# 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

**Institute of Electrical and Electronics Engineers, Inc.**

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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

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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.

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# 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

## 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.

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## 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.


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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.

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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.

[1]English units are rounded.


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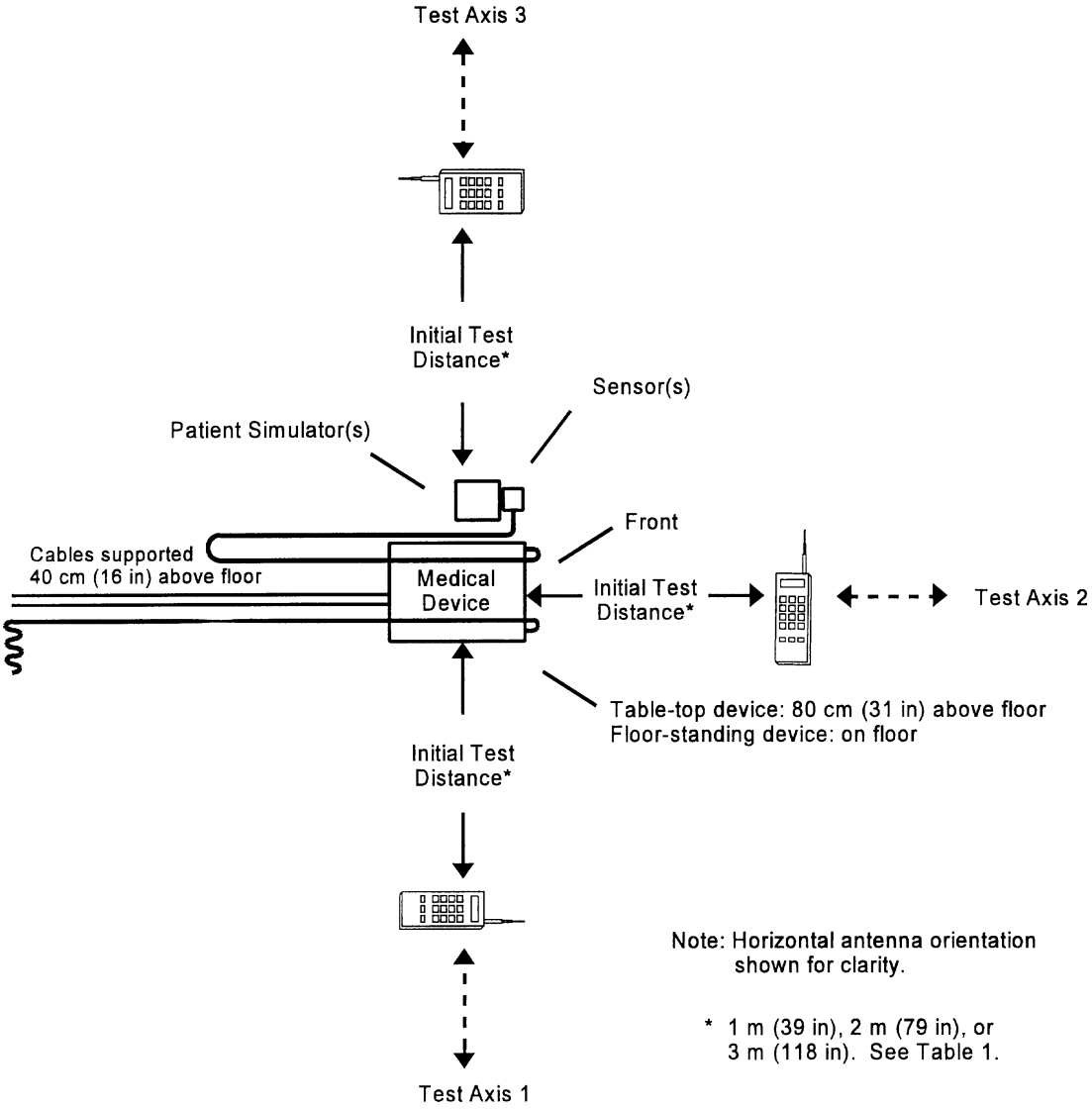



**Figure 1—Test setup (top view)**

During the ad hoc RF immunity test, record the responses of the medical device as a function of the RF transmitter distance, orientation, and frequency. The following list is suggested as a guide in noting device performance degradation that might occur as a result of the test. However, device-specific descriptions of any deviations from normal performance should be recorded.

a) No change in operation
b) Cessation of function without visible and/or audible alarm
c) Cessation of function with visible and/or audible alarm
d) Change in function or delivered therapy with alarm
e) Change in function or delivered therapy without alarm
f) Reboot or power down with loss of data
g) Reboot or power down without loss of data
h) Manual reset required to continue operation

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i) Change in mode or operational state without alarm
j) Change in mode or operational state with alarm
k) Alarm malfunction or failure to alarm
l) Visible and/or audible alarm with continuation of function
m) Change in measured and/or displayed data with change in operation
n) Change in measured and/or displayed data without change in operation
o) Change in audio indicator
p) Distortion of displayed waveforms
q) Display malfunction
r) Recorder malfunction
s) Error message or service code
t) Other (describe)

In noting the response of the medical device to the RF transmitter, it is also important to distinguish between effects that would and effects that would not impact patient or operator safety or the diagnosis, monitoring, and/or treatment of patients. For example, doubling of flow rate by an infusion pump would not be acceptable. Noise on an electrocardiogram (ECG) waveform that would be difficult to distinguish from a physiologic signal should also be considered an unacceptable response. Noise that is readily recognizable as artifact would be unlikely to affect patient or operator safety or diagnosis, monitoring, and/or treatment, and could be considered acceptable. However, health-care organizations should evaluate the response of each medical device tested to determine if it is acceptable or unacceptable.

## 6.4 Initial and recommended minimum test distances

The power of the transmitter is used to determine the initial (starting) test distance, as well as the minimum recommended test distance. If testing is performed closer than the minimum recommended test distance, damage to the medical device under test could result. The transmitter power rating listed on the nameplate is usually a sufficient approximation of the transmitter power, and can be used in determining these distances. In the case of cellular telephones, the output power is controlled by the cell base station. Therefore, cellular telephones should be configured to transmit at maximum power, if possible, as described in 6.5.2.

The initial and minimum recommended test distances as a function of transmitter output power appear in Table 1. The test distances were calculated so that the initial test distance would expose the medical device under test to field strengths of approximately 3 V/m to 7 V/m, and the minimum recommended test distance would expose the medical device under test to no more than approximately 22 V/m. The international standard for EMC of medical devices, IEC 60601-1-2 (1993-04) (see Annex A), specifies a radiated RF immunity of 3 V/m and testing in accordance with IEC 801-3 (second edition under consideration).[2] The international generic standard for immunity of equipment used in residential, commercial, and light industrial environments, IEC 61000-6-1 (1997-07) (see [B12]),[3] also specifies a radiated RF immunity of 3 V/m. It stipulates that the radiated RF immunity testing shall be performed in accordance with IEC 61000-4-3 (1995-03).

