SUMMARY OF SAFETY AND EFFECTIVENESS DATA

1. GENERAL INFORMATION

Device Generic Name:	Advanced Mobility System
Device Trade Name:	INDEPENDENCE™ iBOT™ 3000 Mobility System
Applicant's Name and Address:	Independence Technology, L.L.C. 45 Technology Drive Warren, New Jersey 07059
Premarket Approval (PMA) Application Number:	P020033
Date of Panel Recommendation:	November 20, 2002
Date of Notice of Approval to Applicant:	August 13, 2003

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 up to five operating functions. The purposes of these functions are to provide:

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

3. CONTRAINDICATIONS

- Weight exceeds 250 pounds
- Cannot bend knees enough so that feet fit on standard footrests
- Cannot bend hips enough to sit in a standard wheelchair that does not recline
- Do not have good enough hand function to dial a pushbutton telephone or operate a hand-operated joystick

- Had a loss of consciousness or had a seizure in the past 90 days (some exceptions, ask your Health Care Professional for details)
- Need a tilt or recline seating system for pressure relief or activities of daily living
- Need a mechanical ventilator
- Have severe osteoporosis, osteogenesis imperfecta or metastatic bone cancer (jarring could cause fractures when climbing stairs or curbs or getting out of Balance Function)
- Have not successfully completed a user training program

4. WARNINGS

A list of Warnings can be found in the device labeling.

5. PRECAUTIONS

A list of Warnings can be found in the device labeling.

6. PRESCRIBING INFORMATION

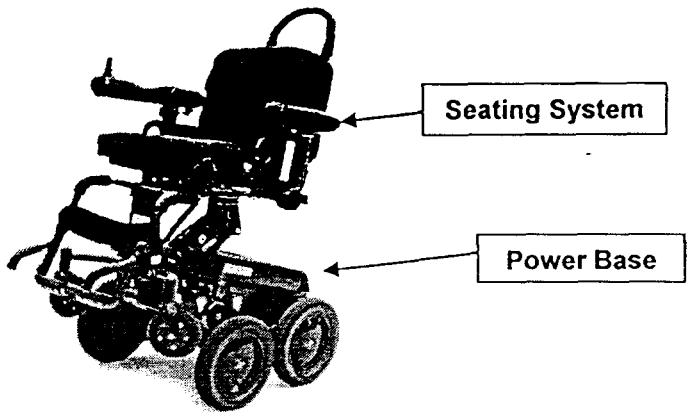
The INDEPENDENCE™ iBOT™ 3000 Mobility System is a prescription device.

Clinician certification and user training are required.

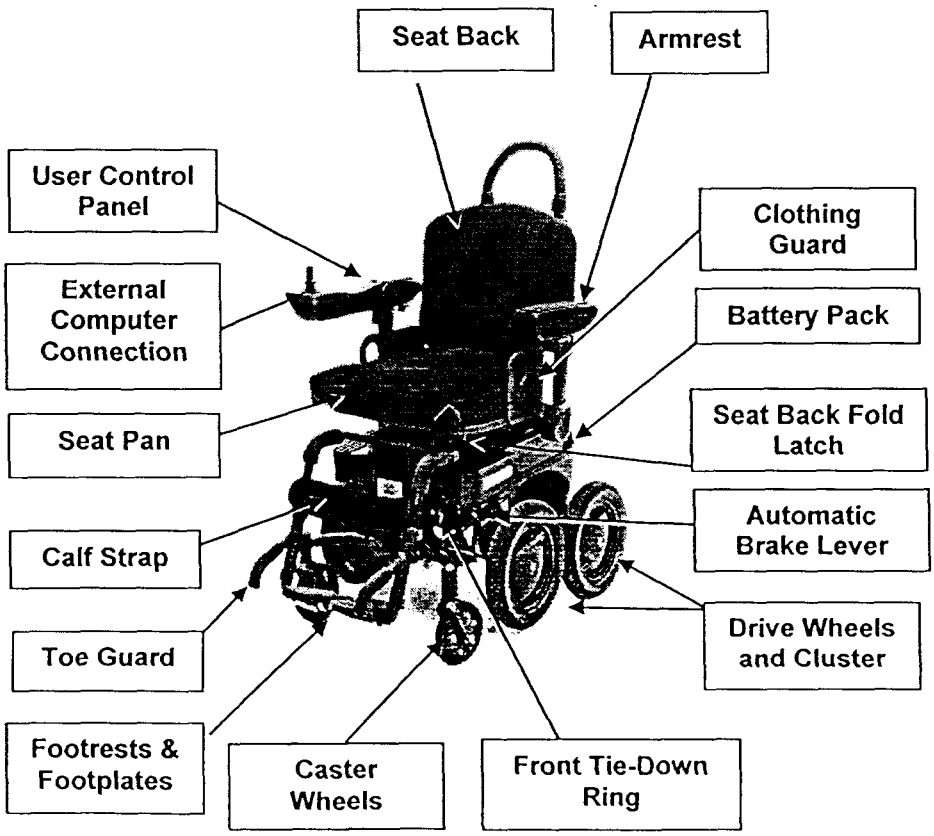
7. DEVICE DESCRIPTION

The INDEPENDENCE™ iBOT™ 3000 Mobility System (also referred to as iBOT™ Mobility System, or iBOT™) 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.



