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REPORT

Biomedical Wireless Sensor Network Phase II

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Biomedical Wireless Sensor Network – phase II

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ABSTRACT

Care for patients in advanced intra-hospital clinical environments as operating rooms and critical care environments like dedicated intensive care units, requires use of an increasing number of point-of-care medical devices with sensors attached to the patient to monitor and generate information for clinical decision making to support vital processes. Monitoring implies automated detection impending life-threatening situations, imminent danger or diagnostic entities by collection of, and serial evaluation of time-stamped data. In the hands of human clinical experts such information is assessed and combined with the individual patient's context to facilitate mitigation of physiological derangement by rapid titration of patient therapy and prevention of adverse events eventually leading to improved patient outcome.

This project developed, implemented and tested a multi sensor, vendor independent biomedical sensor network for the future wireless hospital and home care scenarios. The sensors came from six different Scandinavian sensor developers. All sensors were implemented on a commercial software platform and were tested in a hospital environment.

The project consortium represented a unique transnational value chain, crossing Denmark, Finland, Norway and Sweden's borders. The project was funded by the Nordic Innovation Centre (NICe) and Svensk-Norsk Næringslivssamarbeid (SNN).

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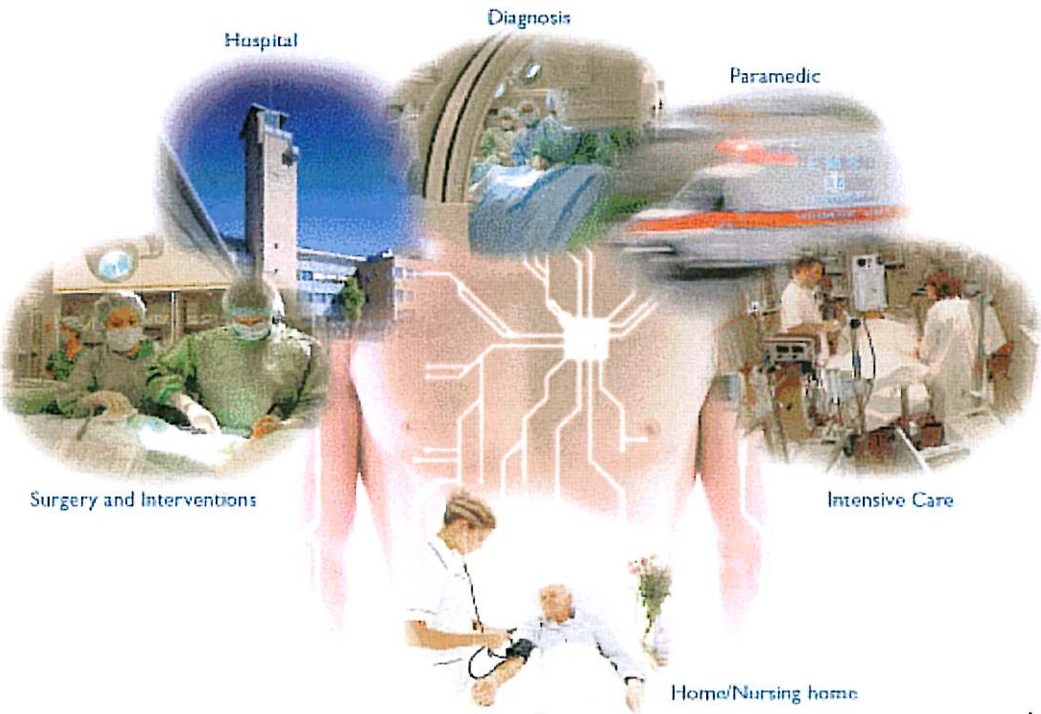
Biomedical Wireless Sensor Network – phase II



MEMSCAP *The Power of a Small World™*   Millicore   Novosense   novelda

VTT   IMEGO Solutions beyond sensors   DELTA

RIKSHOSPITALET   SINTEF   EUREKA

February 2010

Authors: Eirik Næss-Ulseth, Dag Ausen and Karl Øyri with support from all partners

Participants

The project consists of the following partners:

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Novelda has been responsible for overall project management.

Title: Biomedical Wireless Sensor Network – phase II (BWSN II)		
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Authors: Eirik Næss-Ulseth, Novelda AS, Dag Ausen, SINTEF, Karl Øyri, IVS		
Institution(s): Delta (DK), Imego (SE), IVS (NO), Memscap AS (NO), Millicore AB (SE), Novelda AS (NO), Novosense AB (SE), SINTEF (NO), VTT (FIN)		
Abstract: Care for patients in advanced intra-hospital clinical environments as operating rooms and critical care environments like dedicated intensive care units, requires use of an increasing number of point-of-care medical devices with sensors attached to the patient to monitor and generate information for clinical decision making to support vital processes (1-3). Monitoring implies automated detection impending life-threatening situations, imminent danger or diagnostic entities by collection of, and serial evaluation of time-stamped data (4). In the hands of human clinical experts such information is assessed and combined with the individual patient's context to facilitate mitigation of physiological derangement by rapid titration of patient therapy (3;5) and prevention of adverse events eventually leading to improved patient outcome. This project developed, implemented and tested a multi sensor, vendor independent biomedical sensor network for the future wireless hospital and home care scenarios. The sensors came from six different Scandinavian sensor developers. All sensors were implemented on a commercial software platform and were tested in a hospital environment. The project consortium represented a unique transnational value chain, crossing Denmark, Finland, Norway and Sweden's borders. The project was funded by the Nordic Innovation Centre (NICe) and Svensk-Norsk Næringslivssamarbeid (SNN). The main conclusion is that the generic wireless communication platform developed in the BWSN project facilitates monitoring of vital body functions in hospital and home care scenarios. The biomedical wireless sensor network (BWSN) was implemented on a commercial sensor integration platform from the Norwegian company Imatis AS, and solved several technical barriers, e.g. sensor synchronization and noise handling. There are still needs for improvements related to security handling, monitoring of several patients/persons at the same time, and further adaptations to medical experts needs for information. The BWSN and the collaboration form an important platform for further technical development and business development in order to penetrate a market expected to increase substantially in the future.		
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Executive Summary

Traditionally, sensor data in most clinical settings are transferred to patient monitors and medical devices based on wired network solutions. One of the wireless exceptions is cardiac telemetry which has been used for more than 4 decades (6). This type of monitoring allows patient ambulation confined to the telemetry department only.

New areas of sensor use in healthcare are opened by low-cost wireless communication platforms capable of handling biomedical sensors tailored to the individual patients changing needs. They have low transmission power, modest battery and energy requirements, and can operate unattended over time in robust and high data rate networks. This type of wireless technological platforms can be modified, optimized and applied to various medical settings in order to replace existing cabled technologies (7). The generic technology can be used to facilitate remote monitoring within hospitals as well as patient homes with a number potential benefits.

The first phase of the BWSN project demonstrated wireless monitoring of vital body signs during surgery. The second phase of the project has complemented the vital signs monitoring with new sensors, follow the patient into the intensive care monitoring, and further into the patient room. The wireless vital signs have been implemented in a commercial software platform / database providing the doctors with 24/7 signals whenever they needs this information.

The overall goal of the project was to achieve a biomedical wireless sensor network utilizing a commercial sensor integration platform, and supporting monitoring related to different diseases, patient profiles and treatment life cycle included home care.

The project was funded by the Nordic Innovation Centre (NICe) and Svensk-Norsk Næringslivssamarbeid (SNN).

The project objective was obtained by the following actions:

- Analysis of the patient treatment life cycle with focus on monitoring needs by use of wireless sensors related to different diseases, patient profiles and treatment life cycle including home care.
- Evaluating different commercial sensor integration platforms. BWSN decided the Imatis platform, and negotiated an agreement with them as the vendor of the sensor integration platform to the project.
- Sensor network integration platform extensions, especially visualization software improvements.
- Integration of biomedical sensors covering monitoring needs related to different diseases and the complete patient treatment life cycle
- Ensure reliability and stability in monitoring of vital patient data
- Support the effort of building a test bed at the Interventional Centre for testing biomedical wireless sensor networks. This will make it possible for the sensor and communication suppliers to achieve documented verification and approval supporting market penetration of their products
- Testing of individual sensors and complete sensor network.

Project results and conclusions

The biomedical wireless sensor network (BWSN) was developed, implemented and tested at the Interventional Centre at the Oslo University Hospital. The BWSN allows simultaneous use of all wireless sensors. Six different sensors were integrated:

- Memscap - Wireless Pressure Transducer
- Millicore - DigiVent Pulmonary Air Leakage
- Novosense - CardioPatch ECG sensor
- Novelda - Medical UWB-IR radar
- VTT - Heart Monitoring Accelerometer
- SINTEF - SpO2 & Temperature sensors

A BWSN website is established www.bwsn.net for internal communication, document archiving, and also external communication.

Wireless sensor network end points are to improve current practice and patient outcome. This involves facilitation of technological platforms to facilitate more aggressive early patient ambulation and unrestricted mobility by integration of appropriate wireless biomedical sensors in various phases of the chain of treatment. This implies monitoring not only confined to certain hospital locations but to the patient vicinity with fewer restrictions related to geographical location. This applies to post procedure monitoring of patients with acute disease, as length of hospital stays are shortening (8) due to minimally invasive procedures and generally escalating healthcare costs.

Patient autonomy and independence is also potentially improved by this new option of potentially consistent and safer and individualized remote monitoring of patients during rehabilitation after hospitalization and healthcare incidents.

Escalating healthcare costs linked to the growing proportion of ageing population, often with increased co-morbidity (9), calls for organizational changes where MST (micro systems technologies) might have an important role to play. Elderly with chronic disease also seek independent living to minimize consequences of their disease on their personal life. Independent living and patient autonomy implies reduced expensive healthcare resource consumption.

By improvement in monitoring consistency, continuous monitoring enhances data quality and precision for decision support leading to better titration of therapeutic interventions. Provision of improved monitoring based on information from uninterrupted data streams from miniaturized and wearable wireless sensors has a potential impact on mitigation of complications. Better clinical decision support contributes to improve healthcare provider's decision making processes. This increases precision in timing of therapeutic interventions leading to reduced risks for concomitant disease progression.

