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Automatic System to Test Semiautomatic External Defibrillators for Sensitivity and Specificity

by:

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Abstract

"*Sudden cardiac death* (SCD) represents an enormous public health problem in all developed countries of the world." [30, page 177] *Automatic external defibrillators* (AEDs) provide an effective treatment for the most common appearances of SCD. One key feature of these AEDs is to decide whether or not a life saving electrical shock needs to be delivered in a given situation. Delivering a shock, when it is not required, is life threatening, too. In order to check the decision accuracy of various AEDs a test system was developed, which feeds a defibrillator with an assessed *electrocardiography* ECG signal and then retrieves the decisions of its analysis. These decisions are compared with the according annotations of two cardiologists. An existing MATLAB tool is used in order to calculate the quality parameters. The main components of the test system are the ECG database, an image capture device and a data acquisition card. A software developed in C# controls these components and the test process, which finally creates a table including the decisions of the defibrillator and the annotations of the cardiologist. The thesis presents the ready to use test system. Whether the noise in the created ECG signal disturbs the test process in a significant manner remains an open problem. Final tests have to be performed in a continuative work.

Kurzfassung

"*Sudden cardiac death* (SCD) represents an enormous public health problem in all developed countries of the world." [30, page 177][1] *Automatische externe Defibrillatoren* (AEDs) ermöglichen eine effiziente Behandlung für die häufigsten Formen des plötzlichen Herztots. AEDs müssen erkennen, ob ein lebensrettender elektrischer Schock abgegeben werden muss. Denn eine Schockabgabe ist lebensbedrohlich, wenn kein Kammerflimmern vorliegt. Zur Überprüfung der Erkennungsqualität verschiedener AEDs wurde ein Testsystem entwickelt. Das Testsystem speist einen Defibrillator mit einem EKG Signal und erfaßt dessen Analyseentscheidung. Um die Qualitätsparameter des Defibrillators zu berechnen, werden die Entscheidungen der Analyse mit den Beurteilungen von zwei Kardiologen verglichen. Hierfür wird ein bestehendes MATLAB Tool verwendet. Die Hauptkomponenten des Testsystems sind die EKG Datenbank, ein Bilderfassungssystem und eine Datenerfassungskarte. Eine in C# entwickelte Software steuert diese Komponenten und kontrolliert den Testprozess, welcher eine Tabelle mit den Analyseergebnissen des Defibrillators zusammen mit den Beurteilungen der Kardiologen erzeugt. Diese Diplomarbeit präsentiert dieses einsatzbereite Testsystem. Die Frage, ob das im EKG Signal vorhandene Rauschen den Testprozess stört, konnte in dieser Arbeit nicht ausgeräumt werden. Die Anwendung des Testsystems an verschiedenen Defibrillatoren ist Gegenstand von weiterführenden Arbeiten.

[1] Plötzlicher Herztot stellt ein enormes öffentliches Gesundheitsproblem in allen entwickelten Ländern der Welt dar.

Preface

Motivation

Finding a proper topic is one of the more challenging parts of writing a thesis, but I immediately was taken by this topic as it offered a wide range of different fields I am interested in. Technical medicine has always been a study field I would reckon to be a good choice as it offers the possibility to help people and technology gets more sense than all the gewgaws flooding into the market or even technology developed for destruction. Furthermore, you gain knowledge of the amazing details of the human body, which was in this case very narrowed down to the topic of the heart, but still very challenging. I also chose this topic due to the wide range of topics related to this matter like electronics, measurement techniques, medicine, image editing and software. Hence, I expected to learn a lot from the project. However the number of new topics (C-Sharp, MIT Database, DAQ Card, Frameworks for the SmartImage Sensor, LaTeX) I had to impropriate was really challenging.

Acknowledgments

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I also like to thank my grandmother Lydia Fellinger. Finally, I owe special gratitude to my mother for looking after my plants when I was abroad.

Statutory Explanation

Within this statement I declare that I honestly wrote this thesis on my own. Direct or oblique assumed thoughts taken from foreign sources are marked as such.

This thesis also was not submitted to any other commission nor published.

Hannes SÄLY, Götzis August 16, 2004

Made with LaTeXusing WinEdt/MikTex

Contents

Nomenclature

ADC	Analog to Digital Converter
AED	Automatic External Defibrillator
AHA	American Heart Association
AV	Atrioventricular
BIH	Beth Israel Hospital
BPM	Beats Per Minute
DAQ Card	Data Acquiring Card
ECG	Electrocardiography
EMS	Emergency Medical Service
FRED	First Responder External Defibrillator
ICD	Implantable Cardioverter Defibrillator
MIT	Massachusetts Institute of Technology
NI	National Instruments
OCR	Optical Character Recognition
SA	Sinoatrial
SCD	Sudden Cardiac Death
SVT	Supraventricular Tachycardia
VF	Ventricular Fibrillation
VT	Ventricular Tachycardia
WFDB	Waveform Database

1. Introduction

Myerburg and Spooner [30, page 177] state that from the perspective of the clinician and basic scientist alike, *sudden cardiac death* (SCD) remains a most difficult problem, representing a public health threat that accounts for approximately half of all cardiovascular deaths in the US. SCD is related to arrhythmia of the heart (described in Chapter 2), where the mainly appearing forms of arrhythmia are *ventricular fibrillation* (VF) and *ventricular tachycardia* (VT). The most effective treatment for these arrhythmia is immediate defibrillation, which can be accomplished even by non-medical persons with *automatic external defibrillators* (AEDs), on which this thesis is about.

But let us start off some centuries ago when Carlo Matteucci showed in 1842 that an electric current accompanies each heart beat. He used a preparation known as a *rheoscopic frog* in which the cut nerve of a frog's leg was used as the electrical sensor and twitching of the muscle was used as the visual sign of electrical activity. Fourteen years later Rudolph von Koelliker and Heinrich Muller confirmed this by applying a galvanometer to the base and apex of an exposed ventricle[1]. Frederic Batelli and Jean-Loius Prevost reported in 1899 that not only could a weak current can cause fibrillation, but a stronger current was capable of terminating fibrillation altogether. William Einthoven first recorded electrocardiograms in 1903 using a string galvanometer shown in Figure 1.1 to record the P, QRS, and T wave. With this galvanometer conduction was achieved using a sodium chloride bath instead of electrodes. Later, electrodes, metal disks with wire leads, were placed on a man's chest and attached to wire leads, and the heart beat of the patient was recorded.

[1] lower chamber of the heart, for details see Section 2.2

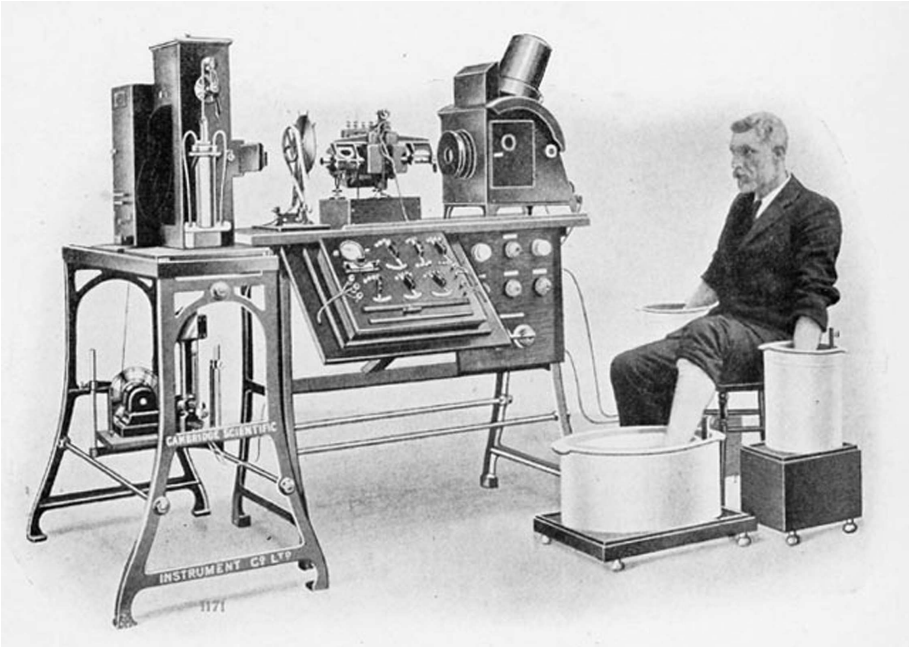

Figure 1.1.: Photograph of a complete Electrocardiograph, showing the manner in which the electrodes are attached to the patient, in this case the hands and one foot being immersed in jars of salt solution. [17]

Even though a lot of research had been done regarding *electrocardiogram* (ECG) acquisition, it was not until Hooker's experimental work demonstrated the feasibility of using *alternating current* (AC) to terminate VF. According to Nisam and Barold in "Historical Evolution of the Automatic Implantable Cardio Defibrillator in the Treatment of Malignant Ventricular Tachyarrhythmias" [2], the first defibrillation in humans was achieved by Beck et al. in 1947, who used 110V AC directly applied to the heart, to convert VF during thoracic surgery. In 1954 the era of transthoracic defibrillation, where electrodes are applied to the chest wall of the patient, was initiated when Zoll et al. applied AC via copper electrodes to terminate cardiac arrest. As early as 1962 Bernard Lown developed the first battery operated, transportable *direct current* (DC) defibrillator. The possibility of mobile defibrillators marked the beginning of a strategy to prevent SCD called *early defibrillation*. According to [32] the rational use of early defibrillation stems from four observations:

1. Ventricular Tachyarrhythmias are the commonest cause of sudden, unexpected cardiac arrest in adults.

2. Defibrillation is the most effective treatment of VF and pulseless ventricular tachycardia.

3. The effectiveness of defibrillation diminishes rapidly over time.

4. Unless treated promptly, VF degenerates into the less treatable rhythm of asystole.

It had taken another 20 years until miniaturization made the first implantation of an *implantable cardioverter defibrillator* (ICDs) possible. The use of ICDs for a subset of patients is a very successful intervention of cardiac arrest, but due to the high expenses the use for a more general segment of the population remains unrealistic [30]. A more community based program is the using of AEDs. The market shows increasing demand for AEDs, which is also supported by Bartes, who stated in "Die Zeit" that the market potential for external defibrillators was estimated to 700 millions Euros worldwide [7]. The information about history of defibrillators and electrocardiography was taken from [17], [19], [32] and [38].

In this thesis, then, I have set out to develop a test system to retrieve information on the quality of AEDs to detect fibrillation. The detection quality of AEDs is expressed in the parameters *Sensitivity* and *Specificity*, where

$$Sensitivity = \frac{TP}{TP + FN} \tag{1.1}$$

$$Specificity = \frac{TN}{TN + FP} \tag{1.2}$$

The parameters are described as follows:

TP ...the number of true positive decisions, which means to diagnose VF in the case of VF

FN ...the number of false negative decisions, meaning that VF was not detected

TN ...the number of true negative decisions, which means that normal heart beat was recognized as such

FP ...the number of false positive decisions, meaning to diagnose VF in the case of no VF

To summarize, sensitivity indicates the probability to detect VF, whereas specificity indicates the probability to identify "no VF" correctly.

Many different papers deal with the quality parameters of a specific algorithm to detect VF. In [3] twelve different algorithms were analyzed and the reliability of the fibrillation detection algorithms itself was checked. According to [3] no algorithm achieves optimal values

for the sensitivity or specificity. Looking at various defibrillator specifications the producers allege that their products reach a much better sensitivity and specificity than achieved by the algorithms themselves analyzed in [3]. So, my assumption is that their products do not accomplish the suggested detection quality. To prove this, a test system is developed in this thesis to evaluate not only abstract algorithms, but even the effective quality of the actual artefact invented to save life in the first place: the automatic external defibrillator. Hence the entire system consisting of algorithms and front-end data acquisition hardware such as amplifiers and filters is analyzed. Similar systems already exist to check whether defibrillators require re-calibration. For example MTK - Systems of Medical Measurement - offers a system to generate some predefined, artificial ECG signals and sinus, rectangle and other waveforms to check, whether arrhythmia is detected at all and to measure the delivered shock energy and waveform. Hence not the quality of detection is proofed, but the quality of the delivered shock pulse.

This thesis is divided into the following chapters: After this introduction, Chapter 2 offers a general overview, after which I will present some details about the electric activation of the heart. Afterwards, we take a brief look at the interpretation of the ECG signal for both a healthy heartbeat and arrhythmias. Chapter 3 then describes the function of a defibrillator and its various components. After the theoretical part of the thesis the composition of the test system with the individual components of the ECG database, the developed software, the interfaces, data acquisition card and camera, as well as the overvoltage protection are delineated, and the challenging task of their connection to a functioning test system are outlined. The thesis finishes with a summery and conclusion of the received results.

2. Heart

The human heart beats about three billion times during its lifetime and circulates approximately 250 million liter blood through the body. No artificial motor or pump possesses this indefatigable ability for maximum demand. Most people take this performance for granted, but in industrial countries heart disease like cardiac infarction and insufficiency are still the number one cause of death [25].

To understand the complexity of signal acquisition (described in Subsection 3.3.1) and detecting arrhythmias some background anatomy of the heart, the circulatory system and especially the electric activation of the heart is provided in this chapter. Furthermore, a brief look at the ECG signal interpretation and the different arrhythmias is given.

2.1. Anatomy and Physiology

The heart is placed under the rib cage, to the left of the breastbone and between the lungs and has about the size of a fist. It consists of four layers: The pericardium, the outmost layer is the thin bag (membrane) that surrounds the heart. The next layer is the outer skin of the heart called epicard. The myocardium is the layer of interest to us, as it is the muscular wall which contracts and relaxes, because of the electrical signals described in this chapter. The most inner layer is the heart's inner skin also called endocard, which is smooth to reduce the resistance for the blood-current.

