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

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

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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is entirely informative in nature and does not have to be reviewed until the data it provides are considered to be no longer valid or useful.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 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 report must be regarded as a "living document" and comments for improvement will therefore be welcomed.

The current Technical Report strongly parallels the AAMI TIR #18, which provides similar recommendations for wireless equipment in healthcare facilities.

Introduction

There is a growing need in healthcare facilities throughout the world to incorporate new technology to offer more efficient, cost-effective and higher quality healthcare. In that regard, wireless communication and computing technologies have the potential to 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.a/b/g local area networks and wireless modems for laptop computers, 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 use of personal mobile phones and other wireless devices within healthcare facilities increasingly indispensable, especially in times of crisis.

Currently, no uniform international guideline exists for the appropriate deployment, use, and management of mobile wireless communication and computing technology within healthcare facilities to mitigate potential electromagnetic interference (EMI) with sensitive medical devices. Although medical device manufacturers generally comply with recommended immunity guidelines (10 V/m for life-critical devices as outlined in the recently approved second edition of the IEC International Standard 60601-1-2), there is no consistent international regulation enforcing this recommendation. In addition, many mobile wireless transmitters exceed this field strength threshold when operating at their upper power limits and in close proximity. Finally, there are a number of older medical devices still in circulation that have not been designed with the above immunity considerations in mind.

Misinformation regarding mobile wireless systems, electromagnetic interference, and management procedures has led to a range of inconsistent policies among healthcare organizations. At one extreme, overly-restrictive policies may act as obstacles to beneficial technology as well as not address the growing personal communication needs of patients, visitors, and the workforce. At the other extreme, unmanaged use 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 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 that desire to fully implement comprehensive management procedures, while sufficient safeguards are offered to organizations where these same comprehensive management procedures cannot be, or otherwise have not been, fully implemented.

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 restricting use in sensitive areas where life-critical medical devices are in routine operation may be appropriate. Such restrictive policies might be facilitated by offering numerous and easily accessible alternative areas where the use of mobile wireless equipment is encouraged. For mobile wireless equipment that is provided to doctors and staff under more controlled conditions, operation throughout the healthcare facility (even in sensitive areas) 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.

Because most mobile wireless communication and computing systems can be effectively managed to mitigate EMI issues, the choice of technology for a controlled system should be based upon which solution best addresses the needs of the organization, not on what RF signal types may be inherently more or less prone to EMI under unmanaged conditions.

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

1 Scope

This International Standard provides guidance for the deployment, use and management of mobile wireless communication and computing equipment in the healthcare facility in a way that helps mitigate potential hazards due to electromagnetic interference (EMI) with medical devices. The recommendations 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 facility, as well as selective restrictions for healthcare organizations that have decided comprehensive management procedures are not feasible, practical, or desirable at the present time. The recommendations also distinguish between controlled systems used by doctors and staff for healthcare-specific communication and health informatics transport vs. non-controlled (personal) mobile wireless equipment randomly brought into the facility by visitors, patients, and 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
a relative ratio, one tenth of the common logarithm of the ratio of relative powers, equal to 0,1 B (bel)

NOTE The ratio in dB is given by $dB = 10\log_{10}(P_1/P_2)$.

2.1.3
decibel
dBm
decibels as above, but relative to a fixed 1 milliwatt of power

2.2 Abbreviated terms

AAMI	Association for the Advancement of Medical Instrumentation
AHA	American Hospital Association
AMA	American Medical Association
AMPS	Advanced Mobile Phone System
ANSI	American National Standards Institute
ASHE	American Society for Healthcare Engineering
CDMA	Code Division Multiple Access
CDRH	Center for Devices and Radiological Health, Department within FDA (United States)
CISPR	International Special Committee on Radio Interference
COMAR	IEEE Committee on Man and Radiation
DECT	Digitally Enhanced Cordless Telecommunications
ECG	Electrocardiogram
EEG	Electroencephalogram
EMC	Electromagnetic Compatibility
EMI	Electromagnetic Interference
ESD	Electrostatic Discharge
FDA	Food and Drug Administration (United States)
FOMA	Freedom of Mobile Multimedia Access
GPRS	General Packet Radio Service
GSM	Global System for Mobile
iDEN	Integrated Dispatch Enhanced Network
IEC	International Electrotechnical Commission
IEEE	Institute for Electrical and Electronics Engineers
ISM	Industry, Science and Medicine
ITU	International Telecommunication Union
IVDs	In Vitro Diagnostic Devices
JCAHO	Joint Commission on Accreditation of Healthcare Organizations
JTACS	Japanese Total Access Communications System
LAN	Local Area Network, including 802.11b and 802.11a systems
LMR	Land Mobile Radio
MHRA	Medicines and Healthcare Products Regulatory Agency (United Kingdom)
NADC	North American Digital Cellular
PAN	Personal Area Network, including 802.15.1 (Bluetooth), 802.15.4 (Zigbee), 802.15.3a, etc.
PDA	Personal Digital Assistant

