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# Hi Resolution Electrocardiogram Recorder

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Electronics

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<p>High-quality medical instrument and equipment design is important to ensure functionality, quality and aesthetics. Engineers need the right tools to develop new products that exceed requirements increase innovation and reduce costs. This bachelor's thesis develops a concept and provides an insight into the design process of a new tool – a device that will collect vital physiological data – a portable hi resolution EKG recorder.</p> <p>The main objectives of this thesis were to prove the concept of a hi resolution EKG recorder and provide a basic knowledge bank for anyone willing to design and manufacture a practical implementation of the tool. These objectives were fulfilled by providing use case scenarios, conducting market research and finally building a functional prototype with focus on both hardware and software architecture.</p> <p>This bachelor's thesis sequentially covers the basics of electrocardiogram as well as minimal safety design requirements. Finally, current performance and design limitations of the recorder as well as several improvement ideas are given.</p>	
Keywords	EKG, ECG, portable recorder, pacemaker, physiologic signals, verification, validation, ADC, instrumentation amplifier, RX71M, Renesas FIT, USB Host Mass Storage, LabVIEW.

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## 1 Introduction

In 1902 a Dutch physician Willem Einthoven recorded the first practical cardiogram from the human heart using a device called string galvanometer. Einthoven's invention consisted of a very long silver coated quartz filament of a very small mass that conducted electrical currents generated by the heart. Powerful electromagnets positioned on either sides of the filament caused its deflection from side to side in proportion to the current carried. The movement in the filament was heavily magnified and projected onto a moving photographic plate. Three buckets of saline solution acted as electrodes for both arms and left leg. These limbs produce what is known as Einthoven's triangle, a principle still used today in modern EKG recording. Willem Einthoven Was awarded the 1924 Nobel prize in Physiology or Medicine. (ethw.org, 2016)

As one can already guess, electrocardiography is a non-invasive, fairly simple process of recording the electrical activity of the heart over a period of time, using electrodes placed on the skin. It is a tool of remarkable clinical power. One glance at an EKG (electrocardiogram) can diagnose an evolving myocardial infarction, identify a potentially life-threatening arrhythmia, pinpoint the chronic effects of sustained hypertension or the acute effect of a massive pulmonary embolus, or simply provide a measure of reassurance to someone who wants to begin an exercise program. (Thaler, 2015)

Going little bit ahead, the ultimate goal of my work is to create a prototype able to acquire live data from real patients, which would be crucial for the design, optimisation and verification of various medical equipment like physiological monitors and electrocardiographs. The idea of this thesis was brought to me by two of my colleagues at General Electric Healthcare Oy: Juha Virtanen (Hardware Architect) and Kimmo Hauskaviita (Test Automation Engineer).

## 2 Electricity and the Heart

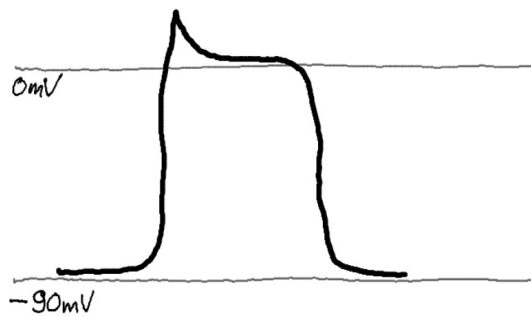
In this chapter the fundamentals of EKG as well as artificial pacemaker devices will be discussed. "Cardiac Cells" and "12 Views of the Heart" chapters are based on Thaler Malcolm's book - "The Only EKG Book You'll Ever Need".

## 2.1 Cardiac Cells (Thaler, 2015)

Cardiac cells, in their resting state are negatively charged on the inside with respect to their outsides. This electrical polarity is maintained by membrane pumps, that insure the appropriate distribution of ions (mainly sodium, potassium, chloride and calcium). These ions pass into and out of the cell via special ion channels in the cell membrane.

Cardiac cells can lose their internal negativity in a process called **depolarization**. In some cells, known as pacemaker cells, it occurs spontaneously. In others, it is initiated by an arrival of an electrical impulse that causes positively charged ions to cross the cell membrane. After depolarization is complete, the cardiac cells restore their resting polarity through a process called **repolarization**. Repolarization is accomplished by membrane pumps which reverse the flow of ions across the cell membranes.

An electrical tracing called **action potential** can be obtained if one cycle of depolarization and repolarization of a single cell is being recorded *Figure 2-1*. With each spontaneous depolarization, a new action potential is generated, which in turn stimulates neighbouring (adjacent) cells to depolarize and generate their own action potential.



*Figure 2-1 Generic action potential of a cardiac cell.*

Depolarization is propagated from cell to cell, producing a wave of depolarization that can be transmitted across the entire heart *Figure 2-2*. This wave of depolarization represents a flow of electricity, an electrical current, that can be detected by electrodes placed on the surface of the body.

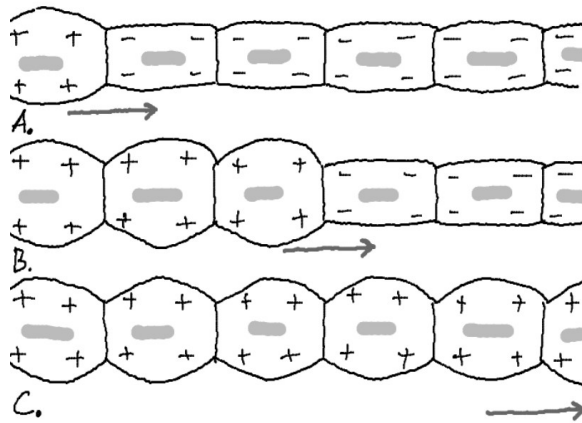


Figure 2-2 Wave of depolarization spreading from cell to cell.

All the different waveforms that can be seen on an EKG are manifestations of these two processes: depolarization and consequent repolarization.

From the standpoint of the electrocardiographer, the heart consists of three types of cells:

- Pacemaker cells – under normal circumstances, the electrical power source of the heart.
- Electrical conducting cells – the hard wiring of the heart.
- Myocardial cells – the contractile machinery of the heart.

### 2.1.1 Pacemaker Cells

Pacemaker cells are small cells approximately 5 to 10  $\mu\text{m}$  long. These cells are able to depolarize spontaneously over and over again. Each spontaneous depolarization serves as a trigger for a wave of depolarization that initiates one complete cycle of cardiac contraction and relaxation. The dominant pacemaker cells are located high up in the right atrium. The group of cells is called sinoatrial (SA) node, or sinus node for short *Figure 2-3*. These cells typically fire at a rate of 60 to 100 time per minute, but the rate can vary tremendously depending upon the activity of the autonomic nervous system and the demand of the body for increased cardiac output.



Figure 2-3 Sinus node location in the heart.

### 2.1.2 Electrical Conducting Cells

Electrical conducting cells are long, thin cells, these cells carry current rapidly and efficiently to distant regions of the heart *Figure 2-4*.

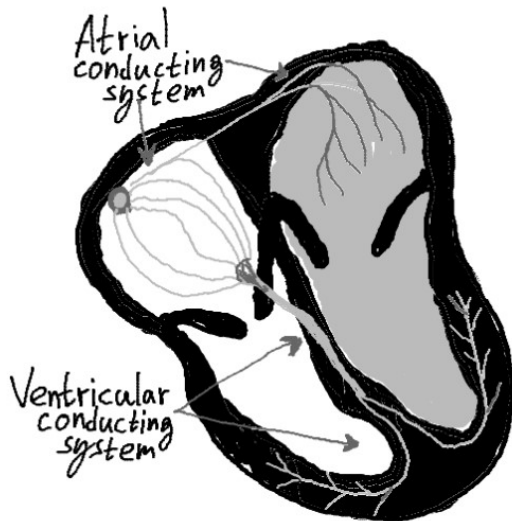


Figure 2-4 The hard wiring of the heart.



### 2.1.3 Myocardial Cells

The myocardial cells constitute by far the largest part of the heart tissue. They responsible for the heavy labour of repeatedly contracting and relaxing, thereby delivering blood to the rest of the body.

When a wave of depolarization reaches a myocardial cell, calcium is released within the cell, causing the cell to contract. This process, in which calcium plays the key intermediate role, is called excitation – contraction coupling.

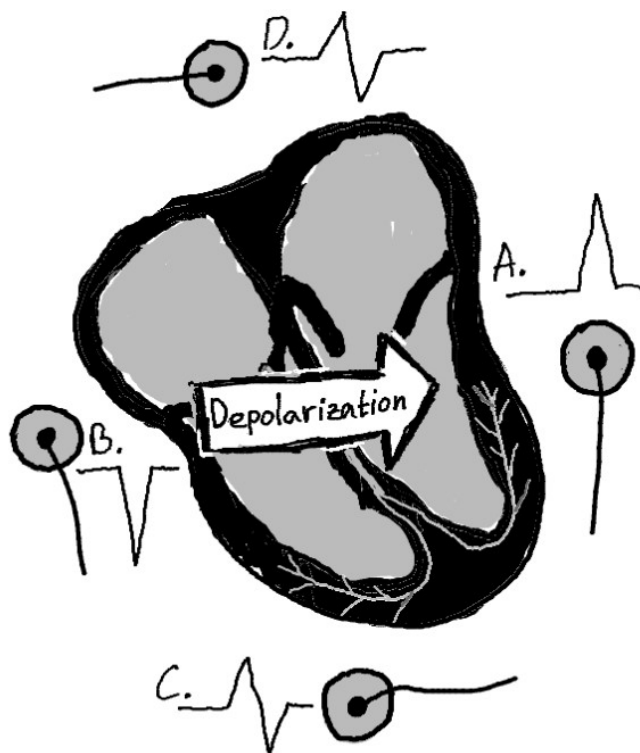
Myocardial cells can transmit an electrical current just like electrical conducting cells, but they do so far less efficiently. Thus, wave of depolarization, upon reaching the myocardial cells, will spread slowly across the entire myocardium.

The waves that appear on the EKG primarily reflect the electrical activity of the myocardial cells, which make the vast bulk of the heart. Pacemaker activity and transmission by the conducting system are generally not seen on the EKG. These events simply do not generate sufficient voltage to be recorded by surface electrodes.

## 2.2 12 Views of the Heart (Thaler, 2015)

Electrodes can be placed anywhere on the surface of the body to record the heart's electrical activity. If we do this, we quickly discover that waves recorded by a positive electrode on the left arm look very different from those recorded by a positive electrode on the right arm (or any other limb).

If a wave of depolarization passing through the heart is moving toward a surface electrode, that electrode will record a positive deflection (electrode A) *Figure 2-5*. If the wave of depolarization is moving away from the electrode, this electrode will record a negative deflection (electrode B). If the wave of depolarization is moving perpendicularly to the electrode, the electrode will record a biphasic wave (electrodes C and D). The effects of repolarization are precisely the opposite.



*Figure 2-5 Wave of depolarization moving through the heart. Voltage deflections on 4 different positive electrodes are represented.*

An EKG **lead** can be formed by observing the differential signal between any two physical electrodes. It is important to notice that the wave of depolarization represented on the image above will be best seen by forming an EKG lead out of electrodes A and B, while electrodes D and C may not be very useful.

The heart is a three-dimensional organ and its electrical activity must be understood in three dimensions as well. A couple of electrodes are not adequate to do this. Today, the standard EKG is made using 10 electrodes, which all together form 12 leads. Each lead views the heart at a unique angle, enhancing its sensitivity to a particular region of the heart at the expense of others. The more views the more the information provided.

To prepare a patient for a 12-lead EKG, two electrodes are placed on two arms and two are placed on the legs *Figure 2-6*. These provide the basis for the six limb leads, which include three standard leads and the three augmented leads. Six electrodes are also placed across the chest, forming the six precordial leads.

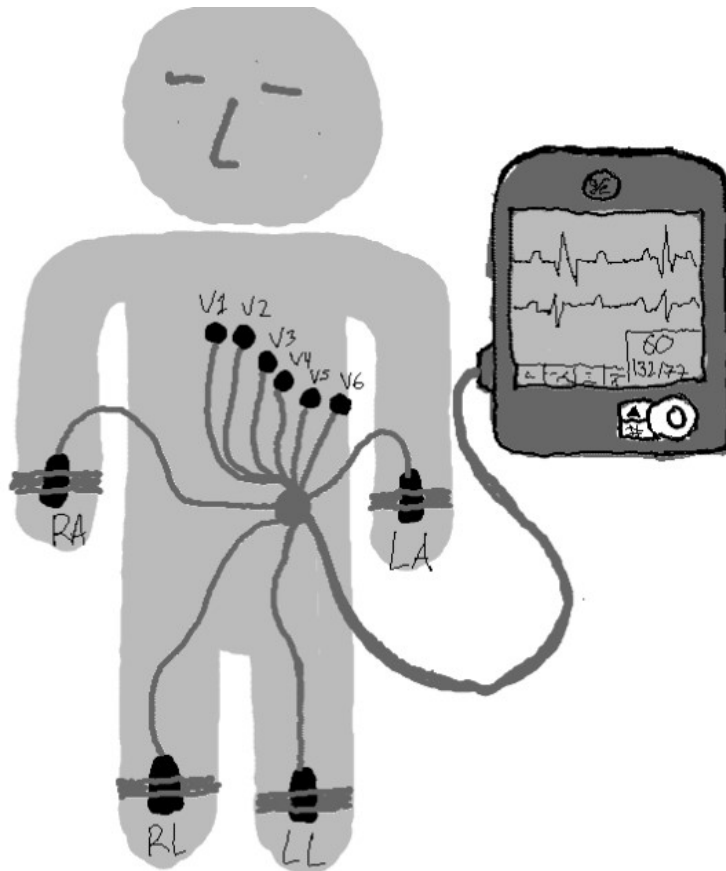


Figure 2-6 EKG electrodes for 12 lead full EKG

### 2.2.1 The Six Limb Leads

The limb leads view the heart in a vertical plane called the frontal plane. The frontal plane can be thought of as a giant circle superimposed on the patient's body. The limb leads view electrical fields (waves of depolarization and repolarization) moving up and down and left and right through this circle *Figure 2-7*.

- Lead **I** is the voltage between the positive left arm electrode and right arm electrode:

$$I = LA - RA \quad (1)$$

- Lead **II** is the voltage between the positive left leg electrode and the right arm electrode:

$$II = LL - RA \quad (2)$$

- Lead **III** is the voltage between the positive left leg electrode and the left arm electrode:

$$III = LL - LA \quad (3)$$

The three augmented limb leads are created somewhat differently. A single lead is chosen to be positive and all the others are made to be negative, with their average essentially serving as the negative electrode (common ground) *Figure 2-7*.

