THE CLINICAL ENGINEER: A GHOST HUNTER OR MANAGER OF EMI

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Reprinted from **BIOMEDICAL INSTRUMENTATION & TECHNOLOGY**
Published by HANLEY & BELFUS, INC., Philadelphia, PA

The Clinical Engineer: A Ghost Hunter or Manager of EMI

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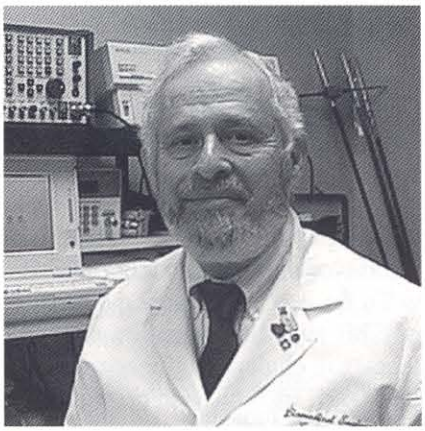
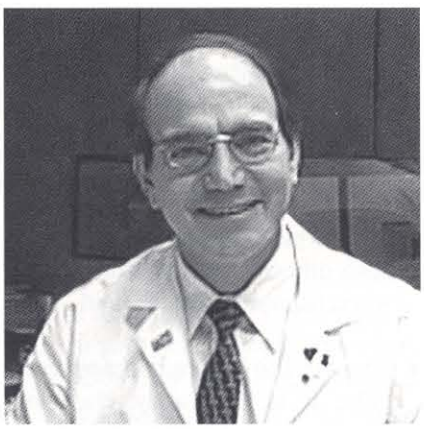
The dependence in medicine on technology to deliver services is continuously growing. The number of microprocessor-based diagnostic, therapeutic, and patient-monitoring devices used in the clinical environment is ever-increasing. As device malfunctions are noted and investigated by clinical engineers, increases in the number of device failures attributable to interference generated by equipment producing electromagnetic energy in the radio frequency (RF) spectrum have been documented. Warnings are issued by manufacturers and agencies that monitor the safe uses of biomedical instrumentation. For the most part, manufacturers and agencies depend on reports from institutions using the affected products. In spite of the risks to devices, and therefore to patients, many events attributable to electromagnetic interference (EMI) go unreported. The clinical engineer, educated in the causes and effects of EMI, is capable of implementing a risk-reduction program that includes training for users, environmental assessment, identification of possible sources, and mitigation of the risks (wherever possible) resulting from these conditions.

Years of research have shown that all clinical facilities, whether in urban, suburban, or rural areas, are subject in varying degree to the effects of EMI. The quantity of documented incidents of EMI affecting clinical devices may represent but the tip of the iceberg. Experiences during investigations of EMI at Texas Children's Hospital, St. Luke's Episcopal Hospital, and various other facilities indicate statistically that many events demonstrably attributable to EMI go unreported. Under-reporting appears to be caused by lack of training and knowledge in the identification of EMI-related device failures, lack of reporting structure, and concern with a potential admission of implied risk that could result in subsequent litigation.





W. David Paperman (top) and Yadin David

BENEFITS OF CONTROLLING THE ELECTROMAGNETIC ENVIRONMENT

Patients as well as the facility in which they are cared for are dependent on the reliable operation of clinical devices. Reliable operation is complicated by an environment made ever more hostile by increasingly complex impinging electromagnetic fields emanating from a variety of sources. This has resulted in the increase of momentary, partial (visible and invisible), and complete failure of clinical devices due to EMI. Failure of active clinical devices increases risk to patients and reduces cost-effectiveness, because use of the device is restricted until the cause of failure can be diagnosed and corrected. Therefore, a comprehensive program for managing EMI through monitoring, education, and control has proven to be of benefit in terms of both risk avoidance and cost containment.

ROUTES TO A SUCCESSFUL PROGRAM

In order to be successful, a program for managing the risks associated with EMI must have the following elements:

- Facility commitment for the operation of a comprehensive program supported by qualified personnel

and test equipment appropriate for the tasks required, including the performance of the necessary tests and analysis and interpretation of the test data.

