

**SUMMARY MINUTES**

**MEETING OF THE ORTHOPAEDICS AND REHABILITATION DEVICES  
ADVISORY PANEL**

**OPEN SESSION**

**NOVEMBER 20, 2002**

**Gaithersburg Holiday Inn  
Gaithersburg, MD**

## Meeting of the Orthopaedics and Rehabilitation Devices Advisory Panel

### Attendees

November 20, 2002

#### *Chairperson*

Michael Yaszemski, M.D., Ph.D.

#### *Executive Secretary*

Hany Demian, M.S.

#### *Members*

Maureen A. Finnegan, M.D.

Richard J. Friedman, M.D., FRCS

John S. Kirkpatrick, M.D.

Kinley Larntz, Ph.D.

Sanjiv H. Naidu, M.D., Ph.D.

#### *Consultants*

Gary Abrams, M.D.

Ann Buzaid, OT

Gary Fenical

Robert Goldman, M.D.

Blake Hannaford, Ph.D.

Kevin McQuade, PT, MPH, Ph.D.

Joel Myklebust, Ph.D.

Steve Steins, M.D.

#### *Consumer Representative*

Karen Rue

#### *Patient Representative*

Robert Herman, J.D.

#### *Industry Representative*

Sally Maher, Esq.

#### *FDA Representative*

Celia Witten, M.D., Ph.D.

## **CALL TO ORDER**

**Executive Secretary Hany Demian** called the meeting to order at 9:34 a.m. He stated that panel consultants Gary Abrams, M.D., Ann Buzaid, OT, Gary Fenical, Robert Goldman, M.D., Blake Hannaford, Ph.D., Kevin McQuade, PT, MPH, Ph.D., Joel Myklebust, Ph.D., and Steve Steins, M.D., had been appointed to temporary voting status. He then read the conflict of interest statement. John S. Kirkpatrick, M.D., had received a waiver for his interests in a firm that could be affected by the panel's recommendations. The Agency took into consideration other matters concerning Ann Buzaid, OT, who reported interests in a firm at issue in matters that were not affected by the day's agenda. Both Dr. Kirkpatrick and Dr. Buzaid could participate fully in the panel's deliberations. Mr. Demian then asked the panel members to introduce themselves.

**Panel Chair Michael Yaszemski, M.D., Ph.D.**, stated that the purpose of meeting was to make recommendations concerning a PMA for Independence Technologies' iBOT 3000 mobility system. He noted for the record that the members constituted a quorum.

## **OPEN PUBLIC HEARING**

No comments were made.

## **SPONSOR PRESENTATION**

**Jim O'Donnell, vice president, regulatory affairs, Independence Technology**, provided an overview of the sponsor's presentation. He stated that the iBOT wheelchair is designed for people with mobility impairments who have the ability to use at least one upper extremity. He showed a short video depicting the device in use.

**Susan Eichler-Huston, manager, Regulatory Affairs, Independence Technology**, described the iBOT in more detail. The device is a wheelchair consisting of two components: a seating system and a power base. The latter provides mobility and consists of wheels, batteries, and a computer controller. Current wheelchairs are passively stable; they have no sensors or data

concerning pitch (i.e., the inclination of the machine with respect to gravity). The device's "i-Balance" technology monitors the pitch and adjusts the device accordingly to keep the seat relatively level when moving forward and backward. The device has 5 functions: standard, four-wheel, balance, stair, and remote; i-Balance is not active in standard mode. Ms. Eichler-Huston described each function in detail.

Ms. Eichler-Huston then described the nonclinical testing for the iBOT's software and for its mechanical, electrical, performance, anomalous, and environmental characteristics. Software testing includes the development process, risk management, verification, and validation; documentation describing those activities is consistent with FDA's *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices* dated May 29, 1998. CDRH-recognized ISO, ANSI, IEC, and ASTM performance standards were used. The iBOT has unique features that were not envisioned when the standards were written, so many test criteria were generated from international standards and system requirements. A total of 36 test reports contain all the qualification testing. The system meets safety and efficacy standards for the device's intended use.

