

Memorandum

Date October 24, 2002

From Director Regulatory Review Officer

Subject P020033 – INDEPENDENCE™ IBOT™ 3000 Mobility System by Independence Technology, L.L.C.

To Robert De Luca, Lead Reviewer, Biomedical and Electrical Engineer

This memorandum contains my review of P020033 for the INDEPENDENCE™ IBOT™ 3000 Mobility System.

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Background

The application under review is an original premarket approval (PMA) application that has been granted expedited review status.

Attachment 1 provides identifies the PMA volumes and page numbers for each study report and study protocol for the pilot and pivotal studies.

The pivotal study is the only clinical trial that assessed the version of the IBOT™ that will be marketed and that used the clinician and patient training methods and materials that are intended for the marketed device.

Indications for Use

The INDEPENDENCE™ IBOT™ 3000 Mobility System is a powered mobility device for individuals who have mobility impairments and the use of at least one upper extremity. The device is intended to provide indoor and outdoor mobility in confined spaces, at an elevated height, climb curbs, ascend/descend stairs, traverse obstacles, travel over a wide variety of terrain and negotiate uneven/inclined surfaces.

The IBOT™ 3000 Mobility System is intended to be a prescription device.

Clinicians will require certification in order to train patients on the IBOT™ 3000 Mobility System.

Device Description

The INDEPENDENCE™ IBOT™ 3000 Mobility System consists of a seating system mounted onto a power base. The power base includes wheels (4 drive wheels mounted onto cluster and 2 caster wheels), batteries, motors and computers. The device has 5 functions:

- Standard (level surfaces; uses 2 caster wheels and 2 drive wheels)
- 4-Wheel (uneven surfaces; slopes $\leq 8^\circ$ and curb-like obstacles ≤ 4 inches; uses 4 drive wheels)
- Balance (dry, even, stable, level surfaces; slopes $\leq 5^\circ$ and obstacles $\leq \frac{1}{2}$ inch; uses 2 drive wheels)
- Stair (flat, level, strong, dry stairs; stairs must be 30 inches wide, 5-8 inches height, 10-17 inches deep, maximum of 1 inch tread overhang and must have 1 or 2 handrails that extend beyond the step approximately 6 inches; uses 4 drive wheels)
- Remote (for loading into vehicle; slopes $\leq 25^\circ$; uses 4 drive wheels)

There is a dynamic stability technology (I-BALANCE™ Technology) that is active during every function except the standard function. This dynamic stability is achieved through use of gyroscopes that sense movement and a computer that processes the signals from the gyroscopes, subsequently controlling the motors to move the wheels to maintain stability in the sagittal plane only. There is no dynamic lateral stability technology. The I-BALANCE™ Technology is active in every function except the standard function. The IBOT™ can elevate the seat in the 4-wheel, balance and stair functions. In the balance function, the device can elevate the user to eye level of a standing person. The device is meant to be used independently or with an assistant (for the stair function only).

Device configurations that will be available in the marketed version of this device include the following:

| <u>Configuration</u> | <u>Functions</u> | | | | |
|----------------------|------------------|----------------|----------------|--------------|---------------|
| | <u>Standard</u> | <u>4-Wheel</u> | <u>Balance</u> | <u>Stair</u> | <u>Remote</u> |
| Solo | X | X | On or Off | Solo | X |
| Stair Assist | X | X | On or OFF | Assist | X |

| <u>Speed Template</u> | <u>Speeds</u> | |
|-----------------------|------------------------------|------------------------------|
| | <u>Drive Setting 1 (mph)</u> | <u>Drive Setting 2 (mph)</u> |
| Slow | 1 | 2 |
| Medium | 2.5 | 4.5 |
| Fast | 4 | 6 |

Note that although the maximum speed is to be 6 mph (Fast Speed Template with Drive Setting 2), it is possible that the wheel velocity can exceed 8 mph in the standard function (e-mail received October 15, 2002) at which point the device determines it cannot control the stability of the device and/or the subject and the device will go into system shutdown.

Labeling

Labeling was revised in accordance with two of the falls experienced with the IBOT™ as noted on page 14-064. A number of additional revisions should be made to improve safe and effective use of the IBOT™, e.g., amend *User Manual* to include contraindications in the first section and to provide a glossary, clarify the entire process and materials required for clinician certification as well as for patient training, amend the clinician's manuals to clarify the deletion of the 4-wheel assist option and to include an index for each, etc.

Pilot Studies

Three non-randomized pilot clinical studies were conducted with earlier versions of the IBOT™. The following table provides a brief overview of these pilot studies.

| Title | Study Duration | Number of Patients | Duration of IBOT™ Use |
|---|--|---|---|
| <p>Use of the INDEPENDENCE™ 3000 IBOT™ Transporter at Home and in the Community</p> <ul style="list-style-type: none"> • Report (page 15-125) • Protocol (page 16-179) | <p>March-July, 2001</p> <p>(pages 14-004 & 14-006)</p> | <p>10 unimpaired users;</p> <p>4 expert manual wheelchair users (spinal cord injured [SCI])</p> | <p>3 days (unimpaired)</p> <p>1 week (expert)</p> |
| <p>Preliminary Assessment of a Prototype Advanced Mobility Device in the Work Environment of Veterans with Spinal Cord Injury</p> <ul style="list-style-type: none"> • Report (page 15-147) • Protocol (page 16-179) | <p>April 11-12, 2001</p> <p>(page 14-006)</p> | <p>4 SCI males, manual wheelchair users</p> <p>(2 paraplegia, 2 tetraplegia)</p> | <p>1 session for at least 4 hours (after training)</p> <p>Trained therapists were present at all times to coach and spot subjects</p> |
| <p>Controlled Environment Study for INDEPENDENCE™ 3000 Advanced Mobility System</p> <ul style="list-style-type: none"> • Report (page 15-173) • Protocol (page 16-304) | <p>March 15 – June 3, 1999</p> <p>(page 15-173)</p> | <p>96 evaluable subjects</p> | <p>1 visit (approximately 6 hours)</p> |

Use of the INDEPENDENCE™ IBOT™ 3000 Transporter at Home and in the Community

Study Design

Non-randomized study performed at 2 sites. The purpose was to gain experience with the IBOT at home and in the community using 10 unimpaired non-wheelchair subjects and 4 expert manual wheelchair subjects having spinal cord injuries (SCI). The unimpaired subjects used the IBOT™ for 3 days during the period from March – July, 2001. The expert subjects were then trained and used the IBOT™ for 1 week during the period from July – September, 2001. Primary outcome measures for the expert subjects were the Activities of Daily Living Assessment (ADLA) and the Subject Specific Functional Scale (SSFS). Both of these assessments were conducted with the subjects in their own wheelchair versus the IBOT™. However, it is not clear whether unimpaired subjects were evaluated with these assessments using the IBOT™ as this is not discussed and data are not provided.

