Office of Evidence Based Practice – Electromagnetic Interference (EMI) Specific Care Question

Specific Care Question What is the effect of electromagnetic interference (EMI) on medical devices?

Source of the Question: CJ Hutto, Senior Director Operations, Patient Care Services.

Team Members:
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Summary:

Based on moderate to high quality evidence a weak recommendation is made to allow the use of cellular phones within the hospital and clinics. The desirable effects of cell phone use are closely balanced with the undesirable effects EMI. Strong evidence from unbiased observational studies supports this recommendation. Evidence for no malfunction occurring was seen in 4 cohort studies and no malfunction occurring at distances ≥ 5cm in an additional 4 cohort studies support the recommendation,

The best action may differ, depending on circumstances or patients or societal values. Since the undesirable effects include the malfunction of medical equipment, the following caveats are made. From the included studies, the median distance for most inference is 10 cm (range: 0-125 cm) or 2 in. (range 0-50 in.). Cohen, et al. (2005) introduces idea of specifying a "sphere of risk" in specific locations medical equipment malfunction has the greatest impact on patient well being (i.e. critical care areas). In most instances the sphere would be ~ 10 cm (4 in.) around medical devices

Policy makers should be aware that EMI comes from various sources (tablet computers, alphanumeric pagers, radiofrequency tags and readers (RFID), walkie-talkies, computers on wheels, wireless monitors etc), not just cellular telephones. See Table 1. The specific effects of the devices included in this review can be found on Table 3.

The FDA regulates the shielding requirements of medical devices. The pre-market shielding requirements have been strengthened. However, the FDA recommends that when a medical device is received for service (or repair) and no problem is found, EMI should be investigated as a possible reason for the malfunction.

Significance and importance of the question:

Children's Mercy Hospitals and Clinics is updating the policies related to use of devices that use radiofrequency (RF) wireless transmission. RF devices emit electromagnetic waves that may interfere with the function of medical devices. Current polices include:

- Provision of Wireless Communication Devices and Related Service Plans- this policy includes alphanumeric pagers, Vocera devices, cellular telephones, wireless air cards, and personal digital assistants, such as Blackberry or Treo"
- Communication Equipment Use and Monitoring- this policy includes Vocera devices
- Cellular Telephones (Wireless Devices), 2-Way-Radios, Pagers, and Personal Digital Assistants cellular telephones (wireless devices) – This policy addresses cellular telephones but does not specifically address the other devices in the title of the policy.

Assuring the safety of patients cared for at our hospitals and clinics is the primary goal. This review serves to summarize the available research on this topic.

Other wireless technologies that are likely to be in use within the CMH healthcare system are:

Table 1.
Sources Electromagnetic Interference

In the hospitals and clinics	In patients' homes
Wireless operating room controllers	Cellular (mobile) phones
Wireless monitors	Wireless PDAs
Wireless PDAs	Appliances
High frequency surgical devices	Electronic products
Diathermy	Two-way radios
Wireless local area networks (WLAN)	Amateur radio
Wireless monitors	
Cellular phones	
Radio-frequency identification devices (RFID)	
High RF power vehicle and portable transmitter radios	
Radars	
RF toll systems (e.g., EZ Pass)	

Adapted from: U. S. Department of Health and Human Services, Food and Drug Administration (FDA). (2007). Radio-frequency wireless technology in medical devices: Draft guidance. (Document number 1618). Retrieved from http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm077272.pdf

Search Strategy and Results:
("Cellular Phone"[Mesh] OR "Wireless Technology"[Mesh] OR "Computers, Handheld"[Mesh] OR iPad[All Fields]) AND (interference[All Fields] OR "Equipment and Supplies"[Mesh] OR "Equipment Failure"[Mesh] OR "Equipment Design"[Mesh] OR "Equipment Safety"[Mesh]) AND ("2002/06/18"[PDat] : "2012/06/14"[PDat] AND English[lang])