2.2. Circulatory System

As shown in Figure 2.1 the heart has four chambers through which blood is pumped. The upper two are the right and left atrium. The left atrium is responsible for receiving deoxygenated blood from the veins leading to the heart. When it contracts or depolarizes, blood

is pumped into the lower left chamber called ventricle, which then pumps the blood into the lungs. The right atrium receives the oxygen rich blood from the lungs and pumps it into the right ventricle. This is the strongest muscle as it must force the blood through the aorta into the systemic circuit of the blood vessels in order to bring oxygen to the tissue cells throughout the body and even pushes the blood back to the heart again.

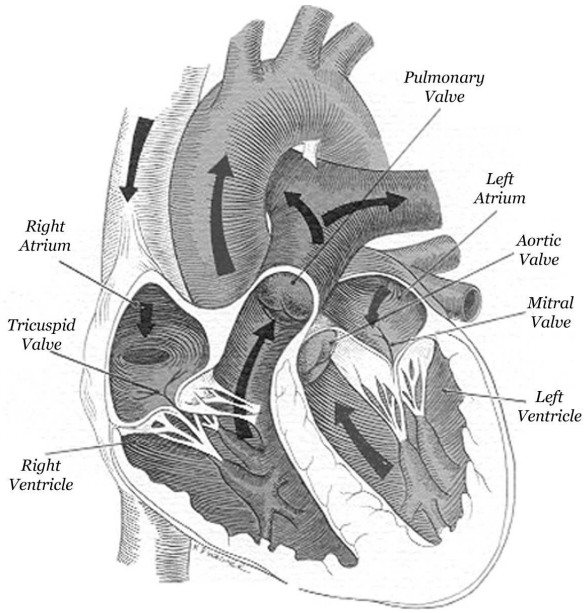

Figure 2.1.: The circulatory system of the heart: Showing the heart's chambers and valves and the blood path through the heart [36]

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Between these chambers four valves, tricuspid, mitral, pulmonary, and aortic valve open and close to let blood flow in only one direction when the heart beats. Blood flow occurs only when there is a difference in pressure across the valves, which causes them to open.

2.3. Electric Activation

Electrical signals cause your heart's chamber to contract and relax as described in the previous section. The chamber contracts, when a signal passes through a chamber wall. As soon as the signal has moved out of the wall, the chamber relaxes [16]. In a healthy heart, the chambers contract and relax in a synchronized way called the sinus rhythm, described in the next chapter. Any kind of abnormal disrupted rhythm or heart rate is called an arrhythmia which are described in detail in Section 2.4.2.

The coordinated depolarization and contraction of the myocardium is carried out through the hearts conducting system, which consists of the sinoatrial node, atrioventricular node and the bundle of His and the Purkinje fibers shown in Figure 2.2.

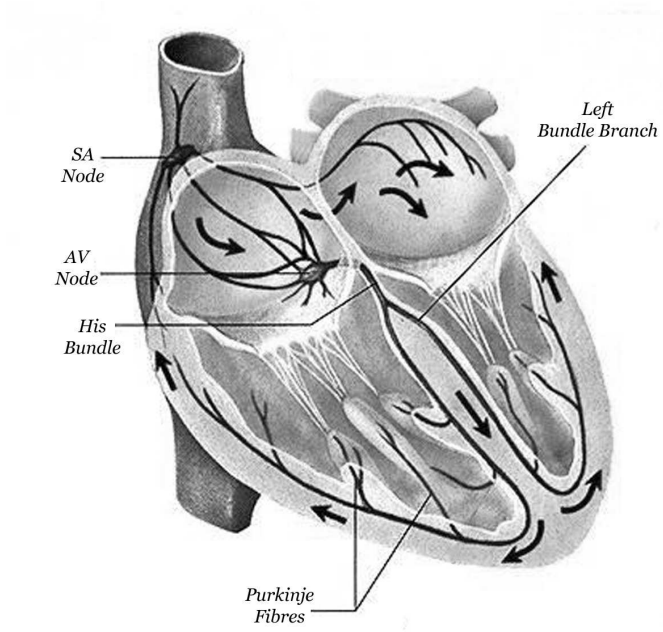

Figure 2.2.: The conduction system of the heart: Showing the specialized cells of the heart and the way the electric impulses are conducted through the heart [36].

2.3.1. The Sinoatrial Node

The heart's natural pacemaker, the *sinoatrial* (SA) node is a bundle of specialized cells in the right atrium. The SA node cells create the electrical pulses which make the heart beat and control the heart rate, usually at 60-100 beats per minute (bpm).

2.3.2. The Atrioventricular Node

The *atrioventricular* (AV) node is the bridge that allows the electrical impulses to pass from the atria to the ventricles. Like the SA node, the AV node is a bundle of specialized cells, which are the only ones allowing electricity to pass through between the atria and the ventricles. Furthermore, the cells slow down the electrical signal so that the delay gives the atria time to contract and relax before the ventricles do.

2.3.3. The His-Purkinje System

The His-Purkinje system is placed in the ventricles and consists of a pathway of fibres sending the electric impulses to the muscular walls of the ventricles, causing them to contract. The parts of the His-Purkinje system include:

- His Bundle or Common Bundle: the start of the His-Purkinje system
- Right and left bundle branch
- Purkinje fibers: the end of the system

2.4. Electrocardiogram

The electric activity of the heart can be recorded and visualized by measuring at the surface of the body using an ECG. This is achieved by connecting various leads to the torso and/or extremities in order for a voltmeter to measure the electrical signal. More technical details of the electrocardiogram and leads will follow in Subsection 3.3.1.

2.4.1. Sinus Rhythm

Three major waves of electric signals appear on the ECG. Each one shows a different part of the heartbeat. The normal range for sinus rhythm is between 60 and 100 bpm. In Figure 2.3 a ECG signal in relation to the heart's conducting system described in the previous subsection is shown. The meanings of each waveform are explained in the next subsection.

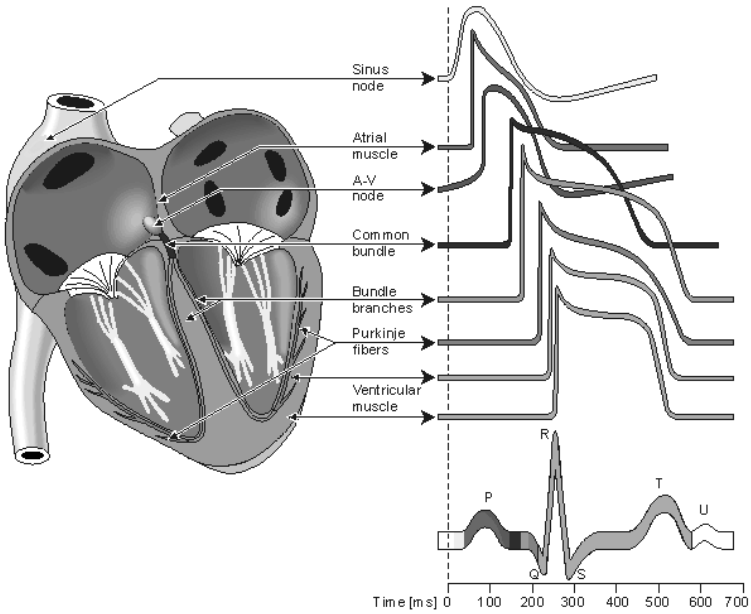

Figure 2.3.: Electrophysiology of the heart. The different waveforms for each of the specialized cells found in the heart are shown. The latency shown approximates the one normally found in the healthy heart [24, Chapter 6]

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Signal Interpretation

The typical ECG shown at the bottom of Figure 2.3 is composed of waves and complexes which Einthoven called P, Q, R, S, T, and U (see Subsection 3.3.1). The first wave is called the P wave. It records the electrical activity of the heart's atria. The next part of the tracing is a short downward section connected to a tall upward section called the QRS complex. This complex indicates that the ventricles are contracting to pump out blood. The QRS complex also ends the PQ interval which represents delay in AV node. The flat part from downward S peak to the upward T wave is called the *ST segment*. The *ST segment* indicates the amount of time from the end of the contraction of the ventricles to the beginning of the rest period before the ventricles begin to contract for the next beat. The last upward curve called T wave, records the heart's return to the resting state.

2.4.2. Arrhythmias

Arrhythmias or dysrhythmias are abnormal heart rhythms. They can cause the heart to pump less effectively which is called cardiac arrest. The main reasons for cardiac arrest are:

- Ventricular Fibrillation (VF)
- Ventricular Tachycardia (VT)
- Pulseless Electrical Activity (PEA)
- Asystole

Sudden Cardiac Death

The field of applications of external defibrillators can be summarized by the term *Sudden Cardiac Death* (SCD). According to *American Heart Association* (AHA) [4], SCD, also called sudden death, occurs when the heart stops abruptly (cardiac arrest). The victim may or may not have diagnosed a heart disease. The time and mode of death are unexpected. It can occur within minutes after symptoms appear, or there may be no symptoms before collapse. The most common underlying reason that patients suddenly die from cardiac arrest is coronary heart disease. The most common arrhythmias are described in detail in the next sections.

Ventricular Fibrillation

VF is a chaotic, disorganized electrical storm, which, if left untreated, will result in an unsalvageable patient. The only effective treatment for VF is immediate defibrillation. The most important predictor of outcome is the rapidity with which a patient who is in VF is defibrillated. The survival from VF decreases approximately 10% for each minute of a delay in defibrillation therapy. With this in mind, the assumption of VF in an arrested patient, with a goal to early defibrillation, has become a priority. Technology has at this point allowed for the development of AEDs, which now are widely used as Public Access Defibrillators (PAD).

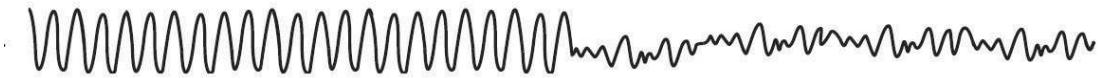

Figure 2.4.: Ventricular Fibrillation (received from [36])

Ventricular Tachycardia

VT occurs when electrical impulses cause rapid ventricular depolarization (140-250 bpm). Since the impulse originates from the ventricles, the QRS complexes are wide and bizarre (see Figure 2.5). VT is often due to some form of heart disease and can occur rarely in response to exercise or anxiety. In this case, the electrical impulses and rhythmic beats are similar to the normal beat, but at a much faster rate. During VT pumping blood is less efficient because the rapid ventricular contractions prevent the ventricles from filling adequately with blood. As a result, less blood is pumped through the body. The reduced blood flow to the body causes weakness, dizziness, and fainting. If left untreated, VT may lead to a more life-threatening condition.

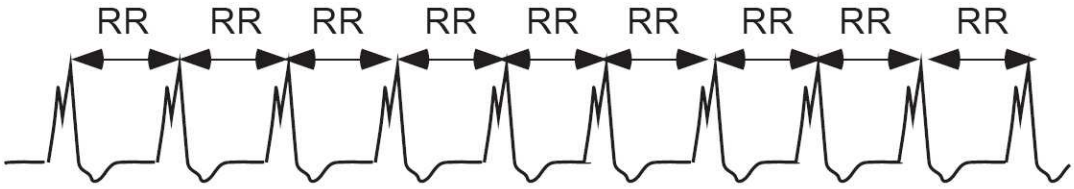

Figure 2.5.: Ventricular Tachycardia [36]

Asystole

Asystole stands for the heart showing no electrical activation and the ECG showing only a straight line. In case of asystole no shock is advised. Only advanced care and drugs are capable of reviving the heart back to the normal sinus rhythm.

Pulseless Electrical Activity

PEA means that the heart creates electrical signals but the Myocardium is not contracting, resulting in the patient having no pulse and blood pressure.

Sinus Bradycardia

A heart's electrical activity is slower than 60 bpm is called a sinus bradycardia. This is observed especially with younger people or sportsmen during rest or sleep, the ECG pattern may be normal but slow. But on the other hand heartbeat constantly below 40 bpm constitutes a life threatening heart disease which may eventually leads to asystole (see: above). In this case, shock is not advised and advanced care and drugs are required to revive the heart.

Figure 2.6.: Bradycardia [36]

Supraventricular Tachycardia

Supraventricular Tachycardia (SVT) includes various kinds of arrhythmias like atria tachycardia and sinus tachycardia, which must not be treated with defibrillation. Like VT the heart beat of SVT is rapid (140-250 bpm) caused by heart tissues in the region above the ventricular. The resulted ECG signal is similar to the VT signal.

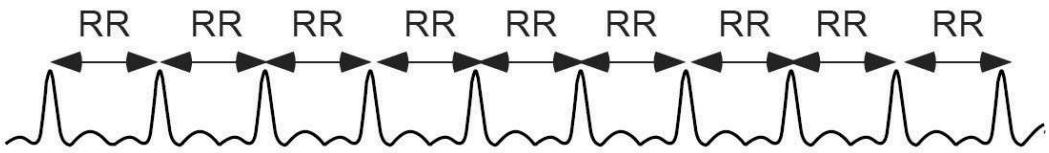

Figure 2.7.: Supraventricular Paroxysmal Tachycardia [36]

3. Technology

Today's modern defibrillators are highly sophisticated microprocessor-based devices, which monitor, assess and automatically treat patients with life-threatening heart rhythms. They capture ECG signals from the therapy electrodes, run an ECG-analysis algorithm to identify shockable rhythms, and then some of them advise the operator about whether defibrillation is necessary or not. In this chapter a brief introduction into the principles of the defibrillator, the various types and some technical details about leads, signal processing, arrhythmia detection, and waveforms are provided.

3.1. Principles

Williams [37] and others define defibrillation as follows:

> Defibrillation is the application of a preset electrical current across the myocardium[1] to cause synchronous depolarization of the cardiac muscle with the aim of converting a dysrhythmia into normal sinus rhythm.

