TECHNICAL REPORT

ISO/TR 21730

Second edition
2007-02-15

Health informatics — Use of mobile wireless communication and computing technology in healthcare facilities — Recommendations for electromagnetic compatibility (management of unintentional electromagnetic interference) with medical devices

Informatique de santé — Utilisation des communications mobiles sans fil et des technologies informatisées dans les structures de soins — Recommandations pour la compatibilité électromagnétique (gestion des interférences électromagnétiques non intentionnelles) avec les dispositifs médicaux

Reference number
ISO/TR 21730:2007(E)

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

In exceptional circumstances, when a technical committee has collected data of a different kind from that which is normally published as an International Standard ("state of the art", for example), it may decide by a simple majority vote of its participating members to publish a Technical Report. A Technical Report is entirely informative in nature and does not have to be reviewed until the data it provides are considered to be no longer valid or useful.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO/TR 21730 was prepared by Technical Committee ISO/TC 215, *Health informatics*, Task Force on EMC in RF mobile communications.

Other international organizations that contributed to the preparation of this Technical Report, mainly in review and comment of the draft text, include: from the UK, the MHRA and the IST/35 Mirror Panel; from the US, the FDA; from Australia, the Australian Therapeutic Goods Administration, Telstra and Monash Medical Center; from Canada, Health Canada Medical Devices Bureau; from the Netherlands, the Health Council of the Netherlands; from Finland, the National Agency for Medicines; and from Switzerland, Swissmedic.

Due to rapidly changing technologies, this Technical Report is to be regarded as a 'living document' and comments for improvement will therefore be welcomed.

This second edition of ISO/TR 21730 cancels and replaces the first edition (ISO/TR 21730:2005), which has been technically revised.

ISO/TR 21730 strongly parallels AAMI TIR No.18, which provides similar recommendations for wireless equipment in healthcare facilities. Many of the recommendations developed within this TR are directly built upon the foundation of earlier documents, such as AAMI TIR No.18 and ANSI/IEEE C63.18.

Introduction

Worldwide, healthcare facilities are recognizing the need to incorporate new technology and provide better point-of-care information to improve healthcare delivery, while reducing medical errors. Computing technologies, electronic medical record systems, and seamless access to information using wireless communication can offer significant advancements to healthcare communication and health informatics exchange. Such wireless technologies include the use of mobile phones, handheld computers/PDAs, WiFi/802.11.x local area networks, personal area networks including 802.15.1 (Bluetooth)/802.15.4 (Zigbee)/802.15.3a (UWB), two-way pagers, radios, etc. In addition, visitors and patients are also finding the use of personal mobile phones and other wireless devices increasingly valuable, especially in times of crisis.

Previously, no uniform international guidelines existed for the appropriate deployment, use and management of mobile wireless communication and computing technology within healthcare facilities to address electromagnetic compatibility (EMC) with medical devices and mitigate potential electromagnetic interference (EMI). Although the recently approved second edition of IEC 60601-1-2 (IEC 60601-1-2:2001) specifies general immunity levels of 3 V/m for medical equipment and systems that are not life-supporting, and 10 V/m for life-supporting medical equipment and systems, manufacturers are allowed to justify lower levels and there is no consistent international regulation enforcing this standard. In addition, many mobile wireless transmitters exceed these field strength thresholds when operating at their upper power limits and in close proximity. Finally, there are a number of older medical devices still in use that have not been designed or tested with the above immunity considerations in mind.

At present, there appears to be a range of inconsistent policies among healthcare organizations with regards to EMC, mobile wireless systems and management procedures. At one extreme, overly-restrictive policies may inadvertently act as obstacles to the deployment of beneficial technology. At the other extreme, the unmanaged use of wireless electromagnetic radiation emitters can place patients at risk. An equally important factor in this issue is that healthcare organizations throughout the world have a variety of different resources, needs, concerns and RF environments that may not all be addressed by the implementation of a single prescriptive management strategy. Because of this, a balanced approach is necessary to ensure that all the benefits of mobile wireless technology can be made available to healthcare organizations, while providing necessary and sufficient safeguards against undesired and unintended risks of EMI.

It may not be feasible for healthcare organizations to manage every mobile wireless handset brought into their facility without certain restrictive limits. The necessary range and extent of restrictive limits within a given healthcare facility will depend upon the level of management that has been implemented. For mobile wireless equipment that is randomly brought into the healthcare facility in an uncontrolled manner, policies may be appropriate that restrict use of wireless equipment in areas where potentially susceptible medical devices are in routine operation. Such restrictive policies might be facilitated by offering numerous and easily accessible alternative areas where the use of mobile wireless equipment is permitted. For mobile wireless equipment that is provided to doctors and staff under more controlled conditions, operation throughout the healthcare facility (even in areas where potentially susceptible medical devices are used) may be achievable with appropriate management. With such management, as outlined in the recommendations below, it is possible to realize many of the benefits of wireless technology for healthcare-specific communication and health information access, while at the same time sufficiently mitigating EMI concerns and create effective EMC among medical devices and wireless technology.

Because most mobile wireless communication and computing systems can be effectively managed for EMC with medical devices, the choice of wireless technology to be deployed in a healthcare facility and managed in a dedicated manner should be based upon the solution that best addresses the needs of the organization and benefit for patients, not on the potential of specific RF transmitter types to cause EMI when used under non-controlled conditions.

Health informatics — Use of mobile wireless communication and computing technology in healthcare facilities — Recommendations for electromagnetic compatibility (management of unintentional electromagnetic interference) with medical devices

1 Scope

This Technical Report provides guidance for the deployment, use and management of mobile wireless communication and computing equipment in healthcare facilities in a way that promotes effective electromagnetic compatibility (EMC) among the wireless technology and active medical devices through mitigation of potential hazards due to electromagnetic interference (EMI). The recommendations given recognize the different resources, needs, concerns and environments of healthcare organizations around the world, and provide detailed management guidelines for healthcare organizations that desire full deployment of mobile wireless communication and computing technology throughout their facilities. In addition, suggestions are included for selective restrictions in cases where healthcare organizations have decided that comprehensive management procedures are not feasible, practical or desirable at the present time. The recommendations herein distinguish between wireless technology controlled by the facility and used by doctors and staff for healthcare-specific communication and health informatics transport versus non-controlled (personal) mobile wireless equipment randomly brought into the facility by visitors, patients or the healthcare organization workforce.

2 Terms, definitions and abbreviated terms

2.1 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

2.1.1
hertz
Hz
unit of frequency of electromagnetic energy based upon the emitted wavelength

2.1.2
decibel
dB
relative ratio, one-tenth of the common logarithm of the ratio of relative powers, equal to 0,1 B (bel)

NOTE 1 The ratio in decibels equals $10 \lg_{10}(P_1/P_2)$.

NOTE 2 Decibels as above, but relative to a fixed 1 mW of power, are sometimes indicated as dBm.

2.2 Abbreviated terms

ASHE American Society for Healthcare Engineering

AAMI Association for the Advancement of Medical Instrumentation

AHA	American Hospital Association
AMA	American Medical Association
ANSI	American National Standards Institute
CDRH	Center for Devices and Radiological Health, Department within FDA (US)
CISPR	International Special Committee on Radio Interference
COMAR	IEEE Committee on Man and Radiation
ECG	Electrocardiogram
EEG	Electroencephalogram
EM	Electromagnetic
EMC	Electromagnetic compatibility
EMD	Electromagnetic disturbance
EMI	Electromagnetic interference
ESD	Electrostatic discharge
FDA	Food and Drug Administration (US)
IEC	International Electrotechnical Commission
IEEE	Institute for Electrical and Electronics Engineers
ISM	Industrial, Scientific, Medical
IVDs	In vitro diagnostic devices
JCAHO	Joint Commission on Accreditation of Healthcare Organizations
LAN	Local Area Network, including 802.11b and 802.11a systems
MHRA	Medicines and Healthcare Products Regulatory Agency (UK)
PAN	Personal Area Network, including 802.15.1 (Bluetooth), 802.15.4 (Zigbee), 802.15.3a, etc.
PDA	Personal digital assistant
R&TTE	Radio and Telecommunications Terminal Equipment
RF	Radiofrequency, classically defined as ranging from a few kHz - 300 GHz
Rx	Reception, received RF signal
TIR	Technical informational report
Tx	Transmission, transmitted RF signal
UWB	Ultra-wideband, refers to RF transmissions spread over at least 500 MHz of spectrum or a fractional bandwidth of $>$ 0,2, with a very low spectral density at any given frequency ($-$41,3 dBm/MHz)

V/m Volts per metre, a measure of RF electrical field strength

WiFi Wireless Fidelity Network system

3 Current status of management of electromagnetic interference

3.1 Mobile wireless equipment in healthcare facilities

The use of mobile wireless equipment by medical healthcare staff to provide point-of-care communication and patient information is increasingly being recognized as required to reduce medical errors and to improve healthcare delivery. Visitors and patients are likewise finding the use of personal mobile (i.e. cellular) phones and wireless devices increasingly valuable, especially in times of crisis. Such wireless devices might include mobile phones, handheld computers/PDAs, WiFi/IEEE 802.11.a/b/g [1] local area networks and wireless modems for laptop computers, personal area networks including IEEE 802.15.1 (Bluetooth) [2] / IEEE 802.15.4 (Zigbee) [3]/IEEE 802.15.3a (UWB), two-way pagers, two-way radios, etc.

Table 1 lists many of the common wireless technologies in use in various healthcare facilities. As can be seen from Table 1, mobile wireless equipment can transmit on exclusive licensed frequencies, as is the case with most mobile phones, pagers and two-way radios, or can operate with many other transmitters on one of the unlicensed Industrial, Scientific, Medical (ISM) bands at 900 MHz and 2,4 GHz, 5,2 GHz and 5,8 GHz as is the case with cordless phones and wireless data network equipment. From an RF signal perspective, mobile wireless transmitters can employ either simple analog or more complex (and sometimes pulse modulated) digital technology. In terms of output power, mobile wireless equipment can be segmented into three broad categories. The first category includes IEEE 802.11, IEEE 802.15, and most cordless phone-type systems that transmit constantly at relatively lower power ($<$ 10 mW). A second category consists of two-way radio and pager systems that transmit at a constant power that is higher by an order of magnitude or more (1 W to 5 W). The third category includes dynamically power-controlled equipment that can transmit at levels between a few milliwatts and 1 W to 2 W, based upon the existing network signal strength at that particular location and time. This Technical Report does not consider in detail the growing number of RFID tags making their way into healthcare. Although such tags and their corresponding readers may transmit RF in either HF (13,56 MHz) or UHF (915 MHz) bands, the amount of energy emitted is often low although long range readers can transmit at up to 10 W. More importantly, they are not considered herein as mainstream communication or computing technology, and are generally used for asset tracking and related functions.

An Institute of Medicine (IOM) report has estimated that common medical errors may contribute to between 44 000 and 98 000 deaths per year in the US [4], with a similar percentage suggested for the UK and Australia. The estimated US number was further increased to 195 000 deaths per year in a recent report by Healthgrades. Wireless technology has the potential to provide untethered and improved, rapid and robust communication and access to patient data, test results, records and medical reference at the point-of-care. These benefits may further help to reduce cost-charging errors, a reduction in cost and maintenance of land-line phone systems, and, potentially, facilitation of more home-based monitoring, recovery and long-term care.

Concern over potential EMI with medical devices due to radiofrequency (RF) emissions, however, has prompted many healthcare organizations around the world to enact broad precautionary policies restricting wireless equipment throughout their facilities. Some healthcare organizations have implemented policies ranging from selective restrictions on where mobile wireless equipment can operate to relatively unrestricted and unmanaged use. While overly restrictive policies may act as obstacles limiting the benefit that wireless technology can bring to healthcare, unmanaged use of RF emitters may expose patients to potentially significant and unnecessary hazards.

