



Health informatics—PoC medical device communication

**Part 00101: Guide—
Guidelines for the use of RF wireless
technology**

IEEE Engineering in Medicine and Biology Society

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Part 00101: Guide— Guidelines for the use of RF wireless technology

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IEEE Engineering in Medicine and Biology Society

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Abstract: This guide addresses the use of radio frequency (RF) wireless technology for the transport of medical data both to and from point-of-care (PoC) medical devices. The context of such wireless medical data transport can range from home- or mobile-based healthcare to in-hospital ambulatory and stationary situations. This guide defines specific use cases to estimate, compare, and contrast performance of known technologies operating on wireless personal area networks (WPANs), wireless local area networks (WLANs), wireless metropolitan area networks (WMANs), and wireless wide area networks (WWAN). Major considerations are the quality of service (QoS) requirements associated with the data being transported, the expected performance of the wireless technology, and the specific needs and resources of the end user. Related issues include network architecture, electromagnetic interference and compatibility (EMI/EMC), coexistence with other data streams, security, cost, power consumption, and technology configurability.

Keywords: data transport, health informatics, information technology, IT, medical device, PoC, point-of-care, radio frequency, RF, shared network infrastructure, Wi-Fi, wireless fidelity, wireless local area network, wireless medical telemetry system, wireless metropolitan area network, wireless personal area network, wireless wide area network, WLAN, WMAN, WMTS, WPAN, WWAN

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Introduction

This introduction is not part of IEEE Std 11073-00101-2008, Health informatics—PoC medical device communication—Part 00101: Guide—Guidelines for the use of RF wireless technology.

In 2004, the IEEE 11073 Point of Care (PoC) Medical Device Communication Standards Committee developed a working group to focus on wireless medical data transport. The effort was intended to highlight and address issues and concerns specific to the convergence of healthcare and medical data being carried over a variety of new and emerging wireless systems. The effort was also aimed at encouraging the use of standardized wireless technologies to promote a plug-and-play (PnP) environment for manufacturers and allow end users more flexibility and less complexity. This guide serves as a foundation and reference matter for several follow-on standards intended to specifically profile different classes of wireless technology: wireless personal area networks (WPANs), wireless local area networks (WLANs), wireless metropolitan area networks (WMANs), and wireless wide area networks (WWANs).

Several annexes provide details about device recommendations, device use cases, and both wireless device and medical device technology. Overviews for typical IEEE 11073 PoC medical device data transport requirements are also provided as well as the expected capabilities of candidate wireless technologies. Common use cases simulate typical hospital scenarios. Each use case has been assigned various medical devices and associated physical and quality of service (QoS) requirements necessary for data transport. A summary evaluation of expected performance follows each use case and is meant to help the reader identify issues and provide guidance for the identification of reliable, practical, and appropriate wireless solutions for his/her specific application and environment.

This guide will be directly applicable to IEEE 11073 PoC medical devices and should be considered in any future implementations of wireless technology. Follow-on ISO/IEEE 11073 standardization projects are expected to profile specific off-the-shelf IEEE standardized radio frequency (RF) technologies with regard to their incorporation into medical equipment. It is anticipated that these standards would be applicable to PoC device interfaces in a way similar to the way the current IEEE 11073 transports are. Interoperability between different technologies operating on a common unlicensed frequency band and possibly using a common shared information technology (IT) network will also be addressed in these follow-on guidelines and will be greatly influenced by the complexity of the environment. As a result, transitioning from either the cable-connected or infrared (IR) wireless transports to an RF transport should be weighed carefully. This statement is especially true when adding more client devices to a network or deploying competing RF wireless networks.

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1. Overview

1.1 Scope

This guide provides guidance for using radio frequency (RF) wireless communication technologies for ISO/IEEE 11073 point-of-care (PoC) medical devices that exchange vital signs and other medical device information using shared information technology (IT) infrastructure. Use cases specific to these technologies are evaluated, and key functional and performance criteria are identified, including quality of service (QoS) management, privacy and security, coexistence with other RF wireless technologies, environmental requirements such as electromagnetic interference and compatibility (EMI/EMC), and power management. Guidelines are provided for each of these areas. Technologies include, but are not limited to, the IEEE 802.11™ and IEEE 802.15™ technologies. Use case environments include traditional clinical settings as well as personal (home and mobile) healthcare. The intent of guide is to be global with respect to wireless spectrum and equipment, although working group participation and expertise have favored detail of scenarios from the United States. Importantly, this guide will not be periodically updated, but instead will act as a source of information for follow-on ISO/IEEE 11073 RF wireless transport standards that will supersede it. These ISO/IEEE 11073 RF wireless transport standards will detail the use of specific wireless networked technology for the purpose of transporting medical data. Periodic updates will be performed on the ISO/IEEE 11073 standards only.

1.2 Purpose

In recent years, there has been rapid growth of RF technology to support wireless communication and data transport, as evidenced by the growing use of personal communication devices (e.g., mobile phones and Wi-Fi-enabled laptop computers). The incorporation of RF technology into PoC medical devices for wireless data transport has the potential to offer significant benefits to healthcare although there are many issues that need to be understood and managed in order to ensure data transfer to computer servers, healthcare professionals, terminal data collection units, or other medical devices is accurate, efficient, and reliable. Specific recommendations are aimed at different stakeholder groups that make up the audience for this guide including healthcare providers, medical device manufacturers/vendors, wireless equipment manufacturers/vendors, and relevant agency groups.

The different functionality and operating environment of medical devices is addressed, ranging from core hospital equipment providing complex waveform and other physiological data to single-parameter, low-data-rate sensors worn in a mobile health scenario. Further, patients, healthcare workers, medical equipment, and medical data move across different areas of the healthcare topology and necessitate that data track in a seamless and managed manner. QoS requirements (e.g., priority, throughput, and latency) can vary significantly across different medical data types (e.g., alarms, real-time wave forms, chart data, asset tracking, and e-prescriptions), and simultaneous transport of different data types on a shared IT infrastructure is considered for the design of appropriate solutions. Other issues associated with operation on standardized “open” networks are security and privacy. Coexistence becomes a significant issue as a growing number of medical devices from multiple manufacturers, perhaps using multiple technologies (e.g., IEEE Std 802.15.1™-2005¹ with IEEE 802.11b technology), start to crowd the RF spectrum and compete for bandwidth and channel access. Other issues considered include EMI/EMC, cost, power consumption, and technology configurability. Several factors influence the performance of the wireless system itself, including whether it operates on a shared IT network (e.g., WLAN and WWAN) or simply maintains a point-to-point connection. The former example is especially important when considering the operation of multiple medical devices from different manufacturers, each with different QoS requirements. An overall effort to promote plug-and-play (PnP) operability between commercially available medical devices and wireless systems (i.e., IEEE, ISO, ANSI, ITU-R, and ITU-T) is supported in this guide as well as in follow-on ISO/IEEE 11073 specialization standards. As private homes are increasingly outfitted with wireless networks and as home and mobile management of healthcare and chronic conditions becomes increasingly common, additional issues may emerge.

Recommendations provided in this guide are not prescriptive, but instead offer general guidance aimed at the different stakeholders to facilitate design and management of wireless medical data transport to support the necessary QoS and performance requirements as well as to coexist in a complex environment with other wireless traffic. Likewise, exercises and comparisons included in this guide are not intended to endorse any particular medical device, wireless technology, or data exchange format, but to offer examples for reference and comparison. Ultimate solutions will vary and depend greatly on healthcare needs, resources, sizes, and environments.

