Learning Outcome Subject	Code	Competency	Examples of evidence	Other competencies which may be demonstrated by this evidence
	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.	

Clinical Measurement & ICT	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
	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.	
ign & 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

Des	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
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.	

Device Risk	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
tation 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

Rehabili	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
CMICT		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.	
		Manipulate a spreadsheet used to calculate a clinical paramete	Observe Student create clincial outcomes using a spreadsheet to calculate relevant clinical parameters	
DD		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
		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
DRM		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
		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
RE		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
		Participate in a wheelchair assessment and complete under supervision a real or shadow report, including recommendations and rationale for each. This 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

Guide for STP Trainees : Clinical Measurement and Development

Learning Outcome Subject	Code	Competency	Examples of evidence	Other competencies which may be demonstrated by this evidence
The Project Life Cycle	DD1-C-1	Devise a plan using an appropriate project management methodology to successfully deliver an innovation and development project controlling the quality, timing and costs of activities.	Devise a Project specification in accordance with local processes.	DD-C-3, DD-C-4
	DD1-C-3	Design a solution to meet the previous point by formulating various options and critically appraising them, taking into account the requirements specification, appropriateness of development tools and sustainability in the proposed operational environment.	Create design description documentation indicating potential options, and justifying why certain options have been considered.	DD-C-7
	DD1-C-2	Work with users to develop a detailed specification of requirements for an innovation and development project.	Create a System/Software requirements for a particular project.	DD-C-5, DD-C-6
	DD1-C-10	Manage a project within the framework of a formal project management methodology.	By familiar and summare your organisations design/development project management framework, as per local quality management systems such as 13485	
	DD1-C-4	Develop and critically evaluate the solution, establishing its appropriateness and limitations, including signal processing, decision support, mathematical modelling and choice of development platform.	Undertake an option appriasal for solutions to a particular design/development project.	DD-C-12
	DD1-C-5	Develop and undertake a validation plan.	Create validation plans to test that the design/product meets all relevant system requirements, ensuring traceability.	DD-C-8
	DD1-C-6	Develop and undertake a verification plan.	Be familiar with the verification plan that shall form part of you rorganisations quality management system.	
	DD1-C-7	Develop user documentation and training.	Create User Manuals, ensuring all user training related mitigations identified within the hazard analysis are considered.	
	DD1-C-8	Develop technical documentation.	Be familiar and summarise the requirements for a full technical file, including software/systems specification, Hazard Analysis, Validation plans and user manuals.	
	DD1-C-9	Follow the requirements of an appropriate development standard (e.g. EN13485, SSADM).	Be familiar with the requirements of the 13485 standard, listing the relevant processes/procedures required to claim compliance.	
	DD1-C-11	Manage security, safety and business risk throughout the development, including the use of ALARP principles.	Follow the requirements within the 14971 standard to assess and mitigate risk.	DRM-C-16, DD1-C-12
	DD1-C-12	Apply risk analysis iteratively to improve and redefine a design.	Follow the requirements within the 14971 standard to assess and mitigate risk.	DRM-C-16, DD1-C-11
	DD1-C-13	Perform end-stage review.	On completion of a project, create project design review which may include indicating aspects of non conformance or issues highlighted during testing.	DD-C-12, DD1-C-4

Advanced Information and Communication Technology Skills	DD2-C-1	Discuss and agree the operation of major ICT hardware, software and networking components.	Create a report on the provision of hardware and network for new software running on new hardware, discuss and agree with Hospital IT or other stakeholders as appropriate, e.g., medical application, medical device firewall, etc.; Review local network standard and relate to medical device requirement of ISO 80001-1 (network component only).	
	DD2-C-2	Undertake implementation of at least one standard server-based operating system, including security management and routine housekeeping tasks.	Install an Operating System (Windows/linux) on a system (hardware/Virtual Machine) following local centre guidelines (network, antivirus, security) and configure for system management, e.g., backup, regular tasks (task schedule/cron) and/or services/daemons.	DD2-C-4
	DD2-C-3	Apply relevant safety standards and guidance for the use of computers in clinical practice, including electrical safety.	Assist in the routine provision and maintenance of clinical workstations. Review local practices for provision of such computers and relate these to the appropriate Medical Devices legislation, ISO80001, IEC60601 and other relevant standards.	
	DD2-C-4	Develop and maintain protective measures for ICT systems, including disaster measures, antivirus protection, maintenance, updating, firewalls and virtual servers/networks.	Configure a computer system (hardware/Virtual Machine) following local centre guidelines relating to network, firewall, antivirus and security; and configure for system management, e.g., backup and regular monitoring and maintenance tasks	DD2-C-2
	DD2-C-5	Critically appraise the ICT standards adopted by the NHS, including Digital Imaging and Communications in Medicine (DICOM) and Health Level 7 International (HL7).	Review DICOM conformance statement for one piece of cllnical software or clinical computer system and relate this to DICOM standard; create a report on processes in use for anonymisation and pseudonimisation of DICOM data, and relate this to the DICOM standard; Review support for HL7 in medical applications in department/centre and consider safety improvement that might be achieved; Review local network standards and relate to medical device requirement of ISO 80001-1	
	DD2-C-6	Plan and carry out the implementation of ICT components in a controlled fashion, taking into account the impact on existing facilities and clinical service.	Undertake a project for an upgrade to existing clinical software or provision of a new installation of software on workstation or server, including a risk assessment and review of any changes required in support and peripheral services, such as backup and archiving.	DD2-C-3
Clinical Measurement	DD3-C-1	Obtain specific clinical measurements from patients under supervision.	Measurements may come from such areas as respiratory, audiology, cardiology, neurophysiology, urology, audiology, opthalmology, GI physiology.	
	DD3-C-2	Interpret data and advise on the use of specific measurements (particularly in terms of accuracy, reproducibility, bias, specificity and sensitivity).	Use statistics as appropriate to interpret measurements and advise on the clinical significance of the results.	DD3-C-11
	DD3-C-3	Critically appraise procedures, applications and strategies and advise on their modification in the light of developing knowledge.	Review scientific literature, critically compare measurement systems, assess guidance documents and protocols between different centres.	DD3-C-6; DD3-C-5; DD3-C-7; DD3-C-11
	DD3-C-4	Write a report on the outcome of the clinical measurement.	Use a report to demonstrate understanding of the clinical significance of the measurement and communicate this to patient/professional appropriately.	DD3-C-2; DD3-C-11
	DD3-C-6	Identify problems, determine their nature and devise a strategy for solving them.	Undertake calibration procedures. Complete quality assurance measurments. Document and present data describring a problem and recommend/implement action.	DD3-C-5; DD3-C-7; DD3-C-8; DD3-C-9
	DD3-C-5	Implement effective corrective actions when performance deteriorates.	Monitor QA results and take action when results are out of tolerance.	DD3-C-3
	DD3-C-7	Solve a problem through application of specialist knowledge and experience.	Identify artefacts on a measurement and be able to take action to remove or advise on the impact on the measurement.	DD3-C-9; DD3-C-10; DD3-C-11
	DD3-C-8	Discuss and agree with co-workers, and the patient where appropriate, the steps being taken to resolve a problem.	Describe reaction to when unexpected issues/difficulties are encountered and reflect upon how these could be avoided or how student would deal with them in the future.	DD3-C-8; DD3-C-10; DD3-C-11

	DD3-C-9	Advise on health and safety issues relevant to the investigation.	Perform risk assessment for a procedure or particular case.	DD3-C-7; DD3-C-11
	DD3-C-10	Take appropriate action in the case of incidents and accidents	Undertake root cause analysis. Knowledge or experience of incident reporting using hospital systems e.g. DATIX	DD3-C-9
	DD3-C-11	Contribute at a professional level to clinical teams and communicate scientific material effectively to professional colleagues.	Write a report from a clinical measurement. Participate in an MDT review meeting. Present measurement data at research meetings, workshops, study days etc	DD3-C-2; DD3-C-3; DD3-C-4; DD3-C-6; DD3-C-8

DOPS

		DOPS	**Examples of evidence**	**Competencies which may share evidence with this DOPS**
The Project Lifecycle		Direct observed practical skill	Observe student create hardware software to fulfil a medical device design specification	
		Produce user documentation and training	Observe student ceate user training material in relation to a newly developed medical device.	DD1-C-7
		Produce technical documentation	Observe student create documents for a technical file, such as a design specification, validation/verification plan and hazard analysis	DD1-C-8
		Review an ongoing project and identify the lifecycle of the project and ways of taking it forward	Observe the student use project methodology to review a current project and understand the steps required to progress the project by developing an appropriate project plan.	DD1-C-1, DD1-C-10
		Undertake vigilance and end of life procedures	Observe the student consider post market surveliance procedures for the device and how feedback will be recorded, prioritised and actioned	
		Develop a specification of requirements	Observe the stiudent develop a safety and functional specification.	DD1-C-2
		Design a solution to respond to a specification of requirements	Observe student create a design that meets the original specification, and documents design in design desciption document.	CC1-C-3, DD1-C-4
		Develop a formal project management plan for a project lifecycle	Observe the student use project methodology to review a current project and understand the steps required to progress the project by developing an appropriate project plan.	DD1-C-1, DD1-C-10
		Undertake a risk analysis of a project	Observe Student create a risk management file for a product design in accordance with ISO 14971.	DD1-C-12
		Produce an implementation plan to manage the risks of medical device	Observe the student plan impementation of a newly developed device including consideration of user training, configurations and access levels, aswell as commisioning procedures.	
		Apply lifecycle process to a project and undertake validation	Observe the student undertake validation in accordance with the pre-created validation plan.	
		Undertake a risk analysis to support the improvement and redefinition of a design	Observe the student undertake a risk assessment in relation to a medical device design/modification	DD1-C-11, DD1-C-12
		Install a system and applications software on a void PC	Install Windows onto a PC, going through the full update cycle of both the Operating System and Anti-Virus.	CMICT-C-12, DD2-C-2, DD2-C-4
		Undertake a range of system administration tasks on a clinical system	Purge log files, review backups, manage user accounts, manage access controls to shared resources.	
		Set up or modify a local area network	Connect a medical device to the local network, following policy and procedure. Refer to ISO 800001-1.	

