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1. General information:

1.1 Name: Prodrobot automatized gait trainer

1.2 Manufacturer: Prodromus Sp. z o.o., Lukasiewiczza 1, 31-429 Krakow, Poland

2 Description of the assessed product and its intended use

2.1 Description of the product

Prodrobot is the active medical device designed for the rehabilitation of the lower limbs of patients with gait dysfunctions. The product is equipped with a movable brace fitted with clamps patient's legs, which are driven by electric motors controlled electronically. The device is equipped with a unit that allows the execution of sitting position on the device, which is designed to facilitate placement and attachment of the patient, then its verticalization (exercises are held in a standing position). The device is controlled via buttons on the robot and the display screen commands, operating parameters and messages.

The product does not contain any medicinal products, blood products, or tissues of animal or human origin.

Construction materials include aluminum, steel with powder coating, textiles clamps (tape, velcro, fabric), artificial leather (a seat and a back support), plastic (housing).

The device is controlled electronically by 2 computers paramount and 7 drivers dedicated, responsible for the operation of the joints 6 and 1 lift device. The software is based on the firmware provided by the manufacturer of components and the dedicated linux. The device consists of basics, support construction, 2 movable mechanical orthosis and a seat with an adjustable back support. The device is powered with voltage 230V and lowered through the medical power supply to safe voltage 24V for drives and 12V and 5V for the control system.

Prodrobot can serve to people with a body weight no more than 50kg and a growth no less than approx. 110 and not more than approx. 150 cm.

Device is not sterile and only require typical hygienic practice for medical health care facilities providing services in the field of rehabilitation (sanitization of external surfaces).

The product is applicable to pediatric patients. It is reusable and conducting operations on a standard time of action in tens of minutes. Patient contact is done through clothes in textile mounting clamps for limbs and torso and directly by hand by the handles, supports patient.

The product achieves the intended use by providing mechanical energy to do the limbs of patient. The movement performer by device is consistent with the anatomy of the human body and with idealized gait pattern and other pre-programmed exercises (swings, bike, squats, stairs walking) as stored in the memory of the product. The computer and software allows to implement other movements according to anatomy of human body.

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3 Predicted therapeutic indication and the manufacturer's arrangement

3.1 Application

Robot is dedicated

- for patients suffering from paraplegia [2, 4];
- for persons with stroke affecting gait impairment [1, 4, 8, 11, 13, 16,];
- for people with Parkinson's disease with the slowdown, muscle stiffness and impaired motility disorders of gait and postural [6, 12];
- in disorders of gait and posture in polyneuropathies of different reasons (toxic, metabolic, and autoimmune nature as Guillain-Barre syndrome) with muscle
- weakness of varying severity including a flaccid paralysis, [8, 16];
- for patients with cerebral palsy, in which movement disorders mainly consist of muscle weakness and spasticity [9; 10];
- for patients with muscular diseases such as muscular dystrophy with progressive weakness and atrophy of muscles [14, 15].
- for patients with a body weight no more than 50kg and a growth no less than approx. 110 and not more than approx. 150 cm, hip width not more than approx. 30cm.
- to use as a dynamic standing frame [20, 21, 22, 23]

3.2 Manufacturer's information about indications and contraindications

The manufacturer includes in the instruction manual all information about the indications and contraindications as above and about the information about safety of use:

- Before exercising you should seek medical advice. The doctor is responsible for determining the indications for training on the product Prodrobot.

3.3 Contraindications

In particular, please note the following contraindications:

- the length of the orthosis is not adjusted to the patient's height
- weight greater than 50kg
- considerable muscle contractures
- bone instability (unstable fractures, unstable spine, advanced osteoporosis)
- open skin damage around legs, arms and trunk
- circulation problems
- cardiac contraindications
- patient not cooperative or aggressive, for example suffered from transitory psychotic syndrome
- significant cognitive deficits, no verbal contact with the patient
- patients treated for a long time with intravenous infusions
- mechanical ventilation
- patients with extremely disproportionate length of limbs and/or spine (eg. displasias osteochondral)
- severe vascular disorders of the lower limbs

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- in general, patients with the recommendation of bed rest or immobilization due to eg. osteoarthritis or other inflammatory/infectious
- arthrodesis of the hip, knee or ankle
- active implants

3.4 Safety remarks:

- before use read the operating instructions and follow strictly to its recommendations.
- before use read the section 3.3. Contraindications
- the unit can be operated only by trained operators
- the place of work of the unit must be clean and dry
- in case of large temperature changes (eg. bringing the device in the winter from the outside to a warm room) do not turn on the device until the device temperature is close to ambient temperature.
- The power cable of Prodrobot should be placed in such a way that it can not be accidentally disconnected by a moving person or object. It is recommended to protect cable with cable bridge that prevents damage or accidental pulling on the cable.
- During operation, moving parts can cause a risk of damage to bystanders - keep a safe distance of at least 1m.
- During all activities related to: placing of the patient in the device, its fastening, making adjustments of clamps, device must remain motionless, and the key incorporating the device must be turned to position "off" and be removed from the ignition .
- During device operation any regulation or adjustment of patients clamps is strictly forbidden! All adjustments can be done only when the device is in motionless state.
- In case of emergency that requires immediate stop, press AW button „Safety switch“. 3 AW button are located in upper part of both sides of the device and on a control panel.
After the AW button is pressed, it is not possible to turn on the device again before releasing the AW button. To do so, turn the key in the direction indicated by the arrows on the button AW, or until the button pops up. DEVICE must be run in accordance with section 5 of this manual.
- The control screen is not a touch screen! The control is performed only with the buttons, and any hitting, pushing or repeated touching the screen can cause damage and malfunction.
- Each patient during therapy should be constantly observed by operator
- Prodromus Sp. z o.o. shall not be liable for any damages or accidents arising in case of non-compliance with this instruction manual and the safety rules included in documentation of Prodrobot.
- **WARNING!** During the initialization device is in motion. Keep a safe distance from the machine.
- **WARNING!** Do not make any adjustments to the device when it is in motion!

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- After fastening the patient comfort should be monitored periodically. In case of any alarming symptoms (eg. limbs bruising, pain) an exercise should be stopped. It is necessary to check way of fastening clamps and make appropriate corrections or to completely abandon the exercise.

4. Clinical assessment context and a choice of clinical data

- The product has been designed and built based on the market competing medical devices analysis. Purpose and principle of operation are the same as with the solutions of competing devices, but technical approach was revised (different solutions in the context of mechanical drive and control). Device selection was based on the data on most recognizable commercial devices in the market. Devices that were cited in the literature, but there are on prototype stage or their presence in the market is marginal, were not taken into account in the analysis.
- Creating a clinical evaluation all information contained in a quoted list of scientific literature; experience of team members and the information provided by the manufacturers of similar products under assessment (summarized in the table below) were used. Professional literature in book form was also used.
- Due to technical limitations of the device (up to 50kg weight and growth to approx. 150 cm) an analysis of the literature was conducted both in terms of the literature about pediatric patients and adults therapy. It is assumed that the use of the device may depend on the location of the device (office general rehabilitation, geriatric or cabinet dedicated for children). Either group of adult patients or pediatric patients can be expected, however, estimation which group will be more numerous is not possible, and only depends on the owner and the demand for treatment - the analysis carried out for the wider audience.

