

Static Parapodium Light PSL 150 – 180
Instructions for use

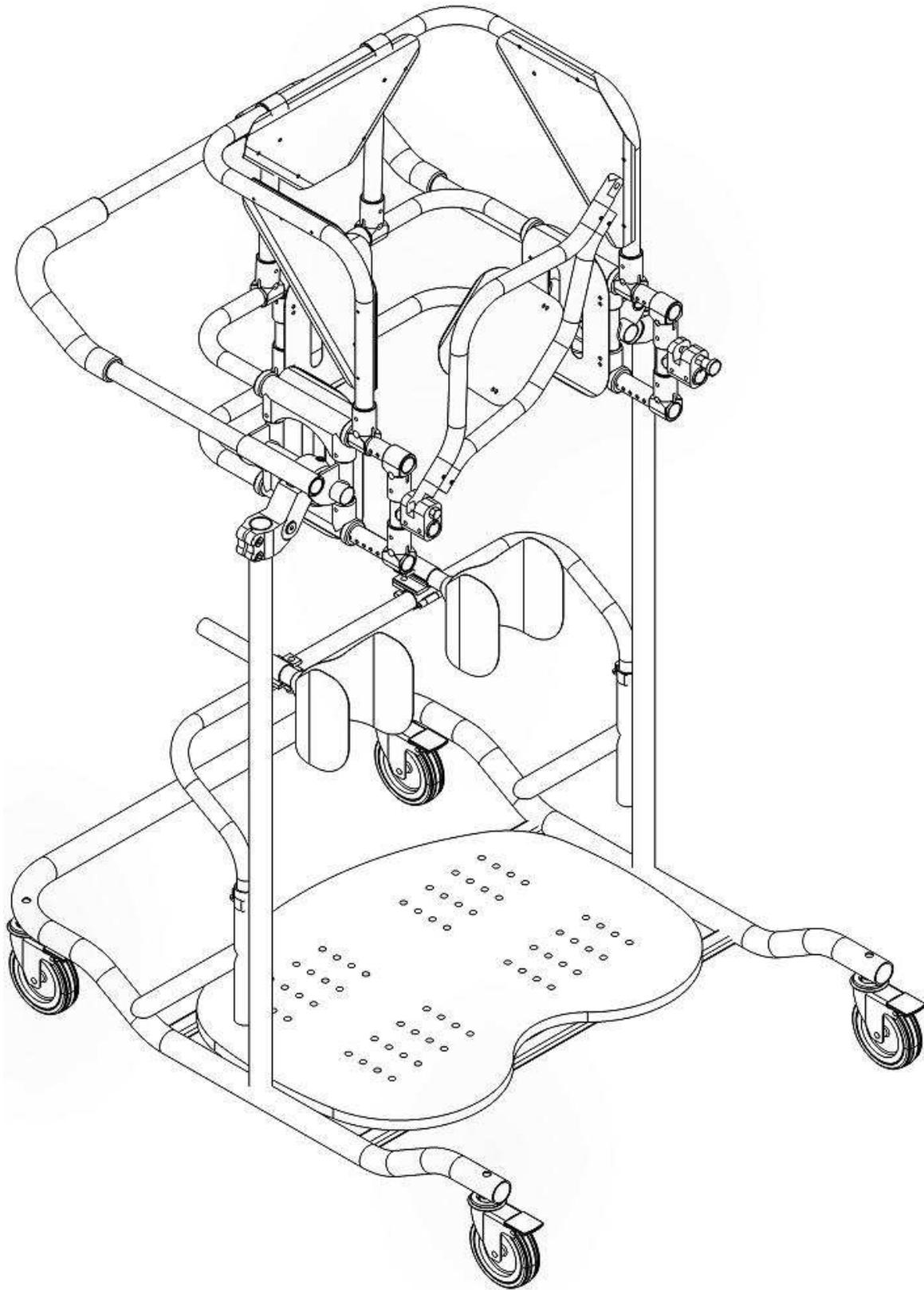


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1. Medical Information

1.1 Introduction, Key Words, Kinesitherapy

Paraplegia and paraparesis and tetraplegia and tetraparesis can be of traumatic or pathologic origin and it most frequently occurs in the following diseases:

- poliomyelitis anterior acuta (Heine–Medin disease, polio),
- spina bifida,
- sclerosis multiplex
- syringomyelia paraplegia
- spondylia, paraplegia
- scoliotica, paraplegia
- neoplasmatica

Indications of the Static Parapodium in rehabilitation is associated with the assumption that the organism is trying to achieve the state of homeostasis by systematic positioning in the upright position. This process involves: loading the bones of low extremities (a part of osteoporosis prevention), stabilizing the joint of lower extremities and the pelvic girdle and the spine in physiological planes (a part of prevention of articular and muscle contractures), strengthening of postural muscles. Obtaining (restoring) the upright position itself is a very important element of adaptation to social relations, by tilting the patient feels equal to his social surrounding.

