troy
Endoscope Capsule Using Ultrasound Technology

SIXTH FRAMEWORK PROGRAMME

Project nº 033110

TROY

Endoscope Capsule Using Ultrasound Technology

Final Periodic Activity Report

Period covered: From 1st of September 2006 to 28th February 2009
Date of Preparation: 14th April 2009

Start date of Project: 1st of September 2006 **Duration:** 30th months
Instrument type: Co-Operative Research Project

Project Coordinator name: João Correia
Project coordinator organization name: IAITI, SA Revision nº: 1

Executive Summary

Endoscope Capsule Using Ultrasound Technology
Project Acronym**: TROY**
www.troy-project.eu

"Endoscope Capsule Using Ultrasound Technology" project is a Cooperative Research project funded under the 6th Framework Programme. It started on the 1st of September 2006 and will finish on the 28th February 2009.

Endoscope Capsule Using Ultrasound Technology

TROY main objective is to prove the concept of an innovative, beyond the state-of-the-art, diagnosis system for prevention and early warning of superficial cancer and premalignant precursor lesions in gastrointestinal tract consisting of an Endoscope Capsule Using Ultrasound Technology capable of creating 3D computer generated images.

The system is based on a wireless Ultrasound Endoscope Capsule (UEC) (for data acquisition), on a body sensor network (to receive ultrasound and position information from the UEC) and on a personal data recorder (to store the data collected during the exam). The UEC includes miniaturized units for ultrasound, processing, localisation, power supply and communication. The information collected by the UEC and recorded in the personal data recorder is later on transferred to a PC where the TROY workstation software processes the data and creates the images.

The TROY concept is based on the following two steps: i) data collection; and ii) data analysis and diagnosis.

The Ultrasound Endoscope Capsule is swallowed by the patient. This allows capturing ultrasound information of all digestive tract. The capsule travels smoothly and painlessly throughout the gastrointestinal tract by natural peristalsis movements, transmitting the ultrasound data to a wearable computing device with data recording capabilities. The wearable computing device will be integrated into a belt pack for patient convenience.

After the exam, the data is downloaded from the belt pack recorder to a customized PC Workstation. The software will then reconstruct a 3D image of the digestive tract and the data mining module will try to recognize problem patterns. This 3D interactive image of the digestive tract will provide to the physicians an excellent tool to analyse the patients' interior body, closing the diagnostic gap by directly viewing the entire digestive tract and can assist them in the diagnosis and treatment of gastrointestinal diseases. TROY System will provide a complete gastrointestinal tract examination, using a non invasive technique which does not require patient sedation and allows him to continue with his daily life.

The results achieved are very encouraging. The results of the several tests conducted throughout the project, to the individual components and to the overall system, validated the concept and the approach.

The consortium firmly believes that the results from TROY project represent an important first step towards a decrease on one of the leading causes of dead worldwide - the cancers of digestive tract, since prevention and early detection are considered at the moment the best way of increasing patient survival rate and quality of life. Future developments based on these results will surely result in new diagnosis systems that contribute to this social objective.

On the projects' first year, the consortium identified and defined the medical and electronic requirements for the TROY system. It was also initiated and almost completed the sensors development and design of the electronic systems. The electronic power supply components were selected for the capsule and wearable devices and design of electronic architecture (capsule and wearable device) was almost complete. Software development for the workstation had a first functional prototype, including 3D rendering and user interface. The ultrasound probe was being developed in miniaturized size (exactly with the intended size for the final version), using 16 sensors array. This first ultrasound probe was nearly completion and the first tests were scheduled for December 2007.

On the second year of the Project the consortium concluded the design and development of the entire system: the ultrasound probes where developed, the electronic system for the capsule was developed and revised, for the Wearable Unit the Body Sensors Network and Personal Data Recorder where developed and revised and the workstation software was improved and concluded. Tests were performed with alpha prototype allowing the awareness of required improvements that were further implemented on the beta prototype. Tests with beta prototype were performed with test rig developed in the project and validation assessment was conducted with encouraging results. A complete functional model was developed, tested and evaluated proving the feasibility of the TROY concept.

Project Contractors:

ORGANIZATION NAME	ORGANIZATION SHORT NAME	TYPE	COUNTRY
Instituto Agilus de Inovação em Tecnologia de Informação, SA (Coordinator)	IAITI, SA	RTD performer	PT
SC IPA SA Sucursula Ciffat Cluj	SC IPA Cluj	SME performer	RO
Dunvegan Systems Ltd	Dunvegan	SME performer	UK
AGT Srl	AGT	SME performer	IT
Ardoran Ou	Ardoran	SME performer	ES
Artica Telemedicina S.L.	Artica	SME performer	SP
Labor Srl	Labor	RTD performer	IT
Ultrasound Institute of Kaunas University of Technology	UI of KTU	RTD performer	LI
Iuliu Hatieganu University of Medicine and Pharmacy Cluj-Napoca	UMF Cluj Napoca	RTD performer	RO

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SECTION 1- Project Objectives and Major Achievements during the Reporting Period

1.1. Project General Objectives

TROY project aimed to prove the concept of an Ultrasound Capsule that can be used as a first line exam for diseases of the gastrointestinal tract such as cancers, Crohn's disease and ulceration. It aims to represent a significant advance in medical research on this domain which currently constitutes a public health problem.

The Troy project idea was to develop a functional model of an Endoscope, using ultrasound technology to generate 3D computer generated images based on the interpretation of ultrasound data, in order to contribute to the increase in early cancer detection. This concept was proved and the results assessed with the use of a test protocol and a test rig specifically developed for the purpose.

Endoscopy is a medical procedure in constant evolution as technological research progresses. Endoscopy closes the diagnostic gap by enabling physicians to observe the entire digestive tract, which is, on average, 9 meters long. Gastrointestinal endoscopes are now recognized as the only medical devices that can simultaneously perform observations, diagnoses and treatments. Based on theses premises, the projects aims to develop a functional prototype that will work as a proof of concept for the usage of 3D computer generated images based on information obtained using ultrasound technology.

The Ultrasound Endoscope Capsule will be swallowed by the patient allowing the capture of ultrasound information from the digestive tract. The capsule travels smoothly and painlessly throughout the gastrointestinal tract by natural peristalsis movements, transmitting the ultrasound data. The patient will wear a shoulder-supported belt pack holding a power supply and a small hard drive for storing the data. After the exam, the data are downloaded from the belt pack recorder to a customized PC Workstation. The software will then reconstruct a 3D image of the digestive tract and the data mining module will try to recognize problem patterns. This 3D interactive image of the digestive tract will provide to the physicians an excellent tool to analyze the patients' interior body, closing the diagnostic gap by directly viewing the entire digestive tract and can assist them in the diagnosis and treatment of gastrointestinal diseases.

The Ultrasound Endoscope Capsule will be therefore capable of rendering 3D high definition images using ultrasound technology located inside the human body and acting as a support to medical procedures, with the help of pattern recognition of lesions. It's possible to conduct ultrasound scanning from inside the body, because it incorporates the necessary miniaturized functions within itself, using the best available technology. Since it radiates ultrasound from inside the body cavities, it is expected to deliver higher-resolution ultrasound images with less

attenuation than those obtainable from external ultrasonography, supporting the diagnosis and follow-up.

At the end of the project, resulted a functional model of a system with the following architecture:

- Ultrasound Endoscope Capsule, for data acquisition, with miniaturized units for data communication, energy supply (batteries) and ultrasound;
- Wearable unit for receiving and recording data with sensors to receive the capsule signal, storage hard drive and energy supply (batteries);
- Troy workstation to process 2D and 3D models based on ultrasounds enabling the analysis of the digestive tract.

The following pictures shows the intended architecture of TROY System :

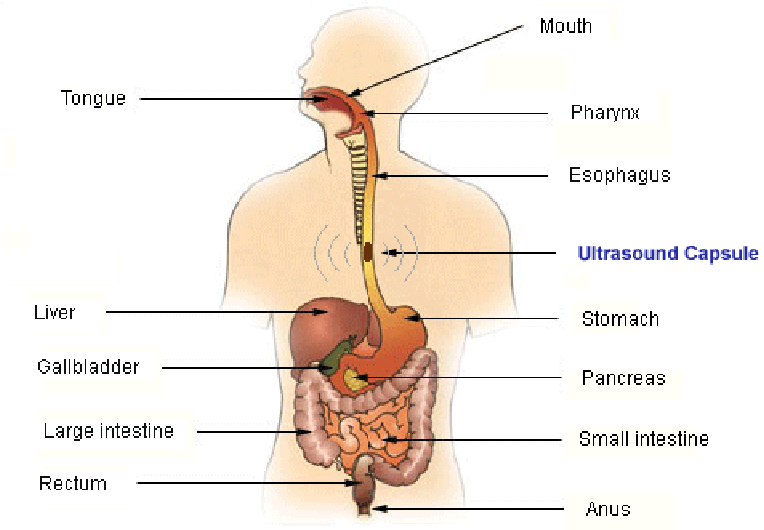

Figure 1 - Ultrasound Capsule inside human gastrointestinal tract

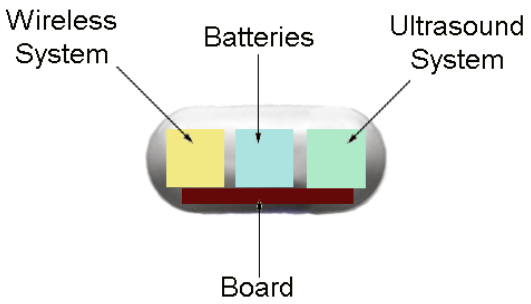

Figure 2 - Main modules of the Ultrasound Capsule

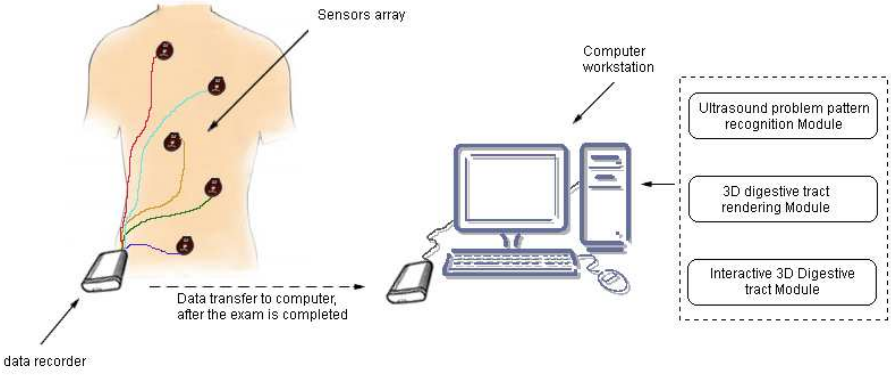

Figure 3 - TROY System

In summary, the intention of TROY project was not to re-design the oncology science, but rather to analyse all medical and patients' requirements, to exploit the various existing and promising technologies relevant to this area, and integrate them with innovative and minimally invasive technologies for a reliable and safe tool that really responds to the doctors and patients demand, increasing the life expectation and significantly improving the quality of life, increasing the percentage of detected pathologies of the direct competitors, estimating greater than 80%.

TROY has been designed in 5 main phases, having each one important results associated (Milestones):

- **Requirements Definitions**: analysis and the identification of user and system requirements in order to define the exact specifications and the architecture of the system. Both technical and medical requirements will be taken into consideration - **M1- Systems Requirements**
- **System Development**: development of the different components and integration. **M2 –Sensor array Specification, M3- Systems Design, M4 – Ultrasound Probe**.
- **Prototype Construction**: system will be refined in all its aspects according to the suggestion coming from laboratory tests; finally, the Troy prototype will be realised with all appropriate technical solutions.
- **Validation**: The prototype realised in the previous phase will be tested according to precise evaluation criteria which take into account the European standards for medical equipment (Council Directive 93/42 EEC). **M5 – Laboratory Tests**
- **Exploitation of Results**: SMEs involved in the project have the potential to bring the TROY system to the market, so that a wide action of dissemination of the achieved results will be performed in all the European interested countries; **M6 – Dissemination and Exploitation Plan**

1.2. Reporting Period Objectives and Achievements

1.2.1. Objectives

The objectives for project were:

WP1 – Preliminary Requirements

- To define the expected requirements of TROY system - Medical and Electronic requirements
- To produce Deliverable D1.1 – Troy Data Sheet
- To produce Milestone 1 – System Requirements

WP2 – Sensors Development

- Procurement and selection of the sensors
- Feasibility of the embedded sensors
- To produce Deliverable D2.1 – Selection of Sensors
- To produce Deliverable D2.2. – Feasibility of embedded sensors
- To produce the associated Milestone nº2 – Sensor Array Specification

WP3 – Electronic System Design

- Definition of the system overall architecture
- To study the available and adequate energy sources
- To have a complete and detailed set of designs and electronic schemes
- To produce Deliverable D3.1 – Draft Architecture of TROY device
- To produce Deliverable D3.2. – Designs and Electronics schemes of TROY device

WP4 – Software Development

- To develop the embedded software
- To create a module for solving ultrasound pattern recognition question
- To develop a module for 3D digestive tract recognition
- To produce Deliverable 4.1 – Software and Software documentation
- To produce the associated Milestone nº3 – System Design

WP5 – Ultrasound Probe Miniaturization

- to develop the ultrasound probe
- To produce Deliverable 5.1 – Ultrasound Probe
- To produce the associated Milestone nº 4– Ultrasound Probe
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WP6 – Prototyping and Testing

- To produce Deliverable 6.1 – TROY Alpha prototype
- To produce Deliverable 6.2 – TROY Beta prototype
- To produce Deliverable 6.3 – TROY Test Rig
- To produce Deliverable 6.4 – Final Assessment
- To produce the associated Milestone nº5 – Laboratory Tests

WP7 – Dissemination and Exploitation

- To initiate the development of a market study
- To initiate the definition of the project exploitation strategy
- To produce D7.1- Knowledge Exploitation and Dissemination Plan (draft version)
- To produce D7.2 – Mid Term Project Review for dissemination
- To produce D7.3 – Market Study & Exploitation Report & Technology Implementation Plan
- To produce D7.4 – Knowledge Exploitation and Dissemination Plan
- To produce the associated Milestone nº6 – Dissemination and Exploitation Plan

WP8 – Project Management

- To organize the project coordination meetings
- Administrative and financial control
- Work planning, control the progress of work and budget allocation
- To assure the necessary Administrative and Financial Control
- Work Planning, control the progress of work and budget allocation
- To produce the Second Year and Final Reports

1.2.2. Main achievements

The consortium identified the medical and electronic requirements for the TROY system, producing the Troy Data Sheet and fulfilling the first milestone M1 – System requirements.

The consortium concluded the work on selection of sensors and on the feasibility for embedded sensors and finished the Sensor Array Specifications. The sensor array was developed and integrated within the wearable unit. Deliverables 2.1, 2.2 and Milestone 2 were concluded successfully.

The electronic and power supply components were selected for capsule and wearable devices. The electronics schemes and designs of Troy devices - wireless capsule and wearable unit – were completed and revised. Deliverables 3.1 and 3.2 were also concluded.

Software was developed for the electronic devices and for the Troy workstation. Ultrasound raw data is capture by the capsule and sent by RF to the wearable unit that reads the capsule position with the magnetic sensors of the body sensors network and save all the data in a memory card. At the end of the exam the card is read in the Troy workstation where the software computes ultrasound raw data and magnetic field information retrieving position and ultrasound images enabling the reconstruction and analysis of 2D and 3D models of the digestive tract. Deliverable 4.1 and Milestone 3 were completed.

The ultrasound probes were developed with 16 and 32 elements at 5 MHz. The probes were produced in its intended miniaturized size. Tests with single elements working at different frequencies were also conducted in order to guarantee the better results. The 16 elements probe was successful assembled within the capsule electronic device. Deliverable 5.1 and Milestone 4 were successfully concluded.

Troy alpha prototype was implemented and tested allowing the consortium to perceive what should be changed, revised and improved for the implementation of the beta prototype. Even thought the 32-elements ultrasound probe was produced and had the best results, the beta prototype was produced with the 16-elements array in order to solve all the problems arisen in the electronics of the alpha prototype. A test rig was designed and built for simulation of small bowel conditions and performed laboratory tests with the Troy system. The entire system was tested together successfully. A final assessment was conducted with a team of medical doctors with positive results. Deliverables 6.1, 6.2, 6.3 and 6.4 were concluded and Milestone 5 was completed.

In Dissemination and Exploitation activities the tasks were completed successfully and the deliverables 7.1 Knowledge Exploitation and Dissemination (draft), 7.2 Mid term Project Review for dissemination, 7.3 Market Study, Exploitation Report and Technology Implementation Plan and 7.4 Knowledge and Exploitation Plan were completed. The Milestone 6 was concluded.

Five management meetings and 5 technical meetings were organized and a request for project extension of six months was conducted and accepted. Financial and activity reports were prepared and delivered.

1.3. Recommendations

Following the recommendations made by the EC based on the analysis of the 1st Year Report, the consortium took all the necessary actions in order to answer all the recommendations, namely:

- Missing milestones for the 1st Year of Activity should be delivered within 3 weeks after the reception of this letter - report was delivered;
- Delayed deliverables should be also provided (selection of sensors, draft architecture of TROY device, feasibility for embedded sensors (D2.2); sensor Array specifications (M2); Designs and electronic schemes of TROY device (D3.2); Software and Software Documentation (D4.1) and System Design (M3) – reports were delivered even thought new revisions were made as improvements were necessary after testing alpha prototype;
- To provide evidence that a Intellectual Property Database search has been performed with enough detail and benchmarking - done;
- To deliver a report on safety issues for patients – report delivered;

- Project Management structures should work towards a stronger involvement of the SMEs, foster a solid IP procurement and exploitation and seriously involve the clinical community - done;
- Prototyping Activities should involve all partners - all partners were involved in discussions, technical meetings and laboratory tests;
- Benchmarking with other recent advances on endoscopy solutions is important for the success of TROY's approach - done;
- The website should be improved – a new version of the website was produced

1.4. Problems and Corrective Actions

As reported on the First year Activity Report, some delays on specific Workpackages occurred, namely on WP1 – System requirements Definition which took more time than the initially planned on the project timetable.

Due to this initial delay, with negative impact on the remaining WPs, the consortium presented on the second year of activity, an amendment to the contract. The initial project proposal contemplated the development of full functional prototype and the execution of a series of field tests performed according to a clinical procedure. However, in the course of the project and based on the results achieved at that time, it was clear that these results were not possible to achieve. This was due mainly to two reasons:

1. Size of the electronic system in the capsule: the electronic systems that drives the capsule was much more complicated than initially predicted; it was not possible to develop this system with the proposed technology – commercial of the shelf (COTS) discrete electronics – and with the size needed to fit inside the capsule; this will only be possible with microelectronics and the development of a specific integrated circuit (ASIC); this approach is not feasible due to the time (2-2.5 years) and resources needed.
2. Time and restrictions on clinical tests: the duration of the procedure needed for the clinical validation of this kind of system is longer than predicted; moreover the fact that the final result is not a full functional prototype (in size and functionalities) turns this clinical validation unfeasible.

To take advantage of the excellent work produced so far and to guarantee its future exploitation the consortium understood that some changes to goal of the project were needed. The main goal of the TROY project was changed from the development of a full functional prototype (and its clinical validation) to the development of a full functional model (and its laboratory validation).

Although most of the components of the TROY system would be fully functional prototypes (as planned), the complexity in the control of the capsule and the need to include analogue and digital circuits for this task proved impossible to get the electronics in the size needed to fit the capsule using discrete components.

The model of the capsule to be developed would be fully functional (the ultrasound probe and all other elements would be of the size needed to fit into the small capsule) and all other parts of the system would be a full functional prototype (the wearable computing and the workstation software). Moreover, to be able to perform extensive and valid tests on the model, the consortium designed and developed a synthetic phantom (test rig) to replicate the specific conditions in the human bowel.

The design and development of the synthetic phantom, and of the laboratory test protocol to be used, would be performed in the 3rd task of WP6 in replacement of the clinical trials. Although an increase in the needed resources was foreseen for this new task (in relation to the previous one) this increase should be incurred by the involved partners.
The consortium believes that this change in the project objective has no negative results in terms of impact or in the level of innovation of the results achieved. Being so, the dissemination and exploitation activities were kept according to the initial plan contemplated in the DOW prepared during the negotiation phase.

Considering that "The TROY project idea is to develop a functional model of an Endoscope Capsule, using Ultrasound technology, to generate high definition 3D computer generated images using ultrasound data, to contribute to the improvement of early cancer detection." (from the DOW), the ultimate goal of the project TROY is to prove that the capsule based ultrasonography is valid concept. With this new approach, this concept would be proved and the results assessed with the use of a test protocol and a test rig specifically developed within the project. The proposed alternative approach would provide enough evidence to validate the concept of capsule based ultrasonography, and the consortium does not expect a limited project result. For this the consortium estimated that an extra 6 (six) months would be needed. This extension was needed in order to compensate for the time spent trying to miniaturize the electronics system in the capsule (which proved to be impossible with the proposed technology) and to enable the development of a synthetic phantom to be used in the validation of the concept and assessment of the results.

These changes impact the project in terms of schedule (duration of tasks, deliverable and milestones due dates) and task work definition (mainly in the 3rd task of WP6). These changes were contemplated in a new version of the DOW.

The amendment was accepted by the Research Directorate-General in June 2008, having the project the new duration of 30 months and the revised Annex I Description of Work of 26th May 2008 replaced the former version.

As a final note, the project baseline presented in "3.3. Project timetable and Status" refers to the project plan after this amendment was approved by the and not to the initial project plan.

SECTION 2 – Workpackages' Progress

2.1 Workpackage 1 – Preliminary Requirements

2.1.1. Objectives

According to the "Annex I- Description of Work" the objectives of WP 1 were:

- *To provide a complete and formalised data-sheet of the expected requirements TROY prototype from medical and users' perspectives, under the three main fields concerned: medical, electronics and communications.*

For the accomplishment of the established objectives the following tasks were foreseen:

a) **Task 1.1 - Medical requirements (M1-M7)**: to define the medical requirements of TROY system.
b) **Task 1.2 – Electronic requirements (M1-M7)**: to define electronic requirements of TROY system.

As a result of both tasks it **Deliverable 1.1** was delivered at – TROY Data Sheet at month 3 and **Milestone 1** – System Requirements Draft at month 7.

2.1.2. Progress

The identification of the preliminary requirements involved the contribution of all partners, being the task 1.1. leaded by UMF of Cluj-Napoca and Task 1.2. by IAITI. These both task were developed simultaneously resulting into one unique document – Milestone 1 –System Requirements Draft prepared by IAITI.

The work developed on the scope of this WP is described on Milestone 1 which has as main contents:

a) State of the Art of Gastrointestinal Exams identifying current approaches and its limitations.
b) Justification for and nature of improvements
c) Improvements not considered
d) Requirements Analysis

It was defined the requirements analysis in order to establish:

- What the system shall be capable of accomplishing.
- How well system products should perform in quantitative, measurable terms.
- The environments in which system products operate.
- The human/system interfaces requirements.
- The physical/aesthetic characteristics.
- Constraints that affect design solutions.

System requirements were presented with medical and patient perspective:

Medical requirements

Table 1 – Medical Requirements

Autonomy	One complete exam (12-24 hours)
Materials	Enterorezistent (acid pH); not reflecting ultrasounds; eventually half radio-opaque and half metallic (for control reasons)
Shape	Tear drop or sand-glass (clepsydra) shape. Shape must be unbalanced, with the centre of gravity in the front
Transducer	Ultrasound radial transducer
Frequency	5 MHz, with the possibility to have specific UEC with different frequencies (7.5, 12.5, 20, 30 MHz)
Localisation	Almost correct location in the body
Output result	2D images (still images and animation) and 3D reconstruction
Area of examination	Small bowel, with the possibility to have specific UEC for oesophagus and large intestine

Patient requirements

Table 2 – Patient Requirements

Maximum acceptable dimensions	Large vitamin pill (25/10 mm)
Mobility	Compatibility with the daily activities
Height of the system	Neglectable
Comfort	No discomfort during the exam
Safety	Population categories that cannot use the system: patients with swallowing disorders; patients with cardiac pacemakers or other implanted electromedical devices and patients with known or suspected gastrointestinal obstruction, strictures, or fistulas based on the clinical picture or pre-procedure testing and profile.
Prior preparation	Must be preformed after fasting, with optional digestive lavage. Normal feeding is permitted eight hours after ingesting the capsule. One hour after swallowing the UEC, the patient can drink liquids, and after two hours can have a small snack

e) System features

The consortiums also draw the use cases of system features. The next 3 figures present the results of this activity. In Figure 4 are the use cases for the Wireless Capsule, the use case for

the Wearable Computing are shown in the Figure 5, and in Figure 6 are the use cases for the Troy Workstation.

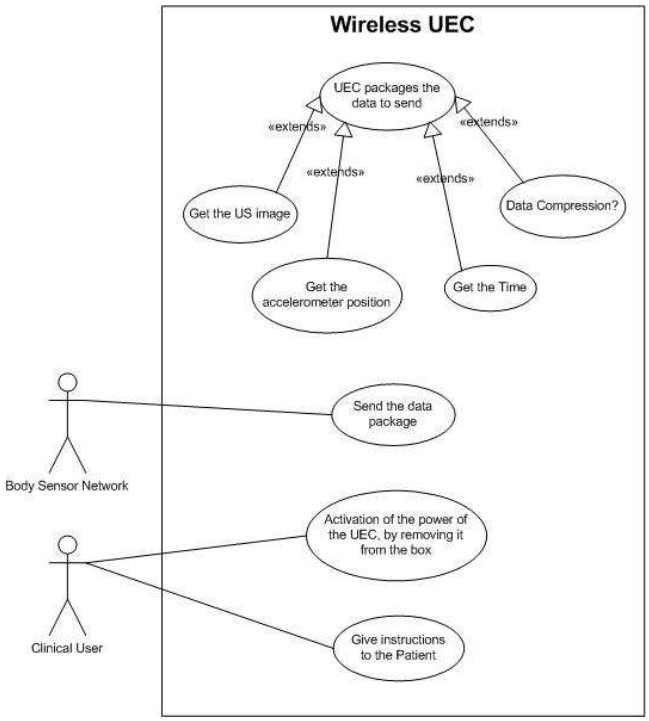


Figure 4 – Use Cases: Wireless Ultrasound Endoscope Capsule

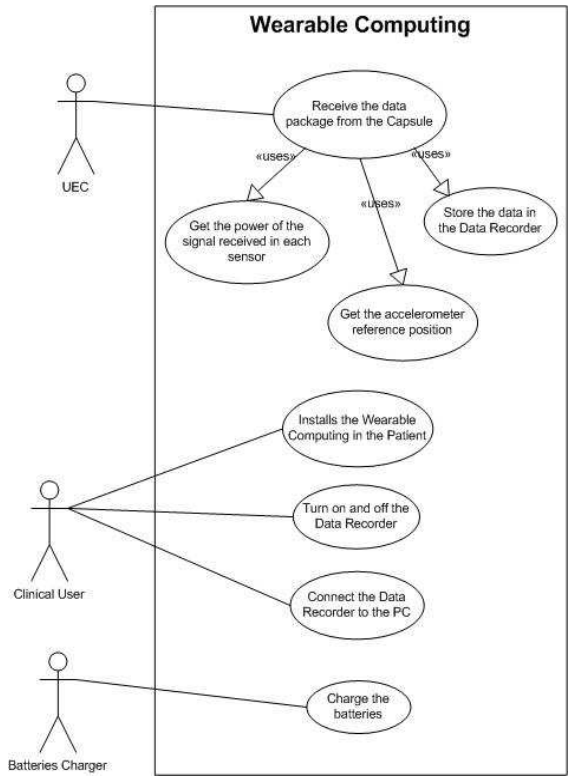


Figure 5 – Use Cases: Wearable Computing

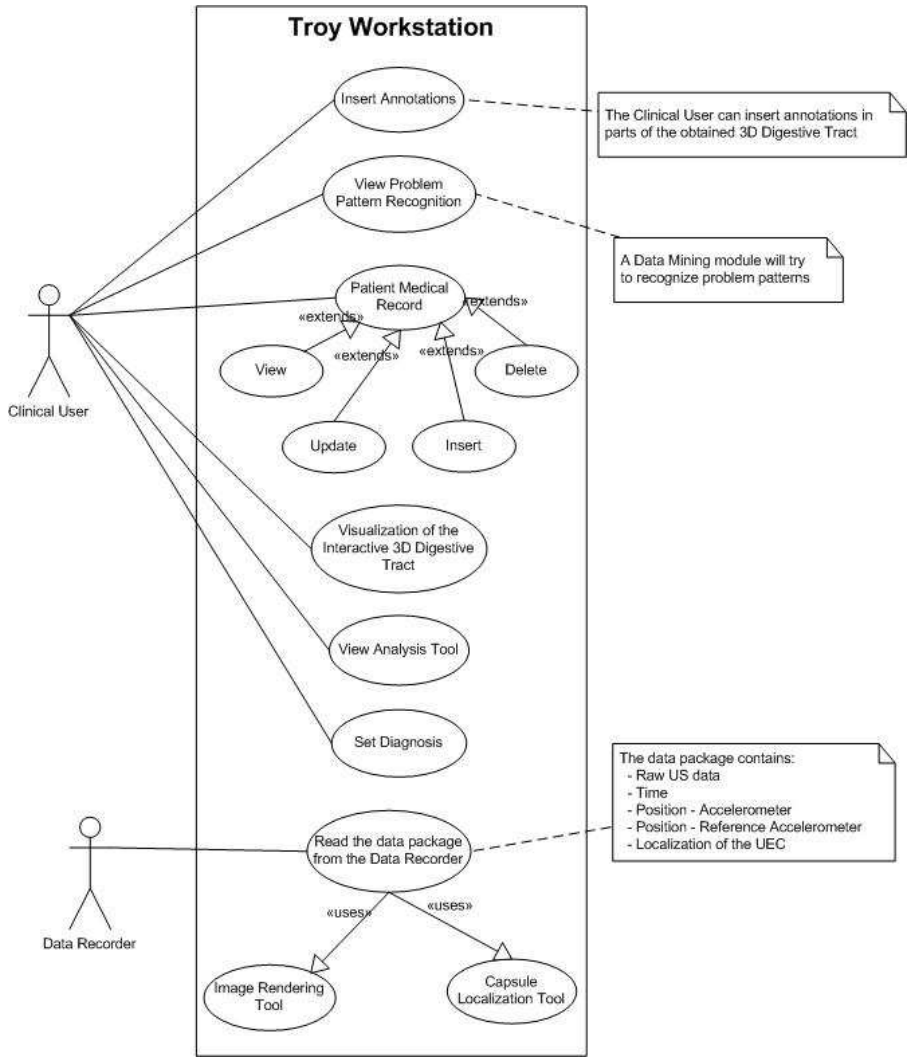


Figure 6 – Use Cases: Troy Workstation

f) System Specifications

As part of the work developed on the WP, a work breakdown structure of TROY system with all the components was defined. The TROY system specifications were subdivided in 3 main categories: wireless ultra-sound endoscope capsule, wearable computing and TROY workstation.

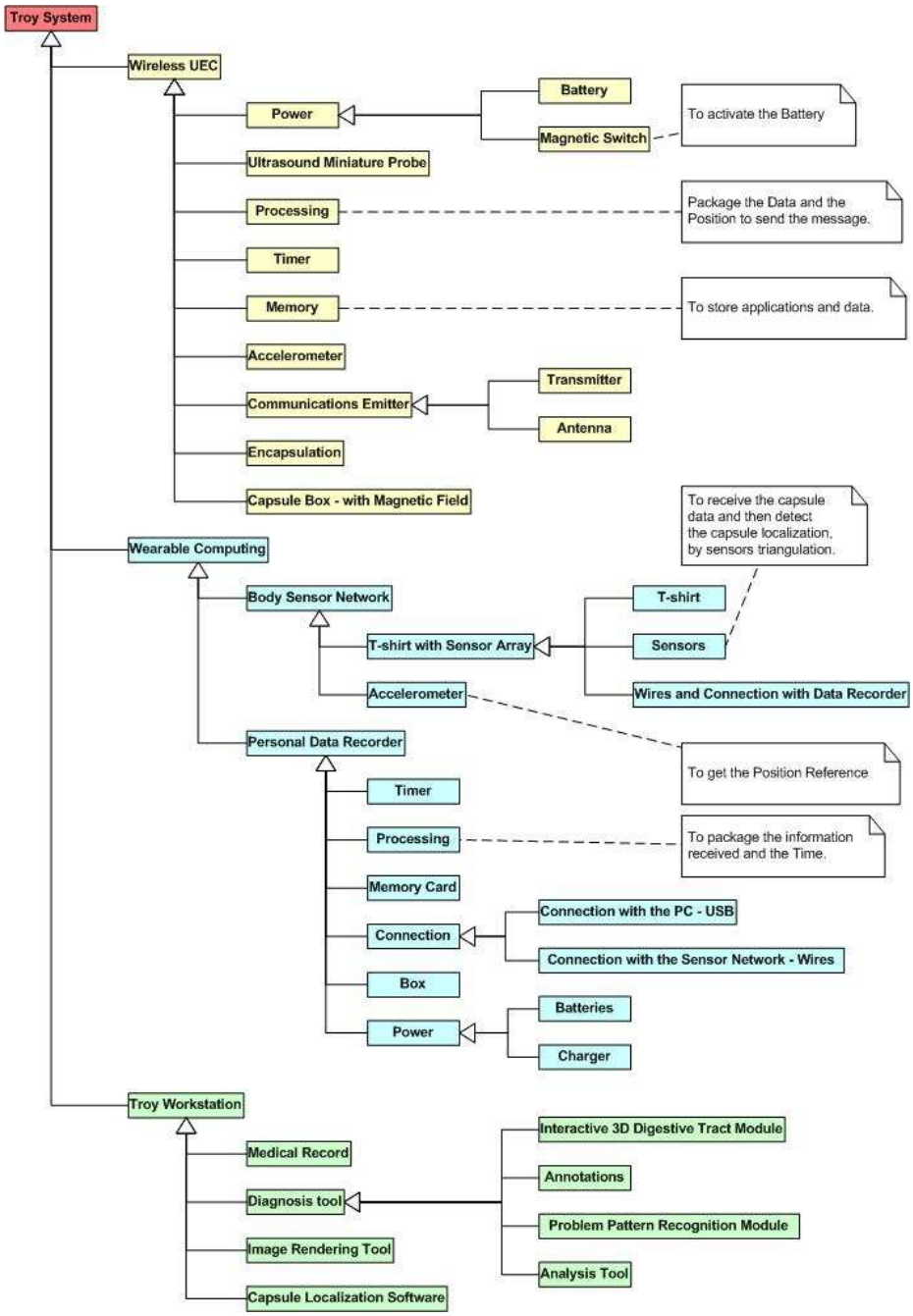


Figure 7 – Work Breakdown Structure

Wireless Ultrasound Endoscope Capsule

At this stage of the project the specification of ultrasound probe and of the others that are included in the capsule are not know. Therefore it is too early to select the correct battery for the capsule. Also the signal probe characteristics are needed to choose the right ADC converter for this application.

None the less, it is already possible to make a first proposal for the capsule battery: two 1.56 V 75 mA-hr silver oxide button cells type SR48. This is a very popular silver-oxide cell that is commonly used in watches and hearing aids. Diameter of the sell is 7.9 mm, height 5.4 mm, weight 1.1 g. Approx. drain 0.15 mA, load 10 kOhm, Manufacturers: Panasonic, Toshiba, Maxell, Varta, Duracell etc. Some manufacturers web sites:

- http://www.smallbattery.company.org.uk;
- http://www.evergreencpusa.com/battery/silvercrossreference.htm

An alternative 1.5V battery is produced by Varta (model LR44), 125mAh with dimensions equal to diameter 11.6mm and height 5.4mm. The diameters is close to the limit dimensions of the capsule. There are also 3V batteries with a diameter of 8mm but the value of the mAh is always lesser than then 30mAh. This value could prove to be enough, but a detailed specification of the capsule components and its consumption is needed.

Due to limitations with the available space, as an alternative only one 3V battery can be used. For example, a battery produced by Shenzhen Sunmoon (model CR1130) is able to give 70mAh. Its dimensions are: diameter 11.6mm, height 3mm. The control of the capsule on/off state will be managed by the use of a reed switch. For tracking the capsule position inside the body a magnet could be used. The use of a known magnetic signature for the capsule is a good idea to detect if the capsule is still inside the patient (it works even if the capsule runs out of power) and maybe it can help find the "exact" capsule position in the bowel. There will be a FM transmitter for data upload to external unit. The power needed for data transmission from the capsule, can be reduced if data is compressed (but extra processing power inside the capsule will be needed) and if the number of "exterior antennas" (RF sensors) is increase.

Wearable Computing

If we will choose the magnet as source of field for the survey of the position of the pill, then we have in mind to make a special "t-shirt" or a "body" that collects and holds firm the sensors close the patient skin. Sensors will be Hall effect sensors type. They are suitable to find the magnetic field intensity. Of course the card will have a demodulator for data receiving, a Real Time Clock, and a USB pen memory. A base board with Linux Embedded will be used. This board might not have any analog acquisition component, so the proper expansion board must be designed.

Workstation

The TROY workstation will enable the doctor to see the results of the examination and perform analyses over the ultrasound endoscope data. At the TROY workstation, the doctor can create the medical record for each patient. After the exam, the data can be transferred from the wearable computer to the Workstation. Then the doctor will be able to see the sequence of 2D Ultrasound images collected during examination and, in order to improve the quality of the diagnosis, the software will also provide a toolset that enables:

- 3D reconstruction of areas of interest selected.
- Insertion of annotations over the images.
- Problem pattern recognition (image analysis and data mining module).

For better interaction with the doctor the TROY workstation interface must be intuitive and user friendly. Thus, it should follow standard rules for software development. The base platform for the workstation will be MS Windows due to its world wide acceptance and support, but other operating system can be supported.

Further details of the developed work are included on Milestone 1.

2.1.3. Deviations from Workplan

Accordingly with the last version of DOW there were no deviations as the task was completed on M7.

2.1.4. List of Deliverables and Milestones

Del. Nº	Deliverable name	Workpackage nº	Date due	Actual/forecast delivery date	Status	Lead Contractor
1.1	TROY Data Sheet	1	M3	M3	Completed	IAITI

Milestone nº	Milestone name	Workpackage nº	Date due	Actual/forecast delivery date	Lead contractor
1	Systems Requirement Draft	1	M7	M7	IAITI

2.2 Workpackage 2 – Sensors Development

2.2.1. Objectives

According to the "Annex I- Description of Work" the objectives of the WP 2 were:

- *To select portable sensors for signal acquisition aiming at the highest level of portability and as much comfortable possible but keeping at the same time adequate performance in accuracy. To assess the feasibility of innovative sensors embedded into conductive textile fibres.*

For the accomplishment of the established objectives the following tasks were foreseen:

a) Task 2.1- Selection of sensors (M3-M13):

i. To select sensors that could be potentiality integrated into the TROY system

ii. This task should produce the deliverable "D2.1- Selection of sensors"

b) Task 2.2- Feasibility of embedded sensors (M3- M22)

i. To assess the feasibility of the sensors.

ii. As a result of this task it should be produced the deliverable "D2.2 – feasibility for embedded sensors"

iii. Task 2.1 and 2.2 should have as a main result Milestone "M2- Sensors Array specifications".

2.2.2. Progress

The work developed on the scope of this WP was leaded by LABOR with contributions from all members.

Task 2.1. – Selection of Sensors

The main endeavour of task 2.1 was focused on the research of the most suitable architecture for tracking the position of the pill inside the body, according to the specification and constraints fixed with Deliverable 1.1. The task All the partners participate in this workpackage leaded by LABOR.

For positioning was presented a body sensor network based on magnetic fields. The idea is to exploit a weak magnetic field generated by a permanent magnet inside the pill and keep track of the position of the capsule. To detect the location of the pill, an array of magnetic sensors is deployed, giving the opportunity to determine the x, y and z coordinates of the capsule as well as its orientation.

The most feasible solution to be implemented in TROY project is to use a small permanent magnet embedded in the pill to track the device during its route, convenient both in terms of the simplification of the requirements of the pill's on-board hardware and for what concerns power consumption, since the magnet does not consume any additional power and less data needs to be transmitted out of the pill. All computing necessary to determine the position can be made on the wearable computing.

The selection of the sensors was performed screening all the possibilities offered by state of the art sensors, and analyzing the performances of two different devices: Anisotrope Magnetic Sensors (AMR) and Hall Effect sensors. While both magneto-resistive and integrated Hall sensors measure the strength of magnetic field components, they do so in different ways and this can directly affect their successful use in a position sensing application. Choosing which of the two is a better fit for our application requires considering sensor characteristics that don't show up on manufacturers' data sheets. To summarize, a designer can expect the following characteristics from the two types of sensors:

For the AMR sensor:

- High sensitivity and a low-noise signal.
- A large operating distance from the magnet is possible.
- Angle of measurement is up to 180° but with higher angle sensitivity.
- Possible disturbance from external stray fields.

For the Hall sensor:

- Because of internal pre-amplification, sensitivity is comparable.

- Sensor functions only in the near field of the magnet.
- Angle of measurement is up to 360°.
- Possible disturbance from external stray "dipole fields."

The final choice, according to the aforementioned features, was to opt for AMR sensors

Consequently, the tracking architecture will be made up of a neodymium super magnet inside the pill, capable of generating static magnetic fields in the range of 12.000-13.000 Gauss, and a set of six sensors to be placed on the skin of the patient in order to measure the local magnetic field.

Afterwards, given the well known magnetic dipole equation, which correlates the magnetic field generated by a dipole with the distance, it will be possible to calculate the distance of each sensor from the pill by inverting the following equation:

$$B(m,r) = \frac{\mu_0}{4\pi|r|^5}\left[3r(r\cdot m) - |r|^2 m\right]$$

Where ***B*** is the magnetic induction of the field generated by a permanent magnet having a magnetic dipole moment ***m***, located at a position ***r***.