Advance ICT Skills		Programme a void PC to produce and report clinical measurement or other laboratory data	Create an interface to a medical device in order to extract information from it. Store this in a database of your design.	CMICT-C-13
		Develop a prototype web-based application for clinical applications	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).	CMICT-C-13
		Analyse, summarise and present complex data using computer software	Data mine a patient database (comprised of more than one table) for information. Present findings to an audience using presentaiton software.	
		Comply with the information governance and operational management requirements for clinical systems	Undertake the local IG training course.	
		Identify the ICT infrastructure requirements for a diagnostic service, including networking, data storage and interconnectivity	Audit an ICT-dependent service (e.g. Nuclear Medicine).	DD2-C-3, DD2-C-5
		Develop a software application to support a clinical service	Use ImageJ (or similar) to create a program for MRI QA which replaces several manual steps/procedures.	CMICT-C-13
		Design a system to analyse quality control results	Extract PPM information from the local equipment management database and report on key performance indicators as held in the local QMS.	
		Develop and maintain protective measures for ICT systems	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-12, DD2-C-2, DD2-C-4
		Implement ICT components in a controlled environment	Undertake a hardware upgrade of a PC, e.g. the addition of RAM or the replacement of a video capture card.	CMICT-C-12
		Undertake a range of routine house keeping tasks associated with standard server based operating systems	Purge log files, review backups, manage user accounts, manage access controls to shared resources.	
		Undertake a governance review of an ICT system	Audit an ICT system according to the local policies and procedures held in the QMS.	
Clinical Measurement		Develop new clinical measurement solution and present to assessor	Modify measurement protocols for a complicated case or spply novel measurement methods	DD3-C-3; DD3-C-6; DD3-C-7; DD3-C-8; DD3-C-11
		Report on a novel or complex clinical measurement	Write a report from a noval case.	DD3-C-2; DD3-C-4; DD3-C-11
		Implement a clinical measurement solution	Observe the student addressing a problem with a measurement or developing an innovation	DD3-C-5; DD3-C-7; DD3-C-10
		Select the appropriate equipment and its use in clinical measurement for 12-lead ECG, polysomnography, ERG or equivalent	Observe the student showing reasoning for the appropriate choice of equipment	DD3-C-2; DD3-C-3
		Identify and implement effective corrective actions when performance deteriorates	Observe student taking corrective action such as recalibration when equipment is deteriorating	DD3-C-5; DD3-C-6; DD3-C-7
		Identify problems, determine their nature and devise a strategy for solving them	Observe student taking appropriate action in response to a measurement error/artefact or equipment problem	DD3-C-6; DD3-C-7; DD3-C-8; DD3-C-9; DD3-C-10

OCEs

		OCEs	**Examples of evidence**	**Competencies which may share evidence with this OCE**

The Project Lifecycle		Present technical information for both technical and non-technical users	Observe student present project status at local or national seminar/conference.	
		Review a completed project, understand the clinical and scientific background, and explain to colleagues the development lifecycle, suggesting alternatives and/or improvements	Observe student write a project proposal including opions for designs including drawbacka and benefits of each one, concluding a preferred option with rationale.	DD1-C-4
		Present information about a project to a range of users and purposes including providing information, training and general reference	Observe student develop training documentation in relation to the developed product	DD1-C-7
		Advise colleagues on health and safety issues relevant to a development project or a medical devise	Observe student undertake a formal risk assessment in relation to design	DD1-C-11
		Contribute at a professional level to clinical teams and communicate scientific material effectively to professional colleagues	Observe student present newly developed device as per specifiction to clincal teams for feedback.	
		Obtain a patient history from a normal volunteer or typical patient referred to your service and present the findings to a colleague or peer	Observe Student review patient notes and suggest conclusions and opinions on test regimes to follow.	
Advance ICT Skills		Discuss with clinical team and agree the operation of major ICT hardware, software and networking components	Observe student present on a networked software system including underlying hardware used in a clinical environment for discussion and feedback.	DD2-C-1, DD2-C-6
		Explain complex software to clinical colleagues	Observe student present a review of complex software used in a clinical environment.	
		Explain key factors affecting security management factors influencing data integrity to a clinical team	Observe student training/presenting to clinical team on 'best practice' related to data integrity.	DD2-C-3, DD2-C-4, DD2-C-5
		Advise on health and safety issues relevant to the investigation	Observe student discuss a self-developed risk assessment with relevant clinical team.	DD2-C-6
		Contribute at a professional level to clinical teams and communicate scientific material	Observe student present at local or other meeting on scientific software.	
		Describe to clinical colleagues the potential influences, advantages, disadvantages of implementation on data management	Observe student present at local or other meeting on data access and management of software used in a clinical environment.	DD2-C-3, DD2-C-4, DD2-C-5
surement		Record complex electrophysiology data such as 12-lead ECG, polysomnography, ERG,and present numerically and graphically the main findings	Obtain electrophysiological measurements and select appropriate methods of reporting.	DD3-C-1; DD3-C-2; DD3-C-4; DD3-C-11
		Obtain specific clinical measurements from patients	Student leads a clinical measurement assessment.	DD3-C-1
		Conduct pressure and flow measurement such as respiratory, blood flow, urodynamics, etc and present numerically and graphically the main findings to clinical colleagues	Observe a student undertaking a measurement and presenting the results	DD3-C-1; DD3-C-2; DD3-C-4; DD3-C-11
		Conduct a gait analysis and present numerically and graphically the main findings to clinical colleagues	Observe a student undertaking a gait analysis and presenting the results	DD3-C-1; DD3-C-2; DD3-C-4; DD3-C-11

Clinical Meas		Take patient consent for the procedure	Observe student discussing the measurement with a patient and recording informed consent. Student understands the process of informed consent.	
		Explain to the patient the procedure and next steps	Observe the student explaining a measurement procedure to a patient. Review/develop patient information literature.	C-2; DD3-C-3; DD3-C-4; DD3-C-6; DD3-C-8; DD3-C-11
		Advise on health and safety issues relevant to the investigation	Observe student discussing a health and safety issue such as a risk assessment	DD3-C-8; DD3-C-9; DD3-C-10; DD3-C-11
		Contribute at a professional level to clinical teams and communicate scientific material effectively to professional colleagues	Observe student taking part in an MDT meeting or presenting scientific material at a local or national conference/seminar	
		Discuss and agree with co-workers, and patient where appropriate, the steps being taken to resolve a problem	Observe student explaining the reasoning behind how a problem has been dealt with	

CBD

	CBD Example	Examples of evidence	Competencies which may share evidence with this CBD
CMICT1	**Setup and evaluate a new piece of measurement equipment and make recommendaitons for its use.**	Development of local guidance, protocol, demonstrate compliance with manufactures reported specifications.	DD3-C-2, DD3-C-3, DD3-C-4, DD3-C-7, DD3-C-11
CMICT2	**Obtain exploratory measurements using either a new measurement technique or an existing technique but in a new application**	Written report, abstract, presentation at meeting/conference.	DD3-C-2, DD3-C-3, DD3-C-4, DD3-C-6, DD3-C-7, DD3-C-11
CMICT3	**Critically compare two or more measurement systems/methods intended to evaluate the same physiolocal parameter.**	Critical comparison. Recommendations	DD3-C-2, DD3-C-3, DD3-C-4