Table 1 — Current and developing wireless technologies that may be used in healthcare facilities

Type of device			Intended application	Transmitted frequency (Tx)	Maximum transmit power
Wireless data network devices	W-LAN (Local Area Networks — WiFi)	802.11a	High Rate Local Area Network	5,15 to 5,8 GHz	40 mW [5,15 to 5,25 GHz] 200 mW [5,25 to 5,35 GHz] 800 mW [5,72 to 5,82 GHz]
		802.11b	Medium Rate Local Area Network	2,4 to 2,462 GHz (North America), 2,412 to 2,472 GHz (Europe), 2,471 to 2,497 GHz (Japan)	**typical app's**: constant ~10 mW, but spec allows for: 1 W [US] 100 mW [Europe] 10 mW/MHz [Japan]
		802.11g	High Rate Local Area Network	2,4 to 2,48 GHz (US, Europe, Japan)	**typical app's**: constant ~10 mW, but spec allows for: 1 W [US], 100 mW [Europe], 10 mW/MHz [Japan]
	W-PAN (Personal Area Networks)	Bluetooth / 802.15.1	Streaming Data, Cable Replcmnt	2,4 to 2,48 GHz (North America & Europe), 2,447 to 2,473 GHz (Spain), 2,448 to 2,482 GHz (France), 2,473 to 2,495 GHz (Japan)	Powerclass I: 100 mW Powerclass II: 2,5 to 10 mW Powerclass III: 1 mW
		802.15.3a	Streaming Video, Data and Voice	UWB in 3 to 10 GHz band	~0,6 mW spread over 100's of MHz
		Zigbee / 802.15.4	Sensor Networks, Low-Latency Data/Control	2,4 to 2,48 GHz (North America & Europe), 2,412 to 2,472 GHz (Europe), 2,471 to 2,497 GHz (Japan)	**typical app's**: constant ~1 mW, but spec allows for: 1 W (US), 100 mW (Europe), 10 mW/MHz (Japan)
	W-MAN (Metropolitan Area Networks)	802.16a (fixed)	Fixed Broadband Wireless Access Systems (Video + simultaneous voice & data)	2 to 11 GHz in unlicensed (e.g. 5,8 GHz) and licensed bands	Watts — potentially higher transmit power in licensed bands as compared to more restrictive unlicensed bands
		802.16e (mobile)	Mobile unlicensed and licensed Broadband Wireless Access Systems (Video + simultaneous voice & data)	2 to 11 GHz in unlicensed (e.g. 5,8 GHz) and licensed bands	Watts — potentially higher transmit power in licensed bands as compared to more restrictive unlicensed bands
		802.20	Mobile (LICENSED) Broadband Wireless Access Systems (Video + simultaneous voice & data)	licensed bands below 3,5 GHz	Watts
Mobile Phones	1st Generation Technologies	Analogue	WAN Mobile Communication	AMPS 824 to 849 MHz (US), NMT 453 to 458 MHz (Europe), TACS 890 to 915 MHz (Europe), JTACS 832 to 925 MHz (Japan)	**AVG PWR**: 0,6 to1 W down to ~6 mW in steps of –4 dB
	2nd Generation (Digital) Technologies	TDMA	WAN Mobile Communication	GSM 824 to 849 & 185 to 1910 MHz (US), GSM 890 to 915 & 1710- to 1785 MHz (Europe, Asia), iDEN 806 to 824 MHz (US), Tetra 380 to 400, 410 to 430, 450 to 470 & 805 to 870 MHz (Europe), PDC 810 to 826 & 1429 to 1453 MHz (Japan)	**AVG PWR**: 200 to 600 mW down to 20 to2 mW in steps of –1 to –4 dB, PEAK PWR 1 to 2 W (depending upon the technology)
		CDMA	WAN Mobile Communication	CDMA 824 to 849 & 1850 to 1910 MHz (US), J-CDMA 832 to 925 MHz (Japan), K-PCS 1750 to 1870 MHz (Korea)	**AVG PWR**: 250 mW to ~1 uW in 1dB steps
	3rd Generation (IMT-2000) Technologies	UMTS	WAN Mobile Communication	1,92 to 1,98 MHz (Europe, Asia), 1,7 to 2 GHz (US)	**AVG PWR**: 250 mW to < 1 mW in steps of 0,25 - 1 dB

Table 1 (*continued*)

Type of device		Intended application	Transmitted frequency (Tx)	Maximum transmit power
	CDMA-2000	WAN Mobile Communication	824 to 849, 1850 to 1910 MHz & 1,7 to 2 GHz (US); 890 to 915 & 1750 to 1780 MHz & 1,92 to 1,98 GHz (Europe, Asia)	**AVG PWR**: 250 mW to < 1 mW in steps of 0,25 to 1 dB
Two-way pagers		WAN Text Messaging	152 to 159, 454 to 460, 902 to 928 MHz	1 W (in short bursts)
Cordless Phones	Analog and Spread Spectrum Technologies		Analog 27, 40 to 49, 900 MHz & 2,4, 5,8 GHz (US), Spectralink 2,4 GHz (US, Europe), CT-1 30-41, 72,8-73, 885, 914, 960 MHz & 1,7-1,8 GHz (Europe)	**AVG PWR**: constant 10 mW, some units up to 1 W
	TDMA		DECT 1880-1900 MHz (Europe), CT2, CT3 864-868 & 944-948 MHz (Europe), PHS 1895-1918 (Japan)	**AVG PWR**: constant 10 mW, PEAK PWR: 250 mW
	VoIP / 802.11b	LAN Mobile Communication	2,4 to 2,462 GHz	**AVG PWR**: constant 10 mW
Short Range Devices	FCC 15.231, FCC 15.249	Low-Power Radio Links	Periodic and continuous transmissions, 300 to 900, 2400 to 5800 MHz	**AVG PWR**: 0,1 to 1 mW
	ETSI 300 220-1	Low-Power Radio Links	Periodic and continuous transmissions, 400 and 800 MHz	**AVG PWR**: 10 to 25 mW
	JPN ARIB T-67	Low-Power Radio Links	Periodic and continuous transmissions, 426 to 449 MHz	**AVG PWR**: 1 and 10 mW
Wired Network [a]	802.3	Hard Line Ethernet	(hard line alternative to wireless)	

[a] Although not a “wireless” technology, the “wired” Ethernet is the current standard being replaced by various wireless technologies and is included in the table for comparison.

3.2 The risk of patient harm due to EMI

The non-controlled/unmanaged use of mobile wireless equipment by individuals visiting or working in healthcare facilities has steadily increased, regardless of existing healthcare organization policy. However, published reports suggest that the level of risk for accidental EMI events from government and other non-profit health agency sources appears to be relatively small [5]-[8], although underreporting of such events may be substantial. Anecdotal observations of suspected EMI events or incidents with ECG and EEG machines, apnoea monitors, ventilators and radiant warmers, infusion pumps, wheelchairs and other devices have been reported or referred to in a number of publications [5]-[19]. Ad hoc test studies [20]-[31], [45] have confirmed that EM interference effects can be caused by certain wireless transmitters in susceptible medical devices, although this generally requires specific conditions (transmission at higher power levels, close proximity, for extended periods of time) that may not be common during normal use. For RF transmitters that operate at constant output power of 100 mW or less, significant interference effects were rare [46], [47].

Although the recently approved second edition of IEC 60601-1-2 specifies general immunity levels of 3 V/m for medical equipment and systems that are not life-supporting, and 10 V/m for life-supporting medical equipment and systems, manufacturers in the US and many other countries are allowed to justify lower levels and there is no consistent international regulation enforcing this standard. Many mobile wireless handsets exceed the 3 V/m and 10 V/m limits when operating at maximum power and in close proximity. Further, older medical devices still in use may not have been constructed or tested to the same EM immunity level. Despite the potentially serious level of risk due to unmanaged mobile wireless handset use, most mobile wireless equipment might be allowed to operate, even where potentially susceptible medical devices are used, if comprehensive management procedures were implemented.

3.3 Existing relevant standards and recommendations

The International Electrotechnical Commission (IEC) has published a series of standards (IEC 61000-x-x) that deal with general EMI mitigation and testing requirements. Relevant sections of this general EMI series apply. The IEC has also published a more relevant standard (IEC 60601-1-2) [33] with respect to medical device interactions with external RF transmitting equipment that recommends life-supporting medical electrical equipment and systems be immune to field strengths of 10 V/m, and those that are not life-supporting be immune to field strengths of 3 V/m in the frequency range 80 MHz to 2,5 GHz. Also, medical-equipment manuals require users to maintain minimal separations between various radio-frequency sources and medical devices. This is the collateral to the general safety standard for medical electrical equipment (IEC 60601-1) [34], based upon basic EMC immunity standards that were developed by IEC Technical Committee TC 77 (EMC). IEC 60601-1-2 also sets limits for emissions and immunity test levels for electrostatic discharge (ESD), conducted radio-frequency electromagnetic fields, bursts, and surges largely based upon CISPR emissions and TC 77 immunity standards. Although many medical device manufacturers comply with recommended immunity guidelines, there is no government regulation enforcing these recommendations in certain parts the world, including the US. Further, many older medical devices still in use in healthcare facilities were not designed or tested to the current immunity levels. Also, the IEC standard [33] permits medical equipment and systems to meet lower immunity levels, with appropriate justification (e.g. IEC 60601-1-2:2001, Annex AAA, subclause 36.202.6 a1, recognizes that some patient-coupled equipment and systems will justify lower immunity compliance levels due to the low magnitudes of some physiological signals, and states: "… it is expected that some PATIENT-COUPLED EQUIPMENT and SYSTEMS will use as a justification for a lower IMMUNITY COMPLIANCE LEVEL the fact that some physiological signals can be substantially below those induced by a field strength of 3 V/m."

The European Community has issued a set of medical device directives to further ensure compliance with electromagnetic immunity for devices operating in Europe. Directive 93/42/EEC [35] specifies that non-implanted medical devices be designed and manufactured in a way that minimizes risks connected with reasonably foreseeable environmental conditions, such as magnetic and radiofrequency fields, external electrical influences, and electrostatic discharge. The horizontal (general) directive 89/336/EEC [36] regarding medical device safety also applies to devices not covered by more specific Directives. Other relevant directives with similar requirements include those for active implantable devices [37] and in vitro diagnostic devices (IVDs) [38]. A recent Radio and Telecommunications Terminal Equipment (R&TTE) Directive [40] now specifies testing protocols and RF immunity levels for radio and telecommunications terminal equipment within the EU. The scope of the R&TTE Directive covers the apparatus that incorporates as an integral part, or an accessory, a medical device as defined within the scope of 93/42/EEC [35] or an active implantable medical device as defined within the scope of 90/385/EEC [37]. The apparatus must be governed by the R&TTE Directive, without prejudice to the application of Directives 93/42/EEC and 90/385/EEC to medical devices and active implantable medical devices, respectively. The purpose is to allow radio and telecommunications terminal equipment manufacturers to follow the same rules for medical devices but bring their products to the European market faster and more easily. While the additional directives in Europe do encourage medical devices to meet the IEC standard, many mobile wireless transmitters operating at full power can exceed the 10 V/m immunity level at distances up to 1 m away, and well exceed the general 3 V/m immunity test level [11]-[13], [21]-[24].

The American National Standards Institute has published a rapid, cost-effective, and straight-forward ad hoc test protocol [41] that can be implemented by individual healthcare organizations to assess EMC between specific mobile wireless equipment and medical devices in their inventory. The protocol not only allows individual healthcare organizations to rapidly generate information to make more informed policies on wireless equipment within their facility, but also provides a consistent protocol allowing comparison of findings between different test sites.

A technical informational report (TIR) published by the Association for the Advancement of Medical Instrumentation [14] is currently the most useful guideline available to healthcare organizations in defining EMC in simple terms for non-engineering healthcare facility staff and describing how potentially significant medical device EMI can occur and how the risk can be managed. The document follows closely from earlier studies performed by ASHE (American Society for Healthcare Engineering) [15], [16] and provides information on assessing and managing the RF environment and a model EMC/EMI policy. The summary recommendations of AAMI TIR 18 are currently listed on the FDA Center for Devices and Radiological Health (CDRH) website [42].

The IEEE Committee on Man and Radiation (COMAR) of the Engineering in Medicine and Biology Society has published a manuscript stating that EMI of life support equipment due to emissions from mobile telephones is a valid concern and steps should be taken by medical device manufacturers to “harden” their devices against increasing environmental RF fields [25]. However, limited guidance to healthcare organizations on how to manage the risk is provided in this document.

The American Medical Association (AMA) identifies the operation of mobile wireless equipment in healthcare facilities as a risk to medical equipment [59] especially when used in close proximity. Their published paper acknowledges that current clinical reports of EMI are uncommon and largely anecdotal suggesting that the risk may be small, and that the variety of communication signal and medical equipment types make EMC difficult to predict. They recommend obtaining (when possible) newer medical equipment “hardened” to extraneous RF emissions, performing ad hoc testing per the ANSI/IEEE C63.18 protocol and applying straight-forward management procedures, maintaining compliance with existing EMC standards, and ongoing vigilance against EMI by the clinical engineering group and medical staff at the healthcare facility. They do not recommend precautionary banning of wireless devices, and while noting that ECRI recommends a general one meter separation distance for mobile phone-type transmitters, the AMA recommends further deliberation by EMC experts on this subject.

