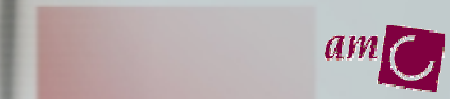
RFID in the critical care environment: it IT safe?

Erik van Lieshout, critical care physician

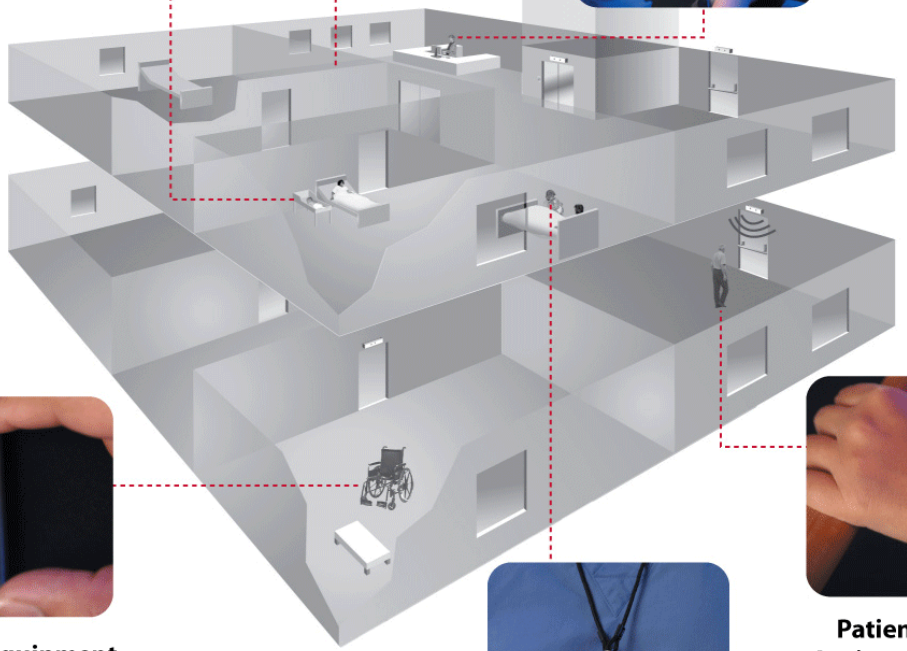
Academic Medical Center, University of Amsterdam, the Netherlands
dept. of Intensive Care

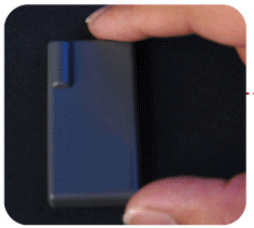


Infant protection
Patented skin-sensing active RFID tag.

Mother/baby matching
Prevent accidental baby switching.

User-friendly software
Visual indication of tag and alarm location.





Medical equipment protection and location
Protect medical items such as IV pumps and multimedia equipment with Asset Tags.

One-touch staff distress alerts
Also provides hands-free access through protected exits.

Patient location
Real-time location of infants and patients.

Wearable

Implantable

VERICHIP

RFID for people

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SOLUTIONS

- PATIENT IDENTIFICATION
- INFANT PROTECTION
- WANDER PREVENTION
- ASSET TRACKING
- TOOL & EQUIPMENT MANAGEMENT
- VIBRATION MONITORING
- EMERGENCY MANAGEMENT

Development of an Implantable Glucose Sensor

Effective Carcinogenicity Assessment of Permanent Implantable Medical Devices

Tissue Reactions to Microchip Implantation in Laboratory Animals and Pets

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RFID in health care

RFID in Health Care: Outcomes and points for consideration

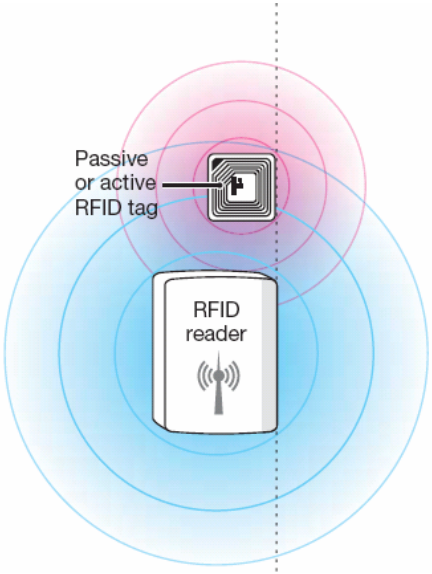
ORACLE Capgemini intel am Geodan

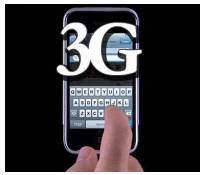
Tracking and tracing of

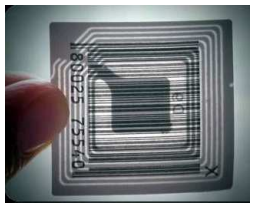
- operation room equipment
- medical personnel
- blood products in OR & ICU
  (including new active RFID tag with temperature monitoring)

