PMA Memorandum

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FDA / Office of Device Evaluation
Division of General, Restorative and Neurological Devices
Restorative Devices Branch

Subject: **ENGINEERING REVIEW SUMMARY**

PMA Number: **P020033** (ORIGINAL PMA)

Device Name: **INDEPENDENCE™ IBOT™ 3000 Mobility System**

Applicant: Independence Technology, L.L.C.

To: The Record

INTRODUCTION

This original premarket approval application (PMA) is submitted for the INDEPENDENCE™ IBOT™ 3000 Mobility System. In this review, the terms "device," "system," and "IBOT" are used interchangeably. The sponsor of this premarket approval application is Independence Technology, L.L.C. This firm is a subsidiary of Johnson & Johnson. In this review, the terms "sponsor" and "applicant" are used interchangeably.

The purpose of this engineering review is to present a general overview of the proposed device and to summarize the non-clinical qualification tests that were performed by the PMA sponsor to ensure that the device performs as intended and in a manner that meets the needs of the identified user population.

INDICATIONS FOR USE

The general intended use of the device is to provide enhanced mobility to individuals who have mobility impairments.

The applicant identifies the specific indications for use as follows:

> *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.*

DEVICE DESCRIPTION

The INDEPENDENCE™ IBOT™ 3000 Mobility System (IBOT) is a powered, multi-functional wheeled mobility system. [An illustration of the IBOT system in four of its operational configurations can be found on page 18-006 (i.e., PMA volume 18, page 006).]

The IBOT system receives information via user commands and numerous onboard sensors. This information is processed by internal software and microprocessors, resulting in appropriate motor commands and/or user feedback. The system has been designed with a redundant, fail-safe architecture to minimize the risk of user injury resulting from individual component failures.

A. Major Components

The system's three primary components consist of a User Seating/Support System [see photo, page 18-019], a User Control Panel [photo, page 18-026], and a Power Base [photo, page 18-019]. Additional components, which are not attached to the device during normal operation, include a portable battery charger and a computer interface. [Photos of the front and rear views of the IBOT device are located on pages 18-020 and 18-021.]

1. User Seating/Support System

The user seating/support system includes the components used to support the user in a seated position, i.e., the seat pan, seat back, seat and backrest cushions, armrests, footrests and footplates, seat frame, lap belt, and calf straps. Also included are the front caster wheels, and an assist handle and assist button.

Many of the dimensions of the body support system are configurable or adjustable across a range of sizes to allow for fitting to the individual user's body dimensions. The size of many of the seat's components can be selected at the time of order or adjusted by the user or clinician to provide proper fit, support, and positioning. Selectable parameters include the seat pan's width and depth (specify), the seat back's width and height, the armrest's height and fore/aft position relative to the seat pan, the seat pan angle, and the leg rest's length and angle. The device is supplied with seat and backrest **cushions** (manufactured by

Vicair) and is designed to accept other commercially available (3rd party) cushions. A conventional airliner-style **lap belt** is provided to secure the user in the seat. The **armrests** provide arm support and may be swung downward to facilitate transfers to and from the device. The **footrests** and **footplates** provide support for the user's legs and feet, a calf strap provides additional leg support, and toe guards located at the forward end of the footrests minimizes impacts to the user's feet. The footrests may be removed by the user to facilitate storage and transport. [See photos, pages 18-043, -047, and -050.] Similarly, the **seatback** may be folded to reduce the overall dimensions during storage and transport. Located behind and extending above the seatback is an **assist handle**, which telescopes upward out of the seatback and locks in position. The assist handle is provides a location for an assistant to grasp and apply leverage during caregiver-assisted stair climbing. An **assist button** is located on the rear of the seatback. The assist button is used by a caregiver to enable assisted stair climbing. The main support frame for the seat is made from welded steel tube, and the seat pan and back are made of plywood. The **seat frame** consists of dual steel structures running underneath the seat pan and behind the seat back. It provides the main structural support to which the seat pan and seat back are mounted. The seat frame attaches to the power base via an attachment point at the top of the power base.

2. User Control Panel

The User Control Panel (UCP) is the component of the device that supports the exchange of information between the user and the device. The UCP receives specific commands (e.g., speed, direction, function, and seat position) from the user via a joystick and pushbuttons and relays these commands to the microprocessors located in the power base. The UCP also provides status information (e.g., battery charge, safety alerts) to the user via an LCD display, colored LEDs, and an audible tone. The UCP also provides a removable door for access to a serial communications port to which an external computer may be connected. Access via this interface may be needed by the clinician to configure the device, by service personnel, and to retrieve stored data for diagnostic purposes.

