NEW DIRECTIVE 2013/35/EU ON OCCUPATIONAL EXPOSURE TO MAGNETIC FIELDS AND ELECTRICAL WORKERS USE OF ACTIVE IMPLANTED MEDICAL DEVICES (AIMDS)

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ABSTRACT

Aim to the paper was to describe our earlier studies of PMs and analyze where it is possible to find such high magnetic fields that the exposure can influence PMs.
We tested PMs with a human-shaped phantom at 400kV substation, where the magnetic field source was a shunt reactor.

INTRODUCTION

In Western countries, the aging population will increase in the future. For example, the number of Europeans aged over 65 years is expected to almost double over the next 50 years, from 87 million in 2010 to 148 million in 2060 [1]. At the same time, the persons with an active implantable medical device (AIMD) make up a large group. For example, in Finland, about 700 out of a million inhabitants received a cardiac pacemaker (PM) in 2010. In addition, neurostimulators and drug pumps are quite popular nowadays.

AIMDs are devices that are fully or partially inside a human body or in a body cavity and are used to perform medical intervention. AIMDs use a power source, which is not based on power produced by human beings themselves. Example AIDMs include PMs; implantable cardioverter defibrillators (ICDs); pain, muscle, bladder, sphincter, or respiration stimulators; cochlear implants; insulin or drug pumps; and pressure, electrocardiogram, and other implantable monitors [2]. Figures 1 and 2 show examples of AIMDs.

Figure 1. Example of AIMD (neurostimulator).

Figure 2. Example of AIMD (insulin pump).

A PM is a device that enables the heart to function properly in patients with a bradycardic heart rate. It has developed from simple, constant-frequency devices into devices that can be programmed individually. The PM system recognises the cardiac function and, if necessary, sends an electrical impulse that causes the heart muscle to contract. The electrode configuration can be bipolar or unipolar. In the bipolar system, one lead has two electrodes very close together within the heart. In the unipolar system, the lead includes one electrode that lies within the heart as a cathode, whereas the anode is the metallic case of the PM itself. [3]. An ICD is a medical device, comprising an implantable pulse generator and leads, intended to detect and correct tachycardia and fibrillation by application of cardioversion/defibrillation pulses to the heart. [4].

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 localized magnetic field. [5]

In this paper, our aim was to describe our earlier studies [6,7] of PMs and analyze where it is possible to find such high magnetic fields that the exposure can affect PMs.

EXPERIMENTS WITH A HUMAN–SHAPED PHANTOM

A human-shaped phantom

A human-shaped phantom was developed using a commercially available plastic mannequin (at TUT). It needed to be water-tight so that it would be possible to put a liquid with salinity 0.9 g/l [8] inside the phantom. Figure 3 reveals the phantom. The height of the phantom is 1.92 m.

Figure 3. Human-shaped phantom near powerlines.

In Figure 3, we can see that during the experiments, we measured the current between the ground and foot/hand was measured with a multimeter to ensure the quality of the ground connection. However, during the test period, the human being was not in proximity to the phantom such that he would not be exposed to electric and magnetic fields. Figures 4 and 5 show examples of the holes in the phantom.

Figure 4. Examples of holes in phantom.

Figure 4 shows a hole at top of the head, which was utilized to measure temperature inside the phantom, and in the back of the phantom, there was a door. Figure 5 reveals that there was a square 80-mm × 80-mm plate onto which the PM could be attached with two rubber bands.

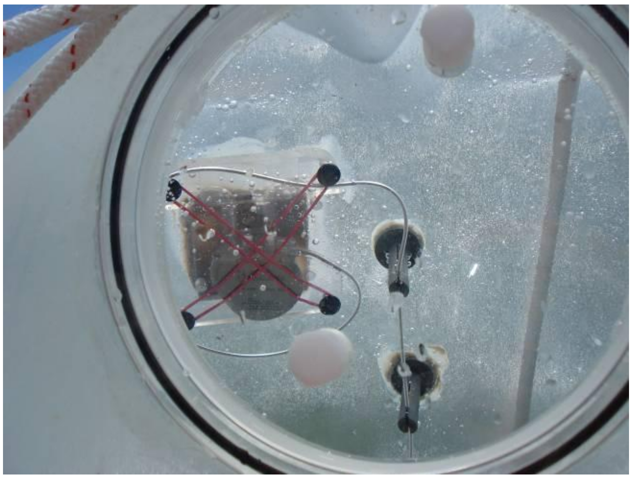

Figure 5. Example of PM inside phantom

Magnetic field measurements

The magnetic field was measured with a Narda ELT-400 meter (L-3 Communications, Narda Safety Test

Solutions, Hauppauge, NY, USA; accuracy ± 4% RMS). We measured magnetic fields inside (Figure 6) of the phantom and outside near the phantom (Figure 7).

