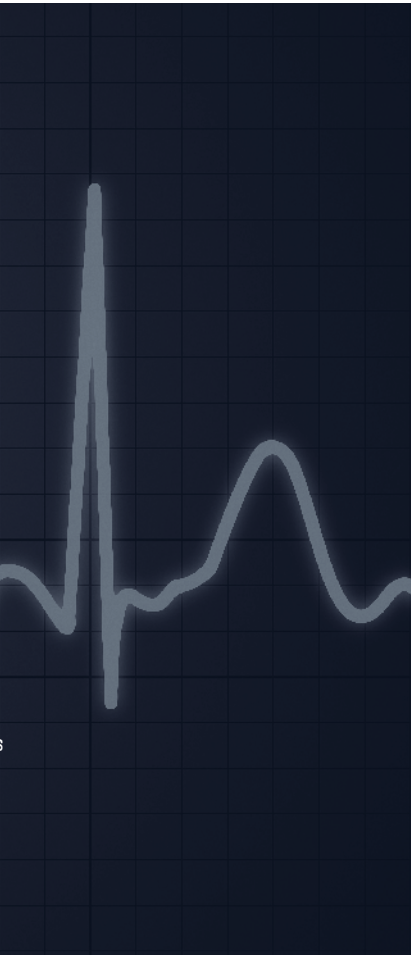
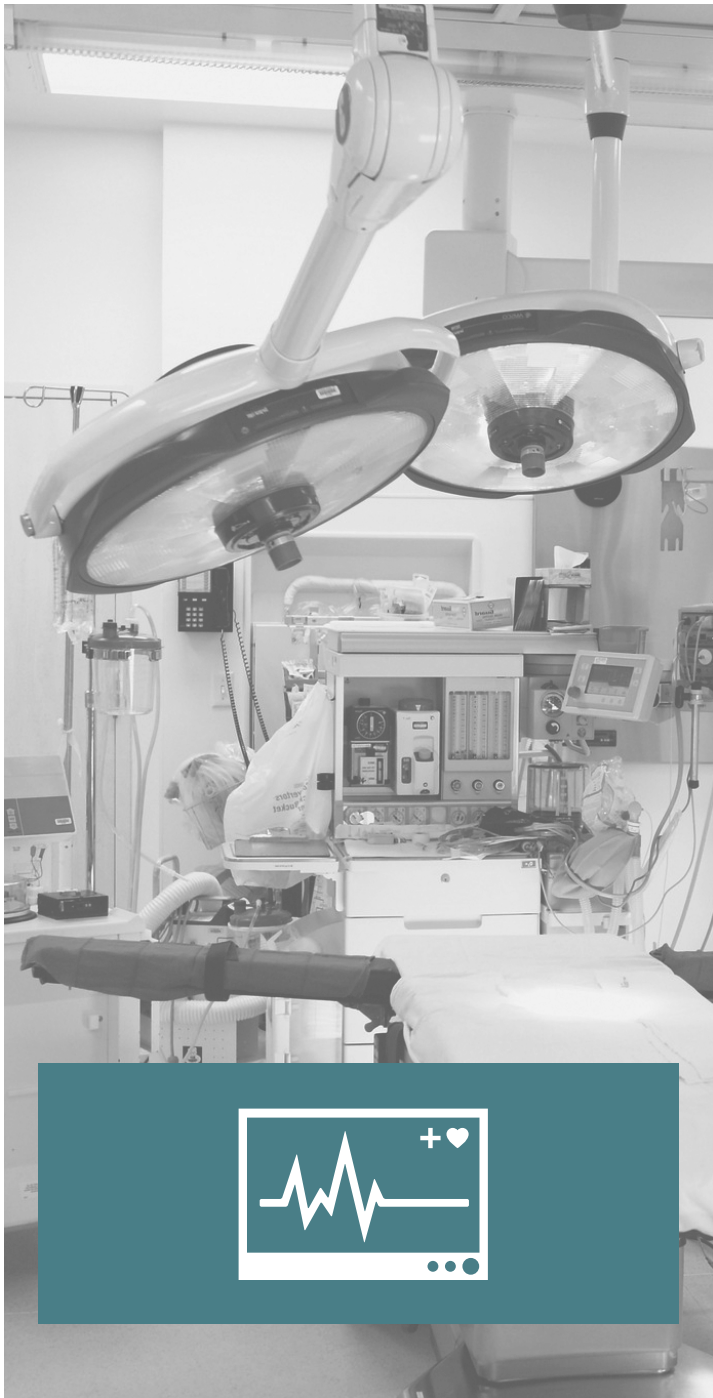
GOSSEN METRAWATT
GMC-INSTRUMENTS GROUP

MEDICAL TECHNOLOGY WHITEBOOK

TESTING OF MEDICAL DEVICES





Introduction

The complexity of medical devices has hugely increased over recent years. Whereas devices used to be mechanically streamlined with a stand-alone design, today's devices are increasingly operated electronically and using software. Ultrasound devices, infusion pumps, ventilators, diagnostic workstations, robot-controlled process and telemedicine are just a few examples of these types of modern devices. The more complex the products, the more likely there are to be specific risks associated with their use.

Users and operating companies both play a role in reducing the risks associated with medical devices and in increasing patient and user safety by complying with obligations relating to briefings and reporting.

In accordance with the German Medical Devices Act (MPDG) and the German Medical Devices Operator Ordinance (MPBetreibV), all medical devices in medical institutions must be tested at a testing interval defined by the manufacturer in accordance with DIN VDE 0751-1 / DIN IEC 62353 / DIN IEC 60601. These testing intervals are between six and 36 months.

During day-to-day operation, numerous devices are used that need to be maintained and/or calibrated at specified intervals. If this necessary procedure is not carried out, there are liability consequences for the operating company. The fundamental principles for the testing of systems and devices are the German Medical Devices Act (MPDG) and the German Medical Devices Operator Ordinance (MPBetreibV) in their role as applicable law, together with the regulations of the Employer's Liability Insurance Association (BGV A3) and the manufacturer information for the particular device. The German Medical Devices Act (MPDG) and the German Medical Devices Operator Ordinance (MPBetreibV) stipulate the requirements for handling medical devices, with the aim of improving the protection of health for employees and patients. These laws prescribe the testing of electrical devices prior to initial commissioning and prior to recommissioning (e.g. following modification work) and at regular intervals.

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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).

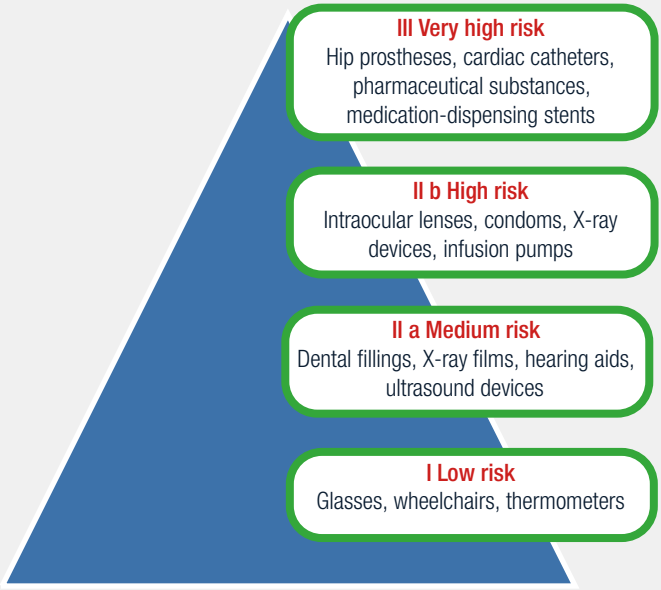


Figure 1: Risk classes for medical devices [3]

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

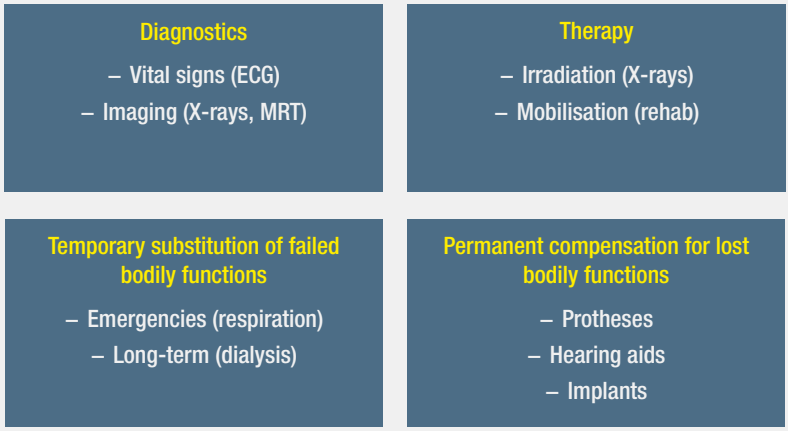


Figure 2: Fields of application of medical devices

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 (MPDG), 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 (MPDG) and the German Medical Devices Operator Ordinance (MPBetreibV)

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

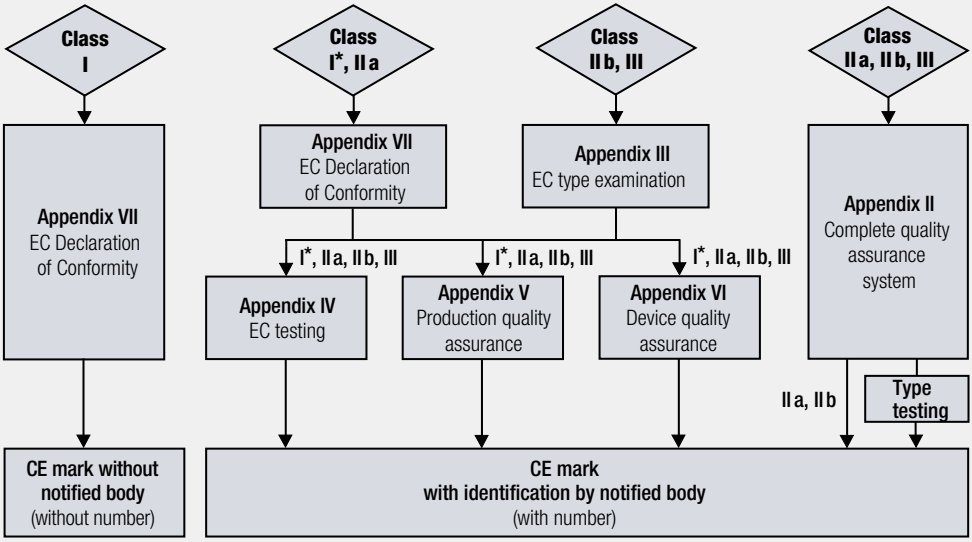
The purpose of this act is to regulate the circulation of medical devices and to therefore ensure the safety, suitability and performance of the medical devices as well as the health and necessary protection of patients, users and third parties.

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 (MPDG), there are also other regulations in German law that are directly related to this act.

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 (MPDG) to issue ordinances. It regulates the installation, operation, use and maintenance of medical devices in accordance with the MPDG, 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.

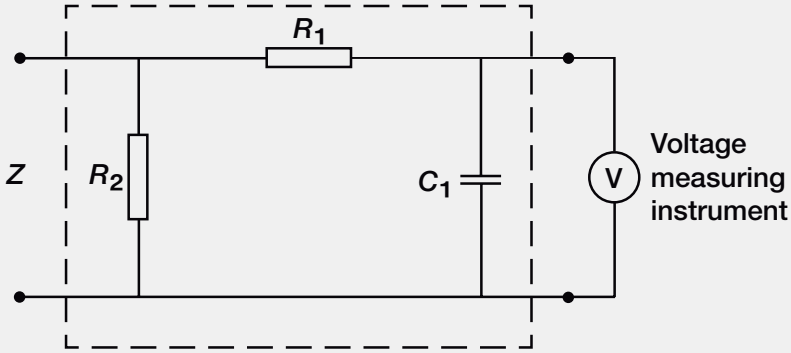
Touch current refers to any current with which the patient can come into contact, and that flows to earth or another part of the housing via an external connection.

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]

1.5 Medical device hygiene

Good medical device hygiene is necessary in order to protect people from germs and pathogens.

Bacteria and germs are becoming increasingly resistant to antibiotics. Studies have shown that approx. 1.8 million hospital infections occur every year over the whole of Europe, of which 180,000 ended in fatality [15].

Numerous surfaces such as cables, ventilator buttons and work surfaces are heavily loaded with germs and can be spread by hospital staff and in turn lead to fatal infections in patients.

It is therefore essential that hygiene regulations defined by specific standards are observed in hospitals in order to take preventive action against this risk.

Hygiene plans in hospitals contain instructions on the disinfection and sterilisation of devices and materials.

Disinfection refers to a 10-to-5-time reduction in germs. It therefore reduces germs to a level where infection is not possible, although germs can never actually be eliminated completely.

With sterilisation, the device being sterilised may have a maximum of 10 - 6 colony-forming units. Unlike disinfection, almost all microorganisms and all viruses, prions, plasmides and DNA fragments are destroyed.

A selection of standards on cleaning and disinfection can be found in Table 1.

Standard	Cleaning/disinfection
DIN EN ISO 15883-1	General requirements for washer-disinfectors
DIN EN ISO 15883-3	Requirements for thermal disinfection
DIN EN ISO 15883-4	Requirements for chemical disinfection
DIN EN ISO 14180	Sterilisation for medical purposes - low temperature steam and formaldehyd

Table 1: Standards relating to cleaning and disinfection

Different sterilisation methods are used depending on the medical device being sterilised. The standard procedure uses moist heat. Hot air is often used with simpler medical devices, although this method takes longer, or alternatively gas can be used with particularly heat-sensitive devices.

The use of computers in the operating room means that hygienic aspects need to be analysed and clarified as part of a risk assessment.

It must be possible to disinfect the keyboard and mouse as these are touched with protective gloves.

For the cleaning of surfaces, it must be clarified whether aqueous solutions (0.5 %) or alcoholic agents are used, and how these agents act on the surface.

Plastics must not be discoloured or dissolved, but are significantly less susceptible to germs.

Because PC fans can cause dust and germs to swirl up in the vicinity of the surgical field, it must be ensured that computers are kept as far away from this area as possible. Computers must also be cleaned on a regular basis and must have a fluff filter. [5]

Hygienic processing of medical devices

The procedure for the processing of medical devices is as follows. [16] (see Figure 6)

Pre-cleaning	• Joints must be opened and cavities made accessible • Open any valves • Observe the manufacturer's recommendations!
Cleaning	• Distinction between manual and machine cleaning • The cleaning method is selected based on the risk assessment (critical products must be cleaned using machinery, whereas uncritical products must be cleaned manually) • Equipment: Brushes, cloths, measuring beakers, cleaning agent, purification tanks • Ultrasound cleaning can be performed on hard-to-access parts
Intermediate flushing	• Chemical residues are removed so as not to impair subsequent disinfection • This step can be omitted under certain circumstances
Disinfection	• Removal of bacteria or pathogenic micro-organisms • Select the disinfectant from the list provided by the German Association for Applied Hygiene • Observe the dosages and exposure times specified by the manufacturer • Equipment: Measuring beakers, disinfectant, disinfectant tanks
Flushing	• Flushing carefully removes cleaning agents and disinfectants

Figure 6: Hygiene procedure

2 Classification of safety testing equipment and functional testing equipment

Medical safety and function testers are available for the reliable testing of medical devices. These testers can be grouped into four different categories (see Table 2):

Safety testers:

Safety testers are used to test the basic electrical safety requirements in accordance with DIN EN 60601 and any other standards. The electrical parameters of medical devices are tested and documented either fully automatically or manually. These parameters include the contact current, the leakage current, the patient auxiliary current and the insulation auxiliary current.

Function testers:

Function testers are used to test the functioning of a medical device in accordance with the necessary specifications. Function testers are available for devices such as defibrillators, infusion pumps, high-frequency generators, electrosurgical devices etc.

Photometry:

Photometry can be used to test the luminance, the illuminance and the ambient lighting of medical monitors. In order to ensure that the physician can make a correct diagnosis, it is important that the screen has the correct brightness so as to prevent incorrect interpretation.

Patient simulators:

A patient simulator is a microprocessor-controlled device that can simulate various signals, making it possible to check whether the simulated input signals are being correctly transmitted to the patient monitor (e.g. ECG monitor).

Safety tester	Function tester	Photometry	Patient simulator
			
SECULIFE ST PRO	SECULIFE IF+	SECULIFE IF	SECULIFE BP PRO

Table 2: Safety and function testers

3 Which devices are tested?

3.1 Patient monitors for measuring vital signs

A monitor (see Figure 7) in the medical sense of the word (also referred to as a vital-sign monitor) is a device or a combination of devices that can be used to measure and monitor the vital signs of a living being.

Monitors are primarily used when a patient is under anaesthetic, during surgery, for critically ill patients in intensive medicine or for other clinical pictures that require continual monitoring. Mobile devices are available for use on emergency patients.

Depending on the minimum standards for monitoring, the devices are fitted with technology for the monitoring of various numbers of vital signs, such as heart rate, temperature, blood pressure, ECG, respiration and pulse oximetry.

Figure 7: Examples of patient monitors

3.1.1 ECG (Eelectrocardiograms)

What is an ECG?

An ECG can be used to assess the heart rhythm and heart rate, allowing the physician to make a variety of statements regarding the health of the heart. The task of the heart muscle (see Figure 8) is to provide the body with a vital supply of oxygen. It is connected to the lungs and supplies the entire body with oxygen via the body's circulatory system.

The heart consists of four chambers; the left and right atrium and the left and right ventricle. The atria and the ventricles are separated by atrioventricular valves. In order to maintain the circulation of blood throughout the body, the heart needs to pump regularly, which involves the rhythmical contraction of the heart muscle.

This stimulates the muscle cells, and the stimulus is then transferred through the body. There are cells that generate electrical impulses (known as pacemaker cells) and cells that contract as a response to an impulse (known as work cells). Normally, the heart's natural rhythm is defined by the sinoatrial node, with the atrioventricular (AV) node only taking over if the sinus node stops working. When a stimulus is generated by the pacemaker cells, both atria contract.

The stimulus then passes through the atria, causing these to contract and fill with blood. Used blood that is low in oxygen passes from the right atrium to the right ventricle, from where it is transferred to the pulmonary artery via a pocket-shaped pulmonary valve. Once in the pulmonary artery, the blood is enriched with oxygen and is then carried back to the left atrium and the left ventricle, from where it travels around the body via the aorta, supplying all of the vital organs with oxygen. The heart's pumping sequence can be roughly divided into two phases:

Filling phase (diastole): The heart muscle is not tensed. This causes oxygen-depleted blood to flow into the right atrium. At the same time, oxygen-rich blood flows into the left atrium and then passes into the ventricle.

Expulsion phase (systole): The heart muscle contracts and the blood flows from the ventricles into the body's circulation system and the pulmonary circulation system.

These two phases can be displayed as electrical activity on an ECG, allowing the physician to determine the extent to which cardiac function is guaranteed. [17, 18]

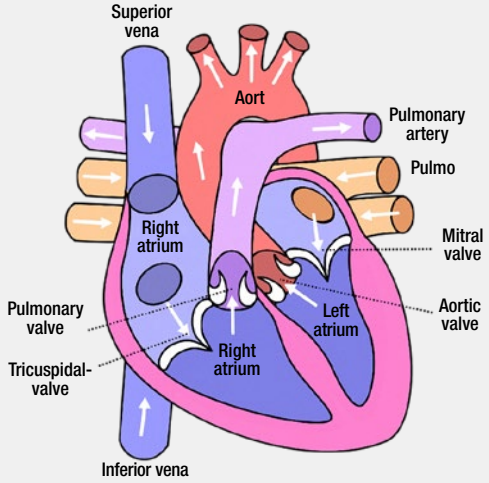


Figure 8: The heart [18]

An electrocardiogram (ECG) is a painless, non-invasive procedure that can be performed almost anywhere and that can be repeated at any time. An ECG records the electrical activity of the heart in millivolts (see Figure 9). The device works based on electrical impulses causing muscular contractions in the heart, which in turn causes electrical current to flow through the body. This current can then be measured by electrodes stuck to body surfaces such as the chest wall. The ECG signal consists of a P-wave, a QRS complex and a T-wave, with this electrical activity typically lasting between 400 and 600 ms. The change in voltage provides information regarding activity in the heart. An ECG can be interpreted based on the level of individual voltages, the durations and the steepness of the signals. [19, 2]

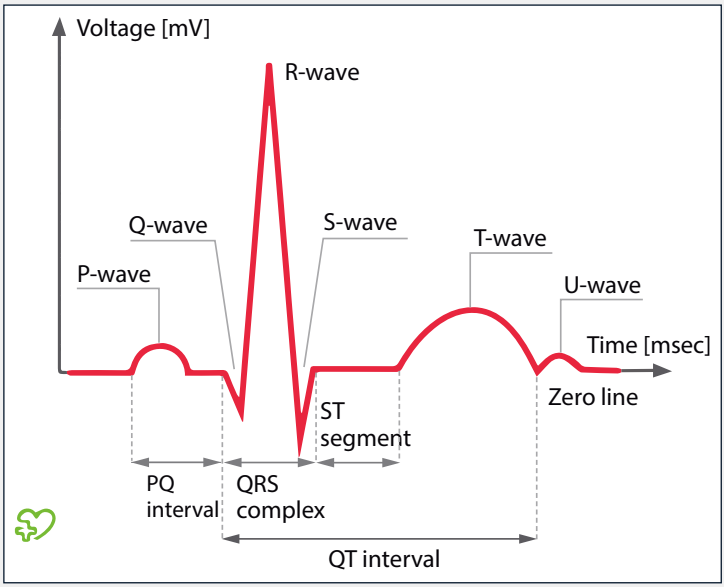


Figure 9: Example ECG [20]

P-wave: The P-wave, which appears as a semi-circular wave, represents the stimulation of the heart's atria.

Q-wave: The Q-wave is the first downward deflection after the P-wave and the end of the PQ interval.

R-wave: The R-wave is usually high and narrow. It is the first upward deflection after the Q-wave. The R-wave represents the stimulus of the ventricles in the heart.

S-wave: The S-wave is small and is the first downward deflection after the R-wave

T-wave: The T-wave is large and wide and represents the repolarisation of the ventricles. Electrical activity in the heart stops at the end of the T-wave, and the cycle then repeats itself.

QRS complex: The QRS complex represents the spread of the stimulus through the heart. This is known as depolarisation. Depolarisation refers to the changes in the potentials in the cardiac cells and ventricles.

How is an ECG signal measured?

