

Wireless Electromagnetic Interference (EMI) in Healthcare Facilities

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Table of Contents

Executive Summary.....	1
Section 1: What is Electromagnetic Interference (EMI)?.....	2
What is EMI?.....	2
Factors Affecting Wireless EMI.....	2
The Challenge: Wireless EMI in Hospitals.....	2
The Hospital Environment and Wireless EMI.....	4
Wireless Devices in Healthcare.....	5
Wireless Network Topologies.....	5
Section 2: Managing and Mitigating Wireless EMI.....	9
Industry Practices.....	9
FDA (US) and MHRA (UK) Recommendations.....	10
EMI Management Guidelines: AAMI TIR-18 and IEEE/ANSI Standard C63.18.....	13
Methodological Approach to Evaluating and Managing Wireless EMI.....	14
Section 3: BlackBerry Overview and EMI Characteristics.....	16
BlackBerry: An End-to-End Wireless Solution.....	16
BlackBerry Enterprise Server Architecture.....	16
BlackBerry Devices.....	17
Conclusion: BlackBerry Adherence to Industry Practice.....	18
APPENDICES.....	19
1) Wireless Network Topologies.....	19
2) BlackBerry Device Transmission Data.....	20
3) C63.18's Recommendations for Mitigation of EMI in Health-Care Facilities.....	22
4) Further Information.....	23
5) WWW Resources.....	23
6) Acronym key.....	24
7) Sources.....	25
8) Endnotes.....	26

Wireless EMI in Healthcare Facilities

Executive Summary

Electromagnetic interference (EMI) between wireless electronic transmitting devices and medical equipment is a small but growing problem in the healthcare industry that should not be ignored by healthcare organizations (HCOs). Although studies and anecdotal evidence show that the critical functions of most modern medical devices are immune to wireless RF emissions, the potential for EMI does exist. While the risk of EMI caused by wireless devices to medical equipment (and patient health) is real, evidence shows that HCOs can successfully manage and mitigate wireless EMI at appropriate levels by following industry best practices and adopting policy guidelines recommended by government and relevant associations and institutions.

Relatively few cases of wireless EMI have been reported despite the prevalence of wireless devices and medical equipment present in healthcare facilities. As wireless technologies continue to penetrate the healthcare industry, HCOs can gain the benefits of wireless technologies (i.e., reduced operating costs, improved productivity, and improved quality and speed of care) while safeguarding medical devices from the effects of wireless EMI by developing policies and procedures that identify and prevent wireless EMI.

Many healthcare facilities have responded to the introduction of wireless devices by banning the use of devices such as cell phones on their premises. However, evidence compiled by industry sources such as the Medicines and Healthcare products Regulatory Agency (MHRA) in the United Kingdom shows that mitigating the EMI risk posed by wireless devices need not be expensive or time-consuming. Suggested industry practices for preventing EMI include:

- Enacting a minimum distance rule to separate medical equipment from potential EMI causing devices. Studies show that a separation distance of 3 meters mitigates almost all the risk of EMI; and
- Establishing “wireless friendly” and “wireless free” zones to allow wireless usage in areas where there is no EMI risk to medical equipment, while enforcing a ban on wireless usage in areas warranted by the presence of sensitive or critical medical equipment.

Each HCO should evaluate industry practices and recommended guidelines within the context of its own facility, since each healthcare facility has a unique electromagnetic environment composed of a heterogeneous mix of medical and wireless devices.

No wireless device can be considered EMI-free, including BlackBerry® devices. Wireless solutions should be evaluated for EMI characteristics by HCOs based on test results from their own facilities. However, the design and operating characteristics of BlackBerry fit within the EMI risk profiles of comparable wireless technologies such as digital cell phones. BlackBerry device characteristics include:

- Power control features that seek to minimize output power when transmitting information, thereby limiting the amount of time the transmitter is active and potentially reducing the possibility of causing EMI;
- The ability for IT managers to disable the BlackBerry device's Bluetooth® feature so as to minimize the possibility of EMI caused by Bluetooth; and
- EMI characteristics that appear to be no worse than for digital cell phones and appear to be reduced by the same management and mitigation measures enacted for cellular phones.

Ultimately, HCOs should evaluate the EMI risk of any device, including BlackBerry, according to the specific requirements of the HCO, and its own policies for EMI management.

Wireless EMI in Healthcare Facilities

Section 1: What is Electromagnetic Interference (EMI)?

What is EMI?

Electromagnetic interference (EMI) occurs when one or more electronic devices adversely interfere with the operation of another electronic device. Any radio frequency (RF) transmitting device, such as a cell phone or laptop computer connected wirelessly to a network, has the potential to electronically interfere with the operation of another electromagnetic device because of the physics governing radio waves: as electrons move, they create electromagnetic waves that spread through free space and potentially interact with each other. In healthcare facilities, wireless EMI occurs when wireless devices interfere with medical equipment, potentially causing equipment malfunction.

Electromagnetic compatibility (EMC) is the opposite of EMI. EMC means that the device is compatible with (i.e., no interference caused by) its Electromagnetic (EM) environment and it does not emit levels of EM energy that cause EMI in other devices in the vicinity¹.

Factors Affecting Wireless EMI

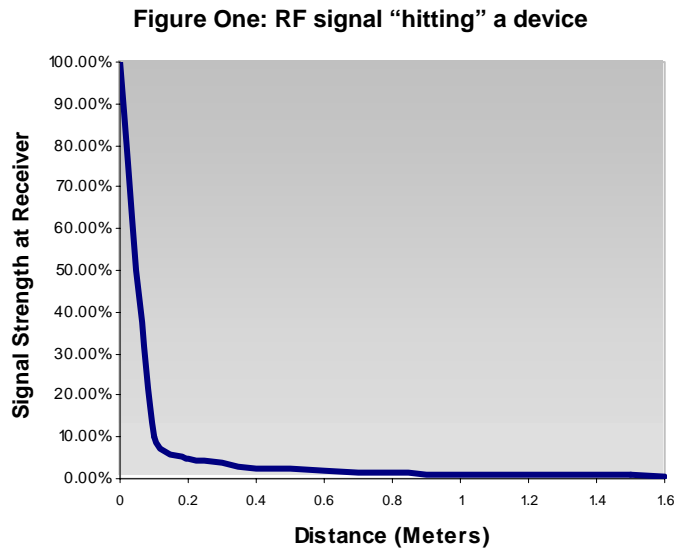
Although studies and anecdotal evidence show that the critical functions of most modern medical devices are immune to wireless RF emissions, the potential for EMI does exist. Tests show that the majority of wireless EMI occurs when wireless devices operate at high power and in close proximity to sensitive areas (e.g., directly over non-shielded plastic gauge covers, etc) of medical equipment for extended periods of time². The three main factors identified as influencing the potential for EMI are:

1. **Power output of the transmitting device:**

the greater the electrical field strength of the transmitting device, the more potential for disruption. Tests show that field strength emissions from cell phones transmitting in close proximity and at full power can exceed the recommended EMI immunity levels set by the IEC for new medical equipment;³

2. **Proximity:** as shown in Figure One the smaller the distance between devices the greater the field strength and the greater the chance for EMI. As distance increases, field strength emissions decay rapidly; and

3. **Radio wave frequency:** certain medical equipment may be more susceptible to interference from specific frequencies. A confluence of several devices operating on similar radio frequencies may enhance the potential for EMI. The absorption and reflection of radio waves by the physical environment the devices are situated in can also affect the chances of EMI occurring; emission field strengths can occasionally be higher than expected at greater distances, and lower than expected at lesser distances.⁴



The Challenge: Wireless EMI in Hospitals

Contributing Factors to Wireless EMI

Although studies on wireless interference have demonstrated that EMI is a potential risk to medical equipment, clear evidence showing that EMI has contributed directly to patient harm are rare⁵. The U.S. Food and Drug Administration's (FDA's) Medical Device Reporting (MDR)

Wireless EMI in Healthcare Facilities

database reveals that only a few hundred entries out of the more than six hundred thousand reports of medical device malfunctions are EMI related. While the threat of EMI is real, anecdotal and scientific evidence suggests the actual number of EMI-related incidences is small, and it is possible for healthcare facilities to successfully balance their use of wireless technologies with measures designed to safeguard medical equipment from the effects of EMI. However, due to the relative newness of wireless technology and the complexity of the problem, there appears to be a lack of advice and consensus for Healthcare Organizations (HCOs) on how to successfully manage the risk of EMI.