4.1 Analysis of the reference products on the market

	Prodrobot	Lokomat	Innowalk Pro	GEO	Lokohelp
Size of device	140kg, 0,88x0,7x1,4m	Over 1000kg, about 3,2x1,5x2,4	about. 50kg; ok. 1,8x1,6x0,7	about. 900kg; 4x1,2x2,8m	raiser for treadmills - the size depends on the treadmill and accessories
Size of patient	120-150cm, 50kg	110-200 cm; 120kg	100 -140 cm, 75 kg small 130 -180 cm 75 kg big	from 90 cm tall	no data
Step length	electronically regulated	electronically regulated	mechanically regulated	electronically regulated	lack
Regulation of step length	stepless	stepless	3 levels	stepless	lack

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Max speed	not more than 2km/h	max 3,2 (for adults)	no data	max 70 steps/min	no data
Exercises	Gait according to gait pattern, swings, squats, bicycle, stairs walking - all the others moves possible according to human anatomy.	Gait pattern (only 4 joints)	No gait pattern - making only alternating movements	Gait according to gait pattern – only 2 joints	No gait pattern - making only alternating movements
Sitting assistant	mounted	lack	mounted	lack	lack
Patient offloading	mounted	mounted	lack	mounted	mounted
Spasticity control	6 joints control	4 joints control	off after exceeding the specified load	1 joint control – limited possibility of showing a place of spasticity appearance	lack
Patient fittings and regulations	numerous micro regulations (7 each leg), 3clamps on each leg; chest clamp (regulated), hips positioning	3 clamps on each leg; 1 feet mounting ; corset suspended	leg set in 2 points	Foot mounting using a shoe	Foot mounting using a shoe

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Indications	<p>paraplegia; for persons with stroke affecting gait impairment; Parkinson's disease with the slowdown, muscle stiffness and impaired motility disorders of gait and postural; in disorders of gait and posture in polyneuropathies of different reasons (toxic, metabolic, and autoimmune nature as Guillain-Barre syndrome) with muscle weakness of varying severity including a flaccid paralysis; for patients with cerebral palsy, in which movement disorders mainly consist of muscle weakness and spasticity, for patients with muscular diseases such as muscular dystrophy with progressive weakness and atrophy of muscles; to use as a standing frame for verticalisation</p>	<p>conditions after stroke (brain or spinal), conditions after spinal cord injury, spinal muscular atrophy, muscle weakness caused by lack of movement, brain injuries; multiple sclerosis (MS); cerebral palsy (CP); Parkinson's disease; Endoprosthesis (</p>	<p>cerebral palsy, spina bifida, muscular dystrophy as well as for accident injuries with different upper and lower limbs.</p>	<p>Stroke brain damage patients orthopedic Parkinson's disease Cerebral Palsy Multiple sclerosis Guillain- Barrégo</p>	<p>Use for stroke, multiple sclerosis, cerebral palsy, Parkinson's disease, spinal cord injury and brain, endoprosthes es, spinal muscular atrophy, patients with hemiplegia, and paraplegia</p>
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Contraindications	<p>the length of the orthosis is not adjusted to the patient's height, weight greater than 50kg, considerable muscle contractures, bone instability (unstable fractures, unstable spine, advanced osteoporosis), open skin damage around legs, arms and trunk, circulation problems, cardiac contraindications, patient not cooperative or aggressive, for example suffered from transitory psychotic syndrome, significant cognitive deficits, no verbal contact with the patient, patients treated for a long time with intravenous infusions, mechanical ventilation, patients with extremely disproportionate length of limbs and/or spine (eg. dysplasias osteochondral), severe vascular disorders of the lower limbs, in general, patients with the recommendation of bed rest or immobilization due to eg.</p>	<p>the inability to adapt the orthosis to the body (legs, for example. due to the significant deformation) weight above 135 kg instability of the skeleton (not fused cracks, instability of the spine, fractures, advanced osteoporosis)</p>	no data	no data	no data

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	osteoarthritis or other inflammatory/infectious, arthrodesis of the hip, knee or ankle, active implants				
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The product meets the requirements of the Directive 93/42 / EEC and Annex II of the directive and requirements specified in a list of harmonized standards according to Technical Documentation document A7-TD1.

5. Justification for the choice of clinical data.

Based on a literature review, scientific evidence was found that using the analyzed medical device is reasonable. Due to a fact that competitive, commercially available products exist and method of operation is known and applied, the literature review was performed. The chosen method is adequate to the risks associated with the use of the evaluated medical device.

5.1 A summary of the clinical data and their assessment

- The list of differences and similarities of competitive medical devices existing on a market listed in section 4.1.
- Medical devices presented in the above table compared to Prodrobot are certified medical devices in Class IIa. Above devices are registered on a Polish market. The main common feature of these devices is that all are moving patient's lower limbs mechanically in a human anatomical range, and all devices imitating gait or imitating other exercises of lower limbs.
- These products are in sales on the European market of medical devices. The essential features of all above devices are: a motorized moving the lower limbs of the patient within human anatomy restraints and performing gait pattern or other exercises of lower limbs. Indications related to a referenced use are the same. Differences are due to the size of device and other approach to design of the mechanical solution (other drives and motion transmission to the patient's limb).
- Clinical data were collected on the basis of a critical evaluation of literature and the comparison of information on competitive products obtained on the basis of the descriptions of the products contained in the advertising materials and instructions for use.

A literature review had been done by searching of keywords in content or abstract of publications available in medical literature databases. After first step of review, all publications without information about using of medical

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device was rejected. One of the main criterion was presence of publication in reliable scientific data bases.

- Based on Pub-med data base, by using key words like: robotised gait training, gait training, rehabilitation robots, clinical evaluation, contraindications. Review was performed since 05.2015 till 06-2018
- Based on Silesian Medical University Library in Katowice domestic literature review was performed.
- In subject of electrical safety, a study - on the need for the RCD in an electrical system to which robot will be connected - was additionally used. The fact was used that the study is a publication review, summarizing the general knowledge in this field with respect to the norms and standards of use.

