



Interference with the operation of medical devices resulting from the use of radio frequency identification technology

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Abstract

Aim To replicate electromagnetic interference (EMI) with a common drug infusion device resulting from the use of radio frequency identification (RFID) technology in a simulated operating theatre environment.

Method An infusion pump, of a type previously reported as having failed due to RFID EMI, was placed in radio frequency (RF) fields of various strengths, and its operation observed. Different strength RF fields were created by varying the number of RFID readers, the use of a high-gain RFID antenna, the distance between the reader(s) and the infusion pump, and the presence of an RFID tag on the infusion pump.

Results The infusion pump was not affected by low-power RFID readers, even when in direct contact. The pump was disrupted by a high-power reader at 10 cm distance when an RFID tag was attached, and by a combination of high-power and low-power readers at 10 cm distance.

Conclusions Electronic medical devices may fail in the presence of high-power RFID readers, especially if the device is tagged. However, low-power RFID readers appear to be safer.

Recent years have seen a slow but steady increase in the use of RFID systems in hospitals. The two major components of RFID systems—readers and tags—are comparable in function to barcode scanners and labels. An RFID reader transmits an RF signal, which is picked up by any nearby tags. Each tag responds with a signal of its own, which encodes data such as a unique identification number.

The reader picks up each tag's response signal, decodes the data, and passes it on to a suitable information system for processing.¹ This wireless communication gives RFID technology a number of advantages over barcodes, in particular the ability to read multiple tags simultaneously without requiring a direct line-of-sight.

These advantages have seen RFID used in hospitals for applications such as patient and staff identification; 'smart cabinets' for secure storage of drugs and supplies; real-time tracking of beds, wheelchairs, and other equipment; and checking for retained surgical items.²

Many types of RFID technology are available to suit the requirements of different applications. Systems that operate within a very small area, such as checking for retained surgical items, typically use handheld, battery-operated, low-power readers, and passive tags, which are powered by the energy in the reader's RF signal.

Systems that operate over a large area, such as tracking equipment, are more likely to use mains-powered, wall- or ceiling-mounted, high-power readers and/or active tags, which are powered by on-board batteries.

A widely acknowledged risk of deploying RFID technology in the hospital environment is electromagnetic interference (EMI) affecting the operation of other electronic medical devices. Research on other technologies that produce EMI, such as mobile phones and wireless computer networks, have shown that they can cause electronic medical devices to function in unexpected ways, or even to fail.³⁻⁵ However, there has been little published research testing the effect of EMI produced by RFID technology specifically. What has been published has tested RFID systems in non-hospital environments, such as Irnich's experiments with pacemakers and electronic security systems in shops.⁶

Two recent articles,^{7,8} testing common types of RFID technology and a wide range of electronic medical devices in realistic hospital settings, are welcome additions to the literature. Both research teams adopted a similar approach: An RFID reader was placed around 2 m away from various electronic medical devices, and then moved closer or further away to determine the maximum range at which EMI affected each device.

Despite this common method, the two teams reported quite disparate findings. Christe et al⁷ report that, in 1600 tests of passive RFID technology operating in the ultra-high frequency (UHF) range, they found no interference with any medical device at any distance tested (from 30 cm up to 1.8 m).

Van der Togt et al⁸ report that, in 246 tests of passive and active RFID technology operating in the UHF range and the low frequency (LF) range, they found 68 instances of interference with the medical devices. This interference ranged from minor effects (such as unexpected noises coming from computer monitors) to potentially hazardous failures (such as infusion pumps and ventilators stopping), and occurred at distances from 1 cm to 6 m away from the device.

Given the other published research, the results of Christe et al⁷ seem surprising. The complete lack of interference found by these authors raises the possibility that some of the results were false negatives, perhaps due to a flaw in the design or execution of the experiments.

Both research teams were using high-power RFID readers, transmitting at their maximum output power of 4 W. Van der Togt et al⁸ note this as a limitation of their research, and note its impact on their results: "the number of EMI incidents increased with higher output power of transmitting RFID systems" (pg 2889).

In many developed countries, telecommunications regulators limit the maximum power output of RF transmitters to 4 W in the UHF frequency band. Under New Zealand regulations,⁹ 4 W is permitted only for RF transmitters that employ specific measures to reduce EMI, such as frequency-hopping. Otherwise the maximum power level permitted is only 1 W.