- Lead **augmented vector right** has the positive electrode on the right arm. The negative pole is a combination of the left leg and left arm electrodes:

$$aVR = RA - \frac{1}{2}(LA + LL) \quad (4)$$

- Lead **augmented vector left** has the positive electrode on the left arm. The negative pole is a combination of the right arm and left leg electrodes:

$$aVL = LA - \frac{1}{2}(RA + LL) \quad (5)$$

- Lead **augmented vector foot** has the positive electrode on the left leg. The negative pole is a combination of the right arm electrode and the left arm electrode:

$$aVF = LL - \frac{1}{2}(RA + LA) \quad (6)$$

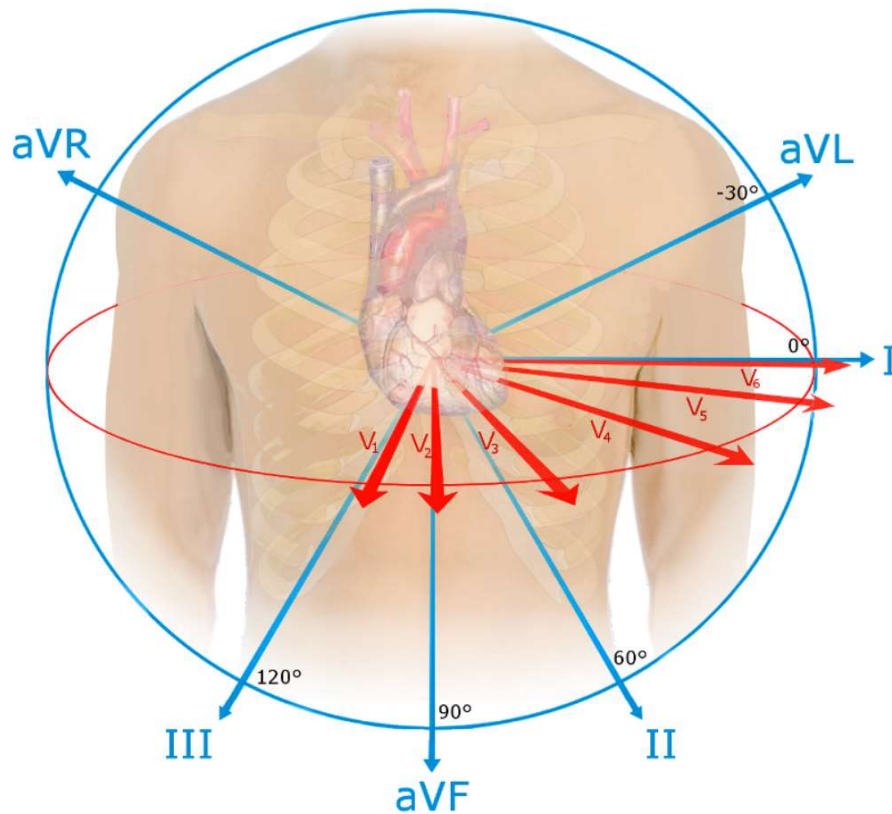


Figure 2-7 The limb leads and augmented limb leads represented as blue and red vectors respectively. Wiki image.

### 2.2.2 The Six Precordial Leads

The six precordial leads are arranged across the chest in a horizontal plane. Whereas the leads of the frontal plane view electric fields acting up, down, left and right, the precordial leads  $V_1$  through  $V_6$  record waves of depolarization and repolarization moving anteriorly and posteriorly.

The six precordial electrodes act as the positive poles for the six corresponding precordial leads:  $V_1$ ,  $V_2$ ,  $V_3$ ,  $V_4$ ,  $V_5$  and  $V_6$ . Wilson's central terminal is used as the negative pole. Wilson's central terminal  $V_w$ , is produced by averaging the measurements from the electrodes  $RA$ ,  $LA$ , and  $LL$  to give an average potential across the body:

$$V_w = \frac{1}{3}(RA + LA + LL) \quad (7)$$

- $V_1$  is placed in the fourth intercostal space to the right of the sternum:

$$V_1 - V_w \quad (8)$$

- $V_2$  is placed in the fourth intercostal space to the left of the sternum:

$$V2 - V_w \quad (9)$$

- V3 is placed between V2 and V4:

$$V3 - V_w \quad (10)$$

- V4 is placed in the fifth intercostal space in the midclavicular line:

$$V4 - V_w \quad (11)$$

- V5 is placed between V4 and V6:

$$V5 - V_w \quad (12)$$

- V6 is placed in the fifth intercostal space in the midaxillary line:

$$V6 - V_w \quad (13)$$

### 2.3 Artificial Cardiac Pacemakers

Artificial pacemaker devices are closely related to the goal of this thesis work, in particular: recording of artificial pacemaker artefacts as seen at the skin surface via EKG leads. In more details this will be discussed in next chapter – “Setting of Goals”. Therefore, it is important to provide the reader with basic information regarding artificial pacemaker devices.

The primary purpose of a pacemaker is to maintain or impose a heart rate on a patient’s heart either because the natural pacemaker cells are not “firing” often enough or because of a blockade in the heart’s electrical conductive system. Thus, it is an implantable device which generates electrical impulses delivered by electrodes to contract the heart’s muscles and normalise the electrical conduction system of the heart. *Figure 2-8* and *Figure 2-9* are an example of an implantable pacemaker and one of its bipolar electrodes.



*Figure 2-8 Implantable bilocular electric pacemaker with telemetry. Manufactured by Izhevsk Mechanical Plant “Baikal” (IMZCorp, 2018).*



*Figure 2-9 Endocardial bipolar electrodes. Along with electric pacemakers are intended for continuous stimulation of the heart activity (IMZCorp, 2018).*

A simple implanted pacer's activity is generally not visible on a normal EKG trace because the very fast pulses with widths of microseconds get filtered out, but in any case, they are too narrow to appear on a trace with resolution in the milliseconds. However, its signals can be inferred by pacing artefacts, voltage pulses that accompany the measurement of the heart's own electrical activity at the skin surface measured on EKG leads. For EKG machines and patient monitors it is important to be able to detect and identify pacing artefacts because they indicate the presence of the pacemaker - and help in evaluating its interaction with the heart.

As an example, AAMI EC11 states:

*"The device shall have the capability of displaying the ECG signal in the presence of pacemaker pulses with amplitudes between 2 mV and 250 mV, durations between 0.1 ms and 2.0 ms, a rise time of less than 100  $\mu$ s, and a frequency of 100 pulses/minute. For pacemaker pulses having durations between 0.5 ms and 2.0 ms (and amplitude, rise time, and frequency parameters as specified above), an indication of the pacemaker pulse shall be visible on the recording; this indication shall be visible on the display with an amplitude of at least 0.2 mV RTI."* (AAMI, 1991) (Kruse & Redmond, 2012) Please refer to Figure 2-10.

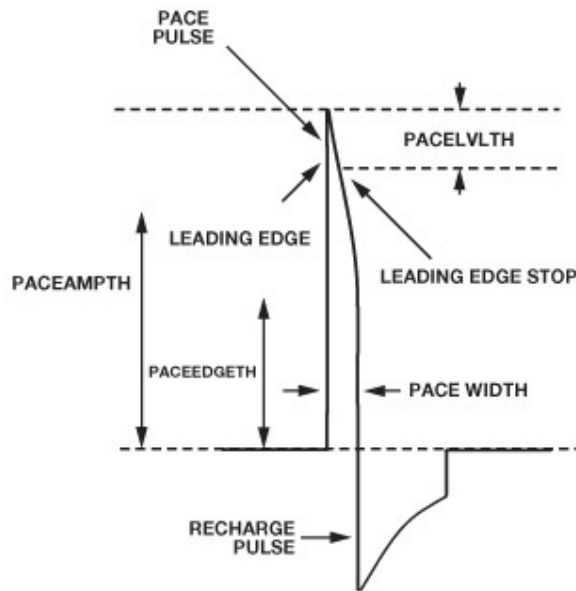


Figure 2-10 Ideal pacing artefact. "Detecting and Distinguishing Cardiac Pacing Artefacts", (Kruse & Redmond, 2012).

### 3 Setting of Goals

#### 3.1 Background

As the benefits of quality management within a manufacturing environment became apparent, so did the need for global standardization. In 1987 the International Standards Organization (ISO) published their ISO 9000 family of quality management system standards, these were made available to provide a process baseline and help companies ensure that their products and services consistently meet the needs of their customers.

Verification process is a crucial step on the way of developing a new product, service or system. This process insures that all design specifications, requirements and regulations involved will be met. As one can imagine verification is important when developing anything: from a pencil to a large cyclotron. Both of those devices/items must serve their own purposes under the imposed conditions: the pencil must be able to leave visible marks on paper and/or glass, film etc. without its core being broken too easily, the cyclotron in turn must accelerate charged particles outwards from the centre along a spiral path without causing harm or executing its user. Complex medical equipment such as a patient monitoring system is certainly not an exception and must be subject of verification process.

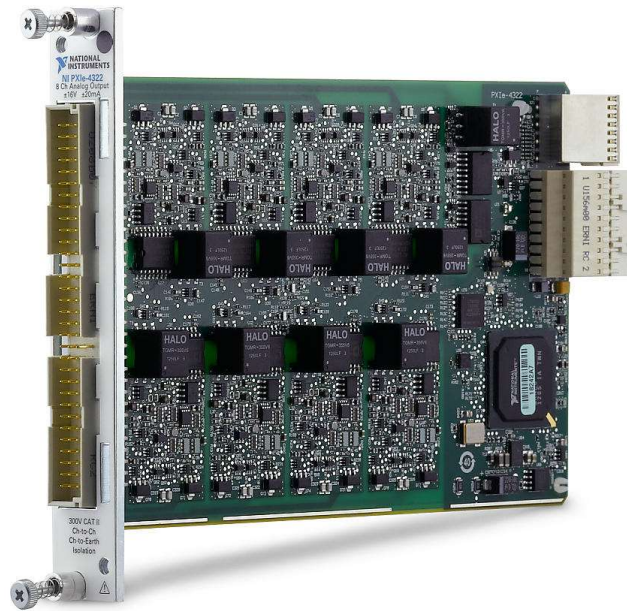


Prior to clinical tests and throughout the development process of a new patient monitoring system it will often be tested using a commercially available patient simulator such as the Fluke ProSim 8 Vital Signs Patient Monitor Simulator *Figure 3-1*. The simulator is capable of outputting pacer pulses of the following pulse widths: 0.1 ms, 0.2 ms, 0.5 ms, 1 ms, and 2 ms  $\pm$  5 % and amplitudes: 0 (off),  $\pm$  2,  $\pm$  4,  $\pm$  6,  $\pm$  8,  $\pm$  10,  $\pm$  12,  $\pm$  14,  $\pm$  16,  $\pm$  18,  $\pm$  20,  $\pm$  50,  $\pm$  100,  $\pm$  200,  $\pm$  500, and  $\pm$  700 mV for lead II (reference lead).



*Figure 3-1* Five EKG electrodes and an SpO<sub>2</sub> sensor are attached to the Fluke ProSim 8 simulator. Image belongs to Fluke Biomedical (Fluke Biomedical, 2018).

Even more interesting would be the results of a test involving a programmable DAC *Figure 3-2* and a database of pre-recorded patient live data. By streaming hundreds of different live EKG records through a patient monitoring system under test and further performing statistical analysis a very good understanding of the monitoring system performance can be obtained. An excellent example of a free physiological signal database is PhysioNet, it will be explained further in this text.



*Figure 3-2 PXIe-4322 8-channel analog output module can be used in verification tests. Image belongs to National Instruments (National Instruments, 2018).*

A portable data acquisition EKG device with high enough bandwidth would allow to acquire additional live data from volunteers during clinical tests, thus enriching and refreshing the existent physiologic signal databases with more up to date information on current pacemaker devices. In a similar manner, the EKG acquisition device may show itself useful when understanding the effects of electromagnetic interference produced by electrosurgery, Left Ventricular Assist Devices (LVAD), Magnetic Resonance Imaging (MRI), Radiation Therapy, Static Noise and other noise sources induced in the human body.

### 3.2 Hi-Resolution EKG Recorder Concept

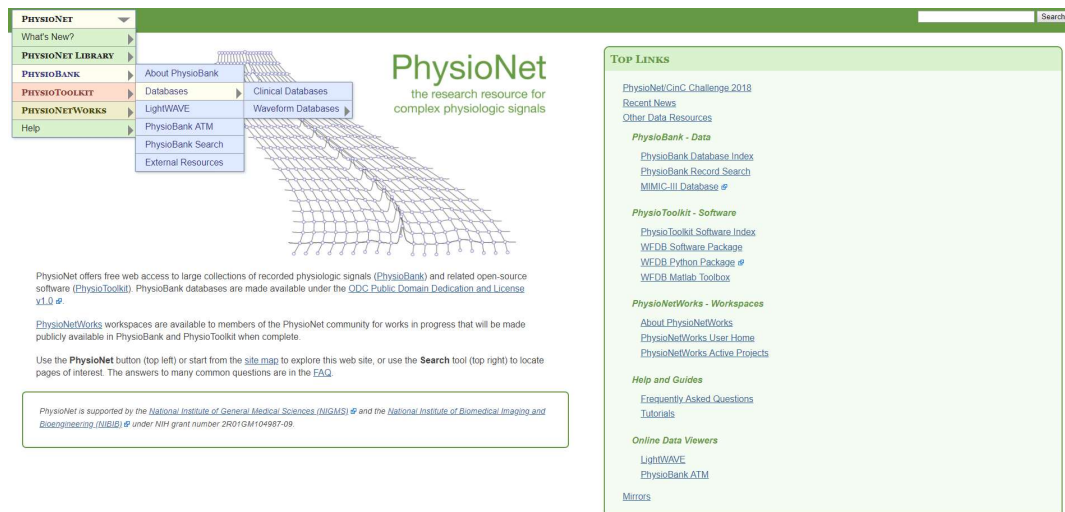
To understand whether there is an actual need for yet another EKG device – firstly, the concept must be formed and specifications estimated, secondly market research must be done where the concept will be compared to already available models, which can be freely obtained.

Device specifications are always set according to the device use case scenarios and overall idea behind. In our case, the specifications of the Hi-Resolution EKG Recorder

will be primarily affected by the basic properties of the input signals expected to be recorded (acquired). Pacemaker pulses are of a major interest; therefore, these must be analysed.

### 3.2.1 EKG & Pace Pulse Artefacts Signal Analysis

One of the EKG databases from <http://www.physionet.org/> will be used for the analysis *Figure 3-3*. In this context, a *database* is simply a collection of recordings (records), available as a set of flat files. PhysioBank databases consist tens to thousands of records that may each be quite large (in some PhysioBank databases, the size of a record can be a gigabyte or more, although typical record sizes are a few megabyte). Many of the databases currently in the PhysioBank Archives were developed at MIT and at Boston's Beth Israel Hospital (now the Beth Israel Deaconess Medical Center).

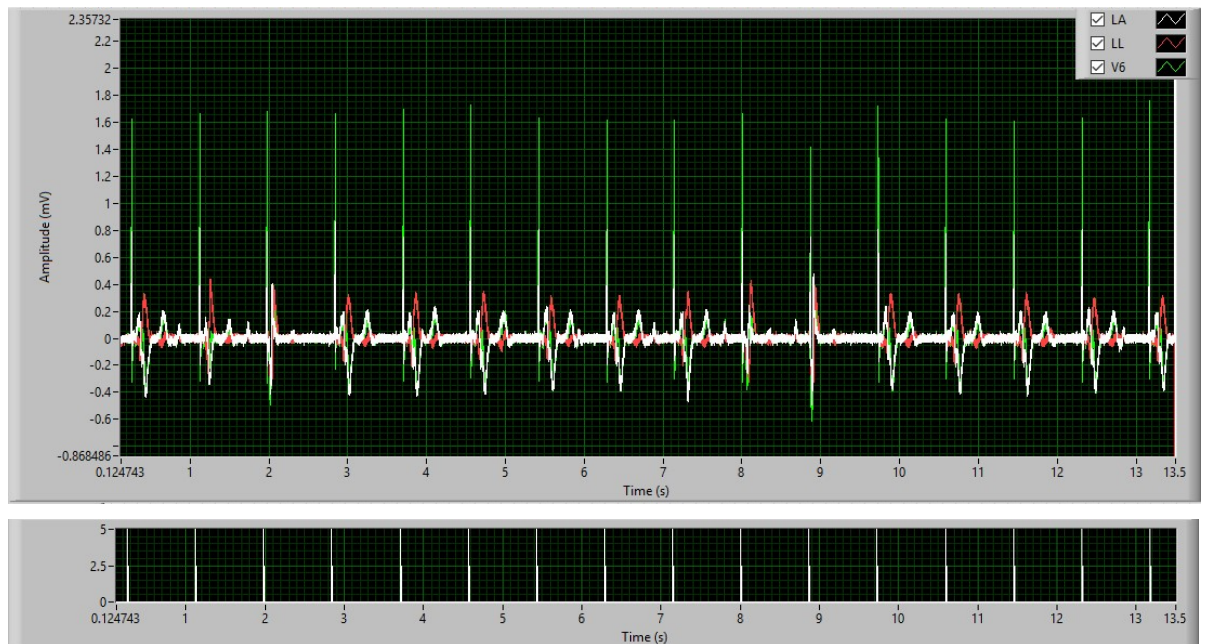


*Figure 3-3* <http://www.physionet.org/> main page (PhysioNet, 2018).

