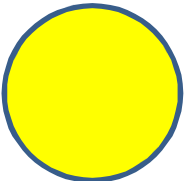


Digi-HTA Recommendation

Indego Exoskeleton for walking rehabilitation

PRODUCT AND ITS INTENDED PURPOSE	
<p>The Indego® Exoskeleton is a wearable walking robot that allows a fully or partially paralyzed person to walk in various environments. The product has two options: Indego Therapy for rehabilitation and Indego Personal for private use. This assessment is for Indego Therapy.¹</p> <p>The device has FDA approval and a CE mark. The device is a class IIa medical device (Medical Device Directive [MDD] 93/42/EEC).¹</p> <p>The manufacturer of the product is Parker Hannifin Corporation, and the distributor in Finland is Fysioline Oy.¹</p> <p>The company uses the ISO 13485:2016 quality management system.¹</p>	
RECOMMENDATION	
Date of Recommendation	10.2.2020; Recommendation for data security and protection: 16.6.2020.
	<p>The device is suitable for use in conjunction with other rehabilitation methods. The use of the device requires sufficient upper extremity strength to manipulate a stability aid, and the rehabilitator should be continuously present.</p> <p>Research evidence on the benefits of the device is scarce.</p>

SUB AREAS OF ASSESSMENT	
Effectiveness	<p>Rehabilitation of Lower-limb Paralysis</p> <p>There are a few studies on the use of the device in the rehabilitation of lower-limb paralysis.²⁻⁵</p> <p>In all of these studies, the rehabilitation clients were able to walk with the help of the device and additional support (crutches, walking support). The level of disability affected how much walking assistance was needed from the rehabilitator, but some subjects were almost completely independent. According to the studies, the walking speed remained slow (0.19 m/s to 0.55 m/s, the results depend on the level of disability), but it accelerated during rehabilitation.^{2,3,5} The device allows walking speeds of up to 0.78 m/s, which is considered sufficient speed for limited community ambulation.⁶</p> <p>There have been some studies on similar devices for the rehabilitation of lower-limb paralysis, and review articles based on them have been published. In summary, these devices enable walking and upright positioning, walking speed increases as the amount of exercise increases but remains reasonably slow, the level of disability and elapsed time since the injury affect walking speed, the evidence of cardiovascular benefits is conflicting and users have found the devices safe and have a positive attitude toward them.⁷⁻¹¹ The devices have the potential to intensify rehabilitation, but the evidence is still scarce.⁷</p> <p>The reviews revealed that there were significant differences in the training times among the studies,^{7-9,11,12} the indicators used⁷⁻¹² and the disability levels.^{7-9,12} Additionally, the sample sizes were small,^{7,8,11} and the quality of the studies was assessed as poor.^{7,9} There were also shortcomings regarding conflicts of interests.⁷</p> <p>In the studies, the most common level of injury was T10, and most of the injuries were between the levels of T4 and T12.¹² When purchasing the device, health professionals should consider whether the disabilities of the patients in a rehabilitation unit's group are of a similar level.</p> <p>Rehabilitation After a Stroke</p> <p>One study looked at the use of the device for rehabilitation after a stroke. The research focused on describing the technical implementation of the device, and the preliminary results of one subject showed improvement in walking ability.¹³ According to the manufacturer, four studies have been conducted on the use of the device in post-stroke rehabilitation (42 participants in total). These participants' gait tests showed improvement in their walking ability, but more detailed information was not available.¹⁴</p> <p>One review of studies on similar types of devices for post-stroke rehabilitation was also found. According to the review, robot-assisted gait therapy is as effective as traditional rehabilitation. In a sub-acute situation, robot-assisted gait therapy can be an added benefit. The results of these studies were partially conflicting, and the authors noted that the research groups were small, most had no control group and the disability ratings were poorly reported.¹⁵</p>