**CAUTION**—To prevent possible damage to the medical device under test and possible malfunction of medical devices used in nearby patient care areas, do not perform this test with transmitters having output power greater than 8 W.

[2]The draft second edition of IEC 801-3 was never published. IEC 801-3 (1984) has been withdrawn and is superseded by IEC 61000-4-3 (1995-03).

[3]The numbers in brackets correspond to those of the bibliography in Annex D.


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**Table 1—Initial and minimum test distances**

| Transmitter output power | Initial test distance | Minimum recommended test distance |
|---|---|---|
| 0 < P < 600 mW | 1 m (39 in) | 0.25 m (10 in) |
| 600 mW ≤ P < 2 W | 2 m (79 in) | 0.5 m (20 in) |
| 2 W ≤ P ≤ 8 W | 3 m (118 in) | 1 m (39 in) |

## 6.5 Use of RF transmitters

This ad hoc test could affect medical devices in use in rooms adjacent to the test area, as well as in rooms on the floors above and below the test area. See 6.6 for precautions.

All RF transmitters should be used within the terms of their license, if a license is required by the Federal Communications Commission (FCC). In general, most transmitters used for testing will be owned by and licensed to the health-care organization, its employees, or its contractors. Cellular telephones and licensed personal communications services (PCS) equipment are exceptions, as the licenses are held by the service provider.

RF transmitters should be operated during the test in a manner that is consistent with normal use, while positioned as described in 6.6. If possible, testing should be performed both with the antenna vertical and with the antenna horizontal. If the antenna location and/or orientation is not apparent (e.g., the antenna is internal or concealed), the transmitter manufacturer should be contacted to determine the orientation of the radiated RF field. Transmitter batteries should be fully charged at the beginning of the test, and periodic recharging may be necessary. It is recommended that two people perform the test. While one operates the transmitter as described below (herein referred to as the transmitter operator), the other should observe the medical device.

Considerations specific to particular types of transmitters are described below. Transmitters not explicitly mentioned below should be used in a manner similar to the type of transmitter listed below to which it is most comparable.

### 6.5.1 Hand-held transceivers

Hand-held transceivers such as walkie-talkies should be used with consideration for other users of the shared frequency or frequencies, particularly in the case of emergency and safety services. If possible, announce in advance over the shared frequency that the testing will be performed. During testing, the transmitter operator should repeat the phrase “this is a test” when transmitting.

Extend the antenna as it is used during normal operation. Turn the transceiver on and listen for other users of shared frequencies. During the entire test, wait until other users of shared frequencies are finished before continuing. Transmit (or key the transmitter) for no longer than 5 s at a time and then listen (for other users of the frequency) for no less than 10 s before proceeding. Alternatively, transmit (or key the transmitter) for no longer than 10 s at a time and then listen for no less than 15 s before proceeding. Repeatedly alternate between transmitting and listening in this manner until the testing is completed.

For each of the three test axes described in 6.6, begin by holding the transceiver at the normal use height with the antenna vertical and on the side of the operator closest to the medical device. Key the transceiver repeatedly, both rapidly and at various rates. Then hold the talk button down and say “this is a test” to establish normal modulation, within the time constraints described above. Proceed as described in 6.6. The entire test should be performed with each antenna used.

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At the conclusion of the test, announce over the shared frequency or frequencies that the testing is finished.

The RF output power of hand-held transceivers can be particularly affected by the state of charge of the batteries. Thus, if prolonged testing is performed with hand-held transceivers, it is important to recharge the batteries periodically.

### 6.5.2 Cellular telephones and PCS equipment

The output power of cellular telephones and PCS equipment is controlled by the base station. To achieve greater sharing of the available frequency spectrum, cellular telephones and PCS equipment are instructed by the nearest base station to transmit at the lowest power setting for which an acceptable signal is obtained. Thus, in the absence of absorbing and/or reflecting structures, the output power of a cellular telephone or PCS transmitter will be lower when it is closer to a base station. Conversely, a cellular telephone or PCS transmitter in a shielded room will attempt to contact the base station by transmitting at its maximum power. Under these conditions, the signal from the base station received by the telephone will be minimum. Therefore, it is recommended that this ad hoc test be performed in a basement or ground-floor location where the received signal indicator (if any) on the cellular telephone or PCS transmitter is as low as possible, with the result that the transmitted power will be maximum. If this is not feasible, it may be possible to place the cellular telephone or PCS equipment in a special mode, as discussed below.

The license for cellular telephones and licensed PCS equipment is held by the service provider. If the cellular telephone or PCS equipment cannot be made to transmit at maximum power consistently, the service provider should be contacted for permission to perform the test and for assistance in placing the transmitter in a special mode, if possible, that will permit it to transmit consistently at maximum power. It may also be necessary to contact the transmitter manufacturer for instructions on setting the equipment to transmit at maximum power. It should be noted that this setting may be a special test mode that transmits continuously and does not permit calls to be made. If this test method is not performed in a well-shielded location, it is important that cellular telephones and PCS equipment set to maximum power be powered on only when testing is in progress. It is also important that they be returned to their normal configuration as soon as possible after testing is completed.

Some cellular telephones are dual-mode, whereby they can operate as analog or digital cellular telephones. If this is the case, the location of the test area may need to be adjusted such that the telephone transmits in maximum power in the digital mode. The digital mode may affect the medical device under test more, or at a greater distance, than the analog mode. The telephone should be observed during the test to determine in which mode it is operating, and this information should be included in the test report.

It is important to note that cellular telephones and PCS equipment transmit intermittently whenever they are turned on (i.e., in the standby mode) to register their location with the base station (registration), even if a call is not in progress.

During the test, extend the antenna as it is used during normal operation. For each of the three test axes described in 6.6, begin by holding the telephone at the normal use height with the antenna vertical and on the side of the operator closest to the medical device. Proceed as described in 6.6. Make and receive calls. If no interference is observed, place the telephone in the standby mode and repeat the entire test procedure, unless standby (i.e., registration) transmissions for that model of telephone (as determined from the service provider) take place only intermittently (e.g., at time intervals longer than 30 s).

It should be noted that if the test is performed in a well-shielded location, it may not be possible to make or receive calls. If the cellular telephone or PCS equipment is placed in a test mode in which it continuously transmits a test signal, this mode may be used instead of making and receiving calls. If the test mode does not allow the RF signal to be modulated (e.g., by talking into the mouthpiece), the power should be switched off and on to simulate modulation.


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### 6.5.3 Table-top RF transmitters

Place the transmitter on a nonconductive, movable table or cart that is approximately 80 cm (31 in) high. Extend the antenna (if any) as it is used during normal operation. If possible, begin the test with the antenna vertical. Move the transmitter table or cart, proceeding as described in 6.6.