Einthoven's leads (see Figure 10):

The body's natural impedance means that there are various electrical potentials throughout the entire body. Attaching electrodes to the body makes it possible to measure these potentials. In accordance with Einthoven, 3 electrodes are placed on the patient in a triangle formation - one on the left leg (LL), one on the right arm (RA) and one on the left arm (LA). According to Kirchhoff's rules, the third line can be calculated if the other two lines are already known. Measuring the voltage at the left and right arms corresponds to a measurement of the projection of the heart vector along this axis. The Einthoven lead is a bipolar lead, i.e. a lead between two points. [20, 21]

Lead I + lead III – lead II = 0 V

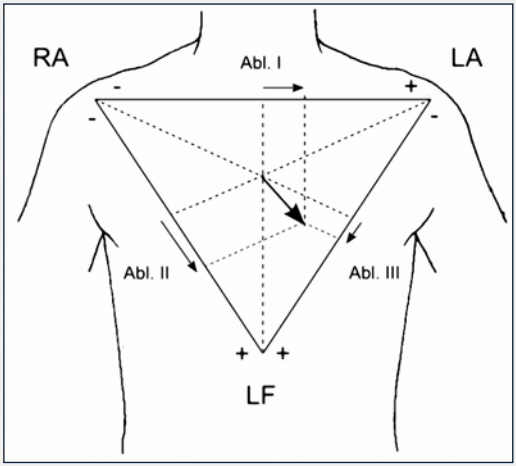


Figure 10: Einthoven's leads [22]

Lead	(+) positive	(-) negative	Potential
I	LA	RA	V1 = Ø LA - Ø RA
II	LL	RA	V2 = Ø LL - Ø RA
III	LL	LA	V3 = Ø LL - Ø LA

Table 3: Einthoven's leads

Goldberger's leads:

With Goldberger's leads (see Figure 11), two electrodes are pooled to form a common ground, against which the voltage is measured at the third electrode. The Goldberger leads are unipolar leads.

With a unipolar lead, the differential electrode is switched to a so-called null electrode. Two extremities are connected via a high-impedance resistance. There are three different leads - aVR, aVL and aVF.

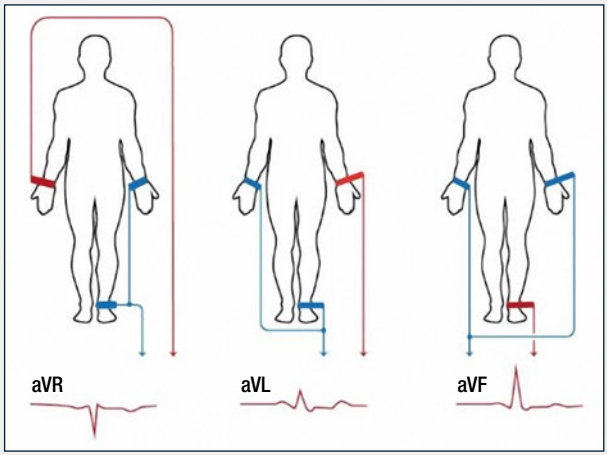


Figure 11: Goldberger' leads [23]

Wilson's leads:

With Wilson's leads (see Figure 12), there are six unipolar chest-wall leads (V1… V6). These are placed on the chest at six defined positions (C1…C6). Three extremities are connected via a high-impedance resistance and are measured from the chest as a collecting electrode. As the chest is relatively close to the heart, the amplitudes of the chest-wall lead that are measured when following the Wilson method are higher than those of the extremity leads. [2]

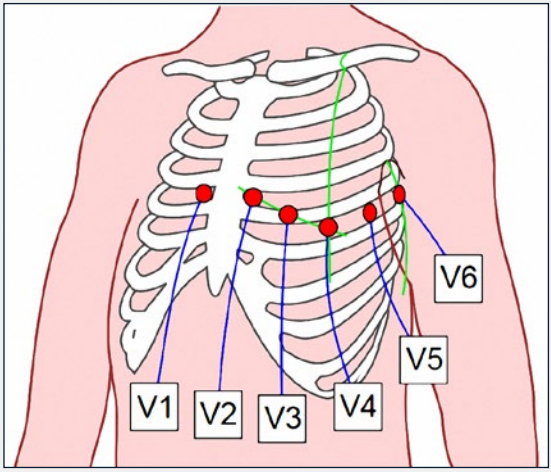


Figure 12: Wilson's leads [24]

ECG devices vary depending on the number of leads. The following types of ECG devices are available, each registering different numbers of leads.

- 1-channel ECG: 1 lead is registered. Emergency use only.
- 3-channel ECG: 3 leads (Einthoven or Goldberger)
- 6-channel ECG: 3 Goldberger leads, 3 Einthoven leads
- 12-channel ECG: 6 Wilson leads, 3 Goldberger leads, 3 Einthoven leads The 12-channel ECG is of high quality with regard to informative value.

An example 12-channel ECG can be seen in Figure 13.

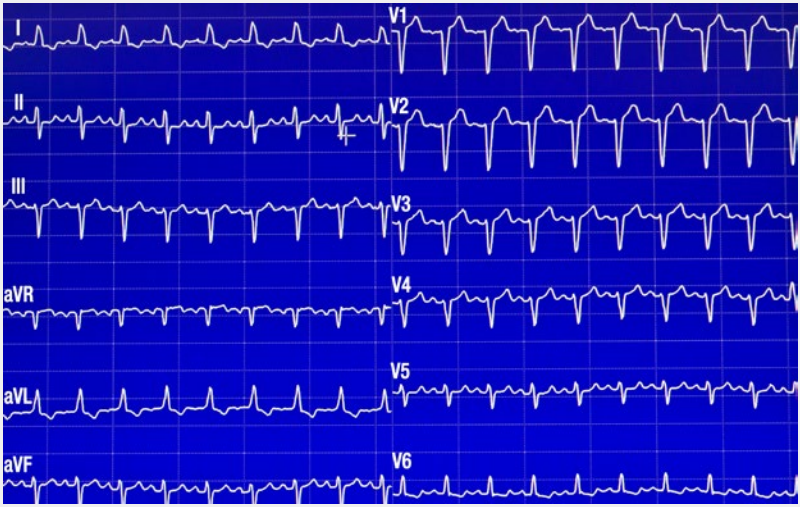


Figure 13: Example of a 12-channel ECG. Goldberger and Einthoven leads can be seen on the left. The chest-wall leads can be seen on the right. [25].

Using the ECG for diagnostics:

In a normal, healthy sinus rhythm (as shown in Figure 9), the QRS complex corresponds to a heartbeat of 50 to 100 BPM ("Beats per Minute"). However, there may be deviations from this rhythm that can be interpreted by the physician, and that are referred to as arrhythmia (= heart rhythm disturbances).

Sinus tachycardia (tachys is Greek for quick): This term refers to an accelerated P wave followed by a normal-looking QRS complex (Figure 14). This results in an elevated heart rate of over 100 beats per minute in adults. The opposite of tachycardia is bradycardia (brady is Greek for slow). In this case, the P-wave occurs far too slowly.

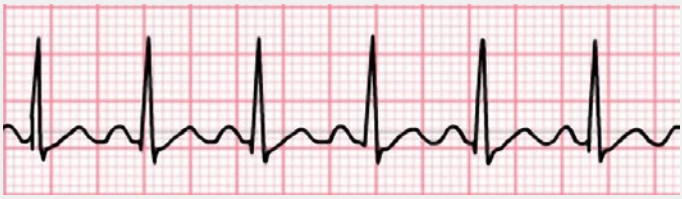


Figure 14: Sinus tachycardia

Bradycardia (brady is Greek for slow):

The opposite of tachycardia is bradycardia (see Figure 15). In this case, the P-wave occurs far too slowly. This occurs when the pacemaker function of the sinoatrial node is impaired or blocked, causing the heart to beat less frequently, or when the electrical impulses can only be passed on slowly. [26]

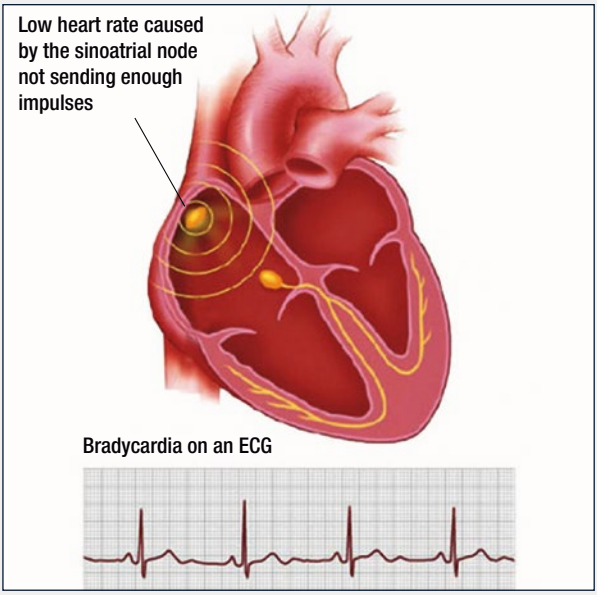


Figure 15: Bradycardia [26]

AV block: With an AV block, the stimulus from the P-wave is not passed on (see Figure 16). The AV node goes into emergency mode. The transfer of the stimulus between the atria and the ventricles is delayed, or can in cases be interrupted. In extreme cases, the heart rate can become so slow that the patient enters a state of bradycardia, which calls for treatment with a pacemaker.

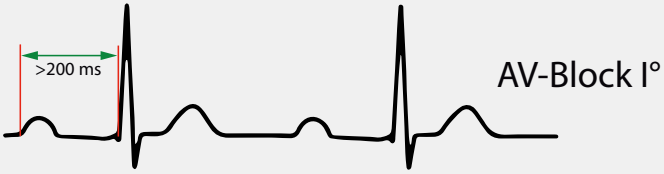


Figure 16: AV block [27]

Ventricular arrhythmia:

Ventricular heart rhythm disturbances (see Figure 17) are disturbances that occur in the ventricles. With VT, the heart beats at ≥ 120 BPM. In the event of a ventricular heart rhythm disturbance, there will be impairments of both the generation of stimulus and the transfer of the stimulus due to damaged heart-muscle tissue, e.g. as a result of a heart attack. In addition to the regular electrical impulses, there will also be unwanted impulses, meaning that the electrical stimulus will no longer have any rest time in the ventricles. Because the heart no longer has enough time to pump blood into the body, meaning that oxygen is not sufficiently transported around the body, ventricular arrhythmia is a life-threatening diagnosis. A heart rate of 250–320 BPM is referred to as ventricular flutter, and a heart rate of over 320 BPM is referred to as ventricular fibrillation. With ventricular fibrillation, no more blood is being pumped around the body and cardiac arrest will occur, which can quickly be fatal. [26]

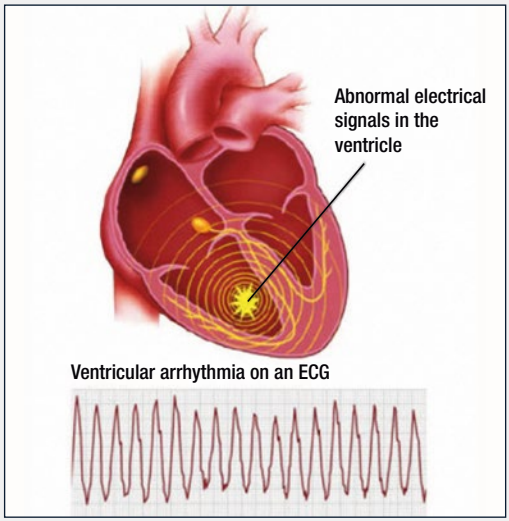


Figure 17: Ventricular tachycardia [26]

3.1.2 How are ECG patient monitors tested?

The standard DIN EN 60601-2-25 contains particular requirements regarding the safety of electrocardiographs. This standard primarily relates to the general safety of ECG devices, and sets out particular requirements designed to supplement the “basic standard” IEC 60601-1, which contains general requirements for the safety of medical electrical equipment. DIN EN 60601-2-27 contains particular requirements regarding the safety and essential performance of electrocardiographic monitoring devices or ECG patient monitors.

An electrocardiographic monitoring device is a device with electrodes, electrode cables and connecting parts for the monitoring and recording of a patient’s heart-action capability and for the display of the acquired data. The monitoring devices are tested for interference immunity, for example. Testing is performed using a set-up consisting of a mains power cable, a signal connection cable, the device being tested (ECG monitoring device), a load for patient simulation (51 kΩ parallel with 47 nF) and a table. Testing is performed using a simulated input signal with an amplitude of 1 mV over a duration of 100 ms, with a heart rate of 100 1/s.

It is not possible to use actual patients to test ECG patient monitors, so special electrical devices such as the SECULIFE PS300 need to be used, which can generate an ECG signal as a reference value. The SECULIFE PS300 is a simple patient simulator with a display on which various vital signs such as SpO2, blood pressure, temperature and respiration parameters can be adjusted (see Figure 18). To test ECG patient monitors, various ECG curves can be simulated using an inbuilt microprocessor and an AD (analogue/digital) converter that then displays these curves as an analogue signal. The SECULIFE PS300 can also simulate 36 types of heart rhythm disturbances, and sends characteristic curves to ECG devices based on three, five or twelve leads.

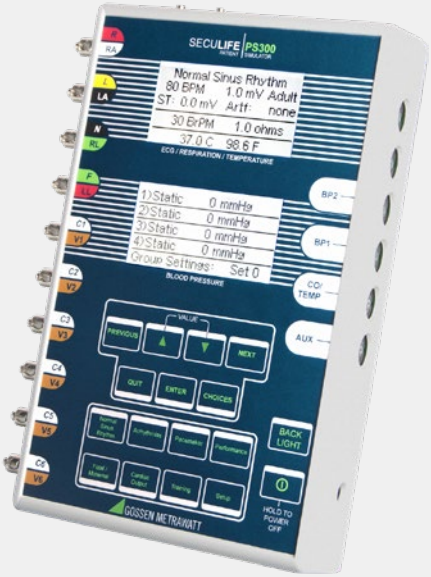


Figure 18: SECULIFE PS300 patient simulator

Housing	227.8 x 153.4 x 43.7 mm/ABS plactic
Weight	0.9 Kg
Front panel	Lexan/printed background
Operating temperature	15 to 40 °C
Storage temperature	-20 to 65 °C
Display	Two LC displays, 128 x 64 pixel, white backlight
Power supply	2 x 9 V

Table 4: Technical specifications of the SECULIFE PS300

The SECULIFE PS300 simulates a sinus rhythm of 80 BPM, an amplitude of 1.0 mV/lead II and a PR interval of 160 ms as standard. The parameters can be adjusted using the appropriate buttons. The terminals must be connected correctly in line with the colour-coding, whereby **RA** stands for right arm, **LA** for left arm and **LL** for left leg. The adjusted values should then be displayed correctly on the ECG, i.e. a BPM of 80 and the correct ECG amplitude should be displayed on the ECG device when a normal sinus rhythm is being simulated (see Figure 19).

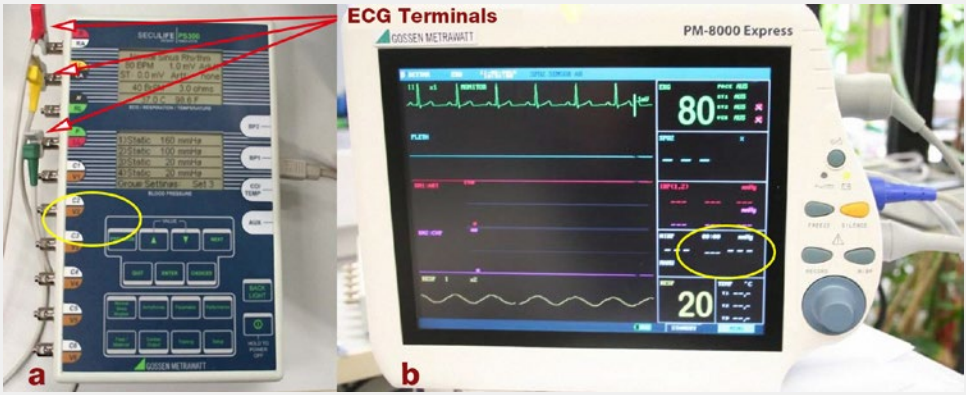


Figure 19: Simulation of a normal sinus rhythm on an ECG device

3.1.3 Defibrillators

What is a defibrillator?

Defibrillators are high-voltage electrical medical devices that are used for resuscitation and to remedy heart rhythm disturbances. Heart rhythm disturbances are caused by a change in the output of stimulus from the heart, which impairs the coordination of the heart muscle fibres. If ventricular fibrillation or pulseless tachycardia (supraventricular and ventricular) occurs, this can lead to irreversible damage incredibly quickly.

Defibrillation (de = 'away'/'removal' (Lat.) + 'fibrillation') stops the fibrillation of the heart muscles five seconds after a shock is administered (see Figure 20).

Thanks to the phasic energy impulse, depolarisation is intended to affect all of the heart muscle fibres, bringing all electrical activity in the heart to a stop. To administer the necessary shock, an electric shock is applied to the chest (transthoracic) area in order to bring about the synchronised stimulation of the heart muscle. This prolongs the repolarisation of all cells, and the heart will normally return to its sinus rhythm. [28]

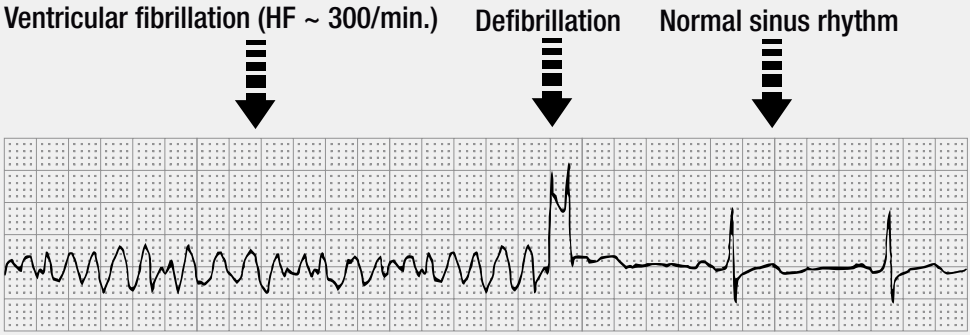


Figure 20: Heart rhythm following defibrillation [2]

When is a defibrillator used?

Only when the electrical activity in the heart is very uncoordinated, e.g. in the event of ventricular fibrillation or ventricular tachycardia. Defibrillators are not used to treat cardiac arrest, and careful diagnosis must be carried out before using an ECG device. The success of a defibrillation depends on the amount of energy that is applied, the position of the electrodes and the transthoracic resistance. Ventricular fibrillation is a life-threatening heart rhythm disturbance involving disordered stimuli in the ventricles, whereby the heart muscle is no longer able to properly contract. The insufficient pumping performance of the heart means that this condition can lead to immediate death. In order to prevent this outcome, immediate defibrillation is required in the event of ventricular fibrillation. This involves giving the patient a short

and powerful electric shock that stimulates all of the heart muscles simultaneously. Heart contractions are then stimulated in the normal manner by the sinoatrial node. Defibrillation is the only promising treatment for ventricular fibrillation. If there is no electrical activity whatsoever, such as in the event of asystole or flatline (see Figure 21), defibrillation must not be performed. Asystole usually occurs as a result of ventricular fibrillation and can lead to death within a few minutes. Cardiac massage and ventilation would be more sensible resuscitation measures in this case. [29]

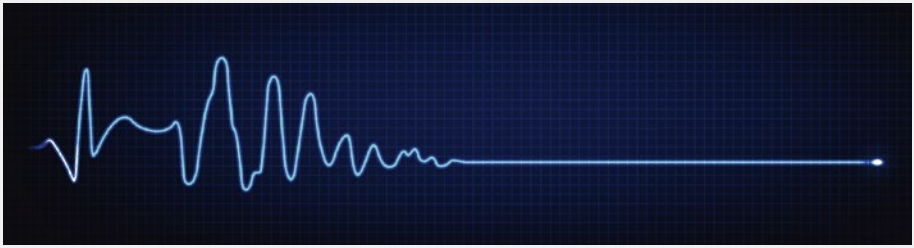


Figure 21: Flatline

What different defibrillator designs are available?

Defibrillators can be divided into the three categories of manual defibrillators, semi-automatic defibrillators and fully automatic defibrillators.

Manual defibrillators (see Figure 22): Manual defibrillators often have a built-in ECG device and can be switched to semi-automatic mode. With a manual defibrillator, the ECG from the electrodes must be interpreted by the user. With a semi-automatic or fully automatic defibrillator, the power does not need to be set manually, and is instead worked out and adjusted based on an analysis of the heart function.

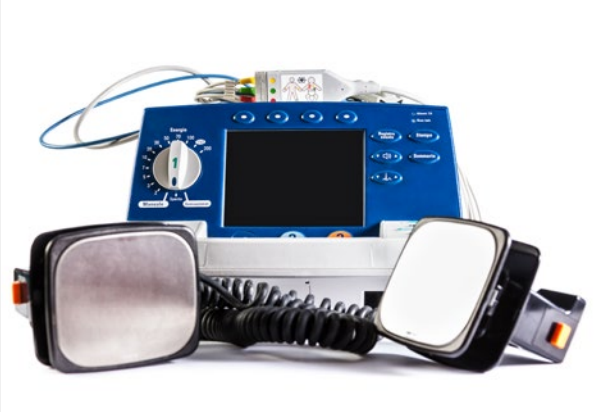


Figure 22: Manual defibrillator [28]

Semi-automatic defibrillator: The shock must be administered manually. The patient undergoes continual ECG monitoring, and recommendations are given as to when the shock should be administered.

Fully automatic defibrillator (see Figure 23): The user places the electrodes on the patient and switches on the device. The shock is then triggered automatically, with no possibility for the user to intervene. This eliminates any potential impact of the user's inhibitions regarding the use of the device.

Figure 23: AED (automated external defibrillator)

How is a defibrillator used?

