actuating control. High-friction surfaces should cover foot-operated controls.

9.7.16.3 Positive indication

A positive indication that the control has been activated should be provided.

9.7.17 New control technologies

It is recognized that new technologies for input are evolving rapidly. Such technologies will be addressed, as they become available, in later editions of this document.

10 Displays

10.1 General

10.1.1 Flicker

Flickering of a display is often a subjective phenomenon and may be perceived differently by different observers. Flickering can be a major source of fatigue and distraction, especially when a display is used for long periods of time. (See ANSI/HFS 100, 1988). Observers in countries with home television refresh rates of 50 Hz may be more tolerant of flicker than those in countries with home television refresh rates of 60 Hz. Flicker is usually eliminated when refresh rates of 70-72 Hz or higher are used. From a design standpoint, a minor sacrifice in resolution to achieve a nonflickering refresh rate may be desirable.

10.1.2 Resolution

Cathode-ray-tube and flat-panel-matrix displays may be used for pictorial, graphic, and alphanumeric displays if the quality of information produced is adequate for the intended use of the device. When a display of complex shape is to be analyzed, the smallest detail of interest should subtend not less than 20 minutes of visual angle at the longest intended viewing distance.

10.1.3 Lines and symbols

For line graphics, such as ECG tracings, line width should subtend at least 1.5 minutes of visual angle at the longest intended viewing distance. Height-to-width ratio, stroke width, and the size and spacing of symbols should ensure legibility of all characters at the maximum viewing angle and distance. Character height should be a minimum of 16 minutes of visual angle.

Where alphanumeric characters appear on CRT-like displays, the font style should allow discrimination between similar characters, such as letter *l* and number *1*; letter *Z* and number *2*. (Refer to DIN Standards 66-234, Parts I and II, and 66-009.)

10.2 Visual

Visual displays should provide the operator with a clear indication of equipment or system status under all conditions consistent with the intended use and maintenance of the system.

10.2.1 Information content

The information displayed to a user should be sufficient to allow the user to perform the intended task but should be limited to what is necessary to perform the task or to make decisions.

10.2.2 Format

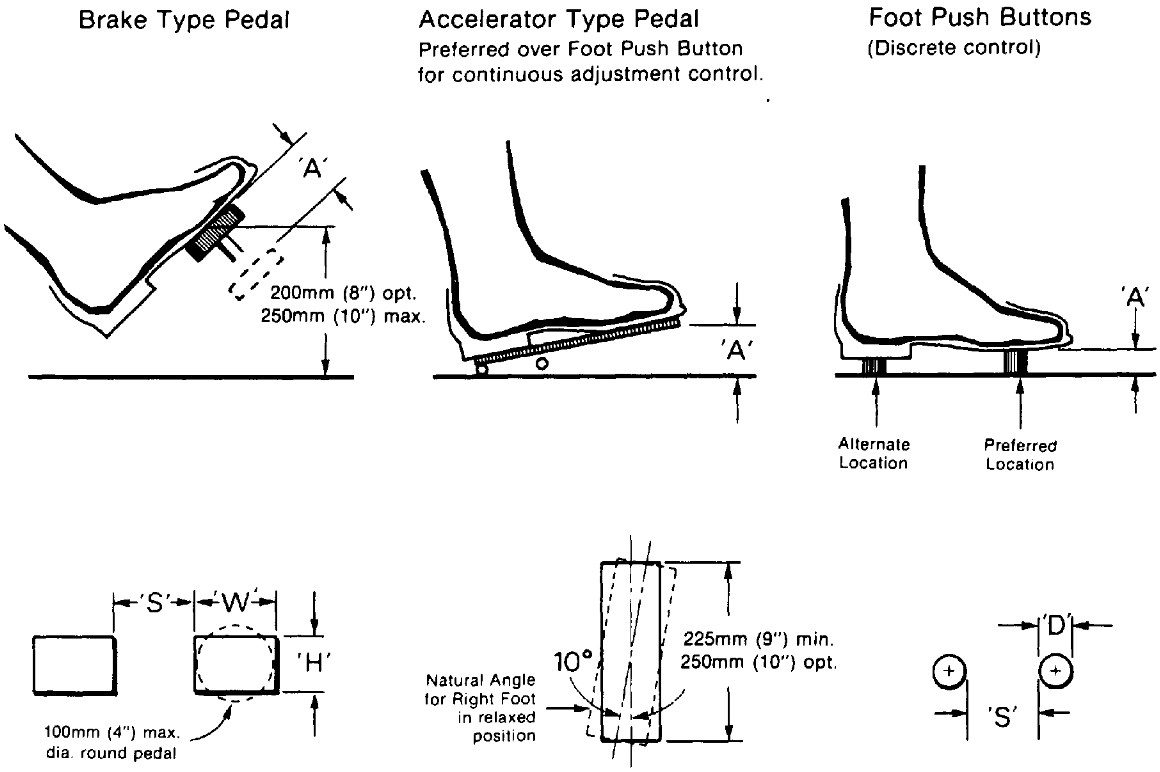
Information should be presented to the operator in a directly usable form and should be limited to what is necessary for specific actions or decisions. Designs requiring the operator to transpose, compute, interpolate, or mentally translate units of measurement should be avoided. Information necessary for performing different activities (e.g., equipment operation versus troubleshooting) should not appear in a single display unless the activities are related and require the same information to be used simultaneously.

10.2.2.1 Graphic displays

The choice of a particular graphical display type can have significant impact on user performance. The designer should consider carefully the tasks to be supported by the display and the conditions under which the user will view the device before selecting a display type (see Bennett and Flach, 1992). Graphic displays (also known as "integrated" or "analog" displays) should be used for the display of information when perception of the pattern of variation is important to proper interpretation. This mode of display may not function well, however when a high degree of ambiguity exists between parameter states. Numeric digital display may be recommended under such circumstances.

10.2.2.2 Numeric digital displays

Numeric digital displays should be used where quantitative accuracy of individual data items is important. They should not be used as the only display of information when perception of the variation pattern is important to proper interpretation or when rapid or slow digital display rates inhibit proper perception.



	DIMENSIONS			DISPLACEMENT			
	'D' Diameter	'H' Height	'W' Width	'A' Normal Operation	Ankle Flexion	Total Leg Movement (pedals)	Total Leg Movement (pushbuttons)
Minimum	13mm (0.5")	25mm (1.0")	75mm (3.0")	13mm (0.5")	25mm (1.0")	25mm (1.0")	25mm (1.0")
Maximum	—	—	—	65mm (2.5")	65mm (2.5")	180mm (7.0")	100mm (4.0")

	RESISTANCE				'S' SEPARATION	
	Foot Not Resting On Pedal	Foot Resting On Pedal	Ankle Flexion Only	Total Leg Movement	One Foot Random	One Foot Sequential
Minimum	18N (4 lb.)	45N (10 lb.)	—	45N (10 lb.)	100mm (4.0")	50 mm (2.0")
Maximum	90N (20 lb.)	90N (20 lb.)	45N (10 lb.)	800N (180 lb.)	150mm (6.0")	100mm (4.0")

Figure 23—Design and separation: basic foot controls

10.2.2.3 Graphical presentation of related variables

A graphical display which emulates or invokes key features of the associated system (e.g., the human cardiovascular system, complex machine functions) may help the user better understand the status of the underlying system and respond in the most appropriate manner (see Bennett and Toms, 1991 and Buttigieg et al., 1988). Presentation of a combination of smaller individual display elements (e.g., particular variables such as heart rate or respiratory rate) in such a way as to suggest the underlying ways in which individual parameters interact or interrelate may reduce the time it takes for the user to assimilate and understand the information being presented. Such displays are particularly good at depicting the performance of dynamic systems. A simple example of this principle is the display of ECG and arterial blood pressure waveforms at the same sweep speed. A more involved example might be a display of mechanical ventilator settings which graphically depict the known interrelationships between respiratory rate, tidal volume, inspiratory flow, inspiratory time, and I:E ratio. However, developers should recognize the potential novelty of such displays and the fact that users may have to think and respond to the underlying system differently. Accordingly, such displays should be rigorously evaluated in actual and simulated task environments with intended users as subjects to assure optimal performance and acceptance.

10.2.3 Precision

Information should be displayed only within the limits of precision required for the intended user activity or decision making and within the limits of accuracy of the measure.

10.2.4 Adequate signal duration

Signals and display information should have durations of sufficient length to be detected reliably under expected operator workload and operational environment.

10.2.5 Redundancy

The display of redundant information to a single user should be avoided unless it is required to achieve specified reliability or when discrepancies exist between two or more measures that are otherwise valid and redundant display is necessary for accurate comprehension. For example, the display of oxygen concentration measured by two different methods may be determined useful because the data by the two methods can be compared. Discrepancies can represent a system fault, sensor failure, or real system perturbation. In any case, when data may come from more than one source or device, the source of the data should be indicated.

10.2.6 Timeliness

Cathode-ray-tube displays, head-up displays, collimated displays, and other displays requiring refreshed information should be updated in a synchronous manner, where possible, and should be refreshed to the degree of timeliness required by users in all operating or servicing modes.

10.2.7 Coding

Displays may be coded by various features, such as color, size, location, shape, or flashing lights (see 8.3). Coding techniques should be used to help discriminate among individual displays and to identify functionally related displays, the relationship among displays, and critical information within a display.

10.2.8 Scale indicators

10.2.8.1 Types

Suitable types of scale indicators are (a) a moving pointer with a fixed scale that is circular, curved (arc), horizontal straight, or vertical straight, and (b) a fixed pointer with a moving scale that is circular, curved (arc), horizontal straight, or vertical straight.

10.2.8.2 Applications

The selection of scale indicators for various applications should be based on the criteria in table 11(see page 63). Scale indicators should be used (a) to display quantitative information in combination with qualitative information (such as trend and direction of motion), or (b) to display only quantitative information where the use of printers, counters, or alphanumeric readouts is unnecessary for speed, accuracy, or other reasons. Linear scales are preferred to nonlinear scales except when operator information requirements clearly dictate the use of nonlinear scales.

10.2.9 Pointers

10.2.9.1 General

The display should be designed so that the control or display pointer will extend to, but not obscure, the shortest scale of graduation marks. The width of the pointer where it intercepts the graduation marks should not exceed the width of the intermediate marks. Whenever precise readings are required, no more than two coaxial pointers should be mounted on one indicator face unless more than two parameters are closely related. To minimize parallax, the pointer should be mounted as close as possible to the face of the dial.

10.2.9.2 Coding

Coding on the face of scale indicators may be used to convey information such as desirable operating range, dangerous operating level, caution, undesirable condition, or inefficient condition. When operating conditions normally fall within a given range on the scale, these areas should be readily identifiable through a pattern, shape, color, or other indication on the face of the instrument.

10.2.10 Scale markings

10.2.10.1 Numerical progression

The numerical progression on fixed scales should increase clockwise, from left to right, or from the bottom up, depending on the display design and orientation. Numbers on stationary scales should be upright. Numerals should be placed outside of graduation marks so that they are not concealed by the pointer. When it is necessary to avoid constricting the scale, however, numerals may be placed inside the graduation marks. In any case, the pointer should extend to, but not obscure, the shortest graduation marks.

