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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

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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ANSI/AAMI HE48:1993 has been withdrawn administratively as an American National Standard.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.

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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:

Cochairs:
Frank E. Block, Jr., MD
Christopher R. Goodrich

Members:
M. Lee Bancroft, Beth Israel Hospital
Frank E. Block, Jr., MD, University of Arkansas for Medical Sciences
Peter Carstensen, Center for Devices and Radiological Health, Food and Drug Administration
Gerald Chaikin, PE, CPE, NAS, Inc.
Richard I. Cook, MD, Ohio State University 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.

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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*

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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.

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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

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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

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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

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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.

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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

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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

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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

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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

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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

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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.

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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.

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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.

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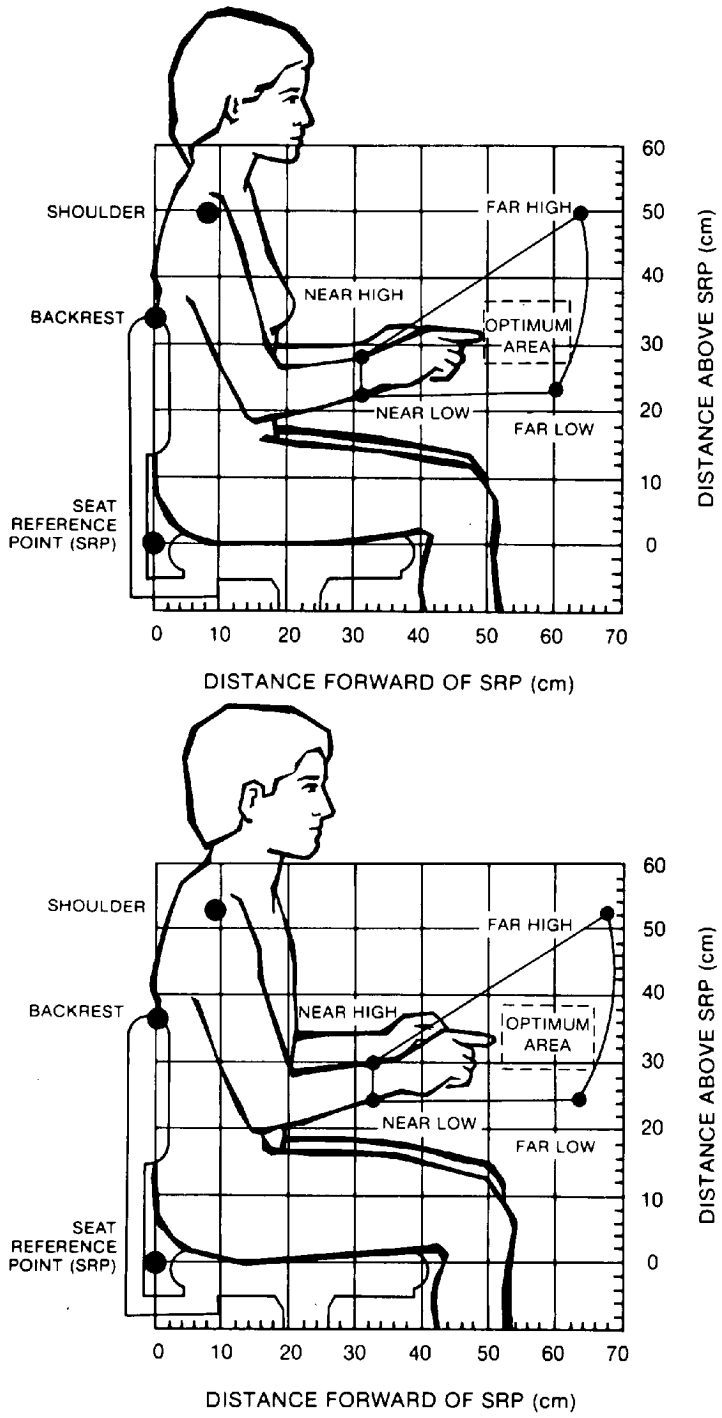


Figure 1—Optimum manual control space: seated operator

(Adapted from MIL-HDBK-759)

