

Technical Bulletin:

**Interference Testing Results of the LifeSync® Wireless
ECG System**

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Background:

This Bulletin focuses on: 1) The coexistence of the LifeSync® Wireless ECG System which uses a Bluetooth® wireless technology radio with other Industrial, Scientific and Medical (ISM) band (2.4-2.5 GHz) users; 2) the robustness of the LifeSync® System in a high noise environment. (i.e. the LifeSync® System's ability to continue to communicate normally in the presence of in-band radiators such as Wi-Fi, microwave ovens, or electrosurgery devices); and, 3) the ability of Wi-Fi or other potential users operating in the 2.4 GHz ISM band to continue to function normally with the LifeSync® System present.

Discussion:

The LifeSync® System has been extensively tested for reliability in an environment where various other 2.4 GHz RF systems are operating concurrently. Conversely, the performance of competing devices for the unallocated 2.4-2.5 GHz RF space was observed to determine the impact of the LifeSync® System on these systems. All testing to date has shown that the LifeSync® System is able to operate reliably up to 30' in open spaces (no walls) even when significant interference is present with no impact on the operation of other users in the 2.4 GHz ISM band. Specific tests performed include:

- Coexistence testing with Wi-Fi (802.11b) in a hospital environment,
- Coexistence testing with Welch Allyn Micropaq® Monitor (802.11 FH) in a hospital environment,
- Operation in the presence of electrosurgery (ES) devices,
- Operation as close as 1' from a microwave oven;
- Operation as close as 1' from other Bluetooth® wireless technology devices.

Testing:

- I. **Coexistence with Wi-Fi (802.11b):** Testing was performed with the LifeSync® System functioning at a hospital in Rochester, MN where an 802.11b IT network was operating. The Wi-Fi access points were set to 30 mW transmission power and the Wi-Fi laptops were set to 100 mW transmission power. Typical range from laptop to access point was up to 40'. Table 1 shows the various combinations of equipment positions and settings.

General Test Conditions:

- The Wi-Fi data transmitted consisted of 128 packets of size 1500 bytes. The Wi-Fi data rate was fixed to 11 Mb/s.
- Network sniffing consisted of checking throughput and retry limit error event. The retry limit error event was set to 64.
- A Cisco IP phone was also intermittently turned ON during the test to increase the collision probability in the 2.4 GHz frequency space.

Table 1
Wi-Fi and LifeSync® System Coexistence Test Results Summary

Separation Distance		Wi-Fi Throughput	Retry Event	LifeSync® System Data Lost	IP Phone Status
Laptop to Access Point	Laptop to LifeSync® System				
40'	6'	589.11 KB/s	None	None	OFF
40'	6"	568.04 KB/s	None	None	ON
40'	Off	574.32 KB/s	None	None	N/A
4'	6'	584.31 KB/s	None	None	ON
4'	Off	575.00 KB/s	None	None	N/A

Note: The typical Wi-Fi throughput is roughly 5 Mb/s (575 KB/s * 8 bit/byte * 1.1) (for packet overhead)

802.11b Coexistence Conclusion: There was not a measurable impact on the performance of the Wi-Fi system with the LifeSync® System operating even at a separation distance of 6". The 4% variance (589 vs. 568 KB/s) in throughput was most likely due to network traffic given that the IT network was not taken out of service during the test but was required to remain live by the hospital facility where the test was performed. There was no data lost by the LifeSync® System in the 802.11b operating environment.

- II. **Coexistence with 802.11 FH – Welch Allyn Micropaq Monitor:** Testing was performed with the LifeSync® System functioning at a hospital in Boston, MA in an area where the Welch Allyn Micropaq Monitors and Acuity System were already installed and operating. See Figure 1 – Experiment Layout.

