

**FINAL REPORT OF THE
EDUCATION WORKGROUP**

December 17, 1998

The following is a list of possible preventive measures that can be taken:

- The use of cellular telephones, two way radios and all other portable radio frequency (RF) generating devices should be prohibited in patient equipment dependent locations (PEDL's). PEDL's are areas where interference induced equipment malfunctions (cardiac and apnea monitors, ventilators, infusion pumps, defibrillators and alarm systems) have the potential to cause serious injury or death to the patient.
- The use of RF transmitting devices should be restricted from within 3 feet of any electronic medical devices. This is based on the eleven month risk assessment performed at Walter Reed Army Medical Center, which clearly indicated that interference from equipment within this range had the potential to sufficiently interfere with equipment operation.
- As outlined in a proposed Ad Hoc test procedure from the FDA's C-63 document, "Whether or not a medical device meets minimum electromagnetic immunity standards, assuring that the medical device is not exposed to ambient RF fields that exceed its radiated immunity, can help prevent interference problems. This can often be accomplished by maintaining physical separation between the medical device and RF transmitters. While the field strength to which a medical device is exposed can only be determined accurately by precise RF measurements, if the radiated immunity of a medical device and the peak effective radiated power of a transmitter are known, the distance to be maintained between them to help prevent interference, referred to as the "protection distance," can be estimated within approximately an order of magnitude".
- Other areas of possible restrictions are loading docks, emergency room driveways and any areas where the use of possible vehicular radios and phones could cause equipment degradation. Vehicles that may cause problems are delivery trucks, taxis, etc. that use high-powered radios or cellular devices for mobile communication. Consideration may be given to have pay phones available on loading docks to allow delivery personnel to contact their dispatcher without utilizing their wireless devices.
- All radio frequency producing electronic equipment ordered for use in the medical treatment facility should be approved by the medical equipment service and repair manager/supervisor to ensure that the equipment conforms to EMC standards and maintain the projected area of use for electromagnetic compatibility prior to the purchase order going to the contract office. The medical equipment service and repair manager/supervisor should be given the authority to restrict the type of equipment purchased in order to minimize the risk. Equipment purchased should conform to appropriate EMC standards. International Electromechanical Commission (IEC) standard 601-1-2 specifies a general immunity test level of 3 V/m. More specific EMC requirements may be specified in product-specific standards. Equipment that meets these standards can have a higher or lower immunity. Therefore, the medical equipment service and repair manager/supervisor should examine the EMC test report to determine the pass/fail criteria used and how the medical device performed during the test. Specifications and/or the SOW (Statement of Work) involving the procurement of new equipment should require manufacturers conformance to IEC 601-1-2.

and other complex solid state components. These devices operate at low energy levels and high speeds making the very susceptible to electrical power noise. However, at the same time they often contribute to the power noise levels in the system as well. The term power quality is commonly used within power utilities in regard to power related EMI problems. High quality indicates a lack of power line disturbances. Therefore, a power quality audit is important to know and understand as a baseline measurement.

- The primary purpose of a grounding system is the control of undesirable electrical currents, fault currents, electrostatic discharge currents, high frequency noise currents, etc. To improve the performance and reliability of the required electronic load equipment to acceptable levels, it is often sufficient to follow the National Electrical Code (NEC) safety requirements and nationally recognized engineering practices (e.g. ANSI. IEEE) and guidelines (e.g. (Federal Information Processing Standard (FIPS)) and correct obvious deficiencies in the AC power wiring and grounding configuration and correct poor wiring installation methods.
- Electromagnetic Shielding is the process whereby susceptible devices are encased in materials, usually metals to prevent stray RF from entering and interfering with the intended design of the device. In some instances, the rooms themselves are shielded that house a particular device from stray RF and also to prevent the device from interfering with other devices (e.g. MRI). This is usually designed by the manufacturer or the Biomedical Engineer to shield a component from stray RF (e.g. a TV monitor used in an MRI suite is being affected by the magnetic field, a properly designed box placed around the monitor can correct the situation).

