

Guidance for Industry

Wireless Medical Telemetry Risks and Recommendations

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

Electronic Product Devices Branch
Division of Enforcement III
Office of Compliance

Preface

Public Comment

Comments and suggestions may be submitted at any time for Agency consideration to, Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, Division of Enforcement III, 2094 Gaither Road, Rockville, Maryland. 20860. Comments may not be acted upon by the Agency until the document is next revised or updated. For questions regarding the use or interpretation of this guidance contact LT Sean Boyd, USPHS, at (301) 594-4654, ext. 128 or by electronic mail at SBB@cdrh.fda.gov.

Additional Copies

World Wide Web Center for Devices and Radiological Health (CDRH) home page: <http://www.fda.gov/cdrh/comp/guidance/1173.html>, or CDRH Facts on Demand at 1-800-899-0381 or 301-827-0111, specify number 1073 when prompted for the document shelf number.

Guidance¹ on Wireless Medical Telemetry Risks and Recommendations

To Wireless medical telemetry manufacturers

Subject Wireless medical telemetry risks and recommendations

Purpose

This notice informs you that the wireless medical telemetry systems you manufacture may be at increased risk of electromagnetic interference (EMI) from other in-band radio-frequency (RF) sources. To address this risk, the Federal Communications Commission (FCC) created a new Wireless Medical Telemetry Service (WMTS) that will allow medical telemetry systems to operate on an interference-protected basis. FDA recommends that you conduct a risk analysis and take action to reduce the risk of interference to your wireless medical telemetry. FDA also urges you to consider using the new WMTS for both new and existing equipment to minimize this risk.

EMI risk

Currently, most wireless medical telemetry equipment operates as a secondary user in commercial broadcast TV bands and in the private land mobile radio service (PLMRS) band. Data from a survey conducted by the American Hospital Association (AHA) indicate that more than half of the existing wireless medical telemetry systems operate in the PLMRS band, with most of the remaining systems operating in VHF TV bands.

Unless appropriate action is taken, two FCC actions are likely to result in increased risk of EMI with wireless medical telemetry equipment operating in the TV and PLMRS bands. Specifically, the FCC is reallocating unused TV channels in the range of channels 7-13 (174-216 MHz) and 14-46 (470-668 MHz) to allow TV stations to test and transmit digital TV (DTV) signals. Additionally, the FCC is “refarming” (subdividing existing channels into multiple, narrower channels) the PLMRS band (450-470 MHz) for increased use, and will begin accepting applications for primary use of the 450-460 MHz portion of the band on January 29, 2001. As a secondary user in each of these bands, existing telemetry technology operating in unused local channels must accept interference from primary users and must not interfere with primary users. It is highly unlikely that wireless medical telemetry will interfere with TV or PLMRS transmissions. However, interference from TV or PLMRS transmissions can render wireless medical telemetry unusable.

¹This 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.

The problem of EMI with wireless medical telemetry gained attention when wireless medical telemetry systems at two hospitals in Texas were disrupted by DTV transmissions from a local TV station. FDA issued a public health advisory and a joint statement with the FCC in March of 1998 to describe the potential for interference between DTV and telemetry and to offer temporary solutions. As a result the AHA formed a Medical Telemetry Task Group with members from FDA, FCC and industry to develop long-term solutions to this problem. FDA/CDRH sent several letters to device manufacturers throughout this process to provide up-to-date information on these issues. This work ultimately resulted in a FCC proposal to establish the WMTS.

On June 8, 2000, the FCC adopted the Report and Order for amendment of parts 2, 15, 90 and 95 of FCC's rules to create the WMTS. The frequencies allocated for WMTS include TV channel 37 (608-614 MHz), as well as 1395 – 1400 MHz and 1429 – 1432 MHz. The WMTS minimizes risk of interference from in-band RF sources in two ways. First, the WMTS allocates spectrum for primary use by wireless medical telemetry. Second, the WMTS designates a frequency coordinator to maintain a database of WMTS transmitters and for notifying users of potential frequency conflicts.

Recommendations

FDA/CDRH strongly recommends that wireless medical telemetry manufacturers use the new WMTS for all products not yet introduced into the market. Use of the WMTS provides FDA assurance that the risk of interference from other in-band sources is minimized. To assist manufacturers in bringing products using the WMTS to market in a least burdensome manner, a guidance document titled “[Deciding when to Submit a New 510\(k\) for a Change to an Existing Wireless Medical Telemetry Device](#)” will be made available on the FDA/CDRH web site at <http://www.fda.gov/cdrh/>.

Wireless medical telemetry systems that are currently on the market present an immediate concern. Our information suggests that there may be more than 5500 facilities using existing wireless medical telemetry technology. We recommend that all manufacturers of wireless medical telemetry conduct a risk analysis and take appropriate action to reduce the risk of interference posed by other in-band RF sources to existing, installed medical equipment. Manufacturers should address the following:

1. Assess the risk of interference from in-band RF sources to your existing, installed wireless medical telemetry equipment.
2. Develop solutions to reduce the risk of interference.
3. Prevent distribution of existing equipment that is at increased risk of interference. (e.g. based on geographic area)

4. Prepare for inquiries from wireless medical telemetry customers on how to assess whether their equipment is at risk and what solutions are available to reduce that risk.
5. Diligently investigate incidents of electromagnetic interference with wireless medical telemetry systems that may have been caused by other in-band RF sources to determine root cause of the interference, where possible.
6. Verify and validate, where appropriate, action(s) to assure that they are effective in reducing the risk of interference, and that they do not adversely effect the function of the device.
7. Disseminate information regarding possible problems with wireless medical telemetry equipment resulting from interference to service personnel and customers.

Note that the FCC will not permit new wireless medical telemetry equipment manufactured after June 8, 2002, two years after adoption of the Report and Order, to operate in the TV or PLMRS bands. FCC will allow existing technology to continue to operate in these bands indefinitely. However, FCC strongly encourages migration of all wireless medical telemetry technology into the WMTS. We support the FCC in this regard and recommend that wireless medical telemetry manufacturers conduct a risk analysis and take action to reduce the risk of interference to existing, installed telemetry equipment within this two year timeframe.

Inspections

As resources permit, FDA plans to inspect manufacturers of wireless medical telemetry systems to verify that appropriate action is being taken to assess and mitigate EMI risks. These inspections will begin after December 8, 2000.

Reporting Adverse Events and Defects to FDA

Manufacturers are required to report deaths, serious injuries and reportable malfunctions within 30 days of becoming aware of a Medical Device Report (MDR) reportable event. A report is due within 5 business days if the event necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health. Thus, if interference with a medical device results in a death or serious injury, or is likely to cause or contribute to a death or serious injury in the event the interference recurs, it must be reported.

Getting More Information

If you have any questions regarding this notice, please contact LT Sean Boyd, CDRH, Office of Compliance (HFZ-342), 2094 Gaither Rd., Rockville, MD 20850, FAX 301-594-4672, or e-mail sbb@cdrh.fda.gov. FDA also issued a public health advisory dated July 10, 2000, to notify users of wireless medical telemetry equipment of the establishment of the WMTS and to provide recommendations to reduce the risk of interference with their equipment. The public health advisory is included with this guidance and is also available on FDA's web site at <http://www.fda.gov/cdrh/safety/emimts.html>.

For additional information regarding FCC issues, please contact Hugh Van Tuyl, FCC, Office of Engineering and Technology, 1919 M Street, NW, Washington, D.C., 20554, FAX 202-418-1944, or e-mail hvantuyl@fcc.gov. The Report and Order to create a Wireless Medical Telemetry Service, ET Docket 99-255, is available on FCC's web site at http://www.fcc.gov/Bureaus/Engineering_Technology/Orders/2000/fcc00211.doc. The announcement to lift the freeze on filing applications for use of the 450-460 MHz portion of the PLMRS band is also available on FCC's web site at http://www.fcc.gov/Bureaus/Wireless/Public_Notices/2000/da001360.doc.

Further information regarding electromagnetic interference and medical devices can be found on our EMC web page at <http://www.fda.gov/cdrh/emc/>. If you are interested in receiving Safety Alerts, Public Health Advisories and other FDA medical device safety notices by e-mail when they are released, subscribe to our list-server. To subscribe, please visit the page located at http://service.govdelivery.com/service/subscribe.html?code=USFDACDRH_10

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