### 6.5.4 Medical telemetry transmitters

Attach the medical telemetry transmitter device to the transmitter operator as if the transmitter operator were the patient, consistent with normal use. During the test, proceed as described in 6.6, with the transmitter on the side closest to the medical device under test.

## 6.6 Test procedure

As noted in 6.5, this ad hoc test could affect medical devices in use in rooms in the vicinity of the test area, including rooms on the floors above and below. For this reason, unless the test area is well-shielded or far from patient-care areas, the ad hoc test should be performed with caution. Health-care personnel that are responsible for patients that might be affected should be informed in advance when the testing will take place. Unless prior ad hoc testing has shown all electronic medical devices in use in nearby areas to be immune to the RF transmitters that will be used during the ad hoc test, the health-care professionals should be alerted that the testing could cause these medical devices to malfunction and that they should maintain heightened vigilance during the test. The health-care professionals should then be notified prior to the beginning of the test and again when testing is completed. If an RF transmitter is found to cause a medical device in use in a nearby area to malfunction in a way that could adversely affect the care of a patient, testing should cease immediately and the test should be moved to another location and/or time. Alternatively, the affected medical device could be substituted with one that has been found to be immune to that particular RF transmitter at that separation distance. Medical devices that are in use in nearby areas and are found to malfunction during this ad hoc test should themselves be referred for ad hoc testing.

A summary of the test procedure is shown in Figure 2. Be sure that the batteries of all equipment (medical devices, RF transmitters, and patient simulators) to be used in the test are charged. With the RF transmitter used as described in 6.5, begin with transmitter on the left side of the medical device (Test Axis 1, as shown in Figure 1), at a distance from the medical device as specified by the initial test distance in Table 1, and at the normal use height.

NOTE—Lines at the 1 m (39 in), 2 m (79 in), and 3 m (118 in) initial test distances can be marked temporarily on the floor.

As stated in 6.5, one person should operate the transmitter and another person should observe the medical device. Neither should stand directly between the transmitter and the medical device, if at all possible. As stated in 6.1, there should be no structures or objects between the transmitter and the medical device.

Observe any degradation in the performance of the medical device. If performance degradation occurs, release the transmitter talk button or turn the transmitter off to see if the performance degradation ceases. Then re-key or turn on the transmitter to see if the performance degradation recurs. If reproducible performance degradation is found, move the transmitter away from the medical device along Test Axis 1 until the performance degradation ceases. Record the effect on the medical device and the distance. The distance at which the interference ceases is the approximate minimum separation distance for the medical device (including cables, sensors, and electrical accessories) and the particular transmitter tested. If the test is performed indoors and the interference does not cease within the test area, proceed out a door with the transmitter until the interference ceases and note the distance, as well as the details of the intervening architecture.

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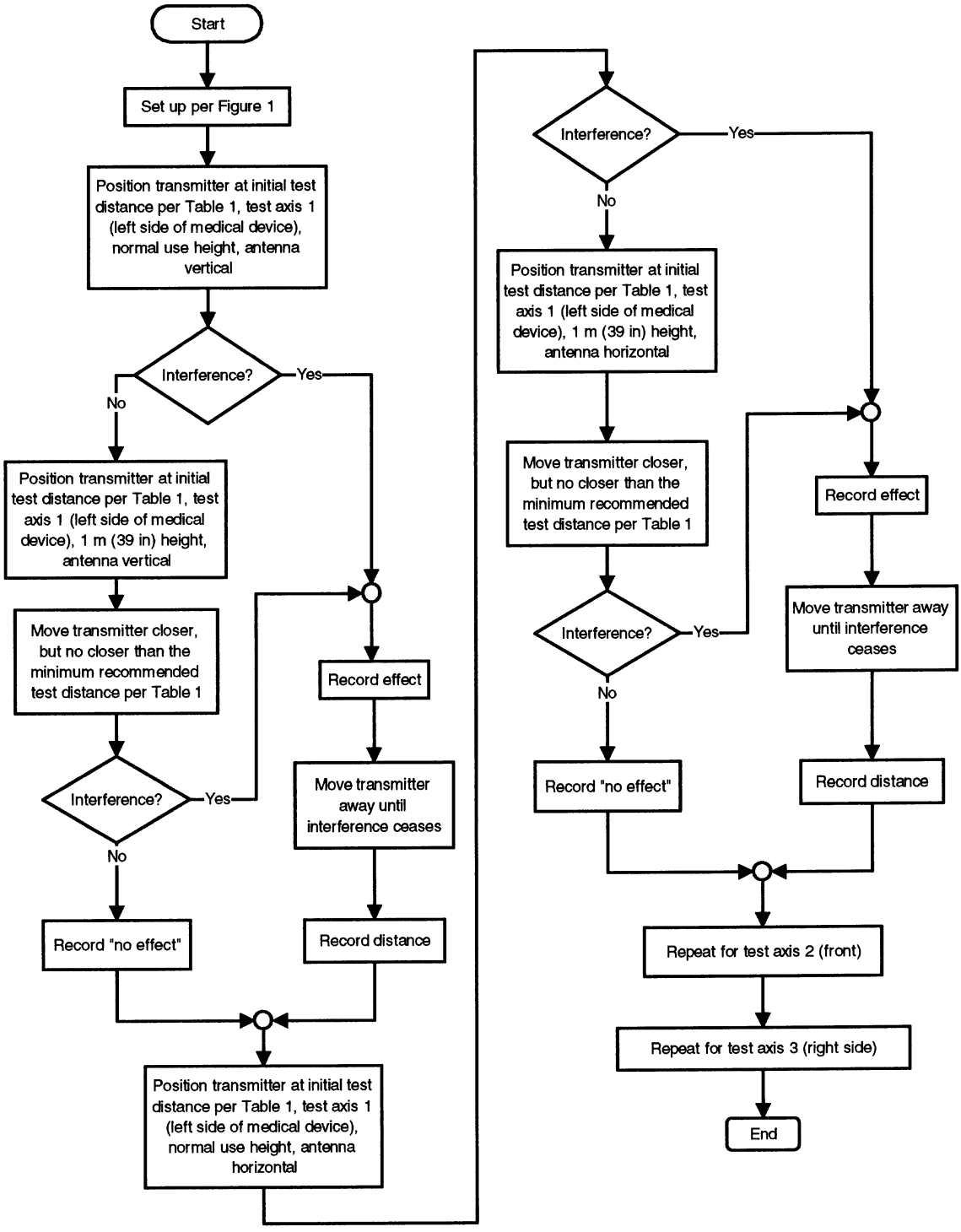



**Figure 2—Test procedure**



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If no interference was observed at the initial test distance, hold (or support, as described in 6.5.3) the transmitter at the initial test distance and at a height of approximately 1 m (39 in), with the antenna vertical. If the normal use height is within 20% of 1 m (39 in), use the normal use height. Bring the transmitter closer to the medical device along Test Axis 1, but no closer than the minimum recommended test distance as per Table 1. If medical device performance degradation occurs, repeat the on/off confirmation procedure described above. If reproducible performance degradation is found, continue to hold (or support) the transmitter at a height of approximately 1 m (39 in) and move the transmitter away from the medical device along Test Axis 1 until the performance degradation ceases. Record the effect on the medical device and the distance.