“The motor process of learning to move (kinesitherapy) is a purposeful, dosed, methodical planned application of motor patterns in order to maintain, support and restore the efficiency of the locomotor and nervous system, circulation, respiration and metabolism.” (Conradi E., Brenke R., Bewegungstherapie-Grundlagen, Ergebnisse, Trends. Ullstein – Mosby, Berlin, 1993)

Parapodium – a kind of orthosis (a technical construction used for the purpose of control of movements, providing aid to, or total or partial reduction of load on the selected elements of the supportive and locomotor system of the body) stabilising, equipped with the base of large surface area, used for subject with lower extremity and trunk paralysis, allowing to assume upright position without additional support on crutches and sitting up.

Static Parapodium = parapodium – orthosis system making passive rehabilitation possible.

Paraparesis (Latin paresis) paresis affecting the lower extremities.

Paraplegia - (Latin paralysis s. Plegia;) palsy affecting the lower extremities. **Tetraparesis** – (Latin paresis) paresis affecting all four extremities. **Tetraplegia** – (Latin paralysis s. Plegia) palsy affecting all four extremities. **Flaccid paralysis** – damage of the peripheral motoneuron.

Spastic paralysis – damage of the central (interior) motoneuron.

Paresis - (Latin paresis) – reduced mobility or power of movement.

Paralysis, plegia - (Latin paralysis) – complete lack of movement.

1.2 Disturbances of Function of Internal Organs in Disabled Subjects Due To Chronic Sitting Position And/Or Bed Ridding

Considerable limitation of physical activity due to chronic supine or/and sitting position leads to the development of interconnected pathological consequences, such as:

- degenerative changes in the cardiovascular system, orthostatic hypotensive syndrome,
- venous stasis, deep venous thrombosis, pulmonary embolism,
- increased risk of coronary disease (lower serum level of high density lipoprotein cholesterol – HDL-C),
- increase of body weight due to lowered basal metabolic rate and reduced daily energy expenditure connected with the lack of physical activity, gas exchange abnormalities,
- Increased risk of
- atelestasis, pneumonia,
- reduced maximum oxygen consumption, which is an indicator of the general patient's condition,
- hyperkalcemia,
- osteoporosis,
- glucose intolerance,
- miction (excretion of urine) and defecation (bowel movement) disturbances, increasing difficulty in everyday activities,
- upper extremity overload syndromes,

- muscular atrophy accompanied by contractures involving multiple
- joints, pathological long bone fractures,
- reduced ability to function independently,
- skin integrity disturbances,
- damage to peripheral nerves,
- increased level of stress associated with everyday
- activities, disturbances of sensory perception,
- social interaction and self-acceptation more difficult (depression),
- increased stigmatisation, stereotypy, discrimination and lack of acceptance among the active members of the society,
- reduced effectiveness and possibility of rehabilitation, which leads to secondary aggravation of the above disorders.

1.3 Advantages of Static Parapodium

1. Standing up, i.e. assuming upright position and sitting down with beneficial forced exercise of the upper extremities, which, in turn, leads to:
 - Elimination of muscular and articular contractures as well as
 - spasticity, Adequate nutrient supply to the connective tissue,
 - Healing of bedsores,
 - Physiological load of the skeletal and articular system (locomotor system),
 - Physiological function (and location in body cavities) of internal organs (peristaltics of the intestines – bowel movements, normalisation of the mechanisms of micturition-neurogenic bladder) and others,
 - Normalisation of function of the cardiovascular and respiratory system.
2. Self-dependent, completely safe and comfortable standing without the necessity to use hands for many hours (even if the patient loses consciousness the upright position is maintained owing to continuous control of the centre of gravity of the body).
3. Wide range of rehabilitation together with ergotherapy.
4. Improving general condition as preparation for practising sports.
5. Preparation of the organism for use of other systems of orthoses of locomotion aid type helping the patient to walk in the environment of healthy people.

However, it should be remembered that only assuming upright position itself is associated with additional exertion.

Advantages – the benefits associated with using such orthotic system as the Static Parapodium place it in the group of exceptionally valuable devices preparing the patient to use other orthotic systems that enable him to walk (dynamic parapodium).

