

# PARAMOBIL \*\*







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!

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



Product marked with the CE sign is Class I medical device, of rule 1, consistent with the requirements of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.



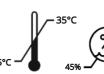
Akces-Med. Sp. z o.o. Company introduced quality management system ISO 13485 regarding production, sales and service. The system is certified by Det Norske Veritas.















## **CONTENTS**

1. The Purpose of user manual	5
2. Indications for use	
3. General characteristics of standing frame	6
3.1 Standard equipment	
3.2 Additional equipment	
4. Size table	
5. Description how to assembly standing frame	11
A. Static version	11
B. Dynamic version	12
C. Rehabilitation version	12
6. Description how to use standing frame	13
A. Static function	13
B. Dynamic function	15
C. Rehabilitation function	
7. The use of standing frame	19
7.1 Preparation of the patient	19
7.2 How to use standing frame	20
7.3 Upright position	
8. Safety rules	23
9. Terms of warranty	
10. Maintenance and cleaning	
11. Labelling	





## INTRODUCTION

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

- preparation before use,
- proper usage,
- maintenance, cleaning and guarantee conditions.

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. Before using the PARAMOBIL™ standing frame, user is obliged to familiarize himself/herself with user manual.

# INDICATIONS AND CONTRINDICATIONS FOR USE

The standing frames are intended for people with orthopedic, neurological and cardiological diseases and for people after surgery who are unable to adopt and maintain a standing position on their own as a result of prolonged immobilization. The device is an irreplaceable aid in the rehabilitation process, both in terms of movement and social integration. It is great help in everyday activities such as rehabilitation but also during playing or studying. The selection of the appropriate size of the device depends on medical indications and anatomical parameters, regardless of the age of the user.

### The device is recommended for people in the following cases:

- cerebral palsy various types and forms,
- brain and spinal cord injuries with lower limbs paralysis and weakness,
- balance and motor coordination disorders with different etiology,
- demyelinating disease (e.g. multiple sclerosis SM),
- meningocele,
- muscles diseases with weakness and paralysis (dystrophy, myasthenia
- gravis, myositis),
- genetic disorders,
- egeneration and neurological diseases,
- other condition connected with muscles weakness, paralysis and
- musculoskeletal disorders.
- after head and spinal cord injuries and spine trauma with paralysis and
- paresis.









### Contraindications:

While standing upright, the user who is in a standing position should be closely monitored. The therapy should be discontinued in case of such side effects as: turning pale, sweating or fainting, joint strain and the resulting deformities of the body. Further proceeding should be consulted with the medical specialist or a physiotherapist who prescribed the treatment. The critical condition of the user is an absolute contraindication to standing upright.

- •Relative contraindications for upright standing are: arterial hypertension at rest above 200/110 mmHg, pulmonary hypertension, cardiac arrythmias, unstable asthma, unstable metabolic disorders, moderate heart valve disease.
- Any condition, such as a healing fracture or severe osteoporosis, that makes it impossible to bear the user's own bodyweight.
- Bone fracture with incomplete union, unless approved by a doctor.
- Postoperative restrictions on joint loading.
- Pain while standing in the standing frame (caused by subluxation or dislocation of the hip joint, overstretching of soft tissues or excessive pressure). Subluxation or dislocation of the hip joint in the absence of pain is not a contraindication.

People with significant flexion in the hip or knee joints, as well as with contractures in the ankle joint, may not be able to use the standing frame. Make sure that the position of the user in the standing frame does not cause excessive pressure or stretching of affected areas of the body. In such cases, standing upright may be contraindicated until a greater range of motion is achieved in the contracted joints.

In case of people with impaired cardiovascular system (arterial hypertension at rest above 200/110 mmHg, pulmonary hypertension, cardiac arrythmias, moderate heart valve disease); respiratory system (unstable asthma) and unstable metabolic disorders, it is necessary to monitor the user while standing in order to prevent serious complications.





