AN *IN VITRO* COST-EFFECTIVE TEST BENCH FOR ACTIVE CARDIAC IMPLANTS, REPRODUCING HUMAN EXPOSURE TO ELECTRIC FIELDS 50 HZ

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Abstract- The European Directive 2013/35/UE sets the minimum requirements for the protection of workers exposed to electromagnetic fields and defines workers bearing implants as workers at particular risk. The European standards 50527-1 and 50527-2-1 propose risk assessments methods for these workers, including numerical and/or experimental in-vitro approaches. This study aims to conceive by using both methods, a cost-effective test bench for active cardiac implants in order to reproduce induced phenomena on a cardiac implant inside a human exposed to 50 Hz electric field, representing exposure up to 100 kV/m, which covers occupational exposure.

Index terms*: Electric Field, Low Frequency, Implanted Cardiac Defibrillators, Pacemaker, *In*-vitro EMC set-up**

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I.   INTRODUCTION

The worldwide WHO (World Health Organization) report point out that cardiovascular diseases are principal major cause of death [1]. When the origin of pathology is a cardio-electrical system dysfunction, one of the possible clinical treatments is active cardiac device implantation: pacemaker (PM) or implantable cardiac defibrillator (ICD). Almost 4 million of active cardiac devices implantation had occurred from 1993 to 2009 only in USA, with an increase of 55% on implantation during these years [2]. For 2014, 8.4% of increase was estimated [3]. Furthermore, studies as cited ones underlines the increasing number of implantations, even to young and professionally active peoples. Electromagnetic fields may interact with active cardiac devices, causing some temporary dysfunction which may present health risks for implanted patient. These facts cause a legal question: may a patient return to its previous job after implantation of an active cardiac implant, even if this occupational environment is electromagnetically exposed?

The European Directive 2013/35/EU sets the minimum requirements for the protection of workers exposed to EMF fields, and defines workers bearing implants as workers at particular risk [4]. European standards 50527-1 and 50527-2-1 propose multiple risk assessments methods for these workers [5, 6]. The necessity of case by case studies is underlined due to the diversity of cases (implant model and settings, morphology and pathology of patient…). These methods include numerical or experimental in-vitro approaches.

In the case of active cardiac implants and extremely low frequency electric or magnetic field, the risk for the workers could be due to the induction of voltage on the implant's leads. Inductions inside the human body cannot be measured. Inductions of electric fields and/or currents have been treated by many scientists through numerical simulations on a virtual human body. However, few of them have conducted these studies taking into consideration medical active implants [7]. Moreover, few studies have compared the *in vitro* approaches, where an experimental homogeneous phantom is used, and the computational approaches [8]. This study describes a test bench to test active medical implants in a low frequency (50-60 Hz) E-field, by linking theoretical and experimental approaches. The objective is to develop a simple system, making possible to test cardiac active implants with electric field representative of occupational exposure, without requiring a huge voltage hall.

II. NUMERICAL METHODS

Our *in-vitro* study aims to be as close as possible to *in-vivo* situation, by using computational methods to design a cost effective test bench and a phantom which has the same inductions then the heart area of a standing human grounded, which the worst case of coupling between 50/60 Hz electric field and human. Figure 1 illustrates the system that we have designed. Device under test (DUT) is exposed to external electric fields in an isolated test bench. The electric field is controlled by varying the voltage sources.
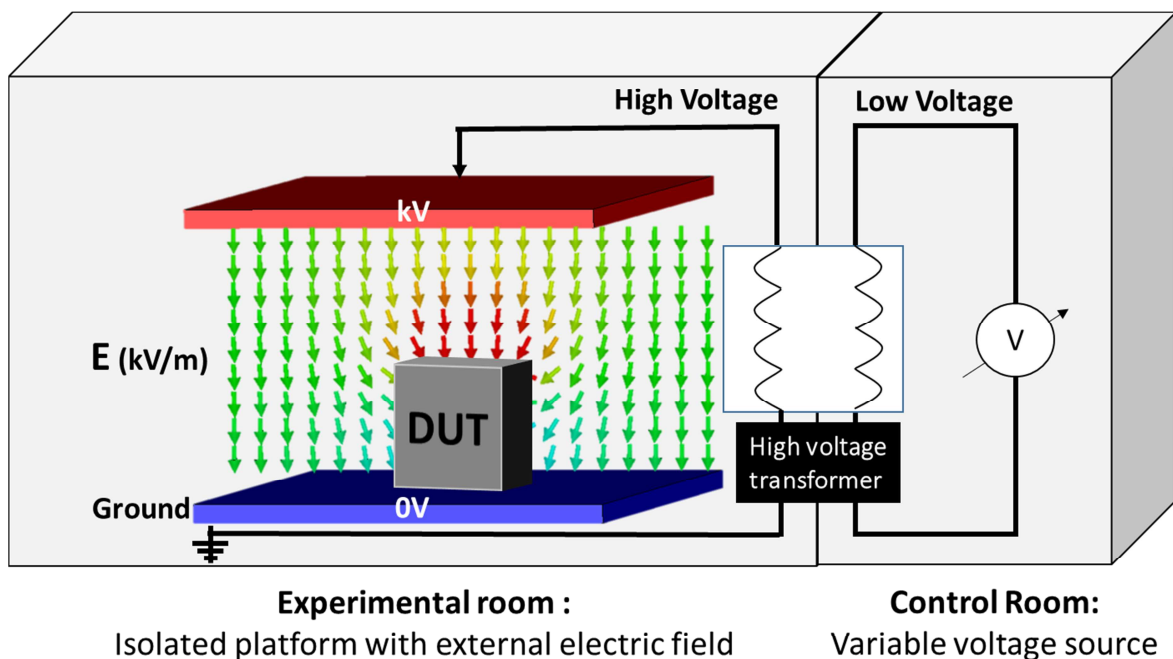

