The New Directive 2013/35/EU on Occupational Exposure to Electromagnetic Fields and Electrical Workers' Use of Cardiac Pacemakers

Leena Korpinen[1], Rauno Pääkkönen[2], Martine Souques[3] and Vesa Virtanen[4]
[1]*Environmental Health, Tampere University of Technology, Tampere, Finland*
[2]*Finnish Institute of Occupational Health, Tampere, Finland*
[3]*EDF – DRH Groupe, Paris, France*
[4]*The Heart Center, Tampere University Hospital, Tampere, Finland*

Keywords: Pacemaker, Worker, Directive.

Abstract: The aim of this paper was to investigate, the new directive 2013/35/EU on occupational exposure to electromagnetic fields and the electrical workers' use of cardiac pacemakers (PMs). The directive includes minimum requirements for the protection of workers from risks to their health and safety. In addition there is information about medical implants, e.g., cardiac pacemakers and possible interference problems. In this paper we describe our earlier studies of PMs and analyze where it is possible to find such high electric or magnetic fields that the exposure can influence the PM. Based on experiments at Tampere University of Technology, the electric field under 400 kV power line may disturb a PM, when the electric field is below the low action level (10 kV/m). The risk of disturbances is not considered to be high, because only one of the several PMs showed a major disturbance.

1 INTRODUCTION

The Directive 2013/35/EU of the European Parliament and of the Council on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields) was published in 2013. The directive (2013/35/EU) includes minimum requirements for the protection of workers from risks to their health and safety arising, or likely to arise, from exposure to electromagnetic fields at their work.

When the frequency is 50 Hz, the action levels (ALs, workers) of the directive regarding magnetic fields are as follows: low ALs 1,000 µT (rms), high ALs 6,000 µT (rms), ALs 18 mT (rms) for exposure of limbs to a localized magnetic field and to electric fields, and low ALs 10 kV/m (rms), and high ALs 20 kV/m (rms) (European Parliament and Council, 2013). The exposure limit value (ELV) for health effects, which is related to electric stimulation of all peripheral and central nervous system tissues in the body, is 1.1 V/m (peak) to 50 Hz, and the sensory effects ELV, which is related to electric field effects on the central nervous system in the head, is 0.14 V/m (peak) (European Parliament and Council, 2013).

The directive also includes information about medical implants, e.g., cardiac pacemakers and defibrillators, cochlear implants, and other implants or medical devices worn on the body. According the directive 2013/35/EU, it is possible that interference problems, especially with pacemakers, may occur at levels below the ALs (European Parliament and Council, 2013).

The directive includes the list of 'indirect effects', which means effects caused by the presence of an object in an electromagnetic field. Those may become the cause of a safety or health hazard, such as interference with medical electronic devices, including cardiac pacemakers and other implants or medical devices worn on the body. (European Parliament and Council, 2013).

According to the directive, when carrying out the risk assessment pursuant to Article 6(3) of Directive 89/391/EEC, the employer shall give particular attention to the following, e.g., interference with medical electronic equipment and devices, including cardiac pacemakers and other implants or medical

Korpinen L., Pääkkönen R., Souques M. and Virtanen V..
The New Directive 2013/35/EU on Occupational Exposure to Electromagnetic Fields and Electrical Workers' Use of Cardiac Pacemakers.
DOI: 10.5220/0004913602490252
In *Proceedings of the International Conference on Biomedical Electronics and Devices* (BIODEVICES-2014), pages 249-252
ISBN: 978-989-758-013-0

devices worn on his or her body. (European Parliament and Council, 2013).

European Committee for Electrotechnical Standardization (CENELEC) has also published some standards from this area (CENELEC 2010, 2011). For example, European Norm 50527-1, according to which magnetic flux density of 100 µT, is considered to be the 'safety level' for pacemakers.

