

**Statement by the RFID Blood Consortium  
On Published Article in Journal of the American Medical Association**

*‘Will RFID in the Blood Product Supply Chain  
Potentially Interfere with Critical Medical Devices?’*

The Journal of the American Medical Association (JAMA) on June 24, 2008 published the results of a 2006 Amsterdam study during which 41 medical devices were tested for electromagnetic interference (EMI) from active 125 kHz and passive 868 MHz RFID systems. A series of 123 tests produced 34 EMI incidents. The study involved realistic power levels and medical devices located at various distances from the RFID source. The RFID Blood Consortium being led by BloodCenter of Wisconsin (Milwaukee, WI) notes that the study appears to have been well designed and executed.

The RFID Blood Consortium has received a considerable number of inquiries about the implications of the study’s findings for the RFID system it is developing to enhance the productivity and safety of the blood product supply chain. The proposed RFID system for blood product tracking will utilize passive 13.56 MHz technology whose properties are considerably different than the active 125 kHz and passive 868 MHz RFID technology investigated in the Amsterdam study. A primary reason 13.56 MHz was selected as the standard is the restricted range of its electromagnetic field that would naturally limit the potential for EMI, and still meets the operational needs for handling blood/blood products.

To date, no EMI incidents with passive 13.56 MHz have been noted in studies, to our knowledge, even with minimum separation (>0 cm) between RFID source and medical device. The RFID Blood Consortium will continue working with leading vendors of 13.56 MHz RFID technology to be kept informed should any EMI-related issues arise.

The FDA Safe Medical Devices Act of 1990 specifies that manufacturers of medical devices are responsible for ensuring proper EMI shielding of their devices. Beyond this, CDRH draft guidance regarding RF Wireless Technology in Medical Devices proposes a framework in the design, development and evaluation of RF technology in medical devices. Each device should use the frequency best suited for its intended use, and the electromagnetic compatibility (EMC) of the device be considered on two fronts – ability to function properly in its intended use in the electromagnetic environment, and that it avoids excessive electromagnetic energy. The use of 13.56 MHz (HF) for blood has taken this into consideration.

Due to the wide range and possible spectrum of RF/wireless devices and technologies already in use, CDRH has provided recommendations to hospitals about implementing various RF/wireless technologies. The biomedical engineering operation at individual hospitals is responsible for ensuring that wireless infrastructure and medical technology are compatible on a continuous basis as medical equipment technologies evolve. As we move forward with our study, members of the Consortium will be delighted to work with any hospital to assist in recommending proximity of medical equipment to the passive 13.56 MHz used in our study.

On behalf of The Blood Consortium

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