Guide for STP Trainees : Medical Device Risk Management and Governance

Learning Outcome Subject	Code	Competency	Examples of evidence	Other competencies which may be demonstrated by this evidence
Medical Device Management Strategy	DRM1-C-1	Undertake a comprehensive review of the institution's medical device management policy against the prevailing national standards and professional best practice.	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.	DRM7-C-3, DRM-C-13
	DRM1-C-2	Outline the key elements of a medical device management strategy and the associated service delivery.	Have awareness of the medical device lifecycle and present and explain one taken from local documentation or other literature, Awareness of ISO 55000 and the NHSSC blueprint. Summarise contents of NHSSC Blueprint and the NHS supply chain assessment tool.	
	DRM1-C-3	Navigate and interpret the IEC 60601 electromedical family of standards, including collateral, particular and performance standards.	Ability to articulate the key features of the IEC 60601 family and different elements, including part 1, collateral and part 2's. Attendance at the Liverpool Electrical Safety Testing course and awareness of IPEM report 90. Devise a Medical Electrical System on paper ensuring compliance with the 60601 standard in terms of electrical safety.	
	DRM1-C-4	Navigate and interpret the healthcare-related risk management standards, including consideration of at least the following specific examples of medical device risks encountered. • Medical Device Decontamination • Equipment on loan	Summarise the contents of IPEM report 95 and requirements indicated in chapter 9 of MHRA document 'Managing medical devices' which relates to decontamination. Also review of local 'Loans and donations' policy.	
Optimisation of Medical Device Effectiveness and Efficiency	DRM2-C-1	Produce material that demonstrates specialist expertise in a range of medical equipment types and aids: • clinicians • technical colleagues to maximise the effectiveness and safe operation of devices, covering all the following areas: • training guides • addressing hazards • improved maintenance • quality assurance/performance checks • risk reduction.	Summarise the contents of IPEM report 95 and 110 and requirements indicated in chapters 6+7 of MHRA document 'Managing medical devices' which relates o Training. Participate in the Risk assessment of Medical devices in terms of training and maintenance. Write maintenance checklists.	DRM7-C-2, DRM4-C-2, DRM4-C-1
	DRM2-C-2	Identify limitations of clinical devices and suggest alternative solutions.	Lead participate on a Medical device Selection and Procurement exercise. Participate in clinical/Technical evaluation of a range of medial devices and critically appraise all solutions.	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-4
	DRM2-C-3	Design processes to ensure prescribed patient medical devices are effectively introduced and managed.	Considering medical devices in the community/home environment, give a good practical example and produce a checklist of key factors to consider prior to deployment.	
	DRM2-C-4	Critically appraise the technical and information governance issues arising from a complex medical installation in a networking environment.	Partipate in the commisioning process of newly selected medical devices that are to be interconneted to a medial network and integrated with software systems. Ensure awareness of the ISO 80001 standard.	
g and Installation	DRM3-C-1	Apply engineering principles and practice to the evaluation and selection of medical devices.	Lead participate on a Medical device Selection and Procurement exercise. Write specifications and evaluations forms as part of a medical device procurement exercise, ensuring stakeholder engagement	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-4
	DRM3-C-2	Write a clinical specification as part of an equipment acquisition process, incorporating any technical standards and regulatory compliance.	Lead participate on a Medical device Selection and Procurement exercise. Ensure reference to applicable standards are included in the specification.	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-4
	DRM3-C-3	Develop evaluation criteria against which to test candidate devices.	Lead participate on a Medical device Selection and Procurement exercise. Develop clinical/Technical evaluation criteria ensuring stakeholder engagement. Awareness of chapter 3 of the MHRA document 'Managing Medical Devices'.	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-4
	DRM3-C-4	Develop and assess responses to pre-tender questionnaires.	Lead participate on a Medical device Selection and Procurement exercise. Critically appraise/compare and score tender responses	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-4

Equipment Acquisition, Acceptance Testing	DRM3-C-5	Arrange equipment trials to ensure devices meet clinical need and evaluate against established criteria	Lead/assist in a full selection/procurement exercise.	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-4
	DRM3-C-6	Evaluate commercially available equipment against clinical requirements.	Lead/assist in a full selection/procurement exercise.	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-4
	DRM3-C-7	Contribute to business case development and write a case for medical device acquisition encompassing key requirements.	Partipate in the replacement plans of key items of Medical devices, risk assessing where required. Attend and participate in Medical Equipment executive meetings	
	DRM3-C-8	Apply project planning methodologies to assist in the procurement and installation process.	Lead/assist in a full selection/procurement exercise.	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-4
	DRM3-C-9	Execute the installation process, including specifying all necessary acceptance tests and commissioning processes.	Familiarity of the requirements of chapter 5 of the MHRA document 'managing medical devices'. Participate in the commissioning of a range of different types of equipment in line with local procedures.	DRM3-C-9, DRM3-C-10, DRM3-C-11, DRM-C-5
	DRM3-C-10	Determine the ongoing maintenance arrangements for the device and associated life cycle issues.	Be familiar with local methodology for assessing maintetance intervals on medical devices. Establish a maintenance programme for a particular medical device alond with the training requirements for end users and technical staff on routine and user maintenance.	DRM3-C-9, DRM3-C-10, DRM3-C-11, DRM-C-5
	DRM3-C-11	Handle rejected items that fail acceptance testing.	Under supervision, follow local acceptance testing process and commsion a new device in accordance with work instruction. Record action on local equipment inventory. Be familiar with dealing with an item that fails an acceptance test and decribe the actions taken.	DRM3-C-9, DRM3-C-10, DRM3-C-11, DRM-C-5
enance and Repairs to Devices	DRM4-C-1	Apply engineering principles to the management of risk in designing and delivering maintenance programmes.	Summarise the contents of IPEM report 95 and 110 in terms of risk classification of medical devices. Follow local procedures in the risk classification of different models of medical devices	DRM2-C-1, DRM4-C-2, DRM7-C-2
	DRM4-C-2	Plan and manage preventive maintenance regimens for individual devices and the larger groupings of medical devices.	Summarise the contents of IPEM report 95 and 110 in terms of risk classification of medical devices. Follow local procedures in the risk classification of different models of medical devices	DRM4-C-1, DRM2-C-1, DRM7-C-2
	DRM4-C-3	Plan and participate in training and deploying the technical workforce to ensure coverage of all equipment types.	Attend a technical training course and create material which can be used to cascade knowledge to other members of the technical team.	
	DRM4-C-4	Specify, arrange and manage external service contract providers.	Familiarity of the requirements of chapter 8 of the MHRA document 'managing medical devices'. Particiapte in the procurement and selection of external maintenance provider ensuring appropriate level of cover and assessment of risk if utilisation of third party providers.	
	DRM4-C-5	Act as an expert on the use and interpretation of medical device safety tests as part of the maintenance process, including the resolution of anomalies.	Participate in the planned preventitaive maintenance of certain types of infusion devices, and re-calibrate where necessary.	
	DRM4-C-6	Design planned maintenance regimens for a range of medical devices.	Be familiar with local methodology for assessing maintenance intervals on medical devices, and show awareness of other such methodologies/tools for assessing maintenance risk of medical devices	DRM4-C-1, DRM4-C-2, DRM2-C-1
	DRM4-C-7	Oversee workmanship standards on a range of medical devices.	Audit a group of staff members undertake a procedure withinin service and provide feedback on observations including non conformances and opportunities for improvement.	
	DRM4-C-8	Specify the calibration requirements for specific test equipment required to assist in the maintenance process.	Summarise local protocols/procedures relating to test equipment calibration. Understand requirements for Traceability to national standards, and how this is claimed for a selection of test apparatus in use.	DRM4-C-14
	DRM4-C-9	Specify the records necessary to support the maintenance process, including determination of records to comply with all of the following: • statutory requirements • prevailing national healthcare standards/NHS requirements • customer requirements • best professional practice • local needs.	Summarise the records requirements as documented in MHRA - Managing Medical Devices section 2. Be familiar with local policy on records and legal requirements.	

Planned Maint	DRM4-C-10	Provide expert advice on the cleaning and decontamination of medical devices as related to the maintenance process.	Be familiar with the requirements indicated in chapter 9 of MHRA document 'Managing medical devices' which relates to decontamination. Be familiar with local policy and procedures in terms of receipt of equipment into the workshop.	
	DRM4-C-11	Specify test equipment required for the workshop.	Spend time within the MEMS worshops ensuring exposure to the wide range of test appratus used. Summarise the test equipment requirements in order to service a selection of medical devices.	DRM4-C-13
	DRM4-C-12	Monitor the service records of technical staff to ensure they are comprehensive and legible.	Participate in the monthly audit of job records completed by technical staff, against the requirements defined in the relevant work instructions for entering a job.	
	DRM4-C-13	Oversee the correct use of hand tools within the workshop.	Spend time within the MEMS worshops ensuring exposure to the wide range of test appratus used. Summarise the test equipment requirements in order to service a selection of medical devices.	DRM4-C-11
	DRM4-C-14	Ensure traceability of product in the maintenance process.	Assist the workshop test apparatus calibration lead in the management of test equipment including internal verification, and how this can be traced back to national standards.	DRM4-C-8
	DRM4-C-15	Identify and minimise health and safety risks in the workshop and clinical environments while maintenance activities are undertaken.	Summarise the Health and Safety at work act, and the implications for Clinical Engineering departments. Assist the health and safety lead review month end status of health and safety actions and become familiar with the full breadth of health and safety considerations necessary.	
	DRM4-C-16	Ensure device modifications are undertaken appropriately.	Summarise section 3.5 of the MHRA document 'Managing Medical devices' which relates to Modification and changes in use. Ensure full risk assessment are conducted aswell as documented specification of the modification requirements	DRM4-C-17, DRM7-C-6
	DRM4-C-17	Advise on the appropriateness of in-house modifications and the necessity for risk assessment and the establishment of a design project.	with reference to an example, (may be theoretical) explain the key steps	DRM4-C-16, DRM7-C-6
Patient Safety	DRM5-C-1	Act as Department of Health Central Alerting System responsible officer, including ability to use the national database.	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-2, DRM5-C-3, DRM5-C-5, DRM-C-11
	DRM5-C-2	Act as the MHRA liaison officer.	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-3, DRM5-C-5, DRM-C-11
	DRM5-C-3	Receive and determine actions associated with a national safety notice.	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, DRM-C-5, DRM-C-11
	DRM5-C-4	Investigate an incident	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-6, DRM8-C-1, DRM7-C-5, DRM-C-12
	DRM5-C-5	Interpret safety alerts and extract key information, such as actions, deadlines and stakeholders.	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, DRM-C-3, DRM-C-11
	DRM5-C-6	Execute root cause analysis on a range of medical device-related incidents, emphasising where device performance has been compromised	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, DRM-C-12
n System	DRM6-C-1	Apply engineering principles to classify and structure the institution's approach to medical device categorisation.	Summarise the Medical Device Type Categoration in terms of GMDN and UMDNS. Understand the requirments of GS1 and the impact this will have on Medical Device Categorisation.	
	DRM6-C-2	Apply engineering principles to the specification, implementation and ongoing use of the medical device information system.	Summarise the importance of the Medical device inventory, identifiying all key requirements. Provide evidience that these requirements are being met with the local system.	
	DRM6-C-3	Analyse and interpret data from the system.	Participate with the end of month KPI analysis, showing evidence of the data that is extracted from the Medical Device inventory.	DRM6-C-7, DRM6-C-9
	DRM6-C-4	Be an expert user of the institution's medical device information system to display or extract all asset-related information.	Participate with the creation of Capital Medical Equipment equipment lists for Clinical Management Groups/Directorates to assist them with submission of capital bids.	DRM6-C-10