Results

The stair function was not used with the expert wheelchair (spinal cord injury [SCI]) subjects, but it is not clear whether the unimpaired subjects used this function.

The summary of activity recorded from the data-logger indicates that both unimpaired subjects and expert wheelchair subjects used the standard, 4-wheel and balance modes.

For the expert subjects, the balance function improved ability to reach higher levels. Otherwise, activities of daily living were essentially unchanged when comparing use of manual wheelchair to use of the IBOT™.

Reportedly, subjects indicated that the greatest benefits to be the ability to easily drive over grass, gravel and dirt using the 4-wheel function and to communicate with friends and colleagues at eye-level and to reach higher levels. The case report forms do not prompt the subjects to report which device, i.e., the manual wheelchair or the IBOT™, was easier to use. It is not clear if this subjective information is documented.

Device problems required visits from the service representative for 3 expert subjects and for 4 unimpaired subjects. One device problem experienced by an unimpaired subject did not require a visit.

Only one adverse event occurred and it was during the unimpaired user trial (unimpaired subjects participated from March – July, 2001 and expert subjects participated from July – September 2002). The device responded inappropriately

on the stairs during assessment of an unimpaired subject. Therefore, the stair function was disabled for the expert users. However, clarification regarding the consequences to this subject was not provided. Additionally, it is not clear whether unimpaired subjects used the stair function, since stair data were not provided. Page 16-286 noted a protocol change that removed the stair function from the protocol text, but this was dated May 9, 2001 and the study was initiated in March, 2001.

The sponsor clarified (E-mail dated October 23, 2002):

- *The primary learnings from this study were (pages 15-212 to 15-223):*
 - ◆ *The inclusion/exclusion criteria identified successful users of the device,*
 - ◆ *The assessment process identified successful users of the device,*
 - ◆ *FIM (Functional Independence Measurement) scores successfully demonstrated an increase in independence when using the device.*

- *The study also led to several changes in:*
 - ◆ *Device hardware – examples include footrest modifications, UCP quick release modifications, and armrest release modifications,*
 - ◆ *Device software - needing the ability for the clinician to turn device functions on/off,*
 - ◆ *Training – recognition that not only should subjects be taught how to operate the device, they also need to be taught how the device operates*
 - ◆ *FIM Scoring – a modification to the scoring system was needed to more accurately evaluate the device.*

Preliminary Assessment of a Prototype Advanced Mobility Device in the Work Environment of Veterans with Spinal Cord Injury

Study Design

This was a 4 patient feasibility study. The purpose was to collect qualitative data on the potential for the INDEPENDENCE™ IBOT™ 3000 to influence the ability of veterans who use wheelchairs to work. There were 4 SCI (2 paraplegia, 2 tetraplegia) subjects who worked in an office environment. The device was used for at least 4 hours to balance on 2 wheels for communicating with colleagues, to climb stairs, to go up steep ramps and to climb curbs. Trained therapists were present at all times to coach and spot subjects.

Note that the protocol for this study was reported to be the same protocol as used for the above pilot study (page 16-179, Appendix C-1) but the actual protocol does not discuss the VA site and data for the outcome measures specified in Appendix C-1 have not been provided.

Results

All 4 subjects used all functions except the remote function. Two of the 4 subjects believed that the IBOT™ would help them at work and all thought it should be made available to veterans who use wheelchairs. Reportedly, the subjects with tetraplegia gave higher ratings to the IBOT™ than the subjects with paraplegia for questions rating ease of getting around in the IBOT™ compared to the currently used wheelchairs. However, these data were not provided. Generally, complaints included difficulty or inability to pick up objects from the floor and difficulty using with office furniture and in tight places. No adverse events were reported, but therapists were present at all times to prevent injuries.

The sponsor clarified (E-mail dated October 23, 2002):

- *The primary learning from this study (page 15-159) was that the seat height was too high making it difficult or impossible to pick up items from the floor.*
- *Subjects also preferred the device be lighter and smaller.*
- *It is recognized this device characteristic (high seat height and device size) will mean the device is not appropriate to meet some people's needs.*
- *In spite of these device limitations, subjects were unanimous in the belief the device could improve integration and work performance in the work environment.*

Controlled Environment Study for INDEPENDENCE™ 3000 Advanced Mobility System

Study Design

This was a prospective, non-randomized, open label, single center evaluation which used participants as their own control.

Study objectives included the following:

- **Primary**
 - To determine the extent to which the FIM is able to demonstrate that successful candidates will have an increase in functional independence with regard to locomotion when using the INDEPENDENCE™ 3000 AMS versus their own device.
- **Secondary**
 - To assess the inclusion criteria and assessment process in identification of successful users of the INDEPENDENCE™ 3000 AMS.
 - To use a consistent assessment process to determine the recommendation or non-recommendation of the device and version of operation.

Ninety-eight subjects (32 skilled manual, 33 slow manual, 33 powered wheelchair users) were enrolled. Ninety-six evaluable subjects completed the study according to the protocol. Of the two non-evaluable subjects, one withdrew consent and one was tested without physician clearance. The subject who was tested without physician clearance had osteogenesis imperfecta (protocol required physician clearance for this medical condition) but had completed the solo testing in the 4-wheel and stair functions without incident. Page 15-194 (Protocol Deviations section) states that this patient was replaced.

Inclusion criteria required the subjects to have as their primary mobility device, a manual wheelchair, a power wheelchair with a hand-operated joystick control or a scooter. Exclusion criteria basically were concerned with the excessive weight and size of the subjects, insufficient joint range of motion to sit in the INDEPENDENCE™ 3000 AMS, inability to use current postural supports with the INDEPENDENCE™ 3000 AMS, inability to tolerate 6 hours of sitting, impaired level of consciousness or seizures in the last 90 days, conflict of interest and function specific cardiac, pulmonary and fracture risk factors.