# **GENERAL CHARACTERISTICS OF STANDING FRAME**

## 3.1. Standard equipment

- 1. Frame with rotating wheels equipped with brakes
- 2. Chest clamping-ring with pelot-pads
- 3. Hip clamping-ring with pelot-pads
- 4. Upper limbs stabilizers (bolsters and grips)
- 5. Feet stabilizer
- 6. Knee stabilizer with pelot-pads
- 7. Table
- 8. Seat
- 9. Mechanical-electric rotor

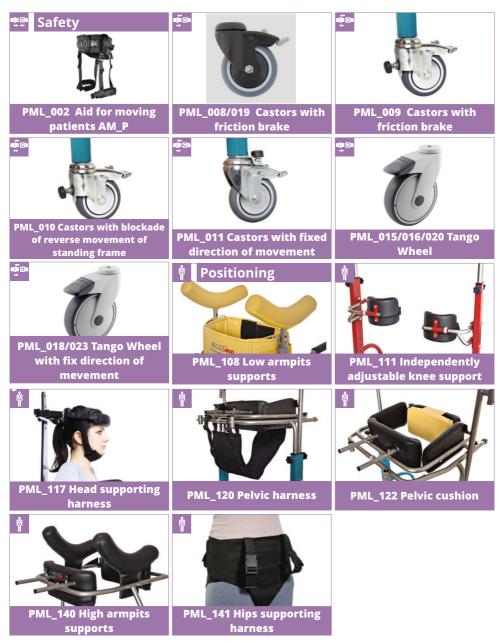








## 3.2. Additional equipment











PML\_406 Rotor gripa



PML\_201 Lower limb immobilizer AM-TUD-KD

PML\_205 Lower limb extension immobilizer OKD-03



PML\_207 Lower limb in 20° flexion immobilizer OKD-03/20



PML\_208 Universal knee immobilizer OKD-01



PML 210 Post operative knee brace with polycentric 20° rom adjustment AM-KD-AM/2R



PML\_211 Post operative knee brace with 15° rom adjustment AM-KD-AM/1R



PML\_212 Foot-drop brace with frontal plate equalization AM-ASS-OS



with splints 2r and dynamic foot made of carbon fibre AM-KDS-AM/2R





# SIZE TABLE





Symbol	Measurement	Unit	Size 0	Size 1	Size 2	Size 3
W	Indicative user height*	[cm]	90 - 150	110 - 170	130 - 190	130 - 200
Α	Pelvic support width	[cm]	25	31	37	42
В	Pelvic support depth	[cm]	15-24	15-28	19-31	22-34
С	Pelvic support length	[cm]	63-90	77-114	86-122	91-128
A1	Chest support width	[cm]	23	30	35	40
B1	Chest support depth	[cm]	15-24	22-34	24-36	27-38
C1	Chest support height	[cm]	75-112	91-131	103-147	107-159
G	Knee supports spacing	[cm]	17-29	17-29	17-29	23-35
Н	Knee supports length	[cm]	25-55	32-60	34-70	39-79
	Footplate length	[cm]	19	28	28	31
	Maximum user weight	[kg]	40	60	90	120

Measurement	Unit		Size 1	Size 2	Size 3
Width	[cm]	59	70	70	76
Length	[cm]	75	90	90	93
Height	[cm]	90	83	93	98
Weight	[kg]	22	39	42	43

<sup>\*</sup>This measurement cannot be the main parameter while choosing the product siz Note: Dimensional tolerance in the table is: +1/-1 cm.







# **DESCRIPTION HOW TO ASSEMBLY STANDING FRAME**

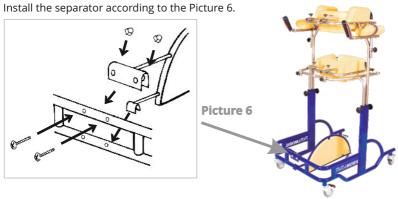






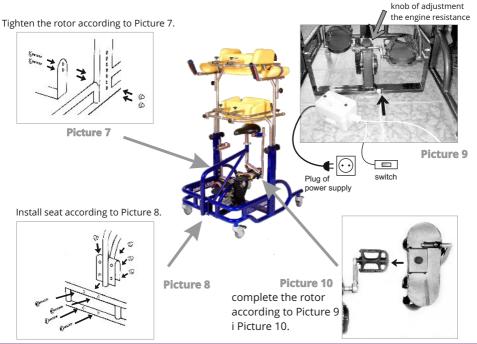
## **B. Dynamic version**

Chest and hip clamping-rings and upper limbs stabilizers should be installed like in static version (Picture 1 i Picture 3)



## C. Rehabilitation version

Chest and hip clamping-rings and upper limbs stabilizers should be installed like in static version (Picture 1, Picture 3)







## DESCRIPTION HOW TO USE STANDING FRAME



**CAUTION!** The adjustment of standing frame to the patient should be always made by suitably trained staff. Suitably trained persons have to assist patient while doing exercises.