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



Front View Features

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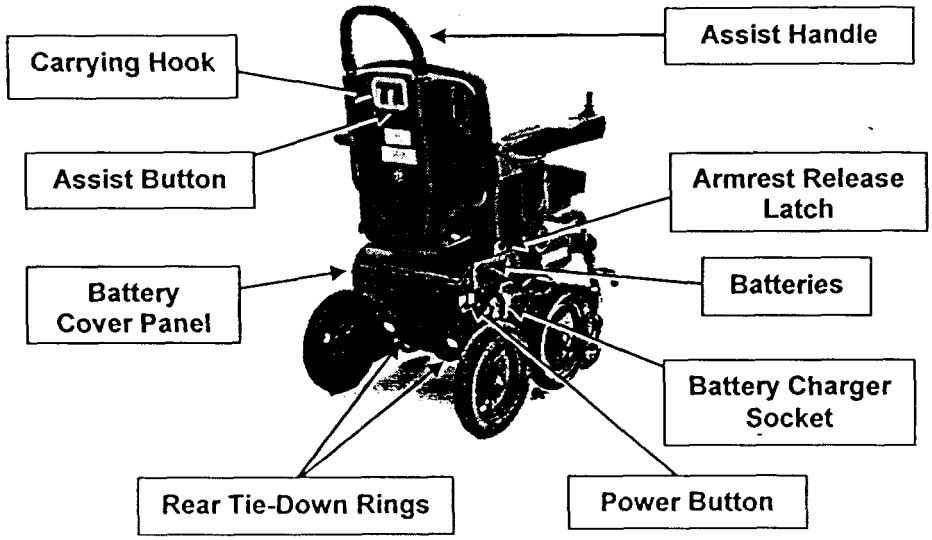
The rear view of the INDEPENDENCE™ iBOT™ 3000 Mobility System:



Rear View Features

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)

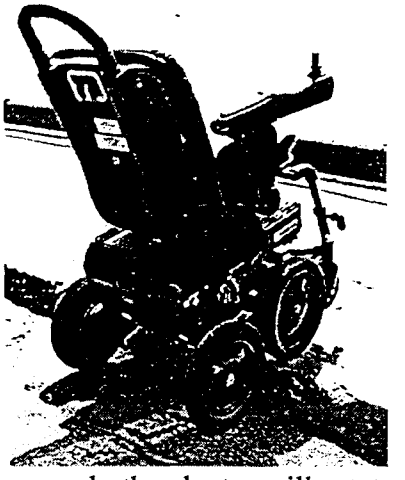
The INDEPENDENCE™ iBOT™ 3000 Mobility System is able to perform in each of these operating environments because it is dynamically stabilized. This dynamic stabilization is called the I-Balance™ Technology.

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.

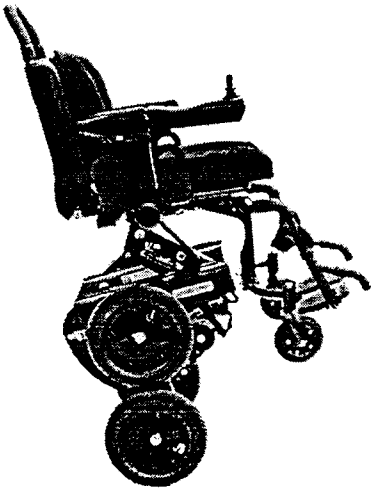
The INDEPENDENCE™ iBOT™ 3000 Mobility System has four operating functions that use the I-BALANCE™ Technology: 4-Wheel, Balance, Stair and Remote. Each function uses the core technology in a slightly different way.