Figure 1. Test bench schematic

Following parts explain the numerical methods and its validation via IEC 622226-3-1 [9]. The numerical conception of the experimental bench will be detailed and the choice of dimensions will be explained.

a. Calculation Methods

The electric and magnetic fields effects on human body can be separately studied at low frequency according to usual quasi-static approach. Analytical methods can be used to estimate the average inductions on human body, analyzing them in simplified geometric forms as semi-

spheroidal, cylindrical or conical with simple homogeneous conductivity and permittivity values. These assumptions neglect the complex geometry of human body, moreover doesn't take into account each organ's specific dielectric properties. However, they are still used to make first estimation and validate the numerical method.

Finite integration method is used with quasi-static assumptions derived from the Maxwell equations [10]. To resume these classical assumptions, time derivative of the magnetic field is neglected on the Faraday law to reduce the number of unknowns. As a consequence, the study domain is described by a complex scalar potential and discretized on tetrahedral meshes to represent more precisely the geometry. The human body proportions as well as the distance to the EMF source are very small compared to these wavelengths so the physical phenomena can be considered occurring instantly in every part of the domain. CST EM$^{®}$ software based on FIT method was used for our simulations in 3D.

b. Validation of numerical methods

From Maxwell's equations, one can deduce derived formulas for the analytical calculation of the induced currents in conductors by electro-quasi-static fields (1):

$$J_{in} = k \times \omega \times E_{ex} \qquad (1)$$

J_{in} is the current density induced within the conductive body, f is the frequency, E_{ex} is the vertical external electric field and k is the shape factor depending on geometry, ratio of length to radius (L/R) of the body, and the location within the body where J_{in} is calculated.

A homogeneous half ellipsoid phantom ($\sigma = 0.2$ S / m, grounded) as defined by the IEC 62226-3-1 standard, was simulated for 50 Hz electric field and the same total current density is obtained with standard results derived from equation 1 (J = 0.134 mA/m², see Fig 2 a) [9]. The currents induced in the axis-symmetric model are numerically calculated with an error of 0.73% for the current density induction in the neck, comparing to results given in IEC 62226-3-1 [9]. The inductions curves announced by IEC and given by our simulations are shown on figure 2 (b,c).

As the European Directive 2013/35/UE defines the inductions due to exposure in induced electric field (mV/m), we present our corresponding results deduced by ohm law in the following parts.
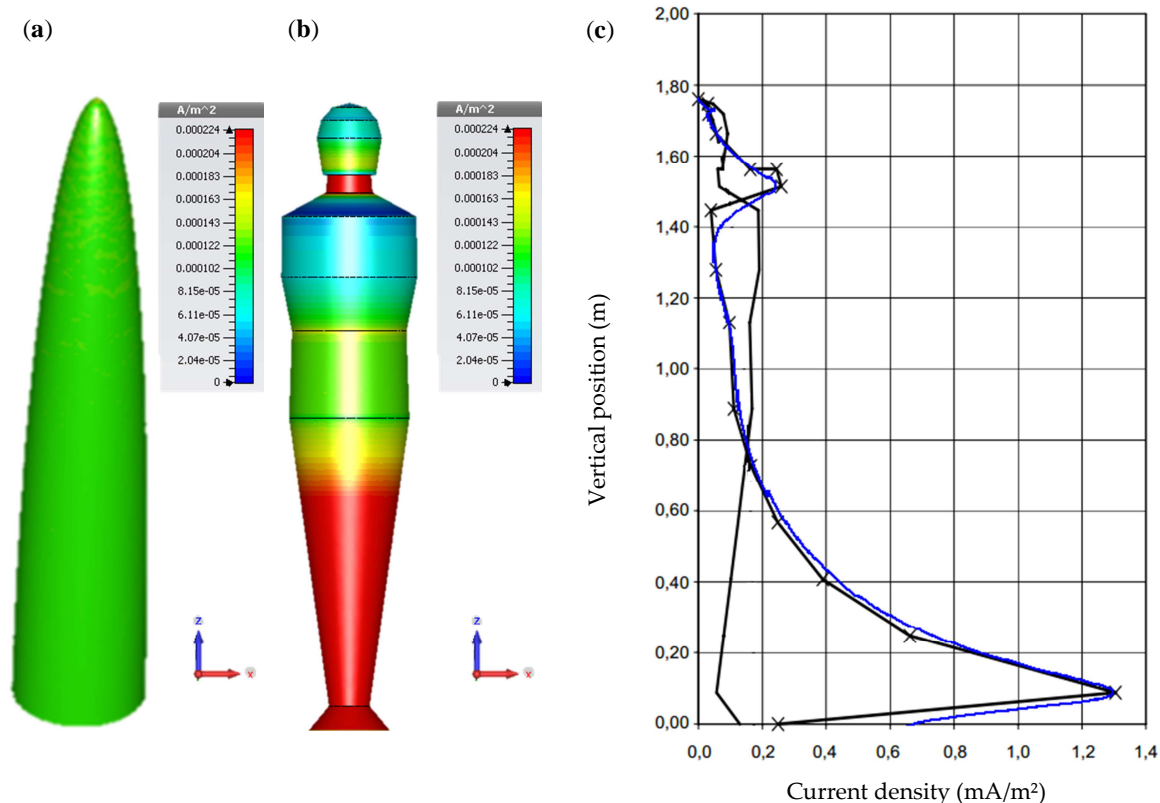
Figure 2. Current density induced on (1 kV/m 50 Hz): (a) spheroidal model (b) axisymmetric model (c) the analytical curve given by IEC 622226-3-1 (cross) compared to our simulation results (blue - no cross) for axisymmetric model [9]

