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***Bulletin of Micro and Nanoelectrotechnologies*** includes the specific research studies on:

- Microelectromechanical and nanoelectromechanical components;
- The typical micro and nanostructure of actuators, micromotors and sensors;
- The harvesting microsystems;
- The conventional and unconventional technologies on MEMS and NEMS;
- The theoretical and experimental studies on electric, magnetic or electromagnetic field with applications on micro and nano actuating and sensing effects;
- The design algorithms or procedures of MEMS and NEMS components;
- The applications of MEMS and NEMS in biology and in biomedical field;
- The new materials in MEMS and NEMS;
- The standardization and reliability preoccupations;
- The economic and financial analysis and evolutions of MEMS and NEMS specific markets.

## CHRONICLE

*We dedicate the 1-2/2019 number of this Bulletin to the INGIMED XIX$^{th}$ Conference "Romanian Biomedical Engineering over the Century of Unification: history, present, perspectives" (November 22$^{nd}$, 2018) organized by INCDIE ICPE-CA Bucharest together with the Romanian Federation of Biomedical Engineering under the auspices of the Academy of Medical Sciences, with the support of the Ministry of Research and Innovation.*

*The papers represent the contributions of the participants to this event.*

*We also present, different images from INGIMED 2018.*

*Editor in Chief,*

*Mircea Ignat*

# "Alexandru Proca" Centre for the Youngsters Initiation in Scientific Research (CICST) – The participation to the INGIMED XIX$^{th}$ Conference, November 22$^{nd}$, 2018



3.3. Perioada de consolidare (~1990-2000~)


A RETROSPECT OF BIOMEDICAL ENGINEERING AT GREATER ROMANIA'S CENTENARY
Radu M. Negoescu
Academy of Medical Sciences & National Institute of Public Health, Bucharest, Romania
Radu NEGOESCU
Gheorghe MIHALAŞ


Tema de cercetare privind contributii
in domeniul microchirurgiei

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**Bioelectrosynthesis (2019) Series Title** Advances in Biochemical Engineering / Biotechnology (vol. 167) (Eds. **nisch**, Falk, **Holtmann**, Dirk) DOI 10.1007/978-3-030-03299-9, Hardcover ISBN 978-3-030-03298-2, p. 420.

The first chapter of this book concerns the *status quo* of the Electrification of Biotechnology whereas the last one concerns the question *Quo Vadis*? on the same topic! An interesting and useful loop followed by the reader of this exciting book. Thus in the first chapter there are clearly presented the history of the field of electrobiotechnology with emphasis on bioelectrosynthesis and tier links with bioeconomy (including electric energy generation via pollutant removal, the synthesis of chemicals and energy carriers etc.). Special attention is devoted to role of bacteria (e.g. the genera *Shewanella* and *Geobacter*) able of extracellular electron transfer for the development of biosensors, including the rather subtle processes involved in direct interspecies electron transfer. The following two chapters deals with the role of enzymes in electrobiotechnology with emphasis for the first chapter on the enzymatic fuel cells and electroenzymatic reactors, as well as enzymatic biosensors whereas the second one discuses mainly about media conductivity optimization, approaches to prevent enzyme inactivation, and the application of advanced cell designs. The following three chapters deal with the significance of microorganisms for bioelectrosynthesis. Engineering of Microbial Electrodes focuses on comparison of electrode materials, and methods to improve microbe–electrode interaction, including macroscopic electrode structures. The following chapters deal with microbial electrosynthesis using pure and defined mixed culture engineering and with mixed culture biocathodes for production of hydrogen, methane, and carboxylates, respectively. The chapter on Reactors for Microbial Electrobiotechnology is as interesting as any other chapters in this book, the conclusion being that there is a deeper discussion on the weaknesses and strengths of the existing types of reactors for bioelectrochemical systems and for the future engineering of MES reactors. Mathematical Modelling Microbial Electrosynthesis offers new tools in improving the performances. One of the most exciting chapters in this book focuses on Electrochemical Applications in Metal Bioleaching with special emphasis on the coupling of a mineral sulphide to a galvanic partner or electrocatalyst (spontaneous electron transfer) or by the application of electrolytic bioreactors (controlled electron transfer). The generating electric current by bioartificial photosynthesis compares the current status of bioartificial photosynthesis with other artificial systems that mimic the chemistry of photosynthetic energy transformation. The style of the whole book is clear and the illustrations very useful to the reader, arguing once again that the authors and editors are true professionals! This book should be read by professionals and managers working in many fields where electrons move from one locus to another….

*Ioan I. Ardelean*

*Microbial Fuel Cell - A Bioelectrochemical System that Converts Waste to Watts* (Ed. **Das**, Debabrata), 2018, Springer International Publishing, 1st Edition, ISBN-978-3-319-66792-8, DOI 10.1007/978-3-319-66793-5, 94 b/w illustrations, 17 illustrations in colour, 506 p.

This is a very comprehensive book which contains 25 chapters treating all aspects of microbial fuel cell. After an introductory chapter written by the editor himself, the reader is smoothly introduced (if needed) in the Characteristics of Microbes Involved in Microbial Fuel Cell as well as in Principles of Microbial Fuel Cell for the Power Generation, the biological and physical fundaments of MFC. Very methodically, the rest of the book is dealing with the anodic world, the cathodic world and with a plethora of applications of MFC. The last, but, of course, not least chapter concerns thoughts about the future of MFC, including challenges. Three chapters are focused on the anode world with special emphasis on the development of suitable anodic materials to promote Anodic Electron Transfer by different Mechanisms, and the consequences on microbial ecology in the anodic compartment. As with the anodic world, the cathodic catalysts as well as the development of biocathodes are covered by pertinent chapters- however, the microbial ecology in the cathode compartment is not covered here (probably at the 2nd edition?). One chapter is logically focused on different types of separators for the two half cells as well as Membraneless Microbial Fuel Cell. Other 7 chapters covers very interesting contributions concerning reactor design and fuel cell performances, microfluidic MFC as well as their scaling up, specific diagnostic tools and modelling reaction and transport processes in MFC. The diverse applications of MFC are presented with respect to power generation from organic wastes, alternate power tools (remote regions, medicine etc.), removal and recovery of metals (nothing said about platinum...), sediment microbial fuel cell, photosynthetic microbial fuel cell, microbial desalination cell as well as their use as biosensor and, very interestingly, microbially mediated electrosynthesis processes. The book is written by true professionals in the field whose clear style and nice illustrations help the reader (student or scientist in different fields, policy maker or anyone interested in the ballet of electrons – and protons- in this world) to progress in this field.

*Ioan I. Ardelean*

# Bioengineering, Biotechnology, Bioethics

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***Abstract*** - Although is much to be said about the effects of biotechnologies on major diseases to be prevented and combated, bioethics must be a mandatory corrective complementary to the introduction of increasingly sophisticated and performing biotechnologies.

***Index Terms*** - Biotechnology, bioengineering, bioethics, clinical engineering, Universal Declaration on the Human Genome and Human Right.

## I. INTRODUCTION

The current advances in medicine, healthcare practice and biomedical research would not have been possible without the contribution of medical bioengineering.

Unfortunately, despite this reality, the status and recognition of the bioengineer, as a necessary member integrated into the medical team, does not receive the necessary attention from the health authorities. The clinical bioengineer has not yet been introduced into the public hospital organigram to capitalize on its training and skills to bring new biomedical technologies to the hands of physicians for the benefit of patients.

These advances have been made possible through the creation and improvement of biotechnologies contributed by engineering scientists, bioengineering being those who have thought and applied the various technologies in the fields of biology and medicine.

## II. DEFINITIONS

Although biotechnology is often used as a term synonymous with bioengineering, they are in fact two different domains with its own delimitation, even if they share common applications, developments and a common protagonist: the bioengineer.

Biotechnology creates specific products that use "biological systems, living organisms or micro-organisms". Even certain complex medical devices can be included in this biotechnology area if their biological function is based on their principle of operation.

Biopharmaceuticals (e.g. vaccines), genetic engineering and some applications in agriculture are some of the main sub-domains of biotechnology. Pharmaceuticals are linked to bioengineering through two indirect ways:

1) certain products fall into both fields of activity (biopharmaceuticals, biosynthetic antibiotics);

2) together they form the area of non-medical medical bioengineering.

Biotechnology, including biopharmaceuticals, is a sub-field of medical bioengineering, along with medical devices and clinical engineering.

Bioengineering integrates the principles of physics, chemistry, mathematics and engineering for the study of biology, medicine, and health. This discipline creates fundamental concepts and knowledge from the molecular level to the systemic level and develops new biological products, materials, processes, implants and computer products for the prevention and treatment of diseases, for patient rehabilitation and increasing the level of health and quality of life in other words. It is worth noting the contribution of medical bioengineering to behavioral education in order to prevent ill-treatment and healing, amelioration and recovery.

Major bioengineering applications include, inter alia, the development of biocompatible prostheses, medical diagnostic and treatment devices ranging from chemical equipment to micro-implantation, imaging equipment such as MRI, biotechnology such as regeneration and tissue growth, and also biosynthesis and synthesis drugs.

Bioengineering is an interdisciplinary field because its applications are varied across multiple fields of practical medicine and biomedical research and, as a result of this diversity, has delimited more subdomains. A comprehensive classification is the one developed by the main US bioengineering organization that divides bioengineering subheadings as follows: biomechanics, bioinstrumentation, biomaterials, bionics, cellular, tissue and genetic engineering, clinical engineering, medical imaging, ortho-plastic bioengineering, rehabilitation engineering, systems physiology, bio-nano-technology and neural engineering.

There is another classification of bioengineering sub-domains by associating with the most well-known engineering fields:

- chemical engineering (includes biochemical, cellular, molecular and tissue engineering, biomaterials and bio-transport);
- electrical engineering (includes bioelectric and neural engineering, bioinstrumentation, medical imaging, medical devices); optics and optical engineering - biomedical optics, imaging and associated medical devices - can also be included here;
- mechanical engineering (includes biomechanics, bio-transport, specific medical devices and biological systems modeling, such as connective tissue mechanics).

Each of these domains and subdomains has overwhelming implications in current medical performance and would require separate development if we only think of organ transplant, the creation of structures similar to natural biological stem cells in human stem cells, genetic engineering, cloning techniques (therapeutics), synthetic insulin and erythropoietin production, pharmaceutical engineering, medical devices (peace-makers, infusion pumps, dialysis machines, artificial organs, implants, artificial limbs, corrective lenses, cochlear implants, ocular prostheses, facial reconstruction prostheses and dental implants.

An example of interdisciplinary use of various general engineering techniques is medical imaging that allows, as is known to investigate organs that are not visible to the human eye, using instruments, magnetism, UV and infrared radiation, X-rays and microwaves.

A few words about clinical engineering that integrates bioengineering with medical practice and whose benefits are most visible in practical healthcare.

Clinical engineering is a branch of medical bioengineering that deals with the implementation of medical equipment and technologies in hospitals. The main role of bioengineers in this field of activity is to prepare and supervise the working technicians who maintain and dismantle the medical equipment but also to choose the products / services and to install and ensure their proper use according to the needs of the hospital specialist clinics. The clinical bioengineer is also in touch with medical device manufacturers to improve their performance based on chemical experience and last but not least to intervene in case of undesirable side effects.

Although medical bioengineering responds to a real need to increase medical performance by outsourcing some of the activities currently carried out by the doctor: good knowledge and maintenance of medical equipment, innovation of new means of protection and the realization of products obtained through biotechnologies, In spite of these advantages, the clinical engineer's status, we repeat, is not the proper one for his role. For bioengineers there is currently no labor market, which does not stimulate the attention of many young people for training in this great future.

## III. BIOETHICS

Although the benefits and benefits of bioengineering and biotechnology are proven and necessary to carry out medical research, performance and innovative research progress, as in any other area of scientific progress, there are also negative side effects. Similar to pharmacotherapy that, along with beneficial, positive, curative effects develops in some cases what is called "side effects" or "adverse or even harmful effects for the body".

Pharmacovigilance, evidence-based medicine has reactions to mitigate these effects. Some of the negative effects of biotechnologies that can reach the organic and functional structures of the human body, particularly its dignity and rights, have prompted reactions to prevent and mitigate such effects.

Thus, bioethics emerged, a field of morality that defines itself as a science emerging as a reaction to these undesirable side effects. The term was proposed and launched by Van Rensselaer Potter, with international bodies currently in place to monitor and combat these effects. There is a UNESCO International Committee on Bioethics and an Intergovernmental Committee on Bioethics, where for a decade I also had the honor to represent Romania as an observer.

Among the negative practices resulting from biotechnological advances can be mentioned organ trafficking for transplantation, human cloning for reproductive purposes, the therapeutic one being beneficial, positive, the direction and choice of new-born sex, the declassification of genetic data, the genetic manipulation, the commercialization of human ovum.

In this respect, the Universal Declaration on the Human Genome and Human Rights was elaborated; in which it is pointed out that there are risks of discernment and that vulnerable groups are exposed and protected, interventions on the germ line being contrary to human dignity. Another

principle to be respected for the same purpose of respecting human dignity is the confidentiality of genetic data; the explained consent is another principle that must be respected, and there is also a controversy over what was called "presumed consent".

## IV. CONCLUSION

In conclusion, although there is much to be said about the effects of biotechnologies on major diseases to be prevented and combated, bioethics must be said to be a mandatory corrective, complementary to the introduction of increasingly sophisticated and performing biotechnologies.

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## VI. BIOGRAPHY

Professor's **Constantin Bogdan** domains of medical practice & research include chronic diseases, geriatrics & gerontology, palliative care, thanatology and bioethics. He is also active in literature and a prolific essay author.

# Cardiovascular Bioengineering at the Crossroad of XX and XXI Centuries: a Message to Deliver for Epidemiology of Sudden Cardiac Death Corde Indemno

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***Abstract*** - Sudden cardiac death (SCD) without myocardial lesion accounts for at least 9 percent of the mortality by cardiovascular diseases (CVD) in Romania which is one of the highest in Europe. The chronic psychosocial stress (CPS) is strongly suspected to be involved in the etiology of SCD. Neurocardiology and cardiovascular bioengineering have made available sensitive "rhythmological" tools able to distinguish among heart repercussions of various states of vigil awareness, including emotional stress – an acute version of CPS. Informational contents of RR time-intervals or QT interval series as derived from high temporal resolution ECG facsimiles have been revealed using spectral and cross spectral analysis. The end-point is detection and limitation of risk for malignant cardiac arrhythmias and SCD as entailed by CPS in both vague-symptomatic non-cardiac subjects living under CPS and cardiac patients, in order to timely devise countermeasures table to save valuable lives at socially acceptable costs.

***Index Terms*** - heart rate variability, psychosocial stress, QT interval variability, sudden cardiac death.

## I. INTRODUCTION

This paper points to a significant interval of the 100 year retrospective of cardiovascular bioengineering in Romania that is 1990-2000 decade when we and others in the US have shown how to bring the Biomedical Engineering (BME) closer to the patient's bed: integrating MEng & MDs common research in the cardiology clinic. The topic was timely detecting the risk of sudden cardiac death in people corde indemno (i.e. without structural heart lesions) living under exacerbated psycho-social stress in order to institute adequate prevention.

Sudden death (SD) is declared when intervening within 1 hour from symptoms appearance. Most sudden deaths are underlain by cardiovascular causes (SCD) worldwide. There may be inconsistencies between pre-symptoms clinical aspects and true causes of SD as found by autopsy. This also applies to the SCD.

## II. SCD IN ROMANIA DURING THE DARK DECADE

Interest of the following medical data consists in their reporting in the most stressful year in Romanian recent history, i.e.1989:

The number of SD (80% during sleep) was standing for 15-26% out of 780 deaths in the Medical Clinic I of the Municipal Hospital in Bucharest over the 1980-1989; 80% of these deaths had cardiac cause (Costică et al, 1989, p 30, [1]).

A 10-year study conducted at the same Hospital showed that SCD was the most frequent in acute myocardial infarction (AMI) patients – 71,9% out of 256 cases (Cinteză et al, 1989, p 25, [1]).

A study of 182 SD cases autopsied at the Colţea Hospital (Mihail et al, 1989, p 21, [1]) showed that 84% of these deaths were cardiovascular in nature, of which 70% were due to coronary atherosclerosis.

A necropsy study conducted at the same hospital (Bruckner et al, 1989, p 24, [1]) on 106 SCD deaths caused by ischemic myopathy showed that:

- in 10% of cases, AMI was the underlying factor;
- in 34% of SCDs the ischemia was asymptomatic;
- in 25% of cases, SCD was the first and only manifestation of coronary lesions.

Another study conducted in Bucharest on over 5000 cases at the Legal-Medical Institute (1983-1988) showed that SCD (vessels, i.e. stroke included) is the most frequent form of SD, representing 20% of overall mortality (Terbancea et al, 1989, p 46, [1]).

18% of 22 SCDs recorded at District 4 Clinical Hospital in Bucharest (Filipescu et al, 1989, p 27, [1]) had no heart lesion, and 12.5% of SCD cases

showed no lesion in a small study at Oradea County Hospital (Lazăr et al, 1989, p. 98, [1]).

Finally, a survey on 258 SCDs in families from Olt County (David et al, 1989, p. 96, [1]) showed that 74% of prime working age population was affected.

Altogether this evidence suggests that about 15% of SCD cases in hospitals had no heart lesions. As studies on big data have shown, SCD accounts for about 60% of all cardiac deaths (Lown, 1990, ref 7). It means that SCD with no heart lesion could account for at least 9% of cardiovascular mortality In Romania.

*

This estimation may reasonably apply to the Romanian population in the post-Revolution epoch, especially in the latest psycho-socio-economic circumstances that exacerbate the psycho-social stress (PSS).

## III. PSYCHO-SOCIAL STRESS AND SYMPATHETIC CONTROL TO THE HEART

PSS is recognised by both clinical expert circles and public perception as one of the top risk factors for cardiovascular diseases (5th place in CINDI report, 1996) and fatalities including SCD.

Methodological issues had impeded until last decade of XX century an efficient, effective, and socially acceptable assessment of pro-arrhythmic dysfunctions subsequent to long-term exposure to of PSS that could eventually lead to SCD in mature asymptomatic, corde indemno subjects.

It is widely accepted that exacerbated (over normal) sympathetic drive to ventricles (SDV) – currently associated with PSS - is arrhythmo-genic, while normal vagal tone exerts anti-arrhythmic protection.

During last 2 decades of XX century research conducted in our and other labs try to enlighten an indicator of the SDV starting from an easy-to-record surface ECG.

When we combined these records with invasive data collected in the cardiology clinic from subjects under specific mental stress protocols in late 1990s years, and then applied engineering techniques (spectral analysis of time series) significant cues for SDV under PSS have resulted.

