Braccio, Nadia

De: Greffe
Objet: TR: À verser aux dossiers R 3863-2013 (observations) et R-3854-2013 ph. 2

Rosemère le 5 mars 2014

À l'attention de Mesdames Louise Pelletier, responsable du dossier et Madame Sophie Giner, greffière

Mesdames,

La présente est pour vous faire part de désinformations véhiculées par Hydro-Québec concernant leur étude sur les défibrillateurs cardiaques (pacemaker) et l'endoprothèse vasculaire (stent) face au compteur nouvelle génération et ces routeurs : Smart Meters and Routers Radiofrequency Disturbances Study with Pacemakers and Implantable Cardiac Defibrillators. L'étude au complet après la signature.

J'ai demandé l'opinion à deux ingénieurs, dont un spécialisé en radiofréquences, à deux chercheurs suédois et à un technicien en mesurage. Vous trouverez après la signature les réponses des deux ingénieurs, le technicien et du Dr Olle Johansson qui est un expert sur les effets biologiques des radiofréquences.

La réponse la plus éloquente nous vient de l'ingénieur spécialisé en RF qui a rapidement décelé les anomalies de cette étude et confirmé qu'elle était une conçue pour ne pas trouver de problème. Les quatre sont d'accord sur le fait que l'aspect humain et autres facteurs environnementaux n'ont pas été pris en considération.

Nous aimerions aussi signaler que cette même étude démontre, sans aucun doute, qu'Hydro-Québec a induit en erreur la Régie en affirmant que le compteur de nouvelle génération n'émet pas des ondes pulsées que 0,1 % du temps quand en réalité le compteur a été conçu pour émettre aux trois (3) secondes. En déclarant cette fausse information, le compteur de nouvelle génération a pu contourner le test du DAS et ainsi ne pas avertir la population la distance à garder de cet appareil émetteur de radiofréquences pulsées les 24 h. Il ne faut pas oublier que 70 % des foyers à Montréal et 35 % à travers la province ont des compteurs à l'intérieur de la maison et souvent ce sont des installations multiples.

En plus d'être exposés aux radiofréquences cumulatives (effet non thermique) qui rebondissent à l'intérieur de leur foyer en augmentant leur puissance et le risque sanitaire, mais aussi ces personnes sont soumisses à l'effet thermique qu'Hydro-Québec a choisi d'ignorer pour ainsi ne pas avertir ses abonnés des distances de précaution à prendre.

Nous espérons compter sur votre collaboration pour donner à suite à ce dossier et nous vous prions d'agréer, Mesdames, nos salutations distinguées.

Maria Acosta
Rosemère (Québec) J7A 4N1
450.939.4491

Références :

Courriels et commentaires des experts sur l'étude sur les compteurs et les routeurs sur les stimulateurs cardiaques et les endoprothèses vasculaires

Le 2013-08-15 à 5:26 PM, Basses-Laurentides Refuse <basses-laurentides-refuse@videotron.ca> a écrit :
For your info. Study paid by Hydro-Québec. Your comments are welcomed.
http://onlinelibrary.wiley.com/doi/10.1111/pace.12225/abstract?deniedAccessCustomisedMessage=&userIsAuthenticated=false

Basses-Laurentides Refuse
Maria Acosta porte-parole
450-939-4549
basses-laurentides-refuse@videotron.ca
facebook.com/BassesLaurentidesRefuse
basseslaurentidesrefuse.com

---000---
Réponses (deux -2) du premier ingénieur

De :
Envoyé : 15 août 2013 23:32
À : Basses-Laurentides Refuse
Objet : Re: Smart Meters and Routers Radiofrequency Disturbances Study with Pacemakers and Implantable Cardiac Defibrillators

