

Dynamic Parapodium
Model **PD100**
Instructions for use

CONTENTS

1	MEDICAL INFORMATION.....	3
1.1	INTRODUCTION, KEY WORDS, KINESITHERAPY.....	3
1.2	DISTURBANCES OF FUNCTION OF INTERNAL ORGANS IN DISABLED SUBJECTS DUE TO CHRONIC SITTING POSITION AND/OR BED RIDDING.....	3
1.3	ADVANTAGES OF DYNAMIC PARAPODIUM.....	4
1.4	MOST COMMON SYSTEMIC DISTURBANCES LIKELY TO OCCUR IN PARAPLEGIA.....	4
1.5	EXEMPLARY PRELIMINARY REHABILITATION PROGRAMME FOR THE PERIOD OF ADAPTATION OF THE ORGANISM TO THE DEVICE.....	5
2	USER'S MANUAL.....	6
2.1	GENERAL PRINCIPLES OF SAFETY.....	6
2.2	GENERAL INFORMATION.....	7
2.3	PREPARATION OF THE PARAPODIUM TO USE.....	8
2.4	USE OF THE PARAPODIUM.....	9
2.5	TRANSPORT OF THE DEVICE.....	11
2.6	STORING, CLEANING AND MAINTENANCE OF THE PARAPODIUM.....	12
2.7	SAFETY PRECAUTIONS.....	12
2.8	ENVIRONMENTAL PROTECTION.....	12
2.9	PERIODICAL SERVICING.....	13
2.10	WARRANTY.....	13
2.11	WARRANTY INSTRUCTIONS.....	13

1 MEDICAL INFORMATION

"It is easier to achieve the intended aim after getting acquainted with the subject-matter of the undertaking – it enables to predict possible consequences adequately and unifies the language of communication between the partners of the dialogue reducing unnecessary, unpleasant experiences".

1.1 Introduction, Key Words, Kinesitherapy

Paraplegia and paraparesis 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,
- paraplegia spondylica,
- paraplegia scoliotica,
- paraplegia neoplasmatica
- Duchenne's dystrophy and others.

Indications of the Dynamic Parapodium in rehabilitation is associated with the assumption that movement (kinesitherapy) is a therapeutic method, providing a stimulus acting specifically on the organism which considerably improves the patient's quality of life.

"The motor process of learning to move (kinesitherapy) is a purposeful, dosed, methodically 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.

Dynamic Parapodium = parapodium – orthosis system making active rehabilitation and movement (gait) possible.

Paraparesis (Latin paresis;) paresis affecting the lower extremities.

Paraplegia - (Latin paralysis s. Plegia;) palsy affecting the lower 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 Dynamic Parapodium

1. Self-dependent standing up, i.e. assuming upright position and self-dependent sitting up 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. Self-dependent, completely safe locomotion using the patient's own muscular strength without the necessity of external source of energy (external power supply) making full self-service and serving other people possible.
4. Wide range of rehabilitation together with ergotherapy.
5. Improving general condition as preparation for practising sports.
6. 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 Dynamic Parapodium place it in the group of exceptionally valuable devices on the world scale.

1.4 Most Common Systemic Disturbances Likely To Occur In Paraplegia



WARNING. The prerequisite for starting rehabilitation of the patient making use of the Dynamic 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 Dynamic Parapodium.
6. **Muscular spasms** (due to hyperactivity resulting from loss of inhibitory control of c). 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 hyper- or hypothermia, 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 Dynamic Parapodium:

- Deep mental impairment (unable to be controlled),
- Advanced osteoporosis with lower limb deformation (considerable deviation from the long axes of the extremities),
- Disturbances of body balance (of a high degree),
- Articular contractures (knees, hip joints) over 30°,
- Very strong muscular spasticity in lower extremities,

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

The period of adaptation, which should last approximately seven weeks, has been divided into stages. The principle is to go on to the next stages after mastering the skills required in the previous stage, providing the patient's condition is good enough to progress to more intensive exercise.

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

The first stage

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 an 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 is **mandatory** during this exercise).

The second stage

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

The aim of the exercise is training the ability to balance the body correctly in the parapodium (the ability to raise the runners and the platforms from the background).

