

Military Institute of Aviation Medicine

Research Protocol

**Clinical evaluation of a fibre-optic sensor system for monitoring
respiration activity and heart work during MRI examinations**

Project PBS3/B9/41/2015

January 3, 2017

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Project summary

The main purpose of the project is to determine the possibility of assessing the level of anxiety by means of the respiration curve and/or ballistocardiographic (BCG) signal acquired from MRI patients using a fibre-optic sensor system. In many patients, the MRI examination causes enormous stress due to limited space in the scanner, isolation during the examination and high noise levels. Usually, anxiety or stress triggers an increase in respiration rate (RR), leading to hyperventilation in extreme cases. There are also frequent cases of disturbances in heart rate (HR). Thus, the symptoms of claustrophobia can be detected by monitoring respiration activity and heart work.

The fibre-optic sensor system consists of a sensor mat, an interrogator and a personal computer (PC), and records respiratory and BCG signals in patients during MRI. The metal-free sensor mat is placed under the patient's back, does not pose a threat to the patient and has no influence over the quality of imaging. The interrogation module detects the optical signal including vital signs, and the PC with software developed for signal processing and visualisation enable the MRI operator to monitor patient's RR and HR.

Up to 200 MRI patients in different age, weight and gender groups will be participated in the study. They will be asked to complete the State Trait Anxiety Inventory (STAI) questionnaire in order to estimate anxiety level before and after the MRI scanning. Relations between the STAI X-1 scores and the mean RR and/or HR values recorded at the beginning and the end of the MRI scanning will be analysed using descriptive statistic methods. Finally, the values of the physiological parameters, which may indicate a dangerous level of anxiety will be determined. Positive results of the clinical evaluation will predestine the fibre-optic sensor system to be implemented in routine MRI procedures.

General information

Protocol Title

Clinical evaluation of a fibre-optic sensor system for monitoring respiration activity and heart work during MRI examinations

Short title

Evaluation of an MRI-compatible vital signs sensor system

Acronym

OPTO-MRI

Sponsor

Military Institute of Aviation Medicine (MIAM)
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Primary Investigator (PI)

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Other medical and/or technical institutions involved in the research

No other co-operators

Rationale & background information

Recently, magnetic resonance imaging (MRI) has become one of the most common and reliable diagnostic methods in medicine. The results of the still improving imaging performances, new functionalities, and more affordable prices represent a pronounced trend toward equipping hospitals and clinics with MRI scanners [1]. The rapid development of this technology has created the need to construct devices capable of monitoring vital signs of at-risk patients during MRI examinations. The risk group in the context of MRI includes neonatal, paediatric, disabled, anesthetised, and insensible patients [2]. The monitoring of life functions is also recommended for persons with implanted pacemakers, patients developing reactions to contrast media, and persons with mental disorders who may not be able to communicate with the system operator or to use the alarm button. However, efforts are being made to monitor at least some basic physiological parameters such as respiration and heart activity [3] during each MRI examination, regardless of the patient category.

Although MRI is a noninvasive method of investigation and does not expose patients to ionizing radiation, it has some psychological effects on patients. Some researchers [4],[5] have already demonstrated that 5 to 10% of patients undergoing MRI examinations experience severe claustrophobia or panic attacks during the scanning process, whereas 30% report milder distress and fear. Such increased stress stimuli and arousal may in turn lead to a phenomenon known as hyperventilation, which is increased ventilation of the lungs and significant acceleration and deepening of the breath, often resulting in fainting.

Hyperventilation has numerous theoretical and empirical links to anxiety, panic, and fear episodes [6],[7]. This phenomenon was investigated in order to understand psychological and physiological mechanisms connected with hyperventilation that cause and maintain anxiety. On the other hand, attempts were also made to find a link between hyperventilation and the therapies used to treat different types of anxiety disorders. Some results [8] support the idea of higher variability and irregularity in the respiratory patterns of subjects with panic disorder. Other clinical studies [9] have shown that controlling and normalising the subject's breathing activity helps to reduce both anxiety and panic symptoms. On the basis of this assumption, different training and therapeutic programs [10] have been created and carried out with the aim of teaching patients to breathe in a specific way to avoid or reverse hyperventilation, e.g., capnometry-assisted respiratory training (CART) [11]. Furthermore, attempts have also been made to study the relationship between different anxiety disorders and cardiological parameters. The literature [12] reveals an increased heart rate (HR) level in a group of people suffering from panic, anxiety disorders, and hyperventilation symptoms.

