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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

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is entirely informative in nature and does not have to be reviewed until the data it provides are considered to be no longer valid or useful.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