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Best Practice Report

Cardio & Brain Signals - Signal conditioning system for physiological signals

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Contact	**: vladimir.jovan@ijs.si**
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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	Bojan Musizza	JSI
	Vladimir Jovan	JSI

1. Best Practice Title

Cardio & Brain Signals - Signal conditioning system for physiological signals

2. Location of Best Practice

Country, region, town

The Cardio & Brain Signals is currently being used at the following institutions:
1. Royal Lancaster Infirmary, Lancaster, UK
2. Ulleval University Hospital, Oslo, Norway
3. Department of Physics, University of Lancaster, Lancaster, UK
4. Medical Faculty, University of Ljubljana, Ljubljana, Slovenia
5. Institute of Pathophysiology, Clinical centre, Ljubljana, Slovenia
6. Department of Psychology, Faculty of Arts, University of Ljubljana, Ljubljana, Slovenia

3. Best Practice Executive Summary

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

The Cardio & Brain Signals was developed by joint effort of several research institutions under the 6th framework project BRACCIA. The development team was funded by the EU and Slovenian research and development agency. The main goal was to design and develop a new system for data acquisition, where the main stress would be on signal conditioning and high quality AD conversion, as well as, the instrument had to be easy to use and operate. The approach was to build an instrument as an embedded system, with soft-core programmable processor, which would process data from high end audio AD converters and send them to the standard PC via USB. The system was successfully used for a number of measurements on humans and rats during anaesthesia under the project BRACCIA. Lately the system is also used by other research institutions for their specific use. More specifically the system was recently used at the Faculty of Arts, at the University of Ljubljana in a study, where cognitive functions were monitored during a mental task.

4. Best Practice Classification

Best Practice Theme
X 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
 X Intelligent Devices
 □ Distributed Control Systems
 □ Flexible Manufacturing Systems
□ Embedded Systems
 □ Industrial Embedded Systems
 □ Nomadic Environments
 □ Private Spaces
 X 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)

The »Cardio & Brain Signals« is a 12-channel signal conditioning and acquisition system, specially designed for the purpose of measuring and observation of the causality of interactions between the natural biophysical oscillations during general anaesthesia. Ideas from different professional backgrounds were included in the specifications for the device. Additionally, several BRACCIA project members contributed to the design specifications. On the other hand, the technical design and construction of the device was performed by single project subcontractor (Jozef Stefan Institute), who was specialized in development of similar devices.

Primarily the device was intended for use by the project members, while the financial exploitation was of secondary importance. With the conclusion of the BRACCIA project the obtained experimental results in combination with the »Cardio & Brain Signals« device show great potential for the commercial exploitation.

The device technical design is based upon high-end A/D conversion. Next, the digitised signals are preprocessed by a soft-core processor and sent via USB to a standard PC equipped with custom software for additional data processing, monitoring and storage. The fact that the signals are preprocessed by an embedded system makes it very easy to use.

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)

The necessity for tackling state of the art problems in medicine under FP6 enforced an innovative approach to the design of the »Cardio & Brain Signals«. First, multidisciplinary team was responsible for design specifications and second, high professional standards were applied in technical design and specification. The scale of the project required funding from various institutions. While the primary phases of the project were funded by the BRACCIA project and Slovenian National Research Agency, the final stages of the project were directly funded by the project members and other users.

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)

The device was designed to target hospitals and various research institutions as primary customers/users. With new publications in international journals from studies performed with the »Cardio & Brain Signals«, the device is proving to be useful on different areas than it was designed for and is being internationally recognised.

Currently, the prospects for economic exploitation look promising. Firstly, because there are many potential customers, e.g. Hospitals. Secondly, the device is very interesting because it has the potential to improve the quality of life for patients. Next, the device is universal and can be used in different fields of medicine either as a purely experimental device or as commercial device targeting specific needs, e.g. Monitoring depth of anaesthesia.

5.2 Objectives

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

The aim of the project was to develop a universal embedded platform for high quality signal acquisition, which could be tailored for a specific need. The hardware could be used in different scenarios by simply modifying the acquisition software running on standard PC. Additionally, the system should be easy to use by personnel with different professional backgrounds, mostly medical staff.

