GUIDANT

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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Subject: Boston Scientific CRM Response to FDA RF Wireless Guidance Document
Docket No. 2006D-0504

Dear Sir or Madam,

Boston Scientific Corporation (BSC) CRM would like to respond to the *Radio-Frequency Wireless Technology in Medical Devices Draft Guidance for Industry and FDA Staff* that was released on January 3, 2007.

The company welcomes and supports the FDA's efforts to advance the capabilities and quality of medical device using wireless telemetry. These technologies, if implemented wisely, have the potential to significantly improve patient care. This guidance is a welcome attempt to provide assistance to manufacturers in the development of reliant, capable telemetry systems intended for transmission and reception of command and data streams through environments with multiple potential interference elements in an increasingly wireless world.

Boston CRM's remarks are structured into general comments regarding the intent of the guidelines and are followed by specific comments for each section and appendix.

Sincerely,

Nicholas J. Horvath

Nicholas J. Horvath
Director, Regulatory Affairs
Boston Scientific Corporation
Cardiac Rhythm Management

Guidant Corporation
4100 Hamline Avenue North
St. Paul, MN 55112-5798
lari.tieso@guidant.com
www.guidant.com

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General Comments:

- BSC has observed that there can be some situations which at first look may appear to be telemetry related, but are in fact driven by other causes (for example, EMI or ESD events which activate fallback systems which appropriately direct the system to change it's operating parameters or mode). Experiences such as these are generally unrelated to telemetry system reliability. Guidance should carefully differentiate between a true telemetry interference issue and device response to other causes.

- The guidance document focuses on telemetry systems that involve propagating Radio Frequency (RF) waves. Some systems use short range magnetic waves with amplitudes that fall off dramatically with distance. These magnetic or inductive systems have different requirements and should have some separate section in the guidance addressing these unique concerns.

- The Active Implantable Medical Device (AIMD) industry has principally used low frequency magnetic or inductive based telemetry systems. As technologies develop, these AIMD products are only now transitioning to increasing usage of typically higher, radio frequency bands. The value of this guidance can be improved by addressing all potential electromagnetic based technologies and frequency bands. References or exclusions of specific bands may be perceived to indicate that the FDA has specific preferences for medical usage of these bands. BSC believes that regardless of the band or technology used, a risk based approach should be equally and broadly applied to assure that requirements and operation of telemetry systems are fully characterized.

- There is no discussion about the medical impact of wireless transceivers implanted in the body. There are measures available to characterize body absorption. Typically referred to as Specific Absorption Rate (SAR), it is the measure of the rate at which radio frequency (RF) energy is absorbed by the body when exposed to radio-frequency electromagnetic field. In the United States, the Federal Communications Commission (FCC) has adopted limits for safe exposure to RF energy produced by mobile devices and requires that cellular phones sold in the U.S. have a SAR level at or below 1.6 watts per kilogram (W/kg) taken over a volume of 1 gram of tissue. Although there may be limitations to SAR measurements, some linkage to current or future FCC requirements in this area may be helpful.

- While guidelines discuss the fact that wireless telemetry systems will likely be required to operate and co-exist in shared frequency bands, the scope of the guidelines may create the perception that the FDA has preferences for operational bands. For example some devices operate under the auspices of FCC Part 15 rules. BSC currently successfully operates devices under these rules with minimal problems from interference. The company strongly believes that wireless telemetry systems need to be able to operate in the presence of both intentional and unintentional in-band interference regardless of the band used. To our knowledge there is no frequency band

[Including MICS, (MedRadio), ISM, and WMTS] today where medical devices would operate under sole use; all bands have shared primary and secondary users.

- The guidelines should allow for progressive but thorough testing methodologies for complex issues such as EMI. Trying to characterize and test the myriad and evolving sources of interference with conventional testing is nearly impossible. Modern testing methods such as laboratory signal generation or advanced virtual simulation is likely to be the best option going forward.