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. In standing position, with the handles of the parapodium held from the top, alternating deflections from the right to the left (attempts to incline the body to the sides), rhythmical shifting of the centre of gravity, standing for 20 minutes.
3. Shifting the body balance for 1 min.; then standing for the rest of the time. We add 1 minute daily of the balance-shifting exercise. Between the balance-shifting exercises, lasting 1 minute each we use a 1 minute break. This stage of training is completed when we are able to do the 1-minute balance-shifting exercise ten times per session.
4. Leaving the parapodium and changing position to sitting on a chair, bed or wheelchair (the presence of an accompanying person **mandatory** during this exercise).

The third stage

Daily training up to 3 repetitions a day (depending on the patient's condition).

The aim of this exercise is a preliminary learning of walking.

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. In standing position, with the handles of the parapodium held from the top, alternating deflections from the right to the left combined with raising the runners and the platforms from the background. During the brakes in the previous exercise, inclining and turning the trunk in various directions, and/or active training of the upper extremities with various loads.
3. Prolongation of the period of patient's stay in the parapodium to 30 minutes guiding the parapodium by holding its handles, with the help of an accompanying person. First attempts of self-dependent walking.
4. Leaving the parapodium and changing position to sitting on a chair, bed or wheelchair (the presence of an accompanying person **mandatory** during this exercise).

The fourth stage

Daily training up to 3 repetitions daily (depending on the patient's condition).

The aim of this exercise is learning to walk without the aid of an accompanying person.

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. Self-dependent walking with changes of directions – 20-30 minutes.
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).

In the subsequent weeks and months the load during the exercise is gradually increased, depending on the patient's condition. The patient learns to carry out everyday routines (in the kitchen, bathroom, etc.). Gradually becoming independent of the help of accompanying persons.

2 USER'S MANUAL

2.1 GENERAL PRINCIPLES OF SAFETY

The greatest concern of mdh sp. z o.o. 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 Dynamic Parapodium Model PD100, 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 mdh sp. z o.o. 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 purpose of this manual.

The manual contains detailed information concerning the conditions of usage of the Dynamic Parapodium Model PD100.

Dynamic 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.

The Dynamic Parapodium Model PD100 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 to the device.

The parapodium consists of the following elements:

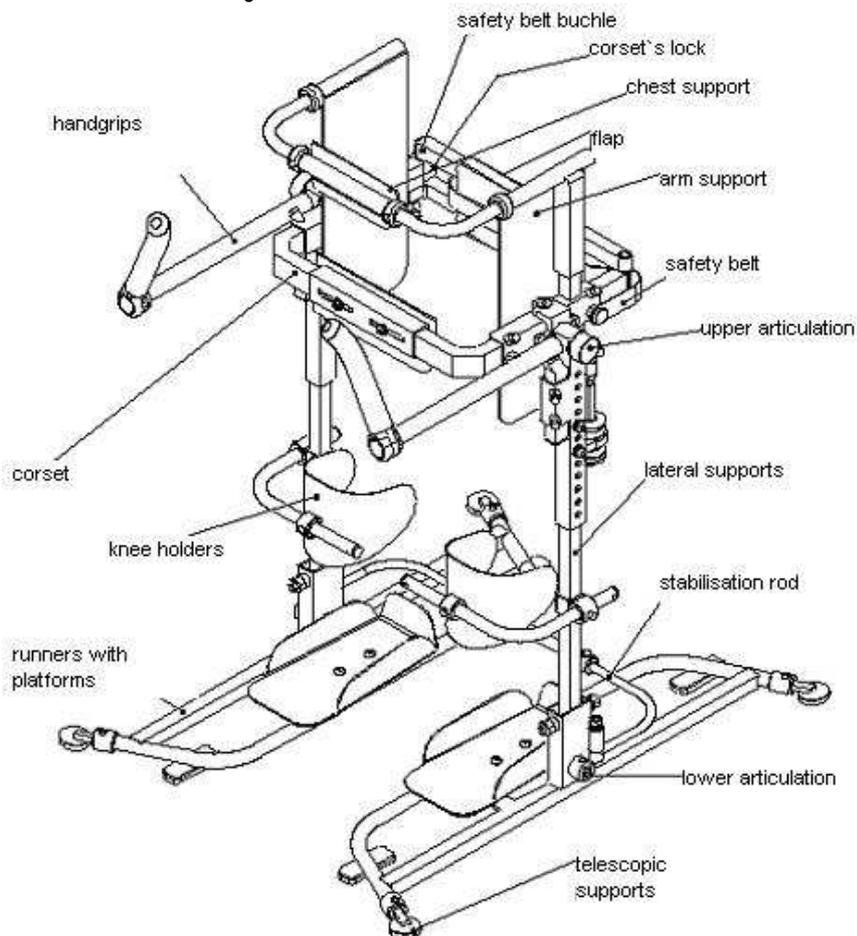


Diagram 1

Principles of Function of Dynamic Parapodium Model PD100.

Many years of experiments and observation of disabled people with paraplegia have proven, how difficult it is to design a simple, easy to operate device for a large group of users characterised by a large diversity of physical conditions of the organism and complications involving the internal organs.

We assumed that the driving force for the device must be provided by the work of the parts of the body unaffected by the disease, i.e. the upper part of the trunk and the hands. Our attempts in this field have been successful. We have designed a device the principles of function of which are presented below.

Unique design of the Dynamic Parapodium makes the device very sensitive to any alterations of its own centre of gravity. The position of the centre of gravity of the parapodium can be changes in two planes:

- The plane perpendicular to the axis of the runners, extending through the corset hanger joint (after positioning the patient in the parapodium, this plane extends through the axis of their hip joints)
- The plane parallel to the axis of the runners and perpendicular to the axis extending through the corset hanger joint.

Alteration of the centre of gravity of the device together with the patient provides the driving force for the movement of the parapodium.

The principles of movement of the Dynamic Parapodium Model PD100.

The driving force for the movement of the parapodium is provided by alteration of the centre of gravity of the patient-parapodium system.

Alterations of the centre of gravity in the plane perpendicular to the intended direction of movement are obtained by slight periodical movements of the upper part of the trunk. Even slight movements of the trunk to the sides are sufficient to cause alternating lifting of the runners with platforms supporting the patient's feet from the ground. Thanks to this, the patient is able to stand (to rest on) on one or the other leg like in a typical walking.

Alterations of the centre of gravity in the parallel to the intended direction of movement are obtained by slight bending of the patient's trunk forth and back, possible owing to the special design of the lower joint and the corset hanger joint.

Obtaining the movement of the parapodium is possible only thanks to the combination of these two types of alterations of the centre of gravity. It is important to move only this leg which is free from the body weight at the moment. Thanks to efficient movement of handles (up-down, right-left) the patient can move in different directions.

DANGER

Even slight sideways movements of the upper part of the trunk, which causes lifting of the runners from the ground, is sufficient to initiate the movement of the parapodium. The runners are equipped with lateral safety supports. It is very difficult to make parapodium swing beyond the support provided by the lateral safety supports by excessive movement. However, exceptionally fit patients are able, by periodical intensive movements of the trunk forth and back co-ordinated with the movement of hands, to make the parapodium tilt forth so much that it can fall down. It should be remembered that any attempt to overturn the parapodium on purpose is contrary to the instructions for use of the device and may cause serious injury of the patient.

2.3 Preparation Of The Parapodium To Use

Detailed information on the preparation of the parapodium for use is contained in the "Assembly Instructions" attached to the device.

Characteristic of the user of parapodium

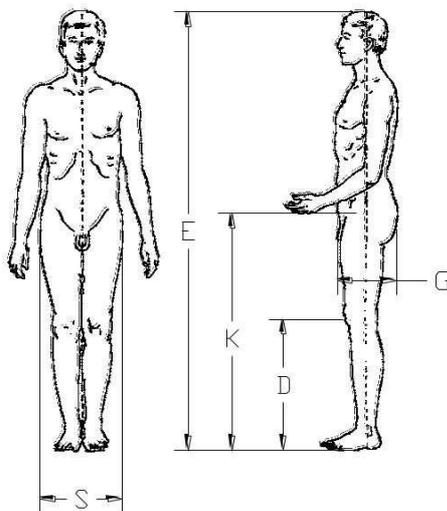


Diagram 2.

Table 1.

