# Inspection and Testing of Electrocardiographs (ECG) Devices

**Ratko Magjarević and Almir Badnjević**

**Abstract** Electrocardiographs are nowadays standard part of diagnostic procedure in healthcare systems since they have high significance in diagnosis of large number of diseases and disorders. Due to development of technology, especially electronics, these devices have been revolutionized since the first prototype was invented. Nowadays, these devices are able to perform automated diagnosis and measure multiple parameters at once. Multiple international standards define device life circle, from production to disposal. However, this sophistication of ECG devices raises numerous questions regarding safety and accuracy. This chapter describes basic principles of electrocardiography and ECG devices as well as gives overview of requirements in area of safety and performance inspection of these devices.

## 1 Historical Aspects of Electrocardiography

Electrocardiography (ECG) is the method of measuring of electrical potentials of the heart in order to discover heart related health problems. The recordings of the potentials of the heart (on paper or on other media) are called the electrocardiogram and the medical device used for the recording are electrocardiographs (the same abbreviation ECG is used for all three terms). The potentials of the heart are recorded against time. The procedure is undertaken from the body surface during standard check-ups, when only a few seconds of the ECG are printed on paper or viewed on a monitor. However, in cases of patients suffering from a heart disease, recordings may be taken for a much longer period, e.g. during emergency or in

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intensive care. In case the abnormality in the heart potential appears rarely, over a period of time longer than a few hours, the ECG is recorded by an ECG holter, typically for 24 h. Digitized signals are stored in a memory, for further computerised analysis. For the recording, electrodes are placed in standardised positions on a patient's body. An ECG is an important part of every preventive medical check-up and it is mandatory for assessment of a patients who are suspected to have a heart related problem. The ECG is considered as an extremely safe procedure and without any risk involved. Adverse effects reported in rare cases, deal with skin irritation from the electrode adhesive. Though ECG is an important procedure in evaluation of cardiac patients, additional examinations are undertaken to get the full picture of symptoms and the disease. In some cases, normal recordings are obtained in patients with heart disease, or some recorded parts of ECG may be recognised as pathological despite the heart is in normal condition. The ECG provides information about the heart's electrical activity and has a great value in finding the causes of symptoms like chest pain or pressure. It is used for interpretation of the severity of a heart attack, inflammation of the pericardium, angina or other symptoms of heart disease like shortness of breath, dizziness or even fainting, and of arrhythmias. By ECG interpretation, physicians may conclude on some physical dimensions of the parts of the heart, e.g. the thickness of the heart chambers walls. ECG reflects the efficiency of medication and enables finding of their side effect. Surface ECG is also used in regular control of implanted devices for heart management, like pacemakers and cardioverters—defibrillators (though modern implantable devices enable telemetric measurement of intra-cardiac ECG). It is also used in assessment of the health of the heart in presence of other diseases or conditions, e.g. high blood pressure, high cholesterol, diabetes, a family history of early heart disease or history of smoking [1, 2].

The first observations of effects of electricity on animal tissues happened in late 17th and early 18th century. The Italian physicist and physician Luigi Galvani noted that touching dissected frog's leg with a metal scalpel causes their twitches and explained it with "animal electricity". Later he showed muscle contraction when contacting them to an electrical generator. A very sensitive device for measurement of small voltages and currents is named a "galvanometer" in his honour. Galvani's research was continued by another Italian scientist and inventor, Alessandro Volta, who showed twitching of frog leg muscles due to electrical current generated by plates of two dissimilar metals set against the muscles.

Willem Einthoven (1860–1927), a Dutch physician and physiologist, introduced to medicine the first practical electrocardiograph based on spring electrometer and introduced the term electrocardiogram for changes in the observed potentials [3], Fig. 1. One may today discuss how really practical that device was, since it had a mass of approx. 270 kg and for recording, the examinee was asked to immerse his hands and a leg into containers with salt water which were serving as electrodes. That formation is still used in routine ECG recording named the I, II and III standard limb leads, while the imaginary triangle these measurement points build is named Einthoven's triangle. Einthoven introduced the letter nomenclature for those five deflections which can be recognised in the ECG: P, Q, R, S and T (and later

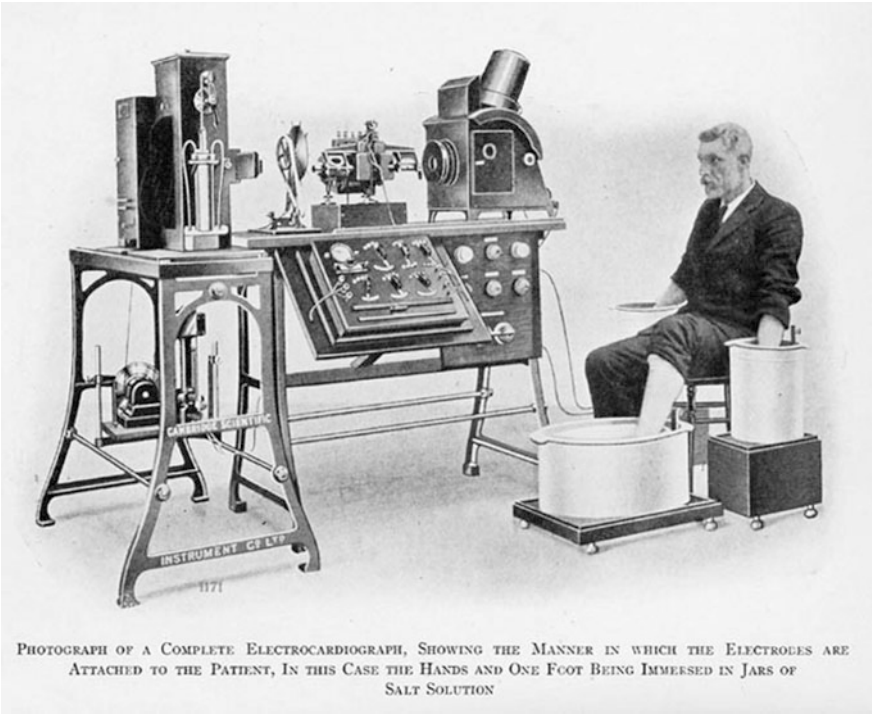


**Fig. 1** An early commercial ECG machine, built in 1911 by the *Cambridge Scientific Instrument Company* [4]

also the U wave). In his publication from 1906, Einthoven described normal and abnormal electrocardiograms recorded by the string galvanometer. In 1924, he was awarded the Nobel Prize in Physiology or Medicine for his discovery of the mechanism of the electrocardiogram [3].