In light of recent scientific reports, it seems obvious that MRI examinations can be a source of extreme stress and cause anxiety and panic symptoms in some patients. People who experience anxiety, fear, or hyperventilation during an MRI scan may either discontinue the procedure altogether or refuse to undergo MRI surveys in the future. In practice, it is very important to identify those who are likely to panic and experience anxiety-related symptoms in the MRI unit as early as possible, because only early detection ensures that appropriate actions can be taken to avoid psychological discomfort for the patient undergoing the scan and unnecessary use of the machine, as well as staff involvement in the entire procedure. Real-time monitoring of certain life functions in the patient, such as respiration rate (RR) and HR, can be helpful in controlling the arousal and anxiety level associated with the MRI examination itself and predicting the probability of a panic attack.

Conventional monitoring equipment is not designed to work in the harsh MRI environment, distinguished by a magnetic induction of 1.5 T, 3.0 T, or even higher values and with radio frequency (RF) impulses of considerable electromagnetic (EM) field intensity [13]. The presence of metal or electronic components under such conditions can cause burns on the patient's skin and alter the EM field distribution and, thus, degrade the quality of imaging. Additionally, the signal transmitted using electrical conductive wires is vulnerable to the effects of a strong EM field, which complements the list of drawbacks of typical electronic measuring devices. On the other hand, optical sensors are fully penetrable in terms of the EM radiation applied in MRI, causing no interference. They are free from metal parts and function via optical fibres, resulting in their immunity to EM fields.

Study goals and objectives

The main objectives include:

1. Testing the sensor system with participation of MRI patients, where the result measures relate both to feasibility and health outcomes.
2. Verifying the signal quality, detecting RR and HR, and checking long-term measurement capabilities of the sensor system.
3. Analysing changes in RR and HR in the context of the system ability to detect a high level of stress, hyperventilation and other symptoms of claustrophobia in MRI patients.

Study Design

The acquisition of physiological signals relies on placing the sensor mat under the patient's back during standard MRI procedures. Before and after the MRI scanning, the patient gets to complete the State Trait Anxiety Inventory (STAI) questionnaire. The part of the body that is being scanned and the time of the MRI examination are not relevant. Although an average MRI scanning lasts from 20 to 40 minutes, we assume that the study will be no longer than 1 hour as the administration of contrast media may prolong the survey. Up to 200 MRI patients of different age, weight and sex will be involved in the study. Exclusion criteria from the study are the same as exclusion criteria from MRI procedures. The sensor mat does not cause health changes in patients and the study is of observational type. The analysis will concern changes in RR and/or HR during MRI, with particular emphasis on the beginning and the end of the examination, i.e., 1- or 2-minute parts of the whole recording, as it shown in Fig. 1. The mean RR and/or HR values recorded at the beginning and the end of the MRI scanning will be referred to the STAI X-1 scores gathered before and after the MRI scanning, respectively. The research scheme includes also the collection of the STAI X-2 subscale before the MRI scanning.