Anecdotal industry evidence regarding the relative safety of using wireless transmitting devices within healthcare facilities shows there is little negative effect despite regular usage. Within healthcare facilities, there are typically a large number of wireless devices in use. For example, upwards of thirty percent of US hospitals have deployed Wireless Local Area Networks (WLANs) in some part of their facilities, with no reported cases of EMI to the FDA⁶. Facility personnel, patients and visitors routinely use a variety of wireless devices -- maintenance and security workers communicate with two-way radios, physicians use cell phones and wireless personal digital assistants (PDAs), ambulance drivers use their vehicle's radios while parked just outside facilities; and patients and visitors operate mobile phones.

Table One: Potential Sources of EMI

Wireless Systems & Devices	Other Potentially Interfering Systems & Devices
Walkie-talkies	Building & fire alarms
Two-way Pagers	Security systems
Mobile Phones	Power distribution systems
Cell Phones	Fluorescent lights
Bluetooth enabled devices	Microwave Ovens
Notebook/laptop computers	Electric Razors
Wireless LAN	CAT scanners
Wireless PDAs	X-Ray machines
Medical Telemetry	MRI machines

Adding to the complexity of radio frequency (RF) environments in hospitals, are other types of transmitting and EMI-radiating devices typically found within healthcare settings such as wireless telemetry equipment, nurse call systems, wireless in-house phone systems, two-way pagers, patients' electric razors, two-way radios, microwave ovens,

fluorescent lighting, in addition to Wireless Local Area Networks (WLANs) and Wireless Personal Area Networks (WPANs). Sources of potential interference can also originate from outside the facility, such as high-definition television (HDTV) transmitters. Given the large number of devices (wireless and non-wireless) operating in the average healthcare facilities' bandwidth spectrum, occasional interference between devices is to be expected. Even when devices do not operate in the same bandwidth, harmonic and intermodulation or sum and difference interference can occur intermittently, making detection difficult⁷.

The Ramifications of Wireless EMI

Although the low number of documented instances in which EMI has been shown to contribute to patient harm suggests that there is an extremely remote possibility of patient injury or death from EMI, the actual risk of EMI to patient health cannot be simply dismissed without due care and diligence. Given the potential disruption that EMI may cause, it is important for healthcare facilities to develop and implement policies that assist in identifying and preventing EMI.

Medical Device Shielding

Multiple Shielding Standards in Place

Most medical equipment in current use has some form of EMI shielding. However, different shielding standards have existed at different points in time, with standards becoming more stringent over the years in response to changes affecting the electromagnetic environment in hospitals (e.g., increasing use of cell phones, increasing reliance on use of electronics for patient monitoring and life-support systems, etc.). In 1993 and in 2002, the International Electrotechnical Commission (IEC) introduced more rigorous shielding standards.

Wireless EMI in Healthcare Facilities

Equipment manufactured prior to 1993 is more susceptible to EMI problems and requires extra attention; older equipment can also degrade over time and become more susceptible to EMI. Healthcare facilities should be aware of situations where older equipment shares the same physical location with more current equipment and should devise EMI management and mitigation policies to alleviate this; possible solutions include moving older equipment to a more shielded location or replacing it with more modern, shielded equipment.

Modern medical equipment is often designed with circuitry that responds only to a narrow frequency range and is therefore less prone to EMI. Although product manufacturers often subject their equipment to EMI testing, the only guaranteed test results are those conducted by the Healthcare organization (HCO) within the HCO's own environment.

Current Shielding Standard: IEC 60601-1-2

IEC Standard 60601-1-2 (EN 60601-1-2 in the European Union) sets out electromagnetic shielding standards for medical equipment. All medical equipment subject to EN 60601-1-2 must comply fully in order to be legally marketable in the European Union (EU), the FDA views IEC 60601-1-2 as a "consensus standard" to which FDA investigators may sometimes have differing or additional requirements.

A key shielding difference between the current and 1993 versions of the standard is the immunity requirement for critical and life support medical devices. The 2002 standard sets immunity for critical devices at 10 V/m, and at 3 V/m for other equipment; while the 1993 version only requires an EMI immunity level of 3 V/m for critical life support equipment. Again, HCOs should pay extra attention to situations where new and old equipment co-habit the same location and either move the older equipment to more shielded areas or enact stricter EMI control measures.

The Hospital Environment and Wireless EMI

Each Healthcare Facility has a Unique Electromagnetic Environment

The risk of wireless EMI increases with the complexity of the hospital's electromagnetic environment and the wireless services active in the environment. Device testing by manufacturers cannot predict or account for the variety of wireless devices used in a healthcare facility, their use of the frequency spectrum, and their power output when transmitting. Different combinations of RF transmitters, medical devices, shielding, and reflecting environments can produce different interference effects. It is not feasible or possible to design a comprehensive EMI solution as no one wireless communication signal is better than another for hospital communication -- all devices have the ability to cause EMI under extreme conditions and all can operate compatibly if appropriate EMC management procedures are employed.⁸

Develop EMI Management Procedures Specific to the Facilities' Environment

Even though the critical functions of most medical devices are immune to RF emissions from handheld devices, significant interference can occur. The majority of EMI has been shown to take place with mobile devices operating under full power in close proximity to medical equipment for extended periods of time; even shielded medical equipment may be susceptible to EMI under these conditions. Although medical equipment manufacturers generally comply with IEC Standard 60601-1-2's recommended 10 V/m immunity level against interference from RF emissions; this level of immunity is not guaranteed. Tests show that modern wireless devices are capable of exceeding these standards when used in close proximity to shielded equipment; cell phones are capable of producing field strength emissions that exceed field strengths of 10 V/m level when transmitting in close proximity and at full power (0.6 watts average power, up to 2 watts peak power depending upon the phone signal type). Most PDA devices operating on Wireless Wide Area Networks (WWANs) transmit RF emissions at power levels comparable to cell phones, but as short bursts spaced approximately 4-10 seconds apart, resulting in a lower average power. Older medical equipment with less stringent shielding is more susceptible to emissions from mobile networked devices even at lower average power outputs.

The sheer variety of radio frequencies, pulse modulation patterns, form factors and antenna positions used by different handheld devices can create different patterns of medical device EMI.

Wireless EMI in Healthcare Facilities

A medical device sensitive to RF emissions from one type of handheld device may be completely immune to RF emissions from a different type of handheld device operating on a different carrier network. The unique physical environment of each hospital also influences the pattern of EMI; EMI effects can be influenced by factors as whether a given medical device is on a metal or plastic cart, how the lead and power cord are arranged, and whether or not it is clustered with other devices.

While HCOs may be focused on mitigating the risk of EMI from prominent wireless technologies such as cell phones and PDAs, it is important to realize that the devices with probably the greatest potential for causing EMI are the walkie-talkies and two-way radios commonly used throughout care delivery organizations (CDOs) by internal security personnel, contractors, and maintenance workers. Walkie-talkies generally have high power transmission outputs in the order of 2 – 5 Watts, and if used in proximity to medical devices, can cause interference.

Due to these variables, CDOs cannot reliably use outside observations or test results to determine whether a specific wireless device is EMI free. Instead, healthcare organizations (HCOs) should perform their own testing, in their own facility, with their own medical device inventory, with the wireless handheld devices that they plan to use in order to develop accurate EMI risk profiles for mobile networked devices and medical equipment. The Institute of Electrical and Electronic Engineers (IEEE) has developed C63.18, an ad hoc on-site test procedure adopted by the American National Standards Institute (ANSI), which is recommended for identifying and characterizing EMI issues.

Despite the inherent complexity of electromagnetic environments in healthcare facilities, it is possible to identify, control, and avert significant EMI problems before they occur with appropriate analysis, evaluation and management of wireless devices.

Wireless Devices in Healthcare

Networked wireless devices are increasingly being adopted by HCOs to deliver tangible benefits such as improved productivity, improved quality and speed of care, and reduced operating costs. BlackBerry, for example, is being used to:

- Access and update medical forms in a timely manner;
- Enable physicians to quickly send and receive information virtually anytime and anywhere; and
- Maintain accurate and timely inventory data.