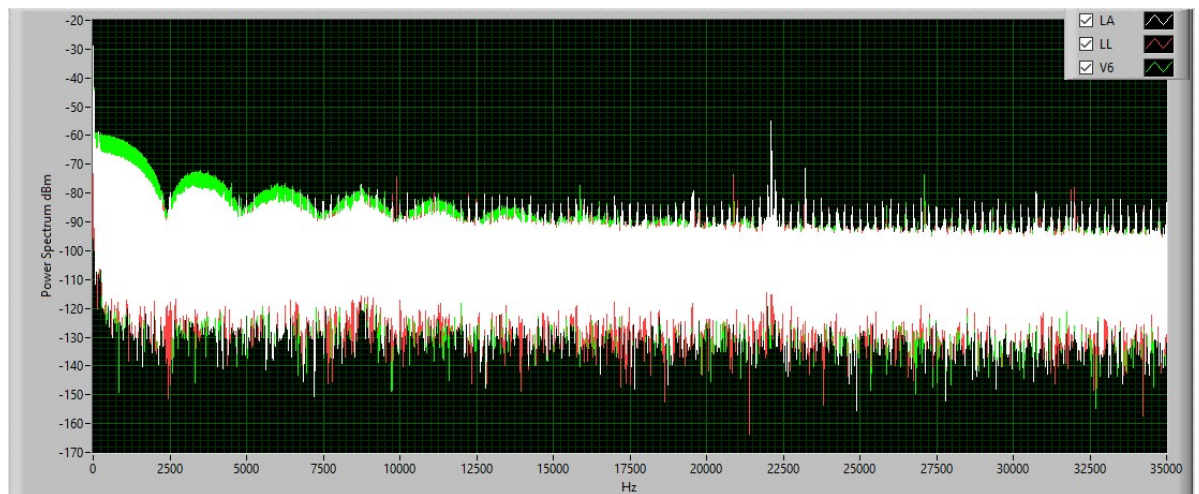
The selected database has hundreds of 12 lead EKG (8 channels) records with artificial pacemaker artefacts being present as part of the physiologic signals. The format of each record is as follows:

- MIT Signal files (.dat) are binary files containing samples of digitized signals. These store the waveforms, but they cannot be interpreted properly without their corresponding header files. These files are in the form: RECORDNAME.dat.
- MIT Header files (.hea) are short text files that describe the contents of associated signal files. These files are in the form: RECORDNAME.hea.
- (.prf) are called annotation files and contain information regarding the exact location of each pacemaker pulse artefact.

Each record is roughly 15 seconds long and contains 16-bit samples at 75 kSa/s. *Figure 3-4, Figure 3-5 and Figure 3-6* are given for better visualization of the database content.



*Figure 3-4* Waveform graph displaying 3 leads of EKG with clearly visible artificial pacemaker pulses. The bottom graph visualizes pacemaker annotation data.



*Figure 3-5* Power spectrum of the above displayed EKG signal.



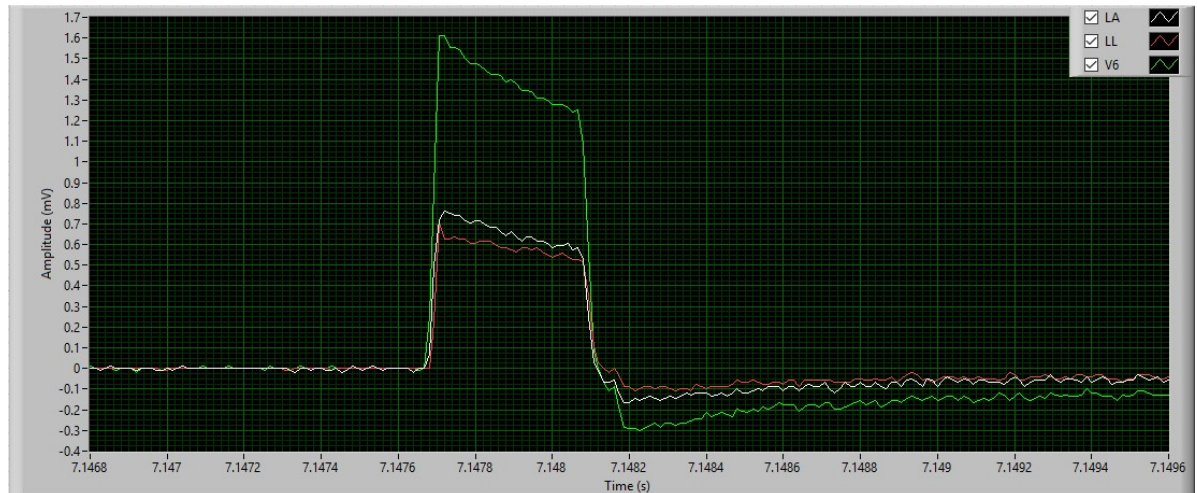


Figure 3-6 Magnified view of the 9th artificial pace pulse of the above 3 lead EKG.

### 3.2.2 Bandwidth Definition

As mentioned in the previous chapter, one of the main functions of the recorder would be to record live patient data, where the cardiac-pacing artefacts (pacemaker pulses) are being part of the signal or EKG trace. To better understand this design requirement let's refer to an ADAS1000 Electrocardiogram Analog Front End designed by Analog Devices Inc. The ISIC has two Low Pass filters to choose from on its EKG channels: “monitoring” and “diagnostic” with 40Hz and 150Hz bandwidths respectively. Such low bandwidth makes an implanted pacemaker’s activity typically not noticeable on a normal EKG trace, because the very fast pulses – with typical widths of hundreds of milliseconds – get filtered. A solution to this problem for my device specifically would be to use high enough filter bandwidth with a corresponding ADC sampling rate.

Similarly, each of the possible electromagnetic interference sources, which are likely to induce noise in the human body, have their own typical frequency spectrum.

PhysioBank EKG records are sampled at 75 kSa/s, as indicated in the previous paragraph. This sampling rate implies to roughly 35 kHz of bandwidth (Nyquist–Shannon sampling theorem). Such ADC bandwidth should be enough to represent an artificial pacemaker signal as well as record various noise sources from the human body such as electrical noises caused by electrosurgery or Left Ventricular Assist Devices (LVAD).

### 3.2.3 Safety Design Requirements

An EKG simply monitors the electrical activity of your heart. It doesn't emit any electricity besides AC Lead Quality currents used to identify bad electrode connections and the driven right leg circuit (DRL) intended to eliminate interference noise by actively canceling the interference. EKG is completely safe. However, both the patient and the operator must be protected from power surges or overvoltage coming from the ac mains and from any current path through the ECG electrodes that could exceed the recommended limit of 10  $\mu\text{A}$  rms. The ultimate goal is to ensure patient and operator safety from dangerous voltages or currents that can occur should there be a fault condition in the ECG subsystem itself or in some other medical device attached to the patient or operator. The human heart is most sensitive to electric current in the 50 Hz to 60 Hz range. As little as 34  $\mu\text{A}$  rms at 50 Hz/60 Hz traveling through the heart has been shown to compromise the heart and cause a life-threatening event. (Crone, 2011)

Defibrillator shocks carry another threat which must be considered. Victims of sudden cardiac arrest (SCA) can be saved with a small, prompt lightning bolt to the chest. The shock (3 to 5 kV and 50 A) stops the heart from unproductive fluttering (fibrillating), which fails to pump blood to the brain and other organs. It also allows the heart to restart orderly pumping of blood. With no warning or any preparations, the EKG recorder must endure this electrical shock and continue working properly. The EKG recorder must maintain the total probable leakage current below the threshold that can harm a human heart as previously explained. (Laumeister, 2014)

These safety challenges will be solved in the next chapter related to design of various parts of the EKG recorder prototype. This will allow for the device to meet basic safety design requirements and be used for practical measurements.

### 3.3 Market Research

Today there are many companies designing and manufacturing devices capable of EKG recording. These EKG devices come in different form-factors, they are designed for various use cases, have different level of complexity and performance. Some are portable EKG recorders that fit into one's hand and are intended for personal use like the Omron HeartScan HCG-801 (can be seen below), others are sophisticated diagnostic EKG machines capable of recording 12 lead EKG like the GE MAC 5500 HD, a third group of commercially available devices is intended for research applications only.

Prior to starting the design of yet another EKG recording device it is important to conduct a basic market research intended to confirm the need for such device.

- **Digidata 1550 Digitizer**

The Axon Digidata® 1550 Digitizer is a low-noise high-resolution 16-bit data acquisition system for electrophysiology recordings.



Figure 3-7

- **IA-400D 4 Channel Physiological Amplifier**

Each channel of the IA-400D has a switch to allow selection of either a 40 Hz or 10 kHz low pass filter.



Figure 3-8

When the above two devices are combined the performance will be good, but the system will be big and bulky. This will limit the usability during clinical tests etc.

- **IX-214 Data Recorder**

Four channel physiological data recording unit.



Figure 3-9

Amplifier frequency response limited to 2 kHz. Is not able to work in standalone mode, requires PC.

- **ECG100C Electrocardiogram Amplifier**



Figure 3-10

Requires additional data logger.

- **HeartScan HCG-801 ECG Monitor**



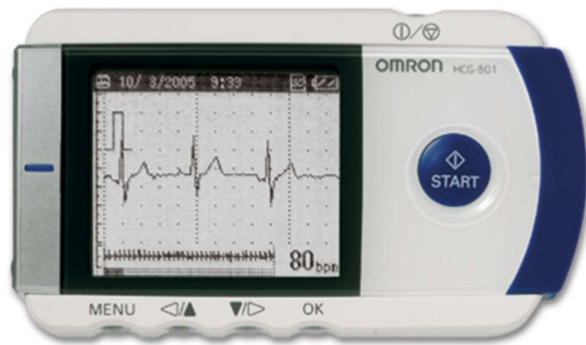


Figure 3-11

Great form factor but low input bandwidth. Only 1 EKG channel.

- **Various patient monitors and EKG machines**



Figure 3-12 GE 800 MAC.



Figure 3-13 GE PROCARE B20

These devices are not suitable due to their low sampling rate. Typical sampling rate used is around 300 Sa/s.

## 4 Prototype Design

### 4.1 Device Architecture, Component Selection and Embedded Software

As we have already set our goals and expectations, we know what we want from the EKG recorder and its specifications has been estimated, it is an appropriate time to start the actual design. The first step would be to define the principle schematic of the device hardware followed by a detailed discussion on the exact hardware architecture, which would be influenced by many factors as discussed further in this text.

#### 4.1.1 EKG recorder Principle Schematic

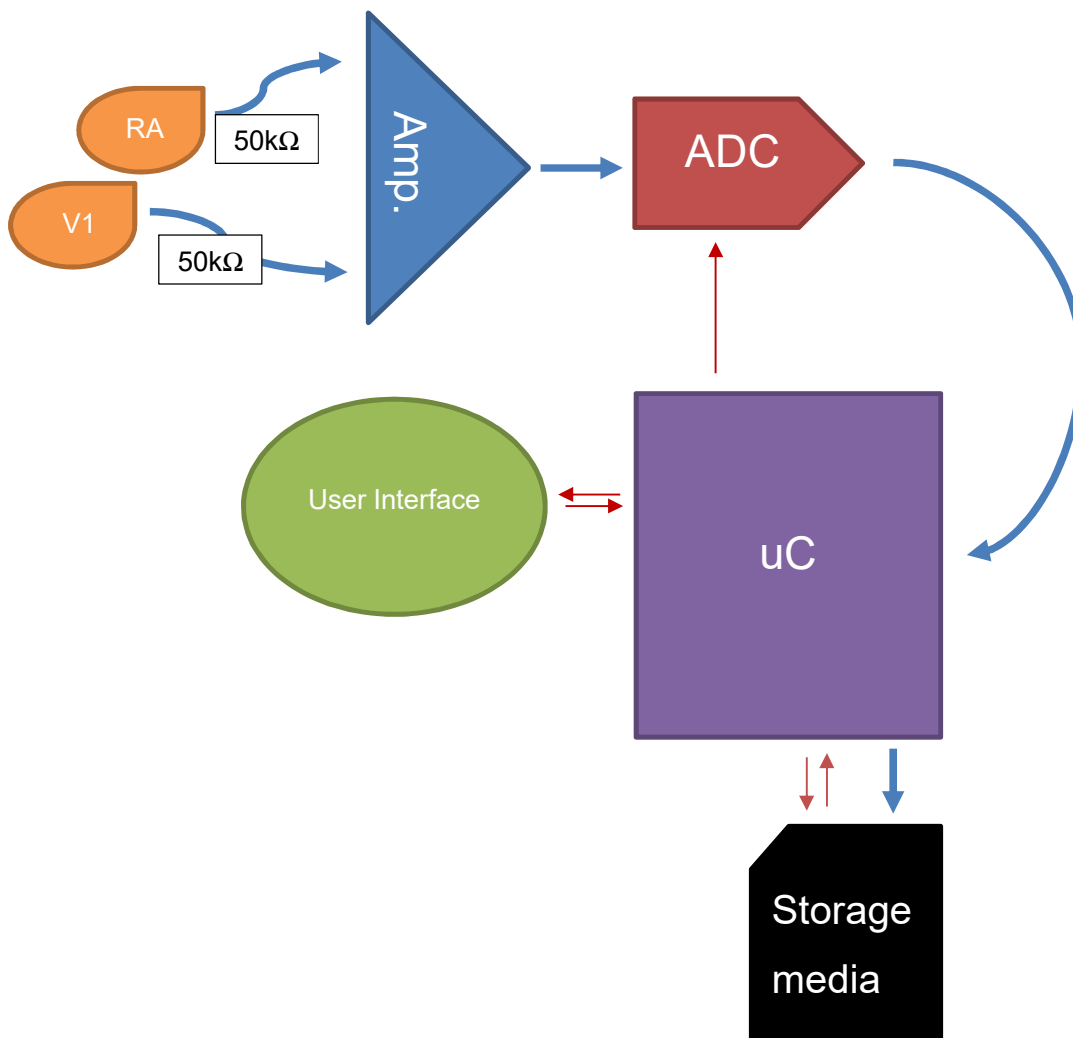
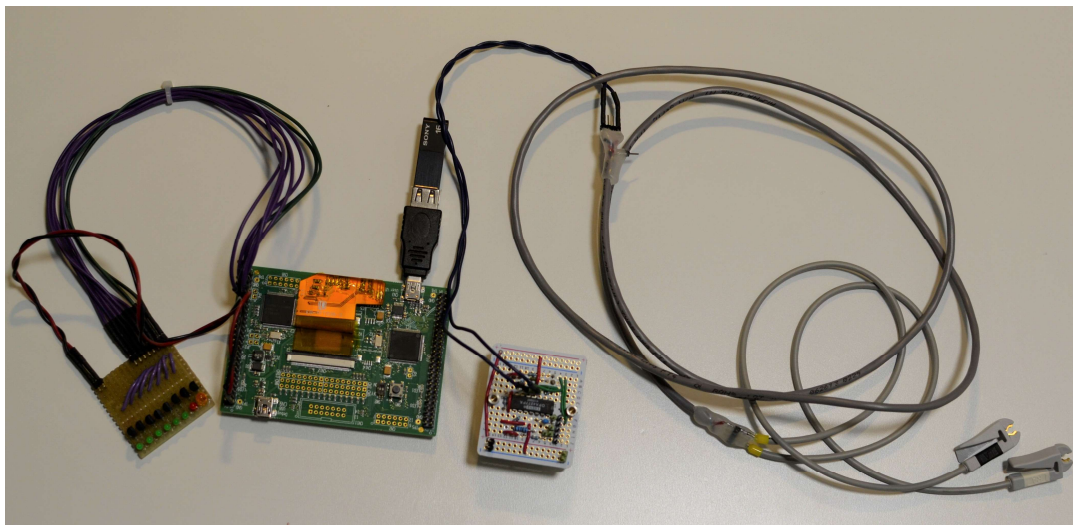


Figure 4-1 Principle schematic of the Hi-Resolution EKG Recorder. To simplify the schematic only one set of electrodes is displayed, denoted here as RA and V1.