All user commands (except system power on/off) are executed on the UCP. The Power On/Off button is located on the right side of the IBOT power base.

The UCP is attached to either the right or left armrest as an integrated assembly. The UCP contains a joystick, which is used to control speed (and braking) and the direction of travel. The joystick is proportional, that is, the extent of joystick displacement from the neutral (vertical) position is directly proportional to the speed/braking/turning response. The UCP contains pushbuttons to select a specific operating function, to select a fast or slow drive setting, to adjust the seat height and fore/aft seat tilt between limits established in software, to illuminate (backlight) the LCD display, to acknowledge an alert or warning condition, and to sound the horn.

The LCD display is a 102 x 65 pixel (minimum) unit with black pixels displayed against a gray background. The viewable area is 2.0 x 1.3-inch (minimum) and backlighting is provided upon user command via light-emitting diodes (LEDs). The display is covered by a glass screen installed underneath a plastic scratch shield in the upper housing of the UCP. The LCD display provides operational and diagnostic information to the user via a series of icons and numbers. Information provided by the LCD display includes an icon depicting the current operating function (i.e., Standard, 4-Wheel, Balance, Stair, or Remote), the drive setting (0, 1, or 2), and the amount of charge remaining in the batteries. Diagnostic information is also provided when appropriate (e.g., a wrench icon denoting service required, a thermometer icon denoting a warm or overheating condition, etc.). [See icon illustrations, pages 18-036 through -039.]

The backlight button provides illumination to the LCD display when needed, such as in low-light conditions. The backlight button toggles, that is, the backlight remains on until the user presses the backlight button a second time to turn it off.

The acknowledge button is used to change the duration of the audible beeps associated with certain non-critical system alerts. When the system detects a fault or other diagnostic condition (e.g., motors getting warm or batteries getting low), the display provides a visual indication via an icon. The visual information is supplemented with an audible tone (varying from one beep per second for a non-critical alert to a continuous tone for more serious conditions). By pressing the acknowledge button, the user can acknowledge the alert while minimizing the annoyance or distraction that the beep may cause. For more serious alerts and warnings, the acknowledge button will not silence or alter the audible signal as the intent is for the user to take immediate action to resolve or mitigate the condition. The acknowledge button may also be pressed to sound a horn.

Three LEDs (green, yellow, and red), which serve as system status lights, are used to supplement the information provided to the user via the LCD icons and audible tones. The green LED represent a normal "Go" status, the yellow LED represents a "Caution" status, and the red LED represents a "Warning" condition. [See status light illustrations, page 18-034.]

The two Function Select buttons (buttons labeled with up arrow and down arrow) are used to scroll through LCD icons representing the available operating functions (i.e., Standard, 4-Wheel, Balance, Stair, and Remote).

The Drive Setting button (button labeled "0-1-2") allows the user to scroll through the three possible drive settings, which are cycled through the LCD display as 0, then 1, then 2 each time the button is pressed. Setting 0 is selected when the user wishes to place the device into a power-saving "sleep" state when the device is stationary; setting 1 is selected when the user wishes to place the device into a slower, less responsive mode and/or where more precise control over mobility is desired; and drive 2 is selected when the user wishes to place the device into a faster, more responsive mode.

The OK button is used to confirm/enable the Function selection and the Drive Setting selection. Prior to confirmation via the OK button, the user's function selection (icon) or drive setting (number) selections will blink on and off in the LCD display. After the selection is confirmed, the icon or number remains solid.

There are four momentary pushbutton switches used to continuously vary the seat position. The seat position control buttons are used to control the seat height (separate buttons to raise and lower seat height) and the fore/aft seat tilt (separate buttons for tilt forward and tilt backward).

3. Power Base

The power base includes the components used to provide mobility, i.e., the batteries, motors, four drive wheels and tires, plus the electronic controllers, microprocessors, and software. The power base houses the motors and transmissions, serves as the structural platform for the user seating/support system, and provides mounting for the electronics enclosure. The power base also includes the linkages to enable adjustment of the height and angle of the seat. Four tie-downs are provided on the underside of the power base to allow the device to be secured in motor vehicles.

The Power Base consists of two transmission assemblies (one per side) that provide torque to each of the four main drive wheels, two cluster assemblies that rotate with respect to the seat and power base, a cluster transmission, a seat height actuator, and a center section. DC motors are used to provide input torque to each of the two drive wheel transmissions and the cluster transmission.

There are two Wheel Transmission Assemblies in the Power Base assembly, one for each pair (left and right) of the main twelve-inch drive wheels. Each Wheel Transmission Assembly contains pulleys and belts that receive input torque from each wheel motor. Low-speed, high-torque power is provided to the wheel shafts via multi-stage belt/pulley reduction.

