HEARTRONIC

Project number:	COOP-CT-2004-508181
Project acronym:	HEARTRONIC
Project title:	HEART Rating for Objective Neural Intelligent Communication

Instrument: Cooperative Research

Thematic priority: “Horizontal research activities involving SMEs”

Publishable Final Activity Report

Period covered: from	M1	to	M27	Date of preparation:	10/06/2007
Start date of the project			15/12/2004	Duration:	27 months
Project coordinator name		Alfredo Picano			
Project coordinator organisation name		LABOR Srl		Revision	0

SECTION 1 Project execution

1.1 Project objectives

The HEARTRONIC Project aims to develop an innovative system for prevention and early warning by a continuous monitoring of heart conditions, integrated in a wearable and light support like a shirt, capable to recognize cardiovascular anomalies and to alert doctors and Hospitals in real time. It must be highlighted the easy but extremely innovative project concept, based on the integration of the system on board and the patient's mobile phone that allows automatic communication with doctors and Public Health without any physical nor distance limitation. The novelty of the approach consists in the almost total elimination of a mass storage device for data storage; this implies sending data over a wireless network in real time. This can be done only by screening the signals on board and transmitting a limited amount of abnormal tracks, miniaturizing the neural classification system.

The results of the research are:

- ✓ ECG T-shirt with Embedded sensors
- ✓ First set of ECG Recognition algorithms (classifier analysis)
- ✓ Heartronic Handheld device
- ✓ PDA Software
- ✓ Wireless Network
- ✓ Database architecture
- ✓ Second set of ECG Recognition algorithms (fine analysis)

The HEARTRONIC system is composed by:

- ✓ Data Acquisition Unit: reads signals from the chest and perform the first diagnosis inside the elaboration unit, composed by a high-end DSP. The digital MEMS accelerometer/inclinometer helps the ECG pattern recognition algorithm to correctly interpret the captured ECG signals.
- ✓ Palmtop computer: collects elaborated signals in suspect heart conditions and send them to the host server for accurate diagnosis.
- ✓ Host server: collects information and ECG signals from all patients, keeps track of all events and is able to redirect data to doctors and Hospitals.

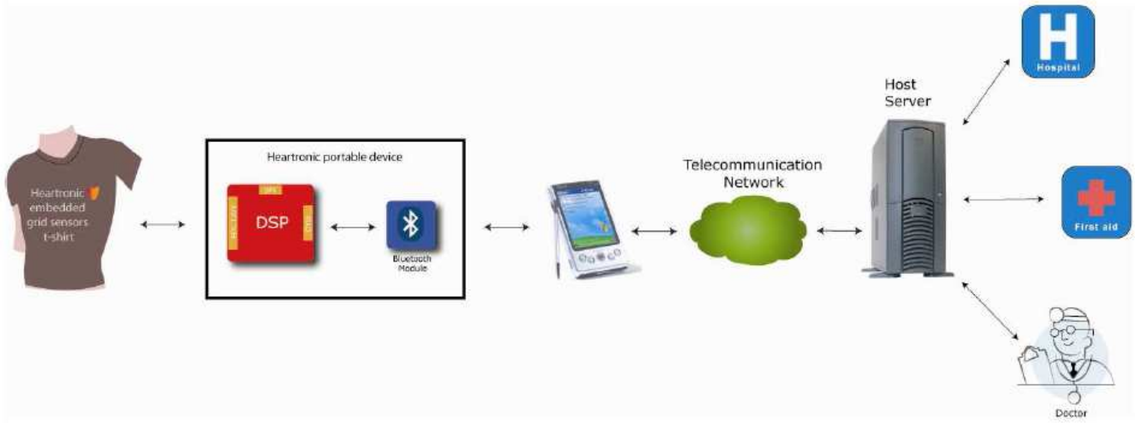

Figure 1: System Architecture

Main significant achievements of the second year of the project are:

- ✓ The possibility to record the personal details, diagnosis and case history of the patient to create an information base that correlates a wide variety of elements, as well as for rapid consultation of clinical records. This will form the basis of a **knowledge management** system, based on **datamining** technology, for early diagnosis of pathologies affecting the cardiovascular apparatus.
- ✓ The system is completely **automatic** and does not require any technical competence from the wearer: the ideal solution for elderly people, disabled, children, etc.
- ✓ The system will have a low production cost, since the **HEARTRONIC project**, not only wants to carry out research, but also exploit and adopt commercially off the shelf technologies (e.g. microprocessors, blue tooth, palm telephones, etc,);
- ✓ The system will meet the oncoming **EU safety Law standards**.

The HEARTRONIC T-shirt can be exploited as a product in the market of wearable diagnostic devices for real time remote analysis of patients at distance, offering an alternative to the classic Holter monitoring systems; its effectiveness and simplicity makes it an ideal candidate for long time patient monitoring, directly providing doctors with patient’s data via BlueTooth™ and GSM technology.

It is a special T-shirt capable of measuring electrocardiogram (ECG) by means of eight embedded sensors, made up by the classic structure metal/salt, like other standard ECG electrodes, but without adhesive, which leads to a good signal to noise ratio along with patient comfort. The particular electrodes configuration, following the Frank’s lead, gives the chance to obtain the classic 12 leads ECG signal by means of a linear transformation, the Dower matrix. During the first year of the project a reliable prototype (the HEARTRONIC T-shirt) has been achieved, which can be used to obtain the three analogical signals describing the cardiac vector.

Concerning the electronic board, it has been designed to receive the three signals coming from the Frank leads configuration adopted, but easily adjustable for the acquisition of the 12 lead classic ECG devices.

It provides a suitable analogical conditioning of the incoming signals, the digital conversion by means of the 12 bit ADC embedded in the DSP processor and the digital filtering in order to remove all the artifacts due to patient's movements and power-line mains.

By means of the pattern recognition system installed on board, the system can recognize potentially harmful cardiovascular anomalies; therefore this board represents a standalone block capable to receive the ECG signal and perform a pre-diagnosis. This could be applied in all the clinical long lasting analyses, in order to alert the doctor only when it is necessary.

1.2 Contractors involved

Participants					
Role	Type	No.	Short name	Country	Date enter project
CO	RTD	1	LABOR	Italy	Month 1
CR	SMEP	2	ACTA	Italy	Month 1
CR	SMEP	3	ESA	Poland	Month 1
CR	SMEP	4	I2M	Spain	Month 1
CR	SMEP	5	TC	Italy	Month 1
CR	SMEP	6	DV	UK	Month 1
CR	SMEP	7	AGT	Italy	Month 1
CR	RTD	8	IAITI	Portugal	Month 1
CR	RTD	9	MUG	Poland	Month 1
CR	RTD	10	OULU	Finland	Month 1
CR	RTD	11	SC	Italy	Month 1

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1.3 Work performed

The work performed in the project was divided in the following Work-packages:

1) **WP1 Preliminary requirements**
    a) Specifications for the HEARTRONIC product were outlined, taking into account the different aspects: medical, electronics and telecommunications.
    b) Sensor configuration was described, explaining the features and the reasons for the adoption of Frank's leads system.
    c) Main pathological situation to be monitored were defined, along with the related alarm system
    d) Electronics of the system was sketched, with the selection of the most suitable components, taking into account patient's comfort, product dimensioning in terms of weight and shape, and taking care of low energy consumption.
    e) Finally, the telecommunication architecture was outlined, with the choice of Bluetooth protocol for transmitting data from the wearable unit to the palmtop and GPRS for transferring data from the PDA to the remote host server.
    f) Medical, electronic and TLC requirements were integrated, their mutual consistency was verified and a consolidated data sheet detailing the full description of the system form users' perspectives was produced.

2) **WP2 ECG sensors development**
    a) A feasibility of ECG sensors embedded into textile fibers was examined, aiming to integrate both the wires and the sensors in the T-Shirt fabric.
    b) The most suitable ECG sensors to be integrated in the T-shirt where selected and purchased, aiming reduce as much as possible the use of gel or adhesive between sensors and skin
    c) The conclusion of the studies conducted in this Workpackage leads to focus the research in Improving electrode preparation techniques and better understanding of the sources of artifact, which can turn in enhancing equipment performance, resulting in improved patient conditions and signal monitoring.
    d) On this basis, a set of experiments were carried out in order to evaluate the ECG sensors performances with and without adhesive, assessing both the Signal to Noise ratio of the acquired data and the patient comfort

3) **WP3 Electronic system design**
   a) All the electronic architecture of the HEARTRONIC system, including energy supply and wireless communication via Bluetooth with the PDA was designed and implemented
   b) DSP firmware for ECG signal analysis was programmed, starting from Matlab code, passing through Simulink model and finally implemented in C code.
   c) Designs and electric schemes necessary to manufacture the alpha prototype were produced, along with several versions of the Printed Circuit Board

4) **WP4 ECG pattern recognition**
   a) Algorithms for digital filtering and statistical classification of ECG patterns were defined and developed in Matlab code.
   b) Matlab algorithms has been converted first in Simulink blocks and then in C code.
   c) These algorithms were implemented into a full potential version on PC and in a light version for the on board firmware.
   d) Translated algorithms were tested to verify the correspondence between the original version and the Simulink model.
   e) Finally, the possibility to optimize the algorithms both in terms of computational requirements for the processor and memory usage was examined.

5) **WP5 TLC integration**
   a) The objective achieved was to provide reliable and efficient communication between the Heartronic device and a cellular phone, as well as data transfer between the cellular phone and a host station, and from the host station to cardiologist’s cellular phone
   b) The PC based host server for data tracking and warning management has been thoroughly developed
   c) The graphic user interface for the PDA was designed, in order to provide the doctors with an easy to use graphic tool to handle the received ECG tracks

6) **WP6 Prototyping and testing**
   a) Testing campaign was focused on:
      - Tests on the acquisition unit, assessing the performances of the sensors both with and without conducting gel.
      - Tests on the algorithms, focused on the performance comparison between original Matlab algorithms and Simulink model
      - Tests on the PDA software and on the graphic interface

- Tests on the Host server and alarm management system
- Tests on the telecommunication architecture

7) **WP7 Exploitation and dissemination**
   a) Exploitation strategy was defined:
      a. The marketing strategy was defined
      b. Routes for future research and development activities were outlined
   b) The dissemination measures carried out in the second year of the project include:
      c. Several fairs, workshops and meetings
      d. A Web page for the dissemination of the aims and results to the wide public
      e. Contacts with potential customers

1.4 Final results

The main results achieved by the HEARTRONIC project are described in the following sections:

1.4.1 HEARTRONIC specifications and design

The main specifications identified for the HEARTRONIC system are the following.

MEDICAL REQUIREMENTS

The goal of Heartronic system according to project assumptions is to detect and record any heart anomaly in real time.

Fig.2 shows a typical ECG signal, with labels for significative time intervals:

- PR interval (from beginning of P to beginning of QRS)
- QRS duration (width of most representative QRS)
- QT interval (from beginning of QRS to end of T)
- QRS axis in frontal plane

ECG monitoring enables complex diagnosis of arrhythmias, myocardial ischemia and QT interval prolongation. Deaths for cardiovascular reasons are in most of cases associated with disturbances of these parameters. Thus, ECG monitoring and analysis are the main part of Heartronic system. The sensitivity at which arrhythmia recognition algorithms should be set is a problem for the further analysis. High sensitivity of the system could result in numerous false positive alarms (because of false ST monitoring alarms and muscle artifact simulating ventricular tachycardia) which must be evaluated by healthcare professional to avoid over-treatment. Low sensitivity may result in misdiagnosis of the potentially life threatening conditions. Furthermore ECG monitoring does not supply sufficient information necessary to evaluate the cardiac function as a pump. It might limit preventive and diagnostic use of Heartronic especially in patients with heart failure.

There is almost no published trials concerning cardiac remote monitoring so it is difficult to develop an algorithm supported by published research. The following propositions concerning Heartronic are based on our partner clinical experience and related research in the field of electrocardiography.

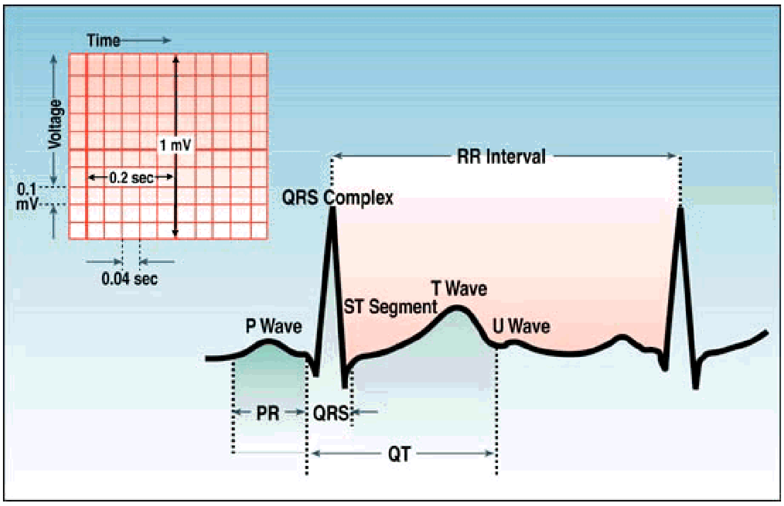


Figure 2: typical electrocardiogram and relative time intervals

The selected sensors' configuration is Orthogonal Frank's leads – X, Y, Z (8 sensors):

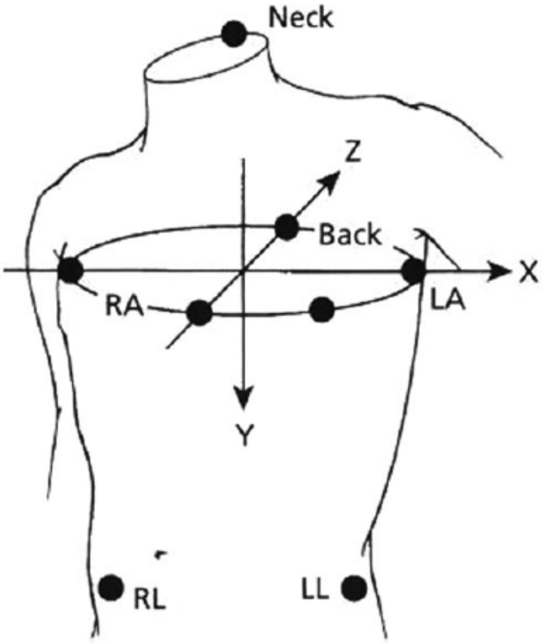


Figure 3: Frank's leads

The advantages are:

☑ Simplicity of electrodes placement

☑ Less susceptibility to artifacts than multileads systems

☑ Three dimensional ST monitoring (use of vectorcardiography in ST analysis)

While the drawbacks are:

☒ Need for mathematical transformation to obtain 12 leads for ST segment monitoring and comparing with standard ECG

☒ Rarely used in clinical practice

The major advantage of this system is direct multiple-lead ST segment analysis without need of approximation of the standard 12-lead ECG. Most of the ischemic events (ST elevation or depression) can be detected using the standard 12-lead ECG without addition of the posterior leads. However, it is important to have right ventricle and posterior leads for right ventricle and posterior wall-related ischemia.

The Frank leads system (8 electrodes) is used in Sweden for hospital monitoring of patients with acute coronary syndrome. The system makes use of vectorocardiographic parameters in detection of ST segment changes.

Beat types

The program for arrhythmia detection classifies and labels each beat according to its shape, width and time of occurrence.

- Normal (N) – beats whose rate of occurrence (dominant type of beat) duration (<120 msec) and timing define a Normal beat, and which does not fulfill criteria for prematurity.
- Supraventricular (S) – a beat which satisfies all requirements for a Normal beat, but which is premature by at least the interval of time set by the prematurity parameter.
- Ventricular (V) – a beat having characteristic similar to those of a cluster comprising beats which based upon frequency of occurrence, width (>=120 msec), and timing, are most likely to be ventricular beat.
- Artifact (A) – exibits characteristics of muscle or baseline artifact.
- Other (O) – other categories such as pacer, aberrantly conducted SVE.

Arrhythmia analysis

Definitions:

“Red alarms”

- Ventricular fibrillation (VF) – - is defined as any polymorphic VT with a ventricular rate >=240 bpm (CL <= 250 ms) for x consecutive seconds (default x=4 seconds).
- Ventricular flutter (VFt) - is defined as any monomorphic VT with a ventricular rate >=240 bpm (CL <= 250 ms) for x consecutive seconds (default x=4 seconds).
- Sustained ventricular tachycardia (sVT) – a run of consecutive V’s (monomorphic or plymorphic) with average rate >=VT rate parameter and < VF, VFt rate lasting for >=30sec (default average VT rate parameter 120 –240bpm, 250 ms<=CL<=500ms).
- Asystole (As) - no QRS for x consecutive seconds in absence of ventricular fibrillation or artifacts (default 4 seconds).

“Yellow alarms”

- Non-sustained ventricular tachycardia (nsVT) – a run of V’s lasting for >=4sec with average rate>= VT rate parameter and < VF, VFt rate (default average VT rate parameter 120 –240bpm, 250 ms<=CL<=500ms) but lasting for less than 30 seconds (default 10 seconds) OR three or more sequential V’s lasting for <4 sec with average rate>= VT rate parameter.
- Extreme tachycardia – heart rate averaged at 60 seconds > tachycardia limit (range 140-200, default 160)
- Severe bradycardia (sB) – average heart rate of sB period of time (range 30-120 seconds, defualt 60) < sB rate (range 30-50, default 35)
- Potentially threatening supraventricular tachycardia (ptSVT) – a run of consecutive SVE’s regular or irregular with average rate >= ptSVT rate parameter (range 140-200, default 160) lasting for >= ptSVT time (range 1-5 minutes, default 1 minute)

“Green alarms”

- Ventricular rhythm – a dominant rhythm (three or more) of consecutive V’s with average rate < VT rate parameter (default 120 bpm)

- Supraventricular tachycardia (SVT) - three or more sequential SVE's with 3 beat average >= SVT rate parameter (range 100-150, default 120)
- Atrial fibrillation (AF) – a complex algorithm uses prematurity of curent and previous beats to produce a number representing the probability that A-fib exists, in selected patients can be moved to yellow alarms
- Bradycardia (B) – three-interval heart rate < bradycardia limit (range 30-50, default 40), in selected patients can be moved to yellow alarms
- Pause (P) – interval between two consecutive beats > pause interval parameter (range 2-4 sec, default 2)

St analysis

ST level measurement definitions:

- Isoelectric point - provides the baseline for the slope measurement, computed by averaging all normal beats in a 60 second (default, range 30-240 s) window
- Baseline J, ST point – provides the baseline for the ST segment changes, computed by averaging all normal beats in a 60 second (default, range 30-240 s) window
- J point – junction of the QRS complex and the ST segment
- ST level - vertical distance in voltage (elevation or depression) between the baseline ST point and the current ST measurement point
- ST slope - The difference between ST level and J point level (with reference to isoeletric point)
- ST episode – excessive depression (>=1 mm in high risk for ischemia patients, > 2 mm in low risk patients) combined with horizontal/negative slope OR excessive elevation (>=2 mm in precordial leads or >= 1mm in limb leads) in at least 2 corresponding leads, measurements are averaged for selected intervals (30-240 seconds, default 60 seconds)
- Minimum Duration - is the least amount of time a specific ST episode lasts to qualify. (The Minimum duration for an event is set by the episode criteria.) The default is 60 seconds
- Minimum Separation - is the minimum distance in time between episodes in seconds. The default is 60 seconds

St episodes

“Red alarms”

- Excessive elevation (>=2 mm in precordial leads or >= 1mm in limb leads) in at least 2 corresponding leads for >= x minutes (default 1 minute) , measurements are averaged for selected intervals (0,5-4 minutes, default 1 minute)

“Green alarms”

- Excessive depresssion (>=1 mm in high risk for ischemia patients, > 2 mm in low risk patients) combined with horizontal/negative slope OR in at least 2 corresponding leads for >= x minutes (default 1 minute) , measurements are averaged for selected intervals (0,5-4 minutes, default 1 minute)
- changes in T waves morphology from positive to negative and vice versa (>= 0,3 uV) in at least 2 corresponding leads for >= x minutes (default 5 minutes)
- ST episode (vectorcardiography – if applicable) ST-VM – ST segment vector magnitude – the vector connecting the tips of the two sumed for all three leads vectors for reference complex and ischemic complex, reversible increase > 50 uV for > 1 min (measured 60 ms after the J point) – represents total, spatial ST shift from the baseline.
- ST level is measured for each normal beat that was preceded by a normal beat in all 12 leads.
- The analyzer should select three measurement points: isoelectric point, J point and ST point.
- The J and ST point levels are measured as the distance of each point above or below the baseline J and ST value. ST point - is measured 80 ms after J point when heart rate < 120 BPM or 60 ms after J point when heart rate >= 120 BPM. The ST measurement point may need to be readjusted if the patient’s heart rate or ECG morphology changes significantly, so manual possibility of adjustment should be available.
- Measurements are averaged at default (60 seconds) or operator-selected intervals (range 30-240 seconds).
- The first two 60 seconds periods of monitoring are used as the reference for all further comparisons.
- The ST segment should not be monitored in patients witch LBBB, intermittent RBBB and ventricular pacing because of frequent false positive alarms.

