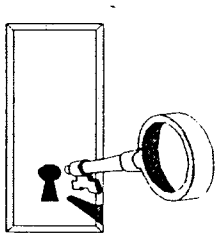
INTRODUCTION



Welcome to your INDEPENDENCE™ iBOT™ 3000 Mobility System User Manual. This is a *how-to* manual that provides step-by-step instructions to help you enjoy using the INDEPENDENCE™ iBOT™ 3000 Mobility System. It is a key reference source. Please read it carefully before you operate the INDEPENDENCE™ iBOT™ 3000 Mobility System. Keep it handy. Refer to it often. Ride safely and enjoy your INDEPENDENCE™ iBOT™ 3000 Mobility System!

Intended Uses

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.

Training and User Requirements

The INDEPENDENCE™ iBOT™ 3000 Mobility System is a sophisticated mobility system that requires a prescription along with Driver completion of a comprehensive training program. This includes safe driving, proper use, and product

maintenance. Total weight capacity should not exceed 250 lbs (113 kg) including the maximum of 20 lbs (9 kg) for carrying items.

Because functional capacity can change over time, adjustments to your INDEPENDENCE™ iBOT™ 3000 Mobility System may be required. These changes include, but are not limited to armrest, footrest, and backrest adjustments. Drivers should be sure to consult their Healthcare Professional, who will need to re-evaluate and make recommendations for changes to the INDEPENDENCE™ iBOT™ 3000 Mobility System. Personal weight gain or loss of more than 20 pounds (9 kg) will require a center-of-gravity recalibration.

Do not use the product if you:

- Weigh more than 250 pounds (113 kg.)
- Cannot bend your knees so that your feet fit on standard footrests
- Cannot bend your 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
- Have lost consciousness or had a seizure in the past 90 days (some exceptions, ask your Healthcare 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 forces could cause fractures when climbing stairs or curbs or transitioning out of Balance Function)

- Have not successfully completed the user training program

Points to consider:

- Front seat to floor height minimum is approximately 22 inches (559 mm)

- Cannot drive or be transported when seated in this product in a motor vehicle

- Power ON/OFF button is located on right side of the power base

Fracture risk

- Users must successfully complete the Standard Function, 4-Wheel Function, and Stair Function Tests in order to obtain this product.

⚠ WARNING – Heart Condition

- If you have heart problems, the use of both arms to climb stairs may induce strain that produces fatigue, palpitations, shortness of breath, or angina (chest pain). You should get clearance from your doctor before using the INDEPENDENCE™ iBOT™ 3000 Mobility System. You may need to have an Assistant help you with stair climbing.

WARNING – Shortness of Breath

- If you have breathing problems, the use of both arms to climb stairs may produce shortness of breath. You should get clearance from your doctor before using the INDEPENDENCE™ iBOT™ 3000 Mobility System. You may need to have an Assistant help you with stair climbing.

WARNING – Change in Vision, Strength, or Balance

- If you have a significant change in your vision, strength, or balance, this may affect your ability to drive the INDEPENDENCE™ iBOT™ 3000 Mobility System. See your Healthcare Professional to discuss whether or not this product is still appropriate for you.

Pivotal Clinical Trial Summary

Clinical 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. Twenty subjects completed the study and nine subjects did not (two failed assessment, three withdrew from the study, four were terminated by the investigators.) The initial two (2) subjects (skilled manual wheelchair users) completed the Pilot Trial. Eighteen (18) subjects (6 skilled manual wheelchair users, 6 slow manual wheelchair users, and 6 power wheelchair users) completed the Real World Trial. 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 trial participant and clinical investigator trained following the INDEPENDENCE™ iBOT™ 3000 Mobility System Training Program.