No.	Parameter (cm)	PD 100	
		MIN.	MAX.
1	Hip width (S)	15	23
2	Hip depth (G)	6,5	13
3	Height to the knees (D)	9	36
4	Height to the trochanter (K)	46	60
5	Weight	-	20
6	Contracture of the knee (°)	-	30°
7	Clawfoot (°)	-	15°
8	Width of footwear	-	8
9	Length of footwear	-	18
10	Total height (E)	85	105



ATTENTION

At qualification the patient's height must not be more than 100 cm. Parapodium must not be used by patients taller than 105 cm.

- Dynamic Parapodium Model PD100, is to be used by patients with parameters corresponding to those in Diagram 2 and table 1.
- The device must be assembled according to the "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.



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, which makes walking much easier.
- 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 the correctness of assembly and blockade of all mobile elements.
- It should be checked whether the screw blocking the elements of the stabilising rod has been fixed tight enough.
- Closing and opening of the back flap and the correct functioning of the lock should be checked.
- 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 eliminating the occurrence of abrasions. 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 orthopaedic devices such as: orthopaedic footwear, orthopaedic collars, corsets and orthosis. **The decision whether to apply particular orthopaedic 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

Dynamic Parapodium is to be used indoors, in the range of temperatures between 10°C and 45°C.

**ATTENTION**

Dynamic Parapodium is to be used only on a flat, horizontal and hardened surface.

**ATTENTION**

Any attempt to overturn the parapodium on purpose more than the maximum lateral tilt (10°) is contrary to the instructions for use of the device and may cause a threat to the patient's life.

Depending on patient's individual parameters the device requires a space less than 75 cm.

The use of the parapodium consists of three phases:

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

Ad 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,
- c) Unblock the lock and open the back belt 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 with the other and stand up to upright position with the aid of the accompanying person,
- g) Shift the hips to the front of the corset,
- h) Pull the handle of the blockade of the lock, close the back belt and release the handle of the blockade,
- i) Check if the blocking of the pelvic girdle region is correct, make sure that the hips are not compressed too much.
- j) Adjust the height of the lateral arm support,
- k) Check the position of the patient's centre of gravity in relation to the axis of corset hanger joints:
 - if **the patient is bent forward** act according to "Assembly Instructions",
 - if **the patient is bent backward** act according to "Assembly Instructions".

**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.

Ad 2. Standing and walking phase including changing directions, etc.**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 Dynamic 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 dysfunctions 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 his centre of gravity .

Walking in the parapodium. We start to learn walking by making periodic movements with the upper part of the trunk, which leads to raising the runners and the platforms supporting the patient's feet from the ground. It leads to the situation when the patient's weight is moved from left leg (runner) to the right one. Walking is possible only when: while moving the body weight on the left leg we pull the handle on the right of the device and the other way round. Performing the next steps can be achieved by regular alterations of the body weight from left leg to the right and simultaneously pulling the handle on the other side.



DANGER

Even slight sideways movements of the upper part of the trunk, which causes lifting of the runners from the ground, is sufficient to initiate the movement of the parapodium. The runners are equipped with lateral safety supports. It is very difficult to make parapodium swing beyond the support provided by the lateral safety supports by excessive movement. It should be remembered that any attempt to overturn the parapodium on purpose is contrary to the instructions for use of the device and may cause serious injury of the patient.



ATTENTION

Even slight periodic movements of the trunk to the left and to the right (5-10° from the vertical axis) leads to lifting the runners from the ground, enabling walking thanks to slightly raising the handles of the parapodium with hands.

1. Walking can be very difficult (or even impossible) if:
 - The patient's centre of gravity is positioned incorrectly in the parapodium; it may be caused by a mistake in assembly of the parapodium, act according to "Assembly Instruction",
 - Front runner ends converge – the parapodium is assembled incorrectly, act according to "Assembly Instruction",
 - When the patient moves the trunk and lifts the runners from the ground, the front of the runners fall down – "Assembly Instruction".
2. The change of direction of movement is obtained by raising higher the handle on the side to which we want to turn.
3. In patients with injuries of the upper segments of the spinal cord and resultant tetraplegia it is very difficult to obtain the effect of self-dependent walking. **Such effect can, however, be obtained with a little help of the accompanying person.**



ATTENTION

During the use of the parapodium the patient's hands should be on the handles. The accompanying person while helping the patient must pay attention not to place his foot before the runner of the parapodium.

