INFLUENCE OF LOW FREQUENCY ELECTROMAGNETIC FIELD ON PACEMAKER OPERATION

A. Babouri, A. Hedjiedj, J.P Andretzko, L.Guendouz, M. Nadi

Laboratoire d'Instrumentation Electronique de Nancy, Faculté des Sciences et Techniques,

Université Henri Poincaré Nancy 1, BP 239, 54506 Vandoeuvre - les - Nancy, France

abdesselam.babouri@lien.uhp-nancy.fr

Abstract: This paper describes the behaviour of single and double chamber pacemakers subjected to a low frequency magnetic field. The results allow to define the detection thresholds of the stimulators in different tests configurations. The tests in the air are completed by in vitro tests which constitute a more realistic approach. The pacemaker's reactions are observed through statistical data, and with the visualisation of the pacemaker-generated-signal.

Introduction

An important number of pacemaker's carriers are exposed daily to numerous sources of electromagnetic interferences that can create some influences on the activities of the implanted device. This article presents a study of the immunity of pacemakers to low frequency electromagnetic interferences. The heart pacemaker through its heart-generated signal listening function is likely to be targeted by these electromagnetic interferences. Its particular function implies to have an accurate knowledge of potentially interfering situations a carrier may be exposed to. Numerous studies have been published and concern with the mobile telecommunication ground which has incredibly scared over the last few years [1-4]. Besides, lower frequency interferences due to the industrial and domestic applications of electricity have also been published [5-8]. This ground, a.k.a. intermediate frequencies, is made more complicated by the diversity of technical data. In the mobile telecommunication ground, a common denominator exists between the different manufacturers (frequencies, sources strengths, beaming elements etc.). On the contrary, for systems implementing low frequency electromagnetic sources that a carrier may be exposed to, in everyday life or in industry (e.g. electrical appliances or induction heating, electronic article surveillance systems) [9,12], the main difficulty essentially linked with the great diversity of situations which makes comparing results difficult [13,14].

This paper presents an in vitro approach dealing with the implementation of a metrological set up dedicated to the characterization of cardiac pacemaker immunity to low frequency electromagnetic disruptions. The general problematic consists in checking this immunity in relation with led disruptions (the electrical voltage signals or current) and in relation with beaming disruptions (magnetic fields).

Material and method

Tests have been carried out for 6 single chamber pacemakers and 4 dual chamber ones. The studied frequencies are 50 Hz, 60 Hz, 10 kHz and 25 kHz. Tracking and programming of the pacemaker housing is achieved with the telemetry system. The devices have all been configured in inhibited stimulation (VVI and DDD for the cardiac pacemakers single chamber and dual chamber mode according to the international codification), this configuration being the most widespread.

Galvanic coupling: Preliminary tests consist in a galvanic coupling (figure1) between the disruptive source and the pacemaker. An in vitro study (figure2) completes the first attempts and allow to take into account the interface constituted by human tissues. These results enable a sequential approach to the problem and will serve as reference.



Figure 1: Galvanic coupling ; in Air tests



Figure 2: Galvanic coupling ; in vitro tests

Magnetic coupling : The second step concerns the behaviour of pacemakers submitted to a magnetic field. The interfering source is an Helmholtz type structure. It consists to two 1.5 m loops separated by a 0.75 m gap. The loops are formed of six jointed 16 mm² wire. This structure, powered by a programmable power generator is used to subject a cardiac pacemaker to a perfectly controlled magnetic field.

The device under test is composed by the probeequipped pacemaker and form a first loop ; this last is completed by a coplanar rectangular loop made of 90 jointed turns. The areas are respectively $A\approx 180$ cm2 and $A_{app} \approx 160$ cm². Using this additional loop allows to increase the effective loop area formed by the stimulator and the probe. This device is studied in two configurations. For the first one the device is completed by a resistance R which represents the load of the pacemaker (fig. 3) and is placed on a directional support at the centre of the Helmholtz source. For dual chamber pacemaker each lead is completed by an additional loop and a resistance.



Figure 3: Magnetic coupling (tests in air).

The second case corresponds to in vitro attempts. In that case, the probe-equipped pacemaker and the additional loop are inserted in a gelatine based equivalent model [15] (fig. 4).