Table 11—Application of various types of mechanical displays

Use	Scales: Moving pointer	Scales: Fixed pointer	Counters	Printers	Flags
Quantitative Information	Fair May be difficult to read while point is in motion.	Fair May be difficult to read while scale is in motion.	Good Minimum time and error for exact numerical value.	Good Minimum time and error for exact numerical value. Provides reference records.	N/A
Qualitative Information	Good Location of pointer easy. Numbers and scale need not be read. Position change easily detected.	Poor Difficult to judge direction and magnitude of deviation without reading numbers and scale.	Poor Numbers should be read. Position changes not easily detected.	Poor Numbers should be read. Position changes not easily detected.	Good Easily detected. Economical of space.
Setting	Good Simple and direct relation of motion of pointer to motion of setting knob. Position change aids monitoring.	Fair Relation to motion of setting knob may be ambiguous. No pointer position change to aid monitoring. Not readable during rapid setting.	Good Most accurate monitoring of numerical setting. Relation to motion of setting knob less direct than for moving pointer. Not readable during rapid setting.	N/A	N/A
Tracking	Good Pointer position readily controlled and monitored. Simplest relation to manual control motion.	Fair No position changes to aid monitoring. Relation to control motion somewhat ambiguous.	Poor No gross position changes to aid monitoring.	N/A	N/A
General	Requires largest exposed and illuminated area on panel. Scale length limited unless multiple pointers used.	Saves panel space. Only small section of scale need be exposed and illuminated. Use of tape allows long scale.	Most economical of space and illumination. Scale length limited only by number of counter drums.	Limited application.	Limited application.

(Reprinted from Department of Defense [1981a], table III)

10.2.10.2 Scale break

An obvious scale break of at least 10° of arc should be provided between the two ends of the scale except on multirevolution instruments such as clocks.

10.2.10.3 Scale face opening

If the display will be used for tuning (e.g., a wavelength) or setting some desired value, the unused portion of the dial face should be covered and the open window should be large enough to permit at least one numbered graduation to appear on each side of any setting.

10.2.11 Legend lights

10.2.11.1 General

Legend lights are preferred to simple indicator lights except when design considerations dictate otherwise. Color coding should be consistent with the recommendations of 8.3.2. Function should also be denoted by means of location, size, flash coding, or a combination of such techniques.

10.2.11.2 Visibility and legibility

With the exception of warning and caution indicators, the lettering on single-legend indicators should be visible and legible at 500 mm (20 inches) in lighting of 215 lux (20 foot candles) whether or not the indicator is energized. Multiple-legend indicators (legend plates aligned one behind another) should be designed so that the rear legend conforms with the following recommendations:

a) An illuminated rear legend should not be obscured by the front legends.

b) Rear legend plates should be placed to minimize parallax.

c) Rear and front legends should be equal in apparent brightness, and the contrast between rear legends and the background should be equal to that between front legends and the background.

10.2.12 Counters

10.2.12.1 Application

Counters should be used when presenting quantitative data where a precise measurement is required but a continuous trend is not.

10.2.12.2 Mounting

Counters should be mounted as close as possible to the panel surface so that parallax and shadows are minimized and the viewing angle is maximized.

10.2.12.3 Numerals

The height-to-width ratio of numerals should be 1:1, with the exception of the number *1* (one stroke width). The horizontal separation between numerals should be between one-fourth and one-half the numeral width. Commas should not be used to separate thousands.

10.2.12.4 Movement

Numbers should change by snap action rather than by continuous movement and, when the operator is expected to read the numbers consecutively, should follow each other at a speed no faster than two numbers per second.

10.2.12.5 Reset

Knobs which turn to reset the counter are preferred over pushbuttons. If a pushbutton needs to be used, it should be located or guarded in a way which reduces the possibility of accidental activation. The counter reset knob should rotate clockwise to increase the counter indication or to reset the counter. Counters signifying the use of equipment in sequence should be designed to reset themselves automatically upon completion of the sequence. Provision should also be made for manual resetting.

10.2.12.6 Finish

The surface of the counter drums and surrounding areas should have a dull finish to minimize glare.

10.2.13 Printers, chart recorders, and plotters

10.2.13.1 Application

Printers and chart recorders should be used when a permanent hardcopy record of data is necessary. Plotters are appropriate when a visual record of continuous graphical data is necessary or desirable.

10.2.13.2 Form of information

Printed information should be presented in a form that requires minimal decoding, transposition, or interpolation. When data are presented on both a display screen and a printer, data recorder, or plotter, the data should be in as similar formats as is practical for the application. To ensure legibility, printed information should not be hidden, masked, or otherwise obscured. If masking cannot be avoided, the device should maximize visibility of that information determined to be most necessary to the user (e.g., current value or trend over some pertinent time period).

10.2.13.3 Materials/supplies

Printers and chart recorders should be designed so that printing materials (e.g., paper, ink, ribbon, toner cartridges, and print engines) can be removed and inserted quickly and easily. If permanent records are required, thermal paper should not be used. A positive indication that printing materials are near depletion should be provided. A take-up device should be provided whenever excess printed material will interfere with the operator's normal activities or system function.

10.2.13.4 Annotation

Where applicable, printers, chart recorders, and plotters should be mounted so that the paper can be easily annotated while still in the recorder. Aids such as graphical overlays should be provided when an operator is required to interpret graphical data, but such aids should neither obscure nor distort the data.

10.2.14 Transilluminated displays

10.2.14.1 General considerations

Transilluminated displays should be used to convey information that requires either immediate reaction by the operator or attention to an important system or device status. Such indicators are also occasionally used for system maintenance and adjustment. This type of display is exemplified by single- and multiple-legend lights, which present information in the form of meaningful words, numbers, symbols, and abbreviations. Other examples are simple indicator lights—such as pilot, "bull's eye," and jewel lights—and transilluminated panel assemblies that present qualitative status or system readiness information.

10.2.14.2 Luminance

The brightness of transilluminated displays should be compatible with the expected level of ambient illumination and should be at least 10 percent greater than the surrounding luminance. Displays intended for use under varied ambient illumination should incorporate a dimming control with a range that permits the displays to be read under all expected ambient illumination levels. A manual dimming control should be located on the front of the device where it is readily accessible to the operator. An automatic dimming control that responds to changes in ambient light levels may also be provided. If dimming controls are employed, they should not allow emergency warning displays to be set to imperceptible levels under any ambient illumination conditions. The luminance contrast within the indicator should be at least 0.5 (i.e., the luminance difference, divided by the higher luminance, should be at least 0.5).

10.2.14.3 Color coding of displays

Transilluminated displays and indicators should conform to table 7 (see page 41) and should be consistent with the recommendations of 8.3.2.

10.2.15 Recommendations relating to cathode-ray-tube (CRT) and other displays

10.2.15.1 Display and ambient illumination

Gray scale uniformity should be maintained at the percent variation level necessary for the intended use of the display. When the illuminance is lower than this, additional internal illuminance should be provided by the device to ensure readability. The variation between any two locations on the display should not exceed 25 percent when the display is uniformly excited. For self-excited displays, the ambient illumination should contribute no more than 25 percent of screen brightness through diffuse reflections and background excitation of the screen. When a CRT display is used in variable ambient illumination, illumination luminance controls should be provided. Automatic adjustment of CRT brightness could be used if the CRT brightness is automatically adjusted as a function of ambient illumination and the range of automatic adjustment is adequate for the full range of ambient illumination. Reflective glare should be minimized by proper orientation of the display device relative to the light source or by means of a hood, shield, optical coating, or filter. Adjustability of display orientation (e.g., fore-aft screen tilt) should be provided to allow the user to compensate for ambient lightning conditions which cause glare or other degradation of the display.

10.2.15.2 Light-emitting-diode displays (LEDs)

LEDs may be used for transilluminated displays, including legend and simple indicator lights, and for matrix displays used for alphanumerics. In general, guidelines for the use of LEDs should be the same as for transilluminated displays unless otherwise specified (see 10.2.14). LEDs should be used only if the display is bright enough to be readable in the environment of intended use. The dimming of LEDs should be compatible with the dimming of incandescent lamps.

10.2.15.3 Electroluminescent displays

Electroluminescent displays can be used wherever monochrome transilluminated displays or CRTs may be used. They offer the advantages of lighter weight, conservation of panel space, lower power requirements, lack of heat production, uniform distribution of illumination, longer life, elimination of parallax, and flexibility of display. Electroluminescent displays may replace existing mechanical instrumentation and may also be used where sudden lamp failure could result in catastrophic consequences.

10.2.15.4 Large-screen displays

10.2.15.4.1 Application

Large-screen displays may be used when

a) a group of users frequently refers to the same information and is required to interact as a team, based on the same information;

b) one or more members of a team of users should move about yet need to refer often to information that is required to make decisions but cannot be carried with them or is not displayed at their assigned position(s);

c) space or other constraints preclude the use of individual displays for each team member to call up commonly used information;

d) it may be desirable to have general information available to persons who should not interrupt ongoing group operations by looking over the shoulder of operators to see their individual displays.

Large-screen displays should be used only when the spatial and environmental conditions allow satisfactory observational geometry to ensure that all critical users have visual access in terms of viewing distance, angle, and lack of interference from intervening objects, personnel, or ambient lighting. If the display is optically projected, see 10.2.15.5.

10.2.15.4.2 Viewing distance

The display should not be placed farther from an observer than will allow appropriate resolution of critical detail presented on the display (see legibility guidelines, 10.1 and 10.2.15.1). The display should not be closer to any observer than half the display width or height, whichever is greater.

10.2.15.4.3 Physical interruption of view

Large-screen displays should be located in such a way that a critical user's view of them will not regularly be obscured by persons using normal traffic patterns.

Table 12—Group viewing of optical projection displays

Factor	Optimum	Preferred Limits	Acceptable Limits
Ratio of viewing distances / screen diagonal	4	3-6	2-8
Angle off centerline	0 mrad (0°)	350 mrad (20°)	525 mrad (30°)
Image luminance (no film in operating projector)*	35 cd/m^2(10 fL)	27—48 cd/m^2 (8—14 fL)	17—70 cd/m^2 (5—20 fL)
Luminance variation across screen (ratio of maximum to minimum luminance)	1	1.5	3.0
Luminance variation as a function of viewing location (ratio of maximum to minimum luminance)	1	2.0	4.0
Ratio of ambient light / brightest part of image	0	0.002—0.01	0.1 max**

*For still projections higher values may be used
**For presentations not involving gray scale or color (e.g., line drawings, tables) 0.2 may be used.
(Reprinted from MIL-STD-1472D)

10.2.15.4.4 Control of displayed information

Control of large-screen group display systems should ensure that critical information cannot be modified or deleted accidentally or arbitrarily.

10.2.15.4.5 Content of displayed information

The content of displayed information should be evident to a trained observer without requiring reference to display control settings. The impact of unauthorized observation of information on large displays should be considered.

10.2.15.5 Large-screen optical projection displays

10.2.15.5.1 Application

Providing that ambient light can be properly controlled, optical projection displays are suitable for applications requiring group presentation, pictorial and spatial information, past history versus real-time presentation, synthetically generated pictures, simulation of the external world, and superposition of data from more than one source. Rear projection should be used where physical obstructions to front projection result in poor visibility or where work areas require high ambient illumination for other activities.

10.2.15.5.2 Seating area

The viewing distance/image width relationship and off-center viewing of optical projection displays for group viewing should conform to the preferred limits of table 12 and should not exceed the acceptable limits. For individual viewing from a fixed location, off-centerline viewing should not exceed 175 mrad (10°).

10.2.15.5.3 Image luminance and light distribution

Image luminance and light distribution should conform to the preferred limits and should not exceed the acceptable limits of table 12. The luminance of the screen center at maximum viewing angle should be at least half its maximum luminance.

10.2.15.5.4 Legibility of projected data

A simple style of numerals and letters should be used. Capital letters should be used, rather than lower case, except for extended copy or lengthy messages. Stroke width should be 1/6 to 1/8 of numeral or letter height but may be narrower for light markings on a dark background. Stroke width should be the same for all letters and numerals of equal height.

The height of letters and numerals should be not less than 4.5 mrad (15 minutes) of visual angle and should never be less than 3 mrad (10 minutes) as measured from the longest anticipated viewing distance.

