Before the
Federal Communications FCC
Washington, D.C. 20554

In the Matter of	)	
	)	
Reassessment of Federal Communications Commission Radio Frequency Exposure Limits and Policies	)	ET Docket No. 13-84
	)	
Proposed Changes in the FCC's Rules Regarding Human Exposure to Radio Frequency Electromagnetic Fields	)	ET Docket No. 03-137

REPLY COMMENTS OF SENSORMATIC ELECTRONICS, LLC

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Summary

The vast majority of commenters in this proceeding addressing the issue support the Sensormatic position that the FCC adopt the IEEE Standard C95.1-2005 as the safe limits or the standard for human exposure to electromagnetic fields ("EMFs"). The IEEE Standard is based on scientific rigor and was established through a transparent process that considered the inputs of all stakeholders, resulting in a fair and balanced standard. Moreover, as other commenters have noted, adopting the IEEE Standard would be a natural update to the current FCC limits, IEEE Standard C95.1-1992.

Other commenters also argue, like Sensormatic, for the rejection of the ICNIRP Guidelines as the FCC's safe limits for human exposure to EMFs. The technical and scientific flaws of the ICNIRP Guidelines are detailed in a paper by J. Patrick Reilly, a leading authority on the subject of neurostimulation of nerve and muscle tissue by electric energy, already submitted in this proceeding by Momentum Dynamics Corporation and Oak Ridge National Laboratory. Among other problems, the ICNIRP Guidelines establish external field limits that are based on unexplained or insupportable assumptions, are inexplicably restrictive, and would needlessly require companies to conduct more costly compliance tests to model and calculate the *in situ* internal fields, i.e., the in-body electric fields, which are the basis for the actual ICNIRP limits (known as the Basic Restrictions).

Moreover, from a process perspective, the ICNIRP organization is essentially a small, closed group, and the ICNIRP Guidelines were not developed in a transparent procedure. This stands in sharp contrast to the IEEE, which is an open, international organization comprised of experts from many countries, 60% or more of whom are from academia or government. Attached as an exhibit to these Reply Comments is a further critique of the flaws in the ICNIRP

Guidelines by Dr. John M. Osepchuk, widely regarded as a pioneer in human exposure standards.

Sensormatic also respectfully requests that the FCC resist the attempt by Medtronic, a medical device manufacturer, and AAMI, an association of medical device manufacturers, to expand this proceeding to address the unrelated topic of electromagnetic compatibility ("EMC") of medical devices. As a procedural matter, the FCC previously stated in its Notice of Inquiry that the EMC issue is beyond the scope of this proceeding. Moreover, the FDA is the agency that has the expertise and jurisdiction to address issues of medical device safety. Indeed, in prior instances where the FCC has discussed medical device EMC, it has consistently deferred to the FDA on medical device safety issues. No commenter has provided any basis to deviate from that longstanding policy.

What the medical device manufacturers are now essentially seeking are additional regulatory protections for the operation of their devices in unlicensed spectrum. That position is completely contrary to existing FCC spectrum management policy – a policy that has worked well over the years, and that the President's Council of Advisors on Science and Technology and the Commission's own Technical Advisory Council have encouraged be reinforced, not abandoned.

Additionally, the current cooperative process between medical device manufacturers and relevant emitter manufacturers, under the FDA's watchful eye, is effectively addressing the medical device safety concerns raised by the commenters. More specifically, for more than 15 years, the medical community, medical implant manufacturers and manufacturers of electronic anti-theft systems, like Sensormatic, have all embraced the FDA's simple "Don't Linger, Don't Lean" advice for cardiac implant patient interactions with electronic anti-theft systems. By all

accounts, this advice has worked extremely well. Attached as exhibits to these Reply Comments are the declarations of three of the country's leading cardiologists, confirming the effectiveness of this approach in protecting users of cardiac implants, without discouraging them from adopting life-saving technology or raising unnecessary fears. This testimony confirms that there is no serious medical device safety issue for cardiac implant patients, despite the widespread use of low frequency emitters, like electronic anti-theft systems. Sensormatic's own investigation, using the FDA's online MAUDE database, which records incidents with medical devices, confirms the absence of any safety issue.

Finally, the FCC should reject the request by medical implant manufacturers to create a special liaison with representatives of their industry. It would be inappropriate and unfair for one group to have a closed-door liaison relationship with the FCC, to the detriment of others with important contributions to make, including manufacturers of electronic anti-theft devices. Additionally, the grant of any such request would undermine the public comment and participation requirements imposed by the Administrative Procedure Act for rulemaking proceedings.

Table of Contents

Summary i

Discussion 2

I. The FCC Should Extend the Lower Frequency of the FCC's Human Exposure Safety Standard Limits From the Current 100 kHz to 9 kHz and Should Adopt IEEE C95.1-2005 as the Safety Standard For Human Exposure to Electromagnetic Fields. 2

II. The FCC Should Reject the Request That the FCC Expand This Proceeding to Address the Electromagnetic Compatibility of Medical Devices.....10

Conclusion 18

Exhibits

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REPLY COMMENTS OF SENSORMATIC ELECTRONICS, LLC

Sensormatic Electronics, LLC ("Sensormatic") hereby submits these Reply Comments with respect to the Notice of Inquiry in the above-referenced dockets.[1] Sensormatic urges adoption of the Institute of Electrical and Electronic Engineers ("IEEE") Standard C95.1-2005 for determining the safe limits of human exposure to electromagnetic fields ("EMFs") or radiofrequency emissions and extension of the application of this standard from the current 100 kHz to 9 kHz.[2] Sensormatic also asks that the FCC reject the requests to address in this proceeding the issue of electromagnetic compatibility ("EMC") of medical devices and, more specifically, to create a special liaison for representatives of medical device manufacturers.

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[1] *In the Matter of Reassessment of Federal Communications FCC Radiofrequency Exposure Limits and Policies et al*., First Report and Order, Further Notice of Proposed Rule Making and Notice of Inquiry, FCC 13-39 (March 29, 2013) ("NOI").

[2] Comments of Sensormatic Electronics, LLC (September 3, 2013) ("Sensormatic Comments"). As explained in its Comments, Sensormatic is a leading supplier of electronic security solutions for the world's retailers. Its products include electronic anti-theft systems and radio frequency identification systems. *Id*. at 2-4.

Discussion

I. THE FCC SHOULD EXTEND THE LOWER FREQUENCY OF THE FCC'S HUMAN EXPOSURE SAFETY STANDARD LIMITS FROM THE CURRENT 100 KHZ TO 9 KHZ AND SHOULD ADOPT IEEE C95.1-2005 AS THE SAFETY STANDARD FOR HUMAN EXPOSURE TO ELECTROMAGNETIC FIELDS.

In its NOI, the Commission requested comments on extending the coverage below 100 kHz of the FCC's safety standard for human exposure to EMFs. Additionally, the Commission noted the existence of two internationally recognized human exposure safety limits: (1) the IEEE C95.1 Standards, and (2) the International Commission on Non-Ionizing Radiation Protection ("ICNIRP")-1998 Guidelines and ICNIRP-2010 Guidelines. The NOI requested comments on the preference, costs and benefits of adopting either set of limits.

As Sensormatic noted in its September 3, 2013 Comments, there are several significant kinds of devices now emitting in frequencies below 100 kHz.[3] Such devices should meet appropriate human exposure safety standard limits.

The Cardiac Rhythm Management Device Committee / Working Group WG02 on EMC Protocols of the Association for Advancement of Medical Instrumentation ("AAMI")[4] proposes applying human exposure safety standard limits to the entire 0 to 100 kHz range to protect cardiac devices, which perform physiological sensing of heart rhythm as high as 0.5 kHz.[5]

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[3] *See* Sensormatic Comments, at 5.

[4] AAMI describes itself on its website as an organization of healthcare technology professionals interested in the development, management, and use of medical technology. *See* http://www.aami.org/about/ (last visited October 10, 2013). It is comprised, however, almost entirely of medical device manufacturers.

[5] *See* Comments of the Cardiac Rhythm Management Device Committee (CRMD)/Working Group WG02 on EMC Protocols of the Association for Advancement of Medical Instrumentation (AAMI), at 3 (September 3, 2013) ("AAMI Comments"). Although an employee of the FDA participated in the preparation of the AAMI Comments, the document clearly discloses on the cover page that the AAMI Comments "solely represents the views of the

While Sensormatic supports extending the lower frequency bound of the human exposure safety standard from the current 100 kHz down to 9 kHz, the lowest frequency for which there is an allocated service, Sensormatic notes that the justification for doing so advanced by AAMI is inappropriate. As discussed in more detail below, this proceeding focuses on the potential health effects from human exposure to EMFs from emitters, not on the EMC susceptibility of medical or other devices to emissions from other equipment – a wholly different topic.

