

Unit 109: Acceptance Testing of New Medical Equipment

Level:	4
Unit type:	Optional (Equipment Management and Clinical Engineering)
Credit value:	6
Guided learning hours:	48

Unit summary

In this unit, you will acquire the knowledge of the acceptance process for new medical equipment within the equipment lifecycle and be able to perform acceptance and safety testing on a defined range of new medical equipment within own area of practice, together with the practical application of appropriate engineering workshop skills. You will be expected to build your professional practice as you build your competence in the workplace.

Unit assessment requirements

There are no specific assessment requirements for this unit. Please refer to the assessment strategy in *Annexe B*.

Additional information

All procedures must be undertaken in accordance with Standard Operating Procedures (SOPs) and legislation.

AC1.3 the stages of acceptance are:

- visual inspections
- electrical safety testing
- mechanical safety testing
- test equipment
- functional testing
- purpose of measurements
- performing measurements
- assessing results.

AC2.6 includes:

- model
- serial number

- CE mark
- electrical type and classification etc.

AC4.11 includes:

- demonstrating the effect of multiple earth paths on medical systems and selecting earth bonding points.

AC4.12 includes:

- voltmeter
- ammeter
- voltage source.

AC5.2 includes:

- static calibrations of blood pressure monitors
- flow rate accuracy of infusion devices
- checking all controls work on hospital beds, to include operation of the patient and nurse handset
- using an ECG simulator to check that monitors recognise normal and abnormal rhythms, and alarm features function according to configuration
- functioning of gas-powered devices such as oxygen flow meters.

AC5.1 includes:

- other means or apparatus, e.g.:
 - comparing the device with a similar device that has been calibrated to verify the performance against a similar model that is not test equipment
 - use of physical measures such as volume of fluid delivered into a burette
 - test equipment could include the burette or powered laboratory equipment.

AC7.5 includes:

- the maintenance of stock levels
- goods inwards processes
- customer supplied product.

Learning outcomes and assessment criteria

To pass this unit, learners need to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements that the learner is expected to meet **in own area of work and in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand how new medical equipment is introduced into own area of work	1.1	Explain the stages of acceptance and safety testing of new medical equipment			
		1.2	Explain the importance of visual inspections			
		1.3	Discuss the purpose of each stage of acceptance and safety testing of new medical equipment			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
2	Be able to inspect new medical equipment	2.1	Examine the packaging for damage			
		2.2	Discuss how to deal with problems identified			
		2.3	Collect appropriate information from packaging and delivery notes, comparing it against the initial order and recording collected information			
		2.4	Unpack equipment in a safe manner			
		2.5	Confirm all items are as per the delivery note and the original order			
		2.6	Examine equipment, cables, accessories and consumables for damage, ensuring the equipment has appropriate markings			
		2.7	Complete acceptance documentation, collecting all relevant information for the equipment management system			
		2.8	Update the equipment management system			
3	Be able to assemble equipment and fit any consumables according to instructions	3.1	Assemble equipment correctly, verifying performance against agreed operating procedures			
		3.2	Fit any consumables according to the instructions			
		3.3	Record quantifiable and objective evidence of device performance to a standard that can be discussed with senior colleagues			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
4	Be able to perform safety testing of new medical equipment in accordance with Standard Operating Procedures (SOPs)	4.1	Evaluate the SOP for electrical and mechanical safety testing			
		4.2	Apply the SOP for electrical and mechanical safety testing			
		4.3	Select suitable test and simulation equipment			
		4.4	Apply the appropriate standards and limits for the equipment under test			
		4.5	Perform a full range of visual inspections on the equipment			
		4.6	Operate a range of test and simulation equipment			
		4.7	Operate a medical grade portable appliance tester			
		4.8	Perform appropriate electrical safety test procedures, following manufacturer or locally agreed SOPs/protocols			
		4.9	Make appropriate measurements on equipment with multiple patient connections			
		4.10	Make safety measurements using discrete test equipment			
		4.11	Compare the use of a manual and automatic electro-medical test			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
		4.12	Confirm the programmable features of the specialist equipment with the agreed equipment set-up			
		4.13	Perform appropriate mechanical safety test procedures, following manufacturer or locally agreed SOPs/protocols			
		4.14	Explain anomalous results that occur as part of testing processes			
		4.15	Complete all records in line with local procedures			
5	Be able to perform calibration or set up procedures and functional tests on new equipment in accordance with Standard Operating Procedures (SOPs)	5.1	Check the calibration of the equipment by confirming that the input or output is within the specification using test equipment or other means or apparatus			
		5.2	Perform appropriate functional tests where necessary, following manufacturer or locally agreed SOPs/protocols			
		5.3	Record clear and unambiguous information, including test results, according to the local SOPs/protocols			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
6	Be able to store the equipment and consumables correctly	6.1	Communicate with the equipment user as required			
		6.2	Store the equipment correctly to ensure the equipment remains fit for purpose and ready for use			
		6.3	Store the consumables correctly to ensure the equipment remains fit for purpose and ready for use			
7	Be able to operate stock control systems	7.1	Explain the importance of maintaining adequate stock levels, including the potential impact on patients and healthcare			
		7.2	Explain the purchasing process in own area of practice, including purchasing authority			
		7.3	Operate stock control systems in own area of practice			
		7.4	Purchase spares and consumables within own area of practice			
		7.5	Participate in the management of spares and consumables			

Learner name: _____

Date: _____

Learner signature: _____

Date: _____

Assessor signature: _____

Date: _____

Internal verifier signature: _____

Date: _____

(if sampled)