1.3 Standards compatibility

This guide is one part of the ISO/IEEE 11073 family of standards and is a companion standard to existing, ongoing, and anticipated ISO/IEEE 11073 specialization standards and wireless profiles including those listed in Annex F.

¹ Information on references can be found in Clause 2.

1.4 Audience

The intended audience (stakeholders) includes the following:

- Healthcare providers (including administrators, IT engineers, clinical engineers) as they look to develop and/or augment existing medical device inventories with devices that will provide increasing services as well as be supported by, and compatible with, existing RF wireless system(s).
- Medical device manufacturers and vendors as they look for guidance in the development of new, robust and cost-effective products that will operate on available RF wireless system infrastructures.
- RF wireless equipment manufacturers and vendors as they look for guidance that will allow them to deploy wireless systems in healthcare facilities that can support the technical requirements of single medical devices, but scale sufficiently to provide adequate QoS under typical use case conditions.
- Government agencies as they look for information and guidance on the issues surrounding the use of RF wireless technology for PoC medical devices.

2. Normative references

The following referenced documents are indispensable for the application of this guide. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments or corrigenda) applies. Other references that are supportive, but not indispensable, are located in the bibliography (Annex G).

IEEE Std 802[®]-2001, IEEE Standard for local and metropolitan area networks: Overview and architecture.^{2, 3}

IEEE Std 802.1X[™]-2004, IEEE Standard for local and metropolitan area networks: Port-based network access control.⁴

IEEE Std 802.3[™]-2005, IEEE Standard for information technology—Telecommunications and information exchange between systems—Local and metropolitan area networks—Specific requirements—Part 3: Carrier sense multiple access with collision detection (CSMA/CD) access method and physical layer specifications.

IEEE Std 802.11[™]-2007, IEEE Standard for information technology—Telecommunications and information exchange between systems—Local and metropolitan area networks—Specific requirements—Part 11: Wireless LAN medium access control (MAC) and physical layer (PHY) specifications.

NOTE—The authors of this guide acknowledge that certain IEEE 802.11 amendments have been rolled into a new base standard dated 2007, but various amendment designations, e.g., IEEE 802.11b, are still used in this guide to distinguish between the IEEE 802.11 technologies.⁵

IEEE Std 802.11r[™]-2008, IEEE Standard for information technology—Telecommunications and information exchange between systems—Local and metropolitan area networks—Specific requirements—Part 11: Wireless LAN medium access control (MAC) and physical layer (PHY) specifications—Amendment2: Fast BSS-Transition.

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IEEE Std 802.15.1™-2005, IEEE Standard for information technology—Telecommunications and information exchange between systems—Local and metropolitan area networks—Specific requirements—Part 15.1: Wireless medium access control (MAC) and physical layer (PHY) specifications for wireless personal area networks (WPANs).

IEEE Std 802.15.3™-2003, IEEE Standard for information technology—Telecommunications and information exchange between systems—Local and metropolitan area networks—Specific requirements—Part 15.3: Wireless medium access control (MAC) and physical layer (PHY) specifications for high-rate wireless personal area networks (HR-WPANs).

IEEE Std 802.15.4™-2006, IEEE Standard for information technology—Telecommunications and information exchange between systems—Local and metropolitan area networks—Specific requirements—Part 15.4: Wireless medium access control (MAC) and physical layer (PHY) specifications for low-rate wireless personal area networks (LR-WPANs).

IEEE Std 802.16™-2004, IEEE Standard for information technology—Telecommunications and information exchange between systems—Local and metropolitan area networks—Part 16: Air interface for fixed broadband wireless access systems.

IEEE Std 802.16e™-2005, IEEE Standard for information technology—Telecommunications and information exchange between systems—Local and metropolitan area networks—Part 16: Air interface for fixed and mobile broadband wireless access systems—Amendment 2: Physical and medium access control layers for combined fixed and mobile operation in licensed bands and Corrigendum 1.

ISO/TR 21730:2007 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.⁶

3. Definitions, acronyms, and abbreviations

3.1 Definitions

For the purposes of this guide, the following terms and definitions apply. *The Authoritative Dictionary of IEEE Standards Terms* [B5]⁷ should be referenced for terms not defined in this clause.

3.1.1 backhaul: Usually refers to a wired (IEEE 802.3™ Ethernet) system that connects directly to a terminal server site. Backhaul may also refer to internodal radio frequency (RF) links in a mesh network.

3.1.2 decibel/milliwatt (dBm): Decibels relative to 1 mW, defined by $10\log_{10}(\text{Power}/1 \text{ mW})$.

3.1.3 event time: Time that the event is first made available at the event source; time for an event to be detected and recorded/confirmed by a medical device.

3.1.4 fronthaul: Usually refers to the wireless network, in this context, the wireless transmission of point-of-contact (PoC) medical data until it reaches its terminal receiver or accesses the wired backhaul system.

3.1.5 logged time: Time that the event is made known to the healthcare professional monitoring the patient; time taken for an event recorded by a medical device to be passed to a monitor, alarm, or other visual or audible indicator.

⁶ ISO publications are available from the ISO Central Secretariat, Case Postale 56, 1 rue de Varembe, CH-1211, Genève 20, Switzerland/Suisse (<http://www.iso.ch/>). ISO publications are also available in the United States from the Sales Department, American National Standards Institute, 25 West 43rd Street, 4th Floor, New York, NY 10036, USA (<http://www.ansi.org/>).

⁷ The numbers in brackets correspond to the numbers in the bibliography in Annex G.

3.1.6 medical device: A device, apparatus, or system that is used for monitoring, treatment, or therapy and that does not normally enter metabolic pathways. For the purposes of this guide, the scope of medical devices is further limited to patient-connected medical devices that provide support for electronic communications. This narrow definition is not intended to exclude or contradict broader definitions for medical devices that may exist.

3.1.7 plug-and-play (PnP): The ability of commercial off-the-shelf medical devices and wireless electronic equipment to interface and communicate with each other without the need for custom modifications or software.

3.1.8 quality of service (QoS): Necessary parameters associated with the support of medical data transfer across a wireless (or wired) infrastructure system. QoS requirements depend largely on the nature (i.e., waveform versus simple text) and criticality of the data being transported and can generally be classified as reliability, latency, priority, and bandwidth requirements.

3.1.9 real time: The difference between event time and logged time. For some medical applications, near instantaneous real-time response is required, for example, an asystole alarm that should be detected by software algorithms with an alarm generated and reaching a nurse station within 10 s end to end. In contrast, many other parameters, such as blood glucose levels or prescription medicine compliance, may be monitored in real time with acceptable delays of many minutes or even hours as long as accurate timestamps are kept. *See also:* **event time**; **logged time**.

3.1.10 service-level agreement (SLA): A contract between a network service provider and a customer that specifies the services the network service provider will furnish.

3.1.11 standard technologies: Wireless technologies operating in either licensed or nonlicensed frequency bands where clear rules of operation exist and where the protocol has been defined and made available to developers through one of many technical standards, such as the standards developed by the IEEE 802® group (e.g., IEEE Std 802.11-2007, IEEE Std 802.15, and IEEE Std 802.16-2004) or telecomm standards (e.g., GSM, CDMA, and iDEN).

3.1.12 Wi-Fi Alliance®: A consortium of relevant industry representatives developing guidelines to ensure commercial products interoperate while implementing IEEE 802.11 standards.

