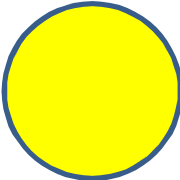


Digi-HTA recommendation

Lokomat robot for walking rehabilitation

PRODUCT AND ITS INTENDED PURPOSE	
<p>Lokomat® is a robotic device for clinical rehabilitation with a dynamic body weight support system.¹</p> <p>The intended purpose of the Lokomat is to support treadmill training to treat patients with walking disabilities caused by neurological, muscular, or bone-related disorders.¹</p> <p>The device has FDA approval and CE-mark. The device is Class II medical device (Medical Device Directive (MDD) 93/42/EEC)¹</p> <p>The manufacturer of the product is Hocoma AG, and the distributor in Finland is Fysioline Oy¹</p> <p>The company has an ISO 13485: 2016 quality management system in use.¹</p>	
RECOMMENDATION	
Date of Recommendation	21.1.2020; recommendation for data security and protection: 20.8.2020.
	The device is suitable for use in combination with other rehabilitation methods. The device must be used under the guidance of a trained physiotherapist.

SUB AREAS OF ASSESSMENT		
Effectiveness	<p>Evidence is available for the beneficial use of the device in the rehabilitation of patients with various neurological disorders^{2,3}.</p> <p>The use of the device in combination with other gait rehabilitation methods in the acute and sub-acute stages after a stroke^{3,4,5} and paraplegia^{2,3} has been found to be beneficial compared with the use of traditional gait rehabilitation methods only.^{2,3,4,5} In some studies, the use of the device was beneficial only for the most severely disabled compared with traditional gait rehabilitation.⁶ In the chronic phase of these diseases, the use of the device had no additional effect over other rehabilitation methods.^{2,3} When robot-assisted gait rehabilitation was compared with traditional gait rehabilitation alone, no differences in results were found.⁶</p> <p>There was no difference compared with traditional walking rehabilitation in the case of multiple sclerosis (MS).³</p> <p>For the rehabilitation of patients with Parkinson's disease, the device would appear to be beneficial in comparison with traditional rehabilitation, but in a 3-month follow-up, no differences between groups with and without the device were seen. When robot-assisted gait rehabilitation was compared with treadmill training, no differences between the groups were observed.⁷</p> <p>The device does not replace traditional rehabilitation methods but works alongside it.^{4,6,8,9} According to several studies, the device is most useful in acute or sub-acute disease stages and for the most severe injuries.^{2,3,6} It is still unclear what the optimal length of a rehabilitation session is and what the optimal rehabilitation intensity or the optimal total duration of the rehabilitation is.^{2,3,4}</p> <p>Other findings from studies</p> <p>The device can make the work of a physiotherapist easier⁶</p> <p>There are other benefits associated with using the device: improvement in the bowel and bladder functions, relief of pain, relief of spasticity, and cardiovascular benefits. However, the evidence for these effects is still scarce.¹⁰</p>	
Safety	<p>Serious incidents have not been reported.¹</p> <p>Adverse effects that have been reported include sag of the skin, skin irritation, muscle and joint pains, and tendon inflammation due to exertion.¹¹</p> <p>Possible safety risks have been taken into consideration, and efforts have been made to minimize them in the product's design.¹²</p> <p>The device has an emergency switch to turn it off in the event of a malfunction.</p>	
Cost	<p>The purchase price of the product is fairly high.¹ An organization purchasing the equipment should carefully evaluate the usage rates and the payback period. The annual maintenance costs are reasonable.¹</p> <p>Using the device can reduce the work amount of a physiotherapist.¹</p>	

