

# Prescription for Evaluation & Treatment

## Instructions for Form A

Please have your physician complete the bottom portion of Form A. Once completed, please take it to a Bioness-trained facility to be evaluated.

To locate the nearest Bioness-trained facility, visit [www.bioness.com](http://www.bioness.com) or contact our Bioness Customer Support team at 800.211.9136, option 2.

NOTE: A trained facility may be a rehabilitation hospital, an outpatient rehabilitation clinic or an orthotist/prosthetist practice.

# Form A - Prescription for Evaluation & Treatment

## NESS L300™ Foot Drop System: Functional Neuromuscular Stimulator

Please have your physician complete this form and bring it with you for evaluation and treatment by a Bioness-trained clinician. For the most updated list of NESS L300 facilities in your area, please visit [www.bioness.com](http://www.bioness.com).

### Sample Prescription

|                     |                             |  |  |
|---------------------|-----------------------------|--|--|
| Date:               | March 31, 2008              |  |  |
| Patient Legal Name: | John Doe                    |  |  |
| Diagnosis:          | Ischemic CVA ÷ R hemiplegia |  |  |
| Date of Onset:      | Jan 2, 2008                 |  |  |

**Rx: Physical Therapy - Evaluate for use of NESS L300 to treat for gait dysfunction secondary to above diagnosis (including gait training), as needed for improvement of ambulation ability, balance, and/or endurance.**

|            |                                       |                     |           |           |
|------------|---------------------------------------|---------------------|-----------|-----------|
| Frequency: | Daily _____                           | TIW <u>X3 weeks</u> | BIW _____ | QIW _____ |
|            | Other <u>Re-evaluate in 4-6 weeks</u> |                     |           |           |

Duration: 3 weeks and re-evaluate in 4-6 weeks

Comments: \_\_\_\_\_  
 \_\_\_\_\_

Physician Signature: \_\_\_\_\_  
 Physician Name: \_\_\_\_\_  
 Physician Phone Number: \_\_\_\_\_

For product information, please turn page over ▶

### Prescription for Evaluation and Treatment

Tear Off

|                     |       |     |      |
|---------------------|-------|-----|------|
| Date:               |       |     |      |
| Patient Legal Name: | First | MI. | Last |
| Diagnosis:          |       |     |      |
| Date of Onset:      |       |     |      |

**Rx: Physical Therapy - Evaluate for use of NESS L300 to treat for gait dysfunction secondary to above diagnosis (including gait training), as needed for improvement of ambulation ability, balance, and/or endurance.**

|            |             |           |           |           |
|------------|-------------|-----------|-----------|-----------|
| Frequency: | Daily _____ | TIW _____ | BIW _____ | QIW _____ |
|            | Other _____ |           |           |           |

Duration: \_\_\_\_\_ weeks and re-evaluate in \_\_\_\_\_

Comments: \_\_\_\_\_  
 \_\_\_\_\_

Physician Signature: \_\_\_\_\_  
 Physician Name: \_\_\_\_\_  
 Physician Phone Number: \_\_\_\_\_



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# About the NESS L300™ Foot Drop System

## Help your patients walk faster, further\*

The NESS L300 is an advanced functional electrical stimulation (FES) system that sends low-level electrical impulses to the common peroneal nerve in the leg, stimulating muscles to lift the foot. The NESS L300 senses—in real time—walking position, varying gait speed, and changing terrain. Therefore the NESS L300 Foot Drop System may assist your patients' gait following an upper motor neuron injury or disease.

### Clinical evidence suggests significant improvements in gait

A recent clinical study showed that the NESS L300 offers significant improvements when compared to walking without the device.<sup>1</sup>

An 8-week study of 15 patients showed that the NESS L300 significantly improves stride time when compared to an Ankle Foot Orthosis (AFO). In addition, 100% of the patients in this study preferred the NESS L300 to their AFO.<sup>2</sup>

### Three small, wireless components

#### 1. Intelli-Sense Gait Sensor™

As patients walk, the Sensor automatically detects “heel off” and “heel on” positions, as well as different surfaces and speeds.

