ULTRAsponder: In vivo Ultrasonic Transponder System for Biomedical Applications

Healthcare methodologies are constantly evolving due to the research and technology advancements made in the field of sensing and monitoring, promoting the use of wearable wireless devices for clinical applications. This opens the way to promising possibilities in terms of **prevention** and **treatment** of **patients requiring continuous surveillance or therapeutics**.

ULTRAsponder consists of a group of scientists, engineers and medical doctors and aims at developing a new system with a very high degree of **reliability and accuracy of the clinical data**, while providing the patients with **high level of safety and user friendliness**. Though the project intends to propose a general solution to several possible pathologies, such as acute diabetes, epilepsy and other debilitating neurological disorders, it will focus its efforts on one **demonstrator devoted to chronic cardiac diseases**.

For this specific application, **continuous monitoring** is particularly important to follow the day and night heart activity, thus allowing to understand **how the heart reacts** to different kinds of **stresses**, to different kinds of **activities** and to different sorts of **medications**. A continuous monitoring of a patient can also give the physicians the possibility to make a **direct comparison** of the actual patient condition with a past condition (one day, one week or one month earlier). Therefore continuous monitoring is a major leap forward in the diagnosis and the treatment of cardiac congestive heart failure (CHF).

Prerequisite for this are very **reliable monitoring** instruments that detect the variables that are the most important for the diagnosis and also for the treatment to be followed.

Current monitoring of CHF consists in **periodical assessments of cardiac parameters** such as blood pressure, EKG, echocardiography and some blood markers. Carrying out these monitoring procedures is **labour intensive and requires a well-trained cardiologist** for the echo-cardiographic study. Furthermore, it is **expensive** to do, in terms of both the personnel costs and blood tests. Current monitoring **only reveals a snapshot** of the cardiac condition. As monitoring is periodical and not continuous, patients may suffer from major changes in their condition that remain undetected during the period of time, which is not monitored.

ULTRAsponder intends to remedy to all these limitations by proposing a simple yet effective solution based on continuous monitoring and data collection on an external control unit. Data can be transmitted over the cellular phone network or Internet during day or night to provide the treating physician with all relevant data timely and cost effectively with minimal discomfort for the patient.

With the technology developed in ULTRAsponder, the **treatment can be tailored** according to each patient's conditions; which means that standard doses or standard combinations can be avoided. As a consequence, not only for treating a single patient but also for larger trials the quality of the treatment and medications can be largely improved and analysed.

ULTRAsponder aims at developing exclusive and unprecedented technologies based on **ultrasonic telemetry techniques**, for communication between one or several sensors or stimulators deeply implanted in the human body (**the transponders**) and a **control unit** which is used for both **wirelessly recharging** the implanted devices and **transmitting the received information** to the external world. A schematic view of the project concept is shown in Figure 1.

Despite the technological advancements made in the past years, the design issues for deeply implanted devices remain numerous, especially concerning **miniaturisation** and **power consumption**. In addition, because of the **body's dielectric nature**, communicating with implants that are located deeply within the body, using conventional techniques like Radio Frequency (RF), may not work effectively.

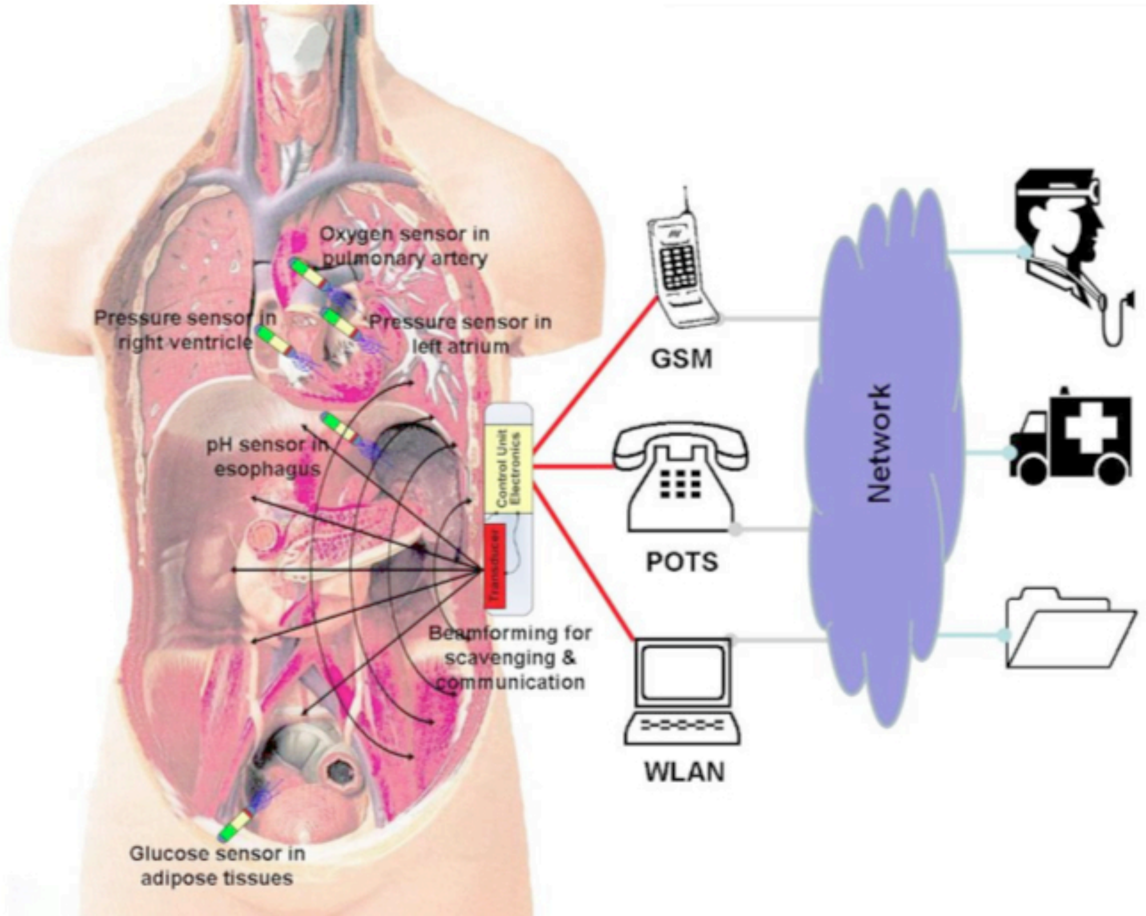

Figure 1. The ULTRAsponder concept.

