



# NIHON KOHDEN

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Mr. Donald W. Witters, Jr.

Subject: Comments on Document #1618  
Radio Frequency Wireless Technology in Medical Devices, Draft Guidance for  
Industry and FDA Staff, dated January 3, 2007.

Dear Mr. Witters,

I am very pleased to see this guidance document on Radio-Frequency wireless technology. As a distributor of patient monitoring products, I am glad that the FDA is recognizing the importance of: wireless coexistence, wireless quality of service (QOS) and the integrity and security of data transmitted wirelessly.

My sales team is often asked by hospital departments to ride on both their wired and wireless backbone.

This request issued by the hospitals IT departments, that are trying to standardize their care delivery models, is becoming more prevalent. My sales team is routinely receiving Request For Proposals (RFP's) that require patient monitoring devices to use the hospital's infrastructure, networks, routers, switches and other similar devices. I find this request very troubling as your guidance document, as I understand it, regulates manufacturers, not hospitals.

No two-hospital infrastructures are the same and as such, we must have to rely on the hospitals numbers for QOS, latency and uptime as they have, in essence, manufactured their own networks

Historically, hospitals have verified their networks but from my understanding and experience, they do not understand the validation process and as such the numbers provided to my staff are often times grossly inadequate. As a result, it is difficult for me, as a distributor, to verify and accept the accuracy numbers provided to me by hospitals regarding QOS, latency and uptime for both their wired and wireless networks. This problem is further compounded by the fact that I have been told by the major manufacturers of wireless networks that Voice over IP takes the highest precedent for QOS because of bandwidth requirements. It is extremely alarming that patient safety and mission critical alarms, takes a lower priority over telephone and other communications technologies.

I have been working in the patient monitoring industry for 30 years and I have always placed quality and patient safety as my number one concern. It is for this reason that I suggest that the FDA takes the following actions to provide this industry with a guidance document that places patient safety as it's number one priority.

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**NIHON KOHDEN AMERICA, INC.**

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1. Expand the scope of this document to cover both wired and wireless networks
2. Inform hospital Risk Managers, CIO's, Clinical Engineers and CEO's of this guidance document.
3. Notify hospitals that if an adverse life-threatening event occurs due to the hospital's network being down, inoperative or critical alarm data being lost that; the hospital shares the same exposure and liability as the distributor/manufacturer.
4. Treat the issue of network interoperability and coexistence on the same level of WMTS and suggest to the AHA that a task force is formed to investigate the full ramifications associated with network interoperability and coexistence.

I look forward to any comments and/or responses you may have and pledge my company's support and resources should a task force or committee be formed.

Sincerely,

A handwritten signature in black ink, appearing to read "Mike Dashefsky". The signature is stylized and written in a cursive-like font.

Mike Dashefsky



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