"electromagnetic interference"[TIAB] AND ("Cellular Phone"[Mesh] OR "Wireless Technology"[Mesh] OR "Computers, Handheld"[Mesh] OR iPad[All Fields]) AND ("2002/06/19"[PDat] : "2012/06/15"[PDat] AND English[lang])

Results of the Search of PubMed can be found at: http://www.ncbi.nlm.nih.gov/sites/myncbi/collections/public/1tsoMk-Ksup4z5cfq972wk_ku/ (131 articles). Jason Newland, MD (Director, Evidence Based Practice) selected 34 articles to be closely read. 5 of these articles are included in the Carranza 2011 systematic review and are not included as separate articles in this review. Eleven articles were excluded (see Table 2.)
18 articles are included.

The following web sites were reviewed:

https://www.ecri.org/Pages/default.aspx
http://www.sciencedaily.com/releases/2007/03/070308220442.htm
http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/TipsandArticlesonDeviceSafety/ucm225359.htm
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm077210.htm#4

Method Used for Appraisal and Synthesis: Studies were appraised by two reviewers, using the Critical Appraisal Skills Programme (CASP) tools for Cohort Studies. (Public Health Service, 2004) and the Review Manager 5.1 (RevMan)

Results:

1. Cellular technology changes rapidly. Cellular phones used by employees or families can be of any of the supported technologies. Although 1G telephones are no longer in use, 2G phones are still in circulation, but support of the technology is waning. 3G phones (smart phones) are most available, and 4G phones are emerging. Most research has been done on 2G and 3G phones, so as more people use 4G phones, these results may not be applicable.
2. Devices other than cellular phones emit EMI (See Table 1.).
3. There is great heterogeneity across the included studies. See Table 3. Specific devices included in each study are found in Table 4. Heterogeneity is also found in the outcomes assessed. The seriousness of the interference ranged from medical device screens going blank to infusion pumps stopping without alarm. Neither the duration of exposure to the RF device nor the duration of the effect of the interference was discussed.
4. In studies performed with human subjects, sample sizes were small.
5. Findings:
    a. By source of potential interference:
        i. Ten studies evaluated either 2G or 3G phones and disruption of various medical devices. The distance where EMI did not occur ranged from 0-125 cm (0-50 in.) away from various medical devices. Median distance was 30 cm (12 in.)
        ii. One study evaluated an in hospital cordless alpha numeric pager and ECG recordings. No interference was found when the distance was 0 cm
        iii. One study evaluated a wireless local area network (WLAN) and multiple medical devices. The distance where EMI did not occur was >5 cm (2 in.)
        iv. One study evaluated the iPad and VP shunts. The distance where EMI did not occur was > 1 cm.
        v. One study evaluated iPod and generic MP3 players against defibrillators and ECG respectively. The distance where EMI did not occur was > 5 cm (2 in.) and >15 cm (6 in.)
    b. By medical device:
        i. Three studies evaluated the performance of ECG recorders against RF emitting devices. The distance where EMI did not occur ranged from 0-125 cm. (0-50 in.)
        ii. Five studies evaluated the performance of infusion pumps (including syringe and enteral pumps) against RF emitting devices. The distance where EMI did not occur ranged from 0-80 cm (0-32 in.). Median distance was 5 cm (2 in.)
        iii. Four studies evaluated respiratory equipment (ventilators and CPAP/BiPAP). The distance where EMI did not occur ranged from 0-100 cm (0-40 in.) The median distance was 18 cm (7 in.)
        iv. Five studies evaluated the performance of internal and external cardio-defibrillators (ICDs and ECDs) or pacemakers against RF emitting devices. The distance where EMI did not occur ranged from 0 cm to 125 cm (0-50 in.). The median distance was 5 cm (2 in).
        v. Five studies evaluated the performance bedside monitors against RF emitting devices. the distance where EMI did not occur ranged from 2- 125 cm (1-50 in.) The median distance was 30 cm (12 in.)
        vi. One study evaluated the performance of VP shunts against the iPad tablet. The distance where EMI did not occur was 0 cm.