4-Wheel Function



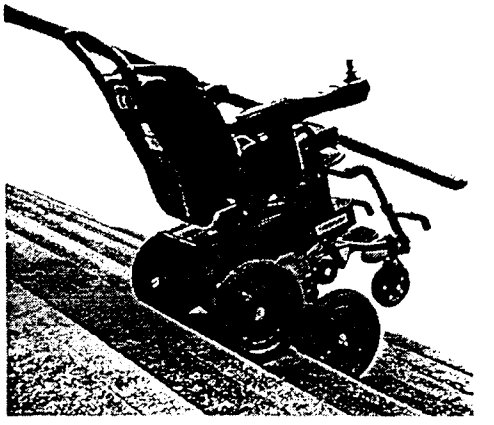
4-Wheel Function provides the user with mobility and flexibility in a wide variety of environments. 4-Wheel Function is the 4-wheel drive of the INDEPENDENCE™ iBOT™ 3000 Mobility System, enabling users to traverse inclines up to 8 degrees and over soft, uneven terrain such as sand, gravel, dirt, grass, 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.

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 an "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.

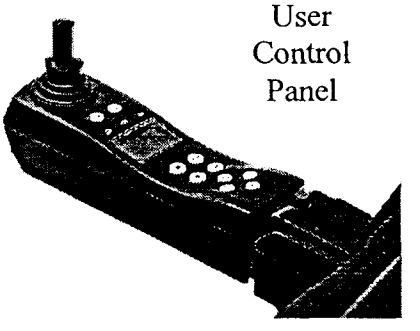
Stair Function



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. 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).

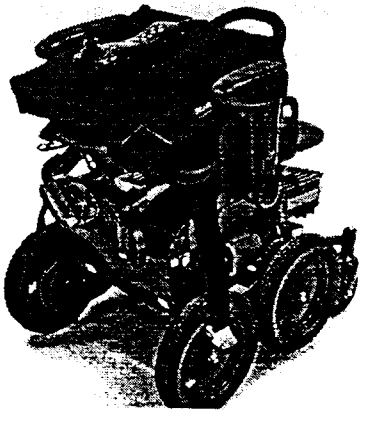
Remote Function

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.



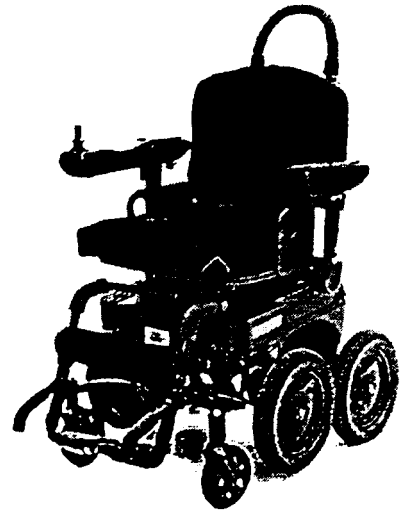
User Control Panel

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. 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.

8. ALTERNATIVE PRACTICES AND PROCEDURES

Mobility devices can be divided into four categories:

- *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. These wheelchairs are most commonly used as transport chairs in hospitals, malls, airports, and other facilities.

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.
- 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. 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. For users who are unable to operate a joystick, alternate controllers (e.g., Sip 'N Puff, breath controller, or 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, 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.

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 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.

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, and available service support.

9. MARKETING HISTORY

The INDEPENDENCE™ iBOT™ 3000 Mobility System has not been marketed in the United States or any foreign country.

10. POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH

The adverse effects listed can occur while using the INDEPENDENCE™ iBOT™ 3000 Mobility System:

- User pinches/crushes finger/hand in moving parts
- 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 experiences jarring forces when climbing stairs or curbs or when transitioning between functions
- User collides with obstacles
- User or product injures other people
- Assistant is injured
- User falls while attempting to climb stairs
- User falls during transfers
- Electromagnetic interference causes device malfunction
- Electrical shock
- Thermal burns

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

- Pinching/crushing injury
- Contusions
- Abrasions
- Lacerations
- Concussion
- Fractures
- Head injuries
- Internal injuries
- Electrical shock
- Burns
- Death

11. SUMMARY OF NON-CLINICAL LABORATORY STUDIES

Objectives: The objectives of the non-clinical laboratory studies were to evaluate the software, mechanical, electrical, performance, environmental, and anomalous device characteristics of the INDEPENDENCE™ iBOT™ 3000 Mobility System.

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).

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 Scoters), 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

- 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
- ISO7176-6:2001 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
- 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 of these standards were used to create the test plans and test cases that the mobility system was tested to. Data were 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, and (36) Exposure to Sunlight.

All results met the pass/fail criteria that were established.

12. SUMMARY OF CLINICAL STUDIES

Pilot Clinical Studies

Three pilot clinical evaluations utilizing the investigational device were conducted in 1999 and 2001, prior to initiation of the pivotal clinical study. These pilot studies utilized previous (non-marketing) versions of both the INDEPENDENCE™ iBOT™ 3000 Mobility System and the training program for the device. While these pilot evaluations were not designed to evaluate the safe and effective use of the investigational device, the information generated by these evaluations was helpful in designing the pivotal clinical trial, the marketing version of the device, and the marketing versions of the clinician and user labeling/training materials.