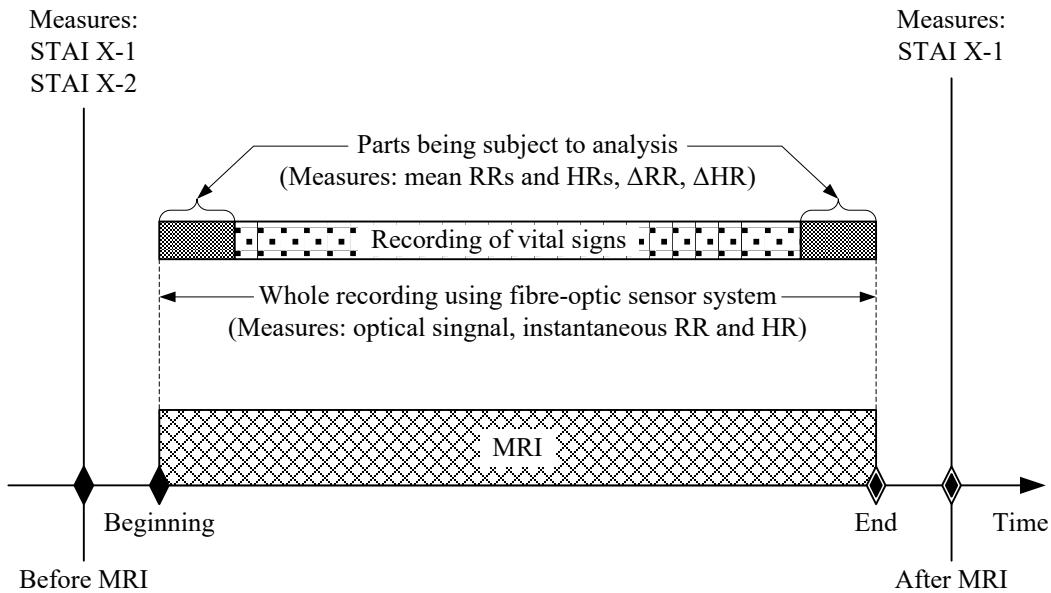


Fig. 1. General scheme of the study.

Methodology

Fibre-optic sensor system

The sensor system consists of a sensor mat, an interrogation module and a laptop personal computer (PC). As shown in Fig. 2, the sensor mat includes a spring-board that converts body movements including lung- and heart-induced motions into strain, and a single fibre Bragg grating (FBG) or an FBG matrix bonded to the board measures this strain. The instantaneous spectral position of the FBG reflection peak can be calibrated in terms of the respiration and heart activity readings. Thus, the sensor also acquires ballistocardiographic (BCG) signals, and to operate effectively, the mat has to be placed between the back of the patient (as close to the heart as possible) and the mattress of the MRI track table.

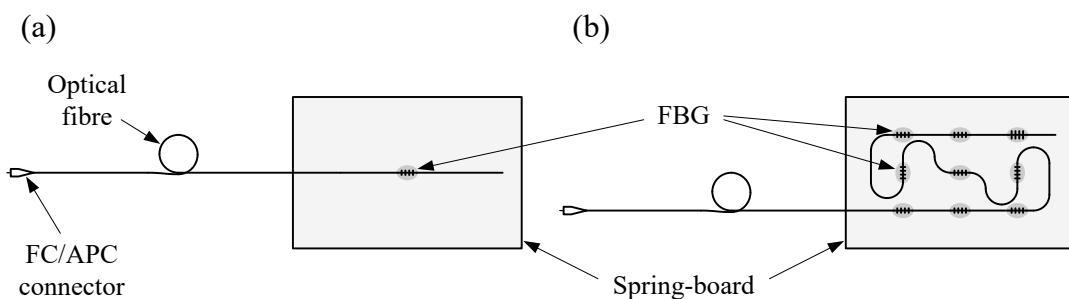


Fig. 2. Sensor mat based on a (a) single FBG and (b) FBG matrix.

A schematic of the research setup is shown in Fig. 3. The sensor mat is placed in the MRI chamber underneath the chest area of the patient to ensure proximity to the heart and lungs. A few meters optical fibre is threaded through a wall opening and connected via a fibre-optic for angled physical contact (FC/APC) -type connector to an FBG interrogation module in the operation room. To interrogate the sensor mat, a commercially available DL-BP1-1501A broadband light source by *DenseLight Semiconductors* [14] with I-MON 256/512 USB monitor by *Ibsen Photonics A/S* [15], or sm130-700 integrated unit by *Micron Optics* [16] will be used. The data from the interrogation module is sent via an USB or Ethernet interface

to the laptop PC with software developed for signal visualisation, data archiving as well as automatic determination of RR and HR.

