HUMAN FACTORS ENGINEERING FOR DESIGN OF MEDICAL DEVICES

4.1 INTRODUCTION

Human factors engineering is a methodology that is crucial to effective user interface design; it entails the iterative application of various procedures and tools throughout the design cycle. Ideally, hardware and software designers, engineers, human factors practitioners, document writers, and clinical staff coordinate their efforts to achieve a user interface design that lends itself to safe device assembly, installation, operation, and maintenance.

The following factors will influence the flow of a given project:

- pre-existing data;
- complexity of the device;
- criticality of errors;
- human factors expertise;
- experience with other devices ;
- similarity of a product to an existing one;
- organizational culture; and
- competitive market pressures.

Many designers, engineers, scientists, and healthcare professionals may be unfamiliar with human factors. The purpose of this primer is to encourage manufacturers to improve the safety of medical devices by reducing the likelihood of user error.

Mistakes made during device operation not only can hamper effective patient treatment, monitoring, or diagnosis but in some cases can lead to injury or death. The

Food and Drug Administration (FDA) believes that this information is important because of its implications for patient and user safety.

4.2 Human factors analysis and testing

In considering the need for, and conduct of, human factors analysis and testing, there are a number of issues and questions to ask.

1. Does the device require user interaction with respect to operation, maintenance, cleaning, or parts installation?
2. Given the combination of user interface, user population, and operating conditions, are errors likely?
3. Could the consequences of error be serious for the patient or user?
4. In doing actual testing:
    - Is someone integral to the design team focusing on the user-related issues?
    - Are users involved?
    - Are hardware and software designers, technical writers, and others coordinating their efforts with respect to human factors?
    - Have user requirements been developed, and are they being updated?
5. What studies, analyses, and test steps are being performed? Are staff examining all relevant issues related to the installation of accessories and operation of the device?

4.2.1 Anthropometry/Ergonomics

- Measuring the Human Size
- Determining Workplace Locations
- Verifying Required Forces and Physical Loads

Anthropometry = Anthro + metry

(human) (measurement)

- **Anthropometry** is the scientific measurement and collection of data about human physical characteristics and the application (engineering anthropometry) of these data in the design and evaluation of systems, equipment, manufactured products, human environments, and facilities.

4.2.2 Workspace Design

- Monitoring

  –Process control

  –Medical applications

- Control

  –Cockpit

  –Remotely piloted vehicles

- Must consider human-environment interactions as well as physical and cognitive limitations

4.2.3 How to Accomplish the Interface

- Make the Man Fit the Job
  - Selection
  - Training
  - Motivation

- Make Job Fit the Man (or Woman)
  - Adjustability
  - Load Regulation 6

4.2.4 Some Common Errors

- Using the Wrong Subject Population

  –Age

  –Gender

  –Race

  –Fitness

4.3 Design Considerations

- Design reference points and zones
  - Seat reference points
  - Arm rotation points
  - Eye reference points or zones
  - Visual envelopes
  - Mobility and/or comfort adjustment ranges
- Dynamic measures
  - Range & strength
  - Grip
  - Grasp
  - Exerted forces
- Push, pull, vertical
- Lifting & carrying

