1 Introduction to the testing of medical devices

Testing is one of the longest-standing human activities there is; human survival has always counted on not making mistakes in certain situations. The process of comparing and measuring is designed to ensure law and order. Testing is a measure designed to determine the condition of a product as well as its properties and characteristics. Measuring makes it possible to carry out a quantitative comparison of these products. When a measured value deviates from the measured variable, this is known as the measurement error. This depends on the measurement method, the measuring equipment and the measuring instrument, and is also subject to environmental influences. In electrotechnology, "current", which is measured in ampere, is the variable that is measured and compared [1, 2].

1.1 What are medical devices?

Medical devices are defined in the Medical Devices Act. Medical devices are devices that do not achieve their principal intended action in or on the human body by pharmacological ("regarding the effect of medication"), immunological or metabolic means. It is important to distinguish between these medical devices and medicaments, which are administered as substances for use on humans or animals. The intended medical use is another key factor regarding allocation. Examples of medical devices include, for example, infusion pumps, implants, products for injection, dental products, transfusion devices, dialysis devices, pacemakers, medical software, sight aids, X-ray devices and condoms, as well as medical instruments and laboratory diagnostic equipment. Medical devices can be allocated to certain risk classes (see Figure 1). An example of a device with a very high risk to people is a pacemaker, which is an active implant and therefore plays a vital function in the human body. The testing of medical devices can only be audited and certified by appointed bodies (e.g. TÜV).

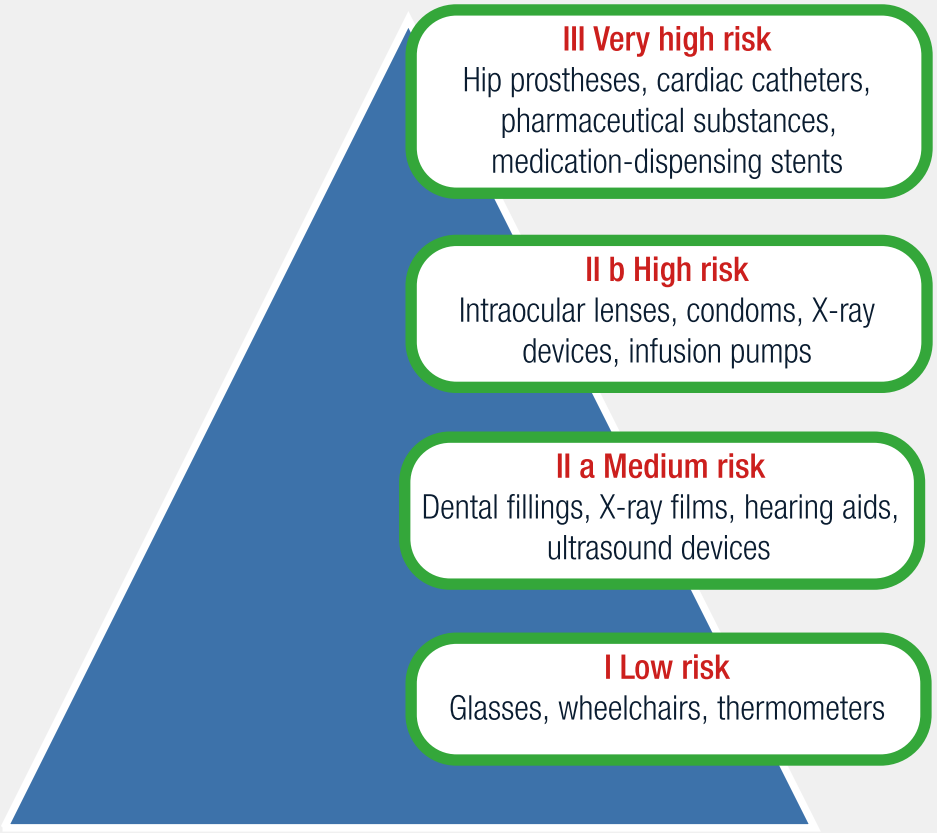


Figure 1: Risk classes for medical devices [3]

Medical devices can be allocated to one of the following categories depending on their purpose (see Figure 2)

