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Effects of hearing aid programming equipment and assistive listening devices on implantable cardiac devices

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EFFECTS OF HEARING AID PROGRAMMING EQUIPMENT AND ASSISTIVE LISTENING DEVICES ON IMPLANTABLE CARDIAC DEVICES

by

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Abstract: *This study examines the potential for electromagnetic interference from the use of neck-worn hearing aid programming equipment and assistive listening devices to affect cardiac pacemakers and defibrillators.*

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ABBREVIATIONS

A/m: Amps Per Meter

AICD: Automatic Implantable Cardioverter Defibrillator

ALD: Assistive Listening Device

dBμA/m: Decibel Micro-Amps Per Meter

ECG: Electrocardiogram

EMI: Electromagnetic Interference

HA: Hearing Aid Programing Equipment

mV: Millivolts

mW: Milliwatts

INTRODUCTION

There is controversy among audiologists regarding the safety of the use of hearing aid programming equipment and assistive listening devices (HA/ALDs) in patients with implantable cardiac devices (Huch & Martin, 2014). ALDs are used in conjunction with hearing aids to allow those with hearing impairment to wirelessly access acoustic output from commonly used devices, such as a television, mobile phone, or microphone, with significantly reduced background noise. HA/ALDs are typically worn around the neck, in close proximity to the heart, as depicted in Figure 1. HA/ALD product materials list varying levels of warnings for the use of these devices concomitantly with cardiac devices (Huch & Martin, 2014; Phonak, 2014; Widex, 2011). In the absence of published data, the safety of simultaneous use of HA/ALDs with cardiac devices remains unclear. This matter is especially urgent due to the growing number of cardiac device users who may also benefit from hearing aids. Nearly 66% of adults 70 years of age and older in the United States have hearing loss (Lin, Thorpe, Gordon-Salant, & Ferrucci, 2011) and approximately 70% of patients implanted with cardiac devices are 65 years of age or older (Zhan, Baine, Sedrakyan, & Steiner, 2008), indicating that a significant population of patients would benefit from both devices.

Implanted cardiac devices include both pacemakers and automatic implantable cardiac defibrillators (AICDs). Cardiac pacemakers are designed to sense normal cardiac activity, and in the absence of normal activity, deliver a pacing stimulus to maintain a normal heart rate. AICDs are designed to sense malignant arrhythmias and deliver a high-voltage shock to terminate the arrhythmias. In order to reliably detect both native cardiac activity and malignant arrhythmias, cardiac devices must detect signals as small as 0.3 mV with a frequency content up to several hundred Hz (ANSI/AAMI, 2007). Non-cardiac electrical signals, if misinterpreted by the device

as cardiac signals, can result in failure to deliver appropriate therapies, including failure to pace when needed, rapid pacing or asynchronous pacing, and failure to deliver a shock when needed, among other effects (ANSI/AAMI, 2007). In general, standards for devices which emit electromagnetic interference (EMI), including Federal Communications Commission (FCC) standards, are concerned with biological safety and not with potential interference from other devices. Standards are voluntary unless mandated by government regulations and are directed to device manufacturers, not healthcare providers or device users (ANSI/AAMI, 2007).

Limited research has been published on the effects of HA/ALDs on cardiac devices. One study examined the effects of a hearing aid programming necklace on a pacemaker, as seen on the electrocardiogram (ECG) (Baranchuk, Kang, Shaw, & Witjes, 2008). This case study focused on interference that occurred as a result of the hearing aid programming necklace making contact with the ECG electrodes, an observation of limited utility as any type of contact with or manipulation of ECG electrodes may result in temporary artifact on the ECG. They did note that no permanent changes occurred in the programming of the single pacemaker being observed.

The objective of this research is to provide information to audiologists and other professionals about the electronic operation parameters of cardiac devices and HA/ALDs. These devices are used daily by specialists in healthcare settings as well as by patients in various other environments. The potential for interference lies in the operation overlap of these devices. This overlap will be examined to determine the likelihood and consequences of interference, using a review of device standards, technical specifications, and empirical testing.