In order to make ECG recording practical, a lot of technological improvements were necessary. Amplifiers with vacuum tubes were introduced in 1928 by Ernstine and Levine [5], and later cathode ray tube for displaying the potentials on the screen. Electrocardiographs designed in analogue technology were equipped with chart recorders, where the first models were writing with ink on grid paper and later using hot wire on temperature sensitive paper. Containers with salt water were replaced with dry electrodes only in 1930s by silver plate electrodes and by suction electrodes, normally used for recording the precordial leads [6]. Early ECGs used vacuum tubes and were therefore heavy, unreliable and they had large power consumption. Invention of silicon transistor in 1947 enabled production of smaller and more practical ECG devices and facilitated diagnostic use of the ECG, Fig. 2.

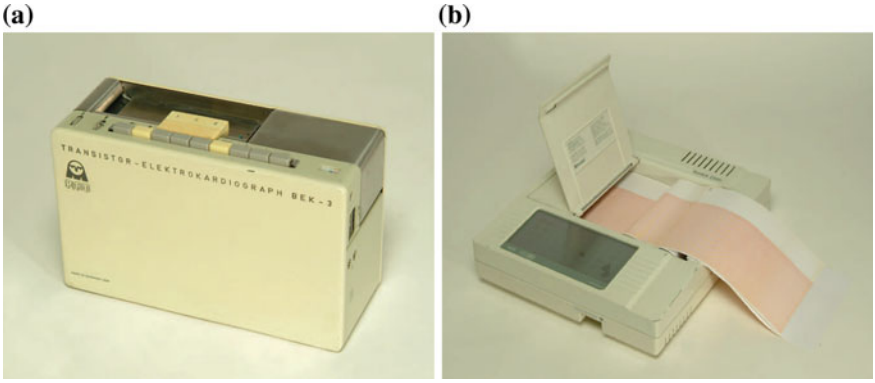


**Fig. 2** **a** Single channel ECG—Transistor—Elektrokardiograph BEK-3 from 1970 and **b** Multichannel ECG Siemens Burdick E 550 approx. 1995

## 2 Medical Aspects

Measurement and analysis of the potentials of the heart has a high diagnostic value and there is a large number of diagnoses that can be determined from the ECG, much more than from any other bioelectric potential. The normal ECG waveform has a regular shape, where five characteristic parts may be easily recognised in time in nearly every standard lead records: P-wave, QRS complex and T-wave. The ECG signal differs from person to person, but it has quasi stationary behaviour. The spectrum of the ECG is characterised mainly by the shape of the five characteristic parts, their time relations within the cardiac cycle and by the variability of the hearth rhythm. The analysis of the ECG enables determination of most irregularities and arrhythmias of the heart muscle.

The heart is a hollow muscle organ consisting of four chambers. The heart is filled with blood and enables the circulation of the blood in the cardiovascular system by regular rhythmic contractions. The heart receives the blood from the veins and pumps it out into the arteries, Fig. 3. The right and the left part of the heart consist each of two chambers, the atrium and the ventricle, and they are separated by a muscle called septum. The left ventricle is the strongest muscle of the heart and it pumps the blood to the largest vessel—the aorta. The directed blood flow in the cardiovascular system is regulated by the rhythmic contractions of the chambers, firstly by synchronous contraction of the atria and then by synchronous contraction of the ventricles. Backflow (reflux) of the blood from ventricles to atria, and from arteries to ventricles, is disabled by four heart valves. The valves are positioned as follows: in the right heart, the tricuspid valve is between the atrium from the right ventricle, and the pulmonary valve between the right ventricle and the pulmonary arteries, whereas in the left heart, the mitral valve is between the left atrium and ventricle and the tricuspid valve between the left ventricle and the aorta.