Electric shocks are used to stop all electrical activity in the heart at the same time. The type of shock that was initially used when defibrillators were first invented was the monophasic shock type (see Figure 24). Based on the results of studies, biphasic shocks (see Figure 24) are now used. The use of this shock type improves the effectiveness of the defibrillator as it has proved to be particularly effective during this procedure. Compared to the monophasic shock type, the biphasic shock type provides a better chance of being able to restore spontaneous circulation. An electric shock device delivers an impulse that initially progresses in an upward direction before then falling in a downward direction. The current direction is reversed in the final 5–15 ms. The biphasic shock discharges the polarised cell membrane, thereby reducing the risk of spontaneous refibrillation caused by electrical energy stored in the heart muscle. The negative phase of the biphasic shock "drains" this energy, meaning that coordinated ventricular stimulation can be restored. This type of shock is very effective and requires a relatively small amount of energy. The defibrillation threshold is reduced by 50% using this method. Almost all modern electric-shock devices work based on the biphasic principle. [30, 31, 2]

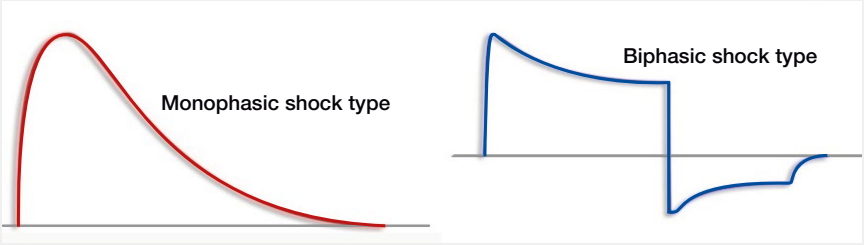


Figure 24: Monophasic and biphasic shock types [32]

3.1.4 How are defibrillators tested?

DIN EN 60601-2-4 contains particular requirements regarding the safety of defibrillators and sets out particular requirements designed to supplement the "basic standard" IEC 60601-1, which contains general requirements for the safety of medical electrical equipment. The technical description contains energy and accuracy specifications for the delivery of energy in a 50-Ohm resistor. The ECG database must contain amplitude rhythms for ventricular fibrillation (VF), ventricular tachycardia (VT) and sinus rhythms. The delivery of energy must not deviate from the set energy value by ±3J or ±15%, whichever value is larger.

The SECULIFE DF PRO (see Figure 25) can be used to measure and display the energy delivered by a defibrillator. It is controlled by a microprocessor and also provides information regarding the patient's pulse. The tester is suitable for testing manual and semi-automatic defibrillators with monophasic and biphasic energy delivery. The SECULIFE DF PRO also allows for the analysis of pacemaker impulses.

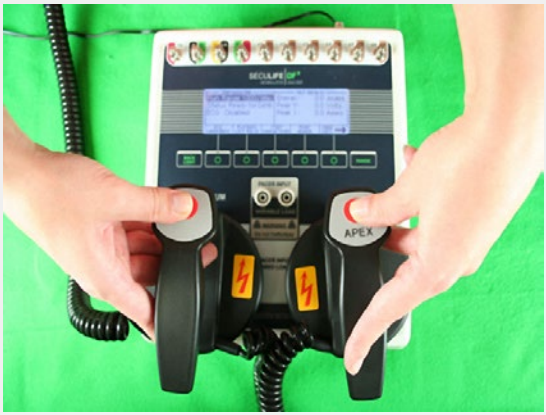


Figure 25: Testing defibrillators using the SECULIFE DF PRO

Once the defibrillator has been started, the energy can be adjusted on the defibrillator's display (e.g. 300 Joule). The red buttons on the SECULIFE DF PRO paddles are used to start the energy test.

When the message: "Administer shock" appears, both buttons should be simultaneously pressed and held down for approx. 5 seconds, and the paddles should be kept pressed onto the plates on the SECULIFE DF PRO for the duration of the shock process.

The energy is then loaded via the defibrillator. The defibrillator is then checked by comparing the set point and the actual value. The energy value that is preset on the defibrillator is compared with the energy value displayed on the SECULIFE DF PRO. The displayed energy value must be within the tolerance range.

3.1.5 Measuring blood pressure

What is blood pressure?

Blood pressure refers to the force that the blood applies to the vessel walls.

Systolic blood pressure: top blood pressure value

Diastolic blood pressure: bottom blood pressure value

Blood pressure is measured in mmHg (millimetres of mercury). The value in mmHg is a measurement unit for pressure. The use of mmHg to measure pressure has a historical origin, as pressure was previously measured using a mercury column (see Figure 26). 1 mm Hg corresponds to the pressure exerted by 1 millimetre of mercury. Normal blood pressure is approx. 120 mmHg: 80 mmHg (systolic value: diastolic value).

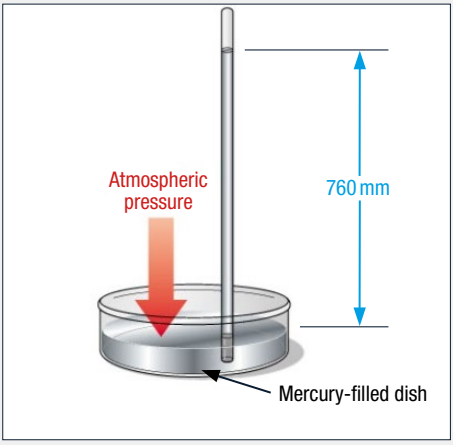


Figure 26: Measuring pressure using a mercury column [33]

Why do we measure blood pressure?

An excessively high blood pressure poses a high risk to health. Over half of all deaths are caused by cardiovascular diseases. Excessively high blood pressure can be a prerequisite factor for additional serious diseases of the cardiovascular system. 30% of the population have high blood pressure, often without even being aware of it. High blood pressure can lead to type-2 diabetes, obesity and hypertension.

Risk factors for hypertension include genetics and lifestyle as well as psychosocial aspects (see Figure 27). If blood pressure is too high for an extended period of time, this can have further negative consequences. Over time, arteries can become blocked, leading to dangerous conditions such as coronary heart disease, heart failure, stroke and heart rhythm disturbances. [34]

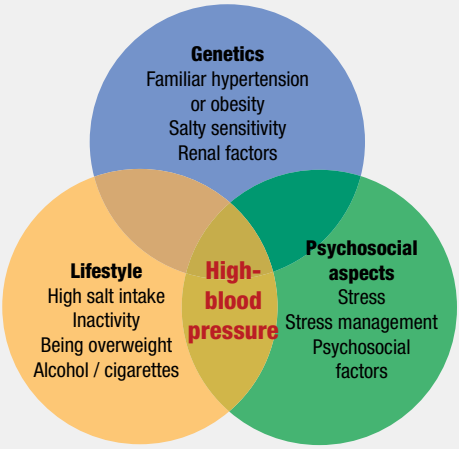


Figure 27: Risk factors for high blood pressure [34]

Measurement method

Blood pressure can be measured using an invasive procedure (direct measurement in conjunction with a surgical procedure) or a non-invasive procedure (indirect blood pressure measurement).

Invasive blood pressure measurement: Invasive blood pressure measurement (see Figure 28) is a continual and fully automatic procedure with a high temporal resolution, meaning that it is a very accurate measurement method. As well as blood pressure, the patient's heart rate and mean arterial pressure are also recorded using this method.

With invasive blood pressure measurement, the patient's artery is punctured by a catheter with a pressure sensor in the tip, and the catheter is then inserted into the patient's blood vessel. This procedure involves an element of risk, as the puncture can lead to bleeding, infection and nerve injury. [35]

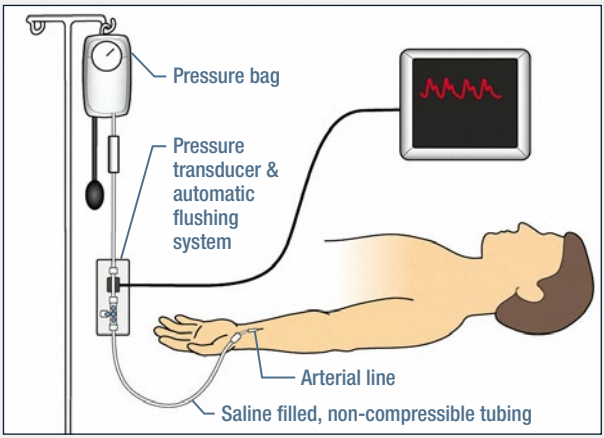


Figure 28: Invasive blood pressure measurement [36]

Non-invasive blood pressure measurement (NIBP): Non-invasive blood pressure measurement is also referred to as an indirect procedure, as unlike invasive procedures, no physical interventions need to be made on the patient's body. A sleeve is usually placed around the patient's upper arm and used to measure the blood pressure. Whereas an invasive procedure is also associated with a degree of risk, non-invasive blood pressure measurement is quick, cost-effective and relatively easy to learn, and can be performed by almost anyone. The sleeve must be kept level with the heart while taking the measurement. There are three methods of indirect blood pressure measurement, namely the palpatory, oscillometric and auscultatory methods.

Palpatory method: This method involves placing a sleeve around the crook of the patient's arm and inflating it until there is no longer a pulse. The pressure is then slowly drained until the pulse can be felt again at the radial artery. This is the systolic blood pressure. However, the diastolic value cannot be measured using this method, meaning that it should only really be used in emergencies (see Figure 29)

Figure 29: Measuring blood pressure using the palpatory method

Oscillometric blood pressure measurement: With the oscillometric method, a sleeve compresses the arteries (see Figure 30), which cuts off the flow of blood. The pressure is then drained, causing oscillations between systolic and diastolic blood pressure, which can be detected using a pulse-synchronous needle. An algorithm is used to record and evaluate the oscillations in the artery and to convert them to a blood pressure value. Oscillometric blood pressure monitors are the most commonly purchased devices for measuring blood pressure, as the measurement is fully automatic and easy to carry out independently.

Figure 30: Oscillometric blood pressure measurement device

Auscultatory method: This method also involves inflating a sleeve and then draining the pressure until the systolic and diastolic values can be identified by certain sounds (Korotkow sounds). These sounds are listened to manually using a stethoscope (see Figure 31). [35]

Figure 31: Auscultatory blood pressure measurement [37]

3.1.6 How are blood pressure monitors tested?

Testing NIBP monitors (non-invasive blood pressure monitors):

Standard DIN EN 60601-2-30 serves as a basis for the testing of automatic cycling non-invasive blood pressure monitoring equipment. This standard sets out the particular requirements for safety and essential performance. It also defines the accuracies for systolic and diastolic pressure for manual and automatic long-term operation.

- Maximum deviation of the mean value ±5 mm Hg
- Maximum standard deviation 8 mm Hg

Devices such as the SECULIFE BP PRO can be used to test non-invasive blood pressure monitors (see Figure 32). The device is small and easy to use. It also has additional functions such as IBP (invasive blood pressure) monitoring, ECG, temperature monitoring, arrhythmia monitoring, respiration monitoring and many more. A differential pressure sensor is used to measure the sleeve pressure.

Figure 32: SECULIFE BP PRO

To test the device, the blood-pressure simulator needs to be connected between the device under test (the monitor) and the blood-pressure sleeve (see Figure 33). To check the blood-pressure value, the value on the SECULIFE BP PRO (in this case: 120/80) must be set and then compared with the values displayed on the device under test (in this case: 123/80).

Figure 33: Complete set-up for testing non-invasive blood pressure monitors

Testing invasive blood pressure (IBP) monitors:

The standard DIN EN 60601-2-34 contains particular requirements for the safety and relevant essential performance of invasive blood pressure monitoring equipment. These requirements are designed to supplement the “basic standard” IEC 60601-1, which contains general requirements for the safety of medical electrical equipment.

This standard contains requirements regarding accuracy, as invasive blood pressure monitoring equipment is used in cases where a high level of accuracy is required. This type of monitoring normally requires intravenous access. During invasive blood pressure measurement, a catheter containing a pressure sensor is inserted intravenously. This device generates an electrical signal in millivolts from the mechanical pressure. In order to simulate this, a simulator needs to be able to deliver a signal in millivolts to the patient monitor for invasive blood pressure measurement, whereby an electrical voltage of 1 mV corresponds to a pressure of 1 mmHg. As is also the case when testing non-invasive blood pressure monitors, to carry out the functional check, the preset value on the SECULIFE BP PRO is compared with the value displayed on the device under test, i.e. the monitor.

Connecting the device correctly is essential in ensuring that the invasive blood pressure monitor can function correctly, thereby preventing any errors. Figure 34 shows the procedure for invasive blood pressure measurement. The simulator can also deliver a test signal in the final block on the patient monitor.

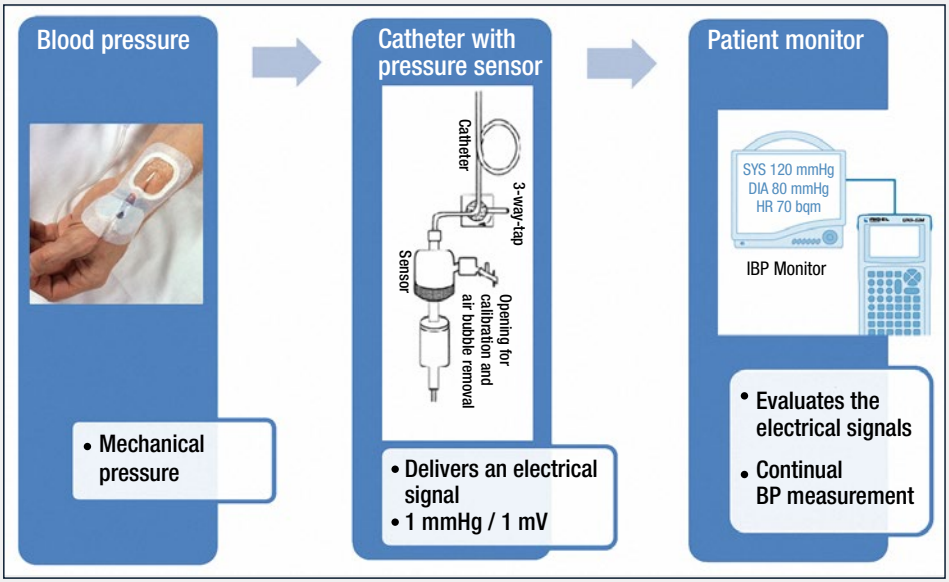


Figure 34: Procedure for invasive blood pressure measurement

3.1.7 Respiration

Functionality: Respiration is the process by which oxygen (O_2) is absorbed into the body and carbon dioxide (CO_2) removed. The inhaled air gets into the body via the upper airways, i.e. via the nasal cavities or the oral cavity.

Natural respiration takes place via the nose, as this allows for the inhaled air to be moistened, cleaned and warmed. The air then travels to the lower airways, i.e. the larynx, epiglottis and vocal chords, and into the trachea, the bronchial tubes and the right and left lungs.

A gas exchange process then takes place in the bronchioles, the pulmonary alveoli and the capillaries inside the lungs.

Aim of respiration: To supply organs and tissue with oxygen right down to the smallest cells.

This system can be visualised as a type of engine, as all individual cells such as muscles cells or brain cells need fuel (or oxygen) to work properly, with exhaust gases being released in the form of CO_2. Oxygen is absorbed in the lungs, from where it is supplied to even the smallest of cells.

Oxygen is passed from the alveoli to the capillaries, and carbon dioxide passes into the alveoli as a waste product (see Figure 35). [38]

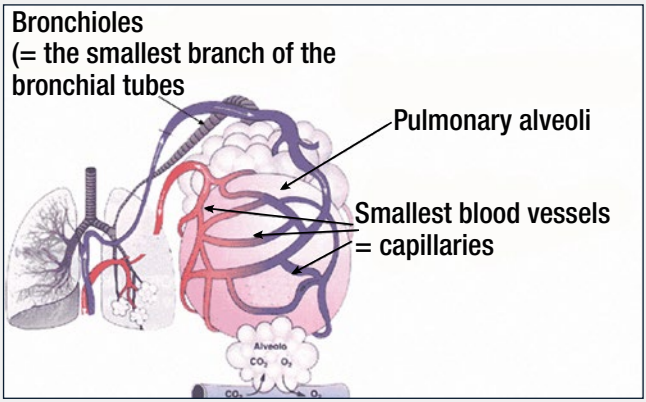


Figure 35: Gas exchange in the lungs during respiration [38]

Respiratory parameters:

There are various different parameters for characterising respiration (see Figure 36). The total capacity of an adult is approx. 7 l, and is made up of the vital capacity and the residual volume. The residual volume is the air that remains in the lungs even after maximum expiration. The lungs are never completely empty of air. A normal inspiration brings approx. 500 ml of inhaled air into the lungs, which is referred to as the inspiration volume. The vital capacity is the maximum volume of air that can be expired after maximum inspiration. The inspiratory reserve volume (IRV) and the expiratory reserve volume (ERV) are the volumes that can be additionally inspired or expired during normal respiration.

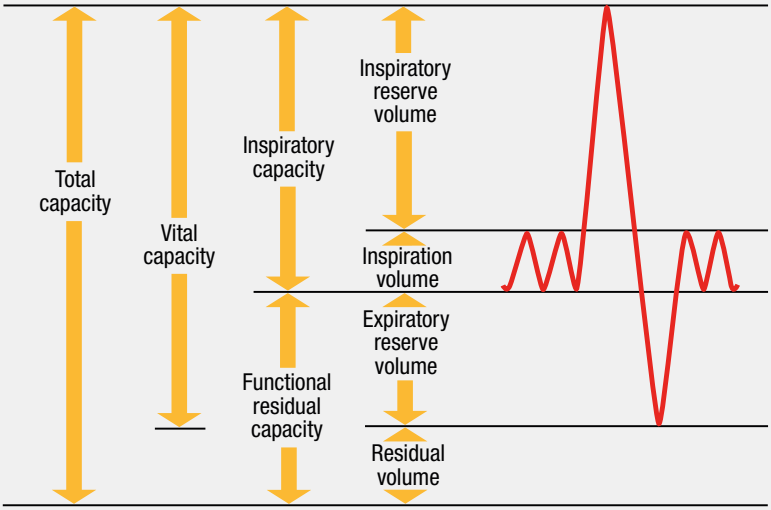
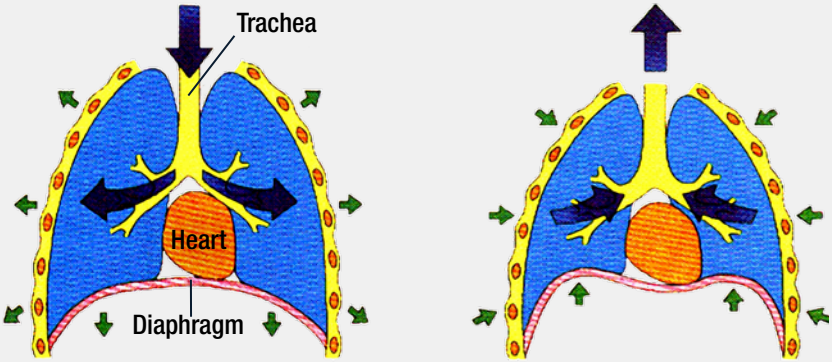


Figure 36: Respiratory parameters

How is respiration induced?

Inspiration is a process in which muscles play an active role. The ribs move upwards while the diaphragm contracts (see Figure 37). The lungs expand due to the loss of pressure, and the inhaled air is sucked in. On expiration, the muscles relax, causing the lung volume to reduce again and air to be expelled. [38]



a) Inspiration b) Expiration

Figure 37: Procedure during inspiration and expiration [38]

Respiratory disorders and measures:

Respiratory disorders involving a lack of oxygen in the body can quickly lead to respiratory distress, insufficient respiration and respiratory arrest. This can be caused by heart or lung diseases, allergies, intoxication or accidents involving damage to the chest. Measures that can be taken in the event of respiratory disorders include adopting positions designed to aid respiration, loosening tight clothing or administering oxygen. Although oxygen is considered a medication and only medical physicians are authorised to administer medications, oxygen can nevertheless be administered by non-medical-professionals in an emergency as it is a life-saving substance with barely any side effects. Adjustable-delivery O_2 cylinders, O_2 probes or an O_2 mask can be used to treat respiratory distress.

3.1.8 How are ventilators tested?

EN ISO 80601-2-12 contains particular requirements regarding the safety of ventilators. and sets out particular requirements designed to supplement the “basic standard” IEC 60601-1, which contains general requirements for the safety of medical electrical equipment. Ventilators are tested for parameters such as delivered volume.

The accuracy of the delivered volume must be specified in the instruction manual. If the accuracy of the delivered volume is 50 ml, for example, this means that the specified delivered volume must be ± (4 ml + 15% of the actual delivered volume).

The SECULIFE PS300 can be used to check whether the signals are being displayed correctly. The SECULIFE PS300 is a simple patient simulator with a display on which various vital signs such as SpO2, blood pressure, temperature and ECG can be adjusted (see Figure 38).

A Delta-Ohm signal is fed into the device via the two ECG inputs LL and LA. The output impedance can be set to 500, 1000, 1500 or 2000 Ohm.

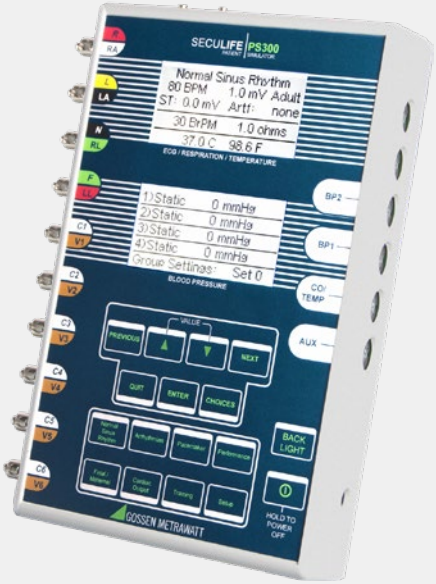


Figure 38: SECULIFE PS300 patient simulator

All values must be aligned with the monitoring device values before starting the simulation. A total of 12 rate settings are available (eight BrPM (breaths per minute) settings, an apnoea (= respiratory arrest i.e.0 BrPM) setting and three apnoea interval settings), with various other settings available for adjustment (Figure 39).

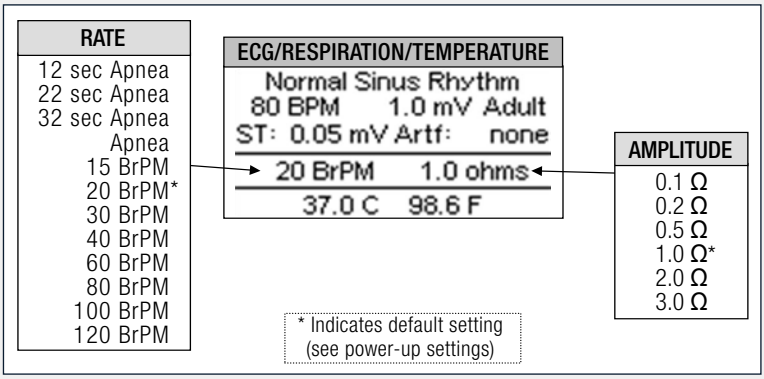


Figure 39: SECULIFE PS300 display

Other devices such as the VenTest 8xx by Rigelmedical (Figure 40) can also be used for the functional testing of ventilators. This device measures and calibrates small flows (+/- 20 l/min), large flows (+/- 300 l/min), volumes, pressures, oxygen levels, temperature and humidity.

It can also be used to measure certain respiratory parameters:

- Inspiration volume and expiration volume
- Respiration rate
- Inspiration time, expiration time
- Ppeak
- Pmean
- Peak expiratory and inspiratory flow

The device is also very well-suited to calibration.