Hello Maria,
I do not have access to the full article, but I have read the abstract.
Here are my quick take on the matter:
-The objective for testing the safety of the electronic device in operation inside a patient's heart should be based on two aspects:
(a) The ability of the device to continue to operate properly under the radiated field by continuing to emit the signal needed to correct the heart beat
(b) The ability of the object not to act as a receiving antenna inside the patient's heart.
Commentary:
a.
The testing of the device was taken by placing the device in saline water. Water is a good attenuator of RF fields, thus the fields to which the device is subjected are reduced by the water attenuation. Furthermore, saline water is used, thus the conductivity of the water is further increased by the salinity factor, which further increases its protective shield to the device under test.
Thus, the device is artificially protected from the RF fields to which it is subjected for testing purposes(i.e.: the test fails to carry out objective (a) reliably.
b.
The frequency of operation of the device (a pacemaker) is well below the frequency of the RF fields of the smart meter; thus, it is very unlikely that the device output electrical signal is impaired. However, what needs to be tested is whether or not the device acts as a receiving antenna for the RF signal because, if it does and probably does so by acting as an antenna, the patient heart will receive a stimulus from the RF currents induced inside the device which will be larger than the stimulus of a heart with no pacemaker. People who have had a heart stent surgery carry the same risk. The test fails to meet objective (b) totally
Conclusion:
The experiment fails to reliably test for objective (a), and fails to test for objective (b); thus, it cannot be used to ascertain the safety of pacemakers or stents in the presence of fields created by the Smart Meter at close distance. The experimental procedure makes the test inconclusive.
Further minor comments:

Contrary to what is portrayed in the article abstract, the Smart meter Landis+Gyr is **NOT** a European technology item, it is fully owned by Toshiba America (please refer to previous e-mail on the subject).
I also notice with interest that the meter has been made to emit 3 times a second.
If the Smart meter was emitting 3 times a second, then it was emitting with an average of 52*55microWatts/m2= 2860microwatts/m2 at 1 meter distance. The SAR test was skipped on the basis (according to Hydro) that it can only emit 0.1% of the time..... only ???

De :
Envoyé : 16 août 2013 17:28
À : Maria Acosta
Objet : Re: smart meter & pacemakers
Maria,
Great work for getting the entire article.
Everything I mentioned before still holds, but there is more.....
They contend in the article that no interference is detected because the recorded Electrocardiogram done on the computer after exposure to the meter shows no change.
One cannot draw such a conclusion at all, at all, at all..... Why?
Because the electrocardiogram recording cannot possible record a frequency component of over 900 MHz in the time domain. The recording filters out the high frequency component of the RF signal that is probably picked up by the device; the recorder cannot record it. There is no electrocardiogram recording program that can record in real-time a 900 MHz signal So, we are left with the signal generated by the pacemaker alone. This is no surprise at all, it proves NOTHING, NOTHING AT ALL.
They could even connect a 900 MHz signal right on the wires of the recorder, it will read zero because it cannot read and record at that frequency.
Did they prove before starting the test that their recorder can see a 900 MHz signal? No, they did not, and it cannot.
The experimental set up is faulty; or, if we want to put it differently, it is meant to generate the wanted result of no interference.
This is not good Science..
---000---

Réponse du deuxième ingénieur
De :
Envoyé : 16 août 2013 15:05
À : 'Basses-Laurentides Refuse'
Objet : Re: Smart Meters and Routers Radiofrequency Disturbances Study with Pacemakers and Implantable Cardiac Defibrillators
J'ai lu en diagonale, et ça semble se tenir et je ne suis pas surpris. D'abord pour qu'il y ait un certain risque d'interférence il faut certaines conditions comme que les deux appareils opèrent sur des fréquences relatives proche. Un exemple facile est le microonde et le téléphone sans fil.
Mais le test est limité, par exemple dans les immeubles appartements, où il y 4-10 compteurs adjacents, que ce passe-t-il, on ne parle pas de cas extrême ici, mais assez commun. De plus, deux appareils côte à côte peuvent provoquer des interférences les uns sur les autres qui engendre des harmoniques qui elles peuvent aussi interférer….. Les maisons à Laval sont assez proches pour ça….
Je crois que l'étude a misé sur des conditions, qui au départ, on savait qui ne causerait pas d'interférence.

<<this study, the Landis+Gyr Smart Meters operating conditions were artificially modified as to generate a more frequent pattern of impulses—up to three impulses per second—instead of one impulse every 50.2 seconds.>>

Je crois savoir que les mesures réelles des compteurs sont assez différentes non?