METHODS

Technical Specifications Review

Device technical specifications were reviewed to estimate magnetic field strength

amplitude and potential frequency bandwidth overlap between HA/ALDs and cardiac devices, as

summarized in Table 1. Specifications for the Widex M-DEX, TV-DEX, USBlink, and the

Phonak iCube II, and ComPilot documented a measured magnetic field strength (in dBµA/m) at

a distance of 10 meters, a standard distance for this measurement. These values were converted

to A/m in order to compare to cardiac device standards and scaled to determine field strength at a

distance of 5 cm. This allowed the investigators to estimate HA/ALD output at a distance similar

to actual use (i.e., in close proximity to the chest). The following equation, derived in Appendix

B, was used for these calculations:

$$\text{Magnetic field strength of HA/ALD} = \left(10^{(x/20)} * (1 * 10^{(-6)})\right) * \left(r_1/r_2\right)$$

x: dBµA/m; r_1: distance at which magnetic field density is desired;
r_2: distance at which field strength was measured as reported on data sheet

The Phonak Inspiro, Roger Pen, and RemoteMic technical specifications did not list a

measured field strength. Instead, radio frequency power was listed. This measure was assumed to

be equal to Effective Radiated Power (ERP) for the purposes of this study and is the power

emitted by the device. ERP was used to calculated power density at a distance of 5 cm, which

was then used to calculate magnetic field strength in A/m in order to compare with the other

HA/ALDs in this study. The following equation, derived in Appendix A, was used:

$$\text{Magnetic Field Strength of HA/ALD} = \frac{1}{r}\frac{\sqrt{\frac{ERP * \mu_0}{4\pi c}}}{\mu_0}$$

$4\pi r^2$: surface area of a sphere; c: speed of light; μ_0: magnetic permeability of free space

Empirical Testing

Empirical testing was performed using the following explanted Medtronic cardiac devices: Consulta CRT-D (pacemaker defibrillator), Adapta L (pacemaker), and Advisa DR (MRI-compatible pacemaker).These devices had been explanted for reasons not related to device malfunction. Cardiac devices and their programming equipment were acquired from Medtronic, Inc. and the Cardiovascular Division at Barnes-Jewish Hospital. HA/ALDs were borrowed from the Adult Audiology Division at the Center for Advanced Medicine. All devices exhibited normal function.

Testing was conducted in the clinical electrophysiology laboratory at Barnes-Jewish Hospital. To generate a cardiac signal for device detection, the devices and lead were taped to the chest of a volunteer and conductive gel used to ensure good electrical contact; the device sensed native cardiac activity in this configuration. To increase the likelihood of interference, a unipolar lead configuration was used and device sensitivity thresholds were decreased to 0.3 mV on each cardiac device. Communication with the cardiac devices was established using the manufacturer specific programmer (Medtronic) and the device response to EMI was continuously monitored. HA/ALDs were arranged in two ways: hearing aids were worn on the ears bilaterally with ALDs and programming necklaces positioned at a distance similar to typical usage (i.e., around the neck, clipped to the volunteer's shirt) or directly on top of the cardiac device. Configurations are depicted in Figure 1.

HA/ALD activity was generated through standard usage and programming. To test for potential interference during hearing aid programming, the Widex USBlink programmer was positioned around the volunteer's neck. The Widex Dream 9 BTE hearing aids were placed on the volunteer's ears and connected to the NOAH programming software wirelessly via the

USBlink. Intensity was increased/decreased, programs were added/removed, and a feedback test was attempted via the programming software. It should be noted that a complete feedback test was not performed due to excessive noise in the environment. This procedure was repeated in an identical manner using the Phonak iCube II Programmer and Bolero Q90P BTE hearing aids. Tests were conducted with ALDs both in the typical position as well as deliberately positioned atop the cardiac device to maximize potential interference.

To test for EMI from hearing aid-specific ALDs during standard usage, cardiac devices, hearing aids, and ALDs were worn by a volunteer. Audio was streamed via Bluetooth® (2.4 GHz) from a cell phone (Motorola Moto X) to the ComPilot and TV-DEX, which were connected to the appropriate hearing aids via a 10.6 MHz wireless connection. The RemoteMic, Inspiro, and M-DEX were tested in a similar manner. The investigators stood at a distance and spoke into the microphones of the aforementioned ALDs which were wirelessly connected to their hearing aid counterparts. Volume was manipulated by the volunteer.

Manufacturer-specific (Medtronic) cardiac device programmers were used to monitor cardiac activity, detect HA/ALD activity, and detect any resultant cardiac device programming or behavioral changes. These changes include inhibition of pacing or inappropriate anti-tachycardia therapy. The Medtronic Consulta CRT-D and Adapta L were connected to the programmer wirelessly. The Medtronic Advisa DR was connected via a programming magnet placed over the device. It should be noted that worst case scenario configuration was slightly altered during Advisa DR testing to avoid the programming wand (i.e., hearing aids were positioned on the chest, slightly farther away from the cardiac device). Cardiac device activity was observed via electrogram tracings that were printed from cardiac device programmers in real time.