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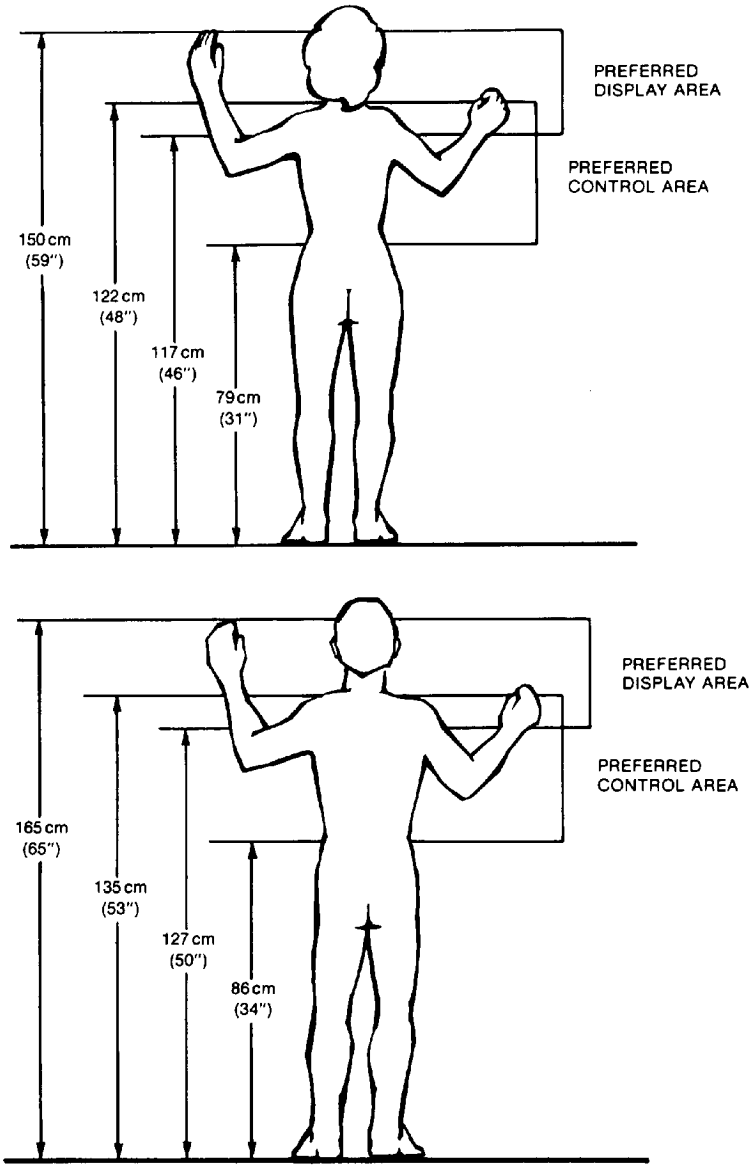


Figure 2—Preferred control and display areas, flat panel: standing operator

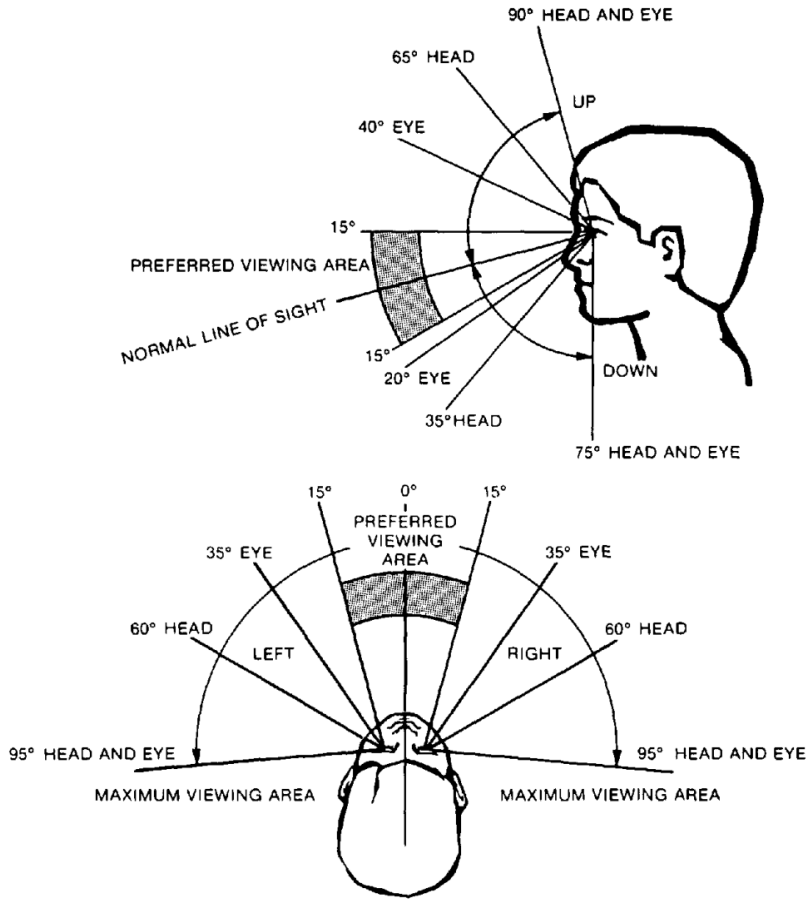
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	PREFERRED	MAXIMUM*		
		EYE ROTATION	HEAD ROTATION	HEAD AND EYE ROTATION
UP	15°	40°	65°	90°
DOWN	15°	20°	35°	75°
RIGHT	15°	35°	60°	95°
LEFT	15°	35°	60°	95°