Cooperation with other Agencies

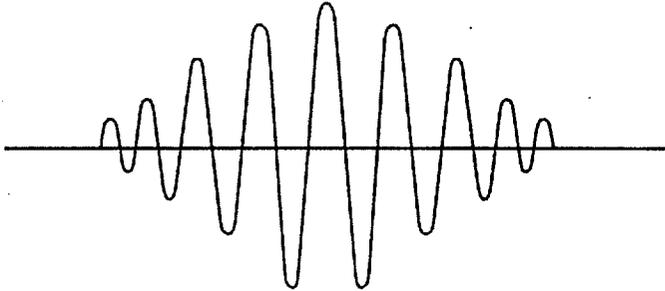
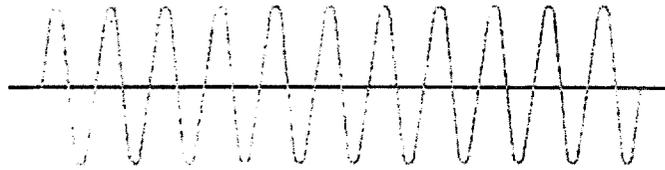
- a) Hospital Departments*
- b) Outside Agencies*
- c) Professional Societies*

For total coverage in the hospital all departments must be on board as a source of information, information is a two way medium. Therefore your number one source of cooperation lies in your own institution. Outside agencies such as JCAHO, FDA, ECRI, etc. are also excellent sources of information and testing data. Again professional organizations such Engineering, Nursing and Medical societies are also avenues for assistance.

FINAL REPORT OF THE WORKGROUP DEFINING
WIRELESS MEDICAL TELEMETRY

December 17, 1998

YADIN DAVID, CHAIR



FINAL REPORT OF THE WORKGROUP DEFINING MEDICAL TELEMETRY

The working group recently completed its task of formulating a definition for present and future applications of medical telemetry systems. The process for arriving at the definition included a series of information exchanges between representatives from the user community, manufacturers of wireless medical telemetry equipment, members of the task force, the regulatory group, and information from professional societies. All input received was reviewed and considered before action was taken. Information received from other working groups, such as the data collected by the working group on parameters driving the spectrum allocation was considered as well. Via the internet, colleagues in other hospitals and professional organizations were able, in a fairly short time frame, to respond to various versions of the definition's draft presented to them. It is the intent of this working group to facilitate the safe, interference-free, and robust use of medical technology in general, and of medical telemetry in particular, at present and for the foreseeable future. This major effort should focus, as it does, on patient's needs and the capacity of medical telemetry to meet those needs.

Wireless Medical Telemetry is defined as follows:

Medical telemetry is defined as a measurement of something at a distance. Wireless medical telemetry is therefore defined as the measurement and recording of physiological parameters and other patient-related information via radiated bi or unidirectional electromagnetic signals. This technology may be contained within a healthcare facility or extend beyond to other buildings and locations.

**FINAL REPORT TO THE AMERICAN
HOSPITAL ASSOCIATION TASKFORCE
ON MEDICAL TELEMETRY**

December 17, 1998

PREPARED BY THE PHYSIOLOGIC PARAMETERS WORKGROUP

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**FINAL REPORT TO THE AMERICAN HOSPITAL ASSOCIATION
TASKFORCE ON MEDICAL TELEMETRY
December 17, 1998**

EXECUTIVE SUMMARY

The Physiologic Parameters Workgroup was created to determine the spectrum bandwidth required to accommodate the needs of medical telemetry. These needs were determined through surveying fourteen hospitals of various sizes in both metropolitan and suburban/rural areas and various professional groups (Attachment A). Based on these survey results, the Workgroup determined what the spectrum needs would be today if appropriate patient care and communication technology were available to the medical community. The physiologic monitoring needs were defined as follows:

CURRENT TELEMETRY MONITORING NEEDS	
Physiologic Parameter	Number of Concurrent Patients
adult electrocardiogram	200 - 600
pulse oximetry	16 - 210
obstetrical (fetal/maternal) parameters	0 - 150
invasive pressures	17 - 420
respirations	4 - 210
12 sets of episodic data, e.g. noninvasive blood pressure, temperature.	up to 500 patients

The telemetry manufacturers represented in the Workgroup have determined that with the use of sophisticated communications technology, these physiologic parameters can be accommodated utilizing the following bandwidth:

Physiologic Parameter	Concurrent Patient Use Model	Required Bandwidth
electrocardiogram	500	4.000 MHz
pulse oximetry	250	0.150 MHz
obstetrical parameters	100	1.300 MHz
invasive pressures	300	0.400 MHz
respirations	100	0.025 MHz
12 sets of parametric data	500	0.250 MHz
TOTAL		6.125 MHz

These bandwidth calculations were based on a spectral efficiency of 0.8 bits per second per Hertz (the current FCC spectral efficiency recommendation).

