

Summary of Data & Information Contained in the PMA

Summary Information

This summary contains the following information:

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 3. Contraindications
 4. Warnings
 5. Precautions
 6. Device Description
 7. Alternative Practices and Procedures
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-

1. General Information

Device Generic Name	Advanced Mobility System
Device Trade Name	INDEPENDENCE™ iBOT™ 3000 Mobility System
Applicant's Name and Address	Independence Technology, LLC. 45 Technology Drive Warren, NJ 07059
PMA Number	P020033
Date of Panel Recommendation	11/20/02
Date of Notice of Approval to Applicant	TBD

2. Indications For Use

The INDEPENDENCE™ iBOT™ 3000 Mobility System is a powered mobility device 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.

**3.
Contra-
indications**

Contraindications are the Inclusion/Exclusion criteria presented in the product labeling.

**4.
Warnings**

- Fracture risks for persons with severe osteopenia, osteogenesis imperfecta and spinal metastatic bone cancer.
 - Additional Warnings regarding proper use are presented throughout the product labeling.
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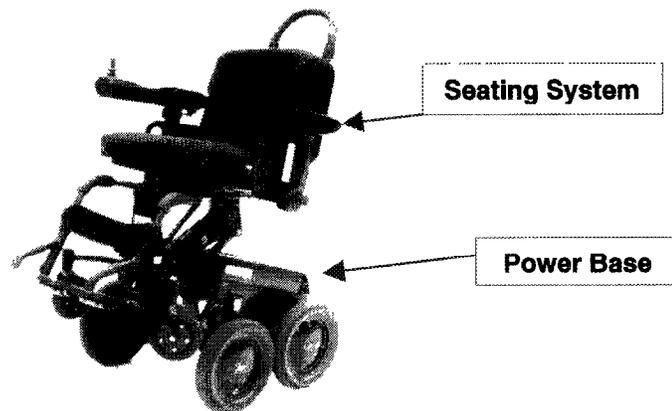
**5.
Precautions**

- Complete training
 - Read product labeling thoroughly. Additional Precautions are presented throughout product labeling.
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**6.
Device
Description**

The INDEPENDENCE™ iBOT™ 3000 Mobility System is a battery operated advanced mobility system designed for both indoor and outdoor use.

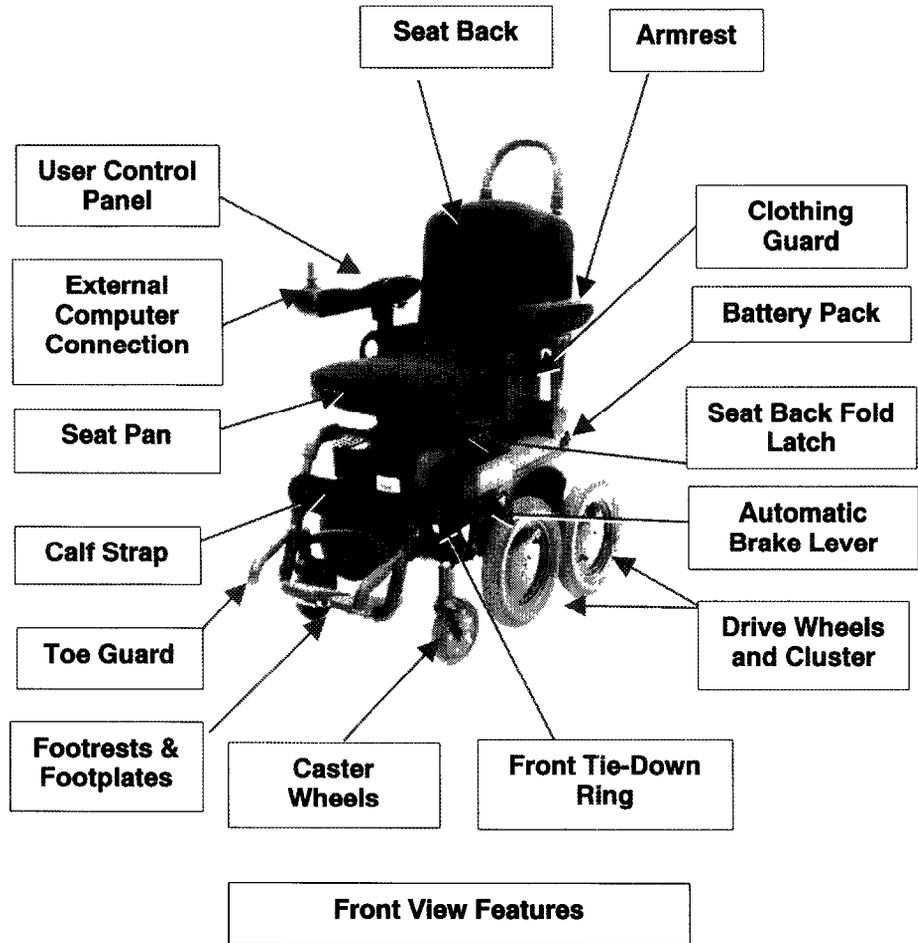
The INDEPENDENCE™ iBOT™ 3000 Mobility System can be divided into two essential parts – a Seating System and a Power Base. The seating system includes all the components designed to support a person in a seated position. The power base includes all the components that provide mobility – the wheels, batteries, motors and computers.