- Qualified personnel educated in both the science and technologies related to EMI and trained in its detection and mitigation. The primary requirement is a knowledge of RF generation and propagation. One path to the attainment of the knowledge and appreciation (almost an instinct) of the nuances of RF propagation is through the pursuit of the avocation of amateur radio, a hobby that requires study and proof of knowledge demonstrated through Federal Communications Commission–sponsored examinations to attain operating privileges.

- A plan of education that includes care givers who use medical devices, security and plant personnel, and other users of hand-held radio transmitters, biomedical equipment technicians, and administrative personnel. Personnel performing educational functions should be able to describe the risk potential of EMI on devices in various clinical areas, the steps necessary to report EMI incidents, and how to mitigate the effects.

- Procedures for reporting, investigating, and monitoring incidents of EMI and their results. These procedures should include scheduled footprinting of high-risk areas and prepurchasing fingerprinting of representative types of incoming devices.*

- Cooperation with manufacturers in the development of devices with higher immunity to EMI and proper maintenance procedures that sustain the properties of the devices as they relate to susceptibility to EMI.

*See "Testing for EMI in the clinical environment," by W.D. Paperman, Y. David, and M. Martinez, on the recommended reading list.

HINTS AND KINKS: THE GIVEN OF GHOST HUNTING

Unlike most applications of maintenance of electronic and electromechanical devices, the detection and mitigation of the effects of EMI have been likened to "ghost hunting." Conventional troubleshooting techniques provide limited results when we are looking for the cause of EMI.

To be successful in the detection of EMI and the mitigation of its effects, the clinical engineer must understand and fully appreciate the following guidelines:

- Approach each instance of EMI from a fresh perspective. There is more than one way EMI can affect a device, and therefore the path to mitigating the effects of EMI varies. At Texas Children's Hospital, we have demonstrated that identical devices placed in close proximity to each other do not react identically when exposed to an RF field.

- Observe the RF environment carefully. It is constantly changing. New licenses for radio-based services are issued daily. More unlicensed devices are being added all the time. Careful observation of the current RF environment coupled with acquisition of data during an aggressive footprinting/fingerprinting program will provide a direction toward the solution of specific EMI problems.

- Involve care givers in the investigation of a device failure. Careful questioning by an educated clinical engineer can provide the engineer with valuable information about a particular EMI problem and at the same time educate the care giver in important ways.

- Understand that there may not always be a tidy solution to a specific problem. Successful detection of the cause of specific EMI will not necessarily point to a practical method of mitigating it. Sometimes alternative solutions must be sought, ranging from more aggressive supervision of the affected device when in clinical use to replacement by a device with greater immunity to EMI.

- Find a place in the building that provides some degree of shielding from RF sources that originate outside. Appropriate locations would be basement or sub-basement areas, preferably in the center of the building, or a radiology area that is still shielded but no longer used. Such an area, after footprinting, will be the area in which individual devices will be fingerprinted.

- Maintain and repair clinical devices properly. A device might pass all bench and manufacturer's tests, but because cabinet hardware was not properly seated, it may now be susceptible to electromagnetic radiation. Or because internal spray shielding used in the control of device susceptibility is worn or otherwise damaged, the device may be more likely to affect other devices through leakage of electromagnetic radiation. Add procedures to the regular maintenance schedule that include inspection and rectification of the RF containment seals and shielding.

- Set repeatable measurement procedures based on standards such as those recommended by ANSI, IEEE, FDA, and others. Realize

that RF emissions and their amplitudes are different in each facility, and therefore an institution may need to deviate from testing standards to produce a viable program of EMI management. You should know how deviation from a published test protocol might affect device performance results.

Responses by institutions have been varied and range from aggressive, adequately funded and staffed EMI reduction programs to apathy based on disbelief. The most common complaint encountered is the lack of personnel with experience in the dynamics of RF and related EMI. Following closely is lack of funding to meet the equipment requirements for successful "ghost hunting," limiting mitigation options. Last is a diminishing number of institutions that do not yet believe that EMI poses a threat to diagnostic and therapeutic clinical devices and, consequentially, risk to patients utilizing those devices. It is hoped that further education of clinical, technical, and administrative staff will further reduce the number of such institutions. Therefore, clinical engineers are faced with the challenge and responsibility to guide these institutions toward safer patient care environments.