This bandwidth will accommodate only today's patient care needs. There are several factors which will result in significant growth in spectrum needs over the next ten years. The main factor influencing this growth is that the patient acuity is rising, e.g. patients entering the hospital are sicker. This means that

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1. WORKGROUP OBJECTIVE

The objective of the Physiologic Parameters Workgroup was to determine the spectrum bandwidth required to accommodate the needs of medical telemetry.

2. PATIENT SAFETY CONCERNS TODAY

In the current secondary user status, medical facilities proactively manage the patient risks associated with interference by avoiding utilization of frequencies occupied by licensed users in their geographic area and by reacting to transient interference from often unknown sources. This transient interference is encountered several times per week (6-12 times depending on the reporting institution), potentially affecting a significant number of patients.

The Physiologic Parameters Workgroup appreciates the need to reallocate spectrum related to digital television and the need to reallocate and redistribute spectrum related to land mobile communications. However, the Workgroup is concerned that the transitional situation lends itself to loss of monitoring capabilities because of the following reasons.

- As broadcasters receive digital television frequency allocations and as frequencies utilized by land mobile radio services expand, the remaining frequencies available for use by medical telemetry is diminished in both the UHF and the VHF bands. In certain geographic locations, this issue is very critical.
- Although the FCC granted use of the upper UHF band (470-668 MHz), these bands are still subject to interference from broadcast and low power television services use. There are currently no products available on the market which utilize that band and given the risk of interference from broadcast and low power television in that band, introduction of these products will be slow at best. Therefore, this grant of spectrum has no practical impact on the shrinking availability of frequencies for use by medical telemetry.
- Although television broadcasters have voluntarily been notifying healthcare facilities in their broadcast region of their intent to begin use of different frequencies, these notifications are not necessarily addressed to the hospital personnel which understand and can react appropriately to that notification.

Given these factors, the Physiologic Parameters Workgroup is concerned that the potential for interference still threatens the safety of the patient population. One of the primary purposes of patient monitoring is early detection of life-threatening physiologic developments so that appropriate intervention can be rendered in a timely manner in support of recovery. Unavailability of spectrum severely restricts the clinicians' ability to provide that intervention. The Workgroup firmly believes that the inherent risks to patient safety caused by the potential for interference and subsequent loss of monitoring capability can

5. TRENDS IMPACTING FUTURE GROWTH

Although the survey data presents a **current** snapshot of the telemetry monitoring needs, there were several very immediate market forces that will increase those needs very dramatically in the future. The Workgroup believes that the unpredictable impact of those market forces has led to a very broad range of anticipated growth rates (from 3% to over 400% in 10 years) to be reported through the survey process.

The relevant market forces are as follows.

- As decreasing reimbursement encourages further cost containment, hospitals are pressured to use innovative approaches to monitoring needs. Toward that end, the respondents were excited about growing capabilities to utilize wireless technologies in support of patient care because of its inherent flexibility.
- As a cost containment and quality improvement effort, hospitals desire to house patients in the specialty ward that is most capable of addressing that patient's acute healthcare needs. While it is not financially feasible to equip every bed in the hospital with a hardwired patient monitor, it is financially feasible to provide for the patient's monitoring needs via telemetry at virtually any location in the hospital. Hence, there is an emerging population of patients that require physiologic monitoring outside of the traditionally hard-wired monitoring wards. Frequently, the monitoring needs of those patients exceed that of the electrocardiogram that has traditionally been provided via telemetry. Therefore, there is also a growing need to include data acquisition from stand-alone equipment, monitoring devices, and therapeutic devices via telemetry.
- Healthcare institutions aggressively pursue reduction in patient lengths of stay as a means of achieving cost containment. One of the methods used to achieve a reduced length of stay is encouraging earlier ambulation while continuing to monitor the patient. This cannot practically be achieved through use of hard-wired technology.
- Consolidation of health care providers continues to escalate. As these healthcare enterprises are developing, it is difficult to predict the monitoring models which will emerge within the enterprise and consequently it is difficult to predict the volume of telemetry services that will be needed. It is certain that the needs will increase as the telemetry services are consolidated and begin to monitor patient populations that do not reside on the campus of the monitoring hospital. These external patient locations may include community based hospitals, ambulatory surgery centers, and long term facilities, and may even support home health care.
- There is a new demand for telemetry in the obstetrical environment. Currently, some expectant mothers need to ambulate during labor in order to promote progression of their labor. Without telemetry, there is no practical means for monitoring, which places this population at risk for negative outcomes.
- It is difficult for clinicians to forecast their monitoring needs prior to the emergence of new technologic capabilities. In other words, prior to the development of a new monitoring capability, it is difficult for the clinician to anticipate its volume of usage.