Neural control of heart depends upon vagal nerves' drive mainly to atria by heart rate (HR) getting down, and the sympathetic (S) one driving atria, as shown by both HR getting up (that is ECG's RR interval decrease followed by its QT subinterval - monitoring ventricular repolarization) and increasing force of ventricular contraction under physical stress.

Under psycho-stress the sympathetical-vagal interplay at ventricles is subtler, the S over-control of ventricles, that cannot be counteracted by the scarce vagal innervation, is believed able to electrically destabilize a myocardium otherwise normal (corde indemno) leading in detrimental circumstances to ventricular fibrillation and SCD. Such interplay can be monitored by focusing on beat-by-beat (bbb) RR- and QT- time series & their waving.

## IV. ARMAMENTARIUM OF RR AND QT BEAT-BY-BEAT ANALYSIS

Fig. 1 shows a high resolution electrocardiogram with landmarks for measuring the bbb RR and QT (sub)intervals, the 2nd meaning mainly ventricular repolarization.

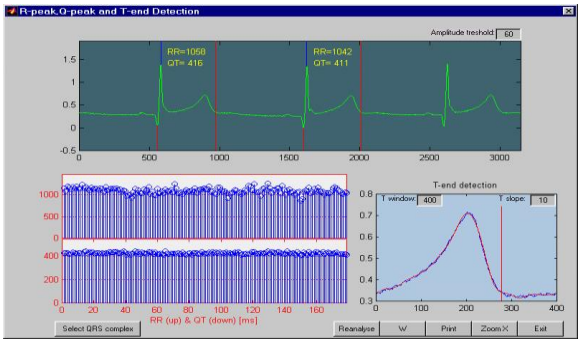


Fig. 1. ECG with RR and QT measurement; beat-by-beat RR-gram (CTG) and QT-gram; filtered T-wave for the automated estimate of QT interval

Fig. 2 shows a 3 minute analogue bbb cardiotachogram (CTG), respiratory and an ear lobe plethysmographic trace. CTG's lower frequency waving reflects respiration while higher ones points to sympathetic influences visible in arterial pressure records.

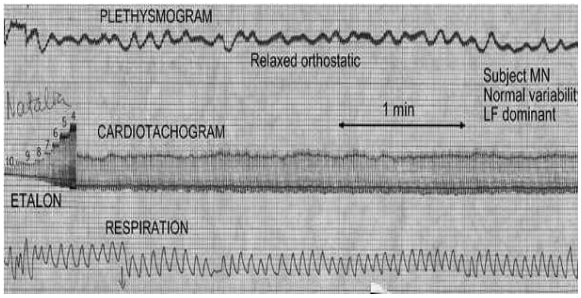


Fig. 2. Plethiysmogram, cardiotachogram, and respiration recordings for a subject in relaxed orthostatic state

Spectral power of variability of the beat-by-beat QT interval, as derived from high resolution ECG, clusters the same way as that of RR interval, that is within "sympathetic" (low frequency, LF: 0.04

- 0.15 Hz) and "respiratory" (high frequency, HF: 0.15 - 0.4 Hz) bands (Fig. 3).

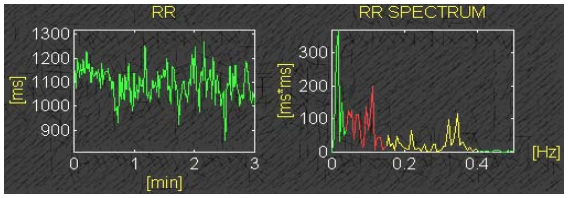


Fig. 3. 3 minutes bbb RR time series and the corresponding Fourier spectrum; red - LF band reflecting sympathetic influences propagated from arterial pressure waving driven by higher brain loci, yellow - mainly respiratory influences propagated from vagal dorsal nucleus

The RR*QT coherence spectrum can track the consistency of the QT modulation by RR, whereas SDV may supra-modulate QT not-necessarily in an RR-coherent manner.

Using the mean squared coherence (MSC) of RR & QT intervals over LF band, one could split and use sympathetic-drive-to-ventricles fraction of beat-by-beat QT variability as a HR-independent index of the SDV.

$$MSC = \frac{\left|\overline{G}_{RR*QT}(f)\right|^2}{\overline{G}_{RR}(f)\cdot\overline{G}_{QT}(f)} = \frac{L(f)^2+Q(f)^2}{\overline{G}_{RR}(f)\cdot\overline{G}_{QT}(f)} \qquad (1)$$

Where $G_{RR}$, $G_{QT}$ are RR and QT autospectra, $G_{RR*QT} = L + iQ$ is the RR x QT cross-spectrum.

$$\varphi(f) = \arctan\left[-\frac{\overline{Q}(f)}{\overline{L}(f)}\right] \qquad (2)$$

To compute MSC we used a 9-line moving-triangle, for optimal trade-off between frequency-resolution and physiological meaning, smoothing of its cross- and quadrature-spectral terms (Fig. 4). To spot SDV fraction of QT-LF, we "corrected" each QT-LF power frequency "line" by multiplying it with 1-MSC at that frequency.

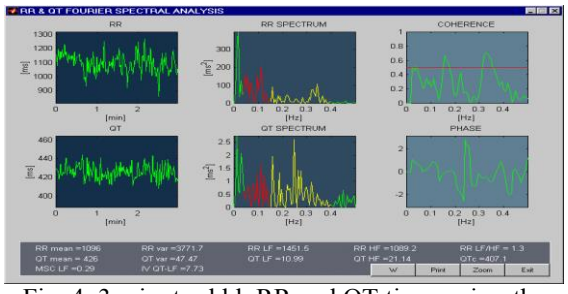


Fig. 4. 3 minutes bbb RR and QT time series, the corresponding Fourier spectra, and the coherence spectral plots

## V. STUDY METHOD

After informed consent, 12 males aged 19-20, entered a 2 day trial:

First day included:

(a) intravenous catheter, electrode placement and habituation (20 min);

(b) baseline in relaxed dorsal decubitus (10 min); this posture was maintained with all next interventions;

(c) mental stress (MS) using a Kraepelin concentrated attention test (arithmetic using one-digit numbers taped at 3 sec/item during 5 min); subjects were previously trained and number delivery-rhythm was selected to stand for a moderate-to-difficult task;

(d) intravenous propranolol 0.4 mg/kg body infusion in 15 min.

The second day included:

(a) setting of an intra-atrial catheter by puncture of right subclavial vein, testing right atrial pacing (RAP) in order to avoid discomfort, electrode placement and habituation;

(b) interventions b and c were the same as in the first day;

(d) right atrial pacing just above sinus-rhythm when relaxed.

*

A bipolar precordial ECG lead, set to provide maximum T-wave visibility was digitized at 1 ms and on line recorded (Codas, Dataq Instruments, Akron, OH), in parallel with an analog cardiotachogram (CTG). Proprietary software written in C was used to mark ECG's critical points.

In each setting the most stationary RR epoch, at visual inspection of the CTG, was selected for RR & QT variability study.

RR and QT natural series were evenly re-sampled at 500 ms, and (auto & cross) Fourier transforms were then applied as shown.

## VI. RESULTS AND DISCUSSION

Despite the manipulation of mean RR with propranolol or RAP, the low frequency component of the sympathetic drive to ventricle SDV-LF (an indicator for the idioventricular sympathetic control - IVSC) is increased significantly under mental stress versus situations with presumably low-moderate stress, which is not the case with QT-LF not being "purified" from RR-LF influences, and not being able to distinguish relaxation from stress when the latter is decreasing dramatically mean RR (TABLE 1).

TABLE I. Wilcoxon test's p for the significant group differences in SDV part of QT-LF. Mean RR is in ms, while RR- LF, QT-LF and SDV QT-LF are in ms$^2$.

| | Baseline | Stress | Propranolol | Baseline | Stress | RAP |
|---|---|---|---|---|---|---|
| **mean RR** | **837 ± 139** | **783 ± 128** | **972 ± 156** | **915 ± 138** | **805 ± 150** | **797 ± 94** |
| **RR-LF** | **605 ± 396** | **623 ± 605** | **854 ± 425** | **640 ± 391** | **940 ± 1297** | **3.52 ± 4.4** |
| **QT-LF** | **1.17 ± 0.80** | **2.36 ± 1.99** | **0.94 ± 0.51** | **1.23 ± 0.84** | **1.41 ± 0.65** | **0.40 ± 0.29** |
| **MSC** | **0.61 ± 0.21** | **0.58 ± 0.26** | **0.63 ± 0.20** | **0.66 ± 0.16** | **0.59 ± 0.19** | **0.19 ± 0.08** |
| ***SDV QT-LF*** | ***0.49 ± 0.68*** | ***1.06 ± 1.62*** | ***0.32 ± 0.30*** | ***0.28 ± 0.20*** | ***0.64 ± 0.45*** | ***0.33 ± 0.26*** |
| ***Wilcoxon p*** | ***0.012*** | ***0.032*** | | ***0.009*** | ***0.033*** | |

We know from both clinical studies and animal research, that supra-normal sympathetic drive is arrhythmogenic and life-threatening as opposed to antiarrhythmic protection due to vagal tone. Since estimates of sympathetic tone derived from RR variability are severely biased by the vagal tone underlying mean RR (whose shortening flattens variabilities of every source), and since they are atrial indices, a race aimed at replacing them with those derived from bbb QT time series bearing information on ventricle status has been started.

Coherence was first used by De Boer et al, 1985 [4] to disentangle phase relation between RR and systolic pressure & respiration waving. The present study is first, to our knowledge, to approach RR and QT cross-information for splitting the S-specific drive to ventricles.

Our results document in a straightforward manner that mental stress facilitates LF oscillations in QT interval in an RR-independent way. It is reasonable to speculate that the psycho-stress could lead to a potentiation of IVSC, as related to cortically initiated, increased central sympathetic tone.

In previous studies [5, 6] we have already shown that an RR-independent factor specifically related to sympathetic drive to ventricles (we named the idio-ventricular sympathetic control, IVSC) may act upon QT variability together with its modulation by RR, as a function of situation (relaxation in supine or standing, with or without mental stress).

In principle, RR*QT coherence spectrum can track the consistency of the latter modulation while IVSC may supra-modulate QT not-necessarily in an RR-coherent manner. Using mean squared coherence (MSC) one could estimate the idio-ventricular sympathetic control (IVSC) fraction from QT-LF.

In our study MSC proved instrumental in subtracting QT modulation by RR from QT-LF: the remaining IVSC fraction is consistently higher during MS versus situations when sympathetic profile is supposed to be low, if any.

In the latter situations, neither mean RR up-going dependent increase of RR-LF by propranolol, nor RAP-dependent vanishing of RR-LF versus baseline misled the IVSC fraction of QT-LF.

Non-invasive accessing SDV by this QT-variability index holds promise towards a socially acceptable monitoring of risk of stress-dependent life-threatening arrhythmias in both cardiac and normal-myocardium subjects using high resolution Holters.

Value of this finding is critically dependent upon how relaxed subjects were, and how much contributed the muscles tension associated with mental stress (including vocalizing of partial results) to ECG noise and QT mis-detection. However we checked the quality of relaxation by monitoring, in parallel with analogue CTG, a respiratory and an ear lobe plethysmo-graphic signal as well; we also authenticated the surface QT-gram with that got from endocavitary (right ventricle) QT that is noise free [7].

Confirming the usefulness of these research results got in young for the prevention of SCD in adults or mature people living/working under exacerbated psychosocial stress requires prospective clinical studies. The stake is not only the probable 9-10% frequency of cases, but also the fact that such subjects are most often involved in material or spiritual progress of their communities or societies.

## VII. CONCLUSIONS

By combining information provided by RR*QT coherence spectrum and QT power spectrum, mental stress-dependent sympathetic drive to ventricles in young people could now be non-invasively spotted and monitored free of confusion caused by concurrent alteration in autonomic balance at sinoatrial node.

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## IX. BIOGRAPHIES

**Serban Dinca-Panaitescu** was born in Bucharest on February 23, 1970. He graduated from Electrical Engineering in 1994 and he received PhD degree in industrial engineering from Bucharest Polytechnic University in 2001.

His employment experience included the Institute of Public Health in Bucharest, Romania and School of Health Policy and Management, York University, Toronto, Canada, where he is now teaching as an associate professor.

Dr. Dinca-Panaitescu has worked for many years in the area of medical informatics focusing on computer processing of physiological signals. His major research contributions address the field of cardiovascular disease prevention by developing decision support tools aiming at detecting the cardiovascular dysfunction in the subclinical phase. He has published numerous articles and one book in this field. Dr. Dinca-Panaitescu's research is also employing statistical modelling techniques to untangle the complex relationship between socio-economic factors and different diseases such as diabetes. Other research interests include medical equipment, health information systems and e-health.

**Mihaela Dinca Panaitescu** graduated from the Faculty of Physics, University of Bucharest and received a MSc in Environmental Applied Sciences and Management.

Her employment experience included the Institute of Public Health in Bucharest, Romania, York University, Toronto, Canada, and United Way, Toronto, Canada.

Her research is crossing a number of disciplines and conceptual frameworks from biomedical engineering and ecosystems modelling to social determinants of health and disability rights.

**Dan Dominic Ionescu** graduated from Faculty of Medicine Bucharest in 1970 and is a renowned professor, medical doctor, researcher and director of the Cardiology Center, Craiova, Romania. He was at the study time with the Department of Cardiology/Arrhythmology of the Central Military Hospital in Bucharest. His numerous cardiac electrophysiology studies have been published in books and high ranking international journals.

Professor **Radu Negoescu**, MEng, MPH has begun studies reported here while being with National Institutes of Health in Bethesda, MD and Totts Gap Institute in Bangor, PA - USA, and continued this track at the (National) Institute of Public Health, in Bucharest, Romania. He is an honorary member of the Academy of Medical Sciences of Romania.

# Four Decades of Medical Informatics in Romania

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***Abstract*** - Medical informatics appeared naturally at the intersection between medical sciences with the young field of informatics. In Romania, these concerns date back to the '70s, an important moment being the First National Symposium of Medical Informatics, organized in Satu-Mare, 1977, followed by annual meetings. Since the pioneering period, a variety of applications have been identified, covering both the needs of current practice in medical units (patient records, hospital resources, etc.) as well as scientific research topics. Another important moment was the introduction of the medical informatics discipline in the medical higher education at UMF Timisoara, 1984. Also, the Computer Centre of the Ministry of Health initiated courses for the medical staff, capitalized by the publication of the first monograph in the country (Medical Informatics, Ed. Medicală, Bucharest 1988, "Gheorghe Marinescu" prize of the Romanian Academy). Romanian Society of Medical Informatics RSMI was established in 1990 and was affiliated in 1994 with the European Federation of Medical Informatics EFMI and the International Medical Informatics Association IMIA. The prestige of the Romanian medical informatics school allowed SIRM to organize two European conferences in Romania: Bucharest 2001 and Timisoara 2006, and our representatives have been elected to the highest positions of EFMI - President (2006 and 2018).

***Index Terms*** - EFMI, history, healthcare applications, IMIA, medical education, medical informatics, Romanian Society of Medical Informatics.

## I. INTRODUCTION

Scientific development in the twentieth century, especially during its second half showed the occurrence of several interdisciplinary domains: biochemistry, biophysics, medical engineering, medical informatics, bioinformatics etc. The scientists realized the enormous potential of the cross-fertilization between adjacent domains. It is not surprising that one of the basic domains which attracted more such developments was the medical domain, as the field dedicated to a noble goal: human health and well-being.

Medical informatics is one of these interdisciplinary domains, born within the intersection of the medical domain with another large and dynamic field: informatics. Since the very beginning, the scientists foresaw the potential support brought by use of computers in medicine and healthcare, first attempts dating back in early sixties. In 1967, the International Federation for Information Processing IFIP, (established in 1960 under the auspices of UNESCO), created its technical committee TC4 – Medical Informatics, which became an independent organization, IMIA – International Medical Informatics Association. IMIA, led by Dr. Hans Peterson, organized the first world congress of medical informatics – MEDINFO – in Stockholm, 1974 [1]. A professional organization was also founded at European level in Copenhagen, 1976, at the initiative of Prof. François Grémy, with the support of WHO, entitled EFMI – European Federation for Medical Informatics. EFMI, led by Dr. Barry Barber, organized the first European congress of medical informatics – MIE, in Cambridge, 1978 [2].

Romania was among the countries with early developments in medical informatics. The series of annual conferences organized since 1975 by Eng. Vasile Peteanu in Cluj-Napoca, „Informatică și Conducere" had in 1977 a special section dedicated to medical applications; it was held in Satu-Mare, under the lead of Dr. Virgil Enatescu, and became the First National Symposium of Medical Informatics [3]; it had about one hundred participants. Since then, these symposia were held annually, with minor exceptions. Romanian scientists participated also in several projects and international conferences, raising the prestige of the Romanian school of medical informatics

## II. MAJOR STAGES OF DEVELOPMENT OF MEDICAL INFORMATICS

The development of the new emerging discipline has some distinctive stages [4]. Although most characteristics were similar in almost all countries, there are also particular regional or national features, which can be better understood within the socio-political context, correlated with the technological development.

*A. Pioneering period (~1950 - ~1975)*

*Socio-political context.* The after war period under communist ruling had specific aspects in Eastern Europe – minimal contacts with Western world, however trying to keep the image of a free and well developing society.

*Technological development.* Romania was among the first countries trying to build computers - Bucharest – CIFA-1, Timisoara – MECIPT-1 and Cluj-Napoca – DACICC-1. Teams of young and enthusiastic scientists were formed around these computers.

*Medical informatics*. The teams who built the first computers in Romania have also tried some medical applications – simulations of neural networks (Dr. Mat. Dan Farcas) or assisted diagnosis in gastroenterology. In the 70's, several inter-disciplinary working groups have been formed with concerns about various medical applications: Haematology Centre with CINOR, Municipal Hospital Bucharest with ICPE, Timisoara Faculty of Medicine with Timis County Hospital, Centre of Mental Health Satu Mare etc. In the same period the Ministry of Health creates the Centre for Computing and Health Statistics (led by Dr. Petru Muresan) [5].

*B. Organizational period (~1975 - ~1990)*

*Socio-political context*. A short window of partial political opening was noticed after the original position of Romania on the invasion in Czechoslovakia, however followed by a strong isolation policy during the 80's.

*Technological development*. In early 70's, Romania started to develop a computer industry, manufacturing the well-known computers Felix C-256. Most central institutions were equipped with computers and a large plan to establish territorial computer centres was implemented.