Pivotal Clinical Study

Objectives

This study had two main objectives:

1. To demonstrate that individuals 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 mobility device.

Study Design

The clinical trial was a single center, prospective, balanced, open label evaluation that utilized participants as their own control. Twenty-nine subjects were enrolled. A total of 20 subjects were required to complete the study. Twenty subjects completed the study and nine subjects did not (two failed assessments, three withdrew from the study, and four were terminated by the investigators). The initial two subjects (skilled manual wheelchair users) completed the Pilot Trial phase, using the marketing version of the device and training program. Eighteen (18) subjects (six skilled manual wheelchair users, six slow manual wheelchair users, and six power wheelchair users) completed the Real World Trial, also using the marketing version of the device and training program. 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. Pilot Trial participants used each device for one week. Each participant and clinical investigator was trained following the INDEPENDENCE™ iBOT™ 3000 Mobility System (iBOT™) Training Program.

Study Period

The study was conducted from February 2002 to May 2002.

Primary Inclusion Criteria

- Subjects were between 18 and 80 years of age
- Subjects used one of the following mobility aides: a manual wheelchair, a power wheelchair with a hand-operated joystick control, or a scooter as their primary mobility device. Additionally, subjects could be defined as:
  - Skilled manual wheelchair user; identified as a new subject who routinely propels faster than walking speed and is able to travel in a "wheelie" position for 10 feet.
  - Slow manual wheelchair user; identified as a subject who self-propels at walking speed or slower and/or is unable to self-propel or travel in a "wheelie" position for 10 feet.
  - Power (including scooter) wheelchair user; identified as a subject who is using a power wheeled mobility device as his/her primary means of mobility outside their home.

Primary Exclusion Criteria

- The subject weighed more than 250 lb.
- The subject was unable to use a wheelchair seat between 14" and 20" wide.
- The subject was not able to bend his/her knees such that his/her feet fit on standard footrests or was not able to bend his/her hips enough to sit in a standard wheelchair.
- The subject did not have sufficient function of at least one upper extremity to dial a pushbutton telephone and operate a hand-operated joystick.
- The subject's postural supports used in their own device were not compatible/comparable with the postural supports on the INDEPENDENCE™ iBOT™ 3000 Mobility System.
- The subject experienced an impaired level of consciousness or had a seizure in the last 90 days.
- Subjects who required use of a tilt or recline seating system.
- Subjects who required assisted mechanical ventilation.
- Subjects who were unable to use their own cushion due to sizing or other reasons if they had prior pelvic/thigh region decubitus ulceration problems.
- Subjects who had an active pelvic/thigh region decubitus ulceration.

Function-Specific Exclusion Criteria

- "Solo" Stair Climbing Function:
  - Cardiac Risk Factors: The subject reported a history of cardiac impairments that limited his/her ability to perform ordinary physical activity.
  - Pulmonary Risks: The subject reported a history of pulmonary impairments that limited his/her ability to perform ordinary physical activity.
  - Fracture Risks: The subject was at a high risk for fracture or spinal instability, secondary to unstable hip or spinal compression as a result of: severe osteopenia, osteogenesis imperfecta, and/or spinal metastatic bone cancer.
- "Curb hopping" in 4-Wheel Function:
  - Fracture Risks: The subject avoided curb-hopping activities, and was at a high risk for fracture or spinal instability secondary to unstable hip, or spinal compression as result of: severe osteopenia, osteogenesis imperfecta, and/or spinal metastatic bone cancer. Until or unless cleared by a physician, no curb climbing activities were tested.
- Balance Function:

  Fracture Risks: The subject was at a high risk for fracture or spinal instability, secondary to unstable hip or spinal compression as a result of: severe osteopenia, osteogenesis imperfecta, and/or spinal metastatic bone cancer. Unless cleared by a physician, Balance Function was deactivated.

How Data Were Collected

Safety, accessibility, operational problem and mechanical problem data were collected on a daily basis through telephone contact with each subject. The primary effectiveness data were

collected when the subject completed the Community Driving Test after having utilized the device for two weeks. Computerized data regarding usage, failures, and alerts were also downloaded over the telephone line on a daily basis. Additional effectiveness data were collected at the last visit.

Demographics

There were 16 male and 4 female subjects with ages ranging from 27 to 67 years (mean age was 43.7 years; median age was 41.5 years). Weight ranged from 81 to 230 pounds (mean weight was 165 pounds; median weight was 160 pounds). Medical conditions included spinal cord injury (SCI) paraplegia (9 subjects), SCI tetraplegia (4 subjects), neuromuscular conditions (4 subjects), amputee (2 subjects), and SCI tetraplegia plus amputee (1 subject).