---000---

Réponse du technicien en mesurage

De :
Envoyé : 15 août 2013 18:26
À : Basses-Laurentides Refuse
Objet : Re: Smart Meters and Routers Radiofrequency Disturbances Study with Pacemakers and Implantable Cardiac Defibrillators
Hi,
I regularly perform industrial assessments towards pacemakers and defibrillators.
The exposure limits for these devices are very high except for hi frequency magnetic fields.
There are precautionary distances to keep from common wireless devices depending of the strength of the emitters. Usually one has to keep devices a couple of inches from the torso.
However, and that is my personal opinion, I do not think this experience is truly valid: they are not real life implants that are "attached" to a person; it does not take possible and multiple interactions in account.
For example, the person's biological reaction to the meter might trigger false signals to the devices that will then react and cause more harm. The manufacturers should perform their own thorough testing towards this important issue.
Best Regards,
---000---

Chercheur sur les effets non thermiques des CEM
De : Olle Johansson [mailto:Olle.Johansson@ki.se]
Envoyé : 16 août 2013 06:14
À : Basses-Laurentides Refuse
Objet : SV: Smart Meters and Routers Radiofrequency Disturbances Study with Pacemakers and Implantable Cardiac Defibrillators
Interesting. --- However, this is only about Technical EMC, not Human EMC (a term coined by me).
Best regards
Yours
Olle
(Olle Johansson
The Experimental Dermatology Unit
Department of Neuroscience
Karolinska Institute
171 77 Stockholm Sweden)

---000---

Smart Meters and Routers Radiofrequency Disturbances Study with Pacemakers and Implantable Cardiac Defibrillators

GENEVI`EVE OSTIGUY, M.D.,* TOM BLACK, P.E.,† LOUIS-JEAN BLUTEAU, B.ENG.,*
LOUIS DUPONT, ENG,* KATIA DYRDA, M.D.,‡ GUILLAUME GIRARD, P. ENG.,§
DUC-HAI NGUYEN, PH.D.,¶ MICHEL PLANTE, M.D.,* and BERNARD THIBAULT, M.D.‡

From the *Hydro-Quebec, Montreal, Canada; †City of Fountain, Colorado; ‡Montreal Heart Institute, Montreal, Canada; §Medtronic, Inc., Minneapolis, Minnesota; and ¶Hydro-Quebec Research Institute (IREQ), Varennes, Canada

Background: *There is no scientific literature that examines radiofrequency (RF) interference fromSmart Meters with cardiac implantable electronic devices (CIEDs). The objective of this in vitro study was to assess any potential interference with Medtronic CIEDs (Medtronic Inc., Minneapolis, MN, USA).*

Methods: *In the Quebec testing, five models of Medtronic CIEDs were placed in an acrylic cylinder filled with a saline solution and faced a Landis+Gyr Smart Meter or Router (Landis+Gyr AG, Zug, Switzerland).*

The distance between CIEDs and the meter casing or router antenna was 10 cm. The Meter's normal operating conditions were modified to artificially set the number of impulsions at an abnormally high level (one, two, and three impulses per second). Each scenario was repeated one to five times, for 1 minute each. In the U.S. testing, 6 cm and 15 cm (~2.25_ and ~6_) separated the six models of Medtronic CIEDs from the Schlumberger Smart Meter (Itron Inc., Liberty Lake, WA, USA), which generally sent out a 96-bit Standard Consumption Message over 3 seconds. The transmission varied in frequencies along with the interval between cycles.

Results: *A total of 6,966 RF transmissions were completed during the 34 tests conducted in Quebec. In the United States, the CIED was exposed to the meter for 10 minutes to provide a minimum of 200 completed RF transmissions. No interference was observed in worst-case scenarios (testing of meters and CIEDs at their performance limits).*

Conclusions: *Landis+Gyr Smart Meters/Routers and Schlumberger Smart Meters do not interfere with the functioning of the Medtronic CIEDs tested, when placed, respectively, 10 cm and 6 cm and 15 cm apart. (PACE 2013; 00:1–10)*

smart meters, routers, in vitro tests, electromagnetic (radiofrequency) interference, CIEDs, pacemakers