The vast majority of commenters addressing the issue support the Sensormatic position that the FCC should adopt the IEEE Standard C95.1-2005.[6] Doing so would be a natural extension of the current FCC limits, IEEE Standard C95.1-1992. Additionally, the IEEE Standard is based on scientific rigor and was established through a transparent process that considered the inputs of all stakeholders, resulting in a fair and balanced standard.[7]

As a possible alternative to the IEEE Standard, the NOI requested comments on the use of the ICNIRP-1998 Guidelines for frequencies above 100 kHz (which ICNIRP acknowledges is

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AAMI CRMD / WG02 membership, and does not necessarily represent a position of AAMI or FDA." *Id*.

[6] *See, e.g*., Comments of the Telecommunications Industry Association, at 3 ("TIA strongly believes that the existing body of scientific evidence supports the adoption of the IEEE's C95.1 (2005) exposure standard.") (citation omitted); Comments of the Wi-Fi Alliance, at 6 (the FCC should "updat[e] its rules to reflect the latest IEEE standard); Comments of the Consumer Electronics Association, at 5 ("CEA agrees with comments ... that urge the Commission to adopt the updated RF exposure guidelines set forth in IEEE Std C95.1-2005."); Comments of Motorola Solution, Inc., at 10 ("[T]he Commission should adopt the limits, practices, and procedures contained with IEEE standard C95.1-2005, and related specifications, which represent the most up-to-date scientific learning in this area, and form the basis for most other international RF exposure regulatory regimes."); Comments of the International Committee on Electromagnetic Safety (ICES) of the Institute of Electrical and Electronics Engineers, Inc. (IEEE), at 2 ("ICES recommends that the Commission adopt the basic restrictions and maximum permissible exposure (MPE) values of IEEE C95.1-2005.")(citation omitted).

[7] *See infra* at pp. 5-7; *see also* Exhibit A attached.

undergoing a revision), and the ICNIRP-2010 Guidelines for frequencies below 100 kHz.[8] Joint commenters Momentum Dynamics Corporation and Oak Ridge National Laboratory (together "Momentum/ORNL") have, however, provided an extensive analysis regarding the flaws of the ICNIRP Guidelines.[9] Sensormatic concurs in that analysis.

More particularly, the significant technical flaws and scientific deficiencies of the ICNIRP Guidelines are detailed in J. Patrick Reilly's paper, "Limits on human exposure to electromagnetic fields in the frequency range 1 Hz to 100 kHz: The case for preference of the ICES [IEEE] standard over that of ICNIRP," which is attached as an appendix to the Momentum/ORNL Joint Comments. Professor Reilly is one of the world's leading authorities on the subject of neurostimulation of nerve and muscle tissue by electric energy, the key human exposure concern for frequencies below 100 kHz. He has published over 145 works, including reference books and journal papers, as well as several books directly addressing the subject of electrostimulation, the subject of interest in this proceeding. Furthermore, Professor Reilly's publications are extensively cited in both the IEEE and the ICNIRP documents, raising doubts about the unduly restrictive nature of the ICNIRP Guidelines, because his research and analysis is a major component of both documents.

A brief comparison of how these two sets of limits were developed may be helpful in explaining the basis for the commenters support for the adoption of the IEEE Standard. The IEEE is the world's largest professional association for the advancement of technology. One of its main activities is the issuance of technical standards, under the supervision of the IEEE Standards Association, many of which are adopted globally. The organization's International

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[8] *See* NOI, at ¶ 213.

[9] *See* Joint Comments of Momentum Dynamics Corporation and Oak Ridge National Laboratory Comments, at 10 (September 3, 2013) ("Momentum/ORNL Joint Comments").

Committee on Electromagnetic Safety ("ICES") sponsors the "IEEE Standard for Safety Levels with Respect to Human Exposure to Radio Frequency Electromagnetic Fields" C95 series of consensus standards on the safe limits for human exposure to electric and magnetic fields. The ICES committee is comprised of 125 expert members from many countries, with over 60% of its members coming from academia or government. The most recent version, IEEE C95.1-2005, covers the frequency range from 3 kHz to 300 GHz, and is the fifth generation of the standard going back to 1966.[10]

The IEEE standard is expressed in terms of Basic Restrictions ("BRs") and Maximum Permissible Exposure ("MPE") levels for both the general population and controlled environments (which includes workers). The BRs are the actual limits of the *in situ* internal electric fields. They include an appropriate safety factor below the direct and indirect effect threshold level for a health hazard. In other words, the BRs are the safe levels for in-body or in-place electric fields. They can be calculated using dosimetric computer models but cannot be directly measured. The BRs must be met to comply with the IEEE Standard. MPEs are mathematically derived from the BRs and represent the external field levels that, if met, conservatively project compliance with the BRs under all exposure conditions. MPEs can be measured with routine laboratory test equipment.

It is certainly possible under localized exposure conditions to exceed the MPEs, while still satisfying the BRs. Compliance with the IEEE Standard, therefore, can be confirmed either by (i) meeting the MPEs through routine measurements, or (ii) meeting the BRs through dosimetric computer models that enable calculating the resultant *in situ* internal electric fields.

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[10] The IEEE C95.6-2002 standard applies only to frequencies below 3 kHz and, therefore, need not be considered here.

ICNIRP was chartered by the International Radiation Protection Association in 1992. In stark contrast to the IEEE, ICNIRP is a relatively small, closed group, composed of a chairman, a vice chairman and up to twelve expert members, essentially elected by the current members, with only three needing to change every four years.[11] The secretariat is headquartered in Munich, Germany. Funding is received from various national government entities, most notably, the German Environmental Ministry.

The ICNIRP Guidelines were first issued in 1998 covering the full 0 to 300 GHz frequency band. Following the lead of the IEEE Standard, the ICNIRP Guidelines specifies limits for BRs, as well as what it calls "Reference Levels" ("RLs"), the external fields that can readily be measured. Though different terms are used, IEEE MPEs and ICNIRP RLs are conceptually the same – both are external fields that can readily be measured. The ICNIRP-1998 Guidelines also provide these limits for both the general population and for workers, but with unduly high precautionary values unsubstantiated by any science.

From 30 MHz to 100 GHz for the general population condition, the IEEE and ICNIRP limits converge to the same BR and RL/MPE levels, as well as essentially the same Specific Absorption Rate ("SAR") limits. (The SAR limits are important at the higher frequencies where tissue heating is the dominant concern.) Under 100 kHz, however, where electrostimulation is the primary issue, the ICNIRP-1998 Guidelines are far more restrictive, but with no scientific evidence or justification offered by ICNIRP for these alternate limits.

As a matter of fact, when the ICNIRP-1998 Guidelines were first issued, many products, especially inductive emission products that had been designed and produced to meet the IEEE

[11] The current members of ICNIRP are available at http://www.icnirp.de/cv.htm (last visited October 9, 2013).

MPE limits, could not meet the lower ICNIRP RLs, triggering widespread compliance issues. The RLs were 32X lower than the IEEE C95.1 MPE field levels for frequencies below 150 kHz. The difference between the two external field limits, in fact, amounted to a 1000X (or 30 dB) reduction in the allowable power level of a system.

When companies appealed to several ICNIRP members for an explanation for the far lower RL limits, those members were themselves reportedly surprised by this unexpected development and suggested that the companies instead demonstrate compliance with the BRs through dosimetric modeling. As a result, costly BR evaluations became an essential part of the ICNIRP compliance process for low frequency products, and are now considered a part of the ICNIRP Guidelines.

Affected industries in Europe, including those related to MRI technology and its applications, reported incurring substantial costs, otherwise unnecessary, in demonstrating compliance with the ICNIRP-1998 Guidelines. Following the identification of this problem, ICNIRP issued the ICNIRP-2010 Guidelines, which replaced the ICNIRP-1998 Guidelines for frequencies less than 100 kHz and increased the RLs by a 4X factor.[12] Undoubtedly, this revision was prompted by the difficulties faced by many in meeting the ICNRIP-1998 Guidelines. But even with these higher RLs under the ICNIRP-2010 Guidelines, the ICNIRP levels still remain nearly 8X lower than the safe IEEE MPE levels for frequencies up to 5 MHz.