*Figure 4-1* Everything starts from the actual EKG electrodes *Figure 4-3* which are responsible for a continuous unbroken pathway from the skin to the rest of the measurement circuitry. Each pair of electrodes that form a lead composition senses electrical signal from a body's skin surface and conducts each signal in differential format via shielded EKG electrode cables, through 50k $\Omega$  protective resistors and defibrillation protection. Low-noise amplifier is used to amplify strictly the difference of a particular lead composition. Next follows the ADC stage responsible for simultaneous digitalization of the amplified signal. After the microcontroller has received enough data from the analog to digital converter – data is being transferred to a storage media in a predefined format. Besides controlling the ADC and storage media the involved microcontroller is also responsible for the user interface operation, which consists of both controls and indicators. *Figure 4-2* gives an overview of the assembled recorder.



*Figure 4-2* Assembled Hi Resolution EKG recorder.

#### 4.1.2 EKG Electrodes. “The Sensors”.

Below is a photograph of a disposable, monitoring EKG electrode:



Figure 4-3 SKINTACT® monitoring EKG electrodes inside their hermetic envelope. (Skintact, 2018)

A typical disposable electrode has an adhesive backing which is made of foam, clear tape, soft cloth or other material and may provide secure placement of the electrode on the skin surface for several days. The carbon sensor itself is in the middle of the adhesive material and is covered by Ag/AgCl layer. Skin to sensor contact is provided by a liquid gel, which actually limits the continues electrode use time, as it dries *Figure 4-4*.

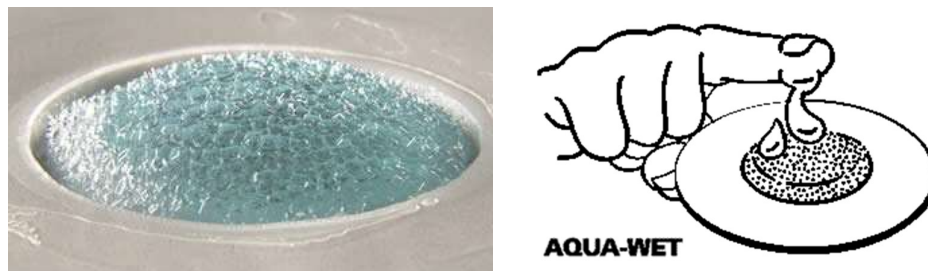


Figure 4-4 Aqua based gel of a disposable EKG electrode. (Skintact, 2018)

#### 4.1.3 Defibrillation Protection and Protective Resistors. Safety First.

As previously explained in “Safety Design Requirements”, defibrillation protection and electrode leakage current protection must be implemented on each channel of the EKG recorder. Application information for the ADAS1000 EKG analog front end will be used as reference for the design *Figure 4-5*.

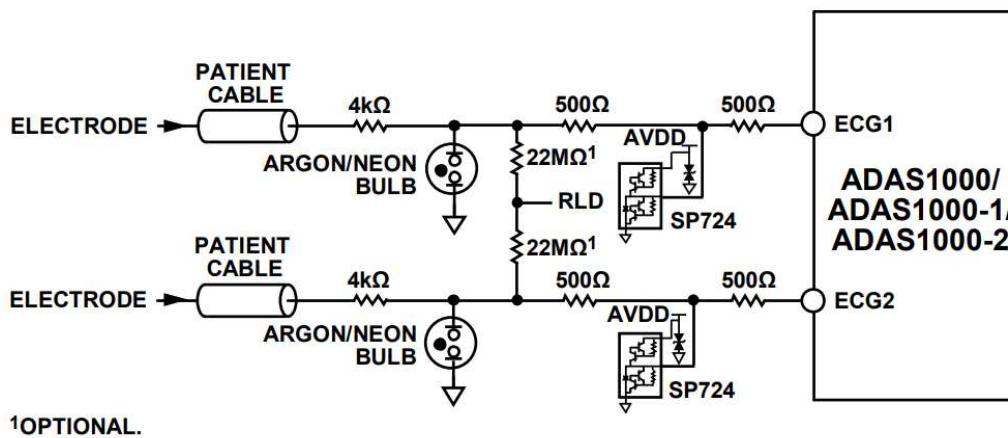


Figure 4-5 Possible defibrillation protection on EKG paths using neon bulbs. Extract from ADAS1000/ADAS1000-1/ADAS1000-2 documentation.

This design uses neon lamps to suppress hi voltage defibrillator surges alternatively transient voltage suppressors (TVSs) or gas-discharge arrestor tubes can be used. The 22 MΩ resistors shown connected to RLD are optional and used to provide a safe termination voltage for an open ECG electrode. Right leg drive (RLD) will not be available in our EKG recorder, alternatively the 22 MΩ resistors can be connected to ground. In addition to the neon lamps, transient voltage clamping circuits such as SP724 can be used to protect the amplification stage of the EKG recorder from overvoltage events.

Please note that the above circuit provides total serial impedance of 5 kΩ per EKG path. To ensure adequate current leakage protection the total serial impedance may be increased to about 50 kΩ. Some EKG patient cables include embedded resistors.

#### 4.1.4 Amplification Stage

In many industrial, measurement, data acquisition and medical applications where dc precision and gain accuracy must be maintained within a noisy environment, and where large scale common-mode signals are present – instrumentation amplifiers are widely used. These devices amplify the difference between two input signal voltages while rejecting any signals that are common to both inputs.

Below is a schematic of a typical instrumentation amplifier based on 3 operational amplifiers *Figure 4-6*. Op-amp U1C is used as a unity gain difference amplifier with precisely matched resistors that are all equal in value:  $R_1$  and  $R_3$ ,  $R_2$  and  $R_4$ . Op-amps U1A and

U1B in their noninverting configurations are used to buffer the inputs of the amplifier, by providing high input impedance and gain.

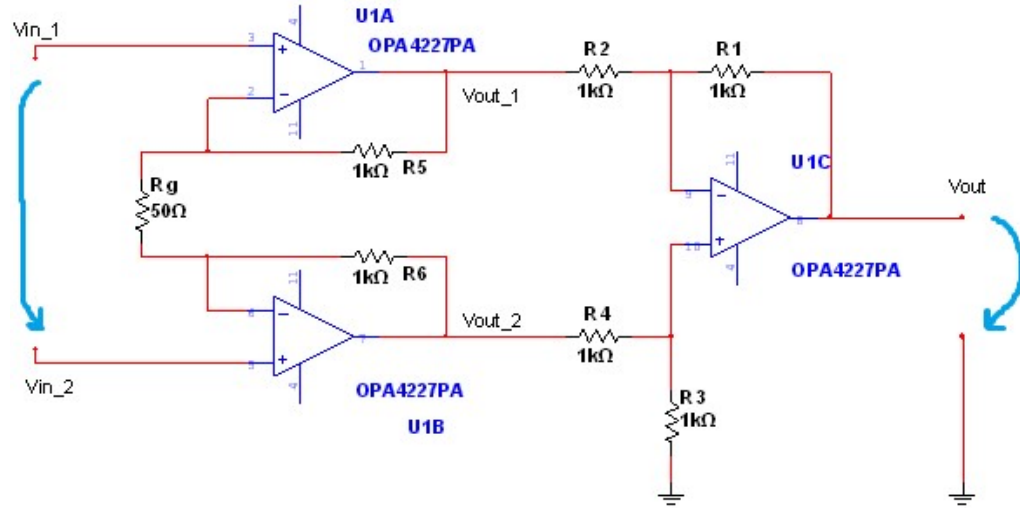


Figure 4-6 Typical op-amp instrumentation amplifier topology.

The output voltage of op-amp U1A in its noninverting configuration is:

$$V_{out1} = V_{in1} \left( 1 + \frac{R_5}{R_G} \right) - V_{in2} \left( \frac{R_5}{R_G} \right) \quad (14)$$

Similarly, the output of U1B can be expressed as:

$$V_{out2} = V_{in2} \left( 1 + \frac{R_6}{R_G} \right) - V_{in1} \left( \frac{R_6}{R_G} \right) \quad (15)$$

Therefore, the differential amplifier at the rightmost (U1C) has a differential input voltage:

$$V_{out2} - V_{out1} = V_{in2} \left( 1 + \frac{R_6}{R_G} + \frac{R_5}{R_G} \right) - V_{in1} \left( 1 + \frac{R_5}{R_G} + \frac{R_6}{R_G} \right) \quad (16)$$

In case of  $R_5 = R_6 = R$  :

$$V_{out2} - V_{out1} = V_{in2} \left( 1 + \frac{2R}{R_G} \right) - V_{in1} \left( 1 + \frac{2R}{R_G} \right) = \left( 1 + \frac{2R}{R_G} \right) (V_{in2} - V_{in1}) \quad (17)$$

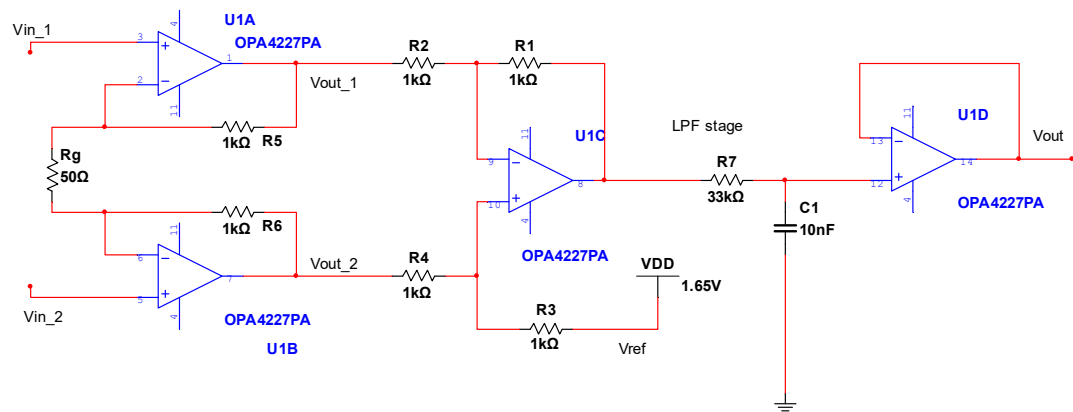
Op-amp U1C has unity gain since,  $R_1 = R_3 = R_2 = R_4$  therefore, the final output of the instrumentation amplifier is:

$$V_{out} = 1(V_{out2} - V_{out1}) = \left( 1 + \frac{2R}{R_G} \right) (V_{in2} - V_{in1}) \quad (18)$$

where:

$$Gain = \frac{V_{out}}{(V_{in2} - V_{in1})} = 1 + \frac{2R}{R_G} \quad (19)$$

Two identical instrumentation amplifiers based on OPA4227PA were built for simultaneous recording of two EKG leads *Figure 4-8, Figure 4-9*. OPA4227PA contains 4 high precision, low noise operational amplifiers *Figure 4-7*. Three were used to build instrumentation amplifier as previously described and one (U1D) was used to buffer an additional low pass filter stage intended to limit the signal bandwidth prior to analog to digital conversion. It is also important to note that resistor  $R_3$  is now connected to a low-impedance source, such as a buffer or a voltage reference. The reference voltage will cause U1C to shift/offset its output by 1.65V. This would allow for the instrumentation amplifier to be directly interfaced to an analog to digital converter expecting signals in the range from 0V to 3.3V. Signal bandwidth and range will be further explained in the Analog to Digital Conversion paragraph.



*Figure 4-7 Amplification stage of the Hi-Resolution EKG Recorder.*



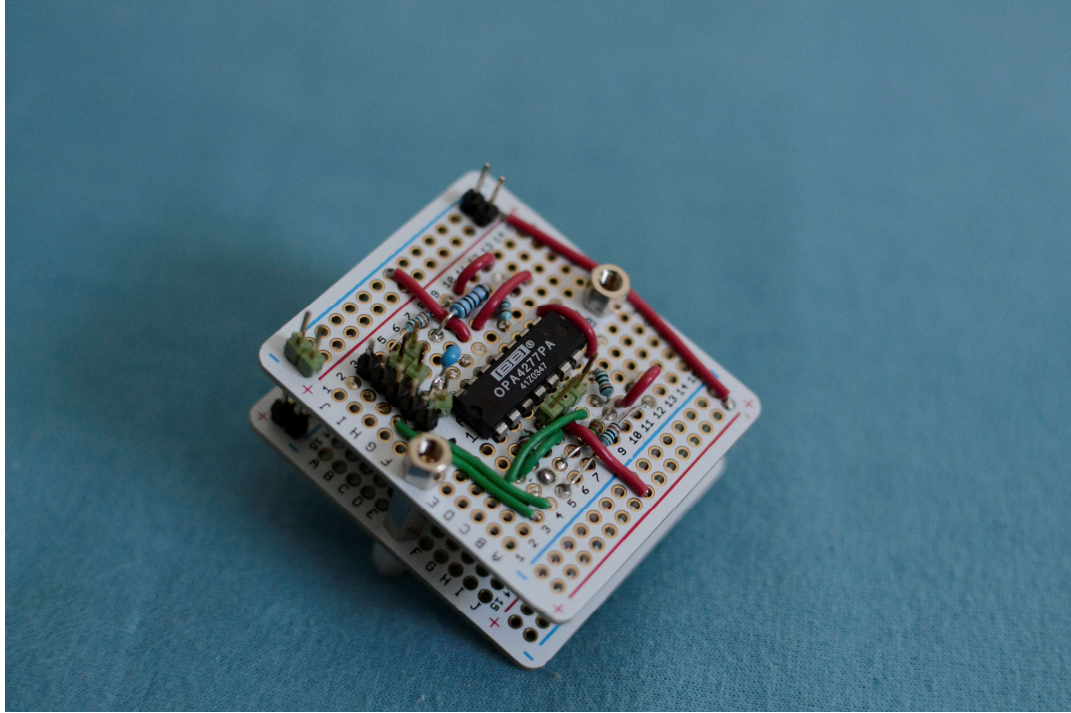


Figure 4-8 Stack of two instrumentation amplifiers based on OPA4277PA.

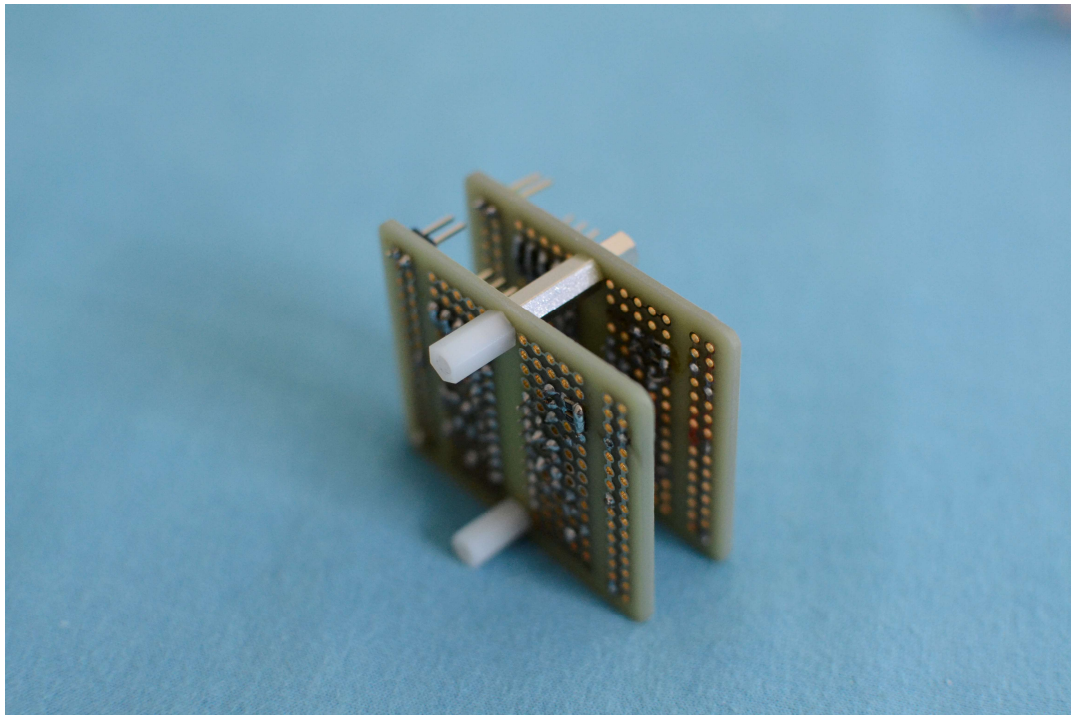


Figure 4-9 Stack of two instrumentation amplifiers based on OPA4277PA, bottom view.