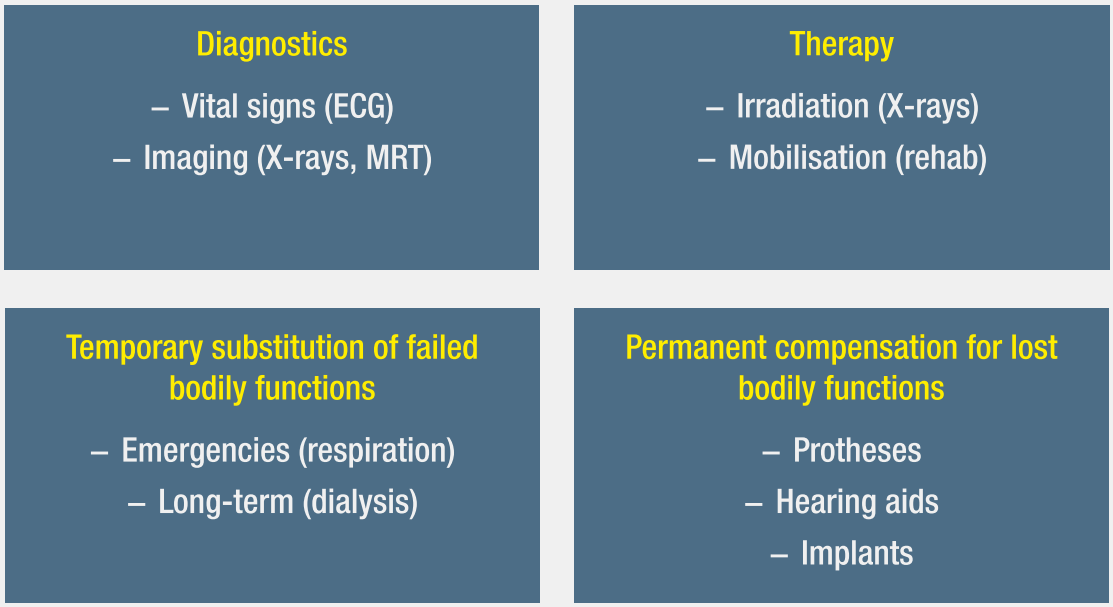


Figure 2: Fields of application of medical devices

1.2 Electrical safety: Why are medical devices tested?

In the field of medical technology, safety is absolutely essential in guaranteeing that people are protected against damage to health.

In order to guarantee the safety of people, reference must always be made to any potential risks and any safety rules, and this information must always be adhered to and put into practice by all involved parties. Safety is not static, but is a continual, ongoing process.

Medical devices must be tested as electrical current can pose a risk when treating and caring for patients. Studies have shown that electrical current poses a high risk of injury to people and can lead to fatal accidents. Electrical conductivity in the human body is very high as it consists of 70% water, which contains dissolved ions.

With invasive procedures in particular, there is a very high risk of electrical current penetrating the patient's body. However, current can barely be perceived by human skin. During an invasive procedure, the patient is often under general or local anaesthetic, meaning that the skin's natural protective function is not effective. Key factors here include the amount of current and the duration of exposure.

The most fragile muscles in the human body are the muscles in the heart, which are over-stimulated by electrical current, leading to a disruption to the normal sinus rhythm. This means that even low currents of 40 mA flowing through the human body for a period of 250 ms can lead to a cardiac arrest. [4, 5, 6]

1.3 How are medical devices tested? Statutory regulations and standards

All over the world, the responsible authorities define laws, standards and regulations designed to ensure the safety of medical devices. A large number of regulations have come about as a result of events, accidents and incidents that caused harm to patients or third parties.

At German national level, there is the German Medical Devices Act (MPG), which takes into account the European Directives 90/385/EEC for active implantable devices, 93/42/EEC for medical devices and 98/79/EC for in-vitro diagnostic devices. The directives are defined by the EU Commission.

1.3.1 The German Medical Devices Act (MPG) and the German Medical Devices Operator Ordinance (MPBetreibV)

The German Medical Devices Act (MPG) contains the technical and medical information requirements for placing a device on the market in the European Economic Area [7].