1.4 Most Common Systematic Disturbances Likely to Occut in Paraplegia and Tetraplegia.



WARNING. The prerequisite for starting rehabilitation of the patient making use of the Static Parapodium is previous consultation with the managing physician. After appropriate qualification of the patient, raising his awareness concerning the possibility of occurrence of certain systemic dysfunctions and giving instructions what the patient should do in case of such dysfunctions, an individual, preliminary therapeutic programme is designed, whose aim is gradual adaptation of the organism to the device.



Danger. Neglecting the above recommendations may lead to natural reaction of the organism to the change of position of many internal organs, unpleasant for the patient, requiring adaptation to the new conditions.

From our experience it follows that particular attention should be paid to:

1. **Efficiency of the circulatory system** (hypotonia – exertion hypotonia, orthostatic hypotonia), because in the cases of high-located spinal cord damages the course of exercise may lead to paradoxical load on the cardiovascular system (exertion hypotonia) with congestion of blood in the lower portion of the body and orthostatic hypotonia due to the effect of gravity. Hypotonia together with reduced cardiac output and cerebral blood flow may cause nausea and vomiting, vertigo, leading even to the loss of consciousness. Performing preliminary ECG and, if necessary, also USG of the heart is mandatory. Reduction of the risk of hypotonia is achieved by training – by lifting legs during exercise, regular orthostatic training (e.g. backward head deflection, assuming upright position on a tilting table, walking aided by orthoses), appropriate hydration, compression stockings, wide abdominal belt and physical fitness. If the above mentioned symptoms occur, first aid involves tilting the patient back to facilitate venous return, increase cardiac output and blood pressure.
2. **Efficiency of the respiratory system.** Spirometric assessment of respiratory efficiency is recommended. Prevention of ventilation disturbances involves among others maintaining mechanical patency of the bronchial tree (positional drainage, liquefaction of secretions, preventing bronchial spasms, etc.), increasing tidal volume by training muscles and teaching the patient to assume appropriate position of the trunk.
3. **Efficiency of the locomotor system.** Frequent dysfunction of the locomotor system accompanying the underlying disease prompt to analyse thoroughly the possible need of passive or dynamic correction, compensation, alleviation or stabilisation of the particular elements of the system by means of appropriate orthoses (collars, etc.), e.g. the cranio-cervical or thoracic segment of the vertebral column in the cases of subluxation symptoms or instability by means of corsets or belts applied for the cases of scoliosis or muscular insufficiency, orthoses for the upper extremities in the cases of contractures or special shoes or insoles – according to the individual needs of the patient. A very important element of preparation, or even prerequisite, for the rehabilitation programme is taking into consideration the necessity of massage and mobilisation in contractures, as well as increasing the muscular strength in the upper extremities.
4. **Possibility of autonomic dysreflexia** (sudden episodes of considerable elevation of arterial blood pressure which may be life-threatening if not controlled immediately). Preventing of disturbances involves the elimination of potentially harmful stimulation by voiding the bladder immediately before exertion and during longer periods of exertion, as well as blood pressure monitoring during the first sessions of exercise. In case of the episode, exercise should be discontinued and upright position should be maintained until blood pressure returns to normal values.
5. **Presence, or predisposition to, the formation of bedsores**, which constitutes a common and important problem. Prevention involves continuous control of body regions anatomically exposed to compression and application of decompression measures (localisation, decompression and protection). The management of patients with bedsores should not exclude rehabilitation by means of the Static Parapodium.
6. **Muscular spasms** (due to hyperactivity resulting from loss of inhibitory control of motoneurons). Prevention is training, which makes it possible to reduce both the frequency and magnitude of spasms. Pharmacological treatment is not recommended, because it limits the possibility of training and may cause unfavourable side effects – depression, vertigo, ataxia. In case of spasms the patient should be protected against injury to the lower extremities due to strong contractions and rapid movements.
7. **Thermoregulation problems.** Limited ability to control body temperature may occur due to reduced perspiration and inappropriate distribution of blood which leads in high temperature of the environment to the earlier occurrence of the over-warming effect than in healthy subjects, associated with the risk of dehydration, elevation of body temperature, heat stroke, or even circulatory collapse, whereas in cold environment it leads to excessive heat loss impairing the cardiovascular control. Prevention involves optimal adjustment of the existing needs of rehabilitation to the efficiency of the organism, with emphasis on regularity of training. In the cases of hypo- or hyperthermia, the exercise should be discontinued and the environmental conditions (air temperature, relative air humidity), as well as the patient's clothes, intensity of the exercise and duration of the session adjusted according to the existing needs and possibilities.



