RESOLUTION AGREEMENT

I. <u>Recitals</u>

- 1. <u>Parties</u>. The Parties to this Resolution Agreement ("Agreement") are:
 - A. The United States Department of Health and Human Services ("HHS"). HHS, through its Office for Civil Rights ("OCR"), enforces the Federal standards that govern the privacy of individually identifiable health information (45 C.F.R. Part 160 and Subparts A and E of Part 164, the "Privacy Rule"), the Federal standards that govern the security of electronic individually identifiable health information (45 C.F.R. Part 160 and Subparts A and C of Part 164, the "Security Rule"), and the Federal standards for notification in the case of breach of unsecured protected health information (45 C.F.R. Part 160 and Subparts A and D of 45 C.F.R. Part 164, the "Breach Notification Rule"). OCR has the authority to conduct compliance reviews and investigations of complaints alleging violations of the Privacy, Security, and Breach Notification Rules (the "HIPAA Rules") by covered entities and business associates, and covered entities and business associates must cooperate with OCR compliance reviews and investigations. *See* 45 C.F.R. §§ 160.306(c), 160.308, 160.310(b), 45 CFR §164.312
 - B. CardioNet, Inc., a covered entity as defined at 45 C.F.R. § 160.103, and required to comply with the HIPAA Rules. CardioNet provides patients with ambulatory cardiac monitoring service. CardioNet is headquartered in Malvern, PA and is a wholly owned subsidiary of BioTelemetry.

HHS and CardioNet shall together be referred to herein as the "Parties".

2. <u>Factual Background and Covered Conduct.</u> On January 10, 2012, and February 27, 2012, OCR received notification from CardioNet regarding breaches of unsecured electronic protected health information (ePHI) affecting 1,391 and 2,219 individuals, respectively. In May 2012, OCR notified CardioNet of OCR's investigations regarding CardioNet's compliance with the Privacy, Security, and Breach Notification Rules.

OCR's investigations indicated that the following conduct occurred ("Covered Conduct")

- A. CardioNet failed to implement the specifications required to establish a security management process to prevent, detect, contain, and correct security violations. Specifically, CardioNet failed to conduct an accurate and thorough risk analysis to assess the potential risks and vulnerabilities to the confidentiality, integrity, and availability of ePHI and failed to plan for and implement security measures sufficient to reduce those risks and vulnerabilities. 45 C.F.R. § 164.308(a)(1)).
- B. CardioNet failed to implement policies and procedures that govern the receipt and removal of hardware and electronic media that contain electronic protected health information into and out of its facilities, the encryption of such media, and the

movement of these items within its facilities until March 2015. 45 C.F.R. § 164.310(d)(1)).

C. CardioNet failed to safeguard against the impermissible disclosure of protected health information by its employees, thereby permitting access to that information by an unauthorized individual, and failed to take sufficient steps to immediately correct the disclosure.

3. <u>No Admission</u>. This Agreement is not an admission of liability by CardioNet.

4. <u>No Concession</u>. This Agreement is not a concession by HHS that CardioNet is not in violation of the HIPAA Rules and not liable for civil money penalties.

5. <u>Intention of Parties to Effect Resolution</u>. This Agreement is intended to resolve OCR Transaction Numbers 12-138753 and 12-139633 and any violations of the HIPAA Rules related to the Covered Conduct specified in paragraph I.2 of this Agreement. In consideration of the Parties' interest in avoiding the uncertainty, burden, and expense of further investigation and proceedings, the Parties agree to resolve this matter according to the Terms and Conditions below.

II. Terms and Conditions

1. <u>Payment</u>. HHS has agreed to accept, and CardioNet has agreed to pay HHS, the amount of **\$2,500,000** ("Resolution Amount"). CardioNet agrees to pay the Resolution Amount on the Effective Date of this Agreement as defined in paragraph II.14 by automated clearing house transaction pursuant to written instructions to be provided by HHS.

2. <u>Corrective Action Plan</u>. CardioNet has entered into and agrees to comply with the Corrective Action Plan ("CAP"), attached as Appendix A, which is incorporated into this Agreement by reference. If CardioNet breaches the CAP and fails to cure the breach as set forth in the CAP, then CardioNet will be in breach of this Agreement, and HHS will not be subject to the Release set forth in paragraph II.8 of this Agreement.