The Cluster Assembly extends power transmission from each wheel motor out to a pair of main drive wheels to provide locomotion. Note that all four drive wheels are driven together, whether or not all four of the wheels are in contact with the ground. The rotary motion of the cluster as an entire assembly allows the device to climb stairs and other obstacles and to transition into and out of Balance function.

The Cluster Transmission provides the mechanical power to rotate the cluster assembly. A DC motor supplies input torque to the cluster transmission. Power is transferred from the motor through a belt drive train coupled to the drive gear set. A worm-drive gear set is mounted to the output shaft to provide the low-speed, high-torque performance necessary for stair climbing, obstacle climbing, and transitions into and out of Balance function. The output shaft delivers torque to a spur gear set to transfer motion from the cluster transmission to the cluster assembly.

The Seat Height Actuator is a linear actuator that raises and lowers the seat with respect to the Power Base. This is accomplished upon user command. The seat height actuator connects at one end to a large arm directly below the seat and at the other end to the two wheel transmission assemblies. A DC motor inside the assembly causes a rotation of a linear screw, producing the desired vertical displacement of the seat.

The Center Section assembly is the mechanical linkage between the seat height actuator and the seat. It allows the seat to be raised and lowered while remaining level. It consists of a four-bar linkage resembling a parallelogram. This design maintains the seat and user in a constant horizontal orientation (with respect to the ground) as the seat is raised and lowered by the action of the seat height actuator.

The Motor/Brake Assemblies are used to take switched electrical current commands as inputs and then output torque to mechanical transmissions that provide desired motion. There are two primary types of motion on the device: wheel and cluster. A wheel motor (one per side) drives each wheel transmission. A single cluster motor drives the single cluster transmission. Unlike the cluster motor, each wheel motor has a lever for manually disengaging its electromechanical brake. This enables the brakes to be disengaged so that the device may be pushed manually when it is powered off. A dual redundant, load-sharing motor configuration has been chosen to enhance device safety and reliability. Each motor has two sets of stator windings driven by two separate amplifiers. The power supply for each amplifier is a separate battery. This configuration minimizes the consequences of any single point failure in the path from the battery to the motor output. The motors include integrated temperature and rotor position sensors. The temperature sensors are used to provide motor over-temperature protection. The rotor position feedback is used to provide commutation.

The Electronics Enclosure houses the primary stabilization sensors and decision-making systems for the device. Stabilization sensors include pitch and pitch rate sensors. Decision-making systems are implements on microprocessors. User commands from the UCP are processed (in conjunction with sensor data) by the microprocessors to deliver motor command requests to power amplifiers. The power amplifiers use these commands to control the wheel motors and cluster motor. Three Power Base Processors in the system provide triple-redundant control processing for dynamically stabilized functions. The device uses six solid state gyroscopes and three tilt sensors to provide dynamic stability (referred to as "I-Balance technology"). Each microprocessor runs software programmed in the language C++. Three Power Source Controllers (PSC's) are used to provide low-voltage power to the three separate Power Base Processors. PSC's A and B derive their power from two separate Battery Packs: A and B, respectively. PSC-C derives its power from diode "OR-ing" of the Battery Packs A and B together to prevent single-point failure modes. In addition, two of the PSC's provide power to the Power Amplifier Controllers and associated Power Amplifiers and the remaining PSC provides power to the UCP. Each PSC contains a microcontroller programmed in assembly language. Load sharing redundancy is used for the power amplifiers, high-voltage power buses, and primary motors in order to size the motors and batteries for normal, no-fault conditions and still allow higher-stress, short-duration operation during a system fault. In the event of a loss of communication with the UCP, the redundant processors in the electronics enclosure continue to execute the control algorithms to maintain stability.

Batteries serve as the device's power source. The device uses two identical batteries to provide a dual redundant source of power. Each battery uses a separate power bus from which other key redundant components draw power. Each battery provides power to sensors, controllers, and motors, through switching power converters. The batteries also accept regeneration power from the motors. The batteries are removable without the use of tools. Each battery consists of a pack of 60 nickel-cadmium (NiCd) cells with an internal charge monitor and charger control module (battery gauge) and an internal over-current protection device. To reduce the risk of electrical shock when removed from the device, each battery contains two sets of 30 cells connected in series, each called a "half-battery" and each terminated separately at a blind-mate connector. The mating connector in the device contains a jumper to connect the two 30-cell half batteries in series, forming a 60-cell 72-volt battery when the battery is mounted on the device. The battery gauge measures battery current, battery temperature, and battery voltage from the lower half-battery, and uses these measurements to estimate and report full charge capacity and relative state of charge. Each battery's nominal capacity is 5.0 amp-hours and the battery has been designed to have a useful life of not less than 18 months or 500 charge/discharge cycles to 80% depth of discharge, whichever occurs first.