Summary

There is currently no scientific literature that specifically examines electromagnetic interference (EMI) from Smart Meters or Routers with pacemakers and implantable cardiac defibrillators (ICDs). The objective of this study was to perform *in vitro* tests in order to determine any potential EMI of Landis+Gyr Smart Meters (Landis+Gyr AG, Zug, Switzerland) and Routers as well as Schlumberger Smart Meters Itron Inc., Liberty Lake, WA, USA) with Medtronic (Medtronic Inc., Minneapolis, MN, USA) cardiac implantable electronic devices (CIEDs), both tested at their performance limits. In the first case, no interference was observed when Medtronic pacemakers and ICDs were placed at a distance of 10 cm from Landis+Gyr Smart Meters or Routers. Similarly, no interference effect was observed with Schlumberger Smart Meters, placed at a distance of 6 cm and 15 cm apart from the CIEDs.

This study was undertaken as a collaborative study between Medtronic, Hydro-Quebec, and Schlumberger. Participation of the Montreal Heart Institute was made possible as part of an already existing research contract with Hydro-Quebec.
Address for reprints: Geneviève Ostiguy, M.D, Hydro- Quebec – Health Center, 75, René-Lévesque West 7th floor, Montréal Quebec H2Z 1A4, Canada. Fax: 514-289-3163; e-mail : genevieveostiguy@hotmail.com
Received February 8, 2013; revised May 7, 2013; accepted June 3, 2013. doi: 10.1111/pace.12225

Introduction

Public Health Issues

The number of pacemakers and ICD carriers increased significantly over the past decade, as population in industrialized countries became older. Worldwide, the total estimated procedure growth was 2.9% in 2011.

In the province of Quebec (Canada), it is estimated that about 30,000 patients are implanted with a pacemaker, while 10,000 more patients have an ICD. In the United States, about 369,400 pacemaker procedures were conducted in 2011, while 200,700 implantable defibrillator procedures were performed. Worldwide, it is estimated
that about a million pacemaker and implantable defibrillator procedures will be performed in 2013.1

In general, various types of responses of cardiac devices to interference have been reported in the scientific literature2:

1. Reversion to asynchronous pacing.

2. Pacing at an elevated rate.
3. Pacing inhibition.
4. Inappropriate therapy of shock from an ICD.
5. Failure to sense an arrhythmia.
6. Rarely: permanent damage, reprogramming, memory change or hard reset.

CIEDs have been designed and tested to operate normally during an exposure to electromagnetic fields commonly encountered in residential, commercial, scientific, or medical environments. To protect patients, several safeguards are built within them to protect the devices from normal daily EMI. Such safeguards include passive and active filters, one of the components that may help distinguish between natural heartbeat signals and interference signs, as well as a titanium shield to reflect most incident electrical fields.3

Smart Meters are electrical meters that measure and record consumption of electric energy from a residential home or commercial building. They have been implanted worldwide, their number having greatly increased in recent years.

Smart Meters communicate the information on a periodic basis back to the utilities using radiofrequency (RF) signals. Supporting telecommunication equipment, sometimes referred to as advanced metering infrastructure (AMI), enables bidirectional communications with the meters4

Smart Meters communicate in the shared 900-MHz band using different power output and digital modulation schemes to effectively form a wireless Mesh Network. Typically, power output varies between 0.125 W and 0.5 W (EIRP), allowing meters to mesh over distances exceeding 1,000 m. The 900-MHz band is effectively shared using a frequency-hopping algorithm (FHSS) over multiple channels and by maintaining very low duty cycles.

Routers collect and relay data from a large number of Smart Meters, forming a wireless Mesh Network. They are placed about 7 m from the ground in a stand-alone pole, separately from the private houses that are equipped with a Smart Meter.

Smart Meters and Routers operate in the non ionizing radiation portion of the electromagnetic spectrum, more specifically referred to as RFs. RFs are well recognized as a potential source of interference with CIEDs.5

On the regulatory side, the Food and Drug Administration requires CIED manufacturers to test their devices for susceptibility to EMI over a wide range of frequencies and to submit the results as a prerequisite for market approval. Electromagnetic shielding and filtering have been incorporated into the design of modern pacemakers to prevent RF signals from interfering with the electronic circuitry in the acemaker.6 Due to the intermittent and brief duration of emissions as well as the distance usually separating individuals from Smart Meters, the likelihood of interference with pacemakers and implantable cardiac devices appears very low. There is currently no scientific literature that specifically examines interference from Smart Meters or Routers with pacemakers and ICDs. Consequently, *in vitro* tests were performed in order to determine any potential interference of Smart Meters and Routers with CIEDs.