Ms. Eichler-Huston summarized the electromagnetic compatibility (EMC) testing for the device and the battery charger. International standards were used to create the EMC testing plan, and FDA documents for testing and labeling also were used. The device was tested in the five operating modes and met the pass criteria. Both the iBOT mobility system and the battery charger meet EMC standards and are safe for their intended use.

**Heikki Uustal, M.D., principal investigator, Johnson Research Institute, Edison, NJ,** presented the results of the pivotal clinical trial. The goal of the trial was to demonstrate that people with a variety of mobility skills, using different configurations of the iBOT system, were

able to safely and effectively use the device in real-world environments. The trial also set out to demonstrate that the participants would have improvements on both objective and subjective measures of functional activities in a real-world environment when using the iBOT device compared with their current device. Dr. Uustal listed the inclusion and exclusion criteria and noted that the study involved 20 wheelchair users divided into three types: skilled manual wheelchair (MSK) users, slow manual (MSL) wheelchair users, and power (P) wheelchair users. The pilot phase involved 2 MSK users; after the pilot phase the remaining 18 participants were divided into the three user categories, six in each category. Users were trained to use the device in half-day sessions on 2 separate days. The first session covered all but the stairclimbing function, and the second session focused on stairclimbing. Users were contacted daily to find out about their activities, and usage information was recorded by the device's computer and downloaded on a daily basis. Half of the participants used their own device for a week, followed by the iBOT for a week; the other half used the iBOT first, then their own wheelchair.

No serious adverse events were reported for any devices. One adverse event for the iBOT was a bruise due to a pinched forearm; another was a bruise due to a fall, for which no treatment was required. Users in both groups experienced similar numbers of falls and similar numbers of mechanical problems with the wheelchairs. The device was demonstrated to be safe.

Efficacy was demonstrated by a community driving test, which consisted of 15 tasks that wheelchair drivers deal with in everyday life. Subjects completed the test in both the iBOT and their own wheelchair and served as their own controls. All subjects showed increased independence with minimal exertion using the balance, four-wheel, and stairclimbing functions.

**Jean Minkel, PT, Minkel Consulting**, presented information on the clinician and consumer training programs to be used in the distribution of device. The training program is

nearly identical to that used in pivotal trial. The clinician training program takes 4 days. First clinicians experience the device as a consumer. The trainer first assesses the consumer's potential to become a safe and effective driver. The consumer needs to complete training for the standard and the four-wheel functions; if he or she cannot stairclimb alone, an assistant must be trained as well. Assuming the consumer has the potential to become a safe and effective driver, he or she is given the user manual before returning to the driver training program. Driver training consists of detailed driving instruction in each function.

Consumer training is the first part of the clinician training program. The second part is assessment training, in which the clinician learns to assess consumers' physical, cognitive, and perceptual skills as they relate to the ability to safely operate the iBOT. The third phase teaches the clinician to deliver the device and train the consumer. The sponsor will be present at delivery of the device. The pivotal trial results demonstrate that the driver and clinical training programs are adequate to ensure safe and effective use of the iBOT.

## **FDA PRESENTATIONS**

**Robert J. DeLuca, M.S., Office of Device Evaluation, PMA team leader**, presented the nonclinical review. After reviewing the iBOT's components and functions, he noted that the device does not have antitip bars. He touched on several issues involving human factors and the user controls. For example, the power button location may present problems for some users.

Mr. De Luca reviewed the sponsor's qualification testing and the evaluations of nonclinical system-level performance. He noted that the tests were conducted in accordance with FDA as well as international standards. Unique features were assessed in accordance with standards developed by the sponsor. Comprehensive system-level tests evaluated a range of

operating functions and conditions, including worst-case scenarios. The results met all the established pass–fail criteria.

FDA is currently working with the sponsor to obtain clarification regarding EMC test methods and results. EMC compatibility is of interest to CDRH because of possible interference issues. Finally, Mr. De Luca reviewed the iBOT’s performance specifications, including braking, turning, driving, and maximum obstacle height. He noted that the device’s noise emissions were quite low both when stationary and moving.

**Capt. Marie A. Schroeder, M.S., P.T., Office of Device Evaluation**, provided FDA’s clinical review. She first reviewed the regulatory history of the PMA, which was granted expedited review. The pivotal study used the marketing version of the iBOT and the associated training and assessment materials. Ms. Schroeder reviewed the indications for use, noting that the device requires a prescription and that clinicians will require certification. This information will be included in the labeling. She summarized the pivotal trial findings and reminded the panel that the training and certification process conducted in the trial is what is proposed for market.