In order to achieve this goal the system included several innovative features. First, international and multidisciplinary team was involved in the development of the specifications for the device. Second, the device was designed by professionals with long term experiences in the field of electronics. Next, the device was designed with simple housing with no buttons. So the operator must only attach the sensors and connect the device to the PC via USB and start the software to begin recording. Next, the device could be powered via mains power supply or in case of bad signal quality with battery. This feature enables the device to operate in electrically polluted environments. Next, the device is operated via software with simple and intuitive GUI design. Consequently, these features enable the device to be universal and easy to use in various scenarios.

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)

The »Cardio & Brain Signals« was developed under the 6 FP project BRACCIA to cover the specific needs of the project. The device is a signal conditioning and acquisition system, specially designed for the purpose of measuring and observation of the causality of interactions between the natural biophysical oscillations during general anesthesia.

The primary users of the device were the members of the BRACCIA project. After the project finished in 2008 new applications and users are appearing. These are mainly hospitals and research institutions.

The development of the device begun with the analysis of the requirements and definition of the specifications for the device. This was performed by an international team of experts. Next, the technical design and the implementation of the device were performed by the Department of Systems and control at »Jozef Stefan Institute«. The department has rich experiences in developing similar medical devices. Here all required standards were incorporated in the design of device. Next, the testing was performed by the BRACCIA project members. The feedback obtained from the test measurements was used to improve the device.

6.1 Project Design

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

In order to tackle state of the art problems in medicine the device had to implement high standards for medical safety. Also, the device had to be reliable and user friendly. The design phase required a multidisciplinary team of experts, while the implementation required a team of dedicate professionals. Additionally, life-cycle concept was introduced in the design of the device.

6.2 Project Management

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

The development and implementation of the device was coordinated by the BRACCIA members specifically by the coordinator of the project. The progress was assessed on biannual project meetings, where the progress was presented. Here different design issues were discussed and resolved. The development process was documented in several internal documents (project and work reports), as well as, as articles in journals and as book chapters. The work that was published in several high impact journals serves as a validation and verification of the device.

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)

The project of design and implementation of the»Cardio & Brain Signals« device included several innovative ideas and approaches. First, the device was designed as a high quality multichannel signal conditioning and acquisition device, with embedded soft-core processor for digital signal preprocessing. Second, the device was constructed to be easy to use, with single USB cable to transfer the data to the standard PC for data monitoring, processing and recording. The software running on PC was designed to be intuitive and easy to use. These ideas were realised by

multidisciplinary approach to the design phase and professional approach to the implementation phase where the technical design was based on rich experiences in design of similar devices.

This approach enables the »Cardio & Brain Signals« to be used in many different medical applications. Because research based on »Cardio & Brain Signals« measurements is still being published new possibilities for applications are constantly arising.

Figure 1: Cardio & Brain Signals

Figure 2: Cardio & Brain Signals in use

6.4 Project Evaluation

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

The project received an important feedback from large set of measurements performed at three research institutions during project BRACCIA. The device and the accompanying software went through several iterations where the hardware and software were upgraded to improve performance and eliminate any possible errors. Besides that, several journal papers were published from data recorded with the »Cardio & Brain Signals«.

7. Description of Research team/Institution

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

The research and development of the device was done in two phases. Firstly, the requirement analysis and specifications were developed by BRACCIA project interdisciplinary team of experts with different professional background (medicine, physics and electronics) from:

- Lancaster University, Department of Physics, UK

- University of Ljubljana, Medical Faculty, Institute of Pathophysiology, Slovenia

- Morecambe Bay Hospitals NHS Trust, Royal Lancaster Hospital, Department of Anaesthesia, UK

- Ecole Polytechnique Federale de Lausanne, School of Computer and communication Sciences, Swiss

- Ulleval University Hospital, Medical Faculty at the University of Oslo, Norway

- Universitaet Potsdam, Institute fuer Physik, Germany

- Ustav Informatiky AVCR, Institute of Computer Science, Czech Republic.