Instrumentation amplifiers are also available as integrated circuits from several manufacturers and will be used in future revisions of the recorder. An IC in-amp typically includes closely matched laser trimmed resistors and therefore offers excellent common mode interference rejection.

#### 4.1.5 Analog to Digital Conversion (Digitalization of EKG)

The world is not digital; it is analog. Microphones, thermometers, speakers, light sensors, and even video cameras are all analog sensors. Electrical signals being sensed with a pair of EKG electrodes are certainly analog as well. Even though the process of analog to digital conversion involves quantization of the original analog signal and thus introduces a certain amount of quantization error such conversion of the pre-amplified EKG signal is a crucial step. This will significantly ease further signal manipulations by using various digital signal processing techniques such as digital filtering (to be discussed more further in this text). In addition, AD conversion will allow for the recorded data to be stored digitally (magnetic tape, flash memory, optical media etc.) with many consecutive benefits related to generation loss, management of records, compatibility with existent systems etc.

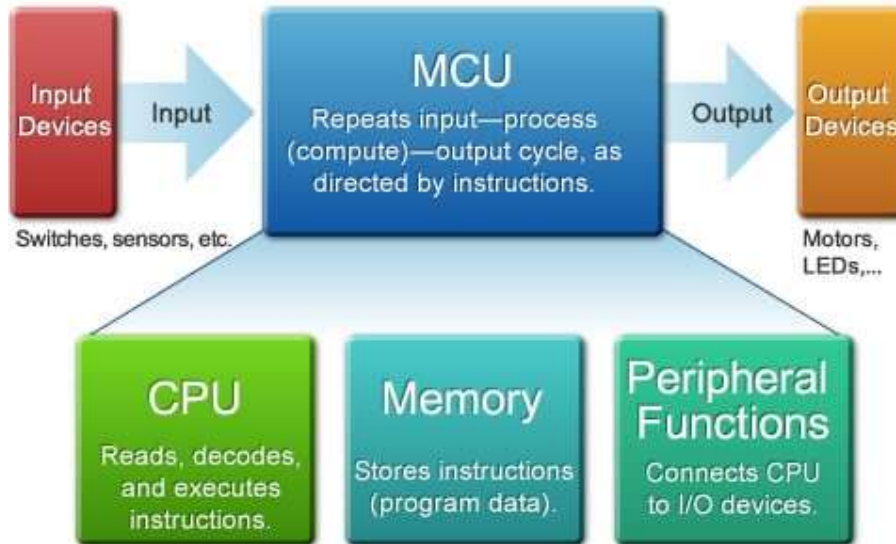
The result of an analog to digital conversion is a sequence of digital values that have been converted from a continuous-time and continuous-amplitude analogue signal to a discrete-time and discrete-amplitude digital signal. The number of bits in such digital value defines the resolution of each conversion or sample. Typical MCU have 8-bit, 10-bit, 12-bit ADC while high precision stand-alone AD converters may have 24-bits or even 32-bits.

$$Resolution = V_{LSB} = \frac{V_{ref}}{2^{N \text{ bits}}} \quad (20)$$

From the above equation, it's clear that the number of bits  $N$  alone is not enough to define resolution which in our case has unit of volts [V]. ADCs also require reference voltage  $V_{ref}$ . This is a stable voltage to which the current reading will be compared to produce the binary output. The analog reference voltage is scaled by the resolution. Another important parameter in any AD conversion is the sampling rate or rate at which new digital values are sampled from the analog signal. An integrated microcontroller analog to digital converter (RX71M, S12ADC) will be used as part of the early prototype design.

#### 4.1.6 Microcontroller Selection

The core component of my Hi Resolution EKG Recorder will be its microcontroller. Its choice will greatly affect the design flow and selection of various components which all together form the device circuitry. *Figure 4-10* shows a general MCU structure to better understand the functionality of the component:



*Figure 4-10 General MCU structure (Renesas Electronics, 2018).*

The MCU incorporates a CPU (central processing unit), some memory, and some circuitry that implements peripheral functionalities. If we wish to anthropomorphize, we can say that the CPU does the "thinking," the memory stores the relevant information, and the peripheral functions implement the nervous system—the inputs (seeing, hearing, feeling) and the responses (hand and foot movements, etc.). (Renesas Electronics, 2018)

The criteria for the project were to find a compact development board, based on a high performance 32-bit microcontroller with a vast range of peripherals primarily targeting connectivity and good development tools provided. These not very strict criteria can be explained with the fact that what was needed, was a good platform with good potential around which to build the system. It was decided to use the "RX71M Revelation Kit". This compact development board is based on 240MHz RX700 series microcontroller, which is the highest performance series in the RX family of 32-bit microcontrollers *Figure 4-11* first introduced in 2009 by Renesas Electronics. RX is an acronym for Renesas Extreme,

a description of the key concept behind the product family, that is "extreme high performance".

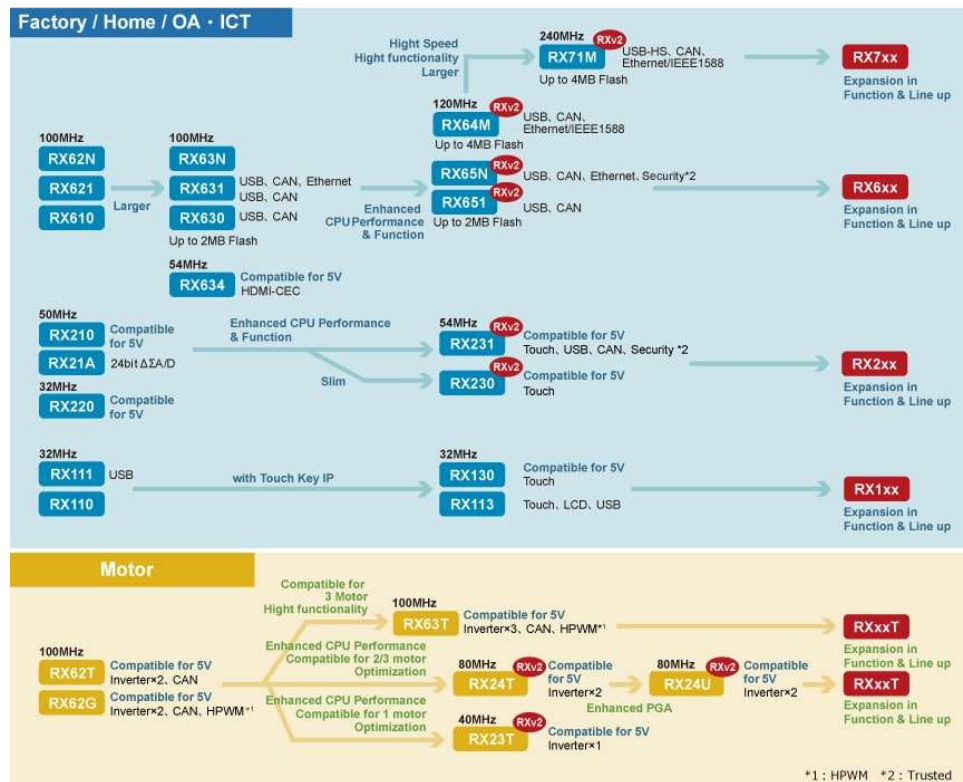


Figure 4-11 Road map of the RX family. (Renesas Electronics, 2018)

Software support includes: "e<sup>2</sup> studio" – "Eclipse" based IDE, which covers build as well as debug interface, Renesas Flash Programmer (programming of the microcontroller's flash) and FIT (Firmware Integrated Technology) *Figure 4-12*, which aims to simplify embedded software development by providing middleware and drivers for I/O Ports (GPIO), Serial Communication Interfaces, USB, FAT File System, ADC and a lot more.

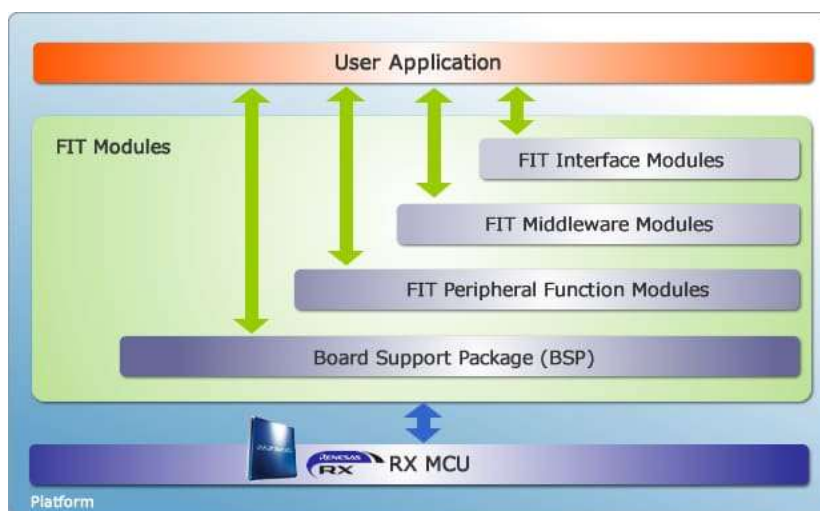


Figure 4-12 Firmware Integration Technology. (Renesas Electronics, 2018)

#### 4.1.7 Secure Digital (SD) card vs USB flash drive.

When comparing user experience of using either SD card or USB flash there are not many differences one may think of. Therefore, the one which would be easier to interface with the RX71M microcontroller was used, providing the required level of performance. In this paragraph, the storage media of choice will be discussed. SD card and USB flash drive are perhaps the first two options one may think of. In general, both are compact, widely spread flash memory devices of closely comparable storage capacity, data transfer speed and price. Both devices can be seamlessly used with an operating system to transfer data. At first sight, these are not the most intriguing but certainly practical solutions for the application. And so, such will be my two options to consider.

If from user experience point of view there are barely any differences, then from interface point of view SD card and USB flash drive are completely different. The default bus protocol for the SD Card is SD mode, but the card can also be configured to operate in the much slower and simpler SPI mode. In SD mode, the card operates in clock serial mode with bus widths of 1-4 bits. In SPI mode, the card operates in 1-bit mode only. In contrast, USB flash drive uses no clock signal but a differential data line to communicate with a host device. USB stands for Universal Serial Bus.

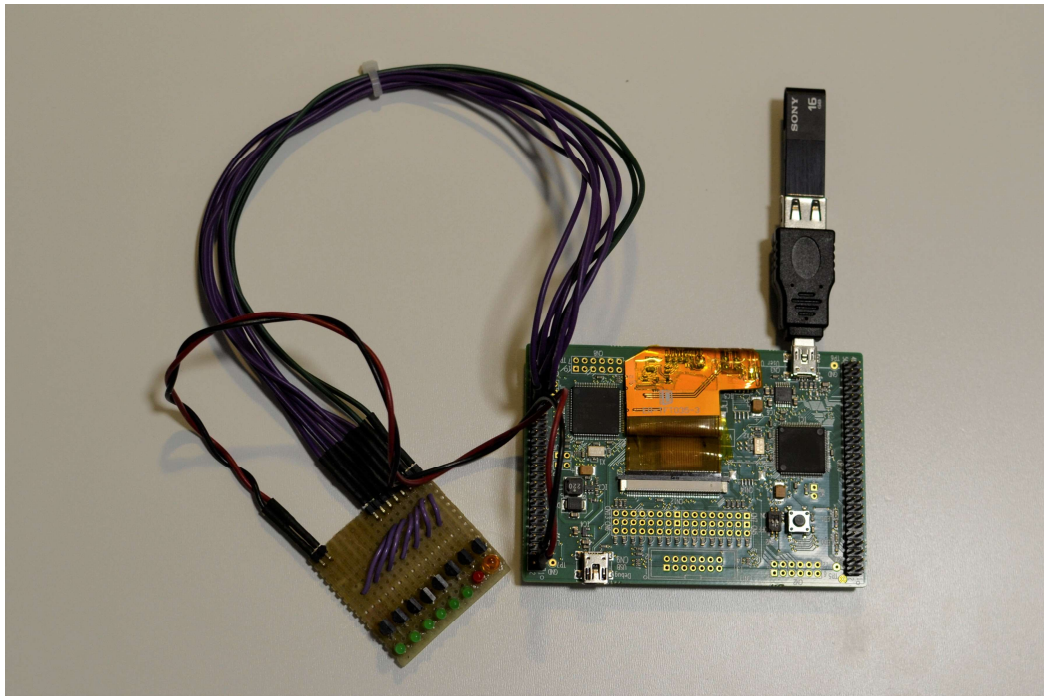
By looking at the RX71M features, both - full-speed USB 2.0 and SD host communication interfaces are supported by hardware (high-speed USB 2.0 is not present in the 100-pin version of RX71M). Therefore, the options to consider remain two: SD card, USB flash drive.

As previously mentioned, "Firmware Integrated Technology" provided by Renesas was used to lighten the embedded program development. "USB Host Mass Storage Class"

and the dependent upon “USB Basic Firmware” are the two provided FIT modules for USB flash drive interface. In contrast, the “SD Host Interface (SDHI)” FIT module required for the SD card functionality in its native Secure Digital mode was not available as of Autumn 2017. Implementation of a custom SDHI drivers would have been simply unpractical due to its complexity. Full-speed USB 2.0 has been selected for the initial prototype design.

#### 4.1.8 RX71M Revelation Board

In the heart of the development board *Figure 4-13* (chip on the left IC1) *Figure 4-14* is a 100-pin version of the 32-bit RX71M microcontroller (R5F571MLCxFP) featuring RXv2 processing core, 4MB Flash, 552kB RAM and vast range of peripherals. A QVGA TFT LCD with touch screen, allows for a HMI (Human Machine Interface) solution on a single chip microcontroller to be implemented. A USB port, several peripheral interfaces and an On-Chip Debug circuit are also provided on-board.