Under optimal ambient lighting conditions, the luminance ratio for optically projected displays should be 500:1. The minimum luminance ratio for viewing charts, printed text and other linework via slides or opaque projectors should be 5:1. For projections that are limited in shadows and detail, such as animation and photographs with limited luminance range, the minimum luminance ratio should be 25:1. For images that show a full range of colors (or grays in black-and-white photographs), the minimum luminance ratio should be 100:1.

Text and images may be either light on a dark background or vice versa, except where superposition is used. For subtractive superposition (at the source), data should be presented as dark markings on a transparent background. For additive superposition (at the screen), data should be presented as light markings on an opaque background. Colored markings against colored backgrounds of comparable brightness should be avoided.

10.2.15.5.5 Alignment

Poor alignment of superimposed alphanumeric data or other symbols should be minimized.

10.2.15.5.6 Distortion

Projector-screen arrangement should minimize distortion of projected data that could arise from the projection axis and the screen not being perpendicular.

10.2.15.6 Liquid crystal displays

Displays that use reflected light, such as liquid crystal displays, may be used for transilluminated displays such as legend and simple indicator lights as well as matrix (alphanumeric) displays. Illumination of 11 lux (1 foot candle) should be available to the display. Dimming of these displays should be compatible with the dimming of incandescent lamps.

Alphanumeric characters generated by a matrix of liquid crystal elements should subtend at least 20 minutes of visual angle at the longest intended viewing distance.

11 Alarms and signals

11.1 Purpose

The purpose of an alarm is to draw attention to the device when the operator's attention may be focused elsewhere. Alarms should not be startling but should elicit the desired action from the user. When appropriate, the alarm message should provide instructions for the corrective action that is required. In general, alarm design will be different for a device that is continuously attended by a trained operator (e.g., an anesthesia machine or an anesthesia monitor) than for a device that is unattended and operated by an untrained patient (e.g., a patient-controlled analgesia device). False alarms, loud and startling alarms, or alarms that recur unnecessarily can be a source of distraction for both an attendant and the patient and thus a hindrance to good patient care. A device designed for both attended and unattended use or a device designed only for attended use might include a "staged alarm," which would become louder and/or more urgent if the alarm condition remained uncorrected or unnoticed by the attendant.

11.2 Classification of alarms

Alarm characteristics are grouped in the following three categories:

a) high-priority alarm. A combination of audible and visual signals indicating that immediate operator response is required;

b) medium-priority alarm. A combination of audible and visual signals indicating that prompt operator response is required;

c) low-priority alarm. A visual signal, or a combination of audible and visual signals indicating that operator awareness is required.

Alarm characteristics can be classified as they are in table 13.

Table 13—Classification of alarms

Alarm category	Operator response	Audible indicators	Indicator colors	Flashing frequency (Hz)
High priority	Imme-diate	Not medium or low priority	Red	1.4 to 2.8 Hz
Medium priority	Prompt	Not high or low priority	Yellow	0.4 to 0.8 Hz
Low priority	Aware-ness	Not high or medium priority	Yellow	Constant (on)

11.3 Classification of signals

11.3.1 Information signal (monitoring)

An information signal is a visual and/or audible signal (such as an illuminated symbol or an intermittent audible tone) that may provide advisory or status information. Examples include a symbol to indicate electrical activity of the heart or respiratory effort, an audible tone to indicate electrical activity of the heart, and a pulse oximeter audible signal that varies with oxygen saturation. Monitoring signals should have an adjustable volume control down to 45 dB and a silencing capability unless a fixed volume level has been determined for the application.

11.3.2 Periodic audible indicator

A periodic tone (every 30 seconds to 5 minutes, depending on the type of device) may be used to indicate a defeated or silenced audible alarm or other conditions, such as battery-powered operation. (This is also called a reminder tone.)

11.3.3 Audible signal comprehension

The effectiveness of audible signals intended to convey critical information, such as an asystole alarm, should be validated through user testing. Tests of less critical audible signals may also be warranted to avoid critical confusions.

NOTE—Testing procedures defined in ANSI Standard Z535.3-1987, paragraph A.2.4, for symbol comprehension testing may be adapted for this purpose. According to one recommended procedure, a 50-person sample of potential users is exposed to each of the audible signals in random order, in conjunction with normally available visual cues, and asked to define its meaning. (Any new audible warning should be tested in conjunction with the ones already present in the environment.) These definitions are judged as correct, incorrect, or indicative of a critical confusion that may be hazardous. ANSI criteria for symbol acceptance are 85 percent correct responses and no more than 5 percent critical confusions.

11.4 Location of high-priority visual displays and controls

High-priority visual displays should be located where they can be seen. An operator with a visual acuity of 20/20 (corrected if necessary) should be able to read correctly from a distance of 1 m and at an angle of 30° either side of a line perpendicular to the center of the display or control panel and under an ambient illuminance in the range of 100 lux to 1,500 lux. Displays such as multifunction displays, cathode-ray-tube displays, head-up displays, collimated displays, and other visual display devices presenting simultaneous and integrated information should advise or alert users to information that becomes critical within the display. Such alerting might include color changes, flashing, reverse video, a box around the critical values, special symbols (such as an asterisk), slight change of location, larger font size, and so forth.

11.5 Visual alarm indicators

The use of flashing lights should, in general, be minimized. When used as listed below, the flash rate should be within the range stated in table 13 (see page 67), with an ON cycle of 20 to 60 percent. The indicator should be designed so that, once energized, the light will illuminate and stay on, even if the flasher device fails.

11.5.1 High-priority alarm

A red flashing light should be used for a high-priority alarm condition unless an alternative visible signal that indicates the alarm condition and its priority is employed. A red flashing light should not be used for any other purpose. This provision does not preclude the use of a nonflashing red indicator for other purposes.

NOTE—In certain environments, an additional or alternative display color will be required. For example, red alarm lights are not visible through the protective goggles used with Nd:YAG lasers. In most instances it is not feasible for a user wearing goggles to remove them. In these and similar cases, additional colors are required instead of, or preferably in addition to, the red flashing light.

11.5.2 Medium-priority alarm

A yellow flashing light should be used for a medium-priority alarm condition unless an alternative visible signal that indicates the alarm condition and its priority is employed. A yellow flashing light should not be used for any other purpose. This does not preclude the use of a nonflashing yellow indicator for other purposes.

11.5.3 Low-priority alarm

A steady (nonflashing) yellow light should be used for a low-priority alarm condition unless an alternative visible signal that indicates the alarm condition and its priority is employed.

11.5.4 Size, brightness, and coding of alarm lights

Lights intended to signal patient alarms or equipment failure, caution, or impending danger—or "go" or "no-go"—should be designed to attract attention more effectively than other lights. Caution should be used when employing lights that change color, change meaning, change from a steady to a flashing state and the like to avoid confusion of different signalled states.

11.6 Audible signals

Audible signals should be used to alert the operator to the status of the patient or the device when the device is out of the operator's line of sight.

NOTE—Standards for audible alarms are under development by standards-making groups, such as the International Standards Organization Technical Committee ISO/TC 121, Subcommittee 3; the Comité Europeén de Normalisation Technical Committee CEN/TC 259; and the American Society for Testing and Materials (ASTM) Committee F-29 on Anesthetic and Respiratory Equipment Subcommittee F-29.03.04 on Harmonization of Alarms.

Audible displays (signals), used as part of the user-computer interface, have application where

a) the common mode of visual display is restricted by overburdening or user mobility needs and it is desirable to cue, alert, or warn the user;

b) the user should be provided feedback after control activation, data entry, or completion of timing cycles and sequences.

Audible signals used in conjunction with visual displays should be supplementary to the visual signals and should be used to alert and direct the user's attention to the appropriate visual display.

11.6.1 Volume and frequency

Design of equipment should take into account the background noise and other audible signals and alarms that will likely be present during the intended use of the device. (For instance, audible alarm tones should not be similar to information monitoring signal tones.) Audible signals should have a fundamental frequency between 150 and 1,000 Hz and at least four frequency components between 300 and 4,000 Hz to ensure that they are well within the normal range of hearing.

NOTE—The fundamental frequency is the same as the first harmonic and it may count toward the four harmonics between 300 and 4,000 Hz.

The lowest volume-control settings of critical life support audible alarms should provide sufficient signal strength to preclude masking by anticipated ambient noise levels; volume-control settings for other signals should similarly preclude such masking. Ambient noise levels in hospital areas can range from 50 dBA in a private room to 60 dBA in intensive care units and emergency rooms, with peaks as high as 65 to 70 dBA in operating rooms due to conversations, alarms, or the activation of venturi devices. The volume of monitoring signals normally should be lower than that of high-priority or medium-priority audible alarms provided on the same device. An alarm signal should have a distinctive sound, audible to a person with normal hearing. High- and medium-priority audible alarms should consist of at least two tones of differing frequency (pitch). In most cases, an intermittent repeating alarm pattern is sufficient and is preferable to a continuous alarm.

11.6.2 Directivity

Audible signals should be located so as to assist the operator in identifying the device that is causing the alarm. For this reason, alarms should ordinarily be louder in the front of the device than in the back of it.

11.7 Integrated audible and visual alarms

Activation of a signal should include both audible and visual components except that a low-priority alarm may omit an audible signal. Alarms should indicate the source of the alarm (for instance, by a visible signal or text message) even when the alarm has been silenced.

11.8 Voice alarms

The use of voice alarms (also called talking, spoken, verbal, synthesized, digital, or recorded alarms) in medical applications should not be considered unless the following potential problems are resolved:

a) Voice alarms are easily masked by ambient noise and other voice messages, such as paging systems, even if the voice message is broadcast through headphones.

b) Voice messages may interfere with communications among personnel who are attempting to address the alarm condition. Similarly, voice messages may not be heard over these conversations.

c) The information conveyed by the voice alarm may reach individuals who should not be given specific information concerning the nature of the alarm. For example, an alert patient, patients' visitors, or operating room personnel may be disturbed by the alarm's message but have no recourse to correct the alarming condition. Indeed, patients with poor directional discrimination may mistakenly assume that an alarm message from another patient's equipment is from their own and become unnecessarily upset.

d) The types of messages that can be transmitted via voice alarms tend to be very specific. Many different messages are necessary to address adequately all the parameters that need to be alarmed. The result may be a further complication and confusion of the alarm environment for both the manufacturer and the user of the device.

e) In many situations, it may be anticipated that multiple alarms will be activated at the same time. In this instance, numerous voice alarm messages would be presented simultaneously or sequentially, resulting in confusion.

f) Spoken messages may convey information that creates an emotional response separate from the message. Depending on the gender used for the voice alarm and the gender of the listener, a voice message may evoke an emotional response that is counterproductive to the goal of the actual message being transmitted. (Digitized or recorded voices may be preferable to synthesized voices for situations where predictable messages may be generated.)

g) Different languages may be required, perhaps within a single device, to accommodate the needs of various users.

NOTE—It should be noted that, with very limited use, the aviation industry has successfully used voice alarms. The keys to this success may include the following:

a) Most alarms are conventional, with voice alarms being reserved for limited situations that occur very infrequently.

b) When used, voice messages are not subject to alarming falsely.

c) Voice messages are reserved for extreme emergencies, instruct the user as to the appropriate action ("Pull up!"), and are directed to a very specific audience (e.g., a pilot and co-pilot).

11.9 Other signals

The use of signaling methods other than visual and auditory ones (for instance, vibration) is discouraged in most medical applications.