III. GENERATION OF ELECTRIC FIELD

The objective is to develop an exposure system with parallel plan conductors that generates an electric field as uniform as possible in the test area to ensure the reproducibility and reliability of tests. A study domain for a human scale phantom in able to produce the uniform electric field is too large in experimental conditions, so it is not easy to realize with classical laboratory facilities. A smaller domain, with acceptable homogeneous field area, should be designed. Therefore, simulations with diverse dimensions of plan conductors are processed in order to classify the heterogeneity of the generated electric field, in an empty space as a first step.

A curve of heterogeneity is showed at right-side of figure 3 in percent, following the vertical axis in the center of two parallel square electrodes. Here, the heterogeneity percentage is the deviance observed over the curve compare to the expected electric field. The distance between two plates
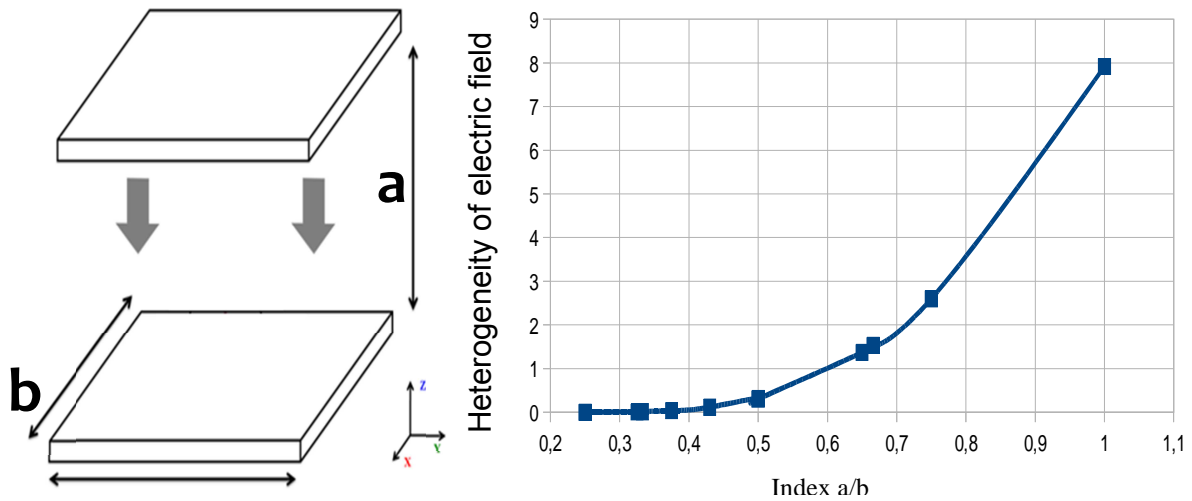
Figure 3. Heterogeneity of electric field depending on dimensions of conductors planes

(a) over the size of the squares (b) is the index a/b; and same index gives the same percentage of heterogeneity in empty space. Using the results and suitable dimensions obtained, we proceeded to simulations in an experimental room to conceive the conductor planes dimensions. Always considering equation 1, the amplitude of induced electric field will change only if the external field amplitude or shape factor of the object will change. As long as the object will stay identically, the amplitude of induced electric currents will be proportional to the external electric field. This linearity will allow us to design a reduced exposure system by applying a homothetic scale factor, in order to use it in an ordinary room (8.5 m x 6.8 m x 3.15 m in our case).