The University of Oklahoma Center for the Study of Wireless EMC [44] released a manual in 1998 for healthcare facilities. With regard to specific recommendations, a significant source of this information was taken (with permission) from Segal [32]. The recommendations promote ad hoc testing and education, and suggest various management procedures including the establishment of a comprehensive EMC policy, establishment of mobile handset exclusion zones and EMI reporting procedures, and replacing and/or increasing immunity of medical devices whenever possible. The manual also suggests maintaining separation distances (up to 6 m for standard radios, 2 m for common mobile phones, 0,3 m for in-building LAN and cordless phone systems).

Health Canada's Medical Devices Bureau has performed extensive ad hoc testing of RF transmitters including mobile phones, 802.11b LAN, electronic article surveillance systems, metal detectors, and 802.15.1 (Bluetooth) transmitters [45]-[47] and reported that while mobile phones and radios may cause interference if their use is not properly managed, the majority of constant output low power transmitters do not pose significant threats to medical devices under normal operating conditions. The Medical Devices Bureau also hosted a roundtable discussion [48] in 1994 to develop recommendations and define a US-Canadian Task Force on Electromagnetic Compatibility in Health Care, with Dr. Bernard Segal of McGill University acting as coordinator. Summary recommendations included promotion of the use of wireless technology in healthcare, coupled with testing and encouraging hospital clinical engineering groups to become proactive in the characterization and management of potential EMC issues in their facilities. Suggested activities included management of medical devices, lowering power of RF transmitters, labelling susceptible devices, educating staff, and upgrading where possible and practical with hardened medical equipment purchases.

The Health Council of the Netherlands [49] recommend a precautionary separation distance of 1,5 m, although they state that they are “unaware of an actual case in which a mobile phone has led to interference with potentially susceptible medical equipment” and do not directly advocate comprehensive precautionary bans. The report states that most healthcare facilities in the Netherlands currently apply blanket bans on wireless communication devices largely as a precautionary measure.

The Medicines and Healthcare Products Regulatory Agency (MHRA, formerly the MDA) in the UK recommends that the use of GSM and TETRA mobile phone handsets on healthcare facility premises follows local healthcare facility policy guidelines [50]. They further recommend that on-site interference due to operation of emergency services radios be treated as secondary to the risks associated with managing the incident.

The American Hospital Association (AHA) and its affiliated group the American Society for Healthcare Engineering (ASHE) published its recommendations in the previously mentioned documents on the subject [15], [16] and are advocates of managed use in the healthcare facility. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) has no specific recommendation, but when performing accreditation reviews, checks whether healthcare facilities are implementing their own EMC management policies, whatever they may be.

The US Army Center for Health Promotion and Preventative Medicine recommends maintaining new medical device inventories, EMC education, appropriate signage guidance and EMI reporting, and restricting all personal wireless equipment in critical care areas [51]. The recommendations also suggest limiting wireless equipment in ER unless it is essential for medical treatment and separated by more than 3,3 ft from medical devices.

A recommended practice document developed by the Consumer Electronics Association (CEA) [52] outlines a standard icon and terminology for transmit disabled use of mobile phones and other personal electronic devices. The current recommended practice (2004) was initially developed to assist flight attendants to monitor appropriate use of personal electronic devices on commercial aircraft, and is available at http://www.cea.org/. It is currently being revised and elevated to an ANSI accredited standard through the CEA Home Networking group (R7, wg11). Healthcare facilities may also wish to adopt this standardized terminology and icon recognition in the development of their policy if there are public use areas where non-controlled RF transmitters are prohibited to transmit, although use of these devices in a "transmit disabled" state (i.e. allowing the user to access internal software, games, address books) is allowed (see Figure 1).

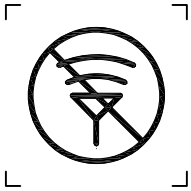

Figure 1 — Consumer Electronics Association icon for transmit-disabled use of mobile phones

Although not discussed in detail in this review, medical device EMI can be caused by RF sources other than mobile wireless equipment, such as other neighbouring medical devices. Emission limits for ISM equipment are specified by International Special Committee on Radio Interference standard CISPR 11 [53]. This standard specifies limits and methods for measuring electromagnetic emissions from ISM equipment in the frequency range 150 KHz to 18 GHz, as well as frequencies at which emissions are unlimited. As a result, medical devices that do not intentionally emit RF energy are not likely to interfere with other equipment that is in compliance with applicable EMC immunity standards.

Overall requirements for risk management of medical devices over the entire life cycle (design, manufacture, service, distribution, use) are outlined in ISO 14971 [54] and are relevant.

3.4 EMC with medical devices and minimization of EMI risk

One goal of the recommendations is to urge medical device manufacturers to increase the EM immunity levels of their medical devices as the healthcare facility environments they operate in become increasingly permeated with radiofrequency emissions from a variety of sources. It should be urged that manufacturers strive to meet, and exceed where possible, current IEC immunity requirements of 3 V/m and 10 V/m, as these fields can be exceeded by many types of mobile wireless transmitters in close proximity when operating at the higher transmit power steps. In addition, the manufacturers and vendors of wireless technology used in healthcare facilities should provide information and support to work toward the common goal of EMC with medical devices.

An equally important goal of the following recommendation is to provide sufficient guidance to allow healthcare organizations to achieve the benefits of mobile wireless technology while at the same time appropriately managing EMC issues to mitigate risk. Wireless systems managed or controlled by healthcare facility staff may include handsets operating on peer-to-peer (e.g. two-way radio), local area (cordless phone, WiFi/IEEE 802.11b /LAN system), or wide area (mobile/cellular phone, pager, PDA) networks. The following recommendations provide for the management of many types of mobile wireless systems, allowing the choice of technology that best addresses the communication and/or computing needs of the healthcare facility to be implemented through proper testing, system design and engineering, medical device management, and user guidelines.

In contrast to wireless communication or computing equipment that is controlled or managed by the healthcare facility, an additional set of recommendations is necessary for non-controlled wireless communication or computing equipment to maintain EMC and avoid medical device interference. For example, while it may be entirely possible to implement a management strategy for a controlled mobile wireless system used by healthcare staff, it may be impractical in many cases to ensure the same level of management for wireless handsets brought into the healthcare facility by visitors, patients or the workforce under non-controlled conditions. Further, healthcare organizations may decide that management procedures for controlled mobile wireless systems are not feasible, practical or desirable. When such is the case, an approach characterized by certain restrictions for use in areas where potentially susceptible medical devices are used, especially those areas with a high concentration of life support medical devices in operation may be appropriate.

4 Recommendations

4.1 General recommendations

The following recommendations are intended to help the healthcare facility achieve a reasonable assurance of EMC with their medical devices while allowing for the deployment of wireless RF technology. These recommendations are built on the foundations from the AAMI TIR 18-1997, recommendations from the AMA Council on Scientific Affairs, the American Society for Healthcare Engineers, and several other publications and reports. In general, the healthcare facility should create a management, testing, procurement and education programme and policies addressing electromagnetic compatibility with active medical devices and the deployment of wireless technology. Because of the wide range of wireless technology involved, there are specific recommendations dealing with both the wireless emitters that are controlled or managed by the healthcare facility and wireless emitters that are not easily controlled by the facility (e.g. patient or visitor PDAs, computers or cellular telephones). Figure 2 illustrates basic steps outlined in the specific recommendations to develop a facility strategy allowing wireless equipment to operate without unnecessary restrictions while at the same time sufficiently managing and mitigating potential EMI issues.

Important recommendations are made equally to medical device manufacturers, healthcare facilities and wireless equipment manufacturers.

Risk management of medical devices is covered in ISO 14971 [54]. All medical devices (including systems of medical devices such as would be formed with wired or wireless communication devices) should meet that standard and be managed to take into account compliance with ISO 14971 over the life cycle of the device.

For medical device manufacturers, they should continue to meet and exceed current IEC 60601-1-2 [33] listed electromagnetic immunity levels in the design of new medical equipment. Medical devices that are not directly covered by this Technical Report should also be designed, manufactured and deployed using the appropriate consensus standards with respect to EMC (e.g., active implanted devices [55], in vitro diagnostics [56]). It is expected that medical devices will increasingly operate in environments where emissions from mobile RF/wireless transmitters are increasingly common.

For healthcare facilities, they should manage wireless equipment within their facility in accordance with the following guidelines, and neither unduly limit the use of otherwise beneficial technology or ignore the potential for EMI issues. Similar recommendations for electromagnetic compatibility with medical devices should also be directly incorporated into corporate policies, strategic plans, and/or governance models.

For wireless equipment manufacturers, they should have full understanding of the potential EMI issues that can arise in worse-case scenarios with medical devices as well as other wireless equipment, and deploy their equipment and systems appropriately in accordance with the following recommendations.

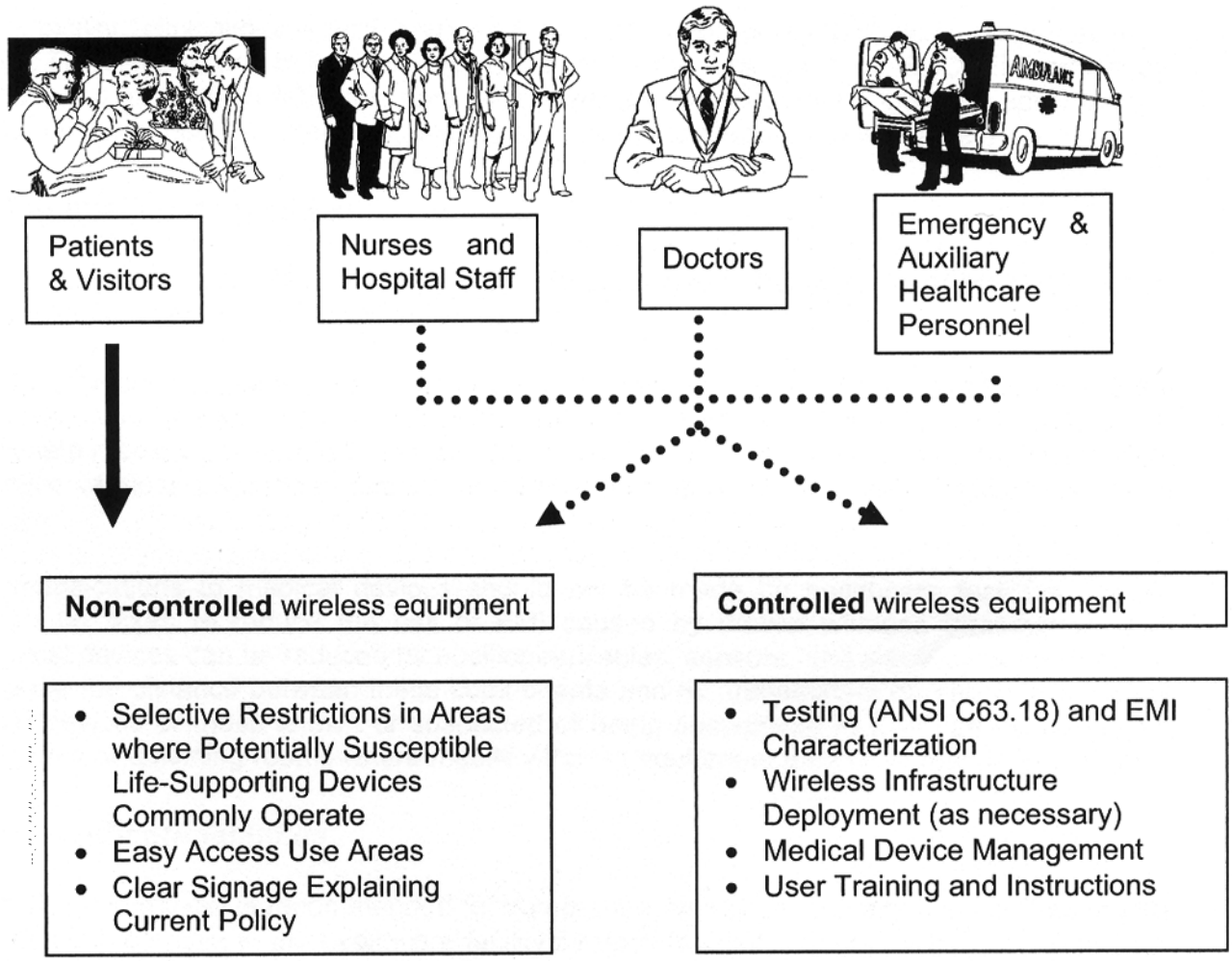

Figure 2 — Relationship of user groups to use strategy

4.2 Responsibility within healthcare facilities

Within the healthcare facility, clinical/biomedical engineers or other appropriate technical personnel (e.g. spectrum management, IT, telecom and building services) should be the focal point for EMC, EMI mitigation, and EMC/EMI education and training. Qualifications are not specified in this Techncial Report, although consideration should be given to appropriate education, expertise, and experience of the responsible individuals.