#### 2. Comfortable, lightweight Leg Cuff

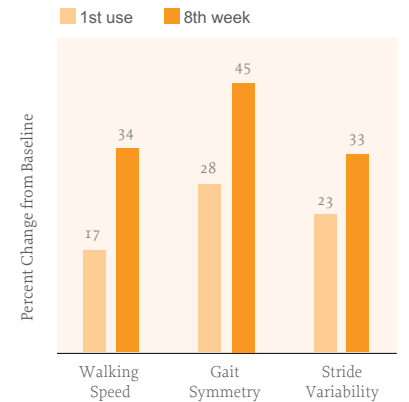
Inside the Cuff are the electrodes, custom positioned for each patient. The Cuff is designed to assure reproducible placement and is easy for patients to put on with one hand.

#### 3. Portable Control Unit

The handheld Control Unit is used to turn the NESS L300 on and off and adjust stimulation.



Patient Outcomes Using the NESS L300<sup>2</sup>



### A range of NESS L300 benefits for a range of patients

The NESS L300 may help your patients regain function for foot drop associated with:

- Stroke
- Traumatic brain injury
- Multiple sclerosis
- Cerebral palsy
- Incomplete spinal cord injury

Beyond producing a more normal gait, the NESS L300 may help:

- Reeducate muscles to function without the system (neuroplasticity)
- Prevent or retard muscle atrophy
- Maintain or increase joint range of motion
- Increase local blood flow

### Contraindications\*\*

- Patients with a demand-type cardiac pacemaker, defibrillator or any electrical or metallic implant should not use the NESS L300.
- The NESS L300 should not be used on the leg if a cancerous lesion is present or suspected.
- The NESS L300 should not be used over areas of regional disorders, such as a fracture or dislocation, which would be adversely affected by motion from the stimulation.

### Clinical References

- 1 - Hausdorff JM, et al. 2008. *Am J Phys Med Rehabil.* 87(1):4-13.
- 2 - Weingarden HP, et al. 2007. *Physiother.* 93(Suppl 1):S359.

\* Individual results vary. Patients are advised to consult with a qualified physician to determine if this product is right for them.

\*\* For additional Contraindications, Adverse Reactions and Precautions, please refer to the NESS L300 Clinician's/User's Guide (also available on-line at [www.bioness.com](http://www.bioness.com)).

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# Prescription for the NESS L300™ Foot Drop System

## Instructions for Form B

Please have your physician complete Form B and fax to Bioness at 877.362.4855.

## NESS® Functional Neuromuscular Stimulator

### Certificate of Medical Necessity/Prescription

- NESS H200® Hand Rehabilitation System
- NESS H200® Supplies: Set of 5 Electrode Pads changed at least every two weeks (per manufacturer's recommendation)  
(Electrode pad prescription must be renewed annually)

- NESS L300™ Foot Drop System
- NESS L300™ Supplies: Pair of Electrodes changed at least every two weeks (per manufacturer's recommendation)  
(Electrode prescription must be renewed annually)

**THIS SECTION MUST BE FILLED OUT COMPLETELY**

|   |                                     |
|---|-------------------------------------|
| Patient Legal Name: <small>First</small> _____ <small>MI.</small> _____ <small>Last</small> _____ |                                     |
| Street Address: _____   | City: _____ State: _____ Zip: _____ |
| Patient DOB: <small>MM/DD/YYYY</small> _____  | Phone: _____                        |

### Medical Necessity

**THIS SECTION MUST BE FILLED OUT COMPLETELY**

|  |   |
|--|---|
| Diagnosis Necessitating NESS H200<br><br><input type="checkbox"/> Hemiplegia/Hemiparesis: _____ ICD-9 Code _____<br><input type="checkbox"/> Other _____ Describe _____ ICD-9 Code _____   | Diagnosis Necessitating NESS L300<br><br><input type="checkbox"/> Foot Drop <b>736.79</b> ICD-9 Code _____<br><input type="checkbox"/> Other _____ Describe _____ ICD-9 Code _____                |
| Diagnosis Secondary to (mark all that apply): <i>optional</i><br><input type="checkbox"/> Stroke _____ ICD-9 Code _____ <input type="checkbox"/> Multiple sclerosis _____ ICD-9 Code _____ <input type="checkbox"/> Spinal cord injury _____ ICD-9 Code _____<br><input type="checkbox"/> Traumatic brain injury _____ ICD-9 Code _____ <input type="checkbox"/> Other _____ Describe _____ ICD-9 Code _____ |   |
| Affected Side (circle):    Right    Left    Both   | Date of Incident/Year of Diagnosis: _____   |
| Functional Limitations:<br><br>  |   |
| Patient's need (mark all that apply):  |   |
| <input type="checkbox"/> Facilitate muscle reeducation<br><input type="checkbox"/> Prevent/retard disuse atrophy<br><input type="checkbox"/> Increase joint range of motion  | <input type="checkbox"/> Increase local blood circulation<br><input type="checkbox"/> Stimulate muscles that dorsiflex the foot to improve gait<br><input type="checkbox"/> Other (explain) _____ |
| Prognosis: _____   |   |

