JOB DESCRIPTION

1. JOB IDENTIFICATION

Job title:	Clinical Engineer
Responsible to:	Head of Medical Equipment Management (MEM)
Department(s):	Medical Physics
Directorate:	Diagnostics, Anaesthetics, Theatres & Critical Care (DATCC)
Operating division:	Lothian University Hospitals Division
Job reference:	185182
No of job holders:	1

2. JOB PURPOSE

Contributes to the safe and effective delivery of clinical engineering services by providing highly specialist advice and support to clinical consultants, senior managers, service managers and clinical staff across NHS Lothian.

Review and risk assess research applications from the R&D office seeking clinical engineering approval for research studies that include medical devices as part of the study. Works in collaboration with academic and industrial collaborators to monitor and review the development of novel medical devices as they progress towards clinical evaluation.

Works in partnership with Health Board staff, both clinical and non-clinical, at all levels, to provide technical support for complex and very complex patient-connected and life support equipment used in critical care units, theatres, general wards, clinical departments and community locations.

Supports the development, implementation and continuous improvement of a NHS Lothian-wide comprehensive medical device management policy, including the production and promotion of process and guidance documentation and key-performance indicators.

3. DIMENSIONS

The service provides scientific and engineering assessment, measurement, management and maintenance services to support an inventory of over 42,000 items of patient-critical diagnostic and therapeutic medical equipment, with a total value in excess of £115M across all areas of NHS Lothian.

The Medical Equipment Management (Clinical Engineering) service operates from four bases: The Royal Hospital for Children and Young People (RHCYP), the Royal Infirmary of Edinburgh (RIE), St John's Hospital at Howden (SJH) and the Western General Hospital (WGH).

The postholder is employed within NHS Lothian and will be required to work flexibly across NHS Lothian sites (both acute and community) to meet service demands. The post-holder will occasionally be required to perform duties outside the normal working hours of the Department.

Staffing responsibilities:

No direct line management responsibility but will participate in the supervision of trainees and students.

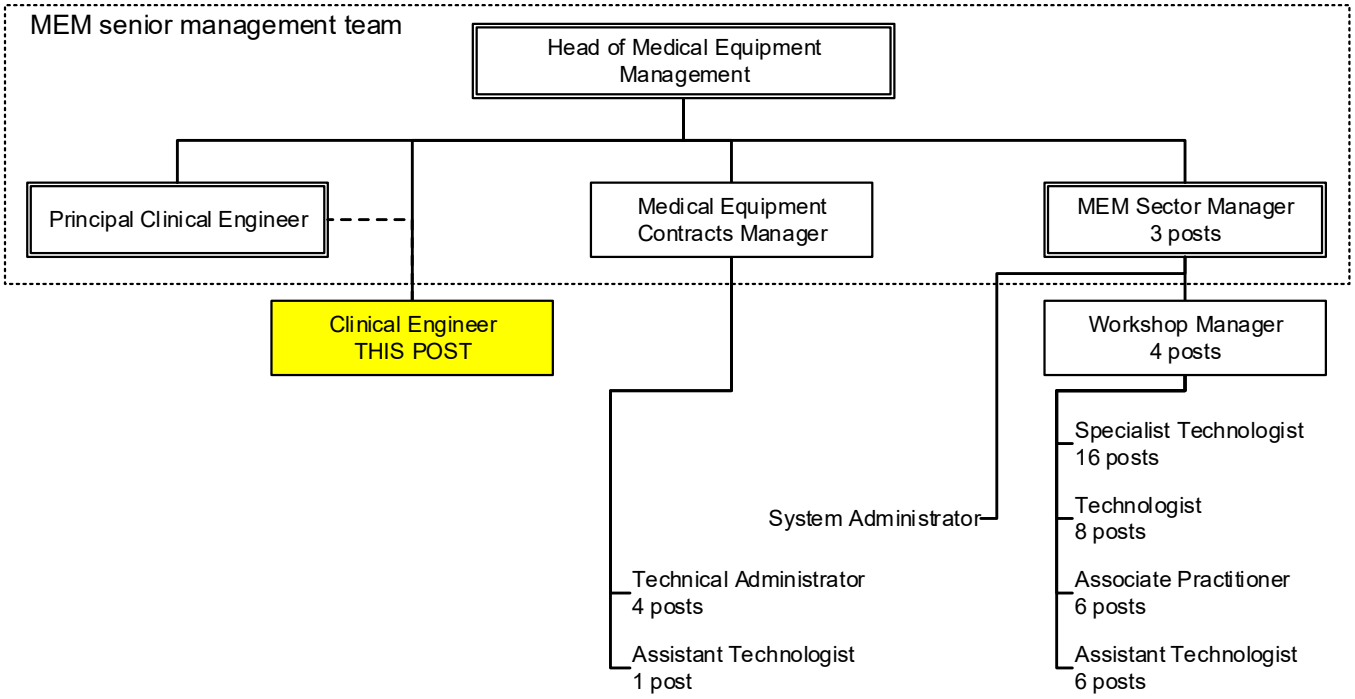
Financial responsibilities:

