Immunity testing for Active Implantable Cardiovascular Devices

Scientific studies have reported increased interference effects in pacemakers.

DANIEL D. HOOLIHAN
Hoolihan EMC Consulting
Lindstrom, MN

INTRODUCTION

ACTIVE IMPLANTABLE CARDIOVASCULAR Devices (AICDs) are now widely distributed within the general population. For example, in the United States, more people (the baby boomers) are approaching the age where these devices will add longevity and value to their lives. The number of electronic emitters of energy grows as microcircuits increase in power (although they may decrease in size). Some new EMC standards have been developed, or are under development, to assure the compatibility of the AICDs with the increasing number of electromagnetic emitters.

AICDS

Active Implantable Cardiovascular Devices consist primarily of (1) pacemakers and (2) implantable cardioverter defibrillators, both of which can be classified as life-sustaining devices. The interaction of electromagnetic emitters in our everyday environment with AICDs is a growing concern for patients using the devices, corporations developing the medical devices, and regulators responsible for safeguarding the health of individuals using these devices.

The risks from the undesirable interaction between environmentally-based emitters and the AICDs include the inhibition of the device's operation and/or delivery of inappropriate therapy that could result in serious injury or death.

For the past 25 years, pacemakers and Implantable Cardiovascular Devices for the United States market have typically been tested for compliance to a 1975 Draft Association for the Advancement of Medical Instrumentation (AAMI) pacemaker standard. That standard requires *in vitro* testing of pacemakers in a 450-MHz electromagnetic field up to a peak intensity of 200 V/m. That intensity was based on levels measured from radars and from close proximity to early-design microwave ovens. When a pacemaker was tested and found to be immune to 200 V/m, it could supposedly operate inside a typical microwave oven without failing!

NEW AND INCREASING EMITTERS

The impetus for a new immunity standard for AICDs arises from the increasing number of new emitters created by improvements in technology. Examples include (1) the proliferation of digital technology, (2) smaller and smaller wireless communication devices (*e.g.*, cell phones), and (3) increasing peak transmitting power.

Scientific studies have reported increased interference effects in pacemakers caused by digital cellular phones that did not occur with the older analog technology. Cell phones have decreased in size so that they are often carried in a shirt pocket directly adjacent to an implanted medical device. There are a number of wireless technologies in use today which involve different combinations of power levels and modulation schemes.

AAMI has had a technical working group looking at a new standard for several years. The standard is being developed in several stages; the first stage addresses near-field interference from wireless communication devices in the 450-

NOTE: All figures reprinted from ANSI/AAMI PC69:2000 with permission. For a free catalog of AAMI Standards, call (800) 332-2264, ext. 217 or visit the AAMI website at www.aami.org.

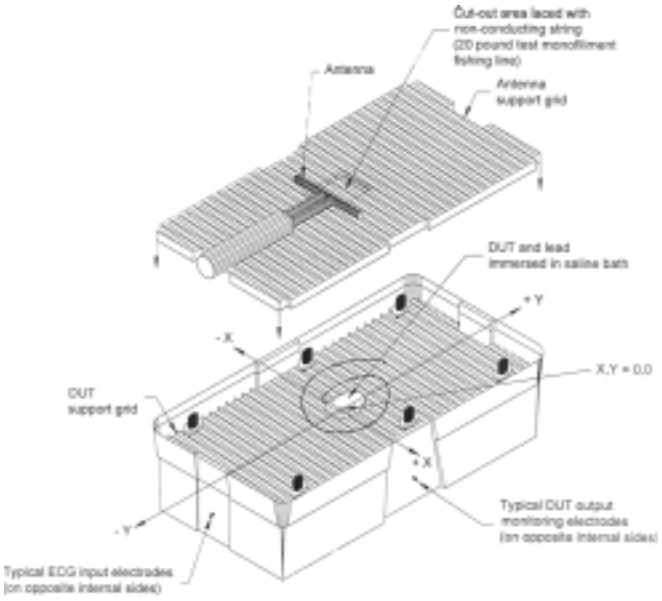

Figure 1. Torso simulator (ANSI/AAMI PC69:2000 – Figure B.1).

MHz to 3000-MHz band. This area is not presently covered by any existing United States standard.

The results of the working group for the first frequency band was published as ANSI/AAMI PC69:2000— *Active Implantable Medical Devices –Electromagnetic Compatibility—EMC Test Protocols for Implantable Cardiac Pacemakers and Implantable Cardioverter Defibrillators*. This standard was approved on May 3, 2000, and the publication date was February 15, 2001.

ANSI/AAMI PC69:2000

The standard specifies testing at 40 milliwatts net power into a dipole antenna for frequencies from 450 MHz to 3000 MHz. This testing simulates a hand-held wireless transmitter placed 15 centimeters from the AICD. The

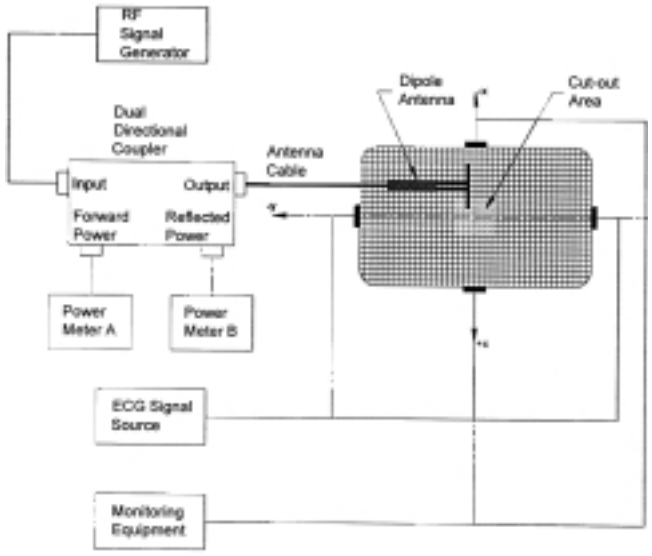

Figure 2. Test setup (ANSI/AAMI PC69:2000 – Figure B-2).

standard recommends that three samples of a particular device be tested.