Accordingly, were the FCC now to select the current ICNIRP Guidelines, many companies would not meet the RLs and would, therefore, face the cost and complexity of

[12] Above the 100 kHz frequency range, however, the ICNIRP-1998 Guidelines still apply. Thus, both ICNIRP-1998 and ICNIRP-2010 would be required to cover the full range above 9 kHz that is covered by IEEE C95.1-2005. Confusingly, the two ICNIRP Guidelines overlap in the 100 kHz to 10 MHz range but have significantly different limits, i.e., ICNIRP-2010 covers electrostimulation effects and ICNIRP-1998 covers the SAR limits.

modeling the *in situ* internal electric field levels of their products to determine compliance with the BRs, a time-consuming process that would add $15,000 to $25,000 per product evaluation. Consequently, adopting the ICNIRP Guidelines would slow product development and innovation – without any demonstrable corresponding benefit.

Another important factor supporting adoption of the IEEE Standard, rather than the ICNIRP Guidelines, is the fact that it recognizes, properly, that a different limit is appropriate for limbs than for other body parts. The ICNIRP Guidelines, by contrast, illogically treat all body parts the same, except for brain tissue. Because body limbs have a significantly smaller induction area, the higher levels allowed by IEEE, which range from 10X to 50X greater depending on frequency, are certainly more appropriate. This approach may be particularly important, for example, for persons performing welding, using hand tools, or operating MRI equipment.

Indeed, a recent clinical trial by Weinberg, *et al.*,[13] in 2012, studied actual magnetic field exposure of the wrist in a mix of people, at five distinct frequencies between 2 kHz and 183 kHz, looking at the Peripheral Nerve Stimulation ("PNS") threshold for the subjects. Although the prime conclusion was that the PNS threshold was essentially constant above 100 kHz, the results provided instructive information about the thresholds below that frequency. Results for the magnetic field thresholds, where any perception was felt, were considerably higher than the MPE in the IEEE C95 Standards and the RLs in the ICNIRP Guidelines, both of which cite PNS stimulation as the major factor in setting the levels. The IEEE MPE values for limbs are more than 250 times lower than the study result at 59 kHz, providing a wide safety margin.

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[13] Weinberg, Irving N. *et al*., "Increasing the oscillation frequency of strong magnetic fields above 101 kHz significantly raises peripheral nerve excitation thresholds," Med. Phys. 39 (5), May 2012.

The ICNIRP Guidelines, by contrast, have no special limb exposure, and thus, the 2010 RLs for occupational exposure are about 3,000X lower than the study results, and for general public exposure are more than 11,000X lower. Other frequency points provide similar results. Because this is a threshold effect, there is no further impact once below the threshold. In other words, there is no change in the level of safety for products 1000X below a threshold than there is for products 100X below that threshold. This significant, undue conservatism in the ICNIRP Guidelines means that the IEEE Standards are far more representative of limb exposures, while still providing large safety margins.

A further perspective on the science and procedures behind the development of the IEEE Standard and the ICNIRP Guidelines is offered by Dr. John M. Osepchuk, whose paper is attached in Exhibit A. Dr. Osepchuk is widely regarded as one of the pioneers in human exposure standards and is a sustaining member of the Bioelectromagnetics Society and a life member of the Committee on Man and Radiation.

Dr. Osepchuk attributes the flaws in the ICNIRP Guidelines to the complete absence of the relevant manufacturers and users of equipment from the standards development process. As an example, he notes that the safety factor ICNIRP used for the general population at 1 kHz amounts to 54 dB, or 500X, less than any other health hazard threshold, which is clearly excessive by any measure.

For all the above reasons, then, Sensormatic recommends that the FCC adopt IEEE C95.1-2005 as its safety standard for human exposure to EMFs.[14] The standard should be

[14] Because Sensormatic products are able to meet the ICNIRP-2010 Guidelines through a demonstration of compliance with the ICNIRP BRs, the company indicated in its Comments that it would be comfortable with the comprehensive adoption of the ICNIRP-2010 Guidelines. Sensormatic Comments, at 6. That said, however, Sensormatic still believes that adoption of the

comprehensively adopted, including the BRs, the MPEs, and the separate approach for body limbs, both for the general population and controlled environment conditions (which includes workers).

II. THE FCC SHOULD REJECT THE REQUEST THAT THE FCC EXPAND THIS PROCEEDING TO ADDRESS THE ELECTROMAGNETIC COMPATIBILITY OF MEDICAL DEVICES.

AAMI and Medtronic suggest that the FCC should expand this proceeding to also address electromagnetic compatibility of medical devices and low frequency emitters.[15] As described in their comments, certain medical devices, such as cardiac pacemakers, function by sensing microvolt-level physiological signals in the low frequency range.[16] These commenters argue that the FCC should use this proceeding to establish emission exposure limits to protect such medical devices and should also create a special liaison between the FCC and AAMI.[17]

As discussed more fully below, the FCC should reject both requests. EMC issues for medical devices are beyond the scope of this proceeding and, in any event, belong before the FDA, not the FCC. The commenters have not alleged that manufacturers producing low frequency emitters, including electronic anti-theft systems, are in violation of the FCC's Part 15 rules. Nor have they provided any basis for the FCC to conclude that the current inter-industry

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ICNIRP Guidelines in lieu of the IEEE Standard would be a mistake because of the resulting, unnecessary expenses and delays that would impact manufacturers of low-frequency emitters, especially including start-ups developing new products in that frequency range.

[15] *See* AAMI Comments, at 1-3; Medtronic Comments, at 6-8.

[16] *See* AAMI Comments, at 2 ("These implantable devices are designed to sense low amplitude (microvolt-millivolt) intrinsic cardiac signals in the frequency range from 0-500 Hz"); Medtronic Comments, at 7 ("It is critical, therefore, that any new RF rules adopted by the FCC ensure that RF exposure limits below 300 kHz do no cause harmful interference to implanted medical devices.")

[17] *See* AAMI Comments, at 3; Medtronic Comments, at 7.

cooperation, under the FDA's watchful eye, for ensuring the electromagnetic compatibility of medical devices, is not working.

A. This is an inappropriate proceeding to address the electromagnetic compatibility of medical devices.

This proceeding is clearly and specifically limited to human exposure to EMFs. Indeed, the FCC expressly stated that it "is specifically not considering ... compatibility with medical devices, implants, or electro-explosive devices" in this proceeding.[18]

This is no surprise, because the two subjects are completely different. The former focuses on the potential health effects to all humans from exposure to EMFs from emitters; the latter deals with the unrelated topic of EMC or the susceptibility of medical or other devices to interference from emitters. Consistent with the foregoing, the IEEE Standard and the ICNIRP Guidelines that are under consideration in this proceeding both specifically note that they focus only on human exposure – with electromagnetic compatibility beyond the scope of both standards.[19]

B. The FDA is the appropriate agency to address medical device safety issues associated with the electromagnetic compatibility of medical devices.

The FCC acknowledges in the NOI that "[m]edical devices are regulated by the Food and Drug Administration (FDA)."[20] Further, the FCC has emphasized the importance and need for the FCC to "seek the opinions of federal agencies with jurisdiction by law or scientific expertise

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[18] NOI, at ¶ 187.

[19] The ICNIRP-2010 Guidelines expressly state that: "Compliance with the present guidelines may not necessarily preclude interference with, or effects on, medical devices such as metallic prostheses, cardiac pacemakers and implanted defibrillators and cochlear implant … advice on avoiding these problems is beyond the scope of the present document." A similar disclaimer statement is included in IEEE C95.1-2005.

[20] NOI, at ¶ 187.

... in terms of safety and effects on human health" and to "work closely with and rely heavily – but not exclusively – on the guidance of other federal agencies with expertise in the health field."[21] Indeed, the adoption of the FCC's current exposure limits "followed recommendations received from the U.S. Environmental Protection Agency (EPA), the Food and Drug Administration (FDA), and other federal health and safety agencies."[22]

The FDA is the agency with the knowledge and expertise to evaluate any EMC-related health risks for cardiac implant patients, and has the ability to take actions to mitigate any such risks. In fact, for many years, the FDA has undertaken and published extensive research on its efforts to assess the compatibility of various radiofrequency emitters -- such as cellphones, RFID, and electronic anti-theft systems -- with pacemakers, defibrillators and neural stimulator devices. To carry out this mission, the FDA operates a state-of-the-art EMC laboratory, one of the best in the country, and utilizes a well-qualified staff of EMC-trained experts.

The FDA's medical expertise and experience in handling health issues associated with EMC supports the conclusion that the FCC should defer to the FDA on that subject. Indeed, that is exactly what the FCC has done over the years with respect to the electromagnetic compatibility of medical devices. For example, in 1975, the FCC initiated a rulemaking proceeding regarding the operation, under the FCC's Part 15 rules, of wide-band radiofrequency emitters used as electronic anti-theft systems.[23] In response to electromagnetic compatibility issues raised at the time, the FCC stated:

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[21] NOI, at ¶ 210.