Ms. Schroeder then reviewed the safety results, including data on adverse events and device failures and the reasons for total device replacement. For both types of devices, the majority of problems were mechanical. She noted that in cases in which the iBOT reported device “failure” (i.e., shutdown or return of the device to a more stable mode), the device was actually responding as intended, and no injury to users resulted. The sponsor clarified that after reviewing the data, patient conditions may have contributed to the two iBOT adverse events. In one case, the subject had a c6–c7 spinal cord injury and below-knee amputation and had poor control of the trunk; he had moved too far off his center of gravity while attempting to move the

rear wheels off the ground and could not move his trunk back into the correct position. Another subject with a c6 injury had difficulty with the joystick grip; the subject had attempted to avoid a hazard, but turned too far, hit a curb, and fell laterally.

Ms. Schroeder noted that the community driving test had several limitations: The two-rail stairclimbing technique was not tested, the balance function was tested with only one task, the remote function was not tested, and speed templates were not distributed evenly across the groups. In addition, the subject-specific function scale had limitations: Not all patients identified the same tasks, and the assessment focused on tasks that subjects were unable to perform or performed with difficulty in their current devices. It would therefore be expected that the scores with the patients' own devices would be low, skewing the results with the iBOT. She reviewed data collected by the individual iBOT computers and data on device failures and replacements, accessibility problems, mechanical and operational difficulties, and home and community maneuvering. Different subjects used different functions for different amounts of time; only one user used the remote function, for example. It is unclear how much time in each mode was actually spent in testing or in the real world.

Users experienced a variety of mechanical and operational difficulties with the batteries, control panels, and techniques. These problems should diminish as a user becomes more comfortable with device. Human factors at issue involve the joystick, pinch points, and the user control panel and display. For example, although the joystick can be disabled, it is not difficult to accidentally reactivate it. Also, the user control panel is difficult to detach from the armrest, and the user might not be able to remove it to use the remote function. The display is difficult to see due to glare, and the user's hand covers it while operating the joystick.

## **PANEL PRESENTATIONS**

**Joel Myklebust, Ph.D.**, provided the panel preclinical review. The sponsor conducted a comprehensive and thorough evaluation, especially with respect to available standards; it was more rigorous than might be routinely required. More data on how the internally generated tests were developed could have been provided, but the study appears to have been well thought out. Another strength is that the sponsor involved some well-respected experts in the area of wheelchair standards. The static and dynamic stability in standard mode is as good as or better than most commercially available systems.

**Gary Fenical** provided the panel EMC review. The EMC data used recognized standards that deal with devices such as the iBOT. The report was quite vague about how EMC was tested in the five functions and did not provide schematics or diagrams. It would be interesting to see how stairclimbing testing was done in an EMC lab environment. The EMC tests were appropriate for the device and included tests for immunity to radiated emissions; electrostatic discharge; and radiated rf fields, such as fields that might come from mobile phones or GPS receivers. The charger was also tested for immunity to large switching transients and surge. The device performed well. The labeling is in accordance with current guidelines and standards. The iBOT meets EMC requirements and EMI labeling requirements. Mr. Fenical concurred with CDRH recommendations that the sponsor provide a clear summary of all EMC testing, including a brief explanation of how each test was performed and reference to appropriate EMC testing standards. Any deviations from reference standards must be explained and justified.

**Kinley Larntz, Ph.D.**, provided the panel statistical review. The sponsor's study shows that the device works. One must be careful in the extending the results of the pivotal study to other patient populations. It is absolutely necessary to qualify individuals for the device. Long-term followup would be helpful.

**Steve Steins, M.D.**, provided the panel clinical review. He circulated a diagram illustrating how he conceptualizes the patient in the environment: Patients must cope with several environments over which they have decreasing control. The intermediate environment is the one that the person has chosen to tune for their own specific needs, such as his or her office or home. Beyond that is the community environment, followed by the natural environment—the unmodified space that is in parks and so forth. The study demonstrated that the device is successful in the community environment, although it did not fully address the natural environment. The four-wheel function expanded user capability over conventional devices and increased efficacy within the natural environment. The ability to balance on two wheels in the intermediate and community environments was impressive. The mechanism for descending stairs was successfully intuitive, but going backwards to ascend stairs presents a challenge.

