APPLICATION

NYU Hospitals Center (NYUHC)

PURPOSE

To establish guidelines for the safe use of wireless technology in NYUHC facilities.

POLICY

The use of wireless devices shall be regulated as follows:

1. **Cell Phone** use is permitted in *almost all* areas of the NYUHC without restrictions. Cell phone use is restricted in the following area:

   - **OR Services (i.e., all anesthetizing and procedural areas):** The use of cell phones in operating rooms facilitates communication which can significantly improve the quality of healthcare. Therefore staff are permitted to use cell phones in these locations under the following conditions:
     - They are educated about the potential for cell phones to interfere with energized medical devices, and to report all incidents involving the malfunction of medical devices to Clinical Engineering promptly for evaluation. See Appendix A for Supplemental Educational Materials.

   NOTE: Air waves are unprotected and conversations may be intercepted by other telephones. Refrain from the disclosure of protected health information during cellular phone conversations to prevent the breach of a patient's right to confidentiality.

2. **Two-way Radios** may be used *in the receive mode only* in all patient care areas.

   Procedures for Emergency Use of Two-Way Radios in Restricted Areas

   Whenever maintenance staff, security officers, EMS personnel, Life Flight employees, or other personnel with two-way radios are in a patient care unit and an emergency occurs which requires the use of their radio, they should make their best effort to adhere to the following guidelines, which are listed in order of preferred compliance:
   - Leave the patient care unit to use the two-way radio. (Interference created by RF devices is minimized as the distance between the RF device and the affected equipment is increased.)
   - Keep the two-way radio at least ten (10) feet away from any energized medical device.
   - If output levels are adjustable, use the lowest setting possible that still facilitates acceptable communications.

- If any equipment in the vicinity of the radio user should malfunction while the radio is in use, terminate use of the radio immediately. Any further use should be conducted from the visitor waiting area or a non-patient care unit.

3. **Laptops and Notebooks** must undergo ad-hoc testing against the major medical equipment to ensure that they do not cause any interference.

RATIONALE FOR POLICY

It was previously the policy of NYUHC to prohibit the use of cellular telephones, two-way beepers, and wireless devices in all patient care areas due to concerns that medical devices may be susceptible to electromagnetic interference (EMI) from wireless communications devices. At the request of the Medical Board, this policy was reevaluated in the summer of 2007 and again in the spring of 2009. A summary of the issues discussed follows:

1. **Evaluation of Risk**
   Risk of patient harm is believed to be extremely low, but not zero.
   - Recent articles have suggested that the risks associated with EMI from cell phones is a diminishing concern since newer cell phone technology produces lower EMI and newer medical devices have improved electromagnetic compatibility. Most notably, a study of the use of cellular telephones in the hospital environment, published by the Mayo Clinic in March 2007, was designed to determine whether cellular telephones used in a normal way would cause interference with medical devices located in patient care areas of hospitals. The authors' conclusion was that "when cellular telephones are used in a normal way, no noticeable interference or interactions occurred with the medical devices." It is important to note that this study did not include the PICU and OR suites. The restrictions in this policy are recommended because certain areas are deemed to be at higher risk than, or different from, those included in the Mayo Clinic study.
   - Ad-hoc testing by Clinical Engineering found no EMI interference between BlackBerry devices and a wide sample of medical equipment used at NYUHC.
   - Despite apparent widespread non-compliance with the previous cell phone policy, there were no reported incidents of suspected medical device failure associated with EMI from cell phones at NYUHC from 2007 to 2009. In 2006, one potential incident was reported; however it is believed that this was more likely user error as the pump setting was reported to have spontaneously changed from 0.4 to 1.4 cc/hour.
   - The following cautionary guidance is provided by ECRI in a December 2006 article: "While the risks may have diminished somewhat, they have not disappeared, so

continuing to enforce certain restrictions is justified. And, in fact, there are some well-documented reports of cell phones affecting medical devices. Therefore, we urge hospitals to modify cell phone use policies only with a full understanding of the facts, and we strongly recommend against lifting cell phone restrictions entirely."

2. **Evaluation of Past Policy**

   Enforcement of a more restrictive policy proved to be very difficult and ineffective. Very frequent reminders were required and overall compliance was low. Most people did not actually turn off their phones; they "complied" by not speaking on their cell phones or placing them in silent mode while keeping them turned on. Phones that are powered on still emit a polling signal even when not in use. For these reasons, the reviewers felt that a restrictive policy had limited efficacy in reducing the potential risk of EMI.

3. **Benefit of a Less Restrictive Policy**

   Uncertainty and concern with regard to EMI have acted as major obstacles to the full deployment of wireless technology in many facilities. Proper application of wireless technology has the potential to increase productivity, decrease costs, and generally improve the quality of healthcare. Cell phone use may provide clinical benefits by providing a fast, convenient way for doctors and other parties to communicate. This is supported in an article in the February 2006 issue of *Anesthesia and Analgesia* (Soto et al.) that concluded that cell phone use offers clinical benefits that outweigh the risks of EMI.