Figure 3.1 shows the block diagram of a DC defibrillator. On the right hand side all functional units to generate and deliver the shock are combined. The controlling and analyzing components are shown on the left side. Because of the life threatening high voltages and currents, defibrillators must be conform to the Medical Products Law, which even leads to some parts been required to be redundant.

[1] The muscular wall of the heart. It contracts to pump blood out of the heart and then relaxes as the heart refills with returning blood [4, page 72].

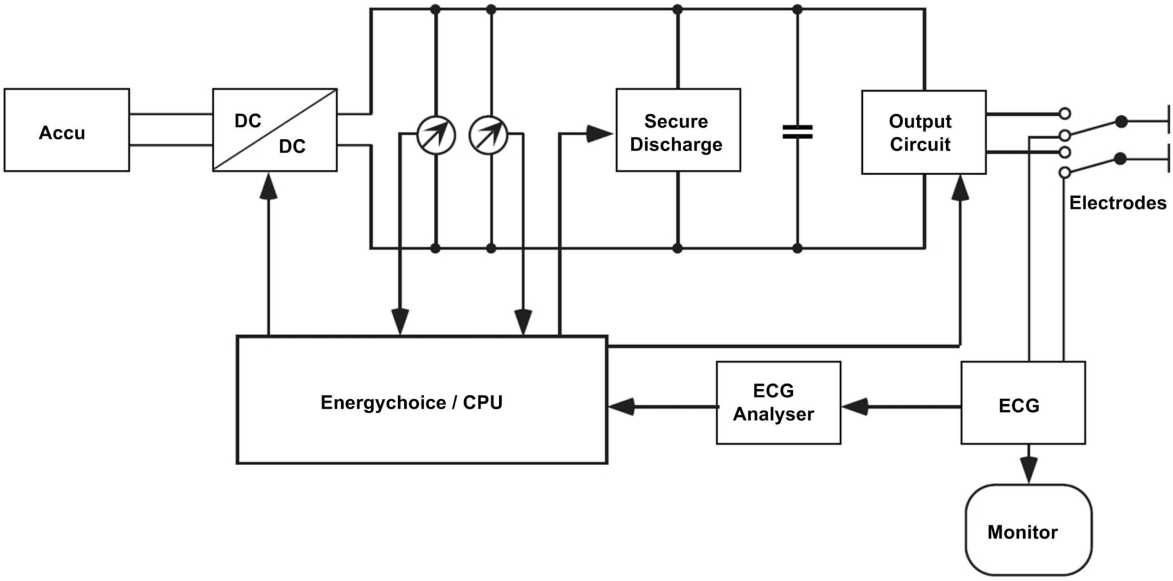

Figure 3.1.: Block diagram of a semiautomatic defibrillator [8, page 406]

The electrodes are connected directly with the ECG unit which also allows to display the ECG signal on the monitor. When the ECG analyzer recognizes arrhythmia, the CPU is advised to start the defibrillation process. The capacitor is loaded to a defined energy level controlled by two different redundant voltage meters. As soon as the energy level is reached, the impulse is delivered to the patient.

3.2. Defibrillator Types

In general we can distinguish three different types of defibrillators described in this section.

3.2.1. Manual Defibrillators

Manual Defibrillators are defibrillators/monitors which provide therapeutic and diagnostic functions, but no ECG analyzing device. They require medical knowledge, as the decision to shock or not is up to the emergency trained medical personnel on the basis of the displayed ECG signal and their knowledge of ECG interpretation.

3.2.2. Semiautomatic Defibrillators

Semiautomated External Defibrillators are small, light-weight, portable devices which perform rhythm analysis [32]. These remarkable devices accurately determine whether the heart is in a shockable rhythm and, if so, instruct the user with a voice chip and mostly also a text display, how to deliver the necessary shock quickly and safely. AED technology allows persons with no medical background to perform lifesaving defibrillation with a minimal amount of training and also permits development of strategies to enhance prompt defibrillation in public places before traditional *emergency medical services* (EMS) personnel can arrive.

The process can be described as follows: After the device is switched on a computerized voice instructs the operator to place two electrodes/pads on the patient's chest. The device analyzes the heart rhythm and decides if a shock is necessary, then the operator must press a button to deliver the shock. The microprocessor will not permit to deliver a shock unless it detects the presence of a heart rhythm that requires defibrillation.

3.2.3. Automatic Defibrillators

Fully automatic defibrillators shock at a preprogrammed energy level once VF or VT is sensed. There is no way to prevent the defibrillator from firing once the machine has detected an arrhythmia. They are distinguished between internal and external devices:

Implantable

Automatic *Implantable Cardioverter Defibrillators* (ICD) are tiny devices (about 6cm in diameter and 1cm high) implanted under the skin with leads connected to the heart to restore the patient's normal heartbeat in the occurrence of potential cardiac arrest. In general, the target group are people with heart failures with an increasing risk for VT or VF and people in wait for a heart transplant. A pacemaker, by contrast, delivers a regular impulse to promote normal contraction of the heart muscle, if the SA or AV node is not working properly.

Since the electrodes of the ICD are connected directly to the heart, a much lower energy level is required. ICDs deliver about 50 to 100 Joule, in comparison to the up to 400 Joule of externally applied electrodes.

External

To monitor a patient permanently, when he/she is in cardiac arrest, electrodes are placed in correct position and the AED is turned on. As soon as the AED detects cardiac arrhythmia the defibrillator loads the capacitor and delivers the shock automatically. The only way to prevent firing once the machine is committed to discharge is by turning off the AED.

3.3. Components of a Semiautomatic Defibrillator

3.3.1. Electrocardiography

Defibrillators are an enhancement of the ECG, hence the signal acquisition technology of the ECG is part of each defibrillator. The Encyclopedia Britannica [11] defines electrocardiography as a method of graphic tracing (electrocardiogram; (ECG), or (EKG)) of the electric current generated by the heart muscle during a heartbeat. The tracing is recorded with an electrocardiograph (actually a relatively simple string galvanometer), and it provides information on the condition and performance of the heart. The main components of an ECG are the leads to acquire the signal, amplifiers and filters to process the signal, and a monitoring unit like displays or plotters, which are not described in this thesis.

Leads

The defibrillator receives the signals of the heart's electrical activation by electrodes connected on defined places on the surface of the patient. The stretch between two limb electrodes (e.g. arm and leg) is called a lead. Bolz and Urbaszek describe the various leads in [8]:

Einthoven Lead: William Einthoven, an important scientist in this field, developed the first ECG (see Chapter 1) and leads still used today. Einthoven named the leads between the three limb electrodes *Standard Lead I, II and III* referring to the two arm electrodes and the left leg electrode shown in Figure 3.2.

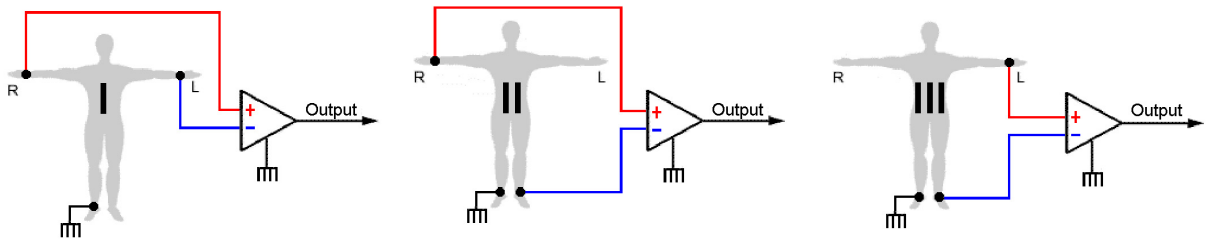

Figure 3.2.: Einthoven Leads I, II, III (adapted from [36])

Wilson Chest Lead: For measuring the potentials close to the heart, Wilson introduced the precordial leads (chest leads) in 1944. These leads, V_1-V_6, are located over the left chest as shown in Figure 3.3.

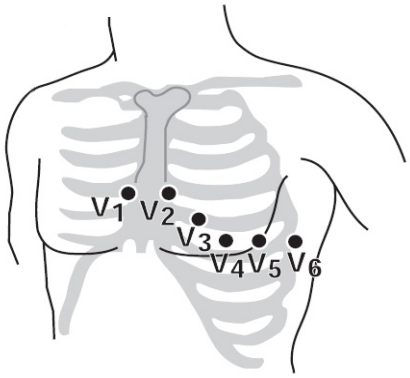

Figure 3.3.: Wilson Leads V_1, V_2, V_3, V_4, V_5 and V_6 [36]

Goldberger Augmented Lead: Goldberger developed another three limb leads measuring the voltage between the arms and the left foot referring to a reference point shown in Figure 3.4.

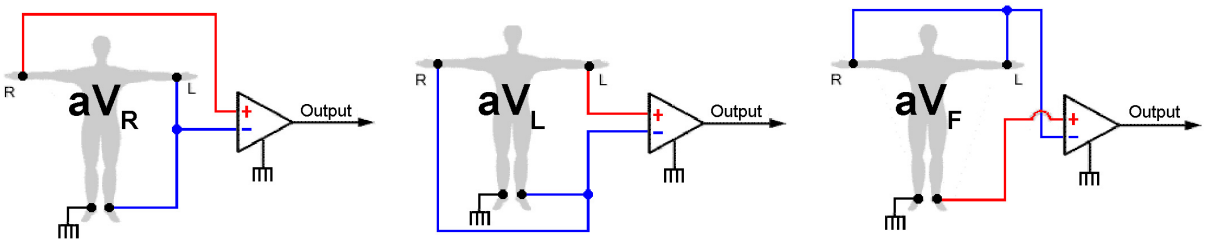

Figure 3.4.: Goldberger Leads aV_R, aV_L, aV_F (adapted from [36])

Today the most commonly used clinical ECG-system, the 12-lead ECG, is a combination of the extremity leads of Einthoven I, II, III and Goldberger's aV_R, aV_L, aV_F lead and the chest leads of Wilson V_1, V_2, V_3, V_4, V_5, V_6.

To defibrillate a heart a high current density through the heart is required, hence the accurate positioning of the electrodes is very important and differs from the leads described above. The typical position of the electrode pads, which was determined empirically, is shown in Figure 3.5 and the ECG signal is similar to the Standard Lead II.

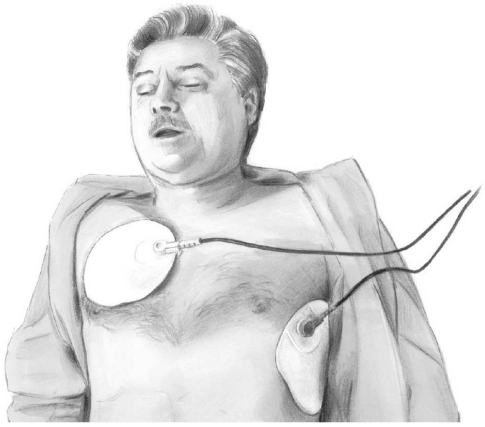

Figure 3.5.: Position of the defibrillator pads on a victim [6]

Signal Processing

The signal amplitude of the heart's electrical activation only reaches a few *millivolts* (mV) on the body's surface. According to Jamshaid and others [18], the surrounding noise generated by power line interference, electrode contact noise, motion artifacts, muscle contraction, base line drift, instrumentation noise of electronic devices and electrosurgical noise is a multiple of the ECG signal. Hence the filtering and amplification plays an important role for a correct ECG signal acquisition. The main part of the information for an ECG is found in the frequency range from 1 and 30 Hz [8], so filters are able to reduce a great part of the noise. The biggest part of the noise is filtered by a band pass like the one the *First Responder External Defibrillator* (FRED) uses, from 0.5 to 40 Hz. Non adaptive band-reject filters are also used to eliminate power-line noise of 50 Hz and 60 Hz. The signal then is rectified by a differential amplifier, which subtracts the potentials of each lead from each other. As noise usually is present with the same amplitude and phase at every point of the body [8], this signal is suspended.

3.3.2. Arrhythmia Recognition

The arrhythmia recognition is another central component of the defibrillator and there exists a wide range of solutions to accomplish this challenge. Bolz and Urbaszek [8] suggested that the defibrillator should at least be able to differ between "VT, VF" and "another signal". The problem here is that Supraventricular Tachycardia SVT is confused with VT, because the SVT signal is very similar to VT (see Subsection 2.4.2). They recommend that defibrillators should be capable to distinguish between: VT, VF, normal sinus rhythm and SVT, and a disturbed signal.

To recognize sinus rhythm an algorithm to detect the QRS complex is used. For detection of VT and VF mainly two different procedures are used, which are the time and frequency based domain. An example for a frequency based algorithm would be to recognize a sudden frequency jump of the heart beat from normal sinus rhythm to VT.

3.3.3. Electric Shock

Peberdy states in [32] that an important goal of modern defibrillation is to provide the lowest amount of energy to successfully terminate a ventricular arrhythmia in hopes of avoiding the myocardial damage which can occur with high energy delivery. But on the other side, if the amount of energy is too small it will not stop the cardiac arrest, hence various wave forms were developed, described in the next section.

Wave Form

Mainly, wave forms can be distinguished to be either monophasic or biphasic. Monophasic waveforms are unipolar, hence drive the current through the heart in one direction only. Yamanouchi and others state in [39] that biphasic waveforms have been reported to be more efficacious for defibrillation than monophasic waveforms . The efficacy of the first defibrillation with a biphasic waveform is even greater with a smaller energy level than the monophasic waveform [26]. Nowadays this technology is available in most AEDs as it is more or less the state of the art. Various representative defibrillation waveforms are shown in Figure 3.6. The damped sine waveform (C) simply is created by a resistance, inductor, capacitor (RLC) circuit, whereas the resistor R is the patient resistance through which the capacitor is dis-

charged. The other two waveforms (A, B) require a much more complex technology as the output current is always measured and regulated.