Subjects were tested in a simulated environment during a single visit. The standard, 4-wheel, balance and stair functions were tested. Outcome measures included:

- **Primary**
 - Combined total FIM score of locomotion and stair tests

- The percent of recommended for INDEPENDENCE™ 3000 AMS evaluable subjects
- Secondary
 - Breakdown by versions, “Assist” “Modified Solo” “Solo” of percent recommended for INDEPENDENCE™ 3000 AMS evaluable subjects
 - Total FIM score of rough terrain (outdoors) test, 4-wheel function
 - Total FIM score for balance function

Results

Ninety-five of the 96 (99%) evaluable patients were identified and recommended as successful prospective users of the INDEPENDENCE™ 3000 AMS based on the results of the comparison of a test drive in the INDEPENDENCE™ 3000 AMS versus the subject’s own mobility device. Fifty-five (57%) of the 96 evaluable subjects were recommended for the Solo operation. The percent of evaluable subjects recommended for Solo operation were as follows:

- 96.8% of the skilled manual users
- 48.5% of the slow manual users
- 28.1% of the power users

The remaining subjects required additional input from an assistant to activate particular functions of the device.

Successful candidates demonstrated a highly significant increase of mobility independence for the standard plus stair-climbing functions when comparing the mean total FIM scores for the investigational versus the subject’s own device. However, note that this was a combined score (i.e., standard function score plus stair climbing score). The 4-wheel function scores (mean total FIM score) also were significantly higher for the investigational device. There was a smaller but significant increase in mean total FIM scores for balance function. Power users and slow manual users experienced a greater gain with respect to uneven surface mobility independence than skilled manual users.

No adverse events were reported during the trial, but an anonymous market research survey sent to the study participants revealed 2 subjects reported adverse events. Of the 98 surveys, 82 were completed and returned. Both subjects reported back pain and one of these subjects also experienced seasickness.

The sponsor clarified (E-mail dated October 23, 2002):

The primary learning from this study was:

- *Training Program – For some study participants the Training Program was too much for a single training session. The training materials were redesigned to be delivered in a modular fashion, which corresponds with the programmability of the product. Training could then be delivered in an all-in-one session or divided along the function modules:*
 - *Standard and 4-Wheel*
 - *Balance*
 - *Remote*
 - *Stair Climbing*
- *Product Design – As a result of the experience with the able-bodied subjects, changes were made to the stair-climbing function to improve both its safe and efficacy.*
 - *Safety Cluster lock was added to prevent multiple cluster rotations if poor stair climbing technique is detected.*
 - *Changes were made in the product's performance on sloped surfaces to prevent the driver from getting stuck between flights of stairs when climbing outdoor stairs.*

Pivotal Trial

Study of the INDEPENDENCE™ IBOT™ 3000 Mobility System During Real World Use

Study Design

Single center, prospective, balanced, open label study. Subjects served as their own control using their own wheelchairs versus the investigational mobility device. This consisted of a 2 subject pilot phase followed by an 18 subject real world phase. The pilot phase was used to refine the real world phase protocol.

Study Duration

This trial was conducted from February to May, 2002 (page 14-003).

Objectives

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

Hypotheses

- Community Driving Test scores will be higher when subjects use the INDEPENDENCE™ IBOT™ 3000 Mobility System versus their current wheelchair (manual, power or scooter) at the end of the real world trial period.
- The Subject Specific Functional Scale (SSFS), a subjective rating form will show an improvement in functional mobility when using the INDEPENDENCE™ IBOT™ 3000 Mobility System versus their current wheelchair.

Study Population

Twenty-nine subjects were enrolled and 20 subjects (2 Pilot Trial subjects and 18 Real World Trial subjects) completed the study.

- Two of the enrolled subjects were not recommended for IBOT™ due to poor dexterity (patient # 10 - diagnosis was rheumatoid arthritis) and vision problems (patient # 23 – diagnosis was head injury with R hemiplegia).

- Six subjects withdrew prior to the Day 1 Training (2 voluntarily withdrew consent and the sponsor ended 4 subjects' participation.)
- One subject voluntarily withdrew after the first day.

Of the 20 subjects who completed the study, the first 2 subjects participated in the pilot phase which included only 1 week of use with the investigational device as compared to 1 week of use with the subjects' current mobility devices. Eighteen subjects completed the Real World Trial which required 2 weeks of use with the investigational device as compared to 2 weeks of use with the subjects' current mobility devices.

Evaluable Subjects

Pilot Phase 2 skilled manual wheelchair users

Real World Phase 18 subjects:

- Skilled manual wheelchair users 6 subjects
- Slow manual wheelchair users 6 subjects
- Power wheelchair users 6 subjects

Demographics:

Gender Males 16 subjects
 Females 4 subjects

Age Mean: 43.7 years
 Range: 27-67 years

Weight Mean: 165 pounds
 Range: 81-230 pounds

Medical conditions Spinal cord injury (SCI) 13 subjects

- Tetraplegia - 4 subjects
- Paraplegia - 9 subjects

SCI Tetraplegia + Amputation 1 subject

- Right Below knee amputation (BKA)

Amputation 2 subjects

- BKA and above knee amputation (AKA) - 2 subjects

Neuromuscular disease 4 subjects

- Transverse myelopathy T10 – 1 subject
- Spina Bifida – 1 subject

- Idiopathic generalized dystonia – 1 subject
- Chronic progressive multiple sclerosis – 1 subject

Inclusion Criteria

- 18-80 years of age
- Willing to use a wheelchair accessible van or accessible public transportation during participation in the study (willing to transfer out of the INDEPENDENCE™ IBOT™ 3000 Mobility System and sit in the vehicle seat of the van and/or public bus)
- Willing to give written, informed consent to participate in the study
- Willing to sign a non-disclosure/confidentiality agreement
- Using one of the following mobility aides:
 - Manual wheelchair
 - Power wheelchair with a hand-operated joystick control
 - Scooter as their primary mobility device
- And can be defined as:
 - Skilled manual wheelchair user; identified as a new user 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 person 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 user who is using a power wheeled mobility device as either his/her primary means of mobility outside their home