11.10 Initialization of a device

The audible components of alarms should be designed to allow silencing until the device is placed in use (i.e., connected to the patient) in order to reduce nuisance alarms. Whenever possible, critical alarms should be enabled automatically when the patient is connected to the device. For example, a device that detects heart beats might be automatically silenced until a certain number of valid heart beats were detected. Then the heart beat alarm would automatically be activated.

11.11 Reasonable alarm limit defaults

Manufacturer's default alarm limits should be provided for critical alarms. These limits should be sufficiently wide to prevent nuisance alarms, and sufficiently narrow to alert the operator to a situation that would be dangerous in the average or usual patient. These manufacturer's default limits should be activated whenever any of the following conditions occur:

a) when the device is switched ON by the operator;

b) when the device has had a loss of all power (mains power and battery power) for a period of time. This period of time should not be less than 5 minutes. The manufacturer's documentation should disclose the period of time after which the manufacturer's default limits are restored;

c) when the user indicates to the device that a different patient has been connected to the device (e.g., through an "admit new patient" function);

NOTE—An "admit new patient" function is desirable on many devices but is not required.

d) upon user request. Manufacturers should provide a convenient means for the user to restore the factory default alarm limits.

NOTE—In cases (a), (b), and (c), the device may instead automatically activate a single set of user-chosen default alarm limits. See 11.11.1.

Alternatively, the manufacturer should suggest typical or default alarm limits to the operator in writing. This approach would normally be used when a mechanical adjustment for alarm limits is provided.

The manufacturer's documentation should list all default alarm limits.

NOTE—Medical devices with identical outward appearance but different software and other internal functions, including the operation of alarm defaults and other alarm features, may cause confusion among users. This is particularly true if a user encounters different software versions in different locations. Care should be used in the design of such devices. For example, this problem may be addressed by maintaining settings as similarly as possible on different devices, offering a single screen to verify all alarm settings, highlighting different or changed alarm settings, and indicating differences and changes in user documentation and training.

11.11.1 User default alarm limits

A device may retain and store one or more sets of alarm limits chosen by the user. When more than one set of user default alarm limits exists, the activation of user default alarm limits should require deliberate action by the user. When there is only one set of user default alarm limits, the device may be configured to activate this set of user default alarm limits automatically in place of the factory default alarm limits. (See 11.11 [a], [b], and [c].) Users should also be able to choose "factory default" alarm limits as an option. In any case, the device should indicate when user default alarm limits are being employed.

11.11.2 Alarm limits

The setting of adjustable alarms should be indicated continuously or on user demand. It should be possible to review alarm limits quickly.

NOTE—Care should be used in the design of medical devices if users are permitted to set alarm limits to extreme values. Such action by the user may have the effect of disabling both the audible and visual portion of the alarm, without providing a visual indication that the alarm is effectively disabled. It is preferable to provide a visual indication of alarm limits set to a value that is likely to be dangerous in the average or typical patient or situation.

11.11.2.1 Monitoring during setting of alarm limits

During user setting of alarm limits, monitoring should continue and alarm conditions should elicit the appropriate alarms.

11.11.2.2 Automatic setting of alarm limits

Alarm limits may be set automatically or upon user action to reasonable ranges and/or percentages above and/or below existing values for monitored variables. Care should be used in the design of such automatic setting systems to help prevent nuisance alarms on variables that are changing within an acceptable range. In some instances, wider or narrower limits may be required at different times. It should also be possible to return to factory default or user default alarm limits at any time.

11.11.3 Checklists for alarm settings

The use of checklists to verify proper settings of alarms is encouraged. Similar checklists should be used whenever there is a change of personnel who will use a device.

11.11.4 Power interruption

If all power is lost (mains power and battery power) for a period of 5 minutes or less, alarm limits should be retained.

11.12 Nonlatching alarms

The audible and visual alarm indicators should reset automatically when the condition causing the alarm has cleared or has been corrected ("nonlatching alarms"). (A user option may be provided to select latching or nonlatching alarms.)

NOTE—Care should be used in the design of alarm systems to make sure that the cause of an alarm can be identified. If the alarm clears quickly, the user may be unable to discover what triggered the alarm. Possible solutions include

a) use of an alarm with a minimum duration (perhaps 10 seconds);

b) special message that persists after the alarm has cleared;

c) alarm log that the user may call up from memory, print, or record.

11.13 Alarm silencing

11.13.1 Momentary silencing

An audible high- or medium-priority signal may have a manually operated, temporary override mechanism that will silence it for a period of time—for example, 120 seconds. After the silencing period, the alarm should begin sounding again if the alarm condition persists or if the condition was temporarily corrected but has now returned. New alarm conditions that develop during the silencing period should initiate audible and visual signals. In this instance the use of intermittent repeating audible patterns is preferred over that of a continuous tone.

If momentary silencing is provided, the silencing should be visually indicated. Momentary silencing of an alarm should not affect the visual representation of the alarm and should not disable the alarm. A periodic audible indicator may be used while the signal is silenced.

NOTES—

1) Alarm design is extremely important to prevent nuisance alarms (which will make users turn off the

alarms) yet always provide important alarms.

2) Standards for specific devices may prescribe additional limitations on momentary silencing.

11.13.2 Permanent silencing

An audible high- or medium-priority signal may be equipped with a means of permanent silencing (for instance, because of the failure of a sensor). Permanent silencing may be appropriate when a continuous alarm is likely to degrade user performance of associated tasks to an unacceptable extent and in cases when users would otherwise be likely to disable the device altogether. If provided, such silencing should require that the user either confirm the intent to silence a critical life support alarm or take more than one step to turn the alarm off. Permanent silencing should be visually indicated and may be signalled by a periodic audible reminder. Permanent silencing of an alarm should not affect the visual representation of the alarm and should not disable the alarm. Alternatively, in a device that monitors more than one variable, it should be possible to disable a section of the monitor that has failed without disabling the entire monitor. This disabled condition should be visually indicated. A condition of permanent silencing should not remain in effect in the event of total power loss for more than 30 seconds, or when the device is turned off by the user, or when the device is disconnected from the patient.

NOTE—Standards for specific devices may prescribe additional limitations on permanent silencing.

11.14 Display failure declaration

Failure of a display or its circuit should be immediately apparent to the user. Display systems should be designed so that the user can verify display or circuit failure. Failure of the display system should not cause a failure in the equipment associated with the display. Where failure of a display system could result in injury because of its absence:

a) some method of backup display of critical information should be made available to the user (perhaps using techniques such as redundancy [see 6.3.3] or distributed processing);

b) the equipment associated with the display should automatically default to, or enable manual setting to, a mode that would minimize the chance of injury to the patient.

11.15 Device failure declaration

Life support devices and devices that monitor a life-critical variable should have an audible alarm to indicate a loss of power or failure of the device. The characteristics of this alarm should be the same as those of the highest priority alarm that becomes inoperative. It may be necessary to use battery power for such an alarm. If additional information is available to indicate that it is of lower priority, then an appropriate lower alarm level may be used (e.g., if an ECG lead failed while oxygen saturation pulse is being recorded, the asystole alarm would not sound.)

12 User-computer interface

12.1 General

Computerized systems should provide a functional interface between the system and users (operators/maintainers) of that system. This interface should be optimally compatible with the intended user and should minimize conditions that can degrade human performance or contribute to human error.

12.1.1 Standardized procedures

Procedures for similar or logically related transactions should be consistent. The development of procedural standards is encouraged.

12.1.2 Computer response

Every input by a user should consistently produce some perceptible response (feedback) or output from the computer.

12.1.3 Online guidance

Sufficient online help should be provided to allow the intended but uninitiated user to operate the device effectively in its basic functional mode without reference to a user's manual or experienced operator. Information about system function and commands, dictionaries, definitions for selection and composition of data and command entries, guides for system options capabilities, procedures, and range of values are examples of topics that should be available at the user's request. Context sensitivity in online help programs is encouraged.

12.1.4 System status

Users should be provided appropriate information at all times on system status either automatically or upon request. Provision of information about system dysfunction is essential.

12.1.5 Log-on/log-off procedures

In applications where users need to log-on to the system, log-on should be a separate procedure that should be completed before a user is required to select among any operational options. Appropriate prompts for log-on should be displayed automatically on the user's terminal with no special action required other than turning on the terminal.

Users should be provided feedback relevant to the log-on procedure that indicates the status of the inputs. If a user cannot log-on to a system, a prompt should be provided to explain the reason for this inability. Log-on processes should require minimum input from the user, consistent with system access security.

When a user signals for log-off, the system should check pending transactions to determine if data loss seems probable. If so, the computer should prompt for confirmation before the log-off command is executed.

12.1.6 Computer failure

In the event of partial hardware/software failure, the program should allow for orderly shutdown and establishment of a checkpoint so restoration can be accomplished without loss of data.

12.1.7 Multiuser interaction

Where two or more users need to have simultaneous access to a computer system, under normal circumstances, operation by one person should not interfere with the operations of another person. For circumstances in which certain operators require immediate access to the system, such as a threat to life or limb, system malfunction, potential loss of data or critical maintenance, an organized system for insuring or avoiding preemption should be provided. Provisions should be made so that preempted users are notified and can resume operations at the point of interference without data loss.

12.2 Manual data entry

12.2.1 General

Manual data entry functions should be designed to establish consistency of data entry transactions, minimize users' input actions and memory load, ensure compatibility of data entry with data display, and provide flexibility of user control of data entry.

12.2.2 User pacing for manual entry

Data entry should be paced by the user, rather than the system.

12.2.3 Feedback to the user

The system should provide feedback to the user about acceptance or rejection of an entry. Feedback response times should conform to 12.5.1.1 and 12.6.

12.2.4 Processing delay

When a processing delay occurs, the system should acknowledge the data entry and provide the user with an indication of the delay. If possible, the system should also advise the user of the time remaining for process completion.

12.2.5 Explicit action (posting)

Data entry should require an explicit completion action, such as the depression of an ENTER key to post an entry into memory.

12.2.6 Validation

Data entries should be checked by the system for correct format, acceptable value, or range of values. Where repetitive entry of data sets is required, data validation for each set should be completed before another transaction can begin. (See also 12.9)

12.2.7 System-available data

The user should not be required to manually enter data that is already available to the system.

12.2.8 Input units

Data should be entered in units that are familiar to the user. If several different systems of units are commonly used, the user should have the option of selecting the units either before or after data entry. Transposition of data from one system of units to another (e.g., Celsius to Fahrenheit) should be accompanied automatically by the device.

12.2.9 Cursors

12.2.9.1 Control

Systems employing cursors should provide cursor control capability. The user should be able to adjust the sensitivity of the cursor movement so that it is compatible with the required task and user skills.

12.2.9.2 Display

A movable cursor within the display should have a distinctive visual attribute that does not obscure other displayed entities. The cursor's shape and size should make it easily visible on the screen and easy to find. When fine positioning accuracy is required, as in some forms of graphic and image-processing applications, the displayed cursor should include an appropriate point designation feature (such as cross hairs). The cursor should not move beyond the display boundaries and disappear from sight. If the cursor is moved by depressing a key, releasing the key should cause the cursor to stop moving.

12.2.9.3 Home default position

The home position for the cursor should be consistent across similar types of displays.

12.2.9.4 Explicit activation

A separate, explicit action, distinct from cursor positioning, should be required for the actual entry (e.g., enabling, activation) of a designated position (For possible exceptions, see 12.5.2.2.1).

12.2.9.5 Consistent positioning

Where cursor positioning is incremental by discrete steps, the step size of cursor movement should be consistent horizontally (i.e., in both right and left directions) and vertically (in both up and down directions).

12.2.9.6 Keyboard cursor control

When position designation is required in a task emphasizing keyed data entry, cursor control should be by some device integral to the keyboard. If cursor movement is accomplished by depressing keys, those keys should be located on the main keyboard.