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**6.
Device
Description
(cont.)**

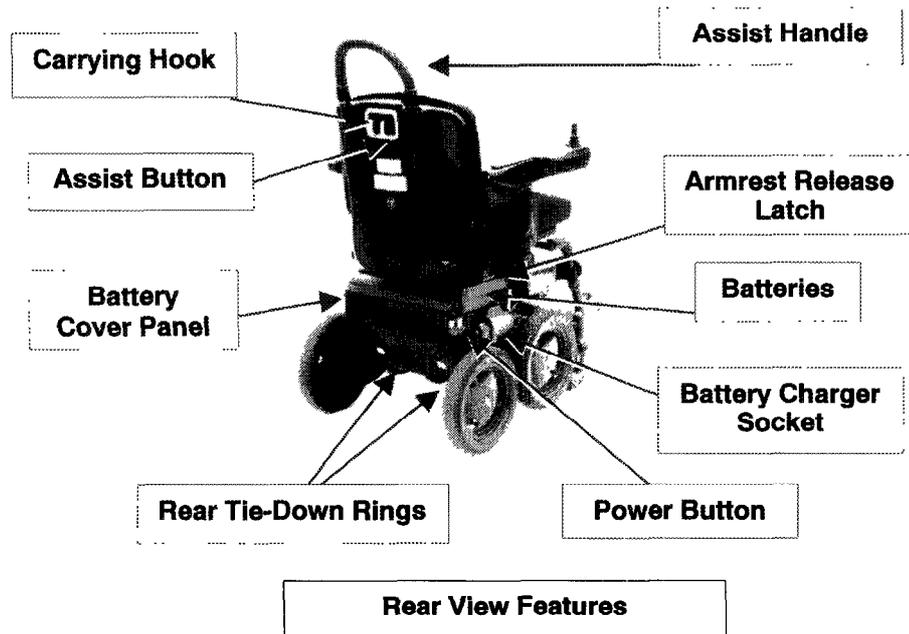
The front view of the INDEPENDENCE™ iBOT™ 3000 Mobility System:



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**6.
Device
Description
(cont.)**

The rear view of the INDEPENDENCE™ iBOT™ 3000 Mobility System:



The device provides up to five operating functions: Standard, 4-Wheel, Balance, Stair and Remote. The purposes of these functions are to provide:

- Mobility on smooth surfaces and inclines at home, work, and in other environments. (Standard Function)
- Movement across obstacles, uneven terrain, curbs, grass, gravel, and other soft surfaces. (4-Wheel Function)
- Mobility in a seated position at an elevated height. (Balance Function)
- Ascent and descent of stairs with or without assistance. (Stair Function)
- Mobility and transportation of the product while unoccupied. (Remote Function)

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**6.
Device
Description
(cont.)**

The INDEPENDENCE™ iBOT™3000 Mobility System is able to perform in each of these operating environments because it is dynamically stabilized. This dynamic stabilization is called the I-Balance™ Technology.

The I-BALANCE™ Technology in the INDEPENDENCE™ iBOT™ 3000 Mobility System uses a computer system that works in conjunction with gyroscopes. When the gyroscopes sense movement, a signal is sent to the computer. The computer processes the information and tells the motors to move the wheels to maintain stability and balance.

The I-BALANCE™ Technology maintains balance in the forward and backward directions. This means the INDEPENDENCE™ iBOT™ 3000 Mobility System will keep the seat relatively level when driving straight up or down curbs or inclines. It does not electronically maintain lateral or side-to-side stability.

The INDEPENDENCE™ iBOT™ 3000 Mobility System has four operating functions that use the I-BALANCE™ Technology: 4-Wheel, Balance, Stair and Remote. Each function uses the core technology in a slightly different way.



4-Wheel Function

4-Wheel Function provides the user with mobility and flexibility in a wide variety of environments. 4-Wheel Function is the 4-wheel drive of the INDEPENDENCE™ iBOT™ 3000 Mobility System, enabling users to traverse inclines up to 8 degrees and over soft, uneven terrain such as sand, gravel, dirt, grass, etc. In 4-Wheel Function the device can also navigate over obstacles up to 4 inches and through water up to 3 inches deep. In 4-Wheel Function the I-Balance™ Technology, sensor data and user commands are processed so that the device reacts to changes in pitch caused by the changes in terrain, external impacts and other factors. The device uses both wheel and cluster position to maintain stability. For example, if the user drives the device up a curb, the cluster will rotate (in reaction to the change in pitch) to maintain a level seat as the wheels drive forward. In this manner stability is enhanced even during a steep ascent.

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**6.
Device
Description
(cont.)**



Balance Function

Balance Function provides mobility at an elevated height. As the name suggests, in Balance Function the INDEPENDENCE™ iBOT™ 3000 Mobility System mimics human balance in that it operates on two points of contact with the ground. This is accomplished by the combined weight of the device and the user shifting over the back wheels. The device reacts to this center of gravity change by transitioning up onto two wheels. A brake locks the clusters into this vertical arrangement. In Balance Function the mobility system maintains stability by driving the wheels to stay under the user. In Balance Function the seat height can be raised and lowered to facilitate the reaching of objects on shelves or having a “eye-level” conversation with a standing person. Balance Function is appropriate for firm surfaces with an incline up to 5 degrees and obstacles up to ½ inch.