Authorised signatory for departmental spare parts and supplies – up to £2k per year.

Identifies items of scientific/test equipment for purchase by the department, typical values £500-£5k.

Works with medical equipment suppliers and managers to achieve cost savings / cost avoidance, typically up to £10k p.a.

4. ORGANISATIONAL POSITION



The Principal Clinical Engineer provides professional supervision and will have input into the postholder's workload.

5. ROLE OF DEPARTMENT

The role of the Medical Physics Department is to facilitate the introduction of new and existing non-medicines technology and scientific methods into healthcare and to ensure their safe and effective use. The Department provides a range of specialised clinical and clinical technical services and highly specialised expertise to NHS Lothian and to other organisations with which it has contractual arrangements. The department employs Healthcare Science staff with a variety of scientific and technical expertise, including physics, electronic & mechanical engineering and computer science. The Department is organised into four sections that specialise in different areas of physics and engineering applied to medicine. The sections are:

Imaging Physics,
Medical Equipment Management (Clinical Engineering),
Nuclear Medicine Physics, and
Radiation Protection.

Services provided by the Medical Equipment Management section:

The Medical Equipment Management (Clinical Engineering) section provides a comprehensive, full-lifecycle equipment management service, including medical equipment library services. From bases at the RIE, RHCYP, SJH and WGH it manages and maintains a wide range of medical devices (approximately 42,000 items within a total medical equipment inventory in excess of £115 million) throughout the Division and to other hospitals, health centres in NHS Lothian, to third parties and to patients in their homes. The section specifies, selects, commissions, calibrates, maintains (scheduled work), repairs and decommissions medical devices. It responds to medical device safety alerts issued by NHS Scotland and others and investigates incidents involving medical devices. It trains professional users in the safe use of medical devices. It supports and initiates Board-wide Research and Development (R&D) and service developments to enhance the use of non-medicines technology in healthcare.

6. KEY RESULT AREAS

Scientific, technical and clinical:

Lifecycle activities.

1. Provide highly specialist medical equipment management advice and support to clinical consultants, senior managers, service managers and clinical staff throughout the medical equipment lifecycle from procurement to disposal. This may include providing advice on the preparation of business cases, risk management of equipment related hazards, the comparison of alternative devices or technologies, equipment trials, evaluation and selection, clinical user training and evaluation of competency, equipment commissioning and configuration, maintenance and quality assurance, equipment use and risk management.
2. Support the work of the MEM service by contributing scientific and engineering input to both business-as-usual activities and projects that encompass the full range of clinical engineering activities, including:
   - performing all aspects of medical equipment lifecycle management (including fault diagnosis and repair work when necessary),
   - problem solving anywhere within the Board that requires a novel medical device technology solution,
   - assisting in the evaluation, development and commissioning of novel diagnostic and therapeutic technologies,
   - authoring and implementing Standard Operating Procedures (SOPs) as required for all aspects of medical equipment management, and
   - taking the lead on engineering, data analytics and business process service improvement projects within MEM.
3. Manage a portfolio of planned medical equipment replacement projects as a member of the Lothian Medical Equipment Replacement Group (LMERG). As the technical and scientific lead, manage each project, including preparation and agreement of specifications and evaluation criteria as part of a multi-disciplinary group, arranging evaluation sessions and tenders, proceeding to purchase, arrangement of clinical and technical training and deployment/commissioning.
4. The postholder will ensure that all activities conform to statutory regulations, Health and Safety legislation, Approved Codes of Conduct and Board procedures (including local rules, Department/Section policies and NHS Lothian incident reporting procedures and mandatory training). Adhere to the health and safety responsibilities laid down in the Department Safety

Handbook. Carry-out the procedures required under the Health and Safety at Work Act 1974 to ensure a safe working environment for patients, visitors and employees.

Incidents.