[22] NOI, at ¶ 211.

[23] *The Amendment of Part 15 to Provide for the Operation of Wide-Band Swept RF Equipment Used as Anti-Pilferage Devices*, 59 FCC 2d 1256 (1976). At the time, electronic anti-theft systems were referred to as "anti-pilferage devices."

> The Commission agrees that it is desirable to establish standards for the pacemakers and anti-pilferage equipment to minimize the personal hazard problem, but feels that the development of such standards is more appropriately left in the hands of the FDA.[24]

In short, the FCC limits its regulations to addressing radiofrequency interference and defers to the FDA on safety matters associated with the electromagnetic compatibility of medical devices.[25]

In 2006, in the context of a proceeding to establish a new medical device service, the FCC reiterated this policy on electromagnetic compatibility issues:

> The Commission's primary efforts focus on promulgating regulations that allocate RF spectrum for their particular use, and that set operational limits on the RF emissions they generate to achieve efficient and effective utilization of the spectrum. The FDA addresses device safety and effectiveness, including EMC issues, as part of its regulation of medical devices.[26]

When the FCC released its order establishing the MedRadio services in that proceeding, it took no action modifying its policy on electromagnetic compatibility.[27]

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[24] *The Amendment of Part 15 to Provide for the Operation of Wide-Band Swept RF Equipment Used as Anti-Pilferage Devices*, 59 FCC 2d 1256, at ¶ 24 (1976).

[25] This is analogous to how the FCC has dealt with the joint regulation of cellphone use on airplanes by the FCC and Federal Aviation Administration ("FAA"). In that context, the FCC's "restrictions on the airborne use of wireless handsets stem from the potential that unwanted emissions could cause harmful interference to terrestrial-based systems[, while] the FAA is concerned with the possibility that PEDs[, portable electronic devices,] could interfere with aircraft communications and navigation systems." *See Amendment of the Commission's Rules to Facilitate the Use of Cellular Telephone and Other Wireless Devices Aboard Airborne Aircraft*, Notice of Proposed Rulemaking, 20 FCC Rcd 3753 (2005); *see also* "A Report From the Portable Electronic Devices Aviation Rulemaking Committee to the Federal Aviation Administration" (September 30, 2013), *available at* http://www.faa.gov/regulations_policies/rulemaking/committees/documents/media/PED.ARC.RR.20130930.pdf (last visited November 8, 2013).

[26] *Investigation of the Spectrum Requirements for Advanced Medical Technologies*, Notice of Proposed Rulemaking, Notice of Inquiry, and Order, 21 FCC Rcd 8164, at ¶ 45 (2006).

[27] *See Investigation of the Spectrum Requirements for Advanced Medical Technologies*, Report and Order, 24 FCC Rcd 3474, at ¶ 11 (2009).

C. The current cooperative inter-industry process has effectively addressed the medical device safety concerns raised by AAMI and Medtronic.

Neither AAMI nor Medtronic offers any scientific basis for concluding that FCC regulations are, in fact, necessary to address any potential problems regarding the electromagnetic compatibility of medical devices. As a preliminary matter, neither party suggests, much less provides any evidence, that any electronic anti-theft system manufacturer has failed to comply with the FCC's Part 15 rules regarding unlicensed devices. Medical devices are also unlicensed and, as such, must operate in the radiofrequency environment on a non-protected basis pursuant to the FCC's rules for such devices.[28] Medical devices are, therefore, designed to be resilient to a wide-variety of sources encountered routinely in the normal environment and, if necessary, to operate in a "safe mode" when encountering interference.

The FCC should not contravene its well-established rule for such unlicensed devices, based on unsubstantiated, speculative fears. Adopting special protection for medical devices could also disincentivize those manufacturers from continuing to improve the interference rejection properties of their equipment and would be contrary to the principle that good spectrum management requires manufacturers to take responsibility for designing resilient devices.[29]

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[28] *See* 47 C.F.R. § 15.5(b) (unlicensed devices are subject to the condition that interference must be accepted).

[29] *See, e.g.*, Report to the President: Realizing the Full Potential of Government-Held Spectrum to Spur Economic Growth, Executive Office of the President, President's Council of Advisors on Science and Technology, at p. 111-21 (July 2012), *available at* http://www.whitehouse.gov/sites/default/files/microsites/ostp/pcast_spectrum_report_final_july_20_2012.pdf (last visited October 8, 2013); Report to Congressional Committees: Further consideration of Options to Improve Receiver Performance Needs, U.S. Government Accountability Office (February 2013), *available at* http://www.gao.gov/assets/660/652284.pdf (last visited October 9, 2013); "Interference Limits Policy – The use of harm claim thresholds to improve the interference tolerance of wireless systems," Receivers and Spectrum Working Group, FCC Technical Advisory Council (February 6, 2013), *available at*

In any event, Sensormatic's own research and analysis demonstrate that the cooperative industry process, under the FDA's review, is effective in handling any medical device safety concerns raised by AAMI and Medtronic. Indeed, for over 25 years, Sensormatic has been actively engaged in helping ensure that medical implant patients can safely walk through the company's electronic anti-theft systems. If there were a material probability of clinically significant interactions, and such interactions were, in fact, occurring, Sensormatic's customers, the world's retailers, would not continue installing electronic anti-theft systems.

The company's earlier comments to this NOI described a series of public meetings, starting in 1998, with the FDA's Technical Electronic Products Radiation Safety Committee ("TEPRSSC"). That meeting was attended by local and federal government agencies, electronic anti-theft manufacturers, and a number of the country's leading cardiologists. These meetings led to the FDA's endorsement of the recommendation that medical implant patients simply practice a "Don't Linger, Don't Lean" approach, which is still the policy in place today. This approach is, in fact, similar to other practical recommendations communicated to cardiac implant patients, such as not to hold mobile phones or radios too close to their medical implants. In addition to the FDA, a long list of international organizations, including the European Society of Cardiology, the UK Medical Devices Agency, the Asia-Pacific Working Group on Cardiac Pacing, and the American Heart Association, each of whom has studied this issue, have all concurred that there is no danger for cardiac implant patients in routinely passing through electronic anti-theft systems.

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http://www.siliconflatirons.com/documents/publications/policy/20130206_DeVires_Interference LimitsPolicy.pdf (last visited October 9, 2013).

Manufacturers of electronic anti-theft systems actively participate in efforts to enhance the EMC of these products by supporting ongoing device compatibility testing, and by participating in device standard-setting activities of various organizations, such as the IEEE, IEC, CENELEC, CEPT and ETSI. This includes the establishment, two decades ago, of a world-class electronic anti-theft system/medical implant test facility at the Georgia Tech Research Institute ("GTRI").[30] Medical device manufacturers are known to regularly test new designs at GTRI before introducing them to the marketplace.

Three of the country's leading cardiologists, two of whom also originally made public presentations at the TEPRSSC meeting 15 years ago, have recently provided an updated assessment regarding the interaction between electronic anti-theft systems and medical devices. Their statements, which are attached in Exhibit B, confirm that the existing approach has indeed been effective in protecting patients with cardiac implants, without discouraging them from adopting life-saving technology or raising unnecessary fears. Their testimony makes it clear that there is no serious medical device safety issue for cardiac implant patients, despite the widespread use of electronic anti-theft devices. A recent query of the FDA's on-line MAUDE database, to find any reported incidents involving electronic anti-theft systems, confirms the absence of any safety issue. All of these facts leave no doubt that, in the real world, the efforts on multiple fronts to ensure the safety of cardiac implant patients are indeed working.

AAMI has expressed the concern that collaboration with other emitter manufacturers might occur long after medical products have reached the marketplace, putting patients at risk. But that does not have to be the case -- and has certainly not been the case for the past two

[30] For a description of the GTRI facility, see http://www.gtri.gatech.edu/casestudy/improving-medical-devices (last visited November 4, 2013).

decades with respect to electronic anti-theft devices, where there has been continuous compatibility testing and analysis.

Sensormatic believes AAMI should similarly initiate an active outreach program to identify emerging technologies and establish a dialogue with those product developers. White papers and technical symposiums present other opportunities for engaging in a dialogue with new emitter manufacturers. Such inter-industry cooperation is where the optimal solution lies – not in FCC regulation.