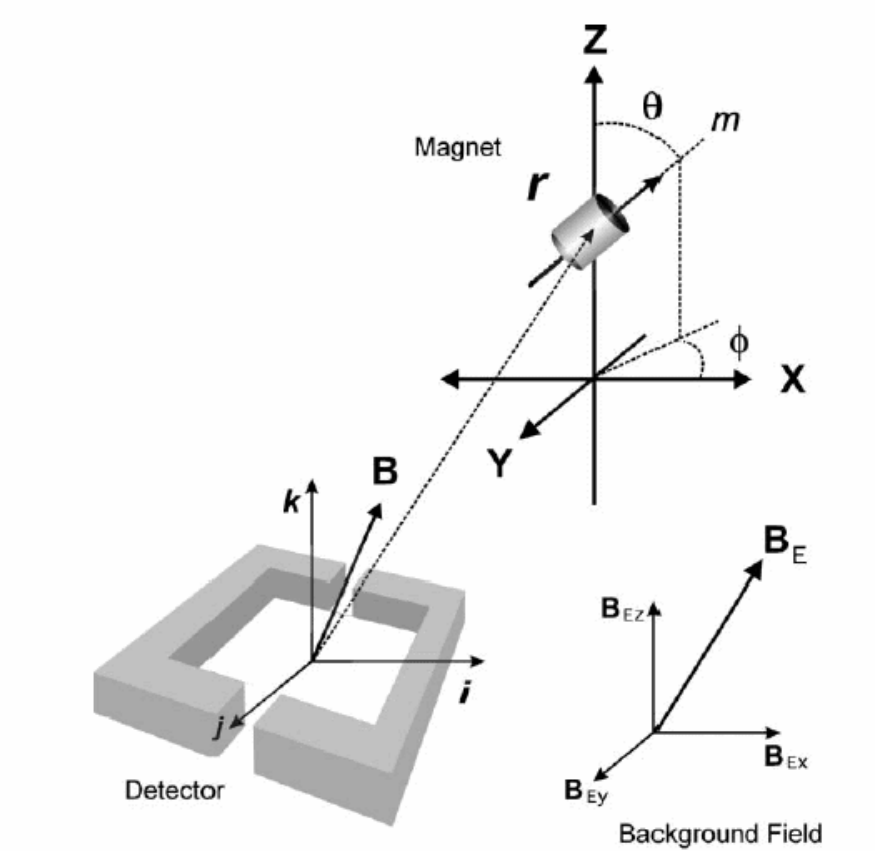


Figure 8 - Relationship between dipole moment (m) and the detection of the related magnetic field (B) from the permanent magnet located at a distance (r) from the detector.

Finally, in order to respect specification about wearable unit consumption and precision, the number of magnetic sensors placed on the abdomen has been decided. A good number of sensors is 5, placed like is shown in the figure below.

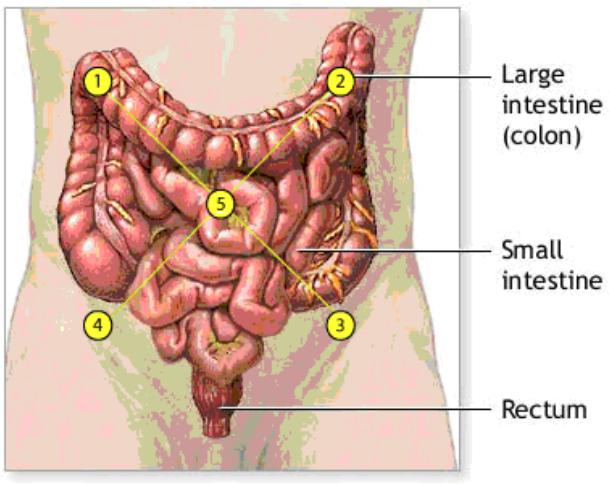


Figure 9 - Five magnetic sensors placement on the body

Once the configuration of the sensors and the algorithm for position estimation have been defined, the following step was the definition of a test set up for the assessment of the accuracy of this system. A possible approach based on an aluminium can with a specifically designed measurement system was used for the evaluation of the performances of the chosen sensors. The magnet will be put inside the can in a known position and the sensors placed outside the can will gauge its magnetic field, calculating the position by inverting the dipole's equation.

The parameters of ultrasonic signal acquisition were analysed as they determine the amount of data which should be received and the required communication speed. Taking into account the number of elements in a transducer array (16 or 32), the required maximal measurement depth into the body (75 mm), the sampling frequency (40/60 MHz) and the dynamic range of the A/D converter (12 bits), it is possible to estimate that the single image may contain 90-300 kBytes of information. It was expected that complete radial image will be obtained each second. So, the required communication speed between the ultrasonic capsule and the electronic unit outside human body should be 90-300 kBytes/s.

The expected result of the whole measurement procedure is 3D ultrasonic image of a gastrointestinal tract. Such an image can be created only precisely fitting measurement data obtained at different capsule positions in the body. As the capsule not only moves in the tract, but also can rotate around its axis, it is necessary to measure both the spatial and the angular position of the capsule in the body. It can expected, that the uncertainty of spatial positioning should be in the range of millimetres (1-2 mm). More complicated is to determine the required uncertainty of angular measurements. In the case of analysis of the reflectors situated close to the pile surface (1-10 mm), the uncertainty of 5° is acceptable (the half angle of the 32

element transducer array). However, such uncertainty will be not suitable to create the image of the reflectors situated at longer distances. So, the general required uncertainty for angular measurement should be approximately 1°.

Additional requirement for sensors is that they should not create acoustic, magnetic and electric noise in the frequency ranges of ultrasonic measurements, that is, in the frequency ranges (2-14) MHz.

Task 2.1 was concluded with the production of Deliverable 2.1 - Selection of sensors which presents more detailed information about the performed work.

Task 2.2- Feasibility of embedded sensors

Task 2.2 was concluded during the second year and Deliverable 2.2 - Feasibility for Embedded Sensors was produced.

The Ultrasound Transducers

In order to choose the most suitable dimensions and frequency of the ultrasonic radial array, to be inserted inside the capsule with the dimensions of 11 mm x 26 mm, simulations of different array configurations were performed.

Dimensional characteristics of the array are:

The outer diameter is D_o=11mm, the outer radius R=5.5mm, the transducer width is l_t=2mm, and the gap between array elements is l_g=0.5mm (Figure 10).

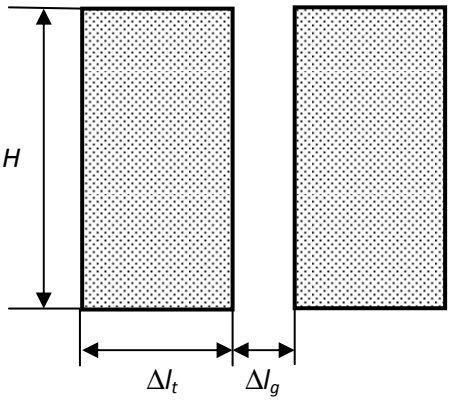


Figure 10 - Geometry and dimensions of the elements of the circular array

The perimeter of the circular array is L=34.558mm and the possible number of elementary transducers *in the array is* N=13.82. It means $N \leq 13$. If to reduce slightly the width of the elementary transducer, the number of elements may be up N=16.

For the 16-elements array each ultrasound emitter/sensor is a parallelepiped of 2x5x0.38mm.

For the 32 transducers array the dimensions of elementary transducers are 0.7x5x0.38 mm.

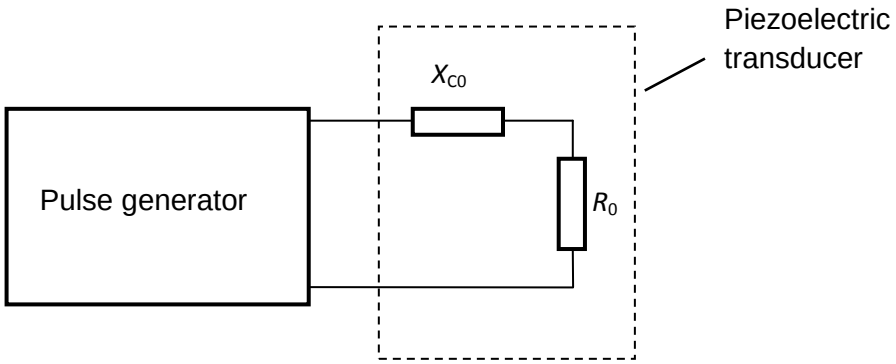


Figure 11 - Ultrasonic piezoelectric transmitter presented as the electrical load for the pulse generator.

Each piezoelectric element (Figure 12) is made of piezoceramics Pz-29. The thickness of piezoceramics is λ/2 that is 0.38 mm. The front surface of each element is coated by acoustic matching layer made of Al_2O_3+epoxy (ultrasound velocity c=2.54 km/s). The thickness of the layer has to be λ/4, that equals to 125 μm, the acoustic impedance Z = 4 MRayl. The backing was made of W+epoxy, the thickness of it is ~0.5 mm, the acoustic impedance Z = 8 MRayl.

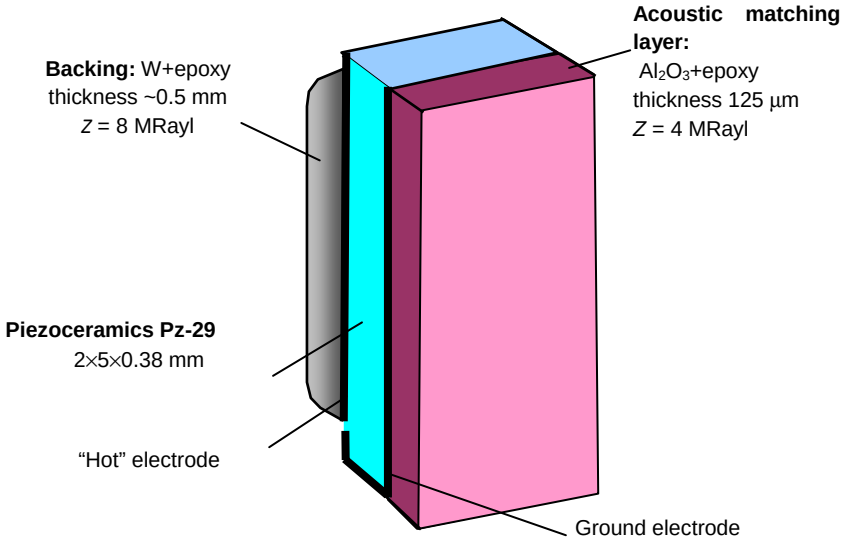


Figure 12 - 5MHz single element

In Figure 13 the photo of a single element 2x5mm is presented, in the photo of a single transducer with backing and acoustic matching layer is presented.

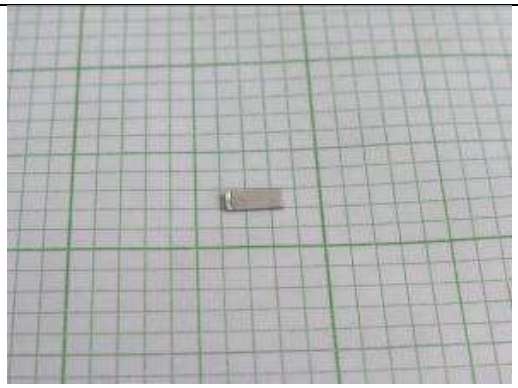


Figure 13.- Photo of a single piezoelectric element 2x5mm

An experimental chamber (Figure 14) was designed for testing of the algorithm of pill's electronic. It contains four piezoceramic transducers as part of the array, the connectors for connecting of each transducer manually or using the designed electronic, the plate with four planar reflectors at different distances for each transducer. The transducers No 1 – No 3 are designed for the 32 element array and transducer No 4 is designed for the 16 element array, which will be used for the initial experimental testing of the pill.

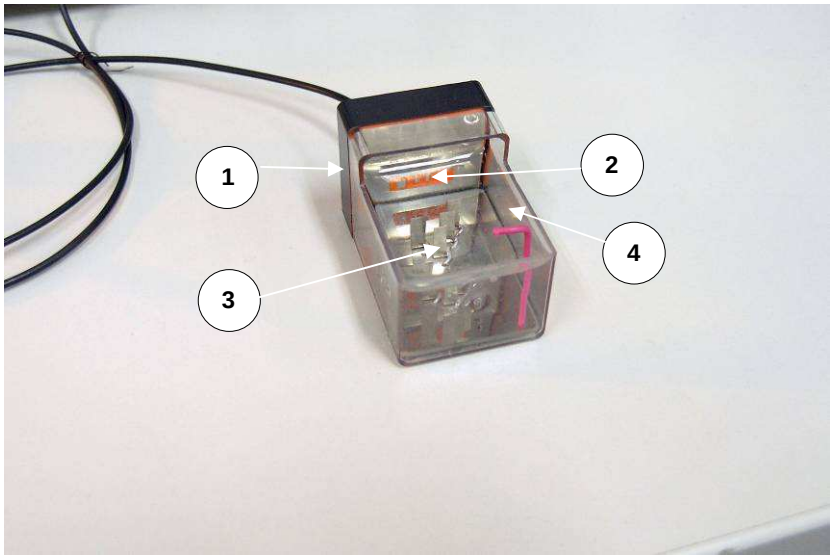
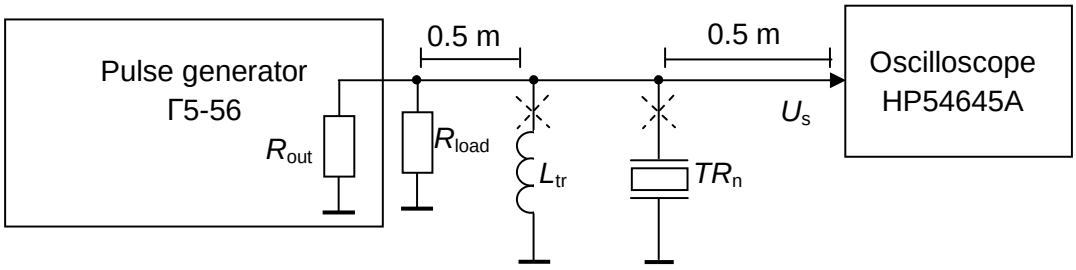


Figure 14 - Experimental chamber of ultrasonic transducers for testing of pill's electronic. 1 – chamber's housing; 2 – ultrasonic transducers; 3 – plane reflectors; 4 – chamber filed by water

The experimental chamber of ultrasonic transducers was investigated using the set-up shown in Figure 15.



R_{out} = 50 Ω; L_{tr} = 2.1 μH;
C_0 = 540 pF (5 MHz, 16 elements)
R_{load} = 50 Ω;

Figure 15 - Block diagram of the experimental set-up for the ultrasonic transducer's investigation

The transducers were excited by the negative pulse with the amplitude U_{exc} = 10 V and duration Δt = 0.08 μs. The signals reflected from the plane reflector for transducer 1 is presented in Figure 16. The time delay of the received signals by each transducer is different because of the different positions (14 ÷ 23 mm) of the plane reflectors. The time window for the amplifier and ADC should be not less than 40 μs from the time instant of the transducer excitation.

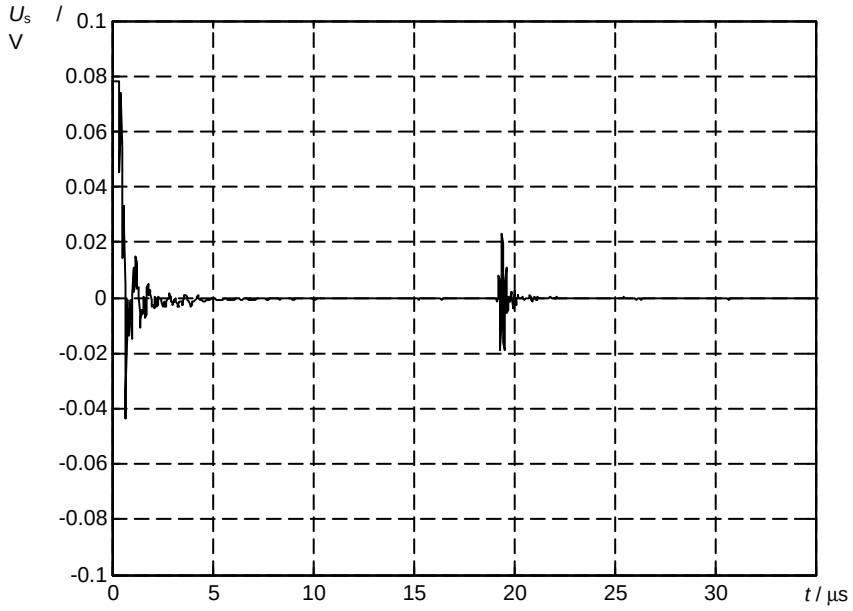


Figure 16 - The pulse reflected from the plane reflector received by the transducer No. 1.

The Body Sensors Network

Troy pill contains a magnet, the one chosen in Deliverable 2.1, necessary to measure the pill position inside the body. Every magneto resistive sensor of the measurement array gives the value of magnetic field in that point, for X, Y and Z direction.

As presented in deliverable 2.1, the magnetic field generated by a permanent magnet having a magnetic dipole moment ***m***, located at a position ***r*** (Figure 8), is given by:

$$\vec{B}(m,r) = \frac{\mu_0}{4\pi|r|^5}\left[3\vec{r}(\vec{r}\cdot\vec{m}) - |r|^2\vec{m}\right] + \vec{B}_{earth}$$

That's a relationship between the magnetic field measured and the distance sensor-magnet. Let's see this relationship:

$$\Delta\vec{B}(m,r) = \vec{B}(m,r) - \vec{B}_{earth} = \frac{\mu_0}{4\pi|r|^5}\left[3\vec{r}(\vec{r}\cdot\vec{m}) - |r|^2\vec{m}\right] =$$

$$= \frac{\mu_0}{4\pi}\left[\frac{3|m|\cos\alpha}{|r|^4}(r_x\hat{x} + r_y\hat{y} + r_z\hat{z}) - \frac{1}{|r|^3}(m_x\hat{x} + m_y\hat{y} + m_z\hat{z})\right] = \Delta B_x\hat{x} + \Delta B_y\hat{y} + \Delta B_z\hat{z}$$

Where $\vec{B}_{earth}$ is the offset due to the magnetic field of the planet: it is constant in the measurement zone.

The equation becomes:

$$\vec{B}_x + \frac{k_1}{|r|^3} = \frac{k_0}{|r|^4}r_x \quad \text{where} \quad k_0 = \frac{\mu_0}{4\pi}3|m|\cos\alpha \quad \text{and} \quad k_1 = \frac{\mu_0}{4\pi}m_x$$

$$\vec{B}_y + \frac{k_2}{|r|^3} = \frac{k_0}{|r|^4}r_y \quad \text{where} \quad k_2 = \frac{\mu_0}{4\pi}m_y$$

$$\vec{B}_z + \frac{k_3}{|r|^3} = \frac{k_0}{|r|^4}r_z \quad \text{where} \quad k_3 = \frac{\mu_0}{4\pi}m_z$$

Since $|r| = \sqrt{r_x^{\,2} + r_y^{\,2} + r_z^{\,2}}$, inverting the last three equations we have (calling $|r| = \omega$):

$$\omega^6(B_x + B_y + B_z) + 2\omega^3(B_xk_1 + B_yk_2 + B_zk_3) + (k_1 + k_2 + k_3 - k_0) = 0$$

Solving this equation respect to $|r| = \omega$ gives the distance between the single sensor and the magnet inside the pill. Crossing all these results from the body sensor network it's possible to have a Gaussian probability to know where the pill magnet is and to reconstruct the trajectory of the pill inside the body.

The magnet employ for testing the magnetic sensors is shown in Figure 17. This magnet has one remnant of 1.35 T, one size of 0.5x0.5x0.2 cm.

Figure 17 - Magnet using for pill tracking.

The magnitude of the magnetic moment is fixed for any particular magnet and is given by:

$$|m| = \frac{B_r}{\mu_0} V$$

Where B_r is the remnant flux density, μ_0 the fundamental constant ($4\pi \times 10^{-7}\, Hm^{-1}$) and V is the volume of magnet. The remnant of this magnet is (theoretic value):

$$|m| = \frac{1.35}{4\pi \times 10^{-7}} \times 5 \times 10^{-8} = 0.054 Am^2$$

Using a magnet with this magnetic moment $\vec{m}$, an estimated distance of 15 cm between magnet and sensor, and with one pole of the magnet directly facing the sensor, the Magnetic Induction is:

$$|B| = \frac{2\mu_0}{4\pi r^3} |m| = 3.2\mu T = 32 mGa$$

The HMC1051Z and HMC1052 [2] magneto resistive sensors from Honeywell are used to measure the intensity of the magnetic field outside the human body. The sensors outputs three analogue voltage signals, one for each axis (X,Y,Z).

The output voltage range is 0-5 V, where 0 V corresponds to -6 Gauss of magnetic field and 5 V represent +6 Gauss and 2.5 V is 0 Gauss. The resolution of sensors is 120 µGauss and it has a sensitivity of about 1 mV/V/Ga. The sensitivity of sensors with a voltage power supply of +5 V is 5 mV for Gauss.

A set/reset circuit, as shown in Figure 18, was designed to recover the sensor from magnetic saturation, which occurs when the sensors is exposed to a field in excess of 20 Gauss.

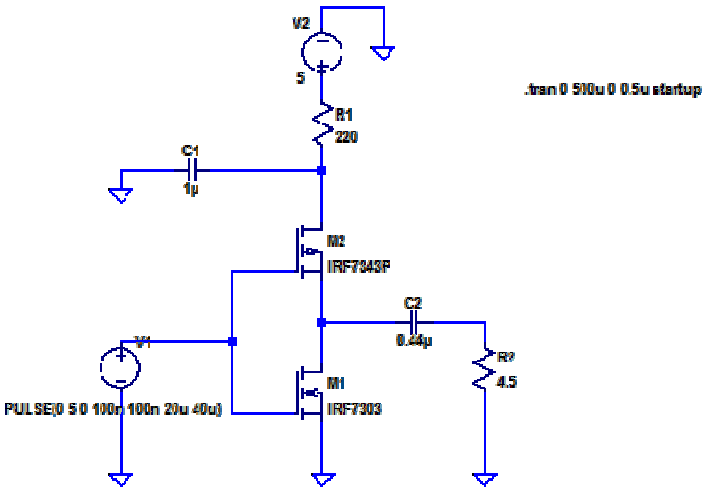


Figure 18 - Circuit set/reset.

This circuit is controlling by current pulse of 2 µs, a duty cycle of 0.1% or less and an amplitude of 0.5 A. The differential output signal of magnetic sensors (V+, V-) is sent to the differential input of instrumentation amplifiers. Amplifier stage is designed in order to increase the sensors sensitivity and increase the signal noise ratio. The output signal is buffered and it has a mean value of 2.5 V, set by a voltage reference.

The chosen components of the expansion board are:

- Instrumentation Amplifier: 3 x Analog Device AD623
- Voltage reference: Linea Technology LT1019-2.5 V
- Op Amps: Maxim MAX4250
- International Rectifier: IRF7309

The Figure 19 shown the PCB whit the sensors mounted, the front end electronics and the electronics for set/reset.

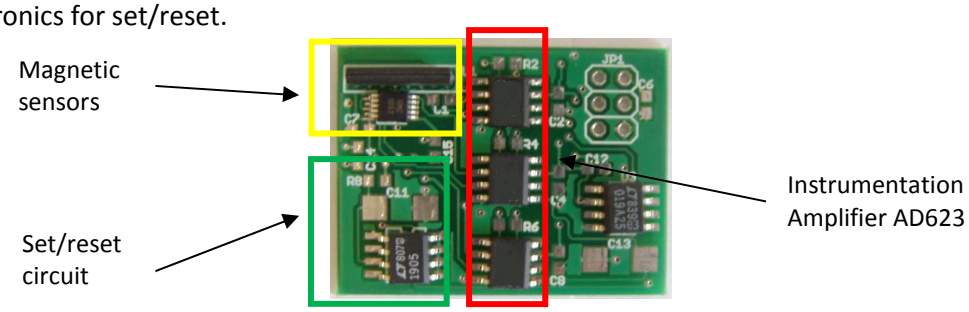


Figure 19 - Single transducer printed circuit board.

An experimental set-up was set to measure the magnetic moment of the magnet. The measurements were made placing the transducers in a fixed position and placing the magnet with its axis aligned to the sensible axis of a magneto resistive sensor. The sensible axis was each time different: a set of measurements were made along x axis, another along y axis and finally along z axis. For example, along the x axis, the magnet was moved in a range of 5 to 15 cm (nominal distance from the pill and body surface), whit a step of 1 cm. The measurement system is shown in Figure 20.

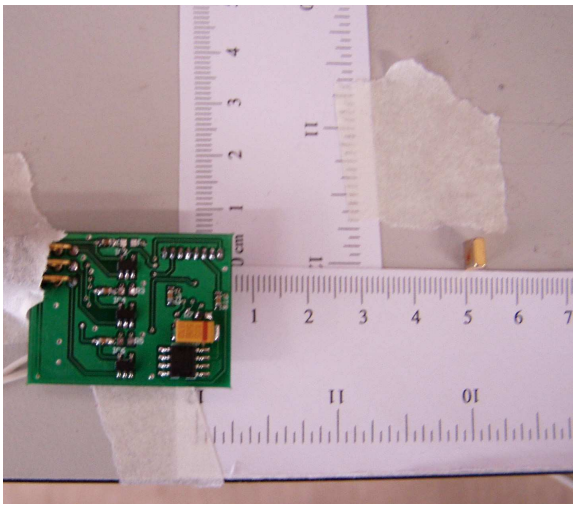


Figure 20 - Measurement of magnetic field at different distances (5 cm in the photo).

The first measurement was made without magnet, to know the offset signal. The voltage value measured in this condition represents the environmental field (including Earth's magnetic field) and the offset of sensors. This value is used in the algorithm of tracking [3] for the cancellation of environmental field. For calculate the magnetic field is necessary to subtract 2.5 V from each sensor output voltage, use the absolute value of difference as the magnitude of the magnetic field, divide it by the gain and obtain the following expression:

$$B_t(mGa) = \frac{\left| ADCValue(outputsensors) \cdot 10^{-3}V - 2.5V \right|}{\frac{Gain}{5\times10^{-3}V}} \cdot 1000 \text{ Where } Gain = 370$$

Using data obtained from these tests, it's possible to calculate the values of magnetic moment $|m|$:

$$|m| = \frac{2\pi r^3}{\mu_0}|B| \quad [\text{A·m}^2]$$

This experimental value is close to the theoretic value. In fact the value of magnetic moment $|m|$ calculated is 0.054 Am^2 while the value of $|m|$ obtained from the experimental measurements is about 0.058 Am^2.

The same practice has been made for all 5 sensors, along the direction X in front of north pole of magnet. In Figure 21 is shown the diagram of position versus the magnetic field measured along the X direction (X axis aligned to the magnet axis), for each sensor. Each sensor response is very similar to the others.

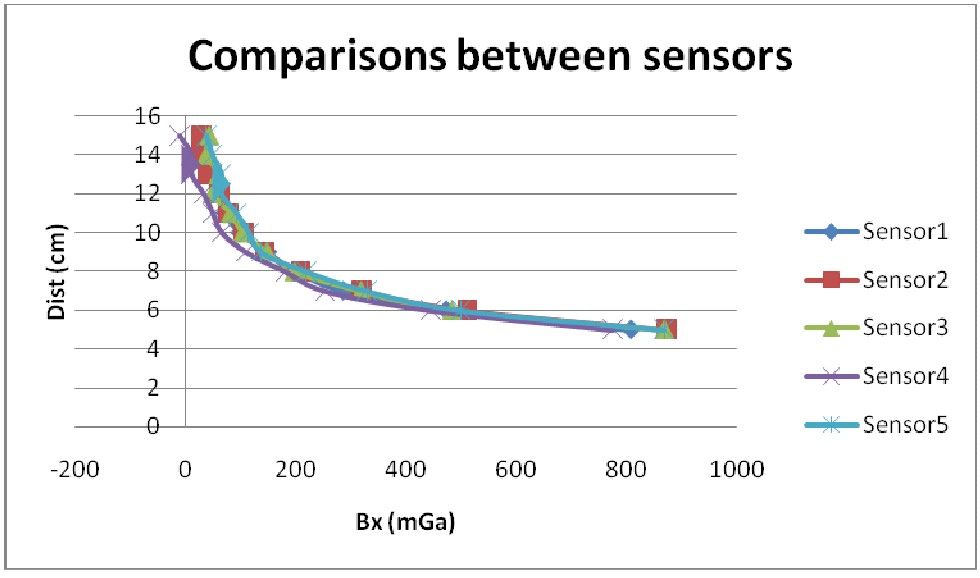


Figure 21 - Measurement of magnetic field along the direction X for the five

The magnetic flux $B_t = \left(B_{tx}, B_{ty}, B_{tz}\right)$ created by a permanent magnet is a high order nonlinear function of the magnet's position $X_t = \left(a, b, c\right)$ and its magnetism's orientation $H_0 = (m, n, p)$. As it is shown in Deliverable 2.2 the magnet's position can be obtained from the magnetic flux measured by the five sensors.

The magnetic field signals (3 from each sensor) are converted into digital value by the A/D converter MAX1238 at 12-bit. The A/D converter uses a reference voltage of 4.096V so each value of the 0-4096 range corresponds to 1 mV (4.096V/2^{12}) which is equivalent 660 µGauss.

2.2.3. Deviations from Workplan

With respect to what was established on DoW, the WP2 suffered the following delays:

- Task 2.1 was completed with a delay of 5 months mainly because of the dependency with Deliverable 1.1. The selection of the right effect to measure (and consequently the right sensors) also took a little longer than expected because several alternative solutions were considered (e.g. RF triangulation)
- A working version of Deliverable 2.2 was released in month 18 but as some improvements were made with beta prototype a revision of the deliverable was produced in the end of the project.

2.2.4. List of Deliverables and Milestones

Del. Nº	Deliverable name	Workpackage nº	Date due	Actual/forecast delivery date	Status	Lead Contractor
2.1	Selection of sensors	2	M5	M11	Completed	Labor
2.2	Feasibility for embedded sensors	2	M12	M18 Revision M30	Completed	Labor

Milestone nº	Milestone name	Workpackage nº	Date due	Actual/forecast delivery date	Lead contractor
2	Sensor Array specifications	2	M12	M22 Revision M30	Labor

2.3 Workpackage 3 – Electronics System Design

2.3.1. Objectives

According to the "Annex I- Description of Work" the objectives of the WP 3 were:

- *To define in all its parts the electronic architecture of the TROY system, including energy supply and wireless communication. And to produce the full range of designs and electric schemes necessary to manufacture the alpha prototype of Task 6.1*

For the accomplishment of the established objectives the following tasks were foreseen:

a) **Task 3.1 – Selection of Hardware components (M3-M9)**:
   i. To identify hardware components that will be used on TROY system
   ii. The deliverable "D3.1- Draft Architecture of TROY device" should be produced.

b) Task 3.2.1 – Energy supply (M5- M21)

i. To evaluate the energy requirements of the system to provide the autonomy required and perform the tasks expected.

c) Task 3.2.2 – Electronic design (M5-M25)

i. To produce the full range of designs and electric schemes necessary to manufacture the alpha prototype.

ii. Through tasks 3.2.1 and 3.2.2, deliverable "D3.2 – Designs and electronic schemes of TROY device" should be produced.

2.3.2. Progress

The WP leader of WP3 is LABOR which has been responsible for all the work developed with the support of the other contractors.

Task 3.1. Selection of Hardware Components

This task was devoted to the design of the block architecture and to the selection of the most suitable components, described in detail in Deliverable 3.1. It was completed on M11 with the production of Deliverable 3.1.

The main goal of the design process was to ensure at the same time a high level of performances of the system and low power consumption, aiming to the maximum possible system autonomy.

The main activities of this Task were the establishment of:

1 – Pill Architecture and components

Having as premises the main functionalities and constrains (dimension and power consumption) of the pill, the architecture of the system was established named of "Digital proposal" because data transmission is fully digital.

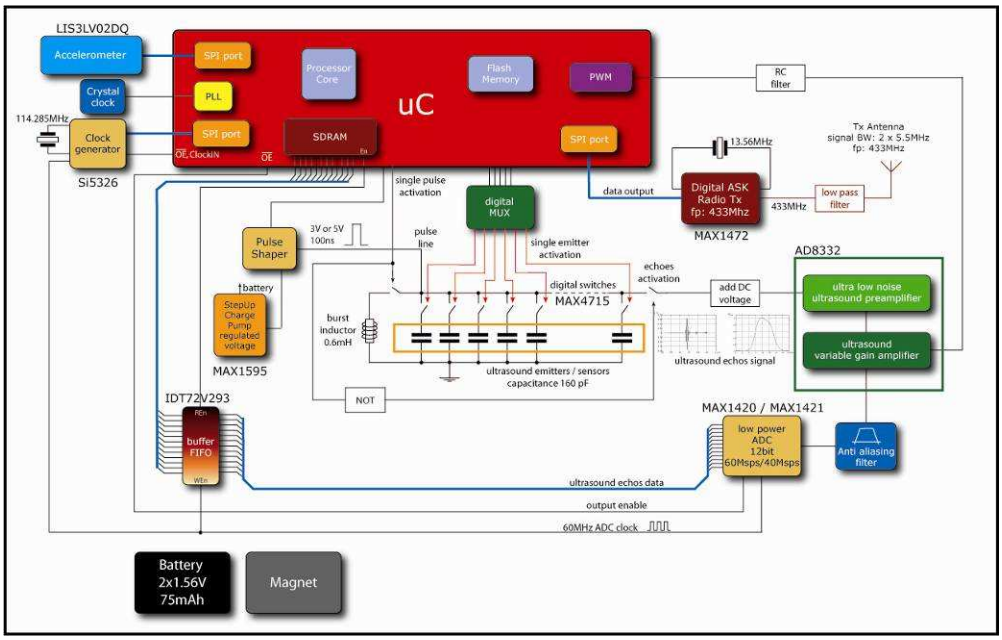


Figure 22 - TROY pill architecture

The architecture of the system is composed by:

- An array of 32 ultrasonic emitters/sensors, for bowel scanning
- A three-axes digital accelerometer, to measure inclination and orientation of the pill
- FPGA driving an analog acquisition block and a digital transmitter to send data to the wearable unit
- A neodymium super-magnet for pill positioning

The basic functionalities of each block of the proposed system are the following (a detailed description is presented on the deliverable 3.1):

a) Ultrasonic Pulses generation

The blocks involved in this sub-component are:

- Step-up charge pump regulator, used to have voltage greater than 3 V if necessary
- Pulse shaper circuit, controlled by the CPU; it shapes the pulse with the desired width and amplitude
- Burst inductor, to improve the performances of the array
- The digital switches, controlled by the CPU, to select the single transducer to be activated at the desired moment

b) Analog acquisition blocks

Components used for the acquisition of ultrasonic echoes are:

- Ultra low noise ultrasound amplifier (LNA)
- Variable Gain Amplifier (UVGA)
- Third-order passive anti aliasing filter, with corner frequency @ 20 MHz
- Analog to Digital Converter, interfaced to the CPU

c) Central processing unit

The core of this pill architecture proposal is the CPU; taking into consideration the mentioned constraints on power consumption, dimensioning, capability of interfacing to 60 MHz ADC (clock generation and data acquisition), we propose to adopt a processor based on Actel Igloo FPGA. This FPGA is designed to be implemented in small, portable electronic devices and it is optimized to work in systems with operation time is much smaller than idle time.

d) Digital transmitter

The digital transmitter is driven by the FPGA and it sends data outside the pill.

e) Antenna issues

Good antenna design is a critical factor in obtaining good range and stable throughput in a wireless application.

2 - Wearable Unit architecture and components

For the wearable unit it was defined the following structure:

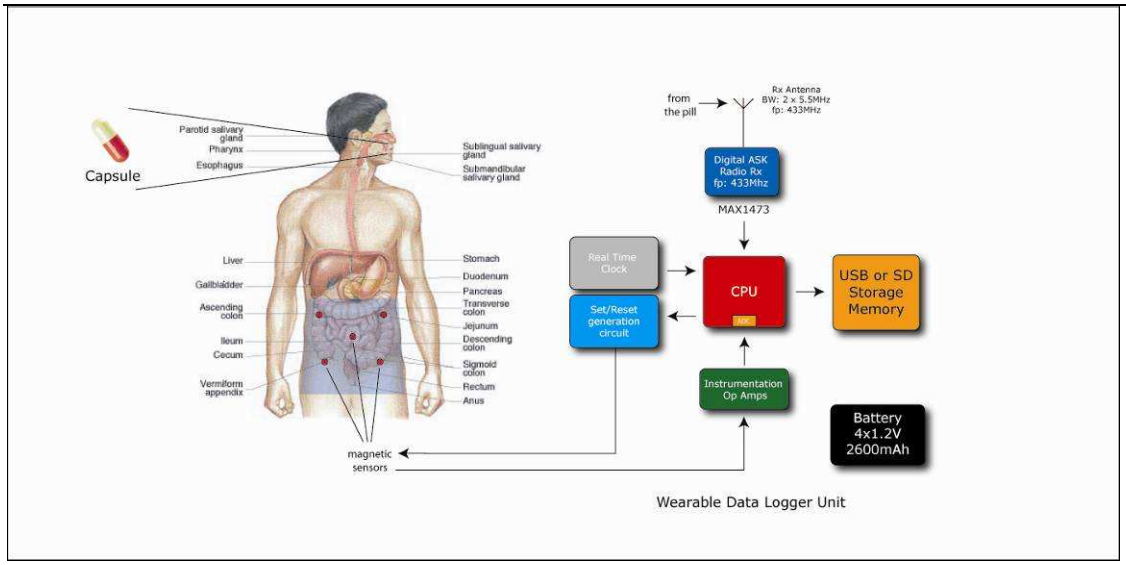


Figure 23 - Wearable unit architecture

- Digital Receiver
- Real Time Clock, useful to add date and hour to the pill information
- Magnetic sensors and Set/Reset generation circuit
- Instrumentation amplifiers
- Storage memory
- Acquisition board and CPU

A complete technical specification of the wearable unit was defined (including the data file format specification, according with the WP4 elaboration software). It was also selected the components for wearable unit ADC, and RF signal acquisition (detect capsule position and receive capsule data) and the electronic components for wearable unit data elaboration core and storage unit.

Task 3.2.1 – Energy supply and Task 3.2.2 – Electronic design

These tasks were completed in the second year. A first version of deliverable D3.2 was delivered on Month 15 but some improvements need to be done in the electronic design to assure the integration with ultrasonic probe. Alternative energy supply components were identified and final choice was done when electronics design was complete.

Electronic Design for the Pill

Two versions of the pill electronics design were made because of some problems detected only with practice with alpha prototype. Both versions will be presented.

The pill prototype follows the architecture (Figure 23) described in Deliverable 3.1. First pill prototype was realized using commercial components: Table 1 presents a summary of

electronics components involved in pill design, with some information about their consumption and the dimensions.

Component	**Pin numbers**	**Consumption**	**Size**	**Component model and notes**
Quartz – transmitter	2	-	10x15mm	16MHz
Quartz – CPU and Quartz – ADC	2	-	10x15mm	30MHz
Accelerometer	28	3.3V; 0.60mA	7x7x1.8mm	LIS3LV02DQ
Radio Transmitter	8	3.3V; 5.3mA	3x3mm	nRF2401 and other components around, like the antenna
CPU	80	3.3V;	15x15mm	PIC18F8722
Analogue switches	5	3.3V; 0.04uA	2x2mm	18 analogue switches for the 16-sensors array
Multiplexer	24	3.3V; 8uA	15x10mm	74HCT154
Pulse Shaper	-	-	-	different components and logic ports involved
Ultrasound sensors	16+1 (GND)		Cylinder, 5x11mm	
Low Noise Amplifier and Variable Gain Amplifier	28	5V; LNA:12mA; VGA:17mA	10x6.5mm	AD8331
Memory buffer	80	3.3V; 35mA	15x15mm	-
ADC	48	3.3V; 75mA	9x9x1.4mm	Consumption will be lower if we use 30MHz ADC instead of 60MHz type
Quartz – ADC	2	-	-	-

Voltage regulator	8	-	4x4mm	MAX1595
Batteries	2	Power supply: 2x1.54V; 75mAh	Cylinder: 7.9x5.4mm	-
Magnet	-	-	5x5x2mm	-
Reed Magnetic Switch	-	-	Cylinder: 3.68x11.43mm	www.reedswitchdevelopments.com for custom switches http://www.reedswitchdevelopments.com/2104series.html

Table 1: summary of commercial electronics components used in first prototype

First version of the TROY pill follows the logic diagram presented in Figure 23. Aim of this first version of the pill was to validate the idea of measuring echoes using the proposed analogue chain. The successive hardware revision implements a higher component integration, to decrease the consumption and noise in the analogue chain. The details of electronic scheme are shown in the deliverable 3.2.

Device PCB scheme

The board has four layers. Layer 1 is shown in Figure 24.

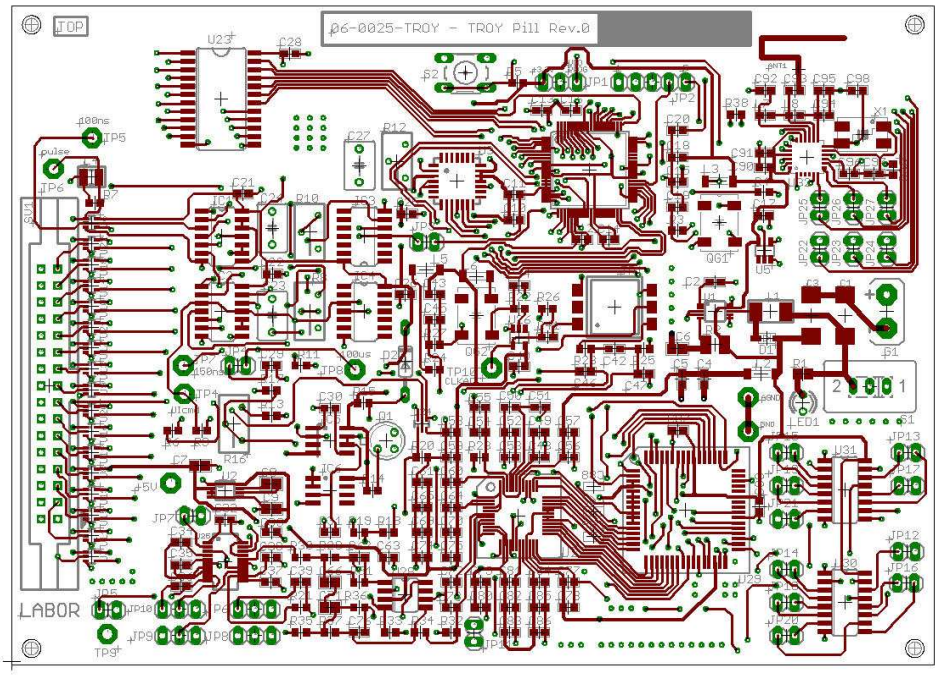


Figure 24: PCB top layer

Layer 1 is a signal and supply layer. At the top right is visible the PCB antenna. On the extreme left is visible the transducer connector. At the top center are visible the CPU and the accelerometer, while at the bottom center are visible the ADC and the FIFO. Layer 2 and 3 are ground layers, for analog ground on the left and digital ground on the right. Grounds connection point is on the top layer, close to the supply section. Two grounds types and two ground planes are necessary to have a more efficient ground return currents and to minimize the link inductance. The bottom layer is a signal layer. In the center it has the data bus involved in reading data from the FIFO memory.

The final realization of the printed circuit board, produced in Italy, is shown in Figure 25.

