

American National Standard Recommended Practice for an On-Site, Ad Hoc Test Method for Estimating Radiated Electromagnetic Immunity of Medical Devices to Specific Radio- Frequency Transmitters

Accredited Standards Committee on Electromagnetic Compatibility, C63

accredited by the

American National Standards Institute

Secretariat

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Abstract: Guidance is provided for health-care organizations in evaluating the radiated RF electromagnetic immunity of their existing inventories of medical devices to their existing inventories of RF transmitters, as well as to RF transmitters that are commonly available. This recommended practice can also be used for newly purchased medical devices and RF transmitters, as well as for pre-purchase evaluation. It applies to medical devices used in health-care facilities and to portable transmitters with a rated power output of 8 W or less. It does not apply to implantable medical devices, transport environments such as ambulances and helicopters, or to RF transmitters rated at more than 8 W.

Keywords: ad hoc testing, electromagnetic compatibility (EMC), electromagnetic immunity, electromagnetic interference (EMI), health-care facilities, in-situ testing, medical devices, on-site testing, portable RF transmitters, test method, test procedure

The Institute of Electrical and Electronics Engineers, Inc.
345 East 47th Street, New York, NY 10017-2394, USA

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Introduction

(This introduction is not part of ANSI, C63.18-1997, American National Standard Recommended Practice for an On-Site, Ad Hoc Test Method for Estimating Radiated Electromagnetic Immunity of Medical Devices to Specific Radio-Frequency Transmitters.)

This recommended practice was developed over a period of two years (1995–1997) in response to a need expressed by clinical and biomedical engineers for a technical guide to aid them in assessing the immunity of medical devices to radiated electromagnetic fields from portable RF transmitters. It is based in part on ad hoc test methods that were used by Dr. Kok-Swang Tan, Medical Devices Bureau, Health Canada, and Dr. Bernard Segal, McGill University and Jewish General Hospital, Montreal.

As wireless communications equipment, especially cellular telephones, have increased in popularity, the need to manage the use of communications equipment in the health-care environment has become apparent. This recommended practice will provide an economical means of obtaining objective data on which to base such management practices, allow health-care organizations to readily assess the immunity of electrical medical devices to portable RF transmitters that might be used nearby, and improve the consistency of such ad hoc Electromagnetic Compatibility (EMC) measurements between health-care facilities.

Participants

At the time this recommended practice was developed, the Working Group for On-Site, Ad Hoc Radiated Measurements had the following membership:

Herbert K. Mertel, *Chair*

Jeffrey L. Silberberg, *Principal Author*

Daniel D. Hoolihan, *Chair, ASC C63, Subcommittee 8*

Joseph Butler

William Kole

Donald M. Witters

At the time that the Accredited Standards Committee on Electromagnetic Compatibility, C63, approved this recommended practice, it had the following membership:

Ralph M. Showers, *Chair*

Edwin L. Bronaugh, *Vice Chair*

<i>Organization Represented</i>	<i>Name of Representative</i>
Aeronautical Radio, Inc. (ARINC).....	Dan Martinec
	Paul Prisaznuk (Alt.)
Alliance for Telecom. Industry Solutions	John F. Lichtig
	O. J. Gusella (Alt.)
American Automobile Manufacturers Association	Terry Rybak
	Barbara Wendling (Alt.)
American Council of Independent Laboratories	Ross A. Hansen
	Walter Poggi (Alt.)
American Radio Relay League.....	Hugh Turnbull
	Edward F. Hare (Alt.)
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Association of Telecommunications Attorneys.....	Glen Dash
	Jon Curtis (Alt.)
AT&T Bell Laboratories	H. Robert Hofmann
Computer and Business Equipment Manufacturing Association.....	William T. Rhoades
	William F. Hanrahan (Alt.)
EEL/Electric Light & Power Group.....	Gary N. Miller (Alt.)
Electronic Industries Association	Ralph Justus
ESD Association.....	Douglas C. Smith
Federal Communications Commission	L. Art Wall
	Richard B. Engleman
	Hugh L. Van Tuyl (Alt.)

