Guide for STP Trainees : Clinical Engineering

Learning Outcome Subject	Code	Competency	Examples of evidence	Other competencies which may be demonstrated by this evidence
Clinical Measurement & ICT	CMICT-C-1	Set up equipment for taking clinical measurements.	Verification and documentation of daily checks made on system functionality / safety / calibration status (modality specific checks e.g. for audiometric, optical, pressure, flow measurements etc) Selection / verification of the appropriate measurement system protocol/s for use in a given clinical investigation. selection, preparation and verification of appropriate transducers / electrodes / consumables for use in a given investigation.	CMICT-C-1; CMICT-C-7
	CMICT-C-2	Control infection risks in accordance with departmental protocols.	Mandatory training for infection control in department. Take suitable action for infection control specific to a particular measurement or situation, including with patient with known or suspected specific infection risks (e.g. MRSA, CJD, HIV, C.def, noro virus etc), including dress codes, decontamination of reusable devices or disposal of single use iterms.	CMICT-C-1
	CMICT-C-3	Obtain a suitably completed request form, the greet patient, and check patient identity and recent clinical history.	Discuss the process of referall for a measurement with relevant staff. Identify relevant clinical history details required for a given measurement procedure and the potential implications of specific answers. Undertake relevant history taking in an appropriate, effective and sensitive manor.	
	CMICT-C-4	Explain the procedure for the clinical measurement, address any procedure-related questions and gain informed consent.	Identify relevant patient information leaflets and/or consent forms used for a specific clinical measurement service. Identify any consent considerations specific to a given measurement (re: contraindications, sensitive questions, invasive procedures etc). Obtain consent from a patient.	
	CMICT-C-5	Undertake clinical measurements in the patient environment.	Acquisition of appropriate, clinically valid test data resulting from a clinical measurement. Demonstrate the ability to recognise the need for and appropriately implement modifications to a given test procedure in light of data already collected or patient related factors. Identify technically deficient recording conditions/data and, as a consequence, act to optimise recording conditions. Examples of test report	CMICT-C-2

Clinical Measurement & ICT	CMICT-C-6	Analyse data and report on the use of specific measurements (particularly in terms of accuracy, reproducibility, bias, specificity and sensitivity).	Present data in a way that is both scientifically and clinically valid and appropriate. Undertake a statistically valid data analysis and present any results in a clinically appropriate context. Demonstrate an understanding of data quality verification, data analysis techniques, statistical and clinical significance considerations, test battery approaches, sources/effects of test variability, interpretation limitations etc. Examples of test reports	CMICT-C-7; CMICT-C-8; CMICT-C-10
	CMICT-C-7	Recognise technical artefacts and deterioration in equipment performance.	Present recorded data to illustrate a variety of artifact sources / effects. An equipment QA data sheet with initial and final results Obtain / present serially recorded data to illustrate the effects of equipment drift, calibration changes, subject/technical factors relating to a specific measurement type.	CMICT-C-6
	CMICT-C-8	Critically appraise reports from a novel or complex clinical measurement.	Obtain a scientific publication relating to a new measurment technique / new application of an existing technique, and undertake a critical appraisal of its rational, scientific underpinnings, assumptions, analysis approach/outcomes, conclusions and proposed application. Consider cost / benefit implications in comparison to any existing measurement alternatives.	CMICT-C-6
	CMICT-C-9	Undertake a literature review of the scientific and clinical evidence base that underpins one of the clinical measurement procedures	Results of a literature review undertakenas a part of a research project. Literarure review undertaken as a part of the clinical implementation process for a new service / measurement procedure. E.g. for scientific/clinical verfication and governance compliance. Review the current literature / evidence base relating to the application of a given measurement procedure for the diagnosis of a given condition or for its application in a given patient population.	
	CMICT-C-10	Analyse, summarise and present complex data using computer software, such as word processing, spreadsheets, databases and online references sources for clinical and scientific applications.	Undertake of an audit and present results to suit a variety of audiences (e.g. for scientifc staff, medical staff, management and patients). Use computer software to process measurement signals to obtain clinicallly relevant data. MSc thesis/project presentation	CMICT-C-8
	CMICT-C-11	Participate in the implementation of ICT components in a controlled fashion, taking into account the impact on existing facilities and clinical service.	Undertake a hardware upgrade of a PC, e.g. the addition of RAM or the replacement of a video capture card. Review the business continuity plan for a service that is dependant on ICT (e.g. endoscopy image capture) and describe the impact of potential ICT failures on the service.	CMICT-C-12