Exclusion Criteria

- Weighs > 250 pounds
- Unable to use a wheelchair seat between 14” and 20” wide
- Not able to bend knees such that feet fit on standard footrests
- Not able to bend hips enough to sit in a standard wheelchair that does not recline
- Does not have sufficient function of at least 1 upper extremity to dial a pushbutton telephone and operate a hand-operated joystick
- Current postural supports are not compatible/comparable with those on the IBOT™
- Experienced impaired level of consciousness or seizure in the last 90 days which did not meet the appropriate exceptions referenced in the advocacy statement overview for Driving Licensing of the 1996-1998 Epilepsy Foundation of America.
- Requires use of a tilt or recline seating system to perform activities of daily living
- Requires use of tilt or recline seating systems as a mechanical method of pressure relief
- Requires assisted mechanical ventilation

Study Specific Exclusion Criteria

- Lives outside the geographical area of trained personnel
- Not able to tolerate sitting for 4 hours or more without requiring tilt and recline to relieve pressure
- Works (subject or family member) for a manufacturer or supplier of wheelchair or seating systems
- Unable to use own cushion due to sizing or other reasons (if subject had prior pelvic/ thigh region decubitus ulceration); if no prior ulceration, subjects will be given currently marketed cushion that fits the IBOT™
- Has active pelvic/ thigh region decubitus ulceration

Function Specific Exclusion Criteria

Solo Stair Function

- Cardiac risks
 - New York Heart Association Classification
 - Class I subjects allowed to try solo stair climbing with questioning and observation regarding fatigue, palpitations, dyspnea or anginal pain
 - Class II or higher subjects allowed to try “assist” stair climbing.
- Pulmonary risks
 - Pulmonary Disability Classification
 - Class III closely monitored and stair climbing halted if shortness of breath is noticed
 - Class IV or higher restricted to “assist” operation and will not participate in solo stair climbing or solo 4-wheel training or testing
(Note: The sponsor clarified that the “assist” 4-Wheel function was not available in this pivotal trial and that they unintentionally forgot to revise this portion of the protocol and the case report form.)
- Fracture risks
 - Severe osteopenia
 - Osteogenesis imperfecta
 - Spinal metastatic bone cancer

Curb hopping in 4-Wheel Function

- Fracture risks
 - Severe osteopenia
 - Osteogenesis imperfecta
 - Spinal metastatic bone cancer

Balance Function

- Fracture risks
 - Severe osteopenia
 - Osteogenesis imperfecta
 - Spinal metastatic bone cancer

Methods

For both the pilot and the real world phases, subjects assessed use of the investigational devices (IBOT™), as well as their own mobility devices, in their own environments for equal amounts of time (1 week during the pilot phase and 2 weeks during the real world phase). With respect to order of use, the monitored home and community use of the investigational device occurred first for the 2 subjects in the pilot phase and for approximately half of the real world subjects. For the rest of the real world subjects, monitored home and community use of their own devices occurred first.

Subjects for the pilot and the real world phases received training (2 days) prior to taking the IBOT™ home. During the period when the IBOT™ was used in the subjects' environments, they maintained daily mobility logs that included inquiries about locations of travel, accessibility and any problems, e.g., injuries, falls, device problems, etc. Subjects were also called daily for downloading of the IBOT™'s event logs (recorded on the IBOT™'s computer) via a modem connection using the Service Interface program and a PCMCIA modem card. These computerized logs documented events of device usage with respect to functions used (e.g., times used and distances traveled per function) and hours without a fault. The logs also documented frequency of various device actions that occurred, e.g., device shutdown due to detection of loss of control of stability, service triggers, and other device actions triggered by detection of a potentially unsafe event. (See Table L, page 14-081 and Table M, page 14-082)

During the period when subjects monitored the use of their own mobility devices, they also maintained daily mobility logs that included inquiries about locations of travel, accessibility and any adverse events or other problems that occurred.

All subjects returned for assessments after the 2-week IBOT™ use period. They completed a Community Driving Test and a post-experience Subject Specific Function Scale (SSFS), first using their own mobility devices and then using the IBOT™.

Assessments and Training

Subjects

Subject assessments and training consisted of the following:

- 1) Telephone Screening
 - (a) Telephone Screening Form (page 16-037)
 - (i) Telephone Screening Form will be revised as the Product Qualification Survey for marketing to eliminate study specific information
- 2) Mailings to Subjects
 - (a) *Home Assessment /Transportation Assessment Survey* (page 16-045)
 - (i) *Home Assessment /Transportation Assessment Survey* has been revised for marketing to eliminate study specific information
 - (b) Cardiac Form, Pulmonary Form and/or Fracture Risk Form (if needed, pages 16-041 & 16-068)
 - (i) For the marketed device, these forms will be revised to condense these 3 forms into one form. A device description will be included along with the risks associated with each function. (E-mail dated October 22, 2002)
- 3) Clinic Assessment (Prior to device delivery)
 - (a) *Verification Survey* (Appendix O, page 16-064)
 - (i) *Verification Survey* has been revised for marketing to eliminate study specific information.
 - (b) *Medical Interface Manual* (page 19-001)
 - (c) *Assessment Guidebook* (page 18-252)
- 4) Materials delivered prior to receipt of device and final training
 - (a) *User Manual* (If deemed appropriate to continue; page 18-006)
 - (b) *Quick Reference Cards* (page 18-232)
- 5) Clinic Training and Assessment (During device delivery and final training)
 - (a) *Delivery Interface Manual* (page 19-072)
 - (b) *Delivery Guidebook* (page 19-133)
 - (c) Videos (Video Scripts - page 19-369)

Clinician Training

Clinician training (Fax dated September 25, 2002) consisted of the following:

- 1) Independence Technology (IT) representative trained non-IT clinicians how to drive/operate the IBOT™ using the following materials:
 - (a) Clinician
 - (i) *User Manual* (page 18-006)
 - (ii) *Quick Reference Cards* (page 18-232)
 - (b) IT representative
 - (i) *Delivery Guidebook* (page 19-133)

- 2) Clinician Training Program
 - (a) Learned how to assess a client for the device:
 - (i) Mat assessment
 - (ii) Calibration lab
 - (iii) Orientation/training of each function
 - (iv) Functional capacity evaluation considerations
 - (b) Materials used:
 - (i) *Medical Interface Manual* (page 19-001)
 - (ii) *Assessment Guidebook* (page 18-252)

- 3) Clinician Training Program
 - (a) Learned how to deliver the training to a client receiving the device:
 - (i) Clinician presentations/driving for each module
 - (ii) Safe and effective driver's test considerations
 - (iii) Role playing
 - (b) Materials used:
 - (i) *Delivery Guidebook* (page 19-133)
 - (ii) *Delivery Interface Manual* (page 19-072)
 - (iii) Clinician Observation Test Video (Video Scripts - page 19-369)