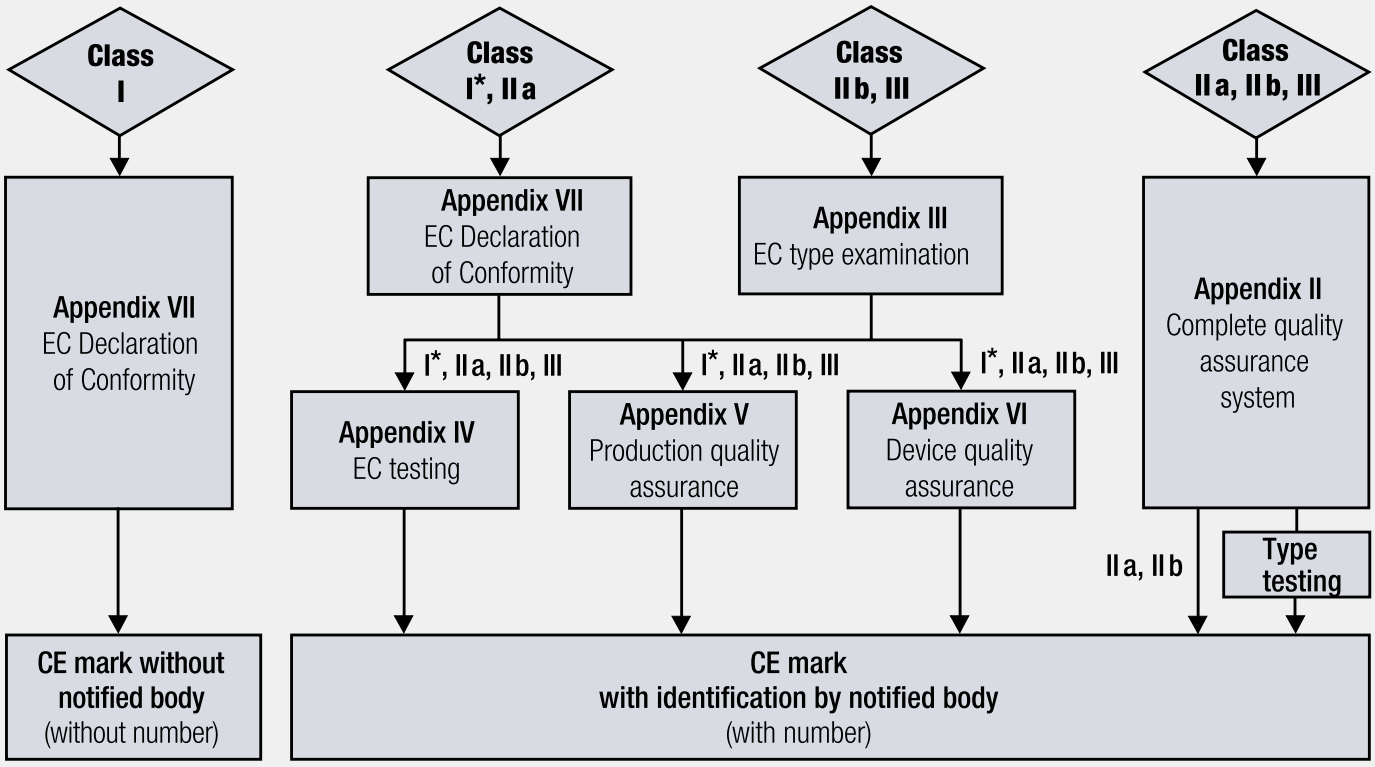
The purpose of this act is to regulate the circulation of medical devices and to therefore ensure the safety, suitability and performance of the medical devices as well as the health and necessary protection of patients, users and third parties.

The necessary prerequisite for placing a device on the market is proof that the device complies with the requirements of the applicable European Directive. This includes proof of the following:

The requirements are in line with the applicable standards. The documents are examined by the "notified bodies" based in the EU.

A "notified body" is a body that is authorised to carry out testing and to issue certificates in connection with a conformity assessment procedure (see Figure 3).

