Electromagnetic Interference From Radio Frequency Identification Inducing Potentially Hazardous Incidents in Critical Care Medical Equipment

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Context Health care applications of autoidentification technologies, such as radio frequency identification (RFID), have been proposed to improve patient safety and also the tracking and tracing of medical equipment. However, electromagnetic interference (EMI) by RFID on medical devices has never been reported.

Objective To assess and classify incidents of EMI by RFID on critical care equipment.

Design and Setting Without a patient being connected, EMI by 2 RFID systems (active 125 kHz and passive 868 MHz) was assessed under controlled conditions during May 2006, in the proximity of 41 medical devices (in 17 categories, 22 different manufacturers) at the Academic Medical Centre, University of Amsterdam, Amsterdam, the Netherlands. Assessment took place according to an international test protocol. Incidents of EMI were classified according to a critical care adverse events scale as hazardous, significant, or light.

Results In 123 EMI tests (3 per medical device), RFID induced 34 EMI incidents: 22 were classified as hazardous, 2 as significant, and 10 as light. The passive 868-MHz RFID signal induced a higher number of incidents (26 incidents in 41 EMI tests; 63%) compared with the active 125-kHz RFID signal (8 incidents in 41 EMI tests; 20%); difference 44% (95% confidence interval, 27%-53%; $P<.001$). The passive 868-MHz RFID signal induced EMI in 26 medical devices, including 8 that were also affected by the active 125-kHz RFID signal (26 in 41 devices; 63%). The median distance between the RFID reader and the medical device in all EMI incidents was 30 cm (range, 0.1-600 cm).

Conclusions In a controlled nonclinical setting, RFID induced potentially hazardous incidents in medical devices. Implementation of RFID in the critical care environment should require on-site EMI tests and updates of international standards.

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APPLICATIONS OF AUTOIDENTIfication technologies such as radio frequency identification (RFID) in everyday life include security access cards, electronic toll collection, and antitheft clips in retail clothing.[1,2] RFID applications in health care have received increasing attention because of the potentially positive effect on patient safety and also on tracking and tracing of medical equipment and devices.[2-11] The current expenditure levels on RFID systems within health care in the United States are estimated to be approximately $90 million per year[12] with 10-year growth projections to $2 billion.[13]

Possible applications of RFID include drug blister packs, which could be intelligently marked to prevent drug counterfeiting; and the quality of blood products being monitored with temperature-sensitive RFID tags.[2,10] The decreasing size and cost of RFID tags also permits incorporation into surgical sponges, endoscopic capsules, and endotracheal tubes, as well as the development of a syringe-implantable glucose-sensing RFID microchip.[3,8,9,14]

For editorial comment see p 2898.

However, the array of literature that promotes RFID in health care is not accompanied by research on the safety of RFID technology within the health care environment.[15] The potential for harmful electromagnetic interference (EMI) by electronic antitheft surveillance systems on implantable pacemakers and defibrillators has already been recognized, but EMI reports on critical care devices are lacking.[16,17]

The focus of the present study was to assess and classify incidents of EMI by RFID on critical care equipment.