*Medical informatics*. By the mid 70's, a "critical mass" of people interested in medical applications of computer technology had already emerged, able to start organized activities - projects within institutions as well as scientific events. In this context we can quote the organization of the first National Symposium on Medical Informatics – MEDINF - by Dr. Virgil Enatescu in May 1977 in Satu Mare followed by annual conferences in different centres in the country, becoming true scientific forums. The papers covered a large area: various databases to keep track of patients, hospital beds, drug supplies or human resources, including the adjacent programs for reporting, planning or prognosis, informatics systems of healthcare units, up to hospital level, clinical applications, comprising both statistical data processing and computer assisted diagnosis or treatment optimization and also specific applications for medical research – new devices for medical investigations, complex analysis of biological signals and medical images as well as theoretical developments – mathematical modelling and computer simulation of biological processes [6].

In early 80's medical informatics penetrated also in the curriculum of medical education: the first optional course of medical informatics in Romania was introduced in 1984 by Prof. Gheorghe Mihalas at the University of Medicine in Timisoara, with a support from Prof. Jan van Bemmel from Erasmus University in Rotterdam, assuring from the very beginning a modern and comprehensive structure [7]. We should also mention here the cycle of „specialization" courses for the leading medical staff of healthcare units organized by the Centre for Computing and Health Statistics of the Ministry of Health (Dr. Traian Ionescu and Dr. Ovidiu Popescu). These courses have been published in 1988 by Ed. Medicala, Bucharest, as the first Romanian monograph on medical informatics, awarded the „Gheorghe Marinescu" Prize of the Romanian Academy in 1990 [8].

*C. Consolidation period (~1990 - ~2000)*

Socio-political context. The same period has brought about great changes of the socio-political context in Eastern Europe, including Romania, favouring international contacts and the engagement of our researchers in several European projects.

Technological development. The last decade of the last century, the technological development in computer science marked a turning, from mainframes to personal computers, offering more independence and flexibility.

Medical informatics. Within this context, an important event was represented by the foundation of the Romanian Society of Medical Informatics RSMI, in 1990 in Sibiu - a scientific association, successor of the community of the professionals interested in this domain. In 1994 RSMI has affiliated with EFMI and IMIA. The scientific level of our national conferences showed a marked increase, being often attended also by foreign scientists. At the same time, the participation of Romanian specialists in various conferences, training programs abroad or European projects

increased [9]; we must mention the support received from Prof. Bernard Richards, dr. Rolf Engelbrecht, Prof. Jana Zvarova [10] etc.

On the educational level, one could notice the development of interdisciplinary domains; medical informatics has become a mandatory discipline in all medical faculties and all profiles [11], most of them adopting the syllabus from Timisoara. New profiles as bio-medical engineering have also been created within medical or polytechnic universities: Iasi (F. Topoliceanu), Bucharest (R. Negoescu, A. Morega, S. Kostrakievici), Timisoara (D Dragulescu), Cluj-Napoca (R. Ciupa). The doctoral level in medical informatics started in 1992, with the support of Acad. Stefan Milcu and Acad. Nicolae Cajal [12].

The Ministry of Health was assaulted by various foreign delegations and companies willing to contribute to the "reform" of the healthcare system. Several smaller projects were carried out during this period, most of them aiming the equipping of healthcare units with computer technology. A larger and better known project was HMIS – Healthcare Management Information System, with credit from the World Bank [13]. Despite the good quality of the project, the final results were quite modest, revealing the complexity of such projects, the weaknesses of the organizational aspects of the healthcare system as well as and the strong dependence on the political support [14]. The positive consequence of this experience was the stimulation of the private sector, which started to penetrate the healthcare sector.

### *D. Maturity period (~2000-present)*

*Socio-political context*. The EU policy to extend in the Eastern Europe brought Romania as a candidate country, then full member since 2007. A wave of reforms flooded the country, comprising almost all sectors and institutions, trying to "align to European standards".

*Technological development*. The Internet era started, facilitating communications by large networks; the PC's market also increased tremendously.

*Medical informatics*. Most departments of medical informatics in medical universities have been equipped with appropriate computer infrastructure [15] and developed their curricula, trying to get close to the IMIA Recommendations [16]. Several young scientists had the opportunity to get scholarships in foreign laboratories, which increased the rate of "brain-drain". Master level study programs dedicated to various applications of computer science in healthcare have been introduced in polytechnic universities [17].

The use of IT in medical research showed a marked increase, yielding a significant presence of Romanian scientists in international conferences.

In the healthcare sector, a new and very large project (~120M€) started in 2002, coordinated by NHIH, National Healthcare Insurance House – SIUI – Integrated Unique Information System [18], which implemented its firs modules in 2008. It is a very complex system, having, besides the main module, other important components: electronic prescription SIPE, patient health card CEAS, patient electronic health record DES. The system has been imposed by the NHIH, despite its weaknesses – unfriendly interface or lack of interoperability with other similar European systems etc. However, it is in current use, covering the majority of population in Romania, and in a permanent process of improving. Several private companies (InfoWorld, Romanian Soft Company, TotalSoft, Syonic, Softeh, Sterio etc) continued to cover various gaps of SIUI or to offer supplementary services.

## III. ROMANIAN SOCIETY OF MEDICAL INFORMATICS - RSMI

### *A. Foundation and objectives*

RSMI was officially founded in 1990, as a follower of the community which used to meet annually at the national conferences of medical informatics. As specified in its statute, "The Romanian Society for Medical Informatics, RSMI, is a legal entity registered as a scientific, professional, non-governmental organization aimed to promote the activities in the development of medical informatics in Romania and to represent the activities in the country and abroad". It has around 120 members, comprising engineers, physicians, informaticians, mathematicians etc. It has six working groups, focused on major topics of high interest, like medical informatics education, medical imaging, interoperability and electronic health record, nursing informatics, wireless devices and sensors or dental informatics.

### *B. Activities at national level*

RSMI organizes annual national conferences; the last edition of ROMEDINF (34th) was held in Timisoara, 23-24 Nov 2017 (for a complete list see [19]), with good participation from the whole country having also invited speakers from abroad.

RSMI has a close cooperation with the Romanian Academy of Medical Sciences - Commission of medical informatics and data protection and with other professional associations: ProRec Romania, FRIB – Romanian Federation of Biomedical Engineering, Romanian Society of Applied Medical Informatics, Romanian Society of Telemedicine, Romanian Society of Dental Informatics, HL7 Romania, Romanian Society of Artificial Intelligence etc. There is a journal – Applied Medical Informatics, published in Cluj-Napoca, having Prof. Sorana Bolboacă as editor-in-chief [20].

*C. International activities*

RSMI is a very active society at international level. Since adhering to EFMI and IMIA, our scientists were constantly present in all MIE's and STC's conferences organized by EFMI, or MEDINFO's organized by IMIA (MIE – Medical Informatics Europe, STC – Special Topic Conference). The prestige of the Romanian medical informatics school has enabled RSMI to organize two European conferences in our country - Bucharest 2001 - Healthcare Telematic Support in Transition Countries [21] and Timisoara 2006 - Integration of Biomedical Information: from e-Cell to e-Patient [22]. Our representatives have also been elected to the highest positions: Prof. G.I. Mihalas as EFMI president (2006), IMIA vice-president (2008) and member of the International Academy of Healthcare Sciences Informatics IAHSI Prof. Lăcrămioara Stoicu-Tivadar as president of EFMI in 2018. Several members of our societies have also been often invited as experts in European Commission or editorial boards of various journals.

## IV. PRESENT STATE OF MEDICAL INFORMATICS IN ROMANIA AND FUTURE PERSPECTIVES

*A. Medical Informatics Education*

The discipline is mandatory in all profiles of medical undergraduate higher education. There are also master level programs, especially within polytechnic universities [23]. There are also doctoral studies in this profile.

*B. Healthcare implementations*

As presented above, in all units contracted by National Health Insurance House, the SIUI system is in use - all. There are also in use programs developed by the private sector, either for a friendlier user interface of SIUI modules, or stand-alone programs for the management of hospitals or other healthcare units, mainly for primary care.

*C. Industry, software developers*

There is a well-developed market of medical informatics in Romania, with several private companies, including SME's with major activity within the healthcare informatics sector. Some of these companies have also research and development departments which cooperate especially with clinical departments of medical universities in scientific research projects.

*D. Legislation, standards and governmental involvement*

As a member of EU, Romania made efforts to cover the gaps inherited from the previous regime. Thus, the documents concerning GDPR General Data Protection Regulation 2016/679 have been translated and applied starting with May 25th 2018 [24]. All healthcare units have the appropriate structure for monitoring the implementation of this act. Concerning the adoption of standards in medical informatics, the situation is far from the expectations. ASRO, the Romanian Standards Association has a technical committee TC319 for this domain, but this TC has not produced any report and has "suspended activity" [25]. The only reference to the medical informatics domain has just recently been posted, referring to security systems for software applications in healthcare [26]. There is no Romanian participation in either ISO TC215 or CEN TC251. We should mention here the activity of the professional society HL7 Romania, which tries to popularize the HL7 standards.

Another feature of high interest concerns the recognition of the profession in health/medical informatics; the official list of the Ministry of Labour, COR – Classification of Occupations in Romania, has introduced up to now only one specialty as profession in this profile, called "specialist in e-health", which does not fully cover our domain [27]. The National Health Insurance House totally ignored all invitations to the conferences organized by the professional associations of medical informatics. The Ministry of Health has a commission of medical informatics, which has been reorganized several times, with sporadic activity, without producing up to now any document to be considered valuable for implementation in healthcare units.

*E. Future perspectives*

Despite the numerous weaknesses and shortcomings, this historical view over the last four decades of medical informatics in Romania shows the real potential to overcome the difficulties and make real steps forward, based on the engagement of the young generation to produce new applications for practical use in healthcare or medical research – the best proof is the consistent participation in both national and international conferences and projects.

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## VI. BIOGRAPHY

**Gheorghe-Ioan Mihalaș** graduated Faculty of Physics in Bucharest in 1967 and had a Fulbright scholarship at Virginia Commonwealth University in 1972-73. He received his PhD degree in biophysics from University of Bucharest in 1979.

He started as an assistant professor of biophysics at Faculty of Medicine in Timisoara and introduced the first course of medical informatics in Romania in 1984. He received the "Gheorghe Marinescu" prize of the Romanian Academy as co-author of "Informatica Medicală" (Ed. Medicală 1988). In 1994 he became member of the Academy of Medical Sciences and full professor at "Victor Babes" University of Medicine and Pharmacy in Timisoara. He was the president of the Romanian Society of Medical informatics (1998-2010) and General Director of the Computer Centre of the Ministry of Health in 2001. He organized two European conferences on medical informatics (2001 and 2006). He was elected as EFMI president in 2006 and founding member of International Academy of Health Sciences Informatics in 2017.

# Applying Anonymous Signature Schemes to the Romanian National Health Insurance System

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***Abstract*** - In a sustained effort to reduce bureaucracy, save resources, and make operating more efficient, a few years ago, Romania introduced the "Single Integrated Information System" that collects, consolidates and processes data from the entire national health insurance system. This, like any other IT system, may present certain vulnerabilities regarding security and privacy of the personal data being trafficked in the system. The implications, in case of the materialization of these vulnerabilities and the loss of data confidentiality, will be of a legal nature also and may lead to substantial financial losses, especially in the context of the introduction of the "General Data Protection Regulation" or GDPR into the European Union. This paper explores the possibility of reducing these vulnerabilities by introducing the anonymous digital signatures schemes into the Romanian "Single Integrated Information System". Following their study, the authors are of the opinion that this solution can improve data privacy and increase citizens' confidence in this system without incurring extremely high costs for implementation. Also, implementing such a solution can reduce the amount of consumables (paper, ink, etc.) used in the system's operation.

***Index Terms*** – health system, digital signatures, Single Integrated Information System, security vulnerabilities.

## I. INTRODUCTION

At present, we can observe a sustained process of automation and switch from physical to electronic means of data storage and processing. This process encompasses almost all of our society. One of the advantages of this process is the improvement of operation efficiency and a substantial reduction in bureaucracy.

The health insurance sector in Romania has introduced the "Single Integrated Information System" or SIIS which represents a first step in the process mentioned above. This system ensures the collection, consolidation and processing of data throughout the national health insurance system [1]. The primary purpose of this system is to provide health insurance providers the necessary platform to conduct their specific activities and manage the health insurance budget.

Of course, like any computer system SIIS has certain security vulnerabilities. In view of the introduction by the European Union, in May 2018, of the new rules for the protection of personal information - GDPR (General Data Protection Regulation), securing the confidentiality of these types of information has become very important. Thus, in order to comply with the new legal provisions, SIIS will have to implement measures to ensure the protection of this information.

Thus, considering the importance of protecting personal data, the purpose of this paper is to propose a solution to improve the protection of these types of information by introducing anonymous signature schemes into the SIIS. These schemes provide all the benefits of standard digital signature schemes, but also ensure that the signature of the signatory is hidden until it decides to disclose it.

After examining the possibility of using anonymous digital signature schemes, the authors concluded that this change will improve security and increase the trust of beneficiaries in the system without incurring high implementation costs.

## II. STANDARD DIGITAL SIGNATURES AND ANONYMOUS DIGITAL SIGNATURES

Digital signatures have become a common element for many suites of cryptographic protocols implemented around the world. They are mainly used to detect and / or prevent the falsification or manipulation of digital messages. The most common examples where digital signatures are used are software distribution, contract management software, paper review software, financial transactions, or any other scenario in which tampering or manipulation of digital messages is to be prevented.

### *A. Standard digital signatures*

A standard digital signature is a mathematical

scheme applied to messages and mostly used to demonstrate the authenticity of those messages. This can be likened to a handwritten signature applied to a paper document. Applying such a signature to a digital document provides to the entities that exchange information in the form of digital documents, authenticity, non-repudiation, and integrity. Authenticity provides to the recipient assurances that the message was indeed sent by the one who claims to have sent it. Non-repudiation implies that the signer of the message cannot subsequently deny sending it, and integrity provides assurances that the message has not been altered or manipulated in transit.

One of the most popular and widely used cryptosystems for digital signing is the Rivest-Shamir-Adleman cryptosystem (known as RSA). It was among the first public keys cryptosystems ever implemented. In such an encryption system, the encryption key is public and differs from the decryption key which is kept secret. In RSA, this asymmetry is based on the practical difficulty of factoring the product of two prime numbers, also called the factorization problem [2].

RSA algorithm users create and publish a public key based on two large prime numbers, along with an auxiliary value. Primary numbers must be kept secret. Anyone can use the public key to encrypt a message, but using the currently available methods when using a large public key, only someone who knows the two prime numbers can successfully decode the message. As mentioned above, to check the origin of a message, RSA can also be used to sign a message. In this case, a hash function is required that will generate a hash value of the message. This value will be encrypted with the signer's private key and the result (i.e., the signature) will be attached to the message. At destination, in order to verify the authenticity of the message, the signature will be decrypted with the public key of the signer and the resulting value will be compared to the result of the recomputed (at destination) hash function on the message, by the recipient. If they are the same, the signature is verified and the recipient has the assurance that the message is authentic and it has not been altered in transit. Also the sender cannot deny sending it, because the message was signed with its private signature.

*B. Anonymous digital signatures*

The first formalization of the notion of anonymous digital signatures was presented in [3] by Yang et al.. The concept was further explored by the authors of paper [4] and reviewed by Saraswat and his colleagues in [5]. This paper attempts to make another proposal on the practical use of these signature schemes for the national health insurance system in Romania.

Anonymous signature schemes are based on standard digital signature algorithms, but instead of demonstrating the identity of the signer (m) at any time, the signature s hides it up to a certain point in time, chosen by the signatory. Anonymous signatures are used in many applications where the signer's identity must be protected, e.g. electronic auction systems, key exchange protocols, electronic systems for reviewing publications or electronic voting systems, such the one described in [6].

There are few anonymous signature schemes proposed so far, but the most noticeable are the ones presented by Yang in [3], [7] and Saraswat in paper [5]. Yang's anonymous signature scheme guarantees anonymity to the signer when the opponent receives only the signature without the message, or when the message contains a random string called a security parameter that is kept secret until the verification phase. But keeping some of the message secret may be inappropriate for some applications, but there are also applications that do not require the whole message to be revealed. In the latter, a signature scheme such as that of Yang can be successfully applied.

The anonymous signature scheme proposed by Saraswat divides the digital signature $\sigma^*$ into two data segments, $\sigma^* = (\sigma, \tau)$, where $\sigma$ is the anonymous signature (or just signature), and $\tau$ is called verification token (or just) token. Generating the signature ($\sigma$) and the token ($\tau$) means employing a signature generation algorithm, denoted $S()$. It uses the secret key of the signer ($s_{key}$) and message $m$ as entries. The verification phase is called when the anonymous signer decides to make public the proof that the anonymous message is signed by him. At this point, the signatory must publish the message $m$ and its token, and the validity of the signature can be verified by anyone using the signer's public key ($p_{key}$) and the signature attached to message $m$. As long as $\tau$ is hidden, no one can find out who is the signatory, its identity cannot be determined from the information in message $m$ and in signature $\sigma$.

An anonymous signature scheme, denoted $\Sigma$,

can be considered a triplet of algorithms denoted $\Sigma = (G, S, V)$. Within this triplet, the algorithm $G()$ is responsible for generating a key pair $(p_{key}, s_{key}) \leftarrow G()$, the algorithm $S()$ produces the signature - verification token pair $\sigma^* = (\sigma, \tau) \rightarrow S(s_{key}, m)$, using the signer's private key ($s_{key}$) and $V()$ algorithm which represents the signature verification algorithm. The latter uses the signer's public key ($p_{key}$), the message $m$ and the signature generated by $S()$ as entries and generates a "true" or "false" output that validates or invalidates the signature. Thus, if the signatory is legitimate and if the message has not been modified or altered in transit, by calling the verification algorithm $V()$ will obtain:

$$V(p_{key}, m, S(s_{key}, m)) = true \quad (1)$$

where $(p_{key}, s_{key})$ represents the key pair generated by $G()$ and $m \in \{0,1\}^*$ is the original message.

## III. THE NATIONAL HEALTH INSURANCE SYSTEM

The plan for the implementation of an electronic health insurance system in Romania was approved by the Executive Order of the Minister of Health no. 645 of 2007. It took several years to reach a functional solution, and in the year 2015 the system became operational and accessible to the general public.

The system has the following five major components [1]: the "Single Integrated Information System" (SIIS), the "Electronic Prescription" (EP), the "Electronic Health Insurance Card" (EHIC), the Health Service Providers (HSP) and the Electronic Reporting Applications (RA).

The primary component of the national health insurance system is the Single Integrated Information System or SIIS for short. It has the role of collecting, consolidating and effectively processing information across the national health insurance system. The main purpose of SIIS is to help the national health insurance providers manage their health insurance budget [1]. As shown in figure 1, the SIIS is based on a hierarchical structure divided into three main levels, national level, county and the level of the health service providers (or HSP for short).