6. BANDWIDTH REQUIREMENT TO SUPPORT TELEMETRY NEEDS

spectrum. In addition, the Workgroup recommends that the Federal Communications Commission give careful consideration to these future spectrum needs in making a dedicated spectrum allocation for medical telemetry. Furthermore, given that the results of the ASHE survey regarding medical telemetry equipment suggests that hospitals will continue to utilize their existing telemetry equipment well into the future, an extended transition period is recommended.

FINAL REPORT TO THE AMERICAN HOSPITAL ASSOCIATION TASKFORCE ON MEDICAL TELEMETRY

December 17, 1998



PREPARED BY THE SPECTRUM SELECTION WORKGROUP

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**FINAL REPORT TO THE AMERICAN HOSPITAL ASSOCIATION
TASKFORCE ON MEDICAL TELEMETRY
December 4, 1998**

EXECUTIVE SUMMARY

The Spectrum Selection Workgroup was created in response to the potential for interference from digital television transmissions and private land mobile radio operations to patient-connected wireless monitoring. Changes in spectrum use for these two services have created uncertainty and concern to medical telemetry users. To address this concern, this Workgroup's mission was to:

- identify spectrum candidates for future medical telemetry use
- evaluate these candidates against objective criteria
- develop specific recommendations for the American Hospital Association (AHA), that will lead to the implementation of dedicated, exclusive spectrum for medical telemetry needs

Three frequency bands are being recommended for dedicated spectrum allocation for medical telemetry operations. These bands include:

- 608 MHz to 614 MHz (TV channel 37)
- 1385 MHz to 1390 MHz
- 1432 MHz to 1435 MHz

Medical telemetry operation should be considered as "primary" status on these bands, preventing incompatible transmissions from causing unacceptable interference to wireless patient monitoring systems.

These three frequency bands are in addition to present medical telemetry spectrum allocations under 47CFR Part 15 and Part 90 of the Federal Communications Commission (FCC) Rules. Within this frequency spectrum (174 MHz to 216 MHz - TV channels 7 through 13; 460 MHz to 470 MHz; 470 MHz to 668 MHz - TV channels 14 through 46), medical telemetry must still operate, but do so as a "secondary" status user, having to accept potential interference from, and to avoid creating interference to, "primary" status users.

The additional recommendations of this Workgroup are:

- New spectrum allocations for medical telemetry should permit the use of flexible communications technologies (e.g. spectrally efficient modulation schemes, telecommand, non-vital signs data, etc.).

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1. GOALS FOR MEDICAL TELEMETRY SPECTRUM SELECTION

In attempting to consider spectrum candidates for medical telemetry use, this Workgroup assumed the following goals for guiding its deliberations:

- **Dedicated, interference-free, spectrum**

Digital television (DTV) services in the VHF spectrum (174 MHz to 216 MHz), and the desired deployment of more spectrally efficient communications devices in the Private Land Mobile Radio portion of the UHF spectrum (450 MHz to 470 MHz) have created two threats to medical telemetry operations. The first threat is the demonstrated potential for disruption of medical telemetry patient monitoring in both frequency bands. The second threat is the limitation of telemetry monitoring growth due to medical telemetry's FCC regulatory status ("secondary") in these bands. There is insufficient spectrum for increases in telemetry channel growth as "primary" users extend their usage of a shared band.