Qt analysis

Definitions and measurements:

- Acute increases in the QT interval can be observed in multiple clinical situations and are associated with an increased risk of syncope and sudden.
- The QT analysis option analyzes the QT segment of the heartbeat.
- The QT interval should be measured from the beginning of the QRS complex to the end of the T wave.
- Discrete U waves, which arise after the T wave has returned to baseline, should not be included in the QT interval.
- The QT analysis is performed only for normal beats.
- Lead selection for QT interval monitoring should be made by noting which lead of the patient's standard 12-lead ECG has the most well-defined T wave end. (Lead II is a commonly used lead in the research literature for measuring QT intervals).
- The system measures two parameters: QT segment width and QTc value based the Bazzet algorithm. (QTc=QT/sqr(RR)
- Both values are averaged each 1 minute interval.
- A normal QTc is <0.46 second in women and <0.45second in men.
- A QTc >0.50 second has been shown to correlate with a higher risk for chest points.

"Yellow alarm"

- QT segment prolongation
- QTc value>= 500 msec observed in > 5% NN intervals during 24 h monitoring OR
- 24hQTC > 450 msec

"Red alarm"

- Apnea - respiratory pause exceeded the preset apnea alarm limit (range 10-60 sec., default 20 sec)
- "Yellow alarms"

- Tachypnoe - respiratory rate exceeded the high alarm limit (range 25-40, default 30)
- Respiratory rate is too low - respiratory rate dropped below the low alarm limit (range 6-12, default 8)
- Erratic respiratory signal – poor contact between the electrode and skin or excessive patient movement

ELECTRONIC REQUIREMENTS

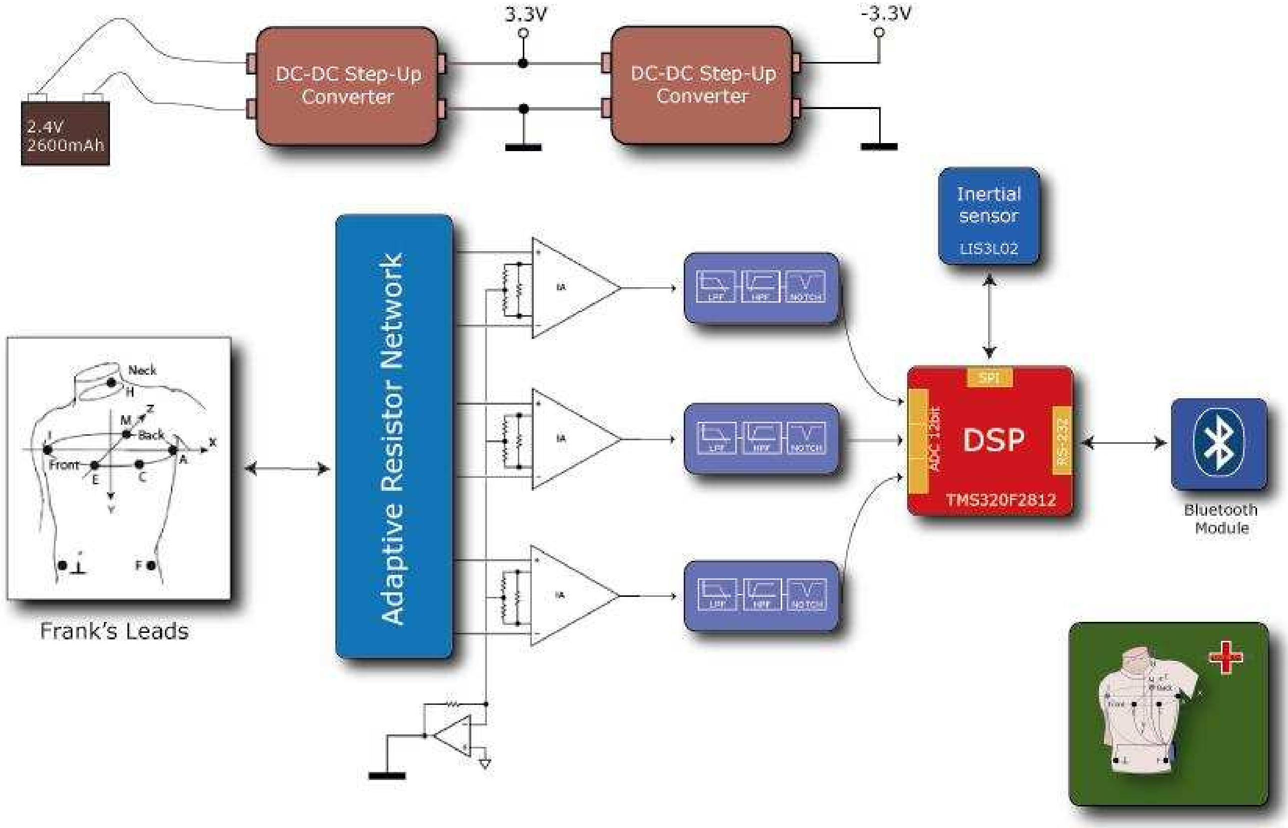


Figure 4: System Architecture

Typical ECG front-end processing algorithms consist of the following phases:

- ✓ *Signal acquisition and filtering* – This phase is performed first as analog filters and then as digital filter on DSP chip.
- ✓ *Initialization* - Used to determine initial signal and timing thresholds, positive and negative peak determination, automatic gain control, etc.
- ✓ *QRS complex detection* - Reliable detection of R-peak is crucial for morphological analysis.

- ✓ *Baseline correction and first diagnosis* - Compensates for low-frequency ECG baseline drift. ST segment processing.- Detects changes in ST segment.

An ECG electronic front-end must have very high input impedance if the very weak electrical signals from the heart are to be detected. A differential mode of amplification is required if the ECG is to be isolated from the large amount of 50Hz mains interference which is ever present. Accordingly, the first stage is a differential amplifier, such as an instrumentation amplifier. The spreading electrical currents create different potentials at different points on the body, which can be sensed by electrodes on the skin surface using biological transducers made of metals and salts. This electrical potential is an alternate current (AC) signal with bandwidth of 0.05 Hz to 50 Hz, sometimes up to 100Hz. It is generally around 1-mV peak-to-peak in the presence of much larger external high frequency noise plus 50-/60-Hz interference normal-mode (mixed with the electrode signal) and common-mode voltages (common to all electrode signals). The right leg driver is necessary because it applies an inverted version of the common-mode interference to the subject’s right leg, with the aim of canceling the interference. Next to this first stage there is a sequence of analog filters, that clean the ECG signal removing noise.

Electrocardiographic signals may be corrupted by various kinds of noise. Typical examples are:

- power-line interference: 50–60 Hz pickup and harmonics from the power mains
- electrode contact noise: variable contact between the electrode and the skin, causing baseline drift (For example, gels that are used to improve contact in the case of EEG electrodes dry out over time).
- motion artifacts: shifts in the baseline caused by changes in the electrode-skin impedance
- muscle contraction: **e**lectro**m**yo**g**ram-type (EMG) signals are generated and mixed with the ECG signals respiration, causing drift in the baseline
- electromagnetic interference from other electronic devices, with the electrode wires serving as antennas
- noise coupled from other electronic devices, usually at high frequencies.

Also, one of the major obstacles to wider use of intelligent wearable medical monitors is that existing sensors are difficult to wear for long periods of time without irritating the skin after prolonged periods. So we had to choose a kind of sensor that doesn’t have adhesives on its surface.

Another important topic is the patient activity recognition: adding a two-axis (or three axis) acceleration sensor integrated in the system, the Heartronic device should be capable of detecting the level of user activity and correlating it with the vital signs.

Unfortunately if the device is more intelligent, its size increases, as well as its weight and energy consumption. The latter is a critical point for this device, since it has to be operative at least for one day without interruptions: consequently it is a very important factor for correct electronic board design.

Technical specifications of the electronics are:

Front-end components:

Basic front-end components are:

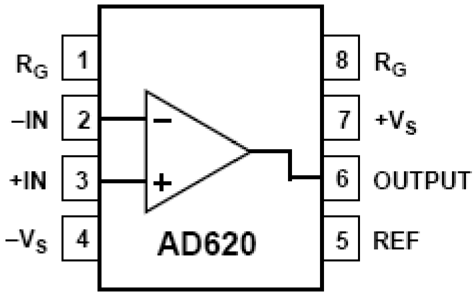
- Instrumentation Amplifier
- Right Leg Driver (reference)

This block is the first signal conditioning block and it performs an analog differential amplification, critical for successive conditioning phase and elaboration phase.

Summarizing the components requirements from D1.1 we have:

Instrumentation Amplifier (IA) requirements:

- Stability in low gain (G = 1 to 10)
- High common-mode rejection ratio (CMRR > 90dB)
- Low input bias current (<30nA)
- Rail-to-rail output
- Low power, 2mA Max Supply Current
- Low noise, <10 nV/√Hz @ 1 kHz
- Very low input offset (<50 µV) and drift (<1 µV/°C)



Operational Amplifier requirements

- Low noise, <50 nV/√Hz @ 1 kHz
- Low power, 1mA max
- High common-mode rejection ratio (CMRR > 90dB)
- Rail-to-rail output
- Very low input offset (<100µV) and drift (<2µV/°C)

Components chosen are respectively:

- Instrumentation amplifier: Analog Devices AD620AN
  Datasheet can be found @
  http://www.analog.com/UploadedFiles/Data_Sheets/897653854AD620_g.pdf
- Operational Amplifier: Analog Devices OP97
  Datasheet can be found @

http://www.analog.com/UploadedFiles/Data_Sheets/39155126371596OP97_e.pdf

Analog Filtering blocks

Filtering components are:

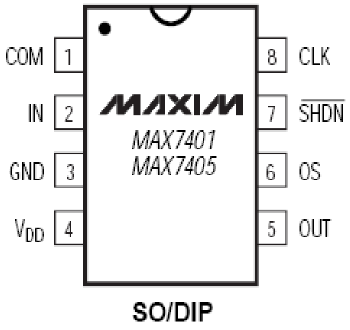
- Low Pass Filter
- High Pass Filter (implemented via software inside digital signal processor code)
- Notch Filter

Standard -3-dB frequency for patient monitoring is 0.05 Hz to 30 Hz, while diagnostic grade monitoring requires 0.05 Hz to 100 Hz or more. All electrocardiogram (ECG) front ends must be alternate current (AC) coupled to remove artifacts from the electrode offset potential, though important features of the ECG waveform have extremely low frequency characteristics.

All filters exhibit phase shift that varies with frequency. This is an expected and normal characteristic of filters, but in certain instances it can present problems. If the phase increases linearly with frequency, its effect is simply to delay the output signal by a constant time period. However, if the phase shift is not directly proportional to frequency, components of the input signal at one frequency will appear at the output shifted in phase (or time) with respect to other frequencies. The overall effect is to distort non-sinusoidal wave-shapes, as happen for example for a square wave passed through a Butterworth low-pass filter. The resulting waveform exhibits ringing and overshoot because the square wave's component frequencies are shifted in time with respect to each other so that the resulting waveform is very different from the input square wave. When the avoidance of this phenomenon is important, like in this project, a Bessel filter may be useful. The Bessel characteristic exhibits approximately linear phase shift with frequency, so its action within the pass-band simulates a delay line with a low-pass characteristic. The higher the filter order, the more linear the Bessel's phase response will be.

Summarizing the analog filter block requirements from D1.1 we have:

- Low Pass active filter requirements
  frequency corner < 100Hz
  filter order > 5 (Bessel equations)
- Notch active filter requirements
  frequency corner = 50Hz
  filter order > 5 (Bessel equations)



Component chosen is a switched capacitor 8th order Bessel filter and it can be used as notch and as lowpass filter:

- Maxim MAX7401

  Datasheet can be found @

  http://pdfserv.maxim-ic.com/en/ds/MAX7401-MAX7405.pdf

High pass filter will be implemented inside DSP code.

Digital Signal Processor (DSP)

The Digital Signal Processor is the core of this project. It must respect some requirements about consume and performance.

Its tasks is to:

- collect all chest filtered signals,
- convert them in digital signal (so it must have an ADC converter),
- elaborate them together with accelerometer information (issues associated to code and data memory requirements)
- drive the communication device

All the requirements depends on how this tasks are realized. First of all the Analog-Digital Converter (ADC) resolution have to be at least 12 bit. Sample frequency is 512hz.

Processor chosen is:

Texas Instruments TMS320F2812, 32-Bit Digital Signal Controller with Flash

Datasheet can be found @:

http://focus.ti.com/general/docs/lit/getliterature.tsp?genericPartNumber=tms320f2812

Main features are:

- Harvard Bus Architecture
- Fixed Point DSP model
- High-Performance Static CMOS Technology
- 150 MHz (6.67-ns Cycle Time)
- Low-Power (1.8-V Core @135 MHz, 1.9-V Core @150 MHz, 3.3-V I/O) Design
- 3.3-V Flash Programming Voltage
- JTAG Input-Output Boundary Scan Support
- Random Access Memory (RAM) 36 KB
- One Time Programmable Read-only memory (OTP ROM) 2 KB
- Flash memory 256 KB

- Analog-Digital Converter (ADC) 1 16-Channel 12-Bit
- Analog-Digital Converter (ADC) Conversion Time 80 ns
- General Purpose Input/Output pins (GPIO) 56
- Serial Peripheral Interface (SPI),
- Controller Area Network (CAN)
- Universal Asynchronous Receiver-Transmitter (UART)
- Core Supply (Volts) 1.9 V
- IO Supply (Volts) 3.3 V

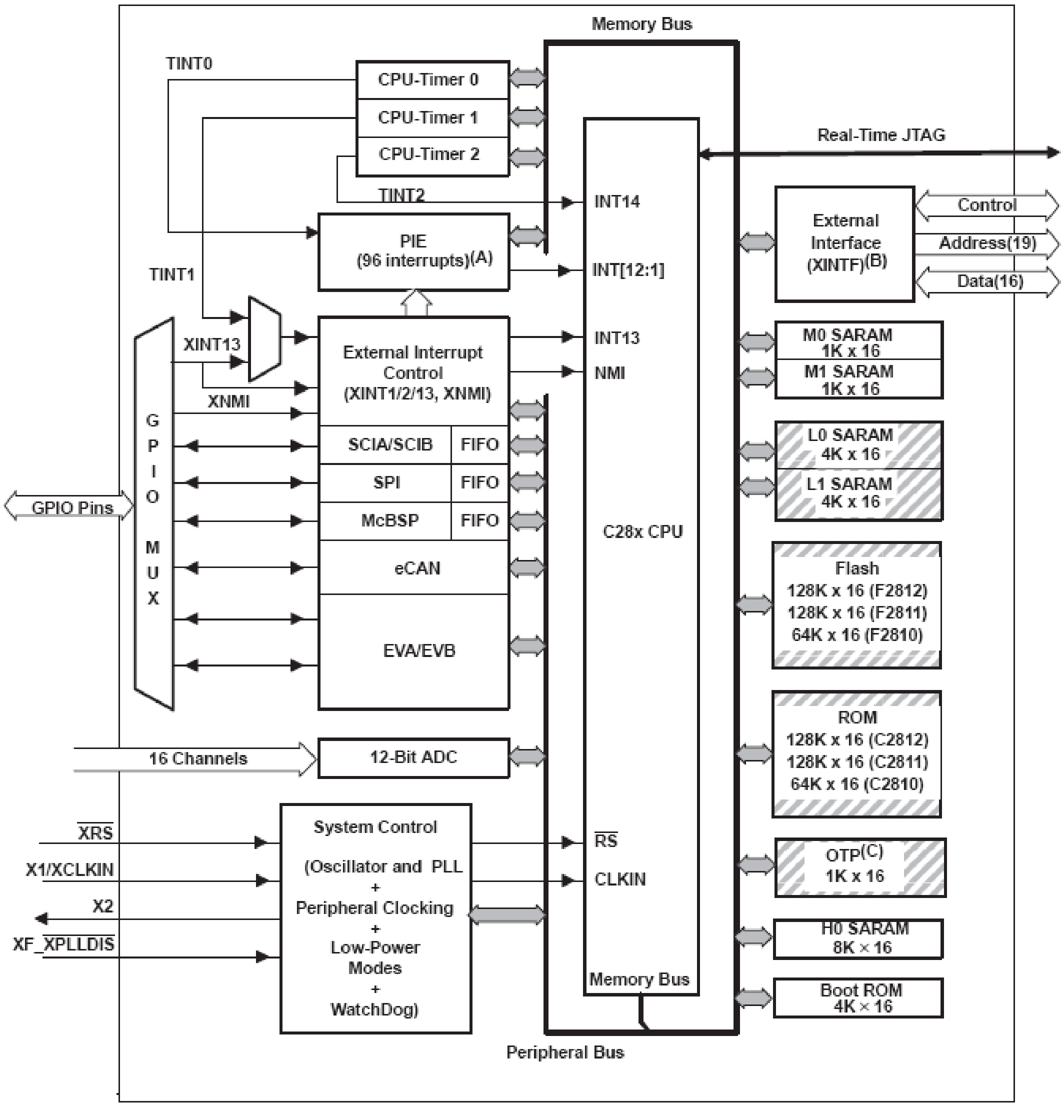


Figure 5: Texas Instruments TMS320F2812 functional overview

MEMS accelerometer

An accelerometer/inclinometer can help not only to have an highly accurate dynamic acceleration data, but also to discriminate between sitting and lying position and between supine and left and right lateral lying position. Further more knowledge of static acceleration in both left-right and forward-backward direction is highly beneficial.

The accelerometer chosen is a chip produced by ST Microelectronics: LIS3L02DQ

This device measures acceleration and tilt. It is a three axes digital output linear accelerometer that includes a sensing element and an IC interface able to take information from the sensing element and to provide the measured acceleration signal to the external world through an I^2C / SPI serial interface. The IC interface is factory calibrated to provide a ready to use device.

The device belongs to MEMS (Micro-Electro-Mechanical-System) Inertial Sensor category. Micro Electro-Mechanical Systems (MEMS) is the integration of mechanical elements, sensors, actuators, and electronics on a common silicon substrate through microfabrication technology. While the electronics are fabricated using integrated circuit (IC) process sequences (e.g., CMOS, Bipolar, or BICMOS processes), the micromechanical components are fabricated using compatible "micromachining" processes that selectively etch away parts of the silicon wafer or add new structural layers to form the mechanical and electromechanical devices.

