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and the Proposed Class

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CLINTON W. ROSS JR., individually and on behalf of all others similarly situated,

Plaintiff,

vs.

ST. JUDE MEDICAL, INC.; ST. JUDE MEDICAL S.C., INC.; and PACESETTER, INC. d/b/a St. Jude Medical Cardiac Rhythm Management Division,

Defendants.

Case No.

CLASS ACTION COMPLAINT

JURY TRIAL DEMANDED

Plaintiff Clinton W. Ross Jr. ("Plaintiff"), individually and on behalf of all others similarly situated, makes the following allegations based upon information and belief, except as to those allegations specifically pertaining to Plaintiff and his counsel, which are based on personal knowledge. Plaintiff brings this action for restitution and monetary damages against defendants St. Jude Medical, Inc., St. Jude Medical S.C., Inc., and Pacesetter, Inc. dba St. Jude Cardiac Rhythm Management Division (collectively referred to as "St. Jude" or "Defendants"), demanding a trial by jury.

THE PARTIES

1. Plaintiff Clinton W. Ross Jr. ("Plaintiff") is a resident of Cook County, Illinois.

2. Defendant St. Jude Medical, Inc. ("St. Jude Medical") is a corporation doing business in each and every state of the United States as well as the District of Columbia, and is organized under the laws of Minnesota, with its principal place of business at One St. Jude Medical Drive, St. Paul, Minnesota. St. Jude Medical is therefore a citizen of Minnesota. See 28 U.S.C. § 1332(c)(1).

3. Defendant St. Jude Medical S.C., Inc. ("St. Jude Medical S.C.") is a corporation doing business in each and every state of the United States as well as the District of Columbia, and is organized under the laws of Minnesota, with its principal place of business at 6300 Bee Cave Road, in Austin, Texas. St. Jude Medical S.C. is therefore a citizen of Minnesota and Texas. See 28 U.S.C. § 1332(c)(1). St. Jude Medical S.C. operates as a wholly owned subsidiary of St. Jude Medical, Inc.

4. Defendant Pacesetter, Inc. ("Pacesetter") is a corporation doing business in each and every state of the United States as well as the District of Columbia, and is organized under the laws of Delaware, with its principle place of business at 15900 Valley View Court, in Sylmar, California. Pacesetter is therefore a citizen of Minnesota and California. See 28 U.S.C. § 1332(c)(1). Pacesetter, doing business as St. Jude Medical Cardiac Rhythm Management Division, develops, manufactures, and distributes cardiac rhythm management products including tachycardia implantable cardioverter defibrillators systems, pacemakers, and cardiac

resynchronization therapy devices. Pacesetter operates as a wholly owned subsidiary of St. Jude Medical, Inc.

JURISDICTION AND VENUE

5. This Court has jurisdiction over this action pursuant to the Class Action Fairness Act (28 U.S.C. § 1332(d)). The aggregated claims of the individual class members exceed $5,000,000, exclusive of interest and costs, at least one class member is of diverse citizenship from one defendant, and there are more than 100 class members.

6. This Court has personal jurisdiction over Defendants because they conducts business in California and have sufficient minimum contacts with California.

7. Venue is proper in this District under 28 U.S.C. § 1391(b) because a substantial part of the events or omissions giving rise to the claims occurred and/or emanated from this District, and because Defendants have caused harm to class members residing in this District. For example, St. Jude maintains its main cardiac rhythm management facility in Sylmar, California, where the company primarily conducts its design, testing, risk and failure analysis for its ICDs, pacemakers and CRT devices. St. Jude's Sylmar facility is registered with the FDA as a medical device manufacturer and operates as the headquarters for the company's Cardiac Rhythm Management Division. In addition, Merlin.net, where the data obtained from the implanted devices is stored and accessed, is operated by Pacesetter, Inc. which has its principal place of business in Sylmar, California.

FACTUAL ALLEGATIONS

A. Implantable Cardiac Devices and the Advent of Remote Monitoring.

8. Implantable Medical Devices ("IMDs") are electronic devices implanted within the body to treat or monitor a medical condition or body part. Examples of IMDs include pacemakers and defibrillators to monitor and treat cardiac conditions; neurostimulators for deep brain stimulation in cases such as epilepsy or Parkinson; and drug delivery systems in the form of infusion pumps. Implantable cardiac devices are the most widely known example of IMDs.

9. Implantable cardiac devices are used to treat bradycardia (debilitating slow heartbeat), tachycardia (life-threatening fast heartbeat), and other cardiac rhythm disorders. These devices fall into three general categories: (i) pacemakers; (ii) implantable cardioverter-defibrillators ("ICDs") and (iii) cardiac resynchronization therapy defibrillators/pacemakers ("CRTs"). A pacemaker is an implanted medical device that uses electrical impulses, delivered by leads contacting the heart muscles, to regulate the beating of the heart. The primary role of a pacemaker is to maintain an adequate heart rate, either because the heart's native pacemaker is not fast enough, or there is a block in the heart's electrical conduction system. An ICD is an electrical impulse generator which is implanted in patients who are at risk of sudden cardiac death due to ventricular fibrillation; these devices are programmed to detect cardiac arrhythmia and correct it by delivering a jolt of electricity. A CRT device sends electrical impulses to both lower chambers of the heart to help them beat together in a more synchronized pattern and thereby improves the heart's ability to pump blood and oxygen to the body.

10. At the time that a cardiac device is implanted, the physician uses a "device programmer" to check and adjust the settings on the cardiac device. A device programmer typically communicates with the device using a telemetry wand. By placing the wand outside of the body and over the implanted device, it can read and display the device information on the programmer screen. The physician can program different sensing and therapy thresholds on the implanted devices for each patient's individual needs.

11. Historically, patients with an implanted cardiac device would typically require an office visit follow-up to their electrophysiologist approximately every three months. At each follow-up visit, the following data would be acquired using the device programmer: patient history, device parameters, stored episodes, device interrogation testing, diagnostic data, and measured data.