5. Provide highly specialist advice in relation to medical device-related incidents, reporting to, and liaising with, the Incident Reporting and Investigation Centre (IRIC) and manufacturers as appropriate. Carry-out investigations, seeking further specialist advice where appropriate and report on conclusions. Advise local managers on the implications and outcomes of complex and sensitive investigations.

6. Apply technical and scientific knowledge of medical devices to promote the safe use of medical devices by:

   - championing the reporting of medical device incidents in accordance with Board policies,
   - maintaining and monitoring datasets to ensure that incident data is analysed to obtain a Board-wide picture of incidents,
   - working with clinical and other professional staff to ensure that remedial actions are taken to resolve medical device incidents and that the learning from incidents is disseminated effectively,
   - providing regular feedback to the Medical Devices Committee on medical device risks.

Research & development and in-house manufacture.

7. Undertake and manage research and development projects which require a high level of scientific and engineering understanding and technical ability, some of which will relate to novel non-CE/UKCA-marked medical devices that originate in industry or university.

8. Conduct specialist audits of the design and manufacturing processes for medical devices within Medical Physics and other services who manufacture medical devices in-house, referencing national and international standards as required.

9. Support requests from the R&D office seeking clinical engineering approval for research studies that include medical devices as part of the study. This involves:

   - Reviewing technical documentation and test data for evidence of compliance with relevant legislation, guidance, and standards.
   - Undertaking hands-on assessments of medical devices developed externally (by sub-contractors, higher education establishments or commercial manufacturers) to evaluate the safety and efficacy against the specified intended purpose, regulation and standards.
   - Seeking advice from senior clinical engineering colleagues when required then making a recommendation to the Head of Medical Equipment Management to approve or reject the study/device.

Regulatory and Health Board policy.

10. Interpret and provide advice on statutory/regulatory requirements (particularly the UK Medical Devices Regulations 2002), approved codes of practice, published technical standards (e.g. BS EN ISO 60601, BS EN ISO 13485 and BE EN ISO 14971), National guidance, directives and clinical governance policies.

11. Review Health Board policies and processes relating to medical device management (including the design and manufacture of medical and non-medical devices). Contribute to continuous improvement work to promote best practice and ensure Board-wide compliance with appropriate regulations. In particular:

    - Identify and evaluate the proposed impact of changes in medical devices policy on NHS-Lothian services.
    - Contribute to the development of medical device guidelines and patient care pathways within an evidence-based framework.
    - Support the implementation of the Board's Medical Devices policy through effective communication, using appropriate methods to facilitate understanding and implementation by all staff groups.

- Monitor implementation and compliance of the Medical Device policies and associate processes/guidance by participating in Board-wide reviews and audits.

Managerial and administrative:

12. Serve on committees and multi-disciplinary management meetings within NHS Lothian to help promote the safety, effective procurement, and efficient deployment of medical devices for the delivery of healthcare.

13. Manage projects and chair project review meetings as directed by the Head of MEM.

Professional and quality:

14. Attend relevant manufacturers' technical courses to achieve a high level of appropriate technical and scientific skill and knowledge of current medical devices.

15. Support the development and maintenance of the Department's Quality Management System (QMS), including through the production of process documentation. Contribute to the running of the QMS as instructed by the Head of Medical Equipment Management, ensuring all activities are carried out within a Quality framework, and meet regulatory requirements. Participate in regular surveys and audits of medical devices practice both within the Department and the wider Organisation.

Teaching, training and research:

16. Identify and undertake research and innovation projects both for service development and with a more fundamental and long-term aim to further the advancement of clinical science, as discussed with and approved by senior members of staff.

17. Develop research links with suppliers and manufacturers of medical devices, university departments and bodies with a remit for innovation, such as SHIL. Collaborate in research and development activities that develop new technologies and enhance the understanding of the safety, reliability, efficacy, availability and limitations of medical devices.

18. Publish the outcome of original work in national and international journals and publications, present at meetings, seminars and conferences.

19. Support medical device training programmes for the safe use and management of medical equipment. Deliver lectures, instruction and training to end-users of medical equipment. Prepare and deliver technical presentations on medical technology, electrical and other safety issues to a scientific/technical audience. Liaise with Medical Education, Practice Development and Manufacturers to facilitate third-party training to NHS Lothian staff.

20. Support trainees taking part in the Scottish Clinical Engineering Training Scheme, the IPEM Clinical Technologist Training Scheme and to other staff, trainees and students as required. Ensure all training and assessment is delivered in accordance with the requirements of the relevant training scheme. Supervise undergraduate and postgraduate projects.