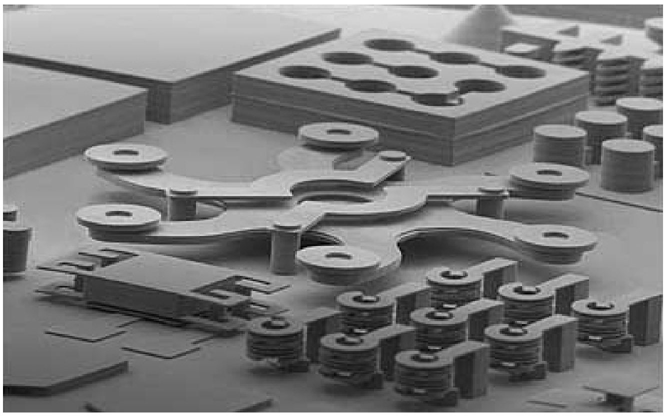
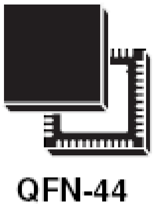


Figure 6: one of the first MEMS devices. At the bottom left with the C-shaped wings is an accelerometer.



The digital output can be decoded by DSP.

Main features are:

- digital output linear accelerometer
- acceleration range: ± 2.0 g on three axis x,y,z
- sensitivity: 1024 LSB/g

  (Typical Value, where 1 LSB is equal to 0.97 mg = 4g / 4096)

Most of work consists in programming Integrated Circuit (IC)'s internal registers. The user will set several parameters like:

- Axis Enable;

- Interrupt Threshold (the device can wakes up when the specified axis measured acceleration is higher (lower) than the threshold set in an internal register.

Datasheet can be found @

http://www.st.com/stonline/books/pdf/docs/10175.pdf

Communication Device

In this section it's presented the Bluetooth communication device, the UARTDNG101 wireless module. It has an Universal Asynchronous Receiver-Transmitter (UART) serial interface (RX,TX,RTS,CTS signals), so it replaces a physical cable (i.e. RS232 serial cable) with a wireless Bluetooth connection. It's suitable for integration in microprocessor systems without operative system since it doesn't need drivers to work. It's based on CSR Chipset has PCB inverted F antenna and 3,3 voltage regulator.

It supports two kinds of connections:

- ✓ ACL link: An asynchronous packet-switched connection between two devices created on the LMP level. ACL packets travel on this link.
- ✓ SCO link: A synchronous circuit-switched connection for reserved bandwidth communications. Use mainly for voice. It is created on the Link Manager Protocol (LMP) level by reserving slots periodically on a physical channel. SCO packets travel here. SCO links can be established only after an ACL link is first established.

Current Consumptions (Power supply 3,3V)

- SCO connection HV3 (1s interval sniff mode) (Slave) 28 mA
- SCO connection HV1 (Slave) 53 mA
- ACL data transfer 115.2kbps UART (Master) 15 mA
- ACL connection, Sniff Mode 40ms interval, 38.4kbps UART 4 mA
- ACL connection, Sniff Mode 1.28s interval, 38.4kbps UART 0.5 mA
- Parked Slave, 1.28s beacon interval, 38.4kbps, UART 0.6 mA
- Deep Sleep Mode 15 µA
- Peak current during RF burst 80 mA

Datasheet can be found @

http://www.blue2bfree.com/site/datasheet/uartdng101.pdf

Supply unit

This section concerns the supply issue, critical for this kind of portable devices.

As in most other applications, the system supply voltage in biophysical monitoring continues the trend toward low, single-supply levels. While bipolar supplies are still used, 5-V systems are now common and trending to single 3.3V supplies. This trend presents a significant challenge for the designer faced with a 500mV electrode potential and emphasizes the need for a precision signal conditioning solution. While the following discussion concentrates on the single supply design, the principles involved apply to bipolar designs as well.

DSP processor requires dual voltages (1.8-V or 1.9-V and 3.3-V) to power up the CPU,

Flash, ROM, ADC, and the I/Os. To ensure the correct reset state for all modules during power up, there are some requirements to be met while powering up/powering down the device. Power sequencing is needed for this device. In other words, 3.3-V and 1.8-V (or 1.9-V) can't ramp together. So it's needed a external power sequencing circuit that allow the DSP to boot correctly. Some regulators can facilitate power-sequencing (with the aid of additional external components) and may be used to meet the power sequencing requirement. Component chosen is TPS767D301 (datasheet @ http://focus.ti.com/general/docs/lit/getliterature.tsp?genericPartNumber=tps767d301) from Texas Instruments.

Using a rechargeable battery pack of 4 AA (2600mAh, 1.2V) placed in parallel to obtain a storage cell of 2.4V (2600mAh), it's needed a step-up DC-DC converter to achieve +3.3V. MAX1760 provided by MaximIC do this work.

Datasheet @ http://pdfserv.maxim-ic.com/en/ds/MAX1760-MAX1760H.pdf

Main features are:

- 0.7V to 5.5V Input Voltage Range
- Up to 800mA Output
- Fixed 3.3V Output (or Adjustable from 2.5V to 5.5V)

Front-end instrumentation amplifiers work with dual supply voltage. To obtain the –3.3V needed it can be used the MAX1697, provided by MaximIC. It's a CMOS charge pump voltage inverter. Main features are:

- 60mA output current
- 150 µA supply current
- +1.25V to +5.5V Input Voltage Range

TELECOMMUNICATION REQUIREMENTS

The system has been organized by following a three-tier based architecture: the *Client Tier* contains Terminals such as a Remote Unit (RU), acting as a Gateway, a Mobile Unit (MU), a Personal Computer (PC) and devices (i.e. sensors). MU Terminals and PCs provide the user interface to the Heartronic Central server through a wireless connection. An example of a Terminal is a PDA.

RUs are mediators between devices and the Server Tier and are responsible for integrating devices into the platform; they are part of the patient equipment and they are PDAs with mobile connectivity.

The *Server or Application tier* contains the Central Server which, by handling data transfer from client level to storage level, acts like an Application Server making access to data transparent to the client level.

Finally Central Server is directly connected to a *DataBase* (DB) which stores ECG patterns and additional data useful for the screening and information analysis.

The following picture is a schematic description of overall architecture:

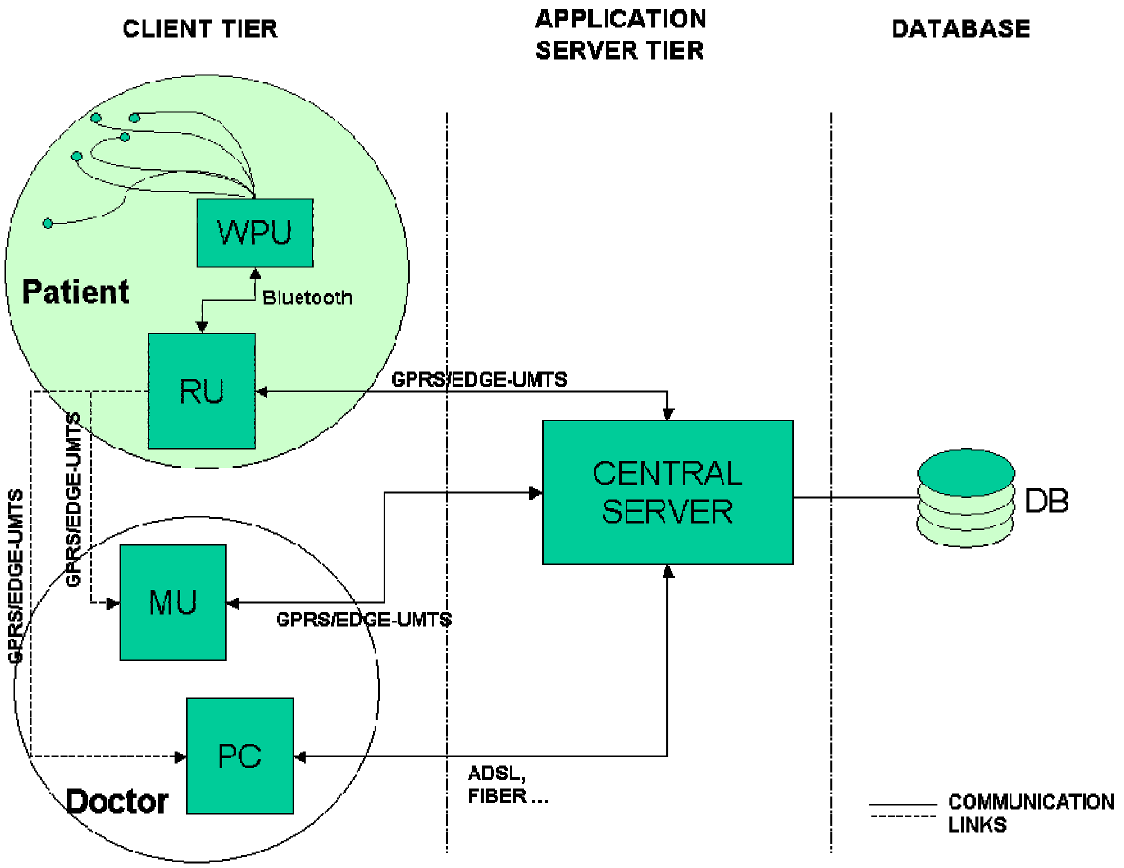


Figure 7: Heartronic overall architecture

Wearable Processing Unit (WPU) transmits data to the RU using a Bluetooth connection while the RU, a PDA with a CF card or an integrated/embedded modem, is able to connect to the Central Server via a GPRS/EDGE or UMTS (if available) connection.

Both RU (Client tier-Patient) and MU (Client tier-Doctor) are connected to the Central Server but, in particular circumstances or emergencies, the RU might be able to talk directly to MU in order to send alerts to the doctor with SMS or phone calls.

Furthermore PC or MU are able to display information and query data to DB via the Central Server through a wireless connection (PC) or a wired link (ADSL, fiber for PC).

Basically a secure HTTP connection has been set up in order to transmit data securely over the Web.

XML and SVG (Scalable Vector Graphics, a language for describing two-dimensional graphics and graphical applications in XML) are standards languages for information exchange.

Furthermore RU is able to transmit alerts to MU with MMS, SMS or triggering an emergency phone call.

An interesting scenario that Java technology is able to implement, regarding triggering alerts, is the possibility to start an application (i.e. a MIDlet) on the MU just sending an SMS.

In fact Mobile Information Device Profile (MIDP) 2.0 version of J2ME technology allows for the creation of a push registry that enables MIDlets to set themselves up to be launched automatically, without user initiation; moreover the Wireless Messaging API (WMA, JSR 120) makes SMS-based push activation possible.

1.4.2 Electronic system design

Electric signals, coming from the embedded sensors are combined inside the Adaptive Resistor Network, designed by Frank in his article (*"An Accurate, Clinically Practical System for Spatial Vectorcardiography",* Frank, 1956). The three signals coming out represent the three Frank's Leads, containing the information about the cardiac vector. Lead X,Y and Z are amplified, cleaned from the 50Hz interference, and filtered by a 100Hz lowpass filter. All this part is an analogic elaboration of electrocardiac signals.

After being cleaned and amplified, the signals are delivered to the analog-digital converter, inside the Texas Instruments DSP, model TMS320F2812.

DSP is connected to a 3-axes digital accelerometer, a 512MB secure digital flash memory, and a Bluetooth transmitter.

Maxim MAX1702B is the main power supply chip for the Heartronic Board, and it integrates three high performance power supplies with associated supervisory and management functions. It includes a step-down DC-DC converter to supply 3.3V I/O and peripherals, a step-down DC-DC converter to supply 0.7V to VIN for the microprocessor core, and a step-down DC-DC converter to supply 1.8V, 2.5V, or 3.3V to power the memory. Management functions include automatic power-up sequencing, useful for TI DSP, power-on-reset and manual reset with timer, and two levels of low-battery detection. The DC-DC converters use fast 1MHz PWM switching, allowing the use of small external components. The input voltage range is from 2.6V to 5.5V, allowing the use of four 1.2V rechargable batteries.

The power supply section contains the MAX1697 that is an ultra-small, CMOS charge-pump voltage inverter. This device features an ultra-low 12ohm output resistance, permitting loads of up to 60mA with maximum efficiency. Also this section shows all the different supply voltages for this board:

- VDD3VFl is the voltage supply for the Flash memory inside TI DSP.
- VDD1 is the +1.8V ADC digital supply, necessary for the ADC components inside TI DSP.
- VDDA1 (+3.3V) and -VDDA1 (-3.3V) are the analog supply voltages.
- OUT1 is the 1.8V DSP core voltage, and OUT3 is the DSP input/output peripheral supply voltage.

The analog filtering section consists of several resistors (Frank Resistor Network), necessary to have the right linear combination between t-shirt sensor signals: results are the three X,Y and Z Frank's Leads.

After this first stage, the X,Y, and Z Lead signals passes through a second stage, composed by the AD620 and OP97 amplifiers.

Amplification of this stage is about 8.5 (because of R55, R58, and R61 are equal to 6K8 ohm).

Following there is the second stage, the 50hz notch filter based on the MAX7413 5th-order Lowpass Bessel filter.

After the notch filter, there's another active third-order lowpass filter: it has a cut-off frequency equal to 100Hz, and it's based on the AD8616 chip.

That is the antialiasing filter, before the DSP analog-digital converter.

The right-leg driver circuit (sheet 5/8) is necessary to have the average patient voltage equal to the Heartronic device ground.

Finally, the board contains the led connections, the JTAG connector for DSP programming, the core clock generation circuit, the bluetooth transmitting chip, and the 3-axes digital accelerometer SPI connections.

Printed circuit board (Rev1), with all components mounted, is shown in figure 8 and 9.

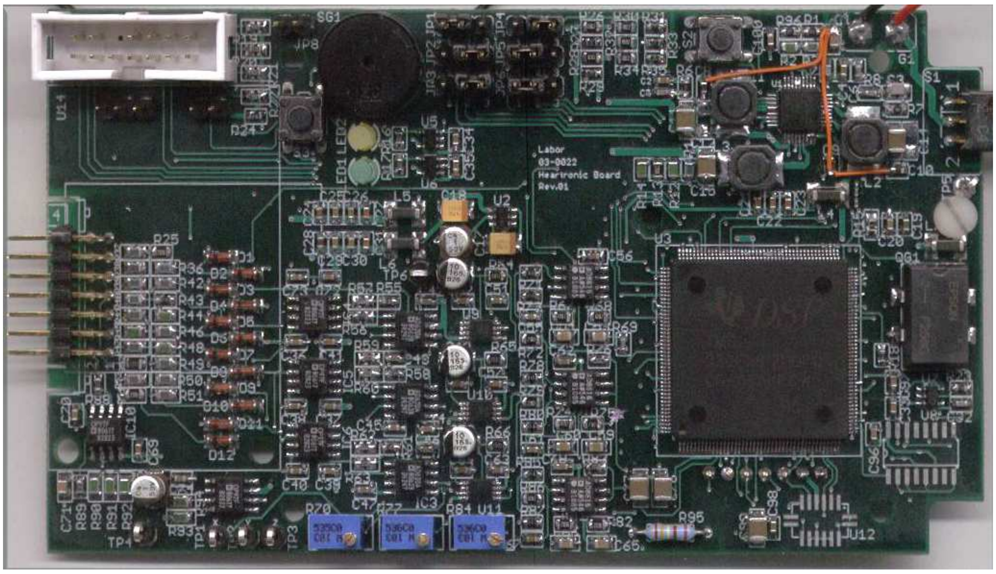


Figure 8: Heartronic board, top side

Figure 9: Heartronic board, bottom side.

The assembled alpha prototype is described in figure 10 and figure 11, with some tips about the logical blocks explained above. Figure 12 shows different point of views for the assembled prototype.

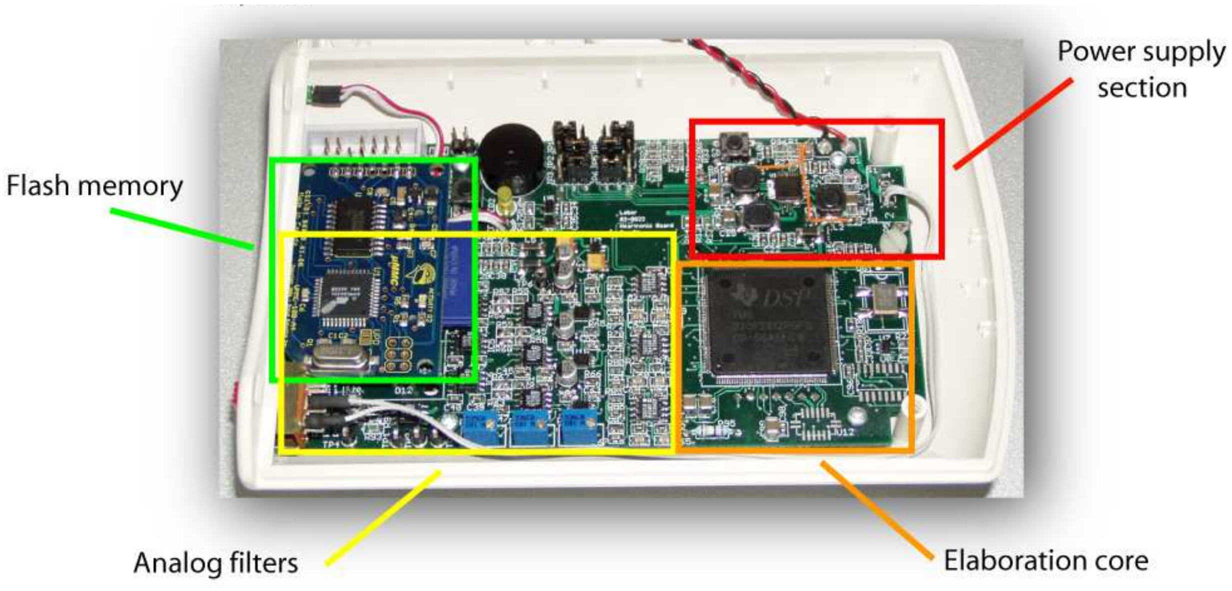


Figure 10: assembled Heartronic prototype board, top side.

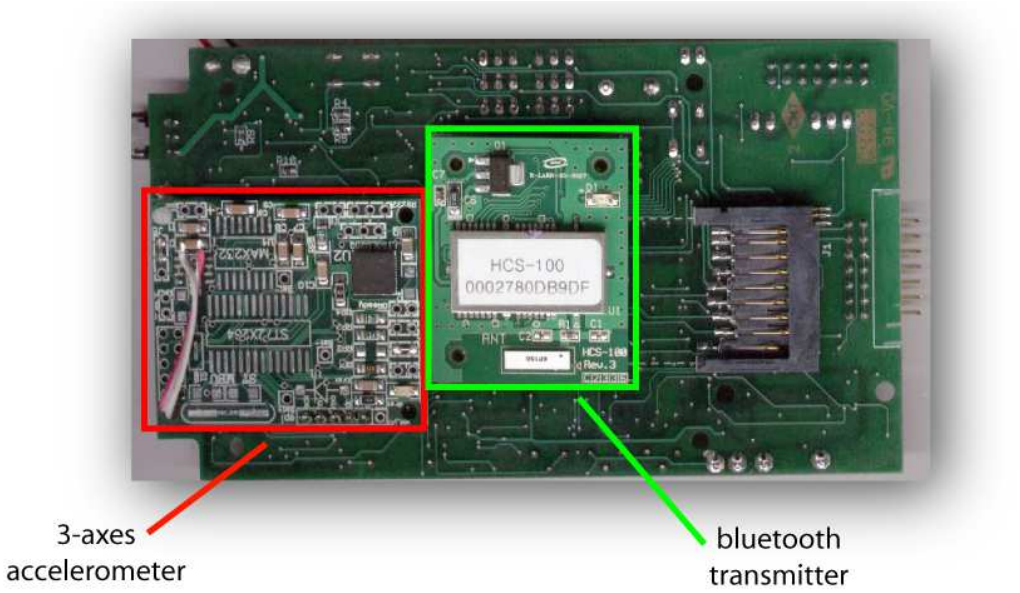


Figure 11: assembled Heartronic prototype board, bottom side.