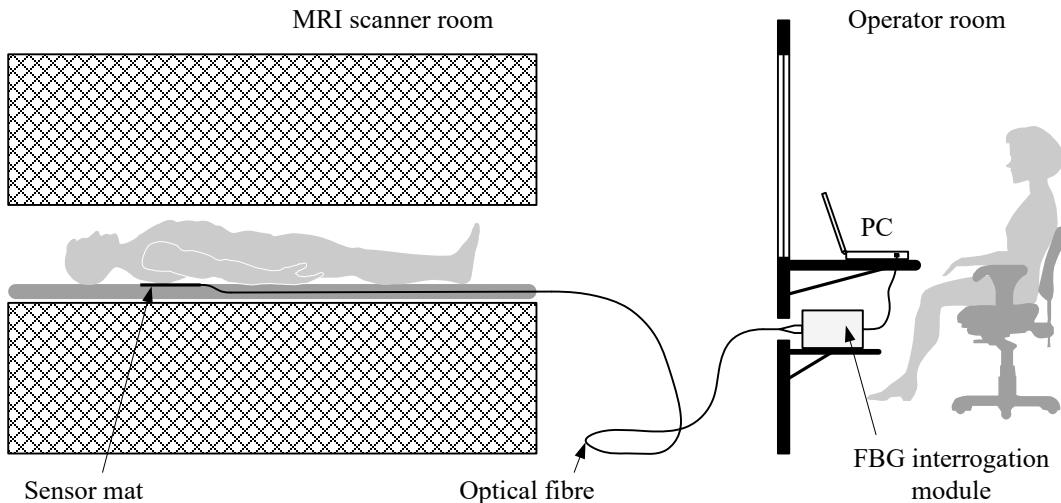


Fig. 3. Research setup.

MRI scanner

Achieva 1.5T by *Philips* [17] or Discovery MR750w 3.0T by *General Electric* [18] MRI scanners will be used in the study.

STAI

In order to measure anxiety in patients undergoing MRI procedures, the Polish version of the STAI by Spielberger et al. [19] was used. The inventory is designed to measure the level of anxiety as a current state in response to a given situation (the X-1 subscale) as well as a relatively stable personal trait (the X-2 subscale). Evaluation of anxiety level in patients will be conducted according to a repeated measurement protocol. The subjects will complete the STAI X-1 subscale twice, i.e., just before entering the MRI scanner and immediately after leaving the scanner. The STAI X-2 subscale will be completed before the MRI scanning. As a result, the level of experienced anxiety before and after the MRI scanning, as well as the level of anxiety as a constant personality trait in patients, will be obtained.

Safety Considerations

The presence of the sensor mat during the MRI examination does not pose a threat to the patient. Because the sensor mat is free from metal elements, it is fully penetrable by the EM radiation used in MRI and causes no interference. We have previously showed that the fibre-optic sensor is transparent to the MRI system and does not introduce any artefacts into the spin echo (SE) T1 weighted and T2 weighted or to the gradient echo (GE) T2 weighted imaging sequences [20],[21].

Follow-Up

No recommendations other than for standard MRI procedures.

Data Management

MIAM is both a research institute and medical centre, where data management and information security are provided in accordance with the ISO IEC 27001 standard. A copy of the certificate is included as **Appendix A**.

Statistical Analysis Plan

Descriptive statistic methods will be used to evaluate the state anxiety and RR and/or HR indicators, as well as to assess the difference between the first and second anxiety measurement. A correlation analysis with the Pearson product-moment correlation coefficient will be performed to check if the initial RR and/or HR level is related to state anxiety measured right before the MRI study.

Since we hypothesise about the individual variability of the change in the RR and/or HR levels during an MRI session, a growth mixture model analysis [22] will be performed to statistically differentiate the subject groups according to the trends in repeated measures of RR and/or HR. After that, the analysis will be performed with the use of the Student's t-test to check whether the so-identified groups differ on the magnitude of change in the state anxiety observed during the study. An Alpha level of 0.05 will be used in all of the statistical tests.