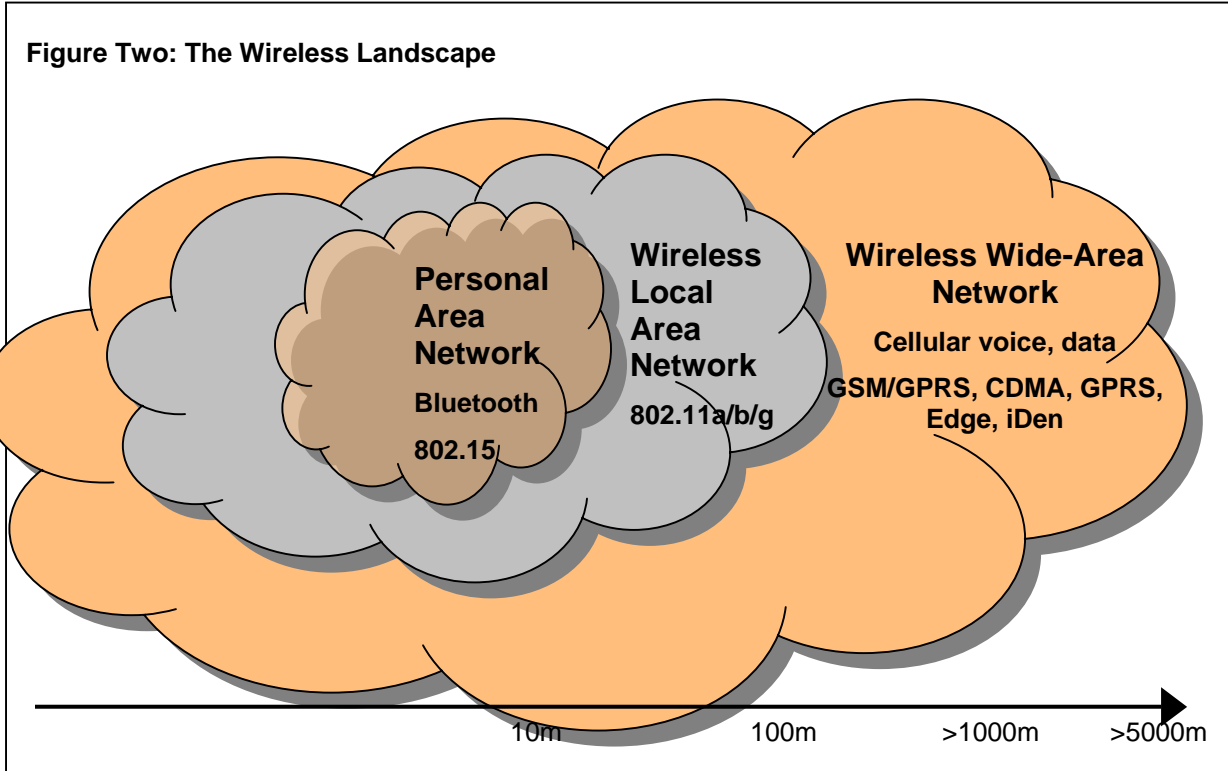
As technology costs fall and handheld capabilities increase, the use of mobile devices such as notebooks, PDAs, tablet PCs and BlackBerry devices in HCOs is growing. According to the 2005 HIMSS Leadership survey, fifty-nine percent of responding healthcare CIOs named PDAs as a technology their organizations planned on implementing over the next two years. A further fifty-one percent of respondents expected their organizations to adopt Wireless Information Appliances within the next two years.⁹ As the functionality and ease-of-use of mobile devices increases, mobile devices are expected to further penetrate the healthcare industry, either through direct introduction by HCOs themselves, or through workers using their personal devices in the workplace to enhance productivity.

Using industry practices, recommendations from regulatory agencies, and standards developed by industry organizations, HCOs can develop policies and procedures that manage and mitigate the risk of wireless EMI to appropriate levels while ensuring that all the benefits of mobile wireless technology are made available.

Wireless Network Topologies

Wireless EMI in Healthcare Facilities

Wireless network topologies have different network infrastructures, coverage areas, data transfer rates which are designed to be appropriate for supporting specific business processes, and meeting varying organizational needs. Diagram Two presents wireless topologies in terms of their network coverage area and communication protocols. Appendix One provides a summary of the technologies and capabilities of common wireless topologies.



Peer-to-Peer Networks

Peer-to-Peer networks are basic networks consisting of handheld radio devices such as walkie-talkies which communicate directly with each other or with base stations. These handhelds have no power control features and transmit at constant rates of approximately 2-5 watts of power when in use. The constant transmission rate at a relatively high power combined with a lack of power control, means that walkie-talkies are potentially the greatest EMI risk in healthcare facilities. Traditionally these devices are used by hospital staff, security, and facility personnel.

Wireless Personal Area Network (WPAN)

WPANs usually operate using Bluetooth, a wireless protocol that, through the use of a short-range radio link, enables devices to communicate voice and data with each other in a small area typically less than 30 feet/10 meters. Bluetooth was developed with the intention of replacing physical cable connections and a Bluetooth-enabled WPAN (sometimes called a piconet) typically connects a group of peripherals (e.g., fax, printer and scanner) with mobile devices such as cell phones, notebook computers, and PDAs. Bluetooth operates in the unlicensed 2.4 GHz spectrum using very low transmission power (10-100 milliwatts) but due to the short range of the network, may contribute to EMI risk by operating in close proximity to other devices.

Wireless Local Area Network (WLAN)

A WLAN (Wireless Local Area Network) is essentially a replacement for a Local Area Network (LAN), using high frequency radio signals instead of physical cabling to communicate data

Wi-Fi

"Wi-Fi", short for "Wireless Fidelity", is a term created by the Wi-Fi Alliance to signify and certify product interoperability with a view to creating a global WLAN standard. Wi-Fi certified networks use IEEE 802.11b or 802.11a WLAN radio technologies to provide wireless connectivity. Products approved as "Wi-Fi Certified™" are certified as interoperable, even if they stem from different manufacturers. Generally, however, any Wi-Fi product using the same radio frequency (for example, 2.4GHz for 802.11b or 11g, 5GHz for 802.11a) will work with any other, even if not "Wi-Fi Certified™."

Wireless EMI in Healthcare Facilities

through networked devices. WLANs consist of multiple wireless access points (base stations or antenna sites) located throughout a building and wirelessly connected to a central “router” unit (typically an Ethernet hub). WLANs transmit and receive signals with a variety of handheld devices over an area of several hundred to a thousand feet, enabling the devices to roam freely through the networked area; as users roam they are handed off from one access point to another, analogous to a cellular phone system. WLANs are based on the 802.11a, 802.11b, and 802.11g standards and usually operate on unlicensed radio band frequencies of 900 MHz, 2.4 GHz, and 5GHz at speeds of up to 11 Mbps (802.11b) or 54 Mbps (802.11a/g). Although WLANs do not have power control features, they transmit at a very low constant power (on the order of 10-100 milliwatts) and are designed to never be very far away from the nearest network node. Networks are limited to use in the building where the WLAN system has been installed although connections can be made at the “hub” to outside networks.

Although initially there were concerns by hospitals about possible parallels between cell phone and WLAN transmission characteristics, there are few similarities between the two technologies. WLANs operate in higher frequency bands using lower transmission power, and therefore are generally less likely to cause interference with medical devices than cell phones.

Wireless Wide Area Network (WWAN)

WWAN Technologies

WWANs (Wireless Wide Area Networks) are carrier-operated cellular networks consisting of interlinked base stations covering large metropolitan areas linked together into nationwide networks spanning large geographic regions. WWANs deliver near-continuous coverage of voice and data traffic to subscribers, enabling widespread access and device roaming throughout the network area.

Because WWANs offer the national wireless coverage and multiple handheld device capability (e.g., cell phones, hybrid devices such as BlackBerry, and PDAs) sought by organizations for their mobile workers, WWANs are becoming increasingly popular with physicians, hospital management and staff; and are rapidly becoming attractive to many HCOs as a principle communications network. WLANs are generally faster and cheaper than WWANs; however WWANs offer broader network coverage and are well-suited for business processes that don't have intensive data-transfer requirements. Table Two describes four leading WWAN technologies in terms of bandwidth, frequency and supported services.

Wireless EMI in Healthcare Facilities

Table Two: Selected WWAN Technologies

Technology	Frequencies	Range	Bit Rate	Business Process
Global System for Mobile Communications (GSM)	900, 1800, 1900 MHz	Carrier network dependent	9.6 Kbps	Digital voice, short message services, short data transactions between field terminals and back-office servers
General Packet Radio Services (GPRS)	900, 1800, 1900 MHz	Carrier network dependent	Up to 171 Kbps	Voice, messaging, email, and wireless web on BlackBerry and other phones, pagers, and PDAs from Cingular, T-Mobile, etc.
Code Division Multiple Access (CDMA)	800, 900, 1700, 1800, 1900 MHz	Carrier network dependent	14.4 Kbps	Digital voice, short message services, PCS, wireless web on WAP Phones
CDMA2000/1X	450, 800, 1700, 1900, 2100 MHz	Carrier network dependent	Up to 307 Kbps	Voice, messaging, email, and wireless web on Smartphones and other phones, pagers, and PDAs from Sprint, Verizon, etc.
iDEN	?	Carrier network dependent	?	Push To Talk with voice overlay on packet switched network.

