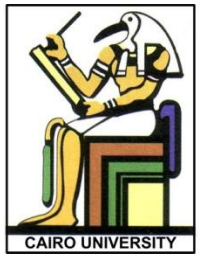


HUMAN FACTORS ENGINEERING: DESIGN OF MEDICAL DEVICES

Lecture 4

Prof. Yasser Mostafa Kadah

Environmental Considerations

- Identify factors within the use environment that affect medical device usability and safety
- Recommend appropriate design approaches that can help overcome poor use conditions
- Design recommendations to address means of overcoming existing sources of noise, illumination, temperature, humidity, vibration, and other environmental parameters that could impede the user's ability to accurately and safely use a medical device
  - Does not recommend ways to design the physical environment for medical device use

Environmental Considerations

- Medical devices are used in very diverse environments
  - hospitals, clinics, homes, public spaces
- It is important to consider how the environmental characteristics of these places differ and to apply human factors principles to device designs.
- Although many medical devices are used in only one location, others do not always remain stationary in one location
  - Example: Infusion pumps frequently used in hospitals but also used in ambulances and increasingly in patients' homes

Environmental Considerations

- Examples of environments where medical devices are used:
  - Patient's home (bedroom, den, bathroom, kitchen)
  - Emergency room (ER)
  - Operating room (OR)
  - Catheterization laboratory
  - Patient's hospital room
  - Hospital or clinic test laboratory
  - Mobile emergency hospital
  - Transport routes in a hospital or clinic (used while a patient is being moved on a bed)
  - Emergency medical transport helicopter or ambulance
  - Shopping centers or airline terminals (e.g., emergency mobile medical devices with public access)
  - Places of employment or passenger airplanes (e.g., emergency mobile medical devices with semipublic access).

General Considerations

- Clinical environment
  - Complex system of medical and support personnel, patients, and a large number of different medical devices.
  - Characterized by interprofessional and interpersonal relationships and communication.
  - Background, knowledge, culture, and experience of personnel and patients are important characteristics of this environment.
- Physical environment
  - Comprises the building and the utilities, physically hosts the clinical environment.
  - Many clinical environments have very specific, medically related physical subsystems (e.g., medical gases, special air conditioning and air filtering, sterilization equipment).

General Considerations

- Designers should consider physical environmental factors
  - Levels of noise, vibration, humidity, and heat that the device generates, and to which the device, patients, device users, and maintenance personnel are exposed in the anticipated use environment
  - Need to protect the device from contamination, electrical and electromagnetic interference, and temperature and humidity extremes
  - Need to protect maintenance personnel, users, and patients from electrical shock, thermal burns, and toxicologic, infection, radiologic, visual-injury, and explosion risks, as well as from potential hazards such as sharp edges and corners on devices, tripping, and devices falling on the patient or user
  - Adequacy of the physical, visual, auditory, and other communication links among users and between users and equipment within the use environment

General Considerations

- Designers should consider physical environmental factors
  - Importance of minimizing psychophysiological stress and fatigue in the use environment;
  - Potential effects that natural or artificial illumination could have on the operation, control, and maintenance of the device
  - Need for rapid, safe, simple, and economical maintenance and repair
  - Possible positions of the device in relation to its users (those who operate, monitor, or maintain the device) and how the device is used as a function of the user's location and mobility;
  - Electrical and electromagnetic characteristics of the physical environments
  - Unique aspects of home use