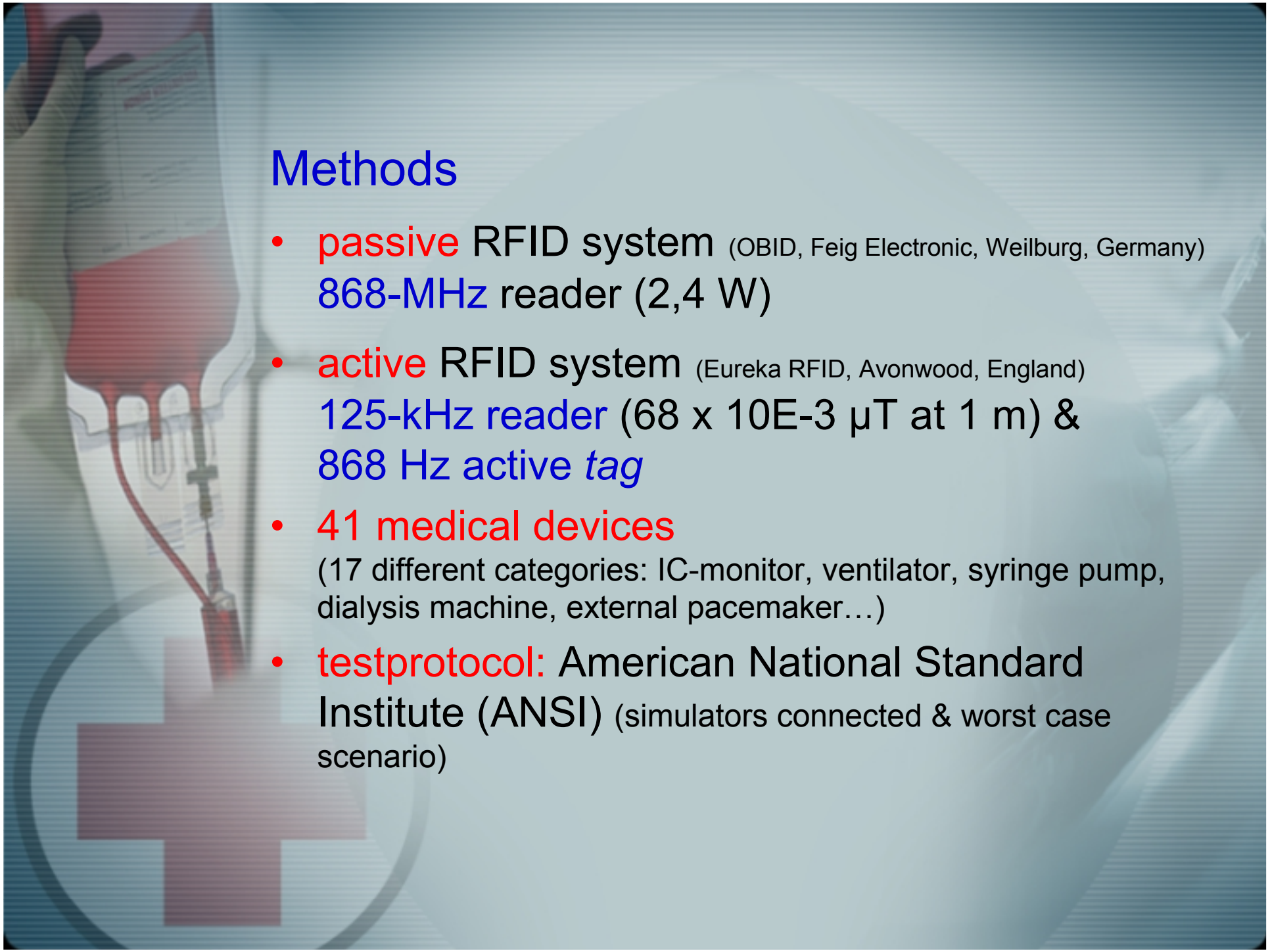
www.RFIDzorg.nl

Is RFID electromagnetic compatible with critical care equipment?



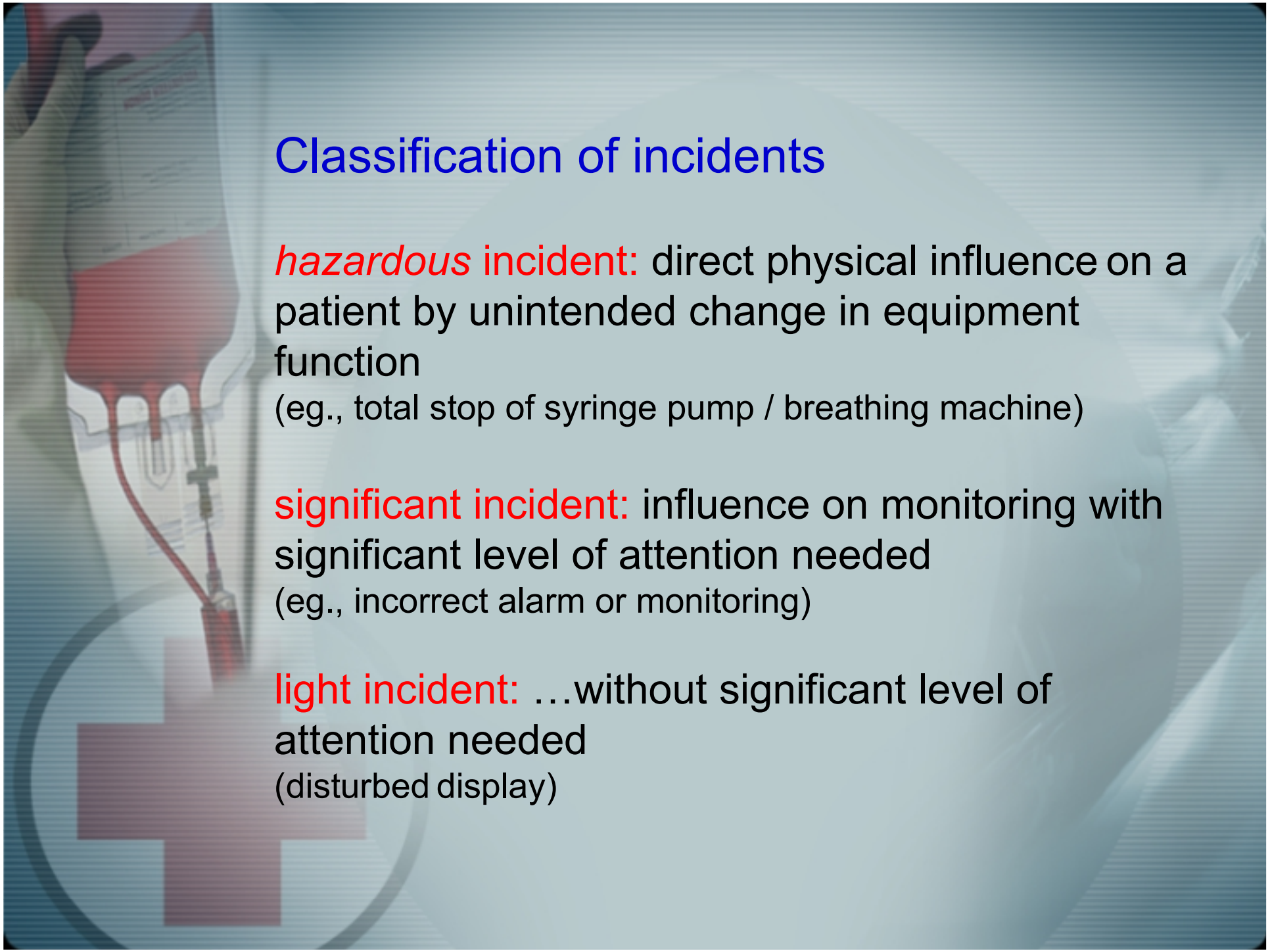






Methods

- passive RFID system (OBID, Feig Electronic, Weilburg, Germany) 868-MHz reader (2,4 W)
- active RFID system (Eureka RFID, Avonwood, England) 125-kHz reader (68 x 10E-3 µT at 1 m) & 868 Hz active *tag*
- 41 medical devices
  (17 different categories: IC-monitor, ventilator, syringe pump, dialysis machine, external pacemaker…)
- testprotocol: American National Standard Institute (ANSI) (simulators connected & worst case scenario)