### Physician Information

**THIS SECTION MUST BE FILLED OUT COMPLETELY**

|                              |                       |              |
|------------------------------|-----------------------|--------------|
| Physician: _____             |                       | NPI #: _____ |
| Address: _____               | Phone: _____          | Fax: _____   |
| City, State, Zip: _____      | Office Contact: _____ |              |
| Physician's Signature: _____ | Date: _____           |              |

*This document serves as a one year PRESCRIPTION and earliest start date for the NESS H200 and/or NESS L300 and/or any associated accessories (electrode pads or electrodes) as checked above. I certify that the above-prescribed equipment is medically indicated and in my opinion is reasonable and necessary for this patient's treatment.*

**Upon completion, fax this form to Bioness Customer Support at 877.362.4855**



# Checklist for Custom Fitting

## Instructions for Form C

Please have a Bioness-trained clinician complete Form C and fax to Bioness at 877.362.4855.

**Patient Information Request & Fitting Form**

**Continuing Home Use Therapy Using Technology from Bioness®**

Your patient has been using technology offered by Bioness Inc. as part of their therapeutic regimen. Bioness' technologies are designed to be used throughout the patient's continuum of care. To continue use at home, we have programs designed to provide your patient with uninterrupted therapy. To learn more:

**With your patient's permission, please provide us with the following information:**

|                        |  |                                  |                                     |      |
|------------------------|--|----------------------------------|-------------------------------------|------|
| Patient Legal Name:    |  | First                            | MI.                                 | Last |
| Contact Name:          |  | First                            | MI.                                 | Last |
| Street Address:        |  |                                  |                                     |      |
| City:                  |  |                                  | State:                              | Zip: |
| Home Phone:            |  | Alternate Phone: (if applicable) |                                     |      |
| E-mail: (if available) |  |                                  |                                     |      |
| Facility/Practice:     |  |                                  | Clinician:                          |      |
| Diagnosis:             |  |                                  | Date of Incident/Year of Diagnosis: |      |
| Clinician Phone:       |  |                                  | Clinician E-mail:                   |      |

**Fitting Checklist for the NESS L300™ Foot Drop System**

**Please Check**

| NESS L300 System         |       |
|--------------------------|-------|
| <input type="checkbox"/> | Right |
| <input type="checkbox"/> | Left  |

| Strap Size               |        |
|--------------------------|--------|
| <input type="checkbox"/> | Small  |
| <input type="checkbox"/> | Medium |
| <input type="checkbox"/> | Large  |



**Upon completion, fax this form to Bioness Customer Support at 877.362.4855**  
 25103 Rye Canyon Loop, Valencia, CA 91355 • info@bioness.com • 800.211.9136 Tel • www.bioness.com



fold and detach here

# Patient Insurance & Information

## Instructions for Form D

Please complete both pages of Form D and fax to Bioness at 877.362.4855 or use the provided prepaid postage envelope behind the form to mail to Bioness.

Once Bioness receives Form D, a Bioness Customer Support Representative will contact you to discuss possible insurance benefits and purchase/trial options.

## Completed All Required Forms?

**Great!**

Please contact Bioness at 800.211.9136, option 2, and let us know when you have scheduled your fitting and training appointment and we will make arrangements to ship the NESS L300™ in advance.

**Patient Insurance & Information Form**

If you have any questions, please contact Bioness Customer Support at 800.211.9136, option 2.