WWAN radio signals operate in the licensed spectrum at frequencies of 450 MHz, 900 MHz, and 1.8 GHz. The two main technologies supporting WWANs are GSM and CDMA, which are being enhanced to increase data throughput speed. Enhanced (2.5G) WWAN technologies such as GPRS are comprised of digital voice networks that have been upgraded to carry data and personal communication services, while third generation (3G) WWANs (currently being developed), are explicitly designed to support higher-speed data and streaming audio/video applications. WWAN technologies in popular use include:

- **GSM™ (Global System for Mobile communication):** an all-digital cellular network used extensively in Europe and across the world. A GSM network can provide, besides telephony services, short messaging services (SMS) and data communication at speeds of up to 9.6 kbps. Operating at the 900 MHz, 1800 MHz or 1900 MHz frequency bands, GSM digitizes and compresses data, then sends it down a channel with two other streams of user data, each in its own time slot. GSM enhancements include General Packet Radio System (GPRS), and Enhanced Data GSM Environment (EDGE).
- **GPRS (General Packet Radio Service):** an enhancement to GSM enabling higher data transmission speeds averaging 43-56 kbps and theoretically up to 170 kbps. GPRS supports packet-switching, using the network only when data is to be sent, and acting as an “always on” technology enabling constant connectivity. Because GPRS is particularly well suited to a “burst” type of data transmission, it effectively brings IP capabilities (e-mail, Internet browsing) to a GSM network.
- **CDMA (Code Division Multiple Access):** a digital cellular technology first commercialized by Qualcomm. Each CDMA transmission is identified by a unique code, allowing multiple calls to use the same frequency spread --voice and data can be transmitted simultaneously during the same call. CDMA advantages include higher user capacity and immunity from interference by other signals. Available in either 800 or 1900 MHz frequencies.
- **iDEN® (Integrated Dispatch Enhanced Network):** a technology developed by Motorola and used by Nextel in the United States, iDEN® combines the capabilities of a digital cellular telephone, two-way radio, alphanumeric pager, and data/fax modem, using the 800MHz and 1,500MHz bands at data speeds of up to 64 Kbps. Nextel’s iDEN® service has proven popular with customers because of its dispatch radio service function which enables two-way radio communication. Nextel’s merger with Sprint PCS places the future of iDEN® in doubt as the companies have announced a planned migration of iDEN® services to Sprint PCS’s CDMA-based network.
- **EDGE (Enhanced Data rate for GSM Evolution):** a faster version of the GSM/GPRS system. Built on the existing GSM standard, EDGE allows GSM operators to use existing GSM radio

Wireless EMI in Healthcare Facilities

bands to deliver multimedia IP-based services (e-mail, messaging, downloading video), and other broadband applications, to cell phone and computer users at theoretical maximum speeds of 384 kbps.

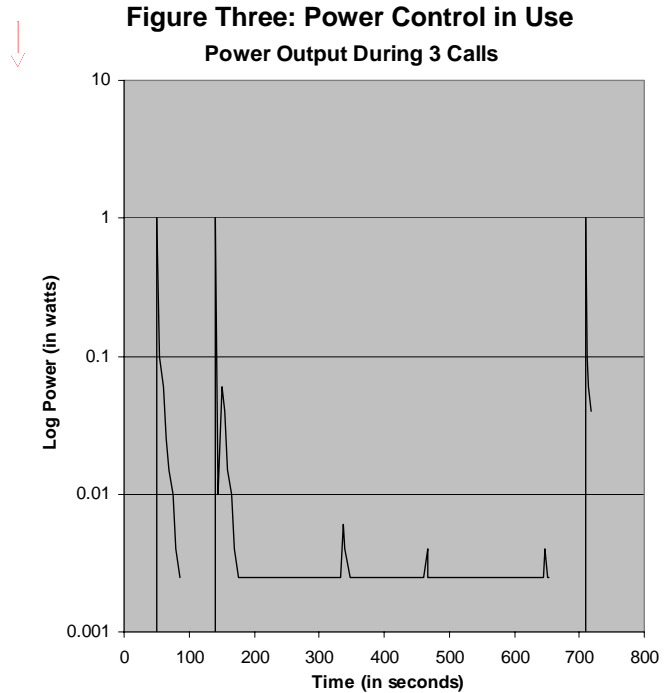
WWAN Handheld Devices

Handheld devices operating on WWANs generally transmit at average power levels of 0.6 watts, reaching levels of 1- 2 watts at peak power. Many WWAN handhelds have power controls and transmit at drastically reduced power levels when operating in the presence of a strong base station signal. Figure Three displays data from a cell phone operating on a 900 MHz/1800 MHz GSM system during three separate calls in the presence of moderate to strong receive signal from a controlling base station.¹⁰ If the signal strength degrades, the handheld will operate at higher power levels in order to obtain the signal.

This can happen if the physical infrastructure of the healthcare facility affects the strength of the base station signal. Heavily constructed building components such as multiple basement floors and lead-lined walls around radiology bays, can create a number of areas that shield signals from the base station, forcing handheld devices to operate at or near full power in order to pick up the signal.

Also, if communications traffic overloads the capacity of the local base station, handheld devices may be “handed-off” to an alternate base station site more distant from the healthcare facility’s system. In this case, if the signal from the alternate cell site is weak or shielded, the handheld devices may transmit at higher power levels to compensate for the weaker signal.

WWANs that do not “hand off” devices if communications traffic becomes excessive may be more consistent in terms of managing RF emission levels from handheld devices. If the amount of communications traffic does create a problem, the network provider has the ability to allocate additional communications channels to compensate for increased user volume. To ensure blanket network coverage of the facility and consistently strong base station signals, supplementary network infrastructure may be installed in the form of microcells or signal repeaters.



Section 2: Managing and Mitigating Wireless EMI

Industry Practices

Healthcare organizations have developed and implemented practices to minimize and mitigate EMI risk. These practices follow the recommendations of regulatory and standards bodies (e.g., FDA, IEEE) conversant with EMI risk factors.

Define and Establish Wireless Zones

Since a facility-wide ban on cell phones and other wireless devices is impractical to enforce, care delivery organizations (CDOs) should limit the number of actively enforced locations by establishing areas where wireless device use is permissible. When defining these zones, policy-

Wireless EMI in Healthcare Facilities

makers should take into account the distance from areas containing critical medical equipment, and the availability of cell phone coverage. More restrictive policies are required for heavily instrumented areas such as operating rooms and intensive-care units.

Implement a Minimum Distance Rule

CDOs should implement rules that specify a minimum separation distance between wireless devices and sensitive medical equipment. Studies show that by increasing the minimum distance between wireless devices and medical equipment to at least one meter (three feet), the risk of EMI can be reduced significantly for most wireless devices, especially cell phones. Enforcing this rule is unlikely to become a burden for staff members since most users will agree to stepping back one meter from sensitive equipment when asked. Because this guideline may not provide for enough separation to safeguard types of medical equipment which may be more sensitive to EMI, it is best viewed as a “rule of thumb”. The exact separation distances for critical equipment should be determined by the hospital’s clinical engineering staff based on ad hoc testing results, current medical device inventory, and what they feel is appropriate given the environment.

Table Three: The Three Meter Rule-- Effects of Device Separation on EMI

Distance	Device Type	Percent of Impacted Medical Equipment
1 meter	EMS handsets	41%
	Security handsets	35%
	Cell phones	4%
	Cordless phones	~0%
	Base stations	~0%
3 meters	All types	4%

(Source: Adapted from “Interference Facts and Fictions”, Ann Geyer)

Install Additional WWAN Base Stations”

CDOs should consider working with their network carriers to install mini base-stations (small independent base stations dedicated to a user population in the hospital) augmented by in-building signal repeaters (antennas interspersed throughout the building with fiber-optic links to directional antenna). This will have the effect of increasing blanket network coverage, thereby lowering the power output required by wireless devices for establishing a strong signal. Sufficient access to base stations will cause wireless devices to operate at power levels below the threshold for EMI in critical care areas where sensitive medical equipment may be in operation¹¹. In exchange for an appropriate service account by the hospital, network carriers may agree to offset the cost of installation.

FDA (US) and MHRA (UK) Recommendations

Both the Food and Drug Administration (FDA) and the Center for Devices and Radiological Health (CDRH) in the United States, and the Medicines and Healthcare products Regulatory Agency (MHRA) of Department of Health in the United Kingdom provide recommendations for EMI management and mitigation in healthcare organizations. These agencies receive information directly from healthcare organizations and medical device manufacturers regarding experiences with and prevention of EMI with medical devices. Their recommendations are intended to help minimize the risk of medical device EMI and promote electromagnetic compatibility (EMC) in healthcare facilities.