Thus, electric field was calculated taking into account the geometry and the components (heaters, etc…) of the room. For 3D reconstruction of the room, all geometries and objects have been taken into account in simulations as well as their electrical properties. For obvious reasons, the system has to be big enough to accept the device under test. Thereby, the phantom in which the active implant will be placed has to have minimum dimensions versus exposure system. In our study, active cardiac implants are taken as a target; however same methods can be used for other active implants. According to EN 50527-2-1, the usual pacemaker lead is about 50 cm [6]. Always in same standard, maximum achievable realistic implant cardiac lead loop area is defined as 225cm² [6]. All taken into account, reduction of human body to 1/5 in height was the optimal solution. As a result, the study domain can also be miniaturized. Different dimensions of the

system were simulated to investigate the homogeneity of the field and their inductions to choose the best compromise (figure 4).
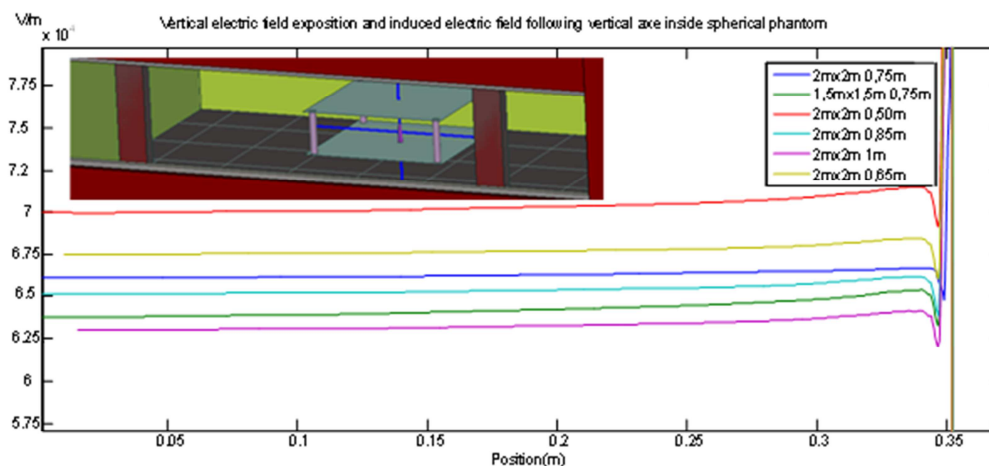

Figure 4. Induced electric fields inside spheroidal human body model, miniaturized to 1/5 and exposed to 1 kV/m with the test bench inside experimental room (CST simulations)

In conclusion, two (2 m x 2 m x 0.002m) conductor plates, spaced by 75 cm, is the best compromise to simulate the exposition (figure 4). Other complementary simulations were done in order to investigate the experimental conditions, as material used (conductor planes, isolators, high voltage cables). Technical improvements have been made in order to reduce some negative effects (bending the edges, other upgrades related to ground).

IV.   ELECTROMAGNETIC PHANTOM

Concerning in-vitro studies, one of the most common methods is based on a rectangular phantom for magnetic field exposure [11, 12]. However, due to the influence of the shape of the human body in an electric field, this rectangular shape cannot be used [9]. To experiment the effects of electric field exposition, the phantom should be designed numerically respecting the inductions occurring inside the human body. The induced electric field in the heart with and without cardiac implant was presented in a previous work [13] with an anatomical human body model (Ansoft). Our results for different organs are similar to other studies without implants [14, 15]. For 1 kV/m 50Hz electric field, the maximum induced field over the heart is calculated as 4 mV/m and mean induced electric field over the thorax is calculated as 0.8 mV/m. Those inductions are aimed to be reproduced in a numerically design experimental phantom.

The height of phantom is 35.2 cm, which is equivalent to 1/5 of human reference [16]. The phantom is miniaturized in order to be able to position it between the test bench conductor planes. However, it keeps the same circumference as a human thorax and is also able to contain a properly positioned cardiac implant. So the height is divided by 5 but if the radius stays unchanged, that will cause a significant decrease of the induction, impacting k which depends on L/R in equation 1. To counter this decrease, the radius had to diminish in order to increase the current density and the electric field. Once the induced electric field reaches those in human heart, the radius will be kept constant. For the reasons explained, our phantom looks like a funnel (Figure 5).