D. The FCC should reject the request to create a special liaison with AAMI.

Both AAMI and Medtronic suggest that the FCC should designate a liaison with AAMI to facilitate collaboration and establishment of guidelines for manufacturers of low frequency emitters.[31] Sensormatic notes that it would be inappropriate for AAMI, an association comprised almost entirely of medical device manufacturers, to have a closed-door liaison relationship with the FCC, regarding matters as important as establishing the emission levels or modulation formats that would affect others. Indeed, this proposal is fundamentally unfair to other stakeholders, including manufacturers of electronic anti-theft systems, and would undermine the public comment and participation requirements imposed by the Administrative Procedure Act for rulemaking proceedings.[32]

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[31] *See* AAMI Comments, at 3; Medtronic Comments, at 7. Although the Medtronic proposal includes the FDA in this collaboration, it excludes other stakeholders.

[32] *See* 5 U.S.C. § 553.

Conclusion

For the reasons stated above, Sensormatic requests that the FCC take action consistent with its Comments and Reply Comments submitted in this proceeding.

Respectfully submitted,

/s/

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November 18, 2013

Exhibit A

Why the FCC Should Adopt IEEE Standard C95 for the Safety of Human EMF Exposure, Especially Below 100 kHz

John M. Osepchuk, Ph.D.

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1. Abstract and Summary:

The FCC is considering the extension of FCC rules on human exposure to EM fields or energy to frequencies below 100 kHz, as well as re-assessing the human exposure safety standard referenced in the FCC rules at the higher frequencies. The recent FCC NOI has posed the choice between the standards of the IEEE/ICES organization (IEEE C95.1/C95.6) vs. the guidelines of ICNIRP (1998 and 2010). Since the FCC rules currently cover frequencies above 9 kHz, IEEE Standard C95.1 would cover the frequencies of interest (IEEE C95.6 covers the 0 to 3.350 kHz range, should the FCC want to include this range). Both ICNIRP Guidelines, 1998 and 2010, would be required to cover the same range of frequencies in the FCC rules and regulations.

I strongly recommend the adoption of the IEEE Standard for several reasons. They are derived by the largest international standards-setting body in the world on this subject, with a very good track record vs. a record of flawed guidelines from ICNIRP—in particular, those of 1998, which could have shut down very important technologies. This was not because of any new research or science, but because of unduly conservative human exposure safety limits relative to any human hazard threshold, i.e., unduly conservative "safety factors." The basic reason for this was the absence of relevant stakeholders in their deliberations; i.e. people who easily could have warned ICNIRP of this calamity.

The IEEE's International Committee on Electromagnetic Safety (ICES) committees operate under the supervision of the leading worldwide standards organization (IEEE Standards Association) that ensures due process, balanced interests, transparency, documentation, appeals, interpretations, etc. In contrast, ICNIRP is a small group of self-perpetuating experts elected by their group with little evidence of these virtues, and a faulty rule of excluding "commercial vested interests"—and thus, barring the participation of the producers and users of EMF equipment who best know the practical consequences of exposure limits, and who can ensure risk vs. benefit deliberations. Lastly, adoption of IEEE/ICES standards is a logical extension of the historical record of adoption of such standards, including those related to mobile phones (through ICES TC 34), by U.S entities as well as non-U.S. entities such as NATO.

2. Background:

We note, first, the significance of the averaging time in various limits. For the IEEE C95 standards, the general population limits at RF/microwave frequencies has an averaging time of 30 minutes, which is different from the averaging time of 6 minutes for controlled environments (includes workers). This allows the limits (in terms of energy) to be the same for short periods of time, and different for long periods of time, reflecting less need for caution in addressing the known acute hazards of short-time exposure—e.g. burns. ICNIRP, by contrast, uses the same averaging time for both groups, which introduces unnecessary conservatism in their guidelines.

Second, while IEEE and ICNIRP both refer to "dosimetric" models that enable calculation of internal fields from external field and vice versa, IEEE applies more details than ICNIRP.[1, 2, 3] In addition, only ICNIRP applies an additional factor of 3X (9.5 dB) to their calculation of external fields to account for "uncertainties." This is a significant contributor to the unjustified, and unexplained, conservatism reflected in choosing excessive safety factors in the ICNIRP process.

We also have high confidence in the detailed work of J. Patrick Reilly and others in the IEEE community in addressing all the detailed steps in developing the low-frequency limits. Reilly, in fact, is probably the world's leading expert on low frequency biological effects from EMF exposure.

These topics and more are addressed in my 2004 paper.[4] On several occasions, IEEE has proposed a joint workshop to address the problems in the ICNIRP Guidelines, but ICNIRP has declined to meet to discuss various matters.

3. An Example of a Huge Flaw in ICNIRP Guidelines Caused by the Absence of the Whole Community of Stakeholders in the ICNIRP Membership:

There is a huge flaw in the 1998 ICNIRP Guidelines that led to a serious disruption of practical applications. This was caused by the absence of producers and users of equipment that could have warned ICNIRP that their approach was unduly conservative.

To illustrate the origin of the flaw, look at the attached Figure. This is a slide used in a presentation on the '98 Guidelines by Dr. Bernhardt, the then Chairman of ICNIRP and a key, if not the chief, author of the '98 Guidelines. In this Figure, we see depicted a hazard threshold curve for stimulation of nerves which is marked as a factor of "10X" above exposure limits for the "working place." In fact, the Figure shows that, from 1 kHz to well over 100 kHz, a ratio that is closer to 80-100X, and not 10X as marked on the Figure. This means 40 dB, and even much more for the "general public," which is 14 dB lower, thus amounting to a safety factor of 54 dB or 500X. That certainly is excessive, and I so stated in a letter[5] to *Health Physics* in 1999, the journal that originally published the ICNIRP Guidelines. There were many other letters to this journal criticizing the '98 Guidelines, mostly criticizing the excessive safety factors

When it was learned around 2007 that the EU would adopt ICNIRP 1998 in a Worker's Directive, there was considerable concern among the practical users of EMF-generating devices in Europe. Dr. Keevil in a presentation[6] to a meeting of ICES in London in 2007 expressed this angst and predicted that the new Directive would, for example, "preclude certain interventional MRI procedures." He said that it appeared that the ICNIRP guidelines "are set without much

thought on their impact." He felt that the risk-benefit considerations should be part of the standard-setting process. Indeed, that is so in the IEEE process, but not in the ICNIRP process. The reason for this is because, in the ICNIRP process, there is a deliberate lack of breadth of interests and a failure to follow sound principles of standards-setting like those prescribed by the IEEE Standards Association.

This threat to the MRI community was the main reason why ICNIRP revised its Guidelines in 2010, with the low frequency limits greatly relaxed. The reason for this relaxation, though not admitted openly, was the belated realization of the adverse impact of the '98 Guidelines. There was no intervening new science that allowed the limits to be relaxed. One only needed to reduce the excessive safety factor by as much as 10 to 20 dB. Even then, though, the ICNIRP Reference Levels were still more conservative than the IEEE C95 levels by as much as 10 to 20 dB, and hence remain a problem for a number of applications.

Thus, ICNIRP partially corrected the flaws in the'98 Guidelines, but it took them over ten years to do so, despite the absence of any new science. The resulting 2010 Guidelines, however, still contain many of the same flaws.

4. The Reason for Excessive Safety Factors in ICNIRP Guidelines is the Absence of Risk-Benefit Deliberations that Should Involve All Stakeholders and Follow the Principles Set Forth by the Best Standards Organizations in the World, which includes the IEEE:

ICES, under IEEE supervision, follows the rules of good standard- setting, including transparency, due process, documentation, breadth and diversity of interests, and geographical distribution. The IEEE/ICES organization conforms to all these, but ICNIRP does not.

ICNIRP is instead composed of ~12 members plus a Chairman and Vice Chairman. They themselves elect the new members to replace retiring members. All meetings are closed, and there is no documentation of their deliberations. Indeed, they deliberately exclude persons with "commercial vested interests"—e.g. industry, reflecting a stunningly narrow guilt-by-association mentality. By this stroke, ICNIRP indefensibly excludes the talents of many professionals, especially those informed on the practical impact of exposure limits on technology in the modern world, and the harms that can follow from unduly conservative safety factors.

In 1998, almost all members of ICNIRP, including the Chairman and Vice Chairman, were from Europe, except for three members from the U.S and one from Japan. Today of 13 voting members in ICNIRP, 7 are from Europe, two from the U.S., two from Australia, one from the Philippines and one from Japan. There is no representation from key countries like China and Korea. By way of contrast, in the IEEE/ICES organization, there are 78 U.S. members in the main TC95 committee, but also 43 non-U.S. members from 22 different countries and 20 members from the important Far East countries of Japan, China, Korea, Thailand, Malaysia, New Zealand and Australia. Similarly, in the key subcommittee, SC3 (low frequency), there are 50 non-U.S. members out of a total of 114, and in SC4 (high frequency), there are 55 non-U.S. members out of a total of 130. ICES is thus far more international than ICNIRP. Note also that membership in ICES committees is open to all, in most cases.