Primary Inclusion Criteria

1. Subjects were between 18-80 years of age
2. 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 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; 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

1. The subject weighed more than 250 pounds (113kg).
2. The subject was unable to use a wheelchair seat between 14-20" wide.
3. 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.
4. The subject did not have sufficient function of at least one upper extremity to dial a pushbutton telephone and operate a hand-operated joystick.
5. 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.
6. The subject experienced an impaired level of consciousness or had a seizure in the last 90 days.
7. Subjects who required use of a tilt or recline seating system.
8. Subjects who required assisted mechanical ventilation.
9. 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.
10. Subjects who had an active pelvic/thigh region decubitus ulceration.

Function Specific Exclusion Criteria

11. "Solo" Stair Climbing Function:
    Cardiac Risks: 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.

12. "Curb climbing" in 4-Wheel Function:
    Fracture Risks: The subject who avoided curb-climbing 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.

13. Balance Function:
    Fracture Risks: The subject 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. Unless cleared by a physician, Balance Function was deactivated.

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 81-230 pounds (mean weight was 165 pounds; median weight was 160 pounds). Medical conditions included spinal cord injured (SCI) paraplegia (9 subjects), SCI tetraplegia (4 subjects), neuromuscular conditions (4 subjects), amputee (2 subjects), SCI tetraplegia plus amputee (1 subject).

Safety Data

The safety of the INDEPENDENCE™ iBOT™ 3000 Mobility System was established by comparing the rate of adverse events occurring in the investigational device and in the subjects' own devices.

Event Type	IBOT™	Own Device
Device Related - Medical Treatment at Hospital	0	0
Not Device Related - Medical Treatment at Home	2	0
Not Device Related - Medical Treatment at Hospital	0	4
Falls Not Requiring Medical Treatment	3	2

There were two adverse events associated with the use of the product. The first was during an assessment in the INDEPENDENCE™ iBOT™ 3000 Mobility System when the subject pinched his mid-forearm between the User Control Panel (UCP) and the armrest, resulting in a small bruise. A forearm pad was utilized to prevent further problems; no other medical treatment was provided. A second subject was driving in Balance Function. The subject observed a tree cutout in the sidewalk and turned right to avoid the tree. He turned too far to the right and the right wheel struck a 5 inch curb, he quickly attempted to turn the device to the left while the right wheel attempted to climb the curb. This caused lateral instability and the device tipped and fell to the left. Passersby lifted the subject in the device to an upright

position, Recovery Mode was activated, and the subject continued on to work. The subject received a bruise on his leg that did not require treatment.

Effectiveness Data

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. Subjects' scores using the INDEPENDENCE™ iBOT™ 3000 Mobility System were compared to scores using their own mobility devices.

- All 20 subjects (2 Pilot and 18 Real World subjects) scored higher in the INDEPENDENCE™ iBOT™ 3000 Mobility System than in their own device and showed an improved level of independence ($p<.001$).
- In **every** task (11 such tasks) in which the Stair Function, the 4-Wheel Function or the Balance Function was utilized there was an improvement in the subject's scores and level of independence (range from $p<.001$ to $p=.008$).
- As expected, in tasks (4 such tasks) in which Standard Function was utilized, only manual slow users tended to show an improvement in test scores and independence level.
- In general the INDEPENDENCE™ iBOT™ 3000 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.

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. 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 two subjects used the fast speed template.

Table 2. Stair Climbing Configuration:

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

Mechanical Failures, Computerized Alerts and Technical Difficulties

Device and Component Replacement

Twelve of the 20 subjects experienced a total of 22 events that resulted in replacement of one or more component replacements. 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 (3) 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, replacing the entire device minimized inconvenience to the subject. In one case there was a battery charging issue in the late evening. Rather than taking time to repair the components (a bent charger port pin) at the subject's 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 just prior to the lunch hour 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 (10) other events where one or more iBOT™ Mobility System component replacements were required.

Computerized Alert and Failure Identification Data

The iBOT™ Mobility System's computer software identified the number and types of computerized alert and failure actions experienced during the device usage period (Table 3). The software is designed to identify these events and to respond in a manner intended to prevent or minimize device damage and user injury. For each alert or failure count, the device responded as it was designed. However, these automated actions represent potentially harmful situations,

e.g. in two of the five controller failure events, the device fell and the patient's medical condition may have contributed to the fall. These types of data are not available for the users' own mobility devices since they did not have these technical features.

