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CLINICAL RESEARCH

Safety of smartwatches and their chargers in patients with cardiac implantable electronic devices

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Aims Cardiac implantable electronic devices (CIEDs) are susceptible to electromagnetic interference (EMI). Smartwatches and their chargers could be a possible source of EMI. We sought to assess whether the latest generation smartwatches and their chargers interfere with proper CIED function.

Methods and results We included consecutive CIED recipients in two centres. We tested two latest generation smartwatches (Apple Watch and Samsung Galaxy Watch) and their charging cables for potential EMI. The testing was performed under continuous electrocardiogram recording and real-time device telemetry, with nominal and 'worst-case' settings. *In vitro* magnetic field measurements were performed to assess the emissions from the tested devices, initially in contact with the probe and then at a distance of 10 cm and 20 cm. In total, 171 patients with CIEDs (71.3% pacemakers–28.7% implantable cardioverter-defibrillators) from five manufacturers were enrolled (63.2% males, 74.8 ± 11.4 years), resulting in 684 EMI tests. No EMI was identified in any patient either under nominal or 'worst-case scenario' programming. The peak magnetic flux density emitted by the smartwatches was similar to the background noise level (0.81 μT) even when in contact with the measuring probe. The respective values for the chargers were 4.696 μT and 4.299 μT for the Samsung and Apple chargers, respectively, which fell at the background noise level when placed at 20 cm and 10 cm, respectively.

Conclusion Two latest generation smartwatches and their chargers resulted in no EMI in CIED recipients. The absence of EMI in conjunction with the extremely low intensity of magnetic fields emitted by these devices support the safety of their use by CIED patients.

Keywords Electromagnetic interference • Smartwatch • Cardiac implantable electronic device

Introduction

Cardiac implantable electronic devices (CIEDs), including pacemakers (PM), implantable cardioverter-defibrillators (ICDs), cardiac resynchronization therapy pacemakers (CRT-Ps), and defibrillators (CRT-Ds) are increasingly used worldwide for treatment of bradyarrhythmias, heart failure, and prevention of sudden cardiac death.[1] Diverse sources of electromagnetic fields either in working environments or daily life can adversely affect the proper function of CIEDs resulting in electromagnetic interference (EMI).[2–4]

Smartwatches are multifunctional wearables that have gained popularity in the last years. These devices could be a possible source of EMI partly due to their inductive charging functionality using wireless power transfer over distances of up to 4 cm (Qi™), exploiting the magnetic field produced by the chargers in the frequency range between 110 kHz and 400 kHz.[5] This safety issue is also commented in

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What's new?

- The use of two latest smartwatches and their chargers did not result in any type of electromagnetic interference in any patient with cardiac implantable electronic device (CIED), under either nominal or 'worst-case scenario' programming.
- The intensity of magnetic fields emitted by the tested smartwatches and their chargers was extremely low.
- The study findings support the safety of smartwatch use by CIED patients.

the respective user guide, where it is stated that smartwatches as well as their chargers contain magnetic components that emit electromagnetic fields and could interfere with PMs or defibrillators. Furthermore, the user guide recommends the maintenance of a safety distance of separation between the smartwatch or charger and the CIED, without further details.

Therefore, there is a knowledge gap regarding the safety of smartwatch use among CIED recipients, while the minimum safety separation distance between smartwatch/charger and CIED has not been defined. In this prospective, multicentre study, we sought to assess whether the use of the latest generation smartwatches and their chargers may interfere with the proper function of CIED.

Methods

In vivo study

We included CIED recipients who presented for routine follow-up in two centres (Mitera General Hospital and Evangelismos General Hospital, Athens, Greece) from March 2019 to November 2019. In total, 214 patients were screened for eligibility. Among them 38 refused to participate, while 5 met the exclusion criteria (i) atrial or ventricular sensing defects not amenable by device reprogramming, (ii) battery longevity less than 3 months, or (iii) intrinsic heart rate > 120 b.p.m., resulting in a sample population of 171 patients. All enrolled patients signed an informed consent form indicating that they had been informed of all aspects of the study and had given consent for their participation. The study was approved by the ethics committee of the participating hospitals. The principles outlined in the Declaration of Helsinki were followed in the study.[6]

We tested for potential EMI two latest generation smartwatches (Apple Watch Series 3 and Samsung Galaxy Watch 42 mm). The magnetic chargers of these smartwatches were also tested.