Secondly, the system was designed and finalized at "Jozef Stefan Institute" by the members of the Department of systems and control. The activities of the Department of Systems and Control include analysis, control and optimization of various systems and processes. Several activities are performed within this frame:

1. research and development of new methods and algorithms for automatic control,
2. the development of procedures and software tools to support the design and building of control systems,
3. the development of special measuring and control modules,
4. the design of computer aided systems for control and supervision of devices, industrial and other processes.

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.)

The development and implementation of the Cardio & Brains Signals was supported by various funding institutions. The basic financial support came from the BRACCIA project, which also gave the initiative to produce a high quality measuring system. Secondly, the design and implementation was partially funded by the Slovenian research agency while the implementation and further development was directly funded by the project members and other end users, such as the above mentioned hospitals and research institutions. The ongoing research is focused on supporting further development and modifications of the system, so it could be used in new research areas to tackle new problems.

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.)

The system represents a universal solution for experimental work in medical research groups. It enabled the BRACCIA project members to obtain complex physiological signals, which are otherwise hard to measure and take long time prepare the measurement setup. Consequently, new algorithms for the analysis of complex cardiovascular and neural signals were developed, which enabled improvement the understanding of the process of anaesthesia. As a result, the newly obtained results were published in distinguished journals.

In addition, the system represents a platform on which a new system for depth of anaesthesia monitoring could be developed. Furthermore, the system can be combined with additional hardware to serve as a prototype to test new medical applications, which have the potential to improve the quality of service in medical institutions.

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.)

The system was primary used for achieving the goals of the BRACCIA project. After the project ended, the system has remained in regular use in various projects and has attracted new potential users. The system enables research groups a sustainable research work in the field of depth of anesthesia monitoring, as well as, on other research fields, where different physiological studies are conducted. Lately the system has been successfully used in a study, which monitored several cognitive functions during a mental task in humans. Currently the other types of applications are being considered in order to expand the range of use of the device.

11. Repeatability and transferability

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

»Cardio & Brain Signals« is a purpose built device for the purpose of measuring and observation of the causality of interactions between the natural biophysical oscillations during general anesthesia. Nevertheless, with minor adaptations the device can be converted for use on different problems.

Although, using multidisciplinary team in design and implementation phases assured the device is constructed according to medical safety standards and is easy to use, operators still experienced minor difficulties when performing measurements. The main sources of problems were the sensor wires, which were impractical in certain measurement setups. Therefore, future effort will be focused in development of wireless sensors, which would simplify the device even further.

12. Evaluation

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

The development and implementation of the described product is a good practice mainly due to the following reasons. Firstly, the innovative ideas were implemented during every stage of its life-cycle, resulting in an adaptable and high precision measuring system. Secondly, the interdisciplinary approach allows the device to be easily adopted in various types of research projects. Next, the system is intended to tackle complex and contemporary medical problems, which gives the user the ability to perform state of the art research. Finally, due to its universal design approach the device can either be used as a complex measuring device, or as a basis of a prototype for new application. This fact gives Cardio & Brain Signals the ability to yield high impact results.

13. Contact of research team/institution	14. Contact of financial mechanism facilitator
Name, address, tel., fax, e-mail, URL	*Name, address, tel., fax, e-mail, URL*
Department of Systems and Control Jožef Stefan Institute dr. Bojan Musizza Jamova cesta 39, SI-1000 Ljubljana, Slovenia Tel: +386 1 477 36 37 Fax: +386 1 477 39 94 E-mail: bojan.musizza@ijs.si http://dsc.ijs.si/en/	Project acronym: BRACCIA Project full title: Brain, respiratory and cardiac causalities in anaesthesia Project reference/Contract number: 517133 Sixth framework programme Call: NEST - New and emerging science and technology Action Line: NEST-2003-Path-1 Complex systems Contract Type: Networks of Excellence begin.: 01/06/2005 end.: 28/02/2009 duration: 45 months