Standing frame **PARAMOBIL**<sup>™</sup> has a module construction equipped with three functions: static, dynamic and rehabilitating. Selection of particular units of the standing frame and their proper adjustment depends on chosen functions.

### A. STATIC FUNCTION

- patient's passive verticalization, keeping optimal and stable posture of user, who is supported in every neuralgic area (feet, knees, hips, chest and back)

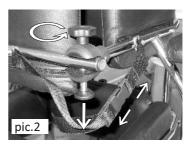
standing frame should be placed back down in front of patient then you should

block the wheels' brakes and unlock the fasteners of hip and chest clamping-ring.

Not blocking the wheels of standing frame can cause its shifting while uprising, which results in patient's fall, breakage or body's injury.

VFI CRO stickers in the feet stabilizer and on knee pelot-pads should be unfastened. Place feet into feet stabilizer, shift them backward maximally to the metal clamping-ring and then fasten VELCRO stickers (picture 1).









Verticalize patient, fasten both fasteners of hip and chest clamping-ring (double protective system - upper and lower blockades). Then adjust the knee pelotpads to user's knees (vertical and horizontal regulation) by unfastening the snap fasteners, shifting pelot-pads and fastening the snap fasteners. Finally button up VELCRO stickers (picture 2 and 3).

Please pay attention during clamp fastening. Characteristic sound "click" should be heard. It inform you that the clamp was fasten correctly.

During coming into standing frame or getting out of it you mustn't rest on rear clamping-rings' locks while they are being opened. The attempts of overloading the opened locks of clamping-ring can cause a fall of device or deformation, which results in incorrect functioning of fastener lock.

After blocking of feet and knees adjust the location of hip and chest clamping-ring.

## Chest clamping-ring - perpendicular regulating

Chest clamping-ring should be installed in such position, which enables patient to rest safely on pelot-pads. To regulate height of chest clamping-ring use knobs (A) (pic. 3)

## Hip clamping-ring - perpendicular and horizontal regulating

Hip clamping-ring should be fixed at the level of trochanter of lower limbs (to regulate perpendicularly use knobs B). After fixing height you must regulate position of hip clamping-ring to the hips



using knobs C (regulation forward and backward) and then the knobs D (hips regulation -picture 3). The proper position of trunk and pelvis depends on precise adjusting. The ideal position is one line of arms, trunk and hips.







**CAUTION!** While regulating the height of the hip clampingring and chest clamping-ring you cannot exceed the double lines on cantilever.

Patient's forearm should be placed on supporters (their height can be regulated), hands should be placed on handles (their ocation can be regulated) by inserting a hand between Velcro sticker and handle picture 4). Applying of handles facilitates control over standing frame and improves safety.



pic.4

Straight position is safe and comfortable. While standing in this position patient is being adapted to the vertical position as well as sense of equilibrium, internal organs, circulation system are being adopted to the new conditions and to bigger load.

Patient can stand in straight position quite long time; can simultaneously do exercises or simple everyday-life activities etc. To facilitate simple everyday-life activities we recommend installation of a table. ). It possesses the regulation of height and surely it will be useful to put a book, a cup or laptop on it (picture 4)

### During exercises and walking the table must be disassembled!

#### **B. DYNAMIC FUNCTION**

- Enables people with paresis of lower limbs moving

Like in static function, before any action with the standing frame block the wheels' brakes, open locks of hip and chest clamping-rings and verticalize the patient.

Hands and forearms should be placed on supports and adjusted similarly as in static function.





If all elements are adjusted and patient feels well, you can unblock the wheels' brakes and start exercises.

When the patent tends to cross lower limbs please use a separator (picture 5), which should be installed according to picture (look page 12).

