

## SFHCHS207

### Test medical devices, products, equipment and associated systems within healthcare



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#### Overview

This standard relates to the physical, engineering and technical checking and testing of new or existing equipment, devices, products and associated systems. The standard involves using defined and acceptable protocols and comparing the results against approved standards.

It ensures that medical equipment, devices, products and associated systems remain safe and fit for their intended purpose. It may be undertaken by health care individuals or external contractors within a wide range of environments

Users of this standard will need to ensure that practice reflects up to date information and policies.

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#### Performance criteria

*You must be able to:*

- P1 work within your level of competence, responsibility and accountability
- P2 liaise with stakeholders for the planned testing and prioritise action based on maintaining clinical services where appropriate
- P3 check the equipment or system is not in use and check the decontamination status of the item prior to testing
- P4 where appropriate carry out suitable decontamination and cleaning procedures prior to and after testing
- P5 identify the required tools and equipment and check they are in a safe working order for the range, type and model of equipment or item under test
- P6 test the components of the equipment /device and associated systems, take appropriate measurements of the required performance parameters in line with the approved policies, protocols and procedures
- P7 check and compare each test result obtained against expected values and as appropriate, complete the testing procedure according to the specified schedule
- P8 compare all the results obtained against the clinical and/or technical performance parameters and recommended acceptable ranges of values
- P9 report any variances or non conformance to the appropriate individual
- P10 record any faults or unexpected events noted in the testing process, referring the item under test to the appropriate individual for action
- P11 clarify all issues affecting the testing, the outcomes and their impact on the delivery of clinical services with relevant stakeholders
- P12 provide the relevant information for repair or replacement equipment when testing does not meet the required parameters
- P13 maintain full, accurate and legible records of information and store in the correct location in line with current legislation, guidelines, local policies and protocols

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### Knowledge and understanding

*You need to know and understand:*

- K1 your own level of competence, authority and specialist knowledge
- K2 the principles of scientific, technological and/or engineering related to your work practice
- K3 the range of stakeholders involved, their information needs, roles and responsibilities
- K4 the importance of and how to schedule testing with relevant stakeholders, including gaining their consent prior to testing
- K5 the range of health and safety measures, infection prevention and control and personal protective equipment, their importance and application within your work practice
- K6 how to balance capabilities, limitations and constraints of resources to type and volume of tests to be conducted
- K7 the range and purpose of the test equipment and performance tests within your scope of work and their application
- K8 how to make informed use of the detailed technical information provided by the manufacturers' service manuals to identify the appropriate test procedure and equipment and where to seek advice if this is outside your competence and level of responsibility
- K9 the correct use and limitations of tools and service aids available
- K10 the relevant protocols and their correct interpretation and how to access them
- K11 the principles, modes of operation and limitations of the item under test and the expected performance parameters
- K12 the range of methods for the validation of data used for checking the test results for equipment, medical devices, products and associated systems
- K13 the importance of quality control tests and their application to the testing processes
- K14 the range of options and contingency plans to deal with unforeseen events
- K15 the codes of conduct and procedures for working in the wide range of environments applicable to your level of responsibility and work practice
- K16 the current national legislation, guidelines, local policies and protocols which affect your work practice
- K17 the policies and guidance that clarify your scope of practice, accountabilities and the working relationship between yourself and others

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### Additional Information

#### External Links

This standard links with the following dimension within the NHS Knowledge and Skills Framework (October 2004):

Dimension: G2 Development and innovation

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**Suite** Clinical Health Skills

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