Our group is currently using low-power, handheld UHF RFID technology as part of a research project at Auckland City Hospital (ACH) and the University of Auckland's Advanced Clinical Skills Centre (ACSC) on improving patient safety during

anaesthesia.¹⁰ RFID readers are placed at various locations around theatre, including close to infusion pumps, ventilators, and other electronic medical devices.

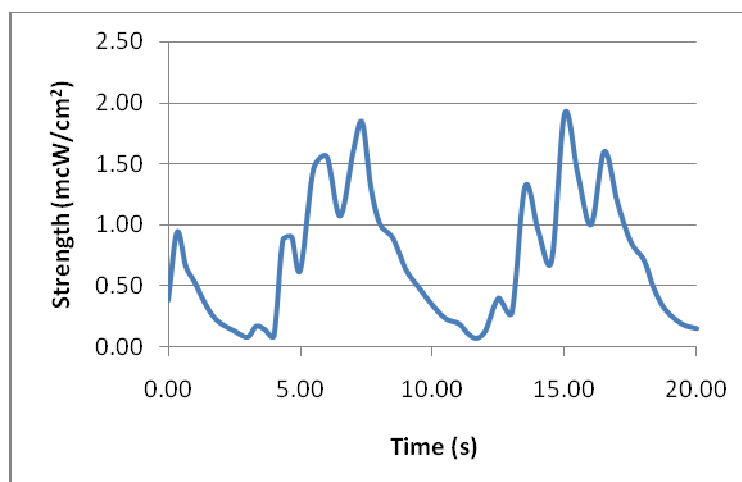
It was therefore considered prudent to replicate one of the serious device failures reported by van der Togt et al,⁸ in order to evaluate the EMI risk posed by low-power RFID readers and whether further study was warranted. This paper presents the results.

Method

Of the medical devices tested by van der Togt et al,⁸ the Graseby 3500 infusion pump appeared to be one of the most sensitive to EMI, experiencing a serious failure at a distance of up to 1 m. Therefore we decided to test a Graseby 3500 infusion pump in these experiments. The pump tested had been in regular use, without any apparent malfunction.

The research project under way at ACH uses the Tracient Padl-R passive UHF RFID reader. This reader has been designed specifically to produce very low levels of EMI. Note that this paper uses the term 'power' to refer to the power output by an RFID reader. When referring to the 'power' experienced by a medical device at some distance from the reader, the term 'field strength' is used, expressed in mcW/cm^2 . As shown in figure 1, the Tracient's field strength at 10 cm peaks at $2 \text{ mcW}/\text{cm}^2$.

Figure 1. RF field strength of Tracient RFID reader at 10 cm



It was expected that the Tracient's low field strength would not be sufficient to interfere with the infusion pump. Bearing in mind the results of Christe et al,⁷ it was desirable to create interference in at least one test, to provide some confidence that negative results (i.e. no interference) were not false negatives. Thus additional experiments were planned in which the infusion pump would be exposed to stronger RF fields, created by:

- Using multiple RFID readers simultaneously.
- Connecting an antenna to the RFID reader. The Tracient Padl-R reader does not allow for an antenna to be connected, so we used a SkyeTek M9 UHF reader with a broadband antenna. The SkyeTek reader itself has the same maximum power output as the Tracient, about 0.5 W. But the broadband antenna increases the SkyeTek's maximum power output to around 2.2 W. As figure 2 illustrates, this higher power output translates into $25 \text{ mcW}/\text{cm}^2$ peak field strength at 10 cm, more than 10 times greater than the Tracient.