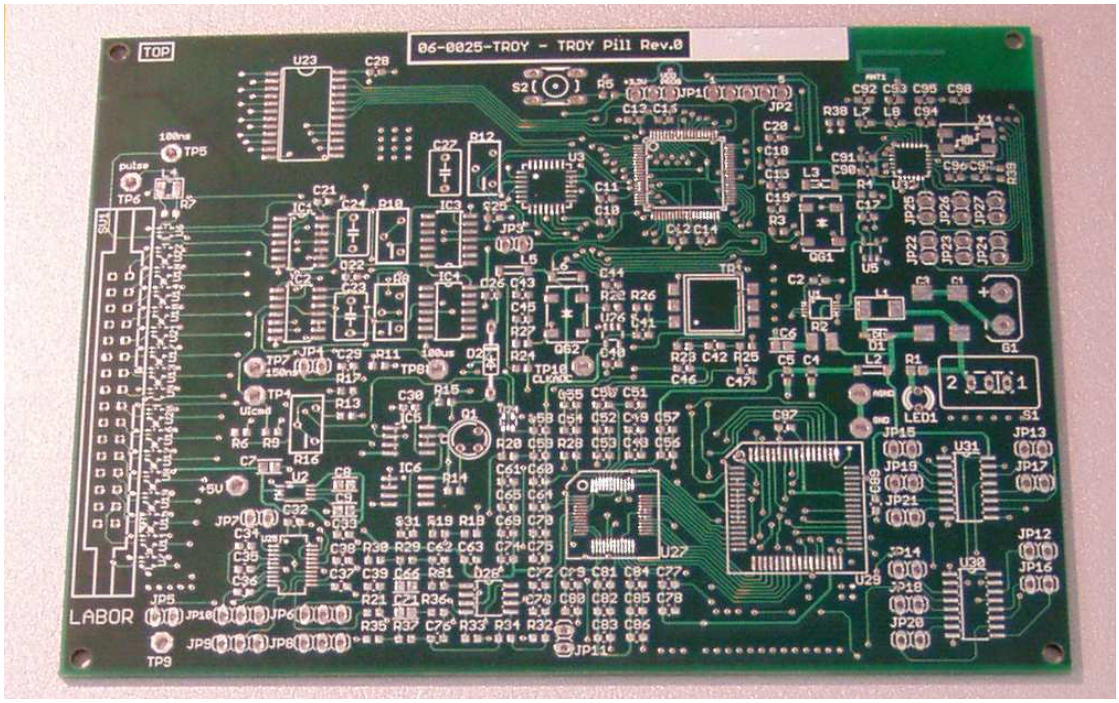


Figure 25: Troy pill rev.0 PCB prototype top photo.

Board in detail is visible in Figure 26, where each functional block is contained inside colored rectangles. Testing phases were:

1. Supply voltages, +3.3V and +5V
2. CPU, accelerometer and radio TX hardware test and firmware programming
3. Short pulses generation
4. Test with the Ultrasound Institute box.
5. Analog amplifier
6. ADC (first phase working at low frequency and after at 30MHz)
7. Buffer management

Main problems arose during tests phase were:

- Too much noise present in the analog amplifier input.
- When the analog amplifier is switched on there is too much attenuation of the short excitation pulse voltage.
- 3 bit noise on the ADC.
- Buffer synchronization.

To solve all these problems in a successive hardware revision it's possible to do:

- Reduce path for analog signals.
- Change discrete components with SMD ones.
- Make a smaller board.
- Change the Maxim MAX1595 with another chip, suitable for this application.

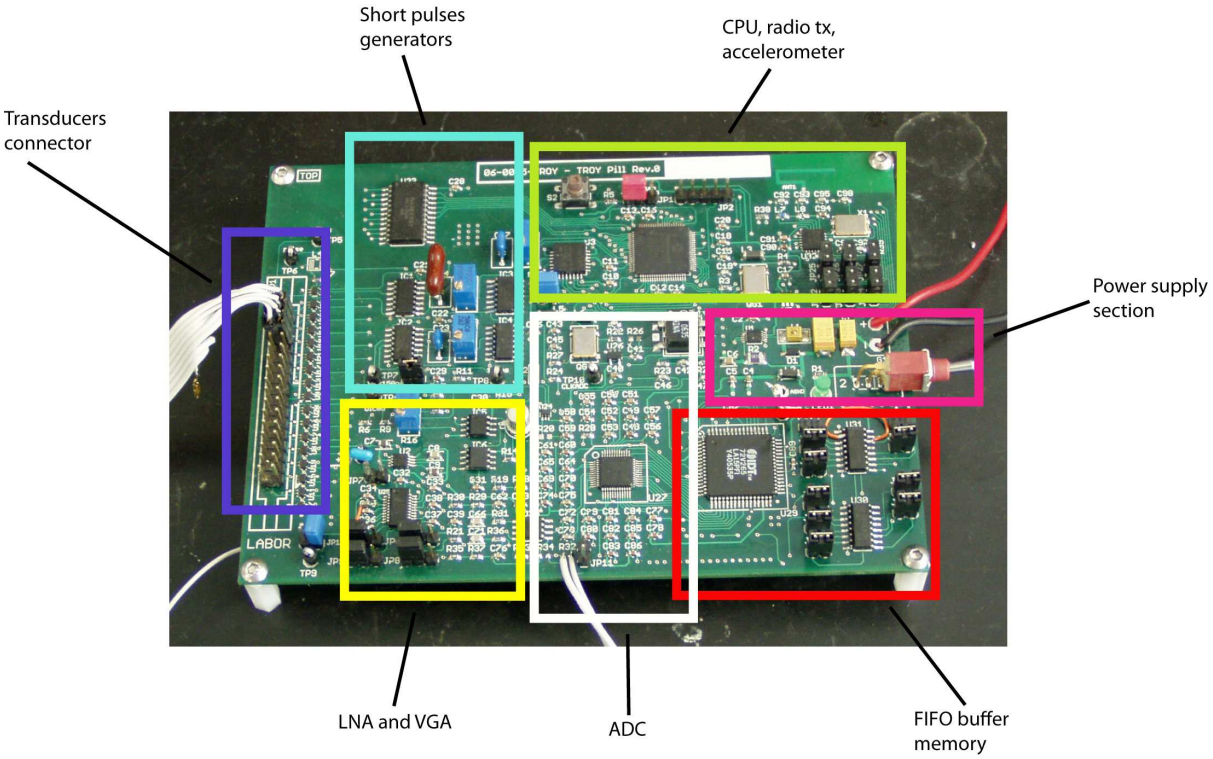


Figure 26: Troy pill rev.0 PCB prototype assembled, with functional blocks explained.

The Pill Revision

In this section it's presented the new hardware revision of the pill. Some hardware changes were done after tests on the first version of the hardware:

✓ Sampling frequency is 40MHz for the ADC, connecting a 18Mhz pass band filter after the VGA amplifier.

✓ New organization of power supply units, +3.3V for analog to digital, +5V and -5V for the frontend, +5V to the excitement of ultrasonic sensors.

✓ The command digital gain can be done with a digital trimmer so we fit into the attenuation curve signal in the human body.

✓ Noise reduction in frontend amplifiers: two bypass capacitors for each active component of frontend amplifiers: 100nF and 100pF.

✓ ADC clock is not more a balanced signal.

✓ Increase input impedance of the anti aliasing filter to avoid matching losses from the amplifier to the ADC.

✓ The write enable delay line is not more necessary.

✓ Change radio transmitter to 2Mbps.

✓ Improve stability (feedback chain) of the AD8331.

✓ Changing the analog switch to having one with a lower input capacitance than the model currently used.

✓ EMI filter between AGND and DGND.

✓ Match the output pulse generator impedance with the impedance of ultrasonic sensor.

✓ Change the window acquisition time from 100us to 40us.

In Figure 27 it's shown the new architecture: main differences are in the sensor frontend amplifiers.

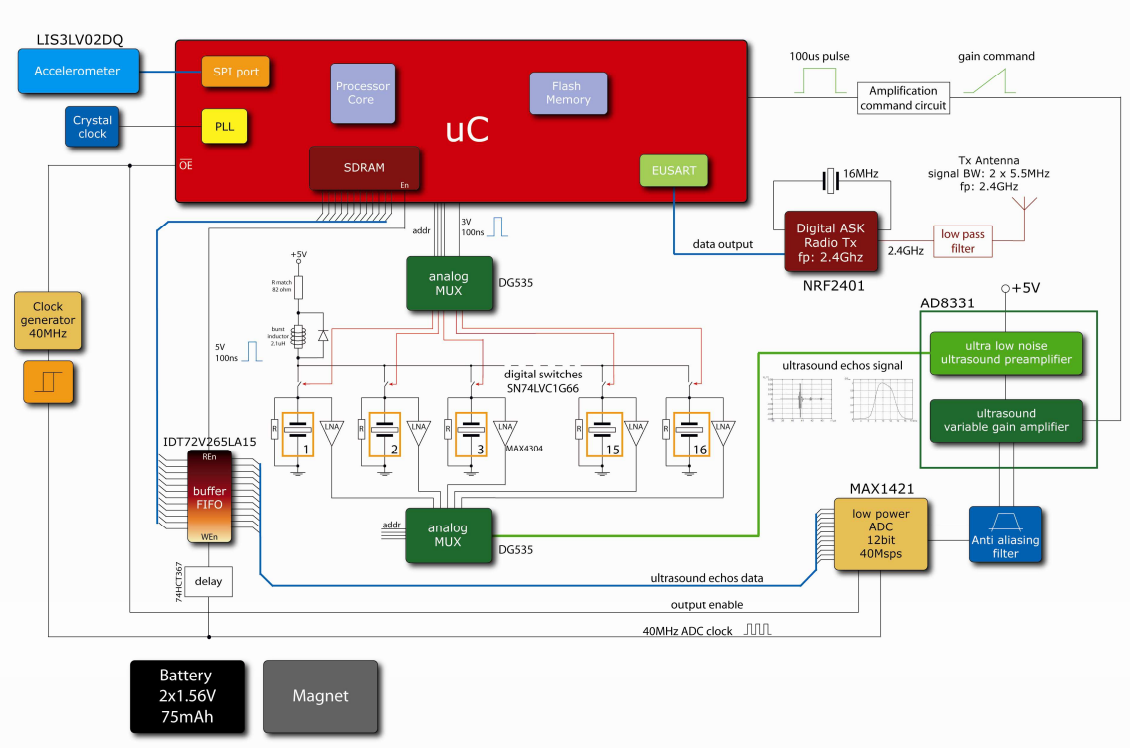


Figure 27: TROY prototype pill revision architecture

Component	Pin numbers	Consumption	Size	Model and notes
Quartz – transmitter	2	-	10x15mm	16MHz
Quartz – CPU and Quartz – ADC	2	-	10x15mm	40MHz
Accelerometer	28	3.3V; 0.60mA	7x7x1.8mm	LIS3LV02DQ
Radio Transmitter	8	3.3V; 5.3mA	3x3mm	nRF2401 and other components around, like the antenna
CPU	80	3.3V;	15x15mm	PIC18F8722
Analogue switches	5	3.3V; 0.04uA	2x2mm	18 analogue switches for the 16-sensors array
Multiplexer	24	3.3V; 8uA	15x10mm	74HCT154
Pulse Shaper	-	-	-	different components and logic ports involved
Ultrasound sensors	16+1 (GND)		Cylinder, 5x11mm	
Frontend amplifers	5	+5V -5V; 20mA	2x3mm	MAX4304
Low Noise Amplifier and Variable Gain Amplifier	28	5V; LNA: 12mA; VGA:17mA	10x6.5mm	AD8331
Memory buffer	80	3.3V; 35mA	15x15mm	-
ADC	48	3.3V; 75mA	9x9x1.4mm	Consumption will be lower if we use 40MHz ADC instead of 60MHz type
Quartz – ADC	2	-	-	-
Voltage regulator for	8	-	4x4mm	MAX774 and MAX1750

amplifiers				
Batteries	2	Power supply: 2x1.54V; 75mAh	Cylinder: 7.9x5.4mm	-
Magnet	-	-	5x5x2mm	-
Reed Magnetic Switch	-	-	Cylinder: 3.68x11.43mm	www.reedswitchdevelopments.com for custom switches http://www.reedswitchdevelopments.com/2104series.html

Table 2: summary of commercial electronics components used in second prototype

The blocks involved in ultrasonic signal generation were changed with respect to first release. Pulse shaper is the core block of the second hardware revision. It accepts the CPU generation command and makes the electric excitation pulse for every single ultrasound transducer during the bowel scanning.

In the hardware revision the +3V - 100ns pulse signal becomes the +5V – 100ns excitation signal. This is made using a matching network directly connected to the +5V dedicated power supply unit.

From the architecture scheme and from the zoomed image, it's visible that the pulse is sent through a matching network that follows the Maximum Power Theorem. The matching network is calculated using considerations presented in deliverable 2.1 about the impedance of a single ultrasound transducer. This double change (+5V instead of +3V and the matching network instead of nothing) allows exciting the sensor correctly and better respect to the first revision.

Close to each sensor now is present a low noise amplifier, MAX4304, that allows to make lower the output impedance of the captured echo signal. This is a further improvement of the second revision. Each amplified echo is sent to the analogue demultiplexer, driven by the MCU, and then to the AD8331, analogue amplifier with variable gain. The address used to select the output in the analogue demultiplexer is the same for each demultiplexer, so when the MCU selects the 5^{th} sensor, it selects also the 5^{th} amplifier and also the 5^{th} echo is sent to

the AD8331: in that moment other sensors and amplifiers are disconnected from the amplifier. The analogue switch close to the sensor is selected by the demultiplexer and makes a “short circuit” between the +5V power supply and the single ultrasound sensor, passing through the matching network. This “short circuit” is valid only for the 100ns excitation time window. In this way the sensor is excited and the ultrasound mechanical wave starts to travel outside the sensor. After the time window the ultrasound sensor is disconnected from the power supply and it’s *free* to receive the echo. The duration of the excitation pulse is the time in which the sensor is blind, because in that time the sensor is not able to receive the echo.

Device electronic schematics

Second version of the TROY pill follows the logic diagram presented in Figure 27. Following the changes described before with the electronic Schemes.

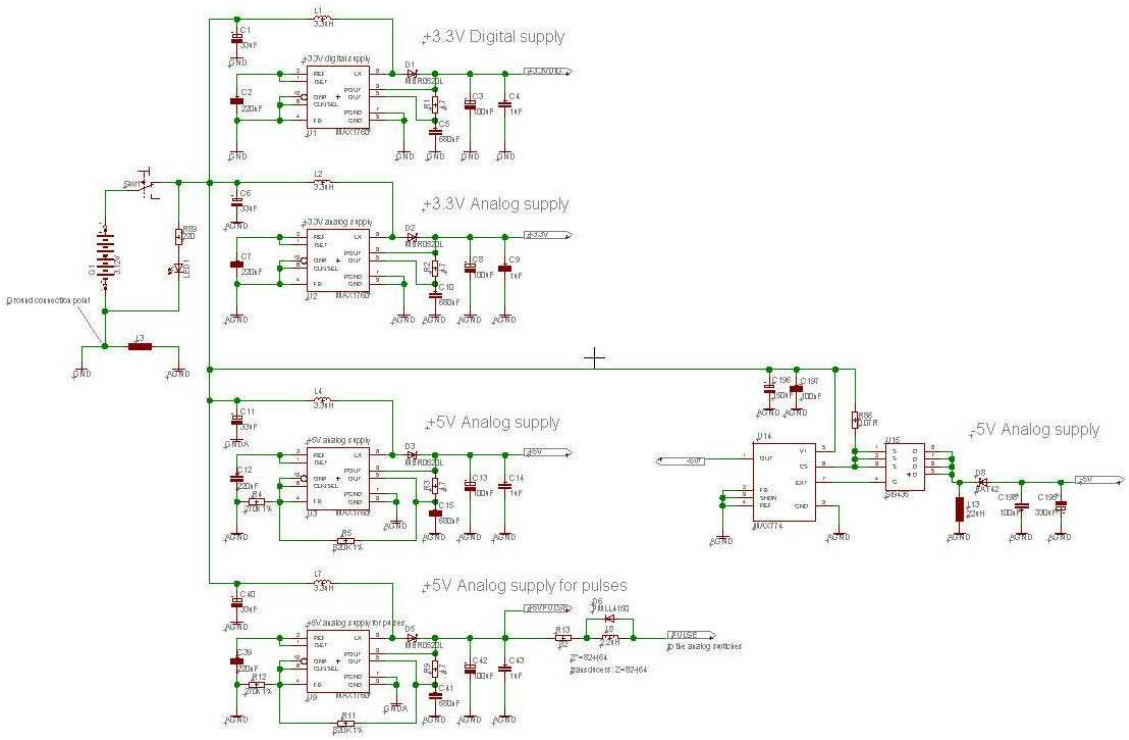


Figure 28: Electronic scheme - Board power supply unit

Board power supply unit

Supply voltages chip are the Maxim MAX1760 and the Maxim MAX774. The first chip is connected to the batteries and converts the +3.12V battery voltage to +3.3V fixed voltage and +5V for supply the entire board. The second chip, that gives the -5V, is necessary for the analog low noise amplifier MAX4304, which works with two power supply voltages of +5V and -5V.

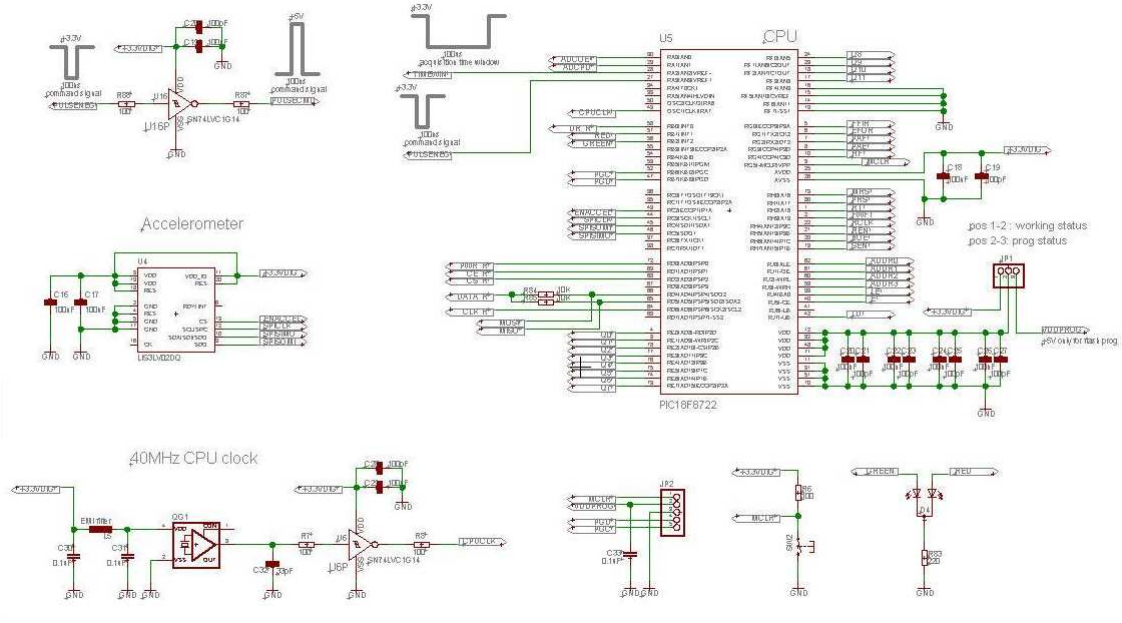


Figure 29: Electronic scheme - MCU and accelerometer

MCU and accelerometer

Core of this board is the MCU, a Microchip PIC18F8722: its function is the same of the first hardware release. Its clock is working at 40MHz.

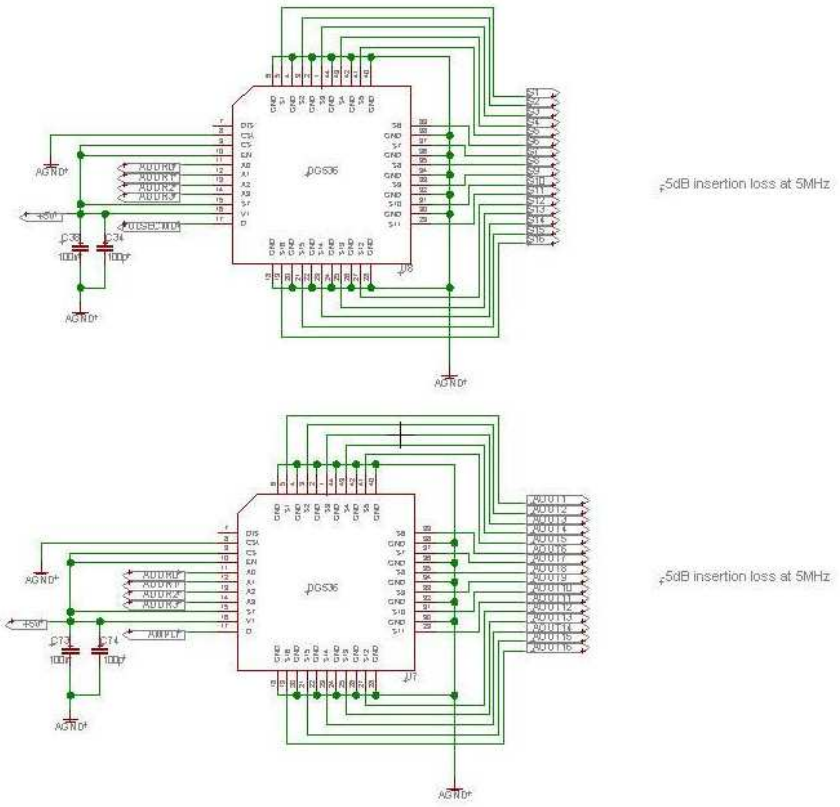


Figure 30: Electronic scheme - Analog demultiplexer

Analog demultiplexer

There are two analog demultiplexers: first one is needed to router the 100ns pulse command to the single analog switch that drives the single ultrasound emitter. The second one is needed because it collects the amplified echo from the single ultrasound emitter and it drives the signal to the main analog amplifier, the AD8331. The address that selects the correct input (about the first demultiplexer) and the output (about the second demultiplexer) is the same and it is decided by the MCU. In this way when the first analog switch is selected (and so the first ultrasound sensor) it's also selected the first frontend amplifier output and its output is connected to the main analog amplifier.

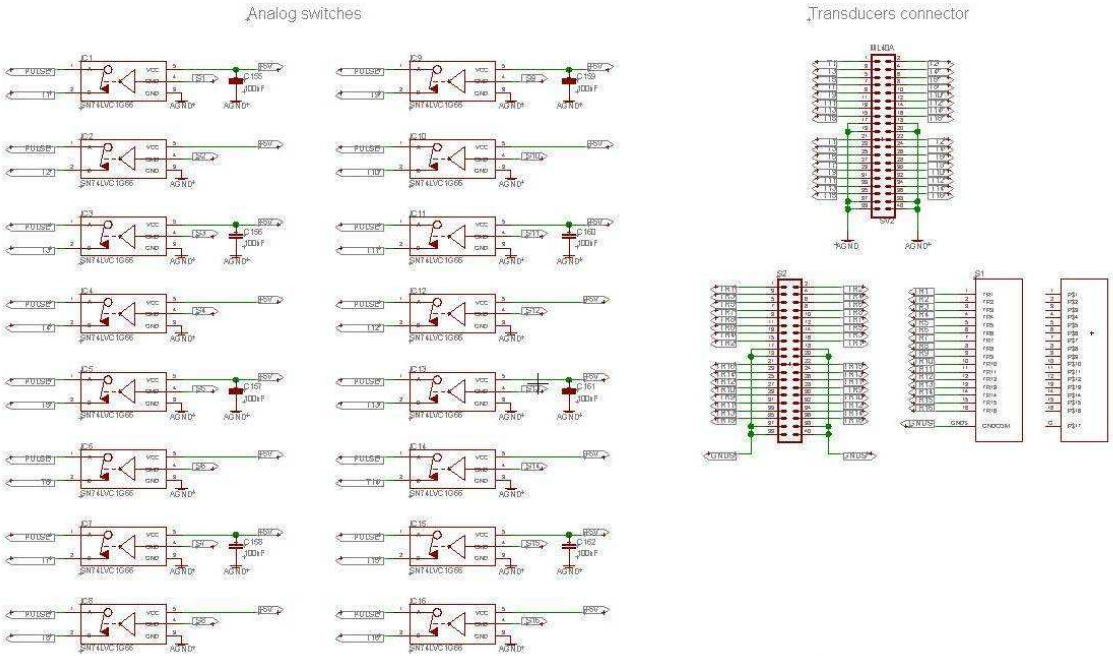


Figure 31: Electronic scheme - Analog switches

Analog switches

Analog switches are changed from the first hardware version. Also it's changed the way in which they are connected to the ultrasound sensor array. In this version the electronic component used is the Texas Instruments SN74LVC1G66. Its main advantage with respect to the other model is that MAX4716 input capacitance is much higher than Texas Instruments' one. This change and the connection reorganization resolves a problem appeared during first tests in the hardware revision 0. The single ultrasound sensor received the main pulse: its voltage increase at the correct value and it remains at that value because of the kind of connection between the pulse generator and all analog switches. This was a problem because the single sensor was not "free" to capture the echoes. In the hardware revision 1 this problem is solved, and the sensor is completely discharged in the time moment when the echoes are expected. This allows having a high value of the echoes in the same experiment (from 5mV of amplitude in the first release to almost 90mV of the second release).

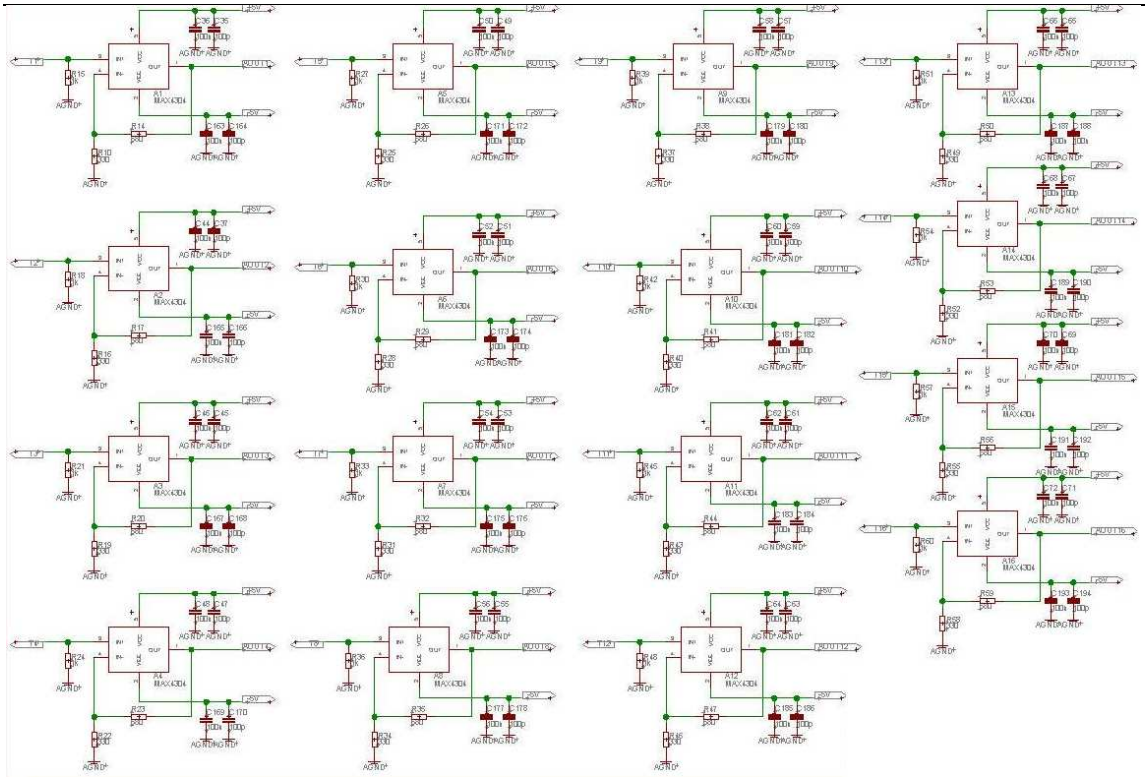


Figure 32: Electronic scheme - Frontend amplifiers

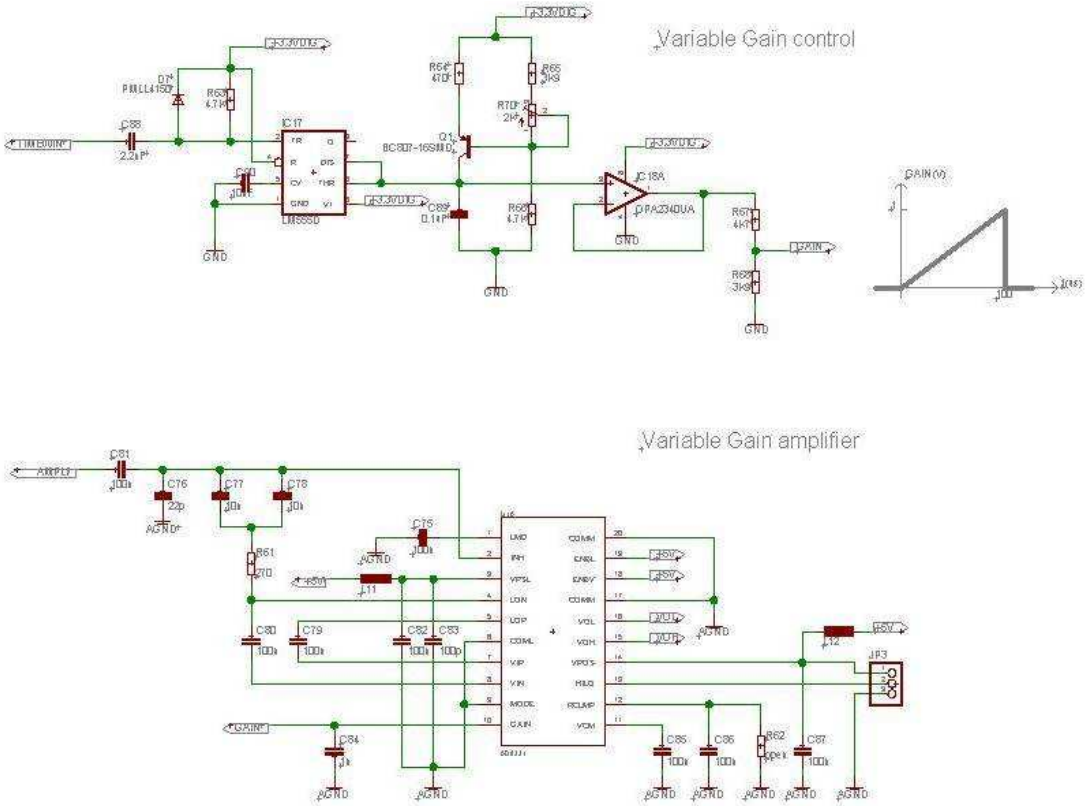


Figure 33: Electronic scheme – low noise amplifier (LNA) and variable gain amplifier (VGA)

Frontend amplifiers, low noise amplifier (LNA) and variable gain amplifier (VGA)

In these sheets are shown the frontend amplifiers, and the LNA-VGA already present in previous release. Also there is the gain command signal generator. The new part consists in the array of frontend amplifiers MAX4304. Since in the previous release there was some noise problems associated to the quality of echo signals at the input of the amplifier, now in this hardware revision it is added an arrays of amplifiers (one for each sensor) allows making the ultrasound echo a robust signal close to the sensor. The gain value compensates the attenuation of the echo inside the analog demultiplexer (5dB in our bandwidth). This amplifiers works with dual power supply voltages (+5V and -5V). There are only small changes about the AD8331: in this revision it's improved the stability of the amplifier: this is done by the gain control circuit because it drives the gain between 0V to 1V. It's little less than the first revision in which the maximum value of the voltage control was 1.15V. A value higher than 1V on the gain pin causes the amplifier starts to oscillate. After the hardware revision this problem is eliminated.

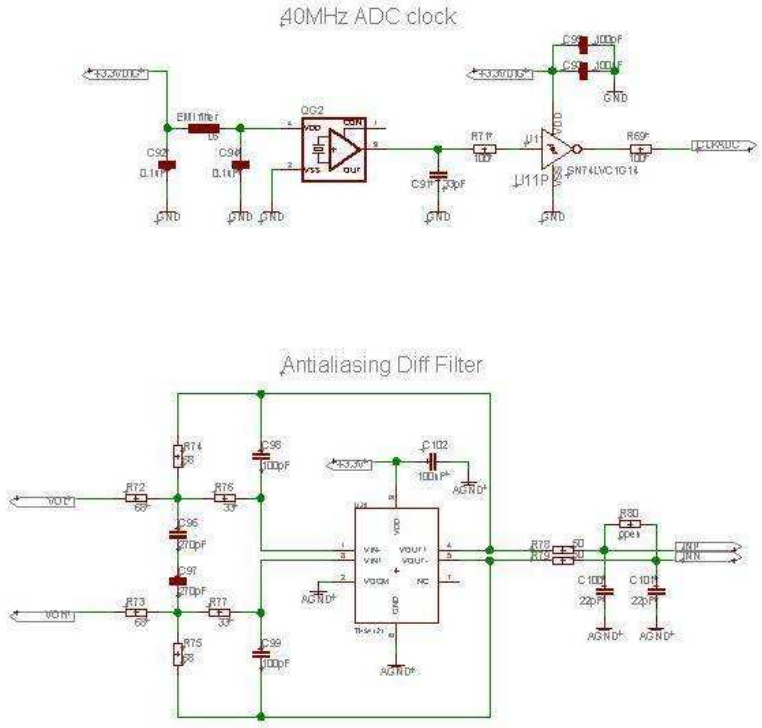


Figure 34: Electronic scheme – Anti-aliasing differential filter

Anti-aliasing differential filter

The anti-aliasing filter is the same of the previous hardware release.

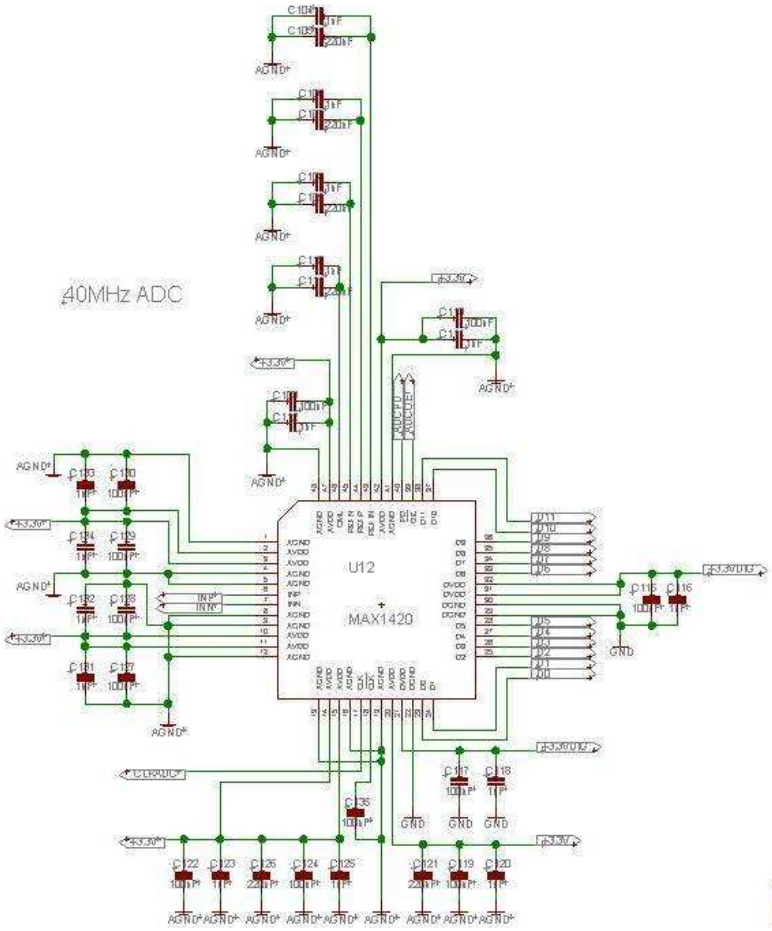


Figure 35: Electronic scheme – ADC

ADC

The ADC is the same of the previous hardware release. Only the sampling frequency is different: the ADC is working at 40MHz.

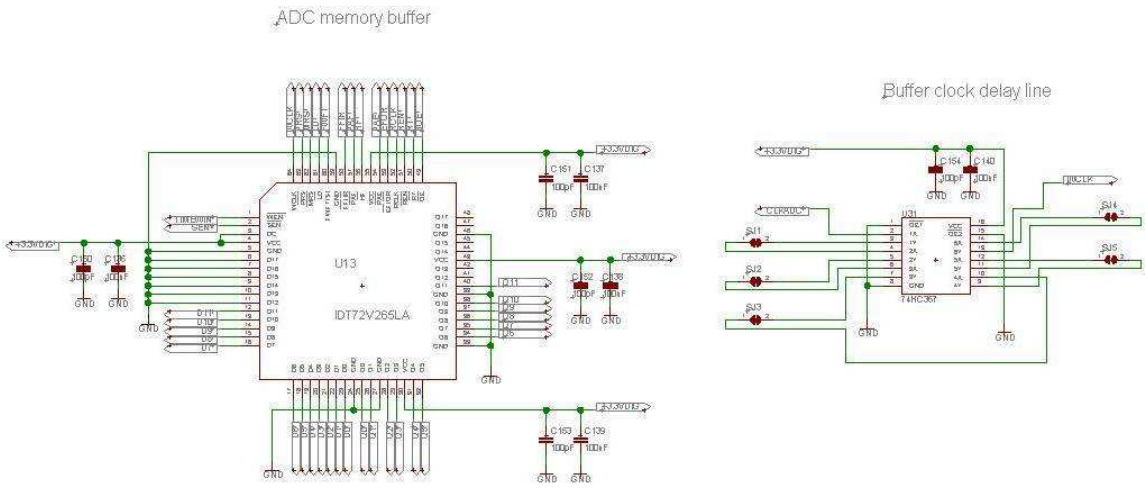


Figure 36: Electronic scheme – FIFO memory buffer

FIFO memory buffer

The FIFO buffer memory is unchanged. The time window in which the FIFO collects samples from the ADC is variable from 40us to 100us. From the point of view of the amount of data to have to be transmitted, the worst case is a time windows equal to 100us. Since the memory is 16Kwords, the sampling frequency is 40MHz, and the time window is 100us, for each single acquisition we have an amount of data equal to 4000samples*12bit/sample=48000bit. Since the memory is organized in words, the real memory occupation for each acquisition is 4000*16=64kbits=4000Kwords. The FIFO memory is enough for our aim.

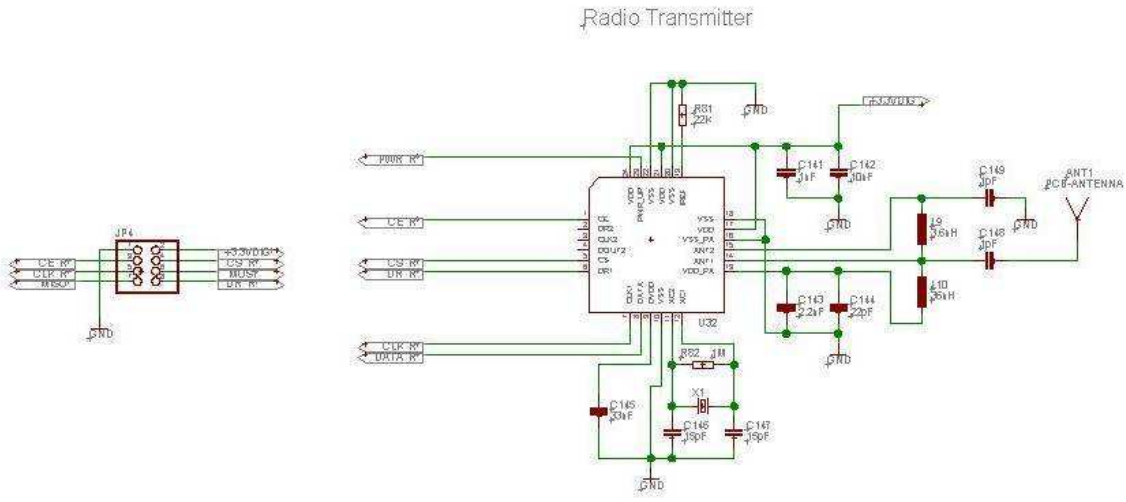


Figure 37: Electronic scheme – Radio transmitter

Radio transmitter

The new nRF24L01 radio transmitter is 2Mbps at 2.4GHz chip. This chip is driven by a high speed pure (hardware) SPI connection by the CPU which collects data from the FIFO, organize the data frame with echoes information and send it to the radio chip. The antenna is a PCB one, suitable for this application, in which we have a short range transmission.

Device PCB rev 1 scheme

Rev 1 board has four layers. Layer 1 is shown in Figure . At the left of the board is present the connector of the ultrasound array sensors support (u-connector), which is visible at the extreme left of the board. The function of the u-connector will be shown later in this document. All around the connector there are the analog switches and amplifiers that prepare the echoes to be sampled by the ADC. Top layer contains almost all active components, while almost all bypass capacitors are in bottom side of the board. Also the radio antenna is a PCB antenna placed on top layer. Like other layers, the top layer has a ground plane, cut off by the signal tracks. Only layer 2 is not broken by signal tracks.

The board is logically divided in two parts: the analog part on the left, and the digital part on the right. Each part has its power supply units and its ground. The analog part consists in the

frontend amplifiers, the variable gain amplifier and the pass band filter. The digital part consists in the ADC, the FIFO memory buffer, the MCU, the accelerometer and the radio transmitter. Blocks are visible in Figure 41.

Layer 2 is the ground plane layer. On the left there's the analog ground, while on the left there's the digital one. They are connected in one point through an EMI filter, just close to the main switch.

Layer 3 is a signal layer. It's used for address line links on the analog demultiplexer and some tracks between MCU and memory buffer. Over bottom layer are mounted almost all bypass capacitors of frontend amplifiers, of the ADC, of the FIFO buffer, of the MCU. It contains also the VGA gain command circuit.

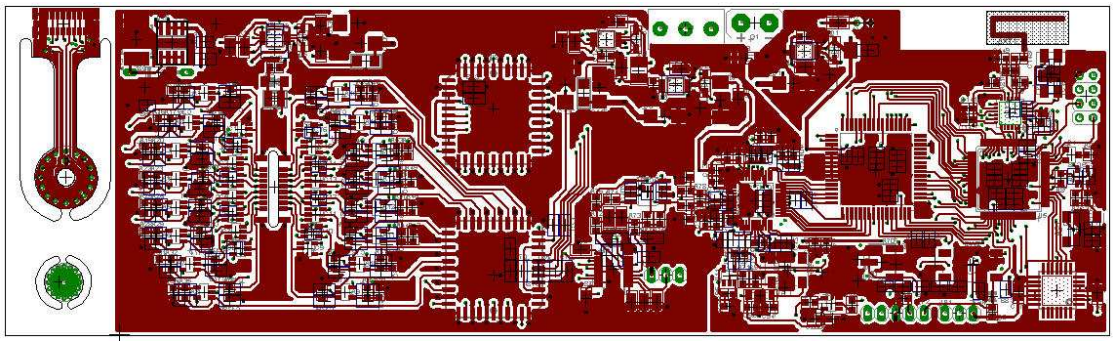


Figure 38: PCB top layer.

