MODELLING METHODS IN THE IMPLANTABLE ECG DEVICE DEVELOPMENT

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Abstract: When designing implantable devices, e.g. those measuring bioelectric signals such as electrocardiograph (ECG), the information regarding the implantation and the implant itself should be available to minimize in vitro and clinical testing. Modelling offers rather inexpensive and effective means of studying and demonstrating the effects of implantation on the ECG measurement prior to any clinical tests, and it can thus provide the designer with valuable information. This paper introduces the use of the finite difference and finite element methods in developing and studying the charactristics related to the ECG implants. The FDM has been applied in the modelling of the measurement of the bioelectric sources with ECG implants in the complex anatomical volume conductor. The FEM has been applied in modelling the changing electrical properties of these tissues surrounding the implant during the healing process. These methods are efficient and usable in the modelling of the characteristiscs of the electric fields measured with the implantable monitors. Thus these methods can be applied as tools in implant designing.

Introduction

Our aim is to design implantable electrocardiography (ECG) instrumentation with wireless data and power transfer (www.ele.tut.fi/tule). The standard 12-lead ECG system is commonly used in clinical monitoring of the electrical activity of the heart. Use of the system calls for skilled personnel and a hospital environment, which entail costs. The measurements can also be impeded by artefacts, common mode interference and imbalances on the electrode-skin interface. Wireless and especially implantable measurement devices could offer stable and long-term monitoring possibilities at less expense. Also new information from cardiac sources could be obtained with implants, since the ECG electrodes could be taken closer to the heart. This enables more accurate monitoring of smaller and more focused source regions followed by more effective treatment methods directed to the specific areas of cardiac tissue instead of the whole heart. Recent clinical studies have shown the efficiency and usefulness of implantable monitors in detecting various cardiac arrhythmias and ECG patterns [1-4].

Measurement of electrical activity of the heart with new implantable devices differ from traditional body surface measurements such as the standard 12-lead ECG. Designing of the new implantable applications with traditional designing protocols including clinical tests with iterations of hardware is expensive and time-consuming. Methods for estimating and predicting the phenomena related to the implantable devices are needed. It would be useful to be able to study the signals measured with implantable devices and the effects of device characteristics on measured signal without time-consuming and expensive clinical trials. Modelling of the physiological systems and measurements could offer usable approaches to meet these needs. Furthermore, the implanted device interacts with the surrounding tissues, changing tissue characteristics such as tissue impedance thus having effects on the measurement. Also these effects can be modelled and the possibilities to measure the impedance changes can be studied.

In this paper we introduce two modelling approaches applied in developing and studying the implantable ECG monitor prior to hardware designing. We have applied finite difference method (FDM) and finite element method (FEM) together with lead field and reciprocity approaches in studying the ECG as well as bioimpedance measurement sensivities of the implant designs.

Materials and Methods

Finite Difference model of the thorax

In the FDM the segmented volume data e.g. from MRI dataset is divided into the cubic elements having resistive values. The elements form a resistor network where the potentials and currents obay the Kirchoff's laws. The FDM allows the implementation of complex anatomic geometries from the image data and the resulting potentials and currents can be calculated within the whole volume conductor model [5]. The model used in our studies has been a 3D male thorax based on the Visible Human Man dataset (VHM) [6, 7]. The highest resolution of the dataset applied in our studies represents the data on 95 segmented slices which each resolution was 1.67 mm x 1.67 mm x 4 mm. The model contains altogether 2.7 million nodes with 2.6 million elements. We have also applied sparser models to achieve faster calculation.

We have employed the FDM in studying and demonstrating the effects of implantation and implant dimensions on the measurement sensitivity of the ECG device [8, 9]. The lead field and reciprocity theories were applied to solve the sensitivity distribution of the implantable ECG system within the heart region.

Finite element model of the implant surrounding

We have applied the finite element method (FEM) in studying the effects of the wound healing process of the tissues surrounding the implant on the bioimpedance. The impedance changes were studied by changing the electrical properties of the surrounding tissue. In our study, we applied commercial FEM based modelling software FEMLAB®.

We modelled an implant for impedance measurement with a three-dimensional box (Figure 1) containing four electrodes (two for the measurement and two for the current injection) in an insulation plate surrounded by specified tissue layers. We applied following materials for the implant model: platinum to represent the electrodes, ultra high molecular weight polyethylene (UHMWPE) to represent the insulation between the electrodes, muscle tissue above the implant block, and fibrous tissue layers (three depths) representing the fibrous encapsulation during the wound healing process. The conductivity values are listed in Table 1.

