PROJECT FINAL REPORT

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Project acronym: ICYHEART

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IcyHeart

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Project Title: Highly integrated ultra-low-power SoC solution for unobtrusive and energy-efficient wireless cardiac monitoring

Call: FP7-SME-2011, Research for SMEs

Grant Agreement no.: 286130

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Coordinator: RTD TALOS Ltd. (TALOS, CY)

Beneficiaries:

Prisma Electronics ABEE	PRISMA	GR
Dolphin Integration SA	DOLPHIN	FR
Docobo Ltd.	DOCOBO	UK
SignalGeneriX Ltd.	SG	CY
CSEM Centre D'Electronique et de Microtechnique SA – Recherche et Developpement	CSEM	CH
Ecole Polytechnique Federale de Lausanne	EPFL	CH

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Executive summary

The objective of the IcyHeart project was to investigate and demonstrate a highly integrated and power-efficient microelectronic solution for remote monitoring of a person's electrocardiogram (ECG) signals. A complete System-on-a-Chip (SoC) has been developed by CSEM which embeds, on a single chip, an ultra-low power signal acquisition front-end, an analogue-to-digital converter (ADC) for ECG, a low-power 32-bit digital signal processor (DSP), and a low-energy radio frequency (RF) transceiver. The SoC enables 3-lead ECG monitoring. In addition it has a fourth auxiliary input channel which can be used for example for impedance measurement. Each channel has a lead-off detection unit to verify that the leads are correctly connected to the body of the patient. The SoC also features an active ground control to compensate large variations of the common mode voltage.

The software for ECG signal analysis running on the embedded processor has been developed by EPFL. It is a whole digital signal processing suite, performing 3-leads filtering, combination of the 3 signals followed by delineation of the ECG signals and finally detection of abnormalities. Raw signals as well as filtered signals and fiducial points can be transmitted by the 900 MHz RF link to an external HUB. For this purpose, SignalGeneriX has developed a Wireless Communication Software to enable communication between a patient module and a central station.

A tiny OEM module has been developed by SignalGeneriX which embeds the IcyHeart SoC, a battery, a battery supervision circuit, a USB connector, buttons and LEDs. This tiny OEM module is incorporated in a wearable prototype, which in addition to 3-lead ECG monitoring is also able to perform pacemaker pulse detection and bio-impedance measurement. It communicates via the 900 MHz RF link to a HUB which serves as a data concentrator and access point to transfer data via internet to a medical doctor for example.

The project has enabled breakthroughs in the area of highly integrated "sensing-converting-processing-transmitting" solutions in a single chip. The IcyHeart technology will generate high market value for European SMEs developing novel cardio-monitoring products in home and professional environments, and create high societal impact for several categories of European citizens requiring miniature, comfortable and easy-to-use wireless tele-healthcare solutions. The end results of the project will be exploited by the 3 SME partners of the consortium – Dolphin Integration (France), Docobo (UK) and Prisma Electronics (Greece).

1. Summary description of the project context and the main objectives

The context of the project is tele-healthcare and cardiac monitoring. Tele-healthcare is about monitoring patients in their homes or when they are mobile, and capturing vital parameters. It concerns the delivery of health-related services and information via telecommunications technologies, and encompasses preventive and curative aspects.

EU and worldwide governments and healthcare organizations have been considering tele-healthcare as a major technological and societal solution for solving the major challenges that the healthcare sector is facing today[1]:

- **Aging population**: The population above the age of 65 is increasing at a higher rate as compared to the working population (15-65 years). Europe had nearly 71 million people above 65 years in 2007 and is expected to reach 80 million by 2014, with major impact on hospitalization costs.
- **Increase of the incidence of chronic illnesses**: More than two-thirds of the population who are above the age of 65 have at least two chronic illnesses. Circulatory and cardiac diseases accounted for 42% of all deaths. Prevention and early intervention are thus acknowledged as essential by the governments[2]**.**
- **Scarcity of resources**: The cost of healthcare is rising exponentially in Europe, whereas governments tend to reduce the funding towards hospitals. Hence hospitals are encouraging discharge of patients by reducing the number of beds[3], while promoting significant investments in tele-healthcare.

Tele-healthcare results in the elimination of wired connections and increases the mobility and comfort of patients. Supported by the advances in wireless technologies and the worldwide deployment of mobile ICT, healthcare organisations and industries have started embedding wireless technologies into an increasing number of medical applications and devices.

A typical tele-healthcare scenario concerns the patients discharged from hospitals or belonging to specific risk categories, and whose vital signs are remotely monitored. When a specific event is detected based on the evolution of vital signals, the concerned medical/healthcare services are remotely informed and specific actions may be taken to improve health either on a preventive or a curative basis. This healthcare model allows hospitalizing ill or at risk patients only when necessary. In all cases, the comfort of the patient is increased because he/she stays at home, and the costs are limited because the number of hospitalization days is minimized.

The global objective of the IcyHeart project was to deliver a miniature and highly integrated microelectronics System-On-a-Chip (SoC), and its assorted embedded signal processing suite, to enable truly low-power wireless electrocardiogram (ECG) monitoring in tele-healthcare. The focus was on ultra-low-power wireless and sensing micro-components for long autonomy and

[1] Frost & Sullivan « E-Healthcare in Western Europe – A huge market opportunity for wireless Technologies », Oct. 2009

[2] Under pressure - Tackling the financial challenge for councils of an ageing population, UK government report, Feb. 2010.

[3] Chronic diseases - A clinical and managerial challenge, HOPE European Hospital and Healthcare Federation, Oct. 2010

unobtrusive body-worn cardiac remote monitoring, in order to enable novel products that will be leveraged in home-centric patient care environments.

A conceptual overview of the IcyHeart platform is illustrated on Figure 1.

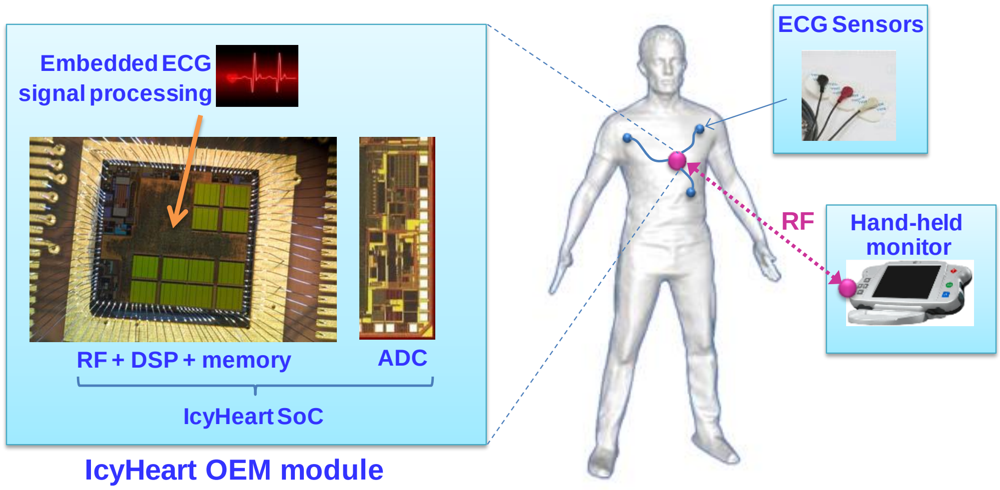

Figure 1: Conceptual view of the IcyHeart platform

The major challenge of IcyHeart was to improve the personal remote ECG sensing through the following objectives:

- The development of the IcyHeart original equipment manufacturer (OEM) module, which is a tiny PCB including all the hardware and software components to enable novel ECG-based tele-healthcare products for the SME participants of IcyHeart, or to be sold to other EU SMEs and industries. The major differentiators is the **tiny module**, and the **low-power operation** compatible with tiny low-voltage coin-cell batteries yielding **a supply as low as 1V** (e.g. single cell Zinc-air or Alkaline type of battery).
- The development of the IcyHeart SoC in 0.18um CMOS, which is the first time realization on a single chip of all the required functions for ECG processing: the analogue ECG signal acquisition chain, the ADC, a low-power icyflex[4] DSP with the required memory, and the short-range 868-915MHz low-power radio. **Embedding and miniaturizing all the hardware resources close to the sensors** is a clear enabler of smart and novel “sensing-processing-transmitting” ECG products.
- The development of an optimized, flexible and **ultra low-power ADC-based sensor interface** silicon IP targeting ECG signals primarily with nominal 12-bit resolution, but studied for enabling flexibility of its configuration (various resolutions up to 16-bit, flexible bandwidth configuration up to 500Hz). Such flexibility of configuration allows addressing other physiological signals. Scalability of the performance of ADC-based sensor interface is crucial for guaranteeing lowest power consumption for 24/7 ECG sensing with tiny battery operation.

[4] icyflex DSP, see http://www.eetimes.com/electronics-news/4088104/CSEM-launches-Icyflex-range-of-controller-DSPs

- The investigation and development of energy-efficient ECG signal processing algorithms, which are implemented on the embedded icyflex DSP within the IcyHeart SoC. Research was carried out to leverage innovative and light-weight algorithms (i.e. based on the discrete-wavelet transform or morphological filtering) that can achieve the best trade-off between accuracy and energy consumption. Through the extraction of the relevant signal features to be wirelessly forwarded to the hand-held monitor, **energy-efficient embedded signal processing is crucial to reduce wireless streaming of raw ECG data over the power-hungry radio link**.
- The realization of a functional demonstrator, which enables wireless communication of the ECG data from a body-worn ECG module to a HealthHub.

2. Description of the main S & T results/foregrounds

2.1. Introduction

Across the European member states there is an increasing need to find ways of managing patients with chronic and acute disease without increasing demand on limited financial and personnel resources. For some time, various initiatives have begun to address the management needs of patients with long term conditions through the introduction of remote care, looking after patients and other vulnerable people in their own homes. Examples from the many areas are the management of patients with hypertension and chronic heart failure.

Up to now medical support is delivered through a range of clinical interventions that address previous disease exacerbations. Whilst this has had significant impact on the disease outcomes, there is an increasing need to provide remote diagnostics with a view to shifting the emphasis away from 'alert intervention management' to 'health and well-being management' through implementation of anticipatory avoidance programmes. Such approaches change the nature of the clinical management approach with the emphasis moving away from crisis alert management to become focused on predictive indicators of change. This requires the provision of new remote diagnostic and monitoring products for the purpose of improving the observation, diagnostics and early stage avoidance pathways for patients within the primary and acute care sectors whilst continuing to meet cost containment and reduction objectives of healthcare providers.