3.1.13 WiMax Forum™: A consortium of relevant industry representatives developing guidelines to ensure commercial products conform to basic IEEE 802.16™ standards as well as operational/performance expectations.

3.1.14 wireless device: A device designed to communicate by sending and/or receiving voice and/or data information to another wireless device by the transmission of RF energy. Such devices can operate using any one of a variety of standardized or nonstandardized (proprietary) technologies, on a variety of different frequency bands, and at different transmit power levels.

3.1.15 wireless medical device: A medical device that has been enabled to communicate its raw data wirelessly across one of several available wireless personal area networks, local area networks, metropolitan area networks, wide area networks, or proprietary systems. *See also:* **medical device**.

3.1.16 wireless medical telemetry service (WMTS): A series of frequency bands at 600 MHz, 1.4 GHz, and 1.43 GHz allocated for co-primary use by the Federal Communications Commission (FCC) for the operation of medical telemetry equipment and shared with radio astronomy and the US government radar systems.

3.1.17 wireless service model: A model that considers the relationship between a given radio frequency (RF) wireless technology and other standard (wireless and wired) service and protocol elements that would also be required to support end-to-end communication between a medical device sending data and a computer server, healthcare professional, or other element receiving (and possibly responding to) the data.

3.2 Acronyms and abbreviations

2G	second generation
3G	third generation
ACL	access control list
AES	Advanced Encryption Standard
AM	amplitude modulation (amplitude modulated)
AP	access point
BER	bit error rate
BIS™	Biofeedback Incentive System™
BP	blood pressure
BSS	basic service set
Cath	cardiac catheterization laboratory
CCMP	CTR [counter mode] with CBC-MAC [cipher block chaining message authentication code] Protocol
CCX	Cisco compatibility extensions
CDMA	code division multiple access (mobile phone technology)
CIS	clinical information systems
CRF	chronic renal failure
DCCP	Datagram Congestion Control Protocol
DFS	dynamic frequency selection
DOS	denial of service
DSL	digital subscriber line
DSSS	direct sequence spread spectrum
EAP	Extensible Authentication Protocol
ECG	electrocardiogram
EDCA	enhanced distributed channel access
EEG	electroencephalogram
EKG	electrocardiogram
EMC	electromagnetic compatibility
EMI	electromagnetic interference
ER	emergency room
ESD	electrostatic discharge
ETCO ₂	end tidal carbon dioxide
FEC	forward error correction
FHSS	frequency hopped spread spectrum
FM	frequency modulation (frequency modulated)
GSM	global system for mobile (mobile phone technology)
HDTV	high definition (digital) television
HID	human interface device
HIPAA	Health Insurance Portability and Accountability Act
HIS	hospital information systems
HL7	Health Level Seven™
HR	heart rate
ICU	intensive care unit
iDEN	integrated digital enhanced network (mobile phone technology)
IP	Internet Protocol
IR	infrared
ISM	industrial, scientific, medical
IT	information technology

ITU-R	ITU Radiocommunication Sector
ITU-T	ITU Telecommunication Standardization Sector
IV	intravenous
IVDs	in vitro diagnostic devices
ld	lead
LED	light emitting-diode
LMR	land mobile radio
LOS	line of sight
MAC	medium access control
MDAP	medical device application profiles
MDDL	Market Data Definition Language
MIB	management information base
MIC	message integrity code
MICS	medical implant communications service
MIMO	multiple-input multiple-output
MPEG	moving picture experts group (a working group within ISO)
MRI	magnetic resonance imaging
NIBP	noninvasive blood pressure
ObGyn	obstetrics and gynecology
OR	operating room
ORI	observation reporting interface
OSI	open systems interconnection
PAR	project authorization request
PCM	pulse code modulation
PCS	personal communications service
PDA	personal digital assistant
PDS	parameter data service
PHY	physical layer
PIN	personal identification number
PLMRS	private land mobile radio service
PnP	plug-and-play
PoC	point of care
PoCT	point-of-care testing
PSK	phase-shift keying or preshared key
Pt	patient
PWD	patient-worn device
QoS	quality of service
RF	radio frequency
RFID	radio frequency identification
Rx	reception, received radio frequency (RF) signal
SCO	synch connection oriented
SCTP	Stream Control Transmission Protocol
SDTV	standard-definition television
SLA	service-level agreement
SNR	signal-to-noise ratio
SNR+	signal-and-noise-to-noise ratio
SpO ₂	blood oxygen saturation (arterial O ₂ using pulse oximetry)
TCP	Transmission Control Protocol
TISL	transport-independent sublayer
TKIP	Temporal Key Integrity Protocol
TPC	transmit power control, power-controlled transmission
TSPEC	traffic specification
Tx	transmission, transmitted radio frequency (RF) signal
UC	use case
UDP	User Datagram Protocol
UMTS	universal mobile telecommunications system

URL	uniform resource locator
UHF	ultra-high frequency
UWB	ultra-wideband
VHF	very high frequency
VoIP	Voice-Over Internet Protocol
Wi-Fi	wireless network system based upon IEEE 802.11 standards and industry performance specifications
VLAN	virtual local area network
VSF	vestigial side band (television)
WEP	wireless equivalent privacy
WLAN	wireless local area network
WMAN	wireless metropolitan area network
WPA	Wi-Fi protected access
WPA2	Wi-Fi protected access, version 2
WPAN	wireless personal area network
WWAN	wireless wide area network
WMTS	wireless medical telemetry service

4. Summary goals and recommendations

4.1 Goals

The following are goals of this guide:

- Facilitate better understanding among all stakeholders with regard to wireless technologies and systems that might be used for PoC medical device data transport, including the following:
 - Available and emerging wireless technologies
 - Capabilities and limitations
 - Different system configurations and conformance specifications/options
 - Potential medical device applications
 - Benefits and drawbacks
 - Costs
- Facilitate communication and coordination among relevant stakeholders, both internally within each stakeholder group and externally between different stakeholder groups, as follows:
 - From the perspective of the healthcare enterprise: What wireless applications would be most beneficial and increase the quality of care and/or decrease healthcare costs?
 - From the perspective of the medical device manufacturer: What available standardized wireless options can be incorporated into their specific medical device(s) that will satisfy the necessary data throughput, link range, and QoS requirements for PoC data transport?
 - From the perspective of the wireless equipment manufacturer: What standardized wireless system technologies lend themselves or can be securely configured to accommodate the data traffic and individual technical requirement needs associated with multiple divergent wireless medical devices?
 - From the perspective of the government regulatory and accreditation body: What common elements might be identified and endorsed for conformance that will facilitate compatible, reliable, and beneficial use of wireless technology for PoC medical data transport within the healthcare system?

- Offer several generic models of typical healthcare use cases and perform numerical modeling exercises to evaluate and compare how various standardized wireless technologies and systems might satisfy the given use case technical/QoS requirements.
- Act as an information guide for the various stakeholder groups as they develop their respective business cases and forecasts for introduction of wireless technology in PoC medical device data transport.
- Drive the replacement of existing proprietary RF technologies with standardized technologies to facilitate interoperability, PnP, and consistent data throughput and QoS capabilities.

