The New Directive 2013/35/EU on Occupational Exposure to Electric Fields and Electrical Workers' Use of Implantable Cardioverter Defibrillators (ICDs)

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Abstract: The indications for implantable cardioverter-defibrillators (ICDs) are expanding and workers' use of ICDs has increased. The aim of this paper was to investigate the new directive, 2013/35/EU, on occupational exposure to ELF electric fields and the electrical workers' use of Implantable Cardioverter Defibrillators (ICDs). For example, the directive includes information about medical implants, e.g. ICDs and possible interference problems. In this paper, we describe our earlier study of ICDs and analyze where it is possible to find such high electric fields that the exposure can influence the ICDs. Based on experiments at Tampere University of Technology, the electric field under a 400 kV power line may disturb an ICD, when the electric field is below the low action level (10 kV/m). However, there were no no effects observed on ICDs functioning up to 0.9 kV/m, and only anomalous behavior in some conditions was observed when levels exceeded 5.1 kV/m. The risk of disturbances is not considered to be high.

1 INTRODUCTION

With the advance of medical technology, a variety of new devices or aids facilitating – or even sustaining – human vital functions have entered the market. For example, these devices include cardiac pacemakers (PMs), implantable cardioverter defibrillators (ICDs), neurostimulators, and drug pumps.

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) 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 during their work. According to directive 2013/35/EU, some specific workers may experience interference problems, so that EMFs can affect the functioning of medical devices (for example, metallic prostheses, PMs and ICDs, cochlear implants, and other implants or medical devices worn on the body). It is possible that interference problems, especially with PMs, may occur at levels below the ALs (action levels), which are (at 50 Hz): (1) for electric fields (EFs): low ALs 10 kV/m (rms), and high ALs 20 kV/m (rms); (2) for magnetic fields (MFs): 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 (European Parliament and Council, 2013).

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

EMF interference with PMs and ICDs has been studied, in vivo and in vitro, for example in Finland and France (Korpinen et al. 2012, 2013a, 2014; Trigano et al. 2005; Katrib et al. 2013; Souques et al., 2011). The PM tests (in Finland) found that the electric field under a 400 kV power line (6.7–7.5 kV/m) may disturb a PM in unipolar mode, which can occur at tasks under 400 kV power lines or at 110 kV (or higher) substations. However, the

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risk of interference is not considered to be high, because only one of the several PMs tested showed a major disturbance (Korpinen et al., 2012). For the 50 Hz magnetic field, PM tests (in France) show no interference under 50 µT in unipolar mode and under 100 µT in bipolar mode (Trigano et al. 2005). For ICDs, in vitro tests (in France) show no interference until 3.000 µT, but only 4 devices were tested (Katrib et al. 2013).

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

In addition, we describe our earlier study of ICDs and analyze where it is possible to find such high electricity that the exposure can influence the ICDs (Korpinen et al., 2014)

2 METHODS

2.1 Measurement Places and Phantom

During the four measurement days, 37 ICD tests were performed using a human-shaped phantom in three different places (A, B and C) near 400 kV power lines. The place A was 5.1 m from the outermost conductor of the 400-kV power line (laterally) on a hill and place B was at a distance of 2.5 m from place A in the direction of the power lines. The place C was located 11.6 m away from place A. Details of the places were published in the earlier article. (Korpinen et al., 2014)

We used a human–shaped phantom (height 1.92 m) for testing ICDs under 400 kV power lines or at 400 kV substations. The phantom was filled with 0.9% saline solution. Figure 1 shows the phantom under the power line. In Figure 2, there is an example ICD inside the phantom.

We used a simulated heart signal in the ICD tests. In the tests, we added a lead from the phantom's leg to the ICD so that we could apply a simulated heart signal to the ICD according to EN 45502–2–1 2003 standards. (EN 45502–2–1, 2003)

The electric field (height 1.7 m) was measured with an EFA-300 meter (Narda Safety Test Solutions GmbH, Pfullingen, Germany; accuracy ± 3%, root mean square [RMS] value) and EFA-3 field meter (Wandel and Goltermann GmbH, Eningen, Germany; accuracy ± 5%, RMS).

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 1: The phantom under the power line (in place B).

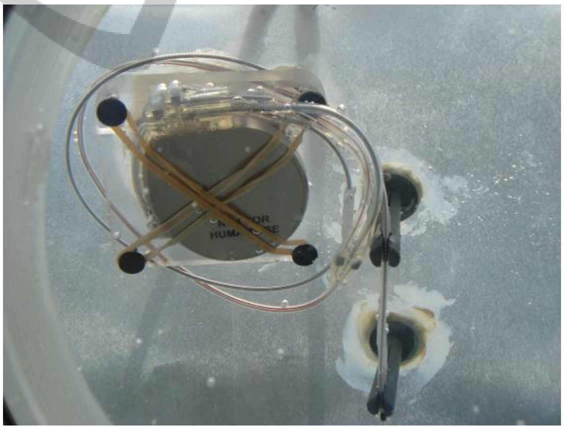

Figure 2: An example of the ICD inside the phantom.