Figure 12: assembled Heartronic prototype

1.4.3 Algorithms for ECG signal analysis

Effective filtering algorithms have been developed to eliminate harmful baseline fluctuation and possible motion artefacts of the sensors used in this project. These algorithms underwent iterative improvement during experimentation; a focused literature review was performed in order to identify the most potential recent solutions for ECG event characterization and classification.

A classifier algorithm for the detection of the motion artefacts and for the pre-diagnosis of the ECG signal anomalies is here described, and it has also been developed in MATLAB.

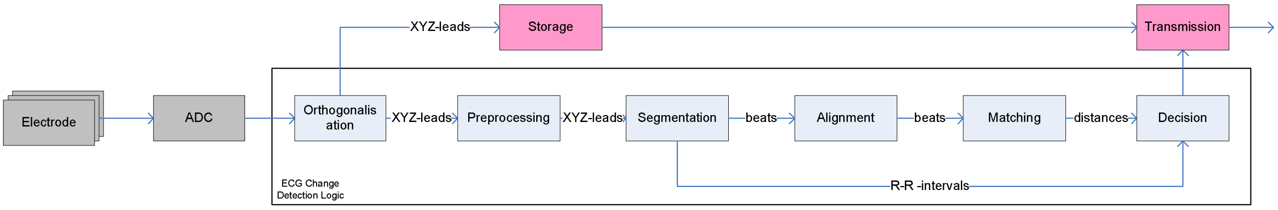


Figure 13: Top level flow chart.

In the supplementary code, the orthogonalization and pre-processing are assumed done already. So, the vectorcardiograms, i.e., vectors X, Y and Z are assumed present. Also the stored and transmitted signals may be the ones before orthogonalization or after the pre-processing instead of the orthogonalized ones.

The sampling rate chosen is 512 Hz that is a suitable choice considering that all the information of the ECG signal is contained in the range of frequencies below 100 Hz. The PRS is composed by several blocks:

- Orthogonalization , that reduces the dimensionality of the signals processed in latter stages
- Pre-processing, that reduces the baseline wander, power line interference and electromyographic noise
- Segmentation, that finds the individual beats by finding the onset of P wave, the R-peak and the offset of T wave.
- Alignment, that reduces changes due to respiration and body position changes
- Matching, when the remaining variation is accounted for
- Decision, takes action if the VCG loops and there are other anomalies.

Since the first set of algorithms has been developed using Matlab language, Labor decided to transform this Matlab code to a Simulink model, and then convert it to a C language project. This last conversion was done using a special Simulink toolbox: “Embedded Target for TI C2000” (figure 14).

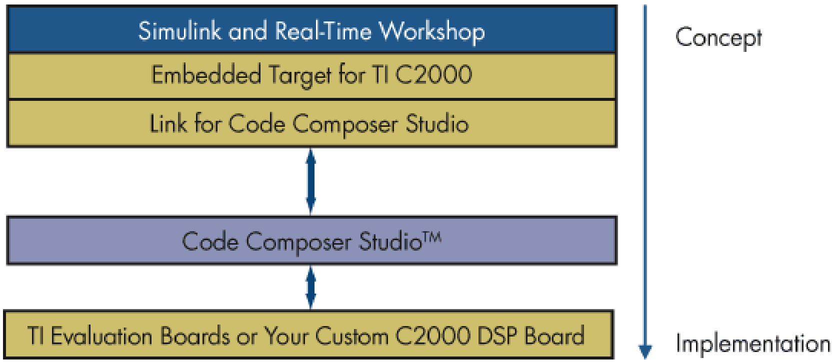


Figure 14: logic diagram for Matlab to C conversion.

Passing through Simulink intermediate block allowed to test OULU algorithm with fixed point mathematics (like DSP mathematics), and it allowed to have an high performance multitask firmware for TI DSP F2812. The drawback, like often occurs, was about the automatic generated code: it is not so simply editable, specially for the sections regarding the multitasking scheduler and the memory mapping file for custom boards.

After a first test phase, useful to become friendly with the OULU algorithm, Labor has developed a Simulink program that produces the same results of Matlab code.

The Simulink model is attached to this document: figure 15 shows a model snapshot.

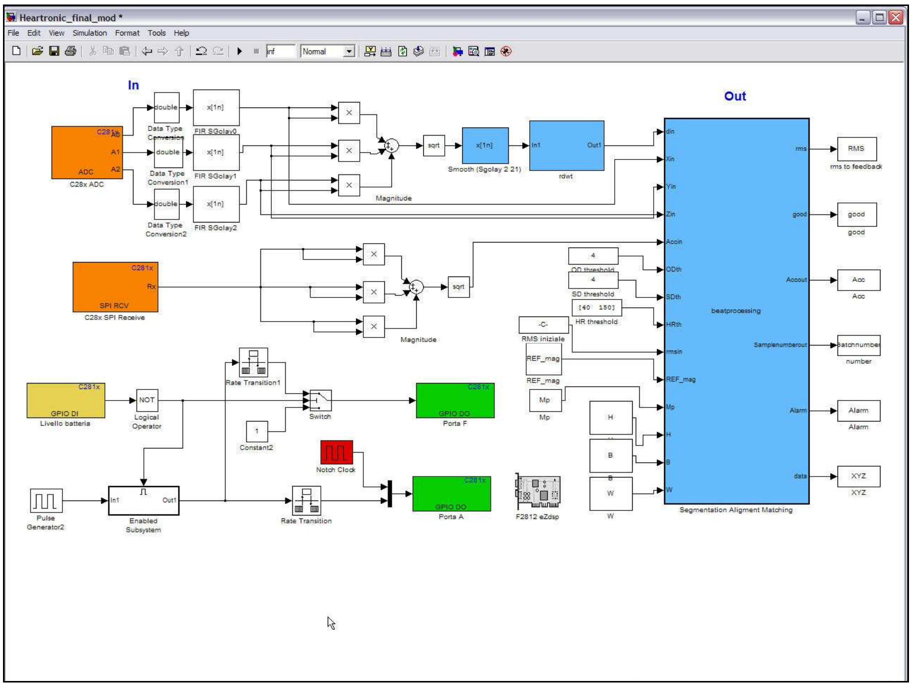


Figure 15: logic diagram for Matlab to C conversion

With the help of the Heartronic Device (ECG acquisition section) Labor has measured a collection of ECG traces, with the aim of using them for testing the outputs of Matlab code and Simulink model.

Main results of the algorithm are:

- number of heart beats found by the algorithm
- OD and SD numbers (these variables are about the difference between a good reference beat and current beat).

The following figures show a test about different interpolating functions used in Matlab and Simulink:

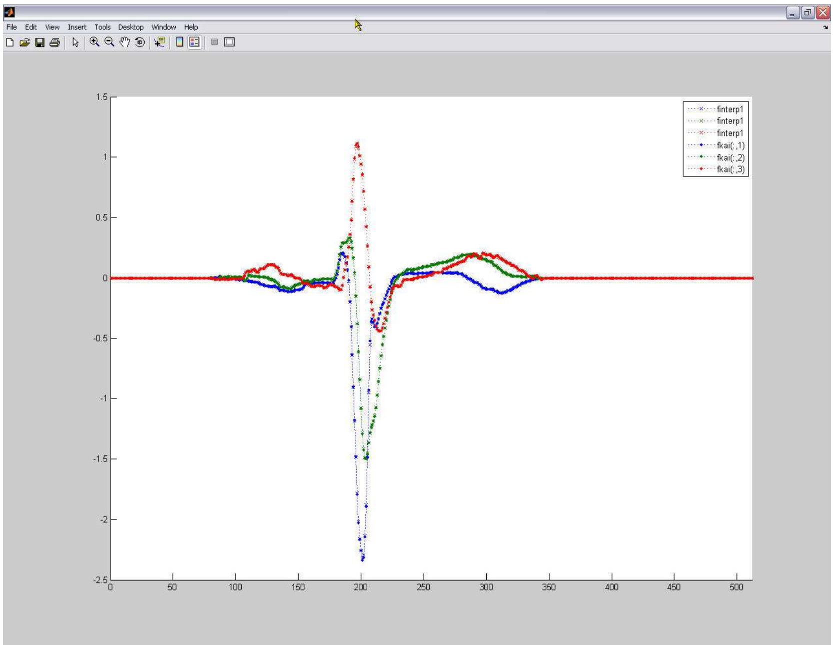


Figure 16: single heart beat, seen by Matlab and Simulink

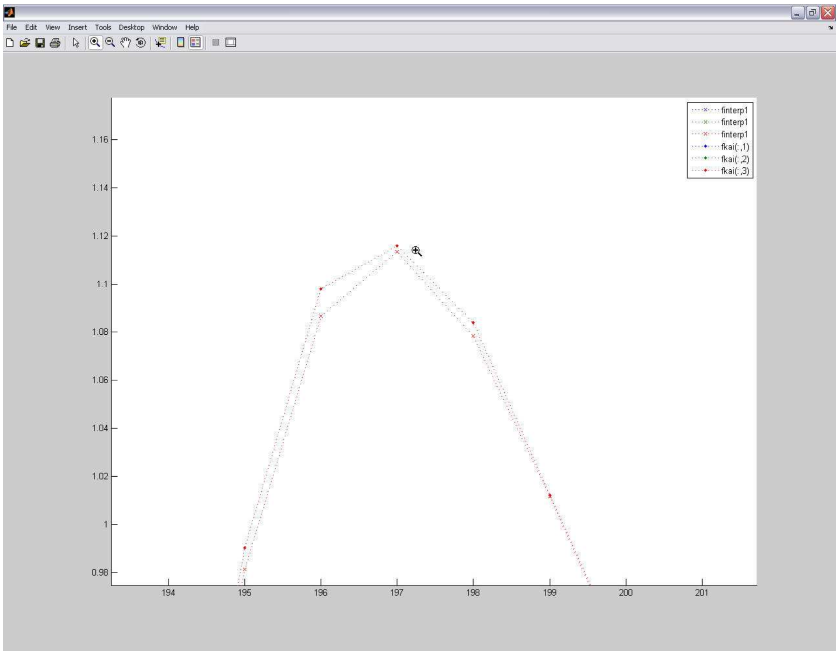


Figure 17: Single heart beat (detail), seen by Matlab and Simulink (using different interpolating functions)

Our tests demonstrate that Matlab code and Simulink model are equivalent for us:

- They find the same number of beats

- For example, a typical error on a frame containing 9 beats is :

  (OD_OULU – OD_Sim)/7 = 0.0397 and (SD_OULU – SD_Sim)/7 = 0.035

These numbers are indexes, to summarize the difference between what measure Matlab code and what see Simulink model.
Main differences between Matlab code and Simulink program are:

- precision is different because Simulink program is oriented to embedded world
- error due to the used interpolating function (interp1)
- rms value estimation: deleting baseline is more precise in Matlab code, because it's based on the entire patient trace, while Simulink check only the last acquisition block

Since Simulink model has a different precision than Matlab code (fixed point vs floating point), and since some interpolating functions used in Matlab are not usable on an embedded system like the DSP, results are not equal: the error (shown by the above indexes), is anyway always lower than the error associated to a bad contact t-shirt sensor – patient skin. That is the critical point of this project.
Finally, Code Composer Studio (Software Development Kit for TI DSP) was used to compile the firmware on the DSP

1.4.4 Telecommunication unit and pda software

The components of the Heartronic system that interact with the Host Server are:

- Patient PDA;
- Web Service;
- Database;
- Alert Manager;
- Web Application;
- Clinical User: Clinical Centre, Doctor, Emergencies Monitor.

The next diagram represents the actions flow through these components.

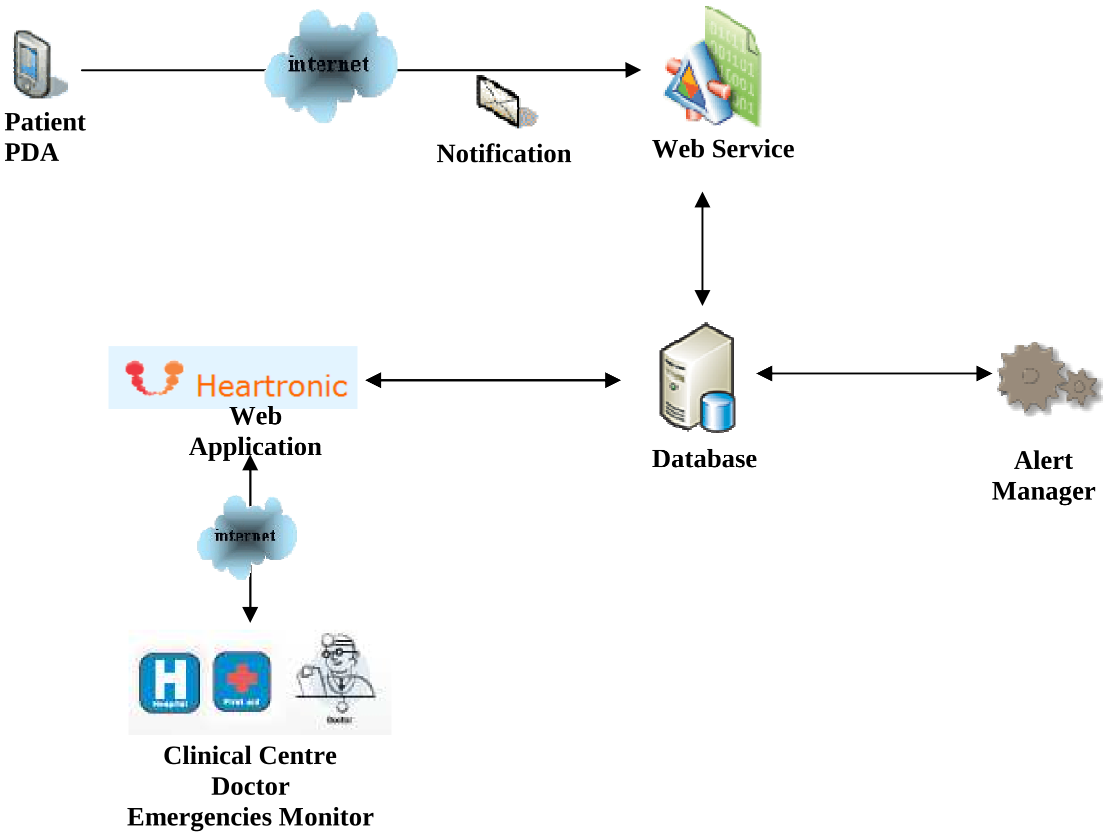


Figure 18: Heartronic communication architecture

The actions taken in the Host Server are:

- a notification is sent to the Web Service through the Internet, by the patient PDA;
- the Web Service processes the notification, calls a diagnosis discovery function and sends data to the Database;
- Alert Manager is always checking the database to manage the notifications that are active. When a new notification arrives to the database, based on automatic diagnosis generated by discovery algorithm and patient's risk status, it will analyse the best way to treat the notification, sending the appropriate alerts to the clinical users. Afterwards, it checks whether the alerts have been acknowledged and, if they were not, it has to guide the alert to other clinical users until the alert has an answer and a final diagnosis.
- By using the internet, the clinical users can interact with the system by assessing to the Web Application. This Web Application searches in the database all the requested information.

Web service

The Web Services are programmable interfaces available for application to application communication.

The W3C defines a Web Service as a software system designed to support interoperable Machine to Machine interaction over a network. Web Services are frequently just Web APIs that can be accessed over a network, such as the Internet, and executed on a remote system hosting the requested services.

The W3C Web Service definition encompasses many different systems, but in common usage the term refers to clients and servers that communicate XML messages that follow the SOAP-standard. Common in both the field and the terminology is the assumption that there is also a machine readable description of the operations supported by the server - the WSDL (Web Services Description Language). The latter is not a requirement of SOAP endpoint, but it is a prerequisite for automated client-side code generation in the mainstream Java and .NET SOAP frameworks.

The WSDL is an XML format for describing network services as a set of endpoints operating on messages containing either document-oriented or procedure-oriented information. The operations and messages are described abstractly, and then bound to a concrete network protocol and message format to define an endpoint. Related concrete endpoints are combined into abstract endpoints (services). WSDL is extensible to allow description of endpoints and their messages regardless of what message formats or network protocols are used to communicate.

The next figure sketches the architectural elements representation of a Web Service.

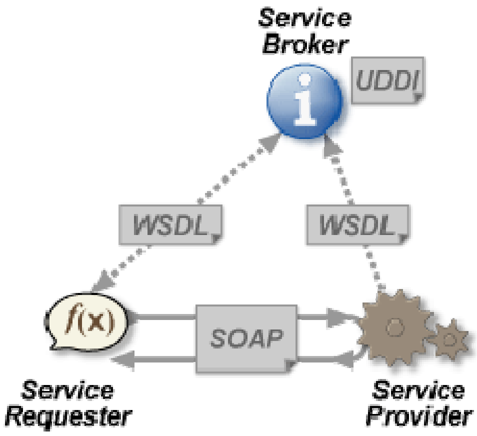
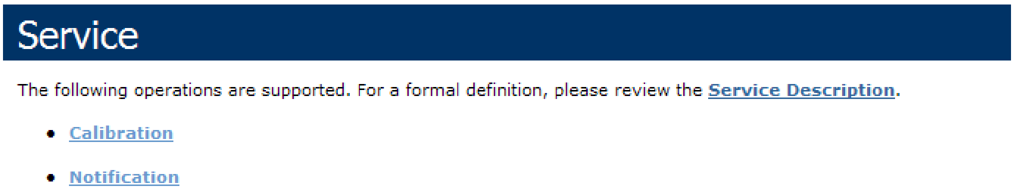


Figure 19: Web service

The Heartronic Web Service has two functions:

- Calibration – the Service receives the calibration data and stores it in the database;
- Notification – the Service receives the data from the notification, runs the diagnosis discovery algorithm (a Matlab dll) and stores the raw and the obtained data in the database.

The next figure is the Heartronic Web Service list of functions.



Service

The following operations are supported. For a formal definition, please review the Service Description.