Figure 6. Example of magnetic field inside phantom.

Figure 7. Example of magnetic field near phantom.

In addition, 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).

PM testing procedure

We used a phantom near 400 kV power lines and at a 400kV substation, where the magnetic field source was a shunt reactor.

We started PM testing when the phantom was filled with saline liquid. We used three 5 min test periods as follows:
1) Phantom isolated from the ground
2) One grounded at a foot (left or right), and
3) One grounded at the left hand.

Details of the testing procedure were described in the previous publications [6,7].

Results of PM testing

At 400 kV substations, we established two experiment locations: A (outside, magnetic field over 1000 μT, Figure 7) and location B (inside, magnetic field over 600 μT). Altogether, seven PMs were tested at the substation. The magnetic field exposure did not disturb the PMs. [7].

Near 400 kV power lines (Figure 1) altogether, 31 PMs were studied. The magnetic field was 2.4–2.9 μT, and the electric field was 6.7–7.5 kV/m. One of the tested PMs in the unipolar configuration entered a safety function with a constant pace of 60 beats per minute. However, the same PM did not receive a disturbance in the bipolar configuration. Other PMs experienced minor disturbances or none at all. [6]

If a person's PM initiates a safety function, he/she needs to consult a physician who can program the PM back to the normal situation.

Because the magnetic field (max 2.9 μT) was so low and near 400 kV power lines and we did not get any disturbances to PMs at the 400 kV substation, it is possible that the electric field under a 400 kV power line could disturb a PM when the electric field is 6.7–7.5 kV/m. This electric field level is below low ALs (10kV/m, according to Directive 2013/35/EU) [5,6].

DISCUSSION

In earlier studies [9–13], researchers found that some older PM models have shown to be susceptible to the electromagnetic fields (EMF) emitted by everyday household and workplace appliances. Tiikkaja et al. [14] studied 11 volunteers with PMs and the possible interference when exposed to sine, pulse, ramp, and square waveform magnetic fields (varied to 300 μT) with frequencies of 2–200 Hz, generated using the Helmholtz coil. They also used an induction cooktop and a metal inert gas (MIG) welding machine to produce exposure. They found that three PMs with unipolar settings were affected by the highest fields of the Helmholtz coil and one of them also by the welding cable. They did not find any interference with any of the unipolar PMs when using the induction cooktop.

EMF interference with PMs and ICDs has also been studied in France [13,15,16]. For the 50 Hz magnetic field, PM tests showed no interference under 50 μT, in unipolar mode, or under 100 μT, in bipolar mode [15]. For ICDs, in vitro tests revealed no interference until 3,000 μT, but only four devices were tested [16].

Moreover, the European Committee for Electrotechnical Standardization (CENELEC) has also published some standards in this area [17,18]. For example, according to the European Norm 50527-1, magnetic flux density of 100 μT is considered to be the 'safety level' for PMs.

In earlier studies at TUT, the electric and magnetic fields were measured at 400 kV and 110 kV substations [19,20]. In one 400 kV substation, magnetic flux density over 500 μT was measured at the safety fence around a three-phase air-core reactor set [19]. In the other study of 110 kV substations, the average values of all measured magnetic fields was 28.6 μT, and in one special work task close to shunt reactor cables (20 kV), the highest magnetic field was 710 μT [20].

Electrical workers could possibly find the highest magnetic field exposures near the reactors at 400 kV substations. The magnetic fields are typically lower than 100 μT at 110 kV substations or near 400 kV (or less) power lines. Therefore, it is not possible to find such high magnetic fields that the exposure could influence the PMs in those working areas. For electrical workers with PMs, the risk of disturbances caused by magnetic fields is not considered to be high.

CONCLUSION

In the future, it is important to further analyze the possible interference with AIDMs, including PMs, ICDs and drug pumps, based on 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).

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