

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

C63[®]

Accredited Standards Committee C63[®] — Electromagnetic Compatibility

Accredited by the
American National Standards Institute

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ANSI C63.18-2014
(Revision of
ANSI C63.18-1997)

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Secretariat

Institute of Electrical and Electronics Engineers, Inc.

Approved 16 May 2014

American National Standards Institute

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Abstract: A guide to evaluating electromagnetic immunity of medical devices against radiated radio-frequency (RF) emissions from common RF transmitters is provided in this recommended practice (e.g., two-way radios; walkie-talkies; mobile phones; wireless-enabled tablets, e-readers, laptop computers, and similar devices; RFID readers; networked mp3 players; two-way pagers; and wireless personal digital assistants [PDAs]). A comprehensive test or a guarantee is not provided by this protocol but, instead, a basic evaluation is given that can help identify medical devices that might be particularly vulnerable to interference from common RF transmitters. Existing or newly purchased medical devices can be evaluated by this ad hoc test protocol or the protocol can be implemented for prepurchase evaluation. This recommended practice applies to medical devices used in health-care facilities but can also be adapted to medical devices in home health-care or mobile health-care settings. It does not apply to implantable medical devices (e.g., pacemakers and defibrillators), transport environments such as ambulances and helicopters, or RF transmitters rated at more than 8 W of output power. Testing with transmitters greater than 8 W in health-care facilities is not recommended because of possible adverse effects on critical-care medical devices that are in use in nearby areas of the facility. Finally, in-band RF interference where the fundamental frequency of an RF transmitter overlaps with frequencies used by a hospital wireless network or monitoring or other medical device wireless links is not addressed by this recommended practice.

Keywords: ad hoc testing, American National Standard, ANSI C63.18, electromagnetic compatibility, electromagnetic immunity, electromagnetic interference, EMC, EMI, health-care facilities, in situ testing, medical devices, on-site testing, portable radio frequency transmitters, test method, test procedure, wireless

The Institute of Electrical and Electronics Engineers, Inc.
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PDF: ISBN 978-0- 7381-9160-7 STD98685
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The Chair would like to acknowledge the significant contributions made to the project by the late Dr. Joseph Morrissey.

Introduction

This introduction is not part of ANSI C63.18-2014, American National Standard Recommended Practice for an On-Site, Ad Hoc Test Method for Estimating Electromagnetic Immunity of Medical Devices to Radiated Radio-Frequency (RF) Emissions from RF Transmitters.

This second edition of this recommended practice updates the recommendations of the first edition in response to developments in the state-of-the art of radio-frequency (RF) wireless communications and to take into account the crucial role that wireless communications have come to play in the delivery of health care. Also, the test procedure has been made more efficient, and recommendations for use of a field-strength meter and setting of power-controlled transmitters to maximum power should result in improved reproducibility of the test results.

As RF wireless communications equipment has increased in popularity and utility in health care, and despite improvements in the electromagnetic immunity of medical devices, it is essential to manage the use of communications equipment in the health-care environment. This recommended practice provides a means of obtaining objective data on which to base such management practices so that health-care organizations can readily assess the immunity of electrically powered medical devices to portable RF transmitters that might be used nearby and improve the consistency of such ad hoc electromagnetic compatibility (EMC) measurements, including between health-care facilities.

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1. Overview

1.1 Scope

This recommended practice is a guide to evaluating the electromagnetic immunity of medical devices to radiated radio-frequency (RF) emissions from common RF transmitters (e.g., two-way radios; walkie-talkies; mobile phones; wireless-enabled tablets, e-readers, laptop computers, and similar devices; radio-frequency identification (RFID) readers; networked mp3 players; two-way pagers; and wireless personal digital assistants [PDAs]). This protocol does *not* provide a comprehensive test or offer any guarantee, but it is a basic evaluation that can help identify medical devices that might be particularly vulnerable to interference from common RF transmitters. The ad hoc test protocol can be used to evaluate existing or newly purchased medical devices or can be implemented for the purpose of prepurchase evaluation. This

recommended practice applies to medical devices used in health-care facilities, but it can also be adapted to medical devices in home health-care or mobile health-care settings. It does not apply to implantable medical devices (e.g., pacemakers and defibrillators), transport environments such as ambulances and helicopters, or RF transmitters rated at more than 8 W of output power. Testing with transmitters greater than 8 W in health-care facilities is not recommended because of possible adverse effects on critical-care medical devices that are in use in nearby areas of the facility. Finally, this recommended practice does not address in-band RF interference where the fundamental frequency of an RF transmitter overlaps with frequencies used by a hospital wireless network or monitoring or used by other medical device wireless links.