Figure 4: Magnetic coupling (in vitro tests).

Results and Discussion

The presented results illustrate the different steps of this study. For each test is for the 4 studied frequencies and for different detection sensitivities. The interfering signal is applied during 15 mn and reading of the statistical data are done after each test.

The results show the influences of electromagnetic field signals on the working of the pacemakers and the behaviour of each pacemaker; this is illustrated by the statistical graph.

Galvanic coupling: Figure 5 summarizes the results obtained on the 6 single chamber pacemakers. In this graph the x-axis represents the amplitude of the applied

signal, and the y-axis represents the different cases called A, B, C, D, E and F. For 10 kHz and 25 kHz red lines and blue lines show the detection thresholds for 10 KHz and 25 KHz interfering signals respectively.

They are variable according to the frequency of the interfering signal, and are also related to the preprogrammed detection sensitivities.



Figure 5: detection thresholds for 6 single chamber pacemakers submitted to a Galvanic coupling (In Air)

Figure 7 corresponds to the in vitro test of a dual chamber pacemaker. These graphs give the values indicated by the statistical counters resulting from each test according to the amplitude of the applied signal. The x-axis represents the effective value of the tension applied between the pacemaker terminals. The y-axis is double. On the scale of right-hand side, which is read from top to bottom, the bars indicate the values of the statistical counters indicating the percentage of atrial and ventricular stimulations recorded by the pacemaker.

The scale on the left, which is read upwards, indicates the percentage of atrial extra systoles (ESA) and atrial detections (detectionA). These figures illustrate in a precise way the reactions of pacemaker subjected to the interfering signal with, in this case a major reduction in the number of atrial stimulations (< 10%).



Figure 6: Behaviour of dual chamber pacemaker submitted to a galvanic coupling (in vitro)

Magnetic coupling: Figures 7 illustrates the behaviour of a dual chamber pacemaker subjected to a 10 KHz magnetic field. On these figures, the x-axis represents the intensity of the applied magnetic field. The vertical axes gives the value given by the statistical counters. Figure 7 corresponds to tests in the air.

This graph shows, as previously, losses of atrial and ventricular impulsions. In the same time, the pacemaker records a number of detections and extra systoles in the atrial and ventricular chambers. For the other pacemakers their behaviours are similar, but the detections levels are different.

The detection levels are obtained with one (or two) additional 90 turns loop in order to increase the induced electromotive force at the pacemaker terminals. These results can however be used as reference, to evaluate the detection thresholds in case of an implanted situation where the coupling surface is weaker.



Figure 7: Behaviour of dual chamber pacemaker submitted to a magnetic coupling (in Air)

From a practical point of view, these various reactions result in modifications of the cycle of operation of the pacemaker under test. The figures 8 and 9 show a comparison between a normal functioning and a disturbing functioning of a pacemaker. Figure 9 relates to a single chamber pacemaker. The upper illustration, corresponding to a

normal functioning, shows impulsions regularly spaced. The graph. in lower part show the reactions of the pacemaker in the case of a disturbed operation. In this case, variations in the time period between two successive pulses are noticed.

Figure 9 presents the signal born out of a dual chamber pacemaker. In case of a normal functioning (upper graph), it generates pre-programmed frequency impulsions which, in the absence of a disruptive signal, occur at regular intervals. Wide amplitude impulsions originate from the ventricular chamber whereas smaller amplitude ones originate from the atrial chamber.



Figure 8 : Stimulator generated signal in the case of normal functioning and disturbed functioning (single chamber).

The lower graph represents pacemaker born signal a slight disruption following the input of a 10 kHz frequency signal. It must be noted that for this representation, large impulsions generate from the atrial chamber whereas small amplitude ones generate from the ventricular chamber. The acquisition of the signals generated from both chambers shows some variations in the ventricular and atrial stimulation frequency and also in the delay between an auricular pulse and the following ventricular pulse.



Figure 9 : Stimulator generated signal in the case of normal functioning and disturbed functioning.

Conclusion

This study enabled to evaluate the behaviour of single and dual chamber pacemakers submitted to low frequency interferences. For each configurations, the tests shows similar reactions that highlight a window effect of the stimulator detection circuits. This study enabled to evaluate the behaviour of heart stimulator when a 50 Hz, 60 Hz, 10 kHz and 25 kHz disruptive sinusoidal signal is applied. This choice, limited as it may be, enables a sequential approach to the problem. Other frequencies or other wave shapes can be applied in the same way.