Section specific comments:

- Section 1: Introduction
  - Use of "Least Burdensome Approach"
    - A statement should be added to the guidance which reflects the rapid evolution of wireless telemetry technology. It is important that the guidance does not inadvertently have the effect of hampering the development and use of new developments in the communications field. This guidance is intended to foster the development of safe and reliable use of RF communications systems in medical products. In the event that new technologies effectively mitigate some of the issues identified herein, it should be clear that the guidance is not intended to prescribe activities no longer relevant or to preclude the use of better technologies where practices described herein are not longer effective or practical.

- Section 2: Scope
  - The list of current wireless technologies does not have an explicit reference to FCC Part 95 (47 CFR 95) MICS ("MedRadio") rules and frequency bands. If frequency bands or protocols are specifically identified, this band should be included. Likewise, WMTS is not mentioned.
  - The list of current wireless technologies combines discussion of products (e.g. cellular phones) with types of services (e.g. WMTS). The devices should be separated from the wireless technologies that they use. The type of device and its application may limit the choice of appropriate bands. The guidance could be improved by making this distinction.
  - The guidelines contain no planning/testing considerations for future/evolving technologies that are yet to be developed.
  - The guidelines should clarify that both inductive based and far-field RF telemetry systems are within scope similar to how the scope of FCC rules regulate these areas.

- Section 3: Definitions
  - The guidance could be improved by using definitions common with other major regulatory and standards bodies.
  - For example, use of terms such as "EMI" and "EMC" should be aligned with FCC or IEEE definitions.
  - Definitions should reference sources where appropriate and exceptions or deviations to accepted industry usage should be clearly noted.
  - For example, IEEE 802.15.2 is the IEEE attempt to define coexistence methods for WLAN and WPAN. According to the IEEE web site, this effort is now 'hibernated', so the reference should be removed.
- Section 4: Concerns Related to RF Wireless Technology Use in and Around Medical Devices
  - First paragraph - The guidelines state that "in general, a wired connection is more reliable than a wireless connection". This is an overly broad statement and does not address elements such as availability, capability, capacity, etc. all of which have a significant impact on the value of any particular data transfer method. BSC recommends removing this incomplete comparative.
  - Page 7 - The guidelines state that "FDA recommends wireless medical devices limit their RF output to the lowest power necessary to reliably accomplish their intended functions" but makes no statements about other potential design strategies such as limitation on transmission times and/or duty cycles. Clearly there may be competition between reliable transmission and power limitations. This is an example where the guidance could be fashioned to encourage the development of new ideas and strategies for RF telemetry methods. The current language with this broad recommendation may discourage innovative design methods for improving wireless transmission reliability.
  - Page 8 - Wireless coexistence - The guidelines state that FCC Part 15 rules may be problematic in that the FCC can reallocate bands and introduce new primary users. These frequency band migrations are well planned and publicized events, for example the recent WMTS band migration. Such moves are not unique and the FCC has well publicized transition plans for these events. BSC does not believe that this is a unique event to FCC part 15 users, but rather should be one aspect of system design considerations where practical.
  - Page 7 – Performance of Wireless functions and Page 9 – EMC – BSC designs AIMDs under 45502-2-2 and are exempted from the IEC 60601-1-2:2001 standard. In cases like this, not all medical devices will fall under the 60601-1-2 standard.
  - Page 9 - Integrity of Data Transmitted Wirelessly – address the following:

- BSC does not feel that the document sufficiently addresses the issue of data integrity. The document speaks to noise, signal level and bit error rate but does not speak to how the system handles bit errors. This property can be a vital strategy for assuring accurate information transfer and can be quantitatively evaluated.
- Data integrity is only part of a design program. Other engineering methods can be applied to minimize the impact of data integrity degradation. For example, specifying command error rate under distinct conditions such as:
  - Quantifying the probability of a command being executed incorrectly.
  - Quantifying the probability that the device will interpret noise as a command and execute it could be an effective quality strategy.
  - Quantifying the impact of ignoring a command in the presence of a bit error could prove extremely insightful.