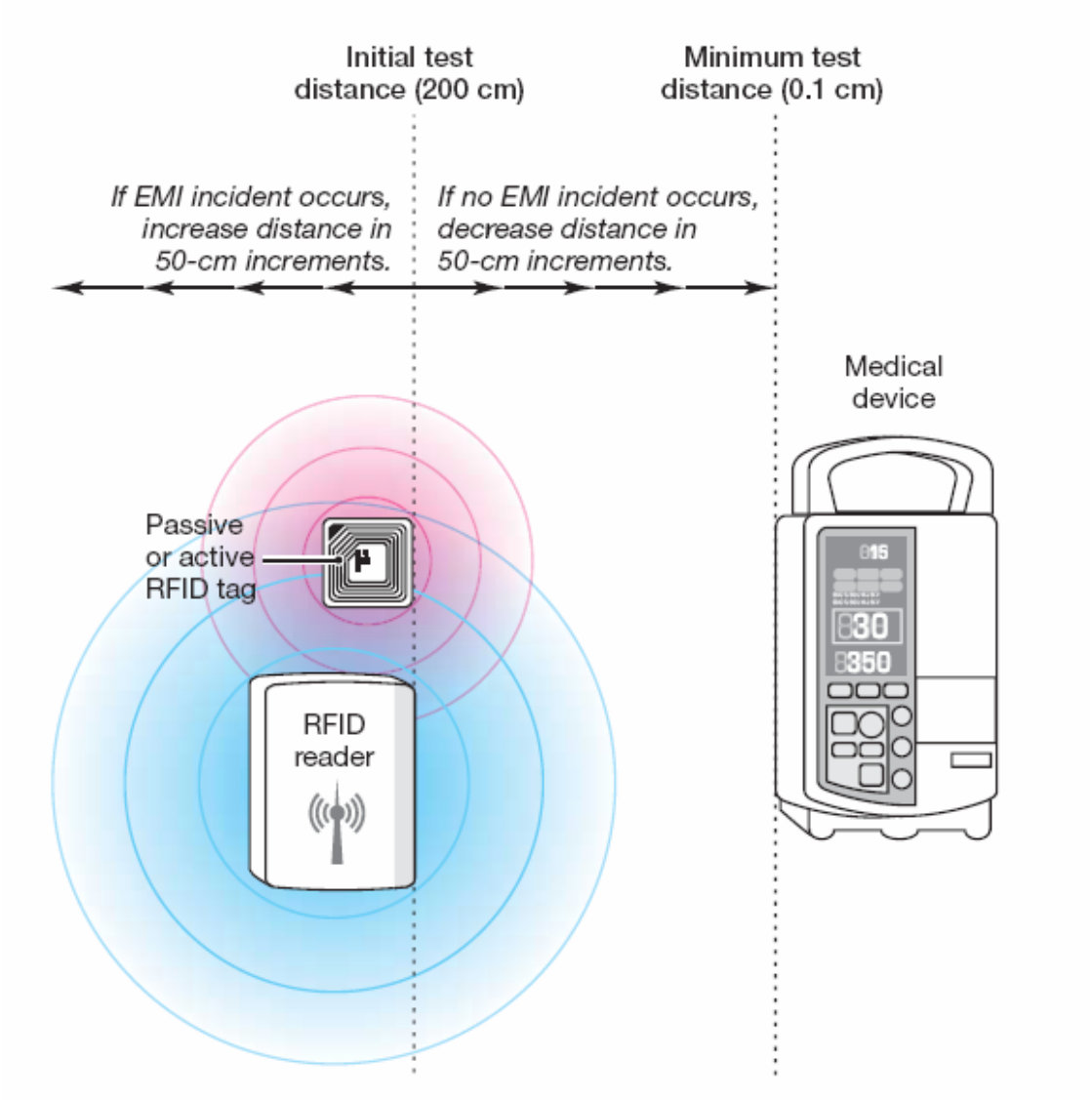


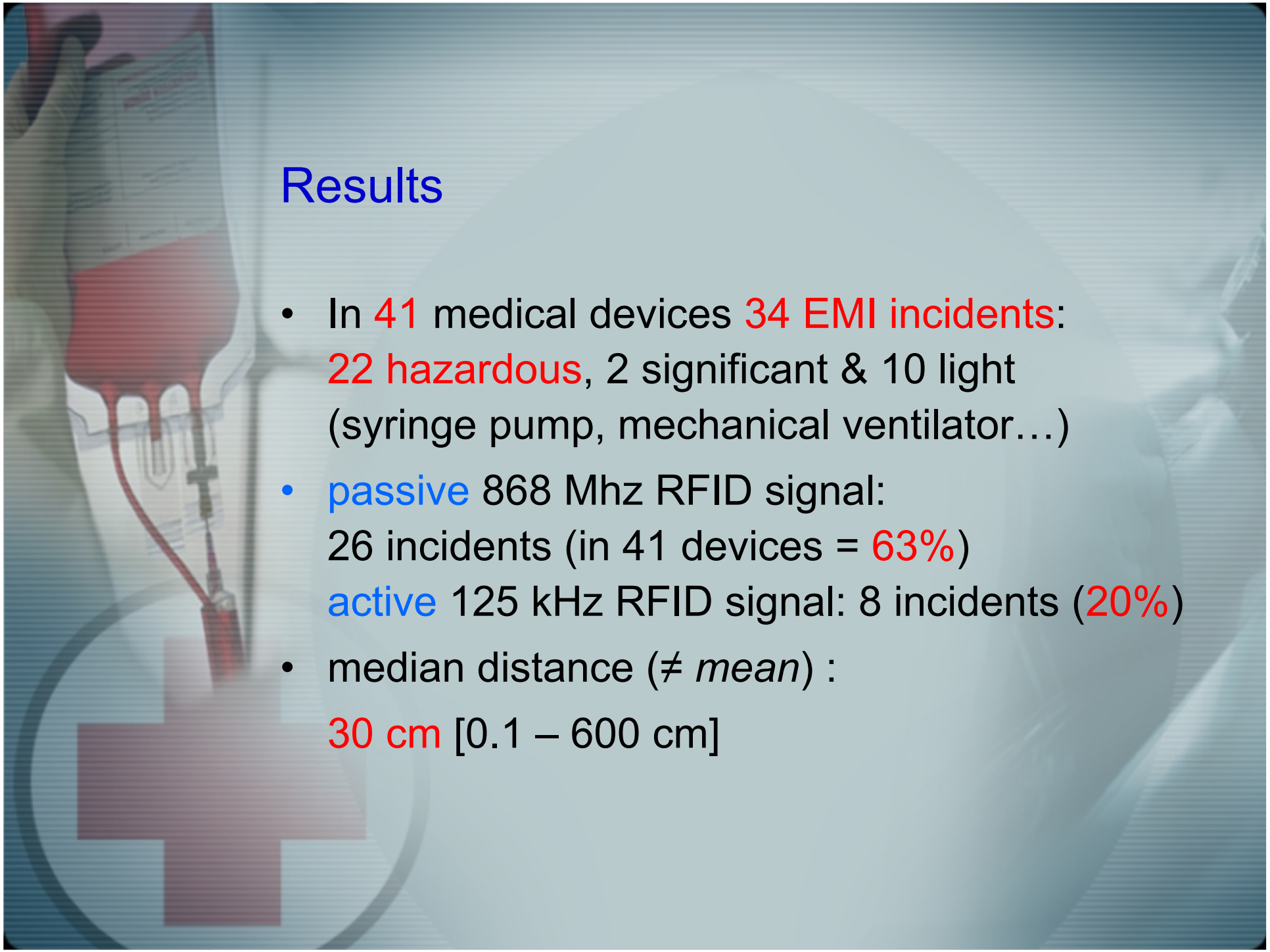
Classification of incidents

hazardous incident: direct physical influence on a patient by unintended change in equipment function
(eg., total stop of syringe pump / breathing machine)

significant incident: influence on monitoring with significant level of attention needed
(eg., incorrect alarm or monitoring)