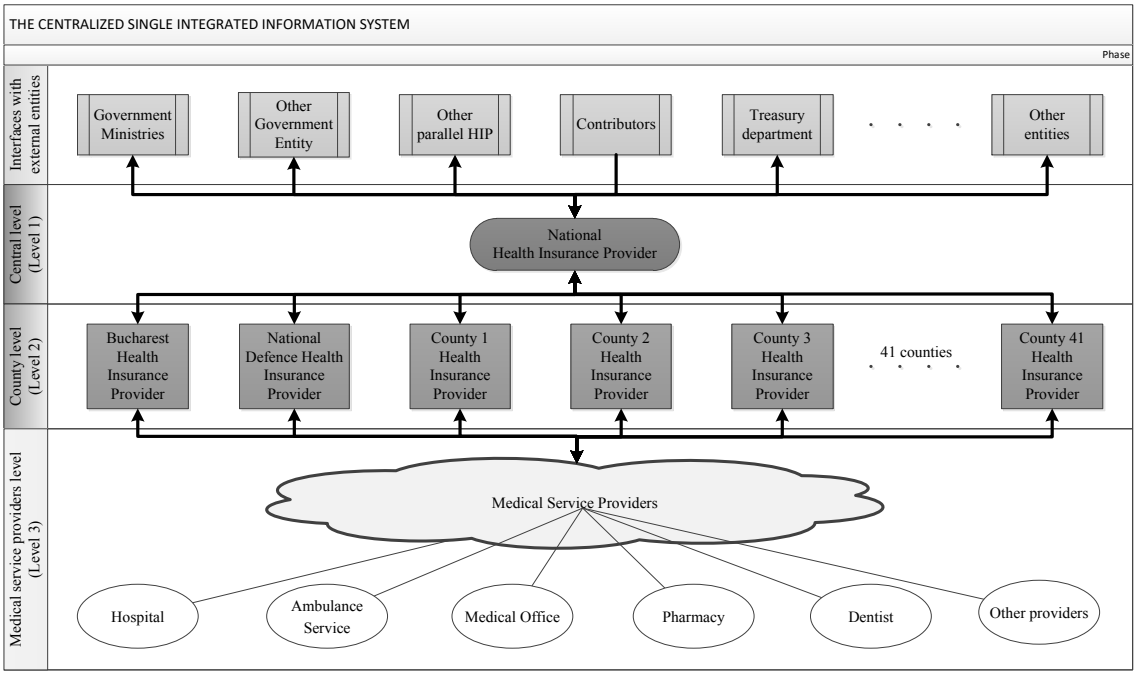


Fig. 1. The hierarchical structure of the Single Integrated Information System

According to [1], SIIS's main functions are to manage health insurance budgets, manage insured persons, maintain records of health service providers (pharmaceutical and medical), maintain records of contributions to the health insurance budget, and ensure quality control for the health insurance system. Data from Health Service Providers (HSP) is collected and analyzed locally at level 2 (Figure 1) of the SIIS's hierarchical structure at county level and then centralized and stored at the central (national) level.

In the development phase of SIIS, seven main objectives were pursued, the collection and management of economic and medical

information necessary for an efficient functioning of the health insurance system, transparency in the use and management of the health insurance budget by the national health insurance provider, keeping records of insured persons and health service providers by setting up and administering national registries for health insurers and health service providers, simplifying data reporting by the HSP, standardizing the implementation of national norms and rules, highlighting and controlling the costs for each insured person and the interface with other entities outside the system (besides the HSP) online and / or offline.

Of course, the benefits of implementing such a system are obvious and have been presented in the introduction of this paper.

### *A. The interfaces of the Single Integrated Information System - SIIS*

SIIS provides external communication interfaces used to transfer information to other entities outside of the system. These interfaces are divided into two main categories: Interfaces with Health Service Providers (pharmaceutical and medical) - HSP and Interfaces with other types of entities.

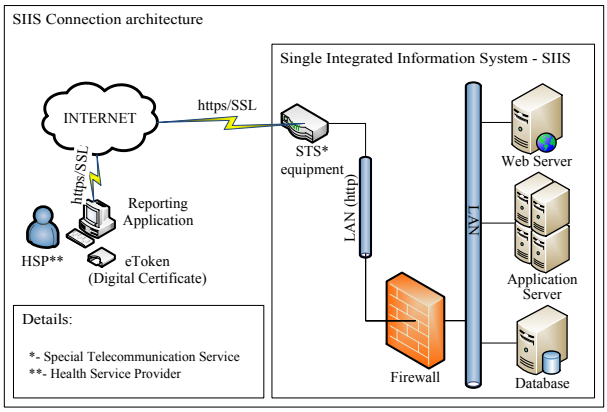


Fig. 2. The connection of the Reporting Applications (RAs) to the Single Integrate Information System

The primary purpose of interfacing with the HSPs is to facilitate the communication with the insurer so that the HSPs can receive payment for the services they provided. These interfaces are also used to transfer information related to the release of medical prescriptions, medical (sick) leaves, or other documents that may be issued by a healthcare provider. Other types of information may be exchanged over these interfaces, but it depends on the individual contracts that each HSP has with the health insurer.

The user (no matter who he or she is, HSP, institution, etc.) is reporting or receiving details to / from the SIIS through the electronic Reporting Applications (RAs). These applications establish connections with the SIIS via the https / SSL protocol (Figure 2).

The SIIS also offers the possibility to validate online prescriptions or to check in real time whether a customer is really insured. This option has been implemented to avoid the situation when a customer or a medical or pharmaceutical service equipment is not covered by insurance. Understandably, this SIIS option uses the system's interface with the HSPs.

SIIS's interfaces with other entities are defined in accordance with the protocols / agreements of those entities with the national health insurance system and are used to obtain and provide the necessary data for the proper functioning of those entities as well as the national health insurance system. Some examples of such entities may be institutions that keep records of the population, financial institutions, anti-fraud institutions, city halls, ministries, treasury department, etc. (Fig. 1).

### *B. Information security in the Single Integrate Information System*

In order to ensure the security of the information exchanged between the reporting applications and the Single Integrated Information System, a Public Key Infrastructure (PKI) was implemented. This PKI was designed to operate with digital certificates issued by approved and well-known certification authorities.

The Public Key Infrastructure (Figure 3), the techniques and methodology that collectively contribute to the implementation and operation of the public key cryptosystems are made up of software, network resources, databases, security procedures, hardware, and legal obligations. These elements are linked to each other and collaborate to implement and provide the necessary security services as well as other services associated with PKI infrastructure such as timestamps.

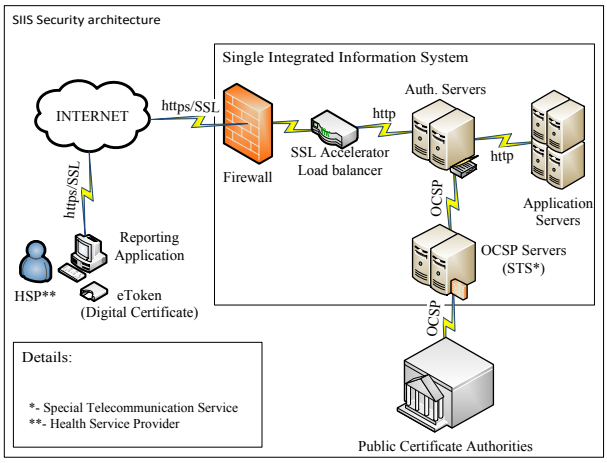


Fig. 3. The security architecture of the Single Integrated Information System

In SIIS the digital certificates are permanently verified and validated. The verification process is applied periodically by the certification authority by checking the revocation status of certificates. The Certificate Authority issues and uploads regularly or whenever required, a Certificate Revocation List (CRL), which contains a list of the serial numbers of certificates that have been revoked for various reasons (the certificate has been compromised, the holder is no longer eligible etc.).

Verifying a digital certificate in SIIS is also done using online certificate verification protocols. One such protocol, which is implemented in SIIS, is the "Online Certificate Status Protocol" or OCSP, defined by RFC2560. Using this method, applications do not need to download and verify a large CRL file, but just sends a request to an OCSP service requesting verification of the certificate of interest (Figure 3).

To access SIIS resources, all HSPs will require digital certificates issued by the above mentioned certification authorities. Also, those certificates will need to be recorded in SIIS for reporting applications to be accepted and running. As an added security measure, user accounts will be defined for each operator of each HSP. This will provide the authorization function for each reporting application operator. And of course, it will ensure, among other things, the mechanism of non-repudiation of operator actions.

The gateway to SIIS is protected by a hardware firewall that also provides SSL acceleration and load balancing. Concurrently, this hardware checks the validity and integrity of digital certificates submitted by the reporting applications when initiating a new SSL session.

After verifying the integrity and validity of the certificates, the SSL accelerator passes the request via http to the authorization and authentication servers (the servers represented graphically in Figure 3). The SSL accelerator includes in the http header also some information regarding the current digital certificate. This information will be used by servers to further assess the status of the certificate through OCSP. The authorization servers will check in the database whether the digital certificate has been submitted by an authorized user. If the user has been validated, the server submits an OCSP request through the services provided by STS – the "Special Telecommunications Service" to verify the status of the digital certificate revocation to the above mentioned public certification authorities.

STS uses, as part of the service, a component that permits the simultaneous query of all national public certification authorities. By this method, the consequences of unfortunate structure changes or the unavailability of a certification authority are avoided.

If the OCSP process shows that the certificate is valid, the authentication servers will check the status of the contract with the HSP in a buffer database. If contract validation results in everything being okay, the server sends a software token to RA called "session-id-hash". This token will be used by the reporting application to confirm that the current session has already been authorized. This will avoid the situation of repeating the full session authorization chain for each request that the reporting application makes in a single session. Also, using this method will speed up the reporting application's operating process, and the authentication / authorization servers will not be overwhelmed with verification requests, which would slow down the entire system.

### *C. Digital signatures in the Single Integrated Information System*

A digital signature is an additional amount of information that is attached to an electronic document and has the same meaning as a hand signature on a normal (paper) document. The signatory is that person or entity that has the necessary devices and / or software to create a signature that can act on its own behalf or as a third party representative.

Just like a hand signature on a paper document, the digital signature proves possession of an

electronic document, but it also gives the addressee the option to check whether the document has undergone tampering or alterations, whether accidental or intentional.

In order to generate a digital signature, the signatory requires a digital certificate the issuance of which meets the aforementioned criteria. The certificate binds the digital signature to the entity or person who created that signature.

To ensure non-repudiation of reported data in the SIIS, all uploaded files must be signed using the signer's digital signature. Electronic signing of these files generates the premises of complete automation of the health insurance system and simplifies procedures by eliminating the need for physical paper documents.

The system keeps track of all reported files, regardless of whether the signature was validated or not. The rationale behind this behavior is always to have the justification of a possible revocation of an application when it is necessary to justify a decision taken by the system.

## IV. AN ANALYSIS OF THE POSSIBLE SECURITY VULNERABILITIES OF THE SINGLE INTEGRATED INFORMATION SYSTEM

Like any other information technology (IT) system, SIIS may present certain vulnerabilities related to information security. Using mainly proven security protocols and cryptographic means, the system can be considered to have a good level of security when it comes to known and well-tried attack methods. A very obvious vulnerability of SIIS stems from the fact that the link between reporting applications and the system is achieved through the Internet. Even though the security protocols used are providing good protection against attacks such as "man-in-the-middle", attempts to decrypt traffic or the impersonation of a legitimate user, SIIS may still be vulnerable to "Denial of Service" (blocking / prohibiting access to services) type attacks. The main reason for this vulnerability is that the Internet is a network open to the entire world, and any malicious person or entity can perform a "Denial of Service" attack, such as attacks that have the effect of occupying the entire bandwidth of the target system ("Bandwidth attacks"). In the event of such an attack, the attacker cannot enter the system and cannot modify or intercept traffic, but taking up all the available bandwidth can prevent the RAs from establishing the required SSL sessions with SIIS.

Most computer systems running over the Internet are very poorly protected against attacks like the bandwidth attack, mainly because there are few options to fight them. The most effective way to protect against these types of attacks is to connect the system to multiple Internet service providers. This method is not guarantee that bandwidth attacks will fail, but this will substantially increase the cost of the attack, as the attacker will have to use significantly more resources to make a successful attack.

After analyzing the security of SIIS, the authors succeeded in identifying another possible vulnerability. The data stored and processed by the system contains a large quantity of personal or private information about its users. This information may include general health insurance information, identification information, medical information and other types of information that might fall under the new European regulations - GDPR.

When stored inside the SIIS, these sensitive data may be considered to have satisfactory protection, but as can be seen in Figure 1, the system is connected externally through interfaces with other entities. An example of an institution that needs a connection with SIIS is the "National Institute of Statistics" - NIS. This institute asks for data stored in the system in order to use it to compute detailed statistics on many aspects of the national health system. The results of the computations done by NIS may include statistics on medical (sick) leaves, different types of medication usage, disease types and their prevalence, etc. To obtain these statistics, NIS needs data generated by the RAs, such as medical prescriptions, medical reports, etc. Within these reports, there is also data that can be used to identify the person or entity for which the reports were created. Under the above mentioned laws, this information is protected and the system should limit access to it. For an institution like NIS, the identification data in the reports is not required, but only the information contained therein. That is why sensitive data protection is very important nowadays.

It should also be borne in mind that the principle of good practice in the field of information security considers any external system connected to its own system as a possible security threat [8]. Thus sensitive identification information must be protected, especially when

leaving SIIS. But there must also be a way to recover it when such a need arises.

Thus, the authors of this paper consider that the protection of identification data in SIIS can be achieved when this data leaves the system, by introducing the anonymous digital signature schemes into the system.

## V. THE PROPOSED SOLUTION

The solution proposed in this paper involves the introduction of anonymous digital signatures in the process of generating and storing SIIS reports as well as a simple method to search the database.

In SIIS both report generation and database report searching are using personal identification data. The data mainly used is the insurance policyholder's name, the personal identification number (PIN), the number and serial of the report and, where appropriate, doctor's stamp number. After the doctor fills a report, such as a prescription, specifying the recommended treatment and the identification information, he validates it in the system and signs it with his own digital signature. Next step is for the system to store it. In order to access the patient's insurance status, the physician uses the patient's Electronic Health Insurance Card - EHIC containing the patient's key pair and digital certificate. When the patient arrives at a pharmacy to pick up the doctor's recommended treatment, the pharmacist either scans the bar code on the patient's prescription (printed by the doctor after being validated and stored in the system), or searches the prescription in the system using the patient's identification information. The pharmacist (i.e. the pharmacy RA) will also check the patient's insurance status using the patient's EHIC (i.e. the data stored on it).

A possible vulnerability that was identified is represented by the fact that the electronic prescription is stored in the system with its user identification information in the clear alongside the diagnostic information and the associated treatment. The risk is even greater when this information is transmitted to another institution outside of the national health insurance system (e.g. the National Institute of Statistics or other similar institutions).

One possibility to mitigate the risk of the above vulnerability is to introduce anonymous signature schemes into the SIIS. This is the main purpose of this research.

The idea is that every health insurance beneficiary should have an electronic health insurance dossier. All electronic documents issued on the insured person's name and all his medical records shall be contained in his personal electronic dossier. Each medical document issued on that beneficiary's name will be added to their own dossier. The electronic dossier will not contain any identification information but will be signed with an anonymous Saraswat signature scheme generated using the information stored on the EHIC of the insured person. This method will also be able to prove the identity of the owner of that dossier.

On the RAs side (applications that generate the medical and pharmaceutical documents to be attached to the insured's electronic dossier), all generated electronic documents (e.g. electronic prescriptions) will have the name and the personal identification number deleted or encrypted (using the insured's public key from the health card) by the application software. Each released document will be added to the insured's electronic dossier once it has been validated from a health insurance point of view, according to the procedures already in place and implemented in the SIIS. When adding a new document to the electronic folder, the system will delete the old signature and regenerate it by including the latest changes to the file (i.e. the addition of the new electronic document). As expected, the signature will be generated using the information stored on the insured's EHIC.

The deletion or encryption of the identification information in the fields of the electronic documents is essential because the other information (diagnosis, prescribed treatment, etc.) will be used for other purposes, such as generating statistical reports, or be sent to other entities or institutions outside SIIS. For this reason, this information must be clearly available and the identification data [of the owner] must be protected.

After applying the anonymous signature a signature and verification token will be generated. The token can be later used, if necessary, to prove the identity of the electronic dossier's owner. The token will be stored on the user's EHIC and will be updated whenever changes are made to the electronic dossier.

The electronic dossier of each insured user will be saved on the database servers (Figure 2). The signature will be generated by an application server alongside the RA.

By adding anonymous signatures, the functioning of the system will not be drastically altered. The mode of operation of the system was

presented in the previous chapters and the introduction of the anonymous signature is added to it according to the graphical diagram in figure 4.

For example, for a pharmacist to issue a prescription, he (i.e., the pharmacy's reporting application) will search that prescription in the database using its serial code and number. Once it is found, the pharmacy's RA will check the validity of the dossier containing that prescription using the token stored on the EHIC according to the signature verification diagram shown in figure 5. If the verification process is successfully completed, the pharmacist will be able to release the prescribed medication. After that, the pharmacy's RA will have to make changes to the insured's dossier by marking the prescription as released, thus being able to settle its services from the national health insurance system. The anonymous signing process of the updated insured's dossier will have to be reinitialized and the new verification token will be stored on the EHIC of the insured person, replacing the old one.

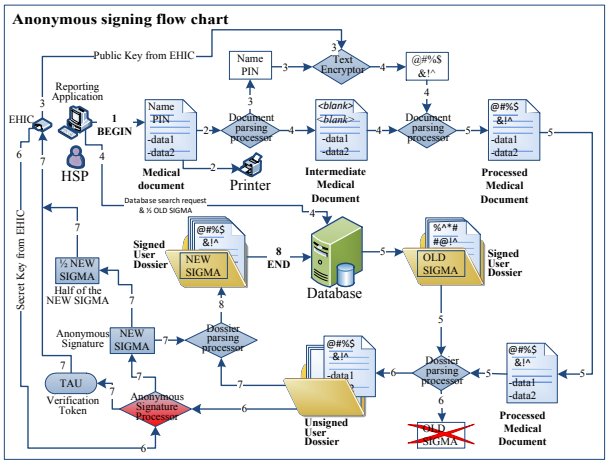


Fig. 4. Anonymous signing flow chart and the modification for simplifying database searches

Following their analysis, the authors realized that a search in the whole database and in each dossier using as search arguments the serial code and number of a specific document (e.g. prescription, recipe, etc.) in a dossier would be very inefficient and would highly increase the response time of the system. Therefore the need arises for a solution that makes database searches more efficient. In this respect, the authors considered that the easiest way would be to look for the insured's dossier first and then look for the document of interest. But by applying anonymous signatures, dossiers can no longer be identified by personal identification data.