Medical Device Information	DRM6-C-5	Access specific equipment types for information from the medical device information system, demonstrating an understanding of equipment classification.	Create lists of a selected 'Types' of Medical Equipment to allow for replacement plans. Understand the different financial classification of equipment in accordance with local 'Standing Financial Instructions'.	
	DRM6-C-6	Establish the institution's equipment holding by value and volume.	Create a list of all 'in service' Capital/Revenue equipment to enable assessment of value for each classification	
	DRM6-C-7	Design, produce and utilise key performance indicators for use in performance management of the medical device risk management and governance service	Participate with the end of month KPI analysis, showing evidence of the data that is extracted from the Medical Device inventory.	DRM6-C-3, DRM6-C-9
	DRM6-C-8	Maintain data integrity and security on the Institution's Medical Device Information System.	Summarise local systems of ensuring data integrity and security, i.e. access levels, audits etc.	
	DRM6-C-9	Use the Institution's Medical Device Information System to monitor progress on all service requests received.	Participate with the end of month KPI analysis, showing evidence of the data that is extracted from the Medical Device inventory.	DRM6-C-3, DRM6-6-7
	DRM6-C-10	Produce a range of complex, bespoke asset based reports.	Participate with the creation of Capital Medical Equipment equipment lists for Clinical Management Groups/Directorates to assist them with submission of capital bids.	DRM6-C-4
	DRM6-C-11	Undertake statistical analysis of device data to establish reliability of devices and cost effectiveness of devices through their life.	Use the Medical device inventory to determine the maintenance cost of a certain model of infusion pump. Undertake analysis to determine common causes of failure and devise action plan to reduce costs.	
Expertise in Medical Device Risk Management	DRM7-C-1	Apply medical device risk management knowledge and engineering principles to identify prevailing medical device-related risks within the institution.	Particpate in the Capital Medical Equipment bidding round process. Critically appraise some of the 'Cases of need' and justify the impact if the bid is not approved.	
	DRM7-C-2	Develop medical device risk management strategies for the institution.	Summarise the contents of IPEM report 95 and 110 in terms of risk classification of medical devices. Follow local procedures in the risk classification of different models of medical devices	DRM2-C-1, DRM4-C-2, DRM4-C-1
	DRM7-C-3	Develop a policy for the organisation to help manage risk.		DRM1-C-1
	DRM7-C-4	Execute a number of complex medical device- or service-related risk assessments.	Undertake a Risk Assessment in relation to use of third party maintenance contract service provider. Conduct a Risk assessment relating to a workshop working practice.	
	DRM7-C-5	Advise on practical risk management actions in medical device risk management and governance.	Participate in an action plan/Root cause analysis in relation to a reported incident and discuss status at MDSO month meeting.	DRM5-C-4, DRM5-C-6, DRM8-C-1, DRM-C-12
	DRM7-C-6	Authorise modifications to medical devices having analysed the associated risks.	with reference to an example, (may be theoretical) explain the key steps	DRM4-C-16, DRM4-C-17
Professional Advisory Services	DRM8-C-1	Implement interdisciplinary medical device risk management forums within the institution.	Attend and Participate in the local Medical Device Safety Officer meetings, devising relevant action plans and ensuring follow-up.	DRM5-C-4, DRM5-C-6, DRM7-C-5, DRM-C-12
	DRM8-C-2	Undertake medical device audits.	Participate in a trust wide Medical Device audit, or assist in a mini audit as per asset verification prior to renewing a maintenance contract. Awareness of the Capital finance capital asset verification, and why this is required.	
	DRM8-C-3	Provide advice on the requirements for a clinical trial involving a novel medical device.	Assist in the Clinical Engineering review of R+D study approval. Awareness of the ethics process and requirements for clinical evaluation as per Medical Devices Regulations. Awareness of MHRA document 'Clinical Investigations of Medical Devices - Guidance for Manufacturers'.	
	DRM8-C-4	Keep up to date with new technologies and developments within the field of medical device management.	Participate in meetings with company representatives in which new products are presented. Keep abreast of new technologies by reviewing journals and attending national conferences.	
	DRM8-C-5	Advise the institution on equipment replacement requirements.	Partipate in the replacement plans of key items of Medical devices, risk assessing where required. Attend and participate in Medical Equipment executive	DRM3-C-7
	DRM8-C-6	Participate in the clinical engineering response to a major business plan involving a significant medical equipment installation.	Partipate in a new build project which involves the requirments of a significnat amount of medical devices to be purchased.	

DOPS

		DOPS	Examples of evidence	Competencies which may share evidence with this DOPS
Medical Device Management Strategy		Undertake a review of the Institution's approach to Device Risk Management, identifying key features of the Medical Device Management policy, governance controls and local arrangements for device life cycle management	Observe Student reviewing MHRA guidance (Managing Medical Devices) and Trust Medical Devices Policy.	DRM1-C-1
		Navigate the IEC 60601-1 standard and associated collateral and particular standards.	Observe Student reviewing 60601 core standard.	DRM1-C-3
		Conduct a medical device related risk assessment	Observe The Student undertake a risk assessment in relation to a medical device e.g. modification, use of third party maintenance providers.	DRM7-C-4
		Clean and decontaminate a re-usable medical device	Observe Student decontam inate a medical device on return to the medical equipment library	
Optimisation of Medical Device Effectiveness & Efficiency		Implement a quality assurance regime for a medical device	Observe Student audit a process which forms part of the medical equipment management quality management system.	DRM4-C-7
		Implement IT and interconnectivity for a medical device installation	Observe student participate in discussions in relation to connection of new/existing medical devices to the trust network.	DRM2-C-4
		Select and utilise specialist test equipment, specifically including electro-medical safety testers, understanding the need for calibrated devices.	Observe Student undertake a medical electrical equipment safety check of a device which has patient connected appled parts	
		Undertake a risk assessment related to the utilisation of medical devices in complex clinical environments	Observe student participate in the risk assessment in relation to neonatal or peadiatric transport system to be used in an ambulance	DRM4-C-16
		Undertake a risk assessment related to the utilisation of medical devices in Theatres Me	Observe student participate in a risk assessment in relation to the introduction of a new model/type of medical device within the theatre environment	
		Undertake a risk assessment related to the utilisation of medical devices in Intensive Care	Observe student participate in a risk assessment in relation to the introduction of a new model/type of medical device within the intensive care environment	
		Outline a prescription for a medical device and develop specific guidance	Observe the trainee identifying the key medical device management issues when a prescribed device is to be issued to a patient. The dop may commonly take the form of advising a fellow healthcare professional.	
		Identify limitations of clinical devices and suggest alternative solutions	Observe Student score feedback from a medical device procurement exercise and develop material to justify decisions.	DRM3-C-1 - DRM3-C-6
		Design processes to ensure prescribed patient medical devices are effectively introduced and managed	Be familiar with relevant policies of when issueing home patients with medical deviecs and obseve student undertaking such a task in an area such as respiratory physiology.	
Testing and Installation		Produce a plan, including the appropriate engineering evaluations to assess and evaluate a medical device against the specification produced to evaluate candidate devices E	Observe student contribute towards creation of a specification and organise/plan appropriate clinical/technical evaluations as to ensure objective assessment of a selection of medical devices	DRM3-C-1 - DRM3-C-6
		Plan a trial of a medical device in a clinical setting, including the design and application of device evaluation material.	Observe student contribute towards creation of a specification and organise/plan appropriate clinical/technical evaluations as to ensure objective assessment of a selection of medical devices	DRM3-C-1 - DRM3-C-6
		Evaluate a Pre-Purchase Questionnaire from a Supplier to inform the selection process	Observe the student assess/evaluate content of a PAQ form and any supplementary information returned from manufacture as part of local purchase approval process	