12.2.9.7 Movement relationships

The response of a cursor to control movements should be consistent, predictable, and compatible with the user's expectations. For example, when the cursor is controlled by key action, a key labeled with a left-pointing arrow should move the cursor leftward on the display; when cursor control is by a joystick, leftward movement of the joystick control should result in leftward movement of the cursor.

12.2.10 Abbreviations, mnemonics, and codes

When mnemonics or codes are used to shorten data entry, they should be distinctive and have a relationship or association to normal language or specific job-related terminology. Abbreviations should be the same length and as short as possible while ensuring they are unique and interpretable.

12.2.11 Explicit delete action

Data deletion or cancellation should require an explicit action, such as the depression of a DELETE key. When a data delete function has been selected by a user, a means of confirming the delete action should be provided, such as a dialogue box with a delete acknowledgment button or a response to a question such as "Are you sure? (y/n)." In general, requiring a second press of the DELETE key is not preferred because of the possibility of an accidental double press. Similarly, after data have been entered, if the user fails to "enter" the data formally (for instance, by pressing an ENTER or OK key), the data should not be deleted or discarded without confirmation from the user.

Deleted data should be maintained in a memory buffer from which they can be salvaged (an "undelete" option). The size and accessibility of this buffer should depend on the value of the data that the user can delete from the system.

12.2.12 Change of data

The user should always be given the opportunity to change a data entry after the data have been posted. When a user requests change (or deletion) of a data item that is not currently being displayed, the option of displaying the old value before confirming the change should be presented.

Where a data archive is being created, the system should record both the original entry and all subsequent amendments.

12.2.13 Single method of data entry

Data entry methods and data displays should not require the user to shift between entry methods unnecessarily.

12.2.14 Data entry display

Where data entry onto an electronic display is permitted only in prescribed areas, a clear visual definition of the entry fields should be provided.

12.3 Automatic data entry

Where data are automatically acquired, the information should conform to 10.2.1.

12.3.1 Format

Data automatically acquired should be stored in a form that is readily accessible and appropriate for the intended user. The display format should conform to 10.2.2.

12.3.2 Sampling intervals

The sampling interval (or polling rate) should be appropriate for the resolution required for each measured variable.

12.3.3 Manual data entry

The capability for manual data entry and manual amendment of automatically acquired data is usually necessary in automatic data acquisition systems. Such manual data entry should conform to 12.2.

12.4 Data display

12.4.1 Display format

12.4.1.1 Consistency

Display formats should be consistent within a system:

a) When appropriate for users, the same format should be used for input and output.

b) Data entry formats should match the source document formats.

c) Essential data, text, and formats should be under computer—not user—control.

d) Display configuration may be included as a user default. See 12.8.2 and 12.8.3.

12.4.1.2 Criticality

Only data essential to the user's needs should be displayed.

12.4.1.3 Readily usable form

Data should be presented in a readily usable and readable form so that the user does not have to transpose, compute, interpolate, or mentally translate into other units, number bases, or languages.

12.4.1.4 Order and sequences

When data fields have a naturally occurring order (e.g., chronological or sequential), such order should be reflected in the format organization of the fields.

12.4.1.4.1 Data grouped by importance

Where some displayed data items are of great significance or require immediate user response, those items should be grouped and displayed prominently.

12.4.1.4.2 Data grouped by function or logical association

Where sets of data are associated with particular questions or related to particular functions, each set may be grouped together to help illustrate those functional relationships.

12.4.1.4.3 Data grouped by frequency

Data items that are used more frequently than others may be grouped together.

12.4.1.5 Data separation

Separation of groups of information should be accomplished through use of blanks, spacing, lines, color coding (see 8.3.2), or other means consistent with the application.

12.4.1.6 Recurring data fields

Data fields that recur within a system should have consistent names and consistent relative positions within displays.

12.4.1.7 Extended alphanumerics

When five or more alphanumeric characters without natural organization are displayed, they should be grouped in blocks of three to five characters within each group, separated by a minimum of one blank space or other separating character such as a hyphen or slash.

12.4.1.8 Comparative data fields

Data fields to be compared on a character-by-character basis should be positioned so that the characters to be compared are aligned.

12.4.1.9 Display labels and titles

Each display window should be identified with a title or label that is unique within the system. Field or column headings should be labeled to make the display as meaningful as possible and to reduce user memorization requirements.

12.4.1.10 Command entry, prompts, messages

A means for command entry, prompting and messaging should be provided on each display. Commonly used methods employ menu bars or reserve a portion of the display for status and error messages, prompts, and command entry.

12.4.1.11 Data group labels

Each individual data group or message should contain a descriptive title, phrase, word, or similar device to designate the content of the group or message. Labels should follow the general guidelines outlined in 8.1 and should also

a) be located in a consistent fashion adjacent to (and preferably above or to the left of) the data group or message they describe;

b) be unambiguously related to the group, field, or message they describe;

c) be highlighted or otherwise accentuated to facilitate operator scanning and recognition. The technique used to accentuate labels should differ from, and should easily be distinguished from, that used to highlight or code emergency or critical messages;

d) be unique and meaningful to distinguish them from data, error messages, or other alphanumerics;

e) be displayed in upper case only, while text may be displayed in upper and lower case;

f) reflect the question or decision being posed to the user, when presenting a list of user options.

12.4.1.12 Paging and scrolling

When a list or collection of related items extends across several pages, the position of each page relative to that of all related pages should be indicated. If items are numbered, those continued on the next page should be numbered relative to the last item on the previous page. When two data items are critically related, they should always be displayed together on the same screen. When items are presented in a scrolling list, the relative position in the list of a highlighted item on the list should be indicated. The scrolling convention should remain consistent throughout the system (activation of an "up" arrow should consistently move the page or the window up).

12.4.1.13 Screen/frame identification

For particular user interface styles and applications, each screen/frame should be identified in a unique manner to facilitate its recognition and to provide a reference for selecting the screen/frame for display or printout. The identifier may be a meaningful title or perhaps an alphanumeric code or abbreviation that is appropriately displayed in a consistent location. Such codes should be short (3 to 7 characters) and/or contextually relevant to facilitate recall.

12.4.2 Display content

12.4.2.1 Standardization

The content of displays within a system should be presented in a consistent, standardized manner.

12.4.2.2 Information density

Information density should be held to a minimum in displays used for critical tasks. A minimum of one character space should be left blank vertically above and below critical information with a minimum of two character spaces left blank horizontally before and after (see 12.4.1.5).

12.4.2.2.1 Crowded displays

When a display contains too much data for presentation in a single frame, the data should be partitioned into separately displayable pages.

12.4.2.2.2 Related data on same page

When partitioning displays into multiple pages, functionally related data items should be displayed together on a single page.

12.4.2.2.3 Page numbering

Each page of a multiple-page display should be labeled to identify the currently displayed page and its relation to the other pages.

12.4.2.2.4 Display of related information

When related information is displayed either in two distinct locations or sequentially in the same display location, the relationship between units of information should be clear and consistent.

12.4.2.3 Abbreviations and acronyms

Information should be displayed in plain, concise text wherever possible. Abbreviations and acronyms should conform to conventions that are familiar to the intended users. Abbreviations should be distinctive to avoid confusion. Words should have only one consistent abbreviation. No punctuation should be used in abbreviations. Definitions of all abbreviations, mnemonics, and codes should be provided—online—at the user's request.

12.4.2.4 Data entry and display consistency

Data display word choice, format, and style should be simple, direct, and consistent with the requirements for data entry and control.

12.4.2.5 Context for displayed data

The user should not have to rely on memory to interpret new data; each data display should provide the needed context, including the recapitulation of prior data from prior displays as necessary.

12.4.3 Display coding

12.4.3.1 Use

Coding should be employed to differentiate between items of information and to call the user's attention to changes in the state of the system. Coding should be used for such things as critical information or commands, out-of-range or abnormal values, items that have been changed, or are to be changed, high-priority messages, special display areas, and errors in data entry. Coding should be consistent and meaningful and should not reduce legibility or increase recognition time.

12.4.3.2 Flash

Flash coding should be employed only to call the user's attention to critical information (see also 11.5). In certain cases, a lowlight/highlight cycle may be preferable to an on/off cycle so the user will be able to read the flashing information at all times.

12.4.3.3 Brightness

Coding through the use of light intensity may be employed to differentiate between items of information. No more than two levels of brightness should be used and these should be separated by at least a 2:1 luminance ratio.

12.4.3.4 Pattern and location

Information should be arranged in logical patterns that are consistent with the intended users' mental model of the system. Generally, information should be displayed consistently in the same spatial location. This is especially important for the display of critical information. Where values for different parameters may be similar, and therefore confused, these parameters should be separately displayed or differentially coded in some other effective manner. Pattern and location coding should be employed to reduce user search time by restricting the area to be searched to prescribed segments.

12.4.3.5 Underlining

Underlining can be employed as a form of highlighting to indicate active items, unusual values, errors in entry, changed items, or items to be changed.

12.4.3.6 Symbol and size

Symbol coding may be employed to enhance the assimilation of information from data displays. Symbols should be analogues of the event or system element they represent, or they should be in general use and be well known to the expected users. Symbol size can be used to indicate the relative importance or priority of the information related to the symbol. Where size differences between symbols are employed, the major dimension of the larger should be at least 150 percent of the major dimension of the smaller, with a maximum of three size levels permitted.

12.4.3.6.1 Special symbols

Special symbols used to signal critical conditions should only be used for that purpose.

12.4.3.6.2 Marker's proximity to words marked

When a special symbol is used to mark a word, the symbol should be separated from the beginning of the word by one space.

12.4.3.7 Color

Color coding may be employed to differentiate between classes of information in complex, dense, or critical displays. The colors selected should not conflict with the color associations specified in 8.3.2 and table 7 (see page 41). Information should not be coded solely by color if the data can be accessed from monochromatic as well as color terminals or printed in monochrome hardcopy versions. Pattern substitution for colors can be used on monochrome displays.

NOTE—See Thorell and Smith, 1990 and ISO 9241-8, 1989 for further information about use of color.

12.4.3.8 Shape

Shape coding may be used for search and identification tasks. When shape coding is used, the codes selected should be based on established standards or conventions.

12.4.3.9 Brightness inversion

Brightness inversion (reverse video) is the display of dark characters on a bright background where bright characters on dark background is the normal display format (or vice versa). It may be used for highlighting critical items that require user attention. When used for alerting purposes, brightness inversion should be reserved for that purpose and should not be used for general highlighting.

12.4.4 Dynamic displays

12.4.4.1 Changing values

Where users need to reliably read alphanumeric values that change, updating such displays should not occur more often than once per second. The updating rate should be determined by the nature of the information and the manner in which it will be used.

12.4.4.2 Display freeze

A display freeze mode should be provided to allow close scrutiny of any selected frame that is updated or advanced automatically by the system. For frozen display frames used during real-time monitoring, the display should resume at the current real-time point. An appropriate label should be provided to remind the operator when the display is in freeze mode.

NOTE—Care should be used in the design of a freeze function for display of a real-time monitoring waveform or data if confusion can arise between frozen data and new data. If the display is frozen and then unfrozen, and the display resumes from the frozen point, disjoint events could appear contiguous. For example, an electrocardiogram tracing could falsely indicate an irregular heart rhythm. In such cases, the frozen display should be cleared before the real-time waveform resumes. Alternatively, frozen data or waveforms should be differentiated from real-time data or waveforms through the use of different colors, shading, highlighting, or the like.

12.4.5 Tabular data

12.4.5.1 Use

Tabular displays should be used to present row-column data to aid the detailed comparison of ordered sets of data.

12.4.5.2 Standard formats

The location of recurring data should be similar among all tabular data displayed and common throughout the system.