The next figure presents a photo of the printed PCB prototype.

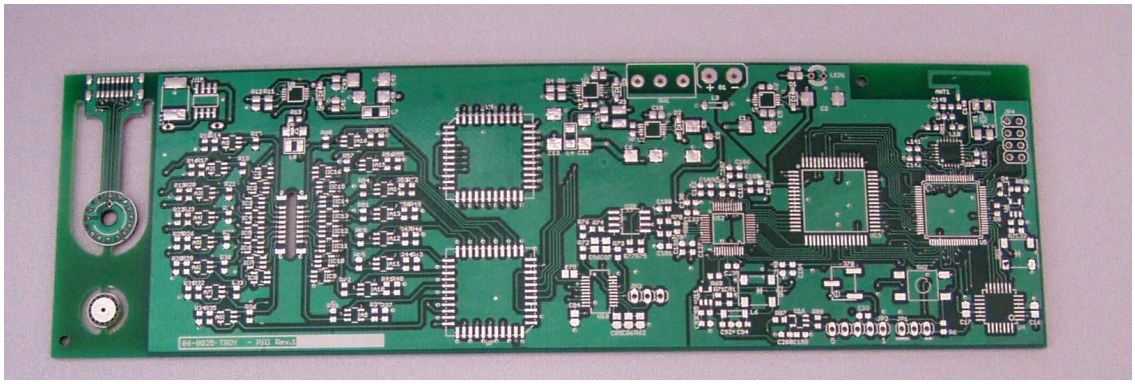


Figure 39: Troy pill rev.1 PCB prototype top and bottom photo.

The PCB support to connect the ultrasonic array is shown in the next figure.

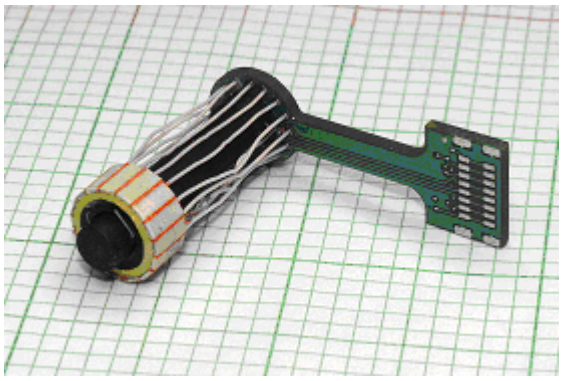


Figure 40. 16 elements ultrasonic array mounted on the PCB support.

Even though the pill is not miniaturized, tests were done in order to demonstrate that the global architecture of the entire system is valid, and verify if the idea of detect and measure the chosen bowel anomalies can be realized with a 16-sensors ultrasound array.

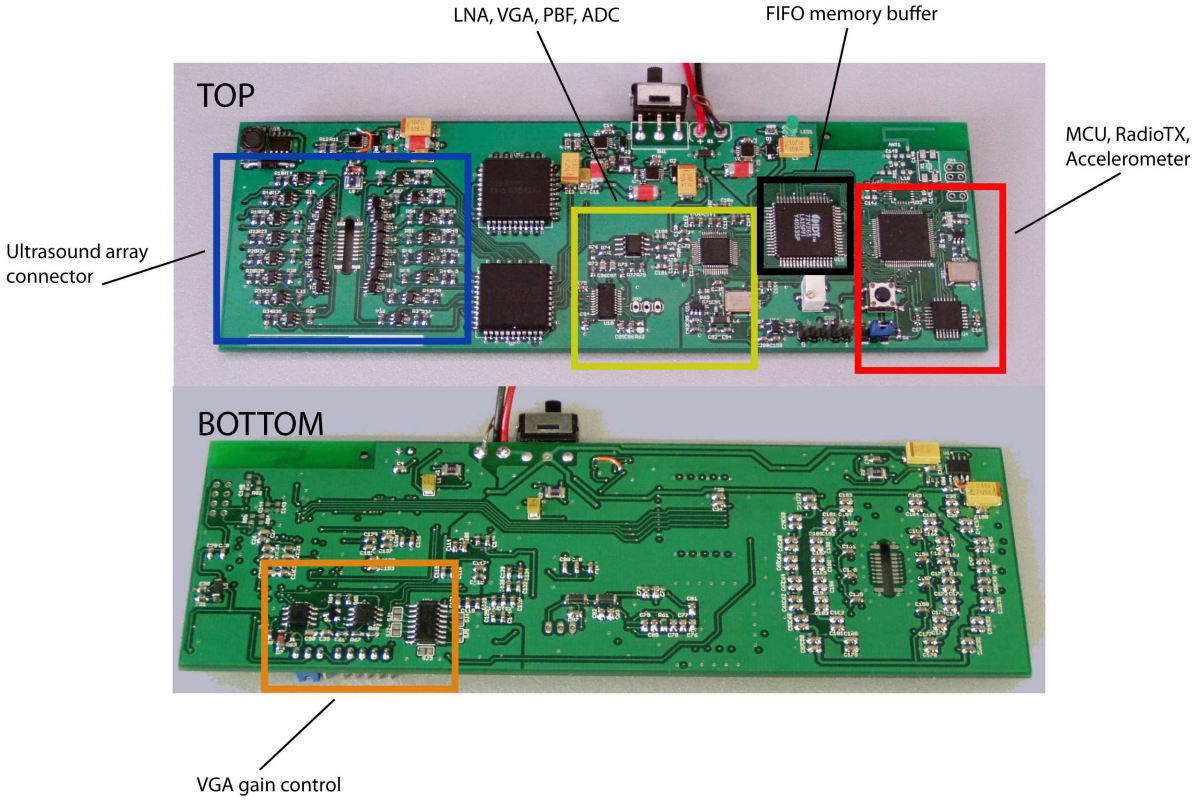


Figure 41: Troy pill rev.1 PCB prototype assembled, with functional blocks explained.

Main tests were performed during two technical meetings in Rome, in October 2008 and January 2009. Tests were divided in two phases: first of all a set of experiments to demonstrate that the board “big pill” was able to drive all the ultrasound emitters correctly.

This set of experiments was performed in laboratory, as shown in Figure 42 with a very simple but effective set-up.

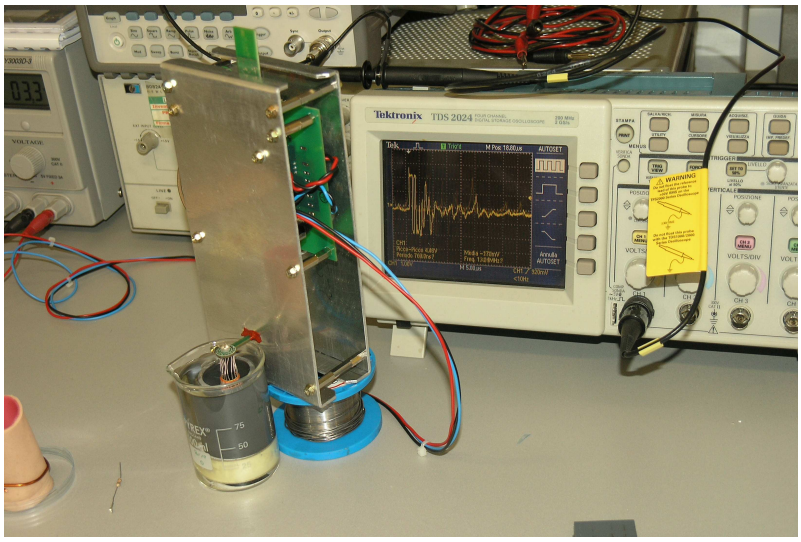


Figure 42: rev 1 board with ultrasound sensor array mounted, during preliminary electrical tests.

After the first phase, the second part of the experiments demonstrates that the array and the electronics can detect different set of “problems” in a phantom bowel.

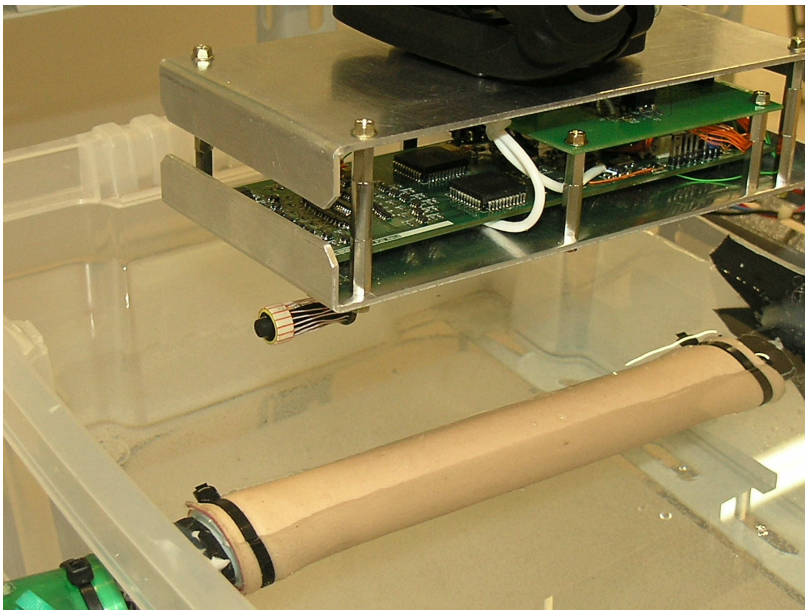


Figure 43: board rev 1 mounted in a protective metallic box, just before tests with phantom bowel.

Future Pill

In this paragraph are presented some images about the pill final layout. Dimensions are realistic, but not completely defined.

ASIC chip is the future solution for the pill electronics. Ultrasound array dimensions are based on the real 16-sensors array, while the batteries dimensions are correct. The magnet is the one chosen in Deliverable 2.1. The batteries are inner components in this future vision of the pill, and the ultrasound emitters array is *around* the two batteries. Reed switch is missing in this first idea of pill internal spaces.

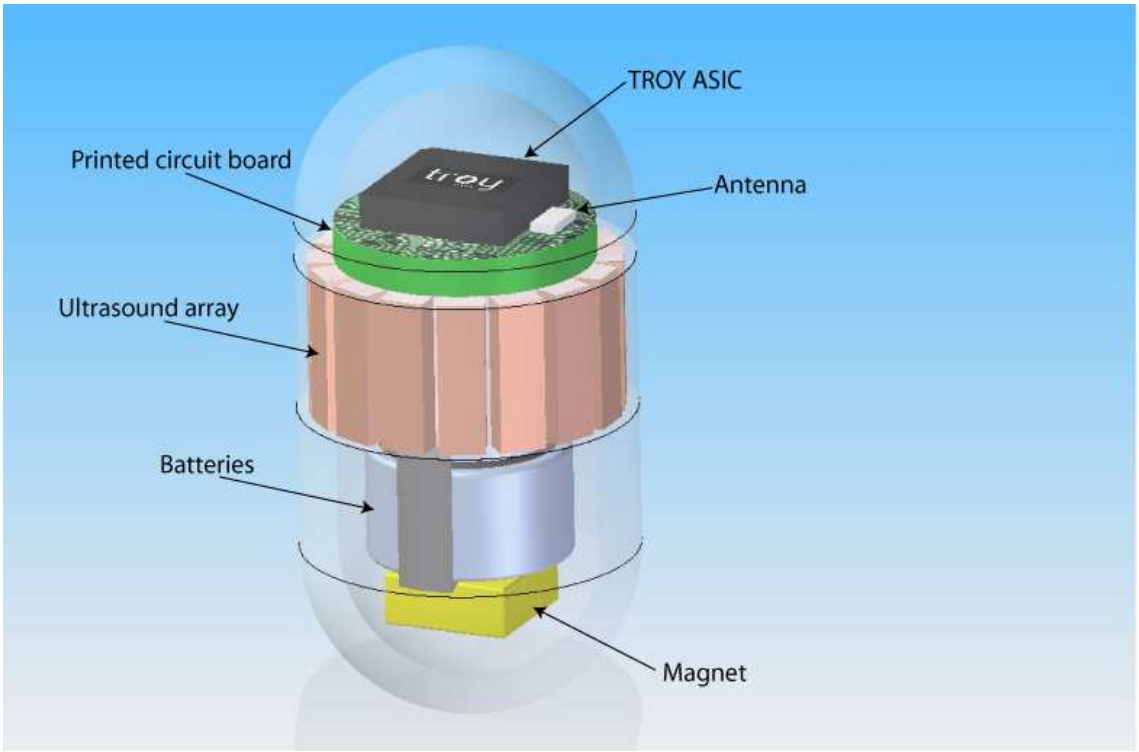


Figure 44: Pill final layout. Dimensions are realistic: pill measures 26mm height and 11mm width.

The Wearable Unit

The TROY wearable unit main functionalities are:

- to receive the ultrasound echoes signal from the pill, that contains information about the bowel status,
- to query magnetic sensors network, to know where the pill is inside the bowel,
- save all this information in a log file, for later analysis.

Two versions of the wearable unit board were developed. The first version was based on a FOX board with add-on boards to the radio and the body sensors network. The second version includes 3 stacked boards, one for the periferals (RF module, gyroscope, accelerometer, realtime clock, body sensors network), another board for the microcontroller, allowing to use the FOX board or another board with a PIC microcontroller, and the third board for the power supply with batteries. The two versions will be presented next and can be studied in detail in deliverable 3.2.

Werable Unit revision 0

The wearable unit is composed by a FOX board, an add-on expansion board for FOX board, and an external five sensor magnetic network, each one connected with a small cable to the main unit.

The magnetic sensor network allows acquiring the magnetic field in space: this measurement is the starting point of the position estimation of the small magnet (pill), following calculations explained in Deliverable 2.2.

Also, the add-on board collects data from the pill using radio receiver nRF24L01.

Summarizing the behavior of the wearable unit, from algorithm point of view, we can say:

1) it receives the echoes data from the pill via radio

2) it reads the value of each magnetic sensor (each magneto-resistive sensor needs a very small set pulse (1us) before reading sensor)

3) the board reads the time in RTC and collects all previous data in a frame

4) the board put data frame in SD memory.

Device electronic schematics (Rev 0)

Board schematics are shown in **Figure 52**. Magnetic sensor signal is filtered by a 100hz low-pass filter, before the ADC. The ADC (for magnetic sensors signal acquisition) is connected to the FOX through the I²C bus. The Real Time Clock is also connected using the I²C bus. The mini SD memory is connected to the FOX board using the SPI software port connection. The Radio module is also connected to the FOX board with the SPI software port.

Chosen components and main characteristics of the expansion board are:

- ADC - 2 x Maxim MAX1238
- RTC - Maxim DS1302
- Radio TX/RX - Nordic Semiconductor nRF24L01

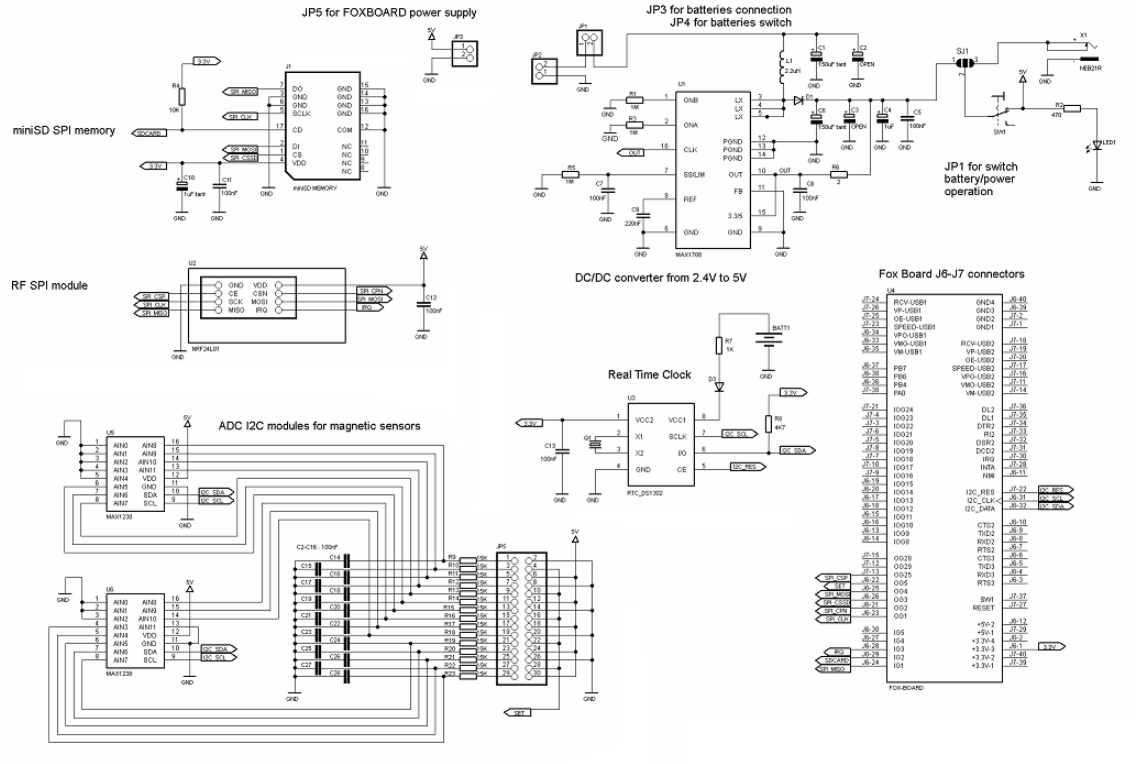


Figure 45: FOX expansion board schematics

In Figure 46 it's shown the wearable unit expansion board with components and connectors.

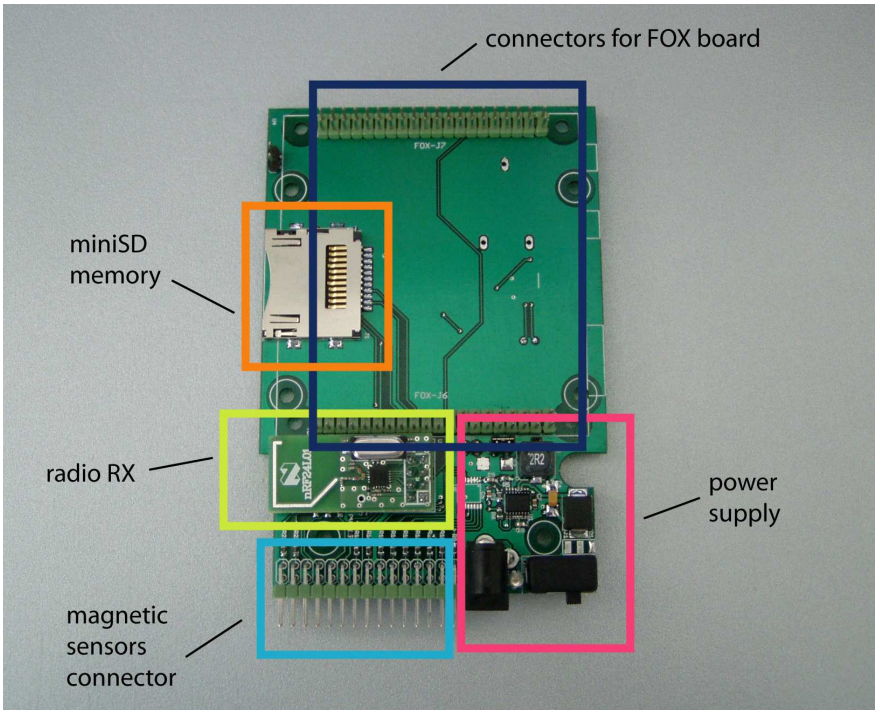


Figure 46: FOX expansion board assembled, with functional blocks explained.

In Figure 47 it's shown the wearable unit and the magnetic sensors.

The device can be work with external power supply unit or internal batteries. A DC/DC step-up converter is used to obtain +5V from 2.4V cell batteries: the converter used is the Maxim MAX1708.

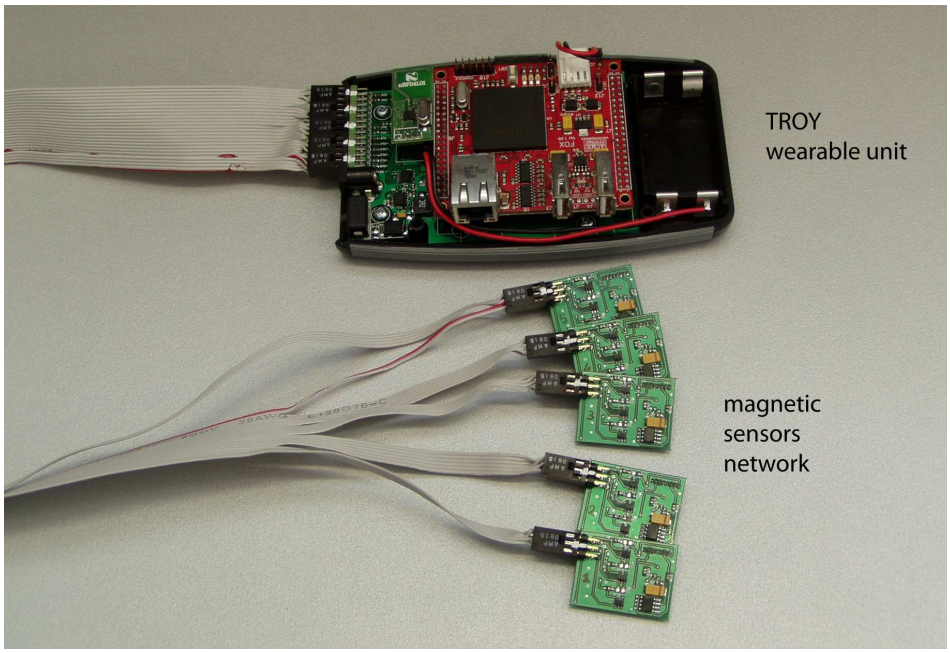


Figure 47: TROY wearable unit assembled, and magnetic sensors network.

Werable Unit revision 1

The new wearable unit includes three boards stacking with each other.

1) The bottom board (**wearable unit board**) is the main board where there are the various peripheral: accelerometer (SPI), miniSDcard (SPI), gyroscope(analog), rfmodule (SPI), ADC (I^2C), realtimeClock (I^2C), the connector for the external supply (5 V stabilized), the connectors for connect with your higher board and the connectors for magnetic sensors.
2) Second board **(wearable unit MCU board**) can replace the Fox board. In the board there are the PIC16F8722, the ualfat for data storage, the clock generator at 32 MHz for PIC, the regulator 5-3.3 V for the supply of peripherals. If you use the Fox board, data will be stored on the miniSDcard on the wearable unit board.
3) Third board (optional) is the **wearable unit supply board**, used to provide battery energy supply to the system. It includes pack battery and the step-up for producing 5 V. Warning: do not use the external supply and the wearable unit supply board together.

Device electronic schematics (Rev 1)

Boards' schematics are shown in Figure 48 to Figure 50.
Magnetic sensor signal is filtered by a 100 Hz low-pass filter, before the ADC. The ADC (for magnetic sensors signal acquisition) is connected to the MCU or FOX through the I²C bus. The Real Time Clock is also connected using the I²C bus. The mini SD memory is connected to the FOX board using the SPI software port connection, the Ualfat is connected to the MCU using the SPI hardware port connection, the Radio module is connected to the FOX with the SPI software port or to the MCU using the SPI hardware port connection, the Accelerometer is connected to the FOX with the SPI software port or to the MCU using the SPI hardware port connection, the Gyroscope is connected to ADC.

Chosen components and main characteristics of the expansion board are:

- ADC: 2 x Maxim MAX1238
- RTC: Maxim DS1302
- Radio TX/RX: Nordic Semiconductor nRF24L01
- Accelerometer: LIS3LV02DQ
- Gyroscope: EVAL-ADXRS610

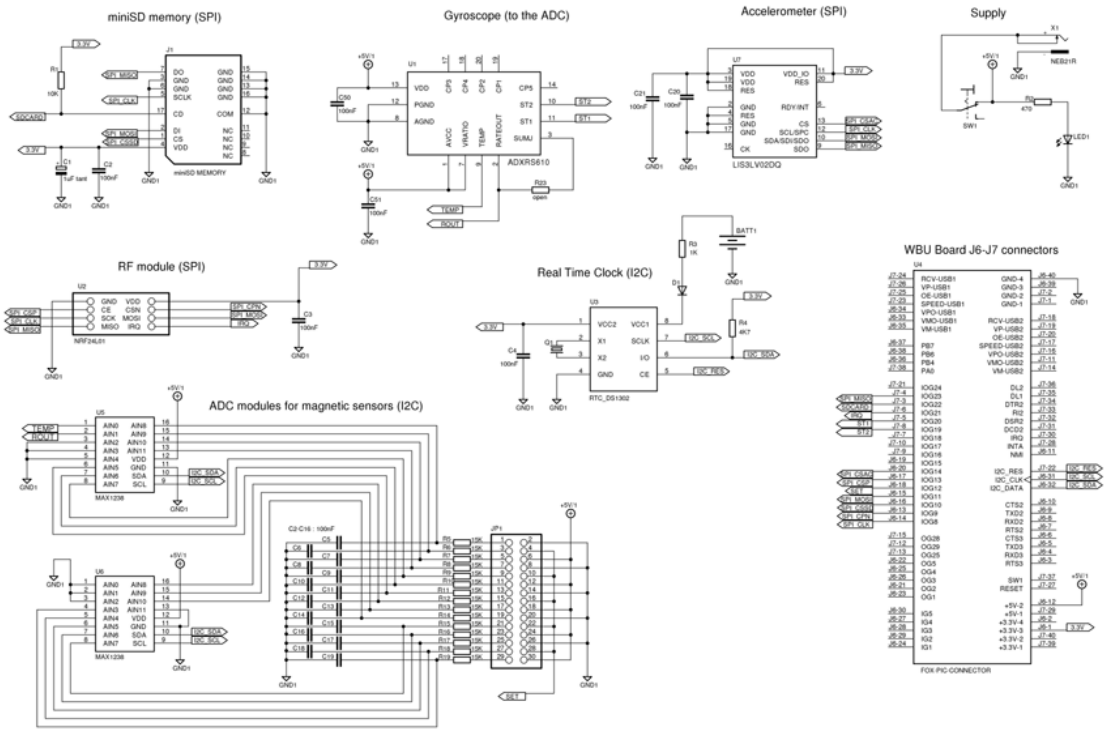


Figure 48: TROY wearable unit board (Rev 1)

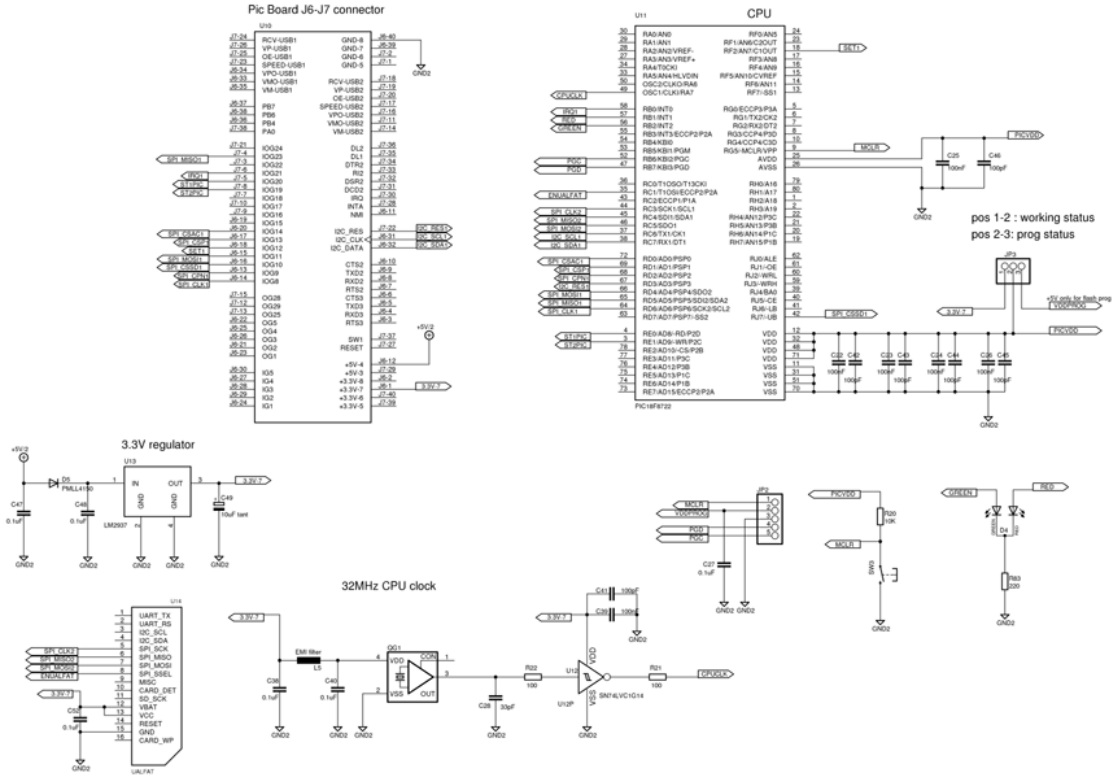


Figure 49: TROY wearable unit MCU board (Rev 1)

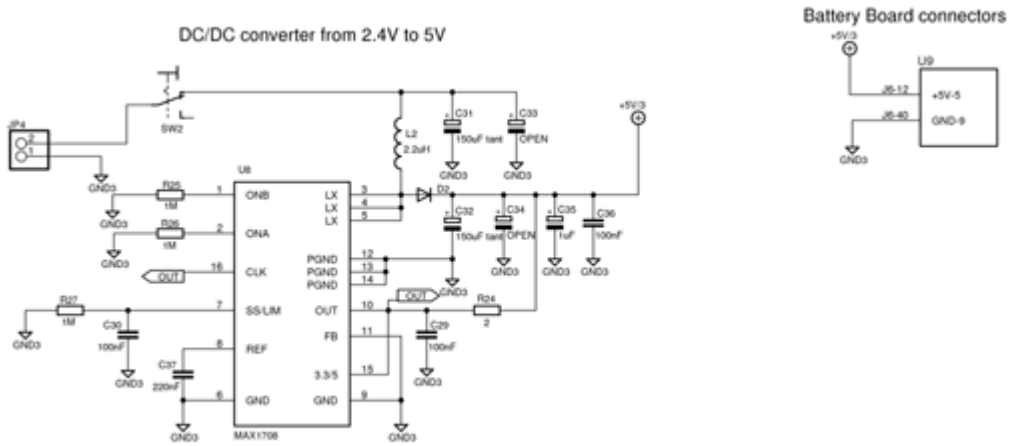


Figure 50: TROY wearable unit supply board (Rev 1)

In Figure 51 it's shown the wearable unit board assembled with FOX Board and batteries power supply.

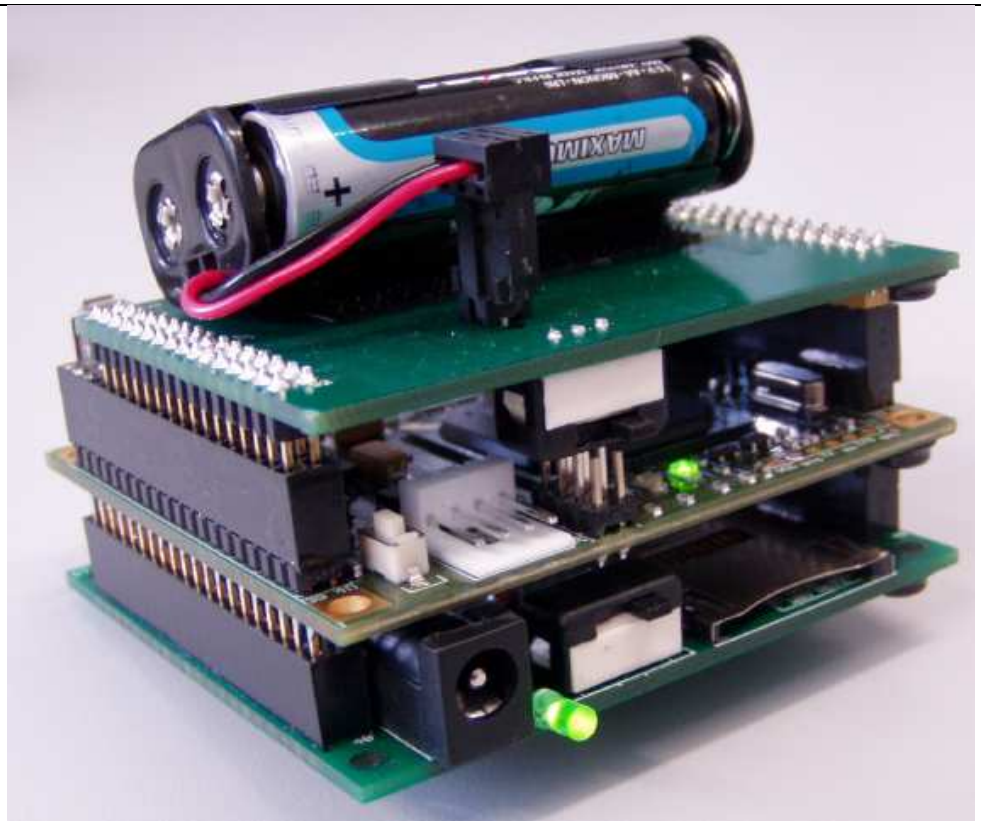


Figure 51: TROY wearable unit board with FOX board and power (Rev 1)

2.3.3. Deviations from Workplan

Tasks 3.1 had a delay of nine months, due to the complexity of the selection of components since some of them weren't compatible or were too big. Being so, deliverable 3.1 was delivered only on Month 11.

The delay in Task 3.1. was also reflected in Tasks 3.2.1. and 3.2.2., causing the a delay in draft version of deliverable 3.2 that was postponed to Month 15. Final version of Deliverable 3.2. was done in the end of the project with 6 months delay.

2.3.4. List of Deliverables and Milestones

Del. Nº	Deliverable name	Workpackage nº	Date due	Actual/forecast delivery date	Status	Lead Contractor
3.1	Draft architecture of Troy device	3	M2	M12	Completed	Labor
3.2	Designs and electronic schemes of Troy device	3	M12 Final M24	M19 Final M30	Completed	Labor

No milestones associated to Workpackage 3.

2.4 Workpackage 4 – Software Development

2.4.1. Objectives

According to the "Annex I- Description of Work" the objectives of the WP 4 were:

- *To define the algorithms for 3D high definition computer generated images and to implement these algorithms into a full potential version on PC*

To accomplish the proposed objectives the following tasks were defined:

a) Task 4.1 - Development of the embedded software (M17-M25):
   i. To develop the embedded software to be integrated in TROY capsule and the portable device.

b) Task 4.2 - Rendering of 3D images (M3-M26)
   i. A focused literature review to identify the most potential recent solutions for pattern recognition characterization and classification.
   ii. To develop a module to solve the problem of the ultrasound pattern recognition and a 3D digestive tract reconstruction module.
   iii. To develop user interface to interact with 3D models and 2D images.

c) Task 4.3 - Patient data management (M20-M22):
   i. To develop the software modules needed to manage medical data records from the patients and export it.

2.4.2. Progress

The work developed on the scope of this WP was leaded by IAITI with contributions from all Partners.

Task 4.1 – Development of the embedded software was successfully concluded on the second year of the project with the development of the software for the personal data recorder of the wearable unit.

Task 4.2 – Rendering of 3D images was improved and completed on the second year. Main improvements during this year were on the pre-processing module for reconstruction of 2D and 3D models from ultrasound raw data with noise filtering and implementation of the positioning algorithm for tracking the pill. On the presentation layer several improvements were also done.

For task 4.3 were identified the patient data requirements, and all partners agreed on a simple patient data structure, knowing that hospitals and clinics have their own patient management applications. This module was implemented during the second year.

This workpackage started with a literature review to identify the most potential recent solutions for pattern recognition characterization and classification. Was produced a document presenting the state of the art in 3D rendering of ultrasound images, describing

current projects and products that can have a significant impact in the development of the software for 3D rendering for the TROY system. Most of the literature regards work with ultrasound data acquired from the outside of the body. Although this is a limitation, this fact also opens up several possibilities in terms of new results arising from the TROY project.
Several recent developments that can be very useful were listed and analysed including:

- New acquisition techniques for 2D slices.
- Free movement of the probe; 360º imaging.

However, also some limitations in current acquisition techniques were identified and, for example, in order enable a complete reconstruction of the 3D image a tracking device (accelerometer) is required (inside and outside for reference).

The consortium identified the data to be acquired and transmitted by the ultra-sound endoscope capsule to the wearable computing unit. This set of data will contain ultra-sound raw data, sequencing clock information and information of capsule rotation. The wireless unit should add positional information provided by the body sensors network and store the information. The algorithm to retrieve the location of the pill inside the body is already designed and will be implemented in the next months. The protocols for data exchange with workstation were defined. This set of data necessary for imaging software should be available from WPU: ultrasound raw data, positioning data (x, y, z, α) from magnetos and timestamp.

Wearable Unit Software

When the Personal Data Recorder (PDR) is turned on, it initializes I2C bus, Magnets, ADC and activates radio communications. The PDR starts listening to the SPI Bus for data packets. When a valid packet is received, a 1us Pulse is sent to the magnetic sensors to get the current magnetic field emitted by the pill. Using the I2C Bus, the data from all sensors is read from the ADC channels. Afterwards the current time stamp is obtained from the Real Time Clock (RTC) and all data is gathered in a frame which is saved the miniSD Card. This is an ongoing process until an external button is pressed and the program finishes.

Figure 52 presents the UML State Chart of the program:

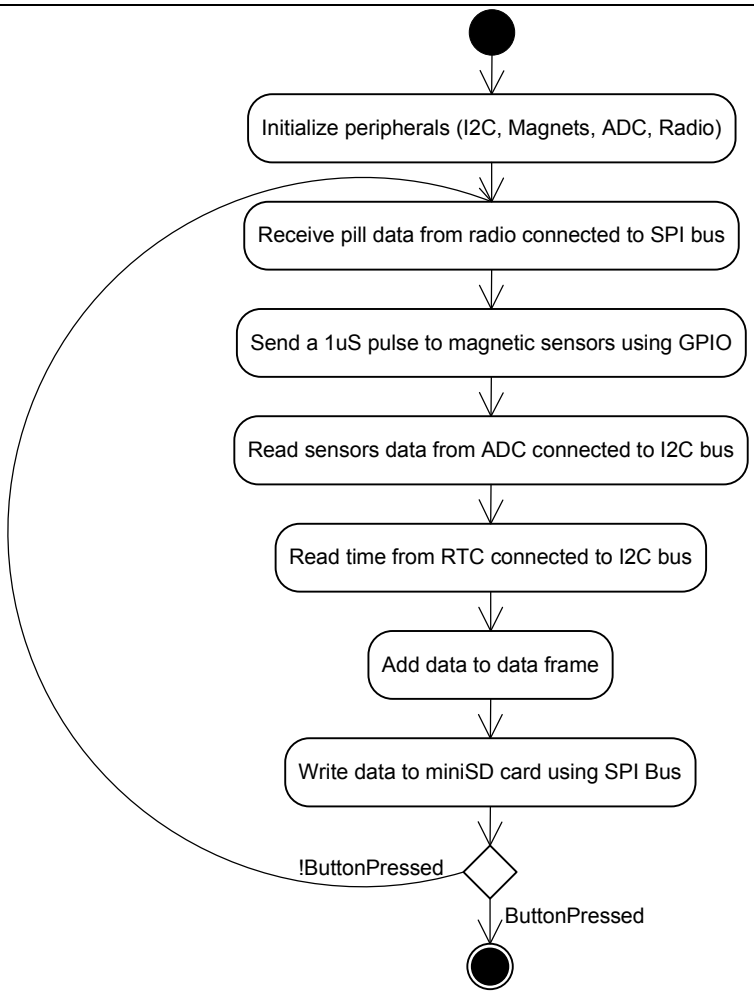


Figure 52 – TROY Personal Data Recorder (PDR) State Chart

To further illustrate the implementation behind the State Chart, a class diagram is presented in Figure 53:

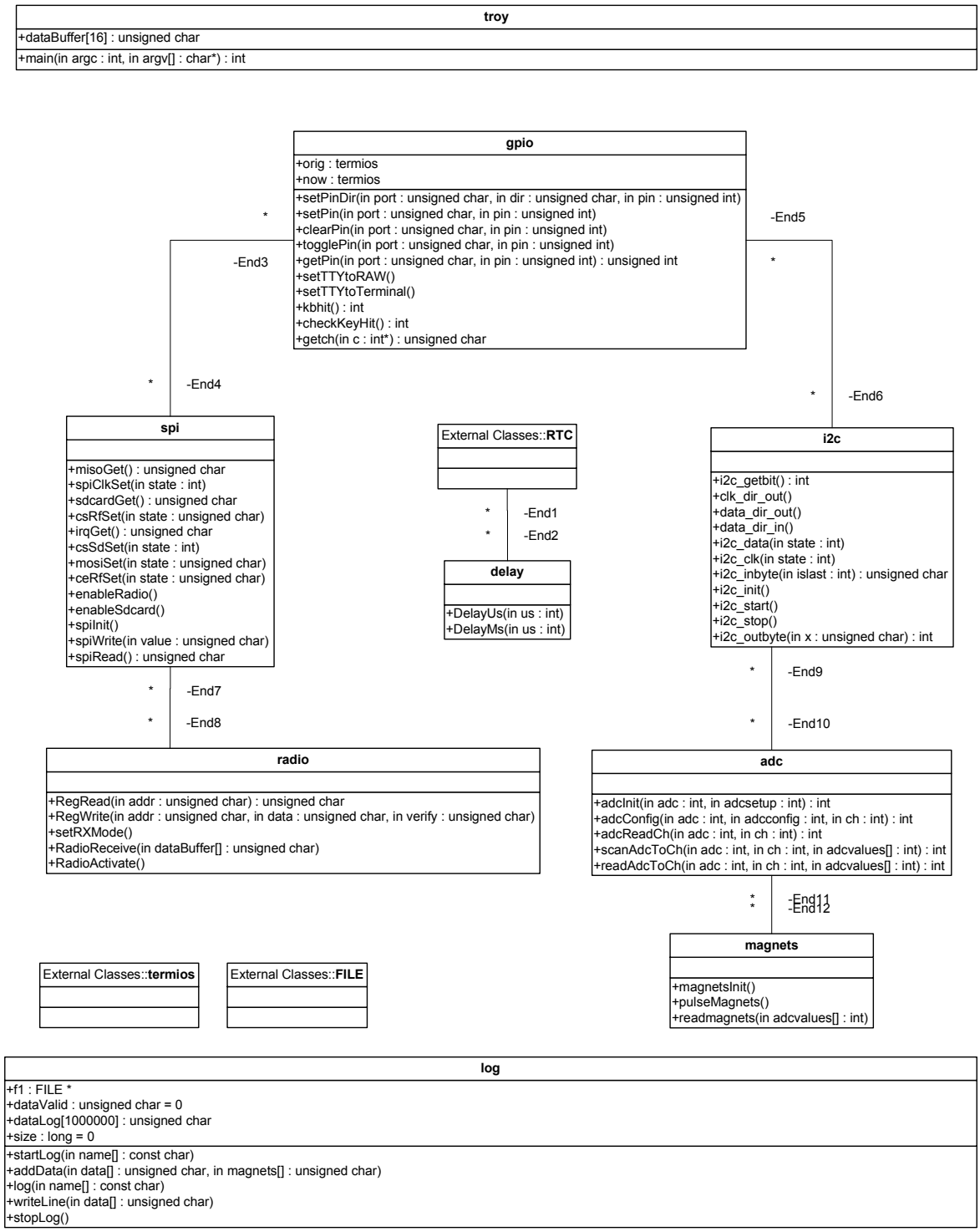


Figure 53 – TROY Personal Data Recorder (PDR) State Chart Class Diagram

Troy Workstation Software

The TROY workstation enables the doctor to see the results of the examination and perform analyses over the ultrasound endoscope data. At the TROY workstation, the doctor can create

the medical record of each examination. After the exam, the data can be transferred from the wearable unit to the workstation. Then the raw data is processed in order to build 2D images and the 3D models. The doctor will be able to manipulate the 3D model and the sequence of 2D Ultrasound images collected during examination and, in order to improve the quality of the diagnosis, the software also provides a toolset that enables:

- 3D and 2D model manipulation;
- Insertion of classified annotations over the models;
- Problem pattern recognition.