12. Obviously, these frequent office visits are time consuming, expensive and inconvenient. In the last decade, cardiac device manufacturers have begun to incorporate networking functions – also known as "telemetry" – into their devices that allow for the remote collection of the same information that is collected in an office visit. With these new, networked

devices, the data that historically could only be collected at a doctor's office through the use of a device programmer, is collected from an external device located in the patient's home which is then transferred through a telephone line to an external server for the electrophysiologist to view. The ability to remotely collect device information has obvious benefits. Not only does remote collection reduce the number of office visits required by the patient, it also allows healthcare providers to constantly monitor the patient's condition.

13. The availability of remote monitoring of implantable cardiac devices – and the reduction in office visits resulting from remote monitoring – is not only more convenient for patients, it also can result in significant cost savings. St. Jude, on a webpage titled "Arrhythmia Management Economics," proclaims that "ICDs and pacemakers with remote monitoring have shown impressive cost reduction opportunities." According to St. Jude:

> Studies of the use of remote monitoring in the U.S. show:
>
> - 36% decrease in cardiac or device-related emergency department or hospital visits
> - 17% reduction in spending (approximately $10,640 per ICD/CRT-D patient) over 3 years
> - 9% reduction in spending (approximately $4,356 per pacemaker patient) over three years
> - 18% reduction in length of hospital stay (an estimated savings of $1,793/stay, per patient)

[Footnotes omitted.]

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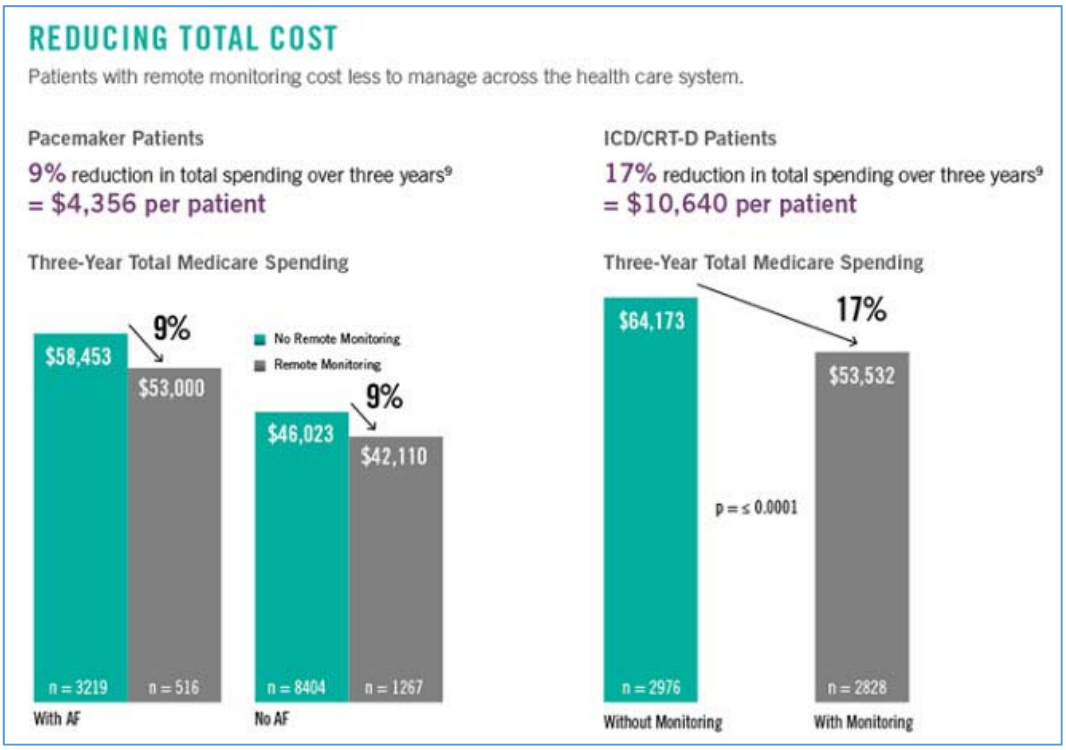
14. On the same "Arrhythmia Management Economics" webpage, St. Jude presents the following chart to highlight the cost savings available from remote monitoring:



15. Not only does remote monitoring of cardiac devices provide significant economic benefits, it also improves patient care. On a webpage titled, "Improved Clinical Outcomes With Remote Monitoring," St. Jude explains:

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> Remote monitoring has been associated with improved survival. Patients with high remote monitoring adherence see a 53-percent greater survival than patients with low remote monitoring adherence and a 140-percent greater survival than patients not using remote monitoring at all. Additional studies have shown the following clinical outcomes:
>
> - 2.4X greater probability of survival
> - 79% reduction in time to detection of clinical events
> - 66% reduction in hospitalizations for AF or stroke admissions
> - 25% reduction in CHF admissions for ICD/CRT-D patients
> - 50% reduction in relative risk of death
> - 34% reduction in all-cause mortality over 3 years for ICD/CRT-D patients
> - 27% reduction in all-cause mortality over 3 years for pacemaker patients

[Footnotes omitted.]

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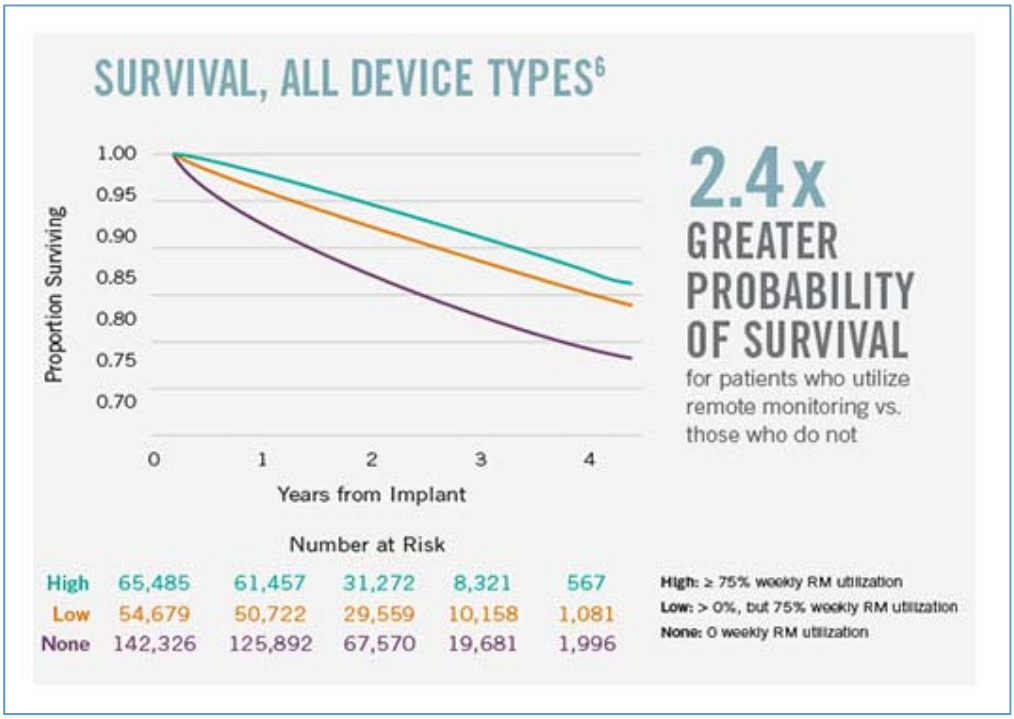
16. St. Jude reinforces the 2.4x greater probability of survival with remote monitoring with the following chart:



17. Although the remote monitoring of cardiac devices provides clear benefits, it also introduces a major source of security risks. For example, an implanted cardiac device that communicates wireless through RF (radiofrequency) is no longer "invisible" since its presence can be remotely detected. Furthermore, a vulnerable communication channel in an implanted cardiac device with RF capabilities could allow unauthorized the access to transmitted data by eavesdroppers. This could result in a major privacy breach, given the sensitive information stored and transmitted by these devices (including vital signals, diagnosed conditions, therapies, and a variety of personal data). A vulnerable communication channel also makes it easier to attack the implant in ways previously not possible. For example, by forging, altering, or replying to previously captured transmissions to or from an implanted cardiac device, a bad actor could monitor and modify the implant without necessarily being close to the victim. Such attacks can put at risk the safety of the patient with the implantable device, with fatal consequences in certain cases.

B. St. Jude's Cardiac Devices, the Merlin@home Transmitter and the Merlin.net Patient Care Network (PCN).

18. The Cardiac Rhythm Management Division of St. Jude Medical designs and manufactures pacemakers, ICDs and CRTs. St. Jude first provided for the capability of remote monitoring of its cardiac devices in about 2003 with the introduction of its Housecall Plus system.

19. The Housecall Plus system used a transmitter that was about the size of a telephone answering machine and consisted of a telemetry wand, which read information from the patient's implanted cardiac device, and a data model which transmits the patient data to a server. The transmitter telemetry wand used inductive telemetry to retrieve information from the device. Inductive telemetry uses two coils, one in the device and the other located on the transmitter wand, with mutual inductance between these coils to communicate information from the device to the transmitter. The transmitter would then retrieve data from the patient's cardiac device and send it via modem to the receiver. Because the Housecall Plus transmitter required the use of a telemetry wand, direct patient involvement was necessary in order to collect data from the implanted cardiac device.

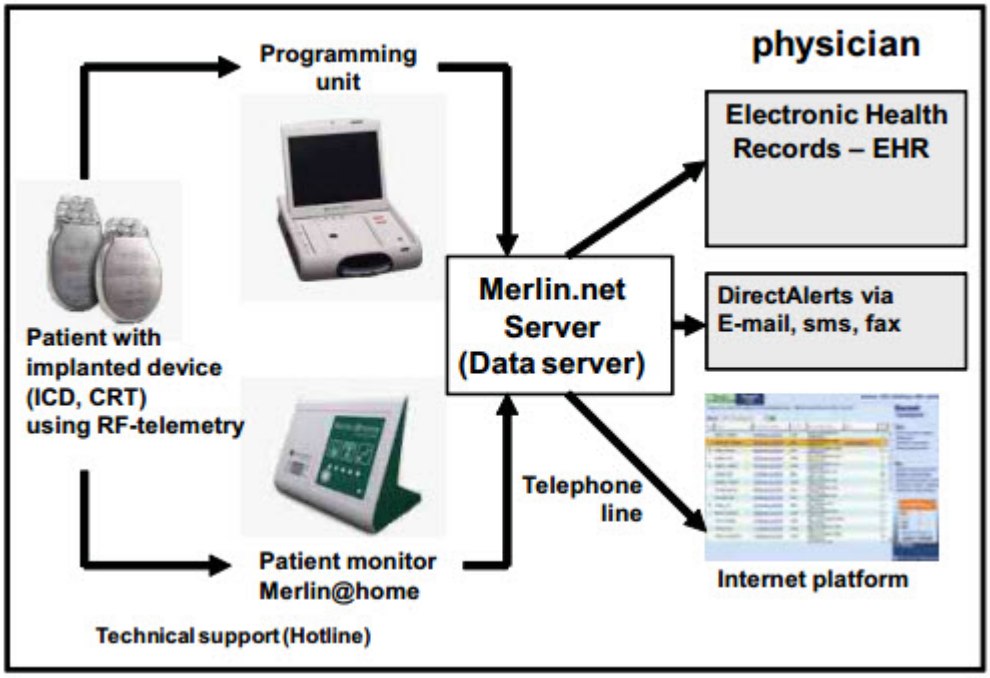
20. On July 15, 2008, St. Jude issued a press release announcing the forthcoming release of its Merlin@home transmitter, an RF wireless technology that allowed for remote monitoring of patients' implanted cardiac devices. Unlike the Housecall Plus system, the Merlin@home transmitter's wireless technology allows the devices to be automatically checked without direct patient involvement. In its July 15, 2008 press release, St. Jude touted the advantage of using RF wireless technology and the ability to automatically download information from the implanted device without any patient involvement:

> Until recently, patients with implanted cardiac devices were typically required to visit doctors' offices several times per year to have their device performance checked. With the advent of transmitters capable of downloading and transmitting device data over telephone lines, patients are now able to initiate and perform many of these follow-ups in their own homes.