12.4.5.3 Arrangement

If the data in the rows have an order, the order should increase from left to right. If the data in the columns have an order, the order should increase from top to bottom of the display unless the requirements of a specific application dictate otherwise.

12.4.5.4 Titles

When tabular data are divided into classifications, the classification titles should be displayed and the subclassifications should be identified. When tabular data extend over more than one page vertically, the columns should be titled identically on each page.

12.4.5.5 Horizontal extension

Tabular displays should not extend over more than one page horizontally.

12.4.5.6 Lists

Items in lists should be arranged in a recognizable order, such as chronological, alphabetical, sequential, or functional, or on the basis of importance. Each item in a list should start on a new line. When listed items are to be numbered, Arabic rather than Roman numerals should be used.

12.4.5.6.1 Multiple columns and rows

Rows and columns should be labeled distinctively to guide data entry. Where items in a list are displayed in multiple columns, items should be ordered vertically within each column. Column spacing within a table and from one table to another should be uniform and consistent. A column separation of at least three spaces should be maintained. In tabular displays, the units of displayed data should be consistently included in the column labels.

In dense tables with many rows, a method of visual separation should be used. For example, a blank line or other delineator may be inserted after a group of rows at regular intervals. Alternatively, rows or groups of rows may have different colored backgrounds or shading. No more than five lines should be displayed without a visual separator.

12.4.5.6.2 Vertical extension

Where lists extend over more than one display page, the last line of one page should be the first line on the following page. Single items in a list that continue for more than one line should be marked in some way (e.g., blank line, indentation) so that continuation of the item is obvious. A hierarchic structure should be used to permit logical partitioning into related shorter lists.

12.4.5.6.3 Numbering and punctuation

Long numeric fields should be punctuated with spaces, commas, or slashes. Conventional punctuation schemes should be used if in common usage. Where none exists, a space should be used after every third or fourth digit. Leading zeros should not be used in numerical data except where needed for clarity.

Strings of alphanumerics should be grouped into sets of 3 to 5 characters or grouped at natural breaks. When a code consists of both letters and digits, common character types should be grouped by character type for ease of location.

Users should be allowed to make numeric entries in tables without concern for justification; the computer should right-justify integers or justify with respect to a decimal point if one is present.

12.4.6 Graphic displays

Graphic data displays may be used to present assessment of trend information, spatially structured data, time-critical information or relatively imprecise information (see 10.2.2.1).

12.4.6.1 Recurring data

See 12.4.1.6

12.4.6.2 Data updating

Graphic displays that require the user visually to integrate changing patterns should be updated at a rate consistent with the user's ability to process the information.

12.4.6.3 Graph axes

The axes of graphs should be labeled and should be graduated in accordance with 10.2.10.

12.4.6.4 Trend lines

When trend lines are to be compared, multiple lines should be used on a single graph.

12.4.6.5 Pointing

An appropriate pointing device (i.e., mouse, trackball, joystick, touch-screen) should be used in conjunction with applications that are suited to direct manipulation, such as identifying landmarks on a scanned image or selecting graphical elements (icons) from a palette of options. The suitability of a given pointing device to user tasks should be assessed by measuring data entry accuracy and speed, as well as user perceptions.

12.4.6.6 Distinctive cursor

The current cursor position on graphic displays should be indicated by a distinctive symbol at that point (e.g., a plus sign, representing abbreviated cross hairs, the intersection of which can mark a position with reasonable precision).

12.4.6.7 Precise positioning

Where data entry requires exact placement of graphic elements, users should be provided the capability to expand the critical display area (e.g., zooming and panning) to make the positioning task easier and more precise.

12.4.6.8 Confirming cursor position

For most graphics data entry, pointing should be a dual action, with the first action positioning the cursor at a desired position and the second, confirming that position to the computer. An exception may be a design allowing "freehand" drawing of continuous lines where the computer should store and display a series of cursor positions as they are entered by the user.

12.4.6.9 Selecting graphic elements

Users should be provided some means of designating and selecting displayed graphic elements for manipulation. Normally this function is performed by pointing when a pointing device is provided for drawing lines.

12.4.6.10 Displaying current attributes

During graphic data entry/editing, selected attributes that will affect current actions should be displayed for ready reference as a reminder of current selections in effect.

12.4.6.11 Easy storage and retrieval

An easy and convenient means should be provided for saving and retrieving graphic displays for their possible reuse. When appropriate, the user should be allowed to designate filenames of his or her choice for the stored graphic data.

12.4.6.12 Automatic data registration

The computer should provide automatic registration or alignment of computer-generated graphic data, so that variable data are shown properly with respect to a fixed background or maybe mapped at any display scale.

12.4.6.13 Predefined graphic formats

Where graphic data should be plotted in predefined standard formats, templates or skeletal displays should be provided for those formats to aid data entry.

12.4.6.14 Computer derivation of graphic data

When graphic data can be derived from data already available in the computer, machine aids for that purpose should be provided.

12.4.6.15 Drawing lines

When line drawing is required, users should be provided with aids for drawing straight line segments. When line segments have to join or intersect, computer aids should be provided to help connect them.

12.4.6.16 Drawing figures

When a user needs to draw figures, computer aids should be provided for that purpose (e.g., templates, tracing techniques, stored forms).

12.4.6.17 Changing size

When editing graphic data, users should be provided with the capability to change the size (scale) of any selected element on the display rather than to delete and recreate the element in a different size.

12.4.6.18 Highlighting critical data

When a user's attention has to be directed to a portion of a graphic display showing critical or abnormal data, that feature should be highlighted through some distinctive means of data coding.

12.4.6.19 Reference index

When a user needs to compare graphic data to some significant level or critical value, a reference index or baseline should be included in the display.

12.4.6.20 Data annotation

When precise reading of a graphic display may be required, the capability to supplement the graphic representation with actual numeric values should be provided.

12.4.6.21 Normal orientation for labels

The label on a dynamic graphic display should adjust position so that the top of the label remains upright when the displayed image rotates.

12.4.6.22 Pictorial symbols

Generally, pictorial symbols (e.g., icons, pictograms) should resemble the objects, features, or processes they represent. The degree to which symbols are abstract versus representative may be varied to provide acceptable legibility and reliable interpretation by users. Symbol sets should reflect graphical consistency and use common elements when possible. The reliability of symbol interpretation by users can be evaluated using procedures provided in ANSI Z535. Additional guidance for symbol selection is presented in the following documents:

IEC 417H (1987) *Graphical symbols for use on equipment*

IEC 878 (1988) *Graphical symbols for electrical equipment in medical practice*

DIN-Fachbericht 4 *Graphische Symbole nach DIN 30 600 Teil 1:* Bildzeichen

12.4.6.23 Display of scale

When a graphic display has been expanded from its normal presentation, an indicator of the scale expansion should be provided.

12.4.6.24 Consistent scaling

When users need to compare graphic data across a series of charts, the same scale should be used for each chart. Where appropriate, an overlay function may be provided to facilitate comparisons.

12.4.6.25 Single versus multiple scale

In general, when graphs are presented, only a single scale should be shown in each axis rather than including different scales for different curves in the graph. In some cases, however, efficient use of available display space may require the use of different scales. In such cases

a) each curve should be associated with its scale through use of color coding; light or heavy lines; dotted, dashed, or solid lines; or a similar technique;

b) each curve and its associated scale should be distinguishable from every other curve and its associated scale;

c) not more than three scales should be used on the same axis.

User testing should verify that the correct scale can be reliably identified for each curve.

12.4.6.26 Unobtrusive grids

When grid lines are displayed, they should be unobtrusive and should not obscure data elements. Grid lines should be displayed or suppressed at the user's option.

12.4.6.27 Direct display of differences

When users need to evaluate the difference between two sets of data, that difference should be plotted directly as a curve in its own right rather than requiring users to compare visually the curves that represent the original data sets.

12.4.6.28 Bar graphs

Bar graphs may be used for comparing a single measure across a set of several entities or for a variable sampled at discrete intervals.

12.4.6.28.1 Bar spacing

Adjacent bars should be spaced closely enough, normally not more than one bar width apart, so that a direct visual comparison can be made without eye movement.

12.4.6.28.2 Histograms (step charts)

Histograms (bar graphs without spaces between the bars) may be used where bar graphs are required and where many intervals must be plotted.

12.4.7 Text/program editing

12.4.7.1 Editing commands

Editing commands—such as MOVE, COPY, and DELETE—for adding, inserting, or deleting text/program segments should be provided.

12.4.7.2 Text editing commands

In text editing, editing commands should be based on character, word, sentence, paragraph, and higher order segments.

12.4.7.3 Program edit commands

In program editing, the special commands should be based on lines or subprograms. Program lines should reflect a numbering scheme for ease in editing and error correction. When available, line-by-line syntax checking should be under user control.

12.4.7.4 Control annotations

Where special formatting features are indicated in the text by use of special codes or annotation, insertion of the special annotation should not disturb the spacing of the displayed text and should not disturb formatting of graphs and tables or alignment of rows and columns.

12.4.7.5 Flexible printing options

In printing text, users should be allowed to select among available output formats (e.g., line spacing, character size, margin size, heading and footing) and to specify the pages of a document to be printed.

12.4.7.6 Head and foot of file

A means should be provided to move the cursor readily to the head or the foot (end) of the file.

12.5 Interactive control

12.5.1 General

General design objectives include consistency of control action, minimized need for control actions, and minimized memory load on the user, with flexibility of interactive control to adapt to different user needs. As a general principle, the user should decide what needs doing and when to do it. The selection of dialogue formats should be based on anticipated task requirements and user skills. Different types of dialogue imply differences in system response time for effective cooperation. Estimated relative requirements for user training and for system response time are given in table 14 (see next page).

12.5.1.1 Response time and feedback

System response times should be consistent with operational requirements. Required user response times should be compatible with required system response time. Required user response times should be within the limits imposed by the total user task load expected in the operational environment (see 12.6).

When system response times exceed 15 seconds for a particular transaction because of transient conditions (e.g., system processing load) the user should be provided with a capability to abort the transaction. Such capability should act like an UNDO command that stops ongoing processing and does not RESET the computer, thereby losing prior processing. The system should also provide a positive indication that the assigned task is being performed.

12.5.1.2 Simplicity

Control-display relationships should be straightforward and explicit. Control actions should be simple and direct, whereas potentially destructive control actions should require focused user attention and command validation/confirmation before they are performed.

12.5.1.3 Accidental activation

Steps should be taken to prevent accidental use of destructive controls, including possible erasures or memory dump.

12.5.1.4 Compatibility with user skill

Controls should be compatible with the lowest anticipated skill levels of users. Experienced users should have options that shortcut intervening steps provided for inexperienced users.

12.5.1.5 Availability of information

Information necessary to select or enter a specific control action should be available to the user when selecting that control action is appropriate.

12.5.1.6 Concurrent display

Control actions to be selected from a discrete set of alternatives should entail the display of those alternatives prior to the time of selection. The current value of any parameter or variable with which the user is interacting should be displayed. User control inputs should result in the display of a positive feedback response to indicate that the requested actions are being performed.

Table 14—Dialogue type versus user training and system response

Dialogue type	Required user training	Tolerable speed of system response
Question and answer	None	Moderate (.5 to less than 2 sec)
Menu selection	None	Very fast (less than .2 sec)
Form filling	Moderate	Slow (greater than 2 sec)
Function keys	Moderate	Very fast (less than .2 sec)
Command language	High	Moderate/slow (.5 to greater than 2 sec)
Natural/query language	Moderate	Fast (.2 to less than .5 sec)
Graphic interaction	High	Very fast (less than .2 sec)

(From MIL-STD-1472D)

12.5.1.7 Hierarchical process

When hierarchical levels of menus are used to control a process or sequence, the number of levels should be minimized. For normal operating modes, no more than three command levels should be used. For critical functions, every effort should be made to implement a single command level. Display and input formats should be similar within levels and the system should indicate the current positions within the sequence at all times.