The temperature inside the head of the phantom was measured with a Yellowspring Industries (YSI) temperature meter, containing a thermistor probe (Yellowspring Industries, Yellowsprings, OH, USA).

We also measured conductivity of the liquid using the conductivity meter DiSTWP 4 (Hanna Instruments, Ann Arbor, MI, USA). Figure 3 shows an example of the conductivity measurements.

Figure 3: An example of the conductivity measurements.

Figure 4 shows an example of an electric field measurement, and figure 5 presents an example of a magnetic field measurement.

Figure 4: An example of a EF measurement (in place A).

Figure 5: An example of a MF measurement (in place A).

Figure 6 shows a laptop, which we used to simulate a heart signal.

Figure 6: A laptop, which simulated a heart signal.

3 RESULTS

Altogether, 37 ICD tests were performed, and we used 10 different ICDs. Details of the ICDs were published in the earlier (Korpinen et al., 2014).

3.1 First Experiment Period

In place A, the electric fields were from 6.8 kV/m to 7.5 kV/m (height 1.7 m), and the humidity of air was 70.5%. The magnetic field was 2.0 µT. In Place B, the measured electric field was 5.1 kV/m (height 1.7 m) when the humidity was 67.0%, and the magnetic field was 3.6 µT. In place C, where the measured electric field was 0.9 kV/m (height 1.7 m) when the humidity was 68%, the magnetic field was 1.4 µT.

In one ICD test with the heart signal (place A), an ICD recorded 258 ventricular beats/min, and in the test with the same ICD without a heart signal, it recorded 194 ventricular beats/min. In Place C, the ICD had no disturbances.

3.2 Second Experiment Period

During the second experiment period, we performed ICD tests in place A. The measured electric field was from 7.2 kV/m to 7.5 kV/m (height 1.7 m) when the humidity was 52.9% and 53.3%.

In the second experiment period, the ICD, which had disturbances in the first experiment period, had no disturbances in the second experiment period.

Details of all ICD tests were published in the earlier article. (Korpinen et al., 2014)

4 DISCUSSION

The earlier publication (Korpinen et al., 2009) presented 15 simulated normal work tasks of workers (n=151) at 400-kV substations. The maximum electric fields were the following: (1) main transformer inspection from maintenance platform: 18.5 kV/m; (2) maintenance of contacts of reach disconnect or from a man hoist: 8.5 kV/m; (3) maintenance of operating device of disconnector from service platform 8.5 kV/m; (4) maintenance of operating device of circuit breaker at ground level 15.5 kV/ m, (5) inspection of primary terminals of current transformer from a man hoist: 19.2 kV/m, (6) inspection of secondary terminals of busbar voltage transformer using ladder 43.5 kV/m; (7) changing a bulb by climbing to a pylon: 35.0 kV/m, (8) walking in the substation 15.2 kV/m; (9) maintenance of operating device of circuit breaker from ladder 44.3 kV/m, (10) maintenance of operating device of circuit breaker from service platform 36.3 kV/m, (11) breaker head maintenance from man hoist 44.3 kV/m and (12) inspection of secondary terminals of current transformer from ladder: 47.0 kV/m.

In another earlier study (Korpinen et al., 2011), the occupational exposure to electric and magnetic fields were 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. 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.

When we compare the electric field exposure at ICD 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 ICD tests.

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

Based on our ICD tests, it is possible to find PM disturbances, when the electric field is below low ALs (10 kV/m). It is important to take it into account, in the future, if an electrical worker will start to use an ICD.

A methodology for evaluating the risk of PMs and ICDs dysfunction with occupational exposure to EMF has been developed at EDF to help the occupational physician make a decision about fitness for work (Souques et al., 2011).

5 CONCLUSIONS

It is important to analyze the possible interference with medical electronic devices, including ICDs and other implants, based on the new directive 2013/35/EU. In the ICD tests at TUT, the electric field under a 400 kV power line, no effect on ICD functioning was observed up to 0.9 kV/m, while anomalous behavior in some conditions was observed when levels exceeded 5.1 kV/m, which is below low ALs (10 kV/m, at Directive). However, the risk of interference problems is not considered to be high, because only one of the several ICDs showed an anomalous behavior.

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