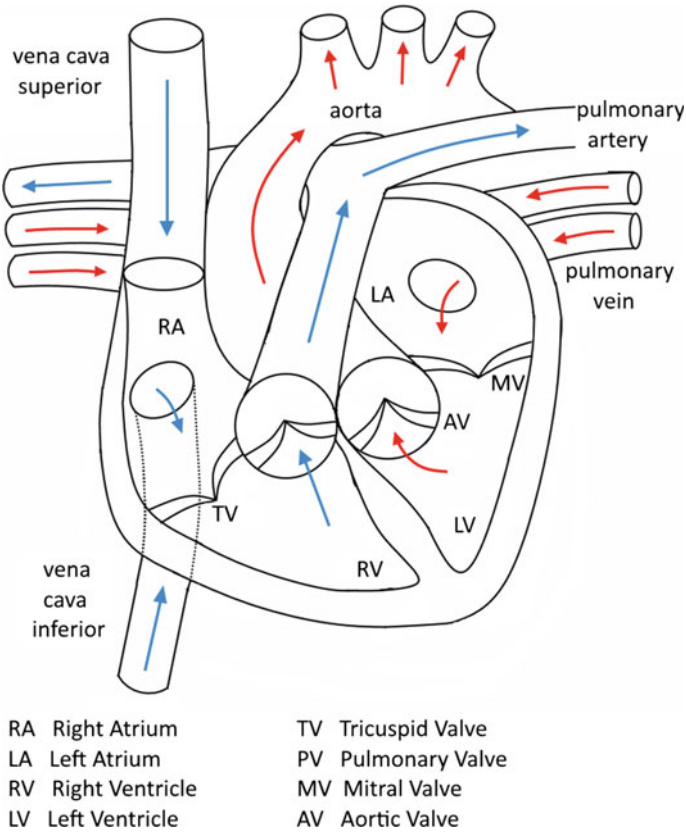


**Fig. 3** Cross-section and blood flow of the heart

The pumping phase of the heart cycle is designated as the systole, and the resting phase as diastole. The contraction of the heart muscles is ruled by precise electrical activity of a specialized conduction system of the heart. The normal cardiac cycle is initiated by activity of special cells positioned on the top of right atrium, at the sinoatrial node (SA) (Fig. 4). These cells are the natural pacemaker of the heart. From the SA node, the depolarization spreads over the whole atria, causing the contraction of atrial tissue. Since the atria and ventricles are separated by a fibrous ring with low conductivity, the electrical depolarization from atria enters ventricles through the atrioventricular (AV) node which generates a short delay in spreading the depolarization. From the AV node, the depolarization spreads by the bundle of His through the left and the right bundle to the left and the right ventricle. In normal rhythm, the contractions of the left and the right heart happen simultaneously, enabling the heart to efficiently pump out the blood into the arteries. The heart is positioned in the thorax between the lungs, protected by the pericardium, the breastbone and the ribs, and covered by a thin layer of muscles that enable

breathing and with the skin. The electrical properties of these tissue are different between themselves but as a whole they act as a low pass volume filter so that the potentials recorded at different positions on the heart significantly differ from the surface ECG (Fig. 4).

The electrical activity of the myocardium (cardiac muscle) is reflected in the surface ECG, Fig. 5. In normal ECG, the P-wave represents the depolarisation of the atria. The QRS complex the depolarisation of ventricles, where the repolarisation of the atria is covered by the much stronger signal of ventricular depolarisation. The T-wave represents the repolarisation of the ventricles. In interpretation of the ECG, the S-T segment has an important role since its waveform, in particular the deviation from the baseline, may designate a serious damage of the heart muscle, e.g. the elevation of the ST-segment may designate acute myocardial infraction. The interval between two R peaks, R-R interval, is often used for calculation of the heart rate since it is its reciprocal value. The normal heart rhythm (also called normal sinus rhythm) lies between 50 and 100 beats per minute (in adult healthy person). Normal heart rate in resting varies a little, and the variation is larger since it adopts to the activity of the person, Fig. 6. Deviations from normal heart rate are called arrhythmias: slow heart rate is called bradycardia and fast heart rate tachycardia. Sustainable long-term tachycardia may lead to ventricular

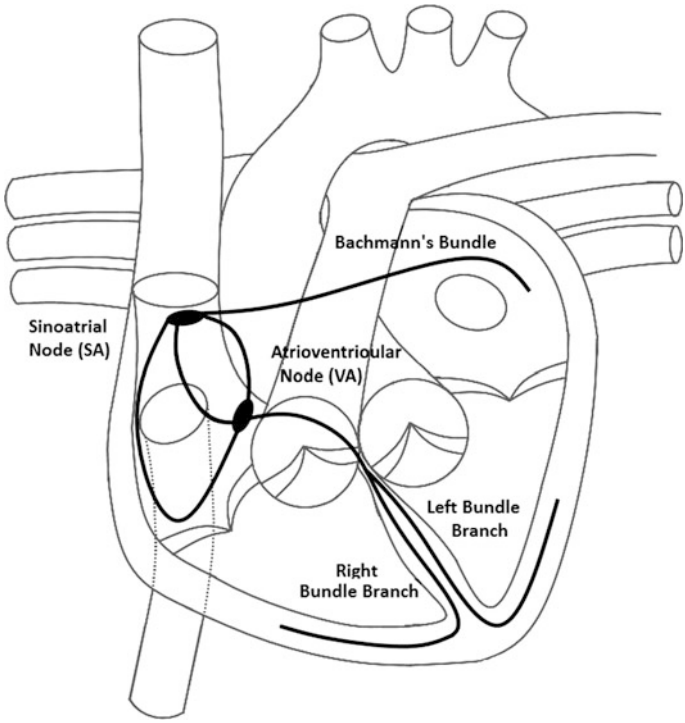


**Fig. 4** Conduction system of the heart

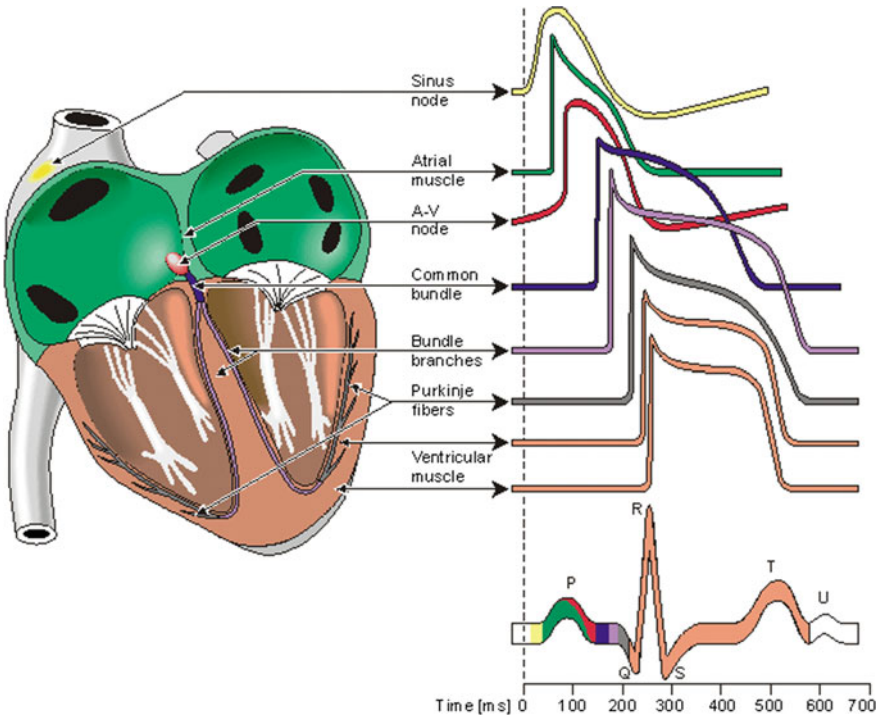


**Fig. 5** Action potentials at different positions within the heart [6]

fibrillation which, in case it is not stopped timely, leads to the death. Since in ventricular fibrillation there is no regular, and synchronized contraction of muscle fibers, the blood flow stops and the oxygen supply of the brain is interrupted. Other frequent deviation from regular heart rhythm includes appearance of ectopic beats, generated by cells in myocardium with lower excitation threshold, which fire asynchronously as referred to the normal heart rhythm and do not contribute to the heart output since they are premature. Interruption in conducting of the pulses from atria to ventricles is called atrioventricular block and leads to absence of ventricular contraction. It can be recognised as missing R peak after a P-wave.