12.5.1.8 User memorization

The requirement to learn mnemonics, codes, special or long sequences, or special instructions should be minimized.

12.5.1.9 User interaction style

The choice of user interaction style dialogue type (e.g., form filling, menus, command language) for interactive control should be compatible with user characteristics, task requirements, and hardware.

12.5.1.10 Number system

When numeric data are displayed or required for control input, such data should be in the decimal system, rather than the binary, octal, hexadecimal, or some other number system.

12.5.1.11 Data manipulation

The user should be able to manipulate data without concern for the internal storage and retrieval mechanisms of the system.

12.5.1.12 Computer processing constraints

The sequence of transaction selection should generally be dictated by user choices and not by internal computer processing constraints.

12.5.1.13 Feedback for correct input

Feedback responses to correct user input should consist of changes in the state or value of those elements of the displays that are being controlled. These responses should be provided in an expected and logical manner. An acknowledgment message should be employed in those cases where the more conventional mechanism is not appropriate or where feedback response time must exceed 1 second.

12.5.1.14 Feedback for erroneous input

Where control input errors are detected by the system (see 12.9.2), error messages should be available as provided in 12.9.5, and error recovery procedures should be as provided in 12.9.8.

12.5.1.15 Control input data display

The presence and location of control input data entered by the user should be clearly and appropriately indicated. Displayed data should not mislead the user with regard to nomenclature, units of measure, sequence of task steps, or time phasing.

12.5.1.16 Originator identification

Except for broadcast communication systems, the transmitter of each message in inter-user communications should be identified automatically.

12.5.2 Menu selection

12.5.2.1 Use

Menu selection can be used for interactive control. Menu selection of commands is useful for tasks that involve the selection of a limited number of options or that can be listed in a menu, or in cases when users may have relatively little training. A menu command system that involves several menu layers can be useful when a command set is so large that users are unable to commit all the commands to memory and a reasonable hierarchy of commands exists for the user.

Menu selection may be significantly less efficient than other means of data entry; this factor should be considered for real-time systems where rapid user response inputs are required.

12.5.2.2 Selection

12.5.2.2.1 Pointing devices

Pointing devices (e.g., mouse, trackballs, lightpens, touch technology; see section 9) should be used for menu selection. Where design constraints do not permit pointing devices, a standard window should be provided for the user to key the selected option code. If menu selection is accomplished by pointing, dual action validation generally should be used. The first action should designate the selected option. This should be followed by a separate action to enter the selection in the computer program. Where separate selection and enter actions are used, and when the absence of a datum is significant (e.g., the system assumes a default value in lieu of the operator's entry), an "enter" action should not be permitted unless the user (a) has made a selection; (b) has indicated a null selection (e.g., by selecting "none" on the menu); and (c) has been warned by the system that no valid selection was made, and the user acknowledges the null section. In certain instances (e.g., typewriting keys or dedicated function keys), a single action may both designate and implement the selected option without requiring a second confirmation action.

12.5.2.2.2 Titles

Each page of options (menu) should have a title that clarifies the purpose of that menu.

12.5.2.2.3 Series entry

Users should be provided the capability of stacking menu selections, (i.e., to make several menu selections without having each menu displayed).

12.5.2.2.4 Sequences

A menu should not consist of a long list of multipage options but should logically be segmented to allow several sequential selections among a few alternatives.

12.5.2.3 Active option presentation

The system should distinguish between available and unavailable menu selections, and permit selection of only those which are currently available.

12.5.2.4 Format consistency

Menus should be presented in a consistent format throughout the system and should be readily available at all times.

12.5.2.5 Option sequence

Menu selections should be listed in a logical order or, if no logical order exists, in descending order of frequency of use.

12.5.2.6 Simple menus

When the number of selections can fit on one page in no more than two columns, a simple menu should be used. If the selection options exceed two columns, hierarchical menus may be used.

12.5.2.7 Option presentation

Selection codes and associated descriptors should be presented on single lines.

12.5.2.8 Direct function call

If several levels of hierarchical menus are provided, a direct function call capability should be provided so that the experienced user does not have to step through multiple menu levels.

12.5.2.9 Consistency with command language

When menu selection is employed to provide training in the use of a command language, the wording and order should be consistent with that of the command language.

12.5.2.10 Option coding

When selections are indicated by coded entry, the code associated with each option should be included on the display in some consistent manner.

12.5.2.11 Keyed codes

If menu selections should be made by keyed codes, the options may be coded using the first several letters of their displayed labels rather than by more arbitrary numeric codes. Defined codes, however, should not duplicate any other user function codes. In some cases, coded keyboard entries or function keys may be used to accelerate menu selection.

12.5.2.12 Position in structure

When a menu can be traversed using clearly defined hierarchical paths, the user should be given some indication of the displayed menu's current position in the overall or relevant structure, such as an optional display of "path" information. A menu tree showing the menu hierarchy should be included in the user manual.

12.5.2.13 Previous menu

When using hierarchical menus, the user should be able to return to the next higher level by using single key action until the initial, top-level menu or display is reached.

12.5.2.14 Return to top level

A function should be provided to recall directly the initial, top-level menu or display without stepping through the menu or display hierarchy.

12.5.3 Form filling

12.5.3.1 Use

Form-filling interactive control may be used when some flexibility in data to be entered is needed and when the users will have moderate training. A form-filling dialogue should not be used when the computer has to handle multiple types of forms and computer response is slow.

12.5.3.2 Grouping

Displayed forms should be arranged so that related items are grouped together.

12.5.3.3 Format and content consistency

The format and content of displayed forms should be perceptually related to that of paper forms if paper forms are used to guide data entry. A standard input form should be used. At a minimum, the items on corresponding paper and displayed forms should be sequenced alike.

12.5.3.4 Distinctiveness of fields

Fields or groups of fields should be separated by spaces, lines, or other delineation cues. Required fields should be distinguished from optional fields.

12.5.3.5 Field labels

Field labels should be presented distinctly so that they can be distinguished from data entry. Labels for data entry fields should incorporate additional cueing of data format where the entry is made up of multiple inputs (e.g., DATE [MM/DD/YY]: _ _/_ _/_ _).

12.5.3.6 Field selection

A displayed cursor should be positioned by the system at the first data entry field when the form is displayed. A convenient procedure should be provided to enable movement into the next appropriate field. The procedure used to enable movement should be distinct from other data entry procedures.

12.5.3.7 Entry length indication

The maximum acceptable length for variable length fields should be indicated.

12.5.3.8 Overwriting

Data entry accomplished by overwriting a set of characters in a field (such as a default) should not be used.

12.5.3.9 Unused underscores

When an item length is variable, the user should not have to remove unused underscores.

12.5.3.10 Dimensional units

When a consistent dimensional unit is used in a given entry field, the dimensional unit should be provided by the computer. When the dimensional unit varies for a given field, it should be provided, or selected, by the user.

12.5.3.11 User omissions

When required data entries have not been input, the omission should be indicated to the user and either immediate or delayed input of the missing items should be allowed. For delayed entry, the user should be provided with a method of indicating that the missing item is delayed, not overlooked.

12.5.3.12 Nonentry areas

Nonentry (protected) areas of the display should be designated and made inaccessible to the user via the cursor.

12.5.3.13 Flexible data entry

When multiple data items are entered as a single transaction, the user should be allowed to reenter, change, or cancel any item before taking a final ENTER action.

12.5.3.14 Informative labels

Descriptive wording should be employed when labeling data fields; use of arbitrary codes should be avoided.

12.5.3.15 Logical order

When no source document or external information is involved, forms should be designed so that data items are ordered in a logical sequence for input.

12.5.3.16 Form filling for control entry

Form filling should be considered as an aid for composing complex control entries. For example, for a print request, a displayed form might help a user invoke the various format controls that are available.

12.5.3.17 Editing capabilities

Where appropriate, the user should be able to modify lengthy text or data entries without having to reenter the entire string.

12.5.4 Fixed-function keys

Fixed-function key, interactive control may be used for tasks requiring a limited number of control inputs or in conjunction with other dialogue types.

12.5.5 Command language

12.5.5.1 Use

Command language interactive control may be used for tasks involving a wide range of user inputs and when user familiarity with the system can take advantage of the flexibility and speed of the control technique.

12.5.5.2 User viewpoint

A command language should reflect the user's point of view in such a way that the commands are logically related to the user's conception of how the system works and what is being done.

12.5.5.3 Distinctiveness

Command names should be distinctive from one another.

12.5.5.4 Punctuation

The command language should contain a minimum of punctuation or other special characters.

12.5.5.5 Abbreviations

The user should be permitted to enter the full command name or an abbreviation for any command of more than 5 characters.

12.5.5.6 Standardization

All commands and their abbreviations, if any, should be standardized and consistent with accepted programming conventions.

12.5.5.7 Displayed location

Commands should be entered and displayed in a standard location on the display.

12.5.5.8 Command prompts

The user should be able to request prompts, as necessary, to determine required parameters or available options for an appropriate next command entry.

12.5.5.9 Complexity

The command language should be programmed in layers of complexity such that the basic layer will allow the inexperienced user to control a transaction. As this person's skill increases, the command language should allow skipping from basic to more advanced layers to meet the user's current needs.

12.5.5.10 User definition of macro commands

Programming should not accept a user-designated macro name without a confirmation step before that macro name is accepted. This confirmation step may be integrated into a feature allowing the user to either replace the existing macro or to edit that macro.

12.5.5.11 Standard techniques for command editing

Editing of erroneous command entries should be performed using the same techniques employed to edit erroneous data entries. Use of consistent editing techniques speeds learning and reduces errors.

12.5.5.12 Destructive commands

When a command entry may have destructive consequences, the user should be required to review and confirm a displayed interpretation of the command before it is executed.

12.5.6 Question and answer

12.5.6.1 Use

Question-and-answer dialogues should be considered for routine data entry tasks when data items are known and their ordering can be constrained, when users have little or no training, and when the computer is expected to have moderate response speed.

12.5.6.2 Questions displayed separately

Each question should be displayed separately in question-and-answer dialogues; users should not be required to answer several questions at once.

12.5.6.3 Recapitulating prior answers

When a series of computer-posed questions are interrelated, answers to previous questions should be displayed when they will provide context to help a user answer the current question.

12.5.6.4 Source document capability

When questions prompt entry of data from a source document, the question sequence should match the data sequence in the source document.

12.5.7 Query language

12.5.7.1 Use

Query language dialogue should be used for tasks emphasizing unpredictable information retrieval with trained users.

12.5.7.2 Natural organization of data

Query languages should reflect a data structure or organization perceived by users to be natural (conforms to the user's system model). For example, if a user supposes that all data about a particular topic are stored in one place, then the query language should permit such data to be retrieved by a single query even though actual computer storage might carry the data in various files.

12.5.7.3 Coherent representation of data organization

A single representation of the data organization for use in formulating queries should be established. For example, the user need not know that different queries will access different data bases over different routes.

12.5.7.4 Task-oriented wording

The wording of a query should simply specify what data are requested; a user should not have to tell the computer how to find the data.

12.5.7.5 Logic to link queries

The query language should be designed to include logic elements (e.g., "and," "or") that permit users to link sequential queries as a single entry.

12.5.7.6 Confirming large-scale retrieval

If a query will result in a large-scale data retrieval, the user should be required to confirm the transaction or take further action to narrow the query before processing.

12.5.8 Graphic interaction

12.5.8.1 Use

Graphic interaction as a dialogue may be used to provide graphic aids as a supplement to other types of interactive control.