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5.2 Tabulation of literature used to develop clinical evaluation

Lp.	Categorization of information in a predetermined scale: 1. reference used to evaluate the effectiveness 2. reference used to evaluate the effectiveness and indications for use 3. reference used to evaluate the effectiveness, indications for use and contraindications, 4. reference used to evaluate the safety and contraindications	Reference	Use of references to assessment:				References analysis
			The effectiveness of the device	Indications for use	Contraindications	Safety and contraindications	
1	2	S. Hesse, C. Werner, D. Uhlenbrock, S. v. Frankenberg, A. Bardeleben, and B. Brand1-Hesse An Electromechanical Gait Trainer for Restoration of Gait in	x	x			Modern concepts of gait rehabilitation after stroke favor a task-specific repetitive approach. In practice, the required physical effort of the therapists limits the realization of this approach. Therefore, a mechanized gait trainer enabling nonambulatory patients to have the repetitive practice of a gait-like movement without overstraining therapists was constructed. This

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		Hemiparetic Stroke Patients: Preliminary Results 2001						preliminary study investigated whether an additional 4-week daily therapy on 12 he gait trainer could improve gait ability in 14 chronic wheelchair-bound hemiparetic subjects. The 4 weeks of physiotherapy and gait-trainer therapy resulted in a relevant improvement of gait ability in all subjects. Velocity, cadence, and stride length improved significantly (p < 0.01). The kinesiological electromyogram of selected lower-limb muscles revealed a more physiologic pattern. The confounding influence of spontaneous recovery, the lack of a control group, and the double amount of therapy limit the clinical relevance of this study. Never theless, the gait trainer seems feasible as an adjunctive tool in gait rehabilitation after stroke; further studies are needed.
2	3	Rupp R, Schließmann D, Plewa H, Schuld C, Gerner HJ, Weidner N, et al. (2015) Safety and Efficacy of At-Home Robotic Locomotion Therapy in Individuals with Chronic Incomplete Spinal Cord Injury: A Prospective, Pre-Post Intervention, Proof-of- Concept Study. PloS ONE 10(3): e0119167. Doi:10.1371/journal.pone.0119167	X	X	X	X	Background The compact Motorized orthosis for home rehabilitation of Gait (MoreGait) was developed for continuation of locomotion training at home. MoreGait generates afferent stimuli of walking with the user in a semi-supine position and provides feedback about deviations from the reference walking pattern. Objective Prospective, pre-post intervention, proof-of-concept study to test the feasibility of an unsu- 12hronic12 home-based application of five MoreGait prototypes in subjects with incomplete spinal cord injury (iSCI). Methods Twenty-five (5 tetraplegia, 20 paraplegia) participants with chronic (mean time since injury: 5.8 ± 5.4 (standard deviation, SD) years) sensorimotor iSCI (7 ASIA Impairment Scale (AIS) C, 18 AIS D; Walking Index for Spinal Cord Injury (WISCI II): Interquartile	



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		March 24, 2015					<p>range 9 to 16) completed the training (45 minutes / day, at least 4 days / week, 8 weeks). Baseline status was documented 4 and 2 weeks before and at training onset. Training effects were assessed after 4 and 8 weeks of therapy.</p> <p>Results</p> <p>After therapy, 9 of 25 study participants improved with respect to the dependency on walking aids assessed by the WISCI II. For all individuals, the short-distance walking velocity measured by the 10-Meter Walk Test showed significant improvements compared to baseline (100%) for both self-selected (Mean 139.4% \pm 35.5% (SD)) and maximum (Mean 143.1% \pm 40.6% (SD)) speed conditions as well as the endurance estimated with the six-minute walk test (Mean 166.6% \pm 72.1% (SD)). One device-related adverse event (pressure sore on the big toe) occurred in over 800 training sessions.</p> <p>Conclusions</p> <p>Home-based robotic locomotion training with MoreGait is feasible and safe. The magnitude of functional improvements achieved by MoreGait in individuals with iSCI is well within the range of complex locomotion robots used in hospitals. Thus, unsupervised MoreGait training potentially represents an option to prolong effective training aiming at recovery of locomotor function beyond in-patient rehabilitation.</p> <p>Trial Registration German Clinical Trials Register (DKRS) DRKS00005587</p>
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3	3	<p>Safety of robotic-assisted treadmill therapy in children and adolescents with gait impairment: A bi-centre survey</p> <p>Ingo Borggraefe, Mirjam Klaiber, Tabea Schuler, Birgit Warken, Sebastian Alexander Schroeder, Florian Heinen, Andreas Meyer-Heim</p> <p>April 2010</p>		X	X	X	<p>Objective: The aim of the present study was to report on adverse events encountered with robotic-assisted treadmill therapy in children and adolescents with gait disorders. Methods: Eighty-nine patients who underwent a trial of robotic assisted treadmill therapy in the two participating centres were analysed. Demographic data and safety data of the patients were analysed using descriptive statistics. Results: In 38 (42.7%) out of 89 patients, adverse events were documented. Most commonly, mild skin erythema at the sites of the cuffs of the device and muscle pain were encountered. In five patients (5.6%), open skin lesions (n 1/4 2), joint pain (n 1/4 2) or tendinopathy (n 1/4 1) limited the continuation of the therapy with the Lokomat. No severe side-effects emerged. Conclusions: Robotic assisted treadmill therapy is a safe method to enable longer periods of gait therapy in children and adolescents with gait disorders.</p>
4	3	<p>Driven gait orthosis for improvement of locomotor training in paraplegic patients</p> <p>G Colombo*,1, M Wirz1 and V Dietz1</p> <p>2001</p>	X	X	X		<p>Design: Single cases. Objective: To compare the effects of manually assisted locomotor training in paraplegic patients with the automated training by a driven gait orthosis. Setting: ParaCare, University Hospital Balgrist in Zurich, Switzerland. Methods: Treadmill training with manual assistance and by a driven gait orthosis was applied to two spinal cord injured patients. The first patient 14a dan incomplete lesion at C3, the second a complete lesion at C5. They were selected by convenience sample. The EMG activity of the leg muscles rectus femoris, biceps femoris, gastrocnemius medialis (GM) and tibialis</p>

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							anterior (TA) was visually compared for the two training methods. GM and TA activity was also quantified by calculating the variation ratio between the EMG of the patients and a set of healthy subjects. Results: No significant difference between the two training methods was found according to the leg muscle EMG activity. Conclusion: Neuronal centers in the spinal cord become activated in a similar way by the manually assisted and the automated locomotor training. With the driven gait orthosis training sessions can be prolonged and workload of therapists can be reduced, and therefore, the automated training represents an alternative to the conventional therapy.
4	2	Feasibility and effects of patient-cooperative robot-aided gait training applied in a 4-week pilot trial Alex Schuck, Rob Labruye`re, Heike Vallery, Robert Riener and Alexander Duschau-Wicke 2012	X	X			Background: Functional training is becoming the state-of-the-art. Therapy approach for rehabilitation of individuals after stroke and spinal cord injury. Robot-aided treadmill training reduces personnel effort, especially when treating severely affected patients. Improving rehabilitation robots towards more patient-cooperative behavior may further increase the effects of robot-aided training. This pilot study aims at investigating the feasibility of applying patient-cooperative robot-aided gait rehabilitation to stroke and incomplete spinal cord injury during a therapy period of four weeks. Short-term effects within one training session as well as the effects of the training on walking function are evaluated. Methods: Two individuals with 15hronic incomplete spinalcord injury and two with chronic stroke trained