The effect of tissue conductivity on the measurement sensitivity was modelled by applying encapsulation layers with three thicknesses around the implant. The different tissue layers were related to the changing anatomical structure of the implant-tissue interface during the wound healing. We defined the thickness of the tissue layers according to Grill and Mortimer. They reported that the encapsulation tissue thickness would be approximately 500 µm [10]. Thus we added three tissue layer, of which thickness were 0.2 in the scale of the model, and which represent the thickness of 200 µm.

The implant surrounded by the muscle tissue was the reference model and effects of added encapsulation layers were compared with the reference. The lead field and reciprocity theories were applied to solve the effects of the encapsulation thickness on the bioimpendance.

Table 1: The conductivity values of the materials, used in three-dimensional box model. All the values are estimated for the frequency of 100 kHz.

Material	σ (S/m)
Platinum	9000000
UHMWPE	0.00001
Skeletal muscle [11]	0.476
Fibrous encapsulation [10]	0.00159

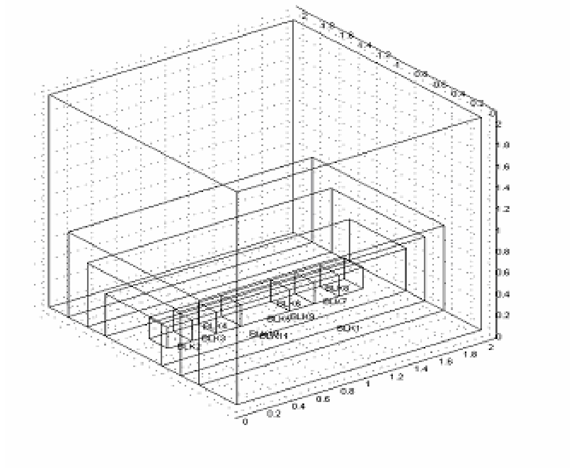

Figure 1: Geometry of the three-dimensional volume conductor of the box model. In the middle of the model is the implant with electrodes. The three fibrous encapsulation tissue layers are surrounding the implant. The outermost box presents the muscle tissue.

Lead field and reciprocity

The sensitivity distributions of the measurement configurations, leads, can be illustrated with lead vectors or lead fields. This holds both for bioelectric measurement and for bioimpedance measurements.

The lead field defines the relationship between the measured bioelectric signal in the lead and the current sources in the volume conductor as shown in Equation 1. [12]

$$V_{LE} = \int \frac{1}{\sigma} \overline{J}_{LE} \bullet \overline{J}^{i} dv \qquad (1)$$

where - V_{LE} is the lead voltage
- $\overline{J}_{LE}$ is the lead current density vector
- $\overline{J}^{i}$ is the current source density vector
- σ is the conductivity of the source location in the volume conductor

The lead field in the volume conductor can be solved by applying the theory of reciprocity. The current field in the volume conductor raised by the reciprocal unit current applied into the measurement electrodes corresponds to the lead field [12]. The essential benefit of the method is that the sensitivity of a measurement lead at the all source locations in the volume conductor can be calculated with a single calculation.

The measured signal depends on the magnitude and direction of the lead field. The average change in the lead field magnitude relates to the change in the magnitude of the measured ECG [13]. Thus, this gives the possibility to use the lead vectors to describe the changes in measurement sensitivity and in the signal strengths when the design of the implantable ECG lead system is changed.

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The measured impedance Z is related to the conductivity σ and measurement sensitivity S as shown in Equation 2. [14]

$$Z = \int \frac{1}{\sigma} S dv \qquad (2)$$

The calculation of the measurement sensitivity in the bioimpedances case has its basis as well on reciprocally calculated lead fields as follows in Equation 3.

$$S = \bar{J}_{LE} \bullet \bar{J}_{LI} \qquad (3)$$

where, the J_{LE} is the lead field generated by the unit current applied to the voltage measurement electrodes. The J_{LI} is the lead field of the current feeding electrodes.

We studied the effects of the tissue encapsulation on the impedance measurement by calculating the measurement sensitivity distributions in all four models: reference model with only muscle tissue surrounding implant and three fibrous encapsulation models, with the encapsulation thicknesses mentioned before. We modelled the lead fields in the FEMLAB® by applying the reciprocal unit current on the current feeding electrodes and on the measurement electrodes. Furthermore the resulting impedance in each case was computed. In this model.