NOTE—This is done because there may be a "hysteresis" effect, in which performance degradation begins as the transmitter is brought closer to the medical device and then continues as the transmitter is moved further away, beyond the distance at which the interference first occurred.

If no performance degradation occurs for a given test axis and transmitter antenna orientation, record this fact.

If possible, position the transmitter so that the antenna is horizontal, parallel to the nearest side of the medical device. Repeat the entire test as described above. Then repeat the test with both vertical and horizontal antenna orientations along Test Axis 2 (front) and Test Axis 3 (right side).

## 6.7 Research testing

If no effect is noted during the testing described in 6.6, the health-care organization may choose to perform research testing. For the purpose of this recommended practice, research testing is defined as ad hoc radiated RF immunity testing in which the transmitter operator brings the transmitter closer than the minimum recommended test distance specified in Table 1 (e.g., in order to determine how the medical device might react if users did not observe the transmitter separation distance recommendations).

If research testing is performed, damage to the medical device could occur. Personnel that decide to perform research testing must assume responsibility for any damage to the medical device under test that might result from research testing. As recommended in 6.5, it is essential that research testing be followed by verification of normal operation of the device.

Research testing should be performed in a manner analogous to testing at the minimum recommended test distance, as described in 6.6; however, testing should also include approaching the medical device from above, first with the antenna vertical and the tip closest to the top of the medical device, and then with it horizontal.

## 6.8 In-situ testing

Some health-care organizations may chose to perform additional in-situ immunity testing, in which minimum separation distances between RF transmitters and medical devices are determined in a location where the medical device is used. While this would include the effects of absorption and reflection by existing structures and objects in the use location, the results are likely to be more variable from location to location within a health-care facility (even within the same room), and from facility to facility, than the test method specified in this recommended practice.

If in-situ testing is performed, it should only be done with extreme caution. There should be no patients undergoing diagnosis, monitoring, and/or treatment in the room in which the testing is performed. The in-situ test could also affect electronic medical devices in use in nearby rooms, as well as on the floors above and below the in-situ test area. See 6.6 for precautions regarding electronic medical devices in use in nearby areas.

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## 7. Test results

The test results should be used to determine a minimum separation distance between each tested transmitter and medical device (including cables, sensors, and electrical accessories). When assessing the test results, it is essential that they be interpreted bearing in mind the caveats and limitations listed in Clause 2. The test results apply only to that specific, individual medical device. Other units of the same model may behave differently. The test results also apply only to the frequency, modulation, and field strength characteristics of the RF transmitter used. The medical device may be either susceptible or immune to other frequencies, modulations, and/or field strengths. In addition, the test is affected by the structure of the facility in which the test is performed, as well as by furniture and nearby objects. Results may be different in another location. Multiple reflections of RF fields in the actual use location can sum in such a way that interference can occur at distances greater than the minimum separation distance determined from this test procedure.

The health-care organization should determine whether each effect or performance degradation observed during the test is acceptable (see 6.3). The advice of clinical staff is helpful in determining the clinical acceptability of any observed performance degradation.

For each transmitter and medical device, the minimum separation distance can be determined as follows (see Figure 3):

a) If there were unacceptable changes in medical device performance during the test, the minimum separation distance is equal to the largest distance at which the performance changes occurred.

b) If research testing was not performed and either there were no changes in medical device performance as a result of this test or the performance changes were acceptable, the minimum separation distance is equal to the minimum recommended test distance for that transmitter from Table 1.

c) If research testing was performed and either there were no changes in medical device performance as a result of this test or the performance changes were acceptable, it would still be prudent to maintain a minimum separation distance of approximately 0.25 m (10 in) due to the variability of this ad hoc test method, particularly the field strengths in the near field (a distance of less than several wavelengths of the transmitter carrier frequency), the power level of the transmitter, and the effects of the test location.

The initial test distance corresponds approximately to the general radiated RF immunity requirements of IEC 60601-1-2 (1993-04) (see [B7]). However, due to the variability in this ad hoc test method (see Clause 2), possible differences in what is considered acceptable device behavior during the test (see 6.3), and the provisions in IEC 60601-1-2 (1993-04) that are listed below, the results of this test method and compliance with IEC 60601-1-2 (1993-04) may not correlate.

The radiated RF immunity requirements and allowances of IEC 60601-1-2 (1993-04) that could lead to differences in test results between IEC 60601-1-2 (1993-04) and this ad hoc test are as follows:

— For patient-coupled medical equipment, immunity test levels and test methods are specified by the manufacturer.

— For medical equipment that is not patient-coupled, manufacturers may claim lower immunity test levels (than 3 V/m), provided the test level can be justified and any actions required of the user as a consequence are described in the equipment documentation.

— Medical equipment that is not life-supporting is only required to be tested at the industrial, scientific, and medical (ISM) frequencies that are between 26 MHz and 1000 MHz. There are only four such frequencies: 27.12 MHz, 40.68 MHz, 433.92 MHz, and 915.00 MHz.