In western countries, persons with cardiac pacemakers represent a large group. In Finland, about 700 recipients out of a million inhabitants received a cardiac pacemaker (PM) in 2010. A PM is a medical device with electrodes. The electrode configuration in cardiac PMs can be unipolar or bipolar. In the unipolar system, the electrode configuration of the PM includes one electrode that lies within the heart as a cathode, whereas the anode is the metallic case of the PM itself, and in the bipolar system, one lead has two electrodes very close within the heart. (Chiara et al., 2007)

The aim of this paper was to investigate, the new directive 2013/35/EU on occupational exposure to electromagnetic fields and the electrical workers' use of cardiac pacemakers.

In addition we describe our earlier studies of PMs and analyze where it is possible to find such high electric or magnetic fields that the exposure can influence on the PM (Korpinen et al., 2012, Korpinen et al., 2013a, Korpinen et al., 2013b).

2 METHODS

2.1 A Human-shaped Phantom

We used a human–shaped phantom for testing PMs under 400 kV power lines or at 400 kV substations. The phantom was made out of a commercial plastic mannequin. In tests, it was filled with 0.9% saline solution. The height of the water-tight, human-shaped phantom is 1.92 m. Figure 1 shows a pacemaker inside the phantom.

Figure 2 shows the phantom under the power line. Details of the phantom were described in the previous publication (Korpinen et al., 2012).

2.2 Electric and Magnetic Field Measurements

Figure 3 shows an example of magnetic field measurement.

The the electric field was measured at the height of 1.7 m with an EFA-300 meter (Narda Safety Test Solutions GmbH, Pfullingen, Germany) (accuracy ± 3%, RMS), and the magnetic field was measured with a Narda ELT-400 meter (L-3 Communications, Narda Safety Test Solutions, Hauppauge, NY, USA; accuracy ± 4% RMS).

Figure 4 shows an example of the electric field measurement.

Figure 1: A pacemaker inside the phantom.

Figure 2: The phantom under the power line.

Figure 3: An example of magnetic field measurement.

Figure 4: An example of electric field measurement.

2.3 Tested PMs

The PMs were tested as the following: (1) 31 PMs were tested near 400 kV power line, and (2) 7 PMs were tested at a 400 kV substation in two locations. Details of the test environments and tested pacemakers were described in the previous publication (Korpinen et al., 2012, Korpinen et al., 2013a, Korpinen et al., 2013b).

2.4 Protocol

The protocol of the experiment was so that we used the phantom in the following ways: (1) isolated from the ground, (2) grounded from a foot, (3) grounded from a hand. Details of the measurement system were described in the previous publication (Korpinen et al., 2012).

3 RESULTS

Altogether, 31 PMs were tested near 400 kV power lines. There, the electric field was 6.7–7.5 kV/m and the magnetic field 2.4–2.9 µT. At a 400 kV substation, 7 PMs were tested. In location A, the magnetic field was over 1000 µT, and in location B, the magnetic field was over 600 µT.

Near the power lines, one of the tested PMs in the unipolar configuration entered a safety function with a constant pace of 60 beats per minute. In the bipolar configuration, however, the same PM showed no disturbance. During our tests, other PMs showed minor disturbances or none at all. (Korpinen et al., 2012)

The magnetic field exposure at the 400 substation did not disturb the PMs (whether in unipolar or bipolar configuration). (Korpinen et al., 2013b)

4 DISCUSSION

4.1 Comparison to Exposure Levels at PM Tests to Occupational Exposure

In the earlier study (Korpinen et al., 2011b) the occupational exposure to electric and magnetic fields was studied during various work tasks at switching and transforming stations of 110 kV (in some situations 20 kV). The electric (n = 765) and magnetic (n = 203) fields were measured during various work tasks. The average values of all measurements were 3.6 kV/m and 28.6 µT.

The maximum value of electric fields was 15.5 kV/m. In one special work task close to shunt reactor cables (20 kV), the highest magnetic field was 710 µT.

In addition at 400 kV substations the occupational exposure to electric fields was studied. The maximum inhomogeneous electric field was 47 kV/m (Korpinen et al., 2009, 2011a).

When we compare the electric field exposure at PM tests to the electric fields at the 110 kV or 400 kV substations, it is possible to find such a high electric field as was in the PM tests.