- Calibration
- Notification

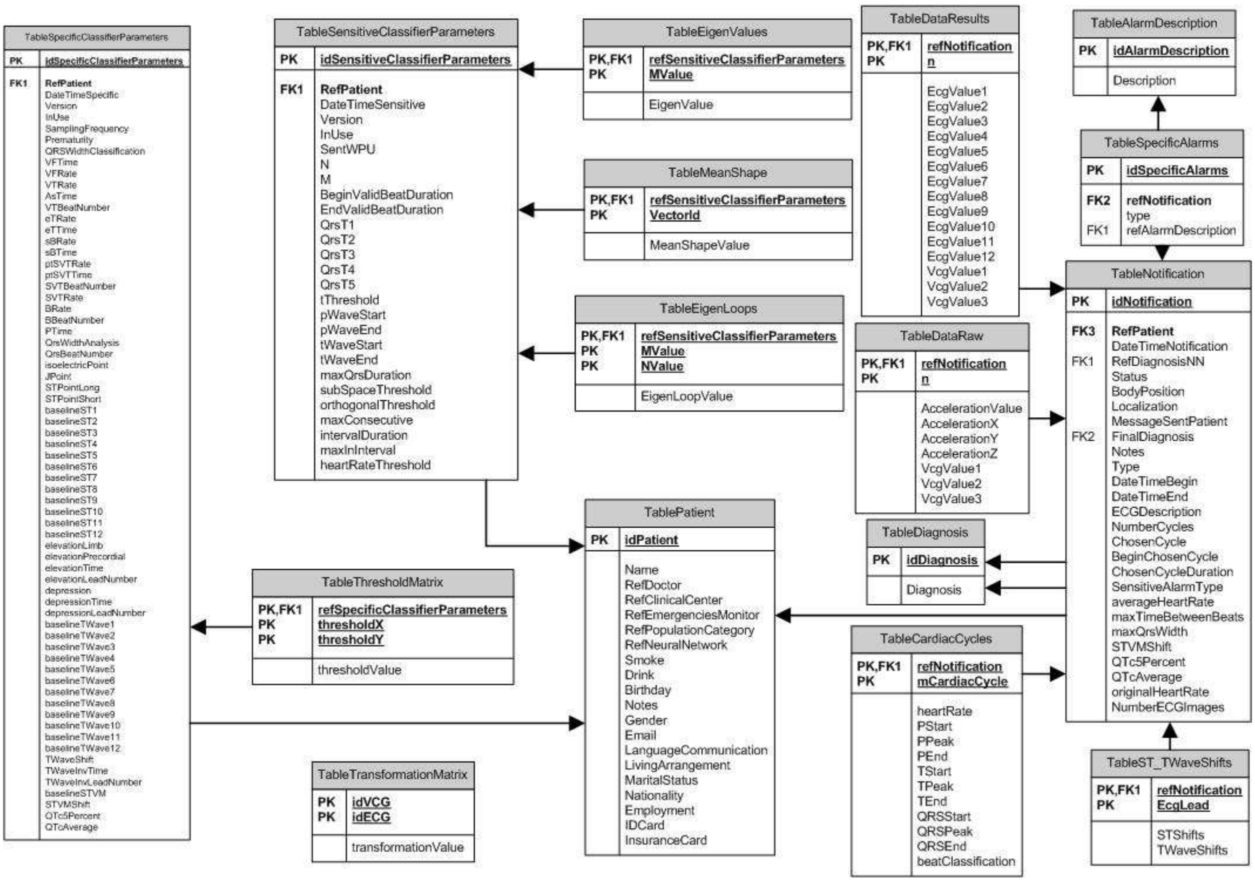
Database

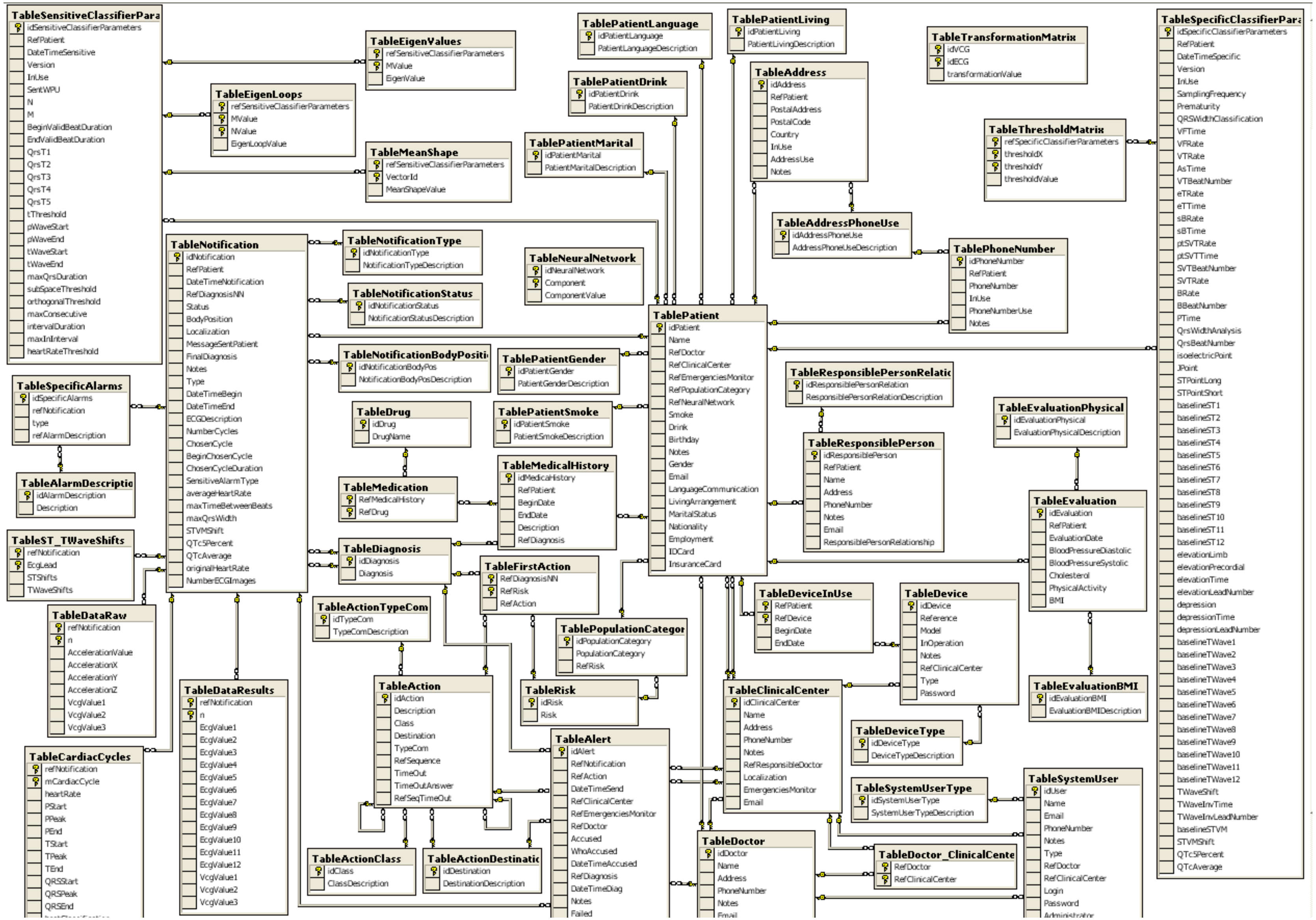
The database was constructed in MS SQL Server.

It was modelled and designed to best fit the requirements of the Heartronic system.

In the database there are several sections:

- Patient information;
- Clinical User information;
- System Users information;
- Notification information;
- Alert information;
- Calibration information;
- Devices information.

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QrsT3
QrsT4
QrsT5
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VFRate
VTRate
AsTime
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eTTime
sBRate
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Notes
Type
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DateTimeEnd
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ChosenCycleDuration
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STVMShift
QTc5Percent
QTcAverage
originalHeartRate
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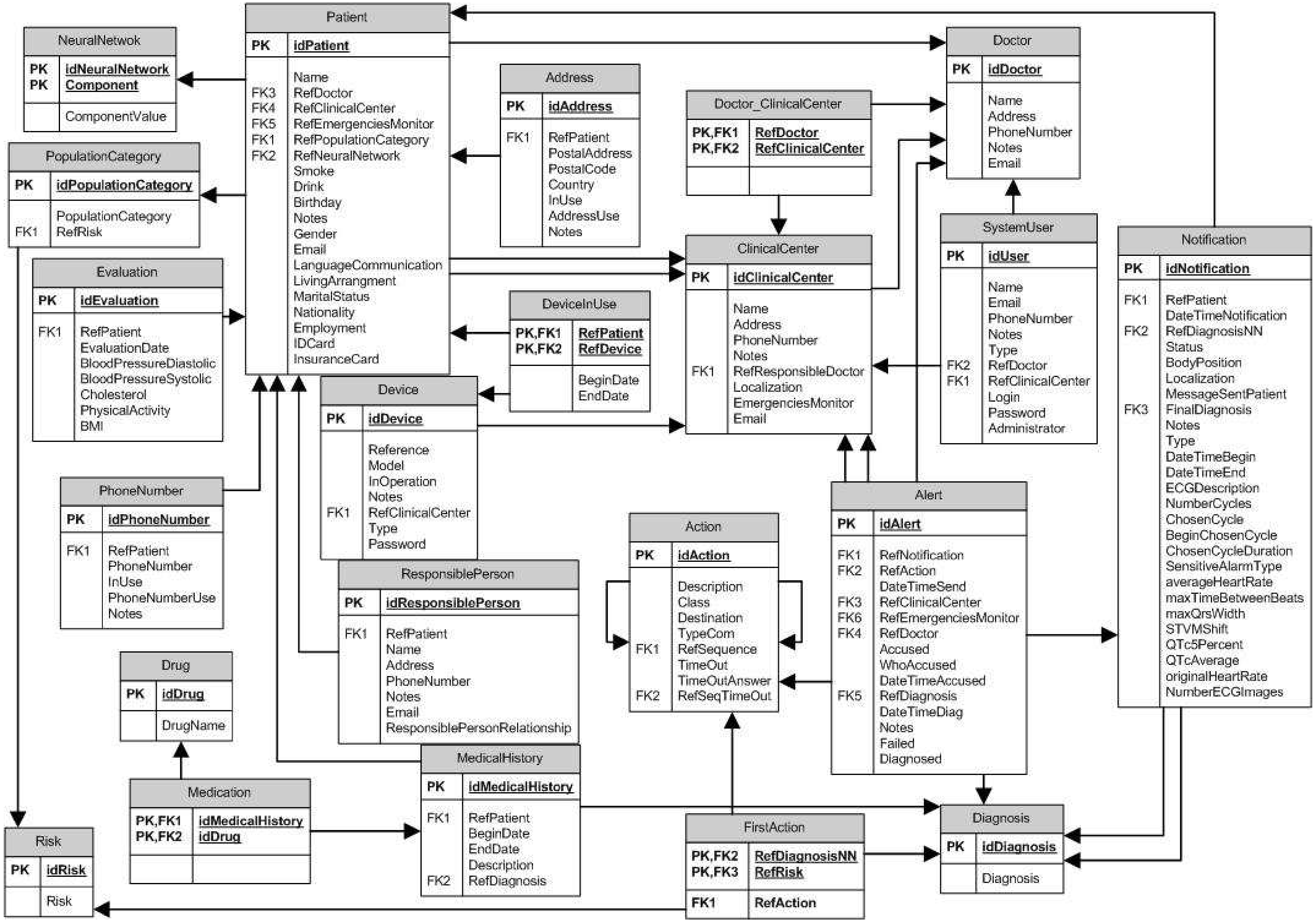
idRisk
Risk
TableClinicalCenter
idClinicalCenter
Name
Address
PhoneNumber
Notes
RefResponsibleDoctor
Localization
EmergenciesMonitor
Email
TableEvaluationBMI
idEvaluationBMI
EvaluationBMIDescription
TableDeviceType
idDeviceType
DeviceTypeDescription
TableCardiacCycles
refNotification
mCardiacCycle
heartRate
PStart
PPeak
PEnd
TStart
TPeak
TEnd
QRSStart
QRSPeak
QRSEnd
TableAlert
idAlert
RefNotification
RefAction
DateTimeSend
RefClinicalCenter
RefEmergenciesMonitor
RefDoctor
Accused
WhoAccused
DateTimeAccused
RefDiagnosis
DateTimeDiag
Notes
Failed
TableSystemUserType
idSystemUserType
SystemUserTypeDescription
TableSystemUser
idUser
Name
Email
PhoneNumber
Notes
Type
RefDoctor
RefClinicalCenter
Login
Password
Administrator
TableActionClass
idClass
ClassDescription
TableActionDestinatic
idDestination
DestinationDescription
TableDoctor
idDoctor
Name
Address
PhoneNumber
Notes
Email
TableDoctor_ClinicalCente
RefDoctor
RefClinicalCenter


Patient
PK idPatient
Name
FK3 RefDoctor
FK4 RefClinicalCenter
FK5 RefEmergenciesMonitor
FK1 RefPopulationCategory
FK2 RefNeuralNetwork
Smoke
Drink
Birthday
Notes
Gender
Email
LanguageCommunication
LivingArrangment
MaritalStatus
Nationality
Employment
IDCard
InsuranceCard
NeuralNetwok
PK idNeuralNetwork
PK Component
ComponentValue
PopulationCategory
PK idPopulationCategory
PopulationCategory
FK1 RefRisk
Evaluation
PK idEvaluation
FK1 RefPatient
EvaluationDate
BloodPressureDiastolic
BloodPressureSystolic
Cholesterol
PhysicalActivity
BMI
PhoneNumber
PK idPhoneNumber
FK1 RefPatient
PhoneNumber
InUse
PhoneNumberUse
Notes
Drug
PK idDrug
DrugName
Medication
PK,FK1 idMedicalHistory
PK,FK2 idDrug
Risk
PK idRisk
Risk
Address
PK idAddress
FK1 RefPatient
PostalAddress
PostalCode
Country
InUse
AddressUse
Notes
DeviceInUse
PK,FK1 RefPatient
PK,FK2 RefDevice
BeginDate
EndDate
Device
PK idDevice
Reference
Model
InOperation
Notes
FK1 RefClinicalCenter
Type
Password
ResponsiblePerson
PK idResponsiblePerson
FK1 RefPatient
Name
Address
PhoneNumber
Notes
Email
ResponsiblePersonRelationship
MedicalHistory
PK idMedicalHistory
FK1 RefPatient
BeginDate
EndDate
Description
FK2 RefDiagnosis
Doctor_ClinicalCenter
PK,FK1 RefDoctor
PK,FK2 RefClinicalCenter
ClinicalCenter
PK idClinicalCenter
Name
Address
PhoneNumber
Notes
FK1 RefResponsibleDoctor
Localization
EmergenciesMonitor
Email
Action
PK idAction
Description
Class
Destination
TypeCom
FK1 RefSequence
TimeOut
TimeOutAnswer
FK2 RefSeqTimeOut
FirstAction
PK,FK2 RefDiagnosisNN
PK,FK3 RefRisk
FK1 RefAction
Doctor
PK idDoctor
Name
Address
PhoneNumber
Notes
Email
SystemUser
PK idUser
Name
Email
PhoneNumber
Notes
Type
FK2 RefDoctor
FK1 RefClinicalCenter
Login
Password
Administrator
Alert
PK idAlert
FK1 RefNotification
FK2 RefAction
DateTimeSend
FK3 RefClinicalCenter
FK6 RefEmergenciesMonitor
FK4 RefDoctor
Accused
WhoAccused
DateTimeAccused
FK5 RefDiagnosis
DateTimeDiag
Notes
Failed
Diagnosed
Diagnosis
PK idDiagnosis
Diagnosis
Notification
PK idNotification
FK1 RefPatient
DateTimeNotification
FK2 RefDiagnosisNN
Status
BodyPosition
Localization
MessageSentPatient
FK3 FinalDiagnosis
Notes
Type
DateTimeBegin
DateTimeEnd
ECGDescription
NumberCycles
ChosenCycle
BeginChosenCycle
ChosenCycleDuration
SensitiveAlarmType
averageHeartRate
maxTimeBetweenBeats
maxQrsWidth
STVMShift
QTc5Percent
QTcAverage
originalHeartRate
NumberECGImages

Alert Manager

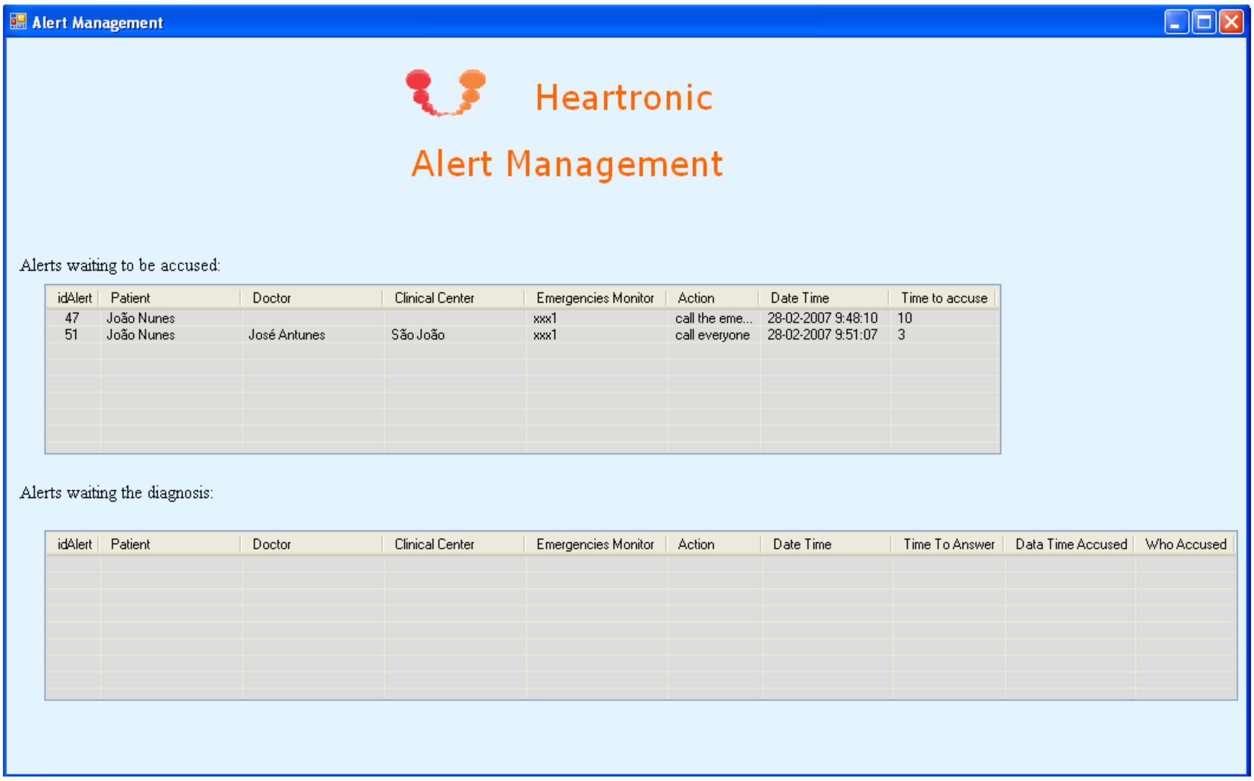
The Alert Manager is a windows application that is constantly monitoring the database for active notifications. This Alert Manager will manage all active notifications since they arrive until they pass to a non active status.

When a new notification is detected in the database, the Alert Manager analyses it, for the best response to be given, and send an alert to the corresponding clinical users.

The Alert Manager will wait the alert to be accepted, otherwise takes another action; it also waits for the diagnosis of the alert.

The Alert Manager will be watching the system until the alert gets an answer and a final diagnosis and action, when the alert passes to a non active status.

Next figure shows the interface of the Alert Manager application, where 2 incoming alerts can be seen.



Alerts waiting to be accused:

idAlert	Patient	Doctor	Clinical Center	Emergencies Monitor	Action	Date Time	Time to accuse
47	João Nunes			xxx1	call the eme...	28-02-2007 9:48:10	10
51	João Nunes	José Antunes	São João	xxx1	call everyone	28-02-2007 9:51:07	3

Alerts waiting the diagnosis:

idAlert	Patient	Doctor	Clinical Center	Emergencies Monitor	Action	Date Time	Time To Answer	Data Time Accused	Who Accused

Figure 20: Alert manager interface

Web Application

The Web Application is the interface for the clinical user to access to all system information, depending to his system user privileges, and only have access to his patients.

The Web Application is accessible at: http://www.inovacao.net/heartronic/.

In the Web application the user can access to:

- All patient information, like medical history, past alerts, contacts, devices in use, responsible persons, etc.;
- Devices management;
- User own profile;
- Doctors and clinical centre information;
- Web Application and Database definitions;
- The alert manager - the tool to:
    - Access new and past alerts;
    - Accept and respond to the alerts;
    - Send the alert diagnosis;
    - See main patient information.

Next figure is a diagram with the Heartronic Web Application Navigation.