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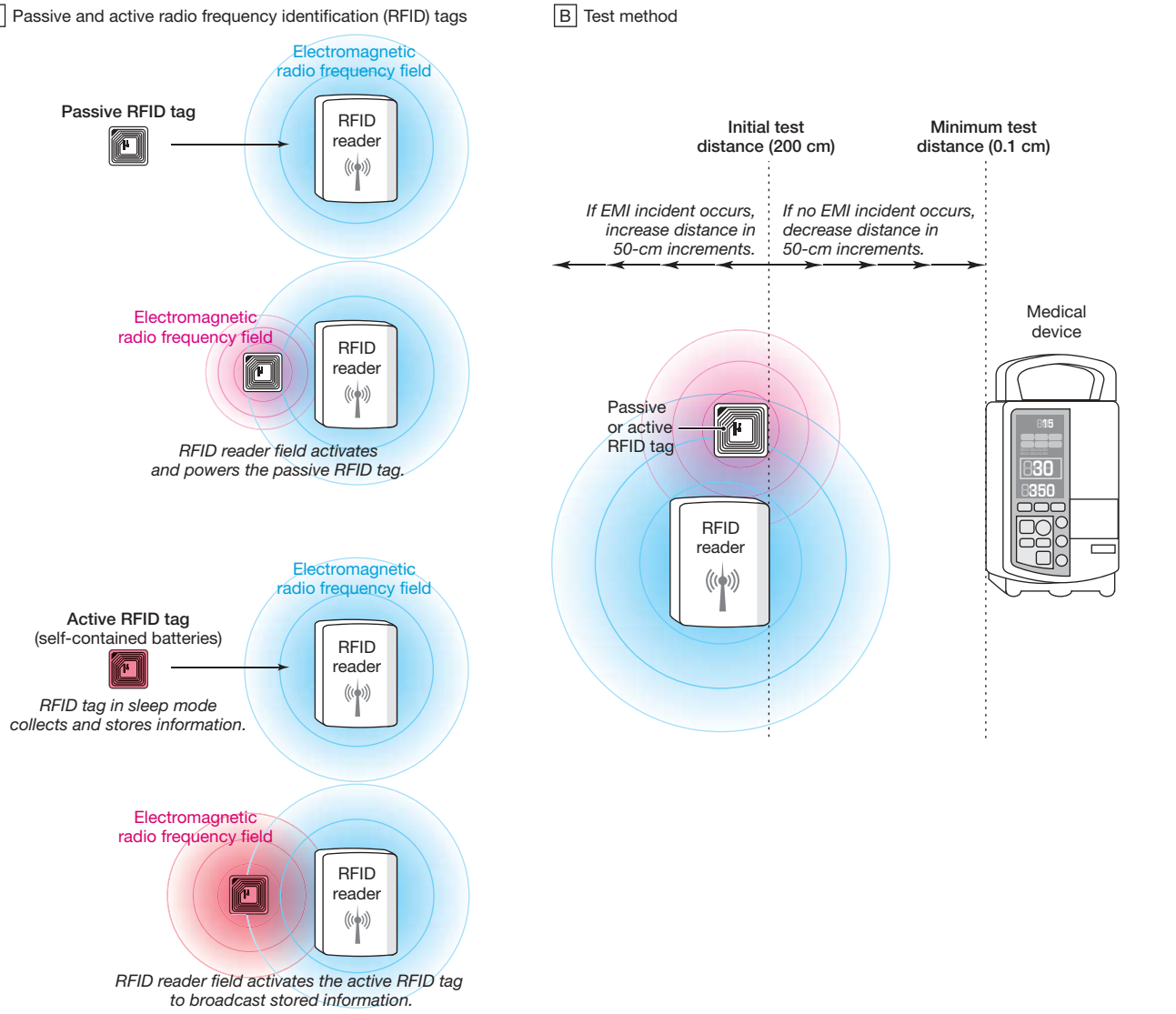
METHODS

Background

The study was part of a research project entitled "RFID in Health Care" that was initiated by the Dutch Ministry of Health[18] in May 2006. The RFID application of interest was the tracking and tracing of blood products and expensive medical supplies (eg, blood vessele prostheses, surgical staplers) in the operation rooms, the intensive care unit (ICU), and the blood transfusion laboratory of the Academic Medical Centre, University of Amsterdam, Amsterdam, the Netherlands (1002-bed university hospital, 25 operation rooms, 32 intensive care beds).

