

# Usability Engineering

## Session 7

# Agenda

- Session 7 Topics
- Questions from Session 6?
- Objectives of Session
  - Environmental Conditions
    - Climate
    - Noise
    - Motion
  - Standards for Medical Devices

# Environmental Conditions Climate

# Heat Stress

- ▶ Simple Cognitive and Perceptual-Motor Performance
  - ▶ Visual and auditory reaction time, arithmetic problem solving, coding and short-term memory
  - ▶ Decrements in performance are not typically found with heat stress and in some cases enhancements in performance is frequently observed
- ▶ Complex Cognitive and Perceptual-Motor Performance
  - ▶ Tracking, vigilance, and complex dual tasks
  - ▶ Decrements can be found after 30-60 min, but findings are not consistent

# Cold Stress

- ▶ Physical Work: decreases muscle strength and endurances
- ▶ Tactile Sensitivity: adversely affects tasks that require manipulation of small objects.
- ▶ Manual Performance: practice in a cold climate increases performance better than in a neutral climate.
- ▶ Tracking Performance: adversely affected by cold
- ▶ Reaction Time: simple reaction time is not affected, but choice reaction time is adversely affected.
- ▶ Mental Activities: there is conflicting evidence that cold temperatures would affect performance.

# Environmental Conditions: Noise

# Noise

- ▶ Noise is an auditory stimulus or stimuli bearing no informational relationship to the presence of completion of the immediate task.
- ▶ Noise is an unwanted sound.
- ▶ Noise can also be defined by the user.
- ▶ Noise/Sound has been used as weapon.

# Standards and Guidelines



# Standards, Guidelines, Requirements

- ▶ IEC 62366-1:2015- Medical devices –Part 1
- ▶ IEC/TR 62366-2 Medical device-Part 2
- ▶ ANSI/AAMI HE75:2009 (R) 2019
- ▶ WC3, [www.usability.gov](http://www.usability.gov)
- ▶ Applying Human Factors and Usability Engineering to Medical Devices, Guidance for Industry and Food and Drug Administration, Feb. 3, 2016, ([www.fda.gov](http://www.fda.gov))
- ▶ MIL-STD-1472G, 11 January 2012