Results

The effects of the electrode implantation on the measurement sensitivity

The lead field and reciprocity method has been applied with FDM in studying the effects of electrode implantation on the measurement sensitivity. The sensitivity distributions were calculated for bipolar electrode pairs implanted in the 12-lead ECG system's precordial electrode locations V1-V2 at seven depths. The depths were approximately 7 mm, 13 mm, 17 mm, 23 mm, 29 mm and 35 mm from the body surface and one at the heart surface. The corresponding surface electrode pair V1-V2 was used as a reference. The implantation depths of the electrode corresponding to the precordial lead V2 are illustrated in Figure 2.

Table 2. presents the average change in lead vector magnitude and the change in maximum sensitivity when the bipolar electrode pair was implanted. The results of the general effects of the implantation on measurement sensitivity indicated that implanting the electrodes just under the skin has minor effect on the measurement sensitivity [8, 15] compared with implanting the electrodes under the costals or even on the heart muscle [15]. The lead field method enable the study of the local measurement sensitivities and thus this should be considered in the studies of the measurement sensitivities related to the implantable monitors. This is because the changes in the local measurement sensitivities are not revealed by the averaged values which is shown in Figures 2 and 3 with the sensitivity distributions and in Table 2 with the change in the maximum sensitivity compared to the change in average lead vector magnitude. Figure 2 presents the changes in the lead vector magnitude at the heart muscle area in one slice when electrodes were implanted 7 mm(A) and 17 mm(B) and the lead fields were compared to the corresponding body surface case. Figure 3 presents the distribution of the lead vector magnitude change in the whole heart muscle volume. These figures indicate that the sensitivity distributions, i.e. lead fields, could and should be used to enable more information on the local variance of the measurement sensitivity of the implant designs.

The focus of the measurement sensitivity of the implanted bipolar electrode pair

The lead fields can also be applied in studying the concentration of the measurement sensitivity. The concept of half-sensitivity volume (HSV) was applied to define the region where the sensitivity of the measurement lead is concentrated. The HSV is within the volume source the region where the magnitude of the detector's sensitivity is more than half of its maximum [12, 16, 17]. The smaller the HSV is the smaller is the region from which the detector's signal arrises. The HSV concept has been applied e.g. for studying the sensitivity distributions of EEG and MEG [16] and studying the effects of skull resistivity on the spatial resolution of EEG and MEG [17].

Table 2: Average changes in the lead vector magnitude, change in the maximum sensitivity and the relative half-sensitive volume with different electrode implantation depths. All cases are compared to the surface case.

Implantation depth	Body Surface	7 mm	13mm	17 mm	23 mm	29 mm	35 mm	Heart Surface
Average Change in Lead Vector Magnitude	**0%**	**-3.0%**	**-4.6%**	**-9.1%**	**+14.2%**	**+17.1%**	**+28.6%**	**+40%**
Change in Maximum Sensitivity	**0%**	**+4%**	**+15%**	**+15%**	**+48%**	**+144%**	**+804%**	**+7554%**
Relative Half-Sensitive Volume	**1**	**0.81**	**0.63**	**0.56**	**0.11**	**0.04**	**0.02**	**0.01**

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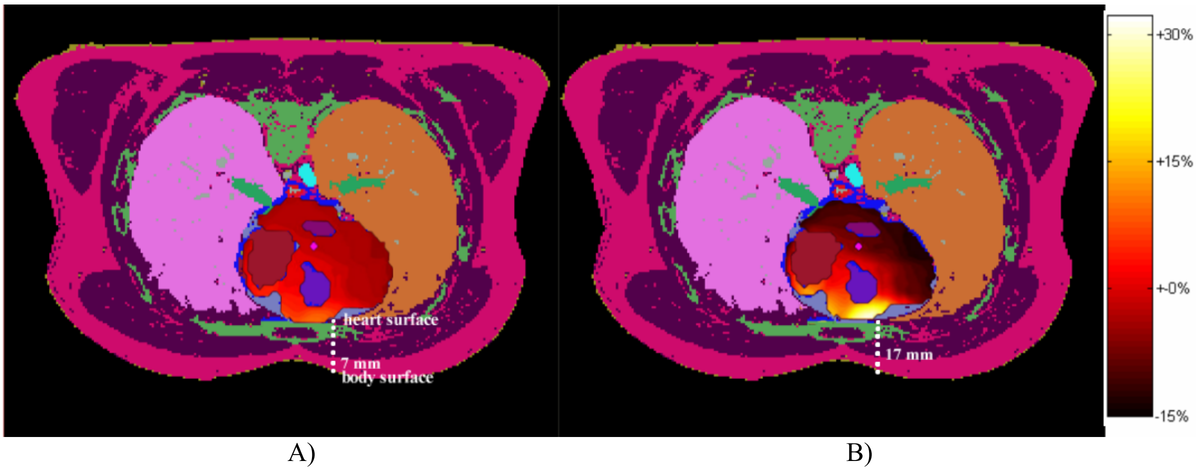