21. Demonstrate NHS Lothian's values of quality, teamwork, care and compassion, dignity and respect, and openness, honesty and responsibility through the application of appropriate behaviours and attitudes.

7a. EQUIPMENT AND MACHINERY

The general types of diagnostic and therapeutic medical devices with which the post holder will be required to be technically cognisant to undertake the role are listed below:

Patient monitoring equipment,
Infusion devices,
Patient physiological diagnostic and data analysis systems,
Endoscopic and laparoscopic surgery systems,
Operating microscopes,

Respiratory equipment
Anaesthesia equipment,
Renal and haemofiltration equipment,
Oxygen therapy equipment,
Resuscitation equipment,
External cardiac pacemakers and cardiac assist devices,
Neurological stimulators,
Intravenous and neuraxial therapy devices, and
Electrosurgery equipment.

The post holder will be authorised to support and maintain a range of devices in accordance with the service's competence and authorisation quality framework and subject to the successful completion of training.

The post holder will be required to use the following types of test equipment:

Standard electronic servicing equipment (e.g. oscilloscopes, multimeters, soldering iron and associated equipment and small hand tools), and

Specialised medical device test equipment (e.g. patient monitor simulators, energy analysers, electrical medical safety analysers, pressure and flow meters, pressure regulators, thermometers, chemistry monitoring equipment and conductivity meters).

Note: New equipment may be introduced as the organisation and technology develops, however training will be provided.

7b. SYSTEMS

The post holder will on occasions work on both isolated medical devices and complex interconnected systems of medical devices. When analysing problems with medical devices, the post holder may be required to consider the whole operating environment; this will include the patient, the clinical staff, the hospital IT network, the electrical supply systems and the medical device or devices in use. Examples of such systems include:

Patient monitoring networks, and
Clinical information systems, incorporating "bedside" networked devices, wireless telemetry systems, central monitoring stations and application software as a medical device (SaMD).

The post holder will be required to use a range of operational technical, quality and clinical applications as required, including the Organisation's medical device management system and the Department's Quality Management system.

Note: New systems may be introduced as the organisation and technology develops, however training will be provided.

8. ASSIGNMENT AND REVIEW OF WORK

The post holder works with significant autonomy to achieve agreed outcomes (many of which are non-routine), under the general direction and guidance of the Head of Medical Equipment Management with support from the Principal Clinical Engineer.

The Head of Medical Equipment Management will allocate operational project work to the post holder while monitoring overall progress.

The post holder will prioritise their workload in response to the demands of clinical services, the Medical Equipment Management service and interactions with third-party suppliers.

The post holder is required to follow standard policies and procedures and to ensure that statutory regulations are followed.

The post holder will have a personal development plan, including objectives, which are set by the Head of Medical Equipment Management on an annual basis.

9. DECISIONS AND JUDGEMENTS

The postholder will utilise their analytical and judgement skills to evaluate highly complex facts, technical information (including regulatory, commercial, technical and clinical constraints), risk data and failure scenarios to provide specialist advice on the clinical needs for medical devices (new and replacement), advising senior clinical, technical and management staff of the optimal technical solution.

Determines the most appropriate medical devices for use in a clinical environment, leading and participating in multidisciplinary equipment evaluations, overseeing tendering and culminating in the recommendation of a preferred medical device.

Assesses the options for managing non-compliant devices to minimise overall harm. For example, a judgement would be required to determine if a device with overdue maintenance/technical faults/safety alerts presents a lower risk if it is left in service compared to removing the device.

Uses investigative skills, technical and scientific judgement to determine the cause(s) of adverse incidents involving medical devices and deciding on appropriate responses (e.g. individual quarantine, withdrawal of a fleet from service, issue of an internal alert and reporting to the regulatory body).

Makes recommendations regarding the suitability and safety of introducing novel devices into clinical use for routine/research purposes.

Discusses problems involving the use of highly complex medical devices with clinical staff and recommends solutions (e.g. providing support and advice to clinical staff in a clinic when they have problems recording physiological data from patients; the solution may be improved staff training, equipment repair or a suggestion to use different equipment).

Diagnoses complex and difficult to identify faults with highly complex medical devices when these are referred to them by workshop team members who request a second opinion. For example, where the service performs first-line maintenance on devices under a contract where there is a call-out fee from the service supplier, potential faults that don't present in the usual manner may be referred to the clinical engineer for a technical opinion before a call is made to the service supplier.

