

Medical Device EMI: FDA Analysis of Incident Reports, and Recent Concerns for Security Systems and Wireless Medical Telemetry

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Abstract: FDA has evaluated reports of medical device malfunctions caused by electromagnetic interference (EMI), performed device testing, and developed standardized test procedures. Over 500 incident reports are suspected to be attributable to EMI affecting cardiac devices. More than 80 of these reports involve cardiac and other medical device interactions with electronic security systems. EMI presents a risk to patient safety and medical device effectiveness that is likely to continue as the use of electromagnetic energy in the medical device environment increases (e.g., cell phones, security systems). Recent developments can reduce these risks, such as the allocation of dedicated frequency bands for the new wireless medical telemetry service (WMTS) designed to protect transmissions of patient vital signs from interference by other intentional transmitters.

Introduction

The FDA, and others, have found that many different electrically powered medical devices can be affected by electromagnetic interference (EMI) that disrupts their function and may pose significant risks to the patient or device user. [1] [2] [3] [4] Figure 1 illustrates the effects of EMI on the wheel speed of a powered wheelchair from testing performed in the FDA laboratories. The changes in wheel speed seen here can pose significant risks for serious injury to the patients using these devices. Critical devices such as ventilators have also been tested and can demonstrate significant disruptions of function from EMI. Figure 2 shows the EMI disruptions to the air flow volume of a ventilator exposed over the range of radio frequencies. Several types of medical device areas have been investigated by FDA for

susceptibility to EMI, including: cardiac pacemakers, implanted cardiac defibrillators (ICDs), apnea monitors, powered wheelchairs, hearing aids, ventilators, and implanted nerve stimulation devices. We have performed extensive tests to evaluate the performance of several of these medical devices when exposed to various types and levels of electromagnetic energy and develop standardized test methods. Much of this work has been useful in the development of medical device standards to address electromagnetic compatibility (EMC). [5]

As part of the effort to examine the potential risks to patients from EMI with medical devices, we have also evaluated several thousand Medical Device Reporting (MDR) incident reports and reports in the literature. Between 1984 and 1995, there were approximately 150,000 reports of incidents involving cardiac type medical devices. Over 1700 of these reports were identified as possibly related to EMI with medical devices. Upon close examination approximately 33% (576) of these reports were found likely to be related to EMI. Most of these 576 reports suggested the source of EMI. However, approximately 19% (109) of these 576 reports did not identify a source of the interference. About 79% (456) of the 576 reports involved cardiac pacemakers or ICDs and indicated that some kind of intervention was needed to prevent adverse patient outcomes. [6] While the incident reports contain details of the device and manufacturer, many of the reports lack specific information about the possible cause of the problems. Thus, the reports can be used to indicate there is cause for concern but may not provide strong trend data on the nature of EMI incidents occurring with medical devices.

Figure 1. Results of EMC tests on a powered wheelchair, wheel speed versus RF exposure frequency for left wheel.

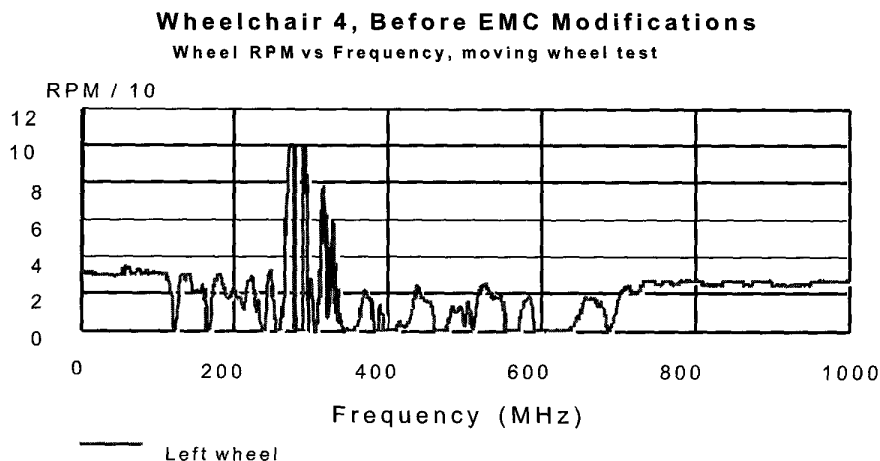
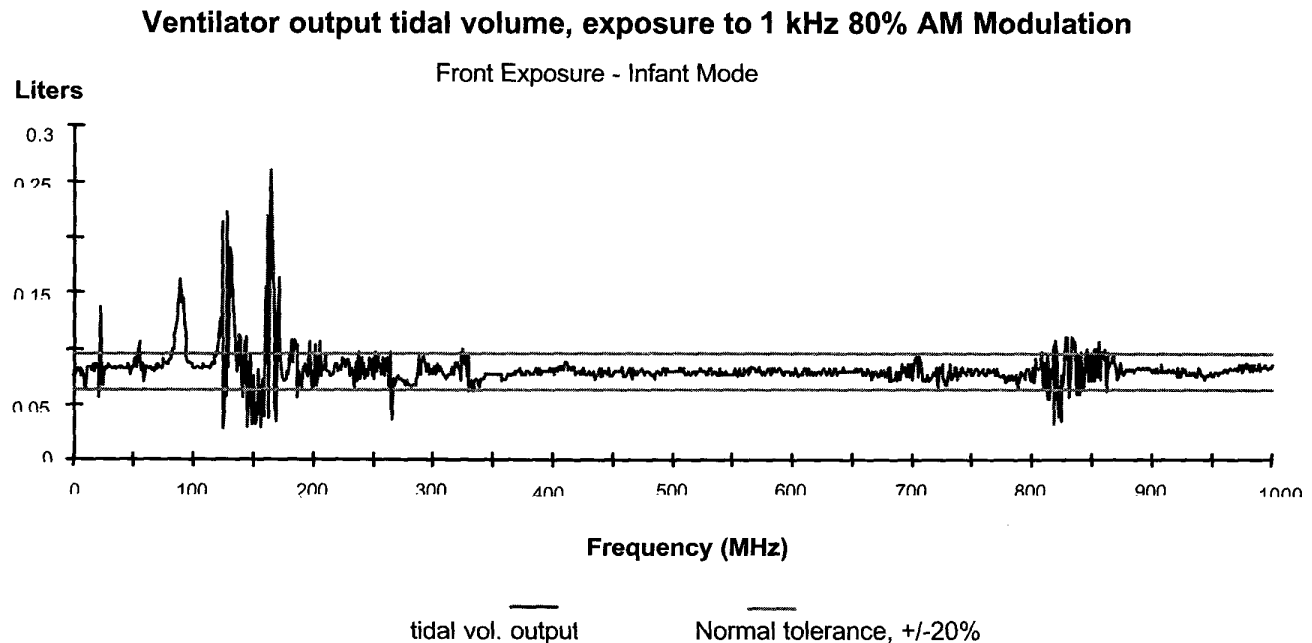


