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 ethicity 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