

Letters

RESEARCH LETTER

Remote Detection of Cardiac Implantable Electrical Devices

Cardiac implantable electrical devices (CIEDs) allow bilateral communication at short range with manufacturer-specific “programmers” that allow for assessment of device status and changes to CIED settings.¹

Many CIEDs also wirelessly broadcast radio frequency signals, such as Bluetooth

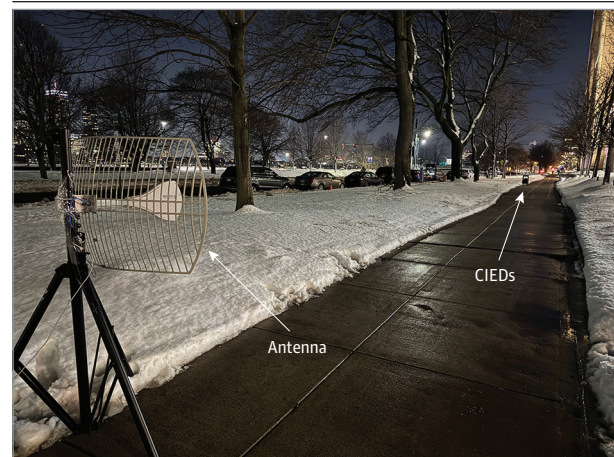
Low Energy (BLE). Once paired with a relay station, either a stand-alone unit typically plugged in at patients’ bedside or a manufacturer-specific smartphone application, wireless CIEDs send transmissions to servers maintained by the manufacturers.² Manufacturer guidance suggests that wireless communication between CIEDs and relay stations extends only to approximately 10 feet.³ A recent kidnapping of a patient publicly reported to have a pacemaker paired with a smartphone application generated broad interest in whether patients with these devices could be geolocated.^{4,5} This report describes efforts to define the technical characteristics of BLE-enabled pacemakers regarding signal detection and the ability to identify specific devices at remote distances.

Methods | This project was reviewed by the Beth Israel Deaconess Medical Center Committee on Clinical Investigations. We evaluated ex vivo Medtronic Azure series pacemakers based on assumptions about the specific model at issue in the missing persons case noted previously.⁶ To assess whether BLE features may facilitate device identification, we characterized observable signals in the absence of a clinical BLE connection such as would be established for a clinical evaluation.

To evaluate detection range, the pacemakers were positioned at increasing distances from the receiving system outdoors, as shown in **Figure 1**. Measurements were conducted at 10-m increments, beginning at 40 m and extending to 120 m. At each distance, 3 pacemakers were spaced roughly 25 cm apart and held stationary for a fixed observation interval to allow sufficient time for BLE advertisement packets to be transmitted. To determine the maximum distance at which pacemaker BLE transmissions could be detected, we measured the received signal strength of 3 Medtronic Azure XT DR MRI SureScan pacemakers as a function of distance. Further details of the experimental setup, which allows for determination of the presence and timing of any electromagnetic signals emitted from these devices even without the Medtronic relay station (stand-alone or smartphone application) or an in-person programmer, are provided in the eMethods in **Supplement 1**.

Results | We observed that pacemakers periodically initiate an advertising window approximately every 3 minutes, each

Figure 1. Photograph Showing the Experimental Setup for Detecting Pacemaker Bluetooth Advertisement Packets



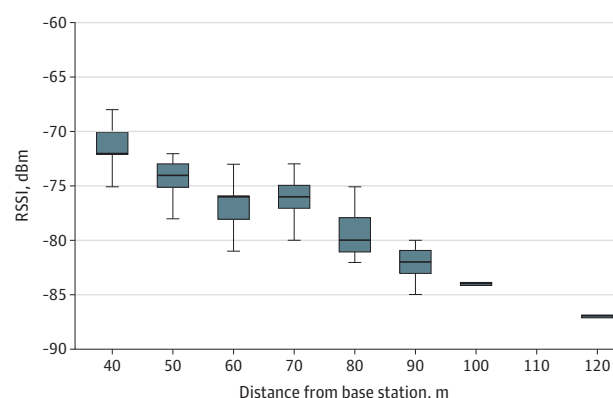
Pacemaker Bluetooth Low Energy advertisement packets were detected outdoors using a long-range parabolic antenna connected to an nRF52840-DK development board (Nordic Semiconductors). During testing, the pacemakers were positioned at increasing distances from the receiving system, beginning at 40 m and extending to 120 m in 10-m increments. CIED indicates cardiac implantable electrical devices.

lasting roughly 400 to 500 milliseconds. During this interval, the pacemaker transmits advertising packets to announce its presence and enable discovery by nearby BLE devices. Because each pacemaker transmits a fixed BLE identifier, a pacemaker can be recognized by its media access control (MAC) address. BLE devices periodically broadcast short advertising packets that include this identifier, corresponding to a manufacturer-assigned MAC address intended to be globally unique and that remains constant over time.