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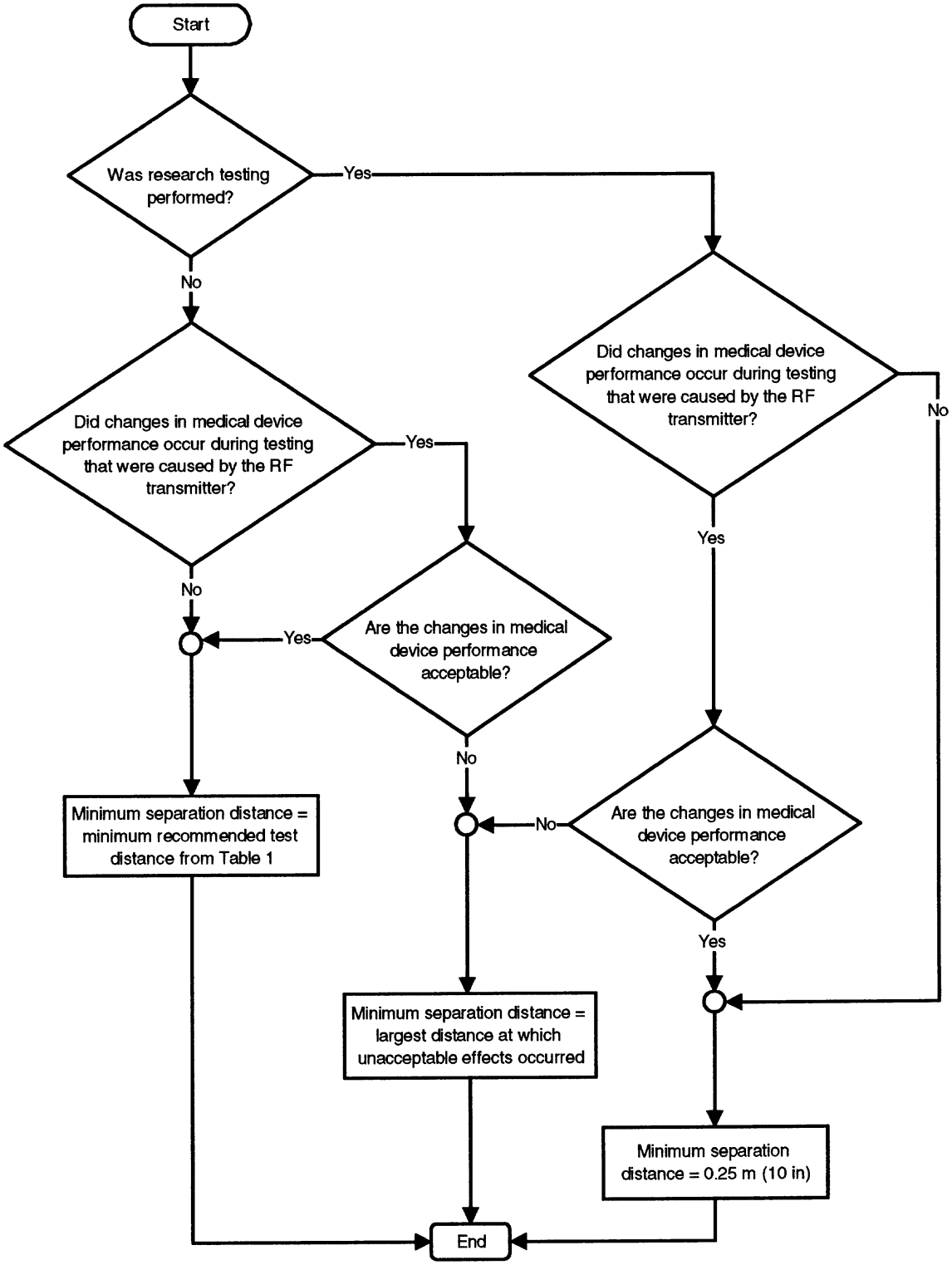



**Figure 3—Determination of minimum separation distance**

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If desired, the radiated RF immunity of the medical device can be estimated using Equation (C.1) of Annex C by solving the equation for *E,* substituting the rated power of the transmitter for *P,* and substituting the experimentally determined minimum separation distance for *d*.

Results of the test should be considered in the development of policies and procedures for mitigation of EMI with respect to each medical device and RF transmitter used in the test (see Clause 9).

## 8. Test report

The test report should document the test conditions and results in detail, to facilitate reproduction of the test results by others. The documentation should include the model and serial numbers of the equipment used. It should also include photographs and/or diagrams of the test area and the test setup. For each transmitter, it should list the frequency, the initial test distance, the antenna orientation, the responses of the medical device (if any), whether the responses were considered acceptable or unacceptable, and the experimentally determined minimum separation distance.

## 9. Use of the test results

The results of this ad hoc test should be considered in setting the health-care organization's policies and procedures for mitigation of EMI, particularly with respect to the medical devices and the RF transmitters used in the test.

The health-care organization's policies and procedures should ensure a separation distance between each RF transmitter and each medical device (including cables, sensors, and electrical accessories) that is greater than the largest experimentally determined minimum separation distance. Individual health-care organizations may choose to take additional action based on changes in medical device performance that were observed during the test.

If unacceptable effects upon a medical device result from a particular RF transmitter during this ad hoc test, the following are actions that health-care organizations should consider:

a) Instituting policies and procedures and educating staff, patients, and visitors to ensure separation of the RF transmitters that caused unacceptable effects from the medical devices (including cables, sensors, and electrical accessories) that were susceptible. For example, cellular telephone users can be requested to turn their telephones off when in certain areas. Hand-held transceiver users can be asked not to transmit when in certain areas, but only to receive. It would be prudent to restrict the use of an RF transmitter to a distance at least twice that which caused an unacceptable effect in a medical device. Larger safety margins may be necessary if there are large, electromagnetically reflective surfaces present in the use location. Health-care organizations should be aware that the composition of walls and floors may or may not be such that transmission of RF signals is blocked appreciably. Informative brochures that explain the reasons for transmitter use restrictions should be available to the affected transmitter users. In addition, these users should be provided with alternative means of communication, such as (wired) pay telephones or house telephones.

b) Relocating sensitive medical devices (including cables, sensors, and electrical accessories) so that they will be further from areas where the particular RF transmitters are commonly used.

c) Using the medical device in a shielded room. In such a case, RF sources should be prohibited from this room.

   NOTE—Unless special RF-absorbing material is installed inside a shielded room, the use of an RF transmitter inside the shielded room can produce field strengths in some areas of the room that are considerably higher than that predicted by free-space calculations [e.g., by using Equation (C.1)]. (See [B13].) Also, transmitters with adjustable output power such a cellular telephones and PCS equipment may attempt to transmit at their maximum power when brought into a shielded room.


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d) Sharing the results of ad hoc testing with the device manufacturer and discussing ways to minimize the potential for EMI.

e) Replacing sensitive medical devices with devices that meet EMC standards (see Annex A).

f) Retaining the services of an EMC consultant for assistance in characterizing the electromagnetic environment, solving specific problems, and/or educating staff.

If medical device performance effects that were noted during the test occur during use of the device, this could indicate possible violations of the health-care organization's separation distance policies and procedures.

When new communications systems, wireless computer systems, or any new RF transmitter systems are being purchased for the facility, particularly those with different frequencies, modulation techniques, and/or output power from transmitters that have already been tested, the health-care organization should consider repeating this ad hoc test with the new transmitters, preferably prior to purchase.

Health-care organizations should consider repeating this ad hoc test periodically because the RF immunity of a medical device can change as it ages and undergoes service and maintenance.

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# Annex A

(informative)

## EMC standards and guidelines containing radiated RF immunity requirements that may be applicable to medical devices

IEC 60601-1-2 (1993-04), Medical electrical equipment—Part 1: General requirements for safety—2. Collateral Standard: Electromagnetic compatibility—Requirements and tests.[4]

IEC 61000-4-3 (1995-03), Electromagnetic compatibility (EMC)—Part 4: Testing and measurement techniques—Section 3: Radiated, radio-frequency, electromagnetic field immunity test [Revision of IEC 801-3 (1984)].

MDS-201-0004: 1979, Electromagnetic Compatibility Standard for Medical Devices (FDA voluntary guideline).[5]

MIL-STD-461D, Requirements for the Control of Electromagnetic Interference Emissions and Susceptibility, 1993.[6]

MIL-STD-462D, Measurement of Electromagnetic Interference Characteristics, 1993.