4.2 Recommendations

General and specific recommendations for each stakeholder group are listed in Annex A. Stakeholder groups are defined as follows:

- Healthcare enterprises (including clinicians, clinical engineers, IT engineers, spectrum coordinator, administrators) as they look to acquire and/or augment existing medical device inventories with devices that provide increasing services as well as that are supported by/compatible with existing RF wireless system(s).
- Medical device manufacturers and vendors as they look for guidance in the development of robust and cost-effective products that operate on available RF wireless system infrastructures (PnP).
- RF wireless equipment manufacturers and vendors as they look for guidance that will allow them to manufacture and deploy wireless systems in healthcare facilities that support the technical requirements of wirelessly enabled medical devices. Further, the wireless systems should scale sufficiently to provide adequate QoS under typical use case conditions.
- Government agencies and health organizations as they look for information and documentation to support their recommendations and policies regarding the use of RF wireless technology for wirelessly enabled PoC medical devices.

5. Benefits and potential risks associated with wireless data transport

Clearly, there are benefits to wireless medical data transport. From the perspective of the hospital, wireless technology has the potential to reduce the need for conventional cords and cable tethers and to transform typically entangled patient areas into less cluttered spaces. Wireless links may also provide freedom with regard to where medical devices can be positioned within patient care areas as well as the physical exchange of medical devices between different areas of the hospital and reestablishment of appropriate patient connections.

From the perspective of the hospital patient, wireless networks deployed throughout the facility allow vital patient data to be made available seamlessly during transport between different areas as well as to the overseeing healthcare professional(s) without the need for them to physically be at the bedside. For ambulatory patients, wireless may facilitate more free movement throughout the facility during the hospital stay as well as earlier release and transition to a home- or mobile-health monitoring situation. For home- or mobile-health patients where chronic disease management is necessary, wireless monitoring can extend many normal freedoms while maintaining regular and frequent supervision of physiologic parameters as well as a direct link to healthcare professionals if issues are detected or predetermined parameter thresholds are exceeded.

From the perspective of the (often mobile) healthcare staff, real-time monitoring and data access of the entire patient registry, including predetermined alert and alarm notifications, can reduce the need for individual patient interaction to obtain critical information. Such technology would also allow more rapid

and mobile access to patient data when needed. Wireless data transport may also facilitate more comprehensive real-time data collection as well as make data available for evaluation by vigilant server-based software algorithms that can monitor patient progress within predefined parameters

For the elderly, recovering, or chronically ill patient based at home, wireless systems operating on a home infrastructure can allow a degree of mobility while maintaining real-time monitoring of parameters or alerting healthcare professionals of adverse conditions before they become life threatening. Similarly, mobile monitoring of chronic disease states or health issues can allow real-time monitoring of a limited set of parameters as well as send alert or reminder information to provide an additional level of freedom for mobile patients.

While wireless systems can clearly increase flexibility and mobility, they also introduce issues that are not normally experienced with IEEE 802.3 Ethernet (wired) links. Depending upon the wireless technology used, data throughput can be markedly restricted. In the extreme, a short-range link carried by IEEE 802.15.4 technology will only support 250 kb/s. With this technology, only low to moderate amounts of data (binary or text) can reasonably be sent to a handheld or other portable device. At the other extreme, IEEE 802.16 may support 75 Mb/s or more, allowing bidirectional sending of graphical applications such as pictures or video. The physical parameters of various wireless technologies are described in more detail in Clause 8. Issues of security, coexistence, and interoperability are also described in more detail in Clause 11, Clause 13, and Clause 0, respectively.

One notable issue is scalability. As a single network system (e.g., an IEEE 802.11b system) is tasked with supporting an increasing number of patients or medical device types, the ability to support QoS can be quickly reduced.

General classes of IEEE standardized wireless technologies that offer options for medical data transport are described in Annex D. Additional technologies as well as variations of the technologies listed may exist, and the current guide is not to be viewed as comprehensive. The follow-on projects (tentative) as listed in Annex F will profile individual technologies with regard to specific medical applications and QoS requirements.

General benefits of incorporating wireless technology include the following:

- Ease of equipment placement (reducing wire and cable “nests”)
- Options for real-time monitoring of ambulatory patients (mobile patients)
- Information easily accessed from anywhere within the coverage area (mobile staff)
- Information can be pushed immediately to clinician (e.g., lab results and alarms/alerts)
- Significantly reduce audio alarm clutter
- Offers on- and off-campus alternatives to wired telephony and paging systems

General drawbacks associated with wireless technology include the following:

- Traditional QoS requirements associated with wired networks may not be fully supported.
- QoS parameters such as throughput and latency may experience significant fluctuations due to coverage, traffic, and other emitters in the environment.
- Cost may limit implementation of multiple/optimal technologies.
- Appropriate prioritization protocols are not always available, and overuse can quickly tax capacity and reduce compliance with QoS requirements.

6. Defining and regulating wireless medical devices

As medical devices increasingly become wirelessly enabled to transport data across a variety of wireless links, the definition of what actually constitutes a “medical device” becomes somewhat ambiguous. Under traditional definitions obtained from the websites of the US-FDA⁸ and UK-MHRA⁹, medical devices are generally defined as products placed on market by a manufacturer for patient health and/or safety that undergo regulatory approval (i.e., CE mark in the European Union and FDA approval in the United States). This might range from “... simple tongue depressors and bedpans to complex programmable pacemakers with micro-chip technology and laser surgical devices ... in vitro diagnostic products ... certain electronic radiation emitting products with medical application [e.g., diagnostic ultrasound, x-ray, medical lasers] ...”¹⁰ Further, under section 201(h) of the US Federal Food, Drug, and Cosmetic Act, if a product is “... recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them, intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of it’s [sic] primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes,” then it is subject to premarketing and post-marketing FDA regulatory controls as a medical device. This Act was primarily written to provide a distinction between medical devices (regulated by FDA’s Center for Devices and Radiological Health) and drugs (regulated by FDA’s Center for Drug Evaluation and Research); and while it does detail the primary characteristics of what is generally considered a medical device, it does not specifically address data transport through either wireless or wired systems. In summary, the issue of wireless (or wired) data transmission is not specifically addressed by current regulatory guidelines.

In the broadest sense, a wirelessly enabled “medical device” might include the medical device itself, the host (e.g., data collection unit, server, or nurse station) as well as the link between the two (e.g., IEEE 802.11, IEEE 802.15, IEEE 802.16, telecomm network, or IEEE 802.3 technology). This broader description of a medical device (including the path of medical data transport) can be subdivided into four main stages as depicted in Figure 1. Stage 1 involves the traditional function of the medical device, and the downstream stages (Stage 2, Stage 3, Stage 4) represent data transport across wireless and wired systems to end server for evaluation. While it may not be possible within the scope of this guide to finalize a comprehensive and consensus definition that applies to all medical devices, the identification and independent characterization of distinct stages, including the regulation and standards rules that currently apply, may offer some clarification for future assessment and regulation.

Stage 1 includes the device units themselves under existing (traditional) definitions and is, therefore, relatively easy to see as remaining under the purview of the FDA as a traditional “medical device.” Many medical devices have already received regulatory approval as wirelessly enabled variations of predicate devices and employ proprietary (e.g., MICS and WMTS) or standardized (e.g., WPAN and WLAN) technologies. The boundaries between Stage 1 and Stage 2 are relatively clear, with data at the boundary being relayed either directly to various wireless network systems or by a short-range (IEEE 802.15-type) link to a gateway device via a common data exchange protocol. As data move through Stage 2, however, issues associated with the definition (and subsequent regulation) of a medical device become more unclear. Present standardized wireless technologies and protocols have not been designed for transport of medical information and the support of corresponding QoS requirements that this transport would entail and are not marketed specifically for healthcare. Such systems might not be considered a medical device when operating under typical conditions and, if employed to transport medical data, may have part or even a majority of their resources dedicated to nonmedical traffic. Stage 2 is currently defined by numerous nonmedical industry standards (e.g., IEEE, telecomm, and computer) and nonmedical industry consortium agreements (e.g., Wi-Fi Alliance, WiMax Forum, ANSI, CTIA, ITU, and TIA) for operation in defined frequency bands, conformance to transmission and data exchange protocols, and interoperability. Regulation of the technology in the United States currently falls under the exclusive scope of the FCC. It is

⁸ See <http://www.fda.gov/cdrh/devadvice/312.html>.