## *2.1 ECG Electrode Placement*

Electrodes are the necessary interface for connecting human body to medical electronic instrumentation. In case of ECG recording, the electrodes can be attached to the surface of the body or implanted. In this chapter, authors consider only recording of surface ECG, so only surface electrodes will be described.

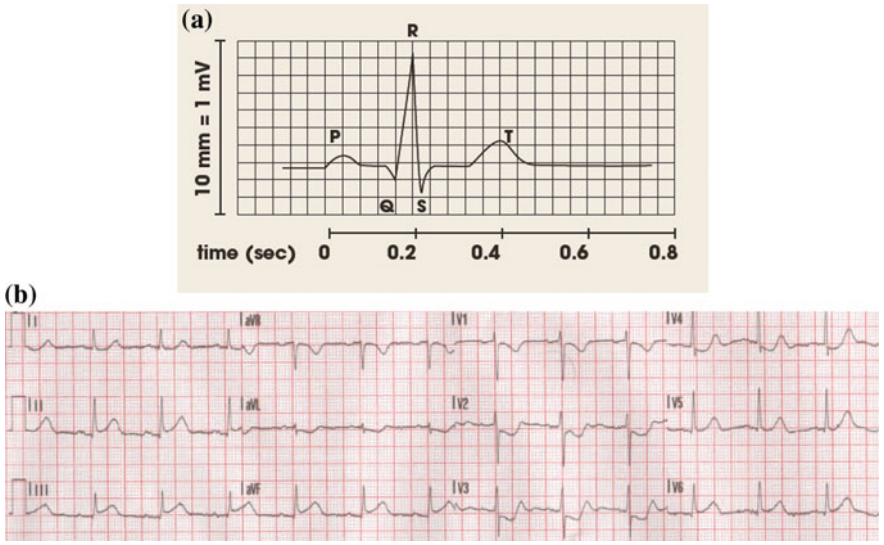


**Fig. 6** Characteristic ECG wave shape **a** symbolic and **b** measured

ECG electrodes are transducers which enable exchange of charge carriers in the system consisting of the human body and the medical device. In the body, charge carriers are ions of both polarities, and in the electronic equipment, the carriers are electrons. Though electrodes seem to be simple in their design, they may cause a lot of interference and noise at the interface. More on technical characteristics of electrodes is presented in the technical description of the ECG equipment later in this chapter.

From the point of interpretation of the ECG, physicians evaluate the recorded curves by comparing them to the recordings they have previously seen and used in their training, and from the experience they got practicing medicine. The American College of Cardiology Foundation stated that it takes 3,500 supervised ECG reads to become an expert [7]. Since the ECG records vary between individuals, a lot of skill is necessary to observe the common in ECG features. Placement of recording electrodes always to the same position on patient's body establishes a reference that helps in observing those common characteristics that lead to accurate diagnostics. For practical reasons, the electrodes for standard ECG recording are positioned on human extremities being easily accessible and the housing of electrodes is colour coded so that they enable rapid connecting to a medical device for e.g. recording in emergency cases, Fig. 7.

Standard ECG recording presents bioelectric potentials of the heart recorded in 12 traces and by 10 electrodes positioned on the body [1]. The potentials measured in-between the electrodes are called leads. The leads can be explained as projections of the heart vector to different planes on the body, as shown in Fig. 8. All leads together represent the heart vector projection in practically all directions, which

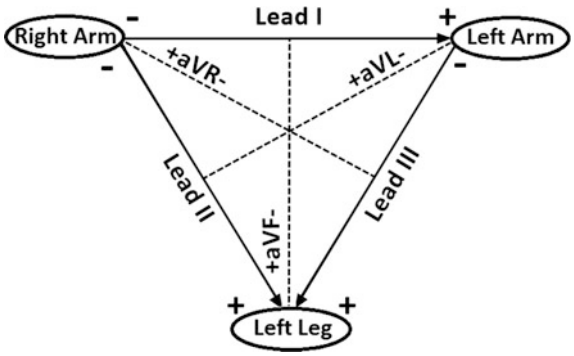


**Fig. 7** Standard electrode placement

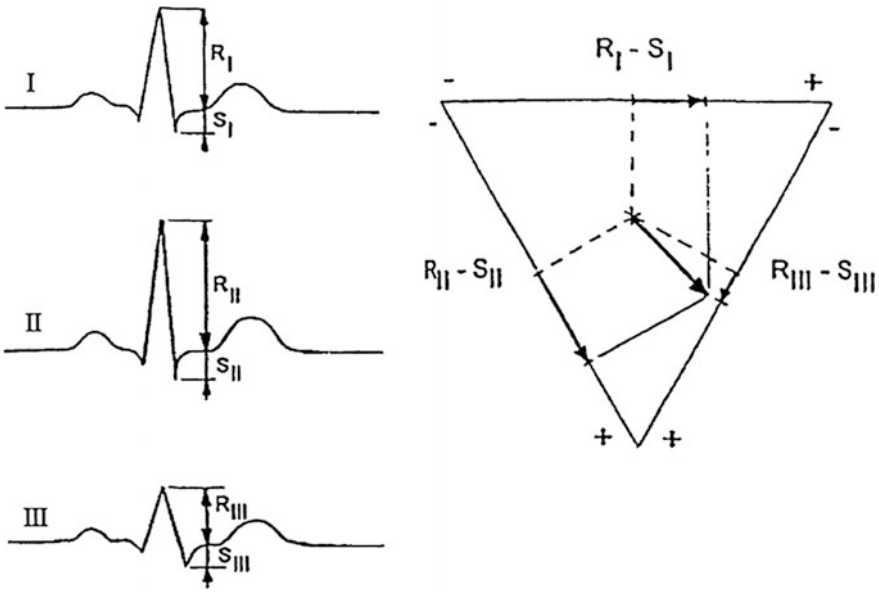


**Fig. 8** Calculation of the heart vector

means that they the information on electrical activity of the heart is acquired with high spatial resolution. Those 12 leads are organized as follows:

- Three bipolar limb leads,
- Three augmented limb leads,
- Six precordial or chest leads.