3. <u>Release by HHS</u>. In consideration of and conditioned upon CardioNet's performance of its obligations under this Agreement, HHS releases CardioNet from any actions it may have against CardioNet under the HIPAA Rules arising out of or related to the Covered Conduct identified in paragraph I.2 of this Agreement. HHS does not release CardioNet from, nor waive any rights, obligations, or causes of action other than those arising out of or related to the Covered Conduct and referred to in this paragraph. This release does not extend to actions that may be brought under section 1177 of the Social Security Act, 42 U.S.C. § 1320d-6.

4. <u>Agreement by Released Parties</u>. CardioNet shall not contest the validity of its obligation to pay, nor the amount of, the Resolution Amount or any other obligations agreed to under this Agreement. CardioNet waives all procedural rights granted under Section 1128A of the Social Security Act (42 U.S.C. § 1320a- 7a) and 45 C.F.R. Part 160 Subpart E, and HHS claims collection regulations at 45 C.F.R. Part 30, including, but not limited to, notice, hearing, and appeal with respect to the Resolution Amount.

5. <u>Binding on Successors</u>. This Agreement is binding on CardioNet and its successors, heirs, transferees, and assigns.

6. <u>Costs</u>. Each Party to this Agreement shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

7. <u>No Additional Releases</u>. This Agreement is intended to be for the benefit of the Parties only, and by this instrument the Parties do not release any claims against or by any other person or entity.

8. <u>Effect of Agreement</u>. This Agreement constitutes the complete agreement between the Parties. All material representations, understandings, and promises of the Parties are contained in this Agreement. Any modifications to this Agreement shall be set forth in writing and signed by both Parties.

9. <u>Execution of Agreement and Effective Date</u>. The Agreement shall become effective (*i.e.*, final and binding) upon the date of signing of this Agreement and the CAP by the last signatory (Effective Date).

10. <u>Tolling of Statute of Limitations</u>. Pursuant to 42 U.S.C. § 1320a-7a(c)(1), a civil money penalty ("CMP") must be imposed within six years from the date of the occurrence of the violation. To ensure that this six-year period does not expire during the term of this Agreement, CardioNet agrees that the time between the Effective Date of this Agreement and the date the Agreement may be terminated by reason of CardioNet's breach, plus one-year thereafter, will not be included in calculating the six (6) year statute of limitations applicable to the violations which are the subject of this Agreement. CardioNet waives and will not plead any statute of limitations, laches, or similar defenses to any administrative action relating to the Covered Conduct identified in paragraph I.2 that is filed by HHS within the time period set forth above, except to the extent that such defenses would have been available had an administrative action been filed on the Effective Date of this Agreement.

11. <u>Disclosure</u>. HHS places no restriction on the publication of the Agreement. In addition, HHS may be required to disclose material related to this Agreement to any person upon request consistent with the applicable provisions of the Freedom of Information Act, 5 U.S.C. § 552, and its implementing regulations, 45 C.F.R. Part 5.

12. <u>Execution in Counterparts</u>. This Agreement may be executed in counterparts, each of which constitutes an original, and all of which shall constitute one and the same agreement.

13. <u>Authorizations</u>. The individual(s) signing this Agreement on behalf of CardioNet represent and warrant that they are duly authorized by BioTelemetry to execute this Agreement on behalf of CardioNet and fully comply with its terms. The individual signing this Agreement on behalf of HHS represents and warrants that she is signing this Agreement in her official capacities and that she is authorized to execute this Agreement.

14. <u>Execution of Agreement and Effective Date.</u> The Agreement shall become effective (i.e., final and binding) on the date of signing of this Agreement and the CAP by the last signatory ("Effective Date").

For Covered Entity

/s/

April 3, 2017

Peter Ferola, Esq. General Counsel CardioNet, Inc.

Date

For the United States Department of Health and Human Services

/s/

April 3, 2017

Barbara J. Holland Regional Manager, Mid-Atlantic Region Office for Civil Rights Date

Appendix A

CORRECTIVE ACTION PLAN

BETWEEN

THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES

AND

CARDIONET, INC.

I. Introduction

Preamble

CardioNet, Inc. ("CardioNet") hereby enters into this Corrective Action Plan ("CAP") with the United States Department of Health and Human Services ("HHS"). Contemporaneously with this CAP, CardioNet is entering into a Resolution Agreement ("Agreement") with HHS, and this CAP is incorporated by reference into the Resolution Agreement as Appendix A. CardioNet enters into this CAP as part of the consideration for the release set forth in paragraph II.3 of the Agreement.