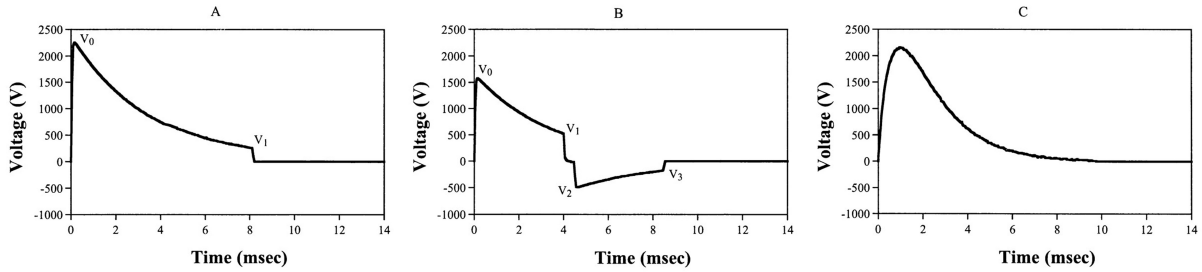

Figure 3.6.: Representative defibrillation waveforms. A, monophasic truncated exponential; B, biphasic truncated exponential; and C, damped sine [15].

Energy

Depending on the waveform, a certain amount of energy is used for defibrillation. With the monophasic waveforms the first defibrillation starts with 200 J, if it was not successful, defibrillation is repeated with 200–300 J. For the last try the energy is increased to 360 J. For biphasic waveforms already a lower energy level is sufficient. To receive the required large amount of energy a capacitor is used independently from the waveform. The energy is measured in *Joule* [J]:

$$Energy\ [Joule]\ =\ Power\ [Watts]\ *\ Time\ [Hours] \tag{3.1}$$

The capacitor consists of a pair of conductors separated by an insulator called dielectric and stores the energy in the form of an electrical charge. This charge is released though the heart in a short period of time by the electrode pads.

4. Test System

This section offers a description of the test system and its components as detailed as required to rebuild the complete test system. First of all we have a look at the requirements of the test system. Before details of the single elements are described a brief overview of the components and a description of a test run is provided. The focus then is set on the software, the ECG database, ECG signal generation and the overvoltage protection as those points demanded most of the work and were the most challenging.

4.1. Overview

4.1.1. Requirements

The aim of the application is to test different defibrillators on their reliability to recognize arrythmia requiring defibrillation and to recognize when there is no need for a shock. So let us have a look at the requirements and outline which points had to be taken into account for the development of the test system software:

- The software must be easily expandable to work with further database formats. The first version supports the *Massachusetts Institute of Technology* (MIT) database format, but additionally also the AHA, *Creighton University* (CU), and also the Innsbruck database, which is still under construction, must be supported. Details about the implemented database can be found in Section 4.3
- The software was developed for the FRED, but it must be possible to test another defibrillator type without knowledge of the programming language and/or big changes on the software.

- As the defibrillator shock output easily can destroy the DAQ Card and the notebook, special care had to be taken programming the software for the defibrillator never to deliver such a fatal shock. But still safety measurements had to be implemented for the case that the software fails and the defibrillator provides a shock to protect the system against this overvoltage. The solution of this challenge is described in Section 4.5.2
- The creation of a proper ECG signal, which equals the original digitized ECG signal is one of the key issues of the test system and a criterion whether the test results are significant at all. Hence the signal created by the DAQ Card should be measured and checked whether it corresponds to the original signal.
- However, according to [27] it is often difficult, however, to establish synchronization between the signal source and the analyzer. This problem is outlined in Subsection 4.2.2.

4.1.2. Components

The whole test system is based on the following main components shown in Figure 4.1:

Notebook: is responsible to control the test process, communicate with the DAQ Card, and store results

ECG database: holds digitized ECG signals files and annotation files for interpretation

DAQ Card: the *Data Acquisition Card* (DAQ Card) creates the analog ECG signal waveform, reads the output of the digital camera, and drives the solenoid to start the analyzing process

Voltage divider: reduces the ECG signal output of the DAQ Card to the original signal amplitude

Overvoltage Protection: protects the test equipment when the defibrillator fires a shock

Solenoid: activates the *start analyze* button of the tested defibrillator

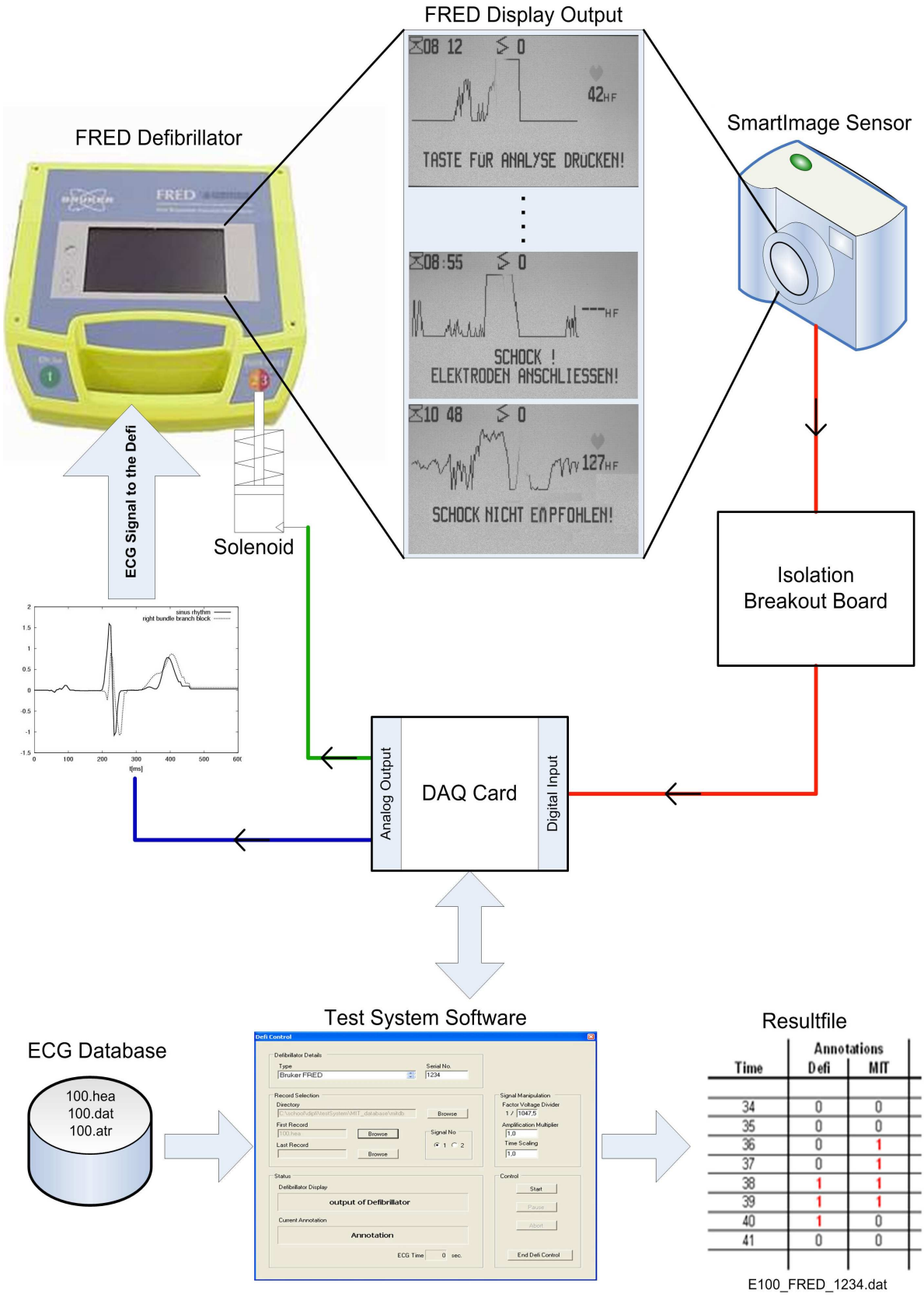

Figure 4.1.: Overview of the test system

Defibrillator: the test object: the FRED - First Responder External Defibrillator

Smart Image Sensor: analyzes and interprets the display output of the defibrillator and sets digital outputs according to the displayed status

Isolation Breakout Board: (Isolation BOB) an interface to connect the output of the smart image sensor and the input of the DAQ card

4.1.3. Description of a Test Run

After starting the test application *defiControl.exe* the user selects the records with which the test is accomplished. Having pressed the start button the software starts the test-cycle and reads the header file of the record to retrieve the signal structure information. Then the binary signal file is read and converted into floating-point numbers according to the information in the header file. Afterwards the DAQ Card receives these values to create an analog ECG signal of the provided data. Since the resolution of the DAQ Card is not high enough to create an ECG signal with such a small signal amplitude as required by the defibrillator (see Subsection 4.4.1), the output signal is reduced by a voltage divider.

The FRED and other defibrillators show their internal state through a display mostly by text messages, and also advise the user by speech. The text messages are captured by a digital camera called SmartImage Sensor, which sets an output of the Isolation BOB according to the recognized status message. The DAQ Card is polling its input lines in a defined interval to be aware of the status of the defibrillator.

As soon as an ECG signal is created by the DAQ Card the solenoid starts the analyzing process of the defibrillator by pressing the *analyze* button. The FRED then needs about eight seconds to analyze the ECG signal and displays its results: “Shock recommended” or “Shock not recommended”. Again the test system receives the defibrillator status through the SmartImage Sensor, the Isolation BOB, and the DAQ Card and stores the received information in an annotation file described in Subsection 4.2.2 (Paragraph: Output of the Program). Then the analyzed ECG signal frame of eight seconds duration is shifted for one second and the process of signal creation and analyzing is started again. The process runs until the hole ECG signal is analyzed, which takes about four hours for a 30 minutes MIT-BIH record.

4.2. Software

One of the most time consuming parts of this thesis was developing the test software, as many different interfaces had to be taken into consideration.

4.2.1. Design Decision

The first question, which operating system should be used, was not problematical to answer, since this specific *National Instruments* (NI) DAQ Card only supports Windows systems. The next point concerned the programming language, where the used interfaces had to be taken into account. NI recommends various software tools such as *LabVIEW*, *LabWindows/CVI* and *Measurement Studio* to programm the DAQ Card, but *Visual Basic*, *C/C++* and *C-Sharp* (C#) are also supported. The recommended software tools are very expensive and only a few functions have to be implemented for the DAQ Card, which are: generating voltage and reading digital input. Furthermore once the system is running it does not require any further changes of the software for controlling the DAQ Card. Hence it has been decided to program the card manually with one of the supported languages. The next criterion regarding the programming language was the MIT-BIH database. Since the delivered libraries do not operate with Windows, the functions to read the records had to be programmed manually. So the language C# was picked, which is further developed. C# also offers the possibility of rapid software development, hence many required functions like handling strings or files are easier to use.

4.2.2. Class Details

Using an object orientated language like C# the software was divided in the following classes, which correspond with the interfaces like database, DAQ Card, defibrillator, user interface and a controller class.

DefiMainForm

This class holds the *Graphical User Interface* (GUI), which handles all interactions with the user. These interactions are performing the selection of records, input of basic configuration parameters, informing the user of the state of the defibrillator and offering control buttons.

The responsibilities of the class are to create an instance of the TestController and some input checking, but basically leaves the logic to the TestController. When starting the application *defiControl.exe* the form shown in Figure 4.2 opens. The window is divided into five sections:

Defibrillator Details Since the software is enhanced with different defibrillator types the user may choose the appropriate defibrillator out of a select box. The serial number of the defibrillator must also be entered for documentation reasons.

Record Selection In this section the user may change the record files directory and select the record from which the automatic test will start. Furthermore the user may select the last record of the test. If the user leaves this text box empty only the record chosen as *First Record* will be tested. With the radio button *Signal No* the user may choose, which signal of the record will be tested.

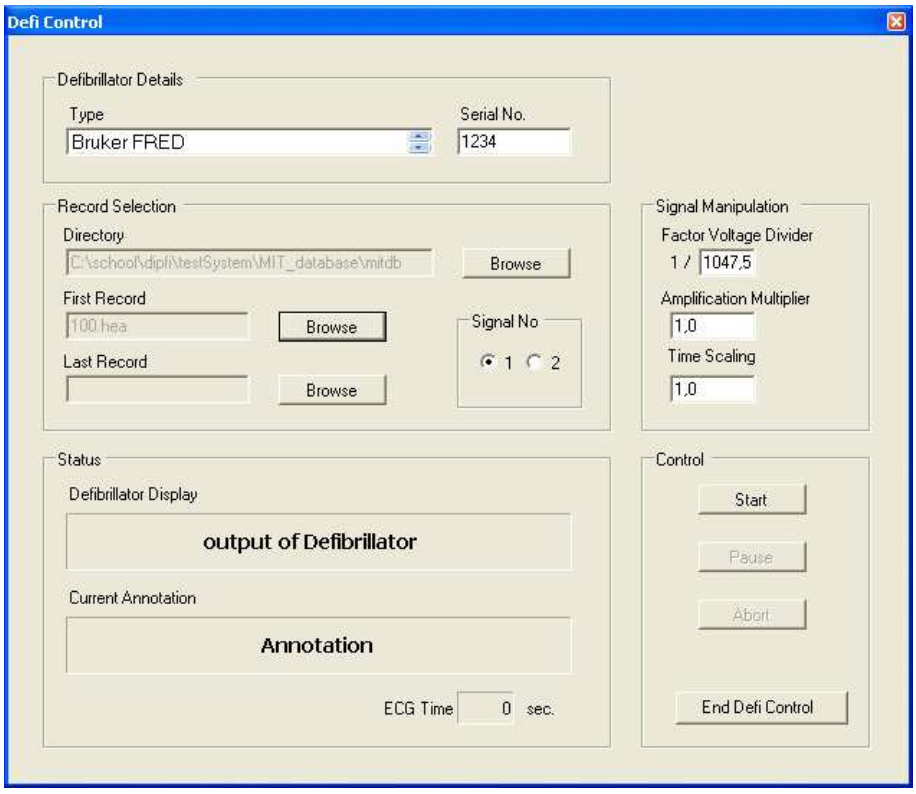

Figure 4.2.: Screen shot of the application

Signal Manipulation In this section it is possible to calibrate the voltage divider with the factor of its attenuation, see Subsection 4.5.1 for calculation of the *Voltage Divider Factor* ($factor_{Vdiv}$). Furthermore, it is possible to amplify or attenuate the ECG signal to a certain degree to check the minimum signal amplitude of a defibrillator, which is not handle as asystole. Finally by changing the *Time Scaling* to a different value than *1* the ECG signal can be stretched or compressed in time.

