BEFORE THE

FEDERAL COMMUNICATIONS COMMISSION

WASHINGTON, DC 20554

In the Matter of Veroscan Inc. Request For Waiver of Section 15.247(b)	ET Docket No. 07-257

REPLY COMMENTS OF MEDTRONIC INC.

Medtronic Inc. respectfully submits these reply comments on the Veroscan Inc. request for waiver of FCC Rule Section 15.247(b). Veroscan is asking the FCC to allow a 10 dB (or greater) increase in radiated power that Veroscan claims is needed to reliably operate an RF identification ("RFID") tracking system at 902-928 MHz to locate tagged medical items, such as surgical sponges, in hospital operating rooms ("ORs"). Although Medtronic recognizes the potential usefulness of such a system, it is concerned that such a substantial increase in radiated power could create electromagnetic compatibility ("EMC") issues with active implantable medical devices ("AIMDs") and critical medical electrical equipment in ORs. Medtronic also is concerned that the Veroscan system appears to greatly exceed the FCC's RF exposure limits. Though these EMC and RF exposure concerns raise significant patient safety issues, Veroscan has not provided information sufficient to fully assess them. As described below, the Commission should request additional technical information regarding the Veroscan system,

including reliable emissions testing and an RF exposure environmental assessment, followed by another round of comments before considering further Veroscan's request.

EMC Concerns. Many of the opening commenters note that Veroscan's proposed operation emits substantially more power than most low power personal communications devices, such as wireless handsets, that are forbidden in many hospitals for fear of interfering with vital medical electrical equipment.[1] Indeed, a typical wireless handset radiates at a power level approximately 20 dB below the EIRP level that Veroscan is proposing.

Not surprisingly, the U.S. Food and Drug Administration states that "the increased emissions from the Veroscan device could cause electromagnetic interference (EMI) to nearby active medical devices that might compromise patient safety."[2] In fact, the potential adverse effects are heightened because the Veroscan "wand" will be waved over (and in many cases in direct contact with) patients – centimeters away from AIMDs. Veroscan has not shown that the electromagnetic fields that its system generates will not cause interference to the normal functioning of implanted devices and other medical electrical systems in the OR. Based on the

---

[1] *See, e.g.*, Comments of U.S. Dep't of Health & Human Services, Food and Drug Administration (Dec. 13, 2007) ("FDA Comments"); Comments of Nonin Medical Inc. (Dec. 11, 2007).

Section 15.247 permits a digital device to operate in the 902 – 928 MHz band with an EIRP of up to 4 watts (*i.e.*, 6 dBW). The Veroscan device has an output power of 25 watts and employs an 8 dBi gain antenna, yielding a maximum EIRP of 157 watts (*i.e.*, 22 dBW). Veroscan claims that the device has a 25% duty cycle that will result in an average power of 6.25 watts into the antenna for an average EIRP of approximately 40 watts (*i.e.*, 16 dBW). This device far exceeds the radiated power limits for *licensed* RFID systems. *See* 47 C.F.R. § 90.205(k).

[2] *See* FDA Comments at 1. The FDA also notes that the increased power levels from the Veroscan system "may present an increased potential for adverse effects on critical medical devices such as life-supporting and monitoring equipment that are likely to be used in proximity to the Veroscan device." *See id.* The FDA comments are based on extensive laboratory testing that was performed in conjunction with the Association for Advancement of Medical Instrumentation (AAMI) Cardiac Rhythm Management Devices Committee EMC Task Force.

limited information currently available, the fields produced by the Veroscan system will exceed the levels medical electrical equipment and AIMDs are required to withstand pursuant to the applicable industry standards.

While medical electrical equipment is typically evaluated for RF immunity in fields of either 10 volts/meter or 3 volts/meter, operation of the Veroscan equipment at the proposed power levels could subject medical electrical equipment to far greater fields,[3] possibly interfering with normal operation. According to the ANSI IEC 60601-1-2 Standard,[4] a 902-928 MHz system operating with 25 W transmitter output power should be kept at least **11 meters away** from both life-supporting and non-life-supporting medical electrical equipment to avoid adverse interaction with medical electrical equipment. Adverse interactions between the Veroscan system and medical electrical equipment used for life-support and/or physiological signal monitoring as well as patient AIMDs could lead to equipment malfunction and impact patient safety.

Additionally, AIMDs such as implantable pacemakers and defibrillators are designed to sense very low level physiologic signals and detect peak signal levels. The RF energy levels that the Veroscan system emits may cause AIMDs to inappropriately sense such unwanted energy

---

[3] 47 C.F.R. § 15.5(b). Certain equipment in ORs such as medical implant devices and programmer/controllers for such devices that operate in the Medical Implant Communications Service (MICS) are licensed by rule under Part 95 of the Commission's Rules. MICS systems are entitled to protection from interference from Part 15 devices.