   In the past, Nursing staff reported that caregivers spent significant time and effort in an effort to make patients and visitors comply with restrictions. They believe relieving this enforcement responsibility facilitates patient/family satisfaction and reduces avoidable conflict.

PROCEDURES

1. **Signage:** Signage will be posted at the entrances to the NICU and PICU: "CELLULAR PHONES **MUST** BE TURNED **OFF** BEYOND THIS POINT."

2. **Electromagnetic Compatibility (EMC):** The Purchasing Department will incorporate language in future bid requests and contracts to require manufacturers to certify the electromagnetic compatibility of the requested medical device(s) as defined by international EMC standards. For example, NFPA 99, Standards for Health Care Facilities, paragraph 9-2.1.6.4, states, "All appliances shall be designed so that they are capable of operating in a radio frequency electromagnetic environment where limits are established by IEC 60601-1-

2". The Center for Devices and Radiological Health (CDRH), a division of the FDA, in cooperation with the Association for the Advancement of Medical Instrumentation (AAMI) has also developed guidance standards for medical device manufacturers seeking pre-market approval.

3. **Incident Reporting:** Any suspected incidents of medical device electromagnetic interference must be reported to Clinical Engineering. Clinical Engineering will investigate each incident, develop recommendations, and report findings to the Patient Safety Officer, Risk Management, the Clinical Safety Committee and/or the EOC Committee as appropriate.

4. **Special Cases**

   - **Implanted Devices**: Patients and staff with implanted devices such as pacemakers; defibrillators, etc. must exercise caution when carrying and using wireless devices. Recommended procedures, as delineated by the medical device manufacturer must be followed.
   - **Emergency Vehicles**: Operators of Hospital emergency vehicles, which transport patients with sensitive medical devices, and their supervisors, must be cognizant of the fact that two-way radios / beepers and cell phones can cause electromagnetic interference at close range. Medical devices used in these applications must be carefully selected for this demanding application.

5. **Review and Exceptions:** Clinical Engineering should be called for any questions about the applicability of using and enforcing the use of wireless devices.

   - **Review**: Clinical Engineering will continue to review technical publications and standards for trends and updates relating to this issue and communicate noteworthy advances to the NYUHC Clinical Safety Committee. Clinical staff will contact Clinical Engineering (212-263-5021) if they suspect that the function of a medical device has been affected by an EMI generating device. All such incidents will be investigated by Clinical Engineering and reported to Risk Management.
   - **Exceptions to the Policy**: Exceptions to this policy must be approved by the Clinical Safety Committee.

6. **Effective Period for Policy:** This policy is effective immediately and will remain active until it is changed or deemed unnecessary by the NYUHC Clinical Safety Committee. Any questions pertaining to this issue should be directed to NYUHC Clinical Engineering at 212-263-5021.

Appendix A	Supplemental Educational Material Considerations for Working with Cell Phones in Operating Rooms

Issue date	06/15
Replaces	04/12
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- The undisciplined use of cellular devices in the OR—whether for telephone, e-mail, or data communication, and whether by the surgeon or by other members of the surgical team—may pose a distraction and may compromise patient care.

- Surgeons should be considerate of the duties of personnel in the OR suite and refrain from engaging them unnecessarily in activities, including assistance in cellular communication, that might divert attention from the patient or the conduct of the procedure.

- Cellular phones must not interfere with patient monitoring devices or with other technologies required for patient care.

- Whenever possible, members of the OR team, including the operating surgeon, should only engage in urgent or emergent outside communication during surgery. Personal and routine calls should be minimized. Calls should be kept as brief as possible.

- Whenever possible, incoming calls should be forwarded to the OR desk or to the hardwired telephone in the OR to minimize the potential distraction of cellular phones.

- Whenever possible, cellular telephone calls and data transmissions should be forwarded to voice mail or to memory. The ring tone should be silenced. An inaudible signal may be employed.

- Whenever possible, a distinct signal for urgent or emergent calls should be enabled. This signal may be implemented via a “page” option in most cellular telephones. Callers should be advised to use this function only for urgent and emergent calls if the phone is unanswered.

- The use of cellular devices or their accessories (such as earphones or keyboards) must not compromise the integrity of the sterile field.

- Special care should be taken to avoid sensitive communication within the hearing of awake or sedated patients.

- Communication using hardwired phones in the operating room is subject to the same discipline as communication using cellular technology.

- The use of cellular devices to take and transmit photographs should be governed by hospital policy on photography of patients and by government regulations pertaining to patient privacy and confidentiality.