Therefore it is possible that a PM disturbance can occur at tasks under 400 kV power lines or at 110 kV (or higher) substations.

In the directive 2013/35/EU the action levels (at 50 Hz) are to electric fields: low ALs 10 kV/m (rms), and high ALs 20 kV/m (rms). Based on the PM tests, it is possible to find PM disturbances, when the electric field is below low ALs. It is essential to take into account in the future if an electrical worker will start to use a PM.

5 CONCLUSIONS

It is important to analyze the possible interference with medical electronic devices, including PMs and other implants, based on the new directive 2013/35/EU of the European Parliament and of the Council on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields). In the PM tests at TUT the electric field under 400 kV power line may disturb a PM, when the electric field (6.7–7.5 kV/m) is below low ALs (10 kV/m, at Directive). However the risk of disturbance is not considered to be high, because only one of the several PMs showed a major disturbance.

ACKNOWLEDGEMENTS

Acknowledgments: The assistance of the staff of the Department of Energy and Process Engineering, Environmental Health, Tampere University of Technology (Markus Annila, Tero Haapala, and Markus Wirta) is gratefully acknowledged. We thank Harri Kuisti and Jarmo Elovaara (Fingrid Oyj) for their advice and Hiroo Tarao (Department of Electrical and Computer Engineering, Kagawa National College of Technology, Japan) for his advice and help with the measurements. In addition, we thank Seppo Malinen (WL-Medical Oy) for making programming devices available.

REFERENCES

CENELEC, European Committee for Electrotechnical Standardization 2010. *Procedure for the assessment of the exposure to electromagnetic fields of workers bearing active implantable medical devices - Part 1: General*. Brussels, Belgium.

CENELEC European Committee for Electrotechnical Standardization 2011. *Procedure for the assessment of the exposure to electromagnetic fields of workers bearing active implantable medical devices d Part 2–1: Specific assessment for workers with cardiac pacemakers*. Brussels, Belgium.

Chiara, G. D., Primiani, V. M., Moglie, F., 2007. Experimental and numeric investigation about electromagnetic interference between implantable cardiac pacemaker and magnetic fields at power line frequency. *Ann Ist Super. Sanità* 43, pp 248–253.

European Parliament and of the Council, 2013. Directive 2013/35/EU of the European Parliament and of the Council of 26 June 2013 on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields) (20th individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) and repealing Directive 2004/40/EC. *Official Journal of the European Union L 179, 29/6/2013*.

http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:179:0001:0021:EN:PDF.

Korpinen, L. H., Elovaara, J. A., Kuisti, H. A, 2009. Evaluation of current densities and total contact currents in occupational exposure at 400 kV substations and power lines. *Bioelectromagnetics* 30, 3, pp 231–240.

Korpinen, L., Elovaara, J., Kuisti, H. A., 2011a. Occupational exposure to electric fields and induced currents associated with 400 kV substation tasks from different service platforms. *Bioelectromagnetics,* pp 79–83.

Korpinen, L., Kuisti, H., Elovaara, J., Virtanen, V., 2012. Cardiac pacemakers in electric and magnetic fields of 400-kV power lines. *Pacing Clin Electrophysiol* 35, pp 422–430.

Korpinen, L., Kuisti, H., Elovaara, J., Virtanen, V., 2013a, *Response Pacing Clin Electrophysiol*, 36, 2, 267-268.

Korpinen, L., Kuisti, H., Pääkkönen, R., Vanhala, P., Elovaara, J., 2011b. Occupational Exposure to Electric and Magnetic Fields While Working at Switching and Transforminig Stations of 110 kV. *Annals of Occupational Hygiene* 55, *5*, pp 526–536.

Korpinen, L., Kuisti, H., Tarao, H., Elovaara, J., Virtanen, V.,. 2013b. Cardiac pacemakers in magnetic fields of a shunt reactor at a 400 kV substation (accepted to *International Journal of Occupational Safety and Ergonomics*).