The standard also recommends that the test tank be placed in a shielded room in order to limit spurious emissions being distributed to the external environment. A torso simulator is called out by the standard; this torso simulator is described in one of the annexes of the standard. It consists basically of a plastic box, 58 x 42.5 x 15.2 centimeters (minimum), filled with saline solution as shown in Figure 1.

The Device Under Test (DUT) is placed 2.5 centimeters below the dipole element and 0.5 centimeter below the surface of the saline solution (Figure 2). The dipole antennas are described in technical detail in another annex of the standard; they are basically tuned, half-wavelength resonant dipoles with a series-parallel coaxial stub balun that is terminated into a suitable 50-ohm coaxial interface connector (Figure 3). The DUT is programmed per a set of parameters described in Annex D of the standard.

Frequencies tested include 450, 600, 800, 825, 850, 875, 900, 930, 1610, 1850, 1910, 2450, and 3000 MHz. The carrier signal is pulse modulated with the following characteristics: the carrier shall be gated on for 25 milliseconds at 500 millisecond intervals; gating rise-and-fall time should be less than one-half a microsecond.

The test procedure called out by the standard includes X-axis testing (the antenna elements are parallel to the X-axis) with electrocardiogram (ECG) signal off; X-axis testing, ECG signal on, bradycardia rate; and X-axis testing, ECG signal on, tachycardia rate (devices intended to treat tachyarrhythmia only). The above procedure is repeated with the antenna elements parallel to the Y-axis. The procedure starts at 450 MHz and proceeds through each of the indicated frequencies in the standard.

Each of the subtest procedures has specified performance criteria in the standard. For example, with the ECG signal off, the DUT shall not exhibit any deviation in pace-to-pace interval that exceeds 10% of the programmed rate. In addition, at the completion of the testing, or immediately prior to any reprogramming during test, the programmed parameters shall be unaltered from pre-exposure values.

FUTURE PHASES OF THE STANDARD

The future development of the standard will cover frequencies below 450 MHz and above 3000 MHz.

Sources of interference below 450 MHz include electronic article surveillance (EAS) systems; access control systems (radio-frequency identification); new wireless services; magnetic levitated rail systems; radio-frequency medical procedures such as high-frequency surgery and ablation therapy; metal detectors at airports and other locations; and magnetic resonance imaging.

New applications for frequencies above 3000 MHz may include marine radar used on pleasure craft, aviation tran-

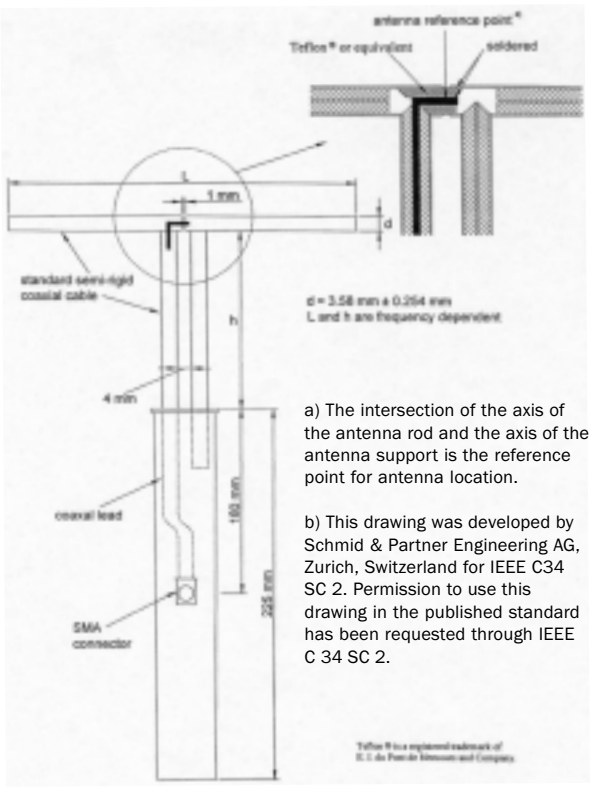

Figure 3. Example of dipole antenna ANSI/AAMI PC69:2000 - Figure C.1).

sponders for small aircraft, and experimental use of transponders for traffic control.

CONCLUSION

Clearly, wearers of AICDs will be exposed to an increasing number of electromagnetic sources in the future. The designs of these devices will need to be re-evaluated continually so as to ensure their successful function in the diverse occupational environments found throughout the United States.

DANIEL D. HOOLIHAN *is past president of the IEEE EMC Society. He has been a member of the Board of Directors of the EMC Society since 1987 and has held several leadership positions in the society. Dan is also active on the ANSI Accredited Standards Committee on EMC, C63 as chairman of the Subcommittee D6 on Laboratory Accreditation and Subcommittee C2 on EMC and Medical Devices. He served as the vice president of the Minnesota operations of TÜV Product Service, Inc. from 1994 to 1999. He was cofounder and past chief operating officer of AMADOR Corporation. Earlier, he was a manager/enginneer with Control Data Corporation. Dan holds an MBA from the University of Minnesota, an MS in physics from Louisiana State University, as well as a BA in physics from St. John's University. Dan may be contacted at www.emcexpert.com.* ■

MORE ON OUR WEBSITE

See our archive of Medical EMC articles at rb**item**.com/archivedarticles/archive.asp Plus a database of suppliers offering testing services can be found at rb**item**.com/products/Categories.asp Keyword: *testing*