Figure 2: Changes in the lead vector magnitude presented in randomly selected slice at the heart muscle area when electrode pairs were implanted 7 mm(A) and 17 mm(B). Both cases are compared to the lead field of the corresponding body surface case. The depths of the electrode implantations are presented with white.

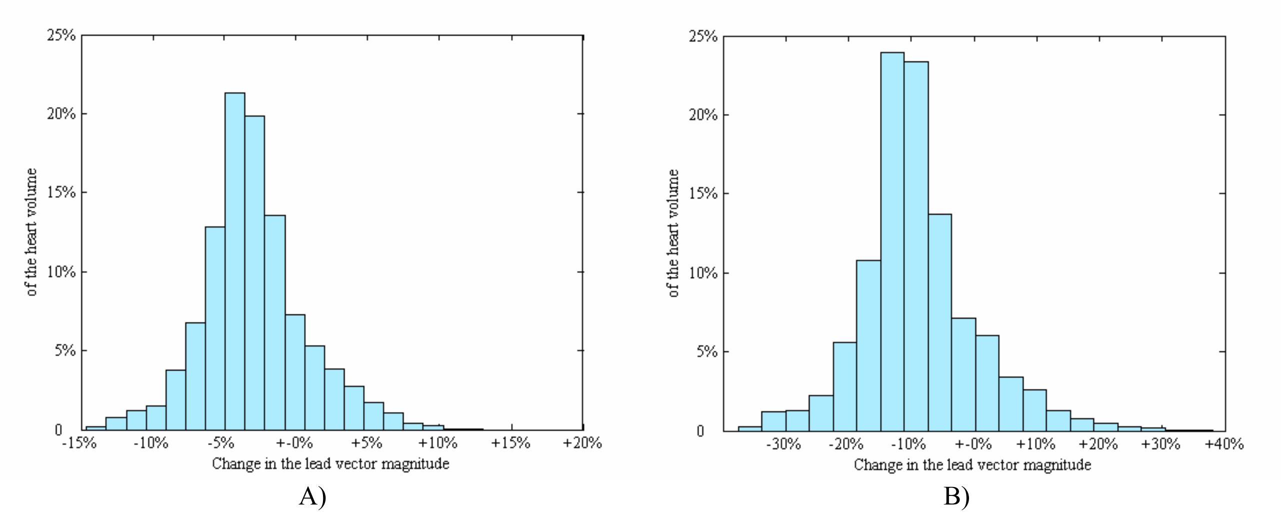

Figure 3: The distribution of the lead vector magnitude change in the heart muscle volume when electrode pairs were implanted 7 mm(A) and 17 mm(B). Both cases are compared to the lead field of the corresponding body surface case.

The half-sensitivity volume (HSV) concept is employed in studying the effects of electrode implantation on the concentration of the measurement sensitivity. The measurement sensitivities were solved by applying FDM together with lead field and reciprocity approaches. [15]

The concentration of the measurement sensitivity of the ECG implant has been studied [15] to predict the source region in the heart from where the measured signals arrises. Table 2 and Figure 4 present the effect of bipolar electrode pair implantation on the relative half-sensitivity volume. The interelectrode distance corresponds to the distance between V1 and V2 in standard 12-lead ECG.

From results is seen that the implantation of the electrodes concentrates the measurement sensitivity i.e. reduces the half-sensitivity volume. If the concentration of the measurement sensitivity is focused on the region of interest in the cardiac tissue it can thus provide more precise detection of cardiac activity arrised by region of interest leading to more accurate treatment of cardiac disorders.