The 35.2 cm highest phantom with 30 cm largest diameter (R4-Figure 5) of the cone has been simulated in order to define the radius which allows the imitation of human body inductions (R2-Figure 5). The phantom is 3.3 mm thickness glass made, filled with a 0.2 S/m solution. The solution permittivity does not matter within the values between 100 and 10^7 as mentioned in [9], and it has been verified by CST simulations. To assure the contact with earth, a metallic sole connected to ground is plugged to the cylindrical base. The higher part contains joints to stop the saline solution, compatible with cylinder. The bottom has been chosen larger enough (R1 = 120 mm) to be able to keep the phantom in vertical position and connect it properly to ground (Figure 5). A picture of experimental phantom is given in the left of figure 5. By simulations, we obtained that for (R4), with a full fill level (R3 = R4), the diameter cylinder has to be 54 mm (R2).
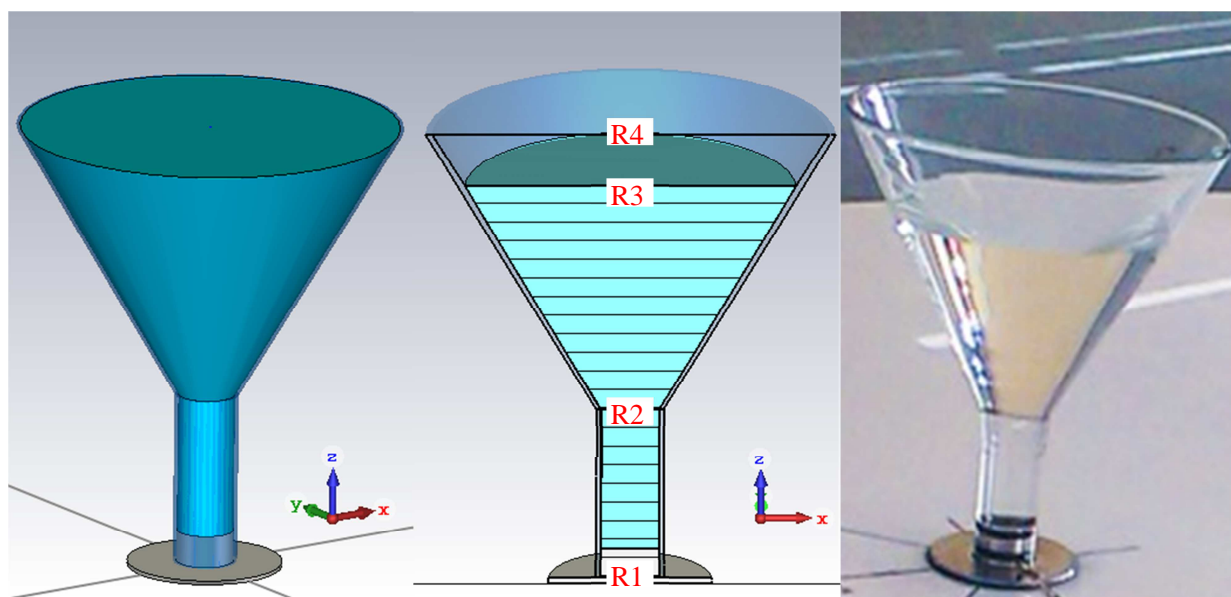
Figure 5. Experimental phantom filled with saline solution

In that way, cylindrical part gives a constant electric field induction, representing maximum heart inductions (4 mV/m) which may contain the probe electrodes of a cardiac implant. The conic part is representing mean value of thorax inductions (0.8 mV/m) which may contain the box of implant. In figure 6, the induced electric field in coronal view at left-side and the induced electric field following vertical axes at right-side is showed.
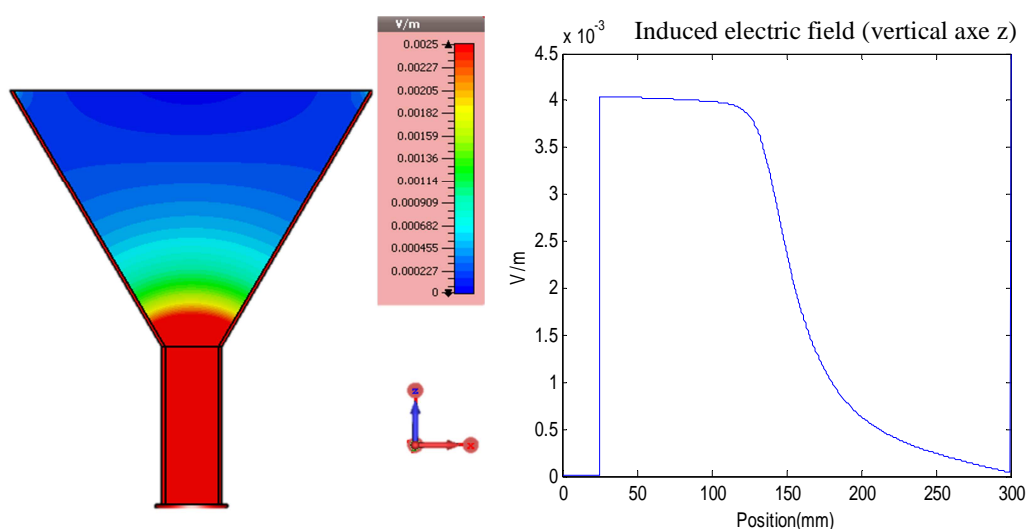

Figure 6. Induced electric fields inside the phantom with coronal view (left), following vertical axe (right)