All patients were examined in a supine position. Initially, a typical evaluation of CIED function was performed (measurement of the battery voltage, pacing threshold, impedance, and sensing values). All initially programmed parameters were recorded for subsequent comparison at the end of the testing protocol to rule out potential device reprogramming.

The following programming of device settings parameters was performed during EMI testing:

Pacemakers

Permanent ventricular pacing was ensured during testing by (i) increasing the basic pacing rate in single-chamber devices above the intrinsic heart rate and (ii) shortening the atrioventricular delay in dual-chamber devices to achieve continuous pacing without fusion or pseudofusion. In all PM recipients, the EMI testing was initially performed under nominal settings (nominal sensitivity and bipolar sensing) and subsequently under 'worst-case scenario' settings (maximal sensitivity and unipolar sensing).

Implantable cardioverter-defibrillators

Antibradycardia parameters were programmed as described for PMs. Furthermore, the tachyarrhythmia detection rate was set as low as possible, and antitachycardia therapies were inactivated to prevent inappropriate therapy delivery.

Following the above mentioned CIED temporary programming and under continuous electrocardiogram (ECG) recording, each of the two smartwatches and the two magnetic charging cables were swiped over the device and along the anticipated course of the leads for a total duration of 20 s. The testing was performed during real-time device telemetry for continuous recording of intracardiac electrograms. Marker channels were monitored continuously to detect either subtle signal noise or oversensing.

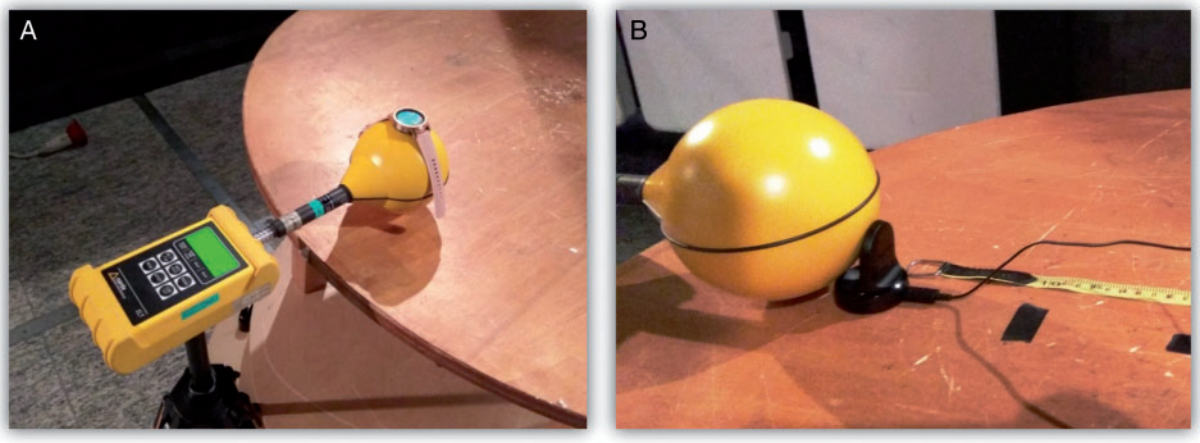

Figure 1 Measurement of low-frequency magnetic field emitted by watch (*A*) and charger (*B*) at 0 cm.

The ECG recording was checked meticulously for the presence of any of the following manifestations: (i) inhibition of atrial or ventricular pacing (atrial or ventricular oversensing), (ii) asynchronous ventricular pacing (mode switch due to atrial oversensing), (iii) rapid ventricular pacing (inappropriate tracking due to atrial oversensing in case of disabled mode switch), or (iv) asynchronous pacing. Subsequently, the device was interrogated to rule out inappropriate tachycardia detection.

Following the completion of each testing, device settings were compared with initially programmed parameters to rule out device reprogramming.

The same test protocol was repeated for each smartwatch and each of the magnetic chargers (not connected to DC power), resulting in four EMI tests in total for each enrolled patient.