- **Spectrum bandwidth to accommodate 1000 telemetry transmitters**

The profile of telemetry patient monitoring is changing. While cardiac patients are still the largest segment of monitored patients in telemetry, more acute patients are being monitored, as are the supplemental devices (e.g. ventilators, infusion pumps, etc.) that support them. It has been observed that many hospitals currently have in excess of 300 patient-connected transmitting devices in use at one time. Initial surveys have indicated that within 10 years, medium to large hospitals will use 1000 patient-connected transmitting devices. With this increase in acute patient monitoring, other vital signs measurements, in addition to ECG, will be added to medical telemetry. Accordingly, this additional telemetered patient data will require suitable spectrum bandwidth for present and future patient populations. The mission critical nature of this increased patient data underscores the requirement that a spectrum candidate be dedicated, exclusive, and free of potential interference.

- **Flexible spectrum allocation to accommodate different applications**

Clinical users will drive different applications for medical telemetry.

- **Propagation Characteristics**

The physical transmission path loss (the attenuation of the radiated telemetry signal through the air and the physical structures within the hospital) of the proposed spectrum candidate was evaluated relative to the current predicate medical telemetry bands. The noise floors (the level of other undesired signals from atmospheric, space, or man-made sources, from which the desired telemetry radio signal must be extracted by the telemetry receiver) and susceptibility to multi-path fading (the propagation properties of two or more electromagnetic waves from the same telemetry transmitter that interfere with each other to attenuate the desired signal at the telemetry receiver) were also reviewed. These characteristics have direct impact on recurring cost of ownership (e.g. battery costs) and initial installation and equipment costs (e.g. upgrade/migration feasibility, antenna system deployment, receiver complexity).

- **Safety Considerations**

This requirement took into account the amount of RF radiated power that the patient, as well as other sensitive medical instrumentation would be exposed to. In general, the higher the operating frequency, the more radiated power is required to overcome additional path loss.

Specifically, the Workgroup reviewed ANSI/IEEE C95.1-1992 for the maximum permissible partial body exposure allowed for an uncontrolled environment. In order for the proposed spectrum solution to meet this requirement, the energy that, in the transmitter in the proposed spectrum solution would need to radiate, must be lower than the C95.1 limit.

The Workgroup also examined the potential for each of the proposed spectrum candidates to require telemetry products to generate field strengths in excess of 3 volts per meter (refer to the international electromagnetic susceptibility standard of EN60601-1-2). These fields could create possible electromagnetic interference to other medical devices.

- **Product Implementation Considerations**

The final requirement is the availability of commercial RF components and low cost field support instrumentation. This is required to bring new product to market in a timely fashion, and to facilitate the site survey/installation process.

3. WORKGROUP INPUTS

Respirations	100	1	0.025 MHz
12 sets of parametric data	500	0	0.250 MHz
TOTAL			6.125 MHz

This use model is based on the assumption of 500 concurrently operating telemetry transmitters today, and a 0.8 bit per second per Hertz spectral efficiency metric currently recommended by FCC (see 47CFR 90.203, Section 3). This results in a spectrum bandwidth requirement of 6.1 MHz (note that nearly 10 MHz is in use today for 25 kHz channelized telemetry units in the UHF band, and approximately 12 MHz in use for 100 kHz channelized telemetry units in the VHF band). This amount of spectrum is expected to double to more than 12 MHz if one considers a growth in 5 to 10 years to 1000 telemetry transmitters. Thus, a potential spectrum band candidate must have at least 6 MHz in available bandwidth.

- **Spectrum Candidates**

The following frequency bands (MHz) were considered for use for medical telemetry operations:

- ◇ 174 - 216
- ◇ 216 - 220
- ◇ 328 - 335
- ◇ 402 - 406
- ◇ 450 - 470
- ◇ 470 - 668
- ◇ 608 - 614
- ◇ 746 - 806
- ◇ 902 - 908
- ◇ 1385 - 1390
- ◇ 1432 - 1435
- ◇ 2385 - 2390
- ◇ 2390 - 2400
- ◇ 3650 - 3700

4. EVALUATION OF SPECTRUM CANDIDATES

The attached spreadsheet below summarizes the evaluation on the final spectrum candidates. Earlier candidates were dismissed due to their potential for in-band/adjacent band interference; inadequate bandwidth; their current FCC regulatory status; undesirable path loss and power requirements; or limited merchant market support for off-the-shelf RF components.