So the chosen method to be able to search for a specific dossier in the database is to use the anonymous signature itself for the search, more precisely half of it. For this, the authors have proposed that once the anonymous signature is generated, half of it is saved on the EHIC. Thus, when a particular file is searched, the reporting application will use the half of the anonymous signature stored on the EHIC to perform the search for the desired file.

It was chosen to store only one half of the signature because storing the entire signature alongside the verification token on the EHIC would reveal the identity of the signatory in some unwanted scenarios.

It is also possible that several files with the same signature index will appear as a search result. This scenario is unlikely, but not impossible. In the event of such an event, the desired document will be searched for by using the serial code and number of the document of interest in all dossiers resulted after the search. This is a substantial improvement over the method of searching the entire database.

The step-by-step diagram of the anonymous signature verification process is shown in Figure 5. It can also be observed that at the start of the verification process, beside the verification request, half the anonymous signature stored on the EHIC is also sent to the database. This is necessary to make the database search process more efficient, as mentioned above.

Next we will note $D \in \{0,1\}^*$, as the insured's dossier. Thereby we can write that $D = \sum_{i=1}^{n \in N^*} r_i$, where $r_i \in \{0,1\}^*$ is the electronic document no $i$ which is part of the user's dossier. There is also the key pair $(p_{key}, s_{key})$ obtained from the key generation algorithm $G()$, where $s_{key}$ is the private / secret key and $p_{key}$ is the public key. The key pair $(p_{key}, s_{key})$ is stored on the insured's personal EHIC. When applying the anonymous signature scheme, $\sigma^* = (\sigma, \tau) \rightarrow Sig(sk, D)$ will be generated, where $\sigma$ is the part which will be added to $D$ and $\tau$ is the verification token to be stored on EHIC, which will be used to verify the signature at a later time. Thus we will have $D' = \sigma + D = \sigma + \sum_{i=1}^{n \in N^*} r_i$, which is the signed dossier to be stored on the database server.

In the verification phase, the system will have to compute relation (1), meaning $V(p_{key}, D, \sigma, \tau)$, which is:

$$V\left(p_{key}, D, Sig\left(s_{key}, D\right)\right) \quad (2)$$

If after computing relation (2) the result will be true, for any $D \in \{0,1\}^*$ and for key pair $(pk, sk)$, the conclusion can be drawn that $D$ truly belongs to the claimant and it has not been altered of modified in transit.

Figure 5 depicts a step-by-step flow-chart diagram of the verification process.

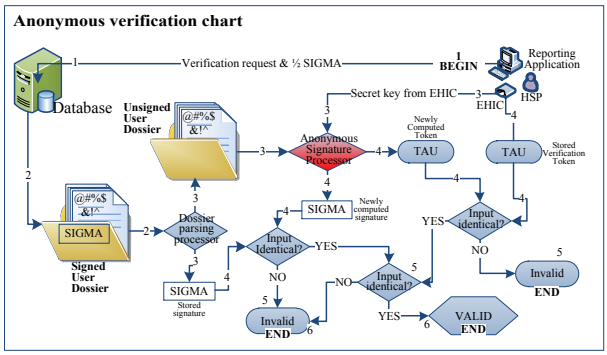


Fig. 5. Anonymous verification flow-chart

*A. Security analysis of the proposed solution*

The proposed solution is using a Saraswat anonymous signing scheme which can be enhanced by adding an asymmetric encryption algorithm. The anonymous signing scheme is needed to protect the identity of the insurance policyholder and to sign its electronic dossier stored on the system. It also ensures non-repudiation and integrity service for the electronic dossier. The asymmetric encryption algorithm is not strictly necessary, but it will encrypt (instead of delete) the identification information of the policyholder (name and PIN) for each electronic document in the insured's electronic dossier, thus providing a wider range of options without compromising security. Note that in the verification phase, the asymmetric encryption algorithm is not required (Figure 5).

In the anonymous signing phase (Figure 4) the old anonymous signature is deleted by a dossier processor so that new electronic documents can be added to the unsigned dossier. Afterwards the dossier is passed through the anonymous signing process and a new signature is computed and added to the updated dossier. The signature $\sigma^*$ was divided into two parts, $(\sigma, \tau)$ by the signature processor. $\sigma$ was attached to the updated dossier as an anonymous signature and $\tau$ was stored on the personal EHIC and will be subsequently used if a verification process is called. The system will also store ½ $\sigma$ on the user's EHIC to facilitate the database dossier search process. During the last step of the signing process the system stores the newly updated and signed dossier on the database servers. This step finishes the signing process.

During verification (Figure 5), the dossier processor will take apart the signature $\sigma$ and the insured's dossier. The unsigned dossier will be passed through the signing process again and the resulting signature $\sigma^{*\prime} = (\sigma', \tau')$ will be retained. The signature extracted from the stored dossier together with token $\tau$ obtained from the EHIC will form the original signature $\sigma^* = (\sigma, \tau)$. The two signatures will be compared and if identical (i.e. $\sigma^{*\prime} = \sigma^*$), it can be concluded that the dossier really belongs to the one who claims it and that it wasn't altered or modified in the meantime.

The integration of anonymous schemes in the Single Integrated Information System will make it possible from an information security point of view to safely transfer the signed electronic dossiers to external entities, without compromising the confidentiality of the insured persons or entities, thus complying with national and European rules and regulations such as GDPR. Addressees external to the system will not be able to identify the owners of the received dossiers and will be able to use the medical information legally in order to fulfill their own goals and missions.

## VI. CONCLUSIONS

Beside the functionalities of standard digital signature schemes, anonymous digital signature schemes keep the identity of the signatory secret until it decides or needs to prove it.

In this paper, a practical example has been investigated in which anonymous signature schemes can be implemented as well as the benefits and improvements it can bring.

The fact that anonymous signatures ensure the protection of users' privacy and identity is a benefit that comes in context of the introduction in the European Union of the General Data Protection Regulations or GDPR. These new regulations require institutions and private companies to apply effective measures to protect the data confidentiality of individuals or their clients. Applying such anonymous signatures can help institutions or companies comply with regulations like the GDPR.

In the context automation and simplifying the operation of state institutions, the national health insurance system has introduced the Single Integrated Information System - SIIS that will maintain and manage health care policyholders electronically and will help to efficiently and quickly manage the national health insurance system.

But, as any IT system, SIIS has some information security vulnerabilities. For example, denial-of-service attacks or unlawful obtaining of medical information about policyholders can seriously affect the functionality and credibility of the national health insurance system. The purpose of this paper was to investigate a possible solution that would remove or diminish the effects of illicitly obtaining medical information about policyholders, protecting their confidentiality and helping to implement the new European regulations (GDPR).

The implementation of anonymous digital signatures in SIIS will allow the system to safely disseminate medical and pharmaceutical data, prepare statistical reports or other purposes without linking that information to the identity of individuals or entities. This solution, in addition to anonymity and signing, will ensure non-repudiation and integrity of information. If necessary, the solution also involves a mechanism for verifying the identity of the signatory.

The cost of implementing anonymous digital signatures in SIIS is estimated to be much lower compared to the costs involved in the initial implementation of the system. The justification behind this statement is that to modify the system by introducing anonymous signatures there is no need for new hardware deployment because it has already been done. The only necessary changes are software implementations and system configurations.

Also, implementing such a solution in the national health insurance system can lead to a reduction in the consumption of consumable materials such as paper and printing ink, because properly securing data and communication links means that will no longer be necessary to maintain a printed archive of documents issued by the health insurance system. This can be considered a small step towards reducing pollution and mitigating our environmental impact.

Anonymous digital signatures can be successfully implemented in other types of applications like the lottery system. Such a solution was proposed in [9]. Here the proposal was to use a hybrid scheme of anonymous signatures to restore players' confidence in the national lottery system, thus increasing the number of lottery players and implicitly the winnings associated with participation in lottery games. The negative side of that solution, unlike the solution researched in this paper, is that it involves high implementation costs because a national electronic lottery (e-lottery) system has not yet been implemented.

## VII. REFERENCES


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## VIII. BIOGRAPHIES

**Narcis-Florentin Antonie** was born in Târgovişte on July 24th 1984. He graduated the courses of the Military Technical Academy in 2008 and is currently studying to obtain his PhD degree in the field of "Electronic Engineering and Telecommunications" with the same university.

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Scientific activity: 14 books published by prestigious publishing houses, 34 papers published in journals (11-ISI indexed), 57 papers published in international proceedings conferences, or nationals with international participation (7-ISI indexed); international research contracts: 4 - project

manager, 2 - research team's member; national research contracts (in the last 15 years): 7 - project manager, 12 - research team's member.

Member of the IEEE professional association.

Domains of excellence: coding information methods, information security methods, communications security systems, radio-relay communications systems.

**Ileana Mariana Mates** was born in Campeni - Alba County on July 11, 1972. She graduated as valedictorian three faculties: Psychology, Sociology and Medical Engineering (Ph.D.c POLITEHNICA University of Bucharest, Romania). Her employment experience included the Central Universitary Emergency Military Hospital Dr. Carol Davila, as Medical Engineer and POLITEHNICA University of Bucharest, as Researcher.

The research preoccupation include: conception, selection, realization, processing of biomaterials and engineering creativity (co-author of 7 patents) in biomaterials and bioengineering fields. She is member of "Romanian Society for Biomaterials"

**Dragoș Glăvan**, was born in Râmnicu Vâlcea on May 3, 1973. He graduated electronics and telecommunications engineering from Military Technical Academy at 1997. He is an active member in Romanian General Association of Engineers.

Position held: Head of IT&C department at Central University Emergency Military Hospital "Dr. Carol Davila"

Scientific activity: 5 papers published in journals.

Domains of excellence: information security methods, communications security systems, radio-relay communications systems, telemedicine.

# Management of the Special Categories of Personal Data in Medical Insurance, for GDPR Compliance

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***Abstract*** - Unlike ordinary companies, Medical Insurance companies process a large range of "special categories of data", as defined by Art.9 of the General Data Protection Regulation (GDPR).
These special categories of data related to heath information may be held across multiple information systems and some systems or components may be shared with other organisations. Many Controllers in the Health and Medical Insurance business use a Data Centric approach, by using data mapping or extraction tools to identify the personal data hold in the enterprise information systems.
This paper discusses health data as it is treated by the GDPR and proposes a different approach, a Data Subject Centric Approach (person Centric Approach), to the management of health of data. The approach is based on treating special categories of data including health data as records and integrating them in the world of corporate records, allowing a unified and consistent management of all corporate information.

***Index Terms*** - Archival standards, Data Subject Centric, Electronic Health Record (EHR), General Data Protection Regulation (GDPR), Health Data, Personal Data Items (PDI), Records Lifecycle, Special Categories of Data, Unstructured Data.

## I. INTRODUCTION

The General Data Protection Regulation (GDPR) is a great piece of law. Based on name, many assume that the GDPR compliance consists of personal data items and processes, and ensuring that data is fully protected from an Information Security point of view.

Health and Medical Insurance companies process a large range of data defined by Art.9 of the GDPR as "special categories of data". Health Data is so important for the GDPR that it is specifically mentioned in five articles and eleven recitals linked to another seven articles EU legislation [1]. There is no other category of personal data that gets so much space in the GDPR.

These special categories of data related to health information may be held across multiple information systems in various environments (structured and unstructured, digital, paper or other media). These systems may be shared between various organisations linked to Public or Private Health bodies.

The GDPR requires the Controllers and Processor to have the capacity to reconstruct the Person's data from the data in structured and unstructured environments to become fully GDPR compliant.

To achieve compliance, it is necessary to adopt a Data Subject (Person) Centric approach, to the management of data. This approach centered on the Person and not on Data is critical for health data. Medical providers and insurers collect health data, which under the GDPR are considered special categories of data, and treated differently than normal personal data. Genetic data and health profiling are also special category of personal data.

## II. THE GDPR REQUIREMENTS

### *1. The General Principles*

The General Data Protection Regulation sets clear principles that apply to all use of personal data, including health data, and to all data controllers and processors. These principles, defined in Article 5, are important and must always be respected by all involved.

### *2. Processing Health and Genetic Data*

The health and medical data of a person, or in GDPR language the Data Subject health data, is specifically defined in the Recital 35 of the GDPR and classified as "special category of data" as per Art.9 [5]. The special categories of data, called in UK "sensitive data", cannot be normally processed unless special conditions are met.

Art. 9.2 indicates that the processing of health data can take place if the patient gives explicit and unambiguous consent to the use of their data or makes it public himself. Data controllers must be able to demonstrate that a person has given consent according to Art.7 paragraph 1. In other words, the burden of the proof is with them, not with the data subject. For children below 16, parental consent is necessary for the processing of data to be lawful Member States may decide to lower that age, but not below 13, as per Article 8 paragraph 1. Recital 38, although not specifically related to health

matters, acknowledges the children need to have their rights protected as they are not able to give a valid consent.

In case of health emergencies, where the consent cannot be taken or other lawful processing cannot be invoked, Article 6 (d) allows the processing of health data if the vital interests of the person require it.

*3. The Patients' Rights*

The GDPR seeks to empower citizens with rights to be informed and puts them more in control of their personal data, data processed in healthcare. The patients retain the same rights concerning personal data as other data subjects [6].

The right of access to medical data concerning the Patient is specified in Recital 63. The patient has the right to object to decisions based solely on automated profiling that can result in legal effects concerning him. Automated decision making and profiling based on special categories of data including medical or genetic data are allowed only under specific conditions, as per Recital 71.

*4. Derogations and Restrictions*

The GDPR bring some important derogations and restrictions related to patients' health data. Recital 52 lists derogations from the prohibition of processing special categories of data. They may apply, according to Recitals 52 and 53, when providing health services, archiving, scientific research and legal defence, among other reasons mentioned.

Recital 54 reiterates that for public health reasons, the consent of the person or patient is not necessary, as long as the rights and freedoms of the natural person are protected. The term Public Health is defined in another EU regulation mentioned by the GDPR, Regulation (EC) 1338/2008.

Recital 65 limits the Data Subject rights to rectification and erasure of health data, on the grounds of public interests in the area of public health.

The Controller has the obligation to undertake a Data Protection Impact Assessment (DPIA) when dealing with special categories of data, especially where high risks to the data subjects are identified (Recital 75). However, small scale health processing as provided by individual medical doctors or pharmacists are exempt from DPIA according to Recital 91.

Recital 112 gives one important derogation to the transfer of personal data between countries in the case of public health emergencies.

## III. STRUCTURED AND UNSTRUCTURED DATA

*1. Structured Data*

Many Controllers in the Medical Insurance business use data mapping, structured queries land data extraction tools to identify the personal data as required by Art.30 of the GDPR. They learn what data items exist, which are the sensitive data processed and where are they located. The end result of the survey is a collection of discrete data.

These methods are limited to personal data located in structured environments like databases, data warehouses and software applications using databases as back end.

In the Health domain, most personal data in a structured form consist of patient data located in Electronic Health Record (EHR) systems or Electronic Medical Records (EMR) systems [2].

*2. The Unstructured Data*

If data items in structured environments can be identified through various querying techniques, not the same happens with unstructured Personal Data.

Unstructured data does not have a predefined structure or model, to allow standard methods.

"Unstructured data" is content without a definite structure that come packaged as an object (files, documents). Unstructured personal data can be found on various media, either digital or non-digital (paper, tapes, film etc.) and in various formats (MS Office formats, PDF, email, video and audio formats, paper, etc.) A lot of personal data exists in the form of unstructured data. It has been estimated by Merrill Lynch [3] that most enterprise data are around 80% in an unstructured form.

In the health domain, unstructured data take form of handwritten clinical notes, letters and email in digital form. This information is not always introduced in EHR, EMR or other information systems but included in the patient's health or medical insurance file.

To extract information from unstructured data, especially for text-based content, various techniques involving specific search engines or text mining have been proposed [4].

## IV. DATA DISCOVERY APPROACHES

### *1. The Data Centric approach*

Art. 30 of the GDPR asks Controllers and Processors to create and maintain a record of processing activities containing information about the categories of personal data and the categories of data subjects processed by them. Various approaches have proposed to meet these data discovery requirements.

In the insurance industry, including medical insurance, the so called "customer journey", a misnomer for the inventory of Personal Data Items collected during the lifecycle of an insurance product, is widely used. The customer data journey is based on interviewing people involved in the data collection, to identify the main events of the customer journey. These events and the corresponding personal data items are identified and analysed in terms of GDPR impact. Interviewing people to find the personal data they process is not efficient: employees often provide incomplete or incorrect information. The customer data journey stops with the end of insurance product, ignoring the mandatory retention following the end of contract.

In parallel, structured data located in databases, data warehouses and similar technologies are queried and mapped, to find the personal data items they contain. In highly integrated environments, data of one person may be held across multiple systems and some systems or components may be shared with other organisations. The extraction of data from information systems results in a collection of discrete personal data items.

All these methods highlighted above follow a data centric approach, the result being a collection of discrete personal data items. But does the Controller or the Processor know the links, the connection between data items? In other words, can the organization reconstruct the person's transaction history if it knows the personal data items located in separate business systems? Discovering discrete subject data items is not enough, it is important to understand the context of this data, the relationship with other items of the same data subject (person).

### *2. Personal Data as Records*

The inventory of the discrete personal data items does not meet the compliance requirements of Art.30. Personal data (PD) is defined as "any information related to an identified or identifiable natural person" as per Art 4. (1). Personal Data is different from the Personal Data Item (PDI), as most PDI cannot, as single data items, identify a natural person. What is missing is the connection between these PDIs.

Personal Data normally consist of two or more Personal Data Items, all together allowing the identification of a natural Person. Neither a name, nor a date of birth (DOB) taken in isolation can identify a specific person. Only the combination of the name and date of birth allows the correct identification of the person and is Personal Data.

This Personal Data can be considered a record. A record is, according to ISO 15489-1:2016, "information created, received and maintained as evidence and as an asset by an organization or person, in pursuit of legal obligations or in the transaction of business". Personal data is the evidence of the identity of a Data subject, in other word a record, a Personal Record.

In the case of Data Subject, be a Person or a Patient, his or her Record is composed by a various personal data items located in various business systems.

As an example, see the image in Fig. 1 [7].

Each table in Fig 1 consists of a number of columns that represent fields containing personal data items. The rows within each table establish linkages between data elements within the different field. The Personal Data records are represented as a number of inter-related data elements that may be connected across one or more tables and comprise data elements from one or more fields [7].