4.3.1 Principles for C/D Layout

- Location

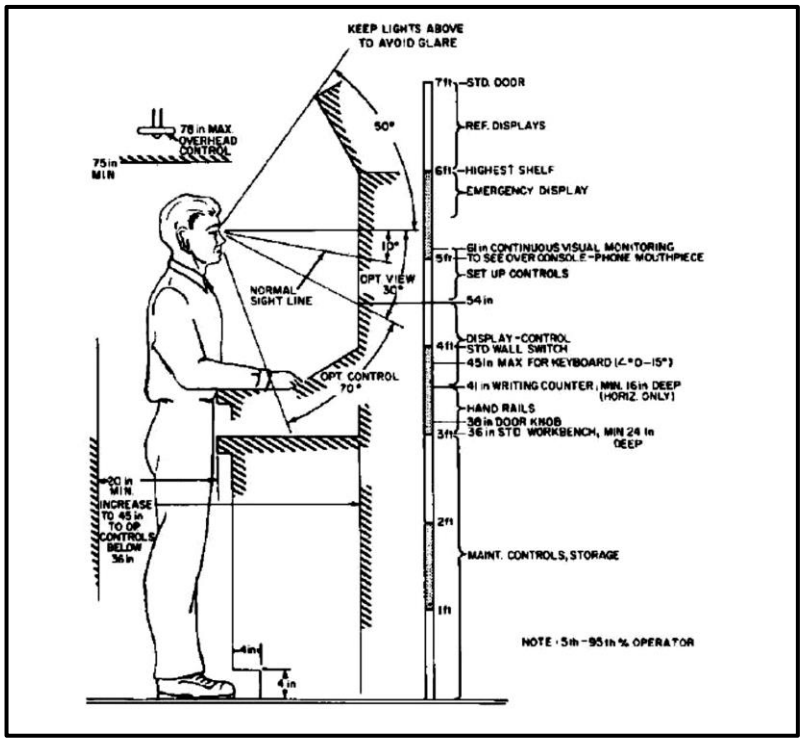
  –Operational importance of C/Ds

  –Frequency of use of C/Ds

- Grouping
  - –Functional
  - –Sequential
  - –Topological
- C/D Identification
- Stereotypical Layouts
- Individual C/D Constraints
  - –Manipulability of control
  - –Visibility of display

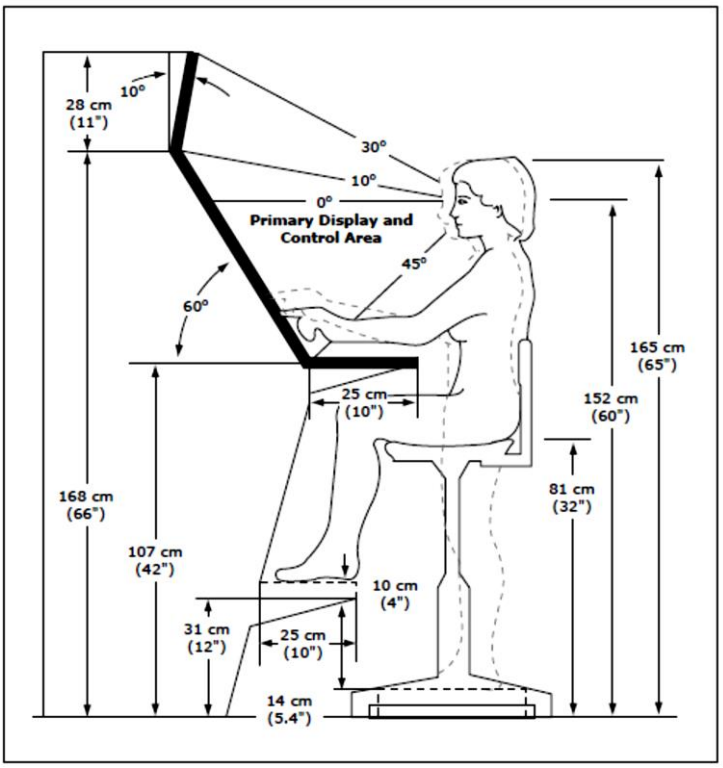
4.3.2 Ergonomics Design Flow

- Priorities
  - – Primary visual tasks & their controls
  - – Emergency controls
  - – Control/display relations
  - – Functional/sequential grouping
  - – Frequency-of-use and consistency in layout
- Priorities in automobile WS



Standing Operator Workplace

Control/Display Locations



4.3.3 Representative Human Models

- A small group of humanoids representing a designated percentage (e.g., 90%) of the target population for product design based on anthropometric data
- Benefits of RHMs in anthropometric design
- Efficient ergonomic design and evaluation
- Good fit between products and the target users.

4.3.4 Workplace Design

- General approach
- Plan the whole, then the detail
- Plan the ideal, then the practical
- Systems requirements process/equipment
- Process/equipment workplace layout
- Evaluate alternatives: models, mockups

- Workplace layout
- Define what the operator needs to see outside ws, inside ws, other people/equipment
- Define what operator needs to hear to communicate to with others, signals, alarms, equipment
- Specify what operator needs to control hand/foot controls, latches, seat adj, emergency
- Determine body clearances