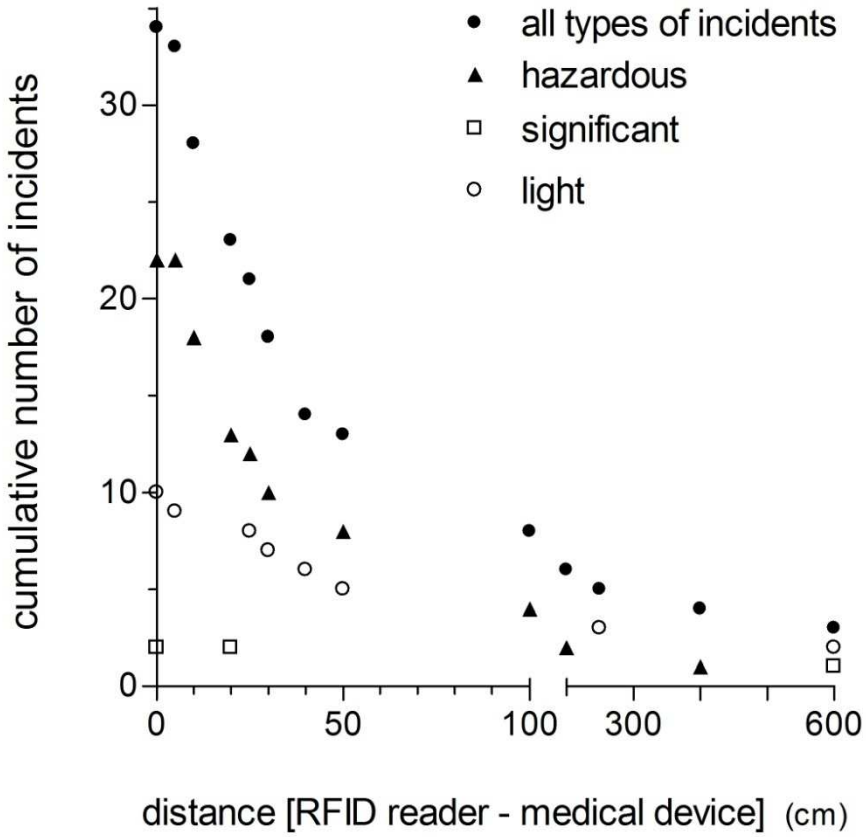
light incident: …without significant level of attention needed
(disturbed display)


Initial test distance (200 cm)
Minimum test distance (0.1 cm)
If EMI incident occurs, increase distance in 50-cm increments.
If no EMI incident occurs, decrease distance in 50-cm increments.
Medical device
Passive or active RFID tag
RFID reader



Results

- In 41 medical devices 34 EMI incidents:
  22 hazardous, 2 significant & 10 light
  (syringe pump, mechanical ventilator…)
- passive 868 Mhz RFID signal:
  26 incidents (in 41 devices = 63%)
  active 125 kHz RFID signal: 8 incidents (20%)
- median distance (≠ *mean*) :
  30 cm [0.1 – 600 cm]


all types of incidents
hazardous
significant
light
cumulative number of incidents
0
10
20
30
0
50
100
300
600
distance [RFID reader - medical device] (cm)

JAMA®
The Journal of the American Medical Association

June 25, 2008

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

Remko van der Togt, MSc
Erik Jan van Lieshout, MD
Reinout Hensbroek, MSc
E. Beinat, PhD
J. M. Binnekade, PhD
P. J. M. Bakker, MD, PhD

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 dur-

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.

JAMA. 2008;299(24):2884-2890 www.jama.com

The New York Times

VITAL SIGNS

Hazards: ID Tags Interfering With Medical Care

By ERIC NAGOURNEY
Published: July 15, 2008

Radio frequency identification tags, the tiny devices that let people drive through tolls without stopping and make life harder for shoplifters, are increasingly being used by hospitals — to monitor the quality of blood products, for example.

But a new study suggests that the tags

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Wireless Disrupts Hospital Devices

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'Hospital risk' from radio tags

Lifesaving equipment in hospitals may be switched off by radio-frequency devices used to track people and machines, Dutch scientists claim.

Radio frequency identification devices (RFIDs) are on the rise in healthcare, helping identify patients, and reveal the location of equipment.

Ventilators could potentially be affected

THE WALL STREET JOURNAL.

June 24, 2008, 4:11 pm

Study: RFID Tags Can Mess Up Medical Devices

Posted by Jacob Goldstein

Radio-frequency identification — a system of using tiny tags to track all sorts of products — could be a smart way for hospitals to keep tabs on everything from surgical sponges to patient beds. Indeed, some hospitals have already started adopting the technology.

But a study out today in JAMA suggests RFID systems can cause "potentially hazardous incidents in medical devices."

Researchers took two standard RFID systems and examined whether they interfered with 41 different medical devices.

Taming the Technology Beast

Donald M. Berwick, MD, MPP, FRCP

THE MIRACLES WROUGHT BY BETTER HEALTH CARE technologies abound—like mended hearts, leukemias cured, noninvasive images, and organ system monitors. But with artificial heart valves came new risks from infections and anticoagulation; with the breakthrough of intrathecal methotrexate to cure leukemia came new deaths from intrathecal vincristine given by mistake; new monitors began sounding new false alarms that could drive nurses and patients crazy. Electronic medical records mitigate some problems[1] and introduce others.[2] Every new technology, like every new drug, brings good and bad news.

In this issue of *JAMA,* the report by van der Togt and colleagues[3] on electromagnetic interference (EMI) from radiofrequency identification (RFID) technologies affecting other medical equipment in intensive care units is of urgent significance. RFID devices are part of modern life, like the transponder on the car windshield that pays the toll automatically and the security card that permits access to an office building. These devices are also making their way quickly into health care including uses in remote monitoring equipment, as tiny chips that identify items in inventory, or even embedded in surgical sponges for tracking during an operation. These tags that lie in whatever is tracked come in 2 forms: active tags, with a power source that can transmit continuously to a reader device; and passive tags, which are powered by the electromagnetic field of the reader.

In simulations not involving patients, the investigators[3] tested the effects of 2 RFID systems (1 active type and 1 passive) on 41 medical devices commonly used in critical care settings, such as infusion pumps, external pacemakers, and mechanical ventilators. In a total of 123 tests, the investigators found 34 EMI incidents. A panel of 5 intensivists rated each incident as hazardous (eg, a syringe pump's power switched off), significant (eg, an inaccurate blood pressure reading), or light (eg, a monitor error that would not require attention). Overall, 22 of the 34 EMI incidents were hazardous. The passive RFID device led to more incidents (26 incidents in 41 tests) than the active device (8 incidents in 41 tests).