⁹ See <http://www.mhra.gov.uk/>.

¹⁰ See FDA Device Advice [B4].

possible to make theoretical arguments both for and against the inclusion of Stage 2 as part of a wireless medical device, although much less freedom exists in practice within that stage for any active regulation in that regard. Such medical device regulation within Stage 2 would be further complicated in practice as data paths could include complex and variable combinations of wireless personal area network (WPAN), wireless local area network (WLAN), wireless metropolitan area network (WMAN), and wireless wide area network (WWAN) technologies as well as RF communication equipment and telephone land lines. Data storage in Stage 3 shares some characteristics with Stage 2 in that it is currently defined by numerous nonmedical standards (e.g., EIA, DISA, NIST, ANSI, and 21 CFR Part 11). However, in contrast to Stage 2, the boundaries of this stage are not as clear and could merge with data evaluation (Stage 4), especially as software algorithms are applied to evaluate patient data and send notifications to patients reminding them to comply with prescriptions or health schedules as well as to healthcare professionals when measured data values exceed predefined thresholds.

7. Medical device use cases

7.1 General

The use cases presented here offer realistic scenarios that allow the reader to more visually navigate through all relevant issues involving the application of wireless technology for medical data transport. Such exercises are useful to convey understanding and support the guidance recommendations presented and will further highlight that QoS from the medical data side is only one of several key performance metrics on which any successful technology solution should be based.

7.2 Use case overview

Separate use cases (UCs) have been developed (Figure 2) representing a broad range of typical healthcare scenarios ranging in degree of criticality as well as potential wireless complexity:

- Personal (home/mobile) monitoring
 - Home health monitoring of an individual cardiac patient (UC1a)
 - Mobile health monitoring of an individual diabetic patient (UC1b)
 - Wellness monitoring of an individual elderly patient in home (UC1c)
 - Wellness monitoring of a congestive heart failure patient in home (UC1d)
- Subacute cases involving telemetry and basic vital sign monitoring beginning with an individual patient localized to a room (UC2)
- Increasing in complexity with additional ambulatory patients (UC3, UC4)
- Cardiac patient moving through three areas (UC5)
- Critical burn patient tracked from medevac to the emergency room (ER), to intensive care unit (ICU), and through recovery (six areas in the hospital) (UC6)
- Rescue and medevac (UC7)
- Ancillary (e.g., dialysis, echo lab, electrocardiogram (ECG) and cardiology, cardiac catheterization lab, and stress lab) (UC8)
- Maternity and obstetrics and gynecology (ObGyn) (UC9)
- Other

Key PoC medical devices involved in these use cases have been identified, and QoS criteria for data transport from these PoC devices have been assigned. The development of use cases and associated QoS criteria has leveraged information developed in related ISO/IEEE 11073 guidance or follow-on standards. The QoS criteria have been used to evaluate and compare the performance of various wireless technologies under defined conditions through simple modeling exercises. Figure 2 provides a graphical overview of the use case topology, while Annex B summaries of the use cases and their respective QoS criteria. Additional detailed use case descriptions are given in Annex C.

7.3 Use case topologies

As patients, data, medical devices, and/or clinicians move across several of the Figure 2 use-case boxes in the course of a given event, seamless transitions are necessary. If wireless technology is to be implemented to carry PoC medical device data, these data should follow in a seamless manner. The overall topology of Figure 2 can be categorized from five different perspectives:

- a) Patients moving through the topology: The main cycle (from right to left in Figure 2) involves patients who are monitored at home through a healthcare service and experience a medical crisis necessitating emergency transport and emergency care. This stage is followed by peri-operative and step-down care and a return home with an updated home monitoring regimen. Two main treatment scenarios are considered in detail. The first involves home monitoring, catheterization lab, and open-heart surgery (coronary artery bypass graft); and the other involves emergency care related to burn trauma. From home (UC1), the former scenario cycles from the left (UC2 through UC5) and back (UC4 through UC2) and then returns home (UC1). The latter scenario moves from right to left (UC 7 through UC2). Related descriptions can be found in a companion document, ISO 11073-60101/IEEE P11073-60101.^{11, 12}
- b) Movement of the PoC: The PoC, in many cases, is the individual patient. So far, the assumption has been that the patient is sequentially moved between various care units while moving through the healthcare process. From a general viewpoint, this assumption is accurate although from the perspective of an individual patient, it is far from the truth. The individual patient may frequently move between the care unit and ancillary units such as radiology, respiratory therapy, rehabilitation, as described in UC8. Indeed, with this viewpoint, the hallways, stairs, and elevators can also become a PoC. The patient, during the latter part of a stay in a health facility, may be ambulatory with privileges to walk throughout the facility and grounds. Currently, the patient may be equipped with a range of ambulatory devices to take along during transport or ambulation. Included are cardiac telemetry, fetal telemetry, intravenous (IV) pumps, vital signs monitors, defibrillators, respiratory monitors, and gastric motility monitors. With further miniaturization, it is possible a wider range of monitoring and therapeutic devices may accompany the patient at all times and will reinforce the concept of a mobile PoC.
- c) Medical devices moving through the topology: This perspective is the same route as the patient and primarily involves transport between care contexts, but also ambulation in cardiac step-down (i.e., “Med/Surg”). The home context may be somewhat different for medical devices and is not specifically considered in this guide.
- d) Clinicians moving through the topology: Healthcare staff members are very mobile, and information needs to be routed to the appropriate staff at the appropriate time, sometimes urgently. In general, clinician workflow generally gravitates to the general PoC area, which may be quite large, although the clinician may also monitor the mobile patient “remotely” from an office or home. Clinicians and nurses generally care for multiple patients concurrently and work in teams. For example, nurses may move among patients in cardiac care units and monitor each patient’s medical state in real time from multiple monitoring stations. Multiple clinicians may converge on a PoC during a crisis, bring equipment with them as necessary, perform intervention, and then disperse to their regular workflow.

¹¹ ISO 11073-60101/IEEE P11073-60101, Application gateway—HL7 Observation reporting interface (ORI).

¹² Numbers preceded by P are IEEE authorized standards projects that were not approved by the IEEE-SA Standards Board at the time this publication went to press. For information about obtaining drafts, contact the IEEE.