[4] American National Standard ANSI/AAMI/IEC 60601-1-2:2007, Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral standard: Electromagnetic compatibility —Requirements and tests (May 2007) ("ANSI IEC 60601-1-2 Standard") Tables 5 and 6, Recommended separation distances between portable and mobile RF communications equipment and medical electrical equipment for life-supporting and not life-supporting medical equipment, respectively (assumes 0 dBi antenna); *see also id*. at § 4.1.1 (medical electrical equipment shall not emit EMI that could affect the "essential performance" of other medical electrical equipment).

and alter the therapy being delivered to the patient.[5] Unnecessary sensing in a pacemaker may lead to inhibition – and potentially the cessation of pacing – or asynchronous pacing – possibly competing with the heart's natural rhythm. Unnecessary sensing in an implantable defibrillator may cause the device to deliver an inappropriate high voltage therapy.

While the FCC rules do not protect Part 15 digital devices from interference caused by other Part 15 devices, before the Commission can make an informed decision in the public interest as to whether to waive the power limits to permit a Part 15 device such as that proposed by Veroscan to operate with greater power levels than the Section 15.247 limits, the agency must assess and account for the RF environment in which the device subject to the waiver will be operated. Veroscan should therefore submit data providing details of its radiated signal EIRP, duty cycle provisions relating to signal format, and time averaging provisions relating to RF exposure.[6] The Commission also should also consider *in situ* measurements to observe the impact on common medical electrical equipment in ORs. As the ANSI IEC 60601-1-2 Standard notes, high level emissions that impact the proper operation of medical electrical equipment "interfere[] with the practice of medicine and cannot be considered an acceptable situation."[7]

RF Exposure Concerns. The FCC's regulations establish separate maximum permitted exposure ("MPE") limits for the "general population" (or "uncontrolled" exposure) and for "occupational" (or "controlled exposure") use. *See* 47 C.F.R. § 1.1310. The general population limits provide the maximum exposure to which most people may be subjected. Several of the

---

[5] *See* American National Standard ANSI/AAMI PC69:2007, Active implantable medical devices—Electromagnetic compatibility—EMC test protocols for implantable cardiac pacemakers and implantable cardioverter defibrillators (Apr. 2007) ("ANSI PC69 Standard")..

[6] *See* ANSI PC69 Standard.

[7] ANSI IEC 60601-1-2 Standard, Introduction.

opening round of commenters noted that Veroscan's requested increase in radiated power would exceed the general population limit for RF exposure.[8] Thus, the Veroscan system, as proposed, is restricted to operation under the higher occupational or controlled RF exposure limits, as Veroscan concedes in its December 13, 2007 submittal.[9]

The occupational limits are for persons exposed to RF as a consequence of their employment, such as RF technicians and engineers, public safety personnel, and, in the case of Veroscan, perhaps medical personnel. In order for Veroscan to take advantage of the occupational limits for purposes of deploying its system, it would need to provide training on the RF exposure potential of the transmitting wand to medical personnel that would use its system (as well as other medical personnel that would be near the equipment during operation) so they can, if possible, manage their exposure during operation. While the patient in the OR would not be considered an occupational user, the higher exposure limits could apply to situations where an individual is passing through a location so long as the individual is made aware of the potential for exposure such as through use of prominent warning labels. The Commission will need to consider whether a patient subjected to the heightened RF exposure limits for up to six minutes at a time would be considered to be "passing through the location of heightened exposure" for it even to be possible for the occupational limits to apply to patients.

Given the RF exposure concerns raised by many parties to this proceeding, the FCC should require Veroscan to submit an Environmental Assessment ("EA"). *See* 47 C.F.R. § 1.1307(d) (giving the Bureau responsible for processing the application, here OET, authority to

---

[8] *See, e.g.,* Comments of Kristopher Kirby (Dec. 3, 2007); Comments of Carlton Davis (Nov. 19, 2007).

[9] *See* Veroscan Inc. Letter (Dec. 13, 2007).

require the applicant to submit an EA where there will be a significant environmental impact). Such a requirement would be completely justified in this circumstance given that Veroscan's proposed operation may exceed the FCC's applicable safety standards for human exposure to RF radiation. *See* 47 C.F.R. § 1.1306(b)(3). Such a requirement also is supported by Veroscan's December 13, 2007 submittal showing very high incident RF exposure power levels.

CONCLUSION

Before the Commission can assess the potential impact of Veroscan's system in hospital ORs and on AIMDs, it must address the EMC and RF exposure issues outlined above. The Commission should require Veroscan to conduct an EA regarding the RF exposure impact and to demonstrate emissions compatibility with medical electrical equipment and AIMDs as outlined above (*i.e.*, the ANSI IEC 60601-1-2 and ANSI PC69 Standards). Laboratory measurements and possibly *in situ* testing may be needed to assess the impact of Veroscan's high-powered RFID system on patient AIMDs and medical electrical equipment in hospital ORs.

Respectfully submitted,

MEDTRONIC, INC.

By: David E. Hilliard

David E. Hilliard
John W. Kuzin
Wiley Rein LLP
1776 K Street, NW
Washington, DC 20006
Its Attorneys

December 28, 2007