Wireless EMI in Healthcare Facilities

FDA/CDRH Recommendations for EMI in Healthcare Facilities

Among other recommendations, the FDA/CDRH urges healthcare organizations to report EMI problems to the FDA MedWatch program.

FDA/CDRH EMI Management Recommendations

- Utilize available resources including EMI professionals and publications and Internet web pages on the subject of medical device EMI;
- Assess the facility's electromagnetic environment (e.g., identify radio transmitters in the facility) and identify areas where critical medical devices are used (e.g., ER, ICU, CCU);
- Manage the electromagnetic environment, RF transmitters and all electrical and electronic equipment, including medical devices, to reduce the risk of EMI;
- Coordinate the purchase, installation, service, and management of all electrical and electronic equipment used in the facility to minimize EMI;
- Educate healthcare facility staff, contractors, visitors, and patients about EMI and how they can recognize medical device EMI and help minimize EMI risks;
- Establish and implement written policies and procedures that document the intentions and methods of the healthcare institution for reducing the risk of medical device EMI;
- Report EMI problems to the FDA MedWatch program and communicate EMI experiences to colleagues in open forums such as medical publications and conferences.

(Source: Adapted from "FDA/CDRH Recommendations for EMC/EMI in Healthcare Facilities" available at <http://www.fda.gov/cdrh/emc/emc-in-hcf.html>)

MHRA Recommendations

The MHRA provides recommendations to CDOs in terms of the EMI risk profiles of common wireless technologies and how to mitigate them, and in terms of specific policy proposals to CDOs for managing EMI risk without losing the benefits of wireless technology.

Mobile Device EMI Risk

In its 2004 report on the use of mobile technology in patient care, the MHRA concludes that most mobile communications systems can be safely used in hospital settings. However, because of the effect EMI can have on medical devices, (CDOs) should "actively manage" the radio frequency spectrum used in their buildings. Accordingly, CDOs should consider establishing areas where no restrictions on the use of mobile devices are necessary because medical devices will not be affected by EMI, and areas where only authorised staff can use mobile devices authorised by the facility. Table Four summarizes the MHRA's findings.

Wireless EMI in Healthcare Facilities

Table Four: MHRA EMI Risk Mitigation Recommendations

EMI Risk	Type of Communication System	Recommendation
High	Analogue emergency service radios	Use in hospitals only in an emergency, never for routine communication.
	Private business radios (PBRs) and PMR446 e.g. porters' and maintenance staff radios (two-way radios).	Minimise risks by changing to alternative lower risk technologies
Medium	Cell phones (mobile phones) TETRA (Terrestrial Trunked Radio System) Laptop computers, palmtops and gaming devices fitted with GPRS* and/or 3G HIPERLAN**	<ul style="list-style-type: none"> • A total ban on these systems is not required and is impossible to enforce effectively. • Should be switched off near critical care or life support medical equipment • Should be used only in designated areas • Authorised health and social care staff and external service personnel should always comply with local rules regarding use
Low	Cordless telephones (including DECT)*** and computer wireless network systems except HIPERLAN and GPRS e.g. WLAN**** systems and Bluetooth®	These systems are very unlikely to cause interference under most circumstances and need not be restricted.
<p>* GPRS - General Packet Radio System.</p> <p>** HIPERLANs - High Performance Radio Local Area Networks</p> <p>*** DECT - Digital European Cordless Technology</p> <p>**** WLAN - Wireless Local Area Networks</p>		

(Source: Adapted from MHRA, 2004)

MHRA Policy Recommendations

The MHRA 's report offers specific policy recommendations to CDOs for managing and mitigating EMI, with an emphasis on how to incorporate wireless technologies into hospital operations without compromising the hospital's ability to safeguard medical equipment from the effects of wireless EMI.

1. Maximum power should be assumed by CDOs when establishing policies for the use of wireless devices because although cellular technology incorporates dynamic power output dependant on the distance from network base stations, propagation of radio waves is highly variable particularly inside buildings.
2. Misinformation regarding mobile wireless systems, EMI and management procedures has lead to a broad range of inconsistent policies among healthcare organisations. A balanced approach is necessary to ensure that all the benefits of mobile wireless technology can be made available to healthcare organisations.
3. Overly-restrictive policies may act as obstacles to beneficial technology and may not address the growing need for personal communication of patients, visitors and staff members. At the other extreme, unmanaged use of mobile communications can place patients at risk. Therefore, restrictive policies for non-controlled mobile wireless handsets can be facilitated by offering numerous areas that are easily accessed throughout the healthcare facility where the use of mobile wireless handsets by patients, visitors and staff is permitted.

Wireless EMI in Healthcare Facilities

EMI Management Guidelines: AAMI TIR-18 and IEEE/ANSI Standard C63.18

The Association for the Advancement of Medical Instrumentation (AAMI) and The Institute of Electrical and Electronics Engineers (IEEE) have published documents which provide recommendations for managing EMI, and detail ad hoc testing procedures for medical equipment EMI susceptibility. The IEEE/ANSI C63.18 protocol is recommended for basic testing using a defined handheld device on representative units of critical and life support medical equipment (ventilators, infusion pumps, anaesthesiology machines, etc.) to identify and characterize significant EMI issues. The protocol is available from the ANSI website (www.ansi.org)

AAMI TIR 18: EMI Policy Recommendations

AAMI's Technical Information Report 18 (TIR 18-1997): provides guidelines for management of EMI in healthcare facilities, including recommendations for management of wireless technologies and guidance for development of EMI policies. TIR-18 helps CDOs avoid having to reinvent the wheel when developing EMI management policies and is available at www.aami.org

AAMI TIR 18 Summary Recommendations

- The purchase, installation, servicing, and management of all electronic equipment (medical, communications, building systems, and IT) should be coordinated to assure compatibility. Clinical/biomedical engineering, facility management, information technology (IT), materials management, and risk management personnel should all be aware of EMI risk and the need for coordination.
- Clinical/biomedical engineers should work with facility management, telecommunications, IT, materials management, and risk management personnel to manage the electromagnetic environment of the health care facility.
- EMI should become a permanent responsibility of the health care organization's Safety Committee.
- Staff, visitors, and patients should be educated regarding EMI and how they can recognize and help prevent it.
- The site selection, design, construction, and layout of health care facilities should consider the potential for EMI.
- The organization's administration should develop and implement policies and procedures clearly communicating organizational intentions regarding management and mitigation of EMI including, the designation of areas where the use of common hand-held RF transmitters (e.g., cellular phones, two-way radios) by staff, visitors, and/or patients is to be managed or restricted.
- Ad hoc radiated RF immunity testing should be considered in situations where EMI is suspected, when RF transmitters are likely to operate in proximity to critical care medical devices and in the pre-purchase evaluations of new types of RF transmitters to determine their effects on existing medical devices, and of new electronic medical devices. Ad hoc testing should also be considered when checking for age-related changes in medical device RF immunity. Ad hoc testing can be used to estimate the minimum distance that should be maintained between a specific RF transmitter and a specific medical device to mitigate EMI. EMI mitigation policies should be based on objective information, such as that obtainable by ad hoc RF immunity testing.
- RF transmitters purchased for use should have the lowest possible output power rating that can be used to achieve the intended purpose.
- EMI problems should be reported to the manufacturer and to regulatory authorities.
- The health care organization may want to consider obtaining the services of professional assistance in evaluating the electromagnetic environment, solving specific EMI problems, and educating staff.

(Source: Adapted from Association for the Advancement of Medical Instrumentation. "Guidance on Electromagnetic Compatibility of Medical Devices for Clinical/Biomedical Engineers". AAMI TIR 18-1997. Arlington, Virginia)

The IEEE/ANSI C63.18 Standard

Standard C63.18 published by the IEEE provides ad hoc testing procedures for medical equipment as well as policy recommendations for managing and mitigating EMI. The standard serves as a guide for HCOs in "evaluating the radiated radio-frequency (RF) electromagnetic immunity of their existing inventories of medical devices to their existing inventories of RF transmitters, as well as to RF transmitters that are commonly available."¹² The IEEE also recommends using C63.18 for evaluation of newly purchased medical devices and RF

Wireless EMI in Healthcare Facilities

transmitters, as well as for pre-purchase evaluation of said devices. Appendix Three provides specific policy recommendations.