Methods

Ad hoc Testing Rationale

Interference occurrence is based on frequency, modulation, field strength (distance), device sensitivity, and sensing vector. However, knowing the field strength would not bring any more insight into the possible interference level. *Ad hoc* testing is performed under direct exposure at a specific distance since no control is possible over the power level of the emitter. Consequently, the worst-case scenario should be when the CIED is as close as possible from the emitter.

Testing Conformation

Pacemakers and ICDs were placed inside a cylinder of 0.25-m diameter and 1.7-m height (standard adult height), filled with a saline solution with an electrical conductivity of 2 mS/cm representing the normal tissue conductivity characteristics (Fig. 1). Pacemakers and ICDs were put in place at the level corresponding to the human torso. Trials were all conducted with the pacemaker or ICD facing directly the Smart Meter or Router (angle of zero degree), the location of maximum RF power density. CIEDs were located close to the surface of the cylinder (the distance between the cylinder and the pacemaker or ICD being of only 0.5 cm). Figure 2 displays the test and lead sets were arranged in order to simulate the average lead area of a device implant. The CIED and associated leads were positioned so that the two-dimensional area enclosed inside the loop was approximately 200 cm2 (ANSI/AAMI PC69:2007 standard

annex L).7 The shape of the Canadian test model is derived from the Radio Transmission and Telecommunication Equipment Standard. The U.S. model is derived from the AAMI PC69 standard with modification of the dimension in order to obtain a result more representative of the human torso.

Quebec Testing: Landis and Gyr Smart Meters and Routers

Trial Rationale

First trials were conducted in October 2011, in the context of the pilot implantation of Landis+Gyr Smart Meters in the province of Quebec, Canada. They took place at Hydro-Quebec's Research Institute (IREQ).

Five CIED models from Medtronic (with their leads) were submitted to RF emissions from modified Landis+Gyr residential Smart Meters or Routers.

Since magnetic and electrical fields are more variable and can cause stronger induced currents in near field (less than 20 cm), the decision was made to conduct the test initially in the near field area. The distance was measured so that the pacemaker or ICD would be located at 10 cm from the Smart Meter casing (Fig. 3). In the case of residential Smart Meters, the antenna is located in the front part of the meter, about 3 cm behind the case. As for the router, 10 cm separated the antenna from the pacemaker or ICD.

Technical and Biological Considerations

In normal operating conditions, the technical characteristics of Landis+Gyr residential and commercial Smart Meters are the following:

1. Nominal power (fixed, as a characteristic of the Smart Meter): 0.425 Watt (W).
2. Frequency range: 902–928 MHz.
3. Mean duration of an impulse: 48 ms.
4. Frequency of impulse: every 50.2 seconds.
5. Total daily duration of impulses: 83 seconds per day.
6. Duty cycle: 1/1041.

We would like to emphasize the fact that carrier frequency for Smart Meters uses cell phone bands. Carrier frequency is between 902 MHz and 928 MHz; it is modulated in frequency during about 50 ms.

Laboratory measurements have shown that RF intensity is at a maximum directly in front of the Smart Meter and much less behind, due to a partial shielding effect of the case. For that reason, the pacemaker or ICD was placed directly in front of the Smart Meter, where inductive currents are more likely to occur.

As a general rule, it can be roughly estimated that the RF level decreases by the square of the distance to the source. For example, when the Smart Meter emits RFs for a short period of time, the expected (and measured) level is 50 mW/m2 1 m in front of the meter; it then drops to 12.5 mW/m2 2 m in front of the meter, etc.

As for the routers, the technical characteristics are the following:

1. Nominal power (fixed, as a characteristic of the router): 1 W.
2. Frequency range: 902–928 MHz.
3. Mean duration of an impulse: 48 ms.
4. Frequency of impulse: every 39.5 seconds.
5. Total daily duration of impulses: 118.5 seconds per day.
6. Duty cycle: 1/727.