Four electrodes are placed on the all four extremities of the human body (therefore also called limb electrodes) on predefined places slightly proximal to the hand and the ankle. These positions are designated by:

- LA standing for left arm,
- RA standing for right arm,
- LL standing for left leg and
- Ground for the reference electrode, positioned on right leg.

The limb electrodes are used for bipolar or differential measurement of the potentials between them and they form the I, II and III standard leads of the ECG with the orientation of the polarity as shown in Fig. 7. These leads are also called Einthoven leads since they are based on the first, historical ECG measurement performed by Einthoven.

The same limb electrodes are used for augmented leads which are unipolar measurements where the potential present at a particular electrode is measured against the average value of the potentials from the other two electrodes. The augmented leads are also called Goldberger's leads in honour of Emanuel Goldberger who introduced the leads to electrocardiography in 1942 in order to increase the recorded voltage aginst Wilson's central terminal. The projections of the heart vector of augmented leads are shown in Fig. 7. The augmented leads are marked $aV_R$, $aV_L$ and $aV_F$.

Precordial or chest leads measure the potential of from the electrodes positioned on the rib cage of a patient in a predefined way against the potential of a reference electrode. The potential of the reference electrode is defined by connecting each of the three limb electrodes through a resistor of 5 kΩ into the reference node which is considered to have 0 potential. The reference node is called Wilson's central terminal or electrode and the precordial leads got the name Wilson's leads and are labelled as $V_1$–$V_6$.

## 2.2 *Bipolar Leads and Einthoven's Law*

The potentials measured between the limb electrodes are projections of the heart vector to the Einthoven equilateral triangle. Einthoven's Law states that the electrical potential of any limb equals the sum of the other two. The electrodes and the polarity when the ECG is measured by the standard limb leads is the following (Fig. 8):

- Lead I—The negative terminal of the ECG amplifier is connected to the right arm, and the positive terminal is connected to the left arm.
- Lead II—The negative terminal of the ECG amplifier is connected to the right arm, and the positive terminal is connected to the left leg.
- Lead III—The negative terminal of the ECG amplifier is connected to the left arm, and the positive terminal is connected to the left leg.

Einthoven's Law states that the electrical potential of any limb equals the sum of the other two (+ and − signs of leads must be observed).

## 2.3 Cardiac Vector

Vectors are used to describe depolarization and repolarization events of the heart muscle. Cardiac vector shows the direction of charge spread in the heart muscle as they happen in time and the magnitude of the electrical activity (Fig. 8). Each lead of the ECG represents a projection of the cardiac vector into different plane. The standard three leads and the augmented leads show each the projection of cardiac vector into a plane which is 60° rotated from the previous lead (Fig. 7). In case there is no electrical activity of the heart, the projection is zero and the ECG shows the baseline, a horizontal line.

Standard record of an ECG is on paper or on the screen of a monitor. In order to make it adopted for measurement in time (duration of ECG waves, segments etc.) the printing is calibrated so that 1 mm equals 40 ms at standard paper speed 25 mm/s. In case better time resolution is needed for diagnostics, paper speed is increased to 50 mm/s. The electrical axis of the heart is a sum of all vectors activated in a particular chamber of the heart. In such a way, each part of the ECG has its own respective vector.

## 2.4 Recording of an ECG

Since the ECG is one of the most informative diagnostic examination of the heart and cardiovascular system, it became a routine procedure in screening patients.

The routine procedure is taken with the patient laying on a bed. The patient's skin on the positions provided for electrode placement on the chest and the extremities are cleaned and the electrodes attached. In standard procedure, suction electrodes are attached to the chest and clip electrodes to the arms and legs. The electrodes are connected to the cables of the electrocardiograph and after the patient calms down, the recording begins. The patients have o remain still during the recording. They may be asked to hold breath for a few seconds. Any movements during the recording may introduce artefacts which degrade the potentials of the heart. In some patients, the diagnostic procedure is specified as a stress test, and then it is recorded under controlled exercising. The recorded electrocardiograms are reviewed by physicians.

Patients taking any kind of medication should inform the physician. They should not be physically active before the test. The procedure itself is comfortable and patients feel well during and after the test.

The diagnostic value of the ECG primarily in screening of cardiac arrhythmias and abnormalities of the conduction system of the heart, as well as in detecting

myocardial ischemia. The ECG is used for monitoring of drug intake and of the performance of implanted devices like pacemaker. The ECG is also used in interpretation of hypertension, cardiomyopathy, valvular disease, metabolic diseases and many others.

## 3 ECG Devices—Technical Description

An electrocardiograph (ECG) is a measuring device and it is designed as an open measurement channel. The main parts of the ECG are: a set of electrodes, a lead selector, an amplifier, filters, a printer and/or a display unit. The ECG may be designed as a 3 channel, 6 channel or a 12 channel device, though for a number of years 12 channel device dominate since they match to 12-lead standard in ECG interpretation. The device is able to record bipolar, augmented and precordial leads. Many multichannel electrocardiographs acquire and analyse the ECG signals since they have embedded microprocessors with ECG signal processing software. The signals recorded at the surface have a range of magnitude of 1 mV and the spectrum between 0.05 and 150 Hz [8]. The block diagram of an analogue front end of an electrocardiograph is presented in Fig. 9. In Fig. 10, a block diagram of an integrated circuit with ECG capabilities is presented. Immediately after amplification, the signals are digitized and further processed digitally. Front-end sampling may be performed at rates from 1000 to 2000 samples per second. Active right leg drive (RDL) is integrated to the circuit as well. Detailed descriptions of the functionalities of the ECG integrated circuits may be found at the Internet sites of leading integrated circuits producers, Fig. 10.