The selection of 2 RFID systems tested in this study was based on 3 characteristics: (1) the systems needed to comply with RFID standards set by the European Telecommunications Standards Institute[19]; (2) radio frequencies needed to fall within the most common internationally used RFID frequency bands[12,20,21]; and (3) performance needed to fulfill the operational requirements of the project including availability of temperature-sensitive RFID tags, low-cost tags suitable for disposable materials, contemporary integration with the local communications network, and location accuracy within a health care facility.

Figure 1. Passive and Active Radio Frequency Identification (RFID) Tags and Test Methods



A, Active RFID tags contain batteries and are able to collect, store, and broadcast information without activation by an RFID reader. To save power, some active RFID tags are in sleep mode and can be awakened by a reader to start broadcasting. B, EMI indicates electromagnetic interference. The same test method was used for both passive and active tags.

Medical Equipment

A total of 41 medical devices (17 categories, 22 different manufacturers) were analyzed according to the American standard C63.18 of the Institute of Electrical and Electronics Engineers during full operation without a patient connected; a simulator (ie, electrocardiogram simulator, artificial lung, syringe filled with saline) was connected if relevant.[22] The tests were performed on all electronic medical devices for use in critical care that could be affected by EMI during the RFID research project.

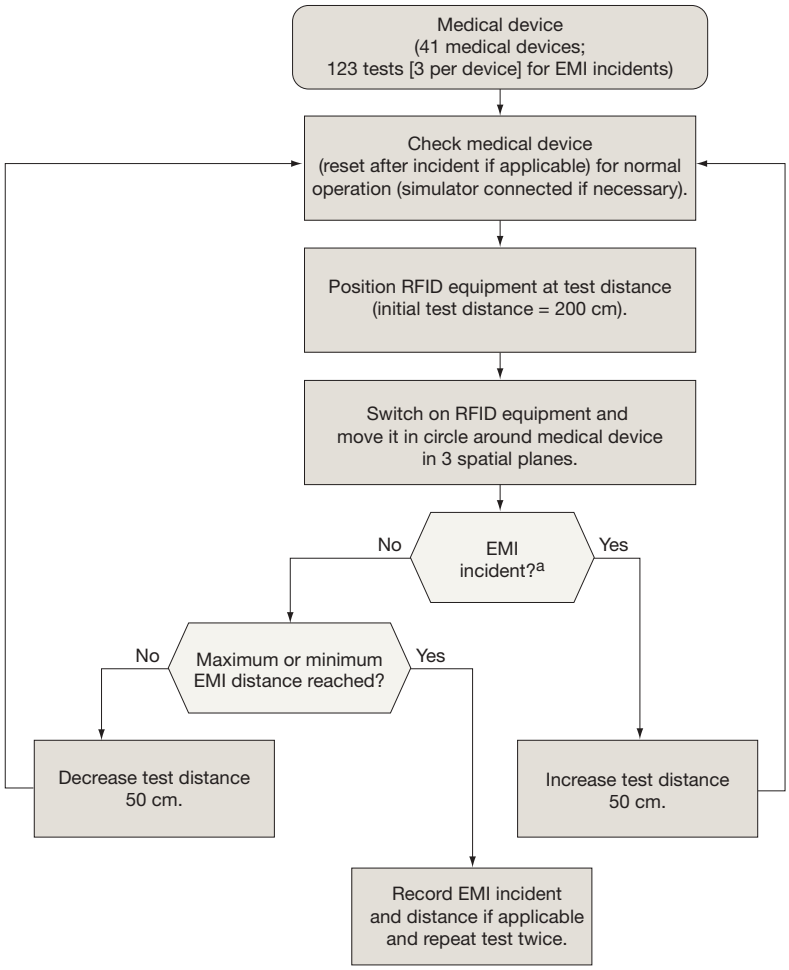
RFID Systems

RFID technology is based on 2 components: tags and readers.[2,13,20]

The tags are manufactured as either passive or active and use radio waves to communicate their identity and possible other information to nearby readers. Passive RFID tags do not have internal power, are activated by the electromagnetic field generated by the reader, and transmit information back to the reader (FIGURE 1). The electromagnetic field can cover a distance ranging from 1 to 50 cm to 10 to 30 m. Active RFID tags are operated by batteries and can broadcast information, such as identity or product temperature, without being activated by the reader.[7,20] An active tag can broadcast over a distance of 50 to 100 m.