A "notified body" is therefore a licensed or authorised private institution that can carry out official tasks without being a public authority.



Declaration: I*: Medical devices with measuring function und sterile devices

Figure 3: Conformity assessment procedure [8]

If a device meets the prerequisites for being placed on the market, it is labelled with a **CE mark** (see Figure 4). However, it is important not to confuse this with a test marking. The CE mark serves as proof that the manufacturer has carried out a conformity assessment procedure. The device can then be approved for distribution on the European market. In addition to the German Medical Devices Act (MPG), there are also other regulations in German law that are directly related to this act.

CE

Figure 4: CE mark of conformity

The basic requirements for medical devices are as follows:

- Acceptable benefit/risk ratio
- Design based on the generally recognised state of the art
- Medical devices must perform the purported services
- Safe storage and transport
- No unacceptable side affects
- Usage information that can be understood even by laypeople

The German Medical Devices Operator Ordinance (MPBetreibV) is based on the power of the German Medical Devices Act (MPG) to issue ordinances. It regulates the installation, operation, use and maintenance of medical devices in accordance with the MPG, and serves as the national guidelines for all professional installers, users and operators of medical devices. The ordinance also includes requirements regarding hygiene during the processing of medical devices, as well as requirements regarding quality assurance.

Important general requirements in line with the German Medical Devices Operator Ordinance are as follows:

- Medical devices must only be operated in accordance with their intended use
- Medical devices must only be used by authorised persons
- Briefings on the correct handling of medical devices
- A function check must be carried out before using medical devices
- Specified error limits must be complied with

1.3.2 Electrical safety series of standards IEC 60601

The series of standards IEC 60601 defines the safety requirements for medical devices. These requirements are published in Germany as a DIN standard by the German Institute for Standardisation.

The series of standards is divided into the general standard IEC 60601-1-X (X denotes collateral standard 1 – 12) for electrical medical devices for which specifications are made regarding the safety of electrical medical devices, including their features, and collateral standards.

IEC 60601-1-X defines the general requirements and basic safety of electrical systems connected to a supply network that are intended for the diagnosis, treatment or monitoring of patients, and applies to devices that have direct physical or electrical contact with the patient.

IEC 60601-2-X (X denotes a specific standard number between 1 and 65) relates specifically to different electrical medical device types, and also provides information on the four basic standards. Appendices B and C provide an overview of the various IEC 60601-1-X and IEC 60601-2-X- standards.

Visual inspection

Visual inspections are a simple way of checking devices for external features and of identifying any visible damage or contamination.

Example features include housing damage or breakages, contaminated moving parts, the perfect (or otherwise) condition of the cables, the accessibility of mechanical components and the clear legibility of any markings.

Visual inspections of medical devices or systems are only carried out if requested by the manufacturer in the accompanying documents.

Before a device can be put back into use following testing, it must be returned to the condition required for intended use.

Earthbond testing

Earthbond testing is carried out on Class I medical devices and tests the low-resistance connection between the earth conductor and any conductive metal parts, which may become live in case of a fault.

IEC 60601-1 requires a test current of at least 25 A with alternating voltage. The load during earthbond testing should correspond to the fault.

Leakage current measurements

Leakage current is unwanted current that flows to earth from an error-free electrical circuit either directly in the form of earth residual current or indirectly (contact leakage current) via conductive parts (housing). Earth leakage current refers to any current flowing from the power supply unit to the protective conductor via the insulation.

The earth leakage current does not pose a risk to patients provided that the contact leakage currents are low.

