

# Clinical Competency for MEDICAL DEVICES

Name	Role:
Base:	Date initial training completed:
Medical Device Document Relates To	

**( this document can also be completed as a training guide and template)**

## Competency Statement:

The participant must perform this activity without assistance and/or direct supervision (level 3) for level descriptors see end.

This document is a self-assessment for registered practitioners. Non registered staff should be signed off by a registered practitioner competent to Level 4.

Line managers must have final sign off for all staff.

Performance Criteria	Assessment Method	Level achieved	Date	Assessor/self assessed
<b>The Participant will be able to:</b>	Verbal Questioning / Demonstration			
1. Understand what the device is to be used.				
2. Has read and / or viewed any manufacturers materials relating to the medical device				
3. Demonstrates an understanding of the specifications of the device				
4. Shows understanding and competency in setting up the device correctly				
5. Understands any safety features on the device and the rationale for them being there.				
6. Understands the difference between models and the effects this may have on safety and function of the device				
7. How to set the controls on the device appropriately				
8. Recognise and malfunction or error from the device and take appropriate action				
9. An awareness of the reliance that should be placed on the device to perform it's required task.				
10) An understanding of how the device produces results and the reliance that should be placed on these.				
11) An understanding of the safety features available on the device and the level of reliance that should be placed on them.				

Performance Criteria	Assessment Method	Level achieved	Date	Assessor/self assessed
12) Demonstrates safe practice by ensuring they double check both the patient and the device.				
13) Demonstrates and understanding of and appropriately sets and uses any alarms.				
14) Able to discuss any potential problems that may arise from the device as well as any likely /potential causes of failure				
15) Able to monitor and check safe functioning of the device as per manufacturers guidance				
<b>16) Able to recognise when the device has failed</b>				
17) Able to recognise any common faults in the use of the device				
18) Appropriately consults manufacturer's instructions or seeks guidance when required				
19) Is able to disassemble and reassemble (including accessories) for safe decontamination of the device				
20) Is able to decontaminate / clean the device as appropriate				
21) Demonstrates understanding of optimal storage of the device				
22) Able to report any concerns relating to the use of the device				
23) When and how to obtain assistance or advice				

Source SH CP 40 Medical Devices Policy (2014) SH CP 41 Medical Devices Toolkit (2014) Appendix B Toolkit

Date all elements of Competency Tool completed to level 3 \_\_\_\_\_

I confirm that I am competent to use this named piece of equipment

Name \_\_\_\_\_ Signature \_\_\_\_\_ Status \_\_\_\_\_ Date \_\_\_\_\_

I confirm that I have assessed the above named person and can verify that he/she demonstrates competency in using the named medical device

Verifier / Manager \_\_\_\_\_ Signature \_\_\_\_\_

Status \_\_\_\_\_ Date \_\_\_\_\_

Review	Competent	Registered	Verifier signature	Comments
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## Levels of competency Rating Scale

	Level of achievement	Level
Novice	Cannot perform this activity satisfactorily to the level required in order to participate in the clinical environment	0
↓	Can perform this activity but not without constant supervision and assistance	1
	Can perform this activity with a basic understanding of theory and practice principles, but requires some supervision and assistance	2
<b>Competent Practitioner</b>	Can perform this activity with understanding of theory and practice principles without assistance and/or direct supervision	3
↓	Can perform this activity with understanding of theory and practice principles without assistance and/or direct supervision, at an appropriate pace and adhering to evidence based practice  At this level competence will have been maintained for at least 6 months and/or is used frequently (2-3 times /week) The practitioner will demonstrate confidence and proficiency and show fluency and dexterity in practice <b>This is the minimum level required to be able to assess practitioners as competent</b>	4
	Can perform this activity with understanding of theory and practice principles without assistance and/or direct supervision, at an appropriate pace and adhering to evidence based practice.  At this level the practitioner will be able to adapt knowledge and skill to special/ novel situations where there may be increased levels of complexity and/or risk	5
Expert	Can perform this activity with understanding of theory and practice principles without assistance and/or direct supervision, at an appropriate pace and adhering to evidence based practice. Demonstrate initiative and adaptability to special problem situations, and can lead others in performing this activity  At this level the practitioner is able to co-ordinate, lead and assess others who are assessing competence. Ideally they will have a teaching and /or mentor qualification	6

Adapted from: Herman GD, Kenyon RJ (1987) Competency-Based Vocational Education. A Case Study, Shaftsbury, FEU, Blackmore Press, cited in Fearon, M. (1998) Assessment and measurement of competence in practice, *Nursing Standard* 12(22), pp43-47