Status This section displays the actual status of the defibrillator and the annotation of the current ECG signal. Furthermore, the current time mark of the ECG signal is displayed.

Control Within this box the user is allowed to control the test by starting, pausing or aborting the test run.

TestController

This class acts as the controller including all logic for the test process and also holds instances of the DAQ_Card and the Record classes. This class offers the function *runTest*, which controls the whole test process. Once executed, this function creates and initializes records. Furthermore, it creates a thread to periodically check the digital input lines of the DAQ Card. The DAQ Card reads the output of the SmartImage Sensor, which equals the various statuses of the FRED.

The various states of the FRED defibrillator are mostly similar to other defibrillator types:

Table 4.1.: Statuses of a AED and the reaction of the software

Defibrillator Status	Reaction
No or black display	Error
Connect electrodes	Error
Press button to analyze	start sub-test sequence
Analyze is running	Wait
Do not move the patient	Wait
Check pulse	Start sub-test sequence
Shock! Connect electrodes	Write annotation
Shock not recommended!	Write annotation

The TestController reacts according to possible states listed in the Table 4.1 above. To start a sub-test sequence the function *runTest* takes an eight seconds long frame from the digitized ECG signal of the record and starts a threat to generate an analog ECG signal with the DAQ Card. While the thread to create the ECG signal is running, the status of the defibrillator is permanently controlled. When the thread to write the analog ECG signal is finished and the annotation is comprehended, the next frame of the digital ECG signal, which starts one second later, is taken and the sub-test sequence starts again.

Synchronization of Annotations In order to permit comparisons of the annotations retrieved from the defibrillator with the original ones, it is required to establish synchronization between the defibrillator and the signal source. To achieve this the time from starting the ECG signal frame till the result of the defibrillator is measured and the first sample number of the test frame is multiplied with the sampling rate and than both values are added together.

Output of the Program The test software creates an ASCII annotation file with an *.dat* extension holding a table. The file name is created by the record name, the defibrillator type, and the serial number e.g. *100_Buker_FRED_01234.dat*. The table consists of three rows, the annotation time in seconds, the decision of the defibrillator and the annotation according to MIT database separated by blank spaces. If the file already exists but the tests were not completed with the record, the test will continue from the last created annotation. The detection quality of a defibrillator is analyzed by running the test program with all records of a database with a specific defibrillator. Then a MATLAB program *res_analysis.m* developed by R. Tratnig for the analysis done in [3] reads all these annotation files to calculate the Sensitivity and Specificity.

Record

The Record class is responsible for all issues regarding the *Waveform Database* (WFDB) containing the data of the header file, the ECG signal and of course the information stored in the annotation file. To receive this data it offers functions to read the information from the database files, but also to store new files containing the test results.

DAQ_Card

This class manages all inquiries of the DAQ Card, which are the creation of tasks to write to the *Analog Output* (AO) and to read from the *Digital Input* (DI). On these tasks channels are created to write an ECG signal (AO task) and also to read the digital input lines (DI task). This tasks are handled similar to threats.

Defi Class

The Defi class holds the specific information of the defibrillator type like the name for documentation of the tests, the display text and information about the sequence of the test.

4.2.3. Possible Further Developments

As already mentioned, the first extension of the software will be to program access to further databases, like the AHA, CU and Innsbruck databases. Once the main databases for analyzing arrhythmia are implemented of course other defibrillator types are included to the test system. For this only low programming knowledge of C# is required, but the SmartImage Sensor must be reprogrammed to capture the different outputs of each defibrillator type. Another future development of the software will be to add a noise signal to the ECG signal to perform a noise stress test on the defibrillator. Therefore, noise in calibrated amounts is added to clean signals. So, any combination of noise and ECG signal is possible as both signals - the distorted and the clear ECG signal - can be analyzed by the same defibrillator, and the effects of the noise can be readily separated [27, page 157].

4.3. MIT Database

Commonly most fibrillation detection algorithms are tested with the MIT-BIH database, hence for a start only the MIT-BIH database is implemented. The test system should run with various other ECG database types, which are not described here. The MIT-BIH database was created in a cooperation between the *Massachusetts Institute of Technology* (MIT) and *Beth Israel Hospital* (BIH) in order to develop and evaluate real-time ECG rhythm analysis. The following sections describe some fundamentals for the test system. All the information was received from [27], [28] and [34].

4.3.1. Software

On the Physionet homepage http://www.physionet.org the WFDB Software Package is offered for downloading. This package includes C-language sources for the WFDB library and for a variety of applications, which offer signal processing and analysis, detection of physiologically significant events using both classical techniques and novel methods based on statistical physics and nonlinear dynamics, interactive display and characterization of signals, creation of new databases, simulation of physiologic and other signals, quantitative evaluation and comparison of analysis methods, and analysis of non-equilibrium and non-stationary processes. The complete software package is written in C for UNIX or Linux operating systems. But according to Physionet, the WFDB Software Package has been successfully compiled under all modern versions of MS Windows using the Cygwin development environment, which is a Linux-like environment for Windows. After installing the Cygwin environment on the laptop the source codes were compiled using the delivered makefile.dos with a gcc compiler. But neither precompiled applications nor the compiled and installed software could be executed and failed to work on this system.

4.3.2. Selection Criteria

The source of the ECGs included in the MIT-BIH Arrhythmia Database is a set of over 4000 long-term Holter[1] recordings which were obtained by the Beth Israel Hospital Arrhythmia Laboratory between 1975 and 1979. The database contains only 48 records, 23 records (100 to 124 inclusive) chosen at random from this set and another 25 records (numbered from 200 to 234 inclusive) selected from the same set to include a variety of rare but clinically important phenomena that would not be well-represented by a small random sample of Holter recordings. Each of the 48 records is slightly over 30 minutes long.

The first group is intended to serve as a representative sample of the variety of waveforms and artifact that an arrhythmia detector might encounter in routine clinical use. The records in the second group were chosen to include complex ventricular, junctional, and supraventricular arrhythmias and conduction abnormalities. Several of these records were selected because features of the rhythm, QRS morphology variation, or signal quality may be expected to present significant difficulty to arrhythmia detectors; these records have gained considerable notoriety among database users.

4.3.3. Digitization

To recreate the original ECG signal we have to take a look on the digitalization process. Primarily the ECG signal was recorded on analog playback units. A bandpass-filter from 0.1 to 100 Hz was used to limit *analog-to-digital converter* (ADC) saturation and for anti-aliasing when the analog outputs of the playback unit were digitized. The bandpass-filtered signals were digitized at 360 Hz per signal. The ADCs were unipolar, with 11-bit resolution over a $\pm 5\,mV$ range. Sample values thus range from 0 to 2047 inclusive, with a value of 1024 corresponding to zero volts. So, to convert samples back into physical units (millivolts), the ADC_{Zero} (1024) is subtracted from the sample value and then divided by the gain. Example: Digital Sample Value = 995;

$$ECG_{analog} = \frac{Digital\ Sample\ Value - ADC_{Zero}}{Gain} = \frac{995 - 1024}{200} = -0.145\,mV. \qquad (4.1)$$

[1] Holter monitoring provides a continuous recording of heart rhythm during normal activity. The monitor is usually worn for 24 hours to obtain a recording of a complete day.

4.3.4. Database Structure

A record of a patient consists of an extensible set of files that may include signal files, annotation files, and the only mandatory header file. All files are associated with the same original signals. The total duration of each record is approximately 30 minutes and 6 seconds. Below, the three different file types are explained in detail:

Header File

For each database record, a header file specifies the names of the associated signal files and their attributes, and contains at a minimum one record line. This line specifies the record name, the number of segments, and the number of signals. Header files for ordinary records also contain a signal specification line for each signal.

```
Example: MIT DB record 100
    record line:  100 2 360 650000 0:0:0 0/0/0
    signal line:  100.dat 212 200 11 1024 995 -22131 0 MLII
    signal line:  100.dat 212 200 11 1024 1011 20052 0 V5
    info line:    \# 69M 1085 1629 x1
    info line:    \# Aldomet, Inderal
```

In the record line the first number specifies the name of the record, then it defines that the record consists of two signals with a sample rate of 360 Hz. Each ECG signal is 650000 samples long. The starting time and date have not been recorded in this example. Each signal line is stored in the file 100.dat in the 12-bit bit-packed format 212 (see next paragraph for details). The gain for each signal is 200 ADC units per millivolt and the ADC had 11-bit resolution for digitization. The next value sets the offset to 1024 ADC units, which is exactly in the middle of the output range. The baseline is not given explicitly, but may be assumed to be equal to the ADC zero value of 1024. Afterwards, the value (995) of the first acquired sample is stored. So the signal begins slightly below 0 V. The checksum of the 650000 samples is -22131 in the first signal line, and I/O may be performed in blocks of any desired size as the block size fields are zero. At last the signal line descriptions specify which leads were used. The header file finally closes with two info lines.

Signal File

WFDB signal files exist in several formats. Any of these formats can be used for multiplexed signal files, in which samples from two or more signals are stored alternately. All signals of the MIT-BIH database are written in the 212 format described next.

Format 212 The 212 format is shown in Figure 4.3. Each sample is represented by a 12-bit two's complement amplitude. The first sample is obtained from the 12 least significant bits of the first byte pair (stored least significant byte first). The second sample is formed from the 4 remaining bits of the first byte pair, which are the 4 high bits of the 12-bit sample and the next byte, which contains the remaining 8 bits of the second sample. The process is repeated for each successive pair of samples.

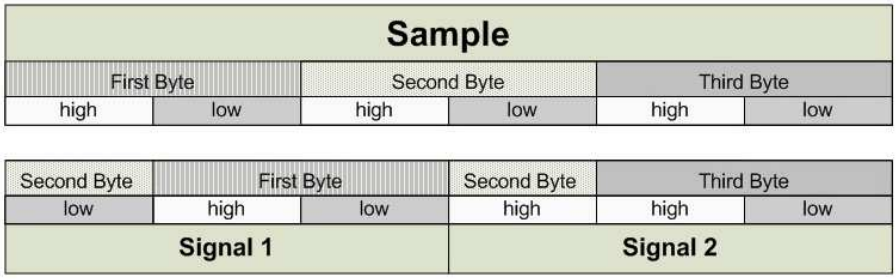

Figure 4.3.: Signal file format 212

Annotation File

The MIT WFDB records are about 30 minutes in duration and are annotated throughout. So each QRS complex of a record was marked by a detector and then the printed ECG recordings were independently judged by two cardiologists. They labelled all abnormal beats or added new beats, where the detector missed one. Furthermore, also rhythm labels, signal quality labels, and comments were added. The compared and over-worked data then were transcribed into a compact and extensible file format, the annotation file. Each annotation usually occupies two bytes size.

As shown in Figure 4.4 the six most significant bits (A) of each byte pair are the annotation type code and the ten remaining bits (I) specify the time of the annotation, measured in sample intervals from the previous annotation (or from the beginning of the record for the first annotation). The annotation code (A) is usually defined in the header file <wfdb/ecgcodes.h> (see CD Contents in Appendix A), but there are some other cases from A = 59 to A = 63, which have to be considered.

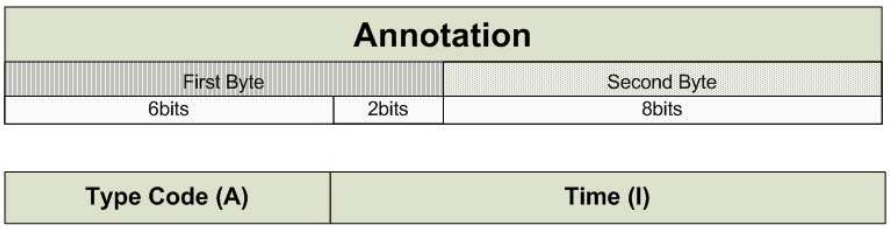

Figure 4.4.: Annotation file format

The time of an annotation is simply the sample number of the sample with which the annotation is associated. Annotations may be associated with a single signal, if desired. Like samples in signals, annotations are kept in time and signal order in annotation files. No more than one annotation in a given annotation file may be associated with any given sample of any given signal. There may be many annotation files associated with the same record distinguished by annotator names. The annotator name "atr" is reserved to identify reference annotation files supplied by the developers of the databases to document correct beat labels.

4.4. Input/Output Interfaces

4.4.1. Data Acquisition Card

The DAQ Card is of Type 6036E from NI connected through the PCMCIA socket. The main task of the DAQ Card is to create the analog ECG signal from the digitized values of the MIT database with its *digital-to-analog converter* (DAC). The DAQ Card also offers 8 *Digital Input/Output* (DIO) lines and as the SmartImage Sensor includes an Isolated Breakout Board, which sets a digital output depending on the captured text information (see Subsection 4.4.2), the DAQ Card was also used to interpret the SmartImage Sensor's output. Finally, the card controls the solenoid to start the analyzing process of the defibrillator and the relay to disconnect the electrodes from the defibrillator.