Warning

Contraindications for use of the Static Parapodium:

Deep mental impairment (unable to be controlled), Conditions preceding cerebral stroke,
Conditions preceding myocardial infarction,
Advanced osteoporosis with lower limb deformation (considerable deviation from the long axes of the extremities),

1.5 Exemplary Preliminary Rehabilitation Programme For The Period of Adaptation Of The Organism To The Device.

The period of adaptation may last from one day up to two weeks depending on the previous attempts of tilting

The exercise should always be done in the presence of an accompanying person!

Daily training: up to 3 repetitions daily (the presence of an accompanying person **mandatory** during the exercises).

The aim of the exercise is to familiarise the patient with the device, making him feel safe while using the parapodium, preliminary adaptation to maintaining upright position.

1. Changing the position from sitting to standing in the parapodium directly from a chair or bed, (the help of a physiotherapist during the exercise is **mandatory**).
2. Maintaining upright position in the parapodium for the following periods of time: 30 sec.– first session, 1 min. – second session in the parapodium. The duration of staying in the upright position is prolonged by one minute per day until the period of 20 minutes. The proposed durations of the exercise on subsequent days of training are dependent on the condition of the patient. If the basic duration has been successfully completed (without the episodes of fainting, vertigo, fatigue) the exercise can be prolonged by one minute. In case of any adverse effects associated with upright position, the exercise should be discontinued immediately. When the symptoms subside, the training should be resumed, starting the stage from the beginning.
3. Leaving the parapodium and changing position to sitting on a chair, bed or wheelchair (the presence of an accompanying person **mandatory** during this exercise).

2. USER'S MANUAL

2.1 General Principles Of Safety

The greatest concern of Doktor Perner is improving the quality of life of the users of the device, ensuring safety to the patients as well as to all individuals helping our patients and coming into contact with the device.

In order to ensure absolute safety to the users of the Static Parapodium Model PSL 150-180 the following recommendations should be strictly observed:

1. Before undertaking any attempts to use the device, read the details in the "Medical Manual" and the "User's Manual".
2. Make sure that you fully understand all information, recommendations and warnings contained in the "Medical Manual" and the "User's Manual".

All the Manuals attached to the devices manufactured by Doktor Perner contain paragraphs marked with symbols **ATTENTION**, **WARNING** and **DANGER** intended to attract the reader's particular attention to their contents. The meaning of the aforementioned symbols is as follows:



ATTENTION. This symbol is used to signal that particular attention to the content of the paragraph marked in this way is needed.



WARNING. This symbol is used for the description of functions (activities), which performed incorrectly, i.e. according to the Manual, may lead to the damage of the device.



DANGER. This symbol is used for the description of the functions (activities), which, performed incorrectly, i.e. according to the instructions, may lead to life-threatening situations or serious injury to the user.

2.2 General information

The manual contains detailed information concerning the conditions of usage of the Static Parapodium Model PSL 150, PSL180.

Static Parapodium is only given on the basis of the physician's opinion.