### *3. The Data Subject Centric Approach*

Many Controllers are informed about the Personal Data existing in structured systems, by example in Electronic Health Record (EHR) systems or Electronic Medical Records (EMR) systems but ignore the unstructured data existing in various repositories in the network or the cloud. This problem has been noticed in the medical research and some attempts were made, to combine both types of data to extract information. The method was a combination of SQL queries with a domain-specific search engine [8].

Most personal information contained in unstructured content, namely in documents, files, emails and written notes remains not identified, as Controllers and Processors do not have the resources, or the knowledge to identify it. These are also records according to ISO 15489.

Table A: Personnel

| Staff no. | Surname | First name | Address | City |
|---|---|---|---|---|
| 0078652 | Larsen | Sevren | 78/1 Hoddle St, Carlton | Melbourne |
| 0078653 | Lee | Jamie | 55 Ramsey St, Vermont | Melbourne |
| 0078654 | Smith | Bob | 7 Pollie Crt, Barton | Canberra |
| 0078655 | Schmidt | Helmutt | 1/123 North Rd, Balmain | Sydney |
| 0078656 | Darcy | Kyra | 67 Green St, Mt Lawley | Perth |

Table B: Salaries

| Pay code | Level | Year | Pay rate |
|---|---|---|---|
| A41 | APS4 | Year 1 | $45,000 |
| A42 | APS4 | Year 2 | $46,000 |
| A43 | APS4 | Year 3 | $47,000 |
| A44 | APS4 | Year 4 | $48,000 |
| A51 | APS5 | Year 1 | $54,000 |
| A52 | APS5 | Year 2 | $55,000 |
| A53 | APS5 | Year 3 | $56,000 |

Table C: Cost centres

| Staff no. | Pay code |
|---|---|
| 0078652 | A53 |
| 0078653 | A42 |
| 0078654 | A42 |
| 0078655 | A41 |
| 0078656 | A51 |

Table D: Staff to pay levels

| Centre code | Cost centre | Director |
|---|---|---|
| M001 | Melbourne Office | Shay Jones |
| S001 | Sydney Office | Fred Nguyen |
| P001 | Perth Office | Alberta Johnson |
| C001 | Canberra Office | John Wasp |

Table E: Staff to cost centres

| Staff no. | Centre code |
|---|---|
| 0078652 | M001 |
| 0078653 | M001 |
| 0078654 | C001 |
| 0078655 | S001 |
| 0078656 | P001 |

Key

Yellow — Data elements comprising the personnel record of Kyra Darcy

Tourquoise — Data elements comprising the record of Bob Smith's address details

Pink — Data elements comprising the record of Melbourne Office staff

Fig. 1. Personal Records in a HR database

To become fully compliant with the GDPR, it is important to bring together Personal data items existing in both structured and unstructured form identified during the discovery phase, to link them to create the record of that Data Subject. By linking together all information about a Person we can add context to the information we have about that person and get a full picture.

This is the Data Subject Centric Approach of managing personal data, where all personal data items are linked together to form a Personal Record. As the name shows, the Data Subject Approach is centred on the Person and not the Data, and the purpose is to link all personal data items to obtain the full picture of that person. The Data Subject's Record, in other words the Personal Record, is that picture.

### *4. Advantages of the Data Subject Centric Approach*

The GDPR never expected Controllers and Processors to manage separately Personal Data but to take control of them in the same way as corporate records are controlled.

Treating Personal Data as records allows the integration of personal data into the world of corporate records. This would ensure that their lifecycle is managed from capture to final erasure, in line with the GDPR requirements and other relevant legislation and regulations. The Personal Data retention would be fully integrated in the corporate retention schedule.

This approach would make it easier to meet Data Subject Access Requests (DSAR), by example the request of all Health data held by a health or Medical Insurer. Other rights that would be easier to meet are the data portability right and the right to be forgotten (erasure of Personal Data if no impediment prevents). Further advantages would be, by example, scientific research on health data.

GDPR is not about data discovery and management but about Data Subject's rights expressed through this data. Behind any personal data, there is a human been whose rights need to be protected and upheld.

## V. ACKNOWLEDGMENT

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## VI. APPENDIX

*GDPR specific articles and recitals on Health Data*

Art 9 Processing special categories of data
Art 17 paragraph 5, Right to erasure for reasons of public health
Art 23 e Restriction on processing
Art 36 Controller prior consultation health
Art 88 Health at work

Recital 35 Definition of health data
Recital 45 Processing for health purposes including public health
Recital 52 Derogation from processing special categories of data including health data
Recital 53 Special categories which merit higher protection,
Recital 54 Processing special categories of data without consent
Recital 63 Right to access medical and health data
Recital 65 Right to rectification of personal data
Recital 71 Automated profiling of special categories under special conditions
Recital 75 Restriction if data subject could be damaged, discriminated
Recital 91 No DPIA for small scale health processing:
Recital 112 Derogation in data transfer on large scale health problems

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## VIII. BIOGRAPHY

**Ing. Lucia Ștefan**, MSc, was born and educated in Bucharest. She was awarded a degree in Chemical Engineering from the Technical University of Bucharest in 1985. She changed her specialisation to Computing and was awarded a Master in Science (MSc) in Computing and Information Systems, by the University of Greenwich in London, UK in 1997. In 2006 she joined The National Archives of UK where acquired a solid grounding in Electronic Records Management and Digital Archiving.

Her employment experience includes major British and International Organisations: The Competition Commission of UK, The Joint Research Centre of The European Commission, The Electoral Commission of UK, Eumetsat, Credit Suisse Bank Switzerland, UNDP Afghanistan, Eurocontrol, Aviva Insurance UK, to name some of her most important clients.

The research interests include digital archiving and data protection.

# A Retrospect of Biomedical Engineering at Greater Romania's Centenary

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**In memoriam Radu Vrâncianu, Stewart Wolf, Swamy Laxminarayan, Joseph Levy and Pompiliu Manea**

***Abstract*** - Biomedical Engineering (BME) features a research branch involved in studying life mechanisms with engineering concepts & tools - bioengineering, and a more practical one involved in patient care within medical units – clinical engineering. The Romanian BME roots before the Great War must be sought at the beginning of the technical/medical (Transylvania 1777/1775, Wallachia 1850/1857, Moldova 1813/1879) higher education in the territories inhabited by Romanians. The end of the 19th century records the first BME-type professionals, with medical education, engaged in the introduction of the radio-diagnosis and therapy. In United Romania first technical (electrician) position in a medical unit (Institute of Radiology in Cluj) was created in 1920. Gradually, in the inter-war period, tens of technical-medical engineers and technicians worked as external collaborators of Cluj Clinics, but many of them being de facto clinical engineers. Nationally, in 1923 the engineer P.N. Georgescu took the lead of the Workshops of the MoH, transformed into the CAMSOM, then into RECAS (1946), and after the 1948 nationalization into the Technical-Medical Enterprise (ITM) in Bucharest/Berceni. Until the 1989 Revolution it was generally about of design, construction, assimilation using imported models, at mild/medium technical level, i.e. a technical-medical industry, adjacent and needful but outside of the BME definition. Bioengineering in the present sense made Radu Vrâncianu since mid '50s as the first research engineer employed in a medical institution. Presence of electro- or mechano- engineers in the clinic was occasional rather as a daily activity together with physicians – what clinical engineering does means. After 1989 there was established a specialized BME education, although there were beforehand a few (mainly electronics) auto- rather than formally educated engineers integrated with biologists, chemists and university physicists into research, or - with timid advent of imported high tech - even in some clinics. Since 2000 clinical engineers or medical bioengineers were introduced in Romanian Occupation Registry, COR, while INGIMED conferences were only to put together year-by-year scientists, professionals and youth, under FRIB auspices backed up by the Institute of Public Health (ISPB), Academy of Medical Sciences and since 2010 by INCDIE ICPE-CA in Bucharest. Despite some progress, the current setting of BME in Romania is still precarious, only about 3% out of graduates being nowadays integrated into the public health system.

***Index Terms*** - BME scientific dissemination in 2000s, communist interval, post-Revolution time, present status of Romanian BME, United Romania.

## I. INTRODUCTION

In Middle Ages simple instruments were developed by craftsmen abreast of advances in human anatomy & physiology – the core of medical art, the science of sciences, whose study lasted ≈ 9 years. Italians championed medicine during Renaissance and later: doctors from Italy bringing with them up-to-date tools are mentioned as caregivers and often counsellors of Stefan the Great or Brancoveanu.

Thus is no wonder that on late 1700s Aloisio Luigi Galvani (1737 –1798), a Bologna-born physician, physicist, biologist and philosopher, remarked in 1780 that the muscles of dead frogs' legs twitched struck by an electrical spark, discovering that way bioelectricity - now a bioengineering sub-domain that studies the electrical patterns and signals from nerves and muscles. He also and pioneered bio-electromagnetics, helped by wife Lucia, one of the first female-scientists [1].

So that many are thinking that Biomedical Engineering (BME) - including bioengineering i.e. the use of the principles and techniques of engineering to solve problems in biology and medicine - began with Luigi Galvani.


Fig. 1. Galvani's effigy at right and the experimental set-up used having been used to demonstrate the effect of electrical current on frog's legs in 1780. In the set-up a Wimshurts electrostatic machine (at left) makes a Leyda glass jar (an early capacitor, at right) to accumulate electric charges before applying them on the biologic preparation.

At the end of 19th and early 20th centuries engineering influenced biomedicine especially through measuring instrumentation and imaging.

By the Great War I, x-ray machines, thermocouples, galvanometers were already regularly present in research milieus. Medical diagnosis and treatment, too, began to get benefits from electrocardiography, electro-surgery, diathermy, and x-ray therapy.

In the two or three decades following World War II, BME emerged as a recognized branch of engineering, combining bioengineering with clinical engineering [2], under the need to put at work new imaging techniques such as ultrasound and computerized tomography, the cardiac pacemakers, or radio-isotopic procedures.

By the end of the 1960s biomedical engineering was also a recognized academic discipline, with degree-granting programs at both graduate and undergraduate levels.

In the last three decades of the XX century and at beginning of the XXI BME grew both as a business and as an academic discipline. It now encompasses many types of engineering and almost all areas of biology and medicine. Some of more recent achievements have been imaging using nuclear magnetic resonance and PET, laser surgery, endoscopic techniques, automated laboratory testing, prosthetic devices, and hospital information systems [3]

Health care industry is world-wide the most important, and its increase never curbed during various economic/financial crises.

## II. ROMANIAN PRELIMINARIES OF BIOMEDICAL ENGINEERING

The BME roots before the Great War must be sought at the beginning of the technical or medical higher education.

In Transylvania imperial regulations *by "Ratio Educationis"* in 1777 launched technical studies of Architecture, Hydro-technics, Geodesy, alongside with Mechanics in Cluj [4].

In Moldova Gh. Asachi has created in Jassy tthe first school to qualify topographers and civil engineers by 1813 [5].

Even though Gh. Lazar had founded in 1818 at St Sava in Bucharest the first broad-spectrum university-type school in Romanian Principalities (including topographers), only in 1850 Barbu Stirbei approved a clearly technical profile (Topography, Bridges & Roads, Architecture), restricted by Alexandru Cuza in 1864 to Bridges, Roads and Mines.

The term "Polytechnic", inspired by the French, was given in 1920 to the Technical Higher School under Ministry of Public Works, that became the Polytechnic Institute after the education reform in '48, with the Electro-technics Dept. since 1951 and the Electronics & Telecom Dept. since 1953 – main sources of BME professionals at us [6].

In Transylvania medical higher education begins at the Medico-Surgical College in Cluj in 1775 offering "masters of surgery and midwifes" certificates; it became in 1784 the Royal High School - teaching in Hungarian, and finally the Faculty of Medicine in 1872, under the Ferenc Jósef University until 1919 [7].

In Romanian Principalities (independent before 1859, united afterward) such studies began in 1857 - Bucharest (National School of Medicine and Pharmacy, since 1869 Faculty of Medicine) and in 1879 – Jassy (Faculty of Medicine, with the inaugural lecture held by Prof. dr. Ștefan Micle with a mechanical engineering formation got at the Vienna University). With multiple technical abilities proved by his innovations in medical instrumentation & lab physics, being fully integrated in the medical world and a large cultural horizon St. Micle has been a professor of sciences and the Rector of the University Moldova & Wallachia created in 1860 in Jassy, being seen by a renowned expert like Dr. Pompiliu Manea as *"the father of medical engineering in Romania"* [8].

In this period the young Carol Bünger specialized in prosthetics and medical instrumentation arrives in Romania to deal with problems of war disabilities subsequent to the Independence War (1877-78). Bünger created in 1880 a medical technology industry held 68 years long by his family until the 1948 nationalization [ibidem].

The end of the 19$^{th}$ century records the first BME-type professionals, with medical education complemented out of necessity with technical abilities, engaged in the introduction of the radio-diagnosis and therapy, shortly after the X-ray discovery in 1895, in Bucharest Military Hospital. Significantly for our perennial mentality, although the first specific equipment was imported in 1887, the actual putting into operation (first radiography) was only done in 1889 by Prof. dr. D. Gerota [9]

The reason? The same as today: the absence of clinically-integrated technicians.

## III. TECHNICAL-MEDICAL ACTIVITIES IN UNITED ROMANIA

At Cluj, technical-medical activities began shortly after the Unification at the "Dacia

Napocensis" University, subsequently University "Ferdinand I" - 1919. Prof. dr. D. Negru asked in 1920 to the Ministry of Health (MoH) and Social Welfare for an electrician position at the Institute of Radiology, assumed by Rudolf Stransky until 1972. In the years 1926-1927 D. Negru brought from Siemens Röntgen equipment (as war reparations) and initiated a School of mechanics for Röntgen apparatuses in 1931 to get rid of the German servicing, with a curriculum of radiation physics, electricity and introductory notions in X-ray machines, using his manual: "Medical Radiology - Preparatory and General Techniques.

On this basis, the core of medical technicians in Cluj developed gradually being hired by: Clinics' Workshops, *Medico-Tehnica* (1940-1948), and farther, under communist rule, by RECAS (*Regia Economică Comercială a Atelierelor Sanitare*, 1948-1957) - Cluj Division, Workshops of the Institute of Medicine & Pharmacy (IMF) Cluj (1948-1990), ARAM (*Atelierul Regional pentru Aparatură Medicală,* 1960-1968), AJIRAM (*Atelierul Județean pentru Întreținerea și Repararea Aparaturii Medicale,* 1968-2003), CJAM (*Centrul Județean pentru Aparatură Medicală,* since 2003). Within this framework tens of technical-medical engineers and technologists, qualified through auto- , profile high-school or workplace formation, activated as external collaborators of Cluj Clinics, but many of them as de facto clinical engineers [7].

At the national level, in 1923 the engineer P.N. Georgescu (graduate of the École supérieure d'électricité – Supélec in Paris) took the lead of the Workshops of the MoH, conceiving the first "nickel bath" for instrumentation, and bringing from the Germany since 1928 stainless steel he used for the first inland sterilization cassolettes, electric sterilizing kettles and thermostats.

In 1937 the MoH Workshops were transformed into the CAMSOM (*Concesiunea Atelierelor Ministerului Sănătății și Ocrotirii Muncii*), then called RECAS (1946), and after the 1948 nationalization the Technical-Medical Enterprise (ITM, *Întreprinderea Tehnico-Medicală*) with the main facility in Berceni but including several remote units like RECAS, Bünger Industries, *Medico-Tehnica* Cluj (radiology), the Workshops for construction of medical devices, Sanitaria (syringes Sighișoara) [10].

A top technical-medical performance in the inter-war period was the first classical tomography made in Romania at the Moroeni/Dâmbovița TBC Sanatorium (1940) [11].

Fig. 2. Dr. Eng. Pompiliu Manea (1935 – 2015), honorary member of the Academy of Medical Sciences of Romania, an educator and a leader of technical-medical community of Cluj, provided main data on the early history of BME.

## IV. BIOMEDICAL TECHNICAL ACTIVITIES DURING COMMUNIST REGIME

In December 1980 the Communist Party evaluated the medical technology production - based that time on copying foreign products. The just concluded quinquennial plan for medical tech had been fulfilled only as 160/300 billion Lei. As Ceaușescu ordered since 1881 the entire instrumentation and all current sanitary materials had be produced internally, and medical students be thoroughly trained in efficient using of equipment and even in their maintenance and repairing (!).

Trying to escape from funding demands expressed by experts (as Prof. Proca, Minister of Health) Ceaușescu literally said, using a well-known communist tactics of converting a half-truth into a dogma: *"We begin to turn medicine into fine mechanics, and physicians are no longer physicians, neither are they mechanics, and they become people without a clear job. Not on the apparatuses we need to focus on people's care [because this] makes of a doctor a human being lacking of human spirit, dehumanizing him. […] We had good medicine when the doctor did not work with the devices, but with the ear, with his sense of man, and that is why we probably had the best doctors in the world* (sic!)*"*.

To mitigate a bit the grim general image Prof. Proca evoked the Medical Electronics Chair from Timisoara Polytechnic and progresses in radiology equipment, anesthesia devices, operatory lamps, and sterilizer production. From 1975 ITM had moved from MoH to the Ministry of Machine Constructions (Ioan Avram), without evident advances [12].

Prior to the Revolution, Eltex 400 radiology apparatuses have been produced at *Electrotehnica,* Cardior electrocardiographs and dentistry equipment at IOR *(Întreprinderea Optică Romană*), and some more advanced devices at *Electronica* and FEMI (*Fabrica de Aparatură Electronică pentru Măsurări Industriale*)

*

It appears that until the Revolution it was generally about of design, construction, assimilation using imported models, at mild or medium technological level, belonging rather to the technical-medical industry, adjacent and needful but outside of the actual BME definition.

Bioengineering in the present sense made the great Prof. dr. Daniel Danielopolu with the polygraph method adapted to IFNP (Institute of Normal & Pathological Physiology), where Radu Vrâncianu (RV), just exiled from Radio-TV, started in mid '50s his full-time bioengineering activity, as the first research engineer employed in a medical institution [13]. RV's activity has stimulated the interest of medical leaders such as Grigore Benetato or Ion Hăulică, breaking in premiere the conceptual wall that had separated engineering from medicine.

About true clinical engineering it will not be yet about, the presence of electro- or mechano-engineers in the clinic being occasional (training of medical personnel, troubleshooting), but not daily activity together with colleagues physicians including clinical research.

However volumes like *Metode bioradiotelemetrice în medicină* by Gr. Benetato, R, Vrancianu, and Val. Ionescu, Ed Academiei 1971, *Electronică Medicală* by R. Strungaru, Ed Didactică & Pedagogică 1982, or *Inițiere in electronica medicală & Instrumentația electronică biomedicală* by R. Negoescu, Ed Tehnică 1985-86 have stimulated interest of youth who later became true BME professionals.