Primary Safety Measurement / Adverse Effects

The safety of the iBOT™ Mobility System was established by comparing the rate of adverse events occurring with the investigational device to the rate with the subjects' own devices (see Table 1).

There were no serious adverse effects observed in this clinical study. The only adverse effects that occurred were bruises, which were experienced by two patients.

The iBOT™ Mobility System fell three times during the clinical trial. Each fall occurred with a different subject and while using a different function, i.e., one fall occurred while operating in each of the following functions: Balance, Standard, and 4-Wheel. One of the three falls resulted in the patient receiving a bruise that did not require treatment.

Table 1: Adverse Events*

Event Type	iBOT™	Own Device
Device Related - Medical Treatment at Hospital	0	0
Device Related - Medical Treatment at Home or No Treatment (Bruises)	2	0
Not Device Related - Medical Treatment at Hospital	0	4
Falls Not Requiring Medical Treatment	3	2

* n = 20 (2 pilot trial subjects plus 18 pivotal trial subjects)

There were four (4) instances of subjects seeking medical attention for events that were not caused or associated with the use of the iBOT™ Mobility System. In all four cases the subject was utilizing his/her own device.

There were five (5) instances which did not require medical attention, but which could have required medical attention should the event have recurred. 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 the subjects' own device. All events were attributable to subject judgment errors; in no cases was the event attributable to a device failure or malfunction.

R3

Primary Effectiveness Measures

The primary effectiveness measure was the score a subject obtained on a Community Driving Test consisting of 15 tasks that one would encounter in everyday life. Subjects' scores using the investigational device were compared to scores using their own mobility device. The scoring system used a 7 point scale. The lowest score (0) was assigned when a subject could not perform the task. The next 3 scores (1, 2, 3) were assigned when a subject could perform 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 perform 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 the level of exertion required to perform the task.

Effectiveness Data Analysis and Results

The Community Driving Test scores were analyzed by applying the Wilcoxon signed-rank test for a difference in the scores between the investigational device and the subject's current mobility device.

Summary of the Community Driving Test results:

- All 20 subjects (2 Pilot and 18 Real World subjects) scored higher overall in the iBOT™ Mobility System than in their own device and showed an improved level of independence ($p < 0.001$).
- In every task (11 such tasks) in which the Stair Climbing Function, the 4-Wheel Function, or the Balance Function was utilized, there was an improvement in the group scores and level of independence (range from $p < 0.001$ to $p = 0.008$).
- As expected, in tasks (4 such tasks) in which Standard Function was utilized, only the manual slow users tended to show an improvement in test scores and independence level.
- In general, the iBOT™ Mobility System was more difficult to maneuver indoors (e.g., due to seat height), but provided greater mobility outdoors as compared to the subjects' own mobility devices.

Outlier Data

One skilled manual wheelchair user was able to go down stairs with minimal exertion in his own device, using his arms to control falling from one step to another while the iBOT™ Mobility System required moderate exertion. Another subject incorrectly concluded that the exit step height exceeded the four-inch limit for the iBOT™ Mobility System and, therefore, used his assistant to descend the one step exit.

Limitations

There were some limitations to the study. The primary effectiveness measure (Community Driving Test) did not test the Remote Function. Nor did it test the ability

to climb stairs using two railings. However, the subjects were assessed for stair climbing with two railings according to the training protocol in the Delivery Guidebook prior to home and community use. (See stair climbing configurations achieved in Table 2). The Balance Function was tested while performing only one task. Seven of the 20 subjects used the Balance Function for less than a total of 2 hours during the study period, and it is not clear whether any of this usage was outside the training and assessment sessions. Only one of the 20 subjects used the Remote Function and only two subjects used the fast speed template.

Table 2: Stair Climbing Configurations

Configuration	# Subjects (n = 20)
Solo only, 1 & 2 Rails*	8
Solo (1 & 2 Rails*) & Stair Assist	2
Solo (2 Rail only*) & Stair Assist	2
Stair Assist only	8

* Although the Community Driving Test did not test stair climbing with 2 railings, subjects were tested during the delivery training and assessment prior to the home and community use phase

Secondary Effectiveness Measures

Subject Specific Function Scores

Subject Specific Function Scores were utilized as a secondary effectiveness measure. At the time of study entry, subjects were asked to self report and rate specific tasks that they had difficulty performing in their own device. These tasks were ones that each subject chose as being important in his/her life. When the subject completed two weeks in the iBOT™ Mobility System, they were asked to rate the difficulty of performing the previously reported tasks in the iBOT™ Mobility System. The scoring system was the same as used with the Community Driving Test. Table 3 summarizes these data.