4. **Battery Charger** [see illustrations, pages 18-184 and -185]

The Battery Charger uses AC line power to charge the batteries while they are installed on the device. The charger can fully charge both batteries in less than six hours from a fully discharged state. The charger can charge both batteries to 80% of rated capacity within four hours from a fully discharged state.

The charger communicates with the charge control module located within each battery. The charge control module requests a trickle charge as full capacity is approached. The charger indicates the status of charging for each battery, as well as any fault condition that is detected. The charger discontinues charging in the event of battery overheating or loss of communications. The charger can use as an input either US electrical service (120 V at 60 Hz nominal) or European service (230 V at 50 Hz nominal).

The charger has two outputs, one for each battery that it must charge simultaneously. Both charger outputs are isolated from the line and neutral conductors of the AC power input. The cable leading from the charger to the device is approximately 2 meters long. A connector that plugs into the device and contains all of the required electrical contacts terminates that the end of the cable. The connector is keyed to prevent incorrect insertion into the device and is touch-proof to isolate all battery terminals from a user or assistant.

B. Operating Functions (Modes of Operation)

The IBOT design incorporates advanced electromechanical systems and control systems to achieve five operationally distinct mobility functions. In four of its five operational functions, the device uses dynamic stabilization (called I-Balance™ Technology) to actively adjust its wheel position and/or frame in response to changes in the fore/aft location of the user's center of gravity relative to the ground-contacting wheels. In the remaining function (i.e., Standard Function), the device is not actively stabilized and, therefore, operates much like a conventional powered wheelchair. It should be noted that the IBOT device does not use anti-tip bars for stabilization.

In the four actively stabilized functions, sensors are used to acquire information on the device's pitch, rate of change in pitch, wheel velocity, wheel position, seat height, and other parameters. This information is processed in the system's closed-loop control algorithms in conjunction with the device configuration parameters (e.g., user's center-of-gravity) and user command inputs (e.g., joystick commands for speed and direction) to provide appropriate commands to the DC motors. Depending on the operating conditions and the operating function selected, different sets of motors are activated to create and maintain stability while executing the user's mobility commands. In each of the device's four actively stabilized functions, the primary goal of the control algorithms is the same: to keep the user upright and stable while simultaneously providing the desired mobility response.

The device's five operating functions are: (1) Standard Function, (2) Four-Wheel Function, (3) Balance Function, (4) Stair Function, and (5) Remote Function.

Each operating function provides the user with a unique set of mobility options suited to different operating conditions and user needs. Standard Function provides functionality equivalent to that found in conventional powered wheelchairs. 4-Wheel Function provides four-wheel drive and is well-suited for use on inclines, and loose or uneven terrain. Balance Function is most appropriate when the user wishes to drive with an elevated seat height or interact with able-bodied individuals at eye level. Balance Function also provides a small turning radius, so this function offers maneuverability in close quarters. Stair Function can be used independently -- or with an assistant – to ascend and descend stairs. Remote Function allows the user to operate the device when not seated in it. This is useful for positioning the device before or after transfers.

The user chooses the desired operating function using the buttons on the User Control Panel (UCP). To select a function, the user presses either the scroll-up or scroll-down button until the appropriate graphical icon for the desired function appears on the LCD display. Once the desired function icon is displayed, the user confirms the selection by pressing the "OK" button. This confirmation step changes the blinking function icon to a steady icon and the operating function is then enabled.

The IBOT system's software controls the allowable function transitions. [See list, page 18-071.] For example, Stair Function is not selectable from Balance Function, since users should be stationary and on four wheels when they start to ascend or descend a flight of stairs. Therefore, Stair Function is allowable only from 4-Wheel Function. Similarly, to maintain stability, the mobility system ignores power-off commands when driving in dynamically stabilized functions (4-Wheel, Balance, and Stair Functions) and can be powered-on only in Standard or Remote Function.

The IBOT provides drive settings for each function. The user chooses the drive setting by pressing the scroll-up or scroll-down button on the UCP and confirming the command by pressing the "OK" button. The drive settings are similar to those found in currently marketed powered wheelchairs. In the IBOT device, two drive settings (designated Drive-1 and Drive-2) are used to enable the user to select between a slower, less responsive setting (e.g., for indoor use) and a faster, more responsive setting (e.g., for outdoor operation). A third setting (Drive-0) provides power conservation or a "sleep" setting that users can select to conserve the battery of they plan on being stationary for a period of time while in Standard Function. The other functions, which rely on real-time stabilization (I-Balance™ Technology), do not offer the user access to a sleep setting. In 4-Wheel and Balance Function, Drive-0 is used to deactivate the joystick (e.g., to remain stationary even when the joystick is accidentally bumped). The joystick is re-activated (and the device "wakes" from the sleep setting in Standard Function) when any button on the User Control Panel is pressed. The joystick is not used and is not responsive in Stair Function.

