

01	A	B	C	D	E
02	A	B	C	D	E
03	A	B	C	D	E
04	A	B	C	D	E
05	A	B	C	D	E
06	A	B	C	D	E
07	A	B	C	D	E
08	A	B	C	D	E
09	A	B	C	D	E
10	A	B	C	D	E
11	A	B	C	D	E
12	A	B	C	D	E
13	A	B	C	D	E

14	A	B	C	D	E
15	A	B	C	D	E
16	A	B	C	D	E
17	A	B	C	D	E
18	A	B	C	D	E
19	A	B	C	D	E
20	A	B	C	D	E
21	A	B	C	D	E
22	A	B	C	D	E
23	A	B	C	D	E
24	A	B	C	D	E
25	A	B	C	D	E
26	A	B	C	D	E

27	A	B	C	D	E
28	A	B	C	D	E
29	A	B	C	D	E
30	A	B	C	D	E
31	A	B	C	D	E
32	A	B	C	D	E
33	A	B	C	D	E
34	A	B	C	D	E
35	A	B	C	D	E
36	A	B	C	D	E
37	A	B	C	D	E
38	A	B	C	D	E
39	A	B	C	D	E

PRACTICE QUESTIONS

Saudi Commission For Health Specialties (SCFHS)

BIOSP

Biomedical Technology Specialist

EDITION

Demo

QUESTIONS

9

FORMAT

Limited Edition PDF

Before you begin

What this is

9 practice questions for Saudi Commission For Health Specialties (SCFHS) BIOSP , each with its answer key and an explanation. Answer a question before you read its key — the explanation is worth more once you have committed.

If something looks wrong

Send us three things and we will check it:

- the exam code, BIOSP
- the question number
- the email address on your order

Write to **support@mometrix.net**. We reply within one business day.

QUESTION 1

SINGLE CHOICE

A biomedical technology specialist is evaluating the replacement of an end-of-life infusion pump fleet. Which framework is most appropriate for a structured healthcare technology assessment (HTA) that compares clinical, economic, and organizational impacts of alternative devices?

- ☐ A Failure Mode and Effects Analysis (FMEA)
- ☒ B Health Technology Assessment (HTA) using the EUnetHTA Core Model
- ☐ C ISO 14971 Risk Management Process
- ☐ D Six Sigma DMAIC methodology

ANSWER B

WHY Health Technology Assessment (HTA) is the recognized multidisciplinary framework used in healthcare to systematically evaluate clinical effectiveness, economic impact, and organizational/ethical considerations of medical technologies. The EUnetHTA Core Model is a widely adopted HTA framework. FMEA and ISO 14971 are risk-management tools, not comparative evaluation frameworks, and DMAIC is a quality-improvement methodology, not a comparative assessment of competing devices.

QUESTION 2

SINGLE CHOICE

A healthcare facility's incident reporting system flags a recurring alarm fatigue issue on a telemetry monitoring system. According to international risk management practice for medical devices, which standard provides the structured process for identifying, estimating, evaluating, controlling, and monitoring risks associated with medical device use?

- ☐ A IEC 60601-1 (Medical electrical equipment – General requirements for basic safety and essential performance)
- ☐ B IEC 62366-1 (Usability engineering)
- ☒ C ISO 14971 (Application of risk management to medical devices)
- ☐ D ISO 13485 (Quality management systems for medical devices)

ANSWER C

WHY ISO 14971 is the international standard that specifies the process for identifying hazards, estimating and evaluating risks, controlling risks, and monitoring the effectiveness of controls throughout the medical device lifecycle. IEC 60601-1 addresses electrical safety and essential performance, IEC 62366-1 covers usability engineering, and ISO 13485 covers the quality management system; none of these provide the full risk-management process that ISO 14971 does.

QUESTION 3

SINGLE CHOICE

A scheduled preventive maintenance (PM) inspection of a defibrillator includes which of the following as a core electrical safety and functional verification activity?

- ☐ A Replacing the device's rechargeable battery regardless of cycle count
- ☒ B Verifying delivered energy output against manufacturer specification using a defibrillator analyzer
- ☐ C Recalibrating the device's internal clock to network time protocol (NTP)
- ☐ D Reformatting the device's internal solid-state storage

ANSWER B

WHY Functional verification of a defibrillator during PM requires delivering a test shock through a defibrillator analyzer (with a test load) and confirming that the delivered energy matches the selected setting within the manufacturer's tolerance. Battery replacement should be condition-based, not automatic; clock synchronization and storage reformatting are not standard PM electrical safety/functional verification activities for a defibrillator.

QUESTION 4

SINGLE CHOICE

Which organization maintains the family of standards that defines the Medical Device Communication Protocol (MDPnP / ICE) and the Integrated Clinical Environment (ICE) framework for safe interoperability among medical devices, sensors, and information systems?

