

PARAPION STANDER



CE



USER MANUAL

Our passion - your independence!











CAUTION! Manufacturer takes responsibility for proper usage of the device only when the product was purchased from qualified Akces-Med employee or at specialized medical store!

CAUTION! AKCES-MED Ltd. reserve the right to introduce technical and trading changes in the content of the instruction without warning.

Medical product first class according to the Regulation 93/42/EWG of European Parliament and Council regarding medical products. For this product the producer issued relevant declaration of conformity.

Akces-Med. Sp. z o.o. Company introduced quality management system ISO 13485 regarding production, sales and service. The system is certified by Det Norske Veritas.







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INTRODUCTION

The static verticalizer PARAPION was designed to help in rehabilitation of people with paresis of lower limbs as well as trunk and to enable standing in upright position. We did our best to give you the product which is functional, ergonomic and safe. The advantages of our verticalizer are: light and stable base, easy regulation of hip-clamping ring and chest-clamping ring etc.

Remember to read this user manual carefully. You will find not only useful information but also guidelines regarding safe and effective use of the product.

If you have any questions or remarks, do not he sitate to contact with us:

Medical consultant: mobile +48 508 382 509 **Akces-MED Sp. z o.o.:** ph. +48 17 864 04 77

e-mail: export@akces-med.com

Thank you for purchasing our product.



CAUTION! Before using the product, user is obliged to familiarize himself/herself with user manual. Remember that complying with guidelines is highly important. It assures safety and extends durability as well as aesthetics of the device.





THE PURPOSE OF USER MANUAL

The present user manual contains basic information which is essential for proper usage, preparation, maintenance, cleaning and guarantee conditions **PARAPION™** standing frame.

User manual should be kept in easily accessible place. It is designed for people who look after the disabled, and for both doctors as well as physiotherapists who operate the device.



CAUTION! Before using the product, user is obliged to familiarize himself/herself with user manual.

INDICATIONS FOR USE

Remember that complying with guidelines is highly important. It assures safety and extends durability as well as aesthetics of the device.

The device is recommended for people in the following cases:

- Degeneration conditions.
- Brain and spinal cord disorders with paraplegia, hemiplegia, balance and motor coordination disorders.
- Demyelinating disease (e.g. multiple sclerosis SM).
- Meningocele.
- Muscles diseases with weakness and paralysis (dystrophy, myasthenia gravis, myositis).
- Genetic disorders.
- Degeneration and metabolic disorders.
- After head and spinal cord injuries and spine trauma with paralysis and paresis with paraplegia, especially in quadriplegia condition (as a stage of rehabilitation process or permanent orthopedic support).
- Cerebral palsy various types and forms.





GENERAL CHARACTERISTICS OF STANDING FRAME

3.1. Standard equipment

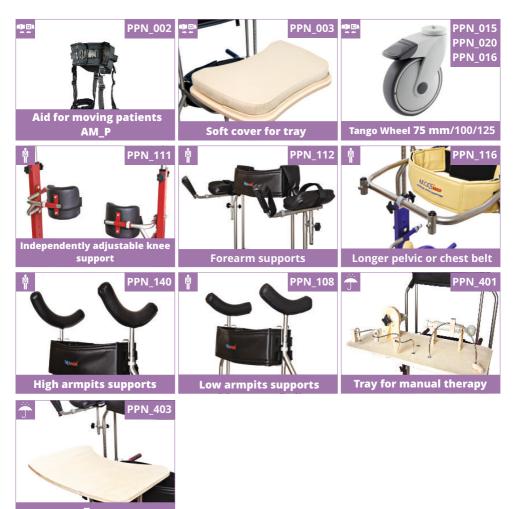
- 1. Frame with rotating wheels equipped with brakes
- 2. Hip clamping-ring with belt
- 3. Chest clamping-ring with belt
- 4. Knee stabilizer with pelot-pads
- 5. Table