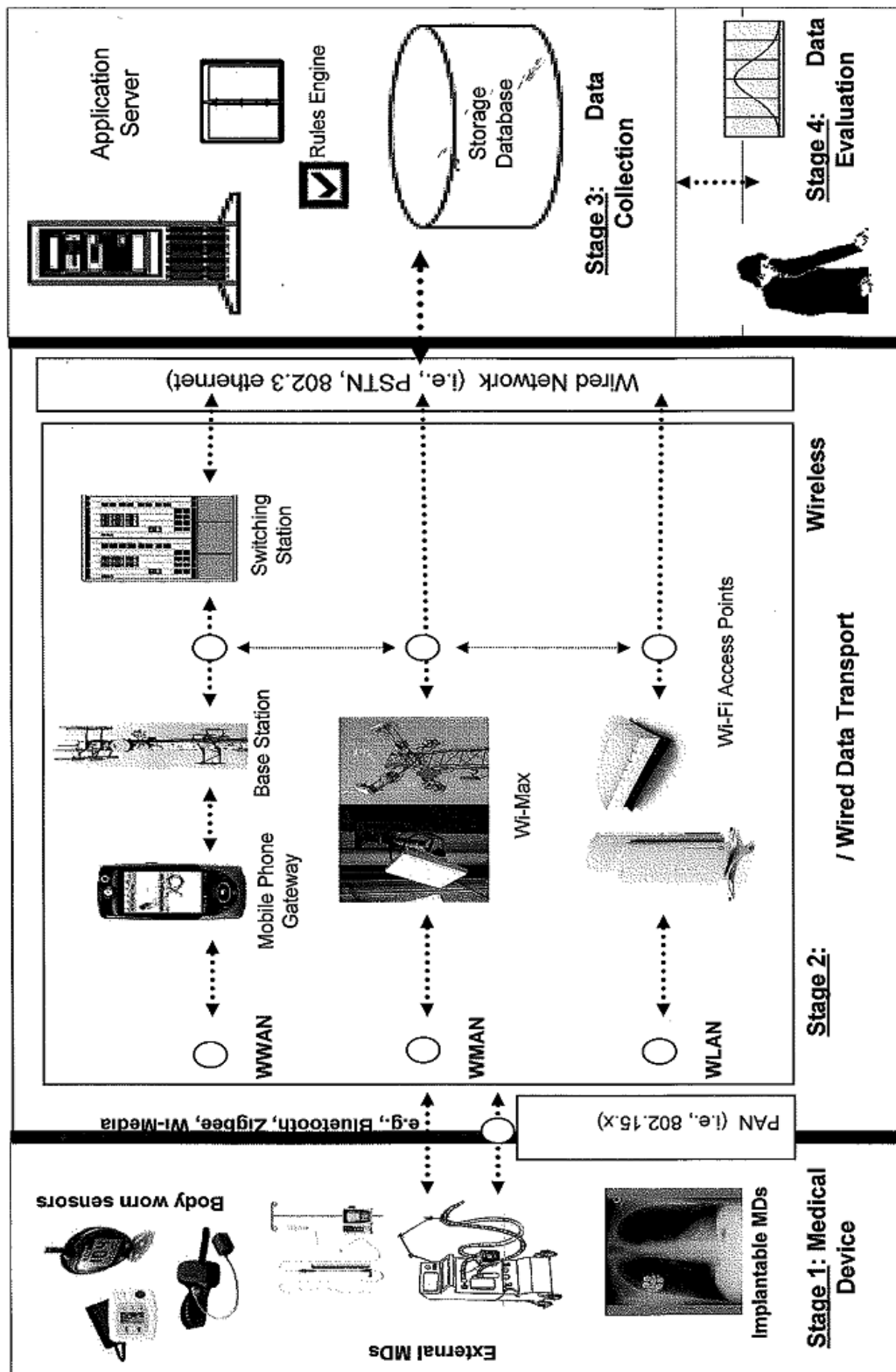
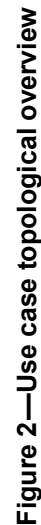


Figure 1—Stages of wireless medical devices



- e) Data moving through the topology: While data are principally thought of as involving patient monitoring information, they can also refer to the use of wireless technology for remote command and control of therapeutic devices. The primary data flow is from the patient through the medical device to a monitoring display. However, data may be transported via a wireless bridge or gateway to other areas such as a nurse's central monitoring station, pager, or personal digital assistant (PDA), and/or a patient's data management system. Data such as settings or controls may also be sent from a remote location to the medical device. Further, one patient's data may be sent to another patient's monitor in situations where a nurse may tend to several patients concurrently and need to follow patient #1 while tending to patient #2 or where a patient's own data may be sent to that patient's room monitor while the patient is ambulating. Patient data should be available on any mobile device that clinicians use, wherever they may be.

7.4 Use case summary and wireless performance evaluation

Short summaries of typical use cases ranging from in home, mobile, and in-hospital settings are described in Annex B, and detailed descriptions are listed in Annex C. These summaries identify the major PoC medical devices where wireless data transport is anticipated and provide tables summarizing the requirements for physical transport, reliability, security, usability, supportability, compatibility/coexistence, standards compliance, and operating environment. At the end of each use case is a summary evaluation of how various classes of wireless technology (i.e., WPAN, WLAN, WMAN, WWAN) might be expected to operate and whether they might afford an appropriate wireless solution. Annex C walks through several of these use cases in more detail (Table C.1 through Table C.17). Annex D provides a review of the different industry standard and IEEE 802 technologies.

8. Wireless technologies

8.1 General

Wireless technologies can be generally categorized in terms of their performance, including link range and data rate, which are related to their transmit power and described in more detail in Clause 10. A simple overview chart is provided in Figure 3 and described in more detail in 8.5. Importantly, link range and data rate can depend upon many additional variables; the figure is intended only as a very general chart to compare different classes of technology. More specific details on data rate and link range are available in Annex D describing wireless technology.

The lower bubbles represent different low transmit power, low link-range WPAN technologies. The WLAN, WMAN, and WWAN technologies increase in link range with a corresponding increase in transmit power. Data rate can be dependent upon transmit power as well as signal technology and occupied bandwidth. The open systems interconnection (OSI) reference model describes a general format for how wireless technologies transmit messages between two points in a telecommunication network allowing them to interoperate. This guide does not go into detail with regard to how different wireless technologies satisfy each of the seven layers in this model, but instead describes general functions associated with the lower and upper layers. The application (top) layer will often be device specific. The receiving device application software interacts with and needs to recognize (i.e., discover services associated with) the application and protocol format of the sending device for proper communication to occur.