CASE HISTORIES: MEMORABLE GHOST HUNTS

Case A. Telemetry on one floor of a multistory facility was intermittently displaying error codes and loss of data. Spectrum analysis revealed the presence of a recurrent but not time-repetitive pulse. Questioning of staff revealed that this occurred during the testing of a newly installed fire alarm system. Working with the fire alarm personnel, the floors and then circuits were isolated, one at a time. Finally the annunciator (A/V unit)

RECOMMENDED READING ON EMI

- Guidance on electromagnetic compatibility of medical devices for clinical/biomedical engineers, I: radiated radio-frequency electromagnetic energy. In: Technical Information Report (TIR) 18. Arlington, VA: Association for the Advancement of Medical Instrumentation, 1997.
- Cellular telephones and radio transmitters: interference with clinical equipment [guidance article]. Health Devices. August-September 1993;22(8–9).
- David Y. Safety and risk control issues: biomedical systems. In: Dorf RC (ed.). The Electrical Engineering Handbook. Boca Raton, FL: CRC Press, 1993.
- Code of Federal Regulations No. 47 (CFR-47): Part 15.103(c) and (e). See also Part 15.3(h), (i), (k), and (z), which deal with digital devices and unintentional radiators.
- Paris DT, Hurd FK. Basic Electromagnetic Theory. New York: McGraw-Hill, 1969.
- IEEE Recommended Practice for the Measurement of Radio Frequency Emission from Industrial, Scientific, and Medical (ISM) Equipment Installed on User's Premises. New York: Institute of Electrical and Electronics Engineers, 1988. Recognized as an ANSI Standard, August 11, 1988.
- Electromagnetic Interference Characteristics: Requirements for Equipment, August 1, 1968, MIL-STD-461A. See also: Measurement of Electromagnetic Interference Characteristics [draft], February 14, 1992, MIL-STD-462(D); and Rollinger DP: The ABCs of MIL-STD-461: EMC Test and Design.
- The American Radio Relay League Handbook for Radio Amateurs. Newington, CT: American Radio Relay League, published annually.
- Hare E (KA1CV), Schetgen R (KU7G) (eds.). Radio Frequency Interference: How to Find it and Fix It. Newington, CT: American Radio Relay League, published periodically.
- Paperman WD, David Y, McKee KA. Electromagnetic Compatibility: Causes and Concerns in the Hospital Environment. Chicago, IL: American Society for Healthcare Engineering, 1994.
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- David Y, Paperman WD, Storch J. EMC: How To Manage the Challenge. Chicago, IL: American Society for Healthcare Engineering, 1997.
- American National Standards Institute. American National Standard for Methods of Measurement of Radio-Noise Emissions from Low-Voltage Electrical and Electronic Equipment in the Range of 9 Khz to 40 Ghz. Washington, DC: ANSI, 1992. IEEE Standards Collection: Electromagnetic Compatibility.

circuits one floor below the affected area were shut down. The pulse disappeared. The fire alarm company had installed different, higher powered A/V units on the floor below, a mechanical floor. These A/V units utilize strobe lights. On discharge, these devices emit a very steep, very narrow spike, and the telemetry antennas were receiving these pulses. Because the pulses were of such short duration, the preamplifiers in the antennas and in the receivers were not saturating or being desensitized by these pulses. The pulses were actually passing right through the RF portions of the telemetry system and essentially corrupting patient data bytes.

Case B. An example of the application of footprinting and fingerprinting that may have prevented an incident occurred when the radiology department was buying new telemetry equipment. Footprinting revealed that the background level in that department was about 67 microvolts (μV). Fingerprinting a representative telemetry transmitter showed a received signal level at the standard test distance of 1 meter to be 12 μV above the background level. An insufficient signal-to-noise ratio (ratio of a received signal to background noise) could cause intolerably long periods of loss of a usable signal throughput. The testing of the telemetry transmitter (fingerprinting) is done under controlled conditions at a fixed distance. However, the patient will not normally maintain a 1-meter distance from the receiving antennas. As the distance between the patient and the receiving antenna increases, the amplitude of the received signal lessens and degrades as it approaches the level of the background noise. As the signal degrades, the level of acceptable data degrades. If the degradation is great enough, there is a high probability that, if a patient is in cardiac distress, the telemetry system will not be able to recognize the emergency.