Example of statistics from a flow test

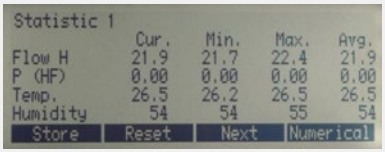


Figure 40: VenTest 8xx for the functional testing of ventilators

3.1.9 Pulse oximetry

Blood tests provide important information for diagnostic and treatment-monitoring purposes. Blood can be divided into two separate phases.

Solid phase: This phase consists of white blood cells (leucocytes), red blood cells (erythrocytes) and platelets (thrombocytes). The solid phase accounts for approximately 42% of the total volume of blood.

Liquid phase: This phase consists of plasma, which accounts for 48% of the total volume of blood and which is 90% made up of water and proteins. The plasma is responsible for transporting glucose, lipids, hormones, carbon dioxide and, to a limited extent, oxygen.

Pulse oximetry measures the oxygen concentration in the blood. This is important for the monitoring of emergency and intensive-care patients, in cases of insensibility and in premature babies. Pulse oximetry is a non-invasive procedure whereby a clip containing a sensor is attached to the patient's finger or earlobe.

Red light and infra-red light is then shone through the clip, allowing for the continual monitoring of the amount of oxygen being supplied to the arterial blood.

This task primarily relies on erythrocytes. These cells contain haemoglobin and are mainly responsible for the transportation of oxygen. The iron in the Heme group allows for the loose binding of oxygen, leading to its oxygenation.

Oxygen saturation refers to the percentage of the total amount of haemoglobin in the blood that is bound to oxygen. Sp02 = Hb02/(Hb02+Hb) * 100 %

Measuring the oxygen saturation allows statements to be made regarding how effectively oxygen is being transported in the blood. The oxygen saturation should be at least 95%; otherwise, the patient's condition is considered critical. Blood that is saturated with O_2 is bright red, whereas de-oxygenated blood is dark red or purple.

How are measurements taken using a pulse oximeter?

The fact that oxygen reflects and is absorbed differently to the other components in haemoglobin, monitoring these parameters allows for conclusions to be drawn regarding the amount of oxygen in the blood.

When oxygen is released, the blood loses its red colour. This means that more red light will be absorbed whereas more of the infra-red light will be able to pass through.

A red LED and an infra-red LED are used as the light sources, and a photo detector is used as the receiver (Figure 41).

The photo detector converts the unabsorbed light into electrical signals. The wavelength of the infra-red LED is approx. 940 nm, whereas the red LED has a wavelength of approx. 660 nm.

The two unchangeable wavelengths used for monitoring the absorption of arterial blood do not have any impact on this absorption.

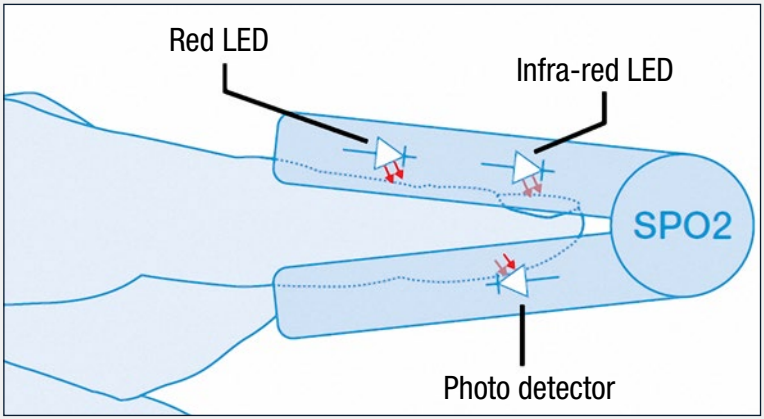


Figure 41: Components of a finger probe pulse oximeter [39]

The wavelength-dependent absorption of haemoglobin or oxyhaemoglobin can be determined based on absorption curves. The red curve shows the absorption of oxygenated haemoglobin (HbO2 – 100% SpO2), whereas the blue curve represents completely deoxygenated haemoglobin (Hb – 0% SpO2). At a wavelength of approx. 800 nm, the HbO2 and the Hb have identical absorption values. [39]

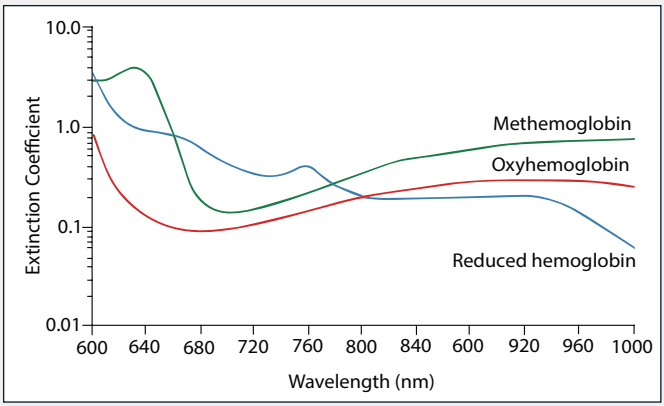


Figure 42: Absorption curves of haemoglobin and oxyhaemoglobin [39]

- 100% SpO2, R/IR ratio approx. 0.5
- 82% SpO2, R/IR ratio approx. 1.0
- 0% SpO2, R/IR ratio approx. 2.0

The problem with measuring oxygen is that a person's pulse is not constant. The finger consists of one solid layer of muscle and skin and one layer of variable thickness (arteries). This problem can be solved by taking measurements from two different points in time, and then working out the pulse as a useful by-product. The pulse in a person's finger occurs as a result of the contraction of the left ventricle filling the network of arterioles in the finger with blood.

The pulsing blood flow in the finger leads to changes in the amount of blood in the vascular bed due to the relatively tight network of arterioles close to the skin. The change in the volume of arterial blood at the finger causes a positive electrical signal to be generated, which is registered by the photoelectric sensor. The pulse has a certain pulse wave amplitude. This may vary due to vascular constriction or dilatation. Vascular constriction brings about a reduced amplitude, which can frequently be attributed to anxiety, pain or stress. Vascular dilation is often a result of anaesthesia, sedation or hypercapnia. [39]

How would the oxygen saturation change if the test subject were to hold their breath during the SpO2 measurement?

There would be barely any change in the oxygen saturation value. The SpO2 saturation would only change if the test subject held their breath for a very long time, as gas-exchange process can continue to take place inside the lungs. The respiratory stimulus is based on the volume of CO_2 in the blood, but the oxygen level will be maintained for a certain amount of time.

Comparing pulse oximetry with blood-gas analysis

The advantage of pulse oximetry is down to the fact that it is a non-invasive procedure, meaning that no blood needs to be taken from the patient, as well as the fact that the pulse is also monitored during the procedure. Disadvantages include the fact that the measurements are less accurate than those taken with a blood-gas analysis, as well as the fact that the CO_2 value and the pH value are also measured automatically during a blood-gas analysis. With a blood-gas analysis, a cream is firstly rubbed on the earlobe to help promote blood flow. A small needle is then used to briefly prick the earlobe, and a few drops of blood are taken. The oxygen content, the carbon dioxide content and the pH of this blood are then measured.

Pulse oximetry is therefore carried out more as an emergency measure when there is no need for extensive analysis. [41]

3.1.10 How are pulse oximeters tested?

The standard DIN EN ISO 9919 contains particular requirements for the safety and essential performance of pulse oximeter equipment and sets out particular requirements designed to supplement the “basic standard” IEC 60601-1, which contains general requirements for the safety of medical electrical equipment.

According to the standard, the accuracy of a pulse oximeter should have an RMS deviation (root-mean-square deviation) of less than or equal to 4.0 % SpO2 over the range of 70% to 100% SaO2. Sa02 indicates the functional oxygen saturation, i.e. the percentage of functional haemoglobin in the arterial blood that is saturated with oxygen, whereas the Sp02 value is merely an estimate of the Sa02.

The SECULIFE PS300 (see Figure 43) has the option of being connected to an external Sp02 module.

There are three Sp02 modules that can simulate oxygen saturations of 80%, 90% or 97%.

The simulation is performed with a heart rate of up to 180 BPM. The module is connected to the AUX connection of the SECULIFE PS300 via a 7-pin mini-DIN plug, as the battery voltage is not sufficient for the operation of this optional function. The output for the SpO2 function can then be activated or deactivated in the Setup menu.

Figure 43: Connecting an SpO2 module to the SECULIFE PS300 patient simulator

3.1.11 Temperature

One of the most commonly monitored vital signs is the body temperature. Several devices have been marketed over the years, ranging from Mercury-filled thermometers (no longer available due to the toxic nature of Mercury) and resistor-based measuring instruments for contact measurements, through to non-contact infrared-based temperature sensors.

Our core body temperature (Tc) varies by gender and can vary between different stages of the day. In women, the core body temperature also changes during the menstrual cycle, peaking at the time of ovulation.

The average core body temperature is 37 °C ± 0.5 °C. Different temperature readings are expected depending on the placement, application and method. The most commonly used temperature measuring instruments for bedside monitoring are resistor-based temperature measuring instruments (thermistors). These thermistors are commonly known as NTCs (Negative Temperature Coefficient – meaning that the resistance decreases as the temperature increases) and PTCs (Positive Temperature Coefficient – meaning that the resistance increases as the temperature increases). The YSI 400 and YSI 700 have become the standard NTCs used in the medical industry.

The YSI 400 has a slightly higher level of accuracy in the range between 0 and 75 °C. The YSI 700 with integrated dual element (Ra = 6 kΩ @ 25 °C and Rb = 30 kΩ @ 25 °C), on the other hand, provides high levels of accuracy over a larger range (-25 °C to 100 °C)

Body temperature is simulated by the application of different resistor value.

See table page 101 Appendix A

3.2 Infusion pumps

3.2.1 Function and areas of application

What is an infusion pump?

Infusion pumps are devices for the controlled administration of fluids with or without medication, with the aim of maintaining or restoring the water and electrolyte balance. They can be used to electronically control the delivery rate of fluids being administered.

The substances enter the body via a needle and a biomembrane. Infusion pumps can administer fluids at defined intervals or on a regular or ad-hoc basis.

Patients can also be transported while using an infusion pump, as the devices now have a mobile design. Various types of infusion pump have stood the test of time, meaning that there is now a choice between devices based on simple principles of gravity and volumetric devices where the substance is administered to the patient via mechanical displacement inside the tube.

The aims of infusion-based treatments are as follows:

- Correcting fluid/volume loss
- Regulating water/electrolyte balance
- Regulating the acid/base balance
- Artificial feeding
- Administering medication

Infusion pumps need to be tested by qualified specialists on a regular basis, as the lines in infusion pumps can become clogged, leading to increased pressure and an impaired delivery performance, which could ultimately pose a risk to the patient.

When testing infusion pumps, the aim is to establish that the volume being administered and the delivery rate are being measured accurately and that the limit values for the alarms are not being reached. [2, 42]

Types of infusion pumps

There are various types of infusion pumps on the market, with all of them designed to supply infusion fluid to patients over a configurable period of time. Depending on their area of use, infusion pumps have, regarding the effective volume, time-dependent accuracy and required delivery output.

Elastomer pumps:

Elastomer pumps (see Figure 44) are used to administer medication such as local anaesthesia or antibiotics. The elastomer balloon extends when filled with infusion fluid. This causes pressure to build up, which is maintained until the entire dose of fluid has been administered. As the delivery rate increases towards the end of administration with this system, a flow restrictor made from fine glass capillary is fitted at the front of the balloon, which helps to regulate the delivery rate. [42]

Figure 44: Elastomer pumps [42]

Advantages	Disadvantages
Very reliable	Single-use device
High medication-dosing accuracy	Delivery rate affected by pump position

Table 5: Advantages and disadvantages of elastomer pumps

Syringe pumps:

Syringe pumps (see Figure 45) are electronically controlled, whereby the syringe piston is slowly pushed in and the fluid is slowly administered in a controlled manner. The electronic system controls the speed (delivery rate), the path (volume) and the power (pressure) with which the syringe piston is pushed in. [42]

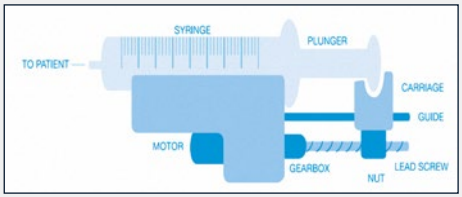


Figure 45: Syringe pump [42]

Advantages	Disadvantages
Well-suited for administering small volumes	Infusion fluid can enter the bloodstream slowly due to slow mechanical progress
Electronically controlled	

Table 6: Advantages and disadvantages of syringe pumps

Volumetric pumps:

Volumetric pumps (see Figure 46) can transfer fluids into a patient's vein by means of pressure and resistance. The infusion bag is positioned above both the patient and the pump. The pumps are linear, peristaltic pumps, which helps to regulate the flow.

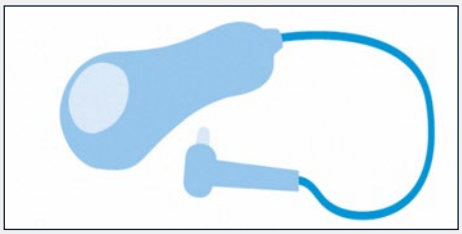


Figure 46: Volumetric infusion pumps

Advantages	Disadvantages
Adjustable delivery rates of 0.1 to 1000 ml/h	Lack of precision with low delivery rates

Table 7: Advantages and disadvantages of infusion pumps

PCA pump:

The PCA pump (see Figure 47) is a patient-controlled syringe pump that a patient can use to independently administer pain relief in a controlled manner when experiencing pain. The patient presses the button on the device to trigger bolus delivery. The volume to be administered is preset by medical personnel.

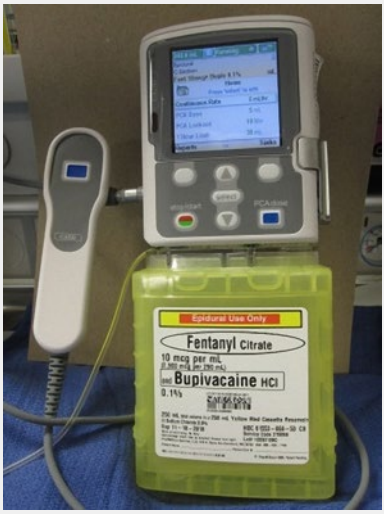


Figure 47: Patient-controlled analgesia

Advantages	Disadvantages
At-home infusion treatment	Increased risk potential in the case of falls, wet conditions or electromagnetic interference
Eases the burden for medical personnel	Cannot be used to administer critical medication

Table 8: Advantages and disadvantages of PCA pumps

Trumpet curve in infusion pumps

DIN VDE 0750 defines curves referred to as trumpet curves for assessing the delivery accuracy and delivery-accuracy consistency in infusion pumps. Trumpet curves (Figure 48) show the delivery rate in relation to time, and provide a graphic representation of the delivery behaviour within the first hour after the pump is put into operation. They also show any delays with the start of delivery and therefore the administration of medication.

Trumpet curves indicate the percentage by which the set delivery rate deviates from the target delivery rate in relation to time, as well as showing the variation in delivery accuracy for observation intervals of different lengths. [2]

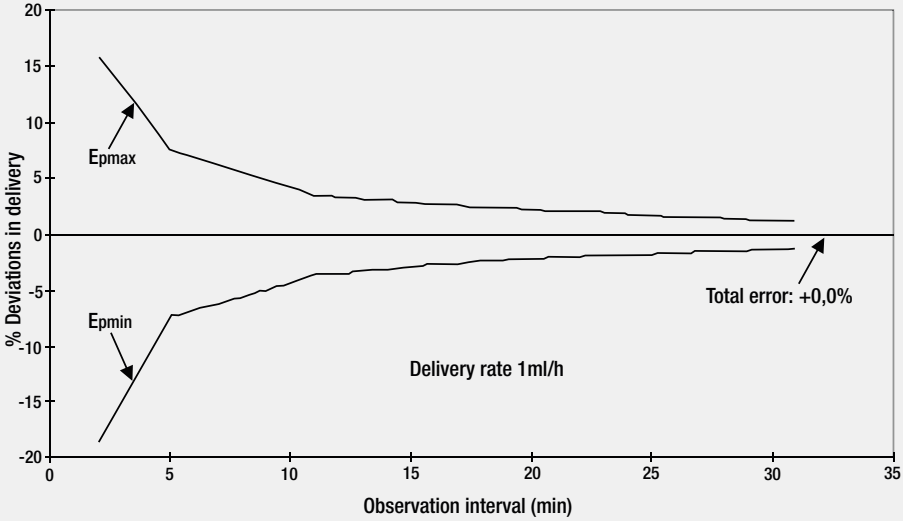


Figure 48: Example trumpet curve. The deviations in delivery (%) are shown in relation to time. As can be seen in the Figure, the deviations are still quite high (approx. 15%) at the start of delivery, and then become increasingly less towards the end of the curve.

Occlusion

Every occlusion or blockage can pose a risk to the patient if treatment is interrupted as a result. With infusion pumps, an occlusion is an obstruction that occurs when fluid is flowing, causing the pressure in the tube to increase and the delivery rate to fall. This can occur if a cannula is blocked or a tube is poorly positioned inside the pump as a result of a kink, or if too much pressure is used. In order to prevent this, pressure sensors are now used that can detect a reduced delivery rate and increased pressure. An occlusion alarm is then output, meaning that measuring can be aborted. With adult patients, an alarm is output when the pressure exceeds the normal working pressure by a minimum of 150 mmHg.

Bolus (from the Latin bolus - 'ball' or 'shot')

In medicine, the word bolus (from the Latin **bolus** -'ball' or 'shot') refers to the rapid administration of medication or another substance, in order to increase the concentration of this substance to the level of the effective dose.

During an infusion, fluid is temporarily administered at a higher delivery rate and with a higher fluid volume following a bolus delivery. [43]

3.2.2 How are infusion pumps tested?

The user is primarily responsible for ensuring the safe use of infusion pumps and infusion controllers. Infusion pumps are tested in accordance with DIN EN 60601-2-24. This standard contains particular requirements for the safety of infusion pumps and infusion controllers and sets out particular requirements designed to supplement the “basic standard” IEC 60601-1, which contains general requirements for the safety of medical electrical equipment. Infusion pumps administer a defined volume of fluid to the patient under the optimal pressure so that ideally there can be no risk to the patient. It is therefore essential to ensure the reliability of the pump.

Infusion pumps must be tested in a way that mimics actual practical use, and testing is the responsibility of the user, i.e. the medical personnel.

The technical and functional information provided by the manufacturer must be verified as part of the testing process, and the equipment recommended by the manufacturer must be used for the tests. When testing infusion pumps, the delivery rate and actual volume must be determined within a particular time span. There are currently several methods for determining the delivery rate. [42]

The volumetric measurement method using a cylinder involves measuring the delivery rate after delivery of a certain volume (see Figure 49). The higher the delivery rate, the higher the volume. With direct volumetric measurement, the rate per minute must be estimated and the volume per minute defined. The pump is set to a certain delivery rate, the total delivery time measured using a stopwatch and the contents of the measuring container then checked. [42]

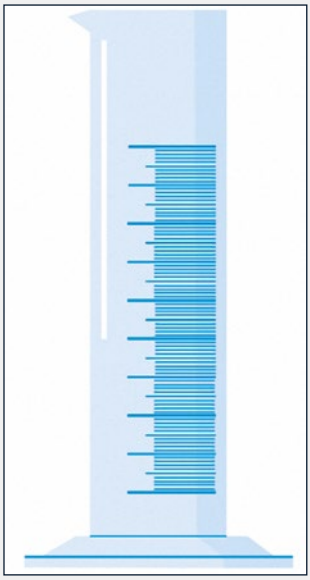


Figure 49: Measuring cylinder [42]

Advantages	Disadvantages
Simple procedure	Accuracy depends on the scale
Not much equipment needed	
No additional electronic equipment	

Table 9: Advantages and disadvantages of measuring using a cylinder

Weighing scales: When using weighing scales (see Figure 50), the delivery rate is determined based on the weight difference. The volume of delivered fluid can be determined from the weight difference in grams. The pump is set to a certain volume within a particular time span, and the measuring container is then weighed again.

Figure 50: Weighing scales [42]

Advantages	Disadvantages
Not much equipment needed	Requires continual manual input
No additional electronic equipment	
Extremely accurate	
Simple procedure	

Table 10: Advantages and disadvantages of measuring using weighing scales

To check the delivery rate, a volumetric infusion pump is set to a rate of 400 ml/h, for example (Figure 51). The pump is then started until a visual and acoustic drop alarm is output. The delivery accuracy is then tested at two different delivery rates of 100 ml/h and 500 ml/h with a set delivery volume of 25 ml. The measurement results must then be 25 ml+/- 5% or 25 g +/- 5%. To perform the test, distilled water is delivered into a receptacle and the weight recorded. Distilled water is also simultaneously delivered into a calibrated measuring cylinder and the delivered volume checked.

Figure 51: Example of a volumetric infusion pump

Test setup with electronic devices

With electronic devices, test setups with fully automated measurement processes are used. The user receives real-time data on the effective delivery rate and volume. Measurement intervals can be shown in graph form, and potential problems can be detected at an early stage. Electronic infusion pump testing devices use sensors to measure the delivery time for a low volume of fluid, thereby determining the accuracy of the infusion pump.

Advantages	Disadvantages
Automated procedure	More expensive than simple manual volumetric measurement
Graph-based depiction	More equipment needed
Option of multi-channel mode	
Reduced test duration	
Improved error analysis	

Table 11: Advantages and disadvantages of measuring using electronic devices

Infusion pump testing device: SECULIFE IF+

Infusion pumps can be tested electronically using an infusion pump testing device such as the SECULIFE IF+ (see Figure 52). This device tests the delivery rate of intravenous infusion pumps.

To carry out a function test, the infusion pump is set to a particular delivery rate (e.g. 200 ml/h) and then started up by pressing the Start button.

A Luer-Lock hose contains fluid that rises into a chamber while the SECULIFE IF+ is starting up (see Figure 52). There are infra-red sensors in the chambers that are connected to a timer. The timer starts when water is detected at the lower edge of the chamber, and stops automatically when water is detected at the upper edge. The results are then displayed on a device.