- 4) Observation in the field
 - (a) (IT representative observed clinicians during each process with a client)

Outcome Measures

The primary outcome measure:

- *Community Driving Test* (15 tasks with 7-point scale, Appendix D, page 16-034)

The secondary outcome measure:

- *Subject Specific Function Scale* (SSFS) (Appendix E, page 16-036)

Additional data:

- Data Logger [computerized accounting of device actions and usage (time and distance) of each of the IBOT™'s functions]
- Daily Mobility Activity Log (own and IBOT™ devices)
 - Accessibility Problems
 - Mechanical and Operational Problems
- Subjective Evaluation of Home and Community Maneuvering

Success Criteria and Timepoints

Success was determined after the end of the IBOT™ home/community use period (1 week for pilot trial and 2 weeks for the real world trial) through comparison of the community driving test scores with the IBOT™ as compared to the scores obtained with the subjects' own mobility devices. Similarly, the SSFS scores with the IBOT™ as compared to the scores obtained with the subjects' own devices were also performed to determine success. The non-parametric method of Wilcoxon signed-ranked test was applied ($p\text{-value} \leq 0.05$).

Results

Safety

The following discusses adverse events with respect to injury to subjects as well as device actions, problems and failures that could potentially place users at risk for injury.

Adverse Events

Bruises were experienced by 2 of the 20 subjects (10%). One of these patients pinched his mid-forearm between the UCP and the armrest and received treatment (forearm pad applied). The other patient received a bruise on his leg due to the device falling over but no treatment was required. (pages 14-061 and 14-065).

Five falls were reported (2 patients fell with their own devices and 3 patients fell with the IBOT™). Only one of these patients reported injury, i.e., 1 bruise was reported (also noted above). (pages 14-062 and 14-065).

Four other adverse events occurred that were not device related as they were experienced when using their own devices (pages 14-061 and 14-062).

Device Failures

Device failures may indicate potentially harmful situations, especially depending on where the user is when the problem occurs. However, none

of the reported device failures resulted in injury to the subjects. Table X (page 14-099) summarizes the device failures and corrective actions for both the investigational device and the subjects' own mobility devices:

Twelve of the 20 subjects experienced a total of 22 events that resulted in device replacement or one or more component replacements. Nine of these events occurred with the subjects' own devices and 13 events occurred with the IBOT™.

The replacements required during this study included the following:

➤ IBOT™ replacements included:

- 3 Devices
 - ◆ One patient had the IBOT™ replaced twice
 - ◆ One other patient also had the IBOT™ replaced
- 1 Powerbase
- 2 Wheel assemblies
- 3 Caster assemblies
- 1 Seat assembly
- 2 Modems
- 3 Modem cables
- 1 Modem card
- 1 Backrest shroud
- 1 Non-UCP armrest
- 1 Non-UCP armrest cover

Regarding the 3 IBOT™ device replacements noted above, the sponsor reports that each of these device replacements could have been handled as a component replacement. The sponsor replaced the device in order to minimize inconvenience to the subject. The problems that prompted these IBOT™ replacements included:

- Bent charger port pin
- Seat height unable to adjust
- UCP backlight failed to function during stair training

➤ Replacements to subjects' own mobility devices included:

- 1 Spring loaded piece in wheel hub
- 1 Bearings on casters
- 1 Armrests
- 1 Lever cable
- 1 Bolt on caster
- 3 Tires (Note: 3 events report replacement of tires but the number of tires is not specified)

- 1 Wheels (Note: 1 event reports replacement of wheels but the number of wheels is not specified)
- 1 Bolt on backrest
- 1 Bolt (not specified)

Data Logger Distributions

Computerized alert and failure data accumulated while subjects were using the investigational device (IBOT™) are provided in Tables L and M (pages 14-081 and 14-082 respectively). These alerts and failure actions may indicate occurrence of potentially harmful situations, especially depending on where the user is when the problem occurs. However, there was only 1 case in this clinical trial where a controller failure was associated with injury, i.e., a bruise that did not require medical attention.

Table L provides data such as counts of various alert and failure situations, as well as other usage data. Table M provides a breakdown of the most of the data presented in Table L into 3 components, i.e., data from the training days, data from the return test day, and data from use at home and in the community. Tables L and M are discussed in more detail under the *Effectiveness* section below. For the purposes of safety discussion, only the alert and failure data will be discussed in this section.

Note that the sponsor identified a mistake on these tables in that there was 1 additional service trigger, i.e., there were a total of 17 service trigger counts. (E-mail October 15, 2002)

The alert/failure data included but were not limited to the following (See Tables L and M for additional data):

| <u>Alert or Failure Action</u> | <u>Total (count)</u> |
|--------------------------------|----------------------|
| 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 |

The sponsor clarified (E-mail dated October 15, 2002) that none of above alert or failure actions were associated with an injury to a subject, except for one case. Subject 27 experienced lateral instability and fell while in the balance function. The right wheel struck a 5 inch curb and attempted

to climb it. The controller failure and subsequent shutdown were triggered when the device sensed that it was falling. The subject received a bruise on his leg that did not require medical attention. It is not clear whether the shutdown contributed to the injury since the IBOT™ was already falling.

With respect to the 5 controller failure counts, three occurred in relation to IBOT™ falls. In two of these cases (subjects 11 and 27), an event occurred which caused the device to fall. In each of these cases, the fall triggered the controller failure and subsequent device shutdown. As noted above, subject 27 received a bruise that did not require medical attention.

The remaining fall was caused by the triggering of the controller failure and subsequent shutdown of the IBOT™. Subject 12 leaned so far forward that his center of gravity went outside of the wheelbase of the device. The device attempted to correct the situation by traveling forward (attempting to move the device under the subject). However, after the IBOT™ traveled approximately 10 feet, the safety check routine assumed the dynamic stabilization was not working and declared a controller failure. This triggered the device to go into total system shutdown to prevent continuance of an out-of-control situation. The device fell subsequent to the device shutdown, but the subject received no injuries. The sponsor noted that the IBOT™ is designed to respond in this fashion because it is believed that allowing the out-of-control situation to continue could cause injury especially if the device runs into something.