1.2 Purpose

The purpose of this recommended practice is to provide an ad hoc test method to estimate the electromagnetic immunity of medical devices and help identify interference issues that might exist with critical medical devices as a result of emissions from RF transmitters increasingly used in health-care facilities, particularly by doctors, staff, patients, and visitors. RF transmitters include two-way radios, walkie-talkies, mobile phones, wireless-enabled laptop computers and similar devices,¹ RFID readers, networked mp3 players, two-way pagers, wireless PDAs, and wireless medical devices. The test protocol is designed to be performed as follows:

- a) By clinical engineers, biomedical engineers, and other technical personnel
- b) In a way that is relatively rapid and practical
- c) In an area and with equipment that are commonly available
- d) To identify specific effects and thresholds (i.e., transmit power and distance) to provide the basic information needed to develop a mitigation action plan
- e) To generate test results that can be used in the formulation of policies and procedures for managing the use of RF transmitters within a health-care facility

A preferred method (5.6.2) and several alternative RF sources and methods (Annex C) for ad hoc testing are outlined in this recommended practice to allow flexibility with regard to the time, personnel, and resources available to perform the testing. As a result, these different options provide different levels of accuracy and comprehensiveness. The most appropriate ad hoc test strategy will depend on the needs and resources of the user of this recommended practice. This recommended practice also provides guidance for selection of the medical devices to be tested, operation of RF transmitters used as RF test sources, and assessment of test results.

The preferred method for evaluation in most circumstances involves the use of the actual RF transmitter(s) (e.g., mobile phones and portable and mobile radios) as test sources to generate the same RF signals that would be encountered in the health-care facility. This approach also assumes that the end user has limited time and resources, a small number of critical medical devices to test, a limited space in which to perform the testing, and a single or a small number of specific RF transmitter signals to examine. In this preferred method, the RF transmitter is placed in a constantly transmitting state (i.e., test mode). The tests can be performed with or without an electric-field-strength (E-field) meter, although the use of an E-field meter is recommended.

Another important function of this recommended practice is to define a consistent test protocol to allow results to be obtained and compared within and across institutions. Clinical and biomedical engineers have

¹ As of the publication of this recommended practice, examples of wireless-enabled devices that comply with IEEE 802[®] technology were commonly referred to as Wireless Local Area Network—wLAN (WiFi[®]), Wireless Personal Area Network—wPAN (Bluetooth[®], ZigBee[®], XBee[®]), Wireless Metropolitan Area Network—wMAN (WiMAX[®]), and Wireless Regional Area Network—wRAN. This information is given for the convenience of users of this standard and does not constitute an endorsement by the IEEE of any trademark or trademark owner. Trademarks are the property of their owners. Other trademarks that are equivalent to those listed may be used to identify wireless technology based on IEEE 802 technology.

performed their own rudimentary (“ad hoc”) electromagnetic compatibility (EMC) testing using in-house methodology, RF transmitter sources, and medical devices. As a result, a comparison of the findings between health-care organizations might not be appropriate. To facilitate a comparison between health-care organizations, it is important that the recommendations herein are followed, deviations are kept to a minimum, and the testing is performed as consistently as possible.

Policies and procedures for mitigation of electromagnetic interference (EMI)² in health-care facilities, including the use or restriction of specific RF transmitters within specific areas, often called an exclusion zone, should be based on objective information, including that obtained by the use of this test method. A common problem with exclusion zones is that they are difficult to enforce, particularly with the increasingly common use of wireless devices and their expanding variety of applications, including use in medical equipment. With regard to purchase evaluation, confirming that medical devices conform to voluntary EMC immunity standards can provide some information, although many RF transmitters are able to exceed these immunity levels greatly when held close to a medical device. This recommended practice can be used to supplement the information obtained by testing for conformance to voluntary EMC standards. A list of EMC standards and guidelines that contain radiated RF immunity requirements applicable to medical devices as well as additional background information and further recommendations for mitigation of EMI in health-care facilities are presented in the annexes.