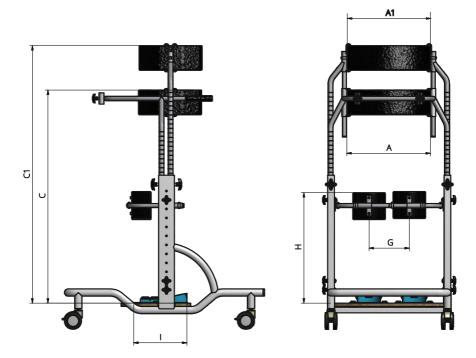
3.2. Additional equipment







SIZE TABLE



Symbol	Measurement	Unit	Size 1	Size 2	Size 3
Α	Pelvic support width	[cm]	23	31	38
C	Pelvic support height	[cm]	61-90	80-104	92-122
	Pelvic support circumference	[cm]	56-76	80-102	95-124
A1	Chest support width	[cm]	23	31	38
C1	Chest support height	[cm]	73-111	92-126	107-163
	Chest support circumference	[cm]	56-76	80-102	95-124
G	Knee supports width	[cm]	12-22	16-24	20-31
Н	Knee supports height	[cm]	18-45	24-49	31-71
	Foot length	[cm]	20	27	30
	Max user weight	[kg]	30	55	95
1	Measurement	Unit	Size 1	Size 2	Size 3
	Szerokość	[cm]	56	56	67
	Długość	[cm]	75	87	93

UWAGA: Tolerancja wymiarów zawartych w tabeli wynosi +/- 1 cm.

Wysokość

Waga

[cm]

[kg]

107

27,5

92

21,5

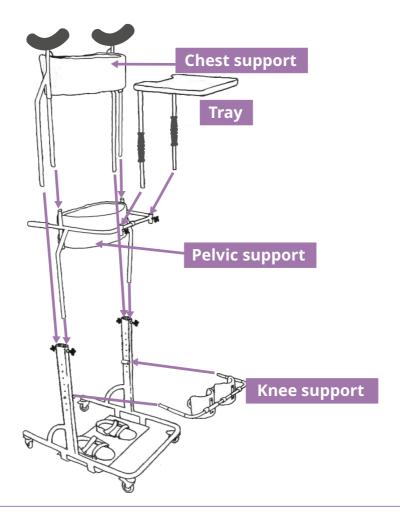
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MOUNTING THE STANDING FRAME





ATTENTION! Assembly of the standing frame should begin by inserting the pelvic support (hip support) into the guides placed in the frame (as seen in the figure). Next, we mount the chest support in a similar way. Afterwards we mount the table and foot stabilizator (in any order) as shown in the picture .





RULES OF ADJUSTING THE STANDING FRAME TO THE USER



WARNING! Adjustment of the standing frame to the patient is done by trained personnel only! All exercises must be performed only in the company of appropriately trained personnel.

Adjusting the device to the patient:

- 1. Measure the length from the ground to the knee joints. Set the knee support at this height.
- 2. Measure the distance between the ground and the trochanter of the thighbone. At this height set the pelvis(hip)support.
- 3. Measure the distance between the ground and axillary(armpit). Set the chest support at this height.
- 4. We approach the standing frame with the patient in his chair.







5. Stabilize feet on the foot stabilizer with the straps.



Straps in the knee stabilizer and knee supports should be unfastened. Place the feet in the foot stabilizer, retracting the foot (pushing it back) to the metal clamp/support and fastening the straps.





In the case of occurrence of abduction-adduction in the forefoot of the

patient, the feet in the foot stabilizer should be set at an appropriate angle.

6. Stabilize the knees in previously set knee supports by additionally fastening the stabilization straps.



7. Open the hip and chest supports.





8. We position the patient in standing frame.





9. Fasten the hip and chest supports, additionally securing with belts.





Chest support fastening











10. Check if the patient is standing straight, and if the projections of shoulders, hips and knees coincide in a straight line. If not than we should adjust the hip, knees and chest support, so that the patient stands straight. This is very important as it prevents the formation of contractures in the ankle joints, knees and hips.







THE USE OF STANDING FRAME



CAUTION! PARAMOBIL™ has to be used with compliance to guidelines included in this user manual. Remember to use the product only with someone who is trained and knowledgeable. Do not forget to prepare both product as well as patient before using **PARAMOBIL™!**

9.1. Preparation of the patient

Before using the product, it is essential to make sure that:

- patient's outfit is light and comfortable sporty clothes are advisable;
- shoes should be comfortable and, moreover, they should stabilize ankle:
- due to hygienic reason and to avoid abrasion it is advisable for the patient to always wear clothes when using the device, skin must not be naked especially in places of regular contact with upholstery;
- drains, bags, catheters etc. if applied, have to be secured to function properly and not to disturb during using the product;
- if it is necessary for a patient to wear orthopedic supply (collar, corset, orthesis, shoes) if it is recommended by doctor.



CAUTION! Outfit should protect patient's skin from direct contact with upholstery as well as other parts of equipment.

CAUTION! Only doctor can make a decision concerning using any kind of orthopedic supply!