Although no significant safety risks were found, the risks are ones that clinicians have not been faced with previously. For example, on stairways, physical therapists do not normally spot a person weighing up to 250 lbs in a device that weighs so much. Although patients did reasonably well in assessing safety risks during the training, many patients come to their disability as a result of risk taking; the rehabilitation team will therefore need to assess patients carefully for the ability to use the device safely. The patients in the clinical study demonstrated few of the mechanical, perceptual, or neuromuscular challenges that other patients might present. Stroke patients will present a conundrum once the device comes to market.

## **PANEL DISCUSSION**

**Question 1:** *Are the electromagnetic compatibility (EMC) testing and labeling (e.g., regarding use of cell phones) sufficient to mitigate the risks in a changing electromagnetic environment over which the user has limited control? If not, what additional measures are recommended?* The panel expressed concern that EMC testing did not mimic environments in which a user

could be exposed to certain frequencies that could interfere with the device, such as those

associated with amateur radio bands. The labeling could address that possibility. One panel member noted that wireless technology will be growing over the next decade; in response, **Dennis Rollinger, CEO, Radiometrics**, stated that current standards do not cover wireless frequencies, but the iBOT was tested beyond current standards. The panel concurred that the sponsor has met all EMC compatibility requirements.

***Question 2:** The sponsor proposes that clinicians obtain certification in order to be able to assess and train prospective iBOT™ users. Is the proposed clinician certification process adequate for assuring that clinicians can identify appropriate users and train them to use the iBOT™ in a safe and effective manner?*

Panel members expressed concern about the power of the clinician over the consumer and asked many questions about the process for obtaining and properly fitting a device. Ms. Minkel stated that the process for obtaining an iBOT will be much like that for current power mobility devices. The device is available only by prescription, and a physician's signature will be required as part of the purchase process. Training is consistent regardless of the payer. The clinician and company representative will partner to fit the device to the user, and company representatives will observe clinicians at delivery to ensure that their skills are adequate. Panel members also noted that patient selection is a critical issue and that it is important to make sure that clinicians do not allow people to have the device if they cannot use it safely. They discussed whether children should be permitted to use the device; Mr. O'Donnell stated that most children will not be able to use the iBOT because they are too small to fit the device. Many panel members thought the analogy of learning to drive a car was appropriate. The panel concurred that the proposed certification process adequately covers cognitive and physical skills; members suggested that the assessment team should include a therapist and a clinician.

**Question 3:** *The sponsor proposes a number of procedures to assess and train potential IBOT™ users. Are these user assessment and training procedures adequate for assuring safe and effective use of the IBOT™?*

The panel concurred that the assessment and training procedures are adequate. One panel member said that training needs to take into account the learning styles of different consumers—the curriculum should be person centered and designed to meet individual consumer learning styles and goals. Several panel members suggested that some training in the user's real-world environment might be useful. Other panel members noted that at some point, the clinician must trust that the patient will have the judgment to correctly use the device. Because the iBOT is calibrated to the individual user, the labeling should recommend that the chair be used only by that user. Panel members asked many questions on details of the training process, which the sponsor representatives answered to their satisfaction.

**Question 4:** *The sponsor conducted a clinical trial that compared 2 weeks of IBOT™ usage to 2 weeks of subjects' own mobility devices usage. The sponsor provided safety data that included summaries of injuries, physical device failures (e.g., device and component replacements) and other events (e.g., falls, intentional device actions, such as system shutdown) that could place the user at risk of injury due to user error and/or device design limitations. Given these data, has reasonable assurance of device safety been demonstrated?*

The panel concurred that the device is safe. Several panel members noted that the stairclimbing feature was not used much in the clinical study, so it is not clear how safe that function is. It would be helpful to see the results stratified by body mechanics or use of arms.