ICES, in conformance to IEEE rules, also shows far more balance of interests than ICNIRP, which follows no rules on balance of interests. The distribution of interests and talents

within ICNIRP is unknown, and there is no supervision by a higher organization to ensure a balance of interests, as in the IEEE.

5. IEEE/ICES Has Much More Practical Relevance to the FCC than ICNIRP:

IEEE/ICES has always had broad membership from U.S government agencies, including: the military, who sponsor a major part of research on bio-effects of EMF; health agencies like the FDA and EPA; safety agencies, including OSHA; regulatory agencies, including the FCC; and various state agencies. Through its TC34 committee, IEEE/ICES develops standards on localized emissions from mobile phones that are transmitted to the FCC. Overall, ICES/IEEE standards, including the C95 series, are generally adopted by ANSI as standards, reinforcing the importance of ICES to the U.S. regulatory world.

Lastly, as reflected in the large non-U.S. membership, ICES deliberations affect safety standards development in many nations, and in particular Canada, which has a strong representation in ICES. In addition, through an agreement between IEEE and NATO, the work within ICES has regularly been transferred to NATO.

6. Conclusions:

IEEE/ICES has an admirable history of setting excellent safe-exposure standards for EMF or electromagnetic energy. It follows the well-defined rules for standards development under the active supervision of the IEEE that is responsible for hundreds of standards in the world. A key feature of ICES under IEEE is broad diversity in world membership and diversity of interests among stakeholders. Flaws that have threatened the existence of useful technologies have been avoided. ICNIRP, by contrast, is a small, closed committee that excludes many from membership. There is thus a real danger – a danger fully realized here – of issuing overly conservative guidelines based on excessive safety factors, which are not a matter of science. This led to seriously flawed ICNIRP guidelines in 1998 that threatened the continued use of MRI and other real-world devices.

The FCC can avoid the danger inherent in such flaws by adopting ICES C95 standards, including those below 100 kHz. It should be remembered that lower limits are not always the superior choice for humanity. Had the proposed lower limits at RF/microwave frequencies, such as those sought by activist groups in the Bio-initiative report[7] or the obsolete Soviet limits at around 1 $\mu W/cm^2$ been adopted, for example, that would have suggested that all broadcast and mobile radio towers be shut down.

Clearly, there must be broad balance in developing safe limits for EMF. Following IEEE/ICES is the choice that will insure a rational balance between safety and usefulness of EMFs to society in this and the future world.

7. References:

1. J. M. Osepchuk and R. C. Petersen, "Safety Standards for Exposure to RF Electromagnetic Fields," *IEEE Microwave Magazine,* Vol. 2, No. 2, pp. 57 – 69, June 2001.

2. J. M. Osepchuk and R. C. Petersen, "Safety and Environmental Issues," Chapter 3.2 in M. Golio, Ed., Revised Second Edition, *The RF and Microwave Handbook,* CRC Press, Boca Raton, 2006.

3. Recent draft standards, e.g. IEEE PC95.1/D2.6-V1, May 2012; *Draft Standard for Safety Levels with Respect to Human Exposure to Electric, Magnetic and Electromagnetic Fields, 0 Hz. to 300 GHz;* IEEE, Piscataway, New Jersey.

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5. J. M. Osepchuk, "Excessive Safety Factors in 1998 ICNIRP Guidelines Reflects Lack of Participation of All Stakeholders in the ICNIRP Process," *Health Physics,* Vol. 76, p. 567 (1999).

6. IEEE/ICES; Approved TC 95 Meeting Minutes; Mobile Operators Association Facility, 12 Russell Square, Bloomsbury, London WC 1B 5EE; Friday, 2 March 2007, pages 6-7.

7. IEEE Committee on Man and Radiation (COMAR); Technical Information Statement (TIS) on the Bio-initiative Report, 2011.

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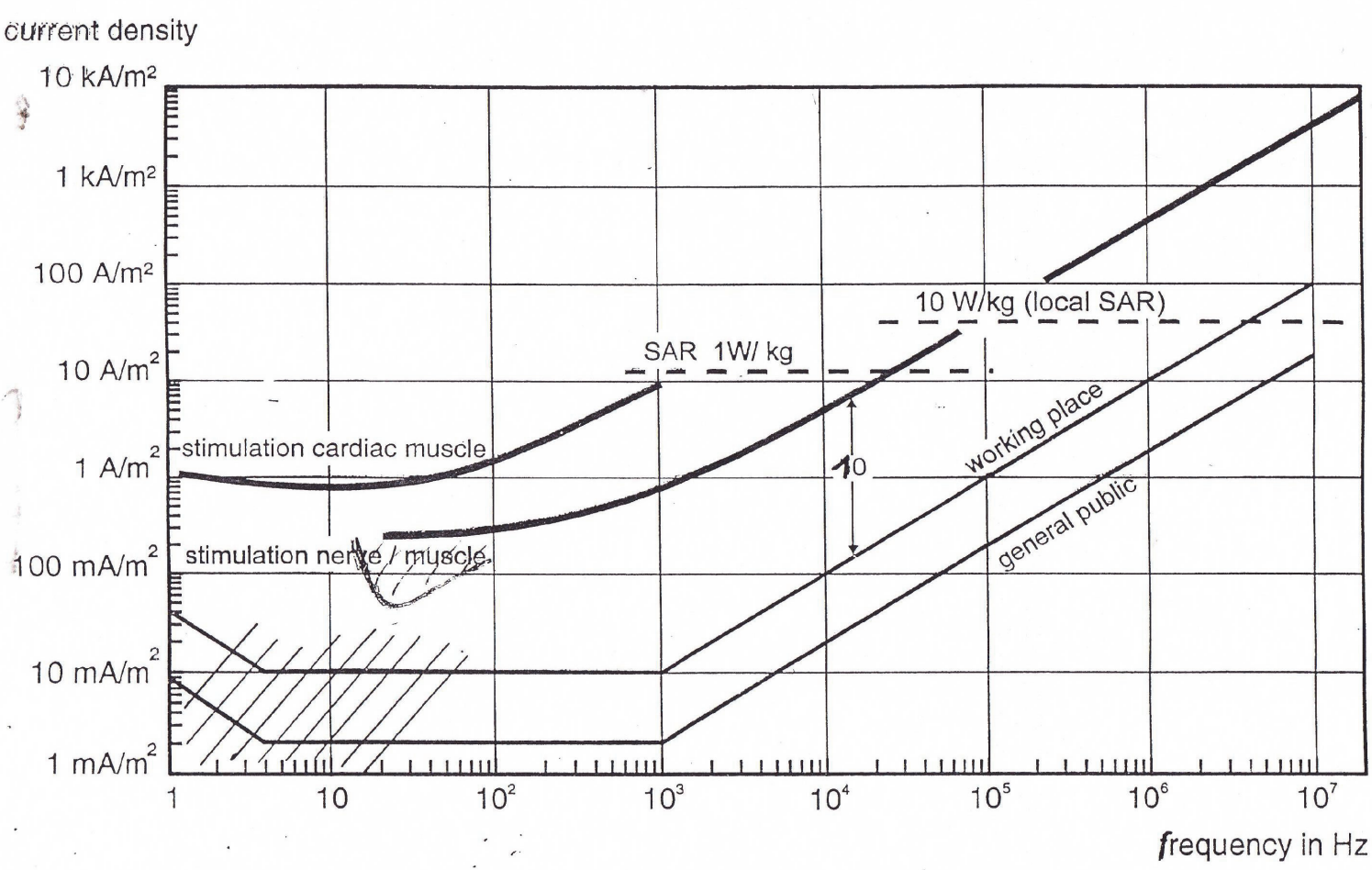
Education: A. B. ('49), Harvard College; A. M. ('50), Ph. D. ('57), Harvard University.