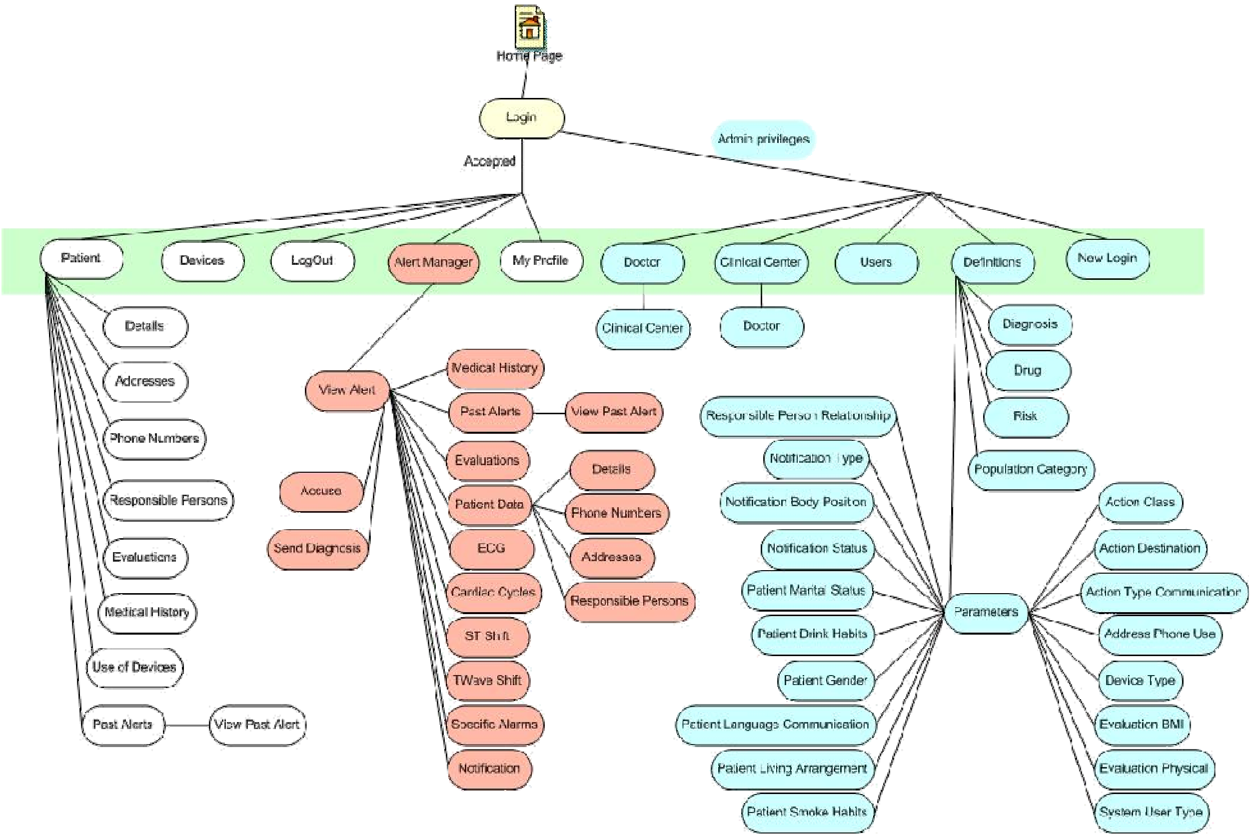
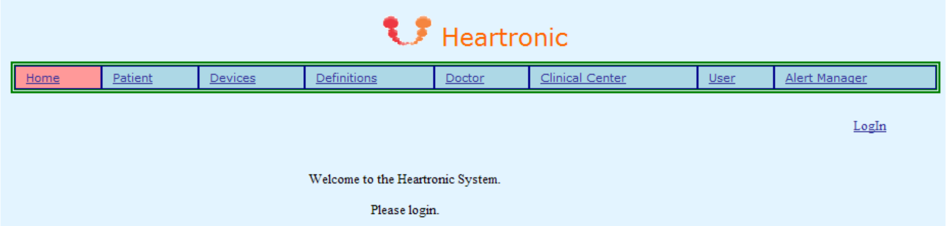


Figure 21: Heartronic Web application structure

In the next figure can be seen the Heartronic Web Application Home Page, with the menu options.



Welcome to the Heartronic System.

Please login.

The next figure shows some fictitious patient information and main system user information.

Patient

	Name	Doctor	Clinical Center
Select Delete	ddddd	Maria Ronaldi	São João
Select Delete	eeee	Michael Jones	São João
Select Delete	João Nunes	José Antunes	São João
Select Delete	Marco Silva	José Antunes	São João
Select Delete	Test2	Bernard Patrice	São João

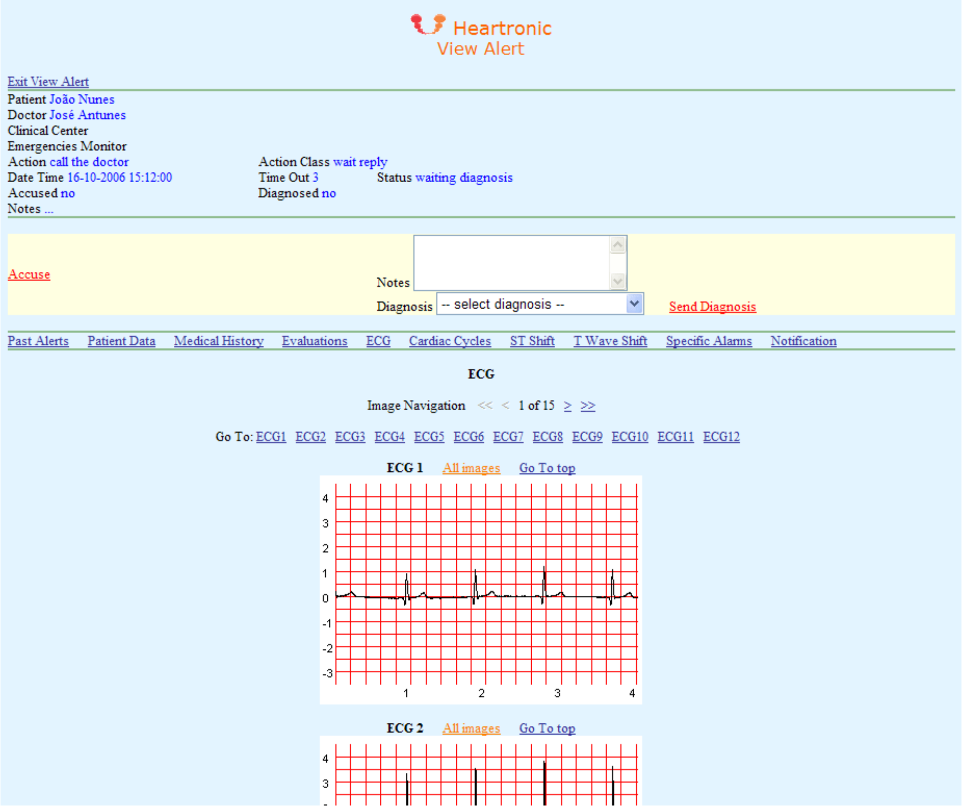
User Name: user
Person: User
Doctor: José Antunes
Clinical Center: São João
Administrator: Yes

Details related with the selected patient:

Name	Marco Silva
Doctor	José Antunes
Clinical Center	São João
Population Category	Had infarct
Neural Network	3
Smoke	Lot
Drink	Lot
Birthday	20-08-1959
Notes	xxxx
Gender	Male
Email	
Language Communication	Portuguese
Living Arrangement	Family
Marital Status	Married
Nationality	Portuguese
Employment	Postman
ID Card	
Insurance Card	

Figure 22: Patient and main system information

In the next figure can be seen an alert, waiting to be accepted and diagnosed. The clinical user is seeing the ECG signal that launched the alert.



Patient João Nunes
Doctor José Antunes
Clinical Center
Emergencies Monitor
Action call the doctor
Action Class wait reply
Date Time 16-10-2006 15:12:00
Time Out 3
Status waiting diagnosis
Accused no
Diagnosed no
Notes ...

Notes
Diagnosis -- select diagnosis --

Figure 23: Alert management

The Heartronic Web Application can be accessed from a PC or a PDA.

The PDA can access to the same Web Application that a PC can access.

In the PDA the screen is much smaller than a PC screen, turning user experience less comfortable. In the future a lighter version of the Web Application should be developed specially for PDA.

The next figures are pictures of the Heartronic Web Application being accessed from a PDA, seeing the list of patients, the alert manager and the ECG signal.

Next step is the PDA, that collects data from the portable unit and send it to the host server. PDA software performs two main functions (figure 24):

- Bridge: transfer ECG data from portable device to the host server, through Internet.
- Viewer: show the classic 12-ECG traces starting from the Frank’s Lead VCG.

ECG Viewer is tested on pc (figure 25) and implemented inside PDA (figure 26).

Some screenshots and photos of the working PDA software and PDA phone are shown in figure 26.

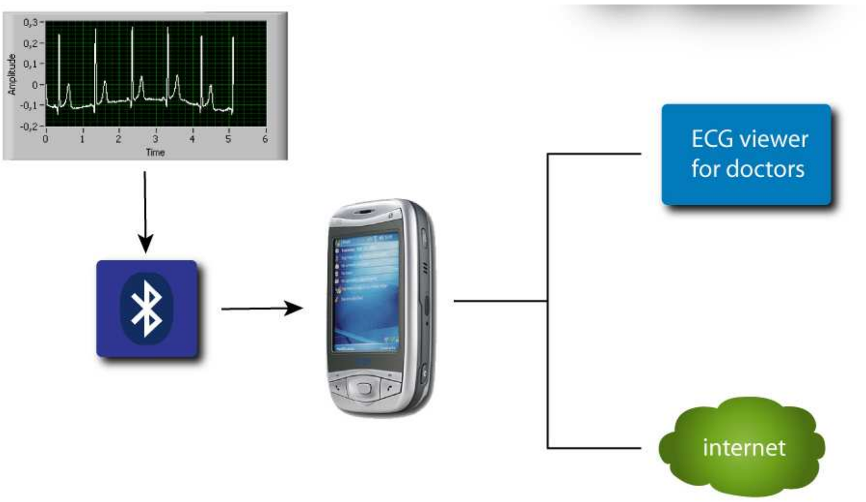


Figure 24: main PDA functions.

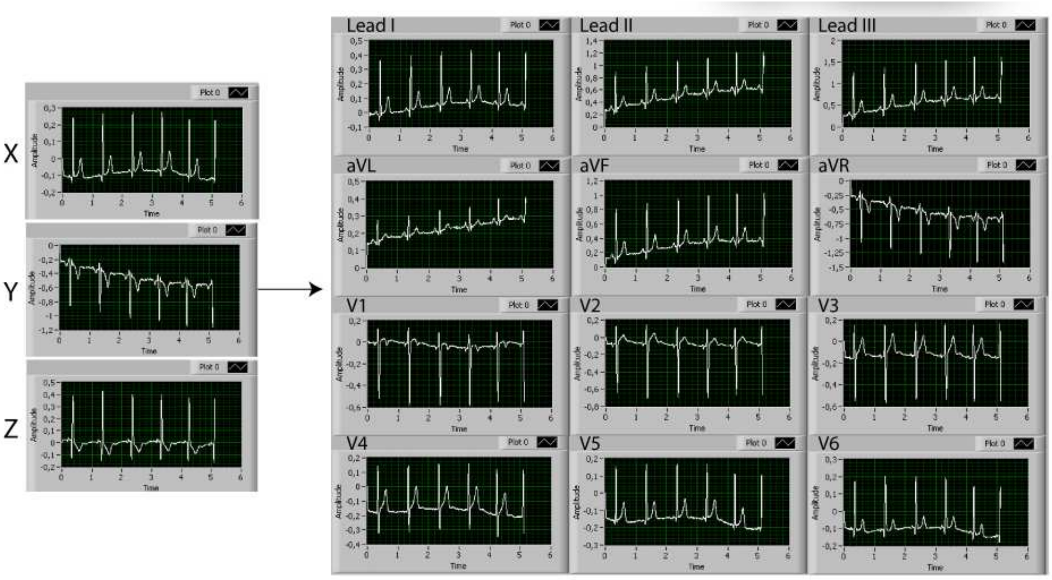


Figure 21: PDA software viewer PC simulation (Frank’s Leads -> 12-ECG conversion).

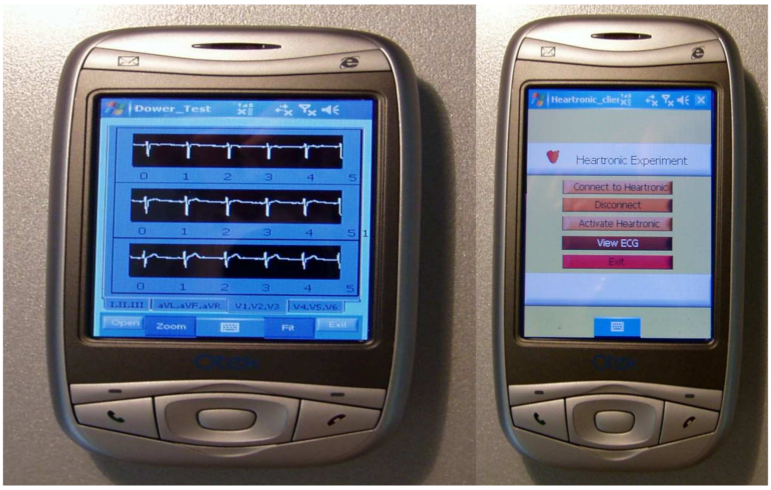
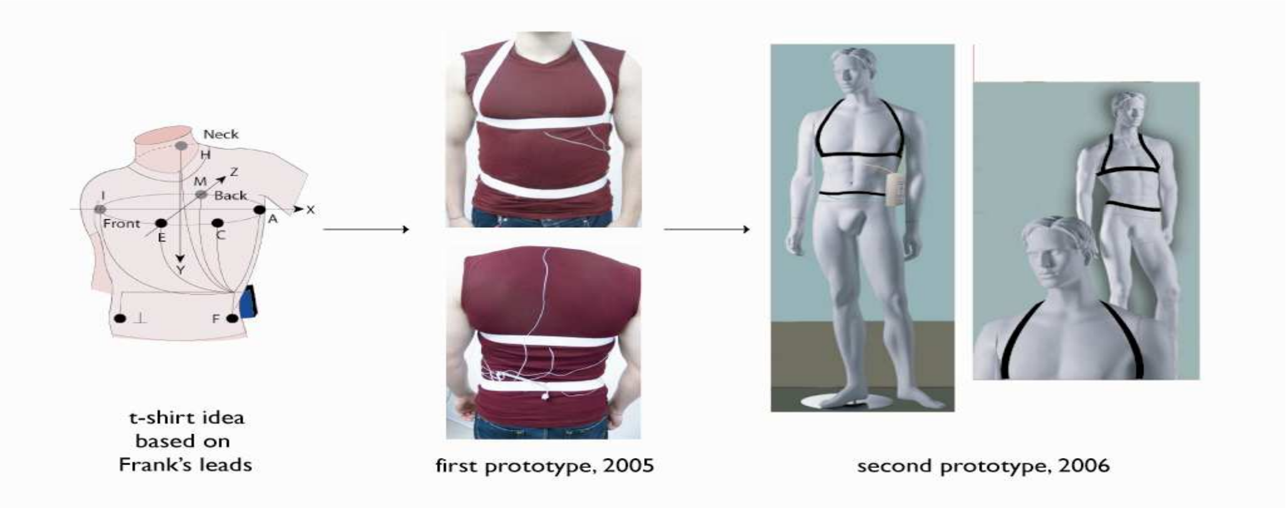


Figure 22: PDA photos during tests (viewer on the left and front panel on the right).

1.4.5 Prototyping and testing

The Heartronic system is composed by a network of ECG sensors, attached to a t-shirt, like it is shown in figure 27. T-shirt electric cables are connected to the Heartronic device.

The Heartronic starting point system is composed by a network of ECG sensors, attached to a t-shirt, like is shown in figure 27. T-shirt electric cables are connected to the Heartronic device.



t-shirt idea based on Frank's leads

first prototype, 2005

second prototype, 2006

Figure 27: Heartronic t-shirt alpha and beta prototypes

Sensors are positioned on the chest using the Frank's Lead configuration.

During the last year project, the t-shirt prototype was transformed into a double piston ring, to have more comfort for the patient (figure 27).

Portable Heartronic device is shown in figure 28. Portable device was also deeply explained in Deliverable 3.2.

Figure 28: assembled Heartronic prototype device.

Next step is the PDA, that collects data from the portable unit and sends it to the host server. PDA software performs two main functions:

- Bridge: transfer ECG data from portable device to the host server, through Internet.
- Viewer: show the classic 12-ECG traces starting from the Frank’s Lead VCG.

ECG Viewer is tested on pc (figure 29) and implemented inside PDA (figure 30).
Some screenshots and photos of the working PDA software and PDA phone are shown in figure 30.
Deliverable 6.3 presents the tests carried out for the complete assessment of Heartronic system, from data simulation to prototype realization and test.

Amongst all the tests performed, we will describe:

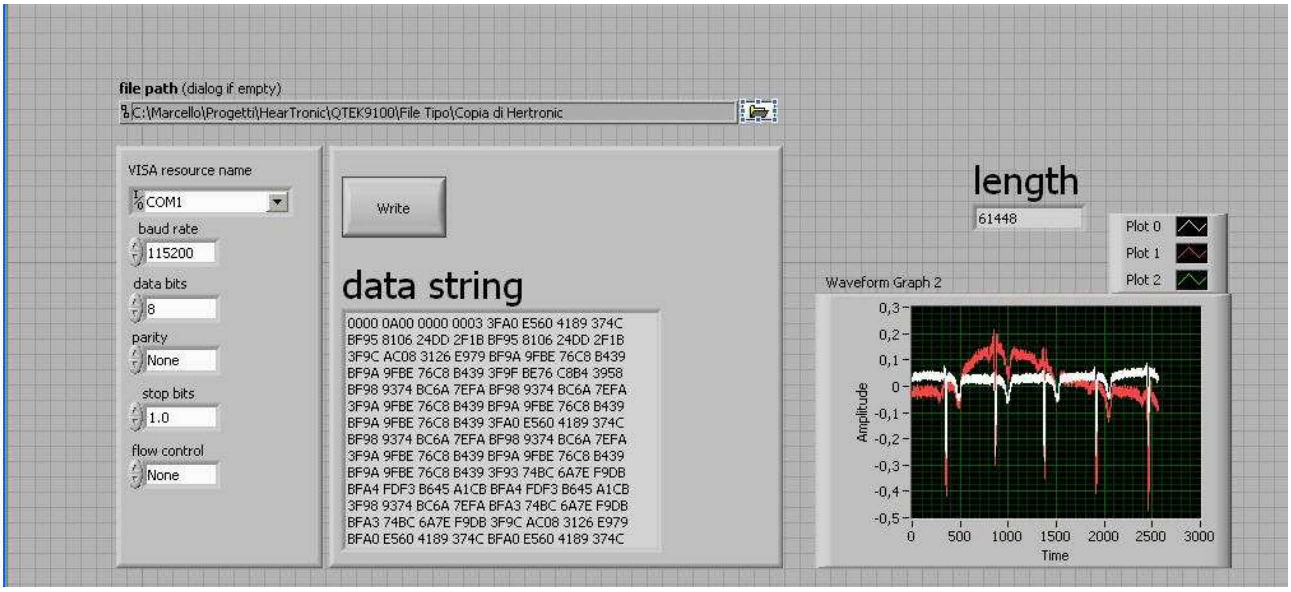
- Tests on the Graphic User Interface on the PDA
- Tests for the conversion of Frank’s VCG in the classical 12 traces ECG, using a linear transformation, the “Heartronic adapted” Dower matrix.
- Data transmission tests from the PDA to the host server
- Tests on the equivalence among Simulink model and Matlab algorithms

- T-shirt acquisition tests, done in different situations: sensors with and without gel, and with moving or unmoving patients

DSP simulation and PDA software

Before programming the PDA software and Graphic User Interface, a DSP simulator was developed in Labview to test the compatibility between data running on the DSP and those of the PDA.