Equipment Acquisition, Acceptance		Determine the acceptance test requirements and test the equipment prior to introducing the devices into service, describing the process for items that fail acceptance	Observe the Student undertake the full Accepance/commissioning process for a new item of medical equipment in accordance with local procedures which form part of quality management system.	DRM3-C-9
		Contribute to a complex installation of a medical device system	Observe the student partricipate in the full acceptance/commissioning process for a large installation of multiple devices in a theatres or intensive care area in accordance with local procedures which form part of quality management system.	DRM3-C-9
		Assess the planned maintenance requirements of a newly acquired device	Observe the student assess/score the maintenance risk classification of a new medical device type/model in accordance with local procedures and allocate PM schedule to device on trust medical device inventory.	DRM4-C-6
		Collate the data to be recorded on the institutions Medical Device Information System	Observe the Student undertake the full Accepance/commissioning process for a new item of medical equipment in accordance with local procedures which form part of quality management system.	DRM3-C-9
Planned Maintenance and Repairs to Devices		Carry out a range of planned maintenance and repairs to a range of medical equipment	Observe the Student participate with a repair and planned preventivice maintenance procedure on low/medium/high risk medical devices in accordance with local procedures that form part of a quality management system.	DRM4-C-6
		Manage the key components of the planned maintenance and repair process, illustrating the approach to maintenance plannning	Observe the student whilst working in the maintenance team, prioritise demand work requests in accordance with local processes/procedures that form part of a quality managament system.	
		Apply quality management systems, such as ISO 9001 to the workshop environment, contributing to internal audits	Observe student participate in local quality management meetings and participate in an audit of a core process such as acceptance, repair, preventative maintenance of medical devices.	DRM4-C-7
		Specify the calibration requirements for specific test equipment required to assist in the maintenance process, and advise on the management of calibration devices and test equipment	Observe Student particpate in a calibration meeting and also participating in an internal verification of a ietms of test apparatus and also revieiwing the calibration certificate of a item of equipment calibrated externally.	DRM4-C-14
		Select one or two devices to follow through the decontamination process	Observe student follow local processes and procedures and trust policy to decontaminate an item of equipment returned to the medical equipment library and also a review the decontamination certificate of an item of equipment returned to the workshop for repair/maintenance.	DRM1-C-4, DRM4-C-10
		Oversee the delivery of a series of planned maintenance visits to a range of clinical areas	Observe student arranging external engineer maintenance visits within critical care areas across the trust, ensuring equipment availability and access where possible. Ensure service records are provided and inventory updates as per local processes/procedures.	
		Develop a range of policies and procedures relating to device maintenance	Observe student lead/participate in the review of a current process or development of a new process which forms part of the local quality management system.	DRM4-C-1, DRM4-C-6
		Undertake risk based planned maintenance on a medical device	Observe the student assess/score the maintenance risk classification of a new medical device type/model in accordance with local procedures and allocate PM schedule to device on trust medical device inventory.	DRM4-C-1, DRM4-C-6
		Oversee workmanship standards on a range of medical devices, including the correct use of hand tools	Observe Student undertake a repair of an infusion pump which includes the use of tools and test apparatus.	DRM4-C-13
Patient Safety		Describe the Institution's approach to the handling of safety alerts. Review current safety alerts on the prevailing national distribution systems	Observe Student review a safety alert or Field Safety Notice and assess impact and devise action plan.	DRM5-C-3
		Assess technical matters that could impair device efficacy	Observe Student participate in discussions in relation to building plans that shall house medial devices, advising on necessary measures to ensure equipment functionality.	
		Review a medical device incident & describe the reporting requirements to the Medicine and Healthcare products Regulatory Aency	Observe student gather all relevant information required to report an incident to the MHRA.	DRM5-C-4

		Describe the institutions approach to the handling of safety alerts	Observe student review local procedure in relation to management of medical device safety alerts and field safety notices	DRM5-C-5
		Execute root cause analysis on a range of medical device related incidents	Observe Student undertake a root cause analysis of an incident	DRM5-C-6
Medical Device Information System		Extract, analyse and interpret data from the Medical Device Information system, producing an analysis of capital and revenue assets held by the Trust, by value and volume,together with a replacement date analysis.	Observe Student extract data from the trust medical equipment inventory and devise a replacement plan including annual costs required for execution, in a form that can be presented to the trust capital equipment panel.	DRM6-C-6
		Use a Medical Device Information System to perform complex equipment management tasks, such as an analysis of last maintenance dates for all devices	Observe Student extract data from trust medical device inventory in relation to maintenance performance of high and medium risk medical devices.	DRM6-C-3, DRM6-C-7
		Use of a Medical Device Information System to produce Key Performance Indicators to measure the performance of the Medical Device Management Organisation	Create KPI data sets as per local processes which form part of quality management system.	DRM6-C-3, DRM6-C-7
		Undertake statistical analysis of device data to establish reliability of devices and cost effectiveness of devices through their life	Use the Medical device inventory to determine the maintenance cost of a certain model of infusion pump. Undertake analysis to determine common causes of failure and devise action plan to reduce costs.	DRM6-C-11
Expertise in Medical Device Risk Management		Draft a risk management strategy for the department	Observe the student undertake a risk assessment in relation to a new or ammended departmental process, such as electrical safety testingn intervals or ammendments to manufacturer preventative maintenance intervals	
		Identify means to ensure compliance with CQC requirements for the safety and availability of equipment	Observe the student review/present the CQC standards in relation to medical devices and provide an action plan to encourage compliance.	
		Undertake a project involving analysis of risk and proposal of solutions to mitigate involving a clinical department	Observe Student participate to a project involving modification of a medical device such a patient transport trolley in line with request from clinical teams	DRM4-C-16, DRM4-C-17, DRM7-C-6
		Modify a medical device and follow necessary procedure	Observe Student participate to a project involving modification of a medical device such a patient transport trolley in line with request from clinical teams.	DRM4-C-16, DRM4-C-17, DRM7-C-6
		Authorise modifications to medical devices having analysed the associated risks	Observe Student participate to a project involving modification of a medical device such a patient transport trolley in line with request from clinical teams.	DRM4-C-16, DRM4-C-17, DRM7-C-6
		Identify key patient risks that exist in the organisation in relation to the acquisition and use of medical devices	Observe student undetake a risk assessment in relation to the selection/procurement of a newly procured medical device model.	
Professional Advisory Services		Underake an audit of medical device use in clinical practice	Observe Student undertake a study of utilisation of an item of medical equipment.	
		Assess the impact of emerging regulation or standardisation	Observe Student present knowledge of new guidance to team members with examples of impact.	
		Use engineering principles to determine the best engineering solutions to effectively manage medical devices	Observe student come up with innovative solutions to a range of problems in relation to medical equipment management within the trust.	

OCEs

		OCEs	**Examples of evidence**	**Competencies which may share evidence with this DOPS**

Medical Device Management Strategy		Describe to clinical staff the reasons for control of medical devices and how this is achieved.	Observe Student participate in a formal discussion with clincial staff regarding a medical device related issues such as invetigating impact of new capital equipment purchase post installation.	DRM7-C-1
		Develop a practical application for a device management protocol in relation to a particular equipment type you're familiar with using information extracted from the standards. Present the protocol to colleagues	Observe Student present rationale behind risk classification of a new medical device and procedures followed to make decision on risk level. Also how classification could be validated.	DRM7-C-2
		Present findings of a risk assessment to clinical colleagues including recommendations to mitigate risk	Observe Student present risk assessment in relation to using a third party contractor for service/repair of their equipment.	DRM7-C-4
Optimisation of Medical Device Effectiveness & Efficiency		Develop training material to aid Technical and Clinical colleagues	Observe student create a competency document in relation to a new medical device introduced into the trust.	
		Attend an MDT meeting and advise on risk associated with a medical device use	Observe Student participate at MDT training meeting.	
		Participate in the resolution of clinical queries and explain possible solutions to clincial colleagues to ensure successful patient delivery	Observe Student participate in a technical issue possibly raised via an incident report or request for equipment replacement. Ensure issues are investigated and options are considered and appraised and solutions recommended, which are fed back to equipment owners.	DRM5-C-4
		Advise on the minimisation of risks associated with device usage	Observe the student investigate an incident and feedback to users ways to mitigate against further re-occurances.	DRM5-C-4
		Explain to clinical users how to effectively and safely configure and use the device	Observe Student provide training to clinical users on medical device set-up and configuration.	
		Develop training material contextualised for the audience, which may range from patients, professional users or practitioners involved in device maintenance	Observe Student produce and use material to train staff groups of varied experience on use ans application of a medical device.	
		Critically appraise the technical and information governance issues arising from a complex medical installations in a networking environment and present to collegues	Assess a medical network installation against requirements of 80001 standard and present conclusions and opinions on safety of the network and possible opportunities for improvement.	DRM2-C-4
Equipment Acquisition, Acceptance and Installation		Identify and articulate the clinical need behind an equipment acquisition to a MDT	Observe student discussing case of need relating to a capital equipment bid for equipment, with bidder as to understand criticality.	
		Write a clinical specification as part of an equipment acquisition process and present to colleagues	Observe student contribute towards creation of a specification and organise/plan appropriate clinical/technical evaluations as to ensure objective assessment of a selection of medical devices	DRM3-C-1 - DRM3-C-6
		Gain feedback from users evaluating equipment, including patient feedback	Observe student contribute towards creation of a specification and organise/plan appropriate clinical/technical evaluations as to ensure objective assessment of a selection of medical devices	DRM3-C-1 - DRM3-C-6
		Interpret, critically appraise and present evaluation findings to multi-disciplinary teams.	Observe student present outcome of a procurement exercise to the trust medical device standardisation group or equivalent.	
		Contribute to the final device selection forum	Observe student present outcome of a procurement exercise to the trust medical device standardisation group or equivalent.	
enance and Repairs to Devices		Carry out maintenance in the clinical environment including liaison with clinical equipment users	Observe Student participate in a repair request for equipment within the ICU environment.	
		Explain to non-scientific staff the governance arrangements for a medical device to be removed form service as a result of a service failure or quality system non-conformity	Observe the student inform senior clinical staff that an item of equipment has failed electrical or functional tests and needs to be removed from service.	
		Plan and participate in training & deploying the technical workforce to ensure coverage of all equipment types	Attend a technical training course and create material which can be used to cascade knowledge to other members of the technical team.	DRM4-C-3