The passive RFID system selected for this study (OBID, Feig Electronic, Weilburg, Germany) had an 868-MHz reader (2-4 W). The active RFID system (Eureka RFID, Avonwood, England) had a 125-kHz reader (68 × 10E-3 μT at 1 m) that forces tags to transmit in its proximity. The active RFID tag had an operational frequency of 868 MHz at 2 μW. This tag was selected for its low use of power, longer transmission range compared with tags operating at lower frequencies,[21] applicability in disposable materials, and existing use in retail and drug supply chains.[23]

Figure 2. Algorithm of Radio Frequency Identification (RFID) Test Methods



EMI indicates electromagnetic interference. Each medical device was tested with the passive 868-MHz RFID system (tag and reader), the active 125-kHz RFID system (tag and reader), and the active RFID tag from the active 125-kHz system alone.

[a] If EMI incident appeared or disappeared during a stepwise increment or decrement of 50 cm, the precise distance of EMI was determined by moving the RFID equipment at a rate of approximately 1 cm per 3 seconds in 3 spatial planes.

Test Method

The test method was based on the American National Standards Institute recommendation (ANSI C63.18),[22] which describes the systematic and reproducible test method for electromagnetic immunity of medical devices by radio frequency transmitters like RFID. In addition to this standard, the maximum distance at which an RFID-induced EMI incident occurred in a critical care medical device was determined. All tests were executed in a 1-bed patient room, without reflecting obstacles nearby, in the ICU of the Academic Medical Centre. These ICU rooms comply with the International Electrotechnical Commission standards on electrical safety in hospitals (IEC 60364-7-710).

The EMI test included 3 procedures. First, each medical device was checked for normal operation with a simulator connected if necessary (FIGURE 2). Second, the RFID equipment was turned on and moved in a circle around the medical device in 3 spatial planes (sagittal, frontal, and transverse).[22,24-26] Third, the test distance was changed stepwise. The initial distance was 200 cm from the medical device according to the American

National Standard Institute recommendation.[22] The minimum distance was reached by holding the RFID equipment against the housing of the medical device, defined as 0.1 cm.

If EMI occurred at the initial distance of 200 cm, the distance was increased stepwise by 50 cm by moving the RFID equipment away from the medical device. The first and second procedures were then repeated. If EMI did not occur at the initial distance of 200 cm the distance was decreased stepwise by 50 cm.

If EMI appeared or disappeared during a stepwise increment or decrement of 50 cm, the precise distance of EMI was determined by moving the RFID equipment at a rate of approximately 1 cm per 3 seconds.[22,24-26] EMI incidents were recorded in detail by 2 examiners and the test was repeated twice to assess reproducibility.

Each medical device was submitted to 3 EMI tests in a random order, one with the passive 868-MHz RFID system, one with the active 125-kHz RFID system, and both with the medical device tags attached to the reader. The third EMI test included the active RFID tag of the 125-kHz system tested separately without its reader.

Classification of Incidents

The term *incident* in this study was defined as "every unintended change in function of a medical device" while the US Food and Drug Administration's definition of EMI was used: "degradation of the performance of a piece of equipment, transmission channel, or system (such as medical devices) caused by an electromagnetic disturbance."[27-29]

Five intensivists, all European board-certified and each with more than 2 years of full-time critical care experience, classified all incidents independently while blinded for the manufacturer of the medical device and the type (active or passive) or part (reader with tag or tag) of the RFID system. The classification was done independently of the incident assessment and according to a critical care adverse event scale.[25,28]

The scale ranges were hazardous incident (direct physical influence on a patient by unintended change in equipment function, eg, total stop of syringe pump or incorrect pacing by an external pacemaker); significant incident (influence on monitoring with significant level of attention needed causing substantial distraction from patient care, eg, incorrect alarm or inaccurate monitoring of blood pressure); and light incident (influence on monitoring without significant level of attention needed, eg, disturbed display).