The markets addressed by the outcome of the IcyHeart project are multivariate, meeting needs of the chronic primary and acute secondary care segments, personal health and wellbeing, occupational healthcare, sports medicine and other health related services such as maternity services. Competition to the IcyHeart outcomes is fragmented. The main Telecare providers concentrate on the instrumentation of the environment in which potential end users operate – traditionally the home. IcyHeart project outcomes will be applied to change the direction towards a predictive model through supporting user providers of the technology to include prevention by integrating cardiac vital signs (ECG and dependent variables) alongside psycho-social assessment and other sensing technologies and communication interfaces to create a range of holistic care devices based on a common health maintenance platform for delivery. This is an ambitious goal but it is expected to be able to deliver such an approach that will take the outcomes beyond the current and short/medium term State of the Art. None of the current Telehealth providers include vital sign monitoring as standard. Two suppliers use OEM secondary care devices which are expensive and limited in volume.

In fact, IcyHeart, in the broadest sense, can conceptually be compared to a wireless Holter. Its main application is directed to the field of electrocardiography, as a novel alternative to current Holter monitoring systems. These systems enable continuous monitoring of the ECG of the patient, allowing for the identification of relevant diagnostic information of various heart diseases such as ischemia, infarction, heart failure, hypertrophy and the occurrence of arrhythmic events. The Holter, also called ambulatory ECG monitoring, performs continuous ECG recording over an extended period of time, usually 24 hours and occasionally 48 hours, using a portable device from which data is then extracted and analyzed for analysis. This monitoring allows the acquisition of diagnostic information related to the presence of arrhythmias, for which ECG observation in a medical consultation (typically lasting few minutes) is unlikely.

In recent years new devices that aim to improve the technological capabilities of the conventional Holter have been proposed. In particular, wireless technologies can offer technical possibilities in the medical field, such as sensors that are not wired (or minimally cabled) for the acquisition of ECG, pressure, thoracic impedance or physical activity level of the patient. However, these technologies have been designed to provide new monitoring services, rather than strengthen existing clinical practice. Thus, the creation and design of a wireless long-term Holter system such as IcyHeart would enjoy an immediate presence in any cardiology service, because the vast majority of Holter tests are performed routinely in clinical practice.

Three scenarios have been considered for the use of the IcyHeart ECG monitoring system. The main scenario – Home Patient Health Monitoring – concerns patients needing a long term ECG monitoring. The patients must be able to operate alone the portable device which will transfer the ECG data to a HUB. The second one – Clinical Diagnosis – concerns patients monitoring in a medical environment. In this case, there may be more than one portable device active at a given time and communicating to different HUBs. The third scenario – Health Monitoring in Extreme environments – will use the IcyHeart module as a subsystem of a personal support device for the technicians and engineers that have to work in extreme environments.

The architecture of the system, illustrated in Figure 2, is made of the following blocks and terminals:

- ECG sensors (three leads plus a lead for electrical reference).
- Auxiliary signal input.
- Antenna for RF communication.
- System-on-Chip (SoC), mainly RF transceiver, ECG sensors interface, LED drivers, icyflex microprocessor, power management.
- USB interface for wired serial connection and battery charging.
- LED indicators: correct fitted electrodes, transfer or record of data, battery's life, and failure.
- Battery, power management, on/off or reset button

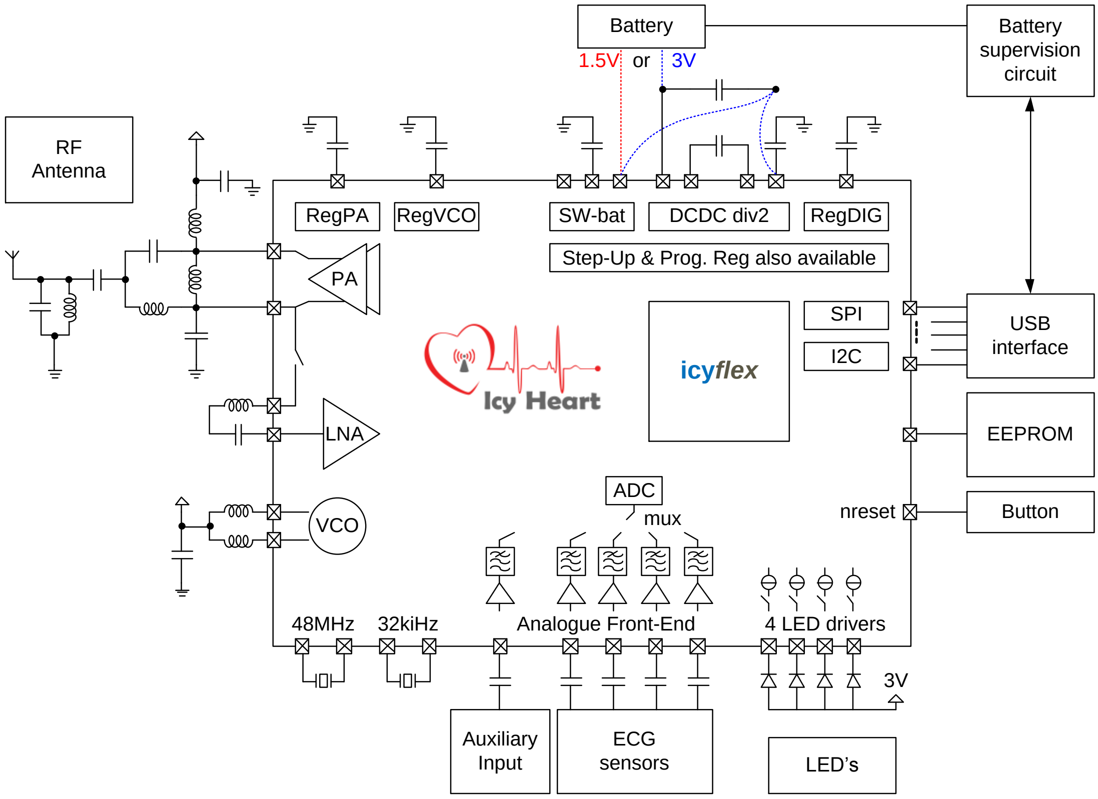

Figure 2: Architecture overview of the IcyHeart system

The System-on-Chip (SoC), the processing embedded in the SoC and running on the icyflex processor, and the OEM module and prototype are described in the next chapters.

2.2. System-on-chip

2.2.1. Requirement

The IcyHeart System-on-Chip (SoC) includes in a single 5x5.3 mm^2 die all the needed features for a three channel ECG acquisition, including signal processing and wireless data transmission. These features include:

- The IcyHeart sensor interface that makes the analog amplification and the A-to-D conversion of ECG signals.
- The icyflex microprocessor 32 bits (including 96 kB of RAM) that embeds the ECG signal processing, digital filtering and delineation software.
- The RF communication in the 863-928 MHz range that allows wireless transmission of the ECG data.
- General Purpose Input/Output (GPIOs) that are used as interfaces to program the icyflex (SPI, I2C, UART) or control external buttons, LEDs or buzzer.
- Power management to assign, from one single battery (3.3V or 1.5V), the high and low voltage parts of the circuit.
- Time and voltage references like the 32.768 kHz for the Real Time Clock (RTC), the 48 MHz for the RF transmitter and the Sigma-Delta ADC, and the 0.6 V bandgap for the regulators and the Sigma-Delta ADC as well.

2.2.2. System view

The IcyHeart SoC has been derived from the IcyCom SoC developed at CSEM. To our knowledge, it is the first time realization of a SoC that embeds an ultra-low-power ADC-based ECG sensing jointly with low-power 32 bits DSP and low-power 868-915 MHz radio on a single silicon die. The SoC runs off a 1 V supply, compatible with a single alkaline cell, and is optimized for long battery life, consuming less than 4 mA in receiving active mode, 40 mA for 10 dBm transmission and 1 µA in standby with RTC running.

Additional peripherals such as voltage-divider to address lithium batteries, SPI, I2C, UART to program the DSP, GPIO's and LED drivers are included on the same chip, resulting in a compact system solution on a silicon area of 26.6 mm^2. IcyHeart SoC targets portable ISM-band applications needing long battery life and signal processing such as WSN and medical.

The digital core of the IcyHeart SoC is built around the **icy*flex*** DSP, a 32 bit low-power micro-controller with DSP functions (parallel dual MAC). The icyflex DSP supports signal processing of ECG signals executing an FFT-256 in only 2.6 k clock cycles with consumption as low as 120 µA/MHz under 1 V supply.

The RF transceiver operates in the 863-928 MHz range for about 3.5 mA. The receiver part is ultra-low-power, not only optimized for continuous operation but also for RF channel power sampling. This allows efficient implementation of low-power protocols minimizing the receiver activity. The transmitter part provides up to 10 dBm with a power efficiency of 25%. The whole transceiver operates under a supply voltage of 0.9 V. A flexible digital baseband allows several type of modulation like FSK, GFSK or OOK modulations.

A schematic overview of the IcyHeart SoC with the name of each block is presented on Figure 3. The external components are also shown, mandatory for antenna adaptation, supply voltage decoupling, quartz oscillators and ECG signal coupling.