V.   DEVICE UNDER TEST

The term device under test (DUT) in figure 1 represents in this study the cardiac implant inserted in the electromagnetic phantom. A cardiac implant is placed in the phantom to estimate numerically the interference voltages occurring over its probe tip. The figure 7 shows the implantation position and the induced electric field when the DUT is exposed to 1 kV/m 50 Hz. A 3 cm x 4 cm x 0.5 cm metallic box pacemaker with its lead and probe is installed mimicking a real case. The dimensions of the lead are respected as furnished in technical sheets from the manufacturer, with 10 mm tip to ring distance and 6.7 Fr cable diameter [17]. The probe characteristics are resumed at Figure 7. Further details about probe characteristics are mentioned in [18].
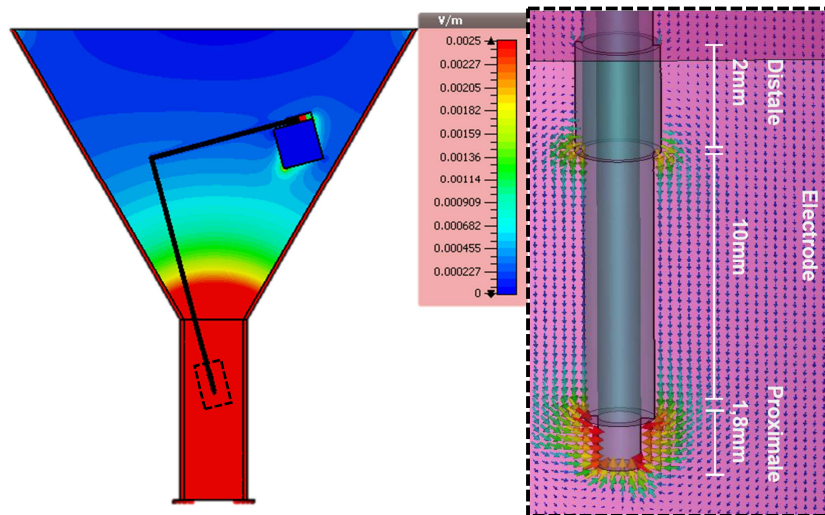

Figure 7. Electric field induction inside the DUT exposed to 1 kV/m 50 Hz

The induced voltages seen by cardiac implant vary depending on which mode of detection and configurations they are set. The most pertinent for this study is the two different detection modes: unipolar mode which uses the box as an electrode (anode) and probe as the other one (cathode), contrary to bipolar mode which employs two electrodes placed at the tip of the probe. For that reason, the detection curve also varies, making much important distance and much important interference voltages for unipolar detection, contrary to bipolar detection where this distance decreases considerably [13].

If the induced electric field over the detection curve is plotted, the integral of this curve gives the induced voltage for the concerned detection mode. Figure 8 shows the induced electric field over

the detection curve of cardiac implant for both detection modes: unipolar (left) and bipolar (right).

Under 1kV/m at 50 Hz electric field, implanted phantom simulations give interference voltages of 73 µV in bipolar detection and 550 µV in unipolar detection seen by the cardiac implant.
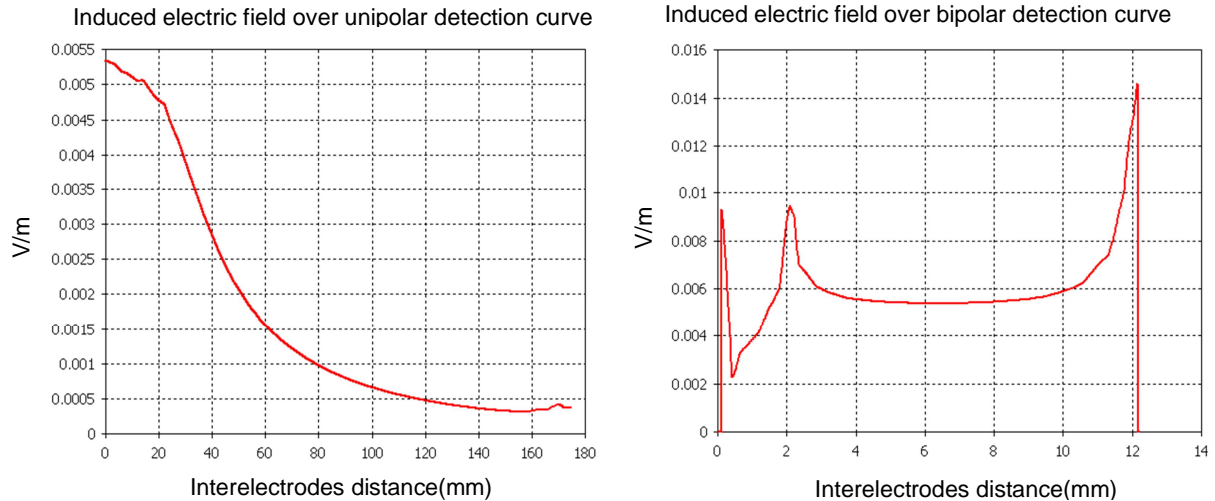

Figure 8. Induced electric field over the detection curve of cardiac implant (1kV/m 50 Hz)

VI. EXPERIMENTAL SETUP

The experimental setup consists of a signal generator (Agilent®) delivering a pure 50 Hz sine wave which is amplified for driving a high voltage transformer up to 80 kV.

The effective field generated between the conductor plates is measured by a 3D H/E field meter ESM-100 (Maschek). The maximum electric field measured at the center of the system is 100 kV/m between two planes separated of 75 cm, for an applied voltage difference of 80 kV. The results presented on figure 9 on the right are obtained in the absence of the phantom. As the system is symmetric, the measurements with the field meter have been performed only in a quarter of the area, on a 25 cm grid step. Both electric field maps, numerically estimated and experimentally measured are shown in figure 8 for 20 kV/m applied. The maximum difference between the two results is about 1%.