4.3 Inventory within healthcare facilities

The medical device inventory within a healthcare facility should be managed to the extent possible and practical to ensure compatibility with the ever-increasing RF environment.

a) In the purchase of new medical devices by healthcare facilities, every effort should be made to ensure the equipment meets (and exceeds if possible) minimum EMC immunity requirements set out by IEC 60601-1-2:2001 or other appropriate medical device EMC standard. Older equipment found to be particularly susceptible to EMI caused by mobile wireless transmitters should be phased out as is possible and practical within the healthcare facility budget.

b) While significant modifications to medical devices should not be made by healthcare facilities, certain simple precautions can be taken to reduce the risk of EMI caused by mobile wireless transmitters. EMI susceptibility in all medical devices can be reduced by positioning cables, sensors and electrical accessories in such a way as to increase the distance between these components and RF transmitters operating in the area. Life-supporting medical devices or those known or suspected of being susceptible

to EMI can be positioned away from high traffic areas or adjoining rooms where mobile wireless equipment may be in routine operation.

4.4 Testing within healthcare facilities

The IEEE/ANSI C63.18 [41] protocol is recommended for comprehensive ad hoc, on-site testing of all mobile wireless equipment that might be used in the healthcare facility by doctors, staff, visitors or patients. However, it is fully understood that exhaustive testing is rarely feasible, and different needs, resources and personnel constraints of the healthcare facility may dictate widely different approaches. General recommendations regarding EMC testing are as follows.

a) Testing should be performed, whenever possible and practical, on selected medical devices in the equipment inventory that are considered to have life supporting functions (i.e., according to the prioritization recommendations of ANSI C63.18) using one of the mobile handsets as a test transmitter (see ANSI C63.18 [41] for details on the test protocol).

b) Testing should take special consideration of older medical devices, life-supporting medical devices, and any device where EMI is suspected. Testing can be extended to other medical devices where feasible and practical (see ANSI C63.18 [41] for details on a recommended prioritization).

c) Periodic testing should be performed on a regular schedule (e.g. once per year), and especially after changes such as the introduction of new communication devices, new medical equipment, or significant repositioning on a regular basis.

d) If comprehensive testing of mobile wireless equipment is not possible, focused testing on mobile wireless equipment routinely operating within the healthcare facility that can transmit at higher power (e.g. two-way radios, mobile/cellular phones) may be most appropriate (see Clause 3, Table 1, and A.4 and A.5 for more detailed information about the frequency and RF output power for several types of wireless equipment). If testing of mobile wireless equipment is not possible at all, some information may be obtained by communicating with larger healthcare facilities that have performed prior testing or from ad hoc EMI testing databases found on the internet (one such ad hoc EMI testing database is currently being developed in cooperation with ASHE, although as of this revision it is not yet operational).

e) Assistance with obtaining transmitter equipment, setting the equipment in test mode for constant output at maximum power, and performing ad hoc testing can often be requested from mobile wireless equipment manufacturers and/or network providers.

f) Consideration may be given to have testing performed by an independent third party, in conjunction with the healthcare organization's clinical engineering group. The involvement of a third party may facilitate a consistent and impartial evaluation of EMI issues and proposed management strategies, and more importantly may offer an independent analysis in cases where a further level of indemnity for the healthcare facility, equipment manufacturer, and/or network service provider is desired.

g) Medical devices found in ad hoc testing to be susceptible to EMI should be replaced whenever feasible and practical with more electromagnetically compatible devices, e.g. those compliant with new requirements of IEC 60601-1-2:2001 and other relevant immunity requirements. However, it should be noted that medical devices meeting IEC 60601-1-2 can still be susceptible to emissions from mobile wireless equipment such as mobile/cellular phones at close range where the electromagnetic fields exceed the immunity testing levels specified in this standard.

h) Results from ad-hoc testing tend to be variable, due to variability in RF source power, medical-device differences, and test-site differences. It is important to understand that the primary function of ad-hoc testing is to identify unreasonably susceptible medical devices so that they can be managed appropriately, not act as a quantitative assessment of their susceptibility.

4.5 Controlled use within healthcare facilities

For controlled mobile wireless equipment to be used by doctors and healthcare organization staff under managed conditions, it is recommended that necessary and sufficient procedures be implemented to identify, characterize and mitigate potential EMI problems.

a) The IEEE/ANSI C63.18 [41] recommended practice (as outlined above) is the suggested test protocol for rapid ad hoc, on-site RF EMI testing for EMI identification and characterization.

   1) Testing should be performed using the mobile wireless handsets to be used in the controlled system as a test transmitter. If multiple in-house systems are to be deployed, testing should be performed with each different RF signal. If new in-house systems are deployed, each different RF signal should be tested. Different EMI effects can be caused by different RF signals.

   2) Ad hoc testing should be an ongoing effort, with a record of EMI test results kept including characterization of new medical device acquisitions and investigation/verification of reported EMI incidents, making any necessary adjustments to policy.

   3) Periodic testing should be performed on a regular schedule (e.g., once per year), and especially after changes such as the introduction of new communication devices, new medical equipment, or significant repositioning on a regular basis.

   4) Given the qualitative nature of the ANSI C63.18 ad hoc testing, even if no significant EMI issues are identified, nominal management policies including recommended minimum separation distances may still be prudent.

b) For mobile handsets that transmit at a constant output power, having no dynamic power control (e.g., standard two-way radios, family radios, two-way pagers, 802.11 systems), EMC management should involve ensuring adequate separation from identified susceptible medical devices. In the case of radio transmitters with relatively high constant power output (1 W or more), this may require significant separation distances and possibly necessitate their restriction from certain areas of the healthcare facility. In the case of pagers with extremely short burst transmissions or IEEE 802.11 a/b/g / Local Area Network or IEEE 802.15 / Bluetooth / Zigbee / IEEE 802.15.3a PAN equipment (see Table 1 for more information about these) with relatively low constant power output (~10 milliwatts), the risk of EMI may be significantly less than for equipment such as two-way radios. Testing is still recommended whenever possible, although it is understood that it may reveal little susceptibility and the feasibility and practicality of all testing must be considered and prioritized.

c) If mobile wireless transmitters are dynamically power controlled (e.g., mobile / cellular phones, PDAs operating on wide area networks), EMC management should involve network characterization, design, and in-building engineering to supplement the wide area network as necessary to insure handsets are directed to transmit at RF power levels sufficient to minimize EMI issues. The existence of numerous shielding and reflecting objects in a healthcare facility may create areas with variations in downlink signal coverage, some of which could lead to significant intermittent changes in transmit power of the handsets causing them to deviate from their normal output power. Such areas should be characterized (by measuring existing signal strength with the mobile wireless handset set to a “trace” mode — this can often be done by the network service provider) and managed appropriately.

d) Medical device management procedures may include identification through labelling, repositioning or other means to reduce exposure to the wireless emissions, or replacing particularly susceptible devices with newer model units. Because of medical device regulations, modifications to a medical device should only be made by the device manufacturer.

e) User guidelines can be provided as an additional layer of management directing healthcare staff to maintain a predetermined and practical separation distance between their mobile wireless handsets and potentially susceptible medical devices (between 25 cm and 2 meters).

f) The AAMI TIR 18 is recommended for additional details on medical device management and EMC/EMI guidelines.

g) Testing of specific fixed-infrastructure components such as local electrical circuits and circuit breakers can be considered for testing if failure could represent a significant hazard, and if testing can be performed without placing the facility at risk.

h) Healthcare facilities should actively manage spectrum usage (e.g, maintain a list of all controlled-use RF sources indicating where they are authorized to operate, as well as the maximal number of such units permitted within each area or zone).

i) Wireless security issues (which are outside of the scope of this document) must be properly considered, otherwise patient safety may be threatened if the informatics system becomes compromised or incapacitated.

4.6 Non-controlled use within healthcare facilities

Non-controlled mobile wireless equipment that may be brought randomly into the healthcare facility by visitors, patients or staff transmit a variety of different signals at different output power levels.

a) Separate EMC/EMI management policies than those listed for controlled mobile wireless handsets should be applied. While ad hoc testing and management solutions are always encouraged whenever possible, this may not be practical for every wireless system.

    1) While certain mobile handsets may be able to operate compatibly throughout a healthcare facility environment, other mobile handsets may have greater potential to cause EMI events due to local differences in output power or signal type. As the number of handsets continues to increase and new models reduce size, internalize antennas, and combine technologies (i.e. mobile phone/pager/PDA device/local area IEEE 802.11a/b/g/personal area IEEE 802.15.1/IEEE 802.15.3a/IEEE 802.15.4, etc.), it is becoming increasingly difficult to differentiate between RF transmitter types based upon visual appearance alone. Further confounders include the growing number of wireless headsets and accessories that relocate the actual RF transmitter to a pocket or purse, keeping them from obvious view even when in use. An increasing number of mobile wireless handsets can transmit multiple signal types, including data transmission that may use different bursting technologies (i.e. GPRS, WAP). Wireless laptop cards and PDAs may operate on either wide area (mobile phone-type) or local (IEEE 802.11.x type) networks with different carrier frequencies, signal types and power output. Ultimately, it may be impossible to enforce any policy that differentiates between different non-controlled mobile wireless handset types with regard to their use in the healthcare facility based upon visual appearance. For this reason, all non-controlled mobile wireless handsets should be treated with the same management/restrictions regardless of whether or not they appear to be the same as controlled handsets.

    2) Restrictive policies might involve requesting that individuals not use their personal mobile wireless handsets in areas of the facility where potentially susceptible medical devices are used. This should involve requesting by appropriate signage or some other reliable mechanism that non-controlled mobile wireless equipment is turned off before entering areas where potentially susceptible life-supporting medical devices are commonly operating, as even well-intentioned individuals may feel compelled to receive and respond to incoming calls or messages.

    3) Implementation and enforcement of restrictive policies should be facilitated by signs, especially in areas where potentially susceptible medical devices are commonly located, to make patients and visitors aware of the existing healthcare facility policy. Compliance with existing policy can be facilitated by defining numerous areas with easy access where the use of wireless handsets by patients, visitors, and staff is unlikely to interfere with medical devices.

    4) Any restrictive policy should be balanced between an informed assessment of EMI risk and the increasing need among patients, visitors and healthcare facility staff for mobile wireless communication and computing. In the extreme, healthcare facilities could ban the use of all non-controlled mobile wireless handsets altogether, although such measures are likely to be excessive from an EMI management perspective [58] and not responsive to the growing needs of individuals for direct access to mobile wireless communication, especially in times of emergency and crisis.

b) While instructing patients and visitors to maintain a minimum separation distance between their personal mobile wireless handsets and medical devices might theoretically act as a safeguard against EMI events, such a recommendation may be impractical in many facility areas, and further be exceedingly difficult to

monitor and enforce. Such minimum separation requirements are not recommended as a primary management strategy. However, the minimum separation distances determined from ad hoc testing can be used as an added layer of management in areas where potentially susceptible life-supporting medical devices are commonly operating.

4.7 RF emissions from network sources

RF emissions from in-building system network antennas (WAN microcells or repeaters, LAN access points) are most appropriately managed by locating them in a place where separation distance mitigates medical device EMI effects, such as the roof of corridors and rooms.

RF emissions from base station sites physically located on healthcare facility roof-top or building structures should conform to existing national radio regulations to limit emissions directly into the supporting building structure.

4.8 Medical devices within healthcare facilities

Although outside the current scope of this Technical Report, the placement and operation of RF-emitting medical devices within the healthcare environment is an area that should be carefully considered. There are many types of medical devices that generate and use electromagnetic energy for their medical function. For example, electric scalpels (e.g. high frequency electrosurgical equipment) often generate RF and microwave fields for cauterization purposes, physio-diathermy units may emit 915 MHz, 433 MHz, 2 450 MHz or other frequencies for deep tissue heating [36], and ultrasound machines may radiate up to their operating frequency of ~ 3 MHz to 20 MHz. The healthcare facility should exercise caution in where and how these types of emitters are used in the vicinity of other potentially susceptible medical devices.