1. *Standard Function* [see top left illustration, page 18-006]

   In Standard Function the device operates much like a conventional powered wheelchair. Dynamic stabilization is not used. The two larger-diameter (approx 12") rear wheels are motor-driven and are used for propulsion and braking, and the two front caster wheels passively follow/lead. Standard Function provides good turning performance and mobility on relatively firm, level surfaces (e.g., indoor environments, sidewalks, and pavement). The seat is in the lowest available position when in Standard Function. With the seat in this position, the casters – which are attached to the base of the seat – are in contact with the ground and the front set of drive wheels is raised off the ground. The casters provide good turning performance; however, as is the case with currently available mobility devices, the use of small-diameter casters limits terrain and obstacle performance. Selection of 4-Wheel Function is usually more appropriate in such cases. Additional details regarding this function are provided on pages 02-019 through 02-020 of the PMA.

2. *4-Wheel Function* [see top right illustration, page 18-006]

   In 4-Wheel Function (also referred to as "Enhanced Function" in the PMA application), the front caster wheels are elevated and do not contact the ground, enabling all four drive wheels to make ground contact. Because all four ground-contacting wheels are actively driven by the system's motors, are of large diameter (relative to the casters), and have a construction that provides superior traction (relative to the casters), 4-Wheel Function is well suited to driving across soft or loose terrain such as dirt, grass, and gravel, and for traversing small curbs and obstacles. 4-Wheel Function is intended primarily for outdoor use. Additional details regarding this function are provided on pages 02-017 through 02-018 of the PMA.

3. *Balance Function* [see bottom left illustration, page 18-006]

   In Balance Function, only one pair of drive wheels makes contact with the ground. The second pair of drive wheels is positioned directly above the ground-contacting drive wheels. The Balance Function provides mobility at an elevated seat height. In Balance Function, the system uses the I-Balance™ Technology to actively maintain stability by driving the wheels to stay under the user. Pitch, wheel position, wheel velocity, and other sensor data are processed along with the user's joystick commands to provide the desired speed and direction while maintaining stability on two wheels. The stabilization is actively controlled only in the fore/aft direction; in the lateral direction the device is not actively stabilized. Consequently, the device is able to maintain stability on much steeper inclines in the front-to-back direction than in the side-to-side direction. Users will be trained and instructed to use caution when executing turns on inclines.

Balance Function will be disabled (via software) for users who are not able to demonstrate that they can use this function safely and effectively. Balance Function provides increased maneuverability with dynamic stability. The dimensions of the device define the turning radius, as the device can pivot in place on two wheels. Balance Function also enables users to execute reaches at standing heights and can interact with able-bodied persons at a standing eye level. With the push of a button on the User Control Panel (UCP), the user can adjust the seat height over a range of several inches in this function. When the device is in Balance Function and when the seat is elevated (thereby raising the user's center-of-gravity), the maximum achievable speed is automatically reduced (via software) to provide improved lateral stability in this otherwise less stable configuration. Because the entire weight of the device and user is distributed over just two wheels, Balance Function does not perform as well in softer terrain. In addition, obstacles greater than ½ inch in height, loose terrain, and slick surfaces are better suited for 4-Wheel Function. Additional details regarding this function are provided on pages 02-010 through 02-012 of the PMA.

4. *Stair Function* [see bottom right illustration, page 18-006]

Stair Function has been designed to enable users to ascend and descend commonly encountered stairs. Rather than rotate individual wheels to maintain stability (as in Balance Function), in Stair Function the clusters (i.e., the left pair and the right pair of drive wheels) are rotated together. Stair climbing is achieved by rotation of the clusters in a closed-loop control algorithm that uses pitch and other sensor data to control a separate cluster motor. A low-speed, high-torque transmission provides the necessary reduction to lift the combined weight of the user and mobility system up or down the steps. As the clusters rotate, they mesh with the envelope of the stairs. Depending on the user's ability to independently perform stair climbing in a safe and effective manner, Stair Function is configured (via software) for either Solo (unassisted) operation or for Stair Assist operation (i.e., with the assistance of a trained caregiver). If the user cannot perform Solo stair climbing, or if a caregiver is not available to be trained to perform the Stair Assist function, then the user will not be permitted to receive an IBOT system. That is, the IBOT device will not be sold without Stair Function enabled.

