

**This Patient Consent section sets forth the benefits and limitations of my LifeVest as well as my ongoing responsibilities for its proper use.**

## **SECTION 1**

### **PATIENT CONSENT**

My physician has informed me that I am at risk from sudden cardiac death. After considering possible alternatives, my physician has recommended that I use the LifeVest® brand wearable defibrillator (together with the accessories, the “LifeVest”) exclusively distributed by prescription only by ZOLL Services LLC, its affiliates, and its third party service providers bound and liable to adhere to the applicable terms of this agreement (collectively “ZOLL”) and I agree to make the LifeVest a part of my treatment plan.

I am aware that my LifeVest is designed to monitor my heart continuously in order to detect life threatening rapid heart arrhythmias. If my LifeVest detects such an arrhythmia it will first issue an alarm. The alarm will be followed by a treatment shock if I lose consciousness or otherwise fail to press the response buttons on the device. The treatment shock is designed to restore my normal heart rhythm and consciousness.

Although my physician has determined that the benefits of continuous protection afforded by my LifeVest outweigh the possible harm, my LifeVest has some limitations including the following:

- A treatment shock can cause skin irritation, rashes, burns, injury to my heart, or abnormal heart rhythms. In rare circumstances it can cause disability or even death.

#### **The LifeVest does not treat every heart condition**

- I understand that the LifeVest device is not designed to treat every life threatening heart problem or condition (e.g., a dangerously slow heart rate, or a complete stoppage of the heart). Delivering a treatment shock under such conditions and could be harmful. Even if the LifeVest administers a treatment shock my condition may be beyond treatment and I may die.

#### **The LifeVest only protects me if I wear it**

- I understand that I am only protected when I wear my LifeVest, and, except during bathing or showering, I should wear it for as long as my physician deems it medically necessary.

#### **No person is monitoring me in real time**

- For as long as I wear my LifeVest as instructed, it will automatically and continuously monitor my heart rhythm and provide treatment if indicated—24 hours a day, 7 days a week. However, this monitoring is localized to the device itself only. While my LifeVest is designed to transmit data about both my condition and the device’s performance which may be used by my physician to provide better medical care and by ZOLL to better provide



technical support, neither my physician nor ZOLL is relying upon, or monitoring, information transmitted by my LifeVest for the purpose of providing me with real time or emergency intervention.

- If my LifeVest is not disconnected before another external defibrillator is used, there is the remote possibility that the other defibrillator's shock may be less effective and may damage my LifeVest.

**I agree to notify my doctor if I have a pacemaker**

- If I have a pacemaker, it may prevent the device from detecting and treating a life threatening heart rhythm.

**Always use the LifeVest under conditions where the vibration and audible alarms can be felt and heard**

- It is possible that my LifeVest may alarm as if I have a life threatening heart rhythm when in fact I do not. I can prevent an unnecessary, and possibly harmful, shock by pressing my response buttons. I understand that responding to the alarms may be more difficult if I have an altered mental state due to taking medications, visual or hearing difficulties, reduced dexterity resulting from arthritis or other causes, diminished mental capacity, or distractions from activities requiring concentration such as operating machinery, or for any other reason. This may increase my risk of receiving a shock when I do not need one.

**No one but me should push the response buttons**

- If a bystander pushes the response buttons after I have lost consciousness my LifeVest may not deliver the necessary treatment shock and death may result.

**After treatment leave the LifeVest on, seek medical assistance, and, when safe to do so, contact ZOLL to ensure continued protection**

- Removal of the LifeVest for any reason will leave me unprotected from sudden cardiac death.
- Failure to use the LifeVest in accordance with the manual may interfere or prevent its proper functioning (e.g., immersion in water, proper care of garment, possible electromagnetic interference, etc.).
- A rash or skin irritation is a potential side effect of wearing my LifeVest. If I experience skin irritation, which may include redness, itching, or swelling, and I believe that medical attention may be required, I will consult my physician.
- Risks to women who are pregnant, breastfeeding, or not taking adequate birth control measures while of childbearing age have not been studied.