4.3.5 Factors Effecting Body Size

•The distributions of body sizes are known to be normal or similar to normal

•Sources of variability

•Age

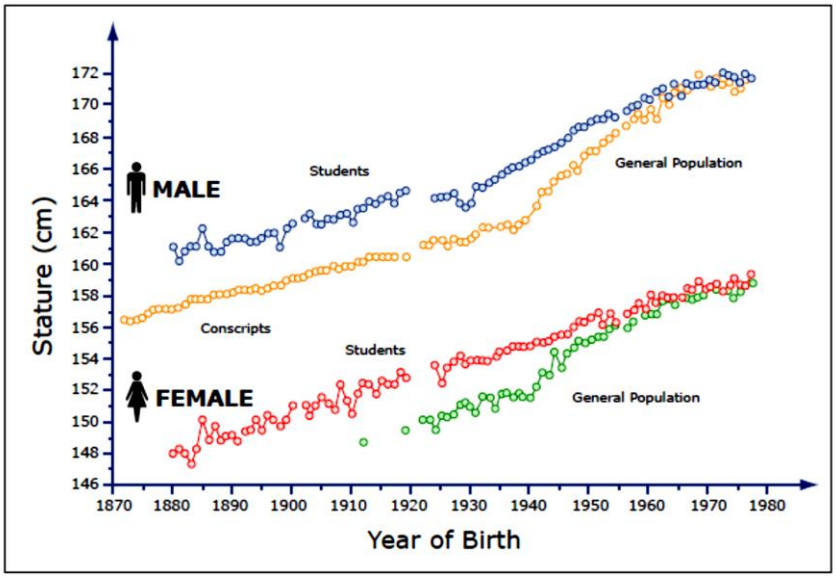
•Gender

•Racial and ethnic group

•Occupation

•Diurnal

•Secular trend



Height Growth in Japan

4.3.6 Design for Repetitive Tasks

- Work related Musculoskeletal Disoreders
  - –Housemaids Knee
  - –Instrumentalists – "Finger Overuse"
  - –Carpal tunnel syndrome (most of us)

- Force over 1kg
- Time < 10 sec
- Repetitive operations
- Lack of regular breaks

4.3.7 Lifting Disorders

- Safe techniques for Lifting
- Safe loads
- Maximum number of lifts
- The EU guideline sates “manual handling should be avoided as much as possible”
- Lower Back Injuries
- Effectiveness of Training
- Abdominal Belts

5.1 THE INTERACTION OF USERS, DESIGN, AND OPERATING ENVIRONMENT

Medical devices are used in many environments, including operating rooms, emergency rooms, patient units, x-ray departments, laboratories, emergency vehicles, critical care facilities, clinics, and homes. Performance often is compromised by noise, poor lighting, glare-producing surfaces, heat, dirt, improper cleaning products, electrical interference, humidity, and moisture. Poorly written procedures, stress, and fatigue can also degrade performance.

A medical device can be used safely and effectively only if the interaction between the operating environment, user capabilities, stress levels, and device design is considered when the manufacturer designs the device. The following dimensions of human capability are basic to an understanding of human factors.

5.1.1 Physical and Sensory Characteristics

A person's most basic physical and sensory capacities include vision, hearing, manual dexterity, strength, and reach. A number of related design factors can interact with them to influence human performance: the legibility and discriminability of displayed symbols, audibility and distinctiveness of alarms, the strength required to make connections, and the requirements for reaching controls.

5.1.2 Perceptual and Cognitive Abilities

Perception is the ability to detect, identify and recognize sensory input. Understanding human limitations and exploiting human strengths in this area is crucial for safe design of equipment. Perceptual characteristics are important in the design and arrangement of controls, keypads, displays, information presentation, and alarms.

5.1.3 DESIGN IMPLICATIONS

Designing the interface with the user in mind usually will result in a device that:

- accommodates a wide range of users working under variable,
- often stressful conditions;
- is less prone to user error; and
- requires less user training.

In general, human capability and limitations are extremely important considerations in device design.

5.1.4 THE USER INTERFACE

This section describes and discusses problems related to human factors.

- Make all facets of design as consistent with user expectations as possible.
- Design workstations, controls, and displays around the basic capabilities of the user, such as strength, dexterity, memory, reach, vision, and hearing.
- Design well-organized and uncluttered control and display arrangements.