Planned Maint		Provide expert advice to clinical staff on the cleaning and decontamination of medical devices as related to the maintenance process	Observe student reject a decontamination form and advise on cause and suggestions to correct.	DRM4-C-10
		Advise on the appropriateness of in-house modifications and the necessity for risk assessment and the establishment of a design project	Observe Student participate to a project involving modification of a medical device such a patient transport trolley in line with request from clinical teams	DRM4-C-16, DRM4-C-17, DRM7-C-6
Patient Safety		Shadow personnel receiving and determining actions in relation to a number of safety alerts and report to your supervisor the considerations for staff and patient care	Observe Student review a safety alert or Field Safety Notice and assess impact and devise action plan.	DRM5-C-3
		Advise clinical colleagues on policy development to assist clinical governance and patient safety within the organisation	Observe student particpate in a trust policy review which includes medical devices.	
		Discuss with clinical colleagues the circumstances of an incident and attempt to establish the root cause.	Observe Student undertake a root cause analysis of an incident	DRM5-C-6
Medical Device Information System		Critically appraise the organisations categorisation of medical devices and report to colleagues	Partipate in the maintenance/training risk classification of a new model of medical equipment, justifying classification	DRM4-C-6
		Present to clinical colleagues an equipment replacement forecast derived from the Medical Device Information system	Observe Student participate in creating a revenue/capital equipment replacement plan for presentation to the trust medical equipment executive or equivalent.	DRM6-C-5
Expertise in Medical Device Risk Management		Draft a strategy to minimise the risks associated with modifying medical devices and present to colleagues	Observe Student participate to a project involving modification of a medical device such a patient transport trolley in line with request from clinical teams	DRM4-C-16, DRM4-C-17, DRM7-C-6
		Advise a clinical colleague on on a practical risk management actions in Medical Device Risk Management & Governance	Observe Student participate to a project involving modification of a medical device such a patient transport trolley in line with request from clinical teams	DRM4-C-16, DRM4-C-17, DRM7-C-6
		Carry out an "Outcome Guardian Audit" in a clinical area	Undertake a CQC readiness inspection of a clinical area focussing on medical device management issues, including providing feedback to clinical staff. Discuss the typical areas of focus such an inspection or audit, including a focus on how the trainee feeds back to clinical colleagues.	
Professional Advisory Services		Contribute to interdisciplinary forum to promote the safe and effective use of technology, e.g. Medical Device Advisory Groups	Attend trust medical equipment executive meetings and contribute to discussions on medical technology management.	
		Present recommendations to a multi disciplinary group on achieving compliance with a medical device guideline	Present outcome of local project in relation to change of practice at a local or national conference	

CBD

	CBD Example	Examples of evidence	Competencies which may share evidence with this CBD
DRM1	**Provide student with a real life MHRA alert/Field Safety Notice and discuss content, risk, priority and actions required and responsibility.**	FSN and action plan	DRM5-C-1 - DRM5-C-3

DRM2	**Provide student with a description of a medical device system and ask them to define safety aspects that will beed to be implemented to ensure compliance with the 60601-1 standard in terms of systems electrical safety.**	Diagram of system with safety measures shown	
DRM3	**Ask Student to present the CQC regulations that relate to medical devices and suggest stratergies to help with compliance.**	Awarness of relevant CQC standards	
DRM4			
DRM5			
DRM6			
DRM7			
DRM8			

Guide for STP Trainees : Rehabilitation Engineering

Learning Outcome Subject	Code	Competency	Examples of evidence	Other competencies which may be demonstrated by this evidence
Assistive Technology	RE-1-C-1	Under supervision, lead a patient assessment in at least two of the modalities listed above, to identify and define individual requirements for intervention.	Clinic report/case study /patient history record and also additionally within reflective practice diary	RE-1-C-2, RE-1-C-3, RE-1-C-4, RE-1-C-7, RE-1-C-9, RE-1-C-10, RE-1-C-11, RE-1-C-12, RE-1-C-13, RE-1-C-14
	RE-1-C-2	Apply 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.	Methods of assessment description (review). Case study detailing methods. Clinic report detailing results e.g. Posture report, access to equipment information	RE-1-C-1, RE-1-C-3, RE-1-C-4, RE-1-C-7, RE-1-C-9, RE-1-C-10, RE-1-C-11, RE-1-C-12, RE-1-C-13, RE-1-C-14
	RE-1-C-3	Analyse and interpret the data obtained from these measurements.	Results of test. Clinical reasoning in report. Prescription form for seaing equipment	RE-1-C-1, RE-1-C-2, RE-1-C-4, RE-1-C-7, RE-1-C-9, RE-1-C-10, RE-1-C-11, RE-1-C-12, RE-1-C-13, RE-1-C-14
	RE-1-C-4	Produce a formal report outlining a diagnostic/therapeutic opinion.	Clinical report. Assessment report put in health records/letter to parents/carers.	RE-1-C-1, RE-1-C-2, RE-1-C-3, RE-1-C-7, RE-1-C-9, RE-1-C-10, RE-1-C-11, RE-1-C-12, RE-1-C-13, RE-1-C-14
	RE-1-C-5	Recognise, quantify and discuss the errors in the measurements obtained and discuss their limitations.	Literature review and examples of using each measurement	
	RE-1-C-6	Present to the patient and clinic team the realistic expectations of the intervention and the expected levels of enhancement.	Excerpt from health record indicating discussion. User instructions re equipment. Letter to clinet or family/handover sheet/ reflective pratice log	
	RE-1-C-7	Develop objectives, recommendations and rationale for intervention.	Clinic report	RE-1-C-1, RE-1-C-2, RE-1-C-3, RE-1-C-4, RE-1-C-9, RE-1-C-10, RE-1-C-11, RE-1-C-12, RE-1-C-13, RE-1-C-14
	RE-1-C-8	Perform a risk assessment; propose a risk management strategy.	Understand the departments risk management stratergy. Complete a risk assessment for an adaptation to a piece of equipment of assistive technology e.g. wheelchair, standing frame, seating system. Or for adding additional equipment to a system e.g. a communication aid and a mounting system to a wheelchair. Or an ethics risk assessment for MSc Research project	
	RE-1-C-9	Identify indicators for and contra-indicators to the use of equipment and/or assessment/measurement techniques.	Case study/ clinic reports/ literature review. For inclusion/exclusion in MSc research project	RE-1-C-1, RE-1-C-2, RE-1-C-3, RE-1-C-4, RE-1-C-7, RE-1-C-10, RE-1-C-11, RE-1-C-12, RE-1-C-13, RE-1-C-14
	RE-1-C-10	Evaluate commercially available equipment against clinical requirements.	Participate in the subjective Evaluation of the technical aspects of a new piece of equipment prior to selection.	RE-1-C-1, RE-1-C-2, RE-1-C-3, RE-1-C-4, RE-1-C-7, RE-1-C-9, RE-1-C-11, RE-1-C-12, RE-1-C-13, RE-1-C-14
	RE-1-C-11	Identify indicators for non-standard bioengineering requirements, e.g. for patient with profound disability.	Clinic report with an assessment showing non-standard requirements. Custom made form with case study. Information on medical devices directive and guidance	RE-1-C-1, RE-1-C-2, RE-1-C-3, RE-1-C-4, RE-1-C-7, RE-1-C-9, RE-1-C-10, RE-1-C-12, RE-1-C-13, RE-1-C-14
	RE-1-C-12	Using case study examples, evaluate the impact of the intervention on the wider clinical situation.	Case studies/ clinic report (e.g. medicines affecting access/posture). Outcome measures e.g. Goal Attainment Scaling (GAS), Psychosocial Impact of Assistive Devices Scale (PIADs), Therapy Outcome Measures (TOMS)	RE-1-C-1, RE-1-C-2, RE-1-C-3, RE-1-C-4, RE-1-C-7, RE-1-C-9, RE-1-C-10, RE-1-C-11, RE-1-C-13, RE-1-C-14

