Guidance for Industry

Labeling for Electronic Anti-Theft Systems

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U.S. Department Of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Electronic Product Devices Branch
Division of Enforcement III
Office of Compliance

Preface

Public Comment

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Guidance[1] on Labeling for Electronic Anti-Theft Systems

August 15, 2000

Dear Electronic Anti-Theft System Manufacturer,

The purpose of this letter is to recommend that all manufacturers of electronic anti-theft systems develop labeling or signage to post on or near all new and currently installed systems, indicating that an electronic anti-theft system is in use. Such labeling or signage will permit implant wearers to avoid lingering around or leaning against systems that may affect their implanted electronic medical devices.

Interference concerns

Implantable electronic medical devices may be affected by the electromagnetic radiation produced by electronic anti-theft systems. The Food and Drug Administration (FDA) received 63 reports over the past 10 years describing electromagnetic interference (EMI) to implantable devices caused by various types of anti-theft systems. Of the 63 reported incidents, 49 were caused either by anti-theft systems, electronic article surveillance (EAS) systems, or security systems. The affected devices in these reports included pacemakers, neurological stimulators, and implantable cardioverter defibrillators. Examples of the reported effects on the device included changes in the rate of stimulation (e.g., increase of pacing rate), changes in the level of stimulation (e.g., neurological over or under stimulation), and changes in the mode of stimulation (e.g., reprogramming). Examples of reported effects on the implant wearer range from unconsciousness and sensation of pain, to wearers being unaware that an interaction occurred. These effects on the implant and the wearer are typically transient and unlikely to cause clinically significant symptoms in most wearers.

Collaborative efforts

At the 1998 and 1999 meetings of the Technical Electronic Products Radiation Safety Standards Committee (TEPRSSC), local and federal government agencies, the anti-theft industry, and the medical community came together to address this issue in a public forum. The TEPRSSC urged each of the stakeholders in this issue to work together, research the

[1] This document is intended to provide guidance. It represents the Agency's current thinking on the above. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

problem, and identify solutions to reduce the risk of EMI to implantable electronic medical devices.

The FDA sent a letter in 1998 containing important information for doctors and patients on the issue of anti-theft system interference with implantable devices. That letter affirmed recommendations made by the anti-theft system industry and medical community that implant wearers should practice "don't linger, don't lean" around electronic anti-theft systems. The FDA applauds the collaborative efforts put forth by the anti-theft industry and the medical community over the past two years to mitigate anti-theft system interference with implantable devices. More importantly, the FDA encourages your continued cooperation toward this effort.

Recommendations

The FDA recognizes that the likelihood of anti-theft systems interfering with implantable electronic medical devices is low. The number of adverse event reports indicates that a relatively small number of individuals have been affected within a large population of implant wearers. Further, the reports describe a majority of the interactions as moderate or mild in nature, with little or no significant effect on the implant wearers.

In light of advances in implantable electronic device technology and increasing numbers of implant wearers, the FDA believes that implant wearers should be notified whenever and wherever electronic anti-theft systems are in use. The FDA recommends that anti-theft system manufacturers develop either labeling or signage that can be posted on or near new and installed anti-theft equipment to further reduce the risk of interference.

Examples of appropriate language for such labeling and signage may include: "ELECTRONIC ANTI-THEFT SYSTEM IN USE" or "ELECTRONIC SECURITY SYSTEM IN USE."

Anti-theft systems employing visible monitoring elements (e.g., towers) may simply have a label affixed to the surface of the element. Signage may be posted for systems employing either visible or concealed (e.g., installed in the walls or ceiling) monitoring elements. In either case, the FDA recommends that labeling or signage be positioned so that it is visible before an individual enters the monitored area. FDA also recommends that you include labeling and signage with all new equipment in addition to the signage provided to facilities wherever anti-theft systems are currently installed.

It is important that manufacturers of anti-theft systems, the retail industry, and the medical community continue to develop mutually agreeable solutions to this issue. The use of labeling or signage on electronic anti-theft systems will enable implant wearers to take appropriate precautions to further minimize the risk of interference, namely to avoid

lingering around or leaning on such systems. The labeling or signage may also provide an additional deterrent against theft while relaying this important information.

If you have any questions regarding this letter, please contact Sean Boyd, CDRH, Office of Compliance (HFZ-342), 2094 Gaither Rd., Rockville, MD 20850, sbb@cdrh.fda.gov (email), 301-594-4672 (fax).

Sincerely yours,

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Acting Director
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Cc: Implantable device manufacturers
Implantable device physicians
Retail industry groups