The authors carefully disclaim that their results apply only to the RFID systems of 2 specific manufacturers and that "... testing one RFID system on EMI in a medical device does not imply immunity or vulnerability to other RFID systems."[3] But frankly the 2 tested systems are not unlike many others in current use, and attention must be paid to these disturbing findings.

Author Affiliation: Institute for Healthcare Improvement, Cambridge, Massachusetts.

Collins: "And it is difficult to say if something, such as an RFID system, will interfere with critical care equipment unless you do a study. Hospitals need to do a risk assessment of every wireless device that comes into the hospital, because [the wireless devices] all create a greater noise level in terms of radio frequency waves. You really don't know what to expect until they are tested."

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☐ **1:** Biomed Instrum Technol. 2008 Nov-Dec;42(6):479-84.

Testing potential interference with RFID usage in the patient care environment.

Christe B, **Cooney E**, **Maggioli G**, **Doty D**, **Frye R**, **Short J**.

Biomedical Engineering Technology, Indiana University Purdue University, Indianapolis (IUPU), USA.

The use of radio frequency identification (RFID) equipment in the clinical setting has become prevalent. The exploration of the potential interactions between the equipment used to implement RFID and medical devices is vital to ensure safe and effective use of both the tracking technology and the patient care equipment. This study examines the effects of two common RFID antennas, Near-Field and Far-Field, and five general types of patient care equipment. Data were collected regarding the function of the patient care equipment in the fields of the antennas. No device performance alterations were observed.

passive 868 MHz (UHF)

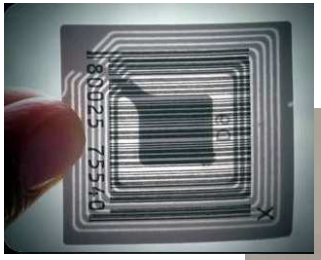
eMJA The Medical Journal of Australia
Established 1914 • Journal of the Australian Medical Association

Lawrentschuk 2004

2 Studies of EMI-related events in medical equipment caused by digital mobile phones operating at frequencies used by single- and dual-band mobile phones in Australia (800–915 MHz)

First author, year	Number of devices tested	Tests per device	EMI observed	Clinically relevant EMI observed	Devices showing clinically relevant EMI	Maximum distance at which EMI recorded (cm)*	Conclusions
Irnich[15] 2002	203	6	107 (53%)	20 (10%)	Apnoea monitor	70	Use mobile phones > 1 m from medical equipment
					Dialysis machine	20	Make sensitive medical equipment used in hospitals resistant to EMR from mobile phones up to 50 cm, thus changing "1 m rule" to "arm's-length rule"
					External pacemaker	90	
					Heart lung machine	30	All medical devices used outside hospital must be made resistant to EMR from mobile phones
					Respirator	80	
Hietanen[16] 2000	23	1	13 (57%)	3 (13%)	Anaesthesia machine	70	Restrict use of mobile phones in clinical areas
					Respirator	5	Patients and visitors should use mobile phones only in designated areas
					Endoflator	10	Hospitals should assess their own risk of interference from the EMR of mobile phones
Trigano[17] 1999	9	3	4 (44%)	4 (44%)	External pacemaker	200	Be aware of potential interference with external pacemakers
							Develop pacemakers resistant to EMI
MDA[18] 1997	224	3	82 (36%)	9 (4%)	Anaesthesia machine	50	Restrict use of mobile phones in clinical areas
					Respirator	0	
					Infusion pump	0	
					External pacemaker	0	
					Defibrillators	100	
Robinson[14] 1997†	5	2	3 (60%)	3 (60%)	Infusion pump	55	Use mobile phones > 1 m from medical equipment
					ECG monitor	99	
Clifford[9] 1994	15	1	8 (53%)	7 (47%)	Infusion pump	200	Use mobile phones > 2 m from medical equipment
					ECG monitor	200	Switch off mobile phones in operating theatres and intensive care units and adjacent areas if it is possible to operate a mobile phone within 2 m of equipment
					Telemetry	20	

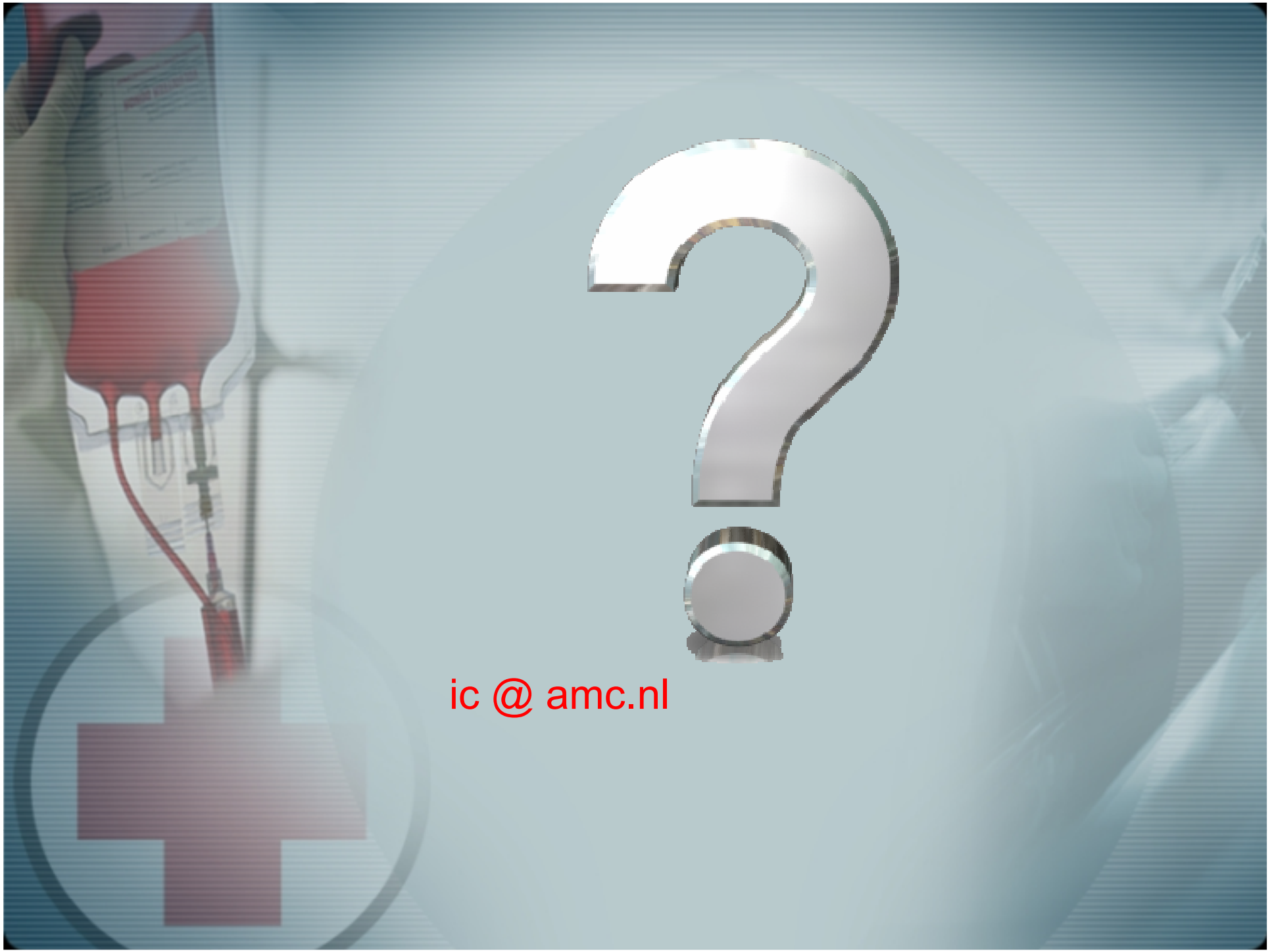
ECG = Electrocardiography. EMI = Electromagnetic interference. EMR = Electromagnetic radiation. MDA = Medical Devices Agency, Department of Health, United Kingdom. * The maximum distance from any single device within the category. † This study used a mobile phone simulator, which was a signal generator coupled with a radiofrequency amplifier and antenna pulsed at the same frequency as phones used in Australia.