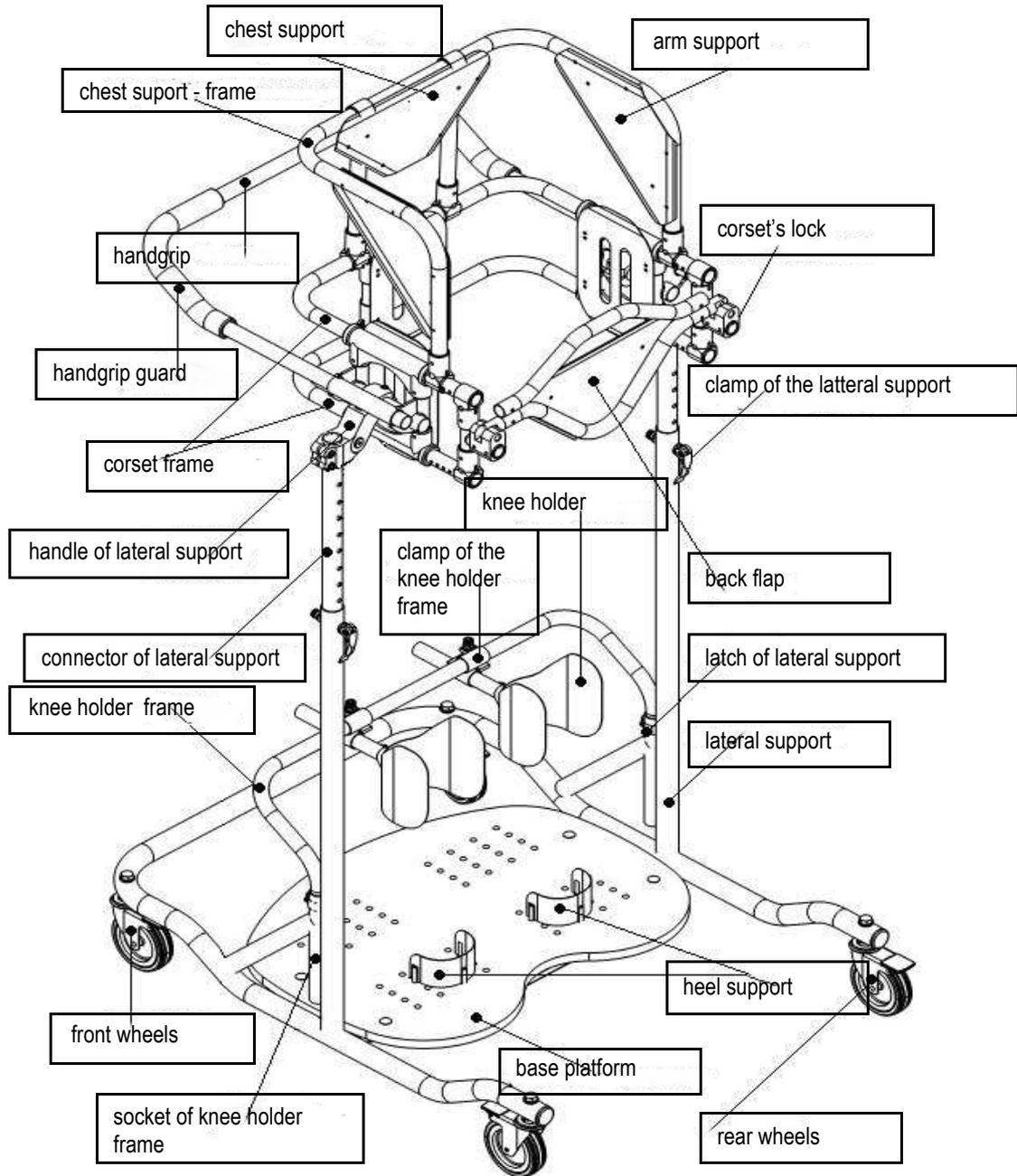
The instruction is directed to the users, the user's attendants, therapists and physicians.



WARNING. Before Reading this part of User's Manual, please, read carefully chapter „Medical Information" and information on the assembly and regulation. The Static Parapodium Model PSL 150, PSL 180 is a mechanical device designed for disabled people with paraplegia or paraparesis.

If the device is used by healthy people the manufacturer does not take any responsibility for any physical injuries or damage of the device.

Static Parapodium Light - parts

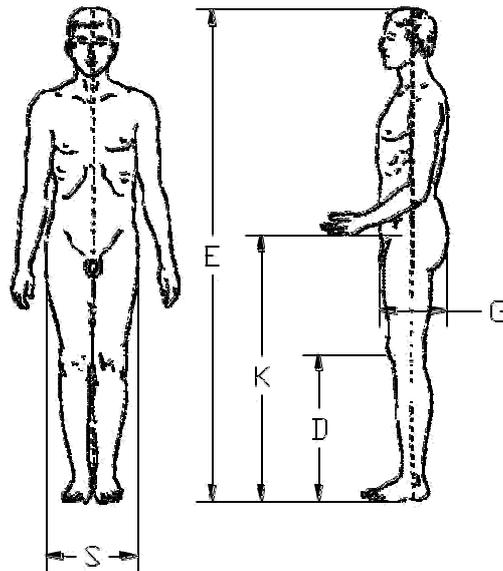


Rys. 1

Static Parapodium is adjusted to the usage of wheels and a table. These elements are additional and have to be ordered with the device.

2.3 Preparation of the Parapodium to Use.

Characteristic of the user of parapodium (Diagram 2, table 1).



Rys. 2.

Tabela 1.

L.p.	Parametr (cm)	PSL 150 - 180	
		Small vest	Large vest
1	Hip width (S)	39	44
2	Hip depth (G)	32	35
3	Height to the knees (D)	38- 50	
4	Height to the trochanter (K)	70-97	
5	Weight	100	
6	Contracture of the knee (°)	30	
7	Total height (E)	150-180	

- Static Parapodium PSL 150,180 is to be used by patients with parameters corresponding to those in Diagram 2 and table 1
- The device must be assembled according to "Assembly Instruction".
- The height of the mounting, the width and depth of the corset, the height of the arm brackets and the height of the knee holders as well as their span are adjusted individually for each patient and depend on his height, the width and depth of the hips, height of the knees, etc. The maximum and minimum parameters are included in table 1.