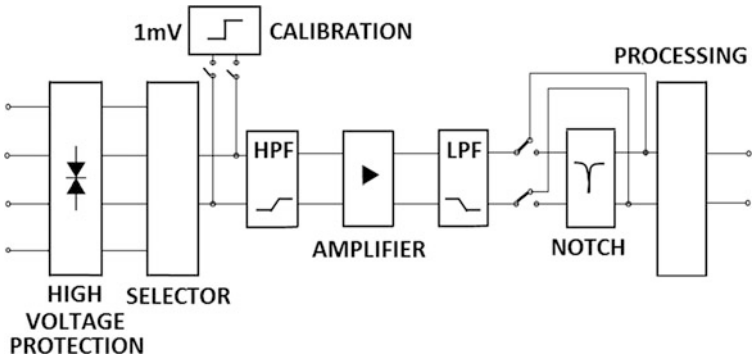


**Fig. 9** Block diagram of an electrocardiograph with analog front end

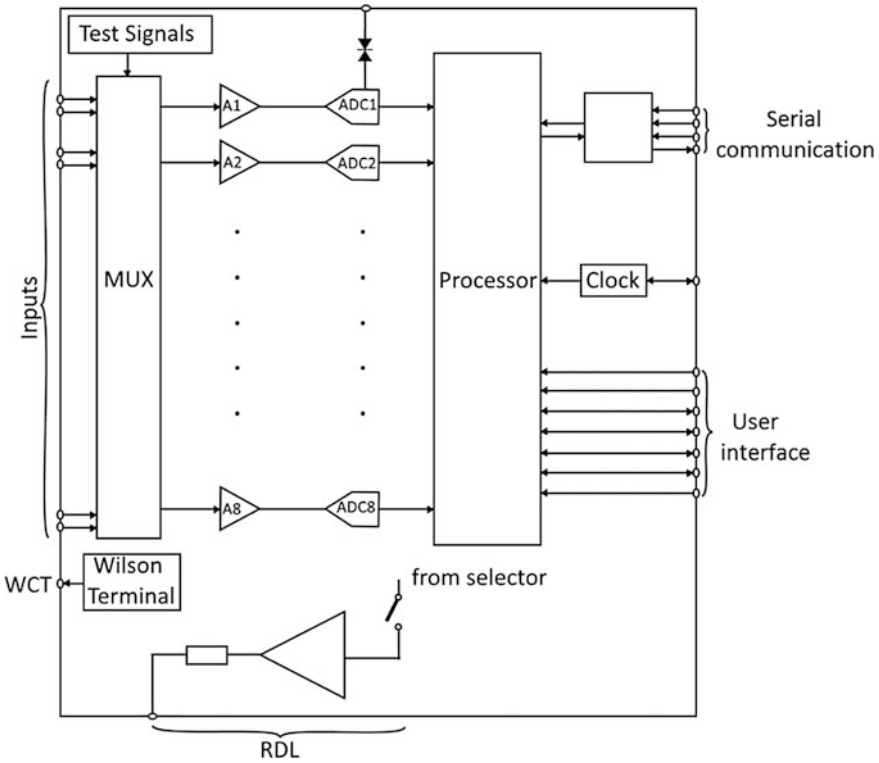


**Fig. 10** Block diagram of an integrated circuit comprising many functionalities of an electrocardiograph

## *3.1 Electrodes*

Electrodes for recording biopotentials are usually produces of an inert metal. In ECG, most commonly silver-silver chloride (Ag-AgCl) or stainless steel are used due to their biocompatibility and chemical stability. Each metal electrode that is in contact with electrolyte (which is always present in biological tissue), produces a double layer where positive ions are attracted to the electrode surface and negative ions forms adjacent to it. The potential drop over the double layer is called half cell potential, which changes in time with changes of ion concentration and temperature. The characteristic of Ag-AgCl electrodes is a constant half cell potential of approximately 0.8 mV. Clip and suction electrodes are usually reusable while selfadhesive ECG electrodes are expendable. They carry a conductive gel soaked sponge under the snap which is applied to the skin once the electrodes are attached into the position for recording. The conductive gel lowers the resistance of the skin under the electrode which contributes to the quality of the recording because it is

lowering the sensitivity of the input stage to interference. Conductive gel may be applied to the skin after cleaning out of the same reason [8].

## 3.2 Lead Selector

Electrodes are connected to the input stage of the ECG by shielded cables with a standardised electrode snap on the electrode end. In the input stage of the device, overvoltage protection circuit in built-in immediately at the front end. The selector has the function to connect the signals from the electrodes to the input of the particular amplifier, directly or through a resistor network so that the selected leads are amplified, processed and displayed according to the number of channels of the ECG. The functionality of the selector is realised by a multiplexer. An important part of the input stage is a calibrator which has to be connected to the input stage in order to ensure that all parts of the measurement channel are calibrated. The calibration of ECG devices is provided by connecting a 1 mV step function to the input of each measurement channel. For devices with printers and paper with millimetre grid, the deflection for 1 mV input voltage should be calibrated to 10 mm [8].

## 3.3 Amplifier

Amplifiers for bioelectric signal must have high sensitivity due to low amplitudes of the original signals. High amplification is achieved by multiple stages of amplification in the measurement channel, though the realisation of these stages is mainly within integrated circuits. For amplification of ECG signals, in the input stage, instrumentation amplifiers are used most commonly. Instrumentation amplifier have very high amplification (100–120 dB), very high input impedance (10 MΩ) and a symmetrical structure of the input stage, which all enables realization of a high common mode rejection ratio (CMRR) of the amplifier. CMRR is a measure of suppression of common mode voltage, compared to amplification of the useful bioelectric signals and should be above 100 dB for biopotential amplifiers. The bioelectric signals are prone to electromagnetic interference, especially from the electrical power lines (230 V/50 Hz in Europe) which are superimposed to the useful ECG signal [2].