* 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)

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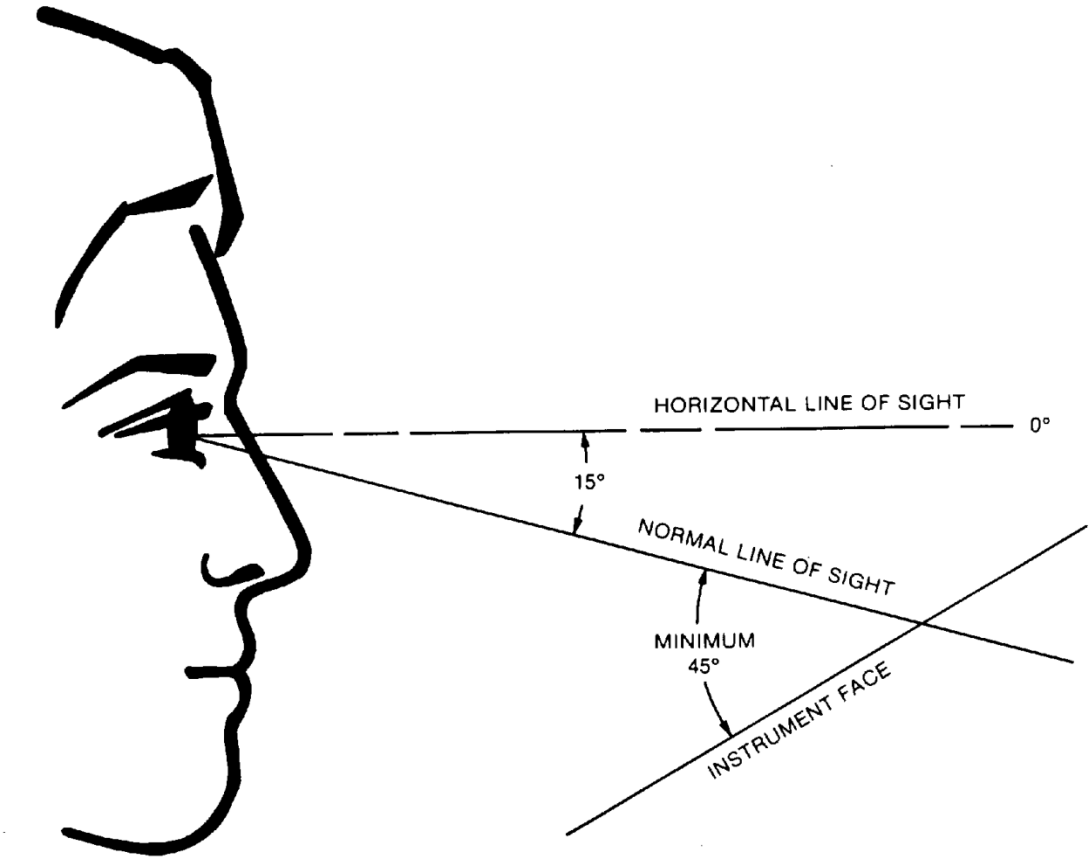