ATTENTION

The distance of the corset hanger from the ground must be adjusted so that the patient, after fastening the back belt, is in upright position and can remain so for a desired period of time without the aid of hands.

The patient must feel safe.

- The width and depth of the corset must be so adjusted that the patient feels kept (blocked) safely in the region of the pelvic girdle, but without any discomfort and unpleasant compression.
- The position of knee holders must be so adjusted that the patient feels safe support for the leg, but without hyperextension of knee joints. This ensures not only safety but also correct position of the body in the parapodium.
- The position of arm supports is adjusted to the patient's needs. For individuals with strong arms it is recommended to fix the supports as low as possible.
- The device must be checked thoroughly for correctness of assembly and blockade off all mobile elements.
- It should be checked whether the screw blocking the connector of the basis rod has been fixed tight enough. It should be checked closing and opening of the back flap and the correct functioning of the lock.
- It should be checked whether the pillow filling the space between the buttocks and the back flap is correctly fixed (if used).

In the parapodium a three-point way of supporting the user enables a firm and safe grasp of the patient's body unabling abrasions to occur. The manufacturer allows to use only the device with the upholstery completely on.

2.4 Use of the Parapodium.



ATTENTION

There are no contraindications for using the parapodium along with other individual orthopedic devices such as: orthopedic footwear, orthopedic collars, corsets and orthosis. **The decision whether to apply particular orthopedic devices is always made by a physician.**



ATTENTION

In case of hyperhidrosis and sensitive skin it is not recommended to use the device without underwear as a protection against abrasions.



ATTENTION

Static Parapodium is to be used indoors, in the range of temperatures between 10⁰C and 40⁰C.



ATTENTION

Static Parapodium is to be used only on a flat, horizontal surface.

While using the device the patient should not be loaded more than the max weight shown in the table.

Depending on patient's individual parameters the device requires the space not less than 750 mm but not more than 960 mm measured as the width of the space on which the device is being moved.

The use of the parapodium consists of three phases:

1. Getting-in phase.
2. Leaving the parapodium.

1. Getting into the parapodium directly from a bed or chair.

In order to get into the parapodium the following activities should be done:

- a) Bring the parapodium in front of the chair or bed, on which the patient is sitting,
- b) Make sure that the chair will not move, block the parapodium's brakes and wheels' brakes,
- c) Unblock the lock and open the back flap of the corset,
- d) Put the feet on the platforms,
- e) Position the knees in the holders and fasten the belts around them,
- f) Get hold of the corset with one hand, and of the arm support,
- g) Shift the hips to the front of the corset,
- h) Lock the additional safety belt,
- i) Check if the blocking of the pelvic girdle region is correct, make sure that the hips are not compressed too much,
- j) Check whether the lateral support of the parapodium is in the axis of patient's leg.



WARNING

During the attempts to stand up the patient must not get hold of or lean against the back flap of the corset. Repeated leaning against the flap, which has to support the whole weight of the body then, may cause slight deformations of the joint and, consequently, problems with closing the flap.



DANGER

Rising from the chair, etc. not protected from slipping back is dangerous for the patient and may lead to an accident, resulting in contusion or injury. **During the attempts to stand up the patient must be helped by an accompanying person.** Non-compliance with the above recommendation may lead to his/her falling down, contusion or injury.



ATTENTION

While coming in and closing the back flap it should be remembered not to put a finger in when locking it.



DANGER

Before starting this phase of using the parapodium the user must get acquainted with the "Medical Manual".



DANGER

A prerequisite for starting the process of rehabilitation using the Static Parapodium is to contact the physician managing the patient. After appropriate qualification of the patient, raising his awareness concerning the probability of certain dysfunction of the organism, and giving instructions how to behave if such dysfunction occur, an individual, initial therapeutic programme, aimed at gradual adaptation of the organism to the device, must be designed. Non-compliance with the above recommendations may lead to the occurrence of unpleasant natural reactions of the organism to the sudden change of position of most internal organs and necessity to adapt to the new conditions.

Standing in the parapodium. The parapodium makes it possible for a disabled person to stand self-dependently and comfortably without the aid of the hands for the period of many hours. Even if the patient faints, upright position is maintained owing to continuous control of the child's gravity centre.