The main conclusion is that the BWSN wireless communication platform facilitates flexibility and mobility which are essential factors in monitoring of vital body functions in hospital as well as home care settings. The BWSN was implemented on a commercial software platform from the Norwegian company Imatis AS. This process involved to overcome several technical barriers, e.g. sensor synchronization and noise handling.

Further improvements related to security handling, monitoring of several patients/persons at the same time are needed.

The BWSN consortium form an important platform for further technical development and business development in order to penetrate a market expected to increase substantially in the future.

Recommendations
The partners will establish follow up projects on sensor network applications, and also on how future wireless patient monitoring and treatment can be performed, and which benefits that would provide. Clusters and networks like Oslo Medtech, MedITNor and MedCoast Scandinavia will be natural partners for this. A-HUS, St.Olavs, Oslo University Hospital are potential Norwegian hospitals. Hospitals in Finland, Denmark and Sweden will also be invited as partners.

Imatis AS is a vendor of data integration platforms on the market. The project partners see a future opportunity if companies like Imatis is offering a complete sensor network solution on the market. It could be difficult for the individual sensor vendors to penetrate the market, and much easier as part of a sensor network as a complete vital sign measurement solution.

Together with IVS, the sensor vendors plan to perform further test and achieve verification documentation or a sensor quality stamp.

IVS has through the BWSN project built up a start of a sensor testbed for clinical tests. It is important that this effort is developed further. Delta has established a testbed for e.g. sensors signal reliability testing. Funding opportunities, and also a possible collaboration between IVS and Delta should be investigated.

Table of Content

Preface

This report describes the major developments in the Biomedical Wireless Sensor Network II (BWSN-II) project. We started in September 2006 and the first version of the BWSN was ready in the end of 2007. We continued the collaboration in the project BWSN-II achieving a new BWSN version in February 2010. We acknowledge the support from Nordic Innovation Centre (NICe) and Svensk-Norsk Næringslivssamarbeid (SNN).

BWSN project partners

March 11th, 2010

Erik Næss-Ulseth, Novelda AS
Dag Ausen, SINTEF
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1. Introduction

Within the hospital or extended care environment, there is an overwhelming need for constant and invisible monitoring of more and more vital body functions. Today's biomedical sensor solutions are effective for an individual measurement (e.g. ECG), but are not integrated into a complete body area network, where many simultaneous sensors are working at the same time on an individual patient. Increased patient mobility is wanted but in many cases, sensors for biomedical monitoring are not yet wireless. This creates the need for the implementation of new biomedical personal wireless networks with a common architecture and the capacity to handle multiple sensors, monitoring different body signals, with different requirements.

The benefit of using wireless sensor technology in health care can be divided into two areas. One area is the use of new technological solutions for individually based, multi-parameter monitoring at home. Patients with chronic diseases, as well as a constantly growing number of seniors, will profit on treatment and medical monitoring in their own environments. These monitoring systems are linked to individuals rather than places. Almost unlimited freedom of movement implies use of wireless and even implanted sensors that will greatly enhance home monitoring and follow-up.

The second area of benefit lies within increasing the efficiency of treatment at hospitals. The cost of continuous treatment and surveillance is already high and growing dramatically. This goes for both external, prior to treatment and internally at the hospital, as well as post-treatment. The type and number of sensors must be configured according to monitoring needs related to different diseases, treatments and the patient treatment life cycle. The biomedical sensors of today are mostly based on hard wiring, in addition to being based on proprietary solutions. Multi-parameter analysis produces new data that can enhance information quality. The implementation of more flexible wireless technology will lead to reduced hospitalization time due to more rapid mobilization, as well as improved documentation by stored, digitalized signals. The result will be enhanced decision making for diagnostics, observation and patient treatment.

Improvements within sensor technology, data quality, data resolution and increase in the number of measurement parameters will in general help to prevent complications. Digital wireless solutions will be able to collect "point of care" information based on new wireless technological platforms. Seamless communications render possible automated and enhanced documentation quality. From a macro economically point of view, it is important to develop technology that can reduce use of resources, improve infrastructure and increase efficiency. From an individual point of view, freedom of movement combined with the confidence of 24/7 medical supervision, will be an important gain.

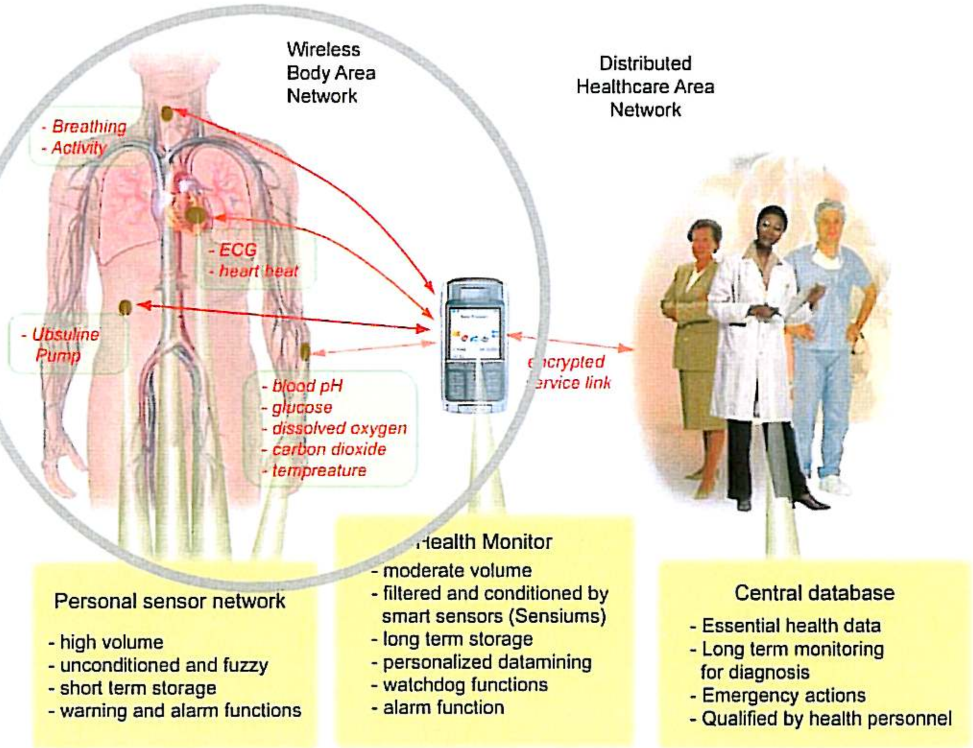
The performed BWSN phase 1 project form an important platform for further technical and business development in order to penetrate a market expected to grow significantly in the future. BWSN-I demonstrated the future opportunities for supporting mobility while monitoring vital body functions during surgery at the hospital. The next phase will be to cover different configuration of wireless sensors related to the patient disease and treatment life cycle, security handling, improved signal integration and visualization, achieve extended mobility outside the surgery room, monitoring of several patients at the same time, and further adaptations to medical experts needs for information included integration with patient records. Even though BWSN-I developed a comprehensive test bed and test procedures, only limited testing were performed within the scope of that project.

2. Overall project objectives

The overall goal of the project has been to achieve a biomedical wireless sensor network supporting monitoring related to different diseases, patient profiles and treatment life cycle included home care.

Sub-goals have been to:

- Analysis the patient treatment life cycle with focus on monitoring needs by use of wireless sensors related to different diseases, patient profiles and treatment life cycle including home care
- Integrate additional biomedical sensors to the BWSN-sensor network covering monitoring needs related to different diseases and the complete patient treatment life cycle
- Ensure reliability in the monitoring of patient vital signs (EMC, stability, security, robustness
- Ensure reliability with multiple wireless network link technologies (Patient or body PAN communication, global communication, seamless integration, network architecture supporting mobility, high and low data rate sensors, self-configuration, etc.)
- Integrate with a central hospital database and decision support systems.



3. Sensors made wireless and integrated

The BWSN shows monitoring of all wireless sensors at the same time. Six different sensors were integrated:

Vendor	Sensor category
Memscap Wireless Pressure Transducer	Invasive
Millicore DigiVent Pulmonary Air Leakage	Invasive
VTT Heart Monitoring Accelerator	Invasive
Novosense CardioPatch ECG sensor	Non-invasive
Novelda Medical UWB-IR radar	Non-invasive
SINTEF SpO_2 and Temperature sensors	Non-invasive

The following sub-chapters give a short description of the different sensors.

The complete portfolio of non-invasive and invasive biomedical sensors represented in the BWSN project covers advanced surgical-, anesthesia-, intensive care-, and research settings. The 3 axis epicardial accelerometer from VTT still represents experimental use. The non-invasive sensors in the portfolio can be used in remote monitoring settings for individualized monitoring of patients in their home environment.

3.1. Memscap Wireless Pressure Transducer

Memscap Wireless Pressure Transducer

The Memscap Wireless Pressure Transducer (WPT) developed during the BWSN project is based on the Memscap SP840 series of physiological pressure sensors with disposable dome.

Memscap WPT is providing digitized and pre-scaled pressure readings over a wireless interface.

The wireless link is utilizing the TinyOS based BWSN Sensor Message Format over an IEEE 802.15.4 compliant radio.

Pressure Range:	-20 to 300 mmHg
Overload Protection:	> 10 000 mmHg
Pressure Medium:	Disposable plastic dome

Memscap AS

Memscap is a leading provider of innovative micro-electromechanical systems (MEMS)-based solutions.

Memscap's Sensor Solutions Business Unit is located at Skoppum in Norway and offers a wide range of multi-applications sensors for critical aerospace/defence, medical/biomedical and energy or industry related equipment.