Technical Details

At the bottom line, the quality of the test system depends on the received ECG signal quality, so I present some relevant details about the analog output of the DAQ Card, which is used to create the ECG signal:

- Resolution: 16 bit
- Maximal Sampling Rate: 200 kS/s
- Relative Accuracy: ±2 LSB maximum
- Current Drive: ±5 mA

All the other tasks accomplished by the DAQ Card, for instance reading the output of the SmartImage Sensor or activating of the solenoid, do not need any special accuracy.

ECG Output Signal

The ECG signal was digitized (see Subsection 4.3.3) with a code width[2] of:

$$CodeWidth = \frac{Range}{Gain * Resolution} = \frac{\pm 1\,V}{200 * 2^{11}} = 4,88\,\mu V. \tag{4.2}$$

So, the smallest signal change recognized during the digitalization process was 4,88 µV. To recreate the signal a DAQ Card with a much higher resolution was chosen, mainly because of the current advanced state of the art. The NI DAQ Card 6036E has a resolution of 16 bit over the chosen output range of ±10 V, so the smallest signal step of the DAQ Card is:

$$SignalStep = \frac{Output\ Range}{Resolution\ of\ DAQ} = \frac{\pm 10\,V}{2^{16}} = 305,18\,\mu V. \tag{4.3}$$

But as the ECG signal is divided by the voltage divider described in Subsection 4.5.1 the finally code width is:

$$CodeWidth = Res * factor_{Vdiv} = 305,18\,\mu V * \frac{47\,\Omega}{47\,\Omega + 100\,k\Omega} = 0,1434\,\mu V. \tag{4.4}$$

Hence the code width of this test system is much smaller than the code width during digitizing the signal, it would not work the other way round.

[2] The range, resolution, and gain available on a DAQ device determine the smallest detectable change in voltage. This change in voltage represents 1 least significant bit (LSB) of the digital value [31].

Programming

The DAQ Card comes with a software package, which includes libraries for various programming languages (see Subsection 4.2.1) and applications. The libraries offer comprehensive prospects to programm the DAQ Card.

Generating Voltage To create the ECG signal first all values of the signal frame are stored in a buffer. Therefore the values read from the signal file of the record are multiplied with a factor composed of following parameters:

- $factor_{Vdiv}$ of the voltage divider calculated in Formula (4.6)
- multiplication value for the amplification or attenuation of the ECG signal
- divided by the overall maximum value, as the DAQ card only takes values between zero and a certain maximum output.

The next step is to create an analog output task on which the process runs. Then a channel is created on this task initialized with the output range, physical units and other parameters. Afterwards the timing of the output is set to the sample rate of the MIT signal. If the ECG signal should be stretched or compressed, the sample rate is multiplied with an appropriate factor.

Reading Digital Input To read a digital input line works similar to the generate voltage procedure. Therefore first a digital input task is created. The next step is to initialize a channel and a defined port with the corresponding lines, which should be read. Then the reader is completed by creating a stream on the task. With this stream the digital inputs are checked in a recurrent loop.

4.4.2. SmartImage Sensor

The DVT's SmartImage sensor is a stand-alone imaging sensor with on-board image acquisition, processing, digital I/O, and serial and Ethernet communications, used for assuring quality in manufacturing and gathering data. The deployed sensor is of type Legend 540MR which is a high speed gray scale sensor with Serial Nr. 540311364. The FrameWork software Version 2.71 was used to setup and configure the sensor.

Environment

To receive a comprehensible environment a tripod from Kaiser RS1 was used. The FRED defibrillator is set to specific coordinates in the middle of the tripod, so the hole display can be captured. For image acquisition also the contrast of the defibrillator display and the ambient light plays a major role. To minimize these factors special care had to be taken to train the sensor (see next section). As the distance between the objective and the defibrillator display is about 30cm a 1 mm spacing ring had to be added to the objective to use the objective in this close-up range.

Programming

With FrameWork software the SmartImage Sensor is setup and configured for precise measurement, counting parts, check the position, part presence or absence, identifying text and other applications. With the FrameWork User Interface the sensor is programmed to recognize the displayed text of the defibrillator and set a digital output according to the captured information. Therefore, the Framework offers an *Optical Character Recognition* (OCR) reader to capture single-lined text, which is fully trainable, meaning that mixed fonts, symbols or foreign characters can be read.

Train the Sensor: To achieve a recognition with a high true probability several parameters had to be set to recognize characters, mainly because of the small character spacing. But the SmartImage Sensor gets too slow for this application, as OCR requires a high processor performance. Hence another possibility to recognize the current state of the defibrillator had to be found. After trying various tools of the Framework software, the Blob Tool, which only counts the objects within a defined area, seemed to be the best solution. This is so for the following reasons:

- it is independent of ambient light, as it only recognizes black and white
- the position of the defibrillator is not relevant, as the frames of each blob may overlap (not possible with OCR)
- it is very fast and reliable

Output

The SmartImage Sensor offers various ways to communicate data from and to the sensor like Ethernet, Serial Communication and also via the Isolation Breakout Board (BOB) which provides digital I/O lines, power supply and strobe illumination lines. As other intelligent cameras mostly also provide a similar system like the BOB, but seldom offer an Ethernet connection, it was chosen to use the BOB. The BOB is connected though the isolated I/O Terminals (Port 2) to the digital input lines of the DAQ Card. BOB's digital IO1 is connected to the DIO0 of the DAQ Card, IO2 is connected to DIO1, and so on.

4.5. Electronic Components

In this section we take a closer look at the electronic components of the test system. The complete electric circuit and the connections between the components is shown in Appendix B.

4.5.1. ECG Signal Processing

The amplitude of ECG signals measured on the surface of the body is only a few millivolts high. To generate such a small signal the DAQ Card produces an ECG signal with an amplitude as high as the output range of the Card. This signal, then is downsized with a Voltage Divider (see Figure 4.5) to the required amplitude of a few millivolts. Common measurements are not able to measure such a tiny signal properly, as the noise is about the same size as the ECG signal.

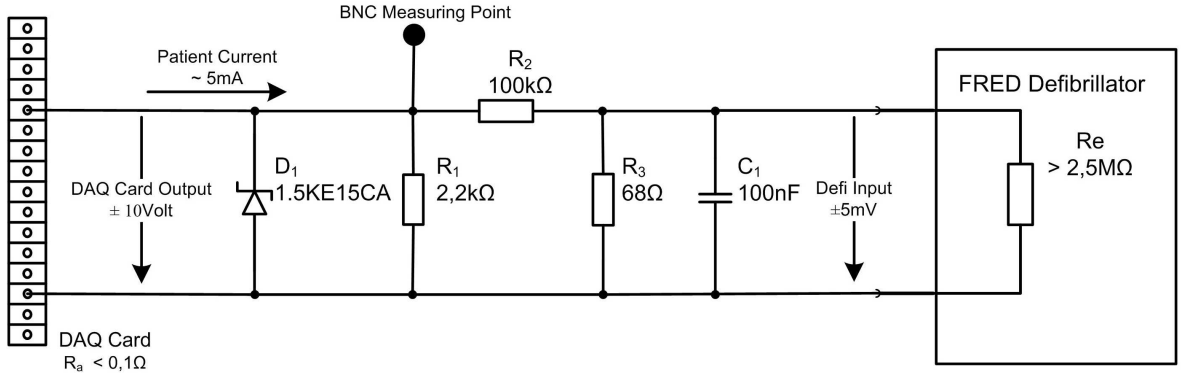

Figure 4.5.: ECG signal processing and overvoltage protection circuite (Section 4.5.2)

Voltage Divider

To reduce the signal amplitude of the ECG signal a common voltage divider is used. The proportion of the input voltage (which is the output of the DAQ Card) to the output voltage of the voltage divider (which is the input of the defibrillator) relates to the proportion of the resistances:

$$\frac{Defi\ Input}{DAQ\ Card\ Output} = \frac{U_O}{U_I} = \frac{R_3}{R_2 + R_3}\ , \tag{4.5}$$

hence the ECG signal U_O after the voltage divider is:

$$U_O = U_I * \frac{R_3}{R_2 + R_3} = \pm 10\,V * \frac{68\,\Omega}{68\,\Omega + 100\,K\Omega} = \pm 6,8\,mV. \tag{4.6}$$

To receive an exact output range of ±5 mV the output of the DAQ Card is calibrated to the voltage divider. The $factor_{Vdiv}$ is calculated in Formula (4.7). But first the resistance of R_2 and R_3 have to be measured. As the values of the resistors are temperature dependent, the system should run for half an hour before they are measured.
For example, the measured resistances are as follows (normative values in brackets):
$R_2 = 99,75\,k\Omega$ $(100\,k\Omega)$, $R_3 = 68,3\Omega$ (68Ω)

$$factor_{Vdiv} = \frac{R_3}{R_2 + R_3} = \frac{68,3\,\Omega}{99818,3\,\Omega} = 1\ /\ 1461,47\ \ (1/1471,59). \tag{4.7}$$

So the $factor_{Vdiv}$ used to calculate the DAQ Card value is 1 / 1461,47 and entered in the according text box when running the program (see Subsection 4.2.2).

Measure ECG Signal

With the first ECG signals generated by the DAQ Card, the signal was checked on accuracy. To achieve this the output of the DAQ Card was measured before and after the voltage divider. For the first measurements an Oscilloscope HP 54600B 100 MHz and a HP Probe was used. The signal amplitude after the voltage divider of a common ECG signal measures about 1,5 mV peak to peak. The smallest vertical scale of the HP Oscilloscope together with the probe, which has an attenuation of factor 10, is 20 mV per division, hence the ECG signal is in the smallest measuring scale.

As shown in Figure 4.6 the signal shapes of the ECG signal before the voltage divider (Channel 2) and the ECG signal afterward (Channel 1) are nearly the same, except for the noise on the ECG signal. The ECG signal amplitude was amplified by a factor of ten to compare the signal shapes with the available oscilloscope. After various tests the supposable main reason of the noise was found in the probe and oscilloscope itself.

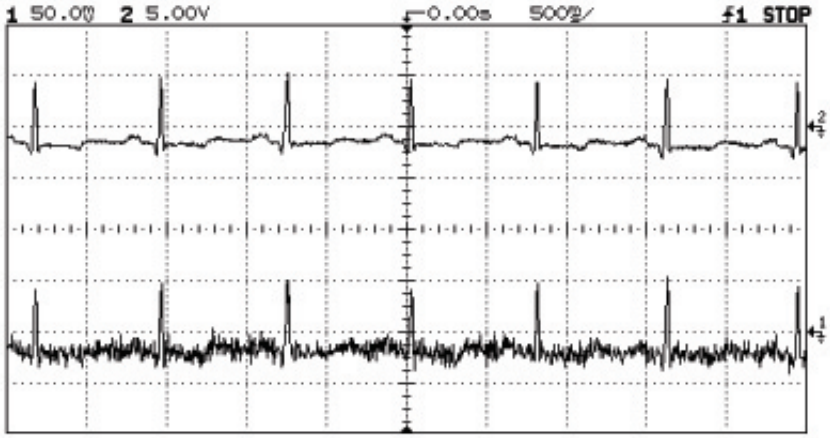

Figure 4.6.: ECG signal before and after the voltage divider

In Figure 4.7 the probe of Channel 2 is connected to *ground* (GND), so usually a flat line without any spikes or noise should be displayed, but we see nearly the same noise as the one superimposed with the ECG signal in Channel 1 after the voltage divider. Here, again the ECG signal amplified by a factor of ten was measured.

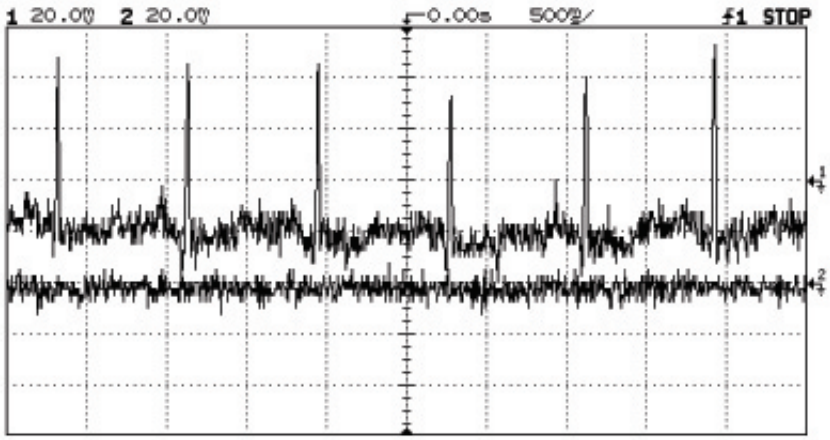

Figure 4.7.: ECG signal and noise of the Oscilloscope shunting the probe to GND

The first measurement was repeated with a more accurate oscilloscope Le Croy Waverunner LT372 DSO Serial No. 00290 and Probe Le Croy PP006A 10:1 500MHz 10MΩ 12pF to check, whether a better result is possible. But the result was the same. So various other methodologies were taken into account, like for instance using an active probe for the oscilloscope, which uses a differential amplifier for signal amplification. Furthermore, it was investigated whether the Lock-In Amplifier SR-830 could solve the measuring problem. But this analyzer is only used to measure the amplitude and phase of signals buried in noise. As measuring did not seem to lead to a solution due to unavailable proper tools, the noise on the signal was calculated.