How to move on with RFID in the critical care environment

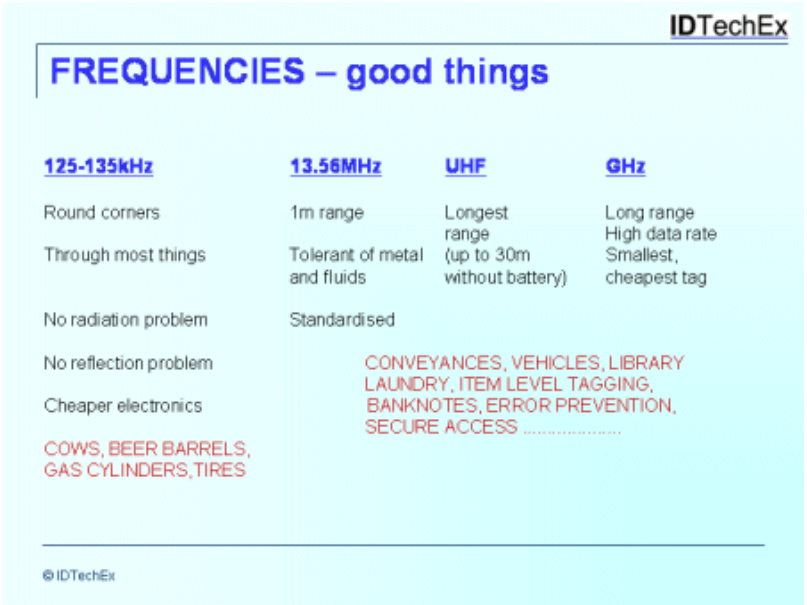
- update of international standards
- careful management of the introduction

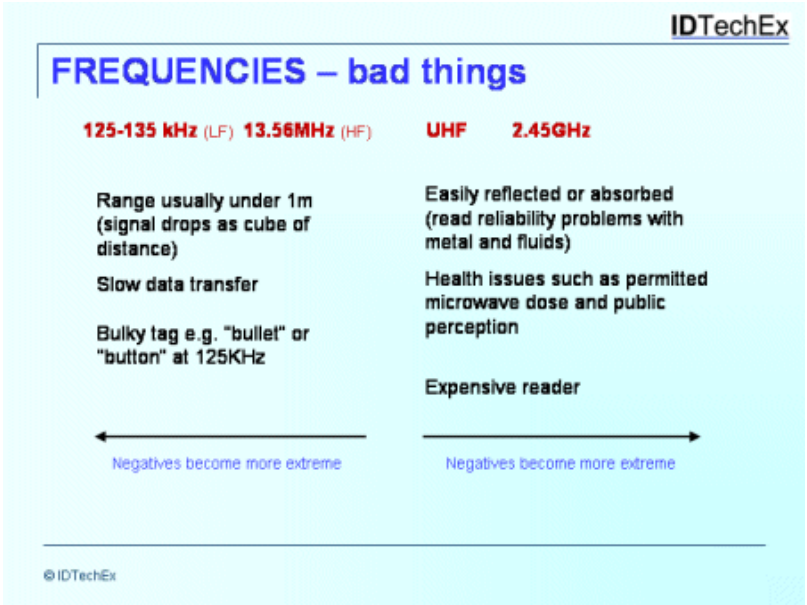
  of new wireless communications such as RFID
- on site tests with RFID and critical care equipment involved