Figure 2. RF field strength of SkyeTek reader at 10 cm

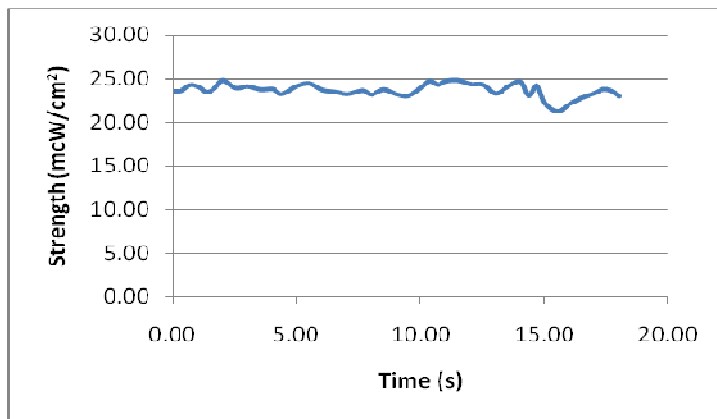


Figure 3. RF field strength of Tracient reader at 10 cm + tag at 0 cm

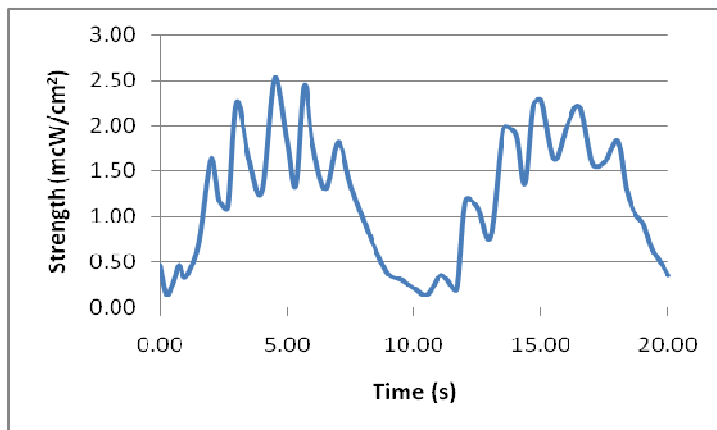
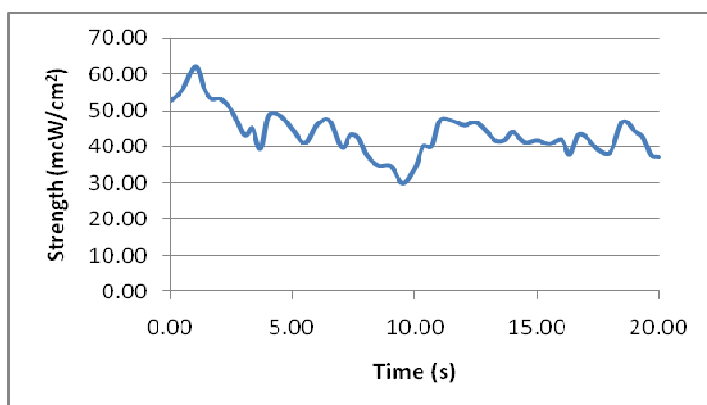


Figure 4. RF field strength of SkyeTek reader at 10 cm + tag at 0 cm



- Attaching an RFID tag to the infusion pump. When an RFID tag responds to a reader, it briefly becomes an RF transmitter. Figures 3 and 4 illustrate this effect for the Tracient and SkyeTek readers respectively. The peak field strength at 10 cm is increased by around 25% for the Tracient, and more than doubled for the SkyeTek.

The final test plan called for up to 15 tests. The first test replicated those of Christe et al⁷ and van der Togt et al.⁸ One Tracient reader was placed 1 m away from the pump, in line with the results from van der Togt et al.⁸ The reader was then moved closer or further away to find the maximum range at which interference occurred.

If no interference resulted, then additional tests were performed, covering combinations of the following three variables:

- Reader setup. Three additional reader setups were used, producing increasingly stronger RF fields: four Tracient readers placed side-by-side, then the SkyeTek reader, and then all five readers placed side-by-side.
- Distance. Tests started with the reader(s) placed 10 cm away from the pump. If no interference resulted, the reader(s) were placed in direct contact with the pump.
- Presence of an RFID tag. If the reader(s) alone did not interfere with the pump, then a Rafsec G2 UHF RFID tag was placed on the pump.

Each test was performed twice to determine reproducibility.

The tests were performed over two days at the ACSC, in an RF-controlled area. Readings taken before testing showed a background field strength of 0.01 mcW/cm.² Tests were conducted on a plastic surface approximately 1 m above the floor and at least 1 m from any conductive surface. In each test the infusion pump was observed for a minimum of three seconds, to determine whether it experienced interference.

Results

Ten tests were conducted. The results are summarised in Table 1. As expected, initial tests using a single Tracient reader did not produce any interference with the infusion pump. The same was true for tests with four Tracient readers. Interference occurred in two tests: using the SkyeTek reader with a tag on the pump, and using all five readers simultaneously.