	CMICT-C-12	Participate in the maintenance of protective measures for ICT systems, including disaster measures, anti-virus protection, maintenance, updating, firewalls and virtual servers/networks.	Undertake an audit of the current disaster recovery plans for a system, including business continuity. Propose amendments. Install Windows onto a PC, going through the full update cycle of both the OS and AV.	CMICT-C-11
	CMICT-C-13	Specify, design, develop and test a small database, web application or image processing solution	Create an interface to a medical device in order to extract information from it. Store this in a database of your design. Create a web interface to an existing (non-web) SQL database in order to allow remote reporting (e.g. allow wards to view their equipment and the current repair status) Use ImageJ (or similar) to create a program for MRI QA which replces several manual steps/procedures.	
Design & Development	DD-C-1	Competently use a CAD software package to produce design drawings.	Identify a small project and produce design drawings of either a medical electronic circuit and/or a CAD model of a structure, required as part of design project.	DD1-C-1
	DD-C-2	Specify manufacturing and machining for production tasks.	For particular project, understand the process of creating prototypes as per design drawings of either/both electronic/mechanical products.	DD1-C-1
	DD-C-3	Communicate technical information effectively with non-technical users.	create presentation informing staff at all levels of product design, including technical detail as to ensur clear understanding, even to a layman.	DD1-C-1
	DD-C-4	Perform a literature search and extract, collate and present information in a structured way.	Research solutions to the project as to determine available 'off the shelf' options, including their effectiveness.	DD1-C-1
	DD-C-5	Translate informal description of a problem into a set of detailed user requirements.	Create a System/Software requirements the particular project, including a risk assessment	DD-C-6, DD1-C-2
	DD-C-6	Identify performance and functional requirements for a design or an application.	Create a System/Software requirements for a particular project.	DD-C-5, DD1-C-2
	DD-C-7	Identify different options for a design and assess merits of each separately.	Create design description documentation indicating potential options, and justifying why certain options have been considered.	DD-C-9
	DD-C-8	Plan, set up and conduct bench experiments to validate concepts, components and systems.	Create validation plans to test that the design/product meets all relevant system requirements, ensuring traceability.	DD1-C-5
	DD-C-9	Plan and perform a design review.	Create design description documentation indicating potential options, and justifying why certain options have been considered.	DD-C-7
	DD-C-10	Plan and perform a validation study.	Write clinical protocols to enable system level validation testing of the product.	
	DD-C-11	Apply statistical analyses to data and to draw conclusions. Present the results and their discussion in a structured manner and written format.	Awareness and use Bland Altman techniques to compare measurement data from two different technologies.	
	DD-C-12	Critically evaluate their proposed methodology.	summarise project methodology and conclude efffectiveness and learning outcomes.	DD1-C-4, DD1-C-13

Device Risk Management & Governance	DRM-C-1	Operate a wide range of commonly encountered medical devices used in the organisation, ensuring coverage of diagnostic, monitoring and therapeutic equipment types.	Spend time in all critical care areas to learn about technologies used and research on how technology works.	
	DRM-C-2	Electrically safety test a range of Class1 and Class 2 devices, of types B, BF and CF, including the testing of applied parts.	Inaccordance with IPEM report 97, Electrical Test a range of medical devices documenting process and tests undertaken.	
	DRM-C-3	Access information sources to aid with the operation of devices, including manufacturer's instructions for use, medical device workshop manuals, organisations medical device training resources.	Work with the trust medical equipment training team to understand the resources and systems avaialable to aid them in using the devices and follow a few through to assess effectiveness and clarity of material.	DRM-C-1, DRM-C-7, DRM-C-8, DRM6-C-3, DRM6-C-4, DRM6-C-6
	DRM-C-4	Participate in the development and execution of a medical device procurement exercise.	Contribute to a procurement project project of a medical device.	DRM2-C-2, DRM3-C-1, DRM3-C-2, DRM3-C-3, DRM3-C-4, DRM3-C-5, DRM3-C-6, DRM3-C-8
	DRM-C-5	Carry out acceptance tests, including commissioning devices into clinical use.	Under supervision, follow local acceptance testing process and commsion a new device in accordance with work instruction. Record action on local equipment inventory.	DRM3-C-9, DRM3-C-10, DRM3-C-11
	DRM-C-6	Medical device training: i. Complete a competency-based training programme for a medical device. ii. Shadow company representatives delivering equipment training to clinical users. iii. Contribute to the delivery of training to support the use of a medical device in the clinical setting in conjunction with training officers in the organisation.	Work closely with Trust Medical device training team, to understand trust processes and procedure relating to user training on medical devices. Participate in the development of a competency assessment for a new model introduced is possible.	
	DRM-C-7	Undertake planned maintenance on a range of medical devices, e.g. Type 1, Type 2, Type 3, and complete service records comprehensively and legibly.	Shadow a Clinical Engineering Maintenance technician in undertaking planned preventative maintenance of a range of medical devices in accordance with local processes.	
	DRM-C-8	Observe the process for device repair and observe medical devices being repaired.	Shadow a Clinical Engineering Maintenance technician in undertaking a repair of a range of medical devices in accordance with local processes.	
	DRM-C-9	Clean and decontaminate a medical device.	Shadow a Clinical Engineering Library assistant in undertaking, collection, delivery, decontamination in accordance with local processes.	
	DRM-C-10	Participate in the removal of a medical device from service.	Shadow and Clinical Engineering Maintenance technician in the decommisioning/disposal of a medical device, in accordance with local processes.	
	DRM-C-11	Participate in the actions on a safety alert from receipt into the organisation, through determination of actions, execution of work, monitoring of progress and closure.	Summarise the responsibilities of the MDSO. Work with the trust MDSO in investigating the impact of an MHRA notice/FSN and ensure actions are implemented.	DRM5-C-1, DRM5-C-2, DRM5-C-3, DRM5-C-5
	DRM-C-12	Participate in the investigation of a medical device incident within the organisation.	Summarise local processes for monitoring medical device incidents. Participate in an action plan/Root cause analysis in relation to a reported incident and discuss status at MDSO month meeting.	DRM5-C-4, DRM8-C-1, DRM7-C-5, DRM5-C-6

