

## HUMAN FACTORS and PATIENT LABELING REVIEW

Pre-Market Path: **P020033**

Name of the Device: **Independence IBOT 3000 Mobility System**

Manufacturer: **Independence Technology**

Intended Use: For individuals who have mobility impairments and the use of at least one upper extremity. The device is intended to provide indoor and outdoor mobility in confined spaces, at an elevated height, climb curbs, ascend/descend stairs, traverse obstacles, travel over a wide variety of terrain, and negotiate uneven/inclined surfaces.

Review Requested by ODE Lead Reviewer: Robert DeLuca

Date of DDUPSA Receipt: 8/1/02

Date Requested for Review Completion: 10/3/02

OHIP/DDUPSA Reviewers: Laurel S. Mendelson (LZM)

DDUPSA Approval: \_\_\_\_\_, \_\_\_\_\_  
(Deputy Division Director) (Date)

Comments Sent to ODE Lead Reviewer: \_\_\_\_\_ via \_\_\_\_\_

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The following comments summarize DDUPSA's review of the human factors issues and patient labeling for the IBOT 3000 Mobility System (P020033). These comments focus on optimizing safe interactions between the user and the device.

### Human Factors Review

Safe use of the IBOT 3000 Mobility System depends on the interaction between the abilities of the user, the use environment, and the device itself. Because this device is intended for individuals with many different functional abilities in many different types of environments, there is the potential for human factors to arise.

- Has any human factors testing been performed on this device? In particular, how have the needs of the users been considered in the design of this device? Please provide us with the design history, showing how you have considered the needs of the potential users in the design.

3/11/02

## *User Abilities*

The IBOT 3000 Mobility System is a complex device that requires the user to constantly assess the environment and choose between different travel routes and device functions. This requires both good memory and good judgment.

- How do you plan to screen users for their ability to operate this device under stressful conditions such as system failures, overheating, low batteries, poor choice of travel routes, retrieving a dropped object, etc.?
- Can users identify, react to, and resolve problems when they receive error messages?

This device was tested with participants typical of the expected user population. As will be done with actual users, each participant received extensive training, and only those who passed the final test were permitted to undertake the rest of the study. Participants in the study used the IBOT system for approximately 2 weeks, after which they took a Community Driving Test consisting of 15 different tasks.

- When users had problems with their devices, were the problems due to a lack of ability or a lack of training?
- How did you develop your criteria for safe use? What level of hazard mitigation are you trying to achieve?
- How did you test for the users' abilities to properly maintain and service their devices?

This device requires good trunk control to stabilize the seating system and prevent the device from taking unwanted automatic control.

- What are your exclusion criteria (in terms of functional abilities) to screen out unsafe users of this device?

This IBOT Mobility System is projected to be quite expensive to purchase and maintain. Obviously, you will want the users to keep and use the device for an extended period of time.

- What is the expected lifespan of this device?
- Are there exclusion criteria for individuals with disabilities that are expected to progress over time?

## ***Use Environment***

This device is intended to be used indoors and outdoors, over potentially rough terrain. When it is sunny or noisy it is not always possible to see the functions on the control panel or to hear the caution and alarm tones.

- Please consider changing the caution and alarm tone to one that is louder and lower frequency.
- Please consider providing some sort of shielding cover to allow the user to see the control panel in direct sunshine.
- Have you done any testing of how the control panel will function if it gets wet (as during a rainstorm)? *[Note from lead reviewer: This question was satisfactorily addressed in the sponsor's Qualification Test Reports. Specifically, testing for ingress of water was performed and reported in PMA volume 13, pages 152 through 157.]*
- Have you tested the braking and steering mechanisms in wet conditions? *[Note from lead reviewer: This question was satisfactorily addressed in the sponsor's Qualification Test Reports. Specifically, testing for driving performance on various indoor and outdoor surfaces (including wet conditions) was conducted and reported in PMA volume 13, pages 213 through 236.]*

## ***Device and User Interface***

The user interacts with the device through the following:

- The User Control Panel
- The battery charger
- The service and maintenance procedures
- The IBalance System
- The Power Switch

### **The User Control Panel**

Overall, the user interface (the User Control Panel) is designed well to prevent or discourage actions that could result in hazards.

- In rest mode, the user must hit any button on the control panel for the device to “wake up.” At times, we observed this resulted in inadvertent activation of the device. Have you considered requiring a “double hit” as a wake up signal?
- Is the joystick operational during stair climbing function? What will happen if the user forgets to transition to 4-wheel and tries to use the joystick to back away from a staircase after ascending the stairs? *[Note from lead reviewer: The PMA indicates that joystick is*

*not operational during stair climbing function, because joystick movement is not designed to control movement in this function.]*

### The Battery Charger

The battery charger and access to the device batteries seem to be designed to optimize user function.

### The Service and Maintenance Procedures

As mentioned above, I have not seen evidence that all users will be able to provide the proper service and maintenance for their devices.

- Please consider adding a section to the user testing regarding daily maintenance.
- Please add details to the patient labeling about how to perform each aspect of the daily visual inspections.

### The IBalance System

The IBalance System provides active correction to correct balance problems.

- What will happen if the user tries to transfer out of the wheelchair without first turning it “off”? What will happen in standard function? What will happen if 4-wheel function?
- In standard function, the IBOT Mobility System has a higher seat height (22”) than standard power wheelchairs (average around 18”-19”), and it has no anti-tip bars. This will make the device *less* stable than other power wheelchairs.
- Have you done any testing to compare the stability of the IBOT in standard function to other power wheelchairs?

### The Power Switch

There are times when the user needs to power off the device. The power switch is located on the right side of the chair. According to the indications for use, not all users need to have a functioning right arm.

- Are there any times when the user will need to turn the device off where the emergency shut off procedure is inappropriate?
- Should there be access to the power switch on the left side of the chair?

## **Patient Labeling Review**

The patient labeling accompanying the product is lengthy and detailed. I have many detailed comments about the labeling that we can review at a later time. However, the following lists some general recommendations about the patient labeling.

1. Consider including a glossary of terms at the beginning of the User Manual.
2. Implement a triage mechanism for receiving all service calls so that users can call one phone number for help. (Change all references to calling the “Customer Zone,” “24-Hour Service Center,” and “Clinician” to calling “Service.”) Provide the phone number for service in a prominent location such as the bottom of each page or on the front cover.
3. Test the User Manual and Quick Reference Cards on a representative sample of intended users to assure that they will be able to understand the instructions in order to use the device correctly.
4. Include information about contraindications for this device in the first section of the User Manual.
5. In each section, review the operating steps and rewrite them using imperative verbs. Try to avoid beginning instructions with terms such as: “be aware of...,” “be sure to consider...,” etc. Also try to keep only one instruction per bullet.

More information about improving the readability of patient documents can be found in the FDA ***Guidance on Medical Device Patient Labeling***, dated April 19, 2001 at: <http://www.fda.gov/cdrh/ohip/guidance/1128.pdf>.