|  |   |   |
|--|---|---|
| Patient Legal Name: <span style="float:right">First</span> <span style="float:right">MI.</span> <span style="float:right">Last</span>  |   |   |
| Patient DOB: <span style="float:right">MM/DD/YYYY</span>   |   |   |
| Home Phone:  | Alternate Phone: <span style="float:right">(if applicable)</span> |   |
| Gender: <input type="checkbox"/> Male <input type="checkbox"/> Female  | SSN:  |   |
| (Check all that apply) <input type="checkbox"/> Employed <input type="checkbox"/> F.T. Student <input type="checkbox"/> P.T. Student <input type="checkbox"/> Retired <input type="checkbox"/> Other |   |   |
| Street Address:  |   |   |
| City:  | State:  | Zip:  |
| E-mail: <span style="float:right">(if available)</span>  |   |   |
| Alternate Contact Name:  |   | Alternate Contact Phone:                                |
| Physician Name:  |   | Phone:  |
| Physician Address:   | Fax:  | NPI: <span style="color:red">For Office Use Only</span> |

|  |  |  |
|--|--|--|
| Primary Insurance Company: <span style="float:right">(Exactly as indicated on Insurance Card)</span>   |  | <input type="checkbox"/> Medicare <input type="checkbox"/> HMO <input type="checkbox"/> PPO <input type="checkbox"/> POS |
| Plan Name:   |  |  |
| Customer Service/Claims Phone Number:  |  |  |
| Name of Policy Holder: <span style="float:right">(Exactly as Indicated on Insurance Card)</span>   |  | Employer:  |
| Policy Holder DOB: <span style="float:right">MM/DD/YYYY</span>   |  | Policy Holder's SSN:   |
| Patient's Relationship to Policy Holder: <input type="checkbox"/> Self <input type="checkbox"/> Spouse <input type="checkbox"/> Child <input type="checkbox"/> Other |  |  |
| Policy Number/Medicare ID Number: <span style="float:right">(Exactly as Indicated on Insurance Card)</span>  |  | Group Number:  |

|  |  |
|--|--|
| Secondary Insurance Company: <span style="float:right">(Exactly as indicated on Insurance Card)</span>   |  |
| Plan Name:   |  |
| Customer Service/Claims Phone Number:  |  |
| Name of Policy Holder: <span style="float:right">(Exactly as Indicated on Insurance Card)</span>   |  |
| Policy Holder DOB: <span style="float:right">MM/DD/YYYY</span>   |  |
| Policy Holder's SSN:   |  |
| Patient's Relationship to Policy Holder: <input type="checkbox"/> Self <input type="checkbox"/> Spouse <input type="checkbox"/> Child <input type="checkbox"/> Other |  |
| Policy Number/Medicare ID Number: <span style="float:right">(Exactly as Indicated on Insurance Card)</span>  |  |
| Group Number:  |  |

**please continue to next page to complete remainder of form ▶**



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**Release of Medical Information - Please initial in the 8 spaces provided below  
MUST BE COMPLETED FULLY TO PROCESS REQUEST**

- INITIAL HERE \_\_\_\_\_ I give my physician, therapist or other healthcare provider permission to release information about my medical condition to Bioness Inc. for the purpose of providing and billing for a functional electrical stimulation device and related healthcare services.
- INITIAL HERE \_\_\_\_\_ I give Bioness Inc. permission to keep my physician, therapist, or other healthcare provider updated on my progress using functional electrical stimulation.
- INITIAL HERE \_\_\_\_\_ I authorize Bioness Inc. to release my medical/billing information to my insurer (e.g., Medicare, Medicaid, private insurance) and/or its agent to determine benefits payable for related services and secure payment of benefits.
- INITIAL HERE \_\_\_\_\_ I may revoke this consent by mailing or faxing a letter to my healthcare provider or Bioness. Revoking this consent will prohibit my healthcare provider and Bioness from sharing information about me, except where such sharing is permitted or required by law. Revocation will not affect the ability of Bioness or my healthcare provider to use information they have already received. I understand that once released, information may be subject to redisclosure and no longer protected by federal privacy laws. Also, my doctors and insurers cannot condition treatment, payment or enrollment or eligibility for benefits on whether or not I sign this release. This release will expire in 30 years.
- INITIAL HERE \_\_\_\_\_ Bioness may use my information consistent with its Notice of Privacy Practices, including without limitation, to contact me for customer satisfaction surveys and other marketing communiques and provide me with information and educational materials about Bioness products.

**One Time Payment Authorization**

- INITIAL HERE \_\_\_\_\_ I request that payment of benefits by my insurer or its agent be made either to me or, on my behalf, to Bioness Inc. for any items or services furnished me by that provider.

**Medicare Supplier Standards (enclosed on page 23)**

- INITIAL HERE \_\_\_\_\_ I acknowledge that I received a copy of the Medicare Supplier Standards.

**Notice of Privacy Practices (enclosed on page 25)**

- INITIAL HERE \_\_\_\_\_ I acknowledge that I have received a copy of Bioness Inc.'s Notice of Privacy Practices.

