Open book/notes (10 questions, 10 points each)

1. (   ) A 510k application (premarket notification) needs to show that the new medical device is substantially equivalent to another earlier device on the market prior to May 28th of the year (A) 1974, (B) 1976, (C) 1978, (D) 1980, (E) none of the above.

2. (   ) A PMA application (premarket approval) for a new medical device needs to demonstrate (A) safety and effectiveness. (B) comfort and cost-effectiveness. (C) acceptable sensitivity and specificity. (D) good laboratory practice and good manufacturing practices. (E) none of the above.

3. (   ) According to the FDA Design Control Guidance for Medical Device Manufacturers, ensuring the conformation to defined user needs and intended uses is part of the (A) design specifications.   (B) design verification.   (C) design validation.   (D) design risk management. (E) none of the above.

4. (   ) For the risk management of a medical device, an event of moderate impact occurs with a probability in the range of 81%-100%. On the risk matrix this event should be classified as: (A) low risk. (B) moderate risk. (C) high risk. (D) extreme risk. (E) none of the above.

5. (   ) CA 19-9, a carbohydrate tumor-associated antigen in the serum, has been used as a biomarker for the pancreatic cancer. In order to determine its accuracy as a screening test, a study was conducted on 1000 human subjects, comprising 800 normal subjects and 200 subjects with pancreatic cancer. The CA 19-9 serum test resulted in 42 false negatives and 144 false positives. What is the sensitivity and specificity, respectively?   (A) 79% and 82%, (B) 82% and 79%, (C) 95% and 86%,   (D) 86% and 95%,   (E) none of the above.

6. (   ) The ROC curves on the right show the diagnostic performances of doctor X (dashed line) and doctor Y (solid line), respectively. Which of the following statements is incorrect?   (A) Dr. Y outperforms Dr. X. (B) Weighting false positive and false negative equally, doctor Y's best performance is 80% sensitivity and 80% specificity. (C) Weighting false positive and false negative equally, doctor X's best performance is 70% sensitivity and 70% specificity. (D) If doctor Y operates at the point of 90% sensitivity, the specificity would drop down to 60%. (E) none of the above.
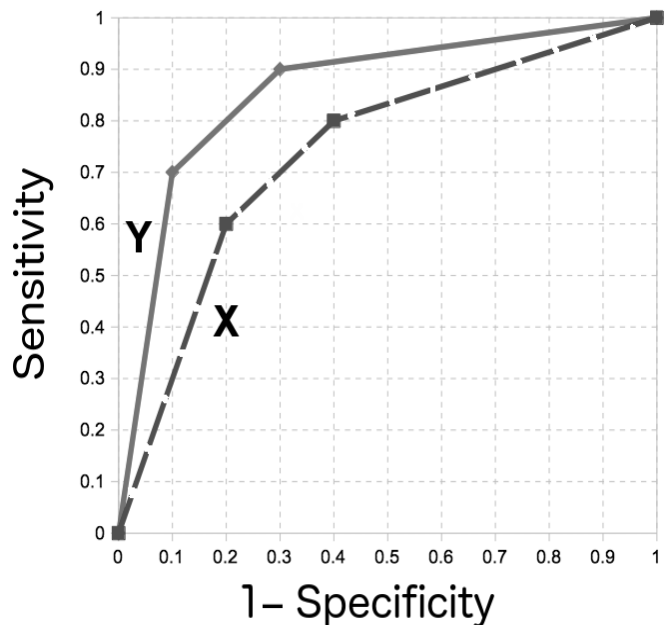
7. (   ) For the above problem, what is the area under the ROC curve (Az) for doctor Y? (A) 0.74, (B) 0.80, (C)) 0.86, (D)) 0.92, (E) none of the above.

8. (   ) Refer to the paper entitled "Automated performance analysis of real-time QRS detection". What is the valid detection interval of the error logger?   (A) a time window around the R-wave reference within which a QRS detection is considered a true positive, (B) a window on the LCD display that shows the number of valid detections, (C) a probability window within which the true detection rate is considered acceptable, (D) a window of thresholds applied to the processed ECG signals for detecting the QRS complexes, (E) none of the above.

MORE QUESTIONS ON THE BACK

9. (   ) What are the frequency range and signal magnitude range, respectively, for the electroencephalogram (EEG)? (A) 0.5–40 Hz and 0.1–5 mV, (B) 25–5000 Hz and 0.1–100 mV, (C) 0–10 KHz and 50–100 mV, (D) 0.1–100 Hz and 0.025–0.1 mV, (E) none of the above.

10. (   ) Under the guideline of the OSI 7-layer network structure, the tasks of routing, forwarding, addressing, internetworking, error handling, congestion control and packet sequencing should be done at the   (A) transport layer, (B) network layer, (C) data link layer, (D) physical layer, (E) none of the above.