PDC	Personal Digital Cellular
PCS	Personal Communications Services
R&TTE	Radio and Telecommunications Terminal Equipment
RF	Radiofrequency, classically defined as ranging from a few KHz – 300 GHz
Rx	Reception, received RF signal
TACS	Total Access Communications System
TDMA	Time Division Multiple Access
TIR	Technical informational Report
Tx	Transmission, transmitted RF signal
UMTS	Universal Mobile Telecommunications Systems
V/m	Volts per metre, a measure of RF electrical field strength
VoIP	Voice-over Internet Protocol
WAN	Wide Area Network
WAP	Wireless Application Protocol
WCDMA	Wide band Code Division Multiple Access
WiFi	Wireless Fidelity network system

3 Requirements

3.1 Mobile wireless equipment in healthcare facilities

The use of mobile wireless equipment by doctors and healthcare staff for improved healthcare communication and computing is becoming increasingly common. Visitors and patients are likewise finding the use of personal mobile phones and wireless devices within healthcare facilities increasingly indispensable, especially in times of crisis. Such wireless devices might include mobile phones, handheld computers / PDAs, WiFi / 802.11.a/b/g [1] local area networks and wireless modems for laptop computers, personal area networks including 802.15.1 (Bluetooth) [2] / 802.15.4 (Zigbee) [3] / 802.15.3a (UWB), two-way pagers, 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 Industry, Science, and Medicine (ISM) bands at 900 MHz and 2,4, 5,2, and 5,8 GHz as is the case with cordless phones and wireless data network equipment. From a radiofrequency (RF) signal perspective, mobile wireless transmitters can employ either simple analogue 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 802.11, 802.15, and most cordless phone-type systems that transmit constantly at relatively lower power ($\leqslant$ 10 milliwatts). 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 of more than 1 to 5 watts. The third category includes dynamically power-controlled equipment that can transmit at levels from a few milliwatts to 1 to 2 watts based upon the existing network signal strength at that particular location and time.

An immediate benefit to healthcare that improved mobile wireless communication and computing may provide is underscored by a U.S. Institute of Medicine (IOM) report estimating that common medical errors, many of which may be avoided with better communication and computing links, contribute to between 44 000 and 98 000 deaths per year in the United States [4]. A similar percentage was also suggested for the

United Kingdom and Australia. Other potential healthcare benefits that wireless technology might provide include immediate communication and access to patient information, test results, records and medical reference at the point-of-care, as well as reduction in cost charging errors, reduction in cost and maintenance of land-line phone systems, and ultimately facilitation of more home-based monitoring, recovery, and long-term care.

Concern over potential EMI with medical devices due to RF emissions, however, has prompted many healthcare organizations around the world to enact broad precautionary policies restricting wireless equipment throughout their facilities. Other 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 may expose patients to potentially significant and unnecessary hazards.