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	<p>Using the device would be cost-effective in stroke rehabilitation based on information from a cost-effectiveness analysis commissioned by the manufacturer.¹³</p>	
<p>Data Security and Protection</p>	<p>The security and data protection assessment is based on the information provided by the manufacturer for this assessment.¹⁴ Based on this information, an organization that purchases the product holds the customer responsible for fulfilling the few requirements regarding security and data protection.</p> <p>The customer is responsible for integrating the device securely into his or her network, managing backups, decommissioning, monitoring access to the device, and protecting patients' personal data, such as biometric data, according to the security and data protection requirements. The device uses Windows; therefore, Windows's security and data protection best practices can be used as a basis for fulfilling these requirements. For example, full disk encryption could be used to protect patient data. We recommend that the customer should determine with his or her security and data protection experts what measures are required to comply with the security and data protection requirements. In addition, the customer can minimize risks by using other measures, such as placing the device in a secure environment that only authorized personnel can access.</p> <p>Device connectivity to the cloud service</p> <p>The device can be used offline. However, it can be connected to a cloud-based service (HocoNet). This service was not taken into consideration in this assessment; therefore, the organization should carry out a new security and data protection assessment that takes this service into account if this service will be used.¹⁴</p> <p>Patient safety</p> <p>Patient safety has not been assessed in the data security and protection assessment. This assessment assumes that an organization considering procurement inspects its requirements in the operational requirements.</p>	
<p>Usability and Accessibility</p>	<p>A person with different kinds of disabling factors (e.g., visual and hearing disabilities) can participate in Lokomat rehabilitation. The suitability of the person being rehabilitated with the Lokomat should be evaluated by the attending physician within the manufacturer's limitations.¹</p> <p>From a physiotherapist point of view, there are no remarks relating to usability.¹</p>	
<p>Other Things to Consider When Using This Product</p>	<p>Getting started with the device requires training, which is provided by the distributor Fysioline in collaboration with the device manufacturer. Training will be held in Finnish. In addition, the distributor will provide user meetings as well as further training and consultation as needed.¹ The manufacturer provides 24/7 phone support (in English) for maintenance issues. The distributor Fysioline will offer on-call service on weekdays for maintenance issues.¹</p> <p>The product does not have interfaces with other software or services. Rehabilitation data saved by the product can be exported as a report in Microsoft Excel or PDF format.¹</p>	

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References	<ol style="list-style-type: none"> 1. Digi-HTA, information provided by manufacturer. Not publicly available. 2. Schwarz I. and Meiner Z. 2015. Robotic-Assisted Gait Training in Neurological Patients: Who may benefit? <i>Annals of Biomedical Engineering</i> 2015; 43(5):1260-1269. DOI: 10.1007/s10439-015-1283-x 3. Nam K. et al 2017. Robot-assisted gait training (Lokomat) improves walking function and activity in people with spinal cord injury: a systematic review. <i>Journal of NeuroEngineering and rehabilitation</i> 2017;14:24. DOI 10.1186/s12984-017-0232-3. 4. Mehrholz J. et al 2017. Electromechanical-assisted training for walking after stroke (Review). <i>Cochrane Database of Systematic reviews</i> 2017, Issue 5, Art.No: CD006185. DOI:10.1002/1465185.pub4. 5. Bruni M. et al 2018. What does best evidence tell us about robotic gait rehabilitation in stroke patients: A systematic review and meta-analysis. <i>Journal of Clinical Neuroscience</i> 2018; 48: 11-17. DOI 10.1016/j.jocn.2017.10.048 6. Lo K., Stephenson M. ja Lockwood C. 2017. Effectiveness of robotic assisted rehabilitation for mobility and functional ability in adult stroke patients: a systematic review. <i> JBI Database of Systematic Reviews and Implementation Reports</i>. DOI. 10.11124/JBISRIR-2017-003456 7. Alwardat et al 2018. Effectiveness of robot-assisted gait training on motor impairments in people with Parkinson’s disease: a systematic review and meta-analysis. <i>International Journal of rehabilitation Research</i> 2018; 41(4):287- 296. DOI 10.1097/MRR.0000000000000312 8. HAS 2012. Accident vasculaire cérébral: méthodes de reéducation de la fonction motrice chez l’adulte. <i>Argumentaire scientifique</i>. 9. Stroke Foundation. <i>Clinical Guidelines for Stroke Management 2017, summary- Physiotherapy</i>. Available from: https://informme.org.au/en/Guidelines/Clinical-Guidelines-for-Stroke-Management-2017 Luettu 26.9.2019 10. Mekki M. et al 2018. Robotic Rehabilitation and Spinal Cord Injury: a Narrative Review. <i>Neurotherapeutics</i> 2018;15: 604-617. DOI 10.1007/s13311-018-0642-3 11. Borggraefe I. et al 2010. Safety of robotic-assisted treadmill therapy in children and adolescents with gait impairment: A bi-centre survey. <i>Developmental Neurorehabilitation</i> 2010; 113(2):114-119. DOI: 10.3109/17518420903321767 12. The manufacturer's safety report, a short version. Not publicly available. 13. Kuntoutusrobotiikan kustannushyöty AVH-potilaiden kävelykuntoutuksessa. 19.9.2019 Nordic Healthcare Group. Available from: https://www.fysioline.fi/kuntoutus/kuntoutusrobotiikan-kustannushyoty/ 14. The data security and protection requirements of the Northern Ostrobothnia Hospital district (PPSHP, the National Emergency Supply Agency’s Cyber Health project 2018-2019, University of Tampere Jari Seppälä). Available from: https://www.kyberturvallisuuskeskus.fi/en/ncsc-news/instructions-and-guides/information-security-and-data-protection-requirements-social Cited 16.12.2019
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The 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>