The signal at the input of the ECG measurement chain consists of four fractions:

1. The measured bioelectric potential (ECG), considered to be the useful signal, with an input range from 50 μV to 1.5 mV.
2. Polarisation voltage which is the difference between the half-cell potentials of two electrodes, ergo, a DC voltage up to 300 mV. The appearance of the polarisation voltage is avoidable whenever the skin is in contact with metal electrodes.

3. Interference from the AC mains frequency (50 Hz or 60 Hz) from line voltages appears as a common mode signal with amplitudes up to 100 mV. Human body, electrodes and connection cables act as an antenna also for signals with higher frequencies but those signals are usually much easier to filter out due to limited frequency range of ECG amplifiers.
4. Interference high voltages that appear at the input of an ECG device are mainly caused by defibrillator shock voltages or by RF surgery equipment. The defibrillator shock can be treated as a single event and the energy of the shock is always known—up to 400 J. The voltages generated by the defibrillator may reach a few thousand volts, but have limited duration. However, the shocks may be repeated several times. Electrosurgical RF devices produce voltages up to a few hundred volts at a frequency between 500 kHz and 5 MHz, but the duration of the application of the voltage through the body is much longer as compared to the defibrillator shock [9]. The protection circuits that are built into the input stage of the ECG protect the internal circuits and the patient from those potentially dangerous voltages.

From the above analysis of the complex signal that can appear at the input of the ECG measurement chain, it is easy to conclude that the bioelectric signal is the weakest and therefore the processing strategy for the input stage has to be well deliberated.

In order to protect the patient from the mains voltage and the other potentially dangerous voltages coming from the mains, and also to protect the device from overvoltage potentially appearing at the patient side e.g. due to defibrillation, the ECG amplifier is in many designs realised as an isolation amplifier. The isolation circuit separates the patient side and the device side with an isolation barrier which can withstand an electrical shock up to 7.5 kV.

## *3.4 Filters*

The frequency range of diagnostic ECG signal spans from 0.05 to 150 Hz thus the instrumentation in the signal processing channel has to band-pass those parts of the ECG spectrum. The electronic filtering circuits for low pass and high pass filter are designed separately. The high pass filter is applied to remove the polarization voltage (DC component) which may be two orders of magnitude larger than the ECG itself and could drive the input amplifier into saturation, and the very slow components of the signal which correspond to wondering of the baseline. The low pass filter removes artefacts from muscle activity and any high frequency interference. Some parts of the myoelectric spectrum overlap with the spectrum of ECG so that remains of the EMG signal can be observed in the records. Also some of the movement artefacts cannot be efficiently removed from the ECG since they spectrums overlap.

The interference from the mains voltage may be eliminated by a notch filter with the central frequency at 50 Hz or 60 Hz. However, due to narrow frequency range of notch filters, analog notch filters have a pronouncedly non-linear phase characteristic, and may change the wave shape of the ECG trace significantly, which may lead to wrong interpretation in reading of the ECG record [10]. Filtering of power noise from ECG is performed mainly by high order linear phase digital filters where the design keeps flatness of the band pass characteristic.

### *3.5 Display Device*

Contemporary electrocardiographs have low power displays and in most cases an embedded printer or wireless connection to a network printer. Digital records may be stored in an appropriate database as a part of the electronic health record of the patient. Electrocardiographs equipped with only paper printers are very rare today.

### *3.6 Final Assembly*

The components of the electrocardiograph are assembled and placed into an appropriate metal frame. The finished devices are then put into final housing along with accessories such as spare electrodes, printout paper, and manuals. They are then sent out to distributors and finally to customers.

## 4 Safety Aspects

Legal and technical requirements for all those who manufacture and design electromedical devices are numerous and may be dependent on the particular requirements in different regions. In Europe, the legal aspects are regulated by the Medical Device Directive (Council Directive 93/42/EEC of 14 June 1993. The Directive intends to harmonise the national laws that relate to medical devices within the European Union and it is a "New Approach" Directive which means that safety aspects relay on Harmonized Safety Standards for the products, including medical electrical equipment. Devices meeting "harmonised standards" are considered to meet the conformity to the Directive which is confirmed by issuing of the CE mark by a EU Notified Body. The Directive was amended by the 2007/47/EC and the revised directive became mandatory in EU on March 21, 2010. In April 2017, a new regulation on medical devices was adopted in the European Parliament—Regulation (EU) 2017/745. The Commission claims that Regulation brings more consistency into legislation covering safety of medical devices but also adaption of significant technological and scientific progress occurring in the sector in recent

past. The new regulation on medical devices will be applied after a transitional period of three years, i.e. in 2020.

The "New Approach" takes standards, which are technical specifications defining requirements for products, production processes, services or test-methods as the measure for safety of products. The specifications are voluntary, but they were developed by stakeholders and they are following the same principles: consensus, openness, transparency and non-discrimination. The standards ensure not only the safety but also interoperability, so important in todays' connected health services.

The European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (CENELEC) closely collaborate with the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC) in order to promote the benefits of the international standardisation for trade and market harmonization. The organizations cooperate based on the Vienna Agreement signed by CEN and ISO and the Frankfurt Agreement between CENELEC and IEC. Many of standards in safety of medical equipment created by these European and International organizations are mutually adopted which can be recognised by e.g. IEC/EN marking in the specification of the particular standard.

The Technical Committee (TC) 62 of the IEC, Electrical equipment in medical practice, prepares international standards concerning electrical equipment, electrical systems and software used in healthcare and their effects on patients, operators, other persons and the environment. IEC 60601 series of technical standards deals with the safety and effectiveness of medical electrical equipment. First standards in this series were published in 1977. In the series, there is a general standard IEC 60601-1 that applies to all electrical medical equipment, some 10 collateral standards which are applied more selectively depending on the topic and about 60 particular standards which apply to specific medical equipment, e.g. electrocardiographs. When designing and testing the equipment standardised by a particular standard, both, general and particular standards have to be obeyed. Full text of above mentioned Directives and Standards is available on-line [11–20].