Table 1 — Geographical region of use, transmitted frequency and expected output power for common wireless technologies used in healthcare facilities

Type of device			Intended application	Transmitted frequency	Maximum transmit power
Wireless data network devices	W-LAN (Local Area Networks — WiFi)	802.11a	High Rate Local Area Network	5,15–5,8 GHz	40 mW [5,15–5,25 GHz] 200 mW [5,25–5,35 GHz] 800 mW [5,72–5,82 GHz]
		802.11b	Medium Rate Local Area Network	2,4-2,462 GHz (North America), 2,412-2,472 GHz (Europe), 2,471-2,497 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	2,4–2,48 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 Replacement	2,4-2,48 GHz (North America & Europe), 2,447-2,473 GHz (Spain), 2,448-2,482 GHz (France), 2,473-2,495 GHz (Japan)	Powerclass I: 100 mW Powerclass II: 2,5-10 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 / 80 2.15.4	Sensor Networks, Low-Latency Data/Control	2,4-2,48 GHz (North America & Europe), 2,412-2,472 GHz (Europe), 2,471-2,497 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)	2-11 GHz in unlicensed (e.g. 5,8 GHz) and licensed (e.g. 10,5, 25, 26, 31, 38 and 39 GHz) bands	
		802.16e (mobile)	Mobile (UNLICENSED & licensed) Broadband Wireless Access Systems (Video + simultaneous voice & data)	2-11 GHz in unlicensed (e.g. 5,8 GHz) and licensed (e.g. 10,5, 25, 26, 31, 38 and 39 GHz) bands	
		802.20	Mobile (LICENSED) Broadband Wireless Access Systems (Video + simultaneous voice & data)	licensed bands below 3,5 GHz	

Table 1 (*continued*)

Type of device			Intended application	Transmitted frequency	Maximum transmit power
Wired Network		*802.3*	*Hard Line Ethernet*	*(hard line)*	
Mobile Phones	1st Generation Technologies	Analogue	WAN Mobile Communication	AMPS 824-849 MHz (US), NMT 453-458 MHz (Europe), TACS 890-915 MHz (Europe), JTACS 832-925 MHz (Japan)	**AVG PWR**: 0,6-1 watt down to ~6 mW in steps of -4dB
	2nd Generation (Digital) Technologies	TDMA	WAN Mobile Communication	GSM 824-849 & 1850-1910 MHz (US), GSM 890-915 & 1710-1785 MHz (Europe, Asia), iDEN 806-824 MHz (US), Tetra 380-400, 410-430, 450-470 & 805-870 MHz (Europe), PDC 810-826 & 1429-1453 MHz (Japan)	**AVG PWR**: 200-600 mW down to 20-2 mW in steps of -1 to -4 dB
		CDMA	WAN Mobile Communication	CDMA 824-849 & 1850-1910 MHz (US), J-CDMA 832-925 MHz (Japan), K-PCS 1750-1870 MHz (Korea)	**AVG PWR**: 250 mW to ≂1 uW in 1dB steps
	3rd Generation (IMT-2000) Technologies	UMTS	WAN Mobile Communication	1,92-1,98 MHz (Europe,Asia), 1,7-2 GHz (US)	**AVG PWR**: 250 mW to ⩽ 1 mW in steps of 0,25-1 dB
		CDMA-2000	WAN Mobile Communication	824-849, 1850-1910 MHz & 1,7-2 GHz (US); 890-915 & 1750-1780 MHz & 1,92-1,98 GHz (Europe, Asia)	**AVG PWR**: 250 mW to ⩽ 1 mW in steps of 0,25-1 dB
2-way pagers			WAN Text Messaging	152-159, 454-460, 902-928 MHz	1 W (in short bursts)
Cordless Phones		Analogue and Spread Spectrum Technologies		Analogue 27, 40-49, 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**: constant 250 mW
		VoIP / 802.11b	LAN Mobile Communication	2,4-2,462 GHz	**AVG PWR**: constant 10 mW
Short Range Devices		FCC 15.231, FCC 15.249	Low-Power Radio Links	Periodic and continuous transmissions, 300-900, 2400, 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, 426-449 MHz	**AVG PWR**: 1 and 10 mW

3.2 The risk of patient harm due to EMI

The uncontrolled use of mobile wireless equipment by individuals visiting and working in healthcare facilities has steadily increased, regardless of existing healthcare organization policy. However, the level of risk for accidental EMI events from government and other non-profit health agency sources appears to be relatively small [5]-[7], although underreporting of such events may be substantial. Anecdotal observations of suspected EMI incidents with ECG and EEG machines, apnea monitors, ventilators and radiant warmers, infusion pumps, wheelchairs, and other devices have been reported or referred to in a number of publications [5]-[18]. Ad hoc test studies [19]-[30], [44] have confirmed that interference effects can be precipitated by certain wireless