Included Single Study Characteristics and Risk of Bias Tables:

Strahle 2012
Characteristic of included study:

Methods	Cohort
Participants	Ten magnetically programmable shunt valves were tested (Strata Valve, Medtronic, Inc.)
Interventions	• Measured magnetic field strength (magnetic flux density) near 32-GB iPad 2 devices • Magnetic field strength near the tablet was recorded at distances between 0 mm (contact of the device to the magnetometer 0 mm and 100 mm. • Magnetic fields were recorded for the tablet with and without the cover in place. • Two valves were set to 5 different performance levels (0.5, 1.0, 1.5, 2.0, and 2.5). • Valves were exposed to the tablet device at distances of less than 1 cm, 1–2.5 cm, 2.5–5 cm, 5–10 cm, and greater than 10 cm. Each exposure lasted 10 seconds. For each distance tested, the valves were exposed 100 times to a tablet with a cover, resulting in 500 total valve exposures. Following exposure, the valve setting was investigated and performance level was recorded. • The tablet alone, without a cover, was also tested at distances less than 1 cm for 30 valve exposures.
Outcomes	To determine the effect of tablet computer on magnetically programmable shunt valves at different distances.
Notes	

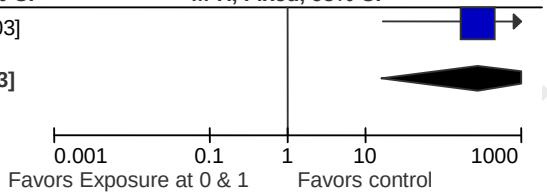
Risk of bias table

Bias	Scholar's judgment	Support for judgment
Random sequence generation (selection bias)	High risk	Unable to Randomize d/t Cohort study.
Allocation concealment (selection bias)	High risk	Unable to conceal d/t Cohort study.
Blinding of participants and personnel (performance bias)	Unclear risk	No participants were used. Unable to blind personnel.
Blinding of outcome assessment (detection bias)	High risk	Not discussed and unlikely d/t Cohort study.
Incomplete outcome data (attrition bias)	Low risk	Unlikely incomplete data was not reported. Although, not discussed.
Selective reporting (reporting bias)	Low risk	Unlikely study used selective reporting. Although, not discussed.
Other bias	High risk	In order to complete a comparison of data this reviewer is making the assumption that "no exposure to the tablet computer" would result in no change in valve settings.

Forrest Plots os Single Study

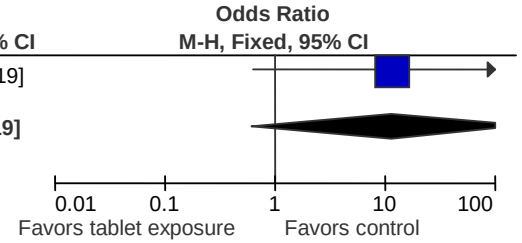
Distance of tablet computer to magnetically programmable shunt (0 and 1 cm.) vs. no exposure to tablet computer. Outcome- Altered valve setting

	Exposure 0 and 1cm		Control			Odds Ratio	Odds Ratio
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Fixed, 95% CI	M-H, Fixed, 95% CI
Strahle 2012	58	100	0	100	100.0%	276.67 [16.71, 4580.03]	
Total (95% CI)		**100**		**100**	**100.0%**	**276.67 [16.71, 4580.03]**	
Total events	58		0				
Heterogeneity: Not applicable							
Test for overall effect: Z = 3.93 (P < 0.0001)							



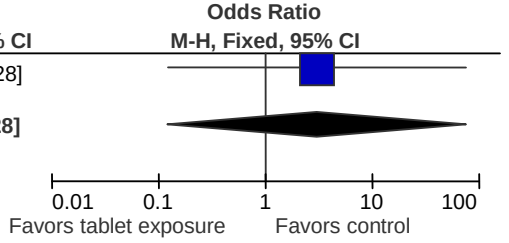
Distance of tablet computer magnetically to programmable shunt (> 1cm to < 2.5 cm) vs. no exposure to tablet computer. Outcome- Altered valve setting.