Stair Function

Stair Function enables the user to ascend or descend commonly encountered stairs either by themselves or with an assistant. Stair climbing is achieved by the rotation of the clusters over the stairs using a similar closed-loop control algorithm that uses pitch and sensor data to control the cluster motors. The device strives to keep the center of gravity of the system over the ground contacting wheels. When a user leans either forward or back (or an assistant leans the device), shifting the center of gravity, the device will rotate the clusters in response, which will result in the device climbing down or up one stair respectively. The user will climb up or down a staircase facing down the stairs with the direction of the weight shift (lean) determining the direction of climbing.

Continued on next page

**6.
Device
Description
(cont.)**

The joystick is deactivated in Stair Function to prevent unintentional deflection of the joystick on the stairs. When a landing is reached the user can transition into 4-Wheel Function and drive away from the stairs. The user/assistant is the input device during stair climbing as they control the rate of climbing and provide stability by holding the stair handrails (user) or the Assist Handle (assistant).



Remote Function

Remote Function provides the user with a way to operate the mobility system when not seated in it. Remote Function is useful for maneuvering the device for transfers, parking the device after a transfer, for driving into a vehicle for transport and for other purposes. The User Control Panel (UCP) may be removed from its mount on the armrest and operated via a five-foot length retractable cable.

Entry into Remote Function is only allowed when the seat is folded to prevent use of this function when a user is seated in the device. This is because the device was designed to have an empty seat in this function. Since the device does not have to keep a user stable it is able to traverse inclines up to 25 degrees (e.g. up a ramp to get into the back of a SUV).

While this function is very good for steep inclines it is not appropriate for obstacles for a wide variety of terrain. Remote Function is appropriate for firm, even surfaces with obstacles no great than 1 inch.



Standard Function

In Standard Function the INDEPENDENCE™ iBOT™ does not use the I-Balance™ Technology. In this function the mobility system behaves like a current power wheelchair. The seat is at the lowest available position in this function. The casters attached to the base of the seat are in contact with the ground and the front drive wheels are raised off the ground. The casters provide good turning performance in this function.

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**6.
Device
Description
(cont.)**

As with currently marketed power wheelchairs, the use of casters limits the terrain and obstacle performance. Standard Function is appropriate for relatively firm (e.g. indoor environments, sidewalks, and pavement) surfaces with up to a 5 degree incline and obstacles up to ½ inch.

**7.
Alternative
Practices and
Procedures**

In 1990, the National Institute for Disability and Rehabilitation Research (NIDRR) and the National Center for Health Statistics (NCHS) conducted a survey to estimate the number of people using assistive technology. Of the 13,128,000 people interviewed, 6,403,000 people, or 48.8% reported that they use assistive mobility technology (LaPlante, et. al., 1992).

Furthermore, in an independent discussion of this survey's findings, LaPlante indicates that this population uses 8,487,000 mobility devices, highlighting the fact that a significant number of people use more than one mobility device.

A wide variety of mobility devices are identified in the above-mentioned report. In general, mobility devices can be divided into four categories (Sprigle, S. & Lane, J.P., 1995):

- *balance aids*
- *dependent mobility devices*
- *independent manual mobility devices*
- *independent power mobility devices*

Balance aids include canes, crutches, and walkers. These devices provide support and stability during ambulation. Canes support approximately 25% of a person's body weight, while walkers are designed to support all of a person's body weight.

Overall, balance aids are used by individuals who have the functional capability to ambulate, but have muscle weakness and incoordination that inhibits them from ambulating safely without assistance.

Dependent mobility devices are manual wheelchairs, which are propelled by a person other than the user. These devices are used by individuals for whom independent mobility is not an option, nor a goal. These wheelchairs tend to be the heaviest type of manual wheelchair, weighing between 50 and 70 pounds (Taylor, S.J. & Kreutz, D., 1997). These wheelchairs are most commonly used as transport chairs in hospitals, malls, airports, and other facilities.

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**7.
Alternative
Practices and
Procedures
(cont.)**

Independent manual mobility devices are self-propelled wheelchairs that are typically designed with two large wheels that can be pushed by the user. These wheelchairs are lighter in weight than the dependent mobility devices, and are far more adjustable to individualize the fit of the chair to a particular rider. There are two main types of *independent manual mobility devices*, namely conventional non-adjustable wheelchairs and lighter weight, multi-adjustable wheelchairs.

- Standard, conventional wheelchairs are used by individuals who intend to traverse on smooth ground and do not desire advanced mobility skills such as ascending and descending curbs (Taylor, et. al., 1997).
- Multi-adjustable or lightweight wheelchairs are designed to provide more maneuverability and smoother operation for the active user.

Independent power mobility devices are used by individuals who do not have the functional ability to self-propel a manual wheelchair, or by persons for whom the physical strain of operating a manual chair negatively impacts their mobility. Restrictions in cardio-pulmonary capacity as well as physical limitations in the upper extremities can indicate the need for power mobility. There are two broad categories of *independent power mobility devices*: power wheelchairs, and scooters.