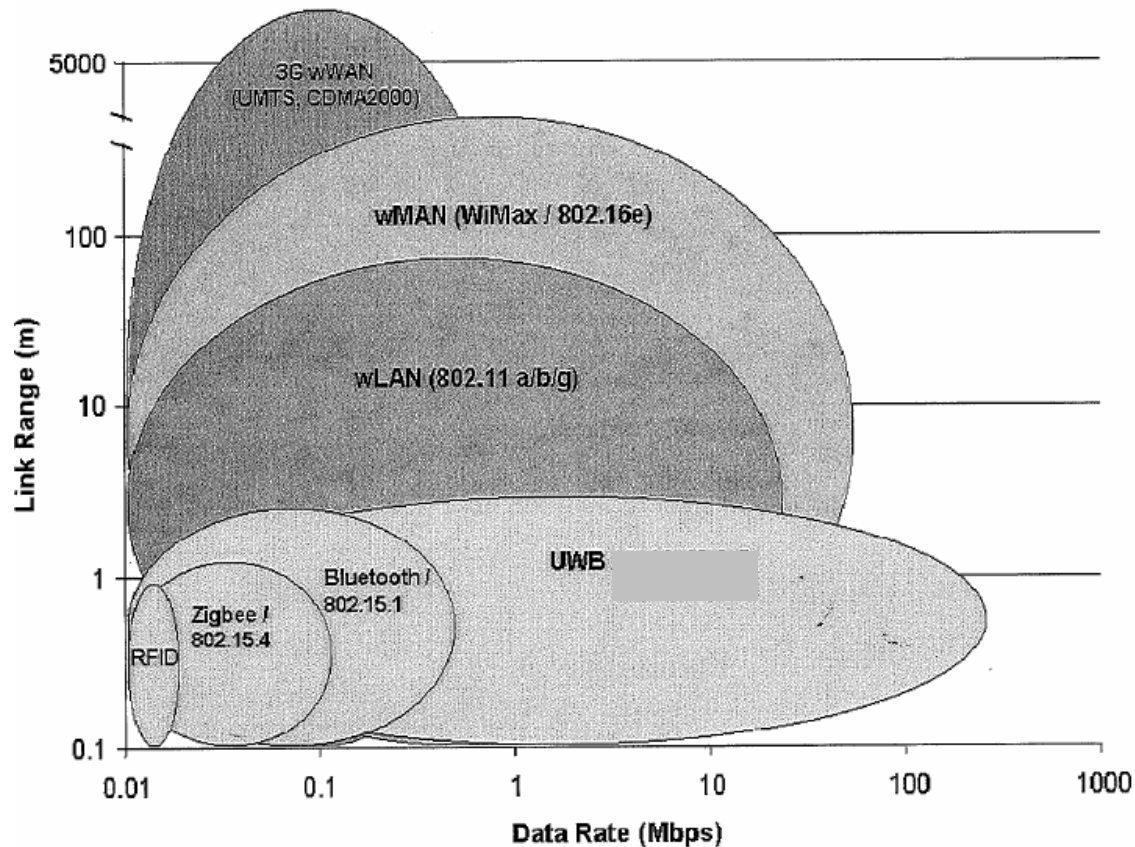


Figure 3—General overview of link range versus data rate

8.2 Lower level layers (i.e., radio/media)

In the most basic terms, the OSI layers of wireless technologies focus on the physical delivery of data. These are generally defined up to the transport layer for various WPAN, WLAN, and WMAN standards. Wireless systems considered for evaluation here include industry and IEEE standardized technologies. While various proprietary technologies [e.g., on-off key amplitude modulation (AM), narrowband frequency modulation (FM) and phase-shift keying (PSK), and custom frequency hopped spread spectrum (FHSS)] exist, these are not considered within the scope of this guide for purposes of promoting PnP operability between commercially available medical devices and wireless systems. Existing standardized technologies can be generally categorized into WPANs, WLANs, WMANs, or WWANs. This guide does not provide detailed specifications for RF technologies, only a broad overview relevant to the issue of medical data transport. Details of the various technologies are available within the IEEE and industry standards themselves and numerous reviews on the subject. Follow-on ISO/IEEE 11073 specialization standards also provide more detail on relevant wireless technologies.

Wireless systems may operate on a number of licensed and/or unlicensed frequency bands. Networks that support licensed frequencies allow for private communication and dedicated service for use only by the licensed client(s). Licensed networks often include a wide area of coverage, options for system control, and limited interference from external or in-band sources. In contrast, operations on unlicensed frequency bands are not associated with cost for use, but may be associated with an up-front cost to purchase, deploy, and maintain the network system. In addition, issues of coexistence and interference can be significant when operating on an unlicensed frequency. For instance, the wireless medical telemetry service (WMTS) was established by the FCC in 2000 by carving out three areas of dedicated spectrum at 608 MHz to 614 MHz, 1395 MHz to 1400 MHz, and 1427 MHz to 1432 MHz for operation of medical telemetry systems. The purpose of the new WMTS bands was to allow older medical telemetry equipment to migrate out of unused upper television channels that are now being used for both traditional vestigial side band (VSB) transmitter television and newer digital-format television. The WMTS bands do share some overlap with other technologies, namely the band of 608 MHz to 614 MHz is “constrained as a result of radio astronomy quiet zones ... and interference from adjacent television channels.”¹³ The FCC also notes “...we are not requiring television broadcasters to protect WMTS from adjacent band interference.”¹⁴ There are 13 radio astronomy sites located throughout the United States that have a protected radius of < 80 km. The bands of 1395 MHz to 1400 MHz and 1427 MHz to 1432 MHz are shared with military radar systems, and several such radar sites within the United States have a protected radius of < 85 km. Other nonmedical applications also share the band of 1427 MHz to 1432 MHz. However, these sources of interference are usually not as problematic as new digital television sources.

Table 1 lists wireless technologies as very general groupings. For example, the industry standards that define Bluetooth^{®15} and Zigbee^{®16} technologies are extensions of IEEE Std 802.15.1-2005 and IEEE Std 802.15.4-2006, respectively. However, for simplicity and for the purposes of this guide, such related technologies have been grouped and described together. A more detailed description of wireless technologies is provided in Annex D, with the initial version of Table 1 extracted in large part from the CEA R7 WG7 Home Network’s Phase 1 Report [B2] (with modification to synchronize format and terminology with this guide). Additional descriptions of technology categorized into WPAN, WLAN, WMAN, and WWAN is also provided in Annex D.

¹³ FCC R&O 00-211, paragraph 11.

¹⁴ FCC R&O 00-211, paragraph 19.

¹⁵ Bluetooth is a registered trademark of Bluetooth SIG, Inc. This information is given for the convenience of users of this standard and does not constitute an endorsement by the IEEE of these products. Equivalent products may be used if they can be shown to lead to the same results.

¹⁶ ZigBee is a registered trademark of the ZigBee Alliance. This information is given for the convenience of users of this standard and does not constitute an endorsement by the IEEE of these products. Equivalent products may be used if they can be shown to lead to the same results.

Table 1—General classes of wireless technology

Wireless technology		General description ^a	Tx/Rx frequency	Potential healthcare applications	Potential healthcare benefits/drawbacks
Mobile phones	WWANs	1st generation (analog)	Long link range (~10–30 km) for voice (becoming obsolete). Tx power controlled, max ~0.6 W.	Licensed bands around 450 & 850 MHz	Benefits: — Improved home monitoring & chronic disease surveillance (reduce healthcare costs & hospital stays). — Mobile (on-/off-campus) alternative to wired telephony & paging. Drawbacks: — Traditional QoS parameters may not be supported. — Throughput and link influenced by network traffic and local coverage.
		2nd generation (2G) (digital)	Low rate (< 20 kb/s), long link range (1–3 km) for voice and limited data transport. Tx power controlled, max 125–2 W. ^b	Licensed bands around 450, 850, 900, 1400, 1800, 1900 MHz	
		3rd generation (3G)	Higher rate (> 1 Mb/s), long link range (1–3 km) for voice and data transport. Tx power controlled, max ~0.25 W. ^c LTE will likely also run on 3G networks.	Licensed bands around 2 GHz	
Wireless broad-band networks	WMAN	IEEE 802.16a/d, IEEE 802.16e, IEEE 802.20, LTE	High rate (< 75 Mb/s), long link range (~3–10 km) for video + simultaneous voice & data. Tx max power ~1 W (range of miles). LTE will likely operate at similar ranges of power as existing 3G communication networks.	Licensed, unlicensed bands within 2–11 GHz	Benefit: Real-time/ immediate access to imaging data from ancillary sites.