Ad 3. 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) Put the chair close to the back of the parapodium and position it firmly,
- b) Unfasten the knee holders,
- c) Unlock the back flap of the corset and make the patient sit down on the chair,
- d) Take out the patient's feet from the platforms,
- e) Close the back flap of the corset,
- f) Put the device 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 order to transport the device, it is recommended to initiate balancing movement as the patient would perform. In case of carrying it through the door or stairs, the parapodium should be kept by handles from the back near the waistcoat, on the side of the entry into the device.

2.6 Storing, Cleaning And Maintenance Of The Parapodium.

The Dynamic Parapodium is a mechanical device, which framework is made of steel coated with lacquer and chromium according to PN-93/C-81515 and PN-83/H-97006. 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 with the patient or without him.
- Aside from the fact that the device has been made of non-flammable materials, attention should be paid when getting close to any sources of fire.
- 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 predicted time of using the device is 4 years. After this period it can be used only after a positive control performed by the manufacturer.

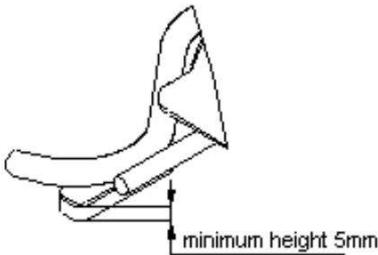
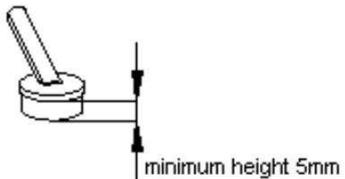
2.8 Environmental protection

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

2.9 Periodical servicing

Table 2 constitutes a periodical servicing card, which includes inspections of the device that need to be performed periodically. Inspections and technical maintenance should be performed according to the schedule specified in the card.

Table 2.

INTERVAL	ELEMENT	INSPECTION	METHOD OF REPAIR
6 months *	Dynamic Parapodium	Check visually the state of parapodium, if there are any visible damages, such as fissures, deformations or any other visible damages, which can affect device usage or safety of the user.	If any damages are found, replace damaged elements with new ones.
	Internal feet ** PD10001 – 4 pieces	Measure height of rubber veneer Minimum permissible height – 5 mm 	Replace
	External feet ** PD10002 - 4 pieces	Measure height of rubber veneer Minimum permissible height – 5 mm 	Replace
	 ATTENTION	Check if all regulation screws, nuts and bolts are fastened	Follow "Assembly and Adjustment Instruction"
12 months *	Lower articulation shock absorber PD10003 - 4 pieces	If any fissures, cuts or permanent deformations of lower articulation shock absorbers are found – replace	Replace
	Corset's shock absorber PD10004 - 4 pieces	If any fissures, cuts or permanent deformations of corset's shock absorbers are found – replace	Replace

* time of intense usage - 2h/day

** if used on hard and rough surfaces (e.g. concrete floor) check every 2 months

2.10 Warranty

Detailed information concerning the terms of warranty are contained in the Warranty Chart.

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 authorised 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 Dynamic Parapodium Model PD100. 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. z o.o. to create a perfect dynamic orthosis that could serve all disabled people with paraplegia, irrespective of the severity of the disorder. It is our aim for the next few years to enable each disabled person to stand up and walk. Therefore, we would like to invite all the users of the Dynamic Parapodium Model PD100 to co-operate with us, in order to improve the existing device and to develop new, more advanced orthoses.

ATTENTION: The models of Dynamic Parapodium delivered to you may slightly differ from the devices on the pictures because mdh sp. z 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



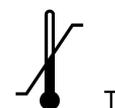
The possibility of fingers jamming.



Warning



Catalog number



Temperature of storage and use



Serial number



Protect from humidity



Medical device

4. Contact details



mdh Sp. z o.o.

ul. Maratońska 104, 94-007, Łódź, Polska

tel. +48 42 674 83 84

fax. +48 42 636 52 21

www.mdh.pl www.viteacare.com