**In order to ensure the safe and effective use of my LifeVest I agree that:**

- I have received training in the use of my LifeVest including: how to properly use the response buttons, charge and replace the batteries, change the garment, transmit data to the LifeVest Network, and the steps I should take after I believe a treatment has been administered.
- I have received instructions on the safe and effective use of my LifeVest. These instructions are included in the Patient Manual that I received during training. I will read the patient manual and contact ZOLL with questions.
- I will cooperate with ZOLL for the repair, exchange, service and/or collection of my LifeVest and I will provide ZOLL with access to my LifeVest as needed.
- I will use my LifeVest for its intended purpose only and in accordance with my physician's instructions and the Patient Manual.
- I will not modify, reverse engineer, or otherwise tamper with my LifeVest.
- I will handle my LifeVest with care and return it, subject to normal wear and tear, and I agree not to immerse or expose it to water (except for the normal laundering of the garment).
- I will promptly report any malfunctions or defects in my LifeVest to **ZOLL** by calling **1-800-543-3267** (24-hour support) so that repair or replacement can be arranged.
- I will provide ZOLL with my current contact information at all times. Among other permissible reasons, this will allow ZOLL to keep me informed of any safety matters relating to my LifeVest as well as keep track of my LifeVest as mandated by the FDA.



**This Financial Responsibility section explains my obligations to pay for the LifeVest in the event my insurance does not pay and to return it to ZOLL when there is no longer a medical necessity to wear it.**

## **SECTION 2**

### **FINANCIAL RESPONSIBILITY**

#### **Personal Liability for Co-Payments, Deductibles and Insurance Shortfalls**

I understand that ZOLL charges **\$3,750.00** per month, or portion of a month, for the LifeVest and related services (the “**Rental Fee**”). My actual out-of-pocket contribution depends on my insurance coverage, co-payments, deductibles, and other factors (e.g., Medicare coinsurance is 20%). I understand that my insurance carrier will be billed for the Rental Fee and that I will be responsible for all deductibles and/or any amounts not paid by my insurance. I agree to contact my insurance company with any questions regarding my policy. I may also contact the **ZOLL** at **1-800-543-3267** for help understanding my benefits, payment options, and financial assistance programs that may be available to me.

#### **Insurance and Hospitalization Changes**

While I wear the LifeVest I agree to inform ZOLL of any changes to my health insurance or any periods of hospitalization or stays in a skilled nursing facility in order to assist ZOLL to bill the correct parties for LifeVest use.

#### **Assignment of Benefits and Rights of Appeal**

I authorize ZOLL to bill Medicare and/or my other insurance carriers for my use of the LifeVest and hereby assign the payment of such benefits directly to ZOLL. I authorize ZOLL to act as my Authorized Representative to appeal on my behalf any full or partial denials of payment for the LifeVest. I understand that if ZOLL files an appeal that I cannot file an appeal on the same issue and that I may rescind this authorization and appointment at any time.

#### **Obligation to Return and Preserve the LifeVest**

I agree to contact **ZOLL** at **1-800-543-3267** promptly once my physician has determined that the LifeVest is no longer medically necessary or I do not wish to continue using the LifeVest for any reason. I will follow ZOLL’s instructions returning the LifeVest. I understand that I will continue to be responsible for accruing Rental Fees until the LifeVest is returned. I will be responsible for the full retail value of the LifeVest if I do not return it after my permitted period of use has expired. Except under limited circumstances (e.g., Medicare beneficiary’s reimbursed use for thirteen (13) consecutive months), title to the LifeVest remains with ZOLL at all times. I will not keep it beyond my period of medical necessity or ever attempt to sell the LifeVest. I will use the LifeVest only in accordance with the Patient Manual and I will not alter, modify, reverse engineer, disassemble, or



otherwise tamper with the LifeVest as doing so may cause it to malfunction thereby putting myself at risk as well as possibly creating financial liability for myself.