Feet separator has been covered with soft upholstery, which eliminates attritions or injuries of lower limbs.

First steps should be made forward then backward and finally to different directions.

While walking, at the beginning you should make normal steps then fester and flower steps.

We recommend using special paths in order to help in order to help in orientation both courageous and not courageous patients.



#### C. REHABILITATION FUNCTION

-Enables active rehabilitation of patient's flower limbs in vertical position.

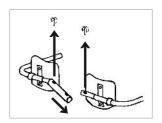
Specific construction of standing frame PARAMOBIL™ enables to use the rehabilitation function separately or by reassembly of accessories of dynamic and static functions (without necessity of leaving the standing frame).

First of all rise the hip clamping-ring maximally up (but the location of chest clamping-ring should not be changed).

Then install a seat (look page 12).

In case of using feet separator (dynamic version) please disassemble it and in that place install the seat. Height of seat should be adjusted to the patient.





pic.7





In static version, at the beginning, disassemble connector of pipes from the pelot-pads (picture 11) and assemble seat. Next, when patient safely seats, screw off the feet stabilizer and knee stabilizer. Saddle should be screw tight with standing frame's frame using the 4 screws wich are added as standard equipment.



**CAUTION!** If you don't screw it tight enough or if you don't use all 4 srews the binding plate can deflect. In such cases the complaints will not be taken into consideration.

The next step is installation of mechanical-electric rotor (look page 12) and connection of protective transformer. Patients' feet should be placed on rotor's feet holders and Velcro stickers should be fastened. Shin also should be supported by Velcro fasteners. After accomplishing the above-mentioned actions you can start exercises:

- Mechanical version patient uses strength of his muscles. Rotor's resistance regulates with a knob (look Picture 9, page 12).
- Electric version work of electric engine is used. In order to this, please connect protective transformer (look Picture 9, page 12).

of engine. Not applying to the above-mentioned recommendation can result in burning of electric engine! Do not leave the rotor on if patient doesn't use it. The electric engine can be blocked and can burn or can be mechanically damaged. In such cases the complaints will not be taken into



During using of electric rotor patient should seat on saddle comfortable. Unacceptable is to stand by patient onto rotor's pedal.

**CAUTION!** Before switching on the transformer to plug-in socket, please switch off the knob that regulates the resistance

After exercising with standing frame PARAMOBIL™ patient must return safely on wheelchair, chair, armchair, bed etc.

consideration. Repair cost will be cover by user.







CAUTION! Patient cannot leave standing frame independently!

To leave standing frame the following should be done

### (hints for doctors of rehabilitation):

- 1. Block the wheels of standing frame using brakes.
- 2. At the back of standing frame put the wheelchair, chair, armchair etc.
- 3. Unfasten Velcro stickers in feet stabilizer and knee pelot-pads (static version)
- 4. Unblock the protection of opening of both pelot-pads
- 5. Seat patient on wheelchair, chair, armchair etc gently.

**CAUTION!** Therapist is obliged to patient's insurance at side or at the back.!



**CAUTION!** You should pay your special attention to block the wheels of wheelchair and protect the chair or armchair before patient is going to seat on it. Backing off of the seat can cause patient's fall or injuries.



# 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™!** 

## 7.1. 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 PARAMOBIL

- 1. Before use it is necessary to:
  - Unfold the device:
  - Place the device on even ground;
  - Make sure that all parts a reserviceable, correctly mounted and stable;
  - Block brakes;
  - Adjust the device to patient's measurements;
  - Undo vest, trunk belts etc so as to place easily the patient is the device;
  - Place patient in the device;
  - Fasten all elements which stabilize patient e.g. vest, trunk belts, feet stabilizing belts etc.;
  - Mount additional equipment e.g. tray.



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.

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





### 7.3. 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
- touch stimulation and others



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

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

It is forbidden to leave the patient unattended!

Only trained staff can adjust standing frame to the patient!

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).







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 **PARAMOBIL™** 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 **PARAMOBIL™** 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. 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.
- 12. Before using the stander, remove all paper and plastic packaging. The packaging is not a toy! Keep away from children and animals.