Smart Meters communicate using small data packets that are "bunched up" into short bursts or impulses, lasting about 50 ms and normally occurring every 50 seconds. Their dominant frequency content is within the

902–928-MHz band. In order to maximize the possibility of interference between the Smart Meter and the CIEDs, we chose to apply an external stimulus (close to the natural heartbeat) by artificially setting the number of impulsions at an abnormally high level. Trials were carried out at a carrier frequency between 902 MHz and 928 MHz using three impulses frequencies:

1. One per second.
2. Two per second.
3. Three per second.

Each of the three scenarios was repeated one to five times. Each trial lasted 1 minute. Impulse duration was set at 63 ms (which is typical of the normal functioning). The nominal power was not modified.

One residential Landis+Gyr Smart Meter was submitted for evaluation since residential and commercial Smart Meters display the same technical features. Furthermore, one Landis+Gyr Router was used to conduct the evaluation.

CIED function was monitored via wireless and inductive telemetry using an implant programmer system. Since Smart Meters and Routers carry high frequency and low power, the inductive and wireless telemetry was observed as relatively stable and did not influence our tests.

Monitoring of the CIED electrocardiogram was performed for noise artifacts and channel markers for inhibition. Devices have been verified pre- and postexposure for pulse pacing bradycardia characteristics and with the programmer for memory corruption, reset, or programming changes.

The Smart Meter or Router (the white box on the picture) was installed on the samehorizontal plane as the pacemakers or ICDs, outside the cylinder but very close to it. A Narda electromagnetic reader (Narda-STS, Pfullingen, Germany) measured RF levels.

Pacemaker and ICD Features

The following Medtronic pacemakers and ICDs were submitted to the trials:

1. Adapta DR (dual chamber implantable pulse generator device, unipolar mode).
2. Advisa MRI (bipolar mode).
3. Enpulse (bipolar mode).
4. Consulta CRT-D (triple-chamber cardiac resynchronization therapy device, bipolar mode).
5. Virtuoso (bipolar mode). During the trials, the pacemakers and ICDs were adjusted according to their nominal parameters, with the following exceptions:

    1. Maximal sensitivity (minimal threshold).
    2. Adjusted rate at 55 beats/min.
    3. Minimal refractory and resting periods.

Table I displays the results obtained.

Results

Examples of Electrocardiogram Strips

Figure 4 displays a Virtuoso electrocardiogram strip showing normal pacing rhythm with no pace inhibition during exposure to the Landis+Gyr Smart Meter. All pacing markers are present.
Figure 5 displays Enpulse electrocardiogram strip showing normal pacing rhythm with no noise artifact or inhibition during exposure to the Landis+Gyr Smart Meter Router. All pacing markers are present.

Summary of Results

Overall, 6,966 RF transmissions were completed during the 34 individual tests conducted on various Medtronic pacemakers and ICDs. No interference was observed.

USA Testing: Schlumberger Automated Meter Reading (AMR) Meters

In April 2012, trials were also conducted on Schlumberger AMR Meters (Fig. 6) in the City of Fountain, Colorado.

Technical Considerations

In normal operating conditions, the technical characteristics of Schlumberger Meters are the following:

1. Mean power density: 90 mW.
2. Mean duration of an impulse: 920 ms.
3. Frequency of impulse: every 3 seconds.
4. Total daily duration of impulses: 28,800 seconds per day.
5. Duty cycle: 1/3.

The meter sends out a 96-bit Standard Consumption Message over a 1- to 3-second period, generally. The transmission varies in frequencies as well as the interval between cycles due to frequency hopping between 910 MHz and 920 MHz to avoid interference with other RF communication devices. Carrier frequency for Schlumberger Smart Meters also uses cell phone bands. Carrier frequency is between 910 MHz and 920 MHz; it is modulated in frequency during 920 ms. The CIED was exposed three times to the meter, for a period of 10 minutes, to provide a maximum exposure to the RF transmission.