Digi-HTA Recommendation

	<p>Rehabilitation for Other Reasons</p> <p>The Canadian Agency for Drugs and Technologies in Health (CADHT) did not find any studies that could draw conclusions on the effectiveness of the devices in patients with lower-limb weakness. Lower-limb paralysis was excluded from the agency’s review.¹⁶</p> <p>In the UK, the National Institute for Health and Care Excellence (NICE) has conducted an assessment for a single device of the same kind. The studies show that the use of the device improved independent walking, walking speed and walking distance. At the same time, NICE highlights evidence-related uncertainty, in particular the small sample sizes of the studies and the lack of control groups.¹⁷</p> <p>The vertical position enabled by the device provides secondary benefits, including pain relief, improved bowel and bladder functions, the relief of spasticity and improved mental well-being.^{5,7,18}</p>	
<p>Safety</p>	<p>According to studies, the safety of the device seems to be at a good level. No serious incidents have been reported, although some issues with losing balance have been reported. Minor adverse events (skin irritation, redness, bruising, abrasion, sweating) have also been reported.^{13,19} When using the device, patients should use either a crutch or walker as additional support, and the rehabilitator must be present at all times.^{2,3}</p> <p>The Indego device contains software functionality that allows the device to detect forward, backward, and sideways falls as they happen and make real-time adjustments during the course of the fall to position the user for minimal risk of injury or allow the user to attempt to recover unassisted.¹</p> <p>The device manufacturer continuously monitors reports of adverse events and makes software updates as needed to improve safety.¹</p>	
<p>Cost</p>	<p>The initial cost of the device is approximately €150,000, and the annual maintenance costs are €5,000 to €15,000. Software updates are included in the price. The estimated service life of the device is five to seven years.¹ The organization purchasing the equipment should carefully evaluate the usage rates and payback period.</p>	
<p>Data Security and Protection</p>	<p>This security and data protection assessment is based on the information provided by the vendor for this assessment.²⁰ The vendor stores personal data in a database located within the United States to enable the synchronization of data across devices within an organization. For this reason, the data subject must give consent for transferring and processing data outside the European Economic Area.²¹ It is recommended that the organization take into consideration the terms of this consent agreement regarding data protection. After the initial setup, the product can be used offline.²²</p> <p>Shortcomings Related to Data Security and Protection</p> <p>The most significant risks in terms of security and data protection are caused by shortcomings in log management and security monitoring. According to the vendor, at the time of conducting this assessment, log management and documentation about how system security is monitored and managed are still in development. For</p>	

Digi-HTA Recommendation

	<p>these reasons, the vendor may not be able to effectively monitor who accessed personal data stored in their database and when.²⁰</p> <p>To minimize risks, it is advised that the organization store the exoskeleton and the iOS device used with the exoskeleton in a secure environment, to which only authorized personnel have access.</p>	
Usability and Accessibility	<p>The device manufacturer imposes restrictions on the health of individuals using the device.^{1,23} Individual assessments should be conducted for every rehabilitated person regarding the suitability of using the device.</p> <p>From a physiotherapist point of view, there are no remarks relating to usability.¹</p>	
Other Things to Consider When Using This Product	<p>Technical stability: On average, according to the manufacturer, the equipment malfunctions once a year. The manufacturer will provide a spare device during this time.¹</p> <p>The use of the device for rehabilitation purposes requires a rehabilitator who has completed three to four days of training. The training will be in English and be organized by the manufacturer together with the distributor. In addition, there is the possibility of further training and consultation if needed.¹</p> <p>The device is battery-powered¹. Various insights have emerged about the battery life^{1,14,24}, which may limit the use of the device for rehabilitation purposes</p>	
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Digi-HTA Recommendation

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Key Assessment Domains

Points	Effectiveness	Safety	Cost	Data security and protection	Usability and accessibility
2	Sufficient	Sufficient	Reasonable	Sufficient	Sufficient
1	Promising but the information is scarce	Probably at a sufficient level but not known well enough	High	Minor shortcomings	Minor shortcomings
-4	Weak or unknown	Weak or unknown	Unreasonably high	Shortcomings	Shortcomings

Recommendation Scale

Total score	Definition
10	<p>USE OF THE PRODUCT IS RECOMMENDED</p> <p>The use of this product is recommended because of strong evidence for its effectiveness. Safety, data security and protection, and usability and accessibility of the product are at an adequate level. The cost of using the product is reasonable.</p>
9	<p>THERE IS ONE THING TO CONSIDER WHEN USING THE PRODUCT</p> <p>An organization considering the deployment of the product should note that in one key area there are things to consider. Information about the effectiveness of the product could be promising, but the information is scarce. Product safety could be at a sufficient level but not known well enough. Product costs may be high. There could be minor shortcomings in the product's data security and protection or in usability and accessibility.</p>
7-8	<p>THERE ARE A FEW THINGS TO CONSIDER WHEN USING THE PRODUCT</p> <p>An organization considering the deployment of the product should note that in two or three key areas there are things to consider. Information about the effectiveness of the product could be promising, but the information is scarce. Product safety could be at a sufficient level but not known well enough. Product costs may be high. There could be minor shortcomings in the product's data security and protection or in usability and accessibility.</p>
5-6	<p>THERE ARE MANY THINGS TO CONSIDER WHEN USING THE PRODUCT</p> <p>An organization considering the deployment of the product should note that in four or five key areas there are things to consider. Information about the effectiveness of the product could be promising, but the information is scarce. Product safety could be at a sufficient level but not known well enough. Product costs may be high. There could be minor shortcomings in the product's data security and protection or in usability and accessibility.</p>
≤4	<p>THERE ARE CRITICAL THINGS TO CONSIDER WHEN USING THE PRODUCT</p> <p>An organization considering the deployment of the product should note that there are shortcomings in one or more key areas. Information about the effectiveness of the product is untrustworthy or of low quality. There may be shortcomings in the product's safety, or information related to it may be unreliable or of low quality. Product costs may be prohibitively high. There could be shortcomings in the product's data security and protection or in usability and accessibility.</p>