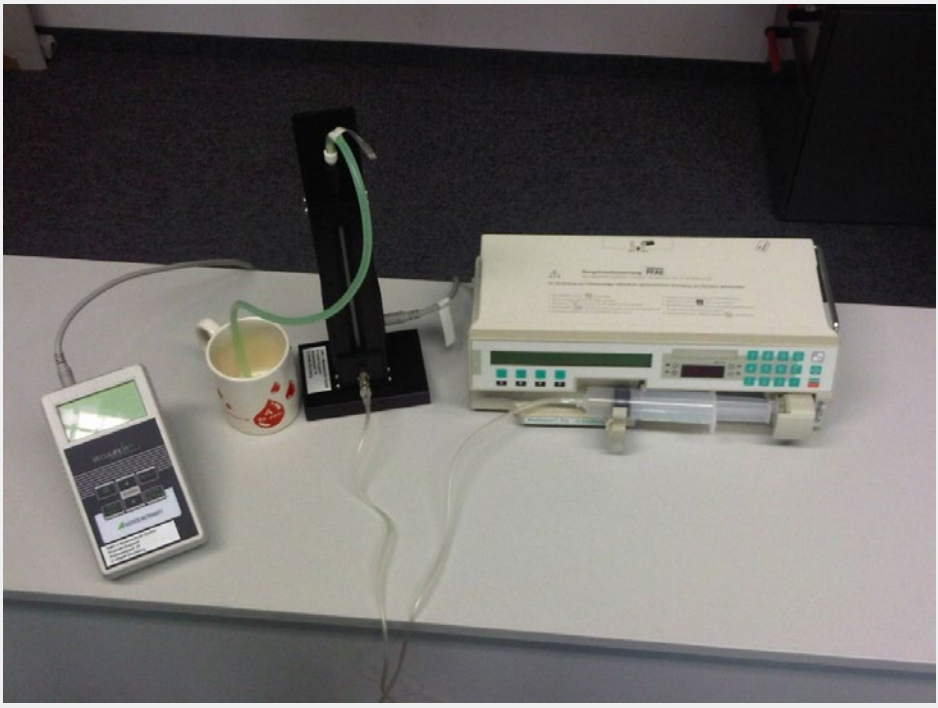


Figure 52: Testing infusion pumps using the SECULIFE IF+

Infusion pump testing device: SECULIFE IF PRO

The SECULIFE IF PRO (Figure 53) is one of the latest infusion pump testing devices on the market. This device not only tests the delivery rate of intravenous infusion pumps, but also allows for PCA and occlusion testing. PCA and occlusion testing is performed fully automatically, and can also be programmed into an automatic sequence. The SECULIFE IF PRO infusion pump analyser is the most compact and well-equipped four-channel testing device on the market. The SECULIFE IF PRO has four delivery modules. These modules are unique, mass-produced components that have been calibrated so that they can be moved from channel to channel or system to system and be automatically detected. This means that up to four infusion pumps can be tested at the same time. If a module needs to be calibrated, the other modules can continue to be used and there is no downtime in the use of the device.

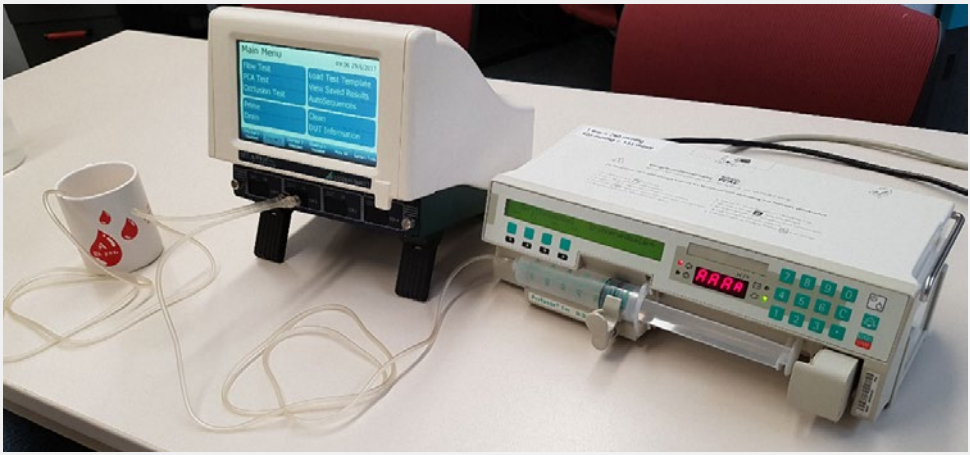


Figure 53: SECULIFE IF PRO infusion pump testing device

3.3 HF high-frequency surgery

3.3.1 Function and areas of application

Even in ancient times, physicians knew that heat could be used to carry out therapeutic interventions on patients.

There is evidence that battle wounds in ancient Egypt were treated using hot stones or boiling oil, which helped to reduce bleeding. In high-frequency surgery, high-frequency electrical energy is used to carry out surgical interventions. Tissue cells are modified or destroyed by this electrical energy.

Aims of high-frequency surgery:

- Cutting tissue (electrotomy)
- Stopping bleeding - (electro) coagulation

The flow of electrical current through the tissue generally has three different effects (see Figure 54).

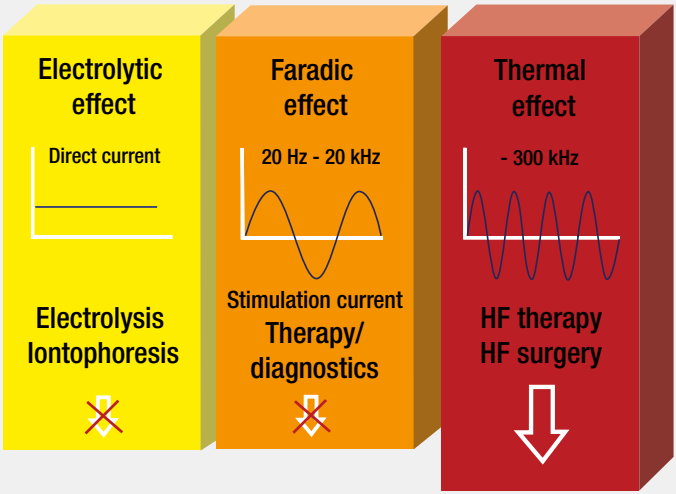


Figure 54: Effects of electrical current flowing through the tissue

Electrolytic effect:

Direct current and low-frequency alternating currents cause ion displacement in the tissue, with positively charged ions moving to the negative pole and negatively charged ions moving to the positive pole. This is an unwanted effect during HF surgery.

Faradic effect:

Faradic current is a term that refers to interrupted direct or alternating current. Alternating currents with a frequency of up to 20 kHz stimulate muscles and nerve cells, allowing the muscles to contract. This is an unwanted effect during HF surgery, as these contractions are unpleasant for the patient and dangerous for the surgeon.

Thermal effect:

The thermal effect occurs with high-frequency alternating currents with a frequency of between 300 kHz and 2 MHz. Outputs of up to 400 W occur in the tissue being treated, where thermal effects occur due to the resistance in the tissue.

In high-frequency surgery, thermal current effects are relevant for the cutting and coagulation (clotting) of tissue. The electrolytic and faradic effects can be largely avoided by using high-frequency alternating current. The high frequencies ensure that there are no neuromuscular contractions.

The fact that the heart is a muscle means that there is no risk to the patient when current passes through the body, as the nerve cells cannot be stimulated by the high-frequency current. Although very high voltages can be used during high-frequency surgery, an accident will not lead to death but merely to a burn injury as a result of the thermal effect.

The extent to which the tissue warms up as a result of the thermal effect depends on the resistance of the tissue, the exposure time and the current density. The electrical energy is converted into thermal energy with no losses, in line with the following formula.

$Q = P*t = U*I*t = I^2*R*t = U^2*t/R$ [J = Ws]

The tissue acts like Ohmic resistance, with the amount of resistance depending on the type of tissue (see Table 12). The greater the specific resistance in the tissue, the greater the energy input.

Tissue type - frequency 1 MHz	Specific resistance p in kΩ *cm
Blood	0.16
Muscle, kidney, heart	0.2
Liver, spleen	0.3
Brain	0.7
Lung	1
Fat	3.3

Table 12: Resistance per tissue type [43]

In HF surgery, a distinction is made between monopolar and bipolar methods.

Monopolar method:

With the monopolar method (see Figure 55), the HF surgery device is equipped with an active electrode and a return electrode. The required effects (cutting, coagulation) are generated at the active electrode. With the monopolar method, current flows from the active electrode to the return electrode via the path of least resistance. As the active electrode has a relatively small surface area, the current density is at its highest at this point, meaning that the thermal effect is strongest here. The return electrode, on the other hand, has as large a surface area as possible, which keeps the current density low so that there is no risk of burn injuries. Nevertheless, there are strict safety rules that need to be followed when positioning the return electrode. In order to prevent burn injuries, the return electrode must have good contact with the skin. If the return electrode is positioned incorrectly, for example, this could reduce the surface area and increase the current density. This could lead to serious burn injuries to the patient.

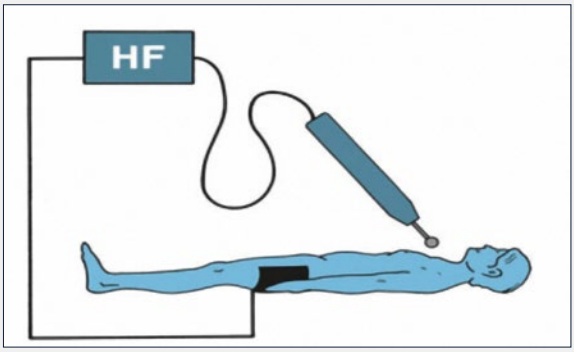


Figure 55: Monopolar method in high-frequency surgery [2]

Bipolar method:

With the bipolar method (see Figure 56), the active and return electrodes are located on one instrument, e.g. bipolar forceps.

Unlike with the monopolar method, current only flows through a very small section of the body where the surgical effect is required.

The current flows into the tissue from one electrode and back to the surgical device via the other electrode. The thermal effect occurs in the tissue held by the forceps.

Approximately 25% less power is required with this method compared to the monopolar method.

As the bipolar method does not cause any damage to the surrounding tissue and does not affect the measuring instruments, it is very well-suited to high-precision and critical applications such as micro, neuro or ENT surgery.

The aims of HF surgery are electrotomy (cutting) and electrocoagulation (clotting).

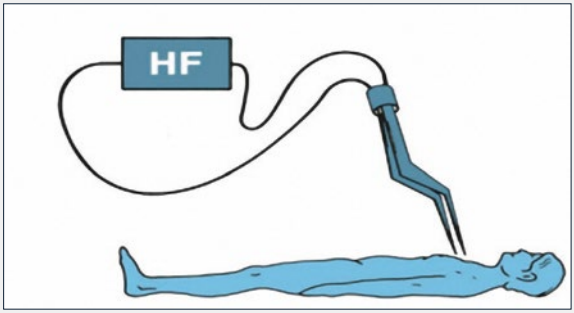


Figure 56: Bipolar method in high-frequency surgery [2]

Coagulation

The term coagulation (see Figure 57) refers to quick and efficient clotting of the blood. This involves the blood vessels contracting, which reduces the space inside the vessels until the vessels are completely closed and no more blood can flow out of them.

Temperatures of between 60° and 70°C are reached in the area of the active electrode during this procedure. These relatively low temperatures cause the intracellular fluid to slowly boil through the cell membrane.

The tissue shrinks in a similar way to a piece of meat in a hot pan. The proteins are denatured and are irreversibly destroyed.

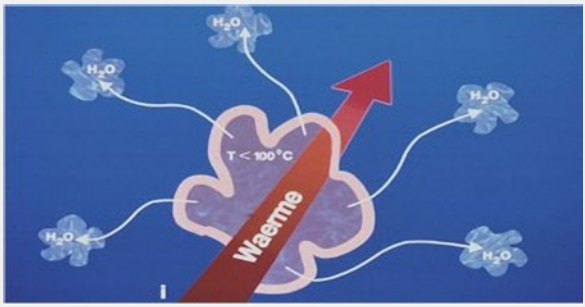


Figure 57: Heat emission due to coagulation during high-frequency surgery

Soft coagulation (< 190 V)

This method does not involve any sparks or electric arcs. It is a relatively uncritical procedure that is performed at low voltages of up to 200 V.

Forced coagulation (up to 3 kV, crest factor 5-7)

This method involves strong, pulsed, modulated output voltages of up to 3 kV. Electric arcs are generated in order to reach a higher coagulation depth. This explains why the method is referred to as 'forced' coagulation, as this method makes it possible to overcome the high-impedance resistances in the tissue. The risk of forced coagulation lies in the potential for carbonisation of the tissue. Nevertheless, forced coagulation offers the physician a quick and effective way of working.

Spray coagulation = fulguration (up to 4 kV, crest factor up to 20)

This no-contact procedure causes long and powerful electric arcs. It is therefore necessary to use inert gases. A high-frequency, pulsed current is used at very high voltages (see Figure 58).

The air between the tissue and the electrode tip ionises very quickly, and the tissue is sprayed by multiple spark discharges.

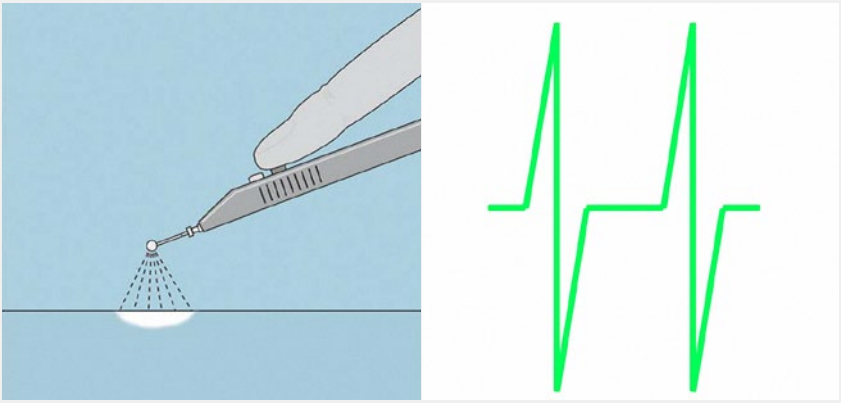


Figure 58: Spray coagulation (also referred to as fulguration) [2]

Electrotomy (cutting) (200 – 650 V):

When cutting tissue (see Figure 59), parts of the tissue can be completely cut through. The tissue is heated to high temperatures at a high enough speed that there is no time for the fluid inside the tissue to slowly evaporate. The high vapour pressure causes the tissue cell walls to abruptly tear, which is what generates the cutting effect.

Figure 59: Thermal effect caused by cutting during HF surgery

There are various methods with different energy inputs that can be used for cutting. If the current is not modulated, this generates a smooth cut that is referred to as a pure cut (see Figure 60). As can be seen in the Figure, this method causes only minimal changes to the edge of the cut.

When cutting during high-frequency surgery, relatively high voltages are required between the electrodes in order to ensure that the electrical sparks can ignite. Sparks are generated from a voltage of 200 V and with the smallest possible distance between the active electrode and the tissue. If the voltage is increased, the intensity of the sparks will increase as well. To make the cut, small needle-shaped electrodes are used that generate relatively high current densities, which causes the tissue to quickly heat up to over 100°C and the cell membranes to tear. [2, 43, 44]

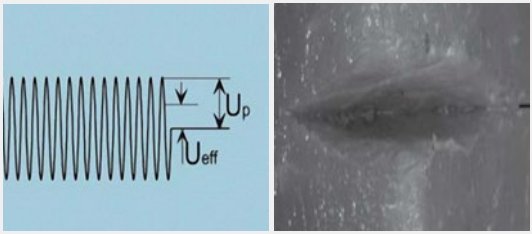


Figure 60: Energy input when cutting using the pure-cut method [2]

If a wider cut needs to be made, the voltage can be modulated (super blend cut) to create a wider coagulation area with slight carbonisation at the edge of the cut (see Figure 61).

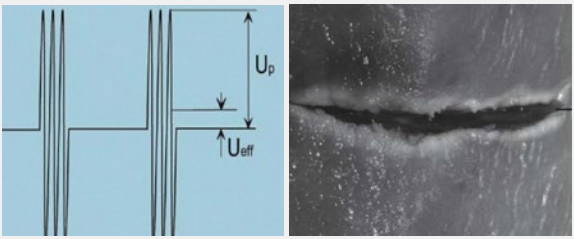


Figure 61: Energy input when cutting using the blend-cut method [2]

Unlike conventional cutting methods, no power is required for electrotomy. Another advantage of this cutting method lies in the fact that, unlike conventional cutting methods using scalpels or scissors, this method seals the affected vessels when the cut is made, thereby preventing further bleeding. This method also protects the tissue and does not involve any risk of germ transfer, and can be used with endoscopic interventions whereby the medical instrument is inserted into the body and surgery then performed.

Crest factor as a way of describing the power input into the tissue

The crest factor is responsible for the power input in high-frequency surgery, and describes the ratio of the peak value to the root mean square of a waveform.

The root mean square value describes the root mean square of a time-variable waveform (Figure 62). The crest factor indicates the extent to which the current is modulated. [45, 2]

- With a sinusoidal signal, the crest factor is $\sqrt{2}/2$
- With a non-sinusoidal signal, it can be larger or smaller than $\sqrt{2}/2$.

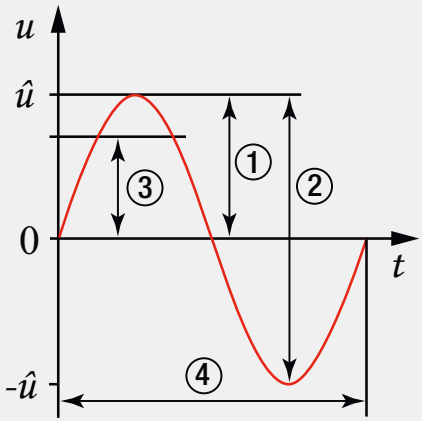


Figure 62: The crest factor describes the ratio of amplitude (1) to the root mean square (3) [46]

In pulsed coagulation, e.g. spray coagulation, the crest factor will be quite high, with a value of up to 20.

Although the root mean square is lower during coagulation due to the fact that barely any energy is applied to certain stretches with pulsed voltages, this is less apparent due to the very high voltage peaks.

When performing cutting work where the cutting surfaces are brownish in appearance, the crest factor is between just 2 and 4. A crest factor of greater than 4 would not be sensible here, as the tissue would only be plucked during the cutting process.

Electrosurgical instruments

Various electrosurgical instruments are available depending on the particular medical application. Figure 63 shows some standard electrosurgical instruments such as snares, needle instruments, forceps and blades for endoscopic applications.

Forceps are used for biopsies (= tissue sampling) and haemostasis (= blood clotting), for example. Needle-shaped instruments and blades are suitable for endoscopic applications where tumours are removed in one piece using a flexible endoscope.

Snares are used during endoscopic operations, for example, whereby the snare is inserted into the stomach, oesophagus or small intestine using an endoscope, and diseased tissue is then removed using the snare. [47]

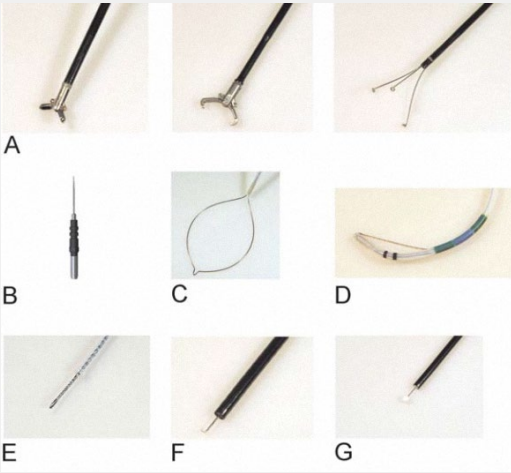


Figure 63: Electrosurgical instruments [47]

(A: coagulation and grasping forceps, B: needle electrode, C: snare electrode, D: instrument for ERCP, E: blade for endoscopic applications, F: blade, G: blade)

How is high-frequency surgical equipment tested?

It is essential that high-frequency surgical equipment be tested as burns can only occur during HF surgery if there are specific causes for this (see Figure 64). These causes must be eliminated before and during the surgical procedure.

DIN EN 60601-2-2 contains particular requirements regarding the safety and essential performance of high-frequency surgical equipment. These requirements are designed to supplement the “basic standard” IEC 60601-1, which contains general requirements for the safety of medical electrical equipment.

Thermal effect caused by high-frequency leakage currents:

The high-frequency leakage current that flows from the return electrode through a purely ohmic resistor of 200 Ω must not exceed 150 mA (with maximum output power).

Accuracy

Output power values that are above 10% of the rated power output must not deviate from the specified power output by more than +/- 20%. Compliance with this rule is tested using at least five determined values:

MONOPOLAR outputs:
100/200/500/1000/2000 Ohm

BIPOLAR outputs:
10/50/200/500/1000 Ohm

Testing devices

Devices such as the SECULIFE ES PRO can be used to test high-frequency surgical equipment (see Figure 64). This device uses external precision resistors (1% tolerance range) and a broadband toroidal transformer. The transformer scans the HF current and specifies a proportional output voltage. The current is converted with a ratio of 1:1 (Volts:Amps) or 0.1:1.

To test the HF output power, a connection must be established between the resistor, the transformer and the device under test. Measured data such as current, voltage, peak voltage, power and crest factor are displayed for the user on a screen.

This method has a range of benefits compared to conventional electrosurgical analysers.

- Improved accuracy and resolution
- 100% compatibility with the test load recommended by the manufacturer
- Smaller and lighter device configuration

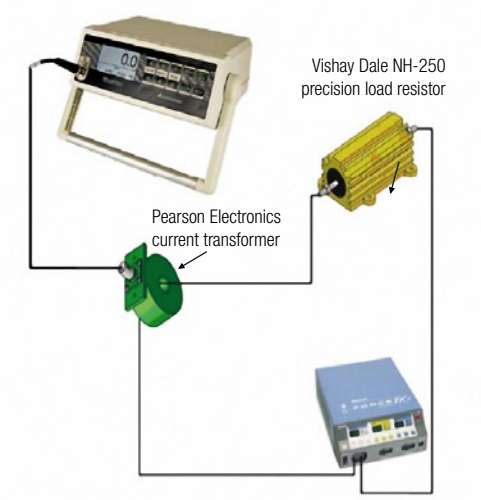


Figure 64: Test setup for testing HF surgical equipment with the SECULIFE ES PRO

In accordance with the aforementioned standard, multiple load resistances must be measured against the power output when testing high-frequency surgical equipment, allowing for the logging of power curves (Figure 65).

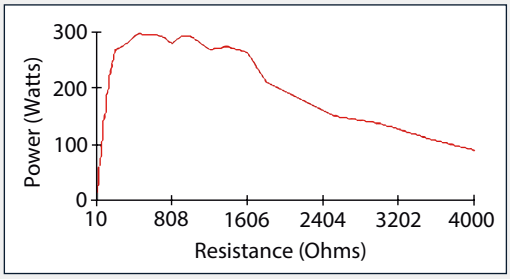


Figure 65: Diagram of output power against the load resistance range

A device such as the SECULIFE ES XTRA can be used to automatically determine the load curve (see Figure 66). This device does not require any external precision resistors to be connected; all of the non-inductive precision resistors are located inside the device.

This is advantageous as it allows for simple programming to be performed, meaning that multiple load resistances can be measured over a short period of time in order to then produce a load curve. The test loads can be set to within a range of 0 Ω to 6400 Ω at 1 Ω increments with an extremely high level of accuracy. As a result, this device is significantly more expensive than the SECULIFE ES PRO.