TABLE 3: Subject Specific Function Scores*

Subject ID	Type	Activity	IBOT	Own Device	Difference
1	MSK	Reaching Objects In High Places	6	0	6
		Not Being Able To Climb Stairs	6	2	4
		Drive Wheelchair Over Curbs And Snow	3	2	1
2	MSK	Climbing Stairs	6	0	6
		Going Up Curbs	6	4	2
		Reaching Top Shelf	6	0	6
3	MSK	Climb Stairs	6	0	6
		Going Over Curbs Greater Than 3"	6	0	6
		Reaching High Shelves	6	0	6
4	MSL	Reach cereal on top shelf	6	4	2
		Visiting the cemetary - grass	6	1	5
6	MSL	Trails	6	2	4
		Stairs - Up	5	0	5
		Stairs - Down	4	0	4
		Up & Down Greater Inclined Ramps	6	5	1
		Reaching High Objects (1)	6	4	2
		Reaching High Objects (2)	6	3	3
7	P	Cooking In Non-Adapted Kitchen	6	4	2
		Climbing Stairs	6	1	5
		All Terrain Travel	6	1	5
8	P	Reaching High Items	6	0	6
		Climbing Stairs (1)	3	4	-1
		Climbing Stairs (2)	3	5	-2
		Going Up Curbs	6	0	6
		Going on Sand	6	0	6
		Turning in small area	6	6	
9	P	Reaching High Cabinets	6	0	6
		Stairs	1	0	1
		Transferring Out Of Drivers Seat	1	4	-3
11	P	Stairs	5	4	1
		Curbs (1)	6	5	1
		Curbs (2)	6	4	2
		Sand/Loose Terrain	6	5	1
12	P	Stair Climbing	6	0	6
		Curbs	6	0	6
		Can't see in mirror	6	0	6
		Can't get in freezer	6	2	4
13	MSK	Beaches	6	0	6
		Woods (1)	6	2	4
		Woods (2)	6	4	2
		Stairs - Down	5	2	3
		Stairs - Up	6	0	6
14	P	Deep sand	6	0	6
		Stairs (1)	2	0	2
		Stairs (2)	3	0	3
		Steep inclines	6	3	3
17	MSK	Reaching items on upper shelves	6	3	3
		Stairs	6	0	6
		Curbs	6	5	1
		Different Terrain	6	4	2
		Beach Sand	6	0	6
19	MSL	Getting chair height to counter level	6	0	6
		Go shopping at Roys	6	0	6
		Steps	2	0	2
20	MSK	Steps over 4"	6	2	4
		operating on grass uphill	6	4	2
		reaching height above 5' (1)	6	3	3
		reaching height above 5' (2)	6	5	1
21	MSK	Reaching in shower to clean	6	0	6
		Reaching into cabinets in kitchen	6	6	
22	MSL	Reaching into shelves/refrigerator	6	3	3
		Rough Terrain - sand	6	4	2
		Steep ramps	6	5	1
26	MSK	Stair Climbing	3	2	1
		Curb Climbing	6	3	3
27	MSL	Going up steps	2	0	2
		Steep ramps	6	2	4
		Pushing long distances	6	2	4
29	MSL	Stairs (1)	6	1	5
		Stairs (2)	1	1	
		Reaching high places	6	5	1
		Trails/wood/uneven terrain (1)	6	4	2
		Trails/wood/uneven terrain (2)	6	1	5

* MSK: skilled manual wheelchair user; MSL: Slow manual wheelchair user; P: power wheelchair/scooter user. See inclusion criteria, above, for detailed definitions.

Statistical Test for the Individual Specific Function Scores

Applying the Wilcoxon Rank Sum Test to these data shows the following:

Test for Increase in Score	
Number of non-zero observations of 73 total observations	70
Wilcoxon Rank Sum Statistic (Large sample approximation)	5.4
Associated p-value	< 0.001

Test for Increase in Independence	
Number of non-zero observations (non-shaded differences)	50
Wilcoxon Rank Sum Statistic (Large sample approximation)	5.3
Associated p-value	< 0.001

Additional Data

Note that in eight instances, the subjects gave two different ratings depending on the type of specific task. For example, some curbs could be climbed with minimal exertion and some curbs could be climbed with moderate exertion. In these cases, both responses are given in the table by having the task appear twice. The tasks are marked (1) and (2).