- Power wheelchairs are most often battery powered, joystick operated, 4 wheeled, motor-driven chairs. Current designs use direct-drive motors attached to two of the 4 wheels. These drive wheels may be mounted at the rear of the chair (rear wheel drive), under the seat (mid-wheel drive) or at the front of the chair (front wheel drive). The power unit (batteries, motors and controller and wheels) is frequently housed together in a power base and the seat unit is mounted to the top of the power base. This modular power-base design adds significant weight (as compared to a scooter), but is particularly advantageous to individuals who frequently encounter uneven or rough terrain (Cook, A. & Hussey, S., 1995). For users who are unable to operate a joystick, alternate controllers (Sip 'N Puff, breath controller, Head controller) may be substituted for the joystick to control many of these power wheelchairs.
- Scooters are available in either three or four wheel designs. Most often a scooter is operated through a tiller,

Continued on next page

**7.
Alternative
Practices and
Procedures
(cont.)**

which is used to control the direction of travel and a lever on the tiller, which controls speed. These devices are most commonly utilized by individuals who are able to ambulate, but are limited in speed and range of ambulation. The wheels are mounted to a platform to which the tiller is mounted, on the front, and a seat is mounted on the rear. The section of the platform between the tiller and the seat serve as a footrest.

Regardless of the type of wheeled mobility device a person uses, there are two major barriers that users commonly experience:

- transporting the mobility device in a car
- ascending and descending stairs

People who use wheeled mobility devices also want access to motor vehicles, such as cars or vans, either as a passenger or as an operator. However, two obstacles pose impediments: accessing the vehicle and stowing the mobility device inside the motor vehicle.

Two door sedans are the most commonly used cars, by persons independently operating a manual wheelchair, because of their wide door opening. The user transfers into a car independently or with the assistance of a transfer board or overhead grab bar. Once in the car, the user must find a way to safely stow the mobility device. Many manual wheelchair users are able to fold and pull the device inside the car while others require an assistant to place the device in the trunk, back seat or on a special carrier on the back bumper of the car.

Scooter users, with sufficient ability to walk from the back of the car to the passenger compartment, may use a commercial lift to lift the scooter in and out of the back of the car. Once the scooter is loaded, the rider walks to the car door and gets into the car.

If the user is unable to transfer into and out of a car, or uses a power wheelchair, then he/she will most often use a modified van. (Van modifications may include raising the roof, dropping the floor, or both.) Two aids are commonly used to assist in accessing a van are ramps and lifts. The selection of either a ramp or a lift depends upon the person's need to independently access the van and negotiate entry and exit from the van.

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**7.
Alternative
Practices and
Procedures
(cont.)**

Ascending and descending stairs typically poses a problem for an individual using a wheeled mobility device. Some very highly, physically capable, manual wheelchair riders are able to descend stairs by keeping their chair in a wheelie position and controlling the descent of the chair one step at a time. Many of these very active users will go up stairs by getting out of their wheelchair, and “bump” up each stair with their arms, bringing their wheelchair up with them.

Other wheelchair users need to rely on some type of mechanical assistance or significant physical assistance by one or more unimpaired persons.

- Mechanical lifts have been developed to assist people who use mobility devices in ascending and descending stairs. For example, electric stair chairs (stair glide) can be installed on a staircase. With this type of device, the individual must transfer to the stair chair, which will transport them between floors. When the stair chair reaches its destination, the person transfers again, either to a second device that stays on the other level of the house, or to their own device, which has been transported up or down the stairs by an assistant.
- Elevators or electric lifts that fit over the stairs can transport the person, as well as their mobility device, from one floor to another.
- To provide access to more than one particular staircase, attendant operated stair climbing devices have been developed. The device is attached to the back of a manual wheelchair, and the assistant uses it on the stairs in a manner similar to a dolly or hand truck.
- To be manually assisted up (and in many cases down the stairs), a manual wheelchair rider can guide one, preferably two assistants in “bumping” the chair up the stairs. The chair and rider are positioned in a wheelie position, one assistant is using the chair push handles, from behind, while a second assistant is positioned at the front of the chair holding on to the frame of the chair. The rider, if possible, pulls back on the wheels, while the assistants are lifting the chair up to the next step. This sequence is repeated for each step and reversed when coming down the steps.

Determination of which type of assisted mobility device a person needs is often made with consideration of many factors including, physical ability, mobility requirements, environments of use, available service support. Increasingly evidence is emerging that the “use it or lose it” philosophy underlying many mobility recommendations is having long term detrimental effects of the user of assisted mobility

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7.
**Alternative
Practices and
Procedures
(cont.)**

devices. Studies, particularly involving persons with a spinal cord injury, indicate the prevalence of shoulder pain in wheelchair riders to range from 36% to 73%, with an apparent increase in prevalence the longer the person has lived with the disability. (Sie, et al, 1992; Pentland, 1991; Subbarao, 1994). These reports of secondary complication to long term, daily use of manual mobility devices are beginning to impact the recommendations for when a person is best suited for a manual versus a powered mobility device.

BIBLIOGRAPHY

Cook, Albert & Hussey, Susan. (1995). Assistive Technology: Principles and Practice. St. Louis, Missouri: Mosby-Year Book, Inc.

LaPlante, Mitchell P., Hendershot, Gerry E., Moss, Abigail J. (1992). Assistive Technology Devices and Home Accessibility Features: Prevalence, Payment, Need, and Trends. Advance Data, (217): 1-12.