Figure 2 shows the received signal strength indicator—a measure of signal power—as a function of the distance between the pacemaker and a high-gain directional parabolic antenna with a 10° beam used to focus reception toward the devices. As expected, the power of the received signal decreased as the distance increased. Despite this decrease, we could reliably detect the pacemaker as far as 90 m and occasionally receive packets at 100 m and 120 m. One experiment without a tissue phantom received packets at a distance of 250 m outdoors from an explanted device; however, this result may overestimate the detection range for implanted devices, where attenuation by human tissue would reduce signal propagation. Additional results are presented in eFigures 1 and 2 in **Supplement 1**.

Discussion | We report the following observations regarding a common model of pacemaker. First, these BLE-enabled devices emit regular signals advertising their presence that include unique identifiers. Second, our experimental models suggest that these signals may be reliably detectable as far as

Figure 2. Box and Whisker Plot Showing Received Signal Strength of the Pacemaker as a Function of Distance



Received signal strength indicator (RSSI) values are shown as a function of distance between the pacemaker and the parabolic receive antenna. Note that the nRF52840-DK development board can only reliably detect Bluetooth Low Energy signals that have an RSSI >-90 decibel-milliwatt (dBm). Measurements were obtained outdoors with pacemakers submerged in a tissue-mimicking phantom to approximate signal propagation through human tissue. For all pacemaker advertisement packets collected at a given distance, the center line indicates the median, the box represents the interquartile range, and the whiskers indicate the range of observed values.

90 m, and potentially farther. We emphasize only observation of 1 pacemaker model, under carefully controlled ex vivo conditions, with no suggestion from these experiments that their function or programming can be altered through these means. However, our results suggest the technical feasibility of observing both the presence of implantable medical devices and specific patients via their devices outside of clinical settings.

Our findings suggest potential privacy and cybersecurity issues arising from BLE-enabled devices. MAC addresses may not be immediately linked to a specific patient absent additional data likely controlled by manufacturers. However, these data likely fall within categories protected under the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule.⁷ Yet because the signals are broadcast directly from the pacemaker (rather than transmitted through hospital systems), the data flows described here may fall outside the scope of HIPAA regulation, since the device makers may not be covered entities under HIPAA.

Alternative communication technologies exist, such as the Medical Implant Communication Service (MICS), but differ in frequency and underlying protocols. MICS is a lower frequency band specifically designated for medical implant communication. It offers better tissue penetration and allows each device manufacturer to design a proprietary communication protocol (ie, what each device transmits and how they are encrypted). On the other hand, BLE occupies a higher frequency band and is a widely used protocol for devices beyond implants (eg, smartphones, headphones).⁹ Due to BLE's wide adoption, BLE-enabled implants can communicate directly with nonspecialized devices, such as smartphones. Due to the increased

adoption of BLE-based pacemaker designs, we chose to focus on the privacy issues of BLE. We note that, in theory, MICS devices might have similar privacy issues. However, unlike BLE, MICS does not define a standard communication protocol, and thus each manufacturer uses a proprietary protocol,⁸ which may not be susceptible to similar privacy risks. Therefore, the exact advertised data and the extent of personally identifiable information revealed with MICS depend on the exact device. Future work can investigate which MICS devices, if any, have similar privacy concerns as demonstrated in our article for Bluetooth.

In summary, we observed that BLE-enabled pacemakers broadcast identifiers that can be detected and associated with a specific device at distances substantially greater than those used clinically. We did not determine an upper bound on detection range. Although these findings were obtained under controlled experimental conditions rather than in ambulatory patients, they demonstrate the technical feasibility of remote device identification and raise unresolved legal and security questions around data emitted directly from implantable medical devices.

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Author Contributions: Drs Kramer and Fu 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.

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Data Sharing Statement: See Supplement 2.

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Supplemental Online Content

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eMethods. Additional Methods

eFigure 1. Pacemakers Submerged in Tissue-Mimicking Solution

eFigure 2. Pacemaker Advertisement Packets Received per Minute as a Function of Distance

eReferences.

This supplemental material has been provided by the authors to give readers additional information about their work.

eMethods. Additional Methods

Characterization of BLE Signals in CIEDs

To assess whether BLE features may facilitate device identification, we characterized observable signals in the absence of a clinical BLE connection such as would be established for an in-person evaluation. Specifically, we conducted passive detection of the pacemaker's BLE communications using a Nordic Semiconductor nRF52840-DK development board flashed with the nRF BLE Sniffer firmware, together with the network protocol analyzer Wireshark for packet capture and protocol level analysis. This experimental set-up allows for determination of the presence and timing of any electromagnetic signals emitted from these devices even without the Medtronic relay station (stand-alone or smartphone app) or an in-person programmer.

All pacemaker experiments were carried out on a tissue-mimicking phantom consisting of 41.5% solution by weight of sugar and distilled water (**Supplemental Figure 1**), following medical radio communications standards.¹ This setup approximates signal attenuation through human tissue by reproducing key dielectric properties of biological tissue. Signal detection was performed using a long-range parabolic antenna² connected to the nRF52840-DK development board.