The front panel (user side) is in figure 29.



file path (dialog if empty): C:\Marcello\Progetti\HearTronic\QTEK9100\File Tipo\Copia di Hertronic

VISA resource name: COM1
baud rate: 115200
data bits: 8
parity: None
stop bits: 1.0
flow control: None

length: 61448

data string

```
0000 0A00 0000 0003 3FA0 E560 4189 374C
BF95 8106 24DD 2F1B BF95 8106 24DD 2F1B
3F9C AC08 3126 E979 BF9A 9FBE 76C8 B439
BF9A 9FBE 76C8 B439 3F9F BE76 C8B4 3958
BF98 9374 BC6A 7EFA BF98 9374 BC6A 7EFA
3F9A 9FBE 76C8 B439 BF9A 9FBE 76C8 B439
BF9A 9FBE 76C8 B439 3FA0 E560 4189 374C
BF98 9374 BC6A 7EFA BF98 9374 BC6A 7EFA
3F9A 9FBE 76C8 B439 BF9A 9FBE 76C8 B439
BF9A 9FBE 76C8 B439 3F93 74BC 6A7E F9DB
BFA4 FDF3 B645 A1CB BFA4 FDF3 B645 A1CB
3F98 9374 BC6A 7EFA BFA3 74BC 6A7E F9DB
BFA3 74BC 6A7E F9DB 3F9C AC08 3126 E979
BFA0 E560 4189 374C BFA0 E560 4189 374C
```

Figure 29: DSP simulation front panel

Close to serial settings, there is 'data string' box to manually write on serial port string like DSP's; alternatively, it is possible to select the file path to load file created with tests on heart sensor. Button 'write' is for sending data and the diagram is for heart waveform preview.

Serial port is connected with serial-Bluetooth converter for transmitting and receiving data in Bluetooth protocol automatically, so PDA can elaborate it directly.

Blocks for port configuration are on the left side: the while event structure is the yellow big box around all graphical code.

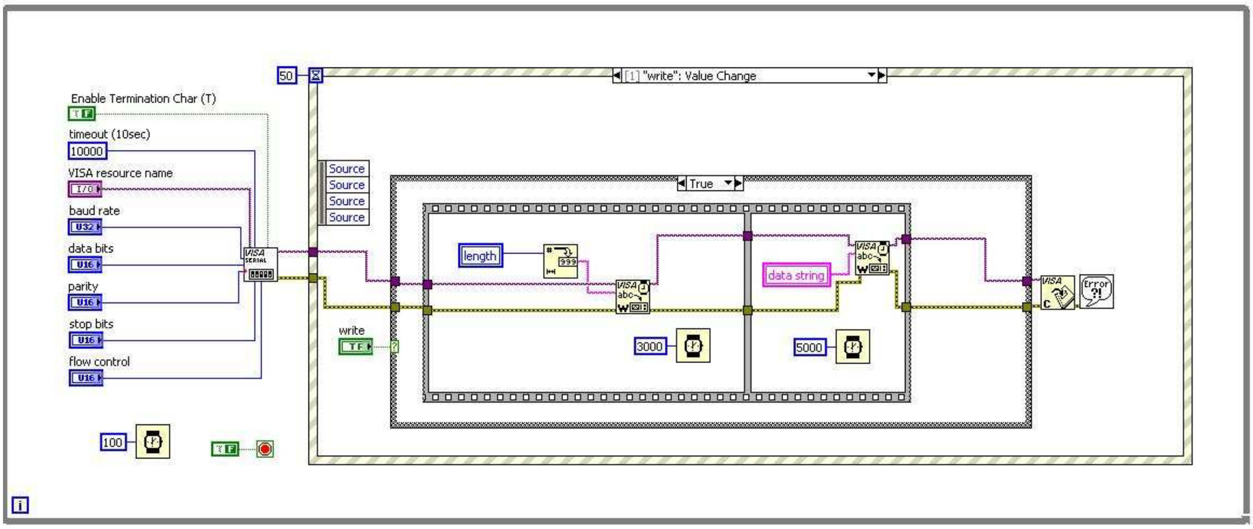


Figure 30: code side of DSP simulation

Data are sent using Bluetooth protocol, and are acquired and elaborated by PDA. Main screenshot of application is shown below in the figure below.

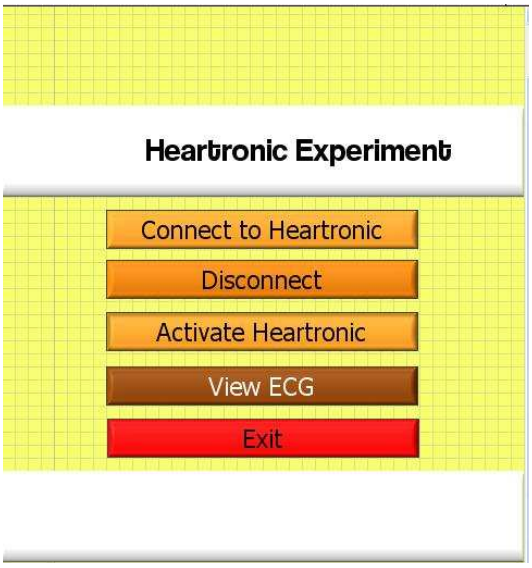


Figure 31: Main screenshot of PDA application

Address and device ID are two basic parameters and dialog box informs about connection status (ok or error). Disconnect mode is simple and immediate.

'Activate' button puts PDA in listening mode and it implements algorithm to recognize true data packet from others. The packet starts with the number of bytes sent by the DSP in the preamble: eight "[" are the start and eight "]" are the end of the packet (figure 32). Inside the packet there is also the checksum: it is received and compared with the calculated one: then file is sent to two different directories inside the PDA.

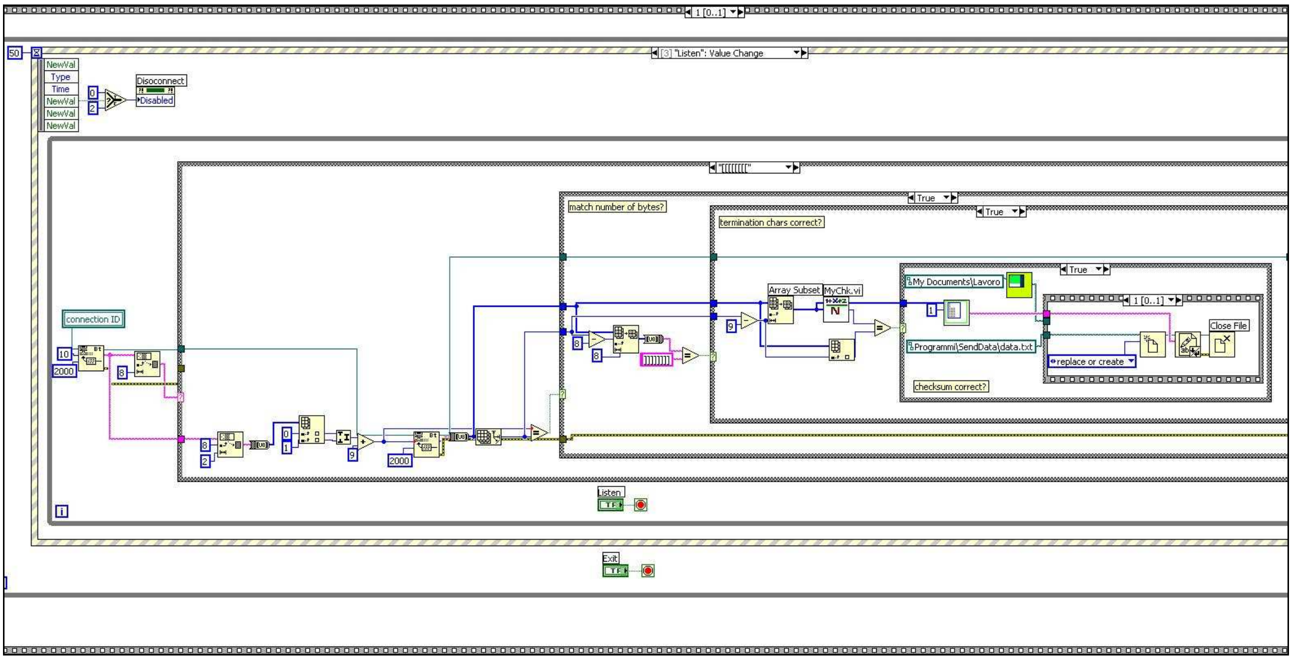


Figure 32: “activate botton” Labview code

Dower elaboration/simulation for viewer

‘View Ecg’ button calls a subroutine with a graphical interface, as shown in figure 32.

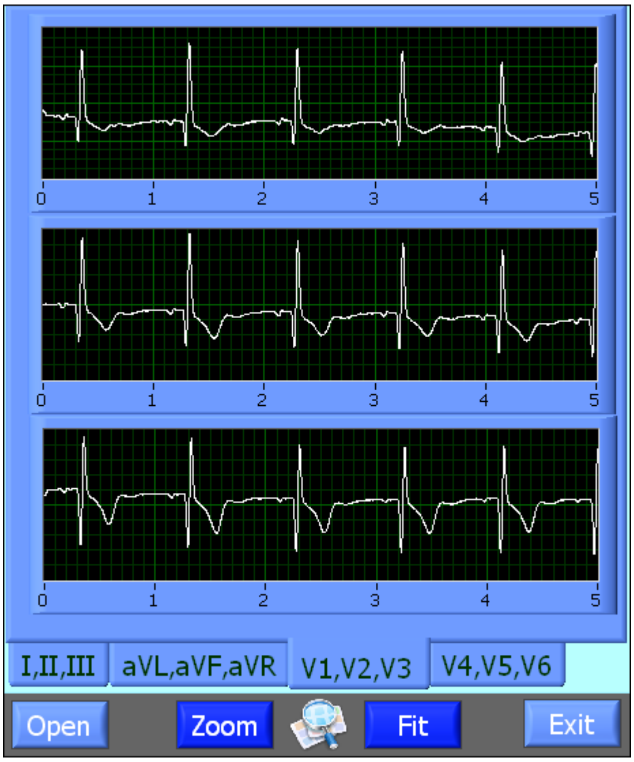


Figure 33: ECG viewer interface

With ‘open’ button a file is selected. This file was received before from DSP and stored progressively. A real time “dower matrix” elaboration is done, as shown in figure 33.

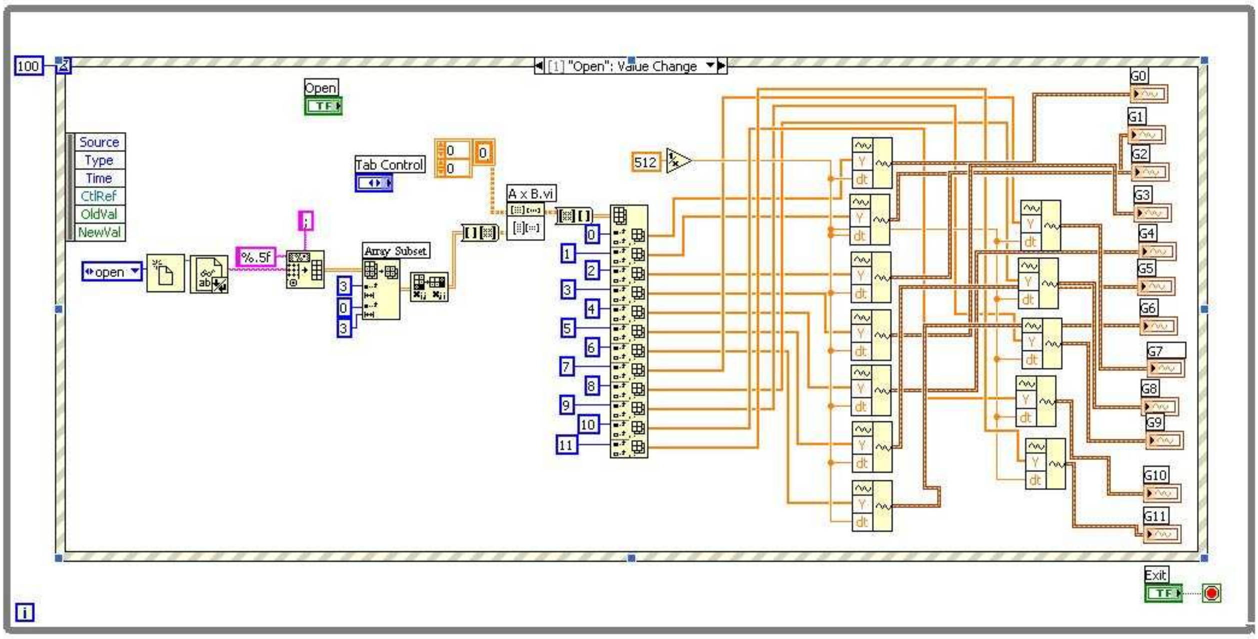


Figure 34: Labview Dower elaboration

Once the ECG file is opened, then a 2d array is obtained. This array is cleaned from preamble and transposed, and a matrix 3xN is made. Now Dower matrix is multiplied for this array obtaining a 12xN array, where N is the total number of samples [512 x 4 (x,y,z,acc),for 10 seconds]. This 12 rows array is charted in 12 graphs according to graphic categories divided in four tabs, as shown in figure 35.

Blocked named as G0-G12 correspond to 12 graphs on front panel.

The used Dower matrix and the results are shown in figure 35 for N=2560:

$$Classic\,12\;ECG = \begin{pmatrix} 0.632 & -0.235 & 0.059 \\ -0.235 & -1.066 & 0.132 \\ 0.397 & -1.301 & 0.191 \\ -0.434 & -0.415 & 0.037 \\ 0.515 & -0.768 & 0.125 \\ -0.081 & 1.184 & -0.162 \\ -0.515 & 0.157 & -0.917 \\ 0.044 & 0.164 & -1.387 \\ 0.882 & 0.098 & -1.277 \\ 1.213 & 0.127 & -0.601 \\ 1.125 & 0.127 & -0.086 \\ 0.831 & 0.076 & 0.230 \end{pmatrix} * \begin{pmatrix} x_0 & x_1 & \cdots & x_N \\ y_0 & \vdots & \ddots & \vdots \\ z_0 & z_1 & \cdots & z_N \end{pmatrix}$$

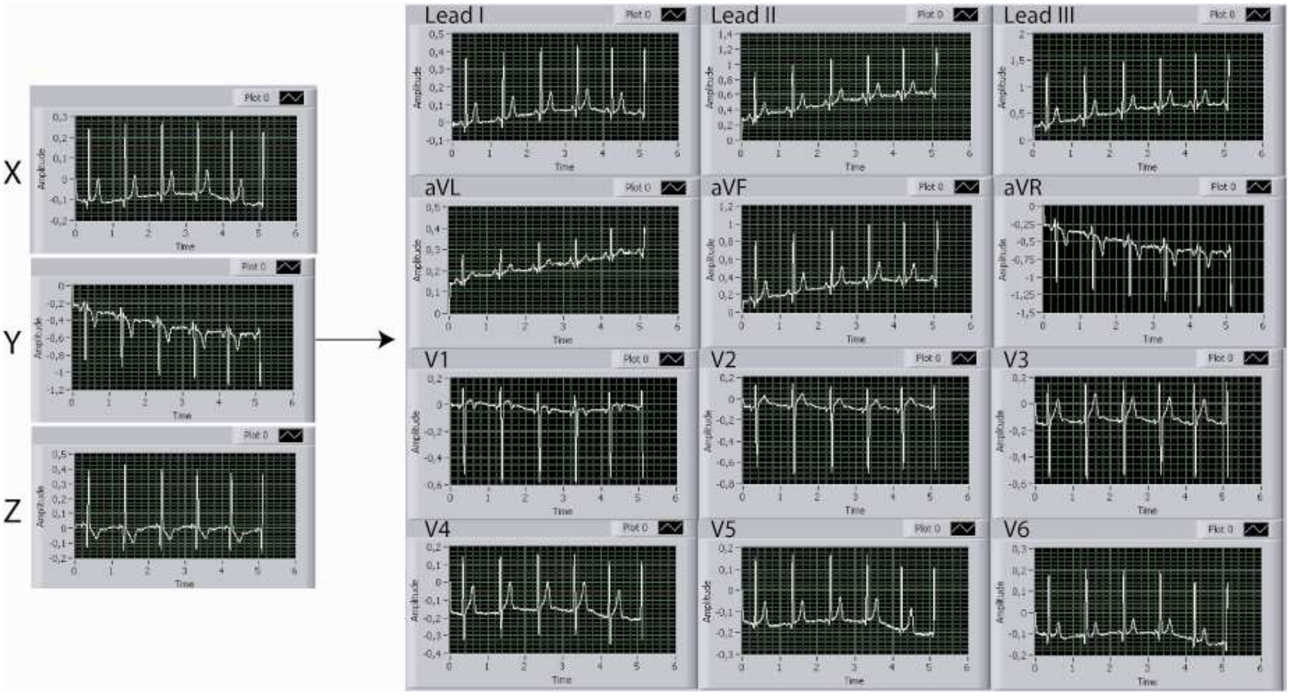


Figure 35: dower elaboration

Sending data to the internet server

As described in the previous section, data arriving from the DSP-Bluetooth communication are saved in two different files.

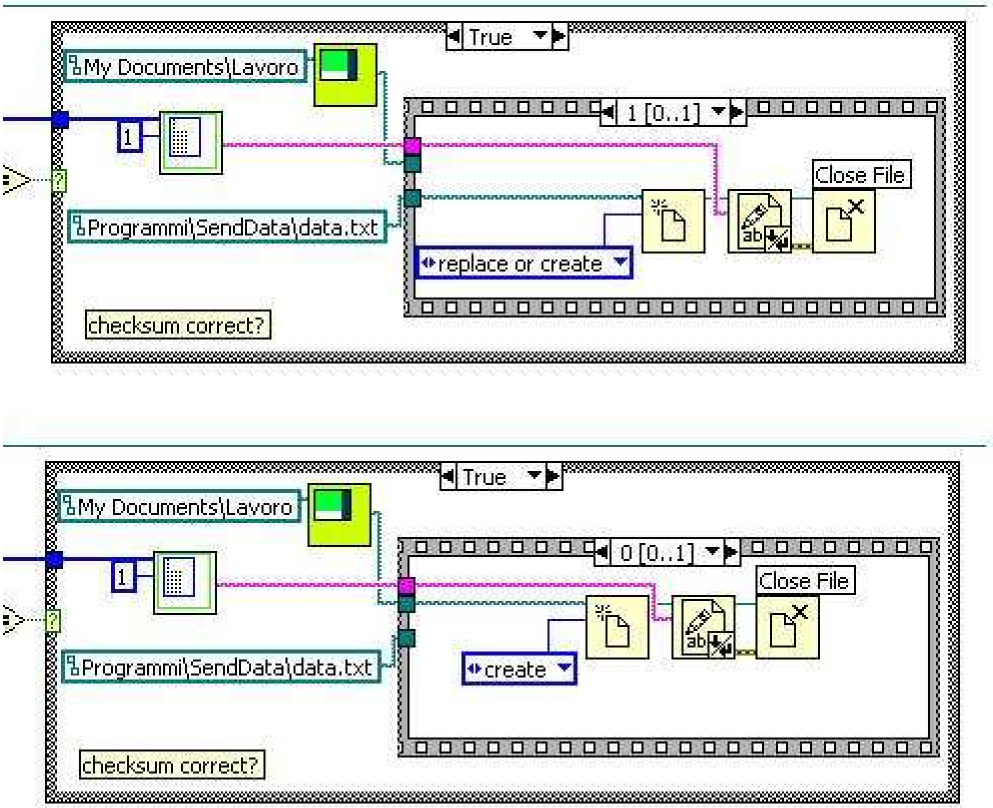


Figure 36: two ways of saving

The protocol used in the data transfer over the internet is a SOAP protocol (Simple Object Access Protocol) that encapsulates the data in a XML (Extensible Markup Language) message. This protocol is implemented on both the client and the server through the Microsoft Web Server library. Patient ID, heart rate, and 3 ECG signals with the acceleration values are encapsulated in the way defined by IAITI on the web-service implemented on their server:

Every minute data contained in the file data.txt are loaded, encapsulated and sent to the server. A successful message is then received. A screenshot of the program is presented on figure 37. SendData is made to run on the background and to search any available link with the internet.