Sprigle, Stephen & Lane, Joseph P. (1995). Assistive Technology for Persons with Physical Disabilities In Mann, William C. & Lane, Joseph P. (Eds.). Assistive Technology for Persons with Disabilities (2nd ed.). Bethesda, Maryland: American Occupational Therapy Association, Inc. 74-81.

Taylor, Susan Johnson & Kreutz, David. (1997). Powered and Manual Wheelchair Mobility. In Angelo, Jennifer (Ed.). Assistive Technology for Rehabilitation Therapists. Philadelphia, PA: F.A. Davis Company. 117-154.

Sie IH, Waters RL, Adkins RH, Gellman H: Upper extremity pain in the postrehabilitation spinal cord injured person. Arch Phys Med Rehabilitation 1992;73:44-48.

Pentland WE, Twomet LT: The weight-bearing upper extremity in women with long term paraplegia. PARAPLEGIA 1991; 29:521-530.

Subbarao JV, Klopstein J, Turpin R: Prevalence and impact of wrist and shoulder pain in patients with spinal cord injury. J Spinal Cord Medicine 1994; 18: 9-13.

8.
**Marketing
History**

The INDEPENDENCE™ iBOT™ 3000 Mobility System has never been offered for sale, and therefore, has no marketing history.

**9.
Adverse
Events**

The adverse events listed can occur while using the INDEPENDENCE™ iBOT™ 3000 Mobility System as well as any power wheelchair:

- Pinching/crushing finger/hands when lowering seat
- User falls out of the product
- Product falls over either forward or backward
- Product falls over laterally (sideways)
- Product becomes inoperable
- Product goes off the edge of obstacles or stairs
- User collides with obstacles
- User or product injures other people
- User suffer injury while attempting to climb stairs
- Assistant is injured
- User injured during transfers
- Electrical Shock

The potential risks listed can result in, but are not limited to:

- Crushing injury
- Contusions
- Abrasions
- Lacerations
- Concussion
- Fractures
- Head injuries
- Internal injuries
- Burns
- Death

**10.
Summary of
Studies**

A summary of the (a) non-clinical laboratory studies and the (b) clinical investigations submitted in the PMA application.

**10 a.
Nonclinical
Studies**

The INDEPENDENCE™ iBOT™ 3000 Mobility System has been tested to a wide range of non-clinical tests quantifying the software, mechanical, electrical, performance, environmental, and anomalous device characteristics.

The software information includes the software development process, risk management, and comprehensive verification and validation. The documentation describing these activities is consistent with the recommendations of the FDA *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (5/29/98)*.

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**10 a.
Nonclinical
Studies
(cont.)**

To test the mechanical, electrical, environmental, performance and anomalous properties of the INDEPENDENCE™ iBOT™ 3000 Mobility System many of the CDRH Recognized Consensus Standards were used as the basis for testing. A list of the consensus standards used is as follows:

- ANSI RESNA WC/08-1991 Wheelchairs – Static, Impact and Fatigue Strength Tests
- ANSI RESNA WC/21-Vol.2-1998 Requirements and test methods for electromagnetic compatibility of powered wheelchairs and motorized scooters
- ISO 7176-3:1988 Wheelchairs – Part 3: Determination of Efficiency of Brakes
- ISO 7176-4:1997 Wheelchairs – Part 4: Energy Consumption of Electric Wheelchairs and Scooters for Determination of Theoretical Distance Range
- ISO 7176-5:1986 Wheelchairs – Part 5: Determination of Overall Dimensions, Mass and Turning Space
- ISO 7176-9:1988 Wheelchairs – Part 9: Climatic tests for electric wheelchairs
- ISO 7176-14:1997 Wheelchairs – Part 14: Power and Control Systems for Electric Wheelchairs – Requirements and Test Methods.
- ISO 7176-15:1996 Wheelchairs – Part 15: Requirements for Information Disclosure, Documentation and Labeling
- ISO 7176-16:1997 Wheelchairs – Part 16: Resistance to Ignition of Upholstered Parts – Requirements and Test Method
- ISO 7176-1:1999 Wheelchairs – Part 1: Determination of Static Stability
- ISO 7176-10:1988 Wheelchairs – Part 10: Determination of Obstacle-Climbing Ability of Electric Wheelchairs

The INDEPENDENCE™ iBOT™ 3000 Mobility System was tested to many other international standards such as:

- ANSI RESNA WC/15-Vol.1-1998 Requirements for Information Disclosure, Documentation and Labeling
- ANSI RESNA WC/19-Vol.1-1998 Requirements and Test Methods for Wheelchairs (Including Scooters), Section 19: Wheelchairs Used as Seats in Motor Vehicles
- ASTM D 4169-01 Standard Practice for Performance Testing of Shipping Containers and Systems
- ASTM D 6179-97 Standard Test Methods for Rough Handling of Unitized Loads and Large Shipping Cases and Crates

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**10 a.
Nonclinical
Studies
(cont.)**