> The Merlin@home transmitter's wireless technology gives patients the additional comfort of having devices automatically checked. ***Since the transmitter initiates the scheduled follow-up and uses RF wireless telemetry to download data from the device, the entire follow-up procedure is conducted without any direct patient involvement. The only requirement is that each patient remains within range of the transmitter while it reads his or her device.*** Patients also may initiate data transmissions as instructed by their physicians.
>
> The Merlin@home transmitter is transportable and can be setup wherever a standard phone line is available, typically by the bedside for data transmission while the patient sleeps. Data downloaded by the Merlin@home transmitter is sent to Merlin.net PCN, a secure, Internet-based data management system, where it is stored for review by the patient's physician.
>
> "We have simplified remote follow-ups to the extent that they are now something that can be performed seamlessly without interrupting the patient's day. Patients simply setup the Merlin@home transmitter; after that, the system handles all aspects of patient follow up, including daily monitoring," said Eric S. Fain, M.D., president of the St. Jude Medical Cardiac Rhythm Management Division. "The simplicity of the system reduces the chance of patients missing follow-up transmissions."
>
> The Merlin@home transmitter also monitors cardiac devices outside of regularly scheduled follow-ups. The system can perform daily checks to monitor for alerts about device performance or about patient heart rhythms that may have been detected by the implanted device. Merlin.net PCN can be programmed to alert a physician directly including an on-call physician outside normal business hours in the event that the monitored data reveals an episode the physician needs to know about as soon as possible.
>
> "By directly alerting physicians, the Merlin@home transmitter and Merlin.net PCN can help reduce risks associated with cardiac episodes that physicians would want to know about right away," said Fain. "Without this notification, these events might go undetected for significant amounts of time. Direct notification is one more way to give physicians more control over their patient's critical health care."

[Emphasis added.]

21. During a Merlin@home session, the transmitter reads the data from the implanted cardiac device and sends it to the Merlin.net Patient Care Network (PCN) a remote server. The data can be accessed by the patient's healthcare provider from Merlin.net. The interaction between the cardiac device, the Merlin@home transmitter and Merlin.net PCN can be illustrated as follows:



C. St. Jude's Representations to Patients and Healthcare Providers.

22. In a brochure, titled "Connecting with Your Doctor From Home," St. Jude represents to patients the benefits of remote monitoring of their implanted cardiac devices, stating, in relevant part:

> We're pleased to bring you a new development in patient care that will give you greater flexibility and allow your doctor to keep a closer eye on your device while you spend less time at the doctor's office.
>
> With Remote Care from St. Jude Medical, your Merlin@home® transmitter allows you to have your device checked from the comfort of your own home, reducing the number of scheduled clinic visits you need to make.

> The transmitter is also able to monitor your device daily between scheduled follow-ups and can alert your doctor's office if it detects anything of which your doctor may wish to be aware.

23. St. Jude's "Connecting with Your Doctor From Home" brochure contains a "Frequently Asked Questions" section, where St. Jude further explains remote monitoring:

> **What are remote follow-ups and remote monitoring?**
>
> Remote follow-ups are checks on your implantable cardiac device from a location other than your doctor's office.
>
> Most patients with implanted devices need to visit their doctor's office several times each year to have their devices checked. Your Merlin@home transmitter can now perform many of these tasks from home. The transmitter simply reads your device's data and transmits it securely over the phone for your doctor to review.
>
> Remote monitoring is when the transmitter checks your device between scheduled follow-ups and transmits data or information about which your doctor has asked to be notified.

24. In the "Connecting with Your Doctor From Home" brochure, St. Jude assures patients that remote monitoring will not affect the implanted cardiac device's performance:

> **Will remote monitoring affect my device's performance?**
>
> No. Your device will continue to function normally during remote follow-ups and monitoring.

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25. St. Jude also represents in the "Connecting with Your Doctor From Home" brochure that patients' data will be secure, stating:

D. St. Jude's Implanted Cardiac Devices and the Merlin@home Transmitter Are Shown to be Grossly Insecure.

26. On August 25, 2016, Muddy Waters Capital LLC issued a report setting forth findings by MedSec Holdings Ltd. ("MedSec") regarding severe security vulnerabilities found in St. Jude's cardiac devices with RF telemetry capabilities, the Merlin@home transmitter and the Merlin.net PCN.

27. As set forth in the Muddy Waters report, MedSec found that St. Jude's cardiac devices with RF telemetry capabilities, the Merlin@home transmitter and the Merlin.net PCN lacked even the most basic security defenses (such as strong authentication, encrypted software and code, anti-debugging tools, anti-tampering mechanisms and the use of a wand to activate RF wireless communications) that are used by other cardiac device manufacturers. The lack of these security defenses, makes it easy to reverse engineer the Merlin@home transmitter and locate numerous vulnerabilities. Indeed, MedSec demonstrated at least three ways to obtain "root access" to the Merlin@home transmitter. Obtaining root access to the Merlin@home transmitter

not only allows a malicious attacker to reverse engineer the device to identify and leverage vulnerabilities, it also exposes sensitive network credentials including the user ID and password for the Merlin.net PCN and SSH keys. St. Jude's failure to protect these important sensitive network credentials reveals a complete lack of any focus on security and provides a potential avenue for obtaining unauthorized access to the Merlin.net PCN.

28. MedSec also discovered that the communication protocol utilized by St. Jude's cardiac devices with RF telemetry capabilities and the Merlin@home transmitter do not employ any unique or one-time tokens, such as a user-provided password. As such, and because there is no strong authentication built into the communication protocol used by these devices, any device programmer or Merlin@home transmitter can communicate with any St. Jude cardiac device with RF telemetry capabilities. Therefore, any attacker who can reverse engineer the communication protocol used by these devices can gain access to (as well as impersonate) any device that utilizes the communication protocol – including any St. Jude cardiac device with RF telemetry capabilities.

29. The lack of even the most basic security defenses allowed MedSec – with relatively little effort – to develop and demonstrate two types of potentially catastrophic attacks that could be used against St. Jude's cardiac devices with RF telemetry capabilities: (i) a "crash attack" that would remotely disable the implanted cardiac devices, and in some cases, appear to cause the device to pace at a dangerous rate; and (ii) a "battery drain attack" that remotely runs down the batteries of the cardiac devices.