For better interaction with the doctor the TROY workstation interface is intuitive and user friendly. The base platform for the workstation is MS Windows due to its world wide acceptance and support.

TROY software logic architecture is illustrated in **Figure 54**. There are two main modules, Data Pre-processing and Data Analysis. For each of the main modules are shown the functionality packages, its components and dependencies.

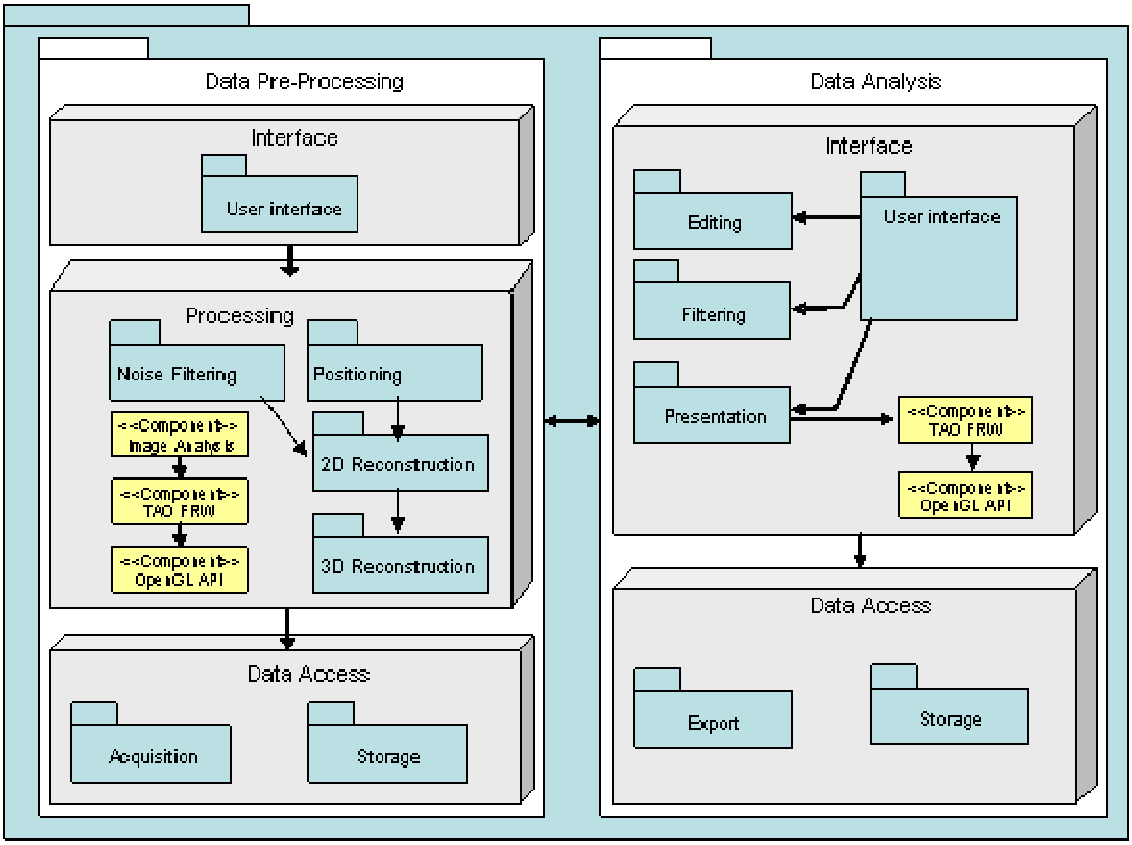


Figure 54 – TROY SW Logic architecture

The interface layer enables the interaction between the user and the entire system, by using its functionalities and invoking other layers in a transparent manner to the final user.

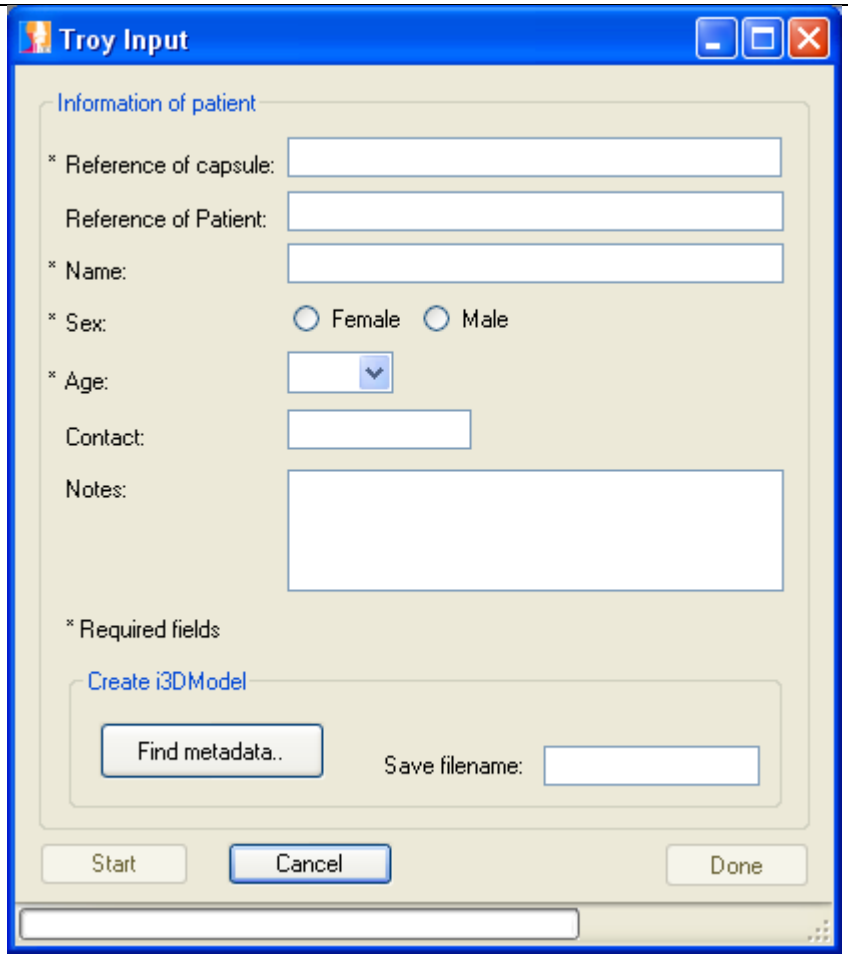


Figure 55 – TROY Data Pre-Processing interface

In the Data Pre-processing module the user should identify the pill and insert some data about the patient. As hospitals maintain large medical records, the patient information on Troy is a simple set enabling the reference with medical record system. Then the user must select the file containing the data of the required exam and can start processing data in order to identify the contours and reconstruct the 2D images and the 3D model.

Troy workstation can process raw data from troy ultrasound capsule and 2D images from other ultrasound probes, in this case, with limited functionality.

Sample for 3D reconstruction based on 2D images:

 # filename pos_x pos_y pos_z orient_x orient_y orient_z rotation time
.\Screen0000.bmp -10,000 -50,000 50,000 0,000 1,000 0,000 0,000 0
.\Screen0001.bmp -9,963 -47,713 49,917 0,016 1,000 -0,018 0,000 1
.\Screen0002.bmp -9,855 -45,356 49,674 0,032 0,999 -0,036 0,000 2
.\Screen0003.bmp -9,679 -42,934 49,279 0,047 0,997 -0,053 0,000 3
…

Sample for 3D reconstruction based on ultrasound raw data:

Position; MS1x; MS1y; MS1z; MS2x; MS2y; MS2z; MS3x; MS3y; MS3z; MS4x; MS4y; MS4z; MS5x; MS5y; MS5z; Acceleration; orient_x; orient_y; orient_z; rotation; time; Sensor 0 ; (3000 values); Sensor 1;…; Sensor 15; (3000 values)

Position;2176;2707;1810;2398;2089;2552;2266;2084;3991;2811;3103;3224;3882;2950;2763;Acceleration;16567;64954;64314;Sensor n. 0;0;0;2075;2076;2074;2072;2074;2071;4054;… Sensor n. 1;0;0;2075;2076… Sensor n. 2;0;0;2075;2076… Sensor n. 3;0;0;2075;2076… Sensor n. 15;0;0;2075;2076…
Position;2176;2707;1810…;Acceleration;16547;64973;64372;Sensor n. 0;0;0;2072;2072;2070;2070;2069;…
Position;2176;2707;1810…;Acceleration;16564;64808;64424;Sensor n. 0;0;0;2060;2058;2060;2062;2062;…
Position;2176;2707;1810…;Acceleration;16570;64912;64352;Sensor n. 0;0;0;2043;2044;2046;2047;2046;…
…

The processing layer implements all the necessary functionalities to process the reconstruction of 2D images and the reconstruction of the 3D model, based on ultrasound raw data. Alternatively the software can build a 3D model based on 2D ultrasound images acquired with other ultrasound probes.

The development of the application is based in two frameworks, 'Tao Framework 2.0', which supports the OpenGL and ‘Microsoft.NET Framework 3.5’.

The processing layer performs four main tasks: position calculation, noise reduction, 2D image reconstruction and 3D model reconstruction.

Position algorithm

For each ultrasound scanning the wearable unit receives, values of magnetic flows in x, y and z axis of the five magnetic sensors are added to the data in order to calculate the position of the capsule. The algorithm to calculate the position needs some computational power and so this calculation is made on the workstation.
The position algorithm, based on the values of magnetic flows in each of the five sensors and in the sensors position will retrieve the position of the capsule.

Having ADC as a matrix with the digital values from magnetic sensors:

ADC = [S1x, S1y, S1z;
S2x, S2y, S2z;
S3x, S3y, S3z;
S4x, S4y, S4z;
S5x, S5y, S5z];

Given the matrix with the position of the sensors:

X = [0, 0, -0.005; magnetic sensor 1
0, 0.12, -0.005; magnetic sensor 2
0.12, 0.12, -0.005; magnetic sensor 3
0.12, 0, -0.005; magnetic sensor 4
0.06, 0.06, -0.005] magnetic sensor 5

The first step is the calculation of the magnetic flux in Tesla:

B = abs(ADC * 1E-3 - 2.5) / (370 * 5E-3) * 1E-4

The matrix M and the vector U used to calculate the matrix R of the distances between the sensors and the magnet can be calculated in three different ways based on X and B. The three different functions enables that M is not singular. The position of the magnetic sensors is arranged on the centre and four corners of a square plane certifying there's a non singular matrix M.

M = [B1,B2,B3,B3*X2-B2*X3,B1*X3-B3*X1] and U = [B1*X2-B2*X1] or
M = [B1, B2, B3, B1*X3-B3*X1, B2*X1-B1*X2] and U = [B2*X3-B3*X2] or
M = [B1, B2, B3, B3*X2-B2*X3, B2*X1-B1*X2] and U = [B3*X1-B1*X3]

The vector R of the distances between the sensors and the magnet is calculated as:

R = inv(M) * U

Given R vector we can calculate the direction of the magnetic field of the magnet H_0 = (m, n, p) as

p = 1 / (sqrt(1 + r4^2 + r5^2)) **m = r4 * p** **n = r5 * p**

The position P = (a, b, c) of the magnet can be deduced from R:

R = [r1, r2, r3, r4, r5] = [(b - c*r5), (c*r4 - a), (a*r5 - b*r4), r4, r5]

And thus we can deduce:

a = r4 * c – r2 and b = r1 + r5 * c

To resolve c we need to use the vectors G1 and G2 calculated in function of the matrices X, B, H_0 and R and five systems are produced in order to the z-axis coordinate of the magnet position:

G11 * c^2 + G12 * c + G13 = 0 and G21 * c^2 + G22 * c + G23 = 0

The roots of c are found and is selected the real one that minimizes the least square error E:

E = SUM ((G11 * c^2 + G12 * c + G13)^2 + (G21 * c^2 + G22 * c + G23)^2)

The position of the magnet P = [a, b, c] is then given by the expressions:

a = R41 * c – R21 and b = R11 + R51 * c

Digital Signal Processing for Noise Reduction

The analogue data acquired from the ultrasound probes is affected by various sources of noise that deteriorate the information that should be extracted.

The power supply introduces noise in the low frequency of 50Hz as well as the digitalization in the ADC – Analogue to Digital Converter introduces noise in the high frequency of 40MHz.
For the low frequency noise, active analogue filters can solve the problem, on the other hand, high frequency noise is introduced by the digital pulsing of the electronics therefore there is the need to filter this noise using digital filters.

There are two categories of digital filters:

- IIR – Infinite Impulse Response;
- FIR – Finite Impulse Response;

Although IIR Filters produces lower order equations for the same results of FIR, there is always the possibility that the filter doesn't converge and becomes unstable in some cases. Another good characteristic of FIR Filters is that there is always the possibility to design a linear phase filter for both cut and pass bands, so we opted to use FIR as our DSP – Digital Signal Processing technique.

The ultrasound probes have an intrinsic frequency near 5MHz so, for the requirements of this project there is the need to design a band pass filter that removes lower and higher frequencies to extract the information from the ultrasound signal.
As the probes were manufactured in small quantities their production could imply small differences between probes in what respects to intrinsic frequency, so we aim to design a filter that removes frequencies below 4.25MHz and above 5.75MHz. Figure 56 illustrates the design of the filter.

There are several types of FIR filters. Equiripple, Least-Squares, Window (Hamming, Kaiser, Rectangular,…), Generalized Equiripple and Constant Band Equiripple are the most used ones. Using the specifications named above, we have tested all of these filters and compared their frequency and phase response versus the number of operations required for the filtering.

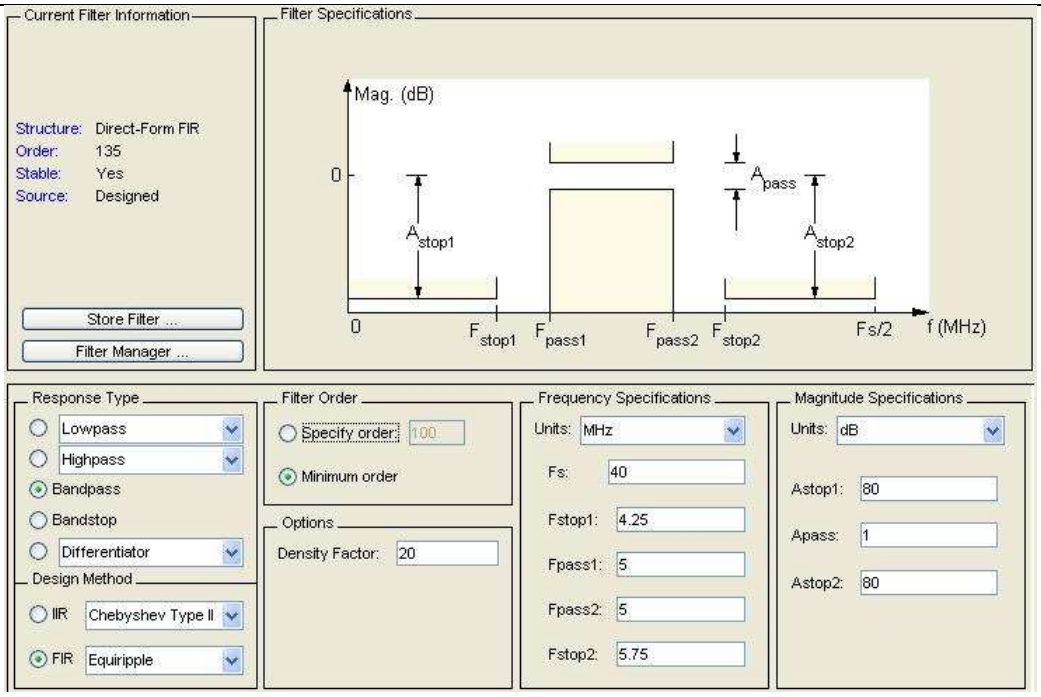


Figure 56. Design of the FIR Filter

For its phase, frequency response and because of its low order, Equiripple was the considered the most suitable for the requirements. Figure 57 shows the frequency response of the filter.

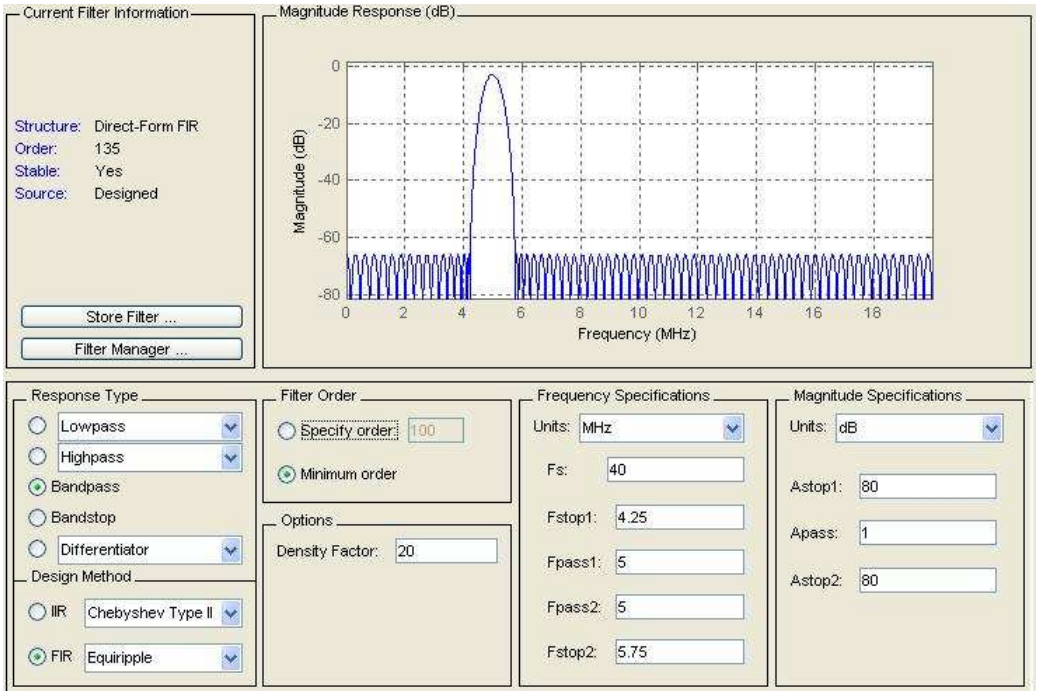


Figure 57. **Frequency response of the Equiripple Filter**

Figure 58 shows the signal without filtering in blue and the filtered signal in red both in the time domain. To further analyze the results of the filtering and its frequency response, we shifted from time domain to frequency domain, using the fast algorithm of the Discrete Fourier Transform (FFT) and obtained Figure 59.

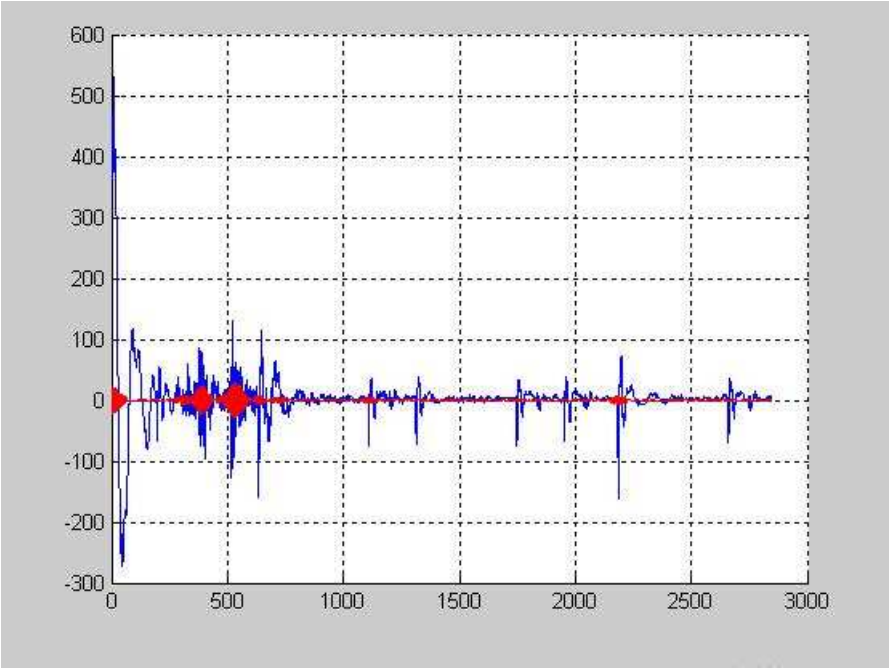


Figure 58. **Ultrasound Time domain raw data (Blue) Filtered data (Red)**

It's very clear in Figure 59 that the noise below 4.25MHz and above 5.75MHz was removed from the signal.

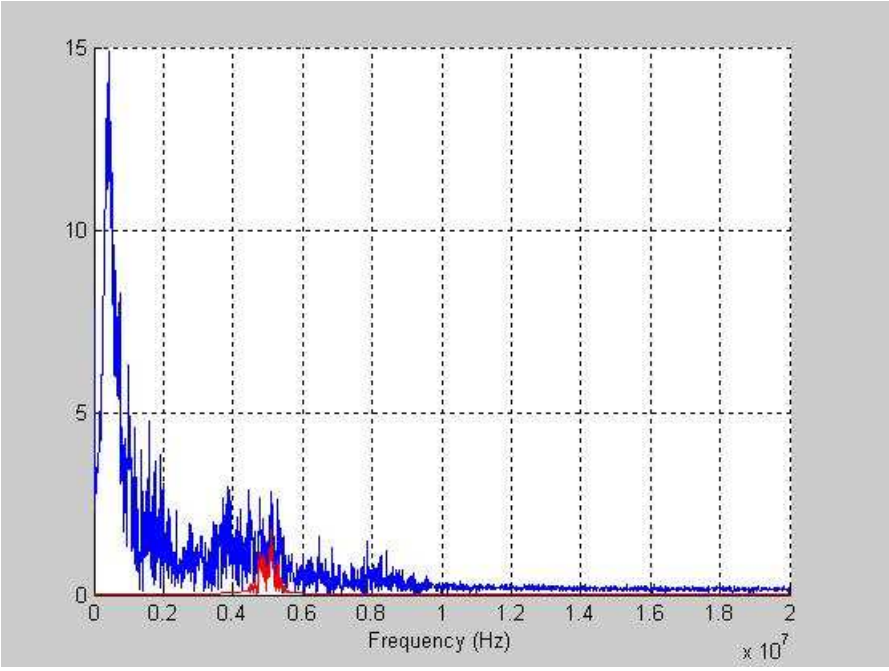


Figure 59. Ultrasound Frequency domain raw data (Blue) Filtered data (Red)

Even after the signal is filtered, it has much variance and to process and detect peeks an envelope algorithm named Hilbert was used. In **Figure 60** we can see the final signal in red. With this approach the peeks become very clear and automatically detectable.

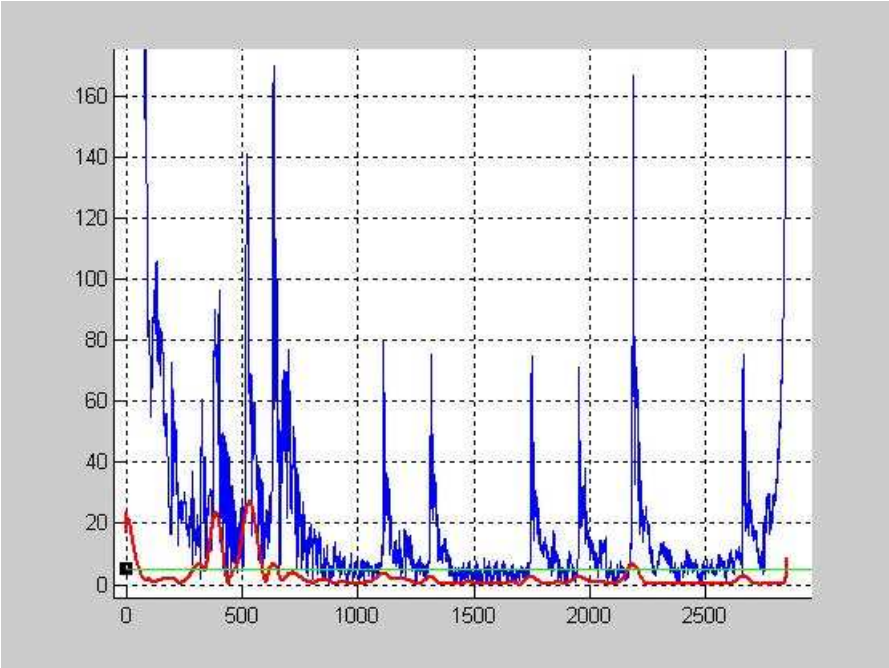


Figure 60. Ultrasound Time domain filtered data (Blue) Hilbert of the filtered data (Red)

The digital signal processing algorithm executes the following steps:

- Centre the signal in amplitude considering that raw data values are in a scale from 0 to 4096;
- Calculate filter order and coefficients;
- Signal filtering;
- Apply Hilbert to the filtered signal;
- Eliminate reverberation effects by turning to zero values until the second minimum in the first 7.5 µs.

2D reconstruction

The 2D reconstruction consists in transforming filtered ultra-sound data to 2D images. The ultrasound array may be formed by 16 or 32 elements in circular shape that acquires 360º slices of data from the digestive tract.

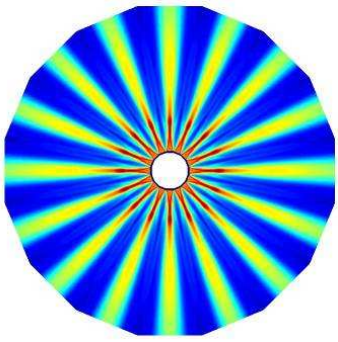


Figure 61 – TROY 16 ultrasound array

Each sensor receives an ultrasound signal which is defined by the amplitude that varies in time. For each element 3000 amplitude values are acquired with an interval of 0.025 µs.

To obtain distance from time we can use formula d= t*c/2 where c= 1.5 mm/µs. Thus, for each 40 values acquired there's an interval of 1µs corresponding to a distance of 0.75 mm.

After noise reduction processing an analysis to the ultrasound signals is performed to identify the wall of the intestine, the different tissues and different layers inside the intestine.

The distance from the sensors to the wall of intestine identify the first, inner contour used for 2D contours functionality and 3D image reconstruction. The 2D image will be reconstructed from the capsule border, adding small layers of 0.375 mm formed by semi-circular sections with colour intensity defined by the mean amplitude of the ultrasound reflected by the tissues in that section of 20 consecutive measurements corresponding to ½ µs.

There's an initial portion of signal containing reverberation that is eliminated. This portion is calculated as being the second local minimum in the first 7.5 µs after applying the Hilbert envelope function. The last 1000 measures usually have signal artifacts. As the interest region is in the first 2000 measures, corresponding to a distance of 37.5mm from the capsule border, the last 1000 measures are also discharged.

The 2D image is designed by layers, 100 thin layers of 0.375 mm each, drawn section by section forming a circular shape. The following image illustrates the sections and layers for 2D image reconstruction.

Figure 62 – Ultrasound 2D reconstruction

Each layer is made up of 16 or 32 sections, depending on the number of sensors, and the colour of each section is defined by the average amplitude of the signal in instances of 0.5µs (20 measurements) indicating the intensity of colour on the grey scale.

Contours are calculated based on filtered signals of 5 consecutive scans applying the following steps:

- Calculate the threshold value for the calculation of local maximums based on the standard deviation of the signal amplitudes;
- Calculate local maximums;
- Calculate MODA of the number of local "maximums" and exclude those outside MODA;
- Calculate mean and standard deviation of time/distance and amplitude and exclude signals outside standard deviation; this is for signals not excluded in step before.
- Calculate mean of valid maximums obtaining the contours.

The contours enable automatic features extraction like distance between layers that may be a sign of some abnormality on the digestive tract. First contour points are used for 3Dmodel rendering.

3D Reconstruction

The 3D reconstruction is based on triangulation of points of contours in sequenced images, positioned accordingly with the referential data sent by the sensors network. The positional data given by the sensors network is composed of position and orientation of the capsule in three axes. This information enables a correct positioning of the sequence of images to perform the triangulation of contour points.

A first version of development was based on 2D images obtained from ultra-sound colonoscopy. The contour points were obtained from 2D images using simulated annealing algorithm. Although a new version of contours extraction directly from ultra-sound raw data is implemented (as shown in 2D reconstruction section) this version is kept as it represents an open door to other systems use Troy 3D models over their 2D images. The two approaches using raw data or 2D images are integrated in the same application.
The 3D rendering process consists of the following steps:

- Based on the contour points, on position and on rotation information the 3D points are calculated.
- The 3D model is reconstructed by triangulation of the 3D points.
- A distributed process was implemented in order to fasten the 3D rendering using several computers.

Data Storage

An XML model was defined to save the 3D and 2D models and methods to read and write the models were created. The sample of XML file is shown bellow:

```
<model xmlns="http://ridl.pt.vu/i3d/schema" pointsPerImage="16" numLayers="120" numFrag="6" typeOfModel="txt">
  <InformationPatient refCap="d11" refPat="" name="d11" sex="Female" age="15" contact="" notes="" />
  <points2D>
    <Point2D Time="0" Annotation="">
      <Position id="1" x="40" y="0" z="0" />
      <Orientation x="16556.000" y="64899.000" z="64400.000" />
      <Rotation y="0" />
      <Distances id="0" d1="5.5" d2="0" d3="0" d4="0" />
      <Distances id="1" d1="5.5" d2="0" d3="0" d4="0" />
      <Distances id="2" d1="5.5" d2="0" d3="0" d4="0" />
      <Distances id="15" d1="5.5" d2="0" d3="0" d4="0" />
    </Point2D>
    <Point2D Time="1" Annotation="">
    <Point2D Time="5" Annotation="">
  </points2D>
  <setColor>
  <points>
    <point3D id="2" x="40.204" y="0.321" z="-0.398" />
    <point3D id="3" x="40.377" y="0.205" z="-0.344" />
    <point3D id="4" x="40.492" y="0.058" z="-0.239" />
    <point3D id="5" x="40.533" y="-0.097" z="-0.096" />
  </points>
  <objects>
    <triangle id="1">
      <normal x="0.000" y="0.000" z="0.000" />
      <point id="19" />
      <point id="3" />
      <point id="2" />
    </triangle>
    <triangle id="2">
  </objects>
  <sections>
    <section name="default">
  </sections>
</model>
```

Figure 63 – XML sample data

Data Analysis

The interface layer of Data Analysis module enables the interaction between the user and the entire system, by using its functionalities and invoking other layers in a transparent manner to the final user.

The user interface for data analysis is composed by a menu bar to open the desired models, manipulate 3D models and 2D images, a time bar enabling a perspective of the current position in the entire model and enabling annotations, and a visualization area enabling the presentation of 3D models and 2D images and its manipulation.

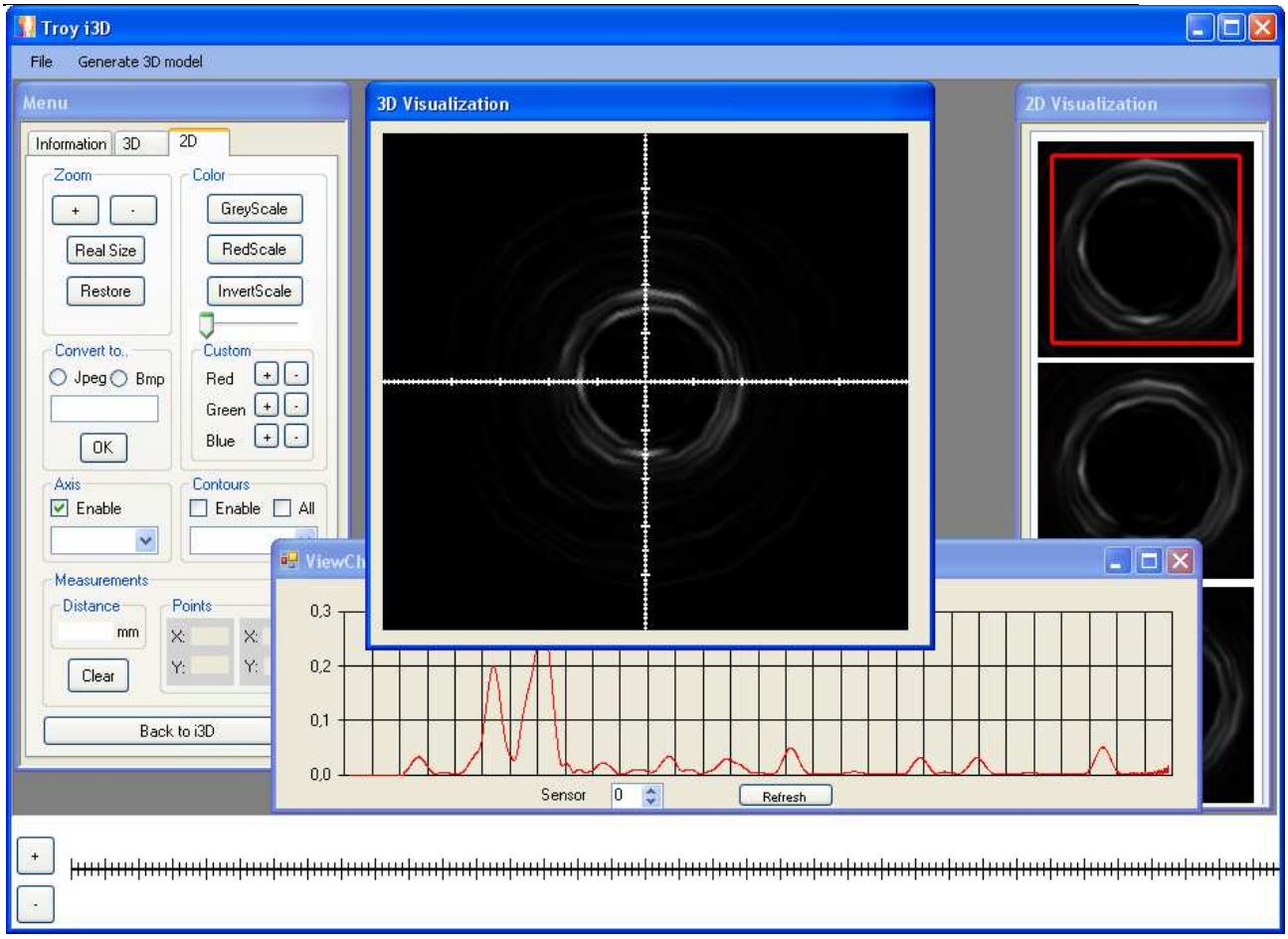


Figure 64 – Interface of Data Analysis module based on Ultrasound raw data – 2D manipulation

The main menu allows the user to open an existing 3D model or to generate a new one invoking the Troy input application. Once the user selects and open a 3D model the information panel will present the patient's information.

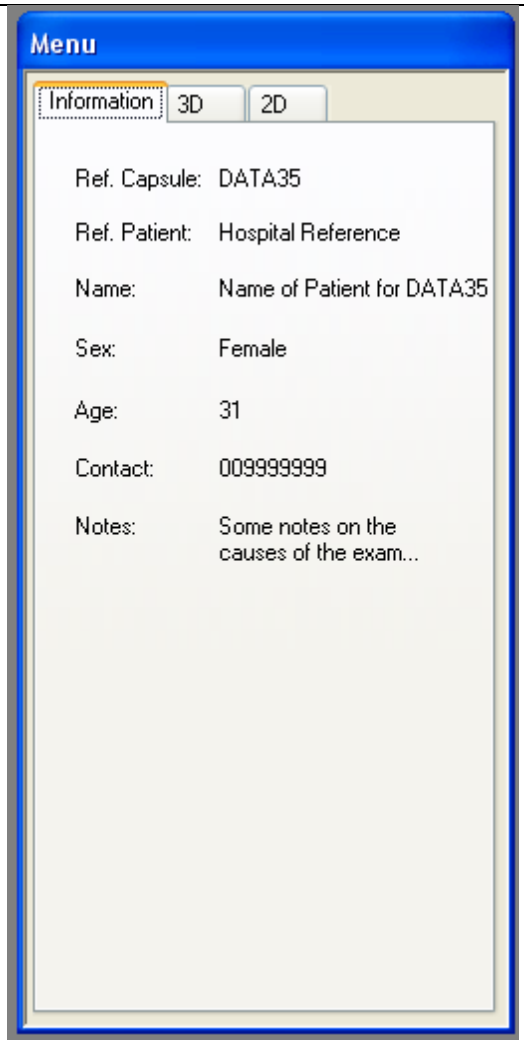


Figure 65 – Patient's information panel

The 3D model and corresponding 2D images will be displayed in the visualization areas. A 3D model manipulation toolbox enables the users to perform several actions on the presented model:

- Zoom in and zoom out, with possibility to define the step;
- Rotate the 3D model in X, Y and Z axis, with possibility to define the rotation step;
- Positioning the 3D model on the visualization window, with step definition;
- Trajectory visualization to perform a trip inside the 3D model, with the possibility of changing the speed of progression;
- Auto-rotation enables an automatic rotation of the 3D model, with the possibility of changing the rotation speed;
- Wireframe option enables the visualization of primitive triangles, with the possibility to change the size of points and the line width;
- Show/hide 3D axis, enabling change their size.

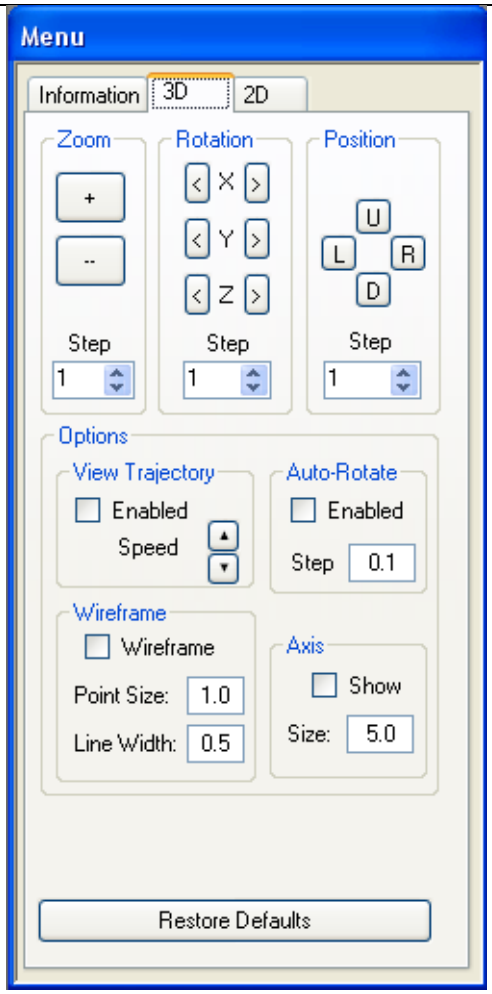


Figure 66 – 3D model manipulation toolbox

With some training it is possible to use the mouse over the visualization panel for positioning, moving and zooming the 3D model.

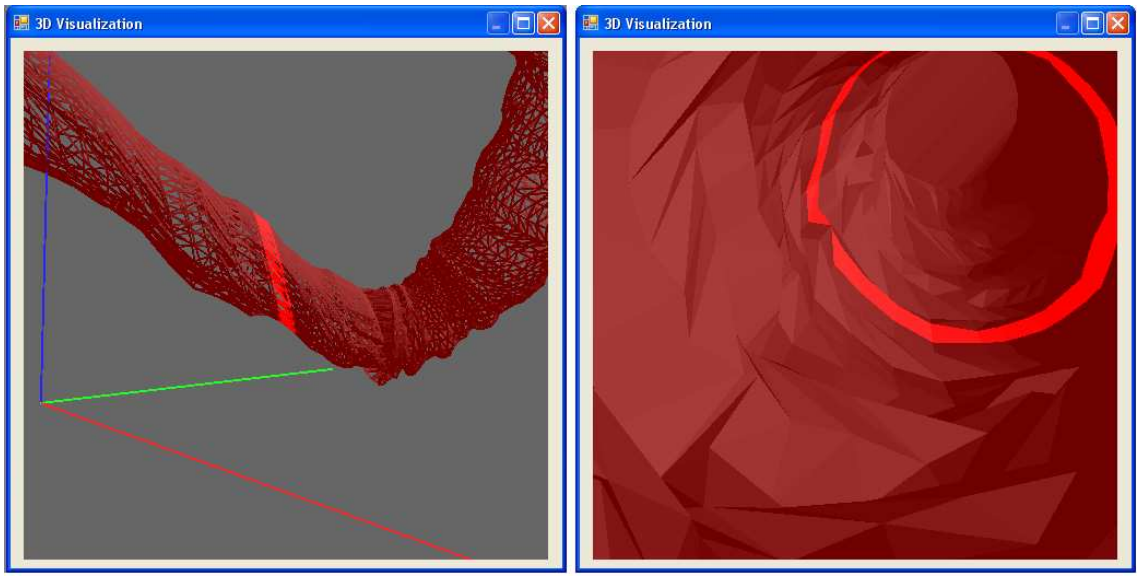


Figure 67 – 3D model using a) wireframe and axis and b) trajectory view

While visualizing the 3D model, it is possible to present the 2D images corresponding to three consecutive scans that originate the 3D slice selected in the time bar. The user can click over one of the 2D images to select it and manipulate that image.
A 2D image manipulation toolbox enables the users to perform several actions on the selected image:

- **Zoom**: Zoom in and out and view the image in the real size;
- **Colour**: It can display the image on the grey scale, red scale, invert scale or personalized scale.