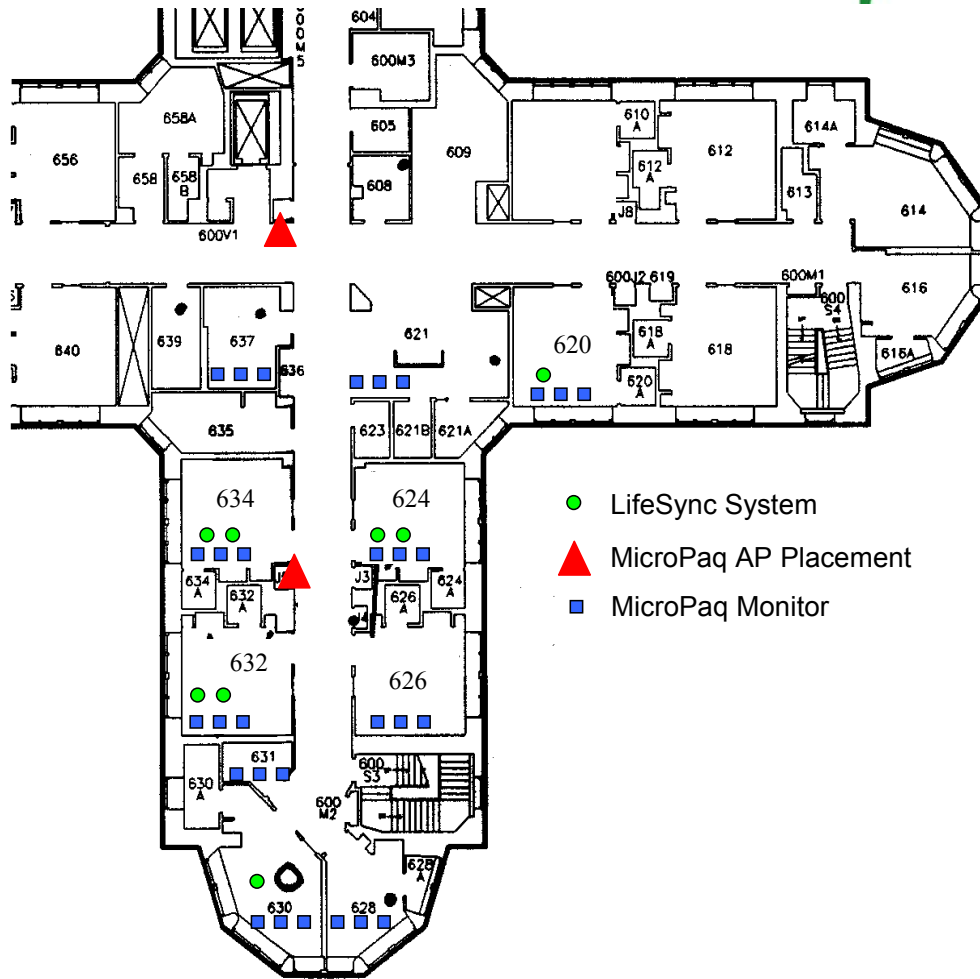


Figure 1
Experiment Layout

Test Conditions for the coexistence test were:

- Eight LifeSync® Systems were deployed in five patient rooms - rooms 620 (1), 624 (2), 630 (1), 632 (2), 634(2)
- Separation distance between the Patient Transceiver and Monitor Transceiver was 5'(1), 10'(3), 15'(3) or 20'(1).
- Three Micropaqs monitors were deployed in each of the five patient rooms with LifeSync® Systems in close proximity. See Figure 2 showing that the MicroPaq monitors were typically placed less than 1' from the LifeSync® System Patient Transceiver(s). Three Micropaqs were deployed in each of five other patient rooms – rooms 621, 626, 628, 631, 637
- ECG data was monitored and recorded from the 8 LifeSync® Systems for approximately 18 hours with and without the MicroPaq monitors operating.

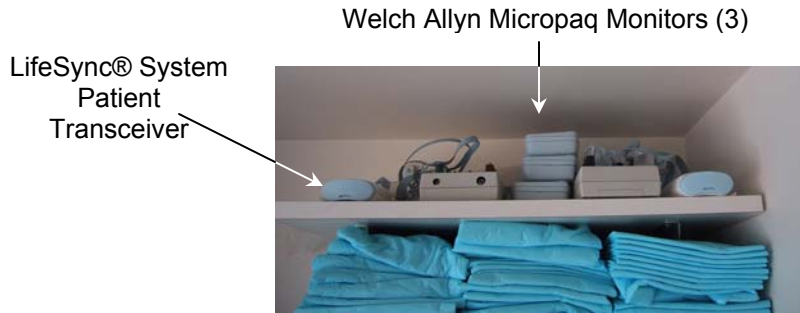


Figure 2: Typical Micropaq and LifeSync® System Placement

802.11 FH Coexistence Conclusions: There was no discernable difference in the LifeSync® System performance with or without the Micropaq operating. Additionally, the LifeSync® System performed the same regardless of whether the transceivers were separated by 5', 10', 15', or 20'. Similarly there was no discernable difference in Micropaq system's performance with the LifeSync® System operating as compared with normal function of the Micropaq.

- III. **Electrosurgical Interference Suppression (ESIS) Tests:** The LifeSync® System was tested in a laboratory environment per ANSI/AAMI EC13:2002 Standard for Cardiac Monitors, Heart Rate Meters, and Alarms - Section 4.2.9.14 for ESIS. An Aspen Labs MF380 Electrosurgery (ES) system was used for this test. The LifeSync® System was tested while the ES was set for 300 W cut and 100 W coagulation mode. See Figure 3 for test setup.

Figure 3 - LifeSync® System ESIS Test Setup





1. At no time during the ESIS testing was there loss of the Bluetooth® wireless technology radio link.
2. ES set to 300 W cut - The ECG waveform was virtually unaffected and the heart rate indicated by the monitor remained unchanged. The respiration waveform became somewhat noisy and was sometimes driven off screen. However, the patient monitor without the LifeSync® System exhibited similar performance.
3. ES set to 100 W coagulation - The ECG waveform had slightly visible increased noise yet the calculated heart rate was steady and remained unchanged. The LifeSync® System was then eliminated from the test and the Propaq connected directly to the test fixture. The Propaq ECG waveform was virtually unaffected in the coagulation test.

ESIS Test Conclusion: The LifeSync® System meets industry requirements for electrosurgical interference suppression¹

- IV. **Other Interference Testing:** The LifeSync® System has been tested by the manufacturer in the presence of other potentially interfering devices such as a microwave oven while popping popcorn. This tends to generate a large amount of broadband noise especially in the 2.4 GHz range. Multiple LifeSync® Systems were operated in close proximity to the microwave oven with no observed interference.

Finally, the LifeSync® System was tested in the same radio space as other Bluetooth® wireless technology enabled devices. Ten LifeSync® System transceivers were setup on a table and monitored for continued operation while a Bluetooth® wireless technology enabled mobile phone headset was operating.

- V. **Electromagnetic Compatibility Testing:** The LifeSync® System meets the strict requirements for emissions as dictated by CISPR 11 Class B limits as called out in IEC 60601-1-2 - "Requirements for Safety: Electrical Medical Equipment – Electromagnetic Compatibility"

Summary Conclusions:

Based on extensive testing performed by the manufacturer, the LifeSync® System can be expected to operate reliably in a hospital and other healthcare settings, even one where other 2.4 GHz wireless systems are operating. We suggest testing of any wireless system, especially patient telemetry, in the environment that it is intended to operate to assure safe and reliable operation.

¹ ANSI/AAMI EC13:2002 "Cardiac Monitors, Heart Rate Monitors, and Alarms" Section 4.2.9.14

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