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- ASTM D 4003-98 Standard Test Methods for Programmable Horizontal Impact Test for Shipping Containers and Systems
 - ASTM D 642-00 Standard Test Method for Determining Compressive Resistance of Shipping Containers, Components and Unit Loads
 - ASTM D 999-01 Standard Test Methods for Vibration Testing of Shipping Containers
 - ASTM D 4728-01 Standard Test Method for Random Vibration Testing of Shipping Containers
 - BS EN 12184:1999 Electrically Powered Wheelchairs, Scooters and Their Chargers – Requirements and Test Methods
 - CISPR-11:1990 Limits and methods of measurement of electromagnetic disturbance characteristics of industrial, scientific and medical (ISM) radio-frequency equipment
 - IEC 61000-4-2:1995 Electromagnetic Compatibility (EMC) Part 4: Testing & Measurement Techniques – Section 2: Electrostatic discharge immunity test
 - IEC 61000-4-3:1995 Electromagnetic Compatibility (EMC) Part 4: Testing & Measurement Techniques – Section 3: Radiated, Radio-Frequency, Electromagnetic Field Immunity Test
 - IEC 61000-4-4:1995 Electromagnetic Compatibility (EMC) Part 4: Testing & Measurement Techniques – Section 4: Radiated, Radio-Frequency, Electromagnetic Field Immunity Test
 - IEC 61000-4-5:1995 Electromagnetic Compatibility (EMC) Part 4: Testing & Measurement Techniques – Section 5: Radiated, Radio-Frequency, Electromagnetic Field Immunity Test
 - IEC 60529:1989-11: Classification of Degrees of Protection Provided by Enclosures
 - IEC 60335-1 Third Edition 1991-04 Safety of Household and Similar Electrical Appliances, Part 1: General Requirements
 - IEC 60601-1 second edition 1998, Medical electrical equipment part 1: General requirements for safety
 - IEC 68-2-14 Fifth Edition 1984: Basic Environmental Testing Procedures, Part 2: Test-Test N: Change of Temperature
 - ISO 7176-2:1999 Wheelchairs – Part 2: Determination of Dynamic Stability of Electric Wheelchairs
 - ISO 7176-6:2001 Wheelchairs – Part 6: Determination of Maximum Speed, Acceleration and Retardation of Electric Wheelchairs
 - ISO 7176-7:1998 Wheelchairs – Part 7: Measurement of Seating and Wheel Dimensions
 - ISO 7176-8:1998 Wheelchairs – Part 8: Requirements and Test Methods for Static, Impact and Fatigue Tests
 - ISO 7176-9:1997 Wheelchairs – Part 9: Climatic Tests for Electric Wheelchairs

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**10 a.
Nonclinical
Studies
(cont.)**

- ISO 7176-9:2001 Wheelchairs – Part 9: Climatic Tests for electric wheelchairs
- ISO 7176-20:1996 Wheelchairs – Part 20: Stand-up type wheelchairs
- ISO 7176-21:1999 Wheelchairs – Part 21: Requirements and Test Methods for Electromagnetic Compatibility of Electric Powered Wheelchairs and Scooters
- ISO 8191-1:1987 Furniture – Assessment of the ignitability of upholstered furniture – Part 1: Ignition source – smoldering cigarette
- ISO 8191-2:1988 Furniture – Assessment of the ignitability of upholstered furniture – Part 2: Ignition source – match- flame equivalent
- ISO 10993-1:1994 Biological evaluation of medical devices Part 1. Guidance on selection of tests
- ISO 10993-5:1999 Biological evaluation of medical devices Part 5. Tests for in vitro cytotoxicity
- ISO 10993-10:1995 Biological evaluation of medical devices Part 10. Tests for irritation and sensitization
- MIL-STD 810E Method 510.3 July 14 1989 Department of Defense Tests Methods Standard for Environmental Engineering Considerations and Laboratory Tests – Sand and Dust
- MIL-STD 810E Method 505.3 Solar Radiation (Sunshine)
- UL 1012, Power Units Other Than Class 2

All these standards were used to create the test plans and test cases that the mobility system was tested to. Data is presented in the following test reports: 1) Static Stability 2) Dynamic Stability 3) Effectiveness of Brakes 4) Electrical Energy Consumption and Distance Range 5) Dimensions, Mass and Turning Space 6) Speed, Acceleration, and Retardation 7) Measurement of Seating and Wheel Dimensions 8) Static Impact & Fatigue 9) Climate 10) Obstacle Climbing Ability 11) Power and Control Systems 12) Nomenclature and Labeling 13) Resistance to Ignition of Upholstered Parts 14) Electromagnetic Compatibility 15) Stair Climbing 16) Fault Insertion 17) System Monitoring 18) Programmable Drive Parameters 19) Stability With Impact 20) Crack Traversal 21) User Control Panel 22) Transporter Power 23) Computer Interface 24) Exposure to Altitude 25) Transitions Between Functions 26) Enclosures Protection 27) Electrical Standards 28) Safety 29) User Comfort and Convenience 30) Packaging 31) Lifetime 32) Operation On Surfaces 33) Environmental 34) Joystick Mechanical 35) Drop Test 36) Exposure to Sunlight

All results met the pass/fail criteria that have been established.

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**10 b.
Clinical
Investigation**

There is a Pivotal Trial for the INDEPENDENCE™ iBOT™ 3000 Mobility System. It is the only study in which individuals with a mobility disability received the training program that will be used when the device is marketed and utilized in uncontrolled environments for an extended period of time. This is the only study capable of generating data regarding the safe and effective use of the device for its intended population.