*Figure 4-13 RX71M Revelation Board with a USB flash drive and user interface LED panel.*

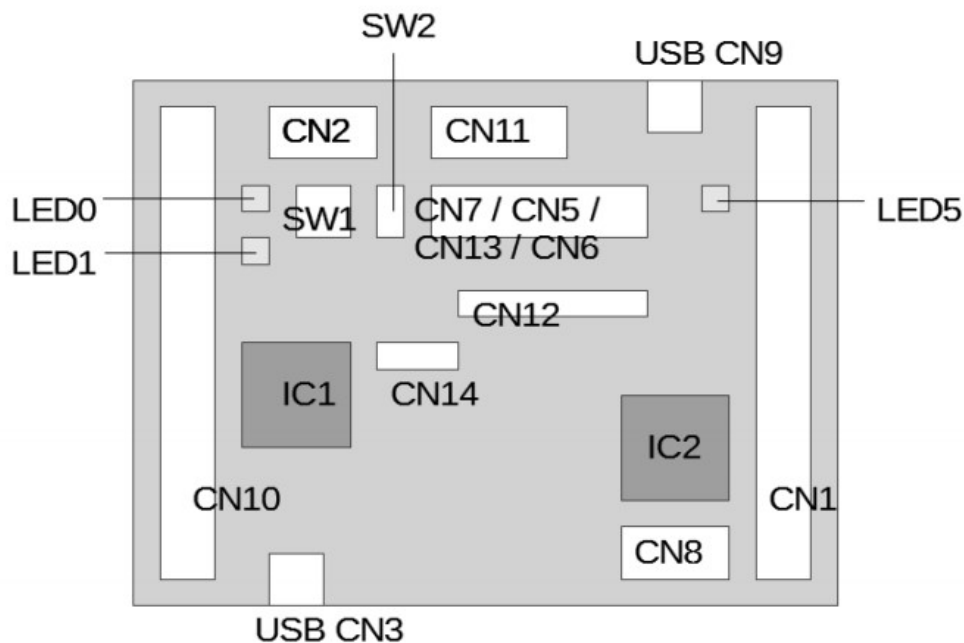


Figure 4-14 Diagram of the bottom side of the RX71M Revelation Board. Top side contains the TFT display and is thus not visible. (Quick start guide for the Renesas RX71M Revelation Kit, 2016)

- **IC1** - 100 pin RX71M microcontroller.
- **IC2** – RX631 E2 Lite on-board debugger chip.
- **USB CN3** – USB connector of RX71M USB unit 0 peripheral.
- **USB CN9** – Power supply and USB port for the E2 Lite on-board debugger. Programming of the board is done via this connector.
- **CN1, CN2, CN8, CN10** – Connectors for hardware extensions.
- **CN5, CN6, CN7, CN13** – Jumper pins for configuring the LCD module located on the top side of the development board.
- **CN12** – Connector for the LCD module. This module is connected via a ribbon cable.
- **CN14** – Connector for a separate touch screen.
- **CN11** – Connector for an external E1 emulator.
- **SW1** – Push buttons for program functions.
- **SW2** – Two switches to turn on the debugger mode or the reset mode, respectively. SW2 functionality is summarized in Table 4-1.

Table 4-1 SW2 functionality.

Use Case	SW2-1	SW2-2
----------	-------	-------

“Renesas Flash Programmer”	ON	OFF
Using debugger in “e <sup>2</sup> studio”	ON	OFF
Program execution (reset mode)	OFF	OFF

- **LED5** – E2 Lite on-board debugger status LED. This LED is continuously ON when the connection to the debugger is established. Please refer to Table 4-2 for more details.

*Table 4-2 LED5 functionality.*

<b>LED5</b>	<b>Meaning</b>
Continuous light	USB connection to the PC driver at the CN9 USB connector is established.
Flashing light	Power supply active, but no USB connection to the PC driver.
No Light	No power supply at the CN9 USB connector.

- **LED0, LED1** – user programmable LEDs.

#### 4.1.9 Getting Started with “e<sup>2</sup> studio”. Development Environment.

Probably the easiest way to start working with the Revelation Board would be installing the Eclipse IDE based “e<sup>2</sup> studio” with selected support for RX devices and the CC-RX compiler.

##### 4.1.9.1 Creating New Project

For detailed instructions on how to create a new project for the Revelation Board in “e<sup>2</sup> studio” please refer to the Appendix 1.

##### 4.1.9.2 Adding FIT Modules to the Project



Before even trying to compile the just created project, `r_bsp` FIT module must be included by using “e<sup>2</sup> studio” FIT Configurator *Figure 4-15*. The `r_bsp` package provides a foundation for code to be built on top of. It provides startup code, iodefines, and MCU information for different boards. There are 2 folders that make up the `r_bsp` package. The 'mcu' folder contains files that are common to a MCU group. These files provide functionality such as easy register access, CPU functions, and a file named 'mcu\_info.h' for each MCU group. The 'mcu\_info.h' file has information about the MCU on the board and is configured based on the information given in `r_bsp_config.h`. The information in 'mcu\_info.h' is used to help configure Renesas middleware that uses the `r_bsp` package. The 'board' folder has a folder with startup code for each supported board. Which MCU and board is chosen is decided by the settings in 'platform.h'.

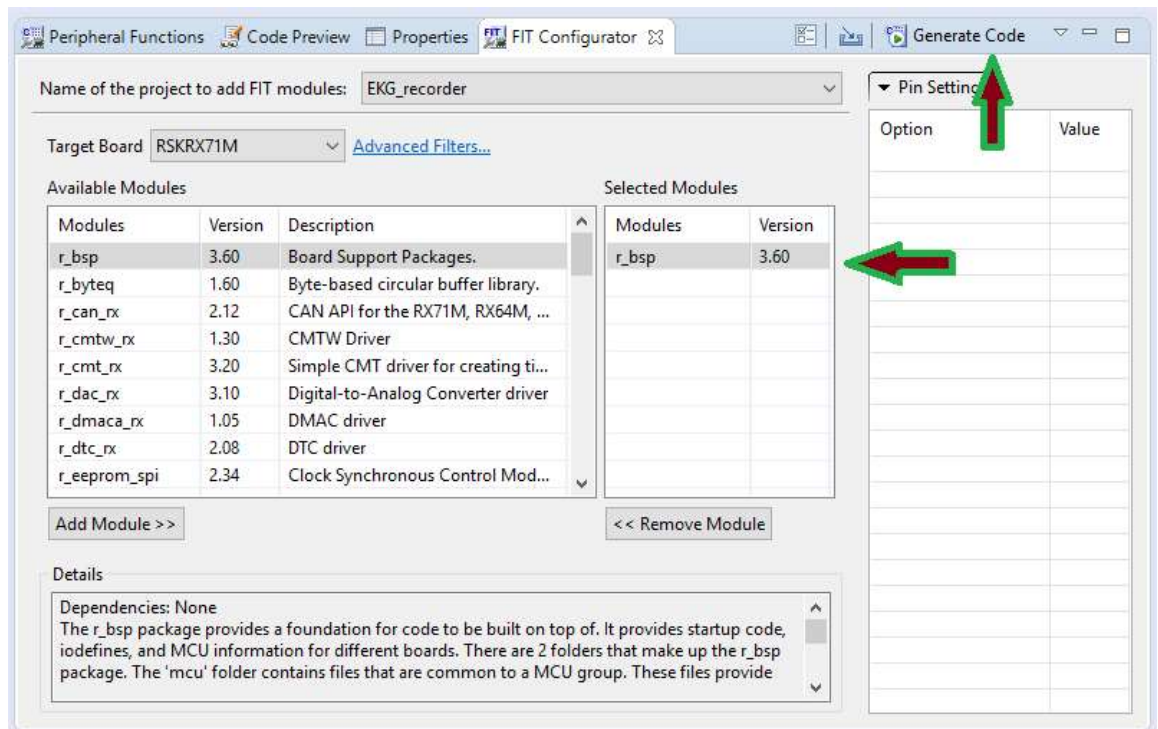


Figure 4-15 Inside FIT configurator list of supported FIT modules by the target board is displayed.

After adding the selected `r_bsp` module “Generate Code” must be clicked in order to add the corresponding module files to the newly created project named `EKG_recorder`.



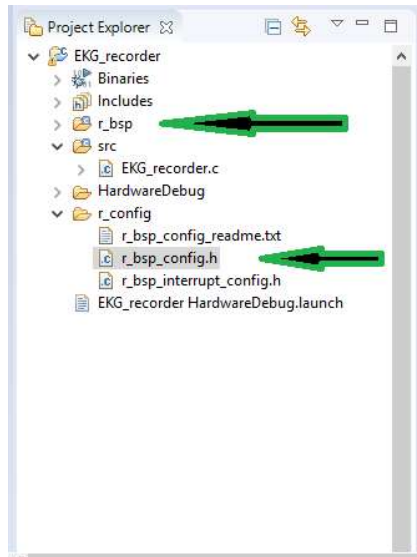


Figure 4-16 Project Explorer window shows changes made by the FIT Configurator. New directory "r\_bsp" and "r\_bsp\_config.h" user configurable file have been included to the project.

The project folder bearing name 'r\_config' contains user configurable files which correspond to drivers or middleware modules added by the FIT Configurator *Figure 4-16*. Each of these files contain various initialization and operation settings for a driver or middleware and usually must be edited by the user for correct operation. In our case the following parameters have been set inside the 'r\_bsp\_config.h' configuration file (part of the Board Support Package) *Figure 4-17*:

- **#define** BSP\_CFG\_XTAL\_HZ           (12000000) -  
Input clock frequency in Hz (XTAL or EXTAL).
- **#define** BSP\_CFG\_PLL\_MUL           (20.0) –  
PLL frequency multiplier factor select.
- **#define** BSP\_CFG\_MCU\_PART\_PACKAGE   (0x5) –  
Microcontroller package type.

The input clock frequency is specified and then the system clocks are set by specifying the multipliers used. The multiplier settings are used to set the clock registers in "resetprg.c". In my case a 12MHz quartz resonator in combination with PLL frequency multiplier set to 20 results in system clock running at 240MHz (ICLK). Same file sets peripheral module clocks (PCLKA, PCLKB, PCLKC, PCLKD), flash-IF clock (FCLK) and external bus clock (BCLK).

```

238
239
240 /* Input clock frequency in Hz (XTAL or EXTAL). */
241 #define BSP_CFG_XTAL_HZ (12000000)
242
243 /* The HOCO can operate at several different frequencies. Choose which one using the macro
244 Available frequency settings:
245 0 = 16MHz (default)
246 1 = 18MHz
247 2 = 20MHz
248 */
249 #define BSP_CFG_HOCO_FREQUENCY (0)
250
251 /* PLL clock source (PLLSRCEL). Choose which clock source to input to the PLL circuit.
252 Available clock sources:
253 0 = Main clock (default)
254 1 = HOCO
255 */
256 #define BSP_CFG_PLL_SRC (0)
257
258 /* PLL Input Frequency Division Ratio Select (PLLDIV).
259 Available divisors = /1 (no division), /2, /3
260 */
261 #define BSP_CFG_PLL_DIV (1)
262
263 /* PLL Frequency Multiplication Factor Select (STC).
264 Available multipliers = x10.0 to x30.0 in 0.5 increments (e.g. 10.0, 10.5, 11.0, 11.5,
265 */
266 #define BSP_CFG_PLL_MUL (20.0)

```

Figure 4-17 "r\_bsp\_config.h" configurable file has been opened for further editing. "r\_bsp\_config.h" is part of the Board Support Package.

Modules	Version	Description
r_rspi_rx	1.70	RSPI Driver
r_rspi_smstr_rx	1.14	RSPI Clock Synchronous Single Master Co...
r_rtc_rx	2.71	Real-Time Clock driver
r_s12ad_rx	2.30	Multi-Channel A/D and Sensor Driver.
r_s2_rx	3.04	ADPCM compress/de-compress codec so...
r_scifa_smstr_rx	1.09	SCIFA Clock Synchronous Single Master C...
r_scif_rx	1.20	Multi-Channel Multi-Mode SCI FIFO Driver.
r_sci_iic_rx	2.20	Simple IIC Driver.
r_sci_rx	2.00	Multi-Channel Multi-Mode SCI Driver.

Modules	Version
r_bsp	3.60
r_usb_basic	1.22
r_usb_hmsc	1.22
r_tfat_driver_rx	1.03
r_tfat_rx	3.03
r_gpio_rx	2.30
r_s12ad_rx	2.30

Figure 4-18 Selecting additional FIT modules for peripherals and file system support.

The selected modules will be needed in our case *Figure 4-18*:

- **r\_bsp** – Board Support Package.
- **r\_usb\_basic** - provides USB basic host and peripheral firmware.
- **r\_usb\_hmsc** - provides USB Host mass storage class driver.

- **r\_tfat\_rx** - TFAT library is a FAT file system which just requires small memory. TFAT library is based on FatFs.
- **r\_tfat\_driver\_rx** - memory driver interface connects TFAT library and Device Drivers(USB etc).
- **r\_gpio\_rx** - implements a General Purpose Input/Output driver.
- **r\_s12ad\_rx** – 12-bit Analog to Digital Converter driver

#### 4.1.10 Embedded Software

Even the most finely crafted prototype will not do anything useful without the microcontroller's on-chip flash memory being programmed with the right set of instructions called a machine code. Compilers and assemblers are used to convert both high-level and assembly language codes into a compact machine code. In the case of RX71M, "e<sup>2</sup> studio" IDE with connected CC-RX compiler will take care of this process. In case of successful compilation of the human readable - high level C programming language, the development environment creates a MOT file (machine code), which can be in turn directly uploaded to the Revelation board (RX71M development board). Image below *Figure 4-19* shows the tool used to upload machine code contained in *Record\_1dot13.mot* to the target device.

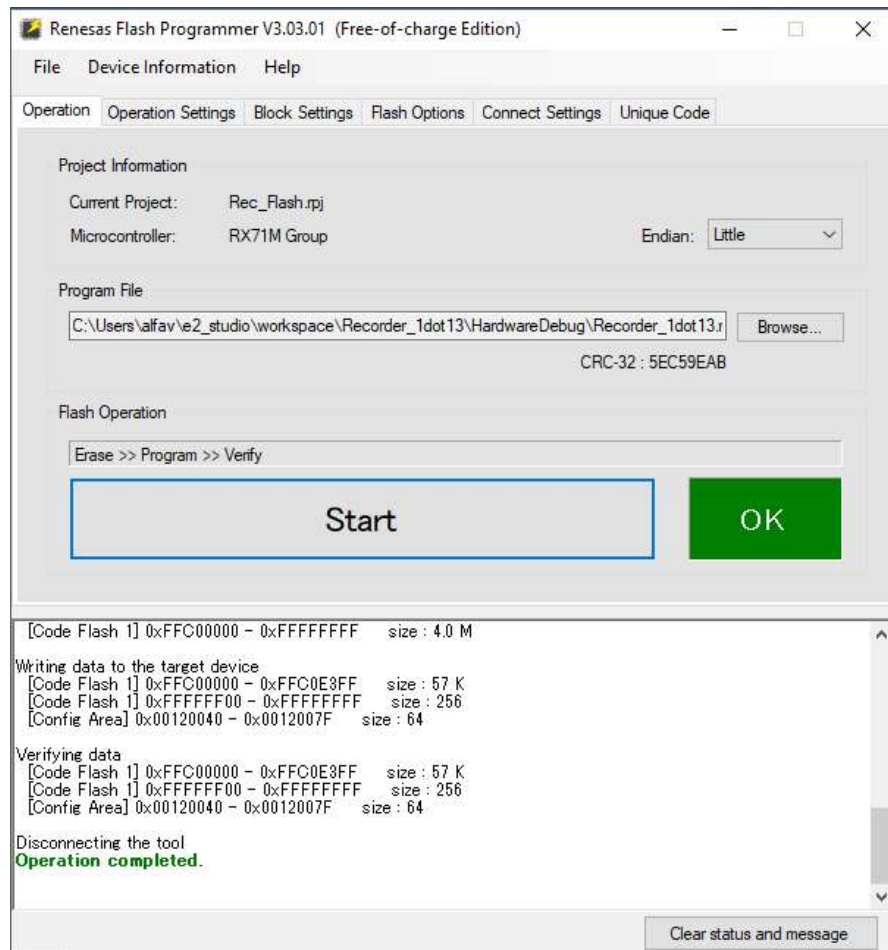


Figure 4-19 Renesas Flash Programmer V3.03.01 used to erase, program and verify the on-chip memory of RX71M.

#### 4.1.10.1 Source Code Explained.

The flowchart below is intended to explain the algorithm of the EKG Recorder typical use case as well as highlight some key points related to the device operation such as initialization of peripherals *Figure 4-20*.