Calculate Noise

In this application we can distinguish between following types of noise [21], [14]:

Thermal Noise also called Johnson noise, is generated by the random thermal motion of electrons in resistive material. It is present in all circuit elements containing resistance and is independent of the composition of the material.

$$U_{tn} = \sqrt{4KT\ R\ \Delta f} = 10,6nV \tag{4.8}$$

K ...Boltzmann's constant $1,38 * 10^{-23} J/°K$

T ... Degree in Kelvin

hence at room temperature 300°K ... $4KT = 1,66 * 10^{-20}$

R ... Resistance = 68 Ω

Δf ... Bandwidth = 100 Hz

Shot Noise is generated by the random emission of electrons or by the random passage of electrons and holes across a potential barrier. But as this kind of noise only occurs on semiconductors, we can ignore it.

Flicker Noise is a noise which has a spectral density that is proportional to $1/f^n$, where $n \simeq 1$. It is also called *one-over-f noise*. This type of noise is caused by fluctuation of the mobility of free charge carriers in semiconductors, but also exists in carbon resistors. It is also generated by the imperfect contact between two conducting materials, then called contact noise.

kT/C Noise is not a fundamental noise source but an extension of the thermal noise in the presence of a capacitor in a low-pass filter. According to Lundberg [23, page 10] the total output noise voltage, which is measured across the capacitor is simply:

$$U_n = \sqrt{\frac{kT}{C}} = 203,7\,nV \tag{4.9}$$

Looking at the kT/C Noise the total noise voltage of 203,7 nV is bigger than the code width of 142,4 nV (see Equation (4.4)). On the other hand the signal to noise ratio is just about 1/7500, but parameters like the contacts of the relay have not been taken into account. Hence, I recommend to measure the ECG signal to determine whether the signal is clear enough.

4.5.2. Overvoltage Protection

As the test system itself is very vulnerable to excess voltage, special protection system must be realized to protect the data acquiring card and the notebook, where the DAQ Card is plugged in through the PCMCIA connection. According to the datasheet of the DAQ 6036E the analog output line of the DAQ Card is protected up to ±25 V when powered on, and even only ±15 V when the system is switched off. The output of a defibrillator is a multitude of that. The problem here is that the defibrillator measures and analyzes the ECG signal generated by the automatic test system with the same connections as the shock is supplied. Furthermore, the button to start the analysis and to deliver the shock is the same with the FRED defibrillator and some other semiautomatic defibrillators. So if the solenoid is switched, when the defibrillator detects VT or VF and recommends a shock, the driven energy (up to 360 Joule) will destroy the test system.

Protection Components

There are various components available to protect electronic equipment from overloads. Some of them break the connection like fuses, while others short-circuit the overload like varistors.

Fuse A fuse protects devices from excessive electrical current, but does nothing for transients and short duration spikes of high voltage. It contains a conductor that melts and breaks the current flow when too much electricity flows through it. Once a fuse is blown, it must be replaced with another one to close the circuit and allow electricity to flow again.

For the application to protect the DAQ Card and the laptop, fuses are to slow [29, page 6], as the protection depends on a thin wire and so the response time of the fuse is slow enough to cause some serious damage to the electronic. Hence, the fuse must be combined with further protection devices.

Varistor A varistor (**vari**able resi**stor**) is a voltage dependent resistor (VDR) with a symmetric, non-linear Current/Voltage-Characteristic like shown in Figure 4.8. From a defined voltage called breakdown voltage the varistor gets a low resistance, hence the voltage does not increase anymore. The superimposed surge voltage V_S is clamped to the operating voltage V_B and the energy is shunt to ground.

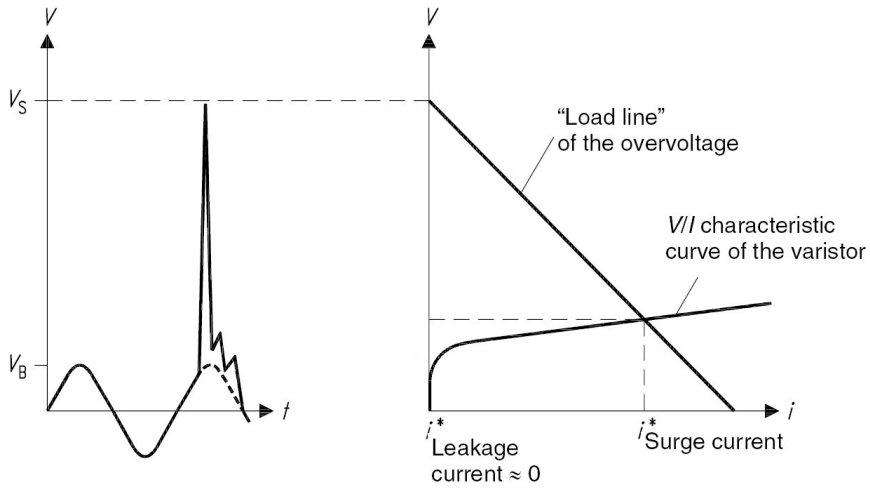

Figure 4.8.: Principle of overvoltage protection by varistors [12, page 45]

The varistor with the best characteristics was found in the Panasonic ERZV20D180. As described in the datasheet, it has the highest energy handling capacity of 12 Joule within 2 ms and even 13 Joule with the 10/1000 μs waveform. But as the component was not deliverable within a reasonable time, replacement had to be found.

Transient Voltage Suppressors The function of a protection diode is to limit the voltage across the device protected in case of accidental overloads such as those caused by electrostatic discharge, inductive load switching, induced lightning or failures of equipment. In certain cases, like in our application, the overload by the defibrillator may destroy the protection diode. We can accept the destruction of the diode, but the equipment requires absolute safety, which is accomplished as the diode remains a short-circuit after the overload, hence keeps the voltage low.

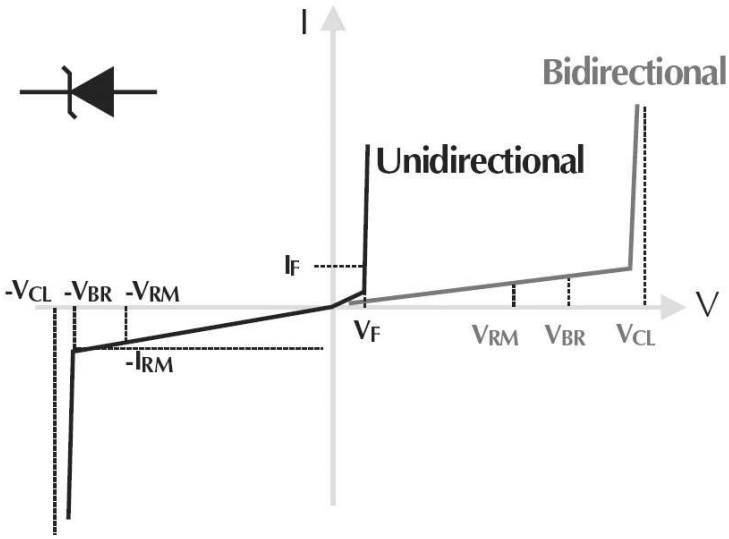

Figure 4.9.: Current/Voltage (I/V) Characteristic of a Transil-diode [35, page 6]

Transient Voltage Suppressor (TVS) Diodes behaves like that and are therefore used to protect vulnerable circuits from electrical overstress. The TVS limits damaging voltage spikes by clamping or avalanche action of a rugged silicon pn junction, which reduces the amplitude of the transient to a nondestructive level. For the rest of the circuit, the TVS should be "invisible" until a transient appears. Hence, all electrical parameters shown in Figure 4.9 such as breakdown voltage V_{BR}, standby voltage V_{RM} or leakage current I_{RM} and capacitance should have no effect on the ECG signal.

Usually the TVS breakdown voltage is chosen 10% above the reverse standoff voltage V_{RM}, but with our application the clamping voltage V_{CL} is chosen to be lower than the overvoltage protection limit of the DAQ Card. When a transient occurs, the TVS clamps instantly to limit the spike voltage to a safe level V_{CL}, while conducting potentially damaging current away from the protected component. The TVS solution offers a very short response time and reproducible operation thanks to its silicon structure.

A suitable TVS device could be found from STMircoelectronics in the BZW50-10 which can absorb up to 5ooo Watts and offers also the required low clamping voltage, which is usually hard to find. Unfortunately the delivery time for the devise is ten weeks, hence another possibility to protect the test system had to be found.

Crowbar The circuit shown in Figure 4.10 uses the "crowbar" method and provides fast protection against transient voltage spikes, transients which could cause damage to sensitive components as the DAQ Card.

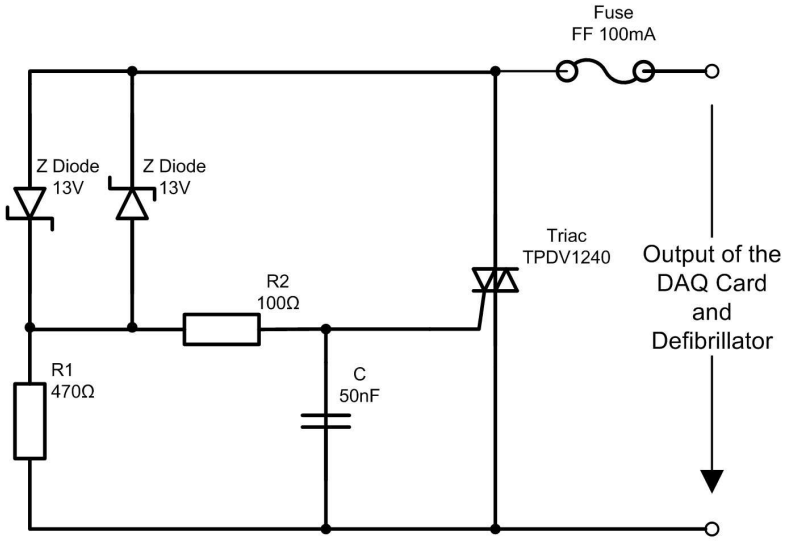

Figure 4.10.: Crowbar overload protection circuit

As soon as the voltage exceeds the limit V_Z set by one of the Zener-diodes[3], the Z-diode gets low resistance and triggers the triac within a few microseconds. This is over 1000 times faster [10] than an ordinary quick blow fuse. As soon as the triac switches the overload is

[3] Zener-diode (Z-diode): As opposed to all other diodes, the Z-diode is used in reverse direction. It has a defined avalanche voltage and is often used for voltage stabilizing.

short circuited. The duration of the short circuit will be only a few milliseconds before the fuse blows. In these few milliseconds the voltage will be greatly reduced.

Further Circuit Description: The Resistor R2 and Capacitor C build a low-pass filter to prevent very short fluctuations and distortions less than half a microsecond from firing the thyristor, as the RC Filter discriminates frequencies higher than ω_B:

$$\omega_B = \frac{1}{R * C} = \frac{1}{100\,\Omega * 5 * 10^9\,F} = 2\,MHz \tag{4.10}$$

The resistor R2 also limits the current through the gate of the triac, as the current through the zener diode may be to high at the beginning. The Z-Diodes are switched in anti parallel to cover possible overloads in both directions of, as the some defibrillators deliver biphasic waveforms (see Subsection 3.3.3). The resistor R1 discharges the leakage current of the Z-diodes, so that the Triac is not triggered.

Trisil-diodes[4] belong to the category of integrated crowbar protection devices. When the voltage across the Trisil-diode exceeds the VBO, the device is triggered and becomes a low impedance path, through which the over-charge is diverted. Figure 4.11 shows the characteristic of a Trisil-diode, hence also the characteristic diagram of the crowbar circuit (Figure 4.10) described above.

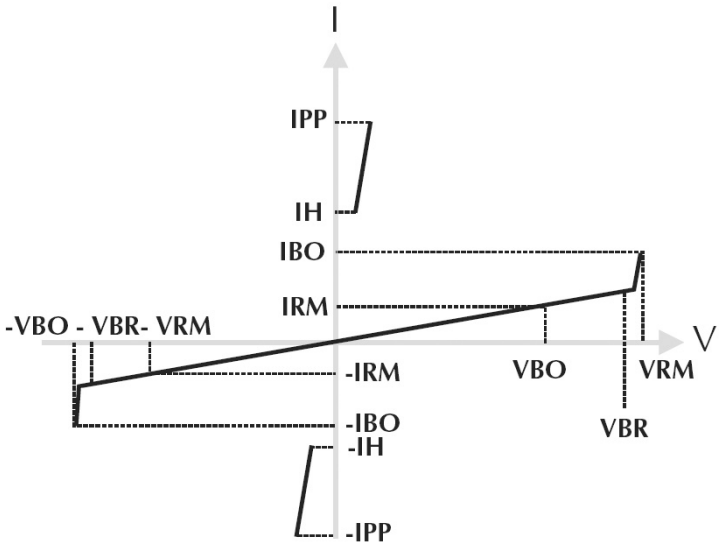

Figure 4.11.: Current/Voltage (I/V) Characteristic of a Trisil-diode [35, page 9]

[4] A semiconductor protection devise, which shunt down an overvoltage

Discussing this circuit with Dr. Helmut Klocker, we came to the conclusion that realizing the circuit would take too much time with an uncertainty, whether the components are fast enough to work with all kinds of waveforms of various defibrillators or not.

Final Solution

As all found protection devises and circuites did not lead to a fast realizable, absolute safe solution for the test system, as they depended on the waveform of the defibrillator, finally I received a draft from Peter Hamm of a circuit to test defibrillators with various waveforms. The draft was adapted for this test system. The adapted circuit is shown in Figure 4.12. A voltage divider was used to break done the overvoltage to a level, which could be handled by a Transil-diode described in Subsection 4.5.2.