**Complaints**

I will call **ZOLL** toll-free, at any time of the day or night, at **1-800-543-3267** for any product or billing related complaints, concerns, or questions.

Within five (5) calendar days of receiving my privacy or billing complaint, ZOLL shall notify me using telephone, e-mail, fax, or letter, that it has received the complaint and that it is investigating. Within fourteen (14) days ZOLL shall send written results of its completed investigation and will maintain in its records documentation relating thereto. I will not be penalized for filing a complaint.

**Limited Power of Attorney to Recover the LifeVest from Others**

If someone else should have possession of my LifeVest, in order to assist ZOLL from recovering the LifeVest from such other persons or parties (e.g., storage units, landlords, etc.), and to avoid my personal liability for replacing the LifeVest:

I hereby grant an irrevocable limited power of attorney to ZOLL, appointing ZOLL as my attorney-in-fact with the power and authority to act in my name and on my behalf solely to recover the LifeVest from any third person, including without limitation any medical provider, storage facility, federal, state, or local government authority, and/or alleged purchaser for value. I grant this power to ZOLL in recognition of ZOLL's ongoing ownership of the LifeVest and this grant shall survive my death or incapacity.

**Government Contractor Obligations**

The LifeVest provided to me by ZOLL is subject to the supplier standards contained at 42 Code of Federal Regulations Section 424.57(c). These standards concern business professional and operational matters (e.g., honoring warranties and hours of operation). The full text of these standards can be obtained at <http://ecfr.gpoaccess.gov>. Upon request ZOLL will provide me with a written copy of these standards.

**Warranty**

I can obtain a written copy of the warranty covering my LifeVest by calling ZOLL at **1-800-543-3267** or at <https://lifest.vest.zoll.com/warranty>.



**This Data Use and Privacy section explains how my personal information will be used by ZOLL to coordinate care, secure payment, and improve the LifeVest for future patients.**

### **SECTION 3**

#### **DATA USE AND PRIVACY**

##### **Consent to Release Medical Records**

I authorize the release of my medical records to ZOLL, its authorized agents, business associates and subcontractors, and to my insurance company, which pertain to my condition, medical history, services rendered, or treatments received from my physician(s) or hospital(s) as necessary for ZOLL to obtain insurance approval and for treating me. I understand that state and federal law requires my explicit authorization in order for ZOLL to access, use and disclose sensitive health information such as HIV/Aids, genetic, alcohol and substance abuse, mental health and sexually transmitted disease information. I hereby authorize ZOLL to access, use and disclose such information, if applicable, as strictly necessary for treatment or obtaining insurance approval.

This authorization is given voluntarily and shall expire twenty-four (24) months from the date of my signature. This authorization may be revoked by me at any time by notifying ZOLL in writing. However, prior authorized uses and disclosures will not be affected by my revocation and there is the potential for health information used or disclosed pursuant to this authorization to be subject to re-disclosure by the recipient in accordance with their own privacy protection policies and procedures and may no longer be protected under state or federal privacy regulations.

I understand that my medical and financial records will be maintained by ZOLL for a period of time prescribed by state and/or federal law, whichever is longer, and that they are available to me at no cost upon written request.

##### **LifeVest Data**

I understand that my physician, and others responsible for my care, may, but need not, access and review data procured from my use of the LifeVest ("**LifeVest Data**") over the Internet.

I understand that ZOLL, including its affiliates, will access and use my LifeVest Data to assist in my care, to ensure that my LifeVest works as designed and for quality assurance purposes.

I understand that my de-identified LifeVest Data may be used by ZOLL to improve LifeVest adoption by clinicians and patients and for clinical research and publications designed to improve the product itself. This use may improve ZOLL's understanding of the causes and mechanisms of sudden cardiac arrest and allow it to design and test new and better life saving medical devices.



