

**BIONESS<sup>®</sup> INC.**  
**NOTICE OF PRIVACY PRACTICES**

**THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY.**

This Notice of Privacy Practices (“Notice”) applies to Bioness Inc., its employees, and other personnel (“Bioness”, “we” or “us”).

**I. OUR PRIVACY OBLIGATIONS**

We are required by the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) to maintain the privacy of health information that identifies you (“Protected Health Information” or “PHI”) and to provide you with this Notice of our legal duties and privacy practices regarding Protected Health Information. When we use or disclose Protected Health Information about you, we are required to abide by the terms of this Notice (or other notice in effect at the time of the use or disclosure). Bioness is committed to protecting the privacy of Protected Health Information about you.

**II. USES AND DISCLOSURES OF PHI**

As permitted by HIPAA, Protected Health Information about you may be used and disclosed for treatment, payment, healthcare operations, and other purposes permitted or required by law. We may use and disclose PHI for the following purposes:

A. Treatment. We may use or disclose Protected Health Information for treatment purposes. For example, we may use PHI about you to provide Durable Medical Equipment (“DME”) for you, according to the prescription provided by your physician. We may document in your record, information related to the DME, medical condition necessitating the DME, measurements, fitting notes and any other services provided to you.

B. Payment. We may use or disclose Protected Health Information about you to obtain payment for health care services we provide. For example, we may disclose PHI to your health plan to receive payment for the services provided to you.

C. Health Care Operations. We may use and disclose Protected Health Information about you for our health care operations. These activities include, for example, monitoring the quality of our products and services, reviewing the competence or qualifications of our professionals, conducting training programs, providing warranty services, and other administrative functions.

D. Personal Representatives. We may disclose Protected Health Information about you to your authorized personal representative, as defined by applicable law, or to an administrator, executor, or other authorized person responsible for your estate.

E. Minors’ Protected Health Information. As permitted by federal and state law, we may disclose Protected Health Information about minors to their parents or guardians.

F. Persons Involved in Your Care or Payment for Your Care. We may disclose Protected Health Information about you to a person involved in your care or payment for your care, such as a family member or close friend. We may use or disclose Protected Health Information for disaster relief efforts or to notify a family member or close friend of your location or general condition. If you do not want us to use or disclose Protected Health Information about you in these ways, you must notify us using the contact information at the end of this Notice.

G. Disclosures to Business Associates. We may disclose Protected Health Information about you to other companies or individuals, known as “business associates,” who need certain PHI to provide services to us. For example, we may use another company to perform billing services on our behalf. Our business associates are required to protect the privacy of Protected Health Information.

H. Communications about Treatment Options and Our Products and Services. We may use and disclose PHI to contact you about treatment options or information about your device, our products or services, which we believe may be of interest to you.

I. As Required by Law. We must disclose Protected Health Information when required to do so by any applicable federal, state or local law.

J. Public Health Activities. We may disclose Protected Health Information for public health-related activities. These activities generally include disclosures to a person subject to the jurisdiction of the Food and Drug Administration (“FDA”) for purposes related to the quality, safety or effectiveness of an FDA-regulated product or activity; prevent or control disease, injury, or disability; report births and deaths; report child abuse or neglect; report reactions to medications or problems with products; notify people of recalls of products they may be using; notify a person who may have been exposed to a disease or may be at risk for contracting or spreading a disease or condition; and conduct medical surveillance in certain limited circumstances concerning workplace illness or injury.

K. Health Oversight Activities. We may disclose PHI to a health care oversight agency for activities authorized by law such as audits, civil, administrative, or criminal investigations and proceedings/actions, inspections, licensure/disciplinary actions, or other activities necessary for appropriate oversight of the health care system, government benefit programs, and compliance with regulatory requirements and civil rights laws.

L. Research. Under certain conditions, we may use or disclose Protected Health Information for research purposes. We may allow researchers to look at Protected Health Information to develop a study, identify prospective research participants, or for similar purposes provided that the information is not removed from our premises. We will not allow PHI to be used or disclosed for any other research activity unless: (1) a special committee reviews the planned research and decides that the research poses little risk to privacy and that there is an adequate plan to safeguard the Protected Health Information; (2) the researcher will be given only information that does not directly identify individuals; or (3) where the information concerns deceased individuals, the researcher gives us assurances that the information is necessary for the research and will be used solely for the research.

M. Organ or Tissue Procurement. We may disclose Protected Health Information to organ procurement organizations or related entities for the purpose of facilitating organ or tissue donation and transplantation.

N. Coroners, Medical Examiners, and Funeral Directors. We may release PHI about you to a coroner or medical examiner. This may be necessary, for example, to identify a deceased person or determine the cause of death. We may also disclose PHI to funeral directors consistent with applicable law to carry out their duties.

O. Fund-raising. We may contact you as part of a fund-raising effort.

P. Judicial and Administrative Proceedings. Under certain circumstances, we may disclose PHI in the course of a judicial or administrative proceeding in response to a court order, subpoena, or other lawful process.

Q. Law Enforcement. We may disclose Protected Health Information about you to the police or other law enforcement officials as required by law or in compliance with a court order, warrant, subpoena, summons, or similar process authorized by law. Under certain circumstances, we also may disclose Protected Health Information to law enforcement officials when the information is needed to: identify or locate a missing person or a suspect, fugitive, or material witness; determine whether an individual has been a victim of a crime; determine if a death resulted from criminal conduct; or investigate suspected criminal activity on our premises.

R. Serious Threats to Health or Safety. We may disclose PHI if necessary to prevent or reduce a serious and/or imminent threat to health or safety to a person or the public or for law enforcement authorities to identify or apprehend an individual.