The analysis will be performed using R statistical software version 3.4.0 [23]. The Growth mixture model analysis will be performed using the lcmm package version 1.7.7 [24]. The power analysis will be performed with the pwr package version 1.2-1 [25]. Plots will be created using the ggplot2 package version 2.2.1 [26].

Quality Assurance

MIAM has a quality management certificate based on the ISO 9001:2008 and AQAP 2120:2009 requirements. Copies of the certificates are included as **Appendix B**.

Expected Outcomes of the Study

Correlations between the STAI X-1 scores collected before and after the MRI scanning and the mean RR values recorded at the beginning and the end of the MRI scanning, respectively, are expected. Similarly, correlations between the STAI X-1 scores and the HR indicators should also be noticeable. We also expect the STAI X-2 scores will be useful in estimating the risk of anxiety symptoms during MRI.

At least two manuscripts, one containing the results of the STAI scores in relation to RR, and the other containing the results of the STAI and HR analysis, will be submitted for publication.

Dissemination of Results and Publication Policy

The results will be first reported to the National Centre of Research and Development (NCRD), Poland, in the form of mile stone reports.

The publications will be prepared under the leadership of the PI. The PI decides on the author lists. Only persons who gave the conception of the sensor system, designed and constructed the sensor mat, designed the experimental protocol, coordinated the study, processed data for analysis, analysed and verified data, and interpreted the results, can be included on the author lists. The person who contributes the most to the preparation of the manuscript will be its first author. If the PI is not the author of the largest contribution, he will be acknowledged as the last author of the article.

All authors will review the manuscripts and accept their final version.

Duration of the Project

Duration of the project is July 2015 - September 2018.

Realisation of the research scenarios is scheduled for January 2017 - September 2018.

Problems Anticipated

Two main types of problems are anticipated: (1) patients' anxiety reactions and (2) hardware failures. In the first case, we will follow typical MRI procedures, including calming the patient and restoring or abandoning the examination. In the event of the fibre-optic sensor system failure, the patient monitoring and data acquisition will take place shortly after the fault has been removed.

Project Management

The project is managed in accordance with the PRINCE2 methodology. The PI manages the investigators including the project coordinator and the study coordinator. The PI shall consult and report the results of the project to the Steering Committee.

Ethics

The fibre-optic sensor system does not pose any threats to the patient. Disturbing symptoms may result from the patient's potential claustrophobic tendencies. In such cases, the standard MRI procedures should be followed.

Potential subjects will be informed on the study at least 2 weeks before the planned study. Those who are initially interested in the study participation will receive a copy of the research protocol for acquainting. They should decide at least 3 days before the beginning of the planned study and inform the study coordinator. Just before the study, the subjects will

receive two copies of the informed consent form to acquaint and sign. One of the signed copies is for the subject whereas the other is for the sponsor.

Informed Consent Forms

Copies of the informed consent forms in English and Polish are included as **Appendix C**.