Electromagnetic type security and inventory systems, such as metal detectors, anti-systems and RFID, emit signals that may disrupt potentially susceptible medical devices. The policies and practices of the healthcare facility should address this equipment. For example, RFID tags used in the healthcare environment may be passive emitters, activated by inductive processes when brought into proximity of RFID readers. However, the readers may emit high field strength magnetic fields and should be included as a transmitter in ad hoc testing and in EMC/EMI management policies. ASTM F 2401-04 [57] provides useful information.

For medical devices used outside the healthcare facility in a domiciliary setting, such as dialysis equipment, blood glucose analyser, infusion pumps, etc., instruction should be provided to patients advising them to maintain at least 1 m of separation distance between the medical device and mobile wireless equipment while it is in operation.

Annex A
(informative)

RF technologies

A.1 Propagation of RF energy through space

Radio frequency waves (300 KHz – 300 GHz) travel through space at the speed of light with wavelength related to the frequency and (in a vacuum) by the following:

frequency (MHz) multiplied by wavelength (metres) equals the speed of light (= 3×10^8 m/s).

Table A.1 — RF propagation characteristics

Frequency MHz	Wavelength m	Frequency MHz	Wavelength m
1	300	100	3
3	100	300	1
10	30	1 000	0,3
30	10	3 000	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 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.

A.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 metre, but may also be measured in terms of the magnitude of the magnetic field vector, in amperes per metre. 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 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 can occur through relatively straight cables, wires and printed circuit board traces, and can occur at large distances from the RF source. Unintended coupling of H fields to medical devices can occur through coiled cables, wire loops and loops formed by printed circuit board traces, usually very close to the RF source.

A.3 Minimum separation distances

In the far field (distance greater than the sum of 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 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, an estimation of immunity can be made by substituting immunity for the field strength and solving the dipole equation for distance:

$$K = \sqrt{\frac{Pd}{E}}$$

where

P is the the output power of the transmitter, in watts;

E is the the immunity of the medical device, in volts per metre;

d is the the minimum separation distance, in metres;

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 mobile phones is approximately 7, and the value for lower-frequency hand-held transmitters such as walkie-talkies can be as low as 3.

This approximation does not apply at distances less than several wavelengths of the transmitter carrier frequency (i.e. in the near field). The limitations of this estimate are described below. The following is assumed:

— a single transmitter is present, radiating at its maximum rated power;

— the worst-case susceptibility of the medical device occurs at the frequency of the transmitter.

In addition, if multiple RF transmitters (e.g. mobile telephones) are in use, the minimum separation distance necessary for compatible operation could be greater than that determined from this 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, radiation pattern, and by absorbing and reflecting objects (including buildings and people). Multipath reflections could result in a minimum separation distance greater than that determined from the equation, and absorption could result in a minimum separation distance less than that determined from the equation.

A.4 Mobile phone technologies

A.4.1 General network considerations

Mobile phones operate on wide area networks (WANs) composed of numerous cell sites using different RF signal technologies. Common first generation (1G) analog technology includes AMPS [Advanced Mobile Phone System] systems in the US, NMT [Nordic Mobile Telephony] technology in Scandinavia as well as in parts of Russia/Eastern Europe/Mid East/Asia, and TACS [Total Access Communications System] in Europe and other parts of the world. These systems as well as smaller systems in France, Germany, Italy, Canada and elsewhere are now largely obsolete or being phased out in many parts of the world where newer digital technologies are predominant.

Analog technology assigns a single channel frequency per user, while newer second generation (2G) “digital” technologies allow multiple users to operate on a single channel frequency creating more capacity on the network by converting voice data into a binary form (0's and 1's) and compressing it.

Second-generation technologies in the US include traditional CDMA [Code Division Multiple Access] and a variety of different TDMA-type [Time Division Multiple Access] technologies, including NADC [North American Digital Cellular] (which is rapidly being phased out), GSM [Global System for Mobile], and iDEN [Integrated Dispatch Enhanced Network]. In Europe, parts of Asia and other locations, the predominant technology is GSM, with Tetra [Terrestrial Trunked Radio] also used in many parts of Europe by public safety departments.

With CDMA, the compressed data is sent in small pieces at discrete frequencies over a series of 40 contiguous channels, or ~1,2 MHz of frequency spectrum, with multiple calls overlaid on top of each other. Each call is then deciphered from the noise floor (composed of all the other callers using that channel block at that time) by its unique sequence code. CDMA technology is also the basis of emerging third-generation communication technologies.

With TDMA, transmission occurs at a single channel frequency, but each user is assigned a specific “time slot” that occurs within a repeating time element (a “frame”) in which to pulse their compressed voice data. The different TDMA technologies have different protocols that define the “pulse” parameters. Other mobile phone technologies that are specific for areas in Asia include Japan CDMA, JTACS [Japanese Total Access Communications System], Japan PDC [Personal Digital Cellular], and Korean PCS [Personal Communications Services].

A global standard for third-generation (3G) wireless communications has been defined by the International Telecommunication Union (ITU) and will implement CDMA technologies engineered to allow more room for data transmissions (up 1 to 2 Mbps as opposed to the 10's of Kbps of 2G technologies) for internet surfing, downloading video, etc.

The common form in Europe called UMTS [Universal Mobile Telecommunications Systems] is a wide band CMDA (WCDMA) technology having a bandwidth of ~ 5 MHz (as opposed to the 1,2 MHz of conventional CDMA) and is starting to take hold in some of the larger metropolitan European regions. In Japan, a similar WCDMA technology is called FOMA [Freedom of Mobile Multimedia Access].

A competing technology in the US is CDMA-2000, which utilizes the conventional 1,2 MHz bandwidth but allows for a much higher data rate and can operate not only on the existing frequency bands but also on the newly allocated 3G bands as well.

In addition to the above, allocation and auction in 2006 by the US FCC of “Advanced Wireless Spectrum” (AWS) in bands at 1 700 MHz and 2 100 MHz is intended to facilitate third-generation communication technologies, although there is flexibility to apply this spectrum to many different communication applications. This spectrum does not directly match similar allocations in European (1 900 MHz, 2 100 MHz) and other countries.

As technology continues to develop, mobile phones allowing simultaneous voice and data communication using general packet radio service (GPRS), wireless application protocols (WAP), and other technologies is becoming increasingly common. Such data transmissions generally emit RF signals as bursts during periods of system availability using the embedded signal technology and under normal power control of the phone on a dedicated data channel.

A.4.2 Mobile phone emissions: Frequency

Relevant agencies throughout the world have allocated specific blocks of frequency spectrum that mobile phone handsets and network base stations can use in that country/geographical area for transmission. Various network companies license the rights to use all or part of these blocks of spectrum in a specifically defined geographical area.

In the US and Canada, an original frequency block (824-849 MHz Tx/869-894 MHz Rx) still supports analog, CDMA, and some NADC-TDMA technologies, although NADC is rapidly being phased out and in its place GSM technology is being implemented in this 850 MHz band. Each channel within this block is 30 KHz wide, and Rx = Tx – 45 MHz. As room within this frequency block became insufficient for the growing number of mobile phone users, another larger block of spectrum was opened up by the FCC for newer second-generation CDMA and TDMA technologies at 1850-1910 MHz Tx/1930-1990 MHz Rx with a channel width of 50 KHz and Rx = Tx - 80 MHz. iDEN technology operates in one of the many Land Mobile Radio (LMR) frequency blocks along with public safety radio systems (806-824 MHz Tx/851-869 Rx) and has a 25 KHz channel width, and Rx = Tx – 45 MHz. In Europe, similar frequency blocks have been defined at 880-915 MHz Tx/925-960 MHz Rx and 1710-1785 MHz Tx/1805-1880 Rx. In Japan, initial bands included 810-826 MHz, 832-925 MHz, and 1429-1453 MHz. In Korea, PCS operates at 1750-1870 MHz Tx/1840-1870 MHz Rx. New third-generation spectrum has also been created in the US at 1,7 GHz to 2,1 GHz and in Europe and Asia at 1,92 GHz to 2,17 GHz.

Mobile phone emissions outside of any assigned channel frequency are minimal in the US due to compliance with FCC (Federal Communications Commission) CFR Part 15 specifications regulating the allowable level of both "spurious" and "out of band" emissions (the actual US spec is attenuation by at least 43 + 10 lg10 (P) dB or 60 dB, whichever is the lesser attenuation (for a 1 W transmitter = −13b Bm or 50 µW. Similar specifications are defined by the International Telecommunications Union (ITU) Radiocommunication Assembly ITU-R SM.329, which sets spurious emissions limits at −16 dBm or 25 µW for a 1 W transmitter in the 900 MHz band [< 960 MHz] and 100 µW for a 1 W transmitter with a carrier frequency of 960 MHz to 17,7 GHz).

During initial power-up or hand-off to a distal base station site, a process of registration occurs between all mobile phones and base stations on a random access or unassigned control channel frequency. This facilitates bidirectional communication between the mobile phone and the base station to exchange registration information.

Following that process, the phone is assigned a dedicated channel frequency to receive call information (called a "downlink channel" or "Rx") and in return is directed to transmit on an assigned "traffic" channel that is commonly 25 MHz to 50 MHz lower in frequency (called the "uplink channel" or "Tx").

As the user crosses over to another location area (i.e. a cluster of cell sites linked within the network covering a particular vicinity), he (or she) will be "handed-off" and assigned new non-overlapping Tx/Rx channels (following another re-registration process) by the next base station.

A.4.3 Mobile phone emissions: Output power

When in use, mobile phones transmit on their assigned Tx channel at an output power that is continuously regulated (many times per second) over a range of incremental power steps as it moves through the network in a manner more-or-less inversely proportional to the base station (Rx) signal strength.

This situation is actually a bit more complex due to the ability of some systems to set different thresholds to initiate power cutback, switch operation to other networks when they cross coverage boundaries and exceed traffic volumes, etc., but the basic description serves for the purpose of this commentary.

Normally, the maximal transmit power of a mobile phone ranges from ~0,6 W to 2 W (depending upon the technology). At the lowest transmit power, the phone may emit a few milliwatts or less. By comparison, 802,11b local area network devices typically transmit continuously at ~10 mW.

Because TDMA signals are emitted in a pulsed fashion, their average power is lower than their pulsed power (e.g. with GSM technology there are 8 possible time slots per channel so an output power of 1 W emitted repeatedly during a single time slot, followed by 7 time slots where no power is emitted, would translate into an average power of 1 W/8 = 125 mW). For analog and CDMA signals, power is emitted in a more continuous fashion, albeit for CDMA the power is spread over ~1,2 MHz.

As an individual mobile phone moves through the network, or even within a building, the output power may fluctuate significantly due to numerous reflecting and shielding structures that influence the path of the RF signal. The handset is constantly directed to transmit at the lowest power control level necessary to maintain a sufficient link, because the lower the Tx power, the longer the battery life and the less possibility of interference with other mobile phones. Sporadic "shadow" coverage areas that cause phone handsets to transmit at significantly higher power levels may be especially problematic in hospital buildings with complex floor plans, lead-impregnated walls in radiology / oncology units, and basement levels.

When analog and TDMA mobile phones cross over to another location area, the hand-off is "hard", meaning that each new registration is performed at full power and then subsequently power controlled by the new base station after 1 s to 2 s. For CDMA technologies, the hand-off is "soft", meaning that power control is maintained during the hand-off and continually regulated so as not to overwhelm the more tightly power controlled nature of the CDMA system.

Another scenario in which some (but not all) mobile phone technologies can change power is when traffic on the local base station within the network has reached capacity and users are transferred to distal sites, coming under the direction (and power control) of the more distant base station. Other technologies simply register a "system busy" message and drop from the network. While both situations can be problematic, both can be avoided if adequate room is available on the network for the local communication traffic.

One final aspect of newer digital mobile phone technology that can influence output power in TDMA-type technologies is delayed transmission (DTx), or the ability of the network to direct a mobile phone handset to further compress its voice data during times of speech inactivity and only send it out during periodic pulses. A similar function in CDMA networks is variable rate speech coding that can assign a lowered data rate level during speech inactivity. The result of each is a markedly reduced transmission (just enough to hear a background "hiss" so the speaker knows he is still connected to someone) with the phone actually not transmitting over a majority of the time during speech inactivity.