30. The "crash attack" involves broadcasting a combination of signals that places St. Jude's cardiac devices with RF telemetry capabilities into a state of malfunction. As shown by MedSec, the "crash attack" can be achieved either through a compromised Merlin@home transmitter or via a software defined radio. According to MedSec, in many cases the "crash attack" made the cardiac device completely unresponsive to interrogations from Merlin@home transmitter and Merlin device programmers. More distressingly, in some cases the "crash attack" caused the cardiac device to pace at rapid rate that could have severe adverse health consequences.

31. MedSec also demonstrated a "battery drain attack" that generates signals from the Merlin@home transmitter to run down batteries in St. Jude's cardiac devices with RF telemetry capabilities. MedSec's testing of this attack depleted the batteries of the cardiac device at approximately three percent of capacity per 24-hour period. MedSec has since developed new code for a "battery drain attack," which it believes would drain devices at six times that rate – allowing the battery for a St. Jude cardiac device to be depleted in approximately two weeks of nightly broadcasts. MedSec also reports that, because of the compromised login credentials, a large-scale "battery drain attack" using the Merlin.net PCN may be possible.

32. As explained by MedSec, the "crash attack" and "battery drain attack" are only two examples of potential attacks. Given the lack of even the most basic security defenses and the ability to obtain root access to the Merlin@home transmitters, it is doubtless that a malicious attacker could find numerous other attacks. Thus, even if the particular attacks outlined by MedSec were addressed, without a completely new communication protocol, St. Jude's cardiac devices with RF telemetry capabilities would continue to be susceptible to other attacks.

E. Plaintiff' Experience.

33. Plaintiff Ross currently has implanted a St. Jude Quadra Assura cardiac resynchronization therapy defibrillator (model number CD-3365-40Q). Prior to his implant surgery, which took place on or about November 2, 2015, Plaintiff Ross was told that the Quadra Assura would be remotely monitored by his physician using the Merlin@home transmitter. Mr. Ross was additionally told that remote monitoring would not in any way affect the performance of the implanted device and that remote monitoring was safe and secure.

34. Following his surgery, Plaintiff Ross installed the Merlin@home transmitter in his bedroom and has since been using the Merlin@home transmitter as directed. Since learning of the security issues with his Quadra Assura and the Merlin@home transmitter, Plaintiff Ross has, based on the recommendation of his physician, discontinued using the Merlin@home transmitter by unplugging the unit from the electrical outlet. Plaintiff Ross, again on the recommendation of his physician, does not intend to use the Merlin@home transmitter until the security issues with his Quadra Assura and the Merlin@home transmitter are resolved and will, therefore, be required

to go in person to his doctor's office to have his cardiac device monitored.

CLASS ALLEGATIONS

35. Plaintiff brings this action on behalf of himself and as a representative of all others who are similarly situated. Pursuant to Rules 23(a), (b)(2), and/or (b)(3) of the Federal Rules of Civil Procedure, Plaintiff seeks certification of a Nationwide Class and a Illinois Class.

36. The Nationwide Class is initially defined as follows:

> *All persons who were implanted with a "Class Device" while residing in the United States (the "Nationwide Class").*

37. The Illinois Class is initially defined as follows:

> *All persons who were implanted with a "Class Device" while residing in Illinois* (the *"Illinois* Class").

38. For purposes of the above class definitions, "Class Device" shall consist of every pacemaker, implantable cardioverter-defibrillator, and cardiac resynchronization therapy pacemaker and/or defibrillator with radiofrequency ("RF") telemetry capability that was designed, manufactured, marketed, distributed or sold by the Defendants, including but not limited to the following models:

Model Name	Model Number(s)	Device Type
Accent DR RF	PM2212; PM2210	Dual-Chamber Pacemaker
Accent SR RF	PM1210	Single-Chamber Pacemaker
Allure Quadra RF	PM3242	Cardiac Resynchronization Therapy Pacemaker
Allure RF	PM3222	Cardiac Resynchronization Therapy Pacemaker
Anthem RF	PM3210	Cardiac Resynchronization Therapy Pacemaker

Model Name	Model Number(s)	Device Type
Assurity	PM1240	Single-Chamber Pacemaker
Assurity	PM2240	Dual-Chamber Pacemaker
Assurity+	PM1260	Single-Chamber Pacemaker
Assurity+	PM2260	Dual-Chamber Pacemaker
Current Accel DR	CD2215-30; CD2215-36; CD2215-36Q	Dual-Chamber Implantable Cardioverter Defibrillator
Current Accel VR	CD1215-30; CD1215-36; CD1215-36Q	Single-Chamber Implantable Cardioverter Defibrillator
Current DR	2107-30; 2107-36; CD2207-36Q	Dual-Chamber Implantable Cardioverter Defibrillator
Current DR RF	2207-30; 2207-36	Dual-Chamber Implantable Cardioverter Defibrillator
Current VR	1107-30; 1107-36; CD1207-36Q	Single-Chamber Implantable Cardioverter Defibrillator
Current VR RF	1207-30; 1207-36	Single-Chamber Implantable Cardioverter Defibrillator
Current+ DR	CD2211-36; CD2211-36Q	Dual-Chamber Implantable Cardioverter Defibrillator
Current+ VR	CD1211-36; CD1211-36Q	Single-Chamber Implantable Cardioverter Defibrillator

Model Name	Model Number(s)	Device Type
Ellipse DR	CD2275-36; CD2257-36Q; CD2311-36; CD2311-36Q; CD2411-36; CD2411-36C; CD2411-36Q; CD2411-36QC	Dual-Chamber Implantable Cardioverter Defibrillator
Ellipse VR	CD1257-36; CD1257-36Q; CD1311-36; CD1311-36Q; CD1411-36; CD1411-36C; CD1411-36Q; CD1411-36QC	Single-Chamber Implantable Cardioverter Defibrillator
Fortify Assura DR	CD2257-40; CD2257-40Q; CD2357-40; CD2357-40C; CD2357-40Q; CD2357-40QC	Dual-Chamber Implantable Cardioverter Defibrillator
Fortify Assura VR	CD1257-40; CD1257-40Q; CD1357-40; CD1357-40C; CD1357-40Q; CD1357-40QC	Single-Chamber Implantable Cardioverter Defibrillator
Fortify DR	CD2231-40; CD2231-40Q	Dual-Chamber Implantable Cardioverter Defibrillator
Fortify VR	CD1231-40; CD1231-40Q	Single-Chamber Implantable Cardioverter Defibrillator
Promote	3107-30; 3107-36; 3107-36Q; CD3207-36Q	Cardiac Resynchronization Therapy Defibrillator