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						<p>with the Lokomat gait rehabilitation robot which was operated in a new, patient-cooperative mode for a period of four weeks with four training sessions of 45 min per week. At baseline, after two and after four weeks, walking function was assessed with the ten meter walking test. Additionally, muscle activity of the major leg muscles, heart rate and the Borg scale were measured under different walking conditions including a non-cooperative position control mode to investigate the short-term effects of patient-cooperative versus non-cooperative robot-aided gait training.</p> <p>Results: Patient-cooperative robot-aided gait training was tolerated well by all subjects and performer without difficulties. The subjects trained more actively and with more physiological muscle activity than in a non-cooperative position-control mode. One subject showed a significant and relevant increase of gait speed after the therapy, the three remaining subjects did not show significant changes.</p> <p>Conclusions: Patient-cooperative robot-aided gait training is feasible in clinical practice and overcomes the main points of criticism against robot-aided gait training: It enables patients to train in an active, variable and more natural way. The limited number of subjects in this pilot trial does not permit valid conclusions on the effect of patient-cooperative robot-aided gait training on walking function. A large, possibly multi-center randomized controlled clinical trial is required to shed more light on this question.</p>
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5	3	Recovery of Locomotion After Spinal Cord Injury: Some Facts and Mechanisms Serge Rossignol ¹ and Alain Frigon 2011	X	X	X		After spinal cord injury (SCI), various sensorimotor functions can recover, ranging from simple spinal reflexes to more 17laboratem o- tor patterns, such as locomotion. Locomotor recovery after complete spinalization (complete SCI) must depend on the presence of spinal cir- cuitry capable of generating the complex sequential activation of various leg muscles. This is achieved by an intrinsic spinal circuitry, termed the central pattern generator (CPG), working in conjunction with sensory feedback from the legs. After SCI, different changes in cellular and circuit properties occur spontaneously and can be promoted by pharmacological, electrical, or rehabilitation strategies. After partial SCI, hindlimb locomotor recovery can result from regeneration or sprouting of spared pathways, but also from mechanisms observed after complete SCI, namely changes within the intrinsic spinal circuitry and sensory inputs.
6	2	Robotic Gait Training Is not Superior to Conventional Treadmill Training in Parkinson Disease: A Single-Blind Randomized Controlled Trial Stefano Carda, MD, PhD, Marco Invernizzi, MD, Alessio Baricich, MD, Cristoforo Comi, MD, PhD, Alexandre Croquelois, MD, MER2, and Carlo Cisari, MD	X	X		X	<i>Background.</i> The use of robots for gait training in Parkinson disease (PD) is growing, but no evidence points to an advantage over the standard treadmill. <i>Methods.</i> In this randomized, single-blind controlled trial, participants aged <75 years with early-stage PD (Hoehn-Yahr <3) were randomly allocated to 2 groups: either 30 minutes of gait training on a treadmill or in the Lokomat for 3 d/wk for 4 weeks. Patients were evaluated by a physical therapist blinded to allocation before and at the end of treatment and then at the 3- and 6-month follow-up.The primary outcome measure was the 6-minute walk test. <i>Results.</i> Of 334 screened patients, the authors randomly allocated 30 to receive gait training with treadmill or the Lokomat.

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		11-12.2012					At baseline, the 2 groups did not differ. At the 6-month follow-up, both groups had improved significantly in the primary outcome measure (treadmill: mean = 490.95 m, 95% confidence interval [CI] = 448.56-533.34, $P = .0006$; Lokomat: 458.6 m, 95% CI = 417.23-499.96, $P = .01$), but no significant differences were found between the 2 groups ($P = .53$). <i>Discussion.</i> Robotic gait training with the Lokomat is not superior to treadmill training in improving gait performance in patients with PD. Both approaches are safe, with results maintained for up to 6 months.
7	3	Szczegółowe wskazania i przeciwwskazania do rehabilitacji uzdrawiskowej w poszczególnych Rodzajach zakładów lecznictwa uzdrawiskowego – załącznik nr 1 do Rozporządzenia Ministra Zdrowia w sprawie sposobu kierowania i kwalifikowania pacjentów do zakładów lecznictwa uzdrawiskowego. 2012			X		I Choroby ortopedyczno-urazowe (ortopedia) – szczegółowe przeciwwskazania; II Choroby układu nerwowego (neurologia) – szczegółowe przeciwwskazania; III Choroby reumatologiczne (reumatologia) – szczegółowe przeciwwskazania XII Osteoporoza – szczegółowe przeciwwskazania
8	3	Walking assist robot and its clinical application. Kakou H1, Shitama H, Kimura Y, Nakamoto	x	x	x		The walking assist robot was developed to improve gait disturbance in patients with severe disabilities. The robot had a trunk supporter, power generator and operating arms which held patient's lower extremities

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		Y, Furuta N, Honda K, Wada F, Hachisuka K. 2009					and simulated walking, a control unit, biofeedback system, and a treadmill. We applied the robot-aided gait training to three patients with severe gait disturbance induced by stroke, axonal Guillan-Barré syndrome or spinal cord injury, and the walking assist robot turned out to be effective in improving the gait disturbance.
9	3	Practical Recommendations for Robot-Assisted Treadmill Therapy (Lokomat) in Children with Cerebral Palsy: Indications, Goal Setting, and Clinical Implementation within the WHO-ICF Framework. Tabea Aurich (-Schuler), Warken B1, Graser JV2, Ulrich T3, Borggraefe I1, Heinen F1, Meyer-Heim A2, van Hedel HJ2, Schroeder AS	x	x	x		Active participation and the highest level of independence during daily living are primary goals in neurorehabilitation. Therefore, standing and walking are key factors in many rehabilitation programs. Despite inconclusive evidence considering the best application and efficacy of robotic tools in the field of pediatric neurorehabilitation, robotic technologies have been implemented to complement conventional therapies in recent years. A group of experienced therapists and physicians joined in an “expert panel.” They compared their clinical application protocols, discussed recurring open questions, and developed experience-based recommendations for robot-assisted treadmill therapy (exemplified by the Lokomat, Hocoma, Volketswil, Switzerland) with a focus on children with cerebral palsy. Specific indications and therapeutic goals were defined considering the severity of motor impairments and the International Classification of Functioning, Disability and Health framework (ICF). After five meetings, consensus was found and recommendations for the implementation of robot-assisted treadmill therapy including postsurgery rehabilitation were proposed. This article aims to provide a comprehensive overview on therapeutical applications in a fast developing field