To ensure the reliability of electric field measurements, the room humidity is measured then controlled by the use of an air dryer. The temperature, humidity and the conductivity of the solution are recorded. Considering the dimensions of the experimental room, a simple

dehumidifier is enough to control the humidity in the room between 30-55%, and the temperatures do not vary much: from 19 to 28 degree Celsius.

Figure 9 shows the transformer providing high voltage to the upper conductive plate and the yellow/green cable from the earth to the lower plate. The experimental phantom is placed as shown figure 10 on the left. The cardiac implants are connected to the same bipolar lead
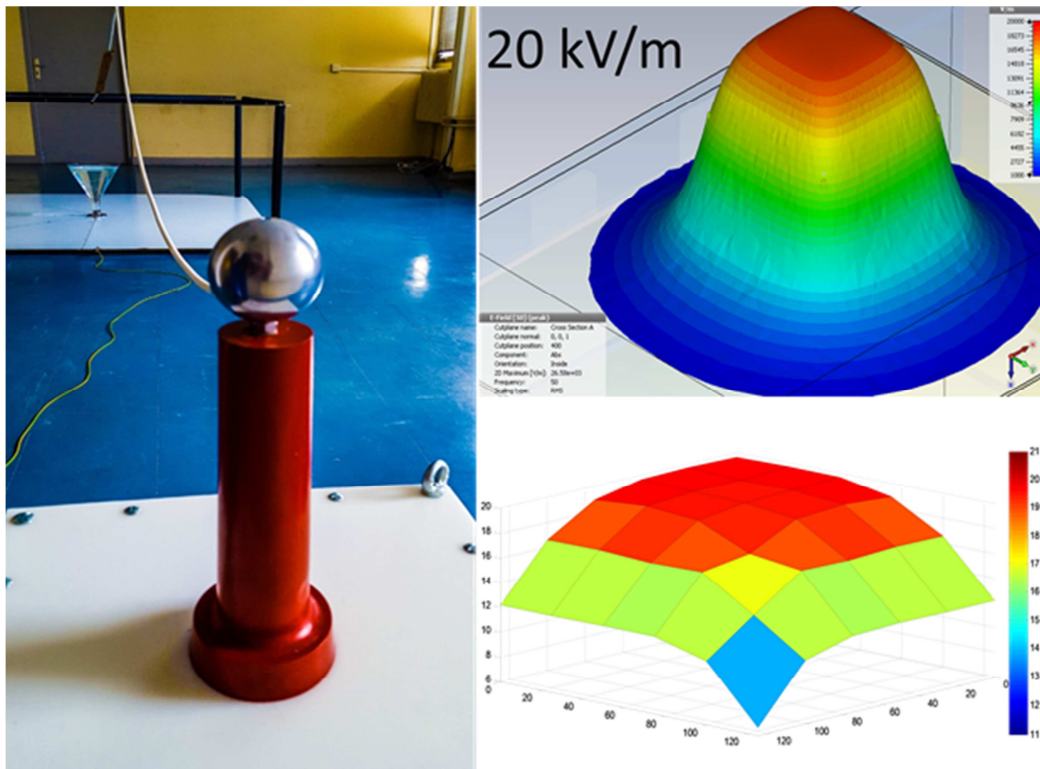

Figure 9. Experimental setup and electric field of the system

respecting the type of device: defibrillator lead or pacing lead. To implant it into the phantom, the box is maintained by a small support. The probe is positioned in the middle of the cylindrical part where the field is homogenous.

The solution has 0.19 – 0.21 S/m, and mixed to make it homogeneous inside all phantom, and checked by conductivity-meter.

Before exposure, interrogation of implant settings and the lead impedance is tested inside the phantom via remote cardiac telemetry. Once the implementation process is completed, the experimental room is locked. The security is checked from the control room via motion sensors and camera, different values of the electric field have been settled to expose the experimental

phantom. The eventual dysfunctions that will occur will be recorded by the cardiac implant and retrieved via telemetry once the exposition will be finished. Figure 10 illustrates the exposure system and the interrogation after exposition of DUT.
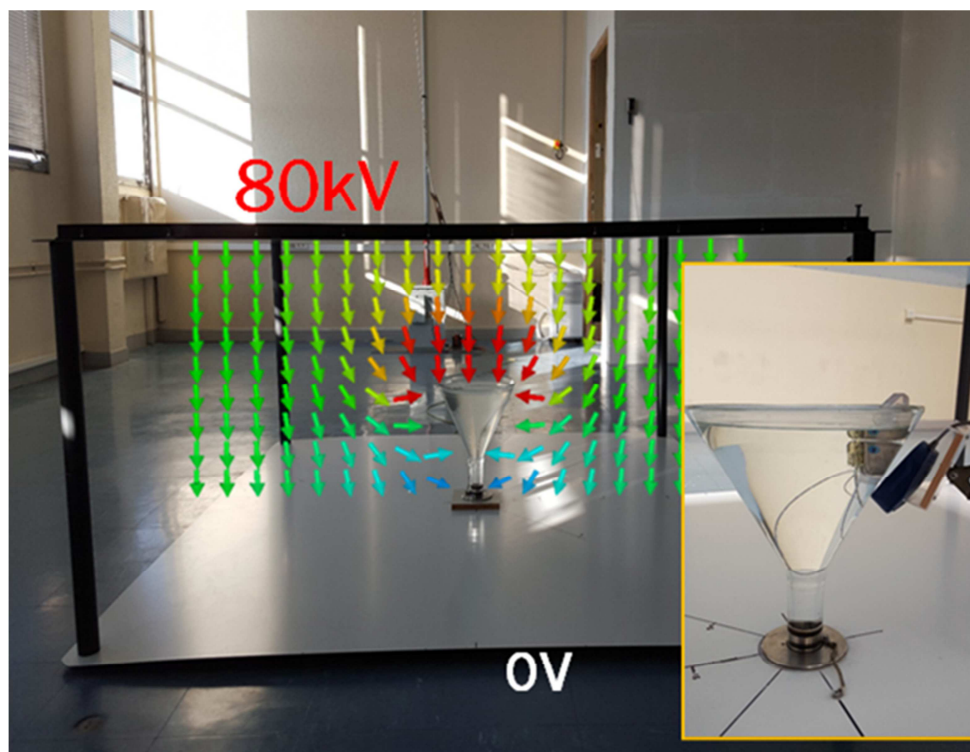