10. MOST CHALLENGING/DIFFICULT PARTS OF THE JOB

Balancing the need to deal with urgent operational issues that are immediately affecting clinical services while progressing operational projects and strategic activities that influence how medical devices and technology are used in NHS Lothian.

Switching between tasks involving widely differing subjects and disciplines that require a highly developed, specialist in-depth knowledge of background, procedures and equipment. For example, a call about bacterial endotoxins in a Renal unit water supply may be followed by a question about retinal imaging systems in ophthalmology, a GP asking which ECG machine to buy or a Service Manager asking how they might secure funding for equipment and service development.

Prioritising workload and external requests with limited and finite staff resources.

Specifying, identifying and procuring the optimal technological solution and most appropriate medical devices for complex clinical use cases, that maximise patient safety with limited financial resources.

Determining the real contributory factors and root causes of complex problems with medical devices and medical device systems, particularly those involving human-machine interaction.

Identify and mitigating risks related to novel devices prior to them entering clinical use.

Communicating effectively with wide variety of people and applying a broad range of scientific and engineering knowledge to solving problems.

11. COMMUNICATIONS AND RELATIONSHIPS

The post holder will require the ability to establish and maintain key relationships and effective communication with a range of individuals internally at all levels within NHS Lothian and when representing the Board in discussions with senior managers, directors and technical representatives of supplying organisations within the commercial sector.

Communication will need to be appropriate and flexible to meet the requirements of the recipient(s), including: The provision of expert technical advice through the production of formal written reports and analyses, presentations at large meetings/conferences, informal briefings, group discussions, email, telephone and in-person/virtual 1:1 meetings.

The information being communicated may often be complex, technical and financial analysis, to be conveyed in a clear and concise manner for non-technical colleagues and stakeholders across professional boundaries.

Internal (Department):

Daily or weekly communication with team members within the Medical Equipment Management service or other services within the Department of Medical Physics - discussing operational activities and team priorities.

Ad-hoc meetings with Contract Management team members to discuss specific fleets of equipment when there is a maintenance-related compliance issue, to provide clarity regarding the implications for clinical and operational risk.

Periodic (typically monthly) 1:1 meetings with the Head of Medical Equipment Management. Twice yearly meetings to receive and review progress towards annual objectives.

Periodic MEM team meetings – to attend, or on occasions chair, various operational and project-specific MEM team meetings.

Internal (Health Board):

Periodic and ad-hoc meetings with senior medical & nursing staff, general managers, heads of department, ward managers and nursing staff - to discuss medical equipment issues, reliability and the impact on clinical services; leasing and maintenance of equipment; advice on selection, purchase and maintenance of equipment; discussing and resolving problems; providing training and instruction.

Ad-hoc discussions with colleagues in Procurement - to ensure that internal processes align with Board procurement processes and when requesting support managing a relationship with a challenging supplier.

Periodic or ad-hoc discussions with finance colleagues including staff in Capital Planning - to discuss project plans and room and building specifications, progress, tendering and other aspects of various projects involving medical equipment.

Attendance at other Board-wide technical, patient safety, risk, governance or finance meetings as required. Discussions typically involve adverse incident evaluation, reporting and follow-up actions; providing advice on the distribution and impact of safety notices.

External:

It is essential that the post holder can build and maintain strong and effective working relationships with a wide range of external collaborators and suppliers. This will include:

Ad-hoc and periodic face to face meetings with a wide and diverse supplier base, along with written and telephone contact, relating to all aspects of procurement or other lifecycle aspects of medical devices.

Attending professional and supplier-led conferences, seminars and presentations to keep up to date with new products and technologies.

Setting up and organising supplier presentations to the Board.

Ad-hoc meetings with colleagues at the Incident Reporting and Investigation Centre (IRIC) within NHS National Services Scotland.

Engagement with academic and industry research partners to understand novel prototype devices at an early stage of their development, where there is the intention that the device will be trialled within the Health Board.

Negotiating with suppliers either directly, with the support of NHS Lothian Procurement colleagues, or in association with other Boards through National Procurement, to achieve best value for money and other value-added benefits in relation to medical equipment procurement.

Developing and maintain relationships with colleagues performing a similar function in other Boards in Scotland.

12. PHYSICAL, MENTAL, EMOTIONAL AND ENVIRONMENTAL DEMANDS OF THE JOB

Physical skills and effort.