Literature

- [1] Magnetic Resonance Imaging (MRI) Equipment - A global strategic business report. San Jose: Global Industry Analysts; 2015.
- [2] Shellock FG. Patient monitoring in the MRI environment. In: Shellock FG, editor. Magnetic resonance procedures: health effects and safety. Boca Raton: CRC Press; 2001. p. 217-241.
- [3] von Smekal A, Seelos KC, Kuper CR, Reiser M. Patient monitoring and safety during MRI examinations. *Eur Radiol* 1995;5:302-305.
- [4] Meléndez JC, McCrank E. Anxiety-related reactions associated with magnetic resonance imaging examinations. *J Am Med Assoc* 1993;270:745-747.
- [5] Harris LM, Robinson J, Menzies RG. Predictors of panic symptoms during magnetic resonance imaging scans. *Int J Behav Med* 2001;8:80-87.
- [6] Meuret AE, Ritz T, Wilhelm FH, Roth WT. Voluntary hyperventilation in the treatment of panic disorder - functions of hyperventilation, their implications for breathing training, and recommendations for standardization. *Clin Psychol Rev* 2005;25:285-306.
- [7] Badour CL, Feldner MT, Blumenthal H., Bujarski SJ, Leen-Feldner EW, Babson KE. Specificity of peritraumatic fear in predicting anxious reactivity to a biological challenge among traumatic event-exposed adolescents. *Cognitive Ther Res* 2012;36:397-406.
- [8] Grassi M, Caldirola D, Vanni G, Guerriero G, Piccinni M, Valchera A, Perna G. Baseline respiratory parameters in panic disorder: a meta-analysis. *J Affect Disorders* 2013;146:158-173.
- [9] Rosenfield D, Seidel A, Bhaskara L, Hofmann SG. New breathing therapy reduces panic and anxiety by reversing hyperventilation. *J Med Sci* 2011;11:327-328.
- [10] Wollburg E, Roth WT, Kim S. Effects of breathing training on voluntary hypo- and hyperventilation in patients with panic disorder and episodic anxiety. *Applied Psychophysiological Biofeedback* 2011;36:81-91.
- [11] Meuret AE, Rosenfield D, Seidel A, Bhaskara L, Hofmann SG. Respiratory and cognitive mediators of treatment change in panic disorder: evidence for intervention specificity. *J Consult Clin Psych* 2010;78:691-704.
- [12] Pittig A, Arch JJ, Lam CW, Craske MG. Heart rate and heart rate variability in panic, social anxiety, obsessive – compulsive, and generalized anxiety disorders at baseline and in response to relaxation and hyperventilation. *Int J Psychophysiol* 2013;87:19-27.
- [13] Niendorf T, Winter L, Frauenrath T. Electrocardiogram in an MRI environment: clinical needs, practical considerations, safety implications, technical solutions and future directions. In: Millis RM, editor. *Advances in electrocardiograms - methods and analysis*. Rijeka: InTech; 2012. p. 309-324.
- [14] Superluminescent LED source with integrated optical circulator DL-BP1-1501A. DenseLight Semiconductors Technical Information; 2010. [Online]. Available: <http://www.denselight.com/>.

- [15] I-MON USB interrogation monitors for FBG sensor systems. Ibsen Photonics Technical Information; 2010. [Online]. Available: <http://www.ibsen.com/>.
- [16] Optical sensing interrogator sm130. Micron Optics Technical Information; 2010. [Online]. Available: <http://www.micronoptics.com/>.
- [17] Philips Magnetic Resonance Achieva 1.5 T A series. Philips Healthcare Technical Information; 2008. [Online]. Available: <http://www.healthcare.philips.com/>.
- [18] Caring design. Insightful technology. Discovery MR750w 3.0T. GE Healthcare Technical Information, 2011. [Online]. Available: <http://www3.gehealthcare.com/>.
- [19] Wrześniowski K, Sosnowski T, Jaworowska A, Fecenec D. STAI. State and Trait Anxiety Inventory, 4th edition. Warszawa: Psychological Tests Laboratory, Polish Psychological Association; 2011.
- [20] Dziuda Ł, Skibniewski FW, Krej M, Baran PM. Fiber Bragg grating-based sensor for monitoring respiration and heart activity during MRI examinations. *J Biomed Opt* 2013;15:057006.
- [21] Dziuda Ł, Krej M, Skibniewski FW. Fiber Bragg grating strain sensor incorporated to monitor patient vital signs during MRI. *IEEE Sens J* 2013;13:4986-4991.
- [22] Jung T, Wickrama KAS. An introduction to latent class growth analysis and growth mixture modelling. *Social and Personality Psychology Compass* 2008;2:302-317.
- [23] R: A language and environment for statistical computing. Vienna: R Foundation for Statistical Computing; 2017. [Online]. Available: <https://www.R-project.org/>.
- [24] Proust-Lima C, Philipps V, Diakite A, Liquet B. lcmm: Extended mixed models using latent classes and catent processes. R package version: 1.7.7; 2017. [Online]. Available: <http://CRAN.R-project.org/package=lcmm>.
- [25] Champely S. pwr: Basic Functions for Power Analysis. R package version 1.2-1; 2017. [Online]. Available: <http://CRAN.R-project.org/package=pwr>.
- [26] H. Wickham. ggplot2: Elegant graphics for data analysis. New York: Springer-Verlag; 2009.