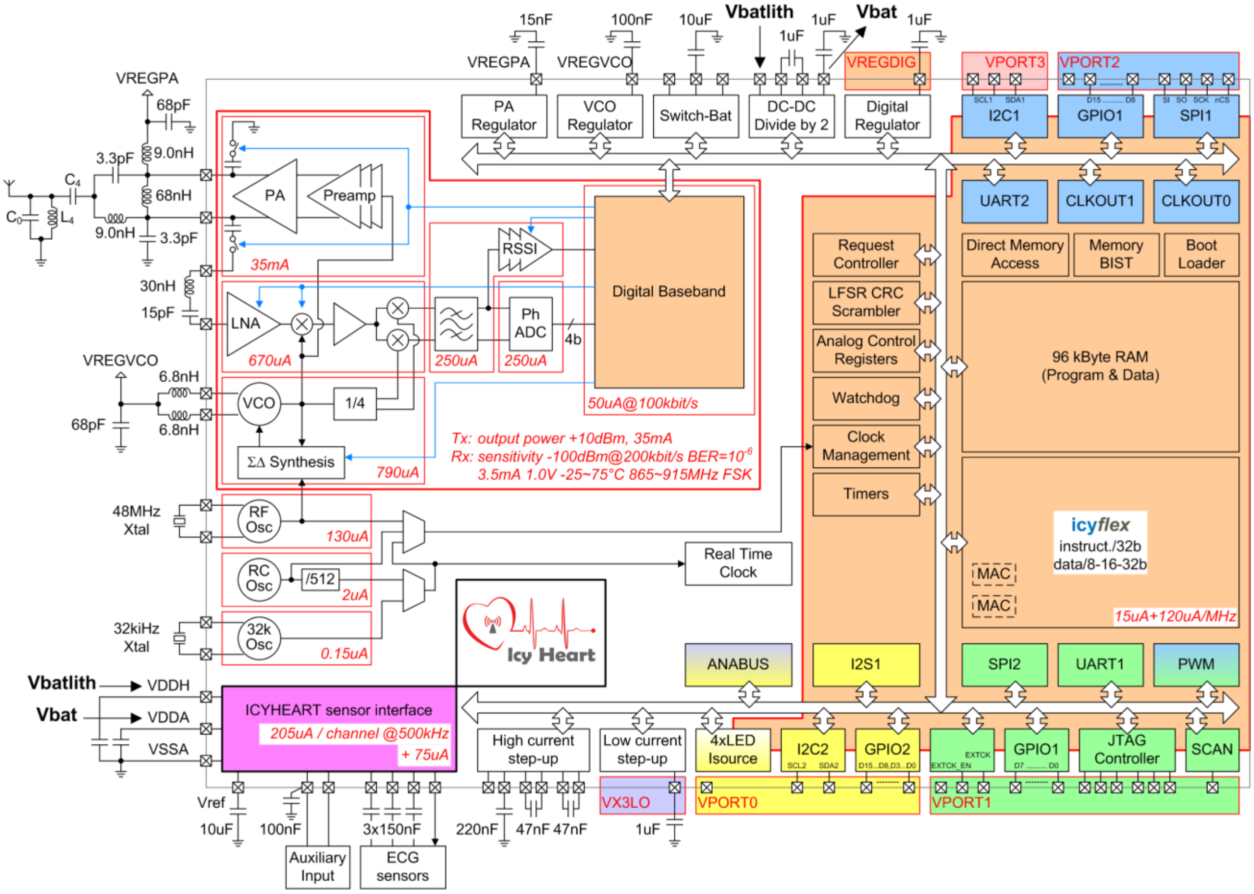

Figure 3: Schematic overview of the IcyHeart SoC

Figure 4 shows the layout implementation of the IcyHeart SoC (chip photography) with an exhaustive description of the padring.

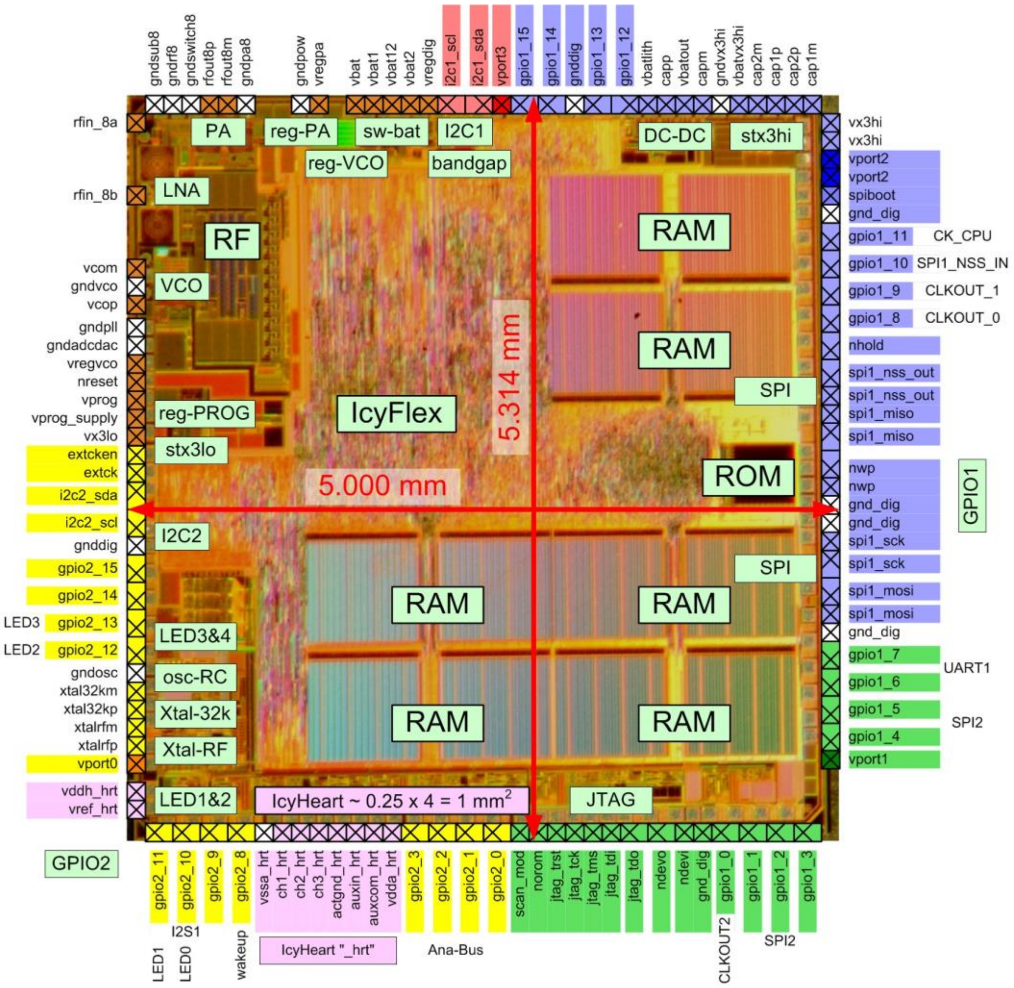

Figure 4: Chip photography of the IcyHeart SoC with padring description

2.2.3. Sensor interface

The IcyHeart sensor interface, at the bottom-left part of the SoC on Figure 3 and Figure 4, is the most critical part of the ECG acquisition. The required specifications are:

- Amplify ECG signals from three leads in the 0.67-500 Hz frequencies range with an input referred noise of less than 1 uV_{RMS}. The ECG signal itself is less than 4 mV_{RMS}.
- Get rid of any DC differential voltage that could be as high as 1 V.
- Set the differential input impedance above 2.5 MΩ (10 MΩ if possible).
- Convert the analog ECG signal into digital with a dedicated Sigma-Delta ADC.
- Control the common mode voltage with an adequate Driven Right Leg circuit (active ground)
- Implement a leadoff detection to ensure a correct placing of the leads
- Target low power and low voltage

From these specifications, the following implementation of the ECG sensor interface has been built (Figure 5).

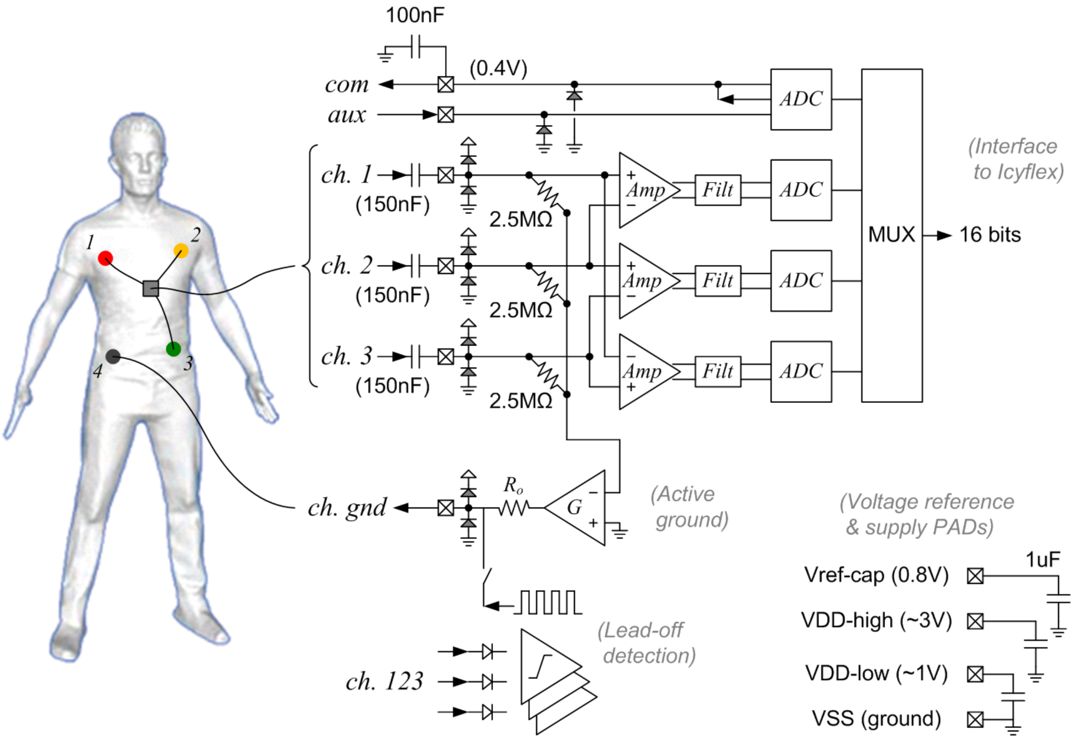

Figure 5: Chip photography of the IcyHeart SoC with padring description

Each of the three ECG lead (red, yellow, green) is capacitively coupled to the input of a channel which input impedance is set to 2.5 MΩ with a simple passive resistor. This allows removing any DC signal still meeting the 60601-2-25 and 60601-2-51 IEC standard requirements respectively for monitoring and analysis ECG systems. The high pass cutoff frequency is set below 0.5 Hz thanks to the 2.5 MΩ-150 nF RC time constant.