Magnetic field measurement

Low-frequency magnetic field measurements were performed to assess the emissions from the tested smartwatches and their magnetic chargers at a frequency range of 110–400 kHz. All measurements were performed inside a semi-anechoic chamber (Lindgren Rayproof S81) to minimize potential external interference (*Figure 1*). The magnetic flux density, B (μT), emitted from the device under test was recorded using the ELT-400 metre (Narda Safety Test Solutions GmbH, Germany) (*Figure 1*). A B-field probe with three orthogonal coils, total sensing area of 100 cm^2, and sensing frequency range between 1 Hz and 400 kHz with flat response was used. The measurement frequency range was selected from 30 Hz up to 400 kHz in order to further reject the background noise (low cut function). The instrument's sensitivity was 0.230 μT (noise floor) and the expanded measurement uncertainty ± 24% for a 95% confidence interval. The detector was set to measure both the root mean square (RMS) and the peak value of the magnetic field. During testing, the field metre with the isotropic probe was mounted on a wooden table and max-hold recordings were time-averaged for a 6-min period (*Figure 1*).[7]

Initially, all devices were deactivated and the background noise inside the chamber was recorded, which is directly related to the sensitivity of the field metre (instrument's minimum detectable magnetic field capability). Then, the smartwatches were activated and measured independently, initially in direct contact with the probe (worst-case scenario—distance 0 cm) and then at a distance of 10 cm and 20 cm (*Figure 1*). The same measurements were performed using the chargers of the tested smartwatches (0–10–20 cm distance from the isotropic probe) (*Figure 1*). Finally, emitted magnetic field values were measured with each watch attached to its charger at a distance of 0 cm, 10 cm, and 20 cm from the isotropic probe.

Results

Interference during *in vivo* testing

We enrolled 171 patients (63.2% males, mean age 74.8 ± 11.4 years), thus resulting in a total of 684 EMI tests in our cohort. The distribution of CIED types, from five manufacturers in total, was as follows: single-chamber PM 25, dual-chamber PM 94, single-chamber ICD 8, dual-chamber ICD 33, CRT-P 3, and CRT-D 8. Among CIED recipients, 55 (32.2%) were PM dependent, as evidenced by the absence of intrinsic ventricular rhythm after temporary programming to VVI30. The indication of device implantations and baseline parameters are presented in *Table 1*.

The testing protocol with both smartwatches and magnetic chargers resulted in no ECG manifestations suggestive of EMI, no detection of oversensing on device telemetry showing electrograms and marker channels, and no device reprogramming following completion of testing. No type of EMI was identified either during testing with nominal programmed parameters or during worst-case scenario settings (maximum sensitivity and unipolar sensing mode where applicable).

Table 1 Device parameters and indications

Pacemaker, *n* (%)	122 (71.3)
Sinus-node dysfunction, *n* (%)	53 (31.0)
Atrioventricular node dysfunction, *n* (%)	66 (38.6)
Heart failure, *n* (%)	3 (1.8)
P wave, mean (SD) (mV)	3.7 (1.7)
R wave, mean (SD) (mV)	12.8 (4.7)
Atrial impedance, mean (SD) (Ω)	585.8 (163.0)
Ventricular impedance, mean (SD) (Ω)	584.5 (134.2)
Atrial threshold, mean (SD) (V/0.5 ms)	0.63 (0.49)
Right ventricular threshold, mean (SD) (V/0.5 ms)	0.67 (0.57)
Left ventricular threshold, mean (SD) (V/0.5 ms)	0.63 (0.18)
ICD, *n* (%)	49 (28.7)
Primary prevention, *n* (%)	41 (24.0)
Secondary prevention, *n* (%)	8 (4.7)
P wave, mean (SD) (mV)	4.7 (1.9)
R wave, mean (SD) (mV)	16.6 (6.4)
Atrial impedance, mean (SD) (Ω)	535.2 (129.1)
Ventricular impedance, mean (SD) (Ω)	579.4 (179.3)
Atrial threshold, mean (SD) (V/0.5 ms)	0.64 (0.23)
Right ventricular threshold, mean (SD) (V/0.5 ms)	0.69 (0.4)
Left ventricular threshold, mean (SD) (V/0.5 ms)	0.9 (0.14)

ICD, implantable cardioverter-defibrillator; SD, standard deviation.

Magnetic field measurements

The values of magnetic flux density emitted by the device under testing (DUT) in different tested scenarios are presented in *Table 2*. The background noise values (RMS value 0.23 μT and peak value 0.81μT) correspond to the instrument's noise floor.