Figure 66: Convenient electrosurgical analyser SECULIFE ES XTRA

3.4 Medical imaging

3.4.1 What is medical imaging used for?

There has been huge progress in the field of medical imaging over the past few decades. Medical imaging allows for the anatomical depiction of the human body with all of its organs and organ boundaries, making it possible to draw conclusions on any pathological changes.

A physician can also use medical imaging to distinguish between pathological structures and between benign and malignant processes. Medical imaging can be split into the two categories of anatomical and functional imaging, whereby a combination of these two technologies allows for conclusions to be drawn regarding abnormalities at a molecular level.

Whereas imaging was previously only used to look at existing damage, the current trend is for imaging technology to be used for the preventive detection of diseases before they actually become apparent. The aim is now to tackle common diseases such as dementia, arterosclerosis or cancer at an early stage by making sure that molecular changes can be quickly identified during medical check-ups.

The fields of application for imaging technologies can be seen in Figure 67. Even today, medical imaging is still undergoing constant change. Regardless of the technology being used, systems need to become increasingly compact (miniaturisation), data needs to be digitalised and devices ideally need to have reduced radiation or no radiation at all.

The long-term objective in the field of medical imaging technology is a move from qualitative imaging to quantitative imaging, which uses figures and data to ensure the reproducibility and comparability of measurement results and stores these in databases. This will vastly improve the significance of the images. [48, 49]

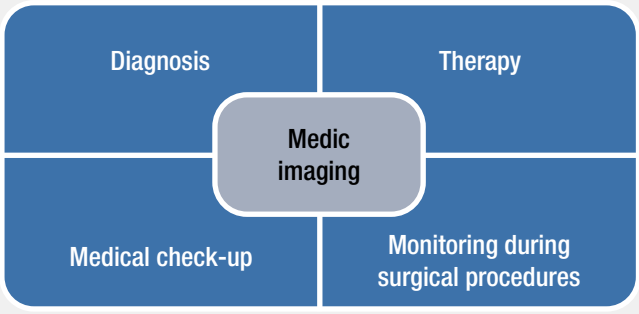
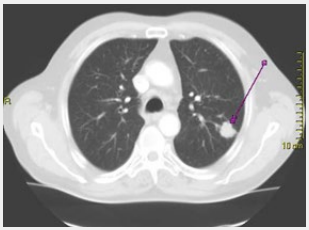
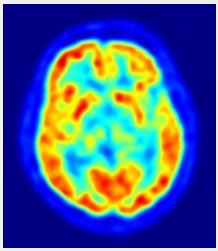


Figure 67: Fields of application of medical imaging

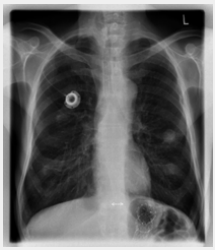
The various basic medical imaging technologies can be seen in Figure 68.



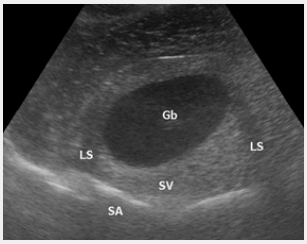
CT thorax



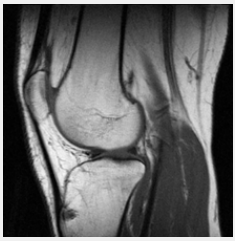
EIT chest



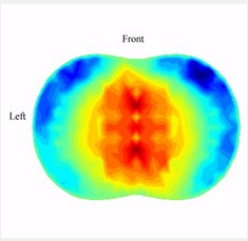
X-ray thorax



Ultrasound gallbladder



MRT knee joint



PET brain

Figure 68: Basic medical imaging technologies

3.4.2 Development of medical imaging

Wilhelm Röntgen invented X-radiation in 1895. The professor was initially investigating the appearance of light in cathode ray tubes, when he made a discovery that could no longer be explained simply in terms of the appearance of light. A test setup involving a glass was able to radiate through a sheet of paper, despite this paper being black in colour. The professor is then said to have holed himself up in his laboratory for six weeks, carrying out more research on the unusual phenomenon he had experienced. He discovered that the radiation he called X-ray radiation was an invisible type of radiation that could pass through almost any material.

In 1895, Mr Röntgen took the first ever X-ray image of the hand of his wife, Anna Bertha Röntgen. This is a very important document from this era. “I have seen my death”, said Ms Röntgen, when her husband showed her the image. From a physical perspective, X-ray radiation is an electromagnetic wave with a wavelength in between ultra-violet light and Gamma radiation. [50, 51]

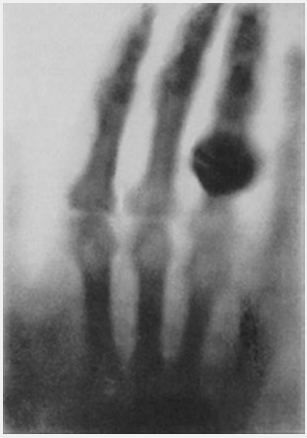


Figure 69: The hand of Anna Bertha Röntgen [50]

The first medical X-ray image was taken one year after this discovery in 1896. Initially, people were not aware of the risks associated with X-ray radiation, and X-rays were performed frequently and with high intensity on various body parts without any medical purpose.

1904 saw the first fatality due to radiation exposure, which lead to a change in thinking regarding the risks of X-rays. [52, 48]

The major disadvantage of conventional X-rays lay in the fact that the technology only provided projection images, meaning that there was no spatial information. The 1960s and 1970s saw the development of computer tomography (CT). CT technology meant that cross-sectional X-ray images of the human body could be recorded with no superimposition for the very first time (Figure 71). This was achieved by segmenting the body into individual image slices and then layering these on top of one another for viewing. [2]

Important milestones in the development of CT technology:

- 1964 Rotation of X-ray tubes by Allen Cormack
- 1968 Prototyp: Prototype: Experimental Scanner, anatomical specimens only
- 1971 First CT scanner developed by G. Hounsfield
- 1972 First device in a hospital in London
- 1974 Whole body
- 1979 Hounsfield and Cormack win the Nobel Prize for Physiology and/or Medicine
- 1989 Spiral CT
- 1998 Multi-slice technology

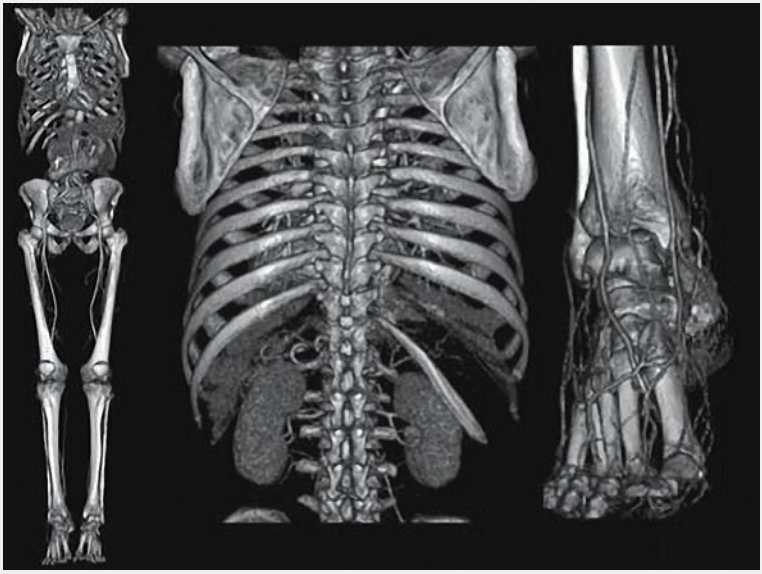


Figure 70: Whole-body images taken using a CT scanner [2]

These innovations were followed by the development of magnetic resonance tomography (MRT), which makes it possible to show the structure and function of organs.

An MRT scan generates cross-sectional images of the human body using strong magnetic fields that stimulate atomic nuclei in the human body, causing an electrical signal to be induced. [2]

3.4.3 Imaging using ultrasound

What are ultrasonic waves?

Ultrasound has existed in nature for thousands of years. Ultrasound technology came into being when the piezoelectrical effect was discovered by Marie und Pierre Curie, and was first used for diagnostic purposes in 1938. Table 13 shows the different sound waves and their frequency ranges.

1.	0 – 20 Hz	Infrasound
2.	20 Hz – 20 kHz	Audible sound
3.	20 kHz – 1 GHz	Ultrasound
4.	1 GHz – 10 THz	Hypersound

Table 13: Sound wave frequency ranges [53]

Ultrasound waves are longitudinal waves with a frequency of over 20 kHz. A longitudinal wave is a pressure wave that starts to vibrate in the direction of propagation. For this to occur, there must be particles in the propagation medium that are able to vibrate. (Figure 71)

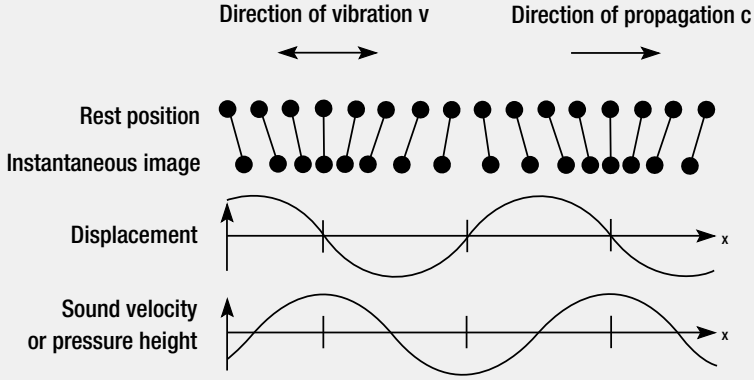


Figure 71: Principle of longitudinal waves [54]

Impacts of impedance differences?

Ultrasound waves move through a medium and are always fully or partially reflected as sound waves at the interfaces with other media, whereas the rest of the waves will continue to pass through the medium (see Figure 72). The diminishing echo signals that occur as a result of this reflection are caused by impedance differences at the interfaces. The impedance differences occur due to different densities within the tissue. The impedance differences are used to calculate the reflection factor R. The following Figure shows the movement of soundwaves from water with its impedance of Z1 to a boundary layer Z2. If the impedance difference between the boundary layers becomes relative, the reflection will prove stronger and the reflection factor will approach 1.0 (total reflection). If the impedance difference is small, there will be no reflection and the reflection factor will approach zero.

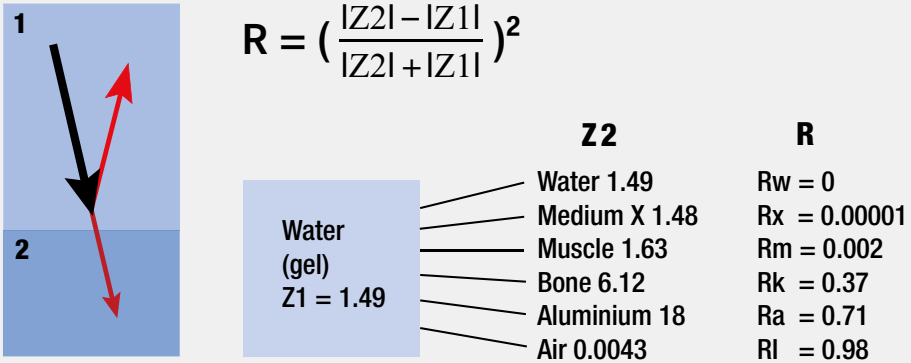


Figure 72: Movement of a medium Z1 to another medium Z2 with the effects of transmission and reflection [2]

How does ultrasound imaging work?

An ultrasound device with transducer can be seen in Figure 73. An ultrasound device contains the electronic equipment for sound generation, signal processing and image depiction. The device is connected to the monitor via an interface.

Ultrasonic probes or transducers also act as transmitters (actuators) and receivers (sensors). They send sound waves into the tissue and receive echo signals for electrical evaluation. [55, 2]

Figure 73: Ultrasound device with transducer

When the transducers send pulses into human tissue, these are reflected or transmitted to varying extents. Measuring the length of the echo is a very simple way to determine the depth of the reflected structure (Figure 74).

If the structures are highly reflective, they will appear white on the image, whereas less reflective structures will appear dark or black. Materials that reflect sound to a very high extent include bone, which appears white on an ultrasound image. [56, 2, 57]

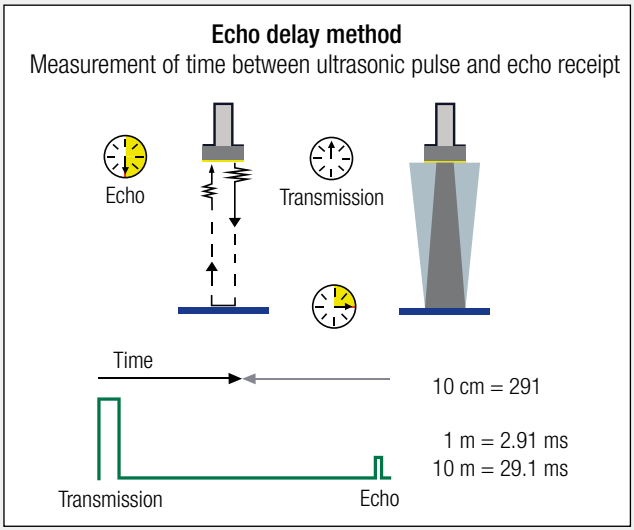


Figure 74: Echo delay method, measurement of time between ultrasonic pulse and echo receipt [58]

How is ultrasound created?

Ultrasound is created by the piezoelectrical effect. When a crystal or ceramic is deformed, sound waves occur when alternating voltage is applied. These sound waves can continue to spread through a connected medium. Polished barium nitrate or a lithium compound is usually used as the crystal. Electrical energy is converted into mechanical energy in the form of sound. A transducer, on the other hand, functions using the inverse piezo effect. With the inverse piezo effect, electrical signals are generated as a result of mechanical voltages being applied to a piezo crystal (Figure 75). This occurs because charges are able to migrate when a mechanical voltage is applied to the piezo crystal. [59]

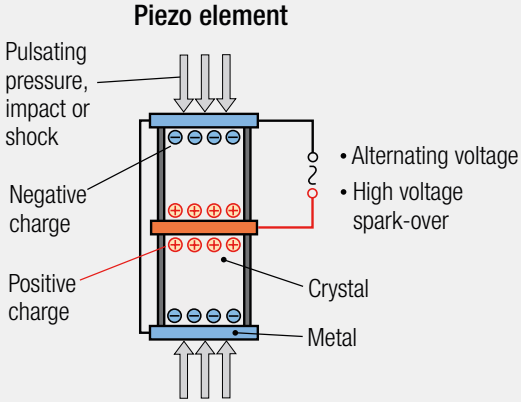


Figure 75: The piezo element converts mechanical pressure into electrical voltage [59]

Types of ultrasound transducers

Ultrasound transducers can be divided into the categories of linear transducers with a large contact area and accurate geometrical depiction, convex transducers for broad-spectrum imaging and sector transducers for mechanical rotation in different positions (Figure 76). The piezoelectrical effect is generated right on the probe itself. Because air has a very low impedance of Z = 0.0043, the reflection factor calculated using the formula will be relatively high, and the ultrasound will be reflected back to a large extent. It is therefore necessary to use a gel with a high water content during ultrasound examinations in order to ensure that the sound waves are not reflected by the air gaps between the transducer and the surface of the skin.

Figure 76: Different transducers

TEE (transoesophageal echocardiography) transducers

The TEE transducers are explained in more detail in the following section relating to the testing of ultrasound devices, as the use of TEE transducers (Figure 77) is not completely without risk. During an ultrasound examination using a TEE transducer, the transducer is inserted into the patient's oesophagus in order to produce better images of sections of the heart. This involves inserting a tube with an ultrasound transducer at the end into the patient's oesophagus. The TEE ultrasound examination is rarely carried out in practice, but may be necessary in the case of overweight patients with the aim of identifying small thrombi (blocked blood vessels) in the heart. [60]

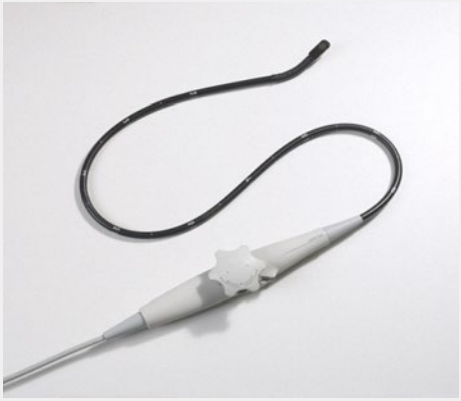


Figure 77: Example of a TEE transducer [60]

Advantages	Disadvantages
Sound waves are safe for use on humans	Can only be performed by a physician
Pain-free, non-invasive procedure	Moderate image quality and lots of artifacts
High level of availability	Moderate spatial resolution
Affordable purchase	Not suitable for all organs
Observations in real-time	

Table 14: Advantages and disadvantages of ultrasound imaging

3.4.4 Testing ultrasound devices

Testing ultrasound output using the SECULIFE UP:

The SECULIFE UP (Figure 78) is a digital ultrasound power meter that is used to document the power output of medical transducers and that measures output in Watts. The SECULIFE UP is primarily used for therapeutic purposes, although power output measurements can sometimes also be relevant for diagnostic purposes in the field of medical imaging.

The device allows for the reliable and reproducible measurement of ultrasound energy. The transducer to be tested is centred above a 45° air-backed cone target in de-gassed water. A coupling is made to a precision balance that measures to an accuracy of ± 0.15 Watts.

When acoustic energy is applied to the cone, the resultant force is directly proportional to the total radiated power. The test tank is lined with sound-absorbent rubber to prevent acoustic reflection. The balance is programmed to convert milligram magnitude forces directly to a readout in Watts with good resolution. The measurement accuracy of the power meter can be verified by placing a calibrated weight on the cone's support arm.

Figure 78: SECULIFE UP

Testing for electrical safety using the SECULIFE UL:

Ultrasound systems and their accessories are usually designed to meet patient safety requirements as stipulated in IEC 60601-1:2005/AMD1:2012. In order to guarantee patient safety, electrical leakage currents need to be reduced to a minimum.

Leakage current is an electrical current that flows via a path not intended to conduct electrical current. As explained in Section 1.2 (Electrical safety), electrical current poses a high risk of injury to people, and can lead to fatal accidents particularly in the absence of the skin's natural protection. Because a TEE transducer is inserted into the patient's body via an endoscope, this procedure constitutes a critical application that should always be performed with care.

The effects of even the lowest electrical leakage current amplitudes on the heart muscle and other internal organs have been investigated for over 30 years, whereby some potential risks are still regarded as critical, primarily if currents occur in the immediate vicinity of the heart, as is the case when using a transducer.

The endoscope used in a TEE system does not usually have any electrically conductive surfaces, and is coated with a material that repels fluid and acts in a similar way to an electrical insulator.

The electrical safety of the transducer is only guaranteed if the material is not damaged in any way. Every TEE transducer must be tested for electrical leakage currents before it can be sent to the customer.

In order to prevent injuries, transducers must never be used if the insulation material is damaged. Testing of the insulation must always end with a visual inspection. Testing for electrical leakage currents should be performed at regular intervals using a particular method.

Standard IEC 60601-1 stipulates a minimum of one test per year, though this may vary in accordance with local regulations. Testing is performed on the ultrasound system using standardised test equipment (Figure 79). The transducer is immersed in an electrically conductive saline solution (50g/l NaCl) up to the 40 cm mark on the endoscope. If leakage currents are present, they will be identified by the test device as they have good conductivity in the NaCl.

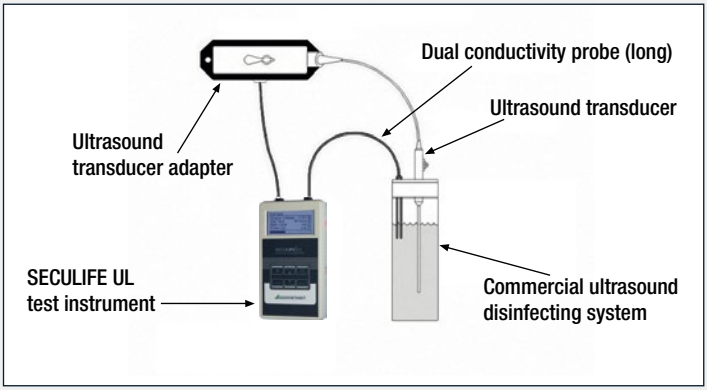


Figure 79: Test setup for testing for electrical leakage currents

3.4.5 Imaging using conventional X-rays

This involves passing X-rays though a patient's body using a radiation source, a screen, a focusing system (collimator) and an image intensifier. Radiation that is not absorbed by the body can be seen on an X-ray film (see Figure 80).

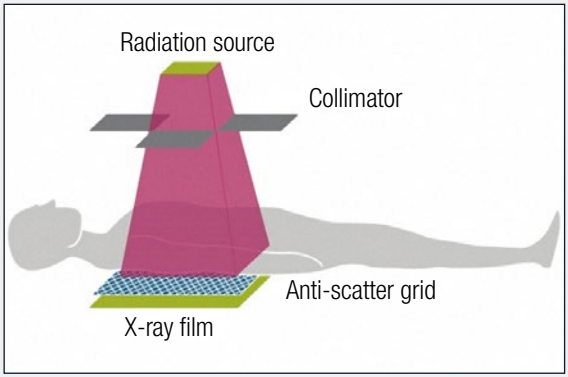


Figure 80: Principle of X-ray technology [61]

X-rays are used in medicine to detect anomalies in the body with the aim of then making a diagnosis. This technology functions based on the fact that X-ray radiation is absorbed to different extents by different tissue types, making it possible to create an image of the inside of the body. The fact that X-ray radiation is well-absorbed by bone but passes unimpeded through muscle tissue means that X-rays are frequently used in cases of suspected fractures.

X-ray images make it very easy to see whether the bone is fractured at a particular point. Other areas of application for X-rays include the examination of abdominal organs such as the liver, the diagnosis of lung changes or mammography screenings to diagnose breast cancer. Different radiation qualities need to be used depending on the area of the body being examined. A distinction is made between soft and hard radiation. The softer the radiation, the more radiation is absorbed into the tissue, although this type of radiation does increase the amount of radiation exposure. [62]

Hard radiation (100 kV): Passes through tissue and materials (e.g. plaster cast, lead aprons). Hard radiation reduces the differences in contrast.

Soft radiation (25 - 35 kV): A large proportion of the radiation is absorbed by the tissue, meaning that even the smallest tissue differences are visible on the X-ray film. Soft radiation is used in mammography screenings, although this could encourage the development of breast cancer due to the relatively high level of radiation exposure. [63]

3.4.6 Imaging using computed tomography

Computer tomography (tomography - from the Greek "cut") is an imaging technology used in radiology. A patient lies on a couch and is introduced into an X-ray tube. A computer then spirals around the body, generating cross-sectional images of different sections of the body (see Figure 81). Detectors are used for each tube position that measure the X-ray radiation.