	DRM-C-13	Investigate and describe the organisational approach to medical device management and the management of the life cycle of medical devices.	Review of own local medical devices policy and also awareness of MHRA document 'Managing medical Devices'. Document the local Medical devices governance structure (s), including Point of Care equipment, and Medical device education.	DRM1-C-1, DRM7-C-3, DRM-C-14
	DRM-C-14	Identify and navigate the standards that underpin or are used within the organisation's medical device management strategy and associated service delivery.	Review of own local medical devices policy and also awareness of MHRA document 'Managing medical Devices'. Document the local Medical devices governance structure (s), including Point of Care equipment, and Medical device education. Also review a slection of processes and procedures that underpin the services Quality management system.	DRM1-C-1, DRM7-C-3, DRM-C-13
	DRM-C-15	Use the organisation's medical device information system to: • recall inventory item details • log an equipment fault or service request • generate asset/maintenance reports, for an individual device or group of devices • generate key performance data.	Be familiar with trust medical device inventory, and perform tasks on requests.	DRM-C-7, DRM-C-8, DRM6-C-3, DRM6-C-4, DRM6-C-6
	DRM-C-16	Undertake a risk assessment on a piece of equipment or a service-related issue in accordance with ISO 14971 and local trust risk management policies and procedures.	Summarise requirements indicated in the 14971 standard. Contrinute towards either creating a Risk assessment template document covering the standard, or if one exists, undertake an assessment for an appropriate application.	DD1-C-11, DD1-C-12
Rehabilitation Engineering	RE-C-1	Control infection risks in accordance with departmental protocols.	Review Trust's policy and local procedures. Statutory and mandatory training	
	RE-C-2	Obtain a suitably completed request form, greet the patient and check patient identity and recent clinical history.	Review referral form and greet client and family/carers. Summary of legislation and guidelines.Case study/ reflective practise log	RE-C-3
	RE-C-3	Explain the procedure for the clinical measurement, address any procedure related questions and gain informed consent.	E.g. plinth assessment for range of movement assessment or levels of ability. Lead discussion and obtain consent. Case study/ reflective practise log	RE-C-2
	RE-C-4	Participate in a patient assessment relative to the clinical placement being undertaken; identify and define individual requirements for intervention; discuss with the patient and clinic team the realistic expectations of the intervention and the expected levels of enhancement.	Clinic report and supporting information of role, case studies	RE-C-6,RE-C-5
	RE-C-5	Use a variety of clinical methods to assess biomechanics and function (e.g. forces, active and passive joint movement, motor assessment, muscle activity, interface pressure, shape and energy expenditure) taking into account the complete clinical picture.	e.g. Evidence of range of movement assessment. Evidence of pressure measurement and explanation. Gait measurements. Taking history - medical, social etc. Clinic report/ case study	RE-C-2, RE-C-3, RE-C-4, RE-C-6
	RE-C-6	Develop objectives, recommendations and rationale for intervention.	Clinic report	RE-C-4, RE-C-5
	RE-C-7	Make appropriate adjustments to equipment or its application to enhance function, comfort and safety.	Make adjustments to equipment and document in task sheet or work order/ clinic report/ health recrord. E.g. FES set-up, powered mobility set-up, seating adjustemnt	RE-C-4, RE-C-6