During testing of smartwatches, the recorded density of the emitted magnetic field was very similar to the background noise (both RMS and peak recordings) even when the watches were placed in contact with the probe (*Table 2, Figure 2*). When the smartwatches were moved away from the probe (at a distance of 10 cm and 20 cm), the magnetic field was reduced to the background noise level.

When the chargers were measured independently at 0, 10, and 20 cm away from the isotropic probe, the highest values of magnetic flux density were recorded when placed in contact with the probe (0 cm distance). The peak values were 4.696 ± 1.127 μT and 4.299 ± 1.032 μT for the Samsung and Apple chargers, respectively (*Table 2, Figure 2*). The recorded peak magnetic field emitted from the Samsung charger significantly decreased to a value of 1.007 ± 0.241 μT when placed at a distance of 10 cm from the probe and fell at the noise floor level when tested 20 cm away from the probe. The recorded peak magnetic flux density from the Apple

Table 2 Values of magnetic flux density recordings for the two smartwatches and chargers in different measurement scenarios

Brand	Measurement test	Distance[a] (cm)	Magnetic flux density, B (μT)	
			RMS	Peak
	Background noise	**–**	**0.230**	**0.810**
Samsung	Watch (only)	0	0.234	0.872
		10	0.231	0.810
		20	0.231	0.810
	Charger (only)	0	1.217	4.696
		10	0.251	1.007
		20	0.231	0.810
	Charger and watch	0	0.328	1.036
		10	0.231	0.810
		20	0.231	0.810
Apple	Watch (only)	0	0.235	0.913
		10	0.231	0.810
		20	0.231	0.810
	Charger (only)	0	0.350	4.299
		10	0.231	0.810
		20	0.231	0.810
	Charger and watch	0	0.230	0.846
		10	0.230	0.810
		20	0.230	0.810

[a]The distance of 0 cm refers to probe placed in contact with the device under testing.
RMS, root mean square.

charger fell within the noise floor even at the shorter distance of 10 cm (*Table 1*).

When the watches were tested while attached to their chargers, the emitted magnetic field was reduced compared with the charger-only scenario. In the case of the Apple watch, the recorded magnetic field was decreased to the noise floor level. On the other hand, the Samsung watch attached to its charger emitted a magnetic field level above the noise floor level when placed in contact with the probe (distance 0 cm), which was though reduced to the background noise level at a distance of 10 cm and beyond (*Table 1*).

Discussion

To our knowledge, this is the first study evaluating the occurrence of EMI by smartwatches and their magnetic chargers in CIED recipients. Our main finding is that no type of EMI was recorded in any patient, even when programming 'worst-case scenario' settings (maximum sensitivity and unipolar sensing mode where applicable), which are practically never encountered in everyday clinical practice.

Previous studies have reported a negligible risk of EMI in CIEDs when exposed to different types of devices including modern smartphones,[4,8] novel security screening body scanners,[9] electric cars,[10] and hand-held metal detectors.[3] On the other hand, Lee *et al.* reported a 30% risk of clinically significant magnetic interference of implanted cardiac devices when using portable headphones in close proximity, advising a minimum safety distance of 3 cm.[11] Furthermore, induction oven has been reported to induce EMI in close proximity.[12] The diversity of the reported findings reflects differences in type and programmed parameters of tested CIEDs as well as in exposure settings (e.g. strength of the emitted magnetic field, the distance between EMI source and CIED). In our cohort, we found no EMI, despite the use of a strict exposure protocol (20 s duration), also including a worst-case scenario with settings that render the CIED extremely vulnerable to EMI. Our negative findings are even more reassuring for patients' safety, if we take into consideration that in everyday life, smartwatches are fixed to the wrist, which by essence augments their distance from the implanted CIED located in the upper chest.

In our study, we also measured the magnetic flux density emitted by the tested devices in different exposure settings. This type of testing is recommended in EMI studies in order to render reported results applicable to different exposure scenarios, including new technologies.[13] Our measurements were performed in a semi-anechoic chamber and different distances were tested, including a worst-case scenario with direct contact of the device under testing with the B-field probe. Based on our results, the main source of magnetic field emissions is the charger rather than the watch itself. Both watches practically emitted a non-detectable magnetic field (similar to noise floor level) even when placed in direct contact with the probe. The peak magnetic flux density of the chargers was about 4–5 μT when placed in direct contact with the B-field probe. These values fell within the noise floor level (non-detectable) at a distance of 10 cm for the Apple charger and 20 cm for the Samsung charger. In order to ascertain the relative magnitude of the reported magnetic flux density values, commonly used electrical household devices have been reported to emit magnetic fields of at least 1000 times higher intensity, e.g., hand mixer 3182 mT at its surface, the washing machine 338 mT at its surface, and hair dryers up to 2000 mT at 3 cm and 7 mT at a distance of 30 cm.[14,15]