Contact Persons

CardioNet has identified the following individual as its authorized representative and contact person regarding the implementation of this CAP and for receipt and submission of notifications and reports:

Peter Ferola, Esq. General Counsel CardioNet, Inc. 1000 Cedar Hollow Road Malvern, PA 19335

HHS has designated the HHS Office of Civil Rights ("OCR") as its authorized representative for the purposes of executing, monitoring, and enforcing this CAP and identified the following individual as the contact person with whom CardioNet is to report information regarding the implementation of this CAP:

Diana E. Vincenzo, Supervisory Investigator HHS, OCR, Mid-Atlantic Region 150 S. Independence Mall West, Suite 372 Philadelphia, PA 19107 Diana.Vincenzo@hhs.gov 215-861-4217 CardioNet and HHS agree to promptly notify each other of any changes in the contact persons or the other information provided above.

Proof of Submissions

Unless otherwise specified, all notifications and reports required by this CAP may be made by any means, including certified mail, overnight mail, or hand delivery, provided that there is proof that such notification was received. For purposes of this requirement, internal facsimile confirmation sheets do not constitute proof of receipt.

Effective Date and Term of CAP

The Effective Date for this CAP shall be calculated in accordance with paragraph II.9 of the Agreement ("Effective Date"). The period for compliance ("Compliance Term") with the obligations assumed by CardioNet under this CAP shall begin on the Effective Date of this CAP and end two (2) years from the Effective Date unless OCR has notified CardioNet under section VIII hereof of its determination that CardioNet breached this CAP. In the event of such a notification by HHS under section VIII hereof, the Compliance Term shall not end until OCR notifies CardioNet that it has determined that the breach has been cured. After the Compliance Term ends, CardioNet shall still be obligated to submit the final Annual Report as required by section VI and comply with the document retention requirement in section VII.

<u>Time</u>

In computing any period of time prescribed or allowed by this CAP, all days referred to shall be calendar days. The day of the act, event, or default from which the designated period of time begins to run shall not be included. The last day of the period so computed shall be included, unless it is a Saturday, a Sunday, or a legal holiday, in which event the period runs until the end of the next day which is not one of the aforementioned days.

II. <u>Corrective Action Obligations</u>

CardioNet agrees to the following

A. Conduct Risk Analysis

1. CardioNet shall provide to HHS for review and approval a current, comprehensive and thorough Risk Analysis of security risks and vulnerabilities that incorporates its current facility or facilities and the electronic equipment, data systems, and applications controlled, currently administered or owned by CardioNet, that contain, store, transmit, or receive electronic protected health information ("ePHI"). CardioNet shall provide such Risk Analysis to HHS within ninety (90) days of the Effective Date.

2. Within sixty (60) days of receipt of CardioNet's Risk Analysis, HHS will inform CardioNet in writing as to whether HHS approves or disapproves the Risk Analysis. If HHS disapproves of the Risk Analysis, HHS shall provide CardioNet

with a detailed, written explanation of the basis of its disapproval, including comments and recommendations that CardioNet can use to prepare a revised Risk Analysis.

3. Upon receiving a disapproval of the Risk Analysis from HHS, and a description of any required changes to the Risk Analysis, CardioNet shall have sixty (60) days in which to revise its Risk Analysis accordingly, and then submit the revised Risk Analysis to HHS for review and approval or disapproval. This process shall continue until HHS approves the Risk Analysis.

4. Thereafter, CardioNet shall review the Risk Analysis annually (or more frequently, if appropriate) and shall promptly update the Risk Analysis in response to environmental or operational changes affecting the security of electronic protected health information. Following an update to the Risk Analysis, CardioNet shall assess whether its existing security measures are sufficient to protect its ePHI and revise its Risk Management Plan, Policies and Procedures, and training materials and implement additional security measures, as needed.

B. Develop and Implement Risk Management Plan

1. CardioNet shall provide to HHS for review and approval an organizationwide Risk Management Plan to address and mitigate any security risks and vulnerabilities found in the Risk Analysis described above. The Risk Management Plan shall include a process and timeline for CardioNet's implementation, evaluation, and revision of its risk remediation activities. CardioNet shall submit its Risk Management Plan to HHS within ninety (90) days of HHS' final approval of the Risk Analysis.