Table 1—General classes of wireless technology

Wireless technology		General description ^a	Tx/Rx frequency	Potential healthcare applications	Potential healthcare benefits/drawbacks
Wireless data networks	WLAN	Higher rate (< 54 Mb/s, 25 Mb/s effective throughput), medium link range (~10–30 M) for data transport. Tx power is regulatory domain dependent, ~10–100 mW normally. FCC limits are 40 mW, 200 mW and 1 W for the ETSI I, II and III bands, respectively. Mesh technology (IEEE 802.11s [B6]) is being added to some networks to allow better coverage, where latency is not critical.	5.8 GHz industrial, scientific, medical (ISM) bands, lower 5 GHz bands not ISM	Can support: — Low-data-rate physiologic parameters, events, control settings. — Continuous waveforms (ECG, EEG, vent.) — Multiple PWD/ECG telemetry. IEEE 802.11a can support high-data-rate applications including streaming video and audio.	Benefits: — Real-time monitoring of stationary & ambulatory patients. — 555 MHz bandwidth and 21 nonoverlapping 54 Mb/s channels allows frequency reuse and almost unlimited capacity in the enterprise. — IEEE 802.1x and IEEE 802.11 authentication and encryption provide a standards-based toolset for HIPAA^d patient data security compliance. — New access point (AP) architectures are more secure than hard-wired network jacks. — Voice-Over Internet Protocol (VoIP) offers in-building communication alternatives to licensed networks, although bandwidth requirements may create other issues — Protocols for conformance and prioritized data flow (Wi-Fi/IEEE 802.11 QoS) available. Drawbacks: — Many technologies (IEEE 802.11b/g) operate within crowded 2.4 GHz ISM band; interoperability could be a significant issue. — Open systems vulnerable to security breaches and virus attacks; necessitates hospitals to invest in enterprise class solutions that close these issues.

Table 1—General classes of wireless technology

Wireless technology		General description ^a	Tx/Rx frequency	Potential healthcare applications	Potential healthcare benefits/drawbacks
Wireless data networks		IEEE 802.11b (Wi-Fi-b)	2.4 GHz (ISM)		
		IEEE 802.11g (Wi-Fi-g)	2.4 GHz (ISM)		
	WPAN	IEEE 802.15.1 (Bluetooth)	2.4 GHz (ISM)	Can support low-data-rate physiologic parameters, events, * Might support control settings, continuous waveforms (ECG, EEG, vent.) Cannot support multiple PWD/ECG telemetry. * IEEE 802.15.4 has two possible operating frequency bands. * Ultra-wideband (UWB) variations of IEEE 802.15.3 or IEEE 802.15.4, or other UWB solutions may offer more robust support of certain functions, but are not yet standardized and/or widely available commercially.	Benefit: Good option for single short-link/cable replacement (esp. IEEE 802.15.1), asset tracking, or low-power/long battery life req. (esp. IEEE 802.15.4). Drawback: Other 2.4 GHz emitters can compete for channel access and significantly increase latency and reduce throughput, making critical data transport a concern.

Table 1—General classes of wireless technology

Wireless technology		General description ^a	Tx/Rx frequency	Potential healthcare applications	Potential healthcare benefits/drawbacks
		UWB technologies	UWB (3–10 GHz)		Offers additional options for short link range/higher data rate cable replacement applications.
		IEEE 802.15.4 (Zigbee)	2.4 GHz (ISM), 902–928 MHz (US), 868–868.6 MHz (Europe), 315/433 MHz		
		Radio frequency identification (RFID)	13, 433, 900, 2450 MHz, 10 GHz	Asset and patient tracking, inventory and medicine.	
Wired network		IEEE 802.3	(hard line)	Can support: all low and high-data-rate parameters.	Benefit: Traditional dependable technology, supports conventional QoS parameters. Drawback: No mobility.

^a Values for typical maximum power reflect common products on the US market and not necessarily the FCC allowable limits in that spectrum band for that technology.
^b Values reflect peak power, with global system for mobile (GSM) having average transmit power of 8 fold less (850/900GSM = 250 mW avg, 1800/1900 MHz GSM = 125 mW avg).
^c 3G mobile phones have increased transmission of high-speed data requiring increased transmit power in addition to increased bandwidth over 2G. CDMA.
^d Health Insurance Portability and Accountability Act.

8.3 Link establishment (authentication, discovery)

In wireless systems, the process of one wireless device's establishing and maintaining a link with another device or network is a defined process that usually involves sharing some form of secret information to ensure authentication and often facilitates some form of encryption for data security. The process and conventional terminology can vary between different wireless technologies circles although the end result is similar. Importantly, some wireless technologies do not currently implement universal or common (multi-profile multi-link) interfaces; this inconsistency makes PnP communication difficult. This guide will provide only a general overview, with more detailed descriptions being relegated to IEEE P11073-30400 and IEEE P11073-30500 follow-up profiles.

In the case of mobile phones, powering the handset on, or initiating or receiving a call, results in a series of communication steps with the WWAN on dedicated pilot channels until eventually the WWAN allocates network resources to the user handset in the form of a traffic channel as well as controls transmit power levels. Travel from one cellular coverage area to another involves a series of communication handoff steps. These steps are described in more detail in IEEE P11073-30505 and Annex D. In IEEE 802.11 technology, a handshake protocol is generally used for authentication and generation of several keys for data encryption and decryption between the client station and the AP. These keys are updated when a client station leaves the network to prevent it from receiving additional messages from the AP. Alternative authentication processes exist for smaller home and business WLAN systems that require less information to access the network. Security has traditionally been implemented on IEEE 802.11 systems during authentication using a wireless equivalent privacy (WEP) security framework that operates within the lower layers. This feature encrypts the data packets prior to transmission, and the receiving station decrypts upon arrival of the data frame. In addition, newer standards describe an updated security profile, i.e., Wi-Fi protected access (WPA), with more robust improvements to protect from attacks and unauthorized access, e.g., WPA2, which uses the Advanced Encryption Standard (AES) and 802.1x port-based authentication. These features are described in more detail in IEEE P11073-30503. With IEEE 802.15.1 (Bluetooth) technology, the process is commonly referred to as *discovery and pairing*. Discovery between Bluetooth devices usually require them to be within range (typically ~30 feet) and have compatible profiles and functionality. For example, communication between a Bluetooth headset and a mobile phone will require both to have a headset profile. If two Bluetooth enabled devices do not have the same profile in common, they will not be able to communicate. Often in Bluetooth, this process is facilitated by a personal identification number (PIN). However, new methods involving use of cryptographic keys can support minimal or one-way authentication. In this latter case, when two Bluetooth devices come into proximity, a common key may be displayed, e.g., on a light emitting-diode (LED) screen, which the user can confirm as corresponding to the intended partner device and acknowledge by a single action/key stroke to allow the devices to pair. This process is discussed in more detail in the relevant follow-on IEEE P11073 standards described in Annex F and in other profiles specific to RFID (ISO/IEC 24730-1:2006 [B15]).

8.4 Upper level layers (i.e., protocol/host)

The upper layer protocols define how data will be presented and moved from a sending to a receiving communication device. A variety of different upper layer protocols exist, with different features for data presentation, translation, and encryption. For example, the Internet Protocol (IP), a standardized format for data-oriented communication across packet-switched networks, is a common lower layer protocol in computer networking that works in conjunction with a variety of possible upper layer protocols that may be relevant to wireless medical data transport. Two common IP-based upper layer protocols that can also be used over IEEE 802-type (and potentially other) wireless systems are Transmission Control Protocol (TCP) and User Datagram Protocol (UDP). TCP is used for many common IP-based applications, including the World Wide Web and e-mail, and can run multiple application protocols concurrently. With TCP, data can be exchanged in defined packets in an ordered and reliable manner. UDP allows for faster and more efficient data packet transfer, but without the reliability and ordering guarantee. Other IP-based protocols, e.g., Datagram Congestion Control Protocol (DCCP) and Stream Control Transmission Protocol (SCTP),