Data not presented in Table 3 include:

- For seven of the identified functions, the subject did not have the opportunity to use the function while in the iBOT™ Mobility System, hence these data are incomplete. These functions were: going to the beach/sand (2 cases), visiting Mom's home (1 case), trails (1 case), traverse an eight-inch step in the home (1 case), going to a specific castle (1 case), and reaching above chest level (1 case).
- In one case, the subject did not specify the function (reaching objects at higher levels) at study entry, but did specify it following use of the iBOT™ Mobility System. Hence, these data are incomplete. The subject rated the function a 6 with the iBOT™ Mobility System.

Summary of Subject Specific Function Scores

While these results are highly significant, it is recognized that its value is limited in showing device effectiveness for the following reasons:

- The tasks were not identified over all subjects; hence, the validity of drawing broad conclusions is questionable.
- Subjects were instructed to choose tasks they had difficulty performing; hence, it is expected scores in their own device would be low. It is worth noting that of the 73 total observations, subjects scored 24 of them as being able to do independently (scored 4, 5, or 6) in his/her own device, and 10 of these were independent with moderate or minimal exertion (score of 5 or 6).

Accessibility Problems

Subjects received daily inquire via telephone which included the following question: "Did you have any accessibility problems when getting around today?" A total of 165 "yes" responses were received; 91 when the subject was in his/her own device and 79 when in the iBOT™ Mobility System. While the total number of "yes" responses was similar for each group, the nature of the responses was different (see Table 4).

Table 4: Accessibility Problems Summary

Nature of Problem	Own Device	iBOT™
Cannot access site due to curbs, terrain, etc.	38	3
Cannot access site due to stairs	28	12
Cannot access high shelves, counters, etc.	13	0
Difficulty maneuvering	6	22
High seat height limits accessibility	1	34
Battery limitation	0	4
Other	5	4
Total	91	79

Accessibility problems with the subjects' own devices are primarily related to accessing a location. Accessibility problems with the iBOT™ Mobility System are primarily related to maneuvering and the high seat height (difficulty getting under tables, etc.).

Home and Community Maneuvering

On the final day of participation with the subject's own device, the subject was asked to rate the following questions using a 4 point scale (poor, fair, good, and excellent):

- How would you rate the ease of maneuvering in your own home?
- How would you rate the ease of maneuvering in the community?

Table 5 shows the change in maneuvering for the iBOT™ Mobility System versus the subject's own device.

Table 5: Home and Community Maneuvering Summary

Maneuvering	Decreased	Remained Same	Increased
Home	13	5	2
Community	1	5	14

These data indicate that the iBOT™ Mobility System tends to be less maneuverable in the home and more maneuverable in the community compared to subjects' own devices.

Mechanical Failures, Computerized Alerts and Technical Difficulties

- **Device and Component Replacements**

  Twelve of the 20 subjects experienced a total of 22 events that resulted in replacement of one or more components. Nine events occurred with the patients' own devices and 13 events occurred with the iBOT™ Mobility System. None of these device failures resulted in subject injury.

  There were three instances where the iBOT™ Mobility System was replaced in its entirety in this study. Each of these could have been handled as a device component replacement; however, the entire device was replaced to minimize inconvenience to the subject. In one case, there was a battery charging problem in the late evening. Rather than taking time to repair the component (a bent charger port pin) at the subjects home it was decided to replace the device and let the subject retire for the evening.

  In the second case, the subject was at a restaurant when the device was unable to change the seat height as intended by the subject. It was decided to replace the device and not further inconvenience the subject.

  In the third case, the UCP backlight failed to function during Stair Training. At the conclusion of Stair Training (approximately ½ day) it was decided to have the subject go home in another device rather than have the subject wait while the device was repaired.

  In addition to these three occurrences, there were ten other events where one or more iBOT™ component replacements were required.

- **Computerized Alert and Failure Identification Data**

  The iBOT™ Mobility System's computer program identified the number and types of computerized alert and failure actions experienced during the iBOT™ Mobility System usage period (Table 6). The software is designed to identify these events and to respond in a fashion intended to prevent or minimize device damage and user injury. For each alert or failure count, the iBOT™ Mobility System responded as it was designed to do. However, these automated actions represent potentially harmful situations, e.g., in two of the 5 controller failure events, the iBOT™

Mobility System fell and the patient's medical condition may have contributed to the fall. These data are not available for the users' own mobility devices since they did not have these technical features.

Table 6: Computerized Alert and Failure Identification Data

Alert/Failure	Total (count)
Controller Failure	5
Controller Auto 4-Wheel	22
Controller Alert Balance	42
Controller Alert 4-Wheel	3
Controller Alert Stair	80
4-Wheel Off Top of Stair	62
Wheel Motor Hot	4
Cluster Motor Hot	89
Security Password	0
Service Trigger	17

- **Mechanical/Operational Difficulties**

Overall, users experienced more mechanical and operational difficulties with the iBOT™ Mobility System than with their own mobility devices, mainly with the batteries, user control panel and user techniques (Table 7). Users' own mobility devices had more tire problems than was experienced with the iBOT™ Mobility System.