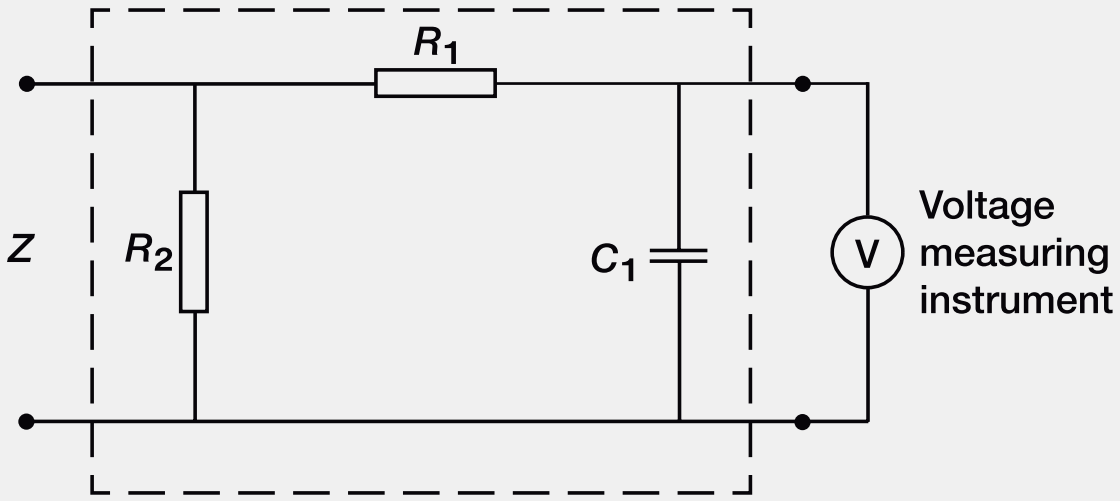
Touch current refers to any current with which the patient can come into contact, and that flows to earth or another part of the housing via an external connection.

In the medical technology sector, two types of leakage current are relevant - the patient leakage current and the patient auxiliary current.

The patient leakage current is determined in the same way as the touch leakage current, but only on the part that would be touched by the patient during treatment. Leakage currents must be measured with mains voltage or a test voltage. The measured current must be evaluated as a root mean square regardless of the waveform.

When using medical devices, the leakage currents that can flow via the heart are limited to a maximum of 10 µA.

The leakage current is measured with the following measuring arrangement (see Figure 5).



R_1 10 kΩ ± 5 %
R_2 1 kΩ ± 5 %
C_1 0,015 µF ± 5 %

Figure 5: Measuring system for measuring the leakage current

The impedance of the capacitor Zc is $\frac{1}{j*2*\pi*f*C}$.

As such, the measuring system constitutes a low-pass as the impedance of the capacitor falls as the frequency increases with AC voltage, meaning that there is less voltage drop at the capacitor.

The accuracy specifications of the measuring instruments apply for 50/60 Hz. When measuring high-frequency leakage currents, an oscilloscope or a high-frequency millivoltmeter must be used.

The patient auxiliary current is any current that flows between the components of the applied part and that is not intended to have any physiological impact, e.g. the input current from amplifiers. [9, 10, 11, 5]

IEC 62353: Electrical safety testing of medical electrical equipment

Throughout the world, testing of the electrical safety of medical electrical devices is performed in accordance with a standard procedure as set out in IEC 62353.

The IEC 62353 aims to set clear and standardised rules regarding the safety assessment of medical devices while maintaining reference to the standard IEC 60601-1. The safety-relevant functions must be tested in accordance with the manufacturer's specifications.

Testing in accordance with IEC 62353 is intended to prevent accidents as a result of unexpected leakage currents.

The measurement process is safe for the tester and for the device being tested. Measurement of the patient auxiliary current is not required by IEC 62353 as the risk of a hazard occurring following a repair or a repeat test is very low. [6, 12, 1]

1.3.3 Functional check of electrical medical devices

The functions that are relevant to the safety of the device must be tested in accordance with the manufacturer's specifications. If necessary, this testing must be performed with the assistance of a person who is familiar with the use of the device.

For medical devices, these include the functional checks required for essential performance as defined in the standard IEC 60601-1:2005 and in the "specific requirements" of the series of standards IEC 60601. These include, for example, defibrillators, infusion pumps, pulse oximeters, ECGs etc. [13]

1.4 Calibration of measuring equipment

In the field of measurement technology, the term calibration refers to a measuring process performed for the reliably reproducible recording and documentation of the deviation of a medical device compared to another device designated as normal (correct measured variable). In order to carry out an objective assessment of the safety of a system, reliable and reproducible measurement results are a prerequisite, as it does not make sense to carry out tests using equipment where measured values would be displayed incorrectly. The term calibration is frequently misunderstood. Calibration does not affect the measuring instrument and measurement errors are not corrected. If the displayed measured value is not within the tolerance range during calibration, there are two options in terms of how to proceed. These two options are explained below.