- Section 5: Risk Management for RF Wireless Medical Devices: General Concepts
  - No comments

- Section 6: Design and Development
  - Page 12 – In order to better understand the definition of wireless quality of service, consider editing the 4th bullet to read "Wireless Quality of Service (e.g. Amplifying parameters such as noise, signal level, and bit error rate*)" (Page 12, section 6, 4th bullet)*
  - Page 13 - Environmental requirements – The Guidance should specifically state that given the highly variable EMI characteristics for the various workplace environments, the obligation to characterize all possible workplace environments is unreasonable. It should be clear that the guidance is not asking manufacturers to characterize every workplace environment. There must be a role for labeling as a practical measure of precluding use in clearly unacceptable environments.

- Section 7: Design and Development Verification
  - Page 16 – The requirement to test "quality of service" is not adequately defined. Consider specifying testing recommendations in more detail (e.g. including signal to noise ratio).

- Section 8: Design and Development Validation
  - Bottom of Page 18 – Testing recommendations – Add a 5th bullet "Signal to noise Ratio"

- Section 9: Labeling
  - At the bottom of page 19, it lists "how testing was conducted" as a recommendation for material which belongs in labeling. It is unclear what "how testing was conducted" might incrementally add in situations where "conformance to existing standards" is already addressed. Perhaps examples in the guidance would provide clarity as to what is desired regarding reporting in labeling "how testing was conducted."
  - On page 20 of the guidance under the statement: "For medical electrical equipment and systems that include RF transmitters, FDA recommends you identify:" add as a 4th bullet "appropriate FCC number according to FCC rule used for licensing". This labeling requirement is an FCC Rule.
  - Labeling should be used as mitigation where all <u>practical</u> engineering steps have been taken to mitigate risk. By over application of the idea that no risk can solely be mitigated in labeling, the guidance could preclude the use of this technology altogether. As an example, patients with pacemakers are increasingly being subjected to MRI examination. BSC believes that the FDA should not preclude the use of pacemakers because the risks of MRI use may not be entirely mitigated by contraindication in labeling. Acceptable risk can only be accurately determined when weighed against probable benefit.
- Section 10: Purchasing Controls
  - No Comments
- Section 11: CAPA
  - Page 22 – Last paragraph of Section 11 - The draft states "When RF wireless or EMC problems are confirmed, you should redesign your device to prevent recurrence, which may include redesigning vulnerable circuits and possibly improving the device's RF shielding. FDA recommends labeling contain warnings or precautions to supplement the design changes." This seems overly prescriptive in nature; clearly redesign may be one result of the problem analysis, but this verbiage requires redesign. For example, Retail Theft Detection (EAS) systems and RFID systems are known to interfere with some AIMDs even though all of these systems comply with existing standards and FCC Rules. It is quite possible that certain interferences may not be correctable in the design of the medical device. For example, extremely high power noise generating sources, or sources which closely mimic the electrical activity of the heart.

- Section 12: Servicing
  - Pages 22-23 – The guidance might consider encouraging servicing to include sweeps of use facilities for manual interference source identification and mitigation. For example, in cases where implanted device RF systems have coexisting interference sources, the only option may be to shield or relocate the conflicting external system.

- Appendix A: Additional Information
  - There is no reference to FCC Part 95 (47 CFR 95) MICS, WMTS or MedRadio rules and frequency bands. All of these bands permit use by designated primary and secondary users and therefore are appropriate for inclusion here.
  - Appendix A lists ISO/TR 21730:2005(E); this has been replaced by ISO/TR 21730:2007

- Appendix B: Reference Standards & Telecomm Info
  - No Comments

At this point we would like to thank FDA for the work on this guidance and the opportunity to comment.