IEEE/ANSI C63.18 Recommendations

1. Consider using the ad hoc test method detailed in C63.18 to test potentially susceptible medical devices;
2. Encourage clinical and biomedical engineers to learn how to assess the electromagnetic environment of their facility;
3. Manage (increase) the distance between sources of electromagnetic disturbance and susceptible medical devices (including cables, sensors, and electrical accessories);
4. Manage (e.g., label, replace, or contact the manufacturer's representative to determine if upgrades are available for) medical devices that are highly susceptible to EMI;
5. Use the lowest output power necessary to accomplish the intended purpose for sources of electromagnetic energy that are internal to the facility and are within the health-care organization's control;
6. Educate staff (including nurses and physicians) to be aware of, and to recognize, EMI-related problems;
7. Share relevant EMI information with others;
8. Consider EMI when planning facility layouts;
9. Consider EMI when purchasing new medical equipment;
10. Educate patients about EMI problem recognition and mitigation, including home-care patients; and
11. Consider retaining the services of an EMC consultant for assistance in characterizing the electromagnetic environment, solving specific problems, and/or educating staff.

(Adapted from: IEEE C63.18, 1997)

Methodological Approach to Evaluating and Managing Wireless EMI

Evaluation, management and mitigation of wireless EMI in healthcare facilities is an ongoing process requiring the participation of all departments in a focused effort to develop policies and procedures appropriate to the organization's electromagnetic environment. Industry associations, standards groups and regulatory bodies have recommended specific EMI management and mitigation guidelines for HCOs to use in developing EMI policies and procedures appropriate to their specific organizational and electromagnetic environment requirements.

Healthcare organizations intent on mitigating EMI should consider training a group of employees (from Information Technology, Biomedical/Clinical Engineering, Telecommunications, Nursing, Physicians, Security, Facilities Engineering, Materials Management) to form an EMI task force. Generally, most end users have limited experience with wireless technology, and it is unreasonable to expect end-users to accurately report on and assess suspected EMI problems, hence the need for a trained, knowledgeable team.

An EMI Task Force would bring a focused and trained group to centralize knowledge, analyze the facility's bandwidth spectrum, and evaluate equipment susceptible to EMI. Task-force members would attend conferences, work with device manufacturers, share resources with other HCOs, and participate in other EMI initiatives. Among their duties would be to perform ad-hoc testing, develop policies, recommend equipment purchases, and develop educational and awareness programs. Identifying and training a Spectrum Manager to manage the task force and be responsible for all wireless and electromagnetic spectrum use at the facility can help departments make solution choices that minimize interference and maximize throughput.

Wireless EMI in Healthcare Facilities

Table Five: Establishing an Organizational Framework for Managing EMI

1. Form an EMI task force

Create a dedicated group representing all healthcare facility departments in order to centralize knowledge, evaluate the facility's electromagnetic environment, and develop policies and procedures for identifying and preventing EMI.

2. Educate

Management, clinical and technical staff should be aware of the issue of EMI in the facility, what policies are in place to manage EMI, the risk of interference, as well as knowledge of how and where to report cases of suspected EMI.

3. Implement EMI Management Policies

HCOs should implement policies as appropriate to their requirements. Potential guidelines include:

- Establish wireless zones and delineate wireless-free zones to safeguard critical medical equipment from risk of EMI;
- Enact a one-meter rule to create separation between RF emitting devices and medical equipment;
- Enable low power transmissions through use of additional base stations and signal repeaters;
- Upgrade telemetry equipment to newly established frequencies in order to mitigate any potential problems with frequency use. The U.S. Federal Communications Commission (FCC) has established 608-614 MHz, 1395-1400 MHz, and 1427-1432 MHz for healthcare telemetry use; and
- Maximize equipment immunity by ensuring new purchases meet IEC requirements.

4. Evaluate EMI

HCOs intent on managing EMI should also establish procedures for investigating and resolving reported cases of suspected EMI. An EMI Task Force is the ideal body to develop and manage a system for testing and evaluating the effects EMI.

- Establish a reporting mechanism for suspected cases of EMI
- Establish a testing mechanism for suspected cases of EMI
 - Define testing protocol
 - Define frequencies/modes of interest
 - Define realistic test conditions
 - Define pass/fail criteria
 - Analyze results carefully
- Use ad hoc testing for EMI when:
 - EMC information for equipment is unavailable
 - An RF source and sensitive equipment are in proximity to each other
 - Purchasing new RF sources and equipment
 - EMI is suspected

Wireless EMI in Healthcare Facilities

Section 3: BlackBerry Overview and EMI Characteristics

BlackBerry: An End-to-End Wireless Solution

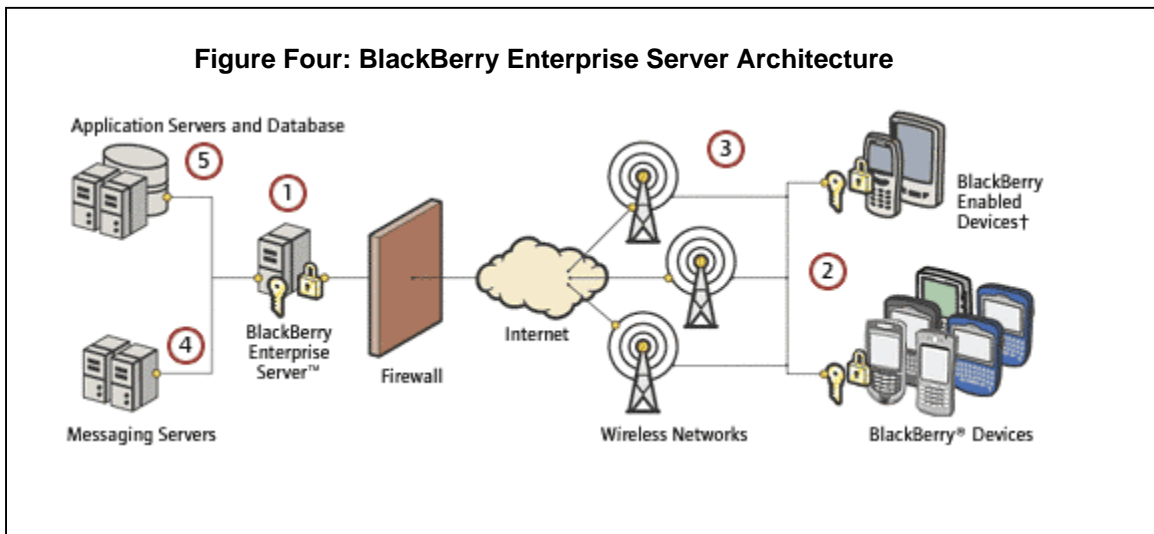
BlackBerry is a complete end-to-end wireless connectivity solution that combines devices, software and services to provide users with effortless, efficient and secure access to a diverse range of applications on a wide variety of wireless devices. BlackBerry solves organizations' business problems by providing a comprehensive, enterprise-wide solution to communication and corporate data access.

Seamlessly operating through third-party carrier networks, BlackBerry provides push-based technology that automatically delivers email and other data to BlackBerry devices. Integrated phone, SMS, web browser and organizer applications available as BlackBerry device features allow users to easily manage all of their information and communication needs from a single, integrated device. Accordingly, BlackBerry has the ability to reduce operating costs by making business processes more efficient, increase revenues by enabling workers to be more productive, and improve the quality and speed of decision-making through rapid, secure distribution of information.

BlackBerry Enterprise Server Architecture

BlackBerry Enterprise Server™ software is securely positioned behind the organization's firewall and tightly integrates with existing enterprise systems. Specifically designed to meet the requirements of enterprises and government organizations, it provides a proven, secure, open architecture for extending wireless communications and corporate data, including email, to mobile users. Enterprise server software options include:

- BlackBerry Enterprise Server for Microsoft Exchange;
- BlackBerry Enterprise Server for IBM Lotus Domino; and
- BlackBerry Enterprise Server for Novell GroupWise.



Key elements of the BlackBerry Enterprise Server architecture include:

1. BlackBerry Enterprise Server software - Robust server software provides advanced security features and acts as the centralized link between wireless devices, applications and wireless networks. The software sits behind the organization's firewall.
2. Broad selection of wireless devices - Organizations and users can choose the devices appropriate to their needs.