Statistical Analysis

When EMI was detected, distance between the reader/tag and the device was measured in centimeters. Median, maximum, and minimum values were registered if normal distribution was not applicable. The distance between the reader and device was set at 0.1 cm if an incident occurred when the reader was held against the housing of the device.

The tests of both passive 868-MHz and active 125-kHz RFID signals on the same medical devices were considered to be repeated measures. Therefore the numbers of EMI incidents by either RFID system were compared using the McNemar test as a nonparametric test comparing 2 related dichotomous variables. The difference in distance between the RFID signal and device at which incidents occurred were analyzed using the Friedman test as a nonparametric test for 2 or more related groups with continuous data. The interobserver reliability of the incident scale score was analyzed using the weighted κ between the 5 indepen-

Table 1. Medical Devices by Category, Interference Distances, and Incidents by Type[a]

Device Category[b]	No. of Devices		Distance, Median (Range), cm	No. of Incidents by Type		
	Tested	Demonstrating EMI		Hazardous[c]	Significant[c]	Light[c]
Infusion/syringe pumps	9	8	30 (0.1-100)	6	Not applicable	3
External pacemakers	3	3	25 (5-30)	5	Not applicable	Not applicable
Mechanical ventilators	4	2	20 (5-400)	2	1	Not applicable
Hemofiltration/dialysis devices	2	2	15 (10-20)	2	Not applicable	Not applicable
Pacemaker programmers	2	2	150 (25-600)	3	1	Not applicable
Intra-aortic balloon pumps	3	1	50[d]	1	Not applicable	Not applicable
Fluid warmer	1	1	50[d]	1	Not applicable	Not applicable
Cardiopulmonary bypass device	1	1	10[d]	1	Not applicable	Not applicable
Autologous blood recovery device	1	1	5[d]	1	Not applicable	Not applicable
Anesthesia devices	4	1	325 (25-600)	Not applicable	Not applicable	2
Defibrillators	3	2	303 (5-600)[e]	Not applicable	Not applicable	2
12-lead ECG device	1	1	138 (25-250)[e]	Not applicable	Not applicable	2
Monitors	3	1	50[d]	Not applicable	Not applicable	1

Abbreviations: ECG, electrocardiogram; EMI, electromagnetic interference.
[a] Details on incident descriptions and manufacturers are available online at the Academic Medical Centre Web site (http://www.amc.nl/?pid=5266).
[b] Devices that did not demonstrate EMI by radio frequency identification are not shown (2 intensive care unit beds, 1 operating table, and 1 hypo/hyperthermia and vacuum pump).
[c] Hazardous denotes direct physical influence on patient by unintended change in equipment function; significant denotes influence on monitoring with significant level of attention needed causing substantial distraction from patient care; and light denotes without significant level of patient influence or change in equipment function.
[d] Shows only the largest distance for EMI and only 1 incident occurred; therefore, range is not applicable.
[e] Mean (range).

dent observers. Statistical uncertainty was expressed in 95% confidence intervals (CIs) if applicable. All *P* values were based on 2-sided tests with .05 considered to be significant. All analyses were completed using SPSS version 14.0.2 (SPSS Inc, Chicago, Illinois).