2. Caveats and limitations

This ad hoc test procedure is *not* intended to provide precise information on the exact threshold for EMI effects but instead to offer a basic test that can help identify extremely vulnerable medical device/RF signal combinations so they can be managed accordingly. It is also not intended to substitute for rigorous laboratory EMC testing (e.g., IEC 60601-1-2:2007 [B7] or IEC 60601-1-2:2014 [B8])³ of medical devices in which the test conditions are more fully controlled and the response of the medical device is characterized over a wide range of frequencies. This ad hoc test cannot fully characterize the radiated RF immunity of a medical device to all RF signals, and it addresses only the narrow frequency range and signal specific to the transmitters used as test sources. Performing the ad hoc test does *not* in any way offer a guarantee against interference risks, but it can assist in identifying medical devices that are particularly vulnerable to the RF signal under evaluation.

Variability of this ad hoc test can be reduced by using an E-field meter to determine incident E-field strength more accurately and by controlling the test variables as much as possible. However, even if an E-field meter is used in the study, variability can be introduced because of the range of response times among different models on the market that affect their ability to capture accurately the energy in complex pulse-modulated signals. If the test method is implemented without the use of an E-field meter, then even greater uncertainty can exist in the test results. Sources of uncertainty include the following:

- a) Variance in the RF output characteristics of the RF transmitter (e.g., as a result of manufacturing differences or battery charge)
- b) The specific type of antenna and small changes in 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
- e) Small changes in cable placement and the relative position of the RF test source and the medical device

The test results for each medical device apply only to that medical device unit and to the frequency, modulation, and field strength characteristics of the RF test transmitter source. The medical device might be either susceptible or immune to other frequencies, modulations, and field strengths. The results for the

² In this recommended practice, the international definition (IEC 60050-161-01-06) for “electromagnetic interference” is used: degradation of the performance of an equipment, transmission channel, or system caused by an electromagnetic disturbance.

³ The numbers in brackets correspond to those of the bibliography in Annex H.

same medical device can vary in the short term due to the variability in the test method; movement of people, equipment, or objects in the test area; or variations in local ambient RF fields. The results can also vary over time as the medical device ages or undergoes service or maintenance. The results for different units of the same model can vary for these same reasons, and differences in design or manufacture (e.g., design revisions, component substitutions, tolerances, physical location of components and wires, and assembly) can affect results.

3. Overview of the test

— Preparation for test

- 1) Select medical device(s)
- 2) Select RF test transmitter source(s)
- 3) Select test area
- 4) Characterize ambient field levels



— Testing

- 1) Place the medical device
- 2) Determine recommended minimum test distance
- 3) Expose medical device with the RF transmitter test source(s)
- 4) Observe medical device operation



— Test results

- 1) Use of test results in determining minimum separation distances
- 2) Test report
- 3) Correlation to laboratory immunity testing
- 4) Use of test results in EMI policies and procedures

4. Preparation for testing

4.1 General

Preparation for ad hoc testing involves selection of the medical device(s) to be evaluated, selection and configuration of RF transmitter test source(s) to be used for testing, and selection of the test area. Ad hoc

testing should be considered for existing equipment as well as for prepurchase evaluation. If prepurchase evaluation is not possible or practical, then testing of new electronic medical devices immediately following purchase should be considered per the selection criteria described in 4.2.