Acknowledgements

This work is supported by EDF.

References

- [1] HAYES DL, WANG PJ, REYNOLDS DW, ESTES III NAM, GRIFFITH JL, STEFENS RA, CARLO GL, FINDLAY GK, JOHNSON CM,(1997): 'Interference with cardiac pacemakers by cellular telephones' New Eng. J. Med. (New England Journal of Medic) 336, 1473-1479.
- [2] KS TAN AND I HINBERG, (1998): 'Can Wireless Communication Systems Affect Implantable Cardiac Pacemakers? An In Vitro Laboratory Study,' Biomedical Instrumentation Technology 32, no. 1,18–24.
- [3] DR. SMITH A.R.P-Bulletin: Electromagnetic compatibility of medical devices with mobile communications – Medical devices Agency – London - 1997.
- [4] CHEN W.H., LAU C.P., LEUNG S.-K., HO D. S.-W., LEE I. S.-F.(1996): 'Interference of cellular

phones with implanted permanent pacemakers' Clin. Cardio 1.., Vol.19, N°.11, pp. 881 – 886.

- [5] SCHOLTEN A, JOOSTEN S, SILNY J,(2005):
 'Unipolar cardiac pacemakers in electromagnetic fields of high voltage overhead lines. med./biol. : J Med Eng Technol ; 29 (4): 170 - 175
- [6] A. SCHOLTEN AND J. SILNY, (2001): 'The interference threshold of cardiac pacemakers in electric 50 Hz fields', Journal of Medical Engineering & Technology, Volume 25, Number 1, pages 1-11.
- [7] TRIGANO A, BLANDEAU O, SOUQUES M, GERNEZ JP,(2005): 'Magne I Clinical study of interference with cardiac pacemakers by a magnetic field at power line frequencies'. med./biol. : J Am Coll Cardiol; 45 (6): 896 – 900 Exposure characteristics: frequency 50 Hz
- [8] KAYE G.G., GHAZWAN S., BUTROUS G.S., ALLEN A., STUART J. AND COLL., (1988): 'The effect of 50 Hz external electrical interference on implanted cardiac pacemakers, Pace, Vol. 11.
- [9] KAINZ W, CASAMENTO JP, RUGGERA PS, CHAN DD AND WITTERS DM.(2005)' Implantable cardiac pacemaker electromagnetic compatibility testing in a novel security system simulator. techn./dosim. : IEEE Trans Biomed Eng; 52 (3): 520 - 530
- [10] DODINOT B., GODENIR J.P., COSTA A.B., (1993) 'Electronic article surveillance : a possible danger for pacemakers patients, Pace, Vol. 16, pp. 46-53.
- [11] BEAUGEARD D., KACET S., BRICOUT M. ET CAMBLIN J. (1992) 'Interférences entre les stimulateurs cardiaques et les détecteurs de vol dans les magasins, Arch. Mal. Coeur, Vol. 85, pp. 1457-1461.
- [12] LUCAS E.H., JOHNSON D., MCELROY B.P., (1994) 'The effects of electronic article surveillance systems on permanent cardiac pacemakers : an in vitro study (Part II), PACE, Vol. 17, pp. 2021-2026.
- [13] M. NADI, A. HEDIEDJ, A. ROUANE: (2000)' Bio structures en environnement électromagnétique', Revue générale, ITBM-RBM;21;135-42.
- [14] NADI M, GOEURY C, GAGNY C, HEDIEDJ A. (1998): 'Interactions of implantable medical devices with electromagnetic sources in the 3KHz -3MHz band. Actes du Workshop biomedical effects of electromagnetic fields. Paris: Ed. L.Miro, publié sous l'égide de l'OMS et du Cost.244 bis; 26-27.
- [15] C. GOEURY, A. HEDJIEDJ, M. NADI. (2001): 'Gel conducteur pour la simulation de la conductivité électrique des tissus humains entre 50Hz et 500 KHz'. ITBM-RBM vol.22,N°4, pp. 371-377.