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							of medicine, where scientific evidence is still scarce. These recommendations can help physicians and therapists to plan the child's individual therapy protocol of robot-assisted treadmill therapy.
10	3	Robot-assisted gait training might be beneficial for more severely affected children with cerebral palsy: Brief report. Van Hedel HJ1, Meyer-Heim A, Rüsç-Bohtz C. 02-04-2015	x	x	x		Purpose: Robot-assisted gait training (RAGT) can complement conventional therapies in children with cerebral palsy. We investigated changes in walking-related outcomes between children with different Gross Motor Function Classification System (GMFCS) levels and the dose-response relationship. Methods: Data from 67 children (3.9-19.9 years) with GMFCS levels II-IV were evaluated retrospectively. Every child received RAGT with the Lokomat complementing a multidisciplinary rehabilitation program. Changes in various walking-related outcomes were assessed. Results: Walking-related outcomes did not improve differently between GMFCS level groups. Significant within-group improvements were mainly observed in children with GMFCS level IV. A dose-response relationship was present for children with GMFCS levels III and IV. Conclusions: Our results indicated that, although children with a GMFCS level IV walked less during an average Lokomat session, they experienced

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							significant improvements in walking-related outcomes. Further, training dose correlated with changes in walking-related outcomes. However, between-group differences in changes in walking-related outcomes were not significant.
11	3	Clinical application of the Hybrid Assistive Limb (HAL) for gait training—a systematic review Anneli Wall, Jörgen Borg and Susanne Palmcrantz 2015	x	x	x		<p>Objective: The aim of this study was to review the literature on clinical applications of the Hybrid Assistive Limb system for gait training.</p> <p>Methods: A systematic literature search was conducted using Web of Science, PubMed, CINAHL and clinicaltrials.gov and additional search was made using reference lists in identified reports. Abstracts were screened, relevant articles were reviewed and subject to quality assessment.</p> <p>Results: Out of 37 studies, 7 studies fulfilled inclusion criteria. Six studies were single group studies and 1 was an explorative randomized controlled trial. In total, these studies involved 140 participants of whom 118 completed the interventions and 107 used HAL for gait training. Five studies concerned gait training after stroke, 1 after spinal cord injury (SCI) and 1 study after stroke, SCI or other diseases affecting walking ability. Minor and transient side effects occurred but no serious adverse events were reported in the studies. Beneficial effects on gait function variables and independence in walking were observed.</p> <p>Conclusions: The accumulated findings demonstrate that the HAL system is feasible when used for gait training of patients with lower extremity paresis in a</p>

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							professional setting. Beneficial effects on gait function and independence in walking were observed but data do not allow conclusions. Further controlled studies are recommended.
12	3	Robot-assisted walking training for individuals with Parkinson's disease: a pilot randomized controlled trial. Sale P, De Pandis MF, Le Pera D, Sova I, Cimolin V, Ancillao A, Albertini G, Galli M, Stocchi F, Franceschini M 2013	x	x		x	BACKGROUND: Over the last years, the introduction of robotic technologies into Parkinson's disease rehabilitation settings has progressed from concept to reality. However, the benefit of robotic training remains elusive. This pilot randomized controlled observer trial is aimed at investigating the feasibility, the effectiveness and the efficacy of new end-effector robot training in people with mild Parkinson's disease. METHODS: Design. Pilot randomized controlled trial. RESULTS: Robot training was feasible, acceptable, safe, and the participants completed 100% of the prescribed training sessions. A statistically significant improvement in gait index was found in favour of the EG (T0 versus T1). In particular, the statistical analysis of primary outcome (gait speed) using the Friedman test showed statistically significant improvements for the EG (p = 0,0195). The statistical analysis performed by Friedman test of Step length left (p = 0,0195) and right (p = 0,0195) and Stride length left (p = 0,0078) and right (p = 0,0195) showed a significant statistical gain. No statistically significant improvements on the CG were found CONCLUSIONS: Robot training is a feasible and safe form of rehabilitative exercise for cognitively intact people with mild PD. This original approach can contribute to increase a short time lower limb motor recovery in idiopathic PD patients. The focus on the gait recovery is a further characteristic that makes this

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						<p>research relevant to clinical practice. On the whole, the simplicity of treatment, the lack of side effects, and the positive results from patients support the recommendation to extend the use of this treatment. Further investigation regarding the long-time effectiveness of robot training is warranted.</p> <p>TRIAL REGISTRATION: ClinicalTrials.gov NCT01668407.</p>
13	3	<p>Plantar Pressure Distribution During Robotic-Assisted Gait in Post-stroke Hemiplegic Patients. Yang JK, Ahn NE, Kim DH, Kim DY 2014</p>	X	X	X	<p><u>OBJECTIVE</u>: To assess the plantar pressure distribution during the robotic-assisted walking, guided through normal symmetrical hip and knee physiological kinematic trajectories, with unassisted walking in post-stroke hemiplegic patients.</p> <p><u>METHODS</u>: Fifteen hemiplegic stroke patients, who were able to walk a minimum of ten meters independently but with asymmetric gait patterns, were enrolled in this study. All the patients performed both the robotic-assisted walking (Lokomat) and the unassisted walking on the treadmill with the same body support in random order. The contact area, contact pressure, trajectory length of center of pressure (COP), temporal data on both limbs and asymmetric index of both limbs were obtained during both walking conditions, using the F-Scan in-shoe pressure measurement system.</p> <p><u>RESULTS</u>: The contact area of midfoot and total foot on the affected side were significantly increased in robotic-assisted walking as compared to unassisted</p>

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							<p>walking ($p < 0.01$). The contact pressure of midfoot and total foot on affected limbs were also significantly increased in robotic-assisted walking ($p < 0.05$). The anteroposterior and mediolateral trajectory length of COP were not significantly different between the two walking conditions, but their trajectory variability of COP was significantly improved ($p < 0.05$). The asymmetric index of area, stance time, and swing time during robotic-assisted walking were statistically improved as compared with unassisted walking ($p < 0.05$).</p> <p><u>CONCLUSION:</u> The robotic-assisted walking may be helpful in improving the gait stability and symmetry, but not the physiologic ankle rocker function.</p>
14	3	<p>Anti-gravity training improves walking capacity and postural balance in patients with muscular dystrophy. Berthelsen MP, Husu E, Christensen SB, Prahm KP, Vissing J, Jensen BR. 2014</p>	X	X		X	<p>Recent studies in patients with muscular dystrophies suggest positive effects of aerobic and strength training. These studies focused training on using bicycle ergometers and conventional strength training, which precludes more severely affected patients from participating, because of their weakness. We investigated the functional effects of combined aerobic and strength training in patients with Becker and limb-girdle muscular dystrophies with knee muscle strength levels as low as 3% of normal strength. Eight patients performed 10 weeks of aerobic and strength training on an anti-gravity treadmill, which offered weight support up to 80% of their body weight. Six minute walking distance, dynamic postural balance, and plasma creatine kinase were assessed 10 weeks prior to training,</p>