In addition to the Pivotal Trial there are three (3) additional clinical evaluations utilizing the investigational device. These three clinical evaluations pre-dated the Pivotal Trial and as such utilized previous versions of both the INDEPENDENCE™ iBOT™ 3000 Mobility System and the training program for the device. While these additional clinical evaluations were not designed to evaluate the safe and effective use of the investigational device, the information generated by these studies was helpful in designing the investigational device and the Pivotal Clinical Trial. Because these additional clinical evaluations were not designed to evaluate the safe and effective use of the investigational device they are not summarized here.

PIVOTAL CLINICAL TRIAL SUMMARY

PRINCIPLE INVESTIGATOR

Heikki Uustal, MD, Department of Rehabilitation Medicine, JFK - Johnson Rehabilitation Institute, Edison, NJ

SUBINVESTIGATORS

Lei Lin, MD, Jean Minkel, PT, Hunter Burgess, PT, Maria Bemont, PT, Sandy Salerno, OT, Stacey Eberhardt, OT, Ann Greiner, PT, Lynne Corriveau, PT, Kevin Corriveau, PT, Jennifer Stafford, OT

INSTITUTIONAL REVIEW BOARD

New England Institutional Review Board, Wellesley, MA

OBJECTIVE

This study had two main objectives:

1. To demonstrate that people with a variety of mobility skills (different capabilities), using different configurations of the INDEPENDENCE™ iBOT™ 3000 Mobility System, will be able to safely and effectively use the product in real world environments.
2. To demonstrate that subjects will have improvements in both objective and subjective measures of functional activities in a real world environment when using the INDEPENDENCE™ iBOT™ 3000 Mobility System compared to their current device.

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**10 b.
Clinical
Investigation
(cont.)**

EXPERIMENTAL DESIGN

The clinical trial was a single center, prospective, balanced, open label evaluation that utilized participants as their own control. A total of 20 Subjects were required to complete the study. The initial two (2) Subjects (skilled manual wheelchair users) completed the Pilot Trial, eighteen (18) Subjects completed the Real World Trial. By design these 18 Subjects consisted of 6 skilled manual wheelchair users, 6 slow manual wheelchair users, and 6 power wheelchair users.

The safety of the investigational device was determined by comparing the rate of adverse events occurring in the investigational device and in the subjects' own devices.

The primary efficacy variable in this study was the score a subject obtained on a Community Driving Test consisting of 15 tasks that one would encounter in everyday life. The scoring system was a 7 point scale. The lowest score (0) was assigned when a subject could not do a task. The next 3 scores (1, 2, 3) were assigned when a subject could do the task with the assistance of someone else (scores within this group were differentiated by the level of exertion required by the assistant).

The highest three scores (4, 5, 6) were assigned when the subject could do the task independently (scores within this group were differentiated by the level of exertion required by the subject). Changes from one group to another show a change in the subject's independence level. Changes within a group show no change in independence, but a change in exertion required to complete the task.

The secondary efficacy variable was also the ability to do specific tasks and they were scored in the same manner as the primary efficacy variable. However, these tasks were ones that each subject chose as being important to them in their life.

The Wilcoxon Signed Rank test was utilized to test for a difference in efficacy variable scores between the investigational device and the subjects' own device.

STUDY PERIOD

The study was conducted from February 2002 to May 2002. Each Pilot Trial subject participated in the study for two weeks; one week in their own device and one week in the investigational device. Each Real World Trial subject participated in the study for four weeks; two weeks in their own device and two weeks in the investigational device.

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**10 b.
Clinical
Investigation
(cont.)**

STUDY POPULATION

The study population consisted of individuals currently using a manual wheelchair, a power wheelchair or a scooter as their primary mobility device.

SUBJECT SELECTION

The key inclusion criteria was subject willingness to use a wheelchair accessible van or accessible public transportation during the study. The key exclusion criteria were a subject weight of more than 250 lbs., the subject living outside of the investigational device service area, numerous criteria related to the subject's physical capabilities to operate the investigational device, and numerous criteria related to the subject's medical condition. Subjects who met the inclusion/exclusion criteria signed an Informed Consent to participate. A trained clinician performed an assessment to determine if the subject was appropriate for the study. Subjects were trained in the use of the investigational device and required to demonstrate proficiency with the device.

HOW DATA WAS COLLECTED

Safety data was collected on a daily basis through telephone contact with the subject. Efficacy data was collected when the subject completed the Community Driving Test after having utilized the investigational device in the Real World for two weeks.

SUBJECT DISCONTINUATION

A total of twenty-nine (29) subjects signed the informed consent. Eight (8) subjects never received training in the investigation. Two (2) of the eight were not recommended for the device by the clinician. Two (2) of the eight voluntarily withdrew from the study prior to training; one withdrew after suffering injuries in an automobile accident and the other withdrew because of issues related to transferring in and out of his van. The Sponsor ended the participation of four (4) of the eight subjects, two (2) because the desired sample size of power chair subjects had been reached, one because participation in the study would have required modifications to the subjects stairs outside his home, and one (1) because the subject had a potential conflict of interest.

Twenty-one (21) subjects received the Day 1 training on the use of the INDEPENDENCE™ iBOT™ 3000 Mobility System. Twenty (20) subjects completed the clinical trial. One (1) subject voluntarily ended their participation in the study after one day in the investigational device because it was difficult to operate the device in the small hallways and rooms of the subject's home.