2. Within sixty (60) days of receipt of CardioNet's Risk Management Plan, HHS will inform CardioNet in writing as to whether HHS approves or disapproves of the Risk Management Plan. If HHS disapproves of the Risk Management Plan, HHS shall provide CardioNet with detailed comments and recommendations so that CardioNet can prepare a revised Risk Management Plan.

3. Upon receiving any required changes to such Risk Management Plan from HHS, CardioNet shall have sixty (60) days in which to revise its Risk Management Plan accordingly, and then submit the revised Risk Management Plan to HHS for review and approval or disapproval. This submission and review process shall continue until HHS approves the Risk Management Plan.

4. Upon HHS' approval of the Risk Management Plan, CardioNet shall begin implementation of any steps to address or mitigate the risks and vulnerabilities as required by the Risk Management Plan.

C. Implement Secure Device and Media Controls

1. CardioNet shall review and, to the extent necessary, revise, its current Security Rule Policies and Procedures ("Policies and Procedures") based on the findings of the Risk Analysis and the implementation of the Risk Management Plan, with particular attention given to policies and procedures with respect to device and media controls. CardioNet's Policies and Procedures must comply with the HIPAA Security Rule. The revised Policies and Procedures, if any, shall be forwarded to HHS within sixty (60) days of the HHS's final approval of the Risk Management Plan for its review and approval.

2. Concurrent with providing HHS with revised Policies and Procedures, CardioNet shall provide certification that all laptops, flashdrives, SD cards, and other portable media devices are encrypted, together with a description of the encryption methods used ("Certification"). Within thirty (30) days of receipt of CardioNet's revised Policies and Procedures and Certification, HHS will inform CardioNet in writing as to whether HHS approves or disapproves of the Policies and Procedures and whether HHS has any response indicating that the Certification is not adequate. If HHS disapproves of the Policies and Procedures or has a response to the Certification, HHS shall provide CardioNet with a detailed, written explanation of the basis of its disapproval and/or response, including comments and recommendations that CardioNet must make to receive approval of both the Policies and Procedures and the Certification.

3. Upon receiving the comments and recommendations, CardioNet shall have thirty (30) days in which to make all changes, revisions, or modifications recommended by HHS for review and approval or disapproval. This process shall continue until HHS approves the Policies and Procedures and Certification.

4. Within thirty (30) days of HHS' approval of any revised Policies and Procedures, CardioNet shall implement same and distribute them to the relevant and appropriate CardioNet workforce members.

D. <u>Review and Revise Training Program</u>

1. CardioNet shall review and, to the extent necessary, revise, its current Security Rule Training Program (Training Program) based on the findings of the Risk Analysis and the Risk Management Plan, as well as any revisions to the Policies and Procedures and/or Certification. CardioNet's Training Program must comply with the HIPAA Security Rule and include a focus on security, encryption, and handling of mobile devices and out-of-office transmissions. The revised Training Program, if applicable, shall be forwarded to HHS for its review and approval within sixty (60) days of the HHS's final approval of any revised Policies and Procedures.

2. Within thirty (30) days of its receipt of CardioNet's revised Training Program, HHS will inform CardioNet in writing as to whether HHS approves or disapproves of the Training Program. If HHS disapproves of the Training Program, HHS shall provide CardioNet with a detailed, written explanation of the basis of its disapproval, including comments and recommendations that CardioNet can use to further revise the Training Program.

3. Upon receiving a disapproval of the Training Program from HHS and a description of any required changes to the Training Program, CardioNet shall have

thirty (30) days in which to revise its Training Program accordingly, and then submit the revised Training Program to HHS for review and approval or disapproval. This process shall continue until HHS approves the Training Program.

4. Within thirty (30) days of HHS' approval of the Training Program, CardioNet shall implement the Training Program by administering the approved Training Program to all members of CardioNet's workforce who have access to and use ePHI.

III. <u>Reportable Events</u>

During the Compliance Term, CardioNet shall, upon receiving information that a workforce member may have failed to comply with its Policies and Procedures, promptly investigate the matter. If CardioNet determines, after review and investigation, that a member of its workforce has failed to comply with these policies and procedures, CardioNet shall notify HHS in writing within thirty (30) days. Such violations shall be known as Reportable Events. The report to HHS shall include the following information:

1. A complete description of the event, including the relevant facts, the persons involved, and the provision(s) of the policies and procedures implicated; and

2. A description of the actions taken and any further steps CardioNet plans to take to address the matter to mitigate any harm, and to prevent it from recurring, including application of appropriate sanctions against workforce members who failed to comply with its Policies and Procedures.