- Ensure that the association between controls and displays is obvious.
- Ensure that the intensity and pitch of auditory signals allow them to be heard easily by device users. Consider the effects of ambient noise.
- Ensure that the brightness and color of visual signals is sufficient to be perceived
- Make labels and displays so that they can be easily read from typical viewing angles and distances.
- Ensure that the abbreviations, symbols, text, and acronyms placed on, or displayed by, the device are also used consistently in the instructional manual.
- Design control knobs and switches so that they correspond to the conventions of the user population

5.1.5 Characterizing the Shift to Software

With a large number of controls and displays, the user must identify and integrate spatially disparate information. Although such designs are still common, the trend is to assign more functions to software. This reduces the number of controls and displays, but it can increase the burden on the user in other ways.

The following are some problems that apply to many medical devices and can lead to errors:

- illogical or cumbersome control sequences;
- unfamiliar language, symbols, or codes;
- inconsistencies among display formats;
- conventions that contradict user expectations;
- uncertain or no feedback after input;
- functions that are hidden from the user;
- missing or ambiguous prompts, symbols, or icons;

Below are some general considerations that, if implemented, can prevent many software-related design errors.

- Do not contradict the user's expectation.
- Be consistent and unambiguous in the use and design of headings, abbreviations, symbols, and formats.
- Always keep users informed about current device status.
- Provide immediate and clear feedback following user entries.
- Design procedures that entail easy-to-remember steps.
- Give users recourse in the case of an error. Provide conspicuous mechanisms for correction and troubleshooting guides.

5.1.6 COMPONENT INSTALLATION

The following are general considerations for reducing the likelihood of confusion between similar components and accessories and making improper connections:

- Cables, tubing, connectors, leuers, and other hardware should be designed for easy installation and connection.
- User instructions should be understandable, and warnings conspicuous.
- If a hazard cannot be eliminated by a design solution, color codes or other markings will help the user achieve proper connections.
- Positive locking mechanisms are desirable whenever the integrity of connections may be compromised by such factors as component durability, motion, or casual contact.
- Protected electrical contacts.
- Components and accessories should be numbered, so that defective ones can be replaced with the proper items.
- Textual complexity in maintenance manuals should be reduced by adding graphics.

5.1.7 ALARMS

Alarms and related advisories are intended to alert device users about problem with

the patient and device status. This seemingly straightforward function often I complex. In some environments, alarms sounding simultaneously or intermittently o one or more devices make proper identification difficult, and staff may become distracted.

Alarm problems include the following: false alarms, delayed alarms, too sensitive or insensitive alarms, alarms drowned out by noise, ambiguous meanings inappropriate silencing, and accidental disabling.

5.1.8 Device Maintainability

Medical devices should be designed for simple maintenance, because poor maintenance can hinder safe, reliable operation. Maintenance personnel often encounter the following problems:

- poor component labeling, coding, or numbering;
- inadequate self-diagnostic capability;
- parts that are hard to locate visually or by touch;
- screws and other parts that are difficult to reach or manipulate;
- confusing component arrangements;
- requirements for difficult-to-find tools;
- inadequate design for easy cleaning; and
- materials that are not durable and degrade the user interface.

5.1.9 Device Packaging

Packaging sometimes affects operation of a device. For example, there have been incidents resulting from packaging materials enclosed in such a way that users failed to detect and remove them.

5.1.10 DOCUMENT REVIEWS

Studying documents about human factors and related device issues is valuable early in the development of a product. Such information is easy to obtain and is useful

in understanding user interface issues and human factors methods.

5.1.11 The Literature

Human factors articles, technical reports, and textbooks offer substantial information. Numerous journals, magazines, and newsletters report studies and surveys on the combined effects of design, environment, and work conditions upon device operation.

5.1.12 Manuals

Review of user instruction manuals may provide information about pitfalls to avoid and possible features to include when considering the development of a new product.

Review of the above types of documents can provide a clearer picture of the following:

- sensory, perceptual, physical and cognitive capabilities and limitations of individuals;
- environmental interactions with human performance, especially as mediated by user interface design;
- human factors principles and methods;
- generic problems associated with types of devices; and
- strengths and weakness of existing devices and the one under development.

Document reviews help one to ask the right questions, avoid pitfalls, and get the product design process off on the right track.

5.2 EXPLORATORY STUDIES

Obtaining first-hand information from physicians, nurses, and lay-users is important in assessing the strengths and weaknesses of a device design.