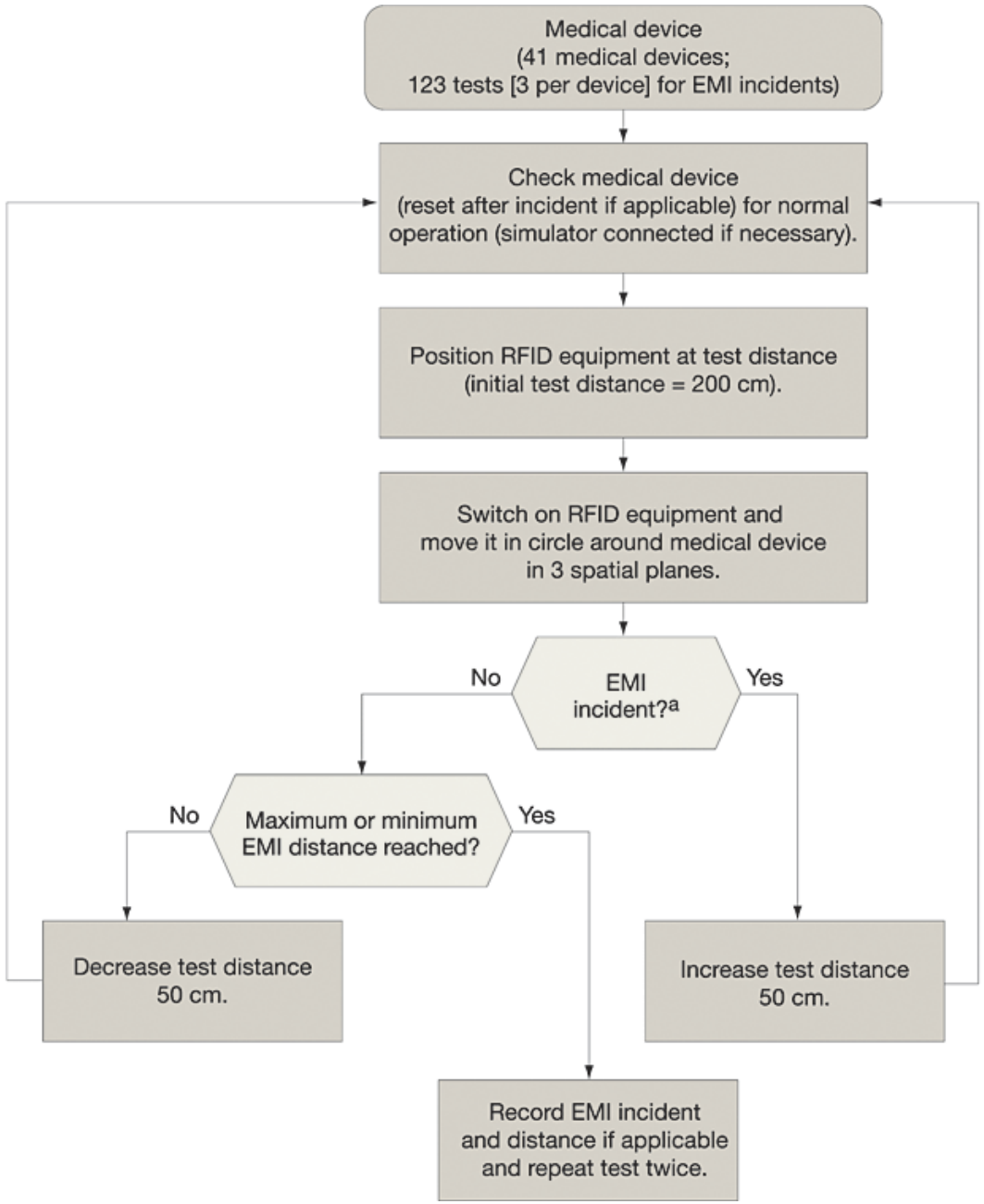

ic @ amc.nl

IDTechEx

Low Frequency (LF)	125-135 KHz
High Frequency (HF)	13.56 MHz
Ultra High Frequency (UHF)	868-930 MHz
Microwave	2.45 GHz
Microwave	5.8 GHz






Medical device
(41 medical devices;
123 tests [3 per device] for EMI incidents)
Check medical device
(reset after incident if applicable) for normal operation (simulator connected if necessary).
Position RFID equipment at test distance
(initial test distance = 200 cm).
Switch on RFID equipment and
move it in circle around medical device
in 3 spatial planes.
EMI
incident?a
No
Yes
Maximum or minimum
EMI distance reached?
No
Yes
Decrease test distance
50 cm.
Increase test distance
50 cm.
Record EMI incident
and distance if applicable
and repeat test twice.

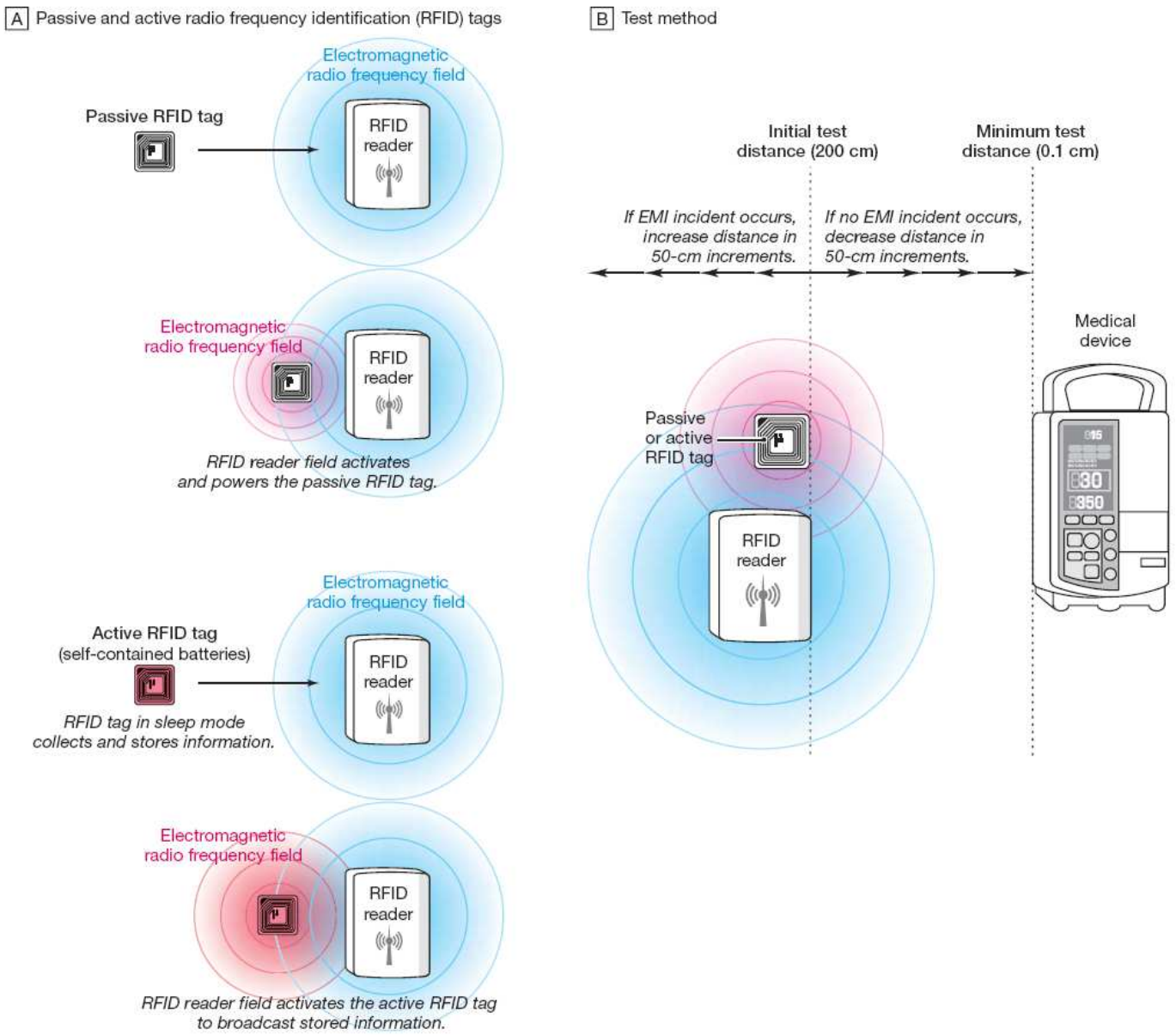

A Passive and active radio frequency identification (RFID) tags
Electromagnetic radio frequency field
Passive RFID tag
RFID reader
Electromagnetic radio frequency field
RFID reader
RFID reader field activates and powers the passive RFID tag.
Electromagnetic radio frequency field
Active RFID tag (self-contained batteries)
RFID reader
RFID tag in sleep mode collects and stores information.
Electromagnetic radio frequency field
RFID reader
RFID reader field activates the active RFID tag to broadcast stored information.
B Test method
Initial test distance (200 cm)
Minimum test distance (0.1 cm)
If EMI incident occurs, increase distance in 50-cm increments.
If no EMI incident occurs, decrease distance in 50-cm increments.
Medical device
Passive or active RFID tag
RFID reader

Table 1 Categories of medical devices, interference distances and type of incidents per signal.