A.4.4 Standby mode

Transmissions in standby mode (often referred to as "sleep" mode — when the power is on but the phone is not actively on a call) can be infrequent for many common mobile phone technologies. However, when full-power standby transmissions occur, they can interfere with potentially susceptible medical devices. Mobile phones that operate on analog or TDMA-type networks (iDEN, GSM, NADC) *do not* usually transmit while in standby mode *if* they remain in the same location area. If a healthcare facility is fully covered by a single location area (which is often the case), TDMA and analog handsets in standby mode operating on that network will remain in receive mode only and will not transmit (unless they are left in standby mode on the order of ~10 h to 20 h without moving from the location area — in which case a short series of full power bursts lasting on the order of 1 s to -2 s may "ping" the controlling cell site).

If the mobile phone handset crosses the location area coverage boundary, re-registration on a different cell site will occur involving a series of full-power burst transmissions lasting on the order of 1 s to 2 s.

It is usually an easy matter to confirm whether a healthcare facility is covered by a single location area by contacting the relevant network service provider and having them perform a walk-through with the mobile phone handset in test/trace mode to characterize the cell site link and available downlink signal.

When an analog or TDMA mobile phone is powered on, or receives a call from the base station, or when the user initiates a dialing sequence, the phone will transmit a short series of bursts at full power on a random access or unassigned control channel lasting 1 s to 2 s, after which channel allocation is assigned and power control is applied.

When powering the handset off there is also a series of RF bursts to disengage from the network, but these are power-controlled.

In contrast to analog and TDMA technologies, phones operating on CDMA networks DO continually transmit while in standby mode every ~2 s to 3 s, even when stationary, for access probes to maintain the link with the current cell site and traffic channel probes to maintain synchronization of the complex CDMA coding scheme. However, these standby CDMA transmissions are all tightly power-controlled, and much shorter than for TDMA-type systems (lasting for only a fraction of a second).

A.4.5 Multi-band transmission

While a given mobile phone will only transmit/receive at any given time on a single defined frequency and using a single technology for voice communications (although simultaneous data transmission is possible), many mobile phones can automatically switch operation to a different frequency band or different technology depending upon the availability of the network.

For example, a phone normally operating on a CDMA or TDMA network may be directed by the network to "roam" to an older analog network system in a rural area or within a healthcare facility when CDMA/TDMA signals are lost.

Alternatively, a CDMA or TDMA phone operating within a given frequency band may be directed to switch to another frequency band if the user has crossed a coverage boundary and the service provider has a license for the other band in the new area, or has an agreement with another service provider for extended coverage in that area.

Another scenario where mobile phones on some (but not all) technologies can change power can occur when traffic on the local base station within the network has reached capacity and users are transferred to distal sites, coming under the direction (and power control) of the more distant base station.

A.5 Common IEEE 802 and other industry standard wireless technologies

A.5.1 General

See Table A.2.

Table A.2 — Industry standard wireless technologies

Techno-logy	US Frequency Bands and Modulation	Reliability	Latency	Priority	Bandwidth	Security	Network Topologies
WIFI a IEEE 802.11a	3 × 100 MHz bands at 5,15 to 5,25 GHz, 5,25 to 5,35 GHz and 5,725 to 5,825 GHz Total 12 × 20 MHz non-overlapping channels OFDM	Forward error correction (FEC) addressed at MAC level Multipath error addressed by OFDM equalization, antenna diversity Coexistence addressed by dynamic channel selection (11h), collision avoidance (DCF, PCF) In-band noise may alter modulation method and impact throughput Network access slows as nodes increase traffic	1-Way (max): Asynch = 2,4 ms (no loading) Round Trip (max): Asynch = 4,8 ms (no loading) Jitter: Asynch = ~700 us, but sensitive to network loading (collisions) (11e not included)	802.11e[7]/WiFi WMM (voice > video > best effort > bckgrnd)	Throughput: 54 Mbps Range: 45 m (at 6 Mbps and through walls) Roaming: implementation specific	Admission: Open, shared key Authentication: Provided by 802.1x[7] mechanisms Encryption: Legacy uses WEP, replaced by WPA, 802.11i[7] defines WPA2	Topology: Ad Hoc, Infrastructure with multiple APs, managed Peer-to-Peer (Direct Link per 802.11e[7]) Nodes per AP: 64-128 (practical) Can also use RTS/CTS to deal with hidden nodes

Table A.2 (*continued*)

Techno-logy	US Frequency Bands and Modulation	Reliability	Latency	Priority	Bandwidth	Security	Network Topologies
WIFI b IEEE 802.11b	1 × 100 MHz band at 2,4-2,5 GHz 14 × 5 MHz overlapping channels 3 × 5 MHz non-overlapping channels DSSS with CCK	Forward error correction (FEC) addressed at MAC level Multipath error addressed by antenna diversity Coexistence addressed by dynamic channel selection (11h), collision avoidance ("b" and "g" networks) In-band noise may alter modulation method and impact throughput Network access slows as nodes increase traffic	1-Way (max): Asynch = 2,4 ms (no loading) Round Trip (max): Asynch = 4,8 ms (no loading) Jitter: Asynch = ~700 us, but sensitive to network loading (collisions) (11e not included)	802.11e[7]/WiFi WMM (voice > video > best effort > bckgrnd)	Throughput: 6 Mbps Range: 45 m (at 2,1 Mbps (AP + 3 devices) Roaming: implementation specific	Admission: Open, shared key Authentication: Provided by 802.1x[7] mechanisms Encryption: Legacy uses WEP, replaced by WPA, 802.11i[7] defines WPA2	Topology: Ad Hoc, Infrastructure with multiple APs, managed Peer-to-Peer (Direct Link per 802.11e[7]) Nodes per AP: 64 to 128 (practical) Can also use RTS/CTS to deal with hidden nodes

Table A.2 (*continued*)

Techno-logy	US Frequency Bands and Modulation	Reliability	Latency	Priority	Bandwidth	Security	Network Topologies
WIFI g IEEE 802.11g	1 × 100 MHz band at 2,4 to 2,5 GHz 14 × 5 MHz overlapping channels 3 × 5 MHz non-overlapping channels OFDM > 20 Mbps; DSSS/CCK < 20 Mbps	Forward error correction (FEC) addressed at MAC level Multipath error addressed by antenna diversity Coexistence addressed by dynamic channel selection (11h), collision avoidance ("b" and "g" networks) In-band noise may alter modulation method and impact throughput Network access slows as nodes increase traffic Backward compatible to legacy systems (g to b) but at slower speeds	1-Way (max): Asynch = 2,4 ms (no loading) Round Trip (max): Asynch = 4,8 ms (no loading) Jitter: Asynch = ~700 us, but sensitive to network loading (collisions) (11e not included)	802.11e[7]/WiFi WMM (voice > video > best effort > bckgrnd)	Throughput: 30 Mbps Range: 45 m (at 6 Mbps and through walls) Roaming: implementation specific	Admission: Open, shared key Authentication: Provided by 802.1x[7] mechanisms Encryption: Legacy uses WEP, replaced by WPA, 802.11i[7] defines WPA2	Topology: Ad Hoc, Infrastructure with multiple APs, managed Peer-to-Peer (Direct Link per 802.11e[7]) Nodes per AP: 64 to 128 (practical) Interoperates with 802.11b[7] at lower speed in "b" mode, uses RTS/CTS to deal with hidden nodes
IEEE 802.15.1	1 × 100 MHz band at 2,4 to 2,5 GHz FHSS	Forward error correction (FEC) available / optional Multipath error addressed by freq hopping Coexistence and inband noise addressed by transmit power control, up to 9 piconets coexist well Network access stable under increased traffic due to piconet controller (allocates network bandwidth)	1-Way (max): Synch connection oriented (SCO) = 1,25 ms (typical loading) Round Trip (max): Synch connection oriented (SCO) = 1,9 ms (typical loading) Jitter: 10 us (max)	No prioritization	Throughput: 1-2 Mbps Range: class 1 (~100 m) class 2 (~10 m) class 3 (~10 cm) No roaming	Admission: E22 algorithm key generator Authentication: PIN key based Encryption: E0 (stream cipher): 128 bit key, 48 bit device address, master clock, and 128 bit random value)	Topology: Infrastructure via Piconet controller Nodes: 7 active and 250 standby Modes: SCO and ACL

Table A.2 (*continued*)

Techno-logy	US Frequency Bands and Modulation	Reliability	Latency	Priority	Bandwidth	Security	Network Topologies
IEEE 802.15.1a (improved QoS, backward compatible)	1 × 100 MHz band at 2,4 to 2,5 GHz	Forward error correction (FEC) available / optional Multipath error addressed by freq hopping Coexistence and inband noise addressed by transmit power control, up to 9 piconets coexist well Network access stable under increased traffic due to piconet controller (allocates network bandwidth)	1-Way (max): Synch connection oriented (SCO) = 1,25 ms (typical loading) Round Trip (max): Synch connection oriented (SCO) = 1,9 ms (typical loading) Jitter: 10 us (max)	No prioritization	Throughput: 700 Kbps Range: class 1 (~100 m) class 2 (~10 m) class 3 (~10 cm) No roaming	Admission: E22 algorithm key generator Authentication: PIN key based Encryption: E0 (stream cipher): 128 bit key, 48 bit device address, master clock, and 128 bit random value)	Topology: Infrastructure via Piconet controller Nodes: 7 active and 250 standby Modes: SCO and ACL
Bluetooth (same as **IEEE 802.15.1a**, with LLC enhanced)						Additional features	LLC enhancements
IEEE 802.15.3	1 × 100 MHz band at 2,4 to 2,5 GHz 4 × 15 MHz RF Channels	Forward error correction (FEC) addressed at MAC level Multipath error addressed by equalizers Coexistence addressed by dynamic channel selection, transmit power control, etc. In-band noise: Can schedule around periodic interferers Network access stable under increased traffic due to piconet controller (allocates network bandwidth)	1-Way (max): Asynch = 65 ms (typical loading); Isoch = < 10 ms (typical loading with channel allocation) Round Trip (max): Isosynch = 65 ms (typical loading) Jitter: Asynch = ~30 us, but (frame boundary)	Prioritized and parameterized Isochronous	Throughput: 42 Mbps Range: 61 m (at 55 Mbps) Roaming: implementation specific (e.g. mesh topology)	Admission: Per piconet controller Authentication: AES-CCM (done higher layers) Encryption: AES-CCM (128 bit key)	Topology: Peer-to-Peer, ad hoc, managed Peer-to-Peer, Mesh (data exchange only), Infrastructure (Star), Bridged Peer-to-Peer (data exchange only) Nodes: 236 (protocol) Modes: Shadow controller1394 PAL

Table A.2 (*continued*)

Techno-logy	US Frequency Bands and Modulation	Reliability	Latency	Priority	Bandwidth	Security	Network Topologies
UWB/ OFDM (incorpo-rate FDM or TDMA to accommo-date multiple users) [former **IEEE 802.15.3a**]	3,1-10,6 GHz OFDM	No MAC level FEC (for FDM) Multipath error addressed by OFDM equalizers (for FDM) Coexistence addressed by low spectral power, dynamic channel selection, transmit power control, etc. In-band noise: Phy layer robust coding, erasure coding (notches), spectral spreading, and interleaving for tolerance to in-band noise (sacrifice throughput or error rate) Network access stable under increased traffic due to piconet controller (allocates network bandwidth)	1-Way (max): ? Round Trip (max): ? Jitter: Isoch = 30 us (frame boundary)	Prioritized and Parameterized Isochronous	Throughput: 460 Mbps Range: ~10 m (at 105 Mbps) Roaming: implementation specific (e.g. mesh topology)	Admission: Per piconet controller Authentication: AES-CCM (done higher layers) Encryption: AES-CCM (128 bit key)	Topology: Peer-to-Peer, ad hoc, managed Peer-to-Peer, Mesh (data exchange only), Infrastructure (Star), Bridged Peer-to-Peer (data exchange only) Nodes: 236 (protocol) Modes: FDM (mandatory); TFC (for multiple networks) 1394 PAL

Table A.2 (*continued*)