7.2. How to use standing frame

Before use it is necessary to:

- Unfold the device:
- Place the device on a flat surface allowing for easy access to the standing frame at a safe distance from sources of ignition and high temperature
- Make sure that all parts are serviceable, correctly mounted and stable;
- Check the condition of castors and brakes:
- Block brakes:
- Adjust the device to patient's measurements;
- Place patient in the device;
- Fasten all elements which stabilize patient;
- Mount additional equipment.

Equipment works correctly only when the device is adjusted according to patient's height as well as weight. Remember to take all these measurements into account while purchasing the product. Correct adjustment is the most important due to the fact that only then the product is safe. It is forbidden to force child to keep specific position because he/she will feel uncomfortable and it may lead to wrong posture.



CAUTION! First adjustment of standing frame can be performed only by someone who is traned. Further adjustment is performed by patient's relatives who had proper training concerning the usage as well as adjustment of this device. Remember that correct adjustment is essential due to the fact that the product is safe and, moreover, the rehabilitation process is proceeding correctly.

CAUTION! Remember to makes sure that all belts and locking and correctly adjusted and fastened. Check also if fastenings from adjustable elements are firmly tightened.





9.3. Upright position

CAUTION!

The length of time for upright position process is different for each patient. It is recommended to extend this time during the initial period (adaption period for the change of position). Either doctor or physiotherapist can make decision concerning the length of upright position process. Upright position process has to be always performed under the supervision of trained person!

It is recommended to divert patient's attention during upright position process by:

- manipulation games
- educational games

CAUTION! It is highly important to adjust the device to the patient before using it!



CAUTION! Make sure that all belts as well as fastenings from adjustable elements are correctly adjusted and fastened.

CAUTION! It is forbidden to leave the patient unattended!

CAUTION! Only trained staff can adjust standing frame to the patient!





CAUTION! As far as first upright standing is concerned, it takes place in rehabilitation, neurosurgery or orthopedics wards. Moreover, it has to be performed together with doctor and physiotherapist due to the fact that medical problems may appear during first treatments such as fainting, drop in blood pressure, dizziness etc. Upright standing is continued in home together with trained staff (rehabilitation technician, district nurse, trained family members).



CAUTION! Incorrect adjustment of the device can lead to side effects such as: fainting, body deformities, overloading joints. It is highly advisable to adjust the device before every use of a standing frame. This adjustment has to be done only by a trained person or therapist. If any of these side effects appear, it is highly important to stop the upright position process, take out the patient from the device and lie him/her down. If these undesirable side-effects still occur it is necessary to contact doctor. If these side effects disappeared, remember to inform doctor so as to make decision concerning further upright position process.





SAFETY RULES



CAUTION! Dynamic standing frame **PARAPION™** has to be used in compliance with guidelines in this user manual.

It is highly important to consult either doctor or physiotherapist in order to make right decision concerning the choice of **PARAPION™** and its size. It is also essential to familiarize with the guidelines described in user manual before using the device.

1. Before use it is necessary to:

- · make sure that there are no damages or different faults which could endanger patient's life; check if all parts are working and are correctly mounted and, moreover, check if they are not broken;
- · check if all screws, knobs and all glued, sewed or tapped parts are tightened;
- check if brakes are operating correctly;
- · check if buckles are operating correctly;
- · always use safety belts, Velcro tapes should overlap min. 8cm;
- · adjust the device according to patient's measurements and needs;
- · make sure that all movable parts and knobs for adjustments are stable and locked;
- · secure patient with the aid of elements such as pelvic harness. It is highly important to secure patient because it safeguards him/her from falling out.





- 2. It is forbidden to use the device for different purposes that it is intended to.
- 3. It is forbidden to use the device when it is damaged or any part is missing.
- 4. It is forbidden to leave the patient unattended.
- 5. The device should be used only when there is someone who is trained and knowledgeable.
- 6.It is forbidden to leave the device and the patient on unstable ground unattended, even if the brake is engaged.
- 7. It is forbidden to either go up or down the stairs; it doesn't matter if the patient is placed in the device or not.
- 8. It is important to engage brake during getting into and getting out the device.
- 9. Make sure that all limbs are not close to spokes or other adjustable elements.
- 10. Although the device and the upholstery are made of fire-resistant materials, please pay your attention when approaching to sources of fire or sources of high temperature during using the device. Moreover, device shouldn't be stored in rooms with high humidity.
- 11. Secure the device during transportation in order to avoid any possible damages. Manufacturer doesn't take responsibility for damages which appeared due to improper preparation of the device during transportation.





CAUTION! This device can be only used inside the buildings.



CAUTION! The device contains small parts which children may swallow.

CAUTION! It is forbidden to make any changes concerning device's structure due to the fact that it is dangerous and it results in loosing warranty.