MEMSCAP
The Power of a Small World™

3.2. *Millicore DigiVent Pulmonary Air Leakage*

DigiVent® Pulmonary Air Leakage

Management System of today

DigiVent® is a Pulmonary Air Leakage Management System used for evacuating air and fluid from the pleural cavity after a pulmonary surgery. Optimal management of the patient is made possible by a MEMS (Micro Electro-Mechanical Systems) flow sensor that measures actual air leakage in ml / min. DigiVent® displays either the real-time air leakage rate, or, with the push of a button displays the average air leakage rate for the past 1, 3, or 6 hours. This enables the clinician to assess patient changes over time. DigiVent® also measures the patient's intrapleural pressure through a pressure sensor.

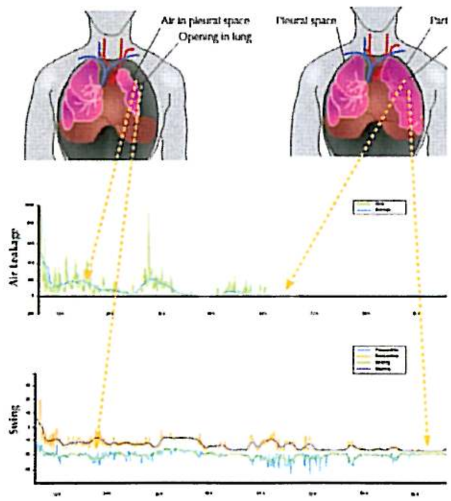
Millicore AB

Millicore is a Swedish medical technology company focusing on smart, MEMS-based, disposable products. Millicore was founded in 2003 and is owned by the founders and by 4 of the largest venture capitalists within life science in Sweden. Head quarters are based in Stockholm with market presence in the US and in Germany.

Millicore

DigiVent® Wireless

The BWSN cooperation makes it possible for Millicore to supply the physician with a more complete data. The actual and historical trend of the patient's intrapleural pressure and flow can be transmitted live and directly from the DigiVent into a monitoring system of his/her choice. This will tremendously increase the amount of information for the physician on which he/she can base decisions on.



As an example the picture illustrates a typical DigiVent® patient. The left picture shows a patient with an air leakage from the lung into the pleural space and thus a collapsed lung. Note the difference in pressure between inspiration and expiration. The right picture shows the re-expanded lung of the patient; no air leakage and note that the pressure curves for inspiration and expiration have converged.

3.3. Novosense CardioPatch ECG sensor

CardioSenseSystem®

The CardioSenseSystem® has been tested by leading ECG experts in clinical trials at Lund University Hospital. Proof of concept was clearly confirmed. The basic idea is to measure ECGs completely wirelessly with low-cost disposable units in the same way as today's wired disposable electrodes. The difference is that no wires have to be connected, thus eliminating the problems with electrodes or wires coming lose. Novosense's patented ECG measurement technology makes it possible to measure all forms of ECG with disposable self-contained units called *CardioPatch®*, no larger than 4 cm in diameter.

Future ECG product from Novosense

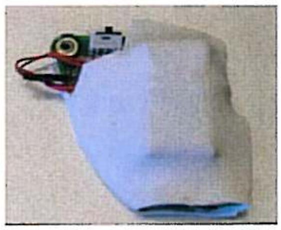
Novosense AB

Novosense AB is a biomedical engineering company located at the Ideon Science Park in Lund, southern Sweden.

Together with leading researchers at Lund University, the company has developed a unique, completely wireless ECG system – CardioSenseSystem®, which will replace today's stationary and portable cable-based ECG monitoring equipment. The system is based on disposable wireless sensors (CardioPatch®) that communicate via radio directly with a base station (CardioBase®).

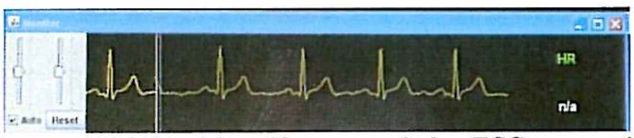
Current activities

In the BWSN-II a wireless ECG prototype has been developed to support the BWSN radio protocol, see figure bellow. The range for the sensor prototype is more than 30 m and operation time about 5 hours. The prototypes meet such demands with respect to size, range and operation time that most scenarios in a hospital can be tested and evaluated. Two wireless sensors were provided for testing.



Novosense ECG prototype for the BWSN-II project

The typical ECG data using the BWSN server can be seen in the figure bellow. The qualities of the signals from the prototypes are in general very high.



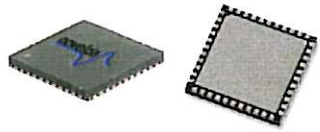
Typical ECG signal from Novosense wireless ECG sensor using the BWSN server.

The protocol developed in BWSN was to some extent modified to provide extended functionality such as more sensors in the network and synchronisation of the sensors to a global clock. The synchronisation is of interest so that different sensors can be synchronised, e.g. ECG signals with blood pressure.

3.4. Novelda UWB-IR Radar

UWB radar chip for medical diagnostics

The NVA3500 is a UWB impulse-radar system all integrated on a single chip designed for low power and requiring very few external components. The chip includes one transmitter part and one receiver part.



NVA3500 chip is available in QFN-44 package

Features:

- Miniaturized single-chip CMOS impulse-radar
- Simultaneous observation of 256 depths with programmable depth resolution.
- Observation window (frame) depth coverage adjustable from 0.5m to 2m
- Adjustable frame offset from ~0 to 20m
- Depth resolution of 2mm, 4mm or 8mm
- Close range sensitivity to a few mm
- Signal recovery through 24-bit digital integration
- 1V and 2.5V supply voltage
- Digital SPI interface
- RoHS Compliant 7×7-mm QFN-44 Package

Novelda AS

novelda

Novelda was established in 2004 by researchers at the University of Oslo, and world leading experts within industrial IC design, and business development. The company has a unique core team for scaling up the company to be a major supplier of radar- and communication IC modules for use in different applications. Novelda offer OEM radar and communication integrated circuit (IC) modules in different variants for use in application products, e.g. nanoscale impulse radar for use in biomedical applications, medical imaging, automotive industry, military applications, RFID, and personal area communication.

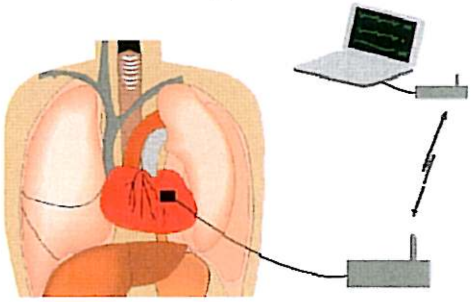
3.5. VTT Heart Monitoring Accelerator

Heart acceleration monitoring

Heart acceleration monitoring can be used to gather additional information of hearth operation both during surgery and post operation treatment. There is a risk of graft occlusion in coronary artery bypass grafting, and acceleration monitoring provides real time data of myocardial function: the method facilitates beat to beat detection of regional myocardical iscemia when heart surface acceleration is monitored during cardiac surgery. During post operational phase, it provides uninterrupted monitoring in of iscemia and arrytmia.

Acceleration monitoring has some benefits over traditional methods: It's more sensitive than ECG or invasive hemodynamic monitoring and otherwise than echocardiography or angiocardiography, it can be used for constant monitoring. Facilitation of local detection of parenchymal inscemia is an added value.

VTT WHAM - VTT Wireless Heart Acceleration Monitoring



As the modern medical patient care requires many different parameters of patient's condition to be monitored, wiring and equipment congestion can became an impediment in everyday work of health care professionals.

The work done in BWSN project will enable easier application of the devices in question: The wireless patient monitoring enables uninterrupted measurement of heart acceleration along the other vital signs.

When no physical wiring between the sensor and the monitoring station is needed, monitoring is continuous and uninterrupted monitoring in the clinical pathway to prevent complications in reached. The solution is also cost effective, since only one common monitoring station for all the wireless sensors is needed. The data can also be collected and analyzed in greater detail later, either for medical diagnosis or scientific work.

VTT - Technical Research Center of Finland

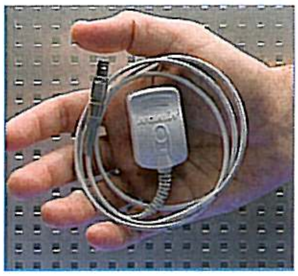
VTT is an independent Finnish research institute which has had a well established position in Finnish industry for several decades, providing our customers new innovations and technologies, and also impartial testing. Our expertise consists of a comprehensive portfolio of scientific know-hows, such as: electronics, ICT, chemistry, energy and material technology.

This project has been carried out in VTT Sensors center, in which world leadin research on smart sensors, micro mechanical systems, nanophysics and radio frequenc systems is being carried out. In addition to single sensor and electronic devices, w also develop system integrated circuits, sensor arrays, related readout an communication electronics and packaging. VTT Sensors is part of the Center o Excellence on Low Temperature Quantum Phenomena and devices, funded by th Academy of Finland.

3.6. SINTEF SpO_2 and temperature sensors

Both sensors are integrated on a stock TelosB mote (ultra low power wireless module) from MoteIV Corp. (www.moteiv.com) using modified firmware and added hardware.

SpO_2 sensor



The SpO_2 sensor uses an ipod - integrated pulse oximetry device, type 3212 from Nonin Medical Inc. (www.nonin.com). This is fed power from the telosB mote and returns a serial packet 75 times per second. This data rate far exceeds the RX capability of the mote because the mote UART is a shared resource. So we inserted a PIC18LF1220 to interpret the data, convert to analog via PWM and a filter and the mote reads and translates the resulting voltage.

Temperature sensor

As temperature sensor an adult temperature probe from Exacon Scientific A/S was used (www.exacon.com). The sensor is a thermistor type with 2252ohm at 25°C and uses a look-up table to correspond to temperature. Taking power from the telosB mote through a 2000ohm resistor the resulting voltage through the divider is fed to the D2 connection of the mote.

SINTEF

SINTEF is an independent research foundation based in Trondheim and Oslo, Norway. The majority of its income originates from contract research for industry and the public sector in Norway and internationally. SINTEF is the largest independent R&D organisation in the Nordic countries, employing around 2000 people. Contract research carried out by SINTEF covers all scientific and technical areas, and ranges from basic research through applied research to commercialisation of results into new products and business ideas, for both the domestic and international markets.

In BWSN, a research group at SINTEF ICT Dep. Instrumentation has carried out the work. This group creates and designs integrated electronics and miniaturized instrumentation systems. The group has a broad competence area that encompasses integrated circuit designs, signal processing, instrumentation, and communication. Health related sensor and instrumentation systems constitutes one out of two research directions in the department. Our projects are based on a holistic research approach that are focused around the *patient*'s needs, and that incorporates of the clinical *care* processes, how sensor and instrumentations can be designed and used to *capture* clinical information, how it is effectively *shared* in a health information system, and finally, how the total patient information is assembled and can be used to clinically *understand* the patient with assistance from multi-parameter decision support systems.

4. Wireless products in healthcare

In BWSN-II, Delta has made an overview of the regulatory requirements for each relevant frequency band for a Biomedical Wireless Sensor Network. The technical note gives an overview of:

- general requirements for world wide wireless products
- often used frequency bands and describes the most relevant bands briefly
- and list criteria's for selection of frequency band for BWSN

The technical note is available as appendix 1.

5. Wireless communication solutions

Today a number of wireless communication solutions are available. Typical short ranges solutions are Bluetooth, ZigBee and several other more or less proprietary solutions. Several of these solutions are intended for short range, in-room (10m) range and are reasonably power efficient. Moving wireless solutions in to body-area networks (BAN) or personal area networks (PAN) for carrying important health information is adding another level of quality of service mostly unavailable in current wireless solutions. In critical applications loss of communication cannot be tolerated.

Based on input from the sensor vendors, the communication solution requirements have been specified. The requirements have been organized as common requirements for all sensors and two cases, where Case 1 is related to the Novosense ECG sensor and Case 2 is valid for the rest of the sensor providers.

Common requirements

- Global synchronization
- Retransmission of lost data
- Two-way communication
- Encryption
- Identification
- Authentication
- Power consumption: <0.4 mW/Kbit
- Error detection/correction
- On-board or On-chip 12-bit A/D converter
- On-board or On-chip microcontroller

Case 1

- Data rate < 100 Kbit
- Global synchronization 250 us resolution
- Range: 70m
- Number of units per piconet: > 120
- Number of A/D channels: >10
- Handover across base stations

Case 2

- Data rate < 50 Kbit
- Global synchronization relaxed resolution
- Range: 10-15m
- Number of units per piconet: 20-40
- Number of A/D channels: 3-5

5.1. BWSN common sensor message format

The first phase of the BWSN project developed and implemented a common sensor message format or communication protocol. All sensors use this message format for communication. ***See report from the first phase of the project for a detailed description of the BWSN Sensor Message Format***[1]

6. Integration platform

6.1. Imatis Medical Archiving and Communication System

The MACS (Medical Archiving and Communication System) is Imatis' solution developed to easily and in a standardized way capture, record, exchange, alert and present data from medical devices and bio sensors used to monitor vital signs in patients home or at the point of care.

There is a critical need for more cost efficient solutions for supervision/monitoring patients during and after surgery, as well as when the patient is at home. Advanced sensors combined with wireless communication will give reduced costs, improved monitoring, and better life quality for the patient.

The MACS is a true Tele Monitoring Solution whether used within a department, across departments or hospitals or even in the patients homes.

Data collection at the hospital (©Imatis AS)

The MACS platform is doing the same for data from medical devices and bio sensors, that the PACS are doing for images, - storing large amount of waveform data and retrieve/present them to end user with the speed of light. By open the platform to patient home, clusters of hospital, or between departments inside the Hospital, the MACS are a true Tele Monitoring Solution.

The IMATIS technology also provides the ability to correlate and trend various sources of information including various waveforms, heart rate and blood pressure. This trending information allows clinicians to analyze the patient's data in the context of other clinically relevant data for a specific time period or episode.

The MACS platform fully supports other software products and solutions from Imatis, including electronic patient chart, Natus electronic maternity record, electronic Whiteboard etc.

The IMATIS MACS modules contain the following core elements:

- DataEngine (DE) for capturing real time data. The DE can be distributed and added with an optional storage for local data storage close to the

[1] NICe report Biomediucal Wireless Sensor Network (BWSN) – December 2007 (http://www.sintef.no/Projectweb/Tradlospasient/Projects/)

medical devices or wireless sensors

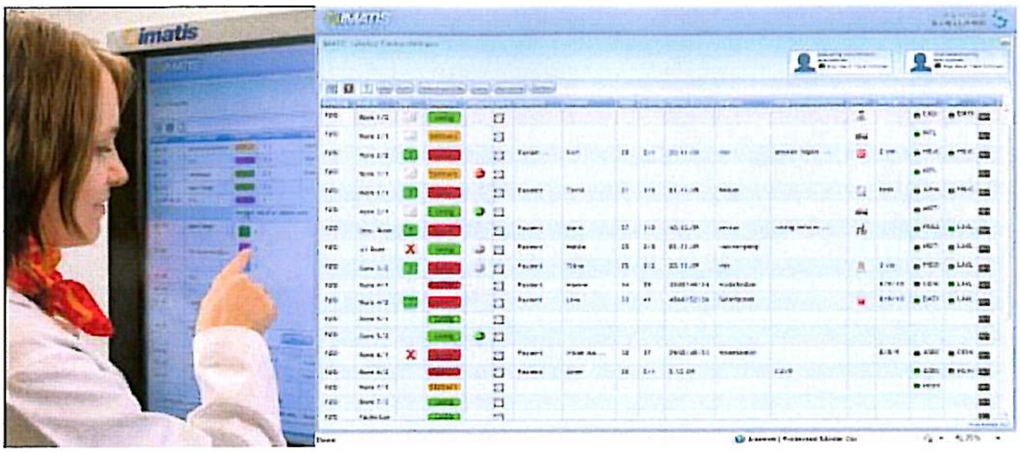
- Medical Device Drivers developed by partners and in-house, based on guidelines and international standards
- The central Historian database, that at permanent basis can store large amount of data from medical devices or sensor
- Client Components that can be opened from the IMATIS web portal or embedded inside the Hospital HER, for access to waveform data in real time and historically

DataEngine	Historian database	Client Components
The DataEngine is the core engine that transfers data at high rates into the Historian database, or in real time to a web browser. The DE can be installed as a basic point-to-point integration, as a Hospital Central Solution or as a SaaS (Software as a Service) for Clusters of Hospitals. Adapters for biosensors and medical devices can be installed, in addition partners and customers can add there own adapters by using .NET or LabVIEW. We also support data capture gateways from Capsule, and wireless biosensor network from the Biomedical Wireless Sensor Network – BWSN.	The Historian is a database for storage of waveform data from medical devices and sensors. The database is scalable and can support thousands of biosensors and medical devices, and depending on the data rate and the disk capacity it can store data for long time.	The Patient View updated with clear and concise visuals of the most essential clinical information and data trends for each patient in the unit, supports a straightforward interpretation of data.

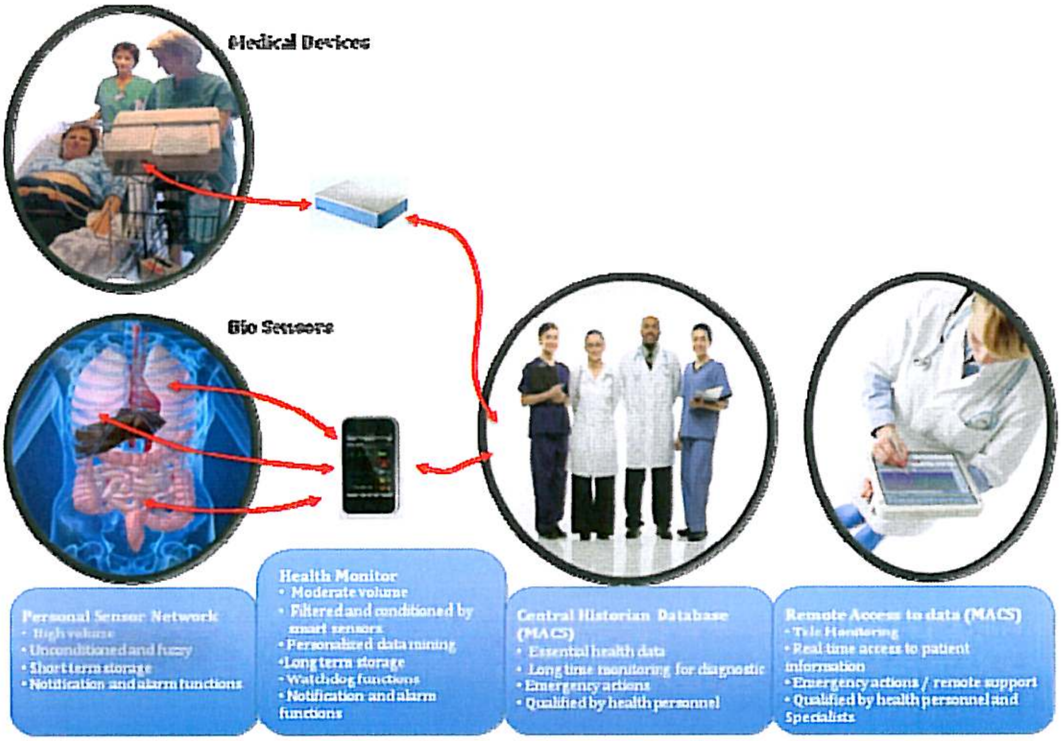
There are several options to show data from the MACS in real time and historically. IMATIS MACS contains components that can be embedded inside EPRs, existing Hospital Portals, Electronic Whiteboard and Electronic Patient Charts. In addition Imatis provide off-the-shelf products that work together with MACS to provide local needs.

Real time ECG in a wireless web portal *(© Imatis AS)*

A graphically overview displaying the status of all patients in the care unit makes it easy to identify those patients who require the highest level of attention. Easy navigation options allow clinicians to quickly switch between patients to view their full details. By one click on the graph component the Graphical View of waveforms data is shown with optional real time or historical data.



Graphically display of the status of all patients in the care unit, with link to the waveform data from Medical Devices and Sensors ***(© Imatis AS)***



IMATIS MACS platform for wireless Bio Sensors and integration of Medical Devices ***(© Imatis AS)***

Important benefits using the MACS platform as a service platform for wireless biosensors and medical device:

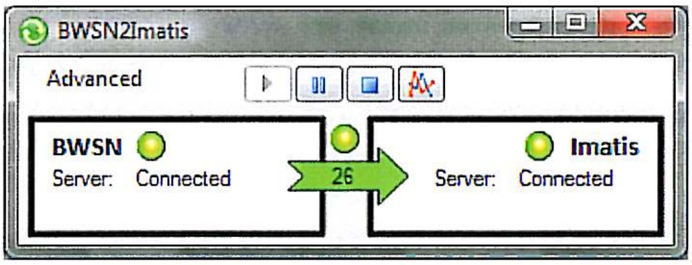
- More effectively prioritize attention given to patients
- Quickly access patient summary information in a clear visual presentation
- Easily navigate between patient summaries
- Better manage resources and tasks across multiple patients

- Follow unit trends over time for effective quality and cost management
- Tele-Monitoring of patients or patient groups
- Real time data from a Ambulance to the Emergency Department
- Real time and remote access of monitoring of baby delivery
- Patients can stay home and less need to be at the Hospital
- Patient self-service

Imatis AS is a Norwegian SME company with innovative software solutions for the healthcare industry. Their products focus on connecting people, information, processes and systems within a healthcare organization. The Integration Engine, Messaging Service and clinical applications are important elements in an Integrated Digital Hospital with focus on patient flow and Lean Thinking. More information about Imatis unified solutions for integrated healthcare: www.imatis.com

6.2. BWSN2Imatis connection

To make it possible to send data from the BWSN server (from BWSN phase I, see project report) to the Medical Archiving and Communication System from Imatis, SINTEF created a small program called BWSN2Imatis acting as a link between the two programs. BWSN2Imatis is connected as a client to the BWSN server, converting all BWSN sensor data packages to Imatis readable "Tag data", thus acting as a feed forward link between the two programs. TCPIP is used for the communication between BWSN Server, BWSN2Imatis and Imatis. A screenshot from BWSN2Imatis when connected and operating is shown below.



The sensor data is stored in the historical database and presented graphically as waveform data in a viewer application, as shown in the figure below.

Demo of wireless sensor data (simulated signals) *(© Imatis AS)*

7. Use case schematic for Acute Heart Diseases

The scope of this chapter is to list the use-cases a patient suffering from an acute heart disease might experience. The use-cases describe the use of wireless transducers and the problems wireless technologies might encounter.

The analysis is conducted on each use-case in order to highlight the standards and requirement that wireless medico devices have to conform to. The following use-cases are studied:

- Sudden critical coronary occlusion
  - Patient moved to hospital by ambulance
  - Patient moved from ambulance into hospital
  - Patient moved to x-ray department for stent catheterization
  - Observation after surgery
- Monitoring of patients during recreation in their homes
- Monitoring of patients during recreation in their local areas
  - Special case: Patient in swimming pool
- Monitoring of patients during transportation

7.1. *Sudden critical coronary occlusion*

Patient moved to hospital by ambulance

Event: PATIENT IS MOVED TO HOSPITAL BY AMBULANCE	Time	Distance 1 Wireless transducer	Distance 2 Mobile telephone
1. Coronary occlusion occurs in the home or at work. Often patient feels increasing chest pain.	0	-	-
2. Patient may already lie down or falls to the ground. Family members or by-passers call an ambulance and paramedics.	1 min	-	
3. After 5-20 minutes the ambulance and paramedics reach the patient.	5-20 min	2 m	2 m
4. Patient is given oxygen by holding a mask over nose and mouth.	1 min		
5. Patient is lifted onto special ambulance bed	1 min		
6. Patient is moved into ambulance	1 min		
7. Tie, belt and shirt are removed.	1 min		
8. If there is a medical doctor in the ambulance, blood thinning medicine is given orally or with a syringe.	1 min		
9. The patient's chest is cleaned with alcohol. Disposable electrodes with electrolytic gel are attached to the left of the chest bone. 10. Alternatively, a wireless patch is mounted on the chest.	5 min	2 m	2 m
11. If the heart is beating irregularly, the patient is regulated with drugs.	-		
12. If the patient is going into shock, a drop is injected into the patients hand veins to give more fluid into the blood.	1 min		
13. If the heart stops beating, the paramedics will give heart massage.	-		
14. Ambulance moves to the hospital as fast as possible.	20		possible loss of GSM signal
15. If the heart goes into fibrillation mode, the paramedics will use the electric de-fibrillation equipment in an attempt to restart the heart.	5 min	high voltage pulse	

Patient moved from ambulance into hospital

Event: PATIENT IS MOVED FROM AMBULANCE INTO HOSPITAL	Time	Distance 1 Wireless transducer	Distance 2 Mobile telephone
1. Patient is moved from the ambulance into the Coronary department of the hospital			
2. Wireless system and mobile phone is transferred from ambulance bed to a hospital bed. Other equipment: drop holder, oxygen gas tank, manually operated lung machine.			
3. The hospital bed is rolled into an elevator to reach the 2^{nd} floor.	2 min	4 m	possible loss of GSM signal
4. Anti-thrombosis treatment must be initiated within 20 minutes from the heart attack. 5. Fibrinolytic treatment 6. Treatment of shock 7. Treatment of arrhythmia	20 min		
8. Patient is stabilized	-		

Patient moved to x-ray department for stent catheterization

Event: PATIENT IS MOVED TO X-RAY DEPARTMENT FOR STENT CATHETERIZATION	Time	Distance 1 Wireless transducer	Distance 2 Mobile telephone
1. If the patient has a history of stenosis in the heart arteries, the patient will be transferred to the 3-axis X-ray department for immediate surgery/catheterization.			
2. The real time X-ray images help the medical staff recognize where a narrow passage has been blocked by an embolus. A contrast agent may be used to make the blood stream visible on the X-ray images. 3. The ECG transducer should not cover the upper or middle parts of the heart. The metal and silicon parts will absorb X-rays and cause dark areas in the images.		Diagnostic X-ray radiation	Risk of interference from GSM signal in surgery room equipment.
4. A stent may be inserted via the femoral artery using a special balloon catheter. Under X-ray the catheter is moved into the aortic arch and into the stenotized artery. The stent is expanded inside the vessel in order to keep it open for blood flow. The catheter is then withdrawn.	45 min	4 m	
5. The wound in the groin is just 10 mm long and is covered with a small patch to stop the bleeding.			
6. After surgery the patient is moved to the wake up room next to the surgery room and stabilized.	60 min		

Observation after surgery

Event: OBSERVATION AFTER SURGERY	Time	Distance 1 Wireless transducer	Distance 2 Mobile telephone
1. Patient ECG is monitored in order to recognize any arrhythmia. 2. 80% of patients have arrhythmia the first few days after heart surgery. 3. Few patients have arrhythmia after catheterization.			
4. Pre-cordial electrode setup or standard 3-electrode setup.			
5. It is possible to check the heart muscle for damages by analyzing the ECG.			
6. Further analysis of tissue damages is possible in Functional MR scanning. 7. Patient must be moved to a different department for this.	60 min	Strong magnetic field and RF waves.	Strong magnetic field and RF waves.
8. Patient is stable and is moved to recovery room.	10 min	2 m	
9. Elevator to 1st floor (for example)	2 min	4 m	Possible loss of GSM signal
10. Typical observation time is between 6 and 30 days	6 days - up to 30 days		
11. Some patients who experience many arrhythmias may have needle electrodes inserted, which are connected to temporary, external pace makers.			
12. Patient is transferred to a local hospital or sent home by taxi.			

7.2. *Monitoring of patients during recreation in their homes*

	Physical dimensions of space or enclosure	Physical distances between units	Special demands and challenges
Sleep		2 m	Monitoring during all night is possible. Skin may become itchy after many hours of contact with adhesive.
Shaving		2 m	Electric shaver (brush commutated motor) may emit electromagnetic noise. The electric shaver may come within a few centimeters of the ECG Patch.
Breakfast		1-5 m	
Making lunch box for kids if any			Standing under low voltage halogen lamp system which may emit some level of electromagnetic noise.
Brushing teeth			Electric tooth brush, electric wide band noise from commutated motor.
Showering / shampoo/hair dryer	The bathroom will be moist during showering. Any units should withstand a relative humidity of 100% if used in the bathroom.		Showering puts the adhesive seal quality to the test. Hot or cold water may alter the adhesive compound elasticity. Shampoo, hair conditioner and shower gel may reduce the contact area of the adhesive.
Using skin crèmes			Any application of skin crème will reduce the adhesive seal contact. The skin must be dry and free of any grease.
Dressing self / dressing kids			Stretching of the skin on the chest from extreme shoulder movements.
Cooking dinner			Induction type electric stove may emit significant levels of low frequency (electro-) magnetic fields. Damp and moist air may reach the mobile phone. Microwave oven may block the 2.4GHz band.
Putting on glasses or contact lenses			Contact lenses which can change color according to blood sugar levels are being developed
Washing clothes, Tumble drying, Ironing shirts			Low frequency magnetic fields.
Walking the dog			Wireless system leaving home area.
Using PC/game consol			PC, laptop, monitor and game consol may emit some level of electromagnetic noise.
Putting kids to bed			Any wireless systems alarms should be set to low/discrete acoustic signal in order not to make the kids worry unnecessarily about the parent's health.
TV show relaxing			TV set may emit some level of electromagnetic noise. Stroboscope effect may trigger epileptic seizure in rare cases.
Bath tub relaxing			Transmission of data may be interrupted when sensor is immersed in water.
Hot date with partner			Wireless patch should look esthetical and discrete so it does not prevent any social activity.

7.3. *Monitoring of patients during recreation in local areas*

Local area	Physical dimensions of space or enclosure	Physical distances between units	Special demands and challenges
Shopping			The wireless system should not interfere with the anti-theft alarms in shops and malls. The system should be so discrete that the patient can go shopping without any visible devices attracting attention. The system should withstand the body posture when pushing shopping cart or carrying heavy bags into the trunk of a car.
Recreational activity			Walking, Running, bicycling. Physical vibration of all the wireless units. Sweat and moist may reach all the wireless units.
Leisure activity / sports			Climbing, kayaking, rowing, wind surfing, sailing, motor cycling. Physical vibration of all the wireless units. Sweat, moist and salt water may reach all the wireless units. Extreme stretching of the skin may degrade the outer surface of the adhesive seal with the result that the patch is loose in one side.

Special case: Patients in swimming pool

Swimming / diving in a pool	Diving under water means dramatically reducing the transmitted signal from the wireless sensor. If a group of epileptic patients is swimming and playing in the indoor public swimming pool and one of the patients experience a seizure, a signal loss time-out should activate an acoustic alarm, in order to attract the attention of the responsible life guard and helpers.	Swimming movements cause strains in the adhesive wireless sensor, which leads to accelerated loss of adherence to the skin. Risk of loosing the wireless sensor in the water. Swimming puts the seal quality to the test. Any chloride water inside the patch may short circuit the electrodes hence reduce the signal amplitude.
Swimming pool monitoring and positioning	Useful parameters: Absolute water *pressure* is a measure of patient swimming depth. *Signal strength* of radio waves penetrating the water surface is a measure of sensor depth. Signal strength can also be used to determine "last known surface position" for any individual patient. Sensor may be attached to the patient skin as high as possible (head, chest, back, neck) or to silicone swimming caps.	Patients with known high risk of heart attacks or epileptic seizures should be monitored while swimming in order to avoid sudden drowning. In order to perform ECG monitoring the transmitter must emit sufficient power to penetrate the water surrounding the swimmer and reach the receivers on the sides of the pool. Water is a dipolar medium and will significantly reduce the transmitted power. Part of the wave may be reflected in the air-water and water-air boundaries.

7.4. Monitoring of patients during transportation

Transportation	Physical dimensions of space or enclosure	Physical distances between units	Special demands and challenges
Using Public Buses	Doors 2x1m, windows 1x1m, metal enclosure	1-2m between patient and handbag.	The wireless system should not interfere with any equipment in the bus. The "GSM hand-over not successful" alarms should not be so loud that it feels embarrassing in the public area.
Using Public Trains	Doors 2x2m, windows 1x1m, metal enclosure	1-2m between patient and handbag.	The wireless systems should not interfere with any equipment in the trains. The "GSM hand-over not successful" alarms should not be so loud that it feels embarrassing in the public area. 3G link may be available for internet access.
Using the Subway	Doors 2x2m, windows 1x1m, metal enclosure	1-2m between patient and handbag.	In the subway under ground there is more frequent loss of GSM signal. The subway traction system can expose the wireless system to substantial levels of electromagnetic noise.
Using the Bicycle	No enclosure	1m between patient and handbag/pocket.	Sweat and moist may reach all the wireless units. Theft of handbag and mobile phone from rear carrier is a risk in urban areas.
Using the specialized handicap types of Scooters	No metal enclosure	1m between patient and handbag behind seat.	
Using the Car or Taxi	Doors 1x1m, windows 0.6x1.8m, metal enclosure	1-2m between patient and handbag on passenger seat or placed in the trunk.	Frequent hand-over means frequent loss of GSM signal. Metal parts may reduce line-of-sight for radio waves if phone is placed in a bag in front of the passenger seat.
Using the Motorcycle	No metal enclosure	0.1-1m between patient and handbag placed in pocket or tank bag or top box.	Frequent hand-over means frequent loss of GSM signal. Sweat and moist may reach all the wireless units. Tank bag is held in place by strong magnetic field.
Transportation by Aircraft	Windows 0.3x0.4m, metal enclosure	1-2m between patient and handbag on passenger seat or placed in the over-head luggage room. IMPORTANT: The wireless patch and other auxiliary equipment must be turned off during flight.	Security point, Patient must prove that the wireless system units do not pose a threat to aircraft security. Probable loss of GSM and 3G signals during flight. Obligation to turn off all electronic equipment. Possibility to connect to in-plane communication system? Satellite link may be available for internet access. NO ACTIVE RADIO transmitter allowed during take off or flight.
Transportation by Ferry	Windows in cabin 0.4x0.4m if any. Metal enclosure		Possible loss of GSM signal. Metal parts may reduce line-of-sight for radio waves. 3G link may be available for internet access. Satellite link may be available for internet access.

7.5. Standards, EU and US requirements for wireless medico devices

For simplification a 2.4 GHz 0 dBm radio platform is assumed.

Use-case	Relevant standard or requirement
Medical requirements that may apply	EN 1060-3:1997+A1 Non-invasive sphygmomanometers – Part 3: Supplementary requirements for electro-mechanical blood pressure measuring systems EN ISO 9919:2009 Medical electrical equipment – Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use EN ISO 10993-10:2009 Bilogical evaluation of medical devices – Part 10: Tests for irritation and delayed-type hypersensitivity EN ISO 13485:2003 Medical devices – Quality management systems – Requirements for regulatory purposes EN ISO 14155-1:2003 Clinical investigation of medical devices for human subjects – Part 1: General requirements EN ISO 14155-2:2003 Clinical investigation of medical devices for human subjects – Part 2: Clinical investigation plans EN ISO 14971:2007 Medical devices – Application of risk management to medical devices EN/IEC 60601-1-6:2007 Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral Standard: Usability EN/IEC 60601-1-8:2007 Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems EN/IEC 62304:2006 Medical device software – Software life-cycle processes EN/IEC 62366:2008 Medical devices – Application of usability engineering to medical devices Draft Guidance for Industry and FDA Staff Class II Special Controls Guidance Document: Electrocardiograph Electrodes Document issued on: October 4, 2007 General Principles of Software Validation; Final Guidance for Industry and FDA Staff Document issued on: January 11, 2002 Quality System Information

Use-case	Relevant standard or requirement
	for Certain Premarket Application Reviews; Guidance for Industry and FDA Staff Document issued on: February 3, 2003 Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management. Guidance for Industry and FDA pre-market and Design Control Reviewers Document issued on July 18, 2000 Guidance for Industry and FDA Staff Class II Special Controls Guidance Document: Arrhythmia Detector and Alarm Document issued on: October 28, 2003 Guidance for Industry Cardiac Monitor Guidance (including Cardiotachometer and Rate Alarm) Document issued on: November 5, 1998 Draft Guidance for Industry and FDA Staff Radio-Frequency Wireless Technology in Medical Devices Draft released for comment on January 3, 2007
General safety requirements	EN/IEC 60601-1:2006 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance EN/IEC 60601-2-25:1995+A1 Medical electrical equipment – Part 2-25: Particular requirements for the safety of electrocardiographs EN/IEC 60601-2-27:2006 Medical electrical equipment – Part 2-27: Particular requirements for the safety, including essential performance, of electrocardiographic monitoring equipment EN/IEC 60601-2-40:1998 Medical electrical equipment – Part 2-40: Particular requirements for the safety of electromyographs and evoked response equipment EN/IEC 60601-2-47:2001 Medical electrical equipment – Part 2-47: Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems EN/IEC 60601-2-49:2001 Medical electrical equipment – Part 2-49: Particular requirements for the safety of multifunction patient monitoring equipment EN/IEC 60601-2-51:2003 Medical electrical equipment – Part 2-51: Particular requirements for safety, including essential performance, of recording and analysing single channel and multichannel electrocardiographs EN/IEC 62311:2008 Assessment of electronic and electrical equipment related to human exposure restrictions for electromagnetic fields (0 Hz - 300 GHz)
General EMC requirements	EN/IEC 60601-1-2:2007 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests

Use-case	Relevant standard or requirement
	EN 301 489-1 V1.8.1: 2008 Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements EN 301 489-3 V1.4.1:2002 Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 3: Specific conditions for Short-Range Devices (SRD) operating on frequencies between 9 kHz and 40 GHz EN 301 489-17 V2.1.1:2009 Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment; Part 17: Specific conditions for Broadband Data Transmission Systems
General radio parameter requirements, EU	EN 300 440-2 V1.3.1:2009 Electromagnetic compatibility and Radio spectrum Matters (ERM); Short range devices; Radio equipment to be used in the 1 GHz to 40 GHz frequency range; Part 2: Harmonized EN covering essential requirements of article 3.2 of the R&TTE Directive EN 300 440-1 V1.5.1:2009 Electromagnetic compatibility and Radio spectrum Matters (ERM); Short range devices; Radio equipment to be used in the 1 GHz to 40 GHz frequency range; Part 1: Technical characteristics and test methods
General radio parameter requirements, USA	CFR Title 47- Telecommunication CHAPTER I-FEDERAL COMMUNICATIONS COMMISSION PART 15-RADIO FREQUENCY DEVICES Subpart C: Intentional Radiators Specific rule part: 15.247 Operation within the bands 902-928 MHz, 2400-2483.5 MHz, and 5725-5850 MHz. FCC Public Notice DA 00-705, March 30, 2000 Filing and Measurement Guidelines for Frequency Hopping Spread Spectrum Systems or KDB Publication No. 558074 Guidance on Measurements for Digital Transmission Systems (47 CFR 15.247)
User Case 1: Ambulance to hospital	EN 1789:2007 Medical vehicles and their equipment – Road ambulances
User Case 2: Patient is moved to x-ray department for stent cauterization.	EN/IEC 60601-2-8:1997+A1 Medical electrical equipment – Part 2: Particular requirements for the safety of therapeutic X-ray equipment operating in the range 10 kV to 1 MV Guidance for Industry and FDA Staff Performance Standard for Diagnostic X-Ray Systems and Their Major Components (21CFR 1020.30, 1020.31, 1020.32, 1020.33); Small Entity Compliance Guide Document Issued on June 7, 2007
User Case 3: Observation after surgery	EN/IEC 60601-2-33:2002 Medical electrical equipment – Part 2-33: Particular requirements for the safety of magnetic resonance equipment for medical diagnosis

Use-case	Relevant standard or requirement
User Case 4: Cardiac defibrillators	EN/IEC 60601-2-4:2003 Medical electrical equipment – Part 2-4: Particular requirements for the safety of cardiac defibrillators

8. Wireless test facilities

DELTA offers testing and technological consulting in the field of wireless technology for medical products.

Delta's Test & Consultancy service have specialists in Systems, HF, Antenna's, Approval & Regulation and Technology choice and support implementation of wireless technology in medical products.

Regulatory test services

We provide accredited regulatory test services and consultancy services related to the regulatory requirements for a wide range of short range wireless technologies. We can help you identify the requirements and procedures relevant for your specific product for the specific markets you are targeting.

Performance test requirements

When the specification for a product goes beyond the regulatory requirements and when companies need help and facilities for troubleshooting and performance tests, Delta offers expertise and equipment that could be essential for the job.

Interference from other wireless systems

Improve resistance to other wireless systems is important. Delta may determine the distance to another interfering wireless system like WiFi, Z-Wave, 802.15.4, and Bluetooth. All this with respect to the size of the data transmitted from those wireless systems. The deliverable will be a report which states how robust the system is when used in real life.

Transmission range

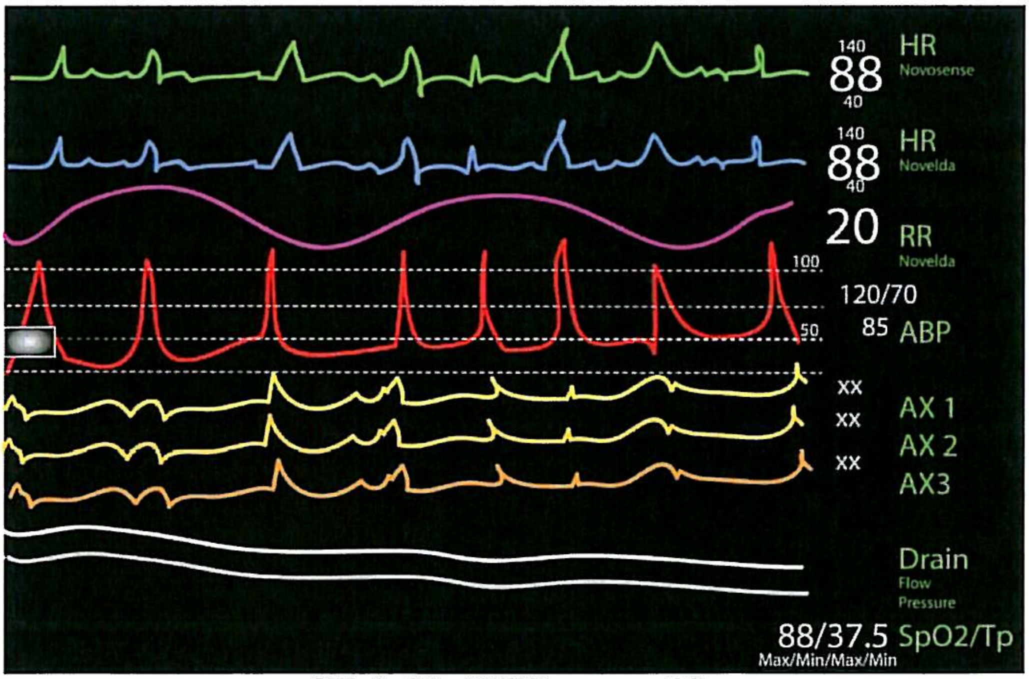
The transmission range of data is important for all wireless systems. Delta offers a service evaluating wireless systems by determining the transmission range. Based on a review we can also advice and suggest design change to increase the transmission range.

9. Clinical test of BWSN system & wireless sensors

Method

In the clinical tests the BWSN2 platform was used during experimental surgery at the Interventional Centre, Oslo University Hospital. For ethical and security reasons the BWSN2 sensor portfolio was tested simultaneously with the hospital's standard monitoring system (with wired sensors) during experimental surgery in a porcine animal research model established for another, running research project focusing on sepsis. The surgery in this project was performed in general anesthesia involving a sternotomy with open chest in a beating heart, off-pump cardiac procedure. Invasive arterial blood pressure was measured from the carotid artery with a serial connection to the arterial line used for the hospital monitor system. The 3-axis accelerometer from VTT was sutured to the left plural surface available in the open chest with a wired connection to the wireless transmission unit placed on top of the abdomen. A CH 36, 12 mm chest tube was inserted through the abdominal wall and inserted in the intrapleural space of the left lung. The tube was connected to the digital air leakage system from Millicore, and the suction level was set to the equivalent of -15cm H2O. The device reservoir was attached to the right side of the OR table. SpO_2 and rectal temperature sensors were put on the research subject with wireless units were also placed on the abdomen. The ECG device was attached to the left thorax wall with two ECG patches. Two base stations were placed in the OR, and were connected via LAN to a laptop with the bridge applications and the Imatis MACS software installed.

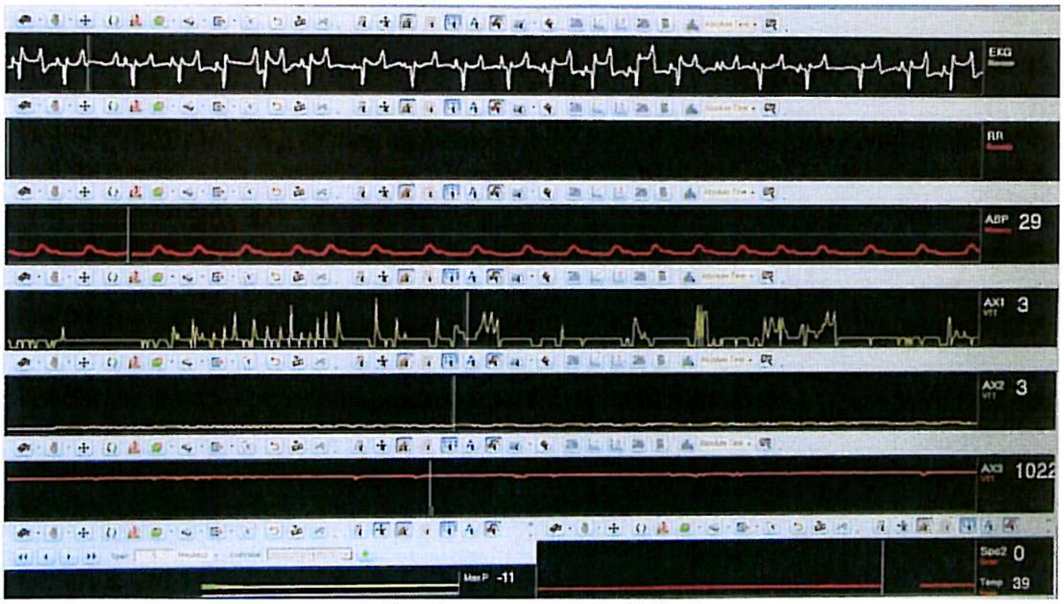
Design of graphical user interface (GUI) and functional requirements for the sensor portfolio monitor was discussed with two anesthesiologists. Based on their input the GUI in the figure below was made and used as a template for development of the Imatis client software monitor GUI.



GUI- draft for BWSN2 sensor portfolio

Clinical OR Test Results

The figure below shows the Imatis live view client application with the sensor portfolio GUI in simultaneous continuous use. It has 8 black fields for sensor information.



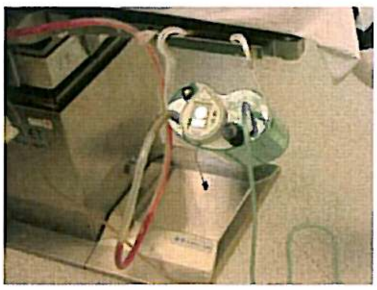
Imatis sensor portfolio GUI

The upper black field in the screen dump above is for ECG data. The second is for the Novelda device which was implemented within the project, but not available during the testing. The third field shows the invasive arterial blood pressure from the Memscap sensor. The fourth to sixth field shows the VTT accelerometer's X, Y and X axes respectively. The bottom seventh field is split in two. The left shows max pressure, min pressure and flow for the digital air leakage system from Millicore. The right bottom field shows SpO_2 and rectal temperature from the SINTEF sensors. Data from these two sensors were displayed as numbers, all other as waveforms.

The figure shows the administrator user profile with a lot of buttons for parameter configuration for each field. Images below are from the clinical test in the OR.

OR-setup

ECG sensor



Air leakage system

A video from the clinical test performed at the Interventional Centre is available on www.bwsn.net or directly at YouTube (www.youtube.com/watch?v=hIHJTl7JMSE).

10. Dissemination and spin-off projects

A BWSN website is established www.bwsn.net for internal communication, document archiving, and also external communication. The project results have been presented at several occasions, e.g. meeting hosted by the Wireless Healthcare initiative. A video is prepared from the sensor network testing, and will be posted on YouTube and our website. The project has given several spin-off projects where the partners collaborate on research, product development and also marketing. Some of the partners have together prepared EU applications achieving funding, e.g. from EU-STREP and EUROSTAR.

11. Conclusions and recommendations

11.1. Conclusions

The biomedical wireless sensor network (BWSN) was developed, implemented and tested at the Interventional Centre at the Norwegian National Hospital. The BWSN shows monitoring of all wireless sensors at the same time. Six different sensors were integrated in commercial software (Imatis Interconnect):

- Memscap Wireless Pressure Transducer
- Millicore DigiVent
- Novosense CardioPatch ECG sensor
- VTT Heart Monitoring Accelerator
- SINTEF SpO_2 and temperature sensors

The main conclusion is that the BWSN Wireless sensor network matches performance of state of the art wired advanced medical monitoring platforms. Wireless systems facilitate more aggressive and early patient ambulation and unrestricted mobility. This applies to post procedure monitoring of patients, as length of hospital stays are shortening(8) due to minimally invasive procedures. Escalating healthcare costs linked to the growing ageing population, often with increased co-morbidity(9), calls for organizational changes. Wireless sensor networks can have an important role close the gap between care providers and patients as elderly with chronic disease also seek independent living to minimize consequences of their disease on their personal life.