Table 3. 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 4). Users' own mobility devices had more tire problems than experienced with the iBOT™ Mobility System.

Table 4. Mechanical/Operational Difficulties

Mechanical/Operational Difficulty	iBOT™	Own Device
Assist Handle/Backrest	1	1
Battery	18	3
Brakes	1	0
Cluster/Wheel/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

Based on these data, the FDA has determined that the INDEPENDENCE™ IBOT™ 3000 Mobility System is safe and effective for its intended use.

THE iBALANCE™ TECHNOLOGY

A few words about stability

Stability is one of the most important features of any mobility system. You need stability to keep from tipping over. However, there is more than one way to achieve stability.

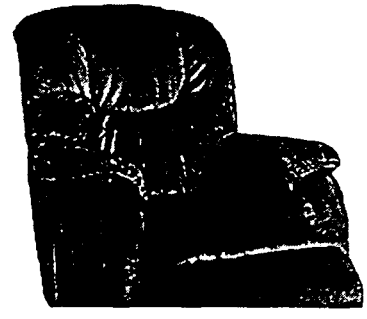


Figure 1–1: Armchair

For example:

Due to its width and weight, an armchair (Figure 1–1) is very stable and would be very difficult to tip over. You could sit on the edge of its arms and still not tip it over. The armchair's wide base, heavy weight, and low height keep it from being easily overturned.

In contrast, a standing man (Figure 1–2) who is 6 feet tall, with feet that are a foot long and a foot apart, may not look very stable at first glance. He has neither a wide base nor a low center of gravity. Yet, he is stable. Why? His inner ear, brain, and body work together to maintain his balance. If he is pushed backwards, he can step back and lean forward to compensate for the backward push. If he is pushed forward, he will step forward and then lean back. His ability to react to changes in his position and to balance himself allows him to achieve stability with a small footprint and tall height.

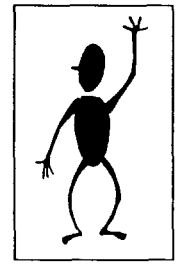


Figure 1-2: Standing Man

How Stability Is Achieved in the INDEPENDENCE™ iBOT™ 3000 Mobility System

The iBALANCE™ Technology at work in the INDEPENDENCE™ iBOT™ 3000 Mobility System uses a

computer system that works in conjunction with gyroscopes. Gyroscopes are complex motion sensors that help maintain balance. When the gyroscopes sense movement, a signal is sent to the computer. The computer processes the information and tells the motors how to move the wheels to maintain stability and balance.

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

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

BEFORE YOU USE YOUR INDEPENDENCE™ iBOT™ 3000 MOBILITY SYSTEM

Complete the Driver's training

You received an overview of the functions and uses of the INDEPENDENCE™ iBOT™ 3000 Mobility System during your clinical assessment. When your customized INDEPENDENCE™ iBOT™ 3000 Mobility System is delivered, your training is provided by a Healthcare Professional trained by Independence Technology. This training is necessary to teach you how to safely use and maintain your INDEPENDENCE™ iBOT™ 3000 Mobility System.

Read this manual

This manual provides several types of important information.

- Sections 1-3: Basic information about your INDEPENDENCE™ iBOT™ 3000 Mobility System.
- Section 4: Information about handling cautions, warnings and system failures. The safety system that is relevant to each function is covered at the conclusion of each operating function instruction.
- Sections 5-9: Detailed information on how to operate the INDEPENDENCE™ iBOT™ 3000 Mobility System.
- Section 10: Information about maintaining your INDEPENDENCE™ iBOT™ 3000 Mobility System in proper working condition.
- Appendix: Reference information to use as needed.

⚠ WARNING - Read the Manual

- Do not operate the INDEPENDENCE™ iBOT™ 3000 Mobility System without first reading and understanding the User Manual. Personal injury or death could result from improper use of this product. If you do not understand the warnings and instructions, contact Service before using the product.