On a daily basis sitting and working at a desk using a computer for long periods, analysing complex data, writing reports, review and commenting on technical information and process documentation.

While not core to the role, several times per month the post holder will require manual dexterity to use fine hand tools and power tools on complex high-density circuit boards for fault-finding, component replacement and equipment assembly, where accuracy is important.

Able to make accurate measurements using a wide range of novel or complex test equipment, either when performing day-to-day technical work, project work, assessment of research devices, when supporting the activities of the MEM workshops or as part of the audit of others' work.

Several times each month there will be a need to participate in lifting and carrying (~15 kg) and moving heavy (<150 kg) medical devices. Required to travel between sites regularly with the need to move equipment by trolley from a vehicle in a car park into a hospital, often across ground that is ill-suited for the purpose.

Mental effort.

Daily need to respond to unpredictable work patterns/emergencies when unplanned medical equipment critical failures and incidents could result in patient care being compromised or an outage would result in impaired patient flow.

Maintain a high level of concentration when: attending meetings, analysing large or complex datasets, processing complex information and preparing reports.

Working in a demanding environment, dealing with time sensitive issues and demands from a wide range of people while responding to constant distractions/interruptions from colleagues seeking advice and assistance.

Intellectual demands in diagnosing and solving complex technical and use-related problems involving medical devices, often under time-pressure and potentially in high-acuity clinical environments.

Emotional effort.

The post holder will interact with many colleagues and clinical service users across all specialties, where each feel that their problem is the most urgent. This will result in challenging situations, particularly where there is a mismatch between need and resources. This calls for expert negotiating skills involving diplomacy, empathy and assertiveness.

The post holder will be occasionally required to work in emotionally distressing environments, when dealing with technically complex and unpredictable issues in proximity to very sick patients and distressed relatives, particularly in areas such as operating theatres, paediatric wards and intensive care.

Occasional need to reassure anxious patients and relatives regarding the safety and efficacy of medical devices.

Infrequent need to deal with sensitive issues such as formally interviewing staff in relation to the events surrounding an adverse event.

Environmental conditions.

The post holder may be required to work in any location where medical equipment may be found, in which locations the following risk factors may be present:

live electrical equipment,
blood-borne viruses and other infection control risks,
confined working spaces,
proximity to high pressure medical gases, and
unpredictable domiciliary working environments,

Consequently, the post holder is required to understand the hazards posed by the above risks and take appropriate precautions to mitigate these risks.

13. KNOWLEDGE, TRAINING AND EXPERIENCE REQUIRED TO DO THE JOB

Qualifications.

Professional engineering knowledge to SCQF level 11. For example, a Masters degree in an Engineering discipline such as electrical/electronic engineering or clinical/medical engineering.

Evidence of continuing professional development by, for example, attendance at appropriate courses.

Registration.

Registration with the HCPC as a Clinical Scientist.

Eligible for membership of a professional organisation such as the IPEM or the IET.

Experience.

Experience working with a wide range of operational medical equipment, leading to a high level of scientific and technical understanding of how medical devices operate, how they are used clinically and how they contribute to patient care.

Experience across the lifecycle (specification, formal evaluation, procurement, commissioning, use, calibration and safety testing) of medical equipment.

Demonstrable experience of electronic systems and/or software applications, particularly those used to configure or manage medical devices or medical device systems.

Experience in relation to the specification, design, development and assessment of novel medical devices.

Some experience undertaking research (at MEng/MSc level) and working with partners in research and development environments such as a University research lab.

Some experience managing technical and service improvement projects involving multiple stakeholders.

Scientific, technical and clinical skills/knowledge.

Knowledge of the standards, guidance and regulations pertaining to the management and use of medical devices.

Knowledge of typical policies and procedures relevant to medical devices.

High level understanding of patient and staff risks arising from the use of medical devices.

Highly specialist technical knowledge of a wide range of medical devices gained through attendance of manufacturers type-specific training courses and practical experience.

Knowledge of quality management systems (e.g. ISO 9001 and ISO 13485).

In depth, specialist knowledge of fault finding and diagnosis to component level, interpreting circuit diagrams on a wide range of medical equipment.

Knowledge of the health and safety regulations pertaining to healthcare and engineering.

Knowledge of anatomy, physiology and medical terminology relevant to clinical engineering.

14. JOB DESCRIPTION AGREEMENT

A separate job description will need to be signed off by each job holder to whom the job description applies.	
Job Holder's Signature:	Date:
Head of Department Signature:	Date: