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Best Practice Report

Intelesens Limited

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Everybody please state revision index and short description of what has been done + partners involved and date.

Final approval	Name	Partner
Reviewer		

1. Best Practice Title

Sensor Technology & Devices (ST&D) now Intelesens

2. Location of Best Practice

Country, region, town

Belfast, Northern Ireland

3. Best Practice Executive Summary

Describe briefly (max 10 lines) the GP context (partnership, funding, objectives, approach followed, results)

Intelesens is an internationally recognized, leading innovator in targeted non-invasive vital signs monitoring. Intelesens was incorporated in August 2000 (with Enterprise Equity leading an investment of £1.7m into the company in May 2005) by 3 of the province's leading scientists as a University of Ulster spin-out company, thereby ensuring the continued identification and design of world beating new products.

Intelesens develops and manufactures its own products and also designs products for OEMs. In addition to products that have been developed specifically for medical device partners, Intelesens have developed their own range of patented products.

The company's strengths lie in non-invasive wireless medical devices combined with medical sensors and electrodes. This involves in-depth expertise including:

- * Wireless telemetry
- * Low power consumption electronics
- * Embedded software
- * Cardiology
- * Body sensors and low level signal processing
- * Screen printing solid gel electrode manufacture
- * Science of the skin including long term non-irritant materials
- * Defibrillation techniques and recovery
- * Medical systems approval – FDA and CE

More specifically, Intelesens designs and manufactures wireless vital signs monitors.

These are ultra miniature intelligent sensors which are worn on the chest. They can monitor a range of vital signs including ecg, heart rate, respiration, temperature and motion – all with hugely reduced motion artifact.

Super efficient, customized patch electrodes, on-board intelligence and efficient electronics and telemetry greatly extend battery life as only the clinically significant data needs to be transmitted.

Intelesens is also an internationally recognized provider of high performance electrodes including a range of cost reducing defibrillation pads.

This year Intelesens began shipping the world's first intelligent ecg arrhythmia event monitor being sold under the V-Patch brand and marketed exclusively by VPMS Ltd.

Intelesens technology and designs are to be found in the products of the some of the world's leading medical device manufacturers.

4. Best Practice Classification

Best Practice Theme

- Research Transformed to Innovative Product*
- Research Transformed to Innovative Service*
- Research Transformed to Innovative Methodology*
- Research Transformed to Innovative Production Process*
- Financial Mechanism for Transformation of Research to Innovation*
- Support Mechanism for Transformation of Research to Innovation*
- Other (describe)*

Best Practice Research / Application Areas

- Industrial / Manufacturing Systems*
 - Industrial Informatics and Communications*
 - Intelligent Devices*
 - Distributed Control Systems*
 - Flexible Manufacturing Systems*
- Embedded Systems*
 - Industrial Embedded Systems*
 - Nomadic Environments*
 - Private Spaces*
 - Public Infrastructures*

5. Description of Best Practice

5.1 Best Practice Context

Overall background of the Best Practice. Location, socio-economic, technical & policy background of the BP (max 10 lines)

Intelesens is one of the spin outs of Ulster University. Primary research begun at the Northern Ireland BioEngineering Centre which was formed in 1990 with a strong emphasis on sensors; biomaterials and device miniaturisation. Intelesens currently has OEM relationships with a number of medical device manufacturers. From V-Patch, a wireless vital signs system that will monitor ECG, temperature and respiration rate continuously, to an in-home foetal monitoring patch that could help expectant mothers predict the onset of their own labour, the OEM products are primarily geared towards the monitoring of human vital signs such as blood pressure and the physiological measurement of muscular or vascular activity.

In addition to products that have been developed specifically for medical device partners, Intelesens have developed their own range of patented products, for example, 'Electronic Nose', which is able to measure any number of gas emissions from a variety of sources including the human breath. This gives a high degree of sensitivity to a full spectrum of components, which can be used to screen for a range of medical conditions from asthma and diabetes to certain types of cancer. The potential applications for the 'electronic nose' are however vast ranging from the brewing and wine making industries to catering and health & safety control.

An interesting publication about Intelesens philosophy and achievements is coming by the following FROST & SALLIVAN TECHNICAL INSIGHTS article (titled "Multiparameter Wireless Monitoring Device Caters to All Levels of Acuity Care Settings"):

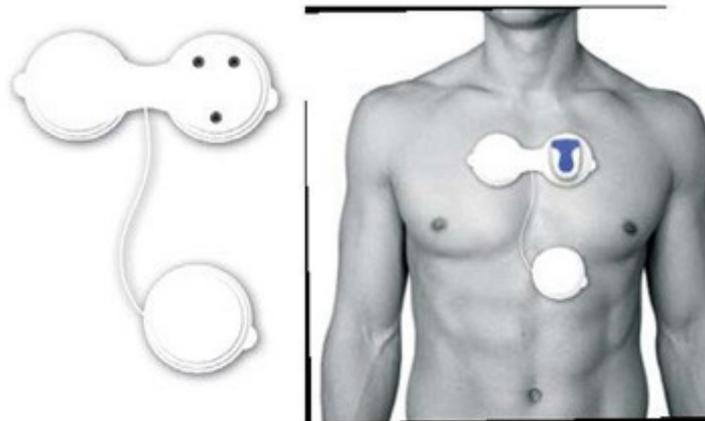
"... With global increase in longevity accompanied by the fact that obesity and chronic illnesses are rising at an alarming rate, there is growing pressure for more efficient monitored healthcare in hospitals and increasingly at home settings. The application of wireless technologies to patient monitoring has enabled patient care and physician effectiveness to reach new levels.

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The advent of telecommunications/computer-based monitoring has paved the way for healthcare practitioners to rely less upon the traditional case sheets hung at the patient's bedside and more on wireless technologies for acquiring patient-related information. For vendors to succeed in this expanding business, one important area of focus should be in product development wherein there is a need to improve the integration of various aspects of patient management and therapy, as and when the patient moves through the hospital care process, if required.

With an aim to cater to universal 'quality of care' demand coming from patients, who are constantly seeking higher level and more effective healthcare from their clinicians and healthcare services, Intelesens Ltd., a Northern Ireland-based firm is involved in designing a flexible wireless vital signs platform. The new plug-and-play vital signs monitoring device named Vitalsens comprises of a disposable electrode patch and a reusable clip on transmitter. Vital data relating to the wearer's health, including heart rate, electrocardiogram (ECG), temperature, and levels of activity are measured in the chest region and transmitted via Bluetooth to software residing on a personal computer or laptop in the wearer's home settings or in a hospital ward.

The health information thus recorded could then be later assessed by the clinician either locally or remotely.



Vitalsens platform with the v-patch product

Picture Credit: Intelesens Ltd. (Northern Ireland, United Kingdom)

This Figure shows the Vitalsens platform with the v-patch product.

This versatile wireless monitoring platform could be customized to provide a range of monitoring products for in-hospital use and deployment at-home or on-the-move scenario. The firm's v-patch device is equipped with ECG arrhythmia algorithms, which could detect and transmit a set of 10 arrhythmias with pre- and post-event data to a remote secure Website and easily accessible by the clinician. The Vitalsens monitoring device is also capable of measuring heart rate, ECG, temperature and activity levels, besides respiration rate and pulse oximetry measurements, which would be added on later this year.

Both v-patch and Vitalsens devices have already gained CE class regulatory approvals and clinical trials are expected to be conducted in Boston and Belfast respectively within Q2 2010. The firm anticipates a set of dual applications coming firstly from the management and care of acutely ill patients in hospital environments. Intelesens is so far well supported in the development of hospital-based wireless monitoring solutions by Partners Healthcare, Boston, and the Wellcome Trust in the UK.

The second application involves the management of chronically ill patients who live at home and whose healthcare needs is provided mainly by primary care organizations. In addition to these two applications, Intelesens is also working with some large healthcare technology firms to develop homecare solutions.

Speaking to Technical Insights, Michael Caulfield, CEO of Intelesens Ltd. explains, "The firm foresees applications for this low-cost Vitalsens multiparameter, body-worn, wireless monitoring device in the management of care for both chronically ill patients at home and to monitor the health of both in-patients as well as out-patients attending hospitals..."

5.1.1 Policy Elements

What are the policy initiatives that have influenced the contextual environment of BP: innovation promotion policies, research funding policies, certification ect as well as relevant tools (max 10 lines)

Example policies of Intelesens:

"... Intelesens joins CIMIT's Industry Liaison Program (CIMIT: Center for Integration of Medicine and Innovative Technology: A non-profit consortium of Boston teaching hospitals and engineering schools, CIMIT fosters interdisciplinary collaboration among world-class experts in medicine, science and engineering, in concert with industry and government, to rapidly improve patient care)

Intelesens is a medical devices company based in Belfast, Northern Ireland and focuses on the development of wireless vital signs monitoring solutions. It has combined advanced technologies to produce a unique miniaturized, battery-powered non-invasive body-worn platform which:

- measures a range of human vital signs using a non-invasive patch electrode*
- sends patient data electronically from the body to a local or remote patient database;*
- records and displays this patient data for access and use by clinicians using web access technology*

It is the company's objective to take this technology to the market in the form of a general purpose wireless monitor which combines up to 5 vital signs in a single unit.

The company has spun out from the University of Ulster in Belfast and was founded by Professors John Anderson, Jim McLaughlin and Eric McAdams. The company's technology and strategic direction have been recently platformed at the Partners Healthcare Connected Health Conference and the CIMIT Exploratorium both held in Boston in October 2008 and at the Medica 2008 Exhibition held in Dusseldorf.

CIMIT represents a unique opportunity for Intelesens to collaborate with CIMIT healthcare clinicians, US-based healthcare organizations and other member companies...."

"... University of Ulster healthcare technology spinout company, Intelesens, is set to expand into new global markets after receiving CE regulatory approval for its life-saving wireless health monitor product, Vitalsens.

CE marking is a mandatory European approval for medical devices to indicate conformity with the essential requirements set out in European Directives. This milestone opens up extensive new markets in Europe and South-East Asia to the Belfast firm, whose products build on sensor technologies developed by the company's founders at the University of Ulster. The device a disposable electrode pad and a reusable clip-on transmitter, offers a low-cost technology solution to help in the management of care for both chronically ill patients at home, as well as monitoring the health of both in-patients and out-patients attending hospital.

Intelesens Chief Executive Michael Caulfield said: "Data relating to the wearer's health, including heart rate, ecg, temperature and levels of activity are measured in the chest area and transmitted via Bluetooth to software residing on a pc or laptop in the wearer's home or in a hospital ward. This vital health information can then be accessed by medical professionals either locally or remotely, and appropriate treatments delivered rapidly."

The CE accreditation is an important step in the growth of the company, said Caulfield. But there is

more to come. "The next step is to gain US FDA (Food and Drug Administration) approval for the product. That will open up the enormous US market to us, taking our business – built on technology developed in Northern Ireland – to a whole new level...."

5.1.2 Socio-economic & Other factors

Other contextual factors such as customer / target market addressed, international validity, customer density, economic conditions, customer values, research area addressed (max 10 lines)

FROST & SALLIVAN TECHNICAL INSIGHTS article (titled "Multiparameter Wireless Monitoring Device Caters to All Levels of Acuity Care Settings"):

"... With global increase in longevity accompanied by the fact that obesity and chronic illnesses are rising at an alarming rate, there is growing pressure for more efficient monitored healthcare in hospitals and increasingly at home settings. The application of wireless technologies to patient monitoring has enabled patient care and physician effectiveness to reach new levels.

The advent of telecommunications/computer-based monitoring has paved the way for healthcare practitioners to rely less upon the traditional case sheets hung at the patient's bedside and more on wireless technologies for acquiring patient-related information. For vendors to succeed in this expanding business, one important area of focus should be in product development wherein there is a need to improve the integration of various aspects of patient management and therapy, as and when the patient moves through the hospital care process, if required..."

The major achievements of Intelesens aim to cover these needs, focused on products in the areas of:

- **Vital Signs Monitor**
- **Cardiac Monitor**
- **Ambient Assisted Living**
- **Electrodes**
- **Sensors**

5.2 Objectives

Aim of the project, specific objectives & strategies to achieve these objectives (max 10 lines)

Intelesens is an internationally recognized, leading innovator in targeted non-invasive vital signs monitoring.

This involves in-depth expertise including:

- Wireless telemetry
- Low power consumption electronics
- Embedded software
- Cardiology
- Body sensors and low level signal processing
- Screen printing solid gel electrode manufacture
- Science of the skin including long term non-irritant materials
- Defibrillation techniques and recovery
- Medical systems approval – FDA and CE

The reasons why companies approach Intelesens include:

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- Wealth of expertise combining medical, electronics and body sensors
- Years of experience in medical electrode/sensor design and manufacture
- Wireless electronics knowledge
- ISO 9001 / ISO 13485
- Medical devices supplied to well known OEMs since 2000

Customers include Welch Allyn, Equipmed and Heartsine.

Intelesens develops and manufactures its own products and also products for other original equipment manufacturers (OEMs). The company business model is very flexible and includes design, design and manufacture and licensing.

The company originally worked in the design and manufacture of high performance sensors and electrodes. This expertise is based largely on the company's three founding professors who have widely published in this field. Their sensors have been used in monitoring for space missions and their technology is licensed to many of the large medical sensor companies throughout the world.

Intelesens naturally broadened into designing the actual monitoring systems and now its market-leading Wireless Vital Signs Platform forms the basis of many OEM products. The benefits and cost savings of wireless monitoring are widely agreed with Intelesens poised to take advantage of this growing market.

With its continued excellent links into a number of world-leading research institutes, Intelesens has an established IP pipeline of new products innovations.

6. Process

Describe the project including key concepts and the overall approach followed. Indicate project end users, target market, main project phases, problems encountered and solutions, problem resolution (max 10 lines)

Intelesens develops and manufactures its own products and also products for other original equipment manufacturers (OEMs). The company business model is very flexible and includes design, design and manufacture and licensing.

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With its continued excellent links into a number of world-leading research institutes, Intelesens has an established IP pipeline of new products innovations.

Intelesens is now focusing on the following product areas:

- **Vital Signs Monitor**
- **Cardiac Monitor**
- **Ambient Assisted Living**
- **Electrodes**
- **Sensors**

Intelesens has a worldwide client list. The following are some of the companies of Intelesens:



6.1 Project Design

Project design based on targeted market complete understanding, project structure, policies and procedures, management and implementation actions (max 10 lines)

The basic aspects per Intelesens product area are summarized as follows:

1. Vital Signs Monitor

With aging populations and an increase in chronic illnesses globally, there is growing pressure for more efficient monitored healthcare in hospital and increasingly at home. Intelesens design and manufacture a flexible Wireless Vital Signs Platform that can be customized to provide a range of monitoring products for in-hospital use and deployment at-home or on-the-move.

A versatile wireless monitoring technology, the platform is designed as a modular system to form the basis of many different products. It can be used as a short range or long range (cellular phone) monitor and specified with a variety of vital sign inputs and wireless systems, including Bluetooth. Highly miniaturized, light weight and with an extremely long battery life, the monitoring devices can be small, unobtrusive and easily worn under clothes allowing patients freedom during monitoring.

This platform forms the ideal basis of rapid development OEM products, especially when combined with Intelesens high quality sensor/electrodes for non-invasive measurement.

Intelesens have also used this platform as the basis of their Pulse Wave Velocity (Pulsesens) system.

2. Cardiac Monitor

Intelesens technology platforms provide physicians with the tools to monitor cardiac patients for both short and long term analysis; before, during and post hospital follow-up.

Traditional ECG monitoring, utilizing the Holter system, would occur over 24 hours before data is returned for analysis. With Intelesens on-board intelligence a system can recognize 11 different heart arrhythmias and immediately send this information directly to the clinician. This can result in much faster treatment, often allowing easier preventative steps instead of the distress of more invasive later procedures.

Benefits of Instantaneous Holter Monitoring with the Intelesens system include:

- Significant data available instantly for improved patient outcomes
- Monitoring at home, outside or in work instead of costly monitored hospital beds
- Sensors can be worn on the body for days and are waterproof for use in the shower thus allowing maximum patient freedom
- Minimization of motion artifacts - high quality results even with the patient moving around
- Detection of unusual activity before the patient becomes aware of being unwell

Based on these fundamental benefits and in partnership with V-Patch Medical Systems, Intelesens have developed and are shipping the CE Approved V-Patch product... the world's first intelligent, wearable, non-invasive, wireless vital signs monitor.

1. Ambient Assisted Living

Ambient Assisted Living (AAL) includes methods, concepts, (electronic) systems, devices as well as services that are providing unobtrusive support for daily life based on context and the situation of the assisted person. The technologies applied for AAL are user-centric, i.e. orientated towards the needs and capabilities of the actual user. They are also integrated into the immediate personal environment of the user. As a consequence, the technology is adapting to the user rather than the other way around. In order to share relevant information between systems and services, technologies for AAL should ideally be based on modular and interoperable concepts. This would also support a "virtual intelligence" of the AAL environment. However, this capacity is not absolutely required.

The potential users of such technologies are not forming a homogeneous group. They include young and healthy individuals, who are mainly interested in "lifestyle functionalities" in order to improve their individual quality of life. On the other hand, they may include individuals suffering from multiple illnesses, who are interested in maintaining a self-determined life at home. The assistance provided through AAL is not limited to the direct user. Products and services in the AAL environment will also address professional care providers, medical professionals as well as family members by providing better means of communication as well as easier social interaction.

A main driver for the development of AAL technologies is population ageing. AAL technologies can be instrumental in tackling the massively increasing cost of healthcare. Another driver is the rising number of single person households in combination with rising expectations towards the quality of life. AAL technologies also cater towards the increasing demand of safety, comfortable living environments as well as the increasing demand for communication and stronger social interaction with others.

Intelesens technology platforms provide caregivers with a set of non-invasive, wearable tools to monitor the health and activity levels of those requiring assistance, such as the elderly, enabling the subject to carry on a normal lifestyle confident in the knowledge that their activity and health indicators are being monitored for behavior outside of that which is expected.

In the event of a measurement or a combination of measurements deviating from the norm, intervention by the carer can be triggered. This can result in much faster intervention and treatment, often allowing easier preventative steps instead of the distress of more invasive later procedures.

3. Electrodes

Intelesens are world-renowned experts in providing high quality electrodes for use on the human body.

Designed and manufactured for use with in-house products and also for use by OEMs with their own products, our electrodes utilize Intelesens long standing expertise in electro-gel applications to provide high quality and long life. This expertise is based largely on the company's three founding professors who have widely published on medical electrodes, sensors and devices.

We have been supplying electrodes to well known defibrillator manufacturers since 2002 and have

established a manufacturing line for the Intelesens Pre-connected Defibrillation Pads. These electrodes are specifically aimed at OEM defibrillator manufacturers and can be provided in own-brand form with any connector required.

Pre-connected electrodes save vital time in AED and PAD systems by allowing electrode connection prior to use without breaking the seal. The Intelesens pre-connected electrodes use a new and unique design which results in a more cost effective and yet very high quality electrode.

These electrodes meet all the relevant standards and are CE and FDA approved:

- Design and manufacture of multi-positional electrode arrays

Our experience in electrodes includes:

- Ability to replace a group of slow-to-fit electrodes with a single 'patch' electrode
- Screen printing electrode manufacture using solid gel allowing all shapes to be catered for while providing the most efficient pick-up of vital signs
- Defibrillation electrodes with excellent recovery times
- AAMI standard and CE/FDA certification of electrodes

Sensors

Intelesens are world-renowned experts in providing high quality sensors for use on the human body.

The quality and depth of our expertise is such that medical device manufacturers from all over the world now approach Intelesens when a new sensor is required. Our expertise is deeply entwined with the extensive skills and facilities at the University of Ulster Belfast, including the Nanotechnology & Integrated BioEngineering Centre.

We design and manufacture sensors to order, for use with in-house products and also for use by OEMs with their own products.

Our experience in sensors includes:

- Extensive manufacturing experience to consistently produce quality sensors in quantity
- Science of the skin including long term non-irritant materials
- Medical design of sensors for best signal to noise
- Design to remove motion artifacts
- Innovative sensing e.g. for core body temperature, respiration, impedance mapping and much more
- Clinical trials of medical devices in controlled conditions with suitable numbers of relevant patients

6.2 Project Management

Activities relevant to project coordination and management, project documentation and reporting, quality control, validation and verification (max 10 lines)

The main team (see also in Description of research team/Institution), that is Clif Alferness - Non Executive Chairman, Michael Caulfield – CEO, Professor John Anderson, Professor James McLaughlin, Deirdre Francis - Business Manager, is responsible for the coordination and management of the Intelesens working groups and staff.

6.3 Project Implementation

Main elements associated with the project implementation. Realization of new idea, or new technological

realization or improvement / novelty to known technology and means to achieve this. Innovation associated with the project realization in terms of new products, services, methodologies. Marketing, advertising and customer service. (max 10 lines)

In designing, manufacturing and gaining approval for wireless vital signs monitors and electrodes/sensors, Intelesens uses a number of core skills. These include:

- Compact, lightweight, wireless telemetry.
- Cellular phone-based communications for immediate data transfer to the clinician.
- Low power consumption electronics enabling body-worn devices to operate for up to a week.
- Cardiology including expert algorithms to automatically identify significant cardiac events.
- Body sensors and low level signal processing to pick up various vital signs with minimum noise.
- Science of the skin including long term non-irritant materials.
- AAMI standard and certification.
- Screen printing solid gel electrode manufacture in any shape.
- Clinical trials of medical devices in controlled conditions with suitable numbers of relevant patients.
- Defibrillation electrodes including low noise, high stability and quick recovery times.
- Medical systems approval – FDA and CE.

In the previous paragraphs details about innovation, products, methodologies, policies and marketing issues are given.

6.4 Project Evaluation

Project feedback mechanisms and evaluation mechanisms. (max 10 lines)

Intelesens operates a Quality Management System which is audited and accredited by:

SGS UK Ltd, Yarsley International Certification Services

ISO 13485:2003 Medical Devices

ISO 9001:2008 Quality Management System



ISO 13485:2003 standard is recognized as the basis for quality systems meeting the Council of the European Communities Medical Device Directive 93/42/EEC.

The Company is registered with MHRA (Medicines and Healthcare products Regulatory Agency) the UK Competent Authority for placing medical devices on the market within the EU member states as required by the Medical Devices Regulations 2002: Regulation 19. As an OEM the company has experience in producing CE marked devices to both MDD and FDA requirements.

In addition, Intelesens proceeds to specific reliable actions to evaluate its products. For example, Intelesens Ltd. announced (on Sept. 2010) the commencement of a world-first clinical trial to evaluate one of their devices at Massachusetts General Hospital (MGH) and Spaulding Rehabilitation Hospital

in Boston, USA. The company has developed a unique body-worn, non-invasive, wireless, vital signs sensor, Aingeal, which is attached via an adhesive electrode patch to a patient's torso and which measures ecg, heart rate, temperature, motion and, for the first time in an ambulatory patient, respiration rate. The device can be worn by the patient from admission at ER all through the patient's journey in hospital, up to discharge. The patient's vital signs are monitored continuously and sent to the hospital records system via their secure Wi-Fi network. The trials running through July are designed to test the sensor accuracy and to gather feedback on the wearability/usability of the Aingeal system. Patient vital signs will be tracked in three settings: the MGH Operating Room (OR), the MGH Sleep Lab and in the Spaulding cardio-pulmonary research centre. The Intelesens team has been collaborating with The Sims Innovation Lab at Partners Healthcare and CIMIT (Center for the Integration of Medicine and Innovative Technology) under the leadership of Dr. Nat Sims. The development of the device has been supported by Invest Northern Ireland and CIMIT in Boston. The results of the trials will be used as part of an FDA regulatory submission expected to be approved by January 2011.

Another example refers to a tiny device invented by Intelesens which will enable clinicians to assess a patient's condition irrespective of where they are. The ground-breaking "no wires" technology will also help to reduce patients' time in hospital, free up beds more quickly and cut down in-patients' appointments. "It won't matter whether the patient is in hospital, at home recuperating - or holidaying in, say, Spain or South Africa," according to Michael Caulfield, chief executive of ST+D. "Doctors will be able to click onto a website and review the state of their patients' health. The breakthrough is based on a disposable adhesive electrode patch worn on the patient's chest. A small electronic unit with wireless technology is attached which sends processed signals back to the doctor."

The company has revealed that a specific version of the device is now being developed by Intelesens and clinically trailed in collaboration with the Royal Victoria Hospital in a project which has been funded by the Wellcome Trust, the UK's largest medical research charity. This programme-related investment by the Trust is the first of its kind for a private sector business in Northern Ireland and will be of significant interest globally to healthcare organizations. Ted Bianco, Director of Technology Transfer at the Wellcome Trust, said: "*Our translation awards are designed to facilitate the development of medical products in areas of unmet need in healthcare. In this way, the Wellcome Trust aims to bridge the gap between a good idea and an innovative tool with the potential to improve the lives of patients.*" This device certainly has the potential to change the way doctors monitor their patients' hearts. Testing it in a hospital environment is the first step to validating the technology and gaining useful insights into how it might best be deployed, both in the clinical setting and beyond."

7. Description of Research team/Institution

Short description of R&D team and institution (max. 10 lines)

The three Founders of Intelesens are part of a knowledgeable R&D group with substantial expertise in the field of sensors and related technologies. They have an impressive record of publications, conference visits, guest speaking assignments and patents demonstrating world-class skills in Clinical Instrumentation, Thin Film Devices & Physiological Sensors. Professor John Anderson is Chief Technology Officer and Professor Jim McLaughlin is Chief Scientific Officer.

On the other hand, NIBEC - the Nanotechnology and Integrated BioEngineering Centre is a research complex at the University of Ulster's Jordanstown campus. NIBEC represents a consolidation of research groups, associated with advanced material types used in medical devices, electronics, photonics, nanotechnology, sensors, MEMS, optical and environmental devices.

The facilities house sophisticated nano-fabrication, biological and characterization equipment. NIBEC is staffed by an experienced team of researchers and academics working predominantly at the interface of bioengineering and nanotechnology. The centre's origins are related to historical local developments in the areas Defibrillators and Remote Sensing otherwise known as Connected Health

today.

Specifically the main team is as follows:

Clif Alferness - Non Executive Chairman

Clif Alferness is based in Seattle USA and is the co-founder of eight medical device companies that have collectively raised more than \$300 million. Alferness is a director of Spiration and Calibra Medical. He is the inventor of the Acorn Cardiac Support device and founded Acorn Cardiovascular, Inc. Mr. Alferness also was a co-founder of InControl, Inc., which developed and patented technology for atrial defibrillation. Mr. Alferness has 35 years of research and development experience in the medical device industry, including management positions at InControl, Inc., Physio-Control Corporation, and Medtronic. He is the author of numerous scientific papers and holds more than 70 issued U.S. patents for medical devices. He is also a co-founder of Cardiac Dimensions Inc., Archus Orthopedics Inc., and EndoGastric Solutions, Inc

Michael Caulfield – CEO

Michael Caulfield joined the company in 2005 following an eight year career in telecoms, working in mainland GB. During that period he held a number of senior roles which included responsibility for the European and Chinese manufacturing divisions of telcoms companies including Marconi, Reltec and Viasystems. Previously he has worked in senior management positions with a number of technology businesses including Seagate and International Rectifier. He was responsible for setting up the Seagate factories in Northern Ireland now employing 2000 people.

Professor John Anderson

Professor Anderson holds a M Phil and D Phil in BioEngineering and was granted a Personal Chair in Medical Electronics in 1990. He has been Head of School, Electrical and Mechanical Engineering, University of Ulster, Head of BioEngineering at the Royal Victoria Hospital and Director of the Northern Ireland Bio-Engineering Centre. In 1994 he was made a founding Fellow of the Biological Engineering Society. He has published over 300 papers in the field of bioengineering research and holds 18 patents in the field. Prof. Anderson was responsible for the development of the world's first truly portable defibrillator designed for use outside of the hospital. He has created a number of companies all providing leading edge medical products in the areas of defibrillators, body surface mapping and implantable atrial defibrillation.

Professor James McLaughlin

Jim is a Professor of Nanotechnology in the School of Electrical and Mechanical Engineering and the Director of the new NIBEC (Nanotechnology and Integrated Bioengineering Centre) where he has over 70 researchers. Specific interests address thin film deposition and characterisation of advanced materials and a wide range of micro-sensor and coating systems. New work is studying dense plasmas and ways of deriving carbon sensing elements via nanotubes with functionalised surfaces for the immobilisation of bio-fluids. He has over three hundred publications and achieved outstanding paper awards at conferences in Japan and Europe as well as being honoured as an invited speaker at ten International Conferences. He has set up formal collaborations with Cambridge, Surrey, Nanyang, North Carolina State University, the National University of Taiwan and various EU universities.

Deirdre Francis - Business Manager

Deirdre, who has been consulting to Intelesens since late 2007, has joined Intelesens's Executive Management team having been appointed Intelesens Business Manager. She has a BA in Business Studies and Postgraduate Diploma in Marketing. Deirdre was Finance Director of Mindready Solutions, the quoted Canadian Technology company (now trading as Avera Europe) . Previously she was a Director of Yelo Limited and part of the team which lead the successful acquisition by Mindready Inc.

8. Applied Financial Mechanism

Describe financial mechanisms applied in transformation of research into innovation within BP, as well as means of connecting scientific research team and financiers (max. 1000 char.)

Intelesens is privately-held and backed by venture investors Enterprise Equity and Clarendon Fund Managers. The company achieved a £1.7m financing round from Enterprise Equity, Invest NI and UUTech, the knowledge and transfer arm of the University of Ulster in 2005.

9. Impact and benefits

Describe achieved benefits of R&D team and/or enterprise implemented innovation, as well as impacts on institutional and policy levels. (max. 1000 char.)

Intelesens Ltd. designs and manufactures non-invasive wireless medical products, and sensors and electrodes for original equipment manufacturers. Its products include vital sign monitoring system, which monitors non-invasively vital signs, such as respiration, oxygen in the blood, temperature, and ECG, as well as used in instantaneous holter monitoring, in-hospital multiple vital signs monitoring, and primary care pulse wave velocity applications; pulse wave velocity system that measures arterial stiffness associated with hypertension, diabetes, and risk of heart attack, as well as used for medical research and physician applications; and electrodes and sensors, including de-fibrillation pads, electronic noses, and biometric sensors. The company also provides electronics systems design, embedded processing and DSP, wireless communication, case and branding design, and sensor/electrode design services.

10. Sustainability

Provide information on sustainability of innovation after financial aid within implemented financial mechanisms, and some multiplier effects as replication and extension of the action performed in BP. Expected use of Best Practice and lifecycle considerations. (max. 1000 char.)

Intelesens has established strong partnerships with a number of key – player companies in the field of medical technology such as Welch Allyn, EquipMed, Intel Digital Health and others. The company has developed a range of tele-sensing devices and also provide sensor device services for Original Equipment Manufacturers (OEMs).

For example, recently it was announced that "...two companies that have already benefited from the Innova programme are Dublin based tele-health software firm Valentia Technologies and medical devices company Intelesens in Belfast. Together they have developed an innovative heart monitoring device that is worn by a patient in the home to monitor vital life signs in real-time and transmit this information directly to the hospital, GP, care-worker or member of the family...". The Irish Times refers to this co-operation on October 29, 2010 to an article titled "Get help in a heartbeat", where it is stated: "...CARDIAC MONITORS: HOLTER MONITORS have been used since the early 1960s to monitor heart activity and, while they are effective, they are cumbersome to wear. Patients also have to visit their hospital or GP to return the device at the end of the monitoring period.

New to the market is the V-Patch, a discreet cardiac arrhythmia detection device that uses the cellular network to transmit data directly to the hospital or GP in real time. When the monitoring period is over, the patient can throw away the adhesive patch securing the monitor and return the rest of the device by post.

The patch was developed by Intelesens, which is at the leading edge of non-invasive vital signs monitor development, using both cellular and wireless technology. The enabling software is the work of Valentia Technologies, which specializes in developing healthcare software for in-community health

and social services delivery.

Co-operation between Valentia Technologies in Dublin and Intelesens in Belfast has enabled the V-patch to be deployed in a clinical setting for the first time.

"Ours is an excellent partnership which has produced a pioneering end-to-end solution for in-community connected healthcare," says David Burrows, Valentia's business development manager. "We have linked up with the cardiac unit in Tallaght Hospital to take things forward and are also very excited by the possibilities of extending this technology into other areas such as weight, blood pressure and chronic disease monitoring. The system can also be linked into existing alert systems ...such as emergency pendants worn by older people."

The V-Patch "can recognize 10 different heart arrhythmias and immediately send this information directly to the clinician," says Michael Caulfield, the chief executive of Intelesens, which is a spin-off from the University of Ulster.

"This can result in much faster treatment, often allowing easier preventative steps instead of the distress of more invasive procedures later on," he says. "V-Patch... reduces the need for in-patient monitoring, which is also advantageous for today's healthcare providers for whom it is all about doing more with less..."

11. Repeatability and transferability

Lessons learned from the project implementation team. Repeatability and transferability of the project. (max. 1000 char.)

Due to the nature and reliability of the Intelesens products and expertise (Wireless telemetry, low power consumption electronics, Embedded software, Cardiology, Body sensors and low level signal processing, Screen printing solid gel electrode manufacture, Science of the skin including long term non-irritant materials, Defibrillation techniques and recovery, Medical systems approval – FDA and CE) the solutions given for the problem of improving the quality of life can be effectively repeatable and transferable.

From the overall description of the philosophy, know-how and products, in addition to its worldwide clients, it is clear that Intelesens is an internationally recognised, leading innovator in targeted non-invasive wireless vital sign monitor development, dynamic and fast growing. Intelesens develops and manufactures its own products and also products for other original equipment manufacturers (OEMs). The company business model is very flexible and includes design, design and manufacture and licensing. Its expertise is focused mainly in the design and manufacture of high performance sensors and electrodes. Intelesens naturally broadened into designing the actual monitoring systems and now its market-leading Wireless Vital Signs Platform forms the basis of many OEM products. The benefits and cost savings of wireless monitoring are widely agreed with Intelesens poised to take advantage of this growing market. With its continued excellent links into a number of world-leading research institutes, Intelesens has an established IP pipeline of new products innovations.

Finally, Intelesens is privately-held and backed by venture investors Enterprise Equity and Clarendon Fund Managers. The company achieved a £1.7m financing round from Enterprise Equity, Invest NI and UUTech, the knowledge and transfer arm of the University of Ulster in 2005.

12. Evaluation

Describe reasons and evaluation criteria why the described example is a best practice. (max. 1000 char.)

This GP is an excellent example how accumulated experience and research transforms to a profitable

Good Practice Report

company with fast growth. Funded by private and public institutions, Intelesens continues to produce cutting edge medical sensor equipment capitalizing on 35 year of research of some of its founders. This company demonstrates a flawless collaboration between academia and the industry in applied research while it clearly illustrates the importance of public and private funding bodies.

13. Contact of research team/institution	14. Contact of financial mechanism facilitator
<i>Name, address, tel., fax, e-mail, URL</i>	<i>Name, address, tel., fax, e-mail, URL</i>
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