**Alternate Contact and Legal Representative Personal Information and Sharing of Personal Health Information**

I hereby affirm that to the best of my knowledge and belief I have the permission to disclose in this Patient Agreement the personal contact information of my Alternate Contact(s) and/or Legal Representative. I will notify ZOLL promptly if this belief is incorrect or if this permission has been revoked.

In the event ZOLL cannot contact me, or if I am incapacitated, or the patient is a minor or otherwise not competent to respond to questions or take actions, I authorize ZOLL to communicate with these contacts regarding matters related to my use of the LifeVest including the sharing, as necessary, of personal health information (“**PHI**”).

**Permitted Contact Methods**

I understand that by providing and submitting my telephone number to ZOLL, including a mobile telephone number, I agree that a representative of ZOLL can contact me at that number, potentially using automated technology (including text/SMS messaging) or a pre-recorded message. My consent is not an obligation to use or receive any of our products or services.

If ZOLL is unable to reach me, my Alternate Contact(s), or Legal Representative, then I acknowledge that ZOLL may use, without revealing my personal health information, social media and other publically available sources to communicate with my friends and relations in order to reestablish contact with me or my Legal Representative.

I am also aware that my charger may be equipped with GPS technology as part of my LifeVest’s cellular transmission capability which may allow ZOLL to determine the charger’s location.

**Complaints**

If I believe my privacy rights have been violated, I may file a complaint with **ZOLL** by calling **1-800-543-3267**, or I may file a complaint with the Secretary of the Department of Health and Human Services, the Pennsylvania Department of Health or the Accreditation Commission for Health Care (ACHC).

Within five (5) calendar days of receiving my privacy complaint, ZOLL shall notify me, using telephone, e-mail, fax, or letter format, that it has received the complaint and that it is investigating. Within 14 days, ZOLL shall provide written notification to me of the results of its investigation. ZOLL shall maintain documentation of all complaints that it receives, as well as copies of the investigations and responses to me. I will not be penalized for filing a complaint.



Part No.	Part Description	Serial No.	Rev.	Qty

I acknowledge that I have been provided with the equipment listed above on a rental basis only and that title to this equipment remains with ZOLL at all times. I agree to promptly notify ZOLL when my physician determines that I am finished using the equipment by calling **1-800-543-3267**. I will follow ZOLL's return instructions and will not return the LifeVest to my physician, hospital, or to any other facility.

I will rely only upon the written materials provided to me today regarding my financial obligations, benefits, and limitations of the LifeVest, and my responsibilities for the effective use of my LifeVest and I shall disregard any verbal representations, promises, or assurances made by any ZOLL employee or ZOLL independent contractor inconsistent with these materials.

I have read and agree to the following sections of the Patient Agreement: Patient Consent, Financial Responsibility, and Data Use and Privacy.

I have been provided with, and have had the opportunity to ask questions about this Patient Agreement (Rev.S). My agreement to the terms of this Patient Agreement is required before ZOLL will provide me with the above listed equipment. ZOLL reserves the right to terminate service and to demand the return of the LifeVest at any time for any legally permissible reason including my breach of this Patient Agreement.

**AGREED:**

Patient's Full Printed Name		Patient's Date of Birth / /	Date Signed / /
Patient's or Legal Representative's Signature		Name and Relationship to Patient (Legal Representative only)	
Discharge Date: (REQUIRED if hospitalized) / /	Discharged to: (REQUIRED if hospitalized – CHECK ONE)  <input type="checkbox"/> Home <input type="checkbox"/> Skilled Nursing Facility <input type="checkbox"/> Assisted Living Facility <input type="checkbox"/> Other	If not discharged to Home, please provide following: Name of Facility: _____ Address: _____ City: _____ State: _____ Phone Number: _____	
Today's date (REQUIRED) / /			
Location where LifeVest Delivered:			
Fitting PSR (print name)	PSR Signature		Garment Size
Territory Manager (print name)	<b>Customer Support: Phone: 1-800-543-3267 Fax: 1-866-567-7615</b>		
Patient's next scheduled appointment is: ____/____/____ (date), with _____ (physician).			