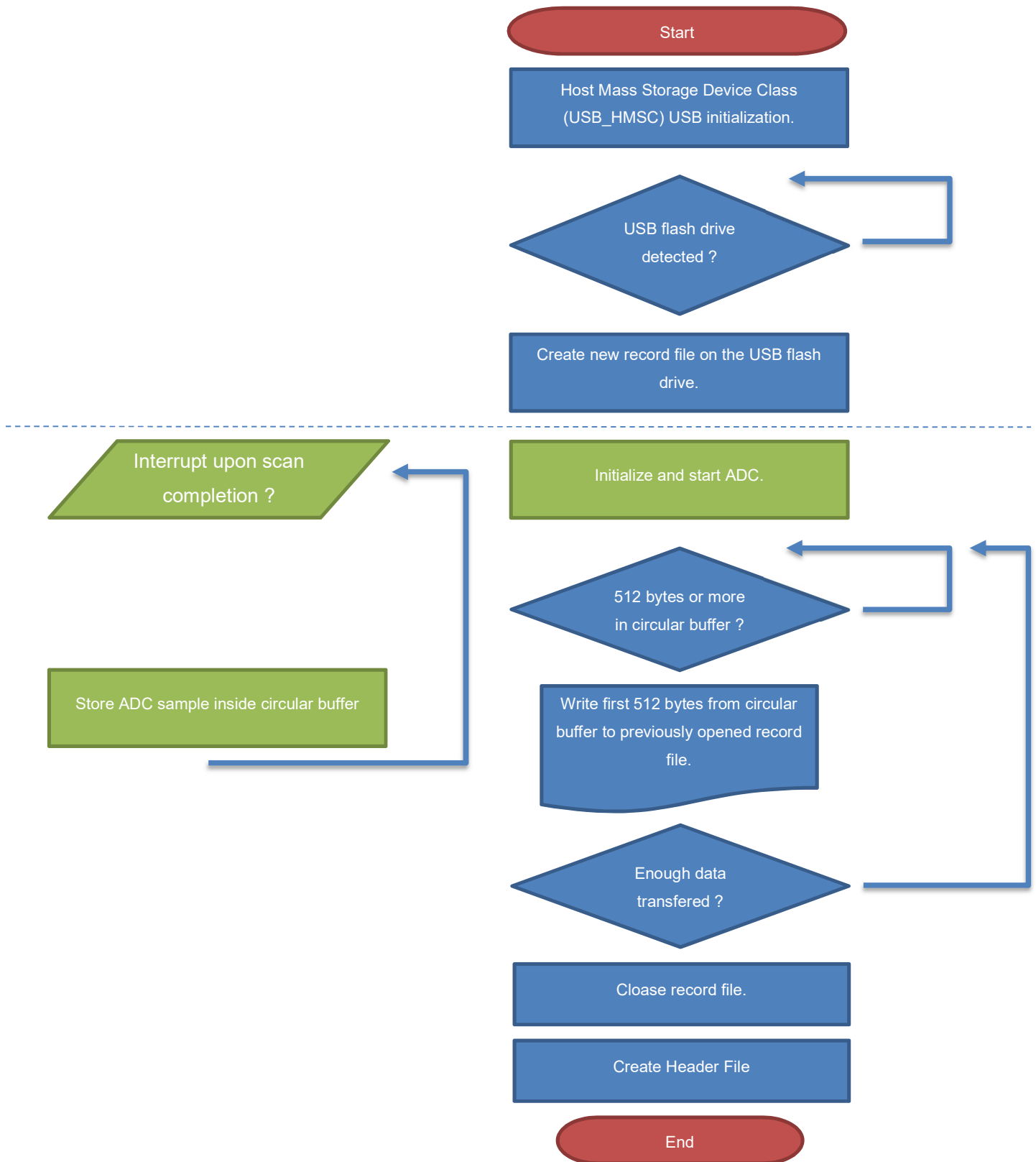


Figure 4-20 RX71M source code flowchart.

Before running the user application there are a series of operations that must be performed to get the MCU set up properly. Common examples include: setting up stack(s), initializing memory, configuring system clocks, and setting up port pins. No matter the application, these steps need to be followed. To make this process easier the Renesas Board Support Package, abbreviated as `r_bsp`, is used. At the lowest level the `r_bsp` provides everything needed to get the MCU from reset state to the start of the application's `main()` function. These post-reset routines are defined in `resetprg.c`.

The first visible step on the flowchart is the RX71M USB peripheral initialization. This is a complex step involving both initialization of the microcontroller and its surrounding hardware. The USB peripheral use is simplified by USB Basic Host and Peripheral Driver (USB-BASIC-F/W FIT). This module performs hardware control of USB communication and initialization. Prior to using any of the driver functionality - input/output signals *Figure 4-21* of the peripheral function have to be allocated to pins with the multi-function pin controller (MPC), as shown below:

- **P2<4> to USB0\_VBUSEN** -Turns the internal charge pump providing VBUS on and off.
- **P2<1> to USB0\_EXICEN** - Connect SHDN to GND to enter shutdown and reduce supply current to less than 1µA. Connect SHDN to VL for normal operation.
- **P2<0> to USB0\_ID** - Output of ID\_IN level translated to VL
- **P1<4> to USB0\_OVRCURA and P2<2> to USB0\_OVRCURB** - Provide output voltage detection for use during HNP handshaking (USB overcurrent detection).

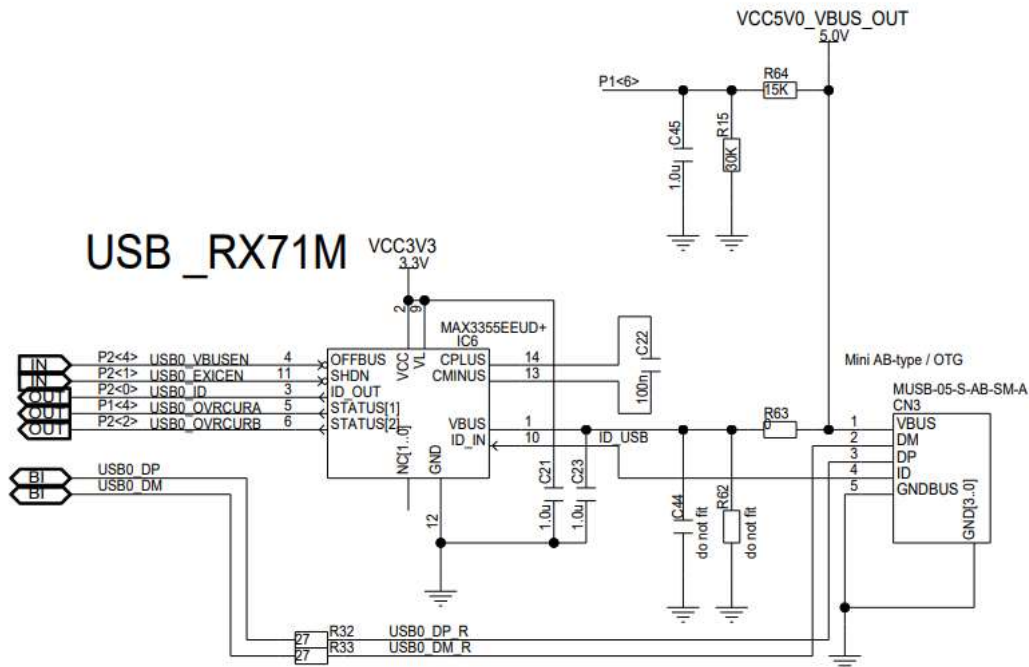


Figure 4-21 Extract from the RX71M Revelation Board schematic featuring the USB port and MAX3355EEUD+ USB OTG chip.

Besides supplying 4.8 V to the USB port when used in host mode and providing ESD protection the OTG chip is intended to automatically notify the system on the type of USB being connected to the USB port, that is A or B and eventually switching the mode of operation from host to peripheral and vice versa. This functionality will not be used by the EKG Recorder; thus, the USB port of the device will always remain in host mode unless an overcurrent condition is detected by the USB-BASIC-F/W FIT driver. Next follows initialization of the USB driver *Listing 1* and powering on the USB module (peripheral).

```

/*USB Initialisation*/
ctrl.module = USB_IP0;
ctrl.type = USB_HMSC;
cfg.usb_speed = USB_FS;
cfg.usb_mode = USB_HOST;
/* Start USB module */
err1 = R_USB_Open(&ctrl, &cfg);
(Listing 1. Initialization routine.)

```

R\_USB\_Open(&ctrl, &cfg); - will supply the USB\_IP0 module and will ensure its functionality as a Full Speed Host Mass Storage Class USB. Finally, for the OTG chip to supply the USB port – external USB0\_VBUSEN pin will be set to high via the USB0 Device State Control Register 0 (USB0.DVSTCTR0).

At this point if a USB flash drive is connected to the EKG recorder it will be recognised but prior to performing file/directory operations a filesystem object needs to be registered with R\_tfat\_f\_mount; function to the logical drive. R\_tfat\_f\_mount and other high level functions intended for file/directory manipulations are part of the Open Source FAT File System [M3S-TFAT-Tiny] Module. FatFs is the File system module for the small embedded systems. FatFs is developed by ChaN Software. For more information on the module please refer to - [http://elm-chan.org/fsw/ff/00index\\_e.html](http://elm-chan.org/fsw/ff/00index_e.html). Lastly a binary record file will be created and ready for analog to digital conversion data to be written (R\_tfat\_f\_open; function).

The S12ADC begins conversion when it receives a trigger. When the conversion is complete, a flag is set and an interrupt issued if enabled. If the S12ADC is operating in a single scan mode, only one scan takes place per trigger. If the S12ADC is operating in a continuous mode, scans continue indefinitely after the initial trigger occurs. Below in *Listing 2* can be seen an extract from the source code, taking care of the initial setting of the RX71M analog to digital converter (S12ADC):

```
config.resolution = ADC_RESOLUTION_12_BIT;
config.alignment = ADC_ALIGN_RIGHT;
config.add_cnt = ADC_ADD_AVG_4_SAMPLES;
config.clearing = ADC_CLEAR_AFTER_READ_OFF;
config.trigger = ADC_TRIG_SOFTWARE;
config.priority = 4;
...
/* S12ADC initialization. Scan does NOT start here. */
R_ADC_Open(1, ADC_MODE_CONT_ONE_CH, &config, NULL);
```

(Listing 2. Part of the ADC initialization routine and start up.)

The key points in the above code are:

- 12-bit resolution.
- Average 4 samples mode.
- Analog to digital conversion will be triggered by software.
- ADC mode: one channel in continuous scan mode.



- Interrupt upon ADC completion is enabled.

Continuous Analog to Digital conversion will be triggered by the following software command (the first argument of the function defines the ADC unit to which it applies):

```
R_ADC_Control(1, ADC_CMD_SCAN_NOW, NULL);
```

(Listing 3)

As defined in the initialization code, upon completion of an AD conversion – an interrupt will be issued. This will lead to an execution of a call-back function intended to store the result of the AD conversion in a circular buffer. Software implemented circular buffer will allow for ADC data to be temporarily accumulated in the RAM of the RX71M. This in turn will improve the data transfer efficiency over the USB as now it would be possible to transfer multiples of 512 bytes (256 samples) at ones, being most optimal way to transfer data into a FAT32 file system. The process of writing sampled data to the USB flash drive as multiples of 512 bytes will continue until enough data has been collected as can be seen from the flowchart, followed by closing of the previously opened record file by means of the M3S-TFAT-Tiny library (module). In addition to the binary record file, a corresponding human-readable header file will be created to make further decoding of the recorded EKG data possible. The header file will contain at least the following information about the record: LSB voltage, channel related information, total number of samples (file length), sampling rate.

## 4.2 PC based Utility

### 4.2.1 Need for a PC based Utility

Soon after the project work started it was clear that there will be a need to develop a PC based supporting software (utility). This software would not only be a crucial extra in addition to the EKG recorder, but also a vital tool which would help test and verify the performance and functionality of the recorder throughout the development process.

Today numerous devices which have been designed to work independently (in standalone mode) are shipped with some sort of software intended to help the end user manage and organize all of the output data, view it in human comprehensive formats as well as post process the raw output data for any further use. One example would be photo cameras supporting RAW format file output. These cameras would typically come

with proprietary software primarily intended to convert RAW image data into standard RGB images suitable for printing and display as well as organization and pre-view of photographs. The entire concept of RAW image files and their further post processing outside of the camera body is intended to bring the user more control and flexibility over noise reduction, white balancing, tone reproduction, compression etc., otherwise done with default or “auto” settings inside the camera right after a picture was taken. Just like in case with the digital cameras, the output files found inside the flash memory of the EKG recorder will be of proprietary format, as previously explained this decision was primarily based on performance considerations and therefore a proprietary software (utility) must be provided to the user of the EKG recorder. This utility will have all typical functionality: data management, preview capabilities and signal processing abilities with further save options.

The utility will be designed for PC and must at least execute under Microsoft Windows although the support of other operating systems would be an advantage. Having pleasant experience with LabVIEW it has been easily decided upon the development environment. LabVIEW is a visual programming language from National Instruments (NI) originally released for the Apple Macintosh in 1986 and is commonly used for data acquisition, instrument control and industrial control. GE Healthcare uses NI software and hardware to test and verify performance of their patient monitoring systems. Another example of a use case will be Subaru advancing their hybrid vehicle testing *Figure 4-22* using similar NI platforms as GE.



*Figure 4-22 National Instruments products used by Subaru Corporation (Fuji Heavy Industries). (Morita, 2014)*

## 4.2.2 Implementation in LabVIEW

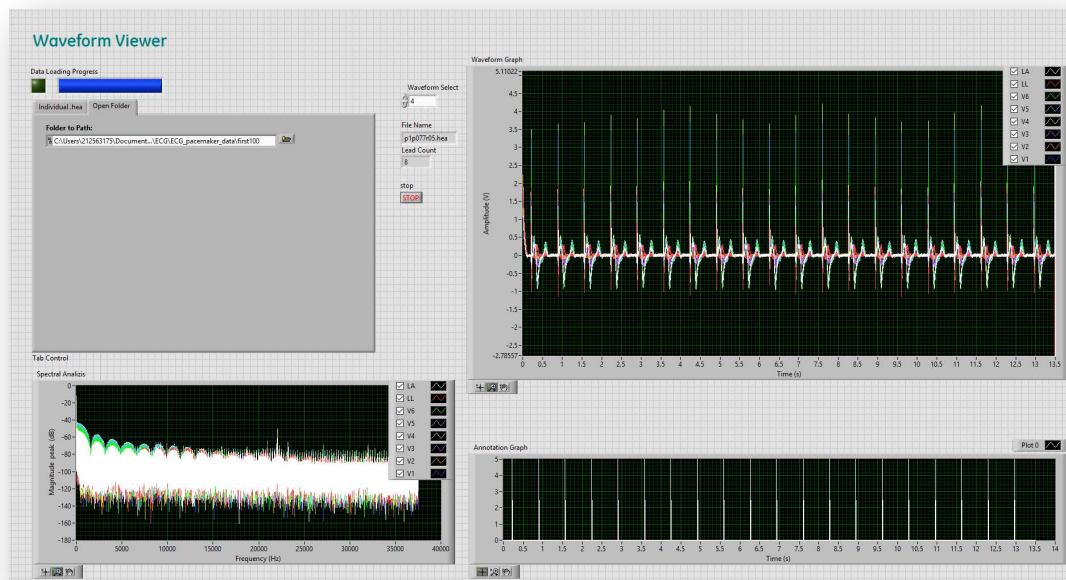


Figure 4-23 Waveform Viewer front panel.

At its current state the Waveform Viewer utility *Figure 4-23* allows the user to open and view individually selected EKG records in 16-bit binary format *Figure 4-24*. Alternatively, it is possible to import multiple EKG records by specifying a folder path *Figure 4-24*. Data must be present in the MIT format, previously described in chapter - 3.2.1 “EKG & Pace Pulse Artefacts Signal Analysis”. When selecting individual EKG records, absolute paths to the corresponding header files (RECORDNAME.heg) must be specified and not the binary files themselves. Besides displaying raw EKG data in time domain, the utility will also show the peak magnitude spectrum for each EKG channel. If an artificial pacer annotation data is available the exact location of each pace pulse will be represented as the “Annotation Graph”.

Future revisions of the Waveform Viewer will include enhanced signal processing functionality with an ability of further export to both MIT and CSV formats.