\_\_\_\_\_  
Patient/Guardian Signature

\_\_\_\_\_  
Relationship

\_\_\_\_\_  
Patient/Guardian Name Printed

\_\_\_\_\_  
Date



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# Personal Records

Please keep the following documents for your records.

# Medicare DMEPOS Supplier Standards

**Note: This is an abbreviated version of the supplier standards every Medicare DMEPOS supplier must meet in order to obtain and retain their billing privileges. These standards, in their entirety, are listed in 42 C.F.R. 424.57(c).**

1. A supplier must be in compliance with all applicable Federal and State licensure and regulatory requirements.
2. A supplier must provide complete and accurate information on the DMEPOS supplier application. Any changes to this information must be reported to the National Supplier Clearinghouse within 30 days.
3. An authorized individual (one whose signature is binding) must sign the application for billing privileges.
4. A supplier must fill orders from its own inventory, or must contract with other companies for the purchase of items necessary to fill the order. A supplier may not contract with any entity that is currently excluded from the Medicare program, any State health care programs, or from any other Federal procurement or non-procurement programs.
5. A supplier must advise beneficiaries that they may rent or purchase inexpensive or routinely purchased durable medical equipment, and of the purchase option for capped rental equipment.
6. A supplier must notify beneficiaries of warranty coverage and honor all warranties under applicable State law, and repair or replace free of charge Medicare covered items that are under warranty.
7. A supplier must maintain a physical facility on an appropriate site.
8. A supplier must permit CMS, or its agents to conduct on-site inspections to ascertain the supplier's compliance with these standards. The supplier location must be accessible to beneficiaries during reasonable business hours, and must maintain a visible sign and posted hours of operation.
9. A supplier must maintain a primary business telephone listed under the name of the business in a local directory or a toll free number available through directory assistance. The exclusive use of a beeper, answering machine or cell phone is prohibited.
10. A supplier must have comprehensive liability insurance in the amount of at least \$300,000 that covers both the supplier's place of business and all customers and employees of the supplier. If the supplier manufactures its own items, this insurance must also cover product liability and completed operations.
11. A supplier must agree not to initiate telephone contact with beneficiaries, with a few exceptions allowed. This standard prohibits suppliers from calling beneficiaries in order to solicit new business.
12. A supplier is responsible for delivery and must instruct beneficiaries on use of Medicare covered items, and maintain proof of delivery.
13. A supplier must answer questions and respond to complaints of beneficiaries, and maintain documentation of such contacts.
14. A supplier must maintain and replace at no charge or repair directly, or through a service contract with another company, Medicare-covered items it has rented to beneficiaries.
15. A supplier must accept returns of substandard (less than full quality for the particular item) or unsuitable items (inappropriate for the beneficiary at the time it was fitted and rented or sold) from beneficiaries.
16. A supplier must disclose these supplier standards to each beneficiary to whom it supplies a Medicare-covered item.
17. A supplier must disclose to the government any person having ownership, financial, or control interest in the supplier.
18. A supplier must not convey or reassign a supplier number; i.e., the supplier may not sell or allow another entity to use its Medicare billing number.
19. A supplier must have a complaint resolution protocol established to address beneficiary complaints that relate to these standards. A record of these complaints must be maintained at the physical facility.
20. Complaint records must include: the name, address, telephone number and health insurance claim number of the beneficiary, a summary of the complaint, and any actions taken to resolve it.
21. A supplier must agree to furnish CMS any information required by the Medicare statute and implementing regulations.
22. All suppliers must be accredited by a CMS-approved accreditation organization in order to receive and retain a supplier billing number. The accreditation must indicate the specific products and services, for which the supplier is accredited in order for the supplier to receive payment of those specific products and services (except for certain exempt pharmaceuticals).
23. All suppliers must notify their accreditation organization when a new DMEPOS location is opened.
24. All supplier locations, whether owned or subcontracted, must meet the DMEPOS quality standards and be separately accredited in order to bill Medicare.
25. All suppliers must disclose upon enrollment all products and services, including the addition of new product lines for which they are seeking accreditation.
26. All suppliers must meet the surety bond requirements specified in 42 C.F.R.424.57(c). *Implementation date - May 4, 2009*

**BIONESS 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. Section VI.
- 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. Sections V, VI.

Please Keep for Your Records

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, 25103 Rye Canyon Loop, Valencia, 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.