Case C. An example of the "ghost that wasn't" involved a report of intermittent interference to an EMG device in a physical therapy department at a hospital. The department felt that this was being caused by the MRI department, which is located directly above the area in which the affected device was located. A spectrum analyzer was set up to measure electromagnetic fields that might be leaking from the shielded MRI facility. No leakage was detected during the test period. Further interviews with the doctors and staff led the clinical engineer to perform a somewhat unorthodox series of tests. The filtration on the EMG was broadened, and the leads were laid out unterminated on the couch on which patients were placed. During this procedure, when pressure was applied to the couch cushion, the baseline of the EMG machine would vary synchronously. It appeared that any motion in the immediate vicinity of the device would cause this baseline shift. Based on the results of these tests and the material composition of the environment (vinyl cushions on the couch, highly waxed vinyl floor), it was determined that the problem was electrostatic, not electromagnetic. The intermittent aspect of the problem was attributed to the fact that hydrotherapy baths were locations two doors away from the EMG room; their use from time to time would raise the humidity sufficiently to reduce the potential for intense electrostatic charges. A decidedly different ghost hunt!

SUMMARY

The management of EMI and risk control in the clinical environment presents the clinical engineer with new challenges and responsibilities. The keys to successfully meeting these challenges and responsibilities are education, cooperation, and the ability to be creative in the quest for solutions to problems of ever-increasing complexity. Experience in detecting and analyzing test results, which is gained over time, enhances the skills that clinical engineering professionals bring to this challenge.

Attention to EMI risks has been influenced by a number of factors, including a spirit of cooperation between manufacturers and users, concerns over patient care and perceived product efficacy, and an increasing number of regulations by European and U.S. regulatory agencies. As a result, device emissions are being reduced and device immunity to EMI is improving.

Further improvements in device immunity are still needed. The radio spectrum with regard to intentional radiators is in a continual state of flux. As industry attempts to improve labor efficiency through the use of radio communications, new and higher-powered sources of RF—both internal and external to the physical plant—appear each day in the clinical environment. Since the distance between intentional radiators and potentially susceptible devices is usually beyond the control of an institution, industry must continue to reduce device susceptibility. There should be a stronger dialogue between institutions (even if they do not have proactive EMI reduction programs) and manufacturers to identify ways to improve device immunity to EMI and to increase product designers' and users' awareness of potential problems.

W. David Paperman joined the Biomedical Engineering Department of Texas Children's Hospital in 1990. He currently serves as a clinical engineer with the Television Services Group. His responsibilities include the

design and implementation of hospital radio communications and broadband multiple television distribution systems, and engineering support of telemedicine system development. He is responsible for the development and implementation of the Texas Children's Hospital Electromagnetic Interference (EMI) testing and control program and contributes to the formulation of hospital policies relating to the control of EMI and emergency response issues.

Mr. Paperman is licensed by the Federal Communications Commission and the National Association of Business and Educational Radio and is certified as a Broadcast Technologist by the Society of Broadcast Engineers. He also carries certifications in many specialty fields including satellite communications, high-frequency and ultra high-frequency radio communications, and digital modes. Mr. Paperman holds an Amateur Radio Extra Class license.

Yadin David, MSc, PhD, PE, CCE, HSP, has served as the Director of the Biomedical Engineering Department at the Texas Children's Hospital, St. Luke's Episcopal Hospital, and Texas Heart Institute since 1982. In this capacity, he directs one of the most comprehensive hospital-based clinical engineering programs in the country.

Dr. David received his masters and doctoral degrees from West Virginia University in 1975 and 1983, respectively. He holds academic appointments of Adjunct Associate Professor in Anesthesia at the University of Texas Health Science Center in Houston and Assistant Professor in the Department of Pediatrics at Baylor College of Medicine. He is a registered professional engineer, a certified clinical engineer, and a certified international health care safety professional.