The input amplifiers treat the ECG signal of two leads in differential. It is built on a g_mR structure. Such amplifiers have the advantage of being very low power and low noise (all the current is used for amplification with a reduced number of transistors). Their main drawback is the non-linearity, but as the amplitude is much lower than 10 mV and the DC part is removed, linearity is not an issue.

A second stage of amplification is done afterwards making the overall amplification value controllable from 22 to 46 dB. Following the amplification part, a passive low-pass filter of second order, with a controllable bandwidth between 100 and 500 Hz is implemented as well as adequate buffer to feed the input switched capacitor of the ΣΔ-ADC (Figure 6).

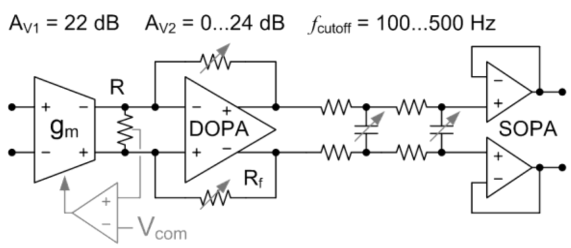

Figure 6: Amplification and filtering part of the analog chain

The achieved specification of the amplification and filtering part (output buffer included) is:

- A gain adjustable from 22 to 46 dB with a Total Harmonic Distortion (THD) of 54 dB for an input signal of 4 mV_{PEAK}.
- An input referred noise within the 0.67-500 Hz bandwidth of 0.87 μV_{RMS}. for the default gain setting (35 dB)
- A current consumption of 24 µA on the high supply voltage (3 V) and 32 µA (buffer and bias included) on the low supply voltage (1 V). This consumption can be reduced by a factor of two still keeping an input referred noise below 1 μV_{RMS}.
- A cutoff frequency of the low pass filter adjustable from 100 to 500 Hz

2.2.4. Sigma-Delta ADC

At the output of the amplification and filter chain is connected the Sigma-Delta Analog to Digital Converter (ΣΔ-ADC). The structure implemented for the IcyHeart system is a second order Chain of Integrators with weighted Feed-Forward summation (CIFF). The integrator weights are fixed with system level simulations from which the best trade-off between bandwidth, integrator output voltage swings (in order to minimize consumption), and chain stability can be done. Figure 7 shows the implementation of the ΣΔ modulator and the digital $SINC^3$ filter.

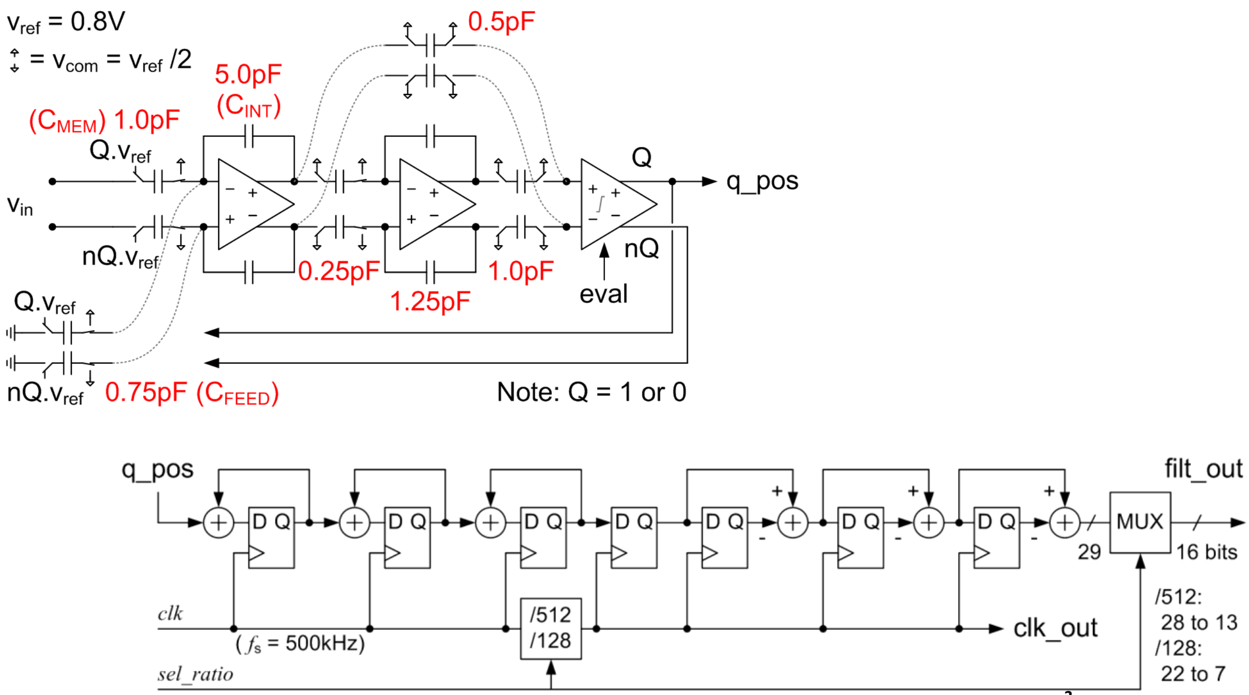

Figure 7: Sigma-Delta ADC with above the analog CIFF part and below the digital $SINC^3$ filter

The implemented ADC reaches 15 bits of Effective Number of Bit (ENOB) over the 0.67-500 Hz bandwidth, with a current consumption of 146 µA on a 1 V supply voltage and a 500 kHz sampling frequency. The corresponding input referred noise of the ADC is 26 μV_{RMS} which includes all the components of the ADC as well as the needed followers to buffer input signals and voltage reference. The maximal allowed amplitude signal at the input is 1 $V_{PEAK\text{-}DIFF}$.

Thanks to programmable registers for currents and sampling frequency, different trade-off between consumption, resolution and bandwidth can be done. Reducing sampling frequency by 4 allows falling down the corresponding ADC's consumption by almost 4 with few losses of resolution. Within the 0.67-500 Hz bandwidth, the ADC's consumption reaches 46 µA for 14 bits of ENOB. Reducing bandwidth to 125 Hz enables to reach 15 bits.

In term of resolution, the ADC performances have been chosen 2 to 3 bits higher than the global resolution required by the ECG application. It ensures that the ADC does not limit the global performance of the chain and allows relaxing the noise constraints on the front-end amplification chain. Both front-end amplification chain and analog to digital converter reach 12 bits of ENOB that corresponds to the expected ADC-based sensor interface resolution.

2.2.5. Measurement results

The presented ADC based sensor interface has a silicon area of 0.32 mm² (0.19 mm^2 for amplification chain, 0.13 mm^2 for Sigma-Delta ADC) which represent 1.2% of the whole SoC area. For a gain setting of 35 dB, a precision of +/-0.9 dB on the gain (including temperature dispersion), a CMRR of 66 dB and an input offset lower than ±1.4 mV have been achieved. The measured power consumption of one analog chain is 100 µW for a 1 V supply voltage, including voltage reference, Sigma-Delta digital decimator filter and biasing blocs.

On the amplification chain, for a current consumption of 56 µA (total current of the high and low supply voltage) the measured input referred noise is 0.87 μV_{RMS} within the 0.67-500 Hz bandwidth. Reducing this current consumption to 27 µA increases this noise to 1 μV_{RMS}.

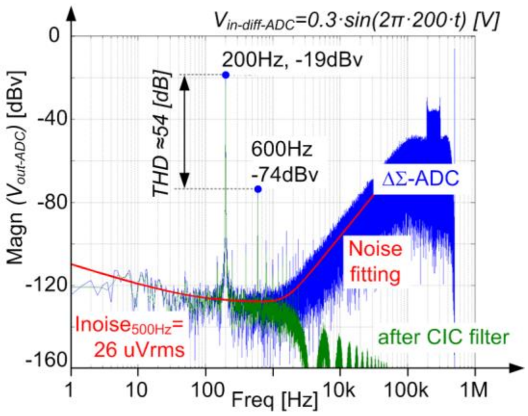

Figure 8: Measurement results of the Sigma-Delta ADC

The Sigma-Delta ADC achieves a THD of 54 dB (Figure 8) for a 300 $mV_{PEAK\text{-}DIFF}$ sinusoidal signal at 200 Hz. Current consumption is 146 µA for a 500 kHz sampling frequency and the input referred noise on the 0.67-500 Hz bandwidth, measured on 10 samples, is between 26 and 31 μV_{RMS}. Reducing sampling frequency to 125 kHz allows lowering this current consumption to 46 µA for an input referred noise of 45 μV_{RMS} on the same bandwidth.

2.3. Processing

The IcyHeart software combines advanced Digital Signal Processing (DSP) capabilities with a light-weight custom communication protocol, allowing wireless transmission of relevant data. It supports acquisition, real-time embedded analysis and streaming of three-leads electrocardiograms (ECGs).

Careful optimization techniques are employed throughout the software stack, allowing for advanced features, such as automated delineation of ECG signals, to be embedded in the low-power IcyHeart SoC. The target platform is, in fact, tightly constrained both in memory space (96 Kbytes of RAM memory) and clock frequency (6 MHz), allowing long-term monitoring applications relaying on small coin batteries.

The IcyHeart platform is a “smart” wireless ECG sensor node, which, in addition to acquiring and transmitting data wirelessly, performs advanced digital signal processing, *filtering* noise typically corrupting the signals and executing an automated *delineation* of heartbeats.

The first phase, that of filtering, uses highly optimized implementations of morphological filters to cancel low-frequency noise components (baseline wandering), due mainly to respiration and perspiration; a similar technique is also applied to reduce higher-frequency noise sources, caused by muscular contractions. Filtering is performed independently on the three acquired ECG signals (leads) that are then fused into a single stream for further analysis, using root-mean-square (RMS) combination.

The second phase (delineation) analyses the RMS-combined signal, automatically detecting the fiducial points of each heartbeat: the start, peak and end of its three characteristic waves (QRS complex, P and T wave, see Figure 9). This clinically relevant data is retrieved using a wavelet-based technique, which employs 5-scales DWT decomposition; the implementation is both computationally efficient and robust to noise (Figure 10).