The International Commission of Non-Ionizing Radiation Protection (ICNIRP) has proposed a limit level of 27 μT for general public exposure to time-varying electric and magnetic fields in the frequency range of 3 kHz–10 MHz.[16] However, these values pertain to the general public and cannot be extrapolated to the CIED patient population when considering the specific risk of EMI. Specific limit values of magnetic field density or strength to prevent potential EMI among CIED recipients have not been defined. In our study though, the absence of detected EMI when smartwatches and chargers were placed in direct contact to the patient, even under 'worst-case' programmed settings, is suggestive that the measured magnetic flux values are not associated with EMI occurrence and thus can be considered safe. It should also be taken into account that both smartwatches emitted a magnetic flux density comparable to the noise level even when placed in direct contact, further supporting that their use by CIED recipients should not raise safety concerns.

Limitations

The main limitations of our study are the small number of enrolled patients and the limited number of device models tested. However, we aimed to overcome this caveat by performing multiple tests, even under 'worst-case' scenario setting, as well as by providing absolute

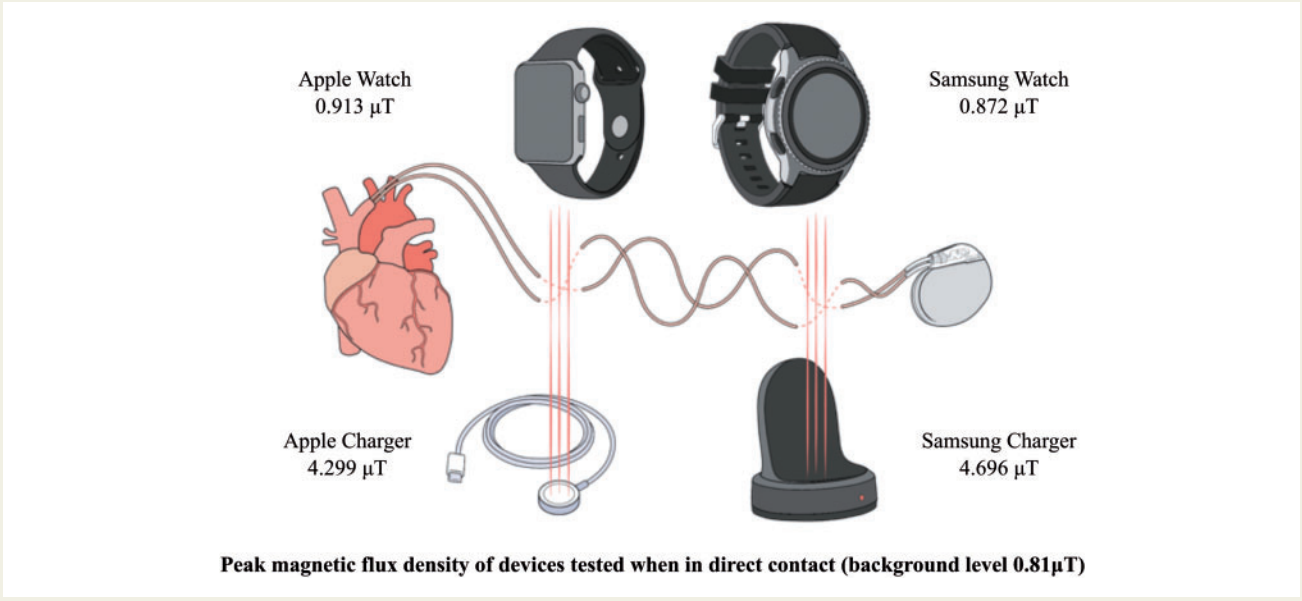

Figure 2 Peak magnetic flux density of devices tested (smartwatches and magnetic chargers) when in direct contact with the probe metre.

measurements of the magnetic field intensity emitted by the tested smartwatches and chargers. We also tested for potential EMI two latest generation smartwatches manufactured by the two companies with the two largest shares of the global smartwatch market. Therefore, several types of smartwatches are not represented, which could theoretically influence the external validity of our results.