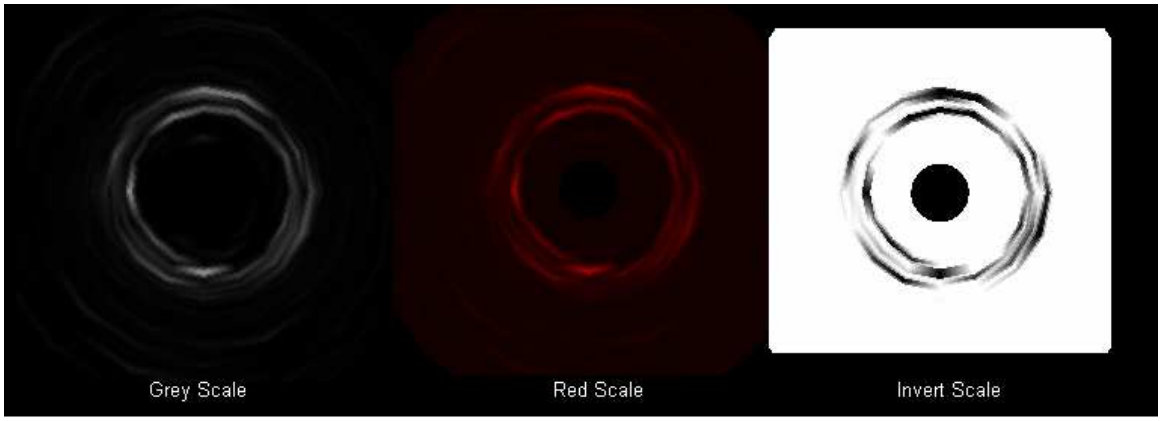


Figure 68 – Colour tools to enhance image details

- **Convert to**: Convert the selected image to JPEG or BMP.
- **Axis**: View the axis.

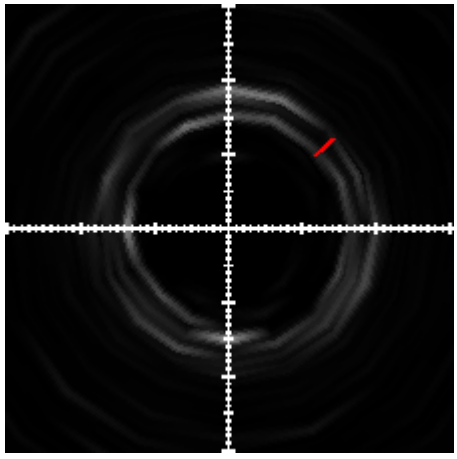


Figure 69 – Axis tools to help with measurements

- **Measurements**: Calculate the distance between two points on the selected image and present the result in the toolbox. In the image draw a line between these points;
- **Contours**: View the contours.

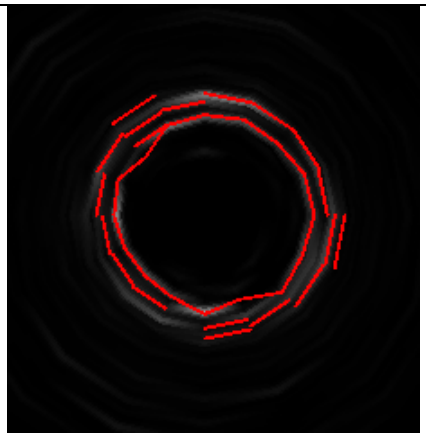


Figure 70 – Present the contours representing different layers of small bowel

The time bar can present the annotations that the user makes over the model. The annotation can have different categories and a small description. The time bar also has two buttons allowing moving forward and backward step by step.

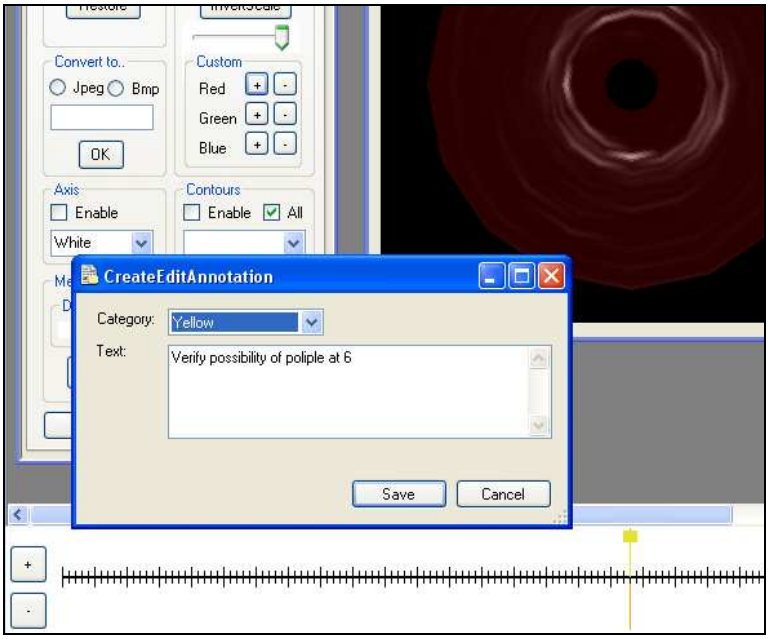


Figure 71 – Annotation tool

2.4.3. Deviations from Workplan

Task 4.1 had some developments in month 7 but because it was depending on the selection of electronic components it was rescheduled to M16 – M24. Developments with beta prototype postponed its finish to month 29 with last improvements on the software. Task 4.2 started 1 month later and should be completed in month 27. It was needed more months than initially planned because of complexity of the modules and the need for experimental data from the Wireless UEC and the body sensors network. Improvements were also made with beta prototype and final version of deliverable 4.1 was only finished in the end of the project.
Task 4.3 was rescheduled in the last DOW and it was finished in time.

2.4.4. List of Deliverables and Milestones

Del. Nº	Deliverable name	Workpackage nº	Date due	Actual/forecast delivery date	Status	Lead Contractor
4.1	Software and Software documentation	4	M12 Final M27	M29 Final M30	Completed	IAITI

Milestone nº	Milestone name	Workpackage nº	Date due	Actual/forecast delivery date	Lead contractor
3	System Design	4	M12 Final M27	M23 Final M30	IAITI

2.5 Workpackage 5 – Ultrasound Probe Minituarization

2.5.1. Objectives

According to the "Annex I- Description of Work" the objectives of the WP 5 were:

- *To develop an ultrasound probe small enough to be inserted inside the capsule.*

For the accomplishment of the established objectives the following tasks were foreseen:

a) **Task 5.1 – Development of the ultrasound probe (M3-M15)**:
   i. The design and implementation of the ultrasound probe.

b) **Task 5.2 – Miniaturization of the ultrasound probe (M7-M25)**:
   ii. The activities for the miniaturization of the ultrasound probe.

2.5.2. Progress

The work which has been developed on this WP is being leaded by UI of KTU with contributions from IAITI, AGT, Ardoran, Dunvegan and UMF of Cluj Napoca. WP5 is a highly demand and crucial for project success.

Task 5.1- Development of the ultrasound probe/ Task 5.2 – Miniaturization of the ultrasound probe

Tasks 5.1 and 5.2 were concluded successfully with the development of two ultrasound probes of 16 and 32 elements working at 5 MHz. Deliverable 5.1 contains detailed information about the characteristics of the probes.

The objective of this workpackage was to develop an ultrasound radial array small enough (D<10 mm, l<6 mm) to be inserted inside the capsule. In order to choose best suitable dimensions and frequency of the ultrasonic radial array, simulations of different array configurations were performed.

In Figure 72 the possible geometry of the ultrasonic array consisting of 32 separate transducers is presented. In this work calculation for the arrays with 32 elements as well as with 16 were carried out. Separate transducers will be mounted on the supporting structure.

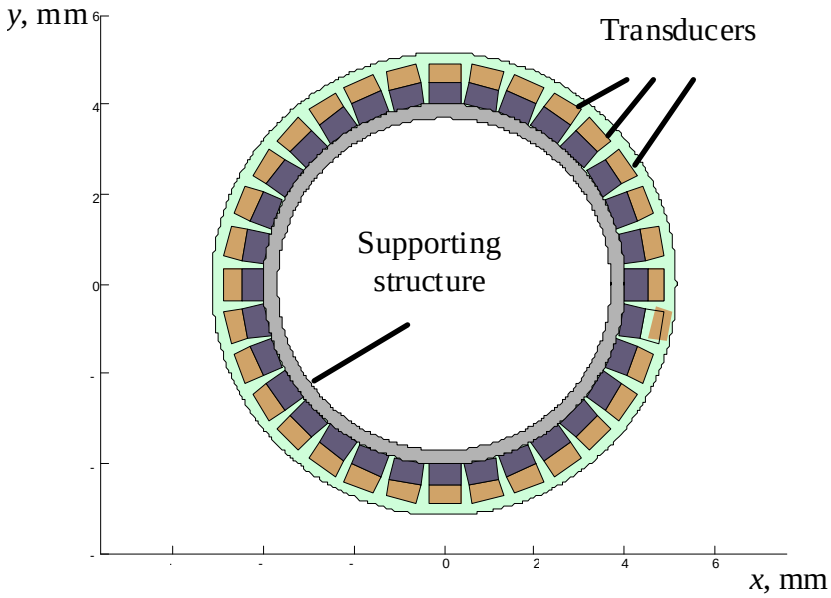


Figure 72 - Ultrasonic array consisting of 32 separate transducers

In Figure 73 geometry of the single array elements is presented. Single transducers in the array will have the rectangular form – height H and width Δl_t and they will be separated from each other by the gap Δl_g. In further calculations it was assumed, that the height of the elements was 5 mm and the width of the elements Δl_t was 2 mm, 1 mm or 0.7 mm. The gap between elements depends on the number of the elements.

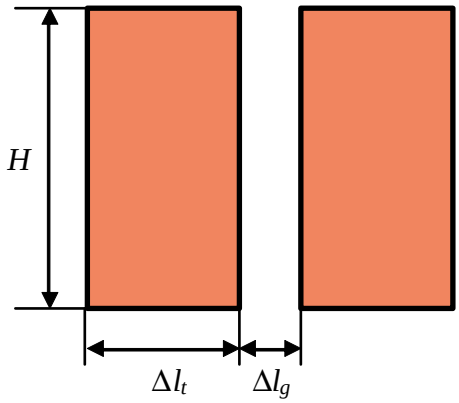


Figure 73 - Geometry of the single elements (side view)

The pulsed acoustic fields radiated by elementary rectangular transducers were calculated using impulse response method proposed by Lockwood and Willete [Lockwood and Willete] and taking into account observations for numerical calculations made by Reibold and Kažys [Reibold and Kažys].

The pulsed acoustic fields were calculated using MATLAB. In order to choose best suitable dimensions and frequency of the ultrasonic radial array, simulations of different array configurations were performed. Ultrasonic fields in a transmission mode of 5 MHz, 7 MHz and 10 MHz transducers with different dimensions (length 5 mm, width – 2 mm, 1 mm and 0.7 mm) were simulated. It was assumed, that in all cases transducer is radiating into water (c=1500m/s), because the value of ultrasonic velocity in biologic tissues is similar to the ultrasonic velocity in water.

In order to visualize the field of the whole radial array, the coverage of the field of the radial array with 16 and 32 elements at different transducer frequencies was simulated. In Figure 74 the coverage of the field of the 16 elements 5x1 mm 10 MHz radial array is presented. The dark zones in the image show, where there is almost no signal, or the signal is with very small amplitude. That means, that in case of the 16 elements 5x1 mm 10 MHz radial array there are too many “dark zones”, from which no information will be available.

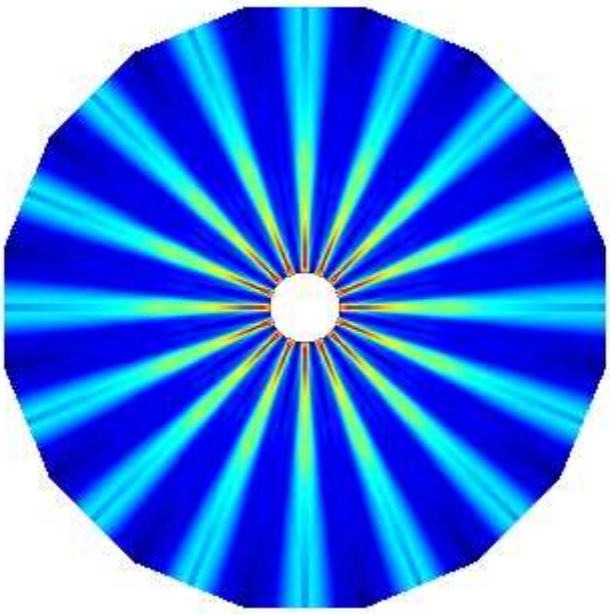


Figure 74 - The coverage of the field of the radial array 10 MHz, 5x1 mm, N=16

In Figure 75 the coverage of the field of the 32 elements 5x0.7 mm 5 MHz radial array is presented. In this case coverage is much better in comparison with the previous case.

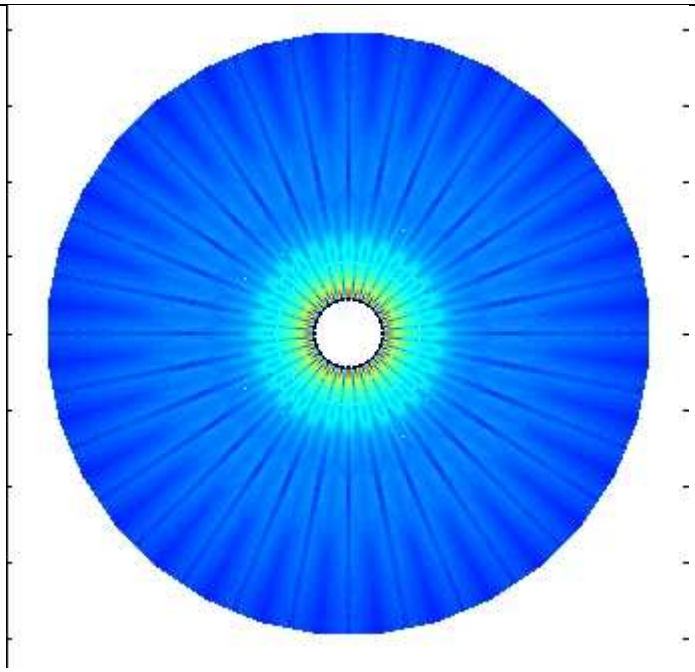


Figure 75 - The coverage of the field of the radial array 5 MHz, 5x0.7 mm, N=32

The performed simulations show that the best results could be achieved using the 5 MHz array consisting of 32 transducers with dimensions of elementary transducers 5x0.7 mm.

Single Element

First of all single array elements were manufactured and tested. For tests single transducer elements of different sizes and frequencies were produced. Dimensions of fabricated single array elements are presented in Table 3.

Table 3 - Dimensions of the array elements

f, MHz	Height, *H*, mm	Width, *l*, mm	Thickness, µm	
			Piezoelement	Matching layer
5.1	5	2	390	125 ± 6
7.0	5	2	290	105 ± 5
10	5	2	220	70 ± 3
10	5	1	220	70 ± 3

In Figure 76 the pulse response of a single transducer without matching layer and backing (excitation by a 10 V pulse, duration 90 ns) measured in a pulse- echo mode is presented. In Figure 77 the pulse response of the same transducer with the λ/4 matching layer and backing (excitation by 10 V pulse, duration 90 ns) measured in the pulse-echo mode is presented. It is possible to see significant improvement of the pulse response.

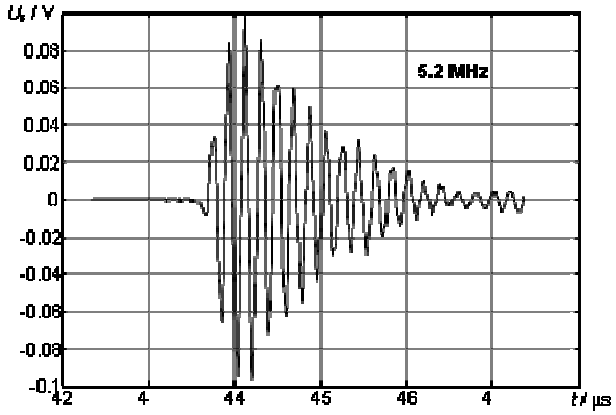


Figure 76 – Pulse response of a single transducer without matching layer and backing (excitation by a 10º V pulse, duration 90º ns) in a pulse echo mode

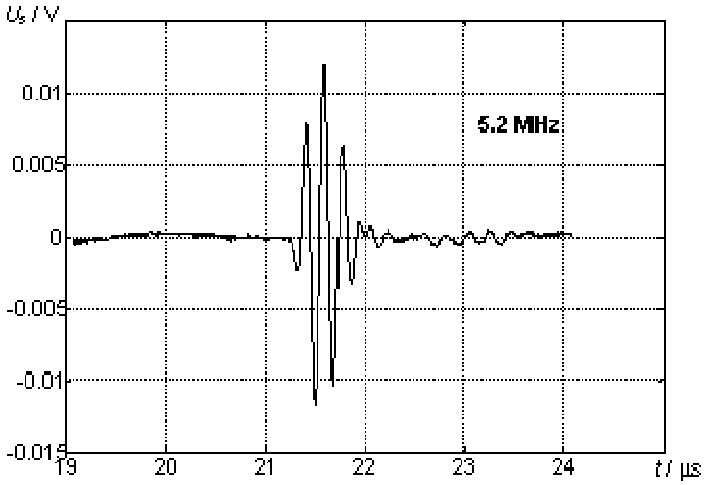


Figure 77 - Pulse response of a single transducer with the λ/4 matching layer and backing (Excitation by a 10 V pulse, duration 90 ns)

In Figure 78 the pulse response of a single 10 MHz transducer (1×5 mm) with the λ/4 matching layer is presented. The signal was reflected from the stainless steel plate at the distance l=30 mm. The acoustic impedance of the reflector was *Z*=45 MRayl, the thickness 3 mm. The transducer was excited by 10 V negative pulse, the duration of which was 50 ns. In Figure 78, b the spectrum of the same signal is presented.

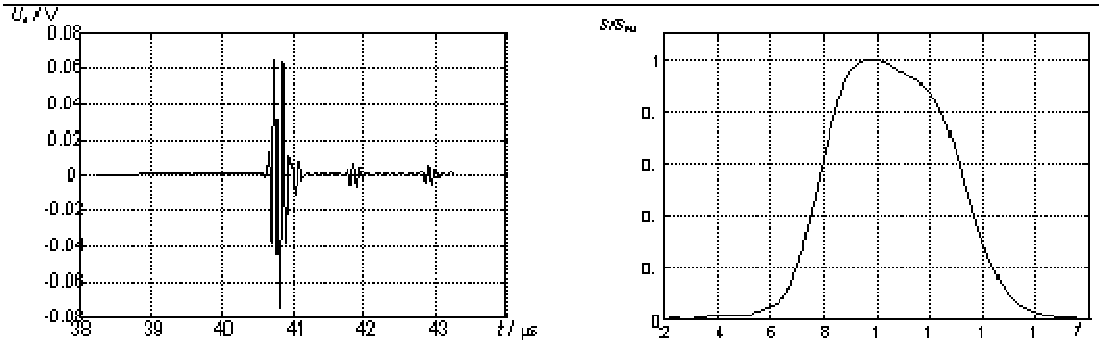


Figure 78 - a) pulse response of a single 10 MHz transducer (1×5 mm); b) spectrum

From experimental measurements presented above the performance of the single 10 MHz 1x5 mm transducer can be calculated. The experimentally determined transfer coefficient of the single transducer in the pulse-echo mode (from a planar reflector) is given by

$$K = \frac{U_r}{U_e} = 0.7 \cdot 10^{-2}. \qquad (3.1)$$

That corresponds to transduction losses $K = -23$ dB. The bandwidth of the transducers is (8-13.5) MHz or Δf=5.5 MHz; the central frequency f_0 = 10.5 MHz.

Experimental investigation with different reflectors was performed. The aim of these experiments was to estimate the potential spatial resolution in a structure which mimics multilayered biological tissue. Reflectors used in measurements are shown in **Figure 79**. In **Figure 79**, a - the multi layered structure is presented, in **Figure 79**, b - spherical (D=3 mm) and needle type reflectors are presented.

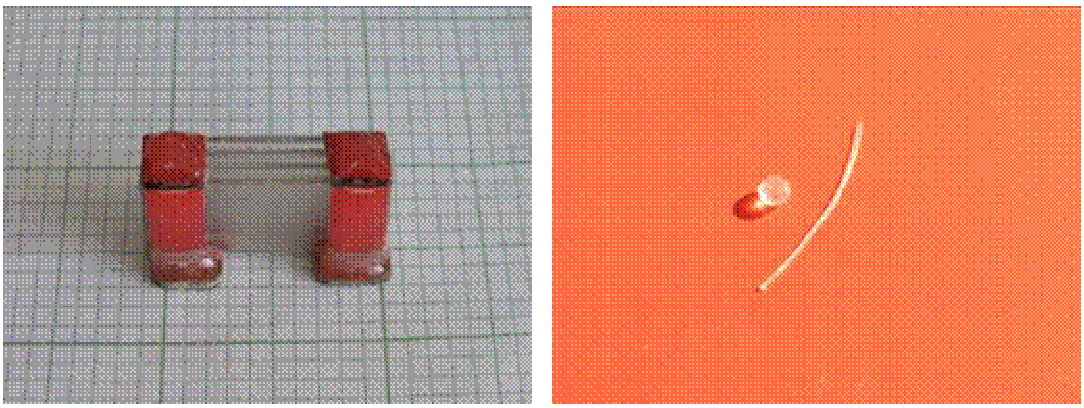


Figure 79 - Reflectors used in measurements: a - Multi-layered structure, b - Spherical (D=3 mm) and needle type reflectors

The distance between adjacent surfaces of the multi layered structure is 0.92 mm. The acoustic impedance of the layer is 2.2 MRayl (For comparison, the specific acoustic impedance of the muscle tissue is Z=1.7 MRayl).

The signals, reflected from different surfaces of the multilayered structure are presented in Figure 80. These results illustrate the depth resolution, which may be obtained.

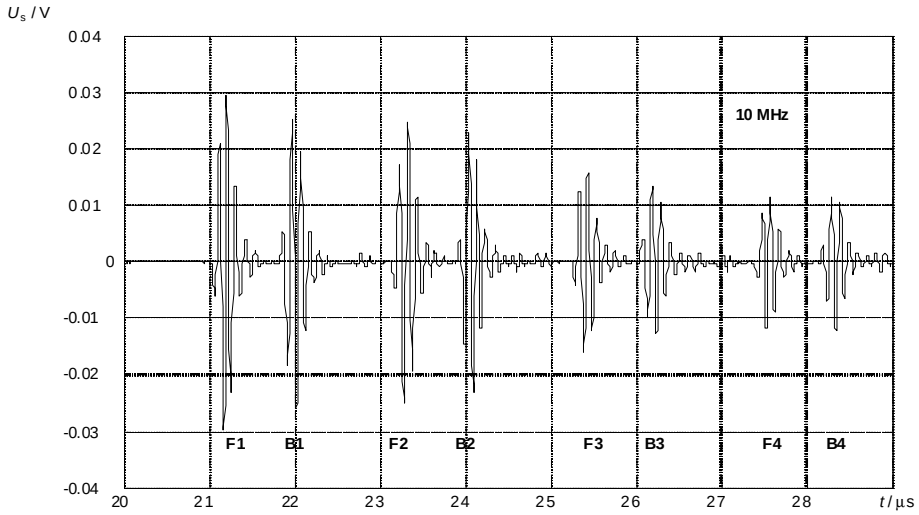


Figure 80 - Reflections from the multilayered structure: F1- reflection from the front surface; B1- reflection from the back surface; the distance between adjacent surfaces (F1- B1)=0.92 mm

Reproducibility of different 10 MHz elementary transducers was experimentally tested as well, confirming good reproducibility of manufacturing of the array elements.

Realization of the ultrasonic array

The ultrasound probe was developed within the dimensions constraints previously defined - small enough to be installed inside a capsule with the dimensions of 11 mm x 26 mm. The probe can send and receive ultrasonic signals in 360 degrees. The obtained in this way information is needed for the software to generate a 2D image.

The structure of the single array element of the 32 elements array is presented **in Figure 81. As** piezoelectric element was used Pz 29. Two matching layers with different acoustic impedances are used, but there is no backing.

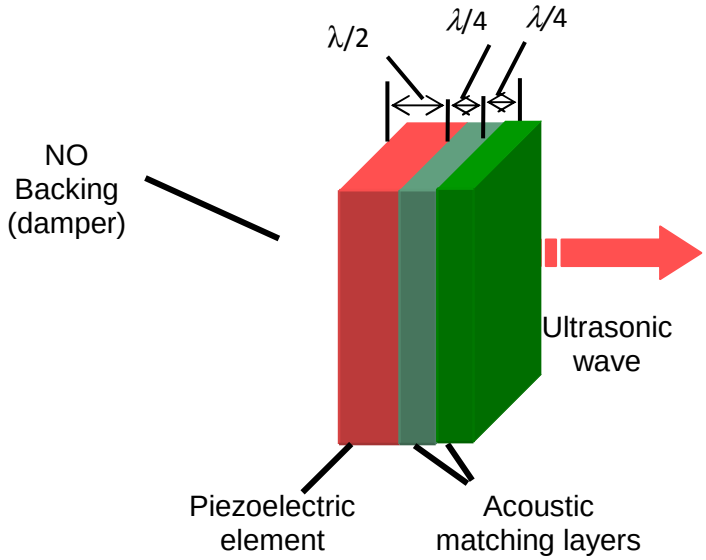


Figure 81 - The single element of 32 element array

Measurements of transduction losses were performed. The experimental set-up for measurement of signal losses is presented in **Figure 82**. In **Figure 82** transmitted pulse and the experimentally measured reflected signal from the copper foil at the distance of 1 mm are presented. In **Figure 83** experimentally measured losses at different distances from transducer are given.

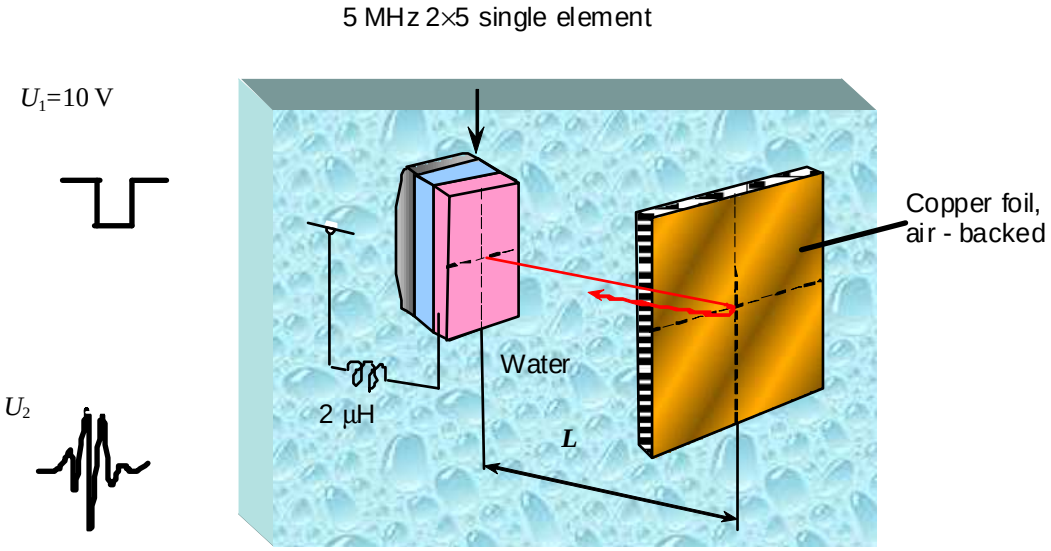


Figure 82 - Measurement of signal losses

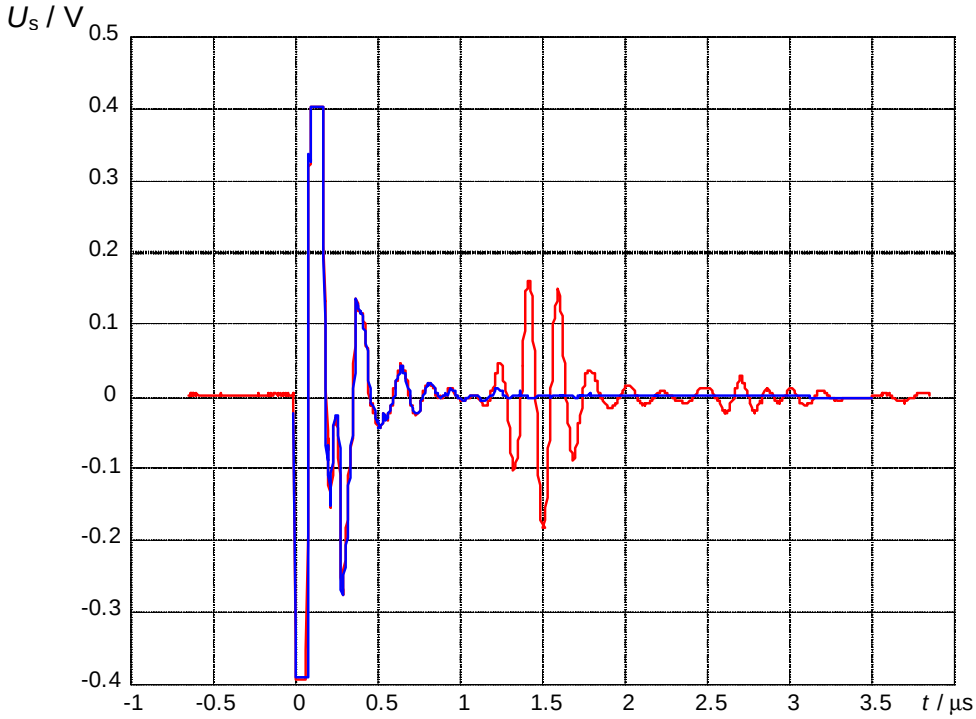


Figure 83 - Experimental investigation of single ultrasonic probe element. Reflection from the copper foil at the distance of 1 mm

Comparison of excitation with 10V and with 3V was also carried out. In **Figure 84** signals reflected from the copper foil at the distance *l*=30 mm with different excitation is presented.

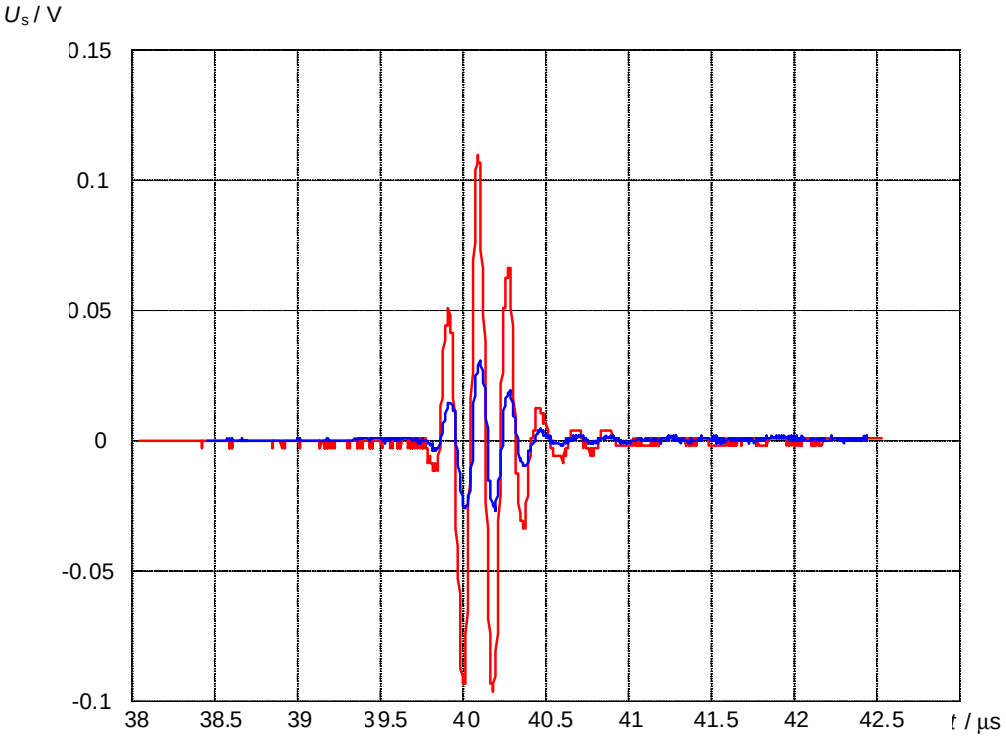


Figure 84 - Comparison of 10V excitation with 3V. Signal reflected from the copper foil at the distance *l*=30 mm.

As it was expected, measurements with the 3V excitation are possible, only the amplitude of the reflected signals is 3.33 times lower.

The ultrasonic 5 MHz arrays consisting of 16 and 32 elements and its manufacturing technology were developed.

The photo of the 16-element ultrasonic radial array assembled for experiments is given in Figure 85.

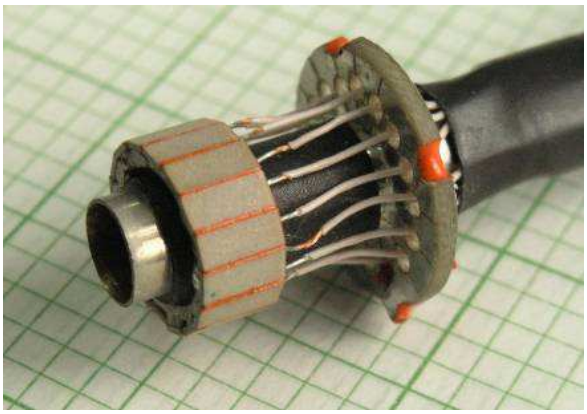


Figure 85. Ultrasonic 16 element array prepared for experiments in water

The photo of the 32element ultrasonic radial array is given in **Figure 86**.

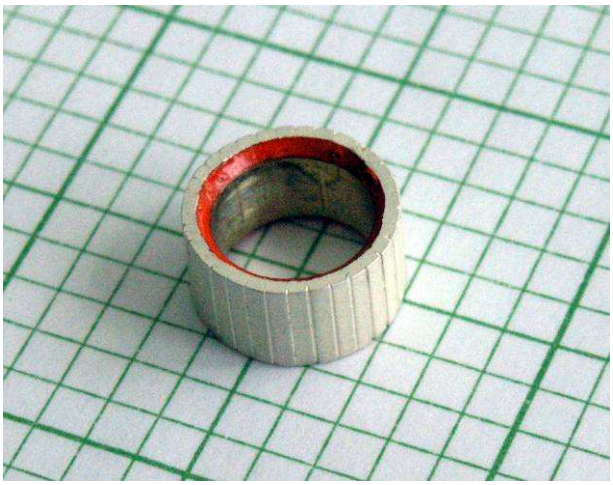


Figure 86 - element ultrasonic radial array.

2.5.3. Deviations from Workplan

The delay in Deliverable 1.1, with the consequent delay in the definition of the size and frequency for the probe, coupled with the complexity of such a miniaturized ultrasound probe, requiring very special process and tools for its production, lead to an extent of the plan in two months for task 5.1.

After request for project extension Task 5.2 should be concluded at month 24 and it was achieved. Deliverable 5.1 was concluded on month 24 and Milestone 4 was concluded at month 30.

2.5.4. List of Deliverables and Milestones

Del. Nº	Deliverable name	Workpackage nº	Date due	Actual/forecast delivery date	Status	Lead Contractor
5.1	Ultrasound Probe	5	M24	M25	Completed	UI of KTU

Milestone nº	Milestone name	Workpackage nº	Date due	Actual/forecast delivery date	Lead contractor
4	Ultrasound Probe	5	M27	M30	UI of KTU

2.6 Workpackage 6 – Prototyping and Testing

2.6.1. Objectives

According to the "Annex I- Description of Work" the objectives of the WP 6 were:

- *To produce one alpha version of the complete system, test and debug it*
- *To produce one beta version of the complete system (functional model)*
- *To produce a test rig and a test protocol*
- *To test the functional model*
- *Assess project results and validate the proposed concept*

For its accomplishment the following tasks were defined:

a) **Task 6.1: *Manufacturing of alpha prototype* (M13-M18)**

- Integration of all components and setup the alpha prototype

b) Task 6.2: *Alpha testing and optimisation* (M18-M21)

- Comparative testing will be performed, in order to assess comparatively its performance and to proceed to Hardware, Software and Firmware debugging;
- Communication protocols with the capsule will be tested and debugged.

c) Task 6.3: *Realisation of the beta prototype* (M25-M30)

- Realise first functional model and checked for full functionality

d) Task 6.4: *Laboratory testing* (M24-M29)

- develop a specific protocol for testing the TROY functional model
- specify and develop a test rig (synthetic phantom)
- execution of the test protocol using the phantom

e) Task 6.5: *Performance assessment* and concept validation (M27-M30)

- Performance assessment

2.6.2. Progress

The activities of this workpackage were all realized in the second year and a half of project.
In Task 6.1 alpha prototype was developed and deliverable 6.1 was completed. In Task 6.2 tests where performed, optimizations were studied and improvements were done in Task 6.3 in the development of the beta prototype. Deliverable 6.2 was also completed. In Task 6.4 a test rig was developed as tests were made with the complete system. The Deliverable 6.3 was completed. Finally in Task 6.5 was conducted performance assessment and concept validation and Deliverable 6.4 was done.

Alpha prototype

Alpha prototype was developed with the integration of the components for the Wireless UEC, the ultrasound probe and UEC electronics, a simple bus for data collection instead of the wearable computing and the Troy Workstation software.

The ultrasonic 16-elements probe was produced in Workpackage 5 and ready for integration as can be shown in Figure 87.

Figure 87. Ultrasonic 16 element array prepared for alpha prototype

Experiments were conducted with a steel ball (Figure 88) and received signals were analyzed and treated (Figure 89).

Figure 88. **Experimental set-up with a steel ball**

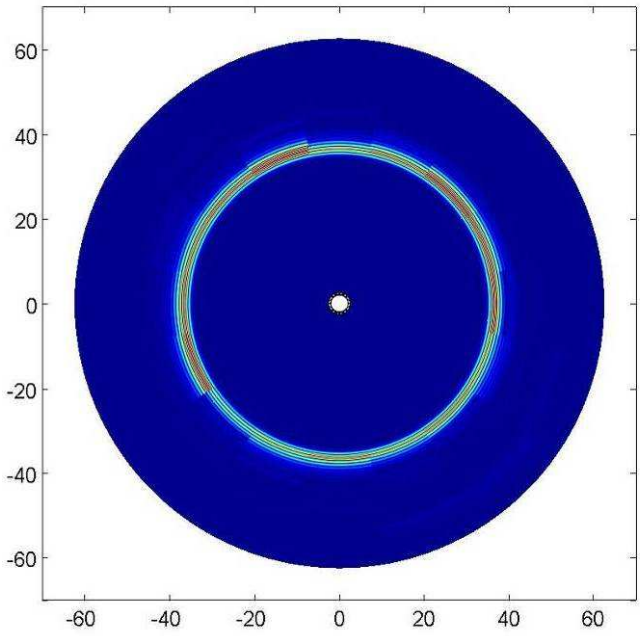
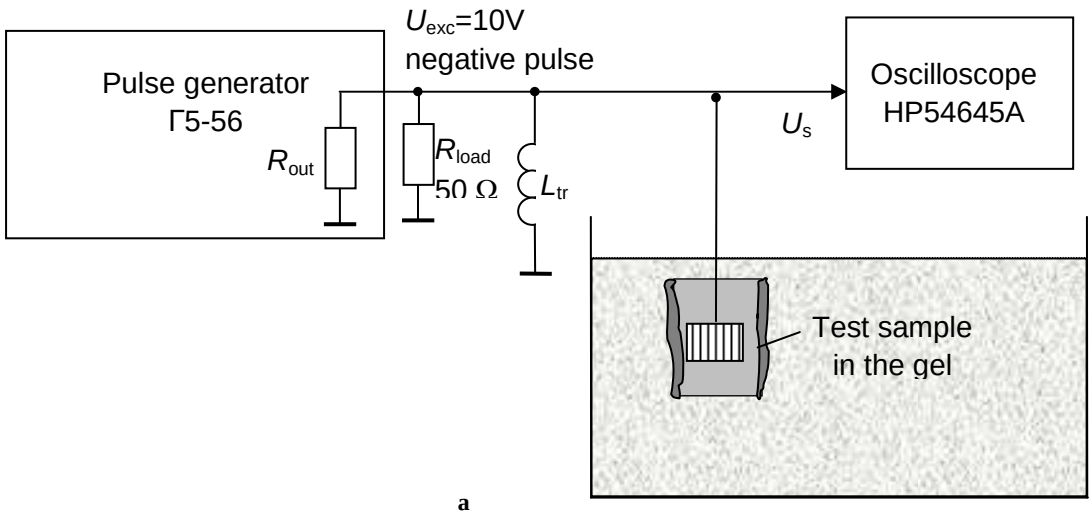
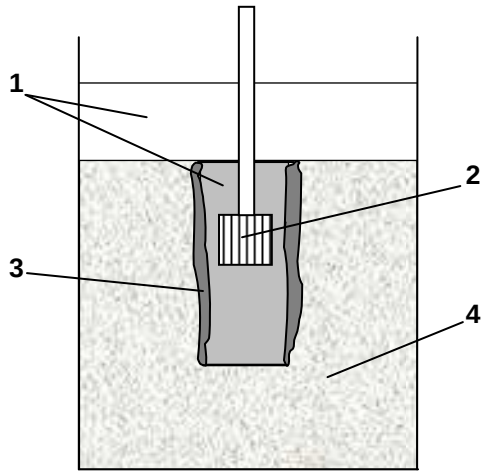


Figure 89. The circular B scan image of the signals received by different element of the transducer array. The signals were aligned in time domain according closest one.