Table 1. Test results

Reader setup	Distance (cm)	Tag?	Interference?
1 Tracient	100	No	No
1 Tracient	50	No	No
1 Tracient	30	No	No
1 Tracient	20	No	No
1 Tracient	10	No	No
1 Tracient	0	No	No
1 Tracient	10	Yes	No
1 Tracient	0	Yes	No
4 Tracients	10	No	No
4 Tracients	10	Yes	No
4 Tracients	0	No	No
4 Tracients	0	Yes	No
SkyeTek	10	No	No
SkyeTek	10	Yes	Yes
SkyeTek + 4 Tracients	10	No	Yes

In both cases the pump failed completely. It stopped working, sounded an alarm, and displayed the message 'FAULT CODE 10'. The pump could not be reset, and had to be switched off and back on. Each failure occurred on only one execution of the test. In other executions of the same test, the pump functioned normally. However, once the pump had failed the first time, the same failure occurred three times between tests, when no RFID readers were active.

Discussion

EMI from high strength RF fields did appear to interfere with a Graseby 3500 infusion pump, producing a failure similar to that described by van der Togt et al.⁸ This provides some confidence that the lack of failures in the other tests were not all false negative results. That the failure could not be reproduced reliably is probably due to the marked fluctuation in the strength of RF fields produced by the RFID readers used, as illustrated in Figures 1–4. Interference is most likely caused only near peak field strength.

'FAULT CODE 10' in the Graseby 3500 indicates a failure in the motor driving the pump. The fault is normally caused by mechanical failure in, or interruption of the power supply to, the motor. It is not clear how EMI could cause such a failure. It seems likely that the interference is not affecting the motor itself, but the pump's control circuitry.

After initial failure, the infusion pump failed subsequently at times when no RFID readers were active. In the controlled test environment it seems unlikely that such failures were caused by EMI from other sources. A more likely explanation is that the process for resetting the infusion pump after the initial failure (i.e. switching it off and then back on) may not have cleared the condition that led to the failure, leaving the pump able to fail again spontaneously. This highlights another possible risk of RFID interference with medical devices, namely the uncertain reliability of a device once it has failed and been reset in the usual way.

It is therefore important that the definitive procedure for resetting each medical device is determined and disseminated to the relevant staff, and we consider this a priority for device manufacturers and theatre technicians.

This research has been subject to the limitations common in EMI testing. The results reflect the properties of the Tracient and SkyeTek readers, notably the variability in RF field strength. The operation of the infusion pump may have been affected by the lack of a recent electrical service check, but it had shown no faults in regular use prior to this research.

The design and execution of the tests may have been improved given better documentation for the infusion pump, particularly on reset procedures. However, switching the pump off and then on again is the method normally thought sufficient to reset such a device. Available time and resources meant that only selected RFID technology and medical devices have been tested to date.

It is, of course, not possible to extrapolate the results for this one device to all the other electronic medical devices common in theatre, such as other infusion pumps, pacemakers, ventilators, fluid warmers, anaesthetic monitors, and diathermy units.

Further testing is planned, but in the meantime our data do provide some degree of reassurance in relation to the safety of low power RFID readers.

The conclusion of van der Togt et al,⁸ that the number of EMI incidents increases with higher output power of transmitting RFID systems, is essentially confirmed by our study but can now be refined. All RFID readers in these tests were operating at the same maximum output power, around 0.5 W.

The SkyeTek's broadband antenna allowed it to produce 2.2 W maximum output power, but this still did not interfere with the infusion pump. However, attaching an RFID tag to the pump, increasing the RF field strength experienced by the device but not the reader's output power, caused the pump to fail.

Thus the chance of EMI incidents appears to increase with higher RF field strengths experienced by medical devices, determined by higher output power of the RFID system, shorter distance between the RFID reader and the medical device, and the presence of an RFID tag.

The low-power Tracient readers produced no failures, even when multiple readers were in direct contact with the infusion pump. These readers appear to be safer for use in theatre, and presumably in the wider hospital environment, in the configuration used by our group.

Competing interests: Craig S Webster and Alan F Merry have financial interests in Safer Sleep LLC, a company that provides products to improve patient safety during anaesthesia.

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