Techno-logy	US Frequency Bands and Modulation	Reliability	Latency	Priority	Bandwidth	Security	Network Topologies
UWB/DS [former **IEEE 802.15.3a**]	3,1 to 5 GHz, 6 to 10,6 DSSS	Forward error correction (FEC) addressed at MAC level Multipath error addressed by equalizers, spreading codes, and coherent wide bands Coexistence addressed by low spectral power, dynamic channel selection, transmit power control, etc. In-band noise: Equalizers, spreading codes, coherent wide bands for tolerance to in-band noise. Can schedule around periodic interferers (sacrifice throughput or error rate) Network access stable under increased traffic due to piconet controller (allocates network bandwidth)	1-Way (max): ? Round Trip (max): ? Jitter: Isoch = 30 us (frame boundary)	Prioritized and parameterized Isochronous	Throughput: 750 Mbps Range: ~10 m (at 85 Mbps) Roaming: implementation specific (e.g. mesh topology)	Admission: Per piconet controller Authentication: AES-CCM (done higher layers) Encryption: AES-CCM (128 bit key)	Topology: Peer-to-Peer, ad hoc, managed Peer-to-Peer, Mesh (data exchange only), Infrastructure (Star), Bridged Peer-to-Peer (data exchange only) Nodes: 236 (protocol) Modes: FDM (mandatory); TFC (for multiple networks) 1394 PAL

Table A.2 (*continued*)

Techno-logy	US Frequency Bands and Modulation	Reliability	Latency	Priority	Bandwidth	Security	Network Topologies
IEEE 802.15.4	900 MHz (10 × 2 MHz Channels) 2,4 GHz (16 × 5 MHz Channels)	No MAC level FEC Multipath error addressed by wave shape and pulse width Coexistence and in-band noise addressed by low duty cycle, dynamic channel selection, transmit power control, etc. Loading: No sensitivity to nodes being added. Network access slows as nodes increase traffic, but has low duty cycle and supports GTS for particular nodes Network access slows with increased traffic	1-Way (max): TDMA = 15 ms (between time slots); CSMA = depends upon network topology and loading Round Trip (max): Isosynch = 30 ms (typical loading) Jitter: TDMA = low; CSMA: max could be infinite, depends on network topology and loading	No priorities Parameterized Synchronous, but not isochronous (no time stamps) Deterministic (contention access period)	Throughput: ~150 Kbps Range: ~10 m (at 150 Mbps, 2,4 GHz, indoor). 1 000 m at 40 Mbps, 900 MHz, line of sight Roaming:	Admission: Per piconet controller Authentication: AES-CCM (done higher layers) Encryption: AES-CCM (128 bit key)	Topology: Peer-to-Peer, Peer-to-multipeer, ad hoc, managed Peer-to-Peer, Mesh (data exchange only), Infrastructure (Star), Bridged Peer-to-Peer (data exchange only) Nodes: 236 (protocol)
ZigBee Adds higher levels to **IEEE 802.15.4** phy and MAC							

Table A.2 (*continued*)

Techno-logy	US Frequency Bands and Modulation	Reliability	Latency	Priority	Bandwidth	Security	Network Topologies
WiMAX IEEE 802.16	2,4 GHz, (4 × 20 MHz or 8 × 10 MHz assumed) 5,1 to 5,35 GHz, (10 × 20 MHz or 20 × 10 MHz assumed) channel assignment varies by implementation OFDM	Forward error correction (FEC) addressed at MAC level, phy downshifts when BER exceeds threshold Multipath error addressed by OFDM equalizers (for FDM) Coexistence addressed by dynamic power selection, transmit power control, etc. In-band noise: Mitigated by OFDM and optional beam-forming Network access stable under increased traffic	1-Way (max): Asynch: < 25 ms (typical loading); Isoch: < 10 ms (typical loading, channel allocation) Round Trip (max): Asynch: ? Isoch: ? Jitter: 2 to 20 ms (phy frame size)	Prioritized (classes implemented at convergence layer) Parameterized Isochronous (precise clock synchronization provided) Deterministic (admission control done above the MAC but enforced by the MAC)	Throughput: 35 Mbps (with 10 MHz channel); 70 Mbps (theoretical with 20 MHz channel) Range: 300 m (at 70 Mbps, 20 MHz) 1 Km (at 23 Mbps, 20 MHz, with beam forming) Roaming: nomadic	Admission: Per BSC controller Authentication: X.509 Encryption: DES/3DES AES-CCM (128 bit key)	Topology: Point-to-multipoint, Mesh (data exchange only and not for indoor), Infrastructure (Star), Bridged Peer-to-Peer (data exchange only) Nodes: 1600 (protocol) 1024 (practical) Modes: QPSK QAM 16 QAM 64

Table A.2 (*continued*)

Techno-logy	US Frequency Bands and Modulation	Reliability	Latency	Priority	Bandwidth	Security	Network Topologies
HiperLAN2 ETSI TR 101 683	5 GHz, 23 × 20 MHz Channels OFDM or CSMA / CA	Forward error correction (FEC) at MAC level. No retransmissions Multipath error addressed by OFDM equalizers Coexistence addressed by dynamic power selection, transmit power control, etc. In-band noise: Alters modulation method and sacrifices throughput for tolerance Central controller schedules transmissions, so network access stable under increased traffic	1-Way (max): Asynch: < 8 ms (typical loading); Isoch: < 6 ms Round Trip (max): ~2 × 1-way delay; Asynch ?, Isoch ? Jitter: 2 to 20 ms (phy frame size)	Prioritized (classes implemented at convergence layer) Parameterized Isochronous (precise clock synchronization provided) Deterministic (admission control done above the MAC but enforced by the MAC)	Throughput: 50 Mbps Range: 8 m (at 50 Mbps, no walls); 30 m (at 25 Mbps, 4 walls); 1 Km (at 23 Mbps, 20 MHz, beam-forming) No roaming	Admission: Per central controller when node joins Authentication: Managed by central controller Encryption: DES (168 bit key)/3DES	Topology: Managed Peer-to-peer (1394 convergence layer), Infrastructure (for Ethernet convergence) Nodes: 20 Modes: QPSK QAM 16 QAM 64
IEEE 1902.1 (RuBee)	< 450 KHz	Similar to 802.15.4		No priorities	Throughput: ~150 Kbps Range: ~10 to 30 m		Topology: Peer-to-Peer, Peer-to-multipeer, ad hoc, managed Peer-to-Peer, Mesh

A.5.2 Description of wPAN, wLAN, wMAN, wWAN

A.5.2.1 wPAN

Wireless personal area technologies (IEEE 802.15x) are generally designed for short range, targeted applications and (usually) operate on unlicensed bands at lower transmit power levels. The most established of these technologies at the time of this draft is Bluetooth, which conforms to the IEEE 802.15.1 standard and was primarily intended as a cable replacement option (although an expanded application base continues to evolve). This technology nominally operates at 10 mW in most applications with a range of ~10 m, although higher power class 1 [100 mW] does exist within the standard that can provide for a range of ~100 m. While limitations do exist within the current IEEE 802.15.1 protocol (usually as a result of being forced to perform functions not initially anticipated), it is making its way into commercially available products allowing some degree of “plug-and-play” communication due to its IEEE standardized format. Another rapidly developing technology is Zigbee, conforming to the IEEE 802.15.4 standard. This technology was designed for low data rate, low power applications such as sensor readings, interactive devices, smart badges, controls, and automation. With regard to medical data transport, it may have application for such functions as RFID and low rate episodic physiological parameters. Like Bluetooth, the IEEE 802.15.4 technology also operates within the unlicensed ISM band at 2450 MHz, but can also operate in the US on the 915 MHz unlicensed band, in

Europe on the 868 MHz unlicensed band, and in theory within the newly allocated WMTS bands. IEEE 802.15.4 still suffers interoperability problems due to the fact that its standard is not yet finalized.

The increased capacity of IEEE 802.15.3a UWB (or the separate efforts to develop an industry standard for wPAN UWB since IEEE 802.15.3a has disbanded) will allow for higher throughput for short link ranges, although this technology at this time is not yet a mature standard. Although it might be assumed that less variability is associated with performance of WPAN systems given more targeted point-to-point applications associated with the limited link range (as compared to WLAN or WWAN), significant variability may exist. IEEE 802.15.4 technology operates at 2,4 GHz along with WiFi, Bluetooth, and many other applications. It was developed to be a low data rate, battery efficient technology to interconnect equipment or send small amounts of data over short ranges. Additional layers have been added to IEEE 802.15.4 to further enhance this technology. Zigbee technology evolved from IEEE 802.15.4 by adding a mesh network that might involve multiple hops from node to node when transporting data over longer distances (> 10s to 100s of metres), and latency can quickly increase with accumulation of relay points. Other single-hop IEEE 802.15.4 developments may be able to operate without the latency issue. Other MESH algorithms may also exist that will minimize latency and be useful for some wireless applications also. Further, performance of both IEEE 802.15.1 and IEEE 802.15.4 may be greatly influenced by other emitters in the unlicensed band that compete for channel access in busy environments (see section on EMC and co-existence). Clearly, such existing WPAN technologies may not be well suited (by themselves) for medical applications involving transport of real-time monitoring or critical alarm and alert data due to capacity and range limitations. However for applications where latency issues are relaxed (e.g. asset tracking/RFID, non-critical control parameters) or distances are minimized (e.g. single wireless link to a WAN or LAN gateway), IEEE 802.15.1 and IEEE 802.15.4 technologies merit consideration. Interoperability of IEEE 802.15.x and IEEE 802.11 WiFi may create local problems for both systems if careful design considerations are not done up front.

Radio Frequency Identification (RFID), also referred to as dedicated short-range communication (DSRC), is a technology that incorporates the use of passive or active electrometric or electrostatic coupling to uniquely identify an object. This technology is currently being deployed in healthcare environments to track assets, to identify patents, and to support security measures. For purposes of this Technical Report, RFID is considered under the wPAN communications section. While there are several recognized standards (e.g. ISO14443 and Ecma-340 (NFCIP-1) family of standards, ISO 15693, ISO 18000-x, EPCglobal 'gen2', etc.) for passive RFID devices, active RFID devices have been largely deployed in the 433 MHz, 900 MHz, 2400 MHz and 10 GHz portions of the electromagnetic spectrum without much standardization.

IEEE P1902.1(TM) is a new standard effort that will improve upon the visibility network protocol known as RuBee(TM) and offer a local network protocol for thousands of low-cost radio tags having a long battery life. It will be a bidirectional, on-demand, peer-to-peer, radiating, transceiver protocol operating at wavelengths below 450 KHz. The protocol works in harsh environments with networks of many thousands of tags and has an area range of 10 to 50 feet. It will fill the gap between the non-networked, non-programmable, backscattered, RFID tags widely used for asset tracking and the high-bandwidth radiating protocols for IEEE 802.11(TM) local area networks and IEEE 802.15(TM) personnel area and data networks.

A.5.2.2 wLAN

Wireless local area network systems offer an attractive option for PoC medical data transport. The technology was initially designed for data transport on unlicensed frequencies (ISM bands), and thus the cost of operating these systems is mainly “up front” and associated with the purchase, installation, and maintenance of the network hardware. This is in direct contrast to WWAN (mobile phone) systems that operate on licensed frequency bands, where the cost is associated with a regular service subscription paid to an FCC licensee (the network operator) to use its network. The architecture traditionally involves a series of access points distributed in a “star” pattern (as opposed to a self organizing “mesh”) throughout the intended coverage area (usually a building) linked to a central hub or switch that usually connects to a wired (Ethernet/IEEE 802.3) “backhaul” system. LAN systems have relatively high data throughput, although traffic control, prioritization, and interference from unrelated sources operating within the same unlicensed band can be an issue.