Model Name	Model Number(s)	Device Type
Promote Accel	CD3215-30; CD3215-36; CD3215-36Q	Cardiac Resynchronization Therapy Defibrillator
Promote Q	CD3221-36	Cardiac Resynchronization Therapy Defibrillator
Promote Quadra	CD3245-40; CD3245-40Q	Cardiac Resynchronization Therapy Defibrillator
Promote RF	3207-30; 3207-36	Cardiac Resynchronization Therapy Defibrillator
Promote+	CD3211-36; CD3211-36Q	Cardiac Resynchronization Therapy Defibrillator
Quadra Allure MP RF	PM3262	Cardiac Resynchronization Therapy Defibrillator
Quadra Assura	CD3265-40; CD3265-40Q; CD3365-40; CD3365-40C; CD3365-40Q; CD3365-40QC	Cardiac Resynchronization Therapy Defibrillator
Quadra Assura MP	CD3269-40; CD3269-40Q; CD3369-40; CD3369-40Q; CD3369-40C; CD3369-40QC;	Cardiac Resynchronization Therapy Defibrillator
Unify	CD3231-40; CD3231-40Q	Cardiac Resynchronization Therapy Defibrillator
Unify Assura	CD3257-40; CD3257-40Q; CD3357-40; CD3357-40C; CD3357-40Q; CD3357-40QC	Cardiac Resynchronization Therapy Defibrillator

Model Name	Model Number(s)	Device Type
Unify Quadra	CD3249-40; CD3249-40Q	Cardiac Resynchronization Therapy Defibrillator

39. Excluded from each of the above Classes are Defendants, including any entity in which Defendants have a controlling interest, are a parent or subsidiary, or which are controlled by Defendants, as well as the officers, directors, affiliates, legal representatives, predecessors, successors, and assigns of Defendants. Also excluded are the judges and court personnel in this case and any members of their immediate families.

40. Plaintiff reserves the right to amend or modify the Class definitions with greater specificity or division into subclasses after having had an opportunity to conduct discovery.

41. This action has been brought and may be properly maintained on behalf of the Classes proposed herein under Rule 23 of the Federal Rules of Civil Procedure.

42. Numerosity. Fed. R. Civ. P. 23(a)(1). The member of each Class is so numerous that joinder of all members is impractical. Plaintiff is informed and believes that there are hundreds of thousands of members of each of the Classes. The precise number of Class members can be ascertained from Defendants' records.

43. Commonality and Predominance. Fed. R. Civ. P. 23(a)(2) and (b)(3). There are questions of law and fact common to each Class, which predominate over any questions affecting individual members of each respective Class. These common questions of law and fact include, without limitation:

a. Whether Defendants' conduct violates warranty laws as asserted herein;

b. Whether Defendants had a duty to disclose that the Class Devices and/or the Merlin@home transmitter lacked the necessary security to protect Class members' personal health information and/or to prevent unauthorized access to and control of the Class Devices;

c. Whether Defendants breached a legal duty to use reasonable security measures to protect to protect Class members' personal health information and/or to prevent

unauthorized access to and control of the Class Devices;

d. Whether Defendants acted negligently in securing the Class Devices; and

e. Whether Class members are entitled to damages and other monetary relief.

44. Typicality. Fed. R. Civ. P. 23 (a)(3). Plaintiff's claims are typical of the claims of the Class he seeks to represent. Plaintiff and all Class members were exposed to uniform practices and sustained injuries arising out of and caused by Defendants' conduct.

45. Adequacy. Fed. R. Civ. P. 23(a)(4). Plaintiff is committed to the vigorous prosecution of this action and have retained competent counsel experienced in the prosecution of class actions. Accordingly, Plaintiff is an adequate representative and will fairly and adequately protect the interests of the Classes.

46. Superiority. Fed. R. Civ. P. 23(b)(3). A class action is superior to other available methods for the fair and efficient adjudication of this controversy. Since the amount of each individual Class member's claim is small relative to the complexity of the litigation, and due to the financial resources of Defendants, no Class member could afford to seek legal redress individually for the claims alleged herein. Therefore, absent a class action, Class members will continue to suffer losses and Defendants' misconduct will proceed without remedy. Even if Class members themselves could afford such individual litigation, the court system could not. Given the complex legal and factual issues involved, individualized litigation would significantly increase the delay and expense to all parties and to the Court. Individualized litigation would also create the potential for inconsistent or contradictory rulings. By contrast, a class action presents far fewer management difficulties, allows claims to be heard which might otherwise go unheard because of the relative expense of bringing individual lawsuits, and provides the benefits of adjudication, economies of scale and comprehensive supervision by a single court. Finally, Plaintiff knows of no difficulty that will be encountered in the management of this litigation which would preclude its maintenance as a class action.

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FIRST CLAIM FOR RELIEF
Breach of Express Warranty
(By Plaintiff and the Nationwide Class, or, Alternatively, the Illinois Class Against Defendants)

47. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1 through 46, inclusive, of this Complaint, as though fully set forth herein and, to the extent necessary, pleads this cause of action in the alternative.

48. Plaintiff brings this claim individually and on behalf of the members of the Nationwide Class against Defendants under California law, or, alternatively, under the laws of the all states, as there is no material difference in the law of breach of express warranty as applied to the claims and questions in this case. Alternatively, Plaintiff brings this claim individually and on behalf of the Illinois Class against Defendants under Illinois law.

