Appendix A:

Living Will for Patients with Pacemakers and Defibrillators

A will is a document that indicates what a person wants done with his or her resources after death. A living will is a document in which patients indicate what they want done (or not done) regarding their health care if they lose the ability to make medical decisions. A living will for patients with pacemakers and defibrillators not only indicates what they would want done or not done with regard to these devices during the course of treatment, but also what they want done with these health care devices after death.

When patients with pacemakers or defibrillators die, the device is often buried with them or discarded before it can be checked with a computer by companies that make or distribute the devices. Sometimes information on these devices also doesn't get back to the company when pacemakers and defibrillators are removed as part of regular clinical care, such as the battery wearing out, devices getting infected or devices malfunctioning. This prevents the companies from examining the pacemakers and defibrillators to obtain data that may be useful in developing better devices. If the device is returned to the company and the checking is done, the devices can, in most cases, be returned to the patient, or the family, if the patient has died. Although pacemakers and defibrillators are not supposed to be reused nor resold in this country, some devices can be donated, enabling charities to clean (sterilize) them, check them for trouble and battery life, and send them overseas to be used in people who otherwise can't afford them. The devices may also be donated to animal hospitals for placement into pets or racehorses.

As you can see, there are several options about what to do with your pacemaker or defibrillator after your death or if it is removed before death. The statement that follows provides you with an opportunity to indicate your wishes. The first part of the document applies only to

patients with pacemakers and defibrillators; the second applies mostly to people with defibrillators (see note at bottom of page). If you change your mind about what you write, the document can be changed at any time. You should keep a copy in your records and a copy should be given to your doctor(s) and your next of kin.

This document is a guide to help decision-making and patient education. It is not legally binding in the way that a traditional living will is. This hospital or clinic and the doctors working here do not officially endorse this document. If your pacemaker or defibrillator is needed as evidence in a court of law or for a clinical trial, it must first be used for this purpose before it can be donated or used in another way.

Instructions: Please circle the option you would choose, or write your own answer in the space provided.

After I die, my wishes concerning my pacemaker or defibrillator (= "my device") are:

A. Check it with a computer device but do not remove it (note: in cases of cremation, all pacemakers and defibrillators must be removed because they will explode when put in fire).

B. Remove it and send it to the company for analysis.

C. Remove it and send it to the company for analysis, but after the analysis, I want it sent back to my family.

D. Donate it to an organization which gives it to health professionals to use for needy people in other countries.

E. Donate it to be put into a pet.

F. Do not check it with a computer or remove it.

G. I don't care what happens to my device after I die.

H. I want _____

(name, phone and address of person)

to decide what to do with my device.

I. other:_____

My wishes concerning my pacemaker or defibrillator (= "my device"), if taken out before death, are:

A. Check it with a computer device but do not send it back to the company.

B. Send it to the company for analysis.

C. Send it to the company for analysis, but after the analysis, I want it sent back to me.

D. Donate it to an organization which gives it to health professionals to use for needy people in other countries.

E. Donate it to be put into a pet.

F. I don't care what happens to my device after it is taken out.

G. other:_____

Signature_____ Date_____

Witness_____ Date_____

Appendix B:

Survey Tool

1. Number of device implants per year?
2. Number of device explants per year?
3. Percentage of explanted devices returned to the manufacturer per year?
4. Number of explanted devices put in medical waste or waste per year?
5. Number of explanted devices given to the patient or family per year?
6. Number of explanted devices donated to charity for implant in poor patients overseas per year?
7. Number of explanted devices donated to veterinary medical schools or practices per year?
8. Number of explanted devices kept in a box in the EP lab or an office per year?
9. Are destinations for ICD, pacemakers, or biventricular devices different?
10. Do you send pre-explant device interrogation reports to the manufacturer?
11. Are there barriers to returning devices to the manufacturers?
12. On a scale of 1 to 5 with 1 being hard and 5 being easy, how would you rate the difficulty of sending devices to the manufacturers?
13. On a scale of 1 to 5 with 1 being hard and 5 being easy, how likely would you be to send the devices to a central agency that would interrogate each device, record the serial number, then forward the device to the individual manufacturers?
14. In your opinion, which one of the following has the most say in what happens to devices after explant?
15. Do you think it would be helpful to have patients fill out a Device Living Will that would say what they would want done with the device after death?