	RE-1-C-13	Utilise appropriate outcome measures for at least two of the modalities; evaluate the results.	Case Study/Clinic report e.g. Goal Attainment Scaling (GAS), Psychosocial Impact of Assistive Devices Scale (PIADs), Therapy Outcome Measures (TOMS)	RE-1-C-1, RE-1-C-2, RE-1-C-3, RE-1-C-4, RE-1-C-7, RE-1-C-9, RE-1-C-10, RE-1-C-11, RE-1-C-12, RE-1-C-14
	RE-1-C-14	Interface appropriate AT to enhance the use of equipment.	Assess and fit appropriate access equipment for EAT. Appropriate postural support for seating, standing, lying e.g. headrest. Integrated access to optimise use of equipment. Case study/clinic report	RE-1-C-1, RE-1-C-2, RE-1-C-3, RE-1-C-4, RE-1-C-7, RE-1-C-9, RE-1-C-10, RE-1-C-11, RE-1-C-12, RE-1-C-13
	RE-1-C-15	Make appropriate adjustments to any equipment or its application to enhance function, comfort and safety.	Evidence in health record/report/task sheet or workorder	
	RE-1-C-16	Train and familiarise the patient and/or carer in the use of the equipment, and develop user instructions.	User instructions/handover sheets/ clinic report (evidence of face to face training)/ casestudy/ reflective practise log. Stability test for wheelchair.	
al Gait Analysis	RE-2-C-1	Under supervision and according to local protocols, conduct a clinical interview with a patient and/or their guardians/carers.	Trainee: It is good to read through and make notes on the template that will be stored locally at your unit. Practice interviewing an experienced member of staff who can be pretend to be a parent/guardian. During the interview with the patient, don't ask too many closed questions like "do you wear your orthoses?" but open ones like "tell me about your orthoses". Use an anonymised recording sheet to enter your interview details for evidence. Trainer: prepare your trainee with mock clinical interviews; closely supervise trainee during live interview. You should be looking for the trainee to cover all the questions that need asking but also for the trainee to be sympathetic and flexible in their questioning.	
	RE-2-C-2	Under supervision, perform a physical/clinical assessment and compare your data with local or published reference ranges.	Trainee:familiarise yourself with the local method for performing a clinical assessment. It is important that you gain the confidence of the subject or patient, so tell them what your doing. It is useful practising your examination methods on a fellow trainee or colleague before you do it on patient. Use an anonymised examination sheet to record your data and present as evidence. Trainer: assess the trainee for their interaction with the patient as much as for their manoeuvres. If the examination is complicated and/or is being done on a non-compliant or young patient, you may consider asking the trainee to perform a subset of the measurements.	
	RE-2-C-3	Interpret and report the results of the clinical assessment.	Trainee: your local centre should have normal ranges for your centre. If not, access published ranges. Consider not only the statistical significance of your measurements but also the functional implications of the measured impairments. Document your findings including any statistically signficant findings, and place them in a clinical context. Trainer: is the trainee's interpretation making sense? Do they understand the scales that they are using or the difference between dorsiflexion and plantarflexion?	
	RE-2-C-4	Place markers on patients in the correct positions according to local protocols/national guidelines.	Trainee: you should be familiar with the local protocols for marker placement. You should be familiar with the surface anatomy necessary to place the markers. You can place markers on colleagues and patients under supervision. Document your marker placement by using anonymised images. Be prepared to explain your placements to your supervisor/assessor. Trainer: inspect the placement of markers by the subjects by the trainee. Look at the processed data - are there any artefacts that could be explained by inadequate marker placement?	
	RE-2-C-5	Conduct Electromyography (EMG) examination relevant to a biomechanical assessment.	Trainee: there should be local protocols at your centre explaining the placement of sensors. If not, you can use a resource like SENIAM to guide your placement. Document your placement using anonymised images. Ask your assessor to review your placement. Trainer/assessor: can the trainee describe the relevant muscular anatomy and the reasons for the placement of the sensors?	

Clinica	RE-2-C-6	Collect kinematic, kinetic and other data from patients with movement disorders. Use complementary clinical methods to further detail the mechanical impairments and functional deficits of these patients.	Trainee: you should be familiar with the multiple measurement tools available in the movement laboratory and of other assessments that are used to detail the impairments of the patient. You should be familiar with the operations of the systems that allow collection of kinematic, kinetic and associated data. Document your activities in the laboratory using a log - which patients you saw, what you did in your session. Have each interaction with a patient signed off by a local registered clinical scientist or other clinician. Assessor: Inspect the trainee's document logging their activities in the unit.	
	RE-2-C-7	Process kinematic, kinetic and other data, identifying and appropriately managing/removing artefacts.	Trainee: Keep a log of your activities in the laboratory (anonymised). Detail any issues you had with the data and which methods you required to account for or modify them. Have	
	RE-2-C-8	Prepare and present a report for the clinical team, summarising findings and interpretation of the data, using alternative presentations of the data to emphasise particular findings.	Trainee: Be familiar with the reporting software at your centre. Inspect prvious reports from the centre to ascertain the style in which reports are written. Write reports according to style of you local centre. Gather feed back on your report from a member of the local team before the full presentation of your findings . Keep an anonymised version of the report for documentation. Assessor: be present at review meetings where the trainee's data and interpretations are reported. Discuss with the trainee any feeedback/corrections from the clinical review team.	
	RE-2-C-9	Perform system checks and calibration tests on a number of pieces of equipment in the laboratory.	Trainee: there will be daily calivbration and system checks carried out in your unit. Try to understand these tests. In your log, record the times you performed these tests and ask a local registered person who saw you conduct the tests to sign off the log. Assessor: inspect the document logging the trainee's activities. Discuss with the trainee what would/did happen if the equipment failed any of the tests.	
	RE-2-C-10	Perform task-specific risk assessments.	Trainee: There will be standard trust forms for conducting a risk assessment at your local centre. Identify an activity performed in the laboratory. Fill out the risk assessment and log a	
	RE-2-C-11	Compare the standard biomechanical model used locally to alternative models by considering and evaluating the strengths and weaknesses of each.	Trainee: modifications can be made to biomechanical models that might improve the interpretation of the patients problem or might be a simplification of an existing model that facilitates its use in a particular population of patients. Comparison of the standard to alternative models might include a detailed understanding of the construction of the axis systems, the order of rotations. Document your comparison in a report. Assessor: does the trainee have a good understanding of the construction of alternative biomechanical models? Do they understand the difference in operation of the standard model to the alternative(s).?	
dical Engineering Design	RE-3-C-1	Develop a detailed functional specification through discussion with the client/users, e.g. clinician and/or patient and their carer.	Design bespoke equipment based on client's clinical need e.g. lateral supports, footbox, switch mount	RE-3-C-2
	RE-3-C-2	Perform and document a design feasibility study from a functional specification.	Design bespoke equipment based on client's clinical need e.g. lateral supports, footbox, switch mount. Follow a standard such as BS 7000 design process model	RE-3-C-1
	RE-3-C-3	Apply the requirements of the Medical Devices Directive and appropriate standards and legislation to the design and manufacturing process.	Design a bespoke AT product resulting from a clinical assessment or departmental need. Project file or technical file	
	RE-3-C-4	Perform a risk assessment; propose a risk management strategy.	Project or technical file or within the bounds of a specific risk assessment for a client	
	RE-3-C-5	Develop technical documentation for development of a medical device.	Technical file (or project file developing into a technical file)	
	RE-3-C-6	Source components and materials in the preparation of an estimate or quotation.	Technical file. Within the client's health record if bespoke/custom equipment	
	RE-3-C-7	Design and develop a medical device.	Technical file. Within the client's health record if bespoke/custom equipment	

Mec	RE-3-C-8	Carry out validation and verification of a medical device realisation.	Ensure the product is appropriate is meets the design brief. Appropriate safety testing prior to use. If bespoke seating this could include pressure. Design of a QA systemmapping	
	RE-3-C-9	Commission a medical device; produce protocols for its safe and effective introduction into service.	Standing operating procedure. Develop user or if required technical instructions. Quality control check protocol	
	RE-3-C-10	Train and familiarise the client/user in the use of the equipment, including the development of user instructions.	User instructions, handover documentation or training presentation. Clincial notes/case study	
	RE-3-C-11	Review the use of a medical device to enhance function, comfort and safety.	Follow up with client or service. Clincial notes/case study	