A computer then generates cross-sectional images from the slice data. The individual images can then be used to create three-dimensional images. Modern computer tomographs have rotation times of under a second, and can generate completed images very quickly. Some advantages and disadvantages of computer tomographs can be seen in Table 15.

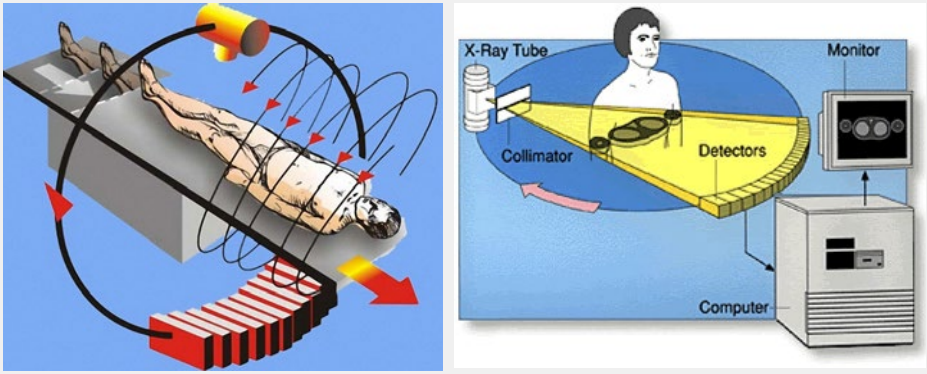


Figure 81: Principle of operation of a computer tomograph [64, 65]

Advantages of computer tomographs	Disadvantages of computer tomographs
Cross-sectional images with no superimposition and high detail resolution	Relatively expensive investment
Depiction of small vessels	Therefore most probably used more than absolutely necessary
	High exposure to X-ray radiation

Table 15: Advantages and disadvantages of computer tomographs

3.4.7 Imaging using magnetic resonance tomography

Magnetic resonance tomography makes it possible to look at structures inside the body. As with CT technology, three-dimensional structures can be generated on the computer using the acquired data. Whereas a CT scan is primarily used to show bone, an MRT scan is used to show soft tissue.

An MRT system consists of a superconducting magnet, high-frequency transmitters, gradient coils, receiver coils, an examination table, a computer console and a shielded MRT examination area with the Faraday cage effect.

The solenoid running through the superconducting magnet is cooled to minus 269°C by liquid nitrogen and liquid helium, which causes the solenoid resistance to fall to approximately zero, allowing it to maintain the strong magnetic fields.

Basic physical properties

MRT is also known as magnetic resonance imaging, or nuclear spin tomography. A nuclear spin is the angular momentum of a proton (positively charged particle) around its centre of gravity (see Figure 82). The atomic nuclei of hydrogen have a particular angular momentum and a magnetic dipole moment as moving charges have magnetic properties.

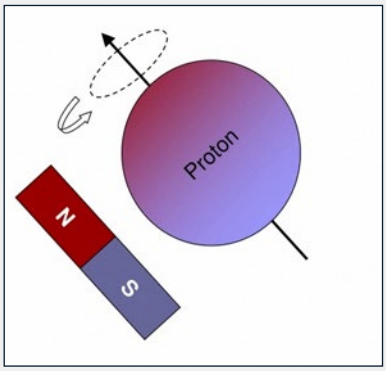


Figure 82: Spin of a hydrogen atom [66]

When a magnetic field is generated, this stimulates movement of the hydrogen protons, which then align themselves based on the magnetic field (see Figure 83). The amount of energy is relatively low when the magnetic dipole moment is in a relatively parallel position to the magnetic field, and is higher when the dipole moment is not parallel.

In the case of a non-parallel alignment, a torque acts upon the atomic nuclei allowing them to align themselves in the direction of the applied magnetic field. In order to acquire a signal for the MRT, a short radio frequency pulse (Larmor frequency) is transmitted. This high-frequency pulse causes the protons to move from their parallel alignment to the magnetic field. After the pulse, the protons return to their previous alignment and emit electrical signals that can be put together by a computer to create images.

Different tissue types have different amounts of water (H^20), which contains the hydrogen protons (H+). Looking at changes in MRT images makes it possible to draw conclusions regarding healthy and diseased tissue. Some advantages and disadvantages of MRT can be seen in Table 16. [67, 68]

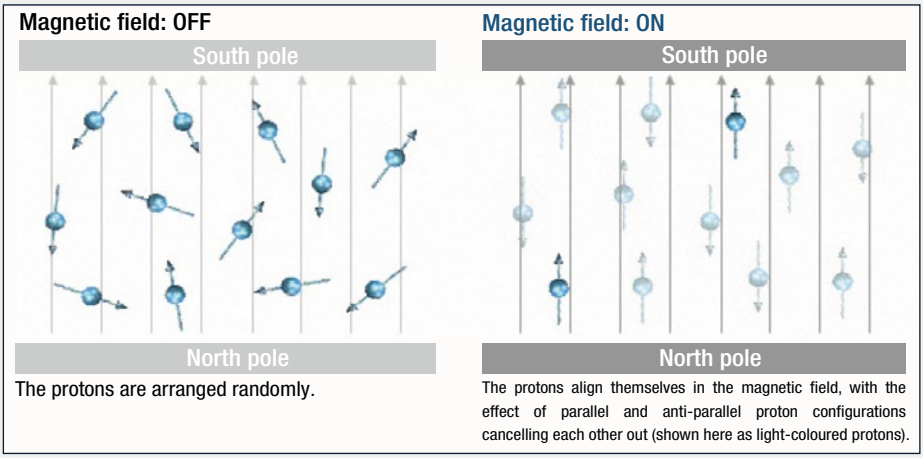


Figure 83: Hydrogen protons in a magnetic field [67]

Advantages of MRT	Disadvantages of MRT
No potentially carcinogenic radiation	Higher purchase price
Organs and tissue can be displayed without contrast agent	Long examination time
	Patient not permitted to move during the examination
	Very difficult to show bone and soft tissue

Table 16: Advantages and disadvantages of MRT

3.4.8 Imaging using PET

Positron emission tomography (PET) is a version of imaging technology that creates cross-sectional images of living organisms by distributing a slightly radioactive substance around the body in order to show metabolic processes. The patient is usually injected with a modified form of glucose, which has been enriched with radioactive particles and which emits positrons.

Positrons are the antiparticles of electrons, as they share the same electrical and magnetic properties as electrons, right down to their signs. If an electron and a positron come into contact, two high-energy photons (approx. 500 kV) will be emitted in the body in precisely opposite directions, i.e. at an angle of 180 degrees from one another.

The PET device contains a large number of ring-shaped detectors arranged around the patient for the detection of these photons (see Figure 84). The line can be accurately determined by the simultaneous detection of both particles.

Multiple such lines can be overlayed to create cross-sectional images with the help of a computer. These cross-sectional images make it possible to see where there is a lot of radioactive decay.

With PET examinations, diagnostics are performed by observing the reconstructed cross-sectional images. If there is a tumour in the patient's body, this will absorb the glucose more intensively in order to meet its increased energy requirements.

The absorbed energy can then be identified by the radioactive decay. A PET examination is usually used following a prior CT examination. It is therefore a type of supplementary examination rather than a stand-alone examination. Some advantages and disadvantages of PET can be seen in Table 17. [69, 48, 70]

Figure 84: Principle of PET

Advantages of PET	Disadvantages of PET
Cancer screening	Relatively high costs
Possible to identify tumours	Radioactive radiation
	Risk of incorrect diagnosis: Inflammations also lead to high metabolisation

Table 17: Advantages and disadvantages of PET

3.4.9 Basic principles of photometry

The following sections contain brief explanations of important terms and basic principles of photometry that may be useful in understanding the information regarding the testing of medical monitors. The term light refers to electromagnetic radiation in a wavelength of between 380 nm and 780 nm (Figure 85). Light is therefore the electromagnetic radiation that can be seen by humans. Human colour perception needs to be recorded and evaluated using measuring technology. If a person sees a green and a red LED with the same output, the green LED appears a lot brighter than the red LED. The way in which the colours are perceived is down to the brightness sensitivity of the human eye.

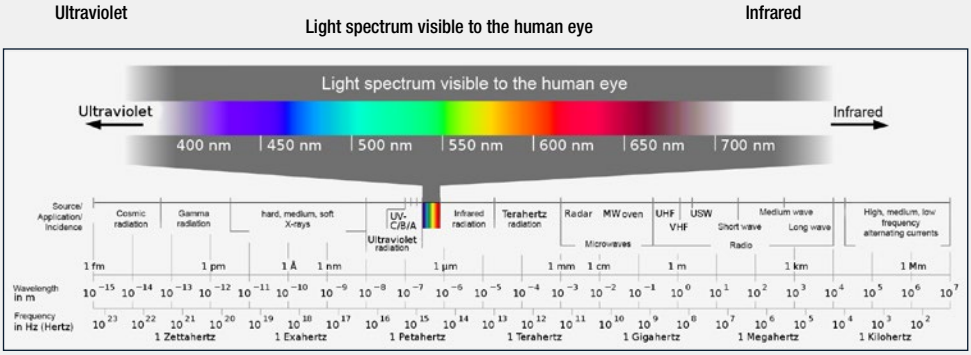


Figure 85: Wavelengths and frequencies of electromagnetic radiation [71]

A few terms from the field of photometry will now be explained using an example (see Figure 86). The most important value from which all other values are derived is the luminous flux.

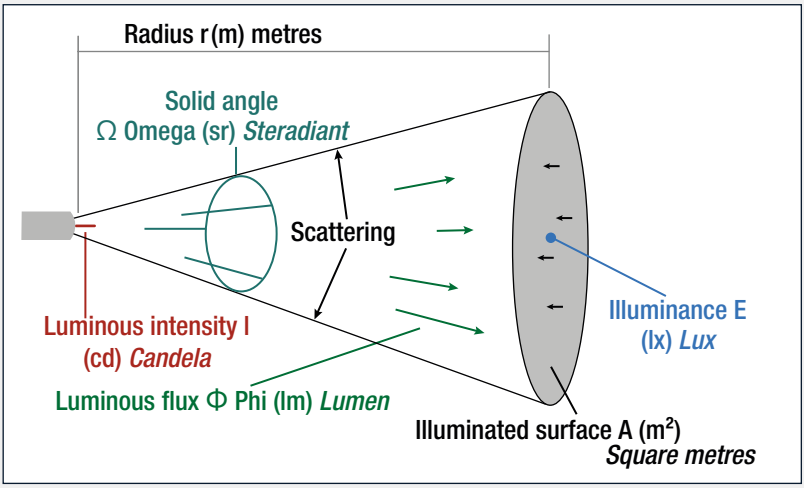


Figure 86: Illustration of basic photometry terms [72]

Luminous flux [lm]:

Luminous flux is the radiation emitted by light sources in the form of visible light. The luminous flux ϕ is its own output variable that can be used to evaluate the brightness sensitivity of the human eye (i.e. visible light). Luminous flux is the amount of light that is emitted over a certain period of time.

With a 100 W bulb, the perceptible output is not in fact 100 W as stated on the packaging. The majority of the consumed energy is actually lost as heat. The heated tungsten wire emits the radiation as heat.

The visible light is only a very small part of the radiation spectrum emitted by the bulb. The luminous efficacy can be calculated in a similar way to a standard efficiency value. The luminous efficacy is the quotient of the luminous flux to the power consumed. To work out the luminous flux, the radiant flux of a wavelength is multiplied by human brightness sensitivity.

As light is not naturally monochromatic (single wavelengths), but actually consists of various different wavelengths, the particular wavelength needs to be multiplied by the brightness sensitivity and then summed up over all wavelengths. This is usually performed mathematically using an integral.

$$\Phi_v = K_m \int_{380\ nm}^{780\ nm} \Phi_e\,(\lambda)*\mathrm{V}(\lambda)*\mathrm{d}\cdot\lambda$$

A constant K_m indicates a photometric radiation equivalent emitting the maximum possible luminous efficacy.

The 'Lumen' unit is ultimately an empirical value relating to the observations of test persons. [73, 74]

Illuminance E [lx]:

The illuminance is a value indicating the brightness of light striking a surface. It is measured in Lux and indicates the intensity with which a surface is illuminated. It therefore indicates the extent to which a surface is illuminated.

Illuminance E = (luminous flux ϕ) /(illuminated surface A)

The illuminance does not indicate how bright a space appears as this is influenced by the reflection of the light.

Luminous intensity [cd] and solid angle [sr]

Luminous intensity refers to the entire luminous flux emitted from a light source in a particular direction. It is therefore the light energy emitted in a particular angular range.

Luminous intensity I = (luminous flux ϕ) / solid angle Ω

Solid angle Ω = (spherical surface area A) / r^2

The luminous intensity is only dependent upon the solid angle and not on the distance to the light source.

The solid angle Ω (see Figure 87) is defined as a part of the spherical surface area A divided by the square of the spherical radius r when observed from the centre of the sphere.

A bulb radiates into space and not onto an even surface. The unit of solid angle is the steradian.

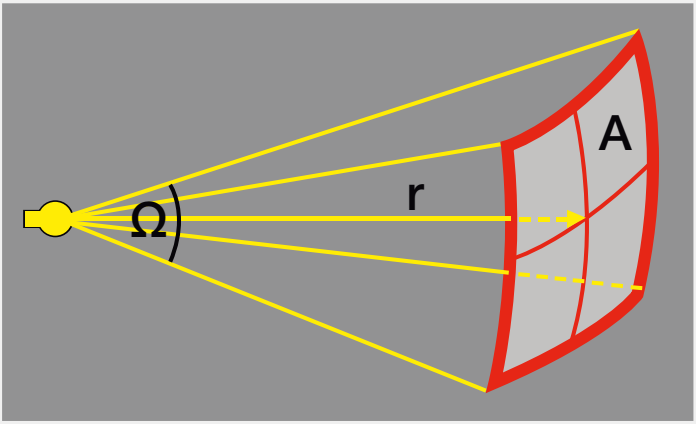


Figure 87: Solid angle Ω

Lumincance [cd/m^2]

The luminance L indicates the eye's brightness impression of an illuminated surface A. It therefore considers the physiological impact of the light on the eye.

Luminance L = (luminous intensity I) / (surface A) [74]

3.4.10 General information on medical monitors

Modern medical monitors (see Figure 88) use LED technology. These monitors are used for radiological applications. LED technology is characterised by a very high service life and high brightness levels over long periods of time. LED is an abbreviation of light-emitting diode. Light-emitting diode). It is therefore a semiconductor device that acts in the same way as a diode and that radiates light, infra-red radiation and ultra-violet radiation in a forward direction when electrical current is applied, with a wavelength dependent upon the material and the doping. Medical monitors need to display colours and grey values correctly so that physicians can make the right prognoses. [75, 74]

Figure 88: Colour and greyscale monitors with LED technology [76]

Basic physiological properties: Weaknesses of the human eye

The human eye has various weaknesses when it comes to colour perception.

- Different colours are perceived with different brightnesses
- Different greyscales are perceived with different brightnesses

Sensitivity also depends on whether it is daytime or night-time. As can be seen in Figure 89, relative sensitivity is better for blue tones at dusk, which therefore appear much brighter at this time. With green and red tones, on the other hand, sensitivity is much better in daylight.

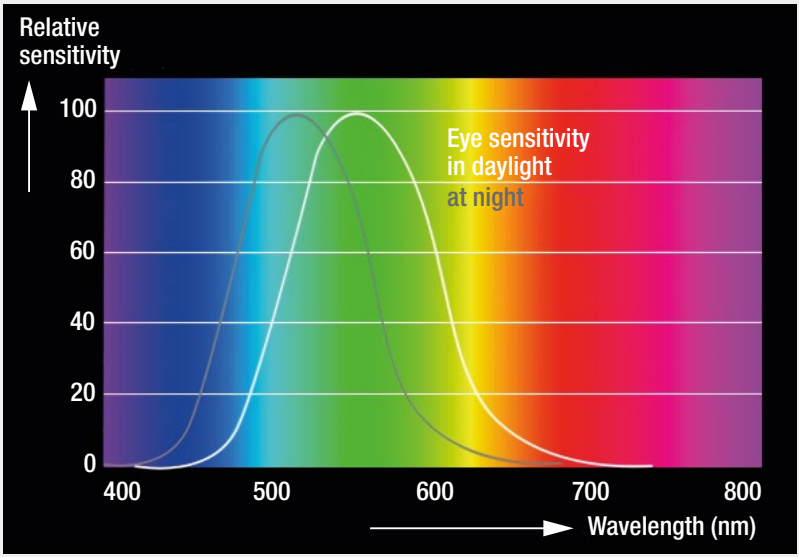


Figure 89: Sensitivity of the human eye in daylight and at night [77]

Criteria and regulations for medical monitors

The following basic criteria and regulations apply for screens used for diagnostics and image viewing:

- MPDG (German Medical Devices Act)
- RöV (German X-ray Ordinance)
- 73/23 EWG (Low Voltage Directive)
- 93/42/ EWG (Medical Devices Directive)
- DIN6868-57/157 (Image Quality Assurance)
- DICOM Standard 3.0
- BildscharbV (German ordinance on VDUs)
- Medical guidelines (e.g. consensus conference)
- Quality Assurance Directive for DIN6868-57
- IEC 1223-2-5 (constancy tests)

Calibration of screens: DICOM Standard

The DICOM Standard was developed and published by US organisation NEMA (National Electrical Manufactures Association). DICOM Part 14 contains specifications regarding how pixels should be interpreted and displayed. The detectability of grey value differences does not behave in a linear manner. Grey value differences are differentiated more clearly in dark areas than in light areas. DICOM specifies a characteristic curve with the pixels arranged in relation to the displayed brightness (see Figure 90). The just noticeable difference (JND) index (X-axis) is an evaluation parameter for the quality of displays, and is decisive in terms of the number of greyscales that can just about be distinguished for a particular LED (Y-axis). The Figure shows how the number of greyscales increases together with the luminance. [77]

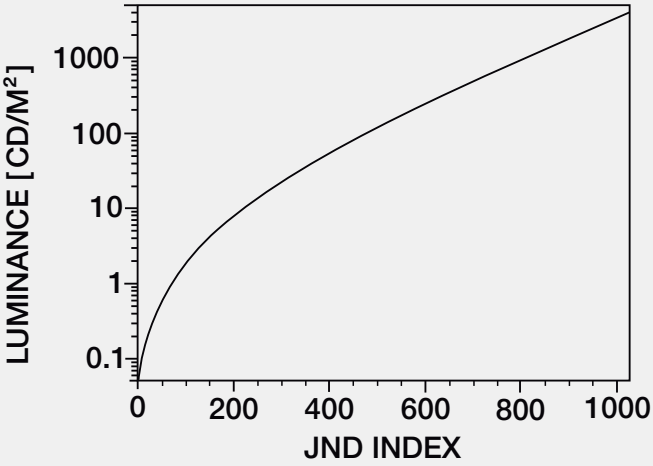


Figure 90: The greyscale screen function is displayed as a logarithmic function whereby a JND index is plotted against the luminance (cd/m²)

Calibration is performed in accordance with the DICOM Standard in order to bring displays into line with the human eye. As the human eye does not work like a computer, the interface between human and digital machine needs to be brought into line with the characteristic properties of the eye. Regular calibration is required as the brightness, contrast and display colour filter (blue on yellow) can change over time. It is therefore necessary to check and adjust the display's white balance on a regular basis. Calibrating the screen also guarantees that an image looks the same in all areas and workstations within a hospital or clinic (diagnostic confidence) while also ensuring that quality assurance standards in the medical industry are maintained and diagnostic times are reduced, which in turn can lead to significant savings.

How are medical monitors calibrated?

Calibration involves the recording of measured values. Reference colours and greyscale are shown on the display and measured using a measuring instrument. A Look Up Table (LUT) is then generated and a correction table created from the target values. This LUT can then be imported into the graphic card or display. The target pixel value is then assigned to every modified grey value of the corresponding pixel.

3.4.11 Testing image display systems

Image quality is crucial for correct diagnostics. Image display systems require continual testing (constancy testing) during operation in accordance with DIN 6868-157, as well as acceptance tests on installation in accordance with DIN 6868-162. If the screen is moved to a different location, it must undergo an acceptance test. The entire image display chain must be tested, including the hardware, software and image display system. This DIN standard specifies test procedures for workplaces in the fields of CT, radiography and digital subtraction angiography. Monitors used for MRT and ultrasound are not tested under this DIN standard. [78]

Constancy testing

Constancy testing involves carrying out a visual inspection every 6 months (see Figure 91), and also covers homogeneity testing within an image display device as well as the testing of colour impression and uniformity. Measurement-based testing is also carried out every six months, whereby the luminance of 18 grey levels (cd/m^2) is determined and verification performed as to whether the DICOM characteristic curve is correctly displayed. The DICOM characteristic curve can be used to calculate the maximum contrast and luminance ratio based on the minimum and maximum luminance (see Figure 92). It also makes it possible to determine the illuminance on the screen.

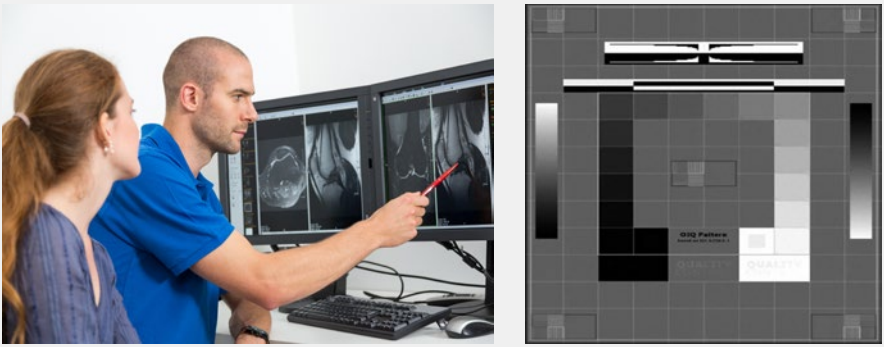


Figure 91: Test image on a medical monitor [78]

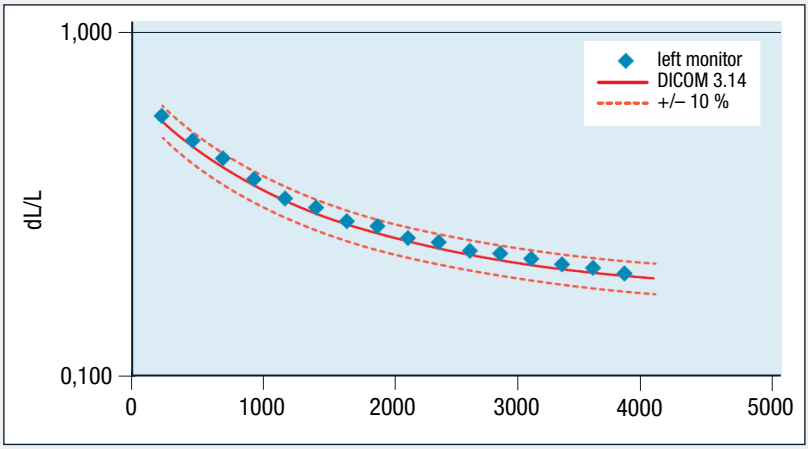


Figure 92: DICOM characteristic curve with the Monitorcheck software. As can be seen in this Figure, the blue pixels are within the tolerance range, meaning that the monitor meets the relevant requirements. [78]

The test is performed using the manufacturer's software. The user is guided through the test process by the software, and must follow the step-by-step instructions provided. The first step involves answering a few general questions before then being prompted to use measuring equipment to carry out the measurement. It is important to ensure that the room is as dark as possible so as not to falsify the test results. The deviation of the luminance (cd/m^2) may only be below 10% for grey-value images. A homogeneity test only needs to be carried out if multiple computers are being used. [78]

Acceptance test

During the acceptance test, the same parameters are determined as with the constancy testing, and a further 3 visual inspections are also carried out. [78]

- Visibility of corners with low contrast
- Distinguishability of 16 luminance surface elements
- Perceptibility of black-white transitions

Testing equipment for the testing of image display systems

Luminance meters, illuminance meters, DICOM and test images are used as testing equipment for acceptance tests and constancy testing (see Table 18).