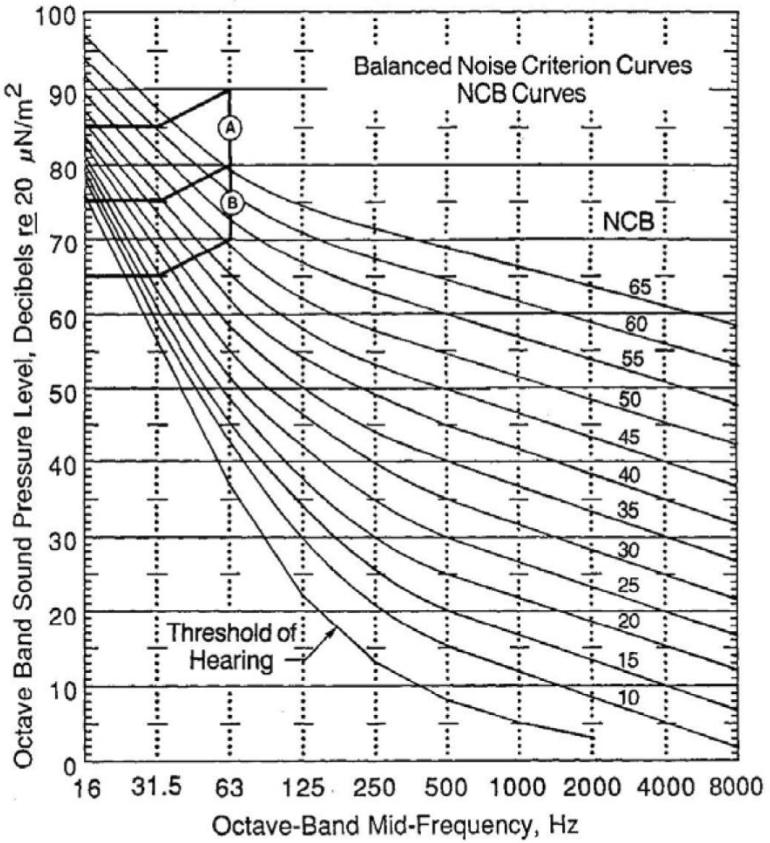
Design Guidelines

- Interruptions and distractions
- Acoustic noise
  - Medical equipment as a source of noise in hospital or home
  - Acoustic noise exposure limits related to safety

Duration per day (hours)	Sound level (dBA)
8	90
6	92
4	95
3	97
2	100
1.50	102
1	105
0.50	110
0.25 or less	115

Design Guidelines

- Acoustic noise limits for auditory communication



Type of space	NCB curve
Hospitals and clinics	
Private rooms	25 to 30
Wards	30 to 35
Operating rooms	25 to 30
Laboratories	33 to 43
Corridors	33 to 43
Public areas	38 to 43
Large auditoriums, large drama theatres	15 to 20
Schools	
Lecture and classrooms	25 to 30
Open-plan classrooms	33 to 37
Office buildings	
Executive offices	25 to 30
Large conference rooms	25 to 30
Small conference rooms and private offices	30 to 35
General secretarial areas	38 to 43
Open-plan areas	35 to 40
Business machines and computers	38 to 43
Public circulation	38 to 48
Small auditoriums	25 to 30
Libraries	33 to 37
Restaurants	38 to 43

Design Guidelines

- Lighting
  - Ambient illumination
  - Device displays and lighting conditions

Table 8.4—Sample lighting levels measured in critical and intensive care units
[Data courtesy of William Muto, Abbott Laboratories]

Locations (number sampled)	Lighting levels (lux)
CCU (2)	30 (measured in both locations, overhead lights off)
ICU (5)	31 (overhead lights off) to 1,200
ICU–trauma (1)	129
Neuro ICU (1)	585
Surgical ICU (4)	38 (overhead lights off) to 1,540

Design Guidelines

- Temperature and humidity
  - Optimum: 21°C to 27°C (warm climate) and 18°C to 24°C (cold climate)
  - Temperature and humidity extremes can degrade performance
  - Surface temperature

Table 8.5—Maximum allowable temperatures for equipment parts likely to be touched[1)]
[ANSI/AAMI ES60601-1:2005]

Equipment and its parts		Maximum temperature (°C)		
		Metal and liquids	Glass, porcelain, vitreous material	Molded material, plastic, rubber, wood
External surfaces of equipment that are likely to be touched for a time "t"	t < 1 sec	74	80	86
	1 sec ≤ t < 10 sec	56	66	71
	10 sec ≤ t < 1 min	51	56	60
	1 min ≤ t	48	48	48

Table 8.6—Maximum temperatures for skin contact with patient-applied parts[1)]
[ANSI/AAMI ES60601-1:2005]

Patient-applied part of the equipment		Maximum temperature (°C)		
		Metal and liquids	Glass, porcelain, vitreous material	Molded material, plastic, rubber, wood
Applied part having contact with the patient for a time "t"	t < 1 min	51	56	60
	1 min ≤ t < 10 min	48	48	48
	10 min ≤ t	43	43	43

Design Guidelines

- Humidity
  - Medical devices should not increase relative humidity in the environment by >15% and should not cause relative humidity to be >45% at 21°C
- Vibration
  - Vibration of visual displays should not compromise user performance
  - Larger characters on display, larger keys to counteract tracking and reach errors that can occur at accelerations higher than 2.0 m/sec^2

Table 8.7—Acceleration levels measured in emergency transport vehicles
[Macnab et al., 1995]

Vehicle	Average acceleration (m/sec^2)	Maximum acceleration (m/sec^2)
Ground ambulance	0.7	1.1
Fixed wing aircraft	0.3 to 0.4	0.8 to 2.2
Rotary wing aircraft	0.7 to 1.3	1.3 to 2.4
Hovercraft	0.6	1.3

Design Guidelines

- Slipperiness and friction
- Atmospheric pressure
- Ease of maintenance
  - Devices used in the home by lay users should require minimal or no maintenance, or the maintenance requirements should be obvious
  - Cleaning and sterilization
  - Adequate access for component replacement and testing
  - Battery-operated devices: battery status indication
- Storage requirements
- Mounting of devices
- Radiant energy
- Emergency environment

Covered Material

- Chapter 8