49. Defendants expressly warranted to Plaintiff, other members of the Class and their healthcare providers that that the Class Devices provided the capability – through the Merlin@home transmitter – for remote follow-ups and remote monitoring that: (i) gave Plaintiff and other members of the Class greater flexibility; (ii) allowed the Plaintiff's and other Class members' healthcare providers to monitor the Class Devices while Plaintiff and other members of the Class are at home; (iii) reduced the number of scheduled clinic visits that Plaintiff and other members of the Class have to make; and (iv) would alert Plaintiff's and other Class members' healthcare providers if it detects anything which the healthcare providers may wish to be aware.

50. Defendants expressly warranted to Plaintiff, other members of the Class and their healthcare providers that the Class Devices' performance would not be affected by the remote follow-ups and remote monitoring capability provided through the Merlin@home transmitter.

51. Defendants expressly warranted to Plaintiff, other members of the Class and their healthcare providers that that the remote follow-ups and remote monitoring capability provided through the Merlin@home transmitter was safe and secure.

52. Defendants expressly warranted to Plaintiff, other members of the Class and their healthcare providers that that their personal health data transmitted through the Merlin@home transmitter and uploaded to Merlin.net PCN was: (i) safe and secure; (ii) protected with industry-

standard safety protocols; (iii) password-protected so only authorized users can access it; and (iv) was subject to stringent worldwide information security standards.

53. Defendants' express warranties as set forth above were expressly communicated to Plaintiff, other members of the Class and their healthcare providers in such a manner that Plaintiff and other members of the Class understood and accepted them.

54. Defendants' affirmations of fact or promise and descriptions of the remote follow-up and remote monitoring capabilities of the Class Devices as provided through the Merlin@home transmitter, were material and created a basis of the bargain for Plaintiff, other members of the Class and their healthcare providers.

55. Plaintiff, other members of the Class, and their healthcare providers reasonably relied upon the skill and judgment of Defendants, and upon said express warranties, in using the Class Devices.

56. Defendants breached the express warranties as set forth above by delivering Class Devices that: (i) do not provide remote follow-ups and remote monitoring; (ii) provide remote follow-ups and remote monitoring that affects the performance of the Class Devices; (iii) provide remote follow-ups and remote monitoring that is not safe and secure; and/or (iv) do not adequately protect the personal health data transmitted through the Merlin@home transmitter and uploaded to Merlin.net PCN.

57. As a result of the foregoing breaches of express warranty, Plaintiff and other Class members have been damaged in that Class Devices do not perform as warranted and did not receive the benefit of the bargain.

58. Plaintiff and Class members seek all damages permitted by law in an amount to be proven at trial.

WHEREFORE, Plaintiff and the Class prays judgment against Defendants as hereafter set forth.

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SECOND CLAIM FOR RELIEF
FRAUDULENT CONCEALMENT
(By Plaintiff and the Nationwide Class, or, Alternatively, the Illinois Class Against Defendants)

59. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1 through 46, inclusive, of this Complaint, as though fully set forth herein and, to the extent necessary, pleads this cause of action in the alternative.

60. Plaintiff brings this claim individually and on behalf of the members of the Nationwide Class against Defendants under California law, or, alternatively, under the laws of the all states, as there is no material difference in the law of fraudulent concealment as applied to the claims and questions in this case. Alternatively, Plaintiff brings this claim individually and on behalf of the Illinois Class against Defendants under Illinois law.

61. At all times relevant herein, Defendants knew that the Class Devices and/or the Merlin@home transmitter lacked the necessary security to protect Plaintiff's and other Class members' personal health information and/or to prevent unauthorized access to and control of the Class Devices.

62. Defendants concealed and suppressed the material facts that the Class Devices and/or the Merlin@home transmitter lacked the necessary security to protect Plaintiff's and other Class members' personal health information and/or to prevent unauthorized access to and control of the Class Devices.

63. Defendants owed Plaintiff, other members of the Class and their healthcare providers a duty to disclose the true facts about the Class Devices and/or the Merlin@home transmitter because the concealed and suppressed facts were known and/or accessible only to Defendants, which had superior knowledge and access to the facts, and the facts were not known to or reasonably discoverable by Plaintiffs, other members of the Class and their healthcare providers since Defendants: (i) possessed exclusive knowledge of the security measures employed in the Class Devices and/or the Merlin@home transmitter; (ii) intentionally concealed the severe security vulnerabilities in the Class Devices and/or the Merlin@home transmitter; and/or (iii) made incomplete representations about the security of the Class Devices and/or the Merlin@home

transmitter while purposefully withholding material facts from Plaintiff, other members of the Class and their healthcare providers that contradicted these representations.

64. The aforementioned concealments were material, because if it had been disclosed, Plaintiff, other members of the Nationwide Class and their healthcare providers would not have used the Class Devices. These omitted and concealed facts were also material because they directly impact the value and use of the Class Devices.

65. Defendants knew or recklessly disregarded that their omissions were material because Defendants knew that the Class Devices and/or the Merlin@home transmitter were not secure. Defendants intentionally concealed and/or omitted the material fact that the Class Devices and/or the Merlin@home transmitter were not secure in order to sell the Class Devices and to avoid the expense and public relations nightmare of a recall.

66. Plaintiff, other members of the Class and their healthcare providers were not aware of the concealed and/or suppressed facts set forth herein.

67. Plaintiff, and other members of the Class and their healthcare providers relied on Defendants' failure to disclose the security vulnerabilities in the Class Devices and/or the Merlin@home transmitter in deciding to use and implant the Class Devices. Specifically, Plaintiff and other members of the Class would never have had the Class Devices implanted had they been aware of the security vulnerabilities in the Class Devices and/or the Merlin@home transmitter.

68. Plaintiff, other members of the Class and their healthcare providers justifiably relied on and/or were induced by Defendants' concealment. It is reasonable that Plaintiff, other members of the Class and their healthcare providers would rely on the statements of Defendants regarding the security of the Class Devices and/or the Merlin@home transmitter because as the manufacturer, Defendants were held to the level of knowledge of an expert in the field.

69. As a proximate result of the concealment and/or suppression of the facts set forth above, Plaintiff, other members of the Class and their healthcare providers reasonably relied on Defendants' deception and Plaintiff and other members of the Class were implanted with the Class Devices.

70. As a result of the foregoing fraudulent and deceitful conduct by Defendants, Plaintiff and other members of the Class have been injured in an amount to be proven at trial, including, but not limited to, their lost benefit of the bargain and overpayment at the time of purchase and/or the diminished value of their Class Devices.