Reviewer Guidance for Premarket Notification Submissions: November 1993 (an FDA reviewer guidance document).[7]

[4]IEC publications are available from IEC Sales Department, Case Postale 131, 3, rue de Varembé, CH-1211, Genève 20, Switzerland/Suisse. IEC publications are also available in the United States from the Sales Department, American National Standards Institute, 11 West 42nd Street, 13th Floor, New York, NY 10036, USA.

[5]Available as Accession Number PB271635 from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161, USA.

[6]MIL-STDs are available from Defense Printing Service Detachment Office, 700 Robbins Avenue, Philadelphia, PA 19111-5094, USA.

[7]Available as Excerpts Related to EMI from Nov. 1993 Anesthesiology and Respiratory Devices Branch from CDRH Facts-on-Demand, (800) 899-0381 or (301) 827-0111.



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# Annex B

(informative)

# Characteristics and types of RF transmitters

## B.1 Characteristics of RF transmitters

### B.1.1 RF propagation and the relationship between frequency and wavelength

The frequency of radio waves (tens of kilohertz and up) permits them to propagate through space. The frequency and wavelength are related by the speed of light, which (in a vacuum) is a constant, by the following equation:

$$\text{frequency} \times \text{wavelength} = \text{speed of light} = 3 \times 10^8 \text{ m/s} \quad \text{(B.1)}$$

The equation is easiest to use when the wavelength is in meters and the frequency is in megahertz:

$$\text{frequency (in MHz)} \times \text{wavelength (in m)} = 300 \quad \text{(B.2)}$$

Table B.1 provides example solutions to this equation.

**Table B.1—Example solutions to Equation (B.2)**

| Frequency (MHz) | Wavelength (m) |
|---|---|
| 1 | 300 |
| 3 | 100 |
| 10 | 30 |
| 30 | 10 |

| Frequency (MHz) | Wavelength (m) |
|---|---|
| 100 | 3 |
| 300 | 1 |
| 1000 | 0.3 |
| 3000 | 0.1 |

Because RF electromagnetic energy propagates through space, it can affect medical devices that are located remotely to the source of RF energy. Interference can be more likely to occur at RF frequencies at which the cables, wires, printed circuit board traces, and components of a medical device are odd multiples of 1/4 of the wavelength. However, in intense RF fields and/or for susceptible circuitry, effects may be observed for longer and/or shorter conductors, including those as small as approximately 1/20 of the wavelength.

### B.1.2 Electric and magnetic fields

RF energy is comprised of two interrelated components, electric (E) and magnetic (H) fields. It is usually expressed in terms of the magnitude of the electric field vector, in volts per meter, but may also be measured in terms of the magnitude of the magnetic field vector, in amperes per meter. For measurements in the near field, where the distance from the source is small compared to the wavelength, the term *electric field strength* or *magnetic field strength* is used according to whether the resultant E field or H field is measured. At lower frequencies (below 100 MHz), measurements are typically made in the near field. The E and H field

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strengths fall off with respect to the distance from the source. However, very close to a source, such as a cellular telephone, the field strengths can be quite high.

Unintended coupling of E fields to medical devices usually occurs through relatively straight cables, wires, and printed circuit board traces in the device, and can occur at large distances from the RF source. Unintended coupling of H fields to medical devices usually occurs through coiled cables, wire loops, and loops formed by printed circuit board traces in the device, and usually occurs very close to the RF source.

### B.1.3 Sources of RF energy

RF energy can be emitted by natural phenomena, as well as by man-made sources. Natural sources include lightning and electrostatic discharge (ESD). Man-made sources can emit RF energy intentionally or unintentionally.

Intentional emitters use RF energy for communications, control, or for treatment of material or patients. Intentional emitters used for communications include hand-held transceivers, cellular telephones, telemetry transmitters and repeaters, radio paging systems, mobile radio transmitters, citizens band (CB) and amateur radio transmitters, television (TV) broadcast transmitters, AM and FM radio broadcast transmitters, radars, and wireless radio local area networks (LANs). Intentional emitters used for control include garage door openers, keyless entry, and radio remote-control transmitters. Intentional emitters used for treatment of material or patients include RF sealers, microwave diathermy, and electrosurgical units.

Unintentional emitters include any electrically powered equipment, even equipment that is battery powered. Unintentional emitters of RF energy include computers, electronic games, and radio and TV receivers. The emissions of some equipment are regulated by the FCC. However, these regulations do not require that RF emissions from unintentional emitters be zero, but rather permit such equipment to emit a very low level of RF energy.

Medical devices having insufficient electromagnetic immunity could be affected by any one of these sources. However, this recommended practice is limited to portable, intentional emitters with output power of 8 W or less.

### B.1.4 Effective radiated power

The effective radiated power of an RF transmitter is a function of its output power and antenna efficiency at the transmission frequency. These parameters are fixed for most transmitters. However, for cellular telephones, the output power is controlled over a wide range, up to its maximum rating, by the base station. In general, the further away and/or the more shielded the use location is from the nearest base station, the higher the output power of the cellular telephone will be, up to its maximum rated power.

A transmitter having a higher power can affect a medical device at a greater distance than one having a lower power at the same frequency. EMI problems in health-care facilities can be minimized by using communications equipment having the lowest possible output power that can accomplish the intended purpose.

### B.1.5 Field strength versus distance

The field strength of an RF transmitter is very high directly adjacent to the antenna. In the near field (up to several wavelengths from the antenna), the field strength falls off very rapidly. In free space, at distances greater than several wavelengths, the field strength falls off as the inverse of the distance ($1/d$), i.e., for every doubling of the distance, the field strength is reduced by one-half. However, in most health-care facilities, reflections from structures and objects result in a very complex relationship between distance and field strength. As a consequence, field strengths can occasionally be higher than expected at greater distances, and


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lower than expected at lesser distances (see [B16]). This can be particularly true inside a shielded room (see [B13]).

Even so, radiated EMI problems in health-care facilities can generally be minimized by managing (increasing) the distance between RF transmitters and susceptible medical devices (including cables, sensors, and electrical accessories).

### B.1.6 Modulation

An RF signal without modulation is known as a continuous wave (CW) signal. In order to carry information, the RF signal is usually modulated in one or more of the following ways: amplitude modulation (AM), frequency modulation (FM), phase modulation (PM), and/or pulse modulation. In AM, the information is carried in the variations of the field strength, which can be as much as 100%. In FM, the information is carried in small changes in the frequency of the signal. In pulse modulation, the amplitude, duration, or time position of pulses in a pulsed RF signal is varied. Morse code is a simple form of pulse modulation. Some (e.g., digital) cellular telephones use both FM and time division multiplexing (TDMA), a form of pulse modulation.