RESULTS

Technical Specification Review

Cardiac devices are engineered to avoid interference by non-cardiac signals and devices are tested extensively in accordance with published standards (ANSI/AAMI, 2007). Devices which meet these standards are expected to be largely resistant to electromagnetic interference outside of the frequency range required for normal sensing and operation. These standards are summarized in Figure 3, which illustrates the ranges of frequency and field strength which are predicted to have little or no impact on device function (zone 2 in Figure 3). To determine whether EMI emitted by ALDs is likely to affect cardiac device performance, we reviewed the published technical specifications for assistive listening devices and calculated the predicted field strength and frequency (as described above). Estimated magnetic field strengths at a distance of 5 cm are summarized in Table 1 and plotted on Figure 3. The majority of HA/ALDs field strength amplitudes are well below the threshold for anticipated device interaction. All HA/ALDs, including those with field strength amplitudes above the threshold for interference, operate at a higher frequency than those predicted to affect cardiac devices. Notably, the strongest HA/ALD output is ten times weaker than that of a cell phone at the same distance (FCC, n.d.).

Empirical Testing

To further evidence the lack of interaction between ALDs and cardiac devices, representative devices manufactured by Medtronic, Inc. were tested as described in Methods. During empiric testing of a representative cardiac pacemaker, defibrillator, and MRI-compatible defibrillator, no HA/ALD activity was detected by the cardiac devices regardless of device configuration or manipulation. Figure 2 shows a representative tracing of the sensed cardiac

signal during ALD usage; EMI from the ALD usage remained undetectable. No changes in device activity, including pacing or arrhythmia detection occurred during exposure to EMI from ALD usage.

The Medtronic Adapta L (pacemaker) was not tested with Phonak products (see Table 1) due to an inexplicable change in electrogram morphology during ComPilot testing. The ComPilot was turned off and the pacemaker ports were cleaned. Abnormal electrogram morphology remained despite cessation of testing. Further investigation with this pacemaker was discontinued as the source of interference could not be determined.

DISCUSSION

As medical device usage becomes more widespread, consideration must be given to potential interactions between devices. Regulatory statues for devices which emit electromagnetic energy are confined to avoiding direct biological effects and do not encompass impact on other devices (ANSI/AAMI, 2007). This study examined the potential interaction between two of the most commonly used devices: implanted cardiac devices (pacemakers and defibrillators) and assistive listening devices.

To an even greater degree than ALDs, cell phones are ubiquitous devices for which EMI with cardiac devices has also been debated for some time. Burri et al (2016) examined the effects of modern 4G cell phones on patients with AICDs. Cardiac devices were tested with therapies deactivated to ensure patient safety (i.e., AICDs would not deliver a shock if EMI was misinterpreted as an arrhythmia). Testing was completed in low cellular network areas to increase the likelihood of interference, as emissions are increased when cell phones are searching for a better signal. They reported that no interference was observed on electrogram tracings during testing. They also noted that current cell phone technology and improvements in cardiac

device shielding allow for almost negligible EMI. These findings support the current study and the same assumption of low EMI risk can be extended to HA/ALDs.

Although cardiac devices are heavily engineered for resistance to inference by environmental EMI, EMI interactions are extremely complex. Potential for interaction depends on the frequency content of emitter, modulation format, power of signal, proximity to patient, coupling factors, and duration of exposure making it nearly impossible to exclude every potential scenario in which interaction can occur (ANSI/AAMI, 2007). However, based on device engineering, the general ranges of frequency and electromagentic field strength against which cardiac devices are expected to be resistant can be estimated. As shown here, published details of the frequency and emitted field of HA/ALDs indicate that HA/ALD-emitted EMI is extremely unlikely to impact cardiac device function. This conclusion is further strengthened by limited empiric testing which demonstrated a failure of representative cardiac devices to even detect, much less be affected by, the HA/ALD-emitted EMI.

LIMITATIONS

The wide variety of both cardiac devices and HA/ALDs, in addition to the complexity of electromagnetic field propagation and interaction, makes it essentially impossible to exclude any possible interaction. In addition, simplifying assumptions regarding the electromagnetic field emitted by HA/ALDs was required to estimate field strengths and allow direct comparisons between devices.