DOPS

		DOPS	Examples of evidence	Competencies which may share evidence with this DOPS
		Undertake under supervision a clinical measurement	Observe Student undertake a clinical meaurement on a patient.	
		Undertake and interpret statistical treatment of clinical data	Observe stsudent perform a 'limits of agreement' analysis of a measure with two different devices as to validate performance.	
		Maintain PC software installation and local area network	Observe student install a new piece of software onto CM systems for use with existing hardware.	
CMICT		Manipulate a spreadsheet used to calculate a clinical paramete	Observe Student create clincial outcomes using a spreadsheet to calculate relevant clinical parameters	
		Produce a design using CAD or other appropriate design tool	Observe student creating CAD model of either an electronic circuit or mechanical structure.	DD1-C-1
		Undertake a design review	Observe student undertake an option appriasal of a product design.	DD-C-9
		Undertake a risk assessment, suggest mitigation measures and show how that reduces the risk	Observe student undertake risk assessment in relation to a product design	
		Set up and undertake a validation experiment.	Observe Student follow validation plan in relation to a product design and obtain necessary data.	DD-C-10
DD		Generate a list of performance and functional requirements from user requirements.	Observe student create a requirements specification in relation to a product.	DD-C-5, DD-C-6
		Generate a list of design specifications from the performance and functional requirements.	Observe student create a requirements specification in relation to a product.	DD-C-5, DD-C-6
		Conduct risk assessment on user, functional and performance requirements and modify to mitigate risks	Observe student create a requirements specification in relation to a product.	DD-C-5, DD-C-6
		Carry out a simple risk assessement	Observe Student undetake a risk assessment as required and requested by supervisor	
		Navigate the medical devices IT system	Observe Student navigate through equipment and maintenance data within the trust medical device inventory	DRM-C-15
DRM		Access and interpret relevant safety standards	Listen to student demonstate awareness of 60601 family of standards relating to medical devices and difference between collateral and specific standards.	DRM-C-2
		Complete a real or shadow change to an operating procedure	Observe the Student review a process which forms part of a Quality Management system and suggest changes according to their observations.	DRM-C-14
		Carry out functional and safety tests	Observe Student commision a new piece of medical electrical equipment.	DRM-C-2, DRM-C-5
		Participate in gait assessment, process the data obtained and complete for the reporting clinical scientist a real or shadow report including options of kinematic, kinetic and/or visual assessment.	Observe trainee participate in gait assessment, process the data obtained and complete for the reporting clinical scientist a real or shadow report including options of kinematic, kinetic and/or visual assessment.	RE-C-4, RE-C-5, RE-C-6
		Participate in the provision of a piece of posture management equipment	Observe trainee complete a specific element of the handover of a piece of postural management equipment	RE-C-7
RE		Participate in a wheelchair assessment and complete under supervision a real or shadow report, including recommendations and rationale for each. Might include manual and/or powered wheelchairs, as applicable.	Observe trainee complete a specific element of an assessment and review a real or shadow report produced by the student	RE-C-2, RE-C-3, RE-C-4, RE-C-5, RE-C-6
		Participate in the provision of a wheelchair and any associated equipment.	Observe trainee complete a specific element of the handover of a wheelchair	

OCEs

		OCEs	Examples of evidence	Competencies which may share evidence with this DOPS
Rehabilitation Engineering		Participate in a clinical assessment, for either electronic assistive technology, functional electrical stimulation, posture management, or wheelchair provision N.B. This will be partly assessed as an OCE.	Observe trainee participate in a clinical assessment, for either electronic assistive technology, functional electrical stimulation, posture management, or wheelchair provision N.B. This will be partly assessed as an OCE.	RE-C-2, RE-C-3, RE-C-4, RE-C-5, RE-C-6
		Participate in a posture management assessment and complete under supervision a real or shadow report including recommendations and rationale for each. This might include wheelchair seating, static seating and/or bed positioning, as applicable.	Observe trainee participate in a posture management assessment and complete under supervision a real or shadow report including recommendations and rationale for each. This might include wheelchair seating, static seating and/or bed positioning, as applicable.	RE-C-2, RE-C-3, RE-C-4, RE-C-5, RE-C-6

CBD

	CBD Example	Examples of evidence	Competencies which may share evidence with this CBD
CMICT			
DD	**Discuss Process of Risk Assessment in relation to a medical device design with emphasis of rationale around scoring and how hazards were identified**	as per example and olat record	DD-C-5
DRM	**Provide Student with an Medical device Alert of FSN and ask them to demonstate understanding of alert,including potential impact and device an action plan.**	as per example and olat record	DRM-C-11
RE	**Discuss a clinical assessment or case study in assistive technology or clinical gait analysis**	as per olat recorrd.	RE-C-3, RE-C-4, RE-C-5, RE-C-6