**Blake Hannaford, Ph.D.**, provided a review of the software and control systems. The device has a clear, clinically meaningful advantage over existing technologies. However, the technology carries significant new risks to users and others. The software uses a triple-redundant system similar to that in Boeing 777 aircraft—it is necessary because both the sponsor and FDA classify the risk level for loss of balance on stairs as catastrophic. In airplanes, the software is different in each processor to reduce the risk of bugs, but in the iBOT, the processors are running

the same code. The classification of software failure in the risk management plan should be modified to list the possibility of failure as remote and the severity as catastrophic. A bug causing a crash on stairs is possible, but the risk is low.

The use of matlab and simulink block diagrams are of concern. The documentation refers to the control system itself, rather than the model. What is the relationship between diagrams or the embedded controller? It needs to be documented better.

Although the clinical and nonclinical testing seem adequate, the sample size is not. Balance mode is relatively compatible with existing wheelchair standards for stability. More information is needed on the magnitude of front and back displacements in balance mode. What are typical displacements during normal operation? In addition, in the testing for stairclimbing, what was the surface material of stairs? Was secured carpet tested? Also, women users were not tested adequately in stairclimbing mode. Only about 13 minutes of stairclimbing per patient took place, and many controller alerts occurred during those minutes, indicating that users were going outside the safe region of operation. More data on solo stair climbs and the types of stairs should be collected. On the whole, however, the testing seems adequate.

Other panel members asked whether the device will alert the user when it needs to be recalibrated. Ms. Minkel stated that the user will feel a change in performance if calibration has changed. Although panel members raised issues concerning the control box, joystick, braking distance, lack of antitip devices, battery life, and changes in center of gravity, the panel concurred that the device is safe for the patients tested in the trial.

***Question 5:** The primary and secondary outcome measures [of the clinical trial] yielded statistically significant results in favor of the IBOT™. In light of the results of the primary and secondary outcome measures and the additional data collected . . . has reasonable assurance of device effectiveness been demonstrated?*

The panel concurred that the device is effective. Panel members asked questions about the maintenance schedule and the lifespan of the device. Ms. Minkel stated that the user can transmit data via modem to determine whether the iBOT needs to be serviced. Mr. O'Donnell stated that the target lifespan of the device is 5 years. Components of the device that failed or were found to be problematic during the trial have been improved.

***Question 6:** This PMA study was conducted with 18 subjects, most of whom had a spinal cord injury, and allowed for 2 weeks of IBOT™ usage. If you recommend that this device is approvable, are there any data that should be collected during the post-market period? For instance, post-market data could be collected for the following purposes [such as] clarifying labeling or refining assessment and training procedures for clinicians and IBOT users.*

Some panel members suggested that any device servicing be accompanied by a questionnaire asking the patient whether the problem with the device was associated with an injury, no matter how small. Several panel members had concerns about the safety of stairclimbing in descending mode; one panel member suggested that FDA engineers work with the sponsor to determine exactly what data collection should be done to implement vigilant monitoring of the safety of stairclimbing. Ms. Maher noted that the company is regulated and must file adverse event reports; it will be evaluating all events to see whether corrective actions are needed. However, Dr. Hannaford stated that it was important to catch problems before adverse events occur.

Dr. O'Donnell noted that if the user does not go in for scheduled maintenance, a wrench will appear on the control panel. It is incumbent on the user to contact the manufacturer.

#### **OPEN PUBLIC HEARING**

No comments were made.

#### **VOTE**

Haney Demian read the voting instructions. The panel voted unanimously to approve the PMA

with four conditions:

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

When asked to explain the reasons for their votes, panel members generally replied that the device is safe and effective. Several panel members expressed concern that the device will be misused by people with poor judgment but noted that on balance, the FDA's postmarket data will uncover any problems. Correct use of the device relies on good judgment, but so does every piece of medical instrumentation. Several panel members expressed that the device is extraordinary and that the safeguards in place for training are commendable.

#### **ADJOURNMENT**

Mr. Demian thanked the participants and adjourned the meeting at 5:08 p.m.

I certify that I attended this meeting of the Orthopaedics and Rehabilitation Devices Advisory Panel on November 20, 2002, and that these minutes accurately reflect what transpired.

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Hany Demian, M.S.  
Executive Secretary

I approve the minutes of the November 20, 2002, meeting as recorded in this summary.

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Michael Yaszemski, M.D.  
Acting Chairperson

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