Subject 29 experienced controller failure while attempting to climb stairs with an assistant. Stair climbing was attempted while in the balance function. The controller failure triggered device shutdown with the rear wheels resting on the first step. Passersby helped move the device (with the subject in the IBOT™) off the step and the device was powered up and functional.

The fifth controller failure was experienced by subject 17. This occurred during an attempt to remove the IBOT™ from a van. The footrest got caught under the van seat and the IBOT™ was pitched >35 degrees at startup. This triggered controller failure and subsequent shutdown. After freeing the footrest, the device powered up and was functional.

With respect to the other reported alerts, there was no consequence to the subjects, unless service alert reaches a count of 3. In such a case, the IBOT™ will not enter the balance function. The sponsor clarified that for each reported alert or failure count, the IBOT™ responded as it was designed to do, i.e., the safeguards incorporated into the device's design worked correctly.

Upon inquiry by FDA regarding whether a subject's medical condition contributed to any of the device failures or problems, the sponsor concluded (E-mail dated October 15, 2002) that a subject's medical condition could contribute to a controller failure. In two cases where the device fell, one in 4-wheel function (Subject 12, page 14-064) and one in balance function (Subject 27, page 14-065), the subjects' physical functioning may have contributed to the falls. For example:

- Subject 12 had a C6-C7 spinal cord injury and a right below knee amputation. His large body build but poor to fair tone and muscle control of the trunk along with his compensation of large movements of his trunk to achieve a functional trunk position may have contributed to the IBOT™'s fall. He had been trying to cause the rear wheels to lift off the ground (which is not the recommended way to use the device) by leaning this trunk far forward. As the device started to travel forward to get the wheels under the subject's center of mass, the subject could not lean backward to attempt to regain control due to his medical condition which compromised his voluntary trunk control.
- Subject 27 had a C6 spinal cord injury and lacked finger flexion to grip the joystick. This may have contributed to his fall. As he attempted to avoid a hazard, he turned too far to the right, struck a curb and fell laterally. Having better grip of the joystick may have prevented the fall. However, the sponsor noted that his joystick control under routine driving situations was consistent with all current power wheelchair users having a lower cervical spinal cord injury.

Effectiveness

Only the 18 Real World Trial subjects were included in the statistical analysis for the *Community Driving Test* and for the *Subject Specific Function Scale (SSFS)*.

Community Driving Test

Scores ranged from 0 to 6 as follows:

- 0 Unable to perform or refuses to perform task
- 1, 2, 3 Performs task with assistance
(Maximum, moderate or minimum exertion respectively)
- 4, 5, 6 Performs task independently
(Maximum, moderate or minimum exertion respectively)

A change from *unable to perform* (0) to any score performed with assistance (i.e., 1, 2, or 3) or to any score performed independently (i.e., 4, 5, or 6) was considered to be an improvement in independence. Likewise, a change from any of the scores requiring assistance to any score

performed independently was considered to be an improvement in independence. Note that the *Community Driving Test* only tested subjects using the 1 rail technique for stair climbing because the stair cases used were too wide to use the 2 rail technique. (E-mail dated October 23, 2002 and photos, pages 14-027 through 029)

Note also that no patients used the slow speed template and 2 of the 20 subjects used the fast speed template. The speed templates assigned were as follows (page 14-058):

- Slow 0 subjects
- Medium 18 subjects
- Fast 2 subjects

The *Community Driving Test* demonstrated a highly statistically significant (using the total scores) difference in favor of the IBOT™ as compared to the users' own mobility devices. (Table H, page 14-070) All subjects' total scores improved with the IBOT™ as compared to the current mobility devices.

Every subject had an increase in total stair scores (Tables H and I, pages 14-070 and 14-071) and was a success in this trial. All but 2 patients improved to a more independent score in all tasks with stairs. Only 1 subject (subject #13) scored 1 point lower for one of the stair tasks (*Down Interior Stair*) using the investigational device as compared to his/her own mobility device. This subject achieved an improvement in independence for all other stair tasks. The other subject (#26) improved by 2 points in each stair task but did not increase to a more independent level.

The stairs scores also indicate that 10 subjects were independent on the stairs when tested with the IBOT™, i.e., scores were 4, 5, or 6. However, the *Demographic Analysis* of the study report (page 14-058) indicates that 12 subjects achieved *solo* status for stairs. This apparent discrepancy was clarified by the sponsor in an E-mail dated October 23, 2002. It was confirmed that 12 subjects achieved *solo* status for stairs (as determined with *Part B - Safe and Effective Driving Test*, page 16-078 and 16-079); however, 2 of these subjects (#6 and # 11) were able to climb stairs with 2 rails only. These subjects also had trained assistants due to expectations that some stairs likely to be encountered in their environments would require assistance. The *Community Driving Test* only tested subjects using the 1 rail technique for stair climbing because the stair cases used were too wide to use the 2 rail technique. Therefore, subjects #6 and #11 were tested using the assistants for stair climbing. In summary:

Solo versus Assist Stair Climbing

- Twelve subjects achieved *solo* status for stair climbing.
 - Four of these 12 *solo* subjects also had a trained assistant for the “assist” stair climbing due to concerns with some of the stairs that were anticipated to be encountered.
 - Two of the 4 solo plus “assist” stair climbing subjects were cleared for solo stair climbing with 2 rails only (not for 1 rail).
- Eight subjects required the “assist” stair configuration. (page 14-058)

Standard function scores were similar to those obtained with the subjects’ own mobility devices. While manual slow subjects showed a benefit with the IBOT™ in the standard mode, this would probably have been accomplished with any power device as noted by the sponsor.

The majority of the real world subjects improved their level of independence in the balance task (i.e., 13 out of 18 subjects) and in 5 of the 6 tasks with the 4-wheel function. For the 4-wheel task, *Negotiate Uneven Terrain*, all of the *manual slow (MSL)* subjects improved their level of independence with the IBOT™, whereas none of the manual skilled subjects and only 1 of the power subjects improved to a higher level of independence in this task when using the IBOT™. Seven of the 11 subjects who did not experience a higher level of independence in this task had better scores (1 point improvement) with respect to level of exertion during the task when performed with the IBOT™. Four of these subjects scored the same with the IBOT™ as with their own mobility devices.