Ad 2. Sitting down and leaving the parapodium (sitting on a chair, bed, etc.).

When the standing and/or walking phase comes to an end, it is necessary for the patient to return to the chair quickly and safely. Leaving the parapodium:

- a) Bring the wheelchair to the parapodium and secure the brakes of the wheelchair and the parapodium
- b) Unfasten the knee,
- c) Unlock the back flap of the corset and make the patient sit down on the chair,
- d) Put the patient's feet on the wheelchair foot platforms,
- e) Close the back flap of the corset,
- f) Unblock the brake and move the wheelchair away.



DANGER The patient can sit down on a chair, etc. only when it is protected from sliding back. While sitting the patient **should always** be helped by an accompanying person. **Non-compliance with the above recommendations may lead to falling down, contusion or injury.**

2.5 Transport of the Device

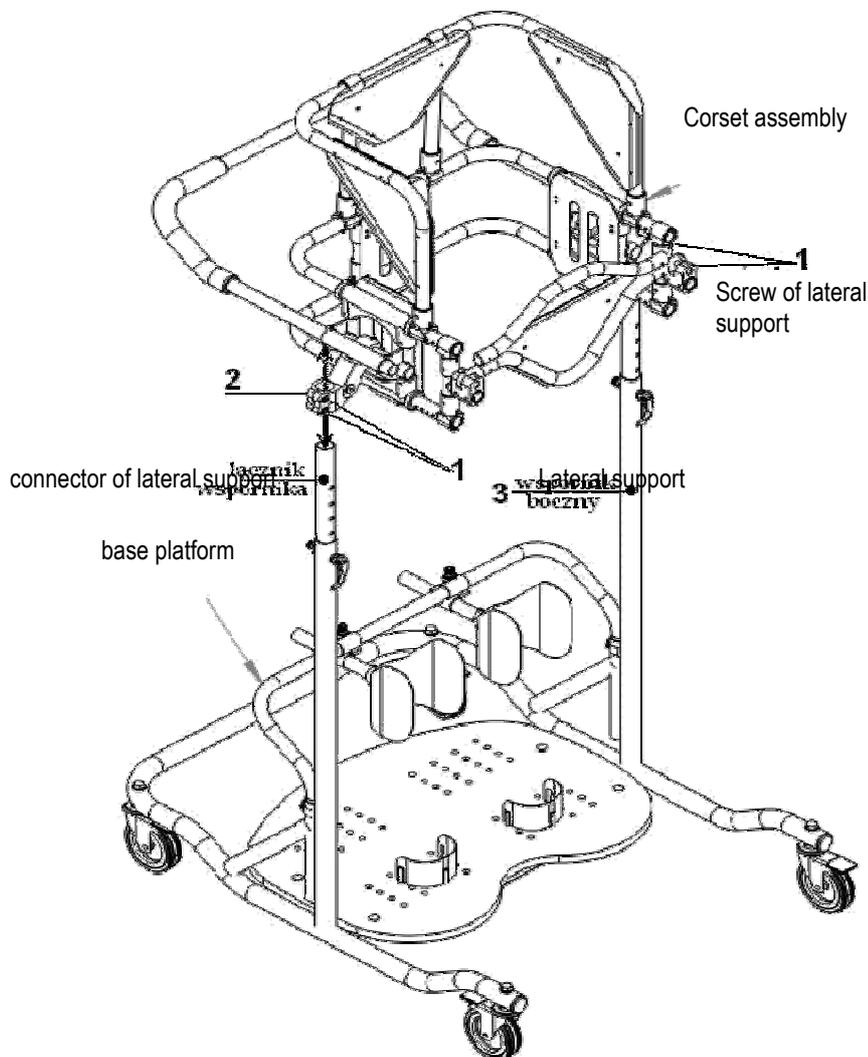
In case of carrying it through the door or stairs the parapodium should be kept by handles from the back near the corset, on the side of the entry into the device. While transporting the device for long distances it is recommended to disassemble it into two parts according to Diagram 3.

In order to disassemble the device follow these instructions:

- a) Unscrew the screws of lateral support (1),
- b) Take off the corset assembly from the basis assembly

In order to reassembly the parapodium follow these instructions:

- a) Put the corset assembly on the basis assembly
- b) **Adjust the previous height of the mounting of the corset assembly**
- c) Screw the screws of lateral support (1),



Rys. 3

2.6 Storing, Clearing And Maintenance of The Parapodium.

The Static Parapodium is a mechanical device, which framework is made of steel and aluminium coated with lacquer and chromium according. The soft elements are made of foam-filled leather (ecological leather) or velour upholstery.