RESULTS

All 41 medical devices were submitted to 3 EMI tests (passive 868-MHz, active 125-kHz, and active tag of the 125-kHz RFID system, respectively) resulting in 123 EMI tests. A total of 34 EMI incidents were found and all were reproducible; 22 were classified as hazardous, 2 as significant, and 10 as light (TABLE 1). The passive 868-MHz RFID signal induced a higher number of incidents (26 in 41 EMI tests; 63%), compared with the 125-kHz RFID signal (8 in 41 EMI tests; 20%), difference was 44% (95% CI, 27%-53%; $P<.001$). The same holds for the 22 hazardous EMI incidents: the passive 868-MHz RFID signal (17 in 41 device tests; 41%) vs the active 125-kHz RFID signal (5 in 41 device tests; 12%), difference was 27% (95% CI, 12%-41%; $P=.007$).

The passive 868-MHz RFID signal induced EMI in 26 of the 41 medical devices tested including 8 devices that were also affected by the active 125-kHz RFID signal (26 in 41; 63%). The medical device details and all incident descriptions are available online at the Academic Medical Centre Web site (http://www.amc.nl/?pid=5266).

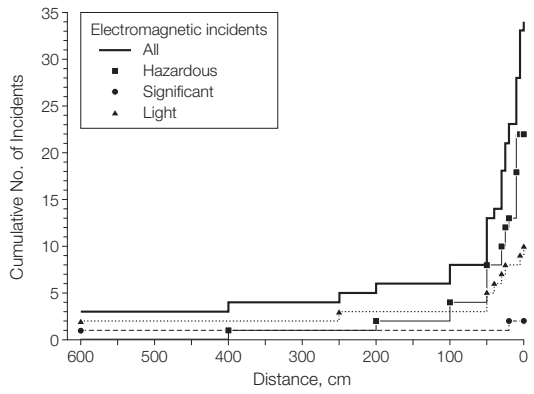
Hazardous incidents occurred in treatment devices due to definition. In 2 out of 4 mechanical ventilators tested, 2 hazardous incidents occurred: a total switch-off and restart at 5 cm; and changes in set ventilation rate at 400 cm. In 6 out of 9 syringe pumps tested, 6 hazardous incidents occurred (median distance 30 cm; range 5-100 cm) and resulted in a complete stoppage of the equipment. In all 3 external pacemakers tested, 5 hazardous incidents demonstrated incorrect inhibition of the pacemakers (median distance 25 cm; range 5-30 cm). In each of 2 renal replacement devices tested, hazardous incidents showed complete stoppage after acoustic alarms (distances 10 and 20 cm).

One hazardous incident at 25 cm occurred during 41 device tests with the active RFID tag of the 125-kHz RFID system. It caused interference in the atrial and ventricular electrogram curve read by the pacemaker programmer which could potentially induce inappropriate inhibition. All other tests with this active tag did not show any incidents of EMI on the 41 medical devices.

The relation between distance and cumulative number of hazardous, significant, and light incidents is depicted in FIGURE 3. The median distance between reader and device at which all types of incidents occurred was 30 cm (range, 0.1-600 cm). Hazardous incidents occurred at a median distance of 25 cm (range, 5-400 cm; TABLE 2). Incidents occurred at greater distances with the 868-MHz RFID signal compared with the 125-kHz RFID signal ($P=.06$).

The interobserver reliability of the incident scale score was substantial ($\kappa=0.85$; 95% CI, 0.77-0.91).

Figure 3. Electromagnetic Incidents by Type and Distance



RFID indicates radio frequency identification. Tests of the relation between the RFID reader and the medical device showed 3 incidents at a distance of 600 cm. The cumulative number of incidents increased by moving the RFID system closer to the medical device. The cumulate number of incidents (n=34) was highest when the RFID system was held against the medical device at 0.01 cm.

Table 2. Types of Electromagnetic Interference Incidents and Distances by Radio Frequency Identification Signal

	Distance, Median (Range), cm	RFID Signal, No. of Incidents	
		868 MHz	125 kHz
Hazardous incidents	25 (5-400)	17	5
Significant incidents	310 (20-600)	1	1
Light incidents	45 (0.1-600)	8	2
All incidents	30 (0.1-600)	26	8

COMMENT

The median distance at which all RFID incidents occurred was 30 cm with a considerable range up to 600 cm. RFID with a passive 868-MHz system seemed to cause more EMI compared with an active 125-kHz RFID system.