Wireless EMI in Healthcare Facilities

- Support for global carrier networks - BlackBerry is supported on over 95 networks in more than 40 countries. BlackBerry devices operate on commonplace and popular networks including: CDMA2000 1X, GSM/GPRS, iDEN and 802.11.
- Integration with messaging servers - The BlackBerry Enterprise Solution™ provides an out-of-the-box solution for wirelessly extending popular messaging and collaboration servers. Supported Enterprise Messaging Servers include: IBM® Lotus® Domino®, Microsoft® Exchange, Novell® GroupWise®, Oracle, SUN
- Wireless extension of application servers and databases - The BlackBerry Enterprise Solution provides the solution components required to wirelessly extend an organization's existing enterprise applications and systems.
 - Supported Enterprise Applications/Environments (ERP, CRM, SCM, NSM) Include: Amdocs Clarify, AS/400, Domino, Linux, NetWare, Oracle®, PeopleSoft®, Remedy, salesforce.com, SAP®, Siebel, UNIX®, Windows®
 - Supported Enterprise Development Frameworks: BEA, Microsoft.NET, Java™ Enterprise Edition (Ea EE[RIM1]), WebSphere
 - Supported Programming Languages Include: HTML, HTTP, JavaScript™, WML, XML
- Support services and programs - Several support services and programs are available to help organizations achieve the full benefit of their wireless solution deployments. Support Services and Programs Include: Corporate Developer Support, BlackBerry Alliance Program, Professional Services, Technical Knowledge Center, Technical Support

BlackBerry Devices

BlackBerry Device Overview

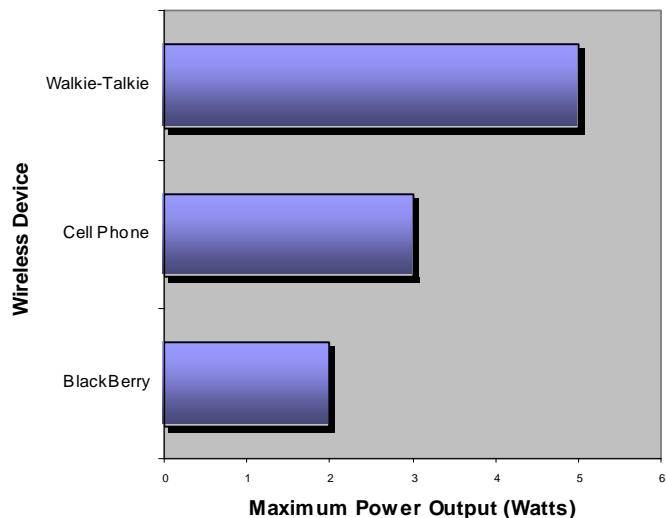
BlackBerry devices provide users with mobile access to email and applications resources. Working in conjunction with the BlackBerry Enterprise Server with BlackBerry Mobile Data Service (MDS), BlackBerry devices provide continuous connectivity, creating a convenient channel for automatically pushing data to users.

Power Control: Low Transmitter Use

The output power of the BlackBerry device varies from 0.06 to 2 Watts; depending on proximity to the base station (the BlackBerry 7270™, designed for WLAN 802.11b, emits a maximum of 30 mW). Refer to Diagram Three for a comparison with other devices. BlackBerry devices have power control features designed to maximize battery life by minimizing transmission output power. A BlackBerry device will transmit only as strong a signal as is necessary to be heard by the base station -- the closer the device to the base station, the lower the output power.

Even though BlackBerry is always connected to the wireless data network, the device's transmitter is nearly always turned off. When the device is in an idle state (i.e., when it is either receiving data or waiting to receive data) the transmitter is not in use. The BlackBerry device turns the transmitter on only when sending data to the network, and this use is occasional and brief (refer to Table Six).

Figure Five: Power Output Comparison



Wireless EMI in Healthcare Facilities

Table Six: BlackBerry Transmitter Use

BlackBerry Action	Total Time Transmitter is Used
Acknowledge receipt of email	0.05 seconds
Send email	0.96 seconds (full packet)
Roam to new base station	0.05 seconds

The transmitter is not used continuously because users are not continually sending email and the time required to send email is very brief (most email takes less than a second to transmit). Because the transmitter is always turned off between emails, even under heavy usage, the transmitter is hardly on at all. For example, a heavy BlackBerry device user might receive 100 emails per day, send 30 emails per day and roam 10 times per day. The total time the transmitter is turned on is $100 \times 0.05 + 10 \times 0.05 + 30 \times 0.96 = 34.3$ seconds. Compared to the usage of a typical cell phone, 34 seconds per day of transmitter use is very slight. During voice transmission, or when using the BlackBerry device as a Push To Talk enabled device, the BlackBerry device will send a continuous stream of pulsed data. When using the Bluetooth feature of BlackBerry (in order to enable voice transmission to and from the hands free headset), the transmitter will operate by sending a continuous stream of pulsed data. Note that system administrators can disable the Bluetooth feature in order to eliminate it as a potential source of EMI. Appendix Two details model specific information in terms of power output and frequency use. For complete technical information about the BlackBerry device's power output ratings, frequency use and transmit times contact a BlackBerry third part solution vendor or Research In Motion.

Conclusion: BlackBerry Adherence to Industry Practice

Each healthcare facility's electromagnetic environment is unique in terms of the mix of devices and medical equipment in use and each organization must develop policies and controls appropriate to its environment. The BlackBerry device's design and power control features make the BlackBerry device an appropriate fit with current healthcare EMI management and mitigation practices.

1. **Low average power output:** BlackBerry devices transmit at power ratings of 0.06 watts to a maximum of 2 watts at frequencies comparable to cell phones which can have higher average power outputs. Accordingly, BlackBerry device EMI risk can be managed through EMI risk reduction measures enacted for cell phones (e.g. the one meter rule). In the worst case scenario, the BlackBerry device is as significant a contributor to EMI risk as digital cell phones.
2. **Dynamic power control:** After establishing an initial connection with the nearest base station, BlackBerry devices will dynamically reduce their transmission power to the minimum required to reach the base station. Therefore, under most normal operating conditions, the BlackBerry device will not transmit at maximum power output. As described, the BlackBerry device transmits at a maximum of 2 watts, falling within the peak power output range of cell phones and other common wireless handhelds.
3. **Brief transmission times for email:** Unlike cell phones and other wireless devices such as PDAs, the BlackBerry device's radio transmitter does not operate continuously when the device is active. The transmitter operates only when acknowledging receipt of email, sending email or during voice communications. Therefore, under most circumstances the BlackBerry device is in an idle state waiting to send or receive data with its transmitter turned off and is not emitting potential EMI causing signals.

No wireless device can claim to be EMI-risk free with absolute certainty; however the design characteristics of the BlackBerry device make it conducive to EMI management and the BlackBerry device is no worse than cell phones in terms of contribution to EMI risk.

Wireless EMI in Healthcare Facilities

APPENDICES

1) Wireless Network Topologies

Network	Technology	Description	Features	Applications	EMI
Peer-to-peer networks		Traditional walkie-talkies, ham radios, public safety radio systems, etc	No power control, constantly transmit at 2-5 watts	Staff communication	Lack of power control combined with high transmission power output make walkie-talkies a high EMI risk
Wireless Personal Area Network (WPAN)	Bluetooth 802.15.1	Ad hoc, mobile, short-range network providing connectivity between devices. Intended to replace physical cable connections by simplifying wireless communication between computers and peripheral devices such as laptops, PDAs, printers and mobile phones..	Range: Effective range of 10-32 feet (10 meters) Transfer Rate: up to 2 mbps. Frequency: unlicensed 2.4GHz band shared with other devices (e.g., cordless phones)	Wireless accessories and links Downloading application data from PDA to desktop computer, sending data to printer from notebook computer	Very low power (~10-100 milliwatts) but may operate in close proximity to other devices
Wireless Local Area Network (WLAN)	IEEE 802.11b/a/g	Substitute for a traditional LAN. Uses electromagnetic radio waves to enable communication between devices in a limited area (e.g., a building).	WLANs provide continuous coverage for devices in a fixed network area, enabling the devices to roam freely within the area covered by the network. Range: 100-500 feet indoors and up to 1000 feet outdoors. Transfer Rate: 11 to 54 mbps. Frequency: 2.4Ghz, 5Ghz	Replacing full functionality of a physical LAN Generally limited to in-building coverage, although "hubs" can access outside networks. Standard mobile phones and many PDA devices	No dynamic power control, transmission in the milliwatt range
Wireless Wide Area Network (WWAN)	CDMA, GSM/GPRS, Edge, iDen	Provide network coverage to areas much larger than WLANs. Compared to WLANs which provide restricted mobility, WWANs enable mobile users to roam larger areas while maintaining access to work-related information and applications.	Usually operated by public carriers using open standards such as CDMA, GSM/GPRS and TDMA. Range: miles. Transfer Rate: 10 kbps - 40 kbps. Frequency: 800, 900, 1700, 1800, 1900 Mhz	Voice, messaging, e-mail and wireless Internet access via handheld devices	Relatively low power, but devices operating at full power and in close proximity to medical equipment can exceed recommended medical equipment EMI shielding standards