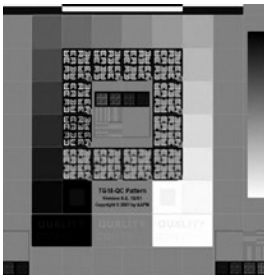
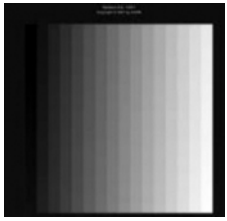
Luminance measurement	Illuminance measurement	Test images TG18 series
Example product SECULIFE Illumination Analyzer - Measures the luminance in an angle of 1° - Records, displays and stores data using software (USB interface)  	**Example product SECULIFE Illuminance Tester** - Reliable measurements in daylight and artificial light - USB interface - Storage of measured values - Can also be used with accessories to measure luminance 	**Example test images** Overall test:  For luminance:  Luminance resolution: 
Example device SECULIFE IS - Measures the ambient lighting - For constant ambient lighting monitoring - 20 lx – 60 lx - Continous operation - LED display - USB interface 		

Table 18: Testing equipment for image display systems

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5 List of figures

6 List of tables

7 Appendix

7.1 Appendix A

Table of reference resistances for testing vital signs.

Temperature, C	YSI 400 Resistance	YSI 700 Resistance A	YSI 700 Resistance B
-1 °C	7741 Ω	20620 Ω	99800 Ω
0 °C	7355 Ω	19590 Ω	94980 Ω
1 °C	6989 Ω	18620 Ω	90410 Ω
2 °C	6644 Ω	17700 Ω	86090 Ω
3 °C	6319 Ω	16830 Ω	81990 Ω
4 °C	6011 Ω	16010 Ω	78110 Ω
5 °C	5719 Ω	15240 Ω	74440 Ω
6 °C	5444 Ω	14500 Ω	70960 Ω
7v°C	5183 Ω	13810 Ω	67660 Ω
8 °C	4937 Ω	13150 Ω	64530 Ω
9 °C	4703 Ω	12530 Ω	61560 Ω
10 °C	4482 Ω	11940 Ω	58750 Ω
11 °C	4273 Ω	11380 Ω	56070 Ω
12 °C	4074 Ω	10850 Ω	53540 Ω
13 °C	3886 Ω	10350 Ω	51130 Ω
14 °C	3708 Ω	9878 Ω	48840 Ω
15 °C	3539 Ω	9428 Ω	46670 Ω
16 °C	3378 Ω	9000 Ω	44600 Ω
17 °C	3226 Ω	8594 Ω	42640 Ω
18 °C	3081 Ω	8210 Ω	40770 Ω
19 °C	2944 Ω	7844 Ω	38990 Ω
20 °C	2814 Ω	7496 Ω	37300 Ω
21 °C	2690 Ω	7166 Ω	35700 Ω
22 °C	2572 Ω	6852 Ω	34170 Ω
23 °C	2460 Ω	6554 Ω	32710 Ω
24 °C	2354 Ω	6270 Ω	31320 Ω
25 °C	2252 Ω	6000 Ω	30000 Ω

Temperature, C	YSI 400 Resistance	YSI 700 Resistance A	YSI 700 Resistance B
26 °C	2156 Ω	5744 Ω	28740 Ω
27 °C	2064 Ω	5500 Ω	27540 Ω
28 °C	1977 Ω	5266 Ω	26400 Ω
29 °C	1894 Ω	5046 Ω	25310 Ω
30 °C	1815 Ω	4834 Ω	24270 Ω
31 °C	1739 Ω	4634 Ω	23280 Ω
32 °C	1667 Ω	4442 Ω	22330 Ω
33 °C	1599 Ω	4260 Ω	21430 Ω
34 °C	1533 Ω	4084 Ω	20570 Ω
35 °C	1471 Ω	3918 Ω	19740 Ω
36 °C	1412 Ω	3760 Ω	18960 Ω
37 °C	1355 Ω	3610 Ω	18210 Ω
38 °C	1301 Ω	3466 Ω	17490 Ω
39 °C	1249 Ω	3328 Ω	16800 Ω
40 °C	1200 Ω	3196 Ω	16150 Ω
41 °C	1152 Ω	3070 Ω	15520 Ω
42 °C	1107 Ω	2950 Ω	14920 Ω
43 °C	1064 Ω	2836 Ω	14350 Ω
44 °C	1023 Ω	2726 Ω	13800 Ω
45 °C	983.8 Ω	2620 Ω	13280 Ω
46 °C	946.2 Ω	2520 Ω	12770 Ω
47 °C	910.2 Ω	2424 Ω	12290 Ω
48 °C	875.8 Ω	2334 Ω	11830 Ω
49 °C	842.8 Ω	2246 Ω	11390 Ω
50 °C	811.3 Ω	2162 Ω	10970 Ω
51 °C	781.1 Ω	2080 Ω	10570 Ω

7.2 Appendix B

Table of standards

IEC standard	Contents
IEC 60601-1-1	Medical electrical equipment - Part 1: General requirements for safety 1: Collateral standard: Safety requirements for medical electrical systems
IEC 60601-1-2 (ACDV)	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests
IEC 0601-1-3	Medical electrical equipment - Part 1: General requirements for safety - Collateral standard: Radiation protection in diagnostic X-ray equipment
IEC 0601-1-4	Medical electrical equipment - Part 1-4: Collateral standard: General requirements for programmable electrical medical systems
IEC 0601-1-6	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
IEC 60601-1-8 (CCDV)	Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral standard: Tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
EC 60601-1-9	Medical electrical equipment - Part 1-9: General requirements for basic safety and essential performance - Collateral standard: Requirements for environmentally conscious design
IEC 60601-1-10	Medical electrical equipment - Part 1-10: General requirements for basic safety and essential performance - Collateral standard: Requirements for the development of physiologic closed-loop controllers
IEC 60601-1-11	Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
IEC 60601-1-12 (CDM)	Medical electrical equipment - Part 1-12: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
IEC 60601-2-1	Medical electrical equipment - Part 2-1: Particular requirements for the safety of electron accelerators in the range 1 MeV to 50 MeV
IEC 60601-2-2	Medical electrical equipment - Part 2-2: Particular requirements for the safety of high frequency surgical equipment
IEC 60601-2-3 (ADIS)	Medical electrical equipment - Part 2: Particular requirements for the safety of short-wave therapy equipment
IEC 60601-2-4	Medical electrical equipment - Part 2: Particular requirements for the safety of cardiac defibrillators
IEC 60601-2-5	Medical electrical equipment - Part 2-5: Particular requirements for the safety of ultrasonic physiotherapy equipment
IEC 60601-2-6 (ADIS)	Medical electrical equipment - Part 2: Particular requirements for the safety of microwave therapy equipment

IEC standard	Contents
IEC 60601-2-7	Medical electrical equipment - Part 2-7: Particular requirements for the safety of high-voltage generators of diagnostic X-ray generators
IEC 60601-2-8	Medical electrical equipment - Part 2-8: Particular requirements for the safety of therapeutic X-ray equipment operating in the range 10 kV to 1 MV
IEC 60601-2-10 (CCDV)	Medical electrical equipment - Part 2: Particular requirements for the safety of nerve and muscle stimulators
EC 60601-2-11	Medical electrical equipment - Part 2: Particular requirements for the safety of gamma beam therapy equipment
IEC 60601-2-13	Medical electrical equipment - Part 2-13: Particular requirements for the safety of anaesthetic systems
IEC 60601-2-16 (RDIS)	Medical electrical equipment - Part 2-16: Particular requirements for basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment
IEC 60601-2-17	Medical electrical equipment - Part 2: Particular requirements for the safety of automatically-controlled brachytherapy afterloading equipment
IEC 60601-2-18	Medical electrical equipment - Part 2: Particular requirements for the safety of endoscopic equipment
IEC 60601-2-19	Medical electrical equipment - Part 2: Particular requirements for the safety of infant incubators
IEC 60601-2-20	Medical electrical equipment - Part 2: Particular requirements for the safety of infant transport incubators
IEC 60601-2-21	Medical electrical equipment - Part 2: Particular requirements for the safety of infant radiant warmers
IEC 60601-2-22	Medical electrical equipment - Part 2: Particular requirements for the safety of surgical, cosmetic, therapeutic and diagnostic laser equipment
IEC 60601-2-23	Medical electrical equipment - Part 2-23: Particular requirements for the basic safety and essential performance of transcutaneous partial pressure monitoring equipment
IEC 60601-2-24 (ADIS}	Medical electrical equipment - Part 2-24: Particular requirements for the basic safety and essential performance of infusion pumps and controllers
IEC 60601-2-25	Medical electrical equipment - Part 2-25: Particular requirements for the safety of electrocardio-graphs
IEC 60601-2-26 (ADIS}	Medical electrical equipment - Part 2: Particular requirements for the safety of electroencephalo-graphs
IEC 60601-2-27	Medical electrical equipment - Part 2: Particular requirements for the safety of electrocardiographic monitoring equipment
IEC 60601-2-28	Medical electrical equipment - Part 2: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis

IEC standard	Contents
IEC 60601-2-29	Medical electrical equipment - Part 2-29: Particular requirements for the safety of radiotherapy simulators
IEC 60601-2-31	Medical electrical equipment - Part 2: Particular requirements for the safety of external cardiac pacemakers with internal power source
IEC 60601-2-32	Medical electrical equipment - Part 2: Particular requirements for the safety of associated equipment of X-ray equipment
IEC 60601-2-33	Medical electrical equipment - Part 2: Particular requirements for the safety of magnetic resonance equipment for medical diagnosis
IEC 60601-2-34	Medical electrical equipment - Part 2: Particular requirements for the basic safety and essential performance of invasive blood pressure monitoring equipment
IEC 60601-2-36 (1CD)	Medical electrical equipment - Part 2: Particular requirements for the safety of equipment for extracorporeally induced lithotripsy
IEC 60601-2-37	Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
IEC 60601-2-39	Medical electrical equipment - Part 2-39: Particular requirements for the safety of peritoneal dialysis equipment
IEC 60601-2-40	Medical electrical equipment - Part 2-40: Particular requirements for the safety of electromyographs and evoked response equipment
IEC 60601-2-41 (CCDV)	Medical electrical equipment - Part 2-41: Particular requirements for the safety of surgical luminaires and luminaires for diagnosis
IEC 60601-2-43	Medical electrical equipment - Part 2-43: Particular requirements for the safety of X-ray equipment for interventional procedures
IEC 60601-2-44 (CCDV)	Medical electrical equipment - Part 2-44: Particular requirements for the safety of X-ray equipment for computed tomography
IEC 60601-2-45	Medical electrical equipment - Part 2-45: Particular requirements for the safety of mammographic X-ray equipment and mammographic stereotactic devices
IEC 60601-2-46	Medical electrical equipment - Part 2-46: Particular requirements for the safety of operating tables
IEC 60601-2-47 (RDIS)	Medical electrical equipment - Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems
IEC 60601-2-49	Medical electrical equipment - Part 2-49: Particular requirements for the safety of multifunction patient monitoring equipment
IEC 60601-2-50	Medical electrical equipment - Part 2-50: Particular requirements for the safety of infant phototherapy equipment
IEC 60601-2-51	Medical electrical equipment - Part 2-51: Particular requirements for safety, including essential performance, of recording and analysing single channel and multichannel electrocardiographs

IEC standard	Contents
IEC 60601-2-52	Medical electrical equipment - Part 2-52: Particular requirements for the basic safety and essential performance of medical beds
IEC 60601-2-53	Medical electrical equipment - Part 2-53: Particular requirements for the safety and essential performance of a standard communications protocol for computer assisted electrocardiography
IEC 60601-2-54	Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy
IEC 60601-2-56	Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement
IEC 60601-2-57	Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use
IEC 60601-2-62 (ACDV)	Medical electrical equipment - Part 2-62: Particular requirements for the basic safety and essential performance of high intensity therapeutic ultrasound (HITU) equipment
IEC 60601-2-63 (CCDV)	Medical electrical equipment - Part 2-63: Particular requirements for the basic safety and essential performance of dental extra-oral X-ray equipment
IEC 60601-2-65 (CCDV)	Medical electrical equipment - Part 2-65: Particular requirements for the basic safety and essential performance of dental intra-oral X-ray equipment

7.3 Appendix C

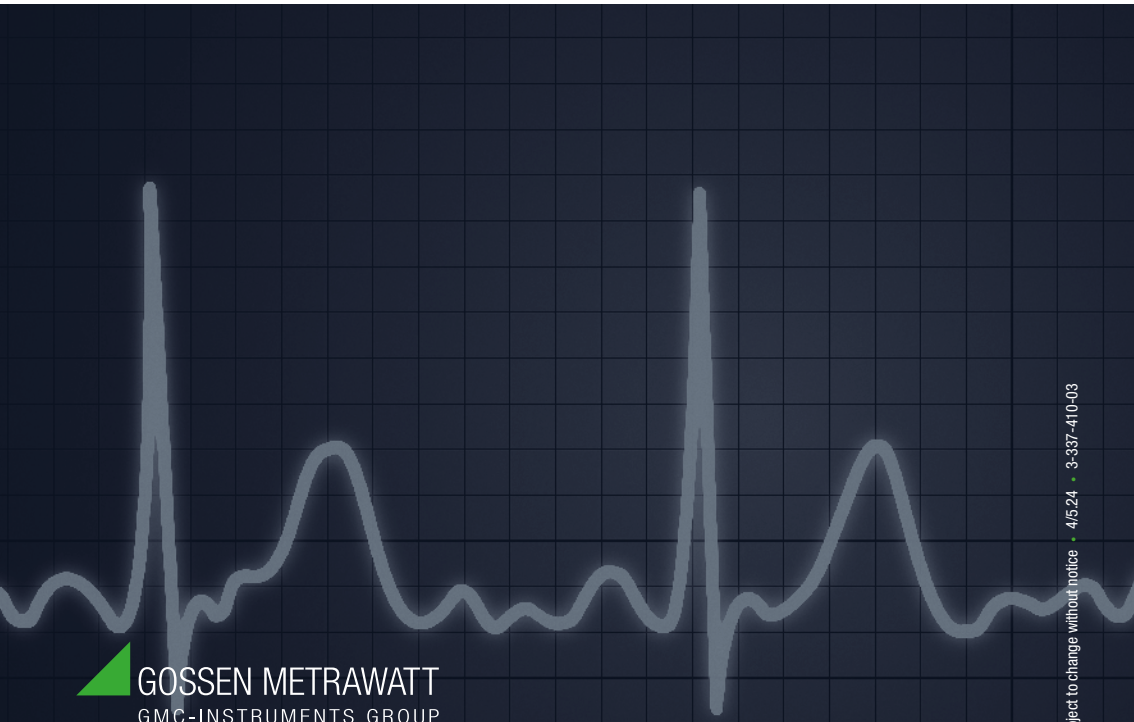
Specialist medical technology terms

Term	Explanation
Abdomen	Stomach
Abuse	Misuse, e.g. alcohol misuse
Achalasia	Disorder of the oesophagus, see also dysphagia
Adiposis	Overweight, obesity
AED	Automated external defibrillator
Anamnesis	Medical history
Aneurysm	Dilation of a blood vessel
AOD	Arterial occlusive disease
Aorta	Main artery
Apoplex	Stroke
Appendicitis	Inflammation of the appendix
Arrhythmias	Heart rhythm disturbances
Ascites	Fluid in the abdomen
Asystole	Flatline
Atrium	Chamber of the heart
Bradycardia	Excessively low heart rate
Carcinoma (abbrev.: ca)	Malignant tumour in the epithelium
Caudal	“Towards the tail“; towards the end of the spinal column
Cecum or caecum	A pouch that forms the first part of the large intestine
Chemotactic	Attracted by chemical attractants
Coagulation	Clotting
Colon	Large intestine
Cranial	Towards the head
CVC	Central venous catheter (inserted via the neck)
Cyst	Clearly defined collection of fluid, demarcated, lined by epithelium, non-flowing
Decubitus	Wound dressing ulcer; pressure sore
DHC	Ductus hepaticus communis (common hepatic duct), part of the bile duct system
Diabetes mellitus	Diabetes
Diastole	Relaxation of the heart muscle
Dilated	Widened
Distal	Part of an extremity located away from the body
Diverticulum	Dilation of the bowel, oesophagus or bladder
Ductus cysticus	Cystic duct

Term	Explanation
Duodenum	Duodenum
Dysphagia	Swallowing difficulties; problems and pain on swallowing
Dyspnoea	Respiratory distress
ECG	Electrocardiography
ED or MS	Multiple sclerosis
Electrotomy	Electrical cutting
Epithelium	Covering/lining tissue (e.g. skin, mucous membrane but also glands)
Filiae	Metastases (spreading of a tumour to the liver, bone, lung etc.)
Haematoma	Bruise
Haemodynamics	Pumping effect
Hypertension	High blood pressure
Hypertensive	Reducing blood pressure
Hyperthyroidism	Over-functioning of the thyroid
Icterus	Jaundice
Insufficiency	Reduced functioning
Intestinal colic	Cramp-like stomach ache caused by peristalsis
Intoxication (intox)	Poisoning
Ischaemia	Lack of blood supply, anaemia
-itis	Inflammation
Jejunum	Jejunum
Latent	Concealed underneath the surface
Lateral	At the side
Leiomyoma (fibroid)	Benign muscle tumour
Medial	In the middle
MI	Myocardial infarction
Mobilisation	Either moving the patient from the bed, e.g. mobilisation following a heart attack or physiotherapeutic measures following a heart attack
MR	Mitral regurgitation (leakage in the mitral valve)
MS or ED	Multiple sclerosis
Narcosis	Artificially created temporary sleep-like state of consciousness and pain perception
Necrosis	Circumscribed (demarcated) dead tissue caused by a metabolic disorder due to cell damage
Negative list	List of medication, remedies and aids that are excluded from payment by statutory health insurance schemes and that must not be prescribed on a public health insurance prescription
Neonatal	Newborn
Nephrectomy	Surgical removal of a kidney

Term	Explanation
Nephritis	Inflammation of the kidney
Nephrolithiasis	Kidney stone disease
Nephros	Kidneys
Neuralgia	Nerve pain
Neurasthenia	Nervousness
Neuritis	Nerve inflammation
Neurology	Area of medicine that incorporates all measures for the diagnosis and treatment of the nervous system and the organs influenced by the nervous system
Neuroses	Disorders of behaviour and experience as well as functions and mental state, with no organic cause
Neurotoxins	Substances that are toxic to nerves and that cause particular damage to the nervous system
Neutrophils	A type of white blood cell
Nitrosamines	Nitrogen-nitroso compounds, many of which are considered to be carcinogenic
Nocturia	Increased night-time urination even without consuming large amounts of fluid in the evening (in healthy people, urination primarily occurs in the daytime)
Noxins	Body protein decomposition products with toxic (poisonous) effect
Occlusion	Closing
Oedema	Collection of fluid in the tissue
Oesophagus	Oesophagus
Pancreas	Pancreas
Patho	Pathological
Pathology	Research and teaching of disease conditions
PEG	Feeding tube inserted into the stomach via the abdominal wall
Perfusion	Passage of fluid through the blood vessels
Pericardium	Pericardium
Peritoneum	Peritoneum
Phenylketonuria	Protein metabolism disorder
Plethysmograph	Pulse wave curve
Pleura	Pleura
Pneumonia	Pneumonia
Positive finding	A (particular) disease is present
Postprandial	After eating
Preprandial	Before eating
Prophylaxis	Precaution
Prospermia	Premature ejaculation as a result of a disorder
Proximal	Part of an extremity located near to the body
Pulmonal	Relating to the lung

Term	Explanation
Pyelon	Renal pelvis
Rectum	Rectum
Refractory period	Temporary lack of excitability
Respiration	Respiration
Retrograde	Against the blood flow
Rupture	Tear, break
Sarcoma	Malignant tumour of the connective tissue
Sclerosis	Hardening, scarring
Sepsis	Blood poisoning
Septum	Wall separating the ventricles and the atria in the heart
Sodium chloride	Salt
Spasmodic colic	Cramp-like pain, cramping of a muscle, e.g. renal colic
Stenosing	Constricted, blocked
Stenosis	Constriction
Sternum	
Stoma	Artificial outlet in the abdominal wall
Struma	Goitre
Syncopes	Blackout; temporary loss of consciousness
Systole	Contraction
Tachycardia	Reduced cardiac output; fluttering
Thorax	Rib cage
Toxic	Poisonous
Toxin	Poison
Tracheotomy	Tracheotomy
Transcutaneous	Through the skin
Transverse	Across
Traumatic brain injury	A violent impact on the skull can cause a commotio cerebri (concussion)
Ulcus	Ulcer
Ulcus cruris	Leg ulcer
Ureter	Tube from the kidneys to the bladder
Urethra	Tube from the bladder to the outside
Vena cava inferior	Vena cava inferior
Vena cava superior	Vena cava superior
Ventricle	Chamber (heart, brain)



GOSSEN METRAWATT
GMC-INSTRUMENTS GROUP

Gossen Metrawatt **GmbH**
Südwestpark 15 ▪ 90449 Nürnberg ▪ Germany
Phone +49 911 8602-0 ▪ Fax +49 911 8602-669

www.gossenmetrawatt.com ▪ info@gossenmetrawatt.com

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