Only 2 subjects scored better on an individual task with their current devices as compared to the IBOT™. One subject scored 1 point higher with the current mobility device for the *Down Interior Stair* task as he descended stairs in the manual wheelchair by going down the steps backwards and using his arms to control falling backwards onto each lower step. Another subject scored 1 point higher with the current mobility device for the *One Step Exit* task because the subject had deemed the exit step to be >4 inches high and did not attempt this task. This subject, however, scored a 6 when using the investigational device for each of the other 4-Wheel tasks.

Standard function was tested by 3 tasks and by one additional task that could be completed in standard or 4-wheel function. 4-wheel function was tested by 6 tasks in addition to the task that could be completed in standard or 4-wheel function. Stair function was tested by 4 tasks. However,

Balance function was only tested by 1 task (*Retrieves Book off High Shelf*) and Remote function was not tested.

Subject Specific Function Scale

Statistical tests for increase in score and for increase in independence are highly statistically significant. (See pages 14-072 through 14-076) However, as noted by the sponsor, this assessment's value is limited since not all patients identified the same tasks and since the assessment is focused on tasks that subjects are unable to perform or perform with difficulty with current devices, it is expected that scores with the current devices would be low. Regardless of the limitations, these data provide insight into some additional benefits and limitations that can be expected with the IBOT™.

Additional Effectiveness Data

Data Logger Distributions

Data accumulated while subjects were using the investigational device (IBOT™) are provided in Tables L and M. (pages 14-081 and 14-082) Table L provides data such as the percent of the time used in each function, the percent of the total distance traveled for each function, the total times and distances for each function and overall, counts of various alert and failure situations, etc. Table M provides a breakdown of the data into 3 components, i.e., data from the training days, data from the return test day, and data from use at home and in the community. However, the data for the home and community use are somewhat underreported because data collected on training or testing days could not be separated into data from home/community use versus data collected during the actual training or testing period.

While only one task was tested in the balance function with the Community Driving Test, data in Tables L and M provide additional data that presents a more complete understanding of the IBOT™'s usage in this function. For example, it indicates that subjects spent a total of 138.0 hours in the Balance function, and 94.7 of these hours were actually spent in the Balance function during home and community use (the rest of the time was experienced during training and testing). The median time spent in balance function was 5.4 hours.

Data listings for individual subjects (E-mail dated October 15, 2002) indicate that 7 subjects used the Balance function for < 2 hours total. One of these patients used the Balance function for 0.7 hours. It is not clear whether any of the time spent in the Balance function was during home

and community use for these subjects. However, 13 subjects used the Balance function for > 2 hours during the real world trial, with 1 patient having used it for 18.4 hours.

While Table M reports a total of 5.9 hours for the Remote Hour Meter, the patient listings (E-mail dated October 15, 2002) indicate that only subject #2 used this function (12% of the total time). None of the other subjects had any experience with the Remote function.

Note that the sponsor identified a mistake on these tables in that there was 1 additional service trigger, i.e., there were a total of 17 service trigger counts. (E-mail October 15, 2002)

The sponsor clarified that none of counted alert or failure events resulted in injury to the subjects, except one fall that triggered the device to go into total system shutdown to prevent continuance of an out-of-control situation. The subject in this case received a bruise that did not require medical attention. In one case, the total system shutdown caused the subject to fall but this subject was not injured. However, if the device had not shutdown, the patient would likely have run into something which may have caused injury. The sponsor clarified that in each case of an alert or failure count, the IBOT™ responded as it was designed to do, i.e., the safeguards incorporated into the device's design worked correctly.

Device Failures

Table X (page 14-099) summarizes the device failures and corrective actions for both the investigational device and the subjects' own mobility devices.

Twelve of the 20 subjects experienced a total of 22 events (for both mobility devices) that resulted in device replacement or one or more component replacements. Nine of these events occurred with the subjects' own mobility devices and 13 events occurred with the IBOT™. See the *Safety: Device Failures* section above for additional details.

Daily Activity Logs

Daily activity logs were maintained to collect information on specific daily activities, accessibility problems, and mechanical /operational difficulties. These data were reported for all 20 subjects (i.e., pilot + real world subjects):

Accessibility Problems

A total of 165 accessibility problems were reported. Table N (page 14-084) reports 86 accessibility problems were experienced with the subject's own mobility device and 79 were experienced with the IBOT™. Accessibility problems were categorized and the results were reported as follows:

| Nature of Accessibility 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 heights limits accessibility | 1 | 34 |
| Battery limitation | 0 | 4 |
| Other | 5 | 4 |

The sponsor noted that the number of accessibility problems was similar for both devices; the nature of problems was different for each device. For example, when in their own devices, subjects mainly experienced accessibility problems with respect to accessing a location. Thirty-eight subjects could not access a site due to curbs, terrain, etc., whereas only 3 subjects experienced problems of this nature when using the IBOT™. Twenty-eight subjects had problems accessing sites due to stairs, whereas only 12 subjects had such a problem using the IBOT™. Similarly, thirteen subjects experienced difficulties accessing high shelves, counters, etc., no subjects had such problems when using the IBOT™.

The nature of the accessibility problems with the IBOT™ were primarily related to the maneuvering the device and the high seat height which makes it difficult to maneuver under tables. Tables O through U (pages 14- 085 through 091) list the comments for each accessibility problem.

Mechanical /Operational Difficulties

Table V (page 14-092) summarizes the number and category of the mechanical /operational difficulties for each device.

| 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 |

Table W (pages14-094 through 097) lists each specific mechanical /operational difficulty. The main differences occurred for *Battery difficulties*, *User Control Panel* difficulties and *User Techniques* difficulties, with subjects reporting these difficulties more often with the IBOT™. However, as noted by the sponsor, manual devices do not have batteries or user control panels. Therefore, the rate of difficulties with these items would be expected to be lower than the rate experienced with the IBOT™, which was used by all of the subjects. The sponsor also points out that 6 of the 18 battery difficulties were for *low battery at end of day* which occurred on a training day when extensive use was required.

Subjective Evaluation of Home and Community Maneuvering

On the final day of participation with the IBOT™ and on the final day of participation with their own mobility devices, subjects answered the following questions:

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

Subjects rated these using a 4-point scale (poor, fair, good, excellent) for each question. The results (Table Y, page 14-100) were presented as follows:

| Home and Community Maneuvering Summary | | | |
|---|------------------|--------------------------|------------------|
| Maneuvering | Decreased | Remained the Same | Increased |
| Home | 13 | 5 | 2 |
| Community | 1 | 5 | 14 |

The IBOT™ tended to be less maneuverable in the home and more maneuverable in the community compared to subjects' own devices.