Wireless EMI in Healthcare Facilities

2) BlackBerry Device Transmission Data

BlackBerry Device	Transmit Frequency	Power Range	Bluetooth Capability	Voice Capable	Walkie-Talkie Functionality
RIM 950™, RIM 957™	900 MHz"	0.06-2 Watts"			
RIM 850™, RIM 857™	800 MHz"	0.06-2 Watts"			
BlackBerry 5790™	900 MHz	0.06-2 Watts			
BlackBerry 5810™	1900 MHz	"		Y	
BlackBerry 6210™	900/1900 MHz	"		Y	
BlackBerry 6230™	900/1800/1900 MHz	"		Y	
BlackBerry 6280™	850/1800/1900 MHz	"		Y	
BlackBerry 6510™	800 MHz	"		Y	Y
BlackBerry 6710™	900/1900 MHz	"		Y	
BlackBerry 6750™	800/1900 MHz	"		Y	
BlackBerry 7210™	900/1900 MHz			Y	
BlackBerry 7230™	900/1800/1900 MHz	"		Y	
BlackBerry 7250™	800/1900 MHz	"	Voice only, can be disabled	Y	
BlackBerry 7280™	850/1800/1900 MHz	"		Y	
BlackBerry 7290™	850/900/1800/1900 MHz	"	Voice only, can be disabled	Y	
BlackBerry 7510™	800 MHz	"		Y	Y
BlackBerry 7520™	800 MHz	"	Voice only, can be disabled	Y	Y
BlackBerry 7730™	900/1800/1900 MHz	"		Y	
BlackBerry 7750™	800/1900 MHz	"		Y	
BlackBerry 7780™	850/1800/1900 MHz	"		Y	
BlackBerry 7100g™	850/900/1800/1900 MHz	"	Voice only, can be disabled	Y	
BlackBerry 7100r™	850/900/1800/1900 MHz	"	Voice only, can be disabled	Y	
BlackBerry 7100t™	850/900/1800/1900 MHz	"	Voice only, can be disabled	Y	
BlackBerry 7100x™	850/900/1800/1900 MHz	"	Voice only, can be disabled	Y	

Wireless EMI in Healthcare Facilities

BlackBerry 7270™	2400-2484 MHz	30 mW		Y	
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Key:

Y=Yes, feature/functionality is enabled

Wireless EMI in Healthcare Facilities

3) C63.18's Recommendations for Mitigation of EMI in Health-Care Facilities

1. All staff members including medical device users, health-care facility engineers, administrators, architects, and planners can help prevent EMI problems. The first step is to make staff, patients, and visitors aware of the potential effects of EMI on medical devices. Equipment purchased should conform to appropriate EMC standards; however, staff should be aware that devices may meet these standards and yet still have a higher or lower immunity than 10 V/m. Therefore, hospital engineers should scrutinize test reports to determine the immunity of the medical device, the pass/fail criteria used, and the performance of the device during the test.
2. Manufacturer's recommendations for avoiding EMI problems should be followed; any problems should be reported to the appropriate regulatory authorities.
3. Healthcare facilities may need to restrict the use of portable RF transmitters such as hand-held transceivers and cellular telephones in proximity to medical devices. Facility engineers should become aware of the existence and operating characteristics of RF transmitters on the roof (and in the vicinity) of the building. If possible, rooftop RF transmitters found to disrupt the performance of medical devices within the facility should be removed. If it is impractical to remove rooftop RF transmitters and if they are found to cause excessive medical device performance degradation, the susceptible devices should be replaced or relocated to other areas, or shielding of the area should be considered. However, shielding an area can result in problems if RF transmitters are allowed inside the shielded area. Until all medical devices in use meet minimum electromagnetic immunity standards, it may also be necessary to restrict the use in the immediate neighborhood of the health-care facility of two-way radios, particularly mobile radios of moderate to high power such as those used by security, police and fire services, delivery services, shuttle busses, and taxis.
4. Ensuring that medical devices (including cables, sensors, and electrical accessories) are not exposed to ambient RF fields that exceed RF immunity standards can help prevent EMI problems, whether or not a medical device meets minimum electromagnetic immunity standards. This can often be accomplished by maintaining physical separation between the medical device and RF transmitters.
5. EMC should also be considered in the design, site analysis, floor planning, and construction of health-care facilities. Architectural EMC techniques should be used in the design and construction of the facilities. Power distribution should be designed to minimize conducted interference from high-power equipment.
6. Floor planning is important for both new and existing facilities, and for units, in which particularly sensitive devices are used, such as fetal heart monitors, EEGs, and electromyographs (EMGs), should not be located near areas where intense RF emissions can occur, including imaging systems, elevators, or electro-surgery suites. Attention should also be paid to equipment located on floors above and below sensitive medical devices, as well as proximity to outside walls or drive-throughs that might be exposed to mobile two-way radios at close range. Some existing rooms may need to be shielded, in order to ensure proper operation of medical devices.
7. If RF transmitters are used inside shielded rooms that are not lined with adequate RF absorbing material, increasing the separation distance could be ineffective and EMI problems could be worse than without the shielding.

(Source: Adapted from C63.18, IEEE, 1997)

Wireless EMI in Healthcare Facilities

4) Further Information

- Institute of Electrical and Electronics Engineers and its C63 Accredited Standards Committee on Electromagnetic Compatibility
- Association for the Advancement of Medical Instrumentation and Technical Information Report 18:1997
- American Society of Healthcare Engineering and its frequency coordination capabilities for the FCC's Wireless Medical Telemetry Service
- IEC and its 60601-1-2 standard for electrical medical equipment development
- The FDA and its Center for Devices and Radiological Health's MDR database
- Mobile Healthcare Alliance, which recently held a Summit on Electromagnetic Compatibility in Hospitals and Clinics and intends to host such meetings in the future
- Emergency Care Research Institute, which has issued position papers on wireless interference
- American Medical Association and the recommendations it has adopted from the Council of Scientific Affairs
- The Telemedicine and Advanced Technology Research Center of the U.S. Army and the EMI testing work being done at Walter Reed Army Medical Center

5) WWW Resources

Regulatory Agencies	
US FDA Electromagnetic Compatibility Program	http://www.fda.gov/cdrh/emc
FDA/CDRH Recommendations for EMC/EMI in Healthcare Facilities	http://www.fda.gov/cdrh/emc/emc-in-hcf.html
Safety Alerts, Public Health Advisories and Notices from CDRH	http://www.fda.gov/cdrh/safety.html
Medicines and Healthcare Products Regulatory Agency: An Executive Agency of the Department of Health, UK	http://www.medical-devices.gov.uk http://www.mhra.gov.uk/
Industry Associations	
Mobile Healthcare Alliance	http://www.mohca.org/
AMA Policy H-215.972 Use of Wireless Radio-Frequency Devices in Hospitals.	http://www.ama-assn.org/apps/pf_new/pf_online
Association for the Advancement of Medical Instrumentation	http://www.aami.org
Accredited Standards Committee on Electromagnetic Compatibility of the Institute of Electrical and Electronics Engineers, Inc.	http://www.ieee.org/portal/site
ECRI (formerly Emergency Care Research Institute)	http://www.ecri.org
Third-Party	
Center for the Study of Wireless Electromagnetic Compatibility. University of Oklahoma School of Industrial Engineering	http://www.ou.edu/engineering/emc
General information about EMI	http://www.arrl.org/tis/info/rfigen.html

Wireless EMI in Healthcare Facilities

6) Acronym key

AAMI	Association for Advancement of Medical Instrumentation
CDO	Care delivery organization
EMC	Electromagnetic compatibility
EMI	Electromagnetic interference
FCC	U.S. Federal Communications Commission
CDRH	Center for Devices and Radiological Health
FDA	U.S. Food and Drug Administration
HCO	Healthcare organization
HDTV	High-definition television
IEC	International Electrotechnical Commission
IEEE	Institute of Electrical and Electronic Engineers (IEEE)
MDR	Medical Device Reporting
MHRA	Medicines and Healthcare products Regulatory Agency (UK)
PDA	Personal digital assistant
RF	Radio Frequency
WLAN	Wireless LAN
WPAN	Wireless personal area network
WWAN	Wireless WAN

Wireless EMI in Healthcare Facilities

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8) Endnotes

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³ “Characterization of Electromagnetic Interference of Medical Devices in the Hospital due to Cell Phones”, Morrissey et al, Health Physics, December 2001 Vol. 81, Number 6

⁴ Standard C63.18, IEEE, 1997

⁵ “Wireless Interference in Healthcare is Real but Manageable”, Gartner Group, 2003

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⁷ Gartner Group, 2003

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⁹ 2005 Annual HIMSS Leadership Survey: http://www.himss.org/2005survey/healthcareCIO_home.asp

¹⁰ “Use of Handheld Wireless Communication Device in Hospitals and Electromagnetic Interference with Medical Equipment, MOHCA, 2001

¹¹ “ibid

¹² Standard C63.18, IEEE, 1997

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Page: 17

[RIM1] As of June 30th, SUN has communicated that J2EE should now be referred to as Java EE