<i>Organization Represented</i>	<i>Name of Representative</i>
Food and Drug Administration	Paul S. Ruggera
	Jeffrey L. Silberberg (Alt.)
Health Industry Manufacturers Association	Eric V. Anderson
	Randall L. Anderson (Alt.)
Hewlett-Packard.....	Ray Magnuson
Institute of Electrical and Electronics Engineers, Inc.....	Edwin L. Bronaugh
	Donald N. Heirman
	Nestor Kolcio
Kaman Science Corporation	Arthur Heath Light
National Association of Broadcasters.....	Kelly Williams
National Electrical Manufacturers Association.....	William J. Murphy
	Kenneth Gettman (Alt.)
National Institute of Standards and Technology.....	Motohisa Kanda
National Telecommunications and Information Administration.....	Karl Nebbia
Radio Shack	Mac Slayton
Siemens ROLM.....	Stephen Berger
Society of Automotive Engineers	Herbert K. Mertel
	Poul Andersen
Southwest Research Institute.....	James J. Polonis
	William E. Cory (Alt.)
Telecommunications Industry Association.....	Eric J. Schimmel
TUV Product Service	Daniel D. Hoolihan
	Tim O'Shea (Alt.)
Underwriters Laboratories	Willard Tuthill
	Corey Hyatt (Alt.)
Unisys Corporation.....	Wallace Amos
University of Oklahoma, EMC Center	Hank Grant
	Robert Schlegel (Alt.)
US Air Force.....	John Zentner
	Dennis Baseley (Alt.)
US Dept. of Energy—Bonneville Power Administration	Vernon L. Chartier
US Dept. of Energy—Oak Ridge National Laboratory.....	Paul Ewing
	Richard A. Hess (Alt.)
US Dept. of Energy—Western Area Power Administration	Scott E. Johnson
US Dept. of the Army, Communications Electronic Command.....	David Cofield
US Dept. of the Navy, Space and Naval Warfare Systems Command.....	Stephen Caine
	Marcus Shellman (Alt.)
US Dept. of Transportation —Federal Aviation Administration	Robert Frazier
Violette Engineering.....	J. L. Norman Violette
	Michael F. Violette (Alt.)
WIN Forum	Anatoly Tsaliovich
Members-at-Large	Ralph Calvecchio
	Robert J. Eagan
	Richard B. Schulz
	Ralph M. Showers

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Valerie E. Zelenty
IEEE Standards Project Editor

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1. Overview

1.1 Scope

This recommended practice is intended to serve as a guide for health-care organizations in evaluating the radiated radio-frequency (RF) electromagnetic immunity of their existing inventories of medical devices to their existing inventories of RF transmitters, as well as to RF transmitters that are commonly available. It can also be used for newly purchased medical devices and RF transmitters, as well as for prepurchase evaluation. This recommended practice applies to medical devices used in health-care facilities and to portable transmitters with a rated power output of 8 W or less. It does not apply to implantable medical devices, transport environments such as ambulances and helicopters, or to RF transmitters rated at more than 8 W. Testing with transmitters greater than 8 W should not be performed in health-care facilities because of possible adverse effects on critical-care medical devices that are in use in other areas of the facility.

1.2 Purpose

The purpose of this recommended practice is to

- a) Provide an inexpensive, relatively reproducible test method for estimating the radiated RF electromagnetic immunity of medical devices to available, portable RF transmitters that might be operated in proximity;
- b) Provide a test method that can be performed by clinical and biomedical engineers;
- c) Improve reproducibility and intercomparability of test results; and
- d) Provide information for and facilitate development of policies and procedures for managing (i.e., allowing or restricting) the use of specific RF transmitters within specific areas of a health-care facility.

2. Caveats and limitations

This recommended practice is not intended to substitute for rigorous laboratory electromagnetic compatibility (EMC) testing, in which the test conditions are more fully controlled and the response of the medical device is characterized over a range of frequencies. This ad hoc test cannot fully characterize the radiated RF immunity of a medical device.

There is considerable variability inherent in this test method. The results can be affected by

- a) Changes in the RF output characteristics of the RF transmitter;
- b) The specific antenna used with the RF transmitter and the antenna orientation with respect to the medical device;
- c) Ambient RF fields;
- d) Reflection and absorption of RF energy by people, objects, and structures in the test area; and
- e) Small changes in cable placement and the relative position of the RF test source and the medical device.

Test results for each medical device apply only to that unit and to the frequency, modulation, and field strength characteristics of the RF test source. The medical device may be either susceptible or immune to other frequencies, modulations, and/or field strengths. Results for the same medical device may vary in the short term due to variability in the test method, movement of people or equipment, and/or variations in local ambient RF fields. They may also vary over time as the medical device ages and/or undergoes service or maintenance. Results for different units of the same model may vary for these reasons and also due to differences in design or manufacture (e.g., design revisions, component substitutions, tolerances, physical location of components and wires, assembly).

3. Purpose of the test method

The purpose of the test method described in this recommended practice is to assess, in a relatively reproducible manner, the radiated RF immunity of specific medical devices to specific RF transmitters, the effects of the RF transmitters on the medical devices tested, and the distance between transmitter and medical device at which the effects cease. Policies and procedures for mitigation of electromagnetic interference (EMI) in health-care facilities should be based on objective information, such as that which can be obtained by the use of this test method.

Ideally, in order to mitigate EMI in medical devices, each health-care organization would:

- a) Fully characterize its electromagnetic environment;
- b) Characterize the EMC of its existing inventory of electrical and electronic medical devices; and
- c) Ensure that any new electrical and electronic equipment purchased is compatible with this environment and with the existing inventory of medical devices.

However, to perform item a) requires constant surveillance with costly and complex equipment, and it is prohibitively expensive to perform item b) by submitting an entire inventory of electrical and electronic equipment to an EMC laboratory for testing.

For these reasons, clinical and biomedical engineers have performed their own rudimentary (“ad hoc”) EMC testing using RF transmitters and medical devices that are in-house. The results of such testing can differ from institution to institution, depending on methodology.