Table 7: Mechanical/Operational Difficulties

Mechanical/Operational Difficulty	iBOT™	Own Device
Assist Handle/Backrest	1	1
Battery	18	3
Brakes	1	0
Cluster/Wheels/Casters	7	6
CPU Fault	2	0
Footrest/Armrest	3	2
Modem Cable	3	0
Seating/Seat Height	4	2
Tires	3	7
User Control Panel	5	0
User Technique	11	2
Other	1	2

13. CONCLUSIONS DRAWN FROM THE STUDIES

Risk-Benefit Analysis: Based on the non-clinical and clinical studies presented, it is reasonable to conclude that the benefits of the use of the INDEPENDENCE™ iBOT™ 3000 Mobility System for the target population outweigh the risk of illness or injury when used as indicated in accordance with the directions for use.

Safety: 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.

Effectiveness: 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.

14. PANEL RECOMMENDATION

The INDEPENDENCE™ iBOT™ 3000 Mobility System was discussed at the November 20, 2002, CDRH Advisory Committee Meeting of the Orthopedic and Rehabilitation Devices Panel. The Panel recommended that Independence Technology's PMA application be approved by FDA, subject to the following four conditions:

1. The device should require a diagnosis and prescription by a physician (i.e., a person licensed to practice medicine by a State medical board);
2. User training should be provided for stair climbing both at the test site and in the home environment;
3. Data logging should be reported for all modes at an interval to be agreed upon by FDA and sponsor; and
4. As improvements are made and changes in provider training occur, information should be communicated to those who prescribe and train users of the device.

15. CDRH DECISION

CDRH concurred with the Panel's approval recommendation of November 20, 2002, and issued a letter to Independence Technology on January 27, 2003, advising that its PMA application was approvable subject to FDA inspections that find the manufacturing facilities, methods, and controls in compliance with the applicable requirements of the Quality System Regulation (21 CFR Part 820).

- With respect to panel condition #1, FDA concluded that it is not necessary for a diagnosis and prescription by a *physician*. FDA concluded that it is more appropriate to require a prescription order by a licensed *practitioner* (consistent with 21 CFR 801.109). The applicant's marketing/distribution plan and labeling are consistent with this requirement. In addition, prescription use language is part of the approval order letter, so an additional condition of approval regarding prescription use would be redundant.

- Regarding panel condition #2, FDA concluded that user training at the test site is satisfactorily addressed by the applicant's business plan and labeling, and that the necessity for training in the user's home environment can be left to the discretion of the clinician. Therefore, FDA has concluded that a condition of approval is not necessary to address user training requirements.

- FDA concurred with the Panel's recommendation for postmarket reporting (panel condition #3). To address this condition, the applicant agreed to provide FDA with four semiannual reports summarizing usage information obtained from device data logs, reported device failures, and reported adverse events. These reports shall be submitted for the period including the first two years of device marketing. This requirement is included as a condition of approval.

- Generational changes to the device (panel condition #4) that significantly affect safety, effectiveness, or labeling must be approved by FDA via the PMA supplement process described in the PMA regulations. Therefore, FDA concluded that a condition of approval is not necessary to address the sponsor's responsibility of communicating significant generational changes in the device and related labeling changes.

FDA reviewed a portion of this PMA application under the modular review PMA process (M990021). All of the modules were incorporated into the review of the PMA (P020033).

This premarket approval (PMA) application was granted expedited review status by FDA on September 13, 2002. Expedited review status was granted because FDA believed the device represented a breakthrough technology with a clear, clinically meaningful advantage over existing technologies and because FDA expected that the device could provide a specific public health benefit in patients with mobility impairments.

An FDA bioresearch monitoring audit of the principal clinical investigator and clinical data was completed in January 2003, with satisfactory findings.

The applicant's three manufacturing facilities were inspected by FDA on January 28-31, June 24-July 2, and July 16-21, 2003, and were found to be in compliance with the Quality System Regulation (21 CFR 820).

FDA issued an approval order to Independence Technology, L.L.C. on August 13, 2003.

16. APPROVAL SPECIFICATIONS

Directions for Use:	See the labeling.
Hazards to Health from Use of the Device:	See Indications, Contraindications, Warnings, Precautions, and Adverse Events in the labeling.
Postapproval Requirements and Restrictions:	See approval order.\

17. REFERENCES

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