Then the experimental investigation of the sample of the bowel “in vitro” was performed. In Figure 90 the experimental setup of the measurements is presented, in Figure 90, a - the structural diagram is presented and in Figure 90, b - the cross-section of the sample of the bowel and ultrasonic array is presented. The concentric shape of the piece of a bowel was fixed using gel. The radial ultrasonic array was inserted in the bowel filed by water. The photo of the experimental set-up is presented in Figure 91.



a



b

Figure 90. The experimental setup of the measurements: a - the structural diagram
b - the cross-section of the sample of the bowel and ultrasonic array
(1 – water, 2 – the radial ultrasonic array, 3 – the piece of a bowel, 4 – gel)

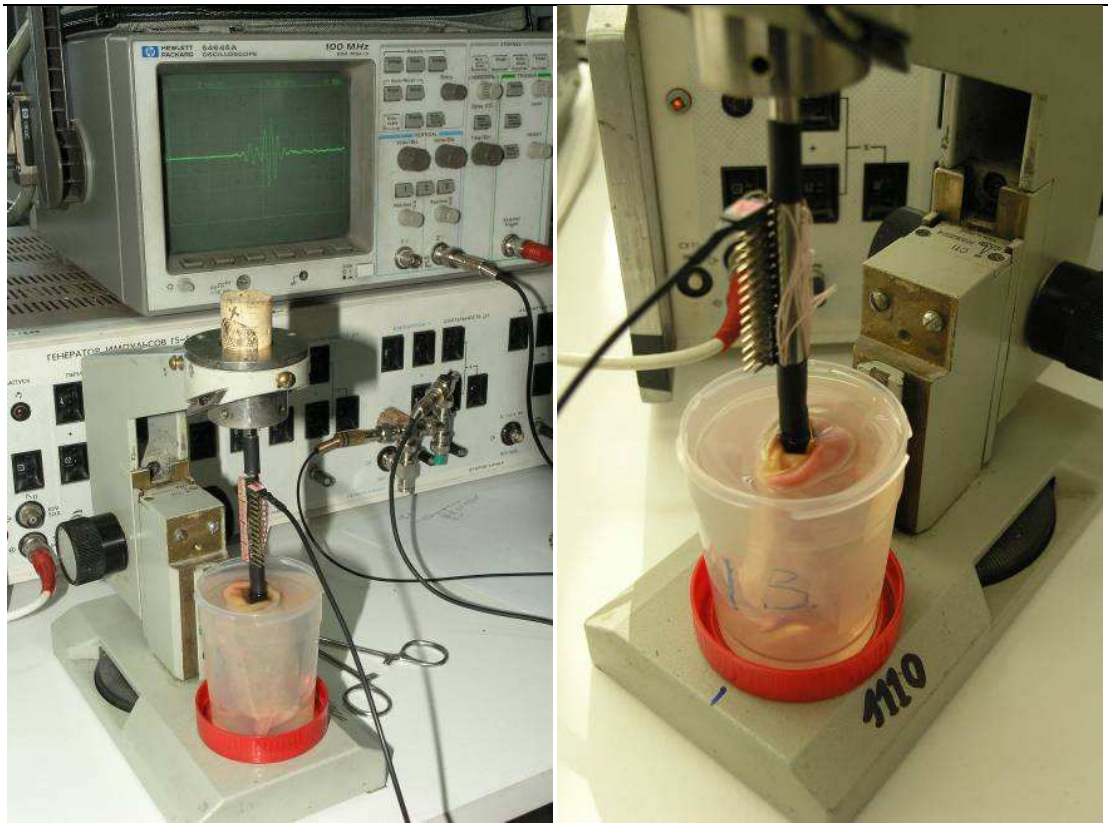


Figure 91. The photo of the experimental set-up

The signals received by element 1 reflected by the sample of the bowel are presented in Figure 92. Due to an electrical contact problem in the circuit of the transducer No. 16 the signal of this transducer was not saved.

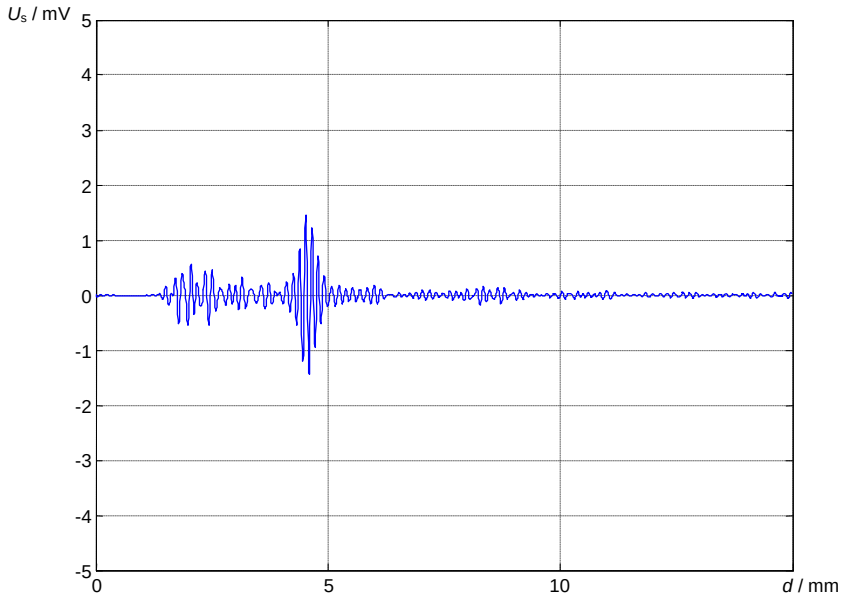


Figure 92. The signal received by the transducer element No. 1

The received signals were processed using following steps:

- Subtraction of the reference signal.
- Clearing of the dead zone (time interval 0-2µs) .
- Filtering in frequency domain.

In Figure 93 the circular B-scan image obtained after processing is presented

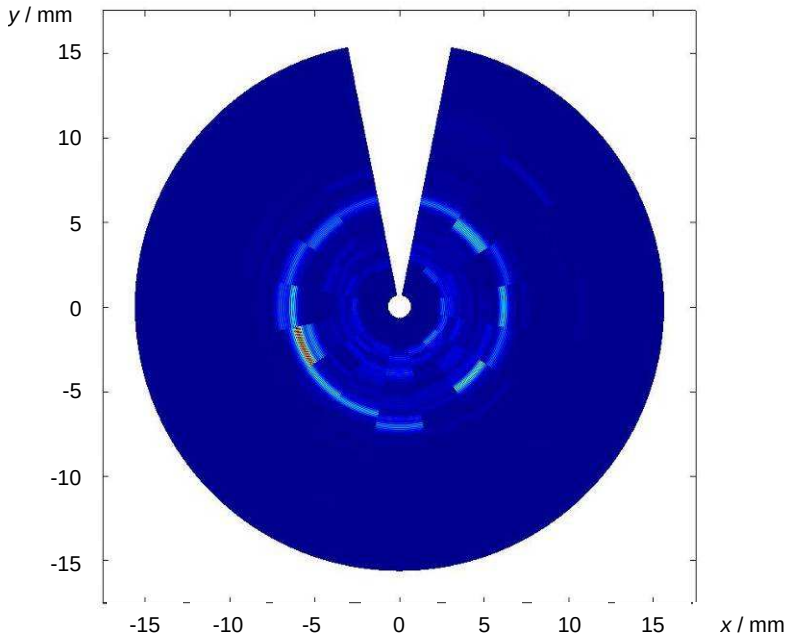


Figure 93. Circular B-scan image obtained after processing

The ultrasonic 5MHz array consisting of 16 elements (to be inserted inside the capsule with the dimensions of 11 mm x 26 mm) and its manufacturing technology were developed. Experimental investigations of the array elements in water and using the sample of the bowel were carried out. Experimental results show, that 5MHz transducer can show the structure of the bowel.

Alpha prototype - UEC Electronics

The UEC electronics of alpha prototype were developed and tested using a chamber of 4 ultrasound elements (**Figure 94**).

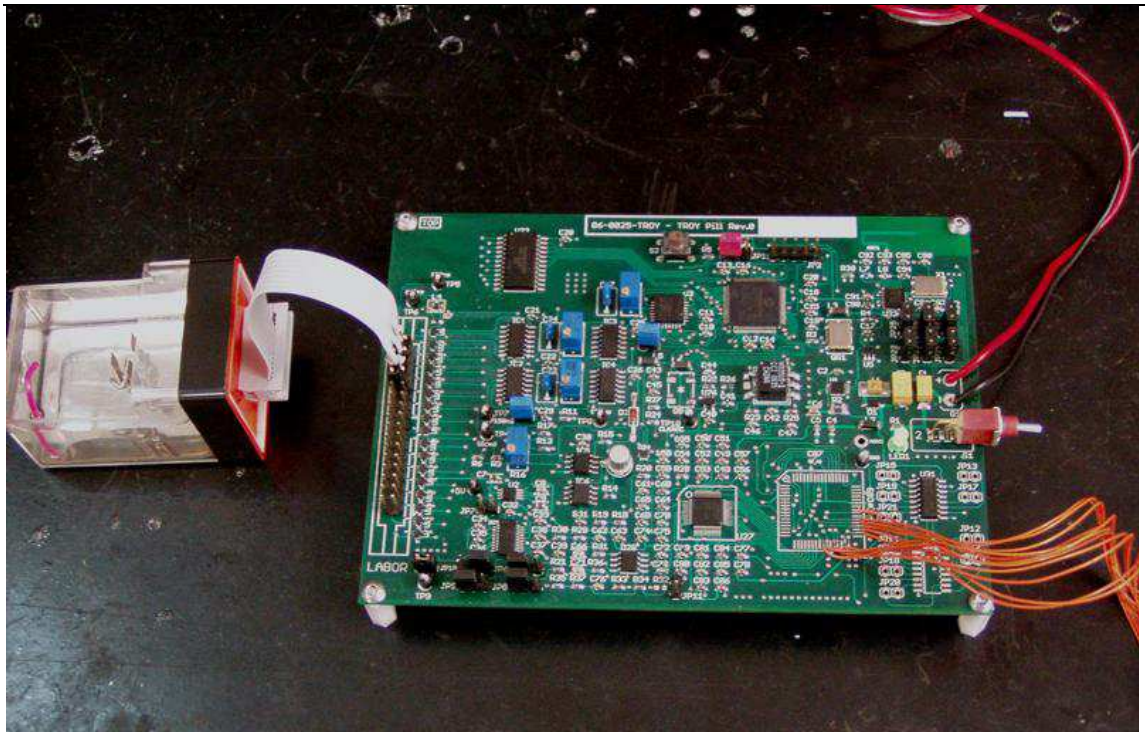


Figure 94. Troy UEC rev.0 PCB prototype assembled, under test.

Board details are presented in Workpackage 3. Testing phases were:

1. Supply voltages, +3.3V and +5V
2. CPU, accelerometer and radio tx hardware test and firmware programming
3. Short pulses generation
4. Test with the Ultrasound Institute box.
5. Analog amplifier
6. ADC (first phase working at low frequency and after at 30MHz)
7. Buffer management

Main problems arose during tests phase were:

- Too much noise present in the analog amplifier input.
- When the analog amplifier is switched on there is too much attenuation of the short excitation pulse voltage.
- 3 bit noise on the ADC.
- Buffer synchronization.

To solve all these problems in a successive hardware revision it's possible to do:

- Reduce path for analog signals.
- Change discrete components with SMD ones.
- Make a smaller board.
- Change the Maxim MAX1595 with another chip, suitable for this application.

These improvements were implemented in beta prototype.

Alpha prototype - Troy Workstation software

For the alpha prototype the main functionalities of the workstation software were developed but, because of the small data set gathered for testing, the contour detection and construction of 2D images still needed developments. As presented in Workpackage 4, workstation software was prepared to receive raw data from ultrasound and build the 2D image. The results were rudimentary and needed improvements on the dimensions, on the filtering and on the construction from the inner contour.

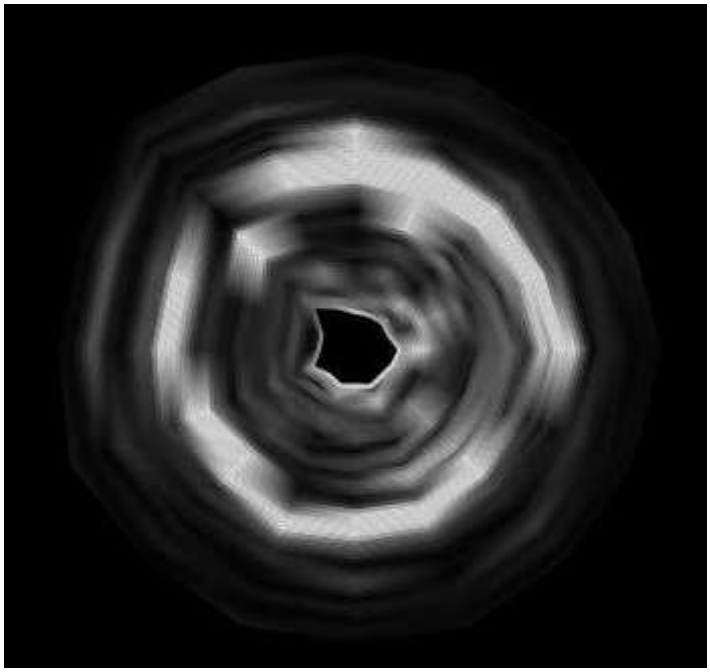


Figure 95. Reconstructed 2D image from alpha prototype

Beta Prototype

Beta prototype was developed with the integration of all the components for the Wireless UEC, the ultrasound probe and UEC electronics revised, the wearable computing with personal data recorder and body sensors network and the Troy Workstation software.

Wireless UEC

Ultrasound 5 MHz array of 32-elements was developed and tested with good results as presented in Workpackage 5 but because of the problems in the electronics of the UEC in alpha prototype, the revision of the board for the beta prototype was produced for 16-elements ultrasound probe. As the tests prove, the system is working fine with the new board

and deployment for 32-elements is now easier. The photo of the 32 - element ultrasonic radial array is given in Figure 86.

Even though the pill is not miniaturized, tests were done in order to demonstrate that the global architecture of the entire system is valid, and verify if the idea of detect and measure the chosen bowel anomalies can be realized with a 16-sensors ultrasound array.

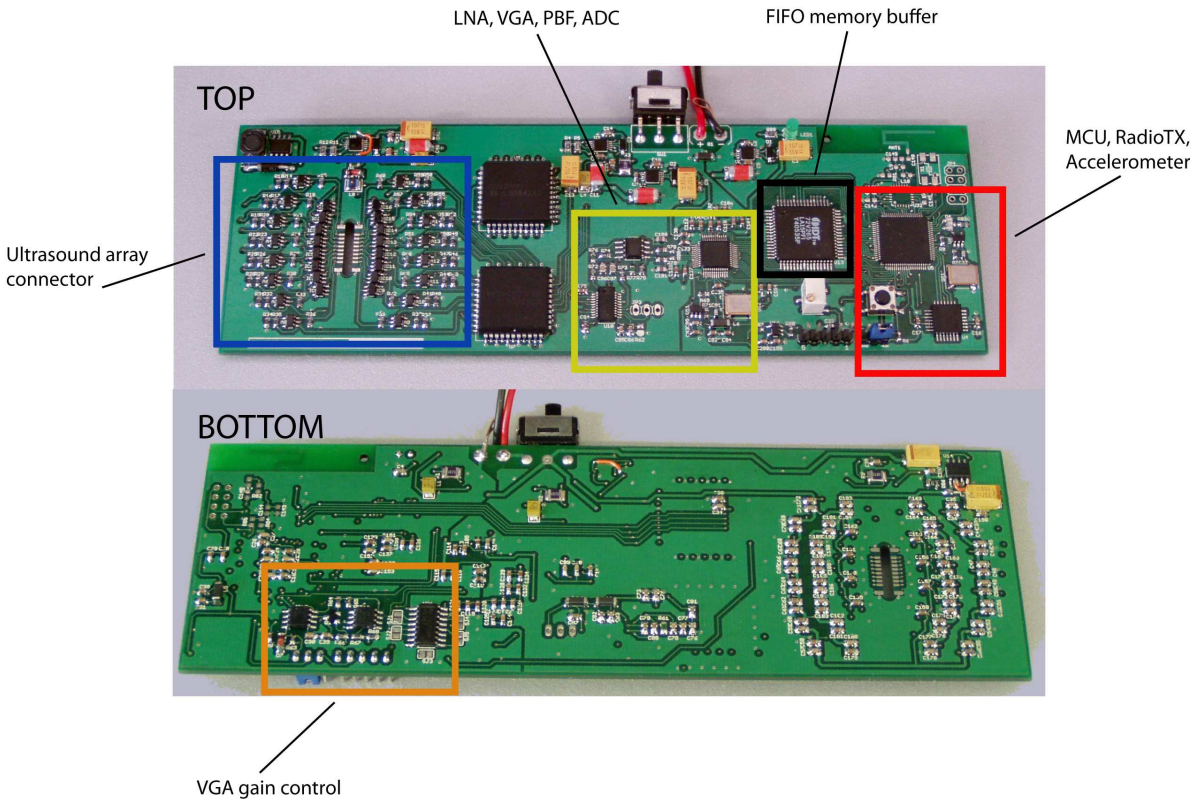


Figure 96: Troy pill rev.1 PCB prototype assembled, with functional blocks explained.

Beta Prototype – Wearable Unit

The wearable unit as two main devices: the personal data recorder and the body sensors network. These devices were developed in Workpackage 3 where details can be found.
The personal data recorder had two versions both tested in beta prototype.

In Figure 97 a photo of the wearable unit is presented showing the assembly of personal data recorder with body sensors network.

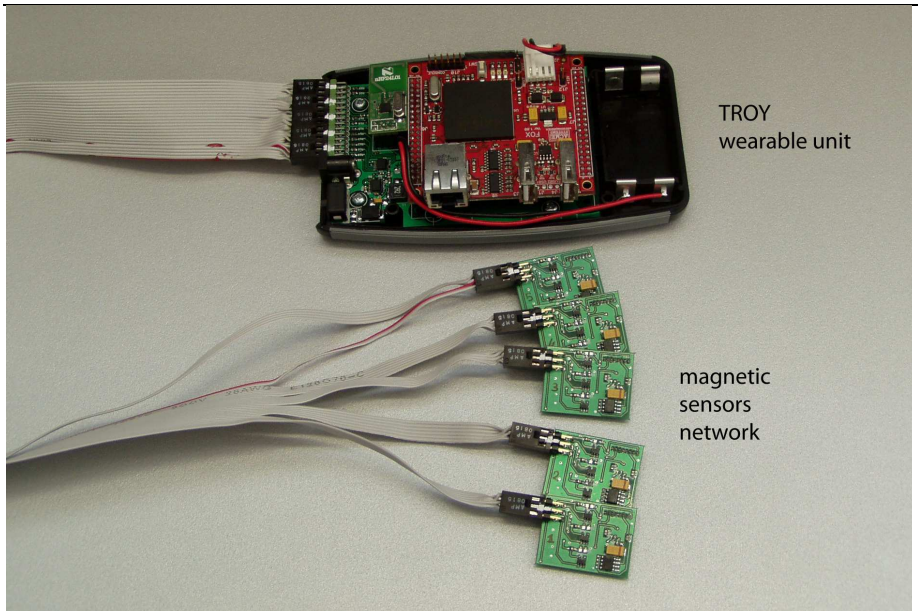


Figure 97: TROY wearable unit assembled, and magnetic sensors network.

The second version of the wearable unit consists of three stacked boards. The bottom board (**wearable unit board**) is the main board where there are the various peripheral. Second board is for the microcontroller **(wearable unit MCU board**) that can be the Fox board or a PIC based board. Third board is the **wearable unit supply board**, used to provide battery energy supply to the system. Compared to the rev0, the new wearable unit has an accelerometer and gyroscope required to provide information on the movements of the patient. Furthermore it is possible to use the Fox board or a new board with a PIC microcontroller (MCU).

In Figure 98 is shown the wearable unit assembled with FOX board and the magnetic sensors network.

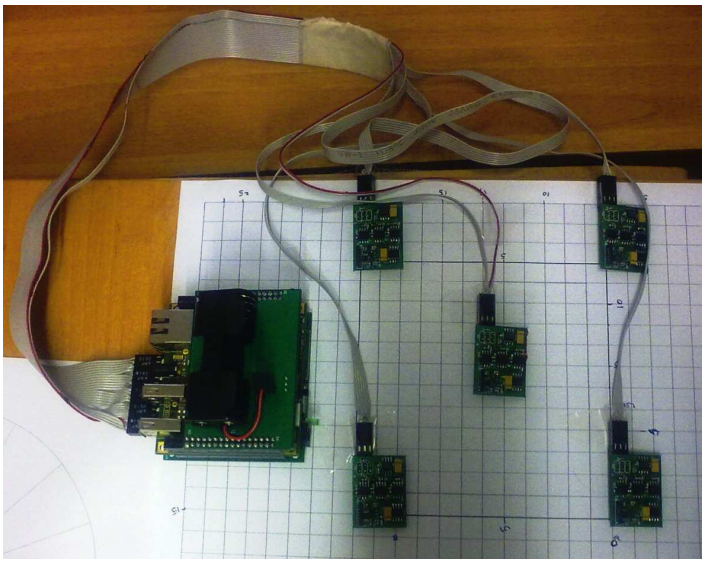


Figure 98. TROY wearable unit assembled, and magnetic sensors network.

The next Figure shows beta prototype with last version of the personal data recorder.

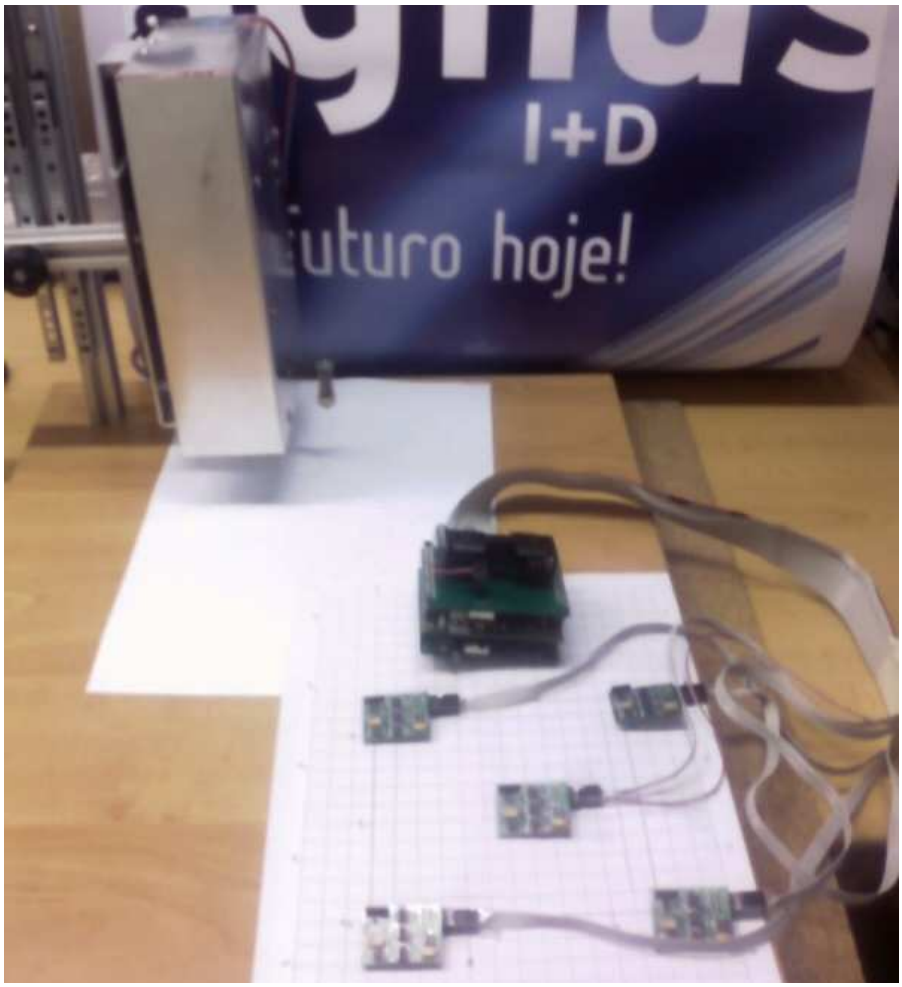


Figure 99 – Wearable Unit receives data through RF, add magnetic sensors information and saves data

Beta Prototype – Troy Workstation software

For the beta prototype the workstation software was improved with positioning algorithm based on the body sensors network, noise filtering in ultrasound raw data, contours extraction and 2D images construction based on the fusion of 5 consecutive data slices and enhanced presentation layer, solving the problems found in alpha prototype.

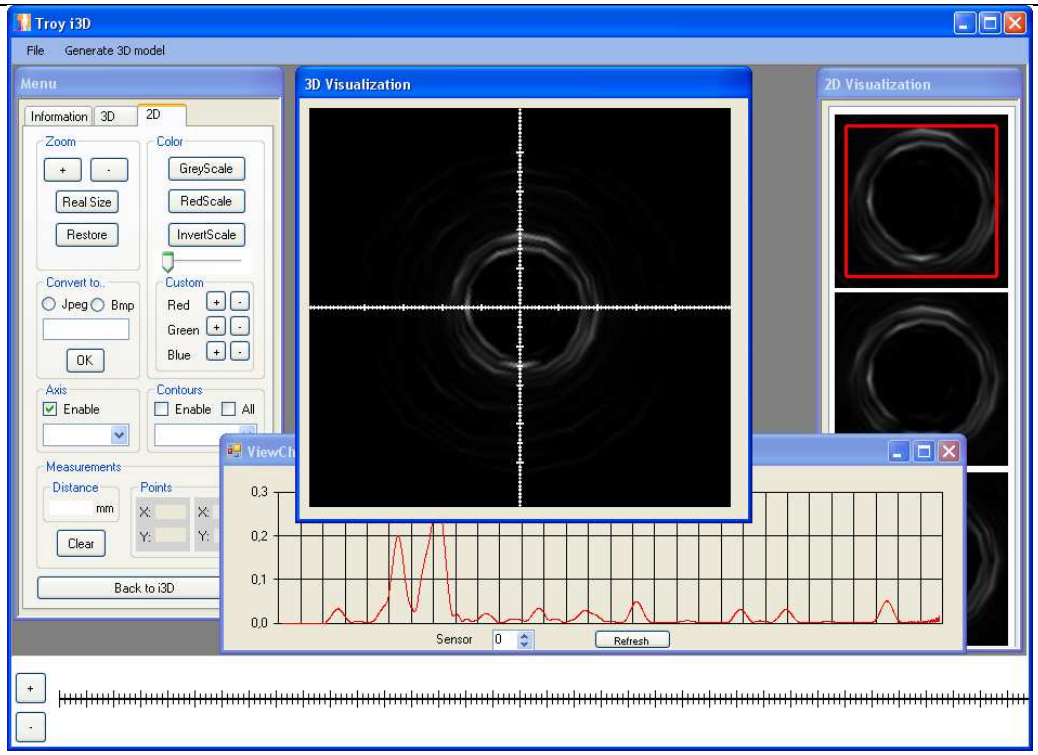


Figure 100 – Interface of Data Analysis module based on Ultrasound raw data – 2D manipulation

Troy Test Rig

Once developed the beta version of the TROY pill and the related PCB, a realistic environment was needed in order to simulate the operating conditions and test the system functioning.
The aim of the test bed was to check the operation of the US transducers in different conditions such as:

- Moving pill
- Tilting/rotating pill
- Presence of air bubbles in the liquids
- Presence of various contaminants in the liquids

A questionnaire was shared amongst the partners to define the parameters of the experiment and the basic requirements for the test bed design.

It was identified a surgical trainer for the simulation of a real bowel. The simulator consisted of a 30mm diam. 2 layers pipe made by special resins.

Figure 101 – Surgical bowel simulator

The first version of the test bed was built as follows:

- Fixed pill, mounted on a moving support allowing controlled tilting and rotation;
- Phantom bowel positioned in a plastic tank filled with physiological solution;
- Physiological solution flowing through the phantom bowel at rated speed (0,1 - 2 cm/sec) controlled by a flow meter;
- Liquid recirculation using a pump;
- Contaminants pumped inside the phantom bowel through openings in the walls of piping to the phantom bowel.

The test bed was then assembled in Rome and completed on the end of Sept. 2008.

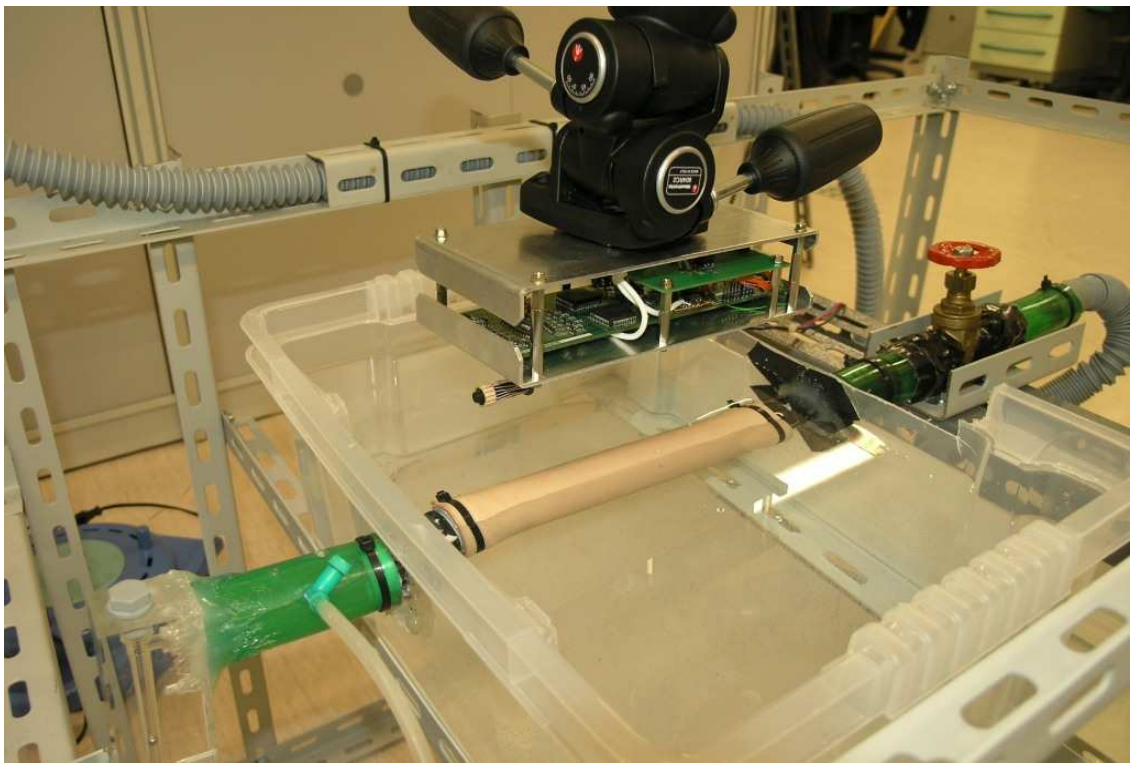


Figure 102 – 1st Test Bed

A second version of the test bed was built, featuring:

- Larger water tank to allow pill movement along the phantom bowel;
- Moving pill/PCB support, for controlled linear translation

- Quickly interchangeable phantom bowel to check many different types and configurations of pathologies

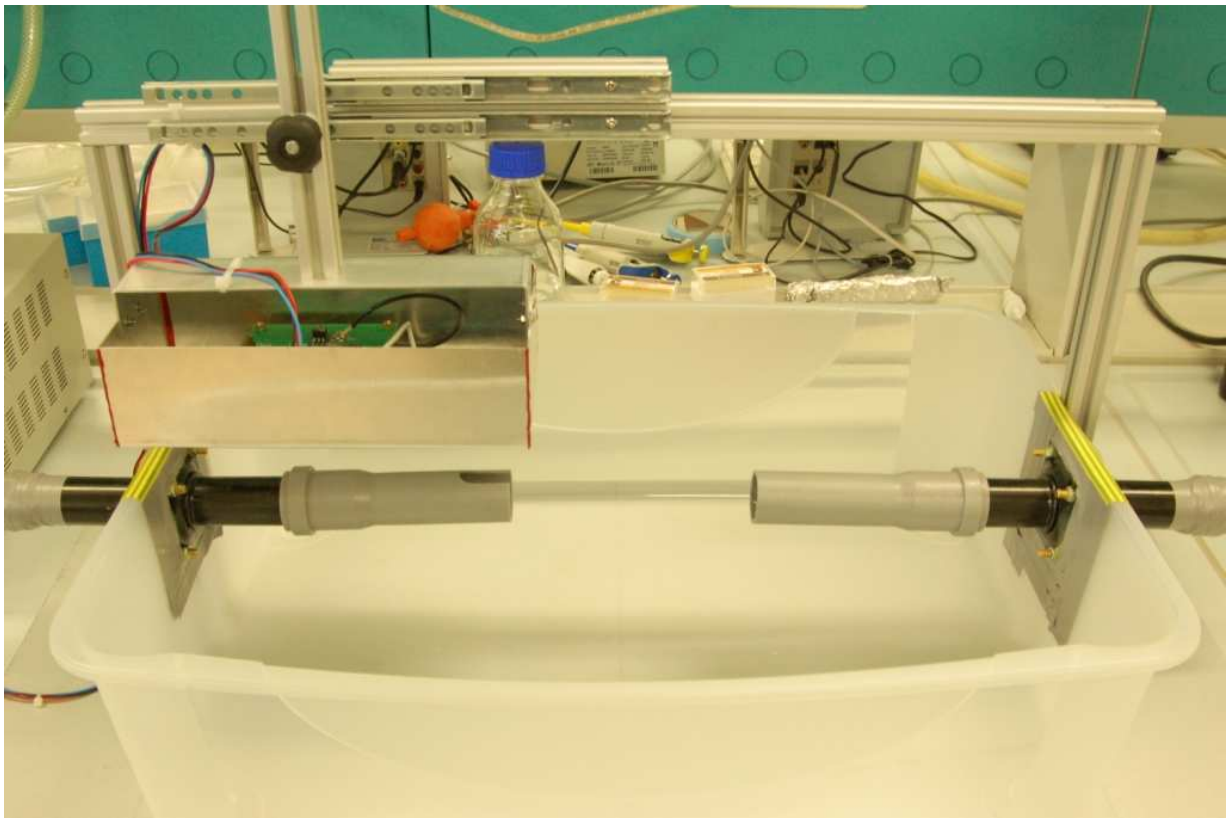


Figure 103 – 2nd Test Bed

After some a battery of tests and its analysis, it was decided build another test rig to further simplify the test bed design, in order to better achieve the 3rd requirement (possibility of testing the system with many different type of bowels and pathologies) which was the most relevant for the project.

It turned out, in fact, that this could not be easily obtained with the previous designs.
A series of short bowel simulators were built, each with its typical pathology (or none):

- bowel with no pathology
- bowel with polyps on the inside
- bowel with polyps on the inside and outside,
- bowel with big annular polyp on the inside, with longitudinal folds

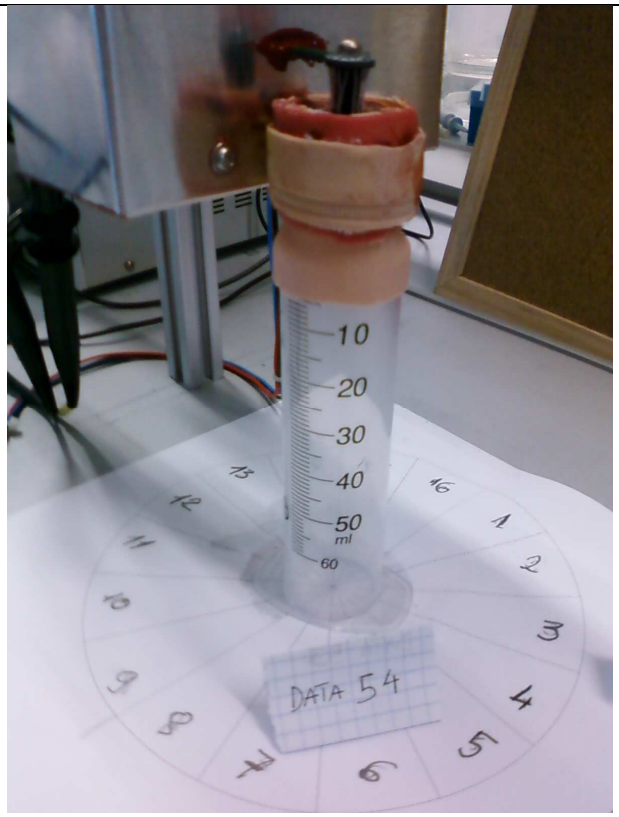


Figure 104 – 3rd Test Bed

A big number of different readings were performed, with each type of simulator. The features of each single reading were recorded to have a punctual log of what performed. The aim was to verify that what interpreted by the visualization software and by the technicians was corresponding to reality.

Given the high number of readings to be performed and the types of bowel simulators, the moving pill support was mounted on a vertical rail, while the bowel sections were filled with physiological solution and placed around the pill.

The simulation of a moving pill inside a bowel (with or without pathologies depending on its position) was then built by creating different series of readings, each one with its specific features.

Final Assessment

For the integrated test (or system test) of the TROY system and concept, several alternatives have been discussed and preliminary tests performed. As described in Deliverable 6.4, several alternatives were proposed for the integrated tests and finally selected the validation procedure – Test concept gamma.

Bowel segments are, with our without pathological conditions, not perfectly round shaped pipes but have variations in shape and contour. These variations consist basically in changes in wall thickness, changes that are true or false, normal or abnormal. True variations in wall

thickness are given by polyps (small tumours growing on the inner face of the bowel, represent abnormal situation), bowel folds (true variations of wall thickness caused by motility, contractions of muscular layer, their shape and size changes with time, represent a normal situation), contact between bowel segments (false wall thickening caused by false allocation of reflected ultrasound waves as belonging to the loop in which the probe is placed and not correctly to the neighbour) and circumferential wall thickening (true and permanent increased wall thickness caused by inflammation and tumoural conditions, which represent abnormal situations). The aim of this test is to assess the ability of a 16 element ultrasound array (probe) placed inside a bowel segment to detect and differentiate between normal bowel segments, bowel segment with polyp inside, bowel segment with real wall thickening and bowel segment with false wall thickening (folds and/or contact between different bowel loops).
For this test five different segments of bowel phantoms are prepared with the following characteristics:

- (PH1) Normal bowel segment.
- (PH2) Bowel segment with a medium size polyp inside.
- (PH3) Bowel segment with longitudinal bowel folds inside.
- (PH4) Bowel segment in contact with other bowel loops.
- (PH5) Bowel segment with increased wall thickness simulating inflammation and/or tumoral condition.

All the segments are built from a synthetic bowel simulator used by medical students to for learn and practice anastomosis techniques. This bowel simulator, manufactured by an Australian company, has two layers and presents realistic tissue response. It´s made of non-biological material (no hygiene issues or problems) and can withstand a fluid flush. It has an outside diameter of 20mm or 30mm and each layer is 1 mm thick (approximately).

All phantoms have at least 5 cm long and all additional structures (to emulate polyps, ganglia, inflammations) are built from the same material as follows. Polyp is simulated by a 8x8 mm square of bowel wall fabric glued on the inner surface of corresponding phantom (Figure 105).

Longitudinal folds and contact between bowel loops were simulated by gluing 6 longitudinal strips of bowel fabric, 5-8 mm wide, longitudinally on all length of the inner or outer layer of bowel segment.

Figure 105 - PH2 phantom

This procedure includes the development of the bowel phantoms (described in section "**Erro! A origem da referência não foi encontrada.**") and of the test rig (described in section "Test rig beta prototype realization" of deliverable "D6.3 – TROY test rig"). Tests were performed according to the test plan and the results were processed by the TROY workstation software in order to build images of the bowel. Result was collected and analysed by ultrasound specialists. Results complied in a questionnaire with information on the possible situations but no information, except 2 images, on each case.

This approach provides a blind evaluation of the test results by a selection of medical doctors specialized in ultrasound.

Table 4 - Efficiency of the TROY system as a screening test

		Classification of disorder (polyp, "strips", tumour/inflammation)	
		Present	Absent
Diagnostic	Positive	With disorder and with positive diagnostic (true positive)	Without disorder and with positive diagnostic (false positive)
	Negative	With disorder and with negative diagnostic (false negative)	Without disorder and with negative diagnostic (true negative)
	Total	Total cases of disorder	Total cases without disorder
	Sensitivity = true positives / total cases of disorder Specificity = true negatives / total cases without disorder		

The results of the questionnaire was collected and analysed according to the methodology proposed in the World Health Organization paper "Principles and practice of screening for

disease"[1] and in "Evidence-based Medicine Guidebook"[2]. According to this methodology, the assessment will concern the effective capacity of the TROY system to detect the bowel structure, simulated lesions, cancer lesions and its reliability. The validation of the functional model used produce the following outputs presented in Table 4.

The test plan to collect the data for the validation procedure was performed according to the methodology described in section "**Erro! A origem da referência não foi encontrada.**". Each of the tests included 5-10 minutes of data recording from the UEC (at a rate of 1 complete scan per second) and during this period the UEC was randomly moved to simulate its progression inside the bowel. The data collected during these tests was later processed and analysed with the TROY workstation software.

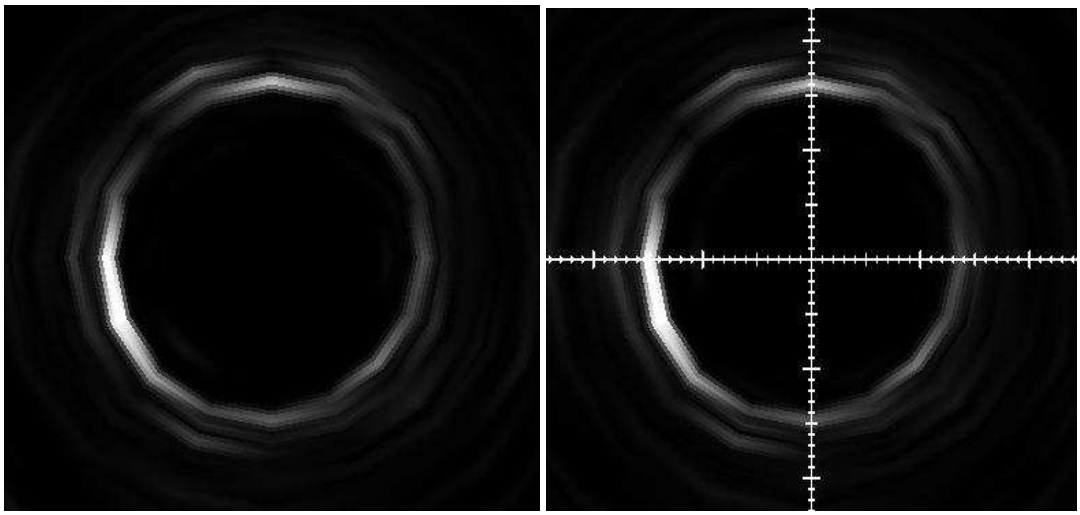


Figure 101 Image (B-scan) of the "bowel with tumour/inflamation"

The survey was performed double blinded and 13 health care professionals answered the image challenge. The answers to the questionnaire were collected and compared with the known classification.