Dr. Osepchuk worked for Raytheon Company in microwave R&D (ferrites, plasmas, tubes and heating systems). He played a leadership role in founding and operating many activities in the IEEE (Institute of Electrical and Electronics Engineers): Life member of COMAR; Chairman Emeritus of IEEE/ICES SCC-28; Adcom member in MTT-S and SIT-S; IMPI (JMP editor and President); EEA (Organizer and officer); and BEMS (Member). He is a Fellow of the IEEE and IMPI, a member of φβκ and ΣΞ, and was awarded the IEEE Standards medallion in 1998, and the IEEE Millennium medal in 2000. Dr. Osepchuk has authored many patents and publications, including a key patent on microwave-oven door-choke seal design. As an independent consultant, his present activities include studies of the microwave auditory effects, microwave heating (for ACP, Inc., AMTek, Inc., Aegina Glass, Inc.), and EMF safety (for wireless companies and the U. S. Air Force). He has been a leader in the effort to strengthen the global influence of the IEEE, through the International Committee on Electromagnetic Safety (ICES) in developing international consensus standards for safe use of electromagnetic energy. He is also a leader in the global effort by the ISM community to resolve the RFI issues accompanying the shared use of ISM bands by wireless systems and ISM equipment.



Limits and experimental values of SAR for high frequency radiation (ICNIRP recommendation)

ISH Institut für Strahlenhygiene

Exhibit B

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October 20, 2013

Office of the Secretary, Federal Communications Commission

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Dear Sir:

I have been asked by Sensormatic Electronics, LLP, to communicate to you my assessment as to whether any serious injuries or deaths of patients implanted with electronic cardiac devices, including pacemakers (PMs) and implantable cardioverter defibrillators (ICDs), have occurred due to interactions with electronic article surveillance systems (EAS) since 1998, and, more generally, to comment upon the efficacy of the 'don't linger/don't lean' advice communicated to cardiac implant patients with respect to those devices.

In 1999, we published (Groh et al. Interactions between electronic article surveillance systems and implantable cardioverter-defibrillators. Circulation 1999; 100:387-392) a study of 170 ICD patients interacting with EAS that included a literature review up to that time. My colleagues and I concluded that, "It is safe for a patient with an ICD to walk through electronic article surveillance systems. Lingering in a surveillance system may result in an inappropriate ICD shock." Therefore, if one did not linger or lean on the surveillance system, a non-rushed walk through was safe. That was my view then, and continues to be my view as of today.

The result of my literature search since that publication is as follows:

Occhetta et al. (Inappropriate implantable cardioverter-defibrillator discharges unrelated to supraventricular tachyarrhythmias. Europace. 2006; 8:863) reported on 13 inappropriate shocks following exposure to external magnetic interference in 336 patients implanted with ICDs but found no patient received a shock as a result of electromagnetic exposure to an EAS system. Kolb et al. (PACE 2001; 24:465-468) reported a similar experience in a retrospective study of 341 patients.

However, Gimbel and Cox reported (Mayo Clin Proc 2007; 82:318) two patients with inappropriate responses of implanted devices after contact with a Sensormatic EAS system. One patient received two shocks from his ICD during a 30-second period while being exposed to an EAS during shopping in the automotive center of a large commercial retail store. The second patient was pacemaker dependent and, pausing between the pedestals of the EAS system, had multiple syncopal spells due to inhibition of pacemaker output by the EAS. The authors recommended more obvious signage and openness of the presence of an EAS system, and not

positioning items of interest close to the EAS system that would encourage lingering. My interpretation of these two cases is that in both instances the patients did not heed the admonition about not lingering near the EAS.

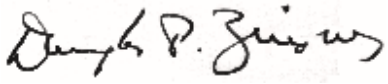
I polled pacemaker and ICD expert colleagues for their experiences. Of the eight responders, two remembered an untoward experience. One emailed, "I have a recollection of a patient I saw approximately 8 years ago – I'm sorry, I don't have further details or recordings. He was a patient with a dual chamber ICD who was pacemaker dependent. He experienced severe presyncope (i.e., almost fainting) that correlated with the exact moment he was exiting a retail store where an electronic article surveillance system was in use. His device interrogation demonstrated noise sensing consistent with electromagnetic interference, with inhibition of ventricular pacing resulting in transient ventricular asystole. The episode was short lived, hence, ventricular arrhythmia detection/therapy did not occur. As far as I can recall, he had no long term consequences." The second expert emailed, "A patient of mine with the Telectronics META noted that when she went to pick up her husband at Home Depot she would stand at the entrance and lean on the transmitters and her heart rate would go up to 120; she said that she felt as if she was in love!" She had no harm from the interaction, however.

In my attendance at scientific sessions in electrophysiology over the past decade, I do not remember having seen, nor heard, any suggestion that the exposure of patients with implanted cardiac devices to electronic anti-theft systems is a source of concern. To the contrary, it is the widespread understanding in the medical community that cardiac implant patients simply need to avoid lingering near, or leaning on, such devices. This conclusion has made the risk a non-issue. In fact, that is the advice I give to my own patients and, to my knowledge, the advice given by my colleagues to their patients.

It is my opinion to a reasonable degree of medical certainty that medical implant patients would be ill-served if the government were now to suggest in any way that cardiac implant patients are at risk in their routine interactions with electronic anti-theft systems. The patient anxiety that would follow any such suggestion would clearly have a harmful effect on patient quality of life, with no corresponding health benefit. Rather, appropriate signage, open display of the EAS, and education of patients with devices are the only necessary steps.

Thank you.

Sincerely,



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Ref: ET Docket Nos. 13-84; 03-137

Dear Sir or Madam, 11-18-13

It is my understanding that concern has been raised over possible interactions between cardiac arrhythmia devices and ambient sources of electromagnetic interference in society and the work place. By way of introduction I should note that I am now in my 51st year in the practice of Cardiology and have dealt with the evolution of cardiac arrhythmia devices since their inception with the first pacemaker insertion in Mr. Arnold Larsen of Stockholm Sweden on October 15th 1958. I am currently a full Professor at Harvard Medical School and during my profession career, I have personally performed or supervised the implantation of over 18,000 arrhythmia devices of all modes of complexity and trained approximately 100 of the current device implanters in this country and abroad. I was one of the four founders of the society that was originally known as NASPE (North American Society of Pacing and Electrophysiology) and now known as The Heart Rhythm Society and served as its first and second president. I continue to play an active role in that society and have attended each annual scientific annual meeting during the 35 years of its existence. I serve as a senior physician at this hospital and remain in the active practice of clinical cardiology.

That electronic interactions between cardiac arrhythmia devices and the environment of their bearers in public and work sites cannot be denied. These arrhythmia devices possess sensing circuitry in order to correctly identify intra-cardiac electrical signals in order to modulate the performance of the device function. Protective circuitry against extraneous sources of electromagnetic interference external to the bearer are provided to these devices through shielding and a Zener diode. Case reports continue to accumulate in the professional literature that devices such as cell phones, ipods, gasoline powered lawn mowers, exposure to strong magnetic fields etc. may, under specific circumstances, be shown to cause momentary alterations in arrhythmia device function. A substantial number of these reports require <u>intentional</u> and <u>unnatural application</u> of the EMI source directly to or within short distances of the arrhythmia device in order to provoke a finding. A common observation is suppression of a single pacemaker stimulus or a short,

limited increase in pacing rate, conditions that occur naturally in the human population without such implanted arrhythmia devices.

Medical reports of such occurrences have diminished in recent years after a flurry of interest in the past. The advice to patients with pacemakers or defibrillators to avoid potential sources of strong electromagnetic fields appears to be sound and this respondent is unaware of any substantiated deaths or physical injury incurred under such accounts. Patients should be advised: "Don't Lean, Don't Linger" in areas where such EMI may be perceived to be present. News media reports have tended to take isolated reports of such interaction out of context and without corroboration of the circumstances and such reports wreak havoc in the minds of the patient population that may become fearful of public transit leading to an "electronic" version of Agoraphobia.

To this respondent's knowledge there has been no new, documented instances of harmful interactions between arrhythmia device patients and sources of electromagnetic interference. I do not believe that it serves the public interest to resurrect this topic once again in the absence of any new data of concern.

