TECHNICAL REPORT

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is entirely informative in nature and does not have to be reviewed until the data it provides are considered to be no longer valid or useful.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