Adjustment

A systematic measurement error is reconciled and rectified. This involves looking at the reference value on a measuring instrument. If a multimeter shows a resistance of 100 Ω but the reference value is 110 Ω, this means that the difference value of 10 Ω would be reconciled during the adjustment process. During a simple calibration, this issue would only be documented, and no change would be made to the measuring equipment. [14]

No change to the measuring equipment

No adjustment is carried out. This may be the case if the user of the testing equipment wishes to document the status of the equipment over a defined period of time. This would allow for statements to be made regarding the equipment's time-related behaviour following calibrations.

Why does measuring equipment need to be calibrated?

The standard for quality management systems DIN EN ISO 9001.2008 stipulates the requirements for monitoring measuring equipment. Equipment must always be calibrated at specific times in order to ensure that the requirements regarding the measuring equipment are met and that product quality is guaranteed. Regular calibration guarantees the quality of products and services based on internationally comparable measurement results.

How often does calibration need to be performed?

Testing equipment should be calibrated on a regular basis. The frequency of calibration depends on the measured variable and the permissible tolerance range, the strain on the measuring and testing equipment, the stability, the necessary level of accuracy and the specifications of the company's internal quality assurance system. The intervals are ultimately defined and monitored by the users themselves. Many devices are only sent for calibration after 3 or 5 years, and therefore have high failure rates. All electronic components are subject to ageing. This causes their parameters to change, which in turn leads to changes in the properties of the device in which they are installed. The components are also affected by environmental influences and their type of use.

Which measured variables have the greatest deviations and what are the reasons for this?

Protective conductor resistance:

The measurement of the protective conductor resistance is the measurement that most frequently fails during calibration. A standard-compliant measurement of the protective conductor resistance must be carried out with a test current of at least 200 mA. The components in the test device are put under more or less strain depending on the test current that is used. Test devices with a test current of 200 mA, for example, can therefore be calibrated at longer intervals than test devices where measurements are carried out with test currents of 10 A or 25 A.

Leakage current measurement:

When measuring the leakage current, a distinction is made between measurement methods that can be performed without mains voltage and measurement methods that require mains voltage in order to be performed. The better option from a calibration perspective is the equivalent leakage current measurement that can be performed without mains voltage. This measurement is actually an impedance measurement rather than a current measurement.

It is carried out with a test voltage of 25 to 250 V, and the determined impedance is compared with a reference resistance so that it can be specified as a current value.

Differential current measurement:

There are also high failure rates with this measurement. The measurement is carried out under mains voltage and often with high (load) currents that frequently strain the components to the limits of their capacity or sometimes even beyond. When using these measurement methods, it is essential to observe the manufacturer's specifications regarding whether high load currents will affect the measurement and if so, under which conditions.

Overload (due to high inrush or cut-off currents, for example) can lead to changes in the properties of the transducers for the differential current measurement, for example, or can overload the measuring impedance during direct measurement, which can in turn cause the measuring impedance to change.

Loop resistance:

This measurement also frequently fails during calibration. The loop impedance is determined by loading the supply network with a test current. The higher the test current, the more effective the measurement of low-impedance loop resistances, but at the same time, the higher the load on the components being used. As the test is performed under mains voltage, the components are also under load from the mains voltage.

Insulation resistance:

With the insulation resistance measurement, the components are subjected to a high test voltage of up to 500 V or 1000 V. However, it has been shown in practice that this measurement practically never fails during calibration and that the measured value is always very close to the setpoint. There is probably no need to adjust the test devices even with longer calibration intervals.

Voltage measurements:

When carrying out voltage measurements such as those using multimeters, there are usually stringent requirements that need to be met with regard to accuracy. In this case, calibration is not usually required due to the load placed on components by high voltages and currents, but rather as a result of component drift due to ageing. The more stringent the accuracy requirements, the more frequently calibration will need to be performed. [14]