Human Factors Concerns

Having the power button next to the charging port initially raised concern, but the sponsor clarified that the charging port is designed so that the user cannot receive an electrical injury from inadvertently placing a finger into the charging port. The following are remaining human factors concerns that have the potential for causing injuries to users:

- Joystick
 - Can be disabled but is re-enabled with pushing any button (except for the backlight button)
 - Subject #6 experienced this problem, i.e., accidentally re-enabled the joystick and a person reaching across caused unexpected movement of the device (page 14-097)
- Pinch points
 - The *User Manual* describes a number of device features where a user can get pinched
- User Control Panel
 - Difficult to detach from armrest and user may get hurt or might not be able to remove for using remote function
- Display
 - Difficult to see due to glare and when operating joystick (hand covers the display)
- Alarm tones and icons
 - Tones/beeps are difficult to hear and background noise can mask entirely
 - There are some situations where a tone/beeping occurs but there is no icon to indicate what the specific problem is, e.g., when an incorrect selection is made or the device is approaching the product operating limits
- Horn
 - Difficult to hear

- Stair Mode

- Does not prompt user to hold onto railing, which is important to safe operation

Conclusions

The device was demonstrated to be effective as measured by the primary outcome measure, the Community Driving Test. This assessment tool had some limitations, e.g., it did not assess use of the remote function or the 2-rail stair function and only one task was assessed using the balance function.

The secondary outcome measure, the Subject Specific Function Scale (SSFS), also demonstrated effectiveness although there were limitations to this assessment method as noted by the sponsor:

- The tasks were not standardized for all subjects; validity drawing broad conclusions is questionable.
- Since subjects were instructed to choose tasks they had difficulty performing, it was anticipated that scores in their own devices would be low. Note however, that of the 73 total observations, subjects scored 24 as being able to do independently and 10 of these were independent with moderate or minimal exertion.

Additional data to be considered for effectiveness included activity and problem logs (manually recorded on a daily basis for both mobility devices) and computerized accountability logs for the IBOT™ (also collected on a daily basis). For example, while only one task was assessed for the balance function in the Community driving test, observational data indicate that all subjects used the balance function but also noted very short usage periods for some subjects. Limitations of these data must also be considered. For instance, subjects were not repeating identical daily tasks in the same locations for the periods of IBOT™ use as compared to the period that they monitored use with their own mobility devices. Therefore, some situations that presented difficulty may not have been attempted with both mobility devices.

The only IBOT™ function that was not used (except for use by 1 subject as noted with data logger data presented by subject; E-mail dated 10-15-02) or tested was the remote function. While subjects were deemed to be safe users of the stair function with 1 and/or 2 rails, the 2-rail function was not tested with the primary outcome measure. Additionally, 18 subjects used the medium speed template and only 2 subjects used the fast speed template; none used the slow template, except 1 subject who used it for 1 day only and then was given the medium speed template (E-mail dated 4, 2002).

The standard function of the IBOT™ appears to provide functions similar to subjects' own mobility devices, although when used in the indoor environment, there were more difficulties primarily related to the maneuvering the IBOT™ and its high seat height which makes it difficult to maneuver under tables. The IBOT™ tended to be less

maneuverable in the home but more maneuverable in the community as compared to subjects' own mobility devices.

Safety analysis reveals that minimal injury (two bruises) occurred during the pivotal trial. While design features (e.g., automatic triggering of device shutdown) having potential for a harmful consequence were experienced, only one case (i.e., controller failure that triggered device shutdown) caused the IBOT™ to fall. This fall did not cause injury to the subject. Only one case of device shutdown was associated with injury, i.e., a bruise that did not require medical attention, however, it is not clear whether the shutdown contributed to this adverse event since shutdown was triggered as the IBOT™ sensed that it was falling over.

Users of the IBOT™ must have adequate physical capabilities and must be capable of decision making, e.g., in order to determine which curbs, obstacles and slopes are within the IBOT™'s performance capabilities. A number of human factors concerns have been identified that may be eliminated with design and/or labeling revisions in order to reduce risk of injury.

The sponsor will require that clinicians receive certification prior to being allowed to train patients and the IBOT™ will bear prescription labeling. The sponsor revised the labeling in accordance with two of the falls experienced with the IBOT™ as noted on page 14-064. A number of additional labeling revisions should be made to improve safe and effective use of the IBOT™.

Additional study limitations that should be considered for this pivotal trial include the relatively small number of patients studied and the short period of time (two weeks) during which the IBOT™ was studied. Assessment and training requirements were intensive (i.e., they required significant time and effort to read and comprehend the materials and to conduct the assessments and training) for subjects and for clinicians, but have been used with only 20 subjects and 9 therapists. Finally, it is not clear whether additional risks will be demonstrated with long term use of this device in users' homes and communities as long term safety and effectiveness data are not available.

ATTACHMENT 1

| PMA Organization: Pilot and Pivotal Study Reports and Protocols | |
|--|-----------------------------------|
| Pivotal Study | |
| Study of the INDEPENDENCE™ IBOT™ 3000 Mobility System During Real World Use (February – May, 2002) | PMA Volume-Page / Appendix |
| • Report | 14-009 Appendix A |
| • Protocol | 15-224 Appendix B |
| • Protocol Amendment 1 | 15-317 Appendix B-1 |
| • Protocol Amendment 2 | 16-002 Appendix B-2 |
| Pilot Studies | |
| Title | PMA Volume-Page / Appendix |
| Use of the INDEPENDENCE™ IBOT™ 3000 Transporter at Home and in the Community (March – July, 2001) | |
| • Report | 15-125 Appendix A-1 |
| • Protocol | 16-179 Appendix C-1 |
| Preliminary Assessment of a Prototype Advanced Mobility Device in the Work Environment of Veterans with Spinal Cord Injury (April 11-12, 2001) | |
| • Report | 15-147 Appendix A-2 |
| • Protocol | 16-179 Appendix C-1 |
| Controlled Environment Study for INDEPENDENCE™ IBOT™ 3000 Mobility System, Integrated Clinical and Statistical Report (March 15 – June 3, 1999) | |
| • Report | 15-173 Appendix A-3 |
| • Protocol | 16-304 Appendix E |