Budget

The project is supported by the resources of NCRD, Poland, within the framework of the Applied Research Programme.

Other support for the Project

No other funds.

Collaboration with other scientists or research institutions

Medical University of Warsaw

1. Maciej Śmietanowski, M.D., Ph.D. (physiologist)

Links to other projects

ID	Project No.	Title	Source of funding	Duration	Publications
1.	UDA-POIG.01.03.01-14-136/08	Development of methods for monitoring psychophysiological activity with automatic hazard detection	European Regional Development Fund	2009–2011	1. DOI: 10.1109/TBME.2012.2194145 2. DOI: 10.1016/j.bbe.2014.02.001 3. DOI: 10.1117/1.JBO.201.1.010901
2.	DOBR/0052/R/ID1/2012/03	Development of the ORTHO-LBNP system for research and training of Polish Air Force pilots under conditions of ischemic hypoxia and orthostatic stress	NCRD	2012-2015 (extended until 2018)	1. DOI: 10.1117/1.JBO.18.5.057006 2. DOI: 10.1109/JSEN.2013.2279160 3. DOI: 10.1109/JBHI.2015.2392796

Curriculum Vitae of investigators

PI's Curriculum Vitae

Personal information

Forename and family name: Łukasz Dziuda

Date of birth: November 21, 1976

Nationality: Polish

ORCID: 0000-0003-1816-4604

URL for web site: http://www.wiml.waw.pl/?q=pl/Lukasz_Dziuda
https://www.researchgate.net/profile/Lukasz_Dziuda

Education

2014 D.Sc.: Nałęcz Institute of Biocybernetics and Biomedical Engineering (IBBE) of the Polish Academy of Sciences (PAS), Poland

2007 Ph.D.: Department of Electronic and Electrical Engineering, University of Strathclyde, UK
Supervisor: Professor Sir Jim McDonald, BSc, MSc, PhD, DSc, CEng

2000 M.Ss.: Department of Electrical Engineering, Lublin University of Technology, Poland

Current position

2017– Associate Professor, Head of the Department of Flight Simulator Innovations, Military Institute of Aviation Medicine (MIAM), Poland

Previous positions

2015–2016 Associate Professor, Head of the Creative Neuro Science Laboratory (CNS Lab), IBBE PAS, Poland

2013–2014 Research Fellow, Head of the LBNP Laboratory, Technical Department of Aeromedical Research and Flight Simulators, MIAM, Poland

2008–2013 Research Fellow, Leader of the Medical Electronics Group, Department of Aviation Bioengineering, MIAM, Poland

2005–2007 Research Assistant, Leader of the Medical Electronics Group, Department of Aviation Bioengineering, MIAM, Poland

2004 – 2005 Temporary Assistant, Department of Electronic and Electrical Engineering, University of Strathclyde, UK

Fellowships

2000–2004 Academic Visitor, Department of Electronic and Electrical Engineering, University of Strathclyde, UK

Institutional responsibilities

2014– Representative of MIAM, Polish Technological Platform on Photonics, Poland

Commissions of trust

2017– Scientific Council, Institute of Medical Technology and Equipment, Poland (Deputy Chairman)

2014– Scientific Council, MIAM, Poland (Deputy Chairman since 2016)

2014– Ethic Committee, MIAM, Poland

2012– Reviewer of Project Applications, National Centre for Research and Development, Poland

Web of Science

h-index 11

Publications: 27

Citations: 172 (without self-citations)

Other

Patents: 3

Scholarship of the Foundation for Polish Science

PRINCE2® Foundation certificate

Other investigators

Military Institute of Aviation Medicine

1. Mariusz Krej, M.Sc. (programmer, project coordinator)
2. Paulina Baran, Ph.D. (psychologist, study coordinator)
3. Ryszard Pacho, Prof., M.D., D.Sc., Ph.D. (radiologist)
4. Paweł Rydzyński (MRI technician)
5. Dorota Okurowska (MRI technician)
6. Piotr Zieliński, Ph.D. (psychologist, statistical analyst)
7. Franciszek W. Skibniewski, Ph.D. (consultant in the field of medical monitoring)