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Clinical
Investigation
(cont.)**

SAFETY DATA/ADVERSE EVENTS

- There were no serious adverse events [any event caused by or associated with the product that required medical treatment outside of the Evaluation Facility or the subject's home].
- There was one adverse event [any event caused by or associated with the product that required medical treatment by (a) the clinician at the Evaluation Facility or (b) by the subject or others at the subjects home]. This event occurred during an assessment of the subject in the investigational device. He pinched his forearm between the UCP and the Armrest. A forearm pad was utilized to prevent further problems; no other medical treatment was provided.
- There were four (4) instances of subjects seeking medical attention for events that were not caused or associated with the use of the device. In all cases the subject was utilizing their own device.
- There were five (5) instances which did not require medical attention, but which could have required medical attention should the event recur. All of the events were related to the device and subject falling, three (3) of these events occurred in the investigational device, two (2) occurred in their own device. All events are attributable to subject judgment errors; in no event did a device fail or otherwise malfunction.

EFFECTIVENESS DATA

- In the Community Driving Test all 20 subjects scored higher in the investigational device than in their own device. The result is statistically significant ($p < .001$).
- In the stair climbing components of the Community Driving Test all 20 subjects scored higher in the investigational device than in their own device. The result is statistically significant ($p < .001$).
- In every task (11) in the Community Driving Test in which the Stair Climbing Function, the 4-Wheel Function or the Balance Function in the investigational device was utilized there was a statistically significant improvement in test scores and there was a statistically significant (range from $p < .001$ to $p = .008$) improvement in the subject's level of independence.
- In the Subject Specific Function Scores subjects scored significantly higher in the investigational device and there was a statistically significant ($p < .001$) improvement in the subject's level of independence.

SUBJECT COMPLAINTS

Telephone contact was made daily with subjects. Subjects were asked if they had any accessibility problems during the day, and if they had any mechanical or operational difficulties with the device.

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Investigation
(cont.)**

A total of eighty-six (86) accessibility problems were noted in their own device and seventy-nine (79) in the investigational device. Accessibility issues in subjects' own devices are primarily related to accessing a location (74 of 86). The data show the investigational device can help subjects overcome these currently non-accessible environments.

Accessibility issues in the investigational device are primarily related to maneuvering the device (22 of 79) and the high seat height (difficulty getting under tables, etc., 34 of 79). These difficulties may be minimized with increased subject experience with the device and future product modifications.

A total of twenty-five (25) mechanical/operational problems were noted in their own device and fifty-nine (59) in the investigational device. Disparities between the two groups appear to exist for Battery difficulties (primarily low battery at end of day, 3 in own device, 18 in investigational device), User Control Panel difficulties (0 versus 5) and User Technique difficulties (2 versus 11). However, when in their own device Manual wheelchair users (14 of 20 in this study) do not have batteries or a User Control Panel. Additionally, 6 of the 18 battery difficulties (low battery at end of day) occurred on a Training Day where there was extensive use of the device. Recognizing this the only true disparity between the two groups is in User Technique difficulties. A review of the User Technique difficulties indicates these are difficulties that would be less likely to occur as one gains experience with the device.

DEVICE FAILURES AND REPLACEMENTS

There were three (3) investigational device replacements in this study. Each of these could have been handled as a device component replacement, however, to minimize inconvenience to the subject the device was replaced.

In addition to these three occurrences that could have been device component replacements, there were ten (10) other investigational device component replacements. There were a total of nine (9) occurrences where the subject reported device component replacements for their own chair.

CONTRAINDICATIONS AND PRECAUTIONS

Contraindications are the Inclusion/Exclusion criteria from the clinical study and presented in product labeling. Precautions are presented throughout the product labeling as Warnings and Cautions.

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**10 b.
Clinical
Investigation
(cont.)**

CONCLUSIONS

The safety of the INDEPENDENCE™ iBOT™ 3000 Mobility System has been demonstrated by showing the safety profile for the device is comparable to the safety profile for the subject's own device.

The effectiveness of the INDEPENDENCE™ iBOT™ 3000 Mobility System has been demonstrated by showing a statistically significant improvement in the primary and secondary efficacy variables.

The effectiveness data demonstrates the clinical utility of the INDEPENDENCE™ iBOT™ 3000 Mobility System. The Balance Function, 4-Wheel Function and Stair Function features of this device increase the independence of individuals with a disability.

As shown by the comparable safety profile, there is little, if any, risk associated with using the INDEPENDENCE™ iBOT™ 3000 Mobility System when compared to current mobility devices. As shown by the efficacy data, there is significant benefit associated with using the INDEPENDENCE™ iBOT™ 3000 Mobility System when compared to current mobility devices.

**11.
Conclusions
Drawn from
the Studies**

Based on the Nonclinical and clinical studies presented, Compared to currently used manual and powered mobility devices the INDEPENDENCE™ iBOT™ 3000 Mobility System, when used for its intended use and conditions of use, and accompanied by adequate directions for use and warnings against unsafe use, will provide clinically significant results with little, if any, additional risk.

**12.
Panel
Recommend-
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TBD

**13.
CDRH
Decision**

TBD

**14.
Approval
Specification**