In Solo stair climbing, the user controls the cluster rotation by leaning, which is induced by using both hands to grasp and apply forces on one handrail or a pair of handrails. The joystick is not active in Stair Function. Control is directed by the lean of the device. The user (or assistant) adjusts the initiation and rate of cluster rotation by controlling the extent of lean. The greater the lean, the faster the rate of cluster rotation and stair climbing. To ascend stairs, the user approaches a staircase backwards at a low speed in 4-Wheel Function, bringing the drive wheels to within a few inches of the first stair riser. Next, the user selects the Stair Function icon from the UCP and presses the "OK" button to confirm this selection. Once Stair Function is activated, the joystick becomes non-operational. To initiate stair climbing, the user uses both hands to apply force to the stair handrail(s), causing the device to lean back which, in turn, causes rotation of the clusters. Once the center-of-gravity of the device and user passes behind the rear drive wheels, the cluster will begin to rotate causing the forward drive wheels to elevate up and over the rear drive wheels and onto the next stair. The user adjusts the amount of force on the handrail(s) to control the rate of cluster rotation, with the objective of placing the drive wheel softly on the tread of the next stair. This process is then repeated for each stair, up the full flight of stairs. At the stair landing, the user pushes back from the stairs and transitions to 4-Wheel Function by scrolling to the appropriate icon on the UCP and confirming with the "OK" button. The process for descending stairs is very similar, except the user pulls the device to the edge of the first step and the cluster rotates downward as the front wheels pass the edge. The user then leans forward while holding the handrail, causing the cluster to rotate down each step.

Ease of stair climbing is dependent upon user technique. In general, the amount of effort required for stair climbing decreases with practice and experience.

As part of the assessment process for this device, a clinician will determine whether a particular user has the necessary physical and cognitive abilities to climb stairs without the assistance of a caregiver. if the user does not have the required abilities, the clinician can configure the device to require the presence of a trained assistant to help the user with stair climbing. This configuration requires activation of the Assist Button located on the seatback. In this "Stair Assist" configuration, Stair Function is not initiated unless and until the assistant presses the Assist Button. The assistant than exerts a lean-backward or lean-forward force on the Assist Handle to cause the clusters to rotate up or down the stairs, respectively. No further input, upper extremity function, or other activity is required of the user. Additional details regarding this function are provided on pages 02-013 through 02-016 of the PMA.

5. *Remote Function* [see illustrations, pages 18-178 through -180]

Remote Function provides the user with a means of operating the device when not seated in it. This function is useful for maneuvering the device for transfers, parking after a transfer, for driving into a vehicle for transport, and other purposes. The UCP can be removed from its mount on the armrest and operated via a five-foot length of retractable cable. To initiate this function, the user selects the Remote Function icon from the UCP and confirms the slection using the "OK" button. Entry into Remote Function is allowed only when the seat back is folded down onto the seat (to prevent use while occupied). In Remote Function, the device recognizes joystick commands only while the "OK" button remains held down. This prevents unintended device motion if the UCP is dropped and the joystick is deflected. It should be noted that uses need the use of two hands (or the help of an assistant) to operate Remote Function. One hand is used to hold the "OK" button and the other hand is used to operate the joystick. Remote Function operates much like 4-Wheel Function, except that the speed, acceleration, and turning response is greatly reduced. Additional details regarding this function are provided on pages 02-018 through 02-019 of the PMA.

C. Braking

There are two types of braking provided by the IBOT mobility device. The service brake is used when the device is in motion and it decelerates the device from a given speed. The automatic brake is used to hold the device in place when the system is powered off. These types of braking systems are also found in conventional powered wheelchairs.

1. *Service Brakes*

   The motor/amplifier drive system provides regenerative service braking. In order to reduce the device speed or stop, the user may release the joystick. To reduce speed more quickly, the user may pull back on the joystick. Braking response is proportional to the extent of joystick displacement.

2. *Automatic Brakes*

   Each of the drive wheels contains a motor with electromagnetically-controlled brake pads packaged as part of the integrated motor/brake assembly. When the IBOT is turned off, these automatic brakes automatically engage to prevent the system from rolling, even on an incline. A lever is provided on each brake that allows the user (or an assistant) to manually disengage the automatic brakes so that the device may be pushed manually when the IBOT is powered-off. If one or both of the automatic brake levers is disengaged at attempted power-on, the device will detect this condition, the LCD display will display an icon indicating that the brake is disengaged, and the power-on command will be ignored. In addition, if the brake is manually disengaged after power is already turned on, any power-off command will be ignored unless the Assist Button on the rear of the seat back is pressed. These lock-outs are intended to prevent unintentional rolling of the device, and the assist button serves as an acknowledgement that an assistant is present to prevent such unintentional rolling.