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							immediately before training and after 10 weeks of training. Training elicited an improvement of walking distance by 8±2% and dynamic postural balance by 13±4%, indicating an improved physical function. Plasma creatine kinase remained unchanged. These results provide evidence that a combination of aerobic and strength training during anti-gravity has the potential to safely improve functional ability in severely affected patients with Becker and limb-girdle muscular dystrophies.
15	3	Posture and gait abilities in patients with myotonic dystrophy (Steinert disease). Evaluation on the short-term of a rehabilitation program. Missaoui B, Rakotovao E, Bendaya S, Mane M, Pichon B, Faucher M, Thoumie P. 2010	X	X			Objective: To evaluate the effects of a rehabilitation program in terms of balance, gait and muscle strength in a population of patients with myotonic dystrophy. PATIENTS: Twenty patients benefited, as outpatients in a hospital setting, from a rehabilitation program with clinical and instrumental evaluations. The evaluation focused on quantitative balance measurement by clinical and stabilometer tests, gait assessed by Locometre and extensors and flexors knee muscle strength measured in isokinetic concentric mode at 60°/s. RESULTS: After the rehabilitation program, we observed a significant improvement in the patients' balance capacities measured with the Berg Balance Scale (BBS), fast gait speed and muscle strength. However, the instrumental evaluation did not report any gains for static balance and spontaneous gait speed after the training program. No correlation was found between the various improvements. CONCLUSION: A rehabilitation program focused on strength, gait and

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							balance allowed for significant improvements in some parameters of myotonic dystrophy. These results attest to the relevance of a short-term rehabilitation protocol for these patients in the framework of a multidisciplinary therapeutic care. The disparity observed in the results measured for these patients suggest the contribution of cognitive involvement in the limitations felt by patients with myotonic dystrophy in the areas of gait and balance.
16	3	Walking assist robot and its clinical application <u>Kakou H, Shitama H, Kimura Y, Nakamoto Y, Furuta N, Honda K, Wada F, Hachisuka K; 2009</u>	x	x			The walking assist robot was developed to improve gait disturbance in patients with severe disabilities. The robot had a trunk supporter, power generator and operating arms which held patient's lower extremities and simulated walking, a control unit, biofeedback system, and a treadmill. We applied the robot-aided gait training to three patients with severe gait disturbance induced by stroke, axonal Guillan-Barré syndrome or spinal cord injury, and the walking assist robot turned out to be effective in improving the gait disturbance.
17	4	Wybrane problemy instalacyjne przy stosowaniu wyłączników różnicowoprądowych. Dr inż. Inż. Stanisław Czapp Politechnika Gdańska				X	Przedstawiono klasyfikację wyłączników różnicowoprądowych oraz zasady ich doboru i instalowania w instalacjach elektrycznych. Omówiono czynniki wpływające na prawidłowe działanie wyłączników i zwrócono uwagę na błędy popełniane przy ich stosowaniu. Wymieniono obwody, w których instalowanie wyłączników różnicowoprądowych jest obowiązkowe, a w których niezalecane. Zwrócono uwagę na problemy działania wyłączników różnicowoprądowych przy prądach różnicowych odkształconych. Przedstawiono zastosowanie specjalnych konstrukcji wyłączników

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							różnicowoprądowych, jakimi są przenośne urządzenia różnicowoprądowe.
18	4	Wykorzystanie robotów rehabilitacyjnych do usprawniania Emilia Mikołajewska (10 Wojskowy Szpital Kliniczny z Polikliniką SP ZOZ w Bydgoszczy) Dariusz Mikołajewski (Uniwersytet Kazimierza Wielkiego w Bydgoszczy Uniwersytet Mikołaja Kopernika w Toruniu) „Niepełnosprawność – zagadnienia, problemy, rozwiązania”. Nr IV/2013(9)	X	X		X	Nauki medyczne oraz praktyka kliniczna coraz częściej sięgają po najnowsze rozwiązania techniczne rozszerzające możliwości terapii oraz podwyższające jej efektywność. We współczesnej rehabilitacji za jedno z takich rozwiązań uważa się wykorzystanie robotów do usprawniania pacjentów. Artykuł ma na celu przedyskutowanie możliwości zastosowań klinicznych oraz ocenę możliwych kierunków rozwoju robotyki.
19	4	Bezpieczeństwo pracy z robotami rehabilitacyjnymi Emilia Mikołajewska (10 Wojskowy Szpital Kliniczny z Polikliniką SP ZOZ w Bydgoszczy) Dariusz Mikołajewski (Uniwersytet Kazimierza Wielkiego w Bydgoszczy Uniwersytet Mikołaja Kopernika w Toruniu)				X	Robotyka rehabilitacyjna jest postrzegana jako użycie robotów w rehabilitacji różnych schorzeń, szczególnie związanych z motoryką człowieka, kardiologicznych i neurologicznych. Może być postrzegana jako dobre rozwiązanie, aby poprawić efektywność, zaoszczędzić czas oraz zmniejszyć koszty opieki zdrowotnej osób niepełnosprawnych, ciężko chorych i w podeszłym wieku. Artykuł jest próbą oceny, w jakim stopniu wykorzystuje się możliwości w tym obszarze, kładąc nacisk na bezpieczeństwo robotów rehabilitacyjnych oraz analizę zagrożeń. Ze względu na brak badań i publikacji konieczne są dalsze badania w omawianym zakresie.

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20	3	Do post-stroke patients benefit from robotic verticalization? A pilot-study focusing on a novel neurophysiological approach. Calabrò, Rocco Salvatore*; 1 Naro, Antonino1 Russo, Margherita Leo, Antonino Balletta, Tina Saccá, Ileana De Luca, Rosaria Bramanti, Placido, 2015	X	X	X	X	Objective: To test the safety and effectiveness of ERIGO treatment on motor and cognitive functions, cortical plasticity within vestibular and sensory-motor systems in a bedridden post-stroke sample. Results: Both the verticalization treatments were well-tolerated. Notably, the G1 patients had a significant improvement in cognitive function (p=0.03), global motor function (p=0.006), sensory-motor (p< 0.001) and vestibular system plasticity (p=0.02) as compared to G2. Conclusions: ERIGO training could be a valuable tool for the adaptation to the vertical position with a better global function improvement, as also suggested by the sensory-motor and vestibular system plasticity induction.
21	3	Effectiveness of standing frame on constipation in children with cerebral palsy: a single-subject study. Rivi E1, Filippi M, Fornasari E, Mascia MT, Ferrari A, Costi S. ; 2014	X	X			The standing frame may positively influence the management of constipation of these children, possibly improving their quality of life.
22	3	Standing activity intervention and motor function in a young child with cerebral palsy: A case report.	X	X			Implementation of a home-based standing program may have contributed to improved motor skills for this child. Further research is needed to determine the effect of standing interventions on functional motor development for children with severe CP.
23	3	Verticalization as a factor of early rehabilitation in the patients with a spinal cord injury	X	X			The number of days from the spinal cord injury to rehabilitation of the victim has significantly decreased. It means that the rehabilitative treatment begins when the risk of secondary trophic lesions,