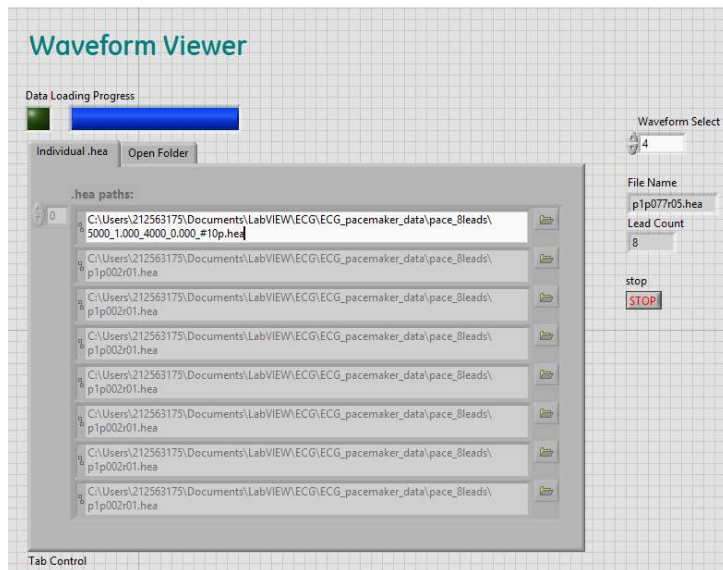


Figure 4-24 Individual EKG record selection. Extract from the Waveform Viewer front panel.

## 5 General Conclusions and Discussions

### 5.1 Overview

In this chapter, main milestones in the prototype design will be summarised and general conclusions based on the overall Hi Resolution EKG recorder concept will be provided. Furthermore, both the strengths and limitations of the recorder design are considered and suggestions for further improvements are presented.

### 5.2 Prototype Summary

The main goal: “to create a prototype able to acquire live data from real patients, which would be crucial for the design, optimisation and verification of various medical equipment” – was first imposed in the introductory chapter to this thesis. The prototype created during this project successfully proves the concept of a portable Hi Resolution EKG recorder. At its current state the device can amplify differentially sensed physiologic signal, perform software triggered analog to digital conversion on one channel and continuously record data to an external USB flash drive. In addition, the Wave Viewer PC utility allows the user to view recorded data as described in chapter 4.2.2 “(Utility) Implementation in LabVIEW”.

### 5.2.1 Prototype Performance

Several tests of the prototype have been conducted to characterize its overall performance. A sequential write test measured the average data transfer rate to a USB flash drive to be 370 kB/s. This figure was obtained by measuring the time span required for 10 MB of binary data to be transferred sequentially as multiples of 512-byte to a 16 GB USB 3.0 compatible flash drive. The 370 kB/s transfer rate corresponds to a theoretical maximum sampling rate of 185 kSa/s at 12-bit (each sample being represented as 16-bit unsigned integer). In combination with software triggered analog to digital conversion the transfer rate has been measured to be as low as 180 kB/s, indicating a practical average sampling rate of 90 kSa/s. Configuring the analog to digital converter of the RX71M (S12ADC) to continuous scan mode and in combination with the implemented in software circular buffer - would allow for higher and more importantly locked sampling frequency. The continuous scan mode is explained in chapter 4.1.10.1 "Source Code Explained".

### 5.3 Further Performance Improvements

It is important to note that the minimum sampling rate depends on the bandwidth of the original signal which is to be recorded and for most applications such as the artificial pace pulse record, the currently available sampling rate should be enough. If an application would require multiple EKG leads to be recorded simultaneously and/or higher sampling rate, number of bits, then the current hardware configuration would not provide adequate transfer rate to FAT USB flash drive over the available full-speed USB. One solution would be to implement a native 4-bit SD host interface on the RX71M Revelation board. As of April 2018, Renesas Electronics provides a device driver that controls the on-chip SD host interface (SDHI) of RX family microcontrollers. Another approach would be using a 177-pin version of the same RX71M group microcontroller to benefit from its high speed USB 2.0 host interface. In this case no new firmware or middleware would be required.

#### 5.4 Real Product Considerations

To turn the prototype into a real product which would be ready for real applications some additional aspects still need to be considered. The list below would summarize the primary areas in which work must be done:

- Mechanical enclosure design and PCB design.
- Implementation of the required defibrillation protection and current leakage electrode protection.
- Power management, battery power source integration.
- Amplification stage using integrated instrumentation amplifiers.
- SD card support implementation may be needed.
- Improved user interface.

#### 5.5 Secondary Goal

Besides the primary goal being – implementation of a Hi Resolution EKG recorder, the secondary goal was to introduce the reader to the many aspects that need to be considered before starting the actual design of a new product, sequentially lead the reader throughout the core elements of a typical design process as well as provide detailed descriptions of particular hardware and software related solutions. Detailed instructions related to the “e<sup>2</sup> studio” IDE as well an overview of the Renesas RX ecosystem may be useful for the ones who are planning to switch from hobbyist oriented platforms such as Arduino to more flexible and diverse solutions of various architectures and vendors used commercially in the electronics industry. It is important to note that mechanical design, manufacture and supply were not mentioned, as both are out of the scope of this thesis, although being certainly vital elements for the design process of any device. I sincerely hope that my secondary goal has been met, although ultimately each reader will decide for themselves.

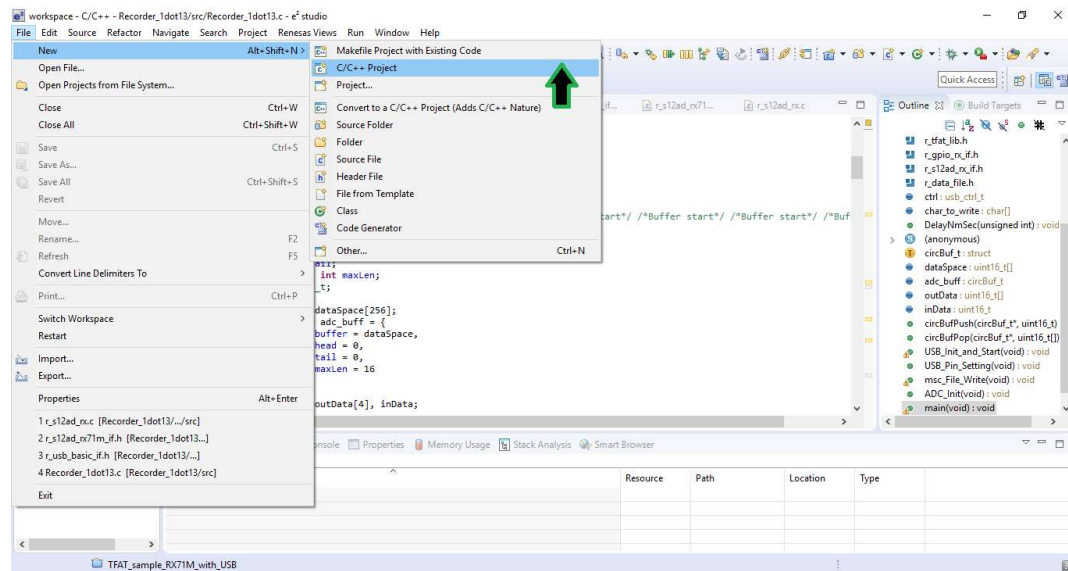
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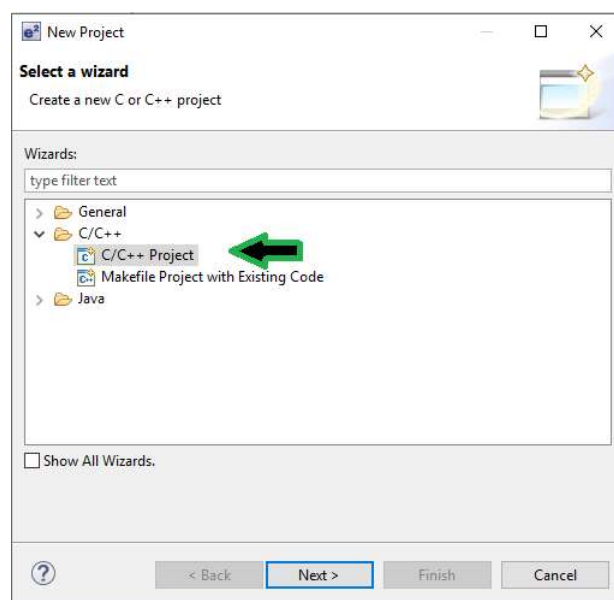
## Appendix 1. Creating New Project

In “e<sup>2</sup> studio” one works in projects. Projects for the RX71M development board (Revelation Board) are “C” language projects, therefore this would be the type of project that must be created.

### Step 1: Specify project type and name.

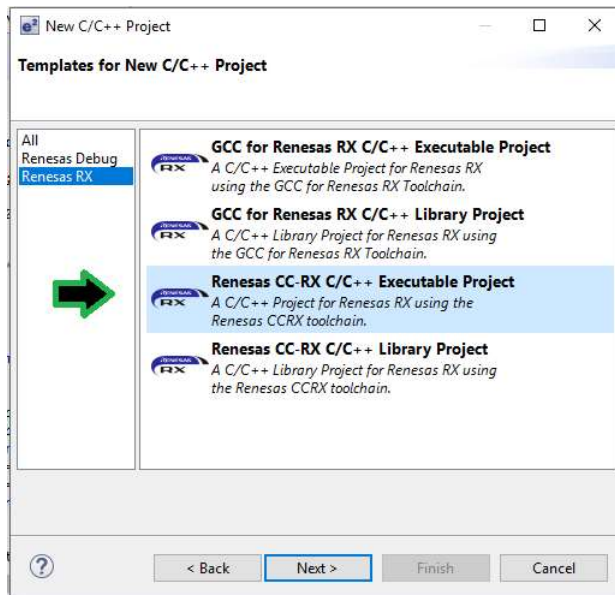


(File \ New \ C/C++ Project to open the New Project dialog.)

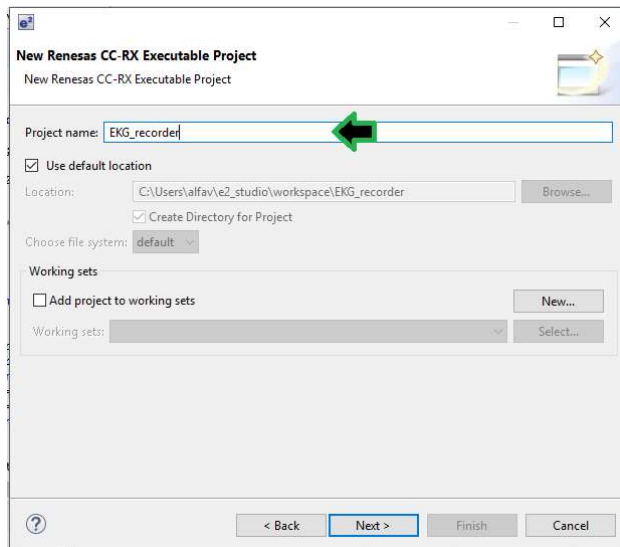




(C/C++ Project should be selected.)

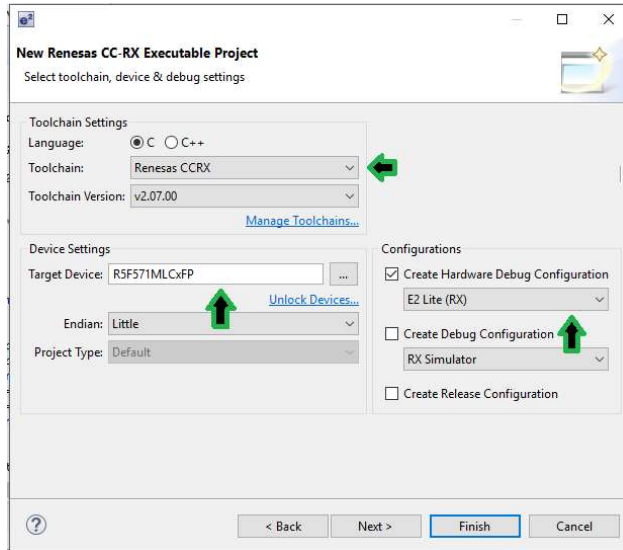


(Renesas CC-RX C/C++ Executable Project will be selected here. Previously installed CC-RX compiler will be used.)



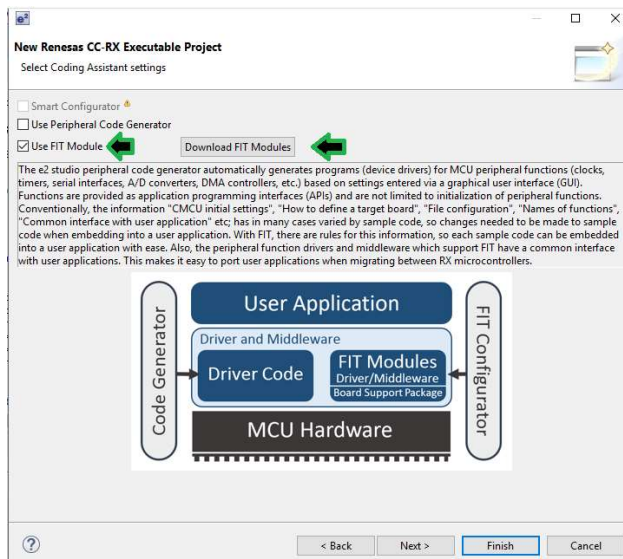
(The project will be given a name “EKG\_recorder” and saved into a default workspace location.)

**Step 2: Configuration of target hardware.**

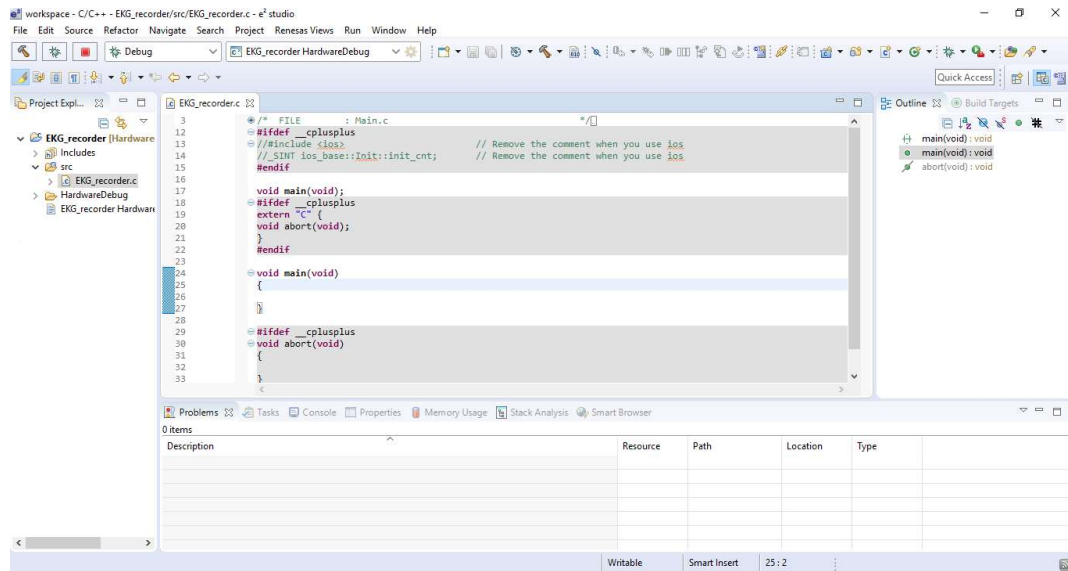


(Exact version of the RX71M device, CC-RX compiler version and the model of the on-board hardware debugger are being selected.)

### Step 3: Adding support for FIT modules.



(“Peripheral Code Generator” capable of automatically generating C code for selected modules will not be used, instead support for FIT Modules will be selected.)



(Project “EKG\_recorder” was successfully created. Main C file “EKG\_recorder.c” has been opened in the text editor of “e<sup>2</sup> studio.