Figure 2b—Lines of sight

(Adapted from MIL-STD-1472D)

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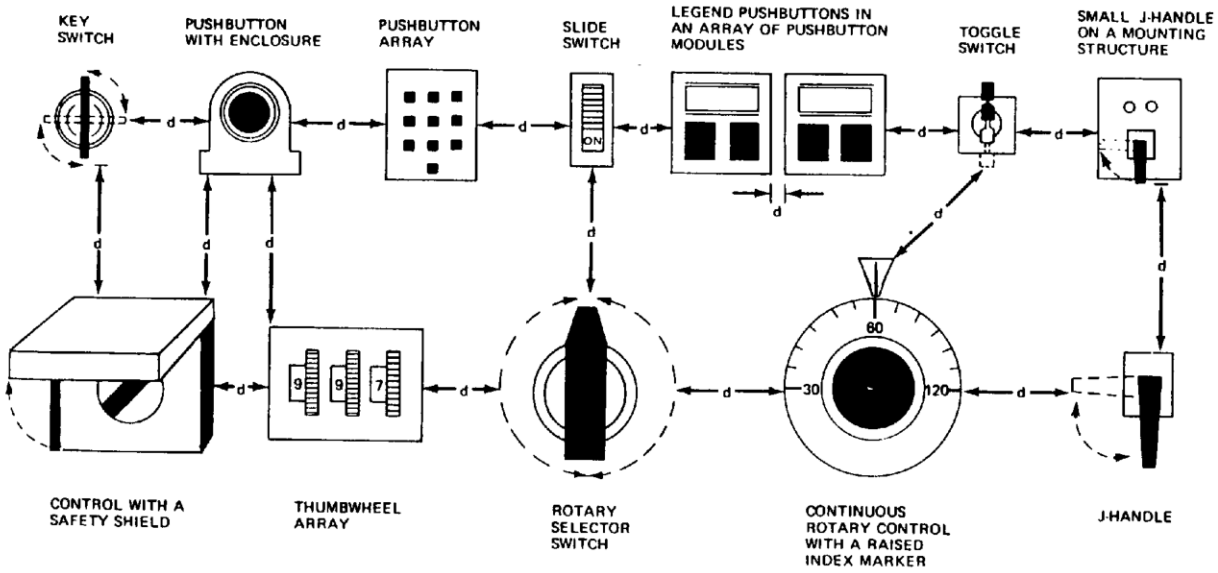


Figure 3—Measurement of minimum separation distance between controls

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)

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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

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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	Contl-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

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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

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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

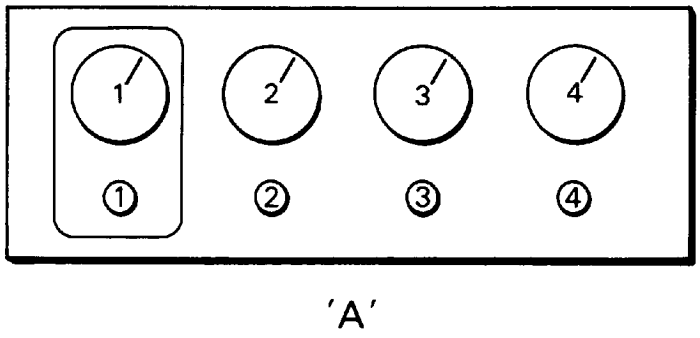
The arrangement of controls and/or displays on moving or rotating parts of a device should remain consistent with respect to each other and with respect to the user despite the device's movement or rotation. Satisfaction of this guideline may be difficult for all but the simplest arrangements. If possible,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

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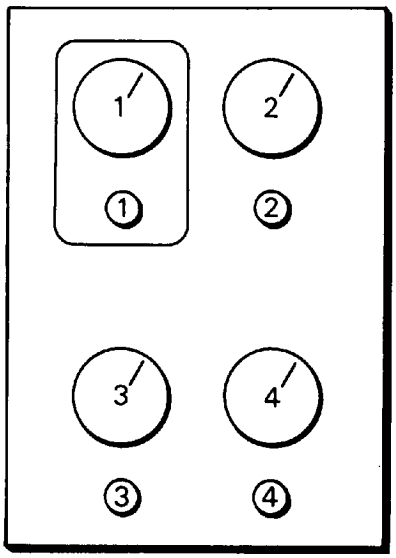
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'A'



'B'

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

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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

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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.)