WHEREFORE, Plaintiff and the Class prays judgment against Defendants as hereafter set forth.

THIRD CLAIM FOR RELIEF
NEGLIGENCE
(By Plaintiff and the Nationwide Class, or, Alternatively, the Illinois Class Against Defendants)

71. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1 through 46, inclusive, of this Complaint, as though fully set forth herein and, to the extent necessary, pleads this cause of action in the alternative.

72. Plaintiff brings this claim individually and on behalf of the members of the Nationwide Class against Defendants under California law, or, alternatively, under the laws of the all states, as there is no material difference in the law of negligence as applied to the claims and questions in this case. Alternatively, Plaintiff brings this claim individually and on behalf of the Illinois Class against Defendants under Illinois law.

73. In making the Class Devices with RF telemetry capabilities and the Merlin@home transmitter, Defendants owed Plaintiff and other members of the Class a duty to exercise reasonable care in safeguarding and protecting the Class Devices from unauthorized access and use. This duty included, among other things, maintaining and testing the Class Devices, the Merlin@home transmitter and the Merlin.net PCN, and taking other reasonable security measures to protect and adequately secure the Class Devices, the Merlin@home transmitter and the Merlin.net PCN from unauthorized access and use.

74. In collecting the personal health information of Plaintiff and other members of the Class, Defendants owed Plaintiff and other members of the Class a duty to exercise reasonable care in safeguarding and protecting that information. This duty included, among other things,

maintaining and testing Defendants' security systems and computer networks, and taking other reasonable security measures to protect and adequately secure the personal health information of Plaintiff and other members of the Class from unauthorized access and use.

75. Defendants' security systems and procedures for handling the personal health information of Plaintiff and other Class members affected Plaintiff and the Class. Likewise, Defendants' security for safeguarding the Class Devices, the Merlin@home transmitter and the Merlin.net PCN from unauthorized access and use affected Plaintiff and the Class. Defendants were aware that by taking sensitive personal health information and making Class Devices with RF telemetry capabilities, they undertook a responsibility to take reasonable security measures to protect the personal health information and the Class Devices from being accessed, viewed or controlled by unauthorized persons.

76. Defendants owed a duty of care to Plaintiff and other Class members because they were the foreseeable and probable victims of any inadequate security practices. It is foreseeable that if Defendants did not take reasonable security measures, the Class Devices could be accessed, viewed or controlled by unauthorized persons. Defendants also knew or should have known their security systems were inadequate.

77. Defendants had the ability to guard against unauthorized access and control of the Class Devices, the Merlin@home transmitter and the Merlin.net PCN by implementing adequate measures to protect these devices and systems.

78. As a result of Defendants' negligence, Plaintiffs and Class members have and will continue to suffer damages.

WHEREFORE, Plaintiff and the Class prays judgment against Defendants as hereafter set forth.

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FOURTH CLAIM FOR RELIEF
UNJUST ENRICHMENT
(By Plaintiff and the Nationwide Class, or, Alternatively, the Illinois Class Against Defendants)

79. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1 through 46, inclusive, of this Complaint, as though fully set forth herein and, to the extent necessary, pleads this cause of action in the alternative.

80. Plaintiff brings this claim individually and on behalf of the members of the Nationwide Class against Defendants under California law, or, alternatively, under the laws of the all states, as there is no material difference in the law of unjust enrichment as applied to the claims and questions in this case. Alternatively, Plaintiff brings this claim individually and on behalf of the Illinois Class against Defendants under Illinois law.

81. Defendants have received and retained a benefit from Plaintiff and the other members of the Class, and inequity has resulted.

82. Plaintiff and the other members of the Class conferred a tangible economic benefit upon Defendants by purchasing the Class Devices. Plaintiff and the other members of the Nationwide Class would have expected remuneration from Defendants at the time this benefit was conferred had they known of the that Class Devices and/or the Merlin@home transmitter lacked the necessary security to protect Plaintiff's and other Class members' personal health information and/or to prevent unauthorized access to and control of the Class Devices.

83. Defendants were enriched, at the expense of the Plaintiff and other each member of the Class, through the payment of the purchase price for the Class Devices.

84. Under the circumstances, it would be against equity and good conscious to permit Defendants to retain the ill-gotten benefits that it received from Plaintiff and the other members of the Class in light of the fact that the Class Devices and/or the Merlin@home transmitter lacked the necessary security to protect Plaintiff's and other Class members' personal health information and/or to prevent unauthorized access to and control of the Class Devices, as set forth more fully above.

85. As such, it is inequitable for Defendants to retain the benefits of their misconduct.

86. As a result of Defendants' conduct, the amount of Defendants' unjust enrichment should be disgorged, in an amount according to proof, or such other appropriate equitable remedy as appropriate, to the Plaintiff and other members of the Class.

WHEREFORE, Plaintiff and the Class prays judgment against Defendants as hereafter set forth.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, individually and on behalf of all others similarly situated, respectfully requests that the Court enter judgment against Defendants, as follows:

1. An order certifying appropriate classes and/or subclasses, designating Plaintiff as the class representative and his counsel as class counsel;

2. An award of restitution, damages, and disgorgement to Plaintiff and the Class in an amount to be determined at trial;

3. An order requiring Defendants to pay both pre- and post-judgment interest on any amounts awarded, as allowed by law;

4. An award of costs and attorneys' fees, as allowed by law; and

5. Such other or further relief as may be appropriate.

Dated: August 26, 2016

ARIAS, SANGUINETTI, STAHLE & TORRIJOS, LLP

By: _____

Mike Arias
Alfredo Torrijos

Counsel for Plaintiff
Clinton W. Ross Jr.

DEMAND FOR JURY TRIAL

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiff, individually and on behalf of all others similarly situated, hereby demands a trial by jury of any and all issues in this action so triable of right.

Dated: August 26, 2016

ARIAS, SANGUINETTI, STAHLE & TORRIJOS, LLP

By: _____
Mike Arias
Alfredo Torrijos

Counsel for Plaintiff
Clinton W. Ross Jr.