Direct contact with the user population is essential for good human factors work. It should be initiated in the earliest stages of product design. Observations, remarks, and

anecdotal comments about existing devices, desirable design features, and working conditions can provide the following:

- a snapshot of how healthcare professionals use devices;
- a picture of how operating conditions, including the multi-device environment, affect use;
- a snapshot of what problems are encountered;
- anecdotal reports or comments;
- a sampling of the user population with respect to individual differences;
- ideas for new designs and reactions to design concepts; and
- information necessary for establishing performance test protocols and performance criteria.

Early studies, along with document reviews and task analyses, are very important. They engender creative thinking and reduce the likelihood of major mistakes in the design process.

5.2.1 Study Methods

Below are some techniques frequently used in early studies. They are not independent of one another, and techniques discussed elsewhere, such as task analysis, may also be integrated into these approaches.

Observations: In a medical facility, the operating rooms, emergency rooms, and critical-care units are fertile areas for observational studies of associated devices.

Interviews: Interviewing is a flexible way of obtaining opinions about specific devices, problems, and user preferences and ideas about improving user-interface design.

Interviewing Users: Healthcare practitioners and lay users often hold perceptions that differ greatly from those of the designer. Valuable data can be obtained by having physicians, nurses, or home users do the following:

- walk through the operational steps;
- compare relative strengths and weaknesses of different models;
- describe "critical incidents" involving a device;
- if needed, recommend device changes; and
- assess a new device concept.

Interviewing Supervisors, Trainers, and Risk Managers: Most healthcare supervisors have fairly broad views of device strengths and weaknesses.

Interviewing Maintenance Personnel: Maintenance personnel may have a unique perspective about device problems. Users often bring to them "broken" devices that, in fact, are functional but difficult to use.

Conducting Focus Groups: Focus group sessions are group interviews of a few individuals from a specified population. The sessions are conducted to obtain opinions and ideas regarding a product concept.

Physical Measurements: Measuring sound and light will help in the assessment of such design-moderated factors as glare, contrast, and masking by ambient noise.

5.3 ANALYSES

Analyses of functions, tasks, and hazards are important to good design and will help shape the user interface by providing information about:

- user requirements and usability goals;
- other devices in the users' environment;
- bottlenecks to potential performance and error-inducing factors;
- possible hazards;
- device impact on user training; and
- device operating logic.

Analyses merit careful attention and should be woven into the development process. Depending upon the scope and purpose, the analyst usually will do some, or all, of the following:

- list the major tasks, such as calibration, entering operating parameters, attaching the device to patient, and cleaning parts;
- describe the necessary information for each task, user actions, required decisions, and related accessories;
- describe the device response for each action or step;
- record observations and inferences about design factors which potentially impact the user;
- list the effects of environmental conditions and other devices on the user interface and performance; and
- list the impact of the user interface on training requirements.

The following table shows a few steps from an analysis of a marketed infusion pump conducted by FDA. The analysts were "troubleshooting" the user interface design.

5.3.1 Hazard Analyses

Human factors should be integrated into procedures used to isolate hazardous device failures. Although these analyses conventionally deal with electrical and mechanical problems, potential hazards associated with the user also should be evaluated.

5.4 USABILITY TESTING

Testing for ease and accuracy of use is the only way to ensure that users can safely and effectively operate, install, and maintain devices. By means of *iterative prototyping*, individual concepts of design can be tested, refined, and retested throughout the

development process.

5.4.1 Testing in the "Real" Environment

The user interface should be tested under conditions that are as realistic as possible. Participants should be reminded that it is the *device*, not themselves, being tested.

Simulating Actual Conditions in the Laboratory: Some aspects of actual use conditions are relatively easy to simulate.

Simulations in Healthcare Facilities: Even without patients, performance testing in healthcare facilities adds substantial realism.

Simulations in Homes: Medical devices intended for home use should be tested in that environment. This can be especially useful in assessing devices that pose problems associated with space, portability, availability of electrical outlets, lighting, noise, and operational complexity. Lay users should participate if possible.

Clinical Trials: Ideally, one could do full testing during clinical trials; however, there are definite limits. First, manipulating the healthcare practitioner's behavior by running scenarios would be disruptive and could endanger patients. Second, the user interface design should be at least adequate *prior to* clinical trials.

Field Studies: Studies of devices already in use offer an excellent opportunity to obtain valuable information once a device is marketed. Because there are few time constraints, data can be obtained from a wide variety of settings and user groups.