CAUTION! The weight of user should not be bigger than maximal weight described on page 10 where you will find information regarding this issue.

- 1) AKCES-MED Sp. z. o. o sells products free from manufacturing defects or faults.
- 2) Manufacturer gives the purchaser 24-month guarantee from the date of purchase. All defects revealed during warranty period will be repaired free of charge.
- 3) All defects which appear after warranty period can be repaired only when the user will pay for it. This rule doesn't apply to refunded products - user can ask National Health Refund for refund.
- 4) Manufacturer claims that the product can be used for 48 months. User can use this product after this period only when he/she will send the device to manufacturer so as to service it. Next, manufacturer determines again how long the product can be used and, moreover, the date of the next service will be determined.
- 5) If product is damaged, please contact our dealer or AKCES-MED customer service (ph. 17/864 04 70)





MAINTENANCE AND CLEANING

PARAPION™ should be kept clean and used in compliance with the manufacturer's recommendations. The device should be kept in clean, dry and ventilated room. Maintenance as well as cleaning have to be performed at least once a month. Regular cleaning and maintenance of device are indispensable to maintain its correct functionality as well as safety.

It is highly advisable to remember about proper maintenance in order to extend product's aesthetics. So as to do that, it is essential to comply with these guidelines:

- 1. It is recommended to clean upholstery with the aid of cleaning product, soft sponge and warm water. If you use sponge which is too wet, stain may get bigger, upholstery may be destroyed. It is necessary to remember that the excess of dampness should be removed from fabric before next cleaning. Please rinse upholstery with warm water and clean white cloth once stain is removed.
- 2. It is forbidden to soak upholstery!
- 3. It is forbidden to clean upholstery with the aid of hard brushes.
- 4. It is forbidden to clean upholstery with strong chemical agents such as solvent or caustic chemicals.



CAUTION! Akces-MED. Sp z o. o takes no responsibility for damages caused by use of wrong clearing agent.

- 5. It is forbidden to soak upholstery during cleaning. Remember that upholstery has to be always dry before using.
- 6. It is forbidden to clean, make any changes and maintain stroller during using it.
- 7. All metal as well as plastic elements should be cleaned by hand with the aid of general cleaning products. Remember to familiarize yourself with cleaning product's leaflet.





- 8. Pelvic harness should be hand washed in water not exceeding 40°C, using mild detergents. After washing, dry it at room temperature.
- 9. In the case of using the standing frame by many patients in hospitals, rehabilitation wards or other places, and regulations of these facilities do not provide otherwise, the push handles should be disinfected before passing the device to other patient.



CAUTION! Remember that upholstery has to be always dry before using!

Before using it is necessary to:

- clean wheels:
- check if base as well as wheels are correctly mounted; check if brake stops turning wheel;
- make sure that all wooden parts e.g. tray don't have splinters;
- check if stroller construction is free of breaks or any kinds of deformities:
- check if all movable parts are working and all screws, nuts, knobs etc. are correctly tightened;
- check if belts, vests, trunk belts, feet stabilizing belts etc are not frayed; check if buckles and clamps work correctly.



CAUTION! Manufacturer takes responsibility only for hidden faults or damages which appeared despite the fact that user complied with the guidelines.

CAUTION! In case of any damages, it is essential to contact the person who sold you the product.

















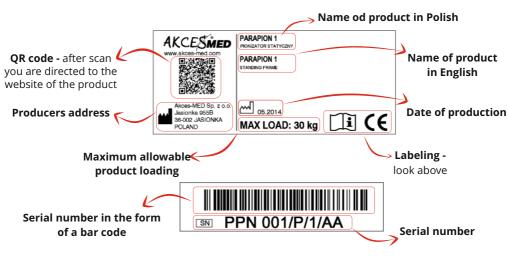


LABELLING

10.1. Symbols

CE	Declaration that the product meets the essential requirements	誉	Protect from sunlight
REF	Catalog number	35°C	Storage temperature limitation
SN	Serial number	45%	Relative humidity storage
[]i	Please read the manual instructions before use		Dry vertically
<u>^</u>	Attention!		Do not chlorinate
***	Producer	\bowtie	Do not iron
	Production date	\boxtimes	Do not dry in a drum dryer
LATEX	The product does not contain	×	Do not bleach
7	Store in a dry place	Ţ	Careful! delicate content
	Prohibition of use without fastened safety belts	*	Prohibition to leave the patient without care during use of the product
		(L)	Product designed for indoor use

10.2. Example of identification plate





ORTHOPAEDIC DEVICES MANUFACTURER



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Authorised Dealer				

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Our passion – your independence!