Another important concern is the electromagnetic compatibility, which is associated to communication based on radio frequency. It is becoming more and more difficult to ensure a radio communication characterised by a high immunity to external sources. The ever-increasing number of wireless hot-spots associated with the use of wide frequency spectrum in modern radio devices, render the use of **electromagnetic waves a questionable transmission medium**. Consequently, new roads need to be opened to overcome these limitations and to ensure the viability of emerging deeply implanted medical devices.

ULTRAsponder is aimed at developing systems and methods, not using RF or electromagnetic telemetry with their limitations, but **acoustic waves (ultrasounds)**, for communicating with, and charging efficiently a network of transponders that are placed deep inside a human body. Such systems are **small and light**, allowing them to be placed either via open surgery or minimally invasive techniques. A transponder may include one or more

sensors for **monitoring a variety of parameters,** such as temperature, pressure, strain or fluid flow and chemical, electrical or magnetic properties. It may also **perform therapeutic functions** such as drug delivery, defibrillation or electrical stimulation. As part of a network, several transponders can **communicate** and exchange information to the external control unit, leading to **address complex** biological and clinical **applications**.

This project is also dedicated to external systems for controlling, charging and communicating with such a transponder network, and to methods using such systems. In addition, the external control unit acts as a gateway for the entire system.

The **key objectives** of **ULTRAsponder** are the following:

- *To develop innovative wireless data and energy transmission techniques for ultra low power sensor/actuator nodes immersed in aqueous media,*
- *To achieve small footprint, high flexibility, modularity and generality, which can easily be adaptable to any implantable microsystem,*
- *To perform bidirectional acoustic wireless data transmission,*
- *To enable local low massive signal processing capabilities to reduce transmission time and data load,*
- *To develop ultrasonic transponders actuating and either intermittently or continuously monitoring parameters for biological applications, where considerations are given to miniaturization, power consumption, functionality, production and cost aspects,*
- *To prove the concept by developing a new technology for a network of ultra-low power transponders deeply implanted inside the body for long term periods,*
- *To assess the overall system in a real environment for a particular application aimed at measuring physiological parameters and correlating them (data fusion) to perform advanced diagnostics.*

In order to **enhance the quality of life** of people who need to wear implanted monitoring devices, ULTRAsponder intends to develop a **minimally invasive technology** to be integrated into a minuscule implant, requiring **no antenna,** cumbersome **battery, or** connecting **leads**.

The ULTRAsponder implantable transponder contains an **energy exchanger** which converts acoustic energy into electrical energy, a small local **energy storage**, a control and processing **chip**, and a **sensor or actuator**, all enclosed in a **miniaturized biocompatible casing**, hermetically sealed. The device may be equipped with an **alarm** function, to facilitate critical care monitoring in certain applications. When the device has to operate autonomously, i.e. without external power, it shall be able to operate at least for one week, which depends on the application. This longevity parameter dictates the power consumption level of the implant.

The ULTRAsponder solution will also incorporate a dedicated **external control unit**, capable of energising the transponder or transponder network and receiving information directly from the implanted transponders. This device should facilitate the communication with up to 10 implants and should provide its user with relevant data. For devices operating autonomously, a critical asset is power management during periodical charging of the implant(s). The charge status will be monitored continuously, and when the implant is fully charged, it will stop requiring energy from the control unit;

the total charge time for the implanted transponder shall not exceed 30 min.

In addition to the technology breakthrough proposed by the project, **in vitro experiments** as well as **animal trials** will be performed to **validate the concept**. In vitro experiments with phantoms will be exercised before animal trials will be organised. The **ultrasound propagation in the body** will be studied and visualised, and models will be validated. Animal trials will be conducted in accordance with the "**three R's**" rules (Reduction, Replacement, Refinement) wherever possible and will be in compliance with the national directives. In particular, the use of "technical phantoms" will be examined in the design and testing steps of the development cycle to minimise the number of animals.

ULTRAsponder will have a **strong impact** on the **European medical community and the way medical surveillance is undertaken** today by providing innovative solutions enabling **remote monitoring** of vital parameters **reliably and continuously**, and **relaying these data,** through wireless communication channels, to appropriate centres. To attain this goal, the patient acceptability as well as the device functionality and reliability are of utmost consideration during the project.

It is a general principle in medicine that an **early detection of a disease implies a better chance for a cure**. Accordingly, the continuous monitoring of organs or diseases will alert the physicians at an earlier point and thereby allow an earlier and more efficient treatment to be initiated. This is **particularly true for cardiac diseases**. There is often a very short time period from a cardiac arrhythmia to a cardiac arrest. By continuous monitoring, the initial phase of life threatening arrhythmias can be detected and treated, possibly **saving the patient's life**.

ULTRAsponder in brief:

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Partners: Medtronic, Netherlands
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CSEM, Switzerland
INSERM, France
HEIG-VD, Switzerland
Rikshospitalet, Norway
IMST, Germany
SCIPROM, Switzerland

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