IV. Annual Reports

The one-year period beginning on the Effective Date and subsequent one-year period during the course of the period of compliance shall be referred to as "the Reporting Periods." CardioNet shall submit to HHS Annual Reports with respect to the status of and findings regarding CardioNet's compliance with this CAP for each of the Reporting Periods. CardioNet shall submit each Annual Report to HHS no later than 60 days after the end of the Reporting Period. The Annual Report shall include:

V. A detailed description of updates or changes, if any, to the risk analysis or risk management plan. This shall include:

1. a summary of CardioNet's strategy related to the assessment of the potential risks and vulnerabilities to the confidentiality, integrity, and availability of e-PHI held by CardioNet; the identification of all outside entities assisting CardioNet in this process; and documentation related to the security measures CardioNet implemented or is implementing, if any, to sufficiently reduce the identified risks and vulnerabilities to a reasonable and appropriate level;

2. A detailed description of any revisions to CardioNet's Policies and Procedures and training materials, if any;

3. A summary of Reportable Events, as defined in section V.E, if any, identified during the Reporting Period and the status of any corrective and preventative action relating to all such Reportable Events;

4. A summary of the corrective action measures (defined in section V) taken during the Reporting Period;

5. An attestation signed by an owner or officer of CardioNet attesting that he or she has reviewed the Annual Final Report, has made a reasonable inquiry regarding its content and believes that, upon such inquiry, the information is accurate and truthful.

VI. Document Retention

CardioNet shall maintain for inspection and copying, and shall provide to OCR, upon request, all documents and records relating to compliance with this CAP for six (6) years from the Effective Date.

VII. Breach Provisions

CardioNet is expected to fully and timely comply with all provisions contained in this CAP.

VIII. <u>Timely Written Requests for Extensions</u>

CardioNet may, in advance of any due date set forth in this CAP, submit a timely written request for an extension of time to perform any act required by this CAP. A "timely written request" is defined as a request in writing received by HHS at least five (5) days prior to the date such an act is required or due to be performed.

IX. Notice of Breach of this CAP and Intent to Impose Civil Monetary Penalty

The parties agree that a material breach of this CAP by CardioNet constitutes a breach of the Agreement. Upon a determination by HHS that CardioNet has materially breached this CAP, HHS may notify CardioNet of: (1) CardioNet's breach; and (2) HHS' intent to impose a civil money penalty ("CMP") pursuant to 45 C.F.R. Part 160, or other remedies for the Covered Conduct set forth in paragraph I.2 of the Agreement and any other conduct that constitutes a violation of the HIPAA Privacy, Security, or Breach Notification Rules ("Notice of Breach and Intent to Impose CMP").

X. <u>CardioNet's Response</u>

1. CardioNet shall have thirty (30) days from the date of receipt of the Notice of Breach and Intent to Impose CMP to demonstrate to HHS' satisfaction that:

CardioNet is in compliance with the obligations of the CAP that HHS cited as the basis for the breach;

2. The alleged breach has been cured; or

3. The alleged breach cannot be cured within the 30-day period, but that: (a) CardioNet has begun to take action to cure the breach; (b) CardioNet is pursuing such action with due diligence; and (c) CardioNet has provided to HHS a reasonable timetable for curing the breach.

XI. Imposition of CMP

If at the conclusion of the 30-day period, CardioNet fails to meet the requirements of this section to HHS' satisfaction, HHS may proceed with the imposition of a CMP pursuant to 45 C.F.R. Part 160 for any violations of the Covered Conduct set forth in paragraph I.2 of the Agreement and for any other act or failure to act that constitutes a violation of the HIPAA Rules. HHS shall notify CardioNet in writing of its determination to proceed with the imposition of a CMP.

The undersigned are authorized to enter into this agreement, intending to be legally bound thereby.

For CardioNet

/s/

Peter Ferola Vice President CardioNet, Inc.

For the United States Department of Health and Human Services

/s/

April 3, 2017

Barbara J. Holland Regional Manager, Mid-Atlantic Region Office for Civil Rights Date

April 3, 2017

Date