CONCLUSION

Due to the complexity of EMI, variations in individual anatomy, the large number of different implantable cardiac devices, and the large number of different HA/ALDs, it is impossible to definitively rule out the possibility of EMI. However, HA/ALDs operate with a

power output and in a frequency range which is extremely unlikely to cause significant

interference with cardiac devices. Empiric *ex vivo* testing of select devices confirmed that the

cardiac devices failed to sense HA/ALD-generated signals. Although specific cases of potential

interaction require assessment by a cardiologist or manufacturer representative, HA/ALDs can

most likely be used by patients with implanted cardiac devices without concern.

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| Manufacturer	Device Name	Function	Operation Frequency	Field Strength (dBμA/m)	Effective Radiated Power (mW)	Field Strength (A/m at 5 cm)
Phonak	Bolero Q90P BTE	hearing aid				
	iCube II	programming necklace	10.6 MHz, 2.4 GHz	-21		1.78e-5
	ComPilot	multimedia audio streamer	10.6 MHz, 2.4 GHz	-34, -11.5		3.99e-6, 5.32e-5
	RemoteMic	wireless microphone	2.4 GHz		10	2.90e-2
	Inspiro	dynamic FM transmitter	169 - 176 MHz, 214 - 220 MHz		2, 100	1.30e-1, 9.19e-2
	Roger Pen*	dynamic transmitter	2.4 GHz		25	4.56e-2
Widex	Dream 9 BTE	hearing aid				
	USBlink	programming necklace	10.6 MHz, 2.4 GHz	-12		5.02e-5
	M-DEX	wireless microphone	10.6 MHz, 2.4 GHz	-11		5.64e-5
	TV-DEX	TV streamer	10.6 MHz, 2.4 GHz	-9		3.55e-7
	Mobile Phone*		800 MHz - 2.4 GHz		7 watts	7.69e-1