To evaluate detection range, the pacemakers were positioned at increasing distances from the receiving system outside, as shown in **Figure 2**. Measurements were conducted at 10 m increments beginning at 40 m and extending to 120 m. At each distance, we placed the three pacemakers spaced roughly 25 cm apart. This evaluates the validity of our detection across devices, while also testing multiple positions at a given same range since some positions may result in more packet detections than others, even at the same range. At each distance,

the devices were held stationary for a fixed observation interval to allow sufficient time for BLE advertisement packets to be transmitted.

Range Experiments

To determine the maximum distance at which pacemaker BLE transmissions can be detected we measured the received signal strength of three Medtronic Azure XT DR MRI SureScan pacemakers as a function of distance. Supplemental **Figure 2** shows the received signal strength indicator (RSSI), a measure of signal power, as a function of the distance between the pacemaker and a high-gain directional parabolic antenna with a 10° beam used to focus reception towards the devices. As expected, the power of the received signal decreases as the distance increases. Despite this decrease, we can reliably detect the pacemaker as far as 90 m, and occasionally receive packets at 100 m and 120 m. We further note that RSSI is a function of not only distance, but also the location of the device within the environment. This explains why the RSSI is not monotonically decreasing. For example, the RSSI at 70 m is slightly higher than RSSI at 60 m; additionally, some packets were received at 120 m but not 110 m. One experiment without a tissue phantom received packets at a distance of 250 m outdoors from an explanted device; however, this result may overestimate the detection range for implanted devices, where attenuation by human tissue would reduce signal propagation.

To estimate how reliably a pacemaker can be detected at increasing distances, we measured how many BLE transmissions could be captured by the receiving antenna.

Supplemental Figure 2 shows the number of pacemaker BLE transmissions (i.e., packets) received per minute as a function of the distance to the parabolic receive antenna. Similar to the power of the received signal discussed above, the number of packets per minute also

decreases as a function of distance. This is because packets are less likely to be detected as their power decreases. Despite this decrease, the parabolic receive antenna still captures approximately 0.28 packets per minute at 90 m.

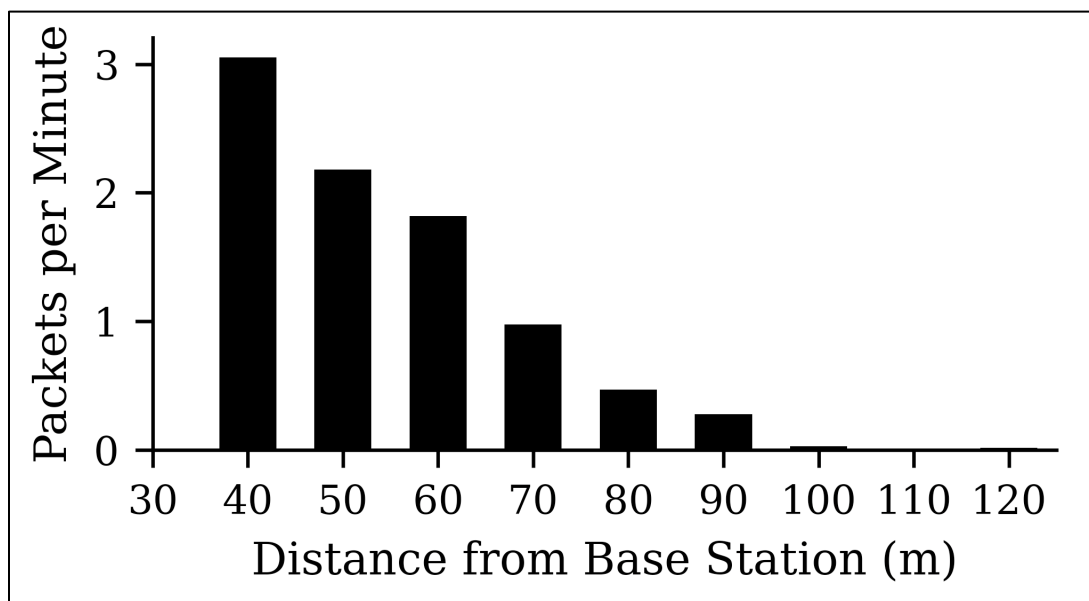
eFigure 1. Pacemakers Submerged in Tissue-Mimicking Solution

Three pacemakers were submerged in a tissue-mimicking phantom solution to approximate the dielectric properties and signal attenuation of human tissue. This setup was used to simulate signal propagation from implanted devices. The devices were spaced approximately 25 cm apart from each other.



eFigure 2. Pacemaker Advertisement Packets Received per Minute as a Function of Distance

The number of pacemaker advertisement packets received per minute is shown as a function of the distance between the pacemaker and the parabolic receive antenna. Packets were collected over fixed sampling intervals at each distance, and the packet rate (packets per minute) was computed from the total number of packets received during each interval. Measurements were obtained outdoors with pacemakers submerged in a tissue-mimicking phantom to approximate signal propagation through human tissue.



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