Based on these results it is possible to determine a set of classifiers for the TROY concept and its characterization as a screening test. The most significant parameters, according to Wilson and Jungner, are the following:

- Specificity TN/(FP+TN).
- Sensitivity TP/(TP+FN).
- Prevalence (TP+FN)/(TP+FP+FN+TN).
- Likelihood ratio + sensitivity/(1-specificity).
- Likelihood ratio - (1-sensitivity)/specificity.
- Positive predictive value TP/(TP+FP).

[1] Wilson J. M. G., Jungner G., "Principles and practice of screening for disease", World Health Organization, Public Health Paper 34 (1968)
[2] UCI College of Medicine, "Evidence-based Medicine Guidebook" (2004)

- Negative predictive value TN/(FN+TN).
- Pretest odds prevalence/(1-prevalence).
- Post-test odds pretest odds x likelihood ratio.
- Post-test probability post-test odds/(post-test odds+1).

These parameters were calculated and are presented in Table 5.

Table 5 Screening parameters of the TROY concept

Specificity	97%
Sensitivity	88%
Prevalence	80%
Likelihood ratio +	31,34
Likelihood ratio -	0,13
Positive predictive value	0,99
Negative predictive value	0,67
Pretest odds	3,91
Post-test odds	122,5
Post-test probability	99%

Starting with the two most important parameters for a screening diagnostic exam, the results demonstrate that the sensitivity and specificity of the test are both high (97% and 88%) which shows that this exam is very accurate in classifying as positive the abnormal cases and as negative the normal cases. The other parameters are also very interesting and demonstrate that the TROY system can be a very useful tool for screening possible disorders in the gastrointestinal tract and a good indicator to the need of the patient to perform additional, and in principle more invasive and painful, exams.

2.6.3. Deviations from Workplan

2.6.4. List of Deliverables and Milestones

Del. Nº	Deliverable name	Workpackage nº	Date due	Actual/forecast delivery date	Status	Lead Contractor
6.1	TROY Alpha prototype	6	M15	M25	Completed	UI of KTU
6.2	TROY Beta prototype (functional model)	6	M26	M30	Completed	
6.3	TROY test rig (phantom)	6	M26	M30	Completed	
6.4	Final assessment	6	M30	M30	Completed	

Milestone nº	Milestone name	Workpackage nº	Date due	Actual/forecast delivery date	Lead contractor
5	Field Tests	6	M30	M30	UI of KTU

2.7 Workpackage 7 – Dissemination and Exploitation

2.7.1. Objectives

According to the "Annex I -Description of Work" the objectives defined for the WP7 were:

- *To provide an adequate implementation plan for the new technology, exploring all possible market applications at world level and possible marketing strategies and visibility to the project results.*

For its accomplishment the following tasks were defined:

a) Task 7.1 – Market Study (M6 – M24)

i. To evaluate the commercial potentialities of the proposed system, demand and market segmentation;

ii. To benchmark the proposed solution against market competitors

b) Task 7.2 – Exploitation Strategy (M1-M30)

i. To define the strategy for the commercial exploitation of the project results;

ii. As a result of tasks 7.1 and 7.2, deliverables "D7.1- Knowledge Exploitation and Dissemination draft" and "D7.4 – Knowledge Exploitation and Dissemination Final "should be produced

c) Task 7.3- Dissemination Activities (M6-M30)

i. To disseminate project activities and results through seminars participation, internet, e-mail newsletters.

ii. Task 7.3 should produce "D7.2. Mid Term project Review for dissemination"

2.7.2. Progress

Task 7.1. and 7.2. – Market Study and Exploitation Strategy

Task 7.3 – Dissemination Activities

As part of the dissemination activities developed on the first 12th months of the project we have:

i. Project Web Site (www.troy-project.eu): first version launched in October 2006;

ii. Quarterly edition of a Newsletter (also available on the project website)

Since Troy project involved a significant number of SMEs (5 out of 9 partners), the resulting product exploitation is a major aspect. The product and/ or technologies resulting from the project will be exploited by the partners according to the previously defined feasibility study. Some elements of this feasibility study are incorporated in this document, and served as the starting point for partners in development of their own business plans.

Were identified existing technologies for diagnosis of gastrointestinal malignancies and evaluated its main advantages and disadvantages. Some of those systems were benchmarked against the proposed system on TROY project.

The analysis to the market for a system like TROY identifying possible clients and competitors was initiated on this first year and concluded in the second year of the project.

A SWOT Analysis was conducted allowing evaluating the Strengths, Weaknesses, Opportunities, and Threats involved in the project. As conclusion could be stated that the fact that there is no Ultrasound Capsule in the market is the greatest of the consortium opportunities while in general the lack of resources in comparison with the potential of the competitors could be one of the principal weaknesses for achieving the goal of placing UC on the market.

Analyses of the costs of the solutions on the market and of TROY system future solution were conducted. For the analysis several facts should be considered:

- The **direct** and **maintenance cost** of the necessary equipment for diagnosis.
- The **cost per examination**, based on the calculation of the resources needed for each examination, such us medical staff time and supplies.
- The **social cost** of each procedure, basing its calculation of patient absence of its normal life. Work absence, for example, directly reflects as a cost for the employer of the patient or its health insurance institution.
- Medical benefits for using Ultrasound Endoscope Capsule (UEC) were identified. The UEC joins together the Capsule Endoscopy benefits and the ultrasound benefits.
- A large set of premises for technological transfer and production of the Troy ultrasound endoscope capsule was acknowledged.

Knowledge exploitation opportunities were identified. A review of the existing patents was made helping the consortium to define the current start of the art and to:

- Identify the potential for patenting innovations resulting from the TROY project.
- Identify ideas that can be incorporated into the TROY system based on previous research.
- Where alternative implementations exist, to identify the optimal choice in respect of not infringing upon existing patented technology.

The dissemination activities developed during the project:

- Project Web Site (www.troy-project.eu): two versions launched;

- Quarterly edition of the TROY Newsletter (also available on the project website);
- A few papers publication and posters in international events;
- Interaction with medical societies and patients organizations;
- Dissemination with direct contacts in hospitals, clinics, universities and fairs.

Deliverables 7.1 Knowledge Exploitation and Dissemination (draft), 7.2 Mid term project review for dissemination, 7.3 Market Study & Exploitation report & technology Implementation plan and 7.4 Knowledge Exploitation and Dissemination were completed.

2.7.3. Deviations from Workplan

Major deviations on WP7 refer to anticipation of the work to be developed, namely:

- Task 7.1 was anticipated to M7, being developed in simultaneous with Task 7.2
- Anticipation of Task 7.3 to M1 assuring therefore an effective dissemination of the project since the beginning of the project.

2.7.4. List of Deliverables and Milestones

Del. Nº	Deliverable name	Workpackage nº	Date due	Actual/forecast delivery date	Status	Lead Contractor
7.1	Knowledge Exploitation and Dissemination (draft)	7	M12	M14	Completed	Dunvegan
7.2	Mid term project review for dissemination	7	M12	M14	Completed	IAITI
7.3	Market Study & Exploitation report & technology Implementation plan	7	M30	M30	Completed	Dunvegan
7.4	Knowledge Exploitation and Dissemination	7	M30	M30	Completed	Dunvegan

Milestone nº	Milestone name	Workpackage nº	Date due	Actual/forecast delivery date	Lead contractor
6	Dissemination and Exploitation Plan	7	30	30	Dunvegan

2.8 Workpackage 8 – Project Management

2.8.1. Objectives

According to the "Annex I- Description of Work" the objectives of the WP8 were:

- *To assure the success of the project through co-ordinating the activities and maintaining an efficient and pro-active relation with the partners and the EC services In particular this workpackage intends to achieve the highest standards of quality of deliverables, within the constraints of time schedule and budget.*

For the accomplishment of the established objectives the following task was foreseen:

a) Task 8.1- Project Management (M1-M30)

i. To ensure the fulfilment of the goals of the project, within time and budget constrains; project planning and scheduling; responsibility for internal and external reporting and documentation; organization of kick-off and regular meetings of the project; financial management and liaison with the Commission.

2.8.2. Progress

The project coordinator with the support of the Project Coordination Committee assured the administration and financial control, control of work, budget allocation and the link with the EC.

On the first year of project the contract was signed and pre-financing of 503. 021, 30€ (five hundred and three thousand and twenty one euro and eighty two cents) of the estimated Community financial contribution was paid to the coordinator. The project coordinator assured the distribution of the payments to partners according to the conditions specified in the "Consortium Agreement".

On the "second year" of TROY activity, the main management activities were: elaboration of the 1st Year Activity and Management Reports; the request for a 6th month's extension of the project and the preparation of the second year and final reports.

The Mid Term Report (First Year Activity Report, First Periodic Management Report, First Plan for Using and Disseminating Knowledge, Periodic Report on the Distribution of the Community's Contribution) was prepared by the consortium during September and October 2007. All the necessary reports were sent to European Commission on the 15th October 2007 to the attention of Mrs. Agnes Boucheron and Mrs. Annabelle Ascher and approved.

Following the approval of the 1st Year Reports, the EC made a 2nd Pre-financing Transfer on the amount of 11.620,97€ (eleven thousand six hundred and twenty Euros and ninety seven cents). IAITI assured the distribution of the payments based on the following criteria: values presented by partners on the 1st Period Report, values paid on the 1st advance payment and estimation of the needed values for the project 2nd year having in mind the EC ceiling of 85%.

Another important activity of Workpackage 8 was the request for a project extension. Following the decision taken on the Fifth Meeting of the project (15th and 16th of April, Madrid Spain), TROY consortium asked for a 6th months extension of the project. The process was concluded on May and it was officially approved on the 18th June 2008.

As part of the Project Management WP activities, the following meetings were organized:

	Type of meeting	Partners	Date	Place
TROY Kick-off meeting	Management	All with exception of AGT	18th and 19th September 2006	Matosinhos, Portugal
Work meeting	Technical	IAITI, ARTICA, SC IPA, UMF	3rd and 4th of November 2006	Cluj Napoca, Romania
Troy Second meeting	Technical	All with exception of AGT	26th and 27th April 2007	Kaunas, Lithuania
Troy Mid Term meeting	Management	All with exception of AGT	25th and 26th September 2007	Cluj Napoca, Romania
Troy Fourth Meeting	Technical	All with exception of UI of KTU and AGT	4th - 6th March 2008	Kaunas, Lithuania
Troy Fifth Meeting	Management	All with exception of ARDORAN and DUNVEGAN	15th and 16th of April 2008	Madrid, Spain
Troy Sixth meeting	Technical	IAITI, LABOR, UMF, KTU and AGT	27th - 29th of October 2008	Rome, Italy
	Management	All with exception of DUNVEGAN	29th - 30th of October 2008	Rome, Italy
Troy Seventh meeting	Technical	AGT, IAITI, LABOR, UI of KTU and UMF	27th - 29th of January 2009	Rome, Italy
Final meeting	Management	All	18th and 19th February 2009	Matosinhos, Portugal

Further information about this WP work is presented on the "Consortium Management Section" of the present report.

2.8.3. Deviations from the Workplan

There were no significant deviations on this WP

2.8.4. List of Deliverables and Milestones

Del. Nº	Deliverable name	Workpackage nº	Date due	Actual/forecast delivery date	Status	Lead Contractor
8.1	Mid-Term Report	8	M12	M12	Completed	IAITI
8.2	Final Report	8	M30	M30	Completed	IAITI

Milestone nº	Milestone name	Workpackage nº	Date due	Actual/forecast delivery date	Lead contractor
7	Final Report	8	M30	M30	IAITI

Section 3 – Consortium Management

3.1. Consortium Activities and Achievements

IAITI performed all the general daily coordination activities to ensure the success of the project through coordinating the activities and maintaining an efficient and pro-active relation with partners and EC services.

As the most important consortium activities during project life time, we should point out:

1st Year (1st September 2006 – 31st August 2007)

- The contract was signed and the pre-financing of 503. 021, 30€ (five hundred and three thousand and twenty one euro and eighty two cents) of the estimated Community financial contribution was paid to the coordinator. For its distribution, it were considered the conditions specified in the "Consortium Agreement";

2nd Year (1st September 2007 – 28th February 2009)

- Preparation and submission of the First Year Report to the EC (Mid Term Report which included the 1st Year Activity Report, 1st Periodic Management Report, 1st Periodic Report on the Distribution of the Community's Contribution and the Plan for Dissemination and Knowledge Exploitation); The Mid Term report was sent by post and electronically to the EC on the 15th of October 2007.
- To prepare and submit to the Recommendations made the EC on the scope of 1st Year review Report;
- Distribution of the 2nd Year EC Contribution within the consortium according to the following criteria: values presented by partners on the 1st Period Report; Values paid to partners on the 1st advance payment; estimation of the needed values for the project 2nd year having in mind the EC ceiling of 85%;

The remaining management activities performed during this last 30 months will be presented on the next items.

3.1.1. Project Management Structure

As stated on the "Annex I – Description of Work" a project management structure and decision making structure were created and established on the Kick-Off Meeting (18th and 19th of September 2006).

Project Manager	Daniela Lopes (IAITI)
Project Coordination Committee	One representative of each partner SMEs and

	RTDs: – Daniela Lopes (IAITI) – Ioan Stoian (SC IPA SA) – Douglas Reid (Dunvegan) – Fillippo Ugolini (AGT) – Alexander Girfanov (Ardoran) – Alejandro Sánchez-Rico (Artica) – Paolo de Stefanis (Labor) – Rymantas Kazys (UI of KTU) – Horia Stefanescu (UMF Cluj Napoca)
Technical Manager	Gil Gonçalves (IAITI)
Project Exploitation Manager	Douglas Reid (DUNVEGAN)
Workpackage Leaders	As defined on DoW

3.1.2. Communication Strategy

The communication strategy for TROY project was based in a set of tools that allowed the consortium to assure an effective communication, the exchange of information and knowledge between all members of the consortium. The main tools were:

- Project Website;
- Groupware – private web -based tool;
- Detailed list of Partners Contacts
- Telephonic meetings
- Bilateral Meetings

1. Project WebSite (www.troy-project.eu)

On the kick-off meeting, the consortium decided as the most adequate address for the project website – www.troy-project.eu , which was registered during the month of October 2006. A first version of the website was launched on the first year with the objective of promoting project objectivities and activities. It was renewed on July 2008 in order to improve its attractiveness. More detailed information about the website is presented on the Final Plan for Using and Disseminating Knowledge.

2. Groupware

In order to facilitate the communication among the consortium it was implemented a web based tool, the Groupware, which is available to all partners through the project website and after secure authentication and it is the central project repository, allowing interaction among partners. Several sections and services have been implemented, like calendars, mailing to remind deadlines, file database and sharing, central data base for relevant technical information. It also includes all official and contractual documents.

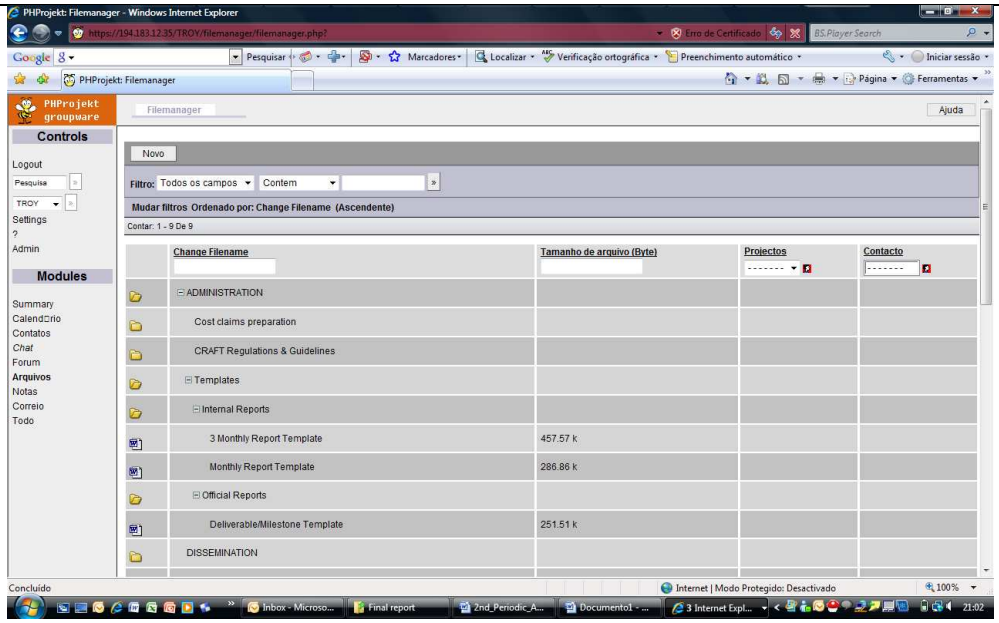


Fig. 106 – Groupware Structure Example

3. Detailed List of Partners Contacts

It prepared a detailed contact list of all partners with contact persons for the management and technical aspects of the project in order to facilitate the exchange of information and organization of the different tasks within the consortium. This list was distributed within the consortium by email.

4. Telephonic Meetings

Several telephonic meetings were organized in order to promote information exchange regarding the different tasks of the project.

5. Bilateral Meetings

On the scope of other activities or projects where partners were cooperating, small meetings were organized in order to discuss and define some specific tasks.

3.1.3. Project Meetings

One of the most important management activities, were the management and technical meetings, an important opportunity to discuss face to face the project activities, objectivities, achievements and an opportunity to explore other cooperation activities apart from the project scope.

In this project it were organized 10 meetings: 5 of management and 5 technical:

1	Type of meeting	Date	Place
TROY Kick-off meeting	**Management**	**18th and 19th September 2006**	**Matosinhos, Portugal**

Main Agenda Contents

- Welcome, check of attendees and Introduction by IAITI
- Partners' Presentation
- Project Presentation
- Project Management
- Detailed Work Planning
- Joint Discussion on project activities
- Future Action Points

Attendees:

- **IAITI**: Ms. Daniela Lopes; Mr. Gil Gonçalves; Mr. João Correia; Mr. Sérgio Rocha; Ms. Sónia Pereira
- **ARTICA**: Mr. Alejandro Sánchez-Rico
- **LABOR**: Mr. Alessandro Mascioletti
- **ARDORAN**: Mr. Alexander Girfanov
- **DUNVEGAN**: Mr. Douglas Reid
- **UMF Cluj-NAPOCA**: Mr. Horia Stefânescu
- **SC IPA SA**: Mr. Ioan Stoian
- **UI of KTU**: Mr. Reimondas Sliteris

2	Type of meeting	Date	Place
Work Meeting	**Technical**	**3rd and 4th November 2006**	**Cluj-Napoca, Romania**

Main Agenda Contents

- Discussions about project's objectives and expectations from the EUS capsule
- Presentation of the principles of endoscope capsule
- Demonstration of endoscope capsule examination
- how to provide one or two new endoscope capsules for the Consortium (for better understanding of its function) remained open for further discussion

Attendees:

- **IAITI**: Mr. Gil Gonçalves, Mr. João Correia
- **Artica**: Mr. Alejandro Sánchez-Rico
- **SC IPA**: Mr. Ioan Stoian, Mr. Ovidiu Dancea,
- **UMF Cluj-NAPOCA**: Mr. Radu Badea, Mr. Horia Stefânescu; Mr. Oliviu Pascu, mr. Andrada Seicean

3	Type of meeting	Date	Place
General Meeting	**Technical**	**26th and 27th April 2007**	**Kaunas, Lithuania**

Main Agenda Contents

- Welcome and check of attendees by the UI of KTU
- Current status and objectives of the meeting
- Presentation of Results of WP1
- Objectives and current status of WP2, WP3, WP4, WP5 and WP7
- Working sessions concerning WP2 and WP4

Attendees:

- **IAITI**: Mr. Gil Gonçalves; Mr. João Correia;
- **ARTICA**: Mr. Alejandro Sánchez-Rico
- **LABOR**: Mr. Alessandro Mascioletti
- **ARDORAN**: Mr. Alexander Girfanov
- **DUNVEGAN**: Mr. Douglas Reid
- **UMF Cluj-NAPOCA**: Mr. Horia Stefânescu
- **SC IPA SA**: Mr. Ioan Stoian
- **UI of KTU**: Mr. Reimondas Sliteris, Mr. Rymantas Kazys, Mr. Liudas Mazeika, Mrs. Elena Jasiuniene, Mr. Algirdas Voleisis.

4	Type of meeting	Date	Place
TROY Mid Term meeting	**Management**	**25th and 26th September 2007**	**Cluj Napoca, Romania**

Main Agenda Contents

- Welcome and Start of the Mid Term Meeting by the UMF
- Objectives and Current Status of WP2 - WP5
- Objectives and Activities of WP6
- Work session
  - Wireless UEC prototype (UI of KTU)
  - Wearable Computer prototype (LABOR)
  - Workstation Software prototype IAITI)
  - Test rig prototype (IAITI)
- Current Status of WP7
- Project Management by IAITI
- Future activities WP2 – WP5
- Detailed planning of WP6

Attendees:

- **ARDORAN**: Mr. Alexander Girfanov
- **ARTICA**: Mr. Alejandro Sánchez-Rico

- **IAITI**: Mr. Gil Gonçalves; Mr. João Correia; Mrs. Daniela Lopes
- **LABOR**: Mr. Alessandro Mascioletti; Mr. Paolo De Stefanis
- **SC IPA SA**: Mr. Ion Stoain; Mr. Ovidiu Dancea; Mrs. Dorina Capatana
- **UI of KTU**: Mrs. Elena Jasiuniene
- **UMF Cluj-NAPOCA**: Mr. Radu Badea; Mr. Horia Stefanescu

5	Type of meeting	Date	Place
TROY fourth meeting	**Technical**	**4th - 6th March 2008**	**Kaunas, Lithuania**

Main Agenda Contents

- Welcome and Start of the Meeting by the UI of KTU
- Objectives and detailed planning by the IAITI
- Test setup and first test
- Exploitation and Dissemination (SMEs performers)
- Discussion on results of the tests
- Debriefing and discussion on the next steps

Attendees:

- **ARDORAN**: Mr. Alexander Girfanov
- **ARTICA**: Mr. Alejandro Sánchez-Rico
- **DUNVEGAN**: Mr. Douglas Reid
- **IAITI**: Mr. Gil Gonçalves; Mr. João Correia
- **LABOR**: Mr. Alessandro Mascioletti
- **SC IPA SA**: Mr. Ion Stoain; Mr. Ovidiu Dancea
- **UMF Cluj-NAPOCA**: Mr. Tudor Vasile; Mr. Horia Stefanescu

6	Type of meeting	Date	Place
TROY Fifth meeting	**Management**	**15th and 16th of April 2008**	**Madrid, Spain**

Main Agenda Contents

- Welcome and Start of the 5th Meeting by the ARTICA
- Results from March tests at UI-KTU
- Current state of the project Vs. Planned
- Work session
- Future perspectives
- Project Management
- “Joint Ownership Contract” and “Intellectual Property Rights”

Attendees:

- **AGT**: Mr. Filippo Ugolini
- **ARTICA**: Mr. Alejandro Sánchez-Rico
- **IAITI**: Mr. Gil Gonçalves; Mr. João Correia; Mrs. Daniela Lopes
- **LABOR**: Mr. Alessandro Mascioletti
- **SC IPA SA**: Mr. Ion Stoain; Mr. Ovidiu Dancea
- **UI of KTU**: Ms. Elena Jasiuniene
- **UMF Cluj-NAPOCA**: Mr. Tudor Vasile

7.1	Type of meeting	Date	Place
TROY Sixth meeting	**Technical**	**27th -29th of October 2008**	**Roma, Italy**

Main Agenda Contents

- Status and Planning of the Experiments
- Tests and Fixes

Attendees:

- **AGT**: Mr. Paolo Piergentili; Mr. Filippo Ugolini; Mrs. Andrea Ugolini
- **IAITI**: Mr. Gil Gonçalves; Mr. João Correia; Mrs. Daniela Lopes
- **LABOR**: Mr. Alessandro Mascioletti
- **UI of KTU**: Mr. Reimondas Sliteris; Mr. Algirdas Voleisis
- **UMF Cluj-NAPOCA**: Mr. Tudor Vasile

7.2	Type of meeting	Date	Place
TROY Sixth Meeting	**Management**	**29th -30th of October 2008**	**Roma, Italy**

Main Agenda Contents

- Welcome and Start of the Coordination Meeting
- Presentation of the test results by the IAITI
- Discussion on future steps and results
- Knowledge Exploitation and Dissemination Plan by the AGT
- Revision of Dissemination Activities by the IAITI
- Intellectual and Property Rights Issues by the IAITI
- Financial and Administrative Status of the Project by the IAITI

Attendees:

- **AGT**: Mr. Paolo Piergentili; Mr. Filippo Ugolini; Mr. Andrea Ugolini
- **ARDORAN**: Mr. Alexander Girfanov; Mr. Andrei Guljajev
- **ARTICA**: Mr. Alejandro Sánchez-Rico
- **IAITI**: Mr. Gil Gonçalves; Mr. João Correia; Mrs. Daniela Lopes
- **LABOR**: Mr. Alessandro Mascioletti
- **SC IPA SA**: Mr. Ion Stoain; Mr. Ovidiu Dancea
- **UI of KTU**: Mr. Reimondas Sliteris; Mr. Algirdas Voleisis
- **UMF Cluj-NAPOCA**: Mr. Tudor Vasile

8	Type of meeting	Date	Place
TROY Seventh meeting	**Technical**	**27th -29th of January 2009**	**Roma, Italy**

Main Agenda Contents

- Status and Planning of the Experiments
- Tests and Fixes
- Summary and Results of the Tests and next steps

Attendees:

- **AGT**: Mr. Paolo Piergentili; Mr. Filippo Ugolini
- **IAITI**: Mr. João Correia
- **LABOR**: Mr. Alessandro Mascioletti
- **UI of KTU**: Mr. Reimondas Sliteris; Mr. Algirdas Voleisis
- **UMF Cluj-NAPOCA**: Mr. Tudor Vasile

9	Type of meeting	Date	Place
Final meeting	**Management**	**18th and 19th February 2009**	**Matosinhos, Portugal**

Main Agenda Contents

- Welcome and Start of the Final Meeting by the IAITI
- Presentation of Test Results by the IAITI
- Revision of Project Workpackages and Associated Deliverables/Milestones
- Demonstration
- Intellectual and Property Rights Issues
- Project Final Report
- Financial and Administrative Status of the Project

Attendees:

- **AGT**: Mr. Paolo Piergentili
- **ARDORAN**: Mr. Alexander Girfanov
- **ARTICA**: Mr. Alejandro Sánchez
- **DUNVEGAN**: Mr. Douglas Reid
- **IAITI**: Mr. Gil Gonçalves; Mr. João Correia; Mrs. Daniela Lopes; Mrs. Raquel Sousa; Mr. Valter Rocha
- **LABOR**: Mr. Alessandro Mascioletti
- **SC IPA SA**: Mr. Ion Stoain; Mr. Ovidiu Dancea
- **UI of KTU**: Mr. Reimondas Sliteris; Mrs. Elena Jasiuniene
- **UMF Cluj-NAPOCA**: Mr. Tudor Vasile; Mr. Horia Stefanescu

3.1.4. Other management activities

The contract with the European Commission was signed on the 28th August 2006 and it was established as the project start date, 1st of September 2006.

On the 1st year (beginning of September 2006) IAITI received a communication of MEDSONIC, with their decision to withdraw the project due to internal reasons. This decision was communicated to the consortium and a final decision about how to proceed in this situation was remitted to the Kick-Off meeting. The consortium decided to replace this partner by AGT, an Italian enterprise. This replacement was officially requested to the European Commission in October 2006 and approved in February 2007.

On the first year, it were also prepared and delivered several management documents: templates for reporting deliverables and milestones and to define the Pre-existing know-how.

During the project second year, the consortium decided to present a Request for Amendment to the Contract, namely the extension of the project duration from 24 months to 30 months. This decision was taken by the consortium on the 5th Project Meeting held on the 15th and 16th of April 2008 at Madrid, Spain, and it was a consequence of the difficulty felt to achieve the initially proposed objectives – development of full functional prototype and the execution of a series of field tests performed according to a clinical procedure. Being so, and in order to take advantage of the excellent work produced so far and to guarantee its future exploitation, the consortium understands that some changes to the main goal of the project were needed. The main objective of the TROY project changed “from the development of a functional prototype (and its clinical validation)” to the “development of a full functional model (its laboratory validation). This change of objectives impacts on the project in terms of schedule (duration of tasks, deliverable and milestones due dates) and therefore a request for an extension was made.

All the necessary documents were sent to the European Commission, namely “Request for an Amendment”, the modified Annex 1 –Description of Work, Justification on May 2008 and it was officially approved in June 2008.

3.1.5. Other Cooperation Activities

During the project life time, members of the consortium have identified other areas of common interest, and in that sense, promoted several initiatives in order to increase their RTD cooperation levels on the development of new RTD activities, projects and new ideas. The consortium presented on the scope of 7th Framework Programme, the following projects:

- **Ulysses (FP7-HEALTH-2007-A):** Ultrasound, Images and Reflected Light Multimodal Analysis for digestive tract Diseases;
- **UbCared (FP7-ICT-2007-1):** Ubiquitous Healthcare for Chronic Disease Patients;
- **MobilAnalyser (FP7-ICT-2007-2):** Microchip for biological fluids analysis;
- **MySkin (FP7-ICT-2007-2):** Early diagnosis of skin cancer based on ICT tools;
- **GUIDANCE (FP7-PEOPLE-IAPP-2008):** Gastrointestinal Intraluminal Diagnosis based on Ultrasound Endoscope Capsule;
- **AIGLE (FP7-SME-2008-1):** gAstrointestinal Intraluminal diaGnosis based on uLtrasound Endoscope capsule;

3.2. Contractors

As mentioned before, during the project's first year, MEDSONIC, an SME partner of TROY project informed the project coordinator, on the beginning of September 2006 of their decision to withdraw the project due to internal reasons. This decision was communicated to the consortium and a final decision about how to proceed in this situation was remitted to the Kick-Off meeting.

A partner search was promoted in order to identify possible enterprises to replace the withdrawing partner. Following this search, the consortium identified an Italian enterprise – AGT, S.r.l highly interested and motivated for TROY project. On the project Kick-off meeting, , the consortium decide to replace MEDSONIC by the new enterprise AGT, Srl. This decision was taken based on two main aspects/questions: one of the partners, the Ultrasound Institute of Kaunas University of Technology possesses all the need competencies in ultrasounds for the project. Also, the consortium felt the need of a partner with competencies on bioengineering domain.

Due to the profile and experience of this new company, it was not necessary to perform major changes on the TROY work plan. AGT replaced MEDSONIC in all of their tasks. It was however needed to proceed to some adjustments on the Project Effort Form, due to the higher experience and qualifications of the persons to be involved on project activities, with higher monthly rates

The replacement of Medsonic by AGT was officially requested to the European Commission in October 2006 and approved in February 2007.

Concerning the deliverables, there were no changes on the different partners responsibilities, which are the following:

Deliverable Nº	Deliverable Title	Lead Participant	Nature	Dissemination Level
D1.1	TROY Data sheet	IAITI	R	RE
D3.1	Draft architecture of TROY device	LABOR	D	CO
D2.1	Selection of sensors	LABOR	P	RE
D2.2	Feasibility of embedded sensors	LABOR	R	CO
D3.2	Designs and electronic schemes of TROY device (final version)	LABOR	D	CO
D4.1	Software and Software documentation (final version)	IAITI	P/R	CO
D7.1	Knowledge Exploitation and Dissemination (draft)	DUNVEGAN	R	PU
D7.2	Mid term Project Review for dissemination	DUNVEGAN	R	PU
D6.1	TROY Alpha prototype	UI OF KTU	P	CO
D5.1	Ultrasound probe	UI OF KTU	P	CO
D6.2	TROY Beta prototype (functional model)	UI OF KTU	P	CO
D6.3	TROY test rig (phantom)	AGT	P	C0
D6.4	Final assessment	UI OF KTU	R	CO
D7.3	Market Study & Exploitation report & Technological Implementation Plan	DUNVEGAN	R	RE
D7.4	Knowledge Exploitation and Dissemination (final)	DUNVEGAN	R	PU
D8.1	Mid Term Report	IAITI	R	CO
D8.2	2nd Year Report	IAITI	R	CO
D8.2	Final Report	IAITI	R	CO

Nature of the deliverable using the following codes:

R - Report;

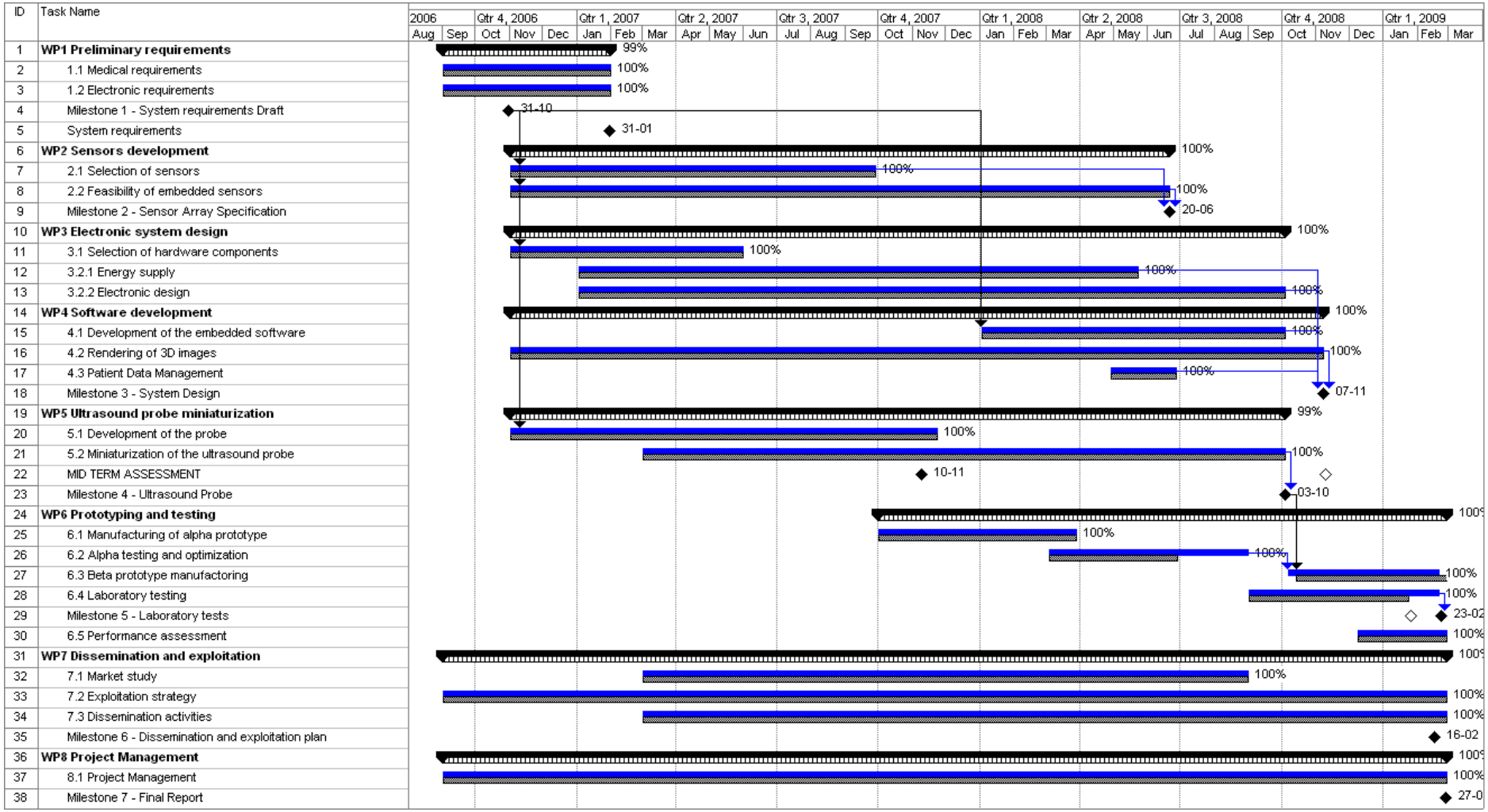
P - Prototype;

D - Demonstrator;

O - Other.

3.3. Project timetable and Status

The following frontlined barchart describes the status of the project at month 30:



The project baseline presented in the chart refers to the project plan after the project amendment referred to in "Problems and Corrective Actions" and not to the initial project plan.

As it's possible to observe through the project time table presented above, the following changes occurred:

WP 1:

- Experienced a delay of one month, being the Deliverable 1.1 concluded at M3 and Milestone 1 at M7.

WP2:

- Task 2.1 was overdue due to the delay of Deliverable 1.1. and Deliverable 2.1 was only delivered on M11.
- A working version of Deliverable 2.2 was released in month 18 but as some improvements were made with beta prototype a revision of the deliverable was produced in the end of the project.

WP3:

- Task 3.1 was subject of some delay and D3.1 was only delivered at M 11.
- Draft version of Deliverable 3.2 was postponed to Month 19. The final version of was completed only at the end of the project.

WP4

b) Task 4.1 had some developments in month 7 but because it was depending on the selection of electronic components it was rescheduled to M16 – M24. Developments with beta prototype postponed its finish to month 30 with last improvements on the software.

c) Task 4.2 started 1 month later and its conclusion was planned for month 27. It was needed more months than initially planned because of complexity of the modules and the need for experimental data from the Wireless UEC and the body sensors network. Improvements were also made with beta prototype and final version of deliverable 4.1 was only finished in the end of the project.

WP5

- The delay in Deliverable 1.1, with the consequent delay in the definition of the size and frequency for the probe, coupled with the complexity of such a miniaturized ultrasound probe, requiring very special process and tools for its production, lead to an extent of the plan in two months for task 5.1.
- After request for project extension Task 5.2 should be concluded at month 24 and it was achieved. Deliverable 5.1 was concluded on month 24 and Milestone 4 was concluded at month 30.

WP6

- Alpha prototype was delayed and full integration was not possible. Several improvements were needed to beta prototype and were successful implemented.
- Laboratory testing was only finished in the end of the project, because of the last improvements on beta prototype.

WP7

- Task 7.1 was anticipated to M7 to be developed in simultaneous with Task 7.2
- Task 7.3 was anticipated to M1, assuring by this an effective dissemination of the project since its beginning.

These modifications do not present any impact on the associated deliverables and milestones.

Section 4 – Other Issues

The role and involvement of SMEs partners (IPA, Dunvegan, AGT, ARTICA and Ardoran) on project activities was of higher importance for the achievement of the established objectives for TROY project.

SMEs performers were involved on the development of work foreseen on WP1 for definition and validation of the requirements, WP 2 – Sensors Development, WP3 – Electronic System Design, WP4 – Software Development, WP5 – Ultrasound Probe, WP6 – Prototyping and Testing and they were the leaders of all the activities developed under WP7 – Dissemination and Exploitation.

Due to their technical skills, SMEs were involved on the selection of sensors and on the design of the electronic system as well as on the prototyping and testing phases of the project. SMEs partners were involved on the Technical meetings organized during the second year of the project and AGT was the partner responsible for Deliverable 6.3- Test rig phantom.

They were also responsible for leading the development of WP7 - Dissemination and Exploitation of Project Results, namely for the definition of the exploitation strategy of project results. Two major documents were produced on the scope of this activity, D7.3. - Market Study & Exploitation Plan and D7.4. – Knowledge Exploitation and Dissemination.

SMEs partners have identified the following opportunities as potentially patentable Intellectual Property on the scope of TROY project:

1. Core concept of an US endoscope capsule
   - Ultrasonic scanning of the bowel and near structures with a capsule endoscope which has battery autonomy to carry on Ultrasound examinations of the digestive tract.
   - Pill orientation/inclination measurements
   - Data transmission to the wearable unit
   - Must be traceable
   - Multichannel (16 to 32 in prototyping, expandable), with no moving parts
   - Derivative concepts of increasing the number of channels: rotate the transducers array within the capsule

2. Multi-element miniaturised US transducers and fabrication techniques
   - Transducers array within capsule (Size restrictions)

3. Position Tracking

- For trajectory calculation the system needs a precise time management integrated with a 3D real-time positioning, including a 3D sensors array, which allows precise identification of the pill position, by means of magnetic signal coming from the magnet inside the pill using a triangulation technique. Also, the wearable unit has a real time clock which enables the synchronisation with the tracking mechanism, so a time stamp is assign to each set of 3D coordinates.

4. Techniques used for data transmission
   - No compression for power saving and space constrictions
   - Low power consumption

5. Battery management
   - Power consumption minimisation techniques: only one channel is active at a time;
   - Ultrasound pulses send with exciting pulse of only 3V;

6. Capsule design, materials, and construction techniques
   - Optimised for ultrasonic performance (combination of two different components (gold plating, plastic) for cost effective and high performance benefits
   - Housing manufacturing techniques (manufacture good housing at lower temperatures; join the gold and plastic materials)
   - Capsule shape: elicoidal stripes on the surface, for easy travelling and rotating;

7. Ultrasonic imaging techniques to extract and present useful information from the data
   - Contour extraction (from raw data)
   - 3D rendering of the small bowel surface
   - New ways of presenting the data (visualisation methods)
   - Small bowel layers identification
   - Artifact elimination software
   - Calibration techniques to compensate for individual elements of multichannel transducer variation to provide a uniform omnidirectional response
   - Allow user control to optimise the information extraction and presentation algorithms
   - Adaptive sampling – adjustable frame rate, based on tracking the capsule, its movement and acceleration.

Due to the highly innovative character of the project, and since it involved a significant number of SMEs (5 out of 9 partners), the resulting product exploitation is considered a major aspect.

In order to effectively exploit project results, the original contract provided for ownership of results to be on the basis of specific aspects of the TROY system being owned by particular SME partners with the rights of each being restricted to defined geographical areas was modified. The previous arrangement was considered to be impractical. There are interdependencies between each module of the system resulting in it being more realistic to

consider the TROY system as a complete entity. Partners are exploring opportunities for exploiting the results in cooperation with large OEMs. For such an exploitation strategy to be successful a coordinated approach is necessary and the system must be available to be offered without restriction on specific parts or geographical scope.

Based on these factors, the SME partners have decided to redefine ownership of the results on the basis of a Joint Ownership Contract. The agreement deals with a number of issues related to the exploitation and utilisation of the commonly owned knowledge.

This project allows the SME partners to become owners of an extremely innovative technology not yet present on the market. The transnational character of the consortium and the projected market that each SME will address, assures a wide coverage for the exploitation. Indeed, it is clear that the final product is independent of national peculiarities and developed according to EU standards, thereby representing an excellent opportunity for the SMEs to operate in a transnational perspective and cooperation.

The group of RTD performers – IAITI, LABOR, UMF, UI of KTU – was actively involved in all activities of the project. Besides their active contribution to the research activities, some of these activities contributed to the extension of knowledge in the field (scientific publications are under preparation and their submission the scientific journals) of the project area.

Annexes

1. Milestone 1,2,3, 4,5 ,6
2. Plan for Using and Disseminating Knowledge