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		Makarova MR, Romashin OV. 2013				cardiovascular and respiratory complications is especially high. Training with the use of a tilt-table equipped with the dynamic foot support is considered to be the highly effective method for the prevention or reduction of orthostatic hypotension, impaired ventilation, and pressure sores. This approach makes it possible to influence the patient's motivation for further recovery, decrease the duration of hospitalization in the intensive therapy ward, accelerate adaptation of the patients to the vertical posture, decrease hypotension and hypoxia, reduce to a minimum the occurrence of secondary neurologic disorders. Dynamic tilt-table training is considered to be a more effective modality for the adaptation of the patient to the vertical position than standing with the assistance of a simple table.
24	3	<p>Effect of reducing assistance during robotassisted gait training on step length asymmetry in patients with hemiplegic stroke.</p> <p>A randomized controlled pilot trial.</p> <p>Jin Seok Seo, MD, BS, Hee Seung Yang, MD, MS, Suk Jung, PT, MS, Chang Soon Kang, PT, BS, Sunghun Jang, PT, BS, Dae Hyun Kim, MD, MS 07.2018</p>	x	X		<p>Background: An assist-as-needed robot-assisted gait training protocol was recently developed. It allows active movement during training, but its exact criteria remain unknown. Asymmetric step length is a common abnormal gait pattern in hemiplegic stroke patients. We compared the effects of assist-as-needed robot-assisted gait training on the unaffected and affected limbs of hemiplegic stroke patients.</p> <p>Method: Twenty-four chronic stroke patients with asymmetric step lengths were randomly assigned to 1 of 2 groups. Twelve completed the study protocol. Group 1 underwent 20 sessions of assist-as-needed robot-assisted gait training for the unaffected</p>

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						limb and fully-assisted robot-assisted training for the affected limb. Group 2 underwent 20 sessions of robot-assisted gait training using the opposite protocol. Clinical measurements were obtained and 3-dimensional gait analyses were performed at baseline and after 10 and 20 training sessions. Results: Clinical measurements improved in both groups after 20 training sessions. The unaffected limb's step length asymmetry ratio and hip maximal extension moment significantly improved in group 1. The affected limb's maximal dorsiflexion angle for the ankle in the swing phase significantly improved in group 2.
25	2	<p>Evaluation of training using Lokomat (Hocoma)[®] in physiotherapy process of children and adolescents with cerebral palsy – preliminary report.</p> <p>Mariusz Pawłowski, Jakub Gąsior, Patrycja Mrozek, Marcin Bonikowski, Janusz Błaszczuk, Marek Dąbrowski 2014</p>	X	X		<p>Background. Gait disturbances often result in the reduction of independence and participation in society. In the group of children with cerebral palsy (CP) correct gait attributes are often disrupted. The automated gait orthosis – Lokomat (Hocoma) provides training that can complement the process of gait rehabilitation. The aim of the study was to evaluate the influence of supporting role of robotic orthosis – Lokomat on the mobility of children with cerebral palsy. Material and Methods. 20 children (13 boys) with a diagnosis of CP (spastic diplegia), aged 5 to 17, were enrolled in the study. Patients were divided into 2 groups: control (n = 10) which took part in a standard, complex rehabilitation program six times a week, and an experimental group with locomotion training using Lokomat orthosis three times a week in addition to standard, complex rehabilitation program. Groups were compared before and after 4-week rehabilitation</p>

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						<p>program. Gait function was evaluated by the 6-minute walk test (6minWT), Timed Up & Go Test (TUG) and 10-meter walking test (10MWT). A comparative analysis using GMFCS (Gross Motor Function Classification System) in the experimental group between patients at I–II and III–IV levels was made.</p> <p>Results. The mean duration of 10MWT decreased in the experimental group by 7.5 s and in the control group by 2.4 s. The average distance of 6MinWT increased significantly in the experimental group by 56.5 m and in the control group by 24 m. The mean duration of the TUG test decreased significantly in the experimental group by 5.1 s and in the control group by 6 s. There were no statistically significant differences between groups after a 4-week treatment program in any of the performed test. Patients classified on I and II GMFCS level significantly increased walking speed (10MWT: $1.26 \pm 0,31$ m/s before vs. 1.46 ± 0.33 m/s after; $p < 0.05$) and shortened TUG test duration (11.3 ± 3.9 s before vs. 8.2 ± 1.8 s after; $p < 0.05$). Such results were not observed among patients classified on III and IV GMFCS level. Conclusions. Therapy with the automated gait orthosis Lokomat can be used as a form of support to standard rehabilitation process of patients with CP.</p> <p>Key words: locomotor therapy, gait, Lokomat</p>
26	3	State-of-the-art robotic gait rehabilitation orthoses: design and control aspects	x	x	x	<p>Abstract</p> <p>BACKGROUND:</p> <p>Robot assisted gait training is a rapidly evolving rehabilitation practice. Various robotic orthoses have been developed during the past two decades for the</p>

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		<p>Department of Robotics and Mechatronics, Nazarbayev University, Astana, Kazakhstan 2014</p>				<p>gait training of patients suffering from neurologic injuries. These robotic orthoses can provide systematic gait training and reduce the work load of physical therapists. Biomechanical gait parameters can also be recorded and analysed more precisely as compared to manual physical therapy.</p> <p>OBJECTIVES: A review of robotic orthoses developed for providing gait training of neurologically impaired patients is provided in this paper.</p> <p>METHODS: Recent developments in the mechanism design and actuation methods of these robotic gait training orthoses are presented. Control strategies developed for these robotic gait training orthoses in the recent years are also discussed in detail. These control strategies have the capability to provide customised gait training according to the disability level and stage of rehabilitation of neurologically impaired subjects.</p> <p>RESULTS: A detailed discussion regarding the mechanism design, actuation and control strategies with potential developments and improvements is provided at the end of the paper.</p> <p>CONCLUSIONS: A number of robotic orthoses and novel control strategies have been developed to provide gait training according to the disability level of patients</p>
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							and have shown encouraging results. There is a need to develop improved robotic mechanisms, actuation methods and control strategies that can provide naturalistic gait patterns, safe human-robot interaction and customized gait training, respectively. Extensive clinical trials need to be carried out to ascertain the efficacy of these robotic rehabilitation orthoses.
27	1	Effectiveness of robotic assisted rehabilitation for mobility and functional ability in adult stroke patients: a systematic review Stephenson M, Lockwood C. 2017	x			x	<p>BACKGROUND: Stroke is a leading cause of long-term disability, and rehabilitation, involving repetitive, high intensity, task-specific exercises, is the pathway to restoring motor skills. Robotic assistive devices are increasingly being used and it is hoped that with robotic devices, rehabilitation progress can be achieved for patients.</p> <p>CONCLUSIONS: Robotic training is just as effective as conventional training for upper limb motor movement, lower limb walking mobility and for activities of daily living. For lower limb patients with severe impairment, robotic training produces better outcomes than conventional training. The sufficient quantity of studies included and the reasonable quality of Grading of Recommendations Assessment, Development and Evaluation (GRADE) evidence support the findings. For treatment sustainability of upper and lower limbs, robotic training is just as effective as conventional training. However, the low quality of GRADE evidence and the lower number of studies included require caution for this finding. For treatment sustainability of activities of daily living, the better quality of GRADE evidence and the larger</p>



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							number of studies analyzed indicate that robotic training is just as effective as conventional training.
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6. Analysis of clinical data

6.1 Effectiveness

Data analysis was based on literature searching for keywords in the content of the text relating to the scope of the clinical evaluation. Due to the fact that the evaluated device is similar to that other analogical commonly used medical devices and both restriction and indications are well known - it seems reasonable to conclude that the efficacy of the medical device Prodrobot is confirmed.