Research activities of the PI

ID	Project No.	Title	Source of funding	Duration	Involvement
1.	DOBR/0052/R/ID1/2012/03	Development of the ORTHO-LBNP system for research and training of Polish Air Force pilots under conditions of ischemic hypoxia and orthostatic stress	NCRD	2012–2018	60%
2.	PBS3/B9/41/2015	Optoelectronic patient monitoring in magnetic resonance	NCRD	2015–2018	20%
3.	PBS3/B9/29/2015	Detector of early fatigue symptoms as an element of improved driving safety	NCRD	2015–2018	10%
4.	PBS3/B9/37/2015	System of evacuation and rescue of victims in natural disasters	NCRD	2015–2017	10%

Financing and Insurance

All diagnostic surveys and clinical trials performed at MIAM are insured.

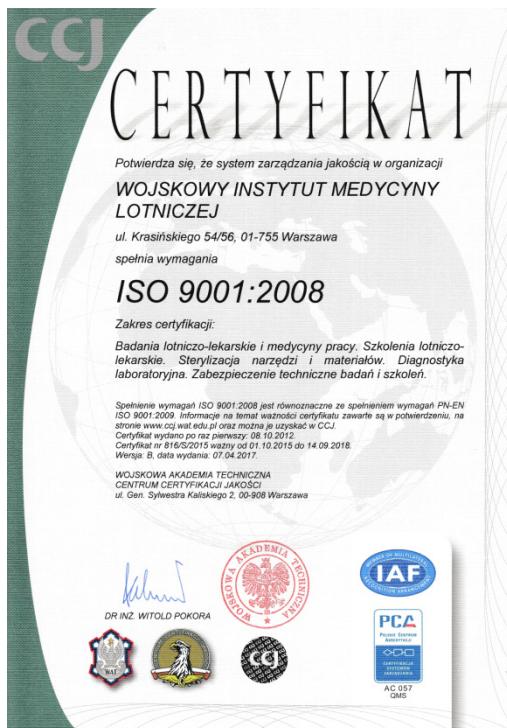
Appendix A

(Copy of ISO/IEC 27001:2013 certificate)



Appendix B

(Copies of ISO 9001:2008 and AQAP 2120:2009 certificates)



Appendix C

(Informed consent form in English)

INFORMED CONSENT FORM

Forename and family name, age:

Address:

Protocol title: Clinical evaluation of a fibre-optic sensor system for monitoring respiration activity and heart work during MRI examinations.

I hereby declare that I have been informed on the purpose of the intended research and the manner in which it is carried out. I understand what it is supposed to be and what my consent is for. I have been informed that I may refuse to participate in the study or withdraw the consent at any time, also during the study.

I express my informed consent to participate in the study, which is described on the back of this form.

I gave this consent in the presence of the witness.

Place and date:

.....

Subject's signature

.....

PI's signature

INFORMATION ON THE STUDY

Protocol title: Clinical evaluation of a fibre-optic sensor system for monitoring respiration activity and heart work during MRI examinations.

Purpose of the study: Determining the possibility of assessing the level of anxiety and stress in MRI patients using physiological data acquired by the fibre-optic sensor system.

Study design:

1. Before MRI: to complete the X-1 and X-2 forms of the STAI questionnaire.
2. During MRI: to place the sensor mat of the fibre-optic sensor system between the back of the patient (in the heart area) and the mattress of the track table of the MRI scanner.
3. After MRI: to complete the X-1 form of the STAI questionnaire.

Information:

The sensor mat placed in the MRI scanner tube does not affect the examination or its outcome in any way. The sensor mat does not pose a threat to the health and life of the patient, and also does not affect his/her well-being or comfort during the MRI examination.

Place and date:

.....

Subject's signature