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

Contents

Page

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is entirely informative in nature and does not have to be reviewed until the data it provides are considered to be no longer valid or useful.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.