	Tablet Exposure		No Tablet Exposure			Odds Ratio	Odds Ratio
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Fixed, 95% CI	M-H, Fixed, 95% CI
Strahle 2012	5	100	0	100	100.0%	11.58 [0.63, 212.19]	
Total (95% CI)		**100**		**100**	**100.0%**	**11.58 [0.63, 212.19]**	
Total events	5		0				
Heterogeneity: Not applicable							
Test for overall effect: Z = 1.65 (P = 0.10)							



Distance of tablet computer to magnetically programmable shunt (> 2.5cm to < 5 cm) vs. no exposure to tablet computer. Outcome- Altered valve setting.

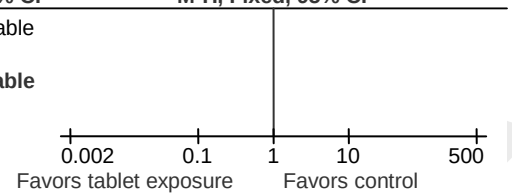
	Tablet Exposure		No Tablet Exposure			Odds Ratio	Odds Ratio
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Fixed, 95% CI	M-H, Fixed, 95% CI
Strahle 2012	1	100	0	100	100.0%	3.03 [0.12, 75.28]	
Total (95% CI)		**100**		**100**	**100.0%**	**3.03 [0.12, 75.28]**	
Total events	1		0				
Heterogeneity: Not applicable							
Test for overall effect: Z = 0.68 (P = 0.50)							



Distance of tablet computer to magnetically programmable shunt (>5 to < 10 cm) vs. no exposure. Outcome- Altered valve setting.

	Tablet Exposure		No Tablet Exposure			Odds Ratio	Odds Ratio
Study or Subgroup	**Events**	**Total**	**Events**	**Total**	**Weight**	**M-H, Fixed, 95% CI**	**M-H, Fixed, 95% CI**
Strahle 2012	0	100	0	100		Not estimable	
Total (95% CI)		**100**		**100**		**Not estimable**	
Total events	0		0				

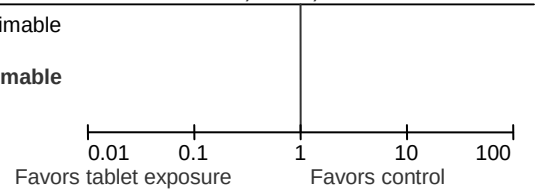
Heterogeneity: Not applicable
Test for overall effect: Not applicable



Distance of tablet computer to magnetically programmable shunt (>10 cm) vs., no exposure. Outcome – Altered valve setting.

	Tablet Exposure		No Tablet Exposure			Odds Ratio	Odds Ratio
Study or Subgroup	**Events**	**Total**	**Events**	**Total**	**Weight**	**M-H, Fixed, 95% CI**	**M-H, Fixed, 95% CI**
Strahle 2012	0	100	0	100		Not estimable	
Total (95% CI)		**100**		**100**		**Not estimable**	
Total events	0		0				

Heterogeneity: Not applicable
Test for overall effect: Not applicable



Synthesis of relevant studies:

Author, date, country, and industry of funding	Devices (See Table 4 for list of devices per study)	Level of Evidence (Oxford)	Research design	Significant results	Limitations
Baranchuk 2009 Canada	Communication devices tested: 3 cell phones 3G (CDMA) 1 in hospital phone- cordless 1 alpha-numeric pager Three ECG Instruments	1b Validating cohort study	Devices were tested on 3 different ECG instruments at 4 distances -(2 m, 1 m, 0.5 m and 0.25 m. and 0 cm in both the active and deactivated mode	No interference was detected when any of the devices were at 2 m, 1 m, 0.50 m, or 0.25 m in either the active or deactivated mode.	Are the ECG instruments similar to those used in our hospital? Reporting bias- They report EMI when a phone is placed on the ECG instrument- it is not a study question at the outset of the study Reporting bias- also occurred when they stated the differences in ECG interpretation among different levels of practitioners (RN, med student, cardiologist). This was not question at the outset, and there could be other reasons for misinterpretation than EMI.
Calcagnini 2004 Italy	Three mobile phones 2G (GSM) were tested against seven infusion pumps and four syringe pumps	1b Validating cohort study	Cohort pump study Outcomes: Interference	Five out of seven infusion pumps and 1 out of 4 syringe pumps were affected by the GSM phones either at 900 MHz or 1800 MHz. The distance varied, did not get better or worse with various MHz or distances. Emitted power (W) of each phone has an effect on EMI Suggest reducing the emitted power (W) will reduce the risk of EMI significantly. GSM phone are designed to reduce W to battery saving if adequate signal is present Install in building amplifiers Install hospital base-stations	It is an old study, cell phone technology has changed since 2004.
Calcagnini 2007 Italy		3a Systematic Review of heterogeneous cohort studies	Systematic Review	The SR includes 6 studies of GSM mobile phones and infusion pumps. The percentage of interference reported is greater in the 1997 included study than in the 2006 included study, suggesting as cell phone and blocking technology becomes more sophisticated, interference becomes less likely. Suggests the probability of EMI would be reduced if the field coverage was increased by installing in-building repeaters amplifiers or dedicated mini base amplifiers	Search strategy is not specific. Method to select include articles is not clear. Did not rate the quality of the included studies. Did not group the studies in any way, due to heterogeneity of the included studies.
Calcagnini	Communication	1b Validating	Cohort pump study	There were 8 syringe pumps, 7 volumetric	Uncertain if technology of

Table 2
Studies excluded from the review

Study	Reason
Aliyev 2010	Case report
Censi 2007	Narrative review
Censi 2010	Narrative review
Ettelt 2006	Narrative review
Hahn 2005	Letter to the editor
Pearce 2009	Abstract
Phunchongharn 2010	Narrative review
Ramesh, 2008	Does not address the question asked
Rogan 2005	Letter to the editor
Ruskin 2006	Narrative review
Simon 2009	Letter

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Table 3. *Study Summary, by RF and Medical Device*

Author, date, country, and industry of funding	RF device					Medical device- This is not inclusive of all devices. Many studies looked at many devices, not included here						Greatest distance where interference did not occur
	Cellular phone GSM CMDA	In hospital cordless Alphanumeric pager	WLAN	iPad tablet	MP3 players	ECG	Infusion pump (incl syringe pumps)	Resp equip Vents & Cpap/Bipap	Defibrillators ICDs ECDs and pacemakers	Bedside monitors	VP Shunts	
Baranchuk 2009 Canada	x	x				x						0 cm
Calcagnini 2004 Italy	x						x					0 cm
Calcagnini 2008 Italy	x						x					30 cm
Calcagnini 2011 Italy			x				x	x	x	x		5 cm
Dang 2007 Canada	x							x				1 m (40 in)
Hans 2008 India	x							x		x		30 cm (12 in)
Ismail 2010 Germany	x								x			0 cm
Helhel 2011 Turkey	x					x			x	x		1.25 m (50 in)
Strahle 2012 USA				x							X	2 cm
Thaker,					X				x			5 cm (2 in)