Pacemakers and ICD Features

Six models of pacemakers or ICDs were submitted to the tests:

1. Adapta (unipolar and bipolar mode).
2. EnRhythm MRI (bipolar mode).
3. Advisa (bipolar mode).
4. Concerto (bipolar mode).
5. Virtuoso (bipolar mode).
6. Consulta (bipolar mode).

Table II displays the results obtained.

Results

Examples of Electrocardiogram Strips

Figure 7 shows an Adapta electrocardiogram strip with normal rhythm and no noise artifact during exposure to Smart Meter from Schlumberger. All pacing markers are present.

Figure 8 displays a Consulta electrocardiogram strip with normal rhythm and no noise artifact during exposure to a Schlumberger Smart Meter. All pacing markers are present. The first few paces at the beginning of the strip are induced inhibition to verify model sensing using an external pulse generator.

Global Discussion

On a technical point of view, it should be emphasized that meters and CIEDs were tested at their performance limits. As explained earlier, we modified the Smart Meters normal operating conditions in order to maximize the possibility of interference. Similarly, CIEDs were set as to display maximal sensitivity (minimal threshold) as well as minimal refractory and resting periods; thus the absence of interference is reported for worst-case scenarios that are seldom encountered in daily life and clinical practice.

It is also worth mentioning that in the Quebec evaluation, 30 trials were originally negative, whereas four trials initially *seemed* to have yielded a positive result. The so-called positive results were indeed false positives, since the communication link connecting the pacemakers and the computer proved to be dropping at the beginning of these four trials due to the timing with the sessions. Consequently, the false positive results were indeed attributable to a loss of communication between the probe and the pacemakers, hence loss of pacing markers. False positives have been confirmed using data from a Reveal XT at the bottom of the tank. Telemetry function is not clinically relevant for the application as it is unlikely a session will be performed next or near a Smart Meter.

Indeed, the interest of studying home monitors (which use the same telemetry schemes as the programmer) seemed lower to us since they are used only as monitors and do not provide therapy at the present time. Finally, no programming changes are made while on telemetry outside of dedicated, protected hospital, and clinic environments.

Despite the above-mentioned arguments, we do recognize that studying home monitors may become of interest. Considering the growing use of home monitoring, there is a small possibility that observed interferences during such monitoring may falsely alert patients and prompt medical visits that could otherwise have been avoided.

We did not test home monitors in this first pilot study but further testing is planned in the follow up studies.

In the U.S. evaluation, the test was repeated after loss of telemetry during device monitoring. No inhibition or electromagnetic disturbance related to device clinical function was observed during the telemetry loss. Verification was performed using an implantable loop recorder, Reveal XT, placed in the saline tank for blind and redundancy monitoring of CIED pacing activities.

Furthermore, although there are no data directly measuring the stability of the telemetry, one can assume that position of the telemetry wand could not interfere in a manner to reduce the Smart Meter coupling. Indeed, it could create a worst-case scenario and actually increase the signal.

That said, it is widely recognized that individuals with CIEDs need to be cautious about many sources of RF-emitting devices in occupational and residential environments.

For example, cell phone users having a pacemaker or ICD9 are advised to maintain a 6” (15 cm) distance between the cell phone and the implant location on their body. This specific distance is in relation to current standards such as AAMIPC692, EN45502–2–1,10 and EN45502–2–2.11 The standards specify an immunity test level of 120 mW for the frequency range of 450 MHz to 3 GHz relating to a 6-inch separation from most common RF intentional source. An optional 8-W immunity test is recommended and adopted by most CIED manufacturers, mostly for capability and diligence. The 8-W recommended level of immunity is to compensate for closer separation distance and higher emitter power level.

In the case of Smart Meters, they are classified as being low-wattage devices. Following the same rationale, a standard 6-inch separation would in theory have to be maintained between the Smart Meter and the CIED carrier.

However, the findings of this study indicate that, despite conservative advice regarding low wattage devices, no interference should occur when placed at a minimal distance from Landis and Gyr Smart Meters and Routers as well as Schlumberger Smart Meters. This finding is consistent with the fact that RF emissions from Smart Meters and Routers are very brief and intermittent. Furthermore, they usually occur at a significant distance from the individuals by usage and design.