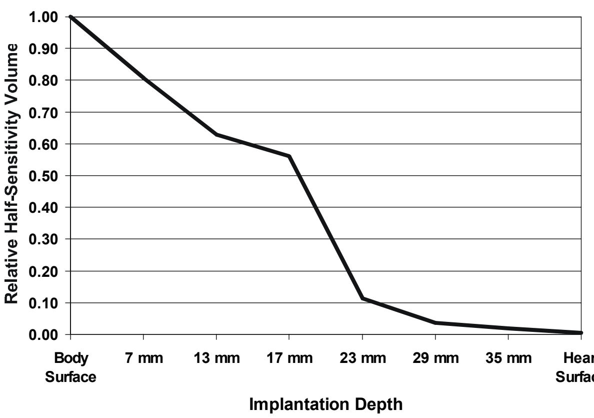

Figure 4: Effect of the implantation depth on the relative half-sensitivity volume

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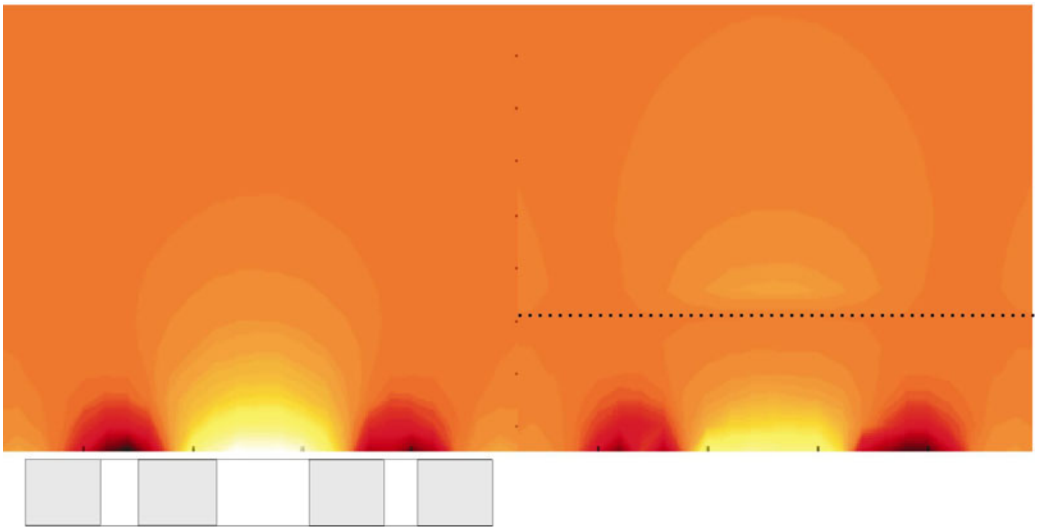

Figure 5: The cross-sections of the sensitivity distributions (S) and crossection of the implant with electrodes indicated on gray. Positive sensitivity indicated with yellow and negative with red. (A)Reference model where muscle tissue is surrounding the implant and (B) three fibrous encapsulation layers between the implant and muscle tissue. The interface between muscle and fibrous tissue indicated with dot line.

The effect of fibrous encapsulation on the impedance around the implant

Figure 5 presents the change in sensitivity distribution S between the cases where only muscle tissue is surrounding the implant (A) and case of three fibrous encapsulation layers between implant and muscle tissue. Table 3 presents the relative impedances calculated with Equation 2. The effect of the fibrous encapsulation is seen both in the sensitivity distribution and in the impedance value.

Table 3: Relative impedances for implant models with muscle layer and one to three fibrous encapsulation layers attached

Relative Impedance	Muscle	1 layer	2 layer	3 layer
Z	1	492	1234	1779

Discussion and Conclusions

Modelling of the physiological systems and the measurement of the cardiac electrical activity furnishes an effective means of studying the effects of the ECG electrode implantation on the ECG measurement prior to any clinical tests. Modelling can be used e.g. when the location or the effects of the electrode implantation and implant dimensions are studied. Especially the use of modelling in designing of the implants could reduce the need for expensive testing and iteration rounds. Different characteristics of the implant, such as dimensions could be tested with models and it can thus provide the designer with valuable information. Furthermore, modelling allows estimation of signals measured from implants and the way measured signal correlates with the ECG measured from standard surface leads. Moreover, estimation of an ECG signal measured with an implanted system from surface measurement could offer a way to optimize the location of the implant prior to insertation.

The lead field approach with FDM was seen to be a powerful tool in studying the measurement sensitivities of implanted ECG monitors as well. Our simulation of the lead field for the model containing 2.6 million elements took time approximately 15 minutes. The methods are effective and applicable because the sensitivity distributions of the measurement lead can be solved by defining only the electrode locations instead of defining all the sources in the heart region and calculating the measured field generated by all the sources. Another approach could be to simulate the heart activation and then calculate the resulting ECG. However, this provides information only on the particular source pattern.