Yours truly,

J. Warren Harthorne

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HISTORICAL BACKGROUND:

The evolution of cardiac arrhythmia devices (Pacemakers and Defibrillators) was surely one of the most significant medical triumphs of the last century. Tens of thousands of lives have been saved and improved upon by these miraculous devices. The initial systems were simple, asynchronous devices consisting only of an output circuit and timing circuit that stimulated the heart constantly at factory set rates regardless of intrinsic cardiac rhythms. The invention of the sensing circuitry by Barough Berkovits (1.) led to the era of the "demand", or non competitive devices. In such systems, the pacing lead not only carried the output stimulus to the heart chamber but served as an antenna through which spontaneous cardiac rhythms inhibit or alter the output circuitry. Unipolar devices, because of the larger dipole subtended between the cathodal electrode in the heart and the anodal contact at the pulse generator were then, and are now, more vulnerable to extra cardiac signals that include pectoral muscle contractions in the vicinity of the pulse generator and extrinsic electromagnetic fields generated by extracorporeal sources in the patient's environment. Bipolar devices, because of the short dipole between the intracardiac lead anode and cathode are less vulnerable to such signals. While it is true that unipolar generators are no longer manufactured, it must be recognized that, through programmability, a bipolar device can be programmed to the unipolar mode if clinical circumstances dictate this. Extensive efforts have been made by the manufacturers to screen out such undesirable effects on device function. Even within the heart, it is essential that sensing circuitry distinguish between selected components of the cardiac cycle (QRS, T waves, P waves, premature atrial and ventricular contraction and cardiac arrhythmias such as fibrillation in the atria or ventricles and various forms of tachycardias). The development of dual chamber pacing systems provided a "learning curve" for physicians and engineers alike. It must be remembered that the stimulus in the atrial chamber occurs in volts whereas the sensitivity settings of the ventricular channel is adjusted in milli-volts leading to a problem of "crosstalk inhibition" in which the stimulus in the atrium is detected by the ventricular sense amplifier causing cessation of ventricular stimulation with resultant asystole. Various innovations of avoiding this occurrence included committing the ventricular channel to stimulate whenever an atrial stimulus has been issued. Examples included the Cyberlith device of Intermedics and the Pacesetter Programalith. The concept of "blanking" on the ventricular sense amplifier coincident with emission of the atrial stimulus has essentially eliminated this problem. (2.). Modern day dual chamber pacemakers, although not totally free

of erratic sensing characteristics offer millions of programmable options that can resolve nearly every circumstance.

ENVIRONMENTAL ELECTROMAGNETIC INTERFERENCE:

The problem of electromagnetic interference with pacemaker circuitry has been recognized for many decades. The extensive use of electrical equipment in a hospital environment makes this a common source of concern. Simple and common examples in the operating room include the interaction of pacemaker sensing circuits with surgical electrocautery which may cause device inhibition, tracking by atrial sensing circuitry to cause a temporary increased in pacer rate while the cautery is in use, actual destruction of the pacemaker circuitry or initiation of inappropriate defibrillation of the patient when defibrillators have not been programmed off during such surgical procedures. Protective measures in the operating room may involve avoidance of use of electrocautery, application of a magnet over the pulse generator to cause it to stimulate asynchronously, selective positioning of electrocautery ground plates, use of bipolar electrocautery or to use the cautery in short bursts to minimize sustained effects on the arrhythmia device. Despite such precautions, some devices will revert to a "backup" mode and require re-programming post operatively. Other examples of medical devices that may cause interference or device damage include the hyfrecator, and diathermy.

Magnetic resonance imaging cannot yet be done safely in the device recipient. Aside from damage to the pulse generator, the strong magnetic field can heat the lead systems and cause myocardial burns with alteration of stimulation threshold. Death has been reported. One manufacturer has developed a pacemaker that is immune to magnetic resonance imaging yet the lead is bulky and difficult to manipulate.

Isolated case reports of transient effects on pacemaker devices that cause skipped stimuli or acceleration of pacing rate when there is close apposition of the offending item to the pulse generator (cell phones, ipods etc), while they provide inflammatory news headlines are often the result of diligent attempts to produce such an effect and of little practical importance in the every day lives of device recipients. This writer has often acknowledged the possibility of taking any device recipient into his garage (where there are a variety of electric power tools and gasoline powered garden instruments) to demonstrate transient alteration of arrhythmia device function. Such a patient would have to be maniacal or suicidal to participate in such an experiment.

AVOIDANCE OF ELECTROMECHANICAL INTERFERENCE

"DON'T LEAN, DON'T LINGER" is the standard advice issued to patients who approach or sense that they are in an environment in which extracorporeal energy may affect their cardiac arrhythmia devices. Sources of potential interference are identified in Table 1.(3.)

NATURE OF INTERFERENCE	EXAMPLES
Electrically Coupled	Electrical appliances with large motors Gasoline powered lawn mowers Gasoline powered saws High voltage power lines Ham radios Arc Welders Cell phones Metal detectors
Magnetic	Large electromagnets Powerful and large loudspeakers Induction furnaces used in industry Large generators Magnetic Resonance Imaging
Galvanic	Defibrillation / Cardioversion Electrocautery Diathermy TENS Devices Workplace(electrical/computer industry Household (current leakage form defective wiring
Ultrasonics and subsonics	Ultrasound equipment Lithotripsy
Ionizing radiation	Therapeutic Radiation
Miscellaneous	Ablation: radiofrequency or direct current Electro-acupuncture Electroshock therapy Electronic article surveillance Radar

In most instances, for these sources of EMI to alter the function of an implanted arrhythmia device, there needs to be close proximity between the source and the device. Thus, although it has been shown that interactions with cell phones or ipods can cause single beat pauses, the simple act of separating the emitting device 6 inches away from the pulse generator eliminates this problem. A tabulation of interventions that may minimize EMI impact on arrhythmia device is seen in Table 2.(4.)

FACTORS INFLUENCING ELECTROMAGNETIC INTERFERENCE

CONTROLLABLE FACTORS:
1.) Programmed parameters:
-Sensitivity Settings
-Sensing Polarity
-Pacing Mode
-Refractory Periods
-Blanking Periods
-Committed Cross Talk Detection window
-Sensor Settings
2.) Distance of Position of the Patient
3.) Duration of the Exposure
LESS CONTROLLABLE FACTORS:
1.) Intensity of the EMI Field
2.)Non programmable Device characteristics and settings
3.) Frequency of the signals
4.) Zener diode
5.) Lead Configuration
6.) Access Codes, Parity Links, and Reed Switch Closure

IMPACT UPON THE PATIENT:

The news media are not to be relied upon to present any data relative to demonstrable flaws in device function or manufacturing errors in an objective and cautious manner. Those patients whose cardiac stability is supported by such devices are often terrorized by inflammatory presentation of potential failure modes that lack basic statistical analysis of occurrence frequency. A single leading edge failure of new technology seems enough to open the flood gates of national reportage that infers that a maelstrom of unforeseen electronic mayhem is about to descend on an elderly population of device recipients. The occurrence of any of the foregoing examples of device interaction with ambient electromagnetic sources of energy in established case reports is rare to non existent. Recognizing that a majority of arrhythmia device recipients are no longer in the work force due to age or concurrent illness eliminates the vast majority of industrial exposures. That electronic article surveillance equipment has led to brief alterations in device performance has been demonstrated in the past(5.) yet simply walking through such systems or airport screening devices eliminates most interactions. Point of sale interactions at cash registers, RFID technology and barcode readers have merited isolated case reports yet, recognizing the frequency with which such interactions must occur in every day life suggests that there is little reason for clinical concern over device recipients who shop and pay bills multiple times each day.

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November 7, 2013

Office of the Secretary
Federal Communications Commission
445 12th Street, SW
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Re: ET Dockets No. 13-84; 03-137

Ladies and Gentlemen:

I am the David J. Carver Professor of Medicine, and Professor of Biomedical Engineering and Radiology at the Johns Hopkins Medical Institutions. My areas of expertise include Cardiology, Cardiovascular Disease, Electrophysiology, Medical Devices, and Heart Disease. I am also a Distinguished Scientist and Fellow of the American Heart Association and past chair of the AHA's Advanced Cardiovascular Life Support Subcommittee. I am also a Fellow of the Heart Rhythm Society. I have authored or co-authored over 140 peer-reviewed publications and have received more than 45 issued patents.

I write, first, to share with you the fruits of my review of the current scientific literature, which confirms that, since 1998 -- when the American Heart Association expressly noted the absence of any serious injuries or deaths of cardiac implant patients linked to electronic anti-theft systems -- no such serious injuries or deaths have been reported in the literature.

Second, I want to note that, in my attendance at scientific sessions over the past decade, I have neither seen, nor heard, any suggestion that the exposure of cardiac implant patients to electronic anti-theft systems is a source of concern. To the contrary, the widespread understanding in the medical community is that cardiac implant patients simply need to avoid lingering near, or leaning on, such devices. Implementation of that advice has effectively made this a non-issue. That is indeed the advice that we at Johns Hopkins give to our own cardiac implant patients and, to my knowledge, it is the advice given by our colleagues at other institutions to their cardiac implant patients.

Third, I want to make it clear that cardiac implant patients would be ill-served if the government were now to suggest in any way that cardiac implant patients are at risk in their routine interactions with electronic anti-theft systems. The patient anxiety that would follow any such suggestion would clearly have a harmful effect on patient quality of life, with no corresponding health benefit, and no real data to support such a suggestion.

Respectfully submitted,

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