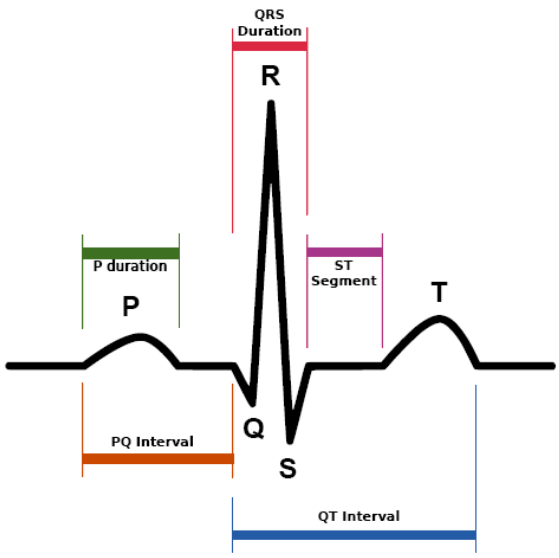

Figure 9: Fiducial points of an ECG heartbeat

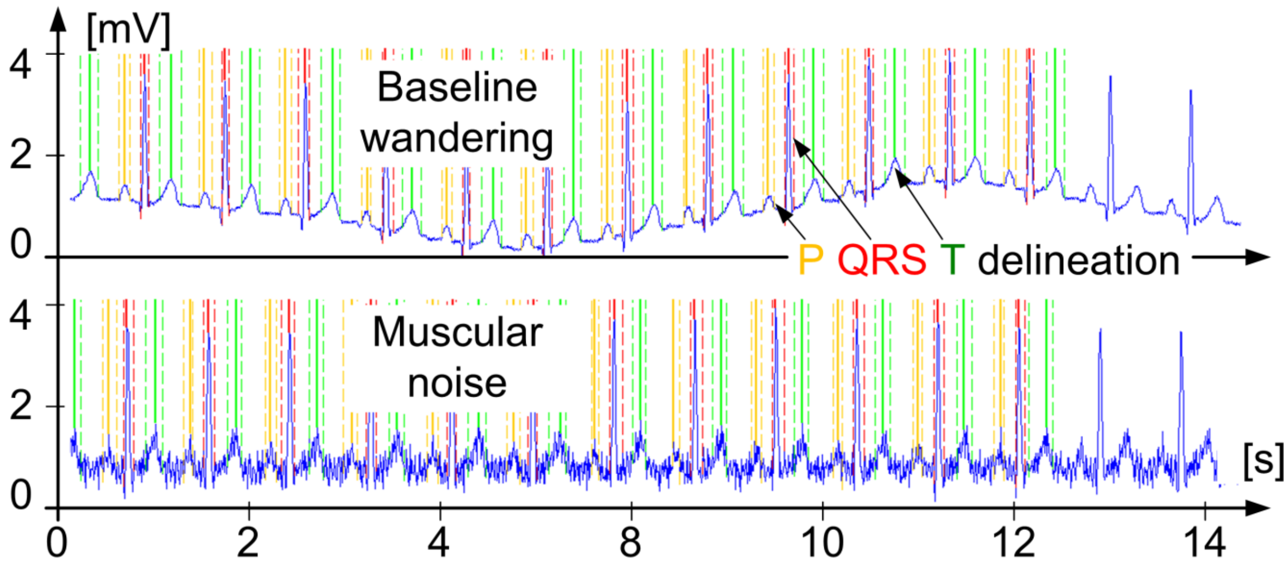

Figure 10: Delineation results in presence of muscular noise

Depending on the application scenario, different data can be communicated to a remote hub, allowing for different bandwidths requirements and, ultimately, energy consumption levels and mean time between charges. By only transmitting the retrieved fiducial points, battery life can be maximised; raw acquired data of each lead, filtered and/or RMS-combined data can be added if a more detailed inspection is needed.

Finally, the IcyHeart DSP software allows for detection of abnormal conditions, such as tachy- or brady-cardia or abnormal S-T segment duration, activating a corresponding "alarm" message.

A light-weight custom communication protocol has been developed and embedded on the IcyHeart SoC enabling the wireless communication between IcyHeart modules. The designed MAC protocol enables all the relevant data to be transmitted by a worn ECG device (Patient Module) towards the hand-held monitoring device where signals can be visually displayed or further processed. Moreover the protocol allows the remote control of the Patient Module through the hand-held device.

More particularly, the focus was to realize basic point-to-point communication within simple star topology network (Figure 11). Each patient module can be paired only to one Handheld module at a time and no other modules can enter the communication link between two paired modules. In this way several different pairs of patient-handheld modules may exist in the same room. To ensure data integrity, correctness and transmission of data, each packet includes CRC (Cyclic Redundancy Check) field while acknowledgment packets are systematically exchanged between the two modules during communication.

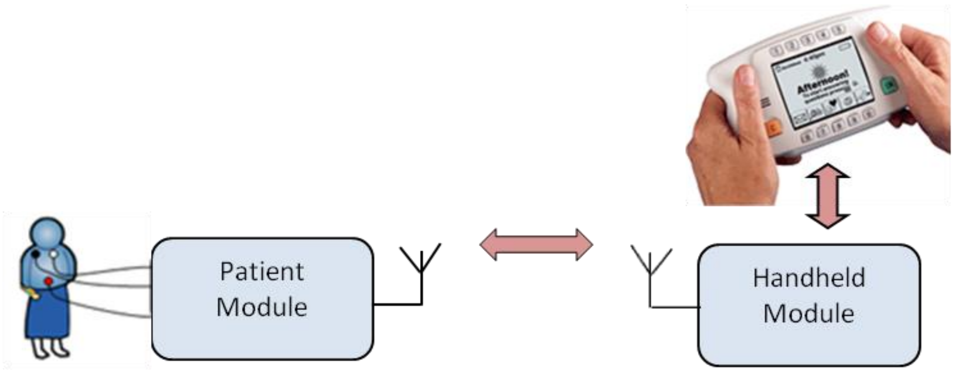

Figure 11: Wireless Communication Protocol

2.4. Module

The IcyHeart module consists of a single tiny PCB which includes all the basic technology bricks developed in the framework of the IcyHeart project. In particular, the PCB embeds the IcyHeart SoC having embedded the signal processing and communication software, the necessary miniature passive components, the antenna and the power supply and battery supervision circuit.

The general architecture of the module is shown in Figure 12.

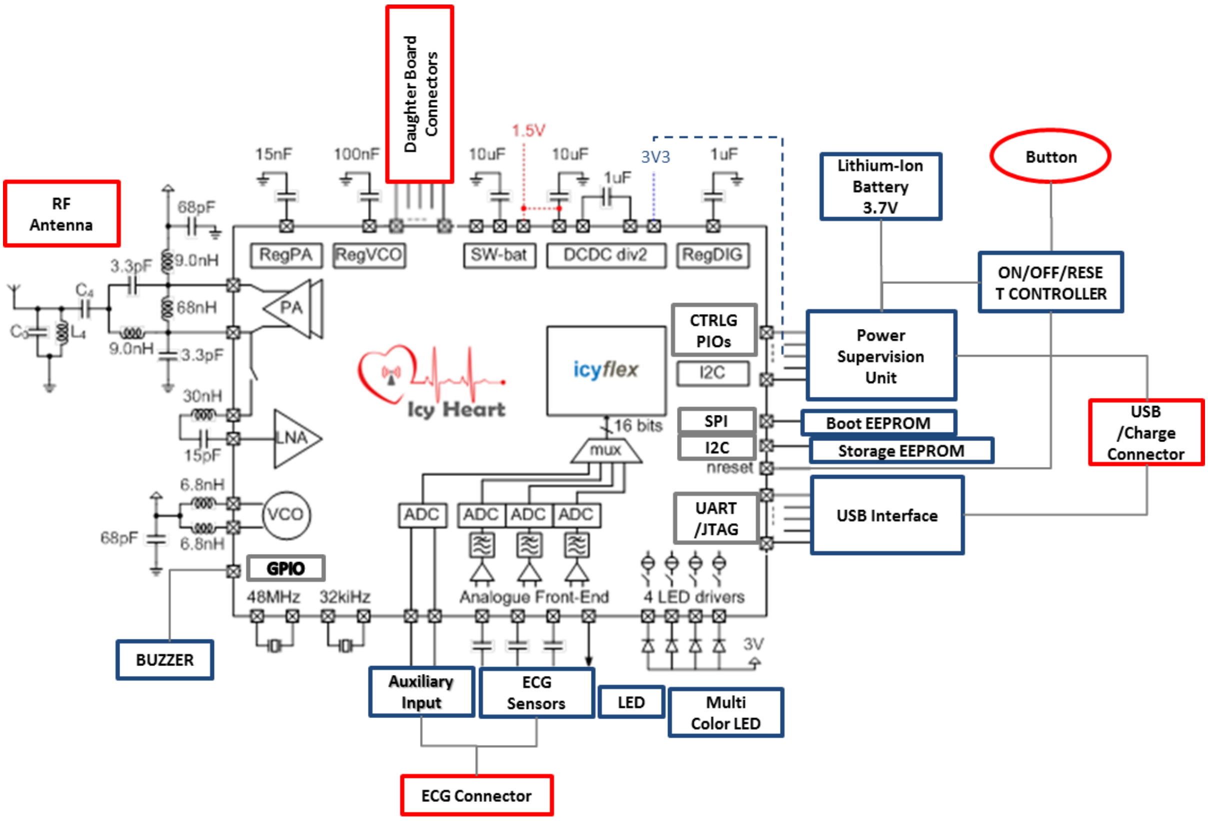

Figure 12: General Architecture of the IcyHeart Module

The IcyHeart SoC, incorporating the icyflex microprocessor, the RF transceiver and the ECG sensors interface consists of the module ‘Heart’ while several blocks and terminals are built around the SoC so as to support all the requested functionalities:

- Power Supervision Unit allowing:
  - Battery charging/discharging monitoring.
  - Module powering management.
  - ON/OFF/RESET Functionalities
- LEDs and Buzzer indicators providing the user interface of the module.
- USB interface allowing:
  - The charging of the module
  - Communication with module
  - Reprogramming of the module
- Daughter Board Connectors allowing its expandability

2.5. Demonstrator System

A working demonstrator system was created by incorporating a pair of IcyHeart modules into a patient unit and a "HealthHub" hand-held unit. The HealthHub is a domestic appliance that acts as data aggregator, storage and gateway to the internet.

