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Independence™ iBOT™ 3000 Mobility System: A Stair-climbing Wheelchair

Summary

- ✓ **Independence™ iBOT™ 3000 is a wheelchair that may be used to climb stairs, elevate the user to standing adult eye level and cross uneven terrain.**
- ✓ **Limited evidence indicates that the device may offer more mobility and freedom to users than conventional wheelchairs.**
- ✓ **The iBOT may be difficult to manoeuvre indoors due to the seat height, but it operates well outdoors.**
- ✓ **The use of this technology is limited by the high cost of ownership and uncertain incremental benefit for users.**
- ✓ **While the device is not yet licensed for use in Canada, it is approved by the Food and Drug Administration for use in the US.**

The Technology

The iBOT™ 3000 Mobility System (iBOT) is a battery-operated, programmable wheelchair manufactured by Independence Technology, a Johnson & Johnson company in Warren, NJ, US. Sensors and processors are used to make automatic adjustments to wheel position, seat orientation and elevation. The wheelchair is 104 cm long, 60 cm to 70 cm wide and weighs 113 kg. It uses two rechargeable nickel-cadmium (Ni-Cad) batteries and can travel for up to 15 km to 24 km when charged for four hours.

The iBOT has five functions:

- standard: acts as a conventional power wheelchair
- balance: elevates user to move around at standing adult eye level
- remote: remotely drives the device inside a vehicle
- four-wheel: crosses uneven terrain while maintaining balance and traction
- stairs: climbs up and down stairs unaided.

Regulatory Status

The iBOT, which is not licensed in Canada, was approved in the US, on August 13, 2003, by the Food and Drug Administration (FDA), for use as a prescription device requiring clinician certification and user training.¹ The approval was based on a review of product bench testing conducted by the manufacturer and on a clinical study.

User Group

This device is intended for wheelchair users with severe disabilities who cannot perform routine tasks using conventional power wheelchairs or who desire the additional features to improve their quality of life.

It is approved for use by individuals weighing ≤ 113.64 kg (≤ 250 lb) and capable of operating the wheelchair with at least one arm. The wheelchair is contraindicated for users who have difficulty bending their knees and hips; had a loss of consciousness or a seizure in the past 90 days; require a mechanical ventilator; have severe osteoporosis, osteogenesis imperfecta or metastatic bone cancer; or who have not successfully completed a training program.²

Current Practice

A wide range of manual and power wheelchairs is available.³ A review of power wheelchairs was done by the Agence d'évaluation des technologies et des modes d'intervention en santé (AETMIS).⁴ None of the wheelchairs available in Canada can climb stairs or elevate the user to the eye level of a standing adult.

The Evidence

Safety and effectiveness evidence was mainly derived from the clinical trial used for FDA approval.² The trial was a single-centre, prospective, balanced, open-label evaluation of 29 participants who served as their own controls over four months. Of the 29 participants, nine did not complete the study (two failed assessments, three withdrew and four had their participation terminated by the investigators). Eight participants were skilled manual wheelchair users, six were slow manual wheelchair users and six were power wheelchair users. All participants and clinical investigators attended an iBOT training program.

Safety and accessibility data, operational and mechanical data and computerized data regarding usage and failures were collected daily by telephone contact with each subject. The primary effectiveness data were collected when subjects undertook the community driving test, consisting of 15 everyday tasks, for two weeks. The only serious adverse effects observed were device-related bruises experienced by two participants, who required minor or no treatment at home. The device fell three times during the study. Effectiveness was measured using a seven-point scoring scale. The scores for subjects using iBOT were compared to those for subjects using their own mobility device. All 20 participants scored higher in the iBOT than in their own device, showing a statistically significant improvement in independence. The iBOT was more difficult to manoeuvre indoors because of the seat height, but easier to use outdoors than conventional chairs.

The study had several limitations. The sample size was too small to adequately determine the device's safety and effectiveness in the community. The report did not explain why four subjects had their participation terminated by the investigators. The missing data on nine of the original 29 participants suggested that nearly 30% of participants may be unable to use the device. The iBOT was not tested for its ability to function on ice and snow. Finally, the safety and effectiveness evaluation of the device was based on self-reported data only.

Cooper *et al.* examined the use of the iBOT transporter at home and in the community.⁵ Ten unimpaired non-wheelchair users (six men and four women) and four expert wheelchair users (men with spinal cord injuries T7 to L1) participated in the study. Data were based on observations by trained clinicians, computerized data and reports from trained participants. On completion of training, the unimpaired and expert wheelchair users took the device home for three days and one week respectively to use as their primary mobility device. They used the iBOT to hold eye-level conversations; shop while balancing on two wheels; traverse steep ramps and uneven terrain; and climb curbs.

The computerized data logger assessed compliance. The expert users' performance was assessed by comparing the test scores for the iBOT versus those for manual wheelchairs. The balance and four-wheel functions worked well and were helpful to users. The users had to pay attention when controlling the iBOT's standard function. The seat height was too high for most tables and desks; and the iBOT was difficult to use in the bathroom. There were five service calls. One adverse event was reported by an unimpaired user when the device responded inappropriately on stairs. Two expert users experienced faults ranging from a computer malfunction to a flat tire without any reported adverse event. The study concluded the iBOT is a functional mobility device that expands the choice of wheelchair users and that is most useful outdoors where there is ample space.

The study had several limitations. The trial included a limited sample size. Four participants were expert users who had extensive driving experience during the iBOT's design and development stages. Furthermore, the study did not explain the rationale for selecting 10 unimpaired non-wheelchair users.

Adverse Effects

The FDA approval reports the device falling three times and causing device-related bruises during the study.² Each year in the US, there are >36,000 wheelchair injuries serious enough to warrant a visit to an emergency room.⁶ Two-thirds of these injuries are due to problems with wheelchair stability.⁶

The FDA approval contains the following potential adverse effects on health. Many apply to manual and power wheelchairs.^{1,2}

- user pinches or crushes finger or hand in moving parts
- user falls out of product
- product falls forward, backward or sideways or becomes inoperable
- user experiences jarring forces or falls when climbing stairs or curbs or when in transition between functions
- user collides with obstacles
- user or product injures other people or assistant
- electromagnetic interference causes malfunction
- product causes electrical shock and thermal burns.

Administration and Cost

The retail price of the iBOT in the US is estimated to be between US\$25,000 and US\$30,000.⁷⁻¹¹ Most power wheelchairs sell for between US\$5,000 and US\$10,000, with customized models selling for about US\$20,000.⁷ Manual wheelchairs and scooters, which some potential users of iBOT may use, cost <US\$5,000.^{7,9-11}

The iBOT comes with a one-year warranty on parts and labour, including batteries. The manufacturer has not released information about the replacement cost of batteries.

Concurrent Developments

A stair-climbing wheelchair with high single-step capability is being developed.¹² Research is also underway to improve the wheelchair controlling mechanism.^{13,14} Yanco proposes an outdoor navigation system for a wheelchair that uses a vision system to avoid obstacles.¹⁴ The development of a smart wheelchair system that can assist persons with low vision, spasticity, tremors and cognitive deficits is underway.¹⁵

Rate of Technology Diffusion

The diffusion of this technology may be limited by the high cost of owning the device; lack of evidence on its ability to function on ice and snow; difficulty in manoeuvring indoors; and the lack of long-term safety and effectiveness data.

Implementation Issues

As the iBOT is at an early stage of development, there are limited safety and effectiveness data. Training-related costs and potential benefits to users require consideration. Additional community-based trials are needed to provide evidence about this technology; and trials in Canadian weather conditions must be conducted.

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