Login: pda01
Password: pda01

Figure 37: Screen shot of the SendData program

Two timers are implemented, one ticks when is time of sending information and the other ticks when is time of waiting. When data is being sent a message “Sending raw data, please wait... “ is displayed. Also label4 displays the time. Besides, any message that arrives from the server is displayed. An example or an error message is display in figure 38.

Login: pda01
Password: pda01

Error in connection - Impossibile trovare una parte del percorso

01:00

Figure 38: Display error message of Send Data

This program was tested both, using a wire and wireless internet connection. Its performance strongly depends on the amount of data to encapsulate and the velocity of the internet connection. For instance, 60 seconds of acquired data, that is 720 kbytes of information has around 18 minutes of transfer time using an internet connection of 945kb/s. However, 5 seconds of data, that is a message of 96 kbytes takes only 23 seconds to successfully arrive to the server.

From these tests it can be seen that is better to increase the frequency of the transmission and decrease the amount of information contained on the message. For this reason for the HEARTRONIC system the size of the message to be sent was defined to 5 seconds of acquired data.

Finally, it can be said that the Web Server protocol is very useful when security issues of information transfer are required, but at the same time, its implementation requires a more powerful device, other than the available PDA, to guaranty the speed of the transmission.

Heartronic device ECG acquisition tests

A basic stage on the alpha prototype was the ECG acquisition testing phase, done in different patient conditions and different kind of sensors.

Just to show only a small part of all tests done in this stage, the following figures display acquisition tests with ECG sensors with and without gel, and when the patient is moving or not.

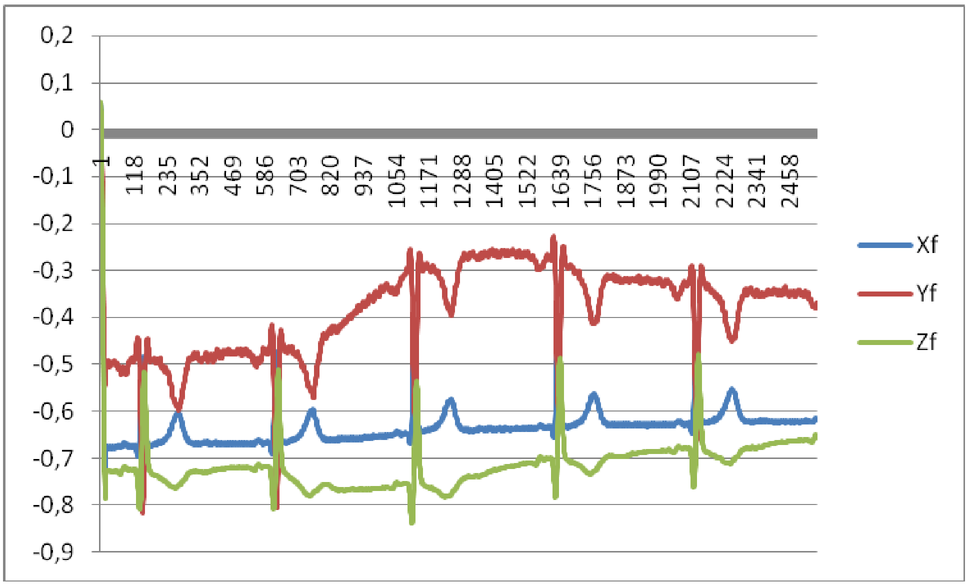


Figure 39: ECG acquisition test, sensors with gel and moving patient.

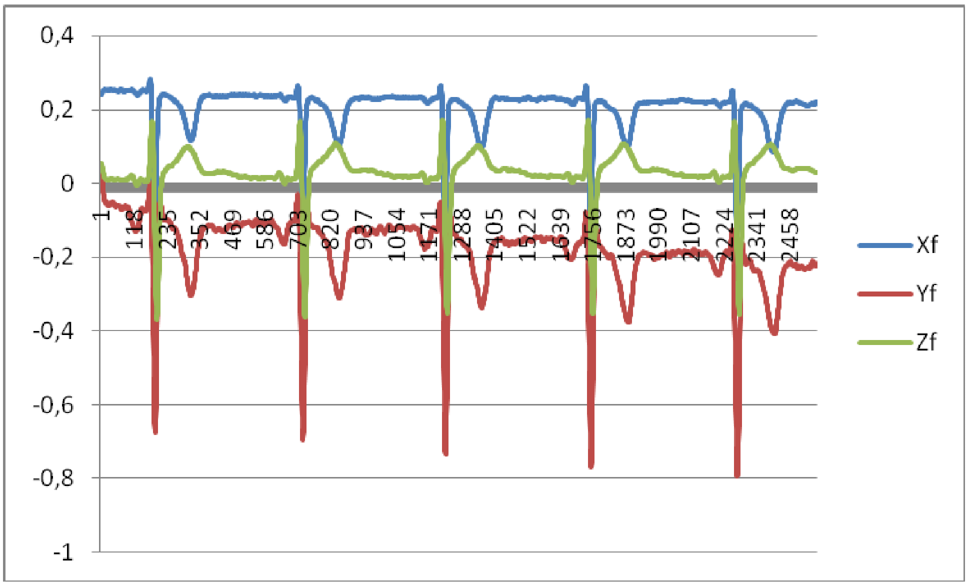


Figure 40: ECG acquisition test, sensors with gel and unmoving patient. Note about the inverse polarity for Xf and Zf signals among the same traces on fig.39: this is due to a small change on the electronic board, during the test phase. The polarity of the input signals of the Lead X and Lead Z on AD620 stages was inverted.

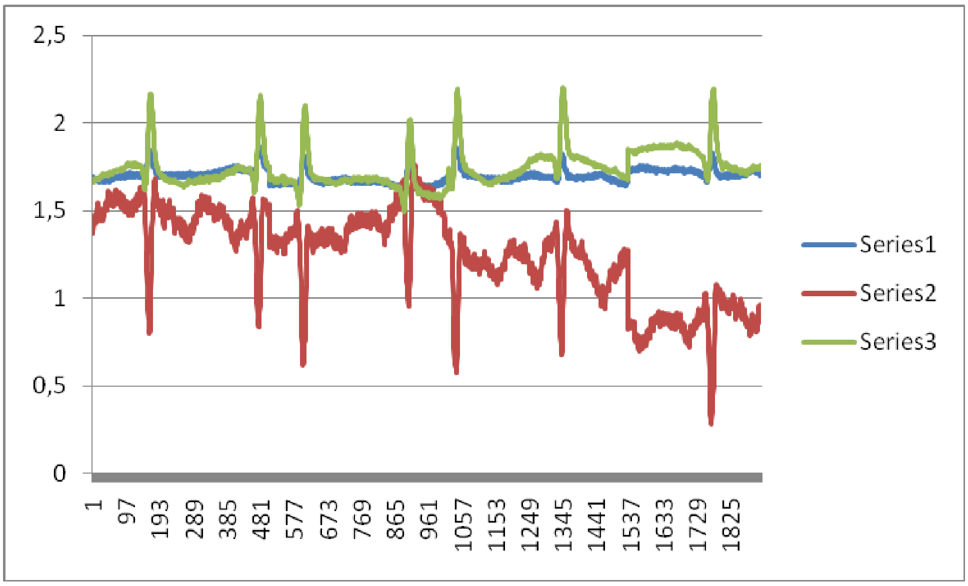


Figure 41: ECG acquisition test, sensors without gel and moving patient.

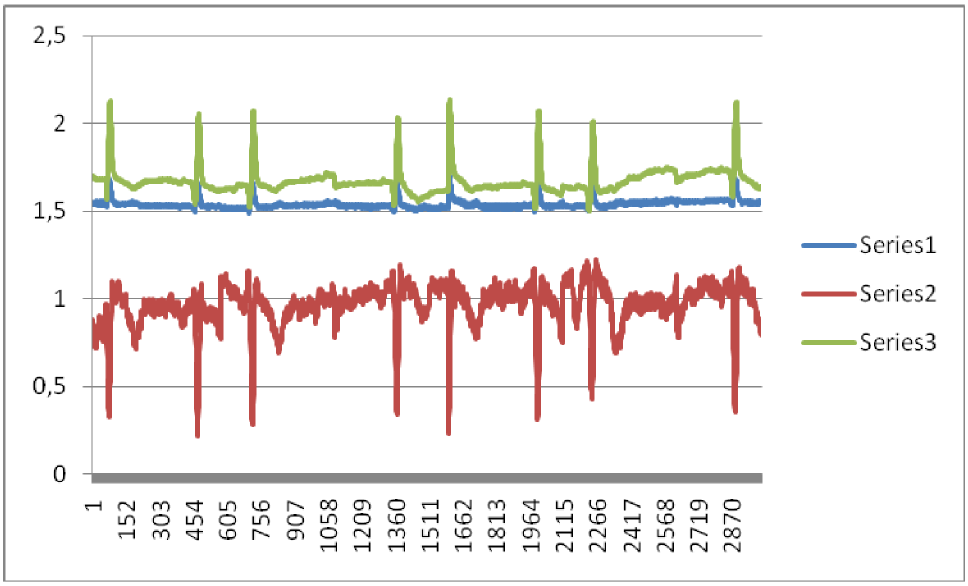


Figure 42: ECG acquisition test, sensors without gel and unmoving patient.

Some considerations can be done after these tests: first of all about the utilization of gel in common ECG sensors. As explained in theory in previous deliverables, sensor gel is needed to better transmit the cardiac signals from the patient skin to the acquisition board. These tests confirm this idea.

Without gel, cardiac signals has a lot of attenuation passing through skin and SNR is lower: besides, the acquisition become very sensible to the patient movement. On the contrary, using gel on sensors, the quality of acquisition improves, and this helps the next phase in the DSP processor: the diagnosis using the OULU's algorithm. Tests with moving patients were done walking and moving arms and legs.

SECTION 2 Dissemination and use

2.1 Description of exploitable results

Exploitable Knowledge (description)	Exploitable product(s) or measure(s)	Sector(s) of application	Timetable for commercial use	Patents or other IPR protection	Owner & Other Partner(s) involved
T-shirt embedded sensors	**Heartronic T-shirt**	**ECG measurements**	**Few months after project completion**	**To be defined if applicable**	**SMEPs**
Electronic board design + ECG Pattern recognition algorithms	**Heartronic acquisition board**	**Portable medical devices with intelligence on board**	**Few months after project completion**	**To be defined if applicable**	**SMEPs**
Accurate ECG diagnosis and TLC integration	**Heartronic complete system**	**Portable medical devices with intelligence on board**	**Few months after project completion**	**To be defined if applicable**	**SMEPs**
Software for PDAs	**Heartronic complete system**	**Portable medical devices with intelligence on board**	**Few months after project completion**	**To be defined if applicable**	**SMEPs**

2.1.1 T-shirt embedded sensors

2.1.1.1 Description of result

The HEARTRONIC T-shirt can be exploited as a product in the market of wearable diagnostic devices for real time remote analysis of patients at distance, offering an alternative to the classic Holter monitoring systems; its effectiveness and simplicity makes it an ideal candidate for long time patient monitoring, directly providing doctors with patient's data via Blue Tooth™ and GSM technology.

It is a special T-shirt capable of measuring electrocardiogram (ECG) by means of eight innovative embedded sensors, made up by the classic structure metal/salt, like other standard ECG electrodes, but without adhesive, which leads to a good signal to noise ratio along with patient comfort. The particular electrodes configuration, following the Frank's lead, gives the chance to obtain the classic 12 leads ECG signal by means of a linear transformation, the Dower matrix. During the second year of the project the final prototype (the HEARTRONIC T-shirt) has been achieved, which can be used to obtain the three analogic signals describing the cardiac vector. It is the only system available so far able to record Frank's leads tracks and convert them in 12 leads ECG.

It is to say that, in order to exploit this stand alone product on the market, further development needs to be carried out; in particular, in order to promote the development of smart clothes extensive collaboration of industry partners of the fields of fiber, fabric and clothing technologies together with research partners of the fields of information and micro system technologies has been launched.

Although experts estimate a high potential for smart clothes applications in the future, so far there are no promising industrial applications at hand.

2.1.1.2 Partners involved

Medical and biomedical partners provided their expertise and standpoint in identifying characteristics such as level of performance, range of monitoring parameters, size, weight, interface and communication.

In particular, the Medical University of Gdansk and S.Camillo carried out:

- ⇨ A list of cardiovascular diseases that can be monitored by the intended system
- ⇨ Information about each selected disease, specifying symptoms and related therapy

All the information carried out has been used to optimise the design and realisation of the intended system.

Labor and ACTA, in strong cooperation with the cardiologist of S.Camillo and UniGdansk, defined the last version of the T-shirt, coming also into contact with an important Italian company involved in smart fabric development in order to produce the final version of the T-Shirt, with embedded wires and sensors. This further development will be undertaken after the project closure, aiming at a more effective market penetration.

AGT and Dunvegan carried out a deep market survey to identify the potential market for this new device and the required actions in order to protect the results.

2.1.1.3 Possible exploitation

The high market penetration of low cost wearable and portable ECG devices used in home care, telemedicine, and personal health management is expected to play a key role in the evolution of e-Health and mobile health services. E-Health in the information society is recognized as “an integrated intelligent person-centred health care delivery system that contributes to the improvement of quality, access, and efficiency of healthcare.” Unfortunately, the eHealth sector in Europe demonstrates tardiness when compared to other sectors. User acceptance is a critical factor in the recognition of eHealth as part of the health care delivery process.

In this scenario, the Heartronic T-shirt could be exploited as a stand alone, easy to use recording system, the only one in the market able to present the vectorcardiogram as well as 12 leads classic ECG signal, in order to provide doctors with a complete diagnostic tool.

2.1.2 Electronic board design and ECG Pattern recognition algorithms

2.1.2.1 Description of result

The electronic architecture of the HEARTRONIC system, developed during the activities of WP3, including energy supply and DSP processing for the ECG signal, is a powerful tool to elaborate the signal coming from an analog source, like the typical wire connections of the standard ECG systems. It is designed to receive the three signals coming from the Frank leads configuration adopted for this project, but it could be easily modified for the acquisition of the 12 lead classic ECG devices. It provides a suitable analogic conditioning of the incoming signals, the digital conversion by means of the 12 bit ADC embedded in the DSP processor and the digital filtering in order to remove all the artefacts due to patient’s movements and power-line mains. This board represents a stand-alone block capable to receive the ECG signal and perform a pre-diagnosis. This could be applied in all the clinical long lasting analyses, in order to alert the doctor only when it is necessary.

The system can be also easily re-designed to fit user requirements (in order to receive, for instance, 12 classic ECG leads), and allows to transmit data via Bluetooth technology for subsequent visualization and evaluation.

2.1.2.2 Partners involved

Labor, with the support of ACTA, DUNVEGAN and T-CONNECT completed the design of the board, as it is described in Deliverable 3.2 and in the Final Activity Report.

2.1.2.3 Possible exploitation

The electronic board represents a powerful stand-alone block capable to receive the analogic signal coming from the standard electrode's wires of the ECG and VCG system, those electrodes could be wired to the board that performs the ADC and the pre-diagnostic analysis and yields the results on the pc screen.

Considering the amount of time and money saved by not going to the clinic and taking the reading as many times as one wants, the amount of man hours saved are significantly large as compared to the one time investment on the hardware.

The market reference for this type of product is that of the hospitals, clinics and analysis laboratories, where the higher performances of an innovative product can be recognized more easily and the system can be commercialised after the assessment of the needed security requirements.

2.1.3 Accurate ECG diagnosis and TLC integration

2.1.3.1 Description of result

One of the main tasks of this project is the integration of a pre-diagnostic algorithm in the electronic board, which, in cooperation with the algorithms running in the host server, performs the complete diagnosis of the ECG signal. This algorithm recognizes the typical features of the main anomalies of the ECG signal, which are considered the early signs of cardiovascular diseases, such as arrhythmia or infarct.

2.1.3.2 Partners involved

The algorithm has been studied and proposed by UNIOULU in cooperation with IAITI and with the supervision of the doctors of S.CAMILLO and UNIGDANSK, while LABOR and ACTA took care of its implementation in the firmware of the DSP.

2.1.3.3 Possible exploitation

The complete set of algorithms could be exploited as a stand-alone software for early diagnosis, provided that the signal analysed is in Frank's leads format.

2.1.4 Communication software for PDAs

2.1.4.1 Description of result

The first important feature of the PDA software is the capability of collecting the information gathered by means of Bluetooth transmission and visualizing the ECG tracks on the screen, giving the doctor the opportunity to check the signal features and zoom in to better analyse the waveforms.

Besides, another important characteristic implemented is the communication protocol, which transmits information in a graphic format, transferring data to the host server for subsequent evaluation and visualization.

Another information to be transmitted in case of warning is the patient's position, which can be extracted from the phone itself; presently a rough localisation through the number of the GSM or UMTS cell is available, yet very useful in case of emergency; anyway one should not forget that precise localisation technologies are actively developed to be integrated into next generation portable phones, and will provide a very accurate localisation.

As to the Host server for data management**,** it incorporates several important features:

- post treatment of ECG signal for further analysis and screening (implemented in Matlab)
- redirection of warning signals to the cardiologist in the form of joint digital and graphic signals
- management of warning situation according to pre-set options
- data base of events and registration of data transmitted
- transmission of messages to the patient

The host server will be also interfaced with most common tools for the management of medical data of patients; in this way, it will be possible for the host server to reach the cardiologist's phone not only with the ECG pattern of the patient, but also with his case sheet.

2.1.4.2 Partners involved

This task has been carried by IAITI, who was in charge of developing the host server architecture with the help of S.Camillo and UniGdansk, and by Labor, who cooperated with ACTA SERVICE and T-Connect for the development of PDA software.

2.1.4.3 Possible exploitation

A longitudinal study was carried out to make a first evaluation of the doctors' attitudes to the introduction of the new ECG Viewer on the Pocket PC or new generation cellular phones environment in. This study highlights the importance of planning, effort, cooperation and an appropriate approach to this implementation in order for telemedicine using PDAs to be accepted. Thus, S. Camillo and Uni Gdansk, partners of the project, were interviewed to evaluate the telemedicine application and to measure the effectiveness and the quality of the PDA based HEARTRONIC system.

Cardiologists were fairly positive about the telemedicine system and felt that it was both easy to use and reliable. The availability of PDA with the capability of ECG displaying was considered remarkable. The most frequent benefits of the ECG Viewer on PDAs were indicated in: easier access to staff and patients, time saving and increased quality of care. From a diagnostic point of view, in comparison to the quality of an ECG provided on paper, the ECG Viewer was rated good and very good in the context of benefits to patient care.

The results of these interviews confirms the general will of using PDAs by doctors, giving a further feeling that the PDAs diffusion should increase in the next years.

The access to the multimedia patient record and the e-Health services through such devices will further on benefit the doctors providing them with the access to the integrated health care record from the point of need. On the other side, full ubiquity can be reached through PDAs with wireless connectivity, when they have the capability of displaying all the information available in the patient record including the clinical examinations with the necessary graphical details and without any need of sitting at a desktop station for their graphical display.

Finally, according to Mobile Village, more than 90% doctors feel that a PDA based system would help them providing better care to their patients but only 10% medical professionals currently own PDA software that integrate prescription, billing or patient records systems.1

Our solution empowers the doctor to give quality treatment to more patients without the constraints of location and time. The portability of our device makes it perfect for use in varied places and provides the benefits of remote consultancy. The doctors could analyse this data at their ease, even when they are on the move and give medical advice in the form of a printable prescription. These readings can be conveniently saved and available for future reference and advice.

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[1] Mobile Village, 15 Dec. 2003, http://www.mobilevillage.com/news/2003.12.17/docsurvey.htm