## V. BIOMEDICAL ENGINEERING IN THE POST-REVOLUTION TIME

After the 1989 Revolution, Romania have established the true specialized higher BME education, whose roots ought be searched early in 1935-1946, when the engineer Gh. Harnagea organized a Division of radiology & electro-physio-therapy within the School for Army Specialists, and, still, in 1948 when Prof. dr. Octav Costăchel had introduced the college teaching for biomedical technologists specialized in electro-physio-radiology [11], and farther in late '70s when medical electronics chairs in Timisoara and Bucharest Polytechnics were guiding specific diploma projects. At the same time there were - in a modest number - electronics engineers with auto- rather than formal biomedical education integrated with biologists, chemists and university physicists into medical research, or - with the timid advent of imported high tech apparatuses - even in some clinics.

On these pre-Revolution foundations, there are or have been in last 2 decades a Faculty of Medical Bioengineering at the University & Pharmacy "Gr. T. Popa" in Jassy, a Faculty of Medical Engineering at Polytechnic University of Bucharest, profile specializations with the Polytechnics of Cluj, Timișoara, Craiova, and, in the private, a profile department with the Institute of Applied Informatics of AISTEDA University (until 2002).

Fig. 3. Prof. Dr. Engineer Bedros Petru Naianu (1947 – 2008) has developed BME teaching with AISTEDA University and created in 2001 the Romanian Federation of Biomedical Engineering.

In 2012, a report from Technical University of Cluj estimated as BME-registered 450 out of its 30,000 students. A survey on 2012 data was reporting about 1,000 BME specialists, of whom only about 3% were integrated into the public health system, although since 2000 clinical engineers or medical bioengineers were introduced in Romanian Occupation Registry, COR, as follows [14]:

- 2000, February: the profession of clinical engineer (by diligences of the AISTEDA University) has been introduced in Romania's COR; in the COR 2014 (harmonized with ISCO 08) the clinical engineer features the code 226301 (Major group 2 – Specialists, Major subgroup 22 – health specialists);
- 2000, June: idem for the medical bioengineer (due to University of Medicine and Pharmacy "Gr. T. Popa", Jassy); COR code 2014: 226904.

## VI. SCIENTIFIC DISSEMINATION OF BME IN 2000s

Salutary periodic conferences (every 2-3 years) took place in Jassy (UMF, Department of Medical Bioengineering) or Cluj (Technical University Electrical Engineering School, medical bioengineering specialization) under Romanian Society of Medical & Biological Engineering). Romanian Society of Medical Informatics led by Prof. dr. Gh. Mihalaș followed this trend in a sister-discipline.

However, since 2000 INGIMED conferences only put together year-by-year scientists, professionals and young attracted by a BME career, under sustained FRIB auspices, backed up since beginning or gradually by the Institute of Public Health (ISPB), the AISTEDA University, the Academy of Medical Sciences and since 2010 by the National Institute for Research and Development in Electrical Engineering ICPE-CA (INCDIE ICPE-CA) in Bucharest [14].

## VII. INGIMED MILESTONES

2001, May 28: The Romanian Federation of Biomedical Engineering (FRIB) - 7 founding members - academic and research units - led by the general director Assoc. Prof. Dr. Bedros Nae (Naianu).

2001, December 13: The first INGIMED under this name, which becomes II by attributing suffix I to the 1st December 2000 BME conference at the ISPB.

2002, Nov 29-30: INGIMED III; Academicians Mihai Drăgănescu & Nicolae Cajal - Honorary Presidents.

Ingimed 2003 - 2009: large conferences, international participation along 1½ days, hosted by ISPB, Polytechnic University, ICPE, University of Medicine & Pharmacy (UMF), and AISTEDA University.

Ingimed 2010 - 2017: round table format of ½ day; the generosity of ICPE-CA, Prof. Dr. Wilhelm Kappel, allowed maintaining regularity, quality standards and post-publishing due to the Bulletin of Micro & Nano Electro-technologies - Chief Editor Dr. Engineer Mircea Ignat [ibidem].

## VIII. CURENT SETTING OF ROMANIAN BIOMEDICAL ENGINEERING

Despite post-revolutionary progress in teaching and scientific societies/dissemination, the current setting of BME in Romania is still precarious, how precarious is the one in Europe vs United States [15].

Hopes are in youth, like those guided by Dr. M. Ignat for research at ICPE-CA, who working here or part-time between Romania and the States - for example, could shorten the gap versus advances countries in benefit of our co-nationals - patients or still healthy subjects.

The recent political move that doubles (rightly) the earnings of medical staff but leaves wages of para-clinical colleagues at a shameful level throws the seed of disruption between brains already differently educated and does not promise anything good for the near future.

Yet, politicians and governments change and, after all, Jean Moscopol will be right: *"Everything that is Romanian does not perish, and it will not perish"*, what applies, for sure, to Romanian BME too.

## IX. SUMMARY

The roots and early growth of inland technical-medical activity co-existed with introduction and development of technical and medical higher education in late 1700s or early-to-mid 1800s in Romanian Principalities, and in Transylvania province that time belonging to Austrian/Austro-Hungarian Empire, as well as with founding of European-type hospitals.

The end of the 19th century records the first BME-type professionals, with medical education, engaged in the introduction of the radio-diagnosis and therapy (as the facto clinical engineers).

After Unification of Romania in 1918 there was instituted a more formal BME education at technologist's level, but clinical integration of such specialists had to wait many decades for the advent of imported high tech medical equipment, lesser under communist rule but gradually increasing after the Revolution.

At its turn, bioengineering was also a matter of interest shown by top medical personalities, taken afterward over by specifically auto-educated electro- or mechano- engineers before introduction of formal BME education in mid 1990s.

The current setting of BME in Romania is still precarious because of a nonsignificant clinical integration of BME graduates (despite of existence of the legal provisions as far back as 2000), the public health system remaining tributary to onerous external servicing contracted with foreign equipment producers on patient's account in terms of costs as well as of inadequate dedication & promptitude.

The recent political move that doubles (rightly) the earnings of medical staff on para-clinical personnel's account left at a shameful level of revenue *("anyhow they are less prone to leave the country")* does not promise anything good for the near future. The Resolution of the INGIMED XIX Centenary Conference on 2018, November 22 tried to counteract this serious drawback.

## X. ACKNOWLEDGMENTS

The author is indebted to Mr Bogdan Manea and Mrs Ioana Alexandra Cirebea who made available unpublished manuscripts of late Dr. Pompiliu Manea in preparing a monograph dealing with *"Medical Engineering and Technics in Romania from Beginning to Present Days. Men and Institutions."*

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## VI. BIOGRAPHY

Professor **Radu Negoescu**, M.Eng., MPH has a background of electronics engineering with the Bucharest Polytechnic and a doctoral/master specialization in cardiovascular bioengineering and public health. His professional itinerary includes National Institutes of Health in Bethesda, MD & Totts Gap Institute in Bangor, PA, USA, and the (National) Institute of Public Health, in Bucharest. He is an honorary member of the Academy of Medical Sciences of Romania.

# Research theme regarding the contributions in the microsurgical domain

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***Abstract*** **-** This paper presents and analyzes the most important microsurgical procedures and develops several mechanisms capable of improving the skills of aspiring surgeons and even specialists. The prototype's final models allow the surgeon's performance to be interpreted by analyzing the pressure exerted by the surgeon on the tissue and the precision of the incision.

***Index Terms*** – Microsurgery, piezoelectric sensor, sutures, precision game, vertical frame procedure, horizontal frame procedure.

## I. INTRODUCTION

Microsurgery is a general term for surgery requiring an operational microscope. The most obvious evolutions have been developed to allow the anastomoses of blood vessels and smaller successive nerves (usually 1 mm in diameter) that have allowed the transfer of tissue from one part of the body to another and the reattachment of the cut parts.

We have developed a series of games and procedures that will allow the surgeons to improve themselves by practicing different techniques, such as suture or incision at a micro and macro level.

## II. CONTRIBUTIONS

### *A. The surgeon's mark*

We started this game by attaching a piezoelectric sensor to a knife and connecting it to an oscilloscope. Then, we started doing an incision on rubber and polystyrene (Fig. 1 & 2).

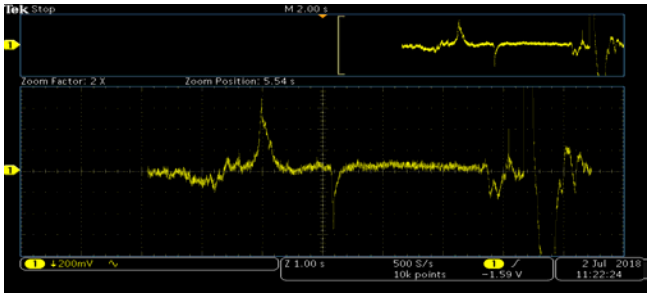


Fig. 1. The incision of the knife through the polystyrene. We weren't satisfied with the results the knife provided us, because the tension is very unsteady

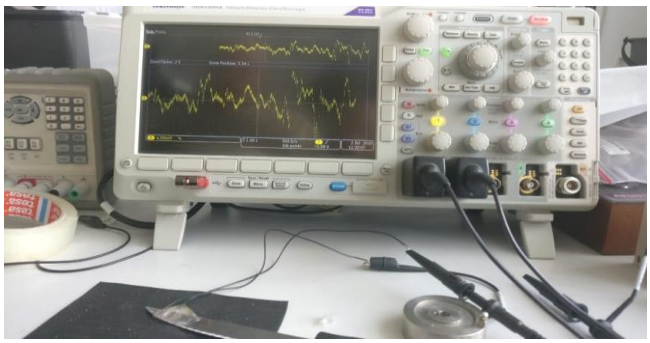

Fig. 2. The oscilloscope that we used in our experiments

The knife didn't prove to be really precise, as you can see in the graph above, because we have put the piezoelectric sensor too close to the tip and also we have stuck the sensor to the knife with duct tape, resulting in very little tension felt by the sensor (that is why this graph is the only one where we have set the tension of the oscilloscope to 200 mV).

We have then put another piezoelectric sensor below the material this material was as soft as the human tissue, and we measured both the mechanical tension felt by the scalpel and the "tissue" (Fig. 4). The moment where the scalpel cuts the material over the piezoelectric sensor is described in the graph by the big difference in tension, seen at the start and at the end of the incision. (Fig. 3)

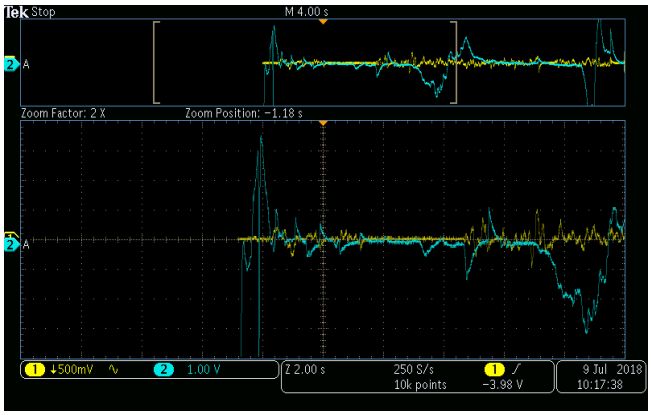


Fig. 3. The mechanical tension felt by the tissue (blue line) and the mechanical tension felt by the scalpel (yellow line)

The incision starts where tension rises suddenly, almost above 1V, and ends at the end of the graph, where the tension drops. Both these big

voltage fluctuations show both the start of the incision and the moment the scalpel cuts over the material, under which the piezoelectric sensor is.

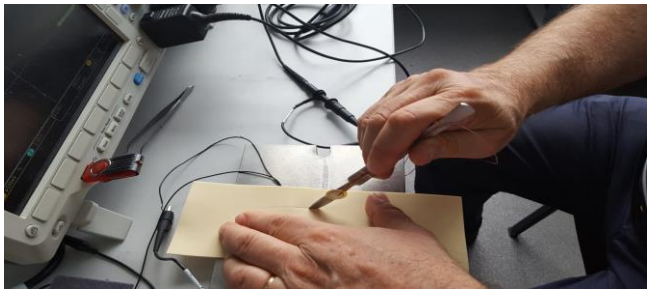

Fig. 4. Picture of the material, under which the piezoelectric sensor is, and the scalpel, with the piezoelectric sensor on it, performing an incision

As a continuation to this game, we have added an accelerometer and a gyroscope to the wrist of the hand which did the incision. This way we can observe also the movement of the hand as well as its acceleration.

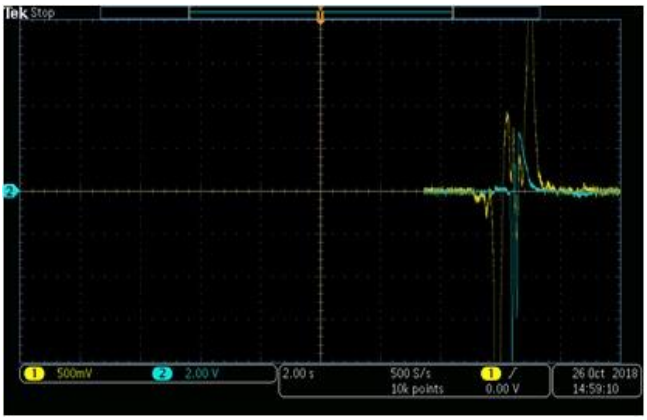


Fig. 5. The oscilloscope graph

The first graph (Fig. 5) represents the incision, the tension felt by the material (blue line) and the tension on the scalpel (yellow line). The tension felt on the material exceeds 8 V when the scalpel passes over the sensor, and the tension felt by the scalpel grows over 2 V when the test subject applies more tension to the incision.

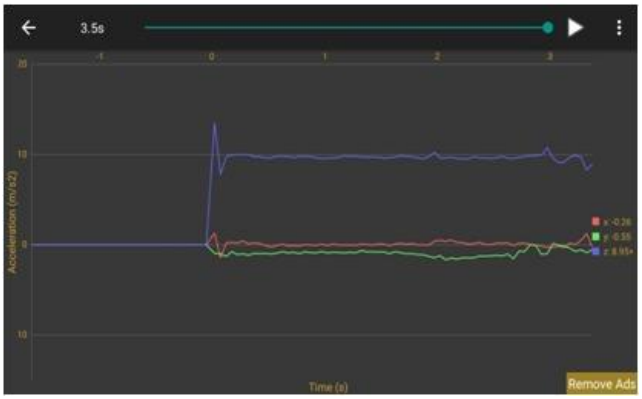


Fig. 6. The accelerometer graph of the suture in Fig. 5

The acceleration graph (Fig. 6) is represented by three axes - x (red line), y (green line) and z (blue line) - in a two-dimensional plane. You can see the constant of the blue line from the beginning of the incision to the end, representing the acceleration on the z axis of the hand. This indicates that the incision was made with a constant speed, and judging by the oscilloscope graphic, with a scalpel's tension that surpasses 2000 mV (2 V) and a material's tension that reaches 2 V.

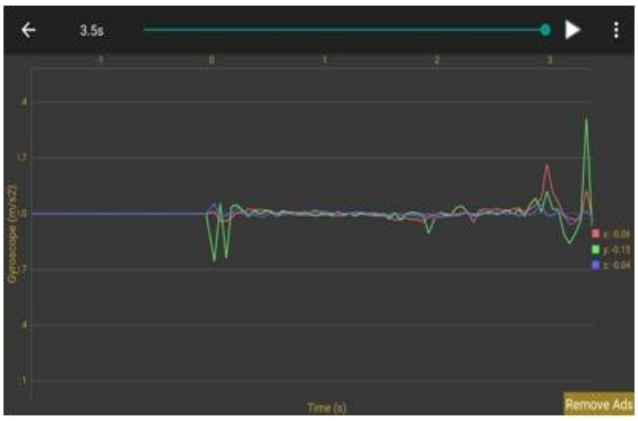


Fig. 7. The gyroscope graph of the suture in Fig. 5

The gyroscope chart (Fig. 7) is represented by the same axes of the same colors as the accelerometer, and the variations of the hand movements can be observed in the x, y, z coordinate system from the beginning of the incision to the end.

### *B. In-depth study of mechanical tension on the material at the time of suture*

This evaluation method is based on the previous game and consists of attaching a piezoelectric sensor to the material, which tries to mimic the skin model, then connecting it to the oscilloscope (Fig. 8) and measuring the tension felt by the tissue, during a stitch (Fig. 9). Also we will keep track of the maximum tension at which the material will break. (Fig. 10)

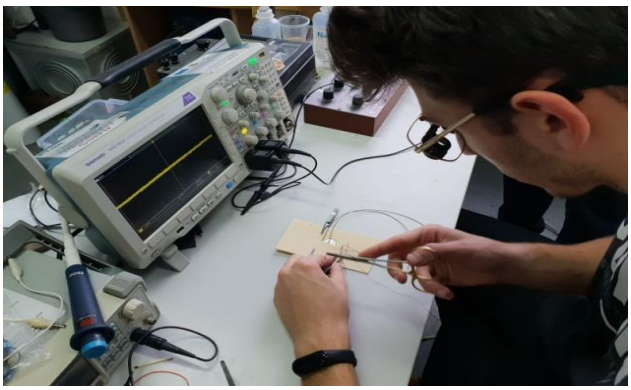

Fig. 8. The suture with the piezoelectric sensor inside the material

This picture is an outside view of the game, illustrating the oscilloscope connected to the piezoelectric sensor, inside the material, and the needle holder.

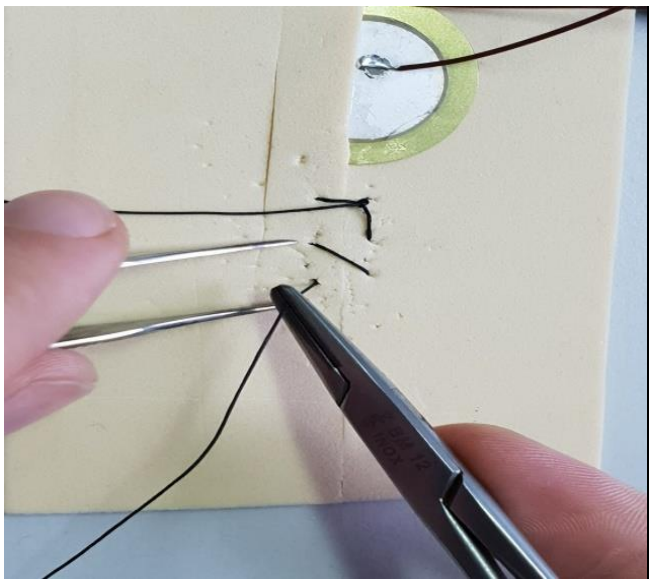

Fig. 9. Close look at the suture

Here we can see a closer look of the suture and the piezoelectric sensor, placed inside the material. The needle holder is locked on top of the thread, ready to close the suture.