The BWSN was implemented on a commercial sensor integration platform from Imatis, and solved several technical barriers, e.g. sensor synchronization and noise handling. There are still needs for improvements in order to cover security handling, achieve extended mobility outside the surgery room, monitoring of several patients/persons at the same time.

Interoperability with other hospital systems by integration of sensor data has not been pursued in the project. The BWSN and the collaboration form an important platform for further technical development and business development in order to penetrate a market expected to increase substantially in the future.

11.2. Recommendations

The partners will establish follow up projects on sensor network applications, and also on how future wireless patient monitoring and treatment can be performed, and which benefits that would provide. Clusters and networks like Oslo Medtech, MedITNor and MedCoast Scandinavia will be natural partners for this. A-HUS, St.Olavs, Oslo University Hospital are potential Norwegian hospitals. Hospitals in Finland, Denmark and Sweden will also be invited as partners.

Imatis AS is a vendor of data integration platforms on the market. The project partners see a future opportunity if companies like Imatis is offering a complete sensor network solution on the market. It could be difficult for the individual sensor vendors to penetrate the market, and much easier as part of a sensor network as a complete vital sign measurement solution.

Together with IVS, the sensor vendors plan to perform further test and achieve verification documentation or a sensor quality stamp.

IVS has through the BWSN project built up a start of a sensor testbed for clinical tests. It is important that this effort is developed further. Delta has established a testbed for e.g. sensors signal reliability testing. Funding opportunities, and also a possible collaboration between IVS and Delta should be investigated.

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Appendix 1: Wireless products in healthcare

Delta report A505803-1 (8 pages)

We help ideas meet the real world

DELTA Technical note

Wireless networks in healthcare – Selection of frequency band

Performed for BWSN-II

Project no.: A505803
Page 1 of 6

13. October 2008

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1. Introduction

This document is an appendix to Biomedical Wireless Sensor Network – BWSN from January 2008, authors: Eirik Næss-Ulseth.

An evaluation of the different technologies is reported in the report above and is not covered in this technical note.

2. Scope

The purpose is to give an overview of the regulatory requirements for each relevant frequency band before the selection of frequency band for the Biomedical Wireless Sensor Network.

3. Frequency band for a World Wide Biomedical Wireless Sensor Network

3.1 General requirement for World Wide Wireless Products

Short Range Wireless Devices typically use the unlicensed frequency bands, these bands can be used without paying license, normally to the national government.
The unlicensed frequency bands are implemented in national regulatory frequency plans, but they are normally different from country to country.
This means that it is necessary to adopt frequency and transmitted output power (and other parameters) to the different countries regulatory frequency plans and requirements.

In some countries it is a requirement to get a certification of the wireless devices and in other countries it is enough to state compliance with all relevant requirements.

E.g. in EC it is enough to state compliance with all relevant directives and standards and CE mark your product. You only need to archive your technical constructions file.
In USA and Canada your product needs a certificate from FCC and IC, this can be obtained by sending your technical file with measurements and technical documentation for approval.

3.2 Offend used frequency bands

The most offend used frequency bands for short range wireless technologies are:

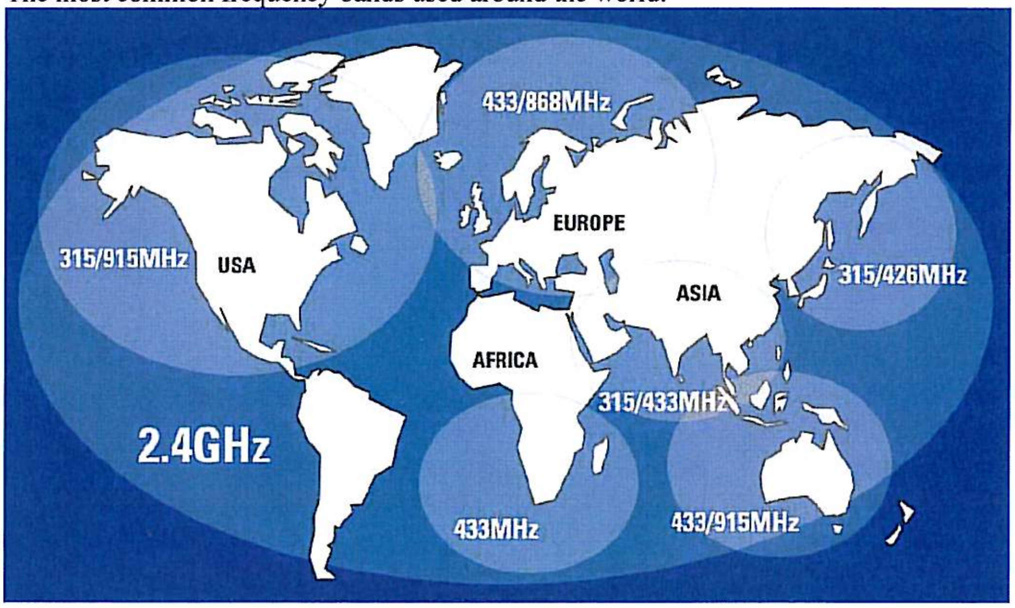
- 315/433 MHz
- 868/915 MHz
- 2400-2480 MHz

Dedicated frequency band for wireless application in healthcare in Europe

- 402 MHz

Different national requirements for transmitting output power, modulation, used frequency and how to measure the different radio parameter in the different countries are a challenge and it is expensive to get a world wide regulatory approval.

The most common frequency bands used around the world.



3.2.1 315/433 MHz-band

As the map indicates the two different frequency bands (315 MHz and 433 MHz) are used in different geographic areas. The 315 MHz band is originally from Asia but is now commonly used in USA for consumer products. The 433MHz bands are commonly used around the rest of the world.
All this will increase the complexity of the product because the frequency needs to be adapted to where you are located in the world

The 315/433 MHz frequency bands are generally used in consumer products with short transmissions of control signal, e.g. for garage doors openers.

3.2.2 402 MHz-band

This band is open for use in Europe for ultra low power active medical implants covered by applicable harmonized standards in a point to point communication system.

The transmitting power is very low, 25μW e.r.p. (-16dBm)

3.2.3 868/915 MHz-band

As the map indicates the two different frequency bands (868 MHz and 915 MHz) are used in different geographical areas. In EU the 868 MHz can be used, whereas the 915 MHz band is used in USA and Australia.
All this will increase the complexity of the product due to the frequency needs to change regards where you are placed in the world. Chipset has normally both radio frequency bands build into it.

These frequency bands are generally used in consumer products with short transmissions of control signal for home automation and data transmission from wireless sensors at low data transmission rates.

3.2.4 2400 MHz-band

This frequency band is the most harmonized frequency band in the world. In general it is possible to implement a 2400 MHz radio for transmission of medium to high data rate. Most technologies are present in this frequency band including multiple suppliers of each technology.

This frequency band is the most used one and therefore interference from other radios nearby is to be expected. WiFi is a critical source of interference in this band due to high power and high bandwidths. But other technologies are also relevant as they may be used in closer proximity.

4. Selection of frequency Band

4.1 Summary

- A platform needs to be designed with all use cases followed up by a risk assessment.
- It is the requirements that determine the choice of frequency band. The use of the product, implantation, full network facilities, range, battery life, size, placements, market and many other requirements will give a guide to the selection of frequency band.
- The range of short range wireless device is very dependent at the different use of the product.
    - The use in building gives a shorter range from 10 to 30 meter, through concrete wall even less.
    - Lower frequencies give longer ranges but the antennas are larger or less effective and less effective antennas will reduce the advantage.
- For all technologies it is possible to build in some facilities to add robustness against interference and to ensure a more secure data transmission. Some of the technologies have built in robustness like the Bluetooth technology, which uses frequency hopping to avoid other interferers, but the disadvantage is higher energy consumption and lower network ability. Few suppliers deliver diversity antennas options in their radio modules, which can give more secure data transmission. Many suppliers of chipsets have built in the opportunity to implement simple antenna diversity but this is rarely used.
    - The best solution is to build your own radio optimized for secure data transmission with frequency hopping, diversity antennas and other advantageous technical solutions. This implementation can be done using IEEE802.15.4 or selected parts of the standard.
- If battery life for more then one year of operation is needed then design for extreme low power consumption is needed. If energy harvesting (no battery or external power supply) is needed another design philosophy is necessary.
    - Network routing with battery in a secure data transmission application is very difficult to implement for battery life about ½-1 year or even less.
- The frequency band matrix can give an overview before making a selection of frequency band based on the requirement for the platform.
    - See next page for matrix.

Frequency band matrix:

Frequency band/ Technology	315 MHz	402 MHz	433 MHz	868 MHz	915 MHz	2400 MHz
Availability in the world	USA/Asia	Europe	Europe+	Europe	US + Australia	World wide
Application	Consumer	Medico Implants	Consumer	Consumer/ Sensor	Consume/ Sensor	All
Data rate	2-4 kbps	2-4 kbps	2-4 kbps	20 kbps	40 kbps	11 mbps
Power		25 µW	10 mW	25 mW	XXX	100 mW
Number of notes	NA	NA	NA	Medium	High	High
Antenna size (free space ¼λ)	238 mm	185 mm	173 mm	86 mm	82 mm	31 mm
Antenna size Ceramics Same loss (¼λ, ξr=16)	60 mm	46 mm	43 mm	22 mm	21 mm	8 mm
Antenna loss Same size Ceramics	High	Medium-High	Medium – High	Low – Medium	Low - Medium	Low
Antenna Integration Size and loss	+	+	+	++	++	+++
Technology	Custom	Custom	Custom	Zigbee 802.15.4	Zigbee 802.15.4	All
Range factor free space, N=2	8	6	6	3	3	1
Range factor Typ.Indoor,N=6	2	1,8	1,8	1,4	1,4	1
Interference	Low	Low	Medium	Medium	Medium	High