Extent of changes needed to FCC rules	3	4.60	3.00	3.00	2.50
Weighted Ranking		408.00	376.50	319.80	267.83
SMI Ranking		420	394	306	254
HP Ranking		344	322	234	252
MQ Ranking		422	376	316	266
VC Ranking		419	0	335	251
TCH Ranking		409	0	405	0

Comments on 608 - 614 MHz (TV 37):

- ◇ multiple component vendors available with off-the-shelf parts
- ◇ requires frequency coordination around radio astronomy facilities as defined in 47CFR 2.106 (US 311)
- ◇ telemetry can be compatible with radio astronomy
- ◇ currently authorized for medical telemetry by FCC 97-379
- ◇ band is not internationally harmonized
- ◇ estimated path loss is 6 dB greater than that at 470 MHz
- ◇ measured indoor path loss was 3 dB greater than that at 470 MHz
- ◇ spectrum surveys revealed low noise floors in Workgroup member locations

Comments on 608 - 614 + MHz (TV 14 to TV 46):

- ◇ similar characteristics to 608 MHz to 614 MHz
- ◇ medical telemetry already granted "secondary" status
- ◇ unused television channel spectrum near TV 37 may be available on a "secondary" status basis in regional areas where use of TV 37 bandwidth is exceeded or areas of the country where "radio quiet" zones exist and coordination for "primary" status may not be available
- ◇ unused TV channels in this band may be used by LPTV without notification

Comments on 1385 - 1390/1432-1435 MHz:

- ◇ multiple component vendors available with off-the-shelf parts
- ◇ band has geographic exclusion zones affecting AK, AL, AZ, CA, FL, ID, MD, NC, NM, NV, OH, UT, VA, WA. (See NTIA web-site for Final Spectrum Reallocation Report, Appendix F of NTIA Special Publication 95-32)
- ◇ grandfathered radars shut off after 2008

- ◇ band is not allocated in Regions 1 (Europe, Africa) and 3 (Australia, East Asia)
- ◇ estimated path loss is 17 dB greater than that at 470 MHz
- ◇ spectrum surveys revealed low noise floors in Workgroup member locations

5. RECOMMENDATIONS

Given existing exclusion zones and frequency administration requirements around the two proposed dedicated candidate bands, and the prospect that growth for medical telemetry will need more than 12 MHz of spectrum once 1000 telemetry devices are required, the Spectrum Selection Workgroup makes the following recommendations:

- Medical telemetry should seek “co-primary” status for the 608 - 614 MHz band (TV37), and “primary status” for 1385 - 1390 MHz/1432 - 1435 MHz band.
- Current Medical telemetry spectrum allocations (174 - 216 MHz/460 - 470 MHz/470 MHz - 668 MHz) should continue. Existing users of this equipment who are not at risk of interference from “primary” status users may still use these bands under existing rules.
- The American Hospital Association (AHA) should serve as the frequency administrator for the medical telemetry industry. In this capacity, AHA can speak for the Hospital users and their spectrum needs. Further, for those Hospital users whose spectrum needs exceed the bandwidth capacities of the above dedicated primary status bands, AHA can advise manufacturers and end-users on clear, “secondary” spectrum status, and alert end-users when these bands may be licensed by primary status users (such alerts will be necessary to permit these medical telemetry “secondary” users to gracefully relocate to other acceptable spectrum). This role is needed to give medical telemetry single point representation in spectrum allocation discussions and facilitate industry migration to the dedicated frequency bands.
- All new spectrum allocations for medical telemetry shall permit the use of flexible communications technologies, including, but not limited to, bi-directional transmissions (telecommand), spectrally efficient modulation schemes, and non-vital signs data (e.g. voice).
- The Spectrum Selection Workgroup strongly urges the AHA to retain legal counsel for purposes of promptly preparing and submitting petitions embodying the intent of these recommendations.