Medical Equipment III Part 3 Midterm Exam – November 2010 (Model Answer)

Solve as Much as You Can – Maximum Grade: 100 Points

Part I. Answer these questions by marking the best answer among the choices given (4 point each):

1. To accommodate medical device users' needs and preferences, …
    a. rely exclusively on thought leaders to put the product specifications
    b. plan a comprehensive training for users
    c. let users set the pace while working with the medical device (*)
2. Positive transfer in human factors engineering means …
    a. users applying past experience to a new device, reducing their learning time (*)
    b. designers using past experience to design a new device user interface
    c. feedback from usability testing making devices more error-tolerant
3. Anesthesia machines use … to ensure that users turn the correct knob to increase the flow of O_2 vs. air or N_2O.
    a. Visible alarm
    b. Redundant coding (*)
    c. Error messages
4. Designers should distinguish power cable receptacles from sensor cable receptacles to …
    a. prevent user confusion (*)
    b. reduce signal noise
    c. increase device appeal
5. Developing compatible medical device designs involve …
    a. Knowledge of other devices in contact with the target device in the clinical environment
    b. Accommodating mental models (*)
    c. Effective choice of biomaterials for safety
6. Undesirable or unexpected events resulting from the interaction between a user and a device is called …
    a. Slip
    b. Lapse
    c. User error (*)
7. Omitting steps in a device operating procedure is classified as …
    a. Slip
    b. Lapse (*)
    c. Mistake
8. With respect to medical devices, harm does not include …
    a. Delayed treatment
    b. Injury to patient
    c. Fatigue of device operator (*)
9. Fault tree analysis (FTA) differs from failure mode effects analysis (FMEA) is that …
    a. FMEA involves brainstorming that is not required in FTA
    b. FMEA works from the bottom up, while FTA starts from top-level hazards down. (*)
    c. FTA is more suitable for clinical environment whereas FMEA is best for industrial settings.
10. To prioritize different types of hazards in a medical device, … is used.
    a. Risk equation (*)

b. FTA
c. FMEA

11. The minimum light level in which an object can be visually identified is called …
    a. Visual acuity
    b. Visual threshold (*)
    c. Rods
12. For a visual angle of 18 min of arc, the font of a sign to be readable from 3 m away should be at least …
    a. 24
    b. 36
    c. 45 (*)
13. …… is the apparent change in the position of an object because of changes in the observer's line of sight.
    a. Visual illusion
    b. Motion error
    c. Parallax error (*)
14. for colored lights, the easiest colors to be recognized by color normal people are … and …
    a. Red , Green (*)
    b. Blue , white
    c. Yellow , Orange
15. The energy of speech signals is mostly below … Hz.
    a. 300 Hz
    b. 1000 Hz (*)
    c. 4000 Hz

Part II. Mark the following statement as either True (T) or False (F) (2 point each):

1. Designers should anticipate medical device migration into other uses or use environments. (T)
2. Designers should not diverge substantially from conventional design practice or industry standards unless necessary. (T)
3. Users regard action confirmation messages as a wasted extra step and therefore should be avoided. (F)
4. Medical devices designed with multiple operational modes must clarify the present operating mode to the user. (T)
5. When possible, medical monitoring device designs should help users forecast patient variables. (T)
6. It is necessary to mitigate abnormal use by a user who actually intends to use a device incorrectly. (F)
7. Usability test participants should include someone from the design team in addition to doctors and nurses. (F)
8. Intended use of a medical device includes clinical application and use environment. (F)
9. Mistakes arise from applying the wrong knowledge when making a decision. (T)
10. Validation must be done by clinicians whereas verification is mainly done by design engineers. (T)
11. Display devices intended for use in the hospital rooms of seizure patients should be of interlaced CRT type. (F)
12. After implementing design change to mitigate a risk, new risks may arise as a result of this change. (T)
13. A text written in Black on Yellow should have good legibility. (T)
14. An audible alarm can be designed as a pure tone with frequency of 100Hz and intensity level of 20 dB. (F)
15. An old man is more likely to hear a high frequency tone than a low frequency tone. (F)
16. Sensory data needed to maintain balance and to detect motion of the body is based on proprioceptors. (F)
17. Device user interface designs usually violate a human factors engineering guideline. (T)
18. Medical device users always receive complete and proper training before using a given device. (F)
19. Designers should treat warnings as the main option for preventing problems in medical devices. (F)
20. Reaction time for auditory alarms is usually faster than that for visible alarms. (T)

Best of Luck!