D. Technical Specifications

Dimensional Specifications:

Payload (driver + items carried):	250 lbs., maximum
Total System Weight:	246 to 251 lbs.
Battery Weight:	22 lbs (each)

Overall Dimensions:	
- maximum configuration	41"(L) x 56"(H) x 27"(W)
- minimum configuration	33"(L) x 27"(H) x 24"(W)
Seat Pan (6 sizes available), W x D:	16"x 16", 16"x 18", 16"x 20" 18"x 16", 18"x 18", 18"x 20"
Back Rest (2 sizes available), W x D:	16"x 18", 18"x 18"
Seat Height:	
- Standard Function	22 inches
- 4-Wheel Function	25½ to 28 inches
- Balance Function	32 to 36 inches
Armrest Height (relative to seat pan):	10½ to 13 ½ inches
Footrest (distance from seat pan):	12 to 18 inches
Wheelbase:	
- Standard Function	22.0 in.
- 4-Wheel Function	12.8 in.
Caster Wheel Diameter:	6 inches, approx.
Drive Wheel Diameter:	12½ inches, approx.

Performance Specifications:

Maximum Speed (measured, approx):		Forward	Reverse
- Standard Function	(fast template)	5.7 mph	1.0 mph
	(mid template)	4.4 mph	1.0 mph
	(slow template)	1.8 mph	1.0 mph
- 4-Wheel Function	(fast template)	3.4 mph	1.5 mph
	(mid template)	3.4 mph	1.5 mph
	(slow template)	2.0 mph	1.1 mph
- Balance Function	(fast template)	3.2 mph	1.2 mph
	(mid template)	3.1 mph	1.2 mph
	(slow template)	2.2 mph	1.0 mph
- Remote Function	(fast template)	0.25 mph	0.25 mph
	(mid template)	0.25 mph	0.25 mph
	(slow template)	0.25 mph	0.25 mph

Braking Distance (from Max Speed):	
- Standard Function	9.5 ft.
- 4-Wheel Function	5.6 ft.
- Balance Function	9.5 ft.
Minimum Turning Radius:	
- Standard Function	36 inches
- 4-Wheel Function	28 inches
- Balance Function	30 inches
Driving Range (per battery charge):	
- Standard Function	9.3 mi.
- 4-Wheel Function	7.4 mi.
- Balance Function	12.4 mi.
Combined Battery Capacity:	10 Amp-hours
Battery Charge Time:	
- Full Charge	6 hours
- 80% of Full Charge	4 hours
Maximum Obstacle Height:	
- Standard Function	½ inch
- 4-Wheel Function	4 inches
- Balance Function	½ inch
Maximum Surface Slope:	
- Standard Function	5 degrees
- 4-Wheel Function	8 degrees
- Balance Function	5 degrees
- Remote Function	25 degrees
Stair (Step) Dimensions:	
- Tread Depth	10 to 17 inches
- Riser Height	5 to 8 inches
- Nosing	1.0 inch, maximum

Acoustical Noise Emissions*:	Stationary	Driving
- Sleep Mode	45 dB(A)	- - - -
- Standard Function	45 dB(A)	73-81 dB(A)
- 4-Wheel Function	45 dB(A)	65-69 dB(A)
- Balance Function	45 dB(A)	65-70 dB(A)
- Stair Function	- - - -	66-80 dB(A)

* Measured in 44 dB(A) background environment.

E. Auxiliary Functions

The IBOT mobility system provides two auxiliary functions that are used by clinicians for user assessments and device customization, and by technicians for service. These auxiliary functions are the Update Function and the Calibration Function.

Update Function is used for setting "templates" and configuration parameters on the device and for performing service tasks (such as downloading data logs). Four external software applications, which run on a personal computer, have been developed to access the device's Update Function. All of these external software applications access the Update Function via an RS-232 serial connection between a personal computer and the PCMCIA slot located on the underside of the UCP. Update Function allows the external applications to read configuration and diagnostic data from the device and write configuration data to the device's memory (which is either temporary or permanent, depending on the application). Update Function can be initiated only when the device is stationary, when it is in Standard Function, and the PCMCIA card is inserted. All UCP commands are inactive. The device automatically returns to Standard Function when the PCMCIA card is removed from the UCP's slot.

Calibration Function is used to optimize device performance by calibrating the system to the user's center-of-gravity. Clinicians perform user calibration by seating the user in the device and taking data samples with the device in several automated and predetermined balance positions. A total of six balance points are measured while the calibration routine is executed. Calibration Function is accessed by the clinician via the Update Function and through commands provided in the Medical Interface and Delivery Interface external software applications.