	number of devices		distance (cm)	type of incidents per RFID signal	
	tested	*influenced*	*median [range]*	868 MHz	125 kHz
infusion / syringe pumps	9	8	30 [0,1-100]	5H*, 3L***	1H
external pacemakers	3	3	25 [5-30]	3H	2H
mechanical ventilators	4	2	20 [5-400]	2H	1S
dialysis devices	2	2	15 [10-20]	2H	
pacemaker programmers	2	2	150 [25-600]	1H, 1S**	2H
balloon pumps	3	1	50	1H	
blood warmers	1	1	50	1H	
heart-lung machines	1	1	10	1H	
cell savers	1	1	5	1H	
anaesthesia devices	4	1	325 [25-600]	1L	1L
defibrillators	3	2	302,5 [5-600]	2L	
electrocardiogram devices	1	1	137,5 [25-250]	1L	1L
monitors	3	1	50	1L	
IC beds	2	0			
operating tables	1	0			
cooling machines	1	0			
vacuum pumps	1	0			
hazardous incidents			25 cm [5-400]	17H	5H
significant incidents			310 cm [20-600]	1S	1S
light incidents			45 cm [0,1-600]	8L	2L
	42	**26**	**30 [0,1-600]**		

Table 1 B type of incidents and distances per signal

	distance (cm)	type of incidents per RFID signal	
	median [range]	868 MHz	125 kHz
hazardous incidents	25 cm [5-400]	17 H	5 H
significant incidents	310 cm [20-600]	1 S	1 S
light incidents	45 cm [0,1-600]	8 L	2 L
	30 [0,1-600]	**26**	**8**

CRITICAL CARE IMPACT FACTOR 3.83

Research

Open Access

Interference by new-generation mobile phones on critical care medical equipment

Erik Jan van Lieshout[1,2], Sabine N van der Veer[3], Reinout Hensbroek[4], Johanna C Korevaar[5], Margreeth B Vroom[1] and Marcus J Schultz[1,6]

[1]Department of Intensive Care Medicine, Academic Medical Centre, University of Amsterdam, Meibergdreef 9, 1105 AZ Amsterdam, The Netherlands
[2]Mobile Intensive Care Unit, Academic Medical Centre, University of Amsterdam, Meibergdreef 9, 1105 AZ Amsterdam, The Netherlands
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[5]Department of Clinical Epidemiology, Biostatistics and Bioinformatics, Academic Medical Centre, University of Amsterdam, Meibergdreef 9, 1105 AZ Amsterdam, The Netherlands
[6]Laboratory of Experimental Intensive Care and Anaesthesiology, Academic Medical Centre, University of Amsterdam, Meibergdreef 9, 1105 AZ Amsterdam, The Netherlands

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MOBILE INTELLIGENCE

2. **The problem described by van der Togt et al is not a real problem (to date); it is only a potential problem.** On the day the article was published, FDA spokeswoman Peper Long was quoted in RFID Journal saying that the Agency has never received a single report of injury directly caused by EMI with medical devices: "We certainly understand there is a potential for problems, and of course, we are looking into this." She further stated that the FDA is currently working with standards organizations and device manufacturers to address the issue.[2]

3. **The study was a feasibility study, not a clinical study—no patients were involved, and the manner in which the tests were performed was not analogous to the way RFID systems are conventionally used in a modern hospital.** RFID tags and exciters were initially placed in close proximity (~6.5 feet) to the device under study. If no interference was noted, the RFID components were brought closer, to the point of physical contact with the device, until EMI (or no EMI) was observed. If EMI was observed at initial power-up, the device was moved farther from the device, until EMI ceased. The median distance between RFID exciter and device in all tests producing interference was 30 cm (range: 1–600 cm), i.e., less than 12 inches.

InfoLogix RFID systems are primarily employed to track patients through admission and treatment in emergency departments and to track, locate and prevent the loss of valuable hospital equipment, including the kinds of devices tested by van der Togt et al. The exciters, which activate and/or read output from the RFID tag, are mainly installed in the ceiling and at hospital entrances and exits.

RFID JOURNAL
THE WORLD'S RFID AUTHORITY

NEWS

Researchers Warn RFID May Disrupt Medical Equipment

Experts not involved with the study note that there have been no reports of injuries caused by electromagnetic interference with medical devices, though they do recommend further study.

By Beth Bacheldor

June 25, 2008—A new study published today in the Journal of the American Medical Association warns that radio frequency identification may disrupt the operation of defibrillators and other medical equipment, and occasionally induce "potentially hazardous incidents in medical devices." Experts not involved in the study note that no injuries related to electromagnetic interference (EMI) have been reported in an actual clinical setting, but recommend that before deploying a specific RFID system, a hospital should test it first to see if it has any effect on the medical devices the facility uses.

The study, conducted by Remko van der Togt, Erik Jan van Lieshout, and four of their colleagues at the University of Amsterdam's Academic Medical Center (AMC), in the Netherlands, was part of a research project entitled RFID in Health Care, initiated by the Dutch Ministry of Health in May 2006. That project has been focused on the use of RFID to track and trace blood products and expensive medical supplies in the operating rooms, intensive care unit (ICU) and blood transfusion lab at the 1,002-bed hospital.

RFID JOURNAL
THE WORLD'S RFID AUTHORITY

EXPERT VIEWS

Dutch RFID Interference Study Is a Worst-Case Test

A recent study published in The Journal of the American Medical Association is not in line with the reality of most current hospital RFID deployments.

By Martin Payne

July 14, 2008—A recent study published in *The Journal of the American Medical Association* (*JAMA*) found that RFID systems in hospitals can cause "potentially hazardous incidents in medical devices." But while these findings have sparked a flurry of media attention and panic regarding the safety of RFID, there might not be as much to fear as initially thought.

When you digest the full contents of the study (see Researchers Warn RFID May Disrupt Medical Equipment), you will find the research—though carefully and thoughtfully completed—is not in line with the reality of most current hospital RFID deployments. Unfortunately, the report ignores mainstream passive RFID in favor of technology that not only misrepresents the vast majority of today's deployments, but also poses the highest risk and probability of generating electromagnetic interference (EMI) in adjacent devices. Although I see the study as a good warning for future RFID deployments based on ultrahigh-frequency (UHF) tags, the research team did not examine high-frequency (HF) tags, which is important for two main reasons.

First, the reader power employed in the test conditions exceeds what would presently be used and seen in embedded UHF applications for medical environments. Most UHF deployments call for a 1-watt (30 dBm) reader or less, because this power level provides up to 10 meters (32.8 feet) of read range. The study utilized 3-watt readers, which are far more powerful than interrogators typically found in existing hospital RFID deployments, as they were designed for supply chain applications.

What's more, when you combine the conducted wattage (3 watts) of the UHF interrogator employed in the study (most likely Feig Electronic's ID ISC.LRMU2000 Fixed UHF Long Range Reader) with the gain of the antenna used, it is highly unlikely the study was in compliance with FCC regulations. An HF RFID reader typically operates at lower power levels (usually 200 milliwatts) than UHF, and an HF reader and tag utilize the magnetic portion of the radio wave to communicate with each other. These characteristics make HF much less susceptible to EMI with adjacent devices than UHF. This is the same technology used for security badge access to offices and buildings.