12.5.8.2 Iconic menus

Graphic menus may be used that display icons to represent the control options. This may be particularly valuable when system users have different linguistic backgrounds.

12.5.8.3 Supplementary text labels

When icons are used to represent control actions in menus, textual labels may be desirable with each icon to help assure that its intended meaning will be understood. This is essential in life critical control actions.

12.6 Feedback

12.6.1 Use

Feedback should be provided that presents status information, confirmation, and verification throughout the interaction.

12.6.2 Standby

When system functioning requires the user to standby, WORKING, BUSY, or WAIT messages should be displayed until user interaction is again possible. When the delay is likely to exceed 15 sec, the user should be informed. For delays exceeding 30 sec, a numerical or graphical indication of the remaining delay time should be provided (see also 12.5.1.1).

12.6.3 Process outcome

When a control process or sequence is completed or aborted by the system, a positive indication should be presented to the user about the outcome of the process and the requirements for subsequent user action.

12.6.4 Current modes

When multiple modes of operation exist, a means should be provided to remind the user of the current mode.

12.6.5 Highlighted option selection

When a displayed message or datum is selected as an option or input to the system, the subject item should be highlighted to indicate acknowledgment by the system.

12.6.6 User input rejection

If the system rejects a user input, feedback should be provided to indicate why the input was rejected and the required corrective action. Feedback should be self-explanatory.

12.6.7 Feedback message content

Users should not be required to translate feedback messages by using a reference system or code sheets. Abbreviations should not be used unless necessary.

12.6.8 Time-consuming processes

The system should give warning information when a command will invoke a time-consuming process (see 12.5.1.1 and 12.6.2).

12.7 Prompts

12.7.1 Use

Prompts and help instructions should be used to explain commands, error messages, system capabilities, display formats, procedures, and sequences as well as to provide data. Prompting should conform to the following:

a) When operating in special modes, the system should display the mode designation and file(s) being processed.

b) Before processing any user requests that would result in extensive or final changes to existing data, the system should require user confirmation.

c) When missing data are detected, the system should prompt the user.

d) When data entries or changes will be nullified by an abort action, the user should be requested to confirm the abort.

e) Neither humor nor admonishment should be used in structuring messages; the dialogue should be strictly factual and informative.

f) Error messages should appear as close as possible in time and space to the user entry that caused the message.

g) If a user repeats an entry error, the second error message should be revised to include a noticeable change so that the user may be certain that the computer has processed the attempted correction.

12.7.2 Standard display

Prompting messages should be displayed in a standardized area of the display.

12.7.3 Explicit prompts

Prompts and help instructions for system-controlled dialogue should be explicit, and the user should not be required to memorize lengthy sequences or refer to secondary written procedural references.

12.7.4 Prompt clarity

Prompts should be clear and understandable. They should not require reference to coding schemes or conventions that may be unfamiliar to occasional users.

12.7.5 Definitions

A dictionary of abbreviations and codes should be available online. Definitions of allowable options and ranges of values should be displayable at the user's request.

12.7.6 Consistent terminology

Online documentation, offline documentation, and help instructions should use consistent terminology.

12.7.7 User confirmation

User acceptance of stored data or defaults should be possible using a single confirming keystroke.

12.8 Defaults

12.8.1 Workload reduction

Default values should be used to reduce user workload. Currently defined default values should be displayed automatically in their appropriate data fields with the initiation of a data entry transaction, and the user should indicate acceptance of the default.

12.8.2 Factory default settings

Manufacturer's default settings and configurations should be provided. These manufacturer's default settings and configurations should be activated whenever

a) the device is switched ON by the operator;

b) the device has had a loss of all power (mains power and battery power) for a period of time (this period should not be less than 5 minutes). The manufacturer's documentation should disclose the period of time after which the manufacturer's default settings are restored;

c) the user informs the device that a different patient has been connected to it (e.g., through an "admit new patient" function);

NOTE—An "admit new patient" function is desirable on many devices but is not required.

Upon user request, manufacturers should provide a convenient means by which the user may restore factory default settings.

NOTES—

1) In cases (a), (b) and (c), the device may instead automatically activate a single set of user-chosen default settings. See 12.8.3.

2) Medical devices with identical outward appearances, but different software and other internal functions, including the operation of alarm defaults and other alarm features, may cause confusion among users. This is particularly true if a user encounters different software versions in different locations. Care should be used in the design of such devices. For example, this problem may be addressed by maintaining settings as similarly as possible on different devices, offering a single screen to verify all settings and configurations, highlighting different or changed settings, and indicating differences and changes in user documentation and training.

12.8.3 User default settings

Users should have the option of defining their own default values for alarms and configurations on the basis of personal experience. A device may retain and store one or more sets of default settings chosen by the user. When more than one set of user default settings exist, the activation of these settings should require deliberate action by the user. When only one set of user default settings exist, the device may be configured to activate this set of user default settings automatically, in place of the factory default settings. (See 12.8.2 [a], [b], and [c].) Users should be able to choose factory default settings as an option. In any case, the device should indicate when user default settings are being employed.

12.8.4 Default substitution

The user should be able to replace any default value during a given transaction without changing the default definition.

12.8.5 Defaults for sequential entries

When a series of default values have been defined for a data entry sequence, the user should be allowed to default all entries or to default until the next required entry. The experienced user may not wish to accept each default value for each data field individually.

12.9 Error management/data protection

12.9.1 Error correction

When users are required to make entries into a system, an easy means of correcting erroneous entries should be provided. The system should permit correction of individual errors without requiring reentry of correctly entered commands or data elements.

NOTE—Permitting user modification of patient care data may have legal implications. While not an HFE issue, this may be important to consider nonetheless.

12.9.2 Early detection

A capability should be provided to facilitate detection and correction of errors after they are keyed in, but before they enter the system. Although it is desirable that errors be detected early, error checking should occur at logical data entry breaks (e.g., at the end of data fields rather than character by character) to avoid disrupting the user.

12.9.3 Internal software checks

User errors should be minimized by using internal software checks of user entries for validity of item, sequence of entry, completeness of entry, and range of value.

12.9.4 Critical entries

The system should require the user to acknowledge critical entries before it implements those entries. This acknowledgment may be accomplished by pressing a second, different key (such as a CONFIRM key) or by a second pressing of the ENTER key. In the latter case, a 1-second pause between presses should be required to prevent inadvertent "double presses."

12.9.5 Error message content

Error messages should be constructive and neutral in tone, avoiding phrases that suggest a judgment of the user's behavior. They should reflect the user's view, not the programmer's. Error messages should be appropriate to the user's level of training; they should be as specific as possible to the user's particular application, and should describe a way to remedy, recover, or escape from the error situation.

12.9.6 Error recovery and process change

The user should be able to stop the control process at any point in a sequence as a result of an indicated error or as an option. The user should be able to return easily to previous levels in multistep processes to rectify an error or to effect a desired change.

12.9.7 Diagnostic information

Error messages should explicitly provide as much diagnostic information and remedial direction as can reliably be inferred from the error condition. When clear inference is not possible, probable helpful inference(s) may be offered.

12.9.8 Correction entry and confirmation

User correction of an error should take effect after the user takes an explicit completion action (e.g., activation of an ENTER key). The system should acknowledge all error corrections by the user either by indicating that a correct entry has been made or by generating another error message.

12.9.9 Spelling errors

Spelling and other common errors should not produce valid system commands or initiate transactions different from those intended. When possible, the system should recognize common misspellings of commands and should execute the commands as if spelling had been correct. Computer-corrected commands, values, and spellings should be displayed and highlighted for user confirmation.

12.9.10 Errors in stacked commands

To prompt for correction of an error in stacked commands, the system should display the stacked sequence with the error highlighted. When possible, a procedure should be provided to correct the error and salvage the stack.

12.9.11 Display of erroneous entries

A computer-detected error, as well as the error message, should be displayed continuously until the error is corrected.

12.9.12 Help

In addition to explicit error management aids (labels, prompts, advisory messages) and implicit aids (cueing), users should be able to obtain further online guidance by requesting HELP. Following the output of a simple error message, users should be permitted to request a more detailed discussion at levels of increasing detail.

12.9.12.1 Standard action to request help

A simple, standard action that is always available should be provided to request HELP.

12.9.12.2 Multilevel HELP

When an initial HELP display provides only summary information, more detailed explanations should be provided in response to repeated user requests for HELP.

12.9.12.3 Browsing HELP

Users should be permitted to browse through online HELP displays, just as they would through a printed manual, to gain familiarity with system functions and operating procedures.

12.9.13 Data security

Data should be protected from user errors, potential loss from equipment failure, and unauthorized use. Automated measures to minimize data loss from errors resulting from legitimate users' or intruders' activities should be provided. Where indicated, computer logic should be provided that will generate messages and/or alarm signals to warn users of attempted intrusion by unauthorized users.

12.10 User identification

User identification procedures should be the simplest possible that are still consistent with adequate data protection. To ensure password security, passwords should not be echoed on a visual display unless visual masking is used (i.e., display a nonrelated character for each password character [see 12.1.2]). Audible, rather than visual, feedback can be used when logging in passwords if audible masking is provided. When passwords are required, users should be allowed to choose their own passwords since a password chosen by a user will generally be easier for that individual to remember. Guidelines for password selection should be provided to help users choose passwords that are not easily guessed. Users should be allowed to change passwords whenever they choose; all passwords should be changed at periodic intervals.

12.11 Other requirements

12.11.1 Overlays

Mechanical overlays, such as coverings over the keyboard or transparent sheets placed on the display, should be avoided.

12.11.2 Hardcopy

The user should have the capability to obtain a paper copy of the exact contents of the alphanumeric or digital graphic display in those systems where

a) mass storage is restricted;

b) mass stored data can be lost by power interruption;

c) recordkeeping is required.

12.11.2.1 Display print

The user should be able to print a display by simple request (e.g., PRINT-SCREEN) without having to take a series of other actions first, such as calling for the display to be filed, specifying a filename, then calling for a print of that named file. Both mechanisms may be available, however.

12.11.2.2 Print page

The user should be able to request printing of a single page or a sequence of pages by specifying the page numbers.

12.12 Data and message transmission

Data security should be considered whenever data transmission is used (see 12.10).

12.12.1 Functional integration

Data transmission functions should be integrated with other information handling functions within a system. A user should be able to transmit data using the same computer system and procedures used for general entry, display, and other processing of data.

12.12.2 Consistent procedures

Procedures for preparing, sending, and receiving data and messages should be consistent from one transaction to another and consistent with procedures for other information handling tasks.

12.12.3 Minimal memory load on users

The data transmission procedures should minimize memory load on the users by providing computer aids for automatic insertion of standard information, such as headers and distribution lists.

12.12.4 Interrupt

Users should be allowed to interrupt message preparation, review, or disposition and then resume any of those tasks from the point of interruption.

12.12.5 Stored message forms

Where message formats conform to a defined standard or are predictable in other ways, a forms library should be provided to aid users in message preparation.

12.12.6 Incorporate existing files

Users should be allowed to incorporate an existing data file in a message to combine several files into a single message for transmission and to combine stored data with new data when preparing messages for transmission. Reentry of data already entered for other purposes should not be necessary.

12.12.7 Addresses

12.12.7.1 Prompting address entry

When users need to specify the address for messages, prompting should be provided to guide the user in the process.

12.12.7.2 Address directory

Users should be provided with an online directory showing all acceptable forms of message addressing for each destination in the system and for links to external systems.

12.12.7.3 Aids for directory search

Computer aids should be provided so that a user can search an address directory by specifying a complete or partial name. It should also be possible to extract selected addresses from a directory for direct insertion into a header in order to specify the destination(s) for a message.

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Annex 1
(Informative)

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