Fig. 10. The gap that appears at the moment of adding too much tension to the suture

After we have completed the suture, we have added tension to the yarn ,in order to see at what tension a gap appears in the material(Fig.10).For this material, we have recorded, using the oscilloscope, that the tension required to widen the gap through which the thread comes out is approximately 500 mV.

The goal of this game is to record the maximum amount of mechanical stress applied to the support material so that it becomes a threshold value that should not be exceeded.

Also, in the vascular anastomoses, it is important both the blood vessel tension and the number of stitches applied. Thus, the higher the tension in the vessel and the yarn, the higher the risk of creating holes through which there may be blood leakage.

*C. Demonstration of sutures on materials that imitate the skin*

As a method of practice, we have started to suture on a material that imitates the softness of the skin, so that we would familiarize ourselves with different types of sutures (Fig. 11 & 12).

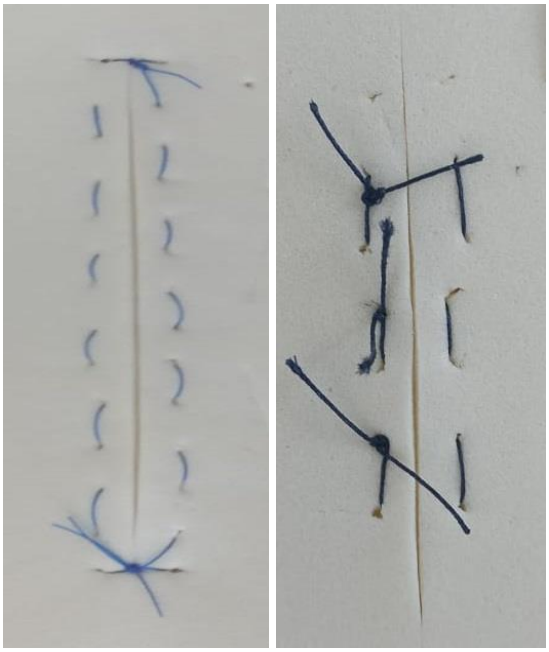

Fig. 11. Demonstration of the orizontal continous suture and the orizontal interrupted suture

Like every beginner, we didn't know how to make sutures, so these materials have helped us develop this skill. We have also found out for the type of wound which type of suture is used. For example, the continuous sutures are used for suturing internal organs, because they take less time to be made (Fig. 11, left image).

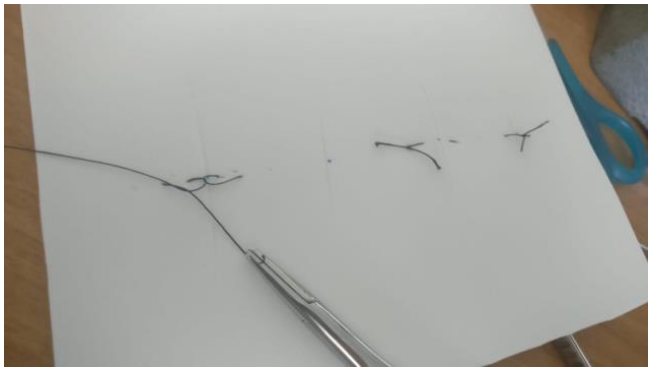

Fig. 12. (from left to right) - vertical suture, normal suture and the simple interrupt suture

The interrupted sutures are used for skin wounds, but are also used for vascular anastomoses. (Fig. 11, right image & Fig. 12, right suture)

*D. Precision game*

This game involves the use of a metallic frame in several hypostases, a scalpel and a multimeter. The scalpel and the metal frame are connected to the multimeter. Because the metal frame and the scalpel are connected both to the same multimeter, at the moment of touching, a short circuit will happen, causing the multimeter to sound a beep, warning the touch.

*1. The vertical frame procedure*

For this procedure, we will need a scalpel, a multimeter, a vise and a metal frame.

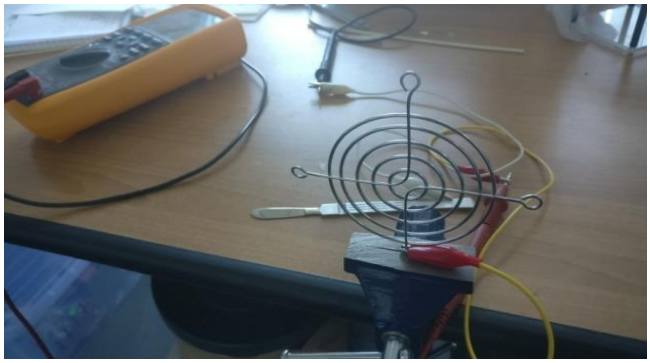

Fig. 13. The vertical frame connected to the multimeter

The metal frame will be fixed inside the vise, and both the metal frame and the scalpel will be connected to the multimeter (Fig. 13).

After all the equipment has been set up, the procedure can begin. The trainee must hold their hand on the table, so that the shake of the hand will be minimal. The trainee will be tasked to complete several routes through the metal frame as fast as possible (Fig. 14). The routes will vary, regarding the tightness and the length of the route.

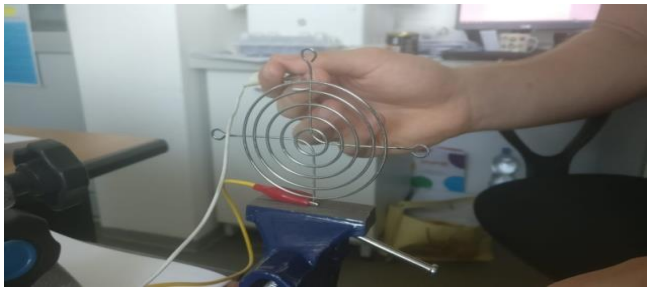

Fig. 14. The route with the scalpel inside the frame

- How will we evaluate the trainee?

We have developed a table which will guide and allow the evaluator to perform a complete evaluation of the procedure, which all will result in a mark given to the trainee. We believe that in order for the student to "pass" this procedure it would be recommended to have a mark over 8.

Table I. Vertical frame

| Criteria | Parameters | Penalization points |
|---|---|---|
| **I. Route through the frame** | 1 Touch--1p<br>2-5 Touches--2p<br>6-9 Touches--3p | |
| **II. Time** | < 45 seconds--0p<br>45-55 seconds--2p<br>55-65 seconds--4p<br>> 65 seconds--6p | |

- Observations:

1) The maximum score of this procedure is 10 points.
2) At the start of the procedure, the trainee starts with 10 points.
3) The hand must be held on the table at all the time.
4) The route is started clockwise, and then the trainee moves on to the next circle, changing direction each time, until the route through the frame is completed.

*2. The horizontal frame procedure*

For this procedure we will need a multimeter, a scalpel, a metallic frame and a material that will have the same texture as the skin. The scalpel and the metallic frame will be connected to the multimeter, and the metallic frame will be put over the material (Fig. 15).

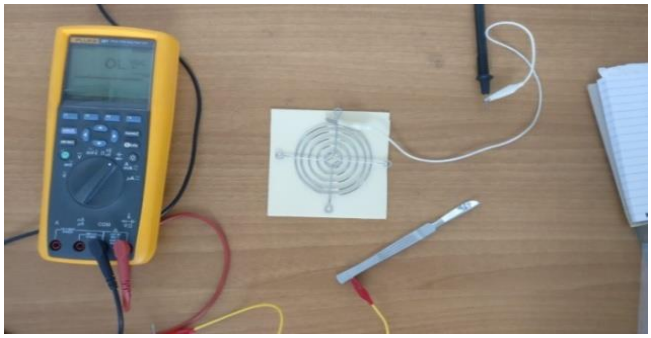

Fig. 15. The scalpel and the frame,both connected to the multimetre, on the horizontal side

Just like the other procedure, after the equipment has been set up, the trainee can start the procedure after the equipment has been set up. The trainee must hold their hand on the table, so that the shake of the hand will be minimal. The trainee will be tasked to complete several routes through

the metal frame as fast as possible, cutting through the material under it.

- How will we evaluate the trainee?

Just like the other procedure we have developed a table which will guide and allow the evaluator to perform a complete evaluation of the procedure, which all will result in a mark given to the trainee. We believe that in order for the student to "pass" this procedure it would be recommended to have a mark over 8.

TABLE II. Horizontal frame

| Criteria | Parameters | Penalization points |
|---|---|---|
| **I. Route through the metal frame** | 1 Touch--1p<br>2-5 Touches--2p<br>6-9 Touches--3p | |
| **II. Time** | < 45 seconds--0p<br>45-55 seconds--1p<br>55-65 seconds--2p<br>> 65 seconds--3p | |
| **III. Cutting of the material** | Uniform cut--0p<br>< 3 uncut places --1p<br>3-5 uncut places--2p<br>> 5 uncut places--3p | |

- Observations

1) The maximum score of this procedure is 10 points.
2) At the start of the procedure, the trainee starts with 10 points.
3) The hand must be held on the table at all the time.
4) The route is started clockwise, then the trainee moves on to the next circle, changing direction each time, until the route through the frame is completed.
5) The support must be held with one hand so that the material will stay in once place whilst it is being cut.

The purpose of this game is to help the trainee develop accuracy and steadiness, whilst also helping him do a proper incision.

## III. ACKNOWLEDGMENT

The authors gratefully acknowledge the contributions of Mircea Ignat for the guidance and the help he has given during the creation of the theme. Also the authors would like to thank the National Institute for Research and Development in Electrical Engineering ICPE-CA Bucharest (INCDIE ICPE-CA) "Alexandru Proca" for support.

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## V. BIOGRAPHIES

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# Preparation of a Formatted Technical Paper for the Bulletin of Micro and Nanoelectrotechnologies

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***Abstract*** - This document is itself an example of the desired layout (inclusive of this abstract) and can be used as a template. The document contains information regarding desktop publishing format, type sizes, and typefaces. Style rules are provided explaining how to handle equations, units, figures, tables, abbreviations, and acronyms. Sections are also devoted to the preparation of acknowledgments, references, and authors' biographies. The abstract is limited to 150 words and cannot contain equations, figures, tables, or references. It should concisely state what was done, how it was done, principal results, and their significance.

***Index Terms*** - The author shall provide up to 10 keywords (in alphabetical order) to help identify the major topics of the paper and to be enough referenced.

## I. INTRODUCTION

This document provides an example of the desired layout for a published MNE technical paper and can be used as a Microsoft Word template. It contains information regarding desktop publishing format, type sizes, and typefaces. Style rules are provided explaining how to handle equations, units, figures, tables, abbreviations, and acronyms. Sections are also devoted to the preparation of acknowledgments, references, and authors' biographies.

## II. TECHNICALWORK PREPARATION

Please use automatic language check for your spelling. Additionally, be sure your sentences are complete and that there is continuity within your paragraphs. Check the numbering of your graphics (figures and tables) and make sure that all appropriate references are included.

### *A. Template*

This document may be used as a template for preparing your technical paper. When you open the file, select "Page Layout" from the "View" menu (View | Page Layout), which allows you to see the footnotes. You may then type over sections of the document, cut and paste into it (Edit | Paste Special | Unformatted Text), and/or use markup styles. The pull-down style menu is at the left of the Formatting Toolbar at the top of your Word window (for example, the style at this point in the document is "Text"). Highlight a section that you want to designate with a certain style, and then select the appropriate name on the style menu.

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If you choose not to use this document as a template, prepare your technical work in single-spaced, double-column format, on paper A4 (21x29.7 centimeters). Set top, bottom margins and right margins to 15 millimeters and left margins to about 20 millimeters. Do not violate margins (i.e., text, tables, figures, and equations may not extend into the margins).

### *C. Typefaces and Sizes*

Please use a Times New Roman font. (See your software's "Help" section if you do not know how to embed fonts.) Table I is a sample of the appropriate type sizes and styles to use.

TABLE I. Table name will be written in Times New Roman font.

| Micromotor Code | b [mm] | a [mm] | h [mm] | Material |
|---|---|---|---|---|
| MPR33 | 33 | 25 | 20 | PZT 5 |
| MPR27 | 27 | 18 | 9 | PZT 5 |
| MPR15 | 16 | 10 | 10 | PZT 5 |

### *D. Section Headings*

A primary section heading is enumerated by a Roman numeral followed by a period and is centred above the text.

A primary heading should be in capital letters and bolded. The standard text format is considered times new roman 12.

The paper title should be in times new roman 20 uppercase and lowercase letters, not all uppercase.

Author name is set to times new roman 12, institution and contact address (E-mail) are set to times new roman 10.

Financial support should be acknowledged below the author name and institution. Example: This work was supported in part by the U.K. Department of Defence under Grant TX123.

A secondary section heading is enumerated by a capital letter followed by a period and is flush left above the section. The first letter of each important starting word is capitalized and the heading italicized.

Tertiary and quaternary sections are accepted only in special cases, so usually must be avoided in order to keep a clear article structure. If required, a tertiary and quaternary section heading must be italicized and enumerated by adding an Arabic numeral after each letter.

### *E. Figures and Tables*

Figure axis labels are often a source of confusion. Try to use words rather than symbols. As an example, write the quantity "Torque," or "Torque, *M*," not just "*M*." Put units in parentheses. Do not label axes only with units. As in Fig. 1, write "Torque (cNm)" not just "(cNm)". Do not label axes with a ratio of quantities and units. For example, write "Current (A)," not "Current/A." Figure labels should be legible, approximately 10-point type.

Large figures and tables may span both columns, but may not extend into the page margins. Figure captions should be below the figures; table captions should be above the tables. Do not put captions in "text boxes" linked to the figures. Do not put borders around your figures.

All figures and tables must be in place in the text centered and written with times new roman 10. Use the abbreviation "Fig. 1" in sentence and for each figure name. Each table must be defined as „TABLE I", with capital letters and roman numbers.

Digitize your tables and figures. To insert images in Word, use: Insert | Picture | From File.

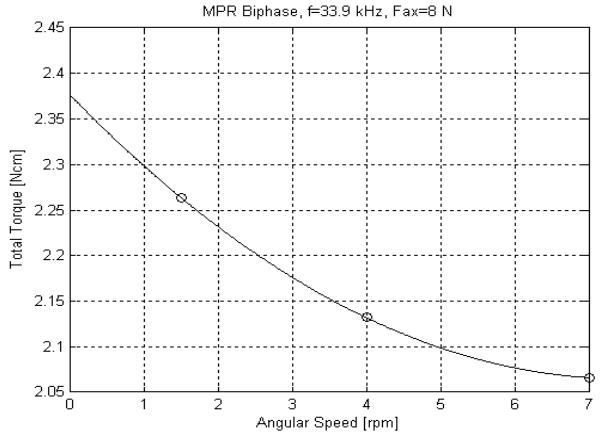


Fig. 1. Total torque function of angular speed. (Note that "Fig." is abbreviated and there is a space after the figure number.)

### *F. Numbering*

Please number reference citations consecutively in square brackets [1]. The sentence punctuation follows the brackets [2]. Multiple references [2], [3] are each numbered with separate brackets [1]-[3]. Refer simply to the reference number, as in [3]. Do not use "Ref. [3]" or "reference [3]" except at the beginning of a sentence: "Reference [3] shows….".

Number footnotes separately with superscripts (Insert | Footnote). Place the actual footnote at the bottom of the column in which it is cited. Do not put footnotes in the reference list. Use letters for table footnotes.

Check that all figures and tables are numbered correctly. Use Arabic numerals for figures and Roman numerals for tables.

Appendix figures and tables should be numbered consecutively with the figures and tables appearing in the rest of the paper. They should not have their own numbering system.

### *G. Units*

Metric units are preferred in light of their global readership and the inherent convenience of these units in many fields. In particular, the use of the International System of Units ("Système International d'Unités" or SI Units) is advocated. This system includes a subsystem of units based on the meter, kilogram, second, and ampere (MKSA). British units may be used as secondary units (in parentheses). An exception is when British units are used as identifiers in trade, such as 3.5-inch disk drive.

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Define less common abbreviations and acronyms the first time they are used in the text, even after they have been defined in the abstract. Standard abbreviations such as SI, CGS, AC, DC, and *rms* do not have to be defined. Do not use abbreviations in the title unless they are unavoidable.

### *I. Math and Equations*

Use either the Microsoft Equation Editor or the *MathType* commercial add-on for MS Word for all math objects in your paper (Insert | Object | Create New | Microsoft Equation *or* MathType Equation). "Float over text" should *not* be selected.

To make your equations more compact, you may use the solidus ( / ), the exp function, or appropriate exponents. Italicize symbols for quantities and variables. Use a long dash for a minus sign or after the definition of constants and

variables. Use parentheses to avoid ambiguities in denominators.

The number of each equation must be consecutively added in parentheses and arranged at the right margin, as in (1). Be sure that the symbols in your equation have been defined before the equation appears or immediately following.

Don't use "Eq. (1)" abbreviation instead of "equation (1)", in a sentence.

$$L_m = \frac{m}{A^2} \tag{1}$$

with $m$ - mechanical mass, $A$ - force factor, $L_m$ - electromechanical inductance.

## III. ACKNOWLEDGMENT

The following is an example of an acknowledgment.

The authors gratefully acknowledge the contributions of Mircea Ignat and Puflea Ioan for their work on the original version of this document.

## IV. APPENDIX

Appendixes, if needed, appear after the acknowledgment.

## V. REFERENCES

References are important to the reader; therefore, each citation must be complete and correct. There is no editorial check on references, only the format Times new roman 10 must be considered.

[1] Satanobu J., Lee D.K, Nakamura K., Ueha S., "Improvement of the Longitudinal Vibration System for the Hybrid Transducer Ultrasonic Motor", IEEE Trans. On Ultrasonic ferroelectrics and Frequency Control, vol. 47, no. 1, January 2000, pp. 216-220.

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## VI. BIOGRAPHIES

A technical biography for each author must be included. It should begin with the author's name (as it appears in the byline). Please do try to finish the two last columns on the last page at the same height. The following is an example of the text of a technical biography:

**Mircea Ignat** was born in Bucharest on March 4, 1953. He graduated at 1977 and he received Ph.D. degrees in electrical engineering from Bucharest Polytechnic University in 1999.

His employment experience included the National Institute for Research and Development in Electrical Engineering ICPE-CA, Dep. of Electrical Micromachines Research and he is the head of Electromechanics Department.

The research preoccupation include: the synchronous generators and the high speed electric machines. He is member of IEEE.