IMPORTANT SAFETY INFORMATION

Every mobility system must be operated with appropriate considerations for safety. There are additional safety rules

you must follow to get full mobility and value from your INDEPENDENCE™ iBOT™ 3000 Mobility System.

This manual contains two types of safety messages: cautions and warnings.

CAUTION

- Caution messages describe hazards or unsafe practices that may cause **damage** to your INDEPENDENCE™ iBOT™ 3000 Mobility System or other property.
- Take caution messages *seriously*.

WARNING

- Warning messages describe hazards or unsafe practices that may cause **injury or death** to you or people around you.
- Take warning messages *very seriously*.

Where You Will Find Safety Information

- Section 3 presents written warnings that apply to *all* operating functions.
- Section 4 describes caution and warning signals the product can give you through the user control panel.
- Other sections present cautions and warnings that pertain to specific topics, as well as additional safety guidelines.

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SAFETY AND RESPONSIBILITIES

Safe operation of the INDEPENDENCE™ iBOT™ 3000 Mobility System depends on your good judgment. This means there are important safety duties that must be performed by you and the people who may assist you.

The device offers significantly more capability than a power wheelchair and, as a result, requires significantly more training and awareness to operate safely.

Safety pointers for you

- Drive safely. Carefully follow the operating procedures, safety rules, and driving guidelines given in this manual.
- Heed all caution and warning **messages** printed in this manual. Respond quickly and correctly to caution and warning **signals** you see or hear when driving the device by using the procedures and guidelines given in this manual.
- Always select the operating function best suited to your current driving needs, the terrain, and any other conditions in which you are driving.
- Keep your device in good working condition. Maintain and service it according to the procedures in this manual and requirements of the warranty. If the product appears damaged or unsafe to operate, **DO NOT DRIVE.** Call Service.
- Do not attempt to modify the hardware, software, components, or programming of your device.

Safety pointers for people who may assist you

- A trained Healthcare Professional must train Assistants for assisted stair climbing.

- Stair climbing Assistants need to know how the product operates. This includes understanding operating procedures and safety rules.
- Stair Climbing Assistants must demonstrate that they can perform both the physical and decision-making tasks you request of them.

⚠ WARNING - No Unauthorized Drivers

- The product has been configured and calibrated for a specific user. Personal injury or death could result if unauthorized persons operate the product. Only the person for whom the INDEPENDENCE™ iBOT™ 3000 Mobility System has been configured and calibrated may operate the product.

⚠ WARNING - No Riders

- Never operate the INDEPENDENCE™ iBOT™ 3000 Mobility System with another person on the product or in your lap. Personal injury or death could result. The product has been calibrated to your weight and body size. Different weights and distributions could affect the stability of the product.

⚠ WARNING - Maximum Weight Capacity

- Never operate the product if the combined weight of you, your accessories, and your packages exceeds 250 pounds (113 kg). Excess weight may interfere with the iBALANCE™ Technology. Personal injury or death could result.

⚠ WARNING – Weight Capacity

- Never operate the product with more than 20 pounds (9 kg) hanging from the carrying hook. The iBALANCE™ Technology may not function properly. Personal injury or death could result. Hang no more than 20 pounds (9 kg) from the carrying hook.

⚠ WARNING – Personal Weight Change

- Never operate the product if you have gained or lost 20 or more pounds (9 kg) since the product was calibrated for you, or if your fully clothed weight exceeds 250 pounds (113 kg). The iBALANCE™ Technology may not function properly. Personal injury or death could result. It is your responsibility to call Service to arrange for an appointment with a trained Healthcare Professional to recalibrate the iBALANCE™ Technology if your weight has changed by 20 pounds (9 kg).

⚠ WARNING – Flammability

- Some cushions and covers do not meet flammability requirements. Fire and personal injury can result from their use. Use only seating products and upholstery that have been tested or certified for the flammability requirements of *ISO or **ANSI//RESNA standards (Part 16).

* International Standards Organization
** American National Standards Institute/Rehabilitation Engineering and Assistive Technology Society of North America.