Local area network systems are defined by a series of IEEE 802.11 standards. In addition, the industry group Wireless Fidelity (WiFi) Alliance has been formed to champion and certify equipment developed to these standards to make sure they are interoperable with each other. There are a number of relevant standardized protocols that define various derivatives of the general IEEE 802.11 technology. IEEE 802.11b is currently the

most common version of IEEE 802.11 and operates in the unlicensed 2,4 GHz band. It supports a maximum theoretical data rate of 11 Mbit/s, but more realistic throughput somewhere between 4 to 6 Mbit/s in normal traffic conditions. It uses 3 non-overlapping channels with a direct sequence spread spectrum communications scheme. It has a typical range of ~30 m to 75 m. Other RF transmitters operating within the 2,4 GHz band (Bluetooth/IEEE 802.15.1, ZigBee/IEEE 802.15.4, 2,4 GHz cordless phones, microwave ovens, commercial high efficiency lighting, wireless toys) are all potential sources of interference. IEEE 802.11a operates within the unlicensed 5 GHz band, and supports a maximum theoretical data rate of 54 Mbit/s, using four, eight, or more channels depending on the country. However, a more realistic data throughput might be 20 to 25 Mbit/s under normal traffic conditions with a typical range between 20 m to 45 m. Like the "11b" version, IEEE 802.11g operates in the 2,4 GHz band but supports a maximum theoretical data rate of 6 to 54 Mbit/s offering a throughput similar to IEEE 802.11a but with backward compatibility to existing IEEE 802.11b technology. The IEEE 802.11g technology uses 3 non-overlapping channel sets and supports complementary code keying (CCK) modulation for IEEE 802.11b and for faster link rates allows packet binary convolutional coding (PBCC) modulation. The IEEE 802.11h protocol, which is still under development within IEEE 802.11, allows operation in the unlicensed 5 GHz band to comply with European regulations for 5 GHz WLANs (power-controlled transmission [TPC] and dynamic frequency selection [DFS]). TPC limits the transmitted power to the minimum needed to reach the furthest user. DFS selects the radio channel at the access point to minimize interference with other systems. The IEEE 802.11i draft standard may have significant relevance to the current technical report with respect to patient information security. This protocol defines new encryption key protocols (Temporal Key Integrity Protocol [TKIP] and the Advanced Encryption Standard [AES]) for WLAN.

A key standard relevant to this report involves the draft of the IEEE 802.11e standard that allows prioritized levels of service, which may define Quality of Service (QoS) support for LAN applications (critical for priority and delay-sensitive voice and video applications). An IEEE 802.11e network could assign priority to data, voice, and video streams for managed service. Prioritization is a key issue in the successful application of a wireless solution for medical data transport. From Table 4 of IEE 802.11:1999, there can be a wide range in the priority criteria associated with PoC medical device data. In the case of alarms and alerts, it may be essential for these messages to reach an attending staff member within a matter of seconds after an event or significant adverse effects (e.g. death) may result. For data such as patient history retrieval, delays on the order of 10s of seconds (while admittedly inconvenient) are not often associated with such serious consequences. For simple point-to-point or cable replacement applications, contention with other data streams is often not an issue so latencies tend to be more predictable and consistent. No prioritization protocol for data exists on current WWAN, WMAN, or WPAN networks, and data is basically allocated the first available transmission time slot by the network on a best effort basis. With increasing traffic load, channel access may be blocked and several retries may be required before data can be successfully transmitted. This problem of delayed channel access may be difficult to control with WLAN and WPAN technologies that operate on unlicensed frequency bands (e.g. 2 450 MHz ISM) where different manufacturer products will likely be sharing the same network infrastructure, unless the WLAN is upgraded with newly-developed technologies to control channel access. In addition, as more access points and/or mesh nodes become involved in a transport chain, latency issues may increase depending on design. Within the IEEE 802.11 standards group, however, the task group "e" has developed a protocol for prioritization of data streams operating on IEEE 802.11 systems. This protocol has been endorsed by the WiFi Alliance, and they offer a certification for commercial equipment to ensure conformance with the IEEE 802.11e protocol specifications.

Voice over internet protocol (VoIP) is an option available on IEEE 802.11 networks allowing voice communication on the in-building system. This feature has a number of benefits and drawbacks to consider before it is implemented. If an appropriate LAN network has been deployed within the healthcare facility, VoIP handsets can be used as an in-building mobile communication alternative to land-line and paging systems. Operation on the unlicensed frequency of the LAN system allows unlimited communication without a service fee, in contrast to the service agreements required to operate on either paging or mobile phone networks. Obviously, this does necessitate that the hospital has purchased and deployed a LAN system throughout the intended coverage area of the facility, and one clear disadvantage of VoIP-based communication is the inability to operate outside the facility coverage area. A larger concern, however, may be that the bandwidth required to operate multiple VoIP handsets can be considerable, and may quickly overload the LAN. Current G.711 protocols for VoIP encoding compress digitized voice into a 64 Kbit/s data stream and the bandwidth requirements are likely to be ~80 Kbit/s due to the overhead of the IP header, although more efficient codes are becoming available to compress VoIP data streams and decrease the required bandwidth to ~16 Kbit/s. To maintain an acceptable latency for voice communication, defined as 300 ms by the ITU, the VoIP data is generally assigned highest priority in protocols such as IEEE 802.11e. This can be problematic when high

priority medical data also uses the same network and channel access limitations result in latency increases that begin to exceed the QoS threshold. As additional multimedia applications over WLAN evolve, including audio (e.g. net radio, MP3 music) and video (e.g. streaming video, DVD, HDTV), they will demand additional bandwidth requirements if deployed on a LAN system.

Attention should be given to the degree of variability associated with the performance of any wireless system. This variability will depend upon both the conditions of use as well as the operating environment. For LAN technologies, the maximally-rated throughput of IEEE 802.11b may be 11 Mbit/s although an expected rate of 4 to 5 Mbit/s might be more realistic under typical use conditions with multiple traffic streams. While the link range of IEEE 802.11a transmitting 6 Mbit/s at a nominal 40 mW (+16 dBm) may be estimated at 50 m, when the rate is increased to a maximal 54 Mbit/s the link range is reduced. Similarly, the link range of IEEE 802.11b transmitting 1 Mbit/s at nominal 100 mW (+20 dBm) can be 100 m or more, but when the rate is increased to 11 Mbit/s the range decreases to ~40 m. The IEEE 802.11g technology has been developed to share higher throughput while maintaining backward compatibility with IEEE 802.11b, and has an expected link range of 12 m to 15 m when transmitting 54 Mbit/s at ~30 mW. FCC specifications for network systems allows transmission on the 2,45 GHz ISM band at up to 1 W, although most systems operated below 100 mW, and optimal performance may be achieved with a carefully designed access point distribution and transmit power of 30 mW or less. The IEEE 802.11 TGt group is developing a standard protocol for estimating and benchmarking the performance of various IEEE 802.11 equipment and network systems. Finally, IEEE 802.11FH is currently used by certain medical devices and in hospitals, with 900 MHz versions operating in some robots and in-building phones.

A.5.2.3 wMAN

Designed to provide high throughput voice, data, video for residential and enterprise use in 10-66 GHz and 2 GHz to 11 GHz bands, the IEEE 802.16 standard is basically a wireless alternative to fiber optic, cable modems, and DSL lines that can link to core IEEE 802.3 and/or telecommunication networks. The technology has been optimized for non line-of-site coverage (by incorporation of orthogonal frequency division multiplexing [OFDM] technology). While coverage distances of 3 km to 10 km may be typical in complex and obstructed (urban / suburban) environments, coverage of up to 50 km under line-of-site conditions may be possible. Like the WiFi Alliance for IEEE 802.11, the industry consortium WiMax formed to ensure that IEEE 802.16 devices are interoperable and develop guidelines (profiles) specifying operating frequencies, PHY, and other parameters for common functionality. The detailed protocol has been specified in IEEE 802.16a (2001) and upgraded IEEE 802.16d (2004). The IEEE 802.16e standard (ongoing) will allow support of the broadband technology when traveling at speeds of 110 km/h to 130 km/h as well as provide an asymmetrical link structure that enables use of the technology within a handheld device (such as a mobile phone, PDA, laptop, etc.). At the time of this Techncial Report, various companies have publicized plans to employ IEEE 802.16-type or other OFDM technology protocols to implement commercial broadband communication. Recent US auction of spectrum in the 700 MHz to 800 MHz region with flexible allowed usage and made available due to digital TV may be utilized for broadband communication. wMAN technology may also be envisioned for use within a mesh network with OFDM protocols to allow large data throughput options for mobile vehicles, with obvious potential application in ambulances and MedEvac.

A.5.2.4 wWAN

The principle advantages of wWAN systems (e.g. mobile phones) are probably the most intuitively obvious and familiar to the general reader. Such technology is well established in our society, and most users have first-hand experience with the benefits and limitations of mobile phone use. As pagers and paging networks become obsolete, alternate forms of mobile (on- and off-campus) communication will be necessary. This may take the form of voice communication on a mobile phone-type handset, text communication on a PDA-type handset, or a hybrid of both. Whatever the solution, it is almost certain that the information will be carried over existing wWAN. Expanding the function of the existing mobile phone handset to transmit and/or receive certain types of PoC medical data, therefore, would be relatively straightforward in concept. While the current throughput rate for data transport on existing second generation (2G) mobile phones is on the order of ~20 Kbit/s, third-generation (3G) technology conforms to the International Mobile Telecommunications (IMT-2000) specification developed by the International Telecommunications Union (ITU) for higher data rates and internet access. Current 3G technologies include the UMTS that employs a wideband CDMA signal spanning a 5 MHz channel on newly provisioned frequency bands in Europe at 1 920 MHz to 2 170 MHz, as well as CDMA2000 in the US which realizes higher data rates using currently licensed 1,25 MHz channels in existing

PCS (1 900 MHz) bands, and can also operate on newly allocated bands around 2 GHz. Such evolving technology might soon compete for medical data applications, especially in situations where access to the wWAN is essential (such as mobile healthcare and disease management). However, caution should be exercised in recommending the use of wWANs for home health monitoring, given the extreme variability in coverage due to base station proximity and the layout and building materials in the home.

Radio systems operating in various VHF, UHF, and 800/900 MHz bands are another form of wWAN, although capable of transmitting only limited amounts of data. Older Motorola radio models may support data at 1 200 bit/s, current radios following APCO 25 standards may support up to 9 600 bit/s, and newer technologies may support up to 4 Kbit/s. Newer digital technologies are currently being developed which may support additional data capacity. While not an optimal solution for most PoC medical data transport considerations, the common use of radio systems by ambulance and MedEvac personnel may allow certain limited applications.

A.5.2.5 Variations on standard wireless technologies

MIMO (multiple-input multiple-output) is not a standard per se, but a developing protocol that may soon be applied to several standardized wireless technologies. MIMO allows for the distribution of information bits among multiple antennas and a technique of data transmission using multiple signal paths to increase throughput and decrease fading effects through multipath propagation. For spatial multiplexing, the goal is to send two totally independent data streams and thus achieve a 2 times increase in data throughput. Other MIMO systems employ transmit diversity and receive diversity to achieve similar data throughput at lower power. Finally, some systems might employ the use of two entirely different RF channels for transmission of data and refer to this as MIMO. The MIMO protocol might be applied to 3G WWAN technologies (UMTS), IEEE 802.16/ WiMax, and WiFi (via IEEE 802.11n). Although there is simultaneous transmission by multiple antennas, these are not in phase so there is an ability to transmit more data with less power, especially within highly scattering environments (e.g. hospital buildings).

In addition to mobile phones, other wireless systems are also becoming increasingly common in healthcare facilities.

In the US, initial bands allocated by the FCC for cordless phones at 27 MHz and 47 MHz to 49 MHz were used, but most common cordless phones in the US today utilize unlicensed ISM (Industry, Science, and Medicine) frequency bands at 900 MHz, 2,4 GHz, and 5,8 GHz. These devices generally emit ~10 mW of power, although some models can emit as much as 1 W for longer range of the wireless link. Many cordless phones are analogue, but some have incorporated a digital technology that is not pulsed (as is the case with TDMA-type mobile phones) but spread over a broader spectrum using technology referred to as frequency hopping. This digital technology allows more privacy during calls.

In Europe, initial cordless phone standards (CT0) gave way to digital technologies with TDMA-type characteristics that emit pulses of RF.

There are now cordless phone-type systems throughout the world that employ a network of in-building access points that act as mini base stations to allow the cordless phone-type handset to roam throughout a local area or building outfitted with coverage, however from an RF emission and EMI perspective, these can be looked upon as similar to a standard cordless phone.

In the US, such systems are available from Spectralink, NEC, and others.

A similar cordless phone network technology in Europe commonly deployed in healthcare facilities is DECT (Digitally Enhanced Cordless Telecommunications).

Finally, many companies are now releasing cordless phone handsets that work over existing 802.11.b systems using a voice over Internet protocol (VoIP).

Other wireless systems include wide fidelity (WiFi) or local area network (LAN) systems (802.11.a, 802.11.b, 802.11.g) and personal area networks (PAN) systems (Bluetooth, 802.15.3a, Zigbee). These technologies also usually operate on unlicensed ISM bands using frequency-hopping digital signals, and are each designed for particular applications having different data rates, range, and power consumption requirements.

From an EMC perspective, frequency-hopping signals are more akin to analog signals in that the RF energy is relatively evenly distributed (although over a somewhat larger frequency range). These systems are also typically not dynamically power controlled, and thus emit RF energy in a more constant fashion (albeit usually at a relatively low constant power).

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