- ☐ A DICOM Standards Committee
- ☒ B ASTM International (Committee F29 on Anesthesia and Respiratory Equipment)
- ☐ C HL7 International
- ☐ D Integrating the Healthcare Enterprise (IHE)

ANSWER B

WHY The Integrated Clinical Environment (ICE) standard, ASTM F2761, and related Medical Device Communication / Interoperable Device Connectivity efforts originate from ASTM International, particularly Committee F29 (and related subcommittees). HL7 handles clinical data exchange (e.g., FHIR, v2.x), DICOM handles imaging, and IHE profiles integration workflows; ICE itself is the ASTM F2761 framework.

QUESTION 5 SINGLE CHOICE

A biomedical technology specialist is reviewing electrical safety test results. Which leakage current measurement in a patient-connected medical device most directly addresses the risk of microshock to a patient with an intracardiac catheter?

- ☐ A Enclosure leakage current
- ☐ B Protective earth leakage current
- ☒ C Patient auxiliary current (between patient-applied parts) and patient leakage current under normal and single-fault conditions
- ☐ D Earth continuity current

ANSWER C

WHY Microshock risk is associated with very small currents applied directly to or within the heart (e.g., via intracardiac catheters, pacing leads). The relevant IEC 60601-1 measurements are patient leakage current and patient auxiliary current, evaluated under normal condition and single-fault condition (e.g., open protective earth, reversed mains polarity). Enclosure, earth, and protective-earth continuity currents address chassis-level or operator shock, not microshock.

QUESTION 6 SINGLE CHOICE

In healthcare technology management (HTM), the equipment replacement prioritization index most commonly combines which factors?

- ☐ A Device color, vendor logo, and purchase year
- ☒ B Age, condition, maintenance cost, and clinical risk/criticality
- ☐ C Number of operators trained, parking availability, and floor finish
- ☐ D Hospital bed count, room temperature, and Wi-Fi signal strength

ANSWER B

WHY Standard equipment replacement prioritization methods used in clinical engineering (e.g., AAMI's guidance and various HTM replacement models) weight factors such as device age, current condition/remaining useful life, annual maintenance cost, downtime, and clinical risk/criticality (mission criticality and patient safety impact). The other options contain irrelevant or non-standard factors.

QUESTION 7

SINGLE CHOICE

Which healthcare data standard is specifically designed for the storage, retrieval, and transfer of medical imaging studies and related information across modalities and vendors?

- ☐ A HL7 FHIR
- ☒ B DICOM (Digital Imaging and Communications in Medicine)
- ☐ C ICD-10
- ☐ D LOINC

ANSWER B

WHY DICOM is the international standard (maintained by the DICOM Standards Committee, with roots in NEMA) for handling, storing, printing, and transmitting medical imaging information. HL7 FHIR is for clinical/healthcare data exchange broadly, ICD-10 is for diagnosis coding, and LOINC is for identifying laboratory and clinical observations.

QUESTION 8

SINGLE CHOICE

During corrective maintenance of a ventilator that intermittently fails its self-test, which systematic troubleshooting approach is most appropriate to isolate a root cause?

- ☐ A Replace every printed circuit board at once to minimize downtime
- ☒ B Apply the half-split method combined with manufacturer diagnostic codes and service manual fault trees
- ☐ C Open the device's firmware source and rewrite the control algorithm
- ☐ D Return the device to the manufacturer without documenting the symptoms

ANSWER B

WHY A disciplined approach using the half-split (divide-and-conquer) method along with the manufacturer's diagnostic fault codes, service manual troubleshooting flowcharts, and event logs efficiently narrows the fault domain. Wholesale board replacement ('shotgunning') is inefficient and risks introducing new faults; firmware source modification is outside the scope of a clinical engineer and violates regulatory controls; and returning without documentation loses vital troubleshooting information and may violate incident reporting policies.

QUESTION 9

MULTIPLE CHOICE

A clinical engineer is establishing a medical device cybersecurity program in a hospital. Which of the following are recommended control categories consistent with recognized healthcare security guidance (e.g., NIST SP 800-66 and the FDA cybersecurity premarket/postmarket guidance)? (Choose two.)

- ☒ **A** Maintaining an accurate medical device inventory that includes software versions and network interfaces
- ☒ **B** Segmenting medical devices onto appropriate network zones (e.g., separate VLANs for clinical networks)
- ☐ **C** Disabling all authentication on medical devices to simplify clinician workflow
- ☐ **D** Using default vendor passwords indefinitely to avoid lockouts during emergencies

ANSWER A • B

WHY Maintaining a detailed asset inventory (including hardware, firmware/software versions, and network connectivity) and segmenting medical devices onto appropriate network zones (e.g., VLANs, firewalls, isolation from general-purpose IT) are core technical and administrative controls recommended by NIST SP 800-66 Rev. 2 and FDA cybersecurity guidance. Disabling authentication and retaining default vendor passwords are explicitly discouraged because they increase the attack surface and violate basic access-control practice.