



قائمة الاسئلة

اختبار النهائي للعام الجامعي 2025/2024-مكلية الهندسة :: تصميم الانظمة الحيوية - كلية الهندسة - قسم الطبية الحيوية- المستوى الرابع - 3 ساعات  
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- 1) What is design?
  - 1)  + The process of creating products and services
  - 2)  - The study of ancient artifacts
  - 3)  - The act of selling products
  - 4)  - The process of destruction n
- 2) Which of the following is NOT a characteristic of design?
  - 1)  - To conceive or invent
  - 2)  + To copy without innovation
  - 3)  - To have a purpose or intent
  - 4)  - To formulate plan
- 3) A surgical tool for use in spinal bifida falls under which category?
  - 1)  - Biomedical systems
  - 2)  + Biomedical devices
  - 3)  - None biomedical engineering solutions
  - 4)  - Rehabilitation tools
- 4) Why is medical device design is important?
  - 1)  - It helps in reducing manufacturing costs
  - 2)  + It ensures the device complies with regulatory requirements and market needs
  - 3)  - Ie eliminates the need for testing
  - 4)  - It allows medical devices to be made quickly
- 5) What are key aspects of designing a medical device?
  - 1)  - Ignoring customer needs
  - 2)  - Reducing design time as much as possible
  - 3)  + Strong scope definition, collaboration, risk mitigation and quality adherence
  - 4)  - Avoiding regulations to save costs
- 6) What is required to develop a successful medical device?
  - 1)  + Efforts to meet customer demands and quality standards
  - 2)  - Avoidance of team work to maintain consistency
  - 3)  - Eliminating risk assessment to speeds up the process
  - 4)  - Developing product without considering specifications
- 7) What is the primary goal of the product development process in medical design?
  - 1)  - To increase product sells
  - 2)  + To ensure the product is safe, effective, and meets user needs
  - 3)  - To reduce manufacturing costs
  - 4)  - To create an aesthetically pleasing design
- 8) What is the first step in the product development process?
  - 1)  - Design validation
  - 2)  - Design transfer
  - 3)  + Product requirement
  - 4)  - System requirement specification
- 9) Which aspect ensures that the device adheres to government and industry standards ?
  - 1)  + Regulatory
  - 2)  - Quality
  - 3)  - Labelling
  - 4)  - Physical characteristics
- 10) Which factor is essential for ensuring a device can be easily repaired and maintained?





- 1)  Serviceability
  - 2)  Sterility
  - 3)  Manufacturability
  - 4)  Human factors
- 11) Which of the following best describes design history file (DHF)?
- 1)  A record of device's production history
  - 2)  A compilation of records describing the design history of a finished device
  - 3)  A list of regulatory approves for a device
  - 4)  A collection of customer reviews on a device
- 12) Why are design controls integrated into the design and development process?
- 1)  To speed up production regardless of quality
  - 2)  To assure that device specifications align with user needs and intended use
  - 3)  To prevent engineers from making design changes
  - 4)  To increase the cost of medical devices
- 13) Which of the following is NOT a subsystem of the quality system?
- 1)  Corrective and preventive action control
  - 2)  Production and process control
  - 3)  Sales and marketing control
  - 4)  Facility and equipment control
- 14) What do design inputs represent in device design?
- 1)  The physical and performance characteristics of a device
  - 2)  The final appearance of the device
  - 3)  The marketing strategy for the device
  - 4)  The cost analysis of the device
- 15) Which of the following is NOT considered a design input?
- 1)  Marketing budget
  - 2)  Device function
  - 3)  Reliability
  - 4)  Environmental limits
- 16) How can manufactures prevent an infusion pump from malfunctioning due to electromagnetic interference?
- 1)  By making the device heavier
  - 2)  By using shielding technique
  - 3)  By placing a warning label on the packaging
  - 4)  By increasing the power supply voltage
- 17) What does user need refer to in the design process?
- 1)  The technical specifications of a product
  - 2)  The requirements and expectations of the end user
  - 3)  The budget allocated for product development
  - 4)  The final prototype of a product
- 18) Which of the following best defines design output?
- 1)  The initial brainstorming ideas for a product
  - 2)  The requirements and constraints that guide product development
  - 3)  The results of design effort at each phase and at the end of the design process
  - 4)  The financial costs associated with product development
- 19) What should design output reference?
- 1)  Acceptance criteria
  - 2)  User preference
  - 3)  Market demand
  - 4)  Product pricing





- 20) Which process ensures that design outputs meet design input requirements ?
- 1) - Marketing research
  - 2)  Verification and validation
  - 3) - Mass production
  - 4) - Brainstorming
- 21) Why should design output be measurable?
- 1)  To confirm compliance with acceptance criteria
  - 2) - To ensure it is innovative
  - 3) - To increase manufacturing cost
  - 4) - To enhance product marketing
- 22) What does design review ensure?
- 1)  That all design outputs are approved before release
  - 2) - That the product looks aesthetically pleasing
  - 3) - That the manufacturing cost is minimized
  - 4) - That only the development team is involved
- 23) Which process typically involves external customer acceptance?
- 1) - Verification
  - 2)  Validation
  - 3) - Manufacturing
  - 4) - Testing
- 24) What is the main purpose of usability testing in medical device design ?
- 1) - To ensure the device is marketed effectively
  - 2)  To refine designs based on user feedback
  - 3) - To increase production costs
  - 4) - To eliminate the need for safety checks
- 25) What is a key consideration when selecting users for usability testing?
- 1)  Users should be representative of the intended population
  - 2) - All users should be experts in medical technology
  - 3) - Only the most skilled users should be selected
  - 4) - Only hospital staff should be involved
- 26) Designing the interface with the user in mind helps in all of the following EXCEPT:
- 1) - Accommodating users working under variable conditions
  - 2)  Increasing the need for extensive training
  - 3) - Enhancing usability
  - 4) - Reducing user errors
- 27) Physical and performance requirements specify:
- 1) - The marketing strategy of the product
  - 2) - The operational aspects of the device
  - 3) - The visual appeal of the device
  - 4)  How well the design must perform, including speed, accuracy, and reliability
- 28) Which of the following is NOT an example of a design problem leading to unintentional use errors?
- 1) - Mismatch between device capability and user input
  - 2) - Insufficient feedback for user actions
  - 3)  Clear and simple user interface design
  - 4) - Lack of alarms or critical indicators
- 29) Which factor is important in defining a device's intended use?
- 1) - Only its primary function in hospitals
  - 2)  Its clinical applications and potential future use
  - 3) - Only the number of expected users





- 4) - Its retail price and market competition
- 30) What is an example of a perceptual ability relevant to medical device design?
- 1) + Ability to detect and identify sensors input
  - 2) - Memory recall speed
  - 3) - Physical strength for lifting devices
  - 4) - Resistance to fatigue