The absence of studies on the safety of RFID may be explained by the relative novelty of this autoidentification technology in health care, although many hospitals have already implemented RFID.[12,13] The EMI incidents induced by RFID on critical care equipment could be assessed in comparison with those induced by mobile phones. There is considerable variation in reported EMI by mobile phones depend-

ing on the medical devices selected and the type of telecommunication signals with different levels of output power.[24,25,30,31] Recently it was shown that even the second- and third-generation mobile phones are capable of inducing clinically significant EMI.[25] The reported hazardous incidents like switching off a mechanical ventilator or syringe pump are similar to EMI incidents by RFID found in this study. The 30-cm median distance for all incidents found with RFID might be more critical compared with the median range of 3 cm with modern mobile phones.

The same limitation of studies on EMI by mobile phones, generalization of demonstrated EMI incidents, applies to the present study on RFID. Our results apply only on the technology of 1 active and 1 passive RFID system from 2 specified manufacturers. The 2 systems were meticulously selected to study the application of RFID in the tracking and tracing of blood products and expensive medical supplies in an ICU and operating room with RFID technology. The 2 systems are comparable with those used in many other RFID case studies and could be considered as a representative sample of RFID equipment used for applications in health care.[2,12,20,21,23,32] However, testing 1 RFID system on EMI in a medical device does not implicate immunity or vulnerability to other RFID systems if based on different signal characteristics or deployments. Medical technology assessment of EMI should be considered as qualitative rather than quantitative research by its inability to test all past and future equipment, both in radio signals emitting as well as medical devices.[33]

Another limitation of this study is the use of maximal output power of both RFID systems, which was set to mimic a worst-case but at the same time realistic scenario. The number of EMI incidents increased with higher output power of transmitting RFID systems; similar to mobile phone technology.[34] In health care facilities, coverage of RFID signals might be poor due to the attenuation effects of building structures. This might necessitate maximum power settings for adequate performance.[30] Furthermore, this could be used to increase a signal's coverage area to simplify installation. This study illustrates the risks of such practices. RFID in health care, therefore, requires additional precautions compared with noncritical environments such as retail.

The lack of standardization of RFID in health care permits RFID systems originally designed for logistics to enter the medical arena on the basis of requirements such as the range at which medical tagged items or individuals are to be detected.[12,20,21] However, the economic benefits of optimal health care logistics, including a supply chain of RFID-tagged disposables or pharmaceuticals, could face barriers in the critical care environment. The intensity of electronic life-supporting medical devices in this area requires careful management of the introduction of new wireless communications such as RFID.[13,33]

In conclusion, in a controlled nonclinical trial setting, RFID technology is capable of inducing potentially hazardous incidents in medical devices. Implementation of RFID in the ICU and other similar health care environments should require on-site EMI tests in addition to updated international standards.

Author Contributions: Mr van der Togt and Dr van Lieshout had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. Both contributed equally to the study and are co-first authors.
Study concept and design: van der Togt, van Lieshout, Hensbroek, Beinat, Bakker.
Acquisition of data: van der Togt, van Lieshout, Hensbroek.
Analysis and interpretation of data: van der Togt, van Lieshout, Hensbroek, Binnekade.
Drafting of the manuscript: van der Togt, van Lieshout, Hensbroek, Beinat, Binnekade, Bakker.
Critical revision of the manuscript for important intellectual content: van der Togt, van Lieshout, Hensbroek.
Statistical analysis: van der Togt, van Lieshout, Hensbroek, Beinat, Binnekade.
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The process of discovery is very simple. An unwearied and systematic application of known laws to nature causes the unknown to reveal themselves.
—Henry David Thoreau (1817-1862)