6.2 Safety

- In order to ensure maximum safety of the patient during use of the product, tests were carried out to fulfill the requirements of PN-EN 60601-1: 2011 and EN 60601-1-2: 2007 + AC: 2010. A study done in an accredited laboratory have demonstrated the safety of the product. Developed documentation of risk management implemented according to the requirements of EN ISO 14971: 2012 includes a description of the risks and defined measures to control risks. The mechanical hazards study was performed independently by manufacturer according to the risk analysis of the device and results show that Prodrobot can be considered safe for the patient and for the operator within the way of use predicted by the manufacturer and described in the manual.
- The review of medical incidents and events associated with robots was performed - medical devices having a similar effect, present on the Polish, European market and on some others (see table below). From 01.01.2015 to the date of preparation of this assessment any notes related to the safety of any similar product registered in given markets has not been issued.
- It was found only one case of a risky situation, but the situation there is no reference to the device Prodrobot. In a report published on <https://www.swissmedic.ch> informed users Lokomat device, about the possibility of incorrectly set parameters for pediatric patients in the case where the device is also used by adult patients. The device Prodrobot is dedicated to pediatric patients and the design and operating parameters are adapted to the dimensions of children.

Selected medical incidents data bases used for review:	
Country:	URL:
Poland	http://www.urpl.gov.pl/pl/wyroby-medyczne/komunikaty-bezpiecze%C5%84stwa
United Kingdom	https://www.gov.uk/drug-device-alerts
Swiss	https://www.swissmedic.ch/rueckrufe_medizinprodukte/archiv/index.html?lang=en&RIArchiv=2009-01
Germany	http://www.bfarm.de/SiteGlobals/Forms/Suche/EN/kundeninfo_Filtersuche_Formular_en.html
Ireland	http://www.hpra.ie/homepage/medical-devices/safety-information/safety-notice
USA	http://www.fda.gov/Safety/Recalls/default.htm

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Canada	http://www.healthycanadians.gc.ca/recall-alert-rappel-avis/search-recherche/simple?s=robot%2A++&plain_text=robot&js_en=0&per_page=5
Australian	https://www.tga.gov.au/all-alerts http://www.tga.gov.au/SARA/arn-entry.aspx
Kingdom of Saudi Arabia	https://ncmdr.sfda.gov.sa/Secure/CA/AdvanceSearch.aspx

6.3 Labeling, manual and promotional materials

Based on instruction manual and labels review, it is proved that defined risks and hazards are taken into account and described according to EN 1041:2008 standard and EN ISO 15223-1:2012 standard.

7. Conclusions

On the basis of the assessment involving the analysis of the scientific literature, comparing with products manufactured by competitors, defining the rules applicable, the risk analysis and precautions that should be taken in the production and use of the product it is reasonable to argue that the product can be used as intended.

After review in December 2016 – January 2017 above conclusions are upheld and updated in “Indications” and “Safety”

During review in July 2018 company details have been changed. Based on new scientific articles, indications were confirmed. Safety information review (internal data and available externally) did not reveal any new hazards of using Prodrobot automated gait trainer.

8. Clinical assesment team:

- **Agnieszka Piątek- Rybińska** – a range of vocational experience used for clinical assesment: rehabilitation
- **Grzegorz Piątek** – a range of vocational experience used for clinical assesment: design and manufacture of medical devices
- **Wojciech Roman** – a range of vocational experience used for clinical assesment: production of medical devices supervision, medical incidents supervision, scientific medical data bases review
- **Bartłomiej Wielogorski** - a range of vocational experience used for clinical assesment: production of medical devices supervision, medical incidents supervision, scientific medical data bases review

9. Team CV:

Agnieszka Piątek-Rybińska

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Education: Academy of Physical Education – MSc. – field of study: physiotherapy, 2001

Experience: Private praxis

Trainings:

The course of manual therapy "Upper limb - the spine I" 2009

The course of manual therapy "Upper limb - the spine II" 2010

The course of manual therapy "Lower limb - the spine I" 2010

The basic course PNF Proprioceptive Neuromuscular Facilitation, 2010

The course of manual therapy "Lower limb - the spine II" 2011

The course of manual therapy „Carpal tunnels, clinical images, temporomandibular joints” 2011

The course "Medical Functional Training "2012

Training Fascial Distortion Model (according to EFDMA), 2015

Grzegorz Piątek

Education: AGH University of Science and Technology – MSc. – field of study Mechanical Engineering, Cybernetics and Mechatronics, 2011

Experience:

From 2013 Director of Development - Constructor - developed from scratch the concept to ready-to-use medical device Prodrobot.

Before worked in IT and production companies as technical equipment inventor and constructor.

He worked successfully on several projects robotic devices.

Winner of many awards associated with the prototype and final version of medical device Prodrobot.

Wojciech Roman

Education: Jagiellonian University – MSc – field of study: Quality management systems

Experience:

09-11.2004 Centrum Zarządzania Jakością INFOP sp. z o.o. Management Systems consultant

12.2004 – at present: CEO RQS Wojciech Roman – consultancy in the field of medical devices and quality management

Over 90 projects done in the field of medical devices; 2 medical robots projects.

Leading auditor ISO 9001 since 2007 r, (ISOQAR LTD; IRCA nr A17395)

Leading auditor ISO/IEC 27001 since 2006 r, (EXCEL Partnership; IRCA nr 17293)

Bartłomiej Wielogórski

Education: AGH University of Science and Technology – MSc. – field of study

Mechanical Engineering, 2000; postgraduate study: Quality Management Systems, 2003, Production Management 2009,

Experience:

From 2013 C.E.O. and Quality Management System Plenipotentiary in ISO 13485 in Prodromus.

The course for ISO 13486 plenipotentiary and internal auditor; 2013



Technical documentation
Prodrobot automatized gait trainer

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The course "Changes in medical devices regulations"; 2016
Before worked in production companies as quality management specialist, manager,
internal and external auditor, external consultant, trainer.
Experience in scientific medical data bases review.