Incorrect product adjustment can lead to such side effects as fainting, body deformities, joint overload, etc. If the abovementioned symptoms occur, stop using the product immediately, take the user out of the product and lay them down. If the undesirable symptoms persist, contact a physician immediately. If the symptoms have disappeared, inform the attending physician about this fact in order to make a decision about the further rehabilitation process.

This device can be only used inside the buildings.

The device contains small parts which children may swallow.

Do not use a product that has any signs of damage, tearing or wear. Only anundamaged product and proper use guarantee its right and safe working. If the product is damaged, discontinue use and contact the manufacturer.







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.

Under no circumstances should an unqualified person repair or alter the product and its construction, as the health and safety of the user depend on it as well as it will lead to the loss of warranty.

The weight of user should not be bigger than maximal weight described on page 9 where you will find information regarding this issue.

Serious incidents involving this device should be reported both to manufacturer and to the competent authority in your country.

## **TERMS OF WARRANTY**

- 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 **36 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 Sp. z. o. o customer service (ph. 17/864 04 77)





# 10 MAINTENANCE AND CLEANING

The standing frame **PARAMOBIL**™, which is a medical device, should always be kept clean and should be used in accordance with the manufacturer's instructions. The standing frame should be kept in a clean, dry and ventilated room. Maintenance and cleaning must be done at least once a month. Periodic cleaning and maintenance of the device is essential to keep its proper functioning and safety.

#### Recommendations for cleaning the upholstery and other elements of the device:

- 1. Wash with warm water using a soft cloth and mild cleaners.
- 2. Make sure the cloth is not too wet, as this may enlarge the stain and damage the upholstery or foam inside the upholstery.
- 3. Remember to remove excess moisture from the upholstery before the next cleaning.
- 4. The upholstery must not get wet during cleaning.
- 5. You must not soak the upholstery.!
- 6. After cleaning the stains, the upholstery should be rinsed with lukewarm water and dried with a clean cloth.
- 7. Do not use hard brushes for cleaning the upholstery.
- 8. Do not clean the upholstery with strong chemicals, e.g. solvents or chlorine-based caustics.
- 9. Do not clean, replace any elements or maintain the standing frame during use.
- 10. Metal and plastic elements should be cleaned by hand with suitable cleaners, after having read the recommendations of the manufacturer of the given cleaner
- 11. It is possible to disinfect metal, plastic, wooden and upholstery elements of the product with a generally available disinfectant. In order to disinfect the selected element, spray its surface with a disinfectant generally available on the market and wipe with a dry, clean cloth. After disinfection, wait until the element is completely dry, especially in the case of upholstery. Before using the disinfectant, first check in an invisible place whether the product will not discolor or damage the disinfected surface.







Remember that upholstery has to be always dry before using!

The manufacturer of the standing frame, Akces-MED Sp. z o. o., is not responsible for any damages caused by using unsuitable cleaners.

#### Before using it is necessary to:

- clean wheels:
- check if base as well as wheels are correctly mounted; check if brake stops turning wheel:
- check if standing frame 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 are not frayed; check if buckles and clamps work correctly.



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

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



















# LABELLING

### 11.1. Symbols

Declaration that the product meets the essential requirements

REF Catalog number

Serial number SN

Please read the manual instructions before

You need to take special precautions

Manufacturer

**Production date** 

The product does not contain latex

Store in a dry place

**Careful! Delicate content** 

Storage temperature limitation

Relative humidity storage

Protect from sunlight

Dry vertically

Do not chlorinate

Do not iron

Do not dry in a drum dryer

Do not bleach

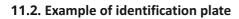
The product is intended for indoor use

Prohibition of use without fastened safety

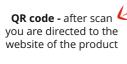
Prohibition to leave the patient without care during use of the product

You need to read the additional information

You need to use the tools indicated in the assembly description



Name od product in Polish



**Producers address** 



Labeling -

Name of product

in English

Date of production

Maximum allowable < product loading look above

Serial number in the form of a bar code



Serial number

## **MANUFACTURER**



Jasionka 955B 36-002 Jasionka tel. +48 17 864 04 70 e-mail: export@akces-med.com

BDO: 000031619



**Authorised Dealer** 



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