This recommended practice describes a test method intended to improve the reproducibility of such ad hoc EMC testing. It also provides guidance for selection of the medical devices to be tested, selection of transmitters for use as RF test sources, assessment of the test results, and use of the test results in the mitigation of EMI.

Item c) is a prospective activity that, in theory, can be implemented in purchasing policy. However, such complete information is seldom available, for the environment or for the medical device. Purchasing medical devices that conform to voluntary EMC standards will provide reasonable assurance of compatibility. Annex A lists EMC standards and guidelines that contain radiated RF immunity requirements applicable to medical devices. This recommended practice can be used to supplement the information obtained by testing to voluntary EMC standards.

4. Selection of medical devices to be tested

Health-care organizations should use their judgment in prioritizing medical devices for ad hoc electromagnetic immunity testing. However, the following factors should be considered:

- a) The criticality of the medical device (whether it is life-supporting, used to monitor critical patient parameters, provides a diagnosis, delivers drugs);
- b) Whether the medical device has been tested for compliance with applicable EMC standards;
- c) The potential impact of medical device failure or malfunction on the patient (e.g., whether there is potential for patient injury or death);
- d) Known EMI problems with similar medical devices due to insufficient RF immunity;
- e) Whether the medical device contains sensitive components or circuitry (e.g., circuits with high-gain amplifiers, patient leads, and microprocessors can be particularly sensitive);
- f) Whether RF transmitters are frequently used in the vicinity of the medical device (e.g., in emergency rooms);
- g) Whether the medical device has been noted to perform erratically; and
- h) Whether the medical device is repeatedly referred for service, yet when the performance of the medical device is tested, no problem is found, particularly when tested in a service location which may be elsewhere in the building (e.g., the basement) or off-site.

5. Selection of RF transmitters

Any RF transmitter that is or will be used in or near the health-care facility, has an output power up to 8 W, and can be conveniently relocated to the test area, can be used for testing. Hand-held transceivers (e.g., walkie-talkies), telemetry transmitters and repeaters, cellular telephones, and wireless (RF-linked) information technology equipment can be used as RF test sources. For further information on RF transmitters, see Annex B.

6. Test method

6.1 Selection of the test area

The test area should be located away from critical-care areas. Medical devices in use in adjacent rooms and on the floors above and below could be adversely affected. See 6.6 for precautions regarding electronic medical devices in use in nearby areas.

If possible, perform the ad hoc RF immunity test in a location that meets the test facility requirements of IEC 61000-4-3 (1995-03) (see Annex A). If such a facility is not available, the test should be performed in an area free of structures and metallic objects that extends at least 3 m (10 ft)¹ beyond the initial test distance on each side of the medical device and its attached cables, when arranged as specified in 6.2. Thus, for transmitters up to 8 W, at least 9 m x 9 m (30 ft x 30 ft) of clear area is recommended. The test area should be in a basement location, if possible. When selecting an indoor test area, B.1.8 should be considered. If no suitable indoor facility is available, the test can be performed in a vacant area of a parking lot.

Staff members not participating in the test, visitors, and patients should be excluded from the test area during testing.

6.2 Placement of the medical device

Place the medical device to be tested and its cables in the center of the clear area as shown in Figure 1, with the cables extended to the rear of the device. Cables that exit the front of the device should be routed over the top and to the rear. For cables longer than 3 m (10 ft), stretch out the first 3 m (10 ft) from the device and bundle the remainder noninductively (i.e., in a serpentine, or “S”-shaped bundle). If the device is normally used on a table, place it on a nonconductive (e.g., wooden) table approximately 80 cm (31 in) high. If the medical device is floor-standing, position it on the floor or ground. Support the cables approximately 40 cm (16 in) off the floor or ground using nonconductive objects (e.g., wooden or nonconductive plastic chairs or wastebaskets). The transition of the cable from the height of the medical device to a height of 40 cm (16 in) should be over as short a distance as possible.

Medical device sensors should be placed next to the device, approximately 80 cm (31 in) off the floor or ground, and approximately even with the front panel or surface of the medical device as shown in Figure 1. If patient simulators are used, care must be taken to ensure that they are not affected by the RF transmitter and that they do not conduct RF energy into the medical device. The preferred method for avoiding the conduction of additional RF energy into the medical device is to use nonconductive means such as fiber optics to couple the simulated patient signals to the vicinity of the medical device sensors. If this type of coupling is not available, small, shielded, battery-operated simulators are recommended. If patient simulators are found to be affected by the RF transmitters used, the test should be performed with the simulators located away from the test area, unless the method used to couple the simulator signals to the medical device sensors (e.g., cables) is found to affect the test results. If patient simulators must be in proximity to the sensors, they should be supported at a height of approximately 80 cm (31 in) and placed behind the sensors, as shown in Figure 1. If human volunteers must be used to provide patient signals during the test, institutional review board (IRB) approval should be obtained.

6.3 Evaluation of medical device performance

With the RF transmitter off, establish and verify normal operation of the medical device. During the ad hoc RF immunity test, observe any abnormal operation. (See the following suggested list of response descriptions). After the RF immunity test is completed, verify that the medical device operates normally and was not damaged during the test.

¹English units are rounded.