F. External Software Applications

Four external windows-based software applications are used to assess users, choose configuration parameters, and retrieve information from the device. These external software applications are the Medical Interface, the Manufacturing Interface, the Delivery Interface, and the Service Interface.

The Medical Interface (MI) is used to configure available functions and to control parameter settings for a generic IBOT device that is to be used temporarily (for evaluation purposes) by a specific user. This interface is designed for use by trained and authorized clinicians or sales representatives. The MI is used to calibrate the IBOT system to the user's specific center-of-gravity and to configure the device with different operational functions in order to assess the user's ability to operate the various functions of the device. The MI does not save any data to the device's permanent memory; instead, it only updates the working memory to allow the consumer to test (and the clinician to observe) various settings. The settings selected by the clinician are used to support the subsequent assessment and ordering processes for the user's specific device. Note that the device used with the MI is not the same device that the consumer will receive following successful assessment and ordering. The MI produces a hard copy output for use during the manufacturing process.

The Manufacturing Interface (MFI) performs the three basic functions: (1) it initializes the device after final assembly; (2) it sets the prescribed speed and allowable functions on the device, based on the user assessment performed by the clinician using the MI; and (3) it retrieves and saves the device's configuration for the Device History Record. The system is configured according to the user's individual needs and based on the clinician's assessment of the user. One of three templates is set. The three template options are Fast, Medium, and Slow. The choice of template affects the speed, acceleration, and turning response of the IBOT device. Note that the user is not provided access to modify the template, as this is a clinician-programmed feature. However, the user does have control over the device responsiveness via the Drive Settings described in the User Control Panel section, described above. The other clinician-controlled configuration is the available operating mobility functions. Each prospective user must demonstrate an ability to use the IBOT safely and effectively in Standard Function, 4-Wheel Function, Stair Function, and Remote Function, because these four functions are always to be enabled in the device delivered to the user. However, Balance Function may or may not be enabled for a particular user, depending upon the clinician's assessment of the user's performance in Balance Function. Similarly, Stair Function will be enabled for either "Solo" (unassisted) use or for "Stair Assist" use (i.e., requiring the assistance of a trained caregiver).

The Delivery Interface (DI) verifies the user's configuration on the device that was set using the MFI, performs user center-of-gravity calibration, and saves the center-of-gravity calibration information to the IBOT device's permanent memory. The DI also can be used to read an electronic configuration file and load the values into permanent memory on the device.

The Service Interface (SI) is used to support IBOT diagnostics and maintenance. The SI is used only by personnel trained and authorized by Independence Technology.

NON-CLINICAL TESTING

The PMA sponsor has provided documentation regarding numerous non-clinical tests conducted to evaluate the system-level performance of the IBOT device. The sponsor refers to this as the Qualification Testing. Many of these tests were conducted in accordance with FDA-recognized consensus standards and other voluntary international standards. These include standards developed specifically for mobility devices (e.g., ANSI/RESNA and ISO standards that apply to wheelchairs and scooters), as well as more widely-applicable standards regarding electromagnetic compatibility, electrical safety, flammability, biocompatibility, environmental performance, and others. When necessary (e.g., to evaluate unique features of the IBOT system), these standards were supplemented by the sponsor's own test methods and acceptance criteria.

The sponsor has compiled the qualification testing documentation into the following 36 reports:

- Static Stability
- Dynamic Stability
- Effectiveness of Brakes
- Electrical Energy Consumption and Distance Range
- Dimension, Mass, and Turning Space
- Speed, Acceleration, and Retardation
- Measurement of Seating and Wheel Dimensions
- Static Impact and Fatigue
- Climate
- Obstacle Climbing Ability
- Power and Control Systems
- Nomenclature and Labeling
- Resistance to ignition of Upholstered Parts
- Electromagnetic Compatibility
- Stair Climbing
- Fault Insertion
- System Monitoring
- Environmental
- Electrical Standards
- Safety
- Programmable Drive Parameters
- Stability with Impact
- Crack Traversal
- User Control Panel
- Transporter Power
- Computer interface
- Exposure to Altitude
- Transitions between Functions
- Enclosures Protection
- User Comfort and Convenience
- Packaging
- Lifetime
- Operation on Surfaces
- Joystick Mechanical
- Drop Test
- Exposure to Sunlight

These comprehensive system-level tests were performed to evaluate the performance of the IBOT system across its range of operating functions and configurations. The tests represented both normal and worst-case conditions. The results documented in each of these test reports demonstrate that the device met all of the established pass/fail criteria. These non-clinical test reports are provided in Volumes 10 through 13 of the sponsor's PMA application.