The overall architecture of the demonstrator is illustrated in Figure 13. It incorporates 2 IcyHeart modules, one in a patient unit that is associated with the gathering of physiological; data, the other within an accessory for a DOCOBO HealthHub, which is an existing telehealth product.

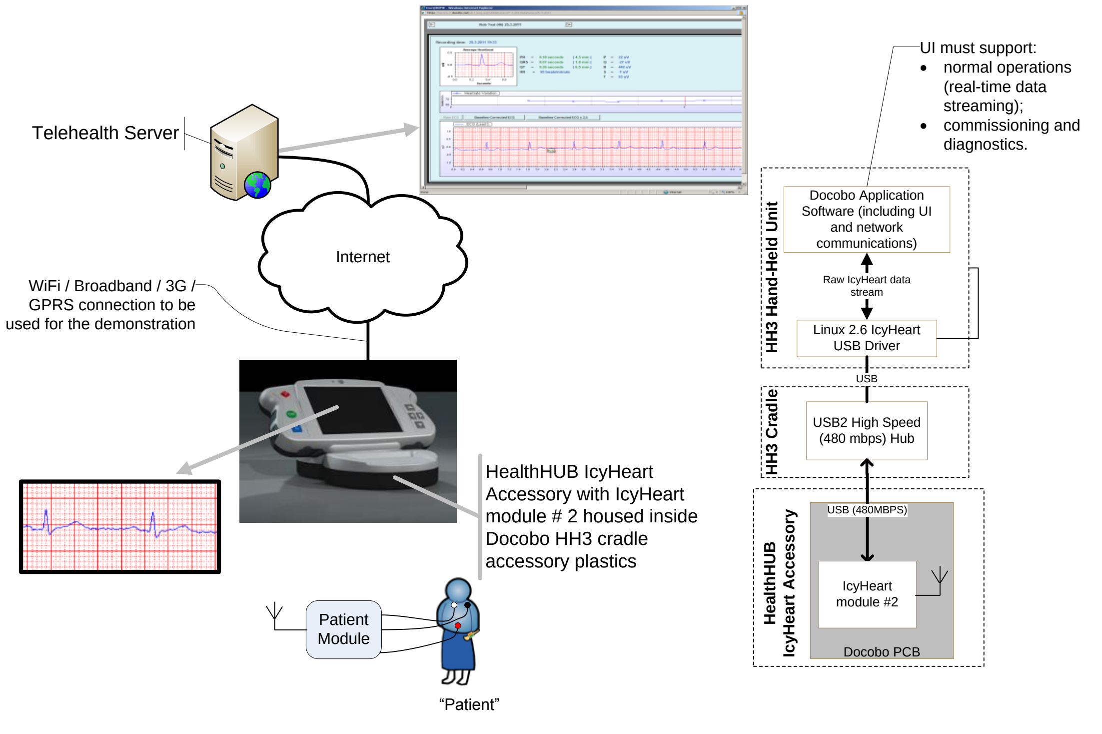

Figure 13: Demonstrator architecture

The use of the IcyHeart modules within the overall architecture of the demonstrator allows the following key operations to be performed:

1. Set up of the patient unit by a patient or relatively unskilled carer, with feedback provided on the patient module.

2. Wireless, transfer of both raw physiological data and associated analysis results from the patient module to the HealthHub with feedback being provided to the patient on the the screen of the HealthHub.
3. Real-time viewing of the physiological data and analysis results on the HealthHub.
4. Transfer of the physiological data and analysis results to a telehealth server, where they are made available for graphically rich, interactive viewing on the context of other physiological and symptomatic data.

Figures 14 illustrates the IcyHeart HealthHub. It contains an IcyHeart OEM module used to receive wirelessly data from the patient unit and feed them to a standard USB-A type connector. The IcyHeart OEM module is powered through the USB input.

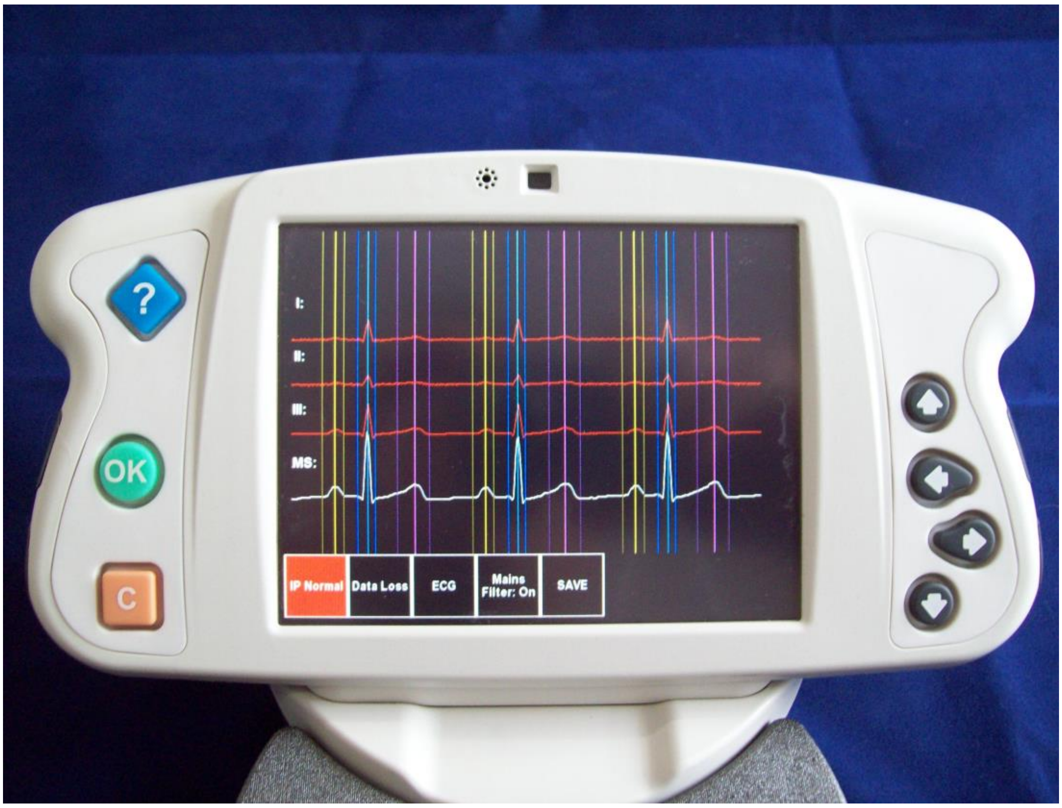

Figure 14: HealthHub during a data acquisition session with an IcyHeart patient unit

Figure 15 shows the patient unit. It is built around an IcyHeart OEM module, with supporting circuitry being provided on a carrier, including among others LEDs, a rechargeable battery, a micro USB socket for charging and diagnostics / commissioning, lead-off detection circuitry, over voltage circuitry, bio-impedance auxiliary signal conditioning and ECG lead connectors.

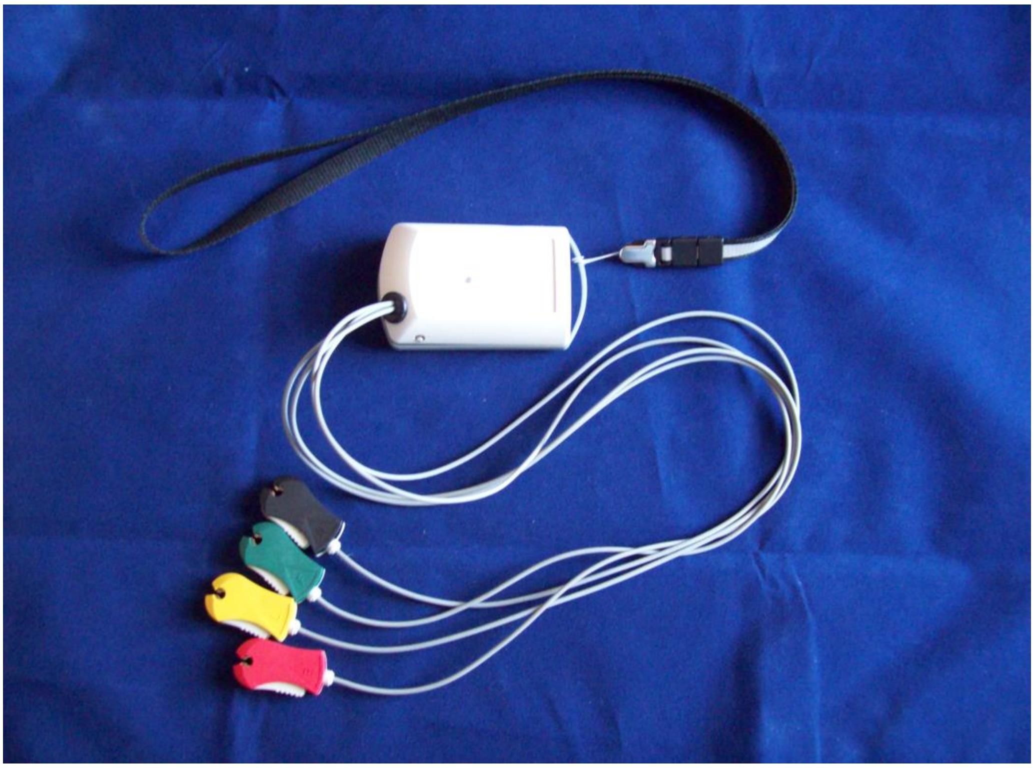

Figure 15: Patient unit showing clips for attachment to the patient's electrodes

Upon completion of the patient session, the HealthHub uploads the cardiac data to a secure server, where the detailed information may be viewed along with further interpreted cardiac measures, statistical and historical data which allows trends in the patient's cardiac health to be observed.

A video has been made that demonstrates the use of patient and HealthHub units, the capture and delineation of ECG signals and the uploaded-to-server session with interpreted and trend information.