It is often the modulation that interferes with susceptible electronic equipment, particularly AM and pulse modulation. The modulation riding on the CW RF carrier can be demodulated by nonlinear circuit elements such as semiconductor junctions in diodes, transistors, and integrated circuits. Demodulated waves can appear as unintended AC signals or can be filtered by circuit capacitance, resulting in unintended DC offsets.

Two-way radio communications usually consist of a series of short transmissions. This on-off keying can be likened to very-low-rate pulse modulation and can affect susceptible circuitry, even in the case of FM transceivers.

### B.1.7 Duty cycle

The duty cycle (percent on-time) of RF transmissions differs widely among transmitters. AM, FM, and TV broadcast transmitters operate continuously. Hand-held transceivers, CB, and amateur radios transmit only while the talk button is pressed (keying). When active, cellular telephones transmit either continuously or intermittently, depending on the technology. Cellular telephones and PCS equipment also transmit intermittently in the standby mode, to register their location with the base station (registration).

Some medical devices are particularly susceptible to keying and/or to intermittent transmissions.

### B.1.8 Architectural effects

The architecture of a health-care facility can significantly affect the field strengths that result at any given location (see [B22]), from RF transmitters both inside and outside the facility. Structures such as solid or screen metal walls or siding can attenuate RF signals entering the health-care facility or the treatment area. Steel reinforcing rods in concrete walls and floors can provide a certain degree of shielding, as can the earth itself (e.g., in the basement). However, RF can pass through walls, floors, and ceilings. Standing waves can occur within a building, resulting in floor-to-floor propagation patterns that differ from what might be expected (see [B16]). This can have particular implications for rooftop transmitters and their effect on equipment within the building. Also, a wide range of RF frequencies can pass readily through glass windows, depending on the reflection/glare reduction material used (if any) and the adequacy of the bonding (if any) between the reflection/glare reduction material, the window frame, and earth ground.

Some very sensitive medical devices [e.g., electroencephalographs (EEGs) and audiometers] are routinely used in shielded rooms or booths. Magnetic resonance imaging (MRI) is operated in a shielded room to

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prevent EMI from affecting the imaging system. While x-ray shielding may be effective for x-rays, windows and door seams in x-ray shielded rooms generally do not attenuate higher frequency RF fields, and seams in the x-ray shield can re-radiate RF.

Depending on their placement, however, metallic objects (e.g., steel reinforcing rods, metal cabinets, neighboring buildings) can also reflect RF fields. If the direct and reflected RF waves arrive in phase, the field strength will be higher than that of the original incident wave. Also, large metallic objects such as heating/cooling ductwork and/or electrical wiring and conduit can re-radiate RF within a facility.

## B.2 Types of RF transmitters

### B.2.1 Portable RF transmitters

The most prevalent portable RF transmitter is the cellular telephone. Cellular telephones periodically radiate RF energy while they are turned on, even if a telephone call is not in process. Cellular telephones cease to be an RF signal source only when the power is switched off. Other portable transmitters include hand-held transceivers used by emergency, maintenance, and security personnel, as well as amateur radios used for emergency communications or for recreation.

### B.2.2 Mobile RF transmitters

Mobile radio transmitters are usually installed in vehicles and aircraft. These include cellular “car phones” and CB radios, as well as radio transmitters in ambulances, police and fire vehicles, delivery vehicles, taxis, shuttle buses, and aircraft, including helicopters.

Mobile transmitters are excluded from this recommended practice because their higher power levels would necessitate large test areas and large initial test distances. However, mobile RF transmitters can cause EMI at greater distances than can portable RF transmitters because of their higher power levels.

### B.2.3 Fixed RF transmitters

Fixed RF transmitters include AM, FM, and TV broadcast stations as well as a multitude of RF transmitters used for paging, short-wave radio, aeronautics, cellular base stations, radio LANs, amateur radio, and many other purposes. In a heath-care facility, the in-house radio paging system is a likely source of high-field-strength RF.

Fixed transmitters are excluded from this test procedure because it is difficult to vary the spatial relationship between the device under test and a fixed transmitter in a meaningful way, and they usually cannot be switched off and on to determine correlation with malfunctions.

### B.2.4 Transmitter frequency bands, output power levels, and estimated field strengths at 1 m (39 in)

For prevalent RF transmitters, Table B.2 presents the frequency bands, output power levels, and estimated field strength at a distance of 1 m (39 in). The field strength estimates are presented in volts per meter. Most were calculated using Equation (C.1), which appears in Annex C.


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**Table B.2—Typical transmitters, output power levels, and estimated field strengths at 1 m (39 in)**

| Product | Frequency (MHz) | Power (W) | Field strength @ 1 m (V/m) |
|---|---|---|---|
| Paging transmitters | 49 | 250 | 110[a] |
| Mobile radios | 138–470 | 25 | 35[a] |
| Hand-held transceivers | 27, 49, 138–470 | 5 | 15[a] |
| Police/ambulance | 138–900 | 10–100 | 22–70[a] |
| Wireless LANs | 912, 2400 | 0.1 | 2.2 |
| Personal digital assistants | 896–940 | 4 | 14 |
| Radio modems | 896–901 | 10 | 22 |
| Cellular telephones[b] | 800–900 | 0.6 | 5.4 |
| Personal communications satellite telephones | 1610–1626.5 | 1 | 7 |
| Licensed PCS equipment | 1850–1910 | 1 | 7 |
| CISPR 11, CISPR 22[c] | 25–1000 | $0.04 \times 10^{-6}$ | 0.0014[d] |

[a]For these transmitters, 1 m (39 in) is in the near field. Therefore, these field strength estimates may be very inaccurate.
[b]Global systems mobile (GSM) cellular telephones, particularly in Europe, may use higher power levels.
[c]Industrial, scientific, and medical (CISPR 11) devices that are not intentional emitters of RF and information technology equipment (CISPR 22), each of which are in compliance with the respective emissions standard.
[d]This represents the approximate maximum RF field strength at a distance of 1 m (39 in) from this equipment.

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# Annex C

(informative)

## Recommendations for mitigation of EMI in health-care facilities

Medical device users and health-care facility engineers, administrators, architects, and planners can help prevent EMI problems. For additional guidance on this subject, see [B1], [B2], [B4], [B9], [B10], [B11], [B14], [B15], [B17], [B18], [B19], [B20], [B21], [B22], [B23], and [B24]. The first step is to promote awareness among staff, patients, and visitors, in a nonalarming manner, of the potential effects of EMI on medical devices. Equipment purchased should conform to appropriate EMC standards. For electromedical equipment, IEC 60601-1-2 (1993-04) specifies a general immunity test level of 3 V/m over the frequency range 26 MHz to 1 GHz. More specific EMC requirements may be specified in product-specific standards. Devices can meet these standards and yet have a higher or lower immunity than 3 V/m. Therefore, hospital engineers should examine the EMC test report to determine the immunity of the medical device, the pass/fail criteria used, and how the device performed during the test.