Appendix C:

I. Sample Letter from manufacturer regarding returned device with malfunction identified on analysis, edited for anonymity:

Re: Patient:

Model: Serial Number: Report:

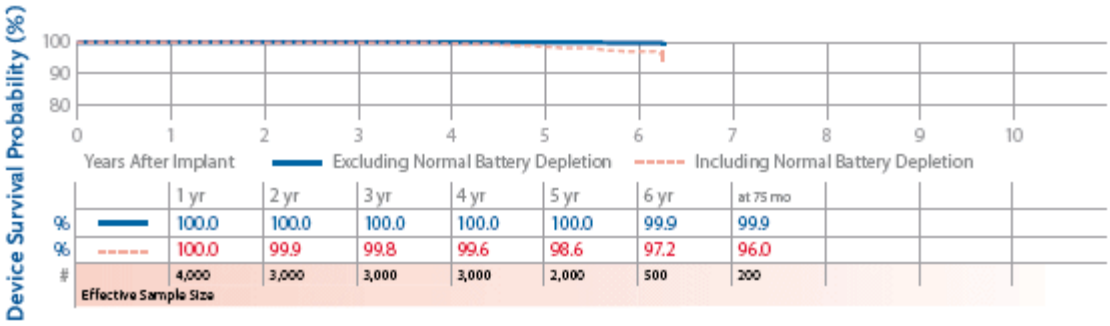
Implant Date: Explant Date: Receipt Date:

Dear Dr. xxxx:

Thank you for returning the referenced device to us for evaluation. The information accompanying the device indicated there was no output and no telemetry.

Our evaluation of the device confirmed an anomaly was present with the interconnect wires between the battery and the device circuitry. To be more specific, the wires had separated at the point where they are connected to the circuitry in a phenomenon known as "lifted wire bond". Wire bond lifts can manifest from repetitive motion between components, blunt trauma/external force to the device or occur over time.

The figure below, published in [Company X] CRDM Product Performance Report[i], shows the survival probability of [model X] devices as a function of implant time. For [model X], the solid line shows the overall device survival rate excluding normal battery depletion (99.9% survival @ 6 yrs). It's important to note, the device referenced above falls into the 0.1%. The dashed line shows the overall device survival rate including expected normal battery depletions (97.2% @ 6 years).



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	at 75 mo
%	100.0	100.0	100.0	100.0	100.0	99.9	99.9
%	100.0	99.9	99.8	99.6	98.6	97.2	96.0
#	4,000	3,000	3,000	3,000	2,000	500	200

Effective Sample Size

This device is not included in the [most recent] Physician Communication. If you would like additional information regarding this communication, please visit our website.

[Company X] takes the performance of its devices very seriously. All events, including this one, are reviewed for Medical Device Reporting criteria and, if appropriate, a MedWatch 3500 A Form is

submitted to the FDA.

We welcome the opportunity to address your concerns. Please contact me or your Representative if we may be of further assistance.

Sincerely,

II. Letter from manufacturer regarding device with no identified malfunction on analysis, edited for anonymity:

Prepared for: **Date:**

Patient:

Report:

Model: **Serial Number:**

Model: **Serial Number:**

Model: **Serial Number:**

Implant Date: **Explant Date:** **Receipt Date:**

Clinical Observation(s) Reported:

The referenced ICD and leads were returned to [Company X] for analysis. The returned paperwork indicated the device was replaced due to ERI. The lead model X was replaced due to dislodgement, and the X lead was prophylactically replaced during lead revision procedure.

