



## Safety of Medical Electrical Equipment BS EN 60601-1:2006 (SME)

### **Introduction**

There is a legal requirement under the Medical Devices Directive to design and construct equipment in such a way to minimise the risk to the patient and the operator. In order to comply with the MDD, manufacturers must demonstrate that they have met its essential requirements for safety, this is demonstrated by compliance with the relevant Harmonised Standards. For Medical Electrical Equipment, the Harmonised Standard for safety is BS EN 60601-1. The third edition of the standard (released 2006) incorporates some of the old collateral standards, with considerable effort in the new edition to align requirements for electrical performance of medical devices with those for I.T. There are also considerable additions on risk management issues.

### **Objectives**

To provide Biomedical Engineers & Technicians with a thorough knowledge of the safety aspects of the 2006 BS EN60601-1 Standard and to improve their competence in performing field safety testing.

### **Course Summary**

- Introduction to the 60601-1 standard
- Effects of electricity on the body
- Electrical hazards from equipment
- Small/large currents arising from working and faulty equipment
- Allowable leakages and impedances for different classes of medical equipment and types of applied part
- Test configurations for compliance
- Safety testing and Inspection
- Review of pre-course questionnaire

## Safety of Medical Electrical Systems BS EN 60601-1:2006 (SMS)

### **Introduction**

Medical equipment is often found interconnected with other medical equipment, or with non-medical apparatus such as computers. Medical equipment may also be connected remotely to other equipment in non-medical rooms such as a Hospital Information System (HIS). These systems may be supplied by a manufacturer as a package, or may be configured locally. Examples of such systems include theatre trolleys, infusion stacks, endoscopy towers, image recording facilities, ITU networks, etc. Until recently, the safety of medical electrical systems were dealt with in the separate collateral standard BS EN 60601-1-1:2001. This subject is now incorporated in the main BS EN 60601-1 standard, third edition.

### **Objectives**

To provide Biomedical Engineers & Technicians with a thorough knowledge of the safety aspects of the 60601 standard related specifically to systems. On completion of the course, participants should be competent to configure medical/non-medical equipment systems and know the extra protection methods recommended in the standard.

### **Course Summary**

- Relevant items from the 60601-1 standard
- Main points from the systems chapter
- Management of leakage currents
- Exercises on test requirements
- System configurations and solutions
- Practical test configuration session
- Review of pre-course questionnaire
- Who is the manufacturer of a system?
- Remaining hazards

## General Course Information Terms & Conditions (SME & SMS)

### **Learning Method**

Each course contains both taught and practical sessions. Three weeks prior to the course, participants will receive a questionnaire to be completed before attending, requiring study of the BS EN 60601-1:2006 standard.

### **Learning Structure**

Both courses are designed to be free standing, however, it is highly recommended that the Safety of Medical Electrical Equipment course is attended first as it provides basic background knowledge.

### **Who should attend**

- Biomedical Engineers and Technicians who are required to configure, test or approve medical equipment or systems.
- Manufacturers and suppliers of medical electrical equipment, systems and electrical safety testers.

### **Course Staff**

- Prof. Azzam Taktak
- Dr Tristan Payne
- Mr Dave Smith
- Mrs Lynsey Holmes

### **Registration**

Registration takes place between 9:00 – 9:30am.  
Courses are scheduled to conclude at 4:30pm.

### **Application & Fees**

The application form and fees can be found overleaf. We recommend that you check availability of places with the course organisers prior to booking.

### **Accommodation**

We do not organise accommodation however we can provide a list of hotels located close to the course venue.

### **Venue**

Dept. Medical Physics & Clinical Engineering  
1<sup>st</sup> Floor Duncan Building  
Royal Liverpool University Hospital  
Liverpool, L7 8XP  
Maps / directions provided with confirmation of course place.