This video is available for download and viewing from:
http://www.youtube.com/watch?v=RdbSzrTYmVc

3. Potential impact

The IcyHeart project has delivered a miniature and highly integrated microelectronics System-On-a-Chip (SoC), and its assorted embedded signal processing suite, to enable truly low-power wireless electrocardiogram (ECG) monitoring in tele-healthcare. The focus was on **ultra-low-power wireless and sensing micro-components for long autonomy and unobtrusive body-worn cardiac remote monitoring**, in order to enable novel products that will be leveraged in home-centric patient care environments. More precisely, the achieved results of the project are:

- **Result 1 - IcyHeart OEM module**: The generic IcyHeart OEM module is the core element of the wireless tele-healthcare solution: it consists of a small PCB embarking the IcyHeart SoC (868MH/915MHz radio, icyflex micro-processor and digital peripherals, ADC-based interface for ECG signals encompassing Result 2), a software package (wireless connectivity, ECG sensor signal processing encompassing Result 3). It also includes a development environment (IcyHeart HDK and SDK), and the associated documentation to enable further evaluation and application-dedicated SW development.
- **Result 2 - IcyHeart ADC:** The IcyHeart ADC is the silicon IP, designed in 0.18um CMOS technology from TSMC, which serves as the basis for the ECG signal processing. It includes an input multiplexer, a signal amplification chain, and a sigma-delta ADC. It has been delivered in the form of a GDS2 layout file and the schematics.
- **Result 3 - IcyHeart ECG signal processing:** The IcyHeart ECG signal processing consists of the signal processing algorithms (3-lead ECG delineation, artefact and electromyographic noise filtering) and the signal processing software developed for the icyflex1 micro-processor. It has been delivered in the form of a software library and the associated documentation to enable further evaluation and application-dedicated SW development.

A demonstrator prototype has been developed in the IcyHeart project which utilises the IcyHeart technologies to facilitate the collection and initial analysis of physiological data from body worn sensors, as well as the wireless transfer of these to a hand-held monitoring device, as well as to interface the IcyHeart sensor nodes with existing products provided by the end users SMEs, clearly showing the potential application of the technology.

The results of the IcyHeart project will be exploited by the SME partners in different forms and significant international market potential is forecasted in the segments targeted by the IcyHeart SMEs (Figure 16).

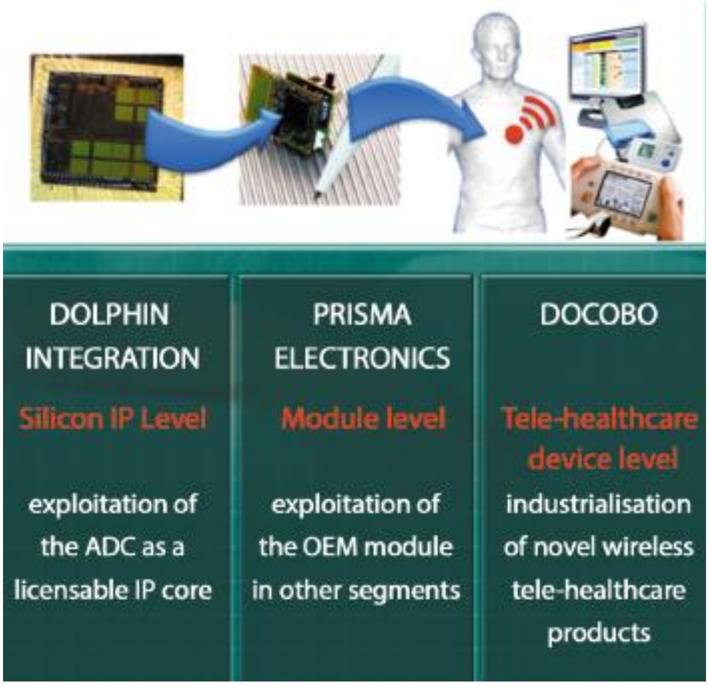

Figure 16: Exploitation of the project results by the SME partners

Industrialisation of novel wireless tele-healthcare products

DOCOBO intends to use the IcyHeart OEM module and the IcyHeart ECG signal processing in its next generation tele-healthcare products, shifting from today's non-wireless 2-lead ECG HealthHUB product towards 3-lead wireless ECG and bio-impedance measuring devices. It is anticipated that this will take the form of a wireless body worn ECG unit which will be in contact with the CarePortal at the appropriate time for the capture and transmission of the ECG data to the clinical server.

From DOCOBO's perspective, the primary target market sector will be home tele-health applications in which cardiac monitoring is relevant. More specifically, this will be segmented into 5 key vertical segments, such as assessment, falls prevention, long term condition, maternal care and pre- and post-hospital care / step down.

DOCOBO expects to be able to enter the remote cardiac monitoring market. The IcyHeart technology will extend the capability of the DOCOBO product line, which is already routinely monitoring many thousands of patients.

Exploitation of the IcyHeart OEM module in other segments

The main exploitation route of the IcyHeart OEM module will be that **PRISMA** will deliver the OEM module into DOCOBO's next generation products cited above.

Another market field for the IcyHeart OEM module is the health-monitoring in hazardous environments, such as nuclear plants, mines, oil refineries, space and heavy industry, where technicians and engineers have daily exposure to execute work in extreme environments (e.g. high or low temperature, high humidity, radiation, small spaces, etc.). Integrating the OEM module into portable devices, the technicians' health and general condition during periods of work under extreme conditions and stress of the human body can be monitored.

Exploitation of the IcyHeart ADC as a licensable IP core

DOLPHIN will exploit the ADC (Analog to Digital Converter) silicon IP towards fabless semiconductor customers either in the frame of DOLPHIN’s Custom Fabless Products activity or as a product, through licensing to fabless or SoC integrator companies.

Focusing in the field of semiconductor IP, DOLPHIN is targeting two types of market: the market of the mixed signal Virtual Components (or silicon IP) and the ASIC market. The revenues for Virtual Components is made from license fees or from royalties based on the fabrication of integrated circuits using the silicon IP. Customers are mainly fabless companies and IDM, like ST Microelectronic (Fr), Cambridge Silicon Radio (UK), and other semiconductor companies worldwide which are designing chips for various industrial and consumer applications. The project results will allow extending the markets currently addressed by DOLPHIN to applications that are very sensitive to ultra-low-power consumption, like other medical applications or wireless smart sensor applications. Such markets are not currently addressed by silicon IP providers, and DOLPHIN expects this market experience significant growth in the coming years. The second market on which DOLPHIN expects to generate revenue is the ASIC market, where DOLPHIN acts today as a design service company providing turnkey solutions to its customers.

The technology created in the frame of the project shows a high potential impact, as it will allow to generate novel services and revenue in tele-healthcare and ECG-monitoring as the principle applicative segments of the project. Beyond IcyHeart, the project results can bring added value also in other technical fields and market segments, as they can be applicable in the segments of bio-medical sensing, sports, wellness and rescue/fire-fighting.

The IcyHeart technology will clearly contribute to increasing the comfort, health and security for a wide category of users in the European population:

- *Elderly, sick or disabled people*: unobtrusive, easy-to-use tele-healthcare devices and services will improve their comfort and daily life, bringing them dignity and continuous support, and reduce the number of hospitalization days thanks to preventive monitoring.
- *Active young and older adults* will act as early adopters for lifestyle and sports applications, where miniature solutions are a must in order to monitor activity without being a burden to wear.
- *Safety professionals like fire-fighters, rescue or marine professionals*, for increasing their own safety, in situations where the remote monitoring of their physiological parameters is vital to anticipate critical accidental situations.
- *Pregnant women and new-born children and mothers*. Care of the mother and child throughout and beyond pregnancy is an area of interest especially as demand grows and risk complications increase. Simple sensor devices that can monitor risk complications remotely will serve to protect and enhance care for the expectant mother and allow such care to be delivered in the home during pregnancy.
- *Support for patients, of any of the above mentioned categories*, at home is known to produce better clinical outcomes. Pilot studies have shown that the use of appropriate technology reduces the levels of anxiety and depression in patients and consequently this leads to an improvement in their quality of life.

Address of the project public website: www.icyheart-project.eu

4. Dissemination activities of the project

The dissemination activities of the project have been consistent with the originally planned activities of the project proposal as well as with the dissemination plan that was formulated at the beginning of the project. In the first project period, the partners' dissemination focused mainly on the identification and reaching of the target groups and providing efforts to successfully raise awareness of the project among all stakeholders. While, in the second period the emphasis was on the promotion of the project results, and on the supporting of exploitation and sustainability of the project results.

All the partners have been actively involved in the dissemination activities; as depicted in Table 1 below, they have used an array of media and tools in order to successfully disseminate the project to the relevant audience. Each partner has played a different role in the dissemination activities based on their profiles and core competences: the RTD partners have focused on the dissemination of scientific and technological information mostly targeted at scientific communities, whereas the SME participants' main interest was the promotion of the IcyHeart results among their potential customers.

Table 1 consists of a detailed list of dissemination activities (publications, conferences, workshops, web sites/applications, press releases, flyers, articles published in the popular press, videos, media briefings, presentations, exhibitions, thesis, interviews, films, TV clips, posters).