The lead field and reciprocity approaches can be applied with different element methods. Here we have applied it also with FEM in modelling of changes in the bioimpedance when fibrous encapsulation is attached on the implant. The simulations of interaction between implant and tissue indicated that bioimpedance can be applied to study the interactions between implantable system and tissues. The methods could be assigned in the designing of the implanted four electrode bioimpedance measurement which could be applied to detect the impedance changes between the different phases of wound healing process and the amount of fibrous encapsulation around the implant.

Lead field analysis provides a universally applicable mode of analysis and a designing tool and together with reciprocity theorem and element methods it provides straightforward approach to study and illustrate the bioelectrical phenomena related to the human body and its measurements.

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References

[1] BOERSMA L., MONT L., SIONIS A., GARCIA E., BRUGADA J. (2004): 'Value of the Implantable Loop Recorder for the Management of Patients with Unexplained Syncope', Europace, 6, pp. 70-6
[2] CHRYSOSTOMAKIS S. I., KLAPSINOS N. C., SIMANTIRAKIS E. N., MARKETOU M. E., KAMBOURAKI D. C., VARDAS P. E. (2003): 'Sensing Issues Related to the Clinical Use of Implantable Loop Recorders', Europace, 5, pp. 143-8
[3] FARWELL D. J., FREEMANTLE N., SULKE A. N. (2004): 'Use of Implantable Loop Recorders in the Diagnosis and Management of Syncope', Eur Heart J, 25, pp. 1257-63
[4] SONG Z., JENKINS J., BURKE M., ARZBAECHER R. (2004): 'The Feasibility of St-Segment Monitoring with a Subcutaneous Device', J Electrocardiol, 37 Suppl, pp. 174-9
[5] JOHNSON C. R. (1997): 'Computational and Numerical Methods for Bioelectric Field Problems', Crit Rev Biomed Eng, 25, pp. 1-81
[6] ACKERMAN M. J. (1991): 'The Visible Human Project', J Biocommun, 18, pp. 14
[7] KAUPPINEN P., HYTTINEN J., HEINONEN T., MALMIVUO J. (1998): 'Detailed Model of the Thorax as a Volume Conductor Based on the Visible Human Man Data', J Med Eng Technol, 22, pp. 126-33
[8] VÄISÄNEN J., HYTTINEN J., PUURTINEN M., KAUPPINEN P., MALMIVUO J. (2004): 'Prediction of Implantable Ecg Lead Systems by Using Thorax Models', Engineering in Medicine and Biology Society, 2004. Proceedings of the 26th Annual International Conference of the IEEE, pp. 809-812
[9] VÄISÄNEN J., HYTTINEN J., MALMIVUO J. (2005): 'Development of Implantable Cardiac Measurement Device - Modeling Approach', 13th Nordic Baltic Conference on Biomedical Engineering and Medical Physics, pp. 99-100
[10] GRILL W. M., MORTIMER J. T. (1994): 'Electrical Properties of Implant Encapsulation Tissue', Ann Biomed Eng, 22, pp. 23-33
[11] http://niremf.ifac.cnr.it/docs/HANDBOOK/tbl-48.htm
[12] MALMIVUO J., PLONSEY R. (1995): 'Bioelectromagnetism: Principles and Applications of Bioelectric and Biomagnetic Fields', Oxford University Press
[13] PUURTINEN M., HYTTINEN J., KAUPPINEN P., MALMIVUO J. (2004): 'Estimation of Ecg Signal of Closely Separated Bipolar Electrodes Using Thorax Models', 26th Annual International Conference of the IEEE Engineering in Medicine and Biology Society, pp. 801-804
[14] KAUPPINEN P. K., HYTTINEN J. A., KOOBI T., MALMIVUO J. (1999): 'Lead Field Theoretical Approach in Bioimpedance Measurements: Towards More Controlled Measurement Sensitivity', Ann N Y Acad Sci, 873, pp. 135-42
[15] VÄISÄNEN J., HYTTINEN J., MALMIVUO J. (2005): 'Focus of the Implantable Device's Measurement Sensitivity -Application of Half-Sensitivity Volume Concept', International Journal of Bioelectromagnetism, 7, pp. 240-242
[16] MALMIVUO J., SUIHKO V., ESKOLA H. (1997): 'Sensitivity Distributions of Eeg and Meg Measurements', IEEE Trans Biomed Eng, 44, pp. 196-208
[17] MALMIVUO J. A., SUIHKO V. E. (2004): 'Effect of Skull Resistivity on the Spatial Resolutions of Eeg and Meg', IEEE Trans Biomed Eng, 51, pp. 1276-80