Parapodium, as any medical device, should be cleaned regularly and used according to the manufacturer's instructions.

Recommendations concerning storing

The device should be stored in a dry, air-conditioned room, in which the relative humidity is not higher than 80%.

Recommendations concerning cleaning and maintenance:

- Lacquer coated surfaces should be cleaned with a damp piece of cloth. Adding mild detergents used to clean household appliances is acceptable.
- Leather upholstery should be cleaned and conserved with special agents used to clean leather clothing
- Velour upholstery should be washed at 40°C with water containing mild detergents used to wash underwear and coloured clothing.
- Metal surfaces should be cleaned with alcohol. The case of cutting the metal layer should be reported to the service point and a safety layer should be put on. Moreover, any trace of corrosion should also be reported.

In case of using the parapodium in hospitals and clinics by many patients, and their regulations do not contradict it is recommended to disinfect the handles (with alcohol) before giving the device to another patient. It is not allowed to the patient to have contact with the upholstery unless different upholstery is being used for each patient.

2.7 Safety precautions

- The device must not be overturned, thrown or dragged (does not concern the device equipped with wheels) with the patient or without him.
- Although the device was made of non-flammable materials you should pay attention while closing to the fire sources.
- Occurrence of corrosion points does not influence the safety but lowers the aesthetic. The manufacturer does not allow to use a corroded device. The upper layer guarantees safety for 24 months against corrosion.
- The users of the device must not be under the influence of alcohol or drugs.
- The predicted time of using the device is 2 years. After this period it can be used only after a positive control performed by the manufacturer.

2.8 Certificates

- The product is signed with CE sign
- Biocompatibility of the upholstery was confirmed by The Institute of Medicines on the basis of ISO 10993-10 norm. Research protocol nr: IL-1653/02.

2.9 Environmental Protection

The device excluding the upholstery is made of steel and undergoes recycling in 95%.

After delivery the service is to collect the packaging.

2.10 Warranty

1. The manufacturer warrants that the product is free from defects in material and workmanship under normal use and service. Warranty is 12 months from the delivery date.
2. The manufacturer guarantees, excluding any other responsibility, that during the warranty period, in case of material or workmanship defects, the damaged product will be repaired or the defective parts will be replaced free of charge by the manufacturer or its authorized service point/dealer.
3. The warranty becomes automatically void if the product has been damaged or rendered defective as a result of misuse, if the product has been damaged or rendered defective by modification or service performer by unauthorized person, if the product has been damaged or rendered defective because of force majeure, if the product has been damaged or rendered defective as a result of normal wear and tear or any other condition outlined in the Warranty Claim Form.
4. The detailed warranty conditions are outlined in the Warranty Claim Form and in Warranty Instructions.

2.11 Warranty Instructions

Failure to comply with the procedures presented below will result in the loss of warranty.

- In case of any damage, the use of the device should be discontinued until the moment of repair.
- No unauthorised repairs are permitted.
- No original parts of the device can be replaced with self-made or commercially available spare parts.

The only person authorised to maintain the assembly and all the repairs to the device is the person authorized by the manufacturer.

Mdh Sp. z o.o. hopes that the present manual will meet all your expectations and needs in the field of usage of Static Parapodium PSL 150, PSL 180. However, if you think that any modifications or supplements to the above instructions are needed, please share your opinion with us, and we will consider introducing the appropriate changes.

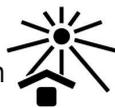
It is a great challenge for Mdh sp zo.o. to create a perfect static orthosis. Therefore, we would like to invite all the users of the Static Parapodium Model PSL 150, PSL 180 to co-operate with us, in order to improve the existing device and to develop new, more advanced orthoses.

ATTENTION: The models of Static Parapodium delivered to you may slightly differ from the devices on the pictures because Mdh sp z o.o.o. constantly improves them.

3. Symbols



Confirmation of compliance with EU standards



Protect from sunlight



Manufacturer



Permitted user weight.



Date of production



Use inside buildings



Read the user's manual



The possibility of fingers jamming.



Warning



Catalog number



Temperature of storage and use



Serial number



Protect from humidity



Medical device

Contact details



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„Parapodium statyczne. Instrukcja Użycia jest własnością firmy mdh Sp. z o.o.
Powielanie w całości lub części bez zgody firmy mdh jest zabronione,

Uwaga:

Producent zastrzega sobie prawo do wprowadzania zmian technicznych i handlowych w treści instrukcji.