2008 USA					(iPod)							
Tri 2005 USA	x						x		x	x		80 cm (32 in)
Tri 2007 USA	x						x	x		x		0
Trigano 2006 France	x								x			2 cm
Webster 2008 USA					x	x						15 cm (6 in)
Total	10	1	1	1	2	3	5	4	5	5	1	
Calcagnini 2007 Italy	Systematic review					States interference between 1.5-5% if the time. There was in inverse relationship between the distance from the medical device and the interferences. Major recommendation is to decrease power emitted by increasing coverage						Restrict use of mobile phones, 1 m, 1.2 m, 0 for PHS phones
Carranza 2011 Spain	Systematic review -EMI of GSM (2G) phones on infusion pumps.					Effect s: none, hazardous, % with possible real damage, interferences on the screen, cardiac rhythm changes and malfunction display						200 cm, 8.6 cm; 10 cm; 0 cm (PHS phones, Asia);
Guertin 2007 USA	GI procedure room electrocautery vs. defibrillators											
Houliston 2009 New Zealand	RFID tags placed on medical devices evaluated interference when in proximity to two RFID readers, one high power and one low power vs. infusion pump					The high power RFID reader interfered with the infusion pump when an RFID tag was on the infusion pump and the high power reader was within 10 cm of the pump						
Kruk, 2003 Australia	Guideline from New South Wales											

Table 4. *Type of Electromagnetic interference device and medical device in the included studies*

Study	EMI Device	Medical Instrument
Baranchuk 2009	GSM- (Motorola V220; 900 MHz, 1800 MHz, 1900 MHz) CDMA- (Sanyo SCP 2300; 800 MHz, 1900 MHz) Analog phone (Nokia 6275i; 800 MHz) In-hospital cordless phone- (Nortel WLAN Handset 2211; 2 400–2483.5 MHz) Alpha-numeric pager -(Suntelecom ST800 Flex; 900 MHz).	ECG instruments MAC 5000 (General Electric, Chicago, IL, USA) MAC 1200 (General Electric, Chicago, IL, USA) ELI 100 (Mortara, Milwaukee, MN, USA)
Calcagnini 2004	Motorola V3688 Nokia 3510 Ericsson SH888	Infusion pumps (not specified) From the following manufacturers Alairs Abbot Nutricia B|Braun
Calcagnini 2008	Nokia 6125- Type RM178 (max ear SAR 0.64 W/kg) Nokia 6070-Type RM166 (max ear SAR 0.88) Siemens C72 (max SAR 0.70)	Infusion pumps (year of fabrication) Alaris - Asena PK-MK III (2005) Alaris - Asena CC-MK III (2001) Alaris - CC Guadrails (2007) Bbrown Perfusor Compact (-) Fresenius Pilot A2 (-) Fresenius Orchestra DPS (-) Alaris PK 2007 (2007) Alaris SE 7131 (2007) Alaris 7231 (2002) Alaris 7101 (1999) Abbott lifecare 5000 (2002) Bbraun infusomat FMS (-) MicroMacro XL (-) Orchestra Module MVP PT Tyco Kangaroo 624 2002 Nutricia Flocare 800 2000

Calcagnini 2011	Local area networks WLAN IEE 802.11 b/g 2.45 Ghz, 100 mW	Medical devices (not by brand name, but by type)
Dang 2007	MRK Ericcson GE (radio) 810-815 mHz/ Samsung 680 (TDMA) idle mode Samsung 680 (TDMA) conversation mode Samsung 680 (TDMA) search mode Motorola v300 (GSM) idle mode Motorola v300 (GSM) conversation mode Motorola v300 (GSM) search mode	Puritan-Bennet 7200 (adult) at 1.0m Siemens Servo 300 Pulmonetics LTV 1000 (adult) at 0m Draeger Babylog 8000 (ped) at 0m Bird VIP GOLD (Ped) at 0m Respironics BiPAP Synchrony at 0m Siemens Servo 300 Pediatric CPAP Sullivan III
Guertin 2007	Unipolar electrocautery device: Endostat TM !! Bipolar/Monopolar Electrosurgical Generator (Boston Scientific Natik, MA, USA)	Placement of ICDs Transvenous left pectoral implants n=40 and one left abdominal implant
Hans 2008	GSM- (Motorola V3i, Nokia 6600, and Nokia 5310) CDMA- (LG 5130)	Syringe infusion pumps- B Braun Mechanical ventilator- Versa Med Bedside monitor- Philips-Intellivu MP40
Helhel 2011	GSM900 GMS1800 3G	Cardiofax (Effort-1 ECG Intensive Care Monitor Serum Equipment Cardiofax (Surgical Unit) Cardiofax (Surgical Unit) Delivery Unit Equipment Dialysis equipment Ultrasound equipment Non-Stres Test Equipment X Ray Equipment Neurofax (EEG) Injector Equipment Emergency Baby Care Unit Monitor Causally Department Monitor