4.2 Selection of medical devices to be tested

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

- a) If the medical device is critical (i.e., life-supporting, used to monitor critical patient parameters, provides a diagnosis, or delivers drugs)
- b) If the medical device has not been tested for compliance with applicable EMC standards
- c) If failure or malfunction of the medical device could adversely affect the patient (e.g., if there is potential for patient injury or death)
- d) If there are known EMC problems with similar medical devices due to insufficient RF immunity
- e) If RF transmitters are frequently used in the vicinity of the medical device (e.g., in emergency rooms)
- f) If the medical device uses sensitive components or circuitry (e.g., circuits with high-gain amplifiers, patient lead wires and cables, and microprocessors can be particularly sensitive)
- g) If the medical device has been noted to perform erratically
- h) If 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 elsewhere in the building (e.g., the basement) or off-site

Medical devices that have demonstrated vulnerability to RF transmitter emissions in the past include some electroencephalography (EEG) and electrocardiography (ECG) monitors, some ventilators, some infusion pumps, some oxygen meters, and some fetal heart monitors. Critical medical devices include infusion pumps and ventilators.

4.3 Selection of RF test transmitter sources

4.3.1 General

RF transmitters that will be used in or near the health-care facility, have transmitter power up to 8 W, and can be conveniently relocated to the test area are candidates for use as test transmitters. Several different options for RF test transmitter sources are provided in 4.3.2 and 4.3.3. Users of this recommended practice are responsible for determining the test plan and RF test transmitter options that are most suitable for their requirements. The preferred method for evaluation in this recommended practice involves the use of actual handsets as RF transmitters (e.g., mobile phones and radios). Such an approach will be more likely to generate an RF signal most similar to what will be encountered in the health-care facility. This procedure will be described in the main text, with many common RF test transmitter sources listed in Table B.2 and the alternative RF test transmitter options listed in Annex C.

4.3.2 RF transmitters with fixed output power

RF transmitters that can be used as RF test sources include hand-held transceivers (e.g., walkie-talkies), telemetry transmitters and repeaters, wireless-enabled laptop computers, RFID readers, wireless-enabled

devices (e.g., wireless headsets), access points, and other RF wireless communication and information technology (IT) equipment. Wireless-enabled devices transmit at predefined power levels when linked to appropriate network and master devices, respectively. For more information on RF transmitters, see Annex B.

4.3.3 RF transmitters that are dynamically controlled

Many types of networks control the transmit power, frequency, and modulation format of devices attached to the network to manage total network performance. This means that the power, frequency, and modulation envelope of a specific device changes dynamically. In general, the user cannot control or predict these changes, as they are controlled by the network. Dynamically controlled transmitters are described in Annex B. A dynamically controlled transmitter linked to the network might be transmitting at a lower power on one frequency at one time, but at a later time, due to differences in network loading or operation, the same transmitter might be transmitting at a higher power level on a different frequency. This makes it difficult to use as a reproducible RF test source a dynamically controlled transmitter that is linked to the network.

Some mobile phones can be placed in a test transmit mode that is not associated with, or managed by, the network. This test mode is directed by internal software to transmit at a constant output power, independent of network control. Use of this mode is the preferred test method because in this mode, the transmitter output is not subject to the uncertainty inherent with network dynamic control.

There are two general methods of placing mobile phone handsets in test mode (described in 4.3.3.1 and 4.3.3.2), involving either key-code sequences or a link to a base-station simulator.

4.3.3.1 Placing in test mode via handset software modifications or settings

Placing a mobile phone handset in test mode usually requires either a unique key sequence or additional software and cabling to a laptop computer. These can sometimes be obtained from the local network operator (mobile phone service provider). Contact the network service provider to obtain permission to set mobile phones to test mode as well as any code information, software, or hardware that might be required.

4.3.3.2 Placing in test mode using a base-station simulator

As an alternative to obtaining key-codes or software unlocks, a base-station simulator can be used to control the power and mode of handsets (e.g., instructing them to transmit at maximum power). To mitigate the expense of obtaining such equipment, it might be possible to borrow or rent base-station simulators. It should be noted that it could be difficult to move this equipment throughout the health-care facility to perform in situ testing.

4.4 Selection of the test area

WARNING

The area in which ad hoc testing is to be performed should be located away from critical-care areas. It should be selected such that there are no critical medical devices in use in adjacent rooms or on the floors above and below that could be adversely affected by the test. During the test, no other RF transmitters should be operating in the test room or in adjacent rooms or on the floors above or below that could affect the testing. See 5.1 for precautions regarding electronic medical devices in use in nearby areas.