Device Analysis Findings: Device Model X

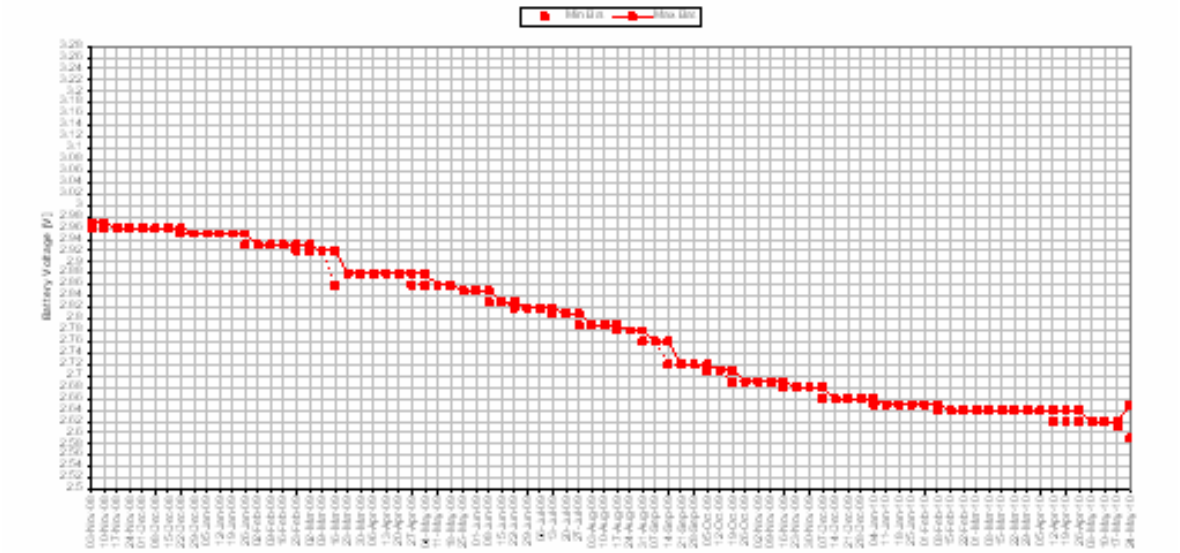
Visual Inspection: *Examination of Grommet, Setscrew/Block, Connector, and Shield.*

Findings: Visual examination found no anomalies**.**

Preliminary Analysis: *Data retrieval, Telemetry, battery measurement*.

Findings: Preliminary and functional testing found battery depletion. The battery measured 2.59 volts and the charge time was 10.37 seconds. Longevity calculations showed the device lasted 95% of its projected longevity. The calculation uses the known settings from the ICD when received in our laboratory and cannot account for

programming changes throughout the life of the device, which would alter this result.



Device analysis continued-

Functional Testing: *Manual and Automatic testing***.**

Findings: No anomalies found.

Lead Analysis Findings: (RV) Lead Model X

Visual inspection:

Findings: The full lead was returned**.** Environmental stress cracking (ESC) was observed on the surface of the outer tubing overlay. This process is of a cosmetic nature and would have no effect on the electrical characteristics of the device. A cosmetic depression was noted on the surface of the outer insulation at the connector. Some damage from explant was noted.

Electrical Continuity:

Findings*:* Electrical testing determined that continuity of the conductors was complete. The lead was considered functionally normal.

Lead Analysis Findings: (LV) Lead Model X

Visual inspection:

Findings: The full lead was returned. Environmental stress cracking (ESC) was observed on the surface of the outer insulation. This process is of a cosmetic nature and would have no effect on the electrical characteristics of the device. A cosmetic depression was noted on the surface of the outer insulation at the connector. Damage from explant was noted.

Electrical Continuity:

Findings: Electrical testing determined that continuity of the conductors was complete. The lead was considered functionally normal.

Replacement Information:

[Model numbers]

If you need additional information or have specific concerns regarding this analysis, please feel free to contact me or your [Company X] representative at (800)xxx-xxxx.