Table 1. Summary of device technical specifications. *Devices not empirically tested - listed for comparison only.
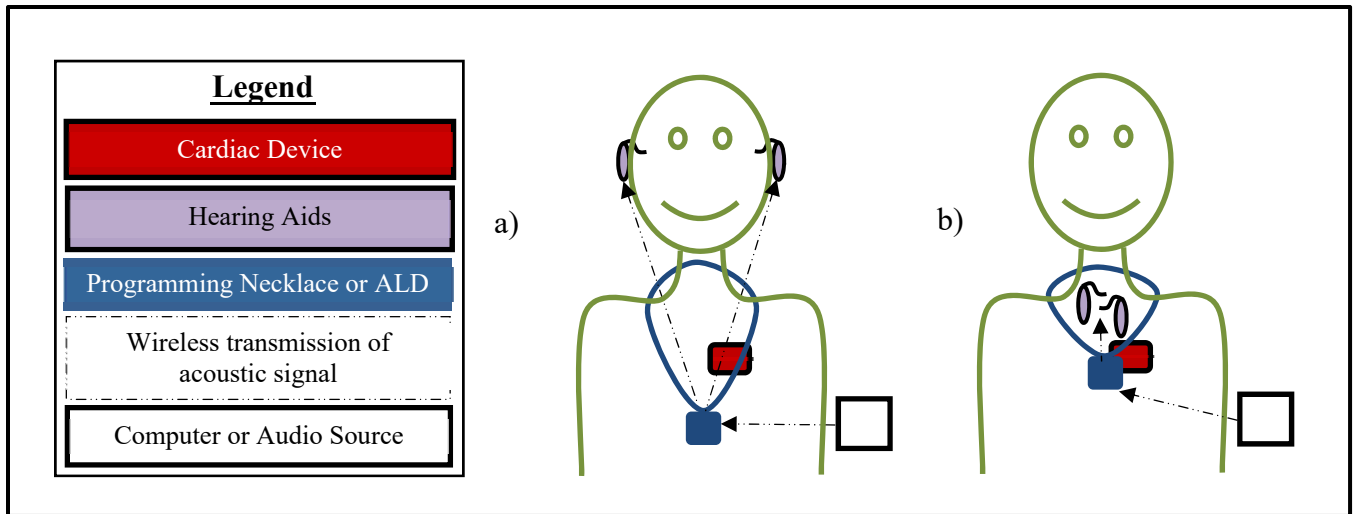
Figure 1. Depiction of device orientation a) during typical use and b) to maximize interference.
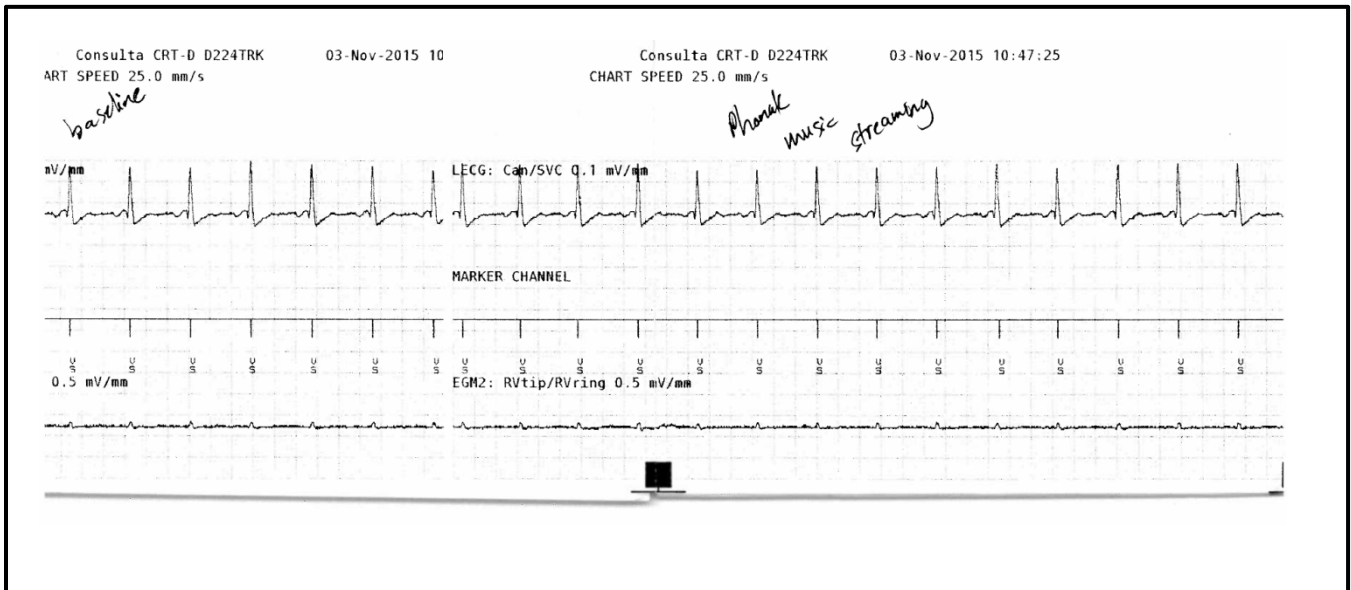
Figure 2. Cardiac device activity – no difference in tracings at baseline and during device use.
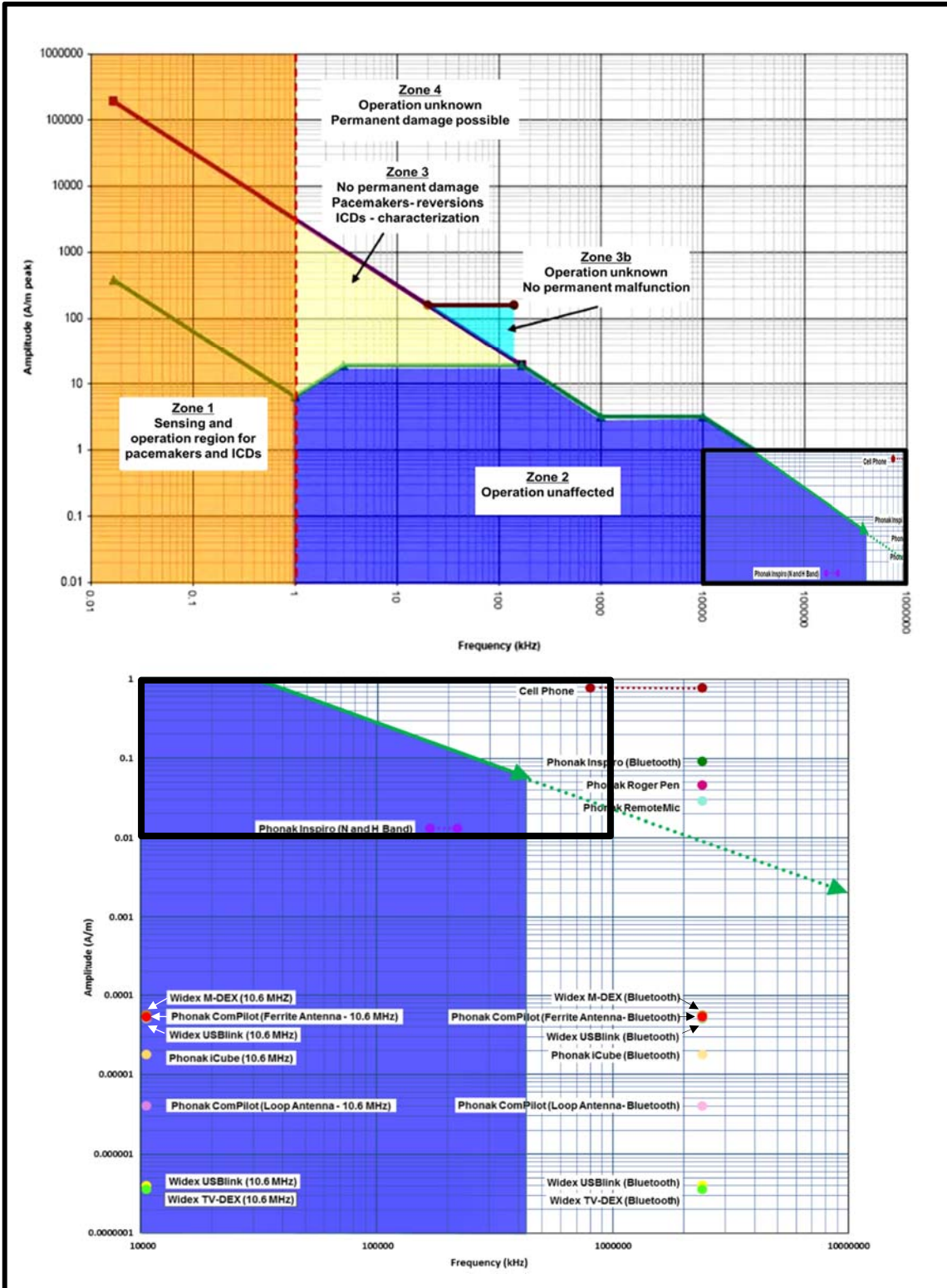
Figure 3. Estimated frequency and field strength resulting in EMI affecting implanted cardiac devices. Adapted from Figure M.4 – Magnetic Fields and used with permission from ANSI/AAMI 2012

