

Ethical and legal issues in clinical practice: Medical devices  
Post-test

Directions: Select the letter corresponding to the MOST CORRECT response.

1. Conformance with \_\_\_\_\_ determines the ethicality and legality of a clinical decision.
  - A. current local practices
  - B. professional standards of care
  - C. economics
  - D. supervisors' instructions
  
2. Which of the following are legitimate sources for standards of care?
  - A. AARC Clinical Practice Guidelines
  - B. The Joint Commission for Accrediting Healthcare Organizations (JCAHO)
  - C. State professional credentialing boards
  - D. All of the above
  
3. Most respiratory care devices are classified by the Federal Drug Administration in which category?
  - A. Class I
  - B. Class II
  - C. Class III
  - D. Class IV
  
4. The Federal Drug Administration would classify a new type of ventilator, that is not equivalent to those currently on the market, in which category?
  - A. Class I
  - B. Class II
  - C. Class III
  - D. Class IV

5. Deaths that occur due to medical devices must be reported to the Federal Drug Administration within what time interval?
- A. 24 hours
  - B. 10 days
  - C. 30 days
  - D. No report is required
6. Which of the following is an organization that provides means for voluntary reporting of problems with medical devices?
- A. The Emergency Care Research Institute (ECRI)
  - B. The Commission for Accreditation of Respiratory Care (CoARC)
  - C. The Joint Commission for Accrediting Healthcare Organizations (JCAHO)
  - D. The National Board for Respiratory Care (NBRC)
7. When a medical device functions according to manufacturer's specifications; but, fails under specific clinical circumstances, this is an example of \_\_\_\_\_.
- A. product defect
  - B. device misuse
  - C. design defect
  - D. all of the above
8. The Joint Commission's analysis of contributing factors in deaths and injuries associated with long-term ventilation found that \_\_\_\_\_ was the most significant factor.
- A. staffing
  - B. ventilator malfunction
  - C. communication
  - D. incomplete patient assessment

9. Measuring a patient's oxygen saturation by applying a finger sensor to the forehead is an example of:

- A. device misuse
- B. product defect
- C. design defect
- D. appropriate clinical practice

10. Which of the following are responsibilities of respiratory care managers in promoting device safety?

- A. Final device adoption decisions
- B. Directing evaluation trials
- C. Ensuring staff competency
- D. All of the above