Medical device users should follow the manufacturer's recommendations for avoiding EMI problems. Problems that occur should be reported to the appropriate regulatory authorities.

The use of portable RF transmitters such as hand-held transceivers and cellular telephones in proximity to medical devices may need to be restricted. Health-care facility engineers should become aware of the existence of and the operating characteristics of RF transmitters on the roof of the building and also those in the vicinity. Rooftop RF transmitters found to disrupt the performance of medical devices within the facility should be removed, if possible. If it is impractical to remove rooftop RF transmitters and if they are found to cause excessive medical device performance degradation, the susceptible devices should be replaced or relocated to other areas, or shielding of the area should be considered. However, shielding an area can result in problems if RF transmitters are allowed inside the shielded area (see discussion below). Until all medical devices in use meet minimum electromagnetic immunity standards, it may also be necessary to restrict the use in the immediate neighborhood of the health-care facility of two-way radios, particularly mobile radios of moderate to high power such as those used by security, police and fire services, delivery services, shuttle busses, and taxis.

Whether or not a medical device meets minimum electromagnetic immunity standards, ensuring that the medical device (including cables, sensors, and electrical accessories) is not exposed to ambient RF fields that exceed its radiated RF immunity can help prevent interference problems. This can often be accomplished by maintaining physical separation between the medical device and RF transmitters. While the field strength to which a medical device is exposed can only be determined accurately by precise RF measurements, if the radiated immunity of a medical device and the rated output power of a transmitter are known, the minimum separation distance to be maintained between them to help prevent interference can be estimated within approximately a factor of ten.

In free space, in the far field (distance greater than several wavelengths of the transmitter carrier frequency), and for typical antennas, the field strength from a transmitter varies proportionally to the inverse of the distance from the transmitter. If the output power of a transmitter is known, the dipole equation (see [B5] and [B8]) can be used to calculate an estimate of the field strength in the far field as a function of distance. If the radiated RF immunity of a medical device is known, substituting the immunity for the field strength and solving the dipole equation for distance yields the following:

$$d = k\frac{\sqrt{P}}{E} \tag{C.1}$$


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where

*P* is the output power of the transmitter in watts;
*E* is the immunity of the medical device in volts per meter;
*d* is the minimum separation distance in meters;
*k* is a constant in the range of 0.45 to 7, depending on the antenna efficiency of the transmitter.

The value of *k* for cellular telephones is approximately 7 (see [B5]), and the value for lower-frequency hand-held transmitters such as walkie-talkies can be as low as 3 (see [B8]).

This approximation does not apply at distances less than several wavelengths of the transmitter carrier frequency (i.e., in the near field). Therefore, for medium-power RF transmitters that are normally hand-held, an appropriate minimum separation distance should be on the order of 1 m (39 in).

The limitations of this estimate are described below. The following is assumed:

— A single transmitter is present, radiating at its maximum rated power; and
— The worst-case susceptibility of the medical device occurs at the frequency of the transmitter.

In addition, if multiple RF transmitters (e.g., cellular telephones) are in use, the actual minimum separation distance could be greater than that determined from the equation. If a single RF transmitter is radiating less than its maximum power rating or the worst-case susceptibility of the medical device occurs at a frequency other than that of the RF transmitter of interest, the actual minimum separation distance could be less than that determined from the equation.

The actual minimum separation distance is also affected by antenna efficiency and pattern and by absorption and reflection by buildings, objects, and people. Multipath reflections could result in an actual minimum separation distance that is greater than that determined from the equation, and absorption could result in an actual minimum separation distance that is less than that determined from the equation. If an RF transmitter is used in a shielded area that is not lined with adequate RF absorbing material, reflections within the shielding can result in areas of high field strength (see [B13]). In this case, Equation (C.1) should not be used.

Table C.1 presents some example free-space, far-field estimates for the case in which $k = 7$.

**Table C.1—Example minimum separation distance estimates for k = 7[a]**

| Output power of RF transmitter | Immunity of medical device | | |
|---|---|---|---|
| | 0.1 V/m | 3 V/m | 10 V/m |
| 10 mW | 7 m | 0.25 m[b] | 0.25 m[b] |
| 100 mW | 22 m | 0.74 m | 0.25 m[b] |
| 600 mW | 54 m | 1.8 m | 0.54 m |
| 2 W | 99 m | 3.3 m | 1 m |
| 100 W | 700 m | 23 m | 7 m |

[a]See previous discussion of the limitations of this estimation in this annex.
[b]See discussion of minimum distance in Clause 7.

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EMC should also be considered in the design, site analysis, floor planning, and construction of health-care facilities. Architectural EMC techniques should be used in the design and construction of the facilities (see [B22]). Power distribution should be designed to minimize conducted interference from high-power equipment. Potential sites under consideration for new facilities should be examined for proximity to high-power transmitting antennas, and an electromagnetic site survey should be made. Floor planning is important for both new and existing facilities, and units in which particularly sensitive devices are used, such as fetal heart monitors, EEGs, electromyographs (EMGs), and older apnea monitors, should not be located near areas where intense RF emissions can occur, including imaging systems, elevators, or electrosurgery suites. Attention should also be paid to equipment located on the floor above and below sensitive medical devices, as well as proximity to outside walls or drive-throughs that might be exposed to mobile two-way radios at close range. Some existing rooms may need to be shielded, in order to ensure proper operation of medical devices. However, if RF transmitters are used inside shielded rooms that are not lined with adequate RF absorbing material, increasing the separation distance could be ineffective and EMI problems could be worse than without the shielding.

In summary, health-care organizations should

a) Consider using this ad hoc test method to test potentially susceptible medical devices;
b) Encourage clinical and biomedical engineers to learn how to assess the electromagnetic environment of their facility;
c) Manage (increase) the distance between sources of electromagnetic disturbance and susceptible medical devices (including cables, sensors, and electrical accessories);
d) Manage (e.g., label, replace, or contact the manufacturer's representative to determine if EMC upgrades are available for) medical devices that are highly susceptible to EMI;
e) Use the lowest output power necessary to accomplish the intended purpose for sources of electromagnetic energy that are internal to the facility and are within the health-care organization's control;
f) Educate staff (including nurses and physicians) to be aware of, and to recognize, EMI-related problems;
g) Share relevant EMI/EMC information with others;
h) Consider EMI when planning facility layouts;
i) Consider EMC when purchasing new medical equipment [e.g., acquire devices that meet the requirements of IEC 60601-1 (1988-12) as amended (see [B6]), its collateral standards, and any applicable IEC 60601-2 ("particular" or "part two") standards];
j) Educate patients about EMI problem recognition and mitigation, including home-care patients; and
k) Consider retaining the services of an EMC consultant for assistance in characterizing the electromagnetic environment, solving specific problems, and/or educating staff.


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# Annex D

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