S. Victims of Abuse, Neglect, or Domestic Violence. We may disclose PHI about you to a government authority, such as a social service or protective services agency, if we reasonably believe you are a victim of abuse, neglect, or domestic violence. We will only disclose this type of information to the extent required by law, if you agree to the disclosure, or if the disclosure is allowed by law and we believe it is necessary to prevent serious harm to you or someone else or, if you cannot agree due to incapacity, the law enforcement or public official that is to receive the report represents that it is necessary and will not be used against you.

T. Specialized Government Functions. Under certain circumstances, we may disclose Protected Health Information in response to requests by authorized government officials conducting specialized functions. For example, we may disclose PHI about inmates and persons in legal custody to correctional or law enforcement officials as necessary for health, safety, or security reasons. We may disclose the Protected Health Information of military personnel and veterans as required by military authorities. We also may disclose to authorized federal officials Protected Health Information required for lawful intelligence, counterintelligence, or other national security activities, or to protect the President of the United States or other designated officials. In addition, in certain situations, we may disclose PHI about foreign military personnel to relevant foreign military authorities.

U. Workers Compensation. We may disclose Protected Health Information about you as necessary to comply with requirements of workers' compensation or similar programs that provide benefits for work-related injuries or illness without regard to fault.

### III. OTHER USES AND DISCLOSURES OF PHI

We will ask for your written authorization before using or disclosing Protected Health Information about you for any purpose not described above. You may revoke (take back) your authorization, in writing, at any time. Upon receipt of the written authorization, we will stop using or disclosing PHI about you, except that a revocation will not affect any action that has been taken in reliance on your authorization.

#### IV. YOUR RIGHTS REGARDING PHI

You have the following rights with respect to Protected Health Information about you. To exercise any of these rights, please contact our Privacy Office using the contact information provided at the end of this Notice.

A. Receive a Paper Copy of Bioness Notice of Privacy Practices. You have a right to receive a copy of the Bioness Notice of Privacy Practices at any time. Even if you have agreed to receive the Notice electronically, you are still entitled to a paper copy. To obtain a paper copy, contact the Customer Support Department at (800) 211-9136. This Notice will also be posted on the Bioness internet site at [www.bioness.com](http://www.bioness.com).

B. Request Restrictions on Certain Uses and Disclosures of PHI. You have the right to request restrictions on our use and disclosure of Protected Health Information about you by sending a written request to Bioness. While we will consider all requests for additional restrictions carefully, we are not required to agree to a requested restriction. If we do agree to a requested restriction, we will notify you in writing.

C. Inspect and Copy PHI. You or your authorized or designated personal representative have the right to inspect and copy Protected Health Information about you contained in a designated record set for as long as Bioness Inc. maintains the PHI. The “designated record set” usually will include treatment and billing records. To inspect or obtain a copy of PHI about you, your request must be in writing. We may charge you a fee for the costs of copying, mailing, or other supplies that are necessary to grant your request. We may deny access to certain information for specific reasons, for example, where state law prohibits such patient access. If you are denied access to PHI about you, you may request that the denial be reviewed.

D. Request an Amendment of PHI. If you believe the Protected Health Information we maintain about you is incomplete or incorrect, you may request that we amend it. You may request an amendment for as long as we maintain the PHI. In addition, you must include a reason that explains why your PHI should be amended. In certain cases, we may deny your request for amendment. If we deny your request for amendment, you have the right to file a statement of disagreement with the decision and we will give you a rebuttal to your statement.

E. Receive an Accounting of Disclosures. You may request a list, or accounting, of certain disclosures of Protected Health Information made by us or our business associates for purposes other than treatment, payment, healthcare operations, and certain other activities. The request must be in writing. Your request must specify the time period for which you would like the accounting, but may not be longer than the prior six years and not before April 14, 2003. The first accounting you request within a 12 month period will be provided free of charge, but you may be charged for the cost of providing additional accountings. We will notify you of the cost involved and you may choose to withdraw or modify your request at that time.

F. Request Confidential Communications. You have the right to request that we communicate with you about Protected Health Information about you by alternative means or to an alternative address. Your request must be in writing and must specify the alternative means or location. We will accommodate all reasonable requests for confidential communications.

## **V. HOW TO EXERCISE YOUR RIGHTS REGARDING PHI**

To exercise any of your rights described in this Notice (other than the right to receive a copy of our Notice), you must send a written request to: Bioness Inc., Attn: Customer Support Department, 25134 Rye Canyon Loop, Suite 300, Santa Clarita, CA 91355.

## **VI. QUESTIONS AND COMPLAINTS**

If you have questions or would like additional information about our privacy practices, you may contact our Compliance Officer at (800) 211-9136.

If you are concerned that we may have violated your privacy rights, you may file a complaint with our Compliance Officer using the contact information above. You also may submit a written complaint to the U.S. Department of Health and Human Services. We will provide you with the address to file your complaint with the U.S. Department of Health and Human Services upon request.

We support your right to the privacy of your health information. We will not retaliate against you in any way if you choose to file a complaint with us or with the U.S. Department of Health and Human Services.

## **VI. CHANGES TO OUR NOTICE OF PRIVACY PRACTICES**

We reserve the right to change our privacy practices and the terms of this Notice at any time, provided such changes are permitted by applicable law. If we change this Notice, we may make the new notice terms effective for all Protected Health Information that we maintain, including any information created or received prior to issuing the new Notice.

If we make changes to this Notice, we will promptly post a copy of the updated Notice on our website at [www.bioness.com](http://www.bioness.com). Please review this website periodically to ensure that you are aware of any updates. You also may request a copy of the current Notice by contacting our Customer Support Department at (800) 211-9136.

**EFFECTIVE DATE OF NOTICE:** This Notice is effective as of April 14, 2003.

**REVISED:** December 8, 2006.