Figure 2. Results of EMC testing on Ventilator air volume output vs exposure frequency.



Medical Device EMI from Security Systems

More recently there has been concern about reports of interactions of ambulatory medical devices, such as implanted electrical stimulators, with electronic security systems. There have been several recent reports in the medical literature addressing this concern for implanted pacemakers and defibrillators. [7] [8] [9] In the last 10 years there have been over 80 incident reports filed with FDA that indicate medical devices reacted to EMI from such security systems. The security systems are identified in some of the incident reports as metal detectors or anti-theft systems (also known as electronic article surveillance systems or EASS). However, many of the reports fail to specify the probable source of EMI other than generally stating "security system".

We have rated these incident reports from mild to severe for severity of the device disruption and the potential impact on the patient. Several reports were rated as moderate when the medical device lost some function or provided moderate, non-injurious, over-stimulation. In one case rated as a severe consequence, a drug infusion device appeared to have overdosed the patient and required treatment to remove the excess drug from the patient's system. The table below contains a summary of the report ratings for a variety of devices and security systems. While the numbers of incidents with security systems appears low and thus not likely a major public health hazard, the findings raise enough concern to promote clinician awareness (FDA Safety Alert [10]) and further examination of the issue.

Table. Assessment of the severity of incident reports to FDA related to electronic security systems

Medical Device	Security System	Airport M. Detector	Hand M. Detector	Metal Detector	EAS
Pacemaker	1 severe 6 moderate 4 mild	2 severe	1 severe 1 moderate	2 moderate 1 mild	1 severe 6 moderate 3 mild
Spinal stimulator	3 severe 30 moderate 4 mild	1 severe 1 mild		1 moderate	1 moderate
ICD	1 moderate	2 moderate	3 moderate	1 moderate 1 mild	2 moderate
Infusion pump				1 severe	
Hearing Aid	1 moderate				

Concerns and Solutions for Wireless Medical Telemetry

Because of the increasing congestion in the use of RF spectrum, and recent incidents of EMI with medical devices, FDA has also been addressing the use of wireless medical telemetry. In 1998 wireless medical telemetry equipment at two Texas hospitals experienced interference from DTV broadcasts. Over the years wireless medical telemetry has largely utilized two frequency bands (a mobile radio band from 450 MHz to 470 MHz, and vacant TV channels 7 to 13 and, more recently 14 to 46) for its transmissions between the patient worn monitoring transmitters and central monitoring stations. Medical telemetry signals have generally been considered secondary users of the airways, meaning they must accept EMI and not cause interference to the primary licensee. These devices are commonly used in intermediate intensive care units to monitor ambulatory patient vital signs. However, even momentary disruptions of the transmission of these signals could lead to a patient not obtaining appropriate medical care or to potentially serious adverse events. In addressing our concerns for wireless medical telemetry the FDA enlisted help from the American Hospital Association (AHA), the Federal Communication Commission (FCC), device manufacturers, and clinicians to develop solutions and mitigate this interference problem. The AHA Telemetry task group led the way and petitioned the FCC for separate frequency allocations and coordination to provide protections and reduce the risks of EMI with wireless medical telemetry. The FCC responded by establishing the new Wireless Medical Telemetry Service (WMTS). [11]

This presentation will provide information on the need to address medical device susceptibility to EMI and some of the solutions that have been facilitated by FDA. It will provide an overview of the FDA perspective, including results of incident report evaluations, device testing, and cooperative efforts undertaken to address the complex medical device EMC issues.

One of the most far reaching issues, interference with wireless medical telemetry and the creation of the new WMTS, will require manufacturers and users alike to assess the risks of EMI with their wireless monitoring devices and develop actions to address these risks. The new WMTS is recommended for wireless telemetry because of its protections against interference from other in-band transmissions and frequency coordination among users.

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