Figure 10. Exposure and interrogation of DUT after exposure

VII.   DISCUSSION

The test bench permits to reach 100 kV/m for 50 Hz and 83 kV/m for 60 Hz; they correspond to 20 times the public limit (5 kV/m) proposed by ICNIRP 2010 [18]. Even for professional exposure, these fields are much higher than the exposure limit values proposed in 2013/35/EU, and the measures effectuated in professional environments in France [4,19]. Always according to the limits given by European directive, 10 times the low action level (10 kV/m) and 5 times the high action level (20 kV/m) are achieved [4]. These high levels would permit to test the immunity of active cardiac implants even in extreme conditions.

Comparing to literature, with the test bench proposed in this paper, the conductivity homogeneity and the external field homogeneity is easier to reproduce and measure. The phantom weight is very light (7kg), comparing to human scale phantoms (≈200kg) making it easier to manipulate,

plus the control and the experimental rooms are separated and isolated [20-22]. Even when the DUT is exposed to maximum field (100kV/m) in the experimental room, the field measured in the control room is inferior to public limits (5 kV/m) according to ICNIRP 2010 [18]. Plus, the test bench is cost effective, not only for its construction but also the cost of each test effectuated. The external field may be varied to search a level of threshold in a uniform field, contrary to literature, where the aim is to test 3 range of non-uniform, in-situ electric field under lines. Additionally, that means the electric field is combined with magnetic field in such studies [21-22]. Last but not least, the in-vivo studies are conducted recently by [23] with a statistically significant number of patient (110). To represent the external field, current injections by electrodes over patients have been use rather the real exposition, the methods are presented in [24]. There are many parameters as the morphology and the state of the patient, making it very complex to interpret the results and to compare the inductions in exposition and in current injection [25]. The in-vitro studies and numerical analyses are an indispensable tool to analyses the problems seen in in-vivo studies.

Concerning DUT, the interference voltages are calculated for the two detection modes for active cardiac implants. The level of external electric field causing an induced interference voltage bigger then sensitivity voltage of the implant may be defined as threshold level. As the interference voltages are given per kV/m, we may estimate threshold levels of the cardiac implant depending on its sensitivity. Nevertheless, the values should be correlated to obtain the corresponding human exposition level. The interference voltages of an implanted virtual human body grounded has to be calculated. In that way, the external electric field dysfunction level of a cardiac implant for a grounded human may be obtained. As the maximum of heart inductions are taken into account for electromagnetic phantom, the numerical results in human body in same conditions are expected to be lesser. So, the thresholds (kV/m) would be greater than those of DUT.

Another point, the in-vitro electric fields thresholds are expected to be greater than numerical estimations, because of various precautions taken against the electromagnetic interferences by implant manufacturers. Actually, all these precautions are subject of many patents and cannot be simulated entirely due to computational limits, lack of data and patent protection, which underlines the necessity of complementary in-vitro tests.

VIII.   CONCLUSION

Homogeneous conductivity phantoms are used in bioelectromagnetics to test EMF effects on cardiac implants [11, 20, 21]. In this study, we have designed an in vitro test bench for active implants, reproducing external exposure to electric fields at 50, up to 100 kV/m, which is higher than occupational exposure. This low cost design permits to test different medical devices without needing a huge high voltage hall. The conception of the phantom respects the electric field amplitudes occurring in human body. Moreover, the configuration has been chosen by taking into consideration the heart inductions for cardiac implants testing, especially bipolar detection. Unipolar detection tests are also available by the mean value of inductions.

As perspective, *in-vitro* tests of cardiac implants would be realized with this test bench and electromagnetic phantom, in order to determine experimental thresholds. These are expected to be superior to the numerical ones.

Different organs, morphologies and types of active medical implants could be tested with this test bench, simply by adapting the cylindrical part diameter of the phantom in order to reproduce concerned organ inductions.

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