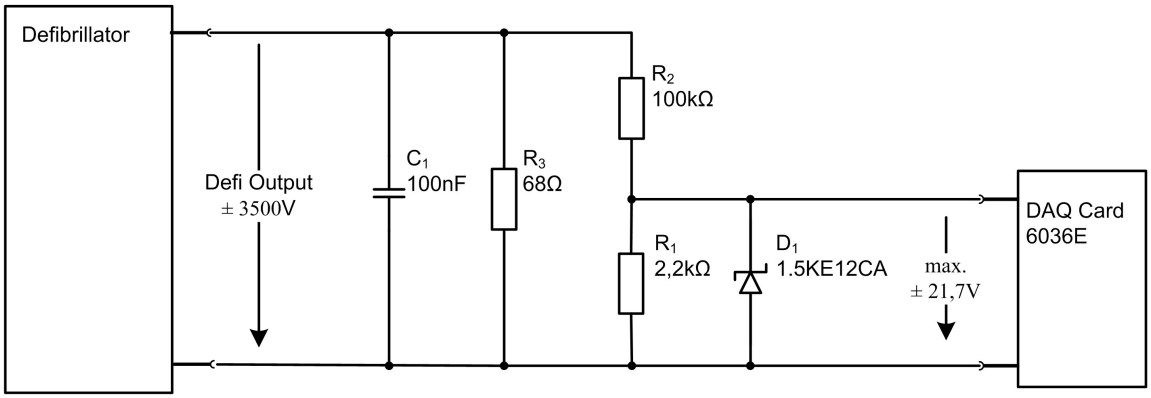

Figure 4.12.: Final overload protection circuit

The output of the defibrillator "sees" the 68 Ω power resistor as the patient's resistance. Parallel to the patient's resistance the 100 kΩ high voltage resistor and a 2.2 kΩ resistor are switched. As an example, when the defibrillator yields approximately 3500 V the voltage is divided by R_2 and R_1, hence nearly all of the voltage drops on the high voltage resistor, which holds a maximum voltage of 7500V. On the resistor R_1 about 75 V would be left, but are limited by the Transil Diode D_1 of type 1.5KE12CA to a maximum of 21,7 V, hence the DAQ Card is safe from overvoltage of the defibrillator. The 100 W power wirewound resistance R_3 takes all the energy delivered from the defibrillator and must be high voltage proofed too.

4.5.3. Solenoid

With most AEDs the analyzing process must be started by pressing a button, which is accomplished by a solenoid[5] to run the system automatically. Therefore the DAQ Card controls a bipolar transistor, which works as a switch to drive the solenoid.

4.5.4. Relay

The FRED needs about 20 seconds, when detecting VF, before the next analyzing process may be started without delivering a shock. So, to optimize the test process a relay is required to disconnect the electrode pads of the defibrillator, so that the analyzing process can be started immediately again. But unfortunately the contacts of the relay generate contact noise (see the next subsection). The relay is also switched by the DAQ Card and driven by a bipolar transistor.

4.6. First Responder External Defibrillator (FRED)

The developed test system was initially designed for the FRED - First Responder External Defibrillator from Bruker Medical, which is a semiautomatic defibrillator for EMS personal also offering a manual modus, if a doctor is on location. It uses a biphasic waveform, which Bruker calls Multipulse Biowave. This waveforms are highly effective pulsed energy with a more gentle impact on heart tissue. Details regarding the test system are the dynamic ECG input of ± 5 mV and the frequency range of the input channel from 0.5 to 40 Hz. Furthermore, it offers filters to suppress distortions of the power line for 50 and 60 Hz. According to the manual the FRED reaches a Sensitivity of 97,99% and a Specificity of 99,97% using the databases of AHA and MIT. None of the algorithms in [3] reaches such a high detection quality, so this test system will prove, if the specifications are true.

[5] A solenoid is a coil, which forces a plunger into a certain position when voltage is impressed.

4.6.1. Connected Electrodes not Recognized

After an ECG signal could be generated with the DAQ Card and was measured and checked with an oscilloscope (described in Subsection 4.5.1) the FRED was connected to the ECG signal through the front connector for the defibrillator pads.

The FRED was switched on and after the selftest the display showed "Connect the Electrodes". When connecting the test system the FRED should recognize it and show "Push Analyze Button", but the FRED did not respond though the ECG signal created by the test system was displayed in the defibrillator's monitor. With the used circuit the FRED "sees" a body resistance of the patient of 68 Ω (see circuit diagram in Figure 4.12), the common patient impedance over the torso takes values from 50 to 150 Ω [37]. In a next step I connected the FRED to myself, but still it did not recognize the electrodes and only showed the ECG on the display. To check if the FRED might identify connected electrodes at a different resistance a potentiometer was connected and adjusted from 20 to 400 Ω, but the result was unaltered. The last step was to check the optional ECG input of the FRED, which uses a 3-lead patient cable. By connecting the potentiometer the FRED immediately detected connected electrodes.

Hence, it is very likely that the input circuit to detect connected electrodes by measuring the resistance between the electrode pads is broken.

5. Conclusion

Now we have the complete test system for a defibrillator of type Bruker FRED and the system is ready to check the quality of the arrythmia detection. The main problem was to find a way to connect the various components and get them communicate between each other. So regarding the Waveform Database (WFDB) the provided tools were of no use and the required functions had be programmed manually. Programming the DAQ Card was a lot of trial and error, because NI offers only little documentation to program the DAQ Card in C#. The image capturing tool worked too slow with Optical Character Recognition (OCR), hence the captured information had to be cut down to the number of chars. The final programming of the SmartImage Sensor can be found on the enclosed CD, whose contents is listed in Appendix A. Another challenge was the protection of the test system from overvoltage. Here only a simple voltage divider with a power resistor in combination with a common protection device solved the problem, because of the high voltage and energy of an electrical shock from the defibrillator. The complete electronic schematic of the test system is shown in Appendix B and the assembled running test system is shown in Appendix C. Finally the created ECG signal is correct before the voltage divider, but because of the tiny signal amplitude after the voltage divider noise plays an important role for the signal quality. The amount of noise could not be measured and only calculated approximately so far. Hence, still some work have to be done regarding the noise measurements, but that might be done after the first test results. Afterwards it is planned to adapt the test system for other defibrillator types, too.

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List of Figures

A. CD Contends

thesis.pdf ..... This thesis

A0_poster.pdf ..... Poster of the thesis

defiControl.exe ..... Executable of the test software

/literature ..... Folder containing the used literature, especially the articles of journals retrieved in electronic form and also sources taken from the internet.

/testSoftware ..... Folder containing the required C# source files and MS Visual Studio project files for further extensions of the test software, like adding other defibrillator types or adding noise to the ECG signal.

/SmartImage Sensor ..... Folder containing the program of the SmartImage Sensor to read the FRED defibrillator output and system environment files for Framework 2.7.

/datasheets ..... Folder containing datasheets of the used electronic components, like DAQ Card, SmartImage Sensor, solenoid, special resistors, transistors, and diodes.

/MIT_database ..... Folder containing some freely available records of MIT-BIH database, downloaded from http://www.physionet.org.

B. Electronic Schematic

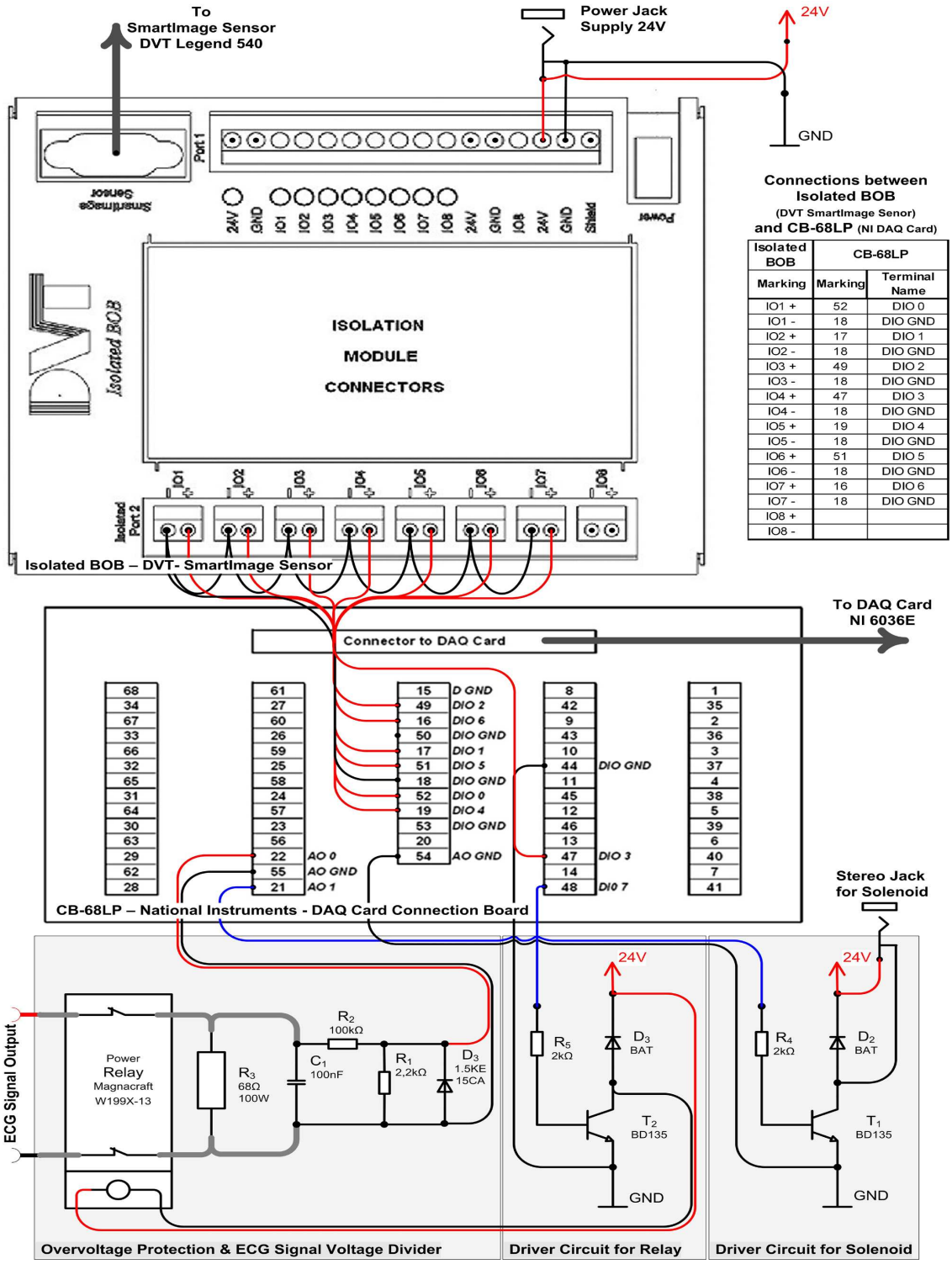

Figure B.1.: Electronic schematic of the complete test system

C. Picture of the Final Test System

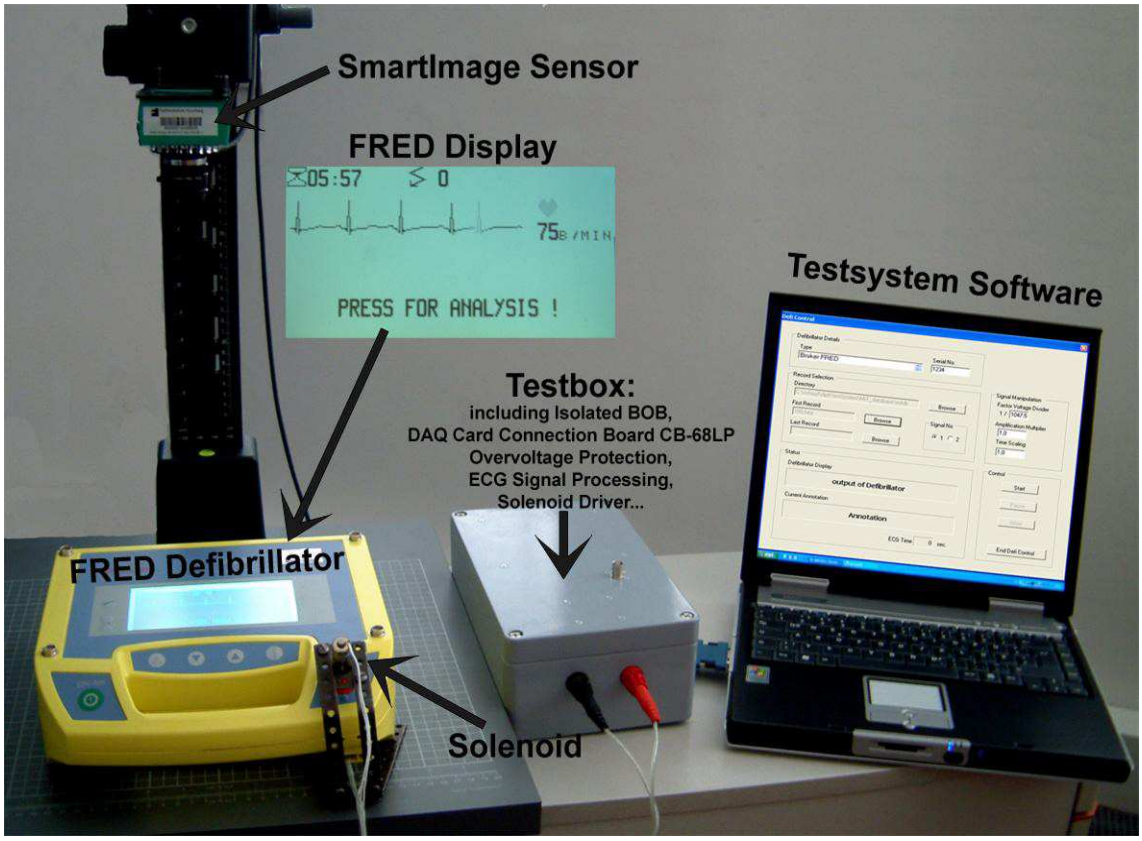

Figure C.1.: Final test system