Item	Number of models tested
Syringe pumps	4
Volumetric pumps	8
Enteral pumps	2
Defibrillators	8
Monitors	11
Lung ventilators	5
Anesthesia machines	6
External pacemaker	1

		Defibrillator EMG Equipment
Tri 2005	Cellular phone technologies Code Division Multiple Access (CDMA) Global System of Mobile communications (GSM) Integrated Digital Enhanced Network Time Division Multiple Access Analog	Philips Viridia 24C vital sign monitor ○ With Rev 1001A ECG/Resp module (older module) ○ With Rev 1002B ECG/Resp module (newer module Hewlett-Packard (Merlin) component monitoring system ○ With Rev 1001A ECG/Resp module (older module ○ With Rev 1002B ECG/Resp module (newer module)⁄⁄None NA Xltek EEG desktop system With Mobee amplifier With Mobee amplifier and patient connected Philips IntelliVue MP 70 monitor Propaq 104 portable patient monitor Marquette/GE ECG cart Nellcor N-595 Pulse Oximeter Zoll M series defibrillator Baxter Colleague Volumetric Infusion Pump Datascope System 97 Intra-Aortic Balloon Pump Siemens ventilator Nellcor Puritan Bennett 840 Ventilator System Respironics Esprit 2581 ventilator TBird Legacy 15812 portable ventilator B Datex-Ohmeda Aestiva anesthesia system Philips 2600 telemetry pack b`
Tri 2007	Nokia 3587i CDMA Nokia 3120 GSM	Xltek EEG system with Mobee Amp Philips VS1 vital signs monitor Respironics CPAP machine Philips IntelliVue MP30 and MP70 patient monitors Baxter COLLEAGUE Volumetric Infusion Pump Siemens ACUSON Sequoia ultrasound system GE Vivid 7 cardiovascular ultrasound system Medtronic 5388 external pacemaker Puritan Bennett 7200 Ventilatory System Nellcor Ross Patrol enteral feeding pump Hospira, Bard CritiCore System urine output monitor

		LifeCare PCA Plus 3 Infusion Pump Hospira, Philips Model M4841A Telemetry Pack Philips Viridia 1176 Patient Monitor Baxter blanket heater and water pump Abbott LifeCare PCA3 Infusion System Puritan Bennett 840 Ventilator System Philips IntelliVue with intracranial pressure monitoring capability Aircast VenaFlow System Nellcor OxiMax N-595 pulse oximeter GE DINAMAP PRO 100 noninvasive blood pressure monitor Datascope CS100 with IntelliSync counter pulsation balloon pump Total No. of medical devices 192 24
Trigano 2006	GSM receiver PCS receiver (Personal Communication Services)	LifePack 20 monitor/defibrillator LifePak 20P monitor/defibrillator/stimnulator HeartStart XL M4735A monitor/defibrillator
Webster 2008	Apple Nano Apple Video SanDisk Sansa Microsoft Zune	29 unique pacemaker/.ICD models Manufactures: Medtrionic, Inc (15 models, 27 devices Boston Scientific Corporation/Guidant (7 models, 13 devices St. Jude Medical Inc.(7 models, 11 devices)