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Table 4—Direction of control movement and resulting display responses

		Type of Movement	Display plane: Front			Left			Right			Bottom			Overhead		
			Up	Right	Clock-wise	Up	Forward	Clock-wise	Up	Forward	Clock-wise	Forward	Right	Clock-wise	Forward	Right	Clock-wise
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

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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

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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.

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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

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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

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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).

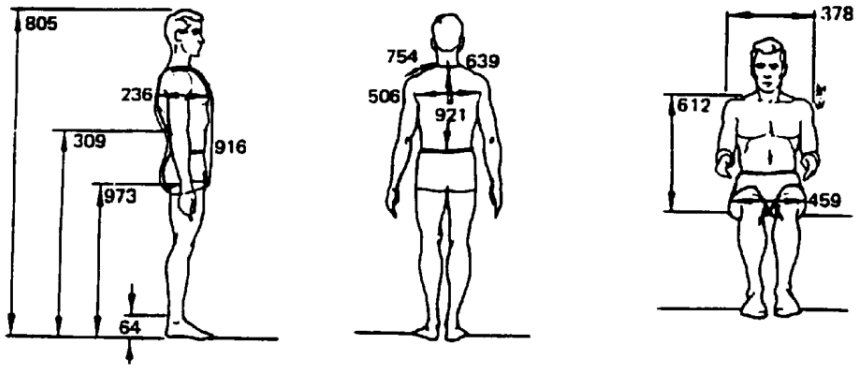
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Male



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

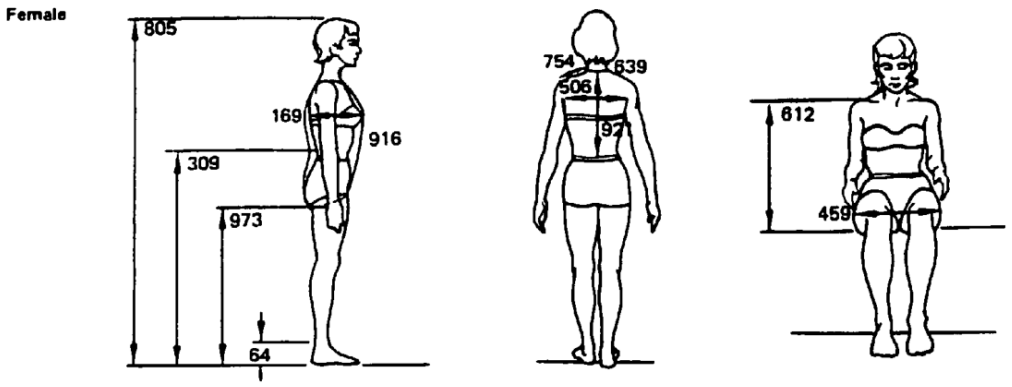
(from NASA -STD-3000)

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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)

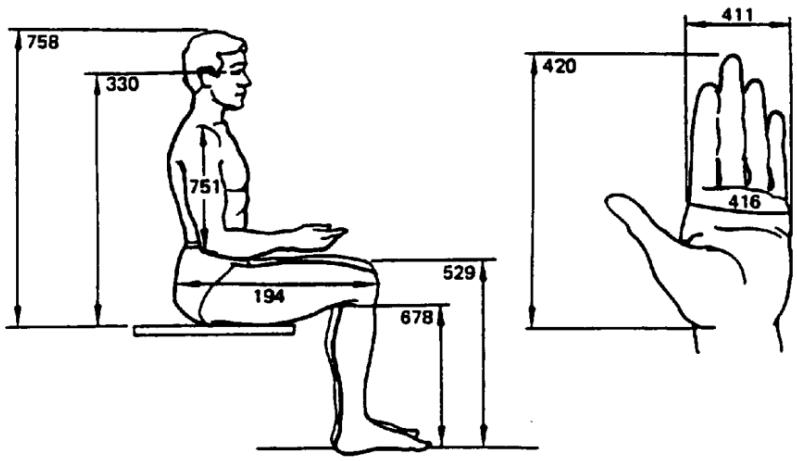
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Male



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)

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