APPENDIX A

Derivation of Magnetic Field Strength Calculation (given ERP) (Inan & Inan, 1999):

Equation 1:

$$S = \frac{ERP}{4\pi r^2}$$

S: power density;
r: distance from the source (HA/ALD)

Equation 2:

$$B = \sqrt{\frac{S * \mu_0}{c}}$$

B: magnetic flux density;
μ_0: magnetic permeability of free space; *c:* speed of light

Equation 1 and 2 combine to give Equation 3:

$$B = \sqrt{\left(\frac{ERP}{4\pi r^2}\right)\frac{\mu_0}{c}} = \frac{1}{r}\sqrt{\frac{ERP * \mu_0}{4\pi c}}$$

Equation 4:

$$H = \frac{B}{\mu_0}$$

H: magnetic field intensity

Equation 3 and 4 combine to give Equation 5:

$$H = \frac{1}{r}\frac{\sqrt{\frac{ERP * \mu_0}{4\pi c}}}{\mu_0}$$

APPENDIX B

Derivation of Magnetic Field Strength Calculation (at one distance, given magnetic field intensity at another distance):
(Inan and Inan, 1999)

Equation 6: Given magnetic field strength (H_1) at a given distance (r_1) and rearranging Equation 5 (in Appendix I):

$$ERP = \frac{(H_1 r_1 \mu_0)^2 * 4\pi c}{\mu_0}$$

H_1: magnetic field intensity; r_1: distance

To find a magnetic field intensity (H_2) at a given distance (r_2) using the same value of ERP, Equation 6 into Equation 5 gives:

$$H_2 = H_1 \frac{r_1}{r_2}$$

Convert dBµA/m to A/m:

$$y = \left(10^{(x/20)} * (1 * 10^{(-6)})\right)$$

y: A/m; x: dBµA/m