The standard IEC 60601-1:2005 *Medical electrical equipment—Part 1: General requirements for basic safety and essential performance*, describes requirements for basic safety and essential performance applicable generally to all medical electrical equipment. A collateral standard, take IEC 60601-1-2:2014 *Medical electrical equipment—Part 1-2: General requirements for basic safety and essential performance—Collateral Standard: Electromagnetic disturbances—Requirements and tests*, as an example, describes as well basic safety and essential performance of medical equipment but in the presence of electromagnetic disturbances as well as electromagnetic disturbances emitted by medical equipment. Particular standards from 60601 series that deal with electrocardiographs are:

– IEC/EN 60601-2-27 Medical electrical equipment—Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment

- IEC/EN 60601-2-47 Medical electrical equipment—Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems
- IEC/EN 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

## 5 Verification and Calibration

Even though different international standards and regulative prescribe all steps in device life cycle, nowadays more attention is given to safety and performance inspections or verifications of these devices during normal usage. These procedure consist of visual inspection of the device, safety inspection in accordance with IEC 60601 and performance evaluation also in accordance with IEC 60601 and manufacturer's recommendations. The purpose of these inspections/verifications is to ensure that device performance during usage is still in stated limits. At this point, metrology as science of measurements is introduced into medical device management. These inspections should be periodical, recommendations is once a year, like preventive check-ups that are basic practice of medical device management in most of the healthcare institutions in the world.

For performing verification/inspection of devices, etalons should be used. For safety inspection there are electrical safety analyser available in the market that allow safety inspection according to IEC 60601, but also in accordance to vast number of electrical safety standards. These analyzers are portable and easy to use, and usually they have software support.

For performance inspections, various analysers can be used also. Generally these analyser's comprise of slots for connecting ECG leads, casing, battery, power supply, user interface. They are often supported with software that enables generation of different performance ECG tests.

The accuracy of the ECG depends on the condition being tested. ECG devices must be constructed and made in a proper way so that in normal working conditions there is protection from electric shock, too high temperature, dust and water into the housing of instrumentation. Reference conditions for ECG:

- Voltage 220–240 V AC, 50 Hz
- Battery of 12 V
- Working time minimally 1 h
- Input impedance > 10 MΩ
- Calibrational voltage 1 mV ± 2%

Every part of electrical medical device that comes into contact with patient's body has some risk of electrical shock caused by unsafe leakage currents. The

electrical safety inspection involve testing of ground wire resistance, chassis leakage, patient leakage currents and mains on applied parts.

During the verification of ECG by etalon, range of measuring which must be controlled are next:

- Amplitude of voltage signal identified by ECG in mV is 0.5, 1.0, 1.5 or 2.0 mV
- Speed of beats in time frame of 1 min is: 30, 40, 60, 80, 90, 100, 120, 140, 150, 160, 180, 200, 210, 220, 240, 260, 270, 280, 300.
- Limits of allowed mistakes are:
- In case of measuring amplitude of voltage signal is ±5%
- In case of measuring speed of beats in time frame of 1 min is ±2%

Performance inspection is performed in order to determine measurement error of the device under test. If the error is in any of these cases bigger than maximum allowed error, ECG cannot be used and it must be serviced and verified again.

ECG device must have on visible place tile with accurately written label. These labels and marks should be written in language official for country.

Electrocardiographs must pass through procedure of examination and approval type, and before letting it into work, they must pass procedure of first verification and have certificates of verification. Examination of type is done based on documentation which producer or his agent must contribute along with application for approval. Documentation must have general, technical and other documentation and instructions for usage. First verification includes visual examination and is done by specific instruments. Maximum error allowed when done in regular verifications cannot extend maximum allowed by first verification. Periods of verification are defined by national regulations, e.g. [21].

## 6 Conclusion

ECG device is one of the biomedical instruments with wide history and enormous significance in everyday life of many people around the world. For centuries, scientists were trying to understand the principles and laws which this device would "obey". On the other side, some of them accidentally discovered secrets that were crucial for ECG development. From the 17th century, a dozen of different experiments were done by many scientists who, in that period, didn't know that their observations are going to be forerunner of today's most used device. Experiments started to improve in 18th century, so in 19th and 20th century development of ECG was done every day. Finally, in 1924, leading scientist acquired the most eminent award for his prominent achievement. That year was certainly one of the most important figures in history of science. However, it was not so easy to complete this task and produce consummate ECG. In any case, ECG device is real miracle. Its design nowadays seems simple for the engineers to understand, because of the technology rapidly moving forward. But, what is sure is that beginnings of

this device were far more complex than anyone could possibly imagine. It is more than complex thing to invent any gadget without knowing how it will perform, will it be safe and is it going to serve as it should. Significance of the ECG is unimaginable. ECGs' usage is aimed at the heart—which enables us to be alive. When we think in that way, we can see of how great importance it is to human race. Heart diseases are number one in world right now, especially heart attack. With accurate ECG device, doctors can detect impending cardiac arrest and save life of many people. Also, whole spectrum of disorders or diseases can be seen, prevented and treated through the use of ECG and its features. It doesn't matter if we are talking about young athlete or elder, male or female, ECG is determining type of treatment, diet or any other important characteristic of persons' lifestyle. It's usage is not necessarily intended only for people who have heart issues. It should be used to prevent diseases by means of yearly control and tracking work of the heart. In a few years, it is expected for great improvements in the ECG systems to be achieved. Anyhow, device is used, and will be used always in everyday life because of:

- its features
- need for it
- no risk for patients, nor for doctors or nurses
- ensured diagnosis.

We can see that ECG has much of importance. Following that, people should get familiar with its basics; how does it work, why it is used and how to properly use it. Also, its availability should be very high, in order for wide population to always have access to it. For example, every pharmacy could have modern ECGs and people could test themselves in any moment. It would probably lower the need for seeing the doctor and at the same time would be useful to always have control of the heart.

There is never lack of the need to highlight significance of ECG devices. In a few years, it could be part of the daily routine, just like measuring body's temperature, arterial blood pressure or blood sugar concentration. ECG may become everyday habit.

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