Conclusions

Two latest generation smartwatches and their chargers resulted in no EMI when tested in a cohort of CIED recipients. The absence of EMI in conjunction with the extremely low intensity of the magnetic field emitted by these devices support the safety of smartwatch use by patients with CIEDs.

Conflict of interest: none declared.

References

1. Timmis A, Townsend N, Gale CP, Torbica A, Lettino M, Petersen SE; European Society of Cardiology *et al.* European Society of Cardiology: cardiovascular disease statistics 2019. *Eur Heart J* 2020;**41**:12–85.
2. Tiikkaja M, Aro AL, Alanko T, Lindholm H, Sistonen H, Hartikainen JEK *et al.* Electromagnetic interference with cardiac pacemakers and implantable cardioverter-defibrillators from low-frequency electromagnetic fields in vivo. *Europace* 2013;**15**:388–94.
3. Jilek C, Tzeis S, Vrazic H, Semmler V, Andrikopoulos G, Reents T *et al.* Safety of screening procedures with hand-held metal detectors among patients with implanted cardiac rhythm devices: a cross-sectional analysis. *Ann Intern Med* 2011;**155**:587–92.
4. Lennerz C, Pavaci H, Grebmer C, Semmler V, Bourier F, Haller B *et al.* Electromagnetic interference in cardiac implantable electronic devices: is the use of smartphones safe? *J Am Coll Cardiol* 2017;**69**:108–10.
5. Liu X. Qi standard wireless power transfer technology development toward spatial freedom. *IEEE Circuits Syst Mag* 2015;**15**:32–9.
6. World Medical Association. World Medical Association Declaration of Helsinki: ethical principles for medical research involving human subjects. *JAMA* 2013;**310**:2191–4.
7. International Commission on Non-Ionizing Radiation Protection. Guidelines for limiting exposure to time-varying electric, magnetic, and electromagnetic fields (up to 300 GHz). *Health Phys* 1998;**74**:494–522.
8. Burri H, Mondouagne Engkolo LP, Dayal N, Etemadi A, Makhlouf AM, Stettler C *et al.* Low risk of electromagnetic interference between smartphones and contemporary implantable cardioverter defibrillators. *Europace* 2016;**18**:726–31.
9. Lennerz C, O'Connor MJ, Blažek P, Weigand S, Grebmer C, Reif S *et al.* Modern security screening and electromagnetic interference with cardiac implantable electronic devices. *J Am Coll Cardiol* 2020;**75**:1238–9.
10. Lennerz C, O'Connor M, Horlbeck L, Michel J, Weigand S, Grebmer C *et al.* Electric cars and electromagnetic interference with cardiac implantable electronic devices: a cross-sectional evaluation. *Ann Intern Med* 2018;**169**:350–2.
11. Lee S, Fu K, Kohno T, Ransford B, Maisel WH. Clinically significant magnetic interference of implanted cardiac devices by portable headphones. *Heart Rhythm* 2009;**6**:1432–6.
12. Binggeli C, Rickli H, Ammann P, Brunckhorst C, Hufschmid U, Luechinger R *et al.* Induction ovens and electromagnetic interference: what is the risk for patients with implantable cardioverter defibrillators? *J Cardiovasc Electrophysiol* 2005;**16**:399–401.
13. Driessen S, Napp A, Schmiedchen K, Kraus T, Stunder D. Electromagnetic interference in cardiac electronic implants caused by novel electrical appliances emitting electromagnetic fields in the intermediate frequency range: a systematic review. *Europace* 2019;**21**:219–29.
14. Leitgeb N, Cech R, Schröttner J, Lehofer P, Schmidpeter U, Rampetsreiter M. Magnetic emission ranking of electrical appliances. A comprehensive market survey. *Radiat Prot Dosimetry* 2007;**129**:439–45.
15. Napp A, Stunder D, Maytin M, Kraus T, Marx N, Driessen S. Are patients with cardiac implants protected against electromagnetic interference in daily life and occupational environment? *Eur Heart J* 2015;**36**:1798–804.
16. International Commission on Non-Ionizing Radiation Protection. Guidelines for limiting exposure to time-varying electric and magnetic fields (1 Hz to 100 kHz). *Health Phys* 2010;**99**:818–36.