Potential Limitations

At first glance, the testing of only one residential Landis and Gyr and one Schlumberger Smart Meter could appear as a limitation to this study. However, this potential limitation is alleviated by the fact that residential and commercial Landis+Gyr Smart Meters display the same technical features.

For other Smart Meter manufacturers, the outcomes cannot be automatically extrapolated from the results of this *in vitro* study, even though it is highly probable that they would be similar due to the nature and brief duration of the RF impulses in normal conditions. Moreover, it should again be emphasized that for the purpose of this study, the Landis+Gyr Smart Meters operating conditions were artificially modified as to generate a more frequent pattern of impulses—up to three impulses per second—instead of one impulse every 50.2 seconds.

Since this was a pilot study and contacts had initially been made with a single manufacturer (Medtronic), we chose to test the models of this manufacturer at first. Since this study included a limited number of their CIEDs sharing similar filter characteristics of the sensing amplifier, no statement can be made about other Medtronic CIEDs or about CIEDs from other manufacturers. These first results justify further testing with other CIED manufacturers for confirmation. Such studies are underway.

Conclusions

Landis+Gyr Smart Meters and Routers do not interfere with the normal functioning of the Medtronic pacemakers and ICDs tested, when placed at a distance of approximately 10 cm apart, even in worst-case scenarios (testing of meters and CIEDs at their performance limits). Similarly, Schlumberger Meters were not shown to be responsible for interfering with the Medtronic cardiac devices submitted for evaluation within 6 cm and 15 cm apart from CIEDs.

Acknowledgment: The authors wish to thank Landis+Gyr for providing technical expertise and information regarding the Smart Meters and Routers. The U.S. part of the
study was initiated at the request of the City of Fountain, Colorado.

References

1. Millenium Research Group. Global Markets for Cardiac Rhythm Management Devices 2011. RPGL12CR10, October 2010.
2. Misiri J, Kusumoto F, Goldschlager N. Electromagnetic interference and implanted cardiac devices: The Nonmedical environment (Part I). Clin Cardiol 2012a; 35:276–280.
3. Misiri J, Kusumoto F, Goldschlager N. Electromagnetic interference and implanted cardiac devices: The medical environment (Part II). Clin Cardiol 2012b; 35:321–328.
4. California Council on Science and Technology (CCST) report. Health Impacts of Radio Frequency Exposure from Smart Meters. Sacramento, CA, CCST, 2011, pp. 1–52.
5. Pinski SL. Electromagnetic interference and implantable devices. In: Ellenbogen KA, Kay GN, Lau CL, Wilkoff BL (eds.): Clinical Cardiac Pacing, Defibrillation, and Resynchronization Therapy. Philadelphia, PA, Saunders, 2007, pp. 1150–
1176.
6. Federal Communications Commission (FCC) office of Engineering and Technology Bulletin 56. Questions and Answers about Biological Effects and Potential Hazards of Radiofrequency Electromagnetic Fields, 4th Ed., Washington, DC, Federal Communications Commission OFfice of Engineering and Technology, 1999.
7. ANSI/AAMI PC69. Active Implantable Medical Devices— Electromagnetic Compatibility—EMC Test Protocols for Implantable Cardiac Pacemakers and Implantable Cardioverter Defibrillators, 2nd Ed. Arlington, VA, Association for the Advancement of Medical Instrumentation, 2007.
8. Health Canada. Limits of human exposure to radiofrequency electromagnetic energy in the frequency range from 3 kHz to 300 GHz. Safety Code 6, 2009, p. 6.

9. Hayes DL, Wang PJ, Reynolds DW, Estes M 3rd, Griffith JL, Steffens RA, Carlo GL, et al. Interference with cardiac pacemakers by cellular telephones. The New England Journal of Medicine 1997; 336:1473– 1479.
10. EN 45502–2–1, 2003–12; Active Implantable Medical Device— Part 2–1: Particular Requirements for AIMD's Intended to Treat Bradyarrhythmia (Cardiac pacemakers).
11. EN 45502–2–2, 2008–03; Active Implantable Medical Device— Part 2–2: Particular Requirements for AIMDs Intended to Treat Tachyarrhythmia (Includes implantable defibrillators).