Table 1: List of Dissemination activities

LIST OF DISSEMINATION ACTIVITIES PERFORMED DURING THE PROJECT								
NO.	**Type of activities[5]**	**Main leader**	**Title**	**Date**	**Place**	**Type of audience[6]**	**Size of audience**	**Countries addressed**
1	Press release	SG	SignalGeneriX new contract on medical DSP	13/10/2011	Web	Scientific Community, Industry, Media	300 from December 2011 to May 2012	Cyprus, UK, Greece, United States, China, France, Italy. Luxembourg, Poland, Australia, Hungary, Sweden, Romania, Netherlands, Spain, Germany, Switzerland, Belgium, Canada
2	Conference	SG	Presentation of the scientific paper titled: "Highly integrated ultra-low-power SoC solution for unobtrusive and energy-efficient wireless cardiac monitoring", at the 12th IEEE International Conference on BioInformatics and BioEngineering (BIBE2012)	11-13/11/2012	Larnaca, Cyprus	Scientific Community	~200	International
3	Dedicated website	TALOS	IcyHeart website	30/11/2011	IcyHeart project website	Scientific Community, Industry, Civil society, Policy Makers, Media	NA	Worldwide
4	Article	TALOS	IcyHeart EU project launch: Highly integrated ultra-low-power SoC solution for unobtrusive and energy-efficient wireless cardiac monitoring	05/01/2012	TALOS website, News & Events	Scientific Community, Industry, Civil society, Policy Makers, Media	NA	Worldwide

[5] A drop down list allows choosing the dissemination activity: **publications, conferences, workshops, web, press releases, flyers, articles published in the popular press, videos, media briefings, presentations, exhibitions, thesis, interviews, films, TV clips, posters, Other**.
[6] A drop down list allows choosing the type of public: **Scientific Community (higher education, Research), Industry, Civil Society, Policy makers, Medias ('multiple choices' is possible.**

NO.	Type of activities[5]	Main leader	Title	Date	Place	Type of audience[6]	Size of audience	Countries addressed
5	Article	TALOS	IcyHeart project M5 meeting successfully held	29/02/2012	TALOS website, News & Events	Scientific Community, Industry, Civil society, Policy Makers, Media	NA	Worldwide
6	Article	TALOS	IcyHeart project M9 meeting	21/06/2012	TALOS website, News & Events	Scientific Community, Industry, Civil society, Policy Makers, Media	NA	Worldwide
7	Forum	DOCOBO	AAL Forum meeting	11/2011	Lecce, Italy	Scientific Community	2000	European
8	Meeting & Workshop	DOCOBO	EU JADE Meeting and workshop: Telehealth	11,18/11/2011	Istanbul, Turkey	Scientific Community	300	European
9	Conference	DOCOBO	'I WANT TO BREAK FREE' Assistive Living Innovation Programme Telehealth Project day at British Medical Association	04/2012	London, UK	Scientific Community, Industry, Clinical and 3rd sector	100	International
10	Conference	DOCOBO	'Managing Patients with Complex Conditions' Clinical Commissioning Conference	05/2012	Buckinghamshire, UK	Industry, Clinical	50	UK
11	Conference & workshop	DOCOBO	EU JADE Conference and Workshop: Health Clusters	11,14/06/2012	Helsinki, Finland	Scientific Community	2000	European
12	Trade show	DOCOBO	Comissioning 2012	27, 28/06/2012	Olympia, London, UK	Policy makers, Public Healthcare	2000	UK
13	Conference Exhibition Stand	DOCOBO	AAL Forum	24– 27 /9/12	Eindhoven	Research, Industry and Users of Assisted Living	1500	EU and others engaged in the EU Ambient Assisted Living activity
14	Conference Exhibition Stand	DOCOBO	Assisted Living Innovation Platform Showcase	4-7/3/13	Liverpool	Research, Industry and Users of Assisted Living	300	UK and others engaged in UK Technology Strategy Assisted Living Innovation Platform activity

NO.	Type of activities[5]	Main leader	Title	Date	Place	Type of audience[6]	Size of audience	Countries addressed
15	Conference and Exhibition Stand	DOCOBO	AAL European Knowledge Tree Conference	8- 9/4/13	London	Research Industry and Users of Assisted Living	70	EU and others engaged in the EU Ambient Assisted Living activity
16	Workshop Presentation	DOCOBO	CUHTec Regional Telecare Forum	24/4/13	Newcastle	Industry and End Users	30	UK
17	Presentation	DOCOBO	Plymouth University British Computer Society event and Student Showcase	21- 22/5/13	Plymouth	Industry and End Users	12 - 100	UK
18	Knowledge Transfer & Networking	DOCOBO	Technology Strategy Board Information Day	18/07/2012	London	Industry and End Users	120	UK
19	Press release	DOLPHIN	IcyHeart EU project launch: Highly integrated ultra-low-power SoC solution for unobtrusive and energy-efficient wireless cardiac monitoring	16/01/2012	Dolphin Website, news room	Scientific Community, Industry, Civil society, Policy Makers, Media	4100 for January + February (Average / month : 750)	France, USA, Germany, China, Taiwan, UK, Japan, Italy
20	Press release	DOLPHIN	IcyHeart EU project launch: Highly integrated ultra-low-power SoC solution for unobtrusive and energy-efficient wireless cardiac monitoring	16/01/2012	www.design-reuse.com	Scientific Community, Industry, Civil society, Policy Makers, Media	42 clics	Europe, Asia
21	Press release	DOLPHIN	IcyHeart EU project launch: Highly integrated ultra-low-power SoC solution for unobtrusive and energy-efficient wireless cardiac monitoring	16/01/2012	www.chipestimate.com	Scientific Community, Industry, Civil society, Policy Makers, Media	NA	USA, Europe
22	Press release	DOLPHIN	IcyHeart EU project launch: Highly integrated ultra-low-power SoC solution for unobtrusive and energy-efficient wireless cardiac monitoring	16/01/2012	www.electronics-eetimes.com and newsletter	Scientific Community, Industry, Civil society, Policy Makers, Media	60,000 contacts	Europe

NO.	Type of activities[5]	Main leader	Title	Date	Place	Type of audience[6]	Size of audience	Countries addressed
23	Press release	DOLPHIN	IcyHeart EU project launch: Highly integrated ultra-low-power SoC solution for unobtrusive and energy-efficient wireless cardiac monitoring	28/02/2012	Sitelesc newsletter	Scientific Community, Industry, Civil society, Policy Makers, Media	1,500 contacts	France
24	Press release	DOLPHIN	IcyHeart EU project launch: Highly integrated ultra-low-power SoC solution for unobtrusive and energy-efficient wireless cardiac monitoring	02/2012	Minalogic newsletter	Scientific Community, Industry, Civil society, Policy Makers, Media	2,370 contacts/1800 had opened it	France
25	Marketing emailing	DOLPHIN	Direct e-mailing through DOLPHIN's database (informing customers on the IcyHeart ADC foreground)	September 2012	Web	Fabless IC supplier	~100	Worldwide
26	Flyer	DOLPHIN	Marketing material: Presentation sheet on the ADC foreground	November 2012	Web	Fabless IC supplier	~50	Worldwide
27	Presentation	DOLPHIN	Presentation of project results #2 (IcyHeart ADC): key performances, block diagram, added-values	January 18, 2013	Neuchatel	Fabless IC supplier	5	Switzerland
28	Presentation	DOLPHIN	Presentation of project results #2 (IcyHeart ADC): key performances, block diagram, added-values	January 28 – February 1, 2013	Toronto, Ottawa, Syracus, Boston, NY, Austin	Fabless IC suppliers	~50	North of America (Canada + US)
29	Presentation	DOLPHIN	Presentation of project results #2 (IcyHeart ADC): key performances, block diagram, added-values	March 18 – March 22, 2013	Shanghai, Beijing, Suzhou	Fabless IC suppliers	~50	China
30	Presentation	DOLPHIN	Presentation of project results #2 (IcyHeart ADC): key performances, block diagram, added-values	June 3 – June 7, 2013	Shanghai, Hong-Kong, Beijing	Fabless IC suppliers	~50	China

NO.	Type of activities[5]	Main leader	Title	Date	Place	Type of audience[6]	Size of audience	Countries addressed
31	Phone calls, emails	DOLPHIN	Product presentation (communication with potential customers: mails, conference calls)	Dec 2012 – June 2013	Web	Fabless IC suppliers and SoC integrators	~10	Worldwide
32	Press release	CSEM	Innovative tele-healthcare solutions with the European IcyHeart project	23/02/2012	www.ictjournal.ch	Media, Scientific community, Industry	NA	USA
33	Press release	CSEM	Innovative tele-healthcare solutions with the European IcyHeart project	23/02/2012	www.electronics-eetimes.com and newsletter	Media, Scientific community, Industry	60,000 contacts	France
34	Press release	CSEM	Innovative tele-healthcare solutions with the European IcyHeart project	23/02/2012	lemondeinformatique website	Media, Scientific community, Industry	NA	France
35	Press release	CSEM	Innovative tele-healthcare solutions with the European IcyHeart project	23/02/2012	CSEM website	Scientific Community	24 clicks (from February 23 to May 20)	Europe
36	Conference	CSEM	"Highly integrated ultra-low-power SoC solution for unobtrusive and energy-efficient wireless cardiac monitoring" at FETCH 2013	7-9/01/2013	Leysin, Switzerland	Scientific community	~100	French speaking countries
37	Conference	CSEM	"A Miniature Wearable 3-Lead ECG Monitoring System for Tele-Healthcare " at eHealth and Telemedicine in Cardiovascular Prevention and Rehabilitation Conference	7-8/06/2013	Bern, Switzerland	Health Professionals, Industry Representatives and Service Providers	~100	Europe
38	Marketing document	CSEM	"IcyHeart, an ECG Sensor Interface in a SoC" in CSEM Scientific report 2012	June 2013	Website and CSEM Scientific Report	Scientific and Industrial community		Switzerland and world
39	Forum	CSEM	World Medtech	25-27/09/2012	Lucerne, Switzerland	Industrial	3200	Worldwide
40	Exhibition	CSEM	Electronica	Nov. 2012	Munich, Germany	Industrial	72000	Worldwide

NO.	Type of activities[5]	Main leader	Title	Date	Place	Type of audience[6]	Size of audience	Countries addressed
41	Conference	EPFL	Presentation of the scientific paper titled: "Embedded Real-Time ECG Delineation Methods: a Comparative Evaluation" at the 12th IEEE International Conference on BioInformatics and BioEngineering (BIBE2012)	11-13/11/2012	Larnaca, Cyprus	Scientific Community	~200	International
42	Conference	EPFL	Presentation of the paper "A Methodology for Embedded Classification of Heartbeats Using Random Projections" at Design, Automation, and Test in Europe (DATE) 2013	20/03/2013	Grenoble, France	Scientific Community	50	International
43	Conference	EPFL	Keynote speech at BODYNETS 2012, the 7th International Conference on Body Area Networks	24/09/2012	Oslo, Norway	Scientific Community	200	International
44	Presentation	PRISMA	Product presentation for potential use in a new system for technicians support unit in CERN.		CERN Geneva	Scientific Community	~6	Switzerland
45	Technical Meeting	PRISMA	The IcyHeart Module included in the main architecture of the new CERN's system for the technician support.	5-8/06/2013	Tuscany	Project Manager and Technical Committee	~20	Italy
46	Exhibition	PRISMA	Presentation of the potential product at CEATEC Japan 2012	1-6/10/2012	Tokyo	Industry	>100	Japan
47	Conference	PRISMA	Product presentation (communication with potential customers) at the International Conference APMS 2012	24-26/09/2012	Rhodes	Industry, Scientific Community	~250	Worldwide