DOPS

		DOPS	Examples of evidence	Competencies which may share evidence with this DOPS
Assistive Technology		Analyse and interpret the data/information obtained from the history and physical assessment.	Observe trainee analyse and interpret data/information obtained from the patient history and physical assessment	RE-1-C-3, RE-1-C-5
		Prepare a clinical report, documenting the relevant and critical elements of the assessment.	Observe trainee prepare a clinical report which documents the relevant and critical elements of the assessment	RE-1-C-4
		Prepare a funding application for a piece of equipment	Observe trainee prepare a funding application for a piece of equipment	
		Manufacture a custom contoured seating system and interface to a wheelchair base	Observe trainee manufacture a custom contoured seating system and interface it to a wheelchair base.	RE-3-C-7
		Manufacture a custom made orthosis	Observe trainee manufacture a custom made orthosis	
		Assemble and bench align a prosthetic limb	Observe trainee assemble and bench align a prosthetic limb	
		Manufacture/substantially modify another type of AT.	Observe trainee manufacture/ substantially modify another type of AT	RE-3-C-7
		Interface non-standard switching mechanisms to an EAT or FES device.	Observe trainee interface non-standard switching mechanisms to an EAT or FES device	RE-1-C-14
		Complete a risk assessment relevant to the modality and produce an action plan to reduce/manage the risk.	Observe trainee complete a risk assessment relevant to the modailty and produce an action plan to reduce/manage the risk	RE-1-C-8
		Set up a piece of AT for a patient, making the necessary adjustments and modifications to meet the previously agreed objectives	Observe trainee set up a piece of AT for a patiend and make the necessary adjustments and modifications to meet the previously agreed objectives	RE-1-C-15
		Select and use an outcome measure appropriate to monitor performance of the intervention.	Observe trainee select and use an outcome measure appropriate to monitor performance of the intervention	RE-1-C-13
		Prepare and calibrate equipment	Observe trainee prepare and calibrate equipment	
Clinical Gait Analysis		Perform system tests and QA checks on the	Observe trainee perform system checks and QA checks on the laboratory equipment	
		Prepare and calibrate the laboratory and its equipment, ready for clinical data collection.	Observe trainee prepare and calibrate the laboratory and its equipment, ready for clinical data collection	
		Analyse and interpret the data/information obtained from the history and physical assessment, and compare your data to local or published reference ranges.	Observe trainee analyse and interpret data/information obtained from the history and physical assessment, and compare your data to local or published reference ranges	
		Process and report data and appropriately manage/remove artefacts	Observe trainee process and report data and appropriately manage/remove artefacts	
		Interpret the data obtained and complete a clinical report appropriate to a multi-disciplinary audience	Observe trainee interpret the data obtained and copmlete a clinical report appropriate to a multi-disciplinary audience	
		Complete a risk assessment relevant to the modality and produce an action plan to manage the risk.	Observe trainee copmlete a risk assessment relevant to the modailty and produce an action plan to manage the risk	

Medical Engineering Design		Present a functional specification to a project initiator.	Observe trainee present a functional specification to a project initiator	RE-3-C-1
		Lead a project design multi-disciplinary meeting to formally appraise the developed design concepts.	Observe trainee lead a project multi-disciplinary meeting to formally appraise the developed design concepts	RE-3-C-2
		Produce a CAD drawing, or part thereof, from the specification for either a mechanical or electronic piece of equipment	Observe trainee produce a CAD drawing, or part theror, from the specification for either a mechanical or electronic piece of equipment	RE-3-C-5
		Demonstrate appropriate analysis/critique/detail development of a design throughout the process	Observe trainee demonstrate appropriate analysis/critique/detail development of a design throughout the process	RE-3-C-3, RE-3-C-4, RE-3-C-5, RE-3-C-6, RE-3-C-7
		Manufacture or assist in the manufacture or direct the manufacturing of the designed equipment.	Observe trainee manufacture or assist in the manufacture or direct the manufacturing of the designed equipment	RE-3-C-7
		Perform verification and validation tests on the equipment produced	Observe trainee perform verification and validation tests on the equipment produced	RE-3-C-8
		Commission the piece of equipment, taking account of staff and patient safety issues	Observe trainee commission the piece of equipment, taking account of staff and patient safety issues	RE-3-C-9
		Appraise commercially available products against the design specification in order to justify the development of a custom made device, or part thereof	Observe trainee appraise commercially available products against the design specification in order to justify the development of a custom made device, or part thereof	

CBD

	CBD Example	Examples of evidence	Competencies which may share evidence with this CBD
RE1	Discuss clincial assessment, outcome and reasons using a clinic report		
RE2	Discuss process of the development of a medical devices and its success		

OCEs

		OCEs	Examples of evidence	Competencies which may share evidence with this DOPS
ssistive Technology		Review the information contained in the referral; clarify this with the patient and identify their personal aims/objectives	Observe trainee review referral at the beginning of an assessment/appointment and confirm details with patient and/or family/carers (depending on capacity). Agree aims and objectives of appointment with patient and/or family/carers	RE-1-C-1
		Gain consent from a patient for the assessment and/or provision of equipment.	Observe trainee gain informed consent from the patient for the assessment and/or provision of equipment. If informed consent cannot be obtained to follow the appropriate mental capacity act proceedures.	RE-1-C-1
		Take a patient history relevant to the modality	Observe trainee take a relevant patient history for that assessment	RE-1-C-1
		Carry out a physical assessment of a patient to inform provision of an AT	Observe trainee carry out a physical assessment to inform provision of an AT. This could be a range of movement examination, postural assessment, functional assessment	RE-1-C-2
		Review a piece of AT with the patient following previous provision, agree the changes required, including reprioritisation of objectives; make any necessary adjustments/modifications/replacements; document the clinical reasoning involved	Observe trainee review current AT equipment with patient (or following … their power of attorney for health) and agree changes with them. Observe trainee prioritise adjustments/modifcations with patient and clinic MDT. Review clinic report/notes	RE-1-C-1, RE-1-C-15
		Train a patient and/or carers in the use of a piece of AT, recognising the need to communicate with people having a range of physical and cognitive abilities.	Observe trainee provide training to patient and fmaily/carers on use of a piece of AT. Observe trainee using different communication strategies as appropriate.	RE-1-C-15

A		Lead or take an active role in a multidisciplinary clinical event, such as a case conference or patient assessment which may include a ward environment; understand the intervention in the wider clinical setting.	Observe trainee lead or take an active role in an MDT assessment or case conference and the effect of the intervention in the wider clinical setting.	RE-1-C-1, RE-1-C-2
		Explain the relevant and critical findings of the assessment to the patient, related to the reason for referral and the patient aims, and resolve any conflicting requirements	Observe trainee explain the relevant critical findings of the assessment to the patient or family/carer if appropriate. Relate these findings to the reason for the referral, stated aims of the patient. Observe trainee resolve any conflicitng requirements	RE-1-C-3, RE-1-C-4, RE-1-C-5, RE-1-C-6, RE-1-C-7
		Report to the patient detailed recommendations and rationale based on the data obtained	Observe trainee explain in appropriate detail the recommendations and rational based on the data obtained. Review clinic report.	RE-1-C-6
		Set up a piece of AT for a patient, making the necessary adjustments and modifications to meet the previously agreed objectives	Observe trainee set up a piece of AT for a patient and make adjustments accordingly	RE-1-C-15
Clinical Gait Analysis		Review the information contained in the referral to determine the reason for referral, clarify this with the patient and identify their personal aims/objectives	Observe trainee review the information contained in the referral to determine the reason for referral, clarify this with the patient and identify their personal aims/objectives	
		Gain consent from a patient for the assessment; explain to the patient the steps to be taken during the assessment.	Observe trainee gain consent from a patient for the assessment; explain to the patient the steps to be taken during the assessment.	
		Take a patient history relevant to the modality	Observe trainee take a patient history relevant to the modality	
		Carry out a physical assessment of a patient, following SOPs, to inform the assessment.	Observe trainee carry out a physical assessment of a patient, following SOPs, to inform the assessment.	
		Place markers on patients in the correct positions according to the laboratory's SOP	Observe trainee place markers on patients in the correct positions according to the laboratory's SOP	
		Collect gait data, as relevant to the referral and the patient's abilities and physical limitations.	Observe trainee collect gait data, as relevant to the referral and the patient's abilities and physical limitations.	
		Lead or take an active role in a multidisciplinary case conference, leading to recommendations for future treatments; understand this in the wider clinical setting.	Observe trainee lead or take an active role in a multidisciplinary case conference, leading to recommendations for future treatments; understand this in the wider clinical setting.	
		Explain the relevant and critical findings of the assessment to the patient, related to the reason for referral and the patient aims	Observe trainee explain the relevant and critical findings of the assessment to the patient, related to the reason for referral and the patient aims	
Medical Engineering Design		Present to the project team and other healthcare professionals the final piece of equipment produced, including compromises in the design, risk assessment, test results and competitor analysis.	Observe trainee present to the project team and other healthcare professionals the final piece of equipment produced, including compromises in the design, risk assessment, test results and competitor analysis.	
		Provide training to healthcare professionals and/or patient in the use of the equipment, using both verbal and written communication	Observe trainee provide training to healthcare professionals and/or patient in the use of the equipment, using both verbal and written communication	RE-3-C-10
		Lead a meeting to produce a risk assessment for the piece of equipment being commissioned.	Observe trainee lead a meeting to produce a risk assessment for the piece of equipment being commissioned.	RE-3-C-4
		Obtain a patient history from a normal volunteer or typical patient referred to your service and present the findings to a colleague or peer.	Observe trainee obtain a patient history from a normal volunteer or typical patient referred to your service and present the findings to a colleague or peer.	RE-1-C-1