FDA Public Health Advisory: Risk of Electromagnetic Interference with Medical Telemetry Systems

(You are encouraged to copy and distribute this information)

July 10, 2000

To: Director, Clinical/Biomedical Engineering
Risk Manager
Hospital Administrator
Nursing Home Director

I am writing to inform you that your existing wireless medical telemetry systems may be at increased risk of electromagnetic interference (EMI) if they continue to operate in the range of frequencies in which most medical telemetry devices are currently operating. To address this risk, the Federal Communications Commission (FCC) has created a new Wireless Medical Telemetry Service (WMTS) that will allow medical telemetry systems to operate on an interference-protected basis. We recommend that you evaluate whether your medical telemetry systems are at risk and take appropriate measures to reduce that risk. **We believe that the best way to accomplish this is to use telemetry systems operating in the new WMTS frequency bands.**

Background

Currently, most wireless medical telemetry devices operate as secondary users in commercial broadcast TV bands and in the private land mobile radio service (PLMRS) band. As secondary users, medical telemetry must accept interference from, and not interfere with, primary licensed users. Typically, if there is interference from a primary user, the medical telemetry system will be unusable. This happened in 1998 when DTV transmissions disrupted medical telemetry systems in two Texas hospitals. These frequency bands will be used more extensively by digital TV and high power PLMRS operators, which is likely to result in an increased risk of interference with medical telemetry. (For details of these actions, see the Additional Detailed Information Section at the end of this notification.)

Recommendations

We recommend that you determine whether your wireless medical telemetry systems are at risk of EMI and that you take appropriate action, if necessary, to reduce that risk. In doing this, we recommend that you consult with the telemetry equipment manufacturer. This action should include, at a minimum, determining at which frequencies your telemetry systems are currently operating (i.e., what frequency band, channel) and comparing that data with the frequencies allocated to digital television (DTV) in your area and the PLMRS band. A list of all DTV allocations can be found on the FCC web site http://www.fcc.gov/healthnet/dtv.html.

- If you and/or the telemetry equipment manufacturer determine that your medical telemetry equipment is at risk of EMI from other in-band radio frequency (RF) sources (e.g., DTV or PLMRS transmitters), you should either replace your existing telemetry systems with equipment that operates in the WMTS bands (608-614 MHz, 1395-1400 MHz, and 1429-1432 MHz), when this equipment is available, or modify it to operate in the WMTS band.

- If you and/or the telemetry equipment manufacturer determine that your medical telemetry equipment is not at risk of EMI from other in-band RF sources (e.g., DTV or PLMRS transmitters), then no change is necessary.

You should assess the risks and make necessary changes to your equipment as soon as reasonable because licensed TV stations are authorized to begin testing and transmitting in DTV channels as soon as they are ready, and because the FCC will begin accepting applications for high-powered users in the 450-460 MHz band January 29, 2001. Again, we recommend use of medical telemetry systems that operate in the WMTS bands, particularly for new purchases, to minimize the risk of EMI with wireless medical telemetry.

Reporting Adverse Events to FDA

The Safe Medical Devices Act of 1990 (SMDA) requires hospitals and other user facilities to report deaths and serious illnesses and injuries associated with the use of medical devices. This means that if interference with a medical device results in a death or serious injury, you must report that event. We request that you follow the procedures established by your facility for such mandatory reporting.

If a telemetry system fails to function due to electromagnetic interference or any other reason, it is a device malfunction. Such malfunctions should be reported to the manufacturer. Alternatively, they can be reported directly to MedWatch, the FDA's voluntary reporting program. Submit reports to MedWatch by telephone at

1-800-FDA-1088, by FAX at 1-800-FDA-0178, or by mail to MedWatch, Food and Drug Administration, HF-2, 5600 Fishers Lane, Rockville, MD 20857.

Getting More Information

If you have any questions regarding this notice that are related to FDA issues, please contact Nancy Pressly, FDA, CDRH, Office of Surveillance and Biometrics, 1350 Piccard Drive, HFZ-510, Rockville, MD 20850, fax 301-594-2968, or by e-mail at phann@cdrh.fda.gov. A voice mail message may be left at 301-594-0650 and your call will be returned as soon as possible. Additional copies of this notice, as well as all of FDA's medical device postmarket safety notifications, can be found on FDA's website at http://www.fda.gov/cdrh/safety.html.

For additional information regarding FCC issues, please contact Hugh L. Van Tuyl, FCC, Office of Engineering and Technology, 445 12th Street, SW, Room 7-A162, Washington, D.C., 20554, phone 202-418-7506, fax 202-418-1944, or e-mail hvantuyl@fcc.gov. A copy of the FCC final rules can be found on FCC's website at http://www.fcc.gov/Bureaus/Engineering_Technology/Orders/2000/fcc00211.doc.

Further information regarding electromagnetic interference and medical devices can be found on the FDA EMC web site at http://www.fda.gov/cdrh/emc/index.html. 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. Subscribe at: http://list.nih.gov/cgi-bin/wa?SUBED1=dev-alert&A=1

Sincerely yours,

David W. Feigal, Jr., MD, MPH
Director,
Center for Devices and Radiological Health

Additional Detailed Information

Technical aspects

Currently, most wireless medical telemetry devices operate as secondary users in select commercial broadcast TV bands (174-216 MHz (channels 7 to 13) and 470-668 MHz (channels 14 to 46)), and in the private land mobile radio service (PLMRS, 450-470 MHz) band. As secondary users, medical telemetry must accept interference from, and not interfere with, primary licensed users. These frequency bands will be used more extensively by digital TV and high power PLMRS operators, which is likely to result in an increased risk of interference with medical telemetry. Specifically, the FCC has reallocated previously vacant TV channels in the range of channels 7-46 for digital TV (DTV) transmission, and will allow high power operation in the 12.5 kHz offset channels (where medical telemetry operates) of the PLMRS band. In addition to these bands, some telemetry equipment may operate on a shared basis in the industrial, scientific, medical (ISM) or other bands. Users of such equipment are also encouraged to assess their systems for risks that may be associated with EMI, even though current FCC changes do not specifically affect them, particularly since bands are now available where medical telemetry is the primary user.

History

This problem of interference with medical telemetry systems initially gained much attention when systems at two hospitals in Texas were disrupted by DTV transmissions from a local TV station. FDA issued a public health advisory on March 20, 1998, (that can be found at http://www.fda.gov/cdrh/dtvalert.html) which was followed by a joint FDA/FCC statement on March 28, 1998, describing the potential for interference between DTV and medical telemetry and offering temporary solutions. As a result, the FDA, FCC, and the American Hospital Association (AHA) began work toward developing permanent solutions to this potential problem. This work ultimately led to the FCC proposing the WMTS frequency bands.

The Wireless Medical Telemetry Service (WMTS)

On June 8, 2000, the FCC commissioners adopted a Report and Order that amends 47 C.F.R. Parts 2, 15, 90 and 95 to establish the new Wireless Medical Telemetry Service (WMTS). (The Report and Order can be found at http://www.fcc.gov/Bureaus/Engineering_Technology/Orders/2000/fcc00211.doc.) The frequency bands 608-614 MHz (TV channel 37), 1395-1400 MHz, and 1429-1432

MHz, have been allocated to the WMTS for use on a primary basis. The 608-614 MHz band will be shared on a co-primary basis with radio astronomy and operation of medical telemetry in this band must not interfere with radio astronomy operations. The 1395-1400 MHz frequency band has been allocated to WMTS. However, there are 17 government sites that are authorized to continue to use that band on a fully protected basis until January 1, 2009. Also, there are 14 government sites authorized to use the 1429-1432 MHz band until January 1, 2004. A listing of these sites and their locations is included in the appendices of the FCC Report and Order. The FCC will also designate one or more frequency coordinators, whose task will be to maintain a database of WMTS transmitters and notify users of potential frequency conflicts.

Starting two years from the effective date of the final rules on WMTS, the FCC will not approve new medical telemetry equipment that operates in the TV or PLMRS bands. There is no cutoff on the sale or use of equipment approved before that date to operate in the TV and PLMRS bands. However, the FCC will begin accepting high-power land mobile applications for the 450-460 MHz band January 29, 2001. They will begin accepting high-power land mobile applications for the 460-470 MHz band within three years. At the same time, TV broadcasters have deadlines by which they are required by the FCC to begin testing and transmitting in their allocated DTV channel. These actions will continue to increase the risk of interference to medical telemetry systems